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Enhanced Recovery after Surgery Protocols for Amelioration of Surgical Outcomes

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Abstract

Enhanced recovery after surgery (ERAS) protocols termed as “fast track surgery” have now become an essential component in the perioperative period to improve post-operative outcomes. It is both the patient and the health services who receive the benefits of ERAS. It is a new and different approach when compared to traditional practices which aims at enhanced care of surgical patients. It includes pre-operative, intraoperative, and post-operative components which when applied altogether give best possible results. Effective implementation of ERAS protocols is associated with fast recovery of gut function and reduced rate of complications. All these factors further lead to decreased post-operative hospital stay, thereby decreasing hospital cost and increasing patient satisfaction.

Key words: Carbohydrate loading, Enhanced recovery, Goal-directed fluid therapy, Multimodal analgesia, Post-operative nausea and vomiting prophylaxis

INTRODUCTION

The concept of enhanced recovery after surgery (ERAS) was given by Prof. Kehlet and Wilmore somewhere around the past decade of the 20th century.^[1] His area of work was in colorectal surgeries where multiple factors were considered to be the reason for lengthened hospital stay and delayed recovery. One important factor being delayed return of bowel function.^[2] ERAS is a multimodal, multidisciplinary approach which involves application of perioperative care protocols to reduce length of hospital stay, and post-operative complications. Both the patient and the health services as a whole receive the benefits of ERAS. The major focus of these protocols is on:^[3]

1. Pre-operative evaluation and optimization
2. Use of cost-effective medications

3. Goal-directed fluid therapy (GDT) in perioperative period
4. Avoidance of perioperative fasting and carbohydrate loading up to 2 h preoperatively
5. Multimodal pain management
6. Standardized anesthetic and analgesic regimens (epidural and non-opioid analgesia)
7. Early mobilization in the post-operative period.

Successful implementation of these ERAS protocols requires proper coordination between the surgeon, the anesthesiologist, the nursing staff, and the patient as well as the people taking care of the patient in the post-operative period. The patient outcome depends on the type and extent of surgical insults, susceptibility of the patient to these insults and perioperative stress, and the quality of perioperative care received by the patient. An ERAS Society was formed in 2010. It is a multidisciplinary society which has played an important role in providing guidelines, educational meetings, and other support.^[4,5] The main aim of this society is the development of a good perioperative care and improvement of recovery through research, education, and implementation of evidence-based practice.

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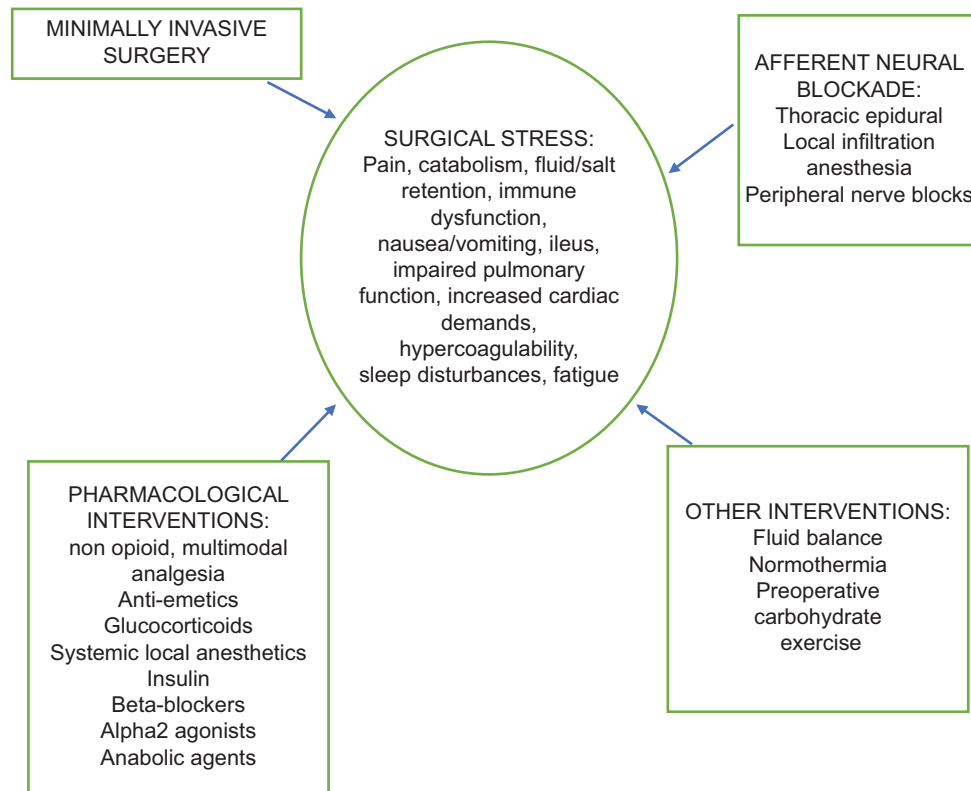


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APPROACHES TO REDUCE SURGICAL STRESS AND IMPROVING OUTCOMES



GENERAL PRINCIPLES OF ERAS

- Decrease stress response to surgery: Metabolic, endocrine, and inflammatory response as well as reduce protein catabolism
- Standardization and optimization of perioperative medical care
- Decrease in the duration of stay in the hospital and return to normal life at the earliest
- Promotion of improved pain control
- Promotion of early mobility with adequate analgesia and decrease immobility related complications
- Improvement of gastrointestinal (GI) function recovery.

Traditional care in the perioperative period involves pre-operative overnight fasting (8h or more) and practice of routine mechanical bowel preparation (MBP). Routine usage of nasogastric (NG) tubes, abdominal drains and urinary catheters is recommended in the intraoperative period along with empirical hydration in the perioperative period. Traditional practices include post-operative removal of tubes on return of bowel motility, delayed enteral nutrition once bowel motility is restored and delayed mobilization of patient. All these factors are associated with prolonged hospital stay and an increase in morbidity and mortality in the post-operative period.

Certain changes which have been made in ERAS care protocols when compared with traditional care practices include minimum starvation (stop solids 6 h and liquids 2 h before surgery), no routine MBP, intake of drinks rich in carbohydrate 2 h before surgery, smoking cessation and abstinence from alcohol consumption, pre-operative exercises, use of NG tubes, abdominal drains, urinary catheters only when necessary, GDT, multimodal analgesic techniques, post-operative nausea and vomiting (PONV) prophylaxis and its management, early removal of drains, tubes and catheters, early enteral nutrition, and early post-operative mobilization.

Until now, ERAS protocols have been implemented in high-income countries. Efforts should be made for their utilization in middle- and low-income countries where they would prove to be beneficial.^[6] It has the potential to improve outcome for all patients by improving the surgical pathway processes, planning and standardization of pre-operative and post-operative scenarios, and limitation of cost.^[3]

Specific recommendations for specific procedures have been given by ERAS society for major elective surgeries such as colonic resection, rectal resection, gastric resection, major gynecology, bariatric surgery, breast reconstruction,

pancreaticoduodenectomy, cystectomy liver resection, head and neck cancer surgery, hip and knee replacement, thoracic surgery, and esophageal resection.^[7] At present, ERAS protocols are used mainly for adult patients undergoing elective procedures. Whether similar advantages can be achieved in cases of geriatric and pediatric populations and in situations of trauma and emergency are yet to be explored.^[8]

Based on scientific knowledge, there are 24 core elements of ERAS care and no single element alone can improve the outcome after surgery. It is only by the cumulative effect of these elements that the patient outcome can be improved.

PERIOPERATIVE INTERVENTIONS IN ERAS TO EXPEDITE RECOVERY AFTER MAJOR OPERATIONS

Pre-operative Components in Eras

Patient and family education and counseling

Preadmission education and counseling of the patient, as well as the family members who take care of the patient postoperatively, are essential components of ERAS. The provision of information by the surgeon to the patient in a tactful manner is the main purpose of the counseling session.^[9] Pre-operative information and instructions about surgery to be undertaken and possible complications lead to reduction in emotional and psychological distress and thus improve post-operative recovery and discharge. It is especially found to be beneficial for patients who have depression, unrealistic expectations, and those who have limited support. Various methods which can be used for the disclosure of information include preadmission group teaching classes, video recordings, booklets, post-admission teaching sessions, and pre-operative visits from nurse/anesthesiologist.^[10]

Nutrition

The term “prehabilitation” refers to the process of optimizing the functional and nutritional capacity and preparation of the patient to cope with the surgical stress.^[11] Nutritional status of the patient should be properly assessed while doing a pre-operative assessment. The European Society for Clinical Nutrition and Metabolism (ESPEN) states that malnutrition can be taken as an independent risk factor for an increased rate of mortality, infection, and increased cost.^[12] It is associated with delayed wound healing, wound infection, and sepsis. Pre-operative oral nutritional support for 7–14 days for severely malnourished patients is suggested under ESPEN guidelines. However, specific nutrition support goals still need to be further delineated.^[12] Immunonutrition, which is enteral nutrition fortified with arginine, glutamine, and omega 3 fatty acids,

reduces the complications and length of hospital stay in patients undergoing GI surgeries.

Pre-operative cessation of smoking, drinking, and recreational drugs

An increased risk of delayed healing of wounds and severe cardiovascular and pulmonary complications postoperatively has been observed in patients with history of cigarette smoking.^[13] Decreased incidence of post-operative pulmonary complications is associated with increased duration of abstinence from smoking in pre-operative period.^[14] Studies have shown that intensive smoking and alcohol cessation intervention 6–8 weeks before surgery could reduce post-operative morbidity by about 50%. A careful pre-operative evaluation by the anesthesiologist is pivotal.

Pre-operative exercise

Exercise promotes an improvement in inspiratory muscle endurance, functional mobility, reduces anxiety, reduces incidence of post-operative pain, and improves the quality of life. A recent meta-analysis has concluded that inspiratory muscle training and aerobic activities are associated with reduced post-operative complications after abdominal surgeries.^[15]

Pre-operative fasting

Based on various studies, it has been found that it is perfectly safe to allow patients to drink clear fluids up until 2 h before elective surgery. Overnight fasting increases the stress response and contributes to the ongoing catabolic state of the body. Minimum fasting for different ingested materials that have been recommended by the American Society of Anesthesiologists (ASA) is as follows:

- (a) Clear liquid – 2 h
- (b) Breast milk – 4 h
- (c) Infant formula – 6 h
- (d) Non-human milk – 6 h
- (e) Light meal – 6 h
- (f) Fried, fatty food – 8 h or more.

Carbohydrate loading

Surgical outcomes can be improved by optimization of metabolic state of the patient before major surgery. These perioperative metabolic strategies aim at reducing the activation of inflammatory reactions by corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), and minimally invasive surgery. Besides reducing insulin resistance, carbohydrate loading also leads to reduction in nitrogen and protein loss and thus improves muscle function. It is also found to be beneficial in reducing pre-operative hunger, thirst, and anxiety.^[16,17] Allowing solid food up to 6 h preoperatively and a carbohydrate-rich drink (12.5%), preferably containing complex carbohydrates,

800 ml at bedtime, and 400 ml 2 h before surgery is the recommended protocol.^[18] At the time of preanesthetic checkup, the patients are counseled about benefits of taking carbohydrates before surgery and accordingly strict orders are advised regarding carbohydrate loading and its timings. Regular monitoring of the blood glucose levels in the perioperative period is essential.^[19] Carbohydrate loading reduces the metabolic stress of surgery, effectively reduces insulin resistance, improves pre/post-operative well-being, improves post-operative muscle function, reduces lean body mass losses, and results in faster recovery.

Pre-operative bowel preparation

MBP was used before in colorectal surgeries to reduce the fecal content in the gut, but it has been found that routine MBP leads to dehydration in the pre-operative period and is unpleasant for the patients.^[20]

Disadvantages of MBP include an increase in expenses, requirement of admission to hospital before surgery, abdominal pain and bloating, fluid and electrolyte imbalance, histological changes in the colorectal mucosa, and potential bacterial translocation and disruption of anastomosis.^[21,22]

Oral antibiotics may be administered for the improvement of these disadvantages caused by MBP.^[23] In addition, drinking of clear fluids by the patient is encouraged up to 2 h before the induction of anesthesia.^[24]

A meta-analysis of seven randomized controlled trials performed on patients who underwent elective colorectal surgery, it was found that the incidence of infection (total and surgical site infection) was less in patients who were given systemic antibiotics and MBP both in pre-operative period compared with those who were given either of the two alone.^[25] Thus, ERAS guidelines with regard to the use of MBP may need to be revisited in the future.

Prophylaxis of infections

Most common nosocomial infections in surgical patients are surgical site infections, which account for approximately 500,000 infections annually and lead to an increased hospital stay, higher costs, and an increase in mortality and morbidity. Thus, prophylactic use of antibiotic regimes must be encouraged to improve surgical outcomes. It is recommended that a single dose of a broad-spectrum antibiotic, which covers both aerobic and anaerobic organisms be administered just before the administration of an incision.^[26] A second dose is given if the surgical procedure lasts for more than 4 h or there is a blood loss of more than 1500 ml. Longer courses of antibiotics are no longer recommended as they are associated with risk of clostridium difficile infection.

Prophylaxis of thromboembolic events

The annual incidence of venous thromboembolism (VTE) is estimated to be 1–2/1000/year among the general population. It includes both deep vein thrombosis and pulmonary embolism.^[27] Previous VTE, immobility, age >70 years, history of thromboembolic condition, heart or respiratory failure, obesity, and acute infarction or stroke are certain risk factors which are associated with an increased incidence of VTE. There are various mechanical and pharmacological measures which can be used for decreasing the incidence of thromboembolism.^[28,29] The mechanical measures include use of graduated compression stockings or intermittent pneumatic compression devices. Pharmacological measures include use of low-molecular-weight heparin of which 5000 units are given subcutaneously every 8–12 h. A pre-operative assessment of the patient for the identification of the presence of any of the risk factors for thromboembolism is essential for management of anticoagulation therapy in the perioperative period >7 days before surgery to improve post-operative outcome.^[30]

Other pre-operative considerations include mild perioperative hypothermia, prevention of aspiration, optimization of pre-operative hemoglobin levels, mental/psychological preparedness, fluid management, prevention of PONV, and post-operative ileus.

INTRAOPERATIVE COMPONENTS IN ERAS

Anesthesia Techniques

Use of short-acting anesthetic agents, avoidance of salt and water overload, and maintenance of normothermia using a body warmer and a fluid warmer have all been shown to decrease patient complications when incorporated into an intraoperative ERAS protocol. Heat loss which occurs intraoperatively is a major risk factor that leads to increased stress response. Thus, maintenance of normothermia intraoperatively is an important component of ERAS protocols.

Opioid Sparing and Multimodal Analgesia

Perioperative multimodal analgesia uses a combination of analgesic medications that act on different sites and pathways in an additive or synergistic manner to achieve pain relief with minimal or no opiate consumption.^[31] Although all medications have certain side effects, opioids, in particular, are associated with multisystem, short- and long-term effects. The strategy of post-operative minimization of opioid use reduces nausea and vomiting, impairment of bowel function, delayed mobilization, and pulmonary morbidity. Thus, ERAS protocols aim at opioid-sparing analgesia to decrease morbidity and mortality

associated with the same. Nonopioids that are commonly used in ERAS protocols include NSAIDs, gabapentin, glucocorticoids, acetaminophen, ketamine, and tramadol.^[32] The regional anesthetic techniques commonly used in ERAS pathways include neuraxial techniques (epidural and spinal) and peripheral nerve blocks (transversus abdominal plane, paravertebral, brachial plexus, sciatic, and femoral nerve blocks). A regional anesthesia block used in addition to genetic algorithm is useful as it leads to:

- Reduced post-operative use of opiates
- Rapid awakening from anesthesia
- Early enteral intake and mobilization.

One of the essential missions for treating pain is the identification of high-risk patients for intractable post-operative pain, patients with history of hyperalgesia, substance abuse, and opioid dependence.

Surgical Approach

Use of laparoscopic and minimally invasive techniques is preferred. For open procedures, either a transverse or a smaller vertical incision is recommended. High inspired oxygen improves blood flow at the anastomotic site and reduces risk of wound infections. It also helps in enhancing defense against microbes and improves wound healing.^[33]

GDT

Perioperative fluid management is a key element for the success of ERAS protocols. GDT related to ERAS protocols will minimize the complications associated with perioperative fluid imbalance. As such, there are no specified goals mentioned anywhere in GDT. The basic principle of the practice is to maximize tissue oxygenation by achieving maximum hemodynamic status with the required amount of fluid therapy. It is associated with decreased incidence of post-operative infections and organ dysfunction.^[34] The parameters that matter in GDT are: Cardiac index, stroke volume, stroke volume variation, mixed venous oxygen saturation, systemic vascular resistance, and plethysmography variability index. Commonly used techniques in GDT are transesophageal echocardiography,^[35] pulmonary artery catheterization,^[35] arterial waveform analysis-based techniques,^[36] Esophageal Doppler, and Bioimpedance based technologies.^[37]

If a patient is undergoing low-risk surgery, then a “zero balance” technique should be encouraged. It has been well established that both hypervolemia and hypovolemia are associated with increased incidence of post-operative morbidity and mortality. Thus, maintenance of intravascular euvolemia throughout the perioperative period is ideal. Hypotension associated with general anesthesia or epidural should be treated with vasoconstrictors rather than fluids.

Avoidance of Drains and NG Tubes

Prophylactic NG tubes are not inserted routinely after bowel surgery. Meta-analyses of trials performed in GI surgery (mainly lower GI surgeries) found that avoidance of use of NG tubes was associated with acceleration of bowel functions and reduced pulmonary complications.^[38] NG tube insertion postoperatively may be required in up to 15% of patients. In a meta-analysis which compared routine use of NG tube versus no use of NG tube after gastrectomy, it was found that the time to start of oral diet was short in group with no NG tube. However, no difference was observed in other complications.^[39] A disadvantage of using drains is that they pose problem in early mobilization of the patient, which is further detrimental for the health of the patient. Thus avoidance/early removal of drains and NG tubes is an essential component of ERAS protocols.

PONV Prophylaxis

PONV still poses an important problem in anesthesia. A simple scoring system for the identification of risk factors for PONV may be used in patients who are undergoing surgery who may benefit from prophylactic antiemetic medication. The simplified Apfel score includes four factors: Female gender, non-smoking status, post-operative use of opioids, and previous history of PONV or motion sickness.^[40] Multimodal approaches involving the use of two or more prophylactic antiemetic drugs, avoiding highly emetogenic anesthetics and analgesics, and ensuring adequate hydration are strongly recommended for all patients at increased risk of developing PONV.^[41,42] The ASA guidelines of 2014 suggest use of a multimodal approach with different strategies, which include reduction of baseline risks (e.g., adequate hydration, intraoperative use of propofol, dexmedetomidine, etc.), combination therapy of antiemetics using a 5HT₃ antagonist with droperidol or dexamethasone to effectively reduce incidence of PONV.^[43] The choice of drug basically depends on patient factors, cost effectiveness, and practical considerations.

POST-OPERATIVE COMPONENTS IN ERAS

Early Nutrition

Starting early feed in the post-operative period decreases the need for intravenous fluid therapy as well as decreases the incidence of ileus. It reduces insulin resistance, improves muscle function, and prevents breakdown of proteins. Adequate nutrition leads to a significant decrease in mortality and morbidity, probably due to reduction in conditions which lead to death such as sepsis, pneumonia, cardiac dysfunction, and anastomotic dehiscence as well a reduction in length of hospital stay.

Early Mobilization

Immobilization has deleterious effects on patients, especially on the musculoskeletal, cardiovascular, and respiratory

systems. Thus, early mobilization is an essential component of ERAS protocols to reduce post-operative complications. Reduction in skeletal muscle loss and improvement of respiratory function and delivery of oxygen to tissues is observed with early mobilization.^[44] Physical activity is associated with improvement in cardiopulmonary functions, decreased fatigue symptoms, and improved muscular strength and quality of life. It is recommended that on the day of surgery, the patients should sit out of bed for 2 h and at least 6 h a day until discharge.^[45] The involvement of physiotherapy and rehabilitation departments is essential. Adequate analgesia with multimodal approach is vital to ensure successful and less distressing early ambulation.

Multimodal Analgesia

Post-operative pain relief promotes early mobilization, early feeding, and reduces stress-related complications.^[46] It consists of the use of a combination of regular acetaminophen, NSAIDs, local infiltration techniques, regional blocks, epidural techniques, patient-controlled analgesia, and patient-controlled epidural analgesia. Epidural when used in major surgeries are known to be associated with decreased incidence of bowel ileus and respiratory complications.^[47] ERAS protocols promote the use of opioid sparing analgesia because excessive use of opioids is associated with an increase in risk of sedation, PONV, ileus, and respiratory complications.^[48]

Post-operative Glycemic Control

Target blood sugar should be between 180 mg/dl and 200 mg/dl and patients having blood glucose higher than this range should be treated with insulin therapy. It is recommended to do regular blood glucose monitoring to prevent iatrogenic hypoglycemia.

Maintenance of Hydration

ERAS promotes abstinence from intravenous fluid therapy as soon as the patient can take fluids orally. Early starting of oral fluids including carbohydrate drinks should be encouraged as it improves healing conditions and promotes early discharge without an increase in morbidity. There are several benefits of improved perioperative management of fluids. These benefits range from improved pulmonary functions, GI motility, tissue oxygenation, and wound healing. One important aspect that needs to be kept in mind is prevention of fluid overload. Wound healing is delayed in case of tissue hypoxia, which results from fluid overload.^[49] In the post-operative period, in response to stress of surgery, some extent of oliguria appears to be a normal physiological response. Although traditionally oliguria is considered a sign of hypovolemia, perioperative oliguria is not considered to be abnormal always if it is not associated with other signs of hypovolemia.^[50] Oliguria is considered to be an expected occurrence due to judicious

fluid management in the perioperative period. However, if a patient presents with anuria, it should be taken seriously.

Patient and Family Education

Post-operative care of the patient by the family members creates a positive environment and promotes early recovery of the patient. The patient as well as the family members should be informed about the possible complications in the post-operative period to reduce emotional and psychological stress.

CONCLUSION

ERAS protocols aim at blunting of the catabolic response of the body towards the stress of surgery. They require proper implementation in the pre-operative, intraoperative, and post-operative periods for the achievement of better results; in terms of early post-operative recovery. Although a protocolized approach is recommended by the ERAS guidelines for a good outcome, it has been observed that even the individual elements of ERAS protocols when applied, have been found to be beneficial.

ERAS is patient centered and includes evidence-based protocols that have a significant effect on early post-operative recovery and reduced length of hospital stay. However, in spite of the significant progress in its implementation in recent years, still its widespread adoption is limited and there is significant work and research to be done in near future.

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An Interesting Case of Familial Medullary Carcinoma Thyroid – Seldom Seen by Surgeons

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Abstract

Medullary thyroid carcinoma (MTC) constitutes around 5% of all thyroid cancers with a worse prognosis. It accounts for 13% of thyroid cancer-related deaths. A 23-year-old male presented with a 4-year history of progressively increasing thyroid swelling with similar family history. On examination, butterfly-shaped firm swelling of size 7 × 3 cm in the right and 7 × 4 cm in the left seen on the anterior aspect of neck with regular margins and nodular surface moving with deglutition extending from the thyroid cartilage to clavicle head and laterally beyond the sternocleidomastoid into the posterior triangle muscle. Pemberton's sign was negative. Computed tomography neck showed enlarged both thyroid lobes with areas of cystic degeneration and 15 mm retrosternal extension of the left lobe of thyroid with bilateral IB, II, and V lymphadenopathy. Serum calcitonin level was 4435 pg/ml. Fine-needle aspiration cytology favored features of MTC. Total thyroidectomy with central compartment neck dissection was done. Intraoperative frozen sections of bilateral level III were found to be tumor free, so proceeded with thyroid excision and central compartment neck dissection. Histopathology revealed MTC with bilateral multifocal capsular and lymphovascular invasion and metastatic foci in the right central compartment lymph node. Hence, early diagnosis in family members offers a higher likelihood of cure and long-term survival.

Key words: Familial medullary thyroid carcinoma, Medullary thyroid carcinoma, Medullary thyroid carcinoma, MTC

INTRODUCTION

Medullary thyroid carcinoma (MTC) constitutes around 5% of all thyroid cancers^[1] with a worse prognosis. It accounts for 13% of thyroid cancer-related deaths. MTC usually arises from parafollicular cells that normally secrete a number of peptide hormones such as calcitonin, serotonin, and vasoactive intestinal peptide.^[2] Thus, it is widely accepted as neuroendocrine tumor. Both sporadic and familial forms are seen, with 70% and 30% incidence, respectively.^[3] The hereditary form of MTC accounts for 5%–10% of all malignancies of thyroid; hence, early detection in family members offers a long-term survival. Here, we present a case report of familial MTC (FMTC).

CASE REPORT

A 25-year-old male presented with progressively increasing swelling in the thyroid region for the past 4 years, with a history of neck swelling in the family. No history of associated complaints such as pain, dysphagia, breathlessness, change in voice, palpitations, weight gain or loss, and restlessness. The patient is a known smoker and alcoholic. There was a history of similar complaints in the family for sister who is on treatment and uncle who was expired.

On examination, the patient was found to be thin built and moderately nourished. Vitals were normal. Inspection findings showed swelling seen on the anterior aspect of neck which is butterfly shaped with regular margins. Size was 7 × 3 cm in the right side and 7 × 4 cm in the left side. The swelling moved with deglutition and the surface appeared nodular and skin over the swelling appeared normal. Veins over the swelling were visible and there were no scars and sinuses. Trachea appeared to be in midline.

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Palpatory findings showed the swelling extended superiorly from the thyroid cartilage and inferiorly up to clavicle head. Lateral border was not applicable and extended beyond the sternocleidomastoid into the posterior triangle muscle. Medially it extended up to 1 cm lateral to midline on the right side. Swelling was firm and nodular. Trachea was deviated to the right. Swelling was situated deep to the deep fascia. Cervical lymph nodes were not palpable. Pemberton's sign was negative. Examination of other systems showed eye signs as negative, skull, and oral cavity normal. Cardiovascular system, respiratory system, and central nervous system appeared normal.

Ultrasonography of the neck revealed enlarged right and left lobes of thyroid with retrosternal extension of the left lobe of thyroid. Ultrasonography features were suggestive of multinodular goiter (MNG) with bilateral level IB, II, and V subcentric lymph nodes. Computed tomography (CT) neck – showed enlarged both thyroid lobes with areas of cystic degeneration and retrosternal extension of the left lobe of thyroid for a distance of 15 mm. Bilateral level IB, II, and V subcentimetric enlarged lymph nodes were seen.

Serum calcitonin level was 4435 pg/ml and serum calcium level was 9.6 mg/dl. Thyroid function tests and routine blood investigations were done and are within normal limits. Antithyroid peroxidase level was found to be 1.26 IU/ml. CT chest and abdomen were normal and no signs of metastasis noted.

Fine-needle aspiration (FNA) cytology was done in the swelling over neck. Cellular smears studied show cells arranged in clusters of varying sizes and in dispersion in a hemorrhagic background. The cellular smears studied showed round to oval to polygonal to many spindle-shaped cells and plasmacytoid cells, many with cytoplasm showing coarse granularity.

Moderate anisonucleosis noted with few binucleate and trinucleate forms and occasional bizarre cells, the nuclei showing uniform stippled, finely dispersed chromatin to mildly hyperchromatic nuclei. Occasional areas show cells arranged in follicular pattern. Occasional cells show intranuclear cytoplasmic inclusions. Cyst macrophages also noted.

RESULTS

Pre-operative workup was done and the patient was taken up for surgery. Total thyroidectomy with central compartment neck dissection was done. Intraoperatively, frozen sections of bilateral level III were found to be free of tumor and hence proceeded with thyroid excision and central compartment neck dissection [Figures 1 and 2].

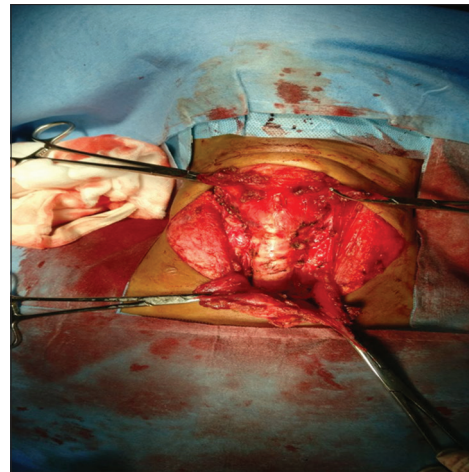


Figure 1: Picture after total thyroidectomy and central compartment node dissection

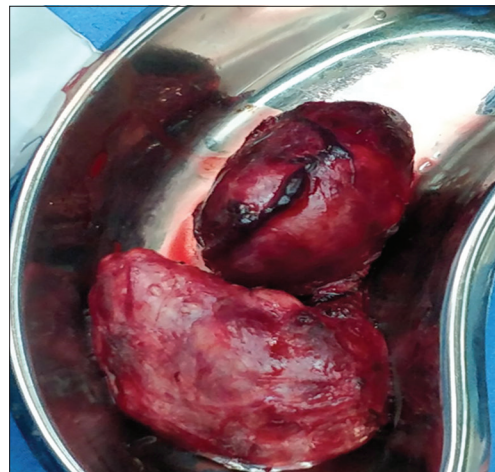


Figure 2: Excised thyroid gland

Histopathology revealed MTC with bilateral multifocal capsular and lymphovascular invasion and metastatic foci in the right central compartment lymph node [Figure 3a-c].

After 2 months, a repeat serum calcitonin showed 5 pg/ml.

DISCUSSION

MTC originates from the parafollicular or C-cells of the thyroid gland, which produce calcitonin as well as other secretory products such as carcinoembryonic antigen (CEA), adrenocorticotrophic hormone (ACTH), chromogranin, histaminases, neurotensin, somatostatin, and B-melanocyte-stimulating hormone.^[4] Most MTCs occur sporadically (75–80%), but they are also found in hereditary syndromes such as multiple endocrine neoplasia (MEN 2A) (Sipple syndrome), MEN 2B (Wagenmann–Froboese syndrome), and FMTC.^[4] MEN 2A that accounts for 95% of MEN 2 cases is characterized by MTC, primary hyperparathyroidism (HPT), and pheochromocytoma.^[5,6] There are four variants

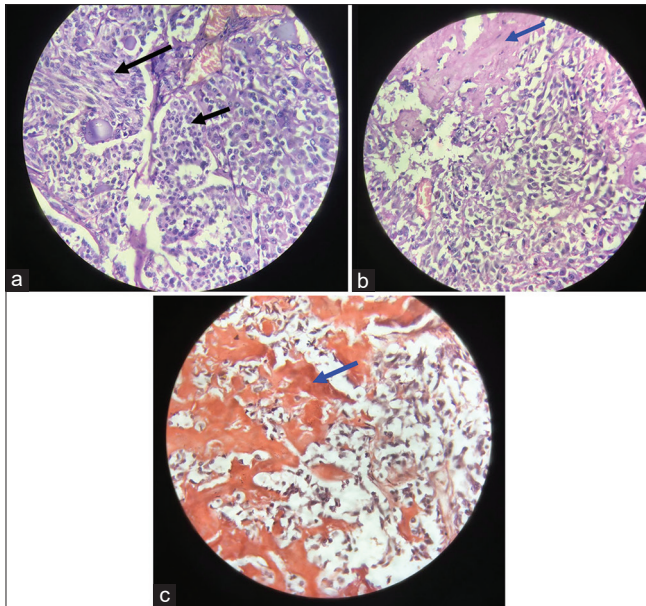


Figure 3: Histopathological images: (a) Round cells (short arrow) and spindle-shaped cells (long arrow), (b) pink amorphous deposition depicting amyloid deposition (blue arrow), (c) amyloid deposition confirmed by Congo red stain (blue arrow)

of the MEN 2A syndrome: Classical MEN 2A, MEN 2A with cutaneous lichen amyloidosis, MEN 2A with Hirschsprung disease, and FMTC, in which the families or individuals have MTC but not pheochromocytomas or HPT.^[7] The hereditary forms are characterized by germline mutations in the rearranged during transfection (RET) proto-oncogene located on chromosome 10q11.2.^[5,7,8] This oncogene encodes a transmembrane protein receptor kinase and is usually expressed in the cells of the neural crest, branchial arches, and the urogenital system. Approximately 50% of sporadic MTCs harbor RET mutations and up to 80% of the remaining carry RAS (HRAS, KRAS, or NRAS) mutations.^[9-11] Sporadic MTC typically occurs between the fourth to sixth decades of life; however, patients with hereditary disease present earlier like our patient. Patients often have a thyroid nodule, which may be associated with palpable cervical lymphadenopathy (15–20% of the cases).^[12]

Approximately 2–4% of patients develop Cushing syndrome as a result of ectopic production of ACTH. FNA biopsy is used to make the diagnosis of MTC in patients with a solitary thyroid nodule (or a dominant nodule within an MNG).^[12] The sensitivity of FNA for the diagnosis of MTC is 50%–80%, though a higher sensitivity can be achieved by adding the immunohistochemical staining for calcitonin.^[13-15] When the suspicion for MTC is high (patient with flushing, diarrhea, and in the context of a thyroid nodule), calcitonin can be measured in the washout of the FNA biopsy needle.^[14] The FNA cytology report often displays discohesive or weakly cohesive cells

that may be spindle shaped, plasmacytoid, or epithelioid in appearance.^[12,16] Furthermore, giant cells, oncocytic clear cells, and small carcinoma-like cells may also be present. The nuclei are generally eccentric, and chromatin granularity is seen as a salt and pepper appearance similar to other neuroendocrine tumors.^[12] The presence of amyloid is helpful but not by itself diagnostic.^[17] The diagnosis is confirmed by immunostaining for calcitonin, chromogranin, or CEA.^[12] Thyroglobulin staining is usually negative. As it is not possible to distinguish sporadic from familial disease at initial presentation, all new patients with MTC should be screened for RET point mutations, pheochromocytoma, and HPT. Pre-operative calcitonin levels may correlate with tumor size in both sporadic and familial cases of MTC.^[18] Pre-operative calcitonin level of cutoff 50 pg/mL may help predict who will have a biochemical complete response after surgery. Our patient calcitonin was 4435 pg/mL prior to surgery which decreased to 5 pg/mL in the post-operative period. Machens *et al.*^[19] reported that 62% of the patients with MTC without nodal metastases had normal calcitonin postoperatively, while 10% of patients with nodal metastasis had normal post-operative calcitonin levels. Contrast-enhanced CT of the neck and chest, three-phase contrast-enhanced multidetector liver CT, or contrast-enhanced magnetic resonance imaging (MRI) of the liver, and axial MRI and bone scintigraphy are recommended in patients with extensive neck disease and signs or symptoms of regional or distant metastases and in all patients with a serum calcitonin >500 pg/mL.^[4] 18F-Fluorodeoxyglucose-positron emission tomography (PET)/CT nor F-DOPA-PET/CT is recommended to detect the presence of distant metastases.^[5] MTC can only be cured by complete resection of the thyroid tumor and any local and regional metastases.^[20,21] Total thyroidectomy is the treatment of choice for patients with MTC due to the high incidence of multicentricity, the more aggressive course compared with differentiated thyroid cancer, and the fact that 131I therapy is usually not effective.^[20] For MTC limited to the neck and no evidence of involved cervical lymph nodes on pre-operative ultrasound, total thyroidectomy with prophylactic bilateral central compartment lymph node dissection is the desired initial treatment and this was the recommended management that we offered our patient. Roughly, 10% of patients with sporadic MTC and all patients with FMTC have bilateral or multifocal disease; likewise, the latter all have premalignant diffuse C-cell hyperplasia.^[4] Therefore, total thyroidectomy rather than unilateral lobectomy is the preferred surgical approach.^[4] MTC patients with unilateral intrathyroidal tumors are reported to have lymph node metastases in 81% of central compartment (Level VI) dissections, 81% of ipsilateral lateral compartment (Levels II–V) dissections, and 44% of contralateral lateral compartment (Levels II–V)

dissections.^[22] Very similar numbers are reported for patients with bilateral tumors. In addition, the incidence of lateral compartment nodal disease depends on the frequency of metastases in the central compartment. Pre-operative neck ultrasonography and basal calcitonin/CEA levels may be helpful to define the extent of nodal metastases and hence guide surgery, although this is debatable. Patients with basal calcitonin levels >20 pg/mL are unlikely to have nodal metastases.^[19] Increasing calcitonin levels (>20 pg/mL) are associated with metastases to the ipsilateral central and ipsilateral lateral compartment, contralateral central compartment (>50 pg/mL), contralateral lateral compartment (>200 pg/mL), and upper mediastinum (>500 pg/mL).^[22] As such, biochemical cure can be achieved in patients with pre-operative calcitonin levels <1000 pg/mL but is unlikely in patients with levels $>10,000$ pg/mL.^[19] The current American Thyroid Association (ATA) guidelines recommend that patients without nodal metastases on ultrasonography and no distant disease undergo total thyroidectomy and bilateral level VI node dissection.^[4] In this scenario, no consensus was reached regarding the optimal management of the lateral compartments, and the guidelines indicate that a prophylactic lateral neck dissection may be considered based on calcitonin levels.^[4] The ATA guidelines could not attain a consensus agreement on this topic but did recommend that prophylactic lateral neck dissections may be considered based on serum calcitonin levels.^[4] In contrast, the NCCN guidelines suggest considering a prophylactic ipsilateral modified neck dissection for high-volume or gross disease in the adjacent central compartment if the tumor is ≥ 1 cm in size or the disease is bilateral.^[20] In patients with diagnosed lymph node metastases (but no distant disease), total thyroidectomy, bilateral level VI dissection, and dissection of Levels II–V in the involved compartment are recommended.^[20] Prophylactic dissection of the contralateral neck can be considered if the calcitonin level is >200 pg/mL.^[20] Some authors have suggested that prophylactic central compartment neck dissection is not required in patients with small intrathyroidal MTCs with a pre-operative calcitonin <20 pg/mL, as metastatic lymph nodes are exceedingly rare in these circumstances.^[19] Patients with MTC limited to the neck and cervical lymph nodes should have a total thyroidectomy, dissection of the central compartment lymph nodes (Level VI), and dissection of the involved lateral neck compartments (Levels II–V). When pre-operative imaging is positive in the ipsilateral lateral neck compartment but negative in the contralateral neck compartment, contralateral neck dissection should be considered if the basal serum calcitonin level is >200 pg/mL.^[4]

External beam radiation therapy (EBRT) as adjuvant therapy to the neck and mediastinum is not routinely indicated

but should be considered in patients with incompletely resected disease and those considered at high risk for locally recurrent disease.^[20] This includes patients with microscopic residual disease, the presence of extrathyroidal extension, or extensive lymph node metastases.^[4] The potential benefits must be weighed against the acute and chronic toxicity linked with this treatment modality.^[12] EBRT appears to be effective for local tumor control.^[23,24] As a general rule, patients should no longer be candidates for repeat neck surgery, as the operation becomes more technically challenging after EBRT.^[12] If recommended, 60–66 Gy is delivered to the thyroid bed over a 6-week period, although higher doses are needed for gross residual disease.^[25]

Intensity-modulated radiation therapy is recommended for disease adjacent to the spinal cord to reduce toxicity. Patients in the post-operative period are risk stratified based on their risk of recurrence into low-risk disease and high-risk tumors. Serum calcitonin and CEA levels are measured at 3 months after surgery and if undetectable or within the normal range, the NCCN guidelines recommend annual serum calcitonin and CEA testing.^[20] However, the ATA guidelines diverge somewhat and recommend measurement at 6-month intervals for 1 year and then once yearly, provided physical examination is also normal. We are performing the ATA recommended follow-up and surveillance strategy. Patients with elevated calcitonin levels, as our patient was found to have 3 months after surgery, need additional imaging.^[20] If calcitonin is <150 pg/mL, ultrasound is recommended and if no disease is identified and the physical examination is unremarkable, these patients can be followed at 6-month intervals with examination, laboratories, and neck ultrasonography.^[4] If post-operative calcitonin is >150 pg/mL, the patients need evaluation by neck ultrasonography, chest CT, contrast-enhanced MRI, or triple-phase contrast-enhanced CT of the liver, bone scintigraphy, and MRI of the axial skeleton and pelvis to evaluate for metastatic disease.^[20] The liver is the most common site of distant metastases in patients with MTC, occurring roughly in 45% of patients with advanced disease.^[4] Other sites of distant metastasis include bone, brain, and lung.^[12] If imaging work-up is negative, monitoring with history and physical examination, calcitonin and CEA levels, and evaluation of the neck with ultrasonography should continue. Brain imaging is indicated only if patients have neurological symptoms.^[20] Measurement of calcitonin and CEA doubling times can also be used to determine the rate of progression of MTC.^[26,27] The frequency of repeating imaging studies will be dependent on the magnitude and rate of rise of the calcitonin and CEA levels. Patients with stable post-operative calcitonin levels in 150 pg/mL–300 pg/mL range are usually followed with yearly neck ultrasound for several years, reserving repeat cross-sectional imaging (neck,

chest, abdomen, and pelvis) looking for distant metastases in those patients with rising calcitonin or CEA levels. PET/CT scans are considered only when the calcitonin concentrations are higher than 500 pg/mL–1000 pg/mL.^[28] Radionuclide bone scan can be helpful in selected cases when cross-sectional imaging fails to identify the source of the elevated calcitonin levels.^[29-31]

CONCLUSION

MTC being an uncommon thyroid malignancy, genetic screening for evaluation of FMTC, MEN2A, and MEN2B should always be considered in pre-operative workup. Early diagnosis in family members offers a higher likelihood of cure and long-term survival.

Total thyroidectomy with central compartment neck dissection is the mainstay of treatment and regular follow-up is a must to prevent recurrence. Family counseling and screening of family members are a prerequisite in cases of familial medullary carcinoma.

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Instrument Retrieval from Central Incisor – A Case Report

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Abstract

Instrument separation is a very common mishap in routine endodontic practice. Although fractured fragment does not affect the prognosis of the case, it may affect the subsequent steps in endodontic therapy, such as chemomechanical preparation, obturating root canals. In case of separated instrument, attempts should be made to retrieve the instrument where possible or one should try to bypass the fragment. This case report describes the retrieval of a separated instrument from central incisor of 18-year-old boy.

Key words: Instrument retrieval, Instrument separation, Retrieval methods

INTRODUCTION

A clinician can face a variety of procedural problems during endodontic treatments. These include formation of ledges, strip perforations, or separation of instruments in the canals.^[1] The introduction of nickel–titanium (NiTi) instruments has revolutionized the way we shape the canal system. Despite the various advantages and increased use of NiTi instruments, the chances of procedural mishaps are much greater (1.3% and 10.0%, respectively) than that those of stainless steel instruments (0.25% and 6%, respectively).^[2] Improper use, inadequately extended access cavities, unpredictable root canal anatomy, and very rarely manufacturing defects are the most common causes of instrument separation.^[3] The separated fragment hinders through cleaning and shaping of canals beyond the separated fragment. If the separation has occurred at the apex and a part of it protrudes out, it can cause tissue irritation and adversely affect the prognosis of the case.

Over the past decade, there has been a significant rise in the use of rotary endodontic files and with this the

incidence of separated instruments. Many factors can be attributed to the fracture of these instruments, which include operator experience, speed of rotation, degree of canal curvature, instrument design and technique, torque, manufacturing process, and most importantly absence of a well-established glide path.^[4] Instrument breakage during treatment may also lead to considerable anxiety to the clinician. The success rate for retrieval of separated instruments has been found to be between 55% and 79%.^[5] Various devices and techniques have been used for retrieving instruments. The use of ultrasonics and dental operating microscope improves the chances of successful retrievals. This article reports a case of instrument retrieval of a long fragment with the help of ultrasonics, and finally, two files twist technique.

CASE REPORT

An 18-year-old male patient was referred to our clinic with pain and swelling with maxillary left central incisor. Mild swelling and pus discharge were seen with respect to 21 and 22. The patient was referred for the management of separated endodontic file. The referring dentist gave a history of separation of Proglider file in the central incisor 2 days ago. He also sent the pre-operative intraoral periapical (IOPA) [Figure 1].

IOPA radiographs were taken to confirm the fractured fragment in the canal [Figure 2]. Periapical radiolucency

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was seen with respect to 21 and 22. The patient was informed about the separated instrument and the prognosis of the tooth and consent was taken. Routine endodontic treatment with instrument retrieval was planned for the patient. After complete history taking, local anesthesia was administered to the patient. The concerned teeth (21 and 22) were isolated using rubber dam. The temporary filling material was removed. Starting with an ISO # 6 K-file, an attempt was made to bypass the instrument at working length. Progressively, ISO # 8, 10, and 15 K-files were used. The files were used along with ethylenediaminetetraacetic acid (EDTA) gel and copious irrigation of 3% sodium hypochlorite. At every step, apex locator (i-Root) was used to check if the file had been bypassed and if the apex was reached. Once the file had been bypassed and apex was reached, a confirmatory radiograph was taken. Working length was measured to be 20 mm. Subsequent biomechanical preparation was done using progressive files along with EDTA and sodium hypochlorite for irrigation. Calcium hydroxide dressing

was placed for 7 days (Iodotin, Techno Dent) in both 21 and 22.

After 7 days, the patient was recalled. No swelling was observed. After removing the temporary filling, the calcium hydroxide dressing was removed from the canals of both the teeth and the canals were thoroughly irrigated.

After biomechanical preparation up to F2, the separated fragment became little loose in the canal. Ultrasonic tips (Cric Dental) were used to loosen it further. Two K-files No. 15 and No. 20 were inserted simultaneously to engage the fractured fragment. Once the fragment was engaged, the files were used to retrieve the fragment [Figure 3]. IOPA was taken to confirm the complete retrieval [Figures 4 and 5].

After the retrieval, through irrigation with 3% sodium hypochlorite was done. Master cone selection was done [Figure 6]. Canals were dried with paper points and obturated using cold lateral condensation technique [Figure 7]. The patient was then kept under recall.



Figure 1: Intra-oral periapical radiograph



Figure 2: Intra-oral periapical radiograph to confirm the separated instrument in canal



Figure 3: Engaging the fractured fragment in two files



Figure 4: Intra-oral periapical radiograph to confirm retrieval of file

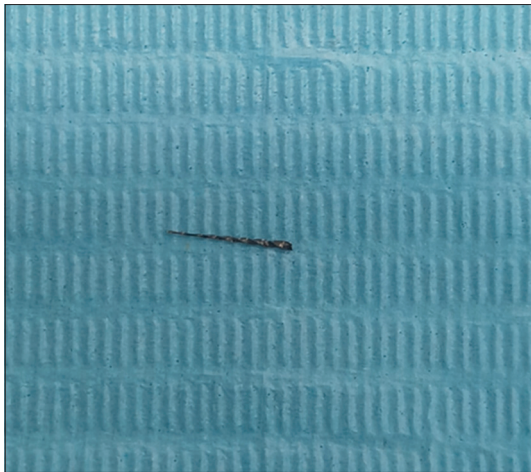


Figure 5: Retrieved fragment



Figure 6: Master cone selection



Figure 7: Post obturation intra-oral periapical radiograph

DISCUSSION

Fracture of an endodontic instrument is one of the most common procedural errors. There are various factors that

contribute to fracture of endodontic files, of which a few are listed below:^[6]

1. Operators skill – inadequate access cavity preparation, failure to achieve glide path, and improper instrumentation technique
2. Dynamics of instrument use – torque, rotational speed, engine driven or hand driven
3. Root canal anatomy or morphology
4. Fatigue of instrument and overuse.

Every case of endodontic instrument fracture creates dilemma for the operator, whether to bypass or remove the fragment. Furthermore, it is important to stress the need for additional armamentarium that is required for instrument retrieval which includes microscope, ultrasonic endodontic tips, and special endodontic instrument retrieval kits. All the devices, techniques, and methods vary in their effectiveness, cost, and mechanism of action. Hence, before a final treatment plan is designed, it is advisable to weigh the advantages and disadvantages for the success of the treatment.

Sometimes, the clinician may have to consider other factors such as periodontal status of the tooth, periapical lesion, additional financial expense, patient's anxiety related to a broken instrument in the tooth, and a potential medicolegal scenario. A few factors that should be considered in management of fracture endodontic instrument; (1) length of the fragment, (2) location of fractured fragment - beyond the apex, near apex, mid root (3) Root curvature, length, thickness.

The fracture of endodontic instrument is unpredictable but few precautions that one should take to reduce the risk of fracture,^[7]

1. Access cavity preparation should be adequate for visual access
2. Choosing the right armamentarium based on the instrumentation technique
3. Establish a glide path and a straight-line access to reduce flexion of files and resistance at multiple points
4. Follow the recommended torque values for rotary instruments.

CONCLUSION

Prevention is the best solution to avoid fracture of instruments. However, if such a situation arises, its best to weigh the advantages and disadvantages of bypassing, retrieving, or leaving the instrument *in situ*.

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Clinical Study of Chronic Lower Limb Ischemia and its Management

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Abstract

Background: The aim of the study was to study the modes of presentation of chronic lower limb ischemia, to study the effect of comorbid conditions such as smoking, diabetes, and hypertension on the presentation, progression of lower limb ischemia, and to correlate the above study finding with management and outcome.

Materials and Methods: This is a study of 77 cases of chronic lower limb ischemia admitted in Mahatma Gandhi Memorial Hospital, attached to Kakatiya Medical College, Warangal, Telangana state, during the period of October 2011–October 2013. All the patients with a history of chronic lower limb ischemia requiring admission during the study period are included in this study. Results were analyzed.

Results: In our hospital, 125,263 patients were admitted between the study period, i.e., October 2011 and October 2013. Among them, the number of cases of chronic lower limb ischemia was 77. Thus, the incidence of chronic lower limb ischemia among the total number of hospital admissions was found to be 0.06%. The total number of surgical admissions in our institute during the period from October 2011 to October 2013 was 12,877, of which the number of cases of chronic lower limb ischemia was 77 (incidence – 0.597%). The highest incidence of chronic lower limb ischemia is seen to occur in the age group of 50 years and above. The main features at the time of presentation were with gangrenous changes in the lower limb, ischemic ulceration, claudication, and rest pain.

Conclusion: Atherosclerosis (77.92%) is the major etiological factor causing chronic lower limb ischemia. Thromboangiitis obliterans is the second cause and it exclusively affects males. Smoking plays a major role in the etiology of chronic lower limb ischemia and smokers get affected at a younger age, 12.1 years, than non-smokers. Diabetes has a major role in the etiology of chronic lower limb ischemia. It also has a crucial role in the outcome of the patients. Most of the cases in the present study with diabetes had surgical intervention (92.59%) with very few cases managed by conservative approach alone (7.41%).

Key words: Gangrene, Intermittent claudication, Limb ischemia, Rest pain

INTRODUCTION

Peripheral arterial disease results from any disease-causing stenosis or occlusion of the lower limb arteries.^[1] Peripheral arterial disease is an important manifestation of atherosclerosis involving the arteries of legs.^[2] Vascular surgeons continue to encounter complications of atherosclerosis as their most common clinical challenge.^[3]

Management of atherosclerosis plays an important role in adult medical care.

Vascular disease is a leading cause of morbidity and mortality in people with diabetes. Diabetic foot problems are due to the combination of ischemia and neuropathy often complicated by infection.^[4] Ischemia inhibits the ability of the wound to heal, further complicated by the development of infection and gangrene. When associated with significant ischemia, diabetic foot ulcers require arterial revascularization to achieve wound healing.^[5]

Thromboangiitis obliterans (TAO) is an inflammatory occlusive disease primarily involving the medium-sized muscular and smaller arteries in extremities, with smoking as the strong associated causative factor. In the lower

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limb, the disease commences in the digital arteries and small arteries of the foot and then proceeds to involve the crural arteries.^[6] The risks to involve limbs are greater in TAO than in peripheral arteriosclerosis occlusive arterial disease. However, patients with TAO have a normal life span, whereas those with atherosclerosis have a greatly decreased survival compared with a normal population of the same age.^[7]

Intermittent claudication, heralded by pain in leg muscles during ambulation, is the earliest and the most classic symptom among patients with peripheral arterial^[2] disease. As the severity of arterial occlusion progresses, symptoms occur even at rest and may culminate in lower limb ulceration and gangrene.^[8]

At present, the appropriate management of patients with chronic lower limb ischemia is a complex clinical issue. Despite the advance in technical issues of revascularization, there remains much that can be done regarding education, risk factor modification, and non-operative therapy for these patients. Major amputation is eventually required in more than half of the patients once limb-threatening symptoms and signs occur.^[9] Nevertheless, the cause of death in patients with peripheral arterial disease is seldom direct result of lower limb ischemia, most patients die from complications of coronary artery or cerebrovascular disease.^[10]

Popliteal artery entrapment syndrome and cystic adventitial disease of popliteal artery are rare causes of chronic arterial ischemia of generally young healthy individuals. Although these diseases can produce severe disability if left untreated, normal circulation can be restored surgically.^[11]

MATERIALS AND METHODS

This is a study of 77 cases of chronic lower limb ischemia admitted in Mahatma Gandhi Memorial (MGM) Hospital, attached to Kakatiya Medical College, Warangal, Telangana state, during the period of October 2011–October 2013.

All the patients with a history of chronic lower limb ischemia requiring admission during the study period are included in this study. Documentation of patients, which included identification, thorough history and clinical examination, diagnostic tests, operative procedure, and complications during the stay in the hospital and during the subsequent follow-up period were all recorded on a pro forma specially prepared. The patients were followed up for a period up to the end of the study after discharge from the hospital.

Cases were collected as and when they presented with the following inclusion and exclusion criteria.

Inclusion Criteria

The following criteria were included in the study:

1. Patients presenting with signs and symptoms of chronic lower limb ischemia such as intermittent claudication, rest pain, ulceration and gangrene
2. Patients with evidence of lower limb arterial occlusive disease on Doppler study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients presenting with pain of skeletal or neurologic origin with no evidence of vascular damage
2. Patients presenting with paralysis and paresthesia of neurologic origin
3. Patients presenting with ulcers of traumatic or infective origin with no evidence of ischemia.

These cases were analyzed in detail with reference to age, sex incidences, clinical presentation, investigations, and treatment, they underwent during the period of hospital stay.

RESULTS

In our hospital, 125,263 patients were admitted between the study period, i.e., October 2011 and October 2013. Among them, the number of cases of chronic lower limb ischemia was 77. Thus, the incidence of chronic lower limb ischemia among the total number of hospital admissions was found to be 0.06%.

The total number of surgical admissions during the same period was 12,877, and hence, the incidence of chronic lower limb ischemia among total admissions under the Department of General Surgery at MGM Hospital was found to be 0.597%.

Among the total number of (77) cases, 47 were male and 30 female. There is a higher involvement in males (61.04%) when compared to females (38.96%).

The previous studies by Criqui *et al.*, 1997, and Murabito *et al.*, 1997, show that the prevalence has been shown to be higher in men than in women.^[12,13]

Criqui *et al.*, 1998, showed that 4.7% of men (12/256) and 1.9% of women (6/309) had severe peripheral artery disease (PAD) (ankle–brachial index [ABI]: <0.6); the respective percentages for moderate PAD (ABI: 0.6–0.9) were 3.5% (9/256) and 2.9% (9/309) for men and women, respectively.^[14]

Table 1 shows the distribution of the incidence of chronic lower limb insufficiency in different age groups. It clearly suggests that the incidence is more in the age group of 50 years and above.

In several studies, the risk for PAD increased 1.5–2.0-fold for every 10-year rise in age.^[15,16]

The prevalence of PAD is highly age dependent. In a survey conducted in San Diego, in an older defined population, the prevalence was 2.5% in people aged <60 years old; this rose to 8.3% at 60–69 years and reached 18.8% in people >70 years of age.^[17]

PAD prevalence rates, Murabito *et al.*, 1997, by non-invasive testing are reported to be 2.5% at ages 40–59 years, 8.3% at ages 60–69 years, and 18.8% at ages 70–79 years.^[13]

In a study done by Selvin and Erlinger on the prevalence of and risk factors for PAD in the United States, it was found that, although, there was a slightly higher prevalence in men than in women, the prevalence dramatically increased with age, rising from 0.9% in those younger than 50 years to 14.5% in those 70 years or older.^[18]

Life expectancy of the Indian population is less than the Western population. Hence, the number of cases above 70 years is less than the Western studies.

In the present study, out of 77 cases, most of the cases were caused by atherosclerosis (77.92%) and few cases were caused by TAO (22.08%). The diagnosis was based on Shionoya criteria and also on the biopsy reports of the vessels taken from the amputated specimens [Table 2].

Mills and Porter reported that TAO constitutes 1–3% of PAD in the Western population;^[19] Khanna reported that TAO is the most common type of PAD in India.^[20] There are widely varying prevalence rates of Buerger's disease in patients with PAD in Europe and Asia. The rates of TAO among all patients with PAD have been reported as 0.5–5.6% in Western European countries, 3% in Poland, 6.7% in East Germany, 11.5% in Czechoslovakia, 39% in Yugoslavia, 80% in Israel, 45–63% in India, and 16–66% in Korea and Japan.^[21]

Kelkar conducted an Indian study of 489 cases of chronic lower limb ischemia and found that 50% were due to TAO and 43% were due to atherosclerosis, the rest being due to miscellaneous causes.^[22]

A study done by Nigam had a higher incidence of TAO, accounting for 63% of the cases and atherosclerosis only 15%, the rest being miscellaneous causes.^[23]

In the present study, 82.35% of the patients with TAO (14 cases) were between 31 and 50 years of age. Nigam reported in his study that 88% of the TAO cases were aged between 31 and 50 years.^[23]

In the present study, most of the patients presented to the hospital with gangrenous changes in the lower limb, 57 out of 77 cases (74.02%), 11 out of 77 cases presented with ischemic ulceration, and 9 out of 77 cases presented with claudication and rest pain [Table 3].

A recently published study states that the public is poorly informed about peripheral arterial disease; this leads to delay in presentation and diagnosis. Hence, poor outcome of any intervention or procedure, the patient ultimately requiring amputation in some form.^[24]

In the present study, Doppler study was undertaken for all the cases of chronic lower limb ischemia. The most common site of obstruction was found to be infrapopliteal vessels (37.67%) followed by ankle region vessels (31.17%) [Table 4].

Most patients in this study presented to the hospital in an advanced stage of limb ischemia where the ankle–brachial pressure index of most of the patients was below 0.5 [Table 5]. All the patients with ankle–brachial pressure

Table 1: Incidence of chronic lower limb insufficiency in different age groups

Age group	Number of patients (%)
20–30	2 (2.60)
30–40	7 (9.09)
40–50	12 (15.58)
50–60	18 (23.38)
60–70	21 (27.27)
70–80	15 (19.48)
80–90	2 (2.60)

Table 2: Cause of chronic lower limb insufficiency

Sex	Atherosclerosis	TAO
Male	30	17
Female	30	0
Total (%)	60 (77.92)	17 (22.08)

TAO: Thromboangiitis obliterans

Table 3: Modes of presentation in the present study

Intermittent claudication only	Nil
Intermittent claudication and rest pain	9 (11.69)
Intermittent claudication and rest pain and gangrene	57 (74.02)
Intermittent claudication and rest pain and ulceration	11 (14.29)

Table 4: Doppler findings in the affected limbs

Level of obstruction	Number of cases (%)
Supra-popliteal	12 (15.58)
Popliteal	12 (15.58)
Infrapopliteal	29 (37.67)
Ankle region	24 (31.17)

index above 0.5 could be managed either conservatively or by sympathectomy or by toe disarticulation. Most of the patients with ankle-brachial pressure index below 0.5 ended up with amputation.

This can be compared with the existing studies, Hirsch *et al.*,^[25] 2005, and Sacks *et al.*,^[26] 2002, which state that an ABI <0.4 increases the risk of limb loss, gangrene, ulceration, and delayed wound healing.

In the present study, more number of patients were managed surgically, either toe disarticulation or limb amputations, 10 cases were managed conservatively alone with cessation of smoking, limb exercises, low-dose aspirin, cilostazol, and pentoxifylline. Nine cases were managed by lumbar sympathectomy. Sixteen cases underwent disarticulation of one or more toes and 42 cases underwent limb amputations, both above-knee and below-knee amputations. All the cases which underwent some form of surgery also were supplemented with medical therapy [Table 6].

The present study shows that the average age of cases of lower limb ischemia with smoking history tends to present 12.1 years earlier than non-smokers. This is represented in Table 7. A study by transatlantic intersociety consensus working group states that, on average, the diagnosis

of PAD is made 10 years earlier in smokers than non-smokers.^[27]

Outcome of Diabetic Patients with Chronic Lower Limb Ischemia in this Study [Table 8]

The present study shows the effect of diabetes on peripheral vascular disease. This clearly suggests that only 2 out of 27 diabetic cases could be managed conservatively with strict glycemic control and foot care education, whereas majority of them (92.59%) required surgical intervention either in the form of toe/toes disarticulation (29.63%) or limb amputations (62.96%). This result can be correlated with the existing data which clearly suggests that worse outcomes including limb loss are more in individuals with peripheral vascular disease and diabetes.^[28,29] The Centers for Disease Control and Prevention reported in 1997 that, in the United States, the LEA rate among those with diabetes was 28 times that of those without diabetes 73. In the present study, of the 42 amputations, 17 were of diabetic patients.

Normally in diabetic patients, digital amputations are done. However, if associated with peripheral vascular disease, rate of proximal limb amputations increases.

The present study shows the influence of diabetes and hypertension, in combination, on the outcome of lower limb ischemia. Table 9 clearly suggests that most of the cases, 12 out of 14, with both diabetes and hypertension, needed surgical intervention, either in the form of disarticulation or amputation. In that, majority of them, 9 out of 13, ended up having amputation. This suggests the effect of hypertension and diabetes on the outcome.

In the present study, 23 cases (29.88%) out of 77 were found to be hypertensive. Hypertension has been linked

Table 5: Ankle-brachial pressure index in the patients of chronic lower limb ischemia in this study

Ankle-brachial pressure index	Number of patients (%)
0.2	18 (23.38)
0.3	21 (27.27)
0.4	13 (16.88)
0.5	18 (23.38)
0.6	6 (7.79)
0.7	1 (1.3)

Table 6: Treatment in patients of chronic lower limb ischemia in the present study

Treatment	Number (%)
Only conservatively managed	10 (12.99)
Toe/toes disarticulation	16 (20.78)
Lumbar sympathectomy	9 (11.69)
Limb amputations	42 (54.54)

Table 7: Comparison of the average age of presentation of smokers and non-smokers in the present study

Cases	Average age of presentation
Smokers	53.58
Non-smokers	65.68

Table 8: Treatment in chronic lower limb ischemia patients with diabetes in the present study

Treatment	Number (%)
Conservatively managed	2 (7.41)
Toe/toes disarticulation	8 (29.63)
Lower limb amputation	17 (62.96)
Total	27

Table 9: Effect of combination of diabetes and hypertension on outcome in the present study

Treatment	Number (%)
Conservatively managed	2 (14.29)
Lumbar sympathectomy	0 (0)
Toe/toes disarticulation	3 (21.43)
Lower limb amputation	9 (64.28)

with an increased risk of peripheral arterial occlusive disease in some studies. The Framingham data documented a 2.5-fold increase in the risk of PAD in men with hypertension and a 3.9-fold increase in women with hypertension.^[30] Almost every study has shown a strong association between hypertension and PAD, and as many as, 50–92% of patients with PAD have hypertension. In the systolic hypertension in the elderly program, 5.5% of the participants had an ABI under 0.90.^[31]

In the present study, 3 patients (3.9%) had a prior history of myocardial infarction (MI) and 1 patient (1.3%) had a history of cerebrovascular accident (CVA). Three patients with a history of MI were found to be diabetic. All the three patients underwent amputations. One patient with CVA was hypertensive and underwent amputation. In a study, among the subjects with ischemic claudication identified in the general population, the prevalence of ischemic heart disease varied between 30% and 40% and 6% of the patients gave a history of the previous stroke.^[32]

In the present study, 2 patients (2.6%) were found to have hypercholesterolemia and serum cholesterol >200 mg/dl and were managed with atorvastatin postoperatively. In epidemiological studies, total cholesterol levels are generally higher in patients with intermittent claudication than in those without lower extremity peripheral arterial disease.^[33]

Outcome of the Cases Treated

The outcome of treated cases, apart from amputations, was assessed by the following criteria:

1. Relief of rest pain, a subjective improvement from the patient point of view
2. Rise in cutaneous temperature as judged by palpation
3. Healing of trophic ulcers.

DISCUSSION

In this study of 77 cases, conservative treatment was adopted in all the cases. They were treated by cessation of smoking, limb exercise, cilostazol (100 mg BD), and pentoxifylline (400 mg BD). Medical treatment also included antibiotics, analgesics, antidiabetic, antihypertensive drugs, and low-dose aspirin (150 mg OD).

In this study, 10 cases out of 77 cases were exclusively managed conservatively. Out of 10 cases, 6 presented with claudication and rest pain. Four out of these six cases had symptomatic relief in rest pain. Remaining two cases had no improvement in the pain. Four cases with small ischemic ulcers were managed conservatively alone and all the four cases showed symptomatic relief from pain and three of them had healing of the ulcer. Remaining one case showed

no improvement in the ulcer but had symptomatic relief by the end of the study period.

In this study, 9 out of 77 cases underwent lumbar sympathectomy. Three cases had claudication with rest pain and all the three cases had symptomatic relief from pain. Clinical improvement was also noted with the raise of cutaneous temperature. Three cases had shallow small ulcers and two of them showed healthy granulation tissue at the base, one case the ulcer remained the same by the end of the study period. Three cases had gangrene of the digits, which had autoamputated with healthy granulation tissue at the base.

In this study, 16 cases out of 77 cases were treated by toe/toes disarticulation. They also received medical treatment simultaneously. Thirteen cases out of 16 had normal healing of the skin. Two cases developed superficial infection with wound gaping, for which secondary suturing was done. One case developed non-healing ulcer at the base of disarticulation by the end of the study period.

In this study, 42 cases out of 77 cases had underwent lower limb amputations. Seventeen out of 42 cases underwent below-knee amputation. The remaining 25 cases underwent above-knee amputation. One case of below-knee amputation underwent revision amputation due to compression of the stump of the tibia onto the skin causing skin necrosis. Five cases had wound gaping that was subsequently closed by secondary suturing. Remaining 36 cases had uneventful recovery. All the cases of amputations were treated medically postoperatively. All the cases had relief of pain on follow-up.

Post-operative period in amputations in the present study

Uneventful (%)	36 (85.71)
Secondary suturing (%)	5 (11.91)
Revision amputation (%)	1 (2.38)
Total	42

CONCLUSION

The present study, 77 cases of chronic lower limb ischemia, was studied during the period of October 2011–November 2013. A clinical study was done regarding the age and sex distribution, modes of clinical presentation, relevant investigations, and various modalities of treatment. The present study shows: Chronic lower limb ischemia cases constitute about 0.6% of total general surgical admissions.

Males (61.04%) are more commonly affected than females (38.96%), due to their habit of cigarette smoking.

The percentage of females affected increased with increasing age.

The age group of 60–70 years is the most common presenting age (27.27%) of chronic lower limb ischemia.

The youngest patient was 23 years of age and the oldest patient being 90 years of age.

Atherosclerosis (77.92%) is the major etiological factor causing chronic lower limb ischemia.

TAO is the second cause and it exclusively affects males. Female patients were not affected with TAO as they are non-smokers.

Most of the patients (74.02%) presented with gangrene of some part of the lower limb.

Smoking plays a major role in the etiology of chronic lower limb ischemia and smokers get affected at a younger age, 12.1 years, than non-smokers.

Diabetes has a major role in the etiology of chronic lower limb ischemia. It also has a crucial role in the outcome of the patients. Most of the cases in the present study with diabetes had surgical intervention (92.59%) with very few cases managed by conservative approach alone (7.41%).

Color Doppler was the main investigating modality used in the present study.

Majority of the cases had block in the infrapopliteal segment (37.67%) and in the ankle region (31.17%), with few cases having obstruction at popliteal (15.58%) and superficial femoral level (15.58%).

Most of the patients (54.54%) ended up having lower limb amputations. Remaining cases were treated either with lumbar sympathectomy (11.69%), disarticulation (20.78%), or conservative approach alone (12.99%).

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Clinical Study of Maternal Near Miss

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Abstract

Introduction: The women who survive serious complications of pregnancy are referred to as “near miss.” For every maternal death, there are many others who suffer serious life-threatening complications of pregnancy, referred to as “near miss” morbidity. In fact, for the over 500,000 mothers who die annually worldwide, and mostly in developing countries, there are more than 8 million who suffer severe maternal morbidity (WHO 2004). There is currently no standard definition of “near miss” such as there is for a maternal death because it is difficult to determine exactly at which point a woman becomes a “near miss.” WHO defines maternal “near miss” as a woman who nearly died but survived complications that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy.

Aims and Objectives: The aim of the study was to determine the magnitude and types of life-threatening maternal complications in pregnant and recently delivered women, timing and management, blood transfusion and major surgery, and inpatient duration of stay of patients with “near miss” morbidity.

Materials and Methods: The prospective cohort study was done by the Department of Obstetrics and Gynaecology, Kamla Raja Hospital, Gwalior, study period from 1 year, November 2014 to October 2015. **Inclusion Criteria:** Acute cyanosis, Gasping, Respiratory rate >40 or <6/min, shock, oliguria, clotting failure, loss of consciousness lasting >12 h, stroke, uncontrolled fit/total paralysis, and jaundice in the presence of pre-eclampsia were included in the study. **Exclusion Criteria:** Morbidity resulting from causes not related to pregnancy or its complication or management, for example, malignancies, ca breast, and liver rupture. Morbidity from accidental or incidental causes no way related to pregnancy, for example, morbidity from automobile accident/suicide. Women who develop these conditions unrelated to pregnancy.

Results: Near miss to maternal death ratio as 3.69:1 which means out of five women with severe morbidity we are saving four cases. Near miss cases are 97 (61%) war multigravida and only 61 (39%) war primigravida. Referred cases were 102 to which means 66.1% of near miss were referred to our institute from various center. Only 57 cases (33.9%) came directly. Fifty-four patients (33.9%) have 4 days intensive care unit (ICU) stay followed by 50 cases (31.44%) having 3 days ICU stay and maximum stay was of 6 days in 11 cases.

Conclusion: Still, it needs improvement, which can be achieved by ongoing training and simulation sessions for obstetrical staff in early recognition and management of severe obstetric morbidity and also by resource allocation that is required in the management of the near miss cases.

Key words: Maternal near miss, Pre-eclampsia, Primi gravida

INTRODUCTION

The woman who survives serious complications of pregnancy is referred to as “near miss.” For every maternal death, there are many others who suffer serious life-

threatening complications of pregnancy, referred to as “near miss” morbidity.

Mantel *et al.*^[1] identified 5 times as many “near misses” as maternal deaths. In fact, for the over 500,000 mothers who die annually worldwide, and mostly in developing countries, there are more than 8 million who suffer severe maternal morbidity (WHO 2004).

There is currently no standard definition of “near miss” such as there is a maternal death because it is difficult to determine exactly at which point a woman becomes a “near miss.” Locally appropriate and acceptable definitions are

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encouraged and have been used by various researchers. For instance, the West African “near miss” audit network used the following definition for the case review of “near miss.” “Any pregnant or recently delivered woman (within 6 weeks termination of pregnancy) in whom immediate survival is threatened and who survives due to chance or hospital care she receives.”^[2]

Mantel *et al.*^[1] defined a “near miss” as a patient with an acute organ system dysfunction which if not treated appropriately, could result in death.

Basket and Sternadel^[3] proposed to define maternal “near miss” cases as those women requiring critical care or transfer to an intensive care unit (ICU).

In a study in Benin, a “near miss” was defined as “a severe life-threatening obstetric complication necessitating urgent medical interventions to prevent the likely death of the mother.”^[4]

WHO^[5] defines maternal “near miss” as a woman who nearly died but survived complications that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy.

It is estimated that 80% of complications of pregnancy and maternal death are avoidable, even in resource-poor countries. Studies including those by Kassas^[6] It is estimated that 80% of complications of pregnancy and maternal death are avoidable, even in resource-poor countries. Studies including those by Kassas^[6] in Egypt (1995) and Bouvier-Colle *et al.*^[7] in France (2001) have shown that the quality of care provided to pregnant women is critical and that appropriate emergency obstetric care can save many lives. In the past, maternal audit using that have traditionally been used to improve maternal health outcomes.

Confidential inquiries into maternal death in the United Kingdom Malaysia and other countries have resulted in continuous improvement of maternal health in those countries (WHO, 2004; Rowe *et al.*^[8] 2005). Martey *et al.*^[9] in Ghana and Mbaruku and Bergstrom^[10] in Tanzania reported on the use of maternal mortality review to identify avoidable factors and improve on services. In Tanzania, there was a 50% reduction in maternal mortality over 3 years of interventions following implementation of the maternal death reviews.

Over the past decade, review of near misses or severe maternal morbidity 2008,^[11,12] prevalence was 3.3 using disease-specific and management-based criteria. The leading causes were hemorrhage, pregnancy-induced hypertension, and sepsis, immediate resuscitation mechanical ventilation,

laparotomy, hysterectomy, manual removal of placenta, and repositioning of inverted uterus. Blood transfusion remains the mainstay for near miss management.

Maternal near miss analysis will

- provides us information which helps in understanding patterns of maternal morbidity, use of clinical and other health-care interventions
- Used to develop culture of early identification of complications and preparedness for acute morbidities.

Aims and Objectives

Main objectives

The aim of the study was to determine the incidence of and describe the type of life-threatening maternal complications in pregnant and recently delivered women on admission to the Kamla Raja Hospital Obstetrical ICU.

Specific objectives

The objectives are as follows:

1. To determine the magnitude and types of life-threatening maternal complications in pregnant and recently delivered women (“near miss” morbidity) admitted at Kamla Raja Hospital Obstetrical ICU
2. To describe the characteristics of women (demographic and pregnancy) related that have a “near miss”
3. To assess the timing and management of “near miss” morbidity
4. To determine the use of blood transfusion and major surgery in the management of “near miss” morbidity patients
5. To determine the inpatient duration of stay of patients with “near miss” morbidity.

MATERIALS AND METHODS

The prospective cohort study was done by the Department of Obstetrics and Gynaecology, Kamla Raja Hospital, Gwalior, study period from 1 year, November 2014 to October 2015.

Inclusion Criteria

Acute cyanosis, Gasping, Respiratory rate >40 or <6/min, Shock, Oligouria, Clotting failure, loss of consciousness lasting >12 h, stroke, uncontrolled fit/total paralysis, and jaundice in presence of pre-eclampsia were included in the study.

Exclusion Criteria

Morbidity resulting from causes not related to pregnancy or its complication or management, for example, malignancies, carcinoma breast, and liver rupture morbidity from accidental or incidental causes no way related to pregnancy, for example, morbidity from automobile accident/suicide

were excluded from the study. Women who develop these conditions unrelated to pregnancy.

RESULTS

Our study used a case definition that included clinical laboratory management and interventional criteria. This yielded the proportion of near miss at 1.3% of admissions [Table 1].

Our study also yielded near miss incidence ratio as 20.7/1000 live births and maternal near miss to maternal death ratio as 3.69:1 [Table 1].

Our study shows 105 cases 66.03% belongs to a rural area with 98 cases (61.6%) being referred from nearby institutes [Table 2].

The reason may lie in fact that referral from interiors of community due to lack of proper transportation facilities can lead to severe maternal morbidity to life-threatening complications while arriving at tertiary center [Table 1]. About 66.03% cases belong to rural communities as less knowledge toward health-seeking behavior as well as low health facility in that area.

The age range of cases was from 18 to 40 years 115 cases that are 72.32% of total cases belongs to 21 to 30 years, which is the most active reproductive age group. However, younger and older are group both (13.8% of total) were markedly represented.

Our study has 97 cases (61%) to be multigravida and 62 cases (39%) to be primigravida. As would be expected, there was a close correlation between gravidity and cause of near miss. Nulliparity is an important risk factor of hypertensive disorder and responsible for most of the cases, whereas hemorrhage cases were having higher parity.

Maximum referrals are from district hospital (DH) Shivpuri ($n = 28$, 17.61%) followed by DH Morena ($n = 20$, 12.57%). This is consistent with the transportation distance between our institute and referral center [Table 2].

Two main clinical diagnoses in the near miss cases hypertensive disorders of pregnancy ($n = 56$; 35.22%) and hemorrhage ($n = 42$; 26.41%). Other two main causes were severe anemia ($n = 21$, 13%) followed by rupture uterus $n = 16$, 10.0.6%) [Graph 1].

DISCUSSION

During the 1 year study period, November 2014–October 2015, 12,137 of obstetric patients were admitted in the department of obstetric and gynecology; 159 cases (1.3% of all the cases admitted) had life-threatening complications of pregnancy or the puerperium and fulfilled the case definition used in this dissertation for a near miss. These patients nearly died but survived a severe complication during pregnancy, delivery or the puerperium.

The WHO is still in the process of establishing a uniform set of identification criteria and standard definition of near miss cases at the moment it is difficult to make comparisons across studies from different regions because of the different definitions used.

Say *et al.*^[13] reported in a systematic review by WHO that many near miss studies used criteria of admission to an ICU worldwide prevalence for search criteria range from 0.01% to 2.99%. In another systematic review, Wilson and Salihu^[14] found that serious forms of maternal mortality occur to about 1% of women in the United State to 3% in some developing countries.

The prevalence of maternal near miss by a systematic review^[15] covering nearly 4000 articles between January 2004 and December 2010 by BJOG 2004 using disease-

Table 1: Prevalence and comparison of near miss, maternal deaths, and blood transfusion

Months	Total no. of admissions	Live births	Total near miss cases	Maternal deaths	Blood transfusion
November 14	905	636	14	-	65
December 14	976	609	14	1	55
January 15	1080	616	12	4	40
February 15	574	553	15	1	49
March 15	746	601	11	2	37
April 15	864	538	11	1	45
May 15	963	660	10	4	35
June 15	1181	626	12	3	34
July 15	1202	710	16	7	57
August 15	1272	753	18	7	55
September 15	1182	619	14	8	40
October 15	1242	742	12	5	46
Total	12187	7663	159	43	558

specific criteria – 0.6% and 14.98%, management base criteria 0.04% and 4.5%, and organ dysfunction mantel^[1] criteria 0.14 % and 0.92%.

Our study used a case definition that included clinical laboratory management and interventional criteria. This yielded the proportion of near miss at 1.3% of admissions.

Our study also yielded near miss incidence ratio as 20.7/1000 live births and maternal near miss to maternal death ratio as 3.69:1, the study conducted in tertiary care hospital, Karachi^[16] from April 2010 to September 2010, have maternal near miss ratio as 76.97/1000 lives birth and near miss mortality ratio 5.8:1. Similar study in tertiary hospital of Delhi^[17] in October 2008 reveals maternal near miss incidence ratio as 33/1000 live births.

It is not possible to compare proportions to the general prevalence found across other studies worldwide because

Table 2: Demographic profile according to direct or referred cases

Months	Direct cases	Referred cases
November 14	03	11
December 14	04	10
January 15	04	08
February 15	05	10
March 15	05	06
April 15	05	06
May 15	04	06
June 15	04	08
July 15	05	11
August 15	07	11
September 15	03	11
October 15	08	04
Total	57	102

of the many differences in the terms of geographical location, population, and study methodologies used.

Management of Near Miss Cases

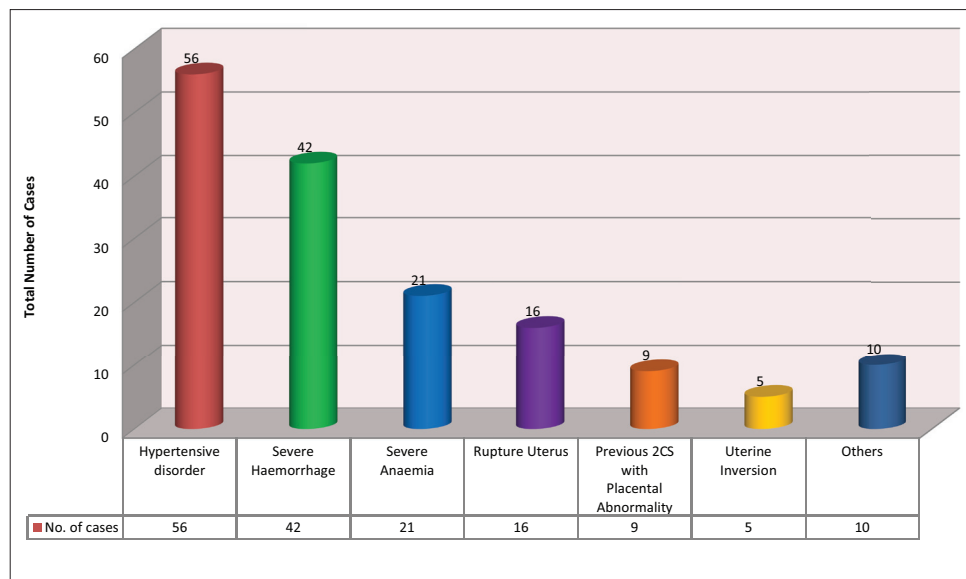
Surgical management is the mainstay for near miss cases. One hundred and fourteen cases (11.69%) managed surgically, out of which $n = 60$; 37.73%) by lower segment cesarean section (LSCS) and by cesarean hysterectomy ($n = 20$, 12.5%). Study in tertiary hospital, Delhi^[17] (October 2008) revealed 54.5% cesarean section and hysterectomy rate 14.8%, whereas hysterectomy rate was 3.6% in near miss study in civil hospital Karachi^[16] in September 2010.

Thirty-two cases that were 20.1% of total cases need ventilatory support which also remains one of the important inclusion criteria for our study. Almost all cases got blood transfusion either as primary management or supportive management packed red cell transfusion being life-saving in severely anemia patient and fresh frozen plasma in hypertensive disorders to prevent coagulation disorders.

Average ICU stay of patient was 4 days ($n = 54$; 33.96%) and 3 days ($n = 50$, 11.44%) very less patient ($n = 11$, 6.91%) with severe life-threatening complication required 6 days ICU stay. There was no significant difference among different causes of near miss.

Summary

- Total number of admission during study period 12,187 and live birth 7663. Our near miss cases were 159 the prevalence of near miss cases. Maternal near miss incidence ratio was 20.7/1000 live births



Graph 1: Causes of near miss

- Near miss to maternal death ratio as 3.69:1 which means out of five women with severe morbidity we are saving 4 cases
- Maximum number of near miss cases 115 was in 21–30 years, followed by equal distribution in both extremes of age group
- Maximum near miss cases that are 97 (61%) war multigravida and only 61 (39%) war primigravida
- Maximum near miss cases 105 (66.03%) belongs to rural community and only 54 (34.07%) belong to the urban community
- Referred cases were 102 to which means 66.1% of near miss were referred to our Institute from various center. Only 57 cases (33.9%) cases came directly
- Referrals 26 were from DH Shivpuri followed by DH Morena (20) and other primary health centers (14). DTH Guna and DH Bhind that is 12 and 10 cases, respectively, also contribute significantly
- Maximum cases of near miss were due to hypertensive disorder (56) followed by severe hemorrhage (42), severe anemia (21), and rupture uterus (16) also contributed significantly. Nine cases were due to previous section with placental abnormality and 5 cases due to uterine inversion. The other 10 cases were due to heart disease; lower respiratory infection perennial obstructed labor and hepatic encephalopathy
- Maximum number of near miss cases that is 37 in whom continuous vasoactive drugs are given and 31 cases required ventilatory support 24 cases required transfusion >5 units of red blood cell and hysterectomy done following hemorrhage in 20 cases
- LSCS as surgical management in 60 cases (37.73%) followed by hysterectomy in 20 cases (12.5%). Laparotomy for rupture uterus was done in 16 (9.43%) cases and for ectopic pregnancy in 6 cases (3.7%) other management include laparotomy for uterine inversion (4), intrauterine packing (4), and hematoma drainage (1). D and C (1), internal iliac artery ligation (1) uterine reposition followed by vaginal packing (1) and manual removal of placenta (1)
- Only 32 cases that that is 20.1% require ventilatory support
- Total 368 packed cell red blood cells and 190 other blood components transfused all 159 near miss cases. Almost all cases require blood transfusion
- Maximum number of patients 54 (33.9%) have 4 days ICU stay followed by 50 cases (31.44%) having 3 days ICU stay and maximum stay was of 6 days in 11 cases.

CONCLUSION

This study has shown that near miss cases constituent some 1.3% of life-threatening complications at KRH, Obstetrical

ICU, Gwalior, which despite different case definitions is consistent with other studies in developing and developed countries.

Eclampsia, hemorrhage rupture uterus still remains main cause for severe acute maternal morbidity and ultimately maternal death. As in present study, 98.77% near miss cases were diagnosed at admission and already had these complications because of inability to reach to facility on time, further strengthening of antenatal care services at peripheral level and robust referral system through better availability of transport facilities is needed to reaching higher level facility on time.

I hereby conclude that due to the presence of Obstetrical ICU at KRH and immediate active intervention the maternal mortality rate (MMR) has been reduced from 868/lakh live births in 2012–2013 to 694/per lakh live birth in 2013–2014 to 561/lakh in our study period (2014 to 2015).

Still, it needs improvement, which can be achieved by ongoing training and stimulation sessions for obstetrical staff in early recognition and management of severe obstetric morbidity and also by resource allocation that is required in the management of the near miss cases.

Study Limitations

Our study was carried out in a single unit (KRH, Obstetrics and Gynaecology Department) in 1 year duration period. The results cannot be applied to general population due to variations in geographical location and population awareness.

The patients were only followed up to discharge from the obstetric ICU. Following up patients for a longer period would determine whether they survived the puerperium, developed Sheehan's syndrome and about their quality of life, mensurational abnormality. However, this would have required the community to follow-up.

Data, as was obtained for near miss cases, were not obtained from all those died as the intent was not to study maternal mortality. However, if it had been collected, it would have allowed for a detailed comparison and identification of risk factors in cases of life-threatening complications leading to survival (near miss) as a pose to death (maternal mortality).

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Treatment of Distal End Radius Fractures - By Various Modalities

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Abstract

Introduction: Fractures of the distal end radius represent approximately 16% of all fractures treated by orthopedic surgeons. Our study is intended to find both conceptual and practical guidance for precision treatment with an expectant favorable result.

Materials and Methods: A total of 50 patients of distal end radius fractures were treated with cast immobilization, percutaneous pinning, external fixation, and volar locking plate fixation. Fernandez classification was used. Functional outcomes were assessed using Demerit Point System of Gartland and Werley (modified). The anatomical evaluation was done by Lindstrom criteria (modified).

Results: Functional outcomes depend on patient's age, fracture anatomy, displacement, reducibility, stability, and articular incongruity of fractures. They are related more to the anatomical reduction than to the method of immobilization. Volar locking plate is a safe and effective treatment for unstable and metaphyseal comminuted fractures.

Conclusion: According to Fernandez classification, Type I fractures were the most common. The volar locking compression plate fixation gives excellent functional and anatomical results than other modalities of treatment. Hence, we recommend volar locking plate fixation is the best modality of treatment among others.

Key words: Fernandez classification, Fracture distal end radius, Volar plating

INTRODUCTION

Fractures of the distal radius are a common clinical problem affecting skeletally mature people. The young sustain this injury as a result of significant local trauma. The elderly have predisposing risks of disuse or postmenopausal osteoporosis.^[1]

The overall male to female ratio is about one to five. However, before the age of 40 the incidence is equal in both sexes. In males, the incidence rises only slightly from the age of 40 to 80 but in the females it is 8–10 times from 40 to 60 after which it remains constant. This correlates with an increased incidence of osteoporosis after menopause in females.^[2,3]

These fractures are generally closed and usually involve displacement of fracture fragments. They may be either extra-articular or intra-articular. In particular, “Colles’ fracture” is still the terminology used for a fracture in which there is an obvious and typical clinical deformity.^[4]

Two centuries have passed since the first description of Colles’ fracture, still there is no unanimity about its best management. Different authors have claimed varied results with various treatment modalities.

The final choice of treatment method will be influenced by many considerations including the nature of the fracture, bone stock and fragility, the presence of local complications (compound injury and nerve injury) or other injuries, the patient's general medical condition, the expected functional loading (activity demands), and patient motivation.^[3]

In our study, we have included closed reduction with plaster cast; percutaneous pinning; external fixation with external fixator using the principle of ligamentotaxis; and internal

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fixation with plates, pins, and screws, depending on the type of fracture and patients general condition.

Aims

The aims are as follows:

1. To study the outcomes different treatment modalities of fractures of distal end of radius
2. To compare the anatomical results between various treatment modalities
3. To compare the functional outcomes between various treatment modalities
4. To study the complications of different treatment modalities.

Inclusion Criteria

All isolated fractures of the distal end of radius between the age group of 18 and 80 years among males and females were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. All compound fractures of distal end radius
2. Pathological fractures
3. Distal radius fractures with other injuries around the wrist joint.

Radiographic Assessment

Radiographic imaging is important in diagnosis, classification, treatment, and follow-up assessment of these fractures.

Guidelines for acceptable closed reduction as given by Nana *et al.* (2005)^[5] include:

1. Radial inclination: Greater than or equal to 15 degrees on the posteroanterior view
2. Radial length: Less than or equal to 5 mm shortening on posteroanterior view
3. Radial Tilt: Less than 15 degrees dorsal or 20 degrees volar tilt on the lateral view
4. Articular incongruity: Less than 2 mm of step off.

Radiographic signs that alert the surgeon that the fracture is probably unstable and closed reduction alone will be insufficient include the following:^[6-8]

- a. Dorsal comminution >50% of the width in lateral view
- b. Palmar metaphyseal comminution
- c. Initial dorsal tilt >20 degrees
- d. Initial displacement (fragment translation) >1 cm
- e. Initial radial shortening more than 5 mm
- f. Intra-articular disruption
- g. Associated ulna fracture
- h. Severe osteoporosis

Classification

We have used Fernandez classification – According to the mechanism of injury^[9] in our study:

Table 1: Demerit Point System used to evaluate end results of healed colles fractures

Result	Points
Residual deformity	
Prominent ulnar styloid	1
Residual dorsal tilt	2
Radial deviation of hand	2–3
Point range	0–3
Subjective evaluation	
Excellent: No pain, disability or limitation of motion	0
Good: Occasional pain, slight limitation of motion, no disability	2
Fair: Occasional pain, some limitation of motion, feeling of weakness in wrist, no particular disability if careful, activities slightly restricted	4
Poor: Pain, limitation of motion, disability, activities more or less markedly restricted	6
Point range	0–6
Objective evaluation of range of motion	
Loss of dorsiflexion	5
Loss of ulnar deviation	3
Loss of supination	2
Loss of palmar flexion	1
Loss of radial deviation	1
Loss of circumduction	1
Loss of pronation	2
Pain in distal radioulnar joint	1
Grip strength – 60% or less of opposite side	1
Point range	0–5
Complications arthritic change	
Minimum	1
Minimum with pain	3
Moderate	2
Moderate with pain	4
Severe	3
Severe with pain	5
Nerve complications (median)	1–3
Poor finger functions due to cast	1–2
Point range	0–5
End result point ranges	
Excellent	0–2
Good	3–8
Fair	9–20
Poor	21 and above

Table 2: Age and sex distribution

Age in years	Male No. of cases (%)	Female No. of cases (%)	Total No. of cases (%)
<20	1 (3.57)	0	1 (2)
21–30	10 (35.71)	2 (9.09)	12 (24)
31–40	6 (21.43)	3 (13.63)	9 (18)
41–50	2 (7.14)	2 (9.09)	4 (8)
51–60	6 (21.43)	6 (27.27)	12 (24)
61–70	2 (7.14)	5 (22.73)	7 (14)
>70	1 (3.57)	4 (18.19)	5 (10)
Total	28 (56)	22 (44)	50 (100)
Mean±SD	39.70±8.87	54.40±11.02	46.15±9.88

- Type I: Fractures are extra-articular metaphyseal bending fractures, such as Colles' (dorsal angulation) or Smith (volar angulation) fractures. One cortex fails in tension, and the opposite cortex is comminuted and impacted

- Type II: Fractures are intra-articular and are produced by shearing. These include volar Barton, dorsal Barton, and radial styloid fractures
- Type III: Fractures result from compression injuries that cause intra-articular fractures and impaction of metaphyseal bone. These include complex articular fractures and radial pilon fractures
- Type IV: Fractures are avulsion fractures of ligament attachments that occur with radiocarpal fracture-dislocations
- Type V: Combined injuries with significant soft tissue involvement due to the high-energy nature of these fractures.

Treatment Modalities

Closed reduction and plaster cast method

From 1925 plaster immobilization was used for Colles' fracture. Most frequently used cast or splint is a below the elbow. It relies on the principle of ligamentotaxis to reduce fracture fragments. No control can be expected for depressed articular fragments that lack ligament attachment.^[2,10,11] For disimpaction of fragment traction was given for 2–5 min followed by additional manual pressure on the distal fragment to achieve reduction. This is commonly used method.^[11,12] According to Bohler, the wrist should be positioned between volar and dorsal flexion, with moderate ulnar deviation.^[13] Weber documented that collapse of the fracture is unavoidable because the compressive forces generated by the tendons of flexor and the extensor muscles

crossing the wrist cannot be counteracted by the supporting plaster.^[14]

Several factors have been associated with re-displacement following closed manipulation of a distal radius fracture:

1. The initial displacement of the fracture
2. The age of the patient
3. The extent of metaphyseal comminution (the metaphyseal defect)
4. Displacement following closed treatment is a predictor of instability.

We used below-elbow cast with forearm in pronation and above elbow cast in cases of comminution and associated ulna styloid fracture.

Percutaneous pin fixation

Percutaneous pinning techniques are an attempt to bridge the therapeutic gap between external fixation. Indications for percutaneous pin fixation are as follows:^[15]

- Extra-articular undisplaced Colles' fracture
- Extra-articular displaced Colles' fracture
- Intra-articular fracture with two fragments where the radial styloid fragment is larger
- Intra-articular fracture with radio-ulnar joint involvement
- Subluxation of the distal radio-ulnar joint.

The method we used first achieved the reduction by traction and counter traction followed by insertion of smooth Kirschner wires through the radial styloid and through the ulnar end of the radius. After this, they immobilized the extremity in a plaster cast; wrist in ulnar deviation and 15-degree flexion and elbow flexion for above-elbow cast.^[15]

Fractures with volar comminution, fractures with any articular displacement and fractures with more

Table 3: Mode of trauma (overall cases)

Mode of trauma	No. of cases (%)
Fall	33 (66)
RTA	17 (34)
Total	50

RTA: Road traffic accident

Table 4: Modality of treatment and type of fracture (Fernandez classification)

Fernandez classification	Modality of treatment (%)				
Type of fracture	CMRC	External fixator	PL	Percutaneous pinning	Total
I	10 (55.55)	2	1 (5.55)	5 (27.78)	18 (36)
II	0	2	8 (57.15)	4 (28.57)	14 (28)
III	4 (26.67)	7	2 (13.033)	1 (6.67)	14 (28)
IV	0	0	0	0	0
V	0	4	0	0	4 (8)
Total	14 (28)	15 (30)	11 (22)	10 (20)	50

Value of $\chi^2=29.12$, $df=12$, significant, $P<0.05$. CMRC: Closed manual reduction with cast, PL: Plating

Table 5: Mean follow-up of patients (weeks)

Duration of follow-up (weeks)	Treatment modality				
	Plaster cast	External fixator	Plating	Percutaneous pinning	Mean total
Mean±SD	20.285±3.62	22.60±1.80	21.82±2.13	20.50±2.83	21.30±2.14

Mean follow-up of all patients in our study was 21.3 weeks

Table 6: Mean values of the range of movements of various treatment modalities (in degrees)

Range of motion	CMRC	Percutaneous pinning	External fixator	PL
Dorsiflexion	49.28	72	63.33	75.45
Palmar flexion	46.42	64	53	70.90
Radial deviation	12.14	12.5	12.0	18.63
Ulnar deviation	16.78	21.5	20	27.27
Pronation	48.92	68	62.66	77.27
Supination	51.07	71	63.33	76.36

CMRC: Closed manual reduction with cast, PL: Plating

than “minimal articular involvement” are reported contraindications for this technique.^[16]

The early loss of reduction and the late collapse after Colle’s fracture were blamed for poor functional outcome. Need for intact volar buttress and dorsal tension by traction or external fixator was stressed to prevent them.^[17]

External fixation

It was indicated when there was failure to maintain adequate closed reduction using plaster, unstable fractures which on radiography had dorsal angulations of more than 20 degree, fractures involving the joint, radial shortening of more than 10 mm, and severe dorsal comminution.^[18]

For Frykman’s Type VII or Type VIII fractures, external fixation is the treatment of choice. The importance of reduction of Sheck’s dorsomedial “Die-punch fragment” was also emphasized.^[19,20] The fixator should be retained for 8 weeks to reduce the risk of loss of position and it gives good or excellent anatomical results on radiological assessment after removal of fixator; the functional results were good or excellent in 80% in these complicated fractures.^[21]

The principles of the application of external fixator for distal radius fractures are as follows:^[22]

1. The distance between the skin and fixator should be as small as possible
2. The fixator should be fixed as close as possible to the fracture
3. The diameter of the pins should be as great as possible
4. If more than 2 pins per plane are used, the pins should be wide apart
5. If only two pins per plane are used the bending force on each pin is high
6. If more than two parallel pins per plane are used the axial forces on each pin are high
7. The pins should be placed at the right angle to the fractured bone.

External fixators could be combined with percutaneous pin manipulation of key fragments, percutaneous screw

fixation of larger fragments, or open reduction, and internal fixation.^[23]

Open reduction and internal fixation by plates

Surgical treatment (plating in particular) ensures more consistent correction of displacement and maintenance of reduction. The choice of surgical technique for reduction and fixation depends on fracture displacement, joint surface involvement, patient age, bone quality, occupation, and avocation. Surgeon experience and preference also dictate the treatment method.

With the advent of new fixed-angle screw plate designs, volar fixation should be the standard approach for distal radius fractures. When the comminution involves both the palmar and the dorsal cortices, the use of palmer locking plate is preferred. Volar plating is also ideally used in unstable bending fractures of the radial metaphysis due to the ability to control and maintain physiologic palmer tilt, prevent collapse with external fixation and avoid bridging the radio-carpal joint. The emphasis on optimal management of articular shear fractures is on anatomical reduction of the articular surface and compression across the fracture site, which is achieved with a volar buttress plate.^[24]

Volar plates fall into four functional categories: Buttress plates (with or without distal screws), tiny or blade plates, fixed-angled locking plates, and polyaxial locking plates.

Martineau *et al.* documented that the locking nature of the screw-plate construct produces fixation even in bone defects and osteopenic bone and permits early range of motion exercises. In contrast to external fixation and percutaneous pinning, no tethering of muscle, tendon, or capsule occurs with plate fixation and therefore motion of the wrist and fingers is uninhibited. These advantages would permit earlier and more aggressive rehabilitation and more rapid regain of function.

MATERIALS AND METHODS

This study is carried out on the patients with fractures of the distal end radius, admitted and treated in CIMS Medical College and Hospital, Bilaspur, C.G. from 2016 to 2018. Fifty patients with fractures of the distal radius were included in the study.

On arrival of patient, detail history regarding age, sex, mode of injury, days since injury, associated injuries were noted carefully. The patients were assessed clinically and radiologically. The fracture pattern was noted and the fractures were classified according to Fernandez (1993) classification system. Radiological assessment was done

in terms residual dorsal tilt, radial shortening and loss of radial inclination and the results were graded according to Sarmiento's modification of Lindstrom criteria^[2,25] which is:

Results	Deformity	Residual dorsal tilt	Radial shortening	Loss of radial inclination
Excellent	No or insignificant	0°	<3 mm	<5°
Good	Slight	1°–10°	3–6 mm	5°–9°
Fair	Moderate	11°–14°	7–11 mm	10°–14°
Poor	Severe	≥15°	≥12 mm	>14°

Functional evaluation of the patients was done at last follow-up according to the demerit point system of Gartland and Werley with Sarmiento *et al.*'s modification.^[25]

Follow-up

The follow-up was on 10th day, and 6, 12, and 24 weeks, respectively. They were assessed for any wound dehiscence, radiological assessment for fracture healing, swelling secondary to tightness of cast, compartment syndrome, pin tract infection, redisplacement of fracture in cast, and in percutaneous pinning category patients, pin loosening, and re-alignment of distracter accordingly.

All the patients were motivated for physiotherapy and range of motion exercises in every follow-up.

OBSERVATIONS AND RESULTS

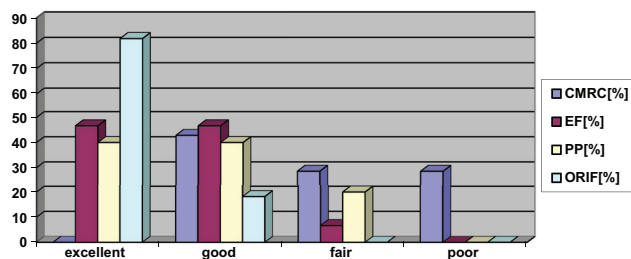
In our study of 50 patients, 28 were males and 22 were females. The fractures were most common among 21–30 and 51–60 years of age group. The youngest patient was 18 years old and the eldest was 80 years old.

By applying the Chi-square test, there is a significant association between the modality of treatment and type of fracture (Fernandez classification) ($P < 0.05$).

The most common fracture in our study, according to Fernandez classification, was Type I followed by Types II, III, and V.

Anatomical Evaluation

Anatomical evaluation results according to Sarmiento's modification of Lindstrom criteria were obtained.



In our study, anatomically excellent results according to Sarmiento's modification of Lindstrom criteria were obtained in open reduction and plate fixation (81.81%) followed by ligamentotaxis by external fixator application (46.66%) and percutaneous pinning (40%).

Functional Evaluation

Functional evaluation of the patients was done at last follow-up according to Demerit Point System of Gartland and Werley with Sarmiento *et al.*'s modification.

For closed reduction and cast application group

Out of 14 patients, 57.14% had good results and 42.86% had fair to poor results.

For external fixator group

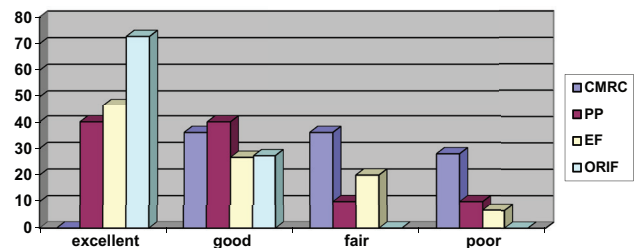
Out of 15 patients, 73% has given us excellent to good results, with the most common type of fracture being Type III and 27% has given fair to poor results with Type V fractures.

For percutaneous pinning group

Out of 10 patients treated with this modality, 90% gave excellent to good results and 10% gave poor results. The poor results were due to complexity of fracture.

For open reduction and plate fixation group

Out of 11 patients, 72.72% has given us excellent results and 27.27% has given us good results. There were no poor results in this group.



In our study, assessment of functional outcome by Demerit's Point System of Gartland and Werley with Sarmiento *et al.* modification revealed excellent results with open reduction and plate fixation modality (72.72%), followed by ligamentotaxis by external fixator application (46.67%) and percutaneous pinning modality.

Complications

The most common complications encountered in our series were stiffness and pain in the wrist joint after removal of cast or external fixator because of lack of wrist movements for prolonged time. We observed Plaster sores in two patients, pin tract infections in three patients, which were superficial and got treated by oral antibiotics, pin loosening in two patients treated by external fixator due

to osteoporotic bone. Three patients developed minimal arthritic changes at 24 weeks of follow-up. The presence of deformity in six patients, which was mostly prominence of ulna styloid and residual dorsal tilt, which is seen in patients treated nonoperatively [Tables 1-6].

CONCLUSION

We have concluded:

1. Fracture of distal end of radius is one of the most common fractures occurring in all age groups. The youngest patient in our study was 18 years of age while the eldest was 80 years, with the mean age being 49 years
2. This fracture is more common in males (56%) than females (44%)
3. Fall is still the common mode of injury than road traffic accidents. Among which females were more common in sustaining this type of fracture, due to domestic fall and post menopausal osteoporosis, while road traffic accident was common in males
4. From Fernandez classification we have concluded, that bending type of injury is most common
5. Closed manual reduction and cast application modality gives good functional results in undisplaced, extra-articular distal radius fractures, but at a later stage. It has given poor results in displaced extra-articular, and in intra-articular fractures
6. Among the operative treatment, percutaneous pinning has given us excellent results in displaced extra-articular fractures and intra-articular fractures where the radial styloid is the major fragment
7. External fixator has given us good results by the principle of ligamentotaxis in complex fractures sustained by high-velocity injuries. Although anatomical results were good and functional results were delayed due to prolong immobilization of wrist in external fixator
8. Open reduction and internal fixation with plates and screws in our study have given excellent anatomical and functional results in displaced extra-articular, intra-articular, and complex fractures sustained by high-velocity trauma. With this treatment modality, the patient can start mobilization of wrist immediately after surgery and attain full range of motion in 6–8 weeks postoperatively, with no loss of grip strength.

Hence, to achieve good anatomical reduction and stable fixation and for early functional recovery with negligible complications, we recommend open reduction and volar

locking plate fixation treatment modality is best suited, among others.

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Perception toward Ocular Health and Assessment of Visual Acuity among Adults Aged >30 Years Living in Rural Area of Jammu: A Cross-sectional Study

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Abstract

Purpose: The purpose of this study was to determine the perception toward ocular health and assessment of visual acuity among adults aged >30 years, living in a rural area of Jammu.

Materials and Methods: The population-based study is based on the vision screening camp which was conducted at Panchayat Ghar of village Dhanu, Keri Zone, Block Kot Bhalwal. The study instrument consisted of sociodemographic data and pre-tested structured questionnaire. Eye examinations included vision testing using Snellen chart and Jaeger chart, and fundus examination using ophthalmoscope performed by ophthalmologists and optometrists.

Results: Among 139 participants who attended the screening camp, 76.97% (107 participants) reported trouble seeing near objects, whereas only 65.46% (91 participants) reported trouble seeing far objects. However, 85% (119 participants) and 74.1% (103 participants) had impaired near vision and far vision, respectively. All participants reported consulting a doctor for eye-related problems. Fifty-three patients reported that they never got any eye checkups before. As such, cases of cataract ($n = 21$), glaucoma ($n = 5$), hypertensive retinopathy ($n = 6$), pterygium ($n = 3$), and diabetic retinopathy ($n = 2$) patients were detected during this screening.

Conclusion: The prevalence of visual impairment (VI) was quite high. Refractive error and cataract were the major cause of vision impairment. Screening the adult population of 30 years and above providing them with proper lens and timely referral can help in reducing VI and further improving their quality of life.

Key words: Cataract, Glaucoma, Pterygium, Refractive error, Visual acuity

INTRODUCTION

There is ever-increasing aging population as the result of demographic transition and increased access to health-care services. Low vision and blindness are emerging as important public health problems.^[1-3] They pose a threat to the healthy aging.

Low vision is defined as visual acuity (VA) <6/18 and equal to or better than 3/60 in the better eye with the best correction. A person with low vision is defined as one who has impairment of visual functioning even after treatment and/or standard refractive correction and has a VA of <6/18 to light perception or a visual field of <10° from the point of fixation, but who uses, or is potentially able to use, vision for the planning and/or execution of a task for which vision is essential.^[4]

About 80% of the global visual impairment (VI) burden is preventable. It is estimated that more than 90% of the visually impaired people live in developing countries. This was conducted with aim of assessing VA and perceptions about ocular health among adults aged >30 years, living in the rural area of Jammu.

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MATERIALS AND METHODS

After seeking ethical permission, vision screening camp was conducted at Panchayat Ghar of village Dhanu, Zone – Keri, Block Kot Bhalwal. Using non-probability sampling method, 139 eligible participants who attended this camp were interviewed by investigator after taking informed verbal consent.

The visual acuity test was performed by a trained ophthalmic assistant, using Snellen chart and Jaeger chart. Vision was recorded separately for each eye, with any distance correction that the person was using. For those participants who were unable to read the topmost line of Snellen chart, counting fingers, hand movements, and light perception were recorded.

After vision testing, participants received consultation by an ophthalmologist. Eye examinations included anterior segment and fundus examination. Those candidates who did not give their consent for interview to the investigator were excluded from the study. However, they received routine eye screening examination and treatment by ophthalmologists and ophthalmic assistants. Findings of eye examinations including VA were recorded by ophthalmologists and ophthalmic assistant. Blindness was defined as presenting VA <6/60 in the better eye. VI was defined as presenting VA 6/18–6/60 in the better eye.

The study instrument used for interviewing consisted of questions related to sociodemographic data, perception of vision, and health-care-seeking behavior for ocular health issues.

All data recorded during this survey were entered into MS Excel and analyzed in the form of percentage and proportions whenever necessary.

RESULTS

A total of 153 patients attended this screening camp, of which 144 eligible patients were briefed regarding this study. Only 139 patients, who agreed to participate in this study by giving informed verbal consent, were included in this study. Majority of the participants in our study were in the age group of 50–70 years, mostly Muslims (73.38%). More than half of the study respondents were illiterate (51.83%) [Table 1].

As seen in Table 2, about three-quarters of participants reported trouble seeing near objects, while nearly two-third (65.46%) of the participants reported experiencing difficulty in distant vision. About 100% agreed that they

would visit vision-related issues, but only 32.45% were using corrected glasses for near or distant vision.

The prevalence of blindness, based on VA worse than 6/60 in both eyes, was 6.47% with presenting vision and 2.5% with the best correction. Impaired near vision was seen in 85% of the sample population. Nearly 47% were found to have presenting VA worse than 6/18 in the better eye. As such, cases of cataract ($n = 21$ patients), glaucoma ($n = 5$), hypertensive retinopathy ($n = 6$), pterygium ($n = 3$), and diabetic retinopathy ($n = 2$) patients were detected during this screening [Table 3].

Table 1: Sociodemographic profile of the study participants

Variable	Category	n (%)
Age groups (in years)	<40*	9 (6.48)
	40–49	34 (24.46)
	50–59	44 (31.65)
	60–69	36 (25.9)
	≥70	16 (11.51)
Religion	Hindu	37 (26.62)
	Muslim	102 (73.38)
Sex	Male	60 (43.17)
	Female	79 (56.83)
Education	Illiterate	71 (51.08)
	Up to middle	53 (38.13)
	Up to higher secondary	12 (8.63)
	Higher education/degree	3 (2.16)

Table 2: Ocular health perceptions and access to care of the total sample population

Question	Answer	n (%)
Trouble seeing near objects	Yes	107 (76.97)
	No	32 (23.02)
Trouble seeing far object	Yes	91 (65.46)
	No	48 (34.53)
Time since last eyes were examination	1 year	19 (13.66)
	1–5 years	23 (16.54)
	5+ years	44 (31.66)
	Never	53 (38.12)
Ever corrected vision (glasses or contacts)?	Yes	45 (32.37)
	No	94 (67.62)
For vision-related issues whom you would consult	Doctor/hospital/clinic	100
	Faith healers/quack	0
	I do not know	0

Table 3: Pattern of ocular morbidities

Ocular morbidity	n (%)
Impaired near vision	119 (85)
Impaired far vision	65 (46.7)
Blindness	9 (6.47)
Dryness	91 (65.46)
Cataract (one/both eye)	21 (15.1)
Glaucoma (one/both eye)	5 (3.6)
Hypertensive retinopathy	6 (4.3)
Pterygium	3 (2.18)
Diabetic retinopathy	2 (1.43)

DISCUSSION

In this study, the prevalence of VI (for distant vision) was found quite high. All the participants reported that they would consult none other than a doctor in case of any eye-related problem which is welcoming. However, it is worth mentioning that despite the fact that nearly two-third of participants in our study reported difficulty in seeing far object, but only 13.66% has got last checkup within 1 year.

Similar results were reported by Fletcher *et al.* (2012)^[5] (43.8%). However, Nirmalan *et al.* (2002) reported that 59.4% presenting VA >6/18 in both eyes was 59.4%. Kovai *et al.* (2007)^[6] reported the prevalence of VI 16.2% in the subjects >15 years of age. This variation of results could be explained by difference in sample population and size. The prevalence of blindness reported in our study was similar with the prevalence of blindness reported by the studies conducted in Southern India.^[7,8] The possible explanations for this discrepancy which we discovered were old age, dependency, poverty, lack of awareness, ignorance, and difficulty in traveling due to hilly terrain. Although, more concrete efforts are needed to enhance their awareness regarding ocular health.

The main limitations of the study were cross-sectional design and small sample size which has inherent limitations regarding generalizability of the results. However, the main strength of the study was that it was exploratory and we conducted this screening camp in a remote village which recently got blacktop road for 1st time; thus, this study can be seen as insight view of ocular health perception and visual acuity status of people from such areas. All documented patients were provided free medicines and referral services for treatment in tertiary hospital settings with the help of a local non-governmental organization.

CONCLUSION

The need of the hour is to provide health education and conduction of regular information, education, and communication activities regarding ocular health and preventable causes of VI along with screening camps, especially in the rural community setting. The prevalence and severity of VI were found to be quite high. Population-based screening and generating awareness regarding VI along with timely referral can contribute in enhancing and improvement in quality of life, especially in those who are above 50 years of age.

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Approach to Proximal Humerus Fractures: An Observational Study in a Tertiary Care Centre at Bilaspur

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Abstract

Introduction: The proximal humerus fractures are a relatively common entity and are very difficult to treat as the shoulder joint is a versatile joint with high degree of motion. The fracture comprises 4–5% of all fractures and as high as 45% of the humerus fractures.

Materials and Methods: A total of 19 patients of complex fractures of proximal humerus and fracture-dislocations of proximal humerus, who were managed with proximal humerus internal locking system plating were included in the study.

Results: In 11 patients, the right-sided injury was seen and in eight patients, injury was left sided. The age of the patients ranged from 28 years to 56 years with a mean age of 42.7 years. Most of our patients were Neer's three-part and four-part fractures, and fracture-dislocations as two-part fractures were again managed differently (conservatively or J nails, cross K-wires, Rush nails, and external fixators). We had five fracture-dislocations, 12 patients with comminuted three- and four-part fractures, and two patients with two-part fractures.

Conclusion: Proximal humeral fractures are relatively common fractures and difficult to treat entities for the age; they occur frequent comminution and difficulty in achieving reduction and hardware application.

Key words: Fracture, Patients, Proximal

INTRODUCTION

The proximal humerus fractures are a relatively common entity and are very difficult to treat as the shoulder joint is a versatile joint with a high degree of motion. The fracture comprises 4–5% of all fractures and as high as 45% of the humerus fractures. The fractures are seen in all ages from children to the elderly. In the elderly, the fracture is mostly osteoporosis related, which makes it all the more difficult to treat. In young adults, the fracture management is tough due to high functional demands, frequent comminution and the fracture being a high energy trauma.

There are a large number of surgical treatment options for fracture of proximal humerus ranging from cross K-wires, titanium elastic nailing system/Ender's nails used in the form of J nails, proximal humerus plates, and even prosthetic replacement in the form of hemiarthroplasty for severely comminuted fractures. However, there is no general consensus available for deciding the management protocol. Neer's classification is widely accepted for the classification of these fractures into two-part, three-part, four-part, fracture-dislocations, and articular surface fractures.^[1] Management becomes difficult in three-part and four-part fractures and further for fracture-dislocations and articular surface fractures and humeral head fractures.

We here present our experience with proximal humerus internal locking system (PHILOS) plate with complex fractures and fracture-dislocations of proximal humerus at a tertiary care center at Bilaspur.

Purpose of the Study

The purpose of the study was to find out the functional outcome of PHILOS plating in complex fractures and

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fracture-dislocations of proximal humerus, in patients presenting to a tertiary care center at Bilaspur from April 1, 2014, to March 31, 2016.

MATERIALS AND METHODS

A total of 19 patients of complex fractures of proximal humerus and fracture-dislocations of proximal humerus, who were managed with PHILOS plating were included in the study.

Inclusion Criteria

All the proximal humerus fractures managed by PHILOS plates during the study period were included in the study between 18 and 60 years of age.

Exclusion Criteria

Patients above 60 years of age or below 18 years of age were excluded from the study as protocol for their management was different and age would become one of the important confounding variables in terms of bone quality and muscle strength in patients above 60 years of age and delayed healing in such patients due to severe osteoporosis.

As opposed to plate fixation, children with proximal humerus fractures in our institute, were managed by K wire fixation and were excluded from the study.

Table 1: Pain scores

Pain	Scores
No pain	35
Slight, occasional, no compromise in activity	30
Mild, no effect on ordinary activity	25
Moderate, tolerable, makes concessions	15
Marked, serious limitations	5
Totally disabled	0

Table 2: Function

Function	Scores
Strength-normal	10
Good	8
Fair	6
Poor	4
Trace	2
Zero	0
Reaching-top of head	2
Mouth	2
Belt buckle	2
Opposite axilla	2
Brassiere hook	2
Stability-lifting	2
Throwing	2
Pounding	2
Pushing	2
Hold overhead	2

One patient who did not turn up for follow-up was excluded from the study. One patient of fracture-dislocation of humerus was taken for surgery but due to lack of bone stock and improper hold of the implant, the fracture fixation could not be done. The patient later denied shoulder arthroplasty and was excluded from the study.

The patients' age distribution was from 28 years to 56 years. In all these patients, primary management of the fracture by slab immobilization/shoulder immobilizer was given, and cold fomentation and anti-inflammatory agents were started at the time of admission. After all routine investigations and proper pre-operative assessment, the patients were taken for surgery. All patients were operated by the author and his team. Standard beach chair position was utilized for the surgery and in all patients, deltopectoral approach was taken. General anesthesia with brachial plexus block for post-operative pain was instituted for all patients. Preoperatively, two shots of the third-generation cephalosporin were given. The mean time between injury and surgery was 10.9 days. The mean duration of surgery was 137 min. Postoperatively, arm pouch sling was applied. Physiotherapy was started as soon as

Table 3: Range of movement

Range of movement	Scores
Flexion-180°	6
170°	5
130°	4
100°	3
80°	2
<80°	1
Abduction-180°	6
170°	5
140°	4
100°	3
80°	2
<80°	1
Extension-45°	3
30°	2
15°	1
<15°	0
External rotation-60°	5
30°	3
10°	1
<10°	0
Internal rotation-90°	5
70°	4
50°	3
30°	2
<30°	0

Table 4: Anatomy

Rotation, Angulation, Joint incongruity, Retracted Tuberosities, Failure Metal, Myositis, Non Union, Avn	Scores
None	10
Mild	8
Moderate	4
Marked	0-2



Figure 1: Comminuted three-part fracture proximal humerus pre-operative

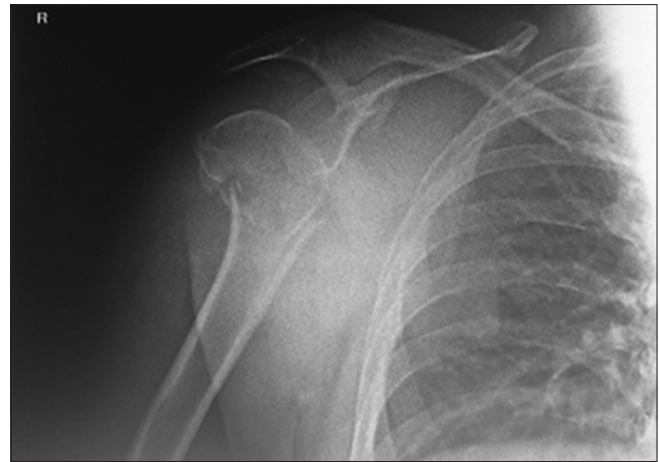


Figure 4: Pre-operative image of another comminuted fracture proximal humerus



Figure 2: Three-dimensional computed tomography scan of the same patient

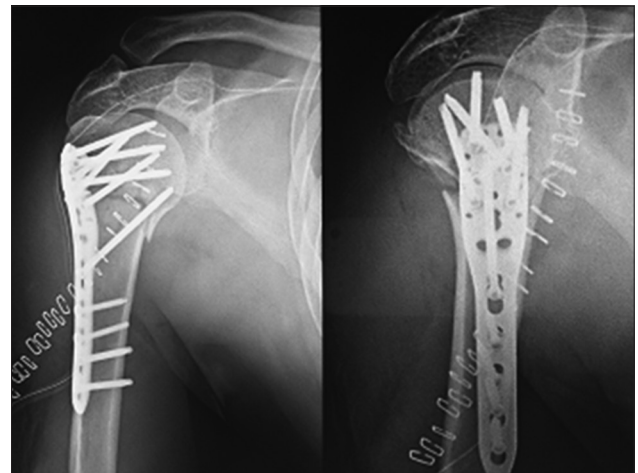


Figure 5: Post-operative image of the same patient

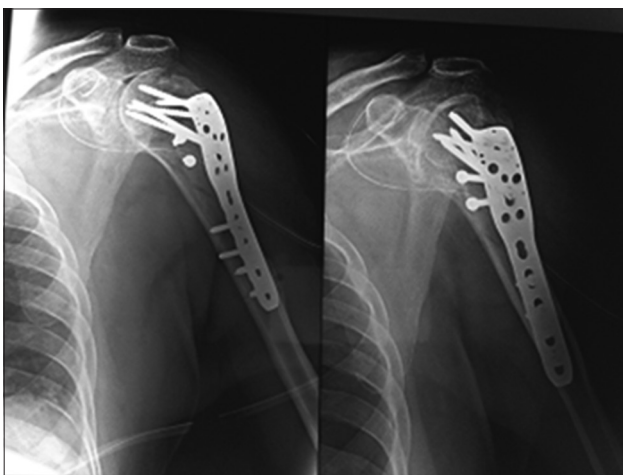


Figure 3: Post-operative image of the patient



Figure 6: Patient with fracture-dislocation

patient was comfortable in the post-operative period which progressed from passive range of movement exercises to active gradually to patients' comfort and pain tolerance. The

patients were followed up at 14 days, 6 weeks, 3 months, and 6 months and further monthly follow-up until fracture union. In all the follow-ups, patient's parameters in terms



Figure 7: Post-operative image of the same patient

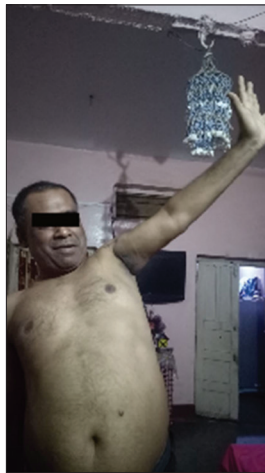


Figure 8: Clinical image of a patient operated for fracture-dislocation with satisfactory results

of pain, function, and range of movements were noted and patient's X-rays anteroposterior views and axial views were taken to see for union. One patient did not turn up for follow-up after suture removal and was excluded from the study. Another patient, who was taken for surgery but due to inadequate bone left for fixation due to a large defect in the humeral head, had to be kept out of the study. The patient was later given the option of shoulder hemiarthroplasty but she refused. Finally, 19 patients were included in the study who had completed all the mentioned follow-ups or achieved union. The outcome was evaluated by Neer's score which is an objective score taking into consideration pain, function, range of movement, and anatomy.

RESULTS

A score of 90–100 was excellent, 80–89 satisfactory, 70–79 unsatisfactory, and <70 was considered failure (Neer's scoring system) [Tables 1-4].

A total of 19 patients were included in the study. There were 12 male patients and 7 female patients. In 11 patients, the right-sided injury was seen and in eight patients, injury was left sided. The age of the patients ranged from 28 years to 56 years with a mean age of 42.7 years. Most of our patients were Neer's three-part and four-part fractures, and fracture-dislocations as two-part fractures were again managed differently (conservatively or J nails, cross K-wires, Rush nails, and external fixators). We had five fracture-dislocations, 12 patients with comminuted three- and four-part fractures, and two patients with two-part fractures. Union was achieved in all patients at a mean of 4.6 months. We had no patients who had avascular necrosis (AVN). Six patients had excellent results. In nine patients, the result was satisfactory. Three patients had unsatisfactory results and in one patient, we had infection due to which he needed implant removal in the 8th month post-operative period and had poor result. As such, there was no fixation failure after primary fixation.

Figure 1 depicts the pre operative X ray of a patient with comminuted 3 part fracture of proximal humerus. The CT scan of the same patient is shown in Figure 2. We can see how effectively CT scan can delineate the fracture configuration. The patient was taken for PHILOS plating and the plate was applied. Post operative X rays of the patient can be seen in Figure 3 showing good reduction.

X rays of another patient with comminuted fracture proximal humerus is seen in Figure 4. The post op X rays of the same patient are shown in Figure 5.

Figure 6 depicts X rays of a patient with fracture dislocation. The patient was managed successfully by PHILOS plating. The patient had good reduction [Figure 7] and good functional outcome with good range of movement [Figure 8].

DISCUSSION

Proximal humerus fractures are one of the most difficult to treat entities. The treatment becomes all the more difficult due to reduced bone stock due to osteoporosis in elderly population where these fractures are common.

There are multiple treatment options in the management of these fractures including percutaneous pinning, J nailing, external fixator application, Rush nails, MultiLoc nails, hemiarthroplasty, simple non-locking plates, and internally locked plates or PHILOS. As per literature for a periarticular and intra-articular fracture, one has to achieve good anatomical reduction and rigid stable internal fixation which can allow early mobilization and early fracture healing

at the same time. Percutaneous K-wires, external fixators, J nails, and Rush nails are more biological and less invasive. Neither the reduction achieved with them is anatomical (due to closed techniques) nor the fixation is rigid enough for initiation of early range of movement. To add to it, complications such as pin-tract infections further limit their use.^[2] With non-locking plates used the chances of loss of reduction, screw cutout and fixation failure are high as the region of fixation is mainly metaphyseal-epiphyseal region which is mainly cancellous bone and the situation is confounded by osteoporosis. In addition, most of the fractures we catered to were comminuted three-part, four-part fractures or fracture-dislocations, in which there were multiple fragments and fixation with simple plates was tough to achieve and hold. The torsional stability is better with locking plates that were confirmed by Siffri *et al.*^[3] in their cadaveric studies. MultiLoc nailing, in a study by Hessmann *et al.*,^[4] has yielded good results. However, we have little experience with such MultiLoc nailing devices. In view of all the above, we performed our study with PHILOS plates.

Screw cutouts and implant failures, we had none. Owsley and Gorczyca *et al.*^[5] in their study had a screw cutout rate of 23% and Doshi *et al.*^[6] in their study had it at 5.66%. We had one case where we could not achieve fixation due to no hold of the screws due to very less bone stock and comminution. This patient was not included in the study. If we include the patient in the study, as a case of failed fixation or failure to achieve fixation, our fixation failure rate was 5% which is comparable to Doshi *et al.* We had no cases of AVN which is again comparable to Doshi *et al.*

Computed tomography scan (CT) is of undue importance before proceeding for surgery and deciding the plan of action. In most of the cases of fracture especially those with a fracture-dislocation, the CT scan was performed at the fragments of fracture identified preoperatively so that planning of reduction and fixation could be done preoperatively. We suggest a pre-operative CT scan for all comminuted proximal humerus fracture patients. It is also important so as to see if the humeral head is also fractured. In case of humeral head fracture, it is better to go for replacement as there are high chances of AVN and loss of fixation.

Finally, accuracy of reduction and rigidity of fixation are another deciding factor for outcome in such cases. A valgus reduction is a must with little space for varus reduction. A varus reduction may lead to loss of fixation, implant cutout,

and high stress on rotator cuff, leading to poor functional outcome.^[7] Furthermore, we must stress here on the fact that in all cases, author and his team aimed for anatomical reduction with special care to restore the medial calcar and maintain the calcar with oblique calcar screws (superiorly directed inferomedially placed) in most of the cases. This was in accordance with Krappinger *et al.*^[8] who said that anatomical fracture reduction and good medial cortical alignment are the most important factors for secondary displacement. Gardner *et al.*^[9] have previously shown that screw cutout rates are high following loss of medial support.

CONCLUSION

Proximal humeral fractures are relatively common fractures and difficult to treat entities for the age; they occur frequent comminution and difficulty in achieving reduction and hardware application. However, with the advent of locking plates, the results are good in our experience. Understanding the fracture anatomy and obtaining near anatomical reduction with medial calcar restoration is the key to surgical management of these fractures.

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Quantitative Variation of Time-Activity Curve Derived Parameters with Regional Variation of Background Region of Interest, in Salivary Scintigraphy: A Retrospective Comparative Evaluation

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Abstract

Aim and Objective: Quantitative analysis of time-activity curve (TAC) derived from 99mTc-pertechnetate salivary gland scintigraphy, used in the evaluation of salivary gland function, is almost always corrected for background count. The objective of this study was to: (a) Examine the effect of the alteration of anatomical position of the background region of interest (ROI) on the (1) semi-quantitative parameters, i.e., upslope (Us) and stimulated downslope (Ds), derived from TAC and (2) on minimum and maximum pixel counts of pixel histogram of background ROI. (b) Examine the effect of minimum and the maximum pixel counts of the background ROI on the values of Us and Ds.

Materials and Methods: In this retrospective study, 16 patients were included who had undergone 99mTc-pertechnetate salivary scintigraphy for various reasons but had normal salivary scintigraphy reports. Three different sets of background in different anatomical positions were chosen: (i) A pair of supraclavicular background ROI, (ii) an isolated central rectangular background ROI in brain, and (iii) an isolated suprathyroid ROI. We then calculated two important semi quantitative parameters, i.e., Us and Ds from the TAC of the salivary glands. Individual TAC was generated against each set of the above-mentioned backgrounds. Individual pixel histogram was also generated against each TAC. Minimum and maximum pixel count of the generated background pixel histograms was identified. Comparative studies were made among the afore-mentioned variables.

Results and Conclusion: The values of Us and Ds derived from respective background corrected TAC matched well among each other irrespective of the altered anatomical positions of the background ROI. The minimum pixel counts per second (CPS) of the background pixel histogram varied with the change in anatomical position of the background ROI but it did not affect the values of Us and Ds. In contrast, the maximum pixel CPS of the background pixel histogram varied inversely with the values of Ds, although the value of Ds, showed no variation with the change in position of the background ROI.

Key words: Maximum pixel count per second, Minimum pixel count per second, Partial volume effect, Pixel histogram, Rate constant, Region of interest, Stimulated downslope, Upslope

INTRODUCTION

The aim of the present study was to compare the influence of regional variation of the background region of interests (ROIs) on the uptake and secretion related semi-quantitative

parameters of the salivary glands. We also aimed to assess the correlation among the derived semi-quantitative parameters with minimum and maximum pixel count of background ROIs in different anatomical positions. These two parameters were assessed in during salivary scintigraphy through: (a) accumulation (uptake) of 99mTc-pertechnetate and (b) stimulated secretion (excretion) of 99mTc-pertechnetate. The accumulation in the salivary gland is usually assessed as the ratio of gland counts to background counts at the point of maximum activity and the clearance or secretion is defined by subtraction of the ratio of salivary gland counts to background counts at the

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nadir (achieved after lemon juice stimulation), from that of gland to background counts at the point of maximum counts.^[1] Thus, it is evident from the definition that the selection of background counts is of critical importance for calculating both the parameters and that over or under subtraction of the background counts while drawing the ROI would falsely elevate or reduce the clearance or secretion index of the salivary glands.

ROI in the functional imaging is defined as a closed boundary surrounding some features or area, from which some statistics (such as counts) are derived. There are many ways to determine the shape and position of the background ROI. In salivary scintigraphy, to standardize the level of salivary gland accumulation and secretion, the correction of vascular background is recommended. However, the area chosen for the correction of vascular background varies widely, for example, skull, midline brain, the region above and lateral to the thyroid gland, and bilateral supraclavicular region all have been used and recommended from time to time by different authors.

The required semiquantitative parameters, i.e., upslope (Us) and downslope (Ds) were calculated from each time-activity curve (TAC) derived from salivary scintigraphy following subtraction of backgrounds in different anatomical positions. In addition, against each set of TAC, a pixel histogram was produced. The influence of regional variation of the background ROIs on the salivary gland uptake and secretion related semi-quantitative parameters was calculated first. The correlation among the derived semi-quantitative parameters with minimum and maximum pixel count of background ROIs in different anatomical positions was assessed next.

At the further basic level, the counts per pixel in the background ROI are calculated and subtracted from the counts per pixel in the organ of interest. The number of counts per pixel per second is proportional to the radioactivity concentration. ROI data from a series of frames can be used to create a TAC showing radiotracer concentration as a function of time for that ROI. TAC can be generated from each pixel, and it usually shows average changes in the count density within the ROI. Thus, the number of counts in a particular pixel is replaced finally by the semi-quantitative parameters like parameter (Ds, Us, etc.) derived from its TAC.

MATERIALS AND METHODS

We studied retrospectively those patients who had been referred to the nuclear medicine department for the purpose of ^{99m}Tc-pertechnetate salivary scintigraphy due to various reasons. However, normal functioning salivary

glands were detected as the scintigraphy outcome in these patients. Sixteen such patients were included in the study. Among these 16 patients, five patients had been referred due to recurrent swelling of parotid glands, ten patients had symptoms of mild dryness of mouth, and one patient was referred from surgery department due to failure to detect ductal orifice.

Salivary Scintigraphy Protocol

Dynamic salivary gland scintigraphy was performed following the injection of 370 MBq ^{99m}Tc sodium-pertechnetate with the gamma camera and data analysis system dual-head gamma camera (Siemens), equipped with low energy high-resolution parallel-hole collimator was used for imaging. Sequential anterior images of the salivary glands were obtained at 20 s per frame^[1,2] for 50 min. Forty minutes after the injection of the tracer, 2 mL of lemon juice was administered orally for salivary glands stimulation. We selected the frame after 20 min with optimum counts, have drawn ROI on each of the salivary glands (parotid and submandibular). Then for each patient, we applied different sets of background ROIs. Against each set of background ROI, TAC for each of the parotid gland and submandibular glands were generated.

Generation of Background ROI and TACs

The following sets of different background ROIs were generated for the study: (a) A pair of supraclavicular ROIs, and (b) an isolated central rectangular background ROI in brain, and an^[3] isolated suprathyroid ROI (superior and lateral to thyroid gland). System generated simple geometric ROI was drawn to avoid error in the manual ROI. Standard rectangular ROI was drawn for the background and oval-shaped^[2] ROIs for the salivary glands. When number of backgrounds was more than one, the average number of pixel of the background ROIs was considered for calculation.

Count Normalization According to Area and Number of Pixels

Counts in the target salivary gland ROI were normalized^[4] with respect to the pixel count of the background and then counted in the target organ was calculated by the following formula:

$$C = (CR - CB) \times PR / PB$$

CR=COUNTS IN THE TARGET ROI

CB=COUNTS IN THE BACKGROUND

PR=AREA OF TARGET ROI IN PIXELS

PB=AREA OF BACKGROUND ROI IN PIXELS

C=COUNTS IN THE TARGET ROI AFTER BACKGROUND SUBTRACTION correction factor is the ratio of pixel counts of target ROI and the pixel counts of background ROI. When multiple

backgrounds were selected, the correction factor is the ratio of pixel count of the salivary gland ROI to the average pixel count of background (calculated by dividing the sum of pixel numbers of all the backgrounds selected by the number of backgrounds selected).

Generating the TACs

Subsequently, the respective curves of background and salivary organ of interest were generated sequentially using the software, as follows:

- Curve 1: Was drawn from either the TAC of the selected isolated background or the sum of selected background ROIs
- Curve 2: Was generated by averaging of the background TAC when multiple backgrounds are used. This was undertaken by dividing the curve with the constant number, equal to the number of background ROIs
- Curve 3: The provisional TAC of the organ of interest
- Curve 4: Curve 3 is then normalized by multiplying it by the correction factor to generate the curve 4
- Curve 5: Is the final target salivary gland TAC. This is generated by subtracting Curve 2 from curve 4.

Curve 5 was subjected to a linear fit. The knowledge of the physiological activity of a normal salivary gland as well as physiological concentration of radiopharmaceutical with time allows us to fit a mathematical function to the TAC curve. Analysis of curve slope and shape following fit of

the mathematical function helps to extract the different functionally significant parameters as described below:

Calculation, analysis, and comparison of two parameters U_s and D_s of curve 5 were undertaken next.

The activity uptake rate, represented by the U_s , is a simple measure of the efficacy of the gland to extract the radiotracer from the circulation. The TAC of dynamic scan of normal salivary gland is more or less linear during the interval between 0 s and 240 s due to progressive accumulation of tracer. Following the application of the linear fit^[5] in the desired portion of TAC curve one can calculate the slope 3 or direction-coefficient (D_c) at the desired points of time in the curve between a specific time interval. The U_s represents the D_c between 2 and 4 min after injection [Figures 1-3]. The stimulated D_s was defined as the D_c Between the application of citric acid and minimum uptake or the lowest value after stimulation [Figures 4, 5 and 6]. The next step was to generate pixel histograms in the same way as the TAC was generated against each set of backgrounds. For each such set of histogram, the negative peaks indicated the background [Figures 7-9]. The range of pixel counts per second (CPS) along X-axis was noted.

Observation

Numerical variables of the whole cohort were subjected to Kolmogorov–Smirnov goodness-of-fit test and found



Figure 1: a1 value represents the upslope value. Background is central brain



Figure 2: a1 value represents upslope value. Background is suprathyroid



Figure 3: a1 value represents the downslope. Background is central brain

to be normally distributed. Comparison of the four parameters (Us, Ds, minimum CPS, and maximum CPS) between three background related subgroups by one-way analysis of variance and *post hoc* testing following

ANOVA by Tukey's test [Tables 1 and 2] show that the change in anatomical position of the background had no statistical significant effect on the Us and Ds derived from TAC.



Figure 4: a1 value represents the upslope value. Background is bilateral supraclavicular



Figure 5: a1 value represents the downslope value. Background is bilateral supraclavicular

Comparison of the Four Parameters between the Three Background Related Subgroups One-way Analysis of Variance

However, it was observed that minimum CPS of the background pixels in pixel histogram varies with the change in the anatomical position of background ROI, but this

change had not affected the semi-quantitative parameters of TAC [Tables 3 and 4]. On the other hand, the maximum CPS of background ROI did not change with the positional change of background, but it affects the Ds inversely in contrast to the Us that remains largely unaffected by the maximum counts [Tables 3 and 4].



Figure 6: a1 value represents the downslope value. Background is suprathyroid

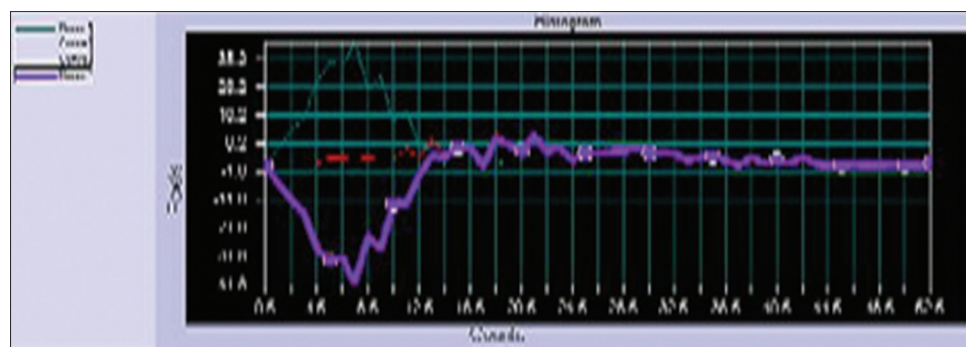


Figure 7: Pixel histogram of bilateral supraclavicular background. Curve below the baseline is of the background

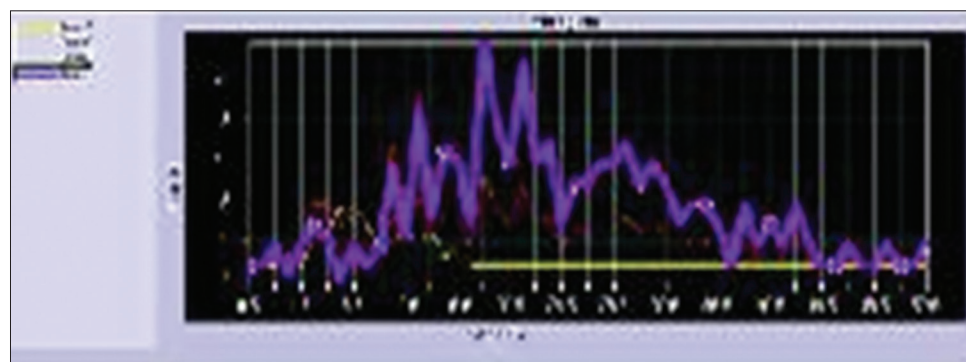


Figure 8: Pixel histogram of suprathyroid background. Curve below the baseline is of the suprathyroid background

DISCUSSION

Thus, as observed in the study, change in the anatomical position of background ROI does not seem to affect the

quantitative parameters of the salivary glands significantly. The two most important factors that determine the radioactivity quantification in an organ are (1) photon interaction and (2) partial volume effect (PVE). Both

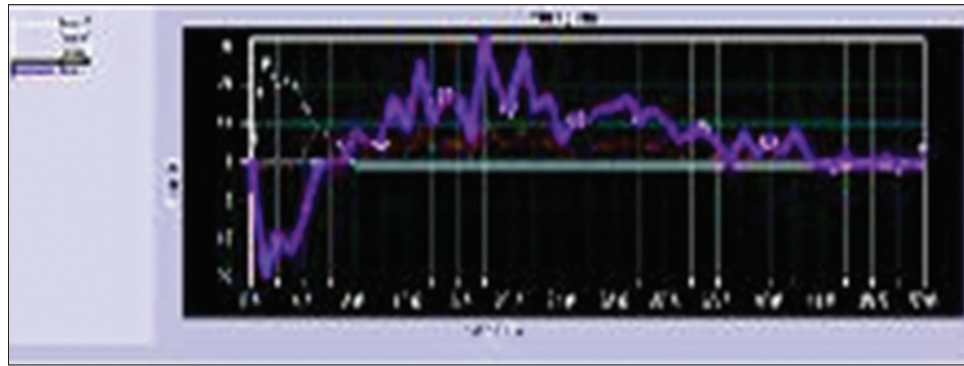


Figure 9: Pixel histogram of central brain background. Curve below the baseline is of central brain background

Table 1: *Post hoc* testing following ANOVA by Tukey's test

Dependent Variable	(I)	(J)	Mean difference (I-J)	Standard error	Significant	95% Confidence interval	
	SubGr	SubGr				Lower bound	Upper Bound
Us	1	2	-0.00300	0.02952	0.994	-0.0745	0.0685
		3	-0.00975	0.02952	0.942	-0.0813	0.0618
	2	1	0.00300	0.02952	0.994	-0.0685	0.0745
		3	-0.00675	0.02952	0.972	-0.0783	0.0648
	3	1	0.00975	0.02952	0.942	-0.0618	0.0813
		2	0.00675	0.02952	0.972	-0.0648	0.0783
Ds	1	2	-0.0006	0.1907	1.000	-0.463	0.462
		3	-0.0950	0.1907	0.873	-0.557	0.367
	2	1	0.0006	0.1907	1.000	-0.462	0.463
		3	-0.0944	0.1907	0.874	-0.557	0.368
	3	1	0.0950	0.1907	0.873	-0.367	0.557
		2	0.0944	0.1907	0.874	-0.368	0.557
Min CPS	1	2	-4.781	13.662	0.935	-37.89	28.33
		3	-35.031*	13.662	0.036	-68.14	-1.92
	2	1	4.781	13.662	0.935	-28.33	37.89
		3	-30.250	13.662	0.080	-63.36	2.86
	3	1	35.031*	13.662	0.036	1.92	68.14
		2	30.250	13.662	0.080	-2.86	63.36
Max CPS	1	2	-6.654	21.574	0.949	-58.94	45.63
		3	-39.564	21.574	0.170	-91.85	12.72
	2	1	6.654	21.574	0.949	-45.63	58.94
		3	-32.909	21.574	0.289	-85.20	19.38
	3	1	39.564	21.574	0.170	-12.72	91.85
		2	32.909	21.574	0.289	-19.38	85.20

* The mean difference is significant at the 0.05 level. CPS: Counts per second. Numerical variables of the whole cohort were subjected to Kolmogorov-Smirnov goodness-of-fit test and found to be normally distributed

parotid glands and submandibular glands are very superficial structures and so are their background structures. By altering the anatomical positions of background ROIs, the physical factors such as attenuation and scattering do not affect their counts due to less depth of the origin of the radioactivity. Besides, the PVE does not contribute to play a significant role in this case scenario, because the PVE^[6,7] is most important while quantifying the activity within objects of sizes less than twice the full width half maximum spatial resolution of the imaging system. Organs that are smaller or elongated will have greater PVE.^[7] The size of both the salivary glands and background structures is usually more than the full width at half maximum of the system, as described earlier. Furthermore, in the present analysis, it was observed that although minimum CPS of

the background pixels in pixel histogram varied with the change of the anatomical position of background ROI, this change did not affect the semi-quantitative parameters of TAC curve. Furthermore, although CPS determine the uptake, the change in the minimum CPS of the background ROI does not affect the semi-quantitative parameters.^[7]

This observation can be explained in the following manner: Following tracer administration into the central compartment, initially there is very fast decay in the distribution phase and the efflux rate constant k_{12} plays the dominant role.^[8] The minimum CPS of any region solely depends on k_{12} but while the drug is distributing from the central to the peripheral compartment, there is drug returning back to the central compartment at a certain

Table 2: Comparison of the 4 parameters between the 3 background related subgroups One way analysis of variance

Semi-quantitative parameters	SS	df	MS	SS	df	MS	F	P
Us	0.00	2	0.000	0.3	45	0.007	0.057227	0.944
Ds	0.10	2	0.048	13.1	45	0.291	0.164402	0.849
Min CPS	11547.26	2	5773.630	67198.1	45	1493.292	3.866377	0.028
Max CPS	14360.52	2	7180.261	167552.6	45	3723.391	1.928420	0.157

Us: Upslope, Ds: Downslope, TAC: Time-activity curve, CPS: Counts per second. The change in anatomical position of the background had no statistical significant effect on the Us and Ds derived from TAC

Table 3: Baseline profile of the background ROI group

Parameter	Bilateral supraclavicular background	Suprathyroid background	Central brain background	P-value
Us				
Range	0.10–0.29	0.014–0.28	0.10–0.28	0.944
Mean±SD	0.09±0.080	0.10±0.090	0.09±0.080	
Ds				
Range	0.260–0.39	0.150–1.90	0.260–1.90	0.849
Mean±SD	0.75±0.535	0.85±0.548	0.75±0.534	
Min CPS				
Range	2.5–67	3.50–247	2.5–63	0.028
Mean±SD	23.62±19.581	53.87±61.220	18.84±18.66	
Max CPS				
Range	17.85–199	20–317	18–195	0.157
Mean±SD	67.57±53.979	100.4±78.303	60.92±46.099	

SD: Standard deviation, CPS: Counts per second. Minimum CPS of the background pixels in pixel histogram varies with the change in the anatomical position of background region of interest, but this change had not affected the semi-quantitative parameters of time-activity curve

rate, defined by the rate constant k_{21} , and also there is elimination from the peripheral compartment affected by the rate constant k_{10} . Hence, the observed rate of the distribution process is described by the hybrid rate constant α , which is dependent on the three rate constants k_{12} , k_{21} , and k_{10} , as in Equation 17.9. Thus, it is obvious that although k_{12} varies with the tissue composition, the minimum CPS of the background ROI changes with the change in anatomical position. However, it does not affect the overall distribution in the salivary glands as explained by the above-mentioned equation, so the value of Us is not dependent on k_{12} independently.

$$\alpha = \frac{1}{2} \left[\frac{(k_{12} + k_{21} + k_{10}) + \sqrt{(k_{12} + k_{21} + k_{10})^2 - 4k_{21}k_{10}}}{2} \right] \quad (17.9)$$

Both the minimum counts and the maximum CPS depend on k_{12} , but the maximum count does not depend solely on k_{12} , unlike the minimum CPS because with the progression of time, the central elimination, k_e , becomes the most sensitive determining factor [Figure 10]. Thus, the maximum CPS remains independent of tissue composition only as well as change in anatomical position of background ROI.

This k_e may be written in terms of the micro constants (k_{10} , k_{12} , and k_{21})^[8,9] used in the two-compartment model. This point of equilibrium is unique in that there is one overall elimination rate constant, k_e , just as we saw in the

Table 4: Association between Us, Ds with minimum CPS and maximum CPS in the whole cohort correlation analysis calculation of Pearson's correlation coefficient

Parameters	Correlation coefficient r	P-value	95% Confidence interval for r
Us and minimum CPS	0.1325	0.3693	−0.1576–0.4015
Ds and maximum CPS	−0.3972	0.0052	−0.6123–−0.1275
Us and maximum CPS	0.05237	0.7237	−0.2353–0.3316
Ds and minimum CPS	−0.2471	0.0904	−0.4964–0.3979

Ds: Downslope, Us: Upslope, CPS: Counts per second. Maximum CPS of background region of interest did not change with the positional change of background, but it affects the Ds inversely in contrast to the Us that remains largely unaffected by the maximum counts

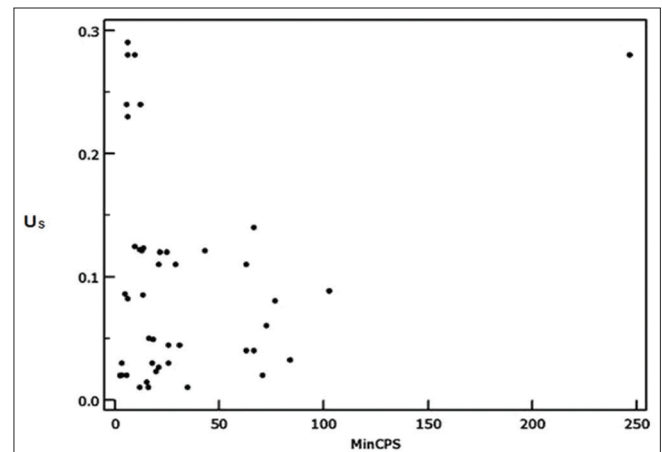


Figure 10: Scatter diagram pattern for upslope data and minimum CPS data

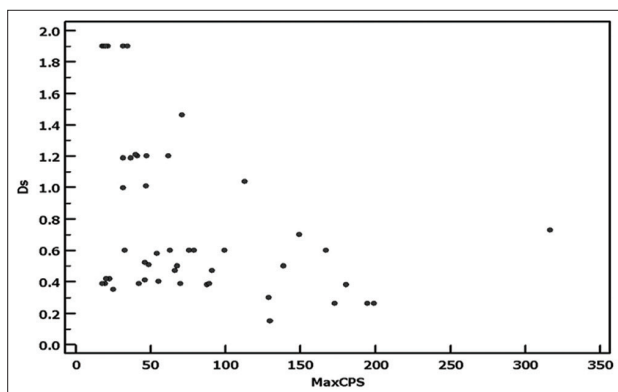


Figure 11: Scatter diagram pattern for Downslope data and maximum CPS data

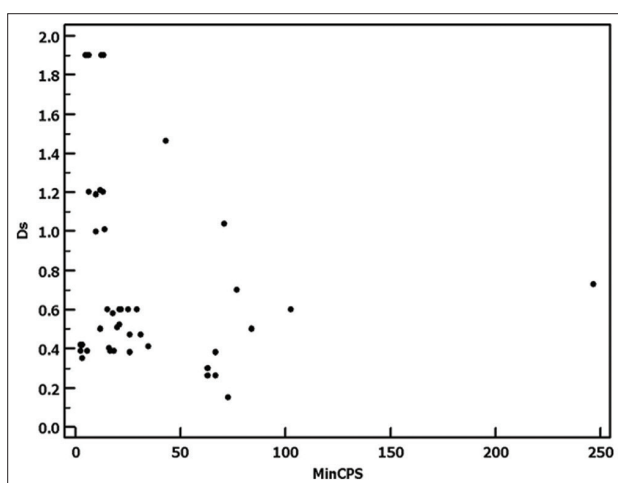


Figure 12: Scatter diagram pattern for Downslope data and minimum CPS data

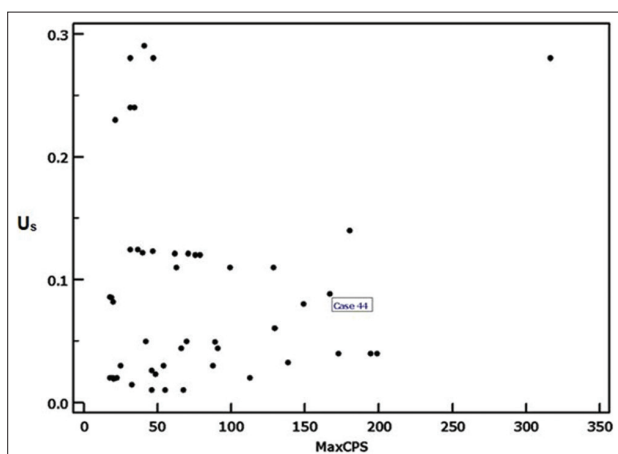


Figure 13: Scatter diagram pattern for upslope data and maximum CPS data

one-compartment model. The smaller hybrid rate constant β is the rate constant for the elimination process as in $\alpha + \beta = \{k_{12} + k_{21} + k_{10}\}$,^[8] hence, it is obvious that tissue-dependent k_{12} , alone is of no importance in calculation of elimination rate constant β .

This might be one of the reasons that maximum CPS of background ROI also does not change with the positional change of background. This is due to developing insignificance of the individual effect of k_{12} with the progression of time. The maximum CPS in background are inversely proportional to maximum CPS of salivary glands, and stimulated secretion index varies with the maximum count in the salivary gland directly. Hence, greater the maximum pixel count of the background less the stimulated Ds index [Figure 11].

CONCLUSION

In salivary scintigraphy, the major important semi-quantitative parameters do not vary with the change in the anatomical position of background but pixel histogram analysis of the background ROI reveals that it is the minimum CPS of the background pixel histogram that varies with the changing position but does not affect the overall quantitative parameters [Figure 10 and 12]. On the contrary, it was observed that the maximum CPS that affects the downslope inversely although U_s remains unaffected [Figure 13 and 11].

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Mortality in Cervical Spine Injury: A Study in a Tertiary Care Center in India

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Abstract

Introduction: Cervical spine injury is a common injury worldwide. When cervical cord is also affected, it is the most devastating injuries due to poor recovery and disabling consequences. The management is still in the process of continuous evolution. However, even after so much ongoing research, there is no satisfactory treatment which can give complete restoration of the function.

Materials and Methods: The study was carried out as an observational study and had both prospective and retrospective components. The patient with cervical spine quadriplegia coming to the Department of Orthopedics as well as the bodies of the deceased with quadriplegia at the Department of Jurisprudence, Sir Sunderlal Hospital, Institute of Medical Sciences, Banaras Hindu University, over a period of 2 years from June 2005 to June 2007 were included in the study.

Results: A total of 92 patients of traumatic quadriplegia were admitted in orthopedics ward from May 2005 to June 2007. Of this, 44 patients expired either during the hospital stay or during follow-up period, a maximum of 6 months. The results are well depicted in tables.

Conclusion: There must be a training of primary health center staffs regarding the role of cervical immobilization during transportation to a hospital and also for rapid transportation of a cervical spine injury patient to a respective well-equipped hospital. The trained nursing staffs and a team approach along with well-equipped intensive care unit must be constituted for the management of traumatic quadriplegia patients.

Key words: Health, Injury, Spine

INTRODUCTION

Cervical spine injury is a common injury worldwide. When cervical cord is also affected, it is the most devastating injuries due to poor recovery and disabling consequences.

The management is still in the process of continuous evolution. However, even after so much ongoing research, there is no satisfactory treatment which can give complete restoration of the function.

Cervical spinal cord injury accounts for 2–3% of all traumatic injuries and 8.2% of all trauma-related

deaths.^[1-3] In cervical spine injury, mortality can be as high as 15-30%.^[4]

Due to the absence of spinal cord injury registries in India, there are little data about the demography, social and economic burden, and mortality from these injuries in India.^[5] Furthermore, there are a limited number of studies from India, where the demographics vary from the rest of the world due to varied population and their customs.

MATERIALS AND METHODS

The study was carried out as an observational study and had both prospective and retrospective components. The patient with cervical spine quadriplegia coming to the Department of Orthopedics as well as the bodies of the deceased with quadriplegia at the Department of Jurisprudence, Sir Sunderlal Hospital, Institute of Medical Sciences (IMS), Banaras Hindu University (BHU), over

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a period of 2 years from June 2005 to June 2007 were included in the study.

All the patients of traumatic quadriplegia were included and all dead quadriplegic patients coming from all hospitals for autopsy to the institute were included in the study.

All admitted patients were subjected to a detailed questionnaire and clinical examination as per pro forma. Details about family, social and economic background, contact details, and postal address were taken. Documentation regarding clinical photographs of the patients and X-rays of the patients was done. Detailed history about the mode of trauma, mode of transportation to hospital, details about spinal immobilization, methylprednisolone use, or any treatment carried out before visiting the hospital was noted. A thorough neurological evaluation of the sensory, motor, and autonomic affection of the patient by the injury was done.

Frankel's classification of neurological deficits in traumatic quadriplegia and classification of injury was done.

Frankel's Classification of Neurologic Deficits in Patients with Traumatic Quadriplegia

- A. Absent motor and sensory function
- B. Sensation present, motor function absent
- C. Sensation present, motor function active but not useful (Grade 2–3/5)
- D. Sensation present, motor function active and useful (Grade 4/5)
- E. Normal motor and sensory function.

Classifications of Injury

All cervical spine injuries were classified on the basis of

- Level of injury
- Type of injury
- Stability of injury.

On the basis of neurological examination and local examination, the level of vertebral injury was clinically detected. For cervical spine injury, standard anteroposterior and lateral radiographs of the cervical spine were done. An anteroposterior open mouth view for suspected fracture C1–C2 and a lateral swimmers view for C6–C7 fracture were taken. For unilateral facet fracture or facet unlock, the left and the right oblique views were taken. In cases of doubtful subluxation, flexion extension views of the spine were taken till the point patient was comfortable.

In cases, where no bony injury was anticipated on X-rays and whenever a patient could afford, magnetic resonance imaging was done. All routine and baseline investigations, chest X-rays, and other relevant investigations concerned with the pre-existing disease of the patient were done at the time of admission. In suspected cases of head injury,

computed tomography scan of head and brain was done and all investigations (ultrasound chest/abdomen, etc.) related to other associated injuries were undertaken.

Indoor Patients

For all indoor patients with a traumatic cervical spine injury except in those with a minor fracture or those with no neurological deficits, crutch field tongs (CFTs) were applied and traction given for 3–4 weeks.

Rest were given head halter traction. After 3–4 weeks of CFTs, the CFT was removed; patients were given head halter traction. For the patients managed on domiciliary basis, head halter traction was given.

The protocol for the management is given in Table 1.

Treatment

1. Minor fracture (all without neurological deficit)	Hard cervical collar for 2 months.
2. Stable fracture without neurological deficit	Four post collar for 2 months. Hard cervical collar for next 1 month.
3. Stable fracture with neurological deficit	Traction and bed rest for 3 months.
4. Unstable fracture without neurological deficit	Traction and bed rest for 3 months followed by ambulation with four post collar for next 3 months followed by hard cervical collar for next 3 months or surgical stabilization.
5. Fracture with neurological deficit	Traction and bed rest for 3 months or surgical stabilization.

General Care

Proper back care, bowel and bladder care, and quadriplegics care were explained and taught to the attendant.

General Examination

Regular neurological charting was done to look for neurological recovery. Daily clinical examination and auscultation of the chest were done to see for impending respiratory tract infections. In cases of respiratory tract infections, patient was started on oxygen, intravenous fluids, and antibiotics. Whenever required, the patient was shifted to intensive care unit (ICU). Daily clinical examination of the lower limb was done to look for deep vein thrombosis (DVT). In cases of suspected DVT, anticoagulant therapy was started. Daily examination for bedsores was done. Waterbed was given for those with bedsores or impending bedsores. In patients with bedsores, daily dressings/debridements were done.

Investigations

- In case of suspected DVT, color Doppler was done in the 1st and 3rd weeks after injury
- Urine routine microscopy and culture/sensitivity were

sent in every 1st and 3rd week after injury directly from the catheter

- Serum electrolytes and creatinine were done every fortnightly to look for electrolyte imbalance
- Whenever chest infection was suspected, portable X-ray chest was done
- In cases of deterioration, all routine investigations were sent and basic life-saving measures were employed and when required and when patients could afford, the patient shifted to ICU
- In cases of death.

In patients, in whom autopsy was possible, relevant clinical photographic documentation was done.

In cases, where autopsy was not possible, cause of death was determined on the basis of antemortem symptoms and signs presented by the patients and clinical investigations.

Follow-up

The patients were followed at an interval of 6 weeks for the first 6 months. During follow-up, patients were thoroughly examined clinically as well as neurologically and recovery in neurological status, and bowel and bladder function was noted. Patients were evaluated for any new complication.

In cases of mortality at home, all relevant information were acquired through telephonic conversation with relatives and if possible a visit to the site of death was made.

All the patients who had useful or normal motor power in lower limbs (Frankel Grade D or E) were allowed walking after 3 months with or without orthosis and/or crutches depending on the stability of the fracture and/or extent of neurologic deficit.

The patients who had absent or useless motor power in lower limbs (Frankel A, B, or C) were allowed walking after 3 months on wheelchair, orthosis.

After 6 months, these patients were trained to stand and walk independently with the help of high knee-ankle-

foot orthosis with fixed pelvic belt and walker or axillary crutches.

Cases Directly Coming for Autopsy at the Department of Medical Jurisprudence, IMS, BHU

All relevant information were collected from the relative accompanying the dead body and the hospital where patient was being treated/admitted before his death. Photographic documentation was done of autopsy findings of cervical spine injury and any other related injuries contributing to the cause of death.

RESULTS

A total of 92 patients of traumatic quadriplegia were admitted in orthopedics ward from May 2005 to June 2007. Of this, 44 patients expired either during the hospital stay or during follow-up period, a maximum of 6 months.

There were 14 dead bodies of traumatic quadriplegia patients coming for autopsy at the department of medical jurisprudence.

A total of 58 deaths were considered for the final analysis.

Age Distribution

It is obvious from Table 1 that out of all deaths 65.6% were in the age group of 21–50 years.

Mode of Injury

Cases included in this study were further divided into seven groups according to different modes of injury [Table 2].

Fall from height was the most common mechanism of injury (48.3%). The most common type of falls was fall from roof (without parapet), trees, electric pole, and stairs.

Only patients coming directly to SS Hospital were included in this table.

Most of the patients were brought to our hospital without any cervical immobilization (95.7%).

Table 1: Description of patients in terms of age

Age	Number of cases	Percentage
0–9	0	0.0
10–19	7	12.1
20–29	12	20.7
30–39	11	19.0
40–49	15	25.9
50–59	4	6.9
60–69	7	12.1
≥ 70	2	3.4
Total	58	100

Table 2: Mode of injury

Mode of injury	Number of cases	Percentage
Fall from height	28	48.4
Road traffic accident	8	13.8
Railway accident	4	6.9
Assault	6	10.3
Firearm injury	4	6.9
Hit by animal	2	3.4
Others	6	10.3
Total	58	100

Time Interval between Injury and Reporting to Hospital

Only patients coming directly to SS Hospital were included in the table. Patients treated in other hospitals whose dead bodies came for autopsy in our hospital were not included in the table.

About 36.4% of patients reached hospital within 24 h of injury and 40.9% of patients reached hospital after 48 h–1 week of injury [Table 3].

Most of the deaths were recorded in lower cervical group as 67.3% [Table 4].

Patients hospitalized in our hospital were further classified into various groups on the basis of level of injury. Then, mortality in each group was assessed.

The most common injury in hospitalized patients was lower cervical vertebrae (68.5%). Percentage mortality of upper cervical injury was 53% as compared to lower cervical injury which was 46% [Table 5].

All the cases were further classified according to the type of injury into the following groups.

The most common type of injury was fracture dislocation/subluxation 52.3% followed by burst fracture 18.1% [Table 6].

All the hospital deaths were further classified, on the basis of Frankel's grading into five groups [Table 7].

Most of deaths were observed in Frankel's Group A (52.3%) followed by Frankel's Group B (47.7%). No deaths were observed in Frankel's Groups C, D, and E.

Associated Injuries [Table 8]

Sixteen of 58 cases had other associated injuries. Most common being head and facial injury, followed by skeletal injury, chest, and abdominal injury.

Hence, 27.2% of patients had associated injury. The most common injury was head and facial injury in 15.3% of cases. Skeletal injury occurred in 6.8% of cases.

Time Interval between Injury and Death [Table 9]

The 1st week after injury was the most crucial period for the survival of traumatic quadriplegia patients.

Most of the deaths were recorded in the 1st week after injury in 70.7% of cases.

Causes of Death [Table 10]

Causes of death were classified into pneumonia, acute respiratory failure (death within 3–4 days of injury without

any other apparent cause), head injury with coma, bedsores, hemorrhagic shock, laryngospasm, medical causes (renal failure, etc.), DVT, and others (drowning, asphyxia, etc.).

Most of the deaths occurred due to pneumonia (27.6%). Other important causes of death were acute respiratory failure (22.4%), head injury with coma (15.5%), and hemorrhagic shock (10.3%).

Most of the deaths occurred within the 1st week of injury which was further classified into the following groups.

Most of the deaths within the 1st week of injury occurred due to acute respiratory failure (36.1%). Other

Table 3: Description of patients in terms of time interval between injury and reporting to hospital (n=44)

Time interval between injury and reporting to hospital	Number of cases	Percentage
0 – 24 h	16	36.4
24 – 48 h	06	13.6
48 h–1 week	18	40.9
1–2 weeks	04	9.1
> 2 weeks	0	0.0
Total	44	100

Table 4: Level of injury in all deaths (n=58)

Level of injury	Number of deaths (n=58)	Percentage mortality
Upper cervical (C ₁ –C ₄)	13	22.4
Lower cervical (C ₅ –C ₇)	39	67.3
No bony injury	6	10.3
Total	58	100.0

Table 5: Level of injury in all deaths in hospitalized group (n=44)

Level of injury	Number of deaths	Number of cases (n=44)	Percentage mortality (%)
Upper cervical	9	17	53
Lower cervical	29	63	46
No bony injury	6	12	50
Total	44	92	47.8

Table 6: Type of injury (n = 44)

Diagnosis	Number of cases	Percentage
Fracture dislocation/subluxation	23	52.3
Burst fracture	8	18.1
Wedge compression	6	13.6
Fracture osteophytes	1	2.2
No obvious bony injury	6	13.6
Total	44	100

Table 7: Frankel's grading

Frankel's	Number of cases	Percentage
A	23	52.3
B	21	47.7
C	0	0
D	0	0
E	0	0
Total	44	100

Table 8: Associated injuries

Associated injuries	Number of cases	Percentage
Skeletal injury	4	6.8
Head and facial injury	9	15.3
Chest injury	2	3.4
Abdominal injury	1	1.7
Total	16 (58)	27.2 (100)

Table 9: Time interval between injury and death

Time interval between injury and death	Number of cases	Percentage
1 week	36	62.1
1–3 weeks	14	24.1
> 3 weeks	8	13.8
Total	58	100

Table 10: Causes of death

Cause of death	Number of cases	Percentage
Pneumonia	16	27.6
Acute respiratory failure	13	22.4
Head injury with coma	9	15.5
Bedsore	4	6.9
Hemorrhagic shock	6	10.3
Laryngospasm	3	5.2
Medical causes	1	1.7
Deep vein thrombosis	3	5.2
Others	3	5.2
Total	58	100

Table 11: Cause of death in cases of mortality within 1 week

Cause of death	Number of cases	Percentage
Pneumonia	3	8.3
Acute respiratory failure	13	36.1
Head injury with coma	9	25
Bedsore	0	0
Hemorrhagic shock	5	13.8
Laryngospasm	2	5.6
Medical causes	0	0
Deep vein thrombosis	2	5.6
Others	2	5.6
Total	36	100

important causes of deaths were head injury with coma (25%), hemorrhagic shock (13.8%), pneumonia (8.3%),

Table 12: Use of cervical immobilization during transportation in hospitalized patients

Cervical immobilization	Number of cases	Percentage
Yes	4	4.3
No	88	95.7
Total	92	100

laryngospasm (5.6%), DVT (5.6%), and others (5.6%) [Table 11].

DISCUSSION

In this study, 65.6% of cases were from 20 to 49 years age group. This is the most physically active age group. Sundram^[6] (1984) in his Madras series of 499 cases and Singh *et al.*^[7] (2003) in his series of 483 cases, of which 164 were tetraplegics and 283 were paraplegics reported similar results.

In this study, 48.3% of patients sustained injury due to fall from height and only 13.8% of patients sustained injury due to road traffic accidents. There is a seasonal variance in incidences of traumatic quadriplegia since most of the people sleep on the roof (without parapet) at night, plucking of seasonal fruits from trees, leading to increased incidences of fall from height. Activities of daily living and living standard of the people living in this part of India (Eastern U.P., M.P., and Bihar) are entirely different from the people living in Metropolitan cities or Western countries which explain why fall from height is the main cause of traumatic quadriplegia in this part of India and not the road traffic vehicular accidents.

Chacko *et al.*^[8] (1985) reported fall from height in 55.2% of cases and road traffic accident in 12.8% of cases, Sundram^[6] (1987) reported 66% of cases in fall from height and 14% in road traffic accident, Dave *et al.*^[9] (1994) reported fall from height in 49.4% of patients and road traffic accident in 36.5% of patients, Singh *et al.*^[7] (2003) reported fall from height in 44.5% of cases and road traffic accident in 34.8% of cases. Karacan *et al.*^[10] (Turkey) (2000) reported fall from height in 36.5% of cases and road traffic accident in 48.8% of cases; Lan *et al.*^[11] (Taiwan) (1993) reported fall from height in 23.3% of cases and road traffic accident in 61.6% of cases; Powell *et al.*^[12] (Australia) (1999) reported fall from height in 31% of cases and road traffic accident in 43% of cases; and spinal cord facts and figures as a Glance – June 2006, USA, reported road traffic accident in 46.9% of cases and fall from height was the second most common cause of injury. Thus, from above data, one can conclude that fall from height is the most common cause in Indian scenario and

road traffic accident is the most common cause in western countries and metropolitan cities in India.

Most of the patients were transported to our hospital without any prior cervical immobilization (95.7%) [Table 12]. Due to repeated movements of the unsupported neck in cases of unstable type of cervical spine injury, there are repeated episodes of secondary insult to cervical spinal cord. This leads to ascending edema of cord which further compromises the respiration, leading to increased mortality due to acute respiratory failure.

Only 36.4% of patients reached hospital with 24 h of injury. Most of the patients reached hospital after 48 h of injury 40.9%, 9.1% reached after 1 week of injury. We have also observed in the study that the maximum number of deaths occurs in the 1st week of injury and that sooner the patient reaches the hospital the chances of his/her survival greatly increase. This is the gray area where we have scope for intervention and improvement. If we could provide cervical immobilization during transportation and provide for early transport of patient to the medical center with improved ambulance facilities, we can definitely reduce the mortality associated with cervical spine injury.

In this study, a total of 92 cases of traumatic quadriplegia patients were admitted in SS Hospital, of this 17 were upper cervical injury, 63 were lower cervical injury, and in 12 cases, no bony injury could be determined. Of this, 9 (53%) cases having upper cervical spine injury expired, number of expiry in lower cervical spine injury group was 29 (46%), and in 6 cases (50%), mortality was recorded in no obvious bony injury group. One can easily argue that upper cervical spine injury is more dangerous than the lower cervical spine injury due to involvement of the diaphragm (C3–C5). Hence, percentage mortality in upper cervical injury is more than the lower cervical spine injury group. However, one should note that the level of bony injury never always corresponds to the level of radiological diagnosis. Cord contusion and necrosis may extend higher up in the cord. Lower cervical spine injuries are further complicated with ascending edema of cord, which may further complicate respiration, leading to increased mortality.

About 52.3% of deaths were observed in complete type of injury (Frankel's A) and 47.7% were in incomplete type of injury (Frankel's B). No mortality was observed in Frankel's Groups C, D, and E.

The number of patients having associated injuries is also very high. The type of the associated injuries greatly modifies the ultimate management of the patients. In

cervical cord injury with head and facial injuries and other musculoskeletal trauma, the management is very difficult. Mortality is high in all these associated injuries individual since cervical cord injury itself is a very critical condition as far as handling of the patients is concerned which is further compounded by associated injury. In our study, the most common associated injuries were head and facial injuries (15.3%) followed by skeletal injury (6.8%). Karamahmetoğlu *et al.*,^[13] 1997, and Nwadinigwe *et al.*,^[14] 2004, reported head and facial injury to be most commonly associated with cervical spine injury.

The causes of death following spinal cord injury have changed. In the past, urinary tract disease and renal failure were leading causes of mortality. At present, renal failure in those with spinal cord injury is unusual. The leading cause of death at present is pneumonia.

In our series, pneumonia is the leading cause of death (27.6%), followed by acute respiratory failure (22.6%), head injury with coma (15.5%), hemorrhagic shock (10.3%), and bedsores (6.9%).

Acute respiratory failure was the most common cause of death within the 1st week (36.1%).

Since the patients in our setup reached to hospital after 48 h after injury in most of the cases, this led to loss of precious time in instituting early emergency life-saving measures. Cervical immobilization was rarely used during transportation of these patients, leading to secondary insult to already damaged cervical spinal cord, causing ascending edema and thus respiratory failure.

CONCLUSION

To reduce the incidence of traumatic quadriplegia patients and deaths due to it, awareness among the patients regarding hazards of rooftop without parapet, and road safety measures should be increased. There must be a training of primary health center staffs regarding the role of cervical immobilization during transportation to a hospital and also for rapid transportation of a cervical spine injury patient to a respective well-equipped hospital. The trained nursing staffs and a team approach along with well-equipped ICU must be constituted for the management of traumatic quadriplegia patients.

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Sociodemographic and Clinical Profile of Breast Cancer Patients in a Tertiary Care Hospital of Kashmir, India

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Abstract

Introduction: Globally, breast cancer is leading to cancer found among women. It is well known that cancer is an age-related disease and this holds true in breast cancer as well. Breast cancer is the most frequently diagnosed cancer in women, and it was estimated that there will be 252,710 new cases of invasive breast cancer and 63,410 new cases of *in situ* breast cancers among women in the United States in 2017.

Purpose: The aim of the present study was to analyze the demographic spectrum of breast cancers in the Kashmir valley.

Materials and Methods: This was an observational chart based study on breast cancer patients aged above 18 years of age who were diagnosed with either invasive or *in situ* breast cancer at Government Medical College Hospital, Srinagar, Kashmir. The duration of the study was from June 2015 to December 2018. A retrospective study was conducted to find the information regarding age, sex, clinical presentation, anatomical site, histopathological type, and stage of the disease.

Results: A total of 151 patients with histopathologically confirmed breast cancers formed the study population. The majority of the patients (46%) among females were <45 years of age and among males >45 years in age, with males and females constituting 4% and 96% of patients in their respective groups. The upper outer quadrant was involved in 81 (54%) patients followed by upper inner 14% and central quadrant involvement in 25 (16%) patients. Among 151 patients, 42 women (28%) presented in Stage IIA, 32 patients (21%) presented with Stage IIB disease, 19 patients (12%) in Stage IIIA, and 20 patients (13%) in Stage IIIC; however, 17 patients (11%) presented with Stage IV disease. G2 was the most common histological grade. On the whole, liver was the most common presenting site for distant metastasis followed by lung and brain metastases.

Conclusion: Early age, female sex, and residence within an endemic geographical region seem to be the prime determinants affecting breast cancer prevalence in a given population. A significant number of breast cancer patients in Kashmir present with early stage of disease and major clinical presentation were breast swelling. The majority of the cases reported in Stages II and III. Furthermore, there was significant number of patients presenting with metastasis, i.e., Stage IV.

Key words: Breast cancer awareness, Breast cancer, Sociodemographic profile

INTRODUCTION

Globally, breast cancer is leading to cancer found among women. It is well known fact that cancer is an age-related

disease which holds true in breast cancer as well. Breast cancer is the most frequently diagnosed cancer in women, and it was estimated that there will be 252,710 new cases of invasive breast cancer and 63,410 new cases of *in situ* breast cancers among women in the United States in 2017.^[1] In contrast to the significant number of breast cancer cases in women, it was expected that 2470 cases of breast cancer will be diagnosed in men in 2017, with approximately 460 breast cancer deaths in men. There is considerable geographic, ethnic, and racial variability in breast cancer incidence. Ethnicity and national origin rank highly as predictors of risk for breast cancer, with up to a 10-fold

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variation throughout the world.^[2] Breast cancer in men is rare, accounting for <1% of breast cancer cases in the US. However, since 1975, the incidence rate has increased slightly from 1.0 case/100,000 men during 1975–1979 to 1.3 cases/100,000 men during 2010–2014. Men are more likely than women to be diagnosed with advanced-stage breast cancer, which likely reflects decreased awareness and delayed detection because screening mammography is not recommended for men due to the rarity of the disease.^[3] Compared with other well-established risk factors such as age of menarche and menopause, age at first childbirth, and family history, geographic and ethnic variability are quite significant. It is likely that a complex interaction of multiple factors, including genetic, environmental, and socioeconomic, contributes to the wide variability in age-adjusted incidence across populations. Breast cancer incidence has increased dramatically in many countries over the past two decades, especially in developing countries, which can be attributed largely to factors such as aging of the population, delaying the period of first pregnancy, and increased intake of high-calorie Western diets.^[4] A study by Hirko *et al.* noted that there was a steep increase in breast cancer cases from 2009 to 2015 especially among women aged 30–39 and among women aged 40–49 years.^[5] Postmenopausal breast cancer risk is about 1.5 times higher in overweight women and about 2 times higher in obese women than in lean women. This is likely due, in part, to higher estrogen levels because fat tissue is the largest source of estrogen in postmenopausal women.^[6] The tumor, node, and metastasis (TNM) classification of tumors uses information on tumor size and how far it has spread within the breast and to adjacent tissues (T), the extent of spread to the nearby lymph nodes (N), and the presence or absence of distant metastases (spread to distant organs) (M).

This study conducted in a tertiary cancer center reviewed the data of breast cancer patients registered and treated there with respect to their sociodemographic and clinical characteristics.

MATERIALS AND METHODS

This was an observational chart based study on breast cancer in female and male patients aged above 18 years of age who were diagnosed with either invasive or *in situ* breast cancer at Government Medical College Hospital, Srinagar, Kashmir. The duration of study was from June 2015 to December 2018. Clinically suspected breast carcinoma subsequently proved to be non-malignant lesions after histological examination; non-Hodgkin lymphoma and other non-epithelial tumors of the breast were excluded from this study. The study was conducted to find the information regarding age, sex, clinical presentation, anatomical site, histopathological type, and

stage of the disease including metastases. Scrutinization of all available records was done to get relevant information. Staging of cancer was done by American Joint Committee on Cancer 2018. Baseline investigations were done to assess the patient's fitness for surgery. Treatment modalities included surgery, neoadjuvant or adjuvant chemotherapy, hormonal therapy, and radiotherapy.

Statistical Analysis

A descriptive analysis was used to report the study results. Categorical data were summarized as percentages. We analyzed the cancer characteristics according to age and sex. The aim of the present study was to analyze the demographic spectrum of breast cancers in the Kashmir valley.

RESULTS

A total of 151 patients with histopathologically confirmed breast cancers formed the study population. The male to female ratio was 1:24. The majority of the patients (46%) among females were <45 years of age and among males >45 years in age, with males and females constituting 4% and 96% of patients in their respective groups. The age group varied from 16 to 80 years with most common age group <45 years followed by patients age 45–64 years. Less than 45 years age group constituted 46% of the cases. The majority of patients had Eastern Cooperative Oncology Group Performance score 1 (50%) followed by 0 (30%). However, 65 (43%) women were overweight body mass index (BMI >25) and 54 (36%) were obese (BMI >30). Married women were 148 (98.00%) and 3 (2%) were unmarried. The salient observations of the study are shown in Table 1.

Clinical Presentation, Anatomical Sites, Histological Patterns, and Tumor Stage

The duration of symptoms at presentation ranged from 1 month to 6 months, with a mean duration of 3 months. In breast cancers local swelling was the chief complaint in 80% of the patients followed by axillary swelling in 11% of the patients and ulcer in 9% of the patients, as shown in Table 1. Table 2 shows distribution of study subjects according to the breast quadrant involved. The upper outer quadrant was involved in 81 (54%) patients followed by upper inner quadrant 21 (14%) and central/retroareolar involvement in 25 (16%) patients. Lower inner quadrant was affected in 7 (5%) patients and lower outer quadrant was involved in 17 (11%) patients. The most common histopathological type of breast cancer detected was invasive ductal carcinoma in 148 (98%) patients followed by lobular carcinoma in 3 (2%) patients.

Table 3 shows the distribution of cases according to clinical stage of cancer at the time of presentation. Among 151

Table 1: Demographic profile

Observation	n	%
Age (years)		
<45	69	46
45–64	61	40
>64	21	14
Gender		
Male	6	4
Female	145	96
Performance score (ECOG)		
0	45	30
1	75	50
2	21	14
3	10	6
Presenting symptoms		
Breast swelling	120	80
Ulcer	14	9
Axillary swelling	17	11
Marital status		
Married	148	98
Unmarried	3	2
BMI (kg/m ²)		
<25	32	21
25–30	65	43
30+	54	36
Laterality in breast		
Right breast	80	53
Left breast	71	47
Total	151	100

ECOG: Eastern Cooperative Oncology Group, BMI: Body mass index

Table 2: Site/quadrants of breast cancer

Site of breast	n	%
Upper outer quadrant	81	54
Lower outer quadrant	17	11
Upper inner quadrant	21	14
Lower inner quadrant	7	5
Center/retroareolar	25	16
Total	151	100

Table 3: Tumor, node, and metastasis staging

Stage	n	%
IA	10	7
IB	4	3
IIA	42	28
IIB	32	21
IIIA	19	12
IIIB	7	5
IIIC	20	13
IV	17	11
Total	151	100

patients, 42 women (28%) presented in Stage IIA, 32 (21%) presented with Stage IIB disease, 19 (12%) in Stage IIIA, and 20 (13%) in Stage IIIC; 17 (11%) presented with Stage IV disease. G2 was the most common histological grade. On the whole, liver was the most common presenting site for distant metastasis followed by lung and brain.

Treatment Modalities

The treatment plan was made according to the stage of disease at presentation assessed by clinical examination and radiological findings. Operability and type of surgery were assessed by the operating surgeon by clinical examination and evaluation of imaging studies. Oncological treatments such as neoadjuvant or adjuvant chemotherapy, hormonal treatment, and radiotherapy were given according to indications and as per protocols.

DISCUSSION

Globally, breast cancer is leading to cancer found among women. It is well known fact that cancer is an age-related disease which holds true for breast cancer as well. Breast cancer is the most frequently diagnosed cancer in women, and it was estimated that there will be 252,710 new cases of invasive breast cancer and 63,410 new cases of *in situ* breast cancers among women in the United States in 2017.^[1]

The present study included 151 patients of breast cancer. A study by Hirko *et al.*^[5] noted that their study results showed a steep increase in breast cancer cases from 2009 to 2015, especially among women aged 30–39 and among women aged 40–49 years. Our study was similar to a study conducted by Hirko *et al.*, which showed the age group varied from 16 to 80 years with most common age group in breast cancer being <45 years followed by age range of 45–64 years.

Breast cancer in men is rare, accounting for <1% of breast cancer cases in the US.^[3] In contrast to the significant number of breast cancer cases in women, it was expected that 2470 cases of breast cancer will be diagnosed in men in 2017, with approximately 460 breast cancer deaths in men. A study conducted by Anderson *et al.* showed since 1975, the incidence rate has increased slightly from 1.0 case/100,000 men during 1975–1979 to 1.3 cases/100,000 men during 2010–2014. Our study was similar to Anderson *et al.*, in that the males and females constituting 4% and 96% of patients in their respective groups. The duration of symptoms at presentation ranged from 1 month to 6 months with mean duration of 3 months. In breast cancers local swelling was the chief complaint in 80% of the patients followed by axillary swelling in 11% of the patients and ulcer in 9% of the patients. The most common histopathological type of breast cancer detected was invasive ductal carcinoma in 148 (98%) patients followed by lobular carcinoma in 3 (3%) patients, findings which were similar to those of Meshram *et al.*^[7] and Sandhu *et al.*^[8] About 98% were married which were consistent with Montazeri *et al.*^[9]

In our study, left breast was affected in 71 (47%) cases while right breast was affected in 80 (53%) cases, which was in

contradiction to study conducted by Meshram *et al.*,^[7] who found that 50.48% of cases had breast cancer on left side and 49.52% of cases had it on right side. On the whole, most studies do show that the left side involvement is more common than right although no reason has been found for this.

The distribution of disease site in this study as per the quadrant of breast involved, showed upper-outer quadrant to be involved in 81 (54%) patients followed by upper-inner quadrant in 14% and central or retroareolar area in 25 (16%) patients. Lower-inner quadrant was involved in 7 (5%) patients and lower-outer quadrant in 17 (11%) patients. This is consistent with Sandhu *et al.* (2010)^[8] who found that majority (47.75%) patients of breast cancer, upper- outer quadrant was involved.

The distribution of cases according to the TNM classification/stage of cancer at the time of presentation showed that among 151 patients, 42 women (28%) presented in Stage IIA, 32 (21%) presented with Stage IIB disease, 19 (12%) in Stage IIIA, and 20 (13%) in Stage IIIC. Around 17 (11%) presented with Stage IV disease. Our study was in contradiction to study conducted by Raina *et al.*^[10] who noted that the most commonly observed stage of presentation was Stage IIIB in 35.2% cases, followed in decreasing order by Stages IIIA, Stage IIB, Stage IV, and Stage I. Meshram *et al.*^[7] and Harrison *et al.*^[11] also found that most of the cases were detected in Stage III and Stage IV.

Postmenopausal breast cancer risk is about 1.5 times higher in overweight women and about 2 times higher in obese women than in lean women. This is likely due, in part, to higher estrogen levels in obese females because fat tissue is the largest source of estrogen in postmenopausal women.^[6] The present study was similar to a study conducted by La Vecchia *et al.* 2011, which also showed that 65 (43%) women were overweight (BMI >25) and 54 (36%) were obese (BMI >30).

Limitations

We do accept that there were some limitations that we appreciated during the course of this study. First, the number of patients enrolled in the study was less, the reason for which, partly, is that majority of patients go for treatment to another tertiary care center in our valley at Skims Soura and a few who can afford to spend money on their treatment go to corporate cancer centers outside Kashmir valley. Hence, our study group may not reflect the actual prevalence and incidence of breast cancer in the whole population in this region. Despite this, our institution is the first level contact between patient and doctor and hence, caters to the initial management of a large chunk

of patients. In this context, our department has started a hospital-based cancer registry for past 1 year so that more comprehensive data will be generated. In any case, the data presented in the current study may reflect the nature of the disease in this population and emphasize the significance of early diagnosis by proper and timely evaluation and management of the disease in a multidisciplinary setting.

CONCLUSION

Early age, female sex, and living within an endemic geographical region seem to be the prime determinants affecting breast cancer prevalence in a given population. Early detection will reduce the number of deaths of breast cancer patients. A significant number of breast cancer patients in Kashmir present with early stage of disease probably due to breast self-examination awareness with major clinical presentation being a breast swelling. The majority of the cases in our study presented in Stages II and III, but there were quite few patients presenting with metastases, i.e., Stage IV. The reason for this may be due to lack of knowledge about the disease in these patients or more commonly due to social reasons, which make females especially in far off rural areas to hesitate in seeking medical advice. People should be educated for an early consultation if and when symptoms develop and high-risk individuals should be encouraged for screening. The health program about breast cancer screening, symptoms, presentation, etc., should be carried out in far off and inaccessible areas to give more information about cancer to people who actually need it and who do not have access to such endeavors and public outreach programs.

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Data Analysis of Ovarian Cancer Patients for Feasibility of Treatment in a Radiation Oncology Department

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Abstract

Introduction: Ovarian cancer is not only the most common but also the most lethal gynecological malignancy, partly, because the majority of patients present with advanced disease. However, as is true for so many cancers, the management of patients with ovarian neoplasms has changed substantially, and outcome results have improved considerably over the years. The reasons for this are many. For example, major advances in chemotherapy have resulted in improved survival, and the role of surgery is constantly evolving and being refined.

Purpose: A retrospective data analyses of ovarian cancer patients to observe their contemporary management in a radiation oncology departmental set up and the post-treatment outcome of these patients.

Materials and Methods: The case records of 117 ovarian neoplasm patients registered in our department from 2011 to 2018 were analyzed. The clinical, histopathological, and treatment details were noted. Contemporary treatment protocols were used.

Results: Of the 117 patients of ovarian cancer treated in our department with conventional diagnostic, imaging, surgical, and contemporary chemotherapy protocols, we found management of such patients is possible with optimum outcomes.

Conclusion: Ovarian cancer patients can safely and optimally be treated in a radiation oncology department.

Key words: Clinicopathologic profile, Ovarian cancer, Treatment in radiation oncology department

INTRODUCTION

Primary carcinoma of the ovary is the fourth most common cancer among women in developed countries. It is the leading cause of death among all gynecologic cancers. Worldwide ovarian cancer incidence rates vary widely between different geographic regions and ethnic groups with the highest incidence in Northern Europe, and lowest incidence is in Japan.^[1] Ovarian cancer is not a single entity but represents tumors of epithelial, germ cell, and sex cord-stromal origin. Approximately 90% of ovarian cancer is epithelial in origin presenting in advanced stages in most of the patients, while other types of ovarian cancer

such as germ cell and sex cord-stromal tumors are often localized in distribution with a more favorable prognosis. While epithelial tumors are seen in elderly women, germ cell tumors occur in young women and sex cord-stromal tumors occur in young as well as elderly women.^[2]

According to the International Federation of Gynecology and Obstetrics (FIGO), patients with ovarian cancer have to be staged surgically which is important for planning therapy and assessing prognosis with the goal being to remove as much disease as possible. The key elements of surgical staging for ovarian cancer are the same for all types of tumors except in young patients wishing to preserve fertility.^[1]

Ovarian cancer is a very chemosensitive disease,^[1] but still, most patients relapse sooner or later needing further treatment with only a handful of patients achieving a long-term survival and a 5 year survival in Stage III/IV epithelial ovarian cancer patients as low as 12% over the past 30 years.^[3,4]

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The purpose of this study was to evaluate and review the clinicopathological profile and feasibility of the management of ovarian cancer patients in radiation oncology department.

MATERIALS AND METHODS

Case records of 117 patients with a diagnosis of ovarian cancer registered in our department from 2011 to 2018 (both years included) were taken for the review (in addition to these, four patients were registered in our department during this period who had only imaging evidence of ovarian malignancy but did not follow so were excluded from the study). Details included registration number (RT number), age, clinical presentation, performance status, type of imaging, histopathological type, treatment given, and post-treatment outcome.

RESULTS

A total of 117 patients with histologically documented ovarian tumors were enrolled over a period of 8 years from 2011 to 2018. For these patients, the imaging modality used for diagnosis was contrast-enhanced computerized tomography (CECT) abdomen and pelvis, an ultrasonography (USG) abdomen and pelvis, magnetic resonance imaging pelvis, and transvaginal sonography. Of all these, CECT was the most commonly used imaging modality followed by USG. Based on the imaging findings regarding the extent of disease, patients were subjected to various types of procedures to obtain a histopathological diagnosis, for example, classic surgical staging procedure

for ovarian cancer (total abdominal hysterectomy + bilateral salpingo-oophorectomy [TAH + BSO]), diagnosis based on ascitic fluid cytology, laparoscopic biopsy, USG guided fine-needle aspiration cytology/core needle biopsy, and exploratory laparotomy. On histopathological analysis, 93 patients had epithelial tumors, 11 patients had germ cell tumors, and 13 had granulosa cell tumors [Table 1].

Within the epithelial tumors, the malignant serous tumor was the most common (46 patients) followed by malignant mucinous tumor (39 patients). In addition to these two main histologic types, other types were also seen, for example, primary peritoneal serous carcinoma, clear cell tumor, small cell carcinoma, and malignant endometrioid tumor. Staging wise distribution of epithelial tumors is shown in Table 2. Eight patients had Stage IV disease. The age range for epithelial origin tumors was between 18 and 74 years.

Among the 11 germ cell tumors, the maximum number of patients had mature cystic teratomas followed by dysgerminoma, in addition to mixed germ cell tumor and yolk sac tumor (endodermal sinus). All these patients were Stage I with an age range between 15 and 24 years. Among the 13 patients of granulosa cell tumor, all had Stage I disease, with an age range between 18 and 65 years.

Treatment

Epithelial tumors

Out of a total of 93 patients with epithelial tumors, 42 patients received chemotherapy in the neoadjuvant setting in view of an advanced stage of disease and remaining 51 patients received chemotherapy in the adjuvant setting (post-surgery).

Table 1: Patient characteristics (n=117)

	Imaging modality CECT 82	USG 23	MRI 10	TVS 2
Histopathological diagnosis established by	TAH+BSO 52	Ascitic fluid cytology 9	Laparoscopic biopsy 10	Image-guided biopsy 17
Histopathology	Epithelial 93 Serous 46 Mucinous 39 Clear cell 2 Endometrioid 1 PPSC 4 Small cell 1	Germ cell 11 Mixed 2 Dysgerminoma 3 Yolk sac 2 Mature teratoma 4	Sex cord-stromal 13 Granulosa cell tumor 13	Exploratory Laparotomy 28 Left supraclavicular node biopsy 1
Stage (FIGO)	IA 10 IC 12 IIA 9 IIB 4 IIC 2 IIIB 14 IIIC 34 IV 8	I in 11	IA 8 IC 5	
Age range (years)	18–74	15–24	18–65	

FIGO: International Federation of Gynecology and Obstetrics, TAH+BSO: Total abdominal hysterectomy+bilateral salpingo-oophorectomy, CECT: Contrast-enhanced computerized tomography, USG: Ultrasonography, MRI: Magnetic resonance imaging, TVS: Transvaginal sonography, PPSC: Primary peritoneal serous carcinoma

Neoadjuvant

Forty-two patients were treated with neoadjuvant (upfront) chemotherapy after diagnosis. In view of the advanced clinical stage, these patients were not operated, but a histopathological diagnosis was established by either a laparoscopic biopsy, imaging-guided biopsy, laparotomy with biopsy from accessible mass, ascitic fluid cytology, and biopsy from the left supraclavicular lymph node [Table 2].

Histopathology wise the most common type was serous (23 patients) followed by mucinous (15 patients). Eight patients had Stage IV disease (four had pleural effusion, one had metastasis left supraclavicular lymph node, and three had liver metastasis), while 34 patients had Stage III disease. For these 34 patients achieving an optimum, surgical resection was not possible, in view of grossly palpable disease and most cases, associated with ascites, hence they were given upfront chemotherapy. The chemotherapeutic drugs used were paclitaxel and carboplatin intravenously repeated at 3 weekly intervals for three cycles.

After three cycles of neoadjuvant chemotherapy, 12 patients showed response, including two Stage IV patients with the downsizing of the disease and an interval cytoreduction was possible. While in rest 30 patients, chemotherapy was continued because response assessment at the completion of three cycles showed persistent disease. At the end of six cycles of chemotherapy, 23 patients showed a response and were therefore referred for surgical cytoreduction, but seven patients totally failed to respond to first-line chemotherapy. These were offered second-line chemotherapy [Table 3].

Table 2: Treatment given to epithelial tumors (n=93)

Surgery	Adjuvant chemo 47	Neoadjuvant chemo 42
TAH+BSO	49	
Laparotomy with ipsilateral salpingo-oophorectomy	1	
Laparotomy with BSO	1	
Laparoscopic biopsy		10
Imaging guided biopsy		17
Laparotomy with biopsy/ mass excision		5
Ascitic fluid cytology		9
Left supraclavicular node		1

TAH+BSO: Total abdominal hysterectomy+bilateral salpingo-oophorectomy

Table 3: Profile of response achieved after neoadjuvant chemotherapy

Neoadjuvant chemotherapy	Response after three cycles	Response after six cycles	Failed to chemotherapy
42 patients	12 patients	23	7

For the 35 patients who returned after surgical cytoreduction (12 patients after three cycles and 23 patients after six cycles of neoadjuvant chemotherapy), all were given three additional cycles of post-operative systemic chemotherapy with the same drugs and schedule as before. Out of these, 23 patients are disease free, alive and on follow-up which included one patient who relapsed after 8 months (platinum-sensitive disease) and received chemotherapy again, while 12 patients relapsed at different times after first-line chemotherapy and received further lines of chemotherapy but ultimately died.

Adjuvant

Out of a total of 51 patients who presented to our department with upfront surgery, in 49 patients diagnosis and staging were established by TAH + BSO, while laparotomy with ipsilateral salpingo-oophorectomy and laparotomy with BSO were done in one patient each [Table 2].

Histopathologically serous type was more common than mucinous, 29 patients versus 22 patients. Stage wise most patients had Stage IIIB disease followed by Stage IC [Table 4].

Of the ten patients with Stage IA disease, four patients had either a Grade I or II disease and hence were put on close follow-up alone while rest of the 47 patients out of a total of 51 were treated with first-line systemic chemotherapy, same drugs and schedule as above for six cycles with interval assessment. All the patients started on chemotherapy received full six cycles of chemotherapy with paclitaxel and carboplatin. After finishing chemotherapy, the patients were put on regular follow-up with assessment based on tumor markers and imaging as and when needed. Out of these 47 patients who received systemic chemotherapy, 33 patients are disease-free, alive, and on follow-up to date while 14 patients have failed treatment at different times during follow-up including two patients who had initially Stage I disease and were put on close observation alone. Failing patients received subsequent lines of chemotherapy depending on their sensitivity to platinum agents, but ultimately all these relapsing patients succumbed to their disease at different times.

Table 4: Profile of patients who received adjuvant chemotherapy

Histopathology		Stage	Chemotherapy given	No chemotherapy
Serous 29	Mucinous 22	IA=10	47	4
		IC=12		
		IIA=9		
		IIB=4		
		IIC=2		
		IIIB=14		

Germ cell tumors

All the 11 patients were first subjected to surgery. The type of surgery done, the histopathological type of tumor, and the chemotherapy given to patients is shown in Table 5. All the patients with mixed germ cell tumors, dysgerminoma, and yolk sac tumors received chemotherapy in the form of bleomycin, etoposide and cisplatin intravenously at 3 weekly intervals for four cycles. All of these patients are alive and on follow-up. Four patients of mature cystic teratoma who did not receive chemotherapy are on close follow-up alone.

Granulosa cell tumors

In all 13 patients, surgery had been done before patients were referred to our department. The details about the type of surgery done, histopathology types and further follow-up are shown in Table 6. After surgery, all these are on follow-up alone with monitoring by tumor markers.

DISCUSSION

The aim of this study was to analyze the feasibility of treating ovarian cancer patients in a radiation oncology departmental set up. Because our department is actually a

radiation oncology cancer department (being more involved with hi-tech equipment and gadgets) we were interested to actually observe whether ovarian cancer patients could be optimally treated in our departmental set up with the same protocols and the same level of care that such patients receive when they are treated in a more conventional medical oncology departmental set ups, especially since these patients develop frequent and multiple relapses and hence require multiple lines of chemotherapeutic drugs.

Ovarian neoplasms are common. Of genital tumors in women, ovarian cancer accounts for a third, about the same proportion as carcinoma of endometrium and cervix.^[3] Ovarian cancer is predominantly a disease of the elderly.^[2] In our department, we come across ovarian cancer patients more frequently than either endometrial or cervical cancers, perhaps due to progressive affluence seen in our society and a possible low cervical cancer incidence due to social and religious practices being practiced here.

Approximately 80% of women with ovarian cancer have a FIGO Stage III/IV at initial presentation and survival is consequently poor (overall 5-year survival of 30–40%); hence, the disease is frequently called the “silent killer.”^[1] More specifically, elderly patients with ovarian cancer have poorer survival, undergo proportionally fewer surgical procedures, receive less aggressive treatments, and are less likely to be referred to a gynecologic oncology specialist. In our study, also, we found a predominance of elderly patients with epithelial origin tumors and a comparatively younger age group with germ cell and granulosa cell tumors. The outcome benefit of achieving no gross residual disease following surgical cytoreduction may be lost on those elderly patients who tolerate the surgery poorly—emphasizing the need for validated pre-operative assessments to help guide appropriate patients to surgery and avoid unnecessary complications for those who should have an alternative treatment.^[2] Therefore, a proper selection of patients for upfront surgery should be done to keep surgical mortality as low as possible.

The histopathological classification of malignant ovarian tumors accepted by the World Health Organization and the FIGO divides them into four major types;

1. Epithelial tumors
2. Sex cord-stromal tumors
3. Germ cell tumors
4. Miscellaneous tumors, for example, Wilms' tumor, lymphoma, and small cell tumor.

While epithelial tumors make 90% of ovarian cancer, germ cell tumors constitute around 2–3%, sex cord-stromal tumors around 5%, and miscellaneous around 1–2%. The standard surgical staging procedure for all ovarian neoplasms,

Table 5: Treatment and histopathology of germ cell tumors (n=11)

Surgery	HP	Adjuvant chemo	Outcome
Left oophorectomy	02 Mixed GCT	BEP	On follow-up
Left salpingo-oophorectomy	03 Dysgerminoma	BEP	On follow-up
B/L cyst excision	02 Yolk sac tumor	BEP	On follow-up
Left oophorectomy	01 Mature cystic teratomas	Close surveillance	On follow-up
Left oophorectomy	03 Mature cystic teratomas	Close surveillance	On follow-up

GCT: Germ cell tumor, BEP: Bleomycin, etoposide, and cisplatin

Table 6: Treatment given to granulosa cell tumors (n=13)

Surgery	Histopathology	Outcome
Right oophorectomy	04 Granulosa cell tumor	On close surveillance
Left salpingo-oophorectomy with right ovarian biopsy	02 Granulosa cell tumor	On close surveillance
Left oophorectomy	02 Granulosa cell tumor	On close surveillance
BSO with the disease in left ovary and cystic lesion in right ovary	03 Granulosa cell tumor	On close surveillance
TAH+BSO with the disease in right ovary	02 Granulosa cell tumor	On close surveillance

TAH+BSO: Total abdominal hysterectomy+bilateral salpingo-oophorectomy

except in young patients wishing to preserve fertility in whom staging is performed without removing contralateral ovary and tube and without hysterectomy, if the extent of disease allows to do so, is TAH + BSO.^[1] This histologically confirms the diagnosis, removes a major portion of disease, and helps in planning therapy and assessing prognosis. The main goal of the procedure is to estimate the extent of the disease while, ideally, achieving macroscopic clearance with a so-called maximal or optimal debulking procedure (≤ 1 cm diameter residual tumor).^[2] However, epithelial tumors usually are seen in elderly postmenopausal women and present in advanced stages, posing significant therapeutic challenges. Hence, in such patients alternative upfront treatment options such as intravenous chemotherapy rather than surgery may be considered, followed by interval cytoreduction. Theoretical advantages of neoadjuvant chemotherapy in this setting are a more rapid improvement in quality of life, and, if interval debulking surgery is ultimately performed, a technically more feasible operation with shorter hospitalization and less morbidity.^[2] In our study, we found use of neoadjuvant (upfront) systemic chemotherapy quite frequently especially for all Stage IV and Stage IIIC patients. In fact, our aim was to keep a very low threshold for upfront systemic chemotherapy while treating advanced epithelial ovarian cancer patients because it is our experience that an incompletely or inadequately performed surgical debulking does not help the cause but lands the patient in a situation where subsequent chemotherapy is not effective and rather poorly tolerated.

Although numerous combination chemotherapy regimens have been studied over the past few decades, the combination of platinum and a taxane compound such as paclitaxel is now the standard first-line in post-operative as well as in neoadjuvant setting with response rates of 70% for patients with sub optimally debulked disease and over 80% for patients who are optimally cytoreduced.^[5,6] A total of six cycles of such combination chemotherapy are considered a reasonable approach for the treatment of ovarian cancer patients when they require such treatments.^[2] For the patients in our study, we followed the commonly accepted approach of using combination of paclitaxel and carboplatin intravenously for three cycles in neoadjuvant setting followed by interval cytoreduction if feasible, or to continue chemo for three more cycles in patients who achieve less than optimum response after three cycles. Patients who did not show any response or who did not become eligible for an optimal debulking after six cycles were offered palliative second and further lines of chemotherapy and supportive measures.

Germ cell tumors occur in younger women, while sex cord-stromal tumors are seen in young as well as elderly. Both these histopathological types are often localized in

distribution, more amenable to surgical resection, and have a more favorable prognosis.^[2] Hence, in most cases an upfront surgery are done followed by a reassessment regarding any further adjuvant treatment. In the M.D. Anderson series four, all patients who received post-operative bleomycin, etoposide, and cisplatin chemotherapy remained disease free and hence, this regime remains the preferred regimen for patients with germ cell tumors.^[7] In our study, patients having mixed germ cell tumors, dysgerminoma, and yolk sac tumors were treated with same systemic chemotherapy after surgical resection (in most cases a fertility-preserving) had been done. Resection of mature teratomas has been shown to result in prolonged survival with little chance of recurrence two; hence, patients with mature teratoma histopathology in keeping with their benign nature and low chances of post-operative recurrences were subjected to close follow-up alone.

Ovarian sex cord-stromal (granulosa cell type) tumors often present with Stage I disease which has excellent prognosis, a 85% 10-year survival for this stage, and no need for post-operative adjuvant chemotherapy.^[8] In our study, all granulosa cell tumor patients had Stage I disease and hence no post-surgery chemotherapy was administered.

Ovarian cancer is a very chemosensitive disease with a number of classes of drugs showing activity.^[1]

Even though there have been major advances in the treatment of ovarian cancer with improvement insurvival, still most patients relapse and require further treatment, and only a minority with advanced disease achieve long-term survival. The results of the International Collaborative Ovarian Neoplasm Trial 1 and Adjuvant Chemotherapy in Ovarian Neoplasm Trial suggest that adjuvant chemotherapy can improve both progression-free and overall survival in patients with high risk, early stage ovarian cancer.^[2] The time tested first-line chemotherapy drugs consisting of a taxane such as paclitaxel and a platinum agent such as carboplatin two were used in our study though very late, around one and a ½ year back, we have started the use of vascular endothelial growth factor receptor blocker like bevacizumab in recurrent disease settings, especially since its cost was slashed and people could afford to buy it. Most patients respond to the combination of these drugs, but true to its nature, ovarian cancer especially epithelial type shows quite high rates of relapse, which mandates a change in the subsequent drugs being used based on the sensitivity profile of these tumors.

CONCLUSION

Our experience of managing and treating ovarian cancer patients in our department was very reassuring and

encouraging keeping in mind our more time-consuming work on radiotherapy equipment involving patient planning and monitoring the treatment protocols. Hence, it would be concluded that ovarian cancer patients can safely be treated in a radiation oncology department provided all contemporary treatment protocols are applied.

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Limb Reconstruction Using Masquelet Technique in the Treatment of Post-traumatic Compound Tibial Fractures with Bone Loss

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Abstract

Introduction: Traumatic segmental bone defects of leg are difficult problem to manage with significant long-term morbidity. Historically, due to difficulty in managing segmental bone defects, amputation was the preferred treatment. Later over the last half-century, limb salvage was done using various techniques such as vascularized fibular grafts, acute limb shortening, external fixator application, and filling the defect with autograft or allograft. More recently, Masquelet described the use of cement spacer application within this defect and staged bone grafting within the induced biomembrane formed around the spacer as a potential treatment strategy to manage these bone defects.

Method: This study describes the clinical, radiological, and functional outcome in 20 patients with traumatic bone loss of up to 5 cm managed using Masquelet technique.

Results: The outcome was analyzed using Association for the study and application of methods of ilizarov (ASAMI) score which showed excellent results in 10 patients, good in 5 patients, fair in 2 patients, and poor in 3 patients.

Conclusion: We conclude that the induced membrane technique can be a valuable addition to the armamentarium of limb reconstruction procedures in patients with small bone defects with or without soft tissue injury.

Key words: Antibiotic cement spacer, Bone grafting, External fixator, Induced biomembrane, Limb salvage, Masquelet technique, Soft tissue reconstruction, Traumatic segmental bone defects

INTRODUCTION

Reconstruction of traumatic segmental bone loss that occurs after compound tibial fractures is a major challenge in orthopedic practice due to the risk of infection, prolonged healing time, and no guarantee of a satisfactory clinical outcome with physical and psychological stress to the patient.^[1] Historically in the early 20th century, due to these problems involved in limb salvage surgery and also lack of technically demanding procedures involving other

specialties, these patients were treated by amputation. Modern techniques of fracture stabilization and soft tissue reconstruction in more severely injured limb with bone loss can now be salvaged in majority of the patients. The French technique of bone grafting within the induced membrane, otherwise known as Masquelet technique, offers a viable alternative for limb reconstruction with minimal complications.^[2,3] Our study was intended to review the clinical, radiological, and functional outcome in the reconstruction of compound traumatic tibial bone defects managed by Masquelet technique.

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MATERIALS AND METHODS

Patients with compound traumatic tibial bone defects were treated by the induced membrane technique in our Institute of Orthopaedics and Traumatology, Rajiv Gandhi Government General Hospital between August 2016 and

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August 2019. The patients included in our study were between 18 and 60 years of age with traumatic compound tibial fractures with bone defects in the diaphysis or metaphysis of size <5 cm with or without soft tissue defect. The exclusion criteria included diaphyseal or metaphyseal defects size more than 5 cm, articular defects, patients with bone defects of etiology other than trauma, patients with persistent infection even after cement spacer application, patients with neurovascular injury, and patients with unreconstructable limb. This study was performed after obtaining Institute's ethical committee approval and patients informed consent before the surgery.

Procedure

Patients with reconstructable limb were evaluated for injury type, size of the soft tissue, and bone defect. In patients with compound fractures, opinion was obtained from plastic and vascular surgeons in the emergency department. Poor prognostic signs for limb salvage were major soft tissue injury, an ischemic time in excess of 6 h, the presence of significant neurological deficit, especially of the tibial nerve, and other major organ injuries. Salvageable and reconstructable limbs were treated in the emergency theatre by surgical debridement to ensure complete removal of contaminated soft tissue and devitalized bone if necessary. An intravenous broad-spectrum antibiotic was given to all patients in the emergency room. Skeletal stabilization was achieved by using external fixator. All compound fractures with bone defects after debridement were filled with antibiotic impregnated cemented spacer [Figure 1]. We preferred to use 2 g vancomycin or gentamicin per 40 g of cement. The cement spacer was kept for a period of 6–8 weeks. Cultures were taken for all patients at the time of debridements and postoperatively if there was any discharge. Antibiotics were given according to the culture and sensitivity report.

The second stage of bone grafting was performed 4–8 weeks after the first surgery. This allowed the formation of biomembrane. The defect was approached through the previous incision down to the encapsulating cement spacer. Once exposed, the cement spacer was removed and the defect was filled with cancellous bone graft harvested from the iliac crest [Figure 2]. An intravenous antibiotic for 2 weeks according to the previous culture and sensitivity report and oral antibiotics for another 3 weeks or until culture report was negative. Patients were followed up clinically and radiologically for graft integration every 6 weeks. Non-weight bearing walking was allowed until radiological signs of union. Partial weight-bearing with the external fixator insitu was continued until radiological consolidation of the graft. Once solid union was achieved and external fixator was removed after dynamization. Functional assessment was measured using ASAMI scoring system.

RESULTS

A total of 20 patients were identified within the time period. All 20 patients were males with average age of 35.5 years (range 18–55 years). In our study, the mode of injury was road traffic accident in sixteen patients and fall from height in four patients. The bone defect size varied from 2 cm to 5 cm (bone defect <3 cm in 13 patients and 3–5 cm bone defect in 7 patients). Grade IIIa compound fracture in 8 patients and Grade IIIb in 12 patients, among them in 4 patients defect was in the proximal tibia, middle third in 11 patients and distal third in 5 patients. The average time between injury to Stage I procedure was 30 days (range 10–90 days) and time duration between Stage I and Stage II was 43.8 days (range 32–56 days). The soft tissue injuries were managed with primary closure of the skin in 2 patients, split skin grafting in 6 patients, and fasciocutaneous flap in 12 patients. The average complete bony union time was 8 months (range 6–12 months). The external fixator was removed after dynamization in all patients except in two patients, the fixator was removed earlier. There was persistent infection in 1 case, non-union in 2 cases, malalignment in 4 cases, and limb shortening of 1 cm in 5 cases. The outcome was analyzed using ASAMI score which showed excellent results in 10 patients, good in 5 patients, fair in 2 patients, and poor in 3 patients.

DISCUSSION

Management of bone defects has received great attention recently by scientific and clinical communities. There are various techniques available in the treatment of compound tibial fractures with bone loss such as circular ring fixators and limb reconstruction systems using the distraction

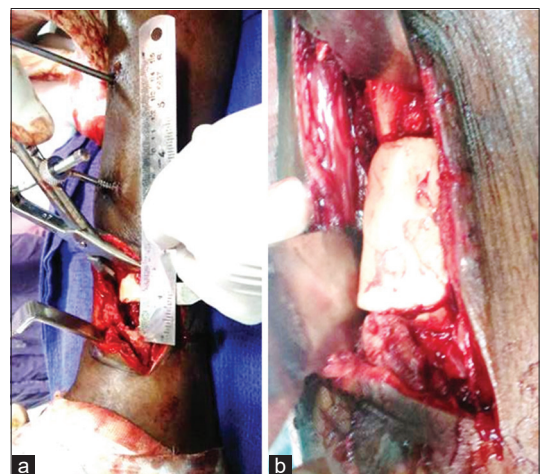


Figure 1: (a) Demonstrating defect size measurement after excising all infected and necrotic bone. (b) Intraoperative photograph showing cement spacer application between the bone defect

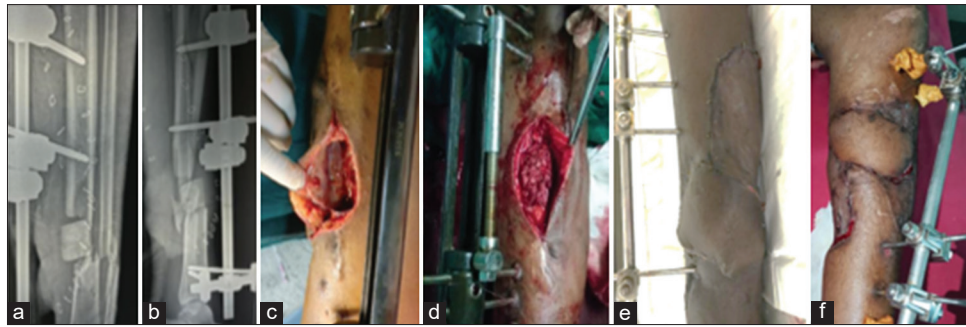


Figure 2: (a and b) X-ray showing antibiotic spacer, (c) intraoperative photograph demonstrating the mature biomembrane of 1 mm thickness, (d) intraoperative photograph showing Stage II surgery – filling the defect with morselized iliac crest autografts, (e) shows inferomedially based transposition fasciocutaneous flap done for soft tissue defect in lower leg, (f) shows superiorly based transposition flap done for middle third soft tissue defect in leg

osteogenesis principle described by Ilizarov and Ledyayev,^[4] but this requires specialized training. In some series, the authors have used vascularized fibula graft for large bone defects with varying results, it is limited by pedicle length and it involves microsurgical anastomosis.^[5] Recently, the induced membrane is a relatively newer method described by Pelissier *et al.*,^[2,3] which is a two-staged technique for reconstruction of bone defect. It is a simple and straight forward procedure with good results. Only few studies have used this technique in the treatment of posttraumatic bone defects until now.^[6-8]

Recent literature has shown that this biomembrane can be 0.5–1 mm thick.^[3] Pelissier *et al.* concluded that these membranes (pseudo-periosteum) possessed a rich capillary network and enriched with growth factors (vascular endothelial growth factor and transforming growth factor beta-1) and osteoinductive factors (bone morphogenetic protein-2). Immunohistochemical studies on induced membranes in a sheep model by Viateau *et al.*^[9] established the presence of cells expressing transcription factor core-binding factor alpha 1 and type-1 collagen-rich extracellular matrix. With the above characteristics, the membrane prevents resorption of bone graft, acts as a barrier to outward diffusion of growth and osteoinductive factors, and it provides a source of osteoprogenitor cells and vascular cells supporting revascularization and osseous consolidation.^[2]

Originally, the bone cement used by many authors was without antibiotic impregnation. In traumatic wounds, antibiotic impregnated cement beads or spacers are often used for local antibiotic administration to the soft tissue bed in high concentration without systemic side effects. In addition, the advantages of inserting such a spacer include maintaining a well-defined void to allow for later placement of bone graft, providing structural support, offloading the implant, inducing the formation of biomembranes, and increased concentration of antibiotics locally.^[10] We used antibiotic impregnated cement as previously done by Wong *et al.* in his study patients.

It was found that the 1-month-old membrane has higher osteogenesis-improving capabilities compared to the 2-month-old membrane. Hence, the study concluded that optimal time for performing second-stage surgery may be within a month after implantation of foreign material (cement spacer).^[11]

In all our patients, the presence of induced membrane was visualized at the fracture gap on removal of the cement spacer as described by Woon *et al.*^[12] We think that at the time of trauma some residual native periosteum is left uninjured so that periosteum along with the biomembrane helps in regeneration of this new bone.

There was persistent infection in 1 case, non-union in 2 cases, malalignment in 4 cases, and limb shortening of 1 cm in 5 patients. One patient underwent amputation for persistent infection in the distal bone defect site and the soft tissue coverage using flap also failed. The 2 patients with nonunion were subjected for ilizarov frames and limb shortening was managed with heel rise.

The outcomes were analyzed using ASAMI score which showed excellent results in 10 patients, good in 5 patients, fair in 2 patients, and poor in 3 patients. The results in our study were comparable with the study done by Karger *et al.*^[6] He reported his experience with the Masquelet technique in the treatment of chronic posttraumatic diaphyseal long bone defect with 90% success rate.

CONCLUSION

The induced membrane technique can be a valuable addition to the armamentarium of limb reconstruction procedures in patients with medium size bone defects with or without soft tissue loss. However, this method of treatment requires long consolidation time and prolonged non-weight-bearing compared to other treatment options. This technique does not require specialized equipment

and can be performed easily in lower trauma centers by surgeons with varying experience and capabilities. We also think that at the time of trauma some residual native periosteum is left uninjured so that periosteum along with the biomembrane helps in regeneration of this new bone.

ACKNOWLEDGMENT

The authors declare that they have no conflict of interests, any grant, or financial profit related to this clinical study.

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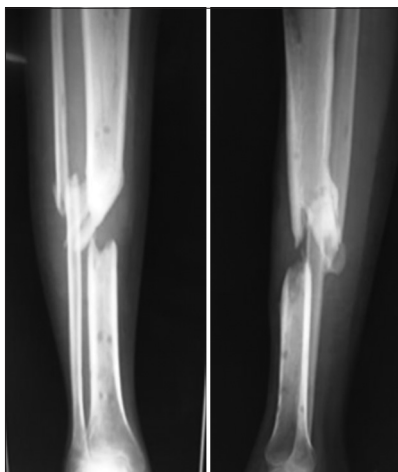
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CASE ILLUSTRATION

A 19-year-old male with the diagnosis of Grade IIIb compound fracture both bones right leg and bone defect size 3 cm

PRE-OPERATIVE



POST-OPERATIVE

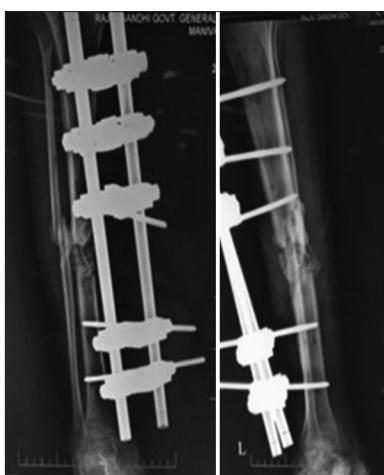
Post-stage I



Post-stage I



12 weeks post-operative



1 year and 8 months post-operative



Knowledge, Attitude, and Practice Study of Adolescent Girls about Safe Sexual Practices

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Abstract

Introduction: Reproductive health of adolescent girls is crucial in determining the health of future generations. Sexually transmitted diseases (STDs) are a major public health problem not only in India but also all over the world. The World Health Organization estimates that 150–300 million new cases of curable STDs occur annually worldwide.

Objective: The aim of this study was to evaluate the adolescent girls' knowledge and attitude toward sexual practices and STDs and HIV.

Materials and Methods: A cross-sectional study was conducted in the city of Jammu from July 2019 to September 2019. The study included adolescent girls who have attended the Outpatient Department in SMGS Hospital for varied complaints and college-going adolescent girls from different colleges of Jammu region. A total of 1000 girls were included in the study.

Results: About girls were aware of all the signs of adolescence. Majority (81%) had the idea about various aspects of sex education. Most (88%) of the girls wanted sex education to be included in the curriculum and 52% wanted it to be started at 13–15 years of age. Emergency contraceptives were known only to 28%. STD awareness was present in only 34.6% of girls. About 95.6% had heard about HIV/AIDS, but only 32.1% knew about abbreviation of AIDS. Only 54% were aware of the right legal age of marriage for girls.

Conclusion: Adolescents should be given education on sexual health in schools and colleges without disturbing the sociocultural norms of the society. Preventions and precautionary measures regarding sexual health should be taught to the young generation to have a healthy nation.

Key words: Adolescents, Awareness, Contraceptives, HIV, Sex education, Sexually transmitted diseases

INTRODUCTION

The World Health Organization defines adolescents as young people aged between 10 and 19 years.^[1] Among the total population of adolescents, 1.3 billion are in developing countries and more than 500 million of them are adolescent females. The adolescent age group represents about one-fifth of the population in India.^[2] About 10.3% of female population belong to the age group of 15–19 years in India and incidence of teenage pregnancy varies from 3.2% to 18.6%.^[3]

In developing countries for many girls, mere the onset of puberty leads to many changes such as child marriage, early pregnancy, heightened vulnerability to school leaving, sexual exploitation, HIV, coercion, and violence. As compared to older women, adolescent girls are less likely to access sexual and reproductive health care.^[4] Improvement of reproductive health education and the social status of women are an important tool for further progress in fertility reduction.^[5]

Young people aged between 15 and 24 years account for 41% of new HIV infections worldwide.^[6] About 5.2 million HIV-infected individuals are present in India, which is the world's second largest. About 35% of reported HIV infection in India occurs among young people between 15 and 24 years of age which indicate that young people are highly vulnerable. The epidemic is becoming more "feminized" with more

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women becoming infected. The present challenge is to keep the young population free from HIV.^[7] Higher risk-taking behavior acquired during adolescence has long-term health consequences. Lack of appropriate information on. Sexually transmitted diseases (STDs), HIV/AIDS, contraception, conception and issues related to adolescent sexuality, and a lack of preventive services, with limited access to service compounds the matter considerably.^[8]

School systems are ambivalent about imparting education on sexual health in India. Teachers are often too embarrassed and uncomfortable to effectively instruct their students, even when sexual and reproductive health education exist in the school curriculum.

Information about knowledge and attitude is necessary to better understand the dynamics of the STD and to plan preventive measures.

Aims and Objectives

The aim of this study was to evaluate the adolescent girls' knowledge and attitude toward sexual practices and STDs and HIV.

MATERIALS AND METHODS

It was a cross-sectional study carried out in Jammu city over a period of 3 months from July to September 2019.

Inclusion Criteria

The following criteria were included in the study:

1. All adolescents girls who have attended the Outpatient Department in SMGS Hospital for varied problems
2. College-going adolescent girls from different colleges of Jammu region.

Exclusion Criteria

Married adolescent girls were excluded from the study.

A total of 1000 girls were included in the study. A questionnaire was prepared regarding various aspects of reproductive health and all the girls were asked to answer the questionnaire. The data were analyzed and results were tabulated.

RESULTS

Table 1 shows that most of the participants (86%) belonged to the age group of 14–16 years. Almost 81% of participants came from the nuclear family. About 42% of mothers were educated up to secondary school and about 37% of mothers were graduated and only 6% were postgraduate.

Table 2 shows that about 68% of girls were aware of physical signs of adolescence. About 82% had awareness of

adolescent health. About 86% had the idea regarding cancer risk and STD association with early sexual activity and multiple sexual partners. About 54% were aware of the right legal age of marriage. About 28% had a sexual relationship and 4% of them had relationship with multiple partners. About 88% were aware that there is a risk of abortion with sexual relationship. About 0.2% of girls admit that they got pregnant. About 28% were aware of emergency contraception. About 2% admit that they have used contraception and 42% knew about condom as a method of contraception.

Table 3 shows the knowledge of adolescents regarding STDs and HIV/AIDS. About 95.6% (956) of the girls had heard about HIV, but only 32.1% knew the abbreviation of AIDS. A total of 66.5% (656) of girls knew that HIV is incurable. Regarding modes of transmission of HIV/AIDS, majority knew that it is transmitted by sexual contact 790 (79%), followed by infected needles and blades 380 (38%), blood transfusion 260 (26%), and only 110 (11%) knew that it can be transmitted from mother to fetus. About 346 (34.6%) aware that there are other STDs apart from HIV, but very few knew about its signs and symptoms. Only 125 (12.5%) knew that the treatment of both the partners is must for treating STDs.

Table 1: Sociodemographic characteristics of participants

Variables	n (%)
Age (years)	
11–13	60 (6)
14–16	860 (86)
17–19	80 (8)
Type of family	
Nuclear	810 (81)
Joint	190 (19)
Mother's literacy status	
Primary	150 (15)
Secondary	420 (42)
Graduate	370 (37)
Postgraduate	60 (6)

Table 2: Distribution of participants according to reproductive health awareness

Health awareness	n (%)
Awareness of physical signs of adolescence	680 (68)
Awareness of the need for adolescent health (nutrition, exercise, sleep, and hygiene)	820 (82)
Early sexual activity and associated cancer risk	860 (86)
Awareness of the right legal age of marriage	540 (54)
Had sexual relation	28 (2.8)
Had multiple sexual partners	4 (0.4)
Aware of abortion risk	880 (88)
Have you ever been pregnant	2 (0.2)
Awareness of emergency contraceptives	280 (28)
Ever use contraception	20 (2)
Do you know condom as a method of contraception	420 (42)
Think to consult doctors for their reproductive health problem	980 (98)

Table 4 shows the attitude of adolescents toward sex education. Majority of the girls (81%) were aware of all the aspects of sex education, namely, study of physiology, safe sex, and reproductive health problem. Most of the girls (88%) wanted sex education to be included in the curriculum and majority, i.e., 52% wanted it to be started between 13 and 15 years. Most of girls, i.e., 73% had received sex education, media being the major source (63%) followed by friends (26%). About 42% think that doctor is the right person to discuss

reproductive health problems followed by parents (30%) and friends (25%).

DISCUSSION

Our country has a full range of Western-type media which appeals our new generation promoting message of liberation, self-development, and taking them away from traditional ways of life. Unfortunately, these messages implicitly and explicitly encourage sexual freedom without much weight on responsibility for sexual behavior finally resulting in various problems in their life.

Majority of the girls in our study were in the age group of 14–16 years (86%). Most of the girls came from the nuclear family (81%). About 42% of mothers were educated up to secondary school and about 37% of mothers were graduated and only 6% were postgraduate.

In our study, 82% of the girls were aware of the physical signs of adolescence and 82% were aware of the need for adolescence health and these rates are comparable with the study done by Agarwal *et al.*,^[9] in which 78% of subjects knew about physical signs of adolescence and 88% were aware of the need for adolescent health. About 86% of the subjects in our study had idea regarding risk of cancer and its association with early sexual activity. Similar rates were observed by Agarwal *et al.*^[9] in their study (94%). Regarding awareness of the right legal age of marriage, only 54% were aware of the right age of marriage in our study. Similar findings were reported by Agarwal *et al.*,^[9] 46% of subjects in their study had idea about the right legal age of marriage. About 2.8% (28) of girls in our study had premarital sexual relation and 0.4% (4) had more than one sexual partner. While in the study by Agarwal *et al.*,^[9] 6% of English medium girls and 0.7% of Hindi medium girls had premarital sexual relationship and none had more than one sexual partner. As per the study by Grunbaum *et al.*,^[10] 47% of high school students had sexual intercourse and 14% of high school students had four or more sex partners, thus showing the rates are higher in Western countries. However, data from Bangladesh in the study done by Sharma^[11] revealed a very high incidence of premarital sex. More males (61%) as compared to females (24%) had premarital sexual activity among adolescent.

Many girls knew that pregnancy can be prevented with the use of contraceptives. Condom was most widely known contraception among adolescents (42%) while emergency contraceptives were least known (28%) and these rates are comparable with the study by Agarwal *et al.*,^[9] 80% of the subjects had idea about contraceptives and 19% knew about emergency contraceptives. Similar findings were observed by Gopal *et al.*^[12] Sexual exposure among young girls who are unmarried is occasional and unplanned so they are in more need of emergency contraceptives.

Table 3: Distribution of participants according to their knowledge of STDs/HIV

Variables	n (%)
Ever heard of HIV/AIDS	
Yes	956 (95.6)
No	44 (4.4)
Abbreviation of AIDS	
Knew	321 (32.1)
Did not know	679 (67.9)
HIV is incurable	
Yes	665 (66.5)
No	335 (33.5)
Modes of transmission of HIV	
Sexual contact	790 (79)
Infected needles/blades	380 (38)
Blood transfusion	260 (26)
Mother to fetus	110 (11)
STD awareness	
Yes	346 (34.6)
No	654 (65.4)
Ulcers in the genital area is a sign of STDs	
Yes	174 (17.4)
No	826 (82.6)
Vaginal discharge could be a sign of STDs	
Yes	350 (35)
No	650 (65)
Treatment of both the partners is must for STDs	
Yes	125 (12.5)
No	234 (23.4)
Did not know	641 (64.1)

STDs: Sexually transmitted diseases

Table 4: Attitude toward sex education

Variables	n (%)
Awareness of sex education	810 (81)
Wanted sex education to be included in the curriculum	880 (88)
Received sex education	730 (73)
Source of sex education	
Parents	30 (3)
Media	630 (63)
Friends	260 (26)
Teachers	80 (8)
Right age for sex education	
13–15 years	520 (52)
16–18 years	480 (48)
Who is the right person to discuss about reproductive health	
Parents	300 (30)
Teachers	30 (3)
Friends	250 (25)
Doctors	420 (42)

In our study, majority (95.6%) of the subjects had heard about HIV/AIDS and only 32.1% knew about the abbreviation of AIDS. In the study carried out by Ahmed and Kusuma,^[13] 94.06% had heard of HIV/AIDS and 40.86% knew the full form of AIDS. Similar findings were reported by Lal *et al.*^[14] and Gopal *et al.*,^[12] in their study, all the students had heard of HIV/AIDS, 51.4% knew the full form of AIDS. In our study, 66.5% of adolescent girls considered that HIV/AIDS could not be cured and in a study by Ahmed and Kusuma,^[13] 62.06% knew this. Regarding modes of transmission in our study, majority knew that it is by sexual contact 79%, followed by infected needles and blades 38%, through blood transfusion 26%, and only 11% knew that it can be transmitted from mother to fetus. Similar findings were reported by Ahmed and Kusuma^[13] and Lal *et al.*^[14] in their study. About 34.6% of girls were aware of STDs in our study while 87% of girls had STD awareness in a study by Agarwal *et al.*^[9] About 86% was reported by Gopal *et al.*^[12] In another study conducted by Das and Desai,^[15] they found that 54.9% of girls had heard about STD, but 65.7% did not know about any feature of STD.

Regarding the source of sex education and information about HIV and STDs, it was from mass media mainly 63%, followed by friends 26% and teachers 8% and least was from parents. Ahmed and Kusuma^[13] and Lal *et al.*^[14] also found the similar findings. This reveals that Information, Education, and Communication activities through mass media are very effective. Girls are getting least information from the teachers who otherwise should play a major role in educating the students. Even parents and siblings are playing a minimal role in providing the information; it means that such types of talks are not encouraged at home. Many (88%) students want sex education to be included in the curriculum. Since 2006, Government of India has launched adolescent reproductive and sexual health services to provide equitable, comprehensive, and accessible services such as counseling on nutrition and sexual problems, immunization, awareness of contraceptives, reproductive tract infections, and HIV/AIDS, behavioral risk factors, and services for pregnancy/abortion.^[16] However, the benefits of these services are yet to be realized by the beneficiaries. School education must directly address stigmatizing attitudes about sex education and HIV/AIDS and fills in the gap regarding sex education and HIV/AIDS.

CONCLUSION

Sexual health is an important area of concern in adolescent health and is intimately connected with the Reproductive and

Child Health, population control, and HIV/AIDS prevention. However, it is also a sensitive issue due to sociocultural taboo of discussion about sexuality and reproduction in the Indian society. Adolescents should be given education on sexual health in schools and colleges without disturbing the sociocultural norms of the society. Preventions and precautionary measures regarding sexual health should be taught to the young generation to have a healthy nation.

Ethical Approval

The study is approved by the Institutional Ethics Committee.

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Clinical Outcome of Monostotic Fibrous Dysplasia Over Proximal Femur Treated with Intramedullary Nailing and Bisphosphonate Therapy

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Abstract

Introduction: Fibrous dysplasia (FD) of bone is an enigma with no proper guideline. Treatment currently consists of curettage and bone grafting in an attempt to eradicate the lesion and to prevent progressive deformity. No definite criteria have been established to identify patients at high risk of presenting pathological fractures.

Purpose: The purpose of the study was to explore the effect of combination bisphosphonate therapy in diminishing pain, preventing fractures, lowering N-telopeptide values, and leading to partial resolution of FD lesions.

Materials and Methods: At Medical College, Kolkata, 10 patients with monostotic FD in lower extremities were treated between 2014 and 2018 and included in the study. All patients underwent full skeletal survey followed by core needle biopsy with the help of magnetic resonance imaging and C-arm guidance. After confirmation, closed intramedullary nail without reaming was used in all cases. Bone grafting was not performed. Zoledronic acid was given intravenously at the dose of 4 mg every 6 months. Patients were allowed full weight-bearing on the affected extremities on the 2nd post-operative day.

Results: Seven patients were female and three were male; their mean age was 26.9 years. The mean duration of follow-up was 30.5 months. We get good to average results. Clinico-radiological improvement of all cases was observed.

Conclusion: As a result of this study, we believe that intramedullary fixation can be performed successfully. Treatment of monostotic fibrous dysplasia with adjuvant bisphosphonate therapy resulted in effective pain control and early return of functional activity. This will avoid problems that may occur following pathological fractures.

Key words: Intramedullary nailing, Monostotic fibrous dysplasia, Zoledronic acid

INTRODUCTION

Fibrous dysplasia (FD) is a challenge to the orthopedic surgeon. FD, first identified by Lichtenstein in 1938,^[1] is an anomaly characterized by widening of the affected bone with cortical thinning and presence of fibro-osseous tissue inside the bone. There may also be areas with islands of cartilage or cysts, and some lesions may be expansile. It may present under a monostotic or polyostotic form.

FD of the proximal femur is difficult to treat due to the varied presentations such as pain, pathological fractures, severe deformity, and high chances of recurrence.^[2] Lesions have a tendency to recur and may result in pathological fractures following curettage and grafting.^[3] No definite criteria have been established to identify patients at high risk of presenting pathological fractures.^[4] Clear guidelines for orthopedic management of FD in the proximal femur have not been established.

We reviewed published data on the treatment of FD with bisphosphonates, calcium, Vitamin D, and phosphorus. We present our results with intramedullary nailing along with intravenous zoledronic acid 4 mg in every 6 months, in 10 patients with monostotic FD, pain increasing with movement. To the best of our knowledge, no previous study has focused on intramedullary nailing of the proximal

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femur along with bisphosphonate therapy over monostotic FD in symptomatic patients.

The aim of our study was to analyze the various presentations of FD of the proximal femur such as pain, fractures, and shepherd crook deformity and describe the results of the various treatment modalities for the same.

MATERIALS AND METHODS

Ten patients with monostotic FD in their upper extremities operated between 2014 and 2018 at Medical College, Kolkata, were included in the study. Seven patients were female and three were male. The mean age of the patients was 26.9 years (range: 19–34). The mean duration of follow-up was 30.5 months. All patients underwent full skeletal survey followed by core needle biopsy with the help of magnetic resonance imaging and C-arm guidance. Patients who had been diagnosed with FD with functional pain or pathological fractures were included in the study and undergone biopsy confirmation and intramedullary nailing, whereas patients who had no functional pain and incidentally diagnosed were excluded from the study. After taking written consent from every patient and their family member, we performed core needle biopsy confirmation for all cases. Under C-arm guidance, we performed intramedullary nail titanium, preferably the third-generation long gamma nail for better fixation of proximal femur, as it is a weight-bearing bone. We put all patients under medical therapy of intravenous zoledronic acid 4 mg dissolved with 100 ml normal saline. The prepared solution was infused slowly over 30 min half yearly. We avoid local curettage and bone grafting because FD is notorious for its recurrence and local fibrous tissue prevents the activity of bone grafting. As well as, it is an open procedure; hence, post-operative morbidity is higher. Resorption and recurrence secondary to grafting after curettage are other problems. Reaming was not used before nailing in our patients, as it was deemed unnecessary for nailing of non-fractured long bones, added to the fact that it might have contributed to weakening the bone to some extent.

We planned for adjuvant medical therapy as we did not use bone graft. Radiological follow up was done to see the effect of zoledronic acid over the pathological fibrous tissue. Functional pain, size of the lesion on radiographs, and stability of prophylactic fixation were evaluated in follow up visits every 6 months. A visual analog scale (VAS) was used in assessing functional pain.

RESULTS

We have done an observational prospective study [Figure 1]. Mean VAS for functional pain was $5.33 \pm$

0.65 preoperatively and 2.26 ± 0.57 at final follow-up ($P < 0.05$). We present our results with intramedullary nailing along with intravenous zoledronic acid 4 mg in every 6 months, in 10 patients with monostotic FD, pain increasing with movement. For statistical analysis, Wilcoxon signed-rank test (with Bonferroni correction) was used and $P < 0.05$ was considered as statistically significant.

Seven patients were female and three were male; their mean age was 26.9 years. The mean duration of follow-up was 30.5 months. Recurrences, pathological fractures, and deformities secondary to the lesion occurred in none of the patients.

DISCUSSION

FD is an orthopedic condition with a wide spectrum of presentation. The treatment of the dysplastic lesions in the proximal femur region is still somewhat unclear and varies widely.^[5] FD of the bone can present as three clinical forms: Monostotic, polyostotic, and as a part of a McCune-Albright syndrome. Lichtenstein^[1] is credited with having coined the term FD, in 1938; in 1942, Lichtenstein and Jaffe^[6] reviewed all known cases of this entity. Those authors established that FD of bone was a distinct pathological and clinical condition. FD may occur due to a failure in remodeling of primitive bone into mature lamellar bone, which negatively affects the mechanical properties of the affected bone. Thus, pain, deformities, and pathological fractures may occur. It is generally accepted that monostotic lesions are easier to treat, are associated with better outcomes, necessitate fewer operations, and result in fewer fractures.^[7]

Healing after pathological fractures in dysplastic bones is comparable with that of normal bone. However, the callus includes dysplastic bone tissue.^[8] The lesion persists despite the healing of the fracture. The accepted principle in the treatment of lesions that are painful or at risk for fracture, even if asymptomatic, is curettage and grafting.^[9] However, according to our review of literature, it is uncertain whether this form of treatment offers a definitive solution.^[10] It has also been reported that curettage or biopsy of an isolated lesion may predispose the bone to pathological fracture or progression of the lesion.^[3] There is no accurate indication of the rate of success of curettage and bone grafting. In their study on patients with FD localized in the neck of the femur, Guille *et al.*^[9] have shown that the lesion was not eradicated with curettage and grafting, and the bone was further weakened due to deformation of the trabecular structure in dysplastic bone as a result of curettage. In the present



Figure 1: (a) Pre-operative X-ray. (b) Magnetic resonance imaging. (c) Core needle biopsy. (d) Histopathology. (e) Post-operative. (f) Follow up post operative X-ray. (g) Post operative rehab painless squatting. (h) Post zoledronic acid therapy 1 yr

Cases	Sex	Age (years)	Site	Indication of intervention	Follow-up (months)	Pre-operative VAS	Post-operative VAS
1	M	34	Proximal femur	Pain	32	5.8	2.4
2	F	23	Proximal femur	Pathological [#]	30	4.9	1.7
3	F	19	Proximal femur	Pain	26	6.4	1.8
4	F	29	Proximal femur	Pain	32	5.7	2
5	M	23	Proximal femur	Pain	27	4.9	1.6
6	F	20	Proximal femur	Pain	29	6.1	2.5
7	F	30	Proximal femur	Pathological [#]	25	5.2	3
8	M	24	Proximal femur	Pain	25	5.3	2.5
9	F	25	Proximal femur	Pain	28	5.7	2.9
10	M	26	Proximal femur	Pathological [#]	29	4.5	1.8

M: Male, F: Female, VAS: Visual analog scale

series, we did not perform curettage and bone grafting. Resorption and recurrence secondary to grafting after curettage are other problems. Guille *et al.*^[10] have shown in their study that all cancellous or cortical grafts they used, in addition to autogenous fibular strut grafts, were resorbed. In addition, according to DiCaprio and Enneking,^[4] cortical grafts are more durable compared to cancellous grafts, as they are only partly replaced by dysplastic host bone: Only their osteonal portion (about 50% of the graft) is replaced by dysplastic bone,

whereas the interstitial lamellae are not replaced and persist. The size of the lesion may change with skeletal growth; however, it is difficult to differentiate whether this is secondary to skeletal growth or to progression of the lesion.^[7] Since FD is a genetic disorder which is not curable, the treatment modality should be long lasting. No definite criteria are available to state in which cases pathological fracture will occur.^[4] In the multicentric study of the European Paediatric Orthopaedic Society, fractures had occurred in 47% of patients with monostotic FD.^[11]

Therefore, we recommend prophylactic intramedullary fixation in patients with monostotic FD. This prophylactic therapy avoids complications such as delayed union and deformities following fracture. A vascularized fibula has been used in some cases following fracture.^[12] It appears more reasonable to take the necessary steps to prevent fracture, considering the technical difficulty, delayed weight-bearing, risks of graft resorption, and refracture in addition to high costs, if the affected bone is not strengthened and fractures.

CONCLUSION

As a result of this study, we believe that intramedullary fixation can be performed successfully in cases of monostotic FD with adjuvant bisphosphonate therapy proven to increase function activity and control of pain. This will avoid problems that may occur following pathological fractures.

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Comparative Evaluation of Ropivacaine Alone with Ropivacaine Nalbuphine Combination in Supraclavicular Brachial Plexus Block for Upper Limb Surgery

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Abstract

Background and Aims: The benefit of post-operative analgesia in regional block is short lived due to limited duration of the action of local anesthetics. Various adjuvants have been tried to enhance the duration of analgesia. The aim of this study was to evaluate the analgesic efficacy and safety of nalbuphine as an adjuvant to 0.5% ropivacaine for supraclavicular brachial plexus block.

Materials and Methods: A prospective, randomized, double-blind study was conducted on 60 patients of American Society of Anesthesiologists physical Status I/II aged 18–60 years scheduled for upper limb surgeries under supraclavicular brachial plexus block. The patients were randomly allocated into two groups of 30 each to receive either 30 ml of 0.5% ropivacaine with 1 ml of normal saline (Group R) or 30 ml of 0.5% ropivacaine with 1 ml (10 mg) of nalbuphine (Group RN). The onset and duration of sensory and motor block, duration of analgesia, and side effects were noted.

Results: The mean onset time for a complete sensory and motor block in Group RN was shorter (8.37 ± 0.79 min; 17.67 ± 1.07 min) as compare to Group R (10.9 ± 1.11 min; 19.17 ± 0.86 min). The mean duration of sensory and motor block in Group RN was longer (725.67 ± 16.06 min; 420.33 ± 14.94 min) as compare to Group R (473.0 ± 22.67 min; 359.67 ± 26.89 min). The mean duration of analgesia in Group RN was 846.33 ± 72.50 min and in Group R was 588.0 ± 27.37 min. All results were statistically significant ($P < 0.0001$). No significant side effects were observed in any of the two groups ($P > 0.05$).

Conclusion: Nalbuphine as an adjuvant to ropivacaine in the supraclavicular brachial block significantly shortens the onset time for sensory and motor block and prolongs the duration of sensory and motor blocks with longer duration of post-operative analgesia.

Key words: Analgesia, Nalbuphine, Ropivacaine, Supraclavicular brachial plexus

INTRODUCTION

Regional anesthesia is an important part of the anesthesiologist's armamentarium. Regional anesthesia is particularly indicated for patients undergoing peripheral

limb surgery because it provides effective intraoperative anesthesia and post-operative pain control. Brachial plexus block is a versatile and reliable regional anesthetic technique and a suitable alternative to general anesthesia for upper limb surgical procedures. Supraclavicular approach of brachial plexus block is the most commonly used approach and provides the most complete and reliable anesthesia for upper limb surgery. For brachial plexus block, a drug that has a fast onset, long duration, and minimal toxicity could be an advantage. The quest for safer local anesthetics began toward the end of the 19th century. Ropivacaine is a long-acting local anesthetic drug belonging to aminoamide group. They are pure S(–) enantiomer, unlike bupivacaine

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which is a racemic mixture. These S enantiomers are considered to produce less neurotoxicity and cardiotoxicity than racemic mixtures or the R-enantiomers of local anesthetics.^[1] Local anesthetics alone for supraclavicular brachial plexus block provide good operative conditions but have a shorter duration of post-operative analgesia. Hence, various drugs such as opioids,^[2] clonidine,^[3] dexamethasone,^[4] midazolam,^[5] and magnesium^[6] were used as an adjuvant with local anesthetics in brachial plexus block.

Nalbuphine, an opioid agonist-antagonist, is used as adjuvant to local anesthetic for various regional anesthetic techniques due to its affinity to κ -opioid receptors to enhance the duration of analgesia. It is widely studied as an adjuvant to local anesthetics in central neuraxial techniques by epidural, caudal, and intrathecal routes. However, after research in literature, we did not find much published data studying the effect of nalbuphine as an adjuvant to local anesthetics in peripheral nerve blocks.^[7]

The aim of our study was to assess the characteristics of supraclavicular brachial plexus block using 0.5% ropivacaine and to study the effect of nalbuphine as an adjuvant.

MATERIALS AND METHODS

After approval of the institutional ethical committee, this prospective, double-blind, randomized trial was conducted on 60 patients of the American Society of Anesthesiologists physical Status I and II of both genders, aged 18–60 years, scheduled for various upper limb surgeries after obtaining written informed consent from each patient. Patients who had not given consent, patients with coagulopathy, infection at the site of block, preexisting peripheral neuromuscular disease, and allergy to any of the study drugs, i.e., nalbuphine or ropivacaine were excluded from the study.

The patients were randomly allocated into two groups of 30 each using computer-generated table of random numbers. The allocation concealment was done using sequentially numbered closed opaque-sealed envelope technique. Group R received 30 ml of 0.5% ropivacaine with 1 ml of normal saline and Group RN received 30 ml of 0.5% ropivacaine with 1 ml (10 mg) of nalbuphine (total volume of study drug is 31 ml in both groups). A resident anesthesiologist, who was not involved in the study process, prepared the syringes loaded with the study drugs for supraclavicular block and the another anesthesiologist who performed the block and observed the patient thereafter was unaware of the contents of the loaded syringes for the

purpose of double blinding so both the anesthesiologists who prepared the drugs and the observer who performed the block as well as assessed the results, were blinded.

Pre-anesthetic assessment was done on evening before surgery. A routine examination was done by assessing general condition, nutritional status, weight, airway assessment, complete examination of cardiovascular, respiratory system, site of block, and investigation in all patients. All patients were kept electively nil per oral 6 h before surgery and before operation patients were explained about the procedure and a written informed consent taken. Intravenous line secured. Standard monitors such as electrocardiogram, pulse oximeter, and blood pressure cuff were applied, and patient's baseline parameter such as pulse, blood pressure, respiratory rate, and SpO₂ was recorded. All patients were premedicated with (on operation table):

- Injection glycopyrrolate 4 µg/kg intravenous
- Injection ondansetron 80 µg/kg intravenous
- Injection midazolam 20 µg/kg intravenous.

For performing brachial plexus blockade through supraclavicular approach, we used classical technique. The patients were placed in the dorsal recumbent position with the head turned away from the site of brachial block, under all aseptic and antiseptic precautions midclavicular point, external jugular vein, and subclavian artery pulsation were identified. About 1 cm above the midclavicular point just lateral to subclavian artery pulsation, a 23G 1.5 inch needle was introduced and directed caudal, downward, and medially toward the first rib until paresthesia was noted along radial and ulnar distribution or motor response was elicited. Here, local anesthetic solution is injected. Before every incremental dose, negative aspiration for blood was performed to avoid any intravascular injection.

End of the injection was taken as time “0.”

Immediately after the block, sensory and motor characteristics of blockade, hemodynamic variables, and SpO₂ were assessed at 1, 3, 5, 10, 15, and 30 min and then at hourly interval till offset of sensory and motor blockade and then at 2 hourly interval for 24 h.

Sensory block was assessed by pinprick test using a needle at each minute after the completion of drug injection in the corresponding dermatomal areas till complete blockade.

The sensory and motor characteristics of the blockade were assessed as per the criteria mentioned below:

Sensory Characteristics

- Onset – It was taken as time duration from the end of injection to dull response to pinprick

- Peak – It was taken as time duration from the onset of sensory block to no response to pinprick
- Duration – It was taken as time duration from complete sensory block to feeling of pinprick sensation.

Motor Characteristics

- Onset – It was taken as time duration from the end of injection to decreased thumb movement
- Peak – It was taken as time duration from the end of injection to complete abolition of thumb movement
- Duration – It was taken as time duration from complete motor block to reappearance of thumb movement.

Duration of post-operative analgesia was taken as time duration from the onset of sensory block to first rescue analgesic requested by the patient at visual analog scale (VAS) ≥ 4 .

If the block was considered to be adequate, surgeons were allowed to apply tourniquet and start the surgery. If the block was considered to be inadequate for surgery, the patient was given general anesthesia and excluded from the study.

Patients were monitored for nausea, vomiting, hypersensitivity reaction, any sign of cardiovascular system (CVS) or central nervous system (CNS) toxicity, evidence of pneumothorax, hematoma, and post-block neuropathy during the study.

The patients were educated regarding reporting of pain using VAS which is of 10 points where “0” indicates no pain and “10” indicates worst possible pain.

In post-operative period, when patient complained of pain at operative site, inj. diclofenac sodium 1.5 mg/kg intravenously and the time for rescue analgesia noted (VAS ≥ 4). Injection tramadol 1 mg/kg intravenously was used as a second analgesic when required.

Both groups were compared for complete onset time and total duration of sensory blockade, complete onset time and total duration of motor blockade, and total duration of analgesia. All the data were filled in pro forma and were statistically analyzed by GraphPad instant 3.0 software. Intergroup comparison of the quantitative data among the different groups was done using the unpaired *t*-test and of the qualitative data was done by Chi-square test. Intragroup comparison of the quantitative data was done using unpaired *t*-test where baseline value was used as control. $P < 0.05$ was taken as statistically significant.

RESULTS

As shown in Table 1, demographic data in terms of age, sex, and weight were comparable in both the groups ($P > 0.05$).

is not statistically significant). The duration of surgery was also comparable in both groups ($P > 0.05$).

On comparing both the groups, Group RN produced statistically significant earlier onset and peak with prolonged duration of sensory blockade as compared to Group R ($P < 0.0001$) [Table 2].

On comparing both the groups, Group RN produced statistically significantly earlier onset and peak with prolonged duration of motor blockade as compared to Group R ($P < 0.0001$) [Table 3].

On comparing both the groups, Group RN produced significantly prolonged the duration of analgesia as compared to Group R ($P < 0.0001$) [Table 4].

In Group RN, most of the patients required rescue analgesics between 14 and 16 h of giving brachial plexus

Table 1: Patient characteristics

Patient characteristics	Group R (n=30) (Mean \pm SD)	Group RN (n=30) (Mean \pm SD)	P value
Age (in years)	36.8 \pm 14.16	33.5 \pm 13.33	0.3565
Weight (in kg)	56.2 \pm 4.08	57.23 \pm 4.37	0.3551
Gender (M/F)	24/6	24/6	1.0000
Duration of surgery (in min)	71.5 \pm 36.27	78 \pm 40.32	0.5141

SD: Standard deviation

Table 2: Sensory characteristics of brachial plexus blockade

Sensory characteristics (min)	Group R (n=30) (Mean \pm SD)	Group RN (n=30) (Mean \pm SD)	P value
Onset	4.47 \pm 1.34	2.47 \pm 0.76	<0.0001
Peak	10.9 \pm 1.11	8.37 \pm 0.79	<0.0001
Duration	473 \pm 22.67	725.67 \pm 16.06	<0.0001

SD: Standard deviation

Table 3: Motor characteristics of brachial plexus blockade

Motor characteristics (min)	Group R (n=30) (Mean \pm SD)	Group RN (n=30) (Mean \pm SD)	P value
Onset	9.9 \pm 1.11	6.6 \pm 1.11	<0.0001
Peak	19.17 \pm 0.86	17.67 \pm 1.07	<0.0001
Duration	359.67 \pm 26.89	420.33 \pm 14.94	<0.0001

SD: Standard deviation

Table 4: Duration of effective analgesia

Variable	Group R (n=30) (Mean \pm SD)	Group RN (n=30) (Mean \pm SD)	P value
Effective analgesia (min)	588 \pm 27.37	846.33 \pm 72.50	<0.0001

SD: Standard deviation

blockade. In Group R, most of the patients required rescue analgesics between 10 and 12 h [Figure 1].

On comparing Group RN with Group R, 29 patients required one injection of rescue analgesia and 1 patient required two injections in 24 h in Group RN while in Group R, 24 patients required one injection and 6 patients required two injections in 24 h. The analgesic requirement and total dose of analgesics were reduced in Group RN as compared to Group R [Table 5].

Figure 2 shows that changes in the heart rate were comparable in both the groups without any statistical significance ($P > 0.05$) except at 10 h (Group R) and 14 h (Group RN), when it shows a significant increase in heart rate ($P = 0.0002$ and 0.006 , respectively).

Figure 3 shows that changes in the mean arterial pressure were comparable in both the groups without any statistical significance ($P > 0.05$) except at 10 h (Group R) and 14 h (Group RN), when it shows significant changes in heart rate ($P = 0.0001$ and <0.0001 , respectively).

Figure 4 shows that SpO_2 remained stable and comparable to baseline in both the groups throughout the study period ($P > 0.05$).

Table 5: Doses of rescue analgesics required in 24 h

Number of analgesic doses	Group R		Group RN	
	Number of patients	%	Number of patients	%
1	24	80	29	97
2	6	20	1	3
3	0	0	0	0

DISCUSSION

Regional anesthesia is practiced in most developing countries. Regional nerve blocks are based on the concept that pain is conveyed by nerve fibers, which are amenable to interruption anywhere along their pathway. Supraclavicular blocks are performed at the level of the brachial plexus trunks. As with other fields, regional anesthesia has undergone major developments both in technique and drugs availability. Gradually, ropivacaine was introduced into clinical practice. Local anesthetics alone for supraclavicular brachial plexus block provide good operative conditions but have a shorter duration of post-operative analgesia. Recently, nalbuphine has been reported as an effective adjuvant for regional anesthetic agents. On reviewing literature, the present study was undertaken to compare analgesia and effectiveness regarding onset and duration of complete motor and a sensory block of 0.5% ropivacaine alone versus 0.5% ropivacaine with nalbuphine in patients undergoing supraclavicular brachial plexus block.

Onset

The mean time of onset of sensory blockade (2.47 ± 0.76 min in Group RN vs. 4.47 ± 1.34 min in Group R) and the motor blockade (6.6 ± 1.11 min in Group RN vs. 9.9 ± 1.11 min in Group R) was faster in Group RN compared to Group R and was statistically significant ($P < 0.0001$).

The peak of sensory block was achieved in 8.37 ± 0.79 min in Group RN versus 10.9 ± 1.11 min in Group R and of motor block was achieved in 17.67 ± 1.07 min in Group RN versus 19.17 ± 0.86 min in Group C which was statistically significant ($P < 0.0001$).

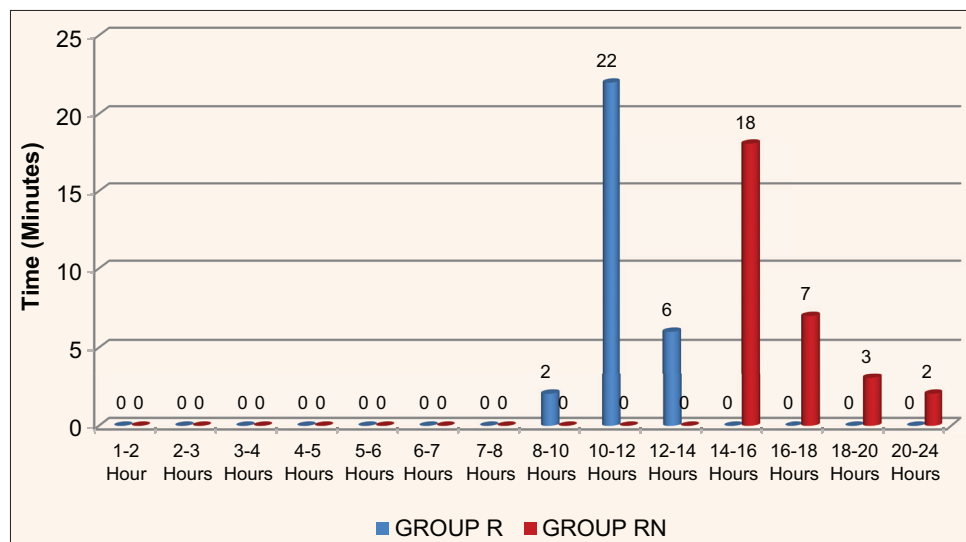


Figure 1: Time of first rescue analgesic required

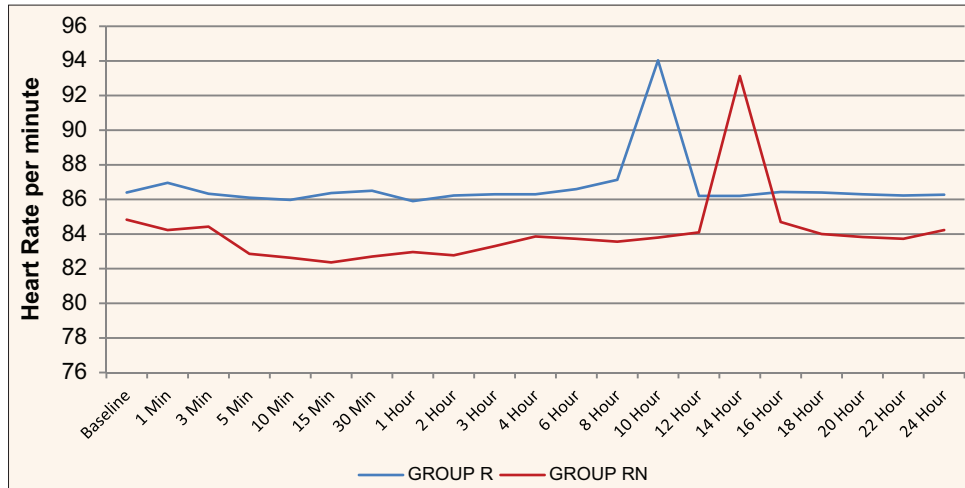


Figure 2: Heart rate at various specified intervals

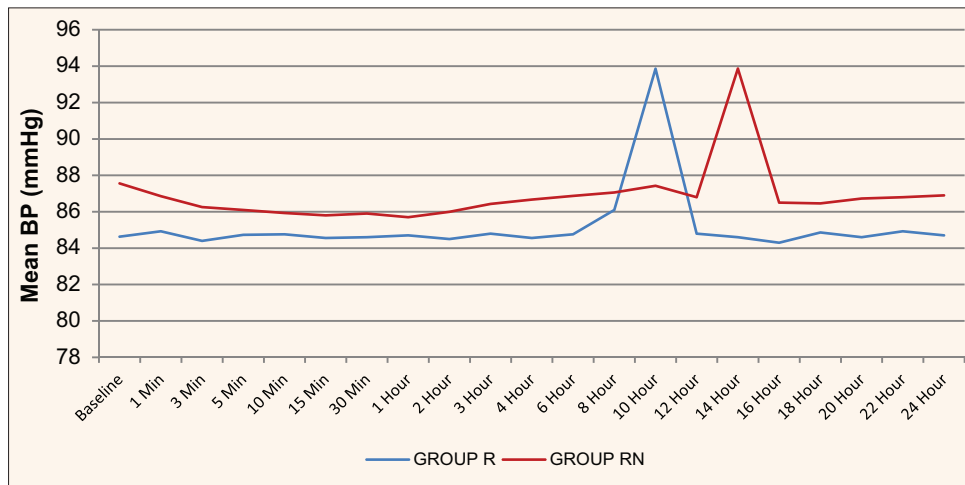


Figure 3: Mean arterial blood pressure

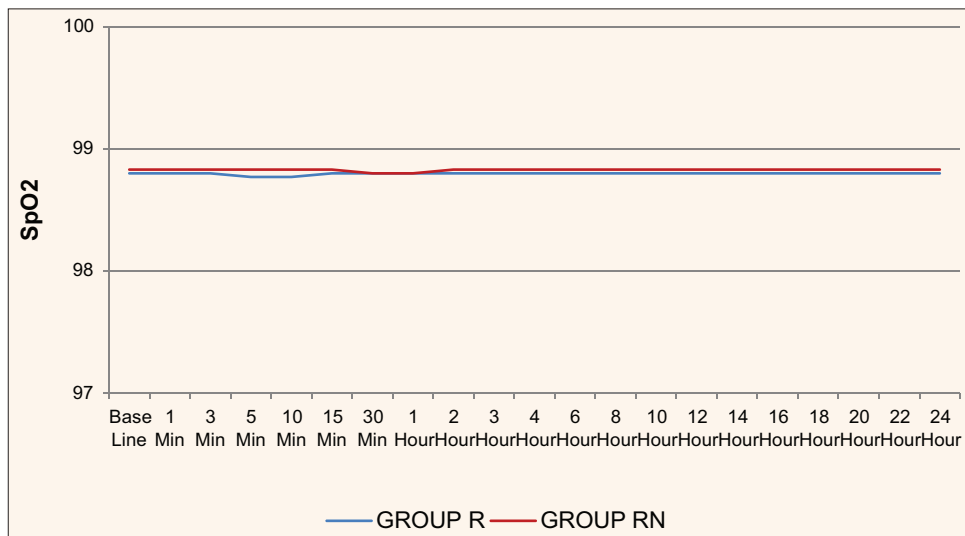


Figure 4: SpO₂ at various specified time period

These results are comparable to other studies:

In a study of Akhtar *et al.*,^[7] they found that Group 2 (0.5% ropivacaine 28 ml + 100 mg tramadol 2 ml) had a rapid onset of both sensory and motor block (sensory onset: 9.40 ± 2.22 min of Group 2 vs. 10.93 ± 2.90 min of Group 1 [0.5% ropivacaine 28 ml + normal saline 2 ml] and motor onset: 13.15 ± 3.64 of Group 2 vs. 13.65 ± 2.17 min of Group 1) but without a statistically significant difference (P value sensory onset 0.10 and motor onset 0.20).

In the study done by Gupta *et al.*,^[8] they found that onset of sensory and motor block was rapid in patients of Group 2 (0.5% bupivacaine 20 ml + 10 mg nalbuphine 1 ml) as compare to Group 1 (0.5% bupivacaine 20 ml + normal saline 1 ml). Sensory onset: 9.57 ± 1.5 min of Group 2 versus 10.36 ± 1.7 min of Group 1; $P = 0.76$ and motor onset: 14.10 ± 1.24 min of Group 2 versus 18.16 ± 1.30 min of Group 1; $P = 0.49$ but showed no statistically significant difference ($P > 0.05$).

Duration of Sensory and Motor Blockade

In the present study, the mean duration of the sensory blockade (725.67 ± 16.06 min in Group RN vs. 473 ± 22.67 in Group R) and the motor blockade (420.33 ± 14.94 min in Group RN vs. 359.67 ± 26.89 min in Group R) was also prolonged and was statistically significant ($P < 0.0001$) which was comparable to the study of Akhtar *et al.*^[7] They found that addition of 100 mg (2 ml) tramadol with 0.5% ropivacaine 28 ml in Group 2 results in significant increase in the duration of sensory (5.27 ± 2.01 h) and motor block (4.38 ± 1.57 h) when compared to control Group 1 (0.5% ropivacaine 28 ml + normal saline 2 ml) (3.9 ± 2.05 h) and (3.19 ± 0.69 h), respectively ($P < 0.05$).

In the study done by Gupta *et al.*,^[8] they found that the mean duration of motor block was 257.69 ± 30.19 min in patients of Group 1 when compared to 278.53 ± 34.61 min in Group 2 and difference was statistically significant ($P = 0.038$).

This study correlates well with the study done by Youssef and ElZayyat^[9] where they compared the efficacy of nalbuphine and tramadol as separate adjuvants to lidocaine in intravenous regional anesthesia (Bier's block) with lignocaine alone. They found that nalbuphine in Group LN causes statistically significant faster onset of sensory (3.8 ± 1.38 min) and motor blockade (5.2 ± 1.51 min) as compared to Group L (4.8 ± 1.15 min and 7.1 ± 1.45 min, respectively) but statistically insignificant faster onset than tramadol in Group LT (3.7 ± 1.14 min and 5.5 ± 1.71 min, respectively). They also found that the duration of sensory (82.7 ± 8.02 min) and motor block (92.9 ± 10.15 min) was prolonged in Group LN as compared to Group L (75.3 ± 4.13 min and 82.1 ± 3.94 min, respectively)

and Group LT (80.7 ± 5.19 min and 91.4 ± 7.59 min, respectively).

Duration of Analgesia

In the present study, the duration of analgesia was prolonged in Group RN (846.33 ± 72.50 min) as compared with Group R (588 ± 27.37 min) which was statistically significant ($P < 0.0001$).

Akhtar *et al.*^[7] also observed that there was a significant increase in the duration of analgesic effect in tramadol group when compared to control group (7 ± 2.77 h vs. 5.4 ± 2.83 h) ($P = 0.03$).

Gupta *et al.*^[8] also observed that the duration of analgesia in patients of Group 2 was 481.53 ± 42.45 min and in patients of Group 1 was 341.31 ± 21.42 min with $P < 0.001$.

Hemodynamic Changes

Regarding the hemodynamic changes, in this study, there were no significant changes in heart rate, mean arterial blood pressure, and SpO_2 at all hours except at 10 and 14 h which are due to pain. Changes were comparable to the study done by Akhtar *et al.*^[7] as well as with Gupta *et al.*^[8]

Complications

There was no incidence of headache, nausea, vomiting, hypotension, bradycardia, chest pain, coughing, convulsion and respiratory depression, and procedure-related complication. There were no CNS and CVS toxicity seen in either group in our study.

CONCLUSION

Nalbuphine as an adjuvant to ropivacaine in the supraclavicular brachial block for upper limb surgery significantly shortens the onset time for sensory and motor block, prolongs the duration of sensory and motor blocks with longer duration of post-operative analgesia, and causes a decrease in need for rescue analgesia in patients with no side effects.

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Paratricipital Approach for Fixation of Distal Humerus Fractures in Adult – A Review of Thirty Cases

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Abstract

Background: Distal humerus fractures are most commonly managed by surgical approaches that disrupt the extensor mechanism of the elbow. Paratricipital approach for distal humerus fracture fixation has been done by orthogonal or parallel plate construct that allows excellent healing of fracture, motion arc of elbow more than 100°, and maintains of extensor mechanism strength.

Materials and Methods: A total of 30 cases of distal humerus fractures are fixed by paratricipital posterior approach. Bicolumnar fixation done by elevating and retracting the triceps of the distal humerus keeping triceps insertion undisturbed by orthogonal or parallel plate construct. Early active-assisted range of motion initiated within limits of pain. The age group was 15–60 years. Among them 21% was Type A fracture, 17% Type B fracture, 33% Type C1 fracture, and 29% Type C2 fracture. More than 60% of cases have 1 year of follow-up. Radiograph and functional evaluation were done by mayo elbow performance score (MEPS), disability of arm, shoulder, and hand questionnaire.

Results: All 30 fractures healed primarily. The median arc of elbow motion was 105° (range 70°–140°). Average MEPS was 91 points (range 65–100) indicating excellent scores.

Conclusion: Treatment of distal humerus fracture in adults by paratricipital posterior approach results in excellent healing, a mean flexion extensor arc more than 100°, maintains of almost normal elbow extensor strength compared with the contralateral normal elbow.

Key words: Distal humerus, Elbow, Extensor mechanism, Para tricipetal

INTRODUCTION

Complex intra-articular distal humerus fractures are a considerable challenge to even the most experienced surgeon.^[1] Distal articular humerus fractures are preferably treated by open reduction and internal fixation.^[2] The surgery is technically demanding and an adequate exposure of the distal humerus articular surface is important for the surgery. The olecranon osteotomy approach has been the gold standard among surgical approaches for fracture

fixation of the distal articular surface of humerus.^[2-4] It is the most commonly used surgical approach and provides good visualization of the fracture.^[4] Complications of this approach include hardware migration and prominence, delayed union, and non-union.^[5,6]

Surgical approaches to elbow joints that dissociate the triceps from olecranon have distinct disadvantages such as triceps avulsion, triceps weakness, and wound healing problem. Such complications necessitate more surgery and predispose to infection.^[7] To avoid these complications an extensor mechanism sparing paratricipital posterior approach to distal humerus through midline posterior incision was suggested by Schildhauer *et al.*^[8]

The bilaterotricipital approach (triceps sparing or triceps-on) was first reported by Alonso-Lames in 1972.

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This approach involves the creation of surgical windows along medial and lateral side of triceps muscle and tendon without disrupting its insertion on olecranon.^[9]

The paratricipital approaches have several advantages: Complications of olecranon osteotomy can be avoided, triceps tendon insertion not disrupted, and allows early range of motion (ROM). This approach also preserves innervations and blood supply of anconeus muscle^[9,10] which provides dynamic posterolateral stability of elbow. Finally, if further exposure required paratricipital approach can be converted to olecranon osteotomy and if further proximal exposure is required for associated fracture shaft humerus, lateral side paratricipital approach can be converted into the Gerwin *et al.*^[11] approach. The disadvantage of paratricipital approach is the limited visualization of articular surface of distal humerus; therefore, this approach is usually inadequate for fixation of Type C3 fractures. The several advantages of this approach certainly indicate its use for AO/OTA Types A2, A3, B1, and B2 and possibly C1 and C2 fractures.^[8,12]

The aim of our study is to prospectively evaluate the results of paratricipital approach in terms of adequacy of exposure of distal humerus for fixation of different types of distal humerus fractures, and ultimately the functional outcome of the elbow.

The specific objectives are as follows:

- To determine the adequacy of exposure of distal humerus in respect to dissection of soft tissue and extensor mechanism of elbow, for fixation of different types of distal humerus fracture in AO/OTA classification
- Time taken for surgery
- Rate of complications
- To evaluate post-operative ROM and functional outcome by visual analog score for pain and Mayo Elbow Performance Score (MEPS).^[13]

MATERIALS AND METHODS

A study of 30 cases of supracondylar and intercondylar fracture of the humerus were conducted in the Department of Orthopaedics, Medical College, Kolkata between January 2011 and June 2012. There were 17 female patients and 13 were males. Left elbow was involved in 21 cases and right elbow was involved in 9 cases. The most common mode of injury was road traffic accident (66.67%), then fall from height (20%), and then simple fall (13.33%). Injury operation interval of <1 week was 56.67%. Among all patients 33% of fractures were Type C1, 29% of fractures were Type C2, and others are Type A and B fractures.

About 63.33% of patients had >12 months of follow-up. About 29.17% of patients had ROM of >120, 54.17% of patients had ROM 90°–120°, and 16.66% of patients had ROM of <90°.

Inclusion Criteria

Displaced supracondylar and intercondylar fracture of the distal humerus in the age group of 15–80 years were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

- Undisplaced distal humerus fracture which can be managed conservatively
- Open fracture of distal humerus
- Patients with medical comorbidities, not fit for anesthesia.

Surgical Technique

Anesthesia

Regional anesthesia.

Position of the patients

Patient was positioned in lateral decubitus with a bolster placed between arm and chest, and the entire upper extremity draped free.

All cases were operated with tourniquet applied over upper arm, if operative time exceeded more than 1 h 45 min tourniquet was deflated.

Surgical exposure

The posterior approach to distal humerus was followed.

Surgical steps

Bony landmarks are marked including olecranon process, subcutaneous border of ulna, medial, and lateral epicondyles.

Incision

A posterior midline longitudinal incision was made over the lower arm and extended distally beyond the elbow joint [Figure 1]. Just above the tip of olecranon, the incision was curved laterally. It was continued 5 cm distal to tip of olecranon.

Superficial surgical dissection

Deep fascia incised in the midline and full-thickness skin flaps is developed [Figure 2]. These are kept as thick as possible, with deep plane consisting of triceps fascia and epitendon proximally and forearm fascia and ulnar periosteum distally. Aponeurosis of the triceps exposed. Ulnar nerve palpated on the back of medial epicondyle. Fascia over the ulnar nerve incised to expose the ulnar

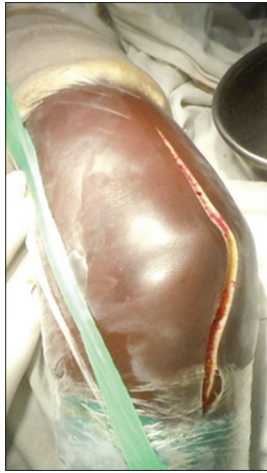


Figure 1: Posterior midline longitudinal skin incision

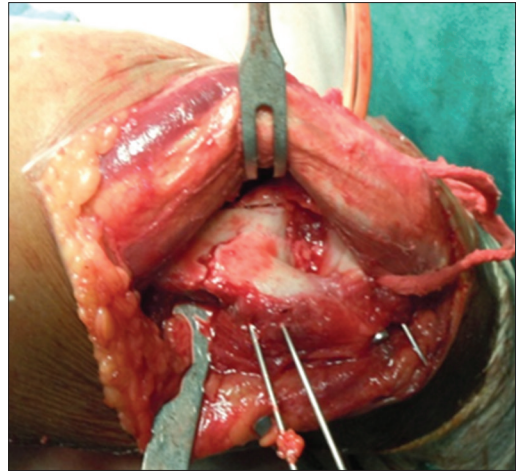


Figure 4: Fracture provisionally fixed with K wires

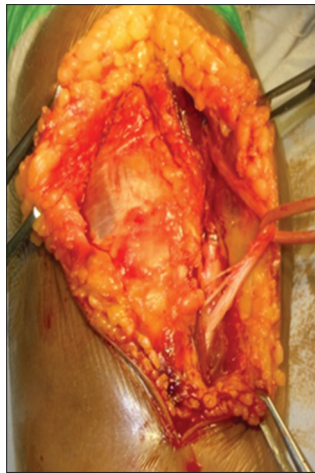


Figure 2: Full-thickness skin flap developed and ulnar nerve exposed

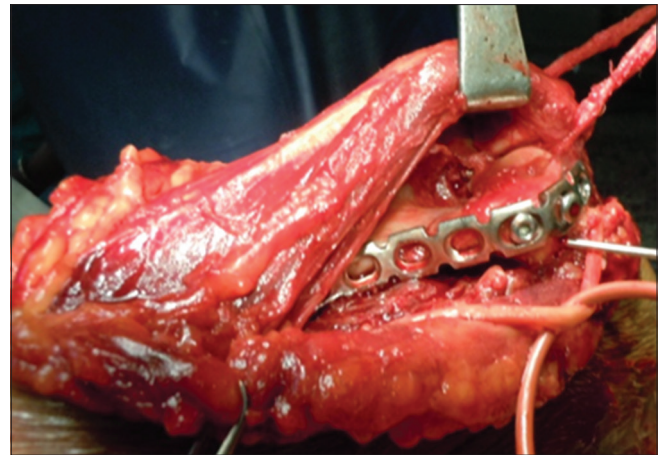


Figure 5: Fracture fixation done with plate and screws

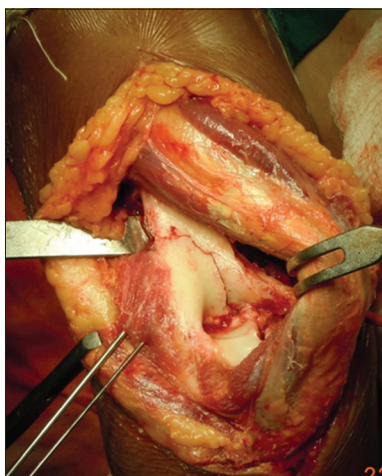


Figure 3: Retracting triceps medially and laterally to expose the intra-articular fracture site

nerve. When more proximal exposure of humerus was required, ulnar nerve was followed further until it pierces the intermuscular septum coming from the anterior

compartment. Distally, it was released from cubital tunnel and dissected to its first branch. Articular branch of the ulnar nerve may be sacrificed.

Deep surgical dissection

Dissection was continued to lateral and medial triceps borders at their respective interfaces with the posterior aspect of intermuscular septum. The distal lateral dissection was continued anteriorly to the anconeus muscle, allowing the muscle to be elevated along with the triceps and preserving its neurovascular supply. The posterolateral humeral shaft approached by elevating the triceps and anconeus muscle from posterior periosteum and by retracting it medially. Medial paratricipital dissection along with the posterior border of intermuscular septum exposed the posteromedial aspect of the distal humerus. The intra-articular fat pad was excised [Figure 3]. This provided visualization of the entire posterior articular surface, comprising roughly 50% of the overall articular surface of the distal part of the humerus. Retracting triceps muscle medially and laterally exposes both columns.

Trochlea can be visualized by flexing elbow more than 90°. A sponge or 0.25 in 0.6 cm, Penrose drain was placed into the ulnohumeral joint to allow distraction of the joint by pulling distally on the olecranon through the sigmoid notch to aid in visualization and facilitate the reduction through ligament taxis.

The distal part of the humerus was anatomically reduced with direct visualization posteriorly and indirectly with fluoroscopy. The intact sigmoid notch was used as a template for reduction.

Techniques of Fracture Reduction

- Articular fragments are reduced and provisionally fixed with guide wire [Figure 4]
- Definitive fixation of intra-articular part is done by 4 mm cannulated cancellous screws
- Care must be taken not to narrow the trochlea with a lag screw when there is bone loss
- Once intra-articular part is fixed, intercondylar fracture is converted into supracondylar fracture
- This is provisionally fixed with Kirschner's wire and converted with definitive fixation with either parallel plate or orthogonal plate construct [Figure 5]
- Fixation stability and motion arcs were assessed before closure.

Technical Objective for Fixation of Fractures

- Every screw should pass through a plate
- Each screw should engage a fragment on the opposite sides that is also fixed to a plate
- As many screws as possible should be placed in distal fragments
- Each screw should be as long as possible
- Each screw should engage as many articular fragments as possible
- Plate should be applied such that compression is achieved at the supracondylar level for both columns
- Plates used must be strong and stiff enough to resist breaking or bending force before union occurs at the supracondylar level.^[14]

Closure

- The ulnar nerve was not anteriorly transposed in any case
- Implants were covered with soft tissue to prevent ulnar neuritis
- Triceps attached with an intermuscular septum
- A negative suction drain was given
- Bulky dressing around elbow done.

After treatment

- Plaster of Paris back slab applied
- Drain was removed at 48 h
- Out of 30 cases, 6 cases were operated under

tourniquet control in rest tourniquet had to be released intraoperatively as operative time exceeded more than 1 h 45 min

- Blood loss in cases operated with tourniquet – measured by collected blood in the suction drain
- In 24 cases, tourniquet had to be removed intraoperatively
- Blood loss in such cases measured with numbers of mops required during surgery plus collection in drain - (one wet mop = 200 ml of blood approx)
- Wound inspection was routinely done on 5th post-operative day
- Suture removal was done on 14th post-operative day.

Post-operative Rehabilitation

The patients are put through active elbow motion of flexion and extension, pronation, and supination within limits of pain at 5th post-operative day.

Follow-up

Patients were reviewed every 2 weeks for the first 2 months, every month for next 6 months, and then every 3rd month and were assessed on:

- Time taken for functional recovery
- ROM
- Any specific complaints
- Time taken for fracture healing
- Functional outcome by MEPS.

Final follow-up was done 1 month before the conclusion of the study and various scoring systems and classification were used to analyze the results.

Results were analyzed statistically using the SPSS software system.

RESULTS

All 30 patients were reviewed clinically and radiographically. Follow-up ranged from 18 months to 6 months, with an average of 12.6 months. Nineteen patients had an excellent result, 10 had good, and one had poor.

Time Taken for Functional Recovery

Functional recovery is an interval between injury and time of return to normal daily activities. The average time is 101.8 days.

ROM

The median arc of elbow motion was 105° (range 70°–140°). Arc of motion >120° seen in 29.17% of patients, arc 90°–120° present in 54.17% of cases, and arc <90° seen in 16.66% of cases.

MEPS

Average score is 91, indicating the excellent results.

Disability of Arm, Shoulder and Hand Questionnaire

Mean score was 32.36.

Strength of Triceps

According to the Medical Research Council grading mean strength was 4.84 (maximum 5, and minimum 0).

Complications

- Symptomatic hardware (23.33%)
- Flap necrosis (6.66%)
- Superficial skin infection (13.33%)
- Tourniquet palsy (10%)
- Ulnar nerve neuropraxia (20%).

DISCUSSION

Thirty patients with distal humerus fractures treated with paratricentral posterior approach and fixation done with either orthogonal or parallel plate construct. In this study, fracture was most common in female patients (56.67%). Left elbow most commonly involved (70%), minimum age of the patient of this study was 15 years, and maximum was 85 years. The mean age of this fracture was 32.89 years. The most common mode of injury was road traffic accident (63.33%). Most of these patients were operated within 1 week of injury (56.67%). Delaying of intervention in others is due to treated elsewhere by quacks or due to time taken for the management of other more serious life-threatening injuries. Among all patients, 33% of fractures were Type C1, 29% of fractures were Type C2, and others are Type A and B fractures. About 63.33% of patients had >12 months of follow-up. About 29.17% of patients had ROM of >120°, 54.17% of patients had ROM 90°–120°, and 16.66% of patients had ROM of <90°. Follow-up ranged from 18 months to 6 months, with an average of 12.6 months. Nineteen patients had an excellent result, 10 had good, and one had poor. Functional recovery is interval between injury and time of return to normal daily activities. Average time is 101.8 days. The average MEPS score is 91, indicating excellent results. The most common complication is symptomatic hardware (23.33%). Others are flap necrosis (6.66%), superficial skin infection (13.33%), tourniquet palsy (10%), and ulnar nerve neuropraxia (20%).

Associated injuries were # distal radius (10%), # acetabulum (3.33%), U/L # shaft ulna (3.33%), closed head injury (26.67%), and closed abdominal injury (6.67%).

CONCLUSION

Treatment of distal humerus fracture in adults by paratricentral posterior approach results in excellent healing, a mean flexion extensor arc more than 100°, maintains of almost normal elbow extensor strength compared with contralateral normal elbow. This approach can be an alternative to other triceps detaching approach, where the complications are more. Although this approach can be easily used for fixation of Type A, B, C1, and C2 fractures according to AO classification, fixation of Type C3 and multifragmentary fractures by this approach can be problematic where there needs a lot of research.

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Prevention of Oral Mucositis Induced by Chemoradiotherapy in Head-and-Neck Carcinoma Patients – A Comparative Study

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Abstract

Introduction: Radiation-induced mucositis is quite bothersome due to acute complications in patients receiving radiotherapy (RT) and even more pronounced with the combined chemoradiotherapy. Mucositis manifests itself as erythema, edema, or ulceration that can be accompanied by a mild burning sensation.

Aim: This study aims to compare the efficacy of oral glutamine in the prevention of chemoradiotherapy-induced oral mucositis in head-and-neck cancer patients.

Materials and Methods: A total of 40 patients with malignancy confirmed in histopathology who were undergoing conventional RT for head-and-neck cancer were divided into two groups, Group A receives oral glutamine 10 g in 1000 ml of water 2 h before the RT and Group B undergoes conventional RT. The outcome was measured in the 6th week of RT and 3rd week of post-RT.

Results: Twenty-six patients (65%) had carcinoma of the oropharynx, while 14 patients (35%) had carcinoma of the larynx. In this study, 75% of patients in Group A and 85% of patients in Group B are in Stage IV cancers. Supplementation with oral glutamine before RT shown a significant reduction in incidence of mucositis compared to the control group. Post-RT, there was a significant reduction in number mucositis cases in Group A than Group B.

Conclusion: Oral glutamine decreased the incidence of chemoradiotherapy-induced oral mucositis.

Key words: Oral glutamine, Oral mucositis, Radiotherapy

INTRODUCTION

Head-and-neck cancer represents the sixth most common cancer worldwide.^[1] It is one of the most common cancers in developing countries like India.^[2] In India, it is the most common cancer in males and forms 30% load of India's cancer burden.^[2]

Radiation therapy plays an important role in the treatment of patients with head-and-neck cancer. Regulated by the location of the malignancy (primary tumor and lymph node metastases), necessarily, the salivary glands, oral mucosa, and jaws have to be included in the radiation treatment

protocols.^[3] Although, that may result in short- and long-term side effects, this kind of treatment is more effective than the others. Possible side effects include mucositis, osteoradionecrosis, taste loss, hyposalivation, radiation caries, periodontal disease, trismus, and so on.^[4] Among the acute clinical side effects, disruption in the function and integrity of the mouth are the most important cases. These complications can result in severe ulceration called mucositis. Recently, many studies have been published on the radiation-induced oropharyngeal mucositis associated with the treatment of head-and-neck tumors. The mucositis may be accompanied with other complications such as oral discomfort, pain, poor nutrition, delays in drug control, increased hospitalization, and costs as well as life-threatening infection in some patients. For all of these reasons, oral mucositis should be prevented or minimized as much as possible.^[5]

Aim

This study aims to compare the efficacy of oral glutamine in the prevention of chemoradiotherapy-induced oral mucositis in head-and-neck cancer patients.

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MATERIALS AND METHODS

This prospective comparative study was conducted in the Department of Radiotherapy at Tirunelveli Medical College from January 2019 to June 2019.

Inclusion Criteria

Patients with malignancy confirmed in histopathology who were undergoing conventional radiotherapy (RT) for head-and-neck cancer were included in the study.

Exclusion Criteria

Patients with a previous history of receiving RT, uncontrolled systemic or disseminated disease, and presence of the synchronous double malignant tumor were excluded from the study.

Patients were randomized into two groups; Group A receives oral glutamine 10 g in 1000 ml of water 2 h before the RT and Group B undergoes conventional RT.

All patients treated with cobalt-60 teletherapy unit by two-dimensional technique with concurrent weekly cisplatin 50 mg.

The patients were evaluated by the same observer at the 3rd and 6th weeks during the treatment protocol and the 3rd week post-RT. All patients had completed dental and oral examination before treatment and underwent oral care. For symptomatic mucositis, oral paracetamol tablets 500 mg or tramadol 100 mg was administered according to the severity of pain. The need for painkillers, adverse events associated with the study drugs, and patient non-adherence to treatment were recorded.

RESULTS

In this study, a total of 20 patients were included in the study. They were divided into two groups; Group A receives oral glutamine 10 g in 1000 ml of water 2 h before the RT and Group B undergoes conventional RT.

In this study, higher number of patients was in the age group between 51 and 60 years in both groups. Male predominance was noted in both groups. There was no statistical difference noted in the demographics of patients [Table 1 and Figures 1-4].

Twenty-six patients (65%) had carcinoma of the oropharynx, while 14 patients (35%) had carcinoma of the larynx.

In this study, 75% of patients in Group A and 85% of patients in Group B are in Stage IV cancers.

Table 1: Distribution of the study parameters

Parameters	Group A	Group B
Age group		
40–50 years	4	4
51–60 years	11	12
>60 years	5	4
Gender		
Male	18	19
Female	2	1

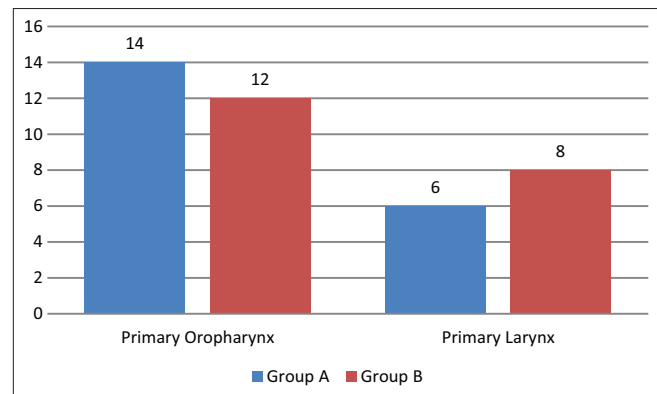


Figure 1: Distribution of site

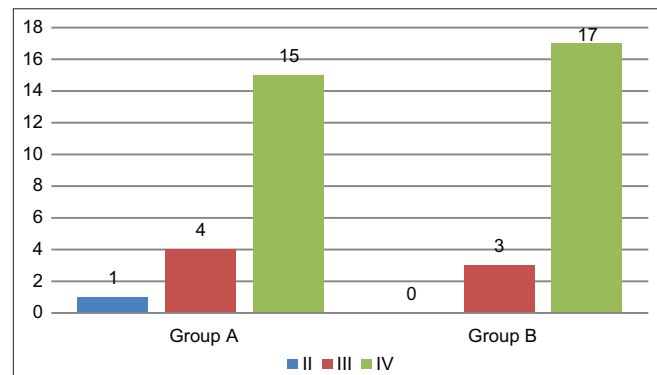


Figure 2: Distribution of AJCC stage

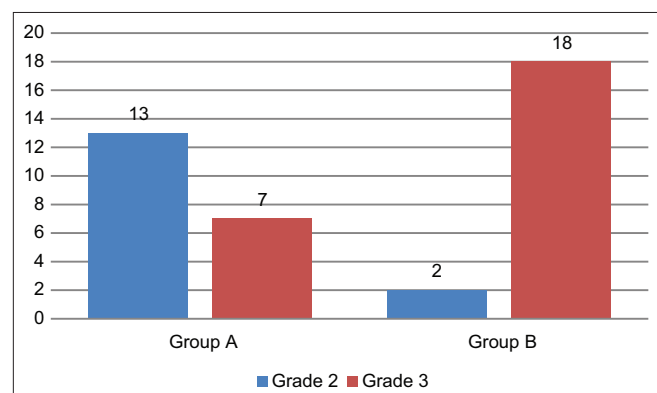


Figure 3: Distribution of outcome at the 6th week of radiotherapy

Supplementation with oral glutamine before RT shown a significant reduction in incidence of mucositis compared to the control group.

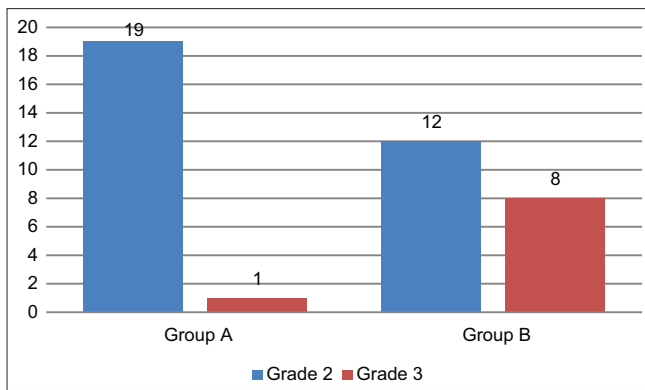


Figure 4: Distribution of outcome after 3 weeks of radiotherapy

Post-RT, there was a significant reduction in the number of mucositis cases in Group A than Group B.

DISCUSSION

Radiation-induced mucositis is quite bothersome due to acute complications in patients receiving RT and even more pronounced with the combined chemoradiotherapy. Mucositis manifests itself as erythema, edema, or ulceration that can be accompanied by a mild burning sensation.^[3] Extreme appearances are characterized by large and painful ulcers that have a large impact on patient's quality of life. It may seriously restrict simple activities such as speaking, eating, or even swallowing saliva.^[6] The early clinical sign of mucositis is erythema appearing at cumulative doses of head-and-neck radiation of about 10 Gy.

In general, oropharyngeal mucositis occurs in more than 90% of patients who receive radiation and/or chemotherapy for head-and-neck tumors.^[7] It occurs in almost all the patients who are treated for cancers of the mouth, oropharynx, nasopharynx, and in approximately two-thirds of those treated for cancers of the hypopharynx or larynx.^[8] Vera-Llonch *et al.* reported that 80% of patients undergoing radiation therapy showed oropharyngeal mucositis and 29% developed severe oropharyngeal mucositis.^[9]

Glutamine is one of the 20 amino acids encoded by the standard genetic code. Glutamine is also used by cells of the immune system, such as lymphocytes and macrophages. Some studies have suggested that dietary supplementation with glutamine may protect the gut from the side effects of both RT and chemotherapy.^[10,11]

Some studies have shown that glutamine increases collagen synthesis in human fibroblasts by a direct stimulatory effect and as a proline and hydroxyproline residue precursor.^[12,13] It also enhances the immune system and is an important fuel for both macrophages and lymphocytes. IV glutamine

supplementation reportedly increased immunoglobulin A production in rats.^[14]

Leitão *et al.* showed that glutamine or alanyl-glutamine accelerated mucosal remodeling from 5-fluorouracil-induced oral mucositis by increasing glutathione stores in hamster mucosa.^[15] Nose *et al.* demonstrated that bolus enteral glutamine prevented cisplatin-induced intestinal mucosal injury in rats, possibly resulting in increased intracellular glutathione.^[16] Several clinical studies have shown the protective effects of glutamine on the mucosal epithelium.^[17-19]

CONCLUSION

The ideal management of oral mucositis that develops during radiation therapy which is even more pronounced with chemoradiotherapy remains a challenging problem. Prophylactic treatments can help reduce the severity of oral mucositis. Considering the morbidity associated with concurrent chemoradiation due to mucositis, interventions like supplementation with oral glutamine will prove beneficial for the patients.

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Assessing Physicians' Communication Skills in their Different Medical Specialties Using the Communication Assessment Tool

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Abstract

Objective: This study assesses and compares physicians' communication skills based on their specialties from a patient perspective. We also compare their communication skills considering various dependent and independent variables.

Methods: This cross-sectional study used the Arabic version of the communication assessment tool (CAT) questionnaire for patients who visited family medicine, internal medicine specialty, and surgical specialty clinics in the Outpatient Department of the King Fahad Medical Military Complex in Dhahran, Saudi Arabia.

Results: Of the prospective 400 participants, 365 agreed to participate, a participation rate of 91.2%. The percentage of "excellent" ratings for all of the CAT questions varies between 80% and 90%. A comparison between specialties according to the CAT scores showed significant variation, with surgeons showing higher scores, compared with other specialties. Patient's responses varied widely when compared with the clinical experience of physicians ($P < 0.001$). Furthermore, there was a statistically significant difference in the results between physicians who had attended a communication skills course and those who did not or did not remember, based on patient's responses.

Conclusion: In general, patients were satisfied with the communication skills of the doctors working at King Fahad Medical Military Complex. Doctors from the surgery department received better feedback regarding their communication skills. Based on our results, we recommend that the questionnaire items that received the lowest rating from patients need to be improved to increase patients' overall satisfaction with physicians' communication skills.

Key words: Communication skills, Family medicine, Internal medicine, Surgery

INTRODUCTION

Communication skills are a vital component of physicians' patient management skills and are essential for delivering high-quality health care concerning both the diagnosis and treatment of disease.^[1] Good communication skills also improve the physician-patient relationship, which can, in turn, improve compliance to physicians' instruction and satisfaction with the care provided. It is a well-known fact

that a successful doctor is the one who knows how to communicate well with their patients. Medical education institutions teach their students to maintain a professional rapport with patients, uphold patients' dignity, and respect their privacy, from the very start. A variety of strategies have been used to assess physicians' communication skills, including behavioral checklists, thorough examinations and evaluations, and patients' satisfaction surveys.^[2-6]

Patients' feedback concerning physicians' interpersonal and communication skills should be included in any evaluation system.^[1] Studies have been conducted to assess how a doctor's communication skills affect patients' satisfaction.^[7,8] Experience alone is not the only way to enhance communication skills; additional courses, lectures, or workshops could help to improve doctors' communication skills with patients. There

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are certain tools that we can use to evaluate patients' satisfaction with doctors' communication skills. However, when researchers used multiple elements in one study to evaluate communication skills, they often treated treatment satisfaction and communication skills as the same variable.^[9,10] It is, therefore, difficult to draw accurate conclusions when using these tools and to highlight areas in need of improvement for physicians concerning their communication skills.^[11]

The Communication Assessment Tool (CAT) was developed by Makoul *et al.* to assess the patients' perception of physicians' communication skills more precisely, compared with other previously developed assessment tools.^[10] The original researchers documented all the steps of developing the instrument that made the tool reliable and valid. Items of the CAT focus on basic communication skill elements and it is vital to obtain patients' responses right after their visit to physician.

In this study, we investigated the impact of the physicians' specialty on their communication skills by comparing physicians' communication skills from a patient perspective in different specialties. Even though the CAT has been used extensively to assess doctors' communication skills, a comparison of these skills between different specialties has not been done. These specialties include family medicine, internal medicine specialty, and surgical specialty. We also compared their communication skills from the perspective of various dependent and independent variables. This comparison allowed us to understand the impact of specialty on physicians' communication skills.

METHODS

This cross-sectional study was conducted from January to April 2019 at outpatient's clinics of the King Fahad Medical Military Complex in Dhahran, Saudi Arabia. We obtained ethics approval for the study from the hospital's ethics committee. We used a stratified sampling technique to calculate sample size and decided to divide the study population into three subgroups: Family medicine, internal medicine specialty, and surgery clinic attendees. The calculated sample sizes for the strata were 298 for family medicine, 70 for internal medicine, and 32 for surgery clinics. Therefore, the total calculated sample size for the study was 400.

Only patients who visited the previously mentioned three outpatient clinics at the King Fahad Medical Military Complex were considered as participants for the study. If the patient was a minor, the parents or guardian could answer the questions. Two carefully selected interviewers

with sound interpersonal communication skills assisted the researcher to interview patients or their guardians. The interviewers also received specific training on conducting the interviews and completing the questionnaire. One interviewer was dedicated to each of the targeted clinics and data were collected through face-to-face interviews. The interviewers introduced themselves, explained the purpose of the study, and obtained informed consent from the patient to participate in the study before starting interview. Participation was voluntary and role of interviewer was to document the patient's answers in an unbiased way, without any interpretations or leading questions.

Only patients who visited the clinics could participate in the study and this was the only inclusion criteria. The exclusion criteria include (1) non-Arabic patients and (2) patient with communication difficulty for medical reasons, i.e., medically unstable or psychiatric patients. The Arabic version of the CAT questionnaire was used after obtaining permission from authors. The tool was developed, translated, and validated by Makoul *et al.* to measure patients' immediate perception of physician communication skills. This questionnaire consists of three parts: The first and second parts were created by the researcher and the third part is the CAT questionnaire. The first part addresses the respondent to explain the purpose of the study and obtain their consent to participate in the study. The second part contains sociodemographic questions, while the third part comprises 14 CAT research questions.^[10] To evaluate the communication and interpersonal skills of the physician, the CAT questionnaire asks the respondents to rate each statement provided using a 5-point Likert-type scale (1 = poor, 2 = fair, 3 = good, 4 = very good, and 5 = excellent). Respondents could also choose "do not know" or "not applicable."

Doctors working in the selected clinics were also asked a number of questions developed by the researcher. The purpose of this part of the data collection process was to evaluate patient's responses while considering information concerning doctors' age, gender, native language, specialty, professional title, clinical experience, and their last time attending a communication skills lecture or workshop. There were 25 doctors who agreed to participate and responded to the questions.

The Statistical Package for the Social Sciences v23 was used for data analysis. For each survey, an overall mean score was calculated as the sum of the items divided by total number of items answered. The percentage of items answered with a rating of 5 ("excellent") was also calculated by dividing the percentage of items scored as "excellent" by the number of items responded to. Cross-tabulation and bar diagrams were used to present descriptive statistics. For inferential statistics, an

analysis of variance (ANOVA) and *post hoc* test were used when the mean score was compared with the type of clinic visited. Two independent sample *t*-tests were used when mean score was tested with the gender of patients. Finally, the average CAT score was also tested with doctors' gender and native language using two independent sample *t*-tests. The physicians' professional title, experience, and last communication skills course attended were tested with an average score using ANOVA and *post hoc* tests. The significance level was set at 0.05.

RESULTS

Of the 400 patients invited to participate, 365 agreed and completed the questionnaire, a response rate of 91.2%. Considering the mean age, most respondents were aged between 45 and 60 years old. Furthermore, there were more male patients than female patients. Table 1 presents the patients' demographic data.

The 25 physicians from the selected clinics provided their demographics and educational information. The demographic data of these doctors are presented in Table 2. Of the 25 doctors who participated in the study, 12 had attended communication skills courses during the past 2 years, four attended 3–5 years ago, one attended 6–10 years ago, and two reported that they attended one more than 10 years ago. Three of them did not remember when they attended and three replied that they had never attended.

The results of the CAT analysis are presented in Table 3. The percentage of “excellent” ratings, the average score for each question, and the medians are provided. The lowest average score for a question was 4.22 and the highest 4.52. The effect of attending a communication skills course was analyzed using patients' CAT responses. It was found that only 82 of the 365 respondents received treatment from doctors who either did not attend any course or

did not remember. The average of the “excellent” scores did vary significantly between the two groups of doctors (those who attended and those who did not attend or did not remember). Furthermore, the effect of attending the communication skills course on CAT score was also analyzed; however, the results were statistically insignificant with $P = 0.087$. Despite the above, Figure 1 shows an upward trend in the average of “excellent” rating in relation to doctors' experience in years. This trend was statistically significant with $P < 0.001$.

Figure 2 presents a comparison of the statements from the CAT questionnaire according to doctor's specialties. The statistical significance values in Table 4 can be read in two ways: Overall significance and significance between the two specialties. The overall significance was observed for each question. Furthermore, a group-wise comparison of specialties provided insignificant results at four decimal places [Table 4]. Concerning question 1, the satisfaction rate for internal medicine specialty and family medicine doctors was the same, while doctors from the surgery department got the highest satisfaction rate. For questions 9 and 10, the satisfaction rate for surgery doctors was also significantly

Table 2: Doctors' demographic and educational information (n=25)

	n (%)
Age (years)	
30 years or younger	5 (20.0)
31–39	13 (52.0)
40–49	6 (24.0)
60 years or older	1 (4.0)
Gender	
Male	16 (64.0)
Female	9 (36.0)
Specialty	
Medical specialty	7 (28.0)
Family medicine	13 (52.0)
Surgery	5 (20.0)
Native language	
Arabic	23 (92.0)
Non-Arabic	2 (8.0)
Professional title	
Resident	6 (24.0)
Registrar	3 (12.0)
Senior registrar	5 (20.0)
Consultant	11 (44.0)
Clinical experience	
5 years or fewer	5 (20.0)
6–10 years	8 (32.0)
11–15 years	5 (20.0)
16–20 years	3 (12.0)
More than 20 years	4 (16.0)
Attendance of communication skills course	
2 years or fewer	12 (48.0)
3–5 years	4 (16)
6–10 years	1 (4)
More than 10 years	2 (8)
Cannot remember	3 (12)
Never attended	3 (12)

Table 1: Patients' demographic

	n (%)
Age (years)	
24 years or younger	90 (24.7)
25–44	135 (37.0)
45–60	95 (26.0)
>60 years	45 (12.3)
Gender	
Male	191 (52.3)
Female	174 (47.7)
Education	
Illiterate	17 (4.7)
Intermediate or less	38 (10.4)
Secondary	134 (36.7)
Higher than secondary	28 (7.7)
University	117 (32.1)
Master's or PhD	31 (8.5)

Table 3: Overall percentage (%) of “excellent” ratings and mean for individual Communication Assessment Tool item

Communication Assessment Tool item	Rating (% excellent)	Mean (standard deviation)	Median
Greeted me in a way that made me feel comfortable	85.64	4.28 (0.85)	5
Treated me with respect	90.35	4.52 (0.69)	5
Showed interest in my ideas about my health	87.56	4.38 (0.76)	5
Understood my main health concern	86.57	4.33 (0.82)	5
Paid attention to me (looked at me, listened carefully)	85.92	4.30 (0.79)	4
Let me speak without interruptions	86.58	4.33 (0.76)	4
Gave me as much information as I wanted	87.29	4.36 (0.77)	5
Spoke in terms I could understand	88.33	4.42 (0.74)	5
Checked to be sure I understand everything	84.99	4.25 (0.83)	4
Encouraged me to ask questions	84.49	4.22 (0.86)	4
Involved me in decisions as much as I wanted	85.97	4.30 (0.84)	5
Discussed next step, including any follow-up plans	86.79	4.34 (0.82)	5
Showed care and concern	88.49	4.42 (0.75)	5
Spent the right amount of time with me	89.48	4.47 (0.79)	5

**Figure 1: Relationship between doctors' clinical experience (years) and average “excellent” Communication Assessment Tool score**

higher than that of the internal medicine specialty and family medicine doctors. In question 14, internal medicine specialty and surgery doctors scored the highest.

No statistical significance was observed in the variations of satisfaction level with doctors' communication skills based on their gender. In addition, except for questions 13 and 14, results concerning doctors' native language were also insignificant, meaning that patients were more satisfied with the communication skills of doctors for whom their native language was Arabic than non-Arabic doctors when asked about the care and concern showed by the doctor ($P = 0.034$). Similarly, significantly different responses were found concerning the time spent by the doctors with patients. Patients were satisfied with doctors for whom Arabic was their native language ($P = 0.016$).

DISCUSSION

The findings of the study showed that patients were generally highly satisfied with the communication skills of their physicians. The minimum average rating for all items

was 4.2, which falls between “very good” and “excellent,” according to the 5-point scale used in the questionnaire. There are very few existing studies from Saudi Arabia that used the CAT questionnaire to assess the patients' satisfaction with doctors' communication skills. Alsaad *et al.* conducted a study in Riyadh in 2016 and found that the lowest rate on items was 4.5.^[12] In addition, the lowest rate of a CAT questionnaire item was reported to be 4.47 in a study conducted in the United States.^[11] Considering all these studies, it can be seen that the CAT questionnaire tends to elicit “excellent” ratings for the majority of the questions. This effect can also be observed in studies that used other tools to assess patients' satisfaction.^[13-16]

A comparison of patient's responses according to the type of clinics they visited showed that the percentage of “excellent” responses was the highest for surgery doctors, compared with internal medicine specialty and family medicine doctors. Patients gave the highest ratings for surgery doctors compared with the other specialties for questions 1, 9, and 10. These three questions concerned how a doctor communicates with their patient. This could be because surgery doctors usually make a point of making their patients completely aware of what the surgical procedure entails and why the procedure is required. Patients need to sign documentation before any surgical procedure; therefore, making them completely aware of all aspects of the procedure is always required. Another possible reason for the high satisfaction with surgery doctors compared with other specialties could be the consistency of patients' visit to a specific doctor when it involves surgery. Multiple visits to a specific doctor can help to develop better understanding and good doctor-patient relationship, which, in turn, develops good communication levels between doctor and patient. Due to limited available literature of the use of the CAT questionnaire to compare various medical specialties, it was difficult to compare the

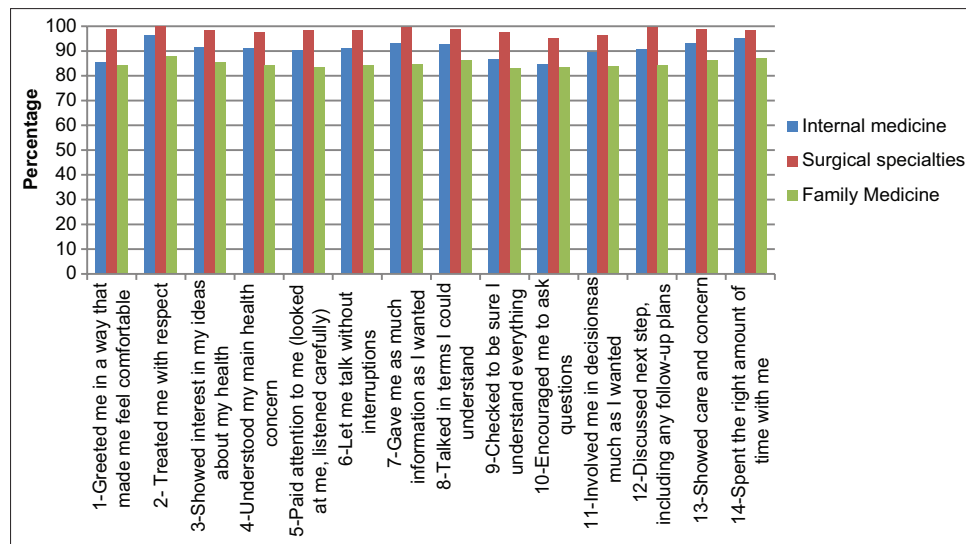


Figure 2: Mean percentages of "excellent" ratings according to doctors' specialty

Table 4: Specialty-based comparison of CAT responses

CAT item	% rated as excellent				M versus S	M versus F	S versus F
	M	S	F	P-value			
Greeted me in a way that made me feel comfortable	85.54	98.75	84.10	0.000*	0.00*	0.548	0.00*
Treated me with respect	96.31	100.00	87.76	0.000*	0.017*	0.00*	0.00*
Shown interest in my ideas about my health	91.38	98.12	85.37	0.000*	0.005*	0.004*	0.00*
Understood my main health concern	91.08	97.50	84.18	0.000*	0.023*	0.002*	0.00*
Paid attention to me (looked at me, listened carefully)	90.46	98.12	83.35	0.000*	0.002*	0.001*	0.00*
Let me talk without interruptions	91.07	98.12	84.10	0.000*	0.001*	0.001*	0.00*
Gave me as much information as I wanted	92.92	99.37	84.47	0.000*	0.00*	0.00*	0.00*
Talked in terms I could understand	92.61	98.75	86.04	0.000*	0.002*	0.001*	0.00*
Checked to be sure I understand everything	86.76	97.50	83.05	0.000*	0.00*	0.106	0.00*
Encouraged me to ask questions	84.61	95.00	83.20	0.000*	0.004*	0.55	0.00*
Involved me in decisions as much as I wanted	89.23	96.25	83.95	0.000*	0.023*	0.021*	0.00*
Discussed next step, including any follow-up plans	90.76	99.37	84.32	0.000*	0.00*	0.005*	0.00*
Shown care and concern	92.92	98.75	86.19	0.000*	0.013*	0.001*	0.00*
Spent the right amount of time with me	95.07	98.12	87.08	0.000*	0.20	0.00*	0.00*

*Statistically significant at 0.05 level of significance. CAT: Communication Assessment Tool

present study's findings with previously conducted studies. However, similar to our findings, Stausmire *et al.* found that questions 1 and 10 were among lowest rated overall.^[17]

Another significant finding of this study was the effect of doctors' native language when the patients were only Arabic speakers. It was found that due to the language barrier, doctors spend less time with the patients and are perhaps not able to show their concern and care for the patients clearly to satisfy their patients. The gender of the physicians was also compared with the CAT scores, but no statistical significance was observed. Furthermore, the effect of attending communication skills lecture or workshop in recent years also did not have any significant relationship with patients' satisfaction with physicians' communication skills. Our findings revealed that the highest rating was received by the registrar for almost all the questions being asked. This may also have an explanation: The consistency

of patient's visits with the registrar would be higher, compared with residents and consultants; therefore, the communication between doctor and patient would be better. We also noted that among the 365 participants, only 19 received treatment from registrars, unlike residents or consultants, who treated more than 100 of the patients that participated in the study. The small number of patients seen by registrars could possibly affect the comparison, considering that it showed the highest satisfaction of all the doctors.

Limitations

First, there was substantial variability in the number of surveys gathered per physician. Makoul *et al.* recommended a minimum of 20 surveys per doctor to reflect patients' perception accurately.^[10] Second, the sample size was not quite enough to represent a health-care facility with a large number of patients registered and receiving treatment.

Studies with large sample sizes are recommended in future as well as including various specialties to provide more valid results and better comparison.

CONCLUSION

This study showed that patients were satisfied with the communication skills of the doctors working at King Fahad Medical Military Complex. Patients showed higher satisfaction with surgery doctors, compared with other specialties. However, there is still room for improvement in doctors' communication skills. This can be accomplished by arranging lectures and workshops to improve communication. We recommend that similar studies be conducted at other hospitals or primary health-care clinics to map out a larger picture of the communication skills of the doctors practicing in the Kingdom of Saudi Arabia.

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Response Rate, Toxicity, and Compliance in Head-and-neck Cancer Patients Treated with Concurrent Chemoradiation – A Retrospective Analysis

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Abstract

Introduction: Head-and-neck cancer (HNC) is heterogeneous group of cancers and as a whole, they are the fifth most common cancer worldwide with an estimated annual global incidence of over half a million. Treatment approaches vary depending on the location of the tumor, staging, and individual patient's characteristics.

Aim: The aim of the study is to retrospectively assess the acute toxicity profile, response rates, and compliance with treatment in locally advanced squamous cell carcinoma of head and neck (SCCHN) treated with concurrent chemoradiation.

Materials and Methods: We analyzed retrospectively 85 patients with histologically proven SCCHN (nasopharynx, oropharynx, larynx, hypopharynx, and oral cavity) treated with definitive chemoradiation. All patients received 60–66 Gy in 30 daily fractions with concomitant weekly cisplatin 40 mg/m². We assessed treatment toxicities and patient compliance.

Results: The radiation therapy oncology group acute Grade 3 or worse mucositis was seen in 29 (34.1%) patients. Grade 3 or more skin reaction was seen in 14 (16.4%) patients. Common toxicity criteria Grade 3 or worse emesis occurred in 4 (4.7%) patients, mostly toward the end of chemoradiotherapy. Acute hematologic toxicity in the form of leukopenia and thrombocytopenia was mild and acceptable. Toxicity of treatment leading to interruption or compromise in the planned dose of radiotherapy was seen in 21 (24.7%) patients and chemotherapy break occurred in 39 (45.8%) patients. Of 100% ($n = 85$), 65.8% (56) had complete clinical response while 27.05% (23) had partial clinical response. Nodal response to treatment was analyzed separately. 19/27 (70.3%) patients in N1 stage, 22/33 (66.66%) patients in N2 stage, and 1/2 (50%) patients in N3 stage had complete clinical response whereas partial response was observed in remaining patients.

Conclusion: Concurrent chemoradiotherapy using cisplatin 40 mg/m² weekly is well tolerated by locally advanced HNC patients. Acute toxicities were reversible with supportive management and were not severe enough to cause discontinuation of treatment. The clinical complete response rates obtained in this study (65.8%) are comparable to the results in published literature (65–70%) and the results confirmed the importance of the stage of the disease as the most significant predictor of outcome. Survival benefits and late normal tissue complications were not predictable due to short period of follow-up. Carefully designed prospective randomized studies are needed to address these issues.

Key words: Chemoradiotherapy, Cisplatin, Head and neck neoplasms

INTRODUCTION

Head-and-neck cancer (HNC) is a major form of cancer in India, accounting for 23% of all cancer in males and

6% in females.^[1] The 5-year survival rate varies from 20% to 90% depending on the subsite of origin and the clinical extent of the disease. India has the dubious distinction of having the world's highest reported incidence of HNC in women.^[2] The disproportionately higher prevalence of HNC in relation to other malignancies in India may be due to the use of tobacco in various forms, consumption of alcohol, and low socioeconomic condition related to poor hygiene, poor diet, or infections of viral origin.^[3]

The baseline risk of developing cancer is acted on throughout life as the genome of different cells interacts

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with environment in the form of exposures (e.g., toxins and infections). As genetic damage is incurred throughout a lifetime (directly to DNA sequences or to the epigenome), events are set in motion to progressively disrupt normal cellular pathways toward tumorigenesis.^[4]

Strong epidemiologic and molecular data now support the conclusion that human papillomavirus infection is responsible for a distinct form of squamous cell carcinoma of head and neck (SCCHN). HNC is best managed in a multidisciplinary setting. Surgery, radiation therapy (RT), chemotherapy, and more recently biologic therapy are often employed in various combinations in an attempt to eradicate both clinically apparent and occult diseases. The goals of treatment include maximizing tumor control while maintaining function and quality of life. Long-term survival is improving with advances in therapy but remains suboptimal. Approximately 50–60% of patients develop local disease recurrence within 2 years.^[5]

Patients with resectable locally advanced SCCHN (LASCCHN) are managed with surgical resection followed by adjuvant RT. The addition of concurrent chemotherapy to adjuvant RT has resulted in significant improvement in survival. For patients with unresectable LASCCHN, concurrent chemoradiotherapy has produced a survival benefit compared to RT alone. With respect to targeted therapy, the epidermal growth factor receptor (EGFR) is overexpressed in many head and neck tumors. EGFR inhibition through anti-EGFR antibody therapy or small molecule inhibitors of EGFR may act in a synergistic fashion with RT through inhibition of cellular proliferation, tumor angiogenesis, and DNA repair.^[6]

Aim

The aim of the study is to retrospectively assess the acute toxicity profile, response rates, and compliance with treatment in LASCCHN treated with concurrent chemoradiation.

MATERIALS AND METHODS

This is a retrospective study which assessed the acute toxicities and response rates in LASCCHN treated with concurrent chemoradiation. Patients included in the study were registered in the Department of Radiotherapy, Medical College Thiruvananthapuram, between June 2008 and June 2010.

Patients were given radiotherapy by Cobalt 60 external beam to a total dose of 60–66 Gy, 1.8–2 Gy per fraction, and 5 days a week. Injection cisplatin was administered intravenously once a week as 40 mg/m² during the whole course of radiotherapy.

Inclusion Criteria

The following criteria were included in the study:

- Patients having LASCCHN
- Patients with histological evidence of malignancy
- Hemoglobin of more than or equal to 10 g%
- Total white blood cell count of more than or equal to 4000/mm³
- Eastern Cooperative Oncology Group performance status of 0–2.

Exclusion Criteria

The following patients were excluded from the study:

- Patients with carcinoma of nasopharynx
- Patients with no evidence of distant metastasis
- Patients with prior history of radiation to head and neck region.

Pretreatment Evaluation

Patients were evaluated by physical examination, ear, nose, throat examination, and necessary laboratory and radiological evaluation. Routine blood counts, liver function test, renal function test, chest X-ray, and indirect and direct laryngoscopy were carried out to determine the extent of the tumor and staging. Biopsy of the tumor was done in all cases for confirmation and fine-needle aspiration cytology of the lymph nodes was done when indicated. Computed tomography scan and magnetic resonance imaging were considered optional. The clinical staging was confirmed by the principal investigator. All patients had a routine dental checkup, scaling, and extraction of teeth as indicated before radiation. The patients were advised to stop smoking, advised proper oral care, and encouraged to drink plenty of water. All patients were introduced Ryle's tube before starting the treatment.

Weekly Assessment

All patients were monitored closely every week during the course of concurrent chemoradiation for assessing the toxicity of therapy. Toxicity grading was done according to the RT oncology group (RTOG) and common toxicity criteria (CTC) grading systems for radiation-related and chemotherapy-related toxicities, respectively. The patients were required to follow-up at 4–6 weeks from completion of therapy to assess response and disease status. Subsequent follow-up visits were scheduled at 3–6 monthly intervals for the first 2 years and annually thereafter. All patients were personally seen at least 2 times a week. They were monitored and recorded every week with the following parameters.

1. Mucosal reaction (grade of mucositis) and skin reaction (grade of skin reaction) were recorded according to the RTOG scale
2. Acute treatment-related side effects such as dysphagia, dryness of mouth, hoarseness of voice, and pain on swallowing were also measured.

Patients who developed Grade 3 reaction were given a break in treatment and were admitted in the ward and treated with supportive medication which included vitamins, hydration, analgesics, mouth wash, antibiotics, and antifungal treatment if required.

Outcome Measurement

Patients were evaluated for response to treatment both primary and lymph nodes at 3 weeks and 6 weeks of completion of treatment.

- Complete response (CR) is complete disappearance of all measurable disease
- Partial response (PR) is regression of more than 50% measurable disease
- No response is regression of <50% of measurable disease
- Progressive disease is progression of the initial disease.

Follow-up of Patients

All patients were assessed at 3 weeks and 6 weeks after treatment for residual disease at the primary site or at the neck. No adjuvant chemotherapy was administered to the patients.

Statistical Analysis

The acute reactions and the response of the tumor were carried out using Fisher's exact test and Chi-square test. The statistical analysis was performed with SPSS software.

RESULTS

A total of 85 patients satisfied the eligibility criteria and form the dataset for this analysis. The sociodemographic and clinicopathologic characteristics of all the analyzable 85 patients with LASCCHN receiving radical RT with concurrent weekly cisplatin were consistent with previously published head and neck literature. Although medical comorbidities consistent with the age-pyramid were prevalent, they were not significant enough in the large majority (such as active tuberculosis, uncontrolled hypertension or diabetes mellitus, or nephropathy) precluding systemic chemotherapy.

Based on the primary site of cancer, of 85 patients, 31 (36.4%) had carcinoma oropharynx, 25 (29.4%) had ca larynx, 15 (17.6%) had ca hypopharynx, and 14 (16.4%) had ca oral cavity.

Majority (40%) of the patients 34 were within the age group 50–59 years. Thirty-one patients (36.4%) belonged to age group of 40–49 years. Age groups 60–69 and 30–39 years were 17.6% (15) and 5.8% (5), respectively. Among 85 patients, 71 (83.5%) were male and 14 (16.4%) were female.

T Status, N Status, and Composite Stages

Of 85 patients, 4 patients (4.7%) had T1 tumor, 18 patients (21.1%) had T2 tumor, 51 patients (60.0%) had T3 tumor, and 12 patients (14.1%) had T4 tumor. Among 85 patients, 23 (27.05%) had N0 status, 27 (31.7%) had N1 status, 33 (38.8%) had N2 status, and 2 (2.3%) had N3 status. Of 85 patients, 39 patients (45.8%) had Stage III and 46 patients (54.2%) had Stage IV [Table 1].

Outcome Analysis

This study has tried to analyze the response rates of the primary tumor and the node to concurrent chemoradiation and the acute reactions during the treatment.

Analysis of the Acute Reactions

The RTOG acute Grade 3 or worse mucositis was seen in 29 (34.1%) patients. Grade 3 or more skin reaction was seen in 14 (16.4%) patients. Mild to moderate nausea and vomiting occurred in almost all patients despite antiemetic prophylaxis.

Difficulty in swallowing was seen in almost all patients and around half of the patients had hoarseness [Table 2]. CTC Grade 3 or worse emesis occurred in 4 (4.7%) patients, mostly toward the end of chemoradiotherapy. Acute hematologic toxicity in the form of leukopenia and thrombocytopenia was mild and acceptable. The incidence of CTC Grade 3 leukopenia was 5.7%. No episodes of febrile neutropenia were recorded. No patients experienced CTC Grade 3 thrombocytopenia. Platelet transfusion or growth factor support due to acute hematologic toxicity was not needed in any patient.

There was minimal acute kidney dysfunction, with no episodes of Grade 3 or worse renal toxicity, because the dose of cisplatin was titrated based on indirect EGFR before each cycle of weekly chemotherapy.

Treatment Interruption

Toxicity of treatment leading to interruption or compromise in the planned dose of radiotherapy was seen in 21 (24.7%) patients and chemotherapy break occurred in 39 (45.8%) patients [Table 3]. The most common cause of radiation break was mucositis and chemotherapy break was mostly due to Grade 3 mucositis. The break duration extended from 7 to 14 days. The patients who had Grade 3 mucosal reactions were given 1 week break. During this period, patients were admitted in ward and given hydration and other supportive care. Overall the regimen was well tolerated with acceptable acute toxicity.

Analysis of Control of Disease

Control of the primary at 6th week

Of 100% ($n = 85$), 65.8 % (56) had complete clinical response while 27.05% (23) had partial clinical response.

Table 1: Patient characteristics – T stage, N stage, and composite stages

	Tumor status				Nodal status				Composite stages	
	T1	T2	T3	T4	N0	N1	N2	N3	Stage III	Stage IV
n (%)	4 (4.7)	18 (21.1)	51 (60.0)	12 (14.1)	23 (27.05)	27 (31.7)	33 (38.8)	2 (2.3)	39 (45.8)	46 (54.2)

Table 2: Outcome analysis – mucositis, skin reaction, and other complications

Mucosal reaction	n (%)
Grade 1 and 2 alone	56 (65.9)
Grade 3 or more	29 (34.1)
Skin reaction	n (%)
Grade 1 and 2 alone	71 (83.5)
Grade 3 or more	14 (16.4)
Other complications	n (%)
Odynophagia	81 (95.2)
Hoarseness	47 (55.2)

Table 3: Outcome analysis – radiation break and chemotherapy break

Radiation break	n (%)
Break present	21 (24.7)
No break	64 (75.3)
Chemotherapy break	n (%)
Break present	39 (45.8)
No break	46 (54.2)

All patients (4/4) in T1 stage, 14/18 (77.8%) patients in T2 stage and 38/51 (70.58%) patients in T3 stage had complete clinical response while PR was seen in remaining patients. CR rates were 61.74% (21/31) for primary oropharynx tumor, 60% (9/15) for hypopharynx, 68% (17/25) for larynx, and 64.2% (9/14) for oral cavity.

Control of node at 6th week

Nodal response to treatment was analyzed separately. 19/27 (70.3%) patients in N1 stage, 22/33 (66.66%) patients in N2 stage, and 1/2 (50%) patients in N3 stage had complete clinical response whereas PR was observed in remaining patients.

Control of the disease stage wise

Of 39 patients with Stage III disease, 27 patients (69.2%) had complete clinical response and of 46 patients with Stage IV disease, 29 patients (63.04%) had complete clinical response, whereas the remaining patients had PR.

DISCUSSION

In India, HNCs account for 30–40% of total cancers.^[7] SCCHN accounts for approximately 5% of newly diagnosed

cancers worldwide each year. The integration of chemotherapy into a combined modality approach involving surgery and/or RT has been investigated in an effort to improve the outcome of LASCCHN based on level I evidence. However, only 60% of patients in clinical trial setting are able to receive all the three planned doses of 3-weekly cisplatin due to unacceptably high systemic and mucosal toxicities,^[8] the lack of uniform reporting of side effects and small size of individual studies limits conclusion about the relative tolerability of one regimen over the other. More frequent administration could provide better radiosensitization to a larger proportion of the administered radiotherapy dose.^[8] Smaller individual doses of the drug may also result in lesser chemotherapy-induced morbidity without compromising the efficacy.

There are now several reports showing benefit in locoregional control and/or survival with alternative cisplatin regimens. A prospective nonrandomized study^[9] compared 3-weekly cisplatin (100 mg/m²) given to younger patients with good Karnofsky performance status (KPS) ($n = 30$) with weekly cisplatin (40 mg/m²) in patients with older age or poor KPS ($n = 20$) along with radical radiotherapy. The CR rate (50% vs. 40%), overall response rate (92% vs. 90%), and Grade 3–4 toxicities (53% vs. 40%) were similar in the two cohorts. The only randomized study comparing daily (6 mg/m²), weekly (40 mg/m²), and 3-weekly (100 mg/m²) schedule of cisplatin with conventionally fractionated radiotherapy^[10] did not find any significant difference in the efficacy of the regimens (similar response rates and locoregional control), but reported varying degrees of mucosal, renal, and hematologic toxicity. Overall the available data suggests that a cumulative cisplatin dose of 200–250 mg/m² given 3-weekly, weekly, or daily during radiotherapy yields therapeutic benefit. The most popular schedule of concurrent cisplatin for SCCHN outside the context of clinical trials is not the 3-weekly regimen but a weekly schedule of cisplatin in the dose range of 30–40 mg/m².

In this setting, the toxicity grading was done according to the RTOG and CTC grading systems for radiation-related and chemotherapy-related toxicities, respectively. Patients were evaluated for response to treatment both primary and lymph nodes at 3 weeks and 6 weeks of completion of treatment. The CR rates obtained in this study are comparable with the data in published literature in which

the clinical CR rate is in the range of 65–70%.^[11-13] The difference in response rates did not reach statistically significant value ($P = 0.50$) in terms of T and N stages. The patients who had composite Stage III disease had better response rates and the difference was statistically significant ($P < 0.05$).

CONCLUSION

Concurrent chemoradiotherapy using cisplatin 40 mg/m² weekly is well tolerated by LASCCHN patients and all the patients were able to complete the total planned dose of radiation. Acute toxicities, most commonly radiation mucositis were reversible with supportive management and were not severe enough to cause discontinuation of treatment. The clinical CR rates obtained in this study (65.8%) are comparable to the results in published literature (65–70%) and the results confirmed the importance of the stage of the disease as the most significant predictor of outcome. Survival benefits and late normal tissue complications were not predictable due to short period of follow-up. Carefully designed prospective randomized studies are needed to address these issues.

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Comparison of Tamsulosin versus Tadalafil as an Effective Expulsive Treatment for Distal Ureteral Stones – A Prospective Comparative Study

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Abstract

Introduction: The increasing prevalence of ureteric stone is a matter of concern in this era and it may be linked to improved quality of life. Medical expulsive therapy, including alpha-blockers, steroids, and calcium channel blockers, has been extensively studied for improving the rate of stone passage in patients who do not require immediate urologic intervention.

Aim: The aim of this study is to compare the efficacy of tamsulosin and tadalafil in expulsive treatment for distal ureteral stones.

Materials and Methods: This was a prospective comparative study included 120 adult patients (>18 years of age) presenting with distal ureteric stones were randomized into 60 patients with tamsulosin 0.4 mg once daily (Group A) or 60 patients with tadalafil 10 mg once daily (Group B) treatment. Therapy was given for a maximum of 4 weeks.

Results: About 85% of study patients had a size between 5 mm and 7 mm and 18 patients had size between 8 mm and 10 mm. There was no statistical difference noted in the pain duration and analgesic usage of both groups. In Group A, 67% of patients had expulsion of stones; in Group B, 63% of patients had expulsion of stones. About 90% of patients in 40 cases of expelled stones are in <5 days in Group A and 89% of patients 38 cases of expelled stones are in <5 days in Group B. There was no statistical difference noted between both groups.

Conclusion: Tamsulosin and tadalafil have shown similar expulsion rate. Both of them simultaneously provides better pain control and significantly lower the needs for analgesia.

Key words: Medical expulsive therapy, Tadalafil, Tamsulosin

INTRODUCTION

Urolithiasis is a major health problem worldwide with increasing incidence and prevalence.^[1] When ureteral stones are diagnosed, the management may consist of observation, shockwave lithotripsy, or ureteroscopy, depending on the clinical situation. The probability of spontaneous stone passage decreases with increasing stone size and location above the distal ureter.^[2,3]

Determining the proper treatment approach involves the size, localization, and composition of the stone, severity of obstruction, symptoms, and anatomy of the urinary system. Medical expulsive therapy (MET) has now become an established modality of treatment and it involves the use of various drugs acting on ureter by different mechanisms. MET has a proven role to promote stone passage and reduce the need for minimally invasive surgery.

MET, including alpha-blockers, steroids, and calcium channel blockers, has been extensively studied for improving the rate of stone passage in patients who do not require immediate urologic intervention.^[4-6]

Tamsulosin, a selective alpha-blocker with equal affinity for both α -1A and α -1D receptors, has a proven role in MET in increasing the stone expulsion rate and decreasing

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expulsion time. Tadalafil has emerged, which acts on nitric oxide/cyclic guanosine monophosphate (cGMP) signaling pathway of smooth muscles, resulting in increased levels of cGMP, and causing ureteric relaxation. Due to its smooth muscle relaxation property, tadalafil received the Food and Drug Administration (FDA) approval for use in lower urinary tract symptoms with benign prostatic hyperplasia and erectile dysfunction. It also received the FDA approval for use in pulmonary arterial hypertension for both men and women.^[7,8]

Aim

The aim of this study is to compare the efficacy of tamsulosin and tadalafil in expulsive treatment for distal ureteral stones.

MATERIALS AND METHODS

This prospective comparative study was conducted in the Department of Urology at Tirunelveli Medical College Hospital for 1 year from 2017 to 2018. After taking written informed consent, patients aged 18 years with a ureteral stone of 5–10 mm in size in the greatest dimension situated below the common iliac vessels as diagnosed by non-contrast computed tomography (CT) or ultrasonography kidney, ureter, and bladder (KUB) were included in this study. Patients with fever, hydronephrosis, acute or chronic renal insufficiency, multiple ureteral stones, open surgery or endoscopic interventions, diabetes, peptic ulcer, or concomitant treatment with b-blockers, calcium antagonists, or nitrates; pregnant or lactating mothers; or who demand immediate intervention were excluded from the study. A total of 120 patients were enrolled in the study. They were divided into 2 groups randomly into Group A and Group B. Group A were given tamsulosin 0.4 mg once daily and Group B was given tadalafil 10 mg once daily, continued until stone expulsion or maximum of 4 weeks. Each enrolled patient was assessed by physical examination, serum creatinine level, urine culture, ultrasonography, and non-contrast CT of the KUB region as needed. The primary endpoint studied was the stone expulsion rate.

RESULTS

In this study, 120 patients were divided into two groups, Group A tamsulosin 0.4 mg once daily and Group B was given tadalafil 10 mg once daily. The mean age of the study patients was 36.42 ± 9.68 years, 56 male patients and 64 female patients were included in the study. No statistical difference was observed in patients demographic characters. There was no significant difference observed in the uric acid level in both groups. No statistical difference noted in the site of the stones, 68 patients had it in lower

ureteral (UR) and followed by 42 patients in vesicoureteric junction [Tables 1 and 2].

About 85% of study patients had a size between 5 and 7 and 18 patients had size between 8 and 10. There was no statistical difference observed between groups [Table 3].

About 52% of patients had the stone in the right side, there was no statistical difference noted between groups [Table 4].

There was no statistical difference noted in the pain duration and analgesic usage of both groups [Table 5].

In Group A, 67% of patients had expulsion of stones; in Group B, 63% of patients had expulsion of stones. About 90% of patients in 40 cases of expelled stones are in <5 days in Group A and 89% of patients 38 cases of expelled stones are in <5 days in Group B. There was no statistical difference noted between both groups [Table 6]. In Group A, 2 patients had body ache, 2 patients had headache, and 3 patients had giddiness. In Group B,

Table 1: Crosstabulation of uric acid level

Group	Uric acid		Total	P value
	Normal	Elevated		
Tamsulosin	42	18	60	0.559
Tadalafil	46	14	60	
Total	88	32	120	

Table 2: Crosstabulation of site

Group	Site			Total	P value
	Lower UR	Vesicoureteric junction	Middle UR		
Tamsulosin	36	20	4	60	0.999
Tadalafil	32	22	6	60	
Total	68	42	10	120	

Table 3: Crosstabulation of size

Group	Size		Total	P value
	5–7 mm	8–10 mm		
Tamsulosin	50	10	60	0.718
Tadalafil	52	8	60	
Total	102	18	120	

Table 4: Crosstabulation of side

Group	Side		Total	P value
	Right	Left		
Tamsulosin	32	28	60	0.796
Tadalafil	30	30	60	
Total	62	58	120	

Table 5: Crosstabulation of pain

Group	Pain		Total	P value
	<1 week	>1 week		
Tamsulosin	26	34	60	0.795
Tadalafil	28	32	60	
Total	54	66	120	

Table 6: Crosstabulation of expulsion days

Group	Days		Total	P value
	<5 days	>5 days		
Tamsulosin	36	4	40	0.957
Tadalafil	34	4	38	
Total	70	8	78	

4 patients had headache, 2 patients had weakness, and 1 painful erection. There was no statistical difference noted between groups.

DISCUSSION

The natural course of ureteral stones without treatment must be balanced against the relatively limited risks of treatment that is now possible with nonsurgical techniques. Management of ureteral stones depends on the type, size, location, number and structure of the stone, and presence of symptoms. The presence of ureteral spasm, mucosal edema or inflammation, and ureteral anatomy also influence stone expulsion.^[9,10]

The management of patients with ureteral calculi has changed dramatically in the current era with a conservative approach being the primary focus, which brings the patient minimum morbidity. Conservative nonsurgical approaches are usually instituted in the treatment plan of distal ureteral stone of size 5–10 mm as they are less likely to pass spontaneously.^[10]

According to earlier studies, the expulsion rate of distal ureteric stone by watchful waiting is 25–54% with mean expulsion time >10 days and associated with high analgesic requirement even for stones <5 mm. To improve the expulsion rate and reduce analgesic requirements, medical therapy is considered for distal ureteral stones.^[11,12]

The first high-quality trial was reported by Hermanns *et al.*^[13] in 2009. They evaluated the expulsion rate of single distal ureteral stones 7 mm confirmed by CT. Ninety participants were randomized between tamsulosin and placebo groups. The mean stone the size was 4.1 and 3.8 mm, respectively. The stone expulsion rate did not differ between the tamsulosin (86.7%) and placebo (88.9%)

groups. The only reported advantage of tamsulosin was the decreased analgesic requirement until stone expulsion.

Phosphodiesterase inhibitors (PDEi) are a class of drugs that inhibit the breakdown of cyclic adenosine monophosphate and cGMP, enhancing smooth muscle relaxation. Therefore, PDEi may be able to decrease ureteral spasm and facilitate stone passage. Tadalafil is a selective phosphodiesterase 5-inhibitor (PDE5i) and due to its smooth muscle relaxation property, tadalafil.^[14,15]

A ureteral stone usually causes severe colicky pain as a result of an increase in intraurethral pressure above the site of ureteral obstruction. At present, nonsteroidal anti-inflammatory drugs and antispasmodic drugs are generally used for relieving the pain caused by acute ureteral obstruction. Tamsulosin and tadalafil might reduce the colicky episodes, hence analgesic requirement and hospital visits by relaxing the ureteral smooth muscles and early stone expulsion.^[15,2]

CONCLUSION

Tamsulosin and tadalafil have shown similar expulsion rates. Both of them simultaneously provide better pain control and significantly lower the needs for analgesia. As $\alpha 1$ adrenoreceptor antagonist (tamsulosin) and PDE5i (tadalafil) act through different pathways, combined therapy can further aid in distinctiveness, uniformity, and stability expulsion.

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A Comprehensive Study of Patients Admitted with Snakebite in Tirunelveli Medical College Hospital

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Abstract

Background: Patients admitted with snakebite can have varied manifestations and complications which needed special care and specialized treatments. To alert the treating physician about the possible presenting symptoms and signs and the possible complications, we need some baseline information about the incidence of snakebite in that given area, the most common type of snake and percentage of patients develops complications, the mortality, and outcome. This study was conducted to provide such information.

Aim: This study aims to study the incidence of snakebite, complications, and predicting the outcome based on variable factors in patients >12 years of age.

Materials and Methods: It was a prospective observational study done in 403 patients admitted in the study period of 1 year (from May 2017 to April 2018). Around 20 parameters were recorded using pre-structured pro forma. Data analyzed using SPSS software version 21.0.

Results: A total of 403 patients were studied. Only 56% of patients showed signs of envenomation; among this the most common is the cellulitis which accounts for 36.4% of patients. The study also showed that those who were presenting late had increased morbidity and mortality and their stay in the hospital also prolonged. It also showed that almost 5% of patients still underwent some form of unauthorized treatment before seeking the medical care. Increase in age is associated with bad outcome. The study also showed 21% of all patients who had snakebite developed complications; the most common was the compartment syndrome accounted for 8.9%. Only in 46% of cases, the snake was identified and the Russell's viper is the most common snake responsible for most of the bites.

Conclusion: Late visit following snakebite is the most important factor which inversely affects the outcome following snakebite. Other factors which contribute to poor outcome include old age, diabetes, native treatment, presence of signs of envenomation on admission, and development of complications.

Key words: Complications, Morbidity, Mortality, Snakebite

INTRODUCTION

Being bitten by a snake is frightening for all. Most of the snakebites produce little more than local pain and do not require medical attention. However, some bites may produce life-threatening complications hence seeking medical attention immediately after bite is mandatory to avoid mortality and morbidity. The terms venomous

and poisonous are not the same. "Venomous" indicates organisms producing toxic material in the specialized gland and injecting through bite specialized venom apparatus and other means. "Poisonous" refers to detrimental effects produced by touching or consuming plants/organisms. Poison found throughout the organisms but venom produced in isolated glands. Most of the world's medically significant snakes belong to four families – *Viperidae*, *Elapidae*, *Colubridae*, and *Atractaspidinae*.^[1,2] In developing countries, most of the snakebites occur to the agricultural workers during their work in the fields. In developed countries, the most common victims are adolescents and young adults due to their risky behavior. About >95% of snakebites occur over lower extremities.^[3] Snake venoms are complex mixtures of proteins including

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enzymes and low-molecular-weight polypeptides. The fear of snakebite itself produces symptoms such as nausea, vomiting, diarrhea, cold clammy skin, and syncope regardless whether injection of venom.^[4] In general, viper bites cause deleterious effects on almost any organ system. Russell's viper is implicated in causing acute kidney injury (AKI) and neurotoxicity apart from the usual local signs and coagulation abnormalities.^[5] In contrast, *Elapidae* family causes more neurotoxic manifestations with little or no envenomation. Exceptions are African spitting cobras (member of *Elapidae* family) produce little or no neurotoxicity but cause severe tissue necrosis and vipers such as Southern Pacific rattlesnake (*Crotalus oreganus helleri*), timber rattlesnake (*Crotalus horridus horridus*), western diamondback rattlesnake (*Crotalus atrox*), and Mohave rattlesnake (*Crotalus scutulatus*) produce significant neurotoxicity.^[6] Krait bites are commonly painless and produce neurotoxicity which will not resolve following administration of anti-snake venom (ASV) or anticholinesterase due to postsynaptic blockade. Sea snakes produce generalized rhabdomyolysis later lead to respiratory failure.^[7]

Aim

This study aims to study the incidence of snakebite, complications, predicting the outcome, and mortality rate.

MATERIALS AND METHODS

In this prospective observational study, patients with snakebite admitted in the Department of General Medicine at Tirunelveli Medical College were included in the study.

Inclusion Criteria

The following criteria were included in the study:

- All known cases of snakebite patients
- Age group >12 years
- All known case of bronchial asthma and chronic obstructive pulmonary disease (COPD) without any acute exacerbation before a snakebite
- All the cases of ischemic heart disease/diabetes/hypertensive/epilepsy with snakebite.

Exclusion Criteria

The following criteria were excluded from the study:

- Age <12 years
- Doubtful bites (patient not sure about what bite them)
- Snakebites (patient found snake beside them at night)
- Known cases of hemophilia and other coagulation disorders
- Known cases of chronic kidney disease/who already undergoing dialysis
- Known cases of sepsis with AKI (before the incidence of snakebite)

- Known cases of patients with cellulitis in the same limb due to other causes apart from snakebite
- Known cases of COPD patients with severe respiratory distress
- Known cases of bronchial asthma with previous episodes of status asthmaticus presenting with respiratory failure onset before the snakebite.

RESULTS

In our study, 403 snakebite patients were selected during the 1 year period (from May 2017 to May 2018) based on inclusion and exclusion criteria, observed, and subjected to relevant investigations and results are compiled. In our study, males (65%) are found to have more incidence of snakebite than females (35%). In our study, most of the patients had the snakebite when they were outside of their home. Among the 403 snakebite patients, we studied around 5% of people (20) underwent some form of unauthorized method of treatment before seeking medical care. The people who went some form of traditional or unauthorized method of treatment show

Table 1: Presenting symptoms

Symptoms	No	Yes	Percentage
Pain and swelling	243	160	39
Bleeding	380	23	5.70
Muscle weakness	361	42	10.40
Gastrointestinal symptoms	393	10	2.40
Breathlessness	369	34	8.40

Table 2: Autonomic hyperactivity

Autonomic hyperactivity	No	Yes	Percentage
Hyperglycemia	379	24	5.90
Hypertension	390	13	3.20
Sweating	359	44	10.90
Tachycardia	340	63	15.60

Table 3: Envenomation signs

Signs of envenomation	Yes	No	Percentage
Cellulitis	147	256	36.40
Whole blood clotting test >20	121	282	30
Neuromuscular weakness	46	357	11.40

Table 4: Complications of snakebite

Complications	No	Yes	Percentage
Acute kidney injury	376	27	6.6
Compartment syndrome	367	36	8.9
Disseminated intravascular coagulation	394	9	2.2
Respiratory failure	379	24	5.9
Sepsis	380	23	5.7

Table 5: Number of complications

Number of complications	Frequency	Percentage
1	342	84.80
2	41	10.10
3	11	2.70
4	8	1.90
5	1	0.20

Table 6: Outcome

Outcome	No	Yes	Percentage
Completely recovered	44	359	89
Disabilities	370	33	8.1
Death	392	11	2.7

Table 7: Complete recovery based on number of complications

Number of complications	Death		Total	P-value
	No	Yes		
1	307	2	309	<0.0001
2	23	45	68	
3	10	7	17	
4	7	1	8	
5	1	0	1	
Total	44	359	403	

Table 8: Morbidity based on number of complications

Number of complications	Death		Total	P-value
	No	Yes		
1	45	23	68	<0.0001
2	10	7	17	
3	7	1	8	
4	1	0	1	
Total	370	33	403	

Table 9: Mortality based on number of complications

Number of complications	Death		Total	P-value
	No	Yes		
No	309	0	309	<0.0001
1	67	1	68	
2	14	3	17	
3	2	6	8	
4	0	1	1	
Total	392	11	403	

increased morbidity (20%) and mortality (10%) than who do not. The snake was correctly identified either with a history of with the help of photographs is in only 46% of the patients. In remaining, the identification was not possible. In more than half of the patients, snakes were not identified. Among the identified snakes, Russell's

viper is the most common snake type accounts for 23% of the cases and least common is krait 10%. The most common presenting complaints in our study is that of pain and swelling at the bite site and least common is the gastrointestinal symptoms (such as vomiting and abdominal pain Table 1). Out of all patients presented with snakebite, only few show the signs of autonomic hyperactivity. Among the most common manifestation was the tachycardia (15.6%) followed by sweating and palpitation (10.9%). Hyperglycemia and hypertension were also not in few Table 2. Out of 403 snakebite patients studied, only 226 (56%) patients showed the sign of envenomation and 177 (44%) patients showed no evidence of envenomation. Among 226 patients who showed signs of envenomation, cellulitis is the major sign followed by the prolonged clotting time and the last is the neuromuscular weakness Table 3. Among the study patients, around 9% were diabetic and 7.4% were hypertensive. Two patients gave a history of pulmonary tuberculosis in the past and eight people had bronchial asthma (mild) who used intermittent inhaler therapy. In our study population of 403 patients, 86 patients (21%) had comorbid conditions. The contribution of these comorbidities in the outcome of the patients had been considered in the studies. Among the 403 patients without snakebite, 61 (15.1%) developed one or more complications. Compartment syndrome (8.9%) is the most frequent complication encountered in the study population. Disseminated intravascular coagulation (DIC) (2.2%) is the least common complication observed in the study group. Among 61 (15.1%) who developed complications, 41 patients (10.1%) had single complication, 11 patients (2.7%) had two complications, 8 patients (1.9%) two complications, and one had four complications Tables 4 and 5. The overall outcome was good for the patients admitted with snakebite. Three hundred and fifty-nine (89%) patients recovered completely following snakebite, 33 patients had morbidity, and 11 patients expired due to complications of snakebite. The patient who presented to the hospital early following the snakebite had good outcome. The delayed presentation resulted in increased morbidity and mortality. According to the study result, patients with young age had good recovery Table 6-9. The mean age of <40 has favorable outcome than the mean age of >40 in the study population. Diabetes is one of the factors play a pivotal role in the outcome of the patients. Around 50% of patients who had morbidity and mortality had diabetes. DIC increases the risk of mortality significantly in patients with snakebite but if treated properly does not produce any morbidity and recovery is complete. According to our study, all the patients who developed respiratory failure showed some kind of neuromuscular weakness. Some patients who showed muscular weakness did not develop respiratory failure due to the treatment given. All the patients who died

had cellulitis. Cellulitis increased morbidity significantly. Twenty-nine out of 33 patients who had morbidity had cellulitis. Cellulitis is one of the major factors which significantly prolonged the hospital stay in snakebite patients. Whole blood clotting test not significantly affects the outcome of the patients. It signifies the risk of the development of DIC, but much of the abnormality corrected by administration of ASV. Patient's outcomes did not greatly vary between those who have prolonged clotting time from those who have normal clotting time. Although neuromuscular weakness leads to respiratory failure and needs for ventilatory support subsequently increased, the outcome is not significantly affected. Out of 46 presented with weakness, 39 recovered completely, only 5 developed some kind of morbidity, and death occurred in 2 of the patients. Sepsis is the major complication which increased the mortality of the patients among 11 people who died 10 developed sepsis. Early treatment of sepsis can prevent mortality. The number of snakebite cases admitted in Tirunelveli Medical College is maximum at mid-year period. May month has the maximum number of cases (49) and February month had the least number of cases (20) followed by September (24). Those who had fewer complications had good clinical recovery than those had more complications. The number of morbidities also increased proportionately with increased number of complications. The number of deaths increases with increasing complications. Among 68 people with single complication, one died but the number increases with 3/17 for two complications, 6/8 for three, and 1/1 for patient who developed four complications.

DISCUSSION

In this study, all the 403 patients admitted to Tirunelveli Medical College Hospital for the period of 1 year (from May 1, 2017, to April 30, 2018) with the definite history of snakebite were studied since the admission till the final endpoint (discharge/death). About 95.30% of bites have occurred when the patients were outside their home (384 patients) and bites were common in rural areas and among the farmers and agricultural laborers. Other activities that are having increases risk of exposure the snakebites are collecting long, gardening, and playing or working near the bushy areas. This is the similar case mentioned in the article^[8] patients (4.7%) who had their bite inside their home were in their sleep and snake was not identified in the majority, but in some cases, the snake was identified and it belongs to the krait variety. This is comparable to Faiz *et al.*,^[9] Ariaratnam *et al.*,^[10] and Sharma *et al.*^[11] where the snake responsible for bite during the sleep is krait in India, Sri Lanka, and Nepal.

During the 1 year study period, the total number of snakebite patients admitted was 403. This contributed to 1.7% of all the admissions (24,847 patients) in our medicine department. The mortality due to snakebite was 11 in our study period which accounted for 0.6% of overall mortality. The practice of unauthorized mode of treatment was present in 20 patients (5%) and the most common method is application of tourniquet above the bitten area followed by incision with sharp objects at the bite site. The morbidity (four patients) and mortality (two patients) showed significantly high in patients underwent treatment by other means; this is partly due to unwanted delay occurs before seeking medical care and administering ASV. It is also due to manipulation at the bite site increases the risk of secondary bacterial infection producing significant sepsis and related complications and decreased blood supply due to tight application of tourniquet aggravates the local effects of envenomation and favors necrosis. This is also mentioned in Pe *et al.*,^[11] Guderian *et al.*,^[12] and Bush *et al.*^[13] The incidence of morbidity is in rising when the age of the patient increases. The mean age of 40 and below is having favorable outcome than the patients with mean age of ≥ 48 . The mortality also increases with age due to the presence of comorbidities which significantly affects the outcome of the patient. This is as same as mentioned in the study by Mohapatra *et al.*^[14] where there are 46,000 snakebite deaths in India per year accounts for 0.5% of all overall mortality. However, in our study, the percentage of admission and deaths was compared with our hospital admissions and deaths in our hospital not with the general population. Among the 403 patients who had the definite snakebite, only 220 patients (56%) showed some form of envenomation. One hundred and seventeen patients (44%) showed no symptoms or signs even though definitely bitten by snake accounts for "dry bites" which is comparable to Warrell *et al.*^[15] and Warrell.^[16] The bitten snake was identified in only 46% (184 patients) and 54% of patients not identified the snake even with the help of photograph. Since most of the bite occurred in the evening and night than the day and the location of bite is outdoor mostly in congested areas, the identification was not possible in most cases. Among the snakes identified, most of the bites are produced by vipers, especially Russell's viper accounts for most of the bites (37%) followed by saw-scaled viper (30%). Cobra (23%) and krait (10%) are the most commonly responsible for the neurotoxic snakebites but Russell's viper also produces some neurotoxicity in three patients but not amounting to respiratory failure; Wüster *et al.*,^[17] the most common presenting symptom following snakebite is pain and swelling at the bite site accounts for 39% of cases and least common is gastrointestinal symptoms (2.4%). Some patients showed signs of autonomic arousal on arrival

to hospital and the most common sign is tachycardia presented in 15.6% of patients. About 5.9% (24) of patients had hyperglycemia on arrival which disappeared on follow-up period and their glycated hemoglobin showed no significant abnormality. Among our study patients, 37 were diabetic which has significant correlation with the outcome of the patient. Mortality and morbidity among diabetic patients were significant with $P < 0.001$. Other comorbidities such as hypertension and coronary artery disease do not affect the outcome of the patients significantly; Sharma *et al.*^[18] Among the 403 patients studied, 121 patients showed coagulation abnormalities, 159 showed signs of local envenomation, and 42 patients showed neurotoxicity but not all who showed coagulation abnormality developed life-threatening bleeding it was present in only nine patients; Sano-Martins *et al.*^[19] Likewise among 46 patients, those who showed some form of neurotoxicity only 28 developed respiratory failure. Other patients improved after administration of ASV and anticholinesterase. Agrawal *et al.*,^[20] the most common complication following snakebite is cellulitis and compartment syndrome (8.9%) leading to fasciotomy increases the morbidity and mortality significantly with $P < 0.0001$. The overall outcome was good, 359 patients out of 403 recovered completely without any disabilities, 33 patients developed complications and underwent some invasive procedures or recurrent blood product transfusion and discharged with some disabilities such as tracheostomy tube and raw area leg, and 11 patients were died in the hospital due to multiple complications. Even though the mortality is less compared to death of other causes, it remains the important health-related issue which could be prevented by proper health education of population and avoiding unwanted delay in seeking medical care following snakebite.

CONCLUSION

The snakebite cases account for 1.7% of all admissions in the Medicine Department in Tirunelveli Medical College and Hospital. Signs of envenomation were present in 56% of patients. About 44% of bites account for the “dry bites.” About 21% of patients developed complications following snakebite. Autonomic hyperactivity was present in 19.8% of patients. The mortality following snakebite is 11 (2.7%) among the snakebite patients.

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Conventional Radiotherapy versus Accelerated Fractionation Radiotherapy in Squamous Cell Head and Neck Cancers – A Prospective Comparative Study

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Abstract

Introduction: Treatment of locally advanced lesions of head and neck cancers includes a combined modality approach such as surgery, radiotherapy (RT), and chemotherapy.

Aim: The aim of the study was to study the treatment response by locoregional control and radiation toxicity of conventional and accelerated fractionation RT in squamous cell head and neck cancers.

Materials and Methods: A total of 30 patients were included in each group, Group A received accelerated six fractions per week and Group B received conventionally fractionated radiation therapy. The patients were assessed for locoregional disease response and radiation toxicities weekly during RT and at the end of treatment.

Results: In this study, 4 patients were dropped out and 26 patients completed the treatment in each group. About 86% of the patients in the accelerated fractionation arm and 82% of the patients in conventional arm showed complete response. Radiation toxicities were slightly higher in accelerated fractionation compared to conventional fractionation RT.

Conclusion: Accelerated fractionation with concurrent chemotherapy can be considered as an alternative treatment strategy to conventional chemoradiation.

Key words: Accelerated fractionation, Conventional fractionation, Head and neck cancer, Radiation toxicity

INTRODUCTION

Radiotherapy (RT) is an extremely effective treatment for head and neck cancer, both as a primary modality and as an adjuvant treatment following surgery. RT causes significant acute (during and up to 3 months post-radiation) and late toxicities when used at doses required to sterilize the locoregional disease (radical doses). The acute toxicities of RT include mucositis, dysphagia, xerostomia, dermatitis, and pain. Radiation-induced mucositis of the upper aerodigestive tract results in significant morbidity and altered quality of life during RT.^[1]

The conventional system of fractionation, i.e., 60–70 Gy in 2 Gy per fraction 5 times a week as the optimal way of delivering RT in all circumstances is highly debatable.^[2] While treating head and neck cancers with radiation, a balance is to be maintained between four parameters, i.e. total radiation dose, dose per fraction, overall treatment time, and the irradiated volume.^[3] One of the most important biological factors hindering the local control is accelerated repopulation of tumor cells after the initiation of treatment. Treatment with chemotherapy or radiation triggers the surviving cells in a tumor to divide faster than before and a larger proportion of tumor clonogenic comes to the replication pool.^[4] This can make the tumor resistant to conventional fractionation of radiation as well as to chemotherapy. There are a number of clinical reports which prove that a decrease in treatment time has improved the clinical outcomes which is clinically and biologically documented.^[5]

Shorter treatment time can be achieved by applying a higher dose per fraction which may increase the rate of

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complications disproportionately. Hence, the number of fractions delivered per week is increased without increasing the dose per fractions. This fractionation is called accelerated RT, i.e., 60–70 Gy in 2 Gy/fractions, 6 times a week, and Monday to Saturday. Accelerated fractionation shortens overall treatment time, minimizes tumor repopulation during treatment and therefore increases the probability of tumor control for a similar total dose.^[6]

In conventional fractionation RT (CFRT), the patients were given a total dose of 60–70 Gy in 2 Gy/fractions, 5 times a week, and Monday to Friday. The main aim was to assess whether similar disease control could be achieved with accelerated fractionation RT (AFRT) as compared with CFRT in head and neck cancers in the Indian population.^[7]

Aim

The aim of the study was to study the treatment response by locoregional control and radiation toxicity of conventional and AFRT in squamous cell head and neck cancers.

MATERIALS AND METHODS

This is a prospective comparative study conducted in the Department of RT at Tirunelveli Medical College in patients with squamous cell head and neck cancers.

Inclusion Criteria

Patients with squamous cell head and neck cancers confirmed with malignant histology, no prior treatment (surgery or neoadjuvant chemotherapy), and no evidence of distant metastases.

The tumor sites include the oral cavity, oropharynx, hypopharynx, and larynx. The tumor stages were confined to Stages I-III. All patients had regional nodal metastases. About 30 patients were enrolled in each arm. The patients were randomly assorted into two groups.

- Group A – Received accelerated six fractions per week, Monday to Saturday, 2 Gy/day up to 66 Gy in 5.3 weeks.
- Group B – Conventionally fractionated radiation therapy – Received conventional five fractions per week, Monday to Friday, 2 Gy/day up to 66 Gy in 6.3 weeks.

During radiation treatment, the field of radiation included the gross primary tumor with a generous margin (2–3 cm) with a bilateral neck. After 44 Gy, the posterior neck field was reduced to spare spinal cord. All the patients were treated in tele cobalt machine. Mostly opposing lateral fields were used. During treatment adequate nutritional support, aggressive hydration, antiemetic therapy, and psychological

support were given. All patients were encouraged to complete the full treatment schedule in the allotted time period. Some patients had minor interruption due to toxicity. Common radiation-induced toxicities encountered were anemia, mucositis, skin reactions, and dysphagia, which were managed with intensive care.

The patients were assessed for locoregional disease response and radiation toxicities weekly during RT and at the end of treatment. The locoregional response was considered to be complete if there was complete regression of the disease with no visible or palpable disease, partial, if there was more than 50% regression in the lesion, stable, if lesion regressed <50% and progressive, and if lesion increased by 25% or appearance of new lesion. During the course of radiation execution, tolerance to treatment was assessed by noting the weight, performance status, and radiation reactions. The radiation toxicity was assessed according to radiation therapy oncology group toxicity criteria.

RESULTS

In this study, 30 patients were recruited in both groups and 4 patients were dropped out in the study for various reasons. All the patients are male with a mean age of 58.4 in Group A and 56.2 in Group B. Figure 1 shows the site of the tumour.

In the end, a total of 26 patients were available for analysis in both groups. At the end of treatment, a complete response (CR) was identified in 86% of patients in accelerated fractionation group (Group A) and in 82% of patients in conventional fractionation group (Group B) Figure 2. During treatment, patients in Group A found difficult to complete the treatment compared to Group B due to the higher incidence of radiation toxicity. Acute skin reactions were observed in both arms which were slightly more in Group A. Acute mucositis was the most important

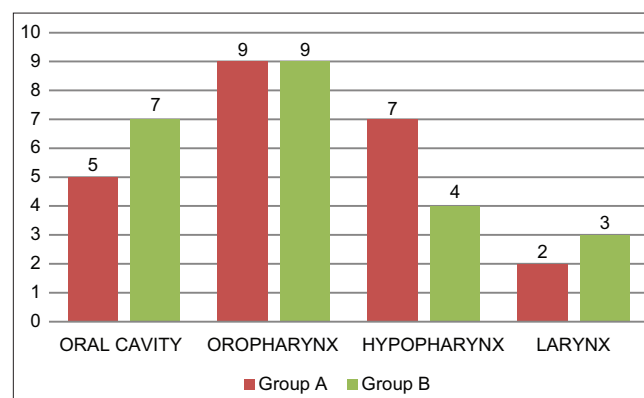


Figure 1: Tumor site

toxicity observed in both groups and appeared early in the accelerated fractionation group. Furthermore, the onset of dysphagia was earlier in Group A, although the severity of dysphagia was the same by the end of treatment. Anemia and neutropenia were encountered in both groups. The toxicities were treated intensively with intravenous fluids, blood transfusion, colony-stimulating factors, antibiotics, etc. All the patients were given psychological support and were encouraged to complete the treatment without increasing the treatment period Figure 3.

DISCUSSION

Head and neck squamous cell carcinomas are notorious for accelerated repopulation during the course of RT. This phenomenon usually sets in after 4 weeks of radiation therapy and to counteract this, 0.6 Gy of extra dose per day is needed.^[8] To increase local control and survival, in the past decade, altered fractionation regimens have been assessed for the treatment of head and neck squamous cell carcinomas. The most commonly used altered fractionation schedules for the RT of advanced head and neck cancers are: Hyperfractionated RT to exploit the differences in radiosensitivity of cancer and normal cells to increase the therapeutic ratio; accelerated RT to overcome

tumor repopulation; and accelerated-hyperfractionated RT to combine the effects of the two irradiation regimens.

Several prospective randomized studies have shown that accelerated RT improves locoregional control in squamous cell carcinoma of head and neck. However, accelerated regimens have been shown to increase treatment-associated acute morbidity, which in severe cases might lead to an increase in late radiation effects. This study was conducted with the objective that pure accelerated RT with concomitant chemotherapy would result in better treatment outcomes compared to conventional chemoradiotherapy. Another objective was to find out whether patients can tolerate the new accelerated schedule.

In a prospective study by Gupta *et al.*,^[9] at first follow-up, 90.9% had a CR at the primary site and 89.1% had a CR at the nodal site in the accelerated arm and in conventional RT arm corresponding figures were 81.5% and 75.9%, respectively. At a median follow-up of 43 months, CR was seen in 29 patients (52.7%) in the accelerated RT arm and 24 patients (44.4%) in the conventional RT arm. Although the difference in locoregional control was not statistically significant, this study clearly indicates a trend toward the improved outcome. In Danish head and neck cancer study group study,^[10] locoregional tumor control improved significantly in the accelerated fractionation group compared with that in the conventional RT group (70% vs. 60% 5 years actuarial rate, $P = 0.0005$). There was 10% statistically significant improvement in locoregional disease control in the accelerated arm. In the International Atomic Energy Agency – ACC study by Overgaard *et al.*,^[11] the 5-year actuarial locoregional control was 42% in the accelerated versus 30% in the conventional group ($P = 0.004$).

CONCLUSION

In this study, there was no statistically significant difference, in the efficacy was noted whereas in the centers with high patient load can consider accelerated fractionation an alternative treatment strategy to conventional fractionation which is radiobiologically superior and also beneficial in squamous cell head and neck cancers.

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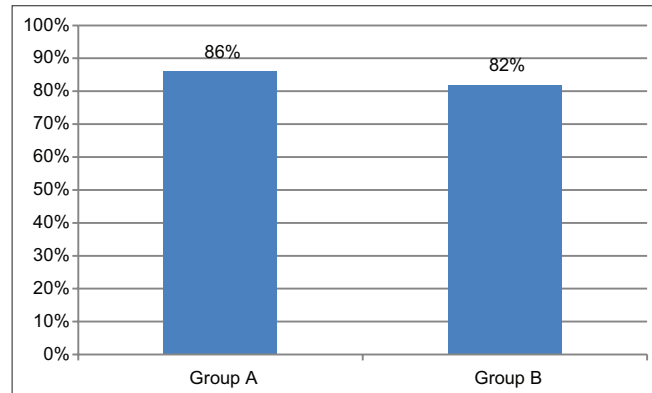


Figure 2: Complete response immediately after the end of the treatment

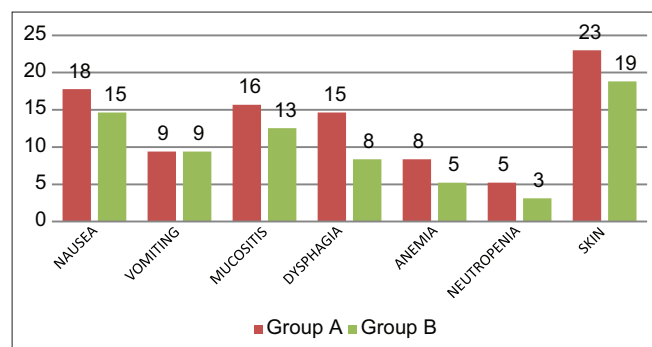


Figure 3: Distribution of toxicity

- conventional fractionation (five fractions per week) and altered fractionation (six fractions per week) in stage I and II squamous cell carcinoma of oropharynx: An institutional study. *Indian J Cancer* 2017;54:6-10.
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