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Original Article

# Comparative Clinical Study between Spinal Anesthesia and Sedation with Local Anesthesia in Orthopedic Procedures of Lower Limb

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## Abstract

**Introduction:** Orthopedic anesthesia presents many challenges to anesthesiologists. Orthopedic procedures of lower limb are performed under general anesthesia, spinal anesthesia, and sedation and local anesthetic infiltration. The orthopedic patients range in age from infant to centenarian. This patient population shows the full spectrum of comorbidities. Many of the procedures are associated with significant post-operative pain. Surgery on isolated extremities can be performed using a variety of regional anesthetic techniques for both anesthesia and post-operative analgesia.

**Aim of the Study:** This study aimed to compare and evaluate the efficacy of sedation with local anesthesia and spinal anesthesia in orthopedic procedures of lower limb, in terms of time taken and subjective analgesia.

**Materials and Methods:** A prospective, randomized controlled clinical trial with two groups of patients, 47 each, was conducted. The age range was 20-55 years. Group A was administered sedation, local anesthesia with fentanyl, midazolam, and propofol infusions were used, and to provide post-operative analgesia, the surgeon used lignocaine and bupivacaine to infiltrate ports and joint cavities. Group B patients were administered spinal anesthesia with 7.5 mg of simple bupivacaine. Different time duration taken during anesthesia and subjective analgesia were evaluated and compared using standard statistical methods.

**Results:** The mean pre-anesthetic period in Group A and B was 36.2 ±4.80 and 58.64 ± 6.22, respectively. The mean time to anesthetize in Group A and B was 26.84 ± 8.20 and 39.50 ± 3.74, respectively. The mean duration of the surgical procedure in Group A and B was 56.48 ± 8.44 and 57.22 ± 3.86, respectively. The mean time spent in recovery room to ambulation in minutes in Group A and B patients was 44.68 ± 6.80 and 74.92 ± 11.24, respectively. The visual analog scale (VAS) score of pain during the surgery in both the groups was 0. The post-operative average VAS score on an average was 3-4 in Group A and 5 to 7 in Group B.

**Conclusions:** The mean values observed for the time of pre-anesthetic period, the mean time to anesthetize, mean duration of the surgical procedure, and mean time spent in recovery room to ambulation were significantly lower in patients anesthetized with sedation and local anesthetic than the spinal block; this technique was found to be a good choice for short orthopedic surgeries of lower limb.

**Key words:** Anesthesia, Arthroscopy, American Society of Anesthesiologists and analgesia, General anesthesia, Joint, Local anesthesia

## INTRODUCTION

Analgesia is a major concern of the anesthetist and orthopedic surgeon while undertaking surgical procedures and forms an object of discussion to understand and achieve it. Pediatric spinal anesthesia was first described by August bier[1] in 1899. Analgesia and muscle relaxation with spinal anesthesia is acceptable; easy to perform; uses small dose of anesthetic; and offers a quick onset. The disadvantages are relatively short duration and post-operative pain when it wears off. Bupivacaine is used for longer procedures, but there is a need to intensify and increase the duration of sensory block without increasing the intensity and duration of motor block, thus prolonging the duration of post-operative analgesia.[1] Knee arthroscopy is usually

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performed under spinal anesthesia; contraindications are rare. However, in some situations, there are restrictions on its use based on the anesthetic risk.[2] Arthroscopy under sedation and local anesthesia is not considered to be novelty; remains a source of strong critical argument and is not proclaimed. Review of literature shows divergent opinions about this topic; some affirming that it is possible as a safe and effective method,[3-5] few others support the view that it should only be used for diagnostic surgery[6,7] and some state that it is unsafe.[8,9] Arthroscopy is a major advancement in the orthopedic surgeries of the century; less invasive. If good post-operative analgesia is provided through local anesthetic techniques, it will help reduce the hospital stay and avoids unnecessary expenses.[10] Sedation and local infiltration at port sites with lignocaine initially and later with bupivacaine followed by intra-articular local anesthesia of the knee is proved as a simple, safe technique accepted by patients. There is low morbidity, reducing analgesic intake as well as reducing hospital stay, and thus leads to a reduction in costs as quoted by Moreno-Regidor *et al.*,[10] who conducted a study on 56 patients using local anesthesia and sedation. Their reports showed that it was necessary to reinforce the pain analgesics in portals or during knee valgus/varus stress maneuvers in six patients. Regional anesthesia and general anesthesia are of greater convenience for the surgeon and better analgesia to the patients, but the disadvantages are risks for the patient and discomfort during recovery, low back pain, urinary retention, and post-puncture headaches.[11] In the context of choice of anesthesia for lower limb surgeries, especially arthroscopy, the present study was conducted to compare and evaluate the efficacy of local anesthesia and spinal anesthesia in orthopedic procedures in terms of duration and analgesia.

## MATERIALS AND METHODS

A prospective, non-blind, randomized, comparative and analyst clinical blind trial was conducted on 94 patients randomized using online randomization services at www.randomization.com. Institutional Ethical Committee clearance was obtained. A committee-approved consent form was used for the patients. The patients were aged between 20 and 55 years. All the patients were with American Society of Anesthesiologists risk I or II. The patients were divided into two groups; Group A were administered sedation, local anesthesia with fentanyl, midazolam, and propofol infusions were used, and to provide post-operative analgesia, the surgeon used lignocaine and bupivacaine to infiltrate ports and joint cavities; Group B patients were administered spinal anesthesia with 7.5 mg of simple bupivacaine.

### Inclusion Criteria

1. Patients aged between 20 and 55 years were included.
2. Patients with minor procedures such as diagnostic and therapeutic arthroscopy, meniscectomy, meniscal repair, joint lavage, and excision of osteochondral lesions were included in the study.

### Exclusion Criteria

1. Patients aged below 20 and above 55 years were excluded.
2. Patients in whom procedures conducted reactive to local anesthetics such as lidocaine, bupivacaine, and ropivacaine were excluded.
3. Patients with combined procedures such as arthroscopy and debridement and osteotomy were excluded.
4. Patients with signs of acute inflammation were excluded from the study.

For both the groups, pre-anesthetic medication of 50 mg of ranitidine intravenous (IV) and metoclopramide 10 mg IV was given. Sedation with midazolam 0.04 mg/kg (IV) with dextrose with normal saline IV at 10 ml/kg was started. Pre-operative monitoring was done with ECG, oxymetry, and noninvasive blood pressure. Oxygen was given through face mask at 4-5 L/min, and initial vital signs were recorded. In Group A patients, 100 mcg of fentanyl was administered and a propofol infusion was started at 1 mg/kg (IV) for maintenance, before port infiltration. The surgeon infiltrated the two ports with 6 cc of lidocaine and subsequently infiltrated the joint cavity with 20 cc of simple lidocaine at 2%. Before starting the surgical procedure, the two ports were infiltrated with 6 ml of bupivacaine and 500 mg (25 cc) of lidocaine was added per liter to the 3 L bags, so the local anesthetic concentration was 0.05%. At the end of the surgery, 20 cc of ropivacaine at 0.75% was injected into the cavity as an analgesic. For Group B patients, regular spinal block was used following all the ascetic precautions; L2-L3 or L3-L4 space was used. 7.5 mg of plain bupivacaine (1.5 ml) was injected into the CSF. Both sensory and motor blockade were assessed with needle prick test and Bromage scale, respectively. The following timings were recorded for both the group patients.

1. Arrival time at the operating room.
2. The beginning of the anesthesia procedure.
3. The start of the surgical procedure.
4. The duration of the surgical procedure.
5. Time spent in recovery room to ambulation. During the surgery, patients' oxygen saturations, blood pressure, and pulse rate were monitored. Intra-operative pain was assessed by visual analog pain scale (VAS).

### Statistical Methods

Socialsciencestatistics.com was used: Data collected were quantitative and qualitative variables. Chi-square

calculator, 5 × 5 contingency table, was used to calculate the significance of values obtained comparing both groups.

## OBSERVATIONS AND RESULTS

There were 47 patients in Group A and 47 patients in Group B. There were 32 males and 15 females in Group A and 35 males and 12 females in Group B. The mean age was 35.6 ± 4.8 years and 37.2 ± 6.2 years in Groups A and B, respectively. The mean weight in Group A was 68.40 ± 11.16 kg, height was 1.54 ± 0.086 m, and the mean body mass index (BMI) was 26.44±5.60. The mean weight in Group B was 71.32 ± 08.16 kg, height was 1.54 ± 0.068 m, and the mean BMI was 28.22 ± 6.42 (Table 1).

Among the various indications for orthopedic surgery the meniscal injury was found in 15 of Group A and 13 of Group B patients; total 28/94 (29.78%); diagnostic arthroscopy were performed in 31/94 (32.97%) patients. Meniscal repair and Joint lavage was done in 11.70% patients each (Table 2).

The mean pre-anesthetic period in Group A was 36.2 ± 4.80 and the mean pre-anesthetic period in Group B was 58.64 ± 6.22. The mean time to anesthetize in Group A was 26.84 ± 8.20 and in Group B it was 39.50 ± 3.74. The mean duration of the surgical procedure in Group A was 56.48 ± 8.44 and in Group B it was 57.22 ± 3.86. The mean time spent in recovery room to ambulation in minutes in Group A was 44.68 ± 6.80 and in Group B it was 74.92 ± 11.24. The VAS score of pain during the surgery in both the groups was 0. The post-operative average VAS score on an average it was 3-4 in Group A and to 7 in Group B (Table 3).

For the above data of both groups, the Chi-square statistic calculated was 17.40 using Chi-square calculator with 5 × 5 contingency table and the $P = 0.00161$ with $P$ significant at 0.05.

**Table 1: The age, gender, and clinical parameters (*n*=94)**

| Observations | Group A-47 | Group B-47 |
|---|---|---|
| 20-35 years | 18 | 15 |
| 36-50 years | 19 | 20 |
| 50 years | 10 | 12 |
| Male | 32 | 35 |
| Female | 15 | 12 |
| Weight | 68.40±11.16 | 71.32±08.16 |
| Height | 1.54±0.086 | 1.54±0.068 |
| BMI | 26.44±5.60 | 28.22±6.42 |

**Table 2: The different orthopedic procedures done in the study groups A and B (*n*=94)**

| Observations (%) | Group A-47 | Group B-47 |
|---|---|---|
| Meniscectomy - 28 (29.78) | 15 | 13 |
| Meniscal repair - 11 (11.70) | 04 | 07 |
| Joint lavage - 11 (11.70) | 05 | 06 |
| Diagnostic and therapeutic arthroscopy - 31 (32.97) | 17 | 14 |
| Excision of osteochondral lesions - 13 (13.82) | 06 | 07 |

**Table 3: Time periods in both groups regarding anesthesia and recovery and VAS scores (*n*=94)**

| Observations | Group A-47 | Group B-47 |
|---|---|---|
| Mean pre-anesthetic period (minutes) | 36.2±4.80 | 58.64±6.22 |
| Mean time to anesthetize (minutes) | 26.84±8.20 | 39.50±3.74 |
| Mean duration of the surgical procedure (minutes) | 56.48±8.44 | 57.22±3.86 |
| Mean time spent in recovery room to ambulation (minutes) | 44.68±6.80 | 74.92±11.24 |
| Pain - post-operative average VAS score | 3-4 | 5-7 |

## DISCUSSION

Among the various methods of anesthesia used in performing lower limb surgeries, two methods are used in the present study. (1) Spinal block anesthesia using 7.5 mg of plain bupivacaine (1.5 ml) was injected into the CSF. (2) Sedation and intra-articular infiltration of the joint cavity with 20 cc of simple lidocaine at 2% in addition to joint lavage with 6 ml of bupivacaine 500 mg (25 cc) of lidocaine was added per liter to the 3 L bags, so the local anesthetic concentration was 0.05%. The other methods available are the general regional peripheral anesthesia (inhaled and/or intravenous) and neuraxial regional blockade. The advantages and disadvantages are well documented in the literature.

Mondino[12] working with sedation and local anesthesia in his study reported a 1.6% failure rate in which conversion to balanced general anesthesia was required in a series of 98 patients. In the present study, no patient was converted to general anesthesia in either of the Group A or B. Maldini and Miskulin[13] while evaluating absence of pain, movement, and the patient referring to pain during the procedure reported a 96.6% success rate; they used local anesthesia and a propofol infusion. In the present study, apart from patients undergoing arthroscopy, patients undergoing meniscectomy - 28 (29.78%), meniscal repair - 11 (11.70%), joint lavage - 11 (11.70%), and excision of osteochondral lesions - 13 (13.82%) also were not converted to general anesthesia. In Group A with sedation and local anesthesia, the mean time to anesthetize was 26.84 ± 8.20 min, the mean duration of the surgical procedure was 56.48 ± 8.44 min, the mean time spent in recovery room to ambulation was 44.68 ± 6.80 min, and the pain measured with VAS score was on average of 3-4. This was significant when compared to the Group B patients wherein the mean time to anesthetize

was 39.50 ± 3.74 min, the mean duration of the surgical procedure was 57.22 ± 3.86 min, the mean time spent in recovery room to ambulation was 74.92 ± 11.24 min, and the pain measured with VAS score was on average of 5-7. For the above data of both groups, using Chi-square calculator with 5 × 5 contingency table, the Chi-square statistic calculated was 17.40 and the $P = 0.00161$ with $P$ significant at 0.05. Takahashi *et al.*[14] reported from their study that there was good pain control among their 63 patients while operated using sedation and local anesthesia which was similar to the present study. They also concluded that the most pain was experienced while intra-articular injection of lidocaine was being given. While reviewing literature on spinal block anesthesia for lower limb orthopedic surgeries, it was found that in a study by Ben-David *et al.*,[15] who analyzed spinal anesthesia for knee arthroscopy and other surgeries on lower limb, they could not achieve non-surgical anesthesia in four of their 15 patients using 5 mg of bupivacaine, but there were no failures at doses of 7.5 mg and above. In the next study, by the same authors, the failure occurred in six of 25 patients who received only 5 mg of bupivacaine, but in none of the 25 patients who received 10 mcg of fentanyl with the same dose of bupivacaine. In the present study, for Group B patients, spinal block technique with 7.5 mg of bupivacaine at 0.5% (1.5 cc) was used, reaching an appropriate surgical level (T10), and the patients reported a VAS of 0 in all the 47 patients. One of the main causes of post spinal headaches is described in the literature as the chosen diameter of the spinal needle. Reina *et al.*[16] stated in their study that Whitacre 25 needles leave a dual hole by separation and disruption of the collagen fibers with an inflammatory component. They describe that an edema produced by the inflammation initiated by the physical trauma leads to closure of the hole in the dura mater, initiating stoppage of CSF leak which subsequently reduces post-spinal headache. In the present study, Whitacre needles are used in all the patients and no complaint of post-spinal headache was reported. Sedation and local anesthesia for lower limb minor procedures is ideal as it has less surgical and recovery time as found in Group A patients of this study. Patients with combined procedures such as arthroscopy and debridement and osteotomy were not included in this study as these take longer time and unpredictable bleeding. Tourniquet cannot be used as the limb above the anesthetic area is not anesthetized. However, during the post-operative recovery period, the analgesia assessed with VAS score in sedation and local anesthesia (Group A) was 3-4 when compared to spinal block (Group B) with 5-7 score. In Group A patients, the post-operative analgesia could be started immediately in the recovery room unlike in the Group B patients in whom it is necessary to wait for the anesthetic recovery time. Unlike in patients undergoing surgery under general anesthesia, there is no necessity of giving opioids in the sedation and local anesthetic group. In patients with spinal block, though the analgesia persists in the post-operative period, there is associated motor deficit, and immediate post-operative rehabilitation is not possible. In Group A patients, the duration of surgery, duration of inducing anesthesia, time spent in recovery, early rehabilitation, and good VAS score of analgesia were possible with least complications. The present study is in concurrence with studies of Moreno-Regidor *et al.*,[10] Mondino,[12] and Maldini and Miskulin[13] who also observed that sedation and local anesthesia for performing minor procedures of lower limb are effective, practical, of low cost, are safe, and with shorter hospital stay.

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