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Original Article

A Prospective Randomized Double-Blind Study Comparing Intrathecal Dexmedetomidine and Fentanyl as Adjuvants to Bupivacaine in Infra Umbilical Surgeries

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Abstract

Background: Regional anesthesia is the preferred technique for most of lower abdominal and lower limb surgeries as it allows the patient to remain awake and minimizes or completely avoids the problem associated with airway management. Hyperbaric bupivacaine 0.5% is extensively used for spinal anesthesia. Fentanyl is a synthetic lipophilic opioid commonly used for post-operative analgesia. Dexmedetomidine, a new highly selective α2-agonist, used intrathecally produces prolonged post-operative analgesic effect with hyperbaric bupivacaine in spinal anesthesia with minimal side effects. The present study was designed to evaluate the effects of 5 μg of dexmedetomidine as an intrathecal adjuvant to compare with the intrathecal 25 μg of fentanyl with 0.5% bupivacaine (heavy).

Aim of the Study: The present study was designed to evaluate the effects of 5 μg of dexmedetomidine as an intrathecal adjuvant in comparison with intrathecal 25 μg of fentanyl along with 3 ml of 0.5% bupivacaine (heavy) in regard to post-operative analgesia and side effects.

Materials and Methods: A prospective randomized double-blind study on 100 patients was conducted by dividing them into two groups Group F: 3 ml of 0.5% hyperbaric bupivacaine and 25 μg fentanyl and Group D: 3 ml of 0.5% hyperbaric bupivacaine and 5 μg of dexmedetomidine used intrathecally during spinal anesthesia for sub umbilical surgeries; the patients of ASA I and II Grades. The onset of sensory block, motor blockade, onset of analgesia, and the duration of analgesia between the groups were observed. Parameters such as systolic blood pressure, diastolic blood pressure, heart rate, SpO_2, mean arterial pressure, and development of other side effects were observed. All the data were analyzed using standard statistical methods.

Observations and Results: The patients of both the groups were identical in terms of their age groups, gender incidence, and weight and height parameters. The basal values of systolic pressure, diastolic pressure, mean arterial pressure, and SpO_2 were similar in both the groups. Both group patients were belonging to ASA I and II types. Comparison of onset time (T10), highest sensory level was compared in both the groups and the data were significant statistically with $P < 0.001$ (P significant at <0.05). Comparison of time of onset of motor blockade were compared in both the groups and was found that the onset of motor blockade was comparable in both the groups, but the duration of the motor blockade was statistically significant with $P < 0.001$. Post-operative analgesia was better in Group D as per the visual analog scale ratings.

Conclusions: 5 μg dexmedetomidine seems to be an attractive alternative to 25 μg fentanyl as an adjuvant to spinal bupivacaine in surgical procedures. It provides good quality of intraoperative analgesia, hemodynamically stable conditions, minimal side effects, and excellent quality of post-operative analgesia.

Key words: Adjuvant, Anesthesia, Bupivacaine, Dexmedetomidine, Fentanyl and analgesia, Spinal anesthesia

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INTRODUCTION

The selection of different drug combinations and suitable doses used as adjuvants with local anesthetics is a critical process and signifies the consideration of factors such as the formation and duration of sensory and motor block, the quality, and duration of post-operative analgesia.[1] Over

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the years, many drugs have been used intrathecally as an adjuvant to local anesthetics to prolong the intraoperative as well as post-operative analgesia with variable effects.[2] Dexmedetomidine is a new and more selective α_2 receptor agonist with higher sedative and analgesic effects. Dexmedetomidine provides stable hemodynamic conditions, good sedation, and good quality of intraoperative and prolonged post-operative analgesia with minimal side effects.[3] Korhonen *et al*.,[4] in 2003, in their double-blind study of 100 patients undergoing knee arthroscopy, received randomly either 4 mg of bupivacaine (B4) or 3 mg of bupivacaine with fentanyl (B3F) intrathecally. They concluded that a combination of local anesthetic and opioid enables the use of less spinal anesthetic and increases the success of anesthesia; addition of small dose of fentanyl does not prolong motor recovery and thus shortens PACU time. A Gupta *et al*.,[5] in 2003, in their comparative study of intrathecal 6 mg and 7.5 mg of bupivacaine with addition of fentanyl l10 μg administered to 40 patients undergoing inguinal herniorrhaphy. They found that no difference was seen in spread, duration, and regression of sensory block between the groups. The time to mobilization and discharge were similar, but return of motor block was earlier with low dose group. They concluded that spinal anesthesia with 7.5 mg bupivacaine plus fentanyl 10 μg offers an alternative to general anesthesia or local anesthesia for ambulatory herniorrhaphy. Kararmaz *et al*.,[6] 2003, evaluated the effects of low dose bupivacaine plus fentanyl administered intrathecally in elderly patients undergoing transurethral prostatectomy. This study showed that addition of fentanyl to local anesthetic provides adequate analgesia with few side effects. Motor block was higher and duration was prolonged.[7] Pruritus is a frequent complication of intrathecal fentanyl. Asokumar *et al*.,[8] 1988, in their study administered intrathecal fentanyl 25 μg with bupivacaine 2.5 mg in laboring parturient. They found that addition of fentanyl to intrathecal bupivacaine 2.5 mg attenuates the frequency of pruritus on all parts of the body except the face. This combination also resulted in rapid and prolonged duration of labor analgesia compared with either drug alone.[9] Belzarena,[10] 1992, assessed the clinical effects of intrathecal fentanyl in patients undergoing cesarean section with varying doses. He concluded that the combination of bupivacaine and low dose fentanyl (25 μg) provides excellent surgical anesthesia with short lasting post-operative analgesia and few side effects. Kuusniemi *et al*.,[11] 2000, evaluated the effects of 25 μg of fentanyl added to varying doses of bupivacaine, on sensory and motor block. Addition of fentanyl 25 μg to low dose bupivacaine 5 mg resulted in short motor blocks whereas 25 μg fentanyl with bupivacaine 10 mg increased the intensity and duration of motor block. Singh *et al*.[12] investigated the effect of intrathecal fentanyl 25 μg on the onset and duration of bupivacaine 13.5 mg induced spinal block in adult male patients who underwent urological procedures. Addition of fentanyl to local anesthetic prolongs the duration of sensory block and reduces the analgesic requirement in the early post-operative period. Akerman *et al*.[13] undertook a study to compare in mice the antinociceptive effect of intrathecal injection of the mixture of morphine with bupivacaine or lidocaine. The results indicate the potentiating effects of local anesthetic on spinal opioids anti-nociception, a finding that has an important clinical implication. Administration of epidural and intraspinal opioids may provide excellent post-operative analgesia, but a minority of patients will suffer from respiratory depression. Etches *et al*. studied shows the effects of respiratory depression following intrathecal opioids administration.[14] Echevarría *et al*.,[15] 1995, conducted a study to compare the hemodynamic effects, level of anesthetic block and advantages at a single dose versus continuous intrathecal anesthesia with hyperbaric bupivacaine with or without fentanyl. They concluded that single dose intrathecal anesthesia produces less hemodynamic changes than a continuous intrathecal block. Reuben *et al*.,[7] 1994, evaluated the dose-response effect of intrathecal fentanyl in elderly patients undergoing lower extremity revascularization procedure. Postoperatively after complete regression of anesthesia, patients received through spinal catheter either 0, 5, 10, 20, 40, or 50 μg fentanyl. They concluded that 40 μg of intrathecal fentanyl provided satisfactory analgesia for approximately 5 h in elderly patients with a low incidence of side effects. Rust *et al*.[9] conducted a study to examine whether intrathecal opioids such as fentanyl, morphine for labor analgesia offer adequate, and cost-effective alternative to epidural analgesia with minimal side effects. They found this technique offered an excellent and cost-effective alternative to epidural analgesia. Addition of fentanyl to bupivacaine administered for spinal anesthesia for cesarean delivery was evaluated by Hunt *et al*.,[16] 1989. Analgesia produced by fentanyl in a dose of 6.25 μg with bupivacaine 10 mg was satisfactory and did not require intraoperative opioids. Increasing the dose of fentanyl above 6.25 μg did not further increase the duration of complete or effective analgesia. Cascio *et al*.[17] proved that intrathecal fentanyl is as effective as labor epidural analgesia in producing pain relief in labor and capable of reducing maternal plasma epinephrine concentration thus reducing maternal distress in the same manner as conventional labor epidural analgesia. In 1996, Fernandez-Galinski *et al*.[18] assessed the risk and benefits of the administration of fentanyl during spinal anesthesia in elderly patients undergoing knee or hip replacement surgeries. The study results show that 25 μg of fentanyl do not modify spinal anesthesia in elderly but induces pruritus and O2 desaturation. Decrease in post-operative pain intensity and the preservation of cognitive

function would justify the use of spinal fentanyl in the elderly. Respiratory depression may occur following intraspinal administration of opioids. Varrasi *et al*.[19] observed the ventilatory effects of subarachnoid fentanyl in elderly patients. They recommended 25 μg fentanyl as the only dose which gives significant analgesia without respiratory depression in older patients; fentanyl has been shown to be effective for labour analgesia and often used as part of combined spinal and epidural technique for this purpose, although effective shortcoming of this technique was limited duration of action and occasional side effect like pruritus. Palmer *et al*.[20] in their study investigated the effect of addition of low dose bupivacaine to intrathecal fentanyl. The results showed that bupivacaine augments intrathecal fentanyl duration and quality of analgesia and speeds onset of analgesia compared with plain intrathecal fentanyl. Ben-David *et al*.[21] studied 50 patients undergoing ambulatory surgical arthroscopy and found that although small dose bupivacaine alone is inadequate for this procedure the addition of fentanyl makes it reliable. Selective spinal anesthesia is the practice of using minimal doses of intrathecal agents so that only the nerve roots supplying a specific area and the modalities that require to be anesthetized are affected. Valanne *et al*.[22] used mini dose of bupivacaine 4 mg versus 6 mg for outpatient knee arthroscopy. They hypothesized that mini-dose induces selective spinal anesthesia with faster recovery and allows discharge criteria to be fulfilled significantly faster. In a double-blind study performed by Dahlgren *et al*.[23] compared the effects of intrathecal sufentanil 2.5 μg and 5 μg of fentanyl and placebo when administered with hyperbaric bupivacaine 0.5% of 12.5 mg for cesarean section. The post-operative analgesia assessed using value-added service (VAS) and umbilical cord blood gases and neonatal Apgar score were same among the groups. Thus, results reveal that small doses of fentanyl and sufentanil added to local anesthetic for spinal anesthesia, reduced need for intraoperative antiemetic medication and increased the duration of analgesia in the early post-operative period, compounded with placebo. Sufentanil had a slight longer duration of action than fentanyl. Liu *et al*.[24] demonstrated that addition fentanyl improves the quality and duration of lidocaine spinal anesthesia. They administered plain lidocaine 5% in dextrose both with and without 20 μg of fentanyl in a randomized double-blind crossover fashion. They recommended the addition of 20 μg of fentanyl to lidocaine spinal anesthesia as a means to improve duration of sensory anesthesia without prolonging recovery of motor function or time to micturition. Palmer *et al*.[25] in their study determined the dose-response relation of intrathecal fentanyl 25 μg for labor analgesia and described the onset duration and quality of analgesia when used as sole analgesic. The further increasing the dose of fentanyl beyond 25 μg has little benefit. Sudarshan *et al*.[26] investigated the efficacy of intermittent doses of fentanyl intrathecally in 30 patients undergoing thoracotomy. They demonstrated using spinal catheters for analgesia with fentanyl; it is possible to titrate optimum effect required with intermittent doses to provide high-quality analgesia for prolonged period. Jacobson *et al*.[27] studied the effects on intrathecal fentanyl on relief of persistent post-operative stump and phantom limb pain. In their study shows that neuraxial fentanyl temporarily abolished the pain and apparently produced its effects by segmental spinal action. Kanazi *et al*.[28] conducted a study on the effect of low dose dexmedetomidine or clonidine on the characteristics of bupivacaine spinal block and found that dexmedetomidine 3 μg or clonidine 30 μg when added to intrathecal bupivacaine, produces a similar prolongation in the duration of the motor and sensory block with preserved hemodynamic stability and lack of sedation. Al-Ghanem *et al*.[3] compared the effect of adding dexmedetomidine 5 μg versus fentanyl 25 μg to intrathecal bupivacaine on spinal block characteristics in gynecological procedures and found that bupivacaine supplemented with 5 μg dexmedetomidine produced prolonged motor and sensory block compared with 25 μg fentanyl. Hala *et al*.[29] conducted a study on the dose-related prolongation of hyperbaric bupivacaine spinal anesthesia by dexmedetomidine and concluded that intrathecal dexmedetomidine in doses of 10 μg and 15 μg significantly prolongs the anesthetic and analgesic effects of spinal hyperbaric bupivacaine in a dose-dependent manner. A 15 μg dose may be of benefit for prolonged complex lower limb surgical procedures. Gupta *et al*.[5] conducted a comparative study of intrathecal dexmedetomidine 5 μg and fentanyl 25 μg as adjuvants to bupivacaine and found that intrathecal dexmedetomidine is associated with prolonged motor and sensory block, hemodynamic stability, and reduced demand for rescue analgesics in 24 h as compared to fentanyl. Dexmedetomidine as an intrathecal adjuvant for post-operative analgesia and found that the addition of 5 μg dexmedetomidine to ropivacaine intrathecally produces prolongation in the duration of motor and sensory block.

Name of the Institute

This study was conducted at the Holdsworth Memorial Hospital, Mandi Mohalla, Mysore.

Type of Study

This was a prospective randomized double-blind study.

Period of Study

This study was from December 2012 to March 2015.

Primary Objectives

The primary objectives of the study were to observe onset and duration of sensory block, onset and duration of motor

blockade, and duration of analgesia and intraoperative sedation.

Secondary Objectives

To also observe perioperative complications such as nausea, vomiting, hypotension, bradycardia shivering, and pruritis are assessed.

MATERIALS AND METHODS: SOURCE OF DATA

The present clinical study was conducted at after obtaining approval from Institutional Ethical Committee; present study was undertaken to compare the efficacy of dexmedetomidine as an adjuvant to 0.5% bupivacaine (heavy) for subarachnoid block in infra-umbilical surgeries including inguinal hernia repair, appendicectomy, hysterectomy, urological, and orthopedic surgeries. It was a prospective randomized control study done on 100 patients undergoing elective lower abdominal surgeries.

Inclusion Criteria

The following criteria were included in the study:

1. Patients satisfying ASA physical status Class I and II and undergoing elective sub umbilical surgeries.
2. Patients with age between 18 and 65 years of either sex.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients undergoing emergency surgeries, deformities of the spine, hypersensitivity to any of the drugs in the study.
2. Patients with contraindications to spinal anesthesia - patient refusal and bleeding diathesis.

Sample Size

The sample size was calculated based on the power analysis performed in a pilot study done in our institution with an $\alpha = 0.05$ and $\beta = 0.90$. A sample size of 45 patients per study group was needed to detect a change of 10% in onset of motor blockade, onset of analgesia, and the duration of analgesia between the groups. However, considering the dropouts, a sample size of 50 patients was considered in each of the groups in our study.

Methodology

After a thorough clinical examination and relevant laboratory investigations of all patients, an informed, valid, and written consent was obtained, both for the conduct of study and administration of spinal anesthesia. All patients were kept nil by mouth from midnight before surgery, and tablet alprazolam (0.01 mg/kg) was administered at bedtime the day before surgery. All the patients were randomly allocated into two groups of 50 each using computer-generated random numbers by simple randomization technique.

1. Group F: 3 ml of 0.5% hyperbaric bupivacaine and 25 μg fentanyl.
2. Group D: 3 ml of 0.5% hyperbaric bupivacaine and 5 μg of dexmedetomidine.

All the patients were re-examined, assessed and weighed preoperatively on the day of surgery. Intravenous (IV) access was established with 18G IV access, and preloading was done with 15 ml/kg Lactated Ringer's solution 30 min before the procedure. Anesthesia machine and accessories were checked, and drugs, including emergency drugs were kept ready. Furthermore, monitoring equipment such as pulse oximeter, non-invasive blood pressure, and electrocardiogram (ECG) monitors were checked and applied to each patient on arrival to the operating room, and baseline parameters (heart rate [HR], blood pressure, and SpO_2) were recorded. Under strict aseptic conditions, with the patient in the left lateral position, a lumbar puncture was performed at L3-L4 intervertebral space. After ensuring the free flow of CSF, Group 1 patients received 0.5% heavy bupivacaine 3 ml with fentanyl (25 μg) 0.25 ml and Group 2 patients received 0.5% heavy bupivacaine 3 ml with 5 μg dexmedetomidine. After the intrathecal injection patients were returned to supine position. Hemodynamic parameters such as pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure, and SpO_2 of the patients were recorded. SBP, DBP, and HR were recorded every 2 min up to 15 min and every 5 min up to 30 min then every 15 min up to 90 min irrespective of the duration of surgery. Hypotension was defined as SBP <90 mmHg or >30% fall from the baseline value whichever was low was treated by injection mephentermine 3 mg IV and IV crystalloids. Bradycardia was defined as HR <60 beats/min or >30% decrease from the baseline value whichever was low was treated with IV atropine 0.3 mg increments. Sensory and motor blockade were assessed at following intervals, every 2 min for first 10 min and every 5 min for next 15 min, and every 10 min for next 30 min until the end of the surgery. Postoperatively every 15 min for the first 2 h and every half hourly for the next 4 h and next every hourly for the next 16 h. Sensory block was assessed by pinprick method using a blunt tipped 23 gauge needle, and motor block was assessed by Bromage scale [Table 1].

Definitions: Onset of Sensory Block

Time from completion of intrathecal injection of study drug until the sensory block occurs at T10 level. Time for the maximum sensory block: Time from completion of intrathecal injection of study drug until maximum sensory block occurs. Duration of two segments regression: Time

from maximum sensory block until there is decreased of the sensory block by two segments.

Duration of Analgesia

Time from completion of intrathecal injection of study drug until the patient requires rescue analgesia with VAS of >4 [Table 2 and Figure 1].

Onset of Motor Blockade

Time from completion of intrathecal injection of study drug until the patient develops Bromage Grade II.

Time for Maximum Blockade

Time from completion of intrathecal injection of study drug until the patient develops Grade IV (Bromage).

Duration of Motor Blockade

Time of injection until the patient recovers to Grade I (Bromage). HR, systolic, DBP, and mean arterial pressure were recorded every 2 min for first 10 min, every 10 min for first 30 min, every 30 min till 3 h, and every 60 min till the requirement of rescue analgesia. ECG, SpO_2, and sedation were monitored continuously. Side effects if any such as nausea, sedation, dry mouth, and bradycardia were recorded during study period.

Duration of analgesia was defined as the time from subarachnoid block to VAS >2, at that point rescue analgesia was given [Table 2 and Figure 1]. Similarly, sedation score was recorded using sedation score [Table 3].

All the data were collected, tabulated, and analyzed statistically. p value <0.05 is considered statistically significant.

Statistical Methods

Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max), and results on categorical measurements are presented in number (%). The significance is assessed at 5% level of significance. The following assumptions on data are made, Assumption: (1) Dependent variables should be normally distributed, (2) Samples drawn from the population should be random, cases of the samples should be independent. Student's test (two-tailed and independent) has been used to find the significance of study parameters on continuous scale between two groups (intergroup analysis) on metric parameters. Chi-square/Fisher exact test has been used to find the significance of study parameters on a categorical scale between two or more groups.

Study Design

A comparative two-group randomized clinical study with 100 patients with 50 patients in Group F (Fentanyl) and 50 patients in Group D (Dexmedetomidine) is undertaken to study the changes in hemodynamic and side effects. Statistical analysis was done by applying Chi-square test, ANOVA test, and Student's *t*-test to analyze the data, *P* value was determined. $P > 0.05$ is not significant; $P < 0.05$ is significant; and $P < 0.001$ is highly significant.

Table 1: Modified Bromage scale

Grade	Criteria	Degree of block
I	Free movement of legs and feet	None
II	Just able to flex knees with free movement of feet	Partial 33%
III	Unable to flex knees, but with free movement of feet	Partial 66%
IV	Unable to move legs or feet	Complete paralysis

Table 2: Visual analog score

0	None
2	Annoying
4	Uncomfortable
6	Dreadful
8	Horrible
10	Agonizing

Table 3: Sedation score

0	No sedation
1	Drowsiness
2	Asleep but arousable
3	Unarousable with loss of verbal contact

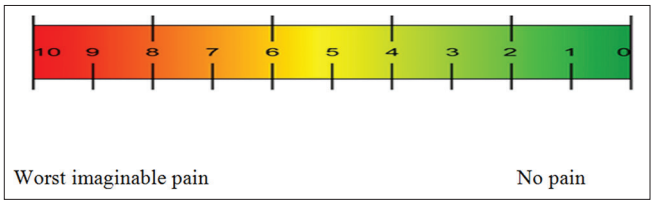


Figure 1: Visual analog scale

OBSERVATIONS AND RESULTS

Table 4 shows the age distribution in each group. The patients who took part in this project were in the age group of 18–65 years. On statistical comparison, the two groups were comparable.

Observing the gender distribution in both the groups and on statistical analysis, it was found that the samples were gender-matched with *P*-1.000 [Table 5 and Figure 2].

Comparing the height and weight of two groups, it was found that the data were comparable [Table 6 and Figure 3].

Distribution of ASA grade was statistically similar in two groups with *P*-0.419 [Table 7 and Figure 4].

The distribution of different surgeries undertaken in both the groups was shown in Table 8, Figures 5 and 6.

Comparison of onset time (T10), highest sensory level was compared in both the groups and the data were significant statistically with $P < 0.001$ (*P* significant at <0.05), [Table 9, Figure 7a and b].

Comparison of time of onset of motor blockade was compared in both the groups and were found that the onset of motor blockade was comparable in both the groups but the duration of the motor blockade was statistically significant with $P < 0.001$ [Table 10, Figure 8a and b].

Comparing the maximum height of sensory blockade achieved in both the groups, it was found that values were comparable and similar in both the groups [Table 11].

Comparison of Maximum Height Wise Distribution of Sensory Blockade in Both Groups ($n = 100$).

The mean values of maximum height of sensory blockade were similar in both the group [Table 12].

In both the groups, the SBP, DBP, mean arterial pressure, HR, respiratory rate, and SpO_2 values were recorded and analyzed in both the groups and their values were found to be comparable and not statistically significant [Tables 13-19, Figures 9-13].

The consumption of mephentermine and atropine in both the groups was compared and found that values were significant [Table 20].

The side effects encountered in both the groups were compared and found to not significant [Figure 13].

The modified Ramsay Sedation Score and Visual Analog Scales of analgesia were compared in both the groups and found that the values were statistically highly significant in this study [Tables 21 and 22, Figures 14 and 15].

DISCUSSION

Lidocaine was regularly being used for intrathecal anesthesia. It had short duration of action and also found to produce transient neurological symptoms.[30,31] Hence, hyperbaric bupivacaine is the standard local anesthetic that is used for spinal anesthesia for infra-umbilical surgeries. Hyperbaric 0.5% bupivacaine is routinely used in a dose

Table 4: Age distribution of patients studied

Age in years	Group F	Group D
	n (%)	*n* (%)
18–20	2 (4.0)	0 (0.0)
21–30	3 (6.0)	4(8.0)
31–40	13 (26.0)	26 (52.0)
41–50	22 (44.0)	14 (28.0)
51–60	8 (16.0)	5 (10.0)
>60	2 (4.0)	1 (2.0)
Total	50 (100.0)	50 (100.0)
Mean±SD	43.76±10.33	40.86±9.27

Table 5: Gender distribution of patients studied

Gender	Group F	Group D
	n (%)	*n* (%)
Male	25 (50.0)	25 (50.0)
Female	25 (50.0)	25 (50.0)
Total	50 (100.0)	50 (100.0)

Table 6: Comparison of height and weight of two groups

Variables	Group F	Group D	*P* value
Height (cm)	155.66±5.16	156.10±5.83	0.690
Weight (kg)	58.12±12.35	56.90±10.18	0.591

Table 7: ASA grade in two groups of patients studied

ASA grade	Group F	Group D
	n (%)	*n* (%)
Grade I	26 (52.0)	31 (62.0)
Grade II	24 (48.0)	19 (38.0)
Total	50 (100.0)	50 (100.0)

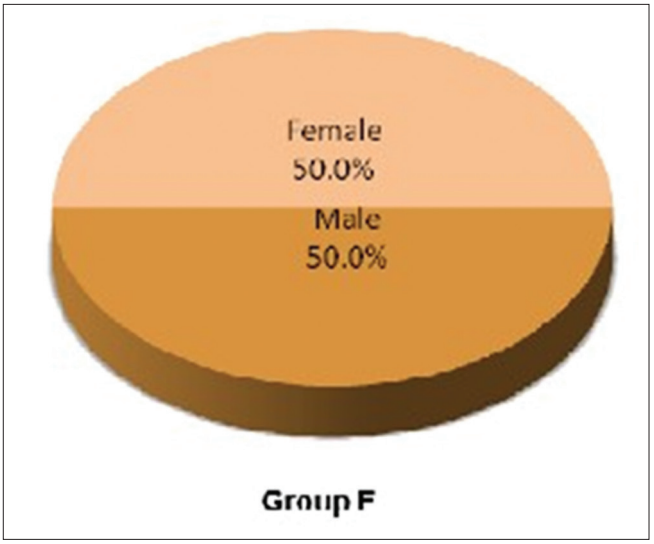


Figure 2: Pie chart showing the gender distribution (*n*-100)

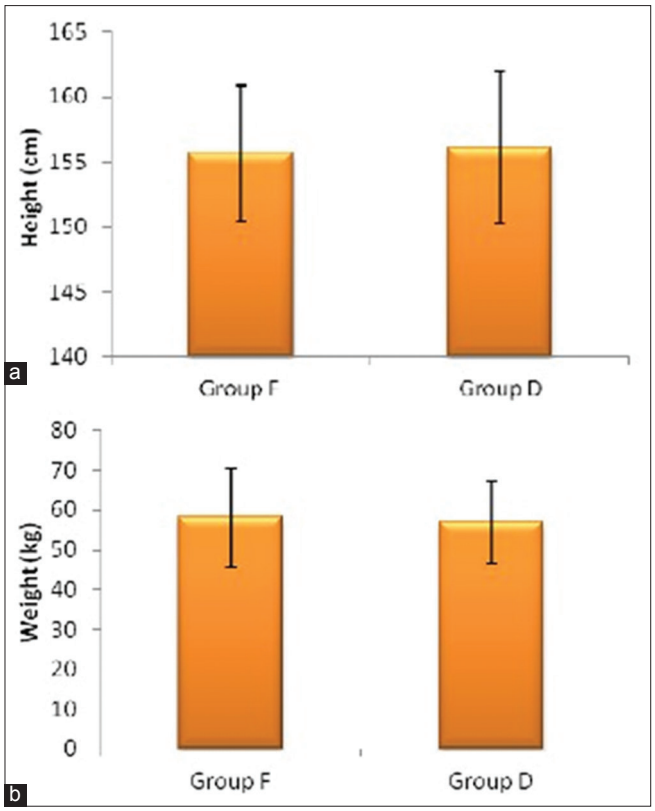


Figure 3: (a and b) Comparison of height and weight in both groups (*n*-100)

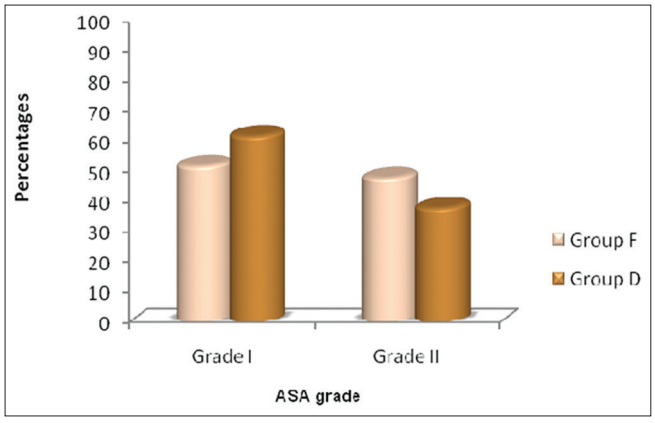


Figure 4: ASA grade distribution in both groups

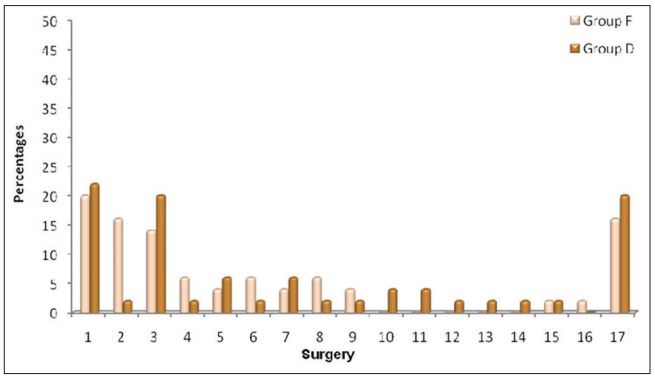


Figure 5: Types of surgeries in both groups

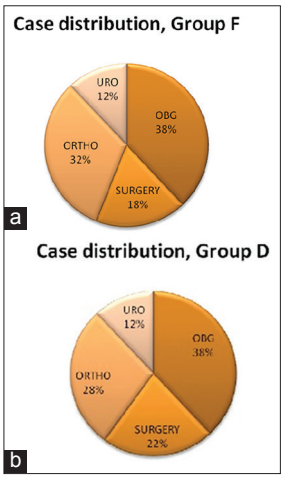


Figure 6: Types of surgeries in both groups

of 3 ml (15 mg) for infra-umbilical surgeries.[32-34] In our institution also, hyperbaric 0.5% bupivacaine 3 ml is regularly used for infra-umbilical surgeries. Hence, in our study, 3 ml of 0.5% bupivacaine was selected. Neuraxial opioids are widely used in conjugation with local anesthetics for spinal anesthesia for providing adequate anesthesia and analgesia. The use of opioids in conjugation with local anesthetics prolonged post-operative analgesia and reduced analgesia requirement.[33,34] Fentanyl is the most commonly used intrathecal opioid adjuvant along with bupivacaine for spinal anesthesia. Various authors have used 25 μg of fentanyl along with hyperbaric bupivacaine.[35-37] Hence, in our study, we have selected fentanyl 25 mcg as the adjuvant along with 0.5% bupivacaine heavy. Fentanyl has limitations as an adjuvant due to: (1) Its duration of action is short - being highly lipid soluble does not stay in the central neuraxial for a long period, and (2) being an opioid, produces a lot of side effects, such as post-operative nausea and vomiting, pruritis, and respiratory depression.[36,37] Hence, other adjuvants like alpha-2 agonists became popular because they do not have the side effects of the opioids. Intrathecal α_2 receptor agonists have antinociceptive action for both somatic and visceral pain. Dexmedetomidine shows more specificity toward α_2-receptor (α_2/α_1 1600:1) compared with clonidine (α_2/α_1 200:1). Several studies have shown that α_2-receptor agonists, when administered intrathecally, will enhance the analgesia provided by subtherapeutic doses of local anesthetics like bupivacaine due to synergistic effects with minimal hemodynamic effects.[32-34] Alpha-2 agonist clonidine has been used as an adjuvant to bupivacaine in higher doses of 55–75 mcg but it was found to have side effects of severe bradycardia and hypotension.[32,38] It was hypothesized that intrathecal dexmedetomidine being more specific to alpha-2 receptors may produce prolonged post-operative analgesia without producing any side effects

Table 8: Surgery in two groups of patients studied

Surgery	Group F (*n*=50)	Group D (*n*=50)
	n(%)	*n*(%)
Vaginal hysterectomy	10 (20.0)	11 (22.00)
Abdominal hysterectomy	8 (16.0)	1 (2.0)
ORIF	7 (4.0)	10 (20.0)
TURP	3 (6.0)	1 (2.0)
URS	2 (4.0)	3 (6.0)
Mesh Repair	3 (6.0)	1 (2.0)
Below knee procedure	2 (4.0)	3 (6.0)
Stripping and ligation	3 (6.0)	1 (2.0)
Tension band wiring	2 (4.0)	1 (2.0)
Implant removal	0 (0.0)	2 (4.0)
Interval appendicectomy	0 (0.0)	2 (4.0)
Fistula repair	0 (0.0)	1 (2.0)
Screw fixation	0 (0.0)	1 (2.0)
Skin grafting	0 (0.0)	1 (2.0)
Internal urethrotomy	1 (2.0)	1 (2.0)
DHS	1 (2.0)	0 (0.0)
Others	8 (16.0)	10 (20.0)

TURP: Transurethral resection of prostate, URS: Ureter lithotomy

Table 9: Comparison of onset time (T10), highest sensory level (*n*-100)

Variables	Group F	Group D	*P* value
Onset time of sensory block (min)	3.38±0.83	2.62±0.56	<0.001
Time from injection to highest sensory level (minutes)	11.47±1.23	11.72±1.23	0.314
Duration of analgesia	240±0.83	360±0.83	<0.001

Table 10: Comparison of time of onset of motor blockade (mean±SD) in both Groups (*n*=100)

Variables	Group F	Group D	*P* value
Onset of motor block	10.38±1.08	10.59±1.00	0.317
Duration of motor block	252.90±8.31	419.70±16.85	<0.001

Table 11: Highest sensory level of patients studied

Maximum height of sensory blockade (segments)	Group 1 (*n*=50)	Group 2 (*n*=50)
T4	2	1
T6	12	13
T8	13	14
T10	3	2

Table 12: Comparison of mean of maximum height of sensory blockade in both Groups (n=100)

Maximum height of sensory blockade	Group F (*n*=50)	Group D (*n*=50)
Mean of maximum height of sensory blockade (segments)	T6-T8	T6-T8

Table 13: Comparison of systolic blood pressure (mmHg) in two groups of patients studied

SBP (mmHg)	Group F	Group D	*P* value
Pre-operative	128.60±11.70	126.20±9.54	0.264
2 min	125.12±12.11	119.40±10.65	0.014
4 min	119.10±11.34	114.84±10.85	0.058
6 min	115.24±9.77	112.76±10.84	0.233
8 min	112.42±9.04	110.92±10.86	0.455
10 min	110.22±9.87	110.50±10.50	0.891
20 min	109.46±9.70	109.38±10.77	0.969
30 min	107.66±9.49	108.34±10.57	0.736
40 min	106.64±9.98	107.32±10.20	0.737
50 min	106.82±10.18	107.12±9.75	0.881
60 min	108.98±9.74	107.82±9.20	0.542
75 min	111.24±9.57	108.60±8.88	0.156
90 min	114.58±8.32	110.56±8.55	0.019

Table 14: Comparison of diastolic blood pressure (mmHg) in two groups of patients studied

DBP (mmHg)	Group F	Group D	*P* value
Pre-operative	80.10±8.58	80.78±7.81	0.679
2 min	77.38±9.68	74.18±9.22	0.094
4 min	72.46±8.56	71.06±9.48	0.440
6 min	69.04±8.65	69.44±9.56	0.827
8 min	65.76±7.87	67.74±10.31	0.283
10 min	62.30±8.39	66.68±10.31	0.022
20 min	60.92±9.23	65.12±9.96	0.031
30 min	61.36±7.40	64.80±9.66	0.048
40 min	60.90±8.25	64.94±9.62	0.026
50 min	61.28±8.50	64.76±9.28	0.053
60 min	62.98±8.79	65.16±8.90	0.221
75 min	65.75±7.53	65.62±8.30	0.933
90 min	69.00±7.54	67.18±8.42	0.258

such as hypotension and bradycardia. Dexmedetomidine has been used in the dose of 5 μg with 0.5% hyperbaric bupivacaine intrathecally as an adjuvant by various authors.[38,39] Dexmedetomidine has been introduced very recently in India and fentanyl was regularly being used as an intrathecal adjuvant in our hospital it was decided to compare 25 μg of fentanyl with 5 μg of dexmedetomidine as adjuvants to 0.5% bupivacaine heavy for infra-umbilical surgeries. 100 adult patients posted for elective infra-umbilical surgeries were randomly divided using computer-generated numbers into two equal groups. Patients in Group F were administered spinal anesthesia using 25 mcg fentanyl and 3 ml of hyperbaric bupivacaine. Patients in Group D were administered 5 mcg dexmedetomidine and 3 ml of 0.5% hyperbaric bupivacaine. There was no statistically significant difference in the age, height, weight, and gender of the patients in both the groups. There was no statistically significant difference in both the groups regarding the type of surgeries and duration of surgeries.

Sensory Block

Onset of sensory block

In our study, we found highly significant difference regarding the onset of sensory block between the two Groups D and F. There was an early onset of sensory

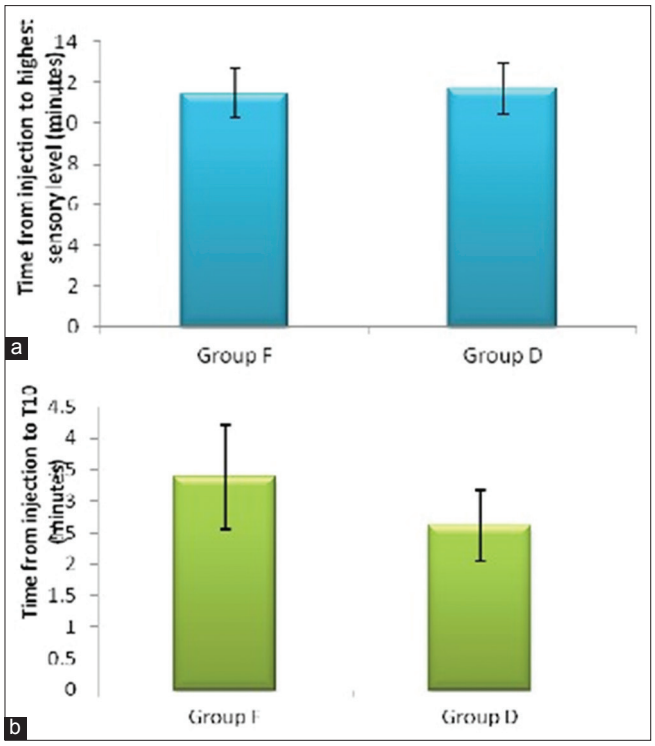


Figure 7: (a) Time from injection to highest sensory level, (b) time from injection to T10 level

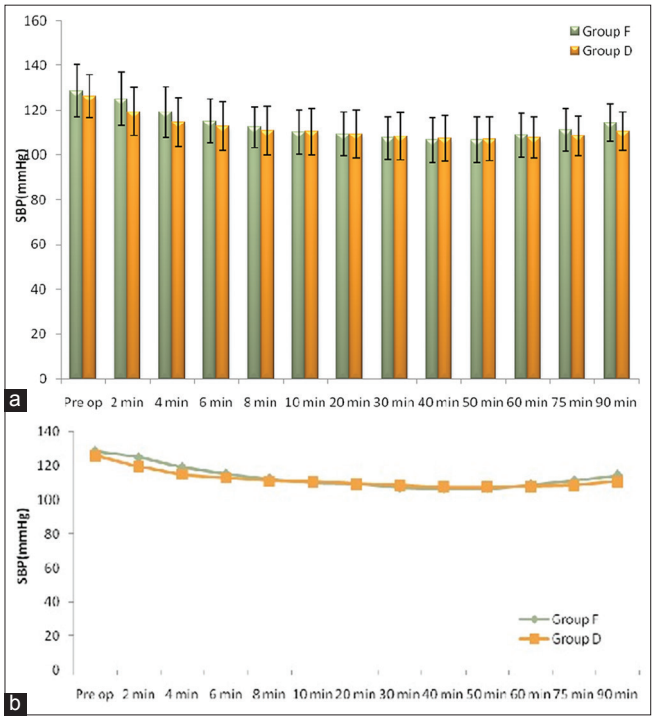


Figure 8: (a and b) Comparison of systolic blood pressure changes in both groups

block with dexmedetomidine group (2.6 ± 0.056 min) compared to the fentanyl group (3.38 ± 0.83 min) in our study. This does not compare with the study conducted by Al-Ghanem *et al.*[3] The authors have not found any

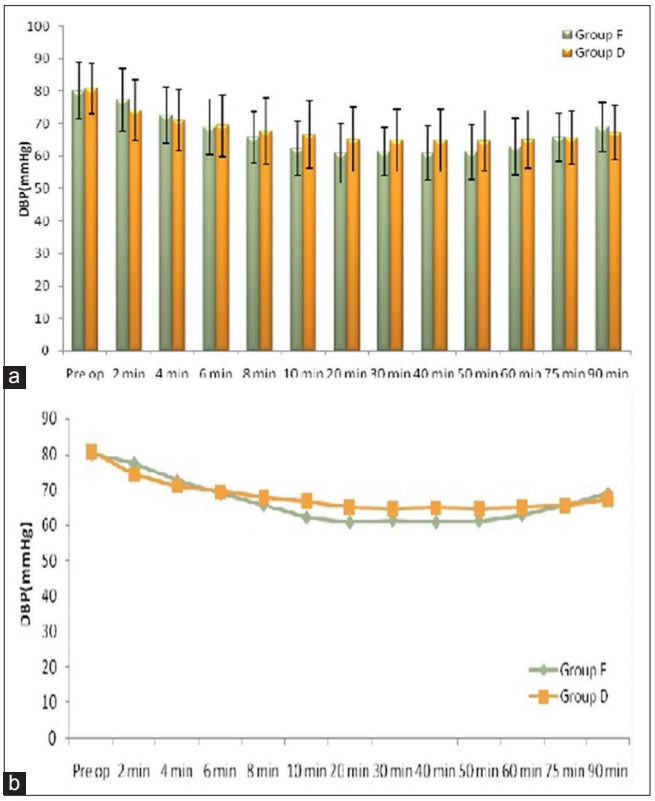


Figure 9: (a and b) Comparison of diastolic blood pressure changes in both groups

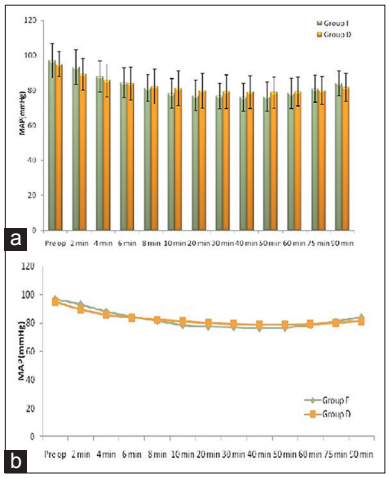


Figure 10: (a and b) Comparison of mean arterial pressure changes in both groups

difference between the two groups regarding the onset of sensory block - dexmedetomidine (7.5 ± 7.4) min and group fentanyl (7.4 ± 7.4) min. These results do not compare with our study probably because, in their study, the position used for the spinal block was sitting position compared to the lateral position used in our study. In their study, they have not specified how much time was used to place the patient from sitting to supine posture and then to lithotomy posture and also when, how frequently the

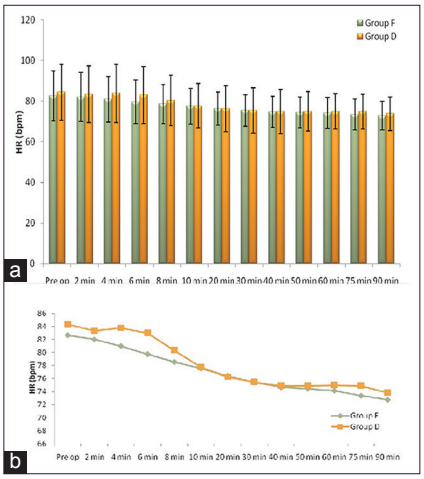


Figure 11: (a and b) Comparison of heart rate in both groups

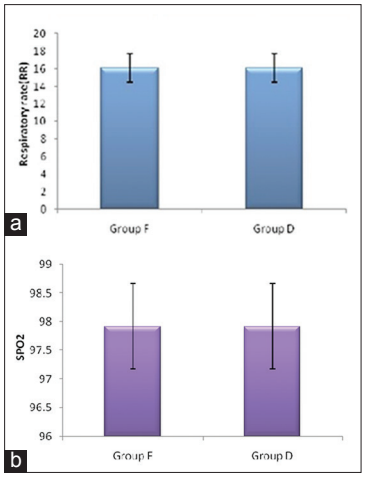


Figure 12: (a and b) Comparison of respiratory rate and SpO_2

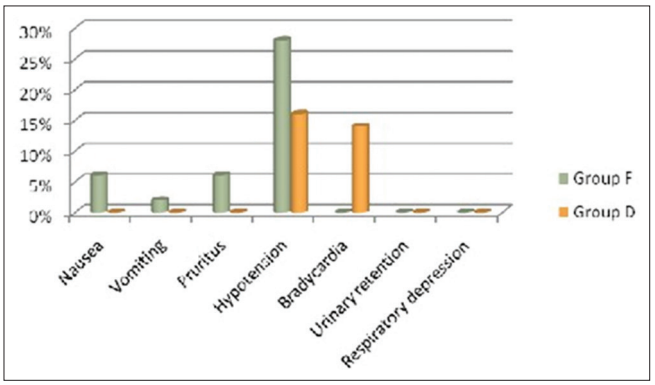


Figure 13: Side effects in both groups

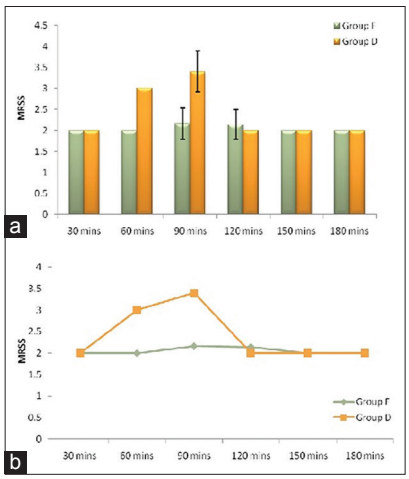


Figure 14: Modified Ramsay Sedation Score in the groups

sensory block was checked. Sensory block was checked, which may be probably the reason for higher onset of time in their study when compared to this study. Our study also does not compare with the study conducted by Hala *et al.*,[29] where in the onset time for sensory block in dexmedetomidine (8.7 ± 3.3) min group was longer than in our study (2.6 ± 0.056) min. This probably because the height of the patients selected was 170 cm in comparison with our study which is 155 cm. The authors have also not mentioned what was the position adopted for administering spinal anesthesia. Our study also compares with the study conducted by Singh *et al.*[12] regarding fentanyl 25 mcg as the adjuvant, in which the onset time was (2.72 ± 1.51) minutes as compared to our study with fentanyl being (3.78 ± 2.8) min which was significant.

Time to achieve maximum sensory block

In our study, we did not find any statistically significant difference in the time to achieve maximum sensory block between the groups dexmedetomidine (11.72 ± 1.23 minutes) and fentanyl (11.47 ± 1.23) min. Our study compares with the study conducted by Gupta *et al.*[5] where they have not found statistically significant difference between dexmedetomidine (12.3 ± 1.8) min and fentanyl (12.1 ± 1.17) min. Our study also compares with the study conducted by Al-Ghanem *et al.*[3] where they also did not find any statistically significant difference between the two groups, but in their study, the time to achieve maximum sensory block was longer in both the groups dexmedetomidine (19.34 ± 2.87) min and fentanyl (18.39 ± 2.46) min. This is probably because the spinal anesthesia was given in sitting posture and also they have not specified how long patients were kept in sitting posture before bringing to supine position.

Duration of Analgesia

In our study, we have found highly significant difference regarding the duration of analgesia with dexmedetomidine group having (360 ± 0.83) min compared to the fentanyl group (240 ± 0.83) min. Our study compares with the study conducted by Al-Ghanem *et al.*,[3] (274 ± 73) min in Group D and (179 ± 47) min in Group F and also with the study conducted by Tarbeeh *et al.*,[38] the fentanyl group was (280 ± 62) min and the dexmedetomidine group was (450 ± 75) min and with the study conducted by Gupta

Table 15: Comparison of MAP (mmHg) in two groups of patients studied

MAP (mmHg)	Group F	Group D	*P* value
Pre-operative	97.02±9.99	94.98±7.02	0.238
2 min	93.29±10.02	89.25±8.97	0.036
4 min	88.00±8.86	85.65±9.27	0.198
6 min	84.44±8.48	83.88±9.50	0.757
8 min	81.31±7.67	82.13±10.08	0.648
10 min	78.27±8.37	81.28±9.98	0.105
20 min	77.10±8.63	79.87±9.84	0.138
30 min	76.79±7.38	79.31±9.50	0.142
40 min	76.14±8.15	79.06±9.35	0.099+
50 min	76.46±8.49	78.88±8.95	0.169
60 min	78.31±8.62	79.38±8.41	0.533
75 min	80.91±7.65	79.94±7.98	0.541
90 min	84.19±7.14	81.64±8.02	0.096+

Table 16:Comparison of HeartRate (beats per min) in two groups of patients studied

HR (bpm)	Group F	Group D	*P* value
Pre-operative	82.68±12.42	84.36±13.71	0.522
2 min	82.04±12.16	83.36±13.94	0.615
4 min	81.02±11.16	83.82±14.32	0.278
6 min	79.78±10.72	83.02±14.03	0.198
8 min	78.58±9.67	80.34±12.51	0.433
10 min	77.60±8.79	77.75±10.80	0.938
20 min	76.42±8.14	76.26±11.38	0.936
30 min	75.46±7.70	75.48±11.20	0.992
40 min	74.68±7.67	74.92±10.87	0.899
50 min	74.48±7.70	74.92±9.70	0.802
60 min	74.18±7.57	74.98±8.64	0.624
75 min	73.40±7.57	74.90±8.54	0.355
90 min	72.78±7.11	73.84±8.22	0.492

Table 17: Comparison of RR and SpO_2 of two groups

Variables	Group F	Group D	*P* value
RR	16.10±1.61	16.10±1.61	1.000
SpO_2	97.92±0.75	97.92±0.75	1.000

RR: Respiratory rate

et al.,[5] (251 ± 21) min in Group D and fentanyl was (168 ± 18) min, wherein there was highly significant difference between dexmedetomidine and fentanyl groups with prolonged duration with the dexmedetomidine group.

Comparison of VAS Score

In our study, patients in the dexmedetomidine group had lower VAS score which was highly significant during the 24 h of the study. Most of the patients, in the Group D had <3.5 ± 0.51 VAS score before 12 h compared to 5.9 ± 0.97 VAS score in the fentanyl group which is highly significant. Our study compares with the study conducted by Tarbeeh *et al.*[38] who also has found highly significant difference in the VAS scoring between the groups.

Table 18: The comparison of respiratory rate values

Side effects	Group F (*n*=50)	Group D (*n*=50)	*P* value
	n (%)	*n* (%)	
Nausea	3 (6.0)	0 (0.0)	<0.05
Vomiting	1 (2.0)	0 (0.0)	>0.05
Pruritus	3 (6.0)	0 (0.0)	<0.05
Urinary retention	0 (0.0)	0 (0.0)	--
Respiratory depression	0 (0.0)	0 (0.0)	--

Table 19: Comparison of the hypotension and bradycardia

No of patients	Group F	Group D	*P* value
Hypotension	8 (16)	14 (28)	<0.001
Bradycardia	0	7 (14)	<0.001
No of patients treated	8	21 (14+7)	

Table 20: Consumption of Mephentermine and Atropine

Group	Mephentermine	Atropine
Fentanyl Group F	48 g	–
Dexmedetomidine-Group D	84 g	2.8 g

Table 21: Comparison of modified Ramsay Sedation Score of two groups

MRSS	Group F	Group D	*P* value
30 min	2.00±0.00	2.00±0.00	1.000
60 min	2.00±0.00	3.00±0.00	<0.001
90 min	2.16±0.37	3.40±0.49	<0.001
120 min	2.14±0.35	2.00±0.00	0.006
150 min	2.00±0.00	2.00±0.00	1.000
180 min	2.00±0.00	2.00±0.00	1.000

MRSS: Modified Ramsay Sedation Score

Table 22: Comparison of visual analog scale of two group

VAS	Group F	Group D	*P* value
6 h	3.50±0.51	0.00±0.00	<0.001
12 h	5.90±0.97	3.50±0.51	<0.001
18 h	7.28±0.95	5.52±0.51	<0.001
24 h	7.24±0.96	3.62±0.69	<0.001

VAS: Value-added service

Highest Sensory Level

Most of the patients in both the groups developed a sensory block between T6 and T8 in our study. Our study does not compare with the study conducted by Tarbeeh *et al.*[38] in which most of the patients reached maximum sensory block below T8. This is probably because 2.5 ml of bupivacaine has been used in their study with a total volume 3 ml including the adjuvant when compared to our

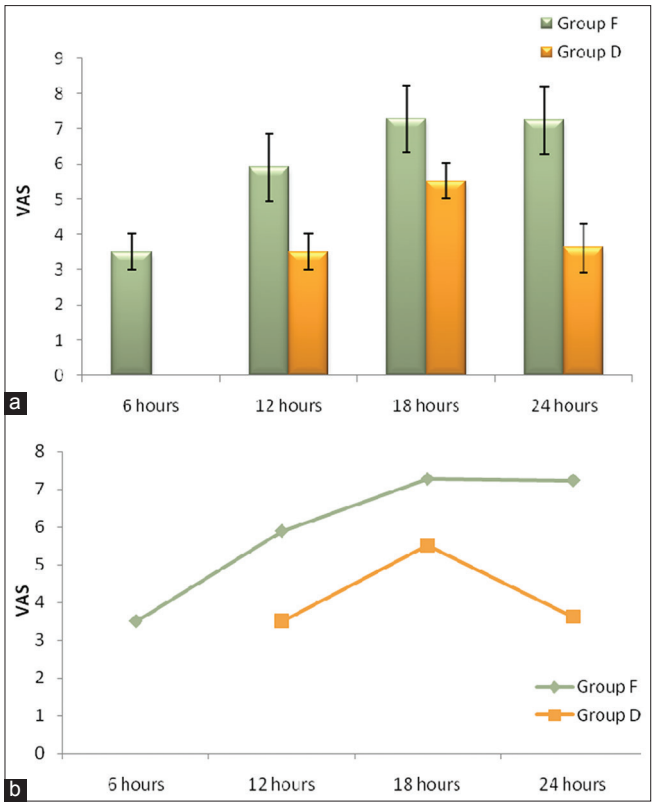
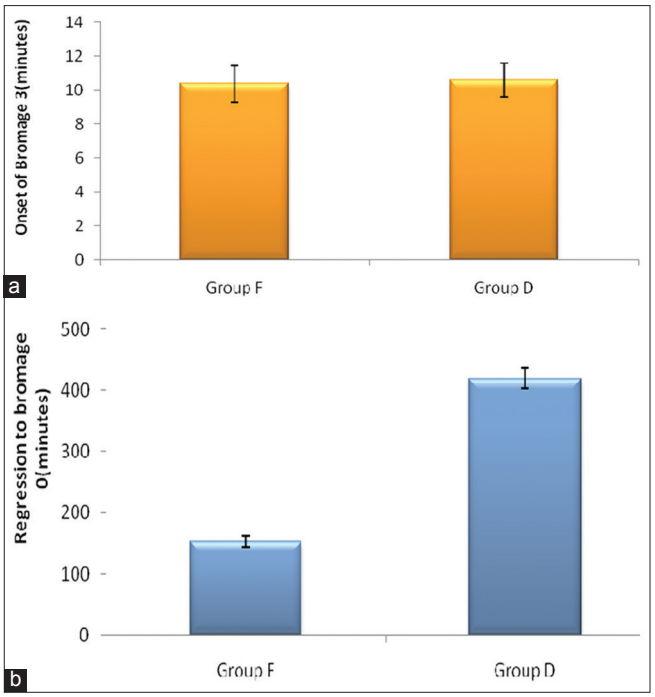


Figure 15: (a and b) Visual analog scales cores in both groups



Graph 1: (a) Onset of motor blockade (in min), (b) duration of motor blockade (in min)

study where local anesthetic 3 ml bupivacaine and total volume 3.5 ml with an adjuvant. Another reason probably because, the spinal anesthesia in their study was given in sitting position and they have not mentioned how long the patient was kept in sitting position, compared to our study where spinal anesthesia given in lateral position [Graph 1].

Motor Blockade

Onset of motor blockade

In our study, onset of motor blockade was (10.38 ± 1.08) min for the dexmedetomidine and (10.59 ± 1.0) min for fentanyl group, respectively, which is statistically not significant. Our study compares with the study conducted by Al-Ghanem *et al.*,[3] where group fentanyl was (14.4 ± 6.7) min and for group dexmedetomidine was (14.3 ± 5.7) min and also with the study conducted by Gupta *et al.*[5] where group fentanyl was (14.4 ± 6.7) min and the group dexmedetomidine was (14.3 ± 5.7) min, who also did not find any significant difference between the two groups.

Duration of motor blockade

In our study, there was a highly significant difference in the duration of motor blockade between the two groups fentanyl (252.90 ± 8.31) min and the dexmedetomidine group (419.70 ± 16.85). Our study compares with the study conducted by Gupta *et al.*[5] where the dexmedetomidine group was 421 ± 21 min and the fentanyl group was 149.3 ± 18.2 min, respectively, where it was highly significant. Our study also compares with the study conducted by Tarbeeh *et al.*[38] where in, group fentanyl was 149 ± 62 min and the group dexmedetomidine was 175 ± 75 min, respectively, which was found to be highly significant. In their study, the duration of motor block was less when compared to our study as they had used 2.5 ml of bupivacaine compared to our study wherein we have used 3 ml of bupivacaine. Furthermore, the patients in their study were taller (175 cm) compared to the patients in our study (155 cm) and as such the level of block was below T8 in their study. Our study also compares with the study conducted by Al-Ghanem *et al.*,[3] where the findings were, group dexmedetomidine was 240 ± 64 min and the group fentanyl F was 155 ± 46 min, respectively, which was highly significant. The duration of motor block in their study was less compared to our study as isobaric bupivacaine 10 mg was used in their study compared to 15 mg of hyperbaric bupivacaine used in our study.

Hemodynamic Parameters

There was no statistical difference regarding the SBP, DBP, and mean arterial pressure at various time interval in our study between the two groups. Our study compares with the study conducted by Tarbeeh *et al.* and with the study of Al-Ghanem *et al.*[3] where they also have not noticed any significant difference between the two groups. In our study, 8 patients of the dexmedetomidine group had hypotension peroperatively in comparison with the fentanyl group it was 14 patients which was statistically highly significant. All the patients who have developed hypotension in the

both the groups had T4 level of sensory block and since more number of patients in fentanyl group had T4 level of sensory block compared to the dexmedetomidine group, there was increase in the number of patients in the fentanyl group to develop hypotension. Our study compares with the study conducted by Al-Ghanem *et al*.[3] who also found more number of patients developing hypotension in fentanyl group (9 patients) compared with dexmedetomidine group (4 patients) and no explanation has been given in their study for the same. Our study does not compare with the study conducted by Tarbeeh *et al*.[38] as all the patients in their study had sensory block achieved below T8 level and hence minimal incidence of hypotension (3 patients in both the groups). It may be because 2.5 ml of bupivacaine heavy was used in their study unlike 3 ml of bupivacaine heavy in the present study. The mean height of patients in their study (175 cm) was also much higher compared to our study (155 cm).

HR

Regarding HR, there was significant bradycardia incidence in the dexmedetomidine group (7) patients compared to the fentanyl group (0) patients in our study. Our study does not compare with the studies conducted by Tarbeeh *et al*.[38] and Al-Ghanem *et al*.[3] where in all the patients developed sensory block below T8 in their study.

Sedation

In our study, at first 1 h and 1½ h interval, there was an increased grade of sedation with dexmedetomidine group compared to fentanyl group, which was highly significant. However, later from 2 h onward there was no statistically significant difference in the sedation grading between the two groups. We could not compare with the studies conducted by Gupta *et al*., Tarbeeh *et al*.,[38] and Al-Ghanem *et al*.[3] where there was no mention of sedation scoring in the results in their studies. There was no respiratory depression in both the groups in our study. Pruritus after intrathecal fentanyl is known but it was not statistically significant in the present study. The α-2 adrenergic agents also have anti-shivering property as observed by Talke *et al*.[40] and Maroof *et al*.[41] We too did not find any incidence of shivering.

CONCLUSIONS

Addition of 5 μg dexmedetomidine with hyperbaric bupivacaine significantly prolongs both sensory and motor block. Intraoperatively, there was less incidence of side effects with intrathecal dexmedetomidine when compared to intrathecal fentanyl. The post-operative 24 h analgesic requirements was significantly less in the dexmedetomidine group than group fentanyl l.5 μg dexmedetomidine seems to be an attractive alternative to 25 μg fentanyl as an adjuvant to spinal bupivacaine in surgical procedures. It provides good quality of intraoperative analgesia, hemodynamically stable conditions, minimal side effects, and excellent quality of post-operative analgesia. Hence, dexmedetomidine seems to be a better choice as intrathecal adjuvant with bupivacaine when compared with fentanyl.

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