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**Dr. Deepali Shetty**

Senior Resident, Department of Anaesthesiology, Kasturba Medical College, Manipal, Karnataka, India

**Dr. Shweta Sinha**

Associate Professor, Department of Anaesthesiology, Kasturba Medical College, Manipal, Karnataka, India

**Dr. Suvajit Podder**

Assistant Professor, Department of Anaesthesiology, Kasturba Medical College, Manipal, Karnataka, India

**Corresponding Author:**

**Dr. Shweta Sinha**

Associate Professor, Department of Anaesthesiology, Kasturba Medical College, Manipal, Karnataka, India

## Comparison of effectiveness of intrathecal dexmedetomidine v/s intrathecal fentanyl as an adjuvant to hyperbaric bupivacaine in elective infraumbilical gynaecological surgeries

**Dr. Deepali Shetty, Dr. Shweta Sinha and Dr. Suvajit Podder**

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### Abstract

**Background:** Spinal anaesthesia is one of the most popular techniques for both elective and emergency lower abdominal surgical procedures. Spinal anaesthesia with a local anaesthetic agent alone is sometimes offset by a relatively short duration of action. To overcome this, several adjuvants are added to the local anaesthetic agent. We aimed to study the effectiveness of dexmedetomidine versus fentanyl as an adjuvant with bupivacaine for spinal anaesthesia in infra-umbilical gynaecological surgeries.

**Methods:** This prospective double-blind, randomised study included 100 patients divided equally into 2 groups (group BD- dexmedetomidine and group BF-fentanyl). Group BD received 0.5% hyperbaric bupivacaine 15 mg + 5 µg Dexmedetomidine and Group BF received 0.5% hyperbaric bupivacaine 15 mg + 25 µg fentanyl intrathecally. The onset, duration of sensory and motor block along with duration and quality of analgesia were recorded.

**Results:** The mean time for onset of sensory block (group BD 3.0±0.97 minutes vs. group BF 3.15±0.99 minutes) and the mean time for motor onset blockade (BD 6.10±1.25 minutes vs. BF 5.54±1.05 minutes) were statistically insignificant. Duration of sensory block (BD 301.06±17.53 minutes vs. BF 208.80±13.42 minutes) and duration of motor block (BD 270.90±17.40 minutes vs. BF, 179.68±10.68 minutes) were statistically significant. Intraoperative analgesia was comparable while post-op analgesia was significantly longer in Group BD.

**Conclusion:** From our study, we concluded that Dexmedetomidine is an attractive alternative to Fentanyl as it provides rapid onset and prolonged sensory and motor block, excellent intra and postoperative analgesia with stable haemodynamics.

**Keywords:** Spinal anesthesia, infraumbilical surgery, dexmedetomidine, intrathecal dexmedetomidine

### Introduction

Spinal anaesthesia, defined as 'the regional anaesthesia obtained by blocking nerves in the subarachnoid space' is a popular and common technique used worldwide. Spinal anaesthesia is one of the standard techniques for both elective and emergency surgical procedures, particularly Caesarean sections, lower abdominal surgeries, orthopaedic and urological surgeries to name a few <sup>[1]</sup>. The advantages of an awake patient, simple to perform, rapid onset of action, minimal drug cost, relatively fewer side effects and rapid patient turnover have made this the choice of anaesthesia for many surgical procedures <sup>[2]</sup>. These advantages are sometimes offset by a relatively short duration of action and an uncomfortable postoperative period when the action of the local anaesthetic agent wears off. Therefore, it forms a challenging forefront in clinical and research advances, wherein one can enhance sensory blockade into the postoperative period by obtaining the lowest dose of the drug with a longer duration of action and its minimal side effects. To achieve this in addition to the local anaesthetic agent like intrathecal bupivacaine, several spinal adjuvants like opioids, clonidine, ketamine, morphine and buprenorphine have been added to prolong the action. However, each drug has its limitations, and a need for alternative methods or drugs always exists <sup>[3]</sup>. Intrathecal opioids are among the most popular, commonly combined with local anaesthetics to improve the onset time of block, duration and quality of analgesia. The addition of morphine, fentanyl, buprenorphine etc. for this purpose has been used regularly.

Fentanyl a lipophilic opioid, has a rapid onset of action following intrathecal administration [4]. It provides good motor blockade as well as postoperative analgesia but has side effects like post-operative urinary retention, respiratory depression, nausea, and constipation among others. Many other alternatives to opioids have also been tried, one such group being  $\alpha_2$ -agonist. Dexmedetomidine is a highly selective  $\alpha_2$ -AR agonist that has sedative, analgesic, perioperative sympatholytic and haemodynamic stabilizing properties with no respiratory depression, making it a safe adjuvant [5]. We aimed to study the effectiveness of dexmedetomidine versus fentanyl with hyperbaric bupivacaine for spinal anaesthesia in infra-umbilical gynaecological surgeries.

### Materials and Methods

This prospective randomised study was conducted at Pravara Institute of Medical Sciences, Loni over 24 months after approval from the institutional ethics committee with Registration No. RMC/PG/2013/38. The study was conducted after obtaining patients' written informed consent after recruiting them based on the inclusion and exclusion criteria. Patients were allocated into two groups of 50 each as per the drug given by the consulting anaesthesiologist:

- **Group "BD":** 0.5% hyperbaric bupivacaine 15 mg + 5  $\mu$ g Dexmedetomidine
- **Group "BF":** 0.5% hyperbaric bupivacaine 15 mg + 25  $\mu$ g fentanyl

The study sample included patients of age 20-60yrs, ASA-PS I&II posted for elective infraumbilical gynaecological procedure and excluded patients who refused, ASA III and IV, local anaesthetic allergy, local infection, spine abnormalities and medical complications like severe heart disease, shock and sepsis.

### Procedure

Pre-anaesthetic checkup was carried out preoperatively with a detailed history, general physical examination and systemic examination. Airway assessment and spinal column examination were done. Written informed consent was taken, NPO orders and other specific orders were given. The procedure of subarachnoid block was explained and the patient was informed to communicate to the anaesthesiologists about perception of any pain or discomfort during the surgery. On the day of surgery, the patient was shifted to the OT (operation theatre) and intravenous (IV) access was obtained. Preloading with Ringer's Lactate solution (500 ml) was done before the block. The monitors connected to the patient included noninvasive blood pressure, pulse oximeter and electrocardiogram. Baseline Heart rate, Blood pressure, Respiratory rate and Oxygen saturation were recorded.

Under strict aseptic precautions, lumbar puncture was performed in the sitting position by midline approach by using a Quincke Babcock spinal needle (25 G) at L3-L4 intervertebral space. Patients were monitored continuously using noninvasive blood pressure, pulse oximeter and electrocardiogram. After spinal anaesthesia, Oxygen (5L  $\text{min}^{-1}$ ) by facemask was given. The table was kept parallel to the ground in all the patients. IV fluids were maintained with Ringer's lactate solution. Vital parameters like heart rate, blood pressure, respiratory rate and oxygen saturation were monitored at 5, 10, 15, 20, 30, 60, 120 minutes.

The onset of sensory block was tested by pin-prick method using a hypodermic 23G needle. The time of onset was taken from the time of injection of the drug into subarachnoid space to loss of pinprick sensation. The highest level of sensory block and time required to achieve it was noted. The time for two dermatomal segments regression of sensory level was noted. The duration of sensory blockade was taken as time from onset to time of the return of pinprick sensation to the S1 (heel) dermatomal area. Assessment of Motor Blockade was by Bromage scale. The time interval between injections of drug into subarachnoid space to the patient's inability to lift the straight extended leg against gravity was taken as onset time (Br. 3). The duration of motor block was taken from the time of injection to complete regression of motor block. (flexion of knees and feet) (Br. 0).

Modified Bromage Scale: [6]

- **Grade 0:** Full flexion of knees and feet.
- **Grade 1:** Just able to flex knees, full flexion of feet.
- **Grade 2:** Unable to flex knees, but some flexion of feet possible.
- **Grade 3:** Unable to move legs or feet.

Assessment of analgesia was by visual analogue scale (VAS): [7]

VAS Score	Intensity of pain
0-2	No pain to slight pain
2-5	Mild pain.
5-7	Moderate pain.
7-9	Severe pain.
10	Worst possible pain.

Duration of effective analgesia was defined as the time from the intrathecal injection to VAS >4. Analgesics were avoided until demanded by the patient and hence the time taken for the first analgesic was noted. VAS was also recorded at 3, 6 and 12 hours (hr) postoperatively.

Quality of intraoperative analgesia was assessed on a four-point modified Belzarena scale: [8]

1. Unable to tolerate pain
2. Able to tolerate discomfort with additional analgesia
3. Some discomfort but no additional analgesics required
4. Completely satisfied.

Sedation scores were assessed every 15 minutes both intraoperatively and postoperatively using a four-point score.

- **Grade 0:** Patient wide awake.
- **Grade 1:** Patient is sleeping comfortably, but responding to verbal commands.
- **Grade 2:** Deep sleep, but arousable.
- **Grade 3:** Deep sleep, unarousable.

The incidence of hypotension (systolic blood pressure < 20% of baseline) was treated with intravenous mephentermine 6 mg intravenous increments and bradycardia as Heart rate < 60/minute was treated with 0.6 mg intravenous atropine. Side effects if any, like sedation, nausea, vomiting and urinary retention were monitored in the recovery room and then shifted to the ward. A neurological examination was done to rule out any neurological deficits at discharge.

### Data analysis

Statistical analysis was done by descriptive statistics such as

mean, SD, percentages etc. Student’s Paired ‘t’ test for before and after data and Unpaired ‘t’ test of difference between two samples are used to compare all groups concerning all parameters under study. The chi-square test was applied to the association between some qualitative variables and groups under study. p-value <0.05 was considered as significant. Statistical analysis software SYSTAT version 12 (By Cranes software, Bangalore) was

used to analyse the data.

**Results**

A total of 100 patients qualifying the inclusion and exclusion criteria were recruited for this study and equally divided in 2 groups -group BF and group BD. Demographic data like age, weight and height in both study groups were comparable and there was no statistical significance.

**Table 1:** Demographic details

	Group BD (n=50) (Mean ± SD)	Group BF(n=50) (Mean ± SD)
Age (years)	44.60±8.36	46.72±9.87
Height (feet)	5.38±0.20	5.30±0.22
Weight (kg)	62.86±7.47	56.28±5.76

The mean time for the onset of sensory block in group BD was 3.0±0.97 minutes and in group BF, it was 3.15±0.99 minutes. In both groups, the onset of sensory block was statistically not significant. The mean time for motor onset

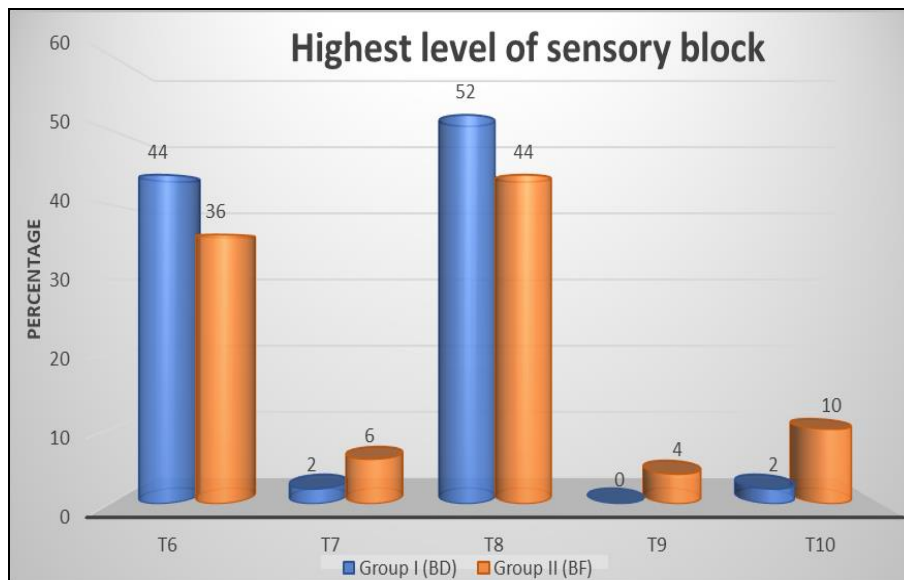
blockade in group BD was 6.10±1.25 minutes and in group BF was 5.54±1.05 minutes. There was statistically no significant difference between the two groups to motor blockade onset.

**Table 2:** Onset of sensory and motor block

	Group BD (n=50)	Group BF (n=50)	Student’s Unpaired ‘t’ test value	‘p’ value and significance
	Mean ± SD	Mean ± SD		
Sensory Onset (min)	3.0 ± 0.97	3.15 ± 0.99	0.76	p>0.05, not significant
Onset to Bromage 3 (min)	6.10±1.25	5.54±1.05	1.32	p>0.05, not significant

In group BD, the percentage of cases achieving various highest sensory levels were as follows: T6 level was achieved by 44% of the cases, 2% of the cases achieved both T7 and T10 levels and T8 level was achieved by 52%. In group BF they were as follows: 36% of the cases

achieved T6 level, 6% achieved T7, 44% achieved T8, 4% achieved T9 and 10% achieved T10 level and there was no statistical significance between the highest sensory levels and groups BD and BF.



**Fig 1:** Highest Level of sensory block

The time for two-segment regression in Group BD was 126.64±7.84 minutes, which was considerably slower than Group BF, where it was found to be 101.40±7.51minutes. The time to complete sensory recovery (the mean duration of the sensory block) was 301.06±17.53 minutes in Group

BD and in Group BF, it was 208.80±13.42minutes. The time to complete motor recovery (the mean duration of the motor block) was 270.90±17.40 minutes in Group BD and in Group BF, it was 179.68±10.68 minutes. All three parameters were statistically significant.

**Table 3:** Recovery parameters in groups BD and BF

Recovery parameters (min)	Group BD (n=50)	Group BF (n=50)	Student’s Unpaired ‘t’ test value	‘p’ value
	Mean ± SD	Mean ± SD		
Time for Two Segment Regression	126.64±7.84	101.40±7.51	16.50	<0.01
Sensory Recovery	301.06±17.53	208.80±13.42	29.55	<0.01
Motor Recovery	270.90±17.40	179.68±10.68	31.59	<0.01

Concerning the quality of intraoperative analgesia as assessed by Belzarena scale, 62% of the patients in Group BD were completely satisfied when compared to 64% of the patients in Group BF. In both groups, 36% of the patients

complained of some discomfort without the requirement of any additional analgesics. 2% of the patients in Group BD required additional analgesics compared to 0% in Group BF which was statistically insignificant.

**Table 4:** Quality of Intra-op Analgesia in groups BD and BF

Quality of Intra-op Analgesia	Group BD (n=50)	Group BF (n=50)
2	1(2%)	0
3	18(36%)	18(36%)
4	31(62%)	32(64%)
Total	50	50
Mean ± SD	3.56±0.58	3.64±0.48

The mean duration of complete analgesia in Group BD was 337.0±27.08 minutes, and in Group BF it was 179.98±20.04 minutes. The mean duration of effective analgesia in Group

BD was 365.70±39.77 minutes and in Group BF was 213.08±25.84 minutes. Both of these were statistically significant.

**Table 5:** Duration of effective analgesia

Duration of analgesia (min)	Group BD (n=50)	Group BF (n=50)	Student's Unpaired 't' test value	'p' value and significance
	Mean ± SD	Mean ± SD		
Duration of complete Analgesia	365.70±39.77	213.08±25.84	22.75	p<0.01

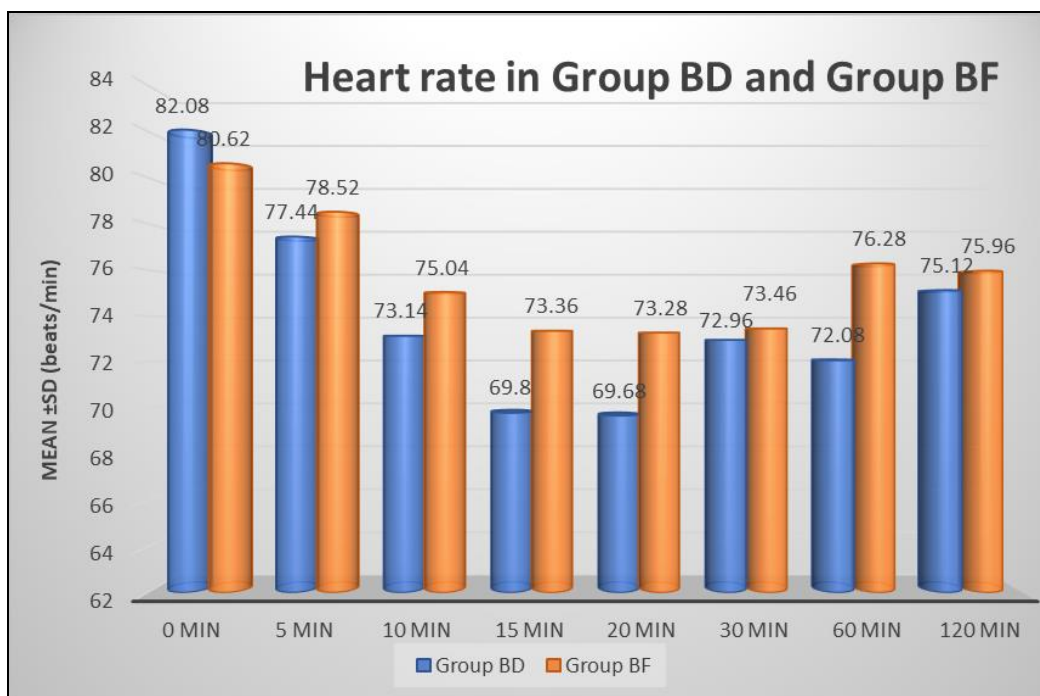
VAS at the end of 3 hours in group BD was 0.04±0.2 and in group BF, it was 0.84±1.08. VAS at end of 6 hours in group BD was 2.66±1.33 and in group BF, it was 3.14±0.88. VAS

at end of 12 hours, in group BD, was 5.90±0.86 and in group BF it was 6.26±0.85. All of these were statistically significant.

**Table 6:** VAS in Group BD and Group BF

VAS (hr)	Group BD (n=50)	Group BF (n=50)	Unpaired t-test	p-value
	Mean ± SD	Mean ± SD		
3	0.04±0.20	0.84±1.08	5.15	0.0001
6	2.66±1.33	3.14±0.88	2.12	0.01
12	5.90±0.86	6.26±0.85	2.10	0.01

Heart rate, systolic blood pressure and diastolic blood pressure were comparable and statistically insignificant.



**Fig 2:** Heart rate in Group BD and Group BF



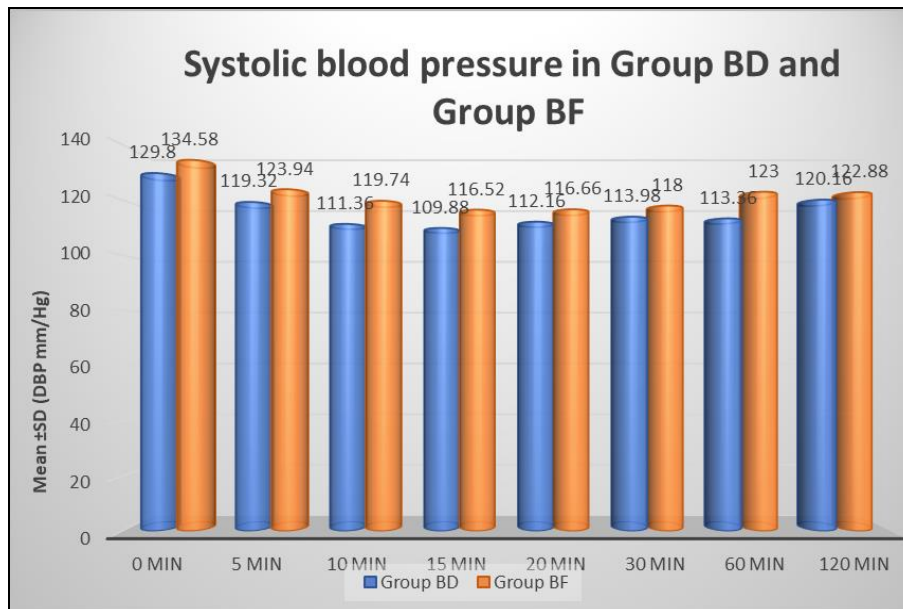


Fig 3: Systolic blood pressure in Group BD and Group BF

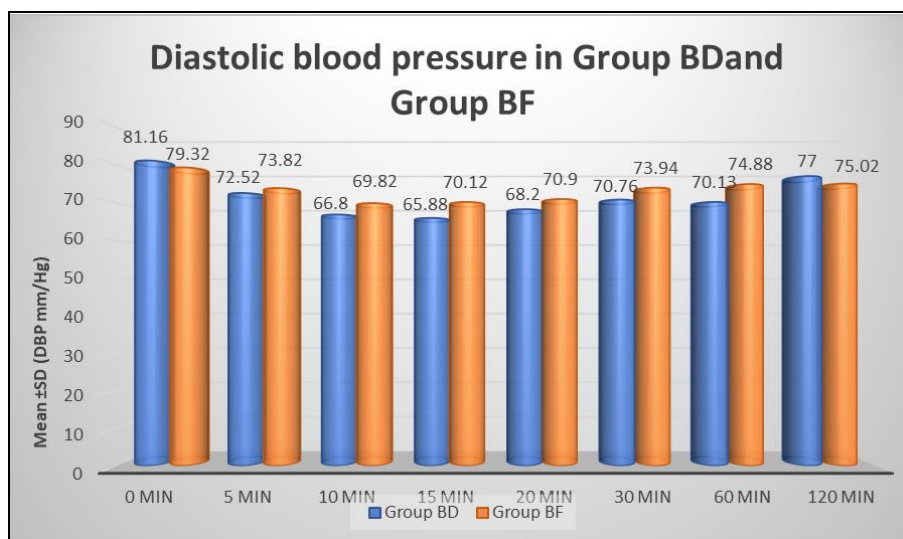


Fig 4: Diastolic blood pressure in Group BD and Group BF

In group BD, 10% of the patients developed hypotension, 8% had bradycardia, 4% had nausea and 4% had urinary retention. In group BF, 6% of the patients developed hypotension, 0% had bradycardia, 6% had nausea, 2% had vomiting, 2% had pruritus and 6% had urinary retention. There was statistically no difference between the two groups.

**Discussion**

Spinal anaesthesia is one of the most popular anaesthetic techniques used across the world [9] given the advantages of excellent pain control, reduced side effects, shortened stay and early recovery in the post-anaesthesia care unit. However, these early advantages can be short-lived and limited by the relatively brief duration of action of currently available local anaesthetics. Bupivacaine is an amide local anaesthetic that has a prolonged duration of action and lower incidence of adverse effects but high doses of intrathecal bupivacaine may lead to bradycardia, hypotension and respiratory depression.

Alpha  $\alpha_2$ -Adrenergic receptor (AR) agonists have been the focus of interest as and adjuvant for their sedative, analgesic, sympatholytic, and hemodynamic-stabilizing properties. Dexmedetomidine, a highly selective  $\alpha_2$ -AR

agonist with a relatively high ratio of  $\alpha_2/\alpha_1$ -activity (1620:1 as compared to 220:1 for clonidine), possesses all these properties and has decreased events of adverse effects like respiratory depression, making it useful and safe adjunct in diverse clinical applications [5]. The affinity of dexmedetomidine to  $\alpha_2$  adrenergic receptors has been reported to be 10 times more than that of clonidine, which makes it a more effective sedative and analgesic agent with a more favourable pharmacodynamic profile [10]. In the spinal cord, activation of both  $\alpha_{2C}$  and  $\alpha_{2A}$ -ARs, situated in the neurons of the superficial dorsal horn especially lamina II, directly reduces pain transmission by decreasing the release of pro-nociceptive transmitter, substance P and glutamate from primary afferent terminals and by hyperpolarizing spinal inter neurons via G-protein-mediated activation of potassium channels.

In our study, the mean time of sensory and motor block onset in both groups was similar with no statistical difference. This was similar to the results of Ranji Gupta *et al.* [11] and Subhi M. Al-Ghanem *et al.* [12]. The highest sensory level was T7 in the dexmedetomidine group and T6 in the fentanyl group which was statistically insignificant. Rahimzadeh *et al.* [13] found similar results in their study where they used 5 micrograms of dexmedetomidine in

comparison to 25 micrograms of fentanyl in 12.5 mg of hyperbaric bupivacaine and the highest sensory level was T6 in both groups.

The time for two-segment regression was considerably slower in group BD with group BF ( $126.64 \pm 7.84$  vs  $101.40 \pm 7.51$ ) and was statistically significant. Similar results were found by Gehan A. Tarbeeh, *et al.* [14] found that in the dexmedetomidine group, the time for two-segment regression was slower ( $150 \pm 42$  minutes) compared to the fentanyl group ( $114 \pm 35$  minutes). The mean sensory and motor block duration in group BD was significantly higher than in group BF (301.06 vs 208.80 minutes for sensory and 270.90 vs 179.68 minutes for motor). These results were similar to the results found by Gehan A. Tarbeeh, *et al.* [14], Rajni Gupta, *et al.* [11] and Subhi M. Al-Ghanem, *et al.* [12] Veena Chatrath, Joginder P *et al.* [15] conducted a study for comparative evaluation of bupivacaine alone (Group B) versus bupivacaine and dexmedetomidine (Group D) for spinal anaesthesia in infra umbilical surgeries on 100 patients. They found a significant difference was observed with total duration of motor block ( $146.94 \pm 9.173$  minutes in group B and  $318.36 \pm 9.374$  minutes in group D)

The mean duration of complete analgesia in group BD was 365.7 minutes and in group BF was 213.08 minutes, which was statistically significant ( $p < 0.001$ ). VAS at the end of 3 hours in group BD was 0.04 and 0.84 in group BF. VAS at the end of 6 hours in group BD was 2.66 and in group BF it was 3.14. VAS at the end of 12 hours in group BD was 5.90 and in group BF it was 6.26. VAS was statistically significant at 3 hours and 12 hours implying patients in group BD had better pain relief (lower VAS) in the postoperative period than group BF.

The two groups did not differ significantly concerning vital parameters like heart rate, systolic, diastolic and mean arterial pressures at any interval which was similar to the results obtained by Mahendru V *et al.* [16] and al Yektas A *et al.* [17] This was unlike the study conducted by Rahimzadeh *et al.* [13] where they noticed significant changes in vital parameters in the dexmedetomidine group. Concerning adverse events, patients in the fentanyl group had pruritus and urinary retention but were statistically insignificant. Different doses of dexmedetomidine with 7.5 micrograms and 10 micrograms have been found to have comparable results regarding haemodynamic effects and adverse events with longer sensory and motor blockade<sup>18</sup> but further studies may be required to prove the same.

### Conclusion

From this study, we observed that intrathecal dexmedetomidine produces early onset and prolonged duration of sensory and motor block as well as prolonged postoperative analgesia resulting in lesser requirement of rescue analgesics in the postoperative period without any serious complications when compared to fentanyl. Hence, we conclude that 5 µg dexmedetomidine seems to be an attractive alternative to 25 µg fentanyl as an adjuvant to intrathecal bupivacaine in infra-umbilical surgical procedures.

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