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A Randomized Comparative Study of Bupivacaine Alone versus Bupivacaine with Fentanyl or Dexmedetomidine for Spinal Anaesthesia: Effects on Block Duration, Analgesia and Haemodynamic Stability.

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Abstract

Background: Spinal anaesthesia with bupivacaine is widely used for infraumbilical procedures; however, its relatively limited duration of postoperative analgesia may necessitate early administration of rescue analgesics. Various intrathecal adjuvants have therefore been evaluated to improve the quality and duration of spinal anaesthesia. Fentanyl is a commonly used opioid adjuvant, whereas dexmedetomidine, an α2-adrenergic agonist, has been reported to prolong sensory and motor blockade with minimal adverse effects. Aim: To compare the effects of intrathecal bupivacaine alone with bupivacaine combined with fentanyl or dexmedetomidine on the characteristics and duration of spinal anaesthesia, postoperative analgesia, haemodynamic parameters and adverse effects. ***Methods***: This prospective, randomized, controlled, double-blind comparative study included 90 patients aged 18–60 years belonging to American Society of Anesthesiologists (ASA) physical status I or II and undergoing elective infraumbilical surgery. Patients were randomly allocated into three groups of 30 each. Group B received 15 mg of 0.5% hyperbaric bupivacaine with normal saline, Group F received 15 mg of 0.5% hyperbaric bupivacaine with fentanyl 25 µg, and Group D received 15 mg of 0.5% hyperbaric bupivacaine with dexmedetomidine 5 µg. Sensory and motor block characteristics, two-segment sensory regression, duration of sensory and motor blockade, duration of analgesia, haemodynamic parameters and adverse effects were assessed. ***Results***: The three groups were comparable with respect to baseline demographic characteristics. The onset of sensory blockade was 3.37 ± 1.13 minutes in Group B, 3.20 ± 1.21 minutes in Group F and 2.87 ± 1.14 minutes in Group D, with no statistically significant difference (P=0.242). The mean two-segment regression time was significantly longer in Group D (152.33 ± 12.30 minutes) compared with Group F (126.17 ± 14.84 minutes) and Group B (100.83 ± 13 minutes; P<0.001). The duration of sensory blockade was 232.67 ± 47.99, 283.67 ± 24.84 and 415.67 ± 25.62 minutes in Groups B, F and D, respectively (P<0.001). Similarly, motor blockade lasted significantly longer in Group D (375.00 ± 24.60 minutes) than in Group F (252.00 ± 44.91 minutes) and Group B (224.17 ± 89.89 minutes; P<0.001). Duration of analgesia was also significantly longer with dexmedetomidine (378.00 ± 54.40 minutes) compared with fentanyl (274.00 ± 26.31 minutes) and bupivacaine alone (210.33 ± 36.53 minutes; P<0.001). Haemodynamic changes were comparable among the groups. Bradycardia occurred more frequently in Group D, although the difference was not statistically significant. ***Conclusion***: Addition of 5 µg dexmedetomidine to hyperbaric bupivacaine significantly prolonged sensory and motor blockade, two-segment regression time and duration of analgesia compared with bupivacaine alone and bupivacaine with fentanyl. Dexmedetomidine provided prolonged postoperative analgesia with a comparable overall haemodynamic and adverse-effect profile and appears to be an effective alternative to fentanyl as an intrathecal adjuvant.

Keywords: Spinal anaesthesia; Bupivacaine; Fentanyl; Dexmedetomidine; Sensory blockade; Motor blockade; Postoperative analgesia; Haemodynamic stability.

INTRODUCTION

Spinal anaesthesia is one of the most commonly used techniques for lower abdominal surgeries as it is very economical and easy to administer with the advantage of providing surgical anaesthesia. However, postoperative pain control is a major problem because spinal anaesthesia using local anaesthetics alone is associated with relatively short duration of action and thus early analgesic intervention is needed in the postoperative period.[1,2,3] Various adjuvants have been used along with local anaesthetic agents to avoid intraoperative visceral and somatic pain and to prolong postoperative analgesia.[1]

Fentanyl is a short acting mu receptor agonist opioid. It exerts its effect by combining with opioid receptor in the dorsal horn of spinal cord and may have a supra-spinal spread and action. Fentanyl produces intense and prolonged analgesic action without gross autonomic changes, loss of motor power or impairment of sensation other than pain when injected into subarachnoid space.[1] Duration of effects of intrathecal fentanyl is dose independent. Side effects include pruritus, nausea and vomiting and rarely serotonin syndrome.[4] Addition of intrathecal Fentanyl as an adjuvant to spinal anaesthesia produces faster onset time, decreases the visceral pain, somatic pain, improved intraoperative analgesia and excellent quality of perioperative analgesia.[2,3]

Recently, α-2 adrenoreceptor agonists are being used as an adjuvant to local anaesthetic agents because of their sedative, analgesic effect, good quality of intraoperative and prolonged postoperative analgesia and haemodynamic stabilizing effects with minimal side effects.[5]

Dexmedetomidine can be used as an adjuvant to local anesthetics for intrathecal anaesthesia[6,7,8], acts by binding to pre-synaptic C-fibers and post-synaptic dorsal horn neurons. Its addition to local anesthetics has been found to prolong the duration of both motor and sensory blockade without much side effects.[8,9,10,11] Dexmedetomidine recently has been introduced in India and not many studies have been done regarding its use as an intrathecal adjuvant to local anaesthetics.

The thesis study was undertaken to compare the traditionally used fentanyl with dexmedetomidine as an adjuvant to hyperbaric bupivacaine. The beginning of sensory and motor blockade, maximum sensory level, two-segment sensory regression, duration of sensory and motor blockade, and overall duration of analgesia were the major objectives; adverse effects and haemodynamic parameters were evaluated as secondary results.

AIMS AND OBJECTIVES OF THE STUDY

To study the effects of intrathecal bupivacaine, bupivacaine plus fentanyl and bupivacaine plus dexmedetomidine. The effects will be studied in terms of:

PRIMARY OBJECTIVES

- Onset of sensory blockade
- Maximal level of sensory blockade
- Onset of motor blockade
- Time for two segment regression of sensory blockade
- Duration of sensory blockade
- Duration of motor blockade
- Total duration of analgesia

SECONDARY OBJECTIVES

- Hemodynamic parameters
- Adverse effects

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, randomized, controlled, double-blind comparative clinical study conducted in the Department of Anaesthesia and Pain Relief, Kidwai Memorial Institute of Oncology, Bangalore, during the period from December 2015 to May 2016. The study received approval from the institutional ethics committee and written informed consent was obtained from all participants.

Study Population

A total of 90 patients were included and randomly allocated into three groups of 30 patients each using computer-generated randomization. Patients with ASA physical status I or II who were between the ages of 18 and 60 and gave their agreement to participate were included in the research. Patients who refused to participate, were classified as ASA III or IV, had hypersensitivity to dexmedetomidine, opioids, or local anaesthetics, had undergone prior spine surgery, had an injection site infection, coagulopathy, elevated intracranial pressure, indeterminate neurological disease, or had a spinal deformity were all excluded.

Study Groups

The participants were divided into:

- **Group B:** 0.5% hyperbaric bupivacaine 3 mL (15 mg) + 0.5 mL normal saline.
- **Group F:** 0.5% hyperbaric bupivacaine 3 mL (15 mg) + fentanyl 25 µg in 0.5 mL.

- **Group D:** 0.5% hyperbaric bupivacaine 3 mL (15 mg) + dexmedetomidine 5 µg in 0.5 mL normal saline.

Anaesthetic Technique

Patients were preloaded with Ringer's lactate at 10 mL/kg. Lumbar puncture was performed under aseptic precautions at the L2–L3 or L3–L4 interspace using a 25-gauge spinal needle, with the patient in the lateral decubitus position. An anaesthesiologist who was not participating in the study prepared the study syringes. Both the patient and the observer were blind to the medication being given. Patients were placed immediately in a supine posture with the operation table kept flat after intrathecal injection. For the first ten minutes, haemodynamic parameters were recorded every two minutes; after that, they were recorded every five minutes for the next sixty minutes. Following surgery, patients were monitored at 4, 8, 12, and 24 hours.

Assessment of Spinal Block

Sensory blockade was assessed using the pin-prick method. Onset of sensory blockade was defined as loss of pain sensation at the T10 dermatome. The level that did not change over the course of four consecutive examinations was referred to be maximum sensory blockage.

The modified Bromage scale was used to evaluate motor blockage. The time needed to attain Bromage grade 3 was used to characterise the onset of motor blockage. The maximal sensory level was used to capture two-segment regression. While the duration of motor blockage was assessed from Bromage grade 3 to regression to Bromage grade 1, the duration of sensory blockade was recorded from accomplishment of T10 till regression below L1. The period from maximal sensory blocking to the patient's request for the first painkiller was considered the total duration of analgesia.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation, while categorical variables were expressed as numbers and percentages. ANOVA was used for comparison among the three groups, followed by post-hoc Tukey testing for intergroup comparisons. Chi-square/Fisher's exact test was used for categorical variables. Statistical significance was assessed at the 5% level.

RESULTS

Baseline Characteristics

The study included 90 patients, with 30 patients in each group. The mean age was 37.73 ± 8.77 years in Group B, 36.83 ± 12.12 years in Group F and 39.67 ± 11.90 years in Group D, with no significant difference among the groups (P=0.599). Mean body weight was 62.07 ± 6.77 kg in Group B, 59.10 ± 7.27 kg in Group F and 62.57 ± 7.20 kg in Group D (P=0.129). Gender distribution and ASA grade were also comparable among the three groups.

Table 1. Baseline characteristics of the study groups

Variable	Group B (n=30)	Group F (n=30)	Group D (n=30)	P value
Age (years), mean ± SD	37.73 ± 8.77	36.83 ± 12.12	39.67 ± 11.90	0.599
Weight (kg), mean ± SD	62.07 ± 6.77	59.10 ± 7.27	62.57 ± 7.20	0.129
ASA I, n (%)	22 (73.3)	22 (73.3)	20 (66.7)	0.805
ASA II, n (%)	8 (26.7)	8 (26.7)	10 (33.3)	0.805

Spinal Block Characteristics

The mean onset time of sensory blockade was 3.37 ± 1.13 minutes in Group B, 3.20 ± 1.21 minutes in Group F and 2.87 ± 1.14 minutes in Group D. Although onset was numerically faster with dexmedetomidine, the difference was not statistically significant (P=0.242).

The onset of motor blockade was similarly comparable among the groups, with mean values of 5.63 ± 1.75 minutes, 5.30 ± 1.34 minutes and 4.87 ± 1.38 minutes in Groups B, F and D, respectively (P=0.147).

Table 2. Spinal block characteristics

Parameter	Group B	Group F	Group D	P value
Sensory onset time (min)	3.37 ± 1.13	3.20 ± 1.21	2.87 ± 1.14	0.242
Two-segment regression (min)	100.83 ± 13.00	126.17 ± 14.84	152.33 ± 12.30	<0.001
Duration of sensory block (min)	232.67 ± 47.99	283.67 ± 24.84	415.67 ± 25.62	<0.001
Motor onset time (min)	5.63 ± 1.75	5.30 ± 1.34	4.87 ± 1.38	0.147
Duration of motor block (min)	224.17 ± 89.89	252.00 ± 44.91	375.00 ± 24.60	<0.001
Duration of analgesia (min)	210.33 ± 36.53	274.00 ± 26.31	378.00 ± 54.40	<0.001

The time for two-segment regression was significantly longer in Group D than in Groups B and F. The mean values were 100.83 ± 13.00 minutes, 126.17 ± 14.84 minutes and 152.33 ± 12.30 minutes, respectively (P<0.001). Compared to Group F (283.67 ± 24.84 minutes) and Group B (232.67 ± 47.99 minutes), Group D's total duration of sensory blockage was much longer (415.67 ± 25.62 minutes) (P<0.001). Similarly, Group D had motor blockage for a substantially longer period of time (375.00 ± 24.60 minutes) than Group F (252.00 ± 44.91 minutes) and Group B (224.17 ± 89.89 minutes) (P<0.001). The length of the motor blockage did not change statistically significantly between Groups B and F (P=0.174).

Duration of Analgesia

The mean duration of analgesia was 210.33 ± 36.53 minutes in Group B, 274.00 ± 26.31 minutes in Group F and 378.00 ± 54.40 minutes in Group D. The difference among all three groups was statistically significant (P<0.001). Dexmedetomidine therefore provided the longest duration before the first request for analgesia.

Table 3. Duration of analgesia

Group	Duration of analgesia (min), mean ± SD
Group B	210.33 ± 36.53
Group F	274.00 ± 26.31
Group D	378.00 ± 54.40
Overall P value	<0.001

HAEMODYNAMIC PARAMETERS AND ADVERSE EFFECTS

Mean arterial pressure and heart rate were comparable among the three groups during the intraoperative and postoperative periods. No patient developed respiratory distress, and peripheral oxygen saturation remained above 96% throughout the observation period without requirement for additional oxygen in the post-anaesthesia care unit.

Five patients (16.7%) in Group B, three patients (10.0%) in Group F, and three patients (10.0%) in Group D had hypotension. There was no statistically significant difference. One patient (3.3%) in Group B, one patient (3.3%) in Group F, and five patients (16.7%) in Group D all had bradycardia. The dexmedetomidine group had a numerically higher incidence of bradycardia, although this difference was not statistically significant. 3.3% of patients in Groups B and F and 6.7% in Group D reported experiencing nausea and vomiting, whereas 6.7% of patients in Groups B and F and 3.3% in Group D reported experiencing shivering. There were no significant side effects mentioned.

Table 4. Haemodynamic and adverse effects

Outcome	Group B	Group F	Group D
Hypotension	5 (16.7%)	3 (10.0%)	3 (10.0%)
Bradycardia	1 (3.3%)	1 (3.3%)	5 (16.7%)
Nausea/vomiting	1 (3.3%)	1 (3.3%)	2 (6.7%)
Shivering	2 (6.7%)	2 (6.7%)	1 (3.3%)

DISCUSSION

Subarachnoid block is widely used for lower abdominal and lower limb procedures because of its rapid onset, reliability and relatively limited requirement for systemic depressant drugs. However, bupivacaine-only spinal anaesthesia may not last long enough to give postoperative analgesia, requiring additional analgesics. Therefore, intrathecal adjuvants such fentanyl and dexmedetomidine have been tested to enhance the length and quality of spinal anaesthesia. In this study, hyperbaric bupivacaine alone was compared to bupivacaine with either 5 µg of dexmedetomidine or 25 µg of fentanyl. The dosages chosen were in line with earlier research that was part of the thesis, wherein 5 µg dexmedetomidine and 25 µg fentanyl were often assessed as intrathecal adjuvants.2,9,10.

The baseline characteristics of the three groups were similar. There was no statistically significant difference (P=0.599) in the mean ages of 37.73 ± 8.77 years in Group B, 36.83 ± 12.12 years in Group F, and 39.67 ± 11.90 years in Group D. Similarly, there was no significant difference in body weight between the groups (P=0.129). With around two-thirds to three-quarters of patients in each group falling into ASA I, the distribution of ASA physical status was likewise comparable (Table 1). Because variations in age, weight, or baseline physical condition may affect the features of spinal blockade and haemodynamic responses, this comparability is crucial. The results are in line with the original thesis discussion, which stated that the demographics of the three groups were well matched.

In the present study, the onset of sensory blockade was comparable among the groups. The mean time to achieve sensory blockade at T10 was 3.37 ± 1.13 min in Group B, 3.20 ± 1.21 min in Group F and 2.87 ± 1.14 min in Group D (P=0.242). Dexmedetomidine had the numerically quickest onset, although the difference was not statistically significant (Table 2).

Similarly, there was no significant difference (P=0.147) in the motor block onset times for Groups B, F, and D, which were 5.63 ± 1.75, 5.30 ± 1.34, and 4.87 ± 1.38 minutes, respectively. These results show that the formation of spinal block was not significantly accelerated by the inclusion of either adjuvant. Al-Ghanem et al., Gupta et al., and Mahendru et al. reported similar findings, finding no discernible difference in the onset of sensory or motor block between groups containing fentanyl and dexmedetomidine.9,10,12.

The study's most noteworthy finding was that dexmedetomidine significantly prolonged the spinal block. Two-segment regression took 100.83 ± 13.00 minutes for Group B, 126.17 ± 14.84 minutes for Group F, and 152.33 ± 12.30 minutes for Group D (P<0.001) (Table 2). When compared to bupivacaine alone, both adjuvants extended sensory regression; however, dexmedetomidine provided the greatest duration. Mahendru et al. found two-segment regression durations of 102 ± 17.2 min, 119.5 ± 22.7 min, and 146 ± 20.5 min for the bupivacaine, fentanyl, and dexmedetomidine groups, respectively12, which is consistent with our observation. Comparing fentanyl plus dexmedetomidine to bupivacaine alone, Farhad Safari et al. similarly showed increasing lengthening of two-segment regression.13.

Additionally, the dexmedetomidine group experienced a much longer overall duration of sensory blockage. The duration of sensory block was 232.67 ± 47.99 minutes when using bupivacaine alone, 283.67 ± 24.84 minutes when using fentanyl, and 415.67 ± 25.62 minutes when using dexmedetomidine (P<0.001) (Table 2). Dexmedetomidine lengthened the mean sensory block duration by around 183 minutes as compared to pure bupivacaine. This noticeable lengthening is in line with earlier research. Al-Ghanem et al. discovered substantially longer sensory blockade with dexmedetomidine than fentanyl, but Gupta et al. observed sensory block lengths of 187 ± 70 min with fentanyl and 476 ± 20 min with dexmedetomidine9,10. For motor blockage, a similar tendency was seen. With a statistically significant overall difference (P<0.001), the mean motor block duration was 224.17 ± 89.89 minutes for Group B, 252.00 ± 44.91 minutes for Group F, and 375.00 ± 24.60 minutes for Group D (Table 2). Dexmedetomidine resulted in a significantly longer motor block, even though the addition of fentanyl caused a little increase over bupivacaine alone. These results closely align with those of Mahendru et al., who found that intrathecal dexmedetomidine considerably extended motor blockade in comparison to bupivacaine and fentanyl. Additionally, Al-Ghanem et al. showed that dexmedetomidine caused a longer motor block than fentanyl.10

An extension of postoperative analgesia that was clinically significant resulted from the prolonging of sensory blocking. Group B experienced analgesia for 210.33 ± 36.53 minutes, Group F had it for 274.00 ± 26.31 minutes, and Group D experienced it for 378.00 ± 54.40 minutes (P<0.001) (Table 3). As a result, dexmedetomidine extended the duration of analgesia by around 168 minutes when compared to bupivacaine alone and 104 minutes when compared to fentanyl. The findings validate dexmedetomidine's analgesic-sparing potential as an intrathecal adjuvant. Mahendru et al. also noted considerably longer postoperative analgesia in the dexmedetomidine group, while Gupta et al. reported a significantly longer time to first analgesic request with dexmedetomidine than fentanyl.9,12

Another crucial factor was haemodynamic stability. While bradycardia affected 3.3% of patients in Groups B and F compared to 16.7% in Group D, hypotension affected 16.7% of patients in Group B and 10.0% each in Groups F and D (Table 4). The thesis stated that while bradycardia was numerically more often when taking dexmedetomidine, this difference was not statistically significant. Shivering and nausea/vomiting were likewise rare and generally similar among groups. There were no significant negative effects noted. These results are in line with other research showing that intrathecal dexmedetomidine produces sustained block and analgesia without significantly increasing side effects.9,10,12

In comparison to bupivacaine alone and bupivacaine with fentanyl 25 µg, the current results show that adding dexmedetomidine 5 µg to hyperbaric bupivacaine significantly increased two-segment sensory regression, sensory and motor block duration, and postoperative analgesia. At the same time, there was no statistically significant decline in haemodynamic stability, and the onset of sensory and motor blockage remained similar. These results indicate dexmedetomidine as a useful substitute for fentanyl for extending spinal anaesthesia and postoperative analgesia, and they are in line with the findings of earlier research presented in the thesis.9,10,12,13

CONCLUSION

The present randomized comparative study evaluated the effects of intrathecal dexmedetomidine and fentanyl as adjuvants to hyperbaric bupivacaine for spinal anaesthesia. Age, weight, and ASA physical state were equivalent among the three research groups, suggesting sufficient baseline comparability. The start of sensory or motor blockage was not considerably changed by the administration of 25 µg of fentanyl or 5 µg of dexmedetomidine. On the other hand, spinal block features were significantly prolonged by dexmedetomidine. When compared to both bupivacaine alone and bupivacaine plus fentanyl, the dexmedetomidine group showed substantially longer two-segment sensory regression, sensory block duration, and motor block duration. Dexmedetomidine produced the longest analgesic effect of the three groups and considerably extended the duration of postoperative analgesia. While bradycardia was quantitatively more common with dexmedetomidine, the frequency of hypotension, nausea/vomiting, and shivering was similar between groups. Overall, the findings indicate that 5 µg intrathecal dexmedetomidine is an effective adjuvant to hyperbaric bupivacaine, providing prolonged sensory and motor blockade and extended postoperative analgesia without major additional adverse effects.

Thus, dexmedetomidine may be considered a useful alternative to intrathecal fentanyl for spinal anaesthesia in appropriately selected patients undergoing infraumbilical surgeries.

LIMITATIONS OF THE STUDY

1. The study included different types of infraumbilical surgical procedures, and variation in the type and duration of surgery may have influenced postoperative analgesic requirements.
2. Since the degree of drowsiness was not officially measured, it was impossible to compare the sedative effects of intrathecal fentanyl and dexmedetomidine.
3. Due to technical issues that arose throughout the trial, postoperative opioid use was not compared between the groups.
4. The study's very modest sample size of 90 patients—30 in each group—may have limited how broadly the results may be applied.
5. Since there was no long-term postoperative monitoring, it was unable to assess any delayed neurological problems or other late adverse effects associated with intrathecal adjuvants.
6. The impact of these intrathecal adjuvants on longer-term pain outcomes could not be ascertained because the study mainly evaluated early postoperative analgesia up to 24 hours.

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