Original Article

Comparing the Efficacy of Intrathecal Dexmedetomidine versus Fentanyl as Adjuvants to Hyperbaric Bupivacaine in Patients Undergoing Elective Cesarean Section

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Abstract

Background: Spinal anaesthesia with hyperbaric bupivacaine is commonly used for elective cesarean section. Adding adjuvants to intrathecal agents improves the quality and duration of anaesthesia and postoperative analgesia. The commonly used adjuvants are opioids such as fentanyl; however, new α2-adrenergic agonists like dexmedetomidine are now being used for their potential to prolong analgesia and enhance block characteristics with minimal neonatal effects. This study aimed to compare the efficacy and safety of intrathecal dexmedetomidine versus fentanyl as adjuvants to hyperbaric bupivacaine in patients undergoing elective cesarean section. **Material and Methods:** This prospective comparative study was done on 120 parturients undergoing elective cesarean section under spinal anaesthesia. The cases were randomly allotted to two groups: Group D and Group F. The Group D cases received intrathecal dexmedetomidine (5µg) with hyperbaric bupivacaine. The Group F cases received intrathecal fentanyl (25 µg) with hyperbaric bupivacaine. The comparison of sensory and motor block characteristics, postoperative analgesia duration, hemodynamic parameters, and adverse effects, including neonatal outcomes, was recorded and analysed. The chi-square test was used to assess statistical significance. **Results:** Group D cases demonstrated a significantly faster onset and longer duration of sensory and motor block compared with Group F ($p<0.001$). The duration of postoperative analgesia and time to first rescue analgesia were significantly prolonged in Group D compared to Group F (385.6 ± 42.5 min vs 245.8 ± 35.6 min, and $p<0.001$). Patients receiving dexmedetomidine required fewer rescue analgesic doses and had lower total tramadol consumption within 24 hours. There was no significant difference in hemodynamic parameters between groups, but moderate bradycardia and sedation were slightly more common in the dexmedetomidine group. Pruritus was noted to be more common in the fentanyl group. There were no adverse effects on neonatal scores; the two groups showed the same APGAR scores at 1 and 5 minutes. **Conclusion:** Intrathecal dexmedetomidine appears to be a better adjuvant to hyperbaric bupivacaine than fentanyl in cesarean section, offering a faster onset, extended sensory and motor block, and longer postoperative analgesia, with safe and acceptable neonatal outcomes.

Keywords: Cesarean section, Dexmedetomidine, Fentanyl, Spinal anaesthesia, Hyperbaric bupivacaine.

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Introduction

Elective Cesarean section is one of the most common surgical operations that is carried out across the world, and selection of the anaesthetic technique is essential to provide maternal safety, analgesia, and favourable neonatal outcomes. Spinal anaesthesia is currently the technique of choice that can be used in elective cesarean section due to its rapid action, dense sensory block, full motor block, low systemic exposure to drugs, and the ability of the mother to be awake during delivery.[1] The most widely used local anaesthetic in spinal anaesthesia in obstetric practice is hyperbaric bupivacaine, as it has a reliable anaesthetic profile and predictable block properties.[2] Nevertheless, bupivacaine has a short analgesic effect on its own and may require relatively larger doses, which may lead to hypotension and other hemodynamic issues.[3] Several adjuvants are used with local anaesthetics to improve the quality and duration of spinal anaesthesia. Bupivacaine has been extensively used as an adjuvant with intrathecal opioids (fentanyl) since they enhance analgesia during the intraoperative period and decrease visceral pain during cesarean surgeries.[4] Fentanyl is an agonist of µ-opioid receptors located in the spinal cord, and it has a high potency of analgesia with minimal or no effect on extension of motor block.[5] Although intrathecal opioids have benefits, they can be linked to some adverse effects like pruritus, nausea, vomiting, and, in isolated cases, respiratory

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depression, which could limit their universal use in certain clinical practices.[6] Over the past years, other potentially useful intrathecal adjuvants have been proposed to replace opioids, such as dexmedetomidine, a highly selective α2-adrenergic receptor agonist. Dexmedetomidine has analgesic and sedative effects by inhibiting norepinephrine release and neuronal activity in the locus coeruleus and the dorsal horn of the spinal cord.[7] Dexmedetomidine, when administered intrathecally with bupivacaine, has been reported to increase sensory and motor block extension, improve postoperative analgesia, and decrease the need to use other analgesics.[8] Furthermore, according to studies, dexmedetomidine causes no significant changes in hemodynamics and minimal respiratory depression, so it is especially appropriate in obstetric anaesthesia.[9]

Few clinical studies have been done to compare dexmedetomidine and fentanyl with bupivacaine as intrathecal analgesic agents during cesarean section. It has been shown that dexmedetomidine can extend the time of analgesia and spinal anaesthesia to a greater extent than fentanyl with similar maternal and neonatal safety.[10] Moreover, dexmedetomidine has also been linked to quicker achieving sensory blockade and lowering the score of postoperative pain in parturients who have undergone cesarean delivery.[11] Systematic reviews and randomised clinical trials also indicate that hyperbaric bupivacaine can be combined with dexmedetomidine to decrease analgesic needs and achieve a higher quality of recovery post-cesarean section.[12] Despite these positive results, the best intrathecal adjuvant for cesarean section remains under investigation. There are only limited studies on direct comparisons of dexmedetomidine and fentanyl on block properties, postoperative analgesia, and safety outcomes in various clinical settings and populations. Thus, the current research is expected to compare the effectiveness of intrathecal dexmedetomidine and fentanyl as adjuvants to hyperbaric bupivacaine in elective cesarean section, with a specific focus on the nature of the blocks, analgesia duration, and maternal safety.

Materials and Methods

This prospective comparative study was conducted in the Department of Anesthesiology, Kakatiya Medical College and CKM Government Maternity Hospital, Warangal. Institutional Ethical approval was obtained from the Institutional Ethics Committee. Written informed consent was obtained from all participants in the study after explaining the nature of the study and its possible outcomes in the vernacular language.

Inclusion Criteria

1. Parturient aged 20 – 35 years.
2. Undergoing elective cesarean section
3. ASA I and II categories
4. Scheduled for lower-segment cesarean under spinal anaesthesia
5. Have signed the informed consent.

Exclusion Criteria

1. Allergy to spinal anaesthetics
2. History of coagulopathy or infection at the site of needle insertion
3. Severe systemic disease
4. Emergency cesarean sections
5. Patients are not willing to sign informed consent.

Based on the inclusion and exclusion criteria, 120 pregnant females were included in the study. They were randomly and equally allotted to two groups based on a computer-generated random number into Group D (Dexmedetomidine Group): Received 0.5% hyperbaric bupivacaine (10mg) with dexmedetomidine 5µg intrathecally, and Group F (Fentanyl Group): Received 0.5% hyperbaric bupivacaine (10 mg) with fentanyl 25µg intrathecally. The total volume of intrathecal injection (bupivacaine) was kept constant in both groups.

Anaesthetic Technique: Upon arrival in the operating room, standard monitors, including electrocardiography (ECG), non-invasive blood pressure (NIBP), and pulse oximetry (SpO2), were set up. The baseline vital parameters were recorded. Ringer's lactate solution 10-15 ml/kg was preloaded to all the patients before spinal anaesthesia was done. A Quincke spinal needle of 25-gauge was inserted in the sitting position at the L3-L4 intervertebral space through strict aseptic precautions, indicating a spinal anaesthesia. In compliance with the assigned group, the study drug was administered after confirmation of free-flowing cerebrospinal fluid intrathecally. The patients were then put in a supine position with the left uterine position.

Outcome Measures were noted and recorded as the primary outcome, including sensory block (the time interval between the onset and regression to the S1 dermatome). Additional outcomes included sensory blockade (time to achieve T6 level), Motor blockade onset, and motor blockade duration (determined by the Modified Bromage Scale). Postoperative analgesia (time of the first rescue analgesia request), and hemodynamic measurements such as heart rate and blood pressure measurements on a timely basis. Record of adverse effects such as hypotension, nausea, vomiting, pruritus, or respiratory depression—neonatal outcome based on APGAR scores at 1 and 5 minutes.

Statistical Analysis: All available data were refined, segregated, and uploaded to an MS Excel spreadsheet, and analysed using SPSS version 26 in Windows. The continuous variables were reported as mean ± standard deviation, frequency, and percentage. Continuous variables were compared using an independent t-test, and Categorical variables were compared using the Chi-square test for differences between two groups; values of $p < 0.05$ were considered significant.

Results

The baseline demographic and clinical characteristics of the cohort are presented in Table 1. Analysis of the table showed that the mean age of Group D cases was 26.8 ± 3.5 years, and that of Group F was 27.2 ± 3.8 years. The p-values were not significant. Similarly, there were no significant differences between the two groups for height, weight, gestational age, ASA Physical status, and duration of surgery ($p > 0.05$). This showed that the study cohort was well-matched and had minimal confounding factors that could influence anaesthesia outcomes.

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Group D (Dexmedetomidine 5 µg g) (n=60)	Group F (Fentanyl 25 µg) (n=60)	p-value
Age (Years)	26.8 ± 3.5	27.2 ± 3.8	0.542
Weight (kg)	62.5 ± 8.2	63.1 ± 7.9	0.678
Height (cm)	158.4 ± 5.6	159.2 ± 5.3	0.412
Gestational Age (Weeks)	38.2 ± 0.8	38.4 ± 0.7	0.156
ASA Physical Status (I: II)	48:12	46:14	0.652
Duration of Surgery (min)	45.8 ± 8.5	44.9 ± 9.2	0.571

The sensory block characteristics are given in [Table 2]. The overall table demonstrated that dexmedetomidine appeared to produce a faster onset as well as a significantly prolonged sensory blockade as compared to fentanyl. The time to reach the T10 level was shorter in Group D than in Group F (2.8 ± 0.6 min vs 3.1 ± 0.7 min), and the difference was significant ($p = 0.02$). Similarly, the time to reach the T6 level and the maximum sensory level were significantly shorter in Group D, with p-values of 0.001 and 0.001, respectively. Both groups achieved a similar highest sensory level (median T4), and the duration of sensory block was longer in the dexmedetomidine group. The regression to T10 and S1 levels and total duration of sensory block were significantly prolonged in the Group D cases, showing more sustained anaesthetic action.

Table 2: Sensory Block Characteristics in the Cohort

Characteristic	Group D (Dexmedetomidine)	Group F (Fentanyl)	p-value
Onset of Sensory Block (min)			
Time to T10 Level	2.8 ± 0.6	3.1 ± 0.7	0.015*
Time to T6 Level (Peak)	5.2 ± 1.1	6.5 ± 1.3	<0.001*
Time to Maximum Sensory Level (min)	5.8 ± 1.2	7.1 ± 1.4	<0.001*
Highest Sensory Level Achieved (Median, Range)	T4 (T2-T6)	T4 (T2-T6)	0.892
Duration of Sensory Block (min)			
Regression to T10 Level	98.5 ± 12.4	82.3 ± 10.8	<0.001*
Regression to S1 Level (Two-dermatome regression)	185.6 ± 18.5	142.8 ± 15.6	<0.001*
Total Duration of Sensory Block (min)	215.8 ± 20.4	168.5 ± 18.2	<0.001*
*Significant			

[Table 3] shows the motor block characteristics among the cases of the study. Analysis of the table showed significant differences between the groups. The onset of motor block was significantly faster in Group D compared to Group F (4.2 ± 1.1 min vs 5.8 ± 1.3 min, $p = 0.001$). The time to achieve maximum motor block (Bromage 3) was significantly shorter in Group D. Similarly, the dexmedetomidine group produced a significantly longer duration of motor block, as shown by delayed regression to Bromage 2 and complete recovery to Bromage 0, which was found to be significant (p=0.001). This showed that the total duration of motor block was prolonged in Group D cases.

Table 3: Motor Block Characteristics (Modified Bromage Scale)

Parameter	Group D (Dexmedetomidine)	Group F (Fentanyl)	p-value
Onset of Motor Block (min)	4.2 ± 1.1	5.8 ± 1.3	0.001*
Time to Maximum Motor Block (Bromage 3) (min)	7.5 ± 1.5	9.2 ± 1.8	0.001*
Duration of Motor Block (min)			
Time to Regression to Bromage 2	125.4 ± 15.8	98.6 ± 12.5	0.001*
Time to Complete Motor Recovery (Bromage 0)	185.2 ± 18.6	142.5 ± 15.8	0.001*
Total Duration of Motor Block (min)	210.5 ± 22.3	165.8 ± 18.9	0.001*
Modified Bromage Scale: 0=No block, 1=Unable to raise extended leg, 2=Unable to flex knee, 3=Unable to flex ankle/foot. *Significant			

Postoperative analgesic outcomes are depicted in [Table 4]. The analysis of the table showed that the duration of postoperative analgesia was significantly longer in Group D compared to Group F (385.6 ± 42.5 min vs 245.8 ± 35.6 min, $p < 0.001$). Similarly, the time to first rescue analgesic request was significantly delayed in Group D cases, and the table also showed significantly lower total tramadol consumption compared with Group F ($p < 0.001$). These findings indicate superior postoperative pain control with intrathecal dexmedetomidine.

Table 4: Postoperative Analgesia Characteristics

Parameter	Group D (Dexmedetomidine)	Group F (Fentanyl)	p-value
Duration of Postoperative Analgesia (min)	385.6 ± 42.5	245.8 ± 35.6	<0.001*
Time to First Rescue Analgesia (min)	390.2 ± 45.8	250.4 ± 38.2	<0.001*
Number of Rescue Analgesic Doses in 24 hours	1.2 ± 0.5	2.4 ± 0.8	<0.001*
Total Tramadol Consumption (mg) in 24 hours	62.5 ± 18.4	118.6 ± 25.2	<0.001*
*Significant			

The analysis of hemodynamic parameters at different time intervals is presented in [Table 5]. The analysis showed that

at intraoperative intervals of 15 and 30 minutes, and at the end of surgery, the heart rate and mean arterial pressure were slightly lower in Group D, and the differences with Group F were statistically significant. Similar trends were also observed in the analysis of mean arterial pressure, as shown in the table.

Table 5: Hemodynamic Parameters (Intraoperative)

Parameter	Time Point	Group D (Dexmedetomidine)	Group F (Fentanyl)	p-value
Heart Rate (bpm)	Baseline	82.5 ± 8.6	83.2 ± 8.9	0.652
	After Spinal (5 min)	78.4 ± 7.8	80.5 ± 8.2	0.145
	After Spinal (15 min)	74.2 ± 7.5	78.6 ± 7.9	0.003*
	After Spinal (30 min)	72.8 ± 7.2	77.4 ± 7.6	0.001*
	End of Surgery	75.5 ±7.4	79.8 ± 8.1	0.004*
Mean Arterial Pressure (MAP, mmHg)	Baseline	88.5 ± 8.4	89.2 ± 8.6	0.648
	After Spinal (5 min)	82.6 ±7.9	84.5 ± 8.1	0.182
	After Spinal (15 min)	78.4 ±7.2	82.3 ± 7.8	0.006*
	After Spinal (30 min)	76.8 ± 6.9	80 ± 7.4	0.005*
	End of Surgery	79.5 ±7.3	83.6 ±7.9	0.004*
*Significant				

[Table 6] presents the intraoperative complications recorded in the study cases. The overall complication rate was comparable between the two groups. The episodes of hypotension and bradycardia appeared to occur at a slightly higher rate in Group D, although the differences were not statistically significant. Pruritus is a known opioid related side effect; hence, it occurred commonly in Group F with a statistically significant difference. Sedation scores (Ramsay score >3) were more common in Group D than in Group F, with a statistically significant difference. No cases of respiratory depression were found in either group.

Table 6: Intraoperative Complications and Interventions

Complication Intervention	Group D (Dexmedetomidine) (n=60)	Group F (Fentanyl) (n=60)	p-value
Hypotension (SBP <90 mmHg or >20% fall)	12 (2.0%)	8 (13.3%)	0.324
Required Ephedrine	8 (13.3%)	5 (8,3%)	0.378
Bradycardia (HR < 50 bpm)	6 (10.0%)	2 (3.3%)	0.142
Required Atropine	4 (6.7%)	1 (1.7%)	0.172
Nausea	4 (6.7%)	8 (13.3%)	0.224
Vomiting	2 (3.3%)	5 (8.3%)	0.244
Pruritus	0 (0.0%)	1.2 (2.0%)	<0.001*
Shivering	3 (5.0%)	8 (13.3%)	0.112
Respiratory Depression (SPO2 <90%)	0 (0.0%)	0 (0.0%)	-
Sedation (Ramsay Score >3)	8 (13.3%)	2 (3.3%)	0.048*
*Significant			

The Neonatal outcomes in the study are given in [Table 7]. Analysis of the table showed both groups were safe for the newborn. The APGAR scores at 1 minute and 5 minutes were comparable between groups, with no statistically significant differences. All neonates had APGAR scores ≥9 at 5 minutes, indicating excellent neonatal well-being.

Table 7: Neonatal outcomes (APGAR scores)

Time Point	Group D (Dexmedetomidine)	Group F (Fentanyl)	p-value
APGAR at 1 minute	8.2 ± 0.6	8.3 ± 0.5	0.324
Score ≥8, n (%)	58 (96.7%)	59 (98.3%)	0.564
Score <8, n (%)	2 (3.3%)	1 (1.7%)	0.564
APGAR at 5 minutes	9.1 ± 0.4	9.2 ± 0.3	0.128
Score ≥9 n (%)	60 (100%)	60 (100%)	-
Score <9, n (%)	0 (0%)	0 (0%)	-
APGAR scores were comparable between groups, indicating no adverse neonatal effects with either adjuvant.			

Discussion

The current study was designed to compare the efficacy and safety of intrathecal dexmedetomidine and fentanyl as adjuvants to hyperbaric bupivacaine in spinal anaesthesia for elective cesarean section patients. The overall results of the study showed that dexmedetomidine elicited a quicker onset and longer duration of sensory block, longer postoperative analgesia, and decreased analgesic requirement compared to fentanyl without compromising hemodynamic stability and neonatal safety. In our current study, no significant differences in baseline demographic and clinical characteristics between the two groups were found, indicating the homogeneity of the study population. The similarity reduces confounding variables and allows the differences in the anaesthetic outcomes to be attributed to the pharmacological properties of the adjuvant drugs employed. Similar baseline comparability has been reported in previous clinical studies comparing intrathecal adjuvants in cesarean delivery.[13]

The results of our study indicated that the sensory block and time taken to achieve the peak level of sensory block were

significantly shorter in the dexmedetomidine group than in the fentanyl group. These findings can be attributed to the α2-adrenergic agonist effects of dexmedetomidine, which enhance the action of local anaesthetics by inhibiting substance P release and hyperpolarising dorsal horn neurons. Similar results were reported in prior research by Al-Mustafa et al,[14] and Gupta et al,[15] which showed that intrathecal dexmedetomidine hastens the onset of sensory block and improves the quality of spinal anaesthesia when combined with bupivacaine. Another notable observation in this study was the significant effect of dexmedetomidine in prolonging the sensory and motor blockade. The sensory block, motor block, and regression times were prolonged significantly compared to the fentanyl group. The results are in line with the previous literature that has demonstrated that dexmedetomidine increases the duration of spinal anaesthesia by slowing the transmission of nociceptive input and amplifying the local anaesthesia effect at the spinal cord.[16] Kanazi et al. in a similar study found a longer sensory and motor blockade by intrathecal dexmedetomidine than fentanyl in the case of an adjuvant to bupivacaine.[17] An essential part of cesarean section anaesthesia is postoperative analgesia. Dexmedetomidine in this study had a significant effect, extending postoperative analgesia and reducing the rescue analgesic requirement, leading to lower analgesic dosage and reduced overall tramadol intake during the 24 hours. These results agree with the findings of Eid et al,[18] and Mahendru et al,[19] who showed that intrathecal dexmedetomidine is significantly more effective in postoperative pain management than intrathecal opioids. This increased analgesic action of dexmedetomidine can be explained by its ability to stimulate presynaptic α2 receptors in the spinal cord, thereby preventing nociceptive neurotransmission. Hemodynamic stability is particularly important during cesarean section. The heart rate and mean arterial pressure were slightly lower in the dexmedetomidine group at some time points in the present study, though they remained within a clinically acceptable range. Cases of hypotension and bradycardia were also encountered but could be managed with standard measures. These results are also in line with the past literature indicating mild sympatholytic actions of dexmedetomidine, which tends to result in slight decreases in blood pressure and heart rate.[20] The common adverse effects associated with opioids are pruritus, which was found to occur in the fentanyl group.

On the other hand, the dexmedetomidine group was found to have a higher incidence of sedation, and this could be explained by the central sedative effect that it has on the locus coeruleus via α2 receptors. Nevertheless, the level of sedation was not severe, and it did not lead to respiratory depression and other complications.[21] Notably, the neonatal outcomes between the two groups were similar, and there were no differences in the APGAR scores at 1 and 5 minutes. This means that the use of intrathecal dexmedetomidine or fentanyl as adjuvants to bupivacaine does not adversely impact the neonatal well-being. Similar observations have been made in previous obstetric anaesthesia studies on the safety of intrathecal adjuvants.[22] Comprehensively, the results of the current research confirm the growing pieces of evidence that intrathecal dexmedetomidine is an effective alternative to opioids as an adjuvant to spinal bupivacaine in cesarean section because of its ability to provide long-term anaesthesia and better analgesia of the postoperative period with minimal side effects.

Conclusion

The present study, within its limitations, has shown that intrathecal dexmedetomidine combined with hyperbaric bupivacaine in patients undergoing elective cesarean section gives better anaesthetic and analgesic effects as compared to intrathecal fentanyl. The application of dexmedetomidine led to earlier onset as well as increased duration of sensory and motor blockage, longer postoperative pain, and lower need for rescue analgesics. Both drugs were stable in terms of hemodynamic stability, but mild bradycardia and sedation were more common in the case of dexmedetomidine. Notably, the neonatal outcomes were similar with both drugs. Overall, dexmedetomidine appears to be a superior intrathecal adjuvant for improving the quality of spinal anaesthesia during cesarean delivery.

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Conflicts of interest

There are no conflicts of interest.

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