Original Article

Comparison of 5 mcg versus 10 mcg Intrathecal Dexmedetomidine with Hyperbaric Bupivacaine for Spinal Anesthesia in Elective Caesarean Section: A Randomized Controlled Trial

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Abstract

Objective: The aim of the study is to compare the effectiveness and mean duration of sensory and motor block after spinal anesthesia with two different doses of dexmedetomidine (5 mcg vs. 10 mcg) along a fixed dose of hyperbaric bupivacaine (0.5%, 12.5 mg) in patients undergoing an elective caesarean section.

Methodology: It was a prospective, randomized controlled trial study was conducted at Bahria International Hospital, Rawalpindi, Pakistan, from Oct to Dec 2025, involving 60 American ASA (Society of Anesthesiologists) Class II Parturients aged between 20-40 years undergoing an elective caesarean section. The patients were randomly assigned into two groups of 30 each. Group A was given 5 mcg of dexmedetomidine intrathecally along with 12.5 mg of hyperbaric bupivacaine (0.5%), while Group B was given 10 mcg of dexmedetomidine and 12.5 mg of hyperbaric bupivacaine (0.5%). The duration of sensory block (time to two-dermatome regression) and motor block (time to Modified Bromage Score of 0) were used as primary outcome measures. The secondary outcomes involved intraoperative hemodynamic stability in the form of heart rate (HR) and mean arterial pressure (MAP) and the incidence of adverse events, including hypotension, bradycardia, postoperative nausea and vomiting, shivering, and APGAR Score for neonatal safety.

Results: No significant difference was found in baseline demographic and surgical characteristics ($p > 0.05$). The mean sensory block duration was significantly prolonged in Group B compared to Group A (351.2 ± 46.8 min vs. 286.4 ± 52.3 min; mean difference = 64.8 min; 95% CI [39.2 to 90.4]; $p < 0.001$). Similarly, motor block duration was significantly extended in Group B (361.5 ± 15.9 min vs. 312.1 ± 29.7 min; mean difference = 49.4 min; 95% CI [37.1 to 61.7]; $p < 0.001$). Intraoperative hemodynamic stability was maintained in both groups, with mean HR being between 76.8 ± 6.5 and 82.5 ± 7.2 beats/min, and MAP was between 87.9 ± 7.5 and 92.3 ± 8.1 mmHg. In both cohorts, no clinically significant instances of hypotension, bradycardia, or other adverse events were documented.

Conclusion: A 10 mcg dose of intrathecal dexmedetomidine in combination with 12.5 mg hyperbaric bupivacaine gives a significantly longer and more reliable sensory and motor blockage than does a 5 mcg dose in elective caesarean surgery. This longer duration of neuraxial analgesia is realized without increasing the incidence of clinically significant hemodynamic instability or adverse maternal effects.

Keywords: Dexmedetomidine; spinal anesthesia; bupivacaine; caesarean section; sensory block; motor block

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Introduction

One of the most widely done surgical procedures in the world is a Caesarean section, which provides a safe delivery in cases where vaginal birth is not possible and considered to be a threat to the mother or neonate. The management of anesthesia in caesarean section involves, effective pain relief with a rapid onset and low

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maternal and neonatal side effects. Hyperbaric bupivacaine in spinal anesthesia has emerged as a method of choice when it comes to elective caesarean section due to its consistency in onset, predictability of spread, and good safety profile in comparison with general anesthesia.[1]

Although it is widely used, bupivacaine alone might not give adequate duration of spinal anesthesia especially in long surgical procedures, and post-operative analgesia is still a clinical problem. Other adjuvants like fentanyl, tramadol, ketamine, and dexmedetomidine have thus become popular. When given intrathecally, dexmedetomidine extends both sensory and motor blockade, decreases intraoperative analgesic needs, and decreases postoperative pain without causing respiratory depression as is seen with opioid adjuvants.[3]

A randomized controlled trial on the use of intrathecal dexmedetomidine of 5 mcg and 10 mcg versus hyperbaric bupivacaine in caesarean section showed a significant dose-dependent increase in the duration of the sensory block (5 mcg group: 286 ± 52.76 min; 10 mcg group: 351 ± 47.00 min).[4] Other researchers who have studied dose-response correlations of intrathecal dexmedetomidine have reported similar results.

Although higher doses of dexmedetomidine have proven to have a longer blockade, the potential of hemodynamic adverse effects such as bradycardia and hypotension is also raised[5] and therefore, the optimum intrathecal dose to maximize the efficacy of dexmedetomidine and patient safety in the obstetric population has not been established in the local Pakistani patient group. The current randomized controlled trial was aimed at comparing the efficacy and safety of intrathecal dexmedetomidine 5 mcg and 10 mcg as an adjuvant to hyperbaric bupivacaine in spinal anesthesia in elective caesarean section. It is hoped that the findings will help provide evidence-based recommendations to optimize anesthetic guidelines and enhance perioperative outcomes in this group of patients. Our hypothesis was that 10 mcg intrathecal dexmedetomidine would significantly increase the time of sensory and motor blockage over a 5 mcg dose, but without clinically significant adverse hemodynamic events.

Methodology

Prospective, double-blind, randomized controlled trial was conducted at Bahria International Hospital, Rawalpindi, Pakistan, over a three-month period. The trial protocol was approved by the Institutional Ethics Review Committee (BIH/ph-8/Administrator/240/2025) and registered prospectively with Trial Registry Number: NCT07395271. All procedures were conducted in accordance with the Declaration of Helsinki, and written informed consent was obtained from all participants.

Parturients classified as ASA II (American Society of Anesthesiologists), aged 20–40 years, and were undergoing elective caesarean section under spinal anesthesia, were recruited consecutively. The exclusion criteria were emergency surgery or prior labor analgesia, cardiovascular or systemic comorbidity, contraindications to spinal anesthesia, or an expected surgical time greater than 60 minutes. Sixty patients were randomly allocated in a 1:1 proportion in two parallel groups (Group A and Group B, n=30 each). A computer-generated sequence was used to randomize. The concealment of allocation was ensured by sequentially numbered, opaque, and sealed envelopes (SNOSE) that were prepared by a separate researcher. The study drugs were prepared by a designated anesthesiologist who was not involved in collecting the data. The anesthesiologist administering the anesthesia, the surgical team, and the patients were fully unaware of the group assignment.

In the operating room, Standard ASA monitoring was set up and patients were preloaded with 500 mL of lactated Ringer solution. A 25-gauge Quincke needle was used to perform spinal anesthesia at the L3-L4 or L4-L5 position in the sitting position. Group A was given 12.5 mg of hyperbaric bupivacaine 0.5% (2.5 mL) plus 5 mcg of dexmedetomidine. Group B was given 12.5 mg hyperbaric bupivacaine 0.5% (2.5 mL) and 10 mcg dexmedetomidine. After the injection (0.2 mL/second), patients were put in a supine position with left lateral uterine displacement.

Outcome Measures: The duration of sensory and motor blockade were the main outcome measures.

- Sensory block assessment: The duration was considered as the time taken after the intrathecal injection to reach a two-dermatome regression of the highest level reached. This was evaluated by a standardized pinprick test of bilateral dermatomes using a 22-gauge hypodermic needle.
- Motor block evaluation: Duration was determined as the time interval between intrathecal injection

and full motor recovery which was formally measured by the use of the Modified Bromage Scale (defined as having a Modified Bromage Score of 0).

- Secondary outcomes included maternal hemodynamics, adverse events, and neonatal safety. The intraoperative maternal hemodynamics (heart rate [HR] and mean arterial pressure [MAP]) were measured at baseline, 30 seconds after the injection, 5-minute intervals intraoperative and 15-minute intervals postoperative. Some of the maternal adverse events monitored were hypotension, bradycardia, shivering, and postoperative nausea/vomiting (PONV). A pediatrician, who was blinded to the group assignment assessed neonatal safety by recording typical Apgar scores at 1 and 5 minutes after delivery.

A prior trial conducted by Mowar et al. [4] was used to calculate sample size based on a mean sensory block duration of 286 ± 52.76 min (5 mcg) and 351 ± 47.00 min (10 mcg). A minimum of 27 patients per group was required to obtain 80 percent power at a 5 percent level of significance; this was set at 30 per group (N=60) to take into consideration the chances of attrition. IBM SPSS version 26 was used to analyze data. Continuous data were checked for normality (Shapiro-Wilk test) and compared with the independent samples t-test. Categorical variables were presented in the form of frequencies and were analyzed accordingly. A p-value of 0.05 or less was taken to indicate statistical significance.

Results

Sixty patients were recruited and divided between Group A (n = 30, dexmedetomidine 5 mcg) and Group B (n = 30, dexmedetomidine 10 mcg). All baseline characteristics were similar between the two groups. Mean age was 29.6 ± 4.2 years in Group A and 30.1 ± 4.5 years in Group B (p = 0.64). Patients were all ASA physical status Class II. Mean duration of surgery was 46.3 ± 6.8 minutes in Group A and 47.1 ± 7.2 minutes in Group B (p = 0.67). There were no statistically significant inter-group differences in any of the baseline variables (Table I).

Intrathecal dexmedetomidine resulted in statistically significant and dose-dependent increase in both the sensory and motor block duration (Table II). The mean sensory block duration was 286.4 ± 52.3 minutes in Group A (5 mcg) compared with 351.2 ± 46.8 minutes in Group B (10 mcg), a difference of 64.8 minutes (p <0.001). The mean motor block duration was 312.1 ± 29.7 minutes in Group A versus 361.5 ± 15.9 minutes in Group B, a difference of 49.4 minutes (p <0.001).

Both groups maintained intraoperative hemodynamic parameters at a safe level (Table III). The mean heart rate was between 76.8 ± 6.5 and 82.5 ± 7.2 beats/min and the mean arterial pressure was between 87.9 ± 7.5 and 92.3 ± 8.1 mmHg in all recorded time points. Both groups did not record any clinically significant instances of hypotension, bradycardia, postoperative nausea and vomiting, or shivering.

Neonatal outcomes were positive and similar throughout the study cohort. All neonates of Group A and Group B had normal Apgar scores (1-minute and

Table I: Comparison of Demographic and Perioperative

Variables	Group A (5 mcg Dexmedetomidine) (n = 30)	Group B (10 mcg Dexmedetomidine) (n = 30)	p-value
Age (years)	29.6 ± 4.2	30.1 ± 4.5	0.64
ASA physical status II, n (%)	30 (100)	30 (100)	—
Duration of surgery (minutes)	46.3 ± 6.8	47.1 ± 7.2	0.67

Values are presented as a number (%) or mean ± standard deviation. The t-test for independent samples was used. Statistical significance was defined as p ≤ 0.05.

Table II: Comparison of Sensory and Motor Block Duration Between Groups.

Variables	Group A (5 mcg Dexmedetomidine) (n = 30)	Group B (10 mcg Dexmedetomidine) (n = 30)	p-value
Sensory block duration (minutes)	286.4 ± 52.3	351.2 ± 46.8	<0.001
Motor block duration (minutes)	312.1 ± 29.7	361.5 ± 15.9	<0.001

Table III: Comparison of Intraoperative Hemodynamic Parameters Between Groups

Time point	HR Group A (5 mcg) (n=30)	HR Group B (10 mcg) (n=30)	p-value	MAP Group A (5 mcg) (n=30)	MAP Group B (10 mcg) (n=30)	p-value
Baseline	82.1 ± 6.5	82.9 ± 7.8	0.67	92.0 ± 7.5	92.6 ± 8.6	0.77
5 min	79.2 ± 6.2	78.6 ± 7.3	0.73	89.8 ± 7.1	89.2 ± 8.6	0.77
15 min	77.8 ± 6.5	77.0 ± 7.4	0.65	89.1 ± 7.6	88.3 ± 8.3	0.70
30 min	77.1 ± 6.0	76.5 ± 6.9	0.72	88.2 ± 7.2	87.6 ± 7.7	0.76
End of surgery	79.5 ± 6.7	78.7 ± 7.0	0.65	89.6 ± 7.4	88.8 ± 8.1	0.69

5-minute) and no statistically significant intergroup differences. Interestingly, neonatal depression incidences were zero, and none of the babies in either group required admission to the Neonatal Intensive Care Unit (NICU).

Discussion

This blinded and randomized controlled trial demonstrates that the use of 10 mcg of intrathecal dexmedetomidine in combination with 12.5 mg hyperbaric bupivacaine has a significant effect in extending both sensory and motor blockade during the elective caesarean section than the use of 5 mcg. Specifically, the 10 mcg dose extended sensory block duration by a mean difference of 64.8 minutes (351.2 ± 46.8 min vs. 286.4 ± 52.3 min; $p < 0.001$) and motor block duration by 49.4 minutes (361.5 ± 15.9 min vs. 312.1 ± 29.7 min; $p < 0.001$). Intraoperative Hemodynamic parameters were stable

with no significant intergroup differences in the time periods recorded ($p > 0.05$). These clinically significant increases in duration confer a benefit specially in cases requiring extended surgical duration, which is obtained without affecting maternal hemodynamic stability or causing adverse neonatal outcomes.

Our main findings show a remarkable quantitative correspondence with the dose-response relationships found in the international body of literature. Mowar et al.[4] adopted the same comparative paradigm (5 mcg vs. 10 mcg dexmedetomidine) in caesarean surgeries and recorded very comparable block durations. They observed sensory block durations of 286.0 ± 52.7 min for the 5 mcg dose and 351.0 ± 47.0 min for the 10 mcg dose ($p < 0.001$), which mirrors our recorded means of 286.4 ± 52.3 min and 351.2 ± 46.8 min, respectively. Singh et al.[3] has further quantified this dose-dependent kinetic pattern by assessing different intrathecal doses of lower abdominal procedures and finding a much longer motor block duration of 387.0 ± 39.4 minutes with the 10 mcg dose, versus 243.8 ± 22.0 minutes with the 5 mcg dose ($p < 0.001$).

Moreover, wide-ranging global meta-analyses support these time extensions. Shen et al.[7] combined the data of 970 patients and proved that intrathecal dexmedetomidine significantly increases the duration of sensory block (Standardized Mean Difference [SMD] = 2.02; 95% CI: 1.29, 2.74) and motor block (SMD = 1.90; 95% CI: 1.21, 2.46). Equally, in a dedicated meta-analysis study by Kumar et al.[15] that analyzed 1,478 patients, the weighted mean difference (WMD) of 134.4 minutes (95% CI: 109.7–159.1) was found in the sensory block prolongation. The 10mcg dose in our cohort exhibited longer block durations that lie squarely within the upper efficacy limits of these pooled global estimates which are a solid confirmation of the greater anesthetic efficacy of the higher dose.

In the South Asian population, our results are further strengthened by recent local experiments. Urooj et al.[11] and Qureshi et al.[12] have shown that intrathecal dexmedetomidine has a better block duration and hemodynamic stability in Parturients in this regional setting. In the assessment of adjuvants, dexmedetomidine has demonstrated a better side-effect profile than the classical opioids. Khosravi et al.[5] found intrathecal dexmedetomidine not only provides better postoperative analgesia than fentanyl but also avoids opioid-induced pruritus, which is a significant benefit in the obstetric group, and directly correlates with the lower incidence of adverse events in our cohorts.

The prolongation of anesthesia by dexmedetomidine is essentially due to its selective alpha-2 adrenergic agonist effects. It works on pre- and post-synaptic receptors of the substantia gelatinosa in the dorsal horn to suppress the release of nociceptive neurotransmitters and cause local vasoconstriction, thus lowering the rate of local anesthetic clearance in the intrathecal space.[19] Notably, Liu et al.[18] showed that intrathecal dexmedetomidine could decrease the effective dose (ED95) of hyperbaric bupivacaine used in caesarean section up to 31%. This bupivacaine-sparing effect is clinically importance, as one of the major approaches to reducing the adverse effects of spinal-induced maternal hypotension is to reduce the dosage of local anesthetics.

key issues when it comes to increased doses of alpha-2 agonists is the possibility of severe bradycardia and hypotension. Nevertheless, the intraoperative hemodynamics in our study were equally stable in both 5 mcg and 10 mcg groups, and this supports the safety limits of the reported clinical standard doses.[6, 23] In terms of fetal safety, the international consensus lies in favor of intrathecal dexmedetomidine. This safety profile was measured in a meta-analysis study by Sun et al.[22] which combined 10 RCTs, and found no significant differences in 1-minute Apgar scores (Mean Difference = -0.03; 95% CI: -0.16 to 0.10; $p = 0.64$) or umbilical cord blood gas, between dexmedetomidine

and bupivacaine only group. These findings are strongly supported by our trial, whereby clinical neonatal safety was unconditional and all 60 neonates had Apgar scores ≥ 8 at both 1-minute and 5-minutes, indicating the no incidence of neonatal depression in international pooled data.

The few limitations to this study include, its single-center nature and the purposely selected sample size, its restriction to ASA Class II which can limit the extrapolation of these results to more invasive obstetric emergencies or patients who have severe cardiovascular comorbidities. Secondly, although clinical neonatal safety was determined through routine Apgar scoring of all patients, more objective measures, namely umbilical cord blood gas analysis, were not prospectively measured. The postoperative analgesic intake and the exact time when the first rescue analgesic request was made was also not able to be measured, which limited our detailed examination of the postoperative analgesic benefits of the 10 mcg dose. Intrathecal dexmedetomidine as an adjuvant in Neuroaxial blocks is an off-label mode of application and long term safety data is still limited. The multicenter randomized controlled trials with objective neonatal biochemical measurements and longitudinal postoperative analgesic profiling are recommended in the future to further strengthen the guidelines for 10 mcg dose as standard obstetric anesthesia.

Conclusion

Compared to a 5 mcg dose, the 10 mcg intrathecal dexmedetomidine with hyperbaric bupivacaine spinal anesthesia in ASA II Parturients undergoing elective caesarean section under spinal anesthesia, offers a much longer sensory and motor blockade. Both 5 mcg and 10 mcg doses of dexmedetomidine displayed stable intraoperative hemodynamics without any clinically significant adverse events. Among the investigated population, the 10 mcg dose can specifically be desired in cases where longer and more predictable neuraxial blockage is required during surgery. Nonetheless, the results should be understood from the perspective of this being a single-center study and with a narrow demographic. Future studies should be multicenter, include neonatal biochemical measurements and postoperative analgesic patterns to further substantiate these results.

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