Original Article

Effect of intrathecal Dexmedetomidine on postoperative analgesia in patients undergoing cesarean section

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Abstract

Introduction: Cesarean section is one of the most common surgical procedures worldwide and adequate postoperative analgesia is crucial to optimal maternal recovery and satisfaction. Spinal anesthesia using intrathecal bupivacaine is widely used; but in addition to its short duration of postoperative pain relief, dependence upon systemic opioids is linked with adverse consequences. Intrathecal administration of dexmedetomidine has become a promising adjuvant to potentiate analgesia and decrease consumption of opioids.

Methods: This study was a prospective, randomized, double blind comparative study, conducted at tertiary care center in Nepal. Eighty ASA I-II parturients undergoing elective cesarean section via spinal anesthesia were randomized to 2 groups: Group A hyperbaric bupivacaine alone (10 mg), and Group B hyperbaric bupivacaine (10 mg) plus dexmedetomidine (10 ug). Postoperative pain scores (VAS), duration of analgesia, total amount of opioid medication (in 24 hours), side effects and maternal satisfaction were assessed.

Results: Baseline characteristics were similar in both groups. Postoperative pain scores at 2, 6 and 24 hours were significantly lower in the dexmedetomidine group (median VAS at 2h: 2[IQR 2-2] vs 3[2-3]; 6h: [3-4] vs 4.5[3-6]; 24h:7[6-7] vs 7[7-8]; p<0.001 for all). The median time to first rescue analgesia was significantly longer in Group B (16[16-18] hours) compared with that in Group A (4[4-8] hours) (p<0.001). Median total opioid consumption over 24 hours was significantly lower in the dexmedetomidine group (50[50-50]mg vs 50[50-100]mg; p<0.001). Maternal satisfaction scores were significantly higher with dexmedetomidine with no adverse neonatal outcomes.

Conclusion: Intrathecal dexmedetomidine as an adjuvant with bupivacaine offers superior and prolonged postoperative analgesia with decreased consumption of opioids and improved maternal satisfaction without increase in adverse effects, in favor of its use in elective cesarean section anesthesia.

Keywords: Bupivacaine; cesarean section; intrathecal dexmedetomidine; maternal satisfaction; opioid-sparing postoperative analgesia; shivering; spinal anesthesia

Introduction

Cesarean section (CS) is one of the most common surgical procedures performed worldwide with a large and progressive increase in global prevalence over the last decades.[1] Given the volume and rising number of cesarean deliveries, optimization of perioperative anesthetic and analgesia management has become increasingly important. Effective postoperative pain control after cesarean section is crucial to maternal recovery and

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wellbeing. Poorly controlled acute postpartum pain has been shown to be an independent association with long-term adverse outcomes, including persistent pain and postpartum depressive symptoms. In a large prospective cohort study, Eisenach et al showed that the severity of acute pain experienced after childbirth, but not the delivery mode itself, predicted both ongoing pain and postpartum depression at follow-up.[2] These findings highlight the importance from a clinical perspective of good analgesia in the immediate postoperative period. Several reviews have gone on to further highlight that inadequate post-cesarean pain relief can lead to a delay in functional recovery, poor return to early ambulation, interfere with maternal-infant bonding, and negatively affect breastfeeding and overall maternal satisfaction.[3-5] Therefore, postoperative analgesia is presently thought to be a central component of quality care after cesarean section.

Spinal anesthesia is one of the most favored neuraxial methods due to its simplicity in administration, reliability, feasibility and quick onset of anesthesia.[6] Spinal anesthesia with intrathecal local anesthetics alone does not offer a long time of postoperative pain relief despite its advantages. Whereas agents like bupivacaine yield satisfactory intraoperative anesthesia, the analgesic action of this agent usually fades away within a few hours following surgery, and in many situations, this agent may need to be supplemented with other analgesic measures.[7] According to a systematic review by Wheeler et al., such adverse events as nausea, vomiting, pruritus, sedation, and respiratory depression are common adverse events associated with opioid administration and all can potentially delay postoperative recovery and decrease patient satisfaction.[8] In addition, the use of opioids postoperatively has been repeatedly cited as a significant substance independent risk factor of postoperative nausea and vomiting (PONV), which is especially uncomfortable in the obstetric population.[9]

Against this background, intrathecal adjuvants have become the focus of growing interest as a method to improve the quality and duration of spinal anesthesia and to decrease opioid needs. α_2 -adrenergic agonists have become a promising neuraxial adjuvants.

Dexmedetomidine is a highly selective α_2-adrenergic agonist. It possesses analgesic, sedative, and sympatholytic properties. These attributes make it an attractive intrathecal adjuvant. Its ability to modulate nociceptive pathways at the spinal and supraspinal levels while reducing anesthetic and opioid requirements have been described in early pharmacologic reviews.[10] The addition of low dose intrathecal dexmedetomidine to bupivacaine significantly enhances the quality of spinal anesthesia by prolonging the duration of both sensory and motor blockade without leading to any major hemodynamic instability and clinical studies have demonstrated this.[11] It has been further shown by subsequent randomized trials that intrathecal dexmedetomidine offers longer post- operative analgesia and reduces the need for rescue analgesics compared with bupivacaine alone or bupivacaine combined with opioids like Fentanyl.[12]

Although such encouraging results were observed, there is some inconsistency in the literature on the extent of analgesic benefit, optimal dosing, and side-effect profile of intrathecal dexmedetomidine. This has a great degree of heterogeneity in the reported outcomes of block duration, postoperative pain scores and adverse events and is due to variation in study design, patient populations and dosing regimen.[13,14] This variability mandates further well-designed region-specific and institution-based research to increase clarity on the role intrathecal dexmedetomidine plays in cesarean section anesthesia. In this regard, the present study intends to compare intrathecal dexmedetomidine use as an adjuvant to bupivacaine in spinal anesthesia during cesarean section with respect to the postoperative analgesia, opioids use, side-effect profile, and maternal satisfaction.

Methods

It was a prospective, randomized, double-blind, and comparative study conducted at the Department of Anesthesiology, in co-ordination with the Department of Obstetrics and Gynecology, Patan Hospital, Patan Academy of Health Sciences, Nepal. The study was conducted upon approval from the Institutional Review Committee of Patan Academy of Health Sciences. Prior to enrollment, written informed consent was obtained from all the participants. Eligibility screening was done on pregnant women who were between 18-45 years of age and were subjected to elective cesarean section under spinal anesthesia. Patient with ASA physical status I or II, singleton pregnancy, and those who were able to provide informed consent were enrolled for the study. Those patient with contraindications to spinal anesthesia, known hypersensitivity to bupivacaine or dexmedetomidine, patients with chronic pain or regular analgesic therapy and patients with fetal distress or emergency cesarean sections were excluded from the study.

Randomization and Blinding

Total 80 patients who met the inclusion criteria were enrolled for the study. Randomization of the participants was done into two groups. An independent investigator not involved in patient care and data collection prepared

computer- generated random numbers. Sealed opaque envelopes were used to conceal group allocation. A double-blind design was followed in the study. The anesthesiologist administering the spinal anesthesia, the patients, and the investigators acquiring postoperative data were all blinded to group allocation. A trained anesthesia assistant not involved in outcome assessment prepared the study drugs. A unique study identification number was used for labeling. Group A (Control group) received 10 mg (2 mL) of hyperbaric bupivacaine intrathecally with 0.1 mL of normal saline and Group B (Dexmedetomidine group) received 10 mg (2 mL) of hyperbaric bupivacaine plus 10 μg (0.1 mL) of dexmedetomidine intrathecally.

Aseptic precautions were taken and spinal anesthesia was introduced at the L3-L4 or L4-L5 space with 25-gauge Quincke spinal needle.

Outcome Measures

The primary and secondary outcomes of the study were:

Postoperative pain intensity: It was assessed using Visual Analog Scale (VAS). A VAS score of 0 indicated no pain. A VAS score of 10 represented worst imaginable pain. Assessments were done at 2-, 6-, and 24-hours post-surgery.

Duration of postoperative analgesia: It was defined as the time duration (expressed in minutes) from intrathecal drug administration to the first request for rescue analgesia by the patient.

Total amount of opioid analgesic required during the first 24 hours postoperatively, expressed in pethidine equivalent doses.

Perioperative side effects observed during spinal anesthesia and the intraoperative period, like the incidence of hypotension, bradycardia, shivering, nausea or vomiting, and sedation.

Maternal satisfaction: It was assessed at 24 hours postoperatively. A 5-point Likert scale was used, where 1 represented very dissatisfied state and 5 showed a very satisfied expression.

Data Collection

Post operative evaluations were done by trained anesthesia residents. Data collectors were unaware of the study group assignments. This was done to minimize observer bias. Pain scores were recorded at predefined postoperative interval, i.e. at 2, 6, and 24 hours. A proper documentation of postoperative pain severity, time to first rescue analgesia, cumulative opioid dose, and perioperative adverse effects was done. A structured and predesigned data collection proforma was used for standardized recording of all study variables.

Statistical Analysis

We entered the collected data into Microsoft Excel for initial data management and cleaning. IBM SPSS Statistics v25 was used for analysis of data. Shapiro- Wilk test was done to assess the distribution of continuous variables. All the continuous variables were found to be significantly deviated from normality ($p<0.05$) and hence, non-parametric statistical methods were applied. We expressed categorical variables as frequencies and percentages. We summarized continuous variables as medians and interquartile ranges (IQR). We used Man Whitney U test for continuous variables. For categorical variables, we used Chi-square test or Fisher's exact test as appropriate. We analyzed the duration of post operative analgesia using Kaplan- Meier survival analysis, and performed intergroup comparison using the log- rank (Mantel -Cox) test. All the statistical tests were two tailed. A p- value less than 0.05 was considered statistically significant. Ethical Considerations

The study was conducted after the approval of the study protocol by the Institutional Review Committee of Patan Academy of Health sciences. Throughout the study, we maintained the patient confidentiality. The patients retained the right to withdraw at any stage, without their clinical care being affected. The investigators declared conflict of interest.

Results

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Group A (n = 40)	Group B (n = 40)	p-value
Age (years), median (IQR)	30 (29–34)	30 (29–34)	0.727
Gestational age (weeks), median (IQR)	37 (37–38)	37 (36–38)	0.087
Duration of surgery (minutes), median (IQR)	55 (50–60)	55 (50–60)	0.617
Parity, n (%)			0.077
• Primiparous	38 (95.0)	33 (82.5)	
• Multiparous	2 (5.0)	7 (17.5)	
ASA physical status, n (%)			0.633
• ASA I	14 (35.0)	12 (30.0)	
• ASA II	26 (65.0)	28 (70.0)	
Any comorbidity present, n (%)	28 (70.0)	28 (70.0)	1.000

Statistical analysis: Continuous variables were compared using the Mann–Whitney U test and categorical variables using the Chi-square test or Fisher's exact test, as appropriate.

In Group A and Group B, the baseline demographic and clinical characteristics were comparable. No statistically significant difference in ages, gestational ages, length of surgery, parity distribution, ASA physical status, or the presence of comorbidities was noted (all $p > 0.05$). This implies that the two groups were well matched at baseline, thereby minimizing the controlling the impact of confounding factors and making the outcomes of postoperative analgesics in the two groups valid for comparison.

Table 2: Comparison of Postoperative Pain Scores (VAS 0–10)

Time point	Group A, median (IQR)	Group B, median (IQR)	p-value*
2 hours	3 (2–3)	2 (2–3)	<0.001
6 hours	4.5 (3–6)	3 (3–4)	<0.001
24 hours	7 (7-8)	7 (6-7)	<0.001

* Mann–Whitney U test

Group B registered significantly lower postoperative pain scores at all the measured time points (2, 6 and 24 hours) as compared to Group A ($p < 0.001$ at all the time points). This demonstrates that the addition of intrathecal dexmedetomidine provided superior and sustained postoperative analgesia compared to bupivacaine alone.

Table 3: Total Opioid Consumption in First 24 Hours

Group	Median opioid consumption (mg), IQR	p-value*
Group A	50 (50–100)	<0.001
Group B	50 (50–50)	

* Mann–Whitney U test

Total opioid consumption during the first 24 hours postoperatively was significantly lower in Group B compared with Group A ($p < 0.001$). This finding indicates a clear opioid-sparing effect associated with the addition of intrathecal dexmedetomidine to bupivacaine.

Table 4: Duration of Postoperative Analgesia

Group	Time to first rescue analgesia (hours), median (IQR)	p-value*
Group A	4 (4–8)	<0.001
Group B	16 (16–18)	

* Mann–Whitney U test

Group B had a significantly long time to first request rescue analgesia than Group A ($p < 0.001$). It indicates that the intrathecal dexmedetomidine significantly increased the proportion of postoperative analgesia when combined with bupivacaine.

Table 5. Comparison of Perioperative Side Effects

Side effect	Group A n (%)	Group B n (%)	p-value
Hypotension	24 (60.0)	9 (22.5)	0.001
Bradycardia	2 (5.0)	2 (5.0)	1.000
Nausea / vomiting	12 (30.0)	11 (27.5)	0.805
Sedation	0 (0.0)	0 (0.0)	NA†
Shivering	23 (57.5)	1 (2.5)	<0.001

† Chi-square not computable as variable constant.

Group A experienced hypotension and shivering much significantly more often than Group B did (p = 0.001 and p < 0.001, respectively). Bradycardia and nausea/vomiting did not differ statistically and were equally prevalent in both the two groups. No patient in the two groups experienced intraoperative sedation. In general, inclusion of intrathecal dexmedetomidine was linked to a more favorable side-effect profile.

Table 6: Maternal Satisfaction with Postoperative Analgesia

Group	Median satisfaction score (IQR)	p-value*
Group A	3 (3–4)	<0.001
Group B	4 (4–5)	

* Mann–Whitney U test

Group B had significantly higher maternal satisfaction with postoperative analgesia than Group A (p < 0.001). This shows better overall quality of analgesia and patient experience with the inclusion of intrathecal dexmedetomidine with bupivacaine.

Table 7: Kaplan-Meier Analysis of Time to First Rescue Analgesics

Group	Median time to first rescue analgesia (hours)	95% Confidence Interval	Log-rank p-value
Group A (Bupivacaine alone)	4.0	3.63 – 4.37	<0.001
Group B (Bupivacaine + Dexmedetomidine)	16.0	15.28 – 16.72	

Kaplan-Meier survival analysis revealed that there was a significant increase in the pain-free survival period in patients that were treated with intrathecal bupivacaine and dexmedetomidine than those that were treated with bupivacaine alone. Group B had a median time to first analgesia of 16.0 hours and Group A had a median first analgesia of 4.0 hours, and the difference in the distributions of survival was highly significant on log-rank (p < 0.001) analysis, proving the existence of the longer-lasting analgesia after the operation with dexmedetomidine.

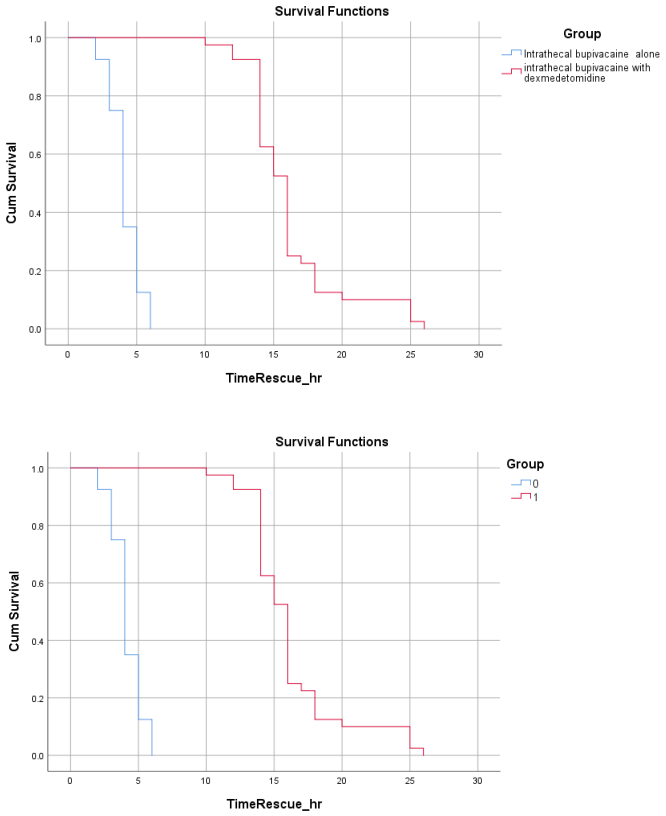


Figure 1: Kaplan- Meier survival curves of time to first rescue analgesia after cesarean section. The Kaplan-Meier curves of survival show that there is a significant difference in time taken by both groups after the operation in the postoperative analgesia. Patients that are treated with intrathecal bupivacaine only experience a high rate of cumulative survival, which is an earlier need of rescue analgesia. Conversely, patients who are treated with intrathecal bupivacaine and dexmedetomidine have their survival curve shifted to the right, indicating a much longer pain free period. The difference of the curves is significant and remains the same over time, which proves the better and more long-term effect of dexmedetomidine as an intrathecal adjuvant (log-rank test, p < 0.001).

Discussion

For the valid interpretation of the interventional effects in randomized and comparative studies in anesthesia, a critical pre- requisite is the adequate baseline comparability between the study groups. In our study, we observed a well-balanced baseline demographic and clinical characteristics including age, gestational age, duration of surgery, parity distribution, ASA physical status, and presence of comorbidities between the intrathecal bupivacaine group and the intrathecal bupivacaine plus dexmedetomidine group with no

statistically significant differences observed across any baseline variable (all p > 0.05). This baseline matching is strong; it restricts the possible confounding variables and thus strengthens the internal validity of the differences seen in the postoperative analgesic effectiveness and adverse events profiles.

These findings are consistent with multiple randomized controlled trials evaluating intrathecal dexmedetomidine in obstetric and non-obstetric populations. Gautam et al. demonstrated comparable demographic variables and sensory block characteristics between fentanyl and dexmedetomidine groups in women undergoing abdominal hysterectomy, allowing valid attribution of prolonged analgesia and reduced visceral pain to dexmedetomidine rather than baseline differences.[15] Similarly, in adults undergoing peri-anal surgeries under saddle spinal block, Gautam and colleagues reported no significant differences in baseline characteristics between groups receiving hyperbaric bupivacaine alone and bupivacaine with dexmedetomidine, reinforcing the methodological rigor of their analgesic comparisons.[16]

In obstetric anesthesia specifically, baseline equivalence has been consistently reported across studies comparing dexmedetomidine with opioids or placebo. Chowdhury et al. found no significant intergroup differences in ASA physical status or gestational age in parturient undergoing elective cesarean section, ensuring unbiased comparison of block characteristics and postoperative analgesia between dexmedetomidine and fentanyl adjuvant groups.[17] Likewise, Shahzadi et al. reported comparable maternal demographics and neonatal Apgar scores between dexmedetomidine and control groups, supporting the safety and interpretability of their analgesic and block-related outcomes.[18]

These observations are further corroborated by randomized trials conducted at large scales and meta-analyses. Wang et al., in a meta-analysis of randomized trials including 278 parturients, reported no clinically relevant baseline imbalances across included studies, thereby validating pooled estimates demonstrating a significant reduction in shivering without increased risks of hypotension, bradycardia, or nausea and vomiting with intrathecal dexmedetomidine.[19] Similarly, Shen et al.'s systematic review of ten trials involving 970 patients confirmed consistent baseline comparability across studies and demonstrated that dexmedetomidine significantly shortened block onset times and prolonged sensory and motor block durations without adversely affecting neonatal outcomes.[20]

Evidence from dose-response studies further emphasize the critical role of adequate baseline matching. Modir et al. evaluated multiple intrathecal dexmedetomidine doses (2.5–7.5 μg) added to ropivacaine for cesarean section and reported comparable baseline hemodynamic parameters and demographic characteristics across all groups, allowing valid assessment of dose-dependent effects on analgesia and block characteristics.[21] Similarly, Xia et al. demonstrated that intrathecal dexmedetomidine significantly reduced the ED95 of hyperbaric bupivacaine while maintaining comparable baseline characteristics between groups, thereby confirming a true pharmacodynamic interaction rather than a confounding demographic effect.[22]

The consistency of baseline equivalence extends to studies focused on shivering prevention. Nasseri et al. and Ismaiel et al. both reported no significant baseline differences between dexmedetomidine and control or comparator groups, strengthening their conclusions that reductions in shivering incidence and intensity were attributable to dexmedetomidine itself rather than patient-related factors.[23,24] Comparable findings have also been reported with intravenous dexmedetomidine, although differences in route of administration limit direct comparison with intrathecal studies.[25]

The present study demonstrates that the addition of intrathecal dexmedetomidine to bupivacaine during spinal anesthesia for elective cesarean section results in significantly superior postoperative analgesia, a marked prolongation of analgesic duration, a substantial opioid-sparing effect, reduced shivering, and higher maternal satisfaction, without an increase in clinically significant adverse effects.

In our cohort, postoperative pain scores measured using the visual analogue scale were significantly lower in the dexmedetomidine group at 2, 6, and 24 hours postoperatively (all p < 0.001). The median time to first rescue analgesia was prolonged four-fold (16 hours vs. 4 hours), a difference confirmed by Kaplan–Meier survival analysis and log-rank testing (p < 0.001). Simultaneously, overall opioid use during the initial 24 hours was highly diminished, which is an obvious indication of an opioid-sparing impact. These advancements were translated into a tremendous increase in maternal satisfaction, and it demonstrates the clinical importance of a high caliber of analgesics.

Comparable findings have been consistently reported in South Asian studies. Samal et al. showed that 5 μg intrathecal dexmedetomidine provided faster onset of sensory block and longer duration of analgesia than intrathecal morphine (125 μg) in elective cesarean

section, with fewer opioid-related side effects, highlighting dexmedetomidine as a viable alternative to neuraxial opioids. [26] Similarly, Sushruth and Rao reported that parturients receiving intrathecal dexmedetomidine experienced a significantly longer time to first rescue analgesic request, lower postoperative pain scores, and reduced need for supplemental analgesics compared with bupivacaine alone.[27]

Evidence from large randomized trials outside South Asia strongly corroborates these observations. Li et al., in a double-blind randomized controlled trial involving 300 parturients, demonstrated that 5 μg intrathecal dexmedetomidine significantly prolonged sensory block duration (148.2 min vs. 108.4 min with bupivacaine alone), improved quality-of-recovery scores, and reduced rescue opioid requirements without adversely affecting neonatal outcomes.[28] Similarly, Qi et al. reported that the time to first rescue analgesia with intrathecal dexmedetomidine (17.6 ± 6.2 h) was comparable to morphine (16.8 ± 5.9 h) and markedly longer than bupivacaine alone (3.5 ± 1.7 h), while also being associated with less pruritus and shivering.[29]

The opioid-sparing effect observed in the present study aligns closely with pharmacodynamic investigations. Xia et al. and Liu et al. demonstrated that intrathecal dexmedetomidine significantly reduced the ED95 of hyperbaric bupivacaine (approximately 7–8 mg vs. 11–12 mg in controls), while simultaneously prolonging analgesia duration and reducing postoperative opioid consumption.[22,30] These findings suggest that dexmedetomidine enhances spinal antinociception and allows effective analgesia with lower local anesthetic doses.

As far as perioperative adverse effects are concerned, our study found significantly lower rates of shivering and hypotension in the dexmedetomidine group, comparable incidences of bradycardia and nausea/vomiting and no episodes of sedation. Multiple trials and meta-analyses support this safety profile. Nasseri et al. reported a significant reduction in shivering incidence with intrathecal dexmedetomidine (24% vs. 52%) without increases in hypotension or bradycardia.[24] He et al. similarly demonstrated dose-dependent reductions in shivering, with only 2 of 30 patients experiencing shivering in the 5 μg dexmedetomidine group compared with 11 of 30 in controls.[31]

High-level evidence further strengthens these conclusions. Paramasivan et al., in a meta-analysis of 24 randomized controlled trials involving approximately 1,460 patients, found that intrathecal dexmedetomidine significantly lowered postoperative VAS pain scores, prolonged time to first rescue analgesia, reduced opioid consumption, and decreased shivering, without a significant increase in hypotension, bradycardia, or postoperative nausea and vomiting.[14] Similar conclusions were reached by Kumar et al. and Miao et al., whose pooled analyses confirmed the analgesic and anti-shivering benefits of intrathecal dexmedetomidine while demonstrating overall hemodynamic safety.[32,33] More recently, Giaccari et al. reported that intrathecal dexmedetomidine consistently prolonged sensory and motor block regression and improved postoperative analgesia in cesarean section, with no meaningful increase in maternal or neonatal adverse outcomes.[34]

Hence, the magnitude of analgesic prolongation (approximately four-fold increase in time to first rescue analgesia), the consistent opioid-sparing effect, and the favorable side-effect profile observed in our cohort reinforce the role of low-dose intrathecal dexmedetomidine as an effective and safe adjuvant to bupivacaine for cesarean section spinal anesthesia. These findings support its routine consideration in obstetric anesthesia practice, particularly in settings where effective postoperative anesthesia with reduced opioid exposure is an essential clinical priority.

Limitations

This study was a single- center study with a rather limited sample size, which can restrict the extrapolation of the findings. The outcomes of neonatal care were measured at the short-term postoperative stage, not in the long-term. No dose-response effects of various doses of intrathecal dexmedetomidine were taken into consideration.

Conclusion

The adjuvant intrathecal dexmedetomidine used in combination with bupivacaine has great effect in reducing postoperative pain and enhancing pain-free time following cesarean section. It offers a distinct opioid sparing effect and good side-effect profile. The results of this study justify the safe and effective application of low dose of intrathecal dexmedetomidine during elective cesarean section anesthesia.

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