ORIGINAL ARTICLE

Effects of Intravenous Dexmedetomidine on Shivering after Cesarean Delivery under Neuraxial Anesthesia - A Randomized Controlled Trial

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Abstract

Background: The role of adjunct medications, particularly the α2-agonist dexmedetomidine, to cause a reduction in the frequency as well as the intensity of the post-operative shivering in surgical patients, has been the topic of study for a considerable time.

Objective: Our study aimed to investigate the effectiveness of dexmedetomidine in reducing post-operative shivering in parturients undergoing Cesarean section following neuraxial anesthesia.

Methods: This double-blind randomised control trial was performed in the Anesthesia Department in Liaquat National Hospital during January to August 2024, involving pregnant females who exhibited shivering during Cesarean delivery under neuraxial anesthesia. Following the delivery, thirty patients in the study group received a single I/V infusion of 30mcg dexmedetomidine in 100ml of normal saline, while an equal number of patients in the control group were given 100ml of normal saline only. Both allocation and randomisation were done *via* a list generated by a computer. The primary outcome was a noticeable reduction in shivering following the administration of dexmedetomidine.

Results: Out of 155 enrolled patients, sixty demonstrated shivering and were randomly assigned to study groups in a 1:1 allocation. In the dexmedetomidine group, 3.3% of patients, in comparison to 100% of patients in the control group, had no post-operative shivering. No events of bradycardia or hypertension were noted. Grade 3 sedation was observed in 4 cases in the dexmedetomidine group.

Conclusion: In conclusion, a single IV infusion of 30mcg dexmedetomidine can effectively reduce events of post-operative shivering in parturients undergoing Cesarean section under neuraxial anesthesia.

Trial registration: The trial was prospectively registered in a clinical trial registry with the number NCT06711913.

Keywords: *Anesthesia, cesarean section, clinical trial, dexmedetomidine, shivering.*

INTRODUCTION

Post-operative shivering has been reported in more than sixty percent of parturients who have undergone cesarean section under neuraxial anesthesia [1]. The impact of post-operative shivering has been known to have a detrimental impact on the various systems of the body. Shivering leads to increased oxygen demand and metabolic rate, which in turn produces undue stress on the cardiovascular system, resulting in reduced tissue oxygenation to important organs. It also increases both the blood pressure and the heart rate, which might potentially impact the maternal-fetal hemodynamic stability. The intense muscle contractions associated with shivering also result in raised blood pressure and heart rate [2]. The associated discomfort with the post-operative shivering can also hurt the overall recovery of the new mother and thus cause a delay in her return to her normal post-operative day-to-day activities [1].

The role of adjunct medications, particularly the α2-agonist dexmedetomidine, to cause a reduction in the frequency as well as the intensity of the post-operative shivering in surgical patients, has been the topic of study for a considerable time. Initially gaining approval by the United States Food and Drug Administration (FDA) in 1999 for sedation in intensive care settings, [3] dexmedetomidine has been a focus of various studies which investigated its efficacy in controlling this post-operative complication, due to its ability as a pain-reliever, sedative, and its effects on reducing shivering [4, 5]. The mode of action of dexmedetomidine is the activation of alpha-2 receptors, which have a predominant presence in the locus coeruleus of the brain stem and along the spinal cord. This results in a decrease in the central noradrenergic activity and thus a lowering of the shivering threshold [6, 7]. Moreover, it promotes the sympatholytic process *via* the central and the peripheral nervous system, leading to marked lowering of both the vasoconstrictive and shivering thresholds [8].

Existing research has demonstrated that the administration of dexmedetomidine can mitigate the blood pressure fluctuations associated with pain and decrease the requirement for additional anesthetic and analgesic agents. By attenuating the body's stress response to surgical interventions, dexmedetomidine facilitates the maintenance of stable blood pressure and reduces reliance on supplementary drugs to manage pain

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and cardiovascular alterations [9]. This characteristic is particularly advantageous in the context of cesarean sections, where preserving the mother's blood pressure is crucial for the well-being of both the mother and the fetus [10]. Diminishing the need for extra pharmaceutical interventions, dexmedetomidine may also contribute to a reduction in the risk of drug-related side effects, further enhancing outcomes for both the mother and the infant [11]. Furthermore, in comparison to traditional treatments such as opioids and other sedatives, dexmedetomidine has shown promise in not only decreasing the occurrence of shivering episodes but also improving patient comfort and promoting better recovery profiles.

The current randomised controlled trial aimed to evaluate the efficacy of intravenous dexmedetomidine in the reduction of post-operative shivering in parturients who underwent cesarean delivery with neuraxial anesthesia. The purpose of the current study is to make a contribution to the existing literature, which supports the clinical benefits of the drug. By evaluating the results of this therapeutic approach, this study tends to present important knowledge towards the improvement in the post-operative care of patients undergoing cesarean delivery, thus leading to an enhanced sense of well-being and contentment in this vulnerable population.

MATERIALS AND METHODS

This single-centre, randomised, double-blind, placebo-controlled, parallel-group trial was conducted over six months in the Anesthesia Department at Liaquat National Hospital from January to August 2024. The study received approval from the Hospital Ethics Committee (App# 0980-2023-LNH-ERC). Then it was prospectively registered on ClinicalTrials.gov with trial number NCT06711913.

Full-term pregnant females aged 18-35 years with an ASA grade of I-II, scheduled for elective lower segment cesarean section (LSCS) under spinal anesthesia were included. Patients undergoing emergency cesarean delivery, receiving anesthesia other than spinal, with dexmedetomidine hypersensitivity, with a history of cardiac, renal, or hepatic disorders requiring follow-up, diagnosed with pre-eclampsia, requiring blood product transfusion during surgery, and with major surgical complications were excluded from the study.

The sample size determination was guided by findings from a prior study by Lamontagne *et al*., which reported that dexmedetomidine decreased the incidence of post-spinal shivering from 72.5% in the control group to 17.5% [2]. Statistical analysis using an α of 0.05 and a power of 0.80 indicated that 12 participants were required per group, resulting in a total sample size of 24. To enhance the robustness of the results, the study was expanded to include 30 patients per group.

Study subjects were randomly assigned to study groups using a computer-generated randomisation list created through the use of the website randomization.com. To conceal the group allocation, the assigned group was placed in a sealed envelope. Based on the randomisation, an anesthesiologist who was not engaged in the trial opened the sealed envelope and produced the drug solution in an unmarked 100 ml normal saline pouch. The anesthesiologist who was in charge of monitoring the patient and giving the block was not aware of the treatment group. The same anesthesiologist collected the data while remaining blind to the group assignment. Two groups, including equal numbers of patients, were randomly assigned. The consort diagram is displayed in **Fig. (1)**.

The research methodology ensured blinding, where the group allocations were concealed from the participants, caregivers, and outcome assessors. An anesthesia assistant prepared the study medications externally before each administration, adhering to a randomisation protocol. The contents of the numbered vials were kept undisclosed to the participants, research personnel, attending anesthesiologist, and data analyst.

Throughout the perioperative period, standard monitoring was implemented in the operating room, including assessment of vital signs such as heart rate, electrocardiogram, non-invasive blood pressure, respiratory rate, and oxygen saturation. Establishing peripheral vascular access involved inserting an 18G IV cannula into the dorsum of the non-dominant hand. A 25-gauge Whitacre needle was placed *via* the L3-L4 or L4-L5 intervertebral spaces using a midline technique to provide spinal anesthetic to all patients while they were seated. The patients were put in a supine position as soon as 12.5mg of hyperbaric 0.5% bupivacaine was given after the proper needle position was confirmed. A warm Ringer's lactate solution of 10ml/kg was concurrently administered with the neuraxial anesthesia. Preoperative or intraoperative opioid administration was prohibited, except for the use of tramadol as a rescue anti-shivering agent. Supplemental oxygen at 3 L/min was provided through a nasal cannula until the end of the surgery. Patients were covered with a standard cotton sheet and received active warming, without the use of additional warming devices. Sensory anesthesia was evaluated using a pinprick test and recorded 10 minutes after the neuraxial injection. Following umbilical cord clamping, a 5 IU intravenous oxytocin bolus was immediately

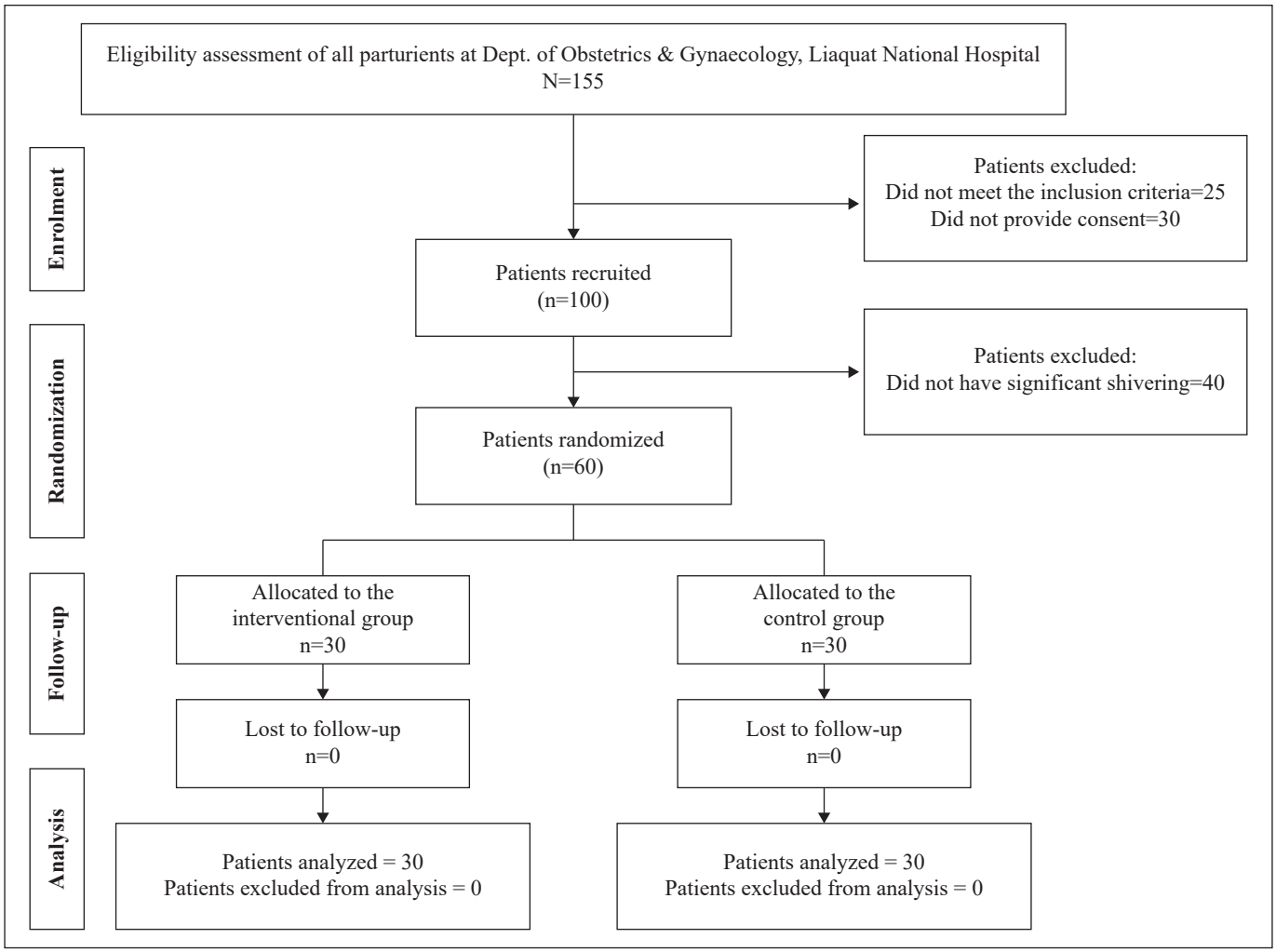

Fig. (1): Consort diagram of the randomised controlled trial.

administered, followed by an infusion of 45 IU oxytocin in 1000 ml of Ringer's lactate. Patients were assessed for shivering at the time of childbirth, and the severity was graded using the 5-item scale described by Crossley and Mahajan *et al*. [12].

Severe shivering (grades III and IV) that persisted for at least 3 minutes was considered a positive finding, indicating the prophylactic intervention was ineffective. An anesthesia assistant not involved in the study was responsible for accessing the study supplies and preparing either a 100 ml solution containing 30 mcg of dexmedetomidine or 100 ml of normal saline, based on a predefined randomisation sequence. Following childbirth, the study anesthesiologist administered the prepared infusion intravenously over 10 minutes when shivering commenced. The infusion start time was recorded, and the patient was closely monitored throughout the surgical procedure to assess any reduction in shivering. A significant decrease was defined as a 2-grade drop from the initial shivering score. If no improvement in shivering was observed after the infusion, rescue medication consisting of a 30 mg Tramadol injection and a 10 mg Metoclopramide injection was provided.

Throughout the infusion administration and surgical procedure, the researchers closely monitored the participants for the development of hypotension, bradycardia, nausea, and sedation. Hypotension was defined as a 20% decrease in blood pressure from the initial measurement or a mean arterial pressure below 60 mmHg (R_x: IV doses of 100-200 µg of phenylephrine and/or 5-10 mg of ephedrine, as needed). Bradycardia, characterised by a 20% decrease in heart rate from baseline or a rate less than 50 beats per minute, was managed with a 0.5 mg intravenous bolus of atropine. Additionally, the level of sedation was assessed using the four-point scale described in the literature [13], evaluated five minutes after the study drug bolus was administered.

The main outcome of interest was the significant reduction in shivering, which was a drop to grades 0 or 1 in accordance with Crossley and Mahajan guidelines from grades 3 or 4 [12]. Follow-up studies examined

the frequency of side effects, such as bradycardia and hypotension, and the degree of sedation as described by Filos *et al*. [13].

The study utilised SPSS Statistics version 26.0 to check, enter, and analyse the data. The Shapiro-Wilk test was employed to assess the normality of the data. Quantitative variables, such as age and shivering score, were summarised using mean or median values. Qualitative variables, including comorbidities, hypotension, bradycardia, sedation, and shivering after 5 minutes, were reported using frequencies and percentages. The association between shivering at 5 minutes and the treatment groups was evaluated using the Chi-Square test. Additionally, the association was examined for the stratified categories of age and comorbidities, utilising either the Chi-Square Test or Fisher's Exact Test. The Mann-Whitney U test was used to compare the medians between the two groups. A p-value of 0.05 or less was considered statistically significant.

RESULTS

In the present study, a total of sixty parturients were enrolled who had significant shivering (Grades 3 or 4). The patients were then randomised into two groups, *i.e*., one receiving dexmedetomidine (n=30) and the other receiving normal saline (n=30). The median (IQR) age of the patients in the dexmedetomidine and normal saline groups was reported to be 29.5 years (24.8-33.0 years) and 29.0 years (25.8-32.0 years), respectively. The comorbidities observed in the two study groups are displayed in **Fig. (2)**.

Following the administration of a single bolus of dexmedetomidine, the shivering was reported to have subsided in all the patients except for one, who was observed to have started shivering after it had completely subsided. In comparison, the event of shivering did not stop in the patients who received normal saline. Moreover, all of them were eventually administered the rescue drug, *i.e*., Tramadol, to overcome the complaint of shivering. The association of the presence of shivering and the drug administered (dexmedetomidine *vs*. normal saline) is demonstrated in Table **1**.

Table 1: Association of the study groups and events of shivering.

Shivering	Study group		
	Dexmedetomidine n (%)	Normal saline n (%)	p-value¥
Yes	1 (3.3)	30 (100)	<0.001*
No	29 (96.7)	0 (0)	

¥ *Pearson Chi-Square test; *Statistically significant at p<0.01.*

Of the known adverse events associated with the administration of dexmedetomidine, no events of bradycardia or hypotension were reported. Sedation was, however, observed in all the patients. The various grades of sedation reported in the current study are displayed in **Fig. (3)**.

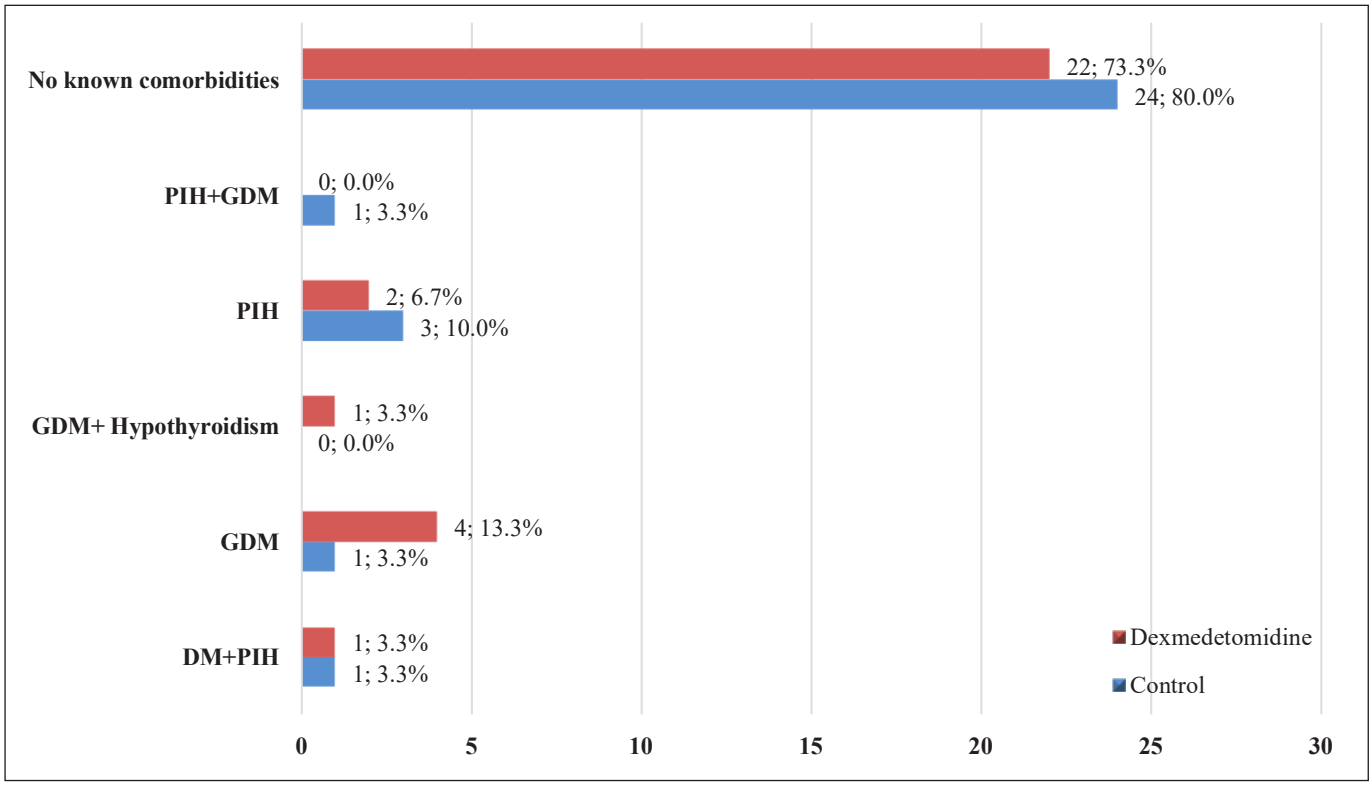

Fig. (2): Comorbidities in the study participants.

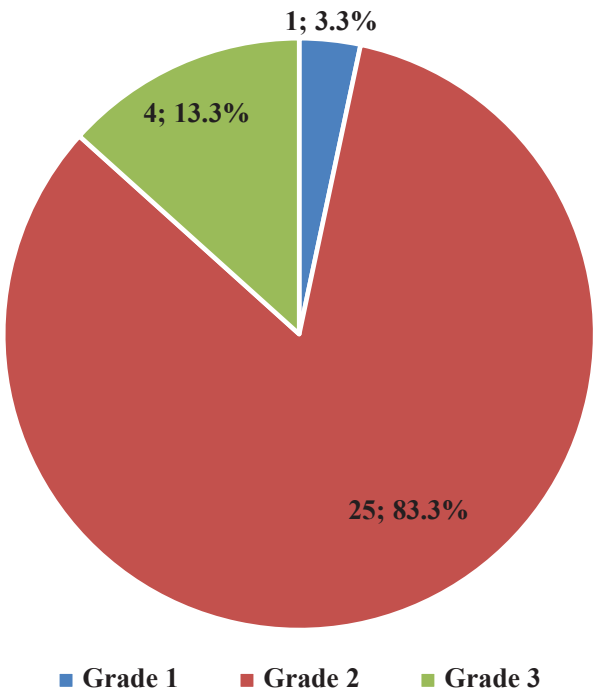

Fig. (3): Frequency of grades of sedation in patients administered the dexmedetomidine group.

DISCUSSION

Shivering is a prevalent and often distressing occurrence experienced by patients undergoing Cesarean sections performed with neuraxial anesthesia [14]. The underlying causes are multifaceted, encompassing both thermogenic and non-thermogenic factors. These include a shift in the distribution of the body's core temperature, a reduction in the threshold for vasoconstriction, and a loss of thermoregulatory vasoconstriction below the level of anesthetic blockade [15]. The interplay between perioperative hypothermia and shivering in this context is complex and not fully elucidated [16]. While interventions such as forced air warming seem intuitively reasonable, research on their efficacy for parturients undergoing Cesarean delivery has produced inconsistent findings and fails to adequately address the intricate mechanisms behind shivering [17].

The study found that a single intravenous administration of 30 micrograms of dexmedetomidine, a drug that acts on α2b-adrenoceptors in the hypothalamus to inhibit spontaneous neuronal activity, reduce central temperature sensitivity, and lower thresholds for vasoconstriction and shivering, [18] effectively reducing post-operative shivering following Cesarean delivery performed under neuraxial anesthesia, without causing significant effects on hemodynamics or sedation levels.

A study by Qi and colleagues reported that approximately 42% of obstetrical patients experience shivering after neuraxial anesthesia [19]. This study's findings aligned with our statistics, revealing a 51.6% (31/60) shivering incidence among study participants. To ensure a representative sample of obstetric populations, the research included parturients who received either spinal or epidural anesthesia. Considering that shivering's underlying causes may differ based on the anesthesia method and whether labour is present, additional studies might be necessary to examine dexmedetomidine's effectiveness across various obstetrical subgroups.

Existing research has established the efficacy of dexmedetomidine in managing anesthesia-induced shivering in vulnerable populations such as pediatric and non-obstetric adult populations [20]. A comparative research by Kundra *et al.* [21] found that dexmedetomidine resulted in a mean shivering cessation time of 2.9 minutes and a 100% response rate at 15 minutes post-administration, which was better in comparison to the findings of the present investigation, in which the cessation time was 5 minutes and the response was 96.7% (29/30). Literature reports that intrathecal administration of dexmedetomidine can alleviate shivering during Cesarean sections [22], but its intravenous application in this context has not been explored.

Bradycardia, sedation, and hypotension are possible side effects of dexmedetomidine. Sedation was indeed noted in the dexmedetomidine group in the current study. The present investigation did not observe any instances of grade 4 sedation (as defined by Filos *et al.*) [13]. However, 13.3% (n=4/30) occurrences of grade 3 sedation were documented following dexmedetomidine administration among study participants. This observation can be attributed to the minimal dosage required to halt shivering. It is important to note that following childbirth, especially after extended labour, patients often displayed signs of relaxation and closed their eyes. Despite this, these individuals remained responsive to verbal cues. Patients' shivering threshold is lowered and sympathetic activity is suppressed by dexmedetomidine because it acts on α-2 adrenergic receptors in the central nervous system [23]. In addition to lowering blood pressure and heart rate, this sympatholytic activity causes drowsiness without affecting breathing [24]. Studies have shown that the lowest dosages of dexmedetomidine that could effectively treat grade 3 and grade 4 shivering brought on by spinal anesthetic were 0.26 µg/kg and 0.3 µg/kg, respectively, without producing bradycardia, hypotension, or severe sedation [25].

The present investigation found that among the 30 patients administered dexmedetomidine, no instances of hypotension were recorded. Bradycardia was not detected, potentially due to dexmedetomidine being given when the parturient was experiencing relative tachycardia. The immediate postpartum period frequently sees an elevation in heart rate owing to the biological changes associated with delivery [12]. Though a brief decrease in heart rate was noted shortly after dexmedetomidine administration, it remained above 50 beats per minute and did not require intervention. Consequently, this study demonstrated that a 30-microgram dose effectively reduced or eliminated shivering without inducing hypotension or bradycardia, which occurred less often than in the control group.

Existing research suggests that the administration of dexmedetomidine may be a safe option for both the maternal patient and the infant. An examination into the amount of dexmedetomidine in colostrum discovered that intravenous infusion of 0.6 μg/kg/hr after umbilical cord clamping was related to minor amounts of dexmedetomidine identified in the breast milk and did not result in substantial unfavourable outcomes for the mothers [26].

LIMITATION AND FUTURE DIRECTIONS

Although our research provides robust evidence supporting the efficacy of dexmedetomidine in this clinical context, it is important to acknowledge certain limitations. The single-centre design of the study and the relatively homogeneous patient population may restrict the broader generalizability of our findings. Additionally, the subjective assessment of shivering and sedation is susceptible to variation between observers, despite the mitigation efforts of having most data collected by only two team members, which remains a methodological limitation. The awareness of patients being monitored for shivering may have influenced their shivering rates, and the strict criteria used for recording shivering episodes could have led to the inclusion of cases that may be overlooked in routine clinical practice, as shivering is often considered a secondary concern during the perioperative period. Furthermore, the discontinuation of shivering grading 15 minutes after the bolus administration disregards any subsequent shivering episodes. Moreover, the fixed dosage regimen may not be appropriate for patients with extreme weights, and a more personalised approach based on individual patient characteristics would be preferable.

Subsequent studies should concentrate on large-scale, multi-centre trials involving diverse patient groups to confirm the enduring impacts and safety of dexmedetomidine across various surgical scenarios. Moreover, exploring optimal dosage regimens and administration timing could enhance its clinical application. This study contributes to the ongoing discussion about postoperative care for obstetric patients and emphasises the importance of exploring new treatments to improve patient comfort and outcomes before surgery. The introduction of dexmedetomidine into routine practice could significantly enhance anesthesia management, as shivering remains a frequent and uncomfortable side effect following neuraxial anesthesia. This promising development requires further investigation and clinical validation to confirm its effectiveness.

CONCLUSION

Our randomised controlled trial reveals that administering dexmedetomidine intravenously effectively reduces shivering in patients undergoing cesarean sections with neuraxial anesthesia. The study's outcomes indicate that dexmedetomidine notably decreases the intensity of shivering and improves patient comfort after surgery. These results suggest that dexmedetomidine could be considered a routine supplementary treatment in this specific clinical scenario. Additional research is required to fully understand its impact on perioperative care, including exploring optimal dosage strategies and long-term effects. This research provides valuable insights for enhancing the post-operative experience of patients undergoing cesarean deliveries.

ETHICAL APPROVAL

Ethical approval was obtained from the Ethical Review Committee of Liaquat National Hospital and Medical College, Karachi (REF letter No. 0980·2023-LNH-ERC). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/ or national research committee and the Helsinki Declaration.

CONSENT FOR PUBLICATION

Written informed consent was taken from the participants.

AVAILABILITY OF DATA

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Declared none.

AUTHORS' CONTRIBUTION

GF: Substantial contributions to the concept/design of work, drafting of the manuscript; SMNN: Data acquisition and analysis; AA: drafting of the manuscript; SH: Critical review of the work for the intellectual content; SA: Critical review of the work for the intellectual content; WT: Data acquisition and critical review of the work for the intellectual content. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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