The Efficacy of Dexamethasone in Reducing Postoperative Shivering after Caesarean Section Under Spinal Anesthesia: A Randomized Controlled Trial

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Abstract

This randomized, triple-blind controlled trial aimed to evaluate the efficacy of prophylactic dexamethasone 0.15 mg/kg in preventing postoperative shivering in 186-term pregnant women scheduled for cesarean section under spinal anesthesia. Participants were computer-randomized with concealed allocation. The treatment group received dexamethasone 0.15 mg/kg diluted to 10 ml while the control group received normal saline 10 ml, both administered by blinded anesthesia nurses. Data were analyzed using repeated measures ANOVA for temperature changes and Fisher's exact test for shivering incidence.

The results showed that dexamethasone significantly reduced the incidence of postoperative shivering (12.90% vs 27.96%, p = 0.010), with a relative risk reduction of 53.85% and the number needed to treat 7. The dexamethasone group maintained significantly higher core temperatures (mean difference 0.376°C, p < 0.001) and required less rescue pethidine (3.23% vs 16.13%, p = 0.005). Both groups showed similarly low rates of postoperative nausea and vomiting (1.08% vs 2.15%, p = 0.50), and no surgical site infections were observed during the follow-up period. These findings suggest that prophylactic dexamethasone 0.15 mg/kg effectively reduces postoperative shivering in cesarean section under spinal anesthesia with a favorable safety profile. This intervention could be considered for incorporation into routine care protocols for eligible patients.

Keywords: Dexamethasone, Cesarean section, Spinal anesthesia, Postoperative shivering

1. Introduction

Postoperative shivering (POS) is a common complication following spinal anesthesia, affecting 40-70% of patients.[1] Beyond patient discomfort, POS can lead to increased oxygen consumption, catecholamine release, elevated cardiac output, and metabolic demands.[2] These complications are particularly concerning in surgical settings where maintaining physiological stability is crucial.

For cesarean sections under spinal anesthesia specifically, the incidence of shivering is notably high, ranging from 52 – 85%.[3] This rate is approximately twice that of general surgery procedures.[4] Pregnant women are particularly susceptible to perioperative shivering due to increased basal metabolism and altered thermoregulation during pregnancy, further compromised by spinal anesthesia-induced vasodilation.[5] This shivering increases maternal oxygen consumption by 200 – 400%, potentially compromising fetal oxygenation and interfering with monitoring.[6]

Various pharmacological and non-pharmacological interventions have been studied for preventing POS. Among these, dexamethasone has emerged as a promising option due to its anti-inflammatory properties and ability to reduce the core-to-peripheral temperature gradient.[7] Through multiple pathways, dexamethasone suppresses pro-inflammatory cytokines, reduces peripheral vasoconstriction, and modulates the hypothalamic thermoregulatory threshold.[8] These effects are particularly relevant in obstetric patients where thermal regulation is already compromised by pregnancy-related physiological changes. Single-dose dexamethasone (0.1-0.2 mg/kg) has shown efficacy in shivering prevention, with studies confirming its safety in cesarean delivery and breastfeeding, showing no increased risk of surgical site infections or significant glycemic changes in non-diabetic mothers.[9] However, the optimal dosing in obstetric patients remains unclear. Previous studies have shown efficacy with dexamethasone doses ranging from 0.1 – 0.6 mg/kg,[10] but a prior study using dexamethasone 0.1 mg/kg showed no significant benefit, possibly due to altered pharmacokinetics in pregnancy.[11]

Khosravi et al.[12] demonstrated a significant reduction in POS using dexamethasone 0.15 mg/kg in non-obstetric patients, while De Oliveira et al.[1] found that a 4 – 5 mg dose of dexamethasone was as effective as higher doses (8 – 10 mg) for preventing postoperative nausea and vomiting, whether used alone or in combination with other antiemetics. This 0.15 mg/kg dose warrants specific investigation in obstetric patients due to pregnancy-altered pharmacokinetics and the inadequate efficacy of lower doses. While effective in non-obstetric surgery,[12] this dose may represent an optimal balance between efficacy and safety for cesarean sections, particularly given the previous unsuccessful trial with 0.1 mg/kg dosing.[11] No studies have specifically evaluated the efficacy of dexamethasone 0.15 mg/kg for preventing POS after cesarean section under spinal anesthesia.

Therefore, this randomized controlled trial aimed to evaluate the efficacy of prophylactic dexamethasone 0.15 mg/kg in preventing shivering and maintaining postoperative temperature in patients undergoing cesarean section under spinal anesthesia. Secondary objectives included assessing safety outcomes and their potential benefits in preventing postoperative nausea and vomiting.

2. Materials and Methods

This was a prospective, randomized, double-blind, controlled trial conducted at the operating room, of Sakon Nakhon Hospital between September 1, 2023, and September 30, 2024. The study protocol was approved by the Ethics Committee of Sakon Nakhon Hospital (Ref SKNH REC No. 036/2566)

We enrolled pregnant women aged ≥18 years with gestational age ≥37 weeks scheduled for cesarean section under spinal anesthesia. Eligible participants were American Society of Anesthesiologists (ASA) physical status I-II. Exclusion criteria were contraindications to spinal anesthesia, dexamethasone allergy, failed spinal block requiring conversion to general anesthesia, pre-existing shivering before spinal anesthesia, gestational diabetes mellitus, chronic steroid use, active infection or fever >37.5°C, and cognitive impairment. After obtaining written informed consent, the sample size was calculated using STATA version 16, based on Khosravi et al.[12] which reported a shivering incidence of 12% in the dexamethasone group versus 31% in the control group. Using a two-sided type I error (α) of 0.05, power (1-β)

of 80%, and 1:1 allocation ratio, this yielded 83 patients per group, which was increased to 93 per group to account for a potential 10% dropout. Subsequently, participants were randomly allocated in a 1:1 ratio using computer-generated random numbers, with allocation concealment achieved using sequentially numbered, sealed, opaque envelopes. The anesthesiologist administering the medication, patients, and outcome assessors were blinded to group assignment, while only designated research staff not involved in patient care or outcome assessment were aware of group allocation.

Study medications (dexamethasone 0.15 mg/kg diluted to 10 ml or normal saline 10 ml) were prepared by the research team and administered by blinded anesthesia nurses, with all patients receiving standardized monitoring including continuous ECG, non-invasive blood pressure measurements (every 3 minutes for 10 minutes post-spinal block, then every 5 minutes), pulse oximetry, and supplemental oxygen via nasal cannula at 3 LPM. Before spinal anesthesia, patients received prewarmed (38°C) Acetated Ringer's solution (10 ml/kg over 15 – 30 minutes), followed by spinal anesthesia at L3-4 using 26/27-gauge needles with 0.5% hyperbaric bupivacaine 2.0 ml plus morphine 0.2 mg, after which patients were positioned supine with left uterine displacement (15-degree wedge) and core (tympanic) and skin (forehead) temperatures were measured before and 15 minutes after spinal block. During the procedure, hypotension (SBP <90 mmHg or >20% decrease) was treated with ephedrine 6 mg IV every 3 minutes and bradycardia (HR <60) with atropine 0.6 mg IV. According to standard protocol, post cord-clamping, oxytocin 4 units IV was given (maximum 10 units), followed by 20 units/1000 ml infusion, along with ondansetron 8 mg IV for antiemesis. In Post Anesthesia Care Unit (PACU), patients received forced-air warming (38°C) with temperature monitoring every 15 minutes, and shivering (Crossley and Mahajan score ≥2) persisting after 15 minutes of warming was treated with pethidine 0.5 mg/kg IV, while patients were continuously monitored for complications throughout their PACU stay and hospitalization.

All outcomes were assessed by a blinded investigator. The primary outcomes were changes in body temperature and incidence of postoperative shivering. Body temperature, including core temperature (tympanic membrane) and skin temperature (forehead), was measured before spinal anesthesia, 15 minutes after spinal anesthesia, and every 15 minutes

in PACU. Postoperative shivering was assessed using the Crossley and Mahajan post-anesthetic shivering score (0 = no shivering; 1 = peripheral vasoconstriction without muscle activity; 2=muscular activity in one muscle group; 3=muscular activity in more than one muscle group; 4 = generalized whole-body shivering).[13] Scores ≥2 indicated clinically significant shivering requiring intervention. Patients with shivering persisting after 15 minutes of forced-air warming received rescue pethidine (0.5 mg/kg IV). Secondary outcomes included postoperative nausea and vomiting and surgical site infection (defined as the presence of purulent drainage, localized pain/tenderness, redness, or fever >38.0℃ at the incision site) assessed at 48 hours postoperatively. Statistical analysis was performed using STATA version 16.0. Continuous variables were presented as mean ± SD and analyzed using an independent t-test. For temperature changes over time, repeated measures ANOVA with Greenhouse-Geisser correction was applied due to violation of sphericity. Categorical data were presented as numbers and percentages and analyzed using Fisher's exact test. Clinical effectiveness was evaluated using relative risk reduction and the number needed to treat. The primary analysis was conducted according to the intention-to-treat analysis. Statistical significance was set at $P < 0.05$. This trial was designed, conducted, and reported following the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized controlled trials.

3. Results

Between September 1, 2023, and September 30, 2024, 186 patients were enrolled and randomly allocated to either the dexamethasone group (n=93) or control group (n=93). All patients completed the study protocol and were included in the final analysis (Figure 1). Baseline demographic and clinical characteristics were comparable between groups (Table 1). The mean age was 29.88 ± 5.38 years in the treatment group and 30.68 ± 5.71 years in the control group ($p = 0.33$). All participants were ASA class II. Pre-spinal core-temperatures (36.44 ± 0.52℃ vs 36.48 ± 0.52℃, $p = 0.58$) and skin temperatures (36.41 ± 0.42℃ vs 36.42 ± 0.45℃, $p = 0.92$) were similar between groups. Surgical characteristics including total intravenous fluid administration, estimated blood loss, and duration of surgery showed no significant differences between groups.

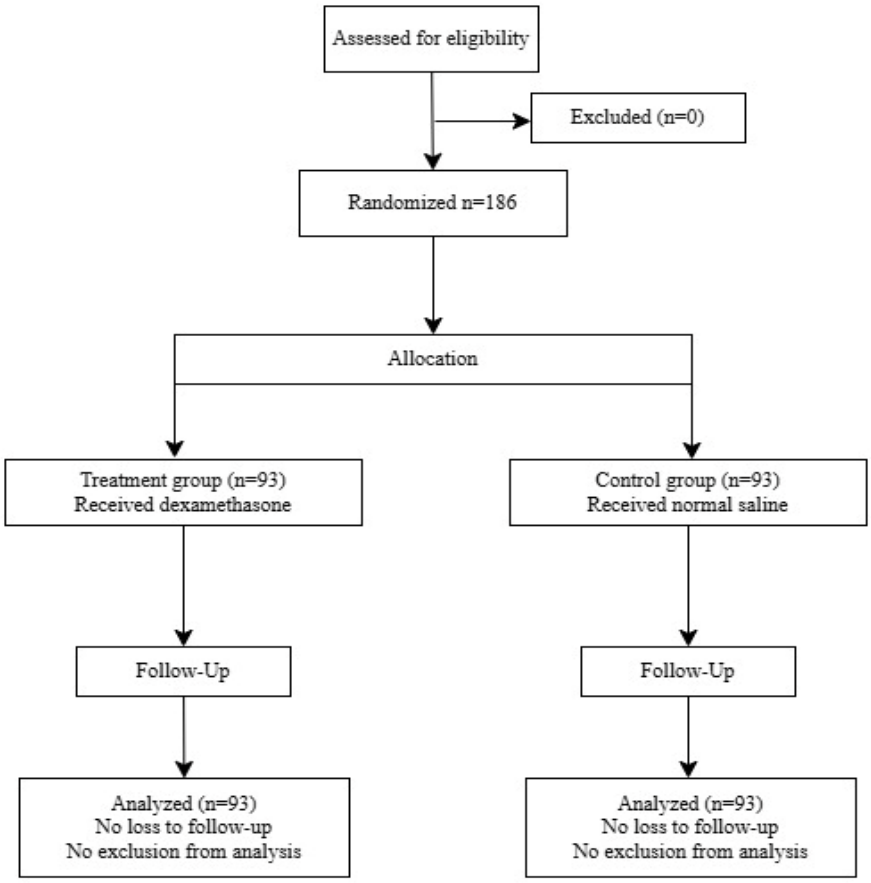

Figure 1 Consolidated standards of reporting trial diagram

Temperature changes during PACU stay were analyzed using repeated measures ANOVA with Greenhouse-Geisser correction due to violation of sphericity. There was a significant main effect of time ($F = 41.33$, $p<0.001$) and group ($F = 67.4$, $p < 0.001$) core temperature, but no significant time-by-group interaction ($F = 1.40$, $p = 0.245$). The dexamethasone group maintained significantly higher core temperatures compared to the control group (mean difference 0.376°C, $p < 0.001$), while skin-temperature differences were not statistically significant (mean difference 1.08°C, $p = 0.131$) (Table 2, Figure 2).

The incidence of postoperative shivering was significantly lower in the dexamethasone group compared to the control group (12.90% vs 27.96%, $p = 0.010$). Furthermore, fewer patients in the dexamethasone group required rescue pethidine for shivering treatment (3.23% vs 16.13%, $p = 0.005$) (Table 3). The relative risk reduction for shivering was 53.85%, with a number needed to treat of 7 patients to prevent one episode of shivering (Table 4).

Table 1 Baseline Demographic and Clinical Characteristics

Parameters	Treatment group (n=93)	Control group (n=93)	*P*
Age (years, mean ±SD)	29.88 (±5.38)	30.68 (±5.71)	0.33
Weight (kg, mean ± SD)	70.58 (±10.92)	71.05 (±11.69)	0.77
Hight (cm, mean ± SD)	158.47 (±6.10)	158.97 (±5.04)	0.54
ASA class II (n, %)	93 (100.00)	93 (100.00)	1.00
Gestational age (weeks, mean ± SD)	38.02 (±0.75)	37.96 (±0.94)	0.66
Pre-Spinal anesthesia temperature			
Core- temperature (℃, mean ± SD)	36.44 (±0 .52)	36.48 (±0.52)	0.58
Skin- temperature (℃, mean ± SD)	36.41 (±0.42)	36.42 (±0.45)	0.92
Post-Spinal anesthesia temperature 15 min			
Core- temperature (℃, mean ± SD)	36.32 (±0.50)	36.45 (±0.55)	0.10
Skin- temperature (℃, mean ± SD)	36.56 (±0.39)	36.58 (±0.41)	0.81
Total Intravenous fluid (ml, mean ± SD)	1467.74 (±239.18)	1485.48 (±253.30)	0.62
Blood loss (ml, mean ± SD)	389.46 (±89.93)	410.75 (±100.50)	0.13
Duration of surgery (min, mean ± SD)	53.22 (±9.93)	55.73 (±11.95)	0.12

℃= degrees Celsius, ASA = American Society of Anesthesiologists

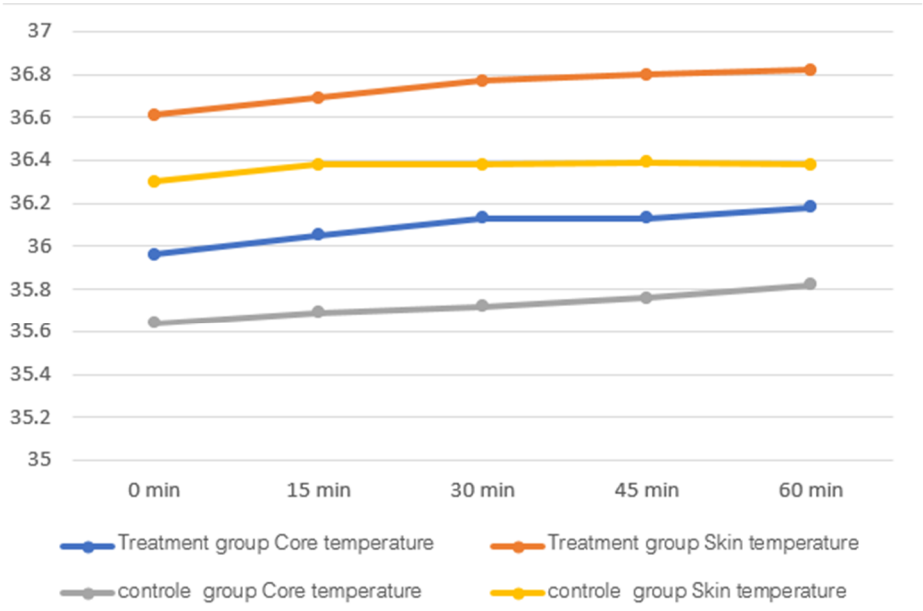

Figure 2 Mean Core and Skin Temperature Changes During Post-Anesthesia Care Unit in Treatment and Control Groups

Table 2 Analysis of Temperature Changes in PACU

Effect	df	F	*P*
Time	2.60	41.33	<0.001†
Groups	1	67.4	<0.001†
Time* Groups	2.60	1.40	0.245
Comparison Treatment -Control	**Mean difference**	**Std. Error**	***P***
Core- temperature	0.376	0.0447	<0.001†
Skin- temperature	1.08	0.714	0.131

† Repeated measures analysis of variance; Greenhouse-Geisser correction was applied due to violation of sphericity; †Significant as p-value < 0.05

Table 3 Incidence of shivering and pethidine requirement in PACU

Group	Treatment group (n=93)	Control group (n=93)	*P*
Shivering (n, %)	12 (12.90)	26 (27.96)	0.010*
Non-Shivering (n, %)	81 (87.10)	67 (72.04)	
Postoperative Pethidine Required			
Required (n, %)	3 (3.23)	15 (16.13)	0.005*
Not Required (n, %)	90 (96.77)	78 (83.87)	

Fisher's exact test; *Significant as P-value < 0.05, Shivering was defined as Crossley and Mahajan post-anesthetic shivering score 2-4; non- shivering defined as score 0-1

Table 4 Treatment Effect Analysis of Dexamethasone on Postoperative Shivering in PACU

Shivering in Treatment group (n, %)	Shivering in Control group (n, %)	Risk Ratio (95%CI)	Relative Risk Reduction (%)	Number Needs to Treat
12 (12.90)	26 (27.96)	0.46 (0.25-0.86)	53.85	7

Shivering was defined as Crossley and Mahajan post anesthetic shivering score 2-4; non- shivering defined as score 0-1

Regarding adverse events, there were no significant differences between groups in the incidence of nausea (1.08% vs 2.15%, p = 0.50) or vomiting (1.08% vs 1.08%, p = 1.00). No surgical site infections were observed in either group during the 48-hour follow-up period (Table 5).

Table 5 Adverse Events Associated with Dexamethasone Administration

Adverse Events	Treatment group (n=93)	Control group (n=93)	*P*
Nausea (n, %)	1 (1.08)	2 (2.15)	0.50
Vomiting (n, %)	1 (1.08)	1 (1.08)	1.00
Wound Infection (n, %)	0 (0.00)	0 (0.00)	NA

Fisher's exact test; *Significant as P-value < 0.05, NA = Not applicable due to zero events in both groups

4. Discussion

This randomized controlled trial demonstrated that prophylactic intravenous dexamethasone 0.15 mg/kg significantly reduced the incidence of postoperative shivering in patients undergoing cesarean section under spinal anesthesia (12.90% vs 27.96%, p=0.010). The clinical significance is substantial, with a relative risk reduction of 53.85%, indicating that dexamethasone treatment reduced the risk of shivering by more than half compared to placebo. The number needed to treat of 7 demonstrates strong practical utility, meaning that only 7 patients need to receive prophylactic dexamethasone to prevent one case of postoperative shivering, a notably efficient intervention compared to many other preventive measures in anesthesia practice. Additionally, the dexamethasone group maintained better temperature control and showed markedly reduced need for rescue pethidine (3.23% vs 16.13%, p=0.005), suggesting that when shivering did occur, it was generally less severe and more manageable than in the control group.

This finding showed greater efficacy than previous studies. While Khosravi et al.[12] reported similar shivering reduction in non-obstetric surgery using the same dosage, our study demonstrated superior outcomes in the obstetric population. This contrasts with earlier research by Arunee Saengsanon et al.,[11] where dexamethasone 0.1 mg/kg failed to show significant benefit, likely due to insufficient dosing considering pregnancy-related pharmacokinetic changes. Our results align with recent meta-analyses suggesting that higher dexamethasone doses (0.1 - 0.2 mg/kg) are more effective for preventing postoperative shivering.[7]

The mechanism behind dexamethasone's effectiveness in preventing shivering involves multiple pathways. Its anti-inflammatory properties reduce the release of pyrogenic cytokines and modulate the hypothalamic thermoregulatory threshold.[1] Furthermore, dexamethasone decreases the core-to-peripheral temperature gradient through vasomotor effects.[2] These mechanisms are particularly relevant in pregnant women, who experience altered thermoregulation due to increased basal metabolism and hormone-induced vasodilation.[14]

Our safety analysis focused on two key aspects. First, we observed very low rates of postoperative nausea and vomiting (PONV) in both groups (1.08% vs 2.15%, p = 0.50), primarily due to routine prophylactic ondansetron 8 mg administration. The marginally lower PONV rate in the dexamethasone group supports De Oliveira et al.'s finding that a 4-5 mg dose of dexamethasone was as effective as higher doses (8-10 mg) for preventing postoperative nausea and vomiting, whether used alone or in combination with other antiemetics.[15] More critically, we found no surgical site infections in either group during the 48-hour follow-up period, consistent with Abebe et al. findings on the safety of single-dose dexamethasone in cesarean delivery.[16] This reassuring safety profile likely reflects the minimal systemic impact of a single perioperative dose, in contrast to the known risks of prolonged steroid therapy.

The clinical implications of our findings are substantial. With an NNT of 7, prophylactic dexamethasone represents an efficient intervention for preventing postoperative shivering. The simplicity of administration, low cost, and dual benefit of shivering prevention and PONV prophylaxis make it an attractive option for routine use in eligible patients.[17] However, careful patient selection remains important, particularly excluding those with gestational diabetes or active infection.

Several limitations should be acknowledged. As a single-center study, our results may not fully generalize to other settings. The 48-hour follow-up period may have missed late-onset complications. We did not assess the impact on breastfeeding or measure blood glucose levels. Additionally, the exclusion of high-risk patients limits our understanding of dexamethasone's effects in these populations.

Future research should address these limitations through multicenter trials with longer follow-up periods. Studies investigating dexamethasone's effects on breastfeeding outcomes

and neonatal well-being are warranted. Research comparing dexamethasone with other prophylactic measures and examining its role in high-risk populations (e.g., gestational diabetes, preeclampsia) would help establish optimal prevention strategies. Additionally, studies exploring the impact of timing and alternative dosing regimens could further optimize this intervention.

5. Conclusion

This randomized controlled trial demonstrates that prophylactic dexamethasone 0.15 mg/kg significantly reduces postoperative shivering in patients undergoing cesarean section under spinal anesthesia. The intervention showed both statistical significance and clinical relevance, with a relative risk reduction of 53.85% and a number needed to treat of only 7 patients. The maintenance of higher core temperatures and reduced requirement for rescue pethidine in the dexamethasone group further supports its efficacy. This evidence, combined with its demonstrated safety profile, low cost, and potential additional benefit in PONV prevention, suggests that prophylactic dexamethasone could be incorporated into routine care protocols for eligible patients undergoing cesarean section. However, careful patient selection remains essential, and future research should focus on long-term safety outcomes and effectiveness in high-risk populations.

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