International Journal of Clinical and Biomedical Research
Vol. 11, No. 2 (2026)
pISSN: 2521-0394 · eISSN: 2395-0471

ORIGINAL RESEARCH

CLONIDINE VERSUS DEXAMETHASONE AS AN ADJUVANT TO 0.25% BUPIVACAINE FOR WOUND INFILTRATION ANALGESIA AFTER ELECTIVE CAESAREAN SECTION

Geetha M[1], Lokesh S B[2*], Sumanth S[3], Balaji Nallathambi[3]

[1,3,4] *Senior Resident, Department of Anaesthesiology, ESIC Medical College and PGIMSR, Rajajinagar, Bengaluru, Karnataka, India.*

[2] *Assistant Professor, Department of Anaesthesiology, ESIC Medical College and PGIMSR, Rajajinagar, Bengaluru, Karnataka, India.*

*Correspondence: Lokesh S B <sblokesh@gmail.com>

ABSTRACT

Background: Pain after caesarean section interferes with early ambulation, maternal comfort and the establishment of breastfeeding. Wound infiltration with local anaesthetic is a simple, inexpensive adjunct to multimodal analgesia, but the duration of relief from bupivacaine alone is limited. Clonidine is an established adjuvant for infiltration analgesia, whereas dexamethasone has been studied mainly in peripheral nerve blockade, with comparatively little evidence in wound infiltration. **Objective:** To compare clonidine and dexamethasone as adjuvants to 0.25% bupivacaine for wound infiltration in prolonging analgesia after elective caesarean section. **Methods**: In this prospective observational study, 60 women of ASA physical status I or II undergoing elective caesarean section under subarachnoid block were observed and grouped according to the wound infiltration adjuvant used, 30 women in each group. Group A received 20 ml of 0.25% bupivacaine with clonidine 3 µg/kg and Group Breceived 20 ml of 0.25% bupivacaine with dexamethasone 8 mg, infiltrated along the incision before skin closure. The primary outcome was duration of analgesia, defined as the interval from infiltration to first rescue analgesic request. Secondary outcomes were 24-hour tramadol consumption, pain intensity on a visual analogue scale, haemodynamic variables and adverse effects. **Results:** All 60 women completed the study. Duration of analgesia was longer in Group B than in Group A (467.5 ± 40.3 versus 364.1 ± 53.4 minutes), a mean difference of 103.4 minutes (95% CI 79.4 to 127.3; $p < 0.001$). Tramadol consumption over 24 hours was lower in Group B (74 ± 28 versus 128 ± 36 mg), a mean difference of −54 mg (95% CI −70.3 to −37.7; $p < 0.001$), a relative reduction of 42%. No adverse effects were recorded in either group. **Conclusion:** Dexamethasone 8 mg was associated with approximately 1.7 hours longer wound infiltration analgesia and a more than 40% lower 24-hour tramadol requirement than clonidine 3 µg/kg. No adverse effects were detected, although with 30 women per group the study could not exclude uncommon events. The findings derive from a single centre, group membership was not randomly assigned, and no bupivacaine-only comparison group was included; the differences reported are therefore unadjusted associations, and the additional benefit of either adjuvant over bupivacaine alone cannot be quantified from these data.

Keywords: Wound infiltration; Bupivacaine; Clonidine; Dexamethasone; Caesarean section; Postoperative analgesia; Adjuvant.

INTRODUCTION

Caesarean section ranks among the more painful surgical procedures in the first 24 postoperative hours, and pain after delivery differs from other postoperative pain in that the mother must mobilise early, care for a newborn and establish breastfeeding while recovering [1]. Inadequate analgesia delays ambulation, prolongs hospital stay, impairs mother-infant bonding and is associated with a higher risk of persistent postsurgical pain [1,2]. Because sedation and opioid transfer into breast milk are particular concerns in this population, opioid-sparing strategies within a multimodal framework are especially valuable [2,3].

Wound infiltration with local anaesthetic is one of the simplest of these strategies. It requires no equipment or expertise beyond that already present in theatre, adds negligible cost, and carries minimal systemic risk. A Cochrane review of local anaesthetic infiltration and abdominal nerve block during caesarean section found reductions in opioid consumption in

women receiving infiltration, although the included trials were heterogeneous in technique and volume [4]. Continuous and single-shot infiltration techniques have shown similar benefit in abdominal surgery more broadly [5].

Bupivacaine is commonly chosen for infiltration because of its long duration of action, yet single-injection analgesia rarely extends much beyond six hours. This limitation has driven interest in adjuvants that prolong the effect without introducing systemic toxicity. Clonidine, a selective α_2-adrenoceptor agonist, is among the best characterised. Its peripheral analgesic action is attributed to hyperpolarisation-mediated inhibition of nerve impulse conduction, local vasoconstriction reducing systemic uptake, and possible anti-inflammatory effects at the wound [6]. Bharti and colleagues, comparing intravenous with wound-infiltrated clonidine 3 µg/kg alongside bupivacaine after open cholecystectomy, found both routes provided good analgesia, with fewer side effects when clonidine was confined to the wound [7]. That study establishes the dose used in the present study.

Dexamethasone has been investigated far more extensively as a perineural than as an infiltration adjuvant. Movafegh et al. showed that dexamethasone added to lidocaine prolonged axillary brachial plexus blockade [8], and a systematic review by Choi and colleagues of randomised trials in brachial plexus block concluded that dexamethasone prolongs analgesia when combined with either short- or long-acting local anaesthetic [9]. Comparable prolongation has been reported with bupivacaine in interscalene block [10] and with mepivacaine in supraclavicular block [11]. The mechanism is incompletely resolved and probably combines local anti-inflammatory action, attenuation of ectopic neuronal discharge and direct effects on potassium channels in nociceptive C fibres; a systemic component cannot be excluded, since intravenous and perineural dexamethasone produce broadly similar prolongation in shoulder surgery [12].

Whether this benefit transfers from perineural administration to wound infiltration, and how it compares against an established adjuvant such as clonidine, has been little studied, particularly in obstetric patients. The present study was therefore undertaken to compare clonidine 3 µg/kg and dexamethasone 8 mg as adjuvants to 0.25% bupivacaine for wound infiltration after elective caesarean section, with duration of analgesia as the primary outcome.

MATERIAL AND METHOD

Design and setting

This was a prospective observational, comparative study conducted in the Department of Anaesthesiology, ESIC Medical College and PGIMSR, Bengaluru. No treatment was assigned by the investigators. Wound infiltration with 0.25% bupivacaine together with an adjuvant was already established departmental practice for elective caesarean section, and the choice of adjuvant rested entirely with the attending anaesthesiologist. Consecutive eligible women already receiving one of these two regimens were enrolled and grouped for analysis according to the adjuvant they had received, clonidine in Group A and dexamethasone in Group B. The investigators had no role in selecting the adjuvant, in determining which women received it, or in any aspect of perioperative care; their role was confined to prospective recording of outcomes. The study was conducted in accordance with the Declaration of Helsinki [13] and is reported in accordance with the STROBE statement for observational studies [14]. Approval was obtained from the Institutional Ethics Committee, ESIC Medical College and PGIMSR, and written informed consent was obtained from every participant before enrolment.

Participants

Women aged 18 to 40 years of ASA physical status I or II scheduled for elective caesarean section under subarachnoid block were eligible. Exclusion criteria were known allergy to any study drug, infection at the operative site, coagulation disorders, significant cardiac, hepatic or renal disease, chronic pain disorder, and opioid dependence.

Sample size and grouping

No a priori sample size calculation was performed. Consecutive eligible women were observed until 30 had accrued in each group. Group A comprised women who received 20 ml of 0.25% bupivacaine with clonidine 3 µg/kg and Group B those who received 20 ml of 0.25% bupivacaine with dexamethasone 8 mg. All infiltrations were performed by a senior faculty member and observations were recorded prospectively on a standard proforma. Because the sample was one of

convenience rather than one determined by calculation, the study is exploratory, and the confidence intervals reported should guide interpretation of precision in preference to the p values.

Anaesthetic technique and wound infiltration

Subarachnoid block was performed at the L3–L4 or L4–L5 interspace with hyperbaric bupivacaine 0.5% (dose to be confirmed by the authors). No intrathecal adjuvant was administered. Following delivery and haemostasis, the operating surgeon infiltrated 20 ml of study solution into the wound edges along the incision line immediately before skin closure:

Group A (n = 30): 0.25% bupivacaine 20 ml with clonidine 3 µg/kg.

Group B (n = 30): 0.25% bupivacaine 20 ml with dexamethasone 8 mg (2 ml).

The total bupivacaine dose was 50 mg in both groups, well within accepted maximum limits for infiltration.

Postoperative analgesia and outcome assessment

Rescue analgesia was provided with intravenous tramadol 100 mg, administered on patient request or whenever the Visual Analogue Scale (VAS) score was ≥4. Background analgesia consisted of intravenous paracetamol 1 g every 8 hours. Pain intensity was assessed using a 0–10 Visual Analogue Scale at 2, 4, 6, 8, 12 and 24 hours postoperatively, and at the time of first rescue analgesic administration. Scheduled assessments were made and recorded before any rescue analgesic was given at that timepoint, so that a scheduled score of 4 or above prompted administration of tramadol immediately afterwards. The scores presented in Table 3 therefore represent pain intensity before, and not after, rescue medication at each timepoint. Heart rate and systolic and diastolic blood pressure were recorded preoperatively (baseline), at the intraoperative nadir, and at 2 hours postoperatively. Diastolic pressure at the intraoperative nadir was not recorded. Adverse effects comprising nausea, vomiting, hypotension, bradycardia, excessive sedation, wound infection and delayed wound healing were assessed throughout the 24-hour postoperative period.

Statistical analysis

Continuous variables are summarised as mean ± SD and categorical variables as counts and percentages. Between-group comparisons used the independent-samples t test for continuous variables and the chi-squared test for categorical variables. Mean differences are presented with 95% CI and a two-sided p value below 0.05 was taken as statistically significant. Because group membership was not randomly assigned, no adjustment for potential confounding was undertaken; all comparisons are therefore unadjusted and describe association rather than causation.

RESULTS

Sixty women completed the study, 30 in each group, with no losses to follow-up. Baseline characteristics of the two groups are shown in Table 1.

Table 1. Baseline characteristics by group

Variable	Group A (n=30)	Group B (n=30)	p value
Age (years)	26.8 ± 3.7	27.2 ± 3.5	0.68
Body weight (kg)	64.3 ± 5.8	63.9 ± 6.1	0.79
Height (cm)	158.7 ± 4.5	159.3 ± 4.8	0.63
Body mass index (kg/m²)	25.5 ± 2.3	25.2 ± 2.4	0.71
ASA I / II, n (%)	19 (63.3%) / 11 (36.7%)	18 (60.0%) / 12 (40.0%)	0.79
Gestational age (weeks)	38.4 ± 0.8	38.5 ± 0.7	0.62
Duration of surgery (minutes)	58.6 ± 8.2	59.3 ± 7.9	0.74
Clonidine dose administered (µg)	193 ± 17	Not applicable	—

Note: Values are mean ± standard deviation or n (%).

Primary outcome

Duration of analgesia was longer in the dexamethasone group than in the clonidine group (Table 2). The mean difference of 103.4 minutes corresponds to a 28% relative prolongation.

Table 2. Primary and secondary analgesic outcomes

Outcome	Group A (n=30)	Group B (n=30)	Mean Difference (95% CI)	p value
Duration of analgesia (minutes)	364.1 ± 53.4	467.5 ± 40.3	103.4 (79.4 to 127.3)	<0.001
24-hour tramadol consumption (mg)	128 ± 36	74 ± 28	−54.0 (−70.3 to −37.7)	<0.001
Participants requiring rescue analgesia, n (%)	30 (100%)	30 (100%)	—	—

Note: Values are mean ± standard deviation. Mean differences are expressed as Group B minus Group A.

Pain scores:

Visual analogue scale scores are shown in Table 3.

Table 3. Visual analogue scale scores

Timepoint	Group A (n = 30)	Group B (n = 30)	p value
2 hours	1.1 ± 0.5	1.0 ± 0.4	0.46
4 hours	2.3 ± 0.7	1.8 ± 0.6	0.01
6 hours	3.9 ± 0.8	2.9 ± 0.7	<0.001
8 hours	5.2 ± 0.9	3.8 ± 0.8	<0.001
12 hours	4.1 ± 0.8	3.2 ± 0.7	<0.001
24 hours	2.0 ± 0.6	1.9 ± 0.5	0.54
At first rescue analgesia	4.8 ± 0.5	4.7 ± 0.4	0.48

Haemodynamic variables: Heart rate and blood pressure at the three recorded timepoints are shown in Table 4 Fig .

Table 4. Haemodynamic variables by group

Variable / timepoint	Group A (n = 30)	Group B (n = 30)	p value
Heart rate (beats/min) baseline	84 ± 8	83 ± 7	0.64
Heart rate intraoperative nadir	76 ± 6	75 ± 7	0.58
Heart rate 2 h postoperative	82 ± 7	80 ± 6	0.27
Systolic blood pressure (mmHg) baseline	118 ± 9	119 ± 8	0.72
Systolic blood pressure intraoperative nadir	106 ± 8	105 ± 7	0.65
Systolic blood pressure 2 h postoperative	116 ± 8	115 ± 7	0.69
Diastolic blood pressure (mmHg) baseline	74 ± 6	75 ± 5	0.55
Diastolic blood pressure 2 h postoperative	73 ± 5	74 ± 6	0.61

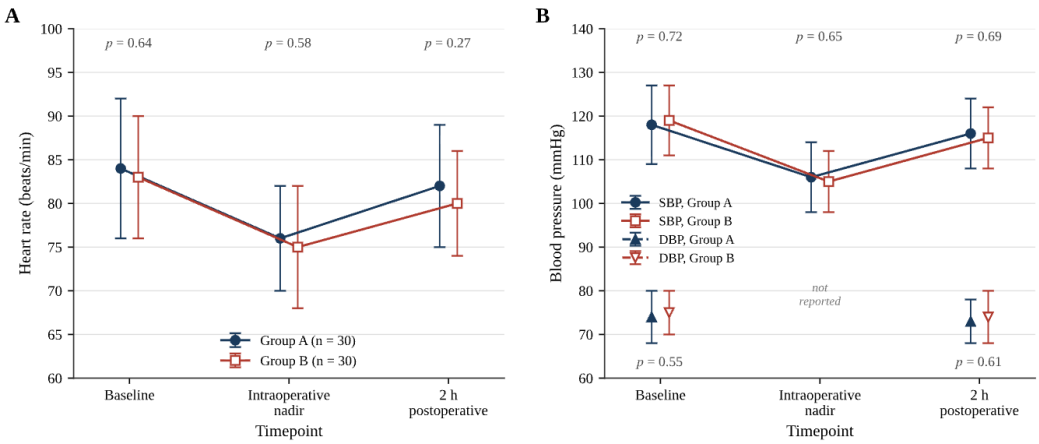

Figure 1. *Perioperative haemodynamic profile. (A) Heart rate and (B) systolic and diastolic blood pressure at baseline, intraoperative nadir, and 2 h postoperatively.*

Note: Values are mean ± standard deviation; n = 30 per group.

Adverse effects

No participant in either group developed hypotension, bradycardia, nausea, vomiting, excessive sedation, wound infection, delayed wound healing or allergic reaction during the observation period. With 30 participants per group, an observed incidence of zero is compatible with a true event rate of up to approximately 11% (upper bound of the 95% confidence interval), so the study can exclude only common adverse effects.

DISCUSSION

In this observational comparison, women who received dexamethasone 8 mg had a mean of 103 minutes longer wound infiltration analgesia after elective caesarean section than women who received clonidine 3 µg/kg, and required 54 mg less tramadol over 24 hours. Both differences were large relative to their confidence intervals and unlikely to reflect chance alone, although in the absence of random assignment they cannot be attributed to the adjuvant with certainty.

The magnitude of prolongation is consistent with the perineural literature from which the rationale for using dexamethasone in this way is drawn. Movafegh et al. reported prolongation of axillary blockade when dexamethasone was added to lidocaine [8], and the meta-analysis by Choi and colleagues found consistent prolongation across trials of brachial plexus block, with the effect apparent for both short- and long-acting local anaesthetics [9]. Similar findings have been reported with bupivacaine in interscalene block [10] and mepivacaine in supraclavicular blockade [11]. The present observations are consistent with the effect not being confined to perineural deposition, but being obtained also when the drug is placed in the wound.

The mechanism deserves care, because it bears on how the result should be interpreted. Dexamethasone is generally held to act locally through suppression of inflammatory mediator release, reduction of ectopic discharge from injured nociceptive fibres and modulation of potassium channel activity in C fibres. A purely local mechanism is not established, however: Desmet et al. found intravenous and perineural dexamethasone broadly equivalent in prolonging interscalene analgesia [12], and a systematic review of perioperative dexamethasone documented a modest opioid-sparing effect from systemic administration alone [15]. Because the present study included no systemic dexamethasone comparison group, it cannot distinguish a local wound effect from systemic absorption of an 8 mg dose. The distinction matters clinically: if the effect is largely systemic, the route of administration becomes a matter of convenience rather than pharmacological necessity.

Clonidine performed less well but was by no means ineffective, and the absence of a bupivacaine-only comparison group means this study can compare the two adjuvants only with each other without quantifying how much either adds to bupivacaine alone. Bharti and colleagues, using the same 3 µg/kg dose in wound infiltration after cholecystectomy, found clonidine reduced 24-hour morphine consumption relative to bupivacaine alone, with fewer systemic effects than the

intravenous route [7]; the peripheral analgesic action of α_2-agonists has been reviewed in detail by Eisenach et al. [6]. Read alongside those reports, the present data are best interpreted as showing dexamethasone to be the more effective of two active adjuvants, not as showing clonidine to be ineffective.

Total rescue analgesic consumption over 24 hours is arguably a more clinically meaningful endpoint than time to first request, since it integrates analgesic quality across the whole period rather than capturing a single moment. The 42% relative reduction in tramadol observed here is consistent in direction with reductions in analgesic requirement reported after wound infiltration with other adjuvants in caesarean section, including tramadol itself [16,17], and with the opioid-sparing effect described in the Cochrane review of infiltration and abdominal nerve block [4]. Comparable reductions have been reported for transversus abdominis plane block in this population [18,19], a technique achieving similar ends by a different route and a reasonable alternative where ultrasound and expertise are available.

No adverse effects were recorded in either group. This is reassuring but should be stated with appropriate caution: with 30 women per group, the upper 95% confidence bound on an observed rate of zero is approximately 11%, so uncommon effects could not have been detected. Clonidine 3 µg/kg represents roughly 180 µg in a 60 kg woman, a dose at which sedation and hypotension are recognised possibilities, and the completeness of adverse-effect ascertainment is therefore material to interpretation. Wound infiltration also entails a theoretical risk of local anaesthetic systemic toxicity, and although the bupivacaine dose used here (50 mg) is well within accepted limits, awareness of this complication remains appropriate whenever infiltration techniques are used [20]. The concern that wound corticosteroid might impair healing was not borne out, but follow-up did not extend beyond the immediate postoperative period.

Limitations: Group membership was not randomly assigned, so the two groups may differ in ways that were not measured. The groups were closely similar in the baseline characteristics recorded (Table 1), but residual confounding by factors such as parity, individual surgical and infiltration technique, attending clinician or pre-existing pain sensitivity cannot be excluded, and the differences reported are unadjusted associations rather than demonstrated causal effects. Neither participants nor observers were blinded to the adjuvant used, and the principal outcomes, namely visual analogue scale scores and the timing of the first rescue analgesic request, are subjective and therefore susceptible to reporting and observer bias when group membership is known. The study was conducted at a single centre in 60 women and included no bupivacaine-only comparison group, so the incremental benefit of either adjuvant over local anaesthetic alone cannot be estimated. Haemodynamic observation was limited to three timepoints, and diastolic pressure at the intraoperative nadir was not recorded, so the haemodynamic comparison is necessarily incomplete. Follow-up was confined to the first 24 hours, too short to assess wound healing, infection, or the development of persistent postsurgical pain an outcome of recognised importance after caesarean delivery.

Adequately powered, randomised multicentre trials incorporating a bupivacaine-only arm, a systemic dexamethasone arm to separate local from systemic effect, and follow-up extending to wound healing and persistent pain would materially strengthen the evidence base for this simple and inexpensive technique.

CONCLUSION

In this prospective observational study, dexamethasone 8 mg added to 20 ml of 0.25% bupivacaine for wound infiltration was associated with approximately 103 minutes longer postoperative analgesia and 42% lower 24-hour tramadol consumption than clonidine 3 µg/kg in women undergoing elective caesarean section under subarachnoid block. No adverse effects were observed in either group, although the sample size permits exclusion only of common events. Dexamethasone appears the more effective of the two adjuvants in this setting, but because group membership was not randomly assigned these findings are hypothesis-generating and require confirmation in a randomised controlled trial. The absence of a local anaesthetic-only comparison group and of a systemic dexamethasone comparison group also means that the size of the benefit over bupivacaine alone, and the contribution of systemic absorption, remain to be established.

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