

## Original Article

# Postoperative Analgesia using Bupivacaine Wound Infiltration with Intravenous Tramadol or Dexamethasone Following Obstetric Spinal Anaesthesia

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### ABSTRACT

**Context:** Effective management of postcesarean section (CS) pain is important for the well-being of mother and child; even in limited-resource areas, there are drug options which can be explored to achieve this. **Aim:** This study aimed to compare the analgesic effects of a combination of bupivacaine wound infiltration with either intravenous (IV) dexamethasone or tramadol after CS. **Setting and Design:** This study was a randomized, double-blind, comparative study in a tertiary hospital. Clearance obtained from the Institution's Ethics and Research Committee. **Methods:** One hundred and twenty American Society of Anesthesiologists I or II pregnant women scheduled for CS under spinal anesthesia were recruited after giving consent. At the end of skin closure, all the patients received 20 ml of 0.1% plain bupivacaine for wound infiltration and IV dexamethasone 8 mg (Group BD) or tramadol 100 mg (Group BT). Outcome measures were time to first analgesic request, visual analog scale (VAS) scores, side effects, and patients' satisfaction. **Results:** Time to first analgesic request was  $3.2 \pm 1.87$  and  $3.3 \pm 2.01$  h for BD and BT groups, respectively ( $P = 0.778$ ). VAS scores for the first 2 h were lower in the bupivacaine/tramadol group compared to bupivacaine/dexamethasone group; the differences were statistically significant at 30 and 60 min ( $P = 0.027$  and  $0.008$ ), respectively. Ninety percent versus 93% of the patients in BD and BT groups, respectively, expressed good to excellent satisfaction with pain relief. **Conclusion:** Combination of bupivacaine wound infiltration and IV tramadol provided better quality pain relief.

**KEYWORDS:** Bupivacaine wound infiltration, cesarean section, intravenous dexamethasone, intravenous tramadol, postoperative pain

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## INTRODUCTION

A significant proportion of women still experience inadequate pain relief following cesarean section (CS).<sup>[1]</sup> There is evidence that severe acute postoperative pain may result in chronic, incapacitating pain after surgery.<sup>[2]</sup> The provision of effective postoperative analgesia is of key importance to facilitate early ambulation, infant care (including breastfeeding and maternal-infant bonding), and prevention of postoperative morbidity.

Infiltration of local anesthetic around the surgical wound is an important component of multimodal analgesia.<sup>[3]</sup>

Bupivacaine wound infiltration at various concentrations has been used with varying successes in the management of post-CS pain.<sup>[4]</sup> Part of the pain from surgery arises from inflammatory response to surgical incision; hence, reducing this inflammation may contribute to analgesia.<sup>[5]</sup>

Tramadol is a popular analgesic routinely used for post-CS pain management in our center at an intravenous (IV) dose

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of 100 mg. Previous studies have reported the efficacy of IV tramadol for the management of post-CS pain.<sup>[6,7]</sup>

Dexamethasone acts on the glucocorticoid receptor resulting in the decreased release of inflammatory mediators.<sup>[8]</sup> It possesses a powerful anti-inflammatory effect and has been shown to enhance analgesia at doses ranging from 1.25 to 20 mg; 8 mg is a common dose used for this purpose.<sup>[9-11]</sup> Dexamethasone may thus be beneficial in post-CS pain management.

The aim of this study was to compare the analgesic effects of a combination of bupivacaine wound infiltration with either IV dexamethasone or IV tramadol on post-CS.

## METHODS

This was a randomized, double-blind, comparative study carried out at a tertiary hospital. Clearance was obtained from the Institution's Ethics and Research Committee. The procedures followed were in accordance with the ethical standards of the Institution's Ethics and Research Committee and with the Helsinki Declaration of 1975, as revised in 2000.

American Society of Anesthesiologists (ASA) I or II pregnant women scheduled for elective or emergency CS under spinal anesthesia, who met the inclusion criteria were recruited in a period of 9 months (January to September, 2011). Written informed consent was obtained from all the participants. Preoperative assessment was done and the use of visual analog scale (VAS) for pain assessment was explained to the participants. Routine investigations (full blood count, blood grouping, and cross-matching of at least two units of blood, urinalysis) were also carried out.

Inclusion criteria were pregnant women scheduled for cesarean delivery under spinal anesthesia, ASA I or II physical health status, and Pfannenstiel incision. Exclusion criteria were patients in labor, patients with chronic pain, prior vertical skin incision, allergy to bupivacaine and the study drugs, patients who had received any form of analgesia 4 h before surgery, diabetic patients, and patients on steroids.

The sample size was determined from a previous study by Ige *et al.*<sup>[12]</sup> They reported mean time to first analgesic request of  $174 \pm 117.6$  min. Our study aimed to increase the time to 235 min because of the addition of dexamethasone or tramadol. Our sample size was 60 for each group. The study is 80% powered.

Randomization of patients was achieved by blind balloting. Equal number (60 each) of pieces of paper on which Group BD or Group BT was written were rolled up and placed in a large opaque envelope. Each patient was asked to pick one, after thoroughly shaking

the envelope, thus randomizing the patients into Group BD (bupivacaine-dexamethasone group) or Group BT (bupivacaine-tramadol group). Bupivacaine-dexamethasone group was to receive 20 ml of 0.1% plain bupivacaine wound infiltration and 8 mg of IV dexamethasone (diluted to 5 ml), while the BT group was scheduled to receive 20 ml of 0.1% plain bupivacaine wound infiltration and 100 mg of IV tramadol (diluted to 5 ml), after skin closure.

In the theater, every patient received acid prophylaxis of IV ranitidine 50 mg and IV metoclopramide 10 mg. Multiparameter monitor was attached to the patients and baseline vital signs of pulse rate, noninvasive blood pressure, arterial oxygen saturation, and electrocardiogram were obtained and recorded. Preloading was done for each patient using 15 ml/kg of IV normal saline. Spinal anesthesia was performed with the patient in the sitting position and under aseptic conditions at L3/L4 or L4/L5 interspace using 25-gauge Whitacre spinal needle. A dose of 2.3–2.5 ml of 0.5% hyperbaric bupivacaine was deposited in the subarachnoid space, depending on the patient's height. On attainment of block height of T6 to T4 dermatomal level, surgery commenced through Pfannenstiel incision. Vital signs were monitored continuously and recordings were taken at intervals of 2 min immediately after the block, then 5 min intraoperatively, and at 15 min interval in the Postanesthesia Care Unit. At the end of skin closure, pain was assessed using the VAS and the pain scores were recorded. The patients then received the study drugs on the paper picked. The 20 ml of 0.1% plain bupivacaine was aseptically prepared and handed to the surgeon; the bupivacaine was injected into the surgical wound on both sides using a 21-gauge hypodermic needle. The dexamethasone or tramadol was prepared in a syringe and slowly administered intravenously over 2 to 3 minutes by another anesthetist. The investigator and the patients were blinded to the study drugs. Postoperative pain was subsequently assessed using VAS at 10, 30, 45, 60 min, and 2, 3, 4, 6, 8, and 24 h after surgery by an anesthetist blinded to the drug allocation. Patients were asked to request for analgesic if pain exceeded mild pain (VAS >3). The time to first request for analgesic was recorded for each patient. On request for analgesic, intramuscular (IM) pentazocine 30 mg, 6 hourly, and prn (VAS score >3 before next scheduled dose) was administered to each individual. The patients' demographic characteristics, hemodynamic parameters, duration of surgery, VAS scores, the total analgesic consumption in 24 h, and incidence of side effects were documented.

The primary outcome measure was time to first analgesic request. Secondary outcomes were VAS scores, total consumption of analgesics in 24 h, side effects, and

patients' satisfaction. Patient's satisfaction was assessed 24 h postoperatively, using a 5-point Likert scale (excellent, very good, good, poor, and very poor).

Statistical analysis was done using SPSS® (Statistical Package for the Social Sciences) version 15.0, Chicago IL, USA. Data are presented as means with standard deviation and counts with percentage as appropriate. Continuous data such as age, weight, height, volume of fluid for preloading, and duration of surgery were analyzed using the unpaired Student's *t*-test. The associations in categorical data such as ASA status and level of block height were determined using Chi-square test or the Fisher's exact test where applicable. *P* < 0.05 was considered statistically significant. All tests were 2-tailed.

## RESULTS

One hundred and twenty women were enrolled in this study, 60 women in each group. There were no

withdrawals or dropouts from the study. There was no statistical difference between the two study groups with regard to age, weight, height, and ASA physical health status. The mean age of women who participated in the study was 30.62 ± 5.93 years in the BD group and 30.90 ± 5.17 years in the BT group (*P* = 0.781). Most of the women in both groups were ASA I [Table I]. The indications for CS were mostly malpresentation, cephalopelvic disproportion, and previous CS.

The difference in maximum subarachnoid block height attained in both groups was not significant statistically [Table II]. In the immediate postoperative period, VAS scores in the BD and BT groups were 1.59 ± 2.21 and 0.59 ± 1.65 cm, respectively (*P* = 0.180). The mean postoperative VAS scores of the BD group were significantly higher than those of the BT group at 30 min (2.06 ± 2.28 cm vs. 1.17 ± 1.89 cm, *P* = 0.027) and 60 min (2.90 ± 2.40 cm vs. 1.82 ± 1.79 cm, *P* = 0.008) [Figure 1].

**Table 1: Sociodemographic characteristics of patients**

	Mean±SD		<i>P</i>
	Bupivacaine-dexamethasone group (n=60), count (%)	Bupivacaine-tramadol group (n=60), count (%)	
Weight (kg)	79.78±18.31	79.29±16.82	0.854
Height (m)	1.49±0.54	1.62±0.05	0.066
ASA			
I	44 (73.3)	40 (66.7)	0.550
II	16 (26.7)	20 (33.3)	

SD=Standard deviation; ASA=American Society of Anesthesiologists

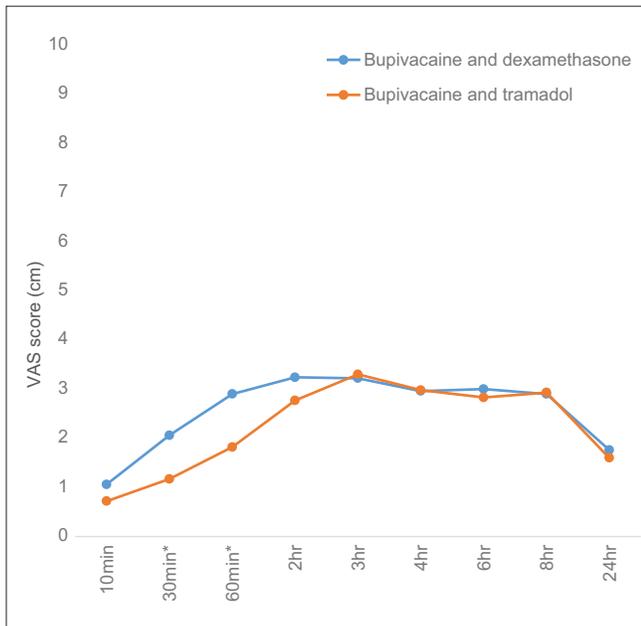
**Table 2: Maximum block height, preload volume, blood loss, duration of surgery, visual analog scale score at analgesic request, and total duration of admission**

Parameter	Mean±SD		<i>P</i>
	Bupivacaine-dexamethasone group (n=60)	Bupivacaine-tramadol group (n=60)	
Maximum block height, count (%)			
T3/T4	37 (61.7)	35 (58.3)	0.852
T5/T6	23 (38.3)	25 (41.7)	
Parameter	Bupivacaine-dexamethasone group	Bupivacaine-tramadol group	<i>P</i>
Volume of preload fluid (ml)	1,133.33±248.16	1,185.83±389.49	0.380
Estimated blood loss (ml)	598.25±464.83	513.90±342.431	0.267
Duration of surgery (h)	1.02±0.26	0.58±0.17	0.328
VAS score at time of first analgesic request (cm)	4.35±2.27	4.16±2.59	0.756
Total duration of admission after CS (days)	5.74±3.16	4.33±2.191	0.455

CS=Cesarean section; VAS=Visual analog scale; SD=Standard deviation

**Table 3: Side effects, patient satisfaction with pain relief**

Parameter	BD group (n=60), count (%)		<i>P</i>
	BD group (n=60), count (%)	BD group (n=60), count (%)	
Side effects			
Nil	52 (86.7)	50 (83.3)	0.799
Nausea and vomiting	8 (13.3)	10 (16.7)	
Satisfaction with pain relief			
Excellent, very good, good	54 (90)	56 (93.3)	0.743
Poor, very poor	6 (10)	4 (6.7)	



**Figure 1:** Mean postoperative visual analog scale scores (cm) \*( $P = 0.027, 0.008$ )

The time to first request for analgesic was  $3.2 \pm 1.87$  h in the BD group comparable to  $3.3 \pm 2.01$  h in the BT group ( $P = 0.778$ ). Total pentazocine consumption in 24 h after CS was significantly higher in the BD group ( $160.34 \pm 70.76$  mg) than in the BT group ( $136.61 \pm 44.65$  mg) ( $P = 0.035$ ).

Table III shows the side effects profile and patients' satisfaction with pain relief. They were similar in both groups.

## DISCUSSION

This study shows that bupivacaine wound infiltration with IV tramadol 100 mg was more effective than bupivacaine wound infiltration with IV dexamethasone 8 mg for post-CS pain. This is evidenced by lower postoperative VAS scores at 30 and 60 min and less total pentazocine consumption at 24 h post-CS in the bupivacaine-tramadol group. However, the study also showed that bupivacaine-dexamethasone combination may be an option for post-CS pain management as seen by the consistent low postoperative pain scores also observed in that group. The lower VAS scores in the bupivacaine-tramadol group may be explained by the fact that tramadol is an analgesic while dexamethasone is a steroid and anti-inflammatory agent.<sup>[13]</sup> Bupivacaine wound infiltration has been shown to be effective in post-CS pain management.<sup>[4,14]</sup> Tramadol (IV and IM) has also been used with some success for postcesarean pain.<sup>[7,15]</sup> Dexamethasone has anti-inflammatory property, and this could explain the low VAS scores also observed in the BD group.

The time to first request for analgesic postoperatively was more than 3 h in both groups. This cannot be attributed solely to residual analgesia from the spinal anesthesia, as previous studies have revealed that using hyperbaric bupivacaine alone intrathecally for CS results in shorter periods of adequate analgesia of 125–146 min from time of intrathecal injection.<sup>[16,17]</sup> The time to first analgesic request in both groups was similar. However, the total analgesic consumption was significantly lower in the tramadol group.

The time to first analgesic request in both groups in this study is comparable to 174 min in the study by Ige *et al.*<sup>[12]</sup> However, the patients in their study received general anesthesia, fentanyl for intraoperative analgesia, and 40 ml of 0.25% bupivacaine for wound infiltration at the end of lower abdominal surgery without any adjuvant. The similarity in the duration of time to first analgesic request in both studies (despite the lower concentration of bupivacaine [0.1%] used in our study) could be attributed to the addition of tramadol or dexamethasone in our study. A study by Momani<sup>[18]</sup> using 0.25% bupivacaine for wound infiltration after CS revealed longer time of 6–8 h before the first request of analgesia in patients who received general anesthesia or spinal anesthesia. The shorter duration of analgesia in our study could be as a result of the lower concentration of bupivacaine (0.1%) used.

Other studies have reported that IV dexamethasone enhanced postoperative analgesia after CS.<sup>[19,20]</sup> Cardoso *et al.*<sup>[19]</sup> recorded reduced postoperative pain scores after the administration of 10 mg IV dexamethasone before CS under spinal anesthesia with morphine. Shahraki *et al.*<sup>[20]</sup> reported reduced postoperative pain severity when 8 mg of IV dexamethasone was administered during CS under epidural anesthesia. In our study, 8 mg of IV dexamethasone was administered at the end of surgery, and its use may have contributed to the reduction of postoperative pain scores.

Postoperative VAS scores in both study groups were low. However, the tramadol group reported significantly lower VAS scores than the dexamethasone group at 30 and 60 min. The lower VAS scores observed in the tramadol group in the immediate postoperative period suggests that tramadol has a faster onset of action than dexamethasone. However, VAS scores in both groups were similar at the 3<sup>rd</sup> h suggesting that dexamethasone at this time had achieved an improved analgesic efficacy. This delayed analgesic effect of dexamethasone could be explained by its anti-inflammatory effect.

The total postoperative consumption of pentazocine was significantly less in the BT group compared to

the BD group, indicating that tramadol reduced the requirement for postoperative analgesia more effectively than dexamethasone. However, there was no statistical difference in the number of days the patients in both groups spent on admission after surgery.

The side effects experienced by the patients in both study groups were nausea and vomiting. Although more patients in the BT group experienced nausea and vomiting, this was not statistically significant. Dexamethasone is one of the modalities for treating postoperative nausea and vomiting; nevertheless, its antiemetic effect is better seen when administered preoperatively and when used in combination therapy.<sup>[21-23]</sup>

Side effects that may result from perioperative use of dexamethasone include gastrointestinal bleeding, impaired wound healing, and increased susceptibility to infection.<sup>[13,23]</sup> None of these side effects was observed in our study. It has been demonstrated that single dose IV dexamethasone is not harmful.<sup>[13,24,25]</sup> Single dose IV dexamethasone of 8 mg as used in this study is therefore relatively safe.

Patients' satisfaction was similar in both study groups. Most of the patients in each group rated satisfaction with pain relief as excellent, very good, or good. This is not surprising as VAS scores at the time of first request for analgesia was about 4 cm which indicated moderate pain and effective postoperative pain management.

### Limitations of the study

There was no control group (bupivacaine wound infiltration and IV normal saline), which would have highlighted further the analgesic effect of the study drugs.

### CONCLUSION

A combination of bupivacaine wound infiltration and IV tramadol after CS reduced postoperative opioid consumption. The addition of IV tramadol 100 mg or IV dexamethasone 8 mg to 20 ml of 0.1% plain bupivacaine for wound infiltration may contribute to post-CS pain relief.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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