DOI -10.21276/obgyn.2025.v12.i1.16 *ISSN Print – 2454-2334; ISSN Online – 2454-2342*

RESEARCH ARTICLE

Intraincisional bupivacaine versus tramadol for the relief of pain of the surgical site after caesarean section

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ABSTRACT

Background: Caesarean section is associated with significant postoperative pain. Pain relief plays a significant role in favourable maternal and neonatal outcome. Both bupivacaine and tramadol have analgesic properties. **Aim:** The aim of this study is to compare the safety and efficacy of intraincisional bupivacaine and tramadol for the relief of pain of the surgical site after cesarean section. **Methods**: A single blind randomized control trial study was conducted on hundred women with singleton live pregnancy undergoing caesarean section under spinal anaesthesia over a period of one and a half years. At the time of closure of abdominal wall, the patient who were allocated to group A (50) received 0.25%of bupivacaine in dose of 0.7mg/kg diluted with normal saline to make a 20ml solution while those of group B (50) patients received 2mg/kg tramadol diluted with normal saline to make a 20ml solution in the rectus sheath and subcutaneous tissue. Postoperative pain was assessed by VAS score at 4, 8 and 12hours and additional analgesic requirement was noted in the first 24 hours. Patient satisfaction assessment was done by VAS score at 24 hours .Any side effect due to these drugs was noted. **Results**: Mean age in group A was 26.78±3.94 yrs and mean age in group B was 27.50 ±3.87 yrs. Mean VAS score at 4, 8 and 12 hours in group A was 2.72 ± 0.88, 4.64±1.01 and 5.80±0.99, whereas in group B was 2.84±1.11, 4.56±1.07 and 5.66± 0.98 respectively showing that pain relief was only slightly better in the bupivacaine group at 4 hours than in the tramadol group whereas at 8 and 12 hours tramadol showed better efficacy. 35 women in group A and 37 in group B expressed satisfactory post operative analgesic management in our study. Additional analgesic was not required in 16% of women postoperatively at 8 hours. Side effects were none in group A and only nausea and vomiting in one patient and headache in 2 patients in group B. **Conclusion**: This study concludes that infiltration of bupivacaine and tramadol at the surgical site can be considered safe and effective for pain relief.

Keywords: Bupivacaine, tramadol, VAS (visual analogue score).

Cesarean section is one of the most frequently performed surgeries in obstetrics [1]. It is mostly done under spinal anesthesia [2]. Postoperative pain relief is important for early restoration of function and ability to breathe, cough and ambulate without limitation, hence preventing hypercarbia, hypoxemia, atelectasis and post operative pneumonia [3]. Enhanced recovery after surgery (ERAS) is a concept necessary especially in postpartum women for early recovery, mobilization, breast feeding, bonding with newborn, reducing thromboembolic events, postpartum depression, further in long term preventing breast cancer [4, 5].

Local infiltration of agents in the wound is one of the safest and simplest methods of pain relief without the systemic side effects of drugs. Both local anesthetics and opiods have been tried for the pain relief. They lessen wound inflammation, peripheral and central hyperalgesia. Bupivacaine is a long acting and potent local anesthetic which acts on sodium channels and blocks sensory nerves at a a lower concentration and motor paralysis at higher concentrations. It reduces local inflammatory mediators like interleukin-1 alpha which stimulate phagocytosis, chemotaxis and degranulation. Bupivacaine has very few

Received: 22nd September 2022, Peer review completed: 24th October 2023, Accepted: 29th May 2024.

Ramola M, Rawat H. Intraincisional bupivacaine versus tramadol for the relief of pain of the surgical site after caesarean section. The New Indian Journal of OBGYN. 2025; 12(1): 87-92.

side effects when used locally otherwise it is cardiotoxic when used systemically [6].

Tramadol is a synthetic codeine analogue racemic compound which is selective μ receptor agonist, has local anaesthetic effect on peripheral nerves. Tramadol has opioid and non-opioid mechanism for pain relief [7, 8]. Initially it was thought that it has only spinal and supraspinal action which causes pain relief but now many clinical studies have demonstrated that it has local anaesthetic action too [9,10]. It inhibits serotonin and nor-epinephrine reuptake. The potential advantage of local administration of tramadol is that it does not have to pass through first pass metabolism and its local action is not reversed by naloxone. Hence, this study was planned to compare the efficacy of intraincisional bupivacaine and tramadol for postcaesarean pain relief.

Materials and methods

A single blind randomized control trial study was conducted in the Department of Obstetrics and Gynaecology, at Shri Mahant Indiresh Hospital, Dehradun, Uttarakhand over a period of one and a half years between 1st August 2020 to December 31, 2021 on 100 women scheduled for caesarean section. Women with singleton live pregnancy undergoing elective or emergency caesarean section under spinal anaesthesia were included in the study. Those women who were allergic to bupivacaine or tramadol, had diabetes mellitus, hypertension, bleeding disorders, severe cardiopulmonary, renal or liver disease were excluded from the study. Patient allocated to group A (50) received 0.25% of bupivacaine in dose of 0.7mg/kg diluted with normal saline to make a 20ml solution while those of group B (50) patients received 2mg/kg tramadol diluted with normal saline to make a 20ml solution. The allocated drug was administered in the rectus sheath and subcutaneous tissue at the time of abdominal wall closure by the operating surgeon. Pain score was noted on visual analogue scale (VAS) of 0-10 as shown in figure 1. A score of 0 would depict 'no pain' and score of 10 would depict 'maximum intolerable pain'. Any additional analgesic requirement by the patient was addressed by giving injection paracetamol 1000mg in infusion form as 100ml solution. Number of doses of paracetamol required was noted for the first 12 hours. The patient was asked after 12 hours if she was satisfied with analgesic support or not and adverse effect, if any, of the drug was noted. Any other maternal or neonatal complications in the postoperative period was also been noted. Postoperative pain as assessed by VAS score at 4, 8 and 12 hours. Secondary outcomes measured were in terms of additional analgesic requirement in first 24 hours and patient satisfaction score as measured by VAS. If VAS score < 4, it means it is satisfactory.

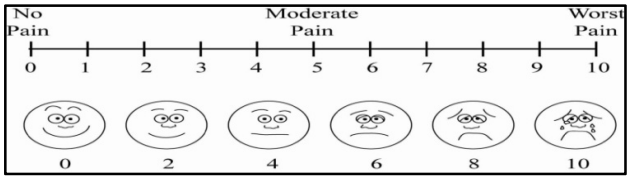

Figure1: Showing visual analogue score (VAS score)

Statistical analysis**:** Data were described in terms of range, mean ± standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups was done using ANOVA. For comparing categorical data, Chi square ($\chi 2$) test was performed and exact test was used when the expected frequency is less than 5. A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations were done using (Statistical Package for the Social Science) SPSS 21 version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

Results

Mean age group was 26.78± 3.94 years in group A and in group B was 27.50±3.87 years as shown in table 1. On statistical analysis, the mean difference between two groups was comparable and statistically not significant (p value = 0.563). In the present study, majority of women were Hindu in both groups as 84% in both group A and B, whereas, 16%women were Muslim in both groups A and B. Mean BMI (kg/m2) of group A was 24.41±2.38 and 25.47±3.28 in group B respectively which was comparable and statistically not significant (p = 0.067). Majority of women in both the groups were multigravidae 52% and 64% in group A and group B respectively. The distribution of parity was similar in both groups and the mean difference was not significant (p = 0.224).

Tables 1: Demographic details

Categories	Group A	Group B	P value
Mean age in years	26.78±3.94 yrs	27.5±3.87 yrs	0.563
Mean BMI (kg/m2)	24.41±2.38	25.47±3.28	0.067
Primi	48%	36%	0.224

The various indications for caesarean section both emergency and elective are shown in table 2 and the difference was not statistically significant.

In our study, emergency LSCS was predominant due to various indications, about 76% in group A and 86% in group B while elective cases were 24% in group A and 14% in group B. The mean birth weight in newborn in group A was

Table 2: Indications of LSCS in both groups

Indications of LSCS	Group A (n=50)		Group B (n=50)		Total	Chi Square value	P value
	N	%	N	%			
Fetal distress	21	42.00	23	46.00	44		
Previous LSCS with refusal for TOLAC	13	26.00	7	14.00	20		
Non-progression of labour (NPOL)	6	12.00	8	16.00	14	5.956	0.428
Breech	6	12.00	6	12.00	12		
2nd stage arrest of labour	3	6.00	2	4.00	5		
Previous 2 LSCS	1	2.00	4	8.00	5		
Total	50	100.00	50	100.00	100		

3071±531.32 gms and mean birth weight of babies in group B was 3017±492.11gms (p = 0.601).

Post-operatively, at 8 hours in group A, maximum women 46 (92%) had VAS score between 4-6 followed by 2 (4%) women with VAS score between 1-3 and 2 (4%) with VAS score between 7-8 and in group B, 42(84%) had VAS score between 4-6, 2(4%) women each had VAS score 7-8 and 1-3. Suggesting that majority of women felt only mild pain at 8 hours post-operatively after intraincisional bupivacaine and tramadol and the difference of VAS score was not significant (p = 0.434).

Table 3: Comparison of VAS score at 4, 8 and 12 hours post-operatively in both groups

VAS Score		Group A		Group B		Total	Chi-square value	P value
		N	%	N	%			
At 4 hours	1-3.0	39	78.0%	39	78.0%	78	.000	1.000
	4-6.0	11	22.0%	11	22.0%	22		
At 8 hours	1-3.0	2	4.0%	5	10.0%	7	1.668	0.434
	4-6.0	46	92.0%	42	84.0%	88		
	7-8.0	2	4.0%	3	6.0%	5		
At 12 hours	4-6.0	37	74.0%	42	84.0%	79	1.507	0.220
	7-8.0	13	26.0%	8	16.0%	21		
Total		50	100.0%	50	100.0%	100		

Overall neonatal outcomes, 1 (2%) baby in both the groups had jaundice, and 1 (2%) baby in group B developed neonatal sepsis. Number of NICU admissions in group A were 1 (2%) and 2 (4%) in group B. The comparison, however, between the two groups was not significant (p = 0.278).

Table 4: Comparative mean VAS scores in both groups at 4, 8 and 12 hours postoperative.

Primary outcomes	Group A		Group B		t	P value
	Mean	SD	Mean	SD		
VAS at 4 hrs:	2.72	0.88	2.84	1.11	-0.598	0.552
VAS at 8 hrs:	4.64	1.01	4.56	1.07	0.385	0.701
VAS at 12 hrs	5.80	0.99	5.66	0.98	0.710	0.479

Table 5: Comparison of additional analgesic requirement in both groups

Parenteral paracetamol infusion	Duration in hours	Group A (n=50)		Group B (n=50)		Total	Chi-square value	P value
		N	%	N	%			
0	8	8	16.0%	8	16.0%	16	1.800	0.180
	12	2	4.0%	0	0.0%	2		
Dose 1	4	9	18.0%	7	14.0%	16	5.420	0.067
	8	28	56.0%	25	50.0%	53		
	12	0	0.0%	5	10.0%	5		
Dose 2	4	2	4.0%	4	8.0%	6	0.178	0.673

Table 6: Comparison of satisfaction level in both groups

Parameters		Group A		Group B		Total	Chi-square value	P value
		N	%	N	%			
Satisfaction level (VAS<4)	Yes	35	70.0%	37	74.0%	72	0.198	0.656
	No	15	30.0%	13	26.0%	28		
Total		50	100.0%	50	100.0%	100		

The VAS scores were calculated after 4, 8 and 12 hours of surgery in both groups as shown in table 3. In group A and B, 39 (78%) women had VAS score between 1-3 and 11 women (22%) had VAS score between 4-6 at 4 hours post operatively. This difference was not significant (p = 1.000).

At 12 hours, 37 (74%) women in group A had VAS score between 4-6 followed by 13 (26%) women had VAS score between 7-8 and in group B, 42 women had a VAS score of 4-6 and 8 women had VAS score between 7-8 postoperatively. Suggesting that majority of women had a good pain relief upto 8 hours and increased thereafter till 12 hours post-operatively (p = 0.220).

The table 4 shows mean post-op VAS score in bupivacaine and tramadol group. Mean VAS score at 4 hours in bupivacaine group was 2.72±0.88 and mean VAS score in tramadol group was 2.84± 1.11 which was statistically not significant (p = 0.552). At 8 hours post-operatively, the mean VAS score in bupivacaine group was 4.64±1.01 and in mean VAS score in tramadol group was 4.56±1.07, this difference was not significant (p = 0.701). At 12 hours post-operatively, the mean VAS score in

bupivacaine group was 5.80±0.99 and mean VAS score in tramadol group was 5.66±0.98, which again was not significant (p = 0.479). Suggesting that at 12 hours post-operatively, tramadol showed better VAS score, difference being statistically insignificant.

As shown in table 5, 8(16%) women in both the groups did not require any additional analgesia upto 8 hours. In group A, 2 (4%) women did not need any analgesic upto 12 hours. This difference was not significant (p = 0.180). Single dose of parenteral paracetamol 1000 mgs was given as additional analgesic postoperatively to 9 (18%) in group A and 7 (14%) in group B upto 4 hours, 28 (56%) in group A and 25 (50%) in group B upto 8 hours and 0 women in group A and 5 (10%) in group B upto 12 hours. This difference was not significant (p-value=0.067). Second dose of additional analgesic was given to 2 (4%) in group A and 4 (8%) in group B upto 4 hours postoperatively (p = 0.673). In group A, none of them had any side effect. In group B, 46 women had no side effects, 2 of them had headache, and 1 patient each had nausea and vomiting.

Out of 50 women, as shown in table 6, 35(70%) of them in group A and 37(74%) in group B expressed satisfactory post operative analgesic management at 24 hour in our study, while,15 (30%) women of group A and 13 (26%) women of group B were not satisfied.

Discussion

The study was done on 100 women who had caesarean section for a period of one and a half years. Behdad et al [11] studied the effect of bupivacaine or tramadol when used as local infiltration in subcutaneous tissue in women undergoing caesarean section in doses of 10 ml of 0.5% and 50mg in 10ml respectively in 60 women divided into two groups of 30 participants each. They reported insignificant difference in the mean age between the two. Similarly, comparable age of the enrolled women has been reported by Sahmeddini et al and Jayashree et al [12, 13]. As our study was a randomized trial, hence it is expected to have comparable age of the participants of the study.

Only few studies have reported on the gravidity of the enrolled women. Behdad et al reported a 36.6% inclusion of primigravidae and remaining multigravidae in their study which was carried out only on elective caesarean section cases [11]. Similar insignificant difference has been reported by Jayashree et al [13].

In a similar study by Mohammad Ali Sahmeddini, et al, in a randomized double blind trial of tramadol and bupivacaine for postoperative pain management in 98 women who had elective cesarean section, the mean age of women understudy was 26.7±3.95 yrs in bupivacaine group and 26.6±3.38 in tramadol group, a finding similar to our study [12]. Other demographic features like weight, BMI and operative time in this study was similar in both the groups.

Sahmeddini et al [12], reported in their study that pain relief with tramadol at 16 hours was better than bupivacaine. Postoperatively, there was no significant difference between these 2 groups in their VAS scores until 16 hours (p>0.05). However, at the 16th and 24th hours, the mean VAS scores were 3.20±2.24 and 2.51±2.55 in the bupivacaine group and 2.51±0.99 and 1.40±0.88 in the tramadol group, respectively (p>0.05) [12]. Similar study was done by Behdad et al [11] where VAS scores did not differ significantly at 1 and 2 hours between two groups but better pain relief was noted in the tramadol group at 6 hours. Our study also observed that tramadol was better analgesic than bupivacaine upto 12 hours but no significant difference was seen between both the groups. Amin et al also compared post-operative pain scores in 100 women undergoing caesarean section using local infiltration of 0.5% bupivacaine and 400mg/24 hours intravenous dose of tramadol. This study also reported that bupivacaine give similar pain relief upto 8 hours and thereafter it is less efficacious than tramadol [14].

However, Givens et al [15] have reported no statistically significant difference in VAS score between bupivacaine and placebo at 12 hours, 24 hours and 48 hours in their study. In another study, conducted by Demiraran et al [16] 90 women were randomly allocated in one of the 3 groups (30 in each group) to receive local wound infiltration of 20 ml of 0.25% levobupivacaine within 0.9% normal saline, 20 ml of 1.5 mg/kg tramadol and 20 ml of 0.9% normal saline. It showed that the mean VAS score of levobupivacaine was lower than tramadol at 2 hours, 4 hours, 8 hours, 12 hours, 16 hours, 20 hours and 24 hours but it was found to be comparable. Jabalameli et al conducted double-blind, prospective, randomized study to compare the efficacy of subcutaneous bupivacaine, pethidine and tramadol for post-caesarean pain relief on 120 women who were scheduled for caesarean section and they were randomly allocated in 4 groups (30 in each group). They showed that tramadol and pethidine provided better pain relief than bupivacaine in the first 2 postoperative hours and also at 12 hours. However, they reported these 3 agents to be equally efficacious at 6 hours and 24 hours postoperatively [17].

Most of the studies available in literature have not evaluated the additional analgesic requirement in term of

dosage and timing of additional analgesic agent required. Some studies have reported the use of other analgesic agents like morphine (Sahmeddini et al [12], Jabalameli et al [17]) pentazocine (Behdad et al [11]) and Amin et al [14] had used additional dose of tramadol as the add on analgesic. Behdad et al [11] shows that postoperative consumption of analgesic was higher in bupivacaine group than tramadol group but the difference was not significant. No side effects were reported in either group.

The present study has demonstrated the safety of both the agents used intraincisionally. Opiates otherwise are expected to cause a deleterious effect on respiration when used systemically. However, it is observed from our study that intraincisional instillation of neither agent has any depressant effect on maternal respiration. Mild nausea and vomiting (4% women had headache and 2% women had vomiting and nausea) with the tramadol group was observed which were manageable symptomatically. Our study also corroborates the safety of these agents for neonates as mostly there were no as such neonatal complications. Other studies have also reported the safety of these agents when used intraincisionally.

In the study by Sahmeddini et al [12], there was no difference in nausea and vomiting during the 24-hour period between the two groups. In our study, 70% women in group A and 74% in group B expressed satisfaction with analgesia, thus making tramadol a better analgesic with prolonged duration of action for postoperative pain control. Only few other studies have reported on the satisfaction levels.

Jabalameli et al [17] classified satisfaction scores in 4 categories like poor, good, very good and excellent. In this study, 33% patients in bupivacaine group and 16.7% patients in tramadol group were not satisfied and most of the other patients had only good satisfaction scores.

Conclusion

The present study concludes that intraincisional local infiltration of bupivacaine and tramadol provide safe post operative analgesia for the first 24 hours after caesarean section, hence leading to exemplary maternal and neonatal outcome. Both drugs i.e bupivacaine and tramadol had similar efficacy for the pain control post operatively for upto 6 hours. The effect of analgesia attained its peak between 4-8 hours and started waning after 8 hours but the difference was not found to be statistically significant. There were no maternal complications seen in both bupivacaine and tramadol groups. Few maternal side-effects like headache, nausea and vomiting were seen in the tramadol group and none in the bupivacaine group.

Conflict of interest: None. **Disclaimer:** Nil.

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