**ORIGINAL RESEARCH**

# Comparison of the Analgesic Efficacy of Wound Infiltration with Tramadol versus Bupivacaine for Postoperative Pain Relief in Caesarean Section Under Subarachnoid Block: A Randomized Controlled Trial

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## ABSTRACT

**Background:** We intend to compare the wound infiltration with tramadol or bupivacaine on postoperative pain relief in patients undergoing caesarean section under subarachnoid block.**Materials &Methods:**A sample size of 40 was taken in each group. Patients belonging to group T received tramadol hydrochloride 2 mg/kg in 20 mL of 0.9% normal saline while those belonging to group B received 20 mL of 0.25% isobaric bupivacaine. Drugs used in the study were prepared by an investigator not involved with patient's enrollment or data collection. The study drug was administered subcutaneously at the time of skin closure on both sides of incision by the operating obstetrician. NRS was assessed at 0, 1, 2, 6, 12 and 24 h after arrival in the recovery room or ward by the anaesthesiologist who was unaware of the drug administered for wound infiltration. Diclofenac sodium 75 mg IV and Paracetamol (1gms) IV was administered as a rescue analgesic if at any time NRS is more than 4 or the patient complained of pain. In the postanesthesia care unit (PACU) and ward, pain was assessed using a Numerical Rating Scale. The consumption of ondansetron and the rescue analgesics (Diclofenac and Paracetamol) over the first 24 h following surgery was noted.**Results:** Mean NRS was significantly higher among patients of group T in comparison to patients of group B at 6 hours, 12 hours and 24 hours. Mean time to first rescue analgesia was significantly higher among patients of group T in comparison to patients of group B. Total dose of analgesia consumed among patients of group B was significantly higher as compared to patients of group T.**Conclusion:** Significantly better results were obtained among patients of tramadol group in comparison to bupivacaine group.

**Key words:** Tramadol, Bupivacaine, Caesarean section.



## INTRODUCTION

Caesarean section is one of the most frequently performed surgeries in obstetrics. Optimal pain relief of the mother results in early mobilization and initiation of breast feeding. Multimodal analgesia is expected to provide high quality analgesia.[1] Different methods such as drugs [nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, corticosteroids], and peroperative local anaesthetic infiltration have been used to reduce pain. Subcutaneous administration of opiates is a method of postoperative pain control after caesarean section.[2]Opioids provide effective analgesia but side-effects, especially respiratory depression, emesis and sedation, reduce the advantages. In addition to decreasing the cost and side effects of opioids, the use of local wound site infiltration with tramadol or bupivacaine also supports the principle of multimodal analgesia. And, it can also be a straightforward, cheap, and effective technique and is employed in various hospitals without any major side effects. The wound site infiltration with bupivacaine has a bacteriostatic and bactericidal effect that reduces the risk of infection at the wound site.[3]Tramadol is a centrally acting analgesic. Its analgesic effects are mediated by at least three different mechanisms: it is a

weak μ opioid receptor agonist, it inhibits the reuptake of the neurotransmitters hydroxytryptamine (5-HT) and noradrenaline in the descending inhibitory pain pathways and facilitates 5-HT release. Recent studies suggest that tramadol possesses some local anesthetic properties when applied to peripheral nerves.[4]The purpose of this study is to gather the evidence and gap of knowledge from the literature. Therefore, we intend to compare the wound infiltration with tramadol or bupivacaine on postoperative pain relief in patients undergoing caesarean section under subarachnoid block.

## MATERIAL AND METHODS

The Hospital-based study was conducted in the Department of Anaesthesiology & Critical Care in Maharaja Agrasen Medical College, Agroha, Hisar, Haryana, India. It was a Double arm, parallel group, double blind, randomized active controlled trial. We enrolled adult female patients between 18- and 35-years age, belonging to American Society of Anaesthesiologists' physical status II[6] undergoing caesarean section under subarachnoid block.According to randomized study done by Sahmeddini et al[5], asample size of 40 was taken in each group.During pre-anaesthetic check-up, a detailed clinical history followed by general physical examination was carried out. Haemoglobin, bleeding time, clotting time, platelet count was carried out in all patients. The protocol of the study was explained to all the patients and informed written consent to participate in the study was taken from the patient. The patient was kept fasting for 6 hours for solids and 2 hours for liquids prior to the scheduled time for surgery. After arrival in the operating room standard monitoring comprising of electrocardiography (ECG), pulse oximetry (Spo2) and non-invasive blood pressure (NIBP) was established. Baseline readings of vital parameters was recorded. Intravenous line (iv) was secured with 18G intravenous cannula and infusion of Ringer's Lactate was started. The patients were positioned by a trained assistant in sitting position. Under all aseptic precautions, 25-gauge Quincke's spinal needle was inserted intrathecally at L4-L5 or L3-L4 intervertebral space. Intrathecal positioning was confirmed by observation of clear, free flow of cerebrospinal fluid through the needle and subarachnoid block was established with 2.0–2.2 mL hyperbaric bupivacaine 0.5%. A level of T6 was considered adequate for surgery.Randomisation was done using computer generated random number sequence. Allocation concealment was done by SNOSE(Sequentially numbered, opaque, sealed envelope) technique. The person who is giving the drug and the analyst was blinded to the study drug.Patients belonging to group T received tramadol hydrochloride 2 mg/kg in 20 mL of 0.9% normal saline while those belonging to group B received20 mL of 0.25% isobaric bupivacaine.Drugs used in the study were prepared by an investigator not involved with patient's enrolment or data collection. The study drug was administered subcutaneously at the time of skin closure on both sides of incision by the operating obstetrician. NRS was assessed at 0, 1, 2, 6, 12 and 24 h after arrival in the recovery room or ward by the anaesthesiologist who was unaware of the drug administered for wound infiltration. Diclofenac sodium 75 mg IV and Paracetamol (1gms) IV was administered as a rescue analgesic if at any time NRS is more than 4 or the patient complained of pain.In the postanesthesia care unit (PACU) and ward, pain was assessed using a Numerical Rating Scale. The scale consists of horizontal lines that range from 0 (no pain) to 10 (extreme pain). Patients was asked to rate their pain on an 11-point scale by a verbal command, and the intensity of the pain was classified as mild (NRS: 0–3), moderate (NRS: 4–6), or severe (NRS: 7–10). [3] Incidence of nausea, vomiting, and shivering was noted. Nausea or vomiting was managed with IV ondansetron 0.1 mg/kg.The consumption of ondansetron and the rescue analgesics (Diclofenac and Paracetamol) over the first 24 h following surgery was noted.The data was entered into a Microsoft Excel spreadsheet and analysed using standard statistical software SPSS® statistical package version 22. Categorical variables were analysed using Chi square test.Normally distributed variables were analysed using the independent sample *t* test.

## RESULTS

Mean age of the patients of group T and group B was 23.98 years and 25.78 years respectively. Mean duration of surgery among patients of group T and group B was 42.63 minutes and 42.38 minutes respectively. Mean length of incision among patients of group T and group B was 8.75 mm and 8.98 mm respectively. Mean NRS was significantly higher among patients of group T in comparison to patients of group B at 6 hours, 12 hours and 24 hours. Mean time to first rescue analgesia was significantly higher among patients of group T in comparison to patients of group B. Total dose of analgesia consumed among patients of group B was significantly higher as compared to patients of group T.

**Table 1: Comparison of duration of surgery (minutes) among study participants in two groups**

| Groups | Mean | Std. Deviation | t value | p value |
|---|---|---|---|---|
| **Group T** | 42.63 | 4.23 | 0.204 | 0.839 |
| **Group B** | 42.38 | 6.50 | | |

**Table 2: Comparison of length of incision (mm) among study participants in two groups**

| Groups | Mean | Std. Deviation | t value | p value |
|---|---|---|---|---|
| **Group T** | 8.75 | 0.98 | -1.016 | 0.313 |
| **Group B** | 8.98 | 1.00 | | |

**Table 3: Comparison of NRS score among study participants in two groups at different time intervals**

| Time Interval | Groups | Mean | Std. Deviation | t value | p value |
|---|---|---|---|---|---|
| **0 Hr** | **Group T** | 0.00 | 0.00 | NA | NA |
| | **Group B** | 0.00 | 0.00 | | |
| **1 Hr** | **Group T** | 0.00 | 0.00 | NA | NA |
| | **Group B** | 0.00 | 0.00 | | |
| **2 Hrs** | **Group T** | 0.00 | 0.00 | NA | NA |
| | **Group B** | 0.00 | 0.00 | | |
| **6 Hrs** | **Group T** | 3.75 | 1.03 | 22.183 | <0.01* |
| | **Group B** | 0.05 | 0.22 | | |
| **12 Hrs** | **Group T** | 6.03 | 0.70 | 20.531 | <0.01* |
| | **Group B** | 0.50 | 1.55 | | |
| **24 Hrs** | **Group T** | 8.28 | 0.88 | 22.697 | <0.01* |
| | **Group B** | 0.75 | 1.90 | | |

**Statistically significant*

**Table 4: Comparison of time to first analgesic demand after surgery(minutes) among study participants in two groups**

| Groups | Mean | Std. Deviation | t value | p value |
|---|---|---|---|---|
| **Group T** | 358.50 | 53.47 | 5.564 | <0.01* |
| **Group B** | 100.50 | 288.36 | | |

**Statistically significant*

**Table 5: Comparison of number of study participants in the two study groups according to analgesic consumption of diclofenac at different time interval**

| Time Interval | Dose (mg) | Group T | | Group B | | Chi square value | p value |
|---|---|---|---|---|---|---|---|
| | | Frequency | Percent | Frequency | Percent | | |
| **0-2 Hrs** | **0** | 40 | 100.0 | 40 | 100.0 | NA | NA |
| **2-4 Hrs** | **0** | 40 | 100.0 | 40 | 100.0 | NA | NA |
| **4-6 Hrs** | **0** | 28 | 70.0 | 40 | 100.0 | 14.117 | <0.01* |
| | **75** | 12 | 30.0 | 0 | 0.0 | | |
| **6-12 Hrs** | **0** | 8 | 20.0 | 39 | 97.5 | 49.56 | <0.01* |
| | **75** | 32 | 80.0 | 1 | 2.5 | | |
| **12-24 Hrs** | **0** | 0 | 0.0 | 35 | 87.5 | 62.27 | <0.01* |
| | **75** | 39 | 97.5 | 5 | 12.5 | | |
| | **150** | 1 | 2.5 | 0 | 0.0 | | |

**Statistically significant*

**Table 6: Comparison of number of study participants in the two study groups according to analgesic consumption of paracetamol at different time interval**

| Time Interval | Dose (gm) | Group T | | Group B | | Chi square value | p value |
|---|---|---|---|---|---|---|---|
| | | Frequency | Percent | Frequency | Percent | | |
| **0-2 Hrs** | **0** | 40 | 100.0 | 40 | 100.0 | NA | NA |
| **2-4 Hrs** | **0** | 40 | 100.0 | 40 | 100.0 | NA | NA |
| **4-6 Hrs** | **0** | 40 | 100.0 | 40 | 100.0 | NA | NA |
| **6-12 Hrs** | **0** | 24 | 60.0 | 40 | 100.0 | 20.00 | <0.01* |
| | **1** | 16 | 40.0 | 0 | 0.0 | | |
| **12-24 Hrs** | **0** | 0 | 0.0 | 36 | 90.0 | 65.45 | <0.01* |
| | **1** | 40 | 100.0 | 4 | 10.0 | | |

**Statistically significant*

**Table 7: Comparison of total dose of analgesic consumed by study participants in the two study groups.**

| Drug | Group | Mean | Std. Deviation | t value | p value |
|---|---|---|---|---|---|
| **Diclofenac (mg)** | **Group B** | 161.25 | 27.12 | 22.616 | <0.01* |
| | **Group T** | 11.25 | 32.00 | | |
| **Paracetamol(gm)** | **Group B** | 1.38 | 0.49 | 13.98 | <0.01* |
| | **Group T** | 0.10 | 0.30 | | |

**Statistically significant*

**Table 8: Comparison of frequency distribution of study participants in the two study groups showing complications**

| Groups | | Frequency | Percent |
|---|---|---|---|
| **Group T** | **None** | 40 | 100.0 |
| **Group B** | **None** | 38 | 95.0 |
| | **Vomiting** | 2 | 5.0 |
| **Chi Square value; p value** | | 2.05; 0.152 | |

## DISCUSSION

The most common surgical procedure in women of childbearing age is caesarean section. Adequate postoperative pain control is an important postoperative care in most procedures to reduce morbidity and mortality in patients. Postoperative pain control assumes even greater importance after caesarean section because the patients are mothers who must be ready to nurse their babies as early as possible. In addition, it should also be safe for neonates, who are being breastfed.[6- 8] Be that as it may, there seems to be no gold standard method for post caesarean pain management and several methods that are currently used include opioids, additional non-opioid painkillers, peripheral nerve block, and other supplementary techniques. Due to the complications of general anesthesia, nowadays, regional anesthesia is commonly used for caesarean section, which provides a route for postoperative analgesia through neuraxial opioids. However, each method has been investigated by several studies and each is proposed to have several advantages and disadvantages.[8- 10]

Mean age of the patients of group B and group T was 23.98 years and 25.78 years respectively. Mean duration of surgery among patients of group T and group B was 42.63 minutes and 42.38 minutes respectively. Mean length of incision among patients of group T and group B was 8.75 mm and 8.98 mm respectively. Mean NRS was significantly higher among patients of group T in comparison to patients of group B at 6 hours, 12 hours and 24 hours. Sachidananda et al conducted a double-blind randomized trial to compare analgesic efficacy of wound infiltration with bupivacaine versus mixture of bupivacaine and tramadol for postoperative pain relief in 60 pregnant women of age group 18–35 years, undergoing elective caesarean section under spinal anaesthesia and concluded that subcutaneous wound infiltration with tramadol and bupivacaine prolongs the pain free period and analgesic consumption.[1] in another study conducted by Sahmeddini et al, authors conducted a double blind randomized controlled study to observe the effect of local Infiltration of Tramadol versus Bupivacaine for post caesarean section pain control in 98 patients eligible for elective caesarean section under general anesthesia, were randomly allocated to 2 groups. Before wound closure, 20 cc of 0.025%bupivacaine and 2 mg/kg of tramadol, diluted to 20 cc, were infiltrated at the wound site in groups A and B, respectively. After surgery, the pain score was measured using the visual analogue scale (VAS).They concluded that local infiltration of tramadol (2 mg/kg) at the incision site of caesarean section was effective in somatic wound pain relief without significant complications.[5]

In the present study, mean time to first rescue analgesia was significantly higher among patients of group T in comparison to patients of group B. Total dose of analgesia consumed among patients of group B was significantly higher as compared to patients of group T. Behdad S et al in another previous study, evaluated the effects of tramadol versus bupivacaine administration at wound closure on postoperative pain relief in patients undergoing caesarean section. Sixty women undergoing caesarean deliveries were randomly assigned to receive either 10 mL of bupivacaine 0.5% (n = 30) or 50 mg of tramadol in 10 mL of normal saline (n = 30), both as local wound infiltration prior to skin closure at the end of operation. Postoperative pain was evaluated with a visual analogue scale (VAS: 0-10) at 1, 2 and 6 hours after operation. Time to first analgesic administration and analgesic consumption in 24 hours after operation were recorded and compared between the two groups. Data were analyzed by SPSS software version 15 and $p < 0.05$ was considered significant. The VAS score did not differ significantly between the two groups at 1 and 2 hours after caesarean section, but it was higher in bupivacaine group than tramadol group 6 hours after operation ($p < 0.05$; Fisher exact test). Postoperative consumption of analgesic was higher in bupivacaine group than tramadol group but the difference was not significant ($p > 0.05$; Fisher exact test). No side effects were reported in either group. Their study showed that subcutaneous administration of tramadol provided analgesic effect equal to

bupivacaine with longer pain relief after caesarean section.[11]

## CONCLUSION

Significantly better results were obtained among patients of tramadol group in comparison to bupivacaine group.

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