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A COMPARATIVE ANALYSIS OF DURATION OF POSTOPERATIVE ANALGESIA BETWEEN LEVOBUPIVACAINE AND LEVOBUPIVACAINE WITH CLONIDINE AFTER ULTRASOUND-GUIDED TRANSVERSE ABDOMINIS PLANE BLOCK IN A PATIENT UNDERGOING LOWER SEGMENT CAESAREAN SECTION UNDER SUBARACHNOID BLOCK

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#### Abstract

Background: Peripheral nerve blockade has gained popularity due to its pain reduction, reduced need for postoperative analgesics, and reduced nausea and vomiting. Ultrasound-guided techniques, such as the posterior approach technique, improve success and reduce complications. The study aimed to compare the duration of postoperative analgesia between 0.25% levobupivacaine & 0.25% levobupivacaine with clonidine after ultrasoundguided transversus abdominis plane block in lower segment caesarean section. Materials and Methods: This prospective randomised, double-blinded, casecontrol study was done at Govt Stanley Medical College, Chennai, on 60 antenatal mothers who underwent caesarean section by Pfannenstiel incision. Sixty patients were divided into two groups: Group A received a subarachnoid block with 0.5% hyperbaric injection of Bupivacaine 10mg followed by a transversus abdominis plane block with 20ml of 0.25% Levobupivacaine, and Group B, consisting of 30 antenatal mothers, with Clonidine 0.5mg/kg. Result: The demographic profile, duration of surgery and hemodynamic parameters were comparable in both groups without any significant difference. There is a significant difference in the duration of analgesia (mins) and Ramsay Sedation Score between groups (p<0.001). There is no significant difference in complications and bradycardia between groups, but a significant difference in Inj. Tramadol consumption between groups (p<0.001). The sedation score of 3 was obtained in about 80% of the patients in group B, which is statistically significant. Conclusion: Ultrasound technology improves the success rate and safety of Transversus Abdominis Plane (TAP) blocks, providing effective postoperative analgesia after caesarean sections with minimal sedation and rescue analgesia.

#### INTRODUCTION

Pain is a crucial postoperative sign, encompassing sensory discriminative and motivational-affective components. It's a physical, emotional, and psychological condition and a fundamental right.<sup>[1]</sup> Postoperative pain in lower-segment caesareansection women is moderate to severe, making it challenging for anesthesiologists to manage effectively and minimise complications.<sup>[2]</sup> This ensures women are alert and comfortable in caring for their newborns. The use of peripheral nerve blockade has grown in popularity because it decreases pain as assessed by visual analogue scores postoperatively, decreases the need for postoperative analgesics, decreases the incidence of nausea and vomiting, short stays at post-anaesthesia care unit time and increases patient satisfaction.<sup>[3]</sup>

In earlier years, abdominal field blocks were provided by multiple injections of local anaesthetics along the abdominal wall layers. Instead of multiple punctures, a single needle puncture technique through the Petit triangle is used in the Transversus Abdominis Plane block.<sup>[4]</sup> Hebbeard et al. described the usage of ultrasound for the Transversus Abdominis Plane Block in 2007.<sup>[5]</sup> The results were better in ultrasound-guided techniques of the Transversus Abdominis Plane Block. The most commonly used ultrasound-guided technique is the posterior approach technique.

Ultrasound guidance for locating peripheral nerves and neurofascial planes improves the success of the Transversus Abdominis Plane block with fewer complications.<sup>[6]</sup> This technique visualises various structures in real-time, guiding the needle towards targeted nerves and reducing opioid requirements. Perineural catheters can be introduced to prolong analgesia beyond the pharmacological duration of local anaesthetics, allowing for prolonged infusion or coadministration of adjuvants like Epinephrine, alpha 2 agonists, Midazolam, or Corticosteroids.<sup>[7]</sup> These techniques can provide analgesia for several days but are limited by difficulties in placement and removal and rarely due to infection.

The adjuvant drugs used with local anaesthetics reduced the dose requirement of local anaesthesia with enhanced analgesic efficacy and reduced incidence of adverse reactions. Injection of  $\alpha 2$ adrenergic agonistic drugs has been suggested for enhancing the quality of nerve block. Clonidine has selective agonistic activity in  $\alpha$ 1 adrenergic receptors with some agonist activity towards  $\alpha 1$  receptors.<sup>[8-10]</sup> The study aimed to compare the duration of postoperative analgesia between 0.25% levobupivacaine & 0.25% levobupivacaine with clonidine after ultrasound-guided transversus abdominis plane block in lower segment caesarean section. We also measured the rescue analgesic consumption in the first 24 hours after the block, patient satisfaction, hemodynamic stability, and possible side effects of the drugs used (Clonidine, Levobupivacaine, Bupivacaine).

# **MATERIALS AND METHODS**

This prospective randomised, double-blinded, casecontrol study was done at, Govt Stanley Medical College, Chennai, on 60 antenatal mothers who underwent caesarean section by Pfannenstiel incision. Institutional Ethical Committee approval was obtained with a proper explanation, and a written informed consent was obtained.

## Inclusion Criteria

All consenting antenatal mothers above 18 years and ASA PS I and II patients were included.

Sixty patients were divided into Group A and Group B. Group A of 30 Antenatal Mothers Subarachnoid Block with 0.5% hyperbaric Inj. Bupivacaine 10mg followed by Transversus Abdominis Plane block with 20 ml of 0.25% Levobupivacaine. Group B of 30 Antenatal Mothers Subarachnoid Block with 0.5% hyperbaric Inj. Bupivacaine 10mg followed by Transversus Abdominis Plane Block with 20ml of 0.25% Levobupivacaine + Clonidine 0.5mic.gm/kg. A detailed history and physical examination were done in the preoperative waiting room. Baseline data like (PR, BP, RR) and basic investigations were collected. Both groups explained the procedures (SAB and TAP Block) and postoperative follow-up patterns. The VAS was explained as a 0-10 cm scale reading, and the patient was asked to tell the number or mark on the scale.

Common to both groups are 18G IV Cannula was secured, and preloading was done with a balanced salt solution. Under aseptic precaution, in the lateral position, a subarachnoid block was given with 0.5% Bupivacaine 10 mg using 25G Quincke's spinal needle to all the patients in both groups. The patient was monitored intra-operatively, and after the surgical procedure, the patient's sensory level was assessed; once the sensory level reached T10, a TAP block was performed.

Under aseptic precaution, TAP Block was performed bilaterally. An ultrasound-guided posterior TAP block technique was used to locate the Transversus abdominis plane. Syringes containing 20ml of 0.25% levobupivacaine or 20ml of 0.25% levobupivacaine with clonidine 0.5mic.gm/kg was prepared aseptically. Investigators were blinded to the injected solution.

A high-frequency ultrasound probe visualised the subcutaneous fat and anterior abdominal wall muscles. A 23G Quincke's needle was inserted anterior to the probe, and a small volume of drug was injected to confirm the correct plane and needle tip. 20 ml of the prepared solution was injected on both the left and right sides. The injection was successful when an echo lucent lens-shape (bi-convex) area appeared between the two muscles. Patients were shifted to the postoperative ward after closely observing for signs of toxicity.

The degree of pain was observed using a 10cm VAS (Visual Analog Scale) in 2, 4, 6, 8, 12, 18, and 24 hours. "0" represents "no pain", and "10" represents "worst pain". Sedation was monitored using a 6-point Ramsay sedation score. Vital parameters pulse rate, blood pressure changes, respiratory rate changes, SpO2, symptoms and signs of local anaesthetic toxicity, clonidine, other side effects of blocks and complications were recorded in the immediate postoperative period after TAP block. The study's primary endpoint was when the VAS score reached  $\geq$ 4. Inj. Tramadol 100mg intramuscularly (with Inj. 75micgm/kg Ondansetron intravenously prophylactically) was used as the first rescue analgesia on demand or when the VAS score was  $\geq$ 4.

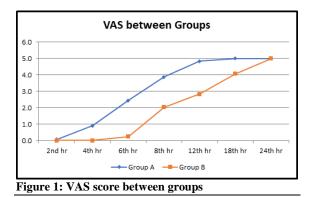
#### **Statistical Analysis**

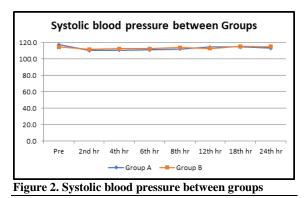
The collected data were analysed with IBM SPSS Statistics for Windows, Version 23.0. (Armonk, NY: IBM Corp). Descriptive statistics frequency analysis and percentage analysis were used for categorical variables, and the mean & SD were used for continuous variables. The Unpaired sample t-test and the Mann-Whitney U were used to find the significant difference between the bivariate samples in independent groups. The Chi-Square test was used similarly to find the significance in categorical data; Fisher's Exact was used if the expected cell frequency was less than 5 in  $2\times 2$  tables. The probability value <0.05 was considered significant in all the statistical tools.

## **RESULTS**

All data were analysed, and the demographic profile, duration of surgery and hemodynamic parameters were comparable in both groups without any significant difference. The average duration of analgesia was 835 minutes in 0.25% levobupivacaine and clonidine group compared to 487 minutes in plain 0.25% levobupivacaine group, and this duration of analgesia was statistically significant (p-value=0.0005), in 0.25% levobupivacaine with clonidine group when compared to 0.25% levobupivacaine group. There is a significant difference in Ramsay Sedation Score between groups (p<0.001) [Table 1].

There is no significant difference in complications and bradycardia between groups. There is a significant difference in Inj. Tramadol consumption between groups (p<0.001) [Table 2].

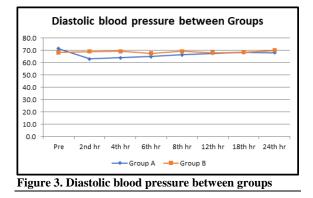




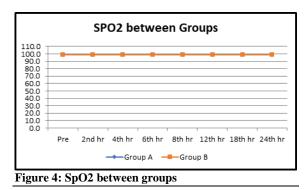
[Figure 1] compares the Visual Analogue Scale with Groups where all the time durations show highly statistically significant differences at p < 0.01. In contrast, the time durations of the Visual Analogue Scale at the 2nd hour (Z-value=1.426, p-value=0.154

> 0.05) and the 24th hour (Z-value=0.000, p-value=1.000 (>0.05) with groups show no statistically significant difference.

[Figure 2] shows systolic blood pressure with groups where all the time durations show no statistically significant difference at p>0.05.



[Figure 3] compares diastolic blood pressure with groups where all the time durations show no statistically significant difference at p > 0.05. In contrast, the time durations of diastolic blood pressure at the 6th hour (t-value=2.155, p-value=0.035<0.05), 8th hour (t-value=2.005, p-value=0.049<0.05) with groups show statistically significant difference at p < 0.05 level. Similarly, the time durations of diastolic blood pressure at 2nd hour (t-value=4.580, p-value=0.0005<0.01), 4th hour (t-value=4.065, p-value=0.0005<0.01) with groups shows highly statistically significant difference at p < 0.01 level.



[Figure 4] shows SpO2 with groups where all the time durations show no statistically significant difference at p>0.05.

The sedation score of 3 was obtained in about 80% of the patients in 0.25% levobupivacaine and clonidine group compared to only 6.67% of patients in plain 0.25% levobupivacaine group. Thus, the sedation score was statistically significant (p=0.0005) in 0.25% levobupivacaine with clonidine group, but it was an arousable sleep. The usage of rescue analgesia was 100% in 0.25% levobupivacaine and only 20% in 0.25% levobupivacaine with clonidine group; thus, the usage of Inj. Tramadol was highly statistically significant (p=0.0005). Hemodynamic stability in terms of changes in pulse rate and blood pressure were compared in both groups, and there was a statistically significant difference between them (p<0.05). Thus, by adding clonidine to 0.25%,

levobupivacine extended the duration of analgesia without any significant side effects in ultrasoundguided transversus abdominis plane block.

|                              | Group A         | Group B        | P-value |
|------------------------------|-----------------|----------------|---------|
| Age/years                    | $28 \pm 4.3$    | $26 \pm 4.1$   | 0.066   |
| BMI                          | $28 \pm 4.4$    | $26.6 \pm 4.7$ | 0.249   |
| Duration of surgery          | $65.3 \pm 10.8$ | $64.2\pm7.6$   | 0.63    |
| Duration of analgesia (mins) | 487 ± 43.5      | 835.8 ± 38.6   | 0.0005  |
| Ramsay Sedation Score        | $2.1 \pm 0.3$   | $2.8 \pm 0.4$  | 0.0005  |

| Table 2: Complications, | Bradycardia, and In  | i. Tramadol consum | ntion between groups |
|-------------------------|----------------------|--------------------|----------------------|
| Tuble 2. Complications, | Diauy cui uiu, unu m | j. ITamaaor consum | phon between groups  |

|                                       |          | Group A    | Group B    | P-value |
|---------------------------------------|----------|------------|------------|---------|
| Complications                         | Nausea   | 2 (6.7%)   | 0.00%      | 0.232   |
|                                       | Vomiting | 1 (3.3%)   | 0.00%      |         |
|                                       | Both     | 1 (3.3%)   | 0.00%      |         |
|                                       | Nil      | 26 (86.7%) | 30 (100%)  |         |
| Bradycardia                           | No       | 30 (100%)  | 26 (86.7%) | 0.112   |
|                                       | Yes      | 0.00%      | 4 (13.3%)  |         |
| Inj. Tramadol consumption in 24 hours | No       | 0.00%      | 24 (80%)   | 0.0005  |
|                                       | Yes      | 30 (100%)  | 6 (20%)    |         |

## DISCUSSION

In this study, 20 ml of 0.25% levobupivacaine or 20 ml of 0.25% levobupivacaine with clonidine 0.5mic.gm/kg on each side for ultrasound-guided TAP block was used, which is comparable to the study conducted by Ranjita Acharya et al,<sup>[11]</sup> where the duration of analgesia and efficacy of TAP block were studied for lower segment caesarean section. Tramadol is selected for rescue analgesia, as several studies have confirmed the analgesic effects of single-dose intramuscular tramadol 1.50-2mg/kg can provide effective analgesia in postoperative patients.<sup>[12-14]</sup>

Ultrasound-guided bilateral TAP block has been shown to provide adequate analgesia to the skin and anterior abdominal wall musculature in patients undergoing caesarean section. All patients in both groups breathed deeply, coughed freely, side by side movement without any limitation and showed good satisfaction. 0.25% levobupivacaine with clonidine group showed an increased duration of analgesia with mild sedation. Duration of postoperative analgesia in this study demonstrated that postoperative ultrasound-guided TAP block reduced VAS score in both groups. In Group A (0.25% levobupivacaine alone), the VAS score was almost zero in the first 2-4 hours, while in Group B, the VAS score was zero for about 6 hours, which explains the effectiveness of the TAP block. The mean time to reach a VAS score of  $\geq$  4 was 835 minutes in 0.25% levobupivacaine with clonidine 0.5 mic.gm/kg (B) group, when compared with 487 minutes in the 0.25% levobupivacaine (A), the difference of 348 minutes with a p-value < 0.05 was very significant statistically.

Extended analgesic duration after TAP blockade may be due to the relatively poor vascularisation and slowed drug clearance from the transversus abdominis plane and may be due to avoidance of central sensitisation by giving TAP block postoperatively. The prolonged action of clonidine may be produced by membrane hyperpolarisation due to opening the potassium channels, which increases the sodium channel blocking property of local anaesthetic. Adding to local anaesthetic enhances the quality and reduces block onset time.

In this study, the usage of rescue analgesics was compared in both groups, and there were highly significant between them. Mothers in the 0.25% levobupivacaine group needed (100%) Inj. Tramadol in the postoperative period, whereas in 0.25% levobupivacaine with clonidine group, mothers did not need that much rescue analgesia (only 20% of mothers needed rescue analgesia). This is according to a study conducted by Baaj et al,<sup>[15]</sup> and Ranjita Acharya et al,<sup>[11]</sup> where rescue analgesia was comparable in both groups.

The mean sedation score of 3 was obtained in 80% of patients in 0.25% levobupivacaine with clonidine group compared to 6.67% of patients in 0.25% levobupivacaine group. Thus, the sedation score was higher in levobupivacaine with clonidine than in the plain levobupivacaine group. Clonidine and levobupivacaine for prolonging analgesic duration also had a significant sedative effect but arousable sleep. Thus, TAP block as a component of multimodal analgesia has significantly increased the total postoperative analgesia, and those who received clonidine in addition to levobupivacaine had a prolonged duration of analgesia with adequate sedation without any complications. This follows a study conducted by Casti A et al,<sup>[16]</sup> where clonidine in peripheral nerve block was added to the duration of analgesia with adequate sedation.

In our study, hemodynamic stability in terms of changes in pulse rate and blood pressure were compared in both groups, and there was a statistically significant difference between them. This follows a study conducted by Manju Sruthi et al,<sup>[17]</sup> where the hemodynamic stability was comparable in both

groups. In this study, postoperative nausea and vomiting incidence was greatly reduced in both groups. This is similar to a study by Baaj et al,<sup>[15]</sup> which reported a reduced incidence of postoperative nausea and vomiting. This study did not encounter complications like peritoneal and visceral punctures related to TAP block. Abdisa Aga et al,<sup>[18]</sup> reported a case of Liver injury while performing Transversus Abdominis Plane Block.

Thorough familiarity with anatomy, safe monitoring and injection technique, and knowledge of local anaesthetic pharmacology and toxicity would prevent complications. The technique TAP block is simplified by proper knowledge and correct ultrasound technique. These precautions will prevent major complications with TAP block. Using the ultrasonography real-time needle position can be confirmed and is a promising approach that should further decrease the risk of visceral injury complications.

#### **CONCLUSION**

With the advancement in ultrasound technology, the success rate and safety of Transversus Abdominis Plane (TAP) blocks have markedly improved. Ultrasound-guided Transversus abdominis plane (TAP) block is highly effective after caesarean sections as a technique for providing postoperative analgesia. The addition of clonidine 0.5micgm/kg to 0.25% levobupivacaine in TAP block extended the duration of analgesia with minimal sedation and minimal usage of rescue analgesia with significant changes in hemodynamic parameters when compared to plain 0.25% levobupivacaine without any complications. Ultrasound-guided TAP block was easier to perform and provided reliable and effective analgesia.

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