

Assessment of Analgesic Efficacy of Transversus Abdominis Plane Block with Local Wound Infiltration Using 0.25% Levobupivacaine for Post Cesarean Analgesia: Prospective, Single-Blind, Randomized, Comparative Study

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Abstract

Aim: Comparison of analgesic efficacy of transversus abdominis plane block with local wound infiltration using 0.25% levobupivacaine for post cesarean analgesia.

Material and methods: This prospective, single-blind, randomized, comparative study conducted in the Department of Anaesthesiology and Critical Care, Patna Medical College and Hospital, Patna, Bihar, India, for 6 months, after obtaining written informed consent, patients were randomly allocated using computer-generated random numbers into 2 groups of 50 patients. An opaque sealed envelope concealing the group number allocated was opened after the enrollment of the patient.

Results: There was no significant difference between the two groups in the incidence of side effects including nausea, vomiting, pruritis, or any other procedure-related complications. In group I, 20% patients had a score of 1 (very satisfied), 68% patients had a score of 2 (satisfied), 12% had a score of 3 (dissatisfied). In group II, 54 had a score of 1, 26% had a score of 2 and 20% had a score of 3. ($P < 0.001$). Patients in the group (T) had a higher mean patient satisfaction score (1.488 ± 0.588) compared to group I (2.098 ± 0.429) ($P < 0.001$). In group I, 20% patients had a score of 1 (very satisfied), 68% patients had a score of 2 (satisfied), 12% had a score of 3 (dissatisfied). In group II, 54 had a score of 1, 26% had a score of 2 and 20% had a score of 3. ($P < 0.001$). There was no significant difference between the two groups in the incidence of side effects including nausea, vomiting, pruritis, or any other procedure-related complications.

Conclusion: TAP provides superior quality of pain relief, decreases total analgesic requirement, and better patient satisfaction.

Keywords: TAP, levobupivacaine, pain relief

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Introduction

Caesarean Section is the most common obstetric surgical procedure performed and it is associated with moderate to severe pain which may last until 48 hours, so adequate postoperative pain control is important to reduce morbidity in these patients. [1] Inadequate pain relief after Caesarean delivery can negatively impact ambulation, breastfeeding, and even maternal bonding. [2]

Pain management in a parturient is challenging and opioids should be avoided in the parturient because of their excretion in milk which predisposes the neonate to their adverse effects[3]. Hence, multimodal approach for pain relief are often selected which include use of intravenous paracetamol, NSAIDs, patient controlled analgesia (PCA), Wound site infiltration (WSI) with local anaesthetic and regional nerve blocks. [4]

Most of the obstetric units practice the WSI with the local anaesthetic after completion of the surgery as part of multimodal approach. It offers the advantage of being a safe simple technique with low cost. However, delayed healing, wound site hematoma and infection are apprehensions cited amongst some obstetricians though scientific documentation of the same is limited.

Transversus abdominis plane (TAP) block which is another popular technique for postoperative analgesia for lower abdominal surgeries such as caesarean section, hernia repair, appendectomy etc. [5] TAP block has been studied in last decade but some researchers have mentioned that there may be an inadequate pain relief specifically of the skin incision extends beyond the dermatome supplied by the peripheral nerve where WSI is needed in addition. Hence, we would like to conduct this study to evaluate and compare the effectiveness of TAP block with wound site infiltration for post-operative analgesia in caesarean section.

Material and methods

This prospective, single-blind, randomized, comparative study conducted in the Department of Anaesthesiology and critical care, Patna Medical College and Hospital, Patna, Bihar, India, for 6 months.

Inclusion criteria

100 ASA I and II pregnant patients, with body weight between 50-70 kg, singleton fetus, >37 weeks of gestation, undergoing cesarean delivery at term with a Pfannenstiel incision under spinal anesthesia were enrolled in the study.

Exclusion criteria

Patients meeting one of the following criteria were excluded from the study, patients in active labor, those aged <19 or >40 years old, height <155cm, weight <50 kg or a Body Mass Index >35 kg/m², not consenting to be a part of the study, history of allergy to drug, local infection at the site of infection or any other neurological disease

Methodology

All parturient visited one day before the surgery were explained about the study protocol and related potential benefits or side effects of both the interventions. They were explained about the VAS ranging from 0 which corresponds to no pain and after obtaining written informed consent, patients were randomly allocated using computer-generated random numbers into 2 groups of 50 patients. An opaque sealed envelope concealing the group number allocated was opened after the enrollment of the patient. Demographic data of all the patients including age, body weight, gestational age (weeks), duration of surgery, height, body mass index, ASA status was recorded. On arrival at the operating theater (OT), standard monitoring with electrocardiogram, pulse oximeter, blood pressure (noninvasively) was established for all the patients. An intravenous line was obtained with 18 G

cannula and all patients were preloaded with 10ml/kg Ringer lactate solution. Spinal anesthesia was given in the sitting position at L3–L4 level using 25 G Quincke Babcock spinal needle; 2 ml of 0.5% hyperbaric bupivacaine (10 mg). After attaining the upper sensory level of T6 or higher, CS was performed. Intraoperative complications included bradycardia (HR less than 20% from baseline or less than 40/min) was managed by using injection atropine intravenously. Furthermore, intraoperative hypotension (SBP <20% from the baseline) and nausea/vomiting were managed by using fluid bolus if required injection ephedrine, and ondansetron (0.1 mg/kg) intravenously respectively.

After the random group allocation, in the Group I, the local anesthetic wound infiltration was performed by the operating obstetrician; 20ml of 0.25% levobupivacaine was injected below the fascia between the unclosed parietal peritoneum and the underside of the transversalis fascia before its closure, along the full length of the wound.

In Group T, a trained anesthesiologist performed TAP block just after completion of surgery by injecting 20 mL of 0.25% levobupivacaine bilaterally. TAP block was performed using the traditional 'double pop' landmark technique in the lumbar triangle of Petit [6] using a blunt regional anesthesia needle (23 G Quincke Babcock spinal needle). After careful aspiration to exclude vascular puncture, 20 mL of 0.25% levobupivacaine solution was then injected through the needle bilaterally. Paracetamol 1gm was given to all the patients 20min before the end of the surgery. [7]

The primary outcome of the study was to measure the quality of postoperative analgesia using the VAS scale in both groups. The secondary outcomes were the total analgesic dose requirement in the first 24 hours in both the groups, the time for

the first and second rescue analgesia, patient satisfaction with pain control and associated side effects.

All patients were monitored in the postoperative period for pain by the VAS at rest at immediate postoperative period (0 min, 2hour, 4hr, 6hr, 12hr, and 24hr) and at the time of first and second rescue analgesic dose limited to the first 24 hours after surgery. The assessment was done by an independent anesthesiologist who had no role in the intraoperative management of the patient or in giving the block. However, in case of pain in between, the patient was asked to inform the nursing staff who further informed the attending anesthesiologist. Rescue analgesia was IV diclofenac 75 mg when VAS was 4. The time to first and second analgesia requirement was noted. The total dose of rescue analgesics required in 24 hours was documented. Patient satisfaction with pain control was recorded after 24 hours with a Verbal response numerical scale (VRNS) varying from 1 (very satisfied) to 3 (dissatisfied) for both the groups. Postoperative side effects like nausea, vomiting, pruritus, sedation, local anesthetic toxicity, any other complications if any, related to drug, technique, or both were also recorded. Hemodynamic parameters (heart rate and mean arterial blood pressure) were also measured at the same time.

Statistical Analysis

Statistical analysis was performed using Statistical Package for the Social Sciences version 25.0 (SPSS, IBM 25.0.), and R environment ver.3.2.2 were used for the analysis of the data, and Microsoft Word and Excel sheets have been used to generate graphs, tables, etc. P-value <0.01 is considered significant.

Results

Total 100 patients were taken for this study of which 50 were categorized into group 1 and remaining 50 were categorized into group 2. The demographic

profile of the two groups was comparable, in terms of anthropometric parameters like age and body weight and other patient factors like ASA grade, obstetric grade, gestational age, co morbidities, and duration of surgery (Table 1). There was no clinically significant difference between the two groups in the baseline and hemodynamic parameters.

The comparison of the distribution of pain scores at the different time points. For this outcome, data was completed for all the participants at 0,2,4,6,12 and 24hr. The median (interquartile range) VAS was more in group I compared to group T and was statistically significant ($p=0.0031$, $P=0.0033$, $P=0.0037$, $P=0.0038$). No statistically significant difference between the groups was observed in VAS values during the immediate postoperative period (0hr) and 2h later. The mean VAS score in group I and group T at the time of first and second rescue analgesia was 7.48 0.63/6.52 0.59 and 6.14 0.70/4.74 1.59 respectively. The difference in the VAS score during both the times in the two

groups was strongly statistically significant ($P < 0.001$). The mean time to first rescue analgesia was 4.059 ± 0.681 hrs in group I and 3.301 ± 0.518 hrs in group T and was statistically significant ($P < 0.001$). The mean total analgesic requirement in 24 hours was reduced in group T (90.63 ± 41.81) as compared to group I (138.2 ± 3.12) ($P < 0.001$) (Table 2). The demand for second rescue analgesia was lower in Group T (26.8%) compared to Group I (78%) ($P < 0.002$).

Patients in the group (T) had a higher mean patient satisfaction score (1.488 ± 0.588) compared to group I (2.098 ± 0.429) ($P < 0.001$). In group I, 20% patients had a score of 1 (very satisfied), 68% patients had a score of 2 (satisfied), 12% had a score of 3 (dissatisfied). In group II, 54 had a score of 1, 26% had a score of 2 and 20% had a score of 3. ($P < 0.001$). There was no significant difference between the two groups in the incidence of side effects including nausea, vomiting, pruritis, or any other procedure-related complications.

Table 1: Baseline characteristics of the patients in each group

Parameters	Group I(n=50)	Group II(n=50)	P-value
Age (in years)	29.22±4.45	29.41±3.71	0.829
Weight (in kg)	68.56±5.51	69.20±4.73	0.577
Comorbidities (%)			
No	24(48%)	22(44%)	0.813
Yes	26(52%)	28(56%)	
Obstetric grade			
Primigravida	23(46%)	15(30%)	0.819
Multigravida	27(54%)	35(70%)	
Gestational age (weeks)	38.59±0.70	38.66±0.68	0.636
Duration of Surgery	81.00±11.34	81.85±8.72	0.703

Values expressed in mean (SD) or median (range) and proportions as applicable

Table 2: Comparing total analgesic consumption between the groups

Group 1	Group 2		
Mean ± SD	Mean ± SD	t - test	P - Value
138.2 ± 33.12	90.63 ± 41.81	5.70	0.001

Values expressed in mean (SD) or median (range) and proportions as applicable

Table 3: Comparison of mean patient's satisfaction between the two groups

Patients' satisfaction	Group 1	Group 2	Chi - square value	p-value
1	10	27	25.53	0.001
2	34	13		
3	6	10		

Values expressed in mean (SD) or median (range) and proportions as applicable

Discussion

Various techniques have been compared for postoperative analgesia in the past. WSI is a simple and convenient method for providing postoperative analgesia, which is being widely practiced for caesarean section. However, many surgical colleagues have apprehensions of infection, wound site hematoma and inadequate analgesia with this technique. Alternatively, TAP block has been recently described and practiced which certainly is more invasive but may have effective analgesia with some sparing effects. [8] Thus, we undertook this study to compare the effectiveness of TAP block with wound site infiltration for post-operative analgesia in caesarean section.

Reported a similar report of improved VAS score in the first 24 hr after TAP block in patients undergoing abdominal surgery. In accordance with our findings, Petersen et al. [9] also found superior postoperative pain scores in patients given USG bilateral TAP block undergoing laparoscopic cholecystectomy. This is because with the TAP block, the local anesthetic directly impedes the afferent nerves before entering the anterior abdominal wall and some visceral pain relief maybe perhaps due to posteromedial diffusion of the anesthetic along the fascial plane in the mid axillary point approach. In contrast, M. Tawfik et al. [10] and Petersen PL et al. [11] found no significant differences between the 2 groups in the pain scores at rest and on movement at 2, 4, 6, 12, and 24 hours. In a meta-analysis and Cochrane review [12,13] done failed to demonstrate the beneficial effect of TAP

block on postoperative pain scores. Although, a meta-analysis found decrease opioid consumption which plays a cardinal role in deciding analgesic regimen. In contrary to our findings, Aydogmus MT et al. found low NRS scores in Group I, compared to Group T, and concluded the difference due to rapid application of wound site administration in contrast to TAP block, which was more time consuming. [14] Q. Guo et al. [15] performed a meta-analysis of 9 randomized control trials comparing TAP block versus local anesthetic wound infiltration for postoperative analgesia and reported that TAP block led to a significant reduction in 24-hour overall morphine consumption compared with wound infiltration.

The most important clinical implication of our findings is the noteworthy reduced mean total analgesic requirement in 24 hours in the TAP block group (89.63 41.82) compared to the local wound infiltration group (137.2 33.13). Das N et al. [16] in their study, also demonstrated reduced cumulative total analgesic consumption in group T in comparison to LIA (LIA 162.5 34.58 vs TAP:107.5 37.8) (P<0.001). In parrel, Telenes A et al. [17] also demonstrated decreased cumulative analgesic consumption (TAP41±34mg vs LIA38±27mg).

Vijaylaxmi sivapurapu et al. 18 also illustrated reduced consumption of analgesia in 24 hours in TAP when compared to the local infiltration group (TAP22.15±4.14 vs LIA 29.15±3.93) (p=0.001).

The time to first rescue analgesia is prolonged in the Infiltration group (Group I) (4.060 0.682 hrs) when compared to Group T (3.302 0.519 hrs) whereas the demand to second rescue analgesia was reduced in Group T compared to Group I. this was quite similar to the study done by Nanze Yu et al. [19] meta-analysis of randomized control trials and found that TAP block demonstrates its advantage gradually over time, making it effective for long-lasting analgesia. The reason for decreased demand for the second dose is the poor vascularity of TAP, leading to prolonged action and minimal side effects.

In our study, we used the landmark technique for performing TAP block as wider applicability and merit have been demonstrated by various previous research with the landmark technique. [20] The mid-axillary approach has paravertebral spread leading to blockade of lateral cutaneous afferents, contrary to Sono-anatomical clear ultrasound-guided anterior approach. [21] The neuro-fascial plane and its contents can act as an armory responsible for a prolonged duration of action in comparison to surgical incision, that is highly vascular and may lead to faster local anesthetic absorption and metabolism, which might explain the shorter duration of action in Group I in which 26.8% required analgesia within 4-6 hours as compared to Group T, where only 4.8% required analgesia within 4-6 hours.

None of the patients in our study had any side effects in either of the group, thus concluding that both the modalities are safe for use as post-cesarean analgesia. This observation is supported by studies by Q. Guo et al. 16 and Skjelsager A et al. [22] In parrel to our study, M Tawfik et al. 10 found that the incidence of side effects (nausea and vomiting and pruritis) were less in the 2 groups comparing TAP block versus local wound infiltration for post cesarean analgesia.

However, in a randomized trial conducted by M. Chandon et al., [23]± there was an occurrence of a severe adverse event following a TAP block demonstrating that local anesthetic toxicity can occur even with continuous ultrasound guidance

In our study also, patients in Group T (1.487 0.589) were more satisfied than in Group I (1.829 0.441) (P 0.002) with higher mean patient satisfaction scores. Tan et al. [17] conducted a randomized trial in which patients who received the TAP block had a statistically significant higher maternal satisfaction score.

Our study has a few limitations. The pain assessment on movement was not done, as our primary aim was the time for the first rescue analgesia, as well as the VAS at that time. Also, both the regional techniques block only the parietal component of pain rather than visceral, which is mainly responsible for pain on movement. Furthermore, studies are needed with ultrasound-guided technique, with various local anesthetics, in varying doses, additives, and concentrations and also comparing pain on the movement. Continuous block with a catheter was not used in our study, as we wanted to assess the time for first rescue analgesia and VAS score at that time, also we assessed the analgesic requirement in the first 24 h, which would have given the biased result. [24]

In summary, our study has demonstrated that, although both strategies seem to be safe and effective, TAP provides better quality of pain relief with reduced analgesia requirement and surpassed patient satisfaction compared to infiltration in CS postoperatively.

Conclusion

The findings of our study inferred that TAP provides superior quality of pain relief, decreases total analgesic requirement, and better patient satisfaction. Thereby, we advocate the use of TAP block as a reliable and safer option

for post-cesarean analgesia as part of a multimodal analgesia regimen. The landmark approach to TAP is also effective and safe.

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