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Original Research Article

Comparison of analgesic efficacy of transversus abdominis plane block with local wound infiltration using 0.25% levobupivacaine for post cesarean analgesia: A randomized controlled trial

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ABSTRACT

Objective: The key component of Enhanced recovery after cesarian section (ERAC) is to improve maternal and child outcome and enhance recovery by dint of effective non opioid based pain control. We aim to compare the efficacy of Transverse abdominis plane (TAP) block with local wound infiltration for postoperative analgesia in cesarian section (CS).

Materials and Methods: Eighty-two patients undergoing caesarean section under spinal anaesthesia were randomized to undergo local wound infiltration(Group I) (n=41) versus landmark guided bilateral TAP plane block (Group T) with 20ml of 0.25% levobupivacaine postoperatively Each patient was assessed post-operatively by a blinded investigator at regular intervals up to 24 h for visual analogue score (VAS). Requirement of analgesia, patient satisfaction, time for the first and second rescue analgesia, and the incidence of side effects was also noted.

Result: The median VAS was more in the group I compared to group II and was statistically significant (p=0.0032). The mean time to first rescue analgesia was prolonged in group I (4.060 ± 0.682 hrs) compared to group T (3.302 ± 0.519 hrs)(P< 0.001). The mean total analgesic requirement in 24 hours was reduced in group T (89.63 ± 41.82) as compared to group I (137.2 ± 33.13) (P<0.001. Group (T) compared to group I patient had a higher mean patient satisfaction score (1.487 ± 0.589) (2.097 ± 0.430) respectably (P < 0.001).

Conclusion: TAP block provides better quality of analgesia and can be safely incorporated as a part of multi-model analgesic regimen postoperative pain over local infiltration in cesarian section.

1. Introduction

CS are the most commonly done surgeries among women in the fertile age group.[1] The rates of Cesarean delivery have substantially increased in the present time and postoperative pain is of great concern for women, affecting postoperative recovery and bonding with the newborn. The reported incidence of pain after the CS varies from 77.4% to 100% postoperatively.[2] Inadequately treated pain can lead to chronic pain and post-traumatic stress syndrome.[3] High patient to paramedic's ratios in developing countries, often also result in inadequate pain assessment and management.[4]

In the present era, Enhanced recovery after Cesarian section (ERAC) is a multi-disciplinary, evidence-based

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approach. The holy grail is to enhance and ameliorate maternal and neonatal outcomes. ERAS society also recommends a multi-modal, opioid-sparing stepwise analgesic approach as the first-line therapy after the CS.[5] Well-established side effects of opioids, NSAIDs circumvent their extensive use and acquisition of alternative strategies to decrease opioid consumption postoperatively.[6] Thereby, multimodal analgesia (MMA) is now recommended for providing effective pain relief after CS.[6]

MMA regimes including regional anesthesia techniques such as nerve block and local infiltration have been suggested to reduce opioids and non-steroidal anti-inflammatory associated side effects. Over the years, truncal blocks have risen in popularity as a part of MMA and one, in this category is the TAP block. It was first described by Rafi as the one-pop technique and later on modified by McDonnell, by inserting the needle perpendicular to the skin, behind the mid-axillary line.[7] The author described that a landmark-based TAP block can provide better postoperative pain relief after the CS.[7] The landmark technique was found to have an 85% success rate among the experienced hands.[8] Infiltration of local anesthetic into the surgical wound is also often used for postoperative analgesia.[9]

Both TAP block and infiltration of a local anesthetic provide analgesia. Notwithstanding, the results of various studies comparing both modalities are controversial and inconclusive. NICE guidelines for CS recommended wound infiltration to be an effective alternative to systematic analgesia.[10] However, there exists conflicting outcome in the research on the analgesic efficacy of wound infiltration.[11] A meta-analysis of 512 patients from 9 RCTs for CS pain has reported that LA wound infiltration can decrease opioid consumption but not pain scores after CS.[12] Furthermore, various RCTs have also documented controversial outcomes with the traditional TAP technique and demonstrated no difference in total opioid consumption at 48 h when compared with wound infiltration of LA for post-Cesarean pain.[13] Multiple recent meta- analyses on both the modalities have also deduced that results of large pooled data are inconclusive and there exists a further exigency for high-quality studies.[14] Also, not much literature is available comparing both these techniques in terms of the quality of analgesia. Into the bargain, a multimodal analgesic regimen (MMA) is the current standard proposal for analgesia in CS. Notwithstanding, a multimodal routine which is presently suggested is as yet at outset. At this point, we don't have a clue what blend will be the best in alleviating torment and the most secure for the mother and her child Thus, the present study was contemplated to compare the efficacy of TAP block group and local wound infiltration group for postoperative analgesia assessed by using the VAS.

2. Materials and Methods

After approval from the Institutional ethical committee and registration at ClinicalTrials.gov (CTRI/2018/03/012337), this prospective, single-blind, randomized, comparative study was conducted in 82 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. 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 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 10 corresponds to worst pain. After obtaining written informed consent, patients were randomly allocated using computer-generated random numbers into 2 groups of 41 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. Intra-operative 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 (12) 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.

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.

2.1. Statistical analysis

The sample size was calculated based on the values of mean and standard deviation employed by Chandon et al. study comparing the analgesic efficacy of transversus abdominis plane block and local wound infiltration. (15). With an alpha error of 0.05 and 95% power of the study, the required sample size of 41 in each group was obtained.

Statistical analysis was performed using Statistical Package for the Social Sciences version 18 (SPSS, IBM 18.0), 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. Statistical analyses applied in the indexed study were Descriptive and inferential. Continuous measurement results are presented as Mean ± SD (Min-Max) and categorical measurements are presented in Number (%). A 5% level of significance is assessed as significant. Student t-test (two-tailed, independent) has been applied to find the significance of study parameters on a continuous scale between two groups (Intergroup analysis) on metric parameters. Leven's test for homogeneity of variance has been applied to evaluate the homogeneity of variance. Chi-square/ Fisher Exact and Wilcoxon test has been used to find the significance of study parameters on a categorical scale between two or more groups, a non-parametric setting for Qualitative data analysis. For the primary outcome, we summarized findings at the various time points using medians and interquartile range (IQR). P-value <0.01 is considered significant.

3. Results

Ninety patients were analyzed for eligibility but 8 patients were excluded from the study, as 5 of them were not willing to participate in the study and three patients did not fulfill the inclusion criteria. Thus, 82 patients were randomized into two groups and analyzed. No patient was excluded from the final analysis. The (CONSORT) consolidated standards of reporting trials flow diagram for this study is shown in (Diagram 1). 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, comorbidities, and duration of surgery (Table 1). There was no clinically significant difference between the two groups in the baseline and hemodynamic parameters.

Figure 1 shows 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=0.0032, P=0.0034, P=0.0038, P=0.0039). 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 7.49±0.64/ 6.53±0.60 and 6.15±0.71/4.75±1.60 respectively. The difference in the VAS score during both the times in the two groups was strongly statistically significant (P < 0.001).

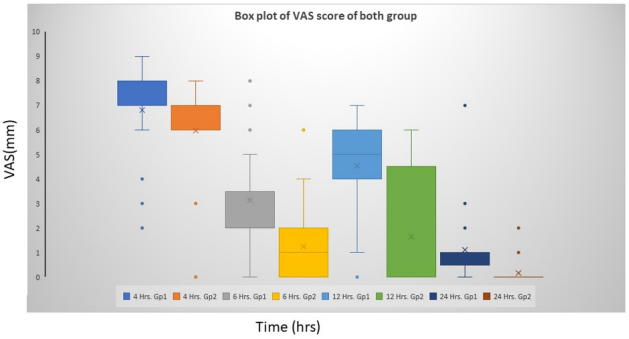

Fig. 1: A box and Whisker plot showing the distribution of Median VAS scores among groups of treatment at 4,6,12 and 24hr

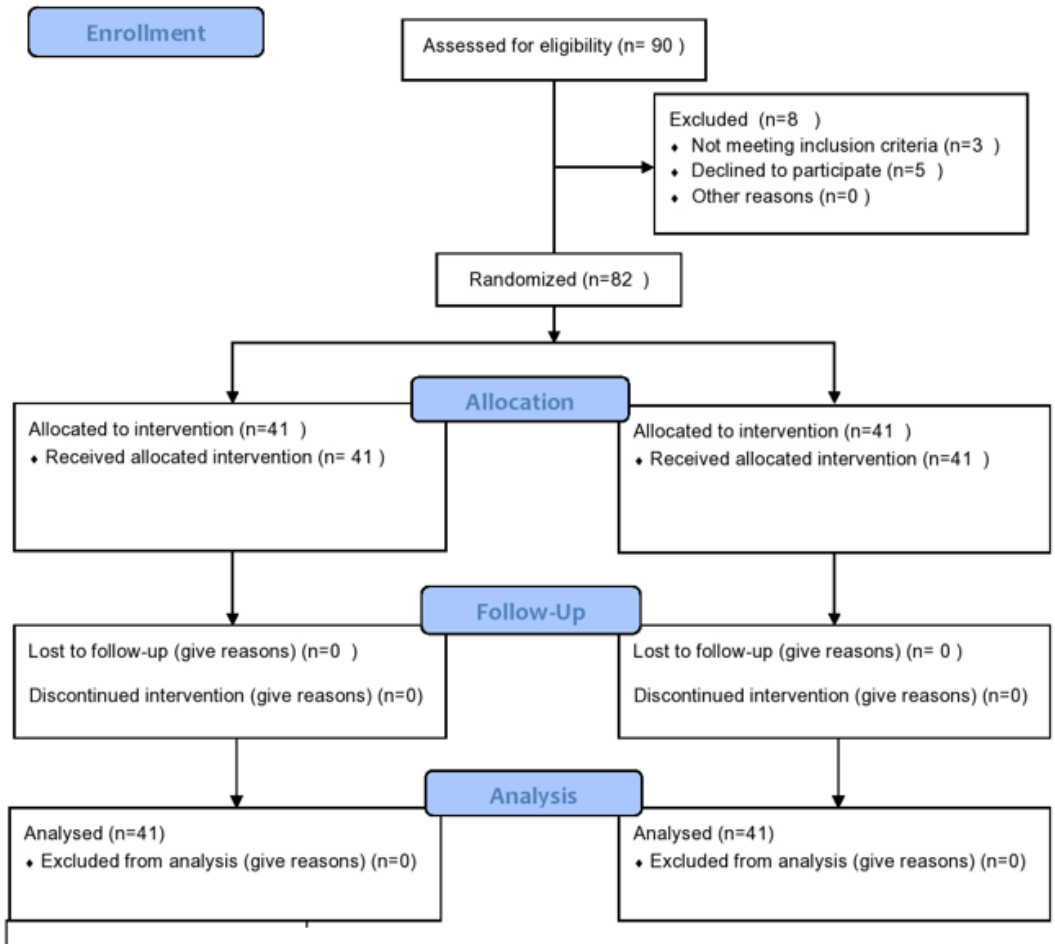

Diagram 1: Consort flow diagram

The mean time to first rescue analgesia was 4.060 ± 0.682 hrs in group I and 3.302 ± 0.519 hrs in group T and was statistically significant (P< 0.001).

The mean total analgesic requirement in 24 hours was reduced in group T (89.63 ± 41.82) as compared to group I (137.2 ± 33.13) (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 (1.487 ± 0.589) compared to group I (2.097 ± 0.430) (P < 0.001). In group I, 4.9% patients had a score of 1 (very satisfied), 80.5% patients had a score of 2 (satisfied), 14.3% had a score of 3 (dissatisfied). In group II, 56.1% had a score of 1, 39% had a score of 2 and 4.9% had a score of 3.(P< 0.001)(Figure 2). 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.

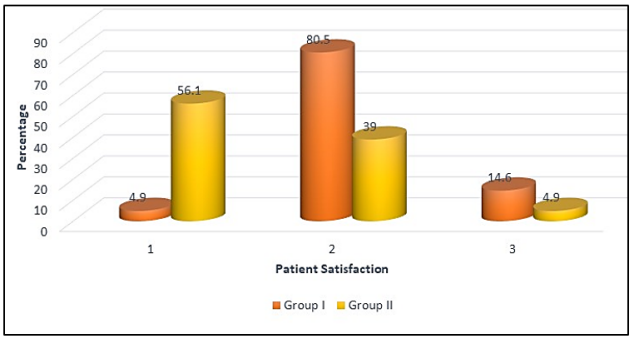

Fig. 2: Distribution of patient satisfaction score in the two groups

4. Discussion

The principal findings of our study demonstrated better quality of analgesia in TAP block; providing effective multimodal postoperative analgesia in patients undergoing CS, reflected by a lower VAS score in group T compared to group I at different periods. The contemporary literature

Table 1: Baseline characteristics of the patients in each group

Parameters	Group I(n=41)	Group II(n=41)	Significance(P-value)
Age (in years)	29.22±4.45	29.41±3.71	0.830
Weight (in kg)	67.56±5.52	68.20±4.74	0.578
Comorbidities (%)			
No	14(34.1%)	13(31.7%)	0.814
Yes	27(65.9%)	28(68.3%)	
Obstetric grade			
Primigravida	16(39.1%)	15(36.6%)	0.820
Multigravida	25(60.9%)	26(63.4%)	
Gestational age (weeks)	37.59±0.71	37.66±0.69	0.637
Duration of Surgery	80.00±11.35	80.85±8.73	0.704

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

Table 2: Comparing total analgesic consumption between the groups

Group 1 Mean ± SD	Group 2 Mean ± SD	t - test	P - Value	Significance
137.2 ± 33.13	89.63 ± 41.82	5.71	0.00001	Highly Significant

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	Significance
1	2	23			
2	33	16	25.54	0.00001	Highly significant
3	6	2			

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

on TAP comparing local infiltration is not concordant to the fact that whether it improves postoperative pain score or not. Our finding is consistent with those of Carney et al.,[15] deducing reduced postoperative pain scores up to 48h in landmark-guided TAP block, planned for total abdominal hysterectomy. Sharma et al.[16] 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.[17] 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.[18] and Petersen PL et al.[19] 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[20,21] 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.[22] Q. Guo et al.[23] 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.[24] 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.[25] also demonstrated decreased cumulative analgesic consumption (TAP41±34mg vs LIA38±27mg).

Vijaylaxmi sivapurapu et al.[26] 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.[27] 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.[28] The mid-axillary approach has paravertebral spread leading to blockade of lateral cutaneous afferents, contrary to Sono-anatomical clear ultrasound-guided anterior approach.[29] 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.[23] and Skjelsager A et al.[30] In parrel to our study, M Tawfik et al.[18] 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.,[31]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.[25] 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.

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.

5. 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.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare no conflict of interest.

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