

Ultrasound-guided transversalis fascia plane block versus wound infiltration for both acute and chronic post-caesarean pain management - A randomised controlled trial

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ABSTRACT

Background and Aims: Ultrasound-guided transversalis fascia plane block (USG-guided TFPB) has recently been evaluated for post-caesarean acute pain management. We compared it with standard wound infiltration for both acute and chronic post-caesarean pain management.

Methods: All patients undergoing caesarean section (CS) under subarachnoid block were included and randomised. Patients in group C received standard wound infiltration (20 ml of 0.375% ropivacaine) and group-T received bilateral USG-guided TFPB (20 ml of 0.375% ropivacaine) at the end of the surgery. Acute pain assessed using numeric rating scale (NRS), time to first request of analgesia and total rescue analgesic consumption in 24 hours. The incidence of chronic persistent post-surgical pain (CPSP), neuropathic pain component and quality of life (QoL) were assessed. Fisher's exact test, Chi-square test, unpaired Student's t-test and Mann-Whitney U test were used. **Results:** Sixty patients were included with 30 in each group. NRS score on rest at 6th and 24th hour and on active movement at 1st hour was significantly decreased in group T. The "time to first request of analgesia" was statistically higher in group T, that is, 10.77 ± 1.39 h versus 6.30 ± 1.60 h. Five (16.6%) and two (6.6%) patients in groups C and T, respectively, required rescue analgesia in first 24 hours. 30% (n = 6) and 10% (n = 2) patients in groups C and T, respectively, developed CPSP. The neuropathic pain component was significantly reduced and QoL was significantly improved in group T. **Conclusion:** TFPB is efficacious for management of both acute and chronic post-caesarean pain management.

Key words: Caesarean section, chronic pain, interventional, ultrasonography

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INTRODUCTION

The incidence of chronic persistent post-surgical pain (CPSP) following caesarean section (CS) has been estimated to be 6-18%^[1] which exerts a negative effect on quality of life (QoL), thus representing an important clinical problem.^[2]

Multimodal analgesia has been the standard for postoperative pain management following CS.^[1] Recently, ultrasound-guided interfascial plane blocks like transversus abdominis plane (TAP) block, quadratus lumborum (QL) block, ilioinguinal-

iliohypogastric (II-IH) block and transversalis fascia plane block (TFPB) are being used for post-caesarean pain management.^[3-5] Transversalis fascia plane

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block being a more posterior block has a higher potential of blocking the subcostal, ilio-inguinal and iliohypogastric nerves. Therefore, recently it has been evaluated for postoperative pain management following CS and has been found to be more efficacious than TAP block^[4] and standard multimodal analgesia utilising systemic analgesics.^[3,5]

In a previous study evaluating the efficacy of interfascial plane blocks in terms of reduction in the incidence of CPSP following CS, it was observed that neither TAP nor QL block has been shown to reduce the incidence of CPSP following CS.^[6] The influence of interfascial plane blocks on chronic pain for post-caesarean pain management warrants further investigation.^[7] Till now, no study has explored the efficacy of TFPB in terms of the incidence of CPSP, neuropathic pain component and QoL following CS. Therefore, this study was conducted with the aim to evaluate and compare ultrasound-guided TFPB with standard multimodal analgesia technique utilising wound infiltration for both acute and chronic pain management following CS.

METHODS

The study was undertaken following approval from the Institutional Ethics Committee- Human Research (IEC-HR/2019/41/2R). The data for this study has been retrieved from the study which was prospectively registered in the clinical trial registry of India (CTRI/2020/01/022813, date of registration: 16.01.2020). A written informed consent was taken from each patient and the study was done in accordance with the principles the Declaration of Helsinki. Patients of American Society of Anesthesiologists (ASA) physical status II undergoing lower segment CS with Pfannenstiel incision under subarachnoid block (SAB) between 15 June 2021 and 31 July 2021 were included. Patients were excluded if they had chronic pain of any etiology, cognitive dysfunction or inability to comprehend various questionnaires, chronic neurological disorders/substance abuse or body mass index $>40 \text{ kg/m}^2$.

Patients were randomised into one of the two groups based on a computer-generated random number table. Allocation concealment was done by using sequentially numbered sealed opaque envelopes by the person not involved in the study. Patients in group C received wound infiltration using 20 ml of 0.375% ropivacaine at the end of the surgery; whereas, patients

in group T (n30) received bilateral ultrasonography (USG)-guided TFPB using 20 ml of 0.375% ropivacaine on both sides at the end of the surgery. The primary investigator was involved in the management of the case including the wound infiltration or TFPB administration and data collection.

Standard anaesthetic technique for SAB was adopted in all patients undergoing CS. Patients with height less than 150 cm or more than 150 cm received 2.0 ml or 2.2 ml of hyperbaric bupivacaine hydrochloride (5 mg/ml) intrathecally, respectively. Soon after delivery of the baby, oxytocin was administered as per the institutional protocol.

In group T, USG-guided TFPB was given in supine position with the machine (SonoRite™ USG scanner) on the opposite side of the bed. Under all aseptic precautions, a curvilinear probe (2-5 MHz) was placed over the lateral torso just above the iliac crest in the midaxillary line. A low-frequency curvilinear transducer was generally preferred for its wider field of view and better penetration with an appropriate depth of field (usually within 4 cm). After visualisation of transversalis fascia, 20 ml of 0.375% ropivacaine was infiltrated on both sides.

In both the groups, following surgery, injection paracetamol 1 gm was administered intravenously (IV) every 6th hourly for first 24 hours and then 12th hourly, the next day. The breakthrough pain in between was treated using injection diclofenac 75 mg IV. In the event of unsatisfactory pain relief, that is, numeric rating scale (NRS) score $\geq 3/10$, injection tramadol 1 mg/kg was administered IV, following IV ondansetron. The dosing interval between two doses of tramadol was at least 6 hours. After two days of CS, oral paracetamol 650 mg was administered twice or thrice a day depending on the pain intensity.

The pain intensity was measured using NRS pain score at rest (NRS-R) and movement (NRS-M) at the end of 1st, 6th, 12th and 24th hour and then at the end of 6th, 10th and 14th week. The total consumption of diclofenac and tramadol in 24 hours was recorded. A detailed evaluation for quality of pain and QoL was done by using different questionnaires mentioned below at the end of 6th, 10th and 14th week postoperatively. All patients were followed up for 14 weeks and the aforesaid time points were chosen to correspond to the immunisation schedule of the newborn baby so as to improve the patient compliance.

The neuropathic component of pain was assessed using pain DETECT questionnaire (PDQ)^[8] and Neuropathic Pain Symptoms Inventory (NPSI) at the various designated time intervals.^[9]

In the PDQ, the score is between 0 and 35, with 13-18 reflecting the possibility of a neuropathic component to the pain, which is considered highly likely if the score is more than 18. The NPSI scoring for various neuropathic sensations like “electric-shock” like pain, “stabbing”, “tingling”, “pins and needles” and “allodynia” were done and graded on a scale of 0-10. If NRS was $\geq 3/10$, capsule pregabalin 75 mg (with adequate interval of 10-12 hours between two consecutive doses) was planned to be started and continued till the NRS score would be $< 3/10$.

The QoL was assessed using short form (SF)-12 questionnaire.^[10] It consisted of two components, that is, physical component summary (PCS) and mental component summary (MCS). Both have a range of 0 to 100 each and were designed to have a mean score of 50 and standard deviation of 10. A score greater than 50 represents an above average health status.

The pain experienced or perceived by the patients was labelled as CPSP if the total duration of pain in the postoperative period persisted for at least three months or 14 weeks and also if other causes of pain had been excluded, that is, chronic infection, continuing malignancy, etc.

The primary outcome was “time to first request of analgesia”. The secondary outcomes were NRS-R, NRS-M, total rescue analgesic consumption, incidence of CPSP, PDQ scores, NPSI scores and SF-12 scores.

To calculate the sample size, we conducted a pilot study in 15 patients utilising multimodal analgesia along with wound infiltration (using ropivacaine) for post-caesarean pain management. The mean time to first request of analgesia was reported to be 3.30 ± 1.5 hours. Considering a 30% increase in the time to the first request of analgesia with the use of TFP block with α of 5%, one sided and 80% power of study, 30 patients were required in each group. Thus, a total sample size of 60 patients was taken.

Data analysis was done by Statistical Package for Social Sciences software (Version-20). Continuous variables were expressed using mean \pm standard deviation (SD) or median. Categorical variables were

expressed using Fisher’s exact test and Chi-square test. Unpaired Student’s t-test was used to compare various demographic parameters and SF-12. Mann-Whitney U test was used to compare NRS, PDQ, NPSI between the two groups. A *P* value of < 0.05 was considered statistically significant.

RESULTS

Seventy obstetric patients scheduled for elective or emergency CS were enrolled and were randomised into one of the two groups. Out of 70, five patients in each group were lost to follow-up. Finally a sample size of 60 with 30 patients in each group was included [Figure 1].

The mean age in group C was 22.6 ± 2.12 years and was 23.2 ± 2.05 years in group T. The mean duration of surgery was 32.83 ± 2.96 min in group C and was 33.93 ± 1.72 min in group T. Both the groups were statistically comparable with respect to age and mean duration of surgery. The two groups were also comparable with respect to ASA physical status.

A decrease in mean NRS-R scores was observed in group T when compared to the group C at all-time points; however, the difference was found to be statistically significant at 6th hour and 24th hour postoperatively [Figure 2]. Similarly, fall in NRS scores on movement was observed in test group at all-time points; however, the difference was statistically significant only at 1st hour [Figure 2].

The time to first request of analgesia was observed to be 6.30 ± 1.60 hours in control group and

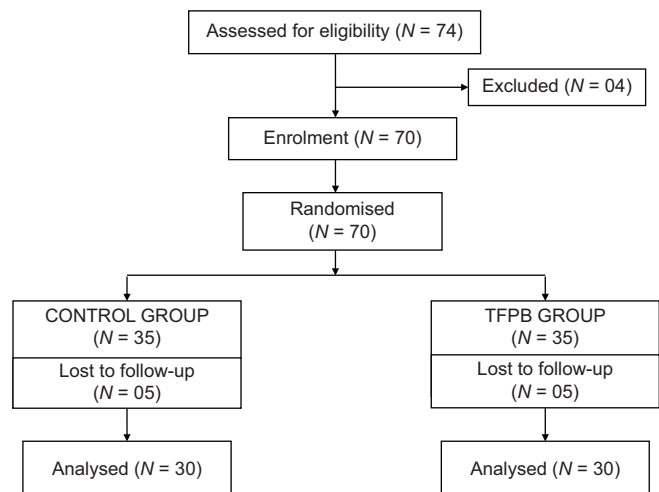


Figure 1: CONSORT flow diagram

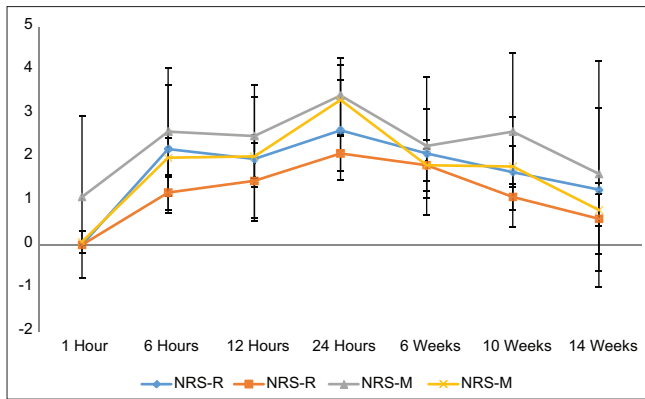


Figure 2: Numeric rating scale-rest and movement (NRS-R and NRS-M) scores

10.77 ± 1.39 hours in test group. This difference was found to be statistically significant.

Five (16.6%) and two (6.6%) patients in groups C and T, respectively, required rescue analgesia in the first 24 hours. A decreased number of patients required rescue analgesia in the group T but was not statistically significant ($P = 0.423$)

On inter-group comparison, the mean ± SD for total consumption of rescue analgesic, that is, injection diclofenac in the first 24 hours was found to be 5.00 ± 19.03 (mg) in test group and 12.50 ± 28.43 (mg) in control group (P value = 0.235). Since only five (16.6%) and two (6.6%) patients in groups C and T, respectively received rescue analgesics, the data is skewed and thus can be treated as outliers. Only one patient in control group was administered a single dose of tramadol (50 mg IV) as additional analgesic.

No technical difficulty was experienced in any patient in the TFPB group while administering USG-guided TFPB. One of the two patients in group C who received IV tramadol complained of nausea which was manageable. There was no significant adverse event in any of the groups.

No significant difference was observed in NRS-R and M scores between the two groups at all-time points, that is, 6th, 10th and 14th weeks. Six (30%) patients and two (10%) patients in groups C and T, respectively, were labelled to have CPSP by the end of 14th week; however, the difference was not significant. None reported NRS ≥ 3, and hence did not need treatment.

On intergroup comparison, a greater fall in PDQ scores was observed in group T at all designated time points; however, it was statistically significant only at 10th and

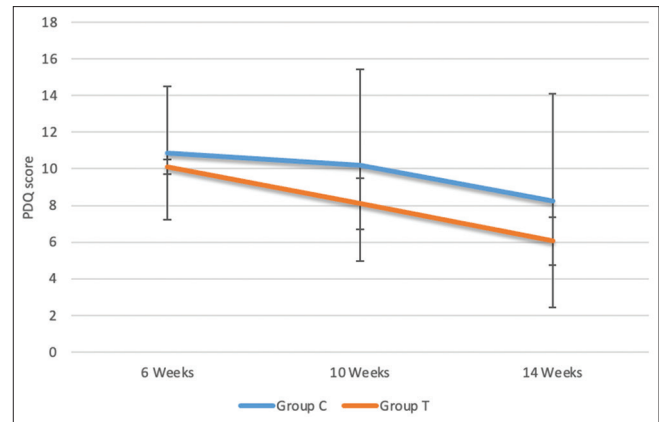


Figure 3: Patient Detect Questionnaire (PDQ) score between the two groups

14th week time points [Figure 3]. A greater fall in NPSI scores for “pins and needle sensation” was observed in group T when compared to group C at each designated time point but the difference was not found to be statistically significant [Figure 4]. NPSI scores for other sensations could not be evaluated as the data generated was insufficient for statistical analysis due to the limited sample size.

A greater rise in both MCS and PCS scores of SF-12 were observed in group T at the end of 10th and 14th week and the difference was observed to be statistically significant; however, it remained comparable to the group C at 6th week for both PCS and MCS [Figure 5].

DISCUSSION

In the present study, amongst the acute pain parameters, a decreased mean NRS score, increased “time to first request of analgesia” and lower consumption of rescue analgesics was observed with the use of TFPB. Amongst chronic pain parameters, although no significant difference was observed in the incidence of CPSP, a reduced neuropathic component of pain and an improved QoL was observed with TFPB.

The reported incidence of CPSP following CS is estimated to be 6-18%.^[2] Multimodal analgesic technique and pre-emptive analgesia have a preventive role in CPSP.^[11] It includes wound infiltration,^[12] epidural analgesia, interfascial plane blocks,^[3-5,13-15] systemic analgesics etc. Currently, ultrasound-guided interfascial plane blocks like TAP block^[13,14], QL block,^[15] II-IH block and TFPB are being used for post-caesarean pain management^[3-5] Most importantly, the severity of acute postoperative pain is an important determinant for the development of CPSP.^[16] Thus,

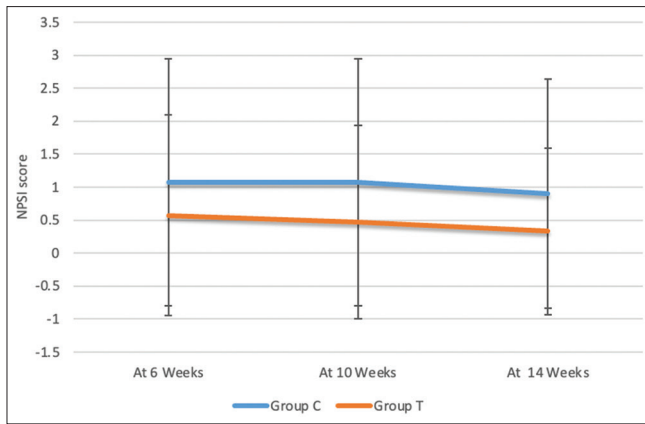


Figure 4: Neuropathic Pain Symptom Inventory (NPSI) scores for “pins and needle” sensation

effective management of acute postoperative pain is an important factor attributing to the prevention of CPSP.^[1] Recently, a few studies have compared the efficacy of USG-guided TFPB with TAP block^[4] and standard multimodal analgesia technique,^[3,5] for post-caesarean pain management. However, no study has explored the efficacy of TFPB in terms of the incidence of chronic pain, neuropathic pain assessment and QoL following CS.

In the present study, with TFPB, we observed reduction in the NRS-R and M scores only in the first 24 hours. In the 6th, 10th and 14th week time points, the mean NRS scores were reduced but were not statistically significant. We observed a significant increase in the “time to first request for analgesia” in the TFPB group and higher consumption of total rescue analgesic consumption in first 24 hours in the control group. Our finding is in concordance to the study done by Serifsoy *et al.*^[3] and Aydin *et al.*^[5] This implies improved acute pain management with the use of TFPB when compared to wound infiltration following CS.

Nerve injury-induced neuropathic pain has been considered to be the main pathogenic mechanism for the development of CPSP. In the present study, a fall in both NPSI and PDQ scores were observed with TFPB when compared to the wound infiltration at all designated time points; however, the difference in the PDQ scores was found to be statistically significant at 10th and 14th week. Similarly, the QoL improved in the patients who had received TFPB for immediate postoperative pain management. This is the first study evaluating the influence of any interfascial plane block on the neuropathic component of chronic pain and QoL.

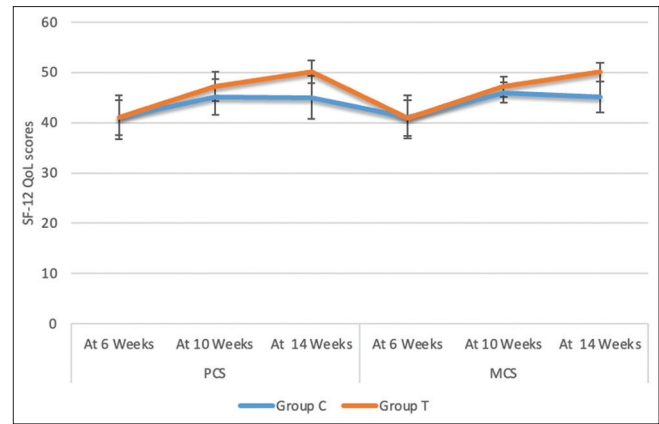


Figure 5: Short Form-12 Quality of Life questionnaire scores (SF-12 QoL scores)

This is also the first study reporting the incidence of CPSP following TFPB for post-caesarean pain management. A decrease in the CPSP incidence from 16.6% in the wound infiltration group to 6.6% with the use of TFPB was found in this study. However, a previous study evaluating TAP block and QL block has not shown any reduction in the incidence of CPSP following CS; this study had evaluated CPSP at various intervals till six months.^[6] Costello *et al.*^[17] also evaluated the chronic pain following the use of TAP as a part of multimodal regimen inclusive of intrathecal morphine following CS but the incidence of CPSP was evaluated at the end of 6th week only; whereas, in our study we evaluated chronic pain at various designated intervals till 14th week.

The study is associated with the following limitations. Firstly, the sensory examination to assure an active TFPB could not be conducted as it was performed while the effect of SAB continued. Secondly, further follow-up until six months or one year could also have been assessed. Thirdly, blinding was not feasible due to the nature of the intervention.

CONCLUSION

The study reiterates the efficacy of TFPB for acute post-caesarean pain management; in addition, a reduction in the incidence of CPSP, fall in neuropathic pain component and improved QoL was observed with the use of TFPB.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be

reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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The data for this study have been retrieved from another study which was prospectively registered in CTRI and approved on 16/10/2020. The study had received Institutional intramural grant from Delhi University and ICMR PG thesis grant for the conduct of genetic part of the study which is not incorporated in this study.

Conflicts of interest

There are no conflicts of interest.

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