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Research Article

Effect of the Modified Surgeon Assisted Bilateral Transversus Abdominis Plane Block on Time Required for First Analgesic Dose after Cesarean Section under Spinal Anesthesia: Randomized placebo-controlled, double blinded clinical trial

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Abstract

Background: The transverses abdominis plane block (TAP block) is one of the widely used regional analgesic techniques in cesarean section. There are different variations of the procedure. The aim of the present study was to evaluate the analgesic effect of the modified surgeon assisted bilateral TAP block in patients undergoing cesarean section

Patients&Methods: Sixty patients undergoing cesarean section under spinal anesthesia were randomized into two groups to receive either TAP block with 40 ml of bupivacaine 0.25%(study group) or 40 ml normal saline as placebo after obtaining informed consent. All patients will receive intravenous diclofencac75mg every 12 hrs postoperatively. Postoperatively, there was an assessment every 2hrs during the first 24hrs by the visual analogue pain scale (VAPS). Time to the first analgesic request will be measured as primary outcome and all patients will receive opioid on demand or VAPS > 4 with 25mg pethidine intramuscularly. Moreover, total opioid requirement in 24hrs will be measured as secondary outcome along with postoperative complications as nausea, vomiting and abdominal distention. Complications related to the TAP procedure will be also assessed.

Results: The median (interquartile range) time to the first analgesic request in the first 24hrs postoperatively was significantly shorter in the placebo group compared to the study group; 4h (4, 6) and 24h (10, 24) with p value < 0.001. Postoperative opioid requirement was significantly higher in the control group (30/30{100%}) than the study group (13/30{43.3%}). The median (interquartile range) number of opioid doses was significantly higher in the placebo group compared with the study group; 2(2, 2) and 0(0, 1) respectively. At all points in the study, pain scores both were lower in the study group ($p < 0.0001$).

Conclusion: The modified surgeon assisted bilateral TAP block is relatively new, safe and cost effective technique which provides adequate postoperative analgesia allowing for better maternal ambulation and better postoperative recovery.

Trial registration: Clinicaltrial.gov registration number: NCT04623632

Key words: transversus abdominis plane block; cesarean section; bupivacaine; spinal anesthesia; opioids; postoperative analgesia

Introduction

Postsurgical pain can adversely affect patient satisfaction and quality of life. Evidence suggests that effective handling of acute pain may have a positive impact on the development of chronic pain after the surgical procedure **[1]**. The proper management of postoperative pain after caesarean section is of paramount importance as it allows early mobilization and enhances breast-feeding **[2]**

Opioids are considered the corner stone of conventional analgesia with both systemic and neuraxial routes used. Neuraxial methods are effective

and safe, however close monitoring and experienced hands should be available **(3)**. Despite being one of the most predominant drugs used for pain relief worldwide, side effects of opioids like nausea, vomiting, constipation and respiratory depression are frequently encountered which can have negative impact on the healthcare costs besides the increase in the overall morbidity **[1].**

The transversus abdominis plane (TAP) block is a regional analgesic technique which blocks T6–L1 nerve branches and has an evolving role in postoperative analgesia for lower abdominal surgeries **[4]**. Compared with morphine, TAP block has similar efficacy with the additional advantages of prolonged postoperative analgesia, less opioid consumption and fewer side effects **[5]**.

Despite the fact that ultrasound guided TAP block is highly successful procedure and associated with very low rate of complications, it has been underutilized. The lack of training as well as the shortage of ultrasound devices are the most prominent reasons **[6]**.

The modified surgeon assisted TAP block is a new technique which can be used in TAP block without the fear of complications in the blind landmark based approach. The advantage of this technique includes avoiding missing the second pop in obese and pregnant patients due to thinning of the internal oblique aponeurosis, reposition of the needle by surgeon if one enters the peritoneal cavity accidentally. Moreover, the possibility of visceral injury is largely reduced. Such simple technique is very useful for beginners who can use it safely without any fear of complication. However, there might be a chance of needle stick injury to the surgeon's hand **[6]**.

Patients & Methods:

This was a randomized, placebo- controlled, double blinded controlled trial which was conducted during the period from the 20th of September 2020 to the 20th of March 2021. After obtaining informed consent, sixty pregnant women above 18 years of age were included in the study and were divided into two groups; the study group received TAP block with 40ml of bupivacaine 0.25ml using the modified surgeon assisted technique while the placebo group received 40 ml of normal saline as placebo using the same technique. Inclusion criteria were American Society of Anesthesiologists physical status 1 or 2, patients scheduled for elective cesarean section (Category 4 CS) under spinal anesthesia at ≥ completed 37 weeks. Patients with BMI ≥ 40 kg/m2, major systemic medical disorder, allergy to bupivacaine, chronic pain disorders and those with intraoperative complications like postpartum hemorrhage, bowel or bladder injury were excluded.

The 60 patients who were included in our study were randomized through a computer-generated system into 2 groups; group T (TAP block) & group P (placebo). Each group included 30 patients. Allocation and concealment were done by sequentially sealed opaque envelopes. 60 envelopes were numbered serially from 1 to 60, 30 envelopes were the letter T and the other 30 were contain the letter P. In each envelope, the corresponding letter which denotes the allocated group was put according to the randomization table and then all envelopes were closed and put in one box. When the first patient arrives, the first envelope was opened and the patient was allocated according to the letter inside. An anesthesiologist not involved in the study prepared the syringes which were filled with either 40ml saline or 40ml of bupivacaine 0.25%. The surgeon who performed the procedure, the patient and the post-operative care providers were all blinded to the group assignment.

All participants received spinal anesthesia using hyperbaric 0.5%, bupivacaine 10mg. Before the closure of the peritoneum, TAP block was performed using the Modified Surgeon Assisted Bilateral TAP block described by Roy and Pattnaik as follows: the landmark is at the level of umbilicus 8 to 10 cm from midline bilaterally. A tiny nick is made in the skin with a 18G sharp needle to obliterate the cushion effect. Then an 18G Tuohy needle will be insert perpendicular to skin directing the needle slightly towards the ipsilateral anterior superior iliac spine just before the closure of peritoneum. After feeling 2 pops of external and internal oblique aponeurosis the drug or the placebo will be injected after aspiration. Once the plane is reached the surgeon places his hand inside the abdominal cavity at the level of needle insertion to reconfirm needle placement. A bleb is palpated by the surgeon as the injection continues. The backflow of drug after injection is one of the signs that drug has been deposited in the TAP plane. The same procedure is repeated on the other side so a bilateral TAP block is performed **[6]**. All patients included in the study received postoperative standard analgesic regimen in the form of diclofenac 75mg intravenously every 12 hrs after the procedure.

All the patients were assessed every 2hrs during the first 24hrs after the procedure. Visual analogue pain rating scale will be assessed ranging from 0: no pain to 10: worst imaginable pain and any patient with VAS ≥ 4 during any assessment point of time received 25 mg pethidine intramuscularly. The primary outcome of our study was the time to the first analgesic request defined as the time from the end of surgery until the patient's first request for analgesia. The secondary measures of outcome were the total pethidine requirement received in 24hrs by each patient in the study or control group, the number of doses and complications which included nausea, vomiting, abdominal distention and fever. Moreover, rare complications related to systemic absorption of bupivacaine like hypotension and arrhythmia were documented if happened.

The sample size was calculated based on PASS 11 program for sample size calculation and according to ***Srivastava et al***, the expected mean time to first demand for analgesia in control group = 6.5 ± 2 hrs and in study group = 12 ±3 hrs, sample size of 30 patients per group can detect the difference between two groups with power > 99% and α – error 0.05. **[7].** Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. The Kolmogorov- Smirnov test was used to verify the normality of distribution of variables, comparisons between groups for categorical variables were assessed using Chi-square test. Student t-test was used to compare two groups for normally distributed quantitative variables. Mann Whitney test was used to compare between two groups for not normally distributed quantitative variables. Kaplan-Meier survival curve was used to showing the % of patients not requiring supplemental analgesia over time. The log rank test was used to determine the significance of difference. Significance of the obtained results was judged at p value < 0.05.

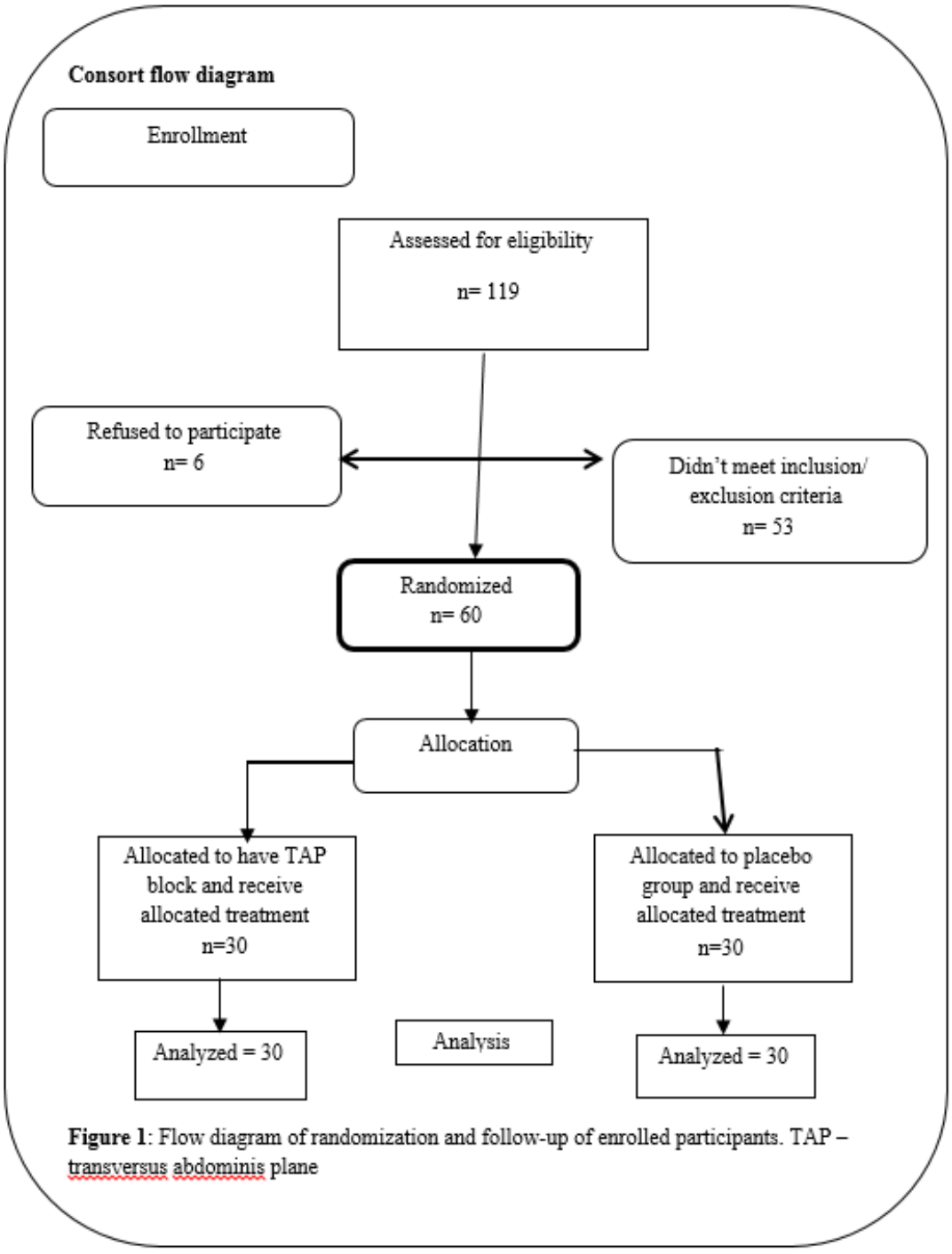

Figure 1: Flow diagram of randomization and follow-up of enrolled participants. TAP – transversus abdominis plane

Results:

A total of 60 pregnant patients who underwent elective LSCS met the inclusion/exclusion criteria of the study. 30 parturients were allocated to the TAP group and the 30 parturients were allocated to the placebo group. Maternal demographic data were similar in both groups ($p > 0.05$) **(Table 1, 2).**

Table 1: Comparison between the two studied groups according to age

Age (years)	Group T n = 30	Group P n = 30	Test	P
Mean±SD	29.50 ± 5.41	30.70 ± 5.58	0.846	0.401

SD: *standard deviation,* ***T: TAP group, P:*** *placebo, test: Student t test, p: p value for comparing between the studied groups*

Table 2: *Comparison between the two groups according to other demographic data:*

Demorgaphic data	Group T n = 30	Group P n = 30	Test	P
Weight(kg) Mean±SD	80.97 ± 5.02	82.37 ± 4.94	t = 1.088	0.281
Height (cm) Mean±SD	166.97 ± 2.89	167.30 ± 2.53	t = 0.475	0.637
BMI (Kg/m2) Mean±SD	29.07± 2.20	29.65 ± 1.99	t = 1.076	0.286
Parity Median (IQR)	2(1 – 3)	2(1 – 3)	U=	

SD*: standard deviation,* ***IQR****: interquartile range,* ***t****: Student t test,* ***U****: Mann Whitney test,* ***p****: p value for comparing between the studied groups*

There was statistically significant difference regarding the operative time in minutes between the two groups; (mean ± SD): TAP group: 61.0 ± 9.77, placebo group: 54.33 ± 6.12 with p value 0.002 **(Table 3).**

Table 3: Comparison between the two groups according to the operative time:

Operative time (minutes)	Group T n = 30	Group P n = 30	Test	P
Mean±SD	61.0 ± 9.77	54.33 ± 6.12	t = 3.166	0.002

SD*: standard deviation,****t****: Student t test,*

The primary outcome of the study was the time to the first analgesic request which was significantly shorter among the placebo group; median (IQR) = 4h (4, 6) in the placebo group compared with 24h (10, 24) in the active group **(Table 4).**

Table 4: Comparison between the two groups according to the first requirement of analgesia (in hours):

First request for analgesia	Group T n = 30	Group P n = 30	Test	P
Median (IQR)	24 (10 -24)	4 (4 -6)	U=30.0	**<0.001**

IQR*: interquartile range,* ***U****: Mann Whitney test,* ***p****: p value for comparing between the studied groups*

Regarding the postoperative opioid consumption, it was significantly greater in the placebo group; all of the 30 participants in the placebo group required postoperative opioids compared to only 13 participants in the active group (43.3%) with p-value <0.001. The median (IQR) number of pethidine doses required in the placebo group (2{2-2}) was significantly more compared with in the active group (0{0-1}) with p value < 0.001 **(Table 5).**

Table 5: *Comparison between the two groups according to number of opioid doses required:*

Number of opioid doses required	Group T n = 30	Group P n = 30	Test	P
Median (IQR)	0 (0 -1)	2 (2 -2)	U= 39.50	**<0.001**

IQR*: interquartile range,* ***U****: Mann Whitney test,* ***p****: p value for comparing between the studied groups*

Regarding the mobilization time, it was significantly shorter among the TAP group (mean ± SD: 4.13 ± 0.57) compared with the placebo group (mean ± SD: 6.53 ± 1.04) with p value < 0.001 **(Table 6)**.

Table 6: Comparison between the two groups according to mobilization time after the operation:

Mobilization time after the procedure	Group T n = 30	GroupP n = 30	Test	P
Mean ± SD	4.13 ± 0.57	6.53 ± 1.04	U= 22.50	**<0.001**

U: *Mann Whitney test,* ***SD:****Standard deviation,* ***p****: p value for comparing between the studied groups*

With each assessment during the first 24hrs postoperatively, the visual analogue pain rating scale was significantly lower in the active arm of the study compared with the placebo arm ($p < 0.001$) **(Table 7).**

Table 7: Comparison between the two groups according to the numerical pain rating visual analogue scale after surgery:

VAS	GroupT n = 30	GroupP n = 30	Test U	P
2hrs	2 (2-2)	4 (4-4)	0.0	<0.001
4hrs	2 (2-3)	4 (4–6)	42.0	<0.001
6hrs	3 (3–4)	4 (4–4)	204.0	<0.001
8hrs	3 (3– 4)	4 (4–4)	177.50	<0.001
10hrs	3 (3 - 4)	5 (4– 6)	143.0	<0.001
12hrs	3 (3– 3)	4 (4– 4)	172.0	<0.001
14hrs	3 (3 - 3)	4 (4– 4)	77.50	<0.001
16hrs	3 (2 - 3)	4 (4– 4)	36.0	<0.001
18hrs	3 (2– 3)	4 (4 – 4)	42.0	<0.001
20hrs	3 (2– 3)	4 (4– 4)	55.0	<0.001
22hrs	3 (3– 3)	4 (4 – 4)	58.0	<0.001
24hrs	3 (2– 3)	4 (4– 4)	66.0	<0.001

*Values are expressed as median (Interquartile range), **U**: Mann Whitney test, **p**: p value for comparing between the studied groups*

The Kaplan-Meier survival curve was used to showing the % of patients not requiring supplemental analgesia over time. (Figure.2). There was no significant difference between the two groups regarding postoperative nausea (2 patients in the active group and 3 patients in the control group suffered from mild nausea) and no complications related to bupivacaine toxicity was reported.

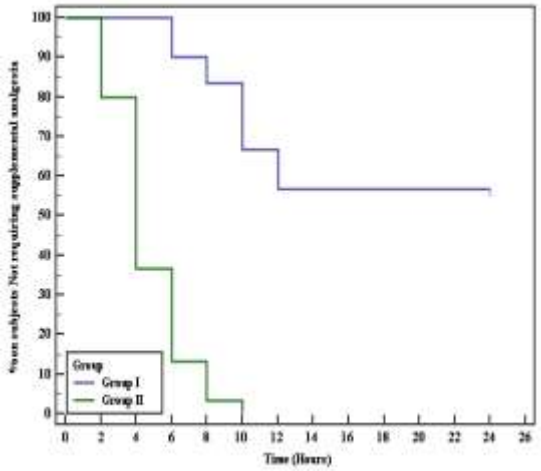

Figure 2: Kaplan-Meier survival curve for percentage of patients not requiring supplemental analgesia over time

Discussion:

Effective pain control is an important aspect of recovery for women after caesarean delivery [8]. Although a variety of choices of drugs and routes of administration are available, we are yet to achieve a safe and effective method of pain control after LSCS(3).The aim of the current study is to evaluate effect of the modified surgeon assisted bilateral TAP block on postoperative analgesia after cesarean section.

As for the time to the first analgesic request, it was significantly longer among the active group. Such results were similar to that obtained by Buluc et al., who evaluated the effect of ultrasound guided TAP block with 60 ml of 0.25% bupivacaine; the time to the first request for analgesia was longer in the active group with p value = 0.003 [9]. Jadon et al., also found similar results with 0.375% ropivacaine used for ultrasound guided TAP on 67 patients who underwent scheduled LSCS. The median (IQR) time to first analgesic request was 11 h [8,12] in the TAP group and 4 h (2.5,6) in the study group with P value < 0.0001[3].

The total postoperative opioid requirement was significantly less among the TAP group as only 13% required postoperative opioids compared to 100% of the placebo group. The placebo group consumed significantly more opioid doses in the postoperative period.

Kupiec et al., also achieved similar results in their study which tested the efficacy of bupivacaine 0.25% as the active component of the ultrasound guided TAP block. The active group of the study showed less on demand tramadol consumption which was delivered via patient controlled analgesia method with p value = 0.005 [10].

The analgesic efficacy of TAP block with bupivacaine was also demonstrated by Tarekegn et al., who showed that the total postoperative tramadol consumption in the first 24 hours was significantly less among

the TAP block group compared with the control group with p value = 0.001[11].

The Numerical pain rating visual analogue scale was measured every 2hrs during the first 24hrs postoperatively and there was statistically significant difference between the two groups with less scores obtained in the TAP block group. Similar results were shown in the study obtained by Jadon et al., who assessed VAS during rest and movement [3]. Eslamian et al., also demonstrated similar results regarding the postoperative VAS which was measured in the recovery room, 6, 12 and 24hrs after the procedure with coughing and during rest. With the exception of the VAS measured after 24hrs at rest, there was a significant difference in the VAS for pain both at rest and during coughing [12].

There were no complications related to TAP block systemic toxicity in our study. However, such complications are rare and larger studies with bigger sample size are needed to detect such complications. Our study was not without limitations. The VAS was measured without documenting whether it was measured during rest or movement; the postoperative analgesia was not delivered via the patient controlled analgesia (PCA) pumps since it's not always available at our institute.

Conclusion:

The Modified assisted surgeon bilateral TAP block is effective technique for providing postoperative analgesia for patients scheduled for elective LSCS under spinal anesthesia via Pfannenstiel incision. It has significant effect on the postoperative pain, time required for the first analgesia, the total postoperative opioid consumption. It can be performed by the surgeon who performed the cesarean section without the need for ultrasound device.

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