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Original article

RANDOMIZED CONTROLLED COMPARATIVE STUDY OF ANTERIOR ABDOMINAL FIELD BLOCK AT LINEA SEMILUNARIS WITH A STANDARD INSTITUTIONAL REGIMEN FOR POSTOPERATIVE ANALGESIA IN CAESAREAN SECTION

(POST-OPERATIVE CAESAREAN SECTION ANALGESIA WITH ABDOMINAL FIELD BLOCK)

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Abstract

Introduction: *A transverse abdominis plane block is a recent and newer method to reduce post-operative pain due to abdominal incisions. The efficacy of anterior abdominal field block at the linea semilunaris technique compared with a placebo.* ***Methods:*** *A randomized controlled comparative interventional study was conducted at Government Dharmapuri Medical College and Hospital, Dharmapuri, Tamil Nadu, India between January 2023 to June 2023. Patients recruited for the study were randomized and allotted to receive either the drug or the placebo. One of the groups received an abdominal field block with 20 ml of 0.25% bupivacaine, and the placebo group received a Normal Saline injection at the same site. A standard institutional protocol of inj. diclofenac 100 mg rectal suppository; and Inj. Tramadol 100 mg intramuscularly was followed in all the cases. Visual Analog score was used to analyse post-operative pain. If indicated, rescue analgesia – injection of tramadol 100 mg (if VAS >4) was given intramuscularly.* ***Results:*** *Final analysis included 40 subjects. 20 participants in treatment and placebo group; This study shows that transversus abdominis plane (TAP) done at linea semilunaris provides adequate postoperative analgesia for a shorter duration. The difference in VAS score was between the procedure group and placebo at 4 hours was significant. After this, there was no significant difference in the VAS score between the two groups. There was a significant reduction in the need for rescue analgesia at 4 hours. The hemodynamic changes in the procedure group compared to the placebo group was not significant.* ***Conclusion:*** *There is a significant usage for anterior approach abdominal field block (Linea semilunaris block) in providing analgesia for post-Caesarean section.*

Keywords: *Caesarean section; Abdominal field block; bupivacaine; linea semilunaris; placebo*

Introduction

Caesarean section delivery is the a regular surgery performed in developing countries.[1] Its rapid increase in recent decades makes the management of caesarean an important research area.[2] Effective postoperative analgesia after caesarean section is important and has an impact on the surgical and also per-partum outcomes.[3,4] Spinal anaesthesia is the used for elective and emergency caesarean delivery. One of the disadvantages of spinal anaesthesia is the duration of analgesia is limited. It requires additional analgesia to be administered to achieve pain control.[5] An increase in early diagnosis of difficult labour has made spinal anaesthesia a major procedure for emergency and also elective caesarean deliveries.[6]

The pain after abdominal surgery is due to the abdominal wall incision. Post-operative analgesia regimes recommend opioids that have undesired side effects. This has initiated development of truncal block techniques.[7] Further randomized controlled trials have been performed to evaluate the efficacy of these approaches.[7,8]

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There are various types of field blocks that can be used for caesarean section based on the anatomical site. These include paravertebral, transversus abdominis plane (TAP), quadratus lumborum (QL), iliohypogastric (IH) and ilioinguinal (II), and continuous wound infiltration (CWI) blocks. The advantages and disadvantages vary significantly among the techniques [7].

A transverse abdominis plane block, which is a type of abdominal block is a newer and recent approach to reduce post-operative pain due to abdominal incision [9] TAP is a neurovascular plane located between the internal oblique and transverse abdominal muscles, it traverses the nerves supplying the abdominal wall.[10] This landmark for this block is at the lumbar triangle of Petit.[11] The myocutaneous block is achieved through injecting local anaesthetic in this space. This block has been evaluated for postoperative analgesia in abdominal surgery like total abdominal hysterectomy and cholecystectomy.[12,13]

The study was performed to assess the efficacy of novel surgically assisted abdominal field block which is a variant of TAP technique at Linea semilunaris in comparison with the standard analgesic regime for postoperative analgesia for women undergoing caesarean section.

Methodology

A randomized controlled comparative study was conducted at Government Dharmapuri Medical College and Hospital, Dharmapuri, Tamil Nadu, India between January 2023 to June 2023. Approval from the institutional ethics committee was taken before the enrolment of the study participants. Pregnant women undergoing lower segment caesarean section (LSCS) were screened. Study participants were finalized, and informed consent was obtained from them. The inclusion exclusion criteria followed are:

Inclusion Criteria:

- Age > 18 years
- The patient was assessed under ASA II

Exclusion Criteria:

- History of cardiac, respiratory, liver, and renal disease
- Allergy to study medications or local anaesthesia.
- History of Psychiatric illness/neurological deficit.

Patients recruited for the study were randomized and allotted to receive either the drug or the placebo. The randomization was done using the SNOSE method. Study group one received an abdominal field block with 20 ml of 0.25% bupivacaine, and the placebo group received a normal saline injection at the same site. Both patients and the post-operative pain assessor were blinded.

Calculation of sample size using the expected median pain score (VAS score) of 3 in the drug group [14] and a probability of 0.87.

$$N = \frac{(Z_{\alpha/2}+Z_{\beta})^2}{12c(1-c)\,(P^n-0.5)}$$

The formula used for calculation is

Where P^n = Probability that a score from X is larger than the score from Y is larger than 1/2.

c =1/(1+k) where k is the Allocation ratio.

The sample size calculated to be drawn is 40. Hence 20 participants in each group (drug and placebo) were included.

Procedure

Women posted for elective caesarean section under spinal anaesthesia were selected for the study. pre-anaesthetic check-up was done. The abdominal field block was carried out intra-operatively. The abdominal field block was done by the anterior approach. A needle was inserted at linea semilunar above the rectus muscle. The needle was inserted in a medial to the lateral direction to place the tip below the anterior rectus sheath, in the myofascial plane, between the tendons of anterior abdominal muscles above and fascia transversalis and peritoneum below.[15] The block was given bilaterally.

Based on the randomization and the group allotted, either 20 ml of the study drug or normal saline was given on either side after negative aspiration. In all patients, as per the Standardized Institutional Protocol – inj. diclofenac 100 mg rectal suppository; and in. tramadol 100 mg intramuscularly was administered after the surgery was completed.

Primary end point is Postoperative Pain which was assessed using a Visual Analog Score.[16] The assessor was blinded concerning the treatment given. If indicated, rescue analgesia – injection of tramadol 100 mg (if VAS >4) was given intramuscularly. Secondary end points are postoperative hemodynamic changes.

Ethical and informed consent: Ethical approval was obtained from the institutional review board [Ref: GDMC:01/2022 of the centre concerned. Informed written consent was obtained before the study started and confidentiality was maintained throughout. Clinical trial registry of India registration was done (CTRI/2023/01/049201).

Statistical analysis: Pain score based on the VAS was the primary outcome variable. Study group (treatments) Drug and Placebo were considered as Primary explanatory variables. For analytical statistics, independent sample t-test, Mann Whitney U test and chi-square tests were used. P value < 0.05 was considered statistically significant. Data were analysed by using coGuide software.

Results

A total of 40 subjects were included in the final analysis; 20 (50.00%) participants had taken drug treatment, and 20 (50.00%) participants had taken placebo treatment.

The mean age (years) within drug treatment was 22.70 ± 3.36, and it was 25.20 ± 4.05 in placebo treatment. The mean difference of age (years) between study groups was statistically significant (P value < 0.05). The mean difference in height (in cm), weight (in kg), and body mass index (BMI) between study groups were statistically not significant (P value > 0.05). In drug treatment, 11 (55.00%) participants were primigravida, and 9 (45.00%) participants were multigravida. In the placebo treatment, 5 (25%) participants were primigravida, and 15 (75%) were multigravida. In drug treatment, the majority of 9 (45.00%) participants had previous LSCS indications, and 14 (50.00%) had previous LSCS indications in placebo treatments. Two (10.00%) participants had GDM and PIH comorbid illness in placebo treatment. In both treatments, 20 (100.00%) participants were ASA grade II. (Table 1)

The median VAS score at 4 hours within drug treatment was 4.00 (3.0 to 5.0), and it was 5.00 (5.0 to 6.0) in placebo treatment. The median difference in VAS score at 4 hours between study groups was statistically significant (P value < 0.001). The median difference of VAS score at 8 hours, 12 hours, 16 hours, and 24 hours between the study group was statistically not significant (P value > 0.05). (Table 2)

The mean difference of heart rate score (bpm), SBP (mmHg), and DBP (mmHg) at all time points (0 hours, 4 hours, 8 hours, 12 hours, 16 hours & 24 hours) between the study group was statistically not statistically significant (P value > 0.05). (Table 3)

In drug treatment, 3 (50.00%) participants had taken tramadol injection at 4 hours, and 3 (50.00%) had taken diclofenac injection at 4 hours. In placebo treatment, 16 (94.12%) participants had taken tramadol injection at 4 hours, and 1 (5.88%) had taken diclofenac injection at 4 hours. The difference in the proportion of rescue analgesia at 4 hours between study groups was statistically significant, with a P-value of 0.0401. (Figure 1). The difference in the proportion of rescue analgesia at 8 hours, 12 hours, and 16 hours between study groups was statistically not significant (P value > 0.05). The majority of 8 (100.00%) participants had taken paracetamol injections in drug treatment. (Table 4)

Discussion

This study shows that TAP done at linea semilunaris provides adequate postoperative analgesia for a shorter duration. There was a significant difference in the VAS score between the procedure group and placebo at 4 hours. After this, there was no significant difference in the VAS score between the two groups. There was a significant reduction in the need for rescue analgesia at 4 hours between the groups. There were no significant hemodynamic changes in the procedure group compared to the placebo group.

The results are similar to the randomized controlled trial by Srivastava et al., where they analysed the effect of TAP block with the control group. The results showed that the use of tramadol as rescue analgesia was reduced in patients given a TAP block by 50% compared to patients given no block 48 hours after surgery (P-value < 0.001) and there

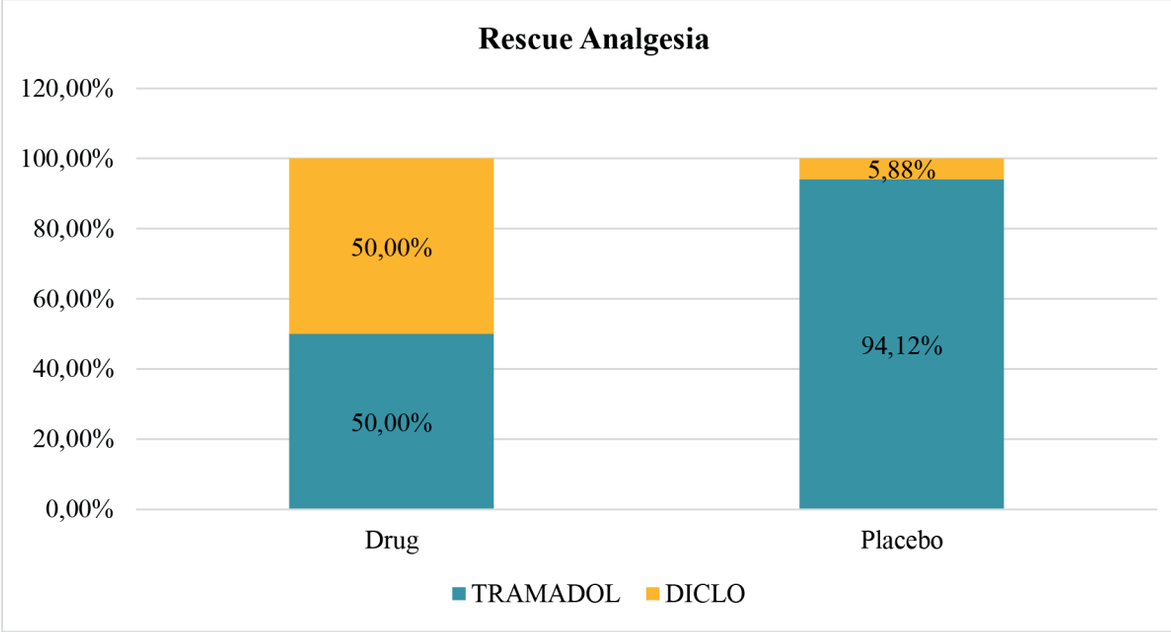

Figure 1: Comparison of rescue analgesia at 4 hours-time point with study group (N = 23)

were no side effects in the treatment group.[17] Another study by Mohapatra et al. also showed that the transversus abdominis plane block with bupivacaine showed decrease in postoperative Visual Analog Scale pain scores in comparison to the placebo block. [18]

A study in low resource setting by Moyo et al. were evaluated post-operative analgesia with TAP in mothers. The randomized placebo-controlled trial showed that there was a statistically significant difference in the Visual Analog Scale for pain at 4 hours. The control group women had shorter pain free period 56.8 min (median 56.5 min) compared to pain free period of 116.5 min (median 103 min) in the study group. There was significant difference in the total period of analgesia between the groups.[19]

A study done in Karnataka by Naveen et al. shows similar results. The mean time to rescue analgesia was long in Group TAP as compared to placebo group. The mean time to rescue analgesia was 88.02 ± 21.62 min and 525.27 ± 114.52 min ($P < 0.001$) in groups CONT and TAP, respectively. [20]

A study done in Pakistan evaluated the meantime for analgesia in patients with TAP and compared it with a placebo. The results showed that meantime for first analgesia was shorter in placebo group compared to transversus abdominus plane block group 4.96 ± 1.44 hours and 11.24 ± 1.83 hours respectively (P-value ≤ 0.01).[21]

TAP block study was conducted in ASA I and II patients undergoing elective caesarean section under spinal anaesthesia by Cansiz et al. The study showed that pain scores were lower and the time of demand for first analgesia was longer in study groups and these were statistically significant. [22] Another study was conducted using 20 ml of 0.375% ropivacaine on either side, which included ASA II patients by Chansoria et al. for patients undergoing caesarean section under spinal anaesthesia showed that there is a reduction in mean Visual Analog Score ($P < 0.001$) and lower opioid consumption in the drug group.[23]

Some studies have also shown no analgesic benefit. McKeen et al. 2014 performed a study using a TAP block and the results showed that 24 hours after caesarean delivery revealed no clinically significant differences between groups in postoperative pain or rescue analgesia consumption.[24]

Anterior approach to the TAP block at linea semilunaris was conducted by Akhade et al. The results showed that the among the participants 96.7% did not require analgesia at 4 hours, 81.7% at 8 hours, 77.5% at 12 hours and 90.8% did not require are 24 hours after analgesia. No patient required rescue analgesia with opioid supplementation. Satisfaction of patient was high, and were ambulated early.[25]

Table 1: Comparison of demographic parameters with study population (N = 40)

Parameter	Study Group		P-value
	Drug (N = 20)	Placebo (N = 20)	
	Mean ± SD	Mean ± SD	
Age (in years)	22.70 ± 3.36	25.20 ± 4.05	0.0400*
Height (in cm)	154.35 ± 4.04	151.90 ± 6.36	0.1541*
Weight (in kg)	67.20 ± 21.78	65.65 ± 11.08	0.7782*
Body Mass Index (BMI)	26.14 ± 3.43	28.26 ± 4.55	0.1044*
Gravida			
PRIMI	11 (55.00%)	5 (25%)	0.053†
Multi	9 (45.00%)	15 (75%)	
Surgical Procedure			
Elective LSCS	2 (10.00%)	2 (10.00%)	1.00‡
Emergency LSCS	18 (90.00%)	18 (90.00%)	
Indication			
Previous LSCS	9 (45.00%)	14 (50.00%)	§
MSL	4 (20.00%)	1 (5.00%)	
CPD	3 (15.00%)	1 (5.00%)	
PROM	1 (5.00%)	1 (5.00%)	
Oligohydramnios	2 (10.00%)	3 (10.00%)	
FAS	1 (5.00%)	0 (0.00%)	
Any Comorbid Illness			
GDM	1 (5.00%)	2 (10.00%)	§
Pre-Eclampsia	1 (5.00%)	0 (0.00%)	
Hypothyroid	0 (0.00%)	1 (5.00%)	
PIH	0 (0.00%)	2 (10.00%)	
Anaemia	0 (0.00%)	1 (5.00%)	
Nil	18 (90.00%)	14 (70.00%)	
ASA PS Class			
II	20 (100.00%)	20 (100.00%)	||

*= Independent t-test P value; †=Chi square test; ‡= Fisher exact test P value;§= No Test was applicable due to zero cell value; ||= No Test was applicable due to nature of the data

Table 2: Comparison of VAS score with a study group at different periods (N = 40)

Parameter	Study Group		P-value (Mann Whitney U Test)
	Drug (Median (IQR)) (N = 20)	Placebo (Median (IQR)) (N = 20)	
VAS score			
4 hours	4.00 (3.0 to 5.0)	5.00 (5.0 to 6.0)	< 0.001
8 hours	4.00 (3.75 to 5.25)	4.00 (3.0 to 5.0)	0.4057
12 hours	4.00 (3.75 to 4.0)	4.00 (3.75 to 4.0)	0.4288
16 hours	4.00 (3.0 to 4.0)	4.00 (3.0 to 4.0)	0.4241
24 hours	3.50 (3.0 to 4.0)	4.00 (3.0 to 4.0)	0.1130

Table 3: Comparison of Heart rate (bpm), SBP (mmHg), and DBP (mmHg) with a study group at different periods (N = 40)

Parameter	Study Group		P-value
	Drug (N = 20)	Placebo (N = 20)	
	Mean ± SD	Mean ± SD	
Heart Rate score (bpm)			
0 hour (baseline)	90.40 ± 6.54	90.05 ± 9.58	0.8934
4 hours	84.40 ± 9.44	86.70 ± 10.02	0.4594
8 hours	80.75 ± 11.76	79.90 ± 10.85	0.8134
12 hours	81.20 ± 8.84	80.00 ± 9.90	0.6882
16 hours	80.60 ± 8.73	77.80 ± 8.99	0.3240
24 hours	77.70 ± 7.49	78.00 ± 8.92	0.9089
Systolic BP (mmHg)			
0 hour (baseline)	114.30 ± 13.52	108.50 ± 10.66	0.1402
4 hours	118.80 ± 13.71	115.40 ± 7.84	0.3418
8 hours	117.40 ± 13.84	115.10 ± 8.45	0.5297
12 hours	115.00 ± 11.14	114.80 ± 5.71	0.9434
16 hours	112.50 ± 8.89	111.70 ± 5.63	0.7358
24 hours	113.60 ± 7.75	112.20 ± 5.76	0.5207
Diastolic BP (mmHg)			
0 hour (baseline)	71.20 ± 6.2	69.60 ± 8.65	0.505
4 hours	78.30 ± 11.83	73.80 ± 5.65	0.1330
8 hours	75.70 ± 8.64	72.90 ± 6.21	0.2465
12 hours	75.80 ± 7.11	72.50 ± 5.87	0.118
16 hours	72.60 ± 5.07	71.60 ± 3.76	0.483
24 hours	72.80 ± 5.63	72.20 ± 4.15	0.7035

Table 4: Comparison of rescue analgesia with a study group at different periods

Rescue analgesia	Study Group		Chi-square value	P-value
	Drug	Placebo		
4 hours	**(N = 6)**	**(N = 17)**		
Injection. Tramadol	3 (50.00%)	16 (94.12%)	6.01	0.0401*
Injection. Diclofenac	3 (50.00%)	1 (5.88%)		
8 hours	**(N = 10)**	**(N = 8)**		
Injection. Tramadol	8 (80.00%)	4 (50.00%)	1.80	0.321*
Injection. Diclofenac	2 (20.00%)	4 (50.00%)		
12 hours	**(N = 10)**	**(N = 7)**		
Injection. Paracetamol	5 (50.00%)	3 (42.86%)	0.084	1.00*
Injection. Diclofenac	5 (50.00%)	4 (57.14%)		
16 hours	**(N = 8)**	**(N = 7)**		
Injection. Paracetamol	5 (50.00%)	3 (42.86%)	0.084	1.00*
Injection. Diclofenac	5 (50.00%)	4 (57.14%)		
24 hours	**(N = 8)**	**(N = 8)**		
Injection. Paracetamol	8 (100.00%)	7 (87.50%)	-	†
Injection. Diclofenac	0 (0.00%)	1 (12.50%)		

*=Fisher exact test P-value; †= No Test was applicable due to zero cell value

Conclusion

There is a significant postoperative analgesia effect with anterior abdominal field block at linea semilunaris for patients undergoing caesarean section. There is a significant reduction in the pain levels as assessed by the VAS score and a requirement of reduced analgesia at a 4-hour post-operative duration. There is considerable potential for analgesia with or anterior approach abdominal field block (Linea semilunaris block) post-Caesarean section.

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