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Original Research Article

A Comparative Study of Efficacy of Landmark-Guided Bilateral Transversus Abdominal Plane Block Using 0.5% Ropivacaine for Post-Operative Analgesia Versus Placebo in Patients Undergoing Caesarean Section Under Spinal Anaesthesia

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Abstract:

Background: Transversus Abdominis Plane (TAP) block is a regional anaesthetic technique that provides analgesia after lower abdominal interventions, especially where somatic pain from the incision in the anterior abdominal wall constitutes the primary component of pain. By depositing local anaesthetic drugs in the neurovascular plane between the Internal oblique aponeurosis and the transverse abdominis muscle, TAP block provides sensory blockade of the epidermis over the lower abdominal wall. In a prospective, randomised, experimental, double-blinded study, we evaluated the efficacy of bilateral TAP block with ropivacaine and placebo for lower segment caesarean section under spinal anaesthetic.

Methodology: This single centre, randomised, double-blind, controlled study was conducted from November 2019 to May 2021 in the Department of Anaesthesiology at the NRI Institute of Medical Sciences in Sangivalasa, Visakhapatnam. Group R and Group P were each comprised of 60 patients, for a total of 120 patients. Using a landmark-guided technique, both groups received a Transversus abdominis plane (TAP) block, with patients in Group R receiving 15ml of 0.5% ropivacaine and patients in Group P receiving 15ml of normal saline on each side. Immediate postoperatively, hemodynamic parameters and VAS score were measured every two hours until the time of rescue analgesia.

Results: Hemodynamic parameters such as heart rate, systolic blood pressure, and diastolic blood pressure between Group R and Group P were statistically significant with p values of <0.0001, <0.0001, and <0.0090 for the second and fourth hourly measurements, respectively. The difference in VAS scores between Groups R and P at the 2nd and 4th hours was statistically significant, with p values of <0.0001 and <0.0001 respectively.

Conclusion: The VAS score of 4 was reached at 618 minutes in Group R and 144 minutes in Group P, indicating that the request time for rescue analgesia was longer in Group R than in

Group P. With its inherent benefits (anaesthetic potency, long duration of action, and favourable safety profile), ropivacaine is preferable to placebo for post-operative pain relief.

Keywords: Caesarean section, Transversus abdominis plane (TAP) Block, Ropivacaine.

Introduction

Anesthesiologists face a unique set of challenges with regard to the patient population in case of caesarean delivery.[1,2] In order to care for their infants, the patients desired to be vigilant, comfortable, pain-free, and ambulatory during the postoperative period. Opioids are required as an initial component of a multimodal analgesic approach to produce effective analgesia. Opioids are associated with dose-dependent adverse effects, such as nausea, vomiting, pruritus, sedation, and respiratory depression. Techniques that reduce the need for opioids will benefit this population.[3] Due to cutaneous incision, uterine incision, and uterine contraction, post-caesarean section pain and discomfort may be anticipated. Significant agony experienced by the patient is caused by the surgical incision. Therefore, obstructing the anterior abdominal wall's sensory nerve supply will provide effective postoperative analgesia. TAP block is one of the regional anaesthetic techniques used to inhibit the abdominal wall's innervations.[3]The TAP block decreases the use of analgesics following abdominal surgery, including Caesarean section[1]. The block reduces the use of antiemetic medications and the VAS score for analgesia. There are no significant neurovascular structures in close proximity to the area to be blocked, which is an advantage for performing this block.[4,5] The majority of caesarean sections in India are performed in secondary health care facilities where ultrasonography is unavailable. In order to apply my research to a large population, we have chosen the landmark-based method.[6]

Even though regional anaesthesia training nowadays is more focused on USG-guided blocks, access to USG is limited in India and other developing nations, and an anaesthesiologist should be trained to provide the best and safest practise in all types of settings.[7,8] This study aimed to evaluate the efficacy of bilateral TAP block with ropivacaine and placebo for lower segment caesarean section under spinal anaesthetic.

Material and Methods

This research was conducted in the obstetrics operating room at NRI Institute of Medical Sciences, Visakhapatnam between 1st November 2019 and 1st May 2021 with approval from the Institutional Ethical Committee. The objective of this study was to compare the efficacy, failure rates, and safety profile of landmark-guided bilateral Transversus abdominal plane (TAP) block with 0.5% ropivacaine versus placebo for postoperative analgesia in patients undergoing lower segment caesarean section. For a landmark-guided TAP block approach, the Triangle of Petit was utilised. The blind landmark-based TAP block technique that we used was based on the description provided by Shiv Kumar Singh in his article.[7] The point of the needle used to pierce fascia was bent by rubbing it against a sterile steel bowl in order to better observe the popping sounds produced.

Study Design

The study was prospective, randomised, and double-masked. Online calculator was utilised to calculate sample size based on the following study:

Staker JJ et al[8], for calculation of sample size. The ilioinguinal-transversus abdominis plane (I-TAP) nerve block for

elective caesarean delivery was investigated in a randomised, double-blind, placebo-controlled study.

Sample size n= $\frac{2\sigma 2}{(m1-m2)^2} \times f(\alpha,\beta)$

σ = expected Standard deviation (30) m1 = mean of first group (48) m2= mean of second group (67) α = 0.05 (level of significance) β= 0.2, power = 1-β = 0.90. f (α, β) = 3.24(from table α = 0.05 and 1-β = 0.90).

Sample size n= $\frac{2(30)^2}{(67-48)^2} \times (3.24)^2$ = 52 each group

15% (minimize effect and data loss) = 52*0.15 = 8, total 52+8 = 60

To minimise any effect of data loss, an additional 15%, or 8 patients, were enrolled, for a total of 60 in Group R and 60 in Group P during the study period. Therefore, a total of 120 patients were enrolled, 60 for each study cohort. The patients were scheduled for lower segment caesarean section (LSCS) under spinal anaesthesia with ASA 2 physical status. After explaining the procedure during the PAC, informed, written consent was obtained from all patients.

Using computer software, sixty patients were assigned randomly to two groups. Group R: 60 patients received a bilateral landmark-guided TAP block with 15ml of Ropivacine at a concentration of 0.5%. Group P: 60 patients received a bilateral landmark-guided TAP block with a placebo solution (15 ml of normal saline on each side).

Both drug solutions were prepared and stored in identical 15ml syringes with solution A and solution B labels by a person who was not involved in conducting the procedure. A TAP block was administered by a consultant anesthesiologist following surgery and prior to transfer to the post-operative care unit. The patients were then monitored, and objective parameters were recorded at regular intervals until it was time to administer rescue analgesia.

Inclusion criteria

- Age: 18-45 years,
- ASA physical status 1 and 2,
- Pregnant women undergoing caesarean section under sub arachnoid block,
- Weight > 50 kgs,
- B.M.I. < 30

Exclusion criteria

- Patient refusal,
- Known allergy to local anaesthetics,
- Age <18 years & >45 years,
- BMI >30,
- ASA Class 3 & 4,
- Localised infection at the site of injection,
- Emergency obstetric surgeries.
- hemodynamic compromise secondary to any aetiology,
- Patients with diabetes mellitus,
- Patients undergoing a vertical midline skin incision.
- Patients with psychiatric disorders,
- Patients with bleeding disorders

Data collection

Vital signs were continuously monitored and recorded at regular intervals (zero hour, second hour, and every second hour until rescue analgesia was administered.

The VAS score was used to evaluate the analgesia provided by either mode (solution A or solution B) immediately postoperatively and every two hours until the patient requested analgesics, which marked the end of the study.

The endpoint for rescue analgesia was determined to be a VAS score greater than or equal to 4. Tramadol 2 mg/kg I.V. bolus was administered as a rescue analgesic to alleviate acute pain.

Assessment of pain intensity: In acute stages, assessing pain can be a simple and straightforward task. The visual analogue scale (VAS) score is used to assess pain

intensity in patients experiencing immediate post-operative pain.[5,7]

Statistical analysis: The data was depicted using Mean Standard Deviation, frequency, and percentages, in addition to bar and line graphs. Independent two-sample t-tests were utilised to determine the statistical difference between the study groups. For statistical purposes, all analyses with a p-value less than 0.05 were considered significant. All statistical analyses were conducted using version 20 of the SPSS statistical software.

Results:

Table 1: Baseline parameters of patients

Baseline Parameters	Group R	Group P	P-Value
Age	26.48	25.42	0.6
BMI	28.29	28.17	0.656
Pre-op HR	98.65	96.25	0.373
Mean duration of Surgery	79.08	76	0.12
Pre-op SBP	116.17	117.45	0.54
Pre-op DBP	69.42	70.5	0.502

The baseline parameters of the two Groups P and R are comparable as shown in the Table 1.

The frequencies of age groups between 18 to 23, 24 to 30 and 31 to 35 were 11 (18.3%), 46 (76.6%) and 3 (5%) respectively in Group R. The frequencies of age group between 18 to 23, 24 to 30 and 31 to 35 were 16 (26.7%), 37 (61.7%) & 7 (11.7%) respectively in Group P.

The mean ages of Group R and Group P was 26.48 years and 25.42 years. The Mean B.M.I of Group R was 28.29kg/m^2 and Group P was 28.17.kg/m^2 (Table 1).

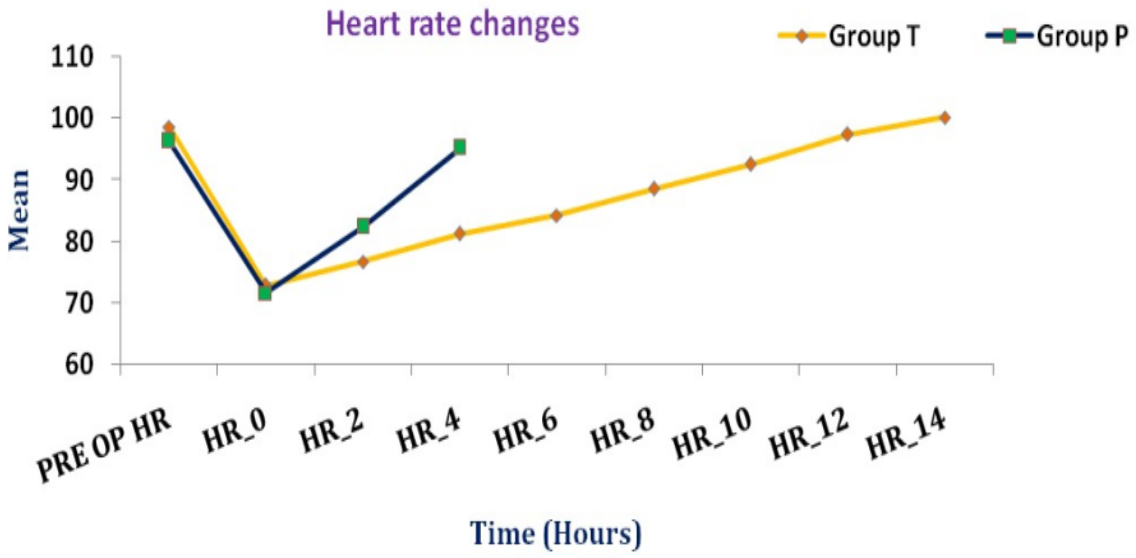

Figure 1: Representation of Mean heart rate between the two groups

Mean heart rate at 2nd hour (76.77 beats/min vs 82.38 beats/min in Group P) having a p-value <0.0001 and at 4th hour (81.22 beats/min in Group R), (95.17 beats /min in Group P) having a p-value of < 0.0001 was found statistically significant (Figure 1).

Table 2: Comparison of mean systolic blood pressure

Parameter	Group R	Group P	t-value	p Value, sig*
PRE OP SBP	116.17	117.45	-0.61	0.5400NS
SBP_0	105.02	106.02	-0.99	0.3240NS
SBP_2	107.38	111.37	-3.93	<0.0001S
SBP_4	110.08	118.00	-5.00	<0.0001S
SBP_6	113.17	.	-	-
SBP_8	116.09	.	-	-
SBP_10	118.35	.	-	-
SBP_12	121.83	.	-	-
SBP_14	125.4	.	-	-

*- P<0.05; Variable mean values are statistically significant between study groups determined by student un-paired t-test. NS: Non-significant S: Significant.

In comparison of Mean systolic blood pressure preoperatively (116.17mm of Hg in Group R), (117.45 mm of Hg in Group P) having a p-value of 0.5400 and at zero hour (105.02 mm of Hg in Group R), (106.02 mm of Hg in Group P) having a p value of 0.3240 was not statistically significant but at 2nd Hour (107.38 mm of Hg in GROUP R), (111.37 mm of Hg in GROUP P) having a p value of <0.0001 and 4th hour (110.08 mm of Hg in GROUP R), (118.0 mm of Hg in GROUP P**)** having a p value <0.0001 was statistically significant (Table 2)**.**

Table 3: Comparison of Mean diastolic blood pressure between two groups

Parameter	Group R	Group P	Mean Difference	95% Confidence Interval of the Difference	t-value	p Value, sig*
PRE OP DBP	69.42	70.5	-1.08	-4.27 to 2.10	-0.67	0.5020NS
DBP_0	63.73	65.12	-1.385	-3.03 to 0.26	-1.67	0.0970NS
DBP_2	65.55	69.48	-3.93	-6.85 to -1.02	-2.67	<0.0090S
DBP_4	68.25	78.75	-10.50	- 13.49 to - 7.51	-6.99	<0.0001S
DBP_6	70.14	-	-	-	-	-
DBP_8	72.7	-	-	-	-	-
DBP_10	76.28	-	-	-	-	-
DBP_12	78.2	-	-	-	-	-
DBP_14	79.8	-		-	-	-

*- P<0.05; Variable mean values are statistically significant between study groups determined by student un-paired t-test. NS: Non-significant S: Significant.

In comparison of Mean diastolic blood pressures at Preoperatively (69.42 mm of Hg in Group R), (70.05 mm of Hg in Group P) having a p value of 0.5020 and zero hour (63.73 mm of Hg in GROUP R), (65.12 mm of Hg in GROUP P) having a p value of 0.0970 was not statistically significant but at 2nd hour (65.55 mm of Hg in Group R), (69.48 mm of Hg in Group P) having a p-value of <0.0090 & at 4th hour (68.25 mm of Hg in Group R), (78.75 mm of Hg in Group P) having a p-value of <0.0001 is statistically significant.

Table 3: Comparison of Mean Visual Analogue Scores (VAS) between the two groups

Parameter	Group R	Group P	Mean Difference	95% Confidence Interval of the Difference	t-value	p Value, sig*
VAS_0	0	0	-	-	-	-
VAS_2	1.6	3.60	-1.93	-2.61 to -1.26	-5.73	<0.0001*
VAS_4	1.7	4.0	-2.27	-2.81 to -1.74	-8.58	<0.0001*
VAS_6	1.7	-	-	-	-	-
VAS_8	2.4	-	-	-	-	-
VAS_10	3.1	-	-	-	-	-
VAS_12	3.8	-	-	-	-	-
VAS_14	4.0	-	-	-	-	-

*- P<0.05; Variable mean values are statistically significant between study groups determined by student un-paired t-test. NS: Non-significant S: Significant

Mean Visual analogue Score (VAS Score) at 2nd hour (1.6 in Group R) (3.6 in Group P) having a p-value of <0.0001 & at 4th hour (1.7 in Group R) (4 in Group P) having a p value of <0.0001 is statistically significant.

Discussion

The transversus abdominis plane block is crucial for abdominal surgeries. In our study, landmark-guided bilateral TAP was performed with 15 ml 0.5% ropivacaine in group R and 15 ml placebo (Normal saline) in group P. The primary objective of this study was to compare the efficacy of landmark-guided bilateral TAP blocks for post-operative analgesia; the secondary objective was to examine the failure rate, safety profile, and the hemodynamic parameters following administration of the block. In our investigation, we compared demographic characteristics with regard to age, BMI, and duration of surgery. We compared patients between the ages of 18 and 35. The mean age was 26.88 years for Group R and 25.42 years for Group P. The p value between the groups was discovered to be 0.0600, which was not statistically significant. Group R had a mean BMI of 28.29mg/kg2 and Group P had a mean BMI of 28.17mg/kg2; the p-value was 0.6560, which was not statistically significant. Compared to the duration of surgery, the mean duration of surgery in Group R was 79.08 minutes and in Group P it was 76.00 minutes, with a p-value of 0.1200, which was not statistically significant, suggesting that it may not affect the duration of analgesia from the weaning off effect of spinal anaesthesia.

Comparing systolic blood pressures prior to surgery, at zero hour, and every two hours. With p-values of 0.5400 and 0.3240, respectively, the mean systolic pressures at pre-operatively and zero hour are not statistically significant, indicating that blood pressures do not vary initially. With p values of < 0.0001 and < 0.0001, the mean systolic pressures at the 2nd and 4th hours are statistically significant, indicating that variations in blood pressure may be attributable to analgesia.

Compared diastolic blood pressures prior to surgery, at zero hour, and every two hours. With p-values of 0.5020 and 0.0970, the mean diastolic pressures at pre-operatively and zero hour are not statistically significant, indicating that baseline blood pressures are not altered initially. The 2nd and 4th hourly mean diastolic pressures were statistically significant with p values of 0.0090 and 0.0001, indicating that variations in pressure may be due to analgesia.

The efficacy of the TAP block was demonstrated by its ability to provide

effective postoperative analgesia in patients undergoing lower segment caesarean section, correlating with the studies conducted by McDonnell et al.[9], Abdallah et al.[10], and Belavy et al.[11].

Ropivacine 0.5% significantly decreased VAS scores compared to placebo. VAS mean (standard deviation) at 2 h for the ropivacaine and placebo groups were 0.16 (0.53) and 3.60 (0.81), respectively, representing a percentage change of 55% (MD=-1.93 with 95% C.I. -2.61 to -1.03; p 0.0001). The percentage change was 57% (MD= -2.27 with 95% C.I. -2.81 to -1.74; p 0.0001) between the ropivacaine and placebo groups at 4h (MD= -2.27 with 95% C.I. -2.81 to -1.74; p 0.0001). Our findings were corroborated by those of Etrusca Brogi et al.[12], who found that analgesia with TAP block was significantly greater than in the placebo group. In their meta-analysis, Etrusca Brogi et al.[12] discovered that TAP block reduced the VAS for pain at six hours by 1.4 (95% confidence interval [CI], -1.9 to -0.8; P <0.001), at 12 hours by 2.0 (95% CI, -2.7 to -1.4; P <0.001), and at 24 hours by 1.2 (95% CI, -1.6 to 0.8). The requirement for rescue analgesia was prolonged with 0.5% Ropivacaine (618 minutes) compared to placebo (144 minutes) by (MD = 474; 95% C.I. difference between 435.02 and 512.98 minutes).

In their study on TAP BLOCK with Ropivacaine (n=30) and normal saline (n=30) under ultrasound guidance, Maitreyi Gajanan Mankikar et al.[13] found that the time to first analgesic administration (tramadol) was significantly prolonged in the ropivacaine group (mean- 9.53 hours) compared to the normal saline group (mean- 4.1 hours). Neha Fuladi et al.[14] conducted a comparative investigation on 75 adult patients with 20 ml of ropivacaine, bupivacaine, and saline solution. In the bupivacaine group, the mean duration of analgesia was 420.6 minutes with a standard deviation of +14.01 minutes, while in the ropivacaine group, it was 2187 minutes with a standard deviation of +1011.09 minutes, which was statistically significant. The increase in mean duration of analgesia in comparison to our group may have been caused by an increase in drug dosage. Therefore, they determined that 0.5% ropivacaine provided longer-lasting analgesia than 0.25 percent bupivacaine.

In their meta-analysis on TAP block, Ma N Duncan jk et al.[15] found that delaying time to first analgesic request [MD = 123.49, 95% CI (48.59, 198.39)]. In TAP block, postoperative discomfort within 24 hours was reduced or at least equivalent to its comparators. In comparison with standard care, placebo, and other analgesic techniques, they conclude that TAP block is a safe and effective procedure.

Conclusion

We have chosen landmark-guided TAP block as a postoperative analgesia for patients undergoing caesarean section because, in India, the vast majority of caesarean sections are performed in peripheral health care centres where ultrasonography accessibility is relatively limited. In conclusion, our study revealed that landmark-guided TAP block had a positive effect on maternal analgesia post-surgery. We propose that the landmark guided TAP block is an additional tool in the anesthesiologist's arsenal for managing post-c-section pain. When administered in a TAP block for postoperative analgesia after lower abdominal procedures, we discovered that 0.5% ropivacaine provided longer-lasting analgesia than placebo. In comparison to other local anaesthetics, it has a very good safety profile.

Bibliography

1. Rafi A. N. Abdominal field block: a new approach via the lumbar triangle. Anaesthesia. 2001;56(10):1024–1026.
2. Gupta A, Gupta A, Yadav N. Effect of dexamethasone as an adjuvant to ropivacaine on duration and quality of analgesia in ultrasound-guided

transversus abdominis plane block in patients undergoing lower segment cesarean section- A prospective, randomised, single-blinded study. Indian J Anaesth. 2019 Jun;63(6):469-474.
3. Siddiqui MRS, Sajid MS, Uncles DR, Cheek L, Baig MK. A meta-analysis on the clinical effectiveness of transversus abdominis plane block. Journal of Clinical Anesthesia. 2011;23(1):7–14
4. Niraj G, Kelkar A, Fox AJ. Oblique sub-costal transversus abdominis plane (TAP) catheters: an alternative to epidural analgesia after upper abdominal surgery. Anaesthesia. 2009; 64(10):1137–1140.
5. Graf BM, Abraham I, Eberbach N, Kunst G, Stowe DF, Martin E. Differences in cardiotoxicity of bupivacaine and ropivacaine are the result of physicochemical and stereoselective properties. Anesthesiology.2002;96:142
6. Porter J, Crowe B, Cahill M, Shorten G. The effects of ropivacaine hydrochloride on platelet function: An assessment using the platelet function analyser (PFA-100) Anaesthesia. 2001; 56:15–8.
7. Singh, Shiv & Gulyam Kuruba, S M. The Loss of Resistance Nerve Blocks. ISRN Anesthesiology. 2011..
8. Staker JJ, Liu D, Church R, Carlson DJ, Panahkhahi M, Lim A, LeCong T. A triple-blind, placebo-controlled randomised trial of the ilioinguinal-transversus abdominis plane (I-TAP) nerve block for elective caesarean section. Anaesthesia. 2018 May; 73(5):594-602.
9. John G. McDonnell, Gerard Curley, John Carney, Aoife Benton, Joseph Costello, Chrisen H. Maharaj, John G. Laffey. The Analgesic Efficacy of Transversus Abdominis Plane Block After Cesarean Delivery: A Randomized Controlled Trial. Vol. 106, No. 1, January 2008, International Anesthesia Research Society
10. F. W. Abdallah1, S. H. Halpern, and C. B. Margarido. Transversus abdominis plane block for postoperative analgesia after Caesarean delivery performed under spinal anaesthesia? A systematic review and meta-analysis British Journal of Anaesthesia.
11. D. Belavy, P. J. Cowlishaw, M. Howes and F. Phillips Ultrasound-guided transversus abdominis plane block for analgesia after Caesarean delivery. British Journal of Anaesthesia.
12. Brogi E, Kazan R, Cyr S, Giunta F, Hemmerling TM. Transversus abdominal plane block for postoperative analgesia: a systematic review and meta-analysis of randomized-controlled trials. Can J Anaesth. 2016 Oct;63(10):1184-96.
13. Mankikar MG, Sardesai SP, Ghodki PS. Ultrasound-guided transversus abdominis plane block for postoperative analgesia in patients undergoing caesarean section. Indian J Anaesth 2016;60:253-7.
14. Neha Fuladi, Shubhada Deshmukh, Anjali Bhure. “Comparative Study of Bupivacaine 0.25% versus Ropivacaine 0.5% in Transversus Abdominis Plane Block for Postoperative Analgesia in Lower Abdominal Surgeries: A Randomised Controlled Trial”. Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 17. April 28; Page: 4569-4576.
15. Ma N, Duncan JK, Scarfe AJ, Schuhmann S, Cameron AL. Clinical safety and effectiveness of transversus abdominis plane (TAP) block in post-operative analgesia: a systematic review and meta-analysis. J Anesth. 2017 Jun;31(3):432-452.