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A Randomized Comparative Clinical Trial to Know the Efficacy of Ultrasound-Guided Transversus Abdominis Plane Block Against Multimodal Analgesia for Postoperative Analgesia Following Caesarean Section

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ABSTRACT

Introduction: Transversus abdominis plane (TAP) block as a regional technique that appeared in anaesthesia literature in 2001, is applied as a segment of multimodal pain regimen in abdominal surgeries like caesarean sections. Ultrasonography (USG)- guided TAP Block provides accurate visualization of underlying structures. Our study aimed to compare the efficacy of ultrasound-guided Transversus Abdominis Plane (TAP) block using 0.25% bupivacaine versus parenteral multimodal analgesia in postoperative caesarean section.

Aims:

To study

- Reduction of the additional Rescue analgesia 24 hours following caesarean section.
- Duration of analgesia, patient satisfaction, adverse effects like- PONV and sedation.

Methods: A total of 60 patients with American Society of Anesthesiologists (ASA) physical status II and III, aged > 18yrs were posted for elective caesarean section were allocated into two groups (n=30). Group, I received a Bilateral TAP Block with 15ml of 0.25% Bupivacaine on each side. Group II received multimodal analgesia according to the Obstetric department protocol. The intensity of pain by Visual Analogue Pain Scale (VAS) Score was assessed, mean duration of analgesia and mean dose of rescue analgesia were recorded.

Results: The Visual Analogue Scale scores at 8, 12 and 24 hours in Group I were 1.1±1.47, 0.93±1.31 and 0.3±0.75 and in group II were 3.67±1.06, 4.73±0.94 and 5.27±0.78, respectively. The mean time to first rescue analgesia was statistically significant in Group I 535.27 ± 118.542 compared to Group II 186.6 ± 67.6 min. The mean dose of rescue analgesia required over 24 hours was significantly lower in group I with 17.2±10.4mg, whereas in group II 28.9±24.2 mg.

Conclusion: We conclude TAP block is more effective when performed under ultrasound guidance. It provides effective analgesia with reduced rescue analgesic requirement for 24 hours following surgery, with a prolonged duration of analgesia.

Key Words: TAP Block, Caesarean Section, Ultrasound-guidance, Multimodal analgesia, Bupivacaine, Post-operative analgesia

INTRODUCTION

There are various analgesic modalities for the management of postoperative pain but still, it continues to be a challenge today.

Pain after caesarean section ranges from moderate to severe and failure to alleviate pain may affect the mother-baby

bonding, care of baby, breastfeeding and immobility which leads to the risk of thromboembolism.^{1,2} These patients require a multimodal postoperative pain treatment regime that provides high-quality analgesia with minimal side effects. The use of opioids for pain management can result in adverse effects like sedation, nausea, vomiting and may also be secreted in breast milk.

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Transversus abdominis plane (TAP) block as a regional technique appeared in the anaesthesia literature in 2001 and has been applied as one of the segments of multimodal pain regimen in abdominal surgeries including caesarean sections. The injection of local anaesthetic solution in the neuro fascial plane in the anterior abdominal wall has proven itself to be an effective adjunct to central neuraxial narcotic administration. TAP block offers greater pain relief with lesser side effects and increased patient satisfaction.

Ultrasonography (USG)- guided TAP Block provides accuracy, as it helps in visualization of underlying structures

The main principle of TAP Block is to block the sensory-motor nerve fibres of the anterior abdominal wall by injecting a local anaesthetic into the plane between the internal oblique and transverse abdomen is muscles, which also covers the incision site.

Our study aimed to compare the efficacy of the ultrasound-guided Transversus Abdominis Plane (TAP) block by using 0.25% bupivacaine versus parenteral multimodal analgesia in postoperative caesarean section.

MATERIAL AND METHODS

Institutional ethical committee approval was taken, written consent was obtained from all the patients after explaining the study protocol.

This randomized prospective clinical study included a total of 60 adult patients allocated into two groups (n=30) using a computerized random number table. Patients with the American Society of Anesthesiologists (ASA) physical status II and III, aged > 18yrs who were posted for elective caesarean section were included in the study.

Patients with any contraindication to spinal anaesthesia, allergy to local anaesthetic agents, local infection, any coagulopathies, cardiac disease, liver disorders and patient refusal were excluded from the study.

Patients in group I received USG-guided bilateral TAP Block with 30ml of 0.25% Bupivacaine on each side following caesarean section and Group II patients received standard analgesia according to Obstetric department protocol consisting of Intramuscular(IM) Diclofenac 75mg, Intravenous(IV) Paracetamol (1 gm) and IV Pentazocine 0.5mg/kg body weight stat at the end of surgery.

Preoperative assessment included medical history, general physical/systemic examination, airway assessment and investigations such as complete haemogram, bleeding time, clotting time, blood glucose, blood urea and serum creatinine. Chest x-ray and Electrocardiography (ECG) if required were done.

Patients were kept nil by mouth for eight hours before surgery. Preoperative vital baseline parameters like heart rate, blood pressure and oxygen saturation were recorded.

Monitoring devices like- pulse oximeter, non-invasive blood pressure (NIBP), ECG were connected. An IV line was secured with a 20G cannula. All patients were preloaded with 1000ml crystalloids and premedicated with Inj. Ondansetron 4 mg IV, 30 mins before surgery. Under aseptic precautions, spinal anaesthesia was given with 0.5% Bupivacaine hyperbaric (10-12mg).

Group, I received Bilateral TAP Block with 15ml of 0.25% Bupivacaine slowly with 5 ml increments after careful negative aspiration using 22G 5 cm long blunt tip with regional anaesthesia needle. The block was given on the other side using the same method.

Group II received standard analgesia according to Obstetric department protocol consisting of IM Diclofenac 75mg, IV Paracetamol 1 gm and IV Pentazocine 0.5mg/kg body weight stat was given at the end of surgery.

Rescue analgesia in both groups was given with IV Pentazocine 0.3mg/kg body weight when the patient complained of pain. The assessment for intensity and presence of pain (both at rest and on passive flexion of hip and knee), vomiting, nausea and sedation and Rescue analgesia were made in Post Anaesthesia Care Unit (PACU) at 0hr, 4,8,12,24 hr after surgery. The intensity of pain was assessed by VISUAL ANALOGUE PAIN SCALE (VAS). Postoperative Nausea and Vomiting(PONV) was assessed by categorical scale(0=no symptoms,1=only nausea,2=nausea and vomiting), Level of sedation was assessed by Ramsay sedation score 0-3(0=awake and alert,1=quietly awake,2=asleep but, easily arousable,3=deep sleep, responding to a painful stimulus). The patients were enquired about their satisfaction with pain management 24 hours after surgery.

Sample size calculation and Statistical Analysis:

According to a study conducted by Mankikar MG et al.,³ sample size was calculated with Anticipated Mean Difference of VAS score between study groups as 2.5 and Anticipated SD as 2.7, the minimum sample size per group is 30 with 90% power and 5% level of significance. The total sample size calculated was 60.

Formula used:

Where Z= Z statistic at a level of significance

$$n = \frac{(z_{\alpha} + z_{\beta})^2 2 SD^2}{MD^2}$$

MD= Anticipated mean the difference

SD= Anticipated Standard deviation

At the end of the study, all data were summarized descriptively. The summary statistics of N, mean, standard deviation (SD) were used for continuous variables. The categorical data were used as percentages and numbers in the summaries and analyzed by Chi-square test for association, means compared using t-test, diagrammatic presentation and ANOVA.

RESULTS

The 60 patients included in the group were comparable concerning demographic variables such as age, height and weight. There was no statistical significance among the two groups with regards to ASA status (Table 1). The mean time to first rescue analgesia in Group I was significant with 535.27 ± 118.542 while in Group II it was 186.6 ± 67.6 min (Graph 1). The difference in mean VAS score was less at 0 and 4-hour intervals in both the groups, but statistically significant differences were found at and after 8-hour intervals with 1.1 ± 1.47 , 0.93 ± 1.31 and 0.3 ± 0.75 respectively at 8, 12 and 24-hour duration in group I and 3.67 ± 1.06 , 4.73 ± 0.94 and 5.27 ± 0.78 in group II (Table 2). The mean dose of rescue analgesia required over 24 hours was significantly lower in group I with 17.2 ± 10.4 mg, whereas in group II 28.9 ± 24.2 mg (Graph 2). There was no difference in the incidence of PONV (Graph 3) and sedation (Table 3) between the two groups statistically.

DISCUSSION

In the present study, we studied the use of the USG-guided TAP block for postoperative analgesia with Bupivacaine 0.25% when compared to multidrug therapy with Diclofenac sodium, Paracetamol and Pentazocine.

Adequate postoperative analgesia benefits the patient by reducing postoperative stress, morbidity and improving operative outcomes in various surgeries. Other advantages of efficient regional analgesics include decreased pain intensity, lower incidence of analgesic adverse reactions and increased patient convenience.

TAP Block is an efficient analgesic mode suitable for surgeries where parietal pain is a major component of postoperative pain. In patients undergoing surgery of the colon with a midline abdominal wall incision, caesarean section and radical prostatectomy TAP Blocks were demonstrated to provide excellent analgesia of the musculature and skin of the anterior abdominal wall.

The principal finding in our study was that TAP block with 0.25% bupivacaine provided effective postoperative analgesia in patients undergoing Lower Segment Caesarean Section.

We found TAP block to be effective in providing immediate postoperative analgesia reflected by a lower VAS score.

In our study patients were assessed for pain post-operatively by VAS at regular time intervals. Rescue analgesia was administered when VAS was more than or equal to 4 at any given time and the time of administration was noted. VAS score was found to be 0.30 in group I Vs 5.27 in group II. Similar results were found in the study by Lee et al.⁴ in 2013, with values of 0.5 and 4.9. Similarly, studies conducted by Sharma et al.,⁵ McDonnell et al.,^{6,7} Nabinta Das et al.⁸ and Abdallah F W et al.⁹ showed reduced VAS scores which were found familiar with our study.

In our study, the time to demand first rescue analgesia was 8.9 hours in group I and 3.1 hours in group II, which was similar to the study conducted by Mankikar MG et al.(3) in the year 2016, which had results of 9.5 hours and 4.1 hours. Similar results were found by the studies conducted by S Naveen et al.¹⁰ and Onishi et al.¹¹

In our study total dose of the opioid requirement was found to be 40% lesser in the patients in group I which was 17.2 ± 10.4 mg compared to group II 28.9 ± 24.2 mg. Our results of the opioid requirement were similar to the study done by Baaj JM et al.¹² who found a 60% reduction in the Morphine requirement in the TAP group. Similarly, in the study conducted by Mankikar MG et al.,³ total Tramadol requirement was reduced from 246.6mg to 140 mg in the TAP block patients and comparative results were found by the studies conducted by several authors,^{10,11,13} which showed opioid-sparing effects of TAP block, which was observed in our study too.

In group I, Nine patients received rescue analgesia in the first 12 hours, out of which 4 patients received it twice. Whereas, in group II 24 patients received rescue analgesia in the first 12 hours, in which 6 patients received it twice.

There were a reduced incidence of PONV and sedation observed in our study which was similar to the findings of Uma Srivastava et al.,¹⁴ Baaj JM et al.¹² and Elsamian et al.¹⁵ They also recorded higher satisfaction of pain management in the patients who had received TAP Block and the findings were similar in our study.

The cause for the prolonged effect of analgesia by a single shot TAP block is unknown. But, the fact that the TAP is relatively poorly vascularized and slower metabolism of drugs could explain this effect.¹⁶ Inadequate analgesia in TAP block may be due to technical failure or visceral pain. Most local anaesthetic techniques have a failure rate of 5-20% which depends on the operator's skill and knowledge. The main clinical implication of our result is the significant opioid-sparing effect of TAP block during the postoperative period. Opioids may be associated with nausea, pruritus and respiratory depression, though they are commonly used in perioperative pain management. Patients with morbid obesi-

ty or obstructive sleep apnea will be benefited from the TAP block, as it significantly reduces the requirement of opioids. For patients with coagulopathy, intra-operative and post-operative analgesia can be provided by TAP Block which is a relatively safer alternative to neuraxial block due to its relative avascularity.

CONCLUSION

Based on our present comparative trial, we conclude that TAP block is easy to perform under ultrasound guidance. It provides effective analgesia with reduced rescue analgesic requirement 24 hours following surgery, prolonging the duration of analgesia and reducing incidence of PONV and sedation along with higher patient satisfaction.

MOST NOTEWORTHY POINTS OF THE RESULTS OF THE ARTICLE:

- 1) Ultrasound-guided TAP block- Ultrasound-guided block is a more accurate block and also aids in reducing the dose of the local anaesthetics.
- 2) Rescue analgesic dose- TAP block reduces the requirement of rescue analgesics for 24hrs post-operatively.
- 3) Reduces the severity of pain- Intensity of pain is decreased.
- 4) Decreases opioid requirement by using ultrasound-guided TAP block.
- 5) Complications following the use of NSAIDs and opioids are reduced by using an Ultrasound-guided TAP block.

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Conflict of Interest: Nil.

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Authors contributions

- 1) Dr. Manoj K P - Concept and design of the study, data collection, statistical analysis, editing.
- 2) Dr. Pratibha S D - literature search, acquisition of data, drafting the article, manuscript preparation and review.
- 3) Dr. Shivavand L K - Editing and manuscript preparation
- 4) Dr. Talikoti D G - Concept and design of the study, final approval of the version

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Table 1: Demographic Profile.

Parameters	GROUP I		GROUP II		p-value
	Mean	SD	Mean	SD	
Weight (kg)	62.40	5.15	61.80	4.96	0.648
Height(cms)	158.33	5.01	157.60	5.51	0.591
AGE (yrs)	24.43	3.35	24.50	3.92	0.944

Note: *significant at 5% level of significance (p<0.05)

Table 2: Vas Scores.

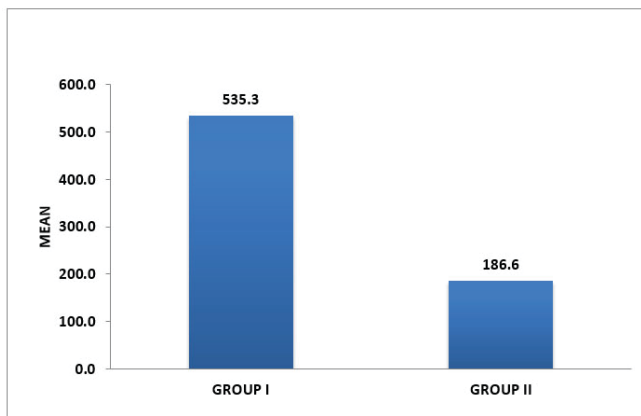
Time	GROUP I		GROUP II		p-value
	Mean	SD	Mean	SD	
0 HOUR	0.0	0.0	0.00	0.00	-
4 HOUR	0.87	1.28	1.37	1.43	0.158
8 HOUR	1.10	1.47	3.67	1.06	<0.001*
12 HOUR	0.93	1.31	4.73	0.94	<0.001*
24 HOUR	0.30	0.75	5.27	0.78	<0.001*

Note: * significant at 5% level of significance (p<0.05)

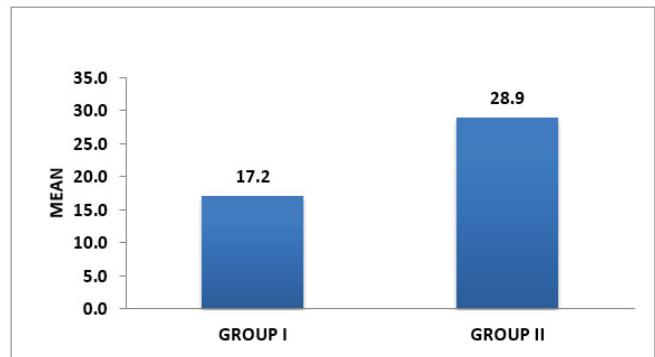
Table 3: Comparison of Sedation Scores

SEDATION SCORES AT	GROUP I		GROUP II		p-value
	Mean	SD	Mean	SD	
0 HOUR	0.00	0.00	0.00	0.00	-
4 HOUR	0.03	0.18	0.10	0.40	0.412
8 HOUR	0.17	0.46	0.07	0.37	0.356
12 HOUR	0.20	0.48	0.13	0.35	0.542
24 HOUR	0.00	0.00	0.10	0.31	0.078

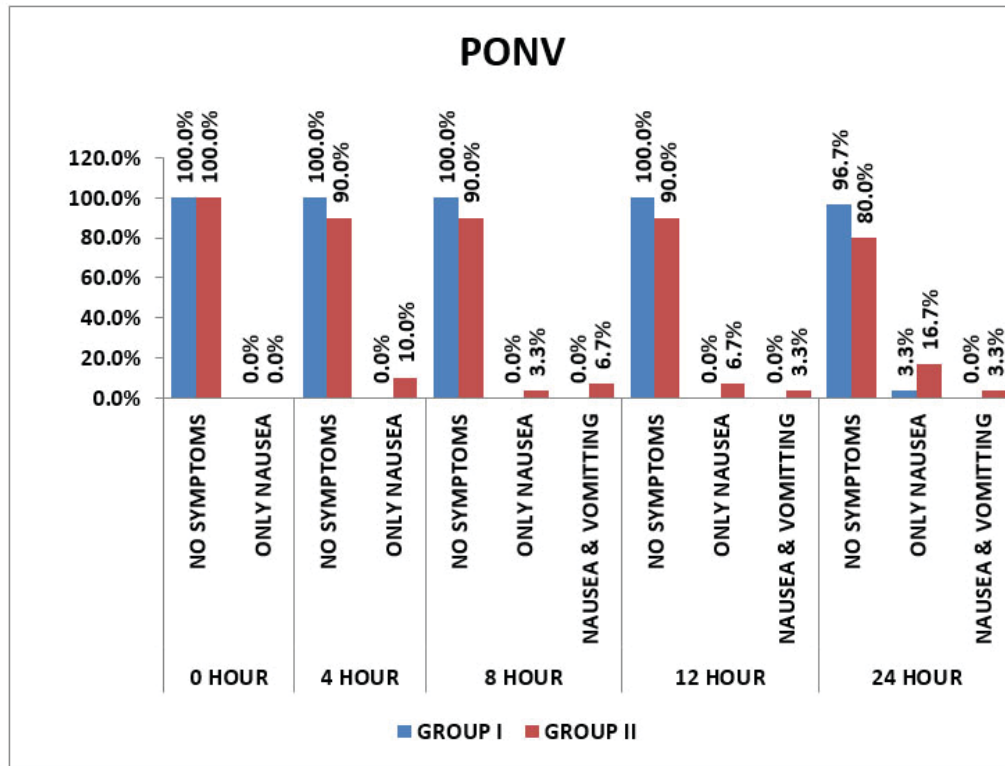
Note: *significant at 5% level of significance (p<0.05)



Graph 1: Mean Time to First Rescue Analgesia.



Graph 2: Mean Dose of Rescue Analgesia.



Graph 3: Comparison of Ponv between the Groups