RESEARCH
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EFFECT OF BILATERAL ULTRASOUND–GUIDED ERECTOR SPINAE PLANE BLOCK FOR POSTOPERATIVE ANALGESIA IN CESAREAN SECTION- A PROSPECTIVE RANDOMIZED SINGLE-BLIND CONTROLLED STUDY

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Abstract

Background: Regional analgesia techniques like Transversus Abdominis Plane (TAP) block, Quadratus Lumborum (QL) block and erector Spinae Plane Block (ESP)have shown their efficacy in postoperative pain management in various surgeries.

Purpose of the Study: Studies showing the efficacy of ESP block in cesarean section was limited in our population. Hence, we conducted this study to analyze the analgesic efficacy erector Spinae Plane block after Cesarean section.

Methods: In this prospective, randomized controlled study, 60 patients scheduled for elective cesarean section was randomized to receive bilateral ultrasound - guided ESP block with 20 ml 0.25% Bupivacaine (n = 30) in Group A or standard intravenous analgesia-in Group B (n=30) postoperatively. The primary outcome assessed was Visual analog scale (VAS) scores for pain in 48 hours and the secondary outcomes assessed were time for the first request to analgesia, total postoperative rescue analgesia consumption and incidence of adverse effects. Statistical analysis was done using the International Business Machines Statistical package for social sciences Statistics-23 software (IBM SPSS).

Results: The VAS score in Group A (ESP group) was significantly less ($P<0.05$) at 2, 4, 6 and 8 hours. The time taken for first request of analgesia was significantly higher in Group A (8.3h) than in Group B (3.6h) ($P<0.05$). The total postoperative rescue tramadol analgesia used was significantly lower in Group A 63.3 mg than in group B (100 mg) ($P<0.05$). Group A had a higher incidence of bradycardia in 4 patients than in Group B 0 patients ($P<0.05$).

Conclusion: ESP block is a promising approach for lowering pain scores and extending the time to first request for analgesia with reduced total postoperative analgesia consumption in lower segment cesarean section.

Keyword: Erector Spinae Plane Block, Cesarean Section, Pain Scores, Analgesic Consumption, Bradycardia

INTRODUCTION

Introduction: Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Acute pain is defined by its sudden onset, lasting for less than six months, and disappearing once the underlying cause is eliminated. Chronic pain, which refers to pain that lasts for more than six months, can cause stress and lead to the development of unpleasant emotions such as anger, anxiety, depression, and physical instability in the body (1). Minimizing postoperative discomfort is a crucial goal, especially with the increasing number of cesarean sections performed worldwide. It is imperative to reduce this surgical side effect. Pain not only correlates with lower quality of life measures but also increases the cost of hospital stays and prolongs recovery periods(2) .

Many individuals often underestimate the intensity of acute discomfort that occurs after cesarean surgery. According to Gerbershagen et al, cesarean delivery was placed ninth out of 179 surgical procedures in Germany in terms of postoperative pain severity (3). Effective pain management after cesarean delivery is crucial for the mother to properly care for her newborn and facilitate early mobilization. Untreated postoperative pain increases the likelihood of a patient experiencing a delay in their ability to resume their normal daily activities. There is a possibility of an elevated risk for postpartum depression, difficulties with feeding, thromboembolic issues, and a lack of strong emotional connection between the mother and child(4). Compared to past methods, patient satisfaction with patient-controlled analgesia (PCA) is greater, making it a valuable technique for alleviating pain. However, the combination of PCA with opioids often leads to significant adverse effects such as drowsiness, nausea, and pruritus. In addition, a specific concern for the group being studied is the release of opioids into breast milk (5). Multimodal analgesia (MMA) is the recommended approach for pain management after surgery. Its goal is to limit the negative effects of pain while reducing the need for opioids and optimizing pain relief(6). Conventionally for cesarean section in spinal anesthesia in some portions of world will add intrathecal morphine or short acting opioids. In our institution we routinely practice spinal anesthesia with 0.5% heavy bupivacaine 2ml along with parenteral analgesics in postoperative period. Ultrasound-guided regional anesthesia has been increasingly popular in recent years because of its accurate administration of local anesthetic, rapid effectiveness, few complications, and high rates of success. Truncal blocks are increasingly replacing long acting neuraxial opioids in obstetric anesthetic treatments due to their superior analgesic efficacy(7) (8). An example of such a block is the Erector Spinae block, which specifically targets its pain-relieving action with little effect on the rest of the body(9) (10) . Hence, we designed this study to compare the effect of erector spinae plane block on postoperative pain scores, amount of analgesic consumption and duration of analgesia.

MATERIALS AND METHODS

The study was a prospective single-blind randomized trial conducted to evaluate the analgesic efficacy of bupivacaine in erector spinae plane block versus standard perioperative analgesia in individuals undergoing cesarean delivery.

SETTING

This study was conducted in the Department of Anaesthesiology in a tertiary care hospital from May 2024 to September 2024. This study was approved by the institutional ethical committee (IEC/19/NOV/155/69) and the clinical trial registry of our nation (CTRI/2024/05/067919). Patients with American Society of Anesthesiologists (ASA)physical status (ASA PS 2) between ages 18 to 65 who were scheduled for elective lower segment cesarean section were included in this study. Patients who declined erector spinae plane block, patients with bleeding disorders, patients hypersensitive to local anesthetic drugs, patients taking antiplatelet medication, patients with an infection at the injection site, patients with significant cardiopulmonary disease, hepatic or renal failure, psychiatric disease, or a BMI over 30, patients unable to provide consent, and patients with uncontrolled diabetes were excluded. Patients who met the study's inclusion criteria were enrolled, and their informed consent was obtained in writing after they were thoroughly informed about the block and the advantages and disadvantages of the medications administered there. Randomization was done using computer-generated block randomization into Group A and Group B. The concealment of allocation sequence was done using opaque sealed envelope and it is opened immediately after the completion of surgical procedure. All outcome assessors were blinded to the type of intervention received. Patients in Group A received ultrasound guided erector spinae plane block. Patients in Group B received standard postoperative monitoring with parenteral analgesia [Figure 1].

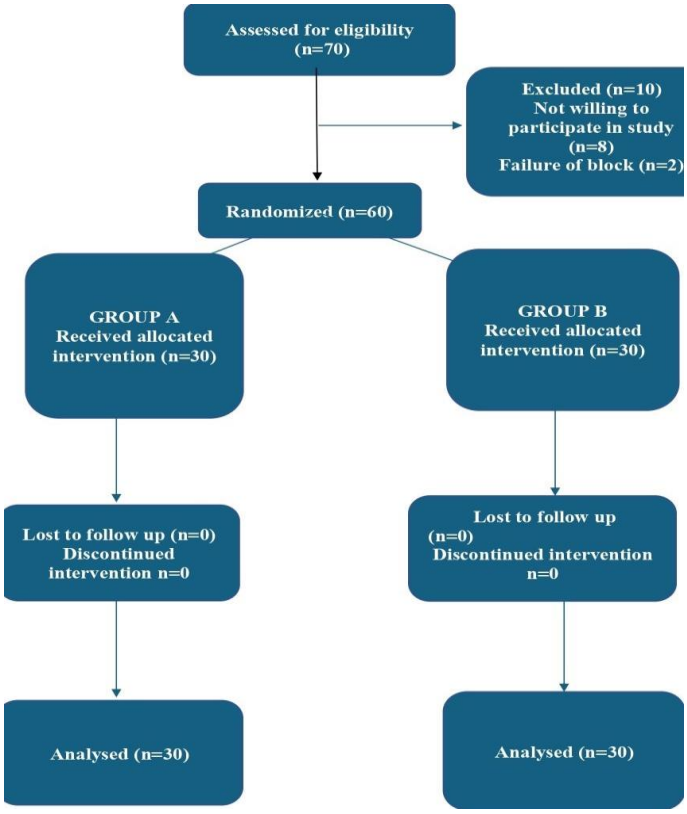

Figure 1 showing Consolidated standards of reporting trials (CONSORT) statement of our trial

All patients were trained to use a 10-cm VAS for pain (0 = nil pain, 10 = maximum imaginable pain) to assess their pain after providing written consent. A basic preoperative assessment was completed the day before surgery, patients were kept at nil per oral for eight hours. After the patients are transferred into the operating room, the hemodynamic monitors like blood pressure cuff, electrocardiography, and pulse oximetry were connected. Hemodynamic baseline values were documented. An intravenous cannula, 18 gauge was inserted into the upper limb. After asking the parturient to sit up, under sterile aseptic precautions 3 ml of 2% lidocaine will be given subcutaneously, and a 27-gauge spinal needle will be used to administer spinal anesthesia into L3-4 interspace via a midline approach. Following confirmation of free cerebrospinal fluid (CSF) flow through the needle, each group will receive a slow injection of 2 milliliters of hyperbaric bupivacaine (0.5%). After the parturient is positioned supine with a 15-degree left tilt, an oxygen mask is applied at a rate of 6 L O2/min-1. Once a suitable level of anesthesia has been achieved, the surgical procedure will begin, with ongoing hemodynamic monitoring and recording. Following fetal delivery, uterotonic medications are administered. All patient's spinal level was evaluated and documented at the end of surgery before administration of block. After the end of the surgery, opaque sealed envelope was opened

by anesthesiologists and patients in ESP block group were turned to a lateral position and received an Ultrasound-guided bilateral ESP block and remaining participants received standard parenteral analgesia in post operative period according to department protocol (Scheduled analgesic Acetaminophen every 6 th hourly along with tramadol 50 mg bolus if patient had vas score more than 4). After properly sterilizing the skin, the vertebrae in the ESP block group were identified from the C7 vertebra to the T10 spinous process, along a cranio-caudal direction. In this study, a linear ultrasound (US) transducer (GE LOGIQ eR7) was positioned vertically, 3 cm lateral to the midline, to visualize the back muscles above the transverse process [Figure 2]. A 20-gauge Jelco needle was placed in a cranial-caudal direction until it established contact with the transverse process. To verify the precise positioning of the needle tip, a 1 ml saline injection was administered to induce hydro dissection between the erector spinae muscle and the transverse process. Following careful aspiration to rule out the possibility of a vascular puncture, individuals in Group A were administered 25 ml of 0.25%bupivacaine [Figure 2].

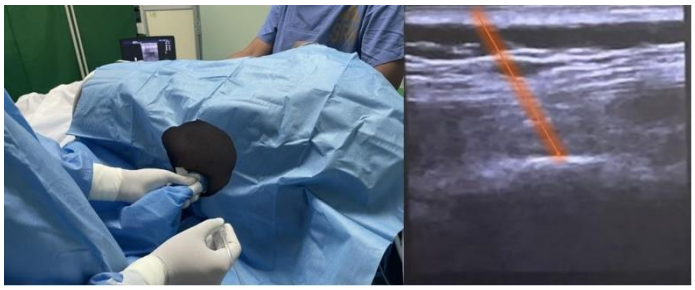

Figure 2 showing Administration of ESP block and red arrow indicated erector spinae fascial plane just above the transverse process

After the block all patients were shifted to post anesthesia care unit (PACU). Following, this, they were observed in the PACU as per standard protocol. The VAS (Visual analog scale) was used by specifically assigned personnel to quantify postoperative pain at time intervals of 0 hours, 2 hours, 4 hours, 6 hours, 8 hours, 12 hours, 24 hours, and 48 hours. Postoperative Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), and mean artery pressure (MAP) were monitored and recorded. MAP<60 mmHg for more than 30 seconds or a 20% drop from the baseline MAP is considered hypotension. Bradycardia is characterized as an HR< 60 bpm). Intravenous paracetamol was administered as a scheduled analgesic regimen every six hours to each study participant. The time of the first request for analgesia, at which point 50 mg of Tramadol is administered for the first time after block administration, and the total number of analgesics taken in the first 24 hours after surgery are all recorded. We also documented adverse effects like nausea and vomiting. A pin-prick test was used to evaluate sensory block with grade 1 being normal sensation, grade 2 indicating decreased pain sensation, and grade 3 indicating loss of pain sensation. The period from the start of the block to 100% cold perception is defined as the length of the sensory block. Analgesia-related patient satisfaction is noted after the initial 24 hours as 0 (poor), 1 (good), and 2 (excellent). The study variables included the patient's age, body mass index (BMI), hemodynamic parameters, time for the initial request for analgesia (VAS score > 4), total rescue analgesics given, and incidence of adverse events. The staff nurses in the PACU and ward recorded the pain scores, number of tramadol rescue bolus used and total amount of tramadol consumption and time to first request for analgesia. They also recorded heart rate, and systolic, diastolic, and mean artery blood Pressure after the block, 0 minutes (immediately after receiving in ICU), 10 minutes, 30 minutes, 1st, 2nd, 4th, 8th, 12th, and 24th hour.

SAMPLE SIZE CALCULATION

The major outcome for determining the sample size was the mean difference of VAS Score at 6 hours in both groups from previous study by Shah B et al.(11).The sample size was calculated with 95% power of detecting the difference (1-beta) and two-sided alpha error of 5%. The study required a sample size of 60 female individuals between the ages of 18 and 65 who were undergoing elective cesarean delivery and had an ASA physical status score of 2. There were 30 patients assigned to each group.

STATISTICAL ANALYSIS

The data acquired were analyzed using version 23.0 of the statistical program for social sciences (SPSS) developed by the International Business Machines Corporation (IBM). The distribution was assessed with two well-known tests of normality, namely the Kolmogorov-Smirnov Test and the Shapiro - Wilk Test. The normally distributed continuous data were expressed in mean ± SDs and compared by student independent "t" test. The categorical data are presented as numbers, percentages and compared by non-parametric test namely $\chi 2$ (Chi-square) test. All the above-described statistical tools regard a probability value of less than or equal to 0.05 ($P \leq 0.05$) as being statistically significant.

RESULTS

Group A and Group B exhibited similar demographic characteristics, including body mass index (BMI), age, Comorbidities (Table 1), Obstetric scores (Table 2), and spinal level at time of intervention (Table 3). The VAS score was significantly lower in Group A compared to Group B at 2, 4, 6 and 8 hours ($P<0.05$) (Table 4) [Figure 3].

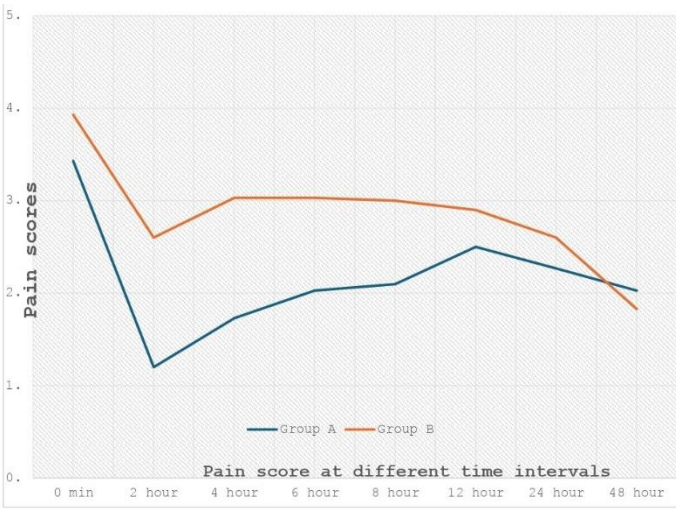

Figure 3 showing Comparison of pain scores at different time intervals

Furthermore, when comparing Group A and Group B, the total number of rescue analgesic dosage was significantly diminished in Group A. Group A also showed a longer mean time to request analgesia (8.30 hours) than Group B (3.64 hours) (Table 5). Total amount of tramadol consumption was significantly lower in Group A [63.3mg] than in Group B [106.6 mg]. The trends of

mean heart rate was significantly lower in Group A, mean systolic blood pressure showed significant variations from 2 hours to 24 hours and mean arterial pressure only showed significant variations at 12 and 24 hours [Figure 4]. Diastolic blood pressure showed no significant variations. Group A had overall significantly better patient satisfaction [P<0.05]. There were no incidents of PONV.

Table 1 Comparison of demographic characteristics between both the groups

	Group A (n=30)	Group B (n=30)	P value
Age in years	29.4±4.2	30.6±3.6	0.22
Body mass index (BMI)	27.9±4.9	29.4±2.8	0.13
Diabetes mellitus	8	6	0.54
Hypertension	2	5	0.22
Hypothyroid	6	11	0.15
Bronchial Asthma	2	3	0.64

Unpaired t test and chi square test were used to compare the differences between both groups

Table 2 Comparison of obstetric scores between the groups

Obstetric Score			Groups		Total	Results
			Group A (n = 30)	Group B (n= 30)		
Gravida	Grade 1	Num	1	3	4	χ^2 =3.040 df=4 P=0.551
		%	25%	75%	6.7%	
	Grade 2	Num	21	17	38	
		%	55.3%	44.7%	63.3%	
	Grade 3	Num	6	8	14	
		%	42.9%	57.1%	23.3%	
	Grade 4	Num	2	1	3	
		%	66.7%	33.3%	5%	
	Grade 5	Num	0	1	1	
		%	0%	100%	1.7%	
Para	Para 0	Num	1	6	7	χ^2 =4.271 df=2 P=0.118
		%	14.3%	85.7%	11.7%	
	Para 1	Num	24	21	45	
		%	53.3%	46.7%	75%	
	Para 2	Num	5	3	8	
		%	62.5%	37.5%	13.3%	
Live	Live nil	Num	2	7	9	χ^2 =3.332 df=2 P=0.189
		%	22.2%	77.8%	15%	
	Live 1	Num	25	20	45	
		%	55.6%	44.4%	75%	
	Live 2	Num	3	3	6	
		%	50%	50%	10%	
	Abortion nil	Num	26	20	46	
		%	56.5%	43.5%	76.7%	
Abortion	Abortion 1	Num	2	8	10	χ^2 =5.761 df=3 P=0.126
		%	20%	80%	16.7%	
	Abortion 2	Num	2	1	3	
		%	66.7%	33.3%	5%	
	Abortion 3	Num	0	1	1	
		%	0%	100%	1.7%	
Dead	Dead nil	Num	27	29	56	χ^2 =1.071 df=1 P=0.301
		%	48.2%	51.8%	93.3%	
	Dead 1	Num	3	1	4	
		%	75%	25%	6.7%	

Chi square test was used to compare difference between both groups

Table 3: Comparison of spinal level before administration of block

Spinal level at the time of block	Group A (n = 30)		Group B (n = 30)		Total (n = 60)		Results
	Num	%	Num	%	Num	%	
T8	2	6.7	4	13.3	6	10	χ^2 =2.997 df=4 P=0.558
T9	2	6.7	0	0	2	3.3	
T10	13	43.3	11	36.7	24	40	
T11	9	30	10	33.3	19	31.7	
T12	4	13.3	5	16.7	9	15	
Total	30	100	30	100	60	100	

Chi square test was used to compare difference between both groups

Table 4: Comparison of pain scores between the groups

VAS	Group A		Group B		Mean Difference	"t"	Df	Sig
	Mean	SD	Mean	SD				
0 min	3.43	1.77	3.93	1.08	0.50	1.318	58	P=0.193
2 h	1.20	0.88	2.60	0.72	1.40	6.669	58	**P=0.001**
4 h	1.73	0.04	3.03	0.85	1.30	5.725	58	**P=0.001**
6 h	2.03	0.89	3.03	0.89	1.00	5.275	58	**P=0.001**
8 h	2.10	0.75	3.00	0.91	0.90	4.161	58	**P=0.001**
12 h	2.50	0.82	2.90	0.75	0.40	1.961	58	P=0.055
24 h	2.27	0.64	2.60	0.72	0.33	1.890	58	P=0.064
48 h	2.03	0.61	1.83	0.46	0.20	1.425	58	P=0.159

Unpaired t test was used to compare the difference between both groups

Table 5 Comparison of postoperative data between both the groups

	Group A		Group B		Difference b/w means	"t"	df	Sig
	Mean	SD	Mean	SD				
Time to 1st request for analgesia	8.3	3.5	3.6	0.5	4.65	7.04	58	**P<0.001**
Total mean number of bolus doses	1.27	0.45	2.13	0.35	0.87	8.36	58	**P<0.001**
Total tramadol consumption (mg)	63.33	22.4	106.6	17.2	43.33	8.36	58	**P<0.001**

Unpaired t test was used to compare the difference between both groups

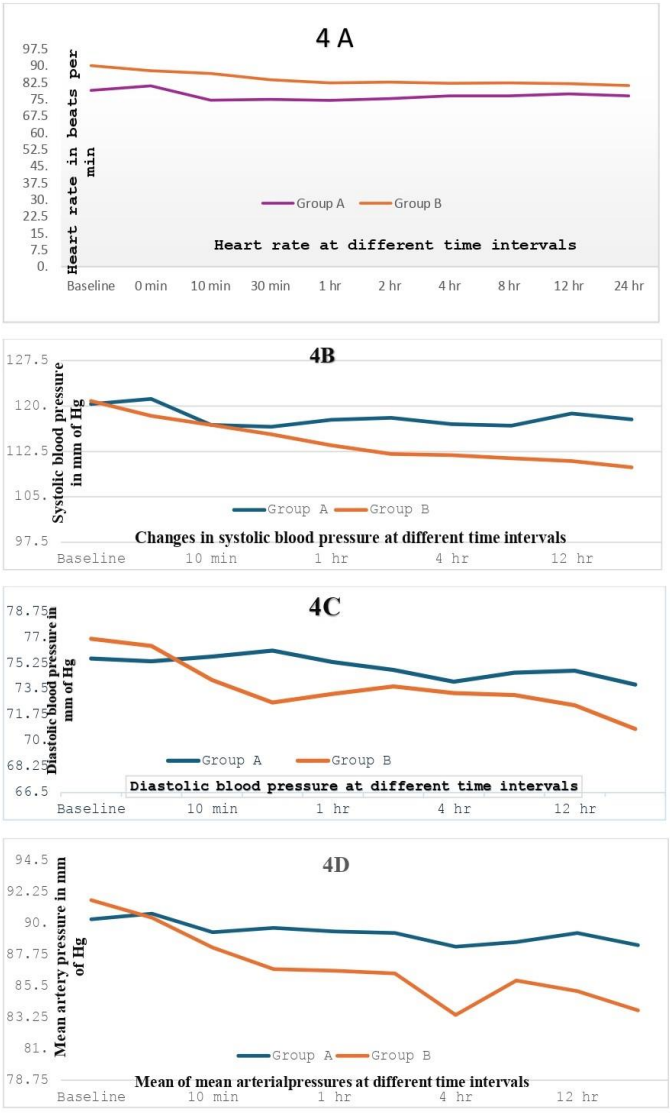

Fig 4: 4 A - indicates changes in heart rate at different time intervals,
4 B - indicates changes in systolic blood pressures at different time intervals,
4 C - indicates changes in diastolic blood pressure at different time intervals
4 D - indicates changes in mean arterial pressures at different time intervals.

DISCUSSION

In our study, both groups were found to be of a comparable body mass index, age, Comorbidities [Table 1] Obstetric scores [Table 2], and spinal level at time of intervention [Table 3]. In our study, Group A (ESP block) VAS score was lower than Group B (control), and the difference was significant (P<0.05) statistically, at 2, 4, 6 and 8 hours [Table 4]. Similar to our findings, Bhavini Shah et al, had observed that erector spinae plane block (ESPB) showed less VAS score at 4 hrs and remained lower thereafter (P < 0.001)(11) . A Dostbil et al. similarly observed that ESPB group significantly outperformed the control group with regards to pain scores (VAS) at 4th, 8th, and 12th hour at rest and on coughing (At rest: P = 0.004, P = 0.046, P = 0.044. On coughing: P = 0.002, P = 0.008, P = 0.028) (12). Similarly, Ribeiro Junior IDV et al conducted a network meta-analysis and comprehensive review including 3 studies (260 patients) to evaluate the effectiveness of Erector spine plane block for pain relief following cesarean delivery. The results indicated that there was no significant difference in pain scores between ESPB and controls at rest following surgery at 4 h (with very low certainty), 12 h (with very low certainty), and 24 h (with very low certainty), which is partly consistent with our findings up to 2hours.(13). A study done by Singh S et al. revealed that the ESP block group had significantly reduced pain scores at 0 hours (P=0.002) and 6 hours after surgery (P=0.040)(14). These results support our findings. Our analysis revealed that Group A (ESP block) needed fewer tramadol boluses than Group B. The mean differences between Groups A and B were statistically significant [P<0.05)][Table 5]. The study, conducted by Singh S et al. also revealed that the ESP group had a much lower postoperative morphine consumption compared to the control group (1.4±1.5 mg vs. 7.2±2.0 mg, respectively; [P<0.001] [14]) Additionally, all patients in the control group needed additional morphine, whereas only 9 patients (45%) in the ESP block group required such medication (P=0.002). Our results are consistent with the previous study conducted by Bhavini Shah et al., which showed that Group ESPB utilized much less postoperative rescue analgesia (P=0.001) (11). A comprehensive review and network meta-analysis conducted by Ribeiro Junior IDV et al supports our current study by showing reduced tramadol intake compared to controls (13). A study conducted by A Dostbil et al demonstrated that the ESP group had a much lower frequency of postoperative fentanyl consumption compared to the control group (279 ± 242.99 µg vs. 423.08 ± 212.55 µg, respectively, P = 0.003) (12). The mean time to request analgesia was substantially longer in Group A (8.30 hours) than in Group B (3.64 hours) in our study (Table 6). Mostafa et al reported longer duration of analgesia in ESP block group (6h) than control group (4h)(15). A Dostbil and colleagues conducted research that supports our current investigation by determining that the initial analgesic requirement time was substantially longer in the ESPB group(12). Malawat A et al also reported prolonged duration of action in ESP block group (43 hours)compared to TAP block (12 hours) (16). Prolonged duration of action in ESP block in our study may be due to paravertebral and circumferential epidural spread of local anesthetic solution(17) .The results of our study indicate that Group A had a statistically significant improvement in total patient satisfaction (P<0.05). This finding is consistent with a study conducted by Singh S et al which also reported that the ESP group had more positive patient satisfaction levels (P<0.0001) (14). Rincon etal also reported significant patient satisfaction levels with ESP block(17).

There were significant variations in the baseline to 24 hours post–operative heart rate and Group A had attended of lower heart rate, and it was statistically significant (P<0.05). The difference in SBP between Group A and Group B from 2 to 24 hours and MAP at 12 and 24 hours was significant (P<0.05) statistically with Group A showing overall lower trends. In our study we did not observe significant difference in DBP between both the groups These differences can be attributed to the analgesic and vasodilator effects of the ESP block in Group A. In Group A, 4 patients had bradycardia (statistically significant) and 2 patients had hypotension. Similarly, a study by Bhavini Shah et al showed HR, SBP and DBP in control group was slightly on the higher side postoperatively at 6 h and 24 h(11). There was no requirement of rescue vasopressors or anticholinergics for any of the patients.

Table 6: Comparison of Patient satisfaction between both groups between both the groups

Patient satisfaction	Group A (n = 30)		Group B (n = 30)		Total (n = 60)		Results
	Num	%	Num	%	Num	%	
Good	15	50	24	80	39	65	χ^2 =5.934
Excellent	15	50	6	20	21	35	df=1
Total	30	100	30	100	60	100	**P=0.015**

Chi square test was used to compare difference between both groups

Table 7: Comparison of adverse effects between both the groups

Adverse effects			Groups		Total	Results
			Group A (N = 30)	Group B (N = 30)		
Bradycardia	Yes	Num	4	0	4	χ^2 =4.286
		%	100%	0%	6.7%	df=1
	No	Num	26	30	56	**P=0.038**
		%	46.4%	53.6%	93.3%	
Hypotension	Yes	Num	2	0	2	χ^2 =2.069
		%	100%	0%	3.3%	df=1
	No	Num	28	30	58	P=0.150
		%	48.3%	51.7%	96.7%	

Chi square test was used to compare difference between both groups

LIMITATIONS

The variability in the spinal level at time of giving block and other intraoperative analgesia given may have affected the trends of VAS and hemodynamics of the patients. As the cut-off for bradycardia was 60 bpm disregarding the baseline value, the bradycardia associated with ESP block may or may not be an incidental finding. We did not use standard intrathecal opioids for control. This will limit the generalizability of our findings to many institutions that are using intrathecal opioids for postoperative pain. Future research could include comparing traditional intrathecal opioids with fascial plane blocks like ESP block.

CONCLUSION

Patients undergoing elective cesarean sections under subarachnoid block along with ESPB with bupivacaine offers lesser pain scores (VAS scale), longer duration of effective analgesia in the postoperative period with reduced postoperative analgesia consumption and better patient satisfaction.

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