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Original Article

Anaesthesia Section

Efficacy of Ultrasound-guided Transverse Abdominis Plane Block versus Epidural Block in Nephrectomy Patients: A Randomised Controlled Study

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ABSTRACT

Introduction: Partially controlled acute pain after abdominal surgery is associated with a variety of unwanted postoperative consequences, like respiratory complications, delirium, myocardial ischaemia, prolonged hospital stays, and chronic pain later on. A good postoperative recovery depends greatly on a proper analgesic regimen. While epidural analgesia has been used to provide postsurgical abdominal pain relief, peripheral nerve blockade is a good alternative.

Aim: To compare the analgesic efficacy of Transverse Abdominis Plane (TAP) block and Epidural block in patients undergoing nephrectomy.

Materials and Methods: In this single-blinded parallel-group randomised controlled study was conducted in the Department of Urology at the Institute f Postgraduate Medical Education and Research in Kolkata, West Bengal, India from November 2021 to October 2022. A total of 78 patients (18-65 years) with American Society of Anaesthesiologists (ASA) Grade-I and II were randomly assigned to Group-EA (Epidural) and Group-TA (TAP Block). Group-EA received 11 mL of 0.125% bupivacaine, and Group-TA received 11 ml of 0.125% bupivacaine, both given at an 8-hour interval for 24 hours. The primary outcome was to compare postoperative pain using the Visual Analogue Scale (VAS) score at 1, 8, 12, and 24 hours after surgery. Secondary outcome measures included assessing motor function using the Bromage Score, monitoring haemodynamic parameters (pulse rate, mean arterial pressure), and evaluating Postoperative Nausea and Vomiting (PONV). A p-value <0.05 was considered statistically significant when comparing the data.

Results: The authors found that the distribution of male and female patients (p=0.650), ASA Grades (I:II) (p=0.515), mean age (p=0.899), and mean SpO_2 (p=0.404) were comparable between the two groups (p>0.05). The pain scores between the EA and TA groups at 1, 8, 12, and 24 hours (0.10 vs. 0.08, 0.74 vs. 0.82, 1.00 vs. 1.31, 1.80 vs. 1.92) showed no significant difference at the specified times. However, the comparison of the mean Bromage scores in the EA and TA groups at the same time intervals (1 vs. 1.15, 1.08 vs. 2.51, 1.97 vs. 3.21, 1.97 vs. 4.74) revealed a significantly higher value in the TAP block group compared to the Epidural block group. The Epidural group had significantly lower blood pressure and pulse rate but experienced more PONV (15.4 vs. 2.6) compared to the TAP block group.

Conclusion: Epidural block resulted in hypotension, bradycardia, shivering, and PONV as side-effects, which were negligible in the TAP block group. However, postoperative analgesia was quite comparable between the two groups. Postoperative pain, as assessed by VAS score, changed significantly in the TAP block group (intragroup p-value=0.0063), whereas it remained constant in the epidural group (intragroup p-value 0.094), and the difference between the two groups was statistically insignificant. The occurrence of hypotension, bradycardia, and PONV was significant in the epidural group, whereas postoperative mobility was better in the TAP group.

Keywords: Bromage score, Postoperative nausea vomiting, Transverse abdominis plane block, Visual analogue scale score

INTRODUCTION

Postoperative pain management is key to a patient's early recovery, especially when the surgery is performed for the benefit of human beings. In recent years, multimodal analgesia methods have been recognised as superior for postoperative pain relief. Although laparoscopic donor nephrectomy has reduced disadvantages associated with open surgery, a significant percentage of donors still experience postoperative pain [1]. In the United Kingdom, Patient-controlled Analgesia (PCA) using morphine is commonly used for postoperative pain relief in most transplant centres, but the novelty is far from being an ideal analgesic due to its adverse effects [2].

Epidural analgesia, a gold-standard pain-relieving method for intra-abdominal surgery, has side-effects such as a fall in blood pressure and urinary retention, leading anaesthesiologists to seek alternative analgesic methods [2-4]. Alternatively, the Transverse Abdominis Plane (TAP) block is a landmark-based procedure performed via the triangle of Petit to produce a field block. The subcostal and posterior approaches of the TAP block involve intercostal nerve innervations in the upper quadrant (T6-T9) and lower quadrant (T7-L1), respectively [5,6].

Epidural analgesia has been proven to provide better analgesia for visceral and somatic pain compared to TAP block [7-10]. Pain following abdominal surgery can be managed using systemic drugs such as Non-steroidal Anti-inflammatory Drugs (NSAIDs), paracetamol, ketamine, opioids, alpha-2 agonists like clonidine, or by epidural anaesthesia using local anaesthetics with or without opioids or other adjuvants [11,12].

The goal of the TAP block is to deposit the local anaesthetic in the plane between the transverse abdominis and internal oblique muscles, targeting the spinal nerves in this plane to control pain in abdominal surgery after general or spinal anaesthesia [13,14]. Ultrasound-guided TAP blocks are technically easier to administer and safer with minimal complications compared to blind techniques [15]. Ultrasound-guided TAP block is used for adults undergoing

colon surgery, caesarean section, and abdominal hysterectomy [16,17]. Additionally, TAP block has been successfully used in inguinal hernioplasty, appendectomy, and open radical prostatectomy [18-23]. Analgesia with TAP block can be achieved using intermittent boluses or continuous infusion, and patients on anticoagulation therapy can also receive TAP block [24-26]. Zhang P et al., conducted a meta-analytic study which found that TAP block, although associated with a lower incidence of hypotension, appears to be equally effective as epidural analgesia for postoperative pain relief based on equivalent rest and dynamic pain scores at 24, 48, and 72 hours, as well as overall morphine requirement [26]. However, there are very few clinical trials comparing the efficacy and safety of ultrasound-guided TAP block and epidural analgesia, and none of them definitively concluded the superiority of one over the other [24-26]. Taking all of these factors into consideration, it was decided to conduct a randomised controlled trial to evaluate and compare the analgesic efficacy of TAP block with epidural analgesia for postoperative pain control and motor function in patients undergoing nephrectomy.

MATERIALS AND METHODS

This single-blind, parallel-group, randomised controlled study was conducted in the Department of Urology at the Institute of Postgraduate Medical Education and Research in Kolkata, West Bengal, India from November 2021 to October 2022. The study was approved by the Institute Ethics Committee (IEC certificate no: IPGME&R/IEC/2021/048) and registered with the Clinical Trials Registry of India (CTRI no: CTRI/2021/09/036998) Written informed consent was obtained from every patient on the day before surgery.

Inclusion criteria: Male and female patients aged between 18 and 65 years, with ASA grades I-II and a Body Mass Index (BMI) below 30 kg/m^2, who were scheduled for elective nephrectomy, were included in the study.

Exclusion criteria: Exclusion criteria included patient refusal, uncontrolled diabetes mellitus, hypertension, cardiovascular disease, known allergy or hypersensitivity to local anaesthetics used, coagulation disorders, infection at the site, and communicative or cognitive impairments interfering with pain measurements. The patients were blinded to the mode of analgesia they were receiving.

Sample size calculation: It was based on a previous study by Niraj G et al., [27]. Using the data, it was estimated that 35 patients would be required per group to detect a result with 80% power and a 5% probability of type 1 error for two-sided testing. Taking into account a 10% margin for dropouts, 39 patients were recruited per group.

Study Procedure

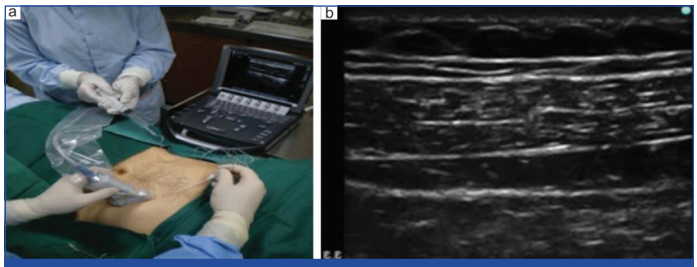
A computer-generated randomisation list was used for randomisation before the application of the Transverse abdominis plane block and the epidural block. The allocation concealment was done using opaque sealed envelopes after arranging the patients in a serial number. The epidural block group was marked as the active control arm. Routine laboratory investigations were performed, including haemoglobin, total count, differential count, Erythrocyte Sedimentation Rate (ESR), platelet count, fasting and postprandial blood sugar, liver function test, thyroid function test, coagulation profile, blood urea, creatinine, electrolytes, chest X-ray, and Electrocardiogram (ECG) (all 12 leads). Only patients with normal blood reports were included in the study. The parameters to be studied included time to first rescue analgesics, VAS scores at 1, 8, 12, and 24 hours postoperatively, heart rate, blood pressure (systolic, diastolic, mean arterial pressure), SpO_2, PONV, and Bromage score.

The study coordinator opened each envelope according to the recruitment sequence on the day of surgery and prepared the study drugs for each patient, but did not participate in the rest of the trial. The study drugs were prepared in 20 mL syringes for both procedures. Apart from the administration of the study drug, other perioperative management was identical in both groups (EA-Epidural Analgesia and TA-Transverse Abdominis plane block). Enrolled patients were educated about the grading of pain intensity using the VAS score, which measures pain on a line with markings from the left-hand end to the point that the patient marks.

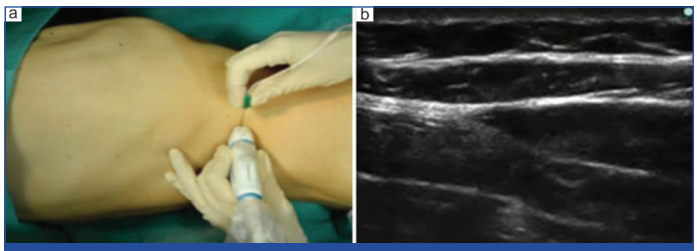
The primary outcome was the comparison of pain intensity in the postoperative period using the VAS score at 1, 8, 12, and 24 hours following surgery. The secondary outcome was the comparison of the Bromage scale score at 1, 8, 12, and 24 hours after surgery between the two groups. Numbered sealed envelopes were used for each subject and opened by the patient in the operating room. The anaesthesia and surgical teams were the same in all cases during this trial, and all patients received the same general anaesthesia as per institutional protocol.

Before administering general anaesthesia, the control group patients received an epidural block. An 18-gauge Tuohy needle was used for epidural anaesthesia after local infiltration with 2% lignocaine, aseptically. Then, an epidural catheter was inserted 6 cm into the epidural space. A test dose of 3 mL of lignocaine and adrenaline 1:200,000 was injected, and no change in heart rate and blood pressure was ensured. At the completion of surgery, the initial bolus dose for the epidural was kept at 3 mL, followed by 10 mL of 0.125% bupivacaine every eight hours for 24 hours. On the second postoperative day, the epidural catheter was removed.

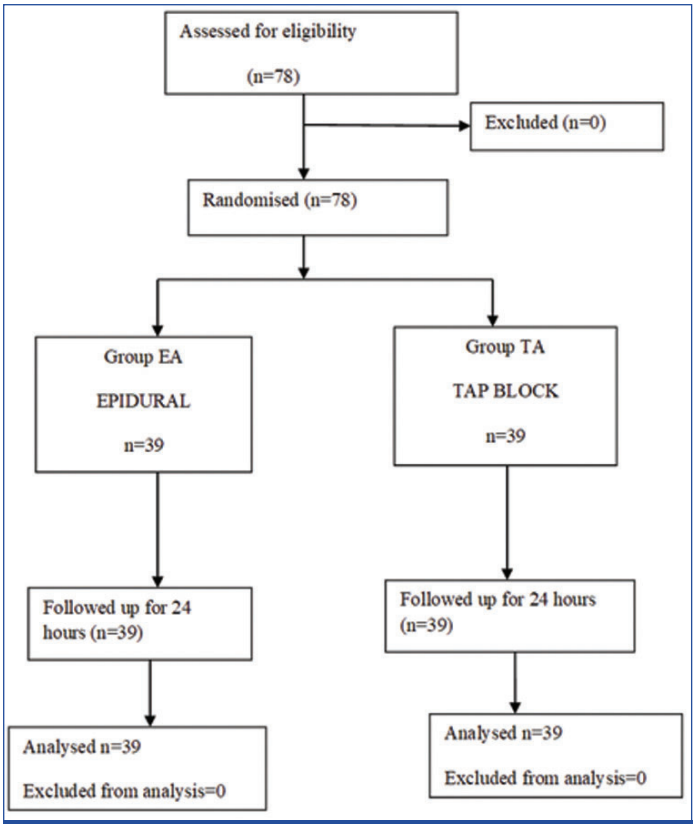
The TAP group patients received an ultrasound-guided TAP block after the completion of the surgery and before reversal from general anaesthesia. An ultrasound probe (7-10 MHz linear array ultrasound transducer) was placed in a supine posture in a plane passing through the midaxillary line transverse to the lateral abdominal wall, between the ipsilateral lower costal margin and the iliac crest on the side of nephrectomy. Under aseptic conditions, the block was administered with an 18-gauge Tuohy needle at the plane between the internal oblique and transverse abdominis muscles [Table/Fig-1a,b,2a,b]. A total of 5 mL of normal saline was injected to confirm the correct needle position, and then the epidural catheter was inserted 4-6 cm beyond the needle tip into the TAP plane, ensuring correct localisation. Each patient in this group received 15 mL of 0.125% bupivacaine at the end of surgery and then at 8-hour intervals during the first 24 hours postoperatively. Ringer lactate solution was administered as intravenous fluid in the perioperative period, and each patient had a Foley's catheter inserted. After reversal from general anaesthesia, the time was noted and taken as the 0 time point. Recruitment and follow-up have been summarised in the Consolidated Standards of Reporting Trial (CONSORT) flow diagram [Table/Fig-3].



[Table/Fig-1a]: Subcostal approach of TAP Block landmark.
[Table/Fig-1b]: Subcostal approach of TAP Block (USG view). (Images from left to right)



[Table/Fig-2a]: Posterior approach of TAP block.
[Table/Fig-2b]: Posterior approach of TAP block (USG view). (Images from left to right)



[Table/Fig-3]: CONSORT flow diagram.

Standard monitors were attached, including ECG (3-leads), non invasive blood pressure, oxygen saturation, capnometry, and a temperature probe. Every patient received premedication with intravenous Glycopyrrolate (200 mcg), Fentanyl (2 mcg/kg), followed by Propofol (2 mg/kg) for induction, and Succinylcholine (2 mg/kg) for muscle relaxation. Subsequent paralysis was achieved with Atracurium (0.5 mg/kg). Anaesthesia maintenance was done with isoflurane to ensure adequate depth. The epidural catheter was removed from each patient on the second postoperative day. The authors identified shivering as a reflex characterised by the involuntary oscillatory activity of the skeletal muscles in the upper limbs, neck, and jaw.

STATISTICAL ANALYSIS

After documenting all the data in the case record form and creating the master chart, the authors arranged all the inputs properly for analysis. Sample size calculation was performed using nMaster 2.0 software. Raw data were entered into a Microsoft excel spreadsheet and analysed using the standard statistical software SPSS® Statistical Package for the Social Sciences version 18.0 (SPSS Inc., Chicago, IL, USA). Pearson's Chi-square test was used to analyse the categorical variables, while the independent sample t-test was used for normally distributed continuous variables. A p-value of <0.05 was considered statistically significant.

RESULTS

Males comprised 56.4% of the study population in the Epidural block group and 51.3% in the TA plane block group. The difference in proportions between the two groups was not statistically significant [Table/Fig-4]. Almost 90% (89.7%) of the study population in the epidural group belonged to ASA Class-I, while 82.1% of the study population in the TA plane block group belonged to ASA Class-I [Table/Fig-4]. The difference in proportions between the groups was also not statistically significant. The Mean±Standard Deviation (SD) age of the study population in the epidural and TA plane block groups was 39.8±10.4 and 39.5±11.0 respectively, with no statistically significant difference [Table/Fig-4].

Variables	Levels	Epidural block n=(39)	TAP block n=(39)	p-value
Sex#	Male	22±56.4	20±51.3	0.650
	Female	17±43.6	19±48.7	
ASA# class	I	35±89.7	32±82.1	0.515
	II	4±10.3	7±17.9	
Mean age (years)γ		39.8	39.5	0.899
Mean Spo_2 (%)γ		98.88	97.34	0.404

[Table/Fig-4]: Comparison of demographic data between two groups.
#Chi-square test γStudent's t-test

Comparison of the VAS scores at 1, 8, 12, and 24 hours shows no significant (p>0.05) difference in pain scores between the TA plane block group and the epidural block group at the specified times [Table/Fig-5]. Postoperative pain, as assessed by VAS score, changed significantly in the TAP block group (intragroup p-value 0.0063), whereas in the epidural group (intragroup p-value 0.094), it remained constant, and the difference between the two groups was statistically insignificant. Comparison of the mean pulse rates at 1, 8, 12, and 24 hours shows comparatively higher and statistically significant (p<0.05) mean pulse rates in the TA plane block group compared to the epidural block group at the specified times [Table/Fig-6].

Mean VAS score timingγ	Epidural block (n=39) Mean±SD	TAP block (n=39) Mean±SD	p-value
1 hour	0.10±0.31	0.08±0.27	0.697
8 hours	0.74±0.75	0.82±0.64	0.629
12 hours	1.00±0.83	1.31±0.61	0.066
24 hours	1.80±0.61	1.92±0.74	0.408

[Table/Fig-5]: Comparison of mean VAS scores between two groups.
γStudent's t-test

Mean pulse (bpm) rate timingγ	Epidural block (n=39) Mean±SD	TAP block (n=39) Mean±SD	p-value
1 hour	74.46±3.34	80.36±3.90	<0.0001*
8 hours	76.54±5.03	81.87±3.45	<0.0001*
12 hours	77.90±5.52	84.03±3.34	<0.0001*
24 hours	80.64±5.88	85.69±3.65	<0.0001*

[Table/Fig-6]: Comparison of pulse rate among two groups.
γStudent's t-test; *Statistically significant

Comparison of the MAP scores at 1, 8, 12, and 24 hours shows significantly higher and statistically significant (p<0.05) mean MAP scores in the TA plane block group compared to the epidural block groups at the specified times [Table/Fig-7].

Mean of (mm of Hg) MAP timingγ	Epidural block (n=39) Mean±SD	TA plane block (n=39) Mean±SD	p-value
1 hour	70.15±2.53	75.67±2.55	<0.0001*
8 hours	73.21±2.33	79.08±2.56	<0.0001*
12 hours	75.31±3.13	80.85±2.81	<0.0001*
24 hours	75.64±3.68	82.72±2.06	<0.0001*

[Table/Fig-7]: Comparison of Mean Arterial Pressure (MAP) between two groups.
γStudent's t-test; *Statistically significant

Comparison of the mean Bromage scores at 1, 8, 12, and 24 hours shows significantly higher (p<0.05) scores in the TA plane block group compared to the epidural block groups at the specified times [Table/Fig-8].

A higher proportion of patients in the TA plane block group (25.64%) needed rescue analgesia compared to the epidural group (10.3%). The difference in proportions was statistically significant (p<0.05) [Table/Fig-9].

Mean Bromage scale score	Epidural block (n=39) Mean±SD	TA plane block (n=39) Mean±SD	p-value
1 hour	1.00 (0)	1.15 (0.37)	0.0001*
8 hours	1.08 (0.27)	2.51 (0.51)	<0.0001*
12 hours	1.97 (0.49)	3.21 (0.73)	<0.0001*
24 hours	1.97 (0.49)	4.74 (0.64)	<0.0001*

[Table/Fig-8]: Comparison of mean Bromage scale among two groups.
[γ]Student's t-test; *Statistically significant

Rescue analgesia[#]	Epidural block number (%)	TA plane block number (%)	p-value
Yes	4 (10.3)	10 (25. 64)	0.0277*
No	35 (80.7)	29 (74.35)	
Timing of Rescue Analgesia (min)[γ]	260.68 ± 30.44	247.35±29.08	0.0516

[Table/Fig-9]: Comparison of rescue analgesic used among two groups.
[#]Chi-square test; [γ]Student's t-test; *Statistically significant

A significantly higher (p<0.05) number of patients in the epidural group (15.4%) presented with nausea and vomiting compared to the TA plane group (2.6%). The differences between the proportions were statistically significant [Table/Fig-10].

PONV[#]	Epidural block N (%) (n=39)	TA plane block N (%) (n=39)	p-value
Yes	6 (15.4)	1 (2.6)	0.048*
No	33 (84.6)	38 (97.4)	
Postoperative shivering	3 (8.46)	1 (2.6)	0.0427*

[Table/Fig-10]: Comparison of postoperative nausea vomiting (PONV) two groups.
[#]Chi-square test; *statistically significant

DISCUSSION

The main aim of the present study was to compare both techniques with respect to postoperative analgesia, haemodynamic parameters, vomiting after the operation, and motoric ability. The findings of the present study are as follows:

The comparison of mean age, sex, and ASA grading was similar in both groups. The VAS scores at 1, 8, 12, and 24 hours were not significantly different in the TA plane block group compared to the epidural block group at the specified times, although the maximum difference was noted at 12 hours (p=0.066) where the epidural group had a lower mean VAS. More patients in the TAP block group needed rescue analgesia compared to the epidural group. However, the difference in proportions was not statistically significant. In 2018, Aditianingsih D et al., found that the addition of dexamethasone in a three-quadrant TAP block was comparable to continuous epidural analgesia in terms of total opioid consumption and pain score in the first 24 hours [28]. Rao Kadam V et al., found no statistical difference in rescue analgesic requirement comparing continuous TAP block with the continuous epidural group in abdominal surgery [22]. Yadav U et al., found comparable postoperative opioid consumption in USG-guided TAP block and epidural block groups following hernia surgery [29]. Baeriswyl M et al., found comparable postoperative analgesia in the two groups comparing TAP block and continuous epidural block [30]. All these findings corroborate with the findings of this study. In a study by Niraj G et al., comparing epidural analgesia with USG-guided subcostal TAP block after upper abdominal surgery, the authors observed that postoperative opioid consumption was significantly higher in TAP block patients [31]. However, Kandi Y found in their study a reduction in morphine requirement by 70% in the TAP group compared to epidural [32].

The comparison of mean pulse rates at 1, 8, 12, and 24 hours shows significantly different and comparatively higher mean pulse rates in the TAP Block group compared to the epidural group at the specified times. The mean MAP scores at 1, 8, 12, and 24 hours also show significantly different and comparatively higher values in the TAP block group compared to the epidural group. Namasivayam SP et al., concluded that haemodynamic parameters such as blood pressure and pulse rate were lower in the epidural group compared to the TAP Block group [29].

The comparison of mean Bromage scores at 1, 8, 12, and 24 hours shows significantly higher scores in the TA plane block group compared to the epidural block groups at the specified times. The maximum difference was noted at 24 hours with a p-value of <0.0001.

A higher proportion of patients in the epidural group (15.4%) experienced nausea and vomiting compared to the TA plane group (2.6%). The differences between the proportions were statistically significant (p=0.0498). Appropriate needle and catheter positioning in the proper plane is aided by ultrasound. Apfel CC et al., found that six patients experienced hypotension-induced PONV requiring ondansetron as an antiemetic [33]. However, Jeong YH et al., did not find any significant difference in PONV between the two groups [34].

Heil JW et al., chose an 18 G Tuohy needle because it is prominently noticed in USG [35]. In 2008, Hebbard and his colleagues confirmed the placement of the 18 G Tuohy needle by injecting normal saline in that plane, which dissected the plane [15].

Limitation(s)

The present study was a single-blinded study, so intraobserver bias might be present. Epidural block was given as a blind block, whereas TAP block was performed with the help of USG, which can be a major drawback for the study influencing outcomes. USG-guided TAP block was a relatively new procedure compared to the time-tested epidural block, so the difference in expertise and skill in performing the two blocks might have been a confounding factor in the present study. The authors have excluded patients with BMI >30; thus, the results of the study cannot be generalised to that population.

CONCLUSION(S)

Based on comparable demographic profiles, postoperative pain in nephrectomy patients, as assessed by VAS score, changes significantly in the TAP block group, whereas in the epidural group, the score remains constant. However, the difference between the two groups is statistically insignificant. Epidural block patients suffered from more bradycardia, hypotension, and PONV than TAP block patients. Postoperative mobility was significantly better in the TAP group, which signifies reduced hospital stay and complications associated with immobility.

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