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Original Research Article

A PROSPECTIVE RANDOMIZED DOUBLE-BLIND COMPARATIVE STUDY OF THE EFFECTIVENESS OF ROPIVACAINE 0.2% WITH BUPIVACAINE 0.25% IN TRANSVERSUS ABDOMINIS PLANE BLOCK FOR PROVIDING EFFECTIVE AND SAFE POSTOPERATIVE ANALGESIA IN LAPAROSCOPIC DONOR NEPHRECTOMY

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Abstract

Background: The use of Ultrasonography (USG) guided Transversus Abdominis Plane (TAP) block for pain management is an upcoming and useful tool for lower abdominal surgeries. This study aims to compare the efficacy of Ropivacaine (0.2%) and Bupivacaine (0.25%) in terms of the duration of postoperative analgesia in laparoscopic Donor Nephrectomy. **Materials and Methods:** Eighty patients undergoing laparoscopic donor nephrectomy were divided into 2 groups of 40 each. After the donor nephrectomy, a USG-guided TAP block was given. One group received TAP block with Ropivacaine 0.2% and the other group received Bupivacaine 0.25%. VAS score was assessed both at rest and on movement (patient was asked to maximally flex his/ her knees) on arrival at Postanaesthesia Care unit (PACU), discharge from PACU, in Intensive Treatment Unit (ITU) at 6, 8, 12, and 24 hours. The time to first rescue dose of tramadol and the total amount of tramadol given in 24 hours were noted. **Result:** A statistically significant difference in VAS score was noted between the two groups in almost all intervals at PACU, discharge from PACU, 6 hours, 8 hours, and 12 hours both at rest and movement, except at 24-hour VAS score which was found to have minimal difference. The time for rescue analgesia was longer in Ropivacaine (0.2%) compared to Bupivacaine (0.25%) which was statistically significant. **Conclusion:** In patients undergoing laparoscopic donor nephrectomy USG-guided deposition of Ropivacaine (0.2%) in the TAP block provides superior analgesia in the postoperative period in comparison to Bupivacaine (0.25%).

INTRODUCTION

Laparoscopic live donor nephrectomy (LLDN) is now the preferred method and gold standard operation for kidney donation.[1,2] Pain following the LLDN is multifactorial. Port pain, low abdominal incisions (to retrieve the kidney), pelvic organ nociception, diaphragmatic irritation (shoulder tip discomfort from residual pneumoperitoneum), and urinary catheter discomfort add up and contribute to the total pain experience.[3-5] Inadequately controlled postoperative pain may have harmful physiologic, and psychological consequences which potentially increase morbidity and mortality.[6,7] In the postoperative period, these patients are often treated with patient-controlled opioids, epidural analgesia, or both. Although effective, both these modalities carry risk, because of the side effect profile of opioids including pruritus, nausea, vomiting, and an increase in the incidence of over-sedation. Epidural has been associated with hypotension, infections, bleeding, nerve injury, and delayed mobilization in the postoperative period.[8] Transversus Abdominis Plane (TAP) block is a regional anaesthesia technique that provides analgesia to the anterior abdominal wall

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by blocking the anterior rami of the lower six thoracic nerves (T7 to T12) and first lumbar nerve (L1) supplying the skin, muscles, and parietal peritoneum.[9] This block avoids the potential hazard associated with opioids and neuraxial blockade. Ultrasound (US) guided TAP block is superior concerning continuous visualization of the needle and good drug deposition leading to better pain control and faster recovery.

Ropivacaine is a long-acting regional anaesthetic that is a pure S(-)enantiomer, unlike bupivacaine which is a racemate.[10] Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres; therefore it has selective action on the pain-transmitting Aδ and C nerves rather than Aβ fibres, which are involved in motor function. Ropivacaine has a significantly higher threshold for cardiotoxicity and central nervous system toxicity than bupivacaine because of its less lipophilicity and stereo-selective properties.[10] Therefore, it would be safer and more effective if ropivacaine (0.2%) instead of bupivacaine (0.25%), is used in US-guided TAP block for postoperative analgesia in laparoscopic donor nephrectomy patients due to adequate pain relief and early ambulation.

Although Ropivacaine and Bupivacaine are commonly used as a local anaesthetic agent for the TAP block,[11] they have not been compared for their relative effectiveness and safety in donor nephrectomy patients. So, the present study aims to evaluate the relative efficacy of ropivacaine versus bupivacaine for postoperative analgesia using US-guided TAP block in laparoscopic donor nephrectomy patients. The primary objective was to compare the total dose of tramadol required as rescue analgesic in the postoperative period in laparoscopic Donor Nephrectomy in the two groups receiving Ropivacaine 0.2% and Bupivacaine 0.25%. The secondary objectives were to compare the time to the first rescue dose of tramadol and the incidence of various side effects in the two groups.

MATERIALS AND METHODS

After obtaining approval from the institutional ethical committee, this prospective randomized double-blind study was conducted following the Helsinki Declaration-2013, in a tertiary-level multi-speciality hospital in eastern India from January 2017 to April 2018 in ASA I and II patients of age 18-60 years undergoing laparoscopic donor nephrectomy under general anaesthesia. Patients who refused to take part in the study, patients with cardiovascular disease, respiratory disease, hepatic disease, neurological disease, renal disease, coagulation disorders, allergy to local anaesthetic, conversion to open nephrectomy, inability to comprehend VAS, psychiatric disease, opioid dependence were excluded from the study. Patients were included after obtaining written informed consent. They were explained in the information sheet that neither protocol will harm them or interfere with the procedure nor they have to pay for that.

Sample size calculation: The sample size was estimated based on the 24-hour tramadol requirement of patients as a rescue analgesic. A pilot study was done using 0.2% Ropivacaine (0.5 ml/kg upto a maximum volume of 30 ml) and 0.25% Bupivacaine (0.5ml/kg upto a maximum volume of 30 ml) for TAP block in laparoscopic donor nephrectomy. The difference in mean dose of rescue tramadol in the two groups came to be 33.3 mg which was considered to be the effect size. The pooled standard deviation for the two groups was calculated to be 28.87 mg. The formula for calculating sample size: $n=2(Z\alpha+Z1-\beta)^2X(\sigma)^2/(\delta)^2$; where: n is the number of samples per arm, Zα is a constant (set by convention according to the accepted α error and whether it is a one-sided or two-sided effect). For a two-sided effect & 5% alpha error, it is 1.96. Z (1-β) is a constant set by convention according to the power of the study so for a power of 90% its value is 1.28. σ is the estimated standard deviation. δ is the difference in the effect of two interventions that are required (estimated effect size). So, putting values in this formula: $n=2(1.96+1.28)^2X(28.87)^2/(33.3)^2=16$ in each arm. Accounting for a 20% dropout the sample size comes to 20 in each arm which is half of our sample size taken (i.e., 40).

Patients were randomly assigned into two groups of 40 patients in each group with the help of a software-generated (sealedenvelope.com) table of random numbers. This random allocation was known only to the research guide. The study drugs were prepared and delivered in identical syringes by the research guide based on the randomization sequence. The patient as well as the investigator administering the study drugs and documenting the study parameters was unaware of the identity of the drug. Subjects were assigned to two groups – Group A (n = 40) received 0.2% Ropivacaine (0.5ml/kg upto a maximum volume of 30 ml), and Group B (n = 40) received 0.25% Bupivacaine (0.5ml/kg upto a maximum volume of 30 ml). The subjects were kept nil per mouth according to the practice guidelines of preoperative fasting by ASA.[12] After taking the patient to the operation theatre intravenous access was established. For all the subjects, standard monitoring i.e., 12 lead ECG, SpO2, non-invasive blood pressure (NIBP), and end-tidal carbon dioxide (etCO2), temperature was used throughout the operation. The study subjects were pre-oxygenated for 3 minutes with 100% Oxygen, then premedicated with Glycopyrrolate 10 mcg/kg, and midazolam 0.02 mg/kg followed by fentanyl 2mcg/kg, propofol 2mg/kg, intubation facilitated by giving Atracurium 0.5 mg/kg. For maintenance, oxygen, isoflurane, and a maintenance dose of Atracurium were used. After completion of the surgery, a US-guided TAP block was performed before the patient was extubated, on the same side as the surgery. Intra-op analgesics used were fentanyl (1mcg/kg of body weight), paracetamol (15mg/kg), and tramadol (1mg/kg)

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given as per the hospital's standard protocol. Ondansetron (0.1mg/kg) was given prophylactically before extubation as an antiemetic. VAS score was assessed both at rest and on movement (patient was asked to maximally flex his/ her knees) on arrival at Post-anaesthesia Care unit (PACU), discharge from PACU, in Intensive Treatment Unit (ITU) at 6, 8, 12, and 24 hours. When the Visual Analogue Score (VAS) was >4, a rescue dose of tramadol was administered. The rescue dose of tramadol (2mg/kg) and the total amount of tramadol given in 24 hours was noted. Postoperatively, paracetamol (15mg/kg body weight) was continued as per the hospital's standard protocol. The side effects that occurred were managed accordingly.

For statistical analysis, data were entered into a Microsoft Excel spreadsheet and then analyzed by SPSS (version 20, SPSS Inc., Chicago, IL, USA). Categorical variables have been expressed as the number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes or Fisher's Exact Test as appropriate. Continuous variables have been expressed as Mean ± Standard Deviation and compared across the 2 groups using the Mann-Whitney U test. An alpha level of 5% has been taken, i.e. if any p-value is less than 0.05 it has been considered as significant.

RESULTS

In this study, 80 adult patients, who underwent elective laparoscopic donor nephrectomy, were assigned to two groups with 40 patients in each group.

[Table 1] shows the demographic characteristics of the patients of both groups. Both the groups were found to be comparable (p >0.05).

[Table 2 and Figure 1] depict that VAS at rest was higher in group 2 compared to group 1 at PACU, shift from PACU, 6 hours, 8 hours, and 12 hours and the differences were statistically significant. For VAS score at movement, Table 3 and Figure 2 showed that VAS in group 2 at PACU, Shift from PACU, 6 hours, 8 hours, 12 hours was more compared to group 1. These differences were statistically significant.

Table 4 shows that the heart rate (HR) at shift from PACU, at 6 hours, at 8 hours, at 12 hours, and 24 hours in group 1 are lower compared to group 2, but those on arrival at PACU showed no significant difference. There is no significant difference in mean arterial blood pressure (MAP) between the two groups [Figure 3].

Table 5 shows that the time to the first rescue dose was longer in group 1 (14.78 ± 5.27 hours) than in group 2 (11.64 ± 3.64 hours) and the difference was statistically significant. Table 6 shows that the amount of rescue analgesic used in 24 hours in the postoperative period in Group 2 was more compared to Group 1. Twenty percent of patients received 150mg tramadol in Group 2 compared to 7.5% in Group 1 for analgesia. Group 2 had 67.5% of patients who received 100 mg tramadol compared to 32.5% in group 1. Ten percent of patients in group 2 received 50 mg tramadol compared to 50% in group 1. Compared to group 2 which had 2.5%, group 1 had 10% of the patients who did not require rescue analgesia. These differences were statistically significant (p<0.001).

Nausea [Table 7] and vomiting [Table 8] were seen in very few subjects of both groups, and no significant difference was found between the two groups (p-value=0.688 and 0.731 respectively).

Table 1: Demographic variables of both group

		Group 1	Group 2	Total	p Value
Age (Mean±SD)		35.65 ± 7.21	38 ± 9.33		0.244
Sex [Frequency(%)]	Male	19(47.5)	20(50)	39(48.75)	0.823
	Female	21(52.5)	20(50)	41(51.25)	
Body Weight (Mean±SD)		57.98 ± 8.59	59.63 ± 7.88		0.415

*SD: Standard Deviation

Table 2: Comparison of VAS score between two groups at rest

	Group		
	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	p-value
VAS at rest in PACU	0.03 ± 0.16	0.38 ± 0.54	<0.001
VAS at rest s.f PACU	0.28 ± 0.72	0.93 ± 0.73	<0.001
VAS REST 6 Hours	0.58 ± 0.81	1.43 ± 0.59	<0.001
VAS REST 8 Hours	1.2 ± 0.97	1.95 ± 0.6	<0.001
VAS REST12 Hours	1.85 ± 0.77	2.28 ± 0.64	0.007
VAS REST 24 Hours	2.43 ± 0.55	2.45 ± 0.6	0.929

*SD: Standard Deviation; PACU: Post anaesthesia Care Unit; s.f.: Shift from

Table 3. Comparison of VAS score between two groups at movement

	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	p-value
VAS AT MOVEMENT IN PACU	0.03 ± 0.16	0.38 ± 0.54	<0.001
VAS AT MOVEMENT S.F PACU	0.28 ± 0.72	0.93 ± 0.73	<0.001
VAS MOVEMENT 6 Hours	0.6 ± 0.81	1.45 ± 0.6	<0.001
VAS MOVEMENT 8Hours	1.28 ± 0.99	1.95 ± 0.6	0.001

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VAS MOVEMENT12 Hours	1.93 ± 0.8	2.3 ± 0.61	0.020
VAS MOVEMENT 24 Hours	2.45 ± 0.6	2.45 ± 0.6	1.000

*SD: Standard Deviation; PACU: Post anaesthesia Care Unit; s.f.: Shift from

Table 4: Comparison of Heart Rate (HR) between two groups

	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	p-value
HR PACU	80.83 ± 12.28	85.05 ± 10.29	0.100
HR S.F. PACU	76.05 ± 8.79	83.5 ± 10.91	0.001
HR 6hours	76.65 ± 8.4	82.23 ± 9.89	0.005
HR 8 hours	79.3 ± 9.81	84.68 ± 8.97	0.006
HR 12 hours	77.6 ± 9.2	83.2 ± 9.48	0.009
HR 24 hours	81.68 ± 9.27	85.35 ± 8.2	0.039

*SD: Standard Deviation; PACU: Post anaesthesia Care Unit; s.f.: Shift from; HR: Heart rate

Table 5: Rescue dose timing after surgery between two groups

	Group 1 (Mean ± SD)	Group 2 (Mean ± SD)	p-value
Rescue Dose Timing After Surgery	14.78 ± 5.27	11.64 ± 3.64	0.007

*SD: Standard Deviation

Table 6: 24 hour's tramadol consumption between two groups

		Group		Total	
		Group 1	Group 2		p-value
24 HOUR TRAMADOL CONSUMPTION	0 mg	4(10)	1(2.5)	5(6.25)	<0.001
	50 mg	20(50)	4(10)	24(30)	
	100 mg	13(32.5)	27(67.5)	40(50)	
	150 mg	3(7.5)	8(20)	11(13.75)	

Table 7: Incidence of nausea between two groups

		Group 1	Group 2	Total	p-value
NAUSEA PACU	Absent	40(100)	38(95)	78(97.5)	0.494
	Present	0(0)	2(5)	2(2.5)	
NAUSEA S.F PACU	Absent	38(95)	38(95)	76(95)	1.00
	Present	2(5)	2(5)	4(5)	
NAUSEA 6 Hours	Absent	39(97.5)	39(97.5)	78(97.5)	1.00
	Present	1(2.5)	1(2.5)	2(2.5)	
NAUSEA 8 Hours	Absent	39(97.5)	40(100)	79(98.75)	0.314
	Present	1(2.5)	0(0)	1(1.25)	
NAUSEA 12 Hours	Absent	40(100)	40(100)	80(100)	NA
NAUSEA 24 Hours	Absent	40(100)	40(100)	80(100)	NA

*SD: Standard Deviation; PACU: Post anaesthesia Care Unit; s.f.: Shift from

Table 8: Incidence of vomiting between two groups

		Group 1	Group 2	Total	p-value
VOMITING PACU	Absent	39(97.5)	40(100)	79(98.75)	0.314
	Present	1(2.5)	0(0)	1(1.25)	

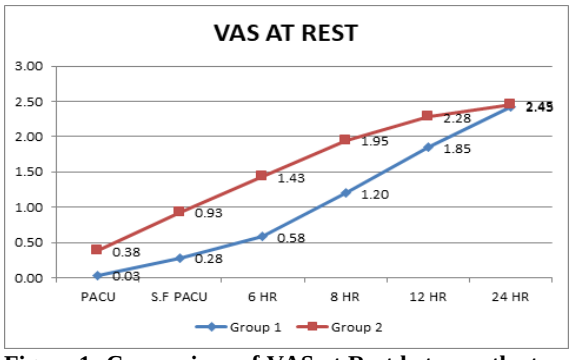

Figure 1: Comparison of VAS at Rest between the two groups

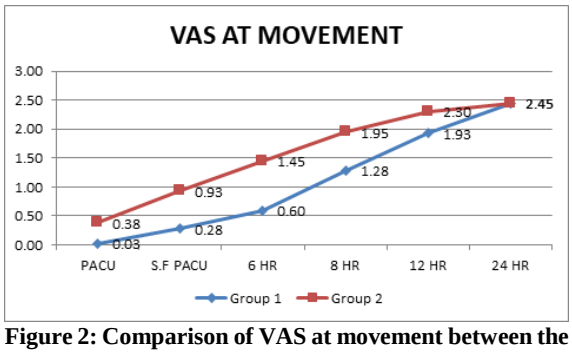

Figure 2: Comparison of VAS at movement between the two groups

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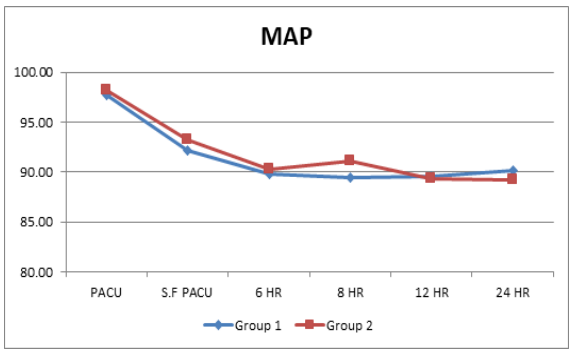

Figure 3: Comparison of MAP between the two groups

DISCUSSION

In the present study, two different local anaesthetic drugs i.e., Ropivacaine 0.2% and bupivacaine 0.25%, in TAP block were compared in laparoscopic donor nephrectomy patients to see if different local anaesthetic would make a difference in terms of postoperative analgesia. Statistically significant differences in pain score (VAS) were found at PACU, discharge from PACU, 6 hours, 8 hours, and 12 hours both at rest and at movement between Ropivacaine (0.2%) and Bupivacaine (0.25%). The present study showed that ropivacaine (0.2%) provides more effective pain relief in the immediate post-operative period as compared to bupivacaine (0.25%) when administered via US-guided TAP block. Adverse effects like nausea and vomiting were noted in both the groups but no significant difference was found. The choice of LA agent used did not have any bearing on postoperative nausea and vomiting parameters, which may be because of prophylactic antiemetic (ondansetron) use.

These findings were similar to a study conducted by Shradha Sinha et al. comparing bupivacaine with ropivacaine as adjuncts for postoperative analgesia in laparoscopic cholecystectomies.[11] In their study, they found that patients receiving ultrasound-guided TAP block with ropivacaine had significantly lower pain scores at 10 minutes, 30 minutes, and 1 hour when compared to patients who received the block with bupivacaine. Another study done by Gildasio S. De Oliveira et al. concluded that the quality of recovery was improved in patients who received a TAP block with 0.25% or 0.5% ropivacaine compared with saline for gynaecological laparoscopic surgery.[13] Stephen Aniskevich et al. also found that a TAP block with ropivacaine 0.5% reduced overall pain scores in undergoing elective living donor nephrectomy or single-sided nephrectomy for tumours with a trend toward decreased total morphine consumption in comparison to placebo.[14] Beena K. Parikh et al. in their study used bupivacaine 0.375% in the study group whereas the control group received normal saline for TAP block and Tramadol 1mg/kg was given as rescue analgesia. The 24-hour consumption of total tramadol was 56 % less in the study group compared to the control group. They also stated that opioid-related side effects like sedation, nausea, and vomiting were low, due to the use of tramadol instead of morphine and prophylactic use of ondansetron.[15] Flower SJL et al. also found that 0.375% 30ml ropivacaine given as a TAP block under US guidance significantly prolonged the post-operative analgesia duration compared to 0.25% 30ml bupivacaine in upper abdomen laparoscopic surgeries.[16]

In the present study, 0.25% Ropivacaine and 0.2% bupivacaine have been compared for TAP block. Fekih Hassen A. et al. found in their study that Ropivacaine 0.2% is equivalent to Bupivacaine 0.25% concerning postoperative and perioperative analgesia.[17] The study conducted by De Oliveira GS Jr et al. found that ropivacaine used in concentrations of 0.25% and 0.5% is equally efficacious on postoperative quality of recovery and analgesia.[13] The risk of local anaesthetic systemic toxicity can be reduced by using lower doses of ropivacaine (0.25%). The present study has certain limitations. Evaluation of sensory block level was not undertaken. The conclusion of this study is based on the TAP block given at the end of the surgery, but it is difficult to conclude whether the outcome have been the same if the TAP block had been given before the start of the surgery.

CONCLUSION

In patients undergoing laparoscopic donor nephrectomy, ultrasound-guided deposition of ropivacaine (0.2%) in the TAP block provided superior analgesia in the postoperative period in comparison to bupivacaine (0.25%). However, after 24 hours in the postoperative period, the analgesic efficacy of both the local anaesthetics are equal.

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