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TRANSVERSUS ABDOMINIS PLANE BLOCK FOR POST-OPERATIVE ANALGESIA IN LAPAROSCOPIC DONOR NEPHRECTOMY: COMPARISON OF TWO DOSES OF ROPIVACAINE

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ABSTRACT

Introduction: The use of TAP block under USG guided for pain management is an upcoming and useful tool for lower abdominal surgeries. Present study aimed to assess the efficacy of a lower dose of ropivacaine 0.15% with ropivacaine 0.2% for post-op analgesia.

Materials & Methods: A total of 144 patients undergoing laparoscopic donor nephrectomy were divided into 2 groups of 72 each. After the surgery the patient position was changed to supine from lateral and TAP block was given under ultrasound guidance. One group received TAP block with ropivacaine 0.2% and the other group received ropivacaine 0.15%. VAS score, time to first rescue dose of tramadol and the total amount of tramadol given in 24 hours was noted. Data was analysed by SPSS software 21.0.

Results: The VAS score was significant at 12 hours both at rest and on movement in post-operative period between the two groups. There was no significant difference in total amount of tramadol consumption in 24 hours post-operative period and the time to first rescue analgesia.

Conclusion: Ropivacaine 0.15% is comparable to Ropivacaine 0.2%, with the added advantage of reducing local anesthesia toxicity.

KEYWORDS : Post-Operative Analgesia, Ropivacaine, Transversus Abdominis Plane Block, VAS score

INTRODUCTION

Pain from surgery or surgery related complications seems to have an impact not only on the physical but also on the emotional, social, spiritual well-being of a patient. Transversus Abdominis Plane (TAP) block is a regional anaesthesia technique that provides analgesia to the anterior abdominal wall and now an emerging technique for postoperative pain control used for lower abdominal surgeries.

The American Society of Anaesthesiologists Task Force on Acute Pain Management have purpose a guidelines including multi modal techniques for pain management to facilitate the safety and effectiveness of acute pain management, maintain the patient's functional abilities, as well as physical and physiological well-being, and enhance the quality of life for patients [1].

Previous studies on TAP block have shown that it not only reduces post-operative pain, and the amount of post-operative requirements of additional analgesia but also leads to faster recovery [2-4].

In many of the recent studies the drugs that have been used in TAP block are comparison between different local anaesthetic agents or local anaesthetics agents of different concentration [3,5,6]. Concentration of 0.2% Ropivacaine is accepted as a standard concentration for effective TAP block [3]. However studies have shown that after TAP block there is a possibility of sudden rise in serum concentration of local anaesthetic, leading to potential local anaesthetic toxicity [3].

Keeping this in mind, in this study we had used Ropivacaine 0.2% (0.5ml/kg) and Ropivacaine 0.15% (0.5ml/kg) with maximum volume of drug being 30 ml in each group. The study hypothesized that lower dose of Ropivacaine (0.15%) provides equal and effective post-operative analgesia for laparoscopic donor Nephrectomy and at the same time improve safety by reducing the chance of local anaesthetic toxicity.

MATERIALS AND METHODS

A Prospective, Randomised, Double Blind comparative study was conducted at NH Rabindranath Tagore International Institute of Cardiac Sciences, a tertiary level multi-speciality hospital in Kolkata. A pilot study was done using 0.2% Ropivacaine (0.5 ml/ kg upto a maximum volume of 30 ml) and 0.15% Ropivacaine (0.5 ml/ 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 5 mg which was considered to be the effect size. The pooled standard deviation for the two groups was calculated to be 10.14 mg.

Formula for calculating sample size:

$$n = 2(Z\alpha + Z1-\beta)^2 X (\sigma)^2 / (\delta)^2$$

Where:

n is number of sample per arm

Z α is a constant (set by convention according to the accepted α error and whether it is a one-sided or two-sided effect)

For two sided effect & 5% alpha error it is 1.96

Z 1- β is a constant set by convention according to power of the study so for a power of 80% it's value is 0.8416.

σ is the estimated standard deviation

δ is difference in effect of two interventions which is required (estimated effect size)

So putting values in this formula:

$n = 2(1.96+0.8416)^2 X (10.14)^2 / (5)^2$

$= 64.52$ ie 65

Accounting for a 10% dropout the sample size comes to be 72.

Thus a total of 144 ASA I/ II grade patients (72 for each group), between 18 years and 60 years posted for laparoscopic donor nephrectomy were included in the study. Subjects with cardiovascular, respiratory, hepatic, renal diseases and coagulation disorder were excluded. Subjects with allergy to local anaesthesia, requiring conversion to open nephrectomy, inability to comprehend VAS, with psychiatric disease and opioids dependence were also excluded.

Patients were randomly assigned into two groups: **Group A** (n = 72) received 0.2 % Ropivacaine (0.5 ml/ kg upto a maximum volume of 30 ml) and; **Group B** (n = 72) received 0.15 % Ropivacaine and 0.15% Ropivacaine (0.5 ml/ kg upto a maximum volume of 30 ml)

The software at sealed envelope.com divides the study sample into two equal groups of 72 patients and randomly allocates each patient, identifiable by a unique code, to one of the treatment groups. This random allocation was known only to the research guide. The study drugs was 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.

Study Procedure

The subjects were kept nil per mouth for 8 hours. After taking the patient in the operation theatre an intravenous access was established. For all the subjects standard monitoring including electrocardiogram leads, plethysmograph probe, non-invasive blood pressure and end tidal carbon dioxide was used throughout the operation. The subject were pre oxygenated for 3 minutes with Oxygen, then pre medicated 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 and isoflurane was used and maintenance dose of Atracurium. After completion of the procedure the subject position was changed to supine. All TAP block was given before the patient was extubated, on the same side as the surgery. The ultrasound probe was placed in the mid axillary line between the costal margin and iliac crest. With ultrasound guidance a 22 G Quinke's spinal needle was placed between the internal oblique Abdominis muscle and Transversus Abdominis muscle under continuous visualisation. When the tip of the needle is seen between the two muscles, after negative aspiration of blood to exclude vascular puncture a small volume of drug (1-2 ml) was given to open the plane between the two muscles. After the solution was seen spreading as an oval dark shape, the remaining drug was injected. Intra-op analgesics used were fentanyl (1mcg/kg body wt.), paracetamol (10mg/kg body wt.) and tramadol (1mg/kg body wt.) given as per hospital's standard protocol. 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. VAS pain rating scale is a 10 cm long horizontal line, anchored by the verbal descriptors “no pain” and “worst pain imaginable” on which patients made a mark to indicate what they feel best represents their perception of intensity of their current pain. When Visual Analogue Score was (VAS)>4, rescue dose was given. The rescue dose of tramadol and the total amount of tramadol given in 24 hours was noted. Post operatively, paracetamol (10mg/kg body wt.) were continued as per hospital's standard protocol. The side effects which occurred were managed accordingly.

Statistical Analysis

Categorical variables were expressed as number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes. Continuous variables were expressed as Mean ± Standard Deviation and compared across the 2 groups using unpaired t test. The statistical software SPSS version 20 has been used for the analysis. 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

Both the groups were comparable with respect to age, gender, ASA grade and BMI (p>0.05). When VAS score was analysed at rest (**Table 1**), VAS in group B (2.97 ± 0.44) at 12 hours was more compared to Group A (2.64 ± 0.59; p<0.01). At 12 hours, VAS score on movement (**Table 2**) was also more in Group B (3 ± 0.41) as compared to group A (2.69 ± 0.52; p<0.01). At other intervals the VAS score at rest and on movement was not significant (p>0.05). When the hemodynamic data of both groups were examined, there was no significant differences in the heart rates (**Graph 1**), diastolic blood pressure (**Graph 2**) and systolic blood pressure (**Graph 3**), of the two groups on arrival in PACU, on discharged from PACU, in ITU at 6 hours, 12 hours, 18 hours and 24 hours. Time for first rescue dose of tramadol was more in group A (7.75 ± 4.16 hrs) than in group B (7.19 ± 3.71 hrs). But this difference was not significant (p value - 0.399). Amount of rescue analgesia (**Table 3**) used in 48 hours post-op period in Group B was more with respect to twice dosing of tramadol (100 mg). Group B had 8% who received 100mg tramadol as compared to only 2 % in group A. Group A had 56 % of single dose of tramadol (50 mg) for analgesia while group B had 53%. Compared to group B which had 13 % Group A had 14 % of the patients who did not required rescue analgesia. Analysis however showed this difference to be non-significant (p value=0.347). Nausea and vomiting (**Table 4**) was seen in both the groups however there was no significant difference between the two groups (p value=0.688 and 0.731 respectively).

DISCUSSION

In this study, we compared two different concentrations of ropivacaine, 0.2% and 0.15%, used for TAP block to see if different concentrations of local anaesthetics would make a difference in terms of postoperative analgesia. We found that there was statistical significant differences in the mean pain scores at 12 hours both at rest (2.64 ± 0.59) and on movement (2.64 ± 0.59). However statistical significance does not necessarily imply a clinical significance. These findings were similar to a study conducted by Jalil RM et al. [3] comparing two different concentrations of ropivacaine for TAP block in patients undergoing appendectomy surgery. In their study, they found that ropivacaine 0.25% had comparable effects on postoperative analgesia and quality of recovery to ropivacaine 0.5%. Another study done by and De Oliveira et al. [4] for gynecological laparoscopic surgery using ropivacaine have similar results. Stephen Aniskevich et al. [7]also found that TAP block with ropivacaine 0.5% reduced overall pain scores in undergoing elective living donor nephrectomy or single sided nephrectomy for tumour with a trend toward decreased total morphine consumption in comparison to placebo.

In present study we found that ropivacaine 0.15% (Group B) was as effective as ropivacaine 0.2% (Group A) in providing postoperative analgesia. Total dose of tramadol required and time to first rescue analgesia was comparable in group A (7.75 ± 4.16) and group B (7.19 ± 3.71; p-0.39). Similarly, no difference was seen in between the groups with respect to adverse events like nausea (17% vs 15%; p-0.68) and vomiting (5% vs 4%; p-0.73).

These findings were comparable to a study conducted by Jalil RM et al. [3] using fentanyl as a rescue analgesia for TAP block with ropivacaine with 0.2% and ropivacaine 0.5%, with no clinical significant difference in rescue analgesia for the two concentration of ropivacaine. Beena K. Parikh et al. [8]in their study with bupivacaine 0.375% study (S) group whereas control group © received normal saline and with Tramadol 1m/kg was given as rescue analgesia. The 24 hour consumption of total tramadol was 56 % less in S group as compared to C group. They also stated that opioid related side effects like sedation, nausea, and vomiting were low, due to use of tramadol instead of morphine and prophylactic used of ondansetron.

Haemodynamically when both groups were compared in terms of heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP) at specific intervals i.e. on arrival in PACU, on discharge from PACU, in ITU at 6 hours, 12 hours, 18 hours, and 24 hours. No significant difference was found between study groups (p>0.05).

There is always an assumption that a higher concentration of a local anesthetic given via TAP block may provide better-quality postoperative analgesia, however this raises the issue of potentially toxic plasma concentrations of the local anesthetic, as the TAP block generally involves injection of a single large dose of local anesthetic. Griffiths et al. [9] conducted a study in which bilateral TAP block was given with 2.5 mg kg^{-1} of ropivacaine. Venous blood samples were collected and assayed for total and free ropivacaine concentrations at 10, 20, 30, 45, 60, 90, 120, 180 and 240 min following the block. The study reported that three patients reported symptoms of mild neurotoxicity, and the mean (SD) peak levels were elevated in these patients, 2.70 (0.46) $\mu g\, ml^{-1}$.

Therefore, it would be safer if we can determine and use the minimum local anaesthetic dose or concentration that can to be given in TAP block which provides adequate analgesia, without causing any toxic or adrverse effects. Based on our study, we would like to suggest that ropivacaine 0.15% would provide a better margin of safety, especially when used for bilateral TAP block where a higher volume of a local anaesthetic is required.

CONCLUSION

Based on the study, we conclude that Ropivacaine 0.15% is equally effective to Ropivacaine 0.2% in providing post-operative analgesia with the added advantage of reducing local anesthesia toxicity.

CONFLICT OF INTEREST

None Declared

TABLES

Table 1. Mean VAS score comparison between the two groups at rest

VAS Score	GROUP A	GROUP B	p-value
	Mean ± Std. Deviation	Mean ± Std. Deviation	
On arrival at PACU at Rest	0.15 ± 0.43	0.17 ± 0.44	0.850
On discharge from PACU at Rest	1.25 ± 0.62	1.33 ± 0.58	0.408
At 6 hours at Rest	2.19 ± 0.66	2.35 ± 0.56	0.138
At 12 hours at Rest	2.64 ± 0.59	2.97 ± 0.44	<0.001
At 18 hours at Rest	2.28 ± 0.45	2.39 ± 0.62	0.220
At 24 hours at Rest	1.53 ± 0.5	1.58 ± 0.55	0.528

Table 2. Mean VAS score comparison between the two groups at movement

VAS Score	GROUP A	GROUP B	p-value
	Mean ± Std. Deviation	Mean ± Std. Deviation	
On arrival at PACU at Rest	0.15 ± 0.43	0.17 ± 0.44	0.850
On discharge from PACU at Rest	1.25 ± 0.62	1.39 ± 0.64	0.189
At 6 hours at Rest	2.22 ± 0.68	2.35 ± 0.56	0.229
At 12 hours at Rest	2.69 ± 0.52	3 ± 0.41	<0.001
At 18 hours at Rest	2.31 ± 0.46	2.43 ± 0.62	0.175
At 24 hours at Rest	1.53 ± 0.5	1.61 ± 0.55	0.342

Table 3. Total dose of tramadol between the two groups

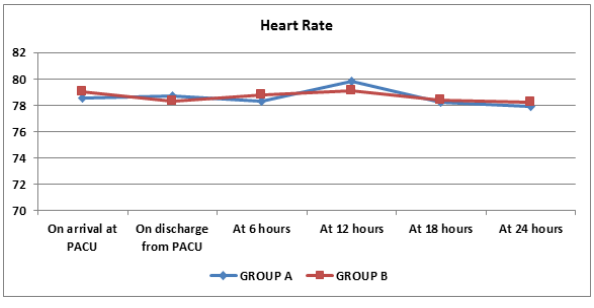
		Group A	Group B	Total	p Value
Total Dose Of Tramadol In 24 Hours (mg)	0	14(19.44)	13(18.06)	27(18.75)	0.347
	50	56(77.78)	53(73.61)	109(75.69)	
	100	2(2.78)	6(8.33)	8(5.56)	
Total		72(100)	72(100)	144(100)	

Table 4. Comparison of Adverse events between the two groups

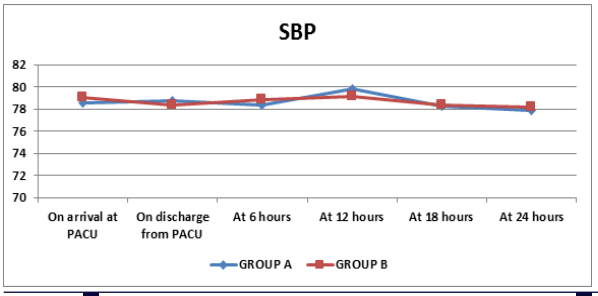
Adverse events	GROUP A	GROUP B	p-value
	N (%)	N (%)	
Nausea	17 (23.6%)	15 (20.8%)	0.68
Vomiting	15 (6.9%)	4 (5.6%)	0.73
Vessel or Visceral organ puncture	0 (0%)	0 (0%)	NA

GRAPHS

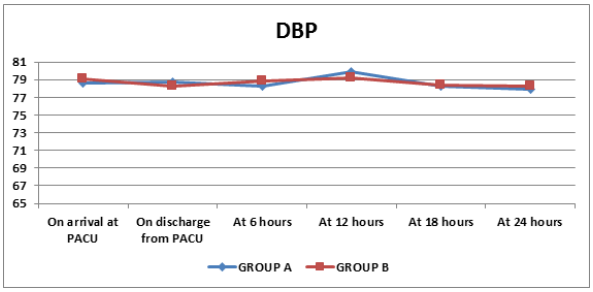
Graph 1. Mean Heart rate comparison between the two groups



Graph 2. Mean Systolic blood pressure comparison between the two groups



Graph 3. Mean Diastolic blood pressure comparison between the two groups



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