

A PROSPECTIVE STUDY COMPARING 0.25% BUPIVACAINE AND 0.375% ROPIVACAINE IN TRANSVERSUS ABDOMINIS PLANE BLOCK FOR POSTOPERATIVE ANALGESIA IN LAPAROSCOPIC ABDOMINAL SURGERY.

ABSTRACT

Transversus abdominis plane block is a beneficial method of pain relief after abdominal surgeries. In the recent past, there had been an increased use of TAP block in laparoscopic surgeries, both as intraoperative and postoperative source of pain relief. Aim : The aim of this study was to compare equipotent doses of two commonly used local anesthetic drugs with respect to efficacy and duration. Method : Sixty adults undergoing elective laparoscopic surgeries were randomised to receive ultrasound-guided TAP block at the end of the surgical procedure with either 0.25% bupivacaine (Group I, n = 30) or 0.375% ropivacaine (Group II, n = 30). And these patients were analysed based on the quality and duration of pain relief, 24 hour mean rescue analgesic consumption and complications. Results : Patients receiving TAPB with ropivacaine and bupivacaine did not have significant differences between the two with respect to the parameters studied. Conclusion : Equipotent doses of ropivacaine and bupivacaine were almost indistinguishable in TAP block and were comparable in terms of duration of analgesia, quality in terms of VAS scores and 24 hours analgesic consumption without any drug related or block related complications. Although both the drugs are in par with each other, bupivacaine carries the risk of cardiotoxicity as quoted in previous studies. Hence, ropivacaine may be considered as a better alternative to bupivacaine in TAP block.

INTRODUCTION

Transversus abdominis plane (TAP) block is a regional anesthetic technique that blocks neural afferents of the anterolateral abdominal wall^[1]. With the aid of ultrasound (US) or anatomical landmark guidance, local anesthetic is injected into the transversus abdominis fascial plane, between internal oblique and transverses abdominis muscle, where the nerves from T6 to L1 are located^[2].

Postoperative pain is most intense on the day of surgery and the following day^[3]. The benefit of adequate postoperative analgesia include a reduction in the postoperative stress response, reduction in postoperative morbidity, and in certain types of surgery, improved surgical outcome. Effective pain control also facilitates rehabilitation and accelerates recovery from surgery^[4].

Modern multimodal analgesia concepts have been demonstrated to provide postoperative analgesia as equally as effective as epidural anaesthesia in patients undergoing abdominal surgeries. The majority of multimodal analgesia concepts rely on the systemic administration of opioids. Unfortunately, opioids are frequently limited by important side effects including

sedation, constipation, itching, postoperative nausea and vomiting (PONV), and respiratory depression^[7]. NSAIDs also have certain side effects like haemostasis alteration, renal dysfunction, gastrointestinal haemorrhage etc^[8].

The occurrence of postoperative pain, although comparatively less severe than in open surgeries, may affect length of hospital stay, may have surgical stress induced postoperative discomfort and early return to normal activity^[9]. As post operative pain after abdominal surgeries is predominantly due to abdominal incision (somatic), the TAP block if used will reduce the need of additional analgesia during 24 hours after surgery, severity of pain and prolong the demand for first analgesic dose and improve patient satisfaction^[10].

Ropivacaine is a new, long-acting local anesthetic, closely related structurally to the group of amino amides in present clinical use, e.g., bupivacaine and mepivacaine. Whereas these are available as racemates, ropivacaine has been developed as the pure S-(-)-enantiomer and does not exist in a racemic mixture. Ropivacaine has pharmacokinetic and pharmacodynamic properties resembling those of bupivacaine when given as a single injection^[11]. Ropivacaine has less cardiovascular toxicity than bupivacaine with respect to direct myocardial depression, success of resuscitation and arrhythmogenic potential when given in equal doses. Onset of action is comparatively rapid in ropivacaine compared to bupivacaine. Also, weaker binding to extra neural tissues and fat contributes to greater availability of ropivacaine to site of action in peripheral nerve blocks^[12].

Studies using the minimum local anesthetic design (MLAC) have found that ropivacaine is approximately 40% less potent than bupivacaine. This is important because equipotent doses must be compared to draw meaningful conclusions regarding analgesic efficacy and side-effect profiles^[13]. Early studies comparing ropivacaine with bupivacaine used equal doses of both, whereas some recent investigations have used larger doses of ropivacaine to adjust for potency differences. Ropivacaine was 60% as potent as Bupivacaine when used for epidural pain relief in labour. The analgesic potency of Ropivacaine was 0.4 relative to Bupivacaine^[14,15].

So we decided to use 20 ml of either 0.25 % Bupivacaine or 0.375 % Ropivacaine as the drugs under study for use in Transversus Abdominis Plane Block.

AIM AND OBJECTIVES :

To compare the effects of 0.25% Bupivacaine and 0.375% Ropivacaine in Transversus abdominis plane block for post operative analgesia in laparoscopic abdominal surgeries.

The TAP block will be studied in terms of : Primary outcome: 1)Duration of analgesia. Secondary outcome: 2)Quality of analgesia(VAS Scores) , 3)24 hours analgesic consumption, 4)Complications; if any - a)Nausea , b)vomiting, c)Others- local anaesthetic toxicity, visceral injury, hematoma , peritonitis.

MATERIAL AND METHODS

This is a prospective, randomized comparative study. After obtaining ethical committee clearance for the research, patients were chosen based on the inclusion and exclusion criteria. INCLUSION CRITERIA: 1) Patients posted for elective laparoscopic abdominal surgeries. 2) Aged between 18 to 60 years. 3) BMI < 40. 4) ASA physical status I/II. EXCLUSION CRITERIA: 1) Patient refusal. 2) Abnormal coagulation profile. 3) Allergy to local anaesthetics, ultrasound conduction gel.

Sample size was estimated based on a reference article by Neha Fuladi et al^[16], which compared duration of analgesia between the same drugs in a study. The sample size was calculated to be 24 cases in each group for a significance level of 0.1 % (confidence level of 99.9%) and a power of 95%. However, for the sake of greater accuracy, considering drop outs, it was decided to take a total of 60 cases (30 cases in each group).

Patients were randomly allocated into two groups, one group to undergo ultrasound-guided TAP block with 20mL of 0.25% bupivacaine (plain) (Group I, $n = 30$) and other group to undergo ultrasound-guided TAP block with 20mL of 0.375% ropivacaine (plain) (Group II, $n = 30$).

After a detailed and comprehensive pre-operative anesthetic evaluation, details of the plan of anaesthesia and postoperative assessment of pain intensity using visual analog scale was clearly explained to the patients. Patients were also explained about the procedure and the expected complications and their consent was obtained.

PROCEDURE

In the operating room, peripheral venous access was secured with a 18-20G iv cannula. Routine baseline vitals were monitored. Patients were thoroughly preoxygenated, Inj.Fentanyl 2 mcg/kg IV was administered and induced with 1.5 to 2 mg/kg Inj.Propofol IV. Mask ventilation was ensured and intubation was carried out using Inj.Atracurium 0.5mg/kg after three minutes of ventilation, with appropriate size endotracheal tube. Bilateral equal air entry was confirmed and the tube was fixed. After the surgery was completed, vitals were noted and TAPB was carried out by the anesthetist.

The patients were placed in supine position with their arms abducted to their sides on an arm rest. The ultrasound guided method was done with the GE health care-Venue 40 ultrasound machine, using a 6-12 MHz linear probe. The transducer was covered with ultrasonic gel and wrapped in a sterile sheath.

Skin preparation with 2% chlorhexidine was done. Broadband linear ultrasound probe was placed in the axial plane across the mid axillary line midway between the costal margin and iliac crest. Following identification of the three layers of the abdominal wall; 21G blunt tipped short bevel sonoplex needle was inserted in plane until its tip is located between internal oblique and transversus abdominis muscle. Successful injection was indicated when an echoluscent lens shaped spread appeared between the two layers. The injectates were prepared aseptically by an observer. The anesthetist who administered the TAP block and the investigator who assessed its outcome were blinded to the drug used. Patients were then

reversed using iv Neostigmine and Glycopyrolate and extubated. They were later observed in the Post anesthesia care unit for duration of analgesia, quality of analgesia based on the Visual Analog Scale at 0hour (time of administration of TAP block), 2hr, 4hr, 6hr, 8hr, 12hr, and 24hr at rest and flexion of hip and knee joint. Inj. Tramadol 25 mg i.v was used as rescue analgesic when $VAS \geq 4$, 24 hours analgesic consumption as the total number of doses of rescue analgesic used was noted down at the end of 24 hours.

STATISTICAL ANALYSIS

The information collected regarding all the cases were recorded in a Master Chart. Data analysis was done with the help of computer using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 22.0 for Windows). Using this software frequencies and percentages were calculated for qualitative variables. Means and standard deviations were calculated for quantitative variables. Student's unpaired 't' test was used to test the significance of difference between quantitative variables and Yate's and Fisher's chi square tests for qualitative variables. A 'p' value less than 0.05 denotes significant relationship.

RESULTS

Fig 1: PROFILE OF CASES STUDIED

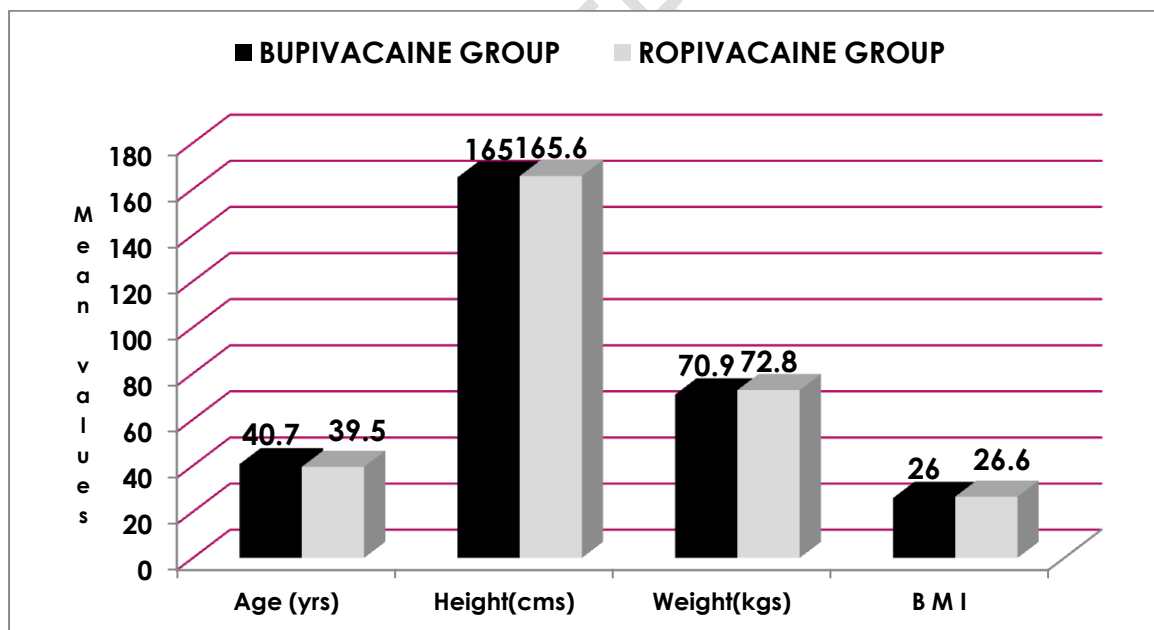


Fig 2: TYPE OF SURGERY

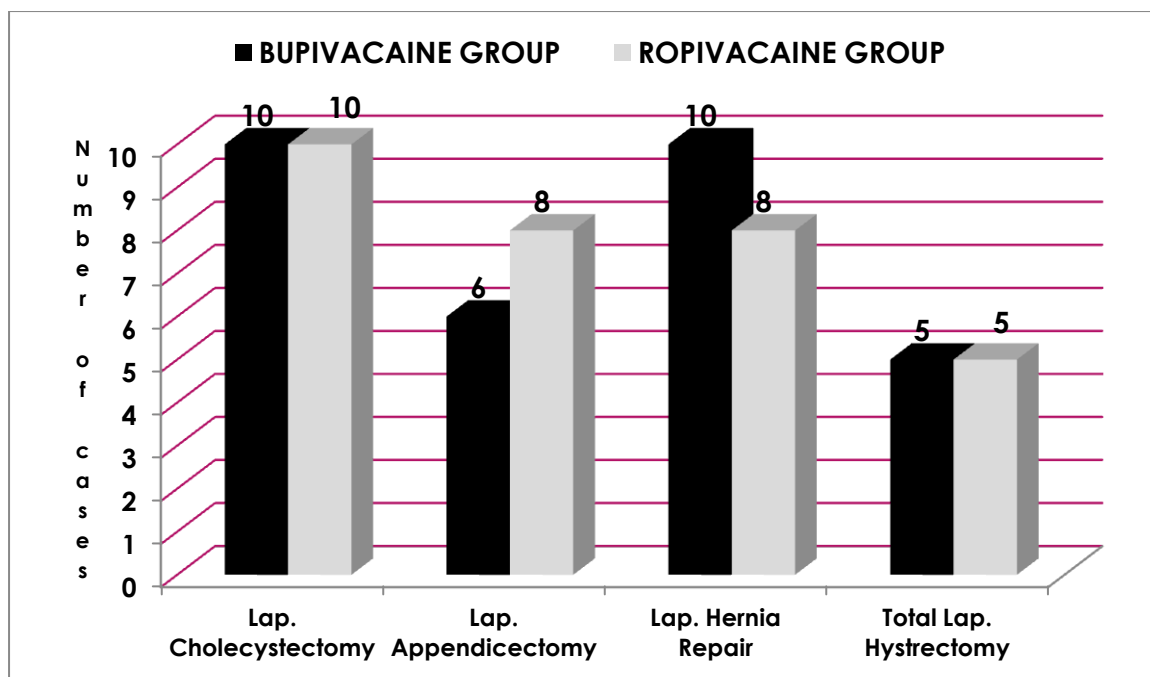


Table 1: DURATION OF ANALGESIA AND TOTAL RESCUE ANALGESIC REQUIREE

Group	Duration of analgesia (minutes)		Total requirement of analgesia (mgs)	
	Mean	S.D.	Mean	S.D.
Bupivacaine Group	1049.0	252.3	29.03	17.2
Ropivacaine Group	1095.8	271.0	25.81	18.8
'p'	0.485		0.484	

Fig 3: DURATION OF ANALGESIA

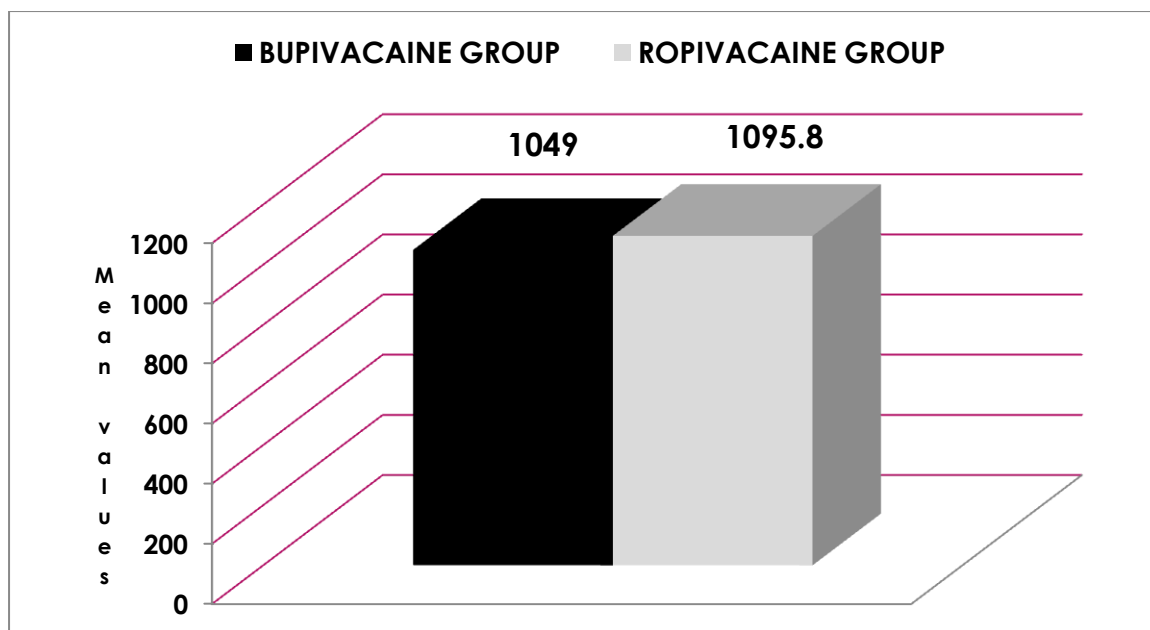
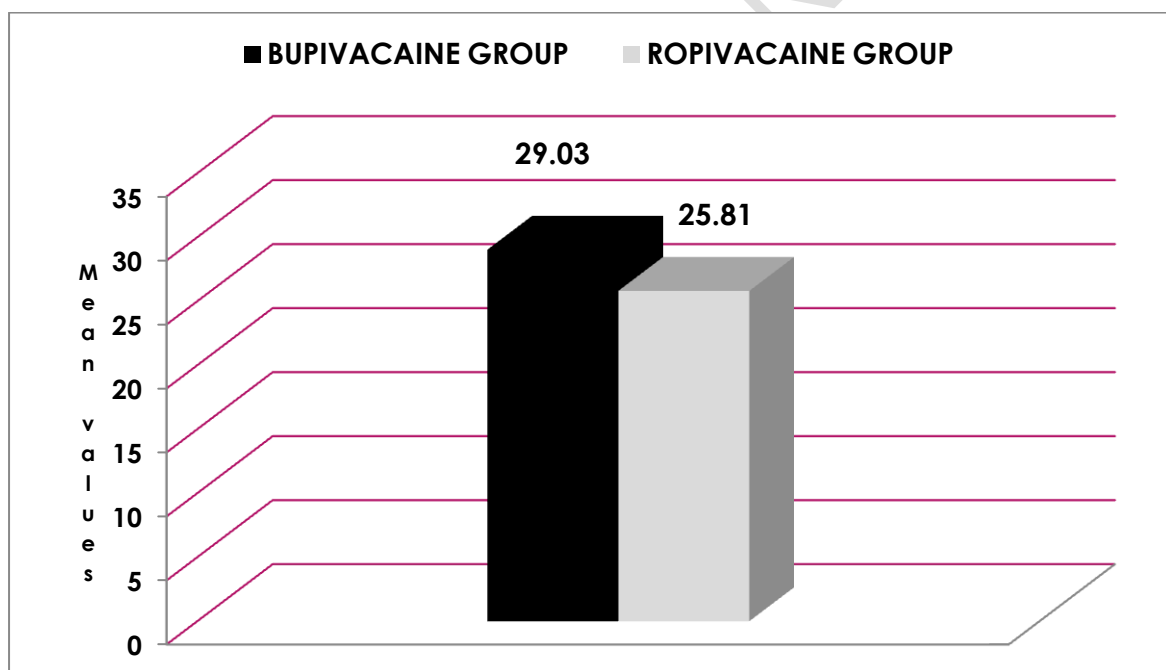


Fig 4: TOTAL RESCUE ANALGESIC REQUIREMENT



The mean duration of analgesia in Bupivacaine group was 1049 \pm 252.3 min, which comes to around 17.48 \pm 4.2 hrs and the mean duration of analgesia in ropivacaine group was 1095.8 \pm 271 min which is 18.26 \pm 4.5 hrs. The p value with respect to mean duration between the two groups was 0.485 which was statistically insignificant.

The mean rescue analgesic requirement in the Bupivacaine group was 29.03 mgs of Inj.Tramadaol i.v, where as in the ropivacaine group it was 25.81 mgs of the same rescue

analgesia. There were no significant difference in the total consumption of analgesia between the two groups with the p value of 0.484.

Table 2: VAS SCORES AT REST AND DURING MOBILITY

Visual Analogue Score at rest at	Visual Analogue Score at rest in				‘p’
	Bupivacaine Group		Ropivacaine Group		
	Mean	SD	Mean	SD	
0 hour	1.06	0.25	1.03	0.18	0.561
2 hours	1.65	0.55	1.68	0.48	0.806
4 hours	1.61	0.5	1.71	0.46	0.429
6 hours	1.97	0.66	2.06	0.68	0.571
12 hours	2.84	0.93	2.9	0.87	0.779
18 hours	3.06	1.0	3.16	0.93	0.695
24 hours	1.71	0.53	1.87	0.34	0.159

Visual Analogue Score on mobility at	Visual Analogue Score on mobility in				‘p’
	Bupivacaine Group		Ropivacaine Group		
	Mean	SD	Mean	SD	
0 hour	1.39	0.5	1.23	0.43	0.174
2 hours	1.55	0.51	1.65	0.49	0.446
4 hours	1.58	0.56	1.68	0.54	0.493
6 hours	1.97	0.61	2.06	0.81	0.597
12 hours	2.97	0.91	3.03	0.75	0.762

18 hours	3.03	1.05	3.06	1.0	0.902
24 hours	1.71	0.53	1.87	0.34	0.159

The quality of analgesia provided by the local anaesthetics were interpreted in terms of visual analog pain scores. On comparing the two groups, the VAS scores at rest and those on mobility were comparable at all study points. There were no significant difference in the pain scores between the two groups. Thus the quality of analgesia proved by both the drugs were comparable.

Fig 5: VAS SCORES AT REST

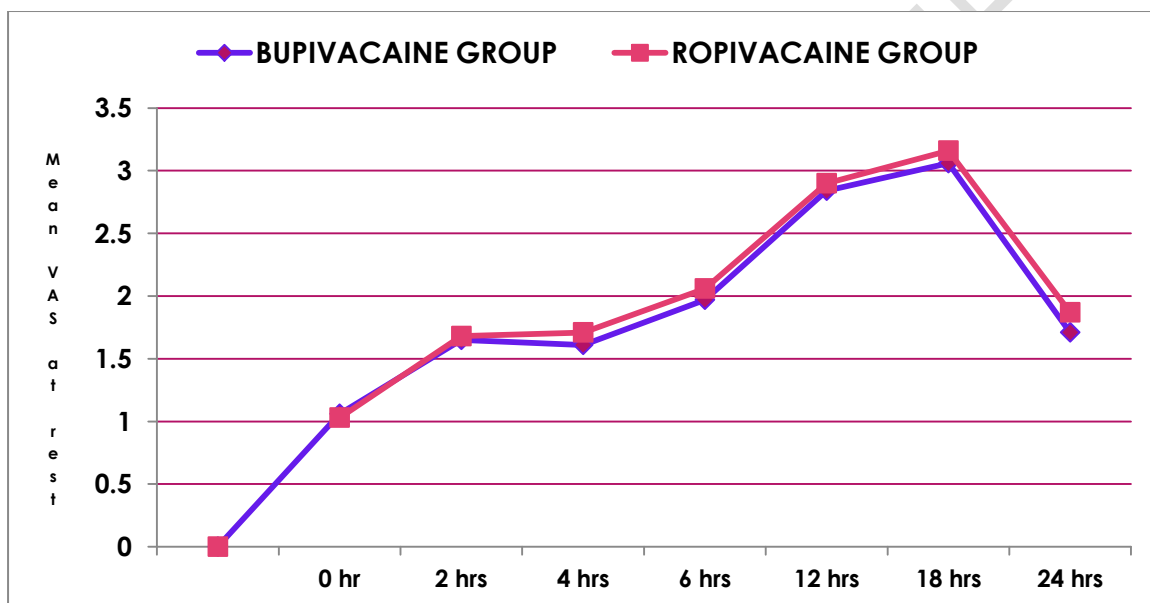
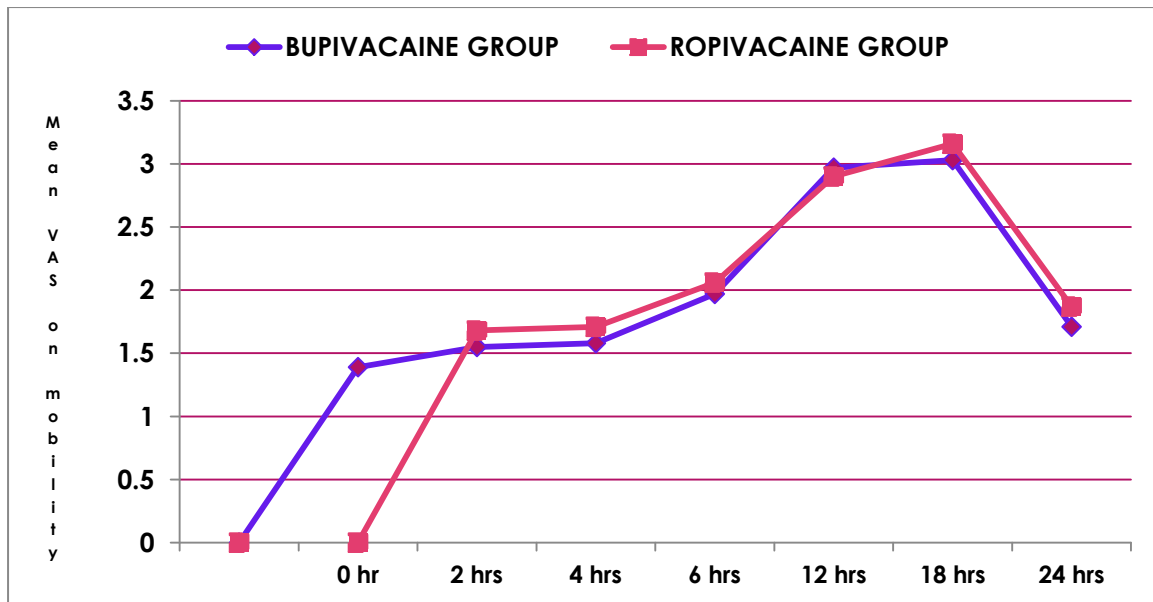


Fig 6: VAS SCORES ON MOBILITY



Both the drugs compared in our study provided safe analgesia without any significant complications or side-effects. There were no patient in either group who had any complaints. Bupivacaine and Ropivacaine were thus comparable in terms of complications.

DISCUSSION

In recent years nerve blocks have gained popularity and this is mainly due to the development of ultrasound guided real time imaging with better accuracy and higher success rate, less patient discomfort and minimal complications. Extension of analgesia in the early post operative period has been very attractive since it allows early patient mobilization, early initiation of oral feeds and rehabilitation. Transversus abdominis plane block has been shown to reduce post operative pain scores and opioid consumption, allowing for early mobilization and faster discharge after a multitude of abdominal surgeries^[17,18,19].

Although ropivacaine and bupivacaine have been commonly used in various blocks and share a similar pharmacokinetic profile except for a few differences and toxicity profile, very few studies have compared their efficacy in TAP block. So in our study we have compared post operative analgesia between these drugs in Transversus abdominis plane block for laparoscopic abdominal surgeries.

Both the groups in our study were comparable demographically with respect to their age, weight, height, BMI and surgical procedure as there was no statistically significant difference ($p > 0.05$).

In the present study, the duration of analgesia in the bupivacaine group was 1049 ± 252.3 minutes and in the ropivacaine group it was 1095.8 ± 271 minutes. Both the groups were comparable to each other and was statistically insignificant ($p > 0.05$). In the study by, Shradha sinha, et al^[20], 0.375% ropivacaine was compared with 0.25% bupivacaine in TAP block as postoperative analgesia for patients undergoing laparoscopic cholecystectomies. The duration of TAP block in bupivacaine group was 7.25 hrs and 9 hrs in

ropivacaine group. There was nil significance with a $p=0.145$. These results are in sync with our study. Although the drugs were comparable to each other in both the studies, there was a huge difference in duration of analgesia between the studies. This difference in duration might be attributed to the fact that, the previous study included only laparoscopic cholecystectomies specifically, with four ports which involved two supra umbilical ports for which the study employed posterior approach of TAP block. The study had a lower duration of TAP block. This might be due to a reason that for supra-umbilical ports, subcostal approach of TAP block is considered ideal as given by Nidhi Bhatia et al^[21]. So, if subcostal TAP block was used in the study, the duration might have lasted longer. Our study included laparoscopic appendicectomies, hernioplasties, hysterectomies and cholecystectomies. Most of these surgeries had infra-umbilical ports and hence our study had a prolonged duration of analgesia with posterior TAP block. Moreover, TAP being an avascular plane has a delayed clearance of drugs and a prolonged duration of local anesthetic action in general. Hence the duration in our study is justifiable.

Post operative mean VAS scores at rest and at mobility were reduced at all study points in both the groups in our study and when they were compared it was found to be statistically insignificant. In the study by, Shradha sinha, et al^[20], it was concluded that pain scores were significantly lower with ropivacaine group at 10 min, 30 min, 1 hr, but no significant difference in pain scores after 2 hrs between the two groups. This goes in hand with our study, since, we compared pain score from the second hour after the block. And there were no significant difference in VAS scores between the two groups in our study. In another study^[22], where 0.75% ropivacaine was compared with 0.5% bupivacaine in TAP block for unilateral hernia surgeries, it was concluded that no significant difference in VAS score was observed between the groups with a p value of 0.074. This study used a higher equipotent concentration and arrived at these comparable results with our study.

The mean 24 hours analgesic consumption between bupivacaine group and ropivacaine were comparable and there were no significant difference between the two groups. The 24 hours mean requirement of analgesia in the bupivacaine group was 29.03 ± 17.2 mg of inj. Tramadol i.v, while in the ropivacaine group it was 25.81 ± 18.8 mg of inj. Tramadol i.v. This goes in hand with the study by Shradha sinha, et al^[20] and the median cumulative diclofenac consumption in 24 h post-operative period was comparable. Tolchard S, et al^[23] studied the efficacy of the subcostal transversus abdominis plane block in laparoscopic cholecystectomy and concluded that TAP block resulted in a significant reduction in serial visual pain analog score values and significantly reduced the fentanyl requirement in recovery by $>35\%$. Kawahara R, et al^[24] studied the analgesic efficacy of ultrasound guided TAP block with the mid-axillary approach in patients undergoing laparoscopic gynecologic surgery and patient-controlled analgesia (PCA) was given postoperatively with tramadol. The study concluded that Postoperative pain/nausea and PCA consumption were significantly lower in patients with TAP block. In par with these studies, we arrived at a similar conclusion of reduced total opioid consumption in the postoperative period after receiving TAP block.

There was no incidence of nausea and vomiting in any of the groups and there was no reported incidence of any other block related complications in either group on patient follow

up. Ma. N. Duncan JK, et al^[25] 's systematic review and meta-analysis on the Clinical safety and effectiveness of TAP block in post-operative analgesia concluded that TAP block showed an equivalent safety profile to all comparators in the incidence of nausea and vomiting . MJ Young, et al^[26] studied clinical implications of the Transversus abdominis plane block in adults and concluded that TAP block is an effective and safe adjunct to multimodal postoperative analgesia for abdominal surgery with a high margin of safety and without any complications. These results go in hand with our study . In another study, Hofmann-Kiefer K, et al^[27] compared Ropivacaine 7.5 mg/ml versus bupivacaine 5 mg/ml for interscalene brachial plexus block. The study concluded that they did not identify any side-effects related to the administration of the local anaesthetics. And hence, showed no difference in complication rate between ropivacaine and bupivacaine. In our study, we compared lower concentration of the same drugs in equipotent doses and arrived at similar results. Although our study was done in TAP block and the mentioned study was on interscalene block, there were no complications pertaining to the local anaesthetics used.

There are certain limitations pertaining to our study. Study is limited to the assessment of postoperative analgesia to the first 24 postoperative hours. However, the TAP block has been demonstrated to produce clinically useful levels of analgesia for at least 48 hrs post-operatively. Though statistical analysis suggested the sample size of 30 to attain a statistical significance, a larger sample size would have given more accurate results. TAP block provides analgesia for the somatic component of pain, but the visceral component of pain which occurs with abdominal surgeries goes unaddressed.

CONCLUSION

On the basis of present study, we conclude that, equipotent doses of ropivacaine and bupivacaine were almost indistinguishable in TAP block and were comparable in terms of duration of analgesia, quality in terms of VAS scores and 24 hours analgesic consumption without any drug related or block related complications. Although both the drugs are in par with each other, bupivacaine still carries the risk of cardiotoxicity as quoted in previous studies. Hence, ropivacaine may be considered as a better alternative to bupivacaine in TAP block.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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