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Original Research Article

A randomized comparative study of transversus abdominis plane block (tap) with 0.25% bupivacaine and 0.375% ropivacaine in the duration of post-operative analgesia in upper abdominal laparoscopic surgeries

S Jesmine Little Flower[1]*, Alex Francisco Nicholas[1], Renu Devaprasath[1]

[1]*Dept .of Anaesthesiology, Dr. Jeyasekharan Hospital and Nursing Home, Nagercoil, Tamil Nadu, India*

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ABSTRACT

Background: Transversus abdominis plane (TAP) block is a successful postoperative analgesia technique in laparoscopic surgeries. This study compared the analgesic efficacy of 0.25% bupivacaine and 0.375% Ropivacaine in TAP block as post-operative analgesia for upper abdomen laparoscopic surgeries.
Materials and Methods: This randomized, double-blinded comparative study was conducted at the Dr Jeyasekharan Medical Trust and Nursing Home for 18 months. Seventy-one consenting adult patients undergoing upper abdominal laparoscopic surgeries qualifying the inclusion criteria to undergo Bilateral Subcostal TAP Block were included. The patient was labelled group A or B according to a computer-generated randomization list. TAP block was administered using 30 ml (15 ml on each side) of 0.25% bupivacaine (A) or 0.375% ropivacaine (B). Similar premedication and induction were given to all patients.
Results: Among 71 patients in group A, males were 5 (14.7%), and females were 29 (85.3%). In group B, males were 7 (18.9%), and female was 30 (81.1%). There is no significant difference in gender, age, and BMI between groups. The mean duration of analgesia with 0.375% ropivacaine (10.21±3.36 hrs.) was significantly higher than 0.25% bupivacaine (6.38±2.03 hrs.). In the first 24 hours postoperatively, the mean total tramadol consumption was 147.06±11.94 mg in group A and 117.57±31.11 mg in group B, which is statistically significant.
Conclusion: This study concludes that 0.375% 30ml ropivacaine given as a TAP block under ultrasound guidance significantly prolonged the post-operative analgesia duration compared to 0.25% 30ml bupivacaine.

1. Introduction

Pain that occurs postoperatively is an acute pain that is considered to start with surgery and probably ends with the healing of tissues. Despite the sophisticated technology, the significant discomfort experienced throughout the post-operative interval due to pain continues.[1] Acute post-operative events, including pain, may lead to sequelae such as post-operative myocardial ischemia, MI and chronic pain syndromes.[2] The most commonly used approach for post-operative pain relief is nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids. However, there are side effects associated which restrict optimal usage. Opioids and essential medications used to manage pain may cause nausea, vomiting, constipation, urinary retention, respiratory depression, renal dysfunction, gastritis, and sedation.[3,4] Hence, an enhanced standard of care for surgical patients[3] has been achieved using analgesia of non-opioid technique.

* *Corresponding author*.
E-mail address: jabarali2009@gmail.com (S. J. L. Flower).

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Laparoscopic surgery, a favoured method, has many benefits, including reduced analgesic requirement and enhanced patient recovery. Despite the minimally invasive nature, pain could be more severe in the post-operative period. Transversus Abdominis Plane (TAP) block was first reported by Rafi in 2001, which provides up to round-the-clock analgesia.[5] The abdominal neural afferents are inhibited by TAP block. The method requires the introduction of local anaesthetic in the fascial plane between the internal oblique and transversus abdominis muscles. Parietal pain is the chief component of post-operative pain in most surgical procedures.[6] TAP block preserves motor and bladder function, enabling early ambulation. Ultrasound guidance is used for precise localization of TAP and for reducing the duration of post-operative pain in abdominal surgery.

Many local anaesthetic drugs have been utilized to yield satisfactory post-operative analgesia.[7,8] The new local anaesthetic, amino-amide and long-acting, is Ropivacaine, an S- enantiomer of bupivacaine. It has greater anaesthetic potency with a longer duration of action and decreased side effects compared to bupivacaine.[9] It is less lipid soluble and has a reduced volume of distribution, considerable drug clearance, and briefer elimination half-life compared with bupivacaine.[9] The study compares the analgesic efficacy of 0.25% bupivacaine and 0.375% Ropivacaine in TAP block as post-operative analgesia for upper abdomen laparoscopic surgeries.

2. Materials and Methods

This prospective randomized double-blinded comparative study was conducted following the acquisition of institutional ethical approval, spanning a duration of 18 months from January 2020 to June 2021. The primary focus of this investigation was to assess the duration of postoperative pain, while the secondary objective was to evaluate the cumulative requirement for rescue analgesic interventions.

The sample size determination was guided by a previous study 'Efficacy of Transversus Abdominis Plane Block in Patients Undergoing Emergency Laparotomies' conducted by Mrunalini P et al.[10] The calculation of the sample size for this research led to the determination of a sample size of 50 participants per group, resulting in a total sample size of 100.

The sample size, denoted as 'N,' was determined through the application of the following formula:

$N = (Z\alpha + Z\beta)^2 \, (S_1^2 + S_2^2) \, (\mu_1 - \mu_2)^2$

Where:

$Z\alpha$ = 1.96 corresponds to the critical value for a 95% significance level (two-tailed).

$Z\beta$ = 7.84 represents the critical value for an 80% statistical power.

S1 = 1.12 denotes the standard deviation of pain scores in the control group.

S2 = 1.49 signifies the standard deviation of pain scores in the TAP block group.

$\mu 1$ = 3.03 indicates the mean pain score in the control group.

$\mu 2$= 3.8 reflects the mean pain score in the TAP block group.

The research cohort consisted of adult patients who had provided informed consent and were scheduled to undergo upper abdominal laparoscopic surgeries. These patients were selected based on a predefined set of inclusion and exclusion criteria. Inclusion criteria encompassed individuals aged between 18 and 65, regardless of gender, with American Society of Anesthesiologists (ASA) grades 1, 2, or 3, and undergoing upper abdominal laparoscopic surgeries, specifically laparoscopic cholecystectomy. Exclusion criteria excluded patients who declined to give informed consent, had a documented history of local anesthetic allergy, were either younger than 18 or older than 65, had ASA grades 4 or higher, or exhibited a body weight below 38 kg.

A pre-anaesthetic check-up was conducted the previous night of surgery by the researcher. The patients were given the information sheet, and if any doubts were there, the researcher clarified them. Then, voluntary informed consent was obtained. The researcher reviewed the patient in the holding area of OT pre-operatively. In the holding area, the patient was explained about the procedures and post-operative follow-up with pain. The NRS (Numerical Rating Scale) was presented to the patient to enable them to tell their pain score postoperatively.

The patients were given Inj.Pantoprazole 40 mg and Inj.Ondansetron 4mg as premedication. The patient was transferred inside the operation theatre, and randomization was done using a computer-generated random table. Patients were divided into two groups. Group A patients were given 30 ml of 0.25% bupivacaine, and Group B patients were given 30 ml of 0.375% ropivacaine.

In the operating room, venous access was obtained. ECG, NIBP, SpO_2, and $EtCO_2$ monitors were connected. Patients were pre-oxygenated and then given Inj. Glycopyrrolate 0.01mg/kg, Inj. Fentanyl (2μg/kg). Induction was done with Inj. Propofol 2mg/kg and Sevoflurane 3%. The patient was paralysed with Inj. Vecuronium (100 μg/kg) IV and intubated and maintained with N_2O: O_2 (65:35%) and sevoflurane 1%. After induction of anaesthesia, an ultrasound-guided subcostal TAP block was conducted with a high-frequency linear probe. A mid-axillary approach was used. 30 ml (15 ml on each side) of Bupivacaine 0.25% or ropivacaine 0.375% was given as per the randomization. The toxic doses of Bupivacaine and Ropivacaine were noted for each patient and not exceeded in any patient. Side effects, if any, namely hypotension,

bradycardia, arrhythmia, ECG changes, and circumoral numbness, were recorded and treated accordingly. Residual neuromuscular block was antagonized by IV neostigmine and glycopyrrolate. Patients were extubated after they were fully awake. The patients were transferred to a recovery room. After confirming the absence of any overt side effects like hypotension, bradycardia, arrhythmia, ECG changes, and circumoral numbness, patients were transferred to the postop ward.

The duration of Postoperative pain was the primary objective, and the secondary objective was the total amount of rescue analgesic given, namely Inj. Tramadol Hydrochloride IV in the Operation theatre and post-operative ward, the patients were observed for HR, BP, SpO2, and pain (NRS score) immediately after extubation (0 mins) and at 10 min to 12 h and 24h. Rescue analgesia was given as needed.

Rescue analgesia in this study was defined as the collective quantity of either Intravenous Tramadol or Intravenous Paracetamol (1 gm, in cases where Tramadol is contraindicated due to factors such as the patient's use of monoamine oxidase inhibitors, epilepsy, or age below one year). Rescue analgesia was administered to research participants in the event of experiencing moderate pain, as determined by a Numerical Rating Scale (NRS) score equal to or exceeding 5, or severe pain within the initial 24 hours following their surgical procedure. Tramadol was prescribed in dosages ranging from 50 to 100 mg, with a maximum frequency of four times daily, and the total daily dosage should not surpass 400 mg for adult patients. In the case of children over one year of age, the dosage is determined at 1 to 2 mg/kg. The cumulative dose of rescue medication is calculated at the conclusion of the observation period.

A comprehensive master chart was meticulously compiled by collating individual data from the patient proforma, serving as the foundational dataset for subsequent analysis. The statistical analysis was executed using the Statistical Package of Social Science (SPSS) version 20. Quantitative data were presented as mean values along with their corresponding standard deviations, and comparisons were conducted using the "independent sample t-test." Significance was established with a threshold p-value of less than 0.05, indicative of statistically significant findings.

3. Results

Among 71 patients in group A, males were 5 (14.7%), and females were 29 (85.3%). In group B, males were 7 (18.9%), and female was 30 (81.1%). Comparison of sex distribution between the two groups shows equal distribution with a p-value of 0.636, which is statistically insignificant (Table 1).

A comparison of the age (years) between the two groups shows that age (years) is higher in the Group A group with a t-value of 0.173 and is statistically not significant with a p-value of 0.863 (Table 1).

3.1. Duration of analgesia (Primary objective)

The mean duration of analgesia with 0.375% ropivacaine (10.21±3.36 hours) was significantly higher than 0.25% bupivacaine (6.38±2.03 hours). A comparison of the duration of analgesia (hours) between the two groups shows that the duration of analgesia (hours) is higher in Group B (Ropivacaine) with a t-value of -5.75 and a p-value of <0.001, which is statistically significant (Table 2). The t-value of -5.75 indicates that there is a substantial difference in the mean duration of analgesia between the two groups, with the 0.375% ropivacaine group having a significantly higher mean duration compared to the 0.25% bupivacaine group. The negative sign of the t-value signifies that the mean duration in the 0.375% ropivacaine group is lower than that in the 0.25% bupivacaine group, and this difference is statistically significant, as indicated by the p-value of <0.001.

3.2. Total rescue analgesic consumption (Secondary objective)

In the first 24 hours post-operatively, the mean total tramadol consumption was 147.06±11.94 mg in group A and 117.57±31.11 mg in group B. Comparison of the rescue analgesic dose for 24 hours between the groups shows that rescue analgesic for 24 hours is higher in group A (Bupivacaine) with a t-value of 5.354 and is statistically significant with a p-value of <0.001 (Table 2). The positive t-value of 5.354 indicates that the mean total tramadol consumption in Group A (Bupivacaine) is significantly higher than in Group B. The difference between the two groups is statistically significant, as denoted by the p-value of <0.001. In this case, a positive t-value implies that Group A required more tramadol in the first 24 hours postoperatively compared to Group B, and this difference is statistically significant.

4. Discussion

The study period was approximately 18 months, from January 2020 to June 2021. During the COVID-19 pandemic, the institution was a COVID hospital, and elective surgeries were stopped. Hence, after discussing with the statistician, we decided to proceed with data analysis with the number of cases already studied. Hence, the sample size was decreased to 71. The principal finding of our study was that ropivacaine 0.375% shows significantly increased analgesia duration (10.21±3.36 hours) compared to bupivacaine 0.25% (6.38 ± 2.03 hours) when given via ultrasound-guided TAP findings of similar studies have been mentioned.

Many studies have been conducted to prove the efficacy of TAP Block, such as those conducted by McDonnell et al.[8] and Carney et al.[11] in open appendicectomy. In 2008, Carney et al. illustrated that anatomical TAP block in total

Table 1: Demographic data of the study

		Group A (n=34)	Group B (n=37)	P-value
Gender	Female	29 (85.3%)	30 (81.1%)	0.636
	Male	5 (14.7%)	7 (18.9%)	
Age (years) (Mean SD)		41.82 ± 14.37	41.22 ± 15.06	0.863
BMI (Mean SD)		24.45±3.12	23.97±3.34	0.541

Table 2: Duration of analgesia and rescue analgesic between groups

	Group A (n=34)	Group B (n=37)	P-value	t-value
Duration of analgesia (Hours)	6.38 ± 2.03	10.21 ± 3.36	<0.001	-5.75
Rescue analgesic for 24 hours (mg)	147.06 ± 11.94	117.57 ± 31.11	<0.001	5.354

abdominal hysterectomy patients considerably reduces post-operative pain scores up to 48h. Morphine consumption postoperatively was also decreased at 12h, 36h and 48h periods.[11] El Dawlatley et al. studied analgesia of USG-guided TAP block following laparoscopic cholecystectomy and found reduced rescue analgesic consumption.[12] In a meta-analysis study by Baeriswyl M et al. reported that the ultrasound-guided TAP block decreased IV morphine consumption at 6 hours postoperatively by a mean difference of 6 mg.[13]

The Vaddi P et al. study found that 0.5% ropivacaine provided prolonged post-operative analgesia than 0.25% Bupivacaine.[14] In Preethi and Kalyan et al.[15] studies, they concluded that 0.5% ropivacaine provided a longer duration of analgesia than 0.25% bupivacaine when used in TAP block for patients undergoing abdominal surgery. Who compared 0.25% bupivacaine with 0.5% ropivacaine, found that the mean duration of analgesia was greater in ropivacaine than in the bupivacaine group. In a similar study by Nidhi Sharma et al.,[16] the duration of analgesia was longer, and the total requirement of analgesic was lesser in group A (20 ml of 0.5% ropivacaine) as compared to group B (20 ml of 0.25% bupivacaine). In our study, 0.375% of ropivacaine showed increased analgesia duration compared to 0.25% of bupivacaine.

Belavy et al. reported that inadequate analgesia might be due to technical failure or visceral pain, even after a TAP block.[17] The most important finding is the significantly increased analgesia duration with patients receiving TAP block with ropivacaine and the reduction in dosage of opioids with the ropivacaine group. Obese patients or those having OSA will benefit most from TAP block as it has opioid-sparing effects.

5. Limitations of the Study

Several limitations were encountered in this study, primarily attributable to the COVID-19 pandemic, which affected the actual sample size attainment. Pain assessment and the monitoring of post-operative analgesic usage were constrained to a 24-hour post-operative period. Additionally, as the block was administered after general anesthesia, it was not feasible to assess the completeness of the block or the extent of sensory coverage of the abdominal wall. Furthermore, it is important to note that this study encompassed only patients undergoing laparoscopic cholecystectomy.

6. Conclusion

The study's findings suggest that administering 0.375% ropivacaine (30ml) via a TAP block under ultrasound guidance significantly extended the duration of analgesia compared to the use of 0.25% bupivacaine (30ml). Furthermore, the study observed that the requirement for rescue analgesics was significantly lower in the ropivacaine group as opposed to the bupivacaine group. Notably, the study reported the absence of adverse events among the study subjects, including hypotension, bradycardia, arrhythmia, facial and extremity twitching, and convulsions. These conclusions highlight the potential benefits of ropivacaine in providing effective and safe postoperative pain management following upper abdominal laparoscopic surgeries.

7. Source of Funding

No funding agency.

8. Conflicts of Interests

The author declares no conflict of interest.

9. Ethical Approval

Obtained.

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Author biography

S Jesmine Little Flower, Resident

Alex Francisco Nicholas, Consultant

Renu Devaprasath, Consultant

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