

An evaluation of (0.25%) Bupivacaine Vs (0.5%) Ropivacaine for postoperative analgesia using ultrasound guided transversus abdominis plane block for abdominal surgeries: A comparative study

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Abstract

Background: Transversus Abdominis Plane (TAP) Block is a regional analgesic technique. It provides analgesia after abdominal surgery particularly where parietal wall pain forms major component of pain. It allows sensory blockade of abdominal wall skin and muscles via local anaesthetic deposition above Transversus Abdominis muscle (TAM). We evaluated efficacy of Bupivacaine and Ropivacaine in Ultrasound guided TAP Block for post-operative analgesia in abdominal surgeries like hernia repair, open cholecystectomy in a hospital based, double blind, prospective, randomized clinical trial.

Method: 60 adult patients undergoing elective abdominal surgery under general anaesthesia were included in this study and were randomly divided into two groups according to computer generated table of randomization. After induction of anaesthesia, TAP Block unilateral or bilateral (depending upon nature of incision of surgery) was performed using 15 ml of 0.5% Ropivacaine or 0.25% Bupivacaine each side. Each patient was assessed intra-operatively for haemodynamic parameters like HR, SBP, DBP, MBP and SPO₂ at 0, 5, 10, 20 minutes (m) and then after every 10m till the end of surgery. Post-operatively patients were assessed for pain with VAS score at 0m, 30 m, 4, 8, 12, 18 and 24 hours (h) by a blinded investigator.

Results: Intra-operatively haemodynamic parameters remained stable and comparable in both the groups. Mean duration of analgesia in Ropivacaine group and Bupivacaine group was 12.61±5.13hrs and 9.92±4.81h respectively, the difference was found to be statistically significant.

Conclusion: 0.5% Ropivacaine provided longer duration of analgesia than 0.25% Bupivacaine when used in Ultrasound guided TAP Block on patients undergoing abdominal surgeries. TAP Block via lumbar approach using Ultrasonography provides better pain relief especially in lower abdominal surgeries as compared to upper abdominal surgeries. There were no complications attributable to TAP Block or drugs under study.

Keywords: TAP block, Ropivacaine, Bupivacaine, Postoperative analgesia

Introduction

Pain is the most dreaded problem which a person fears after any surgery. A substantial component of pain experienced by patients after surgery is derived from abdominal wall incision. Even a relatively small operation such as inguinal herniorrhaphy may be followed by a risk of a chronic pain state in about 12% of patients, with clinically significant effects on daily activities if postoperative pain is not taken care of.⁽¹⁾ Various modalities have been used to manage postoperative pain like NSAIDs, Opioids, epidural block etc. Each of which has its own side-effects. The opioids have number of side effects such as respiratory depression, emesis and reduction in motility of gut, sedation etc. NSAIDs also have certain side effects like haemostasis alteration, renal dysfunction, gastrointestinal haemorrhage etc. The use of peripheral regional analgesic techniques in form of single injection or continuous infusion is gaining popularity for postoperative analgesia.

TAP Block is gaining popularity as one of such regional blocks. TAP block can be performed through the lumbar triangle of Petit formed by external oblique muscle anteriorly, latissimusdorsi muscle posteriorly, iliac crest inferiorly and is usually identified as a defect

1 cm above the iliac crest in midaxillary line.⁽²⁾ The technique involves injection of local anaesthetic into the plane between the transversus abdominis and internal oblique muscles. It allows sensory blockade of plexus of nerves supplying abdominal wall skin and muscles via local anaesthetic drug deposition above the Transversus abdominis muscle and the use of ultrasound for the same improves the success rate, accuracy of the block and prevents potential complications. Over time, local anaesthetic and the concentration of local anaesthetic used for TAP block has changed. Bupivacaine when used in TAP block provides longer duration of action but has been shown to have selective cardiac effects related to the slow rate at which it dissociates from the sodium channel. An important aspect of this toxicity is that it involves a significant degree of stereo-specificity, with the 'S' isomer showing significantly less cardio-depressant effect than the 'R' Ropivacaine is a new amino amide local anaesthetic and exists as an S-enantiomer, having low systemic toxicity than Bupivacaine.^(3,4) Though some studies indicate that higher concentration of Ropivacaine is needed as compared to Bupivacaine but equi-effective doses have been established to be Ropivacaine 0.5% and Bupivacaine 0.25%.⁽⁵⁾

This study compared the efficacy of 0.25% Bupivacaine and 0.5% Ropivacaine used in Ultrasound guided TAP Block for abdominal surgeries.

Material and Method

After obtaining approval by the Institutional Ethics Committee, this study was conducted on 60 patients of ASA grade I to II undergoing elective abdominal surgeries under general anaesthesia. The study was conducted only on those patients who gave informed and written consent for the procedure and study. The inclusion criteria were ASA I and II patients, aged 18 to 65 years, of either sex, with BMI 18-30 kg/m². The exclusion criteria were: patient refusal to procedure; history of allergy to local anaesthetic; patient with infection at the site of injection; inherited or acquired coagulopathy; patient on systemic anticoagulation therapy; patient who had received analgesic drug 24 hours before induction; and patient with ASA Grade III and IV. Subjects fulfilling the inclusion criteria were randomly assigned either of the two groups according to computer generated table of randomization. Group R (n=30): Patients in this group received 15ml 0.5% Ropivacaine in TAP block (unilateral for unilateral incision/ bilateral for midline or transverse incisions) and Group B (n=30): Patients in this group received 15ml of 0.25% Bupivacaine in TAP block (unilateral for unilateral incision/ bilateral for midline or transverse incisions).

Both the groups received USG guided TAP block with either of the drugs (Ropivacaine or Bupivacaine) after induction of anaesthesia either unilateral (U/L) 15ml or bilateral (B/L) 30ml depending on the nature of abdominal wall incision. In this study bilateral TAP block was given for surgeries involving midline or transverse abdominal incisions and unilateral block for unilateral incisions. The study solutions were prepared under aseptic conditions by an anaesthesiologist not involved in performing the block or data collection, so that both the patients and the anaesthesiologist were not aware of the drug given thus forming a double blind study.

Every patient underwent pre-anaesthetic check-up a day prior to surgery that included a detailed history, complete general physical and systemic examination and relevant investigations. Patients were given midazolam 7.5 mg, pantoprazole 40 mg and domperidone 10 mg via the oral route at bedtime night prior to surgery and were kept fasting 8 hours prior to surgery. All patients were made clear about pain scoring on the verbal analogue score (VAS 0=No pain and VAS 10=Worst possible pain). In the preoperative room, an 18 gauge intravenous catheter was secured. In operation theatre, all routine monitoring namely, non-invasive blood pressure (NIBP), pulse oximetry (SpO₂), end-tidal carbon dioxide (EtCO₂) and electrocardiography (ECG) were started. Baseline values of heart rate (HR), systolic blood Pressure

(SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), EtCO₂ and SpO₂ were recorded. Prior to induction of anaesthesia, Inj. Ranitidine (50mg) and Inj. Tramadol (1mg/kg) was given. Anaesthesia was induced with Inj. Propofol (2mg/kg) and Inj. Rocuronium (0.6mg/kg) and appropriate sized cuffed ETT was placed. Immediately after intubation, TAP block was performed using 15ml U/L or 30 ml B/L of 0.5% Ropivacaine in group R and 15ml U/L or 30ml B/L of 0.25% Bupivacaine in group B depending upon the type of incisions under ultrasound guidance using a 22G short bevel 80 mm needle (SonoTAP needle and cannula; Fig. 1) before surgical incision. Inj. Ondansetron (0.1mg/kg) was given intra-operatively. Anaesthesia was maintained with Oxygen (33%), Nitrous oxide (66%) and Isoflurane of varying concentration.



Fig. 1: SonoTAP needle and cannula

Technique of TAP block

An ultrasound-guided approach for TAP block was used as described by Hebbard et al.⁽⁶⁾ In this technique a transversely oriented linear ultrasound probe (6-12 MHz) was applied to visualize the anterolateral abdominal wall where the three muscle layers were most distinct. After identification of the Transversus abdominis plane between the internal oblique and transversus abdominis muscles, the probe was moved posterolaterally to lie across the midaxillary line just superior to the iliac crest (i.e., over the triangle of Petit). The block needle was then introduced anteriorly and advanced in an in-plane approach. Real-time ultrasonography facilitated easy needle visualization as it approached and reached the targeted fascial plane. A hypoechoic layer, created by injection of local anaesthetic, was also easily visualized as described by Trans TM.⁽⁷⁾ Intra-operatively haemodynamic parameters like Blood pressure (systolic, diastolic and mean), heart rate and oxygen saturation were recorded at 0, 5, 10, 20 minutes (m) and after every 10 m till the end of surgery depending upon the duration of surgery. At the end of surgery patient was reversed with inj. Neostigmine (0.05mg/kg) and inj. Glycopyrrolate (0.01mg/kg). In postoperative period, the presence and severity of pain was assessed systematically using Visual Analog Scale (VAS) at 0

m, 30m, 4, 8, 12, 18 and 24 hours (h). The VAS score (0=no pain; 10=most severe pain) was recorded at rest and coughing. Any patient with a VAS score of more than 3 was given inj. Diclofenac 1.5mg/kg iv to a maximum of three doses in 24 hours; in case of inadequate analgesia patient was given inj. Tramadol 1mg/kg iv in 50 ml normal saline infusion corresponding to VAS score of more than 5, with maximum of three doses over 24 hours.

The data was then analysed statistically using student t-test for parametric data and Chi-square test for non-parametric data. P-value less than 0.05 was considered to be statistically significant. All statistical analysis was performed using SPSS statistics for Windows, Version 16.0.

Results

60 patients were entered into the study. 30 patients were randomized to undergo TAP blockade with 0.25% Bupivacaine and 30 with 0.5% Ropivacaine. Both the groups were comparable with regard to age (Table 1), gender (Table 2), ASA physical status grade. Parametric data included were weight, age, heart rate, systolic blood pressure, diastolic blood pressure and VAS score; whereas the non-parametric data included age, ASA status, and type of surgery.

Table 1: Group comparison for age of patients

Groups	Age (years) Mean \pm SD
Group B	40.97 \pm 9.98
Group R	43.23 \pm 8.91
p-value	0.375
Remarks	NS

NS: Non-significant; S: Significant

Table 2: Gender distribution of patients

Sex	Group B		Group R	
	No. of Patients (n)	Percentage (%)	No. of Patients (n)	Percentage (%)
Male	11	36.67	9	30.00
Female	19	63.33	21	70.00
p-value	0.317			
Remarks	NS			

NS: Non-significant S: Significant

In the present study it was found that during intra-operative period the haemodynamic parameters like HR, SBP, DBP, MBP remained stable and comparable in both the groups. In post-operative period the pain was assessed with VAS at 0, 1/2, 4, 8, 12, 18 and 24 h. The pain scores were comparable between both the groups at 0, 1/2, 4, 18 and 24 h but was higher in Bupivacaine group at 8 and 12 h post-operatively (Table 3). Thus, suggesting shorter duration of Bupivacaine as compared to Ropivacaine. The results of this study show that the mean duration of analgesia was longer in Ropivacaine group (12.61 \pm 5.13 hours) as compared to Bupivacaine group (9.92 \pm 4.81) by 2.69 \pm 0.52 h (Table

4), which was statistically significant ($p < 0.05$). The power of this study came to be 55.4% and an alpha error of 0.05%.

Table 3: Group Comparison for VAS Score

Time interval	Mean \pm Standard Deviation		p-value	Remarks
	Group B	Group R		
VAS-R 0	0.10 \pm 0.31	0.07 \pm 0.25	0.647	NS
VAS-R 1/2	0.40 \pm 0.50	0.33 \pm 0.48	0.599	NS
VAS-R 4	0.93 \pm 0.45	1.10 \pm 0.88	0.362	NS
VAS-R 8	1.97 \pm 1.03	1.37 \pm 1.19	0.041	S
VAS-R 12	1.63 \pm 0.89	1.07 \pm 1.23	0.045	S
VAS-R 18	1.40 \pm 0.67	1.33 \pm 0.99	0.762	NS
VAS-R 24	1.43 \pm 0.68	1.40 \pm 0.56	0.837	NS
Grand mean	1.12 \pm 0.31	0.95 \pm 0.38	0.061	NS

Though the total postoperative analgesic requirement in Bupivacaine group was clinically higher but statistically not significant as compared to Ropivacaine group. The postoperative pain control was better in lower abdominal surgeries like inguinal hernia as compared to upper abdominal surgeries like open cholecystectomy in both the groups.

Table 4: Groups Comparison for time of analgesia

Groups	Time of first analgesia (Mean \pm SD)
Group B	9.92 \pm 4.81
Group R	12.61 \pm 5.13
p-value	0.045
Remarks	S

Discussion

TAP block is a simple and effective regional analgesic technique, appropriate for surgical procedures where parietal pain is a significant component of postoperative pain. It also prevents the sudden increase in blood catecholamines due to pain (e.g. during skin incision) thus maintaining intraoperative and postoperative hemodynamics.⁽⁸⁾ The use of local anaesthetic agents in TAP block has demonstrated to provide excellent analgesia to the skin and musculature of the anterior abdominal wall. Using ultrasound for visualization of anatomic structures in real time may prevent improper placement of the needle outside the muscles (behind the peritoneum) or the puncture of the organs situated there. Moreover, the local anaesthetic spread within the tissues can be supervised.⁽⁹⁾

An ideal local anaesthetic should produce effective, controlled sensory block of rapid onset with long duration and an adequate motor block. It should have a high therapeutic index.

Bupivacaine has most of these characteristics but causes refractory cardiotoxicity if accidentally injected in the systemic circulation.⁽¹⁰⁾ Concern about CNS toxicity and therapy resistant cardiovascular toxicity with Bupivacaine⁽¹¹⁾ led to introduction of newer agents like Ropivacaine and Levobupivacaine.⁽¹²⁾ Although

Ropivacaine was introduced in clinical practice as early as 1993 but the wide use of this drug has been propagated only recently and has been patented in India in 2009, so we decided to study this drug with the other most commonly used long acting Bupivacaine. Based on the equipotency ratio of 1.3:1 to 1.5:1 between Ropivacaine and Bupivacaine respectively for epidural anaesthesia, 0.5% Ropivacaine was compared with 0.25% Bupivacaine. This randomized, double blind comparative clinical study was designed to compare the better drug among Ropivacaine and Bupivacaine with respect to their analgesic efficacy and safety profile in ultrasound guided TAP Block for abdominal surgeries.

The average heart rate and blood pressure (systolic, diastolic and mean) readings intra-operatively remained stable with no statistically significant difference between Bupivacaine and Ropivacaine groups. Also, no significant side effects due to drug or procedure were noted during this study. Intra-operatively haemodynamic parameters remained stable in both the groups possibly because of the better pain relief and subsequent controlled sympathetic response. As explained by Kai Li et al,⁽⁸⁾ who conducted a study on ultrasound guided subcostal TAP block in 40 gastric cancer patients undergoing open gastrectomy using 0.35% Ropivacaine and Normal Saline in group R and S respectively. In their study, the changes in SBP, DBP, HR of patients in group R were significantly less compared with their counterparts in group S before and after the surgical incision. Their outcomes revealed that TAP block yielded effective analgesic effect during skin incision. The proposed mechanism is that the projection system of cerebral cortex, limbic system or hypothalamus towards cerebral cortex gets suppressed by medication under general anaesthesia, but the harmful surgical stimulation still exists. The sympathetic nerve adrenal medulla axis still responds under stimulation and cannot block the reflection of central nerve system. TAP block under general anaesthesia effectively inhibits the excitation of area neuron, compensate for the insufficiency of general anaesthesia and prevent the sudden elevation of blood catecholamine during skin incision, which plays an extremely important role in maintaining the stable haemodynamics during skin incision and throughout the surgery. Similar findings were also observed by Neha Fauladi et al,⁽¹³⁾ who evaluated efficacy of U/L TAP block with 0.25% Bupivacaine and 0.5% Ropivacaine for postoperative analgesia in 75 patients undergoing lower abdominal surgeries. Mean duration of analgesia in this study was longer in Ropivacaine group (12.61 ± 5.13 hour) as compared to Bupivacaine group (9.92 ± 4.81) by 2.69 ± 0.52 hours, which was statistically significant. Though the total postoperative analgesic requirement (rescue/demand) in Bupivacaine group was clinically higher but statistically not significant as compared to Ropivacaine group.

Postoperative VAS score of 3 or more was considered benchmark for providing rescue analgesia in form of injection Diclofenac 1mg/kg intramuscular (i.m), with the maximum of three doses in 24 hours in the present study. In case of inadequate pain relief and patient demanded analgesia, demand analgesia was given in form of injection Tramadol 1mg/kg in 50ml NS corresponding to VAS score of more than 5, with the maximum of three doses in 24 hours. In this study we observed the pain scores via VAS at 0 min, 30 m, 4 h, 8 h, 12 h, 18 h and 24 h postoperatively. The mean pain scores at 0 min, 30 min and 4 h were similar in both the groups and inter group comparison was not statistically significant. However, comparison of pain score at 8 h and 12h post operatively showed significant difference in both the groups with Bupivacaine having significantly higher VAS scores both at rest and on coughing. Thus, suggesting shorter duration of action of 0.25% Bupivacaine as compared to 0.5% Ropivacaine. Our results are in line with Neha Fauladi et al⁽¹³⁾ who evaluated efficacy of unilateral TAP block with Bupivacaine and Ropivacaine for postoperative analgesia in lower abdominal surgeries like hernia repair, appendectomy. They concluded that 0.5% Ropivacaine provided longer duration of analgesia than 0.25% Bupivacaine when used in TAP block on patients of lower abdominal surgeries.

The postoperative pain control was better in lower abdominal surgeries like inguinal hernia as compared to upper abdominal surgeries like open cholecystectomy in both the groups. This is in the lines with the study of Shibata Y⁽¹⁴⁾ in which they demonstrated a limited spread of local anesthetic cephalad to T10 when given in lumbar TAP making it more suited for lower abdominal surgeries.

Generally, TAP block has so far displayed a good safety profile. A large incentive for the widespread use of TAP block is the fact that there are few complications attributable to TAP block in the current literature.^(15,16) Rare complications reported are infection, haematoma, nerve injuries, symptoms of toxicity of the local anaesthetic, puncture of peritoneal cavity, intestine perforation and puncture of the liver as described by McDonnell in 2005.⁽¹⁷⁾ A case of liver laceration after landmark based TAP block technique was reported in 2008.⁽¹⁵⁾ Lancaster and Chadwick also reported a case of liver laceration after USG-guided TAP block, which was likely as a result of failure to adequately visualize the needle during the procedure.⁽¹⁸⁾ Another important concern is the local anaesthetic toxicity, particularly when B/L blocks were performed. TAP block has been shown to cause systemic toxicity if local anaesthetic spills over into the adjacent muscles or/and if toxic dose of local anaesthetic has been used.⁽¹⁹⁾ We did not encounter these complications as we did not cross the toxic dose of both the drugs and used ultrasound for visualisation of drug deposition in the right plane.

Hence, the results of this study show that USG-guided TAP block technique for postoperative analgesia is very promising as a part of multi-modal analgesia in abdominal surgeries. Ropivacaine (0.5%) provides significantly longer duration of analgesia as compared to Bupivacaine (0.25%). The limitations of this study were that the postoperative pain was studied for 24 hours only and patient satisfaction score was not observed as far as postoperative analgesia was concerned.

Conclusion

As an emerging technique, transverses abdominis plane (TAP) block besides significantly reducing the pain scores seen as decreased post-operative analgesic requirement, also exerts high efficacy upon maintaining intra-operative hemodynamics. TAP Block (via lumbar technique) reduces postoperative pain effectively especially in lower abdominal surgeries as compared to upper abdominal surgeries. 0.5% Ropivacaine when compared with 0.25% Bupivacaine, provides a longer duration of analgesia in ultrasound guided TAP block. Thus, it is concluded that Ropivacaine can be used as a safe alternative for Bupivacaine, routinely for TAP block for abdominal surgeries.

Competing interests

None declared.

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