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ORIGINAL ARTICLE

COMPARATIVE STUDY OF BUPIVACAINE 0.25% VERSUS ROPIVACAINE 0.5% IN TRANSVERSUS ABDOMINIS PLANE BLOCK FOR POSTOPERATIVE ANALGESIA IN LOWER ABDOMINAL SURGERIES: A RANDOMISED CONTROLLED TRIAL

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ABSTRACT: BACKGROUND: Transversus Abdominis Plane Block (TAPB) is a regional anesthesia technique. It provides analgesia after lower abdominal surgery particularly where parietal wall pain forms major component of pain. It allows sensory blockade of lower abdominal wall skin and muscles via local anesthetic deposition above Transversus Abdominis muscle. We evaluated efficacy of unilateral TAPB with bupivacaine and ropivacaine for postoperative analgesia in lower abdominal surgeries like hernia repair, appendicectomy in a hospital based, single blind, and prospective, randomized controlled clinical trial. **METHOD:** 75 adult patients undergoing elective unilateral lower abdominal surgery were randomized to undergo TAPB with ropivacaine (n = 25) or bupivacaine (n = 25) or Normal saline (n = 25). At end of surgery performed under spinal anesthesia unilateral TAPB on side of surgery was performed using 20 ml of 0.5 % ropivacaine or 0.25 % bupivacaine or saline. Each patient was assessed postoperatively by a blinded investigator in post-anesthesia care unit every 5 minutes for half an hour, then every 15 minutes till 2 hours and at 4, 6, 12, 24, 48 hours postoperatively in ward. **RESULT:** Mean duration of analgesia was 420.6 minutes with SD of +14.01 in Bupivacaine group and 2187 minutes with SD of +1011.09 in Ropivacaine group which was found to be statistically significant. **CONCLUSION:** Hence 0.5% ropivacaine provided longer duration of analgesia than 0.25 % bupivacaine when used in TAPB on patients of lower abdominal surgeries. There were no complications attributable to TAPB or drugs under study.

KEYWORDS: TAPB, Ropivacaine, Bupivacaine, Postoperative analgesia.

INTRODUCTION: The abdominal wall is a significant source of pain after abdominal surgery. 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] The usual trend is to prescribe an opioid or a NSAID for postoperative analgesia. 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. However in regional analgesic technique, drugs have peripheral site of action, hence minimum systemic side effects. Hence regional analgesic technique has gained widespread popularity as an important component of postoperative analgesia regimen. TAPB is gaining popularity as one of such regional blocks.

Transversus Abdominis Plane Block (TAPB) can be performed through the lumbar triangle of Petit formed by external oblique muscle anteriorly, lattissimus dorsi muscle posteriorly, iliac crest inferiorly and is usually identified as a defect 1 cm above the iliac crest in midaxillary line. The

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technique involves injection of local anesthetic into the plane between the transversus abdominis (TAM) and internal Oblique muscles. It allows sensory blockade of plexus of nerves supplying lower abdominal wall skin and muscles via local anesthetic drug deposition above the TAM.

We planned to compare the duration of postoperative analgesia conferred by 0.25 % Bupivacaine and 0.5 % Ropivacaine used in TAPB for unilateral lower abdominal surgeries.

METHODS: After obtaining approval by the Institutional Ethics Committee, and written informed patient consent, we studied 75 ASA physical status I – II patients of either sex, more than 18 years of age with normal liver and renal functions scheduled for unilateral lower abdominal surgery in a prospective, randomized, single-blind, controlled clinical trial. By using single blinded randomization technique we selected 25 patients in each group considering power to be 85%. Patients were not included if there was a history of sensitivity to local anesthetics, abnormal liver function, infection at injection site, clotting abnormalities.

Patients were randomized by Systematic Random Sampling to undergo TAP block with 0.25% Bupivacaine in group B (n = 25) or 0.5 % Ropivacaine in group R (n = 25) or normal saline in group S (n = 25). Standard monitoring, including electrocardiogram, non-invasive blood pressure, arterial oxygen saturation were used throughout. Patients were premedicated with intravenous Ranitidine and intravenous Ondansetron. Patients were preloaded with 500 ml of Ringer Lactate.

All patients received a standardized spinal anaesthesia with 0.5 % hyperbaric Bupivacaine 3.4 ml without any additive in lateral position without any table tilt. Level of analgesia achieved was noted. Assessment of block was done by pinprick. Target height was T6. Patients were monitored intraoperatively. Hypotension was taken as fall in systolic blood pressure > 30% of baseline and was treated with incremental doses of Mephentermine 0.3 mg and bolus of 200 ml of Ringer Lactate. Bradycardia was taken as heart rate < 60 beats per minute and treated accordingly with intravenous Atropine 0.6 mg. No analgesic or sedation was given to any patient intraoperatively.

At end of surgery Petit's triangle was identified on the side of surgery as a defect above the iliac crest between the fibres of external oblique and latissimus dorsi muscles. Same anaesthesiologist gave all TAPBs. Under all aseptic precautions the block was given through Petit' triangle with 22 G hypodermic needle attached to a 20 ml syringe containing the drug as per the group allocation. Needle was introduced perpendicular to skin and advanced until two "POPS" or "give way" were felt. Then the drug was deposited in the fascial plane after aspiration, check aspiration was done every 5 ml to rule out intravascular injection. The patient was observed for 15 minutes and then shifted to post-anaesthesia care unit.

The anaesthesiologist who observed the patients in PACU was blinded to the drug injected in TAPB. Patient was monitored every 5 minutes for half an hour, then every 15 minutes till 2 hours and then at 4, 6, 12, 24, 48 hours postoperatively for pulse rate, systolic and diastolic blood pressure and respiratory rate, pain and complications if any. Pain was assessed according to visual analogue score from 0 to 10. Patient was given rescue analgesia in the form of intramuscular Diclofenac 75 mg at a visual analogue pain score of 4 (i.e. minimal pain). Recession of motor block was noted by movement of ankle and knee joint and that of sensory block by pin prick on the opposite side of block.

The duration of analgesia in TAPB was considered to be from the time of recession of sensory level below T10 on the nonoperated side to pain score of 4 (i.e. minimal pain). Patient was also observed for any other postoperative complications like haematoma, flank fullness, etc.

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At the end of study, data were pooled and analyzed using SPSS version 17 and graphpad version 5 and conclusion was drawn regarding the effectiveness of TAPB in postoperative analgesia and relative efficacy of the two drugs by applying Anova test, Student t test, Tukey test.

RESULTS: Seventy five patients were entered into the study. 25 were randomized to undergo TAP blockade with 0.25 % Bupivacaine, 25 with 0.5 % Ropivacaine and 25 with normal saline. All patients underwent unilateral lower abdominal surgical procedures. All groups were comparable in age, gender, weight and operative procedures performed. [Tables 1, 2]

In our study we found that the mean duration of analgesia was 22.6 minutes with standard deviation of + 3.26 in saline group, 420.6 minutes with a standard deviation of + 14.01 in Bupivacaine group and 2187 minutes with a standard deviation of + 1011.09 in Ropivacaine group and this difference was found to be statistically significant. [Figure 1]

Mean pain scores at 2, 4, 6 and 12 hours in bupivacaine group were 1.56, 2.44, 3.48 and 4 respectively. Mean pain scores at 2, 4, 6, 12, 24, 48 hours in ropivacaine group were 0.76, 1.32, 1.83, 2.54, 3.19 and 4 respectively. 25 Patients in Bupivacaine group required diclofenac in first 12 hours, 9 patients in Ropivacaine group required diclofenac before 48 hours and 25 patients in saline group required diclofenac in first 6 hours.

Mean duration of surgical procedure was 64.2 minutes with standard deviation of +15.34 in saline group, 68.4 minutes with a standard deviation of +16.22 in Bupivacaine group and 66.5 minutes with a standard deviation of +14.98 in Ropivacaine group. Level achieved was T4 in 4 patients, T6 in 18 patients, T8 in 3 patients in B group, T4 in 3 patients, T6 in 16 patients, T8 in 6 patients in R group and T4 in 6 patients, T6 in 17 patients, T8 in 2 patients in S group. 4 patients required 2 doses, 16 patients required single dose of 0.3 mg mephentermine, in B group. 3 patients required 2 doses, 14 patients required single dose of 0.3 mg mephentermine in R group. 5 patients required 2 doses, 13 patients required single dose of 0.3 mg mephentermine in S group.

The difference between the mean pulse rate and mean systolic and diastolic blood pressure were found to be statistically non-significant between group B and group R at all periods of time. Thus the effect of Bupivacaine and Ropivacaine on the pulse rate, mean arterial pressure and respiratory rate was found to be comparable suggesting that Bupivacaine and Ropivacaine have comparable hemodynamic stability in TAP block. In our study we did not encounter any complication that could be attributable to the procedure or the drugs under study.

DISCUSSION: The benefit of adequate postoperative analgesia are clear and 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. Other benefits of effective regional analgesic techniques include reduced pain intensity, decreased incidence of side effects from analgesics and improved patient comfort.

Using local anaesthetic agents in TAPB is a simple and effective analgesic technique, appropriate for surgical procedures where parietal pain is a significant component of postoperative pain. The local anaesthetic agents in TAP block have been demonstrated to provide excellent analgesia to the skin and musculature of the anterior abdominal wall in patients undergoing colonic resection surgery involving a midline abdominal wall incision, [2] patients undergoing caesarean

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delivery,[3] and patients undergoing radical prostatectomy.[4] Findings of similar studies have been mentioned. [View table no 3] In the published studies investigating the use of the TAP block for post-operative analgesia, either ropivacaine in concentrations of 0.5% and 0.375% or bupivacaine 0.5% was utilized.

In this randomized, single blind clinical trial, we compared the duration of analgesia provided by ropivacaine and bupivacaine administered in TAPB. In this study local anaesthetic agents like 0.5% ropivacaine and 0.25% bupivacaine used in TAPB produced effective and prolonged postoperative analgesia when compared with placebo in patients undergoing unilateral lower abdominal surgeries.

The finding that the TAP block provided postoperative analgesia for static pain for up to 48 hours as with Ropivacaine is of importance in that it demonstrates that a single-shot TAP technique using drugs like ropivacaine can produce effective analgesia for up to 48 h. The reasons for the prolonged duration of analgesic effect after TAP blockade are not entirely elucidated. However, this may relate to the fact that the TAP is relatively poorly vascularized, and therefore drug clearance may be slowed.[5]

Over the past 3 yr, a series of studies have highlighted the value of efficacy of various local anaesthetic agents in Transversus Abdominis Plane (TAP) Block, after the initial description of the technique by Rafi.[6] Transversus Abdominis Plane Block as described by Rafi involves identifying the neurovascular plane of the abdominal musculature and injecting a local anaesthetic agent therein. He performed abdominal field block via the lumbar triangle without any untoward sequelae.

With the technique of ultrasound guided nerve blockade gaining popularity, this technique was also applied to injection of bupivacaine and ropivacaine in the TAP block.[7-9] However injection via Petit's triangle using double POP technique resulted in reliable deposition into the transversus abdominis plane.[10] Moreover it may not always be possible to use ultrasound guided techniques for administering TAPB where such facilities are not available.

The landmark-based technique for the TAP block, have been performed without difficulty in the children.[11] Alternative approaches to the TAP block using ultrasound guidance have recently been described in a case series of children undergoing inguinal hernia repair.[12] The optimal approach remains to be demonstrated. There are now a variety of techniques for the TAP block and the analgesic merit of each is being elucidated in ongoing studies. Although it is possible to ultrasonically visualize the 3 muscle layers of the abdominal wall, there is variation in these muscle layers that can restrict the use of ultrasound over the triangle of Petit. [13] As a result, the needle insertion point as described in the ultrasound studies, which is dependent on the adequate identification of the 3 muscle layers, can vary.

This will alter the location of the injectate as will the angle of the needle insertion to skin, which contrasts to the landmark approach's description. Although there is an ever-increasing access to ultrasound, it is far from universal and there is a continuing interest in landmark techniques.[14] Moreover ultrasound machine may not be available at all places especially in peripheral health centers where the blind technique alone is the option for giving TAPB. 100% success rate with TAP block have been obtained using landmark technique for posterior approach of block.[14] To our knowledge till now no study has been performed to compare the efficacy of landmark versus ultrasound technique for posterior approach of TAP block.

TAP injection of local anaesthetic injection cephalad to the iliac crest likely involves T10–L1

nerve roots and implies that the technique may be limited to use in lower abdominal surgery.[15]

Unlike most other studies, we used TAPB as sole method of providing postoperative analgesia. We terminated the study at the first requirement of rescue analgesic or at 48 hours, whichever was earlier.

Epidural Ropivacaine was found to be significantly less potent than Bupivacaine by a factor of 0.4. Ropivacaine was 60% as potent as Bupivacaine when used for epidural pain relief in labour.[16] The analgesic potency of Ropivacaine was 0.6 relative to Bupivacaine.[16] So we used 20 ml of either 0.25 % Bupivacaine or 0.5 % Ropivacaine compared with saline as the drugs under study for use in unilateral TAPB considering Ropivacaine to be approximately half as potent as Bupivacaine.

We assessed the patient for postoperative analgesia by visual analogue scale. At visual analogue pain score of 4 (i.e. minimal pain) we gave rescue analgesic in the form of intramuscular Diclofenac and the duration of analgesia was recorded.

Patients in group B had pain relief for minimum period of 400 minutes and maximum period of 450 minutes postoperatively. While majority of patients i.e. 16 in group R had postoperative analgesia for more than 48 hours. Only 4 patients required rescue analgesia before 12 hours postoperatively. The difference in the duration of analgesia between the two drugs could be attributed to some extent to the intrinsic vasoconstrictor effect of aminoamide local anesthetics like Ropivacaine.[17] This property prolongs the duration of analgesia by Ropivacaine to 2 – 3 times that of Bupivacaine. Moreover the pain after hernia repair is most pronounced the day after surgery and the pain ceases over time gradually.[18]

The study did not assess the dynamic pain component and that could be a potential limitation. We did not measure the number of boluses of analgesic required by the patient and that could be another limitation of this study.

CONCLUSION: Thus we conclude that 0.5% Ropivacaine provided longer duration of analgesia than 0.25% Bupivacaine when used in TAPB for providing postoperative analgesia after lower abdominal surgeries. It has an excellent safety profile to date. It shows outstanding clinical utility in terms of reliability & effective analgesia.

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Characteristic	Group S	Group B	Group R
Mean Age	42.04(+/-15.95)	44.28(+/-16.04)	47.56(+/-15.48)
Mean weight	53.88 (+/- 6.99)	52.04 (+/-10.65)	52.56 (+/-6.87)
Gender male	84 %	96 %	96 %
Gender female	16 %	4 %	4%
ASA grade I	19(76%)	17(68%)	15(60%)
ASA grade II	6(24%)	8(32%)	10(40%)

Table 1: Comparison of Demographic characteristics

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Diagnosis	Group S	Group B	Group R	אל2-value
Open Appendicectomy by Mc Burney's incision	5(20%)	3(12%)	2(8%)	2.58 p-value=0.56 NS, p>0.05
Left inguinal Herniorrhaphy/ Hernioplasty	8(32%)	6(24%)	9(36%)	
Right inguinal Herniorrhaphy/ Hernioplasty	12(48%)	16(64%)	14(56%)	
Total	**25(100%)**	**25(100%)**	**25(100%)**	

Table 2: Distribution of patients according to diagnosis

Study	Local anaesthetic solution	Duration of analgesia by TAPB
McDonnell (2007)	Levobupivacaine 3.75 mg/ml (20ml) bilaterally	24 hrs
McDonnell (2008)	Ropivacaine 7.5 mg/ml (15-20ml) bilaterally	6-12 hrs
Carney (2008)	Ropivacaine 7.5 mg/ml (15-20ml) bilaterally	48 hrs
El-Dawlatly (2009)	Bupivacaine 5mg/ml (15 ml) bilaterally	24 hrs
Niraj (2009)	Bupivacaine 5mg/ml (20 ml)	24 hrs
Belavy (2009)	Ropivacaine 5 mg/ml (20ml) bilaterally	24 hrs

Table 3: Comparison of analgesia with TAPB in different studies

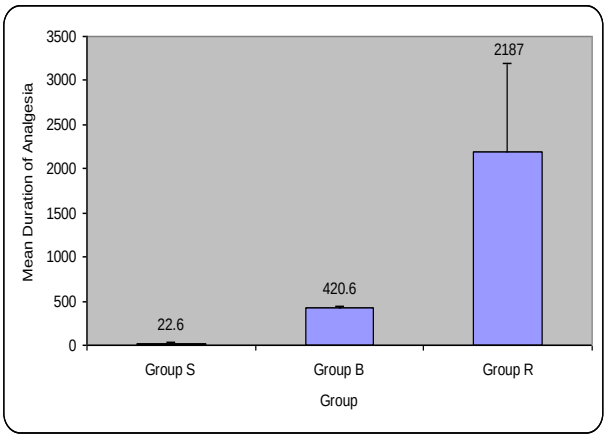

Figure 1: COMPARISON OF DURATION OF ANALGESIA IN ALL THE GROUPS

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