Comparison of 0.375% Bupivacaine in Tranversus Abdominal Plane Block Versus Epidural Block for Post-Operative Analgesia

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Abstract

Epidural analgesia by administration of bupivacaine has been considered as the Gold Standard for management of postoperative pain. On the other hand there is a paucity of literature on the efficacy of bupivacaine administered by Transversus Abdominis Plane (TAP) for postoperative pain relief in patients undergoing infra umbilical abdominal surgeries. The present study was carried out in a tertiary care medical college hospital in a rural setting to compare the efficacy of 0.375% Bupivacaine in the control of postoperative pain in patients undergoing infra umbilical abdominal surgeries when used in epidural space versus in the TAP. Material and Methods: Sixty patients between 20 to 60 years of age of either sex in ASA grade I or II undergoing infra umbilical abdominal surgeries were divided into two groups of 30 each depending upon the route of administration of 0.375% bupivacaine either though TAP (Group T) or through epidural space (Group E). The parameters studied were variations in haemo-dynamics, quality of analgesia by VAS score, duration of analgesia by request for rescue analgesics, adverse effects if any and finally patient satisfaction for the postoperative pain relief. Results: The Heart Rate (HR), Mean Arterial Pressure (MAP), Respiratory Rate (RR) and Oxygen Saturation (SpO2) were comparable between both the groups throughout the postoperative period with no significant change in haemodynamics from the baseline. The quality of postop analgesia in Group T was significantly better than in Group E as observed by lower VAS Scores at rest at various time intervals in Group T as compared to Group E (p<0.05). Considerably higher scores for patient satisfaction for postoperative pain relief were observed in Group T as compared to Group E after 48 hours of administration of the study drug. (p<0.05). Considerably longer duration of postop analgesia was observed in Group T (420.03±30.42) as compared to Group E (240.27±30.1) which was statistically significant (p<0.05). Conclusion: 0.375% bupivacaine is effective for postoperative analgesia in both the groups however TAP block holds considerable promise for patients undergoing infra umbilical surgeries and is an efficient alternative to epidural analgesia on account of its efficacy, safety, affordability and simplicity.

Keywords: Postoperative Analgesia; Transversus Abdominis Plane Block; Epidural Analgesia; Infra Umbilical Surgical Procedures.

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Introduction

anaesthesia (RA), local anaesthesia (LA) or sedation.

Anaesthesia enables the painless performance of procedures that would cause severe or intolerable pain to a non-anaesthetized patient. It could be either general anaesthesia (GA), regional

RA not only avoids the risks and side effects of GA but also has the primary benefit of elimination of both intraoperative and postoperative pain. Neuraxial or peripheral nerve blockade are used to achieve RA.

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The transversus abdominis plane (TAP) block is a relatively new RA technique that provides analgesia to the parietal peritoneum, as well as the skin and muscles of the anterior abdominal wall, for infra umbilical abdominal surgeries.

We conducted a study to compare the treatment outcome of 0.375% bupivacaine administered through TAP block vis-à-vis through epidural space for control of post-operative pain in patients undergoing infra-umbilical abdominal surgery at a tertiary care medical college hospital in rural setting.

The parameters compared were variations in haemo dynamics, quality of analgesia by VAS score, duration of analgesia by request for rescue analgesia, adverse effects if any and finally the patient satisfaction for the postop pain relief.

Objectives

To compare:

- 1. Quality of post-operative analgesia
- VAS scores at rest every hourly for the first 6 hours post-operatively, and every 2 hourly thereafter for the next 12 hours after surgery.
- Patient satisfaction in respect of relief of postoperative pain after 48 hours of administration of 0.375% bupivacaine.
- Time to first request for rescue analgesia.
- 2. Variation in haemodynamic parameters every 15 minutes for the first one hour post-operatively, and every two hours thereafter for the next 12 hours after surgery.
- 3. Adverse effects, if any.

Materials and Methods

Sixty patientswho gave informed written and verbal consent, between 20 to 60 years of age, of either gender, belonging to ASA class I or II, were included in the study.

Inclusion Criteria

Patients

- Aged between 20 to 60 years
- · Of either gender
- Belonging to ASA class I or II
- Posted for infra-umbilical abdominal surgeries
- Willing to give informed written and verbal

consent in local language to participate in the study

Exclusion Criteria

- Patients with known
 - a. Cardio-respiratory disorders
 - b. Hepatic and renal diseases
 - c. Mental retardation or neurological disorders
 - d. Coagulation disorders or receiving anticoagulant medications
- · Patients with
 - a. Spinal deformities and psychiatric disorders
 - b. Hypersensitivity to bupivacaine
 - c. Localised infection/injury/swelling at the spine/site of TAP block
- Pregnant females and lactating mothers

Methodology

Sample size was calculated using OpenEpi version 3.01. Based on previous study parameters conducted by *Kandi et al.* comparing visual analogue scale pain scores post-operatively at various time intervals, for the power of study to be 80% and confidence interval 95%, the minimum sample size calculated was 28 (14 in each group). The Institutional Ethical Committee approval was obtained prior to conduct of the study

Procedure

As per routine protocol of the institution preanaesthetic evaluation was done and patients of both groups were fasted evening prior to surgery.

In the operating room, standard monitoring, including electrocardiogram, mean arterial blood pressure, respiratory rate and oxygen saturation was started using multi-para monitors. The anaesthesia machine, breathing circuits, emergency resuscitation trolley and airway equipment were kept ready.

Both patient groups received standard general anaesthesia using identical drugs and techniques.

Patients in Group T were administered 0.375% bupivacaine 2 mg/kg as a single dose bilaterally in transversus abdominis plane by a qualified anaesthesiologist using the, landmark technique described by McDonnell et al. with a 23 G needlebilaterally and 0.375% bupivacaine 2 mg/kg was injected on either side.

Patients in Group E were administered 0.375% bupivacaine 2 mg/kg as a single dose through a catheter in epidural space by a qualified anaesthesiologist using the loss of resistance technique.

Both patient groups were shifted to the postanaesthesia care, and received the same basic standard of post-operative care.

Observations

Post-operatively, after administration of 0.375% bupivacaine, the following observations were made:

- 1. Quality of post-operative analgesia
 - Mean VAS scores

The patients were asked to rate their average pain at rest by using visual analogue scale (VAS) scores, every hourly for the first 6 hours post-operatively, and every 2 hourly thereafter for the next 12 hours after surgery with 0 corresponding to no pain and 10 to the worst imaginable pain.

• Patient satisfaction with their analgesia after 48 hours of administration of 0.375% bupivacaine.

The patients were asked to rate their satisfaction with the analgesia after 48 hours of administration of 0.375% bupivacaine, which was assessed by a questionnaire.

Scoring scale used for the assessment of patient satisfaction:

Patient Satisfaction	Scoring Scale
Not satisfied	0
Mildly satisfied	1
Moderately satisfied	2
Fully satisfied	3

1. Time to first request for rescue analgesia (duration of post-operative analgesia) was noted. Rescue analgesia using injection diclofenac sodium 1.5 mg/kg intra-muscularly was given when the patient complained of pain at rest, of score ≥ 4 on the visual analogue scale or on patient demand, and was considered as the end point of the study. Duration of post-operative analgesia was defined as the time interval from administration of 0.375% bupivacaine, to the time of first rescue analgesia supplementation.

2. Patients were assessed for variations in heart rate, mean arterial pressure, respiratory rate and oxygen saturation, every 15 minutes for the first one hour post-operatively, and every 2 hourly thereafter for the next 12 hours after surgery. Hypotension is defined as reduction of systolic blood pressure, more than 30% from basal systolic blood pressure (SBP) or SBP less than 90 mmHg and was treated with increased rate of intravenous fluids and if needed, IV mephentermine 3 mg given in increments. Bradycardia (< 60 beats/min) was treated with injection IV atropine 0.6 mg.

Adverse effects such as hypotension, bradycardia, desaturation, respiratory depression, nausea, vomiting, shivering, muscle weakness, pruritus, urinary retention, transient neurological symptoms, post dural puncture headache & infection at local site were noted for up to 48 hours after administration of 0.375% bupivacaine and treated.

Statistical Analysis

The results of the study were entered in a sheet using Microsoft Excel 2016, and statistical analysis was done between the two groups using the software, IBM SPSS Statistics version 25. Parametric data were analysed using the unpaired Student's *t*- test, whereas categorical data were analysed using the Chi-square test. Repeated variables were analysed with repeated measure ANOVA test.

A p value <0.05 was considered statistically significant for this study.

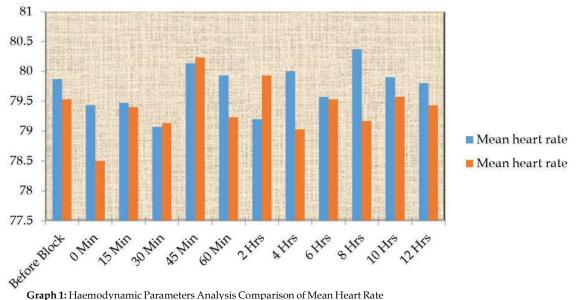
Observations and Results

Therapeutic failure in both the patient groups was defined as inadequate pain control from the surgical wound and drain site. Technical failure in Group T was defined as the inability to insert the 23G blunt regional block needle to administer the TAP block as a result of poor tissue planes, and in Group E as the inability to insert the epidural catheter. Therapeutic and technical failures were not observed in any of the patient groups, and were considered for statistical analysis.

Comparison of age, weight, height, ASA class showed no statistical significance.

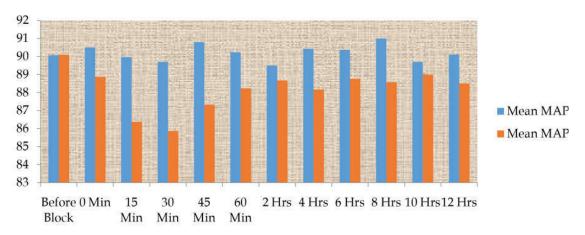
Comparison of Adverse Effect

Adverse effects such as hypotension, bradycardia, desaturation, respiratory depression, shivering,



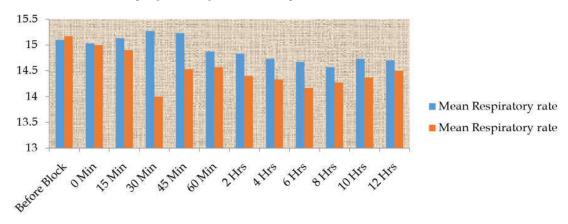
Graph 1: Haemodynamic Parameters Analysis Comparison of Mean Heart Rate

 $Mean\ h\ heart\ rate\ between\ the\ two\ groups\ was\ comparable\ with\ no\ significant\ statistical\ difference.$



Graph 2: Comparison of Mean Map

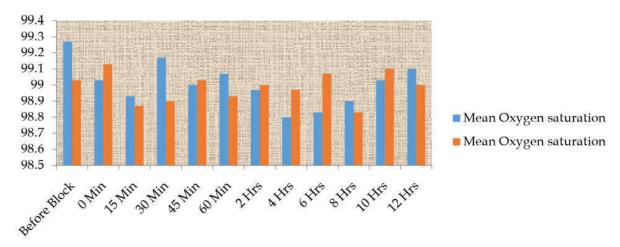
Mean MAP between the two groups was comparable with no significant statistical difference.



Graph 3: Comparison of mean respiratory rate

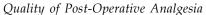
Mean respiratory rate between the two groups was comparable with no significant statistical difference

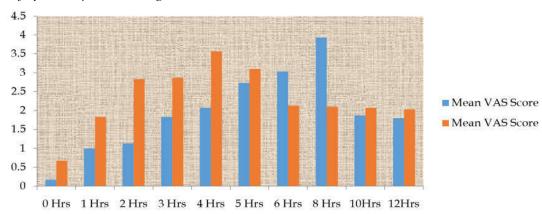
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Graph 4: Comparison of mean oxygen saturation

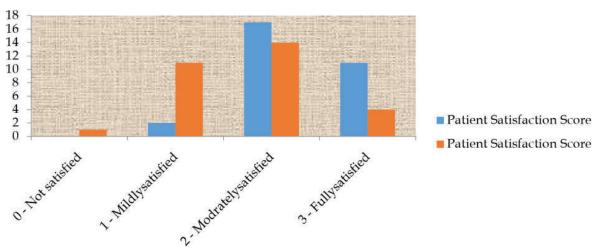
Mean oxygen saturation between the two groups was comparable with no significant statistical difference.





Graph 5: Comparison of mean vas score

Low mean VAS scores at various time intervals were observed in Group T, as compared to Group E

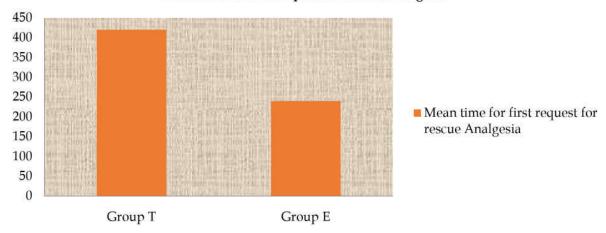


Graph 6: Comparison of patient satisfaction score

Considerably higher patient satisfaction score was observed in Group T, as compared to Group E.

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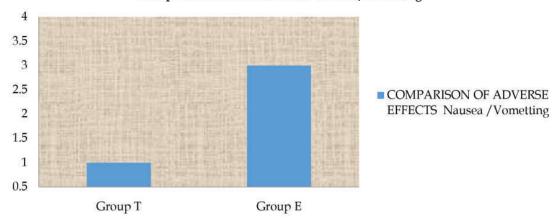
Mean time for first request for rescue Analgesia



Graph 7: Mean time to first request for rescue analgesia

Longer duration of post-operative analgesia was observed in Group T, as compared to Group E.

Comparison of Adverse Effects Nausea/Vometting



Graph 8:

muscle weakness, pruritus, urinary retention, transient neurological symptoms, post dural puncture headache and infection at local site were not observed in any of the patient groups for up to 48 hours after administration of the 0.375% bupivacaine.

Discussion

Pain is a complex subjective experience and its existence has been a constant stimulus to the discovery of both drugs and procedures for relief of pain.

The pain in the post-operative period demands relief not only on humanitarian ground, but also to reduce physical morbidity following the operation. In post-operative period when the effect of the anaesthetic disappears, the tissue injury persists and pain producing substances which are liberated during the operation greatly reduce the normally high threshold of the nociceptors, so that innocuous stimulation produces pain.

A wide range of options exist to combat pain, both pharmacologically and non-pharmacologically. However, despite the increasing complex armamentarium that we have at our disposal, the satisfactory alleviation of pain remains a difficult goal. Thus, the advances in anaesthetic techniques are rather a reflection of our constant efforts to obtain more effective and safer analgesia.

Effective pain control also facilitates rehabilitation and accelerates recovery from surgery.

Although single-shot neuraxial analgesic

techniques such as epidural blocks produce effective analgesia, they are associated with untoward effects such as motor and sensory blockade in the lower limbs. This results in delayed ambulation and recovery, along with decreased patient comfort and satisfaction. Also, the technique is labour intensive and has the risk of serious neuraxial morbidity, albeit rare . Furthermore, it is not always possible to provide neuraxial analgesia due to logistic issues and/or the presence of medical contraindications .

Given these issues, there is considerable potential for a regional technique such as TAP blockade to comprise an effective component of a multimodal regimen for post-operative analgesia following infra-umbilical surgeries.

The transversus abdominis plane block is a relatively new regional anaesthesia technique that can be used for post-operative pain control in abdominal, gynaecologic or urologic surgeries involving the T6 to L1 distribution.

When compared with epidural analgesia, TAP block analgesia does not cause haemodynamic imbalance, spares motor and sensory function of the lower limbs and can be used in patients requiring anticoagulation medication. Also, it provides effective analgesia with a better safety profile, by avoiding the addition of opioids which have significant adverse effects including sedation, nausea, vomiting, urinary retention, respiratory depression, delayed recovery of colonic mobility, and prolonged post-operative ileus .

Despite a low risk of complications and a high success rate using modern techniques, TAP blocks remain overwhelmingly underutilized. There is a paucity of literature on the efficacy of TAP block for control of post-operative pain in patients undergoing infra-umbilical abdominal surgery, in comparison to epidural block.

Selection of Study drug Concentration and Dosage

The efficacy of 0.375% bupivacaine in a dosage of 2 mg/kg has been successfully observed in a few studies like by O'Donnell et al. in 2006 in patients who underwent open retropubic prostatectomy , and by Niraj et al. in 2009 in patients admitted to the intensive care unit following major intraabdominal surgery . They both observed lower mean VAS scores, reduced morphine consumption and no adverse effects post-operatively.

Hence, we chose 0.375% bupivacaine 2 mg/kg to provide both an effective, yet safe concentration

and dosage for prolonged analgesia with a single-shot TAP block and epidural block.

Selection of TAP Block Technique

With the technique of ultrasound guided nerve blockade gaining popularity, USG guided TAP blocks have been performed to confirm the needle position in the TAP block. However, injection via Petit's triangle using anatomical landmark technique resulted in reliable deposition into the transversus abdominis plane.

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 three muscle layers of the abdominal wall, there is variation in these muscle layers that can restrict the use of ultrasound over the lumbar triangle of Petit. 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.

Moreover, it may not always be possible to use ultrasound guided techniques for administering TAP block where such facilities are not available, such as peripheral health centers. Hundred percent success rates with TAP block have been obtained using landmark technique for posterior approach of block. As real time USG guidance may increase the efficacy of TAP block, it will not change the primary findings of this study.

Demographic Data

The demographic data of the patients; including age, gender, weight, height and ASA Class, in both the study groups were comparable in both of our study groups.

Haemodynamic Parameters

As seen in tables and the graphs the heart rate, mean arterial pressure, respiratory rate and oxygen saturation were comparable between the two groups throughout the post-operative period with no significant change in hemodynamic parameters from the baseline. Haemodynamic parameters between the two groups were comparable on applying Student s unpaired t-test (p > 0.05) and on applying repeated measure ANOVA (p>0.05),

with no significant statistical difference in either case.

Parikh et al. in 2013 observed stable haemodynamic parameters using 0.375% bupivacaine while Fuladi et al. in 2014 demonstrated stable haemodynamic parameters using a lower concentration of 0.25% bupivacaine administered via TAP block for postoperative analgesia in patients undergoing lower abdominal surgery.

Considerably longer duration of post-operative analgesia was observed in Group T (420.03 ± 30.42 minutes), as compared to Group E (240.27 ± 30.01 minutes) which was statistically significant (p<0.05).

The number of patients having post-operative nausea and vomiting between the two groups was comparable with no significant statistical difference (p>0.05). No other adverse effects were observed in either of the patient groups.

With the above observations, it can be concluded that 0.375% bupivacaine administered either in the transversus abdominis plane, or through a catheter in the epidural space as a single dose provides satisfactory post-operative analgesia in both the groups.

However, the reduction in post-operative pain intensity with considerably lower VAS scores at rest, combined with longer duration of analgesia and sparing of the motor and sensory function of the lower limbs which allowed for early ambulation in patients in the TAP group facilitated a greater degree of post-operative care, and thereby resulted in high patient satisfaction levels.

Also, TAP block analgesia obviates the need for an epidural catheter whenever not available.

In conclusion, TAP block using 0.375% bupivacaine seems to hold considerable promise for patients undergoing infra-umbilical surgical procedures and is an effective alternative to epidural analgesia on account of its efficacy, safety, affordability and simplicity.

Conclusion

In this comparative observational study, comparison of 0.375% bupivacaine through transversus abdominis plane block versus epidural block for post-operative pain in patients undergoing infra-umbilical abdominal surgery was studied.

It was concluded that there is no significant

change in hemodynamic parameters from the base line between the two groups throughout the postoperative period.

The quality of post-operative analgesia in patients who were administered TAP block was significantly better than in patients who were administered epidural analgesia.

VAS scores at rest in patients who were administered TAP block were significantly lower than in patients who were administered epidural analgesia.

Patient satisfaction score in patients who were administered TAP block were significantly higher than in patients who were administered epidural analgesia.

The duration of post-operative analgesia in patients who were administered TAP block was significantly longer than in patients who were administered epidural analgesia.

The incidence of patients having post-operative nausea and vomiting in patients receiving TAP block or epidural analgesia was not significant. No other adverse effects were observed in either of the patient groups.

In conclusion, 0.375% bupivacaine administered through transversus abdominis plane block is an effective alternative to epidural analgesia for control of post-operative pain in patients undergoing infra-umbilical surgical procedures.

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