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RESEARCH ARTICLE

EVALUATION OF POSTOPERATIVE ANALGESIC EFFICACY OF ULTRASOUND GUIDED TRANSVERSUS ABDOMINIS PLANE BLOCK PLUS IV DICLOFENAC VERSUS IV DICLOFENAC IN LOWER ABDOMINAL SURGERIES

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ABSTRACT

Introduction: After lower abdominal surgeries, postoperative discomfort and pain can be anticipated. The provision of effective postoperative analgesia is of key importance to facilitate early ambulation, reduce pain on physical straining such as coughing, avoid emotional stress and prevention of postoperative morbidity. The use of TAP block,in lower abdominal surgeries is relatively less common. This may be attributed to the usage of ilioinguinal-iliohypogastric (IHN) block, However, after IHN block, the duration of the block is not prolonged enough to allow pain control during all the postoperative period .Also, the reliability of the technique is variable as it is performed blindly and the incidence of peritoneal puncture and consequent peritonitis is considerable. In this context, our study was designed to hypothesize that an ultrasound guided TAP block in addition to conventional analgesics may improve pain relief after lower abdominal surgeries, thus, facilitating early ambulation and improved patient satisfaction. **Material and methods:** 74 male patients belonging to ASA grade I and II physical status, scheduled for lower abdominal surgeries under spinal anaesthesia were randomized into 2 groups of 37male patients each, using a computer generated random number table-

- Spinal anesthesia plus postoperative TAP block and IV diclofenac (Group A), and,
- Only spinal anesthesia without TAP block and only IV diclofenac (Group B).

Results: Both groups were comparable with respect to age, ASA grade, weight and duration of surgery. Patients who received TAP block had a longer time to first rescue analgesic request (tramadol) and lesser total rescue analgesic requirement over 24 hrs when compared to patients who did not receive the block. The total tramadol requirement over 24 hrs was 133 mg in control group as compared to 73 mg in patients who received TAP block. Addition of ultrasound guided TAP block to conventional analgesics thus prolonged the duration of analgesia approximately by more than two hours and also reduced total tramadol requirement by nearly half, thus reducing nausea. **Conclusion:** The present study demonstrated that the addition of ultrasound guided TAP block to conventional analgesics (IV Diclofenac) following lower abdominal surgeries prolonged the time to first rescue analgesic request and reduced total opioid requirements postoperatively.

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INTRODUCTION

"For all the happiness mankind can gain is not in pleasure but in rest from pain."

John Dryden (1661-1731)

The international association for the study of pain defines pain as an "unpleasant sensory and emotional experience associated with acute or potential tissue damage or described in terms of such damage".

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Any postoperative analgesic technique should meet three criteria viz. effective, universally applicable and safe. Failure to relieve pain can lead to severe physiologic responses that are associated with increased morbidity, mortality and costs. Lower abdominal surgeries are commonly performed under neuraxial blockade, or general anaesthesia often combined with an ilioinguinal-iliohypogastric nerve (IHN) block or surgical field infiltration with a long-acting local anaesthetic (LA) agent. The provision of effective postoperative analgesia is of key importance to facilitate early ambulation, reduce pain on physical straining such as coughing, avoid emotional. Regional blocks of the anterior abdominal wall can significantly help with post-operative analgesia in these patients especially when used as a part of multimodal technique.

The nerves that supply anterior abdominal wall course through the neuro-fascial plane between the internal oblique and transversus abdominis muscles.Transversus abdominis plane (TAP) block is a regional anaesthetic technique that blocks the abdominal wall neural afferents by introducing local anaesthetic into the neuro-fascial plane between the internal oblique and the transversus abdominis muscles. Rafi first described the TAP block in 2001 using the anatomical landmark of the lumbar triangle of Petit.In 2004, McDonnell et alpresented preliminary work on TAP blocks in cadavers and in healthy volunteers at the scientific meeting of the American Society of Anaesthesiologists. An ultrasound guided approach for TAP block was first described in 2007 by Hebbard et al . The TAP blocks are increasingly being used as an adjunct for postoperative analgesia in current practice, with bilateral blocks being given in case of surgeries such as caesarean section, abdominal hysterectomy, open cholecystectomy, open radical prostatectomy and colorectal resection, and, unilateral blocks being employed in cases such as open appendectomies and renal transplant donors. The block has also become an option in the scenario of emergency laparotomies, where one encounters patients on anticoagulant therapy in whom the introduction of epidural needle is contraindicated.

The use of TAP block in lower abdominal surgeries is relatively less common. This may be attributed to the usage of ilioinguinal-iliohypogastric block, whenever required. Ilioinguinal-iliohypogastric nerve block, usually performed blindly, has been documented to provide pain relief during the early postoperative hours. However, after IHN block, the duration of the block is not prolonged enough to allow pain control during all the postoperative period and pain relief can also be incomplete. Also, the reliability of the technique is variable as it is performed blindly and the incidence of peritoneal puncture and consequent peritonitis is considerable.

In this context, our study was designed to hypothesizethat an ultrasound guided TAP block in addition to conventional analgesics may improve pain relief after lower abdominal surgeries, thus, facilitating early ambulation and improved patient satisfaction.

Aim and objectives

Aim of the study: To evaluate postoperative analgesic efficacy of Ultrasound Guided unilateral Transversus Abdominis Plane Block plus IV Diclofenac versus IV Diclofenac in patients undergoing lower abdominal surgeries.

Objectives of the study

- To clinically assess the pain relief, in terms of visual analogue scale (VAS) pain scores.
- To evaluate the side effects of the block and document any adverse events occurring during the study.
- To study the effect of the block on hemodynamic parameters in the postoperative Period.
- To assess the amount of opioid consumption in the initial 24 hrsof thepost-operative period and note the time elapsed before first opioid requirement.
- To analyze the overall patient satisfaction with regard to pain relief.

MATERIALS AND METHODS

Study Population: We conducted this study after obtaining approval from the institutional review board and the ethical clearance committee of the ASRAMS. 74 male patients belonging to "American Society of Anaesthesiology" (ASA) grade I and II physical status, scheduled for lower abdominal surgeries like unilateral open inguinal hernia repair(20) open appendectomy(17) under spinal anaesthesia in each group were included in the study. Written informed consent was obtained from all the patients. The patients were randomized into 2 groups of 37male patients each, using a computer generated random number table

- Spinal anesthesia plus postoperative TAP block and IV diclofenac (GroupA), and,
- Only spinal anesthesia without TAP block and only IV diclofenac (Group B).

Study design: A prospective randomized controlled, single blinded clinical study conducted in ALLURI SITA RAMARAJU ACADEMY OF MEDICAL SCIENCES (ASRAMS) from December 1st 2015 to September 30th 2017.

CALCULATION OF SAMPLE SIZE

Sample size is calculated using the following formula,

Formula:

$$n = \frac{t^2 \times p(1-p)}{m^2}$$

where,
n = required sample size
t = confidence level at 95% (standard value of 1.96)
p = estimated prevalence of unilateral inguinal hernia cases undergoing surgery in the project area = 5% = 0.05
m = margin of error at 5% (standard value of 0.05) = 0.05

Substituting the above mentioned values in the formula, we get Required sample size, n= {1.962×0.05(1-0.05)}/0.052 = 72.99, rounded to 74, for the convenience of dividing into 2 equal groups.

Inclusion Criteria

- Patients of either gender between 18 and 80 years of age.
- Patients scheduled to undergo unilateral open inguinal hernia repair surgeries and open appendectomies.
- Patients who give informed valid consent.
- Patients belonging to American Society of Anaesthesiologist (ASA) grade I or II.

Exclusion Criteria

- Patient refusal.
- Patients with coagulopathy or under medication on anticoagulants within the last one week before surgery.
- Patients with known allergy to local anaesthetics.
- Patients posted for emergency surgery.
- Pregnant women.
- Patients with height less than 150 cm and with BMI less than 18 or more than 35.
- Surgeries extending more than two and half hrs or in which any intraoperative surgical complications occur.
- Inadequately acting or patchy spinal block, converted to general anaesthesia during course of surgery.

METHODOLOGY

Preoperative: Pre anesthetic examination included relevant clinical history, general examination, systemic examination of

cardiovascular system, respiratory system, central nervous system and abdominal system. Basic investigations like haemoglobin estimation, total blood count, differential blood count, random blood sugar, blood urea, serum creatinine, serum electrolytes and coagulation profile were assessed and verified before including the patients in the study. All patients received oral alprazolam 0.5 mg the night before surgery and oral rantidine 150 mg in the morning of the day of surgery. Patients in both the groups were counselled about the intensity of pain normally associated with the surgery and pain relief that could be achieved with the technique employed. Patients were trained to assess pain using visual analogue scale (VAS) during preoperative evaluation. The procedure of TAP block, effects and possible complications were explained to patients of both groups.

To assist with identifying these structures, the probe was moved anteriorly to the rectus sheath and then the fascial planes are followed back out laterally. The final position of the probe was no further anterior than the anterior axillary line. The TAP block was performed only if the views were satisfactory. A 23G Quincke spinal needle with 10 cm extension tubing was connected and flushed with 2 ml of saline. The needle was introduced anteriorly in plane under real time ultrasound guidance to lie between the internal oblique and the transversus abdominis muscles with the tip in the midaxillary line. 2 ml of study drug was used to separate fascial layers to confirm needle location. A total of 20 ml of study solution of 0.5% bupivacaine was injected on the operated side in 5 ml increments after aspiration to avoid intravascular placement.

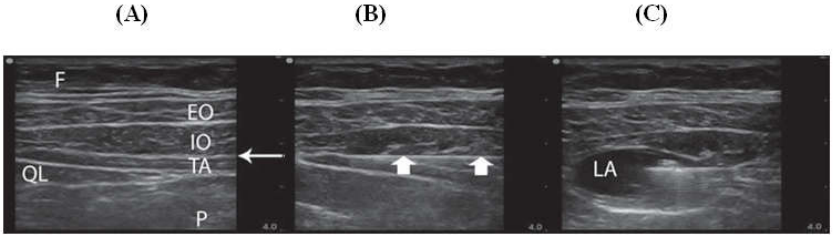


Figure 13. Sonographic anatomy of the ultrasound guided TAP block

Intraoperative: In the operating room, all patients were monitored by non-invasive blood pressure monitoring, five lead electrocardiogram and pulse oximetry. Spinal anaesthesia was initiated in the right lateral position at the L_{2-3} or L_{3-4} interspace with 15 mg of hyperbaric bupivacaine. The time of giving spinal anaesthesia was noted. The patient was then placed in supine position and supplemental oxygen was administered through face mask at 4 litres per minute. Surgery was allowed to proceed after T_{6-8} sensory blockade to pinprick sensation had been established. Intravenous crystalloids and ephedrine or phenylephrine were administered as needed to treat hypotension (mean blood pressure of 70 mm Hg or less).
At the end of surgery, after operative site dressing, an ultrasound guided TAP block was given by the anaesthesiologist to 'Group A' patients using a total volume of 20 ml of 0.5% bupivacaine on the side of the surgical incision.

Ultrasound guided TAP block was given to 'Group A' patients as described by Hebbard and colleagues[11]. After covering the wound with a dressing, the procedure was performed using strict aseptic technique (gown, gloves, facemask and protective sheath for the ultrasound probe). The block was performed using the SIEMENS ultrasound machine. A linear array US probe (12 MHz) was positioned in a transverse plane in the midaxillary line in the axial plane halfway between the iliac crest and the costal margin. Views were considered satisfactory if subcutaneous fat, external oblique muscle,internal oblique muscle, transversus abdominis muscle, peritoneum and intraperitoneal structures were identified. The above images show the lateral abdominal wall using a probe held in the midaxillary line in the axial plane. The right of the image is anterior. **(A)** Narrow arrow, TAP; EO, external oblique muscle; IO, internal oblique muscle; TA, transverses abdominis muscle; QL, quadratus lumborum muscle; F, subcutaneous fat; P, intraperitoneal structures. **(B)** Broad arrows, needle with the tip positioned in the TAP. **(C)** Local anaesthetic forming a lens shaped space in the TAP; LA, local anaesthetic.

After each 5ml bolus, patients were monitored for an increase in heart rate or signs of local anaesthetic toxicity such as tinnitus, perioral numbness, metallic taste in mouth, slurring of speech and mental status changes. An echolucent lens shaped space between the two muscles was taken as a successful injection.

Postoperative: In Group A patients, 0 hour was considered after the TAP block was administered before shifting to post anaesthesia care unit (PACU) and in Group B patients, 0 hour was taken as the end of surgery before shifting to PACU. Patients were observed in the PACU by a blinded investigator till motor blockade wore off (ability to move ankle joint). This was considered as the end of duration of spinal anaesthesia.

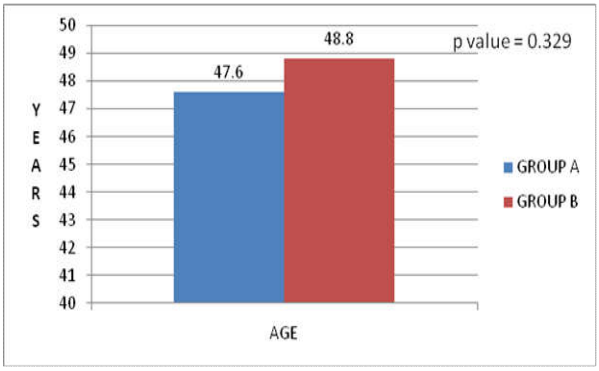
Postoperative analgesia for both the groups for 24 hours consisted of intravenous diclofenac 75mg at the end of surgery and every 12 hours thereafter. And whenever visual analogue score was ≥ 4, rescue analgesia was provided with intermittent boluses of tramadol 1-2mg/ kg given by intravenous route. Postoperatively, time to the first rescue analgesic (tramadol) request and supplemental rescue analgesic requirements with respect to 0 hrs were recorded over 24 hrs by the blinded investigator. Postoperative pain assessment was done in all patients using visual analogue scale (VAS) score. Haemodynamic parameters (blood pressure and heart rate) and side effects were noted in all patients at time points 0, 1, 2, 4, 8, 12 and 24 hrs postoperatively. Side effects such as nausea, vomiting, hypotension (mean blood pressure $\leq$ to 70), hypertension (mean blood pressure ≥ 120), bradycardia (heart rate ≤ 50), respiratory depression (respiratory rate ≤ 8 breaths per minute), restlessness, dysphoria, hallucinations, urinary retention or any other if occurred were noted. The time to first rescue analgesic request and supplemental rescue analgesic requirement over 24 hours were recorded. Nausea and vomiting was treated with 4mg of ondansetron intravenously as and when required upon patient request. The number of doses of antiemetics administered by nurses was recorded as a

measure of antiemetic requirements. Twenty four hours after surgery, patients were asked to rate their satisfaction with pain management on a 3 point scale (1= highly satisfied, 2= satisfied, and 3= dissatisfied). The primary outcome measure in this study was to compare the time to first rescue analgesic request and the total cumulative requirements of rescue analgesic during 24 hrs postoperative study period between the two groups. The secondary outcome measures included assessment of pain scores (VAS), haemodynamics, side effects and patient satisfaction.

STATISTICAL METHODS

The demographic data were analysed using Student's t-test. The time to first request for opioid was analysed using Student's t-test. Normally distributed data were presented as mean ± standard deviation (SD), nonnormally distributed data were presented as median (interquartile range). Visual analogue scores were analysed with ANOVA (Analysis of variance) using general linear model for repeated measures (SPSS 9) and by Student's t-test. The complications were analysed using chi-square test. $p<0.05$ was considered statistically significant. For multiple comparisons, Bonferroni correction was used as appropriate and $p<0.006$ was considered statistically significant.

OBSERVATION AND RESULTS

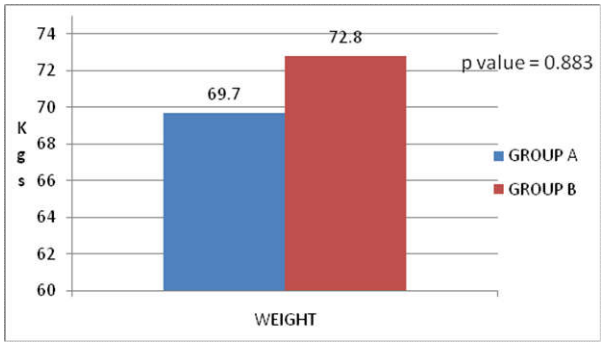


Graph 1. Age (years) distribution

Demographic profile

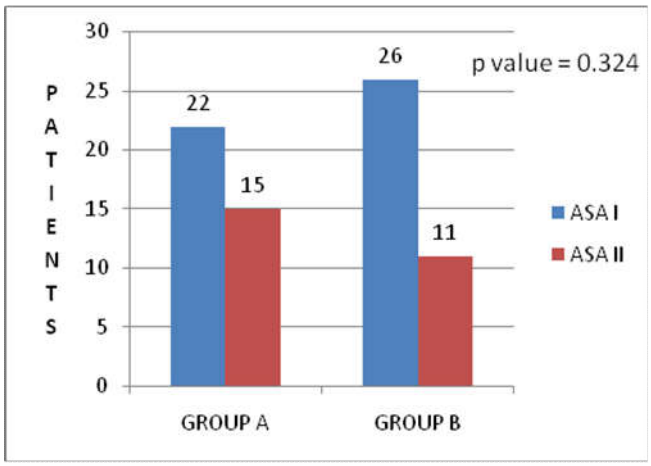
Age (Graph 1)

The mean age of patients in Group A and Group B was 47.6 ± 2.9 yrs and 48.8 ± 3.6 yrs respectively. There was no statistically significant difference between the groups with regards to age.



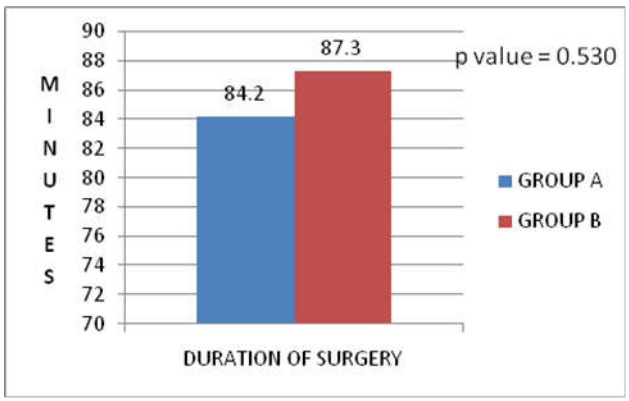
Graph 2. Weight (kg) distribution

Weight (Graph 2)



Graph 3. ASA grade distribution

The mean weight of patients in Group A and Group B was 69.7 ± 10.5 kg and 72.8 ± 8.1 kg respectively. There was no statistically significant difference between the groups with regards to weight. The mean ASA grade distribution (I:II) in Group A and Group B was 22:15 and 26:11 respectively. There was no statistically significant difference between the groups with regards to ASA grading.



Graph 4. Duration of surgery (min)

Duration of surgery (Graph 4)

The mean duration of surgery in Group A and Group B was 84.2± 0.3min and 87.3± 0.3 min respectively. There was no statistically significant difference between the groups with regards to duration of spinal anaesthesia.

Rescue analgesia (tramadol) requirements: The median (interquartile range) time for first tramadol request was 4 hrs (2 hrs 30 min to 8 hrs 45 min) in GroupA patients and 1 hr 45 min (1 hr to 2 hrs 30 min) in Group B patients. This was a statistically significant difference (p=0.001) (Table 4). The mean total tramadol consumption in Group A and Group B was 73 ± 14 mg and 133 ± 28mg respectively. At the end of 24 hrs, the total requirements of tramadol was higher in Group B patients as compared to Group A patients which was statistically significant (p=0.003) (Table 4) (Graph 5). The mean tramadol requirement in initial 12 hours in Group A and Group B was 67 ± 15 mg and 110 ± 18 mg respectively, Group A being lesser, which was statistically significant (p=0.008) ((Graph 5).

Table 1. Time to first tramadol request (hrs), total requirement of tramadol over 24hrs (mg) and requirement of tramadol in initial 12 hrs (mg).

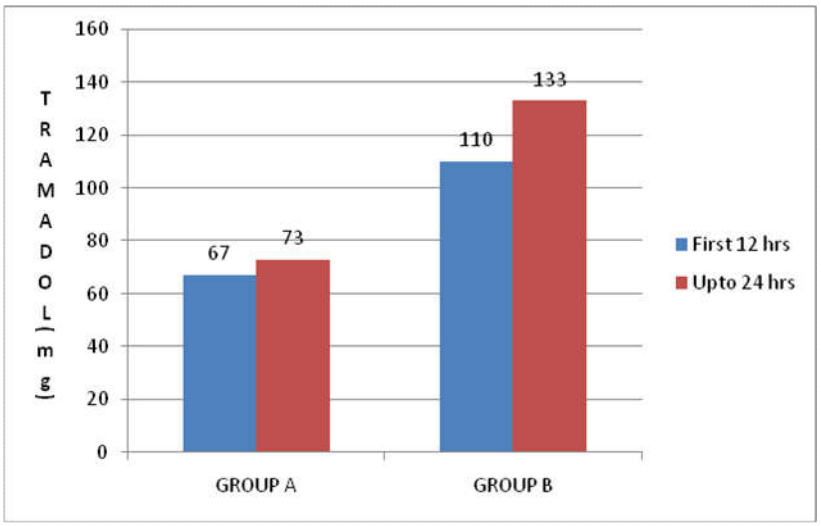
	Group A	Group B	p value
Time to first tramadol requestmedian (interquartile range)	4 hrs (2 hrs 30 min to 8 hrs 45 min)	1 hr 45 min (1 hr to 2 hrs 30 min)	0.001
Total tramadol requirement mg (mean ± SD)	73 ± 14	133 ± 28	0.003
Tramadol requirement in first 12 hrs (mg)	67 ± 15	110 ± 18	0.008

Table 2. Comparison of incidence of side effects .n=no of patients

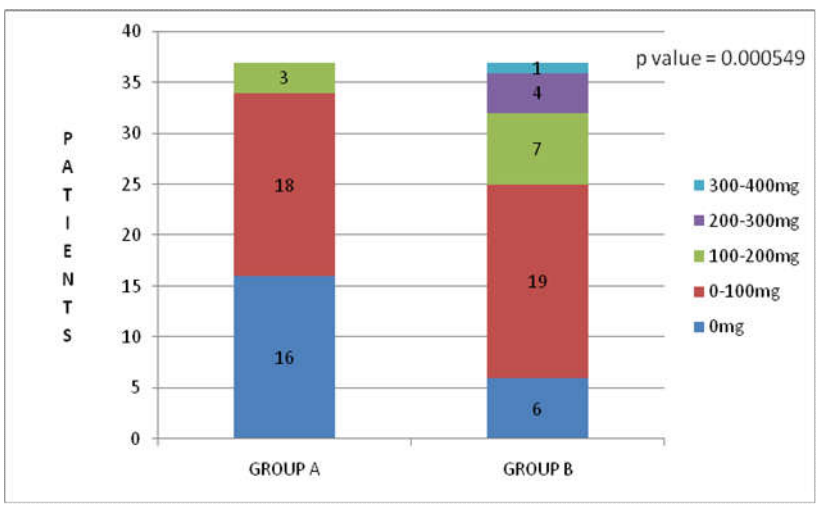
	Group A (n)	Group B (n)	p value
Nausea	1	6	0.043
Vomiting	1	2	0.546
Hypotension	0	0	
Hypertension	0	0	
Bradycardia	0	0	
Hypoventilation	0	0	
Sedation	0	0	
Urinary retention	0	0	
Restlessness	0	0	
Others	0	0	

Table 3. Patient satisfaction

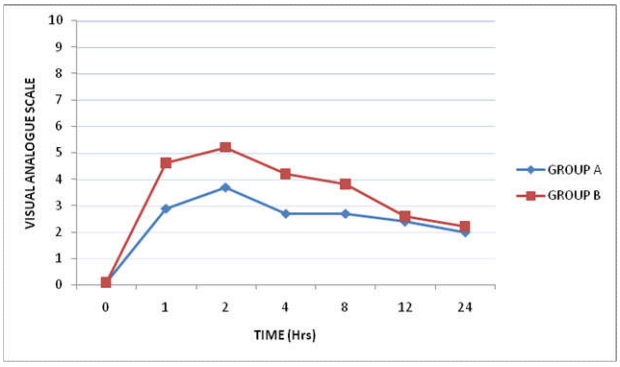
	Group An (%)	Group B n (%)	p value
Highly Satisfied	10(28)	8(22)	
Satisfied	25(69)	21(58)	0.079
Dissatisfied	2(6)	8(19)	



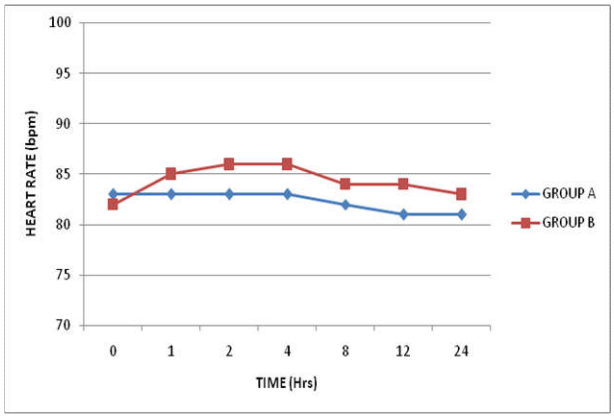
Graph 5. Requirement of tramadol in initial 12 hrs (mg) and total requirement of tramadol over 24 hrs (mg)



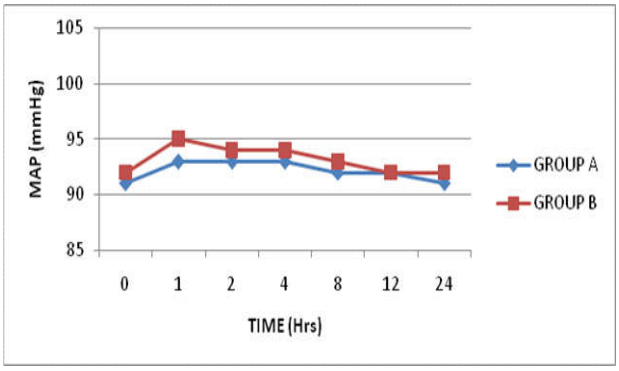
Graph 6. Number of patients in each group who have received 0 mg, 0-100 mg, 100-200 mg, 200-300 mg and 300-400 mg of tramadol respectively



Graph 7. VAS score distribution



Graph 8. Heart rate (beats per minute)



Graph 9. Mean arterial pressure (MAP) (mmHg)

Sixteen (41.7%) patients in Group A and six (13.8%) patients in Group B received 0 mg of tramadol. Eighteen (50%) patients in Group A and nineteen (52.8%) patients in Group B received in between 0-100 mg of tramadol. Three (8.3%) patients in Group A and seven (19%) patients in Group B received 100-200 mg of tramadol. Zero patients in Group A and four (11.1%) patients in Group B received 200-300 mg of tramadol. Zero patients in Group A and one (2.8%) patient in Group B received in between 300-400 mg of tramadol. The tramadol requirements between the 2 groups were statistically significant ($p < 0.001$) (Table 5) (Graph 6).

Vas score for pain: VAS scores were comparably similar in both the groups at 0, 8, 12 and 24 hr intervals postoperatively. But there was statistically significant difference with respect to pain scores between the groups at 1, 2, 4 hr intervals, with the pain scores being lower among Group A patients (Graph 7).

Heart Rate: Heart rate (beats/minute) at 0 hrs in Group A and Group B was 83 ± 8 and 82 ± 10 respectively.

Within the groups, there was no statistically significant change with respect to heart rate during the 24 hours study period with respect to baseline. When Group A and Group B were compared, there was no statistically significant difference in between the groups (Graph 8).

Mean arterial pressure: At 0 hours, mean arterial pressure (MAP) in Group A was 91± 8 mmHg and in Group B was 92 ± 10 mmHg. Within the groups, there was no statistically significant change with respect to MAP during the 24 hrs study with respect to baseline. When Groups A and B were compared, there was no statistically significant difference between the groups with respect to MAP (Graph 11)

Side effects: In Group A, 1 patient had nausea as against 6 patients in Group B which was statistically significant ($p=0.043$). In Group A, 1 patient had vomiting as against 2 patients in Group B ($p=0.546$) which was not statistically significant (Table 11).

Patient Satisfaction: At the end of 24 hrs, there was no statistically significant difference with regards to patient satisfaction with pain relief (Table 12).

DISCUSSION

This prospective randomized, single blinded controlled trial conducted in patients undergoing lower abdominal surgeries, demonstrated that supplementing a standard multimodal analgesic regimen with a TAP block resulted in reduced 24 hrs opioid requirements and pain scores, as well as delayed request for supplemental opioid analgesia, compared with the standard regimen alone. Patients who received TAP block had a longer time to first rescue analgesic request (tramadol) and lesser total rescue analgesic requirement over 24 hrs when compared to patients who did not receive the block. Patients who received TAP block were comfortable for a period of about four hours before the first rescue analgesic was sought, whereas in control group, they were comfortable for a period of only about one hour forty five minutes before the first dose of rescue analgesia. The total tramadol requirement over 24 hrs was 133 mg in control group as compared to 73 mg in patients who received TAP block. Both groups were comparable with respect to age, ASA grade, weight and duration of surgery. Postoperative analgesia was assessed by using visual analogue scale (VAS) pain score. Postoperative analgesia for both the groups for 24 hours consisted of intravenous diclofenac 75mg at the end of surgery and thereafter every 12 hours. For breakthrough pain, the rescue analgesic given was tramadol 1 mg/kg intravenously when VAS score was ≥ four. There was no statistically significant difference with respect to pain scores between the groups at all study intervals. There was no clinically or statistically significant increase or decrease in the heart rate and blood pressure between the groups throughout the study. Addition of ultrasound guided TAP block to conventional analgesics thus prolonged the duration of analgesia approximately by more than two hours and also reduced total tramadol requirement by nearly half, thus reducing nausea. There were no added complications and no difference with respect to patient satisfaction with pain relief.

Conclusion

The present study demonstrated that the addition of ultrasound guided TAP block to conventional analgesics (IV Diclofenac) following lower abdominal surgeries prolonged the time to

first rescue analgesic request and reduced total opioid requirements postoperatively. There was superior analgesia with addition of TAP block in terms of reduced requirements of opioids postoperatively, though clinically, patients did not differ with respect to pain scores at all study intervals. The block was easy to perform, provided reliable and effective analgesia in this study and no complications due to the TAP block were detected.

List of abbreviations

ASA:American Society of Anaesthesiologist

A:Appendicitis
BMI : Body Mass Index
BP:Blood Pressure
DBP:Diastolic Blood Pressure
ECG:Electrocardiogram
EO:External oblique
GA:General Anaesthesia
Hb:Haemoglobin
HR:Heart Rate
IO:Internal oblique
LA:Local Anaesthesia
LTOP:Lumbar triangle of Petit
MAC:Monitored Anaesthesia Care
MAP:Mean Arterial Pressure
NIBP:Noninvasive Blood Pressure
PACU:Post Anaesthesia Care Unit
PCA:Patient Controlled Analgesia
SBP : Systolic blood pressure
SD:Standard Deviation
SpO_2:Oxygen saturation
TAP:Transversus Abdominis Plane
VAS:Visual Analogue Scale
VNRS:Visual Numerical Rating Scale
US : Ultrasound

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