

Efficacy of Ultrasound-Guided Transversus Abdominis Plane Block versus Epidural Block for Postoperative Analgesia Following Lower Abdominal Cancer Surgeries- A Randomised Clinical Study

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ABSTRACT

Introduction: Effective post-operative analgesia improves patient's outcome and satisfaction. Many methods are available to provide best analgesia after major abdominal surgery. Epidural anaesthesia is "gold standard" but it is associated with its own drawbacks. Transversus Abdominis Plane (TAP) block is a comparable technique to epidural to provide reliable analgesia in lower abdominal surgeries.

Aim: To compare the efficacy of Ultrasonography (USG) guided TAP block and the epidural block for the post-operative pain management in lower abdominal cancer surgery.

Materials and Methods: This randomised clinical double-blinded study, conducted in 60 female patients undergoing lower abdominal cancer surgery under General Anaesthesia (GA) from July 2022 to September 2022. Patients were randomised to Group-E and Group-T. Group-E (Epidural) received injection (inj.) 0.2% Ropivacaine (10 ml) plus inj. Morphine 2 mg via epidural. Group-T (TAP) received inj. 0.2% Ropivacaine (20 ml) plus inj. Morphine 2 mg on each side via USG guided TAP block postoperatively. The Visual Analog Scale (VAS) Score, first rescue analgesia, total analgesic consumption and any side-effects in 24 hours were recorded. The Statistical Package

for Social Sciences (SPSS) version 22.0 International Business Management (IBM) Corporation (NY) was used for statistical analysis. Unpaired t test, Chi-square test and Fisher's-exact test and one-way Analysis of Variance (ANOVA) test were used as and when appropriate.

Results: Data of total 60 female patients, 30 patients in each group (Group E mean age: 47.33±9.614 years and Group T mean age: 47.77±12.370 years) was collected and analysed. Both the groups were comparable with respect to age, height, weight, American Society of Anaesthesiologists (ASA) grade, mean duration of surgery and duration of anaesthesia ($p>0.05$). More patients in group-E had moderate pain at rest and coughing (VAS-4 to 6) at six hours and 12 hours which is statistically significant ($p<0.05$). None of the patient in both groups had severe pain. Time for need of first rescue analgesic was lower in Group-E (399.6±25.32 min) and in Group-T it was higher (462.6±26.94 min) which is also statistically highly significant ($p<0.001$).

Conclusion: TAP has advantage over epidural in terms of effective postoperative analgesia, time of need and quantity of postoperative analgesics.

Keywords: Analgesic consumption, Major abdominal surgery, Visual analog scale

INTRODUCTION

Post-operative pain leads to detrimental acute and chronic effects with patient dissatisfaction. Untreated severe pain causes stimulation of the sympathetic system which results in increased heart rate, blood pressure, post-operative ileus, cardiac ischemia, pulmonary complications, delayed mobility and deep vein thrombosis [1]. Multimodal analgesia combining neuraxial opioids, systemic opioids to non-opioids is the best strategy to counteract these delirious effects. But the use of opioids is limited with side-effects like nausea, vomiting, sedation, urinary retention, delayed recovery of intestinal transit and respiratory depression [2].

Analgesia for abdominal surgery has pivoted on epidural analgesia, but transversus abdominis plane block is increasingly being used and compared for the analgesic efficacy and the side-effect profile [3]. The gold standard method to provide best analgesia after major abdominal and thoracic surgery is epidural analgesia [4]. But the unwanted side-effect of this method such as dural puncture, hypotension, post-operative urinary retention and delayed mobilisation of the patient opens up the innovation of another regional analgesia technique such as TAP block [5].

Many studies in the past have compared epidural and TAP block for post-operative analgesia following a variety of surgeries and the results were not consistent [6-8]. Ultrasound helps in better visualisation of muscle and deposition of local anaesthetic drug in the fascial plane between the internal oblique and transversus abdominis muscles [9]. A high success rate of blocked segments was shown at T-10 and T-11 [10]. The aim of this study was to compare the efficacy of USG guided TAP block which is a novel technique and the gold standard epidural block for the post-operative pain management in lower abdominal cancer surgery. Primary objective was pain intensity and secondary objectives were duration of analgesia and post-operative total rescue analgesic requirement.

MATERIALS AND METHODS

After obtaining institutional ethical committee approval (IEC number: IRC/2022/P-39, June 04, 2022) this randomised clinical double-blinded study was done in Gujarat cancer and research institute, Ahmedabad, Gujarat, India, from July 2022 to September 2022. After getting written informed consent, the present study was conducted on 60 adult female patients undergoing lower abdominal

cancer surgery. Participants and anaesthesiologist who recorded data were unaware of the study groups.

Sample size calculation: was done using formula $n=4 pq/E^2$ which is based on Hardy-Weinberg principle [2]. In this formula 'p' is the prevalence of gynecological oncosurgery at our hospital, q is p-1 and E is allowable error. Prevalance value in the present study was 60% and allowable error was 30% of prevalence. By incorporating the values, 24 patients were required for each group. Hence, sixty patients were included in this study to prevent attrition loss. Sixty patients were allocated randomly to two equal groups (30 patients/group).

Inclusion criteria: An 18-60 years female patients, ASA Physical status- I and II undergoing elective lower abdominal cancer surgery with longitudinal incision below umbilicus were included in study.

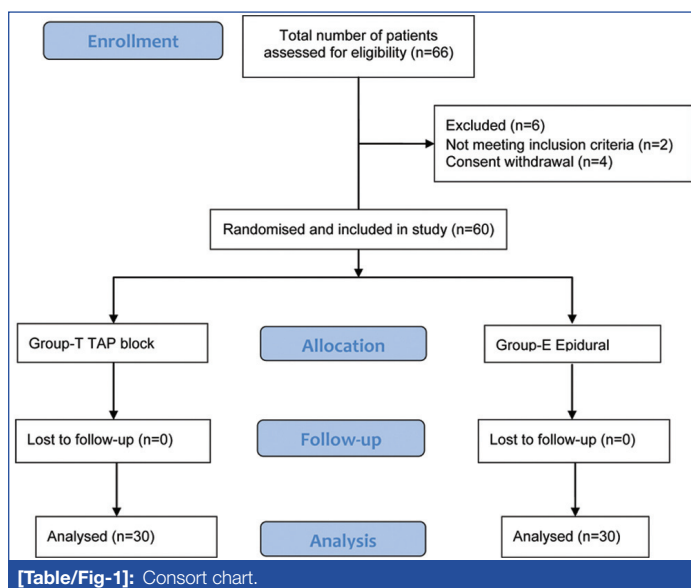
Exclusion criteria: Patient refusal, BMI >30 kg/m², coagulopathy, local site infection, haemodynamic instability, allergic to study drugs were excluded.

Procedure

A total of 60 included patients were instructed about VAS score preoperatively.

Sixty adult patients were randomised in two different groups (30 each) by using computer generated random numbers.

- Group-E- inj.0.2% Ropivacaine (10 mL) plus Inj. Morphine 2 mg via epidural.
- Group-T- inj.0.2% Ropivacaine (20 mL) plus Inj. Morphine 2 mg on each side via USG guided TAP block [Table/Fig-1].



All the patients underwent pre-anaesthetic check-up and all the routine and specific investigations were noted. Patients were kept nil per oral for six hours prior to operation. In Operation Theatres (OT), standard monitors were applied. Intravenous line secured with one 18-gauge cannula. In both the groups, patients were operated under general anaesthesia and premedicated with inj. ranitidine 50 mg. Inj. glycopyrrolate 0.2 mg and inj. ondansetron 8 mg were given intravenously [1].

Induction was done with Inj. fentanyl 2 mcg/kg, Inj. Thiopentone sodium (5 mg/kg) i.v. and Inj. Succinylcholine bromide (2 mg/kg) i.v. anaesthesia was maintained with 50% N₂O:50% O₂ plus sevoflurane. Inj. Atracurium 0.5 mg/kg loading dose followed by 0.1 mg/kg intermittent bolus were used to achieve muscle relaxation. Epidural catheter was placed before the induction when patient was awake. Patient was kept in lateral position under strict aseptic and antiseptic precaution local area was painted and draped. Inj. 2% lignocaine 2 cc was given locally. An 18 G Touhy's needle was inserted at L3-L4 level. Loss of resistance was used to identify

epidural space. A test dose of 3 mL of 2% lignocaine with adrenaline (1:2,00,000) was given to rule out intravascular or intrathecal placement. No drug was given via epidural catheter till the end of surgery. At the end of surgery and before reversal, aspiration through epidural catheter was done to confirm the absence of blood and CSF. Then bolus dose of 10 ml of 0.2% ropivacaine plus inj. morphine 2 mg was given [11], after that epidural catheter was reactivated after completion of 24 hours of study period.

Patients in Group-T received bilateral ultrasound guided TAP block at the end of the surgery and before reversal.

High-frequency linear transducer 8-13 MHz (Fujifilm sonosite, EDGE, USA, 2017 version) was used for this block. Patients were kept in supine position. Following skin and transducer preparation, the transducer was placed posterior to the midaxillary line between the iliac crest and the costal margin. The muscles of anterior abdominal wall external oblique, the internal oblique and transversus abdominis muscle and peritoneum were identified. A 23G Quincke's spinal needle was inserted perpendicular to the skin and advanced in-plane approach in between the internal oblique and the transversus abdominis muscle. Needle was directed to reach the fascial plane upon reaching the plane, hydrodissection was done with 2 ml of saline was injected to confirm correct needle position. After confirming the position 20 ml of 0.2% ropivacaine and inj. morphine 2 mg [12] as injected and the spread of local anaesthetic between internal oblique and transverse abdominis was visualised in real time through ultrasound. Same block was repeated on opposite side of abdomen using same technique and drugs.

All patients were given inj. diclofenac 75 mg infusion over 30 minutes and inj. ondansetron 0.1 mg/kg i.v. half-an-hour before reversal. With return of spontaneous respiration, the neuromuscular blockade was reversed with inj. glycopyrrolate 0.01 mg/kg i.v. and inj. neostigmine 0.05 mg/kg i.v. Patients were shifted to post-anaesthesia care unit. Pain score by VAS during rest and coughing, Pulse, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), respiratory rate and SpO₂ at 0, 1, 2, 4, 6, 12, 18 and 24 hours were noted postoperatively.

Post-operative pain was graded in 4 categories depending upon the VAS for pain score as:

- Nil=VAS score 0.
- Mild=VAS score 1-3.
- Moderate=VAS score 4-6 and
- Severe=VAS >6.

Time for need of first rescue analgesia and total analgesic consumption in 24 hours were recorded. Intravenous diclofenac 1.5 mg/kg i.v. in 20 ml NS was used as first line rescue analgesic if VAS score more than four and Inj. tramadol 1 mg/kg i.v. was used as second line rescue drug [13,14]. Patients were observed for adverse effects like sedation, motor block (Sedation score using Ramsay sedation assessment scale and motor block using Modified Bromage scale [4] were used), pruritus, nausea, vomiting, respiratory depression and hypotension, bradycardia, urinary retention, SpO₂ <94.

STATISTICAL ANALYSIS

The SPSS version 22 IBM Corp. (NY) was used for statistical analysis. Results on continuous measurements are presented on Mean±SD and analysed using unpaired t-test and Chi-square test. Results on categorical measurements are presented in Number (%). Shapiro-wilk test was also conducted to assess normal distribution. Pain scores at rest and coughing were compared using the Analysis of one-way Variance (ANOVA) test. The p-value <0.05 was considered statistically significant.

RESULTS

Data of total 60 participants, divided into 30 patients each in Group-E and Group-T was collected and analysed. [Table/Fig-2]

shows that both the groups were comparable with respect to age, height, weight, ASA grade, mean duration of surgery and duration of anaesthesia (p>0.05).

| Parameters | Group-E (n=30) | Group-T (n=30) | p-value |
|-----------------------------------|----------------|----------------|---------|
| Age (years) | 47.33±9.614 | 47.77±12.370 | 0.880 |
| Height (cm) | 155.27±2.363 | 155.40±2.283 | 0.825 |
| Weight (kg) | 55.63±4.476 | 56.37±5.543 | 0.575 |
| ASA grade (1/2) | 14/16 | 13/17 | 0.795 |
| Duration of surgery (minutes) | 241.80±15.12 | 245.20±13.98 | 0.370 |
| Duration of anaesthesia (minutes) | 266.40±14.55 | 266.57±11.77 | 0.961 |

[Table/Fig-2]: Demographic and clinical data.
ASA: American society of anaesthesiologists; Student t-test

[Table/Fig-3] shows the postoperative VAS score at different time intervals in both the groups. During 0, 1 hour, 2 hour, 4 hours, 18 hours and 24 hours there was no significant difference in VAS score between both the groups. VAS was higher at 6 hours and 12 hours in Group-E than Group-T.

| Time (hours) | VAS Score | Group-E | Group-T | p-value |
|--------------|-----------|------------|------------|--------------|
| 0 h | Nil | 28 (93.3%) | 28 (93.3%) | 1.000 |
| | Mild | 2 (6.7%) | 2 (6.7%) | |
| | Moderate | 0 | 0 | |
| 1 h | Nil | 28 (93.3%) | 28 (93.3%) | 1.000 |
| | Mild | 2 (6.7%) | 2 (6.7%) | |
| | Moderate | 0 | 0 | |
| 2 h | Nil | 28 (93.3%) | 28 (93.3%) | 1.000 |
| | Mild | 2 (6.7%) | 2 (6.7%) | |
| | Moderate | 0 | 0 | |
| 4 h | Nil | 26 (86.7%) | 27 (90.0%) | 0.688 |
| | Mild | 4 (13.3%) | 3 (10.0%) | |
| | Moderate | 0 | 0 | |
| 6 h | Nil | 0 | 0 | 0.002 |
| | Mild | 10 (33.3%) | 22 (73.3%) | |
| | Moderate | 20 (66.7%) | 8 (26.7%) | |
| 12 h | Nil | 0 (0.0%) | 5 (16.7%) | 0.046 |
| | Mild | 21 (70.0%) | 20 (66.7%) | |
| | Moderate | 9 (30.0%) | 5 (16.7%) | |
| 18 h | Nil | 0 | 0 | 0.592 |
| | Mild | 18 (60.0%) | 20 (66.7%) | |
| | Moderate | 12 (40.0%) | 10 (33.3%) | |
| 24 h | Nil | 0 | 0 | 0.592 |
| | Mild | 18 (60.0%) | 20 (66.7%) | |
| | Moderate | 12 (40.0%) | 10 (33.3%) | |

[Table/Fig-3]: Comparison of Visual Analog Scale (VAS) at rest at different time intervals.
ANOVA test used

[Table/Fig-4]: shows the postoperative VAS score at different time intervals in both the groups. During 0 hour, 1 hour, 2 hour, 4 hour, 18 hour and 24 hours there was no significant difference in VAS score on coughing between both the groups. VAS was higher at 6 hours and 12 hours in Group-E than Group-T. Group-E patients required rescue analgesic earlier compared to Group-T. There is no significance between total diclofenac and tramadol doses consumption between the groups [Table/Fig-5].

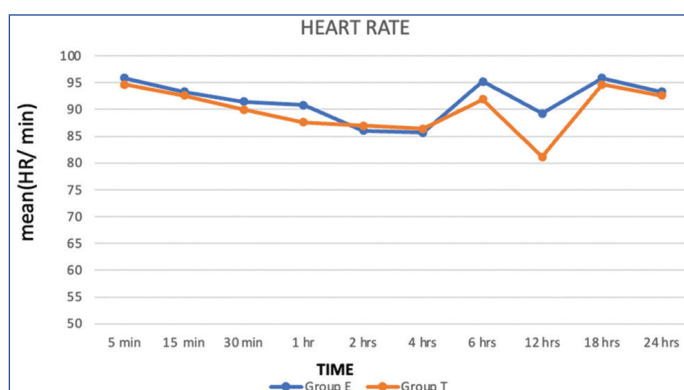
There were no significant changes in heart rate [Table/Fig-6] in both the groups during five minutes (p-value-0.559), 15 minutes (p-value-0.736), 30 minutes (p-value-0.454), one hour (p-value-0.104), two hours (p-value-0.50), four hours (p-value-0.60), 18 hours (p-value-0.559) and 24 hours (p-value-0.736). There were no significant

| Time (hours) | VAS Score | Group-E | Group-T | p-value |
|--------------|-----------|------------|------------|--------------|
| 0 h | Nil | 28 (93.3%) | 28 (93.3%) | 1.000 |
| | Mild | 2 (6.7%) | 2 (6.7%) | |
| | Moderate | 0 | 0 | |
| 1 h | Nil | 26 (86.7%) | 28 (93.3%) | 0.389 |
| | Mild | 4 (13.3%) | 2 (6.7%) | |
| | Moderate | 0 | 0 | |
| 2 h | Nil | 26 (86.7%) | 27 (90.0%) | 0.688 |
| | Mild | 4 (13.3%) | 3 (10.0%) | |
| | Moderate | 0 | 0 | |
| 4 h | Nil | 25 (83.3%) | 27 (90.0%) | 0.448 |
| | Mild | 5 (16.7%) | 3 (10.0%) | |
| | Moderate | 0 | 0 | |
| 6 h | Nil | 0 (0.0%) | 1 (3.3%) | 0.007 |
| | Mild | 8 (26.7%) | 19 (63.3%) | |
| | Moderate | 22 (73.3%) | 10 (33.3%) | |
| 12 h | Nil | 1 (3.33%) | 3 (10.0%) | 0.040 |
| | Mild | 14 (46.6%) | 21 (70.0%) | |
| | Moderate | 15 (50%) | 6 (20.0%) | |
| 18 h | Nil | 0 | 0 | 0.602 |
| | Mild | 16 (53.3%) | 18 (60.0%) | |
| | Moderate | 14 (46.7%) | 12 (40.0%) | |
| 24 h | Nil | 0 | 0 | 0.796 |
| | Mild | 15 (50.0%) | 16 (53.3%) | |
| | Moderate | 15 (50.0%) | 14 (46.7%) | |

[Table/Fig-4]: Comparison of VAS on coughing at different time intervals.
ANOVA test used; bold p-values are significant

| Parameter | Study group (Mean±SD) | | p-value |
|---|-----------------------|-------------|------------------|
| | Group-E | Group-T | |
| | Epidural analgesia | TAP block | |
| Time for need of First Rescue Analgesic (min) | 399.6±25.32 | 462.6±26.94 | <0.001 |
| Total doses of diclofenac consumption | | | |
| 1 | 10 (33.3%) | 12 (40.0%) | 0.592 |
| 2 | 20 (66.7%) | 18 (60.0%) | |
| Total doses of Tramadol consumption | | | |
| 0 | 19 (63.3%) | 21 (70.0%) | 0.584 |
| 1 | 11 (36.7%) | 9 (30.0%) | |

[Table/Fig-5]: Comparison of time for need of first rescue analgesic and total analgesic consumption between groups.
Chi-square test; bold p-values are significant

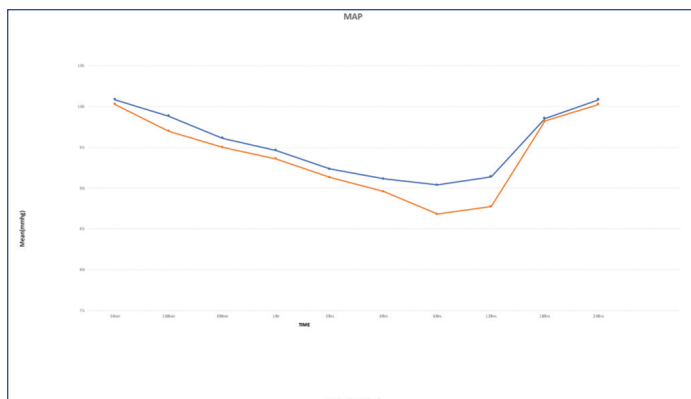


[Table/Fig-6]: Postoperative Heart Rate (HR) during first 24 hours in both groups.
Data presented as mean.

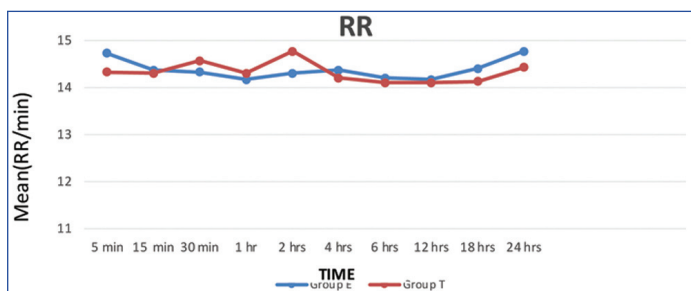
changes in Mean Arterial Pressure (MAP) [Table/Fig-7] in both the groups during five min (p-value-0.522), 15 minutes (p-value-0.065), 30 minutes (p-value-0.192), one hour (p-value-0.235), two hours (p-value-0.188), four hours (p-value-0.086), 18 hours (p-value-

0.675) and 24 hours (p-value-0.522) But significant increase in heart rate (at six hours p-value- 0.045 at 12 hours p-value-0.001) [Table/Fig-6] and MAP (at six hours p-value- <0.001, at 12 hours p-value- <0.001) [Table/Fig-7] were observed in Group-E as compared to Group-T.

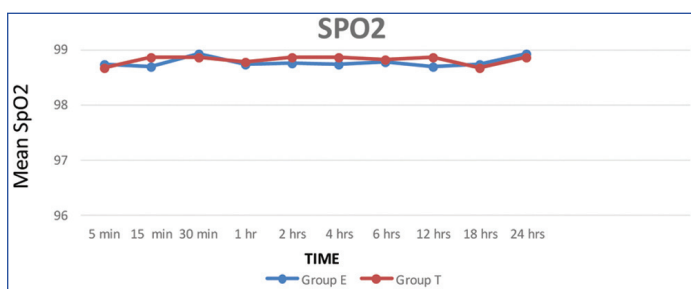
There were no significant changes in RR (p-value-0.317) and SpO₂ in both the groups (p-value-0.375) postoperatively during first 24 hours of study period [Table/Fig-8,9]. Total of 11 patients in Group-E reported vomiting and in Group-T, nine patients reported vomiting (p-value-0.584) (not significant). About four patients in both Group-E and Group-T had nausea (p-value-1). There was no case of pruritis, bradycardia, hypotension, respiratory depression, sedation (Ramsay sedation assessment scale) and motor blockage (Modified Bromage scale) in Group-E as well as Group-T.



[Table/Fig-7]: Postoperative mean arterial pressure (MAP) during first 24 hours in both groups. Data presented as mean.



[Table/Fig-8]: Postoperative mean Respiratory Rate (RR) during first 24 hours in both groups. Data presented as mean.



[Table/Fig-9]: Postoperative mean SpO₂ during first 24 hours in both groups. Data presented as mean.

DISCUSSION

In this study, TAP block and the epidural block was compared to determine efficacy of the post-operative pain relief in lower abdominal cancer surgery and it was found that TAP block provides superior post-operative analgesia which is evident by reduction in VAS score and more time needed for first rescue analgesic.

Shabayek IA et al., compared lumbar epidural versus TAP block for postoperative analgesia after lower abdominal surgeries [14]. There was no statistically significant difference in both VAS at rest and VAS with knee flexion between both groups. Results of this study are contradicted with the present study.

In the present study, VAS score in epidural group at six hours and 12 hours was higher than TAP group at rest and coughing with statistical significance and at zero hour, one hour, two hour, four hour, 18 hour and 24 hours there was no significant difference between the groups. The results were consistent with the study done by Kandi Y; studied efficacy of USG guided TAP block versus epidural analgesia after lower abdominal surgery [15]. In Group-T, bupivacaine 0.5 ml/kg of 0.125% was injected and Group-E received bupivacaine 0.125% at 4-8 mL/h. There was statistically significant decrease in VAS in group TAP compared with group epidural at 2, 6, 10, 14, and 18 hours postoperatively and also with the study done by Bhagasra S et al., in which they found postoperatively at 2, 4, 8 and 12 hours pain score was significantly higher in the Group-E as compared to TAP Group (p<0.05) [11]. In a study by Sinha S et al., during laproscopic cholecystectomy, ultrasound guided TAP block with ropivacaine provided better postoperative analgesia during first hour of postoperative period when compared with bupivacaine [16]. In a meta-analysis of randomised controlled trials, TAP block was found to provide better postoperative analgesia in comparison to local infiltration for open lower abdominal surgeries [17].

TAP block is helpful in providing analgesia to parietal peritoneum, skin and muscles of anterior abdominal wall by blocking afferent nerves of anterior abdominal wall. It is more effective in providing analgesia particularly when used real time under USG guidance [16].

In this study, Time for need of first rescue analgesic for Group-E was 399.6±25.32 minutes and Group-T was 462.6±26.94 minutes and the p-value is <0.001. Group-E patients required rescue analgesic earlier compared to Group-T. This results are supported by the study done by Aditiansih D et al., who found morphine consumption occurred 12 hours after surgery in the TAP block group while it occurred after six hours in the epidural group and also by other study done by Shabayek IA et al., where the first analgesic requirement time was 10.30±8.08 minutes in Control Group, 121.50±20.63 minutes in Group-E and 172.00±15.35 minutes in Group-T [4,14].

The results are also similar in studies done by Kandi Y in which first dose of morphine in Group-T was required at 136.93±92.61 minutes and Group-E at 83.50±47.54 minutes [15]. First dose of paracetamol was needed in Group-T at 391.8±82.8 minutes and Group-E at 307.8±60.97 minutes and Bhagasra S et al., showed that mean duration of analgesia was significantly higher in TAP group as compared to epidural group (340.51±28.24 minutes vs. 273.43±35.80 minutes) [11]. Likewise, in this study, Group-E patients required rescue analgesic earlier compared to Group-T.

Kandi Y found that significant decrease in total morphine required during the first eight hour in group TAP in comparison with group epidural (69.0±12.95 vs. 80.0±11.52, respectively) [15]. Bhagasra S et al., found that total tramadol consumption in the first 24 hours was 120±50.29 in TAP group and 161.42±50.12 in epidural group [11]. In this study, there is no significance between total diclo and tramadol doses consumption between the groups and matches above mentioned studies.

The comparison HR, SBP, DBP and MAP shows significant difference between the two groups in this study. The difference in HR, SBP, DBP & MAP across the two groups were non significant (p-value >0.05) at five minutes, 15 minutes, 30 minutes, one hour, two hours, four hours, 18 hours and 24 hours but higher in Group-E at 6th and 12th hour postoperatively as compared to Group-T (p<0.05).

Shabayek IA et al., reported that MAP, HR and RR, showed no statistically difference among the three groups (Group-E, Group-T and Group-C), except at the first 10 minutes and 20 minutes after starting epidural and application of TAP block [14]. There was significant increase in HR, RR and MAP in Group-T as compared to Group-E at 10, 20 minutes. Other study done by Bhagasra S et al., showed that postoperatively from 30 minutes to eight hours,

SBP, DBP and MAP levels were significantly lower in the epidural group as compared to TAP group ($p < 0.05$). HR and SpO₂ were not significant. ($p > 0.05$) [11].

In this study, incidence of nausea was 4 in both groups. Incidence of vomiting in Group-E was 11 patients and in Group-T were nine patients, which was statistically not significant. There was no case of pruritis, bradycardia, urinary retention, hypotension, respiratory depression, sedation and motor blockage in both groups. The present study finding is in accordance with many studies using Epidural and TAP block [12,15,16].

Limitation(s)

Study period can be extended up to 48 hours. The authors observed and recorded for 24 hours only. Another limitation was a single shot TAP block technique used.

CONCLUSION(S)

Ultrasound guided TAP has significant advantage over epidural analgesia in terms of efficacy of postoperative analgesia and time of need and quantity of postoperative analgesics. So, ultrasound-guided TAP may be an effective alternative for providing postoperative analgesia with haemodynamic stability without any side-effects in lower abdominal cancer surgery under general anaesthesia. In future, the authors can use catheters for TAP block for extended period of analgesia.

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