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Original Research Article

A randomised controlled trial to study the analgesic efficacy of transversus abdominis plane block for adult undergoing elective laparoscopic appendectomy

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ABSTRACT

Background: Laparoscopic appendectomy has evolved over the years as a minimally invasive approach for appendicitis. Routinely opioids are used for pain control postoperatively, however, its widespread use has numerous side effects and delays postoperative recovery. More recent studies have shown that transversus abdominis plane block reduces postoperative pain and analgesic drug usage. This study aims to evaluate the impact of transversus abdominis plane block in managing postoperative pain following elective laparoscopic appendectomy.
Methods: A prospective, randomized, double-blind trial was performed on patients undergoing elective laparoscopic appendectomy. Patients were randomized to receive a TAP block with 0.25% bupivacaine and a control group receiving a TAP block with normal saline infusion. Laparoscopic port sites were infiltrated with bupivacaine in the control group and normal saline in the TAP block intervention group before starting the surgery. Postoperative pain scores were recorded using the visual analog scale scores at dedicated time points.
Results: A total of 20 patients were included in the control group and 19 in the TAP block group. Visual analog scale scores were significantly reduced in the TAP block group at 6 hours, 12 hours, and 18 hours ($p<0.001$ in each). However, there was no significant reduction in the visual analog scale score at 24 hours ($p=0.015$). There was no significant difference between postoperative nausea ($p=0.18$), and length of postoperative hospital stay ($p=0.93$) between the two groups. Consumption of rescue analgesics and antiemetics in the first 24 hours postoperatively between both groups was statistically significant ($p=0.005$).
Conclusions: Bilateral TAP block is safe and effective in reducing the need for analgesics and antiemetics in patients undergoing laparoscopic appendectomy in the postoperative period. In addition, there is a significant improvement in visual analog scale scores in patients after TAP block.

Keywords: Laparoscopy, Appendectomy, Transversus abdominis plane block, Petit triangle, Visual analog score

INTRODUCTION

The incidence of appendicitis is maximum in adults between the second and third decades of life, and approximately 10% of the general population develop acute appendicitis at some point.[1] Management of appendicitis has evolved enormously over the decades from an open to a minimally invasive approach. Open appendectomy was considered the gold standard but has been replaced by the laparoscopic approach, however, the superiority of laparoscopic appendectomy over the open approach is being debated.[1-2] Multiple randomized

controlled trials (RCTs) have shown that the laparoscopic approach results in shorter hospital stays, smaller incisions, less postoperative pain, and early return to daily activities in several gastrointestinal surgeries.[3-4]

Postoperative pain can be assessed by many pain scales, including VAS score.[5] Difference in pain intensity measured at two different points of time by VAS represents the real difference in magnitude of pain, which is major advantage of VAS compared to others.[5] Management of postoperative pain is considered a primary medical challenge.[6] Routinely, opioids are being used to manage postoperative pain, however, the use of opioids is associated with various side effects and delayed discharge from the hospital postoperatively, resulting in less patient satisfaction.[7-8] Transversus abdominis plane (TAP) block is a component of multimodal analgesia and has been shown to reduce postoperative pain and analgesic consumption.[9-10] Infiltration of the TAP with local anesthesia under ultrasound guidance has been very effective for pain control in the postoperative period following appendectomy.[11] This is one of the recent advances in peripheral nerve blocks and is a more straightforward and less time-consuming technique. In the last decade, ultrasound has expanded enormously in various abdominal surgeries. Sonographically guided injection of regional anesthetic agents have proven prolonged pain relief and a considerable reduction in opioid requirement postoperatively. TAP block will be an ideal component of pain management following laparoscopic appendectomy. However, the efficacy of a TAP block in pain relief after appendicectomies is still not adequately proven, with conflicting results.

Only a few past studies have compared the efficacy of the TAP block in patients undergoing appendectomy.[12-13] A RCT conducted by Tanggaard et al. compared the effect of bilateral TAP block on post-operative pain and the need for post-operative analgesics in patients undergoing laparoscopic appendectomy. They found a significant reduction in postoperative pain. However, there was no significant difference in morphine consumption, nausea, and vomiting.[14] Other authors studied the efficacy of TAP block and the need for post-operative pethidine in patients undergoing an open appendectomy.[13] They found a significant decrease in pain and the need for analgesia postoperatively. In our study, we included only patients undergoing elective laparoscopic appendectomy, compared to previous studies where both elective and emergency cases were included. The present study aims to determine the efficacy of TAP block in patients undergoing elective laparoscopic appendectomies for the control of postoperative pain.

METHODS

This study was a prospective RCT conducted between November 2018 and February 2021 in the Department of Surgery Jawaharlal Institute of Medical Education and Research (JIPMER), Puducherry, India. All patients more than 21 years of age and undergoing elective laparoscopic appendectomy were included in the study. Written and informed consent was taken from all the patients. Patients who were pregnant and with a history of surgery in the last six months, chronic pain, chronic opioid use, known allergy to bupivacaine, or who presented with an acute episode of appendicitis were excluded from the study. Patients undergoing laparoscopic appendectomy were randomized into two groups, one group received general anesthesia and TAP block with 20mL of 0.25% bupivacaine and other received general anesthesia and TAP block with 20mL of normal saline infusion.

A total of 60 patients were recruited assuming a two-sided five percent significance level with a 1:1 allocation ratio and 80% power of detecting a mean difference in analgesic consumption between the two groups over the first 24 hours. Taking a standard deviation of 36.79 in the intervention and 47.3 in the control group, we required 28 participants in each group. Considering five percent non-response, we recruited 30 participants in each group. The sample size was calculated using OpenEpi software (version 3.1). A computer-generated random number sequence was used with an allocation ratio of 1:1. The sequence was generated by a third person who was not part of the study. The Serially numbered opaque sealed envelope (SNOSE) technique concealed the random sequence before allocation. After informed consent, the co-investigator allocated the participant to the corresponding arm. Both patient and principal investigator were blinded in the study. These patients were randomized into two groups. One underwent surgery under general anesthesia and TAP block with 0.25% bupivacaine (TAP block group), and the other underwent surgery under general anesthesia and TAP block with normal saline infusion (Figure 1). All patients underwent standard general anesthesia using the same amount and type of anesthetic drug for induction. Ondansetron was given to patients with a previous history of postoperative nausea and vomiting.

Experienced anaesthetists gave TAP block under ultrasound guidance with aseptic precautions. In the TAP block intervention group, 20ml of plain 0.25% bupivacaine was infiltrated into each side of the abdominal wall. In the control group, 20ml of normal saline was infiltrated into each side of the abdominal wall. The needle was advanced into the transversus abdominis plane, which was identified by ultrasound. The local anesthetic was infused into the plane, which was confirmed by the bulge in the plane (Figure 2). Age, gender, and body mass index (BMI) were recorded for all patients. For assessing postoperative pain, the visual analog scale (VAS) scoring was used, which is a self-reported numerical scoring by patients based on the pain perceived (zero for no pain and 10 for maximum pain). Pain assessment was done at 6 hours, 12 hours, 18 hours, and 24 hours after surgery. The analgesia consumption was measured for the first 24 hours postoperatively. The

incidence of postoperative nausea or vomiting was recorded simultaneously along with the severity using a three-point scale (0=none, 1=nausea without vomiting, 2=vomiting with or without nausea) in the first 24 hours postoperatively.

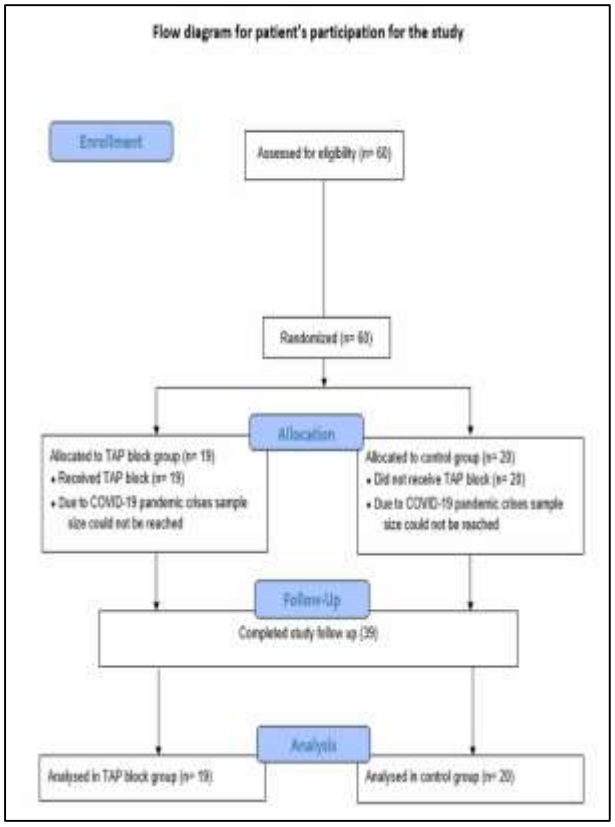

Figure 1: Consolidated standards of reporting trials (CONSORT) diagram and allocation.

Antiemetic was given when the score was one or more than one, and the dose was repeated after eight hours if nausea/vomiting did not subside. Rescue analgesia (paracetamol and tramadol) was given if the VAS score was more than three, and the dose was repeated after four hours if the pain did not come down. All postoperative tudy measurements were documented after shifting the patient to the ward following surgery. The total antiemetics consumed in the first 24 hours after surgery was also measured. The duration of postoperative hospital stays was recorded.

Microsoft Excel was used for collecting data, and statistical analysis was done using Stata software (version 12). Categorical independent variables were summarized as proportions. The outcomes variables (total amount of analgesic consumed post-surgery, VAS scores for pain measurement, postoperative nausea and vomiting, antiemetic consumption, length of postoperative hospital stay) in both groups were summarized as mean with 95% confidence intervals for the mean. The mean difference in outcome variables between baseline and after intervention in each group was calculated. The difference in analysis (between the two arms) was calculated using an unpaired t test. A p value less than 0.05 was taken as statistically significant. To compare the difference in analgesic consumption over time (four-time points- 6 hours, 12 hours, 18 hours, 24 hours) between the two arms, a repeated-measures analysis of variance (ANOVA) test was performed.

RESULTS

Thirty-nine patients were enrolled; 19 were randomized to the TAP block group and 20 to the control group. We compared age, sex, BMI, the need for conversion to an open procedure, the ASA class of the patients, and duration of surgery in both the groups. None of these factors were significant in the groups (Table 1).

Figure 2: A) Triangle of Petit (yellow arrow), bounded by External oblique muscle (white arrow), Lattismus dorsi muscle (red arrow), iliac crest (green arrow) and subcostal margin (blue arrow) and B) Ultrasound picture of the abdominal wall showing External oblique muscle (EO), Internal oblique muscle (IO), Transversus abdominis muscle (TA), with a needle tract (black arrow).

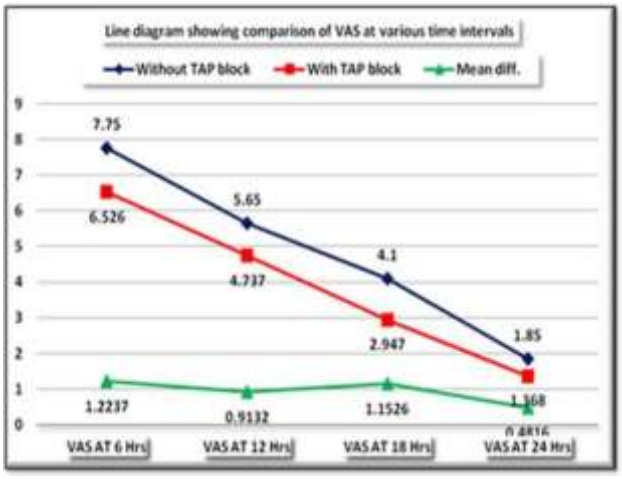

Figure 3: Image of the line diagram showing comparison of VAS score in TAP block group and control group at various time intervals.

Table 1: Baseline characteristics of the patients according to patient group.

Variable	Control group (N=20), Frequency (%)	TAP block group (N=19), Frequency (%)
Age (years)*	37.70±12.84	30.68±12.01
Male	16 (80)	11 (57.90)
Female	4 (20%	8 (42.10)
BMI* (kg/m^2)	20.73±1.01	20.86±1.07
Conversion to open	3 (15)	00 (0)
ASA class I	17 (85)	15 (78.90)
ASA class II	3 (15)	4 (21.1)
Duration of Surgery (hours)*	1±1.4	1.1±2.3

*Data presented as mean±SD; SD: Standard Deviation; TAP: Transversus abdominis plane; BMI: Body mass index; ASA: American Society of Anaesthesiology.

Table 2: Analgesia parameters of the patients according to patient group.

Parameter	Control group (N=20)	TAP block group (N=19)	P value
Total amount of analgesia consumed in first 24 hours (mg)*	114±20.9	90±0	<0.001
VAS score at 6 hours*	7.75±0.72	6.53±0.61	<0.001
VAS score at 12 hours*	5.65±0.87	4.74±0.56	<0.001
VAS score at 18 hours*	4.1±1.07	2.95±0.52	<0.001
VAS score at 24 hours*	1.85±0.67	1.37 ±0.50	0.015

*Data presented as mean±SD; SD: Standard Deviation; TAP: Transversus abdominis plane; VAS score-Visual Analogue score

Table 3: Perioperative timelines of the patients according to patient group.

Parameter	Control group (N=20)	TAP block group (N=19)	P value
Postoperative nausea	5 (25)	4 (21)	0.18
Postoperative vomiting	3 (15)	00 (0)	NA
Total amount of antiemetic consumed in first 24 hours*	11.8±2.42	9.68±2.03	0.005
Length of postoperative hospital stay (days)*	2.65±1.27	2.68±1.38	0.93

*Data presented as mean±SD; SD- Standard Deviation; TAP-Transversus abdominis plane; NA: Not applicable

The amount of postoperative rescue analgesia (paracetamol and tramadol) required by patients as an inpatient was calculated throughout the study period. It was observed that less analgesia was required in the TAP block group than in the control group, and it was statistically significant between the groups (p<0.001). VAS scores were collected using a visual analog scale from zero to 10 at 6 hours, 12 hours, 18 hours, and 24 hours post laparoscopic appendectomy. Patients showed a significant reduction in VAS scores at 6 hours, 12 hours, and 18 hours in patients receiving TAP blocks as compared to the control group (p<0.001) (Figure 3). At 24 hours there was no significant difference in VAS scores between the two groups (Table 2). The incidence of postoperative nausea was 25% in the control group and 21% in the TAP block group (p=0.18). The incidence of postoperative vomiting was 15% in the control group, and no patient developed vomiting in the TAP block group. Both these factors were not significant. The total amount of antiemetic consumed in the first 24 hours in the control group was 11.8+2.42, and in the TAP block group was 9.68+2.03 (p=0.005). The amount of antiemetic consumption was significantly less in the TAP block group. The length of the postoperative hospital stay in the control group was 2.65+1.27 days, and in the TAP block group was 2.68+1.38 days (p=0.93). Comparison of postoperative hospital stay duration between the two groups revealed no differences (Table 3).

DISCUSSION

Acute appendicitis is the most common abdominal emergency worldwide. Appendectomy has evolved over the years due to refinement in surgical techniques and advancement in minimally invasive surgeries like laparoscopic appendectomy. Minimal invasive procedures have been increased to minimize postoperative surgical site pain, limit intraoperative bleeding, decrease postoperative complications, and shorten hospital stay.[15] Although laparoscopic surgeries are associated with more minor complications when compared with open surgeries, postoperative pain remains a concern and it is directly related to quality of life.[16] Modernization and technological advancement have shifted post-operative pain management from conventional analgesics to multimodal analgesia. Better

management of immediate postoperative pain helps in early postoperative ambulation, decreased postoperative hospitalization length, and better patient satisfaction.[10,11,17] Multimodal analgesia is now considered the standard of care for immediate postoperative pain. The TAP block was very effective in reducing the need for postoperative opioid consumption and providing more effective pain relief while decreasing the side effects associated with opioids, such as sedation and postoperative nausea and vomiting. TAP block is a procedure that is easy to perform, provides a longer duration of analgesia, and is associated with minimal side effects. Ultrasound-guided TAP block has gained worldwide traction. Our study evaluated age, gender, BMI, ASA scale, co-morbidities, and postoperative length of hospital stay in both control and TAP block groups. We found that none of these factors were significant in either group.

In our study, the average amount of analgesia consumed in 24 hours postoperatively without a TAP block was found to be a 114 mg and, with TAP block, was 90 mg. There was a significant mean difference of 24 mg ($p<0.001$). These results are similar to the study conducted by McDonnell et al reported that TAP block provided highly adequate postoperative analgesia in the first 24 hours.[10] Niraj et al showed that ultrasound-guided TAP block decreases the use of analgesic consumption and, subsequently, postoperative pain in patients who underwent open appendectomy.[18] Shaaban et al conducted a RCT in children and detected that ultrasound-guided TAP block with bupivacaine provides extended postoperative analgesia with reduced analgesic use after appendectomy.[19] This may be possible because the posterior approach of the TAP block aided in the spread of local anesthetic to the paravertebral space and thus gave complete and prolonged analgesia. The decreased consumption of analgesics in patients with TAP block may be explained by the decreased absorption of local anesthetics solution into the systemic circulation due to poor vascularity of the transversus abdominis plane. In our study, we compared the VAS score of the patients in the first 24-hour period postoperatively in the TAP block group and control group at different time intervals. We found that VAS scores at 6 hours, 12 hours, 18 hours, and 24 hours were statistically significant with a p value of <0.001, <0.001, <0.001, and 0.015, respectively. A study by Carney et al compared the VAS score in patients undergoing open appendicectomy with or without TAP block.[9] They compared VAS scores at rest and on movement in both groups at different time intervals. They found that the VAS score was significantly low when patients were undergoing appendectomy who received TAP block. Another study conducted by McDonnell et al compared patients undergoing abdominal surgeries with or without TAP block.[10] They compared VAS scores in both groups at different times. They found that TAP block group patients had significantly lower scores than the control group. These results are similar to our study results, suggesting that TAP block plays an essential role in reducing VAS score and increasing patients' tolerance to pain in the postoperative period. In our study, we examined the incidence of postoperative nausea and vomiting in both the TAP block and control groups, and the results showed no significant difference between the two groups ($p=0.18$). This finding aligns with prior research conducted by Carney et al and McDonnell et al which also found no significant disparity in nausea and vomiting incidence with or without TAP block intervention, despite variations in the surgical procedures performed.[9,10] These consistent results collectively suggest that TAP block does not substantially influence the occurrence of postoperative nausea and vomiting. However, our study did reveal a noteworthy distinction. Specifically, we observed a significant reduction in the total consumption of antiemetics within the first 24 hours postoperatively in the TAP block group ($p=0.005$). This finding diverged from a study conducted by Tanggaard et al where no significant disparity in antiemetic usage was noted between the bilateral TAP block group and the control group.[14] We propose that this dissimilarity may be attributed to the inadvertent use of morphine in their study, which likely contributed to heightened antiemetic consumption, even in patients who had undergone bilateral TAP block.

There was no significant difference postoperative hospital stays in the present study. Sandeman et al conducted a RCT on children who underwent laparoscopic appendectomy.[20] Duration of surgery between both groups was studied but it was not significant, however there was additional time required for TAP block group for performig it. However, the duration of the hospital stay was identical in both groups. There are a few limitations of our study. First, the number of patients recruited was less, and further studies are needed with a large s ample size for universal acceptance of the TAP block in patients undergoing laparoscopic appendectomy. Second, our study had a follow-up period of 24 hours. Further studies are required with longer follow-up of the patients who undergo TAP block for the possibility of any other complication. Third, we have not included pre-operative risk factors, which can confound the results of postoperative nausea and vomiting. Fourth, there is also a need for further studies to see the effects of TAP block in emergency appendectomies, as we had included only the patients undergoing elective appendectomies. Fifth, no patient in the TAP block group converted to the open procedure; hence it is difficult to comment on the effect of TAP block in an open procedure.

CONCLUSION

In conclusion, the results of our study indicate that TAP block has a consistent and positive impact on patients undergoing laparoscopic appendectomy, regardless of various demographic and clinical factors such as age, gender, BMI, the need for conversion to open surgery, or ASA class. Notably, none of the patients in the TAP

block group required conversion to an open procedure, preventing a direct assessment of TAP block's effect in such cases. One significant finding is the substantial reduction in the consumption of analgesia and antiemetics within the first 24 hours post-surgery in the TAP block group, but not in the incidence of nausea and vomiting. This suggests that TAP block effectively contributes to postoperative pain and nausea management. Hence bilateral TAP block is both safe and effective in reducing the necessity for analgesics and antiemetics in patients undergoing laparoscopic appendectomy during the postoperative period. These results underscore the potential benefits of incorporating TAP block into the postoperative care plan for laparoscopic appendectomy patients.

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