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Efficacy of Laparoscopic-Assisted Subcostal Transversus Abdominis Plane (TAP) Block: A Double-Blind, Randomized Controlled Trial

Sadaf Ishaque, Sarmad Masud, Rizwan Ahmed Khan, Nauman Ismat Butt

ABSTRACT

Objective: To analyze efficacy of laparoscopic administered Transversus Abdominis Plane (TAP) block on pain scores and opioid consumption in the first 24 hours in patients undergoing laparoscopic cholecystectomy.

Study design and setting: The randomized, double-blinded trial was conducted in surgical unit, Shalamar Medical & Dental College Lahore from September 2019 to March 2020.

Methodology: 100 patients of either gender scheduled for elective laparoscopic cholecystectomy were included using consecutive probability sampling method. After informed consent, patients were randomized into Intervention TAP Group-A and Control Group-B. Intervention TAP Group-A received laparoscopic aided TAP block with 20ml 0.5% Ropivacaine in subcostal region while Control Group-B received 20ml saline solution which was used as placebo. Both groups received paracetamol 1gm intravenous eight-hourly and Ketorolac 30mg intravenous 12-hourly. Nalbuphine 5mg intravenous was administered as "rescue analgesic" in patients having pain score of four or above. Postoperative pain scores at rest and on coughing were documented using numerical rating scores (VAS) at 2, 4, 6, 12, and 24 hours.

Results: There was a significant difference (p-value=0.038, 0.000, 0.025, 0.000, 0.000) in pain scores over the first 24 hours postoperatively in laparoscopically assisted Intervention TAP Group-A. The total nalbuphine consumption was significantly reduced in Intervention TAP Group-A as compared to Control Group-B.

Conclusions: Laparoscopic administered TAP block significantly reduced postoperative pain and total opioid consumption following laparoscopic cholecystectomy.

KEYWORDS: Analgesia, VAS, Laparoscopic Cholecystectomy, Transversus Abdominis Plane Block

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INTRODUCTION:

One of the vital issues following abdominal and other major surgeries is effective postoperative pain control. Even though laparoscopic surgeries help to reduce invasiveness and pain severity postoperatively, pain may still lead to significant delay in recovery and patient distress. Patients who suffer complications require more postoperative pain relief and the occurrence of postoperative complications leads to reduced overall health, poor mental health, fatigue and lower physical activity affecting the patient's quality of life.[1] Furthermore, other psychological factors such as depression can also contribute in marked postoperative pain, slow recovery and prolongation of hospital stay.[2,3] Therefore it is important to target these factors to reduce the incidence of postoperative pain and complications so that patient outcomes may be optimized. The use of opioids in pain management is usually standard practice of care worldwide but excessive use may result in various drawbacks such as opiate dependence, abuse and subsequently overdose.[4,5] Patients with comorbid conditions, pre-existing mental health illness and those who develop complications are at highest risk to develop postoperative opioid analgesic dependence.[6] Various preoperative techniques including Shapley additive explanations (SHAP) technique help detect risk factors for severe pain which aid in tailoring the pain management plan thereby providing more effective pain control and mitigating the risk of opioid overuse and dependence.[7]

Laparoscopic cholecystectomy is presently considered the gold standard treatment for gallstone diseases. With significantly less postoperative pain, early mobilization, and enhanced postoperative recovery, this minimally invasive technique has become an appropriate option for day case

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surgeries.[8,9] Despite reduced pain incidence for laparoscopic cholecystectomy, the incision site, trocar insertion site, pneumo-peritoneum, and abdominal muscle stretching may still lead to high levels of discomfort and pain in some patients. Therefore, a multimodal analgesia strategy is adopted in the perioperative period for effective postoperative pain control.[10] Components of multimodal analgesia include non-steroidal anti-inflammatory drugs, paracetamol, local anesthetic infiltration, regional nerve blocks, and non-opioid adjuncts.[10,11] For breakthrough pain, opioids and opioid-related analgesics are used. Initially described in 2001, TAP block used a new approach via the lumbar triangle for effective pain relief.[12] Since then, implications of TAP block in abdominal, urological, and gynecological surgeries have been explored.[13]

Laparoscopic-assisted TAP block involves the injection of the local anesthetic agent between the transversus abdominis and the internal oblique muscles and provides analgesia to the skin, anterior abdominal muscles, and parietal peritoneum.[14] Though ultrasound-guided administration makes the TAP block much easier, the identification of the muscle planes can be difficult in a few cases. A new technique of TAP block directly under observation in open surgery has been advocated and inferences that the conventional approach risks could be avoided with this easy approach.[15] Considering TAP block under direct vision in a laparoscopic procedure, a similar laparoscopic-guided TAP block approach during laparoscopic bariatric surgery and nephrectomy has also been explained.[16] The transabdominal plane (TAP) block is a regional anesthesia technique used for postoperative pain management in abdominal wall procedures, providing somatic analgesia to the anterior and lateral abdominal walls. . Ultrasound-guided transversus abdominis plane (TAP) block involves the injection of LA in between the transversus abdominis (TA) and internal oblique (IO) muscles. The TAP block can also be targeted using anatomical landmarks at the level of the Petit triangle. This interfascial plane contains the intercostal, subcostal, iliohypogastric, and ilioinguinal nerves. These nerves give sensation to the anterior and lateral abdominal wall and the parietal peritoneum, providing only somatic and not visceral analgesia. The TAP block can be used for postoperative analgesia management in open and laparoscopic abdominal surgeries and inpatient and outpatient surgical procedures. However, the efficacy of TAP block administration under direct vision in laparoscopic cholecystectomy remains to be studied in the local population in Pakistan. Thus, our study aims to establish the TAP block efficacy by analyzing the mean pain scores and opioid consumption in patients undertaking laparoscopic cholecystectomy at a tertiary care hospital in Lahore Pakistan.

METHODOLOGY

The study design was a randomized, double-blinded trial was conducted in the surgical unit of Shalamar Hospital, Shalamar Medical & Dental College Lahore Pakistan from September 2019 to March 2020. This clinical trial has been approved by the Institutional Review Board at Shalamar Medical and Dental College (Ref No: SMDC/IRB/21-8/046). The RCT has been registered with Australian New Zealand Clinical Trials Registry (Trial Reg No: ACTRN12621001432808) and the International Clinical Trials Registry Platform (Universal Trial No: u1111-1263-0186). Using postoperative pain as the primary endpoint expressed as mean ± SD pain VAS score, sample size calculation was done using the formula of continuous outcome variables for a randomized controlled trial. Keeping power of study 80% and 95% confidence interval, sample size was calculated to be 100 patients, scheduled for laparoscopic cholecystectomy in the surgery department. A simple random sampling technique was employed in the study. Patients between 20 and 60 years old of either gender, after obtaining written consent and being scheduled for laparoscopic cholecystectomy in the surgical unit of Shalamar Hospital, Lahore were included using a randomized sampling technique. Patients with American Society of Anaesthesiology (ASA) Grade-III and IV, acute cholecystitis, intra-abdominal adhesions, empyema and gall bladder cancer, coagulopathies, previous history of allergy to local anesthetic agents and abdominal wall infections were excluded. Those who did not give written consent were also excluded from the study.

Following a written informed consent form signed by the patients, the recruited patients were randomized into two groups. Using a computerized "random number table" 48 patients were allocated to an Intervention TAP Group-A and 52 patients to a Control Group-B. Intervention TAP Group-A patients received a TAP block with 20 ml 0.5% Ropivacaine (10 ml in each subcostal region), while the Control Group-B received 20 ml saline solution (10 ml in each subcostal region). Injection of paracetamol 1 gm IV 8-hourly and an injection of ketorolac 30 mg IV 12-hourly were given to both groups. All patients received a general anesthesia regimen that included propofol 2 mg/kg, Nalbuphine 6 mg, and Atracurium 0.5 mg/kg for intubation. The provision of anesthesia was managed with volatile Isoflurane 1-2 MAC in oxygen and air (FiO2 0.5). Standard monitoring incorporated pulse oximetry (SpO2), three lead electrocardiography (ECG), non-invasive blood pressure (NIBP), temperature, capnography, and train-of-four (TOF). As part of multimodal analgesia, all patients received 1 gm Paracetamol and 30 mg ketorolac intravenously following induction. After stabilization of the vital signs, patients received intervention according to the group assigned.

Pneumo-peritoneum was created by the Verres needle and a laparoscope was inserted into the abdomen under direct vision. 18G needle was used for insertion at both sides of the abdominal wall using typical surface landmarks. After perpendicular insertion, needle tip was placed between the internal oblique muscle and the transversus abdominis muscle, confirmed by direct laparoscopic vision. A dose of

20 ml of Ropivacaine was injected bilaterally in Intervention Group-A. A bulge inferior to the internal oblique muscle and away from the transversus abdominis muscle confirmed the appropriate location of the local anesthetic injection. Control Group-B received 20 ml of normal saline in the same manner. Towards the treatment groups, the surgeon and the patients were blinded so biased results cannot happen during the study. Postoperative analgesia included paracetamol 1 gm IV 8-hourly and Ketorolac 30 mg IV 12 hourly according to hospital protocol for post-operative pain management. Nalbuphine 5 mg IV was administered as a "rescue analgesic" in patients having pain VAS score 4 or above according to hospital protocol for post-operative pain management. Postoperative pain scores (VAS) at rest and on coughing were documented using numerical rating scores at 2, 4, 6, 12, and 24 hours to analyze the efficacy of laparoscopic administered Transversus Abdominis Plane (TAP) block on pain scores and opioid consumption in the first 24 hours in patients undergoing laparoscopic cholecystectomy.

The data were entered and analyzed using SPSS version 22. Descriptive analysis such as frequencies and percentages were done of categorical variables and for numerical variables, mean and standard deviation were used. For qualitative variables, Chi-square test was applied while Mann-Whitney U test was employed for quantitative variables. The level of significance was 5%.

Table 1: Demographic characteristics in both groups

Variables		Intervention (n=48)	Placebo (n=52)
Age (years) (Mean ± S.D)		45.34 ± 9.48	48.28 ± 11.89
Gender [n (%)]	Female	34 (65%)	34 (71%)
	Male	18 (34%)	14 (29%)

Table 2: Mean Pain Scores at rest and at cough between both groups

Time intervals	Rest/Cough	Group-A	Group-B	P-value
2 hours	At Rest	2.75 ± 0.73	3.48 ± 1.62	0.038
	With Cough	2.90 ± 0.72	3.83 ± 1.44	0.000
4 hours	At Rest	2.46 ± 0.50	3.13 ± 1.05	0.000
	With Cough	2.52 ± 0.58	3.35 ± 0.99	0.000
6 hours	At Rest	2.29 ± 1.27	2.58 ± 0.80	0.025
	With Cough	2.42 ± 1.18	2.71 ± 0.85	0.019
12 hours	At Rest	1.83 ± 1.02	2.52 ± 0.92	0.000
	With Cough	1.92 ± 1.01	2.54 ± 0.92	0.000
24 hours	At Rest	1.02 ± 0.70	2.13 ± 0.35	0.000
	With Cough	1.06 ± 0.69	2.21 ± 0.41	0.000

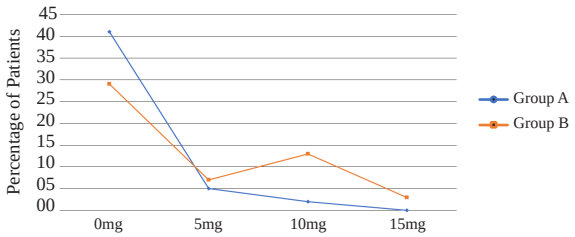
Table 3: Comparison of additional Nalbuphine consumption in both groups

Dose of nalbuphine	Group A	Group B	p-value
	n (%)	n (%)	
0mg	41 (85.4)	29 (55.8)	0.002
5mg	5 (10.4)	7 (13.5)	
10mg	2 (4.2)	13 (25)	
15mg	0	3 (5.8)	

RESULTS

The mean age of patients in Group-A was 48.28 ± 11.89 years and the mean age of patients in Group-B was 45.34 ± 9.48 years. Most of the females were present in both groups A and B. (Table 1). To analyze the efficacy of laparoscopic administered Transversus Abdominis Plane (TAP) block on pain scores and opioid consumption in the first 24 hours in patients undergoing laparoscopic cholecystectomy, the mean pain scores were determined for both groups of patients. It was observed that the difference in means of pain scores at 2, 4, 6, 12, and 24 hours at rest and with cough for both Group-A and Group-B was statistically significant (Table 2). The difference in total Nalbuphine consumption between both groups was statistically significant (p=0.002). This means that the Nalbuphine dose was more used in Group-B patients as the additional drug as compared to Group-A. (Table 3) The graphical representation was shown in Figure 1.

Figure 1: Comparison of additional Nalbuphine consumption in both study groups



DISCUSSION:

The current study has demonstrated the efficacy of laparoscopic administered TAP block for postoperative analgesia. It is significantly linked with lower postoperative pain VAS score and reduced opiate analgesic consumption. The findings of our study are consistent with earlier research showing that, following TAP block in laparoscopic cholecystectomy, there was an alleviation in opioid requirement and lowered pain scores.[13] As depicted in a few other studies, the TAP block method was employed in the laparoscopic form of ultrasound-guided four-quadrant dual-block. So according to the results to provide adequate analgesia, multiple point injection block is highly efficacious.[17,18] Additionally, L-TAP made the hospital stay shorter. Also, the outcomes were predictable if L-TAP is integrated into an Enhanced Recovery After Surgery (ERAS) program. This outcome further affirms past studies that, when added to an ERAS program, L-TAP leads to shortened emergency clinic stay post-procedure, without expanding complexities or subsequent re-admission risk.[18,19] There were no complications observed for TAP block in the present study, indicating that TAP block can exhibit effective

analgesia for upper abdominal laparoscopic surgery.[19,20] Tihan et al.[21] also reported laparoscopic TAP block to be an easy and effective procedure, reducing the operational time and having low risk of adverse effects making it an ideal choice especially in elderly patients.

It was clinically indicated that nalbuphine's analgesic efficacy is comparable to that of morphine, with only a slight breathing depression and a phenomenon known as capping. Our findings suggested that due to its modulatory action on central ê-receptors, nalbuphine can reduce postoperative analgesic requirements and NRS scores related to generalized pain.[22] The requirement for analgesia is the unintended indicator of post-operative pain in the postoperative period. According to the results of the TAP block, it not only reduced the number of patients who required rescue analgesia, but it also significantly reduced the "rescue analgesic" necessity with respect to the other group. So, our outcomes are similar to the recent studies.[23] There has been much focus on Enhanced Recovery After Surgery (ERAS) over the last decade. An effective perioperative pain control strategy is of paramount importance for enhanced recovery.[24] According to a recent study, 20 ml of Bupivacaine, Ropivacaine or Levobupivacaine could be the optimal dose for TAP block with 0.4 mL/kg infiltration at port site, because a low number of side effects, adverse events, and complications.[23] In past studies, TAP block resulted in decrease in pain score (8 mm on a 0 to 100 mm VAS scale) on coughing and a 2.5-mg decline in opiate analgesic necessity in the first 2 hours post-surgery.[25] The present study has certain limitations that should be considered also. Based in a single institution, the present study had a relatively small sample size therefore the results may be not applicable to the entire general population. However, the present study is unique in terms of providing a detailed perspective of TAP block, its effects, and complications during laparoscopic cholecystectomy in a developing country like Pakistan with limited resources. We recommend that further studies should be conducted to explore and compare effectiveness of TAP in other surgeries using the findings of our study as baseline information.

CONCLUSION:

We conclude TAP block to be an easy-to-use, effective and safe technique in laparoscopy surgery that decreases the intensity of post-operative pain, aids in speedy recovery, timely discharge from the hospital, enhanced patient well-being and satisfaction following laparoscopic cholecystectomy.

Authors Contribution:
Sadaf Ishaque: Conception and design, Data collection, Analysis and interpretation of the data, Literature review and drafting of the article
Sarmad Masud: Conception and design, data analysis and interpretation, Critical review and revision of the article
Rizwan Ahmed Khan: Conception and design, Data collection, Literature review and drafting of the article
Nauman Ismat Butt: Conception and design, Data analysis and interpretation, Critical review and revision of the article

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