Ultrasound-Guided Transversus Abdominis Plane Block Versus Intraperitoneal Instillation of Bupivacaine after Laparoscopic Cholecystectomy – A Randomized Control Trial

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ABSTRACT

Background: Postoperative pain prolongs hospital stay after laparoscopic cholecystectomy and remains a major challenge during the postoperative period. Effective pain control encourages early ambulation, which significantly reduces postoperative complications. In recent years, multimodal analgesia has been recommended with fewer adverse effects and more effective analgesia. The primary objective of this study was to compare the efficacy of analgesia between Transversus Abdominis Plane Block (TAP) Block and intraperitoneal instillation of bupivacaine by comparing the meantime of the first dose of rescue analgesia in either group and the total supplementary analgesia required. **Methods:** This retrospective observational study was conducted on 150 patients who underwent laparoscopic cholecystectomy Group 1 comprised of patients who had received Intraperitoneal Bupivacaine for analgesia and Group 2 received TAP Block for pain relief. **Results:** Time of the first dose of analgesia after surgery was observed earlier in Group 1 as compared to Group 2 (Time – hours: 9.2 ± 2 vs. 12.3 ± 1.6 ; p = 0.0001. The Total dose of analgesic was higher in the Intra Peritoneal Bupivacaine Group as compared to the TAP group. **Conclusion:** AP block provided for a better quality of analgesia as assessed by the reduced requirement of intravenous supplementary analgesia which was less in patients who were given TAP Block as compared to local instillation of Bupivacaine.

KEY WORDS: Cholecystectomy, Bupivacaine, Transversus abdominis plane block.

Introduction

ORIGINAL ARTICLE

Laparoscopic cholecystectomy (LC) was first performed four decades back and has replaced open cholecystectomy as the first choice.^[1] It is a minimally invasive surgery that is associated with reduced surgical trauma, smaller and more cosmetic incisions, reduced blood loss, and is associated usually with fewer postoperative complications and decreased length of hospital stay. Postoperative pain prolongs hospital stay and remains a major challenge during the post-op period. Effective pain control



encourages early ambulation, which significantly reduces the risk of deep vein thrombosis and pulmonary embolism; enhances the patient's ability to take deep breaths to decrease the risk of pulmonary complications. In recent years, multimodal analgesia has been recommended to combine additive and synergistic effects of different analgesics, with less adverse effects and more effective analgesia.^[2–4] The transversus abdominis plane (TAP) block involves the injection of a local anaesthetic solution into a plane between the internal oblique muscle and the transversus abdominis muscle. With the advancement of ultrasound technology, TAP blocks became technically easier and safer to perform. Local anesthetics have been injected at port sites in an attempt to reduce somatic pain and have been instilled into the peritoneum to decrease visceral pain. The drug acts by blocking transmembrane sodium channels which results in blockade of action potential transmission across sensory nerves.^[5,6] Ina meta-analysis by Weihua Wang et al., ^[7] in 2021, a

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total of 23 studies with data on 1,450 LC were included. This meta-analysis patients concluded that TAP block is more effective than conventional pain control, but not significantly different from another local incisional pain control which is port site infiltration. Hariom Khandelwal, et al. found,^[8] mean Numerical Rating Scale scores (NRS)^[9] were less in the TAP group than in the intraperitoneal instillation group in the first 6h, which was found to be statistically significant. TAP block was deemed to be a better modality for analgesia compared to intraperitoneal instillation of local anesthetic in patients undergoing elective LC. The Primary objective of this study is to evaluate the efficacy of analgesia between TAP Block and intraperitoneal instillation of bupivacaine by comparing the mean time of the first dose of rescue analgesia in either group. We also aim to compare NRS scores between study groups.

Materials and methods

This prospective, randomized, double-blinded control trial was conducted after Institutional Ethical Committee (IEC) approval (IEC Cert No. 16/2022) and written patient consent. The study was conducted between March 2022 and July 2022 by the principles of the Declaration of Helsinki. One Hundred and fifty patients undergoing laparoscopic cholecystectomy were recruited for the study. All Patients were between 18 and 65 years of age and in ASA class I or II. Patients with allergies to study drugs or on medication for chronic pain were excluded from the study. Morbidly obese (BMI>40 kg/m²) patients were also excluded from the study. A total of 150 patients (75 in each group) were recruited to accommodate a dropout/withdrawal rate of 10%. Randomization was done using a computer-generated random number table Group 1 comprised of patients who received intraperitoneal bupivacaine for analgesia and Group 2 received TAP Block. All patients who met the inclusion criteria were tested. Before surgery, the patient was maintained according to her established Nil Per Oral (NPO) guidelines. Premedication with midazolam 1 mg intravenously (IV) and ondansetron 0.1 mg/kg IV was started approximately 10 minutes before surgery and 0.2 micrograms of glycopyrrolate were injected. American Society of Anaesthesiologists (ASA) standard guidelines for intraoperative monitoring under General Anaesthesia (GA) were followed.^[10] Fentanyl 2 μ g/kg IV was administered for analgesia. GA induction was by injection of propofol 2 mg/kg IV and inhaled sevoflurane in 100% oxygen through a face mask. Neuromuscular blockade was

achieved with 0.5 mg/kg IV injected atracurium. Anaesthesia was maintained with nitrous oxide and oxygen (66% : 33%) supplemented with sevoflurane, with controlled ventilation to maintain end-tidal carbon dioxide (ETCO₂) at 35 ± 5 mm of Hg. At the end of the surgery, all patients received analgesia with injected paracetamol 1 g IV, and neuromuscular blockade was reversed with injected neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg IV. In Group 1, at the end of surgery and before the removal of trocars, 20 ml of 0.25% Bupivacaine was instilled by the surgeon intraperitoneally at the Gallbladder bed, 10 ml under the dome of Rt diaphragm under direct vision and 10 ml was injected in sites of port insertion. In group 2, at the end of the surgery, a TAP block was given under USG guidance by placing the probe under the xiphoid sternum and moving it laterally along the subcostal border to the anterior axillary line. A 100 mm 22 G block needle was passed just below the right costal arch in the anterior axillary line so that the tip was in the neurovascular plane between the transversus abdominis and internal oblique muscles (Figure 1). After aspiration, 20 mL of 0.25% bupivacaine was injected and the same procedure was repeated on the other side. Insufflation pressure was maintained within 10–12 mm Hg in all patients. At the end of the surgery, the CO₂ was vented and the intraperitoneally administered bupivacaine was left in place. Postoperative pain intensity was recorded (on the NRS scale) (Figure 3) at rest, 30 minutes, 2 hours, 6 hours, and 12 hours after surgery. Zero depicted no pain and 10 worst pain. The time when analgesics were first required was recorded, as was the total dose of rescue analgesics to achieve a pain score < 5 (in the form of paracetamol 1 g IV) in the first 24 hours.

Statistical analysis

Data were analyzed using SPSS software version 23. The data collected from 150 participants were entered into Microsoft Excel version 2016. Quantitative data were expressed in mean and standard deviation. Qualitative data were expressed in proportion and percentages. Independent t-test was applied to compare the means of quantitative data, and the Chi-square test was used to compare categorical data. P < 0.05 was considered to be statistically significant.

Sample size

Considering an earlier study^[8] comparing the postop analgesia in patients undergoing elective laparoscopic cholecystectomy, the mean numerical rating score for pain at rest in the first six hours for patients undergoing TAP block was 3.2 ± 1.09 and in patients undergoing instillation of intraperitoneal bupivacaine was 3.77 ± 1.25 . Considering the mean difference of 0.57 in NRS between the two drugs, power of 80%, and α -error of 0.05, the sample size of the present study was calculated using the following formula since the endpoint was quantitative data.

Sample size $= \frac{2(Z\alpha/2 + Z\beta) \sigma_1 \times \sigma_2}{(M1-M2)}$

To accommodate the drop-out and withdrawal of patients, 10% were added to each group. Based on the above, the sample size of the present study was kept at 75.

Results and Observation

A total of 170 patients undergoing Laparoscopic Cholecystectomy were screened and 150 of them were enrolled in the study (Figure 1).



Figure 1: Transducer position for Subcostal TAP block

Patients were randomly allocated to two groups, comprising 75 subjects each, of which one group of patients received Intraperitoneal instillation of bupivacaine and the other received TAP block.

The patients in both groups were comparable with regard to age, weight, body mass index, ASA grade, and duration of surgery (Table 1).

There was no difference in the Mean Systolic and Diastolic BP between both groups (Table 2).



Figure 2: Consort flow diagramof Analgesic characteristics

Till two hours after the surgery, no analgesic was required in either of the groups. At six hours, the requirement of analgesia was significantly higher in Group 1 as compared to Group 2 (36.0% vs. 4.0%, p = 0.0001). Thereafter, analgesic requirement in both the groups was not different at 12 and 24 hours (p>0.05). (Table 3). Time of the first dose of analgesia after surgery was observed earlier in Group 1 as compared to Group 2 {Time (hours): 9.2 ± 2 vs. 12.3 ± 1.6 ; p = 0.0001}. Similarly, a second dose of analgesia after surgery was observed earlier in group 1 {Time — (hours): 17.3 ± 2.2 vs. 20.4 ± 1.6 ; p = 0.0001}. The total dose of analgesic in the form of Injection Paracetamol IV (in grams) was higher in Group 1 (Mean Total Analgesia given in twenty-four hours was 2.5 ± 0.5 grams vs. 2.1 ± 0.2 grams; p = 0.0001) (Tables 3 and 4).

NRS Score

At 30 minutes, there was no significant difference observed in the NRS score between the two groups (p=0.193). Thereafter, the NRS score started declining till two hours, and no significant difference was observed between the groups (p=0.727). After two hours, the NRS score was showing an increasing trend in both groups. At six hours, the NRS score was higher in Group 1 (3.7 ± 0.9) as compared to Group 2 (3.3 ± 1.1) (p-value 0.010) which had statistical significance. But there was no significant difference observed at 12 and 24 hours (p>0.05) in NRS scores between the two groups (Table 5).

Table 1: Demographic Profile				
	Study Group	D value		
	Intra Peritoneal Bupivacaine Group (n= 75)	TAP Group (n= 75)		
Age (Mean \pm SD) in years	42.6±12.7	44.7±11.6	0.296	
BMI (Kg/m ²) (Mean \pm SD)	$25.7{\pm}1.5$	$25.6{\pm}2.2$	0.683	
ASA 1	50 (66.7%)	49 (65.3%)	0.863	
Duration of Surgery (Minutes) (Mean \pm SD)	$40.6{\pm}5.2$	41.1±4.7	0.586	
HTN	15 (20.0%)	23 (30.7%)	0.133	
DM	10 (13.3%)	8 (10.7%)	0.615	
COPD	1 (1.3%)	0 (0.0%)	0.316	
Hypothyroidism	3 (4.0%)	3 (4.0%)	1	

Table 1: Demographic Profile

Table 2: Mean & Standard deviation of BP at different time points

Timing	SBP (mm of Hg)		n-valuo	DBP (mm of Hg)		р-
	Group 1 (n= 75) (Mean ± SD)	Group 2 (n= 75) (Mean ± SD)	p-varue	Group 1 (n= 75) (Mean ± SD)	Group 2 (n= 75) (Mean \pm SD)	value
At 0 Min	120.1±7.1	$120.9{\pm}6.6$	0.449	75.3±7	$77{\pm}6.7$	0.117
At 30 Min	$112.8{\pm}6.5$	$113{\pm}6.2$	0.877	$73.4{\pm}3.7$	$73.9{\pm}3.3$	0.35
At 2 Hours	$114.3{\pm}6.4$	$112.8{\pm}6.4$	0.143	$76.2{\pm}4.4$	$75.4{\pm}4.1$	0.3
At 6 Hours	$115.7 {\pm} 7.8$	$114.8{\pm}7.6$	0.484	$76.5{\pm}4.1$	$76.8{\pm}4.9$	0.691
At 12 Hours	$116.3 {\pm} 7.1$	$116.8{\pm}6.8$	0.691	$76.9{\pm}4.5$	$77.1{\pm}4.5$	0.799
At 24 Hours	$115.8{\pm}6.4$	$116.6{\pm}5.6$	0.431	$74.5{\pm}5.7$	$74.2{\pm}5.1$	0.717

*p value < 0.05 statistically significant

Table 3: Comparison of Analgesic requirements in both the groups				
Timing -	Study Group (P valuo		
	Group 1 (n= 75)	Group 2 (n= 75)	1 Value	
At 30 Min	0 (0.0%)	0 (0.0%)	-	
At 2 Hours	0 (0.0%)	0 (0.0%)	-	
At 6 Hours	27 (36.0%)	3 (4.0%)	0.0001*	
At 12 Hours	58 (77.3%)	60 (80.0%)	0.69	
At 24 Hours	58 (77.3%)	60 (80.0%)	0.69	

*p value < 0.05 statistically significant



Figure 3: Visual Analog Scale

Discussion

LC is one of the most common ambulatory elective outpatient procedures. As for any surgery, postoperative pain and nausea/vomiting may increase the length of hospital stay after the procedure. The pain intensity is shown to be the most severe in the initial 24–48 h, with incisional pain as a major component.^[9] Opioid-sparing methods such as regional blocks, the use of nonsteroidal anti-inflammatory drugs, dexmedetomidine, and ketamine have been used in various other surgeries

Table 4: Comparison of Analgesic characteristics in both the groups				
Analgosic charactoristics	Study Group			
	Group 1 (n= 75) (Mean \pm SD)	Group 2 (n= 75) (Mean \pm SD)		
Time of the first dose of analge- sia after surgery (in hours)	9.2±2	12.3 ± 1.6	0.0001*	
Time of next dose of analgesia after surgery (in hours)	17.3±2.2	$20.4{\pm}1.6$	0.0001*	
Time of next dose of analgesia after surgery (in hours)	$22.8{\pm}0.4$	23±0	0.432	
Mean Total dose of analgesia (Inj PCM in grams)	2.5 ± 0.5	$2.1{\pm}0.2$	0.0001*	
* 1 0 0 - 1 1 1 1 10				

Table 4: Comparison of Analgesic characteristics in both the groups

*p value < 0.05 statistically significant

Post-Operative NRS Score	Study	D valuo	
	Group 1 (n= 75) (Mean \pm SD)	Group 2 (n= 75) (Mean \pm SD)	r value
At 30 Min	$3.4{\pm}0.5$	$3.5{\pm}0.5$	0.193
At 2 Hours	$3.2{\pm}0.6$	$3.3{\pm}0.8$	0.727
At 6 Hours	$3.7{\pm}0.9$	$3.3{\pm}1.1$	0.010*
At 12 Hours	$3.8{\pm}0.7$	$3.9{\pm}0.7$	0.363
At 24 Hours	$3.8{\pm}0.8$	$4{\pm}0.7$	0.273

* p value < 0.05 statistically significant



Figure 4: Ultrasound image during injection of local anesthetic in Transversus Abdominis Plane

for reducing unwanted side effects of opioids that interfere with postoperative recovery and early discharge.^[10] Regional anesthesia is a popular and proven method to decrease the postoperative opioid requirement. TAP block provides sensory analgesia for T10 to L1 dermatomes and the umbilicus is always supplied by T10 dermatome. A bilateral TAP block is thus expected to provide adequate intraand post-operative analgesia for this surgery, which would lead to early recovery.

In the current study, the groups were comparable regarding demographic variables. There were no significant differences in systolic and diastolic blood pressure (p-value > 0.05) and respiratory rate (p > 0.05) in both groups during the observation period. No patient showed respiratory depression (RR <10/min) at any time point during the observation period, and no significant difference (p > 0.05)was observed in the incidence of Postoperative nausea and vomiting (PONV). The mean time to first postoperative analgesic administration was observed to be earlier in the intraperitoneal bupivacaine group than in the TAP group. The second dose of postoperative analgesia was also observed to be earlier in the intraperitoneal bupivacaine group compared to the TAP group. Hamoda et al.,^[11] in a similar study observed the time of the first dose of rescue analgesia to be earlier with the use of local infiltration as compared to TAP block. In the present study, there was no significant difference observed in NRS score at 30 minutes between the groups (p=0.193). Thereafter, NRS scores started to decline till two hours after surgery and no

significant difference was observed between the groups (p=0.727). At six hours, the NRS score increased in both groups which was higher in group 1 as compared to group 2 which was statistically significant (NRS score 3.7 ± 0.9 vs 3.3 ± 1.1) (p-value 0.010). Further, monitoring showed no significant difference in NRS score observed at 12 and 24 hours (p>0.05). Similar results were seen in the studies by Khandelwal et al.^[8] and Hamoda et al.,^[11] with a statistically significant decrease in NRS score up to 8 hours of surgery in the TAP block group in comparison to the intraperitoneal bupivacaine group. In the current study, it was observed that the total analgesic dose required was higher in the intraperitoneal bupivacaine group than in the TAP group. It is imperative to mention a few previous studies which had documented similar results as our study. G Elamin et al.,^[12] showed a statistically significant reduction in pain scores both at rest and coughing in patients receiving ultrasound-assisted TAP blocks till three hours post-surgery. At 12 and 24 hours post LC, pain scores were not found to be significantly less in patients receiving laparoscopic assisted TAP blocks versus conventional periportal LA infiltration. Rao V Kadam et al., [13] found that median pain scores were consistently lower in the TAP group as compared to local infiltration.

We found that cumulative analgesic consumption was reduced in the TAP block group compared with the intraperitoneal injection group (Total Dose of IV Paracetamol: 2.5±0.5gms vs. 2.1±0.2gms; p = 0.0001). According to the study by Hamoda et al.,^[11] the cumulative consumption of analgesia was reduced in the TAP block group in comparison with the intraperitoneal instillation group consistent with our results. Similar results were seen in the study by H Khandelwal et al.,^[8]where the total analgesic consumption was reduced in the TAP block group. In this study, no pain medication was required in any group until two hours after surgery. After six hours, the number of patients requiring analgesics to achieve an NRS score of less than 5 was significantly higher in the intraperitoneal bupivacaine group than in the TAP group (36.0% vs. 4.0%, p=0.0001). Subsequently, the analgesic requirements of the number of patients in both groups were not significantly different after 12 hours and then after 24 hours. (p>0.05. Complications like peritoneal and visceral punctures related to TAP block were not encountered in our study. Farooq M, Carey M, et al.,^[14] reported a case of Liver Trauma with a blunt regional anesthesia needle while performing TAP Block. Thorough familiarity with anatomy, safe monitoring, and injection technique, and knowledge of local anaesthetic pharmacology and toxicity would prevent the possibility of complications and simplify the TAP block technique. These precautions will prevent major complications with TAP block. The use of ultrasound to confirm a needle position is a promising approach that should further reduce the risk of this complication.

Pain following LC can be substantial enough to delay ambulation and may delay discharge from the hospital. To this effect, several modalities have been utilized to provide adequate post-operative pain relief. TAP block is a regional analgesic technique, wherein effective pain relief is achieved by blocking the nerves of the abdominal wall (intercostal nerves: T7-T12 and ilioinguinal and iliohypogastric nerves: L1), which traverse the intervening plane between the internal oblique and transversus abdominis muscles. Thus, even though the gall bladder is a supra-umbilical organ, 4-port laparoscopic cholecystectomy involves the use of infra-umbilical ports also, and the pain caused by abdominal distension as a result of pneumoperitoneum is taken care of by the TAP block. The use of ultrasound has virtually surpassed the limitations of the conventional blind technique of anatomical landmark facilitated approach by providing direct visualization of the target plane. TAP block has also been used as an effective analgesic modality for abdominal surgeries in patients with compromised cardiac status.

The most important clinical implication of our findings is the significant reduction in rescue analgesia due to TAP block in the postoperative period. The study was able to achieve both its primary and secondary objectives by studying the analgesia characteristics of TAP block and intraperitoneal instillation of bupivacaine including port site infiltration. The reason for the longer duration of the analgesic effect after a single-shot TAP block can be explained by the fact that the flank is relatively poorly vascularized, thus possibly slowing drug clearance. The findings from the present study are that the analgesia achieved by TAP block given at the end of surgery to the patients undergoing LC is superior to intraperitoneal instillation of bupivacaine including port site infiltration as evidenced by reduced mean time of first dose of rescue analgesia, higher NRS scores in intraperitoneal bupivacaine group after 06 hours of surgery and higher dose of total analgesic required during the first 24 hours after surgery

in intraperitoneal bupivacaine group. Postoperative TAP block provides good pain relief and is a safe option as a part of multimodal analgesia. Reduction in postoperative pain and requirement of analgesic drugs leads to improved overall patient satisfaction and recovery.

Strengths and limitations of the study

The ideal way to evaluate the effectiveness of the TAP block in the patients would be to confirm the analgesia by the response to either pin prick or cold stimulus after the performance of the block. This was not possible in our study as the block was performed after giving general anaesthesia to facilitate blinding of the patients. The success of sensory block in the target area could not be assessed. Also, the results of our study need to be supported by larger multicentric studies.

Conclusion

Postoperative TAP block is highly analgesic and a safe option for multimodal analgesia. Reducing postoperative pain and the need for analgesics improves overall patient satisfaction and recovery. However, the results of our study need to be supported by larger multicenter studies.

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