ORIGINAL RESEARCH PAPER
Volume - 15 | Issue - 08 | August - 2026 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A COMPARISON BETWEEN ULTRASOUND-GUIDED BILATERAL SUBCOSTAL TRANSVERSUS ABDOMINIS PLANE BLOCK VERSUS INTRAPERITONEAL INSTILLATION OF LOCAL ANAESTHETIC FOR POSTOPERATIVE ANALGESIA IN LAPAROSCOPIC CHOLECYSTECTOMY PATIENTS: A PROSPECTIVE RANDOMIZED COMPARATIVE CLINICAL STUDY

Anaesthesiology

Dr Afroza Syed — Associate Professor, Department of Anaesthesiology, Government Medical College Baroda, Gujarat, India

Dr Amrutha P* — Senior Resident, Department of Anaesthesiology, All India Institute of Medical Sciences Delhi, India *Corresponding Author

Dr Hemangini Patel — Third Year Resident, Department of Anaesthesiology, Government Medical College Baroda, Gujarat, India

Dr Prachi Dwivedi — Senior Resident, Department of Anaesthesiology, Tata Memorial Hospital Mumbai, Maharashtra, India

Dr Kavita Lalchandani — Professor and Head, Department of Anaesthesiology, Government Medical College Baroda, Gujarat, India

ABSTRACT

Background and Aims: Laparoscopic cholecystectomy causes moderate to severe pain mediated by segmental innervation of nociceptor afferent pathways along transabdominal fascial plane requiring effective pain management. Thus we aimed to compare analgesic efficacy of bilateral subcostal TAP block with intraperitoneal instillation in laparoscopic cholecystectomy. **Materials and Methods:** After hospital ethical committee approval, this prospective study allocated 80 patients of age group 20 to 68 years posted for elective laparoscopic cholecystectomy randomized into two groups of 40 each. Group T received ultrasound guided Bilateral Subcostal TAP block with 0.25% Bupivacaine and Group L received intraperitoneal instillation of 0.25% Bupivacaine. Our primary aim was duration of postoperative analgesia, compared by evaluating time needed for administration of first dose of rescue analgesic given when VAS ≥ 4. Total amount of rescue analgesic in 24 hours and intraoperative hemodynamics, were studied as secondary aims. **Results:** Mean time taken for first dose of rescue analgesia was 15.05 ± 5.15 hours in Group T and 9.175 ± 1.83 hours in Group L, ($p < 0.0001$) the difference being highly significant. Mean of total amount of rescue analgesia of Paracetamol required in 24 hours was 1.525 ± 0.81gm in Group T and 2.525 ± 0.55gm in Group L ($p < 0.0001$) **Conclusion:** Bilateral subcostal TAP block was found to have better efficacy with reduced 24 hours postoperative analgesic requirement when compared to intra-peritoneal instillation.

KEYWORDS

INTRODUCTION

Pain is an integral part of laparoscopic cholecystectomy. This pain which was earlier thought to be mild as compared to open cholecystectomy is now considered significant enough to affect the recovery process and delay discharge from post-anaesthesia care unit. The terminal branches of lower intercostal nerves (T6-T11), subcostal nerves (T12) and first lumbar nerves (L1) that contribute to the innervation of the anterior abdominal wall run with their accompanying blood vessels in a neurovascular plane, known as the transversus abdominis plane (TAP) that lies between the internal oblique muscle and the transversus abdominis muscle. Various modes of analgesia, both systemic and regional, are being used for perioperative pain relief to improve the outcome of laparoscopic cholecystectomy patients. Commonly used systemic analgesics like non-steroidal anti-inflammatory drugs (NSAIDs) and opioids are known to be associated with side-effects such as perioperative bleeding, somnolence, postoperative nausea/vomiting (PONV) and respiratory depression resulting in increased morbidity and prolonged hospital stay. To overcome these side-effects, alternative methods of pain relief have been studied over time to improve patient satisfaction and limit hospital stay.[1][2] On the other hand, conventional techniques like port-site infiltration as well as intraperitoneal instillation of local anaesthetics (LA) were found to be useful mainly in the early postoperative period only. Hebbard et al were the first to introduce the ultrasound-guided posterior approach for TAP block. In 2008, Hebbard also published a modification of this block - the oblique subcostal approach of TAP block, which could produce reliable analgesia of the supra-umbilical part of abdomen. In a retrospective study, Kadam et al[3] found that ultrasound-guided TAP block resulted in lesser fentanyl consumption in 24 hours of postoperative period due to better and prolonged analgesia when compared to port-site infiltration of LA. In yet another study, bilateral subcostal TAP block was found to be effective and even superior in providing postoperative analgesia for laparoscopic cholecystectomy with reduced pain scores, longer duration of analgesia and less postoperative analgesic consumption when compared to port-site infiltration of LA.[4] Since studies pertaining to preoperative subcostal TAP block were limited in the available literature, we decided to conduct this study to compare the analgesic efficacy of bilateral subcostal TAP block with that of intraperitoneal instillation of LA, both procedures being done preoperatively, in laparoscopic cholecystectomy patients. Our primary aim was to compare postoperative analgesia, by evaluating time needed for the administration of first dose of rescue analgesic (Inj. Paracetamol) in both groups. Total amount of rescue analgesia i.e. paracetamol required in 24 hours and intraoperative hemodynamics were included in our secondary aims. We hypothesized that bilateral TAP block when given preoperatively has better and longer postoperative analgesia than the conventionally given instillation in laparoscopic cholecystectomy.

MATERIAL AND METHODS

This prospective randomised single centric study was carried out in the department of anaesthesiology of Baroda Medical College in Vadodara, with prior approval from the Institutional Ethics Committee and registration at the Clinical Trials Registry of India (CTRI/2024/01/061269) prior to its start. The study included 80 patients with American Society of Anaesthesiologists (ASA) physical status I/II/III, aged 20 to 68 years with a body mass index (BMI) < 30 kg/m^2 who underwent elective laparoscopic cholecystectomy from February 2024 to July 2024. Patients who refused to give consent to take part in the study, had allergy to local anaesthetics, infection at the injection site and who had coagulopathy or any comorbid conditions were excluded from the study. Patients were randomly divided into two groups of 40 patients each: Group T (USG guided bilateral subcostal TAP block) and Group L (intraperitoneal instillation of LA), using computerised randomization (www.randomizer.org) in a 1:1 ratio and distributed in a closed envelope method. The anaesthesio-logist performing the block in group T and the surgeon giving port site instillation in group L were not involved in the study. Also patients were blinded to the allocated group. Hence it was a double blind study.

All patients were counselled during the pre-anaesthetic check-up and explained regarding Visual Analogue Scale (VAS), block procedure and purpose of the study before taking written informed consent. Standard general anaesthesia was given to all patients in both groups with injection Fentanyl 2µgm/kg intravenously followed by injection Propofol 2-2.5 mg/kg till loss of eyelash reflex. After check ventilation, Succinylcholine 2mg/kg was given to facilitate endotracheal intubation which was done with appropriate sized cuffed PVC endotracheal tube. Correct placement of the tube was confirmed

by five point chest auscultation and capnography waveforms. Maintenance was done with oxygen, air, sevoflurane and Injection Atracurium 0.5mg/kg IV bolus initially and repeated as and when required. Electrocardiogram, pulse rate, non-invasive blood pressure, end-tidal carbon dioxide and pulse oximetry were monitored intraoperatively and documented.

Meanwhile, 30mL volume of 0.25% Bupivacaine with 8mg Dexamethasone was prepared under all aseptic precautions in a sterile tray for either group and kept ready. After induction of general anaesthesia in Group T patients before the start of surgery, skin over the anterior abdominal wall from xiphoid process to umbilicus, extending laterally up-to mid-axillary line was cleansed with Povidone Iodine solution and draped with sterile towel. A high frequency 6 – 8 Hz linear transducer probe of SSMED portable ultrasound machine (DIGI 1100 CD), was positioned parallel to the subcostal margin, oblique to the sagittal plane to scan between anterior axillary line and xyphoid process. The rectus abdominis and the underlying transversus abdominis muscles were identified. A 22 gauge 10 cm echoplex needle was inserted in plane and advanced through the rectus muscle towards the transversus abdominis plane (Figure 1). Once the tip of the needle entered the TAP, 15mL of the total volume of prepared drug was administered. Confirmation of drug spread was observed by dissection of the TAP by depression of the transversus abdominis muscle. The block was then performed likewise on the contralateral side. In Group L, after trocar insertion and creation of pneumoperitoneum, intraperitoneal instillation of the prepared drug solution was done under vision with 15mL through the right hypochondrium port and 5mL each through the other three ports – supraumbilical, epigastric and midclavicular, by the operating surgeon.

At the end of surgery, pneumoperitoneum was evacuated by the operating surgeon, and patients were ventilated with 100% oxygen. Residual neuromuscular blockade was reversed with Injection Neostigmine 50µgm/kg and Glycopyrrolate 5µgm/kg IV. Patients were extubated once they met extubation criteria. Postoperatively, all patients were assessed for pain through VAS score for first 24 hours in successive intervals. Time for first dose of rescue analgesia was noted. Our primary aim was to compare the duration of postoperative analgesia taken as the time from block administration or intra-peritoneal instillation as per the group, to the time at which patient first complained of pain or VAS ≥ 4 at which first dose of rescue analgesia i.e. 1 gm of paracetamol infusion was given. The total amount of rescue analgesia administered in 24 hours was also recorded in both groups. Patients were observed for complications such as hematoma, nausea, vomiting and allergic reactions if any. Secondary objectives included comparison of the total amount of rescue analgesia in 24 hours postoperatively and intraoperative hemodynamics.

Statistical Analysis

Sample size was calculated from the study done by Kadam et al[3]. Keeping a power of 80% and confidence interval of 95% with ratio (group 2: group 1) as 1, a sample size of 28 was required in each group. We recruited 40 patients in each group to compensate for 10% dropouts. Statistical analysis was done using MedCalc software version 19.0. The continuous variables like age, VAS scores, time for first analgesic and total analgesics were reported as mean and standard deviation. The normality of continuous variables was assessed by the Shapiro Wilk test. The difference of mean between the groups were compared using independent student t-test. The categorical variables like gender, ASA grading, complications were reported in terms of frequencies and percentages and compared using Chi square test. The significance in results was expressed as p value. $p < 0.05$ was considered significant and $p < 0.001$ as highly significant

RESULTS AND DISCUSSION

Laparoscopic cholecystectomy is the gold standard of treatment for symptomatic cholelithiasis since 1985. Over time, laparoscopic surgeries have become popular mainly due to decreased postoperative pain and a shorter healing time as compared to open chole-cystectomies, resulting in faster recovery and an early discharge. But further studies, as one done by Sukanya Mitra et al[2] showed that pain following laparoscopic cholecystectomy in the immediate postoperative period was significant enough to affect the recovery process, thus causing a delay in discharge from the hospital. The benefits of adequate postoperative analgesia were well established and included a reduction in the postoperative stress response and perioperative morbidity. Effective pain control also facilitated better rehabilitation and accelerated recovery from surgery.

Systemic analgesics like NSAIDs and opioids were used since long for perioperative analgesia following laparoscopic cholecystectomy. But due to the multifactorial origin of pain in this surgery, as proven by studies, the dose of systemic analgesics required were often higher, leading to increased side effects. This led to the development of various regional analgesia techniques which lowered the dose of systemic analgesics, thereby decreasing the side-effects and improving postoperative analgesia and recovery. The choice of analgesia technique should depend not only on their analgesic efficacy but also on their side effect profile for better patient compliance and recovery which ultimately leads to early discharge of patients. [5,6] Regional techniques consisting of either port-site infiltration or intraperitoneal instillation of LA in combination with systemic analgesics have remained the choice of analgesia since long in laparoscopic cholecystectomy. Newer technique such as TAP block, initially performed through landmark-guided technique via the Lumbar triangle of Petit was first described in literature in 2001 by Rafi et al[6] as useful for postoperative analgesia in lower abdominal surgeries by covering T10 to L1 dermatomal levels. Over the decades various modifications of TAP block have emerged in order to block the upper abdominal dermatomes, latest being the oblique subcostal approach under ultrasound guidance, first described by Hebbard.[7] Subcostal oblique approach of TAP block has thus been found to be a useful technique for analgesia in laparoscopic cholecystectomy as it covers the dermatomes T6 to T11 which are affected in this surgical procedure.[8]

Figure 1: Sonographic Image of Oblique Subcostal Transversus Abdominis Plane (TAP) Block

After thorough search of literature though we found many studies using subcostal TAP block for pain relief in laparoscopic cholecystectomy, most of these studies had used local anaesthetic without adjuvants, and TAP block or intraperitoneal instillation done at the end of surgery. Thus, there was paucity in the literature that administered analgesic techniques before the start of surgery. Therefore, in our study we compared ultrasound guided bilateral subcostal TAP block with intraperitoneal instillation of LA; both techniques performed before the start of surgery.

The CONSORT (consolidated standards of reporting trials) flow diagram of our study is presented as in Figure 2. Our study involved 80 patients divided into two groups namely Group T (TAP Block) and Group L (intraperitoneal instillation) of 40 each.

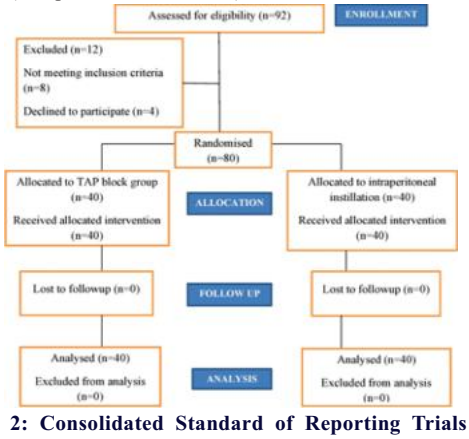

Figure 2: Consolidated Standard of Reporting Trials Flow Diagram

Both the groups were comparable with respect to age, gender and ASA status as shown in Table 1. This was in consonance with similar studies like Kadam et al[3] and Suseela et al[4].

Table 1: Demographic Data

VARIABLE	GROUP T	GROUP L	P VALUE
AGE in years (mean ± SD)	46.125 ± 5.41	48.85 ± 5.15	0.2623 (p > 0.05)
GENDER (male/female)	21/19	22/18	0.9139 (p > 0.05)
ASA GRADE (I/II/III)	8/23/9	9/21/10	P > 0.05

Test Applied: Independent Student T Test and Chi- Square Test

The principle finding of our study, that is, duration of postoperative analgesia in Group T, was significantly longer (15.05 ± 5.15 hours) than Group L (9.175 ± 1.83 hours) with a p value < 0.0001 which was statistically highly significant, depicted in Table 2.

Table 2: Duration of Postoperative Analgesia

GROUP	Total Duration of Analgesia (MEAN ± SD) (hours)	P VALUE
GROUP T	15.05 ± 5.15	< 0.0001 Highly Significant
GROUP L	9.175 ± 1.83	

Test Applied: Independent Student T Test

In a randomised comparative study by Suseela et al[4] the duration of postoperative analgesia with bilateral subcostal TAP block was found to be significantly longer when compared to the traditional port site infiltration with 0.25% Bupivacaine following laparoscopic cholecystectomy. This agrees with our study. A similar result was also obtained in the study by Pratik Kadam et al[9], where it was found that TAP block provided significantly superior postoperative analgesia in terms of time taken for first dose of rescue analgesia, the pain scores and mean analgesic requirement in the 24 hour time period. In a retrospective study by Kadam et al it was seen that the performance of TAP block was equivalent to LA infiltration technique in terms of postoperative pain scores, which is in contrast to our result. The reason could be attributed to our preemptive application of the block as well as usage of dexamethasone as an additive. Varma N P et al[10] had conducted a randomized prospective observational study and observed that preemptive TAP block resulted in superior postoperative analgesia when compared to control group who had received only general anaesthesia.

In our study it was observed that the mean amount of rescue analgesia administered in 24 hours, in the form of Inj. Paracetamol was significantly lower (p < 0.0001) in Group T (1.525 ± 0.81gm) than Group L (2.525 ± 0.55gm) as depicted in Table 3.

Table 3: Total Amount of Rescue Analgesia (Inj. Paracetamol) Required During Postoperative Period

GROUP	Total Amount of Rescue Analgesia Required (MEAN ± SD) Inj. Paracetamol (gm)	P VALUE
GROUP T	1.525 ± 0.81	< 0.0001 Highly Significant
GROUP L	2.525 ± 0.55	

Test Applied: Independent Student T Test

On analysing studies by Kadam et al and Pratik Kadam et al, the total postoperative analgesia requirement was found to be significantly lower in TAP block than with LA infiltration group highlighting a similarity with our study. In a double-blind, randomized controlled trial conducted by Dai L et al[11], it was found that bilateral USG guided TAP block provided significantly better postoperative analgesia with respect to reduced postoperative VAS score and reduced postoperative analgesic requirement, which is again similar to results obtained in our study. In our study, the pain intensity assessed by VAS, was found to be same in both the groups at 2 hours into the postoperative period but from 4 hours onwards till 24 hours it was significantly lower in TAP block group highlighting the superiority of TAP block over intraperitoneal instillation of LA as an option in the array of multimodal analgesia techniques for postoperative pain relief. Similar results were obtained in a meta-analysis trial by Grape S et al[12] comprising of ten trials, with moderate to high quality of evidence concluding that there was a significant difference in pain score at 2, 12 and 24 postoperative hours in favour of TAP block when compared with port-site LA infiltration ($p = 0.008$).

Table 4: Visual Analogue Scale (VAS) During 24 Hour Post-operative Period

TIME	VISUAL ANALOGUE SCALE		P value
	GROUP T (mean ± SD)	GROUP L (mean ± SD)	
2 hours	2.025 ± 0.15	2.1 ± 0.303	0.17 (>0.05)
4 hours	2.025 ± 0.158	2.3 ± 0.46	0.0007 (<0.001)
6 hours	2.15 ± 0.36	2.825 ± 0.67	0.0001 (<0.001)
8 hours	2.65 ± 0.769	3.45 ± 0.59	0.0001 (<0.001)
12 hours	3.225 ± 0.891	3.95 ± 0.22	0.0006 (<0.001)
24 hours	3.95 ± 0.503	4.45 ± 0.503	0.0001 (<0.001)

Test Applied: Independent Student T Test

However, a slightly contrasting result was obtained in a prospective study by Khandelwal H et al [13], where pain scores were found to be significantly lower in TAP block group in the first 6 hours of postoperative period with no significant difference thereafter up to 24 hours when compared with port-site infiltration group. The significantly lower pain scores that we observed in our study throughout the 24 hour postoperative period, could again be attributed to the action of dexamethasone used as an adjuvant to bupivacaine, in addition to the fact that both our techniques were performed pre-emptively. A study conducted by Abdelwahab et al [14] in paediatric patients for major abdominal surgery, where dexamethasone was added to LA in TAP block showed that it significantly decreased pain score up to 24 hours postoperatively. The time to rescue analgesia was prolonged and the total dose of rescue analgesia over 24-hour time period was reduced as well, which was in consonance with our study. This shows that dexamethasone as an adjuvant to LA in various regional analgesia techniques can be used as a safe and effective strategy for postoperative analgesia. Its mechanism can be explained by the fact that it acts by binding to glucocorticoid receptors resulting in inhibition of potassium channels on unmyelinated C fibres which in turn results in blockade of nociceptive information. In addition, dexamethasone also causes a degree of vasoconstriction in tissues, slowing the uptake and absorption of LA, thereby prolonging their duration of action. Also, it's potent anti-inflammatory action by suppressing the synthesis and secretion of various inflammatory mediators like interleukins and cytokines is a well-established fact which adds to prolongation of the duration of analgesia.[15]

Qianlin Zhu et al[16] conducted a study to investigate the effects of CO_2 insufflation on hemodynamic and respiratory functions during laparoscopic inguinal hernioplasty and observed that blood pressure, $EtCO_2$ and $PaCO_2$ increased significantly, whereas heart rate and pH decreased significantly in the intraoperative period. Heart rate and systolic blood pressure gets affected by many factors, the major one being pain. TAP block controls pain at port insertion site and intraoperative pain by blunting the neuro-humoral response to abdominal insufflation as well as intraoperative manipulation so that heart rate and systolic blood pressure gets controlled.

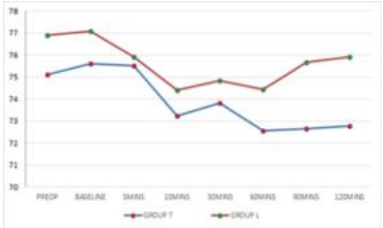

Figure 3: Comparison of Mean Intraoperative Heart Rate

Figure 4: Comparison of Mean Intraoperative Systolic Blood Pressure

In our study we had given TAP block as well as intraperitoneal instillation just after induction of general anaesthesia before the start of surgery in both the groups respectively. So it was found that the intragroup variation of mean heart rate, mean systolic and diastolic blood pressure and $EtCO_2$ during the intraoperative period in both the groups, remained within acceptable limits. While on intergroup comparison, it was found that the mean heart rate (Figure 4) and mean systolic blood pressure (Figure 5) showed a significant difference between Group T and Group L after 60 minutes into the surgery. This finding points towards a relatively better intraoperative hemodynamic stability following TAP block. Similar results were observed by Hong K Y et al [17] who performed pre-emptive TAP block for laparoscopic colorectal surgeries.

Since we performed the block under ultrasound guidance by visualising the anatomical structures, needle trajectory as well as drug deposition, there were no complications reported in any patient. Instillation of drug through port-sites was also done under vision after creation of pneumoperitoneum, thereby ensuring proper deposition of drug over the peritoneum. Also the volume of drug used was 30 mL with concentration of Bupivacaine being 0.25 %. Thus, potential risk of toxicity, which was not seen in our case, could be attributed to the above safety factors.

Limitations

Ours was a single centric study with a small sample size of 80 patients. A larger sample size and a multi-centric study is required to add more evidence to our findings. Further, dynamic VAS score on coughing was not assessed which is a better guide for quality of postoperative analgesia.

CONCLUSION

Ultrasound guided bilateral subcostal TAP block with 30 mL, 0.25% Bupivacaine with 8 mg Dexamethasone as adjuvant can be considered as an effective modality for pain relief in laparoscopic cholecystectomy, prolonging the postoperative analgesia along with reduction in consumption of 24 hours rescue analgesia doses when compared to port-site instillation using the same combination of local anaesthetic and adjuvant as proved by our prospective study.

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