Ultrasound-guided Combined Fascial Plane Blocks as an Intervention for Pain Management after Laparoscopic Cholecystectomy: A Randomized Control Study

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Abstract

Background: Pain associated with laparoscopic cholecystectomy is most severe during the first 24 h and the port sites are the most painful. Recent multimodal approaches target incisional pain instead of visceral pain which has led to the emergence of abdominal fascial plane blocks. This study embraces a novel combination of two independently effective fascial plane blocks, namely rectus sheath block and subcostal transversus abdominis plane (TAP) block to alleviate postoperative pain. Study Objective: The aim is to evaluate the effectiveness of the combination of rectus sheath block and subcostal TAP block, to compare its efficacy with that of subcostal TAP block alone and with conventional port site infiltration (PSI) in alleviating postoperative pain in patients undergoing laparoscopic cholecystectomy. Methodology: This prospective, randomized control, pilot study included 61 patients scheduled for elective laparoscopic cholecystectomy and distributed among three groups, namely Group 1: Combined subcostal TAP block with rectus sheath block (n = 20); Group 2: Oblique subcostal TAP block alone (n = 21); and Group 3: PSI group as an active control (n = 20). Results: Combined group had significantly lower pain scores, higher satisfaction scores, and reduced rescue analgesia both in early and late postoperative periods than the conventional PSI group. Conclusion: Ultrasound-guided combined fascial plane blocks is a novel intervention in pain management of patients undergoing laparoscopic cholecystectomy and should become the standard of care.

Keywords: Laparoscopic cholecystectomy, pain and satisfaction, port site infiltration, rectus sheath block, subcostal transversus abdominis plane block

Introduction

Laparoscopic cholecystectomy surgery though considered to be minimally invasive is associated with significant pain in the early postoperative period.[1] Pain associated with laparoscopic cholecystectomy has been largely underestimated due to minimal access keyhole entry, despite it being associated with significantly high postoperative pain scores.[2] Pain after laparoscopic cholecystectomy has several origins: incisional, local visceral, peritoneal, and referred.[3] Due to the multiple sources of pain, multimodal approaches to target pain has been in practice in the form of the nonsteroidal anti-inflammatory drug, cyclooxygenase-2 inhibitors, gabapentinoids, local anesthetic port site infiltration (PSI), intraperitoneal instillation of local anesthetic, and transversus abdominis plane (TAP) block.[1] Central neuraxial blockade and intraperitoneal lavage of local anesthetic have been super ceded by TAP block, PSI and supplementary opioid analgesia.[4,5] Since the first description of TAP block, it has been increasingly used for providing somatic anesthesia to anterolateral abdominal wall.[6-8] Pain associated with laparoscopic cholecystectomy is mediated by segmental innervation by nociceptor afferent pathways along the trans-abdominal fascial plane.[5,8] Hebbard et al. described the ultrasound-guided continuous oblique subcostal TAP (OSTAP) block which provides analgesia to entire abdomen continuously, especially for supra-umbilical incision.[7,9,10] Bilateral dual TAP block-based on four single shot injections to anesthetize entire abdominal wall was described by Børglum et al.[11] of which two injections were...
subcostal TAP and two were conventional lower abdominal lateral classic TAP blocks.

OSTAP has been evaluated in the control of postoperative pain and better respiratory function in outpatient laparoscopic cholecystectomy.[12] OSTAP block was compared with conventional TAP block and found to provide better analgesia during the first 24 h postoperative period in patients undergoing laparoscopic cholecystectomy.[13] Subcostal TAP block provides excellent postoperative analgesia for laparoscopic cholecystectomy with good opioid sparing effects, faster recovery profile, and reliable unilateral supra-umbilical analgesia.[4,5,7,13,14]

Rectus sheath block (RSB) has been utilized to provide analgesia for midline incision and laparoscopic procedures.[15] Ultrasound-guided rectus sheath block significantly reduced postoperative pain in single incision laparoscopic cholecystectomy surgery.[16] Combination of classic TAP block with RSB has been studied for peri-operative analgesia in conventional upper abdominal surgery and found to be superior.[6,13]

The journey of pain alleviation in laparoscopic surgeries has moved from PSI to the use of fascial plane blocks.[3,4] Classic TAP blocks have been replaced by OSTAP blocks in laparoscopic cholecystectomy, but midline pain still has not been addressed.[4,13] Rectus sheath blocks are in practice in isolation for midline pain but have not been utilised in combination with other blocks in laparoscopic cholecystectomy. On literature search, there were no studies available on this combination in laparoscopic cholecystectomy. The rationale of the present study has been to incorporate combination of these two independently effective fascial plane blocks which has previously not been attempted in laparoscopic cholecystectomy for pain alleviation.

**Methodology**

This study is a prospective, randomized, parallel group, active control, double-blind, and pilot study. Randomization was done utilizing computer generated fixed permuted block randomization technique with a block size of six and concealment was done by sequentially numbered, sealed opaque envelopes.

After obtaining institutional approval from medical research ethics committee, a written informed consent was obtained from patients posted for laparoscopic cholecystectomy. As there were no direct references for ultrasound-guided combined OSTAP block with rectus sheath block in laparoscopic cholecystectomy from previously published studies towards sample size calculation and determining the power of the study, a pilot study was taken up to include 69 patients provisionally.

A total of 69 patients in the age group of 18–65 years, of either sex, physical status ASA classes I, II, and III with symptomatic gall stone disease undergoing laparoscopic cholecystectomy willing to participate in the study were enrolled. Patients excluded were those who declined to participate, had combination surgery along with laparoscopic cholecystectomy, those detected with dense adhesions intra-operatively for which surgery had to be abandoned due to inoperability, conversion to open cholecystectomy, suspicion of malignancy, acute pancreatitis, prior endoscopic retrograde cholangiopancreatography, concomitant common bile duct stone, morbid obesity (body mass index ≥35), underlying cardiopulmonary compromise, anterior wall hernia defects, trauma, pregnancy, and those with previous abdominal surgery.

**Group allocation and randomization**

After exclusion, 61 eligible patients were allocated into three groups:

- **Group 1 (n = 20):** Ultrasound-guided combined right-sided OSTAP block with rectus sheath block (OSTAP + RSB) (40 ml 0.125% bupivacaine [20 ml in each block])
- **Group 2 (n = 21):** Ultrasound-guided right-sided OSTAP block alone (20 ml 0.25% bupivacaine)
- **Group 3 (n = 20):** Control group-surgeon performed PSI of local anesthetic drug (10 ml 0.5% bupivacaine).

The total dose of bupivacaine utilized (in terms of mg) was kept the same in all the three groups with the dilutional volume (ml) being varied.

All patients received standardized anesthesia technique with fentanyl (2 µg/kg) followed by 1 µg/kg/h), dexmedetomidine (0.5 µg/kg followed by 0.5 µg/kg/h), propofol (2 mg/kg) for induction, atracurium (0.5 mg/kg) for intubation, and (0.15 mg/kg/h infusion) for maintenance, air/O2/sevoflurane targeting a minimum alveolar concentration of 1.2.

Toward the end of surgery, before reversal of neuromuscular blockade, patients received either an ultrasound-guided local anesthetic block or port site local anesthetic infiltration according to their group allocation.

The performance of the block was done utilizing 6–13 MHz linear transducer (Sonosite®/M Turbo™, Brothell, USA) using 22 Gauge 10 mm insulated needle (Stimuplex®, B-Braun medical, Melsungen, Germany) with an in-plane technique. The procedure was standardized with horizontal probe position just under the xiphisternum which visualized linea-alba and probe were moved laterally on the right side to identify rectus abdominis muscle for rectus sheath block and then moved further laterally along the right costal margin until the three muscle layers were visualized for performing subcostal TAP block.

Rectus sheath block was performed by in-plane needle juxtapositioned in the posterior bulk of rectus muscle in contact with the posterior rectus sheath. Injection of local anesthetic would displace the posterior rectus sheath below with indentation. The probe was then moved laterally below the right costal margin to visualize the three planes of external oblique, internal oblique and transversus abdominis muscle layers with intervening fascio-aponeurotic plane and the peritoneal lining deep to transversus muscle. The local
anesthetic solution injected between the muscular plane of internal oblique and transversus abdominis in the TAP. PSI was performed by the operating surgeon who infiltrated with 10 ml 0.5% bupivacaine (2.5 ml in each of the two right subcostal and two midline ports).

Patients were reversed from neuromuscular blockade and on fulfilling extubation criteria with no evidence of residual neuromuscular block were extubated in the operating room and shifted to post anesthesia care unit. The postoperative pain scores using visual analog scale (VAS) were assessed using an independent observer blinded to the groups in the postanesthesia care unit and in the postoperative ward over 24 h.

VAS ranging 0–10 on numerical scale with corresponding six facial expression displays ranging from no pain to worst ever experienced pain were utilized. All patients were evaluated a day before surgery and explained about the VAS for pain, where 0 = no pain and 10 = worst imaginable pain.

The postoperative pain score was measured both at rest (VAS R) and on movement (VAS M) (moving in bed/coughing/straining/ambulation) by an independent assessor blinded to the study at 0 and 2 h (immediate postoperative pain). Patients were discharged from the post anesthesia care unit to the ward on meeting the postanesthesia discharge criteria. Assessment of pain at rest and movement was followed up in the postoperative ward at 6, 12, and 24 h (late postoperative pain).

Patient satisfaction score (PSS) was estimated by an independent assessor blinded to study and documented on a 0–100 scale at the end of 24 postoperative h. PSS indicated the overall performance of pain services by obtaining patient feedback by an observer about the overall pain management, patient education as well as communication received and satisfaction from rescue analgesia administered.

The overall satisfaction score (OSS) was the patient declared satisfaction score obtained as feedback from confidential hospital records before discharge from hospital on a simple 0–10 score. This score was not observer elicited, and the scoring autonomy was given to the patient. OSS represents the efficiency of pain services from patient’s perspective which includes overall satisfaction with respect to pain management, the speed of activation of rescue analgesia, satisfactory duration of the pain-free interval, overall peri-operative experience and effective communication of pain relief provided.

Tramadol consumption (TR24) represents the total dose of rescue analgesia administered within 24 h postoperatively. Trained nurse administered 50 mg slow intravenous tramadol under monitoring when VAS score was 4 and if exceeded beyond, further 50 mg was given to treat breakthrough pain over the next hour. A ceiling dose of 300 mg over 24 h was mandated.

**Outcome measurements**

**Primary outcome**

Postoperative pain score measured using VAS at 0, 2, 6, 12, and 24 h both at rest (VAS R) and on movement (VAS M).

**Secondary outcome**

1. PSS at 24 postoperative h
2. Tramadol consumption as rescue analgesia at 24 h postoperatively (TR 24)
3. OSS at the time of discharge from the hospital.

**Statistical analysis**

All quantitative and continuous variables such as age and weight utilizing descriptive statistics were expressed as a mean ± standard deviation. Mean differences between the groups were compared using ANOVA and post hoc analysis using Bonferroni multiple comparison test. For data which were not normally distributed and for evaluation at different time intervals Kruskal–Wallis test was used. For skewed data or for scores, the Mann–Whitney test was applied, and inter-quartile ranges were calculated. Qualitative or categorical variables were described as frequencies and proportions which were compared using Chi-square test. The value of $P < 0.05$ was considered to be statistically significant. Statistical analysis was performed using SPSS version 20 (SPSS Inc. Chicago, Illinois, USA) and Microsoft Excel 2011 (Microsoft Corporation, Redmond, Washington, USA).

**Results**

A total of 69 patients undergoing laparoscopic cholecystectomy were enrolled in the study. Two patients were excluded as an earlier endoscopic retrograde cholangio pancreatography had been attempted, and one patient withdrew consent and declined to participate.

Sixty-six patients enrolled were randomized into three groups of 22 patients each. Intra-operatively, the laparoscopic approach was abandoned in 5 patients. On laparoscopic visualization, two patients had dense adhesions rendering inoperability (1 each in groups combined and PSI), one patient had an inflamed pancreatic duct suggestive of acute pancreatitis (combined group), one patient had peritoneal metastatic deposits (OSTAP group) and one had difficult access due to altered anatomy (PSI group) all needing conversion to open surgery. Data analysis was performed on 61 patients across three groups. Combined group and PSI groups had 20 patients each, whereas OSTAP group had 21 patients [Figure 1].

Patients were comparable among the groups with respect to age, weight, sex, ASA physical status, and duration of surgery [Table 1]. None of the patients suffered from any serious complications arising or related to the performance of the block (local anesthesia systemic toxicity, intravascular needle entry).

**Primary outcome measures [Table 2]**

VAS scores were evaluated at rest (VAS R) and on movement (VAS M) [Table 2, Figures 2 and 3]. In the immediate postoperative period (0 h), there was no statistical difference observed in the VAS score at rest (VAS R0) and VAS score on movement (VAS M0) among the three groups.
At 2 h postoperatively, combined group had lower pain scores when compared with PSI group at rest (P = 0.045). However, other groups failed to achieve statistical significance. VAS score on movement (VAS M2) at 2 h postoperatively showed that the combined group had significantly lower pain scores when compared with the other groups (P = 0.003 and P = 0.03 between combined with PSI and combined with OSTAP group).

At 6 h postoperatively, VAS score at rest (VAS R6) both in the combined group and OSTAP group were statistically significant with lower pain scores when compared with PSI group (P = 0.02 and P = 0.003), although no statistical difference was observed between combined and OSTAP groups. VAS score on movement at 6 h postoperatively (VAS M6) in the combined group alone had less pain experienced when compared with PSI group (P = 0.002). There was no difference between combined group and OSTAP group (P = 0.13) nor among OSTAP and PSI groups (P = 0.14).

At 12 h postoperatively, VAS score at rest (VAS R12) and VAS score on movement (VAS M12) in the combined group had significantly less pain experienced when compared with PSI group (P = 0.002 at rest and P = 0.001 on movement). Similarly, OSTAP group also demonstrated less pain when compared with PSI group (P = 0.007 at rest and P = 0.004 on movement). However, there was no difference among combined and OSTAP groups both at rest and in movement.

At 24 h postoperatively, VAS score at rest (VAS R24) in the combined group was the only group which had significantly less pain when compared with PSI group (P = 0.01). VAS score on movement (VAS M24) failed to show any statistical significance among the groups.

Secondary outcome measures [Table 3]

Patient satisfaction score
There was the statistically significant difference in PSS among the groups in comparison to PSI group [Table 3 and Figure 4]. At 24 h postoperatively, combined group and OSTAP groups had higher satisfaction levels when compared with PSI group (P < 0.001). However, there was no difference in PSS on an intergroup comparison between combined group and OSTAP group (P = 0.17).

Tramadol consumption as rescue analgesia at 24 h (TR 24)
There was statistically significant difference in TR 24 among the groups [Table 3 and Figure 5]. The combined group had significantly lower consumption of tramadol when compared with all the groups (P = 0.011 between combined and OSTAP; P < 0.001 between combined and PSI). The OSTAP group also had significantly lower consumption of tramadol when compared with PSI group (P = 0.006).
There was statistically significant difference in OSS among the groups [Table 3 and Figure 6]. The combined group had significantly higher satisfaction scores than the other groups (P = 0.001 between combined and OSTAP; P < 0.001 between combined and PSI groups). OSTAP group also had significantly better satisfaction scores when compared with the PSI group (P < 0.001).

**Discussion**

The mechanisms that trigger postoperative pain being multifactorial, effective control of pain after laparoscopic cholecystectomy is hence considered difficult.[17] The most likely cause of postoperative pain is visceral pain caused by organ trauma during gall bladder resection and parietal pain due to the skin incision.[17]

The primary aim of this study was to compare the pain scores at various time points among the three groups both at rest and movement as was done in previous studies.[6,12,14,16]

Bisgaard et al.[18] reported that incisional pain contributes more in postlaparoscopic pain than visceral pain and suggested that future studies of pain control should focus on decreasing this type of pain. Therefore, we focused on the utility of...
Ramkiran, et al.: Fascial plane block in laparoscopic cholecystectomy

Figure 4: Comparison of patient satisfaction score at 24 h. PSS 24 = Patient satisfaction score at 24 hours after surgery. Group 1 received ultrasound-guided right subcostal transversus abdominis plane block with rectus sheath block (COMBINED); Group 2 received an ultrasound-guided subcostal transversus abdominis plane block; Group 3 received port site infiltration

Figure 5: Comparison of 24 h tramadol requirement. TR 24 = 24 h tramadol consumption. Group 1 received ultrasound-guided right subcostal transversus abdominis plane block with rectus sheath block (COMBINED); Group 2 received an ultrasound-guided subcostal transversus abdominis plane block; Group 3 received port site infiltration

Figure 6: Comparison of overall patient satisfaction score. OSS = Overall patient satisfaction score. Group 1 received ultrasound-guided right subcostal transversus abdominis plane block with rectus sheath block (COMBINED); Group 2 received an ultrasound-guided subcostal transversus abdominis plane block; Group 3 received port site infiltration

Figure 7: Rectus sheath block

combination blocks of abdominal wall fascial plane in the form of subcostal TAP and rectus sheath block for laparoscopic cholecystectomy to provide pain alleviation in the first 24 h postoperatively. The present study addressed immediate and late postoperative pain scores both at rest and on movement across fixed time intervals similar to the study by Bhatia et al.[14]

The most common pain pattern found in our study was a dull aching discomforting sensation in the midline attributable to pain worsening on movement, coughing, and ambulation. This was a major hindrance to early ambulation and to meet discharge criteria citing the need for rescue analgesia.

There was no significant difference in VAS scores both at rest and on movement in the immediate postoperative period (VAS R0, M0) which may be attributed to the protocol based use of dexmedetomidine with opioid practised in our institute. This finding differed from results of other studies where dexmedetomidine was not included with standard opioid regimen and hence probably had higher pain scores in the immediate postoperative period.[14]

Pain scores were significantly less at 2 h postoperatively both at rest and on movement (VAS R2, VAS M2) in the combined group which provided a favorable analgesic platform into the late postoperative period.

With regard to late postoperative pain, combined group had significantly less pain at rest at 6, 12, and 24 h (VAS R6, 12, 24) when compared with PSI group. The OSTAP group also had lesser pain than the PSI group at 6 and 12 h postoperatively which is comparable with previous studies.[6,13,14,16] There was no difference found in pain scores at rest between combined and OSTAP groups at these time period.

Postoperative pain is most severe during the first 24 h after a laparoscopic surgery and the port sites are the most painful...
regions on the first day postoperatively.\[^{19}\]\ The worsening of late postoperative pain overlaps with ambulatory movement. The combined group provided extended analgesia upon ambulation persisting at 6 and 12 h (VAS M6, M12). However, due to gradual local anesthetic resorption from fascial planes, the analgesic effect was probably not sustained on ambulation. VAS on movement at 24 h (VAS M24) showed all the groups to be comparable. Wearing off effect of local anaesthetic in the plane of abdominal wall could have resulted in comparable pain among the groups on ambulation; although, resting pain score was significantly less in combined group even at 24 h.

The overall peri-operative experience was satisfying needing lesser rescue analgesic requirement in both the combined and OSTAP groups when compared with PSI group as reflected by PSS, OSS, and TR 24.

An intergroup comparison between combined and OSTAP groups revealed better OSS and lesser consumption of rescue tramadol analgesia (TR 24) in the combined group [Table 3]. There was no statistical difference between these groups with respect to the elicited PSS which could have been interviewer biased.

However, the study was not without limitations. The study was conducted on a pilot basis and further studies involving larger population are required to validate the findings. The results of the study cannot be extrapolated on day care laparoscopic surgeries. All assessments were not made by single observer which could have led to inter-observer bias in reporting the scores. Nausea, vomiting, sedation, and drug interactions were not independently evaluated in our study. Bilateral instead of unilateral rectus sheath block in combination with right subcostal TAP block would probably further reduce postoperative pain score, as most reported pain after 24 h was midline in origin. Finally, neither the pharmacological role of adjuvant/continuous catheter delivery system nor the postoperative use of strong opioid was considered in the study.

In conclusion, this study utilized a novel combination of right-sided subcostal TAP block with rectus sheath block [Figures 7 and 8] in laparoscopic cholecystectomy surgery for pain alleviation which has not been previously attempted.

### Conclusion and Future Recommendations

The combination of right-sided subcostal TAP block with rectus sheath block provides effective analgesia both in early as well as late postoperative periods in comparison to conventional PSI. We recommend ultrasound-guided combined fascial plane block as the standard of care for pain alleviation in laparoscopic cholecystectomy surgeries which can be extended for all laparoscopic surgeries in future.

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### Conflicts of Interest

There are no conflicts of interest.

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