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Comparative study of bilateral subcostal transversusabdominis plane block and port-site infiltration with ropivacaine for post-operative analgesia in laparoscopic cholecystectomy

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ABSTRACTS

AIMS AND OBJECTIVES:

Our primary objective was to find the mean total analgesic requirement in 24 h and the duration of analgesia.

Secondary objective to assess the quality of analgesia using Numerical Rating Scale (NRS). In patients undergoing elective laparoscopic cholecystectomy under general anaesthesia were divided into two groups of 50 each to receive ultrasound-guided bilateral subcostal TAP block (A) with 0.375% plain ropivacaine10ml each side or port-site infiltration with 0.375% ropivacaine 5 ml each at 4 ports (B) at the end of the surgery before extubation. All patients received paracetamol 1 g intravenous 8th hourly. Tramadol 1 mg/kg intravenous bolus and inj. Diclofenac 1mg/kg infusion were used as the first- and second-line rescue analgesics when Numerical Rating Scale (NRS) ≥4, or when the patient complained of pain. NRS at 1, 2, 3,6,12 and 24 h after surgery, time to first analgesic request and total dose of analgesics in 24 h were recorded. Chi-square test and independent *t*-test were used to compare qualitative and quantitative data respectively.

RESULTS:

Time to first analgesic (mean±SD) in Group A and Group B was 440.35 ± 148.55 min and 290.7 ± 67.03 min mean tramadol required was 49.69 ± 36.15 mg and 140.8 ± 60.02 mg , respectively (P = 0.001 for both). Mean NRS at 2, 3, 6, 12 and 24 h was significantly lower in Group A.

CONCLUSIONS:

Bilateral subcostal TAP block provides superior post-operative analgesia after laparoscopic cholecystectomy compared to port-site infiltration**.**

Keywords: Ropivacaine, laparoscopic cholecystectomy, post-operative analgesia, transversusabdominis plane block.

1. INTRODUCTION

Laparoscopic cholecystectomy is a safe and effective procedure done for various gall bladder disease conditions and has become the treatment of choice for symptomatic gall stones. Compared to open cholecystectomy, laparoscopic method is associated with less post-operative pain, early recovery reduced hospital expenses and improved cosmesis and patient

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satisfaction, and thus, it is even done as a day-care surgery. Although minimally invasive, many of the patients experience moderate-to-severe pain in the early post-operative period.
Subcostal transversusabdominis plane (TAP) block can provide sensory block of the T7 to T12 nerves as against the classical posterior approach which provides sensory block from T10 to L1 spinal segment levels.The accuracy and quality of nerve blockade can be enhanced with the guidance of ultrasound. Port-site infiltration with local anaesthetics is another effective method of providing analgesia after laparoscopic cholecystectomy. However, there is a paucity of literature comparing the efficacy of these two methods, so we planned this study.
The aim of the study was to compare the efficacy of USG-guided bilateral subcostal TAP block with port-site infiltration using ropivacaine for post-operative analgesia after laparoscopic cholecystectomy with a hypothesis that both TAP block and port-site infiltration are effective in providing post-operative analgesia.

2. METHODS

It was a double-blinded randomised comparative clinical trial done on patients undergoing elective laparoscopic cholecystectomy in our tertiary care teaching hospital during 2020–2021 after getting Institutional Research and Ethical Committee approval. hundred patients with the American Society of Anesthesiologists (ASA) physical status I/II, aged between 20 and 65 years with a body mass index (BMI) of 18–35 kg/m^2 scheduled for elective laparoscopic cholecystectomy, were recruited and randomised into two groups of 50 each using computer-generated random number chart. An informed written consent was obtained from each patient with respect to the nature of anaesthesia and options of analgesia.

Exclusion criteria

Patients with allergy to local anaesthetics, infection at the site of injection, chronic pain syndromes, prolonged opioid medication, coagulopathy and those patients who received any analgesic 24 h before surgery were excluded from the study.
Preoperatively all patients were instructed regarding how to read the NRS that was used for assessing the pain in the post-operative period. Education status of the patients were assessed to eliminate bias due to difference in education level of the participants which may influence the interpretation of NRS. All patients received oral premedication with ranitidine 150 mg and metoclopramide 10 mg 2 h before the proposed surgery, and injection midazolam 0.5 mg was given intravenously (IV) immediately before induction. Induction was with injection propofol 2 mg/kg IV and injection fentanyl 2 μg/kg IV. Endotracheal intubation with appropriate size cuffed endotracheal tube was facilitated with injection succinylcholine 1.5 mg/kg intravenously. Anaesthesia was maintained with oxygen (33%), nitrous oxide (66%) and isoflurane (0.4%to 0.8%) and injection atracurium 0.5 mg/kg IV bolus for muscle relaxation. Additional atracurium was given as deemed necessary by the attending anaesthesiologist. Intraoperative monitors included electrocardiogram, non-invasive blood pressure, pulse oximeter and end-tidal carbon dioxide. Vitals signs were maintained stable throughout intraoperative period.
All patients received injection paracetamol 1 g intravenous infusion intraoperatively at the beginning of surgery. At the end of surgery before extubation, patients received either port-site local anaesthetic infiltration or ultrasound-guided bilateral subcostal TAP block. Port-site infiltration was with 20 mL of 0.375% ropivacaine (5 mL at each of the four port sites – umbilical, epigastric, midclavicular and anterior axillary ports on the right side) by the operating surgeon. Bilateral ultrasound-guided subcostal TAP block was performed by the attending experienced anaesthesiologist with 10 mL of 0.375% ropivacaine on each side

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using transportablemindray ultrasound and high-frequency (6–13 MHz) linear transducer. A total of 75 mg of ropivacaine was used in both groups. The anaesthesiologist and surgeon performing the block were not involved in post operative follow up of patient.

Postoperatively, all patients received paracetamol 1 g intravenous infusion 8^{th} hourly. For breakthrough pain, injection tramadol 1 mg/kg intravenous bolus and diclofenac 1 mg/kg intravenous infusion were given as the first- and second-line rescue analgesics, respectively. NRS for pain was assessed serially at 1, 2, 3, 6, 12 and 24 h after surgery. The assessor and the patients were unaware of the type of intervention received. Rescue analgesics were administered when NRS ≥4 or when the patient complained of pain. Time for first analgesic request and NRS at first analgesic request were recorded. The duration of analgesia was taken as the time from block administration to the time at which patient complained of pain or NRS was ≥4 on assessment at serial intervals. Total doses of rescue analgesics required in the first 24 h were recorded. Occurrence of any complications such as haematoma, bleeding, nausea, vomiting and allergic reactions was also observed.

Our primary objective was to find the mean total analgesic requirement in 24 h and the duration of analgesia and secondary objective to assess the quality of analgesia using Numerical Rating Scale (NRS).

In a previous study[11] the mean post-operative consumption was 86.9 ± 73.79 μg in port-site infiltration compared to 33.16 ± 54.17 μg in TAP block group. Keeping a power at 80% and alpha error at 0.05,a sample size of 23 would be required in each group. Hence, we recruited 50 patients in each group to compensate for the dropouts if any. Statistical analysis of the data was done using the Statistical Package for the Social Sciences for Windows (SPSS Inc., Chicago) software version 18. Qualitative data such as sex, ASA physical status, education and adverse effects were compared using Chi-square test. Quantitative data such as age, height, weight, BMI, Numerical rating scales, time to first analgesic request and total analgesic requirement in 24 h were compared using independent *t*-test. $P < 0.05$ was taken as statistically significant.

3. RESULTS

A total of 100 patients were recruited for the study and all patients completed the study. Both groups were comparable with respect to sex, ASA physical status and educational status. There was no significant difference between the groups with respect to demographic variables such as age, weight, height and BMI

Comparison of demographic variables of study population with P value

(Table-1)

Variable	**Category (Mean SD)**		**P-Value**
	Group A	**Group-B**	
Age(years)	**42.25±12.30**	**44.25±12.92**	**0.672**
Weight(kg)	**65.45±5.25**	**64.82±6.02**	**0.603**
Hight(CM)	**161.82±8.46**	**163.10±8.67**	**0.508**
BMI($kg/m^{2)}$	**25.08±2.21**	**24.31±2.21**	**0.130**

The mean first rescue analgesic (tramadol) requirement was 141.8 ± 60.01 mg in Group B and 48.69 ± 36.14 mg in Group A ($P = 0.001$). Four participants in Group B required second

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rescue analgesic diclofenac but none in Group A. The duration of analgesia was 290.7 ± 67.03 min in Group B and 440.35 ± 154.55 min in Group A (P = 0.001). The mean NRS at first analgesic request was 6.08 ± 0.92 in Group A and 4.38 ± 0.490 in Group B (P = 0.001). The mean NRS for pain was zero at 1 h in both the groups. The mean NRS at 2, 3, 6, 12 and 24 h in Group A and Group B is summarized in Table-2. The mean pain scores at all time frames except at 1 h were lower in Group A compared to Group B and were statistically significant (P < 0.05).

Two patients had vomiting in the post-operative period in Group B, but there was no adverse effect in Group A. The difference in incidence of this adverse effect was not statistically significant (P = 0.152). No other adverse effects were noted in either group

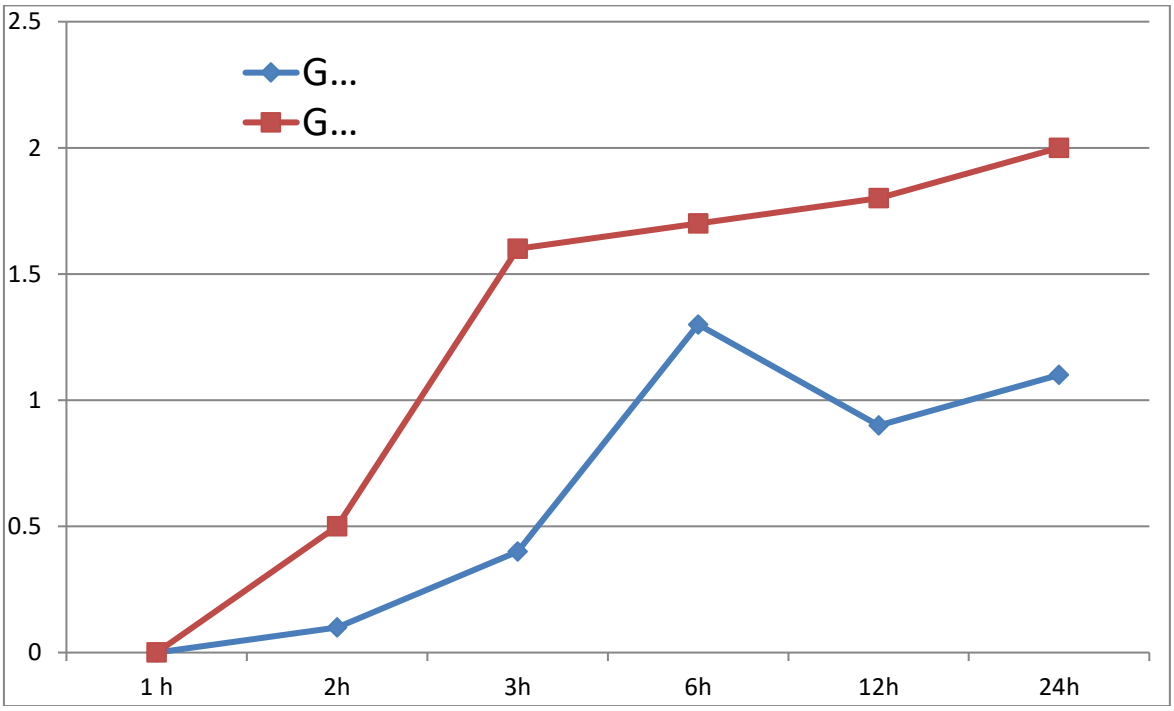
Numerical Rating Scale of study groups with P value

(Table-2)

NRS hours	Category (Mean SD)		P-Value
	Group-A	**Group -B**	
NRS-1	0.0±00.00	0.000±.00	0.004
NRS-2	0.0±20.15	0.2±50.55	0.003
NRS-3	0.4±20.54	2.04±0.95	<0.001
NRS-6	1.34±0.79	3.09±1.18	<0.001
NRS-12	0.9±20.85	2.47±0.81	<0.001
NRS-24	1.12±0.51	2.24±0.58	<0.001

NRS-Numerical Rating Scale, Group A-TAP block group, Group B-Port infiltration group, TAP- Transversusabdominis plane, SD- Standard deviation

Line graph comparing numerical Rating Scale at 1, 2, 3, 6, 12, and 24 h after transverses abdominis plane block (Group A) and port-site infiltration (Group B)



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4. DISCUSSION

Cholecystectomy is a common surgical procedure done for various gall bladder disease conditions including cholelithiasis. It is proven that lack of effective post-operative pain control will not only result in adverse physiological effects but also can end in chronic pain. Because of the excellent quality of analgesia provided by local anaesthetics without much side effects such as sedation, they are widely used for post-operative analgesia in various surgeries including laparoscopic cholecystectomy. Amongst the different analgesic techniques, port-site infiltration and TAP block are found to be very effective in providing post-operative analgesia.[4,14,7] In the present study, a comparison was done between these two methods for post-operative analgesia in laparoscopic cholecystectomy.

Even though the classic approach initially described[15] was through the lumbar triangle of petit, to cover the upper abdominal dermatomes, anterior subcostal approach is also described later block is suitable for our stuty group patients[13] TAP block was not free of complications[10] until the introduction of ultrasound in regional anaesthesia. Ultrasound-guided TAP block helps in clearly demarcating the anatomy, increases the margin of safety and help in deposition of local anaesthetic under vision which increases the success rate and reduces the volume of drug(i.e.10ml only) needed for effective block.[12] Hence, in our study, USG-guided subcostal TAP block was used for post-operative analgesia.

In this study, TAP block was performed using smaller concentration (0.375%) of ropivacaine to reduce local anaesthetic toxicity if any. In both port-site infiltration and TAP block, a total of 75 mg of ropivacaine was used to avoid confounding due to dose differences.

In our study, of the 100 participants, 50 received USG-guided bilateral subcostal TAP block (Group A) and 50 received port-site infiltration (Group B). The groups were comparable with respect to sex, ASA physical status, age, height, BMI and education status.

NRS for pain was zero at 1 h in both the groups. That means port-site infiltration and TAP block are effective in providing analgesia in the 1st h. NRS was significantly lower in Group A compared to Group B at all other time frames. The mean NRS at first analgesic request was 6.08 ± 0.92 in Group B and 4.38 ± 0.49 in Group A which shows that the intensity of pain was less in TAP group compared to infiltration. In a study[4] conducted on 43 patients, the mean pain scores at 1 h and 4 h were less in TAP block compared to port-site infiltration. Our study results were also consistent with a previous study done for post-operative analgesia after laparoscopic cholecystectomy with lower pain scores after TAP block compared to port-site infiltration.

The duration of analgesia was 290.7 ± 67.03 min in Group B and 440.35 ± 148.55 min in Group A. Long duration of analgesia may be due to slow absorption of the drug from the less vascular tissue plane between the muscles in TAP block compared to tissue infiltration. Mean tramadol requirement was 140.8 ± 60.02 mg in Group Band 49.69 ± 36.15 mg in Group A Four patients required second rescue analgesic diclofenac for pain control in Group B but none in Group A. From this, it is evident that TAP block reduces the overall post-operative analgesic requirement and has got both opioid and non-steroidal anti-inflammatory drug-sparing effect in the post-operative period which are consistent with above studies.[4] There were two episodes of vomiting in Group B which was not statistically significant when compared to Group A. Higher incidence of vomiting in Group B may be due to greater tramadol requirement in Group B for pain control.

In a retrospective study[11] where 51 patients underwent day-care laparoscopic cholecystectomy were analysed for post-operative pain scores, patient satisfaction scores and post-operative fentanyl requirement in recovery and cost for the post-operative analgesic

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technique were used. In our study, ropivacaine was used to administer TAP block using ultrasound guidance that may be the reason for the difference in outcome compared to our study. In another study, there was no clinically significant difference in pain scores and post-operative analgesic requirement between TAP block and port-site infiltration even though the duration of analgesia and severity of pain were not assessed. Here, only 10 ml of 0.375% ropivacaine in each side with the classic approach was used for TAP block the difference may be due to uses of ultrasound resulting in précis nerve blockage

In another study post-operative morphine consumption and pain scores were assessed after giving TAP block or port-site infiltration after single-incision laparoscopic cholecystectomy. In contrast to our study, they found that TAP block was not effective in reducing the 24 h morphine consumption even though it provided analgesia in the early post-operative period.

Limitation of study, analgesic techniques were administered postoperatively, but if it was administered preoperatively, it might have decreased the intraoperative pain and opioid requirement also thereby benefitting the patient. No adverse events related to local anaesthetic toxicity. Dynamic pain assessment is more important than static pain to facilitate early mobilisation . Further studies are required to show the analgesic efficacy of USG-guided TAP block in various other abdominal surgeries using different local anaesthetics at different doses and continuous catheter techniques.

5. CONCLUSION

Ultra sound guided Subcostal TAP block is effective and found to be superior in providing post-operative analgesia after laparoscopic cholecystectomy with reduced pain scores, longer duration of analgesia and less post-operative analgesic requirement compared to port-site infiltration.

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Conflicts of interest
There are no conflicts of interest.

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