ORIGINAL RESEARCH

Comparison Of Post-Operative Analgesia By Transverse Abdominis Plane (TAP) Block Done Under Laparoscopy Vs Ultrasound (US) Guidance In Patients Of Laparoscopic Cholecystectomy- A Retrospective Observational Study

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Abstract:
Introduction: Laparoscopic cholecystectomy is one of the most common surgeries done in the surgical specialty. But the incidence of moderate to severe pain remains high for the first 24 hours post-surgery due to segmental innervation of nociceptor afferent pathways. Therefore, for the management of this post-operative pain, bilateral subcostal TAP block is given. This TAP block is given laparoscopically and under ultrasound guidance. Laparoscopic guided TAP Block has recently been introduced, and there are not many studies regarding this technique.
Material and Methods: A retrospective observational study was done on 108 patients with an age range of 18–65 years. The TAP block was done with bilateral injection of 30cc Bupivacaine between layers of internal oblique and transversus abdominis, either under laparoscopic visualization or under US guidance just below the coastal margin in the midclavicular line. The postoperative analgesia assessment was done blindly by the controller with the VAS scale, every half hourly for the first 2 post-operative hours, then every 2 hourly for the next 8 post-operative hours, and later as per need and indication for the next 14 hours, completing 24 hours of assessment for the study. Therefore, the need for rescue analgesia was noticed.
Results: Box-plot analysis with Wald-type and ANOVA-type tests was applied, and calculations for testing group and time effects and interaction were made. Significant differences between the two groups were seen during the initial part of the study. Later, the significant difference was reduced with the consequent formulation of the surgeon's technique of administration. As a result, the post-operative pain with the laparoscopically guided TAP Block significantly improved. With the passage of time, more patients were getting similar results in the control of post-operative pain, either by laparoscopic or ultrasound-guided methods.
Conclusion: The laparoscopic guided TAP Block has some advantages over the ultrasound guided TAP Block, as it can be administered in the operating theatre itself within 30 seconds, and there is no requirement for an interventional radiologist in the operating theatre. Also, there is no need for the ultrasound machine in the operative theatre for the administration of the block. Therefore, laparoscopic guided TAP block must be considered as an effective method for post-operative pain management.

Introduction:

Minimal access surgery is a common surgical treatment across all surgical disciplines. With minimal access surgery, early recovery, mobilization, and less pain are well recognized benefits. Still, the day after laparoscopic cholecystectomy, the incidence of moderate and severe pain remains high at 65% and 23%, respectively, which is mediated by segmental innervation of nociceptor afferent pathways along the trans abdominal fascial plane.[1][2] Abdominal pain is

the most common cause of patient discomfort in the first 24 hours after a laparoscopic cholecystectomy. There are several types of pain that can occur during a laparoscopic cholecystectomy: somatic pain, which originates from the trocar site; local visceral pain, which is deep abdominal discomfort; parietal pain; and referred visceral pain, which is caused by tissue trauma during gall bladder resection.[2] Also, there is pneumoperitoneum associated pain; shoulder tip pain (secondary to irritation of the diaphragm by the capno-peritoneum), peritoneal, diaphragmatic stretching, ischemia, acidosis.[3][4] Along with this, there is systemic hypercarbia causing sympathetic nervous system excitation, resulting in amplification of local tissue inflammatory response.[4] As a result, pain treatment is a major priority in the post-operative period, both for patient comfort and also to lower the metabolic stress response. It may affect the day-care surgery option in some centers. Though, in the literature, subcostal TAP block has been mentioned as one of the successful modalities described by Hebbard et al., 2019 for even better pain control.[5] Routine use of such multi-modal analgesia with protocol has successfully been demonstrated to improve pain management and patient satisfaction in the postoperative period. [6] But the side effects of opioid analgesics such as dizziness, respiratory depression, ileus, nausea, vomiting, urinary retention, somnolence, and itching that result in delayed discharge have led to the better development of peripheral nerve block. There have been several methods used to manage post-operative pain, including intravenous patient-controlled analgesia, patient-controlled thoracic epidural analgesia, intra-peritoneal injection of local anesthetics, intra-operative use of low-pressure pneumoperitoneum techniques, and neuraxial anesthesia.[7][8] Bilateral TAP Block aids in the relief of somatic pain. The Bilateral TAP Block has been previously used for bariatric surgery, gynecological surgeries, and other lower abdominal incisional surgeries.[9] Finally, when there is a predominance of somatic pain over visceral pain, a clinical benefit of the TAP Block might be expected, but for the visceral pain, the TAP Block would be less efficient.[3]

Materials and Methods:

***2*.1 Study Design:** The study was performed at the Adesh Institute of Medical Sciences and Research (AIMSR), Bathinda, Punjab. All the study documents and procedures were approved by the institutional ethical and review committee at the AIMSR. The ethical guidelines of the Declaration of Helsinki were followed. This retrospective, comparative study identified 108 patients who had laparoscopic cholecystectomy, for the past 1 year (September 2021 - September 2022) which was further divided into 2 groups based upon the inclusion and exclusion criteria (CONSORT flow diagram): Group A-54 patients (TAP block via Laparoscopic guidance). Group B-54 patients (TAP block via Ultrasound guidance).

2.2 Inclusion and Exclusion Criteria:

Patients aged 18–65 years undergoing laparoscopic cholecystectomy were enrolled in the study. Patients with any psychological conditions, opioid addiction, laparoscopy converted to open surgery, patient refusal, patients with a history of cardiac or respiratory diseases (>ASA III), patients with allergy to amide local anesthetics or medication included in the study, infection at the needle insertion sites, pregnancy, drug abusers, BMI >35, perforated gall bladder or gall bladder mass were excluded from the study.

2.3 Anesthesia Application:

Patients were shifted to the operation theatre by a trained staff member on a trolley. In the operation theatre, standard monitors for pulse oximetry for saturation (SpO_2), noninvasive blood pressure monitoring (NIBP), and electrocardiogram (ECG) were connected and baseline pulse rate, mean arterial pressure, and oxygen saturation were recorded. Premedication: 0.05mg/kg Midazolam, 0.004mg/kg Glycopyrrolate, 2µg/kg Butorphanol i.v. pre-oxygenation will be done with 100% oxygen for 3 minutes. Induction was done with intravenous inducing agents inj. propofol 1.5 mg/kg i.v. A smooth intubation with an Endotracheal Tube (E.T.T) according to the group allotted was done by an experienced anesthesia consultant, who has a minimum of 5 years of experience, isoflurane maintenance in 33% oxygen and 67% nitrous oxide. Ventilation was controlled to maintain the end tidal CO_2 between 32–36 mmHg with a tidal volume of 6–8 ml/kg and a respiratory rate of 10–12 min. At the end of the surgery, neuromuscular blockade was reversed with inj. neostigmine 40 ug/kg and inj. glycopyrrolate 10 ug/kg i.v.

2.3 Block Intervention:

The TAP block was performed by injecting 30cc Bupivacaine bilaterally between the layers of the internal oblique and transversus abdominis, either laparoscopically or under US guidance right below the coastal margin in the midclavicular line. For Group B patients, an ultrasonogram with a 5-13 MHz linear probe was used. On both sides, the probe was positioned immediately below the coastal borders in the midclavicular line. In the fascial plane between the internal oblique and the transversus abdominis muscle, a 20-gauge needle with tubing was inserted. The hydro-dissection of 30cc of Bupivacaine delivered in Group B confirmed the accurate needle insertion (Figure 1).

The right plane of infiltration in the laparoscopically guided TAP Block was detected by observing the raising of transverse abdominis muscle fibers (Doyle's Bulge) seen intra-peritoneally by hydro-dissection.

Bupivacaine 30cc was administered to both sides of the internal oblique and transverse abdominis muscles in Group A (Figure 2).

2.4 Evaluation of Pain:
The pain was accessed by VAS (Visual Analogue Pain Scale) 0–10 at rest, post-operatively in both groups. The VAS Scale is a 1–10 point scale consisting of integers from 0 through 10. 0 means "no pain", 1-3 means "mild pain", 4-6 means "moderate pain," and 7-10 means "severe pain (worst pain imaginable)". The patient's fascial expression was noticed for the evaluation of the pain. The assessment of postoperative analgesia was done blindly by the controller with the VAS scale, every half hourly for the first 2 post-operative hours, then every 2 hourly for the next 8 post-operative hours, and later as per need and indication for the next 14 hours, completing 24 hours of assessment for the study. The need for rescue analgesia within 24 hours post-operatively in patients who have undergone laparoscopic cholecystectomy was also be noted.

2.**5 Post-Operative Analgesia:** If the patient complains of pain in spite of adequate block or early wear-over of the block, an injection of ketorolac 30 mg diluted in 100 ml of normal saline infused over 15–20 minutes was administered. The VAS assessment was carried out again. If in spite of administering rescue analgesia, the desired pain relief is not obtained, then the patient was excluded from the study and an injection of tramadol 100 mg diluted in 100 ml of normal saline was given for analgesia over 15 to 20 minutes.

2.7 Outcome measures: The Pain Score was analyzed using the VAS Score and the need for rescue analgesia was analyzed for the first 24 postoperative hours.

2.8 Statistical analysis: IBM SPSS Version 23.0, R software environment for statistical computing and graphics (version 4.2.1) and Microsoft Office Excel 2007. Continuous data has been expressed as a mean (standard deviation) or median (interquartile range). The categorical data was summarized as frequencies and percentages. The normality of the continuous data was tested by the Shapiro-Wilk test. The normally distributed continuous variables have been analyzed by the unpaired t test, and the variables which do not assume normal distribution are tested by the Mann-Whitney U test. Categorical data was analyzed using the Chi-square test or Fisher's exact test. The package "nparLD" for Nonparametric Analysis of Longitudinal Data in Factorial Experiments was used to analyze continuous data with repeated measurements with an f1.LD.f1 design. p values < 0.05 are accepted as indicative of statistical significance.

Results:
In total, 130 patients were screened for enrolment in the study. After the exclusion of 22 patients, 12 patients did not meet the inclusion criteria and 10 patients declined to participate, 108 patients participated in the study. Of these, 57 (52.8%) were males and 51 (47.2%) were females. A retrospective comparative study was done in patients undergoing laparoscopic cholecystectomy. Demographic data is summarized in Table I. The treatment to control ratio is 1:1. The duration of stay in the hospital for the participants in the two groups and the median (interquartile range) were analyzed with the Mann-Whitney U test; the result was insignificant (Table II).Comparison of post-operative analgesia in the two groups at time points: 30 min, 60 min, 90 min, 2 hrs, 4 hrs, 6 hrs, and 8 hrs. Nonparametric Tests for the F1-LD-F1 design were done. This function performs several tests for the relative treatment effects with global or patterned alternatives for the F1-LD-F1 design. The F1-LD-F1 design refers to the experimental design with one whole-plot factor and one sub-plot factor. For the experiments with the F1-LD-F1 design, the Wald-type statistic (WTS) (Table III), the ANOVA-type statistic (ATS) (Table IV), and the modified ANOVA type statistic with Box (1954) (Table V), Wald-time test (Table VI) and Anova time test (Table VII) approximations were calculated for testing group and time effects and interaction. Requirement of additional dose of analgesia in 24 hrs in the participants in the two groups was done, no statistically significant difference between Group A and Group B in terms of the requirement for an additional dose of analgesia in the 24-hour period, as indicated by the p-value of 0.678. Most participants in both groups did not require additional analgesia. It was requested by six patients; four patients in group A and two patients in group B (Table VIII). The difference in the pain score at each time point was done using the Mann-Whitney U test (Table IX). Relative treatment effects (RTE) for the pain scores was calculated over time for both the groups A and B (Figure 3)Box-plot analysis was done for the VAS at post-operative 30 mins, 60 mins, 90 mins, 120 mins, 2 hrs, 4 hrs, 6 hrs, and 8 hrs. The graph revealed that the post-operative pain management was equivalent after 6 hrs in both the groups. (Figure 4) Significant differences between the two groups were seen during the initial part of the study. Later, the significant difference was reduced with the consequent formulation of the surgeon's technique of administration. Hence, there was significant improvement in the post-operative pain in the laparoscopically guided TAP Block. With the passage of time, more patients were getting similar results in the control of post-operative pain, either by laparoscopic or ultrasound guided methods.

Table I: Demographic Data

Basic characteristics	Group A	Group B	Total	p value*
Age[#]	49.7 (13.0)	50.6 (11.4)	50.1 (12.2)	0.700
Sex[@]				
Male	31 (57.4%)	26 (48.1%)	57 (52.8%)	0.335
Female	23 (42.6%)	28 (51.9%)	51 (47.2%)	

[#]Mean (Standard deviation). Unpaired t test used.
[@]Frequency (percentage). Chi-square test used *Significance level is 0.05 level

Table II: Duration of stay in the hospital for the participants in the two groups.

	Group A	Group B	Total	p value*
Duration of stay (in days)	5 (3 - 5)	5 (4 - 7)	5 (4 - 6)	0.069

[#] Median (Interquartile range). Mann-Whitney U test used. *Not significant

Table III. Wald Test: the test statistic, the degrees of freedom (df) of the central chi-squared distribution, and the corresponding p-value of the Wald-type test.

	Statistic	df	p-value
Group	21.3	1	**0.00000392***
Time	684.6	6	**1.30e-144***
Group: Time	34.7	6	**0.00000487***

*Significant at <0.05 level

Table IV: ANOVA test: The test statistic, the numerator degrees of freedom (df) of the central F distribution, and the corresponding p-value of the ANOVA-type test; the denominator degrees of freedom is set to infinity.

	Statistic	df	p-value
Group	21.3	1	**0.00000392***
Time	226.5	3.9	**2.66e-190***
Group: Time	5.5	3.9	**0.00023***

*Significant at <0.05 level

Table V: ANOVA test mod Box: The test statistic, numerator and denominator degrees of freedom (df1, df2), respectively, for the central F distribution, and corresponding p-value of the ANOVA-type test for the whole-plot factors and their interaction.

	Statistic	df1	df2	p-value
Group	21.3	1	89.9	**0.0000129***

*Significant at <0.05 level

Table VI: Wald test time: The test statistic and corresponding p-value of the Wald-type test with the hypothesis of no simple time effects.

Group	Statistic	df	p-value
A	296.9	6	**3.77e-61***
B	616.3	6	**7.16e-130***

*Significant at <0.05 level

Table VII: ANOVA test time: The test statistic and corresponding p-value of the ANOVA-type test with the hypothesis of no simple time effects.

	Statistic	df	p-value
A	113.8	3.4	**8.19e-83***
B	119.0	4.2	**5.38e-106***

*Significant at <0.05 level

Table VIII: Requirement of additional dose of analgesia in 24 hrs in the participants in the two groups.

Requirement of additional dose of analgesia in 24 hrs[@]	Group A	Group B	Total	p value*
Yes	4 (7.4)	2 (3.7)	6 (5.6)	0.678
No	50 (92.6)	52 (96.3)	102 (94.4)	

Total	54 (100)	54 (100)	108 (100)	

@Frequency (percentage). Fisher's Exact test used *Significance level is 0.05 level

Table IX: Differences in the pain score at each time point [Median (IQR)]

Time points	Group A	Group B	p value
30 min	7 (5 - 8)	5 (4 - 5)	0.000010*
1 hour	6 (4 - 7)	4 (3 - 5)	0.00000051*
1 hour 30 min	5 (4 - 6)	4 (3 - 4)	0.000004*
2 hours	5 (3 - 6)	3 (3 - 4)	0.000589*
4 hours	4 (3 - 5)	3 (2 - 3)	0.000141*
6 hours	3 (2 - 4)	2 (2 - 3)	0.000454*
8 hours	2 (2 - 3)	2 (2 - 3)	0.445156

*****Significant difference at 0.05 level. Mann-Whitney U test used

Figure 1: In Group B, a 5-13 MHz linear probe guided the precise placement of a 20-gauge needle between the internal oblique and transversus abdominis muscles, followed by hydro-dissection with 30cc of Bupivacaine.

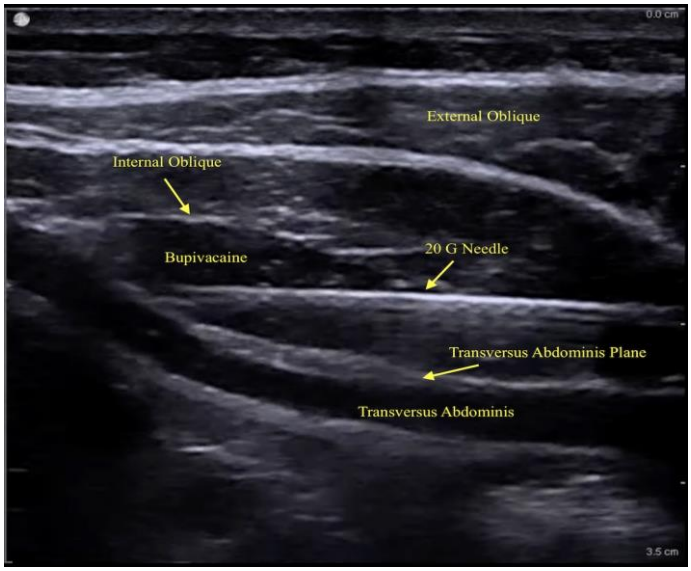


Figure 2: The TAP Block, guided by laparoscopy, utilized 'Doyle's Bulge' for correct plane identification, followed by 30cc of Bupivacaine administration to both muscle layers in Group A (2a: Right side TAP Block; 2b: Left side TAP Block).

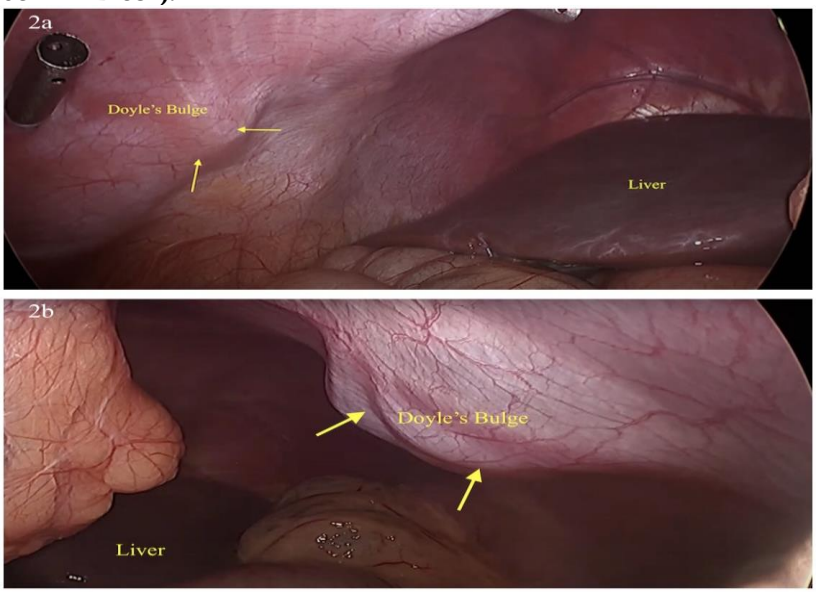


Figure 3: Plot of Relative treatment effects (RTE) for the pain scores over time for Groups A and B

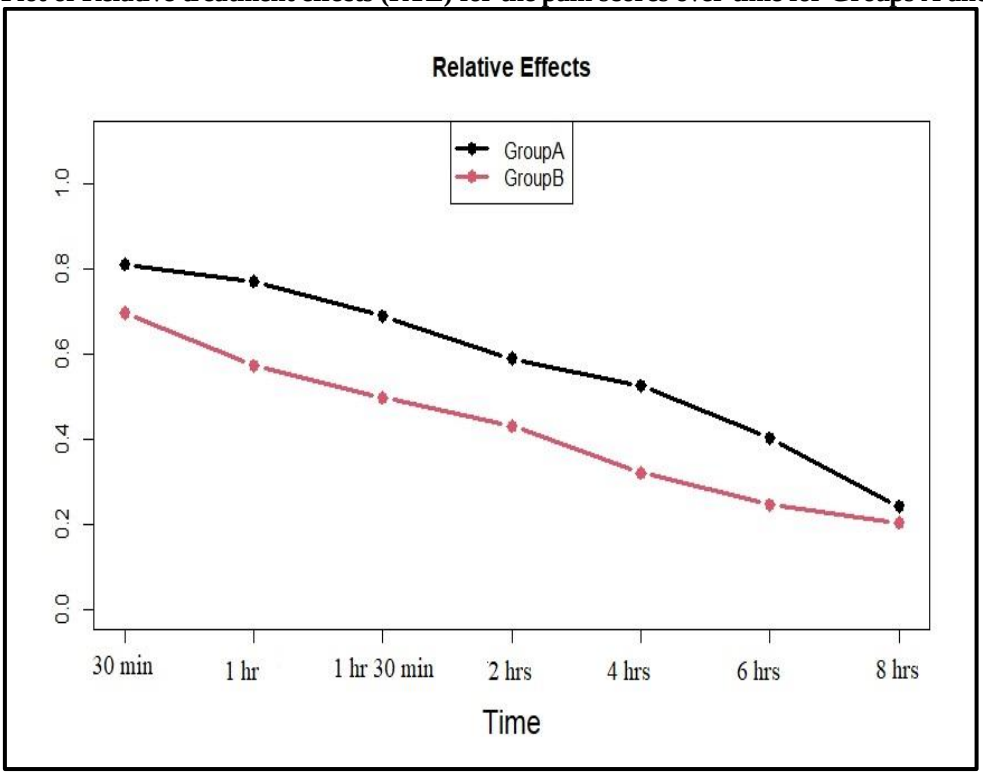
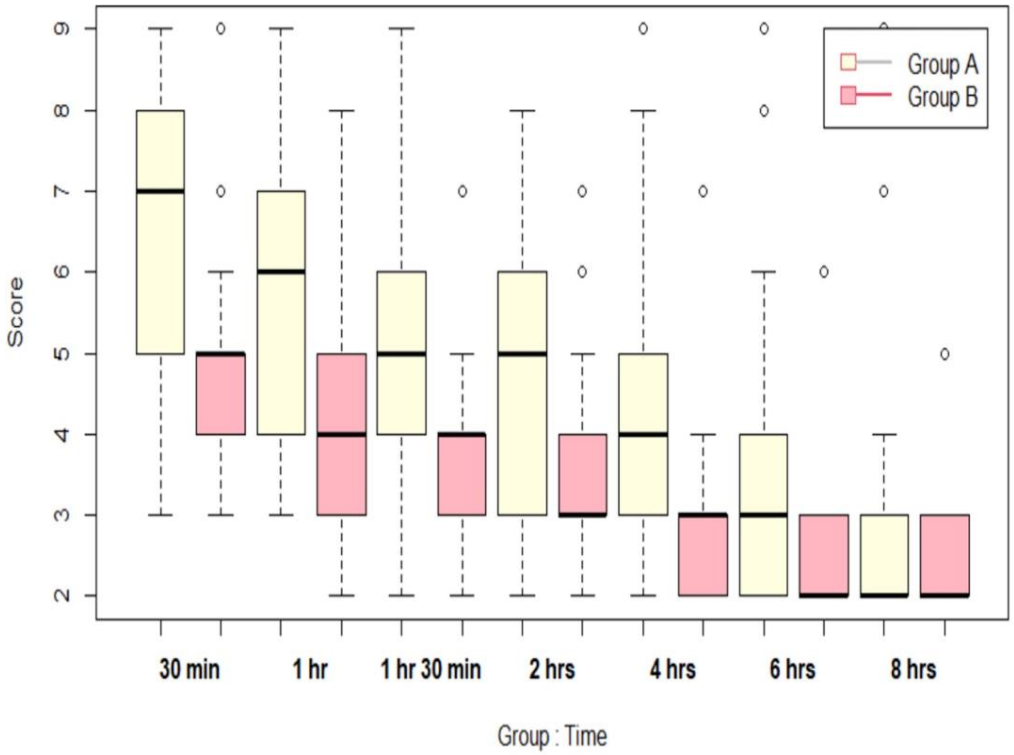
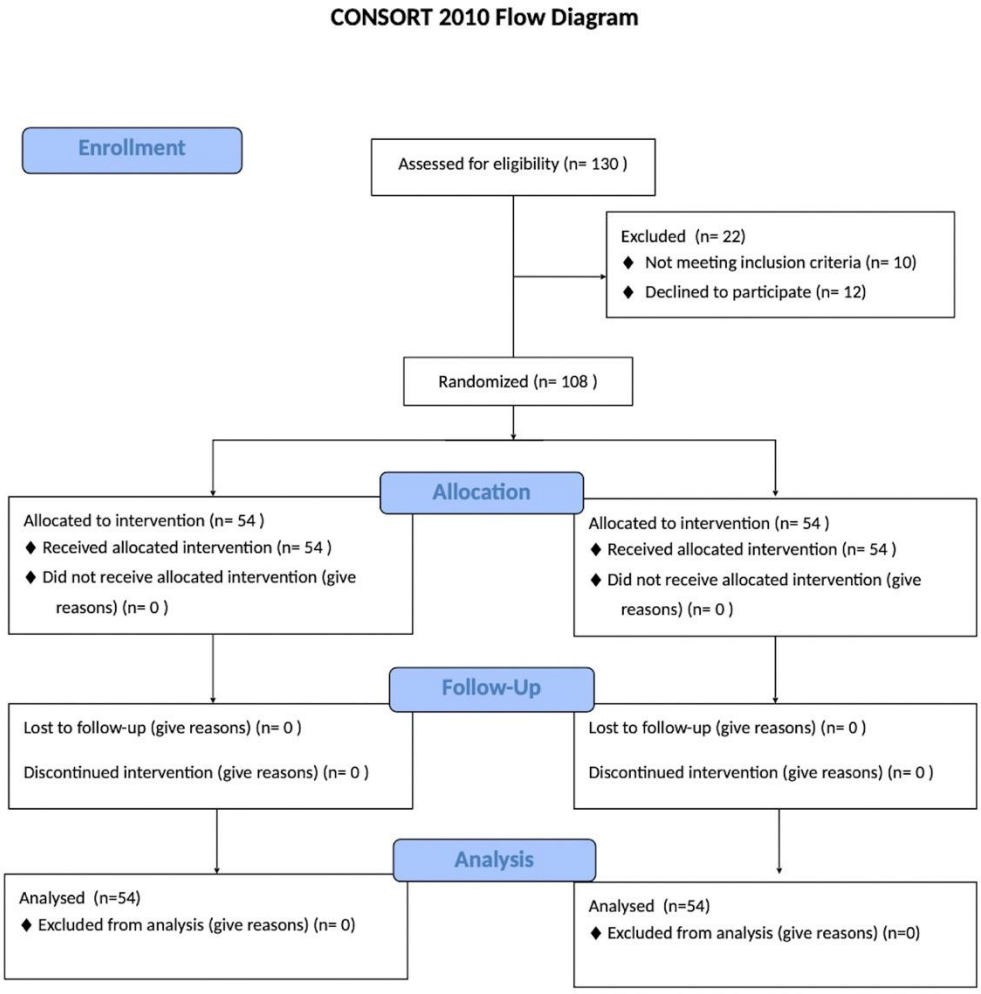


Figure 4: Box-plot analysis of post-operative pain assessed at 30, 60, 90, 120 mins, 2 hrs, 4 hrs, 6 hrs, and 8 hrs showed equivalent pain management in both groups after 6 hours.





Discussion:

Laparoscopic cholecystectomy is one of the commonly done procedure world-wide and gold standard treatment of gall stone disease.[4] Eric Muhe was the first surgeon to perform laparoscopic cholecystectomy in 1985. In the current study, bilateral subcostal TAP block was given by laparoscopy and ultrasound-guided. There was significant reduction in the opioids consumption in the post-operative 24 hrs in both the groups. Both approaches have shown patient satisfaction.Rafi was the first to introduce the TAP Block.[10] It was described in 2001 as a blind "pop" (feeling of giveaway) infiltration technique and a double-blind pop.[11] The efficacy of this blind approach is dependent on the administrator recognizing the pops as the needle passes through the outer two muscle layers before reaching the right planes between the internal oblique and transverse abdominis muscles.[12]Due to the recent sub-costal approach, TAP Block is the most effective in providing long-lasting analgesia in both upper and lower abdominal procedures, including laparoscopic cholecystectomy. [13] The TAP Block utilizes the infiltration of local anesthesia in the fascial plane between the internal oblique and transversus abdominis muscles. From the skin to the parietal peritoneum, the somatic nerves innervate the anterior abdominal wall. This usually blocks the sensitive innervation of the anterolateral wall covering T7-L3 dermatomes; thoracic intercostal nerves T7-T11; subcostal nerve T12; ilio-hypogastric nerve (IHN) and lumbar nerves L1-L3 in the lateral cutaneous branches. [7] [11] [14]The TAP block is generally done under ultrasound guidance, which was first described in 2007. Transverse abdominis plane block is performed by identifying the triangle of Petit (i.e., inferior lumbar triangle) or by direct visualization of the neurofascial plane under ultrasound guidance.[15] The Petit triangle is located between the iliac crest (inferiorly), latissimus dorsi (anterior margin) and external oblique abdominal muscles (posterior margin). [11] This triangular region is also known as a weak area in the posterior abdominal wall.[16] Less intraoperative availability of ultrasound machines, as well as the capacity of the administration to do USG and the time required, appear to be factors in the less prevalent use of TAP block, and hence opioid and non-opioid analgesic medicines have been often employed for post-operative analgesia.Different approaches are used for

the TAP Block administration that include the subcostal approach, posterior approach, and lateral approach. According to Khan et al., 2019 the subcostal technique is best for laparoscopic cholecystectomy because it gives analgesia for the supra-umbilical parietal incisions and provides better analgesia than the posterior method.[3] [18]The technique of delivering TAP Block using laparoscopic as a guide for intra-operative administration was first investigated in 2011 while carrying out laparoscopic nephrectomy. The Laparoscopic TAP Block is done by infiltration into the correct plane guided by a laparoscope after visualizing the lifting of fibers of the transversus abdominis muscle (Doyle's Bulge) seen intra-peritoneally.[12] This prevented the extra/intra-peritoneal infiltration of local anesthesia. Local anesthesia is injected into the neuromuscular plane of the abdominal wall where the nerves from T7-L3 are present. This technique obviated the need for additional skill sets and equipment in the operating room as needed for the ultrasound guided block, thereby saving time.[12] It almost takes 30 seconds to complete, preventing intra-peritoneal injections.[17]. Magee et al., 2016 performed laparoscopic TAP Block under direct laparoscopic vision prior to the laparoscopic surgical intervention and concluded that it prevents the iatrogenic injuries because of the direct visualization, whereas ultrasound guided TAP Block has a greater risk of causing potential damage to adjacent structures.[16]In a triple-blind randomized controlled experiment, Vindal A et al., 2021 found that laparoscopically guided TAP block is a beneficial method of post-operative analgesia for laparoscopic cholecystectomy. It ensures medication distribution inside the right plane with visual guidance without the requirement for extra operating room equipment or surgical training. The process has no effect on the operation time. It reduces post-operative pain, decreases the need for painkillers, promotes early mobilization, and enhances patient recovery. The laparoscopically guided TAP block promotes early discharge and boosts patient satisfaction.[12] The limitations of this procedure require an interprofessional methodology should be implemented to ensure patient safety. The appropriateness of the block should be discussed with the surgeon along with specifics on the site of the incision, the timing of the block, and other special considerations. Before the treatment begins, a required break must be taken to ensure patient safety. Throughout the surgery, it's critical to maintain meaningful conversational contact with the patient in order to keep an eye out for any potential issues including systemic toxicity from the local anesthetic, possible nerve damage, or visceral perforation.

Conclusion:

The current study's findings showed that, in comparison to ultrasound-guided bilateral subcostal TAP Blocks, laparoscopically guided bilateral subcostal TAP Blocks yield comparable outcomes. The laparoscopic guided TAP Block has some advantages over the ultrasound guided TAP Block, as it can be administered in the operating theatre itself within 30 seconds, and there is no requirement for an interventional radiologist in the operating theatre. Also, there is no need for the ultrasound machine in the operative theatre for the administration of the block. Thereby reducing the operative time and decreasing the post-operative pain in patients of laparoscopic cholecystectomy.

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Compliance with the Ethical Committee: This study has been approved by the institutional ethical committee (Reference Number: AU/EC_BHR/2K23/481)

Conflict of Interests: None.

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