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The Analgesic Efficacy of Pre-Operative Subcostal Transverse Abdominis Plane Block in Patients Undergoing Laparoscopic Cholecystectomy: A Randomized Prospective Comparative Study

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ABSTRACT:

Introduction: The purpose of this study was to evaluate the effectiveness of transverse abdominis plane block for postoperative pain relief after laparoscopic cholecystectomy. Primary outcome is post-operative movement and Resting Pain scores in patients undergoing laparoscopic cholecystectomy. Secondary outcome is amount of pain relief provided by rescue analgesics in the first 24 hours after surgery.

Material and Methods: The Department of Anesthesiology examined Saveetha Medical College and Hospital patients from March 2021 to September 2022 in a prospective randomized double-blind controlled trial. This study was approved by the ethics committee. All patients received a detailed explanation of the operation and may consent. The formula from Openepi.info26 required 40 participants per group to attain a 95% confidence interval and an 80% power of study. This study included 88 persons, evenly divided by gender into two 44-person groups. Participants received either normal general anesthesia or pre-operative USG-guided Subcostal TAP block. As required by institutional procedures, they had a 12-lead electrocardiogram, chest radiograph, and hemoglobin, total count, platelet count, Renal Function test, and random blood glucose test before surgery. Airways were examined, including mouth opening, Modified Mallampatti Score, thyromental distance, neck mobility, and upper lip bite test. After verifying the patient was fit and graded according to ASA Risk Stratification, they were advised on the anesthetic plan. Patients were also advised about post-operative multimodal analgesics and how SCTAP block would help them manage pain. Patients were recruited and instructed about the Numeric pain scale and rescue analgesia once they consented to the trial. The study comprised informed consent patients who met inclusion criteria.

Results: It was observed that the bulk of the study population, which consisted of 88 individuals overall, was female. Only one-third of the participants in the research were men. Among those who received subcostal TAP block the dermatome levels were checked for sensory block by using pinprick sensation testing and sensation to ICE. The dermatome levels were found to reach until T_{11} in around 68.2% and attained T_{12} in around 24.98% of the population. Overall, 24-hour consumption across Group S was about 147.73 +/- 30.22 gm whereas that in group C was 211.36 +/- 32.10 gm. The difference was statistically significant.

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Conclusion: This research concludes that intra-operative analgesia is achieved with the pre-operative administration of ultrasound guided bilateral subcostal transverse abdominis plane block, which is also linked with significantly lower resting and movement pain levels in the post-operative period.

1. Introduction

It is now normal practice to treat gall bladder inflammation using laparoscopic cholecystectomy, a revolutionary and less invasive surgical method (Acute cholecystitis).[1] It is a relatively common surgery almost ubiquitously performed in majority of health centers. There is not much need for pre-operative preparation or incidence of post-operative complications that it has almost replaced the open method as mainstay treatment in acute cholecystitis. The minimal invasive nature, the scar-less healing, relatively short duration of the procedure has all made it an ideal day care surgery material. Day care surgery of laparoscopic cholecystectomy has been thoroughly studied and established as a relatively safe procedure for the patient.[2] The surgeon also has a semblance of relieved burden. However, the onus on the anesthesiologist conducting the case must have a lot of considerations to make the surgery as a day care one. The ability to eat and drink orally, to move about independently, to reduce dependence on outside help, and to alleviate postoperative discomfort are all significant goals of rehabilitation. Although traditional opioids are effective in relieving pain, they also cause a number of unwanted side effects, including nausea, vomiting, and drowsiness, which would prevent the patient from recovering quickly after ambulatory surgery. The need for pain management that would be alternative to the opioid regimen of more importance now than ever if one must keep up with the ever-evolving demands of novel surgical principles. Regional anesthetic and analgesic techniques have great potential in decreasing the post-operative pain, reducing the length of hospital stay, expediting the rehabilitation of the patient.[3] Local anaesthetic is placed between the transverse abdominis plane and the inferior aspect of the costal plane to produce a transverse abdominis plane block, a regional analgesic technique.[4] An adequate body of data indicates that the Subcostal Transverse abdominis plane block (SCTAP).[4] effectively provides analgesia for upper abdominal procedures. The traditional TAP block acts on the anterior divisions of the thoracodorsal spinal nerves that arises from T_{10} to L_1 Consistently.[5] However, SCTAP can provide blockade of the upper T_7 nerve roots and those that follow making it effective in conferring analgesia to upper abdominal surgeries too.[6] Neuraxial analgesia especially epidural catheters although known to produce effective analgesia for a prolonged duration, is not without its own list of demerits. The hemodynamic pitfalls and various other concerns that would give the anaesthesiologist pause from activating the epidural[7], has helped in swinging the pendulum in favour of regional analgesic techniques rather than neuraxial ones, which are considered the gold standard in pain management.[7]

SCTAP blocks can be conveniently administered to the patient in either the preoperative or the intra-operative period. The post-operative distortion of the abdominal muscles brought on by surgery can make post-operative blocks to appear challenging.[4] The block is better performed under ultrasound guidance using a Linear Ultrasound probe 5 - 15 MHz.[4]

Several medical professionals have tried to determine whether or not SCTAP is effective as an analgesic modality for patients undergoing laparoscopic cholecystectomy[8], due to its proven track record as a dependable form of analgesia in procedures of the upper abdominal wall. The purpose of this research is to evaluate whether or not this unique alternative to TAP block successfully reduces postoperative pain in patients following laparoscopic cholecystectomy.[9]

The purpose of this study was to evaluate the effectiveness of transverse abdominis plane block for postoperative pain relief after laparoscopic cholecystectomy.[8] Primary outcome is post operative movement and Resting Pain scores in patients undergoing laparoscopic cholecystectomy.[8] Secondary outcome is amount of pain relief provided by rescue analgesics in the first 24 hours after surgery.

2. Material and Methods

A prospective randomized double blinded controlled study from March 2021 to September 2022 patients at Saveetha Medical College and Hospital in Chennai were

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analysed as part of a research project conducted by the Department of Anesthesiology. The institution's ethics board gave its stamp of approval to this research. All patients were given a thorough explanation of the operation and given the opportunity to provide their informed permission. Using the formula developed from Openepi.info26, we found that 40 individuals per group were needed to reach a 95% confidence interval and a power of research of at least 80%. There was a total of 88 people engaged in this research, and they were split evenly (by gender) into two groups of 44. Both groups were allotted to either receive standard general anaesthesia or pre-operative USG guided Subcostal TAP block. The AIMS and objectives of the study. Before patients were recruited, the expected sample size and the planned technique of the research were reported to the institutional ethical clearance committee and appropriate consents were acquired.

Patients who came to the pre -operative assessment clinic for undergoing pre anesthetic evaluation for Laparoscopic Cholecystectomy were routinely screened. Detailed history regarding co-morbidities were taken and adequate optimization advised and ensured. They also underwent a routine pre-operative blood investigation (hemoglobin, total count, platelet count, Renal Function test, random blood glucose), 12-Lead electrocardiogram, chest radiograph as mandated by the institutional protocols. Patients also had a full evaluation of their airways, including their mouth opening, Modified Mallampatti Score, thyromental distance, neck mobility, and upper lip bite test. After ensuring that the individual was fit to undergo the procedure, and appropriately graded according to ASA system of Risk Stratification. they were briefed about the plan of anesthesia. The patients were also counselled about the multimodal analgesic regimen in the post-operative period and were explained how SCTAP block would help them cope up with the pain. After presenting of the options to the patients, once they consented to be a part of the study, they were recruited and educated further regarding the Numeric pain scale and demanding for rescue analgesia. Patients who gave informed permission were included if they satisfied the study's inclusion criteria.

Those who came into ASA's first and second laparoscopic cholecystectomy categories were between the ages of 18 and 70 were included. Patients who refused consent, patients ASA Grade III and above, those going in for emergency surgeries, patients with known cardiac renal or hepatic abnormalities, pregnant patients, infection at the site of injection, those who are allergic to local anesthetic agents or those who have had a previous reaction to local anesthesia, patients with BMI of higher that 30Kg/m^2 body surface area and patients who have undergone previous laparotomy under a subxiphoid incision were excluded.

Patients who met inclusion criteria were split into two groups: one undergoing SCTAP block (Group S) and the other receiving a standard post-operative analgesic regimen (Group C). The allocation was done by sealed opaque envelopes that had random computer-generated numbers. The envelopes were opened sequentially, and the allocated intervention was performed according to the enveloped opened. Patients in two groups received pre-operative medication and underwent specific procedures: Group S received subcostal thoracic aortic block (SCTAP), while Group B received ultrasound-guided subcostal TAP blocks. All patients were assessed for sensory loss and underwent general anesthesia. Procedures included intubation and airway management, with additional measures taken in cases of difficult intubation. Throughout surgery, vital signs were monitored, and anesthesia was maintained. Analgesia administration was blinded to group allocation, with tramadol given as needed. Intra-operative pain indicators were monitored, and rescue analgesia was provided when necessary. Patients were extubated post-surgery and received medication to manage nausea and reverse neuromuscular blockade. Pain scores were assessed post-extubation using numerical rating scales.[10]

3. Results

It was observed that the bulk of the study population, which consisted of 88 individuals overall, was female. Only one-third of the participants in the research were men. Among those who received subcostal TAP block the dermatome levels were checked for sensory block by using pinprick sensation testing and sensation to ICE. The dermatome levels were found to reach until T_{11} in around 68.2% and attained T_{12} in around 24.98% of the population.

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Table 1: Distribution of study population according to highest dermatome level

PARAMETERS	Group S		Group C		CSV	P VALUE
	F	%	F	%		
20 - 30 YEARS	6	13.6	11	25.0	3.620	0.481
31 - 40 YEARS	11	25.0	11	25.0		
41 - 50 YEARS	12	27.3	7	15.9		
51 - 60 YEARS	11	25.0	13	29.5		
61 - 65 YEARS	4	9.1	2	4.5		

An age correlation between the two groups of people in the study showed that they ranged from 20 to 65. Group S and Group C had similar mean ages when evaluated using the T test. Both groups averaged 44.91 +/- 12.13 and 42.11 +/- 12.29 years old. Age and gender distribution were similar across subgroups. Despite differing diagnoses, they all had laparoscopic cholecystectomy.

After the surgery, the patients were scored for pain at rest and from activity like sitting up or coughing, which would strain the abdominal wall musculature. The scores were NRS and NRS MP (Movement Pain). As told, people rated their discomfort from 1 to 10. No pain (0 points), modest pain (2–4 points), moderate pain (5–7 points), and severe pain (8 points and more) are possible responses. A score of 4 or higher prompted rescue analgesia.

Table 2: Distribution of association between groups and NRS pain scores

PARAMETERS	NRS	S	%	C	%	CSV	p-VALUE
NRS Immediate	2	19	43.2	32	72.7	7.881	0.009
	3	25	56.8	12	27.3		
NRS 2 hr	2	9	20.5	1	2.3	7.242	0.027
	3	34	77.3	42	95.5		
	4	1	2.3	1	2.3		

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NRS 4 hr	3	16	36.4	6	13.6	6.165	0.045
	4	27	61.4	36	81.8		
	5	1	2.3	2	4.5		
NRS 8 hr	3	24	54.5	8	18.2	12.579	0.002
	4	19	43.2	34	77.3		
	5	1	2.3	2	4.5		
NRS 24 hr	3	41	93.2	43	97.7	1.048	0.616
	4	3	6.8	1	2.3		

Group C patients reported less discomfort than Group S patients in the first several days after surgery. There was a statistically significant difference between S group NRS instantaneous scores of 2 (43%), and C group scores (72.7 percent). The intra-operative Fentanyl infusion may lessen visceral and somatic discomfort. The mean pain scores were below the rescue analgesia threshold, but statistically significant. After two hours, Group S had significantly lower pain scores than Group C. After four hours, 36.4% of group S and 13.6% of group C had NRS scores of 3. 61.4 percent of group S achieved a 4, whereas 81.8 percent of group C did. The findings are statistically sound. Group C's higher score required rapid intravenous infusion of 100 mg Inj Tramadol. The time component of the multimodal analgesic regimen required both groups to provide paracetamol evenly. After eight hours, 54.5 percent of group S had an NRS score of 3, compared to 18.2 percent of group C. Also, 43.2 percent of group S scored 4 compared to 77.3 percent of group C. Statistics show significance. Group C has statistically significant higher pain scores, proving the efficacy of SCTAP block in multimodal analgesia. After 24 hours, the two groups had similar NRS scores. Bupivacaine's action lasts less than 24 hours. Opioids were consumed less in the first 24 hours post-op.

Table 3: Distribution of association between groups and NRS movement pain scores

PARAMETERS	**NRS MP**	**S**	%	**C**	%	**CSV**	**p-VALUE**
NRS MP 0	2	5	11.4	9	20.5	1.385	0.544
	3	35	79.5	31	70.5		
	4	4	9.1	4	9.1		

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NRS MP 2	3	29	65.9	16	36.3	7.878	0.019
	4	14	31.8	27	61.3		
	5	1	2.2	1	2.2		
NRS MP 4	4	13	29.5	7	15.9	6.789	0.033
	5	18	40.9	12	27.3		
	6	13	29.5	25	56.8		
NRS MP 8	3	5	11.4	0	0.0	6.716	0.054
	4	35	79.5	39	88.6		
	5	3	6.8	5	11.4		
	6	1	2.3	0	0.0		
NRS MP 24	3	31	70.5	31	70.5	0.377	1.000
	4	11	25.0	12	27.3		
	5	2	4.5	1	2.3		

The comparison of movement pain scores over 24 Hours also yielded similar results of statistical significance for the initial 8 hours and became equivalent in following the first post-operative period after the 24-hour mark. The analgesia in both the test groups were found to be comparable in the immediate post-operative period.

Table 4: Association between both groups according to need for rescue analgesia

PARAMETERS	**Group S**		**Group C**		**CS Value**	**P Value**
	N	**%**	**N**	**%**		
0-8 hours	3	6.8	4.4	100	76.76	<0.001

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8-16 hours	19	43.2	5	11.4	64.759	<0.001
16-24 hours	43	97.7	44	100	1.011	0.315

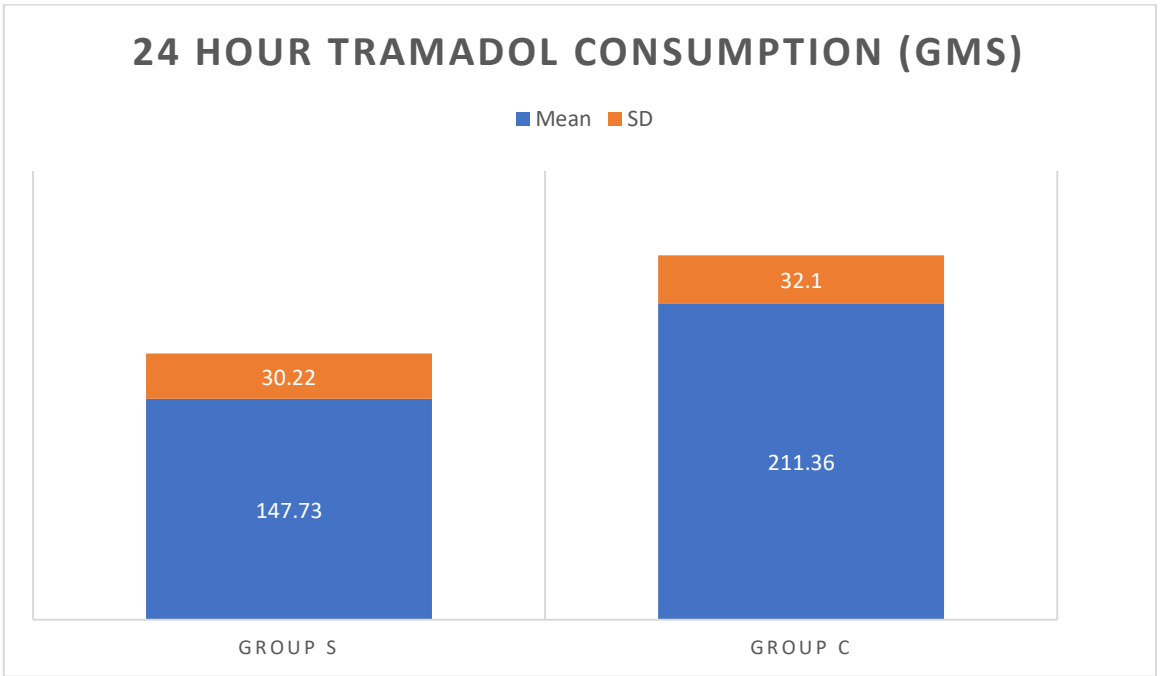
In the first eight hours after surgery, the demand for Tramadol was significantly higher in group C than in group S (100% vs. 6.8%: P<0.001).Between 8-16 hours the need for tramadol was 43.2 % in groups S compared to 11.4% in C group,P<0.001. At 16-24 hours the need for tramadol was nearly equal in both the groups.

Table 5: Comparison of the total dose required in each group at different time intervals

PARAMETERS	Group S		Group C		MD	t Value	P Value
	M	SD	M	SD			
0-8 hours	6.82	25.497	100	0	93.182	-24.242	<0.001
8-16 hours	43.18	50.106	11.36	32.104	31.818	3.547	0.001
16-24 hours	97.73	15.076	100	0	2.273	-1	0.320

Group C required substantially more Tramadol (100 gms vs. 6.82 gms: P<0.001) within the first eight hours after surgery compared to Group S.Between 8-16 hours the need for tramadol was 43.18 gms in groups S compared to 11.36 in group,P<0.001. at 16-24 hours the need for tramadol was nearly equal in both the groups.

Figure 1: Overall 24-hour opioid consumption among two groups



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Overall, 24-hour consumption across Group S was about 147.73 +/- 30.22 gm whereas that in group C was 211.36 +/- 32.10 gm. The difference was statistically significant.

4. Discussion

Laparoscopic cholecystectomy although a minimal access procedure is still a significant pain inducing procedure sue the multiple abdominal wall incisions and the creation of pneumoperitoneum. A TAP block may be used to considerably lessen somatic post-operative discomfort. Conventionally administered through the posterior approach the TAP block does not cover the upper dermatomes like T_6 T_7 and T_8. However, when administered at the subcoastal level has the ability to cover the upper dermatomes providing adequate analgesia in the supra umbilical region. The endeavours of this study were towards reducing post-operative pain. The choice of administering the SCTAP pre-operatively was consciously made with a two-fold benefit in mind". One was to provide a modicum of analgesia in the intra-operative period to alleviate the sympathetic response triggered by trocar insertion and the other was to avoid administering the drug in the TAP after the anatomy has been distorted post-operatively so as to avoid unreliable spread of the local anaesthetic injectate.

With increasing evidence of the inability of a posterior TAP block to spread above the level of T_{10}, to ensure the findings of other studies using SCTAP block, the post block sensory testing was a way of assessing dermatomal spread. Study results showed that T_{12} was the highest dermatome reached (24.98%), with most patients reporting sensory blockage between T_6 and T_{11} (68.1%). Only a meagre amount of population reported a blockade of only up to T_{10} (6.82%)

The distribution level of the dermatomes are in tandem with findings of a systematic review conducted by Hsiao-Chien Tsai, et al.[11] This study attempted at assessing the efficacy of the SCTAP block as modality to be employed in a multimodal analgesic regimen following Laparoscopic cholecystectomy. This study compared the effect of SCTAP against the conventional analgesic regimen after laparoscopic cholecystectomy. Within first 24 hours after surgery, patients reported much less pain when at rest and while moving. The individuals who underwent a SCTAP block did not receive any additional intra-operative opioid doses.

This result was consistent with that of El-Dawlatly AA, et al.[9], who contrasted the use of SCTAP with the delivery of conventional analgesia and came to the conclusion that patients who got the block as one of the pain modes consumed fewer opioids intraoperatively and postoperatively. Subcostal transversus abdominis plane block substantially lowered postoperative pain levels compared to normal analgesia across all time points following surgery, as was previously seen in research by Vladimir Vrsajkov et al.[12] When comparing the subcostal transversus abdominis plane to the conventional analgesia group, the present research indicated that tramadol use was much lower in the latter. Tolchard et al.[8] compared the use of the SCTAP block to the more commonplace practise of infiltrating the port site with local anaesthetic. They discovered that Tap block provided better analgesia and cut down on the need for opioids. In a similar vein to the present research. However, they did not take into account the movement pain of the patients as they had assessed the pain in the VAS scale which is subjective from the observer's perspective rather than the patient's perspective. When compared to wound infiltration, SCTAP block results in significantly reduced pain levels during movement at 24 hours post-treatment compared to 12 hours post-treatment when patients are at rest (Sina Grape et al.[13]). The pain scores and opioid use documented in this research show that postoperative morphine intake is much reduced.

Patients having laparoscopic cholecystectomy, caesarean section, appendicectomy, and other abdominal procedures have benefited from research into the TAP block as an analgesic technique. The difference of surgical techniques and other factors have also lead to various research modalities such as comparison between posterior and subcostal approaches of TAP Block.[14]

This study included population undergoing laparoscopic cholecystectomy, thus majority of ports being supra-umbilical necessitated a higher dermatomal level[14]. The SCTAP itself has shown to provide analgesia until at least T_{10} dermatomal level going up to a maximum level of T_{12}. The findings of this study have been on par with various other studies conducted along the similar lines. Khan KK et al.[15], who attempted to compare the analgesic efficacy of the subcostal TAP block to that of the more commonly used Posterior TAP block, discovered a statistically significant difference in mean static pain scores over 24 hours postoperatively in the

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subcostal TAP group, indicating improved analgesia. While static postoperative pain assessments were significantly different in the two groups, dynamic values were similar. Patients in both groups reported being happy with their pain treatment.[15] The current study had a better analgesic profile in terms of resting and movement pain which is most likely due to the administration of multimodal analgesia along with the SCTAP block.

Bhatia N, et al.[16], endeavoured to identify the difference in the analgesic efficacy of posterior vs SCTAP regarding post-operative pain scores and opioid consumption.[16] Patient pain levels were similar across the subcostal and posterior TAP groups immediately after surgery; however, after 4 hours, patients who had received the subcostal TAP block reported much less discomfort, leading the researchers to conclude that SCTAP is preferable for supra umbilical operations, in particular laparoscopic cholecystectomy.[16] This finding concurs with not just the strategy but also the postoperative pain ratings and opioid use, which provides additional support for the validity of the present study's anticipated results.

Venkatraman R, et al.[17], undertook a study by comparing various routes of administration of TAP block. They recruited 80 patients and divided them into two groups. One was administered TAP via USG guidance and the other had the same administered via laparoscopy. They concluded that higher success rate in the USG group in blocking the higher T_7 dermatomes that lead to superior sensory blockade and reduced post-operative morphine consumption. This lends credibility to the current study in choosing the SCTAP approach via USG guidance rather than following the myriad of other modalities in administering SCTAP block. The frequency of opioid abuse The TAP Block group in this trial also had much lower than the standard analgesia group.

The administration Of SCTAP block although done by the same anaesthesiologist resulted in difference in dermatomal spread which probably might be attributed to the fixed dose of local anaesthetic solution. The lack of definitive nociception monitoring devices intra-operatively led us to the choice of excluding the individuals who received intra-operative opioid top-up doses. However, the conventional analgesic regimen group also did not receive more than one dose as all procedures were concluded within 120 mins.

5. Conclusion

This research concludes that intra-operative analgesia is achieved with the pre-operative administration of ultrasound guided bilateral subcostal transverse abdominis plane block, which is also linked with significantly lower resting and movement pain levels in the post-operative period. When included into a multimodal analgesic regimen, it greatly decreases the need for opioids both during and after surgery.

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