An Observational Study to Evaluate the analgesic efficacy of Ultrasound Guided Subcostal Transversus Abdominis Plane Block and Port Site Infiltration with Ropivacaine (0.2%) in Laparoscopic Cholecystectomy

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Abstract

Background: Significant pain can be experienced after laparoscopic cholecystectomy. Several modalities have been used to manage this pain. The present study compares the impact of bilateral subcostal TAP block and port site local infiltration with Ropivacainei(0.2%) in conventional laparoscopic cholecystectomy for postoperative analgesia and opioid consumption.

Methods: This is a prospective, randomised, single blinded observational study. Sixty patients were enrolled and divided into two groups having 30 patients in each group. Group A received bilateral ultrasound guided subcostal TAP block with 10 mL of 0.2% Ropivacaine on each side after the completion of surgery. Group B received similar amount of local anesthetic infiltrated over all the laparoscopic port sites. Pain at rest and on movement was assessed using NRS scale in the postoperative period at 0 min, 30 min, 2, 4, 6, 12 and 24 hours. Time to first opioid requirement and total opioid consumption over 24 hours were recorded.

Results: There were no significant differences between the two groups with respect to preoperative parameters and duration of surgery. The 24 hours Tramadol consumption was significantly less (78.13mg ±0.70 versus 140.79mg ±40.15, p <0.001) in Subcostal TAP block group. The Time to first Tramadol requirement was prolonged in patients receiving the Subcostal TAP block (4.93±0.70 hours vs 2.44±1.36hours, p <0.001). Compared with port site infiltration group, postoperative NRS pain scores at rest were significantly lower at 30 (min), 2 h and 4 h postoperatively in subcostal TAP block group (P = 0.044, 0.024 and 0.030 respectively); NRS scores at the time of coughing were also significantly lower in subcostal TAP block group than in port site infiltration group at all time points except 0 (min) after extubation (all P < 0.001). The incidence of nausea and vomiting was reduced in subcostal TAP block group.

Conclusions: Ultrasound guided bilateral Subcostal TAP block provides effective post-operative analgesia and reduces opioid consumption in patients undergoing laparoscopic cholecystectomy.

Keywords: Laparoscopic cholecystectomy; post-operative analgesia; subcostal TAP block. _____

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Introduction I.

Laparoscopic cholecystectomy (LC) is the gold standard in many health centers as it is less invasive compared to open cholecystectomy . [1] In the USA, 90% of the cholecystectomies are implemented with the laparoscopic technique. [2] Postoperative pain, length of hospital stay and other surgical complications are minimized by laparoscopic surgery technique. [3,4] Even though the size of the port site incisions is small, severe somatic pain may emerge in the anterior abdominal wall following laparoscopic cholecystectomy. This pain may change its character depending on the number and sites of the ports. [5] Besides, peritoneal distention and diaphragmatic irritation because of high intra-abdominal pressure and insufflations cause visceral pain. [6]

The choice of drugs available are non-steroidal anti-inflammatory drugs, gabapentinoids, intravenous patient-controlled analgesia (PCA), central analgesic interventions, local infiltration analgesia, and regional blocks to control the postoperative pain after laparoscopic cholecystectomy. [7] Current rational analgesia management guidelines recommend opioids only if needed and encourages the usage of multimodal analgesic methods, which can decrease the use of postoperative opioids. [8] Transversus abdominis plane block (TAP) is one of the preferred analgesia methods in abdominal anterolateral wall surgeries. [9] The TAP block is administered between the internal oblique muscle and the transverse abdominal muscle. It provides adequate analgesia in the anterior abdominal wall through the ventral branches of the nerve roots, which is divided into the ventral and dorsal rami after originating from the medulla spinalis. [10] Compared to the TAP implemented between the costal margin and iliac crest in the sidewall of the abdomen, the analgesic effect can be increased in the interventions at upper levels like cholecystectomy with the subcostal TAP (ScTAP), which is performed at the junction of the costal arch and midclavicular line. [10,11]

In this study, our primary aim was to investigate the effects of bilateral subcostal TAP block versus port site infiltration on the opioid consumption in patients undergoing laparoscopic cholecystectomy. Our secondary objective was to investigate the pain scores, rescue analgesia, and side effects.

II. Methods

This was a prospective, randomized, single blinded, observational study, carried out at a tertiary care hospital in Government Medical College Srinagar, J&K from June, 2019 to March, 2020. After ethical clearance from the institutional committee, 60 patients of American Society of Anesthesiologists Physical Status (ASA-PS) I and II of either sex, aged 18–60 years, scheduled to undergo elective four port laparoscopic cholecystectomy under general anesthesia were enrolled and divided into two Groups (Group A and Group B) of 30 each. Patients with a history of allergy to local anaesthetics, psychiatric illness, substance abuse and opioid dependence were excluded from the study. Detailed pre-anesthetic evaluation was done before the day of surgery and written informed consent was taken.

In preoperative assessment, patients were educated regarding the Numeric Rating scale (NRS) in which 0 means no pain and 10 representing the worst pain. Patients were kept nil per oral for 8 hours prior to surgery. On the day of surgery, in operation theatre intravenous access was done with 18G cannula. All the patients received general anaesthesia with standard ASA monitoring. Anaesthesia was induced by fentanyl (2 mcg/kg), propofol (2 mg/kg), and Succinylcholine (1-2 mg/kg). Maintenance was done with isoflurane in 50/50 mixture of O2/Air. All the patients were ventilated to normocapnoea. All patients received injection paracetamol 1 gm immediately after induction. Injection ondansetron 4 mg was given after removal of gall bladder as a prophylactic antiemetic. After the end of surgery, patients in Group A received bilateral ultrasound guided subcostal TAP block by the Consultant Aaesthesiologist sufficiently expert in giving TAP blocks. A linear array ultrasound probe of 6–13 MHz frequency (Micromaxx[™] Sonosite, Inc., Bothell, WA 98021, USA) was used and under all aseptic precautions, the transducer probe was placed 2 cm below the xiphisternum and parallel to the costal margin, and then moved along the subcostal edge to identify the neuro-fascial plane between rectus abdominis and the transversus abdominis muscle. Once these structures were identified, Colour Doppler was used to see any vessels in the direction of needle insertion. A22 G \times 100 mm needle (Stiumplex needle B-Brown, Germany) was introduced in-plane 2-3 cm lateral to the transducer, under direct ultrasound visualization, 1-2 ml of solution was injected in the chosen plane. After confirming the correct placement of the needle and the negative aspiration, the rest of the local anaesthetic was injected (10 ml 0.2% Ropivacaine). The block then performed on the opposite side using an identical technique and similar volume of local anaesthetic. The Group B received 20 ml of 0.2% Ropivacaine infiltrated locally in all the four laparoscopic port sites.

After completion of the surgical procedure and emergence from anaesthesia, patients were shifted to the post-operative ward. Injection Paracetamol 1 g 6 hourly was given as postoperative analgesic in both groups. The severity of pain assessment was done using NRS scale postoperatively at 0 minutes, 30 minutes, 2, 4, 6, 12 and 24 hours.

All patients were asked to give scores for their pain at each time point. NRS score at rest and on movement (on coughing and/or flexing the knees) was recorded. At any point of time if score is \geq 3, injection Tramadol 1 mg/kg was given intravenously as rescue analgesic. The Time to first tramadol requirement and total Tramadol consumption over 24 hrs were recorded.

Postoperative vomiting was managed with injection ondansetron 4 mg intravenously and recorded. At all the time points, patients were monitored for any signs of Local anaesthetic (LA) toxicity, and the sites of injection of the Subcostal TAP block were inspected to detect hematomas or local infections.

The sample size estimation was based on mean VAS score at 2 hours from a previous study [12] where patients received subcostal TAP block following laparoscopic cholecystectomy. Taking confidence interval of 95% and power of study as 80%, the calculated sample size was 30.

Data were analyzed using SPSS 19.0 software (SPSS, Inc., Chicago, IL, USA). The Kolmogorov-Smirnov test was used to check for normal distribution. Parametric data were expressed as mean with 95% confidence intervals and nonparametric data as median with interquartile range. Group means were compared using the Student's t-test or the Mann–Whitney U test as appropriate. For continuous data, overall differences were tested by analysis of variance (ANOVA) followed by a post hoc test with least significant difference t-test (LSD) or Kruskal Wallis test followed by a Mann–Whitney U test when appropriate. Categorical variables were presented as values and percentages and were compared using the $\chi 2$ test. Significance was defined as P < 0.05.

III. Results

All the sixty enrolled patients had completed the study. I	Both groups were comparable in terms of age, gender,
body weight, ASA-PS and duration of surgery (Table1).	

Table 1. Demographic data.			
Variables	Group	Group	p-value
	А	В	
	(n=30)	(n=30)	
		46.83±14.33	
Age(yrs)	44.44±14.31		0.52*
Gender (M/F)	10/20	8/22	0.40†
		73.5±1.15	
Weight (Kg)	74.13±1.85		0.15*
		22/8	
ASA-PS (I/,II)	21/9		0.77†
Duration of surgery (mins)		73.00±15.55	
	74.17±32.23		0.85*

* Values are given as mean ± standard deviation; † Chi square Test

The NRS scores at rest are shown in Table 2. The subcostal TAP block receiving patients had lower NRS pain scores but statistically significant only in the initial 4 hours postoperatively.

	Variables		
Time interval since extubation (hours)	NRS pain score		
	Group A (n=30)	Group B (n=30)	p-value
0 (min)	2(1-3)	2(1-4)	0.070
30 (min)	2(1-2)	2(1-3)	0.044*
2 h	1(1-2)	2(1-3)	0.024*
4 h	1(1-2)	2(1-3)	0.030*
6 h	1(1-2)	1(1-2)	0.402#
12 h	1(1-2)	1(1-2)	0.336#
24 h	2(1-2)	2(1-2)	0.436#

Values are expressed as median (interquartile range) for skew distribution. NRS, numerical rating scale; *indicates statistically significant(p <0.05).

The NRS pain scores at movement (table 3) were lower in group A and statistically significant at all time intervals in comparison to group B except at 0 minutes after extubation (p<0.001)

Table 3: postoperative Nu movement	merical Rating scale (NF	RS) Pain score on	
	Variables		
Time since extubation (hours)	NRS pain score		i
	Group A (n=30)	Group B (n=30)	p-value
0 (min)	4(2-7)	4(2-9)	0.186#
30 (min)	3(1-5)	4(3-7)	< 0.001
2 h	3(1-4)	4(3-8)	< 0.001
4 h	2(1-6)	4(3-7)	< 0.001
6 h	2(1-6)	3(2-6)	< 0.001
12 h	2(1-5)	3(2-6)	< 0.001
24 h	2(1-6)	3(2-6)	< 0.001

Values are expressed as median (interquartile range) for skew distribution. NRS, numerical rating scale; *indicates statistically significant(p < 0.05).

Time for request of first rescue analgesia was significantly prolonged (p < 0.001) in patients receiving subcostal TAP block. The overall 24 hours analgesia consumption was significantly less (p < 0.001) in patients with Subcostal TAP block (Table 4).

Variable	Group A (n=30)	Group B (n=30)	p-value
Total Tramadol consumption in 24 hours	78.13±0.70	140.79±40.15	<0.001
Time to first Tramadol			
requirement	4.93±0.70	2.44±1.36	< 0.001

The number of patients who suffered post-operative nausea and vomiting (PONV) was 4 (13.33) % in the TAP block group and 6(20) % in local infiltration group, but it was not statistically significant. Complications like local anesthesia toxicity, local infection or haematoma were not seen during the study period.

IV. Discussion

Laparoscopic cholecystectomy is the mainstay treatment of benign biliary disease. Pain continues to be an important issue after laparoscopic cholecystectomy resulting in prolonged admissions or readmissions. [13] Patients frequently complain of back, shoulder region pains and discomfort of port site incisions . [14] Shoulder and sub-diaphragmatic pain occurs in about 12% to 60% of patients. [15] Peak of pain intensity is during the first few postoperative hours and usually declines after 2 or 3 days.[16] The etiology of pain after laparoscopic cholecystectomy is multifactorial.[15] One suggested cause of pain after laparoscopy is the peritoneal insufflation with CO_2 and phrenic nerve irritation in the peritoneal cavity . [17,18,19] In fact, the acid milieu created by the dissolution of CO_2 gas causes peritoneal irritation and phrenic nerve damage in laparoscopic cholecystectomy. Additional contributing factors include sociocultural status, and individual factors.[15]

To date, administration of non-steroidal anti-inflammatory drugs (NSAIDs) and narcotics, gas drainages, intraperitoneal saline and intraperitoneal of local anesthetics and opioids were carried out to reduce pain after a laparoscopic cholecystectomy.

Recent literature suggests that TAP block as an efficient method in multimodal analgesia after laparoscopic cholecystectomy. [20,21,12,22] The TAP block was first described in 2001 by Rafi et al. [23] using the 'Petit' triangle, and performed with so-called "pop" or "double-pop" method. In order to reduce the potential local side effects, Hebbard et al. [24] described the ultrasound-guided block that enables direct visualization of all anatomical structures, the needle, and the spread of local anaesthetic by ultrasonographic guidance. The first use of the TAP block for laparoscopic cholecystectomy was described by El-Dawlatly in 2009 using the posterior approach or blind POP method. Ra et al. [21], Peterson et al. [20] and El-Dawlatly [22] reported good postop analgesia after TAP, but Ortiz et al. [25] did not find any statistical significance in postoperative pain and analgesic consumption in patients who received a TAP block, compared to those who received port-site local infiltration with ropivacaine. These different types of results might be explained by differences in the technique used in these studies regarding the type of block like different types of approaches i.e, subcostal approach, posterior approach, blind technique or ultrasound guided TAP, the timing of the block (before or after surgery), the drug and the dose of local anesthetics used.

The present study compared bilateral subcostal TAP block (Group A) with port-site infiltration (Group B) and found better analgesia as evidenced by lower NRS pain scores, prolonged time to first Tramadol requirement and significantly decreased 24 hours Tramadol consumption. Shin et al. [12] also demonstrated lower pain scores and decreased opioid consumption in oblique subcostal TAP block as compared to conventional TAP block.

In four ports laparoscopic cholecystectomy, one of the ports would be at the epigastric region for which more anterior block is desirable. The block can be achieved up to the T6 dermatome by using bilateral subcostal TAP block, which can submerge more nerve segments of anterior abdominal wall and increase the area of diffusion providing better analgesic effect. For distal port, after injection of 1- 2 mL of local anesthetic to separate Rectus abdominis and Transversus abdominis muscles, the needle is further advanced under ultrasound guidance laterally which allows for a more lateral spread of the local anesthetic and provides the effective analgesia to the distal port. [26-28, 29,30] This finding was further confirmed by our study.

In the present study, the time to first Tramadol requirement was significantly prolonged in patients receiving subcostal TAP block (Group A) as compared to port site infiltration $(4.93\pm0.70 \text{ hrs}, 2.44\pm1.36 \text{ hours}, p<0.001)$. The total Tramadol consumption in first 24 hours was significantly lower in subcostal TAP block group $(78.13\pm0.70 \text{ vs} 140.79\pm40.15, p<0.001)$. Ibrahim et al. [31] and Shin et al. [12] also found that the total opioid consumption was significantly decreased in first 24 hrs in patients receiving oblique subcostal TAP block. Our findings are comparable with these recent studies. [31,32] During the study period no local anesthesia

systemic toxicity was noted. This might be due to the use of real time ultrasound and low volume of local anesthetics used. The incidence of nausea and vomiting was found to be less and statistically insignificant which might be the result of decreased consumption of postoperative opioids.

V. Conclusions

This study concludes that the ultrasound guided bilateral Subcostal TAP block provides better postoperative analgesia and reduces postoperative opioid requirements as compared to port site infiltration. It is safe and effective component of multimodal analgesia for the post-operative pain management in patients undergoing laparoscopic cholecystectomy.

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