

A Comparative Study to Evaluate the Effectiveness of Perioperative Multi Modal Analgesia with Ultrasound Guided Bilateral Subcostal TAP Block for Post-Operative Analgesia in Patients undergoing Elective Laparoscopic Cholecystectomy under General Anaesthesia

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ABSTRACT

Background: Laparoscopic cholecystectomy is usually performed as a day care procedure for diseases involving the gall bladder. Pain in the immediate post-operative period is due to multiple factors and hence different modalities of pain relief are used. The present study was conducted to study the effectiveness of Peri-operative Multi-Modal Analgesia with ultrasound guided bilateral subcostal TAP block for Post-operative analgesia in 60 patients undergoing elective laparoscopic cholecystectomy.

Methods: In this hospital based, randomized prospective interventional study patients were randomly allocated into 4 groups of 15 in each group. Group B received Bilateral Ultrasound guided Subcostal TAP Block with 20 ml of 0.25% Bupivacaine, Group P received Tab Pregabalin tablet 150 mg, Group D received Inj Dexamethasone 8 mg IV and Group C was the control group. The hemodynamic changes like heart rate, blood pressure, saturation was monitored both intra and post operatively. The post-operative VAS scoring, duration of analgesia, time for first rescue analgesic and the total dose of analgesics in 24 hours were noted.

Results: The VAS Scores indicated that Group B>P>D>C provided better analgesia to the patients with a P Value of < 0.01. Group B took the longest mean duration (6.8± 1.15 hours) to take the 1st rescue analgesic and least mean total dose of rescue analgesic in 24 hours followed by Group P, Group D and Group C which was statistically significant.

Conclusion: USG guided B/L TAP Block was superior to other modalities in providing postoperative analgesia for patients undergoing laparoscopic cholecystectomy.

Effective postoperative pain control is of great importance for the outcome of surgery as well as patient satisfaction. Improper pain control may result in patient dissatisfaction, prolonged hospital stays, increased morbidity and mortality and more financial burden for the patient. Pain following laparoscopic cholecystectomy is due to multiple factors, which has

prompted to use different modalities to control the pain postoperatively. Multi modal analgesia (MMA) is defined as the use of more than one pharmacological class of analgesic medication targeting different receptors along the pain pathway with the goal of improving analgesia while reducing individual side effects [1]. MMA is recommended for postoperative pain

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management for clinical situations and various guidelines are available from the American Pain Society, American Society of Regional Anesthesia and Pain Medicine (ASRA), and the American Society of Anesthesiologists (ASA) [2]. Transversus abdominis plane (TAP) block deposits the local anesthetic drugs into abdominis plane and provides analgesia thereby reducing the perioperative opioid use in elective abdominal surgery, including open appendicectomy, laparoscopic cholecystectomies, caesarean section and laparotomies [3-6]. The use of point of care ultrasonography in abdominal blocks increases the success rate and safety of the block [7]. In 2007, Hebbard introduced a variant of TAP block that is subcostal TAP block where the local anesthetic is deposited between the transverse abdominis plane inferior and parallel to the costal margin. Due to its more cranial spread, analgesia for supra-umbilical surgeries is adequate with this block [8]. Thus, the present study was designed to study the effectiveness of Peri-operative Multi-Modal Analgesia with Ultrasound guided Bilateral Subcostal TAP block for Postoperative Analgesia in patients undergoing elective laparoscopic cholecystectomy

Methods

This randomized prospective interventional study was conducted in a tertiary care hospital in Karnataka, India. After obtaining approval from the institutional ethical committee (number VIEC/2019/APP/083), the study was conducted in 60 patients aged between 20-60 years of ASA-1 and ASA- 2 scheduled for elective laparoscopic cholecystectomy under general anesthesia. A written informed consent was obtained from all the patients and were kept fasting for 6 hours before the surgery. Patients were shifted two hours prior to the pre-operative room, an intravenous access 18G or 20G was secured, fluids started and multiparameter monitors were attached and baseline vitals were noted. Patients were randomly allocated into 4 groups, using envelope method, containing 15 in each group. Group P- patients received Tab Pregabalin 150 mg two hours before surgery. Group B-Bilateral Ultrasound guided subcostal TAP Block was given on each side with 20 ml of 0.25% Bupivacaine at the end of surgery. Group D- Inj Dexamethasone 8 MG IV at the time of induction. Group C- Control Group. Patients were given general anesthesia starting with pre-medication of Intravenous Ondansetron 0.15mg/kg, Inj Midazolam 0.03 mg/kg; Inj Glycopyrrolate 0.01mg/kg and Inj Fentanyl 2 mcg/kg body weight IV. Pre-oxygenation with 100% oxygen with 5litres/minute was done for 3 minutes. Patients were induced with IV INJ Propofol 2-2.5mg/kg paralyzed with neuromuscular blocker-Inj Atracurium-0.5Mg/kg IV, intubated using direct laryngoscope, appropriate size endotracheal tube was inserted, fixed and cuff was inflated after confirming by 5-point auscultation. Patient was maintained intra-operatively by 40% Oxygen in air and inhalational agent

Isoflurane and neuromuscular blocker Inj. Atracurium 0.1mg/kg body weight. Intra-operative blood pressure, heart rate, Spo₂, Etco₂ was monitored every five minutes. Inj Diclofenac 75mg IV was put in 1st IV fluid, Inj Paracetamol 1 G IV was given after 2nd IV fluid. Additional Inj Fentanyl (1/5th dose of induction) was given if $\geq 20\%$ hemodynamic changes were noted. Local infiltration was given at the end of surgery to all 5 ports using 4 ml of 0.25% bupivacaine by the surgeon to all the groups except to group B in whom bilateral subcostal TAP block was given. The block was performed under sterile aseptic precautions under guidance of Seimens acuson freestyle ultrasound L8-3 MHz Linear Transducer and 22g stimplex needle with 0.25% bupivacaine 20ml on each side. The patients were reversed with Inj Glycopyrrolate 0.01mg/kg + Inj Neostigmine 0.05mg/kg and extubated. In the post-operative period, patients were assessed for pain using Visual analogue scale (VAS) every 15 minutes for 1st hour, subsequently at 2, 4, 8, 12 and 24 hours. When the pain score >3 , rescue analgesia Inj. Tramadol 50 mg IV was given, the time for rescue analgesia and the total amount of analgesics given were noted.

Sample Size Calculation

The sample size was calculated based on the power of study as 90% as to detect a 25% difference at a Type 1 (alpha) error of 0.05 for the duration of analgesia and assuming a drop out of 10%, 15 patients are included in each group to sum up 60 sample size.

Statistical Analysis

It was performed by STATA 11.2 (College Station TX USA). Analysis of variance test has been used to find the significance difference between the heart rate, blood pressure, visual analogue score, age, height, weight, total rescue analgesia, total dose in the last 24 hours among the different groups and it is expressed as mean and standard deviation. Chi square test for goodness of fit was used to measure the association between the gender, ASA grading and it is expressed as frequency and percentage. p value < 0.05 was considered as statistically significant.

Results

Demographic data of patients in all the groups are comparable with no statistically significant difference (Table 1).

From (Table 2), it is evident that there was no significant difference between the groups with respect to gender.

The patients ASA grading was also comparable with no statistically significant difference between the groups (Table 3).

On comparison of the mean heart rate between the study groups at different time intervals post operatively, it was found that heart rate was better for Group B study subjects compared to other groups, and this difference

was statistically significant with a p value of < 0.001 (Table 4).

Similar to heart rate, the mean systolic blood pressure between the study groups at different time intervals post operatively was found to be better for Group B study subjects compared to other groups, and this difference was statistically significant with a p value of < 0.001 (Table 5).

Visual analogue scale (VAS) Score at different time intervals was found to be statistically significant less in group B followed by group P, group D and group C with p value of <0.001 (Table 6).

On comparing the time for 1st rescue analgesic, which is given when the VAS pain score was > 3 among all the 4 groups, it was found that Group B took the longest mean duration (6.8 ± 1.15 hours) to take the 1st rescue analgesic followed by Group P (5.20 ± 0.68 hours), Group C (2.80 ± 0.41) and Group D (1.39 ± 0.84). And this difference was found to be statistically significant with a P Value of < 0.01. In 24 hours, duration, the mean total dose of rescue analgesia was found to be highest with Group C, followed by Group D, Group P and Group B. This difference was found to be statistically significant with a P value of < 0.001 (Table 7).

Table 1- Demographic Variables

Variable	Group B	Group C	Group P	Group D	P value
Age	51.73 ±12.67	48.07±12.02	55.0 ± 14.44	53.13±12.24	0.51 [#]
Weight	73.20 ±10.21	73.67 ± 6.37	67.33 ± 14.71	66.73 ± 10.77	0.191 [#]
Height	169.87±12.46	160.80 ±8.16	161.40 ±7.48	163.20±11.71	0.067 [#]

#no statistical significance

Table 2- Comparison of Gender with Groups

	Group B	Group C	Group P	Group D	Total	P value
Male	9 (60%)	7 (47%)	8 (53%)	10(67%)	34	0.716 [#]
Female	6 (40%)	8 (53%)	7 (47%)	5 (33%)	26	
Total	15	15	15	15	60	

#no statistical significance

Table 3- Comparison of ASA grading with Groups

ASA	Group B Count %	Group C Count %	Group P Count %	Group D Count %	P value
I	0 0.0%	0 0.0%	0 0.0%	2 13.3%	
II	15 100.0%	15 100.0%	15 100.0%	13 86.7%	0.1 [#]
Total	15 100.0%	15 100.0%	15 100.0%	15 100.0%	

#no statistical significance

Table 4- Comparison of heart rate between the study groups

Heart Rate	Group B Mean ± SD	Group C Mean ± SD	Group P Mean ± SD	Group D Mean ± SD	P value
recovery	72.47 ± 3.11	82.60 ± 4.97	74.0 ± 10.76	85.53 ± 3.74	<0.001**
15 Minutes	72.73 ± 6.27	76.40 ± 3.79	72.47 ± 9.75	79.07 ± 6.09	<0.001**
30 Minutes	78.40 ± 6.43	88.60 ± 5.62	78.93± 4.30	103.87 ± 4.64	<0.001**
45 Minutes	83.40 ± 3.62	94.20 ± 3.41	85.27 ± 4.79	102.27 ± 5.78	<0.001**
60 Minutes	85.53 ± 4.65	101.87± 4.64	91.40 ± 6.42	103.4 ± 1.5	<0.001**
75 Minutes	77.20 ± 4.94	86.33 ± 7.09	81.60 ± 6.36	94.07 ± 2.73	<0.001**
90 Minutes	74.13 ± 3.68	94.40 ± 2.41	80.40 ± 6.76	102.07 ± 7.44	<0.001**
105 Minutes	83.60± 3.86	89.73 ± 4.40	84.60 ± 7.84	99.20 ± 4.57	<0.001**
120 Minutes	73.47 ± 3.64	94.60± 5.53	82.67± 5.90	97.27± 4.08	<0.001**

**statistically significant

Table 5- Comparison of Systolic blood pressure between the study groups

Systolic Blood Pressure	Group B Mean ± SD	Group C Mean ± SD	Group P Mean ± SD	Group D Mean ± SD	P value
recovery	131.07 ± 5.89	136.13 ± 5.68	122.27 ± 9.91	136.20 ± 4.37	<0.001**
15 Minutes	144.73 ± 5.51	132.67 ± 5.22	120.67 ± 9.09	132.20 ± 2.21	<0.001**
30 Minutes	145.33 ± 8.12	135.0 ± 3.78	118.33 ± 7.92	140.67 ± 7.47	<0.001**
45 Minutes	135.40 ± 4.89	126.47 ± 0.91	117.87 ± 9.08	130.07 ± 4.48	<0.001**
60 Minutes	139.47 ± 4.24	147.73 ± 4.68	126.40 ± 13.27	150.47 ± 5.26	<0.001**

75 Minutes	128.0 ± 6.41	135.0 ± 3.07	120.27 ± 10.14	138.80 ± 4.04	<0.001**
90 Minutes	129.87 ± 5.87	133.73 ± 2.31	120.20 ± 10.35	130.53 ± 3.54	<0.001**
105 Minutes	127.53 ± 4.05	130.60 ± 3.99	119.13 ± 9.25	128.87 ± 8.47	<0.001**
120 Minutes	124.27 ± 5.02	146.60 ± 1.55	119.93 ± 9.09	144.60 ± 3.79	<0.001**

**statistically significant

Table 6- Comparison of VAS Scores between the study groups

VAS score	Group B	Group C	Group P	Group D	P value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Recovery room	3	4.60 ± 0.51	4	4.67 ± 0.49	<0.001**
15 Minutes	3	5	4	4.67 ± 0.49	<0.001**
30 Minutes	2	5	4	4.73 ± 0.46	<0.001**
45 Minutes	2	4.2 ± 0.41	3.8 ± 0.41	4.27 ± 0.46	<0.001**
60 Minutes	2	4.2 ± 0.41	3.0	4.33 ± 0.49	<0.001**
120 Minutes	2	4.2 ± 0.41	3	4.33 ± 0.52	<0.001**
4 hours	2	4.27 ± 0.46	3	4.53 ± 0.52	<0.001**
8 hours	2	4.2 ± 0.41	3	4.33 ± 0.49	<0.001**
12 hours	2	4.2 ± 0.41	3	4.33 ± 0.49	<0.001**
24 hours	2	4.2 ± 0.41	3	4.33 ± 0.49	<0.001**

**statistically significant

Table 7- Comparison of time to rescue analgesic and total analgesics received between groups

	Group B	Group C	Group P	Group D	P value
Time to rescue analgesic (in hrs.)					
Mean± SD	6.80±1.15	2.80 ± 0.41	5.20 ± 0.68	1.39±0.84	< 0.001**
Tramadol (mg)	53.33±12.91	120 ± 11.52	76.67± 25.82	100	< 0.001**

**statistically significant

Discussion

Cholecystectomy is a commonly performed surgical procedure for treatment of gall bladder disease conditions including cholelithiasis. Adequate perioperative care is vital to manage post-operative pain, which could be due to multi-factorial factors [9]. The type of analgesics used should be very effective, safe, and with minimal possible side effects. In recent years, ultrasound guided regional nerve block techniques which are commonly used for both intra and post-operative analgesia have promising results on efficacy, lower the need for other supplemental analgesics and thereby reducing the incidence of drug-related side effects. [4-5] Bilateral subcostal TAP block has been shown to provide very good analgesia to the skin and musculature of the anterior abdominal wall in case of laparoscopic cholecystectomy [10-12]. The present study was designed to study and compare the effectiveness of Peri-operative Multi-Modal Analgesia with Ultrasound guided Bilateral Subcostal TAP block for Post- Operative Analgesia in patients undergoing laparoscopic cholecystectomy under general anesthesia. This is the first study of its kind comparing all the four groups where different modalities of analgesia are given in patients undergoing laparoscopic cholecystectomy. Total of 60 patients were randomly divided into 4 group of 15 each,

Group P- patients received Tab Pregabalin 150 mg PO two hours before surgery, Group B-Bilateral Ultrasound guided subcostal TAP Block was given on each side with 20 ml of 0.25% Bupivacaine at the end of surgery, Group D-Inj Dexamethasone 8 MG IV at the time of induction and Group C- Control Group. Demographic variables such as age, gender, weight, height, ASA grade distribution was comparable in all the 4 groups with no statistically significant difference. The vital parameters like heart rate and blood pressure were monitored intra-operatively and postoperatively at different time intervals. On comparison of the post-operative mean heart rate between the study groups at different time intervals, it was found that heart rate was lesser for Group B study subjects who received subcostal TAP block compared to other groups, and this difference was statistically significant with a p value of < 0.001. Similarly, the systolic blood pressure was also found to have statistically significant difference between the groups and they were found to be well controlled in Group B. In our study, the post-operative pain was assessed by Visual analogue scale (VAS) Score at different time intervals till 24 hours and compared between all the four groups and it was found to be statistically significant with a p value of < 0.01, indicating that Group B>P>D>C (patients receiving subcostal block followed by oral pregabalin, then Inj

dexamethasone and last with control group) provided better analgesia to the patients. Similarly, in a study conducted by Vrsajkov V et al., they reported that VAS scores for patients who had received Subcostal TAP Block had less postoperative pain scores compared to standard analgesia and stated that the block provides superior postoperative analgesia and reduction in opioid requirement after laparoscopic cholecystectomy [11]. Even Breazu CM et al., reported that the subcostal TAP Bupivacaine group had a statistically significant lower VAS pain score than the placebo group [13]. In the present study, on comparing the demand for 1st rescue analgesic, which was given when the VAS pain score was > 3 among all the 4 groups, it was found that Group B had the longest mean duration (6.8 ± 1.15 hours) to take the 1st rescue analgesic followed by Group P (5.20 ± 0.68 hours), Group C (2.80 ± 0.41) and Group D (1.39 ± 0.84). This difference was found to be statistically significant with a p value of < 0.01 . In 24 hours, the mean total dose of rescue analgesia was found to be highest in Group C, followed by Group D, Group P and Group B, indicating that Ultrasound guided B/L TAP block with 0.25% Bupivacaine provided a longer duration of post-operative analgesia with lesser rescue analgesic requirement followed by those who consumed Tab Pregabalin "P" PO 2 hours prior to surgery, followed by the group which received Inj Dexamethasone 8 mg IV. This difference was found to be statistically significant with a P value of < 0.001 . Similar to our present study, Baral B et al., reported that the postoperative pain in patients receiving Subcostal TAP block was less as compared to patients receiving port site infiltration and was statistically significant in the first 2 hours after surgery and the 24 hours opioids consumption was significantly less ($125 \text{ mg} \pm 25.42$ versus $175 \text{ mg} \pm 25.42$) in block group and also the time for request of first rescue analgesic was prolonged in patients receiving the Subcostal TAP block (3.20 ± 0.84 hours vs. 1.70 ± 0.65 hours, $p < 0.001$) [14]. No complications related to the drugs used or the block procedure such as nausea, vomiting, dizziness, liver trauma was recorded during this study period among the participants. This study has limited external validity and generalizability due to strict inclusion and exclusion criteria and application of intervals by protocol. The postoperative pain was studied for only 24 hours as the patients were shifted to oral analgesics after 24 hours of laparoscopic cholecystectomy.

Conclusion

In our study, Bilateral subcostal TAP block has been demonstrated to provide excellent post-operative analgesia for patients undergoing laparoscopic cholecystectomy. The duration for rescue analgesia after surgery was longer in patients receiving USG Guided subcostal TAP Block and also the total amount of rescue

analgesics used was lesser compared to other groups. There were no complications related to the procedure during our study. Thus, we conclude that USG guided subcostal block provides superior analgesia compared to other modalities for providing post-operative analgesia in patients undergoing laparoscopic cholecystectomy.

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