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COMPARISON OF THE ULTRASOUND GUIDED SUBCOSTAL TRANSVERSUS ABDOMINIS PLANE BLOCK AND PORT SITE INFILTRATION OF LOCAL ANAESTHESIA FOR POST-OPERATIVE PAIN MANAGEMENT IN THE ADULT PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Pain management is necessary for optimal post-operative care in surgical patients. Abdominal wall blocks like Transversus Abdominis plane (TAP) block are new hallmark of multimodal pain strategy for post-operative analgesia. **Study Objective**: To compare the ultrasound-guided subcostal TAP block and port site infiltration using 0.25% levobupivacaine for post-operative analgesia. Primary objective is to compare the duration and quality of analgesia between two groups. Secondary objective is to study the hemodynamic parameters and adverse effects like Hypotension and nausea and vomiting. **Design**: Randomized Comparative Study. **Patients and Interventions**: We enrolled sixty adult patients, divided into two groups. Group A received ultrasound guided bilateral subcostal TAP block with 10ml of 0.25% levobupivacaine and Group B received port site infiltration with 0.25% levobupivacaine, 5ml at each 4 ports before extubation. **Measurements**: The post-operative pain was assessed by visual analog score(VAS). VAS more than 4 or when patient complained of pain, injection tramadol 1mg kg^{-1} was given as first rescue analgesic drug. VAS score was assessed at 15minutes, 30minutes, 1hour, 1.5hours, 2hours, 4hours and 6hours after extubation and the time to first rescue analgesic dose were recorded. The data was statistically analysed using Statistical Package for Social Sciences (SPSS) version 21.0. Qualitative variables were correlated using Chi-Square test. **Results**: Postoperative VAS score in Group A were significantly reduced at 15 minutes, 30minutes, 1hour, 2hours, 4hours and 6hours ($P < 0.001$). The time taken to administer the first rescue analgesic dose was more in the Group A (1.93 ± 0.45) in comparison to Group B (1.2 ± 0.25) with P value < 0.001. **Conclusion**: The duration and quality of analgesia with ultrasound guided subcostal TAP Block was better than port site infiltration.

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INTRODUCTION

Major changes were undergone in the abdominal surgery from open invasive to closed minimally invasive surgery. Accordingly management strategies in pain also have changed.[1] Laparoscopic cholecystectomy is a minimally invasive day care surgery done for removal of diseased gall bladder.

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Though Laparoscopic abdominal surgery is assessed as minimal pain causing, it can be significant and needs to be addressed appropriately.[2]Subcostaltransversus abdominis plane (TAP) block involves the injection of local anaesthetic drug into the neuro-fascial plane between the rectus abdominis muscle and transversus abdominis muscle providing sensory blockade of T6-T10 nerves.[3-4]Ultrasound has reformed the technique by more accurate placement of drug, thereby increasing the margin of safety.[5]Another defined method to provide effective analgesia after surgical procedure is port site infiltration of local anaesthetic drug.[6]

Our study aimed to compare the ultrasound guided subcostal TAP block and port site infiltration using 0.25% levobupivacaine for post-operative analgesia in the adult patients. The primary objective of our study was to compare the duration and quality of analgesia between the two groups and secondary objective was to observe the hemodynamic parameters and adverse effects.

MATERIALS AND METHODS

After approval from Institutional Research and Ethical Committee we conducted a randomized comparative study on adult patients undergoing laparoscopic cholecystectomy under general anaesthesia in our hospital. We enrolled 60 adult patients with the American Society of Anaesthesiologists (ASA) physical status I and II, aged between 18 to 65 years with a body mass index (BMI) of 18–35 kgm^{-2}, for our study and randomizedthem into two groups of 30 each using sealed envelope system. Patients with allergy to local anaesthetics, infection at the site of injection, chronic pain syndromes, morbid obesity (>35 kg m^{-2}), coagulopathy and those who received any pain killera daybefore surgery were omitted from the study. Written consent was signed from all the patients before surgery. A complete pre-anaesthetic evaluation was performed in every patient. All of them received tablet Alprazolam 0.25mg one night before the day of surgery. After receiving the patients in the operation theatre, all standard monitors were attached and baseline parameters were recorded. Anaesthesia machine and airway equipment were checked. 18G intravenous cannula was secured. After giving premedication with injection midazolam 1mg and injection fentanyl l.5mcgkg^{-2} by intravenous route, preoxygenation done for 3minutes and patient was induced with injection propofol 2mg m^{-2} intravenous and neuro-muscular blockage was achieved by giving injection vecuronium bromide 0.1mgkg^{-2}intravenous. After intubation, anaesthesia was maintained under controlled ventilation with oxygen, nitrous oxide, isoflurane and intermittent doses of injection vecuronium bromide. Vitals monitoring were done perioperatively and at the end of surgery, depending on the group allocated, corresponding procedure was performed using 0.25% levobupivacaine before extubation.

Under strict aseptic precautions using transportable ultrasound with high frequency (6-10 MHz) linear transducer probe visualized at depth of 3-4, subcostal TAP block was performed. The probe was transversely placed on anterior abdominal wall inferior to the costal margin. 20G needle was taken and then inserted in the plane between rectus abdominis and transversus abdominis muscle. After negative aspiration, hydro dissection was done and 10ml 0.25% levobupivacaine given. Similar procedure was repeated on opposite side. Port site local infiltration was done with 0.25% levobupivacaine at umblical, epigastric, midclavicular and anterior axillary ports (5ml at each port) under direct vision into the tissues. Infiltrating The layers infiltrated with drug werepreperitoneal, musculofascial plane, and the tissue below the skin. After the completion of procedure neuro-muscular blockage was reversed with 0.01mg kg^{-2} injection glycopyrrolate and 0.05mg kg^{-2}injection neostigmine and then extubation was performed. Patients were shifted to recovery room for post-operative monitoring. We gave Injection paracetamol 15mg kg^{-2} intravenously 1hour before the end of surgery to all patients in both the groups.

The duration of analgesia was assessed by time period between the administration of block and time of first rescue analgesia dose. The quality of the pain was assessed by the VAS (Visual Analog Score) in the recovery room at 15minutes, 30minutes, 1hour, 1.5hours, 2hours, 4hours and 6 hours from the time of procedure done and also as and when patient complains of the pain. Injection tramadol 1mg/kg was given as first rescue analgesic dose. The hemodynamic parameters heart rateand mean arterial blood pressure wereobserved at same time interval as above. Adverse effects like hypotension, nausea and vomiting if present were noted. 29 patients per group provided an 90% power for detecting a difference of 6 hours between the groups with an effective size of 0.86 at an alpha level of 0.05. However, we took 30 patients per group for the study. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used.

Statistical tests applied were as follows

- Quantitative variables were compared using Independent t test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups.
- Qualitative variables were correlated using Chi-Square test.
- A p value of <0.05 was considered statistically significant.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS

Sixty patients divided into two groups of 30 each were enrolled for our study**.** Both the groups were similar and comparable with respect to age, gender, ASA physical status, weight, height and BMI, and no statistically significant difference was found in both the groups. Hence the confounding factor of these variables have probably been neutralised. [Table 1; figure 1] shows the duration of analgesia between two groups.

Table 1. Comparison of time of rescue analgesia between two groups

Time of rescue analgesia (in hours)	A (n=30)	B (n=30)	Total	P value	Test performed
Mean ± SD	1.93 ± 0.45	1.2 ± 0.25	1.57 ± 0.52	<.0001	Mann Whitney test;48

Group A had requested for rescue analgesia after (1.9 ± 0.45) hours whereas Group B had requested for rescue analgesia after (1.2 ± 0.25) hours. Group A had prolonged post-operative analgesia than compared to Group B. [Table 2; figure 2] shows quality of analgesia assessed by VAS. Score was assessed post-operatively after 15minutes, 30minutes, 1hour, 1.5hours, 2hours, 4hours and 6hours in both the groups. Group A showed VAS score of 2.17 after 15minutes, 2.50 after 30 minutes, 2.87 after 1hour, 3.27 after 1.5hours, 4.40 after

2hours, 6.17 after 4hours and 6.93 after 6hours. Group B showed VAS score of 2.70 in 15minutes, 3 in 30minutes, 3.60 in 1hour, 5.13 after 1.5 hours, 6.30 after 2hours, 6.70 after 4hours and 8.13 after 6hours. VAS score more than 4 is taken as cut-off for rescue analgesia. According to our study results, Group A has better analgesic control than Group B. The variable post-operative parameters heartrate and mean arterial blood pressure were not normally distributed, thus non-parametric test was used for comparison. [Figure 3] shows post-operative heart rate, compared between Group A and Group B at same intervals as VAS score.

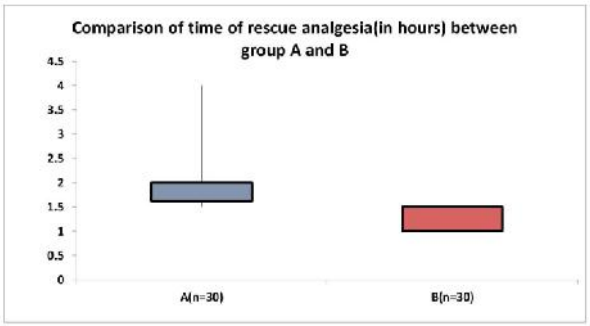

Figure 1. Comparison of time of rescue analgesia between two groups

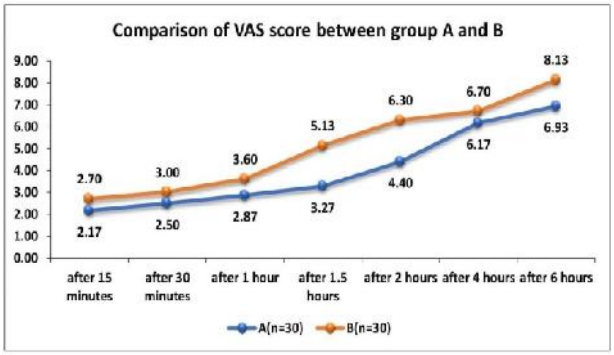

Figure 2. Comparison of VAS score between two groups

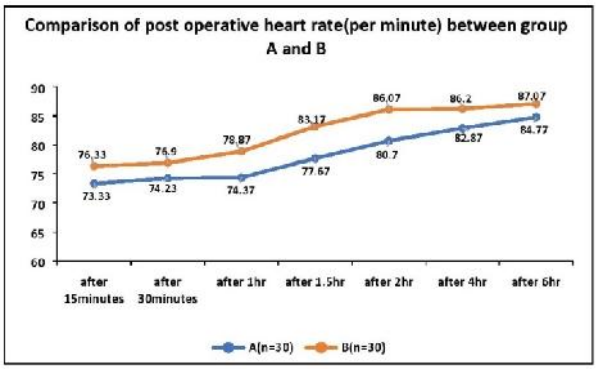

Figure 3. comparison of post-operative heart rate between two groups

Significant difference was observed between the two groups up to 2hours with p value being significant, which is comparable with VAS score. At 4 and 6 hours, it was almost equal in both the groups with no comparable difference. [Figure 4] shows post-operative mean arterial blood pressure, compared between Group A and Group B at same intervals as VAS score. Significant difference was observed between the two groups up to 2hours with p value being significant, which is comparable with VAS score. At 4 and 6 hours, it was almost equal in both the groups with no comparable difference.

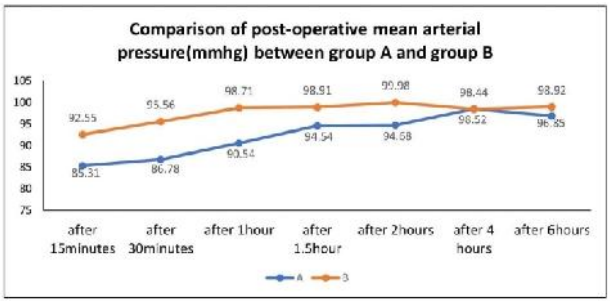

Figure 4. Comparison of post-operative MAP between two groups

Table 2. Comparison of VAS score between two groups

VAS score	A (n=30)	B (n=30)	Total	P value	Test performed
After 15 minutes					
Mean ± SD	2.17 ± 0.46	2.7 ± 0.47	2.43 ± 0.53	0.0001	Mann Whitney test;220.5
After 30 minutes					
Mean ± SD	2.5 ± 0.51	3 ± 0	2.75 ± 0.44	<.0001	Mann Whitney test;225
After 1 hour					
Mean ± SD	2.87 ± 0.35	3.6 ± 0.5	3.23 ± 0.56	<.0001	Mann Whitney test;156
After 1.5 hours					
Mean ± SD	3.27 ± 0.45	5.13 ± 1.04	4.2 ± 1.23	<.0001	Mann Whitney test;48
After 2 hours					
Mean ± SD	4.4 ± 0.89	6.3 ± 0.65	5.35 ± 1.23	<.0001	Mann Whitney test;70.5
After 4 hours					
Mean ± SD	6.17 ± 0.91	6.7 ± 0.53	6.43 ± 0.79	0.019	Mann Whitney test;308.5
After 6 hours					
Mean ± SD	6.93 ± 0.74	8.13 ± 0.68	7.53 ± 0.93	<.0001	Mann Whitney test;120.5

DISCUSSION

Pain management is very important for optimal care in surgical patients. Laparoscopic surgery has displayed advantages over open surgery including less postoperative pain, smaller incisions, and shorter postoperative ileus, reduced blood loss, and reduced length of hospital stay and faster recovery [2]. Laparoscopic Cholecystectomy is a common surgical procedure done for various gall bladder disease conditions including cholelithiasis. Pain after laparoscopic cholecystectomy is less severe than compared to open cholecystectomy, it is still a source of marked discomfort and surgical stress. It is shown that lack of effective post-operative pain control will not only result in adverse physiological effects but also can end in chronic pain [7]. There are various techniques to alleviate post-operative pain in laparoscopic cholecystectomy [8], port site infiltration and ultrasound guided subcostal TAP block techniques [9] were found to be one of the effective way of managing post-operative pain in these patients.

Hence in our present study we had done comparison of the above two techniques for post-operative pain management in laparoscopic cholecystectomy patients using 0.25% levobupivacaine. The Transversus Abdominis Plane (TAP) block was introduced by Rafi in 2001 as a landmark-guided technique [10]. It is done via triangle of petit to provide a field block. The TAP is a potential anatomical space between transversus abdominis and internal oblique (or rectus abdominis) and the field block by local anaesthetic infiltration in this plane is referred to as a TAP block. The thoracolumbar nerves originating from T6 to L1 spinal roots are present in this plane, which gives the sensory supply to the anterolateral part of the abdominal wall [11]. Thus the local anaesthetic solution injected in this plane, spreads and blocks the neural afferents and provides analgesia [12]. TAP block as a blind technique has got few serious complications [13,14] and until the introduction of ultrasound in regional anaesthesia, it was not so easy. Ultrasound guided TAP block helps in clearly demarcating the anatomy, increases the margin of safety and also helps in the deposition of local anaesthetic solution under vision. This not only increases the success rate of the block but also reduces the volume of drug needed for effective block [15,16]. Hence, in our study, USG-guided subcostal TAP block was preferred for post-operative analgesia. In our study we used 0.25% levobupivacaine 20ml for both port site infiltration (5ml at each of the 4port sites) and bilateral ultrasound guided subcostal TAP block (10ml on each side). In a previous study done by Ra YS et al, comparing analgesic efficacy of 0.25% and 0.5% levobupivacaine and placebo for TAP block, the pain scores and post-operative analgesic requirement obtained between the two different doses of levobupivacaine were comparable [17]. So in our study we used 0.25% levobupivacaine to minimize the toxicity profile of the drug if any. Group A were the patients who received ultrasound guided subcostal TAP block with 0.25% levobupivacaine 10 ml on each side (total-20 ml). Group B were the patients who received 20ml of 0.25% levobupivacaine by port site infiltration.(5ml at each of the four port sites- umblical, epigastric, midclavicular and anterior axillary).

DEMOGRAPHIC COMPARISON: Both the groups were taken in comparable with respect to age, sex, ASA physical status, weight, height and BMI, to avoid the confounding factor.

VITAL PARAMETERS COMPARISON: PRE-OPERATIVE Pre-operatively, in the Group A, pulse rate, mean systolic, diastolic pressure and saturation were 71.7 ± 5.31 beats per minute, 122.4 ± 7.94 mmhg, 75.6 ± 6.65 mmhg and 99.9 ± 0.31 respectively ; whereas in the Group B, pulse rate, mean systolic, diastolic pressure and saturation were 72.03 ± 3.76 beats per minute, 124.47 ± 5.41mmhg, 77.17 ± 5.37 mmhg and 99.73 ± 0.45 respectively. The pre-operative vital parameters between the two groups-group A and Group B were not significant and not comparable. We assessed the duration of analgesia by time period between the administration of block and time of first rescue analgesia dose and quality of the analgesia by the VAS (Visual Analog Score) after the arrival of the patient in the recovery room at 15minutes, 30minutes, 1, 1.5, 2, 4 and 6 hours from the time of procedure done and also as and when patient complains of the pain. We also compared the time required for first rescue analgesia dose and hemodynamic parameters between the two groups.

DURATION OF ANALGESIA

Duration of analgesia was assessed between the time of administration of block and time of first rescue analgesic dose requirement. Indususeela et al compared the efficacy of ultrasound guided subcostal TAP block with port site local anaesthesia infiltration for postoperative analgesia after laparoscopic cholecystectomy using 0.25% bupivacaine. They found in their study that time to first rescue analgesia was more in TAP block group compared to local infiltration group[18]. In our study, the time of rescue analgesia in Group A (1.93 ± 0.45)hours and in Group B (1.2 ± 0.25) hours. Time of request for rescue analgesia was prolonged in Group A patients than compared to Group B. Our study results well correlated with the previous study showing more time required for rescue analgesia for Group A than Group B.

VAS SCORE: Quality of the analgesia was assessed by the VAS (Visual Analog Score) after the arrival of the patient in the recovery room at 15minutes, 30minutes, 1, 1.5, 2, 4 and 6 hours from the time of procedure done and also as and when patient complains of the pain. Baral et al, in their study compared the analgesic efficacy of ultrasound guided subcostal transversus abdominis plane block with port site infiltration following laparoscopic cholecystectomy using bupivacaine. They found in their study that patients who received subcostal TAP block had reduced post-operative pain than port site infiltration with time of rescue analgesia request being (3.20+/-0.84 hours vs 1.70+/-0.65 hours, p<0.001) prolonged in subcostal TAP group than port site local infiltration[19]. Prateebha et al, in their study compared the post-operative analgesic efficacy of wound site infiltration and ultrasound guided TAP block with 0.5% ropivacaine for lower abdominal surgeries. Patients who underwent TAP Block took significantly longer time (6 hours) to request for the first rescue analgesic (P = 0.001), with reduced VAS at the time of rescue analgesic (2.64 ± 0.969) when compared to patients who received WSI (3.04 ± 1.105). Postoperative VAS scores in Group TAP were significantly reduced at 30 min, 1st h, 1 h 30 min, 2, 4, and 6 hours (P < 0.001). The VAS scores in the WSI group was high from the beginning of 30 min to 6 hours when compared to the TAP group, but no statistical difference was observed after 6 hours in both the groups[20]. In our study, VAS score was compared between group A (ultrasound guided subcostal TAP block) and group B (port site local infiltration of anaesthesia). Our study correlated well with the above studies showing VAS score in group A after 6hours (6.93 ± 0.74) and in group B (8.13 ± 0.68) with p value <0.0001. Group A had better post-operative analgesic efficacy than compared to Group B with p value being significant until 6 hours. Hence Group A patients who received TAP block had overall reduction of the post-operative analgesic requirement in the post-operative period which are consistent with above studies.

VITAL PARAMETERS COMPARISON: POST-OPERATIVE: In our study, we also compared hemodynamic parameters like pulse rate, systolic and diastolic blood pressure and saturation between Group A and group B in the same intervals as observed for VAS score. Group A had less post-operative pulse rate than compared to group B which is significant till 4hours and at 6hours it is almost equal with no significance. This corresponded well with the VAS score obtained in our study. Similarly post-operative systolic and diastolic blood pressure also showed significant difference

between the two groups up to 2 hours and then became almost nil significant in both the groups. Saturation has no significant difference between the two groups. These findings correlated well with the previous studies.

ADVERSE EFFECTS: In our study, no adverse effects like post-operative nausea and vomiting were observed in either of the group, which correlated with the previous study.

LIMITATIONS

In our study, technique for providing analgesia were administered postoperatively, but if it was given preoperatively, it would have decreased the intraoperative pain also thereby benefitting the patient. Large volume of drug was used in the study, and even though there were no adverse events related to local anaesthetic toxicity, monitoring the plasma level of levobupivacaine will help to reduce local anaesthetic toxicity if it occurs. We did not compare the total analgesic requirement in both the groups, since the follow up of patients was for only 6hours, which could have an impact on the study. We did not assess dynamic pain, which is more important than static pain to facilitate early mobilisation. Further studies are required to show the analgesic efficacy of USG-guided subcostal TAP block in other upper abdominal surgeries using different local anaesthetics at different concentration and doses.

CONCLUSION

Ultrasound-guided subcostal TAP block provides better postoperative analgesic efficacy, prolongs the time required for rescue analgesia decreasing the post-operative analgesic requirement while maintaining better hemodynamic stability than port site infiltration of local anaesthesia in patients undergoing laparoscopic cholecystectomy.

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