Original Article

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Efficacy of Ultrasound Guided Bilateral Subcostal Transversus Abdominis Plane (Tap) Block versus Port- Site Instillation of Bupivacaine in Laparoscopic Cholecystectomy for Post Operative Analgesia at Tertiary Care Centre, Ahmedabad

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Abstract

Background: In this double blinded, randomized controlled clinical study, we have investigated whether ultrasound guided bilateral subcostal transversus abdominis plane (STAP) block was superior to port site instillation of the local anaesthetic in reducing postoperative pain and total rescue analgesic consumption. Hence the aim of the present study was to compare efficacy of ultrasound-guided bilateral subcostal transverses abdominis plane block versus port-site Instillation (Intraperitoneal instillation) of bupivacaine for post operative analgesia. **Subjects and Methods:** Sample was randomized by computer generated randomization sheet of allocation for 80 patients. All patients stand on an equal chance of getting into any group. Group T- 40 patients to receive ultrasound-guided bilateral subcostal TAP block with 0.25% bupivacaine 20 ml on each side (total 40 ml) at the end of the surgery before extubation Group I- 40 patients to receive port-site instillation with 0.25% bupivacaine (total 40 ml) at the end of the surgery before extubation. **Results:** Patients were administered aqueous solution of Injection Diclofenac 75 mg diluted intravenously as rescue analgesic when VAS >=4 or patient complain of pain. Mean time to first rescue analgesic requirement in the postoperative period for group T was 519.80±114.45 minutes and group I was 344.40±137.09 minutes. There was statistically highly significant difference found in the mean time for first rescue analgesic requirement between groups T and I ($p<0.001$). **Conclusion:** Ultrasound guided Subcostal TAP block is effective and found to be superior in providing post operative pain relief after laparoscopic cholecystectomy with following advantages, in comparison to port site instillation: reduced pain scores, longer duration of analgesia and less post operative analgesic requirement and complications.

Keywords: Bupivacaine, Laparoscopic Cholecystectomy, Post Operative Analgesia, Subcostal Transversus Abdominis Plane.

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Introduction

Laparoscopic cholecystectomy (LC) is a safe and effective procedure done for various gall bladder disease conditions and has become the treatment of choice for symptomatic gall stones. Compared to open cholecystectomy, laparoscopic method is associated with less post-operative pain, early recovery, reduced hospital expenses and improved cosmesis and patient satisfaction, and thus, it is even done as a day-care surgery. Although minimally invasive, it is associated with moderate intensity postoperative pain in the early postoperative period.[1,2]

Pain following Laparoscopic Cholecystectomy is multifactorial in etiology: (1) pain arising from incision sites being somatic pain, (2) pain from the gallbladder bed being mainly visceral in nature, (3) Shoulder pain is mainly due to residual Carbon dioxide (CO_2) irritating the diaphragm. As the pain could be incisional, visceral, or referred; the requirement of analgesia post-laparoscopic surgeries could not be achieved by a single technique. Hence, a multimodal approach to analgesia would be apt.[3,4] There are various modalities available for postoperative pain relief ranging from parenteral analgesia (NSAIDS and opioids), epidural analgesia, nerve blocks, incisional infiltration and Port Site Instillation (Intraperitoneal

Instillation) using local anaesthetics. Each method has its own advantage and disadvantage, but their goal is to attenuate pain and reduce side effects.[5] The use of only intravenous opioids has been discouraged because of their potency to cause post-operative respiratory depression, sedation, and post-operative nausea and vomiting. This limits the functional capacity of the patient and hence the wound healing is impaired. It also increases the morbidity of patient and prolongs the hospital stay.[6]

For above-mentioned shortcomings, regional anaesthetic techniques were popularized. Although epidural analgesia is most widely used method of analgesia, recently, regional blocks of nerves innervating the incision site in abdominal surgeries are getting popular.[7]

Transversus abdominis plane (TAP) block is a regional anaesthetic technique that blocks neural afferents of the anterolateral abdominal wall. With the aid of ultrasound (US) or anatomical landmark guidance, local anaesthetic is injected into the transversus abdominis fascial plane, where nerves from T6 to L1 are located.[8] Thus, TAP block has been shown to reduce postoperative opioid use in elective abdominal surgery, including open appendicectomy, laparotomy, caesarean section, and laparoscopic cholecystectomy. The use of ultrasonography (USG) in abdominal blocks increases the success rate and safety of the block. The ultrasound-guided Subcostal Transversus Abdominis Plane (STAP) block is a recently described variation on the TAP block which produces reliable supraumbilical analgesia.[9]

Intraperitoneal instillation of local anesthetic (IPLA) for post operative analgesia have been found to be useful anti-nociceptive technique for post operative analgesia after laparoscopic surgeries.[10] The rationale for using IPLA in laparoscopic surgeries is that the local anesthetic inhibits nociception by affecting nerve membrane associated proteins, by inhibiting release and actions of prostaglandins and other agents that sensitize or stimulates the nociceptors and contribute to inflammation. Thus, the visceral nociceptive conduction pathway from peritoneum is blocked and thereby it provides analgesia.[11]

Intraperitoneal instillation of local anesthetic is simple, easy safe and costeffective method. It does not involve additional central neuraxial block, therefore particularly suited to the practice of ambulatory anesthesia. In this double blinded, randomized controlled clinical study, we have investigated whether ultrasound guided bilateral subcostal transversus abdominis plane (STAP) block was superior to port site instillation of the local anaesthetic in reducing postoperative pain and total rescue analgesic consumption. Hence the aim of the present study was to compare efficacy of ultrasound-guided bilateral subcostal transversus

abdominis plane block versus port-site Instillation (Intraperitoneal instillation) of bupivacaine for post operative analgesia.

Subjects and Methods

The present study was carried out as prospective, double blinded, randomized controlled study. After approval from institutional Ethical Committee, written informed consent from all patients before surgery was obtained. Study Population: All cases of laparoscopic cholecystectomy that fall in the inclusion criteria Study setting: Tertiary health center Sample size 40 for each group. Total 80 cases.

Randomization

Sample was randomized by computer generated randomization sheet of allocation for 80 patients. All patients stand on an equal chance of getting into any group.

Group T- 40 patients to receive ultrasound-guided bilateral subcostal TAP block with 0.25% bupivacaine 20 ml on each side (total 40 ml) at the end of the surgery before extubation

Group I- 40 patients to receive port-site instillation with 0.25% bupivacaine (total 40 ml) at the end of the surgery before extubation

Inclusion Criteria

Patients with the American Society of Anesthesiologists (ASA) physical status I or II, of either sex, aged between 18 and 55 years, scheduled for elective laparoscopic cholecystectomy.

Exclusion criteria -

- Patient refusal
- ASA grade 3 and 4
- BMI < 18 and > 30 kg/m2
- Allergy to local anaesthetic drugs
- Patients with skin condition precluding block, chronic pain syndromes, on prolonged opioid medication, neurological and psychiatric disorders
- Requirement of drainage tube insertion on abdomen
- Conversion to open procedure.
- Patients who are unable to understand visual analogue scale.

Data Collection

Age, Gender, BMI (weight, height), ASA grade, Duration of surgery, VAS score at 1,2,3,6,12,24 hours, Duration of analgesia (Time to first rescue analgesic requirement)

Total rescue analgesic consumption in 24 hours

Pre-anaesthetic preparation:

- Detailed history and Pre-anaesthetic evaluation were done to rule out any associated diseases and necessary investigations were advised to every patient.
- Day before surgery, patient was reviewed and explained about Visual

Analogue Scale (VAS) to analyze post operative pain.Patch test for bupivacaine was done to rule out any allergic reactions.

In Pre operative waiting room,

- On the day of surgery, overnight NBM was confirmed along with reassessment of the patient.
- Standard pre operative vitals like Temperature, Pulse, Blood pressure, Respiratory rate, SpO2 were recorded
- Large bore intravenous line (18 G) was secured and crystalloid fluid in a dose of 7ml/kg/hour was started 1 hour prior to surgery.

In Operation Theatre,

Standard monitoring like pulse oximetry (SPO2), non-invasive blood pressure (NIBP) measuring, electrocardiography (ECG), and end tidal CO2 (ETCO2) attached and baseline values were recorded.

Injection Glycopyrrolate (4 µg/kg), Injection Ondansetron (0.15mg/kg),
Injection Midazolam (0.03 mg/kg), Injection Fentanyl (1.5 µg/kg) were given intravenously as premedication. Preoxygenation done with 100% oxygen (O2) for 3-5 min.
Anaesthesia was induced using Injection Propofol (2.0-2.5 mg/kg) and Injection Succinylcholine (1.5 mg/kg) intravenously. Injection Lignocaine plain 2% (Injection Xylocard 2%) (1-1.5 mg/kg) was given 90 seconds before intubation. Intubation was done by using appropriately sized cuffed portex endotracheal tube. Anaesthesia was maintained with 50% O2 and 50% N2O and Sevoflurane as an inhalation anaesthetic agent. Injection Atracurium (0.5 mg/kg loading dose and 0.1 mg/kg maintenance dose) was used as Non-Depolarizing Muscle Relaxant (NDMR) by intravenous route intraoperatively. Patients were placed in 15-20 º reverse Trendelenberg's with left side tilt position. During laparoscopy, intra-abdominal pressure was maintained 12-14 mm of Hg. At the end of surgery before extubation, patients were received either ultrasound-guided bilateral subcostal TAP block or port site local anaesthetic instillation.
Ultrasound-Guided Bilateral Subcostal TAP block was performed by the attending experienced anaesthesiologist. The entire procedure was carried out in an aseptic manner. The skin area was sterilized with povidone-iodine before the procedure and the probe was covered with sterilized cover.
The ultrasound probe (MindRay) was placed in the midline of the abdomen, beneath the xiphoid process and moved subcostal laterally until the transverse abdominis muscle starts beneath the rectus abdominis muscle. After visualization of neurofacial plane between Internal Oblique and Transverse abdominis muscle, at the level of ANTERIOR AXILLARY LINE, a 22G Quincke's needle was guided in plane and after aspiration, 20ml of 0.25% Bupivacaine was deposited within the plane and the same procedure was done on other side.

Port-site Instillation
Before removal of trocars and after completion of surgery, 40 mL of 0.25% bupivacaine was given intraperitoneally in Trendelenberg's position, into the hepato-diaphragmatic space, on gall bladder bed and near and above hepatoduodenal ligament by operating surgeon.
The anaesthesiologist performing block and surgeon performing instillation were not involved in post operative follow up of patient. Patient was reversed after adequate tidal volume and reflexes, with Injection Glycopyrrolate (8 µg/kg) and Injection Neostigmine (0.05 mg/kg) intravenously and was extubated.

Post Operative Monitoring
Patients were shifted to post anaesthesia care unit (PACU).

Post Operative Pain Assessment
The intensity of postoperative pain was recorded for all the patients using visual analog scale (VAS) score (VAS 0 = no pain and VAS 10 = worst possible pain) at 1, 2, 3, 6, 12 and 24 hours post operatively.
Duration of Analgesia
Those patients with a VAS >=4 or complain of pain were administered Intravenous Injection of Diclofenac sodium (75 mg) as rescue analgesia. Time to first rescue analgesic requirement was considered to be the duration of analgesia.
Total Rescue Analgesic Consumption
Intravenous Injection of Diclofenac sodium (75 mg) was repeated at further time intervals during 24 hours postoperatively at VAS >=4. Mean total analgesic consumption in milligrams in first 24 hours postoperatively also calculated.
Any Post Operative Complication or Adverse Effects: Patients were enquired for post-operative complications up to 24 hours like nausea, vomiting, also assessed for any pneumoperitoneum due to intestinal puncture, bleeding, infection, local hematoma or sign-symptoms of local anesthetic systemic toxicity and treated accordingly.

Statistical analysis
Pre structured pre tested proforma was used for data collection. Sample size was calculated, using Open EPI software considering, alpha error 0.05, power 90% and Difference of means 1.6, Calculated sample size 37 for each group. For present study, a total of 80 patients were selected, 40 patients in each group.
For data analysis, Microsoft excel and SPSS statistical software were used and data were analyzed with the help of mean, Standard Deviation, percentage in the form of table, diagrams and test of significance (Independent t-test for intergroup comparison, Chi square test for demographic data) were applied.

Significance of P value suggested as follow
'P' value > 0.05 = insignificant.
'P' value < 0.05 = significant.
'P' value < 0.001 = highly significant

Results

Both groups were comparable in terms of Age, Gender, BMI, ASA grade, Duration of surgery. No significant difference (p>0.05) was observed between two groups in terms of demographic data.
Post operatively, mean HR was on higher side in group I as compared to group T, which was persistently on lower side. The difference in mean HR between the two study groups T and I was statistically significant (P<0.05) at all time intervals except at 24 hour post- operatively.
The difference in mean HR between the two study groups T and I was statistically insignificant (P>0.05) at 24 hours post operatively. The results show that patients in group I were found to have higher systolic blood pressures, when compared to patients in group T at all time intervals up to 24 hours postoperatively. Statistically significant difference (p<0.05) was found between the two groups at all the time intervals.
The results show that patients in group I were found to have higher diastolic blood pressures, when compared to patients in group T at all time intervals up to 24 hours postoperatively. Statistically significant difference (p<0.05) was found between the two groups at all the time intervals.
The results show that patients in group I were found to have

higher mean arterial pressures, when compared to patients in group T at all time intervals up to 24 hours postoperatively. Statistically significant difference ($p<0.05$) was found between the two groups at all the time intervals.

Postoperative VAS scores were significantly lower in Group T than Group I up to 12 hours postoperatively. Mean VAS score was statistically significant ($p < 0.05$) between group T & group I at 1,2,3,6, and 12 hours postoperatively. Mean VAS score was statistically insignificant ($p >0.05$) between group T & group I at 24 hours postoperatively.

Patients were administered aqueous solution of Injection Diclofenac 75 mg diluted intravenously as rescue analgesic when VAS >=4 or patient complain of pain. Mean time to first rescue analgesic requirement in the postoperative period for group T was 519.80±114.45 minutes and group I was 344.40±137.09 minutes. There was statistically highly significant difference found in the mean time for first rescue analgesic requirement between groups T and I ($p<0.001$).

Table 1: Post-Operative Pain (Vas Score) Data

Post operative time interval	Group T	Group I	P value
1 hour	0.63±0.9	1.03±0.73	0.0021
2 hour	0.85±0.0	1.55±0.68	0.0001
3 hour	1.53±0.4	2.45±0.64	0.0001
6 hour	2.58±0.8	3.55±1.01	0.0001
12 hour	3.18±0.8	4.00±0.88	0.0001
24 hour	2.28±0.5	2.33±0.53	0.3669

Discussion

Postoperative pain is one of the primary concerns because of its close ties with clinical outcome and acute postoperative well-being. Inadequate pain control after surgeries is significant in terms of both physical and psychological trauma and ultimately leads to chronic pain.[12]

Appropriate postoperative pain management improves patient satisfaction, decrease opioid consumption, early recovery, and discharge after the procedure. Use of peripheral nerve block has become increasingly popular in past few decades. Subcostal TAP block is a newly developed block involving nerves of anterior abdominal wall from T7-T12 dermatomes. The accuracy and quality of nerve blockade can be enhanced with guidance of ultrasound.[13]

They were randomly assigned into two groups: Group T - receiving ultrasound guided bilateral subcostal transverse abdominis plane block, and Group I – receiving port site instillation and findings from each group were compared.

Demographic Data

Demographic data like Age, Gender, BMI, ASA grade and Duration of surgery in two groups were compared and there was no statistically significant difference between two groups.

Post operative pain (VAS) scores

In our study, mean VAS scores were significantly lower in TAP block group up to 12 hours postoperatively, when compared to Instillation Group. There was no significant difference noted in pain scores at 24 h postoperatively among the two groups (P = 0.3669). In the study by KHANDELWAL H et al in 201914, The mean NRS for pain was less in TAP block group than in Instillation Group in the first 6 hours, which was statistically significant (P = 0.002). There was no significant difference in pain scores after 6 hours up to 24 hours postoperatively between the two groups (P = 0.72).

In study conducted by, SARASWATHI NAGAPPA et al in 2019, mean VAS scores were significantly lower in TAP block group than Instillation Group at 4 hours (p=0.003), 8 hours (p=0.001), 12 hours (p=0.001) and 24 hours (p=0.001) postoperatively.[15]

In Study Conducted by, KHARBUJA K et al in 2020, mean VAS scores were lower in the subcostal TAP block group compared to the Port-site infiltration group at all the postoperative time periods up to 24 hours and which was statistically significant.[9]

INDU SUSEELA et al in 2018, Mean NRS for pain was zero at 1 hour in both the groups. NRS were significantly lower in TAP block group up to 24 hours, in comparison to infiltration Group at all other time frames. Where in our study, VAS scores were significantly lower in TAP group up to 12 hours postoperatively, when compared to instillation group.[16]

Duration of Analgesia

In our study, the mean time for requirement of first rescue analgesic for TAP block group was 519.80±114.45 minutes (8.66 ± 1.91 hours) and Instillation group was 344.40±137.09 minutes (5.74 ±2.28 hours). and the difference was found to be statistically highly significant (P=0.0001).

In the study by KHANDELWAL H et al in 2019, mean time to first rescue analgesic request in TAP block group was 4.3 ± 1.12 hours, compared with 2.1 ± 0.57 hours in Instillation group. so, duration of analgesia was shorter in compared to our study.

In the study conducted by SARASWATHI NAGAPPA et al in 2019, duration of analgesia was prolonged in TAP block group (997 ± 570.83 minutes) than instillation group (534 ± 532.5 minutes), (p =0.004, statistically significant). so, duration of analgesia was longer in compared to our study.

Total Rescue Analgesic Consumption

In our study, Mean of the total rescue analgesic (diclofenac) consumption in 24 hours was 82.50±22.79 mg in TAP block group and 118.13 ± 37.55 mg in Instillation group. Total analgesic consumption is highly significant between TAP block group and Instillation group (P=0.0001).

In the study conducted by KHARBUJA K et al in 2020, Mean of the total analgesic (fentanyl) consumption in 24 hours was 136 ± 66.31 microgram in TAP block group and 202 ± 80.58 microgram in Instillation group, which was statistically significant (p=0.001), which correlates with findings of our study.

Postoperative complications:

Post-operative nausea-vomiting was found in only 1 patient (2.5%) in TAP block group and 3 patients (7.5%) of Instillation group. None of the patients in the two study groups had complications like pneumoperitoneum, local hematoma, infection or local anaesthetic systemic toxicity in

our study. Farooq M et al reported a case of liver trauma with blunt regional anaesthesia needle while performing TAP block in a patient posted for total abdominal hysterectomy.

Familiarity with anatomy, safe monitoring and injection technique, knowledge of local anaesthetic pharmacology and toxicity would prevent the possibility of complications. The use of ultrasound to confirm the needle position is a promising approach to further reduce the risk of complications.

Conclusion

Ultrasound guided Subcostal TAP block is effective and found to be superior in providing post operative pain relief after laparoscopic cholecystectomy with following advantages, in comparison to port site instillation:

- Reduced pain scores,
- Longer duration of analgesia and
- Less post operative analgesic requirement and complications.

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