ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at:www.ijmacr.com

Volume – 6, Issue – 1, Janaury - 2023, Page No. : 204 - 213

A comparative study on 0.25% bupivacaine and 0.375% ropivacaine in ultrasound guided transverse abdominis plane block for postoperative analgesia in patients undergoing laparoscopic cholecystectomy

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How to citation this article: Dr. Sreeja Sadan, Dr. Kavyashree H S, Dr. Jayanth Kumar H.S, Dr. Thirunavakkarasu Sivaraman, "A comparative study on 0.25% bupivacaine and 0.375% ropivacaine in ultrasound guided transverse abdominis plane block for postoperative analgesia in patients undergoing laparoscopic cholecystectomy", IJMACR- January - 2023, Volume – 6, Issue - 1, P. No. 204 – 213.

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Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background and Aims: Transverse abdominis plane block using local an aesthetic agent is a popular analgesic modality used for abdominal surgeries.

The aim of the study was to compare the analgesic quality of Ropivacaine versus Bupivacaine for postoperative analgesia in ultrasound guided TAP block in patients undergoing laparoscopic cholecystectomy.

Methods: 60 adult patients (ASA1/2), undergoing laparoscopic cholecystectomy was randomly allocated into two groups to receive USG guided TAP block after induction of anaesthesia with either 20 ml of 0.25% Bupivacaine (Group A, n=30) or 0.375% Ropivacaine (Group B, n=30) on each side. All patients were assessed for post-operative pain and rescue analgesia requirement at 0 min, 15 min, 30 min,1 h, 2 h, 4 h, 6 h,12 h, 18 h, 24 h. The patients received rescue analgesia if the pain score was>/=4.

Results: Patients receiving Ropivacaine in TAP block had better analgesia compared to Bupivacaine in patients undergoing laparoscopic cholecystectomy in the initial one hour postoperatively, followed by similar analgesic effect later in the first 24hours,with comparable rescue analgesic requirement and perioperative haemodynamic parameters.

Conclusion: Ultrasound guided TAP block with Ropivacaine provided better analgesia compared to Bupivacaine in the immediate postoperative period with

no significant changes in rescue analgesia requirement or hemodynamic parameters without any adverse effects,hence can be safely used as an analgesic modality for laparoscopic cholecystectomy.

Keywords:

comparison,0.25%bupivacaine,o.375%ropivacaine,usg guided TAP block, laparoscopic cholecystectomy, postoperative analgesia.

Introduction

Among day care surgeries, laparos copic cholecystic tomy is the most commonly performed surgical procedure currently[1]. The commonest reason for pain after laparoscopic cholecystectomy is the abdominal stretch due to pneumoperitoneum, pain from the site of port introduction and hepatic bed disturbances due to the gall bladder removal.[2]The pain following laparoscopic cholecystectomy is felt in the anterior abdominal wall due to the pain sensitive nerve fibres in the transverse abdominal plane between the abdominal muscles internal oblique and transversus abdominis.[3] Even though laparoscopic cholecystectomy is a minimally invasive surgery, the pain scores are significant specifically in the first 24 hours postoperatively and hence controlling it is important for early mobilization and recovery following surgery.[4]

The various surgical procedures like thoracotomy, mastectomy, amputation, inguinal hernia and cholecystectomy result in chronic pain of 10-60%. Whether it is the laparoscopic or open approach of gall bladder removal the risk of development of chronic postoperative pain is 10- 40%. This indicates the necessity of immediate postoperative pain management for preventing the development of chronic pain following a minimally invasive technique like laparoscopic cholecystectomy.[5]

The pain management in the postoperative period is by multimodal analgesic approach with Non-steroidal Anti-inflammatory Drugs (NSAIDs), paracetamol opioids. But pain management with opioids has side effects of postoperative nausea and vomiting (PONV), constipation, urinary retention and excessive sedation resulting in respiratory depression[6]. The usage of NSAID have increased side effects especially in elderly patients, patients with renal failure, cardiac and liver failure and also in patients with gastrointestinal bleed.[7]

For abdominal surgeries, the transverse abdominal plane block has been considered as the most efficient analgesic modality. Now, this technique is adopted for pain management in various surgeries like laparoscopic cholecystic tomy, open/laparoscopic appendicectomy, caesarean section, total abdominal hysteric tomy, open prostatectomy, renal transplantation, and Abdom inoplasty.8- 10TAP block as a part of the multimodal analgesic strategy is a good choice for postoperative pain control following laparoscopic cholecystic tomy.[8,9,12]

The implementation of ultrasound guidance in nerve blockade has become more popular, hence is used to inject bupivacaine or ropivacaine in TAP block under vision.[8,13,14]

Regarding the comparability of different concentrations of Ropivacaine and Bupivacaine, many studies were conducted. According to Capogna et al the analgesic potency of Ropivacaine was 0.6 relative to Bupivacaine when used in epidural space.[15]A study conducted by Sradha Sinha et al regarding USG guided TAP block as an analgesic modality in laparoscopic cholecystectomy considering a similar efficacy of ropivacaine and bupivacaine in 0.375% and 0.25% respectively from many previous studies with 40 ml volume of the drugs.[16,17,18,19] Hence in our study, we used the same

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concentration and volume of local an aesthetics in TAP block for comparing the analgesic property.

Even though bupivacaine and ropivacaine share almost similar physical properties like Pka, plasma protein binding, there were fewer studies comparing their analgesic efficiency in TAP blocks for patients undergoing laparoscopic cholecystectomy in the above-mentioned study concentration.

In the Sradha Sinha et al study, TAP block was given after the surgery16 which eliminated the preemptive component of pain relief for the procedure. Our study aims at comparing the postoperative analgesic effect of 0.25% bupivacaine and 0.375% ropivacaine in ultrasound guided TAP block performed before the surgical incision for patients undergoing laparoscopic cholecystic tomy and quality of analgesia is assessed during the first 24 hours post operatively using numerical rating scale which has the added benefit of preemptive analgesic concept also. At the same time has the advantage of comparing the intraoperative haemo dynamic parameters like pulse rate, mean arterial pressure, respiratory rate and oxygen saturation between the two groups.

Materials and methods

After institutional Ethics Committee approval and obtaining informed written consent from patients A prospective randomised controlled clinical study is conducted in 60 patients undergoing laparoscopic cholecystectomies. The sample size is calculated statistically by Two Means-Hypothesis testing for two means. A sample size of 25 in each group was sufficient to detect a difference of 2 in the Cumulative diclofenac consumption of patients receiving bupivacaine and ropivacaine, assuming a standard deviation of 2.5 in both two groups, a power of 80% and a significance level of 5% (annexure attached). Participants were divided into two groups.

Following a comprehensive pre an aesthetic evaluation, all the patients were explained about numerical rating scale (NRS for pain (0 - no pain, 10 - worst imaginable pain) in their vernacular language and fasted electively according to the institutional protocol, 6 hours to solid and 2 hours to water.

In the operating room, routine monitoring were applied and venous access were secured. Following pre-oxygenation, the patients received IV fentanyl (2µg/kg). Anaesthesia was induced with IV propofol 2 mg/kg, Vecuronium bromide (0.1 mg/kg) IV were utilised to facilitate tracheal intubation. Anaesthesia was maintained with air (50%) and sevoflurane (I mac) in oxygen. The intra- abdominal pressures were maintained at 12 mm Hg in both the groups throughout the procedure. After induction, after ensuring full asepsis, ultrasound- guided TAP block were administered under real- time guidance with a high- frequency (5–10 MHz) ultrasound probe. After confirming negative aspiration of blood, 20 ml of 0.25% plain bupivacaine (group A the control group) or 0.375% plain ropivacaine (group B) were administered on each side as per the randomization. Postoperative pain was evaluated by numerical rating score at 0 min,15 min,30 min, 1 hr, 2 hr, 4 hr, 6 hr, 12 hr, 18 hr, and 24 hr postoperatively. The commercial preparation of ropivacaine was available in our hospital as 0.75% of 20 ml ampoule, which was diluted with 20 ml of sterile water, making the final preparation as 40 ml of 0.375%. All operated patients received paracetamol 15mg/kg intravenously intraoperatively and thereafter eighth hourly. Those patients with a NRS score of >/=4 received the rescue analgesic Diclofenac sodium 75 mg intravenously diluted in 100 ml normal saline. At the end

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of the study the postoperative quality of analgesia, rescue analgesic requirement and haemodynamic parameters between two groups were statistically analysed.

Discussion

This study concluded that patients receiving TAP block for laparoscopic cholecystic tomy with 0.375% Ropivacaine had better analgesia in the first one hour of post operative period than 0.25% Bupivacaine. These findings are in par with other Shradha Sinha et al studies which found 0.375% ropivacaine is more effective in the immediate post operative period than 0.25% bupivacaine when given in TAP block for laparoscopic cholecystic tomy.16 Similarly other studies also supporting the conclusion when these drugs were compared through other routes of administration.[18,40]

In our study the ropivacaine group had better analgesia when assessed in the immediate first hour post op, which were found to be statistically significant with 7(23%) patients from bupivacaine group and 16(53%) patients from ropivacaine had 0 pain score at 0 minute and 23(76%) patients from bupivacaine and 14(46.6%) patients from ropivacaine had pain score 2 at 0 minute,7 patients from bupivacaine group and 15 patients from ropivacine group had 0 pain scores at 15 minutes and 6 patients and 2 patients from bupivacaine had pain scores of 3 and 4 respectively whereas ropivacaine had 0 patients with pain scores 3 and 4,similarly 6 patients from bupivacaine group and 14 patients from ropivacaine had 0 pain score at 30 minutes and 10 patients had pain scores 3 and 4 in bupivacaine group, whereas ropivacine group had only 1 patient with pain score 4, again at 1 hour 5 patients from bupivacaine group and 14 patients from ropivacaine group had 0 pain score and 24 patients from bupivacaine had pain score 2 whereas from ropivacaine group ,only 16 had pain score 2 .The mean pain score values at 0 minute(bupivacaine group-1.53+/- 0.86,ropivacaine group-0.93+/-1.01),at 15 minutes(bupivacaine group-1.87+/- 1.2,ropivacaine group-1+/-1.02),at 30 minutes(bupivacaine group-2.1+/-1.3,ropivacaine group-1.13+/-1.14) and at 1 hour (bupivacaine group-1.73+/-0.87,ropivacaine group-1.07+/-1.01) with respective p values of 0.016,0.004,0.003 and 0.008 for the above mentioned time intervals. Similarly in a study conducted by Shradha Sinha et al comparing 0.375% ropivacaine and 0.25% bupivacaine in TAP blocks for patient undergoing laparoscopic cholecystectomy also reached the similar conclusion of better post operative analgesia with 0.375% ropivacaine when the pain scores were assessed at 10 minutes,30 minutes and 1 hour with p values of 0.044,0.003 and 0.020 respectively.[16]

In our study after one hour post operatively, the pain scores were comparable in both ropivacaine and bupivacaine group for the rest of observation period with statistically no significant difference between rescue analgesic requirement. These observations were similar with Shradha Sinha et al studies when used in TAP blocks in similar concentration and volume in patients undergoing laparoscopic cholecystectomy.[16] 23(76.7%) patients in Bupivacaine group and 27(90%) patients from Ropivacaine group didn't receive any rescue analgesic, whereas 7 patients from Bupivacaine group and 3 patients from Ropivacaine group were received rescue analgesic during the first 24 hours of postoperative period, though it is statistically insignificant (p value =0.298979)

In a study conducted by Basaran et al after laparoscopic cholecystectomy, oblique subcostal TAP block provided significantly less post operative pulmonary deterioration

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when compared with control group.33 Similarly in our study even though we used the basic respiratory parameters, respiratory rate and SPO2 to compare between two TAP blocks groups for pulmonary function there was no statistical significance between groups at the same time with no evidence of pulmonary deterioration. Similarly in another study comparing 0.25%bupivacaine and 0.5%ropivacaine in TAP blocks for lower abdominal surgeries the pulse rate, mean arterial pressure and respiratory rate was found to be comparable suggesting similar haemodynamic stability between two groups, in our study also we compared the pulse rate, mean arterial pressure, respiratory rate and saturation levels intraoperatively and two hours postoperatively and they were comparable in both groups suggesting similar haemodynamic stability in two groups and also we did not encounter any adverse effect neither from the procedure nor from the drugs in our study.[41]

Chronic pain follows 10-60% of cases after various surgical procedures, which includes both traditional open and laparoscopic cholecystectomy the risk being 10-40%.[42]

A meta analytic study on efficacy of TAP block for pain control after laparoscopic cholecystectomy by Weihua et al concluded TAP block is more effective than the conventional pain control technique.29 According to Bisgaard et al, 150 patients who underwent laparoscopic cholecystectomy investigated for one year found a significant association between the intensity of acute postoperative pain and development of chronic pain. This study showing the significance of acute postoperative pain management and the importance of TAP block as a constituent of multimodal analgesia in the postoperative period.[43] Similarly, Kepeng et al in his metanalytic study concluded USG guided TAP block as an effective analgesic strategy for patients undergoing laparoscopic cholecystectomy. Peterson et al in his study concluded that the analgesic effect of TAP block lasted for up to 24 hours after laparoscopic surgeries.35 In our study also we used TAP block as the analgesic technique and compared the quality of analgesia provided by two different local an aesthetic agents for first 24 hrs in the postoperative period.

In another study by Bava et al comparing USG guided TAP block in single incision laparoscopic cholecystic tomy with 0.375% Ropivacaine and local an aesthetic infiltration at port site found a significantly higher VAS score at rest and during coughing, and also requiring intraoperative additional fentanyl in local infiltration group. Hence, we used TAP block as the primary analgesic modality to compare the post- operative analgesic efficacy.[12]

According to a study conducted by Et Dawlat Ly et al comparing ultrasound guided TAP block with conventional systemic analgesia during laparoscopic cholecystic tomy concluded the lesser requirement of perioperative systemic opioids in patients receiving USG guided TAP block with 30 ml of 0.5% Bupivacaine.8 Similarly in our study even though, the rescue analgesia was diclofenac sodium, there was no requirement of any systemic opioids additional to the rescue analgesic doses and the total consumption of diclofenac was lower around 16.7% of the study population compatible with other studies where opioid was the rescue analgesia. The rescue analgesia was required for 10 out of 60 patients. Out of the 10, rescue analgesia requirement 7 were from bupivacaine group and 3 were from the Ropivacaine group, which is statistically insignificant (p value =0.298979). The advantage is avoidance of opioid

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related adverse effects like emesis, nausea, itching, sedation, respiratory depression, increased patient satisfaction and reduce the length of hospital stay.

In a study by Nidhi Bhatia et al comparing posterior and subcostal USG TAP for laparoscopic cholecystic tomy they used 0.375% ropivacaine and compared with control group reached the conclusion of superior analgesia with TAP group to standard intravenous regimen. Though almost comparable pain scores in the initial four hours post operatively and also concluded a significant decrease in systemic analgesia demand in the TAP block groups.28 In our study we used 0.375% ropivacaine for TAP block in 1 group and on comparison with 0.25% bupivacaine group, there was no requirement of any systemic opioids additional to the rescue analgesia dose.

In a study by Ra et al analysing effect of USG guided TAP block after laparoscopic cholecystectomy concluded that TAP block could reduce the amount of opioid needed during operation and post operative analgesia for next 24 hours, similar to our study conclusion.[9]

According to ok sar et al study on TAP block as a component of multimodal analgesia for laparoscopic cholecystic tomy concluded that TAP and oblique subcostal TAP block improved post operative analgesia in patients resulting in lower VAS score and decrease total analgesic consumption similar to our study consuming decreased systemic postoperative analgesia.[30]

Regarding the comparability of different concentrations of Ropivacaine and Bupivacaine, many studies were conducted. According to Capogna et al the analgesic potency of Ropivacaine was 0.6 relative to Bupivacaine when used in epidural space.[15]A study conducted by Sradha Sinha et al regarding USG guided TAP block as an analgesic agent in laparoscopic cholecystectomy considering a similar efficacy of ropivacaine and bupivacaine in 0.75% and 0.5% respectively from many previous studies hence they used half concentration of drugs 0.375% and 0.25% of Ropivacaine and Bupivacaine of 40 ml volume as equipotent doses.[16] Hence in our study, we used the same concentration and volume of local an aesthetics in TAP block for comparing the analgesic property. According to another randomised controlled trial by Neha Fuladi et al comparing 0.25% Bupivacaine and 0.5% Ropivacaine in lower abdominal surgeries, Ropivacaine had a longer duration of analgesia of 2187 minutes (approximately 36.5 hours) than Bupivacaine of 420.6 minutes. In our study after immediate one- hour post-op, the quality of pain relief was almost similar in both groups, Since the observation period was 24 hours postoperatively, the total duration of analgesia of each drug was not followed up separately.[41]

Many studies compared Ropivacaine and Bupivacaine in same and different concentrations, different analgesia techniques including TAP block, brachial plexus block [45,]

local infiltration and compared the analgesic effect and other parameters including adverse effect or toxicity. In a study by Moshe Fayman et al comparing 0.5% Bupivacaine and 0.75% Ropivacaine for infiltration analgesia for bilateral breast surgery and the overall analgesic effects were not statistically different and there was no cardiotoxicity observed.[44]

Similarly, in our study, after the immediate one-hour postop, the analgesic effects of both drugs were similar and also there were no cardiotoxic manifestations or other complications observed during the study.

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Conclusion

The ultrasound guided Transverse Abdominis Plane block using Ropivacaine 0.375% provided better analgesia in the first hour of post operative period in comparison to Bupivacaine 0.25% in patients undergoing laparoscopic cholecystic tomy. However both drugs may be considered equivalent for analgesia in later part of post operative period.

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