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A comparative study to evaluate the analgesic efficacy of unilateral transvere abdominis plane block versus bilateral tap block using 0.25% bupivacaine in laparoscopic nephrectomies

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ABSTRACT

Introduction: Postoperative pain is a common complaint following laparoscopic nephrectomies and in these patients transverse abdominis (TAP) block is a useful an effective analgesic modality in controlling pain compared to other techniques. This prospective randomized comparative study is to compare the analgesic efficacy of unilateral TAP block versus bilateral TAP block for better analgesia postoperatively.
Materials and Methods: A total of 60 ASA I-II patients undergoing lapararoscopic nephrectomies (18-60 years) were included and divided into two groups A(n=30) and B(n=30). Group A: Lateral ultrasound guided(USG) unilateral TAP block with 20ml of 0.25% isobaric bupivacaine. Group B: Lateral USG guided bilateral TAP block with 20ml of 0.25% isobaric bupivacaine at the end of surgery before extubation.
Statistical Design: the statistical testing conducted using statistical package for the social science system. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.
Results: We found that total mean analgesic duration of the block was significantly longer in bilateral (B) group (14.3h±2.48h rs) as compared to group A(6.2±2.14hrs) with p value of 0.000000017564. VAS scores were significantly higher in the group A with p value of 0.00000000124575. The mean number of doses of additional rescue analgesia (i.e fentanyl) in Group A was 3.12 ± 0.72 as compared to 1.04 ± 0.73 in Group B (given at 18 hrs.), the p value comes out to be 0.0000000125 which is statistically significant.
Conclusion: Bilateral USG guided TAP block is of more benefit than unilateral TAP block in reducing postoperative pain and also reduced overall use of opioids in laparoscopic nephrectomies.

1. Introduction

Urological surgeries are one of the most common surgical procedures encountered in the clinical practice and these have evolved over the time from simple removal of renal calculus to radical nephrectomies.[1] The main indications of nephrectomies are renal transplant donor nephrectomies, renal cell carcinoma or upper tract transitional cell carcinoma and conditions leading to poorly functioning and non-functioning kidneys, which range from chronic infections, hypertens ion, recurrent renal calculus to polycystic kidney disease.

At present, laparoscopic nephrectomy is preferred over open nephrectomy as it is less invasive, leading to better patient satisfaction and early patient discharge. While the use of modern laparoscopic techniques has many advantages, they still have high incidence of postoperative pain. In laparoscopic nephrectomies there are various port sites that depend upon the type of approach and the side to be operated. These approaches are in particular, transperitoneal and retroperitoneal approach. Between the two, the most commonly practiced is the transperitoneal approach. The substantial component of the pain experienced by such patients is mainly derived from

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the anterior abdominal wall incisions.[2]

The most common treatment strategy for postoperative pain relief following laparoscopic surgery is multimodal, using patient controlled intravenous analgesia, epidural analgesia, intraperitoneal injection viatrocar infiltration of local anaesthetics and nerve blocks of anterior abdominal wall.[3] In recent years ultrasound guided(USG) subcostal and lateral Transversus Abdominis Plane (TAP) block has been used as a satisfactory approach that provides post-operative analgesia for patients u ndergoing laparoscopic surgeries.[4] It is an effective method of producing reliable supraumbilical analgesia.[2] Also, diminishes or replaces the use of opioids, lowers the incidence of adverse effects like postoperative nausea and vomiting (PONV) and avoid the potential hazards associated with neraxial blockade. In ultrasound guided TAP block, the local anesthetic is injected into the transversus abdominis fascial plane, where the neural afferents of the anterior abdominal wall (T6 to L1) are located.[5] Several studies have been conducted in fresh cadavers and healthy volunteers who have confirmed the demonstration of the spread of local anaesthetic agent in this plane and are associated with the nerve block of T8-L2.[6]

USG guided lateral TAP bloc k has also been used as an effective component of multimodal postoperative analgesia for laparoscopic nephrectomies including renal transplant donors.[7,8] till now only few studies have been done using USG guided lateral TAP block (unilateral approach more routinely used) to evaluate the reduction of postoperative pain in these surgeries. However unilateral TAP block may be insufficient due to incomplete motor blockade of the abdominal wall and so far no study has been done till now to compare the analgesic efficacy of unilateral versus bilateral ultrasound guided lateral TAP block in laparoscopic nephrectomies.

Through this study it was our primary aim to compare the analgesic efficacy of unilateral versus bilateral ultrasound guided lateral TAP block using 0.25% bupivacaine in patients who underwent laparoscopic nephrectomies. The secondary aim of this study was to assess the total consumption of opioids in the postoperative period in these surgeries.

2. Materials and Methods

2.1. Methodology

After obtaining approval from the ethics committee and written informed consent from 60 ASA (American society of Anaesthesiologists) 1 and 2 patients who were to undergo laparoscopic nephrectomy of age 18 to 60 y ears of either sex, weighing between 50 to 80kg and height above 140cms, were included in this prospective randomized comparative study. The exclusion criteria was patient refusal, patients with ASA grade 3,4 and 5,patients with age $<$ 18yrs and $>$60yrs, patients with peripheral neuropathies, patients with coagulation disorders, patients with BM1 $>$ 35, patients with inflammatory skin lesions at the site of giving block. Patients with allergy to local anaesthetics, pregnant mothers and lactating mothers, patients with weight less than 50 kg, patients with serum creatinine $>$2.5, patients with poor LV function and ejection fraction $<$40%. Conversion from laparoscopic to open nephrectomy and if elective laparoscopic nephrectomy is planned along with other intra-abdominal procedures. The study was period was between April 2018 to December 2018.

Randomization chart was prepared by the statistician using the permuted block approach to achieve equal numbers of participants in each group and accordingly randomization was done with 30 patients in each A(unilateral) and B (bilateral) group. The concealment of allocation was not done to avoid the discrepancy in technique of block by multiple hands. Following detailed pre-anesthetic checkup, patients were explained about the Visual Analog Scale Score (VAS) pre-operative. (0- no pain TO 10-maximum pain).

Patients in group A received ultrasound guided unilateral TAP block (lateral approach) with 20ml of 0.25% isobaric bupivacaine at the end of surgery before extubation and patients in group B received ultrasound guided bilateral TAP block (lateral approach) with 20ml of 0.25% isobaric bupivacaine at the end of surgery before extubation. The block was preferably given by the same practioner who had expertise in ultrasound guided blocks, in most of the cases.

All patients were fasted as per protocol i.e. 6 hours for solid food and 2 hours for clear liquids before the scheduled surgery. All patients were premedicated with 50 mg of i.v(intravenous) ranitidine and 10 mg of i.v metoclopramide 2 hours prior to surgery. After taking the patient in the operation theatre, patency of IV cannula was checked for. Non-invasive monitors were attached including pulse oxymeter, electrocardiogram, noninvasive blood pressure monitoring and baseline parameters were noted. Glycopyrolate 0.2mg/kg i.v and injection ondansetron 4mg/kg i.v was given. Induction of general anaesthesia (GA) was done using fentanyl at 2mcg/kg i.v followed by titrated doses of propofol at 1-2mg/kg i.v. After ensuring adequate ventilation, atracurium was given a t a dose of 0.6mg/kg i.v. After adequate muscle relaxation, trachea was intubated with appropriate size of endotracheal tube. A 16 F nasogastric tube was placed to decompress the stomach. Transesophageal temperature probe was used for monitoring temperature. Patient placed in the lateral position on Kidney Bridge taking care of all the pressure points. Maintenance of anaesthesia was done with inhalational mixture of oxygen, air and sevoflurane at 0.9 MAC (minimum alveolar concentration) along with infusion of atracurium at 0.005 mg/kg/min i.v which was stopped 45 minutes prior to the completion of surgery. Intraoperative analgesia was maintained with intermittent

boluses of fentanyl IV and last dose was not repeated at least 1 hour prior to completion of surgery.

After the completion of surgery, patient was made supine positioned for ultrasound guided TAP block before extubation. Under all aseptic precautions, TAP block was given under ultrasound guidance using sonosite M-Turbo ultrasound machine and linear 6-13 MHz ultrasound probe. The transversus abdominis muscle was identified lying beneath and extending lateral to the rectus abdominis muscle. Using the "in-plane technique" a 50mm, 22 guage stimuplex needle was then guided, in - plane, to a point such that the tip was between the internal oblique muscle and the transverse abdominis within the neurovascular fascial plane. Following aspiration, unilaterally 20ml of 0.25% isobaric bupivacaine was injected in patients of Group-A and 20 ml of 0.25% isobaric bupiv acaine was injected on each side in patients of Group –B. Maximum dose of bupivacaine we have taken in our study is 2mg/kg.[9] Residual neuromuscular paralysis was reversed with 0.05 mg/kg i.v. of neostigmine and 0.006 mg/kg i.v. of glycopyrrolate.

Total mean analgesic duration of TAP block was defined as the time interval from administration of local anaesthetic till first demand of first rescue analgesic i.e. injection Paracetamol in this study. VAS score was evaluated post operatively at 30 minutes, then 1 hourly for first 6 hours, thereafter every 3hours for 24hours. The hemodynamic parameters were assessed postoperatively at 30 minutes, then 1 hourly for first 6 hours, thereafter every 3hours for 24hours. The time to first demand for rescue analgesic by the patient was noted i.e when VAS score was $>_-$ 4. At that time, injection paracetamol 20mg/kg i.v was given and was continued thereafter as 8^{th} hourly dose till 24 hours postoperatively. However in some cases if the patient VAS score is less than 4 but patient wanted analgesic then injection paracetamol 20mg/kg i.v was given. If patient had VAS >4 even after one hour of giving paracetamol, then fentanyl at 1 mcg/kg iv was given as additional analgesic for breakthrough pain relief. The time frame of one hour to wait for before giving second rescue analgesic is chosen because peak effect of intravenous paracetamol is 40 min to 60 min.[10] The rescue doses of fentanyl were administered at the discretion of the attending physician. The total number of doses of additional rescue analgesic i.e fentanyl over 24 hours was noted. Patient complaining of nausea and vomiting were treated with ondansetron 4mg i.v. Also the side effects related to technique of block and the local anaesthetic (drug toxicity) used were assessed.

We chose bupivacaine as a local anaesthetic in this study because it is more potent and the effect also is of longer duration as compared to ropivacaine and levobupivacaine. The intensity of motor blockade also is more with bupivacaine.[11]

The nephrectomies in this study were mostly renal transplant donor nephrectomies, and some were partial and radical nephrectomies. The laparoscopic procedure was performed with 4 ports for left nephrectomy (three 5mm ports and one 10mm port) and 5 ports for right nephrectomy (three 5mm ports and two 10mm ports). In both situations, pfannesteil- kerr incision was given to take out the kidney.

Sample size calculation was based on the analgesic efficacy in two groups. Through a preliminary pilot study of 5 patients per group, the mean analgesic duration was calculated as 14.2 hrs in the bilateral group and 6.3 hrs in the unilateral group. The total sample size was set as 44 calculated, with a power of 90%, alpha value of 0.05 where the standard deviation of two groups was 1.06 and 1.19 hrs respectively. However we included a total of 60 patients (30 per group) to counteract any dropouts during the study period.

The formula for calculated sample size is given below

$$n = \frac{(\sigma 1^2 + \sigma 2^2) \cdot [Z_{1-\alpha/2} + Z_{1-\beta}]^2}{(M_1 - M_2)^2}$$

where $Z\alpha/2$ is the critical value of the Normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), $Z\beta$ is the critical value of the Normal distribution at β (e.g. for a power of 90%, β is 0.1) and M1 and M2 are the expected sample mean of the two groups. σ_1 and σ_2 are the expected sample Sd of the two groups. Statistical testing was conducted with the statistical package for the social science system (SPSS version 17, SPSSInc., Chicago, IL, USA) Continuous variables were presented as mean±SD or median if the data is unevenly distributed. Categorical variables were expressed as frequencies and percentages.

The comparison of continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups was compared using Chi-squared test or Fisher's exact test as appropriate. Non-normal distribution continuous variables were compared using Mann Whitney U test. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

3. Results

This comparative study was carried out in 60 ASA 1/2 patients who underwent elective laparoscopic nephrectomies. 30 patients in group A received lateral ultrasound guided unilateral TAP block with 20ml solution of 0.25% bupivacaine and 30 patients in group B received 20ml of 0.25% bupivacaine bilaterally after completion of surgery and before extubation.

Demographic variables were compared between group A and group B (Table 1). All the TAP blocks were performed without any complications. Hemodynamically both groups were comparable at all the time points.

Total mean analgesic duration of ultrasound guided TAP block in group A was found out to be 6.2±2.14hrs as compared to group B which was 14.3h±2.48hrs p value 0.000000017564 (Figure 1), which is statistically

significant implying that ultrasound guided bilateral TAP block provides longer duration of postoperative analgesia as compared to ultrasound guided unilateral TAP block.

The post-operative pain was measured by VAS score at different time intervals. The overall VAS scores were significantly higher in the group A as compared to the group B with p value 0.00000000124575 and maximum difference found at 9hrs, 12hrs and 18 hrs (Figure 2).

The mean number of doses of additional rescue analgesia (i.e fentanyl) in Group A was 3.12 ± 0.72 (given at 9,12,18 hrs.) as compared to 1.04 ± 0.73 in Group B (given at 18 hrs.), the p value comes out to be <0.0000000125 which is statistically significant implying that Group A needed more doses of fentanyl in postoperative period (Figure 3)

There was no incidence of side effects (nausea, vomiting and pruritus) and those due to technique of block and drug volume at any point of time in the post-operative period.

Table 1: Demographic variables

	Study Group	
	Group UL	**Group BL**
	Mean ± SD	Mean ± SD
Weight (kgs)	56.21 ± 1.2	61.10 ± 0.8
Age (Years)	41.16 ± 1.8	45.10 ± 1.3
SEX (M/F)	18/12	13/17
ASA GRADE (1/2)	22/8	17/13
Duration of Surgery (min)	310.2 ± 0.6	304.2 ± 0.9

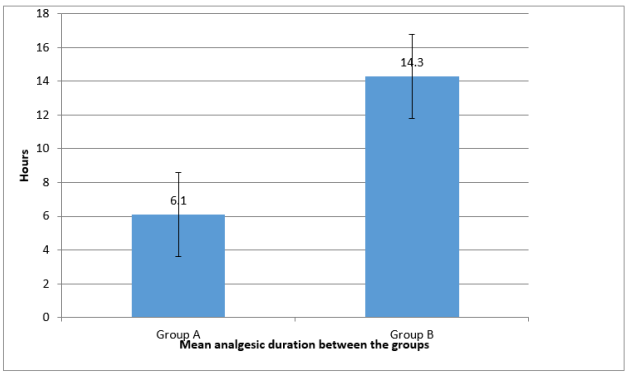

Fig. 1:

4. Discussion

Laparoscopic surgery may be associated with reduced surgical trauma response and shortened recuperation when compared with open procedures. However, early postoperative pain is a frequent complaint among such patients, thus arising need for parenteral opioids and NSAIDs(nonsteroidal anti-inflammatory drugs) especially in the first 24 hours postoperatively but due to adverse

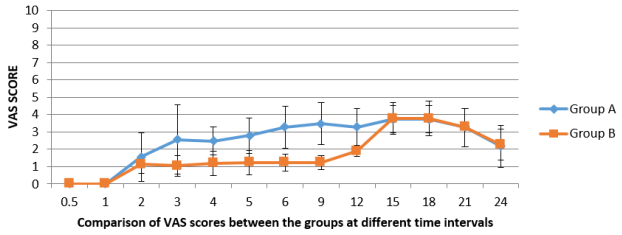

Fig. 2:

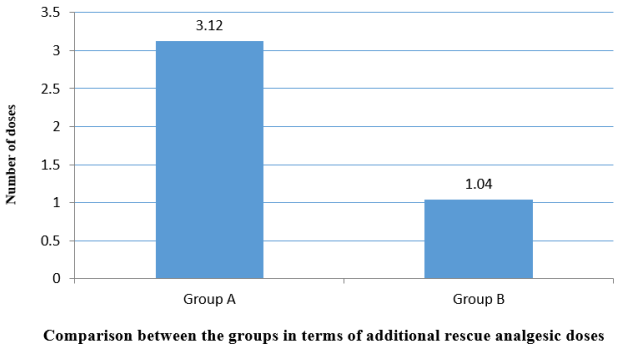

Fig. 3:

effects of opioids and NSAIDs, the use of epidural and TAP block in laparoscopic surgeries including nephrectomies is growing.[8,12–15] TAP block is more effective in somatic pain as it interrupt innervation to the abdominal skin, muscles, and parietal peritoneum but it does not block visceral pain. TAP block effectively reduces opioid consumption and related complications like nausea/vomiting, sedation and also complications related to epidural analgesia like hypotension, bradycardia and motor block. Thus it is a suitable substitute for intravenous analgesia and epidural block.[16–18]

Till date, various studies and review articles have been published to evaluate and demonstrate the efficacy of TAP block in several laparoscopic surgeries.[17,19–21] but only a few studies have been done in laparoscopic nephrectomies. In a randomized controlled trial by Hasgood et al, he found that USG guided TAP blocks reduces VAS scores and the amount of morphine used 6 hours after laparoscopic donor nephrectomy.[8] In another study conducted by Aniskevich et al ,concluded that TAP block for laparoscopic nephrectomy reduced overall pain scores at 24 hours with a trend towards decreased total morphine consumption.[22] Similarly, Parikh et al[23] also concluded the overall reduction in consumption of tramadol up to 12 hours after giving USG guided TAP block at the end of donor nephrectomy.

However, till now no study has been conducted to compare efficacy of lateral USG guided unilateral versus bilateral TAP block in laparoscopic nephrectomies and its effect on total opioid consumption. Hence the strength

of this study is, it is first to compare the effect of USG guided unilateral versus bilateral TAP block for postoperative pain. Here we have found that USG guided bilateral TAP block (lateral approach) using bupivacaine in laparoscopic nephrectomies reduced the total fentanyl requirements and lowered VAS scores more than unilateral TAP block. It also offered good analgesia, cardiopulmonary stability, no significant side effects and had high level of patient satisfaction. We also evaluated total mean analgesic duration of block and it was better in patients who received bilateral TAP block. In this study, two different volumes of local anaesthetic (0.25% bupivacvaine) were used in group A and B, hence it can be one of the reasons leading to significantly better efficacy of TAP block in bilateral group (B) as it provides more complete blockade of the abdominal wall. Total volume of the drug which is to be used in the bilateral group needs to be accurately calculated to avoid any drug overdosage related toxicity. In our study, bupivacaine was used after proper and effective calculation of dose, so as to not exceed 2mg/kg and no incidence of any side effects or toxicity due to higher volume of bupivacaine was manifested. We did not observe any complications either due to unilateral or bilateral TAP block with respect to needle puncture technique as it was practiced under ultrasound guidance.

This study is not without limitations. The calculation of the mean analgesic duration has some flaws, patient may demand rescue analgesic for pain originating from viscera thus we couldn't assessed the exact duration of sensory block as TAP block effectively reduces the somatic pain but doesn't block the visceral pain. The depth of anaesthesia was not monitored in this study and it is suggested that depth of anaesthesia may influences the postoperative analgesia[24,25], and it can also be the limiting factor.

The confounding variable in this study is the amount of dissection which is needed varies with the indication for laparoscopic nephrectomy. The analgesic efficacy of sub costal and lateral TAP block is less in patients who undergo extensive resection compare to simple nephrectomy. The difference in the number of port entry points in right and left sided nephrectomies can also affect the analgesic efficacy of the block.

In summary, patients who received bilateral ultrasound guided TAP block have overall reduced VAS scores, total fentanyl consumption and provided longer duration of analgesia as compared to unilateral TAP block (given on the side of incision) postoperatively. Further large scale studies are warranted and should be undertaken to fully evaluate and address the comparison of bilateral versus unilateral TAP block, its ideal timing, measuring depth of anaesthesia and ideal local anaesthetic agent with adjuvants and dosage to be used in laparoscopic nephrectomies.

5. Source of funding

None.

6. Conflict of interest

None.

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