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Transversus abdominis plane block versus paravertebral block for postoperative pain following open renal surgeries: A randomized clinical trial

Khaled Abdel-Baky Abdelrahman^a, Essam Ezzat Abdel-Hakeem^a, Abdel-Rahman Hussein Ali ^b and Eman Ahmed Ismail^a

^aAssistant Professor of Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Assiut University, Assiut, Egypt; ^bResident Physician of Anesthesia, Faculty of Medicine, Assiut University, Assiut, Egypt

ABSTRACT

Background: : Open renal surgeries are usually associated with significant pain which may increase morbidity and mortality if left untreated. Several methods are used to control pain after these surgeries including opioids, non-steroidal anti-inflammatory drugs and regional anesthetic techniques. This study aimed at comparing the thoracic paravertebral block (PVB) versus transversus abdominis plane block (TAP) in patients undergoing open renal surgeries. **Methods:** Between November 2017 and November 2018 at Assiut University Hospital, urology department 60 patients undergone open renal surgeries had been randomly allocated into two groups; group (PVB) (n = 30) who received (PVB), and group (TAP) (n = 30) who received TAP block. The regional anesthetic technique was performed in each patient after induction of general anesthesia and before performing the surgery. The primary outcome was the total analgesic consumption in the first 24 h postoperatively. Secondary outcomes included the time to the first analgesic request and the Visual Analogue Scale score (VAS) during the first 24 h postoperatively.

Results: : Total analgesic consumption during the first 24 h postoperatively was significantly lower in PVB group compared to TAP group. The VAS scores were significantly lower in PVB group compared to TAP group during the first 12 h postoperatively. However, the time to first analgesic request was non-significant between both groups.

Conclusions: : The TAP block was effective, safe and comparable to PVB for pain control following open renal surgeries. However, the paravertebral block was more potent. **Trial Registry:** : ClinicalTrials.gov: NCT04697420

1. Introduction

Renal surgeries are usually associated with significant postoperative pain. Patients undergoing renal surgeries may have associated medical comorbidities [1]. Untreated postoperative pain may cause undesirable effects [2].

Pain control following renal surgery can be achieved through either systemic analgesics or regional nerve blocks. The use of systemic analgesics may be associated with untoward effects as respiratory depression, delay wound healing, hypotension and hemodynamic instability. Furthermore, it may require dose adjustment in patients with impaired renal functions [3,4].

Hence, the regional nerve blocks may be a good alternative. They include thoracic paravertebral block (PVB), transversus abdominis plane block (TAP) block, intercostals nerve blocks and epidural block. Paravertebral block is used in order to control pain postoperatively following thoracic and abdominal surgeries but may be associated with complications as pneumothorax, epidural spread, subarachnoid spread, and hemodynamic instability [5]. Transversus abdominis plane block is a field block that are used to control pain following gynecological surgeries, upper abdominal surgeries such as cholecystectomy, hepatectomy and renal surgeries. Furthermore, TAP block may not be associate with the complications that may occur with paravertebral block [6]. We hypothesized that the TAP block may be a better alternative to the PVB to control pain in patients undergoing open renal surgery. Our primary outcome was the total analgesic requirements in the first 24 h postoperatively. Secondary outcomes included the time to the first analgesic request and the Visual Analogue Scale score (VAS) during the first 24 h postoperatively.

2. Patients and Methods

This is a prospective randomized clinical trial which was performed at Assiut University Hospitals Urology Department between November 2017 to November 2018. The study was carried out after the approval from the Research Ethical Committee of the Assiut

CONTACT Abdel-Rahman Hussein Ali 🖾 abderahmana@gmail.com 🗈 Resident Physician of Anesthesia, Faculty of Medicine, Assiut University Assiut Egypt

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ARTICLE HISTORY

Received 9 September 2021 Revised 13 October 2021 Accepted 26 October 2021

KEYWORDS

Postoperative pain; renal surgery; transversus abdominis plane block; paravertebral block

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University Hospitals (IRB # 17,100,199) and received written informed consent from each patient. The trial was registered in ClinicalTrials.gov (Clinical Trial ID: NCT04697420). The study was conducted and adherent to the CONSORT guidelines and to the regulations and amendments of Helsinki Declaration. Sixty patients aged 18–60 years with American Society of Anesthesiologists (ASA) I-II physical status who were undergoing open renal surgeries were included in this study. We excluded patients who have contraindication to regional anesthesia block such as coagulopathy, infection at the needle insertion site, patients with allergy to amide local anesthetics or the medications used in this study and patient refusal.

Patients in this study were randomly allocated in 1:1 ratio into two groups, group (P) which included thirty patients who received paravertebral block and group (T) which included also thirty patients who received transversus abdominis plane block. Patients in both groups were received the block technique after induction of general anaesthesia and before performing the scheduled surgery.

All the patients were randomly allocated to two groups by using computer-generated list of random numbers. The allocation sequence was concealed by using dark opaque envelopes and each envelope was opened immediately before performing the scheduled surgery. Determination of whether a patient would receive either paravertebral or transversus abdominis plane block was done by using a list of random numbers prepared by an investigator who did not participate in the study. All of the patients who included in this study were blind to the block technique who received. The anaesthesiologists who performed the technique, the outcome assessors and the data analyser also were blinded through the whole study.

The preoperative assessment was done to all patients which included history, physical examination, and the routine investigations (CBC, ECG, liver function tests, renal function tests and coagulation profile).

A standardized anesthetic management was performed similarly for all patients. Patients fasted for 8 h preoperatively. In the preoperative holding area on the morning of surgery, I.V cannula was inserted in patients' non-dominant hand and then premedicated by I.V midazolam (1–2 mg) and received prophylactic antibiotic before surgery.

In the operating room, the standard monitors were attached to patients which included pulse oximetry, five leads ECG, noninvasive arterial blood pressure and capnogram. After preoxygenation, anesthesia was induced with I.V fentanyl 1 mcg/kg and I.V propofol 2–2.5 mg/kg followed by I.V cisatracurium 0.15 mg/kg to facilitate endotracheal intubation. Anesthesia was maintained with isoflurane 1–1.5% in a mixture of oxygen and air (50:50%).

The assigned block technique was performed after induction of general anesthesia and before the beginning of the surgery as done in some previous studies [7-10]. This was done under complete aseptic technique after cleaning the site of needle injection and sterilization by povidone iodine and draping the patients by sterile drapes.

3. PVB group

Patients in this group were received ultrasound guided paravertebral block by using SonoSite M Turbo (USA) with linear multi-frequency 6-13 MHz transducer (L25x6-13 MHz linear array) scanning probe and 21 G Touhy needle that was used to perform this block at the level of T-11 thoracic vertebra. The block was done for the patients in this group in the lateral decubitus position. After cleaning and sterilization of the injection site and draping the patient with sterile drapes, the ultrasound probe covered with sterile sheath was placed 2-3 cm parallel and lateral to the spinous process of the thoracic vertebra T-11, and the orientation mark was directed cranially. The paravertebral space was visualized as it is located between the spinous processes which appeared as hyperechoic structures with acoustic shadowing and anterior to the costotransverse ligament which appeared as hyperechoic line and posterior to the parietal pleura which appeared as hyperechoic line which moved with respiration.

The block was done by using the in-plane technique through which the needle was inserted in the line of the transducer and advanced from the caudal direction toward the cranial direction until it traversed the costotransverse ligament and 20 ml of 0.5% of plain bupivacaine (Sunnypivacaine[®], Sunny pharmaceuticals, Egypt) was injected in the space and confirmed by seeing the parietal pleura moving anteriorly while injecting the anesthetic agent [9]. When the block is done, the supposed surgery was performed after complete sterilization.

4. TAP block group

This block was done by using SonoSite M Turbo (USA) with linear multi-frequency 6–13 MHz transducer (L25x6–13 MHz linear array) scanning probe and 21 G Toughy needle which used to inject the local anesthetic agent into the TAP space. The block was done for the patients in the supine position and before performing the supposed surgery for them. The ultrasound probe was placed just below the costal margin and parallel to it. The rectus abdominis muscle appeared and the transversus abdominis plane (TAP) appeared as hyperechoic line just posterior to the skin and the subcutaneous tissue. The needle then placed in-plane of the probe and advanced from medial to lateral until reached the TAP space. Then, 20 ml of 0.5% plain bupivacaine (Sunnypivacaine®, Sunny pharmaceuticals, Egypt) was injected in the TAP space. The muscle layers appeared separating from each other which indicated the correct injection of the local anesthetic in the TAP space. After this nerve block had been performed in every patient in this group, the patient then was turned to lateral decubitus position and the site of surgery was cleaned and sterilized with povidone iodine and the patient was draped with sterile drapes and the supposed surgery was performed [8]. Before the end of the surgery, 1 gm IV paracetamol was given for all patients. Upon completion of surgery and reversal of the muscle relaxants, patients were extubated and sent to the recovery room and later to the ward.

5. Study measurements

The following data were recorded by anesthesiologists who didn't participate in this study: The total analgesic requirements in the first 24 h postoperatively. Patients were instructed during the preoperative evaluation about the 100 mm Visual Analogue Scale score (VAS); in which 0 indicated no pain and 100 indicated the worst pain imaginable. The VAS was recorded immediately postoperatively (0 h) at the post anesthesia care unit (PACU) and at 2, 4, 6, 12 and 24 h postoperatively. Time to the first analgesic request which was the time of the first analgesic request given to keep VAS below 30. The incidence of intraoperative and postoperative complications (local anesthetic systemic toxicity, pleural puncture, pneumothorax, or suspected lung injury in PVB group, accidental puncture of abdominal viscera, intraperitoneal injection, or flank hematoma in TAP group), and perioperative changes in the hemodynamic parameters have been recorded. These data were also collected through the intraoperative period and the first 24 h postoperatively. Postoperatively, nalbuphine 10 mg IM was given as a rescue analgesia to keep VAS \leq 30. Nalbuphine consumption was recorded during the first 24 h postoperatively. We have recorded any complications that may occur postoperatively such as nausea, vomiting, pruritis or respiratory depression.

6. Statistical analysis

Sample size was calculated based on first analgesic request from a pilot study. Assuming an effect size of 0.8, $\alpha = 0.05$ and a power of 80%, it yielded a sample size of 26 patients per group using a two-tailed test. Four patients were added to each group to compensate for possible dropouts.

Data were collected and entered to the Statistical Package for Social Science (IBM SPSS) version 20. Shapiro-Wilk test was used to determine the norma distribution of our data. The parametric data in this study as time before the first analgesic request, demographic data, surgical data and hemodynamic parameters were all expressed as mean \pm standard deviation while the total analgesic requirement was expressed as [median (range)] and all compared by using the t-test. The nonparametric data was the VAS scores in both groups at the different intervals and were expressed as median, minimum, and maximum (min-max) and compared by using the Mann–Whitney test. *P* value less than 0.05 was considered statistically significant.

7. Results

Figure 1 shows the study CONSORT flowchart. Seventyeight patients were screened for eligibility to be included in the study, 18 of them were excluded for these reasons: nine patients refused performing the block technique, six patients their ASA classes were between III–IV and three patients reported history of previous allergy to local anesthetics. So, 60 patients were included and completed the study.

Table 1 shows baseline patients' characteristics. There were no significant differences regarding age, gender, weight, ASA class, height, weight, or BMI. As shown in Table 2, there were no significant differences between the two groups regarding the type of surgery, duration of anesthesia or duration of surgery.

Regarding hemodynamic parameters as systolic and diastolic blood pressure or heart rate, there were no statistically significant differences between the two groups in all times of the study, as shown in Table 3.

All patients received the first dose of nalbuphine (IM 10 mg) 2–3 h postoperatively in the PACU. However, only 11 patients in PVB received the

Table 1. Patients' characteristics.

Variable	PVB group (n = 30)	TAP group (n = 30)	p value
	45.3 ± 14.8	43.8 ± 19.2	0.725
Age (years)			
Gender (male/female)	24/6	22/8	0.761
ASA class (I/II)	12/18	17/13	0.301
Height (cm)	172.7 ± 4.1	174.8 ± 5.3	0.096
Weight (Kg)	77.1 ± 10.2	82.4 ± 11.2	0.058

Table 2. Operative data.

Variable	PVB group (n = 30)	TAP group (n = 30)	p value
Type of surgery			
 Nephrolithotomy 	12	14	0.730
 Uretero-lithotomy 	15	12	
Nephrectomy	3	4	
Surgery Time (min.)	112.2 ± 27.9	118 ± 41.7	0.527
Anesthesia Time (min.)	137.3 ± 29.1	138 ± 42.1	0.943

Table 3. Hemodynamic data.

	Systolic blood pressure		Diastolic blood pressure			Heart rate			
	Group 1 (paravertebral block)	Group 2 (TAP block)	P value	Group 1 (paravertebral block)	Group 2 (TAP block)	P value	Group 1 (paravertebral block)	Group 2 (TAP block)	P value
Baseline	132 ± 6	134.7 ± 9.2	0.197	74.8 ± 5.4	76.6 ± 5.3	0.200	79 ± 12.3	80.5 ± 5.2	0.535
After induction	112.6 ± 11.1	117.9 ± 13.8	0.106	68.1 ± 8.5	67.5 ± 9.9	0.781	80.5 ± 12.2	77.5 ± 6.8	0.241
After skin incision	111.5 ± 20	114.5 ± 17.8	0.547	73.8 ± 16.7	77.2 ± 12.5	0.377	84.3 ± 12.3	82 ± 8.6	0.407
After 20 min	122.9 ± 14.8	118.3 ± 10.8	0.169	79.1 ± 12.5	72.9 ± 12.7	0.057	76.5 ± 7.7	78.9 ± 11.1	0.331
After 40 min	120.9 ± 12.9	114.5 ± 12.3	0.056	75.1 ± 13.1	71.8 ± 11.8	0.310	79.4 ± 11.9	82.4 ± 6.6	0.303
After 60 min	121.3 ± 18.15	119.6 ± 20	0.731	65 ± 23.8	71.3 ± 10.6	0.196	75.8 ± 17.6	79.9 ± 8.3	0.233
After 80 min	121.9 ± 8	118.9 ± 2.7	0.198	68.2 ± 11.8	71.2 ± 11.4	0.339	81.1 ± 11	81.5 ± 10	0.910
After 100 min	117.2 ± 9.1	112.9 ± 11.7	0.159	69.8 ± 11.5	66.3 ± 12.4	0.310	86.4 ± 15.6	87.6 ± 8.5	0.747
After 120 min	128 ± 3	117.33 ± 6.3	0.058	75.6 ± 1.5	73 ± 9.8	0.667	90.2 ± 11.1	85.5 ± 7	0.066
At end of surgery	119.3 ± 3.9	116.4 ± 15.3	0.321	68.3 ± 10.5	70.2 ± 13.5	0.532	88.5 ± 15	91.5 ± 10.2	0.570

Table 4. Total	analgesic	consumption	in the first 24 h.

Analgesic	Group 1	Group 2 (transversus	
drug	(paravertebral	abdominis plane block	Р
consumed	block group)	Group)	value
Nalbuphine	10 (13)	12.5(18)	0.022

Table 5. Visual analog scale (VAS) score.

Time	PVB group (n = 30)	TAP group (n = 30)	p value
Immediate postoperative period	4(4–5)	5(5–6)	0.003
After 2 h	4(3-5)	5(4–6)	0.000
After 4 h	3(3-4)	4(4–5)	0.000
After 6 h	3(2-3)	3(3–5)	0.000
After 12 h	2(1-3)	2(2-4)	0.004
After 24 h	1(0–2)	1(0–2)	0.116

second dose (IM 10 mg). For the TAP group, 19 patients received the second dose (IM 10 mg). The total analgesic consumption (mg), as shown in Table 4, was significantly lower in the PVB group 10 (13) mg [median (range)] compared to the TAP group 12.5 (18) [median (range)] (p = 0.022) during the first 24 h postoperatively.

The time before the first order analgesic request was longer in the PVB group (171.7 \pm 32.2) min than the TAP group (166.7 \pm 22.2) min, but this was insignificant difference between the two groups (p = 0.493).

The VAS scores were significantly lower in PVB group compared to TAP group during the first 12 h postoperatively, as shown in Table 5. However, there were no significant differences in the VAS scores at 24 h postoperatively.

During the study period, none of patients in both study groups recorded any complications or adverse effects related to the block or the drugs used in this study such as local anesthetic systemic toxicity, pleural puncture, pneumothorax or suspected lung injury, accidental puncture of abdominal viscera, intraperitoneal injection, nausea, vomiting or respiratory depression. There were only two patients in the paravertebral block group developed hypotension, one of them require only one dose of ephedrine 9 mg i.v, and the other patient responded to fluid administration only intraoperatively. Hypotension in the two patients was transient.

8. Discussion

This study was carried out to compare between the analgesic effects of the thoracic paravertebral block and the transversus abdominis plane block following open renal surgeries. Regional anesthetic techniques may be a good alternative rather than systemic analgesic drugs as opioids and non-steroidal anti-inflammatory drugs, as these drugs may be associated with side effects that may be not tolerated in urological patients especially if they have renal impairment. Thoracic paravertebral block is used widely to provide analgesia following open renal surgeries, by injecting local anesthetic drug in the paravertebral space through either landmark technique or ultrasound guided technique. Although it is effective in pain control, PVB may be associated with adverse effects as pneumothorax, spread to either the epidural space or subarachnoid spread [5]. Transversus abdominis plane block also has been used in pain control following open renal and upper abdominal surgeries [6]. So, it may be an alternative to the paravertebral block with less incidence of complications. It is performed through injecting local anesthetic drug in the space between the internal oblique muscle and the transversus abdominis muscle by using the ultrasound.

The study showed that paravertebral block resulted to lower VAS scores in the paravertebral group compared to the TAP block group through the first 12 h postoperatively. Also, nalbuphine consumption was significantly lower in the paravertebral group than the TAP block group. However, the time to first order analgesic was insignificantly different between the two groups. In agreement with these results, Melnikov et al. found that the PVB had resulted to significant lower pain scores and lower total analgesic consumption than the TAP block after major gynecologic surgeries [10]. Also, Kaya et al. found that PVB had resulted to significant lower pain scores and significant lower diclofenac sodium consumption than TAP block. They do not recommend the routine use of PVB as it has the longer procedural duration, lower patient satisfaction, increased risk of complications and longer hospital

stay [11]. Furthermore, Goda et al. had compared between the PVB and the TAP block after upper abdominal surgeries. The authors had found that pain scores and total analgesic consumption were significantly lower in the PVB group compared to the TAP block group, and the time to first order analgesic was significantly longer in the PVB group than the TAP block group [9].

Although the above-mentioned studies showed the superiority of the PVB than the TAP block in pain control following upper abdominal surgeries, safety and effectiveness of the TAP block were studied in many studies. EL Fawy et al. compared the TAP block to caudal block following surgical pyeloplasty in infants and children and they found that FLACC (Face, Leg, Activity, Crying, Consolability) scores were significantly lower in the TAP block group than the caudal block group through most of the first 24 h postoperatively. The total analgesic consumption was also significantly lower in the TAP block group, and the time to first order analgesic was significantly longer in the TAP block group [12]. Niraj et al. compared the analgesic effect of the subcostal TAP block by using a catheter placed in the TAP space to the thoracic epidural block after surgeries like nephrectomy, partial hepatectomy and pancreatic surgeries. They found that there was no significant difference between the two groups in the VAS scores but tramadol consumption was significantly higher in the TAP block group. They concluded that TAP block with oral analgesic drugs may be a good choice in comparison with epidural block following upper abdominal surgeries [13]. Heba et al. compared the effects of the surgically assisted-TAP analgesia to epidural block following open renal surgeries. They found that the VAS scores were not significantly different between the two groups and the morphine consumption was lower in the epidural group without statistical significance [14].

This study has some limitations which include:

Comparison between the two blocks as a single shot technique in both groups, while comparing between these two blocks by using the continuous catheter in the paravertebral space and the TAP space to provide analgesia postoperatively may prolong the duration of analgesia specially in the TAP group. The second limitation in this study is that both two blocks were done after induction of general anesthesia in all patients through the study, while performing the nerve block in the awake patient and before induction of general anesthesia may give a better chance to evaluate the success and failure of this block as well as the early detection of any complications.

This study concludes that PVB is comparable to TAP block in controlling pain in patients undergoing open renal surgeries. The TAP block can substitute the PVB and its undesirable complications in open renal surgery. However, the PVB was more potent than TAP block.

Disclosure statement

No potential conflict of interest was reported by the author(s).

ORCID

Abdel-Rahman Hussein Ali D http://orcid.org/0000-0003-1114-1290

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