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Ultrasound-guided Paravertebral Block Versus Intravenous Sedative Analgesic using Midazolam /Fentanyl in Patients Undergoing Extracorporeal Shock Wave Lithotripsy

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: Thoracic paravertebral block (TPVB) produces ipsilateral somatic and sympathetic nerve blockade in multiple contiguous dermatomes both above and below the site of injection.
The Aim of This Study: was to compare the effectiveness of ultrasound-guided TPVB versus intravenous (IV) sedative analgesic using midazolam / fentanyl in patients undergoing extracorporeal shock wave lithotripsy (ESWL) procedure.
Patients and Methods: This prospective, randomized study was carried out on sixty patients aged 20-60 years, with radio-opaque renal stone not more than1.5cm. TPVB group (30 patients) received ipsilateral ultrasound-guided TPVB at the level T9-T10 using bupivacaine 0.25% (20 mL) about 30 minutes before the ESWL. Midazolam/fentanyl group (30 patients) received sedatives analgesic drugs using IV midazolam (0.05 mg / kg) and fentanyl (1 µg/kg) about 5 min before the ESWL. The VAS score during and 30 min post procedure, total dose of rescue analgesic

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consumption during ESWL procedure, the success rate of ESWL, the time needed to stone clearance, patient and operator satisfaction scores were recorded.
Result: During and after ESWL procedure, the VAS scores were significantly higher in midazolam/fentanyl group than TPVB group ($P < 0.05$). The number of patients required rescue analgesic during ESWL was significantly higher in midazolam/fentanyl group compared to TPVB group ($P < 0.05$).The success rate of ESWL was insignificantly different between both groups **(**$P > 0.05$). The time needed to stone clearance was significantly shorter in TPVB group compared to midazolam/fentanyl group ($P < 0.05$).
Conclusions: Ultrasound-guided TPVB provided more effective analgesia with reduced number of ESWL sessions and shorter time to renal stone clearance than IV midazolam/fentanyl.

Keywords: Extracorporeal shock wave lithotripsy; midazolam; fantanyl; ultrasonography.

1. INTRODUCTION

The extracorporeal shock wave lithotripsy (ESWL) is a common method for treatment of the urinary tract stones with fewer complications than other invasive procedures [1]. Most patients experience some degree of pain during this procedure [2,3]. Clinical outcomes and success as measured in terms of stone-free rate after ESWL is strongly correlated to pain experienced during treatment [4]. Inadequate pain control during this procedure is associated with an increased risk of complications, reducing the efficiency of the treatment, patients' dissatisfaction, longer hospital stay and increasing costs [5].

Many drugs and methods such as local anesthetic infiltration, intravenous (IV) or oral non steroidal anti inflammatory drugs and opioid agents have been used for pain management during ESWL [2]. Nonetheless, the most effective analgesic regimen during ESWL has not been determined [2,3]. Among the drugs that were used for analgesia during ESWL, opioids seem to be a favorable analgesic; however the opioid administration may be problematic especially at high doses in an outpatient setting, due to a longer recovery time and side effects like nausea, hypotension, respiratory depression and vomiting [5].

The paravertebral block (PVB) produces ipsilateral somatosensory and sympathetic nerve block at multiple vertebral levels and it is widely used in both the pediatric and adult populations. [6]. It is effective in treating acute and chronic pain of origin from the chest and abdomen. Thoracic PVB (TPVB) has been successfully used for a variety of surgical procedure, including breast surgery, thoracotomy, cholecystectomy, nephrectomy and inguinal herniorrhaphy [7-10].

We hypothesized that TPVB is an effective anesthetic technique for ESWL. The aim of this study was to compare the effectiveness of ultrasound-guided TPVB versus IV sedative analgesic using midazolam (0.05 mg/kg)/ fentanyl (1 µg /kg) in patients undergoing ESWL procedure.

2. PATIENTS AND METHODS

This prospective, randomized study was carried out in Tanta University Hospitals from June 2019 to May 2020.After approval of Institutional Ethical Committee (33079 / 04/ 19), a written informed consent was obtained from each patient. This study was carried out on sixty patients aged 20-60 years, with radio-opaque renal stone not more than1.5 cm undergoing ESWL. Every patient received an explanation of the purpose of the study. Patients were trained on the use of visual analogue scale (VAS) for determination of intensity of the pain on scale from (0-100) where 0= no pain and 100=the worst pain.

2.1 Inclusion Criteria

Sixty patients aged 20-60 years, with radio-opaque renal stone not more than1.5cm undergoing ESWL were recruited in the study.

2.2 Exclusion Criteria

1. Contraindications to regional block: Patients refuse regional analgesia, coagulopathy, local infection at the site of the block, known allergy to local anesthetic drugs and spinal deformity.
2. Patients with history of chronic use of sedatives and drug abuse.
3. Patients with body mass index (BMI) more than 35 kg/m^2.
4. Uncooperative patients as mentally retarded patients and patients with cognitive disorders.

2.3 Randomization

Patients were randomly allocated into two equal groups by computer generated sequence through sealed opaque envelopes. Each group included 30 patients.

2.3.1 Group I (TPVB)

Patients received ipsilateral ultrasound-guided TPVB at the level T9-T10 using bupivacaine 0.25% (20mL) about 30 minutes before the ESWL procedure.

2.3.2 Group II (midazolam/fentanyl)

Patients received sedative analgesic drugs using IV midazolam (0.05 mg / kg) and fentanyl (1 µg/kg) about 5 min before the ESWL procedure.

2.4 Ultrasound-guided Thoracic Para-vertebral Block

After sterilization of the back using povidine-iodine solution 10%, ultrasound-guided TPVB was performed with the patient in the sitting position while arching their backs. The high frequency linear ultrasound transducer (5-13 MHz) was positioned in the vertical plane approximately 2.5 cm lateral to the spinous process at level (T9-T10) with its orientation directed cranially. The probe position was allowed for a parasagittal view of the trans-verse processes, superior cost transverse ligament, inter-transverse ligaments, the desired paravertebral space, the pleura, and lung tissue. The transverse processes were hyperechoic, deep to the paraspinal muscles. The block needle was inserted in a caudo-cranial direction in-plane with the ultrasound beam. Once the costotransverse ligament is breached, the needle tip was laid in the thoracic paravertebral space. After negative blood aspiration, 20 mL of bupivacaine 0.25% was administered. The correct needle positioning was confirmed by anterior displacement of the pleura and widening of the paravertebral space [11] (Fig. 1).

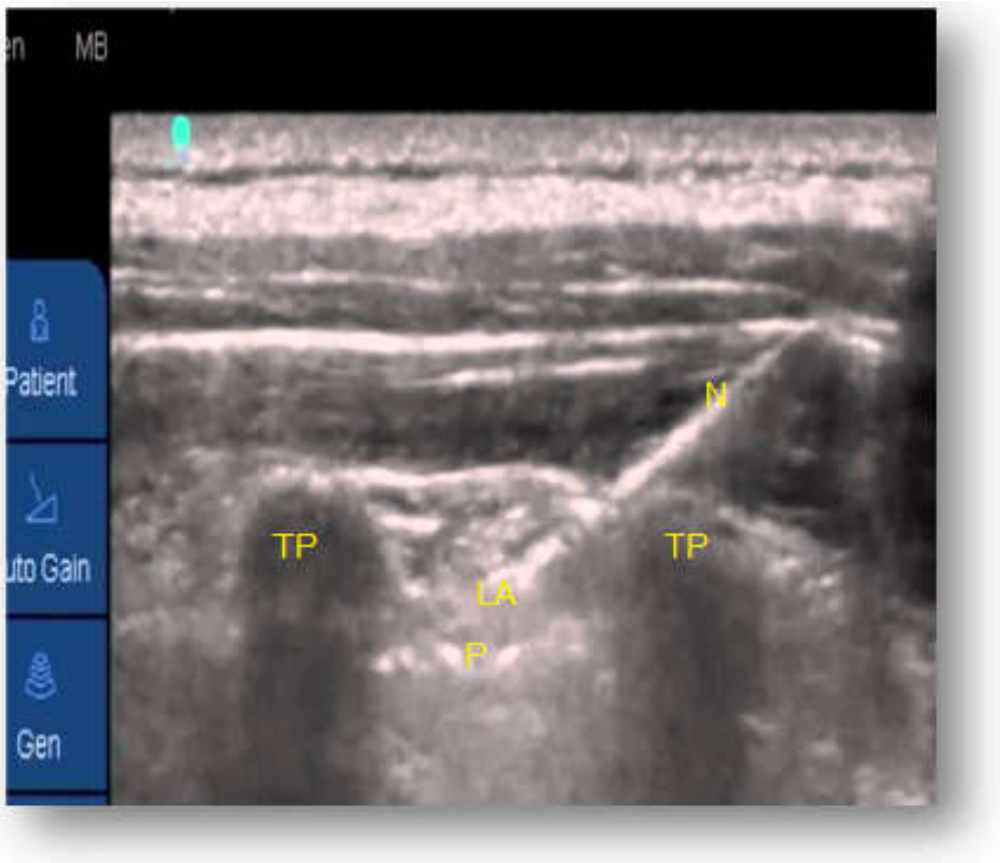

Fig. 1. Ultrasound-guided thoracic paravertebral block. LA; local anesthesia P; pleura, TP; transverse process

2.5 Anesthetic Management

All the patients were under the following procedures;evaluation of medical and surgical histories, clinical examination, assessment of the laboratory investigations including complete blood picture, prothrombin time and activity, liver functions and renal functions (serum urea &creatinine) and establishment of IV line with 20 gaugecannula.

On admission to ESWL room, the monitoring including electrocardiography, noninvasive blood pressure and pulse oximeter were applied. Ringer lactate infusion (10mL/kg/h) was started, and oxygen(5 L/min) by face mask was applied. ESWL was applied with a frequency of 4Hz for a total of 3000 shockwaves. The duration of ESWL session (min), defined as time needed until finishing of 3000shock waves, was recorded.During the ESWL procedure, VAS score was measured every 10 min at regular interval and at 30 min after the procedure. Rescue analgesia in the form of fentanyl (0.5 µg/kg) was given if the VAS score is ≥ 40. Total dose of rescue analgesic consumption during ESWL procedure was calculated. Heart rate and mean arterial blood pressure were recorded pre–procedure and during procedure every 10 min at regular interval and at 30 min after the procedure.

After the end of ESWL procedure, the patients were transferred to the recovery room. Diclofenac sodium (75 mg) was given intramuscular if the VAS score was ≥ 40. The number of patients required postoperative analgesia (diclofenac sodium) were recorded. The patients were allowed to go home when the Post Anesthesia Discharge Scoring System ≥ 9 [12]. Time needed for home discharge (calculated from the end of the ESWL procedure till home discharge) and complications such as hematuria, nausea and vomiting were recorded. The patients were followed up for stone clearance by x-ray KUB and US that was done within 48 hours after ESWL session. If there was incomplete clearance of the stone, a further session of ESWL was done. The time interval between two sessions was minimum one week. The rate of successful ESWL, (defined as elimination of stone fragments within 2 months), number of ESWL sessions needed and time needed for stone clearance were recorded. Patient and operator satisfaction using a 5- point score; (0 = very dissatisfied, 1 = dissatisfied, 2 = neither satisfied nor dissatisfied, 3 = satisfied and 4 = very satisfied) were recorded.

2.6 Outcomes

Primary outcome was the pain intensity during the procedure. Secondary outcome were patient's satisfaction with their analgesic technique and the success rate of the ESWL procedure.

2.7 Statistical Analysis

Sample size calculation was calculated using epi info software computer program created by center of disease prevention and control, Atlanta, USA, WHO, Georgia version 2002. Sample size was calculated based on the pain score during the ESWL procedure. By means of the results of the previous study [13], at least 24 patients in each group were needed to detect a significant difference of the pain score of 20 mm at α error 0.05% and power of the study 95%. Thirty patients were recruited in each group to avoid the drop out cases.

The statistical analysis was performed by SPSS v25 (IBM©, Chicago, IL, USA).The normality of data was checked with Shapiro-Wilks test and visualization of the histograms. Data with normal distribution (such asage, heart rate and mean arterial blood pressure) were presented as mean ± standard deviation (SD). They were analysedusing student's t- test for the comparison between the two groups. Data did not follow the normal distribution (e.g. VAS) were presented as median and interquartile range and analysed using Mann Whitney (U) test for the comparison between the two groups. Qualitative variables (e.g. gender, patients satisfaction and operator satisfaction) were presented as patients number (%) and were analysed utilizing the Chi-square test or Fisher's exact test as appropriate. Time to the stone clearance was analysed using Kaplan–Meier survival analysis and log rank statistics. P value < 0.05 was considered significant.

3. RESULTS

Seventy four patients were assessed for eligibility. Fourteen patients were excluded (9 patients did not meet the criteria and 5 patients refused to participate in the study). The remaining 60 patients were randomly allocated into two groups (30 patients in each one) (Fig 2).

The demographic data and patients' characteristics including age, sex, ASA physical status and stone size were insignificantly different between both groups (P = 0.302, 0.26, 0.582 and 0.369 respectively).The mean duration of ESWL session was 38 ± 5.3 min in the TPVB group and 40.2 ± 5.2 min in midazolam/fentanyl group.There was no significant difference in the duration of the mean ESWL session between both groups (P = 0.199) (Table 1).

The median (IQR) pre-procedure VAS score was insignificantly different between both groups (P = 0.482). The median (IQR) VAS scores of midazolam/fentanyl group were significantly higher at 10, 20, 30 and 40 min during the ESWL procedure and at 30 min post procedure as compared to TPVB group (P <0.05) (Fig 3).

Two patients (5.71%) in TPVB group and 12 patients (40%)in midazolam/fentanyl group required intraoperative rescue fentanyl (P = 0.005).Twenty-two patients in midazolam/fentanyl group, while no patient in TPVB group, required postoperative analgesia (diclofenac sodium) (P < 0.001) (Table 1).

The number of ESWL sessions was significantly higher in midazolam/fentanyl group compared to TPVB group (P = 0.016). The success rate of ESWL was insignificantly different between TPVB group and midazolam/fentanyl group (P = 0.707) (Table 1).

The median time to stone clearance was significantly shorter in TPVB group than midazolam/fentanyl group (P = 0.005) (Fig. 4).

At 10 and 20 min during the ESWL procedure, the mean (± SD) heart rate and mean arterial blood pressure values were significantly higher in midazolam/fentanyl group compared to TPVB group (P<0.05). While the mean (± SD) heart rate values and mean arterial blood pressure were insignificantly different between both groups at 30 and 40 min during the ESWL procedure and at 30 min post-procedure (P> 0.05) (Fig. 5,6).

Patient and operator satisfaction scores were significantly better in TPVB group compared to midazolam/fentanyl group (P = 0.014, < 0.001 respectively).The time needed to home discharge and incidence of nausea and vomiting and hematuria were insignificant different between both groups (P> 0.05) (Table 2).

4. DISCUSSION

The results of our study revealed that ultrasound-guided TPVB provided lower pain scores with less intraoperative fentanyl consumption and lower number of patients required postoperative analgesia than IV midazolam/fentanyl in patients undergoing ESWL procedure. The time needed for stone clearance was shorter with fewer number of ESWL sessions in ultrasound-guided TPVB group without serious side effects.

The analgesic effect of PVB is performed by direct penetration of local anesthetic into the spinal nerves, including the dorsal ramus, the rami communicates and the sympathetic chain [13].

Table 1. Demographic data and patients' characteristics; patients required intraoperative fentanyl and postoperative diclofenac sodium; duration and number of ESWL sessions and success rate in both groups

		TPVB group (n = 30)	Midazolam/ Fentanyl group (n = 30)	P value
Age (years)		38.6 ± 12.33	41.63 ± 10.10	0.302
Sex (Male/ Female)		23/7	19/11	0.26
ASA (I/II)		22/8	25/5	0.582
Stone size (Cm)		1.22±0.18	1.17±0.22	0.369
Patients required intraoperative fentanyl (µg)		2 (5.71%)	12 (40%)	0.005*
Patients required postoperative diclofenac sodium (mg)		0	22 (73.3%)	<0.001*
Duration of ESWL session (min)		38.4±5.3	40.2± 5.2	0.199
Number of ESWL sessions	One session	22 (73.33%)	11 (36.67%)	0.016*
	Two sessions	5 (16.67%)	13 (43.33%)	
	Three sessions	3 (10%)	6 (20%)	
Success rate	Successful	27 (90%)	25 (83.33%)	0.707
	Failed	3 (10%)	5 (16.67%)	

*Data presented as mean ± SD or patients number (%). * Significant as p value <0.05*

Table 2. Patient and operator satisfaction score; time needed for home discharge and adverse effects in both groups

		TPVB group (n = 30)	midazolam/fentanyl group (n = 30)	P value
Patients satisfaction score	0	0 (0%)	0 (0%)	0.014*
	1	0 (0%)	2 (6.67%)	
	2	1 (3.3%)	4 (13.33%)	
	3	7 (23.33%)	14 (46.67%)	
	4	22 (73.33%)	10 (33.33%)	
Operator satisfaction score	0	0 (0%)	0 (0%)	<0.001*
	1	0 (0%)	0 (0%)	
	2	0 (0%)	6 (17.14%)	
	3	8 (22.86%)	16 (45.71%)	
	4	22 (62.86%)	8 (22.86%)	
Time needed to home discharge (min)		149.3 ±13	144.0 ± 18.8	0.208
Side effects	PONV	1 (3.3%)	2 (6.7%)	0.759
	hematuria	30 (100%)	30 (100%)	>0.999

*Data presented as mean ± SD or patients number (%). * significant as p value <0.05*
PONV: Postoperative nausea and vomiting

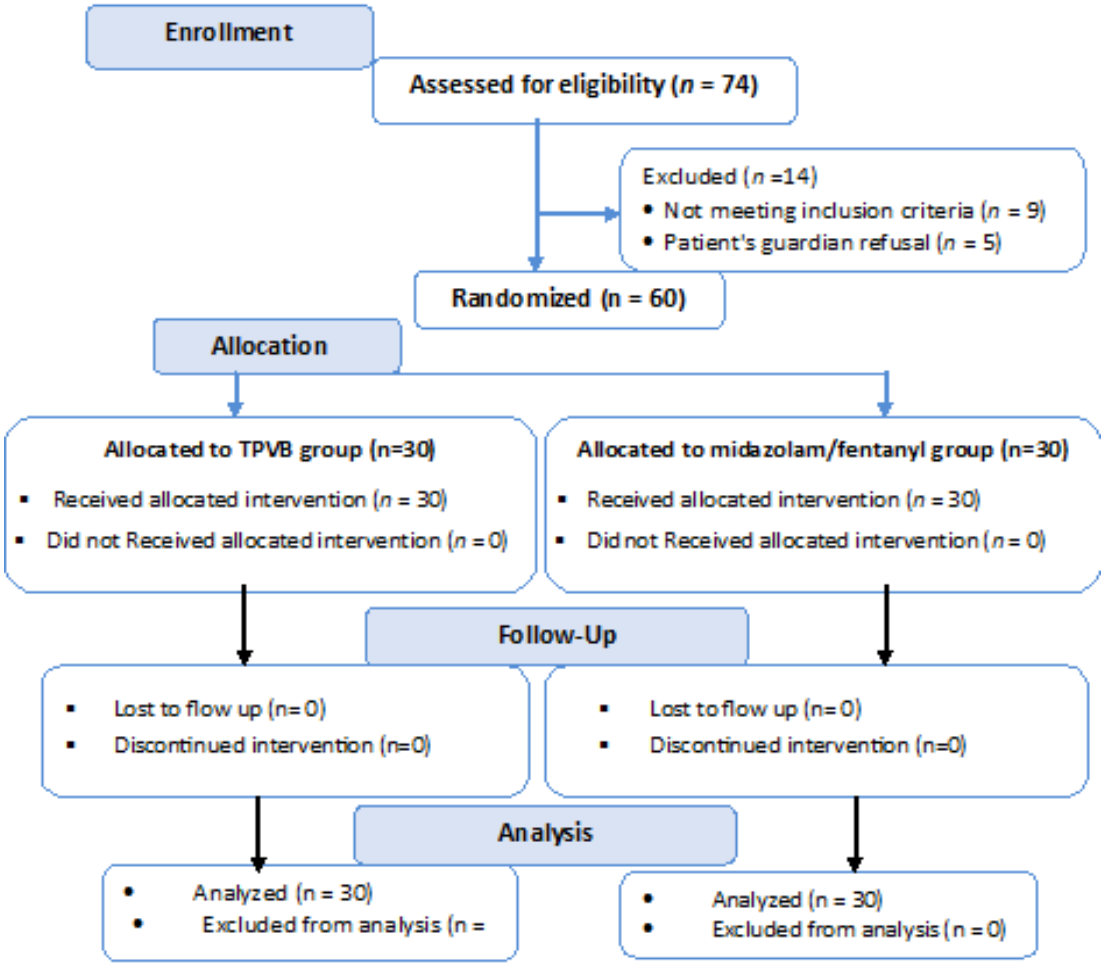

Fig. 2. Consort flow diagram of the participants through each stage of the randomized trial

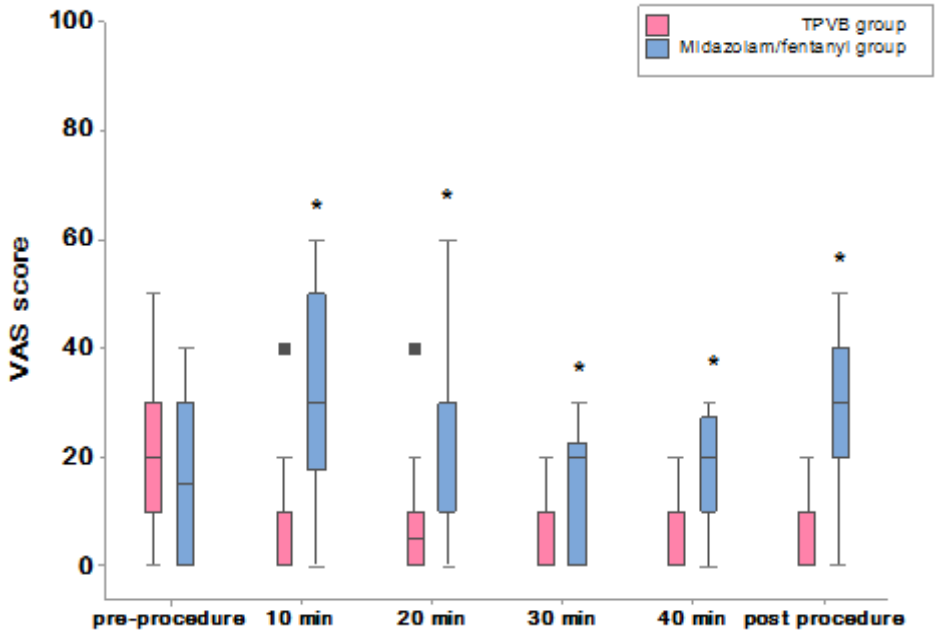

Fig. 3. Visual analogue scale changes in both groups

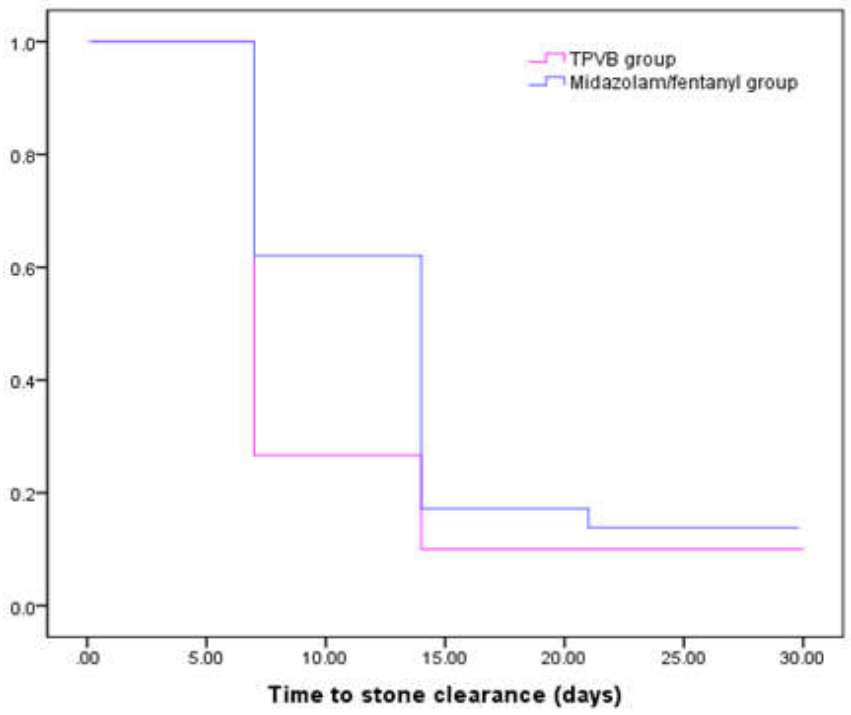

Fig. 4. Time to stone clearance in both groups

The spinal nerve, as it emerges from the intervertebral foramen, are segmented into small bundles devoid of a fascial sheath. This renders them extremely susceptible to the injected local anesthetic. Mass movement of drugs across further tissue planes is unnecessary for analgesia. However, movement of local anesthetic away from the site of deposition in any direction will contribute to analgesia (not counting intravascular spread) [14]. Trans-foramina spread produces a dense block of the spinal nerves. The amount of local anesthetic that passes from PVS to epidural space is impossible to predict but may related to the used approach, the injected local anesthetic volume, practitioner inexperience and spinal deformity [15].

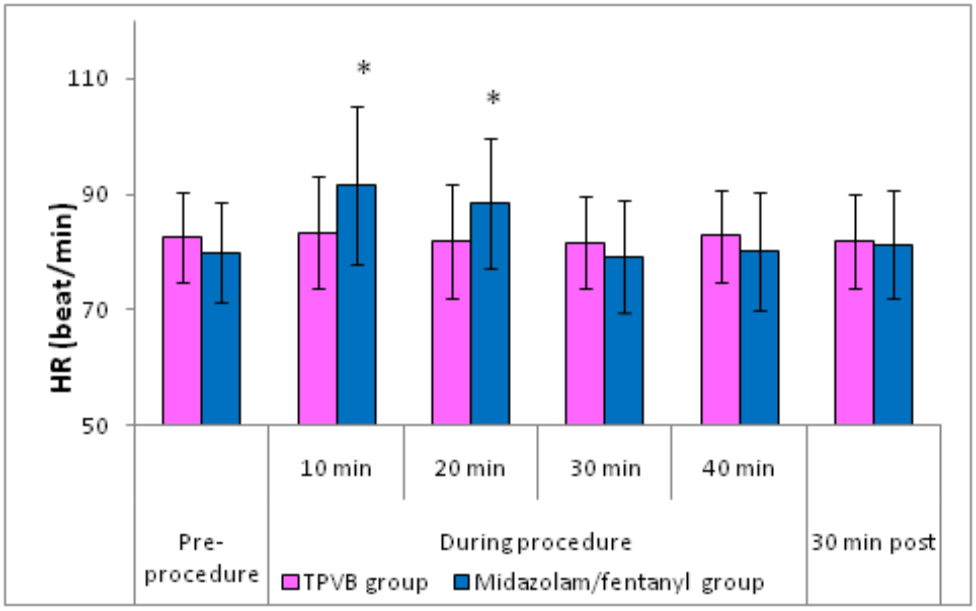

Fig. 5. Heart rate changes in both groups

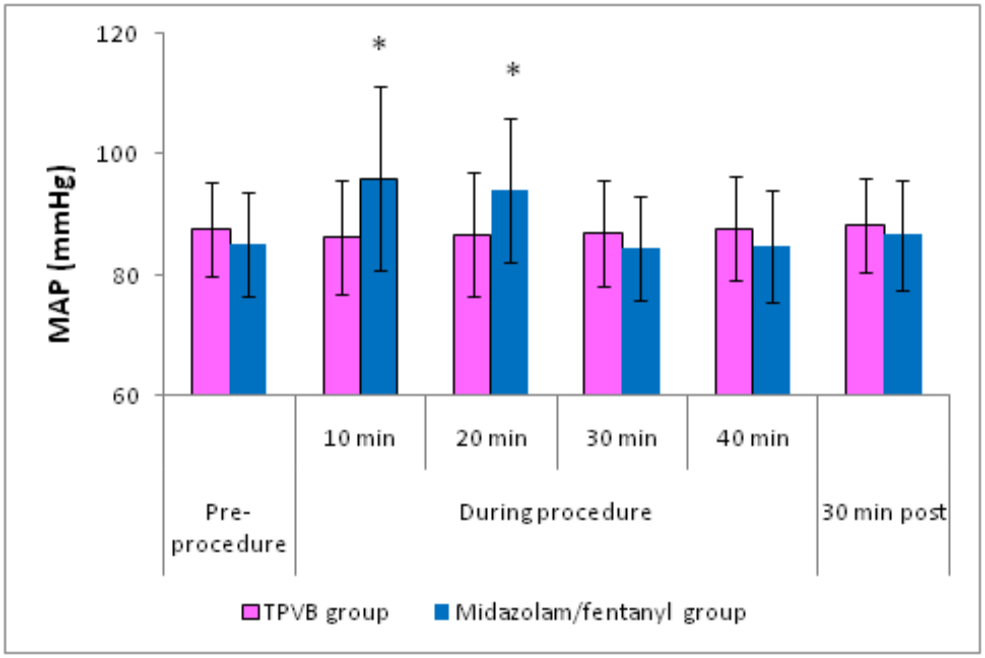

Fig. 6. Mean arterial blood pressure in both groups

The analgesic efficacy of TPVB in patients undergoing ESWL procedure had been proved by Hanoura et al. [16]. who evaluated the use of PVB as an alternative anesthetic technique for ESWL procedure. They carried out their study on 50 patients with renal stones, aged 20-60 years and randomly allocated into two groups. Group P (25 patients) received unilateral PVB (from T8 through L1) using 5 ml of 0.5% bupivacaine at each level. Group L (25 patients) received local infiltration by bupivacaine 0.25% (2 mg/kg) into the 30 cm^2 area around the posterior axillary line, beginning just above the last rib downward and including intradermal, subcutaneous, muscular and periosteal infiltration. They found that VAS was not significant different between both groups either intraoperative or postoperative in first hour. They concluded that PVB is an effective alternative anesthesia for outpatient lithotripsy and provides an optimal anesthetic condition,

with proper analgesia during the procedure and in first hour after finishing of the procedure without adverse events.

Moreover, Jamieson and Mariano, [17] reported the successful application of lumbar and TPVB modality for two outpatients lithotripsy with renal calculi. Preoperatively, PVB with 0.5% ropivacaine was placed with ultrasound and nerve stimulator guidance for two patients. One patient scheduled for cystoscopy and ureteroscopy with laser lithotripsy received general anesthesia intraoperatively. The second patient underwent ESWL with IV propofol IV sedation. They found that pain (VAS) scores of zero for 24 hours.

Concerning the ESWL success rate, our results found that the stone fragmentation success rate was insignificantly different between the ultrasound-guided TPVB and the IV midazolam / fentanyl.However, the number of ESWL sessions and time required for stone clearance were significantly reduced with the ultrasound-guided TPVB block. We could not find any study mentioning the advantage of TPVB in terms of reduced both number of shock sessions and time required for stone clearance. ESWL success rate is multi-factorial and depends on the performance of the lithotripter as well as on the size, location and composition of the stone and patient tolerability. These beneficial effects of TPVB may be due to proper pain relief during ESWL procedure that provides patients comfort, increases patients tolerability, and reduces pain- induced movements and excessive respiratory excursions leading to better targeting on the stone and significantly less wastage of shockwaves.

The proper pain relief during the ESWL procedure plays important role in the ESWL success rate. Gupta et al. [18] compared the influences of IV anesthesia versus local anesthesia on number of ESWL sessions. Their randomized study was performed on 60 patients with renal or upper ureteric solitary calculus in which ESWL was elected as the treatment. The patients allocated into two groups. Group I: in which patients underwent ESWL under IV anesthesia using IV midazolam, fentanyl (1 –2 ug/Kg) and propofol (1 –1.5 mg /kg) as bolus followed by infusion for maintenance (1 mg / Kg/hr). Group II: in which patients underwent ESWL under local anesthesia. They found that there was significant reduction in number of sessions required for complete stone clearance in IV anesthesia group.

Unfortunately, our study has some limitations. First, our study not double blinded. It seemed neither feasible nor realistic to blind the anesthetist monitoring the patient as well as the whole staff in the ESWL room. Second, the sample size is of limited number. Third, we did not check sensory dermatomal levels after local anesthetic injection to confirm the TPVB. Fourth, we did not perform a cost analysis to determine whether TPVB protocol was more cost effective or not.

5. CONCLUSION

Ultrasound-guided TPVB provided more effective analgesia with lower pain scores and lesser rescue analgesics consumption than IV midazolam/fentanyl in patients undergoing ESWL procedure. The effective analgesic effect of ultrasound-guided TPVB associated with reduced the number of ESWL sessions and time to stone clearance with better patient and operator satisfaction without serious side effects.

CONSENT AND ETHICAL APPROVAL

This prospective, randomized study was carried out in Tanta University Hospitals from June 2019 to May 2020.After approval of Institutional Ethical Committee (33079 / 04/ 19), a written informed consent was obtained from each patient.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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