Official Title

Ultrasound guided transversus abdominis plane block versus erector spinae plane block in patients undergoing emergency laparotomies

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Patients and methods

After obtaining Institutional Ethical Committee approval and written informed consent was obtained from all *patients*' *relatives*, this prospective randomized double blind controlled study conducted on 90 adult patients of both sex at El-Minia University Hospital in the period from july 2018 to june 2019 aged 20-50 years, of American Society of Anesthesiologists (ASA) physical status I Emergency to III Emegency, scheduled for emergency laparotomies under general anesthesia.

Exclusion criteria:

Patient refusal

History of allergy to the studied Drugs.

Opiod dependence.

Morbid obesity (BMI >40 kg/m^2).

Psychiatric and neurological disorders.

Bleeding disorders.

Skin lesion or wounds at the site of proposed needle insertion.

Major Organ dysfunction.

Failed block.

Patients remain intubated after surgery.

Preoperative management:

A careful medical history, through physical examination including: CNS, chest, heart, abdomen, lower limbs and back and necessary investigations were done such as complete blood picture, renal and liver function tests, random blood sugar, and electrocardiogram were performed and analyzed in detail prior to procedure.

We explained to the patients how to evaluate their own postoperative pain intensity using 10-point linear visual analogue scale (VAS), scored from 0-10 (where 0=no pain and 10=the worst pain). To score VAS, use a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the “no pain” anchor and the patient's mark.

Equipments and drugs used in the study (fig. 1):

1. Ultrasound machine and scanning probe, the used one was SONOSITE M-TURBO , the scanning probe was the linear multi- frequency 13-6 MHz transducer made in USA.
2. 22-gauge Quinke needle for skin infiltration manufactured by GMS in Egypt.
3. 10 mL syringes for injection.
4. Sterile gloves.
5. Sterile towels and gauze packs.
6. Sunnypivacaine 0.5% vial 20ml: 5mg in each 1ml (sunny pharmaceuticals).

Figure(1):sterile equipments and drugs used

Anesthetic management:

On arrival to the operating theatre, standard monitoring was applied including noninvasive blood pressure (NIBP), Electrocardiography (ECG) and pulse oximetry (NIHON KOHDEN) or (PHILIPS monitor, model: Efficia CM120). Then an intravenous 18 G cannula was inserted after sterilization of the skin and preloading with Ringer's lactate solution 10-15 ml/kg was given.

All patients received the same anesthetic technique; were premeditated by intravenous midazolam 0.05 mg/kg and fentanyl 1 μg/kg. Induction of anesthesia was accomplished by 2 mg/kg of 1% propofol followed by atracurium 0.5 mg/kg to facilitate tracheal intubation with an appropriate size cuffed endotracheal tube.

Anesthesia was maintained with inhalational isoflurane (MAC 1-1.5 in O2) and atracurium bolus 0.1 mg/kg. Mean arterial pressure, Heart rate (HR) SpO2 and end tidal CO_2($ETco_2$) were recorded before and after induction, after intubation and every 10 min intervals until the end of the operation. If hemodynamics increased more than 20 % of base line a rescue analgesia in the form of fentanyl (0.5 mic/kg) was given. Ventilation was controlled with tidal volume of 6-8 ml/kg and respiratory rate of 12-14 breaths/min. The ventilation parameters were adjusted to keep end-tidal CO_2 at 30-35 mmHg with PEEP of 3-5 cmH_2O and O_2 flow of 5 L /min. Intravenous fluid therapy was given according to the calculated formula (4/2/1 rule) per fasting hours for maintenance of fluid requirements, 4 ml/kg/h for third space loss and replacement of surgical bleeding if present.

Nasogastric tube was inserted for all patients after intubation and was removed at the end of the surgery Then, bilateral ultrasound guided TAP or ESP block was given according to groups**.** The surgical intervention was started 15 min after the block.

Before the end of the surgery, residual neuromuscular blockade was reversed with injection of neostigmine 0.05mg/kg and atropine 0.01mg/kg.

After full recovery, the patients were transferred to postoperative care unit and received postoperative care and monitoring of hemodynamics,

analgesics in the form paracetamol 15 mg/kg/6 hs IV (paracetamol 100ml 1%, Pharco B International) was given with a maximum dose of 90 mg/kg/day .

Study groups:

The patients were randomly allocated into three parallel equal groups (30 patients in each group) by using a computer-generated table. The patient and the staff providing the postoperative care were blinded to the group assignment.

Group A (Controlled group): anesthetized with the protocol followed by Minia University Hospital.

- **Group B (Transverse abdominis plane (TAP) block):** received ultrasound guided four quadrants injection TAP block using a bolus injection of 40 ml isobaric bupivacaine hydrochloride 0.25% before skin incision (10ml on each quadrant).
- **Group C (Erector Spinae Plane (*ESP*) *block*):** received ultrasound guided bilateral injection ESP block using a bolus injection of 40 ml isobaric bupivacaine hydrochloride 0.25% before skin incision (20 ml on each side).

Transverse abdominis plane (TAP) block

While positioning of the patient and sterilization of the site of the TAP block , the studied drugs were prepared in (10ml) syringes of total volume 40 ml. To perform posterior TAP, with the anesthetist standing on the same side of the injection, the ultrasound probe was prepared and was positioned on the abdominal wall in the mid-axillary line between the iliac crest and the costal margin and carefully moved postero-laterally for optimal identification of the transversus abdominis fascial plane **(fig. 2)**. The image produce showed

(from superficial to deep) skin and subcutaneous tissue, fat, external oblique, internal oblique, and transversus abdominis muscles, and lastly the peritoneum and bowel may be seen deep to the muscles. The 3 muscle layers can be seen running parallel to one another **(fig 4).** When an adequate ultrasound image was obtained, A 22-G 90-mm spinal needle attached with tubing system to a syringe filled with the local anesthetic was inserted anterior in-plane with the probe.

Once the tip of the needle was visualized to be in plane between the internal oblique and the transversus abdominis muscle and after careful aspiration to exclude vascular puncture,10 ml of the local anesthetic was slowly injected. If the needle was correctly positioned, the fascial plane was seen to separate (hydrodissection) and form a well-defined hypoechoic, elliptical shape between the internal oblique and transversus abdominis muscles. If a patchy opacity appears within the muscle either superficial or deep to the transversus abdominis plane, the needle should be repositioned until local anesthetic was seen to spread within the plane, separating the fascia between the muscles.

Then the ultrasound probe moved to be placed under the costal margin for subcostal TAP block which was performed in a similar manner then the TAP was performed on the opposite site by the same technique.

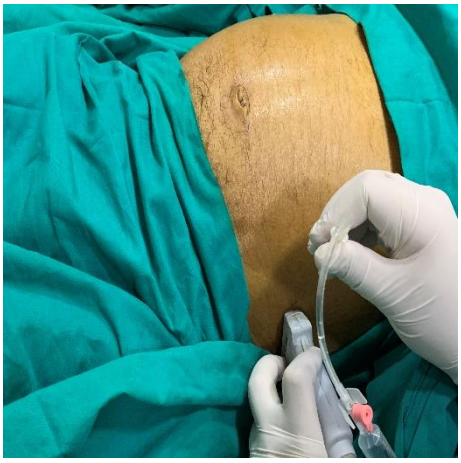


Figure 2 : Technique of TAPB (EL-Minia university hospital)

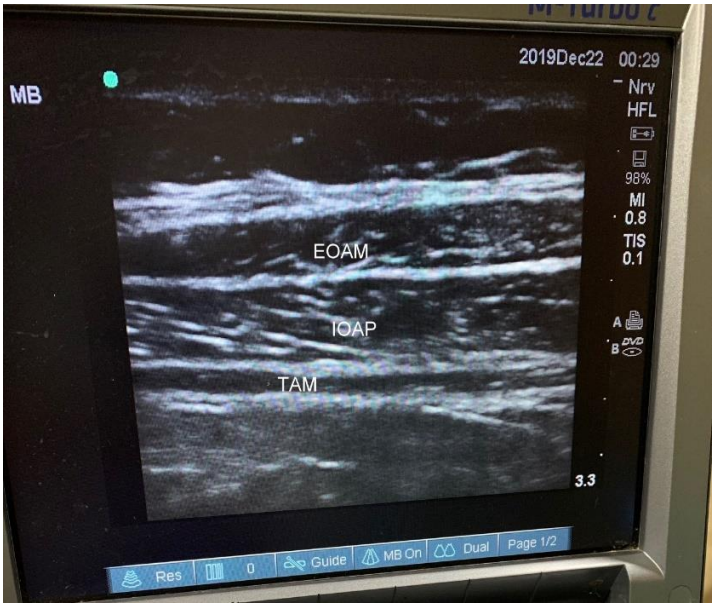


Figure 3: Ultrasound image of TAPB (EL-Minia university hospital)

Erector Spinae Plane (*ESP*) *block*

While on group (C), positioning of the patient on the lateral position, After identifying the level of the intervertebral space (inferior angle of scapula opposite to spinous process T7 or C7 most prominent spinous process downward to T8) and sterilization of the site of the ESP block, the studied drugs were prepared in (10ml) syringes of total volume 40 ml.

After identifying the level of the intervertebral space, the transverse process was traced laterally after identifying the spinous processes and lamina approximately 2.5–3 cm from midline in longitudinal position. The transverse process is identified as a hyperechoic curvilinear structure with pronounced finger-like acoustic shadowing beneath (trident sign) with lamina (sawtooth pattern) and spinous process medially and costochondral

junction laterally. The transverse process has a square contour as compared to rib with rounded contour. The image produce showed (from superficial to deep) skin and subcutaneous tissue, trapezius and erector spinae with simmering pleura in between the transverse processes **(fig. 4).**

The block was administered by in-plane technique using A 22-G 90-mm spinal needle (approximately 1–2 cm away from the probe and advance at a 30–45-degree angle towards the ultrasound beam) attached with tubing system to a syringe filled with the local anesthetic was inserted in cranial–caudad direction and the block needle was advanced through skin, S.C, the trapezius and erector spinae to gently contact transverse process. Needle placement was confirmed by hydrodissection on injecting 2–3 ml of normal saline. Then 20 ml of 0.25% bupivacaine was injected on both sides. On injecting 10 ml of 0.25% bupivacaine into interfascial plane deep to erector spinae, a visible linear pattern was visualized lifting the muscle.

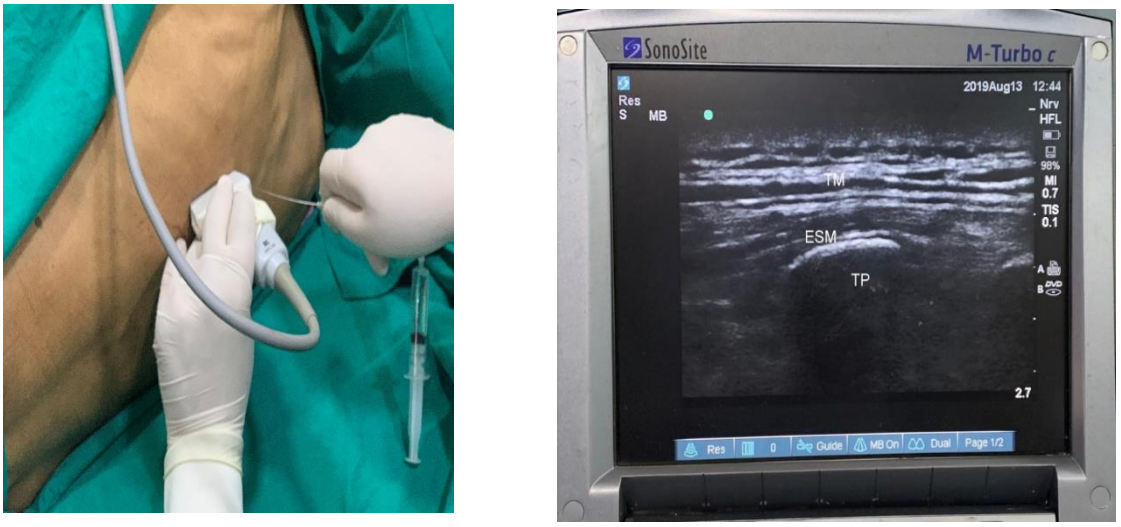


Figure 4 : Ultrasound image of ESPB (EL-Minia university hospital)

Parameters assessed & analyzed:

1. **Hemodynamics**

Basal MAP and HR after induction, at time of filteration, at 5, 10 ,15, 20, 30, 45, 1h, 1.5h, 2hrs and 2.5hrs after the block then heart rate and mean arterial pressure were recorded at 1,2,4,6,8,10,12,18,24 hrs post-operatively.

2. **Recovery score :**

The modified Aldrete scoring system for determining when patients are ready for discharge from the postanesthesia care unit

3. **Visual analogue pain score** (rest and dynamic):

Severity of pain was assessed using Visual Analogue pain scale (VAPS) ranging from 0 to 10. Pain assessment was done by the patients at rest and at movement (sitting position) at the following time points: at 1, 2, 4, 6, 8, 10, 12, 18 and 24 hrs Postoperatively after full recover .

If VAS was ≥4 at rest, rescue analgesia was given in the form intravenous fentanyl (Manuf pharmaceuticals. by sunny - Egypt, under license of Hameln pharmaceuticals- Germany) at 0.5µg/kg was given. Time of 1st analgesic request was recorded. If the analgesia was not adequate (VAS ≥4 for 20 min after fentanyl injection) another dose of fentanyl at 0.5µg/kg was given and total analgesic requirement of fentanyl were recorded.

4. **Time of first analgesic request.**

Defined as the time from the end of surgery until the first patient's request for analgesia; it was recorded and compared between groups.

5. **Patient satisfaction:**

According to patient satisfaction score which is a measure of overall satisfaction with the quality of analgesia provided by asking the patient to rate their satisfaction level based on score 1-4 satisfaction score criteria

(4) Excellent = No complaint from the patient

(3) Good = Minor complaint with no need for analgesia

(2) Fair = Complaint which required supplemental analgesia

(1) Bad = Patient given maximal dose analgesia.

6. **Total analgesic requirement** over 1st 24 h

The total amount of fentanyl (postoperative) was given to the patients as rescue analgesia during 24 hours.

7. **Incidence of any side effect:**

Incidence of post-operative complications related to the drugs or technique as

- Postoperative nausea and vomiting: The severity of postoperative nausea and vomiting (PONV) was graded on a four-point ordinal scale (I) not at all, (II) sometimes, (III) often or most of the time, and (IV) all of the time with vomiting **(Myles & Wengritzky, 2012)**. Rescue antiemetic ondansetron 4 mg IV was given to all patients with PONV score more than II.
- Itching
- Urinary retention
- Bradycardia and hypotension
- Respiratory depression
- Technique related complications as hematoma formation at the injection site, vascular or lymphatic injury, neurologic symptoms and local anesthetic toxicity

The study outcome

- **Primary outcome:**

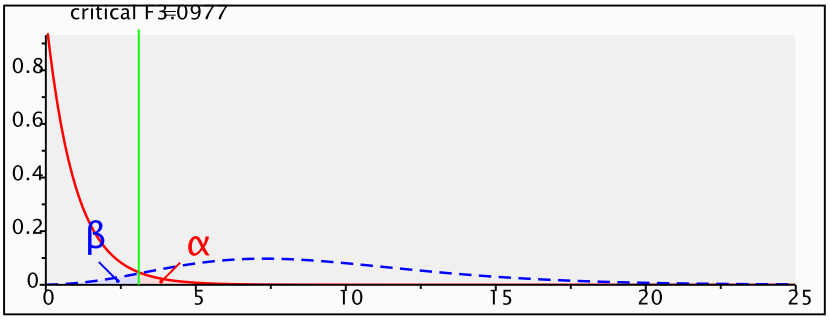
Our primary outcomes were to evaluate pain score (VAPS)t rest and at movement (sitting position)

- **Secondary outcome:**

Our secondary outcomes were to assess post-operative analgesia in the form of time of first analgesic request and total analgesic requirements, hemodynamics, patient satisfaction and side effects or complications.

Sample Size Calculation:

Before the study, the number of patients required in each group was determined after a power calculation according to data obtained Pilot study (6 patients within each group). In that study, mean VAS at 24 in group A was 3.16, in group B was 2.5 and in the group C was 2.16; (with SD = 1 in each group). A sample size of **31** patient in each group was determined to provide 95% power for one way ANOVA test at the level of 0.05 significance using G Power 3.1 9.2 software.



Test family: F tests
Statistical test: ANOVA: Fixed effects, omnibus, one-way

Type of power analysis: A priori: Compute required sample size

Input parameters:	**Output parameters:**
Effect size f =0.4151573	Noncentrality parameter ë= 16.0290693
á err prob =0.05	Critical F=3.0976980
Power (1-â err prob)=0.95	Numerator df=2
Number of groups=3	Denominator df=90
	Total sample size=93
	Actual power=0.9507147

Statistical analysis

The analysis of the data was carried out using the IBM SPSS 20.0 statistical package software. Data were expressed as mean±SD, minimum and maximum of range for quantitative parametric measures or median and interquartile range (IQR) in quantitative non-parametric measures in addition to both number and percentage for categorized data.

Analysis of variance (ANOVA) was used for comparison between independent groups for parametric data followed by LSD post hoc test to assess

intergroup differences, Kruskal Wallis test for non-parametric quantitative data followed by Mann Whitney test to compare each two groups and the Chi-square *test or Fisher's exact test* were used to compare categorical variables.

Analyses were done for parametric quantitative data within each group using paired sample t test, and for non-parametric quantitative data using Wilcoxon signed rank test.

A *P*-value of 0.05 or less was considered significant, whereas values 0.01 and 0.001 were considered highly significant.