The Postoperative Analgesic Effect of Ultrasound-Guided Bilateral Erector Spinae Plane Block versus Bilateral Rectus Sheath Block in adults undergoing Lower Midline Abdominal Surgeries: Randomized Controlled Trial

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Abstract
Background: This study aimed to compare the ultrasound guided ESPB to RSB block in the duration of postoperative analgesia, pain scores and side effects after lower midline abdominal surgery. **Methods:** Adult patients undergoing lower midline abdominal surgeries under general anesthesia were randomized to receive either ultrasound guided bilateral ESPB (ESBP group n= 27) or RSB (RSB group n= 30) before induction of anesthesia. The primary outcome was the time to first request of analgesia, Other outcomes included: total morphine consumption, VAS, perioperative hemodynamics and incidence of complications related to the block. **Results:** The time to first request of analgesia was significantly longer in ESPB group (517.3 ± 49.9) min. compared to RSB group (344.2 ± 54.4) min. The mean difference± standard error (173.1± 13.9 min, 95% confidence interval CI **[**145.3, 201**]**), *P* = 0.001. Postoperative morphine consumption and VAS in ESBP were significantly lower than RSB group. There were no recorded perioperative complications related to the blocks in both groups. **Conclusion:** In adult patients undergoing lower abdominal midline surgeries, the ESPB had a better postoperative analgesic effect and significantly reduced the amount of opioids consumption for up to 24 hours postoperative compared to RSB. Registration URL: https://clinicaltrials.gov/ct2/show/NCT04229420.
Keywords: Ultrasound; pain; Erector Spinae; Rectus Sheath; postoperative; analgesia; abdominal surgeries.

Introduction:

Since the introduction of enhanced recovery after surgery (ERAS) in colorectal surgeries; ERAS programs had gained popularity and acceptance in almost all surgical subspecialties. One of the cornerstones of the ERAS is multimodal analgesia particularly thoracic epidural analgesia (TEA) in abdominal surgeries due to adequate post-operative analgesia provided by TEA which reduces the stress response, improves bowel function, allows early mobilization and reduces hospital stay **(1)**.

The role of TEA in ERAS programs had been questioned lately due to potentially rare but catastrophic neurologic complications as epidural hematoma, abscess and neve injuries **(2)**. Moreover, motor blockade of the lower limbs, urine retention requiring catheterization and hypotension caused by the neuraxial block can prevent the privilege of early ambulation and recovery provided by the better quality of analgesia of TEA **(3)**.

Ultrasound guided fascial plane blocks of the abdominal wall can provide good analgesia for abdominal surgeries without significant hemodynamic effects and avoiding the potential neurologic complications of neuraxial blocks **(4)**.

The rectus sheath block (RSB) is a technique that was described for variety of surgical incisions **(5)**, while the erector spinae plane block (ESPB) is a new technique that was first described for the treatment of chronic thoracic neuropathic pain **(6)**, however, the ESPB has been used successfully to provide analgesia for abdominal surgeries **(7)**.

To our knowledge comparison of post-operative pain management of both ESPB and RSB in adults undergoing lower midline abdominal surgery has not been investigated before.

This randomized, controlled trial aimed to compare the ultrasound guided ESPB to RSB block in the duration of postoperative analgesia, pain scores and side effects after lower midline abdominal surgery.

We hypothesize that ESPB would be more effective in preventing postoperative pain following midline abdominal surgeries with minimal motor affection and postoperative morphine consumption compared to RSB block.

Methods:

This Prospective randomized controlled study was conducted at general surgery operating theatres at a university hospital after approval of institutional scientific and Research Ethics Committee (N-79- 2019/ MD) between February 2020 and March 2021. The study was registered at clinicaltrials.gov registry system. Written informed consent was obtained from all participants before enrolment. An online randomization program (http://www.randomizer.org) was used to generate random list and to allocate patients into two study groups. The study included adult's American society of anesthesiology physical status I, II, aged 18 to 60 years of both sexes presented for lower midline abdominal surgeries under general anaesthesia. Patients were excluded from the study if they had: coagulation disorders (Platelets $\leq$ 50,000 and/or INR> 1.5), history of allergy to local anaesthetics, rash or signs of infection at the injection site, refused to participate or emergency surgery.

Before start of anaesthesia, envelopes were opened by a research assistant who was not involved in the study. The instructions were given to the attending anaesthetist performing the block who was not involved in the data collection.

On arrival of the patients to preparation room, 20-gauge intravenous (IV) cannula was inserted and midazolam 0.02mg/kg IV and ondansetron 8 mg slowly IV were given.

After basic monitoring, all patients receive a standardized anaesthetic induction with 2mcg/kg fentanyl, 2-3 mg/kg propofol, and 0.5 mg/kg atracurium. Mechanical ventilation was adjusted to maintain an end tidal CO2 between (30 - 40 mmHg). Maintenance was achieved with oxygen/air with isoflurane 1.2% and atracurium infusion at a dose of 0.5 mg/kg/h.

Following induction of anaesthesia patients were divided into two equal groups; group 1 received pre-incisional ultrasound (US) guided bilateral RSB using 20 mL volume of bupivacaine 0.25% for each side, and group 2 received pre-incisional US guided bilateral ESPB using 20 mL volume of bupivacaine 0.25% for each side. Both

blocks were performed by an experienced anaesthesiologist in fascial plane blocks who was not involved in the data collection.

RSB group: After preparing the skin with povidone iodine, a high frequency (5–10 MHz) ultrasound probe (S-NerveTM; SonoSite Inc., Bothell, WA, USA) was placed in a longitudinal orientation above the level of the umbilicus with the patient in the supine position. After identifying the rectus abdominis muscle, A 22 G echogenic needle using the in plane technique was inserted just below the costal margin at an angle of approximately 45 degrees to the skin, then, a total of 20 mL of 0.25% bupivacaine was injected into the plane between the rectus muscle and posterior rectus sheath and the same technique was repeated on the other side.

ESPB group: After induction of anaesthesia; the patient was positioned on the lateral position. After skin preparation with povidone iodine, a high frequency (5–10 MHz) ultrasound probe (S-NerveTM; SonoSite Inc., Bothell, WA, USA) was placed in a transverse orientation at the level of T9 spinous process which was located by palpating and counting down from the C7 spinous process. The tip of the T9 transverse process was identified and centred on the ultrasound screen, the probe was then be rotated into a longitudinal orientation to produce a parasagittal view. A 22 G echogenic needle using the in plane technique was inserted and correct location of the needle tip in the fascial plane deep to erector spinae muscle was confirmed by injecting 0.5–1 mL saline and seeing the fluid lifting the erector spinae muscle off the transverse process while not distending the muscle. A total of 20 mL of 0.25% bupivacaine was then be injected into the ESP of each side.

Intraoperative increase of the heart rate and or the mean arterial blood pressure of >20% above the preoperative baseline was managed using 0.5-1 μg/kg of IV fentanyl.

Postoperatively, patients received 1 g paracetamol every 6 h and 30 mg ketorolac every 12 h.

If the visual analogue scale (VAS) is ≥ 4, a morphine increment (2 mg) IV was given and could be repeated every 5 minutes with a maximum dose of 15 mg per 4 hours or 45 mg per 24 hours to maintain a resting VAS at < 4 and the total 24 hours morphine consumption was recorded. Patients who required more than two doses of rescue analgesia in the first hour postoperatively are considered failure of the block and removed from the study.

The primary outcome of the study was the time to first request of rescue postoperative analgesic defined as the time interval between the block performance and the first request to postoperative analgesia and or VAS ≥ 4. Secondary outcomes included: postoperative pain score assessed by VAS at 30 and 60 minutes in the post anaesthesia care unit (PACU) then every 6 hours in the ward for 24 hours, cumulative postoperative opioids for 24 hours, Hemodynamic parameters: heart rate and mean arterial blood pressure recorded at the following intervals: baseline, then every 30 minutes until the patient is extubated, at 30 and 60 minutes in the PACU then every 6 hours postoperative for 24 hours, Block performance time in min (time from probe contact with skin till needle withdrawal) and incidence of perioperative complications (Postoperative nausea and vomiting, hematoma and local anaesthesia toxicity).

Sample size: Based on a previous study Yassin, Abd Elmoneim and El Moutaz, **(8)** sample size calculation was done using time to first request of morphine rescue analgesic as the primary outcome. The time to first request of morphine was (208.82 ± 64.65 minutes) in the RSB group; assuming a mean difference of 25% and for a power of 0.8 and an alpha error of 0.05; a minimum of 52 patients was calculated for both groups. A 15% increase was made to compensate for possible dropouts

therefore; a total of 60 patients (30 in each group) was required. Sample-size calculation was calculated using G*Power 3 software.

Statistical analysis: The Statistical Package of Social Science software program (SPSS), version 21 (Chicago, IL, USA) was used for all statistical comparisons. Continuous quantitative normally distributed data was expressed as means and standard deviations (SD), while non-normally distributed data was expressed as median and range. Qualitative nominal data was expressed as frequency and percentage. After testing for normality, continuous variables were compared using t-test or Mann-Whitney U test as appropriate. Categorical variables were compared using Chi- squared test or Fisher's exact test as appropriate. Repeated measures ANOVA with Bonferroni correction was used to compare measurement changes over time. A p-value <0.05 was considered statistically significant.

Results:

Sixty-four adults were eligible for the study, sixty patients were randomized to receive one of the two interventions. Seven were excluded due to lost follow up (one patient died postoperative, 2 were on mechanical ventilation and 4 had failed block). Fifty-three patients were available for final analysis (figure 1). Demographic data and baseline characteristics were comparable between both study groups (table 1).

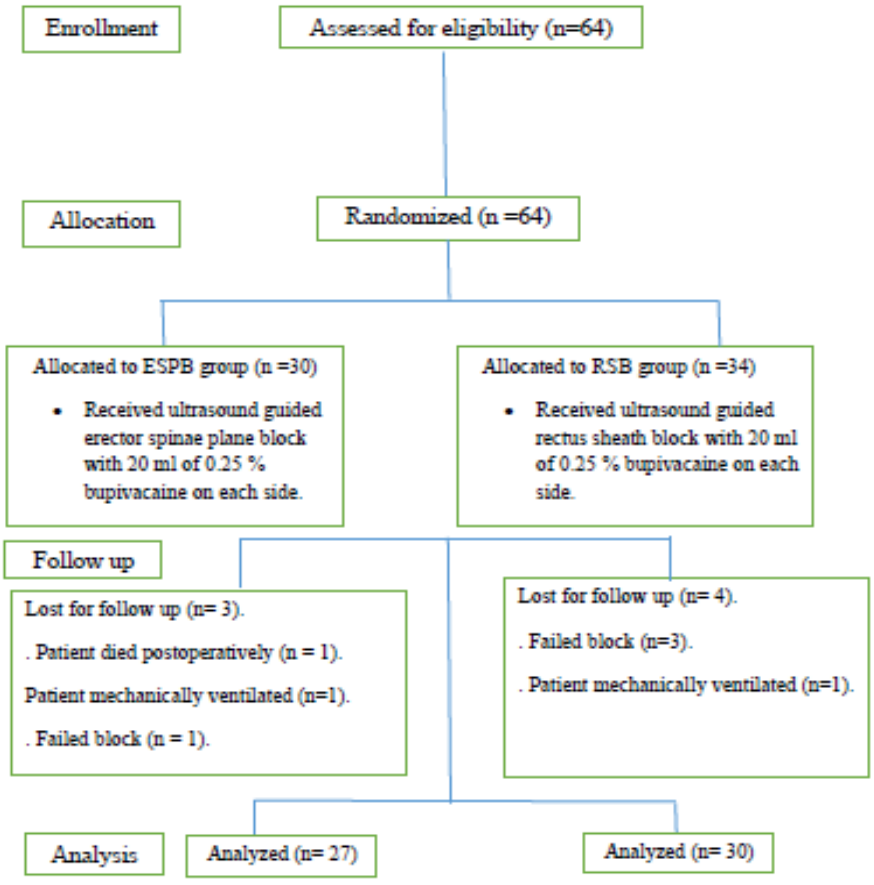

Figure 1: Flow chart showing patients' enrollment

Table 1: Patients demographics and characteristics: The data are expressed as mean ±SD, frequency & percentage or median (Q1, Q3).

	ESPB group (n=27)	**RSB group (n=30)**	**Standardized difference [a]**	**95% confidence interval**

Gender (male)	11 (42.3%)	15 (57.7%)	0.18	(-0.3, 0.7)
Age (years)	57.6 ± 14	57.7 ± 14.8	-0.007	(-0.5, 0.5)
Weight (kg)	82.6 ±14.6	81.7±14.6	0.06	(-0.46, 0.6)
Height (cm)	171.6 ±6.8	170.9 ±6.9	0.11	(-0.4, 0.63)
ASA classification			0.17	(-0.12, 0.9)
ASA I	4 (7%)	8 (14%)		
ASA II	21(36.8%)	22 (38.6%)		
ASA III	2 (3.5%)	0		
Type of surgery			0.15	(-0.2, 0.8)
Colectomy	10 (17.5 %)	15 (26.3 %)		
Hernia repair	11(19 %)	11 (19.3 %)		
Others	6 (10.5 %)	4 (7.0%)		
Duration of surgery (min)	153 (94-177)	124.5 (94.75-153)	0.24	(-0.11, 0.95)

Abbreviations: ESPB: erector spinae plane block, RSB: rectus sheath block, ASA: American society of anesthesiology, Q1: first quartile and Q3: third quartile.

[a] Standardized difference was calculated using Cohen d; and the difference in means or proportions was divided by the pooled standard deviation.

The primary outcome was time to first request of rescue analgesia. The time to first request of analgesia was significantly longer in ESPB group (517.3 ± 49.9) min. compared to RSB group (344.2 ± 54.4) min. The mean difference± standard error (173.1± 13.9 min, 95% confidence interval CI **[**145.3, 201**]**), *P* = 0.001.

The time to first request of rescue analgesia was further assessed using survival analysis which showed a significant difference between both groups (log-rank test *P*= 0.0001) figure 2.

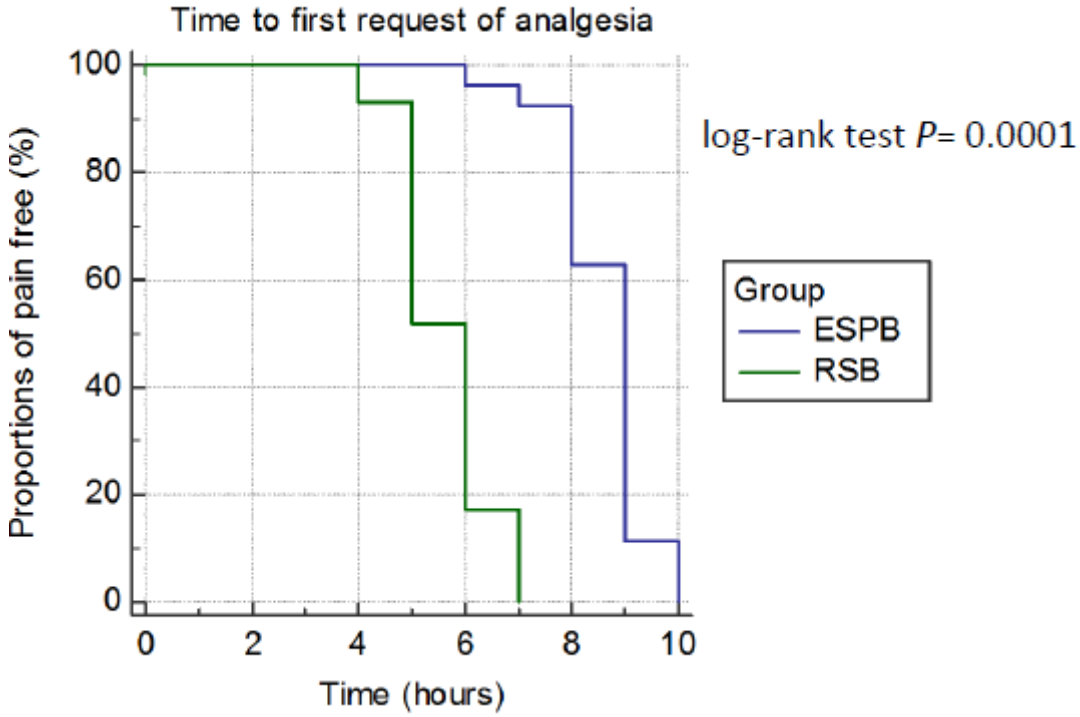

Figure 2: Kaplan–Meier survival curve showing the time to first request of rescue analgesia

The median (Q1, Q3) of the total morphine consumption in 24 hours was lower in ESPB group than RSB group {4 (4,5) mg vs 6 (6,8) mg**}** respectively, *P* =0.001.

There was significant reduction in VAS score in ESPB group than RSPB group up to 18 hours postoperatively (table 2).

Table 2: Postoperative VAS for the two groups, data are expressed as median (Q1, Q3).

Time	ESPB group (1) (n=27)	RSB group (2) (n=30)	P-value
VAS 0.5h	0.7 (0.5 - 1.4)	1.6 (1.4 - 2.4)	0.001*
VAS 1h	1.6 (1.4 - 2.4)	2.4 (2.4 - 2.7)	0.001*
VAS 6h	2.4 (2.4-3.2)	3.5 (3.4 - 4.4)	0.001*
VAS 12h	3.4 (3-3.7)	3.5 (3.4 - 3.6)	0.403
VAS 18h	2.6 (2.4-3.4)	3.4 (2.7 - 3.6)	0.021*
VAS 24h	1.7 (1.5 - 2.7)	2.45 (2.15 - 2.975)	0.126

VAS: visual analogue scale, h: hour, ESPB: erector spinae plane block, RSB: rectus sheath block.
* denotes statistical significance.

Mean arterial pressure MAP was significantly lower in ESBP group compared to RSB group in most of the intraoperative time (figure 3), while perioperative heart rate and postoperative MAP were comparable between both groups.

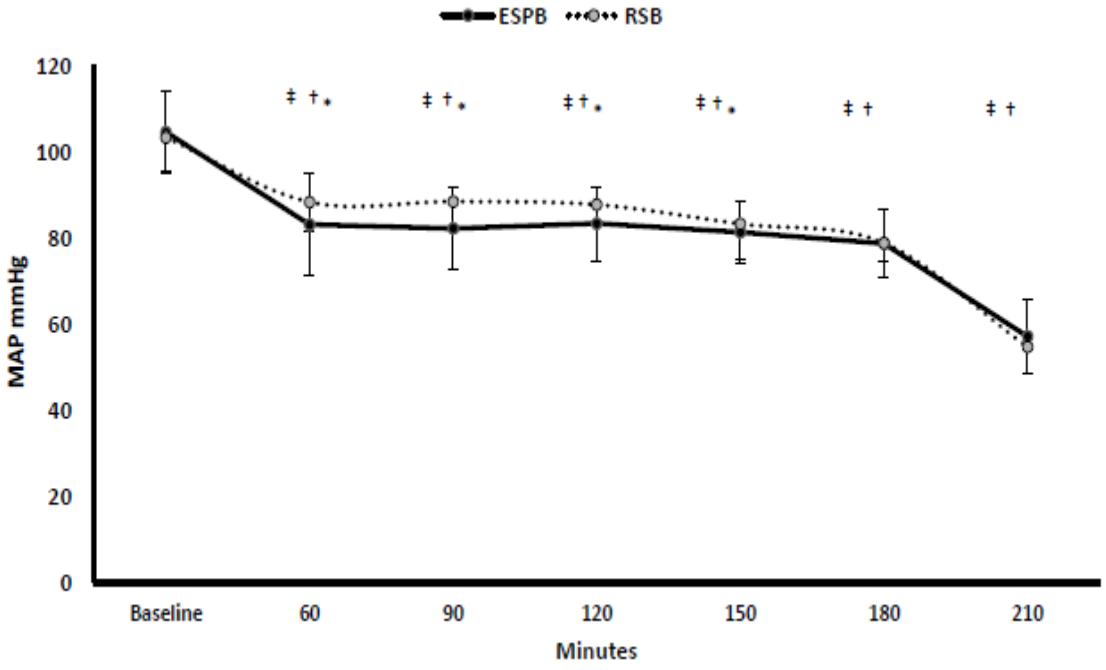

Figure 3: Intraoperative mean arterial pressure in both groups. mean arterial pressure MAP, ESBP: erector spinae plane block, RSB: rectus sheath block, * denotes significance between the 2 groups, †denotes significance compared to the baseline reading within ESPB group, ‡denotes significance compared to the baseline reading within RSB group.

PONV was slightly lower in ESPB group compared to RSPB group {(4/27) **[**7.5%**]** vs (10/26) **[**18.8%**]** **}**respectively, $P = 0.1$.

The block failure rate was lower in ESPB group as 1 (3.7%) compared to RSPB group 3 (11.5%).

There were no recorded perioperative complications related to the blocks in both groups.

Discussion:

Our study is the first to compare both ESPB and RSB in adults undergoing lower abdominal surgeries through midline incisions. We have found a significant reduction in the time to first request of morphine analgesia, VAS, and the total morphine consumption in the first 24 hours postoperative denoting better analgesic profile in patients who received ESBP. This effect could be related to the potential dense and widespread sensory block of both somatic and visceral fibres in ESPB Chin, Adhikary and Forero, (9) unlike the RSB which blocks only the somatic nerves of the anterior abdominal wall.

ESPB is a relatively new fascial plane block, however, it had been experimented against different regional techniques in adult patients having abdominal, thoracic and cardiac surgeries Chin *et al.*, (10); Nagaraja *et al.*, (11); Kot *et al.*, (12). Only one previous trial compared the effect of bilateral RSB vs ESPB in adults undergoing laparoscopic cholecystectomy Kwon *et al.*, (13). They reported lower perioperative opioid consumption in the ESPB group compared to RSB group but the numerical rating score for pain was almost the same in both group unlike our results probably due to minimal surgical laparoscopic and hence, less painful incisions compared to laparotomy incisions.

The erector spinae block involves a group of muscles that are connected with a complex sheath extending from the base of the skull to the sacrum allowing the potential analgesic effect in thoracic, abdominal and lower limb surgeries Chin, Adhikary and Forero, (9). There is evidence that the ESPB could reach the paravertebral space and lateral thoracic nerves through the superior costo-transverse ligament Yang *et al.*, (14) which could explain the dense somatic and visceral analgesic effects of the ESBP. The quality of ESPB analgesia was even better than the traditional TEA in donors for liver transplantation Zubair *et al.*, (15). Our study did not report any perioperative complications related to both blocks. The role of classic TEA as an integral part of ERAS in perioperative analgesia has been questioned over the past few years due to the potential catastrophic complications Cook, Counsell and Wildsmith, (16). There is a recent paradigm shift in the ERAS guidelines towards less invasive and probably equivalent to TEA as paravertebral block Slinger and Naidu, (17). Therefore, the safe, relatively simple and effective ESBP could have a role as a part of multimodal analgesia in the ERAS programs.

Our study reported inferior analgesic profile of RSB compared to ESPB. The RSB has provided better pain control in patients undergoing abdominal surgeries Kartalov *et al.*, (18); Wang *et al.*, (19) compared to the standard of care. However, studies comparing RSB effect against TEA in abdominal surgeries showed conflicting results regarding the analgesic effect of RSB compared to the standard TEA Godden *et al.*, (20); Yassin, Abd Elmoneim and El Moutaz, (8) . A recent large trial Krige *et al.*, (21) have shown superior analgesic effect of the TEA for up to 24 hours postoperative. The better opioid sparing effect of TEA is probably attributed to the dense visceral and somatic analgesic effect of neuraxial block unlike the RSB which blocks the somatic sensory nerves of the anterior abdominal wall only.

Study limitations: Our study has some limitations: first, it is a single centre study with relatively small sample size. Second, as the blocks were done under general anaesthesia, the sensory distribution of both blocks could not have been checked.

Conclusion:

In adult patients undergoing major abdominal surgery through midline incisions the ESPB has a better postoperative analgesic effect and significantly reduced the amount

of opioids consumption for up to 12 hours postoperative compared to RSBP. Both blocks were safe, and no perioperative complications were encountered.

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Declarations
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Authors' contribution:
Khaled Abdelfattah Sarhan: this author helped in study design, acquisition of data, statistical analysis and drafting the manuscript.
Alsayed Mohamed Rabea Alkashawy: this author helped in study design, acquisition of data, and drafting the manuscript.
Mohamed Ahmed Mansour: this author helped in study design and drafting the manuscript.
Maher Fawzy Mahmoud: this is the senior author who helped in conception of the idea, study design, analysis of the data, drafting and revising the manuscript.
Heba Raafat: this author helped in the data analysis and drafting the manuscript.
Dear Sir
We have the honor to submit our article entitled "**The Postoperative Analgesic Effect of Ultrasound-Guided Bilateral Erector Spinae Plane Block versus Bilateral Rectus Sheath Block in adults undergoing Lower Midline Abdominal Surgeries: Randomized Controlled Trial."** in your respectable journal. We certify that the material has not been published, either in whole or in part, and is not under consideration for publication elsewhere. We certify that this work does not violate any trademark registrations nor the right of privacy of any person, contains no libelous, obscene, or other unlawful matter. We certify that there is no conflict of interest of any of the contributing author with any company. We certify no grant or fund was received.
The corresponding author: Khaled Sarhan

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