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ORIGINAL RESEARCH **REGIONAL ANESTHESIA**

Efficacy of ultrasound guided rectus sheath block on the postoperative quality of recovery in laparotomy surgeries; a randomized control trial

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ABSTRACT

Background: Recovery after surgery and anesthesia is a complex process therefore a variety of measurement tools have been developed such as QoR-40 and QoR-15 questionnaires to assess quality of recovery. We assessed the opioid sparing effect of rectus sheath (RS) blocks in improving the quality of recovery following midline laparotomy surgeries.

Methodology: A randomized, controlled, open-labelled trial was conducted in the General surgery unit. Adult patients scheduled for elective midline laparotomy surgery under general anesthesia were included. Patients were divided into two groups: LA group and control group. Patients in the LA group received ultrasound guided, bilateral rectus sheath block, while patients in the control group received patient-controlled analgesia for postoperative control.

Results: Fifty-two patients were screened for eligibility. Median (range) aggregated global QoR-15 scores at 24 h were significantly greater in the LA group, indicating good quality of recovery compared with the control group; 107 (101-112) vs. 72 (68-74) with $P < 0.001$. In addition, pain profile was better in the LA group as 10 out of 24 (41%) Patients in the LA group required additional boluses of morphine during the 24-h period compared to 100% of patients in the control group ($P < 0.001$).

Conclusion: Ultrasound guided rectus sheath block provides better quality of recovery profile in midline laparotomy compared to opioids.

Abbreviations: ERAS - Enhanced Recovery After Surgery; LA - Local Anesthetic; RS - Rectus Sheath; RSB - Rectus Sheath Block; US - Ultrasound; QoR-15 - Quality of Recovery-15 Questionnaire; QoR-40 - Quality of Recovery-40 Questionnaire.

Preregistration: The trial was registered on ClinicalTrials.gov (NCT05244746) after obtaining Ethical committee approval at Kasr AlAiny Cairo University (code:MS-202-2021).

Keywords: Anesthesia Recovery Period; laparotomy; Nerve Block.

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1. INTRODUCTION

The recovery process after surgery and anesthesia is complex and depends on various factors such as the patient, surgical procedure, and anesthetic used. Most studies focus on post-operative pain and adverse events, but fail to consider the patient's perspective on quality of recovery (QoR). To address this, measurement tools like QoR-40 and QoR-15 questionnaires have been developed.[1-4]

The most common method to control pain control is opioids. Opioids are commonly used for pain control but can cause side effects like reduced bowel motility, hindering early mobilization and feeding.[5] Therefore, multimodal opioid sparing analgesia such as regional anesthesia is encouraged in the enhanced recovery after surgery ERAS programs, especially for abdominal surgeries.[6]

Regional anesthesia techniques like ultrasound-guided rectus sheath block (RSB) provide better pain control and QoR compared to systemic analgesics.[7] Ultrasound guidance improves safety and quality of regional blocks by ensuring optimal needle placement. Ultrasound-guided RSB is an emerging anesthetic technique providing excellent analgesia after laparotomy. The anatomic characteristics of this block favor minimal likely serious complications, and this regional block is particularly useful where epidural is contraindicated.[8]

The purpose of this study is to assess the opioid sparing effect of RS blocks in improving the QoR following midline laparotomy surgeries.

2. METHODOLOGY

A randomized, controlled, open-labelled trial was conducted in the General surgery unit, after the approval of the Ethical committee (code:MS-202-2021), clinical trial registered (NCT05244746), the initial release was on 11/2/2022. The study adhered to CONSORT guidelines. The study was conducted from March 2022 to July 2022. The procedure was explained to the patients, written informed consent was obtained from the patients involved in the study. All methods were carried out in accordance with relevant guidelines and regulations.

Adult patients aged 18-60 y old with ASA physical status I or II scheduled for elective midline laparotomy surgery under general anesthesia were included.

Our exclusion criteria included patient refusal, body mass index (BMI) $\leq$ 18.5 kg/m^2 or $\geq$ 40 kg/m^2, Coagulopathy (international normalized ratio > 1.5), previous laparotomy, known sensitivity or contraindication to drugs used in the study (local anesthetics, opioids), history of psychological disorders and/or chronic pain syndrome.

Randomization was achieved by a statistician using an online random number generator. Patient codes were placed into sequentially-numbered sealed opaque envelopes by a research assistant who was not involved in the study. An anesthesia resident not involved in patient management was responsible for opening the envelope.

Anesthesia was standardized to all patients. Electrocardiography, non-invasive blood pressure, peripheral oxygen saturation and end tidal carbon dioxide were applied throughout the duration of the surgical procedure. Induction of general anesthesia was performed using a regimen of fentanyl 2 µg/kg and propofol 2-3 mg/kg IV. Tracheal intubation was facilitated using atracurium 0.5 mg/kg. Anesthesia was maintained with inhaled agent (isoflurane) in oxygen enriched air (FiO_2 50%). Maintenance doses of atracurium 0.1 mg/kg was given every 20-30 min.

At incision, paracetamol 0.5-1.0 g infusion was administered, followed by morphine 0.05 mg/kg IV after 30-45 min, provided as a part of multimodal analgesia. Rescue analgesia with fentanyl 1 µg/kg was used if the mean arterial blood pressure or heart rate rose above 20% of the baseline values.

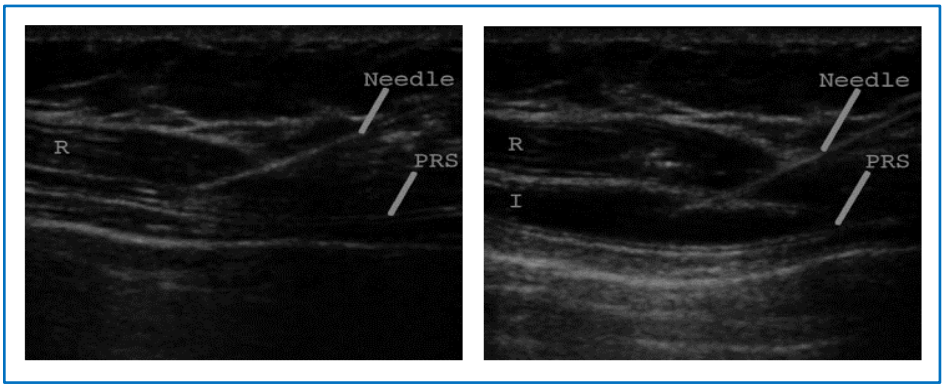

Figure 1: The first ultrasound image shows a needle with the needle tip positioned below the rectus muscle. The second ultrasound image is 1 second later as local anesthetic is injected to lift the rectus muscle off the posterior rectus sheath (PRS). R= rectus muscle

Ringer acetate was infused to replace the fluid deficit, maintenance and losses, and the patients were mechanically ventilated at appropriate settings to keep end-tidal CO_2 at 30-35 mmHg.

At the end of surgery, patients were divided into two groups.

1. Local anesthetic group (LA group) (n = 24): patients in this group received ultrasound-guided RSB with bupivacaine with repeated boluses every 6 h.

2. Control group (PCA group) (n = 24): patients received patient-controlled anesthesia (PCA).

In the LA group, after abdominal wall closure, the rectus muscle was imaged with the ultrasound probe of Mindray portable ultrasound unit (DP25) in a longitudinal orientation above the level of the umbilicus with the patient supine. A broadband (5-12 MHz) linear array probe was used, with an imaging depth of 4-6 cm. An 18G Tuohy needle was introduced in plane to the ultrasound probe just below the costal margin at an angle of approximately 45° to the skin. The ultrasound image allowed the identification of the rectus muscle and hyper-echoic twin lines deep to it (posterior rectus sheath and fascia transversalis) (Figure 1). Under direct vision the needle tip was advanced to the desired position, posterior to the rectus muscle and above the underlying rectus sheath. Injection of 20 mL bolus dose of 0.25% bupivacaine was given to hydro dissect the rectus muscle away from the posterior rectus sheath.

The catheter was inserted through the Tuohy needle and secured to the skin with 8 cm of it placed in the space. The depth of the catheter at the skin varied depending on the angle of insertion and the patient size, but it was typically 12-15 cm with an insertion point just below the costal margin, positioning the tip around the umbilical level. The technique was repeated on the opposite side. The study drug was administered through the catheter every 6 h for 24 h post-operatively, after which patients completed a QoR-15 questionnaire.

In the control group, patients were started morphine with PCA; 40 mg was diluted with normal saline to a total volume of 100 mL as background at 2 mL/h, the bolus doses given by the nurse were calculated.

All patients received paracetamol IV every 6 h and morphine if their VAS score exceeded 4.

The primary outcome measure was the QoR-15 score, which was administered by a blinded investigator at 24 h after surgery. The questionnaire consists of 15 questions that examine the quality of recovery using a ten-point Likert scale. Global QoR-15 scores range from 0-150 representing very poor to outstanding quality of recovery.[2]

The secondary end-points included the incidence of nausea, vomiting and the total analgesic consumption in the first 24 h. Postoperative pain was assessed by a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (worst imaginable pain) at 24 h after surgery.

2.1. Sample size

Our primary outcome was the QoR-15 score. In a previous study, the mean quality of recovery was (92.6 ± 6.6).[9] We calculated a sample size that could detect a mean difference of 10% between both study groups. MedCalc Software version 14 (MedCalc Software bvba, Ostend, Belgium) was used to calculate the sample size. 40 patients (20 patients per group) at least were estimated to have a study power of 95% and an alpha error of 0.05. This number was increased to 48 patients (24 patients per group) to compensate for possible drop-outs.

2,2, Statistical Analysis

SPSS software was used for data analysis. Categorical data were presented as frequencies (%) and analyzed using chi-square test. Continuous data were presented as means (standard deviations) or medians (quartiles) and were analyzed using unpaired t-test or Mann Whitney test as appropriate. Repeated measures were analyzed using two-way Analysis of Variance (ANOVA) test. A $P < 0.05$ was considered statistically significant.

3. RESULTS

Fifty-two patients were screened for eligibility. Four patients were excluded, 48 patients were recruited and randomized into LA group or PCA group. All patient data were used for final analysis (Figure 2).

Both groups were comparable regarding patients' demographic characteristics, and surgical and anesthetic data (Table (1 and 2).

Median (range) aggregated global QoR-15 scores at 24 h were significantly greater in the LA group, indicating

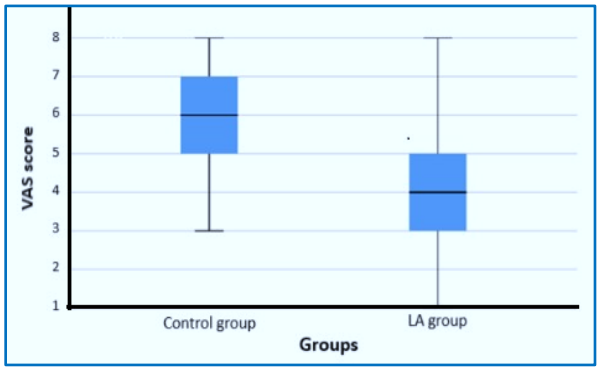

Figure 2: Box plot comparing the pain scores after 24 h

Table 1: Patients demographic data

Parameters	Control group (n = 24)	LA group (n = 24)	P value
Age (y)	39 ± 13	41 ± 9	0.157
Sex: Male	16 (66)	15 (62)	0.706
BMI (kg/m^2)	26.3 ± 3.5	24.4 ± 4.3	0.335
ASA I	12 (50)	18 (75)	0.074
ASA II	12 (50)	6 (25)	
Surgery duration (min)	172.2 ± 19.8	181.3 ± 17.7	0.192
Fentanyl dose (µg)	293 ± 70.3	291 ± 65.3	0.235

Data are shown as n (%) or mean ± SD; P < 0.05 is statistically significant

Table 2: Comparative types of operations

Types of operations	Control group (n = 24)	LA group (n = 24)	Total (n = 48)
Splenectomy	2 (8.3)	2 (8.3)	4 (16.7)
Sigmoidectomy	4 (16.7)	2 (8.3)	6 (25)
Perforated DU	0 (0.0)	2 (8.3)	2 (8.3)
Paraumbilical / incisional hernia	4 (16.7)	0 (0.0)	4 (16.7)
Hernioplasty	4 (16.7)	2 (8.3)	6 (25)
Epigastric hernia	2 (8.3)	0 (0.0)	2 (8.3)
Appendicular mass	2 (8.3)	0 (0.0)	2 (8.3)
Adhesive intestinal obstruction	0 (0.0)	2 (8.3)	2 (8.3)
Abdominal exploration	6 (25)	14 (58)	20 (83)

Data presented as n (%)

good quality of recovery compared with the control group; 107 (101-112) vs. 72 (68-74) respectively; (P < 0.001). Patients in the LA group had better median scores in the dimensions of physical comfort, physical independence, psychological support and emotional status when compared with the control group, except for the dimensions of general well-being, severe pain, and anxiety (Table 3).

The mean postoperative opioid consumption in the first 24 h post-operative was significantly more in the control group in comparison to LA group; 28.4 ± 3.9 mg vs 5.6 ± 1.4 mg, respectively (P < 0.001).

Ten out of 24 (41%) patients in the LA group and all patients in the control group required additional boluses of morphine during the 24-h period (P < 0.001).

The median VAS scores were lower at 24 h postoperatively in the LA group vs control group (P = 0.035) (Figure 2).

Being the 13th question in the QoR-15 questionnaire, nausea was evaluated from 0 to 10 where 10 was none of the time and 0 all of the time. There was significant difference between both study groups (P < 0.001).

Moreover, a significant difference in the frequency of nausea / vomiting was seen in the LA group vs the control group (P < 0.001).

4. DISCUSSION

Our research revealed that patients who received rectus sheath black had better quality of recovery scores compared to control group. Additionally, the use of RS catheters resulted in a significant reduction in pain and morphine consumption 24 h after abdominal surgery, as well as an improvement in morphine-related side effects like nausea and vomiting.

Recovery after surgery and anesthesia is a multifaceted process influenced by various factors, including patient, surgical, and anesthetic characteristics, as well as potential adverse outcomes. While previous studies have focused on physiological endpoints and adverse events, it's important to consider quality of recovery from the patient's perspective. To measure this, tools like the QoR-40 scoring system have been developed by Myles et al.[1] The QoR-15 is a simplified questionnaire, developed by Stark et al. and can be printed on a single page, read, and completed quickly. This minimizes the time required to train staff to use it and represents increased feasibility when compared to the lengthy and slightly more complex QoR-40.[2]

The QoR-15 is a useful tool for measuring a patient's postoperative recovery, as it is valid, reliable, responsive, and easy to use. Compared to the QoR-40, the QoR-15 provides a similarly comprehensive evaluation of a patient's quality of recovery after surgery but is more efficient. It can be used as an outcome measure in clinical trials and for quality assurance purposes.[3]

RSB has gained popularity for abdominal surgery in the era of fast-track day case surgery. It is aiming at deposition of local anesthetic (LA) in the virtual space between the posterior wall of the rectus abdominis

Table 3: Comparative QoR-15 scores in the two groups

Parameter	Control group (n = 24)	LA group (n = 24)	P value
1. Able to breathe easily	10 (9-10)	7 (6-8)	*0.001
2. Been able to enjoy food	6 (3-6)	3 (3-4)	*0.008
3. Feeling rested	8 (7-8)	5 (5-5)	*0.001
4. Have had a good sleep	7[7-7)	4 (3-6)	*0.001
5. Able to look after personal toilet and hygiene unaided	6 (4-6)	4 (4-5)	*0.008
6. Able to communicate with family or friends	8 (7-10)	6 (5-6)	*0.001
7. Getting support from hospital doctors and nurses	7 (6-8)	3 (2-5)	*0.001
8. Able to return to work or usual home activities	5 (3-5)	3 (2-4)	*0.001
9. Feeling comfortable and in control	7 (7-7)	5 (4-5)	*0.004
10. Having a feeling of general well-being	7 (6-8)	6 (5-6)	0.035
11. Moderate pain	7 (7-8)	5 (4-5)	*0.001
12. Severe Pain	10 (9-10)	9 (8-10)	0.265
13. Nausea or vomiting	9 (9-10)	3 (2-3)	*0.001
14. Feeling worried or anxious	6 (6-7)	6 (5-7)	0.1
15. Feeling sad or depressed	8 (5-8)	4 (4-6)	*0.001
Total score	107 (101-112)	72 (68-74)	*0.001

*Data are shown as median (range), P 0.05 considered as statistically significant; * Denotes significant*

muscle and its sheath.[7] The use of ultrasound has made RSB more feasible and accurate in identifying target structures and visualizing needle and local anesthetic spread.[8]

Opioids alone may not provide optimal pain relief after major surgery,[10] which explains the significant difference in pain scores between the LA arm and the control group. The RSB was effective in reducing morphine consumption and incidence of nausea and vomiting while promoting early return of bowel motility as an opioid-sparing pain management technique.

Previous studies have indicated that RSB can reduce pain in the early postoperative period, with beneficial effects reported after various abdominal surgeries.[11-16]

REASONS trial performed in India on 74 females have concluded that the use of intermittent local anesthesia boluses through RS catheters is an effective morphine-sparing pain management strategy for females undergoing midline laparotomy for gynecological cancer surgery.[11]

RSB has also been found to be superior to local anesthesia infiltration for postoperative analgesia in umbilical hernia repair.[13]

Bilateral RSB has shown improved postoperative quality of recovery compared to intraoperative opioids, possibly due to better pain control and fewer opioid side effects. However, our study did not find any differences between the two groups in general well-being, severe pain, or anxiety components of the QoR-15, which may be due to the analgesic and sedative effects of opioids. It is possible that these components should have been assessed no less than 24 h after surgery.

5. LIMITATIONS

Our study had some limitations, including the fact that RS catheters were only placed after the surgery instead of before incision, which could have improved intraoperative opioid use. Additionally, we followed patients for 24 h, potentially missing delayed complications and readmissions. Longer follow-up would have been more appropriate to assess the impact of RSB on physical dependence.

6. CONCLUSIONS

In conclusion, our double-blinded randomized comparative study found that ultrasound-guided rectus sheath block is more effective than patient-controlled analgesia with opioids in providing higher quality of recovery profile in midline laparotomies, as evidenced by lesser postoperative morphine consumption, and low numeric pain scale scores.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Acknowledgement

We gratefully thank Faculty of Medicine

9. Conflict of interest

The study utilized the hospital resources only, and no external or industry funding was involved.

10. Authors' contribution

AA: Concept; data curation; formal analysis; investigation; methodology; supervision; validation; writing original draft

AM: Conceptualization; data curation; formal analysis; investigation; methodology; project administration; resources; supervision; validation; visualization; writing original draft; review & editing

EH: Data curation; investigation; methodology; resources; writing original draft; review & editing

NN, MB: Conceptualization; investigation; methodology; project administration; resources; supervision; validation; visualization; writing original draft; review & editing

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