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Regional Blocks for Multimodal Perioperative Analgesia for Adults Undergoing Para-Umbilical Hernia Repair: A Randomized Controlled Trial.

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KEYWORDS

Hernia, Pain, Rectus sheath block, Stress response, Ultrasound

ABSTRACT:

Background: It is controversial whether ultrasound-guided rectus sheath block (RSB) is superior to field block (FB) in providing postoperative analgesia and obtunding the stress response to surgery for patients undergoing para-umbilical hernia repair.

Methods: A prospective randomized controlled trial (RCT) was designed to compare the effects of ultrasound-guided RSB to FB for the provision of multimodal perioperative analgesia in adult patients undergoing para-umbilical hernia repair under balanced general anesthesia. After receiving standardized general anesthesia, 75 patients (ASA I, II) were randomized to one of the following three groups: a) RSB group receiving bilateral ultrasound-guided RSB using 0.3ml.kg-1 of Bupivacaine 0.5% plus a sham field block, b) FB group receiving a field block using the same volume of Bupivacaine 0.5% plus a sham rectus sheath block, c) control group receiving two sham blocks. All Patients received intravenously 1g of paracetamol 6 hourly and 75 mg of diclofenac 12 hourly starting after induction of anesthesia.

Results: The median Visual analogue score (VAS) was significantly lower in the RSB group compared to the other two groups in the immediate postoperative period as well as 2, 4, and 6 hours postoperatively ($p< 0.001$, for all times). In addition, the RSB group showed a better hemodynamic profile and lower catecholamine levels than the FB group.

Conclusion: RSB is superior to both FB and placebo as part of a multimodal perioperative analgesia regimen in adult patients undergoing para-umbilical hernia repair in terms of analgesia, cardiovascular stability, and suppression of the examined hormonal response to surgery.

Introduction:

Regional anesthesia produces excellent pain relief and can obtund the stress response to surgical trauma, an effect that is particularly desirable in cardiac or elderly patients (1) (2). In the context of para-umbilical hernia repair, regional anesthesia can be provided by local anesthetic infiltration (LAI) or by Rectus Sheath block (RSB).

Early studies concluded a lack of superiority of RSB over no block (2) or LAI (3, 4). Some of these studies were criticized for being susceptible to bias, small-sized with limited power and/or having design flaws, or lacking the use of ultrasound (US) guidance for the RSB (5). These factors have led some authors to question the analgesic value of RSB and accused it of increasing the complexity of the surgical procedure (5).

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A recent study showed lower pain scores and a reduced number of patients requiring opioid rescue analgesia, with an increased incidence of pain-free patients in those who received RSB compared to LAI (6). Moreover, most of the trials that used RSB as an analgesic technique were carried out on children, and none of these studies looked into its effects on the hormonal response to surgery (2, 3, 4, 7).

Therefore, this placebo-controlled study was designed to compare ultrasound-guided RSB and field block (FB) effects on perioperative analgesia and hormonal stress response in adult patients undergoing paraumbilical hernia repair. The primary outcome was chosen to be the postoperative visual analog score (VAS).

Materials and Methods:

Ethical approval for this study (Ref: FWA 000010609) was provided by the Institutional Review Board of Theodor Bilharz Research Institute, Egypt, on April 11th, 2016. The study was done under the Ethical Principles for Medical Research Involving Human Subjects, outlined in the Helsinki Declaration of 1975 (revised 2013). The trial was registered at the clinical trials.gov. Registration number NCT03225313.

The study's inclusion criteria included adults (18 – 60 years old) ASA Class I or II patients of either gender undergoing elective para-umbilical hernia repair surgery. The exclusion criteria included the patient's refusal or request to withdraw, pregnant or lactating women, presence of sepsis or infection at the site of the injection, ASA III or IV patients, history of drug abuse, corticosteroids usage, renal impairment, or any cardio-active medications intake or allergy to any of the study medications. Signed informed consent was obtained from all recruited patients.

The recruited patients were randomly allocated to either the control group (Group C), the field block group (Group FB), or the RSB group (Group RSB) according to a computer-generated randomization table (research randomizer, https://www.randomizer.org). The allocation was kept in brown sealed envelopes. A colleague not participating in the trial prepared the syringes that were used for the blocks. The patients, the anesthetist administering the blocks, and colleagues collecting the postoperative observations were unaware of group allocation or injectate composition.

Following induction of anesthesia and skin sterilization, all patients received first a bilateral ultrasound-guided RSB followed by an FB injection. The RSB group received a bilateral US-guided RSB using a total volume of 0.3ml.kg-1 of 0.5 % bupivacaine plus a sham FB using 0.3 ml.kg-1 of normal saline. The patients in the FB group received a sham bilateral RSB using a total volume of 0.3ml.kg-1 of normal saline plus an FB using 0.3ml.kg-1 of 0.5% bupivacaine. The control group received 0.3 ml.kg-1 of normal saline for each block. On the day of surgery, the recruited patients were educated about the (VAS) and using patient-controlled analgesia (PCA) devices for pain assessment and treatment, respectively. A dedicated 20G intravenous cannula was inserted half an hour before surgery to collect a venous blood sample for hormonal assays. All surgical procedures were done in the range between 10 am and 1 pm. Upon arrival to the theatre, a five-lead ECG, non-invasive blood pressure, pulse oximetry, end-tidal carbon dioxide, and neuromuscular monitoring device (Infinity Kappa, Dräger, Lübeck, Germany) was connected to every patient. Bi-spectral (BIS) module (Infinity® BISxTM SmartPod®, smoothing rate: 15 or 30 seconds, software revision: VF5) was attached to the patient's forehead for the depth of anesthesia monitoring using disposable BIS electrodes (BIS Quatro, Aspect Medical Systems, USA).

General anesthesia was induced for all patients using 2 µg.kg-1 of Fentanyl, 2 mg.kg-1 of Propofol, and 0.5 mg.kg-1 of atracurium followed by tracheal intubation three minutes later. Mechanical ventilation was started and adjusted to maintain end-tidal carbon dioxide of 35-40 mmHg (4.6 – 5.3 kPa) using oxygen in air 30-50% at a rate of 1 L.min-1 adjusted to maintain SpO2 greater than 94%. Anesthesia was maintained using sevoflurane adjusted to maintain BIS values between 40 and 60%. Surgical relaxation was maintained by 0.1 mg. kg-1 of atracurium every 15 minutes.

The RSB was always performed before the FB. The RSB was done using a high-frequency ultrasound probe (B-K Medical Pro-focus, Mileparken34, DK-2730 Herlev, and Denmark). The probe was placed transversely at the level of the umbilicus at the linea semilunaris and adjusted to obtain the best view of the rectus sheath at that level, and then a 100 mm 21G nerve block needle (Stimuplex, B. Braun, Germany) was introduced in-plane. The target site for local anesthetic

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deposition was deep to the rectus muscle superficial to the posterior rectus sheath. After negative aspiration, the test solution was injected into 5 ml aliquots. The FB was done by subcutaneous infiltration 3-4 cm outside the outer border of the hernia. All patients received 1 g paracetamol and 75 mg diclofenac, both intravenously before the start of surgical procedures. Surgery was started 10 minutes after the two blocks were administered.

In the recovery room, the severity of pain was assessed using the VAS. A VAS of more than 3 was controlled by intravenous boluses of morphine (up to 5mg). All patients received an elastomeric PCA device providing a bolus of morphine 1mg intravenously with a lockout interval of 6 minutes with no background infusion (after controlling the pain using morphine boluses). Postoperative nausea and vomiting (PONV) were treated with Ondansetron 4 - 8 mg intravenously and recorded. Postoperatively, the pain was controlled using morphine PCA, paracetamol 1 g intravenously every 6 hours, and Diclofenac 75 mg intravenously every 12 hours. Intra-operatively, the blood pressure and heart rate were measured every 2.5 minutes.

For statistical analysis, only readings at the following times were included:

- Baseline: immediately before the induction of anesthesia.
- Blocks end: after the administration of the two blocks.
- Surgery starts: 10 minutes after the end of blocks.
- Intraoperative 15 minutes, 30 minutes, 45 minutes and 60 minutes.
- At the end of surgery.
- Upon admission to the recovery room.

The number of patients requiring additional intraoperative Fentanyl doses was recorded. The baseline VAS was measured in the recovery room as soon as practicable, then at two, four, and six hours postoperatively. The time to the first analgesic request, the 24-hour postoperative morphine consumption, and the incidence of PONV during the first 24 postoperative hours were also recorded.

In all patients, 3 ml venous blood samples were withdrawn using EDTA-containing vacationers at four time points: at baseline (30 minutes pre-operatively), intra-operatively (1 hour after induction), and 2 and 6 hours postoperatively. The samples were immediately placed onto the ice, cool-centrifuged within 15 minutes, and plasma was separated, divided into three aliquots, and stored at -20 C for the assay of adrenaline, noradrenaline, and cortisol later on. The plasma adrenaline and noradrenaline were estimated using the non-competitive enzyme immunoassay technique using the CatCombi Enzyme-Linked Immuno Sorbent Assay (ELISA) IBL International kit (GmbH Hamburg, Germany). The plasma cortisol was assayed by the ELISA technique following the instructions of the kit available (Astra-Biotech, GmbH, Berlin, Germany).

Sample size:

Sample size calculation was done using the comparison of postoperative pain scores between RSB, local infiltration, and control groups as it was the primary outcome of our study. As reported in previous publications (8, 9), the mean ± S.D. of postoperative pain score in the RSB group was 4.65 ± 2.1, while in the local infiltration group, it was 5.45±1.9 and in the control group, it was 7.1±1.1. We calculated that a sample size of 23 in each group would detect a one-unit difference between the groups with 80% power at $\alpha = 0.05$ level using analysis of variance test (one-way ANOVA test) for independent samples. The sample size calculation was done using the G*Power© software (Institute fur Experiment Elle Psychologies', Heinrich Heine Universität, Düsseldorf, Germany) version 3.1.9.2. To allow for dropouts, we recruited 25 patients in each group.

Results:

The statistical analysis was performed using IBM SPSS® Statistics version 22 (IBM® Corp., Armonk, NY, USA). Numerical data were expressed as mean and standard deviation or median and range as appropriate. The qualitative data were expressed as frequency and percentage. The relation between qualitative variables was examined using either Pearson's Chi-square test or Fisher's exact test. The continuous quantitative data were tested for normality using the Kolmogorov-Smirnov test and the Shapiro-Wilk test. The comparisons between the three groups were made using either analysis of variance (ANOVA) for normally distributed quantitative variables or the Kruskal-Wallis test (non-parametric ANOVA) for none-normally distributed data, then a post hoc test was used for pair-wise comparison. ANOVA with repeated measures (for normally distributed data) or Friedman test (non-

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parametric ANOVA with repeated measures for non-normally distributed data) was used to compare more than two consecutive measures of numerical variables followed by the Man Whitney post hoc test for pairwise comparisons of repeated readings. Due to multiple comparisons, the p-value was corrected using the Bonferroni method. The time to first analgesia request analysis was done using the Kaplan-Meier method, and comparison between groups was done using the log-rank test. The Cox regression method was used to calculate the hazard ratio (HR) for risk estimation with its 95% confidence interval (CI). All tests were two-tailed. A p-value < 0.05 was considered significant.

Eighty-five patients scheduled for midline para-umbilical hernia mesh repair were interviewed. Ten patients were excluded because they fulfilled one or more of the exclusion criteria. The patient's demographics, duration of the procedure, and ASA status are listed in Table 1.

Intra-operatively, there was a statistically significant reduction in the number of patients requiring additional Fentanyl (Table 2), as well as in the Fentanyl consumption in the RSB group compared to the field group (p = 0.004, 0.038 respectively) and the control group (p<0.001 for both). Throughout the first 6 postoperative hours, the VAS in the RSB group showed a statistically significant reduction (p <0.001) compared to the other two groups (Table 2), while there was no statistically significant difference between the FB and the control groups (p =1.0). The time to the first analgesic request in the FB group (15 minutes, range zero to 240 minutes) was not significantly different from that in the control group (30 minutes, range zero to 120 minutes) (p= 1.0). On the contrary, the time to the first analgesic request in the RSB group (420 minutes, range zero to 1440 minutes) was significantly prolonged compared to both groups (p < 0.001).

The Kaplan Meier's survival analysis of the time to first analgesia consumption showed an estimated hazard ratio of requiring rescue analgesia of 16.7 (confidence interval (CI): 5.6- 50.3) in the control group and 18.4 (CI: 6.4- 53.1) in the FB group, compared to the rectus group (p <0.001).

The 24-hour morphine consumption in the rectus sheath group was significantly lower than the corresponding values in the other two groups (Table 2).

The incidence of PONV in the postoperative period was significantly reduced in the FB and RSB groups compared to the control group (Table 2).

The heart rate in the RSB group was found to be lower compared to the other two groups throughout the intra-operative period except when the block administration ended when the difference between the RSB group and the control group did not reach statistical significance (Figure 1A).

The mean arterial blood pressure (MAP) in the RSB group was found to be lower compared to the other two groups throughout the intraoperative period except at the end of block administration when the difference between the RSB and FB groups did not reach statistical significance (Figure 1B).

In the control group, the three measured hormone levels (Fig 2-4) showed a statistically significant increase intra-operatively compared to baseline (p = 0.013 for cortisol, p = 0.011 for adrenaline, p = 0.037 for noradrenaline) and at two and six hours postoperatively (p < 0.001 for all hormones at both times). In the FB group, there was an increase throughout the measurement period in all three measured stress hormones compared to baseline (Fig 2-4) but only reached statistical significance at two and six hours postoperatively (p < 0.001 for both times). Contrary to the other two groups, there was a statistically significant decrease in all three measured stress hormones in the RSB group compared to baseline (Fig 2-4) intra-operatively
(p < 0.001 for cortisol, p = 0.006 for adrenaline and p = 0.011 for noradrenaline) And at two and six hours postoperatively (p <0.001 for all three hormones at both times). The percentage change in the three measured hormones in the rectus sheath group was significantly different from the control and FB groups (p <0.001 for both) throughout the study period. There was no statistically significant difference between the percentage changes in the three studied hormones between the control group and the FB group throughout the measurement period (Figure 2-4).

Discussion:

This study demonstrates that RSB provides superior intra-operative anti-nociception over the other two groups as evidenced by the 36% and 56% reduction of the number of patients requiring intraoperative

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Fentanyl versus the FB and control groups, respectively coupled with the reduction in its consumption (table 2) and the reduction in heart rate, blood pressure and the measured stress hormones level compared to either placebo or FB.

These findings are consistent with those of Gurnaney et al. (4), who reported a 30.8% reduction in the number of children requiring intra-operative morphine and a 46.1% reduction in the dose of intra-operative morphine in patients receiving RSB compared to those who did not. RSB has a superior postoperative analgesia profile over both the placebo and FB as evidenced by the lower VAS throughout the study, by the extended time to the first analgesia request, by reducing the hazards of requiring postoperative morphine, and by reducing morphine consumption.

The superior postoperative analgesia profile shown in this study agrees with several recently published studies performed on children undergoing umbilical hernia repair (7, 10) or abdominal surgery with midline incision (11) or in adults undergoing umbilical hernia repair (12), or abdominal cancer surgery with midline incision (13). None of these studies examined the effect on the hormonal response to surgery. Although some early studies reported the lack of significant analgesic effect of RSB compared to placebo or local anesthetic infiltration, careful and thorough reviewing of these studies suggests otherwise. For example, Isaac et al. (3) concluded that the RSB has no advantage over local anesthetic infiltration into the surgical wound for postoperative pain management in 14 children (1-8 years of age) undergoing umbilical hernia repair. This difference could be explained as their RSB was administered using a landmark technique rather than US guidance (6).

Although our results agree with Gurnaney et al. (4) regarding the reduction in the intra-operative opioid requirement, our results are different from theirs regarding the postoperative analgesic profile. They concluded that RSB and local anesthetic infiltration provided comparable postoperative profiles as shown by similar perioperative analgesia consumption, a trend towards a significant reduction in postoperative analgesic consumption, and similar time to rescue analgesia administration. However, Gurnaney et al. (4) performed their study on children over a wide range of age (5-18 years) and used the revised Bieri FACES pain score rather than the VAS used in this study. More importantly, they used bupivacaine 0.25% with adrenaline, and the volume is graded according to ranges of body weight rather than using a volume-based individual actual body weight as opposed to bupivacaine 0.5% in a volume based on actual body weight used in this study.

The patients in the RSB in our study showed an excellent hemodynamic stability profile compared with the other two groups. This finding concurs with Bashandy and Elkholy's (13) results but differs from a more recent study (12). However, in that study, they used a higher initial Fentanyl dose that had a shorter operative time, and they actively adjusted the volatile agent concentration to maintain hemodynamic stability irrespective of the depth of anesthesia that was not monitored (12). Our observation that the RSB provided an excellent cardiovascular stability profile, compared to FB or placebo, reflects the concomitant inhibition of adrenaline and corticosteroid secretion in response to surgical trauma. Thus our results demonstrate that the pre-incision RSB abolishes these stress hormones. This finding confirms the findings of other authors (1, 2).

It is complementary to the recent findings of Jin et al. (14), who demonstrated that the pre-incision RSB significantly inhibited the four measured pro-inflammatory cytokines (interleukin-6, tumor necrosis factor-α, interleukin -1β, and interferon-gamma). Such cardiovascular stability is of particular importance to cardiac and elderly patients.

In this study, the incidence of PONV was reduced in the RSB and the FB groups compared to placebo. This observation is probably due to the reduction of intraoperative fentanyl consumption. This finding is consistent with the findings of Gurnaney et al. (4).

This study had some limitations due to our inability to measure the effects of the blocks on pro-inflammatory cytokines. Further studies are required to address this issue.

Conclusion:

This study revealed that RSB was superior to FB as part of a multimodal perioperative analgesia regimen in adult patients undergoing para-umbilical hernia repair. It provided excellent perioperative analgesia extending for up to 24 hours postoperatively

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with opioid-sparing and reducing the risks of requiring rescue analgesia, excellent intra-operative cardiovascular stability, and marked suppression of the examined hormonal response to surgery.

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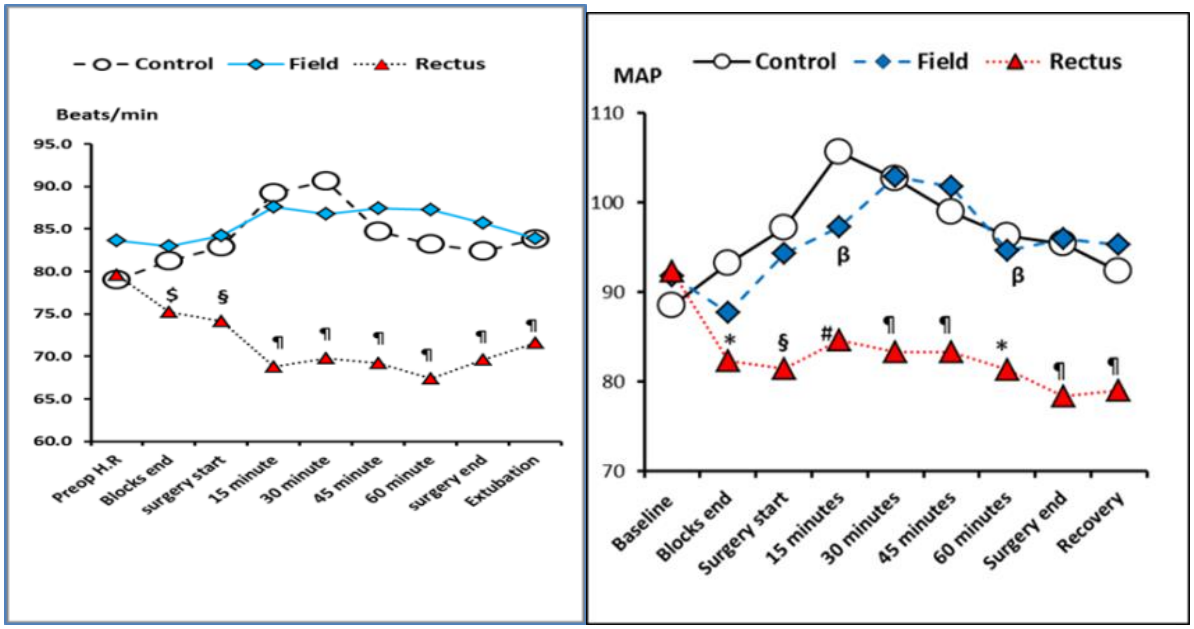

Data are presented as mean ± SD. Rectus: Rectus Sheath Block, Field: Field Block group. *: $p < 0.05$ compared to control group, §: $p \leq 0.01$ compared to both the control & field groups, #: $p \leq 0.001$ compared to the control group, β: < 0.05 compared to the Rectus block group, ¶: $p < 0.001$ compared to control and field block groups. One-way ANOVA test followed by Tukey HSD test (post hoc).

Figure 1: The changes in heart rate (A) & Mean Arterial Pressure (B).

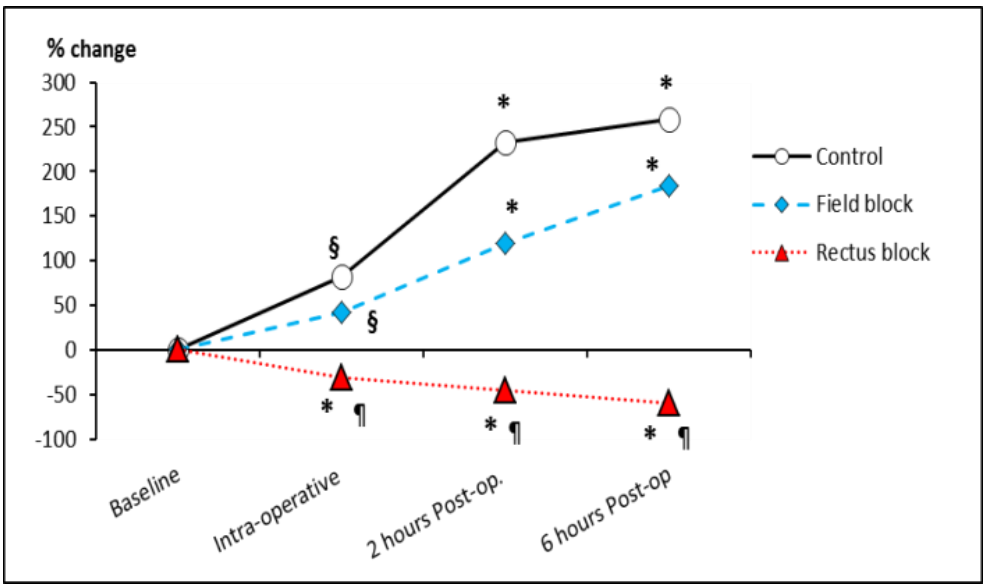

Figure 2: The median cortisol level percentage changes

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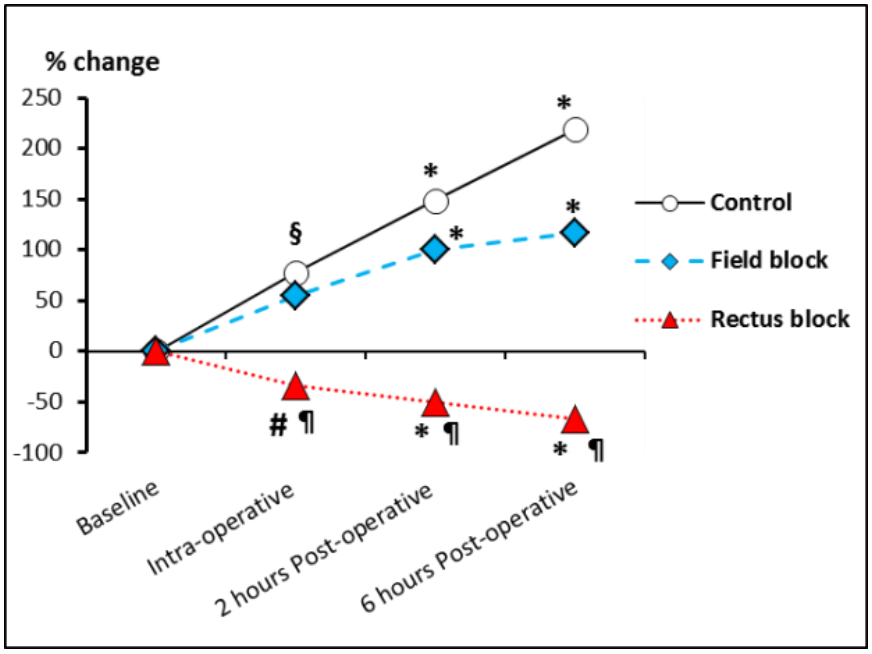

Figure 3: The median adrenaline level percentage change

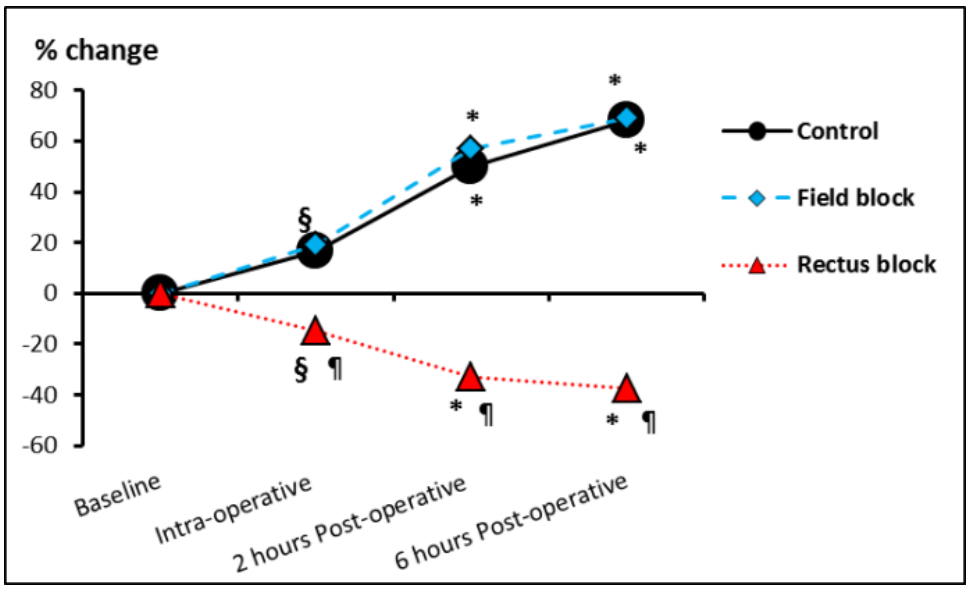

Figure 4: The median noradrenaline level percentage change

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Table 1: The patients' demographics, duration of the procedure, and the ASA status

		Group C (N=25)	Group FB (N=25)	Group RSB (N=25)	P-value
Sex(Male/Female) [a]	:	3/22	9/16	5/20	0.119
		(12/88%)	(36/64%)	(20/80%)	
Age (Years) [b]	:	44.8 ± 9.9	43.9 ± 8.6	42.6 ± 10.4	0.724
Weight (Kg) [b]	:	82.8 ± 14.0	81.6 ± 11.0	84.2 ± 11.5	0.760
Height (cm) [b]	:	167 ± 7.0	170 ± 8	166 ± 8	0.167
Body mass index ($Kg.m^{-2}$) [b]	:	29.7 ± 4.8	28.5 ± 19.8	30.9 ± 5.3	0.189
Duration of the procedure (min) [b]	:	89.8 ± 14.8	84.5 ± 19.8	88.4 ± 21.6	0.594
ASA class (I/II) [c]	:	19/6	22/3	22/3	0.567
		(76/24%)	(88/12%)	(88/12%)	

Data are presented as mean ± (SD) or number (%). ASA: American Society of Anesthesiologists.
C: control, FB: field block, RSB: rectus sheath block. a=Pearson's Chi-square test, b= one-way ANOVA test, c: Fisher's Exact test.

Table 2: Perioperative analgesia consumption, postoperative pain score, and the incidence of PONV:

		Group C (N=25)	Group FB (N=25)	Group RSB (N=25)
Number of patients requiring additional intraoperative fentanyl [a]	:	16(64%)	11 (44%)	2 (8%) *$
Total additional intraoperative fentanyl consumption (µg) [b]	:	50 (0-100)	0(0-100)	0(0-50)*$
24 hours Morphine consumption (mg)	:	20 (10-25)	15(5-25)	5(0-15)¶
The time to first analgesic request (min) [b]	:	30 (0-120)	15 (0-240)	420 (0-1440) ¶
PONV [a]	:	9 (36.0%)	3 (12.0%) §	1 (4.0%) §
Pain Score (VAS) [b]				
VAS Recovery room	:	8 (0-10)	6 (0-10)	0 (0-6) ¶
VAS 2 hours postop.	:	6 (2-8)	6 (2-8)	0 (0-4) ¶
VAS 4 hours postop.	:	6 (2-8)	6 (2-8)	2 (0-6) ¶
VAS 6 hours postop.	:	6 (2-10)	6 (1-8)	2 (0-6) ¶

Data are presented as number (%) or median (minimum-maximum). C: Control, FB: Field block, RSB: Rectus sheath block. PONV: postoperative nausea and vomiting.
*: $p < 0.01$ compared to group C, $: p <0.05$ compared to group FB, ¶: $p <0.001$ compared to either groups C or FB, §: $p <0.05$ compared to group C.
a=Pearson's Chi-square or Fisher exact test, b= Kruskal Wallis test followed by Mann Whitney test.