Comparison Between Ultra Sound Guided Rectus Sheath Block and Field Block for Midline Hernia Repair
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Background and Rationale :

Pain is a complex but an important protective phenomenon. It may be defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (1). Good operative analgesia reduces the stress response to surgery, which is very important for patients with compromised cardiovascular respiratory functions (1). Good postoperative pain relief is important as it alleviates patient's distress and helps in rapid uncomplicated recovery (1).

Field block achieved by wound infiltration is a method of postoperative analgesia commonly used alone or as a part of multimodal analgesic regimens (2). It was developed to improve postoperative analgesia, reduce opioid consumption and

hasten patient recovery .The use of local anesthetics (LAs) instead of opioid minimizes opioid adverse reactions, reduces nursing work, decreases resting pain, pain on motion, and thus allows better patient mobility (2). Field block carries the risk of wound infection and some surgeons oppose its use.

A rectus sheath block can provide effective pain relief for umbilical or other midline surgical incisions by blocking the intercostals nerves. It can be done using the landmark technique but it carries the risk of puncturing the posterior rectus sheath, peritoneum and bowel (3).

Use of ultrasound technology for rectus sheath block has reduced this risk considerably (3).Ultrasound guidance for regional anesthesia is associated with higher block success rates, shorter onset times, and reduced total anesthetic dose required and reduced complications. There is also the advantage of direct observation of pattern of anesthetic spread (4).

Objectives :

To compare between Ultra-sound guided rectus sheath block VS Field block infiltration in providing a good analgesia for patients undergoing midline hernia repair to detect which one is superior.

Study Design :

Prospective randomized double blinded controlled clinical trial will be done with a total number of 75 patients will be divided into 3 groups .

Ethics Committee approval (was it ethically approved by the department) :

This protocol has been approved by the Ethics Committee at Theodor Bilharz Research Institute .

Study Methods :

Population of study & disease condition:

- 75 patients(ASA I or II) undergoing midline hernia repair under general anesthesia will be recruited and will be randomly allocated using a computer generated randomization table (research randomizer, https://www.randomizer.org). The allocation was kept in brown sealed envelopes.
- Control group.
- Field block infilteration group.
- Ultra sound Guided Rectus sheath block group.

Inclusion criteria:

1. Elective midline hernia repair surgery.
2. Age: adult patients between 18 – 60 years old.
3. Gender: Both male and female.
4. ASA Class: I & II.

Exclusion criteria:

1. Refusal of patient.
2. Pregnancy and lactation.
3. Fever or sepsis.
4. Patients ASA III or IV.
5. Renal impairment.
6. Addicts and drug abusers.

7. Patients taking corticosteroids or any cardio - active drugs.
8. Local infection at site of the injection.
9. Allergy to any of the study medications.

Methodology in details :

Anesthesia technique:

✓ **Preoperative :**

- During the pre-operative period visual analog scale (VAS) for pain assessment from 0 to 10, with 0 meaning no pain and 10 meaning the worst pain imaginable will be explained to patients.
- 30 minute before surgery, IV 20 G cannula will be inserted in each patient forearm to collect 5 ml venous blood as preoperative sample for estimation of the level of cortisol and catecholamine.

✓ **Monitoring :**

In theatre, a five-lead ECG, non-invasive blood pressure, pulse oximetry, end-tidal carbon dioxide and neuromuscular monitoring (Infinity Kappa, Dräger, Lübeck, Germany). Bi-spectral (BIS) module (Infinity® BISxTM SmartPod®, smoothing rate: 15 or 30 seconds, software revision: VF5) was attached to the patients' forehead for the depth of anaesthesia monitoring using disposable BIS electrodes (BIS Quatro, Aspect Medical Systems, USA) after proper skin preparation, were attached to the patient

✓ **Induction and maintenance**

- During mask preoxygenation, patients baseline hemodynamic parameters will be recorded regarding blood pressure, heart rate .
- General anesthesia will be standardized for all patients with :

  2 μg kg^{-1} fentanyl and 2 mg kg^{-1} propofol. Neuromuscular blockade will be achieved with 0.5 mg kg^{-1} atracurium followed by tracheal intubation.

  Muscle relaxation will be maintained by 0.1mg / kg / 30 minute of Atracrurium.
- Mechanical ventilation will be adjusted with fresh gas flow oxygen in air 30-50% at a rate of 1 L $min^{-1}$to maintain end-tidal carbon dioxide of 35-40 mm Hg and Spo2 greater than 94%.
- BIS values will be maintained between 40 and 60.
- All surgical procedures will be done in the range between 10 am and 1 pm and by the same surgical team.
- Patients hemodynamic parameters regarding blood pressure and heart rate will be recorded every 2.5 minutes.
- Core temperature will be measured using an esophageal thermometer and normothermia will be maintained using a forced air warming blanket and actively warmed infused solution.
- Patients will receive ringer solution infusion at a rate 2 - 5 ml / kg / hour.
- Patients were randomly allocated to one of three groups namely 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). Patients in the Field block group received a sham bilateral RSB using a total volume of 0.3ml. kg^{-1} of normal

saline plus a field block using 0.3ml. kg^{-1} of 0.5% bupivacaine. The RSB group received a bilateral RSB using a total volume of 0.3ml. kg^{-1} of 0.5 % bupivacaine plus a sham field block using 0.3 ml. kg^{-1} of normal saline. The control group received 0.3 ml. kg^{-1} of normal saline for each block. A colleague not participating in the trial prepared the syringes that were used for the blocks. The patients, the anaesthetist administering the blocks, and colleagues collecting the postoperative observations were not aware of group allocation or injectate composition.

- An increase in HR and/or MAP > 25 % of baseline values will be treated by IV fentanyl 0.5 μg kg^{-1} boluses & the total fentanyl dose will be recorded. Atropine 0.5 mg increments will be used to control bradycardia (<50 beat min^{-1}) while hypotension (less than 20% of preanesthetic level) will be managed by increasing fluid infusion rate or decreasing inhalational anesthetic concentration.

- Reversal of neuromuscular blockade will be achieved by intravenous administration of neostigmine 0.05 mg kg^{-1} and atropine 0.02 mg $kg^{-1.}$

- Patients will be extubated and transferred to post- anesthetic care unit.

- Postoperatively, pain was controlled using morphine PCA, paracetamol 1 gm intravenously every 6 hours and Diclofenac intravenously every 12 hours.

- VAS will be recorded immediately post-operative, after 2, 4 and 6 hours.

- Time to first analgesia requirement will be recorded and 24 hour postoperative morphine consumption will be recorded.

- Nausea and vomiting will be recorded immediately postoperative using a categorical scoring system (0 = none, 1 = nausea, 2 = retching, 3 = vomiting). Ondansteron 4 – 8 mg i.v will be given for patients with score 2.

- Patients will be discharged out after scoring 12 points or more according to Fast track discharge score (5) as follows :

  - Level of consciousness Score

    Awake and oriented 2

    Arousal with minimal stimulation 1

    Responsive only to tactile stimulation 0

  - Physical activity

    Able to move all extremities on command 2

    Some weakness in movement of extremities 1

    Unable to voluntarily move extremities 0

  - Hemodynamic stability

    Blood pressure less than 15% of baseline MAP value 2

    Blood pressure 15%–30% of baseline MAP value 1

    Blood pressure more than 30% below baseline MAP value 0

  - Respiratory stability

    Able to breathe deeply 2

    Tachypnea with good cough 1

    Dyspneic with weak cough 0

  - Oxygen saturation status

    Maintains value more than 90% on

room air 2

Requires supplemental oxygen (nasal prongs) 1

Saturation less than 90% with supplemental oxygen 0

- Postoperative pain assessment

None or mild discomfort 2

Moderate to severe pain controlled with IV analgesics 1

Persistent severe pain 0

- Postoperative emetic symptoms

None or mild nausea with no active vomiting 2

Transient vomiting or retching 1

Persistent moderate to severe nausea and vomiting 0

Total score 14

Sampling :

Patients in the three groups will undergo blood sampling for measurement of cortisol and catecholamine level using ELISA technique 3 times :

- 30 min. pre –op.
- 1 hour after the start of the procedure.

- 2 hour after the end of the procedure.
- 6 hours after the end of the procedure

Pain assessment :

Pain score to surgery will be assessed according to the VAS pain score sheet as follows :

- Immediately after the admission to recovery room.
- 15 minutes following the admission to recovery room.
- 2 hours after the end of the procedure.
- 6 hours after the end of the procedure.
- Time to 1st analgesia request.
- 24 hour post – operative analgesia requirement.
- Intra-operative fentanyl consumption.

Primary outcomes (Most important outcomes to be assessed) :

Assessment of postoperative pain with each technique.

Secondary outcome parameters (other outcomes to be assessed) :

- Assessment of stress response with each technique through measuring cortisol and catecholamine levels.
- Hemodynamic Parameters regarding blood pressure and heart rate.
- Incidence of nausea and vomiting post – operative.

- Modified Aldrete score.
- Time to hospital discharge.

STATISTICAL METHODS:

Sample size calculation was done using the comparison of postoperative pain score between RSB, local infiltration and control groups as it was the primary outcome of our study. As reported in previous publication (6,7) the mean ± S.D. of postoperative pain score in RSB group was 4.65 ± 2.1, while in local infiltration group it was 5.45±1.9 and in control group it was 7.1±1.1. We calculated that a sample size of 23 in each group will be able to 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 (Institut für Experimentelle Psychologie, Heinrich Heine Universität, Düsseldorf, Germany) version 3.1.9.2. To allow for drop-outs, 25 patients in each group were recruited.

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 quantitative continuous data were tested for normality using the Kolmogorov-Smirnov test and the Shapiro-Wilk test. The comparisons between the three groups were done using either analysis of variance (ANOVA) for normally distributed quantitative variables or Kruskal-Wallis test (non-parametric ANOVA) for none-normally distributed data then post-hoc test" was used for pair-wise comparison. ANOVA with repeated measures (for normally distributed data) or Friedman test (non-parametric ANOVA with repeated measures for non- normally distributed data) was used to compare more than two consecutive measures of numerical variables

followed by post hoc tests 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.

Source of funding:

Will be provided by Theodor Bilharz Research Institute.

Time plan:

Starting date: August 2017.

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