BILATERAL RECTUS SHEATH BLOCK AS POST-OPERATIVE ANALGESIA FOR PATIENTS UNDERGOING MIDLINE LAPAROTOMY IN MINILK II REFERRAL HOSPITAL, ADDIS ABABA, ETHIOPIA

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A THESIS SUBMITTED TO THE DEPARTMENT OF ANESTHESIA, COLLEGE OF HEALTH SCIENCES, ADDIS ABABA UNIVERSITY, FOR THE PARTIAL FULFILLMENT OF THE REQUIREMENT OF MASTER DEGREE IN ANESTHESIA.

June, 2018G.C

ADDIS ABABA, ETHIOPIA

ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES DEPARTMENT OF ANESTHESIA

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Full Title of the Research Paper	**BILATERAL RECTUS SHEATH BLOCK AS POSTOPERATIVE ANALGESIA FOR PATIENTS UNDERGOING MIDLINE LAPAROTOMY IN MENELIK II REFERAL HOSPITAL, ADDIS ABABA, ETHIOPIA.**
Total Cost of the project	31,855.00 EB
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Declaration

I, the undersigned and declare that the research entitled efficacy of bilateral rectus sheath blocks for postoperative analgesia for patients undergoing midline abdominal laparotomy in Menelik II referral hospital, Addis Ababa, Ethiopia Institutional based prospective cohort study is my original work in partial fulfillment of the requirements of Master's degree in Anesthesia. I understand that plagiarism is not tolerated and all directly quoted material has been appropriately referenced

Investigator

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Approval of the Board of Examiners

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Date of Submission: _____

Acknowledgement

First of all, praise be to God who helped me walk through this project.

Next, especial thanks go to my advisor, Mr. Abateneh Melekamayhu for his unflagging encouragement and support of this project from the beginning.

I am also deeply grateful to Mr. Wosenyeleh Admasu for his unreserved affirmation in this project which was an added fillip for me.

I am gratefully indebted to my mother and father for their continuous support in their ardent prayers.

I am also moved to express my gratitude to my classmates who treated me as a single rose within the batch whenever I needed support.

Lastly but not least, I want to express my great thanks to my sponsoring organization Addis Ababa University for which accomplishment of this project is impossible without the financial support. I would like to say thanks to my data collectors and study participants.

Abstract

Background: Midline laparotomy incision and other abdominal surgeries are associated with severe postoperative pain. Most experimental studies have showed significant reduction in pain intensity and total analgesia consumption in patients for whom bilateral rectus sheath block was done when compared to none interventional groups.

Objectives: To assess the role of bilateral rectus sheath block as part of post-operative analgesia in patients that undergo midline laparotomy at Menelik II Referral Hospital.

Methods: A prospective cohort study was done from December 25, 2017 to May 10, 2018 at Menelik II Referral hospital on sixty patients who came for midline abdominal laparotomy by using systematic random sampling technique. For analysis and interpretation, collected data were entered into Epi-data 3.1 and transported to the SPSS version 20. Homogeneity of categorical independent variables between the two groups were analyzed using Chi Square. The Manny Whitney test was used to compare median pain score and total analgesia consumption between the rectus sheath block group and control group. Statistical significance was stated at p value < 0.05 with a power of 80%.

Result: There were a statistical significant difference among the groups depending on postoperative pain score measured by numeric rating scale (NRS) in the first 6 hours and total analgesia consumption within the 12 hours post-operatively. The median (inter quartile range) numeric rating scale score at the post anesthesia care unit was 0 (0-3) for treatment and 6 (2-8) for control group with p value of <0.001. Also, the 1^{st} ,2^{nd} ,4^{th} and 6^{th} postoperative hour numeric rating scale score was lower in statistically significant way between the two groups. The median 12-hour postoperative tramadol consumption was 0 mg and 75mg with p value of 0.022 for the rectus sheath group and control group, respectively.

Conclusion and Recommendation: For surgeries done through midline laparotomy, adding bilateral rectus sheath block (BRSB) at the end of the operation with 0.25% bupivacaine is useful postoperative analgesia. Based on these, we recommend the use of BRSB for patients that undergo midline abdominal incision.

Key words: Rectus sheath block, midline laparotomy, post-operative pain, numeric rating scale

Table of Contents

List of Abbreviations

ASA	American Society of Anesthesiologist
BRSB	Bilateral rectus sheath block
DBP	Diastolic Blood Pressure
GA	General Anesthesia
Hr	Hour
IASP	International Association for study of pain
IM	Intra-muscular
IV	Intra-venous
IVPCA	Intra-venous patient-controlled analgesia
LOR	Loss of resistance
MAP	Mean Arterial Pressure
NRS	Numeric Rating Scale
NSAIDS	Non-Steroidal Anti-Inflammatory Drugs
PACU	Post Anesthesia Care Unit
PCA	Patient Controlled Analgesia
PONV	Post-Operative Nausea and Vomiting
PR	Pulse Rate
RSB	Rectus Sheath Block
SBP	Systolic Blood Pressure
TAPB	Transverse abdominis plane block
SPO2	Arterial Blood Saturation
VAS	Visual Analogue Scale

List of Tables and Figures

Chapter One: - Introduction

1.1. Background

Major abdominal surgery is an important part of current medical practice. Surgical incision for abdominal operation is mainly dependent on the area that needs to be exposed, and the surgeon's personal preference. However, the type of incision may have a profound influence on the occurrence of postoperative pain (1, 2).

The most used surgical approach for abdominal surgeries includes transverse, oblique, para median and midline incisions. The midline incision implies a vertical incision through the skin, subcutaneous fat, linea alba, and peritoneum. The incision is easy to perform and results in minimal blood loss, and it can be made quickly, taking seven minutes on average. Moreover, exposure of the abdomen is excellent. Extensions, when required, can easily be made superiorly or inferiorly, providing access to the whole abdominal cavity, including the retro peritoneum(1).

As it is used in most of laparotomies extended midline incision and other abdominal surgeries are associated with severe postoperative splinting pain, typically associated with a neuro-endocrine stress response that cannot be tolerated in certain types of patients particularly cardiac ones (3). The maximized work of breathing and the ablated tidal volumes following this incision is another major problem of those having compromised pulmonary functions(4). Many interventions in developed and developing countries have been tried to reduce such severe pain, including epidural analgesia, intra-venous patient-controlled analgesia (IVPCA), transverse abdominis plane block (TAPB), local wound infiltration, peripheral nerve blocks, in addition to the use of systemic opioids, or non-steroidal anti-inflammatory drugs (NSAID) (3).

Peripheral nerve blocks with local anesthetics are essential tools for the anesthesia practice for pain management. The rectus sheath block (RSB) was first described in 1899 and was initially used for the purpose of abdominal wall muscle relaxation during laparotomy before the adjunct of neuromuscular block. Rectus sheath block will provide somatic pain relief for the abdominal wall structures superficial to the peritoneum (5). Now, it is used for analgesia after umbilical or incisional hernia repairs and other midline surgical incisions (6).

The central portion of the anterior abdominal wall is innervated by the ventral branches of the thoracolumbar nerves, 6th thoracic nerve-1st lumbar nerve (T6-L1); these ventral branches lie between the rectus abdominis muscle (deep) and the posterior rectus sheath (ventral), and enter the rectus muscle near the midline (7, 8). The T6-L1 nerves provide sensory innervation to the rectus muscle and overlying skin. Since the tendinous inscriptions of the rectus muscle are not attached to the posterior rectus sheath, the local anesthetic administered into the spatial space can in theory spread both in the cranial and caudal direction (5).

The aim of RSB technique is to block the thoracic nerve terminal branches of nerves which run in between the internal oblique and transverses the abdominis muscles to penetrate the posterior wall of the rectus abdominis muscle and end in an anterior cutaneous branch supplying the skin of the anterior mid abdomen (6).

The RSB can be performed using a blind technique, with the patient lying supine, a point is identified 2–3 cm from midline then passing a short-beveled 5 cm needle through the anterior rectus sheath (a definitive ‘pop’ should be felt as it passes through) and through the rectus abdominis muscle and the needle is advanced further until a firm resistance of the posterior wall is felt then one can inject the prepared local anesthetic (15–20 ml) on the posterior wall of the rectus sheath after negative aspiration for blood. The procedure is repeated on the opposite side of the midline (6, 9).

1.2. Problem of statement

The International Association for the Study of Pain (IASP) defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage(10). Pain is typically associated with a neuroendocrine stress response that is proportional to pain intensity. It is not just a sensory modality but an experience and it is always subjective. Moderate to severe acute pain, regardless of the site, can affect the function of nearly every organ and may adversely affect perioperative morbidity and mortality(11). Pain management in the perioperative setting refers to actions before, during, and after a procedure that are intended to reduce or eliminate postoperative pain before discharge (12). Adequate pain management will reduce the risk of adverse outcomes like hemodynamic instability and respiratory problems; it also maintains the patient's functional abilities, as well as physical and psychological well-being, and enhance the quality of life for patients with acute pain during the post-operative period.

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Post-operative pain associated with midline incision is very sever influencing the wound healing time, patient satisfaction toward the service provider and the respiratory effort of the patient. Total lung capacity decreases after abdominal surgery; Vital capacity is decreased by 25 to 50% within 1 to 2 days after surgery and generally returns to normal after 1 to 2 weeks; Residual volume increases by 13%, whereas expiratory reserve volume decreases by 25% after lower abdominal surgery and 60% after upper abdominal and thoracic surgery (13). Therefore, adequate postoperative pain control is necessary to ensure a good respiratory effort.

Even though systemic opioids are used for pain management, they are with their own side effects. Paralytic postoperative ileus continues to be a significant problem after abdominal and other types of surgery. Currently, the important factors that could affect the duration and recovery from postoperative ileus include limitation or decreasing the dose of narcotic use by substituting alternative medications like non-steroidal anti-inflammatory drugs (NSAID) (14).

1.3. Justification of the study

Anesthesia is not only about intra-operative management, it is also concerned with the pre-operative and post-operative patient management. In the post-operative period, the pain resulting from surgery is the most feared and unwanted perception by the patient. Nowadays multi-modal analgesia is being used to increase patient satisfaction by using different drugs together that act on different sites of the body resulting in synergetic effects with each other and decreases side effects that could result due to an over dosage of single drug therapy. In Ethiopia, where there is scarcity in resource because of lack or expensiveness of modern pain managing ways and materials like the epidural catheter and patient-controlled analgesia (PCA); RSB could play a big role in alleviating postoperative incisional pain with decreased side effects from usage of systemic opioids.

As far as the author's knowledge goes, there is no previous study done in Ethiopia to assess the analgesic role of RSB, though it has been studied in different parts of the world. The controversies regarding the efficacy of RSB for mid line laparotomy is one of the reasons which call for the study.

On the other hand, it will open the door to bring quality education, training, and further research activities by clinical practitioners and researchers in their pre-service and in-service environment.

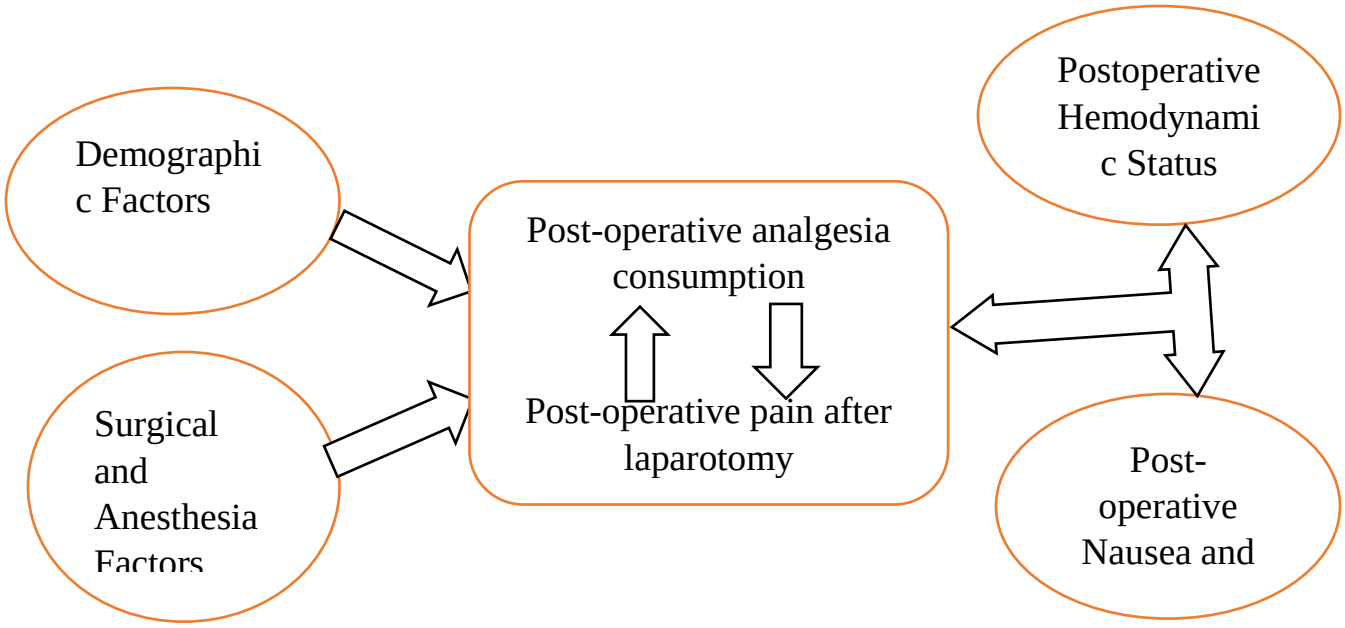

Figure 1: ***Conceptual frame work based on the relation between dependent and independent variable. Developed by the investigators.***

Chapter Two: - Literature Review

Midline laparotomies are needed in gastroenterological, gynecologic and urological operations and these patients need effective analgesia in the postoperative time

The midline laparotomy is associated with greater postoperative pain and alteration on the respiratory function when it is compared with transverse and oblique approaches. Brown et al. in 2005 on their Systematic Reviews showed that the possible increased pain and compromise on pulmonary function with a midline incision may prompt the operating surgeon to use a transverse incision in high risk patients particularly obese patients or those with chronic obstructive airway diseases (15).

In 1988, B. E. Smith et al on their randomized prospective study on sixty adult females scheduled for elective diagnostic laparoscopy surgery, there were thirty patients receiving RSB in addition to general anesthesia (GA) and thirty patients receiving only GA. They found pain scores on patients taking RSB to decrease in a highly significant manner than the GA group at both 1^{st} hr. (0.7 (04 - 0.1) vs 7.1 (3.1 - 8.4)) and 6^{th} hr. (0.4 (0-3.1) vs 4.3 (1.6-6.4)) p-value of <0.005, and in a significant way at 10^{th} hr. (1.6 (0- 2.3) vs 3.2 (1.4 -5.5) after operation p-value < 0.05 respectively. Also, the number of patients in GA group who had received intramuscular (IM) analgesia at the 1-, 6- and 10-hr assessments was 17, 18 and 18 respectively; five patients in this group received two doses of IM analgesia each. The corresponding figures for RSB + GA group were 3, 5 and 5, and no patient received more than a single dose. These differences between the groups were highly significant for each of the three assessments ($p < 0.005$ in all cases) (16).

In contrast, Pandmanbhan et al. at 2007 in United Kingdom, through their prospective randomized study involving 90 patients undergoing midline laparotomy found that intermittent infusion of bupivacaine after the surgery into the rectus sheath-space did not reduce the pain score nor opioid requirement postoperatively. The mean total amounts of morphine used by the bupivacaine and the normal saline groups in the first 24 hr. were 19.4 mg and 21.4 mg ($p = 0.535$), respectively, and during the second 24 hr. were 30.5 mg and 25.3 mg ($p = 0.464$), respectively. Mean subjective pain scores as recorded by the visual analog scale (VAS) in the

bupivacaine and Placebo groups during the first 24hr were 2.2 and 1.8 (p=0.669), and during the second 24 h were 2.2 and 1.8 p-value = 0.558 (17).

In terms of postoperative nausea and vomiting, analgesic consumption and the duration of analgesia, Ozcengiz1 et al. in Turkey at 2012, found that the RSB has superiority to intravenous tramadol in children undergoing major abdominal surgery. The mean and (standard deviation) SD for duration of analgesia was statistically longer in the group with RSB 900 ±553 than the group that received tramadol 133±90, $p < 0.001$. The mean total amounts of tramadol used by the levobupivacaine and the normal saline groups in the first 24hr were 0.95mg/kg and 4.07mg/kg, respectively (P=0.01). The score of parents' satisfaction was higher in children with RSB p-value of 0.003. 40 % of patients had nausea and vomiting and 9% had nausea in group Tramadol and Group RSB, respectively (18).

In Egypt at 2014, Ghada M. and colleagues, in their randomized controlled trial they found a statistical significant difference on VAS score compared between patients receiving RSB with GA and GA alone ($P < 0.05$). Post anesthesia care unit (PACU) morphine consumption in RSB group was lower than GA group patients with mean and SD of 2.1 ± 2.2 and 5.5 ± 2.1, respectively. Similarly, the first post-operative day morphine consumption was statistically lower in RSB than the GA alone group with mean and SD of 0 and 8.4 ± 3 mg respectively (19).

In India, 2016, Shah V A. and Bajaj M. on their randomized clinical trial on 60 patients that undergo laparoscopic tubal ligation, found that patients that received rectus sheath block with bupivacaine showed a statistically significant lower pain score by verbal analogue scale when compared with control group ($p < 0.001$). Also, tramadol requirements in the first 12 postoperative hours were lower for the group with rectus sheath block ($p < 0.001$) (20).

In Egypt, in 2017, Khaled Elbahrawy and Alaa El-Deeb in their randomized single blinded study done on forty patients with mesenteric vascular occlusion scheduled for midline laparotomy, they found that patients in the RSB group consumed statistically significant less opioid in comparison to control group in the postoperative period (15 ± 1.5 and 22.5 ± 1.1 $p<0.001$). Their result also shows median pain scores were statistically significantly less in the

RSB group than in the control group at 2, 4, and 6 h postoperatively with p- value < 0.001 in the all 3 intervals (21).

In 2017, again in Egypt, Moutaz, H. et al. on their prospective, single-blind and randomized clinical trial which was conducted on 60 patients that underwent abdominal surgery through a midline incision found RSB to have a comparable analgesic efficacy to epidural anesthesia. Their result showed that there was no statistical difference on VAS at rest and coughing, at all times of measurement between those who received epidural catheter and bilateral ultrasound-guided rectus sheath block with catheter insertion. But they found a significant lower interval and total morphine consumption in epidural analgesia group as compared to rectus sheath analgesia group. They reported that RSB with catheter insertion can be a good adjunctive in postoperative pain management technique for midline abdominal incision when epidural analgesia is not a suitable option (22).

In 2018, a prospective, randomized, controlled open label clinical trial with four parallel group was conducted in Tertiary Care Hospital in Finland by Purdy et al. A total of 57 patients undergoing midline laparotomy were randomized in to control, single dose RSB, repeated doses RSB, and continuous infusion RSB group. They found 12 hr. post-operative oxycodone consumption to be lower in a clinically significant way for the repeated and continuous RSB group when compared to the single dose RSB and control groups, p-value = 0.07 (23).

Chapter Three: - Objectives of the study

3.1 General objectives

To assess the role of bilateral rectus sheath block as part of post operational analgesia in patients that undergo midline laparotomy at Menelik II Referral Hospital from December 25, 2017 to May 10, 2018, Addis Ababa, Ethiopia,

3.2. Specific objectives

- To compare the pain intensity at Menelik II Referral Hospital Addis Ababa, Ethiopia.
- To compare analgesia consumption in the first 12 hours post-operatively at Menelik II Referral Hospital Addis Ababa, Ethiopia.

Chapter Four: - Methods and Materials

4.1. Study Area

This study was conducted at Minilik II Referral Hospital, one of well-known public hospital in Addis Ababa, capital city of Ethiopia. The hospital is located in Yeka Sub-city, Woreda 06. It is the first modern government run hospital which was built by Emperor Menelik II in 1906. Today the hospital is operated by the Ethiopian Ministry of Health. The hospital surgery department provides all general, urological, gynecological, orthopedics and ophthalmic surgeries. The major operation theater consists three functional operating rooms and one PACU.

4.2. Study Design and Period

Hospital based prospective cohort study was employed from December 25, 2017 to May 10, 2018.

4.3. Population

4.3.1. Source Population

All Patients that undergo midline laparotomy surgery at Minilik II Referral Hospital.

4.3.2. Study Population

Patients who were scheduled for midline laparotomy surgery at Minilik II Referral Hospital, during study period, December 25, 2017 to May 10, 2018.

4.4. Study Variables

4.4.1. Dependent Variables

- Pain intensity measured by numeric rating scale
- Total Analgesia consumption in 12 hours.

4.4.2. Independent Variables

- Socio demographic characteristics: age, ASA and sex
- Surgical Factors: Surgeon experience, types of procedure, and size of midline incision
- Anesthesia Factors: Type of induction agent, type of inhalational agent and duration of anesthesia in minutes
- Post-operative nausea and vomiting
- Post-operative hemodynamic status

4.5. Operational Definition

ASA status: is surgical risk stratifications validated by American Society of Anesthesiologist; described as follows:

ASA I: a healthy patient with no organic/physiological/psychotic problems

ASA II: a patient with controlled medical conditions with mild systemic effect and no limitation of functional ability.

ASA III: medical condition with severe systemic effect, limitation in functional capacity

ASA IV: poorly controlled medical conditions associated with significant impairment in functional ability that is potential threat to life

ASA V: critical condition, little chance of survival without surgical procedure

ASA VI: brain dead patient undergoing organ donation.

Control group: Patients that are not exposed to bilateral rectus sheath block.

Duration of anesthesia: a time in minutes it takes from pre-oxygenation to a time a patient get response to verbal command.

Midline Laparotomy: abdominal cavity operation through medial incision of the abdomen, from xiphi-sternem to symphysis pubis.

NRS: is a valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0-10(11-point scale), 0 means "no pain" and 10 means the "worst possible pain" (24).

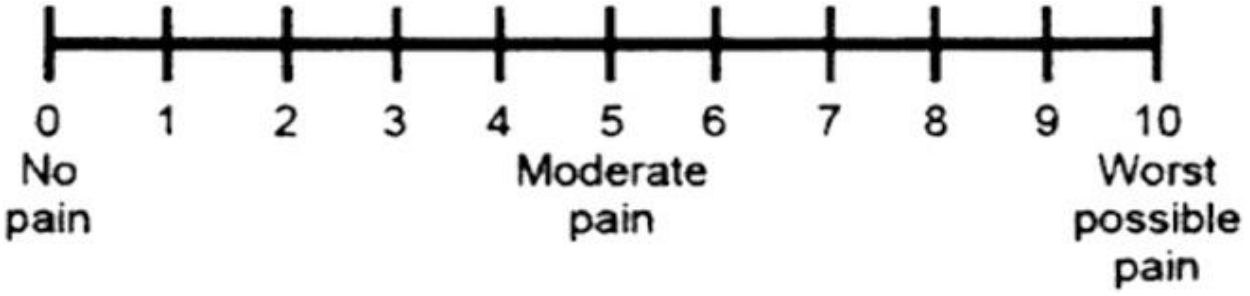

Figure 2:NRS - Adopted from the National Initiative on Pain Control™ (NIPC™)

Postoperative pain: the presence of pain in the postoperative period that is defined as a patient having pain and any pain score other than zero within 12 hours.

Size of midline incision: the midline abdominal laparotomy incision length in centimeters.

Treatment group: those patients that are supplied with rectus sheath block.

Total analgesia consumption: total dose of anti-pain medication given in mg within the first 12hr. after end of surgery for pain.

Type of midline laparotomy: different kinds of procedures performed via midline abdominal incision.

4.6. Inclusion and Exclusive Criteria

4.6.1. Exclusive Criteria

The exclusion criteria include: -

- Patients with Psychiatry problem,
- Age less than 18 years,

- Emergency re-operation
- Patient that takes strong opioids.

4.6.2. Inclusion Criteria

ASA I and II patient scheduled for midline abdominal laparotomy were included in the study.

4.7. Sample Size and Sampling Technique

The appropriate sample size is an important part of the study. Prior to the actual data collection, determination of appropriate sample size which is basically dependent on the purpose of the study, and available resources was done.

Two independent sample size formulas based on the mean difference of VAS score, and total analgesia request among two groups were used to calculate sample size for each group. Having no previous study done in the study area, the result adopted from literature has been used to calculate the sample size based on the two-outcome variables and the largest sample size was used for recruiting study subjects.

The required sample size to show with 95% likelihood that the NRS score within 12 hr is not equal between two groups was calculated as follows.

$$n = \frac{(\sigma_1^2 + \sigma_2^2)\,(\alpha/2+\beta)^2}{(\mu 1 - \mu 2)^2}$$

Where n = the sample size in each of the groups

$\mu 1$ = population mean in control group

$\mu 2$ = population mean in treatment group

$\mu 1 - \mu 2$ = the difference the investigator wishes to detect

$\sigma 2$ = population variance (SD^2)

α= conventional multiplier for alpha =0.05, which is 1.96

β = conventional multiplier for power = 0.80, which is 0.842

from the literature the mean VAS score, μ_1= 1.83 in control group, μ_2= 1.16 in treatment group and $\sigma_1 = 0.74$, $\sigma_2 = 1.20$ (25)

Substituting for these variable yields

$$n = \frac{(1.20)^2 + (0.74)^2 \times (1.96 + 0.842)^2}{(1.16 - 1.83)^2}$$

n = 31, using 1:1 ratio between groups a total of 62 patients were required. By adding 5% contingency the total required patients were 66.

Patients that undergo midline laparotomy was recruited into the study by using systematic random sampling technique. With 95 patients estimated to undergo midline abdominal laparotomy during the study period, 66 participants were included. Considering the consecutive patients scheduled for laparotomy, data collection was made on 2 patients for every 3 patients that underwent the surgery in both groups. Patients were sorted based on time sequence of PACU admission after which data collector recruit 2 patient for every 3 consecutive patients underwent midline laparotomy after grouping based on whether they received BRSB or not. One number was selected by lottery method, then it was used for selection and exclusion made on the rest of the numbers in both groups until the required sample size was met.

4.8. Data Collection Technique and Patients

All patients who were scheduled for midline laparotomy, who fulfilled the inclusion criteria and volunteered to take part in the study was instructed on how to self-report pain using the eleven-point NRS score preoperatively in the waiting room with a trained anesthetist.

After completion of surgery and before dressing the surgical site, M.Sc. anesthesia professionals provided BRSB with 40 ml of 0.25% bupivacaine. In the postoperative time, patients were

transferred to the post anesthesia care unit (PACU) and then transferred to ward when they recovered from anesthesia. In ward, patients were observed by ward nurses and pain is usually managed by tramadol and diclofenac based on patient complaints and sometimes on physician's order.

Patients were asked to report their pain by using the 11-point NRS score after half an hour of the operation in the PACU. Numeric rating scale score and other variables were documented at 1^{st}, 2^{nd}, 4^{th}, 6^{th} and 12^{th} hr. postoperatively. Total analgesia consumed in the first 12 hours were also documented. In addition, when it was reported incidence of nausea and vomiting was recorded postoperatively within the 12 hr. All the data collection was done by four trained anesthetists.

4.9. Data Quality Control

Prior to actual data collection pretest was done on 10% of the sample size to see the effectiveness of the data collecting tool and questioner. Collected data was checked for completeness, accuracy and clarity. Incomplete data was not entered on Epi-data. Data clean up and cross-checking was done before analysis on SPSS version 20. Supervision was done during data collection by principal investigator and supervisor.

4.10. Data Analysis and Interpretation

For analysis purpose and interpretation collected data was entered into Epi-data and transported to SPSS version 20 for analysis. To test for distributions of data Shapiro Wilk test were used while, homogeneity of variance was assessed using non-parametric Levene's test for equality of variance. Comparison of numerical variables between study groups was done using Manny Whitney U test for non-parametric data. Numeric data were described in terms of median and Interquartile range (IQR). Frequency and percentage was used to describe categorical variable and statistical difference between groups was tested using Chi square. p-value less than 0.05 ($p < 0.05$) was considered as statistical significant.

4.11. Ethical consideration

Before starting the study, ethical clearance was obtained from the university ethical clearance committee. The importance of the study was explained & verbal informed consent was obtained

from each participant by the data collectors. There was no coercion and or no incentives for participating in the study. At last, confidentiality of information obtained was fully secured or assured.

4.12. Dissemination plan

The results of the study will be presented to the department of anesthesia as part of M.Sc. in anesthesia thesis. It could also be presented for annual students and staff research conference, annual National Conference of Ethiopian Anesthetists Association (EAA) and will be sent to journals for publishing purpose.

Chapter Five: - Result and Discussion

5.1 Result

5.1.1 Demographic and Perioperative Characteristics

Data were collected from sixty-six patients (i.e. thirty-three in each group). Three data from the treatment group was not included due to loss of follow-up during data collection period and from the control group two data met the exclusion criteria and one data was lost during follow up and were not included in the analysis. Therefore, the statistical analysis was done on sixty data (90%) based on exposed group (as they received BRSB at the end of operation) and unexposed group (those who were not supplied with BRSB at the completion of surgical procedure).

Between the groups there were no statistical significant difference according to the demographic data and type of surgery on age, gender and ASA scores (P > 0.05).

Table 1: ***Demographic characteristics of patients who underwent midline abdominal laparotomy at Minilik II referral Hospital, Addis Ababa, 2017/18.***

Variable	Treatment group (n=30)	Control group (n=30)	P-value
Age (year) ##	46 (23)	45 (39)	0.857
Sex (M/F)	14/16	21/9	0.067
ASA status			0.532
ASA I (n, %)	22 (74%)	25 (84%)	
ASA II (n, %)	8 (26%)	5 (16%)	

Hint: ## = Median (IQR); n (%) = number (proportion), * = statistically significant

Peri-Operative data on types of surgery, length of surgery, estimated surgical blood loss (EBL) and surgical incision length were also comparable in the study groups (all P > 0.05) as shown in Table 2.

Table 2: ***Peri-operative characteristics of patients who underwent midline abdominal laparotomy at Minilik II referral Hospital, Addis Ababa, 2017/18.***

Variable	Treatment group (n=30)	Control group (n=30)	P-value
Types of surgery			0.353
Gastrointestinal (n, %)	26 (87%)	29 (97%)	
Gynecological (n, %)	3 (10%)	1 (3%)	
Urology (n, %)	1 (3%)	0	
Induction agent			0.165
Thiopental (n, %)	12 (40%)	7 (23%)	
Propofol (n, %)	18 (60%)	23 (77%)	
Inhalational Agent			0.739
Halothane (n, %)	25 (83%)	24 (80%)	
Isoflurane (n, %)	5 (17%)	6 (20%)	
Experience of surgeon			0.143
Resident (n, %)	5 (16%)	11 (36%)	
Senior (n, %)	25 (84%)	19 (64%)	
Surgical incision length (cm) ##	14.22 (4.22)	14.50 (6)	0.831
Estimated intraoperative blood loss (ml) ###	367 (295)	272 (304)	0.852
Duration of anesthesia (minutes) ###	140 (52)	175 (98)	0.058

Hint: ## = Median (IQR); n (%) = number (proportion), cm= centimeter, ml= milliliter

5.1.2 Comparison of Postoperative Pain Severity by Numeric Pain Rating scale

The median (Interquartile range) Numeric Rating Scale score between the two groups at different time is presented as shown below in the table.

Table 3: ***The median (IQR) Numeric Rating Scale score between the two groups of patients who underwent midline abdominal laparotomy at Minilik II referral Hospital, Addis Ababa, 2017/18.***

Variables	BRSB group (n=30)	Control group (n=30)	P-value
PACU NRS score	0 (0-3)	6 (2-8)	< 0.001**
1st post-operative time NRS score	0 (0-3)	4.5 (2-7)	< 0.001**
2nd post-operative time NRS score	1 (0-3)	4.5 (2-7)	< 0.001**
4th post-operative time NRS score	2 (0-3)	4 (2-6)	0.001*
6th post-operative time NRS score	2 (0-3)	3 (2-4)	0.007*
12th post-operative time NRS score	2 (1-3)	2 (2-4)	0.194

Hint: ## = Median (Q1-Q3); * = statistically significant, ** = Highly statistical significant

The median NRS score were lowest in the treatment group at PACU, 1st,2nd, 4th, and 6th hour and equals to the control group at the 12th hour post operatively. By Using Many Whitney test, a significant statistical difference was observed at PACU, 1st, 2nd, 4th, and 6th hour but not at the 12th hour post operatively between treatment and control groups.

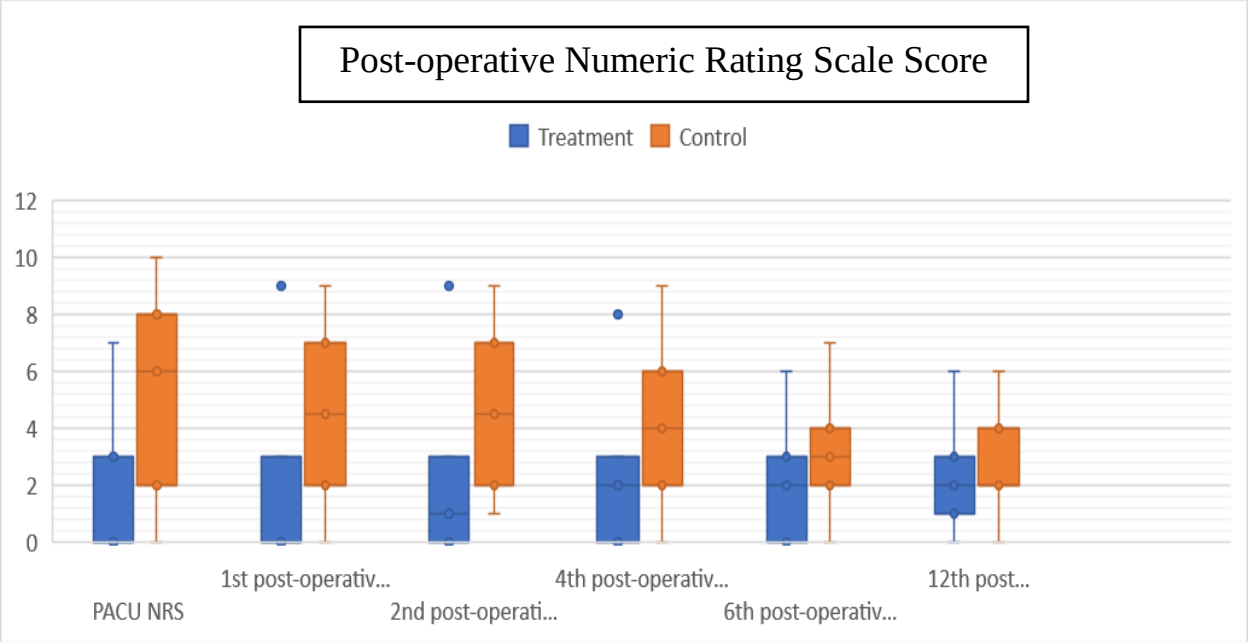

Figure 3: **Post-operative pain comparison of using 11-point NRS score (0-10) At Menelik II Referral Hospital Addis Ababa, Ethiopia 2018. Data is median (Q1-Q3)**

5.1.3 Comparison of Total Analgesia Consumption between Groups

There was statistically significant difference in to median total tramadol consumption within 12 hours postoperatively. There was also statistical significant difference between the two groups in total diclofenac consumption within 12 hours as shown below in the table.

Table 4: ***Comparison of total analgesia consumption between groups at Menelik II Referral Hospital, Addis Ababa, Ethiopia, 2018.***

Variable	Treatment group (n=30)	Control group (n=30)	P-value
Total analgesia consumption within 12 hours			
Tramadol in mg (IV)	0 (62.50)	75 (200)	0.022*
Diclofenac in mg (IM)	0 (75)	75 (75)	0.013*

Hint: ***## = Median (IQR);*** **IV: Intra vascular, IM: Intra muscular, * =** ***statistically significant***

5.1.4 Post Anesthesia Care Unit and Ward data

The **post anesthesia care unit (PACU)** vital sign taken at 30-minute post operatively was comparable between the two groups and there was significant difference between the two groups in terms of PACU analgesia request.

Table 5: ***Post-Anesthesia Care Unit data on vital sign between two groups, PACU stay, and PACU analgesia request at Menelik II referral Hospital Addis Ababa Ethiopia 2018.***

Variable	Treatment Group (N=30)	Control Group (N=30)	P-Value
PACU Stay Time	77.5 (60)	80 (30)	0.628
PACU Systolic Blood Pressure At 30-Minute Post-Operative Time (mmhg)#	120 (29)	134 (18)	0.162
PACU Diastolic Blood Pressure 30-Minute Post-Operative Time (mmhg)#	76 (16)	84 (18)	0.059
PACU Mean Arterial Blood Pressure 30-Minute Post-Operative Time (mmhg)#	87 (19)	92 (16)	0.225
PACU Pulse Rate Per Minute At 30-Minute Post-Operative Time##	75 (17)	81 (27)	0.277
PACU Arterial Oxygen Saturations At 30-Minute Post-Operative Time (%)##	96 (4)	95 (6)	0.476
PACU Analgesia Requirement			0.029*
YES n, (%)	10 (20%)	15 (50%)	
NO n, (%)	20 (80%)	15 (50%)	

Hint: ## = Median (IQR); n (%) = number (proportion*) ** = statistically significant

There was no statistically significant difference regarding the postoperative Systolic Blood pressure, Diastolic Blood pressure and Heart rate at PACU, 1st, 2nd, 4th, 6th and 12th postoperative hours.

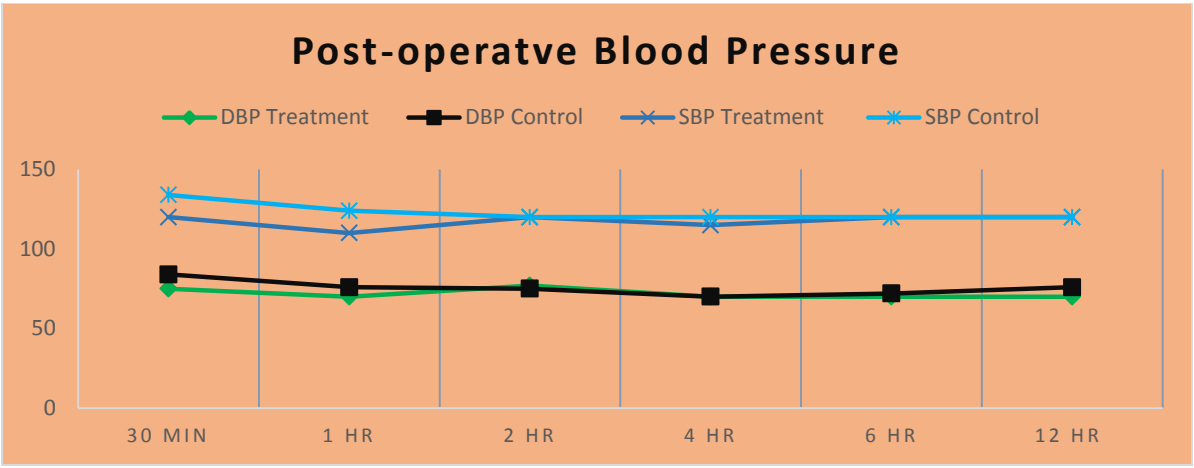

Figure 4: **Post-operative blood pressure (mmHg) at Menelik II Referral Hospital, Addis Ababa, Ethiopia, 2018. Data is median**

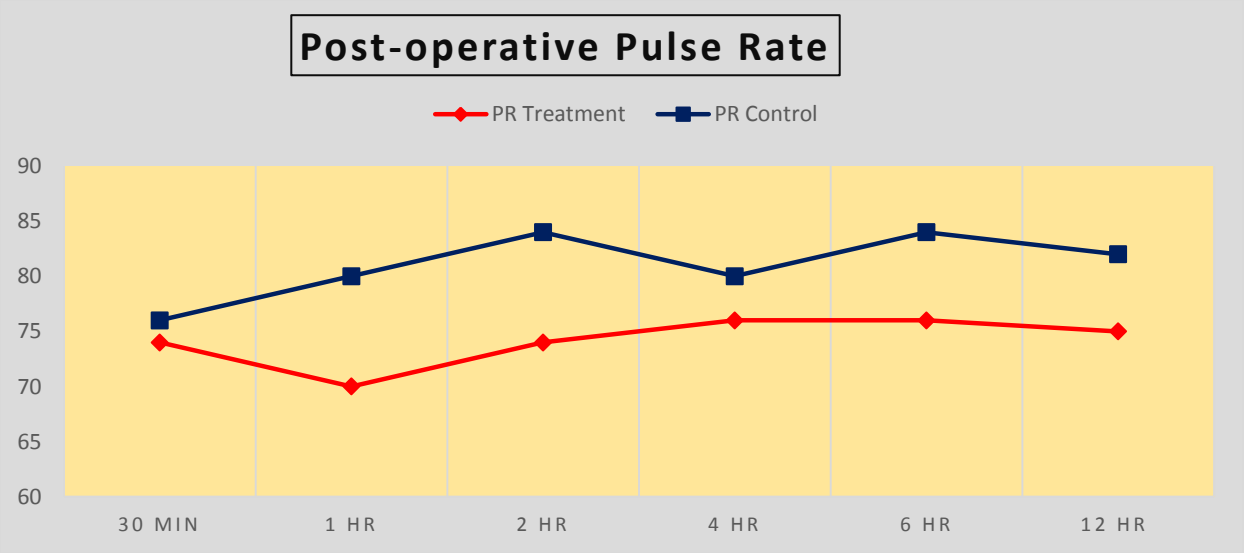

Figure 5**: Post-operative pulse rate per minute at Menelik II Referral Hospital, Addis Ababa, Ethiopia, 2018. Data is median**

5.1.5 Incidence of Nausea and Vomiting

The incidence of nausea and vomiting over 12 hours was 23%. The proportions of patients with nausea and vomiting was lower (20%) in the treatment group (BRSB) compared to the control group which was 27% with a p value of 0.542.

5.2 Discussion

Our study demonstrates rectus sheath block in patients undergoing midline laparotomy resulted in statistically significant lower pain scores in treatment group when compared with the control group at PACU with median (IQR) NRS score of 0 (0-3) versus 6 (2-8) p-value < 0.001. The NRS score was also lower in the 1^{st}, 2^{nd}, 4^{th}, and 6^{th} hr. postoperatively (p-value <0.05) among rectus sheath group and control group: In addition, less 12 hr. analgesia consumption was observed with treatment group when compared with those without block(p-value<0.05).

Though the rectus sheath block was started a century ago, there are some conflicting findings about its effectiveness. In 2009, a study done to compare the accuracy of local anesthetic placement by trainee anesthesiologists using loss of resistance (LOR) or ultrasound guidance, they found in the LOR group, local anesthetic was correctly placed in 45% of abdominal punctures but superficial and deep to the rectus sheath in 34% and 21% of punctures, respectively (26); this difference in accuracy could be affected by the experience of the anesthesia personnel (i.e. as they were trainee anesthesiologists). And because they did not compare the pain measurement score among the groups, we were unable to have a complete view on the variation between the groups that resulted because of the LOR and ultrasound guidance technique while performing the block. On the other hand, a study done to compare the effectiveness of local anesthetic deposition superficial to the rectus abdominus muscle plus on the posterior rectus sheath versus local anesthetic deposition only on the potential space between rectus abdominus muscle and posterior rectus sheath; they found the former group with a statistical significant lower pain score when compared with the second group despite superficial deposition of local anesthetic. Knowing there is a risk of superficial deposition of local anesthetics during LOR technique, it may not affect the pain perception due to local anesthetic deposition on the anterior rectus sheath and will result in blocking the anterior coetaneous branch of intercostal nerves as they emerge from the rectus muscle in anterior rectus sheath. This will increase the chance and effectiveness of block (27).

The blind RSB was found to be effective in a study done in 1986 for patients with midline abdominal incision (i.e. laparoscopic) (16). Even for obese person the loss of resistance technique with careful appreciation of the anatomy could be done effectively as J. Muir and S. Fergusol mentioned on their case report in 1996 (28). Despite recent studies use ultrasound

guidance to increase the accuracy of the block, in our study hospital the block is practiced in LOR technique due to limited resource.

The result of our study is in line with the literature showing the effectiveness of blind rectus sheath block technique and is comparable with studies that performed the block with ultrasound guidance. The median (range) pain score in the ward was 1 (0-3) and 4.5 (2-7) at the 2nd postoperative time with p value <0.001, 2 (0-3) and 4 (2-6) at the 4th postoperative time with p value = 0.001, and 2 (0-3) and 3 (2-4) at the 6th postoperative time with p value of 0.007 in BRSB group and control group respectively. Our finding shows comparable result with a randomized controlled trial by Elbahrawy and El‐Deeb with median (range) 2 (1‐3) and 4 (3‐6) 2nd hour postoperatively, 2 (1‐4) and 4 (3‐6) at the 4th hour postoperatively, and 2 (1‐4) and 3 (2‐4) at the 6th hour postoperatively with p value < 0.001 at all times in treatment and placebo group respectively; even though, they used VAS score to measure pain intensity, have homogeneous cases and used ultrasound guidance while performing the block (21). The VAS and the NRS provide similar information about pain, especially when a similar tool format is being used; but a direct conversion cannot be made between one and the other especially, when the tool formats are different (29). Bijur et al. found a significant correlation between the VAS and the NRS (r = 0.94, 95% CI = 0.93–0.95). Their study also shows a strong level of agreement between the two tools (30).

In this study, there was a comparable PACU staying time between the two groups, median(range) of 77.5 Min. (60-120Min.) for the case group and 80 Min. (60-90 Min.) for the control group with p = 0.628. The proportions of patients who had requested rescue analgesia in the PACU was 20% from the treatment group and 50% from the control group with a statistical significant p value of 0.029. As shown by blinded controlled study by Bashandy GMN et al, there was a statistical significant difference on PACU morphine consumption between the two groups that went under abdominal cancer surgery with midline incision. They found the mean and SD of PACU morphine consumption were 2.1 ± 2.2 and 5.5 ± 2.1 in the treatment and placebo group, respectively and statistical significant p value of 0.001 (19).

A study done by Shah VA and Bajaj M on ultrasound rectus sheath block in management of pain in laparoscopic tubal ligation reveals total 12-hour postoperative tramadol consumption in

treatment group is lower than that of placebo group with mean and SD of 13.33 ± 34.57 compared to 168.33 ± 63.63 respectively with p value of 0.012. Total tramadol consumption within 12 hours in our study were decreased in the group with BRSB compared with those without the block with median (IQR) of 0 (62.50) versus 75 (200), respectively with p-value of 0.022. The difference was our study used blind technique to perform the block, and the block was applied at the end of the surgery unlike the study done by the Shah VA and Bajaj M. (20). Jin et al. in 2018 reveals the pre-operative administration of RSB when compared with RSB performed post operatively for patients undergoing midline transabdominal gynecological surgery, no statistical significant difference on VAS score (p=0.534) and postoperative analgesia consumption (p=0.749) among the groups was found (31).

In addition to variation with 12hr. tramadol consumption there were statistical significant diclofenac consumption difference in the 12 hr. postoperatively among the groups; 0 (0mg - 75mg) and 75 (0mg -75mg) with sig value of 0.013. We lack similar findings that used diclofenac as post-operative pain management drug, as most study used strong opioids like Morphine for postoperative pain management.

Though there was proportional difference among the groups for the incidence of nausea and vomiting, it was statistically insignificant (p = 0.542). Elbahrawy and El‑Deeb on their controlled trial, found postoperative proportion for nausea and vomiting incidence to be 6 (30%) and 1 (5%) for control and rectus sheath block group, respectively a statistical significant p value = 0.037. This difference among the studies could be attributed to follow up time variation; as they followed their patients for 24 hours and we followed for only 12 hours postoperatively (21).

Chapter Six: - Strength and Limitation

6.1 Limitation of the Study

The main limitation of this project was it was observational study. Pain severity was not assessed at movement and body mass index was not calculated due to the hospital operation theater lacked instruments that were required to measure the weight and height of the patient. Lack of standard pain management protocol in the study hospital were among limitation of this project.

6.2 Strength of the Study

This study is the first study in the study area and could be an input to identify efficacy of postoperative BRSB and this study will be useful as baseline information for other researchers. Only MSc anesthesia graduates did the block so reliability is assured. More or less homogenous study participants were included in the study.

Chapter Seven: - Conclusion and Recommendation

7.1 Conclusion

The result of our study shows for surgeries done through midline laparotomy, adding bilateral rectus sheath block (BRSB) at the end of the operation with 0.25% bupivacaine is useful postoperative analgesia.

7.2 Recommendation

We recommend anesthesia professionals to consider bilateral rectus sheath block (BRSB) for patients that undergo midline laparotomy as a post-operative analgesia technique.

We also recommend additional randomized controlled study.

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Annexes

Annex I

Consent form

Dear participant:

This study is planned to assess the effectiveness of bilateral rectus sheath block for midline gastrointestinal laparotomies. By chance you are admitted to participate in the study if you are willing. So, we kindly request your participation in the study and honest response to achieve the objective of the study. Your responses are completely confidential and you have full right either to refuse a single question or leave the study. Thanks for taking part in the study.

Are you willing to participate in the study, please? A) YES B) NO

For further question ask the-

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Annex II

ውድ የዚህ ጥናት ተሳታፊዎች

ይህ ጥናት ታስቦ የተዘጋጀው በመካከለኛ ሆድ ላይ ለሚደረጉ ቀዶ ጥገናዎች ከሆድ ጡንቻ በታች (below the rectus abdominus muscle) ባለው ቦታ ላይ የሚገኙት ነርቮችን ለብቻ በማደንዘዝ ከኦፕራሲዮን በኋላ ህመም በምን ያህል እንደሚቀንስ ለማወቅ ነዉ ::እርሶም እንደ እድል ሆኖ በዚህ ጥናት እንዲሳተፉ ተመርጠዋል ::

የዚህ ጥናት ጥቅም እርስዎ በሚሰጡት ምላሽ መሰረት መረጃዎችን በማማላት በሚገኘዉ ዉጤት መሰረት መረጃዎችን በማጠናቀር ውጤቱን እየተሰራበት ካለው ጋር ለማገናዘብ እንዲቻል ነዉ ::ጥናቱ በትክክል አላማውን እንዲመታ የእርሶዎን ድጋፍ እንጠይቃለን :: የማንኛውም ግለሰብ ስም እንዲሁም ሀሳቡ ሙሉ በሙሉ በሚስጥር የተጠበቀ ነው :: በጥናቱ መሳተፍ አለመሳተፍ የራስዎ ምርጫ ብቻ ነዉ ::ግልፅ የሆነ ምላሽን እንዲሰጡን በአክብሮት እንጠይቃለን ::

ለመሳተፍ ፈቃደኛ ኖት ሀ/ አዎ ፊርማ_____

ለ/ አይደለሁም

ለመሳተፍ ፈቃደኛ ስለሆኑ እናመሰግናለን!!!!!!!

ለበለጠ መረጃ በዚህ ስልክ ይደውሉ፡….0910021150……. ጽንኤል ቀና

Annex III

Section I: Socio Demographic Data (chart review)

Card number:		**Bed no:**	**Code**
S.no	**Question**	**Response**	
1	Age		
2	Sex (M/F)		
3	ASA (I/II)		

Section II: Data during preoperative period

S.no	Question	Response	
5	Diagnosis	_____	
6	Type of surgery:	_____	
7	Base line Pulse rate	____bpm	
8	Base line Blood pressure(MAP)	____/____(____)mmhg	
9	Base line RR & spo2	_____br/m &_____%	
10	Does the patient take premedication?	1. YES 2.NO	
11	If yes for the above question, what was the drug?	A. Paracetamol B. Diclofenac C. Tramadol D. corticosteroid other, specify_____	
12.	Does the patient have any comorbities?		
13.	If yes for the above question, what is the coexisting disease?		
14	What is the drug that the patient is taking for the coexisting disease?		

Annex IV

Section III: Data during Intra-operative period

S.no	Question	Response	Code
15	Does the patient receive any analgesic drug before Induction of Anesthesia?	1. YES 2. NO	
16	If YES specify type and dose	_____(____mg)	
17	Type of Induction agent	1. IV 2. Inhalational 3. Awake	
18	Induction agent type and dose		
19	Intraoperative analgesia given	1. YES 2. NO	
20	If yes specify type, time and dose of the drug given	_____mg	
21	Maintenance of Anesthesia		
22.	Size of the surgical incision		
23	Any complication in the intraoperative time	YES NO	
24	Does the patient extubated in the OR?	YES NO	
25	If yes, does the patient is responsive		
26	Estimated intraoperative blood loss		
27	Experience of the surgeon	1. R3 2. R4 3. Senior	
28	Duration of surgery		
29	Duration of anesthesia		

Annex V

Section IV: Hemodynamic parameters Data during in post-operative period (in the PACU and Ward) 30min post operation, 1st, 2nd, 4th, 6th, and 12th

S.no	V/S	Immediately at Arrival of Recovery Room	30min post op	1st hr. post op	2nd hr. post op	4th hr. post op	6th hr. post op	12th hour post op
30	Date (day/month/ETH year)							
31	Time (local)							
32	BP (mmHg) SBP/DBP(MAP)							
33	PR (bpm)							
34	Respiratory rate							
35	SPO2 (%)							
36	NRS							
37	Analgesia drug given							
38	Other medication given							

37. Does the patient have nausea within the first 12 hours of surgery? A. YES

B. NO

38. Does the patient develop vomiting within first 12 hours of surgery? A. YES

B. NO

39. for how long the patient stayed at the PACU_____

40. Total and type of analgesic consumption at the PACU_____

41.Total and type of analgesic consumption within 12 hours after the patient arrived in recovery/ward_____.

Appendix

አማርኛ ትርጉም

በቁጥር አምሳያ መለኪያ (NRS)

1. ይህ መለኪያ በመጀመሪያው 12 ሰአት 6 ጊዜ የሚወሰድ ሲሆን.
    a. በሽተኛው የሚጠየቃቸው ጥያቄዎች
        i. ቀዶ-ጥገናው የተሠራበት ቦታ ህመም ይሠማዎታል ወይ
        ii. ከዜሮ እስከ አስር ካሉት ቁጥሮች አሁን የሚሰማዎትን ህመም የትኛው ቁጥር ይገልፀዋል
2. ከላይ የተሰጠው ማብራሪያ በቂ ሳይሆን ሲቀር ፣ለበሽተኛው የበለጠ መረጃ መስጠት አስፈላጊ ሆኖ ይገኛል
    a. 0- ምንም ህመም የለም
    b. 1-3 - ትንሽ ህመም አለ
    c. 4-6 - መካከለኛ ህመም አለ
    d. 7-10 - ከባድ ህመም አለ

ቀዶ ጥገናው ካለቀ

- ከ 30 ደቂቃ ቦሐላ.....
- ከ 1 ሰአት ቦሐላ .....
- ከ 2 ሰአት ቦሐላ .....
- ከ 4 ሰአት ቦሐላ.....
- ከ 6 ሰአት ቦሐላ.....
- ከ 12 ሰአት ቦሐላ.....