

Assessment of postoperative analgesic effect of rectus sheath block for patients who had emergency midline laparotomy, in University of Gondar Compressive Specialized Hospital, Northwest Ethiopia: an observational prospective cohort study.

Wubie Birlie Chekol (✉ birliewubie@gmail.com)

University of Gondar

Hailu Yimer Tawuye

University of Gondar

zewuditu abdissa denu

University of Gondar

Abatneh Feleke agegnehu

University of Gondar

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Abstract

Background : Postoperative pain is a major concern after midline abdominal surgeries. Rectus sheath block (RSB) has been indicated after midline laparotomy ; however, the analgesic effect of landmark technique on postoperative pain was not well investigated. **Objectives:** we tested the hypothesis that RSB reduces pain scores, decreased total analgesic consumption and prolong first analgesic request time after emergency midline laparotomy . **Methods :** Prospective cohort study was done from February 1 to May 10, 2018. Eighty eight patients were observed in this study, 44 in the RSB group and 44 in the non exposed group. Pain severity was assessed in first 24 hours postoperative period in terms of total analgesic consumption, first analgesic request time and visual analogue scale (VAS) score at 1 hour , 2 hours , 4 hours , 6 hours , 8 hours , 10 hours, 12 hours and 24 hours. **Results :** The RSB group had significantly reduced VAS score at rest and on movement at (1, 2, 4, 6 and 8 hours), but not at (10, 12 and 24 hours) point assessed. Patients in RSB group had reduced tramadol requirement compared to non exposed group in 24 hours (255.68 ± 80.13) VS (314.77 ± 97.40), $P=0.003$). The 24 hours diclofenac consumption was significantly lowered in RSB group (75 (75-150) than non exposed group (150 (75-150), $P=0.031$). Mean time to first analgesic request was significantly longer in RSB group (372.95 ± 131.41) than non exposed group (50.34 ± 14.12), $p \leq 0.001$). **Conclusions :** The RSB group resulted in less pain scores, reduced total analgesic utilization and stayed for longer time for first analgesic request. Therefore we recommend RSB as part of multimodal analgesia after emergency midline laparotomy. **Keywords:** midline abdominal surgery, rectus sheath block, abdominal field block

Background

Midline abdominal operations are very painful procedures which accounted 86% more to extreme pain after surgery[1]. Postoperative pain management is vital for such patients because, severe pain is associated with difficulty in sleeping, decreased mobility and atelectasis[2, 3]. These factors will result for high health care cost through delayed hospital discharge, less patient satisfaction, delayed postoperative mobilization and enhancement of chronic postoperative pain[4].

Currently analgesic techniques involving parenteral analgesics, abdominal field blocks and thoracic epidural analgesia (TEA) are becoming popular for patients having midline abdominal surgeries[5-7]. Even though, TEA is the gold standard pain management options for major abdominal surgeries, it may not always be possible to apply due to patient specific contraindications, non-availability of experts, hypotension, increased requirement of anesthetic personnel, operation theatre time constraint and technical difficulties of 6-7%[6, 8]. Transversus abdominis plane (TAP) block has gained popularity in recent years after abdominal surgeries but an incision extending above the umbilicus is not guaranteed by this block[5, 9-11].

Recent multimodal approaches target incisional pain instead of visceral pain which leads the emergence of abdominal field block[12]. RSB use has been described in a wide variety of surgeries including

umbilical hernia repair, epigastric hernia repair, open gynecological surgeries, major open urological pelvic surgeries and midline laparotomies[13-18].

RSB can be demonstrated at four places 5cm cephalad-5cm lateral and 5cm caudad-5cm lateral on each side of the umbilicus with 0.25% of 10-15ml at each places[19]. Yarwood et al recommended 0.25% of 30-40 ml bupivacaine as an effective and safe dose for RSB in adult patients[20]. Johnson et al also established the RSB for pediatric patients 2-3 cm from the midline with 0.2-0.3ml/kg of 0.25% bupivacaine which was repeated on the opposite side[21]. The drug is deposited at a potential space that exist between the rectus muscles and posterior rectus sheath [19, 21, 22].

RSB have low risks of hemodynamic changes, avoidance of epidural catheter discomfort and early mobilization[23, 24].

Different studies supported the efficacy of RSB when performed by land mark technique after laparoscopic surgery, umbilical and paraumbilical incisions [13, 21, 25]. Furthermore patients with abdominal wall pain managed with RSB were having a significant improvements in pain and quality of life[26, 27]. However the efficacy and spread of the block can be affected by landmark technique, which might be the imprecise injection of the local anesthetic agent relative to the potential spaces. Ultrasound based RSB may improve the certainty and safety of the block. Obesity largely affects the success rate of the RSB if the body mass index (BMI>35kg/m²[28].

Systemic analgesics and TEA are employed for the treatment of postoperative pain after midline laparotomy; However opioids have so many side effects and epidural analgesia is technically difficult, not easily accessible and not suitable for hemodynamically unstable patients[29, 30]. Emergency midline laparotomy is a common operation done in our hospital and landmark technique of RSB is routinely practiced for such procedures but, no research done before, the analgesic effect is not well investigated and no recent data done about the techniques. Most of the literatures have been investigated to assess the analgesic efficacy of RSB with ultrasound guidance and surgical catheter placement techniques. So this study was aimed at assessing the analgesic effect of RSB block on emergency midline laparotomy patients in terms of VAS score, time to 1st analgesic request and total post operative analgesic consumption in 24 hours period.

Methods

Study objective

The aim of this study was to assess the analgesic effect of RSB block after emergency midline laparotomy in terms of VAS score; time to 1st analgesic request and total post operative analgesic consumption in 24 hours period.

Study design and period study area

Institutional based prospective observational cohort study was done from February 1 to May 10, 2018 in University of Gondar comprehensive specialized Hospital.

Study setting

University of Gondar comprehensive specialized Hospital is located in Amhara region, North Gondar zone, which is about 738km away from Addis Ababa in Northwest of Ethiopia.

Study participants

The non- exposed group of all patients who had emergency midline laparotomy, patient's age ≥ 18 years old, American Society of Anesthesiologist (ASA) physical status I–II, patients who were induced with standard dose of ketamine anesthesia (2mg/kg), maintained with halothane anesthesia and on standard dose of intraoperative morphine analgesia (0.1mg/kg) were included in this study. The **exposed group** of all patients that contented the information listed at the non exposed group plus patients who received 32 ml of 0.25% bupivacaine for the RSB group at the end of surgery were included in this study. On the other hand, patients who were managed with combined TAP and RSB, who had lateral side abdominal wound, BMI $> 35 \text{kg/m}^2$, elective procedures, who were not keen to give consent to contribute in this study and uncooperative patients were our exclusion criteria.

Study variables

In this study the dependant variables were postoperative pain which were assessed using VAS score at rest and on movement, total postoperative analgesics consumption and first analgesic request time. The independent variables were duration of surgery, duration of anesthesia, size of incision, ASA physical status, weight, height, BMI, age and sex of the patients (**Table 1**).

Sample size determination

The sample size was designed using mean \pm standard deviation of the VAS score (1.06 ± 0.82 VS 0.63 ± 0.61) in rectus sheath block group and control group respectively[31]. With a mean comparison formula of: n (in each group) = $(S1^2 + S2^2) f (\alpha, \beta) / (M1 - M2)^2$, where $\beta = 20\%$ and $\alpha = 5\%$. $M1$, $S1$ and $M2$, $S2$ are the mean and standard deviation of the RSB group and non exposed group respectively. n (in each group) = $(0.82^2 + 0.61^2) (1.96 + 0.85)^2 / (0.43)^2 = 44$. N (total) = 88. Then finally we added 5% non response rate with considering of loss of follow up and our sample size came up with 93 patients.

Sampling technique

Patients were categorized as exposed and none exposed group based on the responsible anesthetists' independent decision to use RSB at the end of the surgery. Participants were consecutively selected from each group till the required samples were achieved.

Data collection procedure

Structured questionnaires were prepared for all patients who fulfilled the inclusion criteria. After skin closure RSB was done by the responsible anesthetists using blunted needle on supine position at four places on each side of the umbilicus. The space was identified by moving the needle from side to side to felt the scratching of the sheath and advancing until the resistance of posterior layer of the rectus sheath wall felt. The drug was deposited at a potential space that exists between the rectus muscles and posterior rectus sheath. The first data collector coded patient group and recorded intraoperative information like patient's age, sex, ASA status, height, weight, BMI, incision size, duration of surgery and duration of anesthesia. The second data collector recorded postoperative information within the first 24 hours period in terms of total analgesic consumption, the first analgesic request time and VAS score at 1 hour, 2 hours, 4 hours, 6 hours, 8 hours, 10 hours, 12 hours and 24 hours. The VAS score was determined by patient marking of their pain intensity on a line which is 10 cm long at rest and on movement. The data collection process was supervised by principal investigator.

Data quality management

Data was ensured with pre-test on 5% of the sample and collected data were checked out for the accuracy, clarity and completeness by principal investigator. After pre-test the questionnaires were modified appropriately. Training was given to data collectors for one day on inclusion and exclusion criteria, how to approach the study participants and how to use data collection tools. Finally data clean up and cross-checking was done before analysis.

Data processing and analysis procedures

Data were entered, coded, cleaned and cross checked with SPSS software version 20. Shapiro Wilk normality test was used to identify distribution of data. Normally distributed demographic data were analyzed with independent student t-test. There was normal distribution of data for VAS score at rest and on movement, first analgesic request time and 24 hours total tramadol consumption. Therefore an independent student t-test was performed on these data with a 95% confidence interval and homogeneity of variance was assessed using the Levene's test for equality of variances. There was no normal distribution of data for 24 hours total diclofenac consumption, so Mann-Whitney U test was performed on the data with a 95% confidence interval to analyze the total diclofenac consumption. Normally distributed data was presented as mean \pm SD, whereas not normally distributed data was presented with median (IQR). Categorical variables were analyzed with chi-square test and presented as frequency (percentage). A P value $<$ 0.05 was considered as statistically significant.

Ethical consideration

Ethical clearance was obtained from University of Gondar ethical Committee. Confidentiality was insured by avoiding personal identifications and keeping questionnaires block. The aim of the research was explained to the patients and informed consent was obtained. None willing participants in the study were guaranteed to refuse at any time. The responsible nurses were informed whenever patients feel pain during data collection time by the second data collector.

Results

Socio-demographic and surgical related variables

Total of 88 patients who underwent emergency midline laparotomy were included in this study with 94.6% response rate. Of these patients 44 were received RSB at the end of surgery and 44 without RSB. Five patients (two from exposed group and 3 from the non exposed group) were excluded due to the incomplete data (**Table 2**)

Pain VAS Score at rest

The mean pain VAS scores were statistically significant and less in RSB group than non exposed group at 1,2,4,6 and 8 hours at rest postoperatively (**Table 3**)

Pain VAS Score at movement

The mean pain VAS scores were statistically significant and less in RSB group than non exposed group at 1,2,4,6 and 8 hours on movement postoperatively (**Table 4**)

Postoperative total analgesic consumption and first analgesic request time

Tramadol consumption was significantly higher in none exposed group than rectus sheath block group. The 24 hours diclofenac consumption was significantly lowered in RSB group than non exposed group. The RSB group had a longer time for the first analgesic request than non exposed group (**Table 5**)

Discussion

This study assessed the analgesic effect of RSB by comparing with non exposed group of patients in the first 24 hours post operative period following emergency midline laparotomy. There were lesser pain VAS scores both at rest and on movement, reduced the need for systemic analgesia and prolonged time of first analgesic request in the RSB group.

In this study, RSB in patients with emergency midline laparotomy resulted in a statistically significant less pain scores with compared to non exposed group at 1,2,4,6 and 8 hour postoperative period, but there were no statistically significant differences in pain reduction at 10,12 and 24 hours. Similarly RCT study done in Egypt reported a significantly lower VAS score in RSB group compared with the control group in patients with emergency laparotomy at 2,4 and 6 post operative hours[3]. However in their study the mean VAS score was significant until 6 hours postoperatively which might be they performed the RSB before the start of incision.

Smith et al reported that the VAS pain scores in RSB group were significantly lower than the control group at 1,6 and 10 postoperative hours[22]. The discrepancy at 10 hours could be they tested their hypothesis

with intervening on anesthetic and analgesic management intraoperatively and the procedure was laparoscopic surgery.

In our study RSB was capable to reduce the VAS score for the first eight postoperative hours compared to the non exposed group. A study done at Egypt for elective midline laparotomy exceedingly reduce the VAS score throughout 24 hours postoperative period for RSB group compared to control group[32].The inconsistency in reduction of VAS score after eight hours might be they deposited the local anesthetic agent with direct visualization, patient urgency difference and presence of interventions.

In our study the mean total dose of tramadol consumption within the first 24 hours was lower in RSB group than non exposed group and so statistically significant (255.68 ± 80.13) VS (314.77 ± 97.40), $P=0.003$. This result was comparable with a study conducted in turkey on emergency pediatrics major abdominal surgeries which showed that the amount of tramadol consumption was higher in control group than RSB group and was so statistically significant[18].Similarly Elbahrawy et al showed that the amount of opioid consumption was lower in RSB group than control group on emergency laparotomy patients[3].This similarity might be due to the same midline laparotomy in which the incision site is principally conducted by the same target nerves which gives prolonged pain relief after nerve block.

In our study the first analgesic request was prolonged in the RSB group .The RSB group had the first analgesic request after (372.95 ± 131.41)minutes and non exposed group (50.34 ± 14.12) minutes with $P \leq 0.001$.This finding was in agreement with a study conducted by Ozcengiz et al that described the first analgesic request after (900 ± 553)minutes in the RSB group whereas (133 ± 90)minutes in the control group with $P \leq 0.001$ [18].This finding also in accordance with study conducted in Egypt on patients undergoing elective midline laparotomy[32]. The possible reason might be the prolonged effect of the nerve block.

Conclusions And Recommendations

The RSB group resulted in less VAS scores, reduction of total analgesic consumption and prolonged time for the first analgesic request after emergency midline laparotomy. Therefore we recommend it as part of multimodal pain management techniques in patients after emergency midline laparotomy. We also recommend further study to determine the optimal effects of this abdominal field block on such patients by checking the success rate of RSB, by intervening on anesthetic and analgesic managements and by including other limitations of this study.

Limitation of the study

Patients were not randomly allocated even though there were comparable groups.The involvement of different anesthetists in the management of both RSB group and non exposed group might affect the result of the study. The involvement of different nurses in postoperative pain management might affect the result of the study. Extent of patients compliant of their pain might affect our result. Blinding of data collectors was difficult because, they might get the nerve block information from anesthetic record sheet.

Abbreviations

ASA-American society of anaesthesiologists

BMI-Body mass index

RSB-Rectus sheath block

TAP-transverses abdominis plane

TEA-thoracic epidural analgesia

VAS-visual analogue scale

Declarations

Availability of data and materials: the data sets generated and/or analyzed during the current study are available on the corresponding author and will be submitted upon reasonable request.

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Author's contributions: **WBC:** this author helped in development of proposal, data analysis and manuscript preparation. **HYT, ZAD** and **AFA:** these authors helped in appraising the journals and commenting during proposal development and manuscript preparation.

Ethics approval and consent to participate: ethical clearance was obtained from Gondar College of medicine and health sciences ethical committee.

Consent for publication: not applicable

Competing interests: the authors declared that they have no any competing interest.

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Tables

Table 1: Operational definition

Terminologies	Definition
VAS score	Is a testing technique in which a subject selects from gradient of alternatives as 0= no pain to 10=worst imaginable pain arranged in linear fashion and measured with 10 cm ruler.
	
Time for the first analgesic request	Is defined as the initial time in which patient need pain treatment in the postoperative period.
Emergency midline laparotomy	Defined as a vertical incision that will extends both above and below the umbilicus which allowed wide access to the most abdominal cavities and needs early intervention.
Total analgesic consumption	Defined as the amount of analgesic drugs given to the patient within 24 hours postoperatively.
Pain on movement	Means assessment of pain on coughing and deep respiration.

Table 2:Socio-demographic and surgical related variables in both groups who underwent emergency midline laparotomy, in University of Gondar Referral Hospital, Northwest Ethiopia from February1 to May 10, 2018.

Variables	RSB(n=44)	Non-exposed(n=44)	P-value
Age(years)	41.75 ±15.36	43.57±15.79	0.585
Weight (kilogram)	59.27±5.92	60.05±6.04	0.546
Height (meter)	1.63±0.07	1.65±0.07	0.322
BMI (kilogram/meter ²)	22.31±2.39	22.40±2.05	0.849
Incision size (centimeter)	19.64±1.69	19.39±1.81	0.504
Surgical duration (minute)	175.57±26.98	175±33.69	0.931
Anesthetic duration (minute)	191.70±28.43	190.91±32.99	0.904
Sex			
Male	24(54.5%)	27(61.4%)	0.517
Female	20(45.5%)	17(38.6%)	
ASA physical status			
I	30(68.2%)	26(59.1%)	0.375
II	14(31.8%)	18(40.9%)	

ASA-American Society of Anesthesiologists, BMI-Body Mass Index: Values are presented with

Mean ±SD, frequency (percent %): P value >0.05 was considered as statistically non-significant.

Table 3: Postoperative VAS score at rest over the first 24 postoperative hours in patients who underwent emergency midline laparotomy, University of Gondar Referral Hospital, Northwest Ethiopia, from February 1 to May 10, 2018.

Variables	RSB(n=44)	Non-exposed(n=44)	P-value
VAS score at 1hour	3.65±0.93	4.32±1.51	0.014*
VAS score at 2hour	3.82±0.92	4.41±1.49	0.028*
VAS score at 4 hour	3.28±0.87	3.76±0.94	0.014*
VAS score at 6 hour	3.54±0.98	4.13±0.76	0.002*
VAS score at 8 hour	3.82±0.71	4.24±0.79	0.01*
VAS score at 10 hour	3.88±0.95	4.04±0.77	0.384
VAS score at 12 hour	4.13±0.78	4.33±0.77	0.218
VAS score at 24 hour	4.06±0.76	4.32±0.77	0.117

Data was presented with (mean ±SD).P value <0.05 was considered as statistically significant.

Table 4: Postoperative VAS score on movement over the first 24 postoperative hours in patients who underwent emergency midline laparotomy, University of Gondar Referral Hospital, Northwest Ethiopia, from February 1 to May 10, 2018.

Variables	RSB (n=44)	Non-exposed(n=44)	P-value
VAS score at 1hour	3.98±0.96	4.59±1.48	0.023*
VAS score at 2hour	3.96±0.88	4.57±1.43	0.018*
VAS score at 4 hour	3.46±0.86	3.94±0.92	0.012*
VAS score at 6 hour	3.72±0.99	4.29±0.76	0.003*
VAS score at 8 hour	3.99±0.71	4.42±0.79	0.009*
VAS score at 10 hour	4.08±0.93	4.22±0.77	0.441
VAS score at 12 hour	4.28±0.76	4.53±0.79	0.141
VAS score at 24 hour	4.27±0.76	4.52±0.76	0.132

Data are presented with (mean \pm SD).P value <0.05 was considered as statistically significant

Table 5: The first 24 hours total analgesics consumption and time of first analgesic request for emergency midline laparotomy, University of Gondar Referral Hospital, Northwest Ethiopia, from February 1 to May 10, 2018.

Variables	RSB(n=44)	Non exposed (n=44)	P-value
Total tramadol consumption (mg)	255.68 \pm 80.13	314.77 \pm 97.40	0.003*
Total diclofenac consumption(mg)	75(75-150)	150(75-150)	0.031*
First analgesic request time(minute)	372.95 \pm 131.41	50.34 \pm 14.12	$\leq 0.001^*$

Values are expressed as (mean \pm SD), median (interquartile range).P value <0.05 was considered as statistically significant.