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A Comparative Study of Ultrasound Guided Bilateral Rectus Sheath Block versus Local Incision Site Infiltration for Post Operative Analgesia in Patients Undergoing Laparotomy with Midline Incision

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Abstract
Background: *Good postoperative pain management is effective in reducing perioperative opioid consumption and thereby reducing perioperative morbidity. Ultrasound guided rectus sheath block to decrease postoperative pain makes this block more reproducible and reduces the risk of inadvertent peritoneal and vascular punctures. Local incision site infiltration at the end of surgery also decreases postoperative pain significantly. Therefore the study was planned to compare efficacies of the two techniques in cases of laparotomy with midline incision.*
Methods: *Eighty adult patients aged between 18-60 years of age, American Society of Anaesthesiologists (ASA) physical status 1 and 2, undergoing laparotomy with midline incision under general anaesthesia, were randomly allocated to receive either ultrasound guided bilateral rectus sheath block(Group R, n=40) or local incision site infiltration(Group I, n=40) with same local anaesthetic, i.e. Levobupivacaine 0.25%. Time to receive first rescue analgesia postoperatively, Visual Analogue Scale score (VAS) at different point of time postoperatively, total postoperative analgesic consumption and any adverse effects postoperatively were noted.*
Results: *There was significant ($p<0.05$) reduction of pain in group of patients receiving USG guided RSB at 2nd, 6th, 12th & 24th postoperative hours assessed by VAS. There was also significant reduction ($p=0.000$) in total fentanyl consumption in groups receiving US guided bilateral RSB during the first 24 hours and patients receiving local incision site infiltration required analgesic much earlier than the patients receiving RSB. There was also significant decrease in PONV during the first 2 & 6 hours postoperatively in patients receiving Rectus sheath block and the patient satisfaction score in our study was better in patients receiving RSB ($p=0.000$).*
Conclusion: *Ultrasound guided rectus sheath block seemed to be superior in providing postoperative analgesia. There were also reduced incidences of postoperative nausea and vomiting during the first 2 and 6 hours postoperatively compared with the incision site infiltration group.*
Keywords: *Analgesia, Infiltration, Laparotomy, Levobupivacaine, Rectus sheath block, Ultrasound.*

Introduction

It is the moral responsibility of the perioperative physicians to provide adequate postoperative analgesia not only to suppress the adverse physiological responses to pain but also to improve overall patient satisfaction following surgery. Optimisation of postoperative analgesia facilitates patient's recovery from surgical stress, decreases the length of hospital stay, thus decreasing the burden on health care system. Postoperative pain management imposes further challenge in case of surgeries performed on short stay basis.

The control of postoperative pain is imperative for patient comfort, early mobilization and faster recovery[1]. Specifically, good postoperative pain management has been shown to be effective in reducing perioperative morbidity[2]. Also, there has been an endeavour to reduce perioperative opioid consumption and thereby reducing associated complications. In this respect, an effective multimodal strategy which affords best control of postoperative pain is very important.

The technique of injecting local anesthetics into the various layers of surgical incision (wound) is a commonly used practice in general anesthesia surgical cases[3]. It is inexpensive, technically not difficult, and may potentially reduce the post-operative discomfort[4].

In case of rectus sheath block, introducing the needle under ultrasound guidance to the posterior rectus sheath rather than relying on "pops" such as in traditional, non-ultrasound techniques, makes this block more reproducible and reduces the risk of inadvertent peritoneal and vascular punctures[5].

Unfortunately, the technique of injecting local anesthetics after the surgical incision has been made (prior to ending the surgical procedure) and its reduction in post-operative pain remains in debate as to the effectiveness in both animal and human studies[6].

Therefore, the present study was planned keeping aim to compare the efficiency of USG guided bilateral rectus sheath block with incision site infiltration in respect of postoperative analgesia using the same local anaesthetic i.e. levobupivacaine. It is the s-enantiomer of bupivacaine having similar effect with lesser cardiotoxic and neurotoxic side-effects[7].

Materials and Methods

The present study was carried out after obtaining approval from Institute's Ethics Committee in a tertiary care hospital in West Bengal. Eighty adult patients aged between 18 and 60 years of either sex conforming to American Society of Anaesthesiologists (ASA) physical status I or II undergoing laparotomy under GA were selected for this study. After thorough preoperative evaluation, written informed consent were taken from all patients.

Patients with history of allergy to local anaesthetics, coagulopathy, infection at incision site were excluded from the study. Patients not able to express pain independently, patients with chronic pain syndrome and Patients with any chronic disease were also excluded from the study. Other exclusion criteria were participation in any other clinical trial within past 1 month and any other condition placing the subject at high risk or unfit for the trial.

A thorough pre-anaesthetic evaluation was performed in each patient including detailed history taking, physical examination including neurological assessment, haematological investigations, fasting and postprandial blood sugar, urine for routine and microscopic Examination, Chest X-Ray (PA view) and 12-lead ECG. Their body weights were recorded. Formal examination of the airway was also done.

Patients and guardians were explained the procedure to be done and the risks as well as the benefits associated with it in their own vernacular language. They were explained about their right to opt out from the study at any time during the study. Patients undergoing elective laparotomy remained fasting overnight. The study was a double blinded one. On receiving the patient in the operation theatre, the patients were asked to choose a well-sealed envelope containing Random

numbers. Thus the group to which patient will lie in our study was decided. Group R received Ultrasound guided bilateral rectus sheath block while Group I received local incision site infiltration. The observer was kept completely unaware of the groups. Drugs and equipments for resuscitation were kept ready. After establishing good peripheral Intravenous (IV) access, basic monitors (ECG, NIBP, pulse oximetry) were applied in the operating room. Baseline readings were recorded. All patients were premedicated with inj Ranitidine 50mg IV, inj Metoclopramide 10 mg IV, inj midazolam 0.03 mg/kg IV and inj fentanyl 2 microgram /kg IV. After 3 minutes of preoxygenation with 100% O_2 ,induction was done with propofol 2 mg/kg IV and patients were intubated 3 minutes after administering atracurium 0.5mg/kg IV. Anaesthesia was maintained with oxygen in 66% N2O and sevoflurane (0.6-1%). Intraoperative monitors like ECG, HR, NIBP at 3 minutes interval, SpO2 and $EtCO_2$ were monitored throughout the operation.

After completion of the operative procedure and before extubation, Group R was administered bilateral RSB with 20 ml (10 ml on each side) 0.25% Levobupivacaine (maximum 2mg/kg) under ultrasound guidance after skin disinfection. The needle (22 G, L 85 mm) was inserted in plane in a cephalad to caudad orientation, through the subcutaneous tissue to pierce through the anterior rectus sheath. The needle was further advanced through the body of muscle until the tip rests on the posterior rectus sheath. After negative aspiration, 1 ml of 0.9% saline was injected to verify needle tip location. When injection of 0.9% saline appeared to be intramuscular, the needle was advanced 1- 2mm further and its position was rechecked by injection of another 1 ml of 0.9% saline (hydrodissection).After correct positioning of needle, bilateral rectus sheath block was given using levobupivacaine . Group I received local incision site infiltration with 20 ml of 0.25% levobupivacaine(maximum 2mg/kg). All the drugs were prepared and given by a separate anaesthetist who was not involved in data collection and data analysis. The RSB was performed by a skilled anaesthetist.

A single investigator, who was blinded to group allocation visited the patients at 2,6,12 and 24 hours postoperatively with a data collection sheet and recorded the presence and severity of pain, nausea. Rescue analgesic (Fentanyl) was administered if VAS score> 4 and time was noted. VAS score using a 10cm (100mm) VAS (i.e. 0 =no pain, 10(100mm) =worst imaginable) for pain were assessed serially at 2hrs, 6 hrs, 12 hrs and 24 hrs after surgery. The time for first analgesic request was recorded. Postoperative nausea and vomiting (PONV) were measured using a categorical scoring system (none- 0; mild-moderate-1; and severe- 2). Rescue antiemetics (Inj Ondansetron 4 mg IV) were offered to any patient who complained of nausea or vomiting. Patient satisfaction was determined by asking the patients orally to provide a number between zero and ten (0: not satisfied, 10: satisfied a lot), and the number was recorded. Patient satisfaction evaluation was performed 24 hours after the surgery.

Comparisons for each demographic and clinical variable between the two groups were performed by Independent sample t test for normally distributed variables and Pearson's Chi-square test for categorical variables. The level of significance was set as $p < 0.05$.

Results

The study spanned from May2018 to April 2019 including 80 patients(40 in each group). No patient was lost to follow up. Hence data from eighty patients were available for analysis.

Table 1: Demographic parameters:

Parameters	Group R(n=40)	Group I (n=40)	*p*-value
Age (years)	37.63±8.625	39.58±9.367	0.336
Sex (M/F)*	20/17	14/23	0.243
Height (cm)	165.25±12.634	168.74±11.308	0.197
Weight (Kg)	66.55±13.210	66.88±10.866	0.393
BMI (kg/m 2)	24.162±2.531	24.033±1.699	0.788
ASA (1/2)*	26/14	27/13	0.813

Data expressed as mean±SD, tested with Independent samples t test except marked*, which is categorical data and tested using Pearson's Chi

Square test. $p < 0.05$ is considered statistically significant. Group R patients received USG guided rectus sheath block(RSB). Group I patients received incision site anaesthetic infiltration.

Table 1 Shows that there are no statistically significant differences between the groups in respect to patient's age, height, weight, BMI ($p > 0.05$). Statistical analysis revealed no significant difference of ASA grade and sex distribution between the two groups (Chi-square test) ($p > 0.05$). So both the groups were comparable in terms of demographic parameters.

Table 2: Baseline and Variation of heart rate for 1 hour following extubation of the patient

Heart Rate(bpm)	Group R(n=40)	Group I(n=40)	*p*-value
Baseline	92.63±5.107	91.45±6.645	0.378
At 5 min	80.85±5.466	83.28±4.809	0.619
At 10 min	78.63±7.827	81.85±7.778	0.068
At 15 min	77.43±7.016	79.63±9.060	0.228
At 30 min	79.05±6.748	79.60±10.240	0.777
At 45 min	82.46±8.675	78.82±9.932	0.101
At 60 min	85.90±3.900	86.93±3.817	0.648
Data expressed as mean ± SD and tested with Independent samples t test. $p< 0.05$ is considered statistically significant. Group R patients received USG guided RSB and Group I patients received local incision site anaesthetic infiltration.bpm= beats per minutes			

Table 2 shows the mean and standard deviation of baseline heart rate (measured before premedication) and the variation of heart rate at different points of time for 1 hour after extubation. It shows that there were no statistically significant differences between the groups in respect of change in baseline heart rate as well as for the first hour following extubation ($p>0.05$). Both groups are comparable.

Table 3: Baseline and Variation of MAP(mean arterial pressure) for 1 hour following extubation of the patient.

MAP(mmHg)	Group R(n=40)	Group I(n=40)	*p* value
Baseline	85.05±7.880	86.85±7.192	0.289
5 min	93.80±5.589	93.38±4.143	0.700
10 min	90.70±5.229	90.78±9.138	0.964
15 min	91.08±6.338	89.25±7.951	0.260
30 min	92.43±6.488	90.38±8.053	0.214
45 min	89.50±6.198	90.85±6.938	0.384
60 min	87±5.907	90.50±8.264	0.339
Data expressed as mean ± SD and tested with Independent samples t test. $p< 0.05$ is considered statistically significant. Group R patients received USG guided RSB and Group I patients received local incision site anaesthetic infiltration.			

Table 3 shows the mean and standard deviation of baseline MAP (measured before premedication) and the variation of MAP at different points of time for 1 hour after extubation. It shows that there were no statistically significant differences between the groups in respect of change in baseline MAP as well as for the first hour following extubation ($p>0.05$).Both groups are comparable.

Table 4: Postoperative pain score in Visual Analogue Scale (VAS 100mm)

VAS	Group R (n=40)	Group I (n=40)	*p* value
2 hours	16.68±7.357	31.53±8.184	0.000
6 hours	22.45±9.538	40.65±7.708	0.000
12 hours	30.78±10.479	40.93±7.600	0.000
24 hours	38.75±9.467	46.40±7.745	0.000
Data expressed as mean ± SD tested with Independent samples t test. (p< 0.05 considered significant). Group R patients receiving USG guided RSB. Group I patients receiving local incision site anaesthetic infiltration.			

Table 4 shows the mean values of pain scores (VAS) during 24 postoperative hours in both the groups. The mean VAS scores in group R patients were lower than group I patients postoperatively and was statistically significant.

Table 5: Total analgesic (Fentanyl) requirement in the first 24 postoperative hours

	Group R (n=40)	Group I (n=40)	*p* value
Total analgesic requirement(micro gram)	52.50±37.468	152.50±49.290	0.000
Data expressed as mean ± SD and tested with Independent samples t test. ($p < 0.05$ considered significant). Group R patients receiving USG guided RSB. Group I patients receiving local incision site anaesthetic infiltration.			

Table 5 shows that group I patients required significantly higher amount of analgesic as compared to group R patients during the first 24 postoperative hours to maintain VAS score of ≤40 mm at both rest and movement. Thus it clearly shows that the total requirement of analgesic is statistically significant ($p < 0.05$) when group R is compared with group I. The above result is the most important finding of our study.

Table 6: Time to first analgesic request

	Group R(n=40)	Group I (n=40)	*p* value
Time to 1 st analgesic request (hours)	10.70±3.502	2.78±1.121	0.000
Data expressed as mean ± SD and tested with Independent samples t test. ($p< 0.05$ considered significant). Group R patients receiving USG guided RSB. Group I patients receiving local incision site anaesthetic infiltration.			

Table 6 shows time to first requirement of analgesic in the immediate postoperative period in group I is significantly earlier as compared to group R.

Table 7: Incidence of postoperative nausea and vomiting (PONV)

PONV Grades	**Group R (n=40)**			**Group I (n=40)**			***p* value**
	0	1	2	0	1	2	
2 hours	40	0	0	24	13	3	0.000
6 hours	33	7	0	21	13	6	0.005
12hours	27	7	6	27	9	4	0.131
24hours	30	7	3	29	8	3	0.196
Data expressed in numbers and tested with Pearson's Chi- square test ($p < 0.05$ considered significant). Group R patients receiving RSB. Group I patients receiving local incision site anaesthetic infiltration.							

Table 7 shows incidence of PONV at 2 hours, 6 hours, 12 hours and 24 hours in the postoperative period. During the 2nd postoperative hour, there was no incidence of PONV in group R while 13(32.5%) patients reported mild to moderate PONV and 3(7.5%) patients reported severe PONV in group I and was found statistically significant(p=0.000). At 6th postoperative hour 7(17.5%) patients reported mild to moderate PONV and no patient reported severe PONV in Group R, while 13(32.5%) patients reported mild to moderate PONV and 6(15 %) patients reported severe PONV in Group I and was found to be statistically significant. At 12th postoperative hour, 7(17.5%) patients experienced mild to moderate PONV and 6(15%) patients reported severe PONV in group R, while 9 (22.5%) patients experienced mild to moderate PONV and 4(10%) patients reported severe PONV in group I. This finding was not statistically significant (p=0.131). During 24th postoperative hour 8(20%) patients reported mild PONV and 3(7.5%) patients reported severe PONV in group I while 7 patients (17.5%) of group R experienced mild to moderate PONV and 3(7.5%) patients experienced severe PONV but this observation was not found statistically significant (p=0.336).

Table 8: Patient satisfaction chart

	Group R (n=40)	Group I (n=40)	*p* value
Not satisfied	0	14	0.000
Satisfied	19	22	
Very satisfied	21	4	
Data expressed in numbers and tested with Pearson's Chi- square test. ($p < 0.05$ considered significant).Group R patients receiving RSB. Group I patients receiving local incision site infiltration.			

Table 8 shows that there is statistically difference between the groups in respect to patient's satisfaction at 24 hours postoperatively ($p<0.05$).

Discussion

Postoperative pain management is not only a surgeon's concern but also the moral responsibility of the anaesthesiologists. Inadequate relief of postoperative pain not only causes physical and psychological distress for the patient, but also prolongs recovery and duration of hospital stay, increasing health care costs.

The rectus sheath block was first described in 1899 and was initially used for purpose of abdominal wall muscle relaxation during laparotomy before the adjunct of neuromuscular block[8]. Now it is used for analgesia after umbilical or incisional hernia repair and other midline surgical incisions[9].

Introducing the needle under ultrasound guidance to the posterior rectus sheath rather than relying on "pops" such as in traditional, non-ultrasound techniques, makes this block more reproducible and reduces the risk of inadvertent peritoneal and vascular punctures[5].

We conducted a prospective randomised, double-blinded, comparative study to compare the efficacy of USG guided bilateral RSB with incision site infiltration regarding postoperative analgesia using local anaesthetic levobupivacaine. Eighty consenting adults of ASA grade 1 and 2 patients of either sex posted for laparotomy with midline incision were randomised in our study. Data of 40 patients of group R (patients receiving USG guided rectus sheath block) and 40 patients of group I (patients receiving local incision site infiltration) were analysed.

The present study showed that there was significant ($p<0.05$) reduction of pain in group of patients receiving USG guided RSB at 2nd, 6th, 12th & 24th postoperative hours assessed by VAS. Gurnaney H G et al.[10] in 2011 & Dingeman R S et al.[11] in 2013 did prospective randomized observer blinded study on comparing the efficacy of U/S –guided RSB and local anaesthetic infiltration for umbilical hernia repair and concluded that USG guided RSB is superior for perioperative or postoperative analgesia compared with local anaesthetic infiltration. Similar result was found in our study. Willschke et al.[8] in 2006 found that US guided bilateral RSB with 0.1 ml/kg, 0.25% of levobupivacaine provides effective analgesia for umbilical hernia repair. In our study we also used 0.25% levobupivacaine 20 ml for both the groups.

In our study we recorded the total fentanyl consumption during first 24 postoperative hours & the time to first rescue analgesic requirement in both the groups. There was significant reduction ($p=0.000$) in total fentanyl consumption in group receiving US guided bilateral RSB during the first 24 hours, whereas patients receiving local incision site infiltration required analgesic much earlier than the patients receiving RSB. Our study also showed that use of levobupivacaine significantly decreases PONV during the first 2 & 6 hours postoperatively in patients receiving Rectus sheath block.

Saxena R et al.[12] in 2016 did a comparative study of US guided abdominal field block vs port site infiltration in laparoscopic cholecystectomies for post-operative pain relief where overall patient satisfaction score was much higher in the group receiving US guided abdominal field block ($p<0.05$). Similarly the patient satisfaction score in our study was better in patients receiving RSB ($p=0.000$).

It is clear that ultrasound-guided RSB is safer and reliable technique. Limitations in our study

include the fact that it was not powered to assess differences in opioid-related side-effects, or overall safety. The issue of potential local anaesthetic toxicity was not specifically addressed, but all doses were within the recommended range. Traditional RSB relies on anatomical landmarks & loss of resistance, thereby the remote potential for perforation of intraperitoneal structures & epigastric blood vessels is always present. As our study was USG guided RSB, such complications were not encountered in our study.

Conclusion

The present study concludes that administration of ultrasound guided rectus sheath block or local incision site infiltration of 0.25% levobupivacaine provide postoperative analgesia. Among these techniques, rectus sheath block seemed to be superior in providing postoperative analgesia. Hence, the study favours the administration of rectus sheath block for postoperative pain relief in laparotomy with midline incision.

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