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Original Research Article

Comparision of analgesic efficacy of ropivacaine and bupivacaine in rectus sheath block for midline abdominal surgeries

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ABSTRACT

Background: In the modern setting the rectus sheath block (RSB) has been found effective in decreasing opioid requirement after both diagnostic and interventional laparoscopy and laparotomy. Efficacy of rectus sheath block (RSB) using ropivacaine versus bupivacaine for acute postoperative pain relief is not much investigated.

Material and Methods: 90 patients undergoing elective midline abdominal surgeries under general anaesthesia were randomly divided into three groups of 30 patients each, destined to receive bilateral rectus sheath block using 15 ml on each side (total 30 ml) of 0.25% ropivacaine in Group R, 0.25% bupivacaine in Group B or normal saline in Group C. Three groups were compared regarding time to first rescue analgesic from time of RSB (duration of analgesia), total rescue analgesic (tramadol) consumption in first 10 hours, visual analogue score (VAS), satisfaction score and adverse effects.

Result: Mean duration of analgesia was significantly longer in group R (5.78±0.93h) than group B (3.63±0.90 h) and group C (2.37±0.44 h), $p<0.001$ (group R > group B > group C). This trend was observed in both hernia repair and laparotomy. Rescue analgesic consumption in terms of number of doses was significantly less in Group R (30) than in Group B (38) than in Group C (59), $p<0.05$. Mean VAS was significantly less and patient satisfaction was significantly better in Group R than in Group B than in Group C, ($p<0.001$).

Conclusion: Bilateral single shot rectus sheath block (RSB) using isobaric ropivacaine (0.25%) or bupivacaine (0.25%) is a safe and effective method of providing postoperative analgesia to patients undergoing midline abdominal surgeries. The lower cardio toxicity profile with the excellent prolonged postoperative analgesia makes ropivacaine an excellent choice for the RSB as compared to bupivacaine.

1. Introduction

In 1899, the rectus sheath block (RSB) was first time introduced into clinical practice[1] when it was used to achieve as an analgesic adjuvant and perioperative muscle relaxation. In the modern setting, the RSB has been found effective in decreasing opioid requirement after both diagnostic and interventional laparoscopy[2,3] and laparotomy.

Ropivacaine, a new aminoamide local anaesthetic agent, retains the efficacy of bupivacaine while not being cardiotoxic. In RSB, it is important to perform bilateral block in the abdomen and to use large amount of local anaesthetic solution, hence use of ropivacaine in rectus sheath block may confer benefits over bupivacaine by allowing use of large volume safely. For postoperative analgesia in RSB using bupivacaine,[2] ropivacaine[4] or levobupivacaine[5] was found effective. However, there is lack of data which compare the efficacy of ropivacaine versus bupivacaine in RSB to evaluate the superiority for post-operative pain relief.Several studies have examined

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the comparative effects of bupivacaine and ropivacaine for epidural,[6] axillary[7–10] and femorosciatic blocks[11] with varying results.

Therefore, the present study was planned to compare the analgesic profile of ropivacaine versus bupivacaine and to evaluate whether RSB can improve post-operative analgesia by using bupivacaine or ropivacaine after abdominal surgeries performed via midline incision.

2. Materials and Methods

A prospective randomized double blind controlled study was conducted in department of anesthesiology at MB Govt. Hospital attached to RNT Medical College Udaipur, after informed written consent from the patients & taking approval from institutional ethical committee (IEC). 90 patients, ASA I-II, 18-60 yrs of age & both sex, who were posted to undergo umbilical & paraumbilical hernia repair and laparotomies performed via midline incision under general anaesthesia, were included in present study.

2.1. Exclusion criteria

History of allergy to study drugs, inability to understand and use Visual Analog Scale (VAS), patients having cardio-respiratory disease, renal disease, hypertension and diabetes, having coagulation disorder and if patients required ventilatory support post operatively.

2.2. Sample size

On the basis of previous study - Smith et al,[2] we calculated that a difference on pain score of 3 cms at 6 hrs post operatively would be statistically significant. For the study to have a power of 80% and a type I (α) error of <0.05, it was required to have total 85 patients. To compensate for dropouts, it was decided to include 30 patients in each group.

2.3. Group allocation

By using opaque sealed envelope technique all the patients were randomly divided into 3 groups, of 30 patients each. In group R- RSB with ropivacaine; group B - RSB with bupivacaine; group C (control)- RSB with NS. To evaluate post-operative analgesia, time to first rescue analgesic from time of RSB, was taken as primary outcome whereas total rescue analgesic consumption, VAS score and adverse effects were considered as secondary outcome.

2.4. Drug preparation

For RSB the drug was prepared by taking 15ml of 0.5% ropivacaine in Group R and 0.5% bupivacaine in Group B, it was diluted upto 30 ml with normal saline and concentration made to 0.25%. 15ml of this 0.25% concentration was injected on each side (total 30 ml volume). NS 15 ml on each side was used in Group C.

2.5. Double blindness

One anaesthesiologist prepared the study drugs, who was not involved further in the study. Another anaesthesiologist conducting the study administered the rectus sheath block and recorded data in all patients, who was unaware of group allocation. Patients, nursing staff and surgeon were also unaware of group allocation.

2.6. General anaesthesia technique

In the operation theater, i.v. line was accessed with an 18 G cannula & infusion of Ringer Lactate was started. Basic monitorings (NIBP, SpO2 and ECG) were applied. Patients were pre-medicated with as per institute protocol (inj. glycopyrrolate 0.2 mg, inj. midazolam 1mg & inj. fentanyl 2 μg/kg i.v.). After preoxygenation for 3 minutes, patients were induced with inj. propofol 1.5-3.0 mg/kg followed by inj. vecuronium 0.1 mg/kg and tracheal intubation was done with direct laryngoscopy. Anaesthesia was maintained with nitrous oxide and oxygen (60:40), isoflurane and inj. vecuronium 1 mg as and when required for intra operative muscle relaxation. After completion of surgery, patients were reversed with inj. neostigmine (0.5mg/ kg) and inj. glycopyrrolate (0.1mg/kg). This time was noted as 0 hour (post extubation) for post-operative data collection.

2.7. Rectus sheath block technique

Bilateral RSB was given by two injections one on each side of the abdomen, after induction, before start of the surgery. A (22 G) short bevel needle (B-DLtd) was inserted at a point 3–5 cm above the umbilicus medial to lateral border of the rectus abdominis. The anterior rectus sheath was identified by moving the needle from side to side with a back and forth motion while advancing the needle until it was felt to scratch the sheath. The needle was then advanced until the resistance of the posterior layer of the rectus sheath was felt and the drug was injected after negative aspiration test as per assigned group. Time of RSB was noted and then surgery was allowed to start.

2.8. Data recording

Demographic profile like age, sex, and weight of the patients; and surgical data like diagnosis, type of surgery, duration of surgery (from skin incision to last suture)were recorded. Vital parameters [heart rate(HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP)] were recorded as baseline (before induction), after induction at 0, 15, 30 min, after extubation (0 hour post extubation) and then 1, 6 and 10 hours postoperatively. Pain score: The degree of spontaneous

postoperative abdominal pain was assessed using Visual Analog Scale (VAS) at 1hr, 6 hr and 10 hours after surgery. Visual Analog Scale (VAS) 0-10 cm: was graded as 0-3=no pain; 4-7=discomfort; 8-10=severe pain. Rescue Analgesic: Tramadol 100 mg i.v. over 20 minutes was given as rescue analgesic for abdominal pain when VAS>3 or when patient complained of pain. Duration of analgesia was calculated from time of RSB to the first rescue analgesic. Total rescue analgesic requirement in terms of number of doses and total dose (mg) in first 10 hrs post-operative period was recorded. Side Effects: All episodes of nausea and vomiting were recorded post operatively and treated with injection ondansetron 4 mg i.v. Any other side effect related to RSB like hematoma, gut injury etc. if occurred was noted. Satisfaction Score: Patient satisfaction score (PSS), regarding post-operative pain was measured at 10 hour at the end of the surgery and graded as excellent, good and poor.

2.9. Statistical analysis

Data was entered and analyzed with the help of MS Excel, EPI info 6 and SPSS version 20. Qualitative data was presented as number (proportion) and compared with chi square test. Quantitative variables were presented as Mean ± SD, and compared using student 't' test. ANOVA was applied as per need. Post hoc test was used to assess inter-group variation. Differences were considered statistically significant at $p<0.05$.

3. Results

All three groups were statistically comparable regarding demographic profile (mean age, mean weight), ASA grading, duration of surgery, type of surgery and incidence of use of mesh.($p>0.05$) [Table 1].

Vital parameters (HR, SBP and DBP) in intraoperative period were comparable in three groups, [$p>0.005$]. In immediate post-operative period (post extubation 0 hour) mean HR was significantly higher in group C as compared to group B and group R, [$p<0.05$]. This statistically significant difference in HR was observed for whole 10 hours post-operative period between group R & group B, [$p<0.05$] [Figure 1].

Figure 2 shows SBP & DBP were significantly lower in group R and group B ($p<0.001$) after extubation (0 hour) and at 1 hour, 6 hour post-operatively as compared to group C. There was no significant difference in SBP and DBP at any time interval in group R & group B, [$p>0.05$].

Table 2 shows Mean VAS score was around 3 at all-time intervals in all the 3 groups, [post-operative analgesia-adequate]. Mean VAS score was significantly lower in group R & group B as compared to group C at all-time intervals, [$p<0.05$]. Mean VAS was also significantly less in group R as compared to group B at all-time intervals, $p<0.05$. Thus

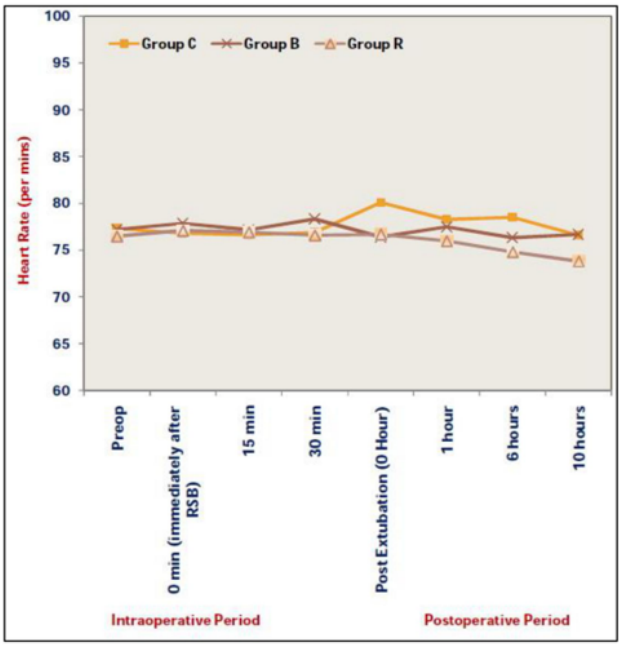

Fig. 1: Change in heart rate in perioperative period

order of VAS was Group R < Group B < Group C.

Mean duration of analgesia was longer in group R (5.78±0.93h) and group B (3.63±0.90 h) as compared to group C (2.37±0.44 h). This difference was statistically significant ($p<0.001$). Thus the order of duration of analgesia was Group R > Group B > Group C.

All patients in three groups were received rescue analgesic at 10 hour post-operative period. A single dose of rescue analgesic was required in all patients of group R [n=30 (100%)] & majority of patients in group B [n=22 (73.33%)] whereas in group C almost all patients [n=29 (96.66%)] & in group B [n=8 (26.66%)] were required two doses of rescue analgesic in 10 hour postoperative period. Hence, total dose of rescue analgesic requirement was significantly higher in group C (59), as compared to group B (38) and group R (30) $p<0.001$ [Table 3].

Patient satisfaction score was significantly better in group R [20 (66.66%) excellent, 10 (33.33%) good] as compared to group B [14 (46.66%) Good, 8 (26.66%) Excellent, 8 (26.66%) Poor], $p<0.001$, and group C [29 (96.66%) Poor, 1 (3.33%) Good], $p<0.001$.

In all 3 groups, incidence of nausea and vomiting was minimal and comparable, [$p>0.05$]. Only 4 patients in group C [2(6.66%), 2(6.66%)], 2 patients in group B [1(3.33%), 1(3.33%)] and 2 patients in group R [1(3.33%), 1(3.33%)] experienced nausea and vomiting. No complications related to RSB like gut injury, hematoma were observed in any patients of three groups.

Table 1: Comparison of age, weight, ASA grading, duration of surgery and type of surgery in two groups

	Group C n=30	Group B n=30	Group R n=30	p Value
Age (yrs)Mean±SD	47.93±10.80	44.57±10.64	45.87±9.39	0.45 (NS)
Weight (Kg)Mean±SD	62.70±5.09	61.67±5.29	62.00±5.02	0.73 (NS)
ASA Grading n (%)				
I	22 (73.33%)	22 (73.33%)	20 (66.66%)	0.80 (NS)
II	8 (26.66%)	8 (26.66%)	10 (33.33%)	
Duration of surgery (hours) Mean ± SD	1.57 ± 0.46	1.74 ± 0.63	1.78 ± 0.49	0.27 (NS)
Types of Surgeryn (%)				
Umbilical hernia repair	8 (26.66%)	3 (10%)	7 (23.33%)	0.50 (NS)
Paraumbilical hernia repair	5 (16.66%)	5 (16.66%)	6 (20%)	
Exploratory laparotomy	17 (56.66%)	22 (73.33%)	17 (56.66%)	
Exploratory laparotomy				

NS- not significant, Data are in Mean ± SD and n%

Table 2: Comparison of postoperative abdominal pain by VAS score (VAS 0-10 Cm)

	VAS Score	Group C n=30	Group B n=30	Group R n=30	p Value R/B	R/C	B/C
	Mean±SD	3.3±1.19	1.73±1.23	0.70±0.70	0.000	0.000	0.000
	Range	0-2	0-5	2-6			
1 hour			Patient Distribution (n%)				
	0-3 No Pain	22 (73.33%)	30 (100%)	30 (100%)	NA	0.002	0.002
	4-7 Discomfort	8 (26.66%)	0	0			
	8-10 Severe Pain	0	0	0			
	Mean±SD	3.07±0.91	2.03±1.25	1.03±1.44	0.006	0.000	0.001
	Range	0-5	2-6	5-9			
6 hours			Patient Distribution (n%)				
	0-3 No Pain	21 (70%)	30 (100%)	30 (100%)	NA	0.001	0.001
	4-7 Discomfort	9 (30%)	0	0			
	8-10 Severe Pain	0	0	0			
	Mean±SD	3.03±1.06	2.27±1.02	1.50±1.04	0.006	0.000	0.005
	Range	1-5	2-6	6-10			
10 hours			Patient Distribution (n%)				
	0-3 No Pain	26 (86.66%)	30 (100%)	30 (100%)	NA	0.038	0.038
	4-7 Discomfort	4 (13.33%)	0	0			
	8-10 Severe Pain	0	0	0			

NA = Not Applicable

Table 3: Comparison of requirement of rescue analgesic in post-operative period (10hrs)

	Group C n=30	Group B n=30	Group R n=30	p Value R/B	R/C	B/C
No. of patient requiring rescue analgesic	30 (100%)	30 (100%)	30 (100%)	-	-	-
Patients Distribution According to No. of Doses						
Single Dose	1 (3.33%)	22 (73.33%)	30 (100%)	-	-	-
Two Dose	29 (96.66%)	8 (26.66%)	0	-	-	-
Total no. of doses	59	38	30	0.000	0.000	0.000
Total dose (mg)	5900	3800	3000	-	-	-
Mean dose ± SD for each patients	1.96±0.37	1.26±0.64	1.00±0.00	0.030	0.000	0.000

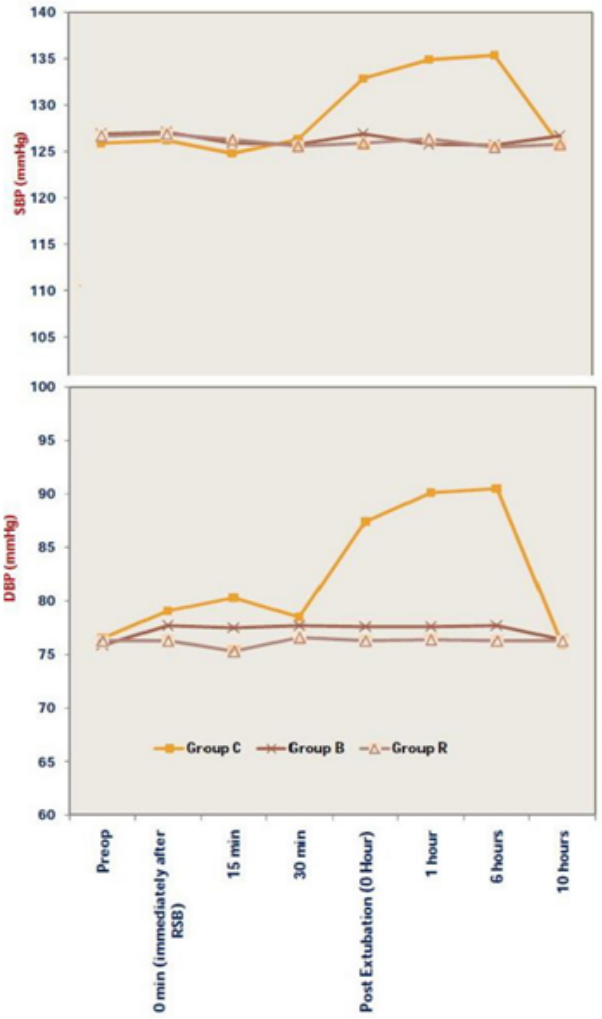

Fig. 2: Changes in systolic blood pressure (SBP) and diastolic blood pressure (DBP) in perioperative

4. Discussion

The Rectus Sheath Block (RSB) was first described by Schleich in 1899[1] to provide perioperative relaxation of the anterior abdominal wall for intra abdominal surgery. But the advent of the neuromuscular blockers in the 1940's led to a rapid decline in the use of regional anaesthetic techniques such as RSB to provide abdominal muscle relaxation. This change in practice meant that the potential for local anaesthesia in provision of postoperative pain relief was largely forgotten. The introduction of local anaesthetic agents with a prolonged duration of action has led a revival of interest in this facet of local anaesthesia.[12]

Previous authors have performed RSB for postoperative analgesia in various surgeries like major abdominal surgeries,[13–15] gynecological surgeries,[16,17] laproscopic surgeries[18] using different local anaesthetics (bupivacaine,[19] ropivacaine,[18] levobupivacaine,[13]) and found promising results.

In present study abdominal surgeries included were umbilical, paraumbilical hernia repair and laparotomies performed via midline incision because the RSB is suited to incision about the midline.[17,19] The present study all the patients who received bilateral RSB with bupivacaine or ropivacaine had significantly longer postoperative analgesia as compared to control group as evidenced by significantly lower pain scores, longer duration of analgesia and lesser rescue analgesic consumption in both group R & B, as compared to group C. This superior postoperative analgesic profile could be attributed to rectus sheath block. In previous studies also use of RSB was found to have significant association with lower pain score,[17,20] onger duration of analgesia and reduction in rescue analgesia consumption.[17,19]

4.1. Mechanism of RSB

In rectus sheath block local anaesthetic deposits between the rectus abdominis muscle and the posterior aspect of the

sheath. This enables blockade of the branches of nerves T7–T11 intercostal nerves within the rectus sheath which provides somatic anaesthesia to the anterior abdominal wall, bilaterally from the xiphoid process to the symphysis pubis.[16,19]

We observed that HR, SBP, DBP were significantly higher in postoperative period in control group, as compared to ropivacaine (group R) and bupivacaine (group B) ($p < 0.05$). The difference in SBP and DBP persisted up to 6 hrs, between group C vs group R & group B. The difference in heart rate was observed in group C vs group R up to 10 hours, and between group C vs group B it was till 1 hr. Group R & group B were statistically comparable regarding haemodynamic variables at all time intervals, $p>0.05$. Above findings point towards a presumably attenuated sympathetic response to postoperative pain in patients receiving RSB with ropivacaine or bupivacaine as compared to control group as observed previously. The fact that increased pain leads to higher mean heart rate and systolic blood pressure is well established.

To the best of our knowledge, this is the first study that has attempted to compare ropivacaine versus bupivacaine in RSB (Google medical search with keyword ropivacaine /bupivacaine /rectus sheath block). Other studies[10,11,21] that have compared ropivacaine with bupivacaine have been in reference to axillary block,femorosciatic block,interscalene blocketc., who found postoperative analgesic profile of two agents comparable.

The chief finding in our study that differs from that of others is that we found ropivacaine to be longer acting than bupivacaine in terms of providing postoperative analgesia whereas all other studies[7–11,21] found that the duration of postoperative analgesia provided by ropivacaine and bupivacaine was equal. It must be noted that all the quoted studies for comparison of ropivacaine and bupivacaine deposited local anaesthetics in closed fascial compartments of extremities, whereas in the rectus sheath block local anaesthetic is deposited in the plane between the rectus abdominis muscle and the posterior rectus sheath. The rectus abdominis muscle is supplied by the supra and infra epigastric artery, a large vascular area.[22,23] Therefore the gradual movement of local anaesthetic out of this plane shall be partially responsible for the termination of action of the rectus sheath block.[24,25] As ropivacaine is a vasoconstrictor and bupivacaine is a vasodilator, ropivacaine is likely to stay in this relavant plane for a more duration of time resulting in prolong postoperative analgesia.[26]

This effect may be similar to the effect that is produced by intradermal injection of plain ropivacaine and plain bupivacaine, where plain ropivacaine solution is longer acting than plain bupivacaine as observed in human volunteers.[26] Therefore when effectiveness of two local anaesthetics in RSB was compared in present study, it was observed that analgesia was significantly better in patients receiving ropivacaine as compared to bupivacaine, as observed by significantly lower VAS, prolonged duration of analgesia and reduced rescue analgesic consumption in ropivacaine group. Thus efficacy of postoperative analgesia was in order of Group R > Group B > Group C.

The rectus sheath block was performed in present study, via traditional approach after induction of anaesthesia, using an anatomical landmark. In this approach there may be chances of vascular or visceral injury. In present study no such complications were present. Similarly Smith et al. (1988),[2] Crosbie et al. (2012)[17] used anatomical landmark guided RSB and no such complications were observed. When patient satisfaction regarding postoperative analgesia was enquired at 10 h postoperatively, patient satisfaction was significantly higher in ropivacaine & bupivacaine group as compared to control group, $p<0.001$. Moreover, satisfaction was significantly better when ropivacaine was used for RSB. This could be attributed to superior postoperative analgesia in group R than in group B than in group C. Ozcengiz et al[13] also reported better patient satisfaction with levobupivacaine (0.25%, 0.2 ml/kg) was given in RSB as compared to patient receiving i.v. tramadol for postoperative analgesia.

5. Limitations of the Study

Firstly, the absence of USG guided block placement facilities at our institution compelled us to place the block in the conventional way using landmark guided technique. This, coupled with the learning curve for rectus sheath block, does place a question over the accurate placement of the blocks. These may also be responsible for the consumption of rescue analgesic (tramadol) in all the three groups postoperatively.

Secondly, it must be noted that the RSB covers only the somatic pain arising out by the anterior abdominal wall and not the visceral pain by laparotomy. This might explain the use of rescue analgesic tramadol in patients who were given Rectus sheath block, through consumption was significantly reduced.

6. Conclusion

We conclude that bilateral single shot rectus sheath (RSB) using isobaric ropivacaine (0.25%) or bupivacaine (0.25%) is a safe and effective method of providing postoperative analgesia to patients undergoing abdominal surgeries performed via midline incisions. The lower cardio toxicity profile of ropivacaine coupled with the excellent prolonged postoperative analgesia makes it an excellent choice for the use in the RSB as compared to bupivacaine.

For future implications the use of USG guidance may greatly improve the accuracy of placement of the RSB, thus enhancing its effectivity. Furthermore, the use of an indwelling rectus sheath catheter will provide a reliable

means to continue analgesia into the postoperative period.

7. Source of Funding

None.

8. Conflict of Interest

None.

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