Original Research Article

A prospective, randomized study to compare epidural bupivacaine 0.125% and ropivacaine 0.2% with fentanyl combination for post-operative analgesia in lower abdominal and lower limb surgeries

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Abstract

Background: A combination of local anesthetic agent with opioids like fentanyl administered in the epidural space provides effective postoperative analgesia in a lower dose to achieve the desired analgesic effect. **Aim:** To compare epidural bupivacaine 0.125% and ropivacaine 0.2% with fentanyl combination for lower abdominal and lower limb surgeries. **Material and Methods:** A total of 72 patients scheduled to undergo elective lower limb or lower abdominal surgery were randomized into two groups. Group 1 received 0.125% Bupivacaine with Fentanyl 2µg/ml, and Group 2 received 0.2% Ropivacaine with Fentanyl 2µg/ml each at 6ml/h via piston driven syringe pump over a period of 24 hours. **Results:** The VAS at rest and movement/cough and the NRS was clinically higher for bupivacaine group, but the difference was statistically not significant ($p>0.05$). Clinically, more doses of rescue analgesic were required in bupivacaine group, but the difference was not significant statistically ($p>0.05$). The number of patients having significant motor blockade was higher in bupivacaine group but the statistically the difference was significant only at '0' hour ($p<0.05$). **Conclusion:** Both the groups were clinically comparable. Patient satisfaction was probably better in ropivacaine group compared to bupivacaine group. Requirement of rescue analgesia was more in bupivacaine group

Key Words: Epidural anaesthesia, ropivacaine, bupivacaine, fentanyl, visual analogue scale, rescue analgesia.

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INTRODUCTION

Epidural anesthesia is a good technique that provides not only peri-operative surgical anesthesia but also post-op analgesia in lower abdominal and limb surgeries.[1,2]Ithas many advantages like graded level of analgesia, haemodynamic stability, and prolonged duration of action.[2]Lack of pain relief or inadequate analgesia may manifest as hemodynamic changes in the form of tachycardia and hypertension. Prolonged immobilization may also lead to catastrophes like deep vein thrombosis and pulmonary embolism.[3] Ropivacaine is a local anaesthetic with a potency similar to bupivacaine and

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displays an improved cardiotoxicity profile and reduced motor blockade at doses which provides analgesia and translates to early mobilization of patients, thereby reducing the in-hospital stay, early physiotherapy of patients and also reduces the financial burden of prolonged hospital stay.[4-6] It also reduces morbidities due to prolonged immobilization like psychological problems, deep vein thrombosis, pulmonary thromboembolism and related catastrophe. Ropivacaine is marketed as a lesser toxic alternative to bupivacaine with better sensory block and lesser motor blockade.[7] Many a time, for achieving the desired peri-operative anaesthetic and analgesic effect, invariably large volumes of local anaesthetics are used, thereby increasing the possibilities of local anaesthetic toxicity and deleterious haemodynamic consequences. A combination of local anesthetic with opioid, by infusion into the epidural space provides effective postoperative analgesia. Opioids like fentanyl have been used traditionally as an adjunct for epidural administration in combination with a lower dose of local anaesthetic to achieve the desired post-operative analgesic effect.[8] This study shall endeavour to objectively test and find a better postoperative analgesic to improve patient comfort. This is proposed to be done by comparing the degree of pain relief and outcome in two groups of patients; those in whom postoperative analgesia is with combination of bupivacaine - fentanyl and those in whom postoperative analgesia is with combination of ropivacaine - fentanyl.

MATERIAL AND METHODS

In this prospective randomized study, 72 patients of both genders, aged 18-60 years, physical status American Society of Anaesthesiologist (ASA) I and II scheduled to undergo elective lower limb or lower abdominal surgery were enrolled. into the present study. The research ethics committee approval and the informed and written consent from each patient was obtained.

Inclusion Criteria

- Patients aged between 18 years and 60 years
- ASA I and II
- Elective lower limb or lower abdominal surgery

Exclusion Criteria

- Patient refusal
- ASA III and above
- Bleeding dyscrasia, hematological disorders and patients on anticoagulants
- Patients with BMI >40 kg/m^2
- Patients allergic to local anesthetics
- Emergency surgery
- Surgeries exceeding a duration of 2 hours

Methodology

The patients were randomized using computer generated random numbers. Allocation was ensured using Serially Numbered Opaque Sealed Envelope (SNOSE) technique and patients enrolled after a thorough pre-anesthetic evaluation prior to the proposed surgery. All patients were given standard fasting guidelines, and were advised to take Tab Ranitidine 150 mg and Tab Diazepam 5 mg, the night before and on the morning of the surgery. In all patients, intravenous access was secured for drug and fluid administration. Standard monitors NIBP, ECG, pulse oximeter wereconnected for baseline recordings of pulse rate, blood pressure, ECG, respiratory rate and SpO2. Combined Spinal Epidural Anesthesia (CSEA) using Double Needle- Double Interspace Technique was administered. We were prepared for induction of general anesthesia should the technique fail or procedure related adverse events occur (with Laryngoscope, endotracheal tubes, induction drugs, emergency drugs). The drug was prepared by a person (registrar or consultant anaesthesiologist) who was not directly involved in the study. Group 1 received 0.125% Bupivacaine with Fentanyl 2µg/ml, and Group 2 received 0.2% Ropivacaine with Fentanyl 2µg/ml each at 6ml/h via piston driven syringe pump over a period of 24 hours. With the patient in sitting position, under strict aseptic precautions, epidural space identified in L2-3 interspace with 16G Touhy Needle using Loss of Resistance-Saline technique and after appreciating a negative response to test dose of 3ml of Inj 2% Lignocaine with Adrenaline, the catheter advanced 3-5cm in the epidural space and secured. Following this, subarachnoid block performed on eintervertebral space below using 25 or 27 G Whittacre needle with 2-2.5ml ofInj0.5% Bupivacaine heavy, i.e., 10-12.5 mg, with Fentanyl 10 mcg as adjuvant. Inj Ephedrine 6mg i.v was administered if a 20% or greater fall in blood pressure and Inj Atropine 0.6 mg i.v if bradycardia was encountered. The surgeries exceeding a duration of 2 hours were excluded. Following the surgery all patients were shifted to PACU. In the PACU, the patients were monitored and the level of sensory blockade checked. Once the Level of sensory blockade regressed toT10, the epidural infusion with either of the study drug was started. This time at which the level regressed to T10 and the epidural infusion was started was defined as the '0' hour for the purpose of the study. Patients received Inj Paracetamol 1g iv Q6h. Inj Pethidine 50mg imwas used for rescue analgesia if patients complained of pain (VAS>3, NRS>3). The following parameters were observed and recorded by the principal investigator at 0, 1, 6, 12, and 24 hours: Wound pain (Visual Analogue Scale) was assessed at rest andmovement /cough, patient satisfaction (Numeric

Rating Scale), motor blockade (modified Bromage scale), sensory blockade(response to pin prick) requirement of rescue analgesia (Inj Pethidine 50mg im),vital parameters (pulse rate, BP, SpO2) and side effects like nausea, pruritus and shivering. DASH® monitor was used for all the cases to make the recordings uniform.

Statistical Analysis: Data analysis was done with the help of computer using SPSS Statistical Package – Version 21.0. Continuous variables were measured as mean, median, interquartile range (IQR) and standard deviations, and categorical variables were measured as percentages. Independent 't' test and Mann Whitney U test was used to test the significance of difference between quantitative variables and Yate's and Fisher's Chi Square test for qualitative variables. p value less than 0.05 was considered statistically significant.

RESULTS

Among the 72 patients in the study sample, one patient developed on-the table pulmonary embolism, and another patient had migration of the epidural catheter into the subarachnoid space and were excluded from the study. None of the patients were excluded based on the duration of surgery (beyond 2 hours). The mean age of patients in ropivacaine group was 50.20 years with a standard deviation of 11.24 years whereas, the mean age in Bupivacaine group was 52.29 years with a standard deviation of 10.84 years. The p-value was 0.3. In Ropivacaine group, 19 patients belonged to male gender and 16 were females. In Bupivacaine group, 21 patients were males and 14 females.

Table 1: VAS at Rest

VAS at Rest	Group										P
	Ropivacaine					Bupivacaine					
	Mean	SD	Median	IQR		Mean	SD	Median	IQR		
VASR_0Hr	0.06	0.24	0.00	0	0	0.14	0.43	0.00	0	0	0.3
VASR_1Hr	0.40	0.81	0.00	0	0	0.66	1.30	0.00	0	2	0.5
VASR_6Hr	0.89	1.59	0.00	0	2	1.20	1.81	0.00	0	2	0.4
VASR_12Hr	0.66	1.21	0.00	0	2	1.00	1.64	0.00	0	2	0.5
VASR_24Hr	0.26	0.82	0.00	0	0	0.60	1.12	0.00	0	1	0.08

Mann Whitney test The VAS at rest though was clinically higher for bupivacaine group (as assessed from mean scores), the difference was statistically not significant (p>0.05 at each interval).

Table 2: VAS on Movement / Cough

VAS on mobility	Group										p
	Ropivacaine					Bupivacaine					
	Mean	SD	Median	IQR		Mean	SD	Median	IQR		
VASM_0Hr	0.06	0.24	0.00	0.00	0.00	0.14	0.43	0.00	0.00	0.00	0.4
VASM_1Hr	0.51	0.92	0.00	0.00	1.00	0.74	1.36	0.00	0.00	2.00	0.7
VASM_6Hr	0.94	1.68	0.00	0.00	2.00	1.43	2.02	0.00	0.00	3.00	0.3
VASM_12Hr	0.71	1.34	0.00	0.00	2.00	1.14	1.78	0.00	0.00	2.00	0.3
VASM_24Hr	0.17	0.51	0.00	0.00	0.00	0.63	1.14	0.00	0.00	1.00	0.06

Mann Whitney test The VAS for movement /cough was found to be clinically higher in bupivacaine group, but the difference was not found to be statistically significant (p>0.05 at each interval).

Table 3: Numeric Rating Scale (NRS)

	Group										p
	Ropivacaine					Bupivacaine					
	Mean	SD	Median	IQR		Mean	SD	Median	IQR		
NRS_0Hr	0.17	0.51	0.00	0.00	0.00	0.20	0.58	0.00	0.00	0.00	0.9
NRS_1Hr	0.57	1.24	0.00	0.00	0.00	1.00	1.59	0.00	0.00	2.00	0.3
NRS_6Hr	1.03	1.72	0.00	0.00	2.00	1.60	2.26	0.00	0.00	4.00	0.3
NRS_12Hr	0.91	1.63	0.00	0.00	2.00	1.23	1.94	0.00	0.00	3.00	0.5
NRS_24Hr	0.46	0.92	0.00	0.00	0.00	0.80	1.32	0.00	0.00	2.00	0.3

Mann Whitney test The NRS was clinically found to be marginally higher in bupivacaine group, but the difference in NRS between ropivacaine and bupivacaine was statistically insignificant (p>0.05 at each interval of assessment).

Table 4: Rescue Analgesia

		Group			
		Ropivacaine		Bupivacaine	
		N	%	n	%
Rescue_Analgesia	No	21	60.0%	17	48.6%
	Yes	14	40.0%	18	51.4%

p=0.4, chi-square test

18 patients in Bupivacaine group required rescue analgesia, whereas in Ropivacaine group, only 14 patients required rescue analgesia. However, this difference was not statistically significant (p = 0.4).

Table 5: No. of Supplemental Doses

		Group			
		Ropivacaine		Bupivacaine	
		N	%	n	%
No. of supplemental doses	0.00	0	0.0	1	5.6
	1.00	5	35.7	4	22.2
	2.00	6	42.9	8	44.4
	3.00	3	21.4	1	5.6
	4.00	0	0.0	4	22.2
Mean± SD		1.86±0.77		2.17±1.20	
Median		2.00		2.00	

p=0.2

The mean supplemental doses of rescue analgesia provided for ropivacaine group was 1.86±0.77 and that for bupivacaine group was 2.17±1.20.Clinically, more doses of rescue analgesic were required in bupivacaine group, but the difference was not significant statistically (p>0.05).There was no statistically significant difference in the mean pulse rate, blood pressure in the two study groups during the study intervals observed.

Table 6: Level of Motor Blockade (Modified Bromage Scale)

		Group				
		Ropivacaine		Bupivacaine		p
		n	%	n	%	
LMB_0_Hr	2.00	12	34.3	3	8.6	0.009
	3.00	23	65.7	32	91.4	
LMB_1_Hr	1.00	7	20.0	5	14.3	
	2.00	18	51.4	17	48.6	0.7
	3.00	10	28.6	13	37.1	
LMB_6_Hr	.00	35	100.0	34	97.1	0.3
	1.00	0	.0	1	2.9	
LMB_12_Hr	.00	35	100.0	35	100.0	NA
LMB_24_Hr	.00	35	100.0	35	100.0	NA

At 6, 12 and 24 hrs period none of the patients in ropivacaine group had motor blockade (Modified Bromage Score of 0). At 12 and 24 hrs period no patient had motor blockade in Bupivacaine group. Clinically, the number of patients having significant motor blockade was higher in bupivacaine group when compared to ropivacaine group but the statistically the difference was significant only at '0' hour (p<0.05).

Table 7: Level of Sensory Blockade

		Group				
		Ropivacaine		Bupivacaine		p
		n	%	n	%	
LSB_0Hr	T10	35	100.0	35	100.0	
	T10	1	2.9	2	5.7	
LSB_1Hr	T12	32	91.4	28	80.0	
	L1	2	5.7	5	14.3	0.4
LSB_6Hr	Nil	35	100.0	35	100.0	
LSB_12Hr	Nil	35	100	35	100	
LSB_24Hr	Nil	35	100.0	35	100.0	

The level of sensory blockade was assessed in response to pin prick and recorded at 0, 1, 6, 12 and 24 hours. At '6', '12' and '24' hour- no patients exhibited sensory blockade. At '6','12' and '24' hour all patients had recovered from sensory blockade. There was no statistical significance among the groups studied.

DISCUSSION

Epidural analgesia is considered by many as gold standard for postoperative analgesia in major surgery. Epidural techniques are particularly effective in providing dynamic analgesia, allowing the patient to mobilize and resume normal activities which are limited by pain, thereby improving postoperative outcomes. Both study groups were comparable in terms of demographic variables. In our study, the subjective pain relief was assessed using VAS. There was no difference in VAS pain scores at rest and movement/cough between ropivacaine and bupivacaine group at 0 and 1hr interval after initiation of the epidural infusion. However, we found that the mean VAS scores measured at 6,12 and 24 hrs were clinically better in ropivacaine group than bupivacaine group but the difference was not statistically significant (p=0.5 VAS-rest, p=0.06 VAS-movement/ cough).Similar results were found by Korula *et al*., although they observed clinically better pain scores in ropivacaine group, there was statistically no difference among the groups in VAS at rest/movement.[9] In another study conducted by Kanai *et al*, wherein, they concluded that VAS scores were definitely better with ropivacaine and it is a better analgesic due to the dynamic analgesia which is an advantage of the drug ($p<0.001$).In a similar study by the same author, they emphasized that the postoperative analgesia was better when given as a local anesthetic – opioid combination, than ropivacaine or bupivacaine alone.[10,11]However, the study conducted by Pouzeratte *et al* concluded that Bupivacaine produced better pain relief than Ropivacaine but this study was done under general anesthesia and epidural analgesia was with local anesthetic-sufentanil combination unlike our study which was purely regional anesthesia technique followed by local anaesthetic-fentanyl epidural infusion.[12]Pitimana *et al* concluded that overall pain at rest and movement was not significantly different (p=0.15 and p=0.58 respectively). Their results could probably have been due to the much dilute drug concentrations used.[13] Some studies reported equipotency, others reported equal analgesic potency, whereas, some have reported decreased analgesic potency with ropivacaine. Thus, relative potencies of epidural ropivacaine versus bupivacaine as sole drugs for postoperative analgesia are unclear. Previous comparisons of epidural analgesia with ropivacaine versus bupivacaine are further clouded by the addition of epidural opioids. Both epidural ropivacaine and bupivacaine are improved by the addition of small doses of fentanyl for postoperative analgesia.[14]The probable reason to deducing statistically insignificant results in our study was a smaller subgroup of patients and limiting the study duration to 24 hours. Patient satisfaction was assessed using NRS, and it was found that patients had similar mean scores at 0 hour and clinically better mean scores in ropivacaine group at 1, 6, 12 and 24 hrs assessment compared to bupivacaine group. However, it was not statistically significant (p=0.3). Korula *et al* also recorded better NRS with ropivacaine in their study but no statistical significance was observed.[9] None of the other authors we reviewed for our study took NRS for objective evaluation into consideration. However, Verbal Pain Score was used by Kanai *et al*,[10] Nakahara *et al*,[11] and concluded that patients receiving ropivacaine recorded clinically and statistically better patient satisfaction than bupivacaine group. However, Berti *et al* concluded that there were no statistically significant differences in the Verbal pain scores in either of the study groups ($p>0.05$).[15] Regarding requirement of supplemental analgesia, in our study, 4 patients in bupivacaine group required supplemental analgesia as compared to patients receiving ropivacaine. The mean number of supplemental doses in ropivacaine group was 1.86±0.77 and 2.17±1.20 in bupivacaine group, however this difference was statistically insignificant (p=0.5). Berti *et al* conducted a similar study in patients undergoing upper abdominal surgery with a finding that the number of rescue analgesic dose in ropivacaine group (n=16) was 1 and that in bupivacaine group (n=16) was 2, and concluded that the difference was statistically insignificant (p=0.21).[15] Jorgensen *et al* concluded that there was no statistically significant difference among patients requesting rescue analgesic between ropivacaine and bupivacaine groups.[16] There was no statistically significant difference in the offset of sensory blockade in both the groups (p=0.4). Similar results were obtained by Jorgensen *et al*,[16] and Berti *et al*[15] in recovery from sensory block. In a dose finding study conducted by Badner and colleagues, demonstrated that patients receiving 0.1 and 0.2% ropivacaine produced comparatively lower motor and sensory blockade than in patients administered 0.3%.[17] The results of this study demonstrated a statistically significant motor blockade in bupivacaine group (91%) compared to ropivacaine group (65%) with ap value of 0.009 at 0 hour. This does not imply a clinical significance to the outcome of the study as the "0" hour interval overlaps with the intrathecal drug activity. Though there was a marginal increase in motor blockade observed in the bupivacaine group, there was no

statistically significant difference (p>0.05) between the two study groups compared at 1, 6, 12 and 24 hours. Casati *et al* compared ropivacaine, bupivacaine and levobupivacaine in major orthopedic surgery found that motor blockade was similar among the groups (p=0.85).[18] A study conducted by Kanai *et al* demonstrated that motor blockade was significant in bupivacaine group (p=0.001).[11]In a study conducted by Jorgensen *et al* on 50 patients undergoing abdominal hysterectomy, 7% patients who received ropivacaine suffered motor block at 6 h compared to 15% in bupivacaine group.[16] This can be attributed to the drug profile of ropivacaine being less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor nerve fibres: therefore, it has selective action on pain transmitting Aδ and C nerves rather Aβ fibers, which are involved in motor function. Various studies reported similar pattern of sensory and motor blockade with ropivacaine and bupivacaine at a dose ratio of approximately 1.5 to 1 suggesting that this was the equipotent dose ratio.[15] We could have probably deduced a statistical significance had we studied the drug over a larger subgroup of patients. We did not find any statistical / clinically significant difference between the groups in the hemodynamic variables observed during the study period. Similar results were found in hemodynamic variables in studies conducted by Kanai *et al*,[10,11]Berti *et al*,[15] Jorgensen *et al*.[16] None of the patients in the study had complaints of nausea, pruritus and shivering associated with continuous epidural infusion receiving either of the drugs. Similar results were obtained by Berti *et al*, Jorgensen *et al* and Kanai *et al*.[10,11,15,16] To conclude,0.2% ropivacaine-fentanyl and 0.125% bupivacaine-fentanyl were clinically comparable for postoperative analgesia in patients undergoing lower abdomen and lower limb surgeries. Patient satisfaction was probably better in ropivacaine group compared to bupivacaine group. Requirement of rescue analgesia was more in bupivacaine group although it was not statistically significant. There were no significant differences demonstrated in motor and sensory blockade between the groups.

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