Comparison Of Epidural Ropivacaine And Bupivacaine For Lower Limb Surgery

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Abstract : Aims and objectives: to compare efficacy, potency, onset of action, effective duration of analgesia, sensory and motor block, peri operative haemodyamic parameters and complications following epidural bupivacaine and ropivacaine. Methods and material: sixty patients of asa i and ii scheduled for lower limb surgery were included in double blind randomized comparison of epidural ropivacaine 0.75% and bupivacaine 0.5%. we divided patients in two groups. group a patients were given inj. bupivacaine 0.5% 20 ml and group b patients were given inj. ropivacaine 0.75% 20 ml via epidural route. we recorded time of onset, highest level, peak and duration for motor and sensory block along with haemodyamic changes and side effects for both drugs. Summary: mean time to initial onset of adequate level of sensory block(t10) was. 21.76±3.37 min in group a and 22.53± 3.09 min in group b($p>0.05$). total duration of sensory block was 403±16.70 min in group a and 413.5±24.67 min in group b ($p=0.0007$). mean time to initial onset of motor block was 12.13±2.16 in group a and 14.4±3.79 min in group b($p<0.05$). peak motor blockade was achieved in 30.17±3.82 min in group a and 29.97±3.27 min in group b ($p>0.05$). total duration of motor block was 292±21.92 min in group a and 262.5±31.03 min in group b(p 0.0007).Conclusion: ropivacaine is safer and effective alternative to bupivacaine in epidural anesthesia . [Chudasama P et al NJIRM 2013; 4(3) : 115-120]

Key Words: Analgesia, Bupivacaine ,Epidural, Ropivacaine

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Introduction: Now-a-days epidural blockade is becoming one of the most useful & versatile procedures in modern anaesthesiology. It is more versatile than spinal anesthesia, as there is less haemodynamic unstability & extended analgesia. It provides better postoperative pain control & more rapid recovery from surgery.

Epidural anesthesia can reduce the adverse physiologic responses to surgery such as autonomic hyperactivity, cardiovascular stress, tissue breakdown, increased metabolic rate, pulmonary dysfunction & immune dysfunction. It reduces incidence of hypercoagubility.

ROPIVACAINE is an amide local anesthetic structurally related to Bupivacaine that is being investigated because it has reduced potential for CNS toxicity and cardiotoxicity than Bupivacaine in animal studies. It is unique among local anaesthetics because it is prepared as a single enantiomer (the S form), rather than a racemic mixture[1,2,3]. Study was undertaken to compare ROPIVACAINE 0.75%(20ml) and BUPIVACAINE 0.5%(20ml) for epidural anesthesia in patients undergoing lower limb orthopaedic surgery.

Material and Methods: After obtaining approval from the Institutional Review Board, 60 patients of ASA I and II scheduled for lower limb surgery were included in double blind randomized Comparison of epidural Ropivacaine 0.75% and Bupivacaine 0.5%.The study was carried out in Department of anesthesia ,B. J. Medical College ,Ahmedabad during June 2011 to October 2011. Written and informed consent was taken after adequate explanation of procedure and complications.

Inclusion criteria : 1. Age of patient-18-75 yrs, 2. Weight of patient 50-100kg, 3. Height of patient 150-200 cm, 4. Written and informed consent 5. ASA I or II (American society of anaesthesiologist)
Exclusion criteria: 1. Patient's refusal for procedure, 2. Abnormal spine, 3. Prior history of neurologic, psychiatric, cardiopulmonary disease & alcoholic, 4. Active liver or renal impairment, 5. Pregnant woman and Patient on antiarrythmic Drugs(beta blockers).

All patients had fasted for 6-8 hrs. Under all aseptic and antiseptic precautions, we gave epidural anesthesia to the patient. We assessed various parameters at 5, 10, 15, 20, 25 and 30 min, and

thereafter every 15 min for 5 hour and then every 30 min until sensory block resolved. It includes sensory as well as motor block On set, Highest level and duration .We also measured time for adequate level of analgesia (T10) and time until total recovery from analgesia.

All the patients were monitored for vital parameters, sensory and motor blockade and complications if any. Vital parameters were monitored using multipara monitor. Pulse Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Oxygen saturation were recorded at 0, 5, 10, 15, 30 ,60 , 120, 180 min and there after till the end of the surgery and at 1 hr,4 hr,6 hr,12 hr and 24 hr.

Differences in characteristics of patients and epidural blockade were assessed by different statistical tests. After calculating MEAN and STANDARD DEVIATION of all parameters, patients' age, height and duration of surgery were analysed by student's unpaired 't'-test. Sex distribution and ASA gradings were analysed by chi-square test. Time for onset of adequate sensory block, duration of sensory and motor block were analysed by student's unpaired 't'test. Modified bromage scale of both groups were analysed by Kruskal-wallis test. Haemodynamic changes i.e. B.P. were compared by Kruskal-wallis test. Comparison of intraoperative complications like bradycardia and hypotension were analysed by Fisher exact test. The p-value was considered significant as shown below: $p > 0.05$ not significant, $p < 0.05$ significant, $p < 0.001$ highly significant

Results : Time for onset of adequate sensory block-'T10' was 21.77 ± 3.37 min in group A and 22.53 ± 3.09 min in group B. Onset time for adequate block was comparable in both groups (p 0.22). Time duration of sensory block was 403.67 ± 16.7 min in group A and 413.5 ± 24.67 min in group B. Time duration of sensory block was comparable in both groups (p 0.22).Results are shown in tables below.

Table 1 : Demography

Parameters	**Group A**	**Group B**	**p-Value**
Age (Yrs) (Mean ± SD)	47.13 ± 14.14	47.2 ± 12.89	>0.05
Hei ght (cms) (Mean ± SD)	172.2 ± 0.70	172.33 ±0 .70	>0.05
Sex Male	22 (73.3 %)	20 (66.67%)	
Female	8 (26.7%)	10 (33.34%	>0.05
ASA Grade I	18 (60 %)	17 (56.67 %)	
II	12 (40%)	13 (43.33%)	>0.05

Table 2 : Motor Block Characteristics (Mins)

	GROUP A	GROUP B	p-VALUE
Onset of motor block	12.13±2.16	14.4±3.79	p<0.05
Peak motor blockade	30.17±3.82	29.97±3.27	p>0.05
Duration of motor block	292.33±21.92	262.5±31.03	p = 0.0007

Table 3: Comparison Of Mean Pulse Rate

TIME(MIN)	GROUP A(BEATS/MIN)	GROUP B(BEATS/MIN)	P VALUE
Baseline	95.2 ± 4.24	94.2 ± 3.53	>0.05
5 min	91.4 ± 7.07	91.3 ± 2.82	>0.05
10 min	87.7 ± 4.24	86.3 ± 2.12	>0.05
15 min	80.1 ± 4.24	79.53 ± 0.70	>0.05
30 min	70.3 ± 9.89	70.43 ± 2.12	>0.05
60 min	75.7 ± 7.92	74.26 ± 4.24	>0.05
120 min	80.86 ± 5.65	79.2±3.53	>0.05
180 min	86.7±2.82	85.16±6.36	>0.05

Table 4: Comparison Of Mean Systolic Bp

	GROUP A	GROUP B	p-VALUE
0 min	121±9.29	124.56 ± 1.41	>0.05
5 min	117±5.65	118.3±5.65	>0.05
10 min	111.23±3.53	111.2 ± 5.65	>0.05
15 min	103.46 ± 7.09	102.76 ± 8.48	>0.05
30 min	96.9± 6.17	94.3 ± 6.36	>0.05
60 min	102.7 ± 7.7	100.4 ± 1.41	>0.05
120 min	110.16 ±1.41	108.43 ± 5.65	>0.05
180 min	113.86 ±18.38	113.56 ± 12.02	>0.05

Table 5: Comparison Of Mean Diastolic BP

	GROUP A	GROUP B	p VALUE
0 min	82.13±2.12	82.16±2.82	>0.05
5 min	77.66±4.24	80.03±1.41	>0.05
10 min	72.23±0.7	74.36±7.07	<0.05
15 min	69.33±4.84	69.53±0.70	>0.05
30 min	66.16±1.41	65.1±5.44	>0.05
60 min	67.83±9.89	66.5±2.12	>0.05
120 min	73.3±12.72	71.63±9.19	>0.05
180 min	75.63±12.72	77.13±6.36	>0.05

Table 6: Postoperative Changes In Mean Pulse Rate

	GROUP A	GROUP B	
Time	Pulse rate (Mean±SD)	Pulse rate (Mean±SD)	p value
IMMEDIATE	84.86±4.86	85.66±5.97	p>0.05
POSTOPERATIVE			
1 hr	84.33±4.1	84.8±4.8	p> 0.05
3 hr	83.47±3.86	84±5.04	p>0.05
6 hr	84.33±3.89	84.27±4.66	p>0.05
12 hr	83.53±3.95	85.13±5.53	p>0.05

Table 7: Postoperative Changes In Mean Systolic Bp

	GROUP A	GROUP B	
TIME	Systolic BP (mm Hg) (Mean±SD)	Systolic BP (mm Hg) (Mean±SD)	p value
IMMEDIATE	118.2±7.63	121.1±6.55	p>0.05
POSTOPERATIVE			
1 hr	118.9±6.14	121.5±6.04	p> 0.05
3 hr	120.2±5.59	121.3±5.99	p>0.05
6 hr	120.5±5.17	122±5.34	p>0.05
12 hr	120.5±5.42	121.3±5.39	p>0.05

Table 8: Postoperative Changes In Mean Diastolic Bp

	GROUP A	GROUP B	
TIME	Diastolic BP(mm Hg) (Mean±SD)	Diastolic BP(mm Hg) (Mean±SD)	p value
IMMEDIATE	73.7±7.39	74.8±5.93	p>0.05
POSTOPERATIVE			
1 hr	74.6±7.07	74±5.53	p> 0.05
3 hr	75.6±6.78	74.5±5.91	p>0.05
6 hr	76.3±6.05	74.6±5.25	p>0.05
12 hr	75.7±6.72	75.2±4.62	p>0.05

Table 9: Intra And Postoperative Complications

	GROUP A	GROUP B
Hypotension	4(13.33%)	3(10%)
Bradycardia	2(6.66%)	3(13.33%)
Pruritus	0	0
Nausea and vomiting	0	0
Sedation	0	0
Shivering	2(6.66%)	1(3.33%)
Respiratory depression	0	0

The incidence of hypotension and shivering was higher in group A as compared to group B but it was statistically insignificant (p>0.05).The incidence of bradycardia is higher in group B; but it was not statistically significant (p>0.05). None of the patients had other side effects except shivering. Hypotension was corrected by adequate intravenous fluids and Inj. Mephentermine 6-12 mg i.v. and bradycardia was corrected by Inj. Atropine 0.02 mg/kg i.v. For treatment of excessive shivering, Inj.Tramadol 50-75 mg i.v. was given.

Discussion: DEMOGRAPHIC DATA: .The mean age of patients was 47.13±14.14 years in Group A and 47.2±12.89 years in Group B (p=NS). The ratio of Male to Female was 22:08 in Group A and 20:10 in Group B. The ASA I patients in group A were 18 and in group B were 17 while ASA II patients in group A were 12 and in group B were 13. It shows there is no statistical difference between two groups. These findings correlates with study by Brown et al[4] and McGlade et al[5] .

BLOCKADE CHARACTERISTICS :

SENSORY BLOCK was assessed using pin prick method. In our study time to initial onset of adequate level of sensory block (T10) was comparable in both groups. It was 21.76±3.37 min in Group A and 22.53±3.09 min in Group B(p>0.05). Peak sensory dermatomal blockade level reached was T6 to T8 in both the groups. Total duration of sensory block was 403±16.70 min in group A and 413.5±24.67 min in group B(p=0.0007). It shows that Ropivacaine 0.75% had longer duration of

sensory block than Bupivacaine 0.5% and it was statistically significant. Our study findings are comparable to previous studies done by Wolff et al[6], N. Christelis et al[7], Bildik et al[8] and Casati et al[9]. Katz et al[10] observed that time to total recovery of sensation were comparable in both groups. Brown et al[4] observed that total duration of sensory block was longer in Bupivacaine (0.5%) group than Ropivacaine (0.75%) group. Brown et al[4] observed that time of onset of adequate level of block(T10) was 10.7±5.6 min in group R (0.5%) and 13.0±10.7% in group B (0.5%) (p>0.05%). Peak block height was T5±2 in groupR (0.5%) and T5±3 in group B(0.5%) (p>0.05%). Total duration of sensory block was 333±54 min in group R and 394±53 min in group B(p=0.001).

B) MOTOR BLOCKADE: It was assessed using Modified Bromage grading (MBG) scale of 1 to 6. In our study time to initial onset of motor block was 12.13±2.16 in group A and 14.4±3.79 min in group B(p<0.05). Our results are in comparable with Brockway et al[11] and Morrison et al[12] who observed slower onset of motor blockade with Ropivacaine than Bupivacaine. It was comparable in both groups. MBG scale 1 was in 90% cases in group A and 73.33% in group B. MBG scale 2 was in 10% cases in group A and 20% cases in group B. Total duration of motor block was 292±21.92 min in Bupivacaine group and 262.5±31.03 min in Ropivacaine group. It was comparable to previous studies done by Brown et al[4], Kim KH et al[13], Wolff et al[6], Crossby et al[14], Kerrkamp et al[15] and Katz et al[9].Our results are also in consonance with Brockway et al[11], Morrison et al[12] and Griffin et al[16] who observed less intense and shorter duration of motor block . Peak bromage score was 1±1 in both groups. Among those having motor blockade, duration of Bromage level 1 was 220±52 min in Ropivacaine 0.5% group and 276±52 min in Bupivacaine group.(p=0.02). Kim KH et al[13] observed mean onset time of Bromage scale 2 was significantly slower with 1% Ropivacaine (14.6±1.3 min) than with 0.5% Bupivacaine (15.7±2.0 min). Each frequency of motor blockade (Bromage scale 1,2 and 3)with 1% Ropivacaine (10, 8 and 7) was greater than that seen with 0.5% Bupivacaine (7,6 and 1). 1% Ropivacaine group had a significantly longer duration than 0.5% Bupivacaine. Crossby et al[14] observed that Bromage 4 motor block persisted longer in those who had received Bupivacaine (p<0.05). Griffin et al[16] observed that onset time of motor block did not differ significantly between the two groups but duration of grade 1 and 2 motor block were significantly shorter in Ropivacaine than Bupivacaine group. Katz et al[10] observed that time to total recovery of motor function were 4.4±0.9 and 4.1±0.9 hrs in Bupivacaine 0.5% and Ropivacaine 0.75%groups respectively.

VITAL PARAMETERS : Pulse rate, Blood pressure and SpO_2 were recorded regularly throughout the period of study and post operatively till 24 hours. In our study the cardiovascular changes, i.e. heart rate and blood pressure changes were similar between both the groups. All previous studies also show that cardiovascular changes were similar between both the groups. However there was a suggestion that sympathetic blockade needed more aggressive management in Ropivacaine group; slightly more intravenous fluids were required, as well as greater dose of ephedrine, although this did not reach statistical significance. Our results are in consonance with Brown et al[10] who observed similar cardiovascular changes between the two groups. Our results are also in consonance with Morrison et al[12], Brockway et al[11], Mc glade et al[5] and Griffin et al[16]. Brown et al[4] observed that the cardiovascular changes, i.e. heart rate and blood pressure changes were similar between both the groups.The measurement of heart rate preblock and 30 and 60 min postblock showed Ropivacaine and Bupivacaine group values of 71±11 and 70±11 beats per min preblock, 72±13 and 72±12 beats per min at 30 min and 65±10 and 62±12 beats per min at 60 min,respectively. The measurement of systolic blood pressure preblock and 30 and 60 min postblock showed Ropivacaine and Bupivacaine group values of 126±21 and 124±16 mmHg preblock,116±19 and 113±16 mmHg at 30 min and 116±19 and 112±14 mmHg at 60 min respectively. **Intraoperative and post operative complications:-** In our study, intraoperative complications were similar in both groups. Bradycardia was 13.33% (2/30) in Bupivacaine group and 10% (3/30) in Ropivacaine group. Hypotension was 6.66% (2/30)in Bupivacaine group and 10% (3/30) in Ropivacaine group. Shivering was 6.66% in Bupivacaine group and 3.33% in

Ropivacaine group. None of the patients had other side effects. Our study findings are comparable to previous studies done by Brown et al[4], Wolff et al[6], Crossby et al[14]. Our results confirm that plain Ropivacaine 0.75% can be used as the local anaesthetic for epidural anesthesia for lower limb surgery. However Ropivacaine produces late onset of motor block compared to Bupivacaine and short duration of total motor blockade.

Conclusion : Epidural Bupivacaine 0.5% and Ropivacaine 0.75%, both drugs are comparable in respect to peak motor block, onset of adequate level of sensory block (T10), duration of sensory block. Ropivacaine 0.75 % has delayed onset of motor block and short duration of motor blockade. Intraoperatively, both drugs are haemodynamically stable and comparable. Incidence of side effects i.e. hypotension and bradycardia are comparable and less in both group of drugs.Both drugs produce adequate surgical relaxation, sensory and motor blockade. None of the above group of patients required supplementation of other drugs. Patients of Ropivacaine group had early motor recovery than Bupivacaine group. Thus, Ropivacaine 0.75% is safer and effective alternative to Bupivacaine in epidural anesthesia.

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