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A comparison of efficacy and tolerablity of *epidural Levobupivacaine* 0.5% with 0.5% *Racemic* mixture *Bupivacaine* for lower abdominal surgery

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ABSTRACT

This study was performed to compare the efficacy and tolerability of 0.5% racemic Bupivacaine and 0.5% Levobupivacaine, in patients undergoing lower abdominal surgery.56 patients, ASA grade 1 and 2, were randomized to receive an epidural injection of study drug (17 ml 0.5% racemic Bupivacaine in group R and 17 ml of 0.5% Levobupivacaine in group L). The time to onset of adequate sensory block (T10 dermatome), maximum dermatome reached, time taken to reach maximum dermatome, time for 2 segment regression, time taken to regress to T10 were comparable. Although the onset of motor block was comparable in both the groups, Group L showed earlier commencement of motor block at 5 min after zero time. (P value 0.002). The regression of motor block was faster in group L (p value 0.042). The time to obtain maximum level of motor blockade was found to be faster in L group. (p value of 0.043). The number of patient obtaining MBS score of 3 was 62.5% in R group and 37.5% in L group. The grade of motor block showed that, the L group had lesser grade than that of Racemic group (p value of 0.016). The duration of motor block was similar in both the groups. The need for rescue analgesics, total IV fluid requirement and ephedrine usage, MAP,HR and the time of request for post-operative analgesia were similar. Both local anaesthetics were well tolerated and effective in producing epidural anaesthesia for patients undergoing lower abdominal surgery.

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INTRODUCTION

Among local anaesthetic drugs in clinical use, racemic bupivacaine has been widely used because of its long duration of action. But, there have been reports of accidental intravascular injection and death attributable to bupivacaine induced cardiotoxicity (McLeod and Burke, 2001), though the incidence of death is small, this is a major disadvantage. In comparison to bupivacaine, levobupivacaine, the isolated S(2) isomer of bupivacaine, has been shown to be less cardiotoxic (Morrison *et al.*, 2000; Burm *et al.*, 1994).

Very few studies have confirmed equal efficacy of epidural racemic mixture bupivacaine and levobupivacine (Shah *et al.*, 2005; Cousins and Bridenbaugh, 1998). We compare the clinical efficacy (onset, duration, and intraoperative parameters) and tolerability of 0.5% levobupivacaine with that of 0.5% racemic mixture bupivacaine in patients undergo-

ing elective lower abdominal surgery with epidural anesthesia.

SUBJECTS AND METHODS

This is a prospective, randomized study to compare the efficacy of epidural 0.5% levobupivacaine versus 0.5% racemic mixture bupivacaine in lower abdominal surgery. After obtaining institutional ethical committees approval and written informed consent, fifty six patients between the age group of 18-60 years belonging to ASA I and II posted for elective lower limb and below umbilical surgeries were randomly divided into two groups.

Each group consisting of 28 patients, received epidurally 17 ml of 0.5% levobupivacaine in group L, and 17 ml of 0.5% racemic mixture bupivacaine in group R. Patients who had contraindication for epidural anaesthesia, patients posted for emergency surgery, patients with BMI> 30 and pregnant patients were excluded from the study.

Patients were randomized into group R and group L, by computer generated random numbers. The study was blinded (Patient and the anaesthesia provider were blinded of the groups).

Group R- Received 17 ml 0.5% racemic mixture bupivacaine

Group L- Received 17 ml 0.5% levobupivacaine.

Informed consent was obtained from all the patients on the preoperative day. The sequence of events in the theatre was explained. After confirming adequate starvation, before induction of epidural anaesthesia, patient was given IV 500 ml of Ringer Lactate solution. Immediately after putting the patient on operation table, non invasive blood pressure monitering, temperature probe, continuous ECG and pulseoximeter were attached. Patient was put on left lateral decubitus position; L3 L4 interspinous space was identified. Skin and subcutaneous tissue was infiltrated with 3 ml of 2% lignocaine plain. Epidural space was identified by loss of resistance technique using 18G Tuohy needle. Once epidural space was identified confirmation of negative aspiration for blood or CSF done and 3ml of 2% lignocaine, 1 in 200000 adrenaline was used as test dose. The double blinded study drug was given 2 minutes after the test dose, once subarachnoid or intravascular injection were excluded.

Group R received 17 ml 0.5% Bupivacaine over 5 min period. (6ml 1 min wait, 6ml 1 min wait and 5ml)

Group L received 17 ml 0.5% Levobupivacaine over 5 min period. (6ml 1 min wait, 6ml 1 min wait and 5ml)

For further assessment, time zero is the end of injection of study drug into the epidural space. A 20 G catheter was advanced 5cm into the epidural space through 18 G epidural needle, the needle was removed and catheter fixed on the back of the patient. The patient was made supine. The patients HR, temperature, BP and SpO^2were monitored. All the patients were put on face mask with O_2 at 4-6l/min flow. The surgical procedure was started 30 min after injecting study drug in to epidural space. A fall in MAP more than 20% was managed with 6mg Ephedrine. A fall in HR less than 50 bpm was managed with Atropine 0.6mg. Level of sensory analgesia was measured by using cotton dipped with spirit. The time taken to achieve T10 sensory dermatomal block level was defined as the onset of sensory block in the study. Maximum dermatomal level achieved and the time taken to reach the level was recorded. The time taken for two segment regression from maximal dermatomal level was also noted. After 30 min surgery is started, whenever it is deemed necessary 7ml more of study drug was given. (Double blinded). Whenever patient demanded for analgesia post operatively 100mg Tramadol diluted to 10ml with distilled water was injected epidurally, and time was noted.

Onset of motor block was defined as when patient has modified bromage score of equal or more than 2. Duration of motor block was defined as time for which the modified score remains at least 2. The regression of motor blockade is MBS grade less than two. Complete regression of motor block is defined as modified bromage score of zero.

The Grading of Motor block as per Modified Bromage scale (MBS)

Zero, no paralysis, full flexion of hips, knees, and ankles;

One, inability to raise extended leg, able to move knees;

Two, inability to flex knees, able to flex ankles;

Or Three, inability to move any portion of the lower limb.

All patients were sedated with midazolam 0.05 mg/kg body weight and were breathing spontaneously. Patients who were found to have inadequate sensory block and in whom dural puncture was encountered were excluded from the study and the procedure was carried out under GA.

Table 1: The observations made for sensory block in groups L and R

Sensory Block	Group	Sensory block at 5 mins time interval	Time to block T10 level in mins	Maximum dermatome reached	Time to reach maximum dermatome In mins	Two segment regression time In mins	Regression to T10 level In mins
Mean±SD	R	11.07±1.15	9.64 ± 4.89	5.36 ± 1.22	25.71 ± 10.77	130.71 ± 45.61	187.50 ± 39.68
	L	11.07± 1.016	8.21 ± 3.65	5.73 ± 1.37	22.50 ± 5.50	113.57 ±31.99	170.36 ± 49.70
Median	R	-	-	6	-	125.35	183.75
	L	-	-	6	-	116.78	205.17
	P value	1.000	0.221	0 .428	0.158	0 .109	0 .160

Table 2: Motor onset at 5 minutes time interval of study

	Mean	SD	Median	Mode	P-value
Group L (Levobupivacaine)	0.89	0.49	1	1	0.002
Group R (Bupivacaine)	0.46	0.5	0	0	

Table 3: Grade of motor block as per MBS

Group	Mean	SD	Median	Mode
Levobupivacaine (L)	2.18	0.86	2	3
Racemic Bupivacaine (R)	2.82	0.48	3	3

Table 4: Time to achieve maximum motor block as per MBS

Group	Mean	SD	Median
Levobupivacaine (L)	17.86	10/84	17.5
Racemic Bupivacaine (R)	23.39	9.13	25

Table 5: Motor Reversal regressions of MBS less than $\leq$2

Group	Mean	SD	Median	Mode
Levobupivacaine (L)	177.15	39.01	180	210
Racemic Bupivacaine (R)	196.67	39.32	210	210

RESULTS

The demographical profile was comparable in both groups with no statistically significant difference.

The time to reach T10 dermatome sensory block (onset of sensory block) in both the groups was similar. (Mean 8.21 minutes in L group and 9.64 minutes in R group with no statistically significant difference). The mean values of maximum dermatome reached (sensory block) in L group and R group are 5.73 and 5.21 level respectively. The p value is 0.428 .The time taken to reach maximum dermatome sensory block level was found to be 22.5 minutes in L group and 25.7 minutes in R group with no statistically significant difference. The time for 2 segment regression of sensory block was found to be 113.57 minutes in L group and 130.71 minutes in R group, the p value being 0.160 with no statistically significant difference. The total duration of analgesia in our study is the first postoperative analgesia request by the patient was similar in both group (170.36 minutes in group L and 187.5 minutes in group R, with no statistically significant difference).

The observations made for sensory block in group L and R are shown in Table 1.

Table 6: The observations made for Motor block in groups L and R

Motor Block	Onset of Motor Block in Minutes		Grade of motor block as per MBS	Time taken to reach maximum motor block as per MBS.	Time for regression of motor block to MBS 1	Duration of Motor block
	AT 5 minute time interval of study	Based on MBS of 2				
Mean±SD R	0.46±1.5	20.55 ± 26.17	3.25± 0.79	23±9.13	196.66±39.32	172.77±44.90
L	0.89±1.32	16.42 ± 11.74	2.50±1.23	17.85±10.83	177.14±39.00	160±46.64
Median R	0	15	3	17.5	210	195
L	1	15	2	25	180	170
Mode R	0	15	3	15	196.66±39.32	172.77±44.90
L	1	10	3	10	177.14±39.00	160±46.64
P Value	0.002	0.069 0.016		0.043	0.042	0.369

Table 7: Summary of analysis of study-sensory

Group	Sensory onset(mins)	Maximum sensory level	Time for maximum sensory level(mins)	Two segment regression (mins)	Duration of sensory block(mins)
R	9.64 ± 4.89	5.36 ± 1.22	25.71 ± 10.77	130.71 ± 45.61	187.50 ± 39.68
L	8.21 ± 3.65	5.73 ± 1.37	22.50 ± 5.50	113.57 ±31.99	170.36 ± 49.70

Table 8: Summary of analysis of study-motor

Group	Motor onset(mins)	Time for motor block to MBS 1(mins)	Duration of motor block(mins)
R	20.55 ± 26.17	196.66±39.32	172.77±44.90
L	16.42 ± 11.74	177.14±39.00	160±46.64

The total duration of motor blockade MBS (Grade ≥2) in group R was 172.77±44.90, whereas the duration of motor block in group L was 160±46.6. In our study the motor block graded by modified bromage scale at the end of 5 minute time interval after injection of study drug was noted in L group and was compared to R group which showed statistically significant difference-p value 0.002.

The mean of motor onset at five minutes time interval between Group R and L is given below in the Table 2.

The Grade of Motor block as per MBS is shown in the Chart 1: for group L (Blue) and R (Red).

The Table 3 shows mean grade of motor block as per MBS for Group L and R.

The mean grade of motor block as per MBS in group L was 2.5 ± 1.23 and in group R was 3.25 ± 0.79, the p value being 0.016 (statistically significant difference), implying the motor grade reached in group R is denser than in Group L.

The number of patient achieving MBS 3 in motor block is 62.5% vs 37.5% in Group R and Group L respectively. This implies lesser grade motor block in levobupivcine than racemic mixture bupivacaine

Chart 2: shows the number of patients who achieved Modified bromage scale 0f 3 for the Group L and R.(Group R: 62.5%, Group L: 37.5%).

The time taken to attain the maximum motor blockade was 23.39±9.13 min in group R and 17.85±10.8 min in group L. This is statistically highly significant. (p value:0.043).

The time to achieve maximum motor block as per

Table 9: Reference articles and their findings -1

Reference	Dose/Concen	No. of Patients	Type of Surgery	Onset Time (minutes)	Duration of the block (minutes)	Motor block (%)
(Kopacz *et al.*, 2000)	20 ml of 0.75%Lev-obupiva-caine	28	Abdominal	13.6±5.6	550±87	
	20 ml of 0.75% bupiva-caine	28		14.0±9.9	505±71	
(Casati *et al.*, 2003)	15 ml of 0.75%Lev-obupiva-caine	15	Hip surgery	25±19	213±53	100
	15 ml of ropivacaine 0.5%	15		30±24	233±34	60
	15 ml of Levobupi-vacaine 0.5%	15		31±16	214±61	80

Modified Bromage Scale for the group L (BLUE) and R (RED) are shown in the Chart 3 and Table 4.

The time of regression of block to MBS grade 1(less than 2) is earlier with 0.5% levobupivacaine when compared to 0.5% racemic mixture bupivacaine,

The Motor block reversal-Regression of MBS less than grade two in Minutes is shown for group L (BLUE) and R (RED) in Chart 4 and Table 5.

The Table 6 shows the observations made for motor block in Group L and R.

The time of request for post-operative analgesia after the injection of study drug was found to be 319.28 min in group L and 222.85 min in group R, p value being 0.553 which shows there was no statistically significant difference. Hypotension (fall in BP more than 20% of its baseline) was treated with injection ephedrine in the increments of 6 mg IV and intravenous crystalloids Only seven patients in group R and 5 patients in group L developed hypotension of significance and were managed by fluids and vasopressors. This is statistically not significant. Bradycardia bpm less than 50 was not seen in both groups. Additional analgesics were required in 7% of patients in group R and 4% of patients in group L. There were no complaints of nausea and vomiting in both groups during the study.

DISCUSSION

Bupivacaine racemic mixture, enantiomer is being regularly used for epidural anaesthesia for lower abdominal and lower limb surgeries. Its stereoisomer, levobupivacaine, without cardio toxic effects is also in use clinically. This study compares the efficacy of epidural 0.5% levobupivacaine versus 0.5% racemic mixture bupivacaine in lower abdominal surgery.

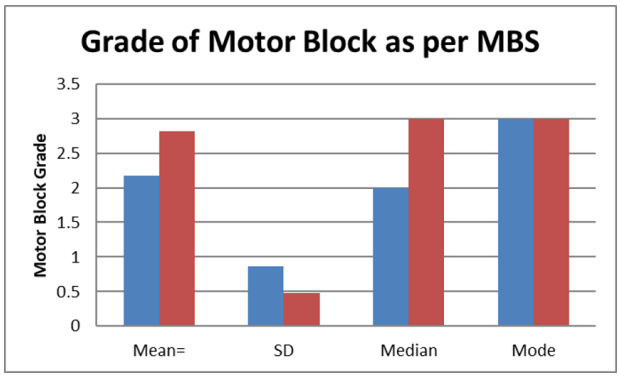

Chart 1: Grade of motor block as per MBS P value: ‹0.05 is significant
P value: 0.016

Both group patients had drugs of 0.5% strength as they have similar potency. The explanation for the

Table 10: Reference articles and their findings -2

Author and Type of Surgery	Dose/concentration	a)Onset time of sensory block(min) b) Maximum sensory dermatoma I level	Duration of sensory block mean(SD) or median(rai min or h	Duration of motor block mean(SD) or median(ran min or h	Incidence of hypotension
(Cok *et al.*, 2011) Thoracic surgery	0.1 ml/kg 0.25% levobupivacaine+CEI 0.1 ml/kg/h	a)4.8± 4.1 b) T8(T7-9)			0
	0.1 ml/kg 0.25% bupivacaine+CEI 0.1 ml/kg/h	a)4.8 ± 3.1 b) T9(T8-9)			0
(Bergamaschi *et al.*, 2005) Caesarean section	100 mg levobupivacaine + 10 ug sufentanil	b) T6-12			66.7
	100 mg bupivacaine + 10 ug sufentanil	b) T6-12			43.5
(Peduto *et al.*, 2003) Lower limb	15 ml levobupivacaine 0.5%	a)29(24)	185(77)	105(63)	3
	15 ml bupivacaine 0.75%	a)25(22)	201(75)	95(48)	12
(Murdoch *et al.*, 2002) Hip or Knee replacement	10-15 ml levobupivacaine 0.75% + CEI levobupivacaine 0.0625% 6 ml/h	b) 8.1(5.0)		3	
	10-15 ml levobupivacaine 0.75% + CEI levobupivacaine 0.0125% 6 ml/h	b) 9.5(7.0)		4	
	10-15 ml levobupivacaine 0.75% + CEI levobupivacaine 0.025% 6 ml/h	b) 16.7(8.3)		7	

CEI- Combined Epidural infusion

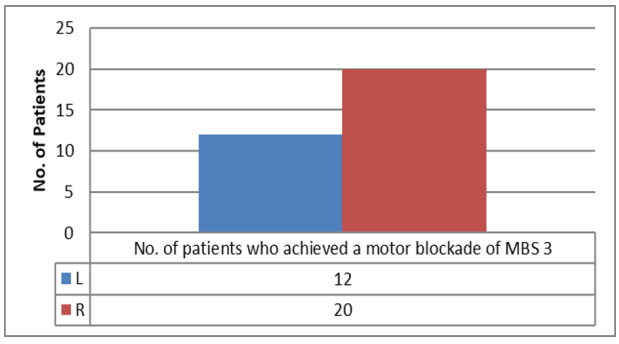

Chart 2: Number of Patients who achieved MBS of 3

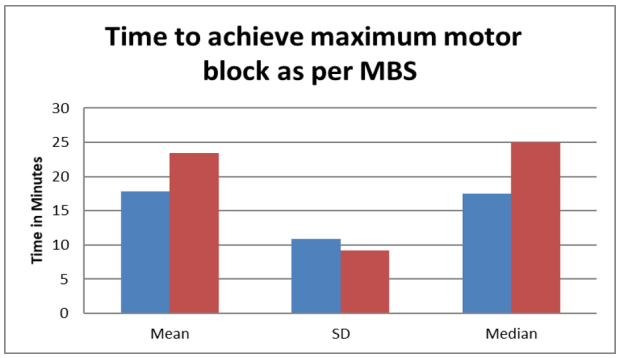

Chart 3: Time to achieve maximum motorblock as per MBS P value: 0.043
P value: ›0.05 is not significant

equal potency of levobupivacaine compared with bupivacaine may be because of the similar lipophilic property. The lipid solubility of both the group is 30.

The comparable efficacy of levobupivacaine and bupivacaine for sensory block for lower abdominal surgery is in agreement with that found in previous clinical trials of these anaesthetics for extradural anaesthesia in lower limb surgery. The study

Table 11: Reference articles and their findings -3

Author and Type of Surgery	Dose/concen	a)Onset time of sensory block(min) b) Maximum sensory dermatoma I level	Duration of sensory block mean(SD) or median(ran min or h	Onset time of motor block mean(SD) or median(rang min	Duration of motor block mean(SD) or median(rang min or h	Incidence of hypotension
(Kopacz *et al.*, 2000) Lower limb, Abdominal	20 ml levobupivacaine 0.75%	a)13(10-18) b) T5-6	550.6(87.6)		355.4(83.4)	82
	20 ml bupivacaine 0.75%	a)13(7-21) b) T5-6	505.9(71)		375.7(99.2)	61
(Cox *et al.*, 1998) a Lower limb	15 ml levobupivacaine 0.5%	a)8(5) b) T8(T2-12)	377(128)	25(23)	185(122)	
	15 ml levobupivacaine 0.75%	a)6(4) b) T8(T6-11)	460(111)	27(30)	256(99)	
	15 ml bupivacaine 0.5	a)7(4) b) T6-L2	345(107)	17(7)	192(74	

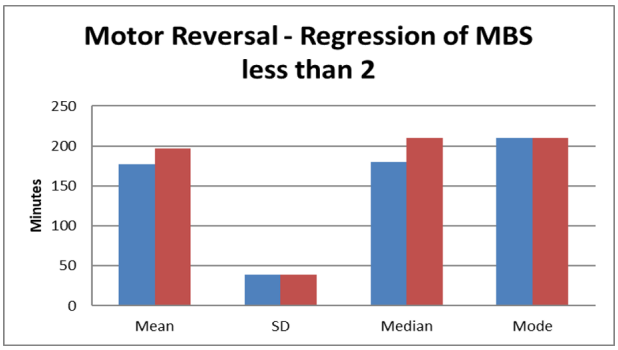

Chart 4: Motor Reversal regressions of MBS less than ≤2 P value: 0.042
P value: ›0.05 is not significant

done by Robinson *et al.* (2001) showed no difference between the MLAC of levobupivacaine (0 083%) and bupivacaine (0 081%). Wang *et al.* (2010) in the year 2010, have stated that the analgesic efficacy mainly depends on the concentration of LA rather than the type of anaesthetics and at least 0.1% is needed for satisfactory analgesia. Hence, 0.5% concentration was chosen for both the drug group. The dosage of 0.5% bupivacaine and levobupivacaine is 2 per kg body wt.(for a 50 kg patient the toxic dose is about 100 mg) The total volume used in our study in both the group is 17 ml(85 mg). Hence, in both the groups 17 ml was elected as the volume of the study drug other than the test dose.

The age, sex, educational qualification and BMI of the patients included in both the groups were comparable with no statistically significant difference.

Sensory block

The time to reach T10 dermatome in both the groups was similar. (Mean 8.21min in L group and 9.64 min in R group, p value being 0.22 which shows there was no statistically significant difference. The onset time of senory block of epidural anaesthesia with Levobupivacaine and Bupivacaine was 4.8±4.1 vs 4.8± 3.1 min (Cok *et al.*, 2011). The time to onset of adequate sensory block (T10 dermatome) was similar in epidural Levobupivacaine 0.75% with racemic Bupivicaine 0.75% for lower abdominal surgery (Kopacz *et al.*, 2000). There was no difference in the onset time for sensory block which concurs with our study (Cox *et al.*, 1998).

The mean values of maximum dermatome reached in L group and R group are 5.73 and 5.21 level respectively. The p value was found to be 0.428 where there was no statistically significant difference. Similar results were found in the studies done

previously (Kopacz *et al.*, 2000; Cox *et al.*, 1998). The number of block dermatomes were similar in both groups(T8 vs T9) (Cok *et al.*, 2011).

The time taken to reach maximum dermatome level was found to be 22.5 min in L group and 25.7 min in R group, the p value being 0.158, which shows there was no statistically significant difference. The time taken to obtain the maximum dermatome level of sensory block was similar in both groups (24.3± 9.4 and 26.5± 13.2 min respectively) (Kopacz *et al.*, 2000).

The Time for 2 segment regression was found to be 113.57 min in L group and 130.71 min in R group, the p value being 0.160 with no statistically significant difference, which shows there was no statistically significant difference. Similar results were obtained for time to regression in a study done in the year 2003 (Casati *et al.*, 2003).

Duration of analgesia in our study was 170.36 min in group L and 187.5 min in group R, p value being 0.160, which shows there was no statistically significant difference. In contrast to our study**,** a study done in the year 1998, showed significant difference in duration of sensory block caused by Levobupivacaine (longer), than racemic Bupivacaine (Cox *et al.*, 1998). A study done in the year 2000, obtained values of 505.9±71.1 min for bupivacaine group and 550.6±87.6 min for levobupivacaine group (p value:0.016). Here the time for complete regression of sensory block in levobupivacaine group was found to be significantly longer (Kopacz *et al.*, 2000).Table 7 , gives the summary of primary objective of sensory block in the study.

Motor block

Table 8, gives the summary of primary objective of motor block in the study.

In our study the motor block at the end of 5 min time interval (Bromage scale grade 1) after injection of study drug was noted in L group compared to R group with statistically significant difference (p value 0.002). Earlier onset of Motor block in L group.

The mean grade of motor block at 5 min time interval of study in group L was 2.5 ± 1.23 and in group R was 3.25 ± 0.79, the p value being 0.018, which shows there was statistically significant difference.

The time to reach MBS grade 2 was 16.42 min in group L and 20.55 min in group R, with p value 0.06 p value being 0.160, which shows there was no statistically significant difference. This corresponds to the results of the previous studies (Cox *et al.*, 1998; Bergamaschi *et al.*, 2005). One study found that the onset of motor block was longer in Bupivacaine group which is contrary to our study (Casati *et al.*, 2003).

Regression of Motor block to MBS grade 1 was found to be 177.14 min in group L and 196.66 min in group R p value being 0.042 (statistically significant difference). Thus, our study finds that the onset of motor block was quicker in group L, the grade of motor block was less dense and regression of motor block quick in L group. Hence, this drug can be used for surgeries which require early ambulation and obstetric analgesia.

Levobupivacaine and has been shown to be less cardio toxic than racemic mixture bupivacaine (Kopacz *et al.*, 2000; Casati *et al.*, 2003) and has equivalent clinical efficacy with racemic bupivacaine (Alley *et al.*, 2002; Glaser *et al.*, 2002; Camorcia *et al.*, 2007) and hence can be used in regional nerve block techniques

Duration of motor block was similar in both the groups (p vale being 0.369 and mean values being 160.71 min in group L and 172.77 min in group R). This result corresponds to a study in the year 2000, which observed that group L showed 355.4 vs Group R 375.7 mins, while analysing the toal duration of motor block study (Kopacz *et al.*, 2000). A study in the year 1998, found out that the duration of motor blockade in Group L was 185 vs Group R 192 mins (Cok *et al.*, 2011).

The grade of motor block as per MBS score was significantly different in both groups. (Mean 2.82±0.47in R vs2.17±0.86 in L) (p value:0.016) which is highly significant, implying the motor grade reached in group R is denser than in Group L. The time taken to attain the maximum motor blockade was 23.39±9.13 min in group R and 17.85±10.8 min in group L. This is statistically highly significant. (p value:0.043). The number patient achieving MBS 3 in motor block is 62.5% vs 37.5% in Group R and Group L respectively. This implies lesser grade motor block which wears off earlier than racemic bupivacaine is observed in this study.

Haemodynamic profile

The intraoperative hemodynamic, which included mean arterial pressure and heart rate of both the groups showed no significant difference among them. The heart rate and MAP of the patients in both the groups were comparable intra operatively with no clinical or statistically significant differences. The incidence of hypotension was studied in the year 2005, found it similar (Group L 66.7% vs 43.5%in Group R) when either Levobupivacaine or Bupivacaine was used for epidural anaesthesia (Bergamaschi *et al.*, 2005). A study in the year 2000, found out that the incidence of hypotension

occurred in 82% of patients in Group L and 61% in Group R (Cox *et al.*, 1998).

There were no clinically significant differences in the total amount of IV fluids infused, ephedrine used and rescue analgesics given intraoperatively among both the groups. The first time request by patients for post-operative analgesia was found to be 319.28 minutes in group L and 222.85 minutes in group R, p value being 0.553 which shows there was no statistically significant difference. Both local anaesthetics are well tolerated and effective in producing epidural anaesthesia for patients undergoing lower abdominal surgery.

From Tables 9, 10 and 11 are the reference articles and their findings which are used in the discussion part of the study.

CONCLUSIONS

Stereoisomers 0.5% levobupivacaine and 0.5% racemic mixture bupivacaine produced effective and similar epidural anaesthesia. Both drugs were well tolerated. Levobupivacaine has been shown to be less cardio toxic than bupivacaine. Hence, it can be used in labor analgesia and regional anaesthesia techniques. One more steroisomer of bupivacaine available in use is ropivacaine whose equipotency concentration is 0.75% when compared to 0.5% levobupivacaine and 0.5% racemic mixture Bupivacaine.

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Conflict of Interest

The authors declare that they have no conflict of interest for this study.

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