IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 18, Issue 8 Ser. 10 (August. 2019), PP 01-09
www.iosrjournals.org

"A Comparative Clinical Study of Effect of Hyperbaric Levobupivacaine and Bupivacaine for Spinal Anaesthesia in Patients Undergoing Elective Lower Abdominal and Limb Surgeries"

Dr Chetan Shukla[1], Dr Neha Sharma[2], Dr Haricharan Meena[3], Dr Garima Goyal[4]

[1](Sr. Professor, Dept of Anaesthesia, Govt Medical College, Kota, India)
[2](Asst. Professor, Dept of Anaesthesia, Govt Medical College, Kota, India)
[3](Ex-resident, Dept of Anaesthesia, Govt Medical College, Kota, India)
[4](PG Resident, Dept of Anaesthesia, Govt Medical College, Kota, India)
Corresponding Author:Dr Neha Sharma

Abstract: *Regional anaesthesia for lower abdominal and lower limb surgeries is held generally to be safer than general anaesthesia. It avoids general anaesthesia related problems such as poly pharmacy, airway manipulation, misplacement of endotracheal tube, hypo or hyper ventilation, vomiting, pulmonary aspiration and metabolic complication. In this study, two groups each of 30 patientswere compared. GROUP B received INJ BUPIVACAINE 3.2 ML + 0.9% NORMAL SALINE 1 ML and GROUP L received INJLEVOBUPIVACAINE 3.2 ML + 25% DEXTROSE 1 ML. Parameters like onset and duration of sensory and motor block, highest level of sensory blockade, duration of analgesia, vitals and side effects were assessed. Our study concluded that the onset of motor block was faster, duration of motor as well as sensory block was longer and duration of analgesia was significantly prolonged in group B than in group L. Fall in systolic blood pressure was more common in group B but other haemodynamic parameters were comparable among both groups.*

Date of Submission: 06-08-2019 Date of Acceptance: 22-08-2019

I. Introduction

The subarachnoid blockade is the common form of central neuraxial blockade performed for lower abdominal and lower limb surgeries. The ensuring sensory block ensures the patient well-being, while motor block facilitates the surgeon's work. It provides effective pain relief in initial post-operative period.The aim of an anesthesiologist is to render the patient pain free, during a surgical procedure. The aim and objectives of our study is to compare efficacy of hyperbaric levobupivacaine and bupivacaine for intrathecal anaesthesiain view of

1. Onset & duration of sensory block
2. Onset & duration of motor block
3. Hemodynamic changes intra & post-operatively
4. Respiratory rate & oxygen saturation
5. Duration of analgesia
6. Side effects & complications (if any).

II. Material And Methods

This study was conducted at MaharavBhim Singh Hospital, Kota in Department of Anaesthesiain 2015-2018. After obtaining institution's ethical committee approval and written informed consent from patients we concluded a study on 60 patients of ASA-I and II of 'American Society of Anesthesiologists' classification between the ages of 20-60 years, who were admitted for lower abdominal or lower limb surgeries under spinal anesthesia. The patients were randomly divided into two equal groups. The study was prospective and interventional in nature.

1. Group B – Patients received intrathecally hyperbaric bupivacaine 3.2 ml (inj. bupivacaine 16 mg+ 1ml 0.9% NS)
2. Group L – patients received intrathecally hyperbaric levobupivacaine 3.2 ml (inj. levobupivacaine 16mg + 1ml 25% dextrose)

INCLUSION CRITERIA
- Patients in the age range 20-60 years.
- ASA category I and II.
- No known history of allergy, sensitivity or other form of reaction to local anesthetics of the amide type.

EXCLUSION CRITERIA
- Patient refusal.
- Patients with coagulopathy
- Patients on potent antiplatelets or on anticoagulants.
- Patients with spine problems.
- Patients with local skin infection at the site of injection.
- Known allergy to the trial drugs.
- Patients with poor myocardial contractility.
- Patients with thoracic spine deformity.
- ASA III or more.

Procedure methodology:

Under strict aseptic precautions, standard subarachnoid block was performed in the sitting position. Skin and subcutaneous infiltration was done with 2 ml of 2% Lignocaine. Spinal needle was inserted in the midlineat L3-4 or L4-5 inter-space. Correct needle placement was identified by free flow of cerebrospinal fluid. Drugs for spinal anaesthesia were prepared under aseptic precautions. For group B-3.2 ml of bupivacaine 0.5% (H) was mixed with 1 ml of 0.9% NS and for group L-3.2 ml of levobupivacaine was mixed with 1 ml of 25% D.Solutions were made in such a way that thebaricity and osmolarity of both the drugs were made similar. 4.2 ml of total drug was injected as per the group.

The patient were placed supine immediately after injection to achieve at least T10 level of sensory block and modified Bromage scale of 3 for motor blockade. When the sensory block of T10 and modifiedBromage scale of 3 was achieved surgeon was allowed to start with the surgery.

Sensory block assessment
- The onset of sensory block was measured from the time of injection till T10dermatome was achieved which was determined bilaterally using pin prick test and cold test using spirit.
- To assess the maximum level of the block, sensory block was assessed at 2 and 5 min post-injection and at 5min intervals thereafter until two consecutive levels of sensory block were identical, after which assessment was done every 30 minutes till the completion of surgery.
- Duration of block was measured from time of onset till the time L1 dermatome had reached.

Motor block assessment
- The onset of motor block was assessed by using a modified Bromage scale.

Modified Bromage scale:
0= full leg movement.
1= inability to raise extended leg, can bend knee.
2=inability to bend knee, can flex ankle.
3=no movement.
- The degree of motor block was assessed from the time of injection at 2 and 5 min and at 5min intervals thereafter until two consecutive degree of motor block was identical, after which assessment was done from the time of onset of modified Bromage scale ≥3 till normal motor function returned.

Statistical analysis

Data were collected, tabulated, coded then analyzed using SPSS® computer software version 12.0.Numerical variables were presented as mean & standard deviation (SD) while categorical variables were presented as percent.As regard to numerical variables, unpaired student-t test was done. p value< 0.05 was considered as significant.

III. Result

In this study, distribution of patients with respect to age, height & weight were comparable in both the groups(p value >0.05, non-significant)**.**The ASA grade of the patients and the type of surgery performed were non-significant in both groups (p >0.05).

Table -1 Types of Surgery

Type of Surgery	Group B	Group L
General Surgery	8(26.7%)	3(10.0%)
Ortho.(lower limb)	2(6.7%)	8(26.7%)
Perineal	2(6.7%)	1(3.3%)
Inguinal hernia	10(33.3%)	11(36.7%)
Urology	7(23.3%)	7(23.3%)
Hysterectomy	1(3.3%)	0
Total	30(100%)	30(100%)

Table-2 American Society of anaesthesia (ASA) Grade

ASA Grade	Group B	Group L
I	24(80.0%)	25(83.3%)
II	6(20.0%)	5(16.7%)
Total	30(100%)	30(100%)

Table -3 Onset of Sensory Block up to T10

Sensory Block	Group L	Group B	p value
Onset (min) Mean± SD	4.46±2.4	4.34±2.3	0.811

The mean onset of sensory block was 4.46 minutes in group L & 4.34 minutes in group B which was statistically non-significant (p value = 0.811).

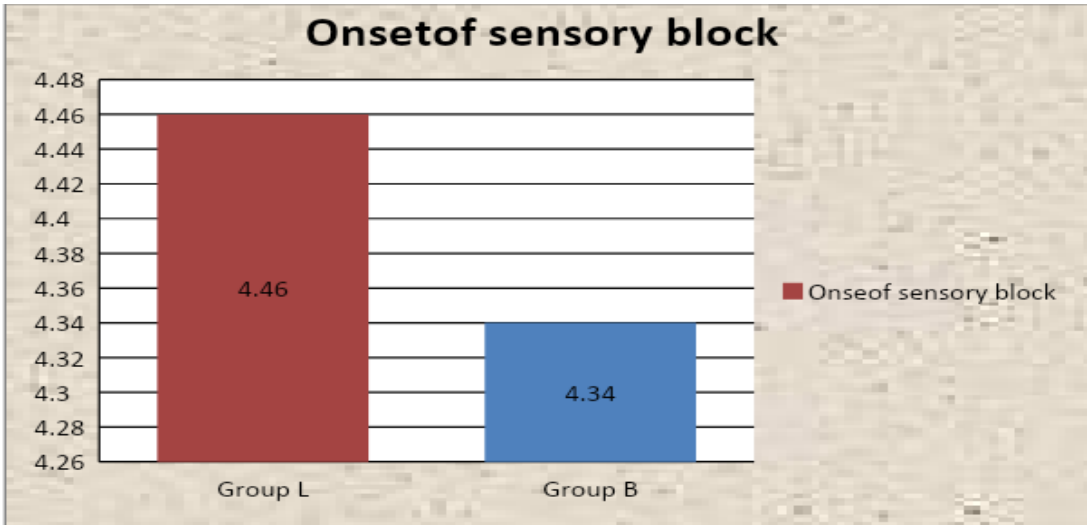


Table -4 Onset of Motor Blockade up to 3 bromage score

Motor Block	Group L	Group B	p value
Onset (min)Mean±SD	4.96±3.16	4.65±2.35	0.591

The mean onset of motor block in group L was 4.96 minutes and in group B it was 4.65 minutes which was statistically non-significant (p value = 0.591).

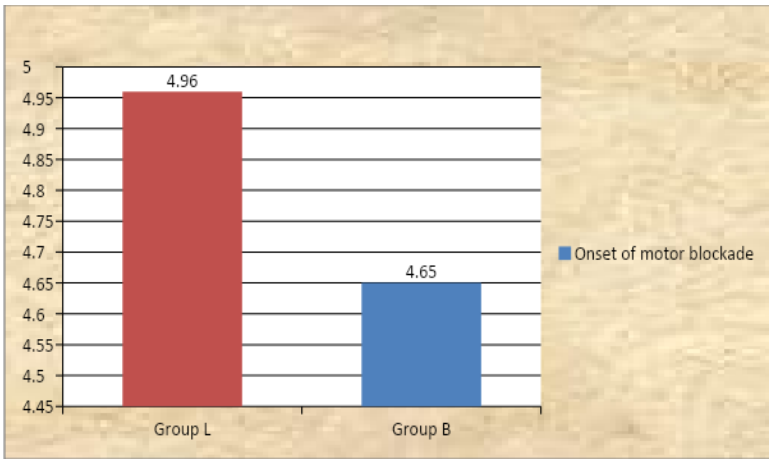


Table -5 Maximum Level of Sensory Block

Level	Group B	Group L
T 10	3(10.0%)	8(26.7%)
T 8	12(40.0%)	17(56.7%)
T 6	15(50.0%)	5(16.7%)
Total	30(100%)	30(100%)

Maximum level of sensory block in both groups was statistically non-significant (p value> 0.05).

Table-6 Maximum degree of motor block (MBS)

MBS	Group L	Group B
3	30(100%)	30(100%)
2	0(0%)	0(0%)
1	0(0%)	0(0%)
0	0(0%)	0(0%)
Total	30(100%)	30(100%)

All patients in both groups had Modified Bromage scale of 3.

Table -7 Duration of Sensory Block up to T10

Time(min)	Group B	Group L
120-149	12(40.0%)	18(60.0%)
150-179	14(46.7%)	10(33.3%)
180-249	4(13.70%)	2(6.7%)
Total	30(100%)	30(100%)

Patients in group L had duration of sensory block upto 134 minutes and in group B was 147 minute (p-value 0.834 which is non-significant).

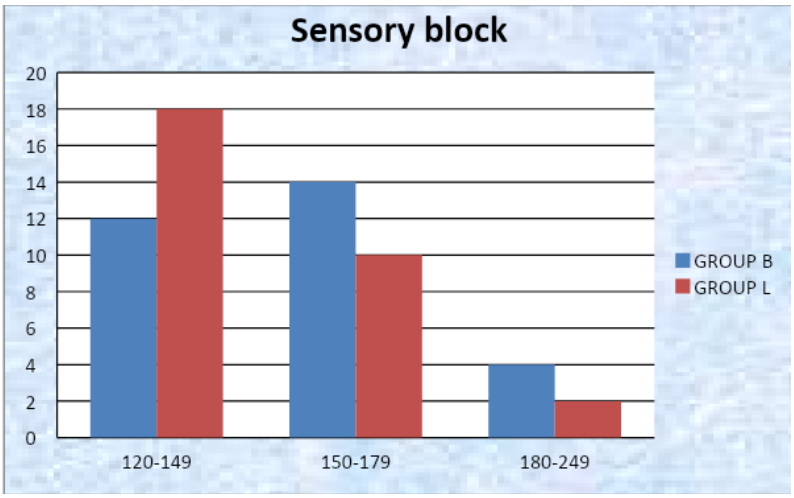


Table-8 Duration of sensory block up T10

Sensory block	Group B	Group L	p value
Duration(min)mean±SD	147±20.78	134±18.86	0.834

Table-9 Duration of motor block up to 0 Bromage

Time (min)	Group B	Group L
91-120	1(3.3%)	1(3.3%)
121-150	4(13.3%)	10(33.3%)
151-180	20 (66.6%)	16(53.30%)
181-240	5(16.6%)	3(10.0%)
Total	30(100.0%)	30(100.0%)

In both group duration of motor block up to Bromage score 0 was 120-240 min (p value = 0.256)

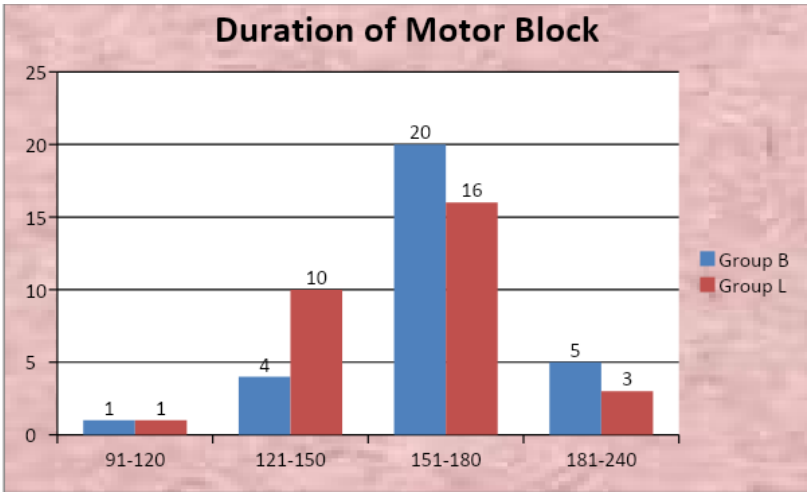


Table-10 Duration of motor block (mean±SD)

Motor Block	Group B	Group L	p value
Duration (in min)	184±33.17	175±27.33	0.256

In group L mean duration of motor blockade was 175 minutes while in group B it was 184minuteswhich is statistically non-significant (p value = 0.256).

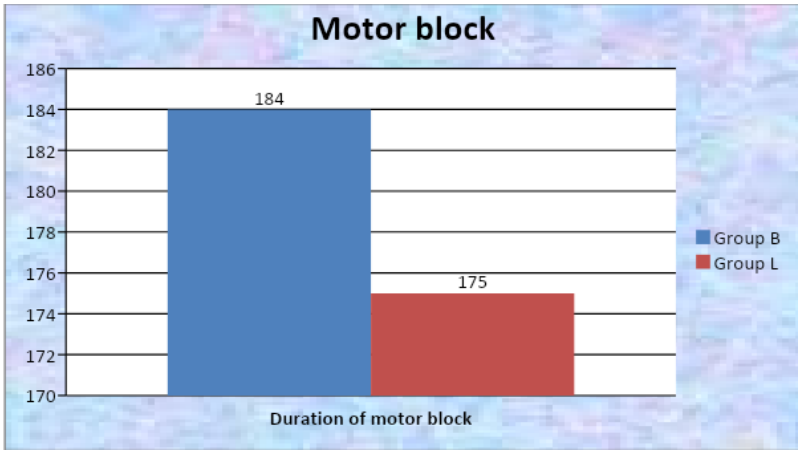


Table -11 Systolic Blood Pressure

Time Interval(min)	Group B (mean ± SD)	Group L (mean ± SD)	%of fall Group B	%of fall Group L	p Value	Remarks
0	128±5.9	128±5.8	0%	0%	0.930	NS
2	118±5.6	121±6.3	8%	5%	0.192	NS
4	114±7.6	118±5.9	11%	8%	0.368	NS
10	115±6.2	117±5.9	10%	8.5%	0.252	NS
15	119±6.2	121±5.0	7%	5.4%	0.207	NS
20	119±5.3	121±6.5	7%	5.4%	0.0599	NS
30	120±6.6	122±5.2	6%	4.6%	0.198	NS
60	121±6.7	123±4.2	6%	4%	0.173	NS
90	120±6.0	122±5.2	6%	4%	00.147	NS
120	121±5.0	123±5.0	6.%	4%	0.0613	NS
180	122±5.7	124±5.7	4.6%	3%	0.157	NS
240	123±5.7	125±5.7	4%	2.3%	0.179	NS

300	124±5.8	126±4.2	4%	1.5%	0.348	NS
480	123±5.6	126±5.6	4%	1.5%	0.103	NS
720	123±5.6	126±5.8	4%	1.5%	0.134	NS

NS – Non significant

As shown in table and graph there was statistically non-significant change in systolic blood pressure in group B compared to group L (p value 0.599) at 20 minutes.

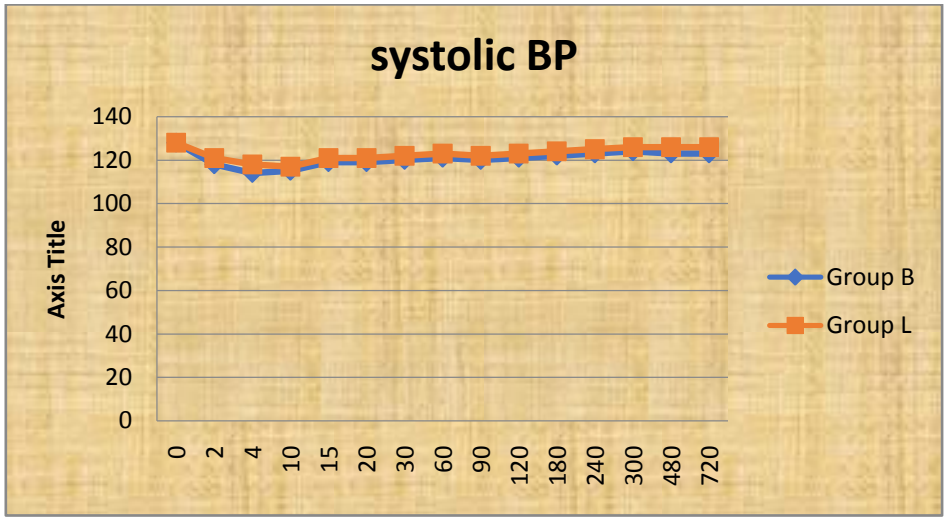


Table -12 % OF FALL IN SYSTOLIC BLOOD PRESSURE

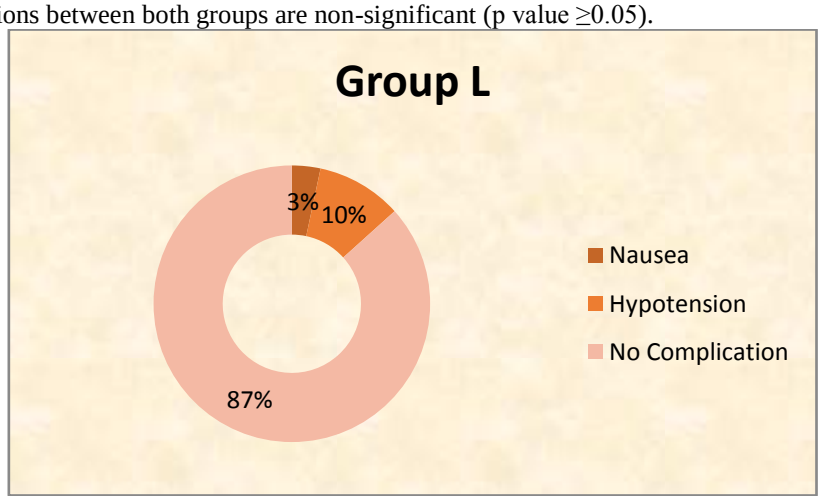
% of fall from baseline	Group B	Group L
0-5%	4(13%)	11(36.6%)
6-10%	10(33%)	9(30%)
11-15%	8(26%)	6(20%)
16-20%	4(13%)	2(6.6%)
21-25%	4(13%0	2(6.6%)
>25%	0(0%)	0(0%)

If systolic pressure fall >20% or SBP <100mg then Inj Ephedrine 6 mg I.V given.

Table-13 Complications

Complication	Group B	Group L	P value
Nausea	2(6.6%)	1(3.3%)	0.283
Vomiting	0(%)	0(%)	0
Tremor	0(0%)	0(0%)	0
Hypotension	7(23.3%)	3(10%)	0.283
Bradycardia	2(6.6%)	0(0%)	0.283
Headache	0(0%)	0(0%)	0
PDPH	0(0%)	0(0%)	0.0

Complications between both groups are non-significant (p value ≥0.05).



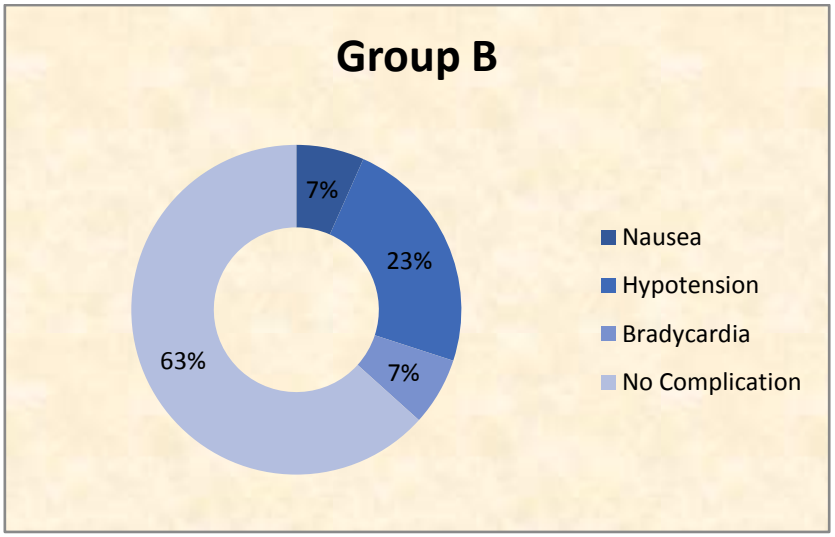


Table-14VAS SCORE≥4

PAIN	GROUP B	GROUP L
180MIN	1(3.3%)	3(10%)
240MIN	16(53.3%)	17(56.6%)
300MIN	13(43.3%)	10(33.3%)

Comparison between group B and group L non-significant (p value is ≥0.05).

VAS SCORE ≥4

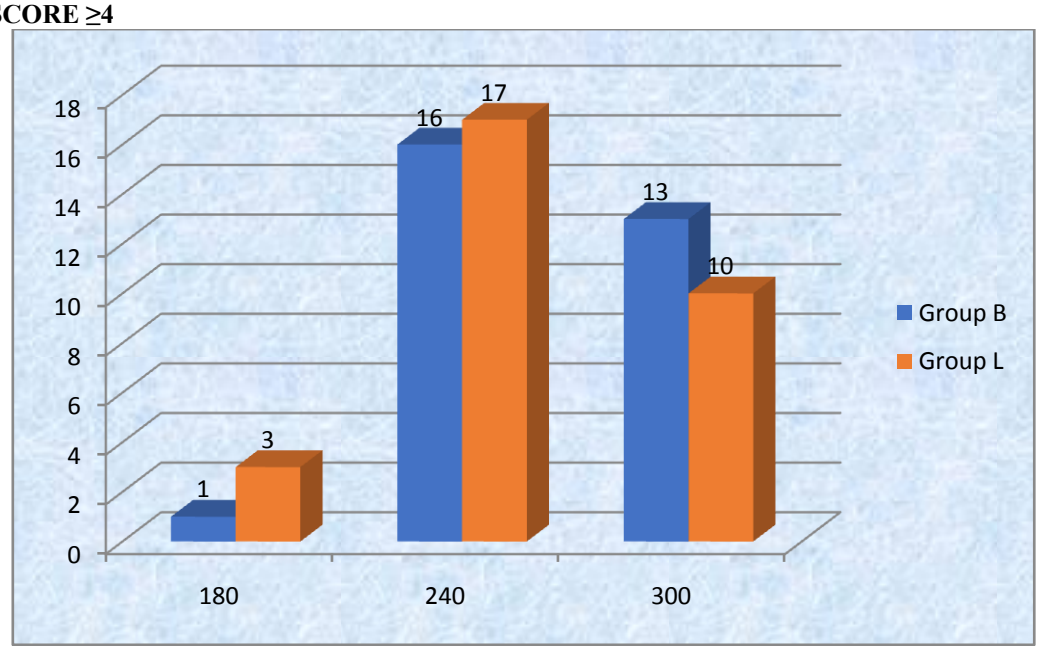


Table-15VAS score≥4 or need of additional analgesia or duration of analgesia

GROUP	Group B	Group L	p value
Time need add. Analgesia(min)	260±39.5	248±40.5	0.253

Duration of analgesia was prolonged in group B then group L but non-significant.

IV. Discussion

Thisprospective double blind randomized study has shown that solutions of bupivacaine and levobupivacaine whichare made hyperbaric relative to CSF by addition of glucose provides reliable and predictable spinal anaesthesia for various elective procedures. In addition the study shows that the block produced by bupivacaine and levobupivacaine are clinically indistinguishable (when each of the drugs is administered at a dose of 16.5 mg).

Demographic parameters:

The demographic data in terms of age, weight and height distribution was comparable in both the groups of the study. The distribution of patients with respect to ASA grading I/II were 23/7 in Group B & 25/5 in Group L (p value > 0.05) respectively which was statistically non-significant.These parameters were kept identical in both groups to avoid variations in the intra-operative and post-operative outcome of the patients.

Onset of Sensory and Motor Block:

In our study the mean onset of sensory block was 4.34±2.3 minutes in group B (30 patients) & 4.46±4.6 minutes in Group L (30 patients) which was statistically non-significant (p value = 0.811). The onset time of motor block for bupivacaine was 4.65±2.55 min & for levobupivacaine 4.96±3.16 min with p value ≥0.05 which was statistically non-significant & was similar to results in another study by **Casati A, Moizo E et al (2004)[1]** and **J.F Luck P.D. Fettes et al (2008)[2]**which had onset time of bupivacaine 4.50 min & levobupivacaine 4.7 min with p value >0.525 which is statistically non-significant.**J.F.Luck P.D.Fettes et al(2008)[2]**&**Casati A, Moizo E et al(2004)[1]** stated that "the motor onset was significantly delayed in Group L compared to Group B with but p value ≥0.05." One study by**Casati A,Moizo E et al (2004)[1]** stated that "time to reach maximum motor blockage was shorter in Group B but (p ≥0.05)" thus supporting our results.

Maximum sensory block level:

Maximum level of sensory block in both groups were comparable with T6 dermatome level in 16.7%(5/30 patients) in group L compared to 50.0%(15/30 patients) in group B and at T8 dermatome 56.7%(17/30 patients) in group L and in group B 40.0%(12/30 patients). The Chi-square value 1.419 & p- value 0.492 which was similar to results of **J.F.Luck P.D.Fettes et al (2008)[2]&Casati A, Moizo E et al (2004)[1]** who had p value of 0.525 similar to our study & supported the findings in which bupivacaine had faster onset.

Duration of sensory block:

Group B had duration of sensory block up to 147±20.78 minutes whereas it was 134±18.86 minutes in Group L. 46.7.0% (14/30 patients) in group B & 33.33% in Group L (10/30 patients) had duration of sensory block upto150-179 minutes. 40.0%(12/30 patients) in group B & 60.0%(18/30 patients) in Group L had duration of sensory block upto 120-149 min respectively with p-value 0.834, which was statistically non-significant.**J. F. Luck and P.D.Fettes et al(2008)[2]&Casati A, Moizo E et al (2004)[1]** who had duration of sensory block 129 min in group B and 131min in group L supported our study. Other studies done by **Ozgur Y, Nilay T et al (2014)[3]** had similar results.

Duration of motor block:

In our study53.3%(16/30) patients in Group L and 66.6%(20/30) in group B had motor block in between 151-180 minutes. Mean motor duration was 175±27.33minutes in group L and 184±33.17 minutes in group B with p value = 0.256 which is non-significant. Our results were similar to**Lee YY, Ngan Kee WD et al (2011)[4]** who had p value of ≥0.05 which is also statistically non-significant.

Hemodynamic profile

Systolic blood pressure:

In our study we recorded significant fall in systolic blood pressure with fall up to15% in73.33 %(22/30 patients) in Group B compared to 86.66%(26/30 patients) in Group L. 15-25% fall in systolic BP was seen in 26.66% (8/30 patients) in Group B as compared to only 13.33% (4/30 patients) in Group L.Blood pressures were stabilized at 20-24% less than baseline in Group B compared to 10-15% in Group L at 60 min interval.**De Cosmo G, Mascia A et al (2005)[5]**stated that more cephalic spread of the block & rapid increase in block level explains the higher incidence of hypotension in Group B. **Kazak Z, Mortimer NM et al (2010)[6]** suggested that levobupivacaine is highly protein bound which attributes to its less cardiac & CNS toxicity.

Diastolic blood pressure:

There was statistically no significant changes in diastolic blood pressure in Group B compared to Group L as both had maximum fall of 11-20% & 0-10%from baseline respectively with p value > 0.05 similar to **Gori F, Corradetti F et al(2010)[7].**

In our study HR, RR &SpO_2 were comparable in both the groups and statistically non-significant. **J.F. Luck P.D. Fettes et al (2008)[2], Ozgur et al (2014)[3]&Bardsley H, Nimmo W et al (1998)[8]**also found the same results.

VAS Score:

Postoperative VAS score of ≥4 was observed in 53.3%(16/30) in group B and 56.6%(17/30) in group L at240 minutes but 43.3%(13/30) in group B and33.3%(10/30) in group L at 300 minutes which ishigher

in levobupivacaine compared to bupivacaine in our study respectively with p value<0.05.Additional analgesia was given in form of Inj Diclofenac Sodium 75mg iv. Our results were similar to result of **J.F. Luck and P.D. Fettes et al (2008)**[2] who also reported the same score.As mentioned by **Onur O, Sibel AM et al (2010)**[9]early regression of sensory blockage was same as our result i.e. higher VAS score in group Levobupivacaine compared to groupBupivacaine.

Side effects:

We noted that incidence of hypotension of more than 15% was higher in bupivacaine group 26.6%(8/30 patients) as compared to levobupivacaine (13.3%,4/30 patients)with p ≥0.05 which is statistically non-significant. We used inj. Ephedrine 6 mg iv when BP fall ≥20% from base line. Similarly **J.F Luck, P.D. Fettes et al**stated "intra operative hypotension requiring treatment with i.v ephedrine occurred more often in the bupivacaine group (42.5%) than in levobupivacaine (17.5%)".**Mc Leod GA et al (2004)**[10]also noted that incidence of hypotension was more common in bupivacaine group.

Similarly incidence of bradycardia upto 50/min & use of inj atropine 0.6 mg was more in Group B (2 patients, 6%) compared to Group L (0 patients, 0%) which was similar to the studies conducted by **J.F.Luck P.D. Fettes et al.**

V. Conclusion

We concluded that spinal anaesthesia performed with both local anaesthetic drug provides effective surgical anaesthesia. Levobupivacaine provides satisfactory anaesthesia, similar onset & duration of motor & sensory block with better haemodynamic stability.Bupivacaine has less VAS score & longer duration of action. From our study we concluded that levobupivacaine can be used as a better & safer alternative tobupivacaine in spinal anaesthesia for elective lower abdominal& lower limb surgery.

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