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Original Research Article

Study of effect of bupivacaine 0.5%, levobupivacaine 0.5%, ropivacaine 0.5% in subarachnoid block for elective lower abdominal surgeries with regard to hemodynamic parameters and complications/side effects

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ABSTRACT

BACKGROUND
In this study we wanted to evaluate and compare the effect of bupivacaine 0.5%, levobupivacaine 0.5%, ropivacaine 0.5% in subarachnoid block for elective lower abdominal surgeries with regard to hemodynamic parameters and complications/side effects.

METHODS
This was a randomized controlled trial. It was conducted between December 2015 and September 2017 in the Department of Anesthesiology and Critical Care, Kempegowda Institute of Medical Sciences, Bangalore, among three groups of 40 subjects each.

RESULTS
Hemodynamic stability was maintained in all the three groups except for the fact that only 10% of patients in group B and 2.5% of patients in group R had mild hypotension treated with 6mg of injection Ephedrine.

CONCLUSION
Levobupivacaine and Ropivacaine are definitive alternatives to Bupivacaine in Subarachnoid block for lower abdominal surgeries as they provide good surgical block, ensuing sensory block which ensures the patient wellbeing, while motor block facilitated the surgeon's work.

KEYWORDS
Bupivacaine 0.5%, Levobupivacaine 0.5%, Ropivacaine 0.5% Subarachnoid Block, Elective Lower Abdominal Surgeries, Haemodynamic Parameters, Complications/Side Effects

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INTRODUCTION

The word "pain" is derived from the Greek term "poine" ("penalty"). Since times immemorial, pain has been a major concern of mankind. It is a real bitter experience where man has been thriving so hard to find out many ways and methods to get rid of this bitter agony. We, as anaesthesiologists have the first and foremost obligation to help patients manage their pain adequately. Most of the Lower abdominal surgeries may be performed under local, regional (spinal or epidural) or general anaesthesia. Spinal is still the first choice because of its rapid onset, superior blockade, low risk of infection, less failure rate and cost effectiveness.[1]

Spinal anaesthesia is most commonly used technique for lower abdominal surgeries as it is very economical and easy to administer.[2] Spinal anaesthesia is a relatively simple technique, which produces adequate surgical conditions by providing a fast onset and effective sensory and motor blockade.[3,4] In spinal anaesthesia a deep nerve block in large part of the body is produced through a relatively simple injection of a small amount of local anaesthetic.[4.]

Dr. August Beir in 1899 reported the first clinical use of spinal anaesthesia, who described the intrathecal cocaine administration[3]. Since then a lot of experience and data had been achieved on physiology, pharmacology and clinical application of spinal anaesthesia.[3]

Local anaesthetic to be used in spinal anaesthesia is selected based on the expected duration of surgery and need of early patient discharge.[3] Bupivacaine is used as the drug of choice for spinal anaesthesia since its introduction in 1956, because of its longer duration of action, producing profound sensory and motor blockade. It is an amide local anaesthetic which is a racemic mixture of S and R enantiomers.[5] The use of Bupivacaine for out-patient spinal anaesthesia has increased over past few years because of concern over the potential neurotoxicity of spinal Lidocaine.[6] Levobupivacaine is a new long acting amide local anaesthetic, which is the isolated S enantiomer of racemic bupivacaine. The sensory blockade last significantly longer with levobupivacaine which might be attributable to a greater intrinsic vasoconstriction potency of levobupivacaine and is less cardiotoxic than bupivacaine because of decreased potency at sodium channels.[7] Ropivacaine, a long acting amide local anaesthetic, is well tolerated after intrathecal use, and is found to have a shorter duration of action than bupivacaine making it a better alternative to Lidocaine for day care surgeries because of reduced incidence of transient neurological symptoms (TNS).[4] Though ropivacaine structurally resembles bupivacaine with similar anaesthetic properties, it has reduced potential for cardiotoxicity and neurotoxicity with improved relative sensory block profile.[8] The claimed benefits of levobupivacaine and ropivacaine are reduced cardiotoxicity and neurotoxicity and more specific effects on sensory rather than motor nerve fibers.[9]

Objectives of the Study

To evaluate and compare the effect of bupivacaine 0.5%, levobupivacaine 0.5%, ropivacaine 0.5% in subarachnoid block for elective lower abdominal surgeries with regard to hemodynamic parameters and complications/side effects.

METHODS

This was a randomized controlled trial carried out at Department of Anaesthesiology and Critical Care, Kempegowda Institute of Medical Sciences, Bangalore, conducted among three groups of 40 subjects each from December 2015 to September 2017.

Sample Size Estimation

Group sample size of 36 in each group achieves 81% power to detect a difference of 4 with known group standard deviation of 6 with significance level of 0.05 using a two-sided two sample T-

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test. Sample size calculation was carried out using PASS software. Sampling Method- random number table

Method of Collection of Data

120 patients aged between 18 to 60 years of physical status ASA grade 1 and ASA grade 2 of either sex, undergoing elective lower abdominal surgeries lasting more than 30 minutes was included in the study. Preoperative evaluation of the patient was done on the day before surgery. After explaining the procedure, written informed consent was obtained. Patient was advised overnight fasting and are premedicated with tablet Alprazolam 0.5mg the night before and on the day of surgery.

Inclusion Criteria

- All patients who are posted for elective lower abdominal surgeries
- Age group- 18- 60 years, of either sex.
- ASA 1 and 2.
- Weight 40-80 kg.
- Height > 150cm.

Exclusion Criteria

All patients with local infection, spine deformities, CNS infections, progressive neuromuscular degenerative disorder, raised intracranial tension, allergy to local anaesthetics, pregnancy and lactation, hypovolaemic shock, bleeding diathesis and coagulopathy and patients belonging to ASA class III and class IV were excluded from the study.

Study Procedure

In the operating room, intravenous line was secured with 18G cannula and patients was preloaded with ringer's lactate solution at 20ml/kg. Patients was randomized to three groups of 40 each, receiving one of the following for the subarachnoid block:

1. Group B (n=40)- Bupivacaine (0.5%) 3ml (15mg)
2. Group L (n= 40)- Levo Bupivacaine (0.5%) 3ml(15mg)
3. Group R (n=40)- Ropivacaine (0.5%) 3ml(15mg)

Baseline heart rate, non invasive blood pressure, SPO2, respiratory rate is recorded using multi-parameter monitor, before starting the procedure. Under aseptic precautions with patient in left lateral position, 26G Quincke spinal needle was introduced into L3-L4 intervertebral space, after confirming clear flow of CSF and negative aspiration for blood, 3ml of test drugs was injected intrathecally at a rate of 0.2ml/sec. Intraoperatively, vital parameters like heart rate, non invasive blood pressure, SPO2 was recorded after 2, 5, 10, 15, 20, 25, 30mins. Thereafter assessed at an interval of 30mins. Alteration in the hemodynamic parameters such as hypotension was treated with injection Ephedrine in incremental doses of 6mg IV bolus and bradycardia was treated with injection Atropine 0.6mg IV bolus. Any adverse events like nausea, vomiting, pruritis, urinary retention etc., are noted and treated accordingly.

Sensory blockade was tested by pin prick test using hypodermic needle and the time of onset, highest level of sensory blockade, time for 2 segment regression of sensory level, duration of sensory block would be noted. Duration of motor blockade is assessed by Modified Bromage scale. Duration of complete analgesia was assessed from the time of onset of analgesia till the appearance of pain for first time (first rescue analgesic). Rescue analgesia is provided with injection Diclofenac 1.5mg/kg slow IV.

Statistical Methods

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Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Analysis of variance (ANOVA) has been used to find the significance of study parameters between three or more groups of patients, Post-hoc Tukey test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small. P value: $0.01<P \leq 0.05$ was considered as moderately significant. P value: $P \leq 0.01$ was considered strongly significant. SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

The present study was conducted on 120 patients aged 18-60yr, 40 patients in three groups. Bupivacaine group (B) received 3ml of 0.5% bupivacaine. Levobupivacaine group (L) received 3ml of 0.5% Levobupivacaine and Ropivacaine group (R) received 3ml of 0.5% Ropivacaine for lower abdominal surgeries under subarachnoid block. Out of 40 patients in Ropivacaine group (R) subarachnoid block failed on two patients.

Demographic Data

Age in years	**Bupivacaine**	**Levobupivacaine**	**Ropivacaine**	**Total**
<20	0(0%)	1(2.5%)	0(0%)	1(0.8%)
20-30	8(20%)	8(20%)	8(20%)	24(20%)
31-40	7(17.5%)	12(30%)	5(12.5%)	24(20%)
41-50	18(45%)	10(25%)	10(25%)	38(31.7%)
51-60	7(17.5%)	9(22.5%)	17(42.5%)	33(27.5%)
Total	40(100%)	40(100%)	40(100%)	120(100%)
Mean ± SD	41.38±10.04	40.15±11.07	44.83±11.76	42.12±11.07
Age distribution				
Gender	**Bupivacaine**	**Levobupivacaine**	**Ropivacaine**	**Total**
Female	12(30%)	12(30%)	9(22.5%)	33(27.5%)
Male	28(70%)	28(70%)	31(77.5%)	87(72.5%)
Total	40(100%)	40(100%)	40(100%)	120(100%)
Gender distribution				
Height (cm)	**Bupivacaine**	**Levobupivacaine**	**Ropivacaine**	**Total**
150-160	42.5	35	40	47.5
161-170	57.5	65	60	52.5
Total	100	100	100	100
Mean ± SD	160.83	162.78	162.33	161.56±4.99
Distribution of Patients According to Height (cm)				
Weight (kg)	**Bupivacaine**	**Levobupivacaine**	**Ropivacaine**	**Total**
<50	1(2.5%)	1(2.5%)	0(0%)	2(1.7%)
50-60	15(37.5%)	14(35%)	9(22.5%)	38(31.7%)
61-70	17(42.5%)	11(27.5%)	21(52.5%)	49(40.8%)
71-80	6(15%)	14(35%)	10(25%)	30(25%)
>80	1(2.5%)	0(0%)	0(0%)	1(0.8%)
Total	40(100%)	40(100%)	40(100%)	120(100%)

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Mean ± SD	64.63±7.46	65.68±8.91	66.60±6.36	65.63±7.63
Distribution of Patients According to Weight (Kg)				
ASA Grade	**Bupivacaine**	**Levobupivacaine**	**Ropivacaine**	**Total**
Grade I	32(80%)	36(90%)	34(85%)	102(85%)
Grade II	8(20%)	4(10%)	6(15%)	18(15%)
Total	40(100%)	40(100%)	40(100%)	120(100%)
Distribution of Patients According to Height (cm) ASA Grade				
Table 1: Distribution of Study Participants According to Various Variables				

Age Distribution of Patients

Samples are age matched with P=0.147, ANOVA test. As shown in the table, all the three groups Bupivacaine, Levobupivacaine and Ropivacaine are age matched. The average age was 41.38±10.04yr in Bupivacaine, 40.15±11.07yr in Levobupivacaine and 44.83±11.76yr in Ropivacaine group.

Gender Distribution of Patients

Samples are gender matched with P= 0.686

As shown in the table, all the three groups Bupivacaine, Levobupivacaine and Ropivacaine are gender matched.

Height Distribution in Three Groups of Patients

Samples are height matched with P= 0.168. The average height was 160.83±4.71cm in Bupivacaine group, 162.78±4.86cm in Levobupivacaine group and 162.33±4.81cm in Ropivacaine group. So there was no significant difference in height of the patients in all the three groups.

Weight Distribution in Three Groups of Patients

Samples are weight matched with P= 0.515. There was no significant difference in all the three groups in terms of weight parameter as the average weight of Bupivacaine group is 64.63±7.46kg, Levobupivacaine group is 65.68±8.91kg and Ropivacaine group is 66.60±6.36kg.

ASA Grade Distribution in Three Groups of Patient Studied

As shown in the table, all the three groups Bupivacaine, Levobupivacaine and Ropivacaine are ASA grade matched. Samples are ASA grade matched with P= 0.456.

Comparison of Heart Rate

Heart rate (bpm)	**Results**			**Pair Wise P Value**		
	Bupivacaine	**Levobupivacaine**	**Ropivacaine**	**B-L**	**B-R**	**L-R**
0 min	84.53±11.50	83.35±12.95	83.21±10.73	0.896	0.875	0.998
2 min	81.40±10.68	82.50±12.98	84.39±11.59	0.909	0.503	0.758
5 min	77.40±10.36	82.80±12.47	85.37±11.65	0.095+	0.008**	0.589
10 min	76.18±9.20	82.00±12.47	85.08±11.94	0.059+	0.002**	0.453
15 min	76.50±8.64	81.03±12.53	83.34±12.01	0.171	0.021*	0.632
20 min	75.50±8.51	79.08±12.11	82.32±11.59	0.307	0.018*	0.387
25 min	74.63±7.85	78.35±12.55	81.32±9.91	0.242	0.013*	0.414
30 min	75.60±7.25	77.80±10.72	80.66±9.81	0.547	0.049*	0.372
60 min	74.75±7.06	75.08±10.25	77.53±9.43	0.986	0.365	0.455
90 min	76.30±7.86	74.33±10.29	75.29±8.91	0.595	0.875	0.886

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120 min	77.20±7.53	75.23±10.15	76.08±9.70	0.603	0.852	0.911
150 min	82.40±6.76	75.33±10.22	76.21±10.26	0.002**	0.010**	0.906
180 min	87.58±11.52	77.73±11.65	76.18±9.94	<0.001**	<0.001**	0.813

Table 2: Comparison of Heart rate (bpm) in three groups of patients studied

Study shows a statistically highly significant difference in Heart rate variation between the Bupivacine and Ropivacaine group at 5th and 10th minute after the subarachnoid block and statistically significant difference from 15th to 30th minute.

Comparison of Systolic Blood Pressure

SBP (mm Hg)	Results			Pair Wise P Value		
	Bupivacaine	Levobupivacaine	Ropivacaine	B-L	B-R	L-R
0 min	128.43±10.41	128.10±12.74	128.32±13.26	0.992	0.999	0.997
2 min	119.43±10.17	123.08±11.70	124.39±13.04	0.345	0.149	0.872
5 min	116.68±12.41	121.98±10.00	122.76±11.89	0.102	0.054	0.951
10 min	114.90±9.33	119.83±9.08	121.87±10.28	0.059	0.005	0.614
15 min	115.45±9.45	117.73±9.03	119.71±9.87	0.530	0.119	0.624
20 min	115.70±9.42	118.13±8.50	118.11±9.37	0.461	0.476	1.000
25 min	115.68±9.52	117.90±8.23	117.24±9.30	0.515	0.726	0.944
30 min	114.35±8.86	117.35±9.79	118.53±11.00	0.368	0.154	0.860
60 min	115.93±8.45	117.53±10.04	117.55±12.49	0.772	0.770	1.000
90 min	114.8±10.92	116.58±9.88	118.87±10.61	0.730	0.204	0.599
120 min	116.75±12.37	119.3±10.75	120.63±11.71	0.590	0.307	0.869
150 min	118.43±7.59	120.35±10.87	120.95±14.17	0.721	0.579	0.970
180 min	135.65±11.00	125.03±13.10	121.89±12.00	<0.001**	<0.001**	0.488

Table 3: Comparison of SBP (mm Hg) in three groups of patients studied

There was no significant difference in systolic blood pressure among the three groups.

Comparison of Diastolic Blood Pressure

DBP (mm Hg)	Results			Pair Wise P Value		
	Bupivacaine	Levobupivacaine	Ropivacaine	B-L	B-R	L-R
0 min	79.28±8.02	75.70±10.07	74.03±9.96	0.209	0.040*	0.712
2 min	73.85±10.20	73.18±10.42	72.55±10.01	0.953	0.841	0.961
5 min	67.73±9.02	68.43±8.73	70.66±10.81	0.942	0.367	0.558
10 min	68.78±8.94	69.05±7.96	69.95±10.29	0.990	0.837	0.901
15 min	68.88±8.27	69.78±8.21	69.58±10.36	0.895	0.936	0.995
20 min	67.95±7.88	67.53±7.49	68.84±10.05	0.973	0.889	0.774
25 min	68.73±6.76	67.23±6.44	67.95±9.78	0.664	0.898	0.911
30 min	68.30±8.66	66.75±8.64	68.11±10.02	0.728	0.995	0.789
60 min	68.60±9.38	67.88±8.10	66.89±9.27	0.930	0.677	0.879
90 min	67.70±7.81	66.43±7.14	67.92±9.16	0.760	0.992	0.692
120 min	67.58±8.39	67.83±7.50	68.05±9.19	0.990	0.966	0.992
150 min	73.43±7.95	69.33±7.00	69.71±9.65	0.071+	0.120	0.977
180 min	82.83±9.44	70.73±9.20	69.37±10.79	<0.001**	<0.001**	0.815

Table 4: Comparison of DBP (mm Hg) in three groups of patients studied

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There was no statistically significant difference in diastolic blood pressure among the three groups

Comparison of Mean Arterial Pressure

MAP (mm Hg)	Results			Pair Wise P Value		
	Bupivacaine	Levobupivacaine	Ropivacaine	B-L	B-R	L-R
0 min	99.63±1.00	99.63±0.95	99.82±0.73	1.000	0.623	0.623
2 min	99.85±0.66	99.75±0.90	99.79±0.74	0.832	0.936	0.972
5 min	99.55±1.04	99.60±1.15	99.84±0.68	0.972	0.390	0.522
10 min	99.95±0.22	99.78±0.89	99.92±0.36	0.361	0.973	0.499
15 min	99.93±0.27	99.80±0.72	99.92±0.36	0.495	0.999	0.526
20 min	99.95±0.22	99.78±0.89	99.71±0.84	0.519	0.304	0.916
25 min	99.93±0.27	99.83±0.84	99.87±0.47	0.723	0.903	0.942
30 min	99.95±0.22	99.85±0.70	99.89±0.39	0.622	0.868	0.911
60 min	99.95±0.22	99.88±0.52	99.95±0.23	0.606	0.999	0.635
90 min	99.95±0.22	99.83±0.64	99.87±0.47	0.470	0.730	0.914
120 min	99.95±0.22	99.90±0.50	99.89±0.51	0.861	0.836	0.998
150 min	99.95±0.22	99.90±0.44	99.92±0.36	0.801	0.930	0.962
180 min	100.00±0.00	99.90±0.44	99.95±0.32	0.337	0.743	0.786

Table 5: Comparison of MAP (mm Hg) in three groups of patients studied

There was no statistically significant difference in mean arterial pressure among the three groups.

Complications

Complications	Bupivacaine (n=40)	Levobupivacaine (n=40)	Ropivacaine (n=40)	Total (n=120)
0 min	0(0%)	0(0%)	0(0%)	0(0%)
2 min	1(2.5%)	0(0%)	0(0%)	1(0.8%)
5 min	3(7.5%)	0(0%)	1(2.5%)	4(3.3%)
10 min	0(0%)	0(0%)	0(0%)	0(0%)
15 min	0(0%)	0(0%)	0(0%)	0(0%)
20 min	0(0%)	0(0%)	0(0%)	0(0%)
25 min	0(0%)	0(0%)	0(0%)	0(0%)
30 min	0(0%)	0(0%)	0(0%)	0(0%)
60 min	0(0%)	0(0%)	0(0%)	0(0%)
90 min	0(0%)	0(0%)	0(0%)	0(0%)
120 min	0(0%)	0(0%)	0(0%)	0(0%)
150 min	0(0%)	0(0%)	0(0%)	0(0%)
180 min	0(0%)	0(0%)	0(0%)	0(0%)

Table 6: Complications in three groups of patients studied

Three patients in Bupivacaine group had mild hypotension at 5th minute and 1 patient at 2nd minute treated with 6mg injection Ephedrine. And only one patient had mild hypotension in Ropivacaine group at 5th minute treated the same like Bupivacaine group. No complications were observed in Levobupivacaine group.

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DISCUSSION

Spinal anaesthesia is a simple technique that provides a deep and fast surgical block through the injection of small doses of local anaesthetic solution into the subarachnoid space. The ensuing sensory block ensures the patient wellbeing, while motor block facilitates the surgeon's work. It has a definitive advantage of profound nerve block that can be produced by simple deposition of a small amount of local anaesthetic into the subarachnoid space.

The ideal local anaesthetic agent for Sub arachnoid block for lower abdominal surgeries should have rapid onset, adequate motor block, long duration of action, adequate postoperative analgesia having minimal or no cardiovascular change.

Different local anaesthetics are used for subarachnoid block like Lignocaine, Bupivacaine and Ropivacaine. The drawback of Lignocaine is its shorter duration of action and that of Ropivacaine is its less intense motor blockade.

The ideal agent for day-care anaesthesia is the one which when injected intrathecally would produce a rapid onset of a reliable block providing adequate surgical anaesthesia of appropriate duration and followed by a rapid regression of the motor and sensory blocks with minimal side-effects or residual effects. The standard agent for use in this setting has been lidocaine, but concerns persist regarding the incidence of TNS. Although not unheard of, the incidence of TNS is much lower with ropivacaine than lidocaine and thus it might warrant consideration as an agent for the day-care setting.[4,10] or ambulatory surgery.

So the aim of this study is to do elective non obstetric lower abdominal surgeries under spinal anaesthesia comparing bupivacaine, levobupivaciane and ropivacaine using equal concentration of their own density directly without any concurrent use of adjuvants with respect to the following:

- Onset and duration of sensory blockade.
- Onset and duration of motor blockade.
- Maximum height of sensory block.
- Time for two segment regression from highest sensory level.
- Duration of analgesia.
- Hemodynamic parameters.
- Complications/side effects

The present study consisted of 120 patients aged between 18-60 years of either sex, ASA physical status of I and II, undergoing subarachnoid block for elective lower abdominal surgeries. The study population was divided into three groups of 40 each using Random number table based on the study drug used in each group as:

1. Group B (n=40)- Bupivacaine(0.5%) 3ml(15mg)
2. Group L (n= 40)- LevoBupivacaine(0.5%) 3ml(15mg)
3. Group R (n=40)- Ropivacaine(0.5%) 3ml(15mg)

Preoperative evaluation of the patient was done on the day before surgery. After explaining the procedure, written informed consent was obtained.

Patient was advised overnight fasting and were premedicated with tablet Alprazolam 0.5mg the night before and on the day of surgery. In the operating room, intravenous line was secured with 18G cannula and patients was preloaded with ringer's lactate solution at 20ml/kg. Baseline heart rate, non invasive blood pressure, SPO_2, respiratory rate is recorded using multi-parameter monitor, before starting the procedure. Under aseptic precautions with patient in left lateral position, 26G Quincke spinal needle was introduced into L3-L4 intervertebral space, after confirming clear flow of CSF and negative aspiration for blood, 3ml of test drugs was injected intrathecally at a rate of 0.2ml/sec. Intraoperatively, vital parameters like heart rate, non invasive blood pressure, SPO_2 was recorded after 2, 5, 10, 15, 20, 25, 30mins. There after assessed at an interval of 30mins. Alteration in the hemodynamic parameters such as hypotension was treated with injection Ephedrine in incremental doses of 6mg IV bolus and events of bradycardia were

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treated with Inj. Atropine 0.6mg. Any adverse events like nausea, vomiting, pruritis, urinary retention etc., were not faced.

Hemodynamic stability was maintained in all the three groups except for the fact that only 10% of patients in group B and 2.5% of patients in group R had mild hypotension treated with 6mg of injection Ephedrine.

CONCLUSION

Levobupivacaine and Ropivacaine are definitive alternatives to Bupivacaine in Subarachnoid block for lower abdominal surgeries as they provide good surgical block, ensuing sensory block which ensures the patient wellbeing, while motor block facilitated the surgeon's work.

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