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A Comparative Study of 0.5% Levobupivacaine and 0.5% Bupivacaine in Spinal Anaesthesia in Geriatric Patients Undergoing Lower Limb Surgeries

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Abstract

Background: The geriatric population faces serious problems. When combined with the tendency for older population to have more unsteady balance and vision problems, it becomes a recipe for increased risk of fracture. *Aims:* Hemodynamic stability during perioperative period is of paramount importance in such scenario and hence the technique of choice becomes neuraxial block. The anesthetist's traditional approach to provide anesthesia for geriatric population has been the emphasis on maintaining hemodynamic stability by maintaining heart rate, saturation, blood pressure and by avoiding hypotension, bradycardia etc. This study aimed to compare the efficacy of intrathecal 0.5% Bupivacaine and 0.5% Levobupivacaine in geriatric patients. *Methods*: After ethical committee permission, a comparative study was conducted in the department of Anesthesia at BLDE (DU's) Shri BM Patil Medical College, Hospital and Research Center, Vijayapur. With prior informed written consent, study was conducted on total of 120 geriatric patients above 60 years of age with American society of anesthesiologist (ASA) Grade II–III scheduled for lower limb surgeries under spinal anesthesia. The patients either received 0.5 % hyperbaric Inj. Bupivacaine 3 ml (60 patients) Group B (Bupivacaine) or 0.5 % hyperbaric Inj. Levobupivacaine 3 ml (60 patients) Group L (Levobupivacaine) The time for onset of sensory block between the two groups was the primary endpoint. Other measurements included were time to Grade 4 motor blockade and time to 2 segment regression, Hemodynamic changes (RR, SpO_2, MAP, HR), Time to rescue analgesia and side effects if any. *Results*: Statistical analysis was done using Chi-square test and Unpaired *t*-test. Time to onset of sensory blockade was significantly faster (p – value < 0.001) in Levobupivacaine Group compared to Bupivacaine Group. Also, there was a significant increase in heart rate, respiratory rate in patients of Group L with $p < 0.001$. Time to Grade 4 motor blockade, time to 2-segment regression and time to rescue analgesia were also increased in Group L patients with $p = 0.872$, $p < 0.046$ and $p < 0.002$ respectively. Mean arterial pressure was increased in Group B patients with $p < 0.02$. Side effects like hypotension was significantly less (p - value < 0.001) with Group Levobupivacaine compared to Group Bupivacaine. *Conclusion*s: Increased incidence of intraoperative hypotension with Bupivacaine suggests that Levobupivacaine is a better drug in maintaining perioperative hemodynamics in a geriatric patient undergoing lower limb orthopedic surgery.

Keywords: Geriatric; Lower limb surgeries; Neuraxial block.

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Introduction

The geriatric population faces serious problems as they age. Their bone mineral density decreases as they grow old. This is in particular a problem in postmenopausal women. Decreased mineral levels tend to translate into weaker and more brittle bones. When combined with the tendency for older adults to have more unsteady balance and vision problems, it becomes a recipe for increased risk of fractures. According to Population census 2011, there are nearly 104 million elderly persons (aged 60 years or above) in India; 51 million males and 53 million females.[1]

Anesthetic technique of choice for lower limb orthopedic surgeries is neuraxial blockade. A clinically precise and skillful anesthetic management of geriatric population requires in-depth knowledge of the numerous patho-physiological alterations and functional changes at this advanced age due to altered and more variable pharmacokinetics and pharmacodynamics and associated comorbidities.[2]

In elderly patients, neuraxial anesthetic blockade has a definite advantage over general anesthesia, as it reduces surgical stress by decreasing sympathetic efferent nerve activity and blocking nociceptive impulses from the operative site. Cardio-respiratory complications and overall morbidity and mortality are also minimized.[3] Evaluating the safety and efficiency of 0.5% levobupivacaine and 0.5% bupivacine (hyperbaric) in spinal anesthesia for lower limb surgeries in geriatric patients, was the sole purpose of this study.

Aims and Objectives

To compare the efficacy of 0.5% Bupivacaine and 0.5% Levobupivacaine in geriatric patients with regard to:

1. Time of onset of sensory blockade and maximum level of sensory blockade;
2. Time to Grade 4 motor blockade and time to 2 segment regression;
3. Time to rescue analgesia, hemodynamic changes (RR, SpO_2, MAP, HR) and side effects if any.

Materials and Methods

Study Design

After receiving approval from the institutional research and ethical committee a comparative study was conducted on 120 geriatric patients undergoing elective lower-limb surgeries under subarachnoid block at Department of Anesthesiology, BLDE (DU's) Shri BM Patil Medical College, Hospital and Research Center, Vijayapura. The study duration was from December 2017–August 2019.

Inclusion criteria

1. Patients age group above 60 years;
2. Patients with ASA Grade II and III;
3. Patients undergoing elective lower-limb surgeries.

Exclusion criteria

1. Patients having deformities of spine;
2. Patients having infection at the site of insertion of spinal needle;
3. Patients having bleeding disorders, coagulation abnormalities, raised Intracranial Pressure (ICP) and neurological deficits.

Preanesthetic examination and preparation

The study protocol received ethical clearance from the institution. Preanesthetic check-up was performed one day prior to the surgery. Patients were evaluated with history, general physical examination, systemic examination of cardiovascular, respiratory, central nervous system and spine examination for deformity was also performed. Investigations like hemogram, bleeding time, clotting time, blood glucose, blood urea, serum creatinine were done. ECG and Chest *X*-ray were done wherever necessary. Patient's weight, height were also recorded prior to surgery. All patients were kept nil orally for 6–8 hours. The procedure of spinal anesthesia was explained to the patients and written informed consent was obtained

Premedication

Patients were premedicated with Tab. Ranitidine 150 mg, on the previous night of surgery. Each patient was preloaded with an IV infusion of 500 ml of Ringer Lactate solution and 50 mg IV Ranitidine, 30 min prior to surgery.

Methods

120 patients were randomly divided into 2 Groups of 60 each:

Group B: 60 patients received 3 ml hyperbaric Inj. 0.5% bupivacaine intrathecally;

Group L: 60 patients received 3 ml hyperbaric Inj. 0.5% levobupivacaine intrathecally.

Preparation of operating room

Anesthesia machine was checked and cock pit drill performed. Appropriate size endotracheal tubes, working laryngoscope with medium and large size blades, stylet, bougie, other emergency airway equipment and working suction apparatus were kept ready prior to the procedure.

After shifting the patient to operating room, patients were monitored for Noninvasive Blood Pressure (NIBP), Heart Rate (HR) and percentage of oxygen saturation (SpO_2). Under all aseptic precautions, subarachnoid block was performed using a 25G Quincke needle, with the patient in the lateral or sitting position depending on the patients comfort, at the L_3-L_4 interspace. The study solution was administered slowly. Patient was repositioned gently to supine position without elevation of extremities and tested every 5 minutes until maximal spread of sensory block and then every 15 minutes during the surgery.

Parameters evaluated

Sensory Blockade

This was assessed by loss of sensation to alcohol cotton swab on each side and patients asked about the sensation–

a. *Time to onset of sensory block:* Defined as the time between injection of the drug to the time of loss of sensation at L_2 level;
b. *Time to maximum sensory block:* Defined as the time to reach highest dermatomal level with loss of sensation;
c. *Time to two segment regression:* Defined as the time period to regain sensation at two dermatomes lower to the initial level of highest dermatome;
d. *Time to rescue analgesia:* Defined as the time at which patient complained pain at the site of surgery intraoperatively or postoperatively.

Motor Blockade

The degree of motor block was assessed using "Bromage Scale". Motor blockade was assessed at 5 minutes and then for every 30 seconds till Grade IV block was achieved. And then every 15 minutes until return of normal motor function.

Onset time for motor block

It is defined as the time between injection and Grade IV block. Heart Rate (HR), Mean Arterial Pressure (MAP), Percentage Saturation of Oxygen (SpO_2) and Respiratory Rate (RR) were recorded every 5 minutes for the first 30 minutes and then every 1 hourly for 3 hours throughout the surgery.

Patients were considered hypotensive when their MAP decreased to < 65 mm Hg, and were treated with Inj. Ephedrine 5 mg IV dose titrated according to response. A decrease in the heart rate to < 50 bpm was treated with Inj. Atropine 0.3–0.6 mg IV.

Parameters recorded intraoperatively

- Time of onset of sensory blockade;
- Time to maximum level of sensory blockade;
- Time to Grade IV motor blockade;
- Time to 2 segment regression;
- Time to rescue analgesia;
- Percentage of oxygen saturation (SpO_2);
- Heart Rate (HR);
- Mean Arterial Pressure (MAP);
- Respiratory Rate (RR).

Bromage Scale

Grade motor activity:

1. Free movement of legs or feet;
2. Just able to flex knees with free movement of feet;
3. Unable to flex knees but with free movement of feet;
4. Unable to move legs or feet.

Complications such as nausea, vomiting and shivering were treated accordingly and the treatment given was recorded.

All the patients were kept under observation in the postoperative period for 4 hrs and Heart Rate (HR), Mean Arterial Pressure (MAP), Percentage of Oxygen Saturation (SpO_2) and Respiratory Rate (RR) were recorded at interval of every 30 min till 4 hours. All the patients were assessed for pain at regular intervals and rescue analgesia was given accordingly.

Statistical Analysis

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean ± Standard Deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square (χ^2) test was used for association between two categorical variables.

The formula for the Chi-square statistic used in the Chi-square test is:

$$\chi_c^2 = \Sigma \frac{(O_i - E_i)^2}{E_i}$$

The subscript "*c*" stands for the degrees of freedom, "O" is observed value and E is expected value.

The difference of the mean of analysis variables between two independent groups was tested by unpaired *t*-test.

The *t* statistic to test whether the means are different can be calculated as follows:

$$t = \frac{(\overline{x_1} - \overline{x_2}) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n1} + \frac{s_2^2}{n2}}}$$

Where X_1 = mean of sample 1

X_2 = mean of sample 2

n_1 = number of subjects in sample 1

n_2 = number of subjects in sample 2

s_1^2 = variance of sample 1 = $\frac{Ó(x_1 - \overline{x}_1)^2}{n_1}$

s_1^2 = variance of sample 2 = $\frac{Ó(x_2 - \overline{x}_2)^2}{n_1}$

If the *p* - value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as statistically insignificant. Data were analyzed using SPSS software V.23.0. on Microsoft office 2007.

Results

One Hundered Twenty patients were chosen for the study. 60 patients were assigned into each of the groups. Group B patients received 3 ml hyperbaric 0.5% bupivacaine and Group L patients received 3 ml hyperbaric 0.5% levobupivacaine.

Time to onset of sensory blockade was significantly faster (*p* – value < 0.001) in Levobupivacaine group compared to Bupivacaine Group. Also, there was a significant increase in heart rate, respiratory rate in patients of Group L with *p* < 0.001. Time to Grade 4 motor blockade, time to 2-segment regression and time to rescue analgesia were also increased in Group L patients with *p* = 0.872, *p* < 0.046 and *p* < 0.002 respectively. Mean arterial pressure was increased in Group B patients with *p* < 0.02. Side effects like hypotension was significantly less (*p* - value < 0.001) with Group Levobupivacaine compared to Group Bupivacaine.

The Table 1 shown, the comparison of mean time of onset of sensory blockade between the bupivacaine and levobupivacaine groups. The mean time of onset of sensory blockade in bupivacaine group was 2.4 ± 0.8 min, while in the levobupivacaine group it was 3 ± 0.8 min, above shown as (Fig. 1).

Table 1: Comparison of mean time of onset of sensory blockade between Bupivacaine and Levobupivacaine Groups.

Time of onset of sensory block	Bupivacaine		Levobupivacaine		*p* - value
	Mean	SD	Mean	SD	
	2.4	0.8	3.0	0.8	< 0.001

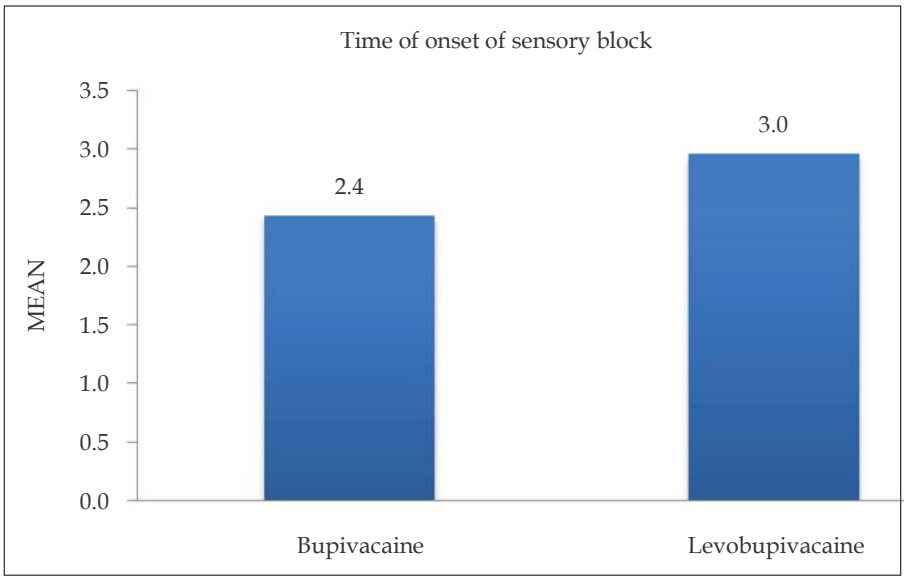

Fig. 1: Time of onset of sensory block

Table 2: Comparison of mean time to 2 segment regression between Bupivacaine and Levobupivacaine Groups.

Time to reach 2-segments regression	Bupivacaine		Levobupivacaine		*p* - value
	Mean	SD	Mean	SD	
	101.7	7.2	104.3	7.2	0.046*

Note: *Significant at 5% level of significance ($p < 0.05$).

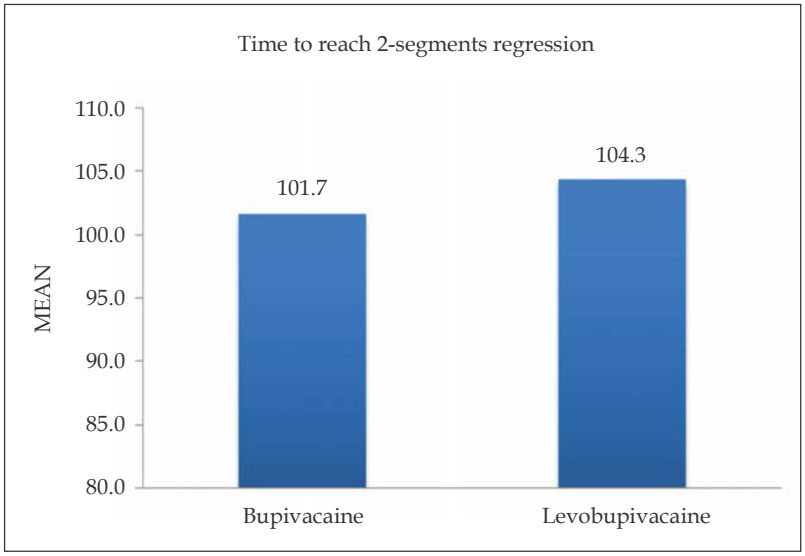

Fig. 2: Time to reach 2-segment regression

The Table 2 shows, the comparison of mean time to 2 segment regression between the bupivacaine and levobupivacaine groups. The mean time to 2 segment regression in bupivacaine group was 101.36 ± 7.76 min, while in the levobupivacaine group it was 104.76 ± 7.62 min, as shown in Fig. 2.

Table 3: Comparison of mean time to rescue analgesia between Bupivacaine and Levobupivacaine Groups.

Time to rescue analgesia	Bupivacaine		Levobupivacaine		*p* - value
	Mean	SD	Mean	SD	
	147.0	14.1	155.5	15.0	0.002*

Note: *Significant at 5% level of significance ($p < 0.05$).

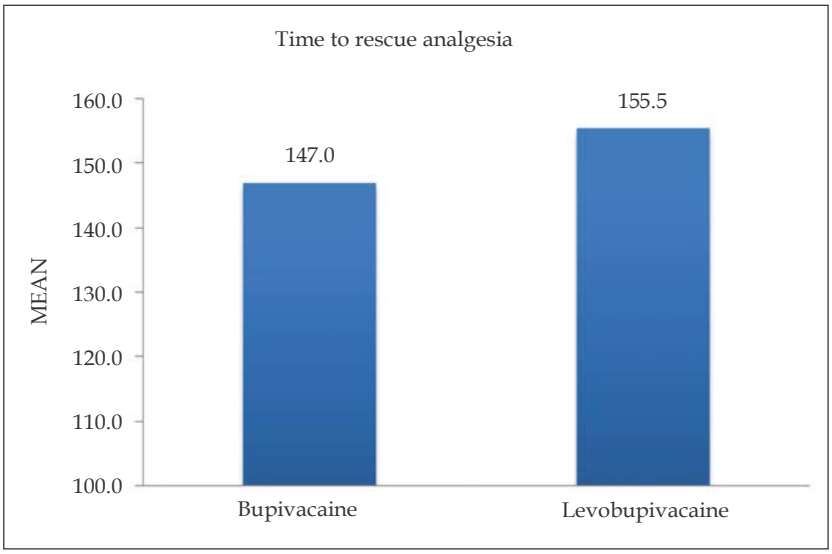

Fig. 3: Time to rescue analgesia

The Table 3 shows, the comparison of mean time to rescue analgesia between the bupivacaine and levobupivacaine groups. The mean time to rescue analgesia in bupivacaine group was 146.22 ± 15.46 min, while in the levobupivacaine group it was 152.04 ± 14.88 min, shown as in Fig. 3.

Table 4: Distribution of patients according to hypotension

Hypotension	Bupivacaine		Levobupivacaine		*p* - value
	N	%	N	%	
YES	21	35.0%	5	8.3%	
NO	39	65.0%	55	91.7%	< 0.001*
Total	60	100.0%	60	100.0%	

Note: *Significant at 5% level of significance ($p < 0.05$).

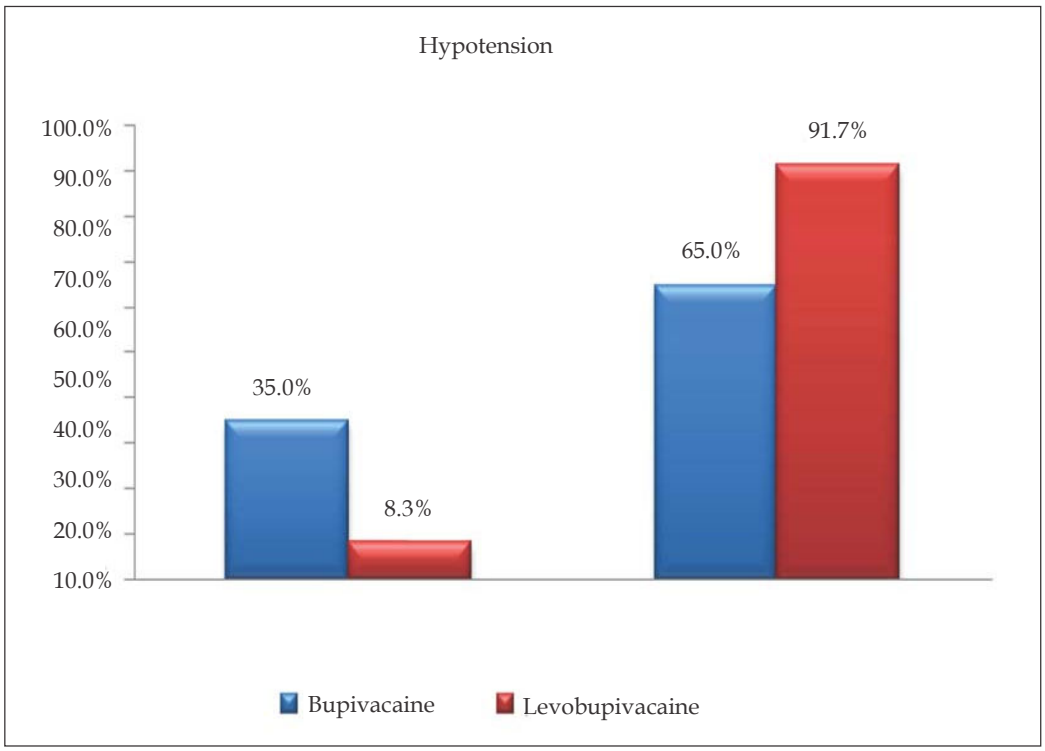

Fig. 4: Hypotension

The Table 4 shows, the distribution of patients as per hypotension in bupivacaine and levobupivacaine groups. In the bupivacaine group, 21 (35%) patients had hypotension, while in the levobupivacaine group 5 (8.3%) patients had hypotension, shown as in Fig. 4.

Discussion

Lower limb fractures are most commonly seen in geriatric population like neck of femur fracture or shaft of femur fracture etc. Various factors such as altered cognitive function, neuromuscular degeneration, reduced bone mineral density and environmental factors are responsible for trivial injury in geriatrics. Surgical fixation of fracture is the definitive treatment. Ageing is a universal and progressive physiological phenomenon clinically characterized by degenerative changes in both the structure and the functional capacity of organs and tissues.

In general, geriatric patients are more sensitive to anesthetic agents. Less medication is usually required to achieve a desired clinical effect, and drug effect is often prolonged. The most important outcome and overall objective of perioperative care of geriatric population, is to speed recovery and avoid functional decline. Spinal anesthesia is a widely used anesthetic technique for lower limb

surgery in the elderly. Spinal anesthesia is often preferred for its efficacy, rapidity, minimal effect on mental status, reduction of blood loss, and protection against thrombo-embolic complications. But risk of severe and prolonged hypotension is associated with spinal anesthesia. This is due to the rapid extension of the sympathetic block, hindering cardiovascular adaptation and causing significant morbidity and mortality. This study largely focuses on the relative potencies, systemic effects, particularly cardiovascular system and the relative degree of sensory and motor blockade with bupivacaine and levobupivacaine in geriatric patients who are undergoing lower limb surgeries.

Comparison of meantime of onset of Sensory Blockade

In present study, the time for sensory block to reach the L2 level were shorter in the bupivacaine group, difference was found to be statistically significant with p - value < 0.05.

This study is comparable with study of Erdil et al.[4] which compared the effect of intrathecal levobupivacaine and bupivacaine in 80 elderly patients and showed mean onset time for sensory blockade at T10 dermatome was about 6.4 minute and 7.8 minute for bupivacaine and levobupivacaine respectively with p - value < 0.05.

Our study also showed the p - value of < 0.05 which is highly significant. Celik et al.[5] studied the effectiveness of bupivacaine and levobupivacaine in hip surgery which showed no significant difference in onset time of sensory blockade. This study was conducted in age group between 18–65 yrs with low dose of drug.

Casati et al.[6] studied the effectiveness of bupivacaine, levobupivacaine and ropivacaine for unilateral spinal anesthesia for inguinal hernioplasty which showed there was no significant difference in onset time of sensory blockade between these drugs. Overall in our study time of sensory blockade was almost similar in bupivacaine and levobupivacaine groups.

Comparison of mean time to two Segments Regression

The study shows that the mean time to two segments regression in bupivacaine group was 101.70 ± 7.2 min, while in the levobupivacaine group it was 104.3 ± 7.2 min. The difference was found to be statistically significant (p - < 0.05), with a higher time for two segments regression in levobupivacaine group in comparison to bupivacaine group.

The study conducted by Erdil et al.[4] for the comparison of effects of levobupivacaine and bupivacaine in elderly observed that the time taken for the two segment regression was 78.3 for bupivacaine and 80.3 for levobupivacaine with p - value > 0.05. But in our study, we found the two segment regression was higher for levobupivacaine than bupivacaine. This difference may be due to the difference in the drug dosages in both the studies.

Comparison of mean time to Rescue Analgesia

This study shows that the mean time to rescue analgesia in bupivacaine group was 147.0 ± 14.1 min, while in the levobupivacaine group it was 155.5 ± 15.0 min. The difference was found to be statistically significant (p - < 0.05), thus, time to rescue analgesia in was earlier in bupivacaine group than in levobupivacaine group.

Erbay et al. (2010)[7] studied 60 patients scheduled for urological procedure undergoing subarachnoid block with bupivacaine and levobupivacaine (hyperbaric solutions) and similar to our study found that the requirement for analgesia was earlier in Group Bupivacaine (305 ± 50 min) than in Group Levobupivacaine (389 ± 146 min), (p - = 0.004).

Comparison of Complications

This study shows that in the bupivacaine group, 21 (35%) patients had hypotension, while in the levobupivacaine group, 5 (8.3%) patients had hypotension. In bupivacaine group, there was higher number of hypotension seen in comparison to levobupivacaine group.

Guler et al. (2012)[8] compared the clinical efficacy of spinal anesthesia for cesarean section in sixty females with bupivacaine and levobupivacaine (hyperbaric solutions). Conclusion was made that as motor blockade time was lesser with fewer adverse effects (fall in blood pressure, heart rate, vomiting), levobupivacaine would make a better alternative, which is similar to the finding in our study. Overall hypotension was most common complication seen with bupivacaine.

Conclusion

From the results obtained from this study, we conclude that even though there was no major statistically significant difference between the efficacy of levobupivacaine and bupivacaine when used in a volume of 3 ml for spinal anesthesia with respect to:

1. Time of onset of sensory blockade;
2. Time to maximum level of sensory blockade;

3. Time to Grade 4 motor blockade;
4. Time to 2 segment regression;
5. Time to rescue analgesia;
6. Hemodynamic change (RR, SpO_2, MAP, HR);
7. Side effects like hypotension.

But the increased incidence of intraoperative hypotension with bupivacaine suggests that levobupivacaine is a better drug in maintaining perioperative hemodynamics in a geriatric patient undergoing lower limb orthopedic surgery.

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