ORIGINAL RESEARCH PAPER
Volume - 12 | Issue - 12 | December - 2023 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A PROSPECTIVE RANDOMIZED STUDY TO COMPARE THE EFFICACY AND SAFETY OF 0.5% LEVOBUPIVACAINE WITH 0.5% BUPIVACAINE IN SPINAL ANAESTHESIA ON PATIENTS UNDERGOING TOTAL KNEE ARTHROPLASTY

Anesthesiology

Dr. M. Suchitra MD, Assistant Professor, Department of Anaesthesiology, BIRRD(T) Hospital, TTD, Tirupati.

Dr. K. Krishnapriya MD, Assistant Professor, Department of Anaesthesiology, BIRRD(T) Hospital, TTD, Tirupati.

Dr. P. Ashalatha MD, Assistant professor, Department of Anaesthesiology, BIRRD(T) Hospital, TTD, Tirupati.

Dr. K. Pradeep Kumar MD, HOD, Department of Anaesthesiology, BIRRD(T) Hospital, TTD, Tirupati.

ABSTRACT

Background: Total knee Arthroplasty(TKA) surgery is a major surgical procedure that requires effective and safe anaesthesia. Spinal anaesthesia is most widely used technique for total knee arthroplasty surgeries. Choice of local anaesthetics depends mainly onset, duration, intensity of sensory and motor block and side effects. **Aim:** To study and compare the efficacy and safety of 0.5% Levobupivacaine with 0.5% Bupivacaine in spinal anaesthesia on patients undergoing total knee replacement surgery . **Design:** Randomised Controlled study. **Material & Methods:** The study includes 40 patients randomly divided into 2 groups of 20 each. Group A patients received 3ml of 0.5% Levobupivacaine (15mg) 5mg/ml with 15 mcg of fentanyl.Group B patients received 3ml of 0.5% Bupivacaine (15mg) 5mg/ml with 15 mcg of fentanyl. **Statistical Analysis:** by using SPSS version 20 (Statistical Package for Social Studies), Chi square test, F table, Mean and standard deviation were used. **Results & Conclusion:** Duration of sensory block and time for first requirement of post-operative analgesia was longer in patients who received 0.5% Levobupivacaine intrathecally when compared to 0.5% Bupivacaine intrathecally. Though there was no statistical significance in terms of onset of sensory block, there was a slow onset of motor block and less duration of motor block seen in Levobupivacaine group. Stable haemodynamics were observed with Levobupicaine. Hence, Levobupivacaine is a better alternative to Bupivacaine.

KEYWORDS

INTRODUCTION

Spinal anaesthesia is one of the most popular techniques for orthopaedic procedures was introduced into clinical practice by Karl August Bier1 in1898.

Spinal anaesthesia, which is defined as 'the regional anaesthesia achieved by blocking nerves in the subarachnoid space' is a common technique worldwide. The advantages of spinal anaesthesia are an awake patient, simple to perform, offers rapid onset of action, has minimal drug cost and relatively less side effects.

The choice of local anaesthetics is determined by the duration of surgery and by the intensity of sensory and motor blockade required.

The major concern about the cardiotoxicity of Bupivacaine has led to the development of Levobupivacaine, a new long acting amide3 with a reasonably stable hemodynamic profile.

Levobupivacaine is the S-enantiomer of racemic bupivacaine and has less of negative inotropism and decreased affinity for cardiac sodium channels than Bupivacaine. Thus it has an improved safety profile over Bupivacaine.

Aims and Objectives

Aim: To study and compare the efficacy and safety of 0.5% Levobupivacaine with 0.5% Bupivacaine in spinal anaesthesia on patients undergoing total knee arthroplasty."

Objectives: To measure and compare the following variables

- Time of Onset of Sensory Block
- Time of Onset of Motor Block
- Time for sensory and motorblock to reach maximum level
- Duration of sensory and motor block.
- Incidence of side effects (Hypotension, bradycardia, nausea and vomting)

Patients and Methods

The study was conducted on 40 ASA physical status I and II patients, undergoing elective total knee replacement surgeries under spinal anesthesia. The age of the patients ranged between 50 - 68 yrs and weighing 50 - 70kgs.

Preoperatively we have examined all the patients and the investigations were checked. The procedure was explained to the patients and consent was taken.

Inclusion Criteria

- Age range 50-68 years of both sex
- Weight 50-70kgs
- ASA grade I & II

Exclusion Criteria

- Patient refusal
- Local infection
- Coagulopathy and bleeding disorders
- ASA grade > 3
- Allergy to either of the drugs

Method: The patients were randomly allocated into two groups of 20 each.

Group A patients received 3ml of 0.5% Levobupivacaine (15mg) 5mg/ml with 15mcg of fentanyl.
Group B patients received 3ml of 0.5% Bupivacaine (15mg) 5mg/ml with 15 mcg of fentanyl.

Then patients were shifted to the operating room and were secured with 18G intravenous cannula and preloaded with10 ml/kgof ringer lactate and monitoring such as ECG, Pulse Oximetry and NIBP were attached. Preoperative baseline mean arterial pressure, pulse rate and SP02 were recorded. All the patients were placed in sitting position, under full aseptic precautions the skin over the back was prepared with antiseptic solution(5% povidoneiodine) and draped with sterile towel. Lumbar puncture was performed with a 25G Quincke Babcock spinal needle at L2-L3 or L3-L4 intervertebral space through midline approach. The drug was injected intrathecally and the time of injection noted.

The following parameters were observed
Sensory Block: The Onset of Sensory Block was defined as the time between the injection of anesthetic solution and the absence of sensation to pinprick up to T10dermatome.

The Duration of Sensory Block was defined as the time from the onset of sensory block to the time when the patient required first dose of

rescue analgesia(for post-operative pain)

Motor Block: Modified Bromage Scale was used to assess motor block.

Modified Bromage Scale

0- No block, able to raise extended legs against gravity
1- Unable to raise extended legs, but just able to flex knees.
2- Unable to flex knees, but able to flex ankle.
3- Total block-inability to flex ankle

Assessment of motor block was started immediately after placing the patient in supine position and continued every minute till Bromage score of 3 was reached.

The Onset of Motor Block was defined as the time to achieve Bromage score of 2or 3 from the time of injection whichever is achieved.

The Duration of Motor Block was taken as the time from subarachnoid injection to return of Bromage score to zero.

Hypotension was defined as a decrease in MAP more than 20% from baseline or systolic blood pressureless than 90mmHg. Hypotension was managed by incremental doses of 6mg intravenous Ephedrine. Bradycardia was defined as heart rate less than 60/min and managed by incremental doses of 0.6 mg intravenous Atropine.

OBSERVATION AND RESULTS

This study includes 40 patients posted for elective Total knee replacement surgeries, divided into two groups of 20 each. Group A-20 patients received 0.5%Levobupivacaine 3ml and group B – 20 patients received 3ml of 0.5% Bupivacaine.

Statistical analysis done by using SPSS version 20 (Statistical Package for Social Studies).

There has been no statistical difference between groups in terms of their demographic characteristics and the duration of the operation (Table 1) Both groups had achieved suffi- cient level of anesthesia and intraoperative analgesia and did not require additional analgesics.

The onset of sensory block similar in both groups ($p > 0.05$). The time taken for the sensory block to reach maximum level (Table 2) and duration of sensory block was shorter in Group A ($p < 0.05$).

The time to onset of motor block in Group B was shorter than Group A ($p < 0.05$). Complete motor block was obtained within 12 minutes in every patient in both groups (Bromage 3). Motor block developed faster and lasted longer with the hyperbaric bupivacaine ($p < 0.05$) (Table 3).

Hypotension and bradycardia were more common in the Group B. In addition, nausea was noticed more frequently in the B group ($p < 0.05$) (Table 4).

1. Demographic data. Groups		
	Group A (n = 20)	Group B (n = 20)
Age (yr)	60 ± 4.29	61 ± 4.31
Height (m)	1.64 ± 0.04	1.63 ± 0.03
Weight (kg)	66 ± 9.45	67 ± 8.80
Surgical time (min)	92 ± 6.76	93± 4.24

Results expressed as mean± SD when applicable. *p <0.05 = statistically significant

Table 2. Characteristics of sensory blocks. Groups		
Group A (n = 20)	Group B(n = 20)	
Time to onset of sensory block (min)	2 ± 0.35 2 (1 - 3)	1.45 ± 0.49 1 (1 - 2)
Time for the sensory block to reach maximum level (min)	12.0 ± 1.96 12 (8 - 15)	13.17 ± 2.57 13.50 (9 - 20)

Data are expressed as mean ± SD and median (interquartile range). $p < 0.05$ = statistically significant.

Table 3. Characteristics of motor blocks. Groups		
Group A (n = 20)	Group B (n = 20)	
Time to onset of motor block (min)	4.2 ± 0.89* 4 (2 - 6)	2.36 ± 0.61 2 (2 - 4)
Time to maximum motor block level (min)	11.38 ± 2.34* 12 (5 - 15)	6.14 ± 1.53 6 (4 - 10)

Data are expressed as mean ±SD and median (interquartile range). $p < 0.05$ = statistically significant. *$p < 0.05$.

Table 4. Side effects observed in the groups. Groups		
	Group A (n = 20)	Group B (n = 20)
Hypotension (n)	3*	8
Bradycardia (n)	2*	6
Nausea (n)	1*	6
Vomiting (n)	1	1

Data are expressed as number. *$p < 0.05$ = statistically significant.

Table 5:		
	Group A	Group B
Duration of sensory block*	185.40+ 9.78	172.46 + 7.23
Duration of motor block*	120 + 5.20	138 + 3.02

*pvalue<0.05 : statistically significant.

DISCUSSION

This study was done on 40 patients, divided into two groups of 20 each. The A and B groups, i.e. Levobupivacaine and Bupivacaine groups, every patient received 3 ml of 0.5% of drug (15mg) intrathecally for total knee replacement surgeries. They were observed for time of Onset of Sensory Block, time of Onset of Motor Block, time for sensory and motor block to reach maximum level ,duration of sensory and motor block and incidence of hypotension, bradycardia, nausea and nausea.

Bupivacaine remains the most widely used and cost effective, long acting local anaesthetic used in spinal anaesthesia. But, it has its own disadvantages like hypotension, bradycardia, cardiotoxicity and neurotoxicity.

Levobupivacaine has a potentially greater margin of safety than the racemic Bupivacaine. The unbound fraction of Levobupivacine was significantly lower than that of unbound Bupivacaine because of its increased protein binding affinity. The early clinical presentation of toxicity in Levobupivacaine mostly consisted of central nervous system symptoms like drowsiness, disorientation, slurred speech which may complicate with tonic clonic seizures in some cases. These symptoms are generally self-limiting or respond to anticonvulsive treatment.

Onset Of Sensory Block: In our study , there is no difference between Levobupivacaine and Bupivacaine for the time of onset for sensory block. These finding is consistant with Guler et al2, Casati et al3, Mantouvalou et al4, Sathikarnmanee et al5 in which the time of onset of sensory block showed no difference.

Time Of Onset Of Motor Block: In our study,there is statistical difference between Levobupivacaine and Bupivacaine Groups in the time of onset of motor block. Present study findings were consistant with Guler et al, Vanna et al6 in which the time of onset of motor block was faster in Bupivacine group than Levobupivacaine group.

Our study differ with F Fattorini,Z Ricci et. al7 and Erbay et al8 in which there was no significant difference in the onset of motor block between Bupivacaine and Levobupivacaine group.

Duration Of Sensory Block: In our study, the duration of sensory block was longer with Levobupivacaine compared with Bupivacaine group, which may be attributed to the greater intrinsic vasoconstrictor property of Levobupivacaine.

These findings were consistent with study by Mantouvalou etal. and Mehtaet al9– in which Levobupivacaine having a longer duration of sensory block than Bupicavaine .

Mean Duration Motor Block: In present study, the mean duration of motor block was found to be more in Bupivacaine group compared to Levobupivacaine group patients.

Guleret al, Erbay et al, and Gautier et al1,concluded that motor block lasted longer in Bupivacaine group compared Levobupivacaine group which correlated with our study.

Delfino J et al12, found in their study for lower limb surgeries, that the duration of motor block was significantly longer in Levobupivacaine group, which differs from our study. Levobupivacaine group showed

more stable hemodynamics compared to Bupivacaine group in our study. Episodes of hypotension, bradycardia and nausea were less compared to Bupivacine group.

Lesser incidence of hemodynamic compromise could be due to the inherent vasoconstrictor properties of Levobupivacaine, after its absorption into systemic circulation.

Coppejans H.C. et al14 compared Bupivacaine, Levobupivacaine and Ropivacaine Hemodynamic values were comparable between the three groups although a trend towards better systolic blood pressures and a lower incidence of severe hypotension were noticed in favour of Levobupivacaine.

Christian Glaser et al., compared Levobupivacaine with Bupivacaine intrathecally for hip surgeries, showed slight reductions in heart rate and mean arterial pressure, but there was no intergroup difference in hemodynamics in both the groups.

Demet Gulec et al15, compared intrathecal Bupivacaine and Levobupivacaine in elderly patients undergoing TURP surgery. They concluded that Levobupivacaine did not cause any significant changes in hemodynamic parameters.

Rosa Herrera etal16 found lower incidence of side effects with Levobupivacaine in elderly patients undergoing hip surgery.

Summary

This study was conducted to compare the efficacy and safety of intrathecal Levobupivacaine and Bupivacaine in 0.5% concentration in patients undergoing total knee replacement surgeries. 40 ASA grade I and II patients of both sexes in the age group of 50-68 years undergoing elective surgery(TKR) under spinal anaesthesia were divided into two groups of 20 each.

Group A patients received 3ml of 0.5% Levobupivacaine (15mg) 5mg/ml with 15mcg of fentanyl.

Group B patients received 3ml of 0.5% Bupivacaine (15mg) 5mg/ml with 15 mcg of fentanyl.

The following parameters were observed time of Onset of Sensory Block, time of Onset of Motor Block,time for sensory and motor block to reach maximum level ,duration of sensory and motor block and incidence of hypotension, bradycardia, nausea and vomting.

The results were analyzed statistically usingSPSS Version 20 package.

On comparision of data we found that the time for onset of sensory block showed no statistical significance in both A and B groups. But the duration of sensory block and time for first requirement of postoperative analgesia was longer in patients who received Levobupivacaine. Patients who were given Bupivacaine had shorter duration of sensory block and earlier requirement of rescue analgesia post operatively. The time for onset of motor block shows significant difference between both groups.

Bupivacaine group has faster onset compared to levobupivacaine group. The duration of motor block was shorter in Levobupivacaine group of patients i.e. they had earlier recovery of motor block and early ambulation compared to group of patients who received Bupivacaine intrathecally. Time for complete reversal of motor block after was lesser in Levobupivacaine group. Incidence of Side effects like hypotension, bradycardia were more in Bupivacaine group.

CONCLUSION

From the present study we conclude that, there is no statistical difference for the time for onset of sensory block and time taken to reach maximum level of sensory block in both A and B groups. But the duration of sensory block was longer in levobupivacaine than bupivacaine group and as a result time for first requirement of post operative analgesia was longer in levobupivacaine group. The time to reach maximum motor block and duration of motor block was longer in bupivacaine group than levobupivacaine group.The duration of motor block was shorter in levobupivacaine group , resulting in early ambulation. Fewer episodes of hypotension and bradycardia and other side effects were observed in Levobupavaine group compared to bupivacaine group.

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