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Original Research Article

To assess the safety and efficacy of intrathecal administration of 17.5 mg Bupivacaine heavy (0.5%) and 26.25 mg Ropivacaine (0.75%) for orthopedic lower limb surgeries.

Dr. Rakhi Murarka[1] (Asst. Prof) & Dr. Achin Murarka[2] (Asst. Prof)

Dept. of Anesthesiology, Amaltas Institute of Medical Sciences, Dewas, M.P.[1]
Dept. of Orthopaedics, Amaltas Institute of Medical Sciences, Dewas, M.P.[2]

Corresponding Author: Dr. Achin Murarka

Abstract

Background & Methods: The aim of the study is to assess the safety and efficacy of intrathecal administration of 17.5 mg Bupivacaine heavy (0.5%) and 26.25 mg Ropivacaine (0.75%) for orthopedic lower limb surgeries. The patients were belonging to physical status I and II as per ASA classification. The patients included in this study were from a wide range of age group 20 to 40 year of age and both sexes schedule for various operation for orthopaedic lower limb surgeries. 30 patients were divided into 2 groups of 15 each. Group I received Bupivacaine 17.5 mg and group II received Ropivacaine 26.25 mg. All the patient included in the study well subjected to through preoperative clinical examination in order to rule out any systemic disease. All the patients were monitor for NIBP, HR, SPO2 & ECG continuously till the end of surgery. Assessment of sensory block was done by pin prick and motor block using a modified Bromage score.

Results: The mean pulse rate was found to be 85.48 minute (SD 6.08) in group I and 85.29 (SD 5.83) in group II. Intraopertive pulse rate in group I highest 101.20 and lowest 78.10. In group II highest pulse rate was 101.30 and lowest 77.70. The groups showed no statistically significance (P>0.05) changes in pulse rate at any point of time from 0 minute till the time of recovery. Thus excluding the possibility of tachycardia and bradycardia.

Conclusion: Ropivacaine is newer amide type of local anaesthetic drug with significant enhanced safety profile and propensity to block sensory fibre more readily. Time of onset of sensory loss is early with Ropivacaine compared to Bupivacaine. Time of onset of motor loss is early with Bupivacaine compared to Ropivacaine. Duration of sensory and motor block are more with Bupivacaine as compared to Ropivacaine. No significant difference in both group for pulse rate and blood pressure. All this suggest that Ropivacaine has early onset of block and less duration as compared to Bupivacaine, so it is use as drug of choice for day care surgeries.

Keywords: To assess the safety and efficacy of intrathecal administration of 17.5 mg Bupivacaine heavy (0.5%) and 26.25 mg Ropivacaine (0.75%) for orthopedic lower limb surgeries.

Study Design: Comparative Study.

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1. Introduction

In 1850, about three centuries after the conquest of Peru by Pizzaro, the Austrian von Scherzer brought a sufficient quantum of coca leaves to Europe to permit the isolation of cocaine[1]. As suggested by his friend Sigmund Freud, descriptions of the properties of the coca prompted the Austrian Koller to perform in 1884 the first clinical operation under local anesthesia, by administration of cocaine on the eye[2]. The use of cocaine for local and regional anesthesia rapidly spread throughout Europe and America. The toxic effects of cocaine were soon identified resulting in many deaths among both patients and addicted medical staff. Local anesthesia was in a profound crisis until the development of modern organic chemistry which led to the synthesis of pure cocaine in 1891[3].

Bupivacaine was synthesised by Ekstam and colleagues in 1957 and used first time in 1963 by Telivio. Bupivacaine is a widely used amide type of long acting local anaesthetic. Chemically it is 1-n butyl-DL peperidine-2-carboxy acid-2-6-Dimethyl anilide hydrochloride. Bupivacaine is a tertiary amine (a base) attached to an aromatic ring by amide linkage. The aromatic ring system gives a lipophilic character to its portion of the molecule, whereas the tertiary amine end is relatively hydrophilic[4].

Injection contains Ropivacaine hcl, which is a member of the amino amide class of local anesthetics. Ropivacaine hcl Injection is a sterile, isotonic solution that contains the enantiomerically pure drug substance, sodium chloride for isotonicity and Water for Injection. Sodium hydroxide and/or hydrochloric acid may be used for pH adjustment. It is administered parenterally[5].

2. Material and Methods

Present study was conducted at AIMS, Dewas, M.P. for 10 Months. This study enrolled 30 patients of ASA grade I and II scheduled for Orthopaedic lower limb surgeries. Patients were randomly divided into two groups of 15 each. All the patients were monitor for NIBP, HR, SPO2 & ECG continuously till the end of surgery. Assessment of sensory block was done by pin prick and motor block using a modified Bromage score (0 = No motor block, Grade I = partial block, just able to flex knee but still full flexion of ankle joint possible, Grade 2 = Almost complete block, unable to flex knee, flexion of ankle joint possible Grade 3 = Complete block.)

Group I – Bupivacaine

Group II – Ropivacaine

Before the patient were given spinal anaesthasia each case was subjected to detailed physical and systemic examination (pulse, BP., General and local disease or deformities of spine)

Inclusion criteria

- Provision of written informed consent.
- Men or women 18 years and above.
- ASA category I and II

Exclusion criteria

- With known hypersensitivity to local anaesthesia.
- Contraindication to spinal such as local infection, generalized septicaemia, platelet and clotting factor abnormalities, significant neurological disease with motor or sensory deficit, diagnosed increased intracranial pressure.

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3. Result

Table No. 1: AGEWISE DISTRIBUTION OF GROUPS

S. No.	Age Group (years)	Group I Bupivacaine		Group II Ropivacaine	
		No. of patients	%	No. of Patients	%
1	20-29	10	66.7%	09	60%
2	30-40	05	36.3%	06	40%
	Total	15	100%	15	100%

Group I
66.7% patients belong to 20-29 years of age and 36.3% patients in between 30-40 years of age.
Group II
60% patients belong to 20-29 years of age and 40% patients in between 30-40 years of age.

Table No. 2: CHARACTERISTICS OF BLOCK

S. No.	Characteristics	Group I Bupivacaine		Group II Ropivacaine		P value
		Mean	SD	Mean	SD	
1	Time for onset of sensory loss	6.29	0.45	4.75	0.19	<0.03
2	Time for onset of motor loss	7.14	0.90	13.51	0.69	<0.04
3	Duration of sensory block	203.20	9.81	154.23	8.47	<0.0001
4	Duration of motor block	211.67	12.17	137.13	11.78	<0.0001

P value was significant (<0.05) and time of onset of sensory loss and time of onset of motor loss.
P value also significantly in duration of sensory loss and duration of motor loss

Table No. 3: COMPARISON OF MOTOR BLOCKADE

Motor Blockade	Group I (Bupivacine)	Group II (Ropivacine)	Total
2^0	01	02	03
3^0	14	13	27
Total	**15**	**15**	**30**

χ^2 **=0.42** This table depicts comparison of motor blockade between the two studied groups.

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Table No. 4: COMPARISON OF MEAN PULSE RATE

Group		PR 0 min	PR 5 min	PR 10 min	PR 15 min	PR 20 min	PR 25 min	PR 30 min	PR 60 min	PR 90 min	PR 120 min	PR 150 min	PR 180 min	PR 210 min	PR 240 min	PR 270 min
I	Mean	91.33	86.40	85.60	82.40	81.73	82.60	78.10	84	91.10	101.20	93.90	82.50	85.30	78.30	84.00
	SD±	5.42	3.27	16.04	13.92	14.97	3.98	14.75	5.29	5.67	8.02	6.62	3.88	3.17	13.85	5.29
II	Mean	83.97	83.70	101.30	77.70	84.55	81.90	81.90	83.60	89.00	88.30	97.10	81.88	83.00	84.30	83.30
	SD±	8.51	14.09	8.66	6.06	2.88	3.35	3.36	4.46	4.37	4.97	6.25	5.25	5.92	6.00	5.99

P value – 0.92

The mean pulse rate was found to be 85.48 minute (SD 6.08) in group I and 85.29 (SD 5.83) in group II. Intraopertive pulse rate in group I highest 101.20 and lowest 78.10.

In group II highest pulse rate was 101.30 and lowest 77.70.

This table shows that both the groups showed no statistically significance (P>0.05) changes in pulse rate at any point of time from 0 minute till the time of recovery. Thus excluding the possibility of tachycardia and bradycardia.

4. Discussion

Highest level of sensory block achieved was up to T8 in 4 patients in group I while up to T8 in 3 patients in group II. The difference was insignificant. Mean time taken for the loss of pinprick sensation at L3 level in group I patients was 5.29 minute with SD of 0.85, while in group II patients it was 3.75 minute with SD of 0.59. The difference in the onset time of sensory block between group I and II was 1.54 minute[6]. On applying statistical tests to these findings, P value was calculated to be <0.001, which means statistically significant difference.

In all patients in both groups, motor paralysis of Bromage 3 level could be achieved but the onset of complete paralysis was quicker in group I patients. The mean time for the onset of complete motor block in group I was 6.14 minute with SD of 0.708 while in group II, it was 12.51 minute with SD of 0.994. The difference in both groups was 6.363 minute. On applying statistical tests to these findings, P value was calculated to be <0.001, which means statistically significant difference[7].

Hypotension was the most common side effect in both groups. There was a significant difference in the incidence of hypotension between the two groups. The studies of various authors[8] support our results of low incidence of hypotension in hyperbaric ropivacaine, but the exact cause of low incidence of hypotension as compared to bupivacaine is not established. The intraoperative and postoperative complications (bradycardia, nausea, shivering, vomiting) did not differ significantly between the two groups. However, our study was not without limitations[9-10]. One of the limitations was that no blinding was done which would have resulted in some degree of bias. Furthermore, we did not standardize the dose based on age, height, and weight.

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5. Conclusion

Ropivacaine is newer amide type of local anaesthetic drug with significant enhanced safety profile and propensity to block sensory fibre more readily. Time of onset of sensory loss is early with Ropivacaine compared to Bupivacaine.Time of onset of motor loss is early with Bupivacaine compared to Ropivacaine. Duration of sensory and motor block are more with Bupivacaine as compared to Ropivacaine. No significant difference in both group for pulse rate and blood pressure. All this suggest that Ropivacaine has early onset of block and less duration as compared to Bupivacaine, so it is use as drug of choice for day care surgeries.

6. References

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