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Original Research Article

Comparative study of ropivacaine (0.5%) plain versus levobupivacaine (0.5%) plain in gynecological surgeries

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ABSTRACT

Background: Regional anesthesia increasingly used for gynecological surgeries, has advantage of decreased stress response to surgery, decreased cardiorespiratory depression, with improved postoperative analgesia.
Methods: This randomized, prospective, double blind study was conducted at Amaltas Institute of Medical Sciences, Banger Dewas in Department of Anesthesia between June 2016-December 2016. Sixty patients who were posted for gynecological surgeries were enrolled and randomly divided into two groups: Group R received 3.5 ml (17.5 mg) 0.5% ropivacaine plain and Group L received 3.5 ml (17.5 mg) 0.5% levobupivacaine plain. The onset and duration of sensory and motor block and any undesirable side effects were noted.
Results: Demographic parameters were comparable between the two groups (P >0.05). Onset of sensory and motor block was significantly faster in Group L, duration of motor and sensory block was significantly less in Group R. Patients in group R were hemodynamically stable (P = 0.032) compared to group L.
Conclusions: Both ropivacaine and levobupivacaine have the desirable blocking property and can be used in gynecological surgeries. Ropivacaine showed shorter duration of sensory and motor block allowed early mobilization and early recovery of patients.

Keywords: Gynecological surgeries, Levobupivacaine, Regional anesthesia, Ropivacaine

INTRODUCTION

The use of spinal anesthesia in gynecological surgeries has been shown to provide effective and comfortable intraoperative condition. Generally, such procedures were performed with hyperbaric racemic bupivacaine. Levobupivacaine and ropivacaine are two new long acting local anesthetics have been developed as alternative to bupivacaine after the evidence of its severe toxicity.[1] A recent clinical trial comparing levobupivacaine 0.5% with ropivacaine 0.5% for the management of postoperative ankle surgery pain found that levobupivacaine provide more long lasting postoperative analgesia compared with the same dose of ropivacaine, in contrast McNamee et al reported that

intrathecal administration of 17.5 mg plain ropivacaine 0.5% or plain bupivacaine 0.5% resulted in similarly effective anesthesia for total hip arthroplasty.[2,3] We have planned the study to evaluate effect of plain ropivacaine 0.5% versus plain levobupivacaine 0.5% in gynecological surgeries.

Racemic bupivacaine is the most common local anaesthetic used intrathecally. Ropivacaine the optically pure S (-) enantiomeric form of the parent chiral molecule propivacaine, belongs to pipecoloxylidide group of local anesthetics, with a propyl group added to the piperidine nitrogen atom compared to butyl group in bupivacaine though ropivacaine structurally resembles bupivacaine with similar anesthetic properties.[4-6] It has reduced potential for cardiotoxicity and neurotoxicity with improved relative sensory and motor block profile. It has lower lipid solubility and blocks nerve fibers involved in pain transmission to a greater than those involved in motor function.[7-9,10] Levobupivacaine is also an S (-) enantiomer of bupivacaine, is equally lipophilic as bupivacaine, more than ropivacaine, as ropivacaine has 3 carbon side chain instead of 4 carbon side chain as substitution of pipecoloxylidine.[1]

The objectives of this study were to compare these newer local anesthetics in terms of clinical and anesthetic properties and to provide observations in spinal anesthesia for gynecological surgeries.

METHODS

A prospective randomized double blind study was done in Department of Anesthesia, Amaltas Institute of Medical Science, Bangar Dewas, Madhya Pradesh, India between June 2016 to December 2016. This study has included 60 female patients of age between 20-70 years between 50-80 kg of ASAI-II physical status, posted for elective gynecological surgeries. A written informed consent from patients and approval from Ethical Committee was obtained before starting the study. Patients who had severe bronchopulmonary disease, any coagulation disorder, any neuromuscular disease, hypersensitivity to local anesthetic, contraindication to spinal anaesthesia as infection at puncture site, spinal deformity, patients who refused were excluded from study.

Patients were randomly distributed into two groups of 30 patients each and randomization was done by lottery method. Group L (n=30) received 17.5 mg plain levobupivacaine (3.5 ml), Group R (n=30) received 17.5 mg plain ropivacaine (3.5 ml). On arrival in anesthesia room a 20 gauze intravenous cannula was inserted and 15 ml/kg ringer lactate solution was infused. Monitored parameters include 3-lead ECG, heart rate (bpm), non-invasive blood pressure (NIBP, mm Hg), pulse oximetry (SpO2%). Spinal anesthesia was obtained by 0.5% plain levobupivacaine 3.5 ml (Group L) or 0.5% plain ropivacaine 3.5 ml (Group R). Syringe of drugs was prepared by an anesthesiologist who was not part of the study further. In sitting position, either of the drugs was aseptically administered through 25G Quincks needle between L3-L4, L4-L5 interspace. As soon as the subarachnoid block was performed patients place in supine position. Sensory block was graded according to Gromley and Hill test using a pin protruding through a guard every 2 min till no sensation was achieved at T8 level. Motor block was graded according to Modified Bromage Scale (0-3), where 0=no motor block (full flexion of hip knee and ankle), 1=ability to move knees and feet, inability to flex hip, 2=ability to move feet only, inability to flex hip or knee, 3=full motor block) respectively.

The onset time of sensory block was assessed referring to the interval between spinal puncture and the maximal pinprick score. The onset time of motor block was assessed evaluating the time interval between puncture and the maximal definitive Bromage score. The offset time was considered as corresponding return to normal sensitivity and motility. The spread of anesthesia was referring to the upper dermatome with any grade of sensory impairment. Any side effects like nausea, vomiting, pain, shivering, sedation, hypotension, bradycardia and respiratory discomfort was noted and treated with appropriate drug if required.

The surgical procedure was start within 30 min of spinal puncture. The management of the patient being switched to general anesthesia in case of score less than Bromage 2 and excluded from the study. Time interval for anesthesia parameters was checked every 2 min till 30 min to note onset and maximum degree of block. Vital parameters was recorded at 0, 5, 10, 15, 20, 25, 30, 45 and 60 min and then every fifteen min till surgery ended, than every hourly postoperatively until motility and sensitivity returns back to basal condition.

A decrease in heart rate more than 50 and decrease in MAP more than 20% from basal value was considered as bradycardia and hypotension and treated with injection Atropine 0.5 mg and injection Mephentermine 6 mg bolus dose repeated as needed. Every patient received supplemental oxygen through face mask with spontaneous breathing. Inj. Diclofenac in 75 mg used as rescue analgesic (if not contraindicated) the maximal dose would be three times a day. In patients where diclofenac is contraindicated, Inj. Tramadol was administered.

Statistical analysis

The mean comparison between the two groups was done using unpaired t test, two group proportions were compared using Z test for two sample proportion. A P-value of <0.05 was taken as statistically significant. Online statistical software were used for analysis of the data.

RESULTS

The mean age in Group L was 46.80±12.41 years and in Group R it was 50.07±9.37 years. The mean age in both the groups was comparable (P>0.05) (Table 1).

The mean weight in Group L was 67.93±8.69 years and in Group R it was 67.47±9.05 years. The mean weight in both the groups was comparable (P>0.05) (Table 1).

The mean sensory block onset time in levobupivacaine group was 6.30±1.39 min, while it was 8.23±2.84 min in ropivacaine group. The mean sensory onset time was higher in ropivacaine as compared to levobupivacaine group (P<0.05). The mean duration of sensory block in levobupivacaine group was 287.23±84.45 min, while it was 245.50±66.22 min in ropivacaine group. The mean duration of sensory block was higher in levobupivacaine group in comparison to ropivacaine group (P<0.05). The mean motor block onset in levobupivacaine group was 5.33±2.19 min, while it was 6.63±2.34 min in ropivacaine group. The mean motor onset time was higher in ropivacaine group in comparison to levobupivacaine group (P<0.05). The mean duration of motor block in levobupivacaine group was 255.83±80.96 min, while it was 213.83±52.57 min in ropivacaine group. The mean duration of motor block was higher in levobupivacaine group in comparison to ropivacaine(P<0.05) (Table1).

Bradycardia (6.7%) was higher in levobupivacaine group in comparison to 3.3% in ropivacaine group. Bradycardia was comparable between both the groups (P>0.05), while incidence of hypotension was higher in levobupivacaine group in comparison to the ropivacaine group (P<0.05) (Table 2).

Table 1: Comparison of various parameters between Ropivacaine and Levobupivacaine Groups (N=60).

Parameter	Levobupivacaine [Mean±SD]	Ropivacaine [Mean±SD]	t Value	P Value
Age (years)	46.80±12.41	50.07±9.37	-1.151, df=58	0.255, NS
Weight (kg)	67.93±8.69	67.47±9.05	0.203, df=58	0.839, NS
Sensory block onset (min)	6.30±1.39	8.23±2.84	-3.351, df=58	0.001*
Duration of sensory block (min)	287.23±84.45	245.50±66.22	2.130, df=58	0.037*
Motor block onset (min)	5.33±2.19	6.63±2.34	-2.223, df=58	0.030*
Duration of motor block (min)	255.83±80.96	213.83±52.57	2.383, df=58	0.020*

Unpaired 't' test applied; P value < 0.05 was taken as statistically significant.

Table 2: Comparison of complications between Ropivacaine and Levobupivacaine Groups (N=60).

Complications	Levobupivacaine group (n=30)		Ropivacaine group (n=30)		Z value	P Value
	No.	%	No.	%		
Bradycardia	2	6.7	1	3.3	0.59	0.552, NS
Hypotension	4	13.3	0	0.0	2.15	0.032*
Total	30	100.0	30	100.0		

Z test for two sample proportion applied; P value <0.05 was taken as statistically significant.

DISCUSSION

Spinal anesthesia is a safe and reliable technique which provides surgical anesthesia as well as prolonged pain relief, blunts autonomic, somatic, endocrine response. Till recently racemic bupivacaine was the frequently used drug. Ropivacaine introduced in 2009 in India and levobupivacaine recently introduced in India. They have been developed as safer alternative to racemic bupivacaine having desirable blocking property with greater margin of safety.[1]

Clinical studies in various patient populations. Ying et al, Kannai et al and Sinnot et al, Allery et al, Gautier et al showed that bupivacaine is the most potent local anesthetic equivalent to levobupivacaine followed by ropivacaine.[11-15] Ropivacaine is less potent because of its lower lipid solubility but that it has an advantage of stronger differentiation between sensory and motor block, a feature that is particularly useful when early mobilization is important to enhance recovery.

Clinical studies have shown that ropivacaine and levobupivacaine are effective in providing analgesia and anesthesia when used for upper or lower limb surgery, but little information is available regarding their comparable clinical profile and as levo-bupivacaine is equally potent to bupivacainecefindings were compared with bupivbupivacaine also.[11-15]

Pianggatelli et al showed faster onset of infraclavicular brachial plexus block with 0.5% levobupivacaine than

0.5% ropivacaine.[16] Chung et al observed that sensory block to T10 or to maximal level took longer in ropivacaine than bupivacaine group (P<0.05).[17] Similar results are seen in our study where sensory onset was significantly faster in levobupivacaine group than ropivacaine group (P=0.001). McNamee et a compared 17.5 mg plain bupivacaine and 17.5 mg plain ropivacaine, resulted in similar effective spinal anesthesia in terms of onset and spread of analgesia for hip arthroplasty.[13]

Mantauvalou et al compared efficacy and safety of three local anesthetic agents namely bupivacaine, levobupivacaine and ropivacaine in patients undergoing lower abdominal surgery and showed that motor block onset was significantly faster in bupivacaine group almost same in levobupivacaine group (P<0.05) than in ropivacaine group.[18] Whiteside et al who found the time to maximum degree of motor block in bupivacaine was significantly less (P<0.001) than ropivacaine group whereas Chung et al found that the both drugs ropivacaine and bupivacaine took similar time to complete motor block.[17,19]

In present study in Group R motor block onset time is significantly higher (P=0.030) than Group L. In our study duration of sensory block and motor block is significantly more in Group L than Group R (P=0.037). Breebart et al compared 10 mg levobupivacaine and 15 mg ropivacaine for out patients knee arthroscopy and found the same results, where ropivacaine group moved early and need for postoperative analgesia was less in levobupivacaine but they discharged home late.[20] Ropivacaine presented with shorter duration of sensory and motor block than bupivacaine and levobupivacaine (P<0.05).

In study done by Mantouvalou et al ropivacaine has lower lipid solubility than levobupivacaine.[18] The inhibition of cardiac contractility is proportionate to lipid solubility and nerve blocking potency of local anesthetic suggesting that cardiotoxic potency of three local anesthetics are in order of bupivacaine >levobupivacaine >ropivacaine i.e. ropivacaine has most stable hemodynamic profile among three.[21] In present study, 4/30 (13.3%) patients in Group L showed hypotension, it is significantly higher than ropivacaine group (P=0.032). 2/30 (6.7%) patients showed bradycardia in Group L and 1 (3.3%) in Group R (P=0.552), which was comparable in both the groups. These patients were treated with mephenteramine and atropine respectively. Hence, it was observed that ropivacaine has better hemodynamic profile that levobupivacaine.

CONCLUSION

Both ropivacaine and bupivacaine having the desirable blocking property of racemic bupivacaine can be used for gynecological surgeries. Ropivacaine showed shorter duration of sensory and motor block allowed early mobilization and early recovery of patients. Ropivacaine also be used for its more favourable hemodynamic profile than levobupivacaine.

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