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COMPARISON OF INTRATHECAL BUPIVACAINE WITH ROPIVACAINE IN TWO DIFFERENT STRENGTHS FOR QUALITY OF ANAESTHESIA AND POST OPERATIVE ANALGESIA IN LOWER ABDOMEN HERNIA SURGERY

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ABSTRACT

Subarachnoid block techniques are widely used for lower abdominal surgeries and offer several benefits compared to general anesthesia.We wanted to investigate the clinical efficacy and safety of Ropivacaine in two strengths as compared to Hyperbaric Bupivacaine for spinal anaesthesia. 90 patients ASA I & II scheduled for elective lower abdomen hernia surgery were randomly divided into 3 groups of 30 each to receive 3.4 ml of isobaric Ropivacaine 0.5% or 3.4 ml of isobaric Ropivacaine 0.75% compared with control group receiving 3.4 ml of Hyperbaric 0.5% Bupivacaine. Subarachnoid block was achieved in L3-L4 space with 23G Quincke's spinal needle. The onset of surgical anesthesia at L1 was delayed with both the Ropivacaine groups as compared to Bupivacaine group. The total duration of analgesia was comparable in Bupivacaine and Ropivacaine 0.75% groups.The total duration of motor block was much longer with Bupivacaine group than Ropivacaine groups. To conclude intrathecal Ropivacaine in the 0.75% strength was found to be a good alternative to 0.5% Hyperbaric Bupivacaine in the terms of less haemodynamic changes, faster regression of both motor and sensory block, and for early mobilization of patient.The patients can be mobilized more quickly,as in patients of daycare surgery.

Key words: Ropivacaine,Bupivacaine,Subarachnoid Block, Analgesia, Hypotention.

INTRODUCTION

Hyperbaric Bupivacaine, an amide type local anesthetic, is most commonly used for subarachnoid block. It has high potency, long duration of action and is relatively more cardiotoxic.Baricity is one of the major determinants of the spread of local anaesthetic in cerebrospinal fluid and the extent of blockade. Hyperbaric solutions of local anesthetics in moderate doses provide mid thoracic (T4-T6) spinal blockade which in turn is another cause of hypotension and bradycardia. Prolonged motor blockade with intrathecal hyperbaric Bupivacaine produces more discomfort and complications like urinary retention for patients where longer duration of blockade is not desirable and delays early mobilisation and discharge. Isobaric solutions of local anesthetics in moderate doses are ideal for providing low thoracic (T8-T10) spinal blockade appropriate for lower abdominal hernia surgeries. A major advantage of isobaric solutions is that a change in the position of the patient has minimal effect on the distribution of the local anesthetic and, therefore limits the cephalic spread of spinal anesthesia.

Ropivacaine is a long acting amide type of local anesthetic that is structurally related to Bupivacaine. It is a pure S (-) enantiomer, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles**(Kuthiala G et al 2011).** Clinical data concerning the characteristics of Ropivacaine following subarachnoid block are limited hence we wanted investigate the clinical efficacy and safety of the two strengths of subarachnoid Ropivacaine in lower abdominal hernia surgery which are very common.

MATERIALS & METHODS

This was a prospective, randomized comparative study, randomization was done by computer generated data .The study was initiated after obtaining permission from the Institutional Ethics Committee**.** Preoperative evaluation included thorough clinical history and examination as well as requisite investigations. All the patients were familiarised with Ten Point Visual Analog Scale in the pre-operative evaluation. 90 adult patients who were scheduled for elective lower abdominal hernia surgery admitted to Lata Mangeshkar Hospital of ASA status I or II were included in the study. Patients with height less than 150 cm as well as any contraindication to regional anesthesia and any known drug allergy were excluded from the study.Written informed consent was obtained from all patients. Patients were randomly allocated to 3 groups of 30 each to receive either

Group A- 3.4ml intrathecal isobaric Ropivacaine 0.5 %.
Group B- 3.4ml intrathecal isobaric Ropivacaine 0.75 %.
Group C- 3.4ml intrathecal Bupivacaine Heavy 0.5%.

In the operation theatre monitors were attached to the patient and parameters like heart rate, non invasive blood pressure, ECG and SpO_2 were noted.

All patients were pre-loaded with 10ml/kg of Ringer's lactate 15 min.prior to subarachnoid block and received premedication with injection Ranitidine 50 mg and injection Ondansetron 4 mg i.v.

Under all aseptic precautions in sitting position and using midline approach subarachnoid block was achieved in L3-L4 space with 23G Quincke's spinal needle. Drug was injected as per the group according to random assignment.

Patients were immediately placed in the supine position. The operation table was horizontal without any detectable tilt. The onset of sensory analgesia and motor blockade were tested. The level of sensory anesthesia-defined as the loss of sharp sensation by using a pinprick test (20-gauge hypodermic needle)was recorded bilaterally at the mid-clavicular line.

Motor blockade was assessed with modified Bromage score. Time taken for complete motor blockade was noted every minute till first 20 minutes.

Modified Bromage score was used for assessment of motor block as follows **(Collins VJ, 3rd edi.1993)**.

Grade	Criteria	Degree of block
I	Free movement of legs and feet	Nil (0%)
II	Just able to flex knees with free movement of feet	Partial (33%)
III	Unable to flex knees, but with free movement of feet	Almost complete (66%)
IV	Unable to move legs or feet	Complete (100%)

Highest sensory level and time taken to achieve it was noted. Patient's heart rate, blood pressure, respiratory rate, oxygen saturation were monitored every minute initially for 5 minutes then at 5 minute interval for next 30 minutes then every 15 minutes till the end of surgery. The quality of intraoperative analgesia was evaluated by the patient using a two-point scale (1 = adequate analgesia: no sensation at all from the surgical site or sensation of motion only; *2* = inadequate analgesia:discomfort but the patient declined additional analgesia,or major discomfort with additional analgesics required) **(Gautier PE et al 1999)**.

Regression of motor blockade and duration of post-operative analgesia were noted. The intensity of pain was assessed using a 10-point Visual Analogue Scale.Visual Analogue Score (VAS) was recorded for assessment post-operative pain at 30, 60, 90, 120, 150, 180, 240,300 & 360 minutes. Period of analgesia was taken as the time from spinal injection to the first request of rescue analgesia. Rescue analgesia was given in the form of Injection Diclofenac AQ 75mg IV at a VAS score of ≥4. In our study we defined hypotension as a decrease of systolic blood pressure more than 20% of baseline and was treated with I.V fluids and Injection Mephentermine Hydrochloride 3mg IV as required. Bradycardia was defined as a decrease in the heart rate to less than 60 per min and was treated with Inj.Atropine 0.6mg IV. All patients were observed postoperatively upto 24 hours.Any intra-operative and post operative complications till 24hrs were recorded and treated accordingly.

Statistical analysis:
All the data were entered into the excel database from paper pro-forma.Following analyses were performed. Results are expressed as the number, percentages, range, median, mean ± SD as appropriate. The comparison of normally distributed continuous

variables between the groups was performed by means of one-way analysis of variance *(ANOVA)* and, if appropriate, followed by *Dunnett t* multiple comparison test. Nominal categorical data among study groups were compared using the chi-square test. Additional exploratory (parametric as well as non-parametric) analysis of the data was performed as deemed essential by using appropriate statistical tests. $P < 0.05$ was considered to be statistically significant.

OBSERVATIONS

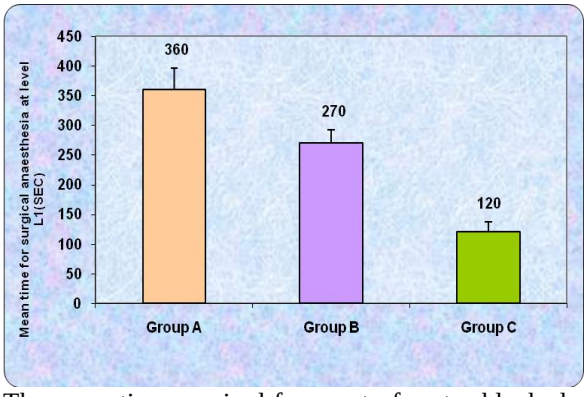
The study & control groups did not differ significantly with respect to any demographic variables (Table 1).

Table 1: Demographic Parameters in all 3 groups.

Demographic Variables	Group A	Group B	Group C
Age (yrs)	32± 2.37 years	33 ± 4.09 years	31±4.48 years
Weight (Kg)	65±5.27 kgs.	66±5.99 kgs.	67.5±5.2 kgs.
Height (cm)	165±4.12 cms.	165±4.63 cms.	167±4.51 cms.
ASA I/II	26/4	26/4	25/5
Duration of Surgery	52±8.09 min.	50±7.38 min.	53±8.22 min.

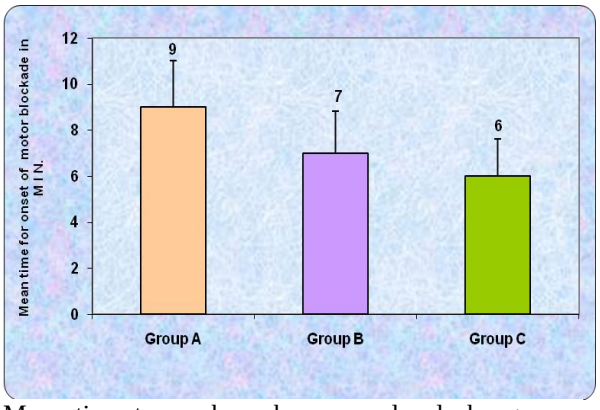
The mean time required for onset of surgical anesthesia at L1 by groups A,B&C were 360 ± 36.07, 270 ± 22.07, and 120 ± 17.43 seconds respectively and found to be statistically significant when study groups compared to control group($P<0.05$).(Graph 1).

Graph 1: Mean time for surgical Anaesthesia at L1 in sec.



The mean time required for onset of motor blockade by groups A,B&C were 9.0±2.03,7.0±1.81 and 6.0±1.61minutes respectively and only Group A found to be statistically significant when compared to control group ($P<0.05$) whereas Groups B and C were comparable.(Graph 2).

Graph 2: Mean time for onset of motor blockade in Min.



Mean time to reach peak sensory level by groups A,B&C were 15±1.8,18±3.12 and 16±1.87 minutes respectively and found to be insignificant to control.

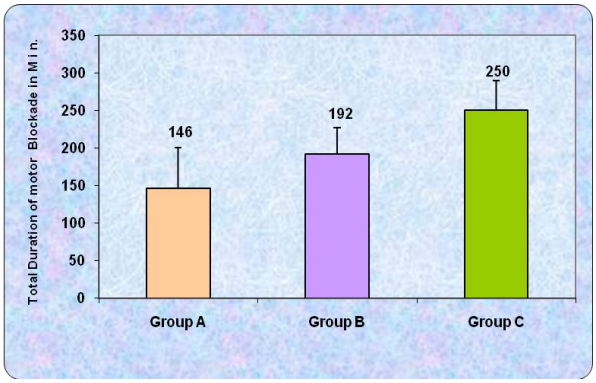
Median peak sensory levels achieved by groups A,B&C were T10,T8 andT4 respectively.

20 patients achieved motor block of modified bromage grade (MBG) 4 and rest of 10 patients achieved grade 3 in Groups A and 25 patients in Group B had MBG 4 and 5 patients showed grade 3 but 28 patients in group C achieved motor block of modified bromage grade 4 and rest 2 patients achieved grade 3.

Total duration of sensory blockade was 225±98,310±39 and 315±42 minutes in groups A,B&C and found to be significant only for Group A when compared to control whereas comparable between Groups B and C ($P<0.001$).

Total duration of motor blockade was 146±54,192±35and 250±40 minutes in groups A, B&C and found to be significant when compared to control group ($P<0.05$)(Graph 3).

Graph 3: Total Duration of Motor Blockade in Min.



DISCUSSION

Ropivacaine, a new amide local anaesthetic , is the first single- enantiomer local anaesthetic produced for commercial purpose having properties similar to Bupivacaine,developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles**(Akerman B et al 1988 and McClure JH et al 1996)**.Till now in many studies Ropivacaine is used for local infiltration,epidural blocks and peripheral nerve blocks but clinical data of its use in intrathecal route is limited. In many animal studies it has been demonstrated that using Ropivacaine intrathecally has very little effect on spinal cord blood flow **(Kristensen JD et al 1998)** and it produces similar sensory block as produced by equivalent dose of Bupivacaine, with reduced degree of motor block**(Feldman HS et al 1988)**. We wanted to investigate the safety and efficacy of the two concentrations of intrathecal Ropivacaine against the traditional Bupivacaine in patients undergoing lower abdominal hernia surgery.We would like to discuss under onset of block,quality of block and duration of blockade, haemodynamic stability,analgesic potency and side effects if any.

Onset of Block:

In our study the onset of sensory anaesthesia at L1 is much earlier in Bupivacaine group as compared to the two strengths of Ropivacaine this is due to the hyperbaric nature of Bupivacaine which produced more cephalad spread of the drug as compared to the isobaric Ropivacaine.**P.D.W.Fettes et al 2005** compared plain & hyperbaric solutions of Ropivacaine for spinal anaesthesia in patients undergoing elective perineal surgery. They noted significant differences in median time to onset of sensory block at T10 (plain 10 min; hyperbaric 5 min; $p<0.01$),thus baricity plays an important role in the onset of block.The onset of motor block was delayed in Ropivacaine groups and it was dose dependant as compared to Bupivacaine group,this may be because Ropivacaine has been regarded as having specific effects on sensitive nervous fibres thereby producing less motor impairments than the other local anaesthetics **(Gautier P et al 2003)**.

Quality of Block and Duration of Blockade:

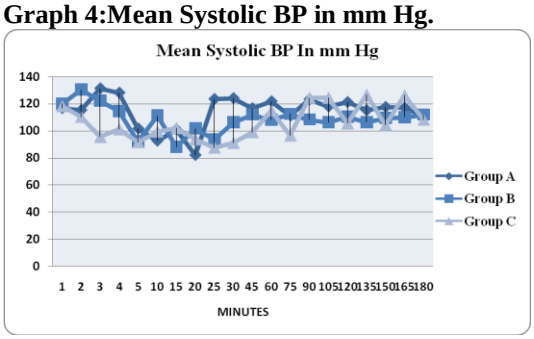
In our study mean peak sensory levels achieved by groups Ropivacaine 0.5% was T10 and Ropivacaine 0.75% was T8.In Group A 20 patients had MBG 4 with peak sensory level at T10,among them 7 patients on two point scale for quality of intraoperative analgesia had score 2 where analgesia was inadequate but patients refused to supplement with additional analgesia and surgery was uneventful.10 patients in Group A had MBG 3 with peak sensory level T8 here 3 patients had score 2 where additional analgesia was not needed but 7 patients had major discomfort and given general anaesthesia.In Group B 3 patients had score 1 where they had sensation of motion only and 2 patients had score 2 who had inadequate analgesia but patients declined additional analgesia and surgery was uneventful.In Bupivacaine group al the patients had score 1 with adequate analgesia.The lipid solubility of Ropivacaine is intermediate between Lidocaine and Bupivacaine. A weaker motor block with Ropivacaine compared to Bupivacaine has also been noted in previous in vitro animal and human epidural studies**(Akerman B et al 1988,Katz JA et al 1990, Feldman HS et al 1988 and Bader AM et al 1989)**.The lesser lipid solubility of Ropivacaine may cause this drug to penetrate the large myelinated A fibers more slowly than more lipid soluble Bupivacaine**(Rosenberg PH et al 1986)**.**Jack W et al 1994** in his study commented that Ropivacaine has good analgesic properties in the two concentrations used,both solutions resulted in a highly variable spread of analgesia.A more reliable motor block was only obtained with 0.75% solution.Spinal anaesthesia with 0.75% Ropivacaine provides most satisfactory condition whereas 0.5% Ropivacaine could be suitable for TURP or minor orthopedic surgery when the degree of motor block is not of critical importance. Thus the degree of motor block and duration of motor block depends upon the concentration of Ropivacaine. **McDonnald SB et al 1999** and **Malinovsky JM et al 2000** in their studies proposed that Ropivacaine is not equipotent to Bupivacaine after intrathecal administration. **Gautier PE et al 1999** also stated that Ropivacaine produces less motor impairment at the same dose as Bupivacaine because it is less potent. **Markham A et al 1996** and **Scott DB et al 1995** also commented that Ropivacaine is shorter acting and may produce less motor blockade. In our study this property of 0.75% Ropivacaine found to be useful in lower abdominal hernia surgery where it provided adequate surgical analgesia comparable with Bupivacaine with early regression of motor blockade hence early ambulation and early voiding without any patient complaining urinary retention.This leads early hospital discharge.

Haemodynamic Stability:

The hemodynamic changes due to subarachnoid block were modest with Ropivacaine groups because all the patients were preloaded with 10ml/kg Lactated Ringer and the sympathetic block was gradual as compared to Bupivacaine and also related to the highest sensory level. After intrathecal injection of local anaestheticss, there is reduced sympathetic

outflow which causes reduction in blood pressure.But due to slower onset and lower levels of blockade the hypotension occurred only in 2 patients in Group A and 4 patients in Group B where no vasopressors were required but giving fluid chalange with 100ml of Ringer's lactate was sufficient.But in Bupivacaine group due to early onset and higher levels of blocked hypotension occurred in 10 patients who responded well to the 1 to 2 doses of Inj.Mephentermine 3 mg I.V. with fluid challenge. No colloid or blood transfusion were required. Only one patient developed bradycardia due to T2 level who responded well to single dose of Inj.Atropine 0.6 mg I.V. well. To minimize the hypotension after spinal anaesthesia, strict protocol for spinal anesthesia was followed.

Graph 4:Mean Systolic BP in mm Hg.



Post operative analgesia and Rescue analgesic requirment:

Ropivacaine 0.5% group patients had higher VAS scores at the predetermined time intervals and needed rescue analgesics earlier and most of the patients were supplemented with three doses in the first 24 hours whereas the VAS scores in groups Ropivacaine 0.75% and Bupivacaine 0.5% were comparable and most patients were given two doses of rescue analgesics in the first 24 hours.

Side Effects:

In our study 4 patients from Bupivacaine group(group C) had retention due to prolonged motor block where catheterization was done.No patient from study group had any side effects due to intrathecal Ropivacaine administration.

Table 2: Side effects (%) in all 3 groups.

Side Effects	Group A	Group B	Group C
Bradycardia	--	--	01(3.3%)
Hypotension	02(6.6%)	04(13.3%)	10(33.3%)
Urinary Retention	--	--	04(13.3%)

CONCLUSION

Ropivacaine 0.75% has shown good analgesia potency comparable to Bupivacaine for lower abdominal hernia surgery.The duration of analgesia and motor block are clearly dependant on the concentration of Ropivacaine used.Due to early recovery from motor block,good haemodynamic stability and no side effects like nausea vomiting, urinary retention or symptoms of transient neurologic irritation and early discharge from hospital , Ropivacaine 0.75% can be successfully and safely used in lower abdominal hernia surgery.Ropivacaine 0.5% can be suitably used where the degree of motor block is not critically important.

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