

Randomised controlled trial comparing efficacy of two different doses of Intrathecal 0.75% Isobaric Ropivacaine in Elective Inguinal hernia surgery

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Abstract

INTRODUCTION : Ropivacaine was approved for a new route of administration, the intrathecal route, in the European Union in February 2004¹. Ropivacaine was introduced into clinical practice in 1996, and has consistently demonstrated an improved safety profile over Bupivacaine, with reduced CNS and cardiotoxicity. In addition it has a wide clinical utility at different doses for a wide range of indications. It has been shown to provide effective, well tolerated surgical anaesthesia via central neuroaxial block, for major and minor nerve blocks and field blocks. It has also shown to have high-quality postoperative analgesia.²

AIM OF STUDY : Comparison of the use of 18.75 MG(2.5 ml) with 22.5 MG(3 ml) isobaric 0.75% Ropivacaine for adequate surgical anaesthesia and motor blockade for elective inguinal hernia surgery.

MATERIAL AND METHODOLOGY: Ethical committee approval obtained. This is prospective, randomized, double-blinded study. All patients with undergoing elective inguinal hernia. The sample size was restricted to 60 due to time constraint allotted for this study. Patients of either sex with age of 18-70 years, patients belonging to ASA grade I&II. Body weight not more than 20% above ideal body weight. Patient exclusion criteria's were patient refusal, local site infection, coagulopathy etc. The nature of study explained to patients and written informed consent taken before enrolling for study. Each group containing 30 patients and received two different doses of Ropivacaine. Computer based randomisation in two groups done as-

Group 1: patients receiving 22.5 mg (3 ml) 0.75% isobaric Ropivacaine intrathecal.

Group 2: patients receiving 18.75 mg (2.5 ml) 0.75% isobaric Ropivacaine intrathecal.

SAB was given in sitting position to all patients under all septic precautions. In this study we investigated the adequacy of surgical anaesthesia of two different doses of Ropivacaine for patients who were posted for elective inguinal hernia surgery. We assessed sensory block using pin prick method and Modified Bromage's score for motor assessment.

RESULTS: The surgery lasted for an average for 40 minutes for which block of up to T10 was considered sufficient and motor block of grade II also noted introp. Three patients from group 1 and three patients from group 2 were excluded in this study.

Onset of Sensory block: Time to attain T₁₀ level was taken as time of onset of sensory block. Median time of onset of sensory block in Group 1 which was 10 minutes. In group 2 it was 10 minutes. There was no statistically significant difference in time of onset of sensory block between Group 1 and Group 2 (p value > 0.05).

Duration of sensory block: Duration of sensory block at T10 was taken as duration of sensory block. Median duration of sensory block in Group 1 was 174 minutes, in Group 2 was 148 minutes. There is no significant difference (p > 0.05). Adequate duration of sensory block at T10 was present with both groups for surgical time.

Onset of motor block: Time to attain motor block up to modified Bromage score 3 was taken as time of onset of motor block. Mean time of onset of motor block in Group 1 was 20 minutes, in group 2 was 20 minutes. There was statistically no significant difference in time of onset of motor block between group 1 and Group 2 (p > 0.05).

Duration of motor block: Median duration of motor block in group 1 was 137 minutes. In Group 2 was 148 minutes. There was statistically no significant difference in duration of motor block between Group 1 & Group 2 (p value > 0.05). So adequate duration of motor block was obtained in both group 1 and group 2.

CONCLUSION: There is no significant advantage in choosing higher dose of 22.5 mg (3 ml) of intrathecal Ropivacaine in inguinal hernia surgery as compared to 18.75 mg (2.5 ml). There is less fluctuation of blood pressure and pulse rate with group 2(2.5 ml) as compared with group 1(3 ml). So this study proves that isobaric 0.75% ropivacaine 18.75 mg (2.5 ml) is sufficient for inguinal hernia surgery with minimum hemodynamic changes compared to 22.5mg(3ml).

Keywords –Subarachnoid block, inguinal hernia surgery, 0.75% isobaric Ropivacaine

Date Of Submission: 28-09-2018

Date of acceptance: 13-10-2018

I. Introduction

Spinal anaesthesia is a very old and popular anaesthetic technique, with a high success rate and a good safety profile. In order to further improve and understand the safety issues as well as the clinical **use** of spinal anaesthesia, new local anaesthetics and analgesic additives are being investigated for different applications. As practice of medicine focuses increasingly on outpatient care, spinal anaesthetics should provide shorter duration of action with adequate anaesthesia without compromising early ambulation and discharge. The main reasons for the wide use of spinal anaesthesia in our country are undoubtedly the shortage of anesthetic equipment's, the prohibitive cost of cylinders, gases and the scarcity of the trained anesthesiologists. Later the introduction of newer local anesthetics such as procaine, tetracaine, lignocaine, bupivacaine, mepivacaine etc. resulted in better and safer anaesthesia. In the past the chief disadvantage has been the unpredictable time element with the subarachnoid blockade. Newer local anesthetics, using refined modern techniques with sedatives, anxiolytics or even 'light' general anesthesia, these disadvantages are almost negated.

Ropivacaine was approved for a new route of administration, the intrathecal route, in the European Union in February 2004. The ideal spinal anaesthetic would provide rapid and adequate surgical anaesthesia together with early ambulation and ability to void to allow early discharge. Reports of transient radicular irritation (TRI) after lidocaine spinal anaesthesia prompted the search for alternatives and ropivacaine could be promising in this setting.[1] Ropivacaine was introduced into clinical practice in 1996, and has consistently demonstrated an improved safety profile over bupivacaine, with reduced CNS and cardiotoxicity. In addition it has a wide clinical utility at different doses for a wide range of indications. It has been shown to provide effective, well tolerated surgical anaesthesia via central neuraxial block, for major and minor nerve blocks and field blocks. It has also shown to have high-quality postoperative analgesia.[2]

Ropivacaine is a long-acting, enantiomerically pure (S-enantiomer) amide local anaesthetic, with a low lipid solubility which blocks nerve fibers involved in pain transmission (A δ and C fibres) to a greater degree than those controlling motor function (A β fibres)[3]

II. Materials and Method:

Ethical committee approval obtained. This is prospective, randomized, double-blinded study. All patients undergoing elective inguinal hernia considered for inclusion in the study if they fulfilled following criteria. The sample size was restricted to 60 due to time constraint allotted for this study.

Inclusion criteria:

- 1) Patients with age of 18-70 years.
- 2) Patients of either sex.
- 3) Body weight not more than 20% above ideal body weight.
- 4) Patients belonging to ASA grade I&II.

Exclusion criteria:

- A. Absolute: 1) Patient refusal.
- 2) Localised infection at skin puncture site.
- 3) Generalised sepsis (septicaemia, bacteraemia)
- 4) Coagulopathy.
- 5) Increased intracranial pressure.
- B. Relative :
 - 1) Localised controlled infection to regional technique site.
 - 2) Hypovolemia.
 - 3) C.N.S. disease.
 - 4) Chronic back pain.

The nature of study explained to patients and written informed consent was taken. Total 60 number of patients taken and divided in two groups. Each group containing 30 patients and receiving two different doses of Ropivacaine.

Group 1: patients receiving 22.50 mg (3 ml) 0.75% isobaric Ropivacaine intrathecal.

Group 2: patients receiving 18.75 mg (2.5 ml) 0.75% isobaric Ropivacaine intrathecal.

All patients will have relevant investigations like hemoglobin, complete blood count, bleeding time, clotting time, chest x ray and ECG in patients above 40 years and other relevant investigation depending upon comorbidities.

Premedication: All 30 min prior surgery

Tab. Ranitidine (150 mg) at night and morning on the day of surgery with sip of water.

Tab. Ondansetron (4 mg) at night and morning on the day of surgery with sip of water.

Tab. Midazolam (7.5 mg) on the day of surgery.

Following arrival in the anaesthetic room IV access was established in upper limb and intravenous fluid 500 ml ringer lactate infused. Non-invasive monitoring applied non-invasive blood pressure, ECG monitor, pulse oximetry, respiratory rate and skin temperature.

Patient placed in the sitting position. Under all aseptic precautions following skin infiltration with 1% lignocaine, a 25-gauge spinal needle inserted at the L2/3 or the L3/4 interspace. Correct needle placement was identified by free flow of cerebrospinal fluid and study drug injected. The spinal needle was removed and the patient placed supine to perform the initial assessments. The upper spread of sensory block was determined using pinprick method. Sensory block was assessed at 2 and 5 min post-injection and later on at 5-min intervals for 30 mins. Assessments were continued at 30-min intervals for the next 3 hours. The degree of motor block assessed at the same time points as sensory block using a modified Bromage scale (0=no motor block, 1=inability to raise extended legs, 2=inability to flex knees, 3=inability to flex ankle joints). Heart rate and arterial pressure were recorded using standard non-invasive techniques/monitors before intrathecal injection and thereafter at 1, 5, 10, 20, 30, 60, 90,120,150 and 180 min.

The onset of sensory block and motor block defined by interval between intrathecal administration and maximum pinprick score at T10 or Modified Bromage score of 3, respectively. The duration of sensory block at T10 is defined as the time of onset at T10 to time of regression to T12. The duration of motor block is defined as the time of onset of motor block from modified Bromage scale 3 to regression to modified Bromage scale 2.

III. Results

Data collected for the study was compiled and analysed statistically using following tests.

For comparison of demographic data on height and weight of the two groups, independent student 't' test was employed. Student 't' test was calculated using the formula.

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\frac{S_1^2}{n_1} + \frac{S_2^2}{n_2}}}$$

Where x_1 and x_2 are the means of group 1 and group 2 respectively for weight and height and s^2 is the pooled variance n_1 and n_2 represents the number of patients in group 1 and group 2 respectively. The results are presented in Table 1(a) and 1(b). For comparison of duration of surgery, median range taken and groups are compared with Chi square test. Results are presented in Table 2. For the comparison of duration of sensory block to T₁₀ level and motor block of grade 3, Chi square test was employed. Median, range and P- values for the significance of the difference between the group 1 and group 2 was taken into consideration. Results are presented in Table 3. 3(a) sensory block at T₁₀ and 3(b) motor block at grade 3. For the comparison of onset of sensory block at T₁₀ and onset of motor block at grade 3 median range taken, and groups were compared with chi square test. They are presented in 4 (a) and 4(b) respectively. Maximum sensory level time at T₆ was studied using median, range and P-value in group 1 and group 2. Chi square test was applied, results are presented in Table 5. And onset of maximum cephalad spread calculated with median range and groups were compared with chi square test. The result is presented in Table. 6. To compare blood pressure and pulse rate between groups and between time periods, two factor ANOVA test was used. They are presented in Table 7 and 8 respectively. The drug effects were found to be significant. The least significant difference at 5% level was worked out. To identify the significant effects, least significant difference was calculated using formula ,

$$\sqrt{2 / r \cdot ve} \times 5\% \text{ table } t,$$

where r is the number of replications and Ve is the error mean square from the ANOVA table.

The percentage cases of failed block and inadequate block for group 1 and group 2 are presented in table 9.

Complication encountered mentioned in Table. 10.

(1). There is no significant difference in the mean height and mean weight of the two groups ($p > 0.05$) indicating that the two groups are drawn from same population and they are comparable. Table.2 gives the result of comparison of duration of surgery between two groups. There is no significant difference in median duration of

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surgery of two groups ($p > 0.05$), indicating median duration of 41.7 minutes in group 1 and 41 minutes in group 2.

(2) For the comparison of duration of sensory block at T10, and motor block of grade 3, there is no significant difference ($p > 0.05$) in the median time of T10 in the two groups. The median duration of sensory block at T10 was 174 minutes in group 1 and 148 minutes in group 2.

Table 3(b) gives the results of the comparison of duration of motor block grade 3 in the two groups. There is no significant difference in the median time of motor block of grade 3 in the two groups ($p > 0.05$). The median duration of motor block at grade 3 in group 1 is 137 minutes and 148 minutes in group 2.

(3) There is no significant difference in median time of onset at T10 sensory level in the two groups ($p > 0.05$). Median time of onset for group 1 is 10 minutes and for group 2 is 10 minutes. There is no significant difference in onset of motor block at grade 3 in group 1 and group 2 ($p > 0.05$). Median time of onset for group 1 is 20 min and for group 2 is 20 minutes.

(4) There is no significant difference in the mean T6 timings between the 2 groups ($p > 0.05$).

(5) Table 6 depicts the maximum cephalad spread in both groups. There is no significant difference in median time of maximum cephalad spread in group 1 and group 2 ($p > 0.05$). Median time of maximum cephalad spread in group 1 is 20 minutes and in group 2 is 20 minutes.

(6) Table 7 gives the results of ANOVA of blood pressure between groups and between periods. It could be seen from the table that there is significant difference between groups ($p < 0.001$) and between time periods ($p < 0.001$). Blood pressure is significantly lesser in group 1 compared to group 2. Regarding blood pressure in different time periods, blood pressure is high during 1 to 5 minutes duration and then decreases and stabilizes from 20 to 180 minutes. ANOVA of pulse rate is presented in table 8. There is significant difference in pulse rate between groups ($p < 0.001$). Group 1 registered significantly lesser pulse rate compared to group 2. Regarding the time periods, pulse rate is high during 1 to 20 minutes and then decreases and stabilizes from 60 to 180 minutes.

(8) There was no complication seen both groups like bradycardia, hypotension, nausea and vomiting.

	GROUP	N	MEAN (centimetres)	VARIANCE	t	Df	P VALUE
HEIGHT (1a)	1	27	170.77	28.04	0.09	52	$P > 0.05$
	2	27	170.67	9.12			
WEIGHT (1b)	1	27	76.40	34.52	0.46	52	$P > 0.05$
	2	27	75.17	47.97			

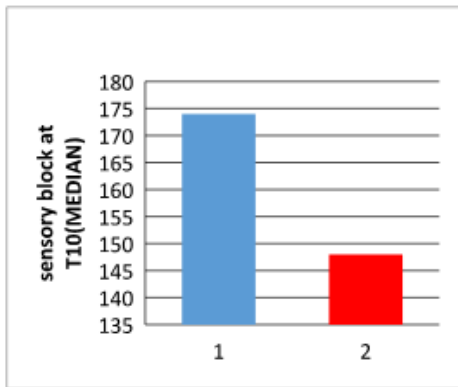
Table 1-Comparison of height and weight of two groups

GR	MEDIAN (minutes)	RANGE (minutes)	X ²	P VALUE
1	41.7 (N=27)	25-68	0.137	$> P.0.05$
2	41 (N=27)	30-65		

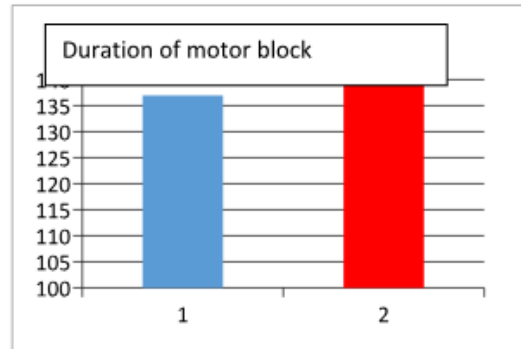
TABLE 2-Comparison of median duration of

	GROUP	MEDIAN (minutes)	RANGE (minutes)	P VALUE
T 10 (3a)	1(N=27)	174.0	110	P>0.05
	2(N=27)	148.0	100	
MOTOR BLOCK (3b)	1(N=27)	137.0	100	P>0.05
	2(N=27)	148.0	130	

Table 3 – Comparison of median duration of sensory block surgery of two groups. T10 and motor block of Gr.3.



(3a)

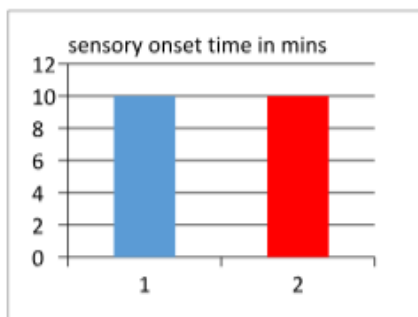


(3b)

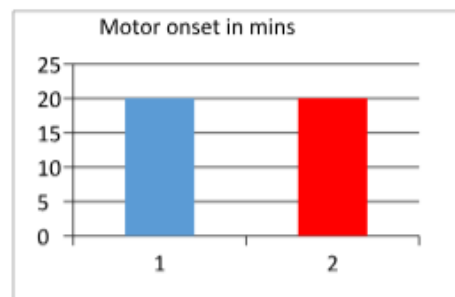
Table 3a: Duration of sensory block at T10 in both group both groups Table 3b: Duration of motor block of Grade.3 I

	GROUP	MEDIAN (minutes)	RANGE (minutes)	X ²	P VALUE
T10 sensory (4a)	1(N=27)	10	5-30	0.034	p>0.05
	2(N=27)	10	5-20		
Motor block (4b)	1(N=27)	20	10-30	1.399	p>0.05
	2(N=27)	20	10-30		

Table 4-Comparison of median time of onset of sensory block at T10 and motor block of Grade 3



(4a)



(4b)

Table 4a-Median time of onset of sensory level in group 1 and 2

Table 4b- Median time of onset motor block Grade 3 in group 1 and 2

	GROUP	MEDIAN (minutes)	RANGE (minutes)	P VALUE
T6	1(N=27)	86.0	70	P>0.05
	2(N=27)	97.0	70	

Table 5: Median duration sensory block at T6 in both groups

GROUP	MEDIAN (minutes)	RANGE (minutes)	X ²	P VALUE
1(N=27)	20	10-30	0.169	P>0.05
2(N=27)	20	10-30		

Table 6- Maximum cephalad spread n onset both groups

SOURCE	SS	Df	MS	F	P VALUE
TOTAL	79110.4	539			
GROUPS	1215.0	1	1215.00	9.31	P<0.001
PERIODS	8824.8	9	980.53	7.51	P<0.001
ERROR	69070.6	529	130.57		

Table 7- Anova of blood pressure

SOURCE	SS	Df	MS	F	P VALUE
TOTAL	42358.8	539			
GROUPS	4050.8	1	4050.80	76.23	P<0.001
PERIODS	10199.0	9	1133.20	21.32	P<0.001
ERROR	28109.0	529	53.14		

TABLE 8- Anova of pulse rate

SS- Sum of squares, df- Degree of freedom, MS-Mean square, F-Variance ratio.

	GROUP 1 (N=30)	GROUP 2 (N=30)
Failed block	2(6.7%)	1(3.3%)
Inadequate block	1(3.3%)	2(6.7%)

Table 9-Data of failed and inadequate SAB

	GROUP 1	GROUP 2
HYPOTENSION	NIL (0%)	NIL (0%)
BRADYCARDIA	NIL (0%)	NIL (0%)
NAUSEA	NIL (0%)	NIL (0%)
VOMITING	NIL (0%)	NIL (0%)

Table.10-data of complications

IV. Discussion

In this study we investigated the adequacy of surgical anaesthesia of two different doses of ropivacaine for patients who were posted for routine inguinal hernia surgery. The surgery lasted for an average for 40 minutes for which block of up to T10 was considered sufficient and motor block of grade 3 also noted. Three patients from group one and three patients from group 2 were not excluded from this study due to inadequate spinal action.

Onset of Sensory block: The sensory block was assessed using the pin prick method in this study. Time to attain T₁₀ level was taken as time of onset of sensory block. Median time of onset of sensory block in Group 1 which was 10 minutes. In group 2 it was 10 minutes. There was no statistically significant difference in time of onset of sensory block between Group 1 and Group 2 (p value > 0.05).

In a randomised, double-blind study by Wahedi W, Nolte H, spinal anaesthesia with ropivacaine was performed in two groups of 20 patients each (group I: Ropivacaine 0.5%, 3 ml = 15 mg; group II: Ropivacaine 0.75%, 3 ml = 22.5 mg) Onset of analgesia occurred at T12 and T10 level at 8 min and 12.5 min respectively in

group I, and at 12.5 min and 13 min, respectively, in group II; these differences were not statistically significant[4].

McNamee D., Parks L., McClelland A., Scott S., Milligan K., Ahlén K., and Gustafson used intrathecal Ropivacaine for total hip arthroplasty: double-blind comparative study with isobaric 7.5 mg/ml and 10 mg/ml solutions. Group 1 ($n=51$) received 2.5 ml of 7.5 mg ml⁻¹ ropivacaine (18.75 mg). Group 2 ($n=53$) received 2.5 ml of 10 mg ml⁻¹ ropivacaine (25 mg). The median time of onset of sensory block at the T10 dermatome was 2 min (range 1–25 min) in Group 1 and 2 min (range 1–21 min) in Group 2[5]

P.D.W.Fettes, G.Hocking, M.K.Peterson, J.F.Luck and J.A.W.Wildsmith has done study on comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia. Forty patients undergoing spinal anaesthesia for a variety of surgical procedures were randomly allocated to receive 3 ml of ropivacaine 5 mg ml⁻¹ in glucose 10 mg ml⁻¹ or 50 mg ml⁻¹ onset of sensory block at T10 was 10 minutes and 5 minutes respectively[6]

Onset of motor block: The motor block was assessed using modified Bromage scale. Time to attain motor block up to Bromage score 3 was taken as time of onset of motor block. Mean time of onset of motor block in Group 1 was 20 minutes, in group 2 was 20 minutes. There was statistically no significant difference in time of onset of motor block between group 1 and Group 2 ($p > 0.05$).

In a randomised, double-blind study by Wahedi W, Nolte H, Spinal anaesthesia with ropivacaine was performed in two groups of 20 patients each (group I: ropivacaine 0.5%, 3 ml = 15 mg; group II: ropivacaine 0.75%, 3 ml = 22.5 mg). Onset of motor block at Modified Bromage score 3 occurred after 15 minutes in group I and 12 min in group II respectively[4]

P.D.W.Fettes, G.Hocking, M.K.Peterson, J.F.Luck and J.A.W.Wildsmith has done study on comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia. Forty patients undergoing spinal anaesthesia for a variety of surgical procedures were randomly allocated to receive 3 ml of ropivacaine 5 mg ml⁻¹ in glucose 10 mg ml⁻¹ or 50 mg ml⁻¹ time onset of motor block was 10 minutes in both[6]

Duration of motor block: Duration of motor block at Modified Bromage score 3. Median duration of motor block in group 1 was 137 minutes. In Group 2 was 148 minutes. There was statistically no significant difference in duration of motor block between Group 1 & Group 2 (p value > 0.05). So adequate duration of motor block was obtained with group 1 and group 2 which was adequate for inguinal hernia surgery.

In a randomised, double-blind study by Wahedi W, Nolte H, Spinal anaesthesia with ropivacaine was performed in two groups of 20 patients each (group I: ropivacaine 0.5%, 3 ml = 15 mg; group II: ropivacaine 0.75%, 3 ml = 22.5 mg). Duration of motor block at Modified Bromage scale 3 was significantly longer (2.8 h) in group II than in group I (1.9 h)[4].

McNamee D., Parks L., McClelland A., Scott S., Milligan K., Ahlén K., and Gustafson used intrathecal ropivacaine for total hip arthroplasty: double-blind comparative study with isobaric 7.5 mg/ml and 10 mg/ml solutions. Group 1 ($n=51$) received 2.5 ml of 7.5 mg ml⁻¹ ropivacaine (18.75 mg). Group 2 ($n=53$) received 2.5 ml of 10 mg ml⁻¹ ropivacaine (25 mg). The median duration of complete motor block was significantly prolonged ($P < 0.05$) in Group 2 compared with Group 1 (1.9 versus 1.2 h, respectively)[5].

Duration of sensory block: Duration of sensory block at T10 was taken as duration of sensory block. Median duration of sensory block in Group 1 was 174 minutes, in Group 2 was 148 minutes. There is no significant difference ($p > 0.05$). Adequate duration of sensory block at T10 was present with both groups that is group 1 and group 2. In a randomised, double-blind study by Wahedi W, Nolte H, spinal anaesthesia with ropivacaine was performed in two groups of 20 patients each (group I: ropivacaine 0.5%, 3 ml = 15 mg; group II: ropivacaine 0.75%, 3 ml = 22.5 mg). Duration of analgesia in the segments relevant to the performed operations in group I at T10 1.6 h and T8 1.5 h and in group II at T10 2.3h, T8 1.8 h[4]

McNamee D., Parks L., McClelland A., Scott S., Milligan K., Ahlén K., and Gustafson used intrathecal ropivacaine for total hip arthroplasty: double-blind comparative study with isobaric 7.5 mg/ml and 10 mg/ml solutions. Group 1 ($n=51$) received 2.5 ml of 7.5 mg ml⁻¹ ropivacaine (18.75 mg). Group 2 ($n=53$) received 2.5 ml of 10 mg ml⁻¹ ropivacaine (25 mg). The median duration of sensory block at the T10 dermatome was 3.0 h (range 0.5–4.2 h) in Group 1 and 3.4 h (1.1–5.9 h) in Group 2 ($P=0.002$)[5].

P.D.W.Fettes, G.Hocking, M.K.Peterson, J.F.Luck and J.A.W.Wildsmith has done study on comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia. Forty patients undergoing spinal anaesthesia for a variety of surgical procedures were randomly allocated to receive 3 ml of ropivacaine 5 mg ml⁻¹ in glucose 10 mg ml⁻¹ or 50 mg ml⁻¹ duration of sensory block at T10 was 108 minutes and 115 minutes respectively[6].

Changes in vital parameters: ANOVA statistical method used for comparison of pulse rate and blood pressure between two groups. There is significant difference in two groups regarding blood pressure and pulse rate.

Group 1 there is lower blood pressure than group 2, and lower pulse rate as compared to group 2. But significantly there is no episode of hypotension or bradycardia in any ropivacaine group after subarachnoid block. There is slight fluctuation in pulse rate and blood pressure but never more than 30% fall of mean arterial pressure (less than 60 mm of Hg) and less than 50/min heart rate in ropivacaine group 1 and 2.

Van Kleef J., Veering B., Burm A., Spinal anaesthesia with ropivacaine: a double-blind study on the efficacy and safety of 0.5% and 0.75% solutions in patients undergoing minor lower limb surgery. The systolic blood pressure and heart rate changed significantly over time (3 h) in both groups, although these changes had no clinical relevance. Ephedrine was given for hypotension in one patient (receiving ropivacaine 0.5%). The intraoperative and postoperative electrocardiogram revealed no significant changes[3].

In a randomised, double-blind study by Wahedi W, Nolte H, Spinal anaesthesia with ropivacaine was performed in two groups of 20 patients each (group I: ropivacaine 0.5%, 3 ml = 15 mg; group II: ropivacaine 0.75%, 3 ml = 22.5 mg). Statistically significant changes in systolic and diastolic blood pressures (BP) and heart rate (HR) were recorded in both groups in the course of the study period. Relative BP changes were assessed in the individual patients. There were no statistically significant changes between the two groups with regard to relative changes in systolic and diastolic BP and HR. Bradycardia occurred a total of 13 times in 10 patients in group I and in 11 patients in group II. A BP decrease of > 20% was measured in 1 patient in each group[4].

McNamee D., Parks L., McClelland A., Scott S., Milligan K., Ahlen K., and Gustafson used intrathecal ropivacaine for total hip arthroplasty: double-blind comparative study with isobaric 7.5 mg/ml and 10 mg/ml solutions. Group 1 (n=51) received 2.5 ml of 7.5 mg ml⁻¹ ropivacaine (18.75 mg). Group 2 (n=53) received 2.5 ml of 10 mg ml⁻¹ ropivacaine (25 mg). Intrathecal ropivacaine produced an initial moderate decrease in arterial pressure. Intraoperative hypotension requiring treatment with intravenous ephedrine occurred in 24% of patients in both the 7.5 and 10 mg ml⁻¹ ropivacaine group. No patients in the ropivacaine 7.5 mg ml⁻¹ group required treatment for intraoperative bradycardia. Three patients in the ropivacaine 10 mg ml⁻¹ group required intravenous atropine 0.6 mg to correct symptomatic bradycardia in the intraoperative period[5].

Onset of maximum cephalic spread: Onset of maximum cephalic spread in group 1 and in group 2 was 20 min. There is no significant difference (p>0.05). The median time to reach the highest level of analgesia was 20 minutes in both groups.

Van Kleef J., Veering B., Burm A., Spinal anaesthesia with ropivacaine: a double-blind study on the efficacy and safety of 0.5% and 0.75% solutions in patients undergoing minor lower limb surgery. The median time to reach the highest level of analgesia was less than 20 min in both groups (ropivacaine 0.5% group, 15 min; ropivacaine 0.75% group, 18.8 min)[3].

In a randomised, double-blind study by Wahedi W, Nolte H, Spinal anaesthesia with ropivacaine was performed in two groups of 20 patients each (group I: ropivacaine 0.5%, 3 ml = 15 mg; group II: ropivacaine 0.75%, 3 ml = 22.5 mg) Onset of maximum cranial spread was 24 min in group I and 32 min in group II[4].

P.D.W.Fettes, G.Hocking, M.K.Peterson, J.F.Luck and J.A.W.Wildsmith has done study on comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia. Forty patients undergoing spinal anaesthesia for a variety of surgical procedures were randomly allocated to receive 3 ml of ropivacaine 5 mg ml⁻¹ in glucose 10 mg ml⁻¹ or 50 mg ml⁻¹ time to maximum cephalic spread was 25 minutes and 20 minutes respectively[6].

Other variables: Three patients each from group 1 and group 2 were excluded in this study.

In group 1, two patients had failure of block and one patient had inadequate level of anaesthesia and analgesia for surgery hence general anaesthesia was given in all three patients. Similarly in group 2 two patients had inadequate level of anaesthesia and one patient had failed block hence general anaesthesia was given in all three patients

Van Kleef J., Veering B., Burm A., Spinal anaesthesia with ropivacaine: a double-blind study on the efficacy and safety of 0.5% and 0.75% solutions in patients undergoing minor lower limb surgery. The present study 22.5 mg glucose-free ropivacaine, given as 3.0 mL of a 0.75% solution and 15 mg glucose-free ropivacaine given as 3.0 mL of a 0.5% solution for spinal analgesia provided similar results regarding onset and highest level of analgesia. However, the analgesic spread was extremely variable with both solutions, sometimes being restricted to the lumbosacral segments, sometimes extending to the upper thoracic segments. Low levels of analgesia were associated with tourniquet discomfort and explain most of the failures. The data suggest that the dose of glucose free ropivacaine has no effect on the spread of analgesia. However, the total duration of analgesia was clearly dose-dependent (P< 0.002), lasting longer with the more concentrated solution[3].

In a randomised, double-blind study by Wahedi W, Nolte H, Spinal anaesthesia with ropivacaine was performed in two groups of 20 patients each (group I: ropivacaine 0.5%, 3 ml = 15 mg; group II: ropivacaine

0.75%, 3 ml = 22.5 mg). In 5 patients (20%) in group I adequate analgesia for the planned surgical intervention was not obtained. In 4 of these 5 patients the required spread of the spinal block was not reached; in 2 general anaesthesia had to be performed and in 2 the required analgesia could be obtained by administration of an analgesic (fentanyl). In the 5th patient the level of spinal block was sufficient for the planned operation, however, the quality of analgesia was not, i.e., additional analgesics were required. In the group that received the 0.75% solution additive analgesics were necessary in 1 patient (5%) because a sufficient level of anaesthesia for the planned operation was not obtained. In group I all patients had a complete motor block in all three joints (hip, knee, and ankle); in group II, however, the motor block was incomplete in 6 patients[4].

McNamee D., Parks L., McClelland A., Scott S., Milligan K., Ahlen K., Gustafson used intrathecal ropivacaine for total hip arthroplasty: double-blind comparative study with isobaric 7.5 mg/ml and 10 mg/ml solutions. Group 1 ($n=51$) received 2.5 ml of 7.5 mg ml⁻¹ ropivacaine (18.75 mg). Group 2 ($n=53$) received 2.5 ml of 10 mg ml⁻¹ ropivacaine (25 mg). Anaesthesia was judged to be excellent in all patients, except for one in the ropivacaine 7.5 mg ml⁻¹ group who complained of deep wound pain approximately 5 min after skin incision despite a pre-operative sensory block to T10. General anaesthesia was instituted[5].

P.D.W.Fettes, G.Hocking, M.K.Peterson, J.F.Luck and J.A.W.Wildsmith has done study on comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia Forty patients undergoing spinal anaesthesia for a variety of surgical procedures were randomly allocated to receive 3 ml of ropivacaine 5 mg ml⁻¹ in glucose 10 mg ml⁻¹ or 50 mg ml⁻¹. The block was suitable for surgery in all patients. Fifteen patients in the glucose 10 mg ml⁻¹ group and 12 in the glucose 50 mg ml⁻¹ group requested intra-operative sedation. Three patients in each group developed mild localized tenderness at the site of lumbar puncture at 24 h, but there were no neurological symptoms and no patient developed a post dural puncture headache. Hypotension that required treatment with a single dose of ephedrine 3 mg in seven patients (10 mg ml⁻¹ group, $n=4$; 50 mg ml⁻¹ group, $n=3$), but repeated dosing was not necessary[6].

V. Conclusion

In comparable groups there is no significant advantage in choosing higher dose of 22.5 mg 3 ml of intrathecal ropivacaine in inguinal hernia surgery as compared to 18.75 mg (2.5 ml) in uncomplicated inguinal hernia not lasting more than one hour of surgical time. 2.5 mL is providing 148 minutes of motor block at modified Bromage Grade 3 and 3ml is providing 137 minutes of motor block at modified Bromage Grade 3 comparable relaxation for surgery. There is less fluctuation of blood pressure and pulse rate with 2.5 ml as compared with 3 ml.

So this study proves that isobaric 0.75% ropivacaine 18.75 mg (2.5 ml) is sufficient for inguinal hernia surgery with minimum hemodynamic changes.

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