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A comparative study of ropivacaine 0.5% versus ropivacaine 0.75% for spinal anesthesia in lower limb orthopedic surgery in ASA Grade – I/II adult patients: A prospective study

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ABSTRACT

Aims and Objectives: The aim of the study was to compare the clinical efficacy and safety of isobaric ropivacaine 0.5% and 0.75% in spinal anesthesia under: (a) Onset and duration of sensory and motor block, (b) duration of analgesia, and (c) adverse effects.

Methods: A total of 60 patients undergoing elective lower limb orthopedic surgery under spinal anesthesia were divided into two groups (I and II) of 30 each. Group I received 3ml of isobaric ropivacaine 0.5% Group II received 3 ml of isobaric ropivacaine 0.75%. The study parameters were recorded at baseline and then at specified intervals.

Statistics: By professional statisticians using SPSS 18 version. Student *t*-test was used for continuous variables, and Chi-square test was used for discrete variables.

Results: The onset of sensory blockage in Group I was 3.17 ± 1.29 min and 2.60 ± 1.19 min in Group II which was statistically not significant ($P > 0.05$). The onset of motor blockade in Group I was 3.90 ± 1.54 min and 3.10 ± 0.96 min in Group II which was statistically significant ($P < 0.05$). Median time to reach the highest level of analgesia was 12.4 ± 2.81 min in Group I, and 10.7 ± 2.56 min in Group II. The difference was statistically significant. Regression of sensory level to T10 dermatome in Group I was 99.64 ± 21.30 min and 139.66 ± 25.70 min in Group II which was statistically significant ($P < 0.05$). Duration of the motor blockade in Group I was 126 ± 14.53 min and 175 ± 30.60 min in Group II which was statistically significant ($P < 0.05$). The time of the first request of analgesics in Group I was 130 ± 16.24 min and 171.1 ± 32.77 min in Group II which was statistically significant ($P < 0.05$). There were no significant differences in the adverse effects of both drugs.

Conclusions: Intrathecal isobaric ropivacaine 0.75% in comparison to isobaric ropivacaine 0.5%: (1) Produces quicker onset of motor block and prolonged duration of sensory and motor block. (2) Does not alter hemodynamic stability. (3) Has no difference in the onset of sensory block.

Key words: Ropivacaine, spinal needle, Spinal anaesthesia

INTRODUCTION

Spinal anesthesia is unparalleled in the way in which a small quantity of drug can produce profound surgical anesthesia. Further, by altering the amount of drug, different types of spinal anesthetics can be produced. Low spinal anesthesia, a block below T10, carriers a different physiologic impact than does a block performed to produce higher spinal anesthesia (>T5). The block is unexcelled for lower abdominal or lower extremity surgical procedures.

The main reasons for the popularity of spinal block are that the block has well-defined endpoints, and the anesthesiologist can produce the block reliably with a single injection.[1-5]

Spinal anesthesia with hyperbaric bupivacaine 0.5% is a very popular method. Bupivacaine is a well-established and most widely used long-acting regional anesthetic, which like all amide anesthetics has been associated with cardiotoxicity when used in high concentration or when accidentally administered intravenously.[6-8]

This led to the discovery of ropivacaine in 1996, which is a long-acting regional anesthetic that is structurally related to bupivacaine. It is a pure S (-) enantiomer, unlike bupivacaine, which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profile.[9-12]

Ropivacaine was approved for a new route of administration, the intrathecal route, in the European Union in February 2004. The efficacy and tolerability of ropivacaine for spinal anesthesia in orthopedic surgery have been demonstrated in several studies. It has shown to produce sufficient surgical anesthesia and analgesia and consistently shown reduced side effect profile. Due to its propensity of blocking sensory fibers more readily,

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it serves all purposes for day care surgery. The patient can be mobilized early and discharged sooner. The formulation that is available for intrathecal administration is 0.75% ropivacaine. However, studies have shown that even 0.5% ropivacaine, when administered intrathecally, can provide good surgical anesthesia for lower abdomen, perineal, and lower limb surgeries with fewer side effects, but convincing evidence is lacking.[13-16]

The aim of this study is to compare the clinical efficacy and safety of two different concentrations of ropivacaine as a local anesthetic for spinal anesthesia.

MATERIALS AND METHODS

The study was approved by the hospital's ethical committee.

Inclusion Criteria

The following criteria were included in this study:

1. Patients of either sex.
2. Patients with ASA Grade I and Grade II.
3. Patients aged between 20 and 60 years.
4. Patients posted for elective orthopedic surgery.[17-23]

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients not fulfilling inclusion criteria.
2. Patients with severe systemic disease, metabolic disorder, neurological, congenital, or cardiovascular disease.
3. Patients with coagulation disorders.
4. Local sepsis at the site of spinal injection.
5. Patients allergic to local anesthetics.
6. Patient's refusal for spinal anesthesia.
7. Patients weighing >120 kg; patients with height <150 cm.[24-27]

Mode of Selection

Double-blind randomized selection. 60 envelopes were divided into two groups of 30 each. The drug to be given was mentioned inside the envelope. An envelope was randomly picked up just before the surgery. The envelope was opened by an anesthesiologist, and the drug was loaded by that person. Another person conducted the procedure of spinal anesthesia, and the observations were done by a third person who did not know what drug was given.

Equipment

1. One L.P. needle 25 G, Quincke type
2. 2 ml and 5 ml syringes
3. One draping towel
4. One small bowl
5. Sponge holding forceps
6. Gauze pieces
7. Betadine, savlon, and spirit solution
8. All equipment necessary for resuscitation was kept ready.[28-32]

Drugs

1. One 4 ml ampoule of ropivacaine plain 0.75%,
2. One 4 ml ampoule of ropivacaine plain 0.5%,
3. All drugs necessary for resuscitation
4. All intravenous (IV) fluids.

Pre-operative Period

On the eve before the surgery, all the patients were visited, and detailed pre-anesthetic examination including history, clinical examination, systemic examination of cardiovascular, respiratory, and central nervous systems and examination of the spine for deformity, infection was carried out.

The anesthetic procedure was briefly explained to the patient. An informed written consent was obtained from the patient. Routine investigations such as hemogram, total leukocyte count, differential leukocyte count, erythrocyte sedimentation rate, complete urine examination, random blood sugar, electrocardiogram, chest X-ray, blood grouping, blood urea, and serum creatinine were carried out. Patient's weight and height were also recorded.

Intraoperative Period

Once the patient was shifted to the operating room, the patient was connected to the routine monitors which included non-invasive blood pressure, pulse oximeter, and continuous electrocardiogram.

All resuscitation equipment such as intubation trolley with airways, laryngoscopes, and endotracheal tubes along with drugs such as atropine, ephedrine, thiopentone, fentanyl, and vecuronium midazolam was kept ready. The anesthesia machine was also checked along with the oxygen delivery system.

The patients were allocated into two groups, namely; Group I: 30 patients receiving 3ml of isobaric ropivacaine 0.5% and Group II: 30 patients receiving 3 ml of isobaric ropivacaine 0.75%. Baseline pulse rate, blood pressure, respiratory rate, and SPO_2 were recorded.

The patients were kept nil orally for 8 h before surgery. A wide bore IV access was obtained and secured on the morning of surgery. All patients were preloaded with 500 ml of Ringer's lactate before spinal anesthesia. The patients were then put in sitting position. Under strict aseptic precautions, lumbar puncture was performed by midline approach using disposable Quincke Babcock spinal needle 25G at L3–L4 intervertebral space.

Patients were continuously monitored using NIBP, pulse oximeter, and electrocardiogram.

After spinal anesthesia, the patient's pulse rate, systolic, diastolic, and mean BP were recorded at 0, 3, 6, 9, 12, 15, 18, 21, 24, 27, 30, 45, 60, 75, 90, 120, 150, and 180 min.

If the systolic arterial pressure decreased to <90 mm Hg, ephedrine, 6 mg, was given intravenously.

Bradycardia (heart rate <60 bpm) was treated with atropine sulfate, 0.3 mg IV.[33-38]

Assessment of Sensory Blockade

This was tested by pin-prick method. The time of onset was taken from time of injection of the drug into the subarachnoid space to loss of pin-prick sensation at any dermatome from T4 to L5. The time to achieve maximum sensory block was noted from the time of injection of a drug to loss of pin-prick sensation at highest dermatomal level. The time for regression of sensory level at T10

and then at surgical site was noted. Duration of sensory blockade was recorded from the time of onset to time of complete return of pin-prick sensation. Analgesics were avoided until the patient complained of pain. This was done to note the total duration of analgesia.[39-42]

Assessment of Motor Blockade

This was assessed by Bromage scale. The time interval between injection of the drug into subarachnoid space, to the patient's inability to lift the straight extended leg, was taken as onset time. The time to achieve maximum motor blockade was noted from the time of injection of the drug to maximum degree of motor block.

Duration of motor block was recorded from onset time to time when the patient was able to lift the extended leg.

Bromage Scale

0 - Full flexion of knees and feet.
1 - Just able to flex knees, full flexion of feet.
2 - Unable to flex knees, but some flexion of feet possible.
3 - Unable to move legs or feet.

The side effects such as shivering, hypotension, bradycardia, high spinal blockade, breathing difficulty, nausea, and vomiting were looked for.

Statistical Analysis

All data recorded were subjected to statistical tests to find the power of the study. Statistical analysis was done by SPSS version 18.0 (Chicago, IL, USA). The sample size was kept large enough ($n = 30$). Parametric data were reported as the arithmetic mean SD. Student t-test was used for continuous variables, and Chi-square test was used for discrete variables, with P value reported at the 95% confidence limit. $P<0.05$ was considered significant.[43-47]

OBSERVATIONS [TABLES 1-15, FIGURES 1-15]

The observations are shown in Tables 1-15 and Figures 1-15.

DISCUSSION

Ropivacaine is a new long-acting, enantiomerically pure (S-enantiomer), and amide local anesthetic with a high pKa and low lipid solubility. It is considered to block sensory nerves to a greater degree than motor nerves. Because of sensory and motor dissociation, ropivacaine should be a favorable local anesthetic for day-care surgery and could be associated with earlier post-operative mobilization than bupivacaine.[48-50]

This double-blind randomized study was conducted to compare two different concentrations of intrathecal ropivacaine in lower limb surgeries. The patients were selected at random, to avoid any kind of bias and to allow comparability of results obtained. This was a double-blinded controlled study where neither the patient nor the observer who recorded the parameters was aware of the group allocation and the drug received.

Patient Characteristics Across the Groups

The patients studied across the group did not vary much with respect to age, weight, sex, or height. These parameters were kept identical in both the groups to avoid variations in the intraoperative and post-operative outcome of the patients. The duration of all surgeries was intermediate, ranging from 45 min to 100 min.[51-55]

Changes in the Perioperative Cardiovascular Parameters

Heart rate, systolic and diastolic blood pressure in both the groups did not vary significantly. Cardiovascular changes were unremarkable throughout and did not varied much in the two groups, as were the volumes of fluid administered.

One patient in Group II who received 0.75% ropivacaine had transient bradycardia of <50 bpm at 60 min after SAB, which was treated with 0.3 mg atropine and improved immediately. [56-60]

His blood pressure at that time was 112/70 mmHg. This patient had a baseline heart rate of 47 beats per minute, and SAB was instituted after 0.3 mg of atropine i.v.[61-67]

Van Kleef *et al.,* in 1994, during a similar study comparing intrathecal ropivacaine 0.5% with ropivacaine 0.75% found that the hemodynamic changes between the two groups were of no clinical importance.[68]

Khaw *et al.,* in 2001, found that the incidence of hypotension was similar in a comparison of different doses of plain ropivacaine.[54]

Wong *et al.,* in 2004, have observed the same that there are no major cardiovascular changes in the two groups receiving plain ropivacaine in different doses compared to each other.[91]

Fettes *et al.,* in 2004, observed that cardiovascular changes were unremarkable in a comparison of plain and hyperbaric ropivacaine.[100]

Kallio *et al.,* in 2004, observed that the groups receiving plain ropivacaine did not have any differences in the hemodynamics after receiving different doses.[92]

From the above studies, we can conclude that use of 15 mg or 22.5 mg of ropivacaine intrathecally causes no gross hemodynamic disturbances.

Table 1: Age distribution of patients

Group	*N*	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	*t* test
0.5%	30	38.70	12.31	2.25	34.10	43.30	20.00	58.00	$P>0.05$
0.75%	30	39.10	11.51	2.101.53	34.80	43.40	20.00	59.00	Not significant
Total	60	38.90	11.82		34.85	41.95	20.00	59.00	

SD: Standard deviation, SE: Standard error

Changes in the Onset of Sensory and Motor Blockade

In the present study, the onset of sensory blockade in Group I was 3.17 ± 1.29 min compared to 2.60 ± 1.19 min in Group II which was statistically not significant ($P > 0.05$).

The onset of the motor blockade in Group I was 3.90 ± 1.54 min compared to 3.10 ± 0.96 min in Group II which was statistically significant ($P < 0.05$).[69-75]

Wong *et al.,* in 2004, opined that the onset of sensory and motor blocks was similar in two groups of ropivacaine.[91]

Lee *et al.,* in 2007, found that the onset of motor blockade was more reliable with the 0.75% ropivacaine.[101]

Time to Maximum Sensory Level

The median time to reach the highest level of analgesia was <20 min in both groups (ropivacaine 0.5% group, 12.4 ± 2.81 min and ropivacaine 0.75% group, 10.7 ± 2.56 min) but the difference was statistically significant.[76-80]

Maximum Sensory Level

Seven patients in 0.75% group had block up to T4 as opposed to only 2 in 0.5% group. The percentage of patients having a block at T4, T6, and T8 was higher in 0.75% group, and the difference was statistically significant ($P < 0.05$).

Time for Regression of Sensory Level

Although none of the patient required supplementary analgesia/anesthesia, the regression of sensory level to T10 dermatome in Group I was 99.64 ± 21.30 min compared to 139.66 ± 25.70 min in Group II which was statistically significant ($P < 0.05$). [81-86]

Van Kleef *et al.,* in 1994, found that the duration of analgesia at the level of T12 was significantly longer in the 0.75% group as compared to 0.5% group.[68]

This shows that ropivacaine 0.75% has a more reliable duration of analgesia.[87-90]

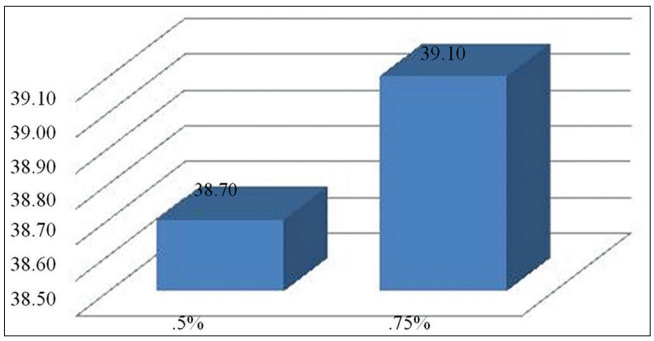

Figure 1: Age distribution of patients

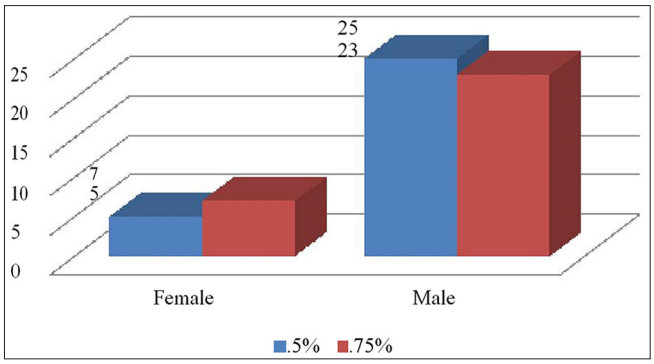

Figure 2: Gender distribution of patients

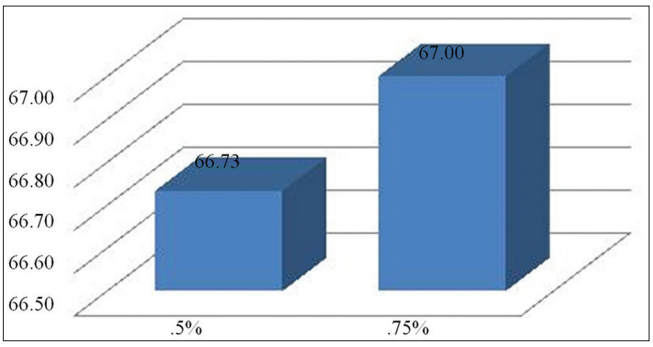

Figure 3: Weight distribution of patients

Table 2: Gender distribution of patients

Group	Gender	
	Female (%)	Male (%)
0.5%	5 (16.67)	25 (83.33)
0.75%	7 (23.33)	23 (76.67)
Total	12 (20.00)	48 (80.00)

χ^2 test; P>0.05 not significant

Table 3: Weight distribution of patients

Group	N	Mean	SD	SE	95% confidence interval for mean		Minimum	Maximum	*t*-test
0.5%	30	66.73	7.40	1.35	63.97	69.50	50.00	80.00	P>0.05
0.75%	30	67.00	6.62	1.21	64.53	69.47	55.00	80.00	Not significant
Total	60	66.87	6.96	0.90	65.07	68.67	50.00	80.00	

SD: Standard deviation, SE: Standard error

Table 4: Height distribution of patients

Height	N	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	*t* test
0.5%	30	158.70	5.06	0.92	156.81	160.59	150.00	170.00	P>0.05
0.75%	30	161.77	8.99	1.64	158.41	165.12	150.00	180.00	Not significant
Total	60	160.23	7.40	0.95	158.32	162.14	150.00	180.00	

SD: Standard deviation, SE: Standard error

Intensity and Duration of Motor Blockade

In the present study, the duration of the motor blockade in Group I was 126 ± 14.53 min compared to 175 ± 30.60 min in Group II which was statistically significant ($P < 0.05$).

Table 5: ASA grade distribution of patients

ASA grade	Grade 1 *n* (%)	Grade 2 *n* (%)
0.5%	19 (63.33)	11 (36.67)
0.75%	17 (56.67)	13 (43.33)
Total	36 (60.00)	24 (40.00)

χ^2 test; $P>0.05$ not significant

The 0.75% ropivacaine solution resulted in a higher frequency of complete motor block and a longer duration of motor block in the lower limbs.[92-95]

Van Kleef *et al.,* in 1994, observed that the greater propensity to produce a complete motor block, and the longer duration of analgesia and motor block produced by the 0.75% ropivacaine solution, should be suitable for orthopedic and vascular surgical procedures of intermediate duration, requiring an intense motor block.[68]

Kallio *et al.,* in 2004, studied the effects of plain ropivacaine 20 mg and 15 mg. They found that there was a significantly

Table 6: Sensory block onset

Group	*N*	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	*t* test
0.5%	30	3.17	1.29	0.24	2.69	3.65	1.00	6.00	$P>0.05$
0.75%	30	2.60	1.19	0.22	2.15	3.05	1.00	6.00	Not significant
Total	60	2.88	1.26	0.16	2.56	3.21	1.00	6.00	

SD: Standard deviation, SE: Standard error

Table 7: Time to max sensory block

Group	*N*	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	*t* test
0.5%	30	12.40	2.81	0.51	11.35	13.45	9.00	18.00	$P<0.05$
0.75%	30	10.07	2.56	0.47	9.11	11.02	6.00	18.00	significant
Total	60	11.23	2.91	0.38	10.48	11.99	6.00	18.00	

SD: Standard deviation, SE: Standard error

Table 8: Maximum sensory level

Maximum sensory level	*n* (%)				
	T4	T6	T8	T10	T12
0.5%	2 (6.67)	13 (43.33)	13 (43.33)	0 (0.00)	2 (6.67)
0.75%	7 (23.33)	14 (46.67)	5 (16.67)	3 (10.00)	1 (3.33)
Total	9 (15.00)	27 (45.00)	18 (30.00)	3 (5.00)	3 (5.00)

χ^2 test; $P<0.05$ not significant

Table 9: Sensory block duration at T10 (min)

Group	*N*	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	*t* test
0.5%	28	99.64	21.30	4.02	91.38	107.90	60.00	120.00	$P<0.05$
0.75%	29	139.66	25.70	4.77	129.88	149.43	90.00	180.00	significant
Total	57	120.00	30.92	4.10	111.79	128.21	60.00	180.00	

SD: Standard deviation, SE: Standard error

Table 10: Sensory block duration at surgical site (min)

Group	*N*	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	*t* test
0.5%	30	146.30	19.00	3.47	139.20	153.40	120.00	180.00	$P<0.05$
0.75%	30	200.00	38.06	6.95	185.79	214.21	90.00	240.00	significant
Total	60	173.15	40.28	5.20	162.74	183.56	90.00	240.00	

SD: Standard deviation, SE: Standard error

Table 11: Total duration of analgesia (min)

Group	*N*	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	*t* test
0.5%	30	130.00	16.24	2.97	123.94	136.06	100.00	160.00	$P<0.05$
0.75%	30	171.17	32.77	5.98	158.93	183.40	80.00	210.00	significant
Total	60	150.58	32.99	4.26	142.06	159.11	80.00	210.00	

SD: Standard deviation, SE: Standard error

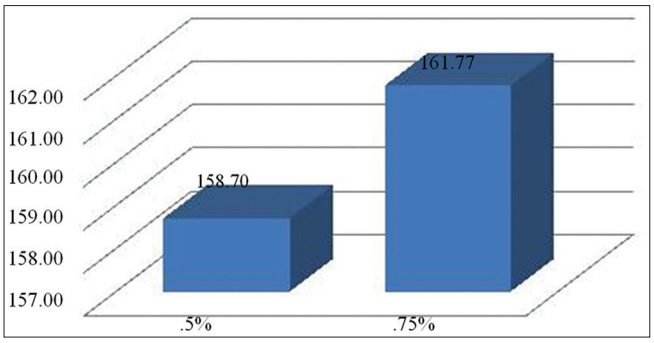

Figure 4: Height distribution of patients

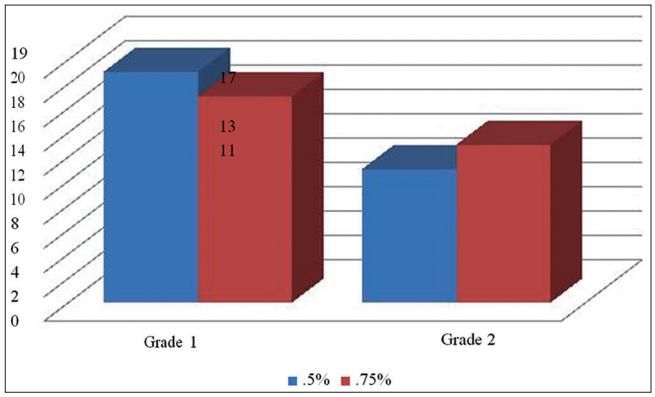

Figure 5: ASA grade distribution of patients

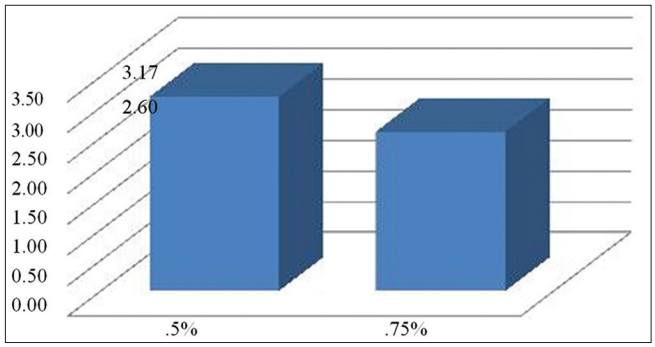

Figure 6: Sensory block onset (min)

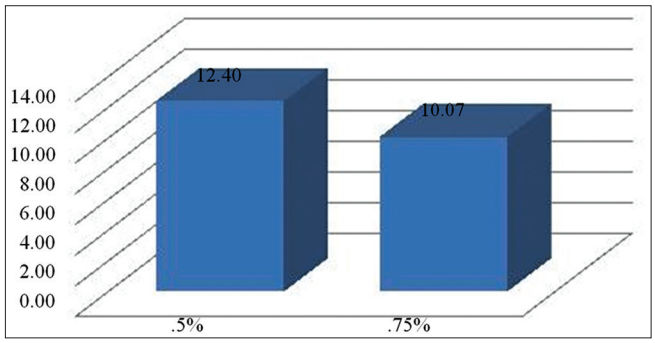

Figure 7: Time to max sensory block

longer duration of motor block with 20 mg than 15 mg of ropivacaine.[92]

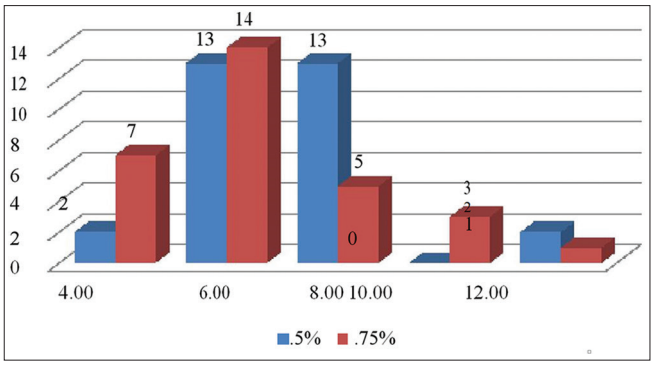

Figure 8: Maximum sensory level

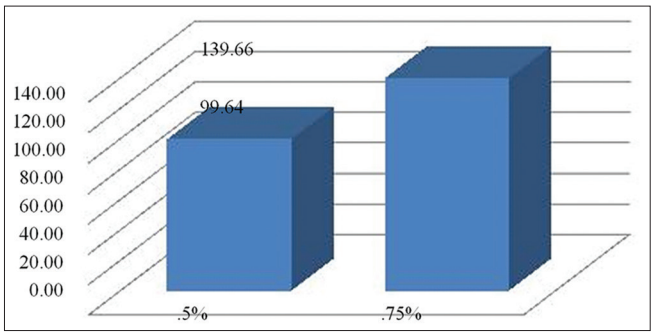

Figure 9: Sensory block duration at T10 (min)

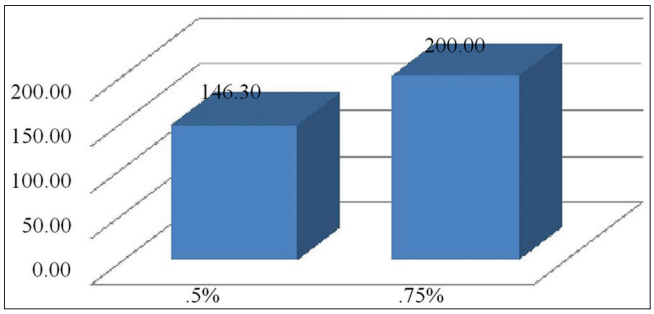

Figure 10: Sensory block duration at surgical site (min)

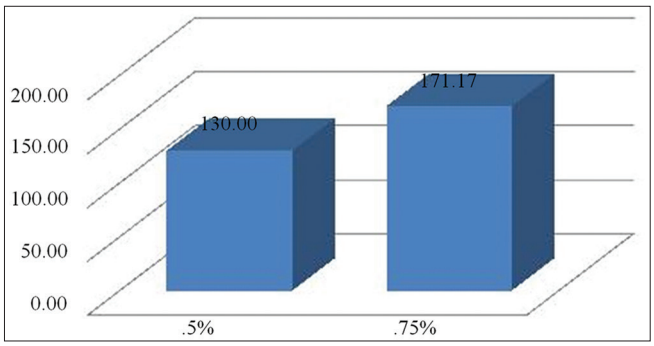

Figure 11: Total duration of analgesia (min)

Kallio *et al.*, in 2004, in another study comparing hyperbaric ropivacaine with plain ropivacaine, found that plain ropivacaine has a longer duration of the motor block than the hyperbaric solution.[101]

Table 12: Motor block onset (min)

Group	N	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	t test
0.5%	30	3.90	1.54	0.28	3.33	4.47	2.00	6.00	P<0.05
0.75%	30	3.10	0.96	0.18	2.74	3.46	2.00	6.00	significant
Total	60	3.50	1.33	0.17	3.16	3.84	2.00	6.00	

SD: Standard deviation, SE: Standard error

Table 13: Time to complete motor block (min)

Group	N	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	t test
0.5%	30	11.30	3.29	0.60	10.07	12.53	5.00	18.00	P<0.05
0.75%	30	7.17	3.21	0.59	5.97	8.36	5.00	21.00	significant
Total	60	9.23	3.84	0.50	8.24	10.22	5.00	21.00	

SD: Standard deviation, SE: Standard error

Table 14: Total duration of motor block (min)

Group	N	Mean	SD	SE	95% Confidence interval for mean		Minimum	Maximum	t test
0.5%	30	126.00	14.53	2.65	120.58	131.42	90.00	150.00	P<0.05
0.75%	30	175.00	30.60	5.59	163.57	186.43	90.00	210.00	significant
Total	60	150.50	34.27	4.42	141.65	159.35	90.00	210.00	

SD: Standard deviation, SE: Standard error

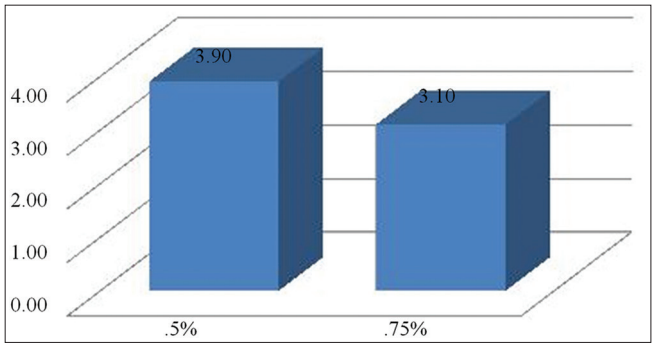

Figure 12: Motor block onset (min)

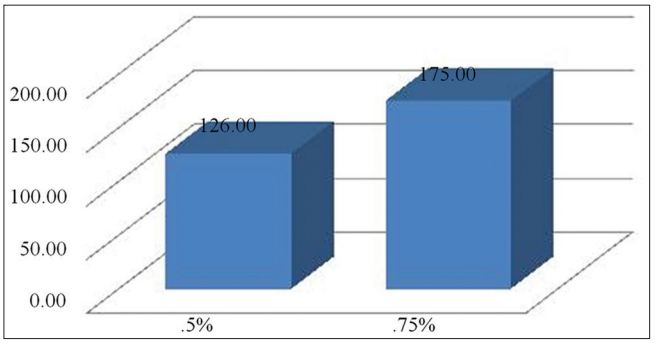

Figure 14: Total duration of motor block (min)

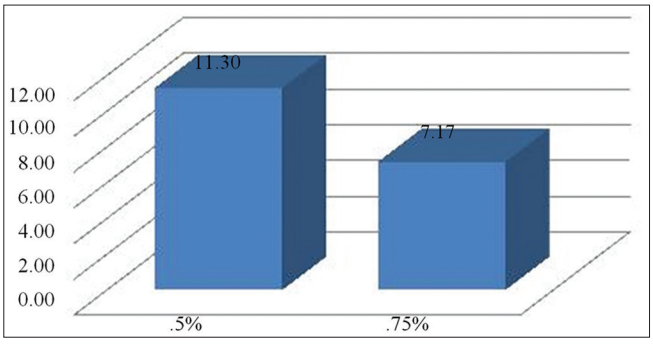

Figure 13: Time to complete motor block (min)

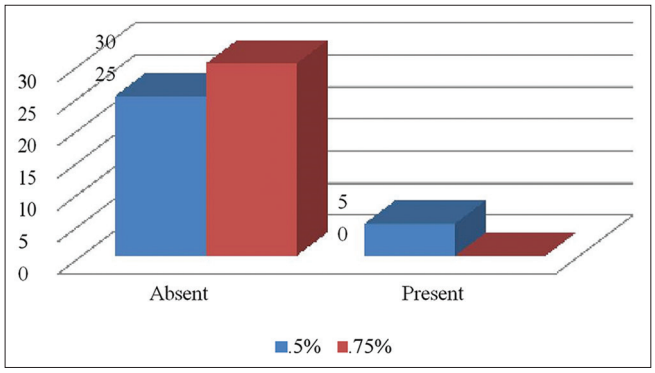

Figure 15: Incidence of adverse effects

Time of First Request of Analgesics

In the present study, the time of the first request of analgesics in group:

Group I was 130 ± 16.24 min compared to 171.1 ± 32.77 min in Group II which was statistically significant ($P < 0.05$).

Van Kleef *et al.,* in 1994, found that the time of the first request for analgesia was significantly longer in the 0.75% group as compared to 0.5% group. This shows that there was significantly longer period of analgesia with 0.75% ropivacaine.[68]

Adverse Effects

Two patients had shivering in both groups. One patient in Group II had bradycardia. Two patients complained of nausea in both the groups. There were no incidences of post-dural-puncture

Table 15: Adverse effects

Adverse	Absent *n* (%)	Present *n* (%)
0.5%	25 (83.33)	5 (16.67)
0.75%	22 (73.33)	8 (26.67)
Total	47 (78.30)	13 (21.70)

χ^2 test; $P>0.05$ not significant

headache in both groups. Six patients in Group II had hypotension as compared to only one in Group I.[97-99,101]

Wong *et al.,* in 2004, found that the incidence of shivering was more in the group receiving 33.75 mg plain ropivacaine than the group receiving 26.25% of plain ropivacaine.[91]

Thus, there were no major differences in the adverse effects in both groups.

SUMMARY AND CONCLUSIONS

Ropivacaine is a newer amide-type local anesthetic drug with the significantly enhanced safety profile and a propensity to block sensory fibers more readily. For these reasons, it has become a drug of interest for day care surgeries.

The present study was conducted on 60 patients, with ASA Grade I or II physical status, planned for lower limb orthopedic surgery. Patients were randomly allocated into two Groups I and II.

Group I patients received 3.0 ml of 0.5 % isobaric ropivacaine.

Group II patients received 3.0 ml of 0.75 % isobaric ropivacaine.

The patients of both groups were demographically comparable. After obtaining written informed consent and preloading with IV ringer lactate, patients were induced using 25 G Quincke type spinal needle in sitting position under full aseptic precautions.

All patients were monitored in the same way throughout surgery and postoperatively. Onset and duration of sensory and motor block, hemodynamic parameters were recorded at regular intervals.

With this study, we conclude that intrathecal isobaric ropivacaine 0.75% in comparison to isobaric ropivacaine 0.5%:

1. Produces quicker onset of motor block and prolonged duration of sensory and motor block.
2. Does not alter hemodynamic stability.
3. Has no difference in the onset of sensory block.

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