# Intrathecal ropivacaine with fentanyl for LSCS Comparison of hyperbaric and isobaric solution

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**ABSTRACT**

*We compared the characteristics of spinal anesthesia with plain and hyperbaric ropivacaine for LSCS. Method:- In this prospective randomized double blind study 60 pregnant patient of ASA physical status1&2 were given 15mg of either isobaric ropivacaine(n=30) or hyperbaric ropivacaine(n=30) in glucose 8% along with fentanyl 25mcg intrathecally for LSCS. The characteristics of spinal anesthesia, hemodynamic parameters, quality of anesthesia and muscle relaxation as well as duration of post-operative analgesia were compared. RESULT: - There were no significant difference in median time to onset of sensory block at T6 (plain6.33±4.62 vs. hyperbaric 4.52±2.84 minutes; p>0.05), maximum sensory level achieved (plain 8.10±3.92 vs. Hyperbaric 6.63±2.47 min, p>0.05) and onset of grade 3 motor block (plain 8.20±5.38 vs. hyperbaric 6.10±2.38 minutes; p>0.05). Median maximum extent achieved was also comparable, but in group H duration of sensory (plain 206.23±24.42 vs. hyperbaric164.50±30.29 min., p<0.001) and motor blockade (plain170.50±39.19vs hyperbaric 133.33±30.17min; p<0.001) and duration of post-operative analgesia were significantly shorter. Incidences of hypotension were more in the group H (43.33%) compared with group I (23.33%). Quality of anesthesia and muscle relaxation was satisfactory in most patients in either group. Total duration of analgesia was 218.37±28.74min in group H and 239.30±28.28min. In group I(p<0.05). CONCLUSION: - 15mg of (0.75%) hyperbaric ropivacaine provides similar, reliable and effective quality of spinal anesthesia with shorter duration of sensory and motor block, when compared with 15mg of (0.75%) isobaric ropivacaine.*

**Keywords:** *LSCS; Ropivacaine; Hyperbaric; Isobaric; Spinal Anaestesia.*

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## INTRODUCTION

Obstetric anaesthetists are faced with the unique situation while providing anaesthesia for caesarean sections, where they have to provide care for both the mother and the unborn baby. Central neuraxial block is preferred over general anaesthesia as it is associated with reduced maternal mortality & morbidity and faster neonatal-maternal bonding. Simplicity of technique, rapidity of onset and reliability of block makes spinal anaesthesia more popular than epidural anaesthesia. Local anesthetic commonly used for spinal anesthesia are lignocaine, bupivacaine, levobupivacaine, and ropivacaine. In the subarachnoid block for caesarian section it is very important to used local anesthetic providing shorter duration of anaesthesia with longer duration of analgesia and minimal side effects or toxicity to mother and fetus; ropivacaine seems to have this profile. Nowadays, ropivacaine is gaining increasing popularity because of reduced risk of central nervous system and cardiac toxicity, early ambulation and good quality of post-operative analgesia.

Use of ropivacaine for spinal anaesthesia has been described for obstetrics and non-obstetrics patients[(1)]. This study was undertaken with the idea of increasing baricity of ropivacaine by addition of glucose would change the clinical characteristics of subarachnoid block after intrathecal injection[(2)]. Fentanyl has been used as an adjuvant to local anesthetics for enhancement of analgesia without intensifying motor and sympathetic block of spinal anesthesia, thus resulting in lower incidence of hypotension, early recovery and mobilization and to decrease the dose of local anesthetic[(3)].

The present study was conducted to evaluate the efficacy intrathecal hyperbaric ropivacaine compared to isobaric ropivacaine in patients undergoing cesarean section with regard to onset and duration of sensory & motor blockade, hemodynamic effects, quality of anesthesia and muscle relaxation, duration of post operative analgesia and side-effect if any.

## METHOD

A prospective randomized double blind study was conducted on 60 pregnant patient of ASA class 1&2, between the age group 18-40 yrs and having height 145-165cm undergoing LSCS. Double blinding was done by – The person assessing the patient was blinded for the group to which patient belongs(drug was prepared by anaesthesiologist who was not involved in subsequent assessment). A detailed preanaesthetic check–up was done before surgery. The procedure to be performed was

explained to patient & patient's relatives and informed written consent was taken. Patients with contraindication to spinal anaesthesia and complicated pregnancies, preterm, preeclampsia, eclampsia, multiple pregnancies, were excluded because of unpredictable outcome of neonate and higher risks of anaesthesia due to obstetric conditions. All patients were premedicated with Inj. Ranitidine 50mg i.v., Inj.ondesetron 4mg i.v. and Inj. Glycopyrrolate 0.2mg iv. Preloading was done with inj. Ringer lactate 15ml/kg.

Patients were randomly and equally divided into 2 groups (randomization was done by computer generated numbers):

1) Group H (Hyperbaric ropivacaine): isobaric ropivacaine (0.75%) 15 mg (2ml) + 25mcg fentanyl (0.5ml) + 50% of dextrose 0.5ml=3ml
2) Group I-(isobaric ropivacaine): isobaric ropivacaine (0.75%) 15 mg (2ml) + 25mcg fentanyl (0.5ml) + normal saline 0.5ml=3ml

After taking patient on operation table, non invasive blood pressure, ECG monitor and pulse oxymeter were applied and baseline pulse rate, blood pressure, RR and $SPO_2$ were recorded. Under strict aseptic precautions spinal anesthesia was given in L3-L4 space with 23/25 gauge spinal needle in left lateral position. Immediately after spinal anesthesia patient was turned supine. The sensory blockade was assessed by pin prick method and motor block was assessed by using a modified Bromage Scale (0=no block, 1=inability to raise extended leg, 2 = inability to flex knee, and 3 = inability to flex ankle and foot), every 2 minutes till highest sensory and motor level was achieved. (highest level were considered as same sensory and motor level for 3 consecutive readings.) Then every 5 minutes till 30 minutes & then every 15 minutes for rest of study period. The following variables were recorded: Time to achieved sensory block at T6; Highest sensory level achieved; Time to max. level of block; Time to 2 segment regression of sensory block from maximum block; Time to complete sensory regression. Maximum motor block achieved; Time to onset of maximum motor block. Duration of motor block was assessed by time to highest scale of motor block to complete recovery; ECG and $SPO_2$ were monitored continuo-usly while BP and pulse were monitord every 2 minutes for 1$^{st}$ 10 minutes, every 5 minutes during intraopertive period and every 10 minutes for rest of study period. To judge the quality of anaesthesia, patient were assessed for feeling of sensation during the operation and were graded as under groups:

A. No sensation throughout the operation.
B. Sensation on manipulation of uterus but no pain
C. Mild pain during operation but no need of analgesia.
D. pain & need of analgesia.

Group A consider as excellent analgesia, Group B & C consider as good analgesia, Group D consider as poor analgesia.

Group D patients were given Inj. Ketamine 10mg iv which was repeated after 5min on request. (this patient was included in study.) Even after 2 doses of ketamine if patient complained of pain GA was supplemented and considered as a fail case. If adequate level of sensory blocked (T6) was not achieved, patient was excluded from study.

Post operatively patient was monitored in recovery room every 15 minutes for regression of motor and sensory effects. Duration of analgesia was assessed by time from injection of intrathecal solution to the first analgesic request.

Side effect like Hypotension (systolic blood pressure systolic BP < 80 mmHg) was treated with IV bolus of RL and Inj. ephedrine 6mg IV bolus. Bradycardia (pulse rate <50 / min) was treated with Inj. Atropine 0.6 mg iv, Incidences of Nausea – vomiting, pruritus were recorded and treated symptomatically.

Quality of muscle relaxation was assessed by obstetrician and graded as Excellent, Satisfactory and Unsatisfactory. At the end of surgery, patients were asked for level of satisfaction and graded as Poor, Good and Excellent**.** Apgar score was monitored at 1 & 10minutes. Patients were followed on post operative day 1 & 5 were evaluated for side effect like headache, Back pain and Transient neurological symptoms.

## STATISTICAL ANALYSIS

The collected data were analyzed by using statistical software namely statistical product and service solutions (SPSS). Data are presented as median (range), mean (SD), or frequencies as appropriate. The unpaired't' test was used for intergroup comparison. Probability values <0.05 were considered significant. All data were presented as mean (SD) except highest sensory level achieved for which Chi- $X^2$ test was applied and for patients Satisfaction and quality of intra-operative muscle relaxation 'Z' test was applied.

## RESULTS

All the parturient in our study groups were comparable with respect to age, weight and height. Two patients from an isobaric group did not achieved required level of sensory block. We considered them as failed case. But we repeated both the cases so, all statistical analyses were still based on 30 patients in each group.

**Table 1**

| | GROUP H | GROUP I |
|---|---|---|
| **AGE (Years)** | **25.7±4.3** | **23.63±3.44** |
| **HEIGHT(cms)** | **152.63±4.7** | **154.23±5.01** |
| **WEIGHT(kg)** | **55.53±7.63** | **55.27±7.39** |

**Sensory & motor block characteristics**

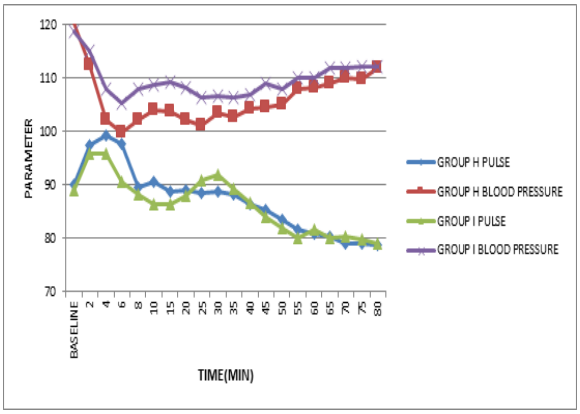
Mean time to achieve **T6 sensory analgesia** was comparable in both groups. (P>0.05) The mean time to attain **maximum sensory level** was comparable in both groups. (P>0.05). The median maximum sensory level achieved was similar in both groups. Two patients in hyperbaric ropivacaine Group and one patient of isobaric group had sensory level of T2 but no patient had sensory level above T2. This variation in the degree of spread of sensory block may be attributed to baricity[2]. Mean time to **regression of sensory level by 2 segments** (77.00 ± 26.46 vs. 100.80 ± 28.20min) and mean time to **complete sensory regression** (164.50±30.29 vs. 206.23±24.42min) were signify-cantly shorter in Group H as compared to Group I. Mean **total duration of sensory analgesia** was 218.37 ± 28.74min in group H and 239.30 ± 28.28min in group I. Mean time to **complete motor block** (6.10±2.38 vs. 8.20±5.38 min.) and Total **duration of motor block** (133.33 ± 30.71 vs. 170.50 ± 39.19 mins.) was significantly shorter in group H as compared to Group I. (p<0.001).

**Table 2**

| Time interval | Group H (n=30) Mean±SD | Group I (n=30) Mean ±SD | P value |
|---|---|---|---|
| Time to achieve T6 sensory level ( min) | 4.52±2.84 | 6.33±4.62 | >0.05 |
| Time to achieve highest sensory level ( min) | 6.63±2.47 | 8.10±3.92 | >0.05 |
| Time to 2 segment regression(min) | 77±26.46 | 100.8±28.2 | <0.05 |
| Time to complete sensory regression | 164.5±30.29 | 206±24.42 | <0.001 |
| Onset of grade 3 motor block (min) | 6.10± 2.38 | 8.20±5.38 | >0.05 |
| Time of return to Bromage 0 (min) | 133.33±30.71 | 170.50±39.19 | <0.001 |

**Hemodynamic Characteristics**

The baseline mean pulse rate and blood pressure were comparable between the groups. The mean value of pulse rate didn't show significant change from baseline values. Both groups have shown significant fall in systolic and diastolic blood pressure. The incidence of hypotension were more frequent in group H (43.33%) than in group I (23.33%) which were treated with injection ephedrine 6 mg bolus intravenously followed by infusion of crystalloids. One patient in Group H(3.33%) and two patients in Group I had Bradycardia which was responded to bolus of injection atropine 0.6 mg intravenous.




**Intra operative analgesia and muscle relaxation**

Most patients in either group (93.33% patients in group H and 86.66% patients in group I) had satisfactory analgesia. Two parturients in Group H and 4 from group I experienced pain during intraoperative period. Out of this, 2 patients of group H and 3 patients of group I had **VAS** > 3 and required a rescue analgesia in the form of ketamine 10mg IV. In one patient of group I, discomfort was relieved by just assurance. Most patients in Group H 28(86.66%) and all the patients in Group I 30(100%) had either excellent or satisfactory muscle relaxation.

**Table – 3**

| Assessment Parameter | Group H | Group I |
|---|---|---|
| a. Quality of Intraoperative Muscle Relaxation | | |
| Excellent | 13 (43.33%) | 25 (83.33%) |
| Satisfactory | 13 (43.33%) | 5 (16.66%) |
| Unsatisfactory | 4 (13.33%) | 0 (0) |
| b. Patient Satisfaction | | |
| Excellent | 10 (33.33%) | 8 (26.66%) |
| Good | 18 (60%) | 18 (60%) |
| Poor | 2 (6.66%) | 4 (13.33%) |

**Neonatal outcome and patient satisfaction**

APGAR score was similar in both groups. All neonates cried immediately after birth and had **mean APGAR score** of 9/10 at 1 minute and 10/10 at 5min. Patient satisfaction were comparable in both groups.

**Side effects**: Four (13.33%) patients in the group H had nausea or vomiting, compared with two (6.66%) patients in Group I which were treated with inj. Ondancetron 4mg IV. Incidences of pruritus were higher in Group H compared to Group I (13.33% vs 10%) which were treated with inj. phenaramine IV. Shivering was observed in one patient (3.33%) in

Group H while none of the patient in Group I. None of the patients had respiratory depression or high block (>T2) in any of the groups.

| | Group H (n=30) | | Group I (n=30) | |
|---|---|---|---|---|
| | NO. | % | NO. | % |
| Hypotension | 13 | 43.33 | 7 | 23.33 |
| Nausae and Vomiting | 4 | 13.33 | 2 | 6.66 |
| Shivering | 1 | 3.33 | 0 | 0 |
| Bradycardia | 1 | 3.33 | 2 | 6.66 |
| Respiratory Depression | 0 | 0 | 0 | 0 |
| High Block | 0 | 0 | 0 | 0 |
| Itching | 4 | 13.33 | 3 | 10 |

## DISCUSSION

We found that the rate of onset and maximum level achieved of sensory and motor blockade were comparable in both groups. Mean time to **regression of sensory level by 2 segments** from highest sensory level attained and mean time **to complete sensory regression** was significantly shorter in group H as compared to group I ( p<0.001). We have choosen T6 level of sensory blockade as an arbitrary study parameter assumed to represent sufficient block level for patient undergoing LSCS. In this respect, adequate level of sensory blockade was achieved in all patients of Group H but two patients in Group I needed general anaesthesia because the sensory block was insufficient for surgery. **Kim S. Khaw[(2)] et al (2002)** observed the cephalic spread and reliability with hyperbaric ropivacaine as compared to isobaric ropivacaine. Hyperbaric solution tends to spread by gravity while isobaric (plain) solution would not have such gravity assisted spread and concentration at segment near site of injection. As hips wider than shoulder in female, lateral position result in head down tilt which may be exaggerated in pregnancy. So, during spinal anaesthesia in lateral position hyperbaric solution tends to spread in cephalic direction and isobaric solution tends to concentrate in lumbar segments.

Many studies (**Rajni Gupta[(4)] et al (2013) Kim S. Khaw[(2)] et al(2002) J. B. Whiteside et al[(5)] (2001)**) have reported that solution of hyperbaric ropivacine had faster rate of onset and offset of sensory and motor blockade with hyperbaric solution compared with plain solution but **H. Kallio[(6)] et al.(2004)** found that hyperbaric and plain ropivacaine 15 mg. when given intrathecally, did not differ in the median onset of analgesia to T10, and the time to reach the highest level of sensory block, for lower limb surgery. **P.D.W.Fettees[(7)] et al (2004),** compare 15mg of plain and hyperbaric solution for elective perineal surgery and found that hyperbaric ropivacaine produce more rapid onset sensory block and the median time to onset of lower limb motor block.

**P.D.W.Fettees[(7)] et al (2004), Rajni Gupta[(4)] et al(2013)**; **Helena Kallio[(6)] et al(2004); Kim S. Khaw[(2)] et al(2002)** observed that median time to complete regression of sensory block and motor blocked were significantly shorter in hyperbaric group compared to isobaric group. Total **duration of motor block** was significantly shorter in group H as compared to group I (p<0.001). This was also noted by **Kim S. Khaw et al[(2)] (2002)** mean time taken for each grade of motor block to recover was faster in hyperbaric ropivacaine compared to plain group(p<0.001). **P.D.W.Fettees[(7)] et al(2004),** median times to complete regression of motor block were longer in the plain group. **Helena Kallio[(6)] et al(2004).**observed that, median onset of complete motor block and the median offset of motor block was faster in hyperbaric ropivacaine group compared with isobaric group(P<0.001).

**Intra-operatively pain** was experienced by two parturients in Group H and 4 from group I. Out of this, 2 patients of group H and 3 patients of group I had **(VAS**) visual analogue scale > 3 and required a rescue analgesia in the form of ketamine 10mg IV. One patient in group I, discomfort was relieved by just assurance.

Addition of glucose to isobaric ropivacaine increases its density that result in an equal distribution of the drug and increase height of the block while isobaric ropivacaine produces less intense, unpredictable, and variable height of block[(5)], therefore, patient of isobaric group felt some discomfort during surgery so supplementation of analgesia and sedation with ketamine was required l in a few patients.

Similarly, several studies (**P.D.W.Fettees[(7)] et al(2004), Rajni Gupta[(4)] et al(2013); Kim S. Khaw[(2)] et al(2002)**)comparing hyperbaric and isobaric ropivacaine for spinal anaesthesia show higher incidences of inadequate block requiring general anaesthesia supplementation in isobaric group compared to hyperbaric group. In our study mean **total duration of sensory analgesia** was shorter in group H compared to group I.(p<0.05). **Kim S. Khaw[(2)] et al(2002)** observed that the time for spinal injection to the time for the first analgesic request was similar between the groups and this is contrast with our study.

## CONCLUSION

15mg of (0.75%) hyperbaric ropivacaine provides similar, reliable and effective quality of spinal anaesthesia with shorter duration of sensory and motor block, without compromising neonatal outcome and minimal side effect but associated with

increased incidences of hypotension which can be treated easily; when compared with 15mg of (0.75%) isobaric ropivacaine.

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