A Comparative Study of Plain and Hyperbaric Solution of Ropivacaine for Spinal Anaesthesia in Minor Gynaecological and Urological Surgeries

Irfan Waris1, Imran Khan KD2

1Assistant Professor, Department of Anesthesiology, KBNIMS, Kalaburgi, Karnataka, 2Chief Anesthesiologist and Intensivist, IQRA Hospital, Gokak, Karnataka.

Abstract

**Background:** To compare the clinical effects of 3ml of intrathecal hyperbaric ropivacaine 0.5% (2ml of 0.75% plain ropivacaine and 1ml of 25%dextrose) with 3ml of plain ropivacaine 0.5% (2ml of 0.75% plain ropivacaine and 1ml of 0.9% normal saline) for spinal anaesthesia in minor gynaecological and urological surgeries. **Subjects and Methods:** 60 patients belonging to ASA physical status I & II scheduled for minor gynaecological and urological surgeries under spinal anaesthesia were randomly selected for the study and are divided into two groups of 30 each. Group H patients received 3 ml of intrathecal hyperbaric ropivacaine 0.5% (2 ml of 0.75% plain ropivacaine and 1 ml of 25% dextrose). Group P patients received 3 ml of plain ropivacaine 0.5% (2 ml of 0.75% plain ropivacaine and 1 ml of 0.9% saline). **Results:** There was significant difference between the two groups in mean time to onset of sensory block at T10, 257.5 ± 23.03 sec with group H and 478.0 ± 16.48 sec with group P, (P<0.0001). Total duration of sensory block was 201.7 ± 8.64 min in group H and 261.17 ± 8.27 min in group P, which is significant (P<0.0001). Mean time of onset of motor block was 355.50 ± 16.83 sec in group H and 568.33 ± 2.76 sec in group P, which is significant (P<0.0001). Duration of motor block was 127.33 ± 6.53 min in group H and 168.83 ± 8.27 min in group P which is clinically and statistically significant (P<0.0001). Hemodynamic parameters were comparable in both groups. **Conclusion:** Addition of glucose to plain ropivacaine increases the speed of onset of both sensory and motor block, and also increases the speed of recovery from sensory and motor block in minor gynaecological and urological surgeries. Plain solutions are less reliable for surgery above a dermatomal level of T10.

Keywords: Ropivacaine, Spinal Anaesthesia, Urological Surgeries.

Corresponding Author: Dr. Imran Khan KD, Chief Anesthesiologist and Intensivist, IQRA Hospital, Gokak, Karnataka.

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Introduction

Day care surgery demands the highest standards of professional skills and organization. Although, the operations could be minor, an anaesthetic is never minor. Day care surgery has now become an accepted method of treatment for a number of surgical patients. Preliminary work has shown that ropivacaine provides spinal anaesthesia of shorter duration than bupivacaine, and may be of particular use in the day-care setting. However, there are few data comparing the actions of plain and hyperbaric solutions of this drug. The disadvantages of spinal anaesthesia with lidocaine and bupivacaine include hypotension and its associated intraoperative nausea and vomiting. There are clinical reports about bupivacaine related cardiac toxicity, like ventricular dysrhythmias. Therefore, a newer drug was always in need to avoid the bupivacaine related toxicity, at the same time, to have more favorable results than the conventional drug, bupivacaine in day care surgeries. Ropivacaine is a relatively new amino amide long acting enantiomerically pure(s-enantiomer) local anaesthetic with high pka and low lipid solubility, and it is considered to block sensory nerves to greater degree than motor nerves and having similar local anaesthetic properties and chemical structure to that of bupivacaine. Ropivacaine being comparatively less cardio toxic, also produces minimal motor blockade of shorter duration which relieves the psychological distress of being immobile for a longer period of time and helps early mobilization postoperatively. The current study was designed to compare the plain and hyperbaric solution of ropivacaine for spinal anaesthesia in minor gynaecological and urological surgeries and their usefulness in day care setting.

Subjects and Methods

The study protocol was approved by Hospital Ethics committee and Ethical clearance was obtained from the institution for the study. Preanaesthetic check up was done one day prior to the surgery. Patients were evaluated for any systemic diseases and laboratory investigations recorded. The procedure of spinal anesthesia was explained to the patients and written consent was obtained.
Patients advised minimum period of fasting and premedicated with inj 10mg metaclopramide and 50mg ranitidine in preoperative holding. Patient was preloaded with an iv infusion of 500 ml of ringer lactate.

Sixty patients were randomly divided into two groups of thirty each.

**Group P:** Thirty patients received 3ml of injection 0.5% plain ropivacaine (2ml of 0.75% plain ropivacaine and 1 ml of 0.9% normal saline) intrathecally. solution was prepared aseptically immediately before injection.

**Group H:** Thirty patients received 3ml of 0.5% hyperbaric ropivacaine (2ml of 0.75% plain ropivacaine and 1ml of 25% dextrose) intrathecally. hyperbaric ropivacaine was aseptically prepared immediately before the injection.

**Preparation of OR**

Boyle’s anesthesia machine with all resuscitative equipments was kept ready before the procedure.

After shifting to the operating theatre, iv access was obtained on the forearm with 18 gauge iv cannula and iv infusion started with Ringer Lactate.

Patients were monitored for heart rate (HR), non invasive blood pressure (NIBP), oxygen saturation (SpO2). Spinal anesthesia was performed with the patient in the lateral position using a 25-gauge Quincke needle at the L3–4 interspace. The spinal analgesic solution was administered in optimum period. Patient was turned gently and placed supine.

After the spinal block, HR, SpO2 and NIBP were measured every 5, 10,15 20,30 minute. Hypotension was defined as 20% decrease in blood pressure from baseline values, and was treated with incremental iv boluses of Inj. mephenteramine 6 mg. Bradycardia was defined as heart rate less than 60bpm and treated with iv atropine 0.6mg.

The following variables were recorded. Haemodynamic parameters, and Time for onset of sensory block at T10, level of sensory block achieved, total duration of sensory block, time of onset of motor block, total duration of motor block.

**Assessment of Sensory Blockade:**

The onset of sensory block was tested by pin-prick method using a hypodermic needle. The time of onset was taken from the time of injection of drug into subarachnoid space to loss of pin prick sensation at T10. The duration of sensory blockade was taken as time from onset to time of return of pinprick sensation to S1 (heel) dermatomal area.

**Assessment of Motor Blockade:**

Motor block was assessed was by Modified Bromage scale. The time interval between injections of drug into subarachnoid space, to the patient’s inability to lift the straight extended leg was taken as onset time (bromage 1). The duration of motor block was taken from time of injection to complete regression of motor block (ability to lift the extended leg). (Modified Bromage scale: 0=full leg movement; 1= inability to raise extended leg, can bend knee; 2= inability to bend knee, can flex ankle; 3=no movement).

**Statistical Analysis:**

Data were expressed in mean ± SD. Comparison between groups was done using student’s t-test for quantitative data and for qualitative data, chi-square test was used. Results were considered statistically significant for p values < 0.05. Data were analyzed using software SPSS v16.0

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### Results

#### Figure 1: Time of Onset of sensory block at T10

In group H, mean duration of onset of sensory blockade was 257.5 ± 23.03 seconds, whereas in group P, mean duration of onset of sensory blockade was 478.0 ± 16.48 seconds. The difference between the groups was statistically highly significant (P < 0.001). Hence, showing that there was faster onset of sensory block in group H.

#### Figure 2: Duration of sensory blockade

In group H, mean duration of sensory blockade was 201.7 ± 8.64 mins, whereas in group P, mean duration of sensory blockade was 261.17 ± 8.27 mins. The difference between the groups was statistically highly significant (P<0.001). Hence, showing that there was early recovery from sensory blockade in group H.

#### Table 1: Comparison of sensory block level in between two group

| Sensory Block Level | Hyperbaric ropivacaine (%) | Plain ropivacaine (%) |
|---------------------|----------------------------|-----------------------|
| T6                  | 17 (57)                    | 0                     |
| T8                  | 11 (35)                    | 8 (27)                |
| T9                  | 0                          | 3 (10)                |
| T10                 | 2 (6)                      | 19 (63)               |

In group H 94% of patients achieved sensory block level above T10, whereas In group P only 37% patients achieved sensory block level above T10. Hence plain ropivacaine is less reliable for surgeries above the level of T10.
In group H, mean duration of onset of motor blockade was 355.50 ± 16.83 seconds, whereas in group P, mean duration of onset of motor blockade was 568.33 ± 2.76 seconds. The difference between the groups was statistically highly significant (P < 0.001). Hence, showing that there was faster onset of motor blockade in group H.

In group H, mean duration of motor blockade was 127.33 ± 6.53 mins, whereas in group P, mean duration of motor blockade was 168.83 ± 8.27. The difference between the groups was statistically highly significant (P < 0.001). Hence, showing that there was early recovery from motor block in group H.

Table 2: Comparison between hyperbaric and plain ropivacaine in different parameters

| Variable                        | Hyperbaric Ropivacaine | Plain Ropivacaine | 95% CI of Difference | t-value | p-value |
|---------------------------------|------------------------|-------------------|----------------------|---------|---------|
| Time of onset of sensory block at T10 (sec) | 257.5 ± 23.03          | 478.0 ± 16.48     | 220.50               | 210.15 - 230.85 | 42.6/4 | P<0.001001 |
| Duration of sensory blockade (min) | 201.7 ± 8.64           | 261.17 ± 8.27     | 59.50                | 55.13 - 63.87 | 27.2/4 | P<0.001001 |
| Time of onset of motor blockade (sec) | 355.50 ± 16.83         | 568.33 ± 2.76     | 212.83               | 202.49 - 223.18 | 41.1/8 | P<0.001001 |
| Duration of motor blockade (min) | 126.33 ± 5.71          | 168.83 ± 8.27     | 42.50                | 38.85 - 46.17 | 23.1/55 | P<0.001001 |

Onset of sensory and motor block is faster in group H compared to group P, and also speed of recovery from sensory and motor block is faster in group H compared to group P.

Discussion

In our study, we noted that mean time for onset of sensory block at T10 was 257.5 ± 23.03 sec (4.2 min) with 15 mg of hyperbaric ropivacaine and 478.0 ± 16.48 sec (8 min) with 15 mg plain ropivacaine which was statistically highly significant (P < 0.001). This shows that there is early onset of sensory block at T10 when ropivacaine is made hyperbaric by addition of glucose.

Our findings are in affirmation with the study conducted by P. D. W. Fettes and colleagues in which Forty patients undergoing elective perineal surgery were randomized to receive 3 ml ropivacaine 5 mg ml−1, either in plain solution or with glucose 50 mg ml−1 intrathecally, and found that median time to onset of sensory block at T10 was 10 minutes with plain ropivacaine and 5 min with hyperbaric ropivacaine.

Our findings are also similar with study conducted by Kallio H and colleagues in which 56 patients undergoing surgery for lower extremities received intrathecally either 1.5 ml of ropivacaine 10 mg ml−1 and 0.5 ml of glucose 300 mg ml−1 (HYP) or 2 ml of ropivacaine 7.5 mg ml−1 (PL) and found that the time for the onset of sensory block at T10 is 5 minutes with hyperbaric ropivacaine and 10 minutes with plain ropivacaine.

In all these studies onset of sensory block at T10 for plain ropivacaine is 10 minutes (range 5 to 40 minutes) and 5 minutes (range 5 to 20 min) for hyperbaric ropivacaine, in our study we found that onset of sensory block at T10 is 478.0 ± 16.48 sec (8 min) for plain ropivacaine and 257.5 ± 23.03 sec (4.2 min) for hyperbaric ropivacaine almost comparable onset of sensory blockade. Our study is in affirmation with other similar studies that addition of glucose to plain ropivacaine increases the speed of onset of sensory block at T10.

P. D. W. Fettes and colleagues noted that median maximum extent of sensory block with plain ropivacaine was T8 and hyperbaric ropivacaine was T4. Kallio H and colleagues noted that all patients in group hyperbaric achieved T (10) dermatome analgesia but only 64% of Group Plain ropivacaine achieved T10 analgesia level. Essam A and colleagues found that median maximum extent of sensory block is T8 for plain ropivacaine and T6 for hyperbaric ropivacaine. In our study we found median maximum extent of sensory block at T10 for plain ropivacaine and T6 for hyperbaric ropivacaine. These difference may be attributed to varying concentrations and volumes of the drug used in each studies. In conclusion in all studies it was found that addition of glucose to plain solution of ropivacaine increases the median maximum extent of sensory blockade.

Kallio H and colleagues noted that time of regression of block to S1 was longer (270 min) with plain ropivacaine when compared to hyperbaric ropivacaine group (210 min). We also observed that regression of block to S1 with
hyperbaric ropivacaine (201 min) was faster compared to plain ropivacaine (261 min). This is in agreement with the above mentioned study and also study conducted by Fettes and colleagues. Fettes and colleagues found that the onset of motor block was earlier in hyperbaric ropivacaine compared to plain ropivacaine. We also noticed that the mean time for onset of motor blockade was faster in hyperbaric ropivacaine (355 sec) compared to plain ropivacaine (568 sec). In studies of Khaw and Kallio, they compared plain ropivacaine versus hyperbaric ropivacaine and found that onset of motor block is faster in hyperbaric group. Fettes and colleagues noted that duration of motor blockade was shorter in hyperbaric ropivacaine group (120 min) compared to plain ropivacaine group (180 min). We observed a shorter duration of motor blockade with hyperbaric ropivacaine (126 min) compared to plain ropivacaine (168 min). This is in agreement with the above mentioned study and also study conducted by Kallio, Essam, and colleagues, who also found shorter duration of motor blockade with hyperbaric ropivacaine when compared to plain ropivacaine.

Conclusion

Our study reveals that 3ml of intrathecal 0.5% of hyperbaric ropivacaine (2ml of 0.75% plain ropivacaine and 1ml of 25% dextrose) produced more predictable and reliable sensory and motor block, with faster onset, than a 3ml of injection 0.5% plain ropivacaine (2ml of 0.75% plain ropivacaine and 1ml of 0.9% normal saline). Recovery from both sensory and motor block was early in hyperbaric ropivacaine compared to plain ropivacaine. Patients therefore mobilized more quickly after spinal anaesthesia with hyperbaric ropivacaine, something that may be particularly useful for ambulatory surgery and any operation when a long duration of block is unnecessary or undesirable. Plain solutions of ropivacaine are associated with a less favourable pattern of block such that we advocate that they should not be used for surgery at or above the dermatomal level of the T10.

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