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Original Research Article

Assessing Clinical Efficacy of Plain and Hyperbaric Solutions of 0.75% Ropivacaine in Spinal Anesthesia in Elective Lower Abdominal and Lower Limb Surgeries: A Retrospective Study

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Abstract

Aim: This study was designed to compare the clinical efficacy of plain and hyperbaric solutions of 0.75% ropivacaine in spinal anesthesia in elective lower abdominal and lower limb surgeries.

Methods: The present study was conducted in the Department of Anesthesiology, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India from February 2023 August 2023, and Fifty ASA grade I–II patients who were to undergo elective perineal (gynecological or urological) surgery under spinal anesthesia gave written informed consent to take part in the study.

Results: In the study, the mean specific gravity of the freshly prepared hyperbaric ropivacaine 0.75% solution (by the addition of 50 mg/mL dextrose) observed was 1.148 and plain ropivacaine 0.75% was 1.160. The two groups were comparable with regard to age, sex, height, weight, ASA status, and types of surgeries and the mean difference was statistically not significant. Hyperbaric ropivacaine produced a more rapid onset of more extensive, but less variable sensory block, which, nonetheless, ultimately regressed more quickly. The onset of analgesia to pinprick at T10 was more rapid, and the maximum block height (median T4 vs T8) was greater, but less variable. Median time to maximum block height was the same in both groups, but the range was considerably greater with the plain solution. The onset of lower limb motor block was slightly faster in the hyperbaric group, but the maximum degree obtained was the same in both groups.

Conclusion: Addition of glucose 50 mg ml1 to ropivacaine 5 mg ml1 increases the speed of onset, block reliability, duration of useful block for perineal surgery, and speed of recovery. Plain solutions are less reliable for surgery above a dermatomal level of L1.

Keywords: Hyperbaric ropivacaine, spinal anesthesia, abdominal, lower limb

Introduction

Ropivacaine, a new long-acting amide local anesthetic, was introduced in clinical practice with the claim that it causes less motor block than bupivacaine, [1,2] and as an alternative to hyperbaric lignocaine because of its higher incidence of transient neurologic symptoms and cauda equina syndrome. [3] The effect of ropivacaine has also been claimed to be less cardiotoxic than that of bupivacaine. [4]

Ropivacaine has been studied relatively little in intrathecal use. Early studies comparing two doses (15 vs 22.5 mg) of glucose-free (plain) ropivacaine found that intrathecal injection produced a sensory block of very variable extent, a proportion of the patients in both studies requiring general anesthesia because of inadequate distribution of block, mainly, but not exclusively, in the patients receiving 15 mg. [5,6] Since then, other studies have shown that plain ropivacaine can produce satisfactory analgesia for surgery, [7-9] but doubt remains about its reliability, as is the case with other agents in plain solution. [10,11] However, two recent studies of hyperbaric ropivacaine (15 mg) have shown that it produces predictable and reliable anesthesia for surgery, [12,13] and with a duration that is shorter than that of bupivacaine.

The preliminary studies evaluated the efficacy and safety of isobaric ropivacaine for neuraxial blockade. [5,6] Intrathecal ropivacaine was found to be safe, having shorter duration of action than

bupivacaine and lesser incidence of transient neurological symptoms (TNS) as compared with intrathecal lignocaine. [3,14] Intrathecal use of hyperbaric LA agents have become more popular as they produce predictable block characteristics and reliable SA. [15,16]

This study was designed to compare the clinical efficacy of plain and hyperbaric solutions of 0.75% ropivacaine in spinal anesthesia in elective lower abdominal and lower limb surgeries.

Materials and Methods

The present study was conducted in the Department of Anesthesiology, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India, from February 2023 August 2023, and Fifty ASA grade I–II patients who were to undergo elective perineal (gynecological or urological) surgery under spinal anesthesia gave written informed consent to take part in the study.

Patients were randomly divided into two groups of 50 each: plain and hyperbaric 0.75% ropivacaine. Patients were pre-medicated with oral temazepam 0–20 mg at the discretion of the responsible clinical anesthetist and, in the anesthetic room, monitoring with pulse oximetry, ECG, and non-invasive blood pressure was initiated, and venous access secured. Lumbar puncture was performed with a 25-swg Whitacre needle using a midline approach at the second or third lumbar interspace with the patient in the left lateral position. The patients were randomized (shuffled, then numbered, opaque envelopes) to receive 3 ml ropivacaine 5 mg ml^{-1} (15 mg) injected over 10–15 s in either plain solution or with glucose 50 mg ml^{-1}. The solution was prepared aseptically by the anesthetist administering the block, immediately before injection, by mixing ropivacaine 10 mg ml^{-1} with an equal volume of either glucose 100 mg ml^{-1} or sodium chloride 9 mg ml^{-1} to give solutions with densities (at 37C) of 1.01949 and 0.99953 g ml^{-1} respectively.[17] The patient was turned supine immediately at the end of injection, the time of which was defined as 'zero'. Thereafter an investigator, blinded to the solution administered, assessed the upper and lower extent of sensory block (analgesia to pinprick with the short bevel end of a 27-swg dental needle: caudal limit of sensory block assessment, S2), and the degree of motor block (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) and recorded the pulse rate and blood pressure 2, 5, 10, 15, 20, 25, and 30 min after injection. The patients were then transferred to the operating room and, if they wished, received sedation with a target-controlled infusion of propofol titrated to maintain verbal contact throughout. Because of this, and to avoid any interference, assessments were not made during surgery, but were continued at 30 min intervals thereafter until the block had regressed completely. I.V. fluid was administered only to replace operative blood loss, hypotension (>30% decrease in systolic pressure from baseline) being treated with i.v. ephedrine 6 mg. Once sensory block had regressed fully, patients were encouraged to mobilize under supervision. Bladder catheterization was performed when surgically indicated, but time to micturition was recorded in all other patients. Patients were visited or telephoned 24 h and 3–7 days later to identify any sequelae.

Statistical Analysis

The sample size was chosen to show a difference in extent of sensory block of 2 dermatomes (SD 1 dermatome) between the groups, based on an a risk of 0.05 and a b risk of 0.10, using data from a previous study.8 Data are presented as median [range], mean (SD) or frequencies as appropriate. Block characteristics were compared using the two-tailed Mann–Whitney U-test. A P value of <0.05 was considered statistically significant. Data were analyzed using a standard computer-based statistics package

Results

Table 1 Patient characteristics and types of surgery performed. Data are median (range), mean (SD) or frequencies

	Plain (n=25)	Hyperbaric (n=25)	P-value
Age (yr)	60 (50–73)	58 (30–75)	0.109
Height (cm)	167 (8)	165 (9)	0.712
Weight (kg)	71 (14)	70 (12)	0.989
Gender (M/F)	14/11	18/7	0.301
ASA I/II	20/5	14/11	0.300
Type of surgery			
Lower abdominal	12	12	0.818
Lower limb	13	13	

In the study, the mean specific gravity of the freshly prepared hyperbaric ropivacaine 0.75% solution (by the addition of 50 mg/mL dextrose) observed was 1.148 and plain ropivacaine 0.75% was 1.160. The two groups were comparable with regard to age, sex, height, weight, ASA status, and types of surgeries and the mean difference was statistically not significant.

Table 2: Characteristics of spinal anesthesia

	Plain (n=25)	Hyperbaric (n=25)	P-value
Onset to T10 (min)	10 [2–25]	5 [2–10]	<0.01
Median maximum block (dermatome)	T8 [T2–L2]	T4 [T2–T9]	<0.05
Time to maximum block (min)	25 [15–150]	25 [10–30]	0.847
Duration at T10 (min)	25 [0–208]	115 [50–178]	<0.001
Sensory regression (min)	270 [150–390]	240 [180–270]	<0.05
Motor regression (min)	180 [90–270]	120 [30–150]	<0.001
Time to mobilize (min)	286 [101–403]	218 [183–347]	<0.01

Hyperbaric ropivacaine produced a more rapid onset of more extensive, but less variable sensory block, which, nonetheless, ultimately regressed more quickly. The onset of analgesia to pinprick at T10 was more rapid, and the maximum block height (median T4 vs T8) was greater, but less variable. Median time to maximum block height was the same in both groups, but the range was considerably greater with the plain solution. The onset of lower limb motor block was slightly faster in the hyperbaric group, but the maximum degree obtained was the same in both groups. Median time to regression of sensory block to T10 (an indicator of useful duration for surgery) was longer in the hyperbaric group, but median times to complete regression of both sensory and motor block were longer in the plain group. Patients therefore mobilized sooner in the hyperbaric group although the data for mobilization time were incomplete because of surgical constraints.

Discussion

Early studies with isobaric ropivacaine reported to have variable or inadequate block patterns foe surgery [5,6] and confirmed that the addition of glucose to the solution of ropivacaine has better effects as with other drugs used for SA. [15,16] It reduces the proportion of a limited block or more extensive block which has been previously reported from studies on both tetracaine [11] and bupivacaine. [19,20]

Addition of glucose led to a more rapid spread to a higher median level and with less variation in maximum sensory and motor block. However, the useful duration was longer and more consistent, but complete regression occurred sooner so that patients mobilized earlier. Similar observations on the effect of adding glucose have been made with other local anaesthetics. [11,18] The increase in density produced by the addition of glucose would appear to result in a more even distribution of the local anesthetic, gravity presumably encouraging spread of the bolus of drug 'down' the slopes of the lumbar curve when the patient is placed supine after injection. [14] Usually, glucose-free solutions are marginally hypobaric, and have been found previously to be 'unpredictable', [10] perhaps because gravity does not encourage their spread in the supine position. Spread is likely to be more dependent on other factors such as the currents produced by injection and simple diffusion. This may mean that more of the injected drug stays closer to the point of injection, making the block less useful for surgery, yet prolonging significantly sacral nerve block and so delaying recovery.

While the addition of glucose to a local anesthetic solution improves predictability, all users of spinal anesthesia must be aware that considerable variation in both total spread and duration of action still occurs. The average duration can be influenced by drug and dose choices, but the variability remains. This variability is even evident between studies. In a previous study the median duration of 15 mg ropivacaine 5 mg ml^{-1} (with glucose 50 mg ml^{-1}) at T10 was 56 [range 28–145] min, whereas it was 115 [50–180] in our study.

Although this study was not performed in the day-case setting, the suitability of hyperbaric ropivacaine for ambulatory surgery should be considered. McDonald and colleagues, using sub-clinical doses of ropivacaine in volunteers, concluded that it was less potent than bupivacaine and offered no advantage for use in outpatient anesthesia. However, what they found was that ropivacaine produced sensory block of similar onset and extent as bupivacaine, but that it was associated with less motor block and faster regression of both sensory and motor block, findings similar to those reported here. [20] Subsequently, clinically relevant doses of hyperbaric ropivacaine have been shown, as in this study, to provide predictable and reliable anesthesia for elective surgery, albeit of a shorter duration than equal doses of bupivacaine. [13] The standard agent for short duration spinal anesthesia has been lidocaine, but continuing concerns about the high incidence of transient neurological symptoms limit its use. [21,22]

Conclusion

Hyperbaric ropivacaine produced more predictable and reliable sensory and motor block, with faster onset, than a plain solution. In addition, although the duration of useful block for surgery was increased, so was the speed of recovery from both sensory and motor block. Patients therefore mobilized more quickly after spinal anesthesia 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, although it should be noted that the drug is unlicensed for this indication at present. Plain solutions of ropivacaine are associated with a less favorable pattern of block such that we advocate that they should not be used for surgery at or above the dermatomal level of the inguinal ligament that is L1.

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