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Comparison of Three Different Doses of Hyperbaric Ropivacaine in Spinal Anesthesia for Caesarean Section

Dr. Dharmendra Carpenter	M.B.B.S, M.D. (Consultant) Department of Anesthesiology
Dr. Neha Agrawal	M.B.B.S., M.D.(Senior Resident) Department of Anesthesiology; S.M.S. Medical College, Jaipur
Dr. Reema Meena	M.B.B.S., M.D. Professor Department of Anesthesiology; S.M.S. Medical College, Jaipur

ABSTRACT

Spinal hyperbaric Ropivacaine may produce more predictable and reliable anesthesia than plain ropivacaine for caesarean section. This double blind, randomised , dose response study compared three different doses of hyperbaric ropivacaine for spinal anesthesia in caesarean section in terms of clinical efficacy and safety.Ninety six parturients undergoing elective caesarean section delivery under spinal anesthesia were randomised to receive spinal hyperbaric ropivacaine in doses of 10mg,12.5 mg and 15mg at L3-L4 intervertebral space. The highest level of sensory block, duration of motor and sensory block, rate of successful anesthesia outcome and rate of hypotension were significantly related to ropivacaine dose. Ropivacaine 12.5 mg is suitable dose for spinal anesthesia for caesarean delivery with adequate anesthesia and minimal side effects.

KEYWORDS : Caesarean section , Ropivacaine, Spinal Anesthesia,

INTRODUCTION

Ropivacaine , a newer amide local anesthetic (introduced to the clinical practice in 1996) has certain advantages over Bupicaine like Ropivacaine has less potential for both cardiac and CNS toxicity, Ropivacaine causes preferential blockade of sensory nerve fibres.

Many investigators reported that ropivacaine can be used safely for spinal anesthesia in obstetric patients (1,2). A previous dose response study with plain ropivacaine for caesarean section had estimated the ED 95 to be 26.8 mg (1) and with hyperbaric ropivacaine had estimated the ED 50 and ED 95 to be 10.37mg and 15.39 mg (3).

However , there is a need to assess the least dose effective for a caesarean section at the same time with minimal side effects. We usually use hyperbaric ropivacaine for spinal anesthesia for caesarean section in clinical practice because spinal hyperbaric ropivacaine may produce more predictable and reliable anesthesia than plain ropivacaine and with a shorter duration of sensory and motor block (4,5,6). The aim of present randomized, double blind study was to compare three different doses of hyperbaric ropivacaine in spinal anesthesia for caesarean section.

METHODS

This study received approval from the ethical committee of the Rajasthan University of Health sciences and written inform consent was taken from all the patients. 96 patients with American society of anaesthesiologist physical status 1 or 2, who were scheduled to undergo elective caesarean delivery at term under spinal anesthesia were enrolled for the study.Patients with allergy to amide type local anesthetics,diabetes, hypertension, spinal deformity, neurological disease, bleeding disorder, multiple pregnancies, suspected fetal abnormality or complicated pregnancies were excluded. On arrival in the O.T., intravenous access was secured with 18 G i.v. cannula and intravenous preload of 10 ml/kg lactated Ringer's solution was administered over approximately 15 min. Baseline Pulse Rate , Non invasive blood pressure,Spo2 and ECG was recorded.

Before the commencement of anesthesia , patients were instructed on the method of sensory and motor assessments and baseline measurements were performed. Sensory changes were recorded bilaterally along the midclavicular line by assessing pin prick sensation using a 20G needle. Motor block in the lower limbs was graded according to the modified bromage scale .

A spinal technique was used with the patient in the right lateral position. After confirming free flow of cerebrospinal fluid, the drug was given intrathecally according to the allocated group. Time of intrathecal injection was noted and considered as zero. After the intrathecal injection patient was turned supine immediately . A pillow was placed under the shoulder and 15 head down tilt was given.

Vitals were checked and noted in every 2 mins in first 10 minutes then in every 10 mins in first hour and in every 15 mins thereafter. Arterial oxygen saturation and ECG were observed continuously. Hypotension was defined as a fall in systolic blood pressure below 90 mm Hg and was treated by incremental doses of Ephedrine 5 mg i.v. Bradycardia was defined as fall in heart rate below 60 beats per min and was treated with incremental doses of atropine 0.4 – 0.6 mg i.v.

The level of sensory block was accessed in every 30 sec till the highest level of sensory block was achieved. After completion of surgery it was accessed in every 2 mins till the regression of sensory block up to two dermatome thereafter every 15 mins till the regression up to L1 dermatome. Onset of sensory block was defined as the time taken fom the intrathecal injection to achieve sensory block up to T10 level. The highest level of sensory block and the time to achieve the same is noted. Time to two dermatome regression and regression up to L1 dermatome level of sensory block were also noted. If the highest level of sensory block was below T10, the case was considered as unsuccessful and converted to general anesthesia.

Degree of motor block was accessed in every 2 mins preoperatively and in every 15 mins postoperatively. Time to achieve complete motor block and time to achieve complete recovery from motor block were noted.

The quality of abdominal muscle relaxation was evaluated by the surgeon at the end of the surgery as excellent = no disturbing muscle strain; satisfactory = disturbing , but acceptable muscle strain ; unsatisfactory = unacceptable muscle strain.

Time from intrathecal injection to the first feeling of pain (complete analgesia) and time to the first rescue or supplemental dose of analgesics (effective analgesia) were noted. Pain was

assessed by visual analogue score (VAS) .VAS was assessed every 30 minuutes . supplemental analgesia was given when VAS score was > 6. Time of supplemental analgesia was noted.

Other adverse effect (if any) in intraoperative or postoperative period was noted and treated accordingly. On post operative days 1 and 5, patients were evaluated regarding side effects including headache , backpain or transient neurologic symptoms (if any).

STATISTICAL ANALYSIS

On the basis of inclusion and exclusion criteria , total 96 eligible patients were selected on the first cum first basis and allocated to different groups using chit and box method. To reduce subject and observer bias double blind technique was used. Results are presented as mean ± SD . The qualitative and quantitative data were analysed by ' chi square ' test and ANOVA. P – value less than 0.05 were considered statistically significant in all the studies.

RESULTS AND DISCUSSION

Despite all its criticisms spinal anesthesia is the most popular and preferred technique of regional anesthesia till date for short duration procedures of obstetrics and gynaecology. Since there is paucity of literature and conflicting reports on intrathecal use of Ropivacaine in obstetric patients, we design this hospital based prospective, randomized and comparative , double blind , analytical study to compare three different doses of hyperbaric ropivacaine in spinal anesthesia for caesarean section in terms of clinical efficacy and safety.

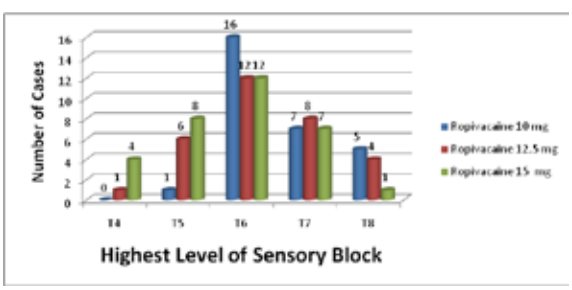
The optimal dosage of spinal Ropivacaine for caesarean section is unknown. The equipotent ratio between bupivacaine and ropivacaine has been 2:1 with hyperbaric solution in volunteers (7) or 3:2 with hyperbaric solution for elective caesarean delivery (8).

Demographic data were statistically similar among all the groups in terms of age, weight and height of the patients. There were no statistical differences in duration of surgery and induction to skin incision time among all the groups.

Fettes et al, in their study concluded that addition of glucose 50 mg /ml to Ropivacaine 5 mg/ ml increases the speed of onset , block reliability , duration of useful block for perineal surgery and speed of recovery. Hyperbaric solutions also enable a smaller dose to be used compared with plain solutions.

Variables (in mins)	Ropivacaine10 mg	Ropivacaine 12.5 mg	Ropivacaine 15 mg
On set of sensory block	4.48 ± 0.49	4.45± 0.46	4.36 ±0.44
Time to achieve highest level of sensory block	11.29 ±0.49	11.26 ± 0.46	11.45 ±0.43
Time to 2 dermatome regression	64.76 ±2.64	66.77 ±2.67	68.06 ± 2.35
Time to regression up to L1 dermatome	85.34 ± 8.12	95.81 ± 13.23	109.84 ±10.36
Onset of motor block	11.81 ± 0.43	11.85 ± 0.49	11.75 ± 0.42
Duration of motor block	85.86 ± 11.96	95.81 ± 12.66	103.13 ± 12.49
Duration of Complete analgesia	88.62 ± 7.89	96.13 ± 9.19	100.94 ± 9.63
Duration of effective analgesia	115.17 ± 8.29	116.13 ± 9.19	125.00 ± 10.47

Table 1 : Characteristics of Sensory and Motor Block (Mean ± SD)



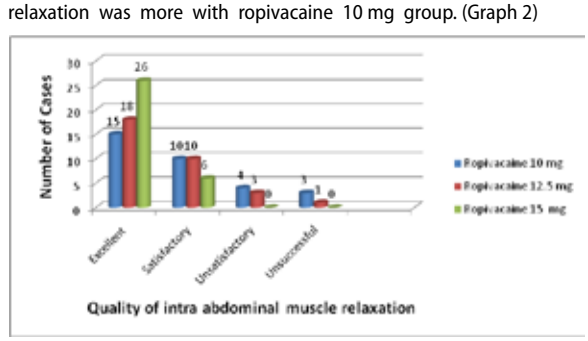
Graph 1 : Highest level of sensory block

There were no significant difference in onset of sensory & motor block and time to achievement of highest block in different doses of Ropivacaine (table 1), but the highest level of sensory block achieved was statistically higher with higher doses(Graph 1). Our result coincided with Chen Xun Zhong et al (3) & Ying Y.Lee et al (9) but in the study done by Khaw et al(1) results were different from our results. According to them the number of segments blocked were not influenced by the dosage. The probable reason behind this could be the use of isobaric solution (3,4).

The duration of motor block was longer(Table 1) & the degree of motor block was more with Ropivacaine 15 mg and 12.5 mg than ropivacaine 10 mg. This result coincides with Ying Y. Lee et al. Study (9).

Time of sensory block to time to two dermatome regression , regression up to L1 dermatome were earlier with Ropivacaine 10 mg than ropivacaine 12.5 mg and ropivacaine 15 mg(table 1) indicating a dose dependent relation . it coincides with all the studies performed by using various plain and hyperbaric solutions of local anesthetics.

Quality of intraoperative muscle relaxation as experienced by operating surgeon was almost similar in both groups ropicvacaine 12.5 mg and ropivacaine 15 mg but incidence of unsatisfactory relaxation was more with ropivacaine 10 mg group. (Graph 2)



Graph 2 : Quality of intra abdominal muscle relaxation

The rate of successful anesthetic outcome was considerably higher than other studies. Of the 96 patients in the study , surgery was completed successfully in 92 patients under spinal anesthesia . Of these patients there were 29 (90.5 %), 31 (96.71 %) and 32 (100%) patients in the 10 mg, 12.5 mg and 15 mg groups, respectively

In Khaw et al.study(1), the success rate of anesthetic outcome was significantly lower because of unpredictable spread of isobaric solution of local anesthetics agents used for spinal anesthesia. The lower rate of successful anesthetic outcome in Chen et al study(3) was probably related to the mean height of the patients. As our study was performed of Indian population while Chen et al study (3) was performed on western population (western population is taller than Indian population)

In our study, 4 out of 6 patients in whom patients developed intraoperative pain, had an adequate level of sensory block. Of these patients, the intra abdominal muscle relaxation as experienced by surgeon was significantly lower in comparison to the patients who had successful anesthesia. So our study also support the practice of adding an opioid to the lower doses

of local anesthetic , which may reduce intraoperative pain that occurs with smaller doses of local anesthetic despite apparently adequate spread of sensory anesthesia. The incidence of intra operative pain in our study was lower than other studies (10). The probable reason behind this is the relatively shorter duration of surgery taken for the study (caesarean section`v/s major orthopaedic surgeries).

The duration of effective analgesia was more with Ropivacaine 15 mg and 12.5 mg group (Table 1).

For the occurrence of nausea and vomiting, shivering and bradycardia there were no significant differences among the three groups however there was a statistically significant correlation between ropivacaine dose and in the rate of maternal hypotension. (Table 2).

Adverse Effect	Ropivacaine 10mg		Ropivacaine 12.5 mg		Ropivacaine 15 mg	
	No.	%	No.	%	No.	%
Hypotension	2	6.2	6	18.7	8	25
Shivering	0	0	1	3.1	1	3.1
Nausea	0	0	1	3.1	1	3.1
Bradycardia	0	0	0	0	1	3.1

Table 2 : Intra operative Adverse effects

In our study no patients had post dural puncture headache and residual neurologic changes or back pain postoperatively till five days of surgery.

CONCLUSION

In conclusion, a dose dependent relation exist between number of segments blocked, the duration of sensory block , motor block and analgesia, success rate of spinal anesthesia and incidence of maternal hypotension whereas the onset of sensory and motor block were not related to dose.

Smaller doses of hyperbaric ropivacaine produces adequate anesthesia required for caesarean section with shorter duration of sensory and motor block without significant hemodynamic or other disturbances. Faster recovery with ropivacaine in caesarean section shortens the stay of post anesthesia care unit after the delivery. Early recovery of motor block allows mother to better newborn care including early starting of feeding. So hyperbaric ropivacaine 10 mg along with opioid may be a suitable agent for spinal anesthesia in caesarean delivery.

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