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A COMPARATIVE STUDY OF HYPERBARIC ROPIVACAINE WITH OR WITHOUT FENTANYL IN CAESAREAN SECTION

Anaesthesiology

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ABSTRACT

Background and objective: Hyperbaric Ropivacaine produces adequate spinal anaesthesia for caesarean delivery. Adding various opioids to the local anaesthetic solution administrated intrathecally improves the analgesic potency of spinal anaesthesia. The purpose of this study was assessment of efficacy and safety of intrathecal Fentanyl 10 µg added to 15 mg hyperbaric Ropivacaine in patient undergoing caesarean section under spinal anaesthesia. **Methods:** 36 healthy, full term parturients were randomly assigned into two groups: Group S (saline group, n=18) received 15 mg hyperbaric Ropivacaine in 2.5 ml + 0.5 ml saline intrathecally and Group F (Fentanyl group, n=18) received 15 mg hyperbaric Ropivacaine in 2.5 ml + 10 µg Fentanyl in 0.5 ml intrathecally. Patients were evaluated for characteristics of spinal anaesthesia, intraoperative and postoperative analgesia and side effects. **Results:** Time to achieve sensory block to T4 level in both the group is almost same. Regression of sensory block to L5 , time to the first feeling of pain and first analgesic requirement were significantly longer in Fentanyl group as compared to saline group. Both the groups were comparable in terms of side effects. **Conclusion:** Addition of Fentanyl 10 µg to hyperbaric Ropivacaine 15 mg, for spinal anaesthesia for caesarean delivery improves intraoperative anaesthesia and increases the duration of analgesia in early postoperative period.

KEYWORDS

Caesarean section, Spinal anaesthesia, Ropivacaine heavy, postoperative analgesia, Fentanyl

INTRODUCTION

Spinal anesthesia is a popular modality of anaesthesia for Caesarean section. As procedure is very simple, quicker onset of action, it is trustworthy in generating generalized sensory & motor blockade. It allows the mother to remain awake, minimizes or completely avoid the problems with airway management and neonatal drug induced depression from general anaesthesia. Spinal anaesthesia offers some advantages like very rapid onset, dense neural block and because of the small doses used, little risk of local anaesthetic toxicity and minimal transfer of drug to the foetus. Spinal anaesthesia with hyperbaric Bupivacaine is the most commonly used anaesthetic technique for elective cesarean section and in urgent and emergency scenarios.

Many physiological and anatomical changes during pregnancy affect spinal anesthesia. The hormonal and mechanical factors make pregnant women require less local anesthetic than nonpregnant women to attain same level of spinal anesthesia. They stand at a greater risk of toxicity to local anesthetics due to increased penetration through tissue membrane, decreased plasma protein binding and progesterone enhanced cardiotoxicity.

In 1979, Albright GA published cardiac complications following regional anaesthesia with Bupivacaine which provided impetus to re evaluate Ropivacaine as alternative to Bupivacaine[6]. Ropivacaine is long acting amide local anaesthetic with structure closely related to Bupivacaine.[1] As spinal anaesthesia has shorter duration of action, it has no long lasting postoperative analgesia. To solve this problem , administration of local anaesthetic with various types of adjuvant is a fair method which provides early commencement and prolonged duration of sensory and motor block in spinal anaesthesia.[5] So it acts synergistically to local anaesthetic agent which lowers local anaesthetic requirement & provide excellent postoperative analgesia. The purpose of this study was to evaluate the efficacy and safety of intrathecal fentanyl 10 µg added to 15 mg hyperbaric ropivacaine in patients undergoing elective caesarean section under spinal anaesthesia.

METHODOLOGY

After approval from the Institutional Ethical committee and informed written consent from patients, this prospective, randomized, study was carried out. Thirty six full term normal gravida, ASA status I and II scheduled for elective caesarean surgeries were enrolled in this study. Patients with multiple pregnancies, foetal abnormalities or complicated pregnancies were excluded from study. All the patients went through to detailed pre-anaesthetic evaluation with clinical history, General and Systemic examination of RS, CVS & CNS. Routine investigations like Haemogram, Random Blood Sugar, Renal Profile for patients were carried out.

All patients were kept nil by mouth for at least 6 hours before surgery. An intravenous line was secured with 18 G intravenous cannula. Preloading was carried out by infusion of lactated Ringer's solution (10 ml/kg). Pulse oximeter, non-invasive blood pressure cuff and ECG electrodes were attached and baseline pulse, blood pressure, oxygen saturation were recorded. Inj. Glycopyrrolate 0.005 mg/kg IV and Inj. Ondansetron 0.1 mg/kg IV given as a premedication. All Patients were divided into two groups randomly on odd and even dates in group S and group F respectively. Group S received Inj. Ropivacaine heavy 0.75% in 2 ml + 0.5 ml saline intrathecally. Group F received Inj. Ropivacaine heavy 0.75% 2 ml +10 µg Inj. Fentanyl in 0.5 ml intrathecally. In our study we used pre-prepared pre-sterile hyperbaric ropivacaine. The Fentanyl solution was prepared by adding 3 ml of distilled water to 2 ml of 50 µg/ml Fentanyl and from which we used 0.5 ml of solution containing 10 µg of Fentanyl. Spinal anaesthesia was performed in sitting position with 25 gauge quincke spinal needle by midline approach at L3-L4 level after confirming free flow of CSF, the drug was injected in sub-arachnoid space. Patient was returned to supine position with left lateral tilt after intrathecal injection.

Onset of sensory and motor block was assessed every minute after the end of injection till peak effects occurs. Sensory block was assessed bilaterally by pinprick method in anterior axillary line and the time from intra-thecal injection to the loss of sensation of pin prick at T10 level was considered as initial onset of sensory block. Time to sensory block to T7, time to sensory block to T4, time to regression to T10 and time to regression to L5 were recorded. Surgery was started when T4 level sensory block was achieved.

Motor block was assessed by modified Bromage (0 = No paralysis, able to flex hip/knee joints/ankles ,1= able to move knees, unable to raise extended legs ,2= able to flex ankles, unable to flex knees , 3= unable to move any part of the lower limb. The time interval between the end of total local anaesthetic administration and complete motor block (MBS score 3) considered as onset time and time interval from complete motor block to the recovery of complete motor function (MBS score 0) considered as duration for motor block.

After spinal anaesthesia the vital parameters pulse rate, BP, respiratory rate and SPO2 were recorded at every 2 min for the first 10 minutes followed by measurements at every 5 minutes till the completion of surgery.

Patients were observed for any cardiovascular or central neural toxicity by changes in hemodynamic or signs of CNS stimulation. Fall in blood pressure of more than 20% of pre-operative value considered as hypotension and was treated by Inj. Mephentermine iv and additional iv fluids. Bradycardia was defined as fall in pulse rate less than 60/min and it was treated with iv Atropine. Other side effects like nausea, vomiting , pruritus were also recorded. Spinal puncture to delivery time, total surgical duration and Apgar score at 1 min and 5 min were also recorded.

Post-operatively pulse rate, blood pressure, Spo2, effect of sensory & motor block and post-operative analgesia (VAS score) were monitored every hourly up to 4 hours, then every 2 hourly up to 12 hours, then every 3 hourly up to 18 hours and then at 24 hours. Time to first request of analgesics (VAS ≥3) was noted and treated with Inj. Diclofenac iv.

Statistical analysis were performed by using SPSS software. Data were analyzed using paired or unpaired t-test. Data are shown as mean ± standard deviation(SD). P value<0.05 considered as statistically significant.

Patients Characteristics And Duration Of Surgery: (table 1)

	Group S (n=18)	Group F(n=18)
Age	30.2 ± 5.6	32 ± 4.5
Height(cm)	160 ± 4.8	160.5 ± 5
Weight(kg)	67 ± 3.8	65.8 ± 5.4
Spinal puncture –delivery time(min)	15.7 ± 5.6	15.2 ± 5.6
Surgical time(min)	57.6 ± 7.1	56.2 ± 7.2

Characteristics Of Spinal Anaesthesia (table 2)

	Group S	Group F
Sensory block (min)		
Time to sensory block to T7	1.7 ± 0.3	1.9 ± 0.4
Time to sensory block to T4	2.6 ± 0.6	2.4 ± 0.4
Time to regression to T10	123.9 ± 6.6	133.7 ± 6.2
Time to regression to L5	151.7 ± 7	172.5 ± 7.2
Motor block (min)		
Time to achieve bromase scale 2	2.3 ± 0.5	2.2 ± 0.4
Complete motor block	6.5 ± 0.7	6.6 ± 0.7
Complete motor recovery	120.2 ± 4.8	122.7 ± 4.9
Time to first request of analgesics(min)	162.3 ± 11	215 ± 10

Intraoperative Analgesia And Postoperative Analgesia (table 3):

	Group S (n=18)	Group F (n=18)
Excellent	13	15
Good	5	3
Fair	0	0
Poor	0	0

Side Effects During Surgery (table 4)

	Group S (n=18)	Group F (n=18)
Bradycardia	3	2
Dyspnoea	0	0
Hypotension	7	6
Mephentermine requirement	4	3
Pruritus	0	1
Nausea	4	4
Shivering	2	2

RESULTS

In all patients, spinal anaesthesia was successfully administered. The demographic data, delivery time for spinal punctures and length of surgery were comparable between both the groups (Table 1).

There was little distinction between the two groups in terms of establishing T7 sensory block and T4 dermatomal level and achieving the highest level of sensory block, but it was not statistically significant. Every patient established a T4 dermatome sensory block (Table 2). In fentanyl group regression of sensory block to L5 was noticeably delayed when compared to the saline group (Table 2; P 0.001). Times of complete motor block, the recovery of complete motor block and the degree of motor block were also similar between the two groups (Table 2).

In the both groups, the overall standard of spinal anaesthesia was comparable. Nobody in the fentanyl group and saline group needed additional intraoperative analgesics. Time to the first feeling of pain and the first analgesic requirement were significantly shorter in the saline group compared with the fentanyl group (Table 3).

The frequency of bradycardia, dyspnea, hypotension, nausea, itchiness, shivering, spinal puncture to delivery time and mean duration of Surgery, requirement of Mephentermine were not significantly different between two groups (Table 4). Apgar score were also similar in both the groups.

DISCUSSION

In the caesarean section, anaesthetic drugs may impact on the pregnant woman and foetus so it is important to use minimal effective dose of local anaesthetic agent to achieve rapid and effective sensory and motor blockage and preventing maternal hemodynamic instability. Ropivacaine is a L-amide anaesthetic that is similar to bupivacaine in structural and pharmacodynamics. Ropivacaine has advantage of separated sensory and motor block, with less toxicity to the cardiovascular system and central nervous system due to its less lipophilic properties. Doses used in clinical studies have ranged from 8 to 22.5 mg.[3]

Hyperbaric ropivacaine 18 mg gave sufficient spinal anaesthesia for caesarean birth in the study by Chung and colleagues but in 10% of patients required intraoperative analgesia supplementation.[1] Due to ropivacaine's short half-life, it may not be enough to last the entire duration of operation, Therefore, additional analgesics may be needed during the intraoperative time. In our study, hyperbaric ropivacaine 15 mg gave sufficient spinal anaesthesia for caesarean delivery, and none of the patient in saline group needed additional analgesics throughout the procedure.

In our study, we have shown that the addition of fentanyl to hyperbaric ropivacaine 15 mg for spinal anaesthesia provides similar sensory and motor blocks and side-effects but increases the duration of complete analgesia and effective analgesia in the early postoperative period in patients undergoing caesarean section. In previous studies hyperbaric ropivacaine was prepared by adding dextrose solution to isobaric ropivacaine. In our study we used prepared solution of hyperbaric ropivacaine, so sterility and baricity of solution was maintained.

In the management of spinal anaesthesia for surgical procedures, the administration of local anaesthetics with opioids has grown to be widely accepted practice. After a caesarean delivery, it is thought to be advantageous to prolong effective postoperative analgesia.

S. sanli et al[5] have shown that the addition of fentanyl 10 µg to 15 mg hyperbaric ropivacaine for spinal anaesthesia improved the quality of intraoperative analgesia and prolonged its duration of sensory block approximately 18 min and provide effective analgesia and prolonged resque analgesics time by approximately 60 min in the early postoperative period at caesarean delivery when compared with the control group. Our results were in agreement with those reported by these authors; in our study, the duration of sensory block was prolonged by approximately 20 min and the time to the first dose of analgesic administration by approximately 60 min in the fentanyl group.

According to research by Chung and colleagues, when fentanyl 10 mg was added to 18 mg of hyperbaric ropivacaine for spinal anaesthesia, it improved the quality of intraoperative analgesia, increased its duration by about 40 minutes, and increased effective analgesia by about 70 minutes in the initial postoperative period following caesarean delivery when compared to the control group.[7] This results were comparable with results of our study.

Chung and colleagues have shown that 18 mg hyperbaric ropivacaine frequently caused hypotension.[1] So we used low dose of local anaesthetic with additive opioid. In our study incidence of hypotension was not significant differ between both the groups all episode of hypotension were corrected by inj. Mephentermine. Incidence of side effects like nausea, vomiting and pruritus were not different between both the groups.

CONCLUSION

Addition of fentanyl 10 µg to hyperbaric ropivacaine 15 mg, for spinal anaesthesia for caesarean delivery improves intraoperative

anaesthesia and increases the duration of analgesia in early postoperative period.

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