VOLUME-8, ISSUE-9, SEPTEMBER-2019 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Anesthesiology

EFFICACY OF LOWER DOSES OF HYPERBARIC BUPIVACAINE WITH OPIOID ADJUVANT IN ELECTIVE CESAREAN DELIVERY: AN OBSERVATIONAL STUDY

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ABSTRACT

Background and aims: Hemodynamic stability following spinal anaesthesia in caesarean delivery may be achieved with lower dose of the drug at the expense of surgical condition which is not desired. So this study was performed to observe whether good surgical condition would be achieved with lower doses of hyperbaric bupivacaine with fentanyl adjuvant during elective caesarean delivery with minimum complications. Methods: After obtaining institutional ethics committee clearance and written informed consent, this prospective observational study was performed among 110 patients,aged between 18-38 years with singleton term pregnancy scheduled for elective caesarean delivery.The study population was randomly divided into 2 equal groups. Group A and Group B patients received 7.5 mg and 10 mg hyperbaric bupivacaine with fentanyl 25 mcg respectively. The onset and duration of sensory and motor block, the time to reach maximum block height, duration of analgesia, intraoperative average mean arterial pressure, heart rate, Apgar score and complications. Data were analyzed using Microsoft excel 2010 and statistical package of social sciences (SPSS) software version 23.The unpaired Student's t-test was used and p value < 0.05 was considered as statistically significant. Results: The onset of sensory and motor block, the time to reach peak sensory block, the duration of analgesia and motor block in Group B were statistically significant than Group A. (p value 0.000).Muscle relaxation was adequate in the both groups. There were significant fall of average mean arterial blood pressure at 5 and 10 minutes following spinal anaesthesia but subsequent values were comparable. The incidence of complications wasminimum in the both groups. Conclusion: The 7.5 mg hyperbaric bupivacaine with 25 mcg fentanyl provides good surgical condition, hemodynamic stability with minimum complications during elective caesarean delivery.

KEYWORDS : caesarean delivery, fentanyl, hyperbaric bupivacaine.

INTRODUCTION:

Spinal anesthesia (SA) is the preferred technique for cesarean delivery (CD). SA provides adequate analgesia, motor block and muscle relaxation. The height of block should reach at the level of 4th thoracic segment (T4) of spinal cord during CD.Good relaxation of abdominal muscles is also required for delivery of the baby and closure of the abdomen.But the major drawback of SA is the maternal hypotension which may jeopardize organ perfusion of both mother and the fetus.[1,2]The degree of hypotension is directly related with the height of block which depends on the dose of the administered drug.[3] So the goals of anesthetic technique are to achieve adequate surgical condition without hypotension.The recommended dose of bupivacaine during CD is 12.5 to 15mg. If lower dose of hyperbaric bupivacaine is used for SA, chance of hypotension will be minimal but adequate surgical condition may not be achieved. So, this study was conducted to compare two different doses(7.5 mg versus 10 mg) of hyperbaric bupivacaine which is lower than the conventional dose to assess surgical condition by comparing the onset and duration of sensory and motor block,maximum height of block, relaxation of abdominal muscles, hemodynamic stability and to observe any side effects between the groups during elective CD.

METHODS:

After obtaining institutional ethics committee clearance and written informed consent, this prospective observational study was performed among 110 patients, aged between 18-38 years with singleton term pregnancy scheduled for elective CD in a tertiary hospital for a period of 6 months.Those having contraindications of SA, suffering from severe cardio respiratory, neurological ,hepatic ,renal and musculoskeletal disorders, abnormal curvature of spine and scheduled for emergency CD were excluded from this study.UsingOpenEpi online calculator after taking difference between the mean for MAP at 5 minutes of 5 mmHg with power of study taken as 80% and confidence interval of 95%, the minimum sample size came 49 in each group. A drop of 10% was considered in enrolment and the final sample sizewas taken as 55 in each group.Clear fluid was allowed 2 hours before surgery. Ranitidine 150mg and metoclopramide10 mg orally were administered 2 hours before surgery. Patients were transported in left lateral position to the operating room and intravenous cannulation was done with 18 gauze(G) cannula and ringer lactate infusion was administered at a rate of 20ml /kg for coloading. Multi channel monitor wasattachedand baseline mean arterial pressure(MAP),heart rate (HR) and oxygen saturation (spO_2) were recorded. Patients were randomly allocated into 2 equal groups. Group A patients received 7.5 mg hyperbaric bupivacaine with fentanyl 25 mcg. Group B patients received 10 mg hyperbaric bupivacaine with fentanyl 25mcg.After antiseptic dressing and draping, SA was administeredin the sitting position with 26 G Quincke-Babcock spinal needleat the L4- L5 intervertebral space with the injection port directed cephalad, the measured amount of the study drug was administered according the allotted group.Following administration of the drug, each patient was made supine and left uterine displacement was done manually to avoid aortocaval compression. Oxygen was administered through the face mask @ 4L/min. After delivery of the presenting part, oxytocin was administered 3U over 5mins.The height of sensory block was assessed by loss of cold sensation tillT_{10} dermatomallevel and considered as onset of sensory block. The time required to reach the block height at least up toT_4 dermatome was considered as thedesiered height of block and the time was noted and allowed the obstetricians to proceed the surgery.Motor block was assessed by modified Bromage Scale[4] which included: 0= no motor block, 1= can flex knee, move foot but cannot raise leg, 2= can move foot only, 3= cannot move foot and grade 3 was considered as onset of motor block. Baseline and intraoperative mean arterial pressure(MAP) and heart rate(HR) were recorded at 5 mins interval. Fall of MAP >30% from the base line and HR < 60 beats/min were considered as

Submitted : 12th July,2019 | Accepted : 17th August,2019 | Publication : 15th September, 2019

hypotension and bradycardia respectively. Hypotension was corrected with phenylephrine 100mcg bolus and repeated when needed. Bradycardia wastreated with atropine 0.6mg intravenously. Adequate abdominal muscle relaxation was assessed by the height of sensory and motor block, duration of analgesia,and the obstetricians' satisfaction as adequate keeping desired level of haemodynamic stability. CDs were performed by the same surgical team to avoid any bias.Two dermatome regression of block height from the T4 level was considered as regression of the block and the time was noted. This time was considered as duration of sensory block. The duration of analgesia was considered at that point when patients needed analgesics and the time was noted. The time to achieve full return of motor power was considered as duration of motor block. Complications like hypotension, bradycardia, tachycardia,nausea and vomiting were recorded. If patient would complain pain or obstetricians would complain inadequate relaxation,general anesthesia (GA) with controlled ventilation would be administered .The number of patients require GA would be documented.Data were analyzed using Microsoft excel 2010and IBM SPSS(International business machines corporation statistical package of social sciences) software version 23. The numerical data between groups were analyzed using the unpaired Student's t-test and p value < 0.05 was considered as statistically significant.

RESULTS:

The age, weight, height, duration of surgery were comparable between the groups.(Table 1).Indications of CD in this study were: post CD(27), intra uterine growth retardation (22), non - progression of labor(33), post- dated pregnancy (28).The onset of sensory block(T_{10}) was significantly ($p<.000$) earlier in group B(3.31±0.46) than group A (3.69±0.54)(Table 2).The maximum block height (T4)was achieved in both groups.The time to reach maximum block height (T_4) was earlier in group B(6.11±0.83) than group A(7.42±0.76) with p value of 0.000 which was statistically significant.(Table 2).The regression of sensory block was earlier in group A than group B(group B : group A= 93.51±3.28 : 84.56±4.14) which was statistically significant with p value of 0.000.(Table2). The onset of motor block was earlier in group B(4.20±0.67) than group A(4.89±0.83) with the p value .000 which was statistically significant. The duration of motor block was prolonged in group B (116.40±3.95) than groupA(112.82±3.45) with p value 0.000 which was statistically significant. The duration of analgesia was prolonged in group B than Group A(Group B:Group A:120.29± 3.50: 116.95 ± 3.07) with p value 0.000 which was statistically significant.(Table 2). Muscle relaxation was adequate in both the groups.(Table3)Only 2 patients of each group required fentanyl 50 mcg i.v during visceral manipulation after delivery of the baby .The baseline MAP and HR were comparable between the groups.(Table 1&2,Fig 1&2). There werestatistically significant fall of average MAP following SA at 5 (Group B: Group A: 75.42 ± 6.35 :78.60 ± 5.84,p value0. 007) and 10 (Group B:Group A:68.24 ± 8.35:73.89 ±7.83, pvalue 0.000) mins in group B than group A. (Table 4,Fig1).Subsequent average MAP valueswere comparable between the groups. The intraoperative average MAP values (Group A :Group B:74.96±3.82 :74.54±2.66) and HR (Group A: Group B: 82.51±3.94: 82.79±4.43) were comparable(Table 4,Fig1 &Fig2).However, 3 patients of group A and 5 ofgroup B required vasopressor due to hypotension during intraoperative period. Tachycardia andbradycardia were observed only in 1 patient of Group B.Nausea and vomiting,pruritus and respiratory depression were not observed in any patient of both groups.

DISCUSSION:

The primary objective of this study was to observe the surgical condition by assessing the sensory and motor block, maximum height of block and abdominal muscle relaxation during elective CD with desired level ofhaemodynamic stability using lower than conventional doses of hyperbaric bupivacaine in presence of fixed dose of opioid. The number of patients received vasopressors and complications like hypotension, bradycardia, tachycardia, nausea and vomiting, pruritus and respiratory depression were observed during the study period.

In this study, the onset of sensory and motor block and the time to reach desired level of block height were significantly earlier in those who received 10 mg bupivacaine with fentanyl in comparison to those who received 7.5 mg hyperbaric bupivacaine with fentanyl. These findings are similar with most of the studies. [5]However,there werealso report that the time of onset of sensory block and to reach desired block height did not differ due to variation of doses among the groups which is contradictory to our findings.[6,7]The delay to achieve surgical condition to proceed CD in those receiving 7.5 mg, did not produce any harm as all were elective cases and there was no difference in Apgar score between the groups. This observation was supported by other investigators.[6]

In this study the desired level of block (T4) was achieved in all patients. The major factors affecting the dermatomal spread of SA include: baricity of anesthetic solution, position of the patient during and immediately after injection, drug dosage and volume, height and cerebrospinal fluid (CSF) volume of the patient, curvature of the spine and site of injection[8] In this study, the height of the patients were comparable between the groups .Hyperbaric solution was used in sitting position with injectable port directed cephalad at L4-L5 intervertebral space during administration of SA. But the drug dose and volume were different between the groups. However, the maximum height of block was achieved even with 7.5 mg hyperbaric bupivacaine mixed with fentanyl 25mcg (total volume of 2ml), that was similar to 10 mg hyperbaric bupivacaine mixed with fentanyl(total volume of 2.5ml). The rise of height of block might be due to raised intra abdominal pressure that causes engorgement of epidural veins leading to decreased CSF volume.Adequate muscle relaxation was achieved in the both groups.The time to start of regression of sensory block, duration of analgesia and motor block were greater in those received 10 mg hyperbaric bupivacaine than 7.5 mg. These findings were similar with most of the studies.[6,9]Good surgical condition was achieved with SA in the both groups.No patients required supplemental analgesics before the delivery of the baby.Only 2 patients of each group required fentanyl 50 mcg i.v during visceral manipulation after delivery of the baby. These may be due perception of discomfort associated with traction on the peritoneum or to handling of the viscera.

Hypotension following SA depends on the height of block, dose of the administered drug.In this study, the fall of average MAP at 5($p<0.007$) and 10($p<0.000$) mins were significantly less in those received 10mg bupivacaine in comparison to those received 7.5 mg. This observation may be due to the time to reach maximum height of sympathetic block.Rest of the intraoperative average MAP values were comparable between the groups. This finding corroborates with the findings of other study.[10]Bradycardia was not seen in any of the 7.5 mg group and only 1 patient found to havebradycardia in those received 10mg drug. But this was transient and corrected spontaneously without requiring any therapy. Tachycardia was also found in 1 patient of the same group which was resolved after administration of intravenous fentanyl.Various studies have been performed using lower doses ofhyperbaric bupivacaine. Even ultra low(3.75mg) bupivacaine was used in spinal space with epidural technique during CD with adequate surgical condition with minimum hypotension.[11]Hemodynamic .stability may be achieved with lower dose of hyperbaric bupivacaine at the

cost of inadequate surgical condition.The addition of opioid decreases the dose of local anesthetic which provides good surgical condition with hemodynamic stability.[12,13,14] So a pilot study was performed among 22 patients using 7.5 mg hyperbaric bupivacaine along with fentanyl before this study.

Limitations:

In this study, only two doses of hyperbaric bupivacaine that wereless than the conventional dose was compared. Blinding was not done as addition of normal saline with 7.5 mg of hyperbaric bupivacaine may alter baricityof the administered drug which may affect the block height. Intraoperative blood loss which might influence hemodynamic changes was not measured. The duration of postoperative analgesia was less with lower doses of hyperbaric bupivacaine following SA and there was early requirement of analgesic in the post operative period.

CONCLUSION:

So, it can be concluded that the 7.5mg dose of bupivacaine along with 25 mcg fentanyl may be used for spinal anesthesia as it provides good surgical condition with preservation of hemodynamic stability with minimal complications during elective cesarean delivery.

Table1: Demographic criteria and duration of surgery (expressed as mean ± SD)

	Group A	Group B	P value
Age(years)	22.51±2.801	23.05±3.176	0.342
Body weight(Kg)	57.05±5.261	56.82±5.358	0.816
Height(cm)	145.47±4.598	146.27±3.699	0.317
Duration of surgery(mins)	53.84±4.008	54±3.209	0.814

Table 2.Onset and duration (minutes) of sensory and motor block and APGAR score(expressed as mean ± SD):

	Group A	Group B	P value
Onset of sensory block (mins) (up to T10)	3.69±0.540	3.31±0.466	<0.0001
Onset of peak height of sensory block(mins) (up toT4)	7.42±0.762	6.11±0.832	<0.0001
Onset of motor block(mins)	4.89±0.832	4.20±0.678	<0.0001
Two dermatome regression of sensory block(mins)	84.56±4.144	93.51±3.288	<0.0001
Duration of motor block(mins)	112.82±3.459	116.40±3.952	<0.0001
Duration of analgesia (mins)	116.95±3.076	120.29±3.505	<0.0001
APGAR score	8.60±0.627	8.51±0.540	0.417

Table 3: Abdominal muscle relaxation:

	Group A	Group B
Adequate	55	55
Inadequate	nil	nil

Table 4: Intraoperative hemodynamic monitoring (exp re ssed as mean ± SD):

	Group A	Group B	P value
Baseline MAP(mm Hg)	81.76 ± 5.40	81.04 ± 4.57	0.447
Baseline HR(beats/min)	84.60± 5.61	85.44±6.46	0.470
Average MAP(mm Hg)	74.96±3.82	74.54±2.66	0.503
Average HR(beats/min)	82.51±3.94	82.79±4.43	0.731

Table 5.Incidence of complications and vasopressor requirement:

	Group A	Group B
Hypotension	03	05
Bradycardia	Nil	01
Tachycardia	Nil	01
Nausea & vomiting	Nil	00
Pruritus	Nil	Nil
Respiratory depression	Nil	Nil
No. of patients requiring vasopressor	03	05

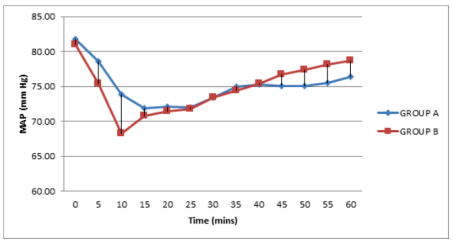

Fig1. Variation of MAP in relation with time

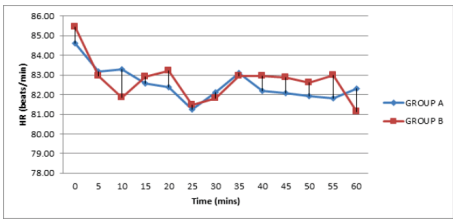

Figure 2: variation of HR in relation with time

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