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Anaesthesiology

KEY WORDS: bupivacaine, spinal anaesthesia, caesarean section

COMPARISON OF THE EFFECTS OF THREE DIFFERENT DOSES OF 0.5% BUPIVACAINE (7.5mg, 8.75mg & 10mg) IN WOMEN UNDERGOING ELECTIVE CAESAREAN SECTION UNDER SPINAL ANAESTHESIA.

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ABSTRACT

BACKGROUND: Caesarean sections both for elective & emergency cases are most commonly done under spinal anaesthesia. For caesarean sections bupivacaine is the most preferred drug now a days. A number of studies have sought an optimal dose of bupivacaine, but produced dissimilar findings with doses ranging from 5 to 15 mg.

MATERIAL & METHODS: 90 patients undergoing elective caesarean section, aged between 18-36years, belonging to ASA I or II were randomly divided into 3 groups after considering the inclusion & exclusion criteria.Group A recieved Inj Bupivacaine hyperbaric 7.5 mg (0.5%), Group B: Inj. Bupivacaine hyperbaric 8.75 mg (0.5%) & Group C: Inj. Bupivacaine hyperbaric 10 mg (0.5%). All the observations were recorded and the results were analysed and data are presented as mean ± S.D. for comparing data between three groups. ANOVA test was used and **p** values <0.05 were interpreted as clinically significant.

RESULTS: The demographic data was comparable in all the 3 groups. The onset of sensory block was 7.30±087 min in group A, 6.78±0.29 min in group B & 5.31±0.56min in group C. Onset of motor block was 6.18±0.31min in group A, 5.30±0.82min in group B & 4.67±0.34min in group C. Duration of sensory block was 137.77±18.80min in group A, 166.65±22.98min in group B & 184.67±24.74 in group C.

CONCLUSION: Increasing the dose of bupivacaine has faster onset and prolong the duration of sensory and motor blockade. There is increased incidence of hypotension, nausea and vomiting with increased dose of bupivacaine. In lower doses there is increased haemodynamic stability & early post-op ambulation at cost of Intraoperative pain and need of general anaesthesia in some cases.

INTRODUCTION

Caesarean sections both for elective & emergency cases are most commonly done under spinal anaesthesia. Spinal anaesthesia is easy to perform and provide fast onset and effective motor and sensory block. Local anaesthetics have been traditionally used for instituting subarachnoid block [1]. For caesarean sections 0.5% hyperbaric bupivacaine is the most preferred drug now a days. Anaesthesiology textbooks recommend bupivacaine in a dose of between 10 and 12 mg. But, this dose has given rise to incidences of maternal arterial hypotension of 69% to >80%, resulting in maternal and neonatal morbidity [2]. There have been many studies to decide an optimal dose of bupivacaine, but produced dissimilar findings with doses ranging from 5 to 15 mg [1,2]. The motive to use a lower dose is to to decrease the incidence of hypotension, intraoperative nausea/vomiting. However such a motive can lead to inadequate anaesthesia & analgesia intraoperatively & may further require conversion to general anaesthesia, a situation known as a risk factor for anaesthesia related maternal morbidity and mortality [3]. This study was undertaken to compare and evaluate efficacy (need of analgesic supplementation) and adverse effects (hypotension, nausea/vomiting) of neuraxial bupivacaine in low dose (7.5mg and 8.75mg) compared with conventional dose (10mg) for elective Caesarean delivery. The aims of the study are-

- To compare sensory & motor effects of low dose & conventional dose of Bupivacaine for spinal anaesthesia in caesarean section.
- To evaluate the hemodynamic stability & adverse effects of spinal anaesthesia in caesarean section with different doses of Bupivacaine.

MATERIAL AND METHODS

The study was initiated after approval by Institutional Ethical Committee. It was prospective, randomised, double-blind study. Informed consent was obtained from all the patients. The study was conducted in 90 female patients, aged 18-36 years, who were scheduled for elective caesarean section at McGann Hospital, Shimoga. Using a computer generated random number table, patients were enrolled into 3 groups. All the patients with significant systemic illness, with history of spine surgery or presence of infectious focus on the back, refusal for spinal anaesthesia, allergy to local anaesthetics were excluded from the study and only ASA I and II patients were included in the study. None of the patients had any contraindications to spinal anaesthesia [5].

The patients received the following dose of drugs intrathecally:
Group A: Inj Bupivacaine hyperbaric 7.5 mg (0.5%)
Group B: Inj. Bupivacaine hyperbaric 8.75 mg (0.5%)
Group C: Inj. Bupivacaine hyperbaric 10 mg (0.5%)

All patients were pre-medicated with oral ranitidine 150mg half an hour before the surgery. Patients were thoroughly counselled during the pre-operative evaluation and were properly explained about the nature of study before taking the written consent. In the operation theatre, a good venous access was secured with 18G cannula and all the patients were pre-hydrated with 15ml/kg of lactated Ringer's solution. All the baseline parameters were observed and recorded which consisted of electrocardiography (ECG), heart rate (HR), non-invasive blood pressure (NIBP), and pulse oximetry (SpO2). In all the patients, under strict aseptic and antiseptic precautions, skin was infiltrated with 2% local anaesthetic (24G hypodermic needle) followed by lumbar puncture, performed with 26G Quincke needle with midline approach in L2-L3 space. After proper and adequate flow of CSF study drug was injected. After injecting the study drug, patients were immediately returned to the supine position. With the help of Visual analog scale, pain was assessed. Duration of analgesia was recorded. VAS was assessed hourly & score of 4 or >4 was indication to give rescue analgesia in the form of I.V Diclofenac sodium 2mg/kg. Any episode of intraoperative hypotension (mean arterial blood pressure < 65 mmHg or 20% or more reduction from baseline) was treated with fast infusion of i.v. fluids and Inj. Mephentermine 6mg intravenous in incremental doses. Bradycardia (pulse <60/min) was treated with Inj. Atropine 0.6 mg i.v .Peri-operative emetic response was recorded. Inj.

Metoclopramide 10 mg i.v was given as rescue antiemetic. The data collected was subjected to statistical analysis using Statistical Package for the Social Sciences (SPSS version 25). During planning, the sample size was calculated with the help of power analysis. Assuming type I error of 0.05 and a type II error of 0.1 to detect 30 min difference in post-operative analgesia so as to yield a power of 80%, a sample size of 27 patients was calculated for each group. The inclusion of 30 patients in each group was done for better validation of results. Data is expressed as mean with a standard deviation. Discrete data is expressed as frequency with percentage of total. Normal distribution was tested using Kolmogorov-Smirnov test. Normally distributed continuous variables were compared using ANOVA with post hoc analysis using Bonferroni test. Chi-square test and Fischer exact test were used to compare discrete variables between the groups. A $P < 0.05$ was considered as a significant difference and $P < 0.0001$ as highly significant.

RESULTS

The study was conducted in 90 patients (n=30each) of ASA grade I and II posted for lower segment caesarean section. The patients received following doses of drugs intrathecally:

Group A: Inj. Bupivacaine hyperbaric 7.5 mg (0.5%)
Group B: Inj. Bupivacaine hyperbaric 8.75mg (0.5%)
Group C: Inj. Bupivacaine hyperbaric 10 mg (0.5%).

Table 1- Demographic Data

Variables	Group A	Group B	Group C	P value
Age (years) (Mean±SD)	26.78±6.56	24.2±8.15	22.73±3.95	0.0536
Wt (kg) (Mean±SD)	66.76±3.16	67.1±2.94	67.46±3.4	0.695
Ht (cm) (Mean±SD)	156.88±4.88	154.80±6.48	155.54±4.36	0.312
ASA Grading (I/II)	14/16	17/13	19/11	
Duration of surgery	48.46±6.42	50.73±11.78	49.75±9.44	0.649

Table 2- Onset of sensory block & motor block in minutes

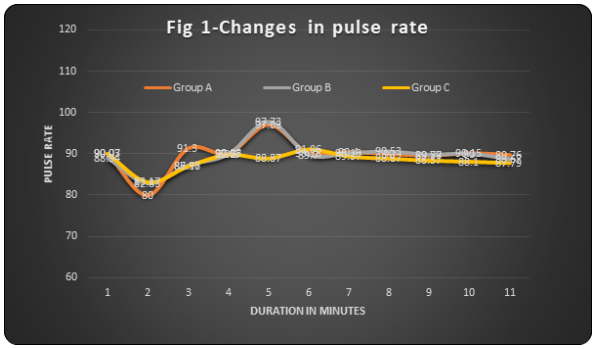
	Group A	Group B	Group C	P value
Time to reach T6	7.300.87	6.78	5.31	<0.0001
Time to reach bromage III	6.18	5.30	4.67	<0.0001

Table 3- Duration of sensory block & motor block in minutes

	Group A	Group B	Group C	P value
Time to reach L1	137.77±18.80	166.65±22.98	184.67±24.74	<0.0001
Time to reach bromage 0	124.54±14.68	145.96±12.36	170.38±23.92	<0.0001

Table 4- Duration of analgesia in minutes

	Group A	Group B	Group C	P value
Duration (min)	114.83±20.32	159.67±24.14	237.95±24.94	<0.0001



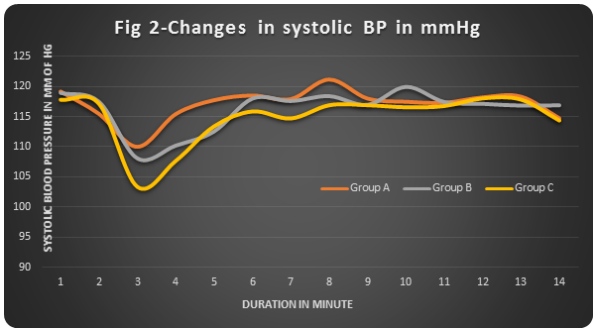


Table 6- Side effects

	Group A	Group B	Group C
Hypotension (MAP≤70)	0	4(10%)	8(20%)
Bradycardia (HR≤60)	0	0	0
Nausea	2 (6.66%)	2(6.66%)	4(12.67%)
Vomiting	0	0	2(6.66%)
Pruritus	0	0	0
Respiratory Depression	0	0	0

DISCUSSION

Duration of spinal anaesthesia for caesarean section should ideally last for the procedure, without incurring maternal or fetal adverse effects, but striking a balance between reliability and efficacy of subarachnoid block and its adverse effects is, at times, challenging.

The most common adverse effect seen after spinal anaesthesia is maternal hypotension which is seen in the absence of prophylactic measures. There are various studies which show that maternal hypotension, nausea & vomiting cause fetal acidemia due to uteroplacental hypoperfusion[4]. Strategies to avoid or limit spinal-induced hypotension include: giving intravenous fluid , administering vasopressor drugs & positioning the mother. The frequency and degree of hypotension is influenced by the dose of subarachnoid local anaesthetic [5] so it is not surprisable that the literature is replete with studies using lower doses than conventionally described. [6] Sympathetic block is usually 2 segments above the sensory block. Hence there is hypotension when sensory level is T6. Level of sensory block is also decided by baricity, volume & dose of the drug, position of the patient , barbotage & the needle direction .[5,7,11] Alan Santos et al studied 0.5% hyperbaric bupivacaine in 22 patients undergoing elective LSCS under spinal anaesthesia. The dose ranged from 7.5 to 10 mg(depending on the patient's height). In 13 patients they had given subarachnoid block at L3-L4 interspace and in the remaining 9 at L2-L3 interspace. They made head down tilt immediately after subarachnoid injection to achieve analgesia upto T3. They found that there was no correlation between the interspace used and level of anaesthesia. The demographic profile in the present study was comparable to similar other studies and did not show any significant difference on statistical comparison.

As L2-L3 space is selected for subarachnoid block in all patients in we have preloaded all patients 10-15 ml/kg ringer lactate and as the position of operation table is fixed, there are no major changes in heart rate and blood pressure in all three groups due to this. Compared to conventional dose, low dose bupivacaine may produce unsatisfactory blockade & hence result in inadequate anaesthesia & analgesia. [8,9,10] In the study done by Alan Santos et al complete regression of sensory analgesia took place after 258±16 min. Regression to the tenth thoracic dermatome took 142± 10 min and to the LI dermatome 178±11 min. Only two of 22 patients developed complete motor blockade (Bromage 3) of the lower extremities, each lasting for approximately 150 min. In the other patients, complete motor block was not achieved within the 12 min of early testing but became manifest when testing was resumed after completion of the operation. Full motor recovery occurred 165 min after induction.

In our study the mean time for regression of sensory block to L1

level was 137.77 ± 18.80 minutes in Group A, 166.65 ±22.98 minutes in Group B and 184.67±24.74 minutes in group C. Thus, the duration of sensory block was longest in group C followed by group B and then group A in decreasing order and the difference was statistically significant ($p < 0.05$).

The mean duration of motor block was 124.54± 14.68 minutes in Group A, 145.96± 12.36 minutes in Group B and 170.38± 23.92 in group C. Thus, the duration of motor block was prolonged in group C as compared to group B which was further longer than group A, the difference was statistically significant ($p < 0.05$).

Intraoperative heart rate was stable in all the three groups. There was no significant fluctuations in heart rate in all three groups as we have achieved level of blockade at T6 in each group and we have not added any adjuvants to any of the groups. C Arzola et al found that low-dose spinal anaesthesia was associated with a lower risk (22% reduction) of hypotension (RR 0.78, 95% CI 0.65–0.93) . The incidence of hypotension was 4.5% in Alan Santos et al study. Our finding was similar to C Arzola et al, Alan Santos et al and M S Islam et al as they also did not find any incidence of bradycardia in their studies.

Table 7- incidence of hypotension compared with other studies

Study	Year	Incidence of hypotension	
		Low dose	Conventional dose
Choi and colleagues[14]	2000	45%	52.5%
Kiran and Singal[12]	2002	20%	45%
Nagata and colleagues[15]	2004	36.8%	85.7%
M S Islam et al[5]	2012	5%	17.5%
Our study	2017	5%	20%

In study done by Alan Santos et al anaesthesia in two out of total 22 patients was judged to be inadequate for the procedure: one patient had a sensory level to T7 and required intravenous administration of ketamine 10 mg, the other, although sensory analgesia as assessed by pinprick extended to T5, complained of pain upon skin incision and had to be given general anesthesia.

In our study only four patients in group A required general anaesthesia. We have secured airway in all the four patients instead of I.V. anaesthetic agents where the duration of sensory blockade was less to complete the surgery.

Table 8- I.V analgesic requirement compared with other studies

Study	Year	i.v. analgesic requirement	
		Low dose	Conventional dose
Choi and colleagues[14]	2000	35%	10%
Kiran and Singal[12]	2002	25%	12.5%
Nagata and colleagues[15]	2004	0%	0%
M S Islam et al[5]	2012	40%	15%
Our study	2017	6.66%	0%

SUMMARY

Low doses of 0.5% hyperbaric bupivacaine in spinal anaesthesia for caesarean section is more likely to avoid undesirable side effects such as hypotension, nausea & vomiting, [10] but simultaneously there is incidence of slow onset & unsatisfactory spinal blockade which causes intraoperative pain & hence may require supplementation of general anesthesia. Low doses have the advantage of early ambulation due to reduced motor block & good maternal satisfaction.

CONCLUSION

Conventional doses (10-12mg) of 0.5% hyperbaric bupivacaine when compared to low doses (7.5 mg-8.75mg) provide faster onset & longer duration of sensory & motor block & hence there is longer duration of analgesia. Though conventional dose has few incidences of hemodynamic instability, hypotension, nausea & vomiting, it provides satisfactory blockade unlike low doses of bupivacaine. But early ambulation in postoperative period is advantage seen only in low doses.

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