

Comparison Between Fractionated and Single Bolus Dose of Local Anaesthetic (Bupivacaine 0.5% Heavy) in Elective Lower Segment Caesarean Section

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Abstract

Context : Fractionated dose of local anaesthetic in spinal anaesthesia has been compared with single bolus dose in terms of hemodynamic stability. **Aims:** Comparison of fractionated dose versus single bolus dose injection of local anaesthetic in spinal anaesthesia for patients undergoing elective caesarean section. **Settings and Design:** This prospective comparative study was conducted at a tertiary care hospital in central India. **Methods and material:** 200 healthy female parturients who were scheduled for elective caesarean section were allocated randomly into two groups- one that received fractionated dose and another that received single bolus dose of bupivacaine heavy (0.5%). With patient in sitting position subarachnoid block was established using dose according to height of the patient (0.07mg/cm height of patient). The single bolus group B received bupivacaine in single bolus over 10s. In Fractionated dose group F, patients received 2/3rd of the total calculated dose given initially followed by 1/3rd dose after 90s, both at a rate 0.2ml/s. After injection of initial 2/3rd dose, the syringe was kept attached to the spinal needle for the remaining 90s, after which remaining one third dose was administered. Data assessed were the number of hypotensive episodes and number of times vasopressors had to be given. **Statistical Analysis:** The data was collected using Microsoft excel and Statistical Package for Social Sciences (SPSS ver. 21). **Results:** There was statistically significant difference between the hemodynamic stability for the two groups. **Conclusion:** Fractionated dose of local anaesthetic was found to be hemodynamically more stable than single bolus dose.

Keywords: hypotension, single bolus dose, fractionated dose, hemodynamic stability.

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Introduction

Caesarean section is very commonly performed in parturients who are unable to deliver baby normally due to some reasons and to avoid complications. Over the years, countless numbers of lives of mothers and babies have been saved from caesarean section.

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General goals in choosing anaesthesia for caesarean section are safety of mother and baby, mother's comfort and ability to perform surgery under that anaesthetic technique. The choice of anaesthesia is determined by

multiple factors like indication for the surgery, its urgency, patient condition and preference and the skills of anaesthetist. Continued improvement in anaesthetic techniques along with emergence of obstetric anaesthesia specialists has greatly increased the effectiveness and safety of Caesarean section. Anaesthetic techniques available for caesarean section are general anaesthesia and neuraxial anaesthesia (spinal anaesthesia, epidural anaesthesia, combined spinal and epidural anaesthesia and continuous spinal anaesthesia).

Regional anaesthesia (spinal or epidural) should be chosen when possible as it has the least associated maternal morbidity. There are more chances of pulmonary aspiration of gastric contents, failed tracheal intubation, difficult airway and mask ventilation or both, which increases the maternal morbidity, with general anaesthesia as compared to neuraxial anaesthesia. Neuraxial blocks on the other hand, spinal

or epidural block, are easier, safer, minimizes neonatal exposure to drugs and increases mother-child bonding by allowing the mother to be awake to witness the delivery of her baby thus enabling her to participate and enjoy the birthing experience. Also the ability to coadminister opioids with local anaesthetics provides painfree postoperative period and more maternal comfort.

Spinal anaesthesia in comparison to epidural anaesthesia is quicker and easier, provides a denser block, is more cost effective and so more preferred. The rapidity of onset of spinal block is advantageous in cases where delivery of the fetus needs to be hastened due to compromised foetal state.

But due to direct action on central neuraxial system causing sympathetic block, the chance of hypotension is greater with spinal anaesthesia than with epidural anaesthesia. Maternal hypotension may lead to decrease in uteroplacental perfusion which may result in foetal acid base imbalance, maternal nausea and vomiting, and may be an important contributory factor for maternal morbidity related to regional anaesthesia. The incidence of hypotension is 75-85% with spinal anaesthesia which is detrimental to both mother and fetus[1, 2]. The administration of fluids, either colloids or crystalloids with left uterine displacement before spinal anaesthesia, administration of a prophylactic vasopressors, employing fractionated doses of local anaesthetic are some of the measures used to minimize the associated hypotension [3,5,6,8,9,10].

Patient characteristics that may influence the level of block include patient height, weight, age, sex, pregnancy, anatomic configuration of the spine, and CSF properties (volume and composition). There are studies which have shown that bolus dose of the local anaesthetic agent in spinal anaesthesia also causes hypotension[4].Badheka et al in their study found that fractionated dose of the local anaesthetic agent, in which two-third of the total calculated dose given initially followed by one-third dose after a time gap of 90s in spinal anaesthesia, achieves adequate anaesthesia and provides a dense block with haemodynamic stability.[13]

There are many studies which compare single bolus dose of local anaesthetic with fractionated dose or continuous infusion, but most of these studies are for epidural anaesthesia, assessing different parameters. [1,2] There are few studies which compare single dose and fractionated doses of local anaesthetic in spinal anaesthesia for elective caesarean section.[11,12,13]

The present study was undertaken to assess for haemodynamic stability between the two groups of patients, one group receiving fractionated dose of local anaesthetic and another group receiving single bolus dose of local anaesthetic.

Materials and Methods

Study Centre

Department of Anaesthesiology M.G.M. Medical College & M.Y. Hospital Indore. Patients admitted in the Obstetrics and Gynaecology Department, planned for elective caesarean section, during the period for 18 months from the time of approval from institutional review board were included in the study.

Study Design

“A Prospective Randomized Comparative Double blind study”.

Inclusion Criteria

- American Society of Anaesthesiologists physical status I–II
- Age between 18 to 40 years
- Height between 140 to 180 cm
- Singleton pregnancies scheduled for elective LSCS under spinal anaesthesia.

Exclusion Criteria

- American society of anaesthesiologist status III-IV
- Patients with pre-existing diseases or pregnancy-induced hypertension,
- Cardiovascular or cerebrovascular disease
- Any contraindication to Spinal Anaesthesia
- Patients weighing more than 110 kg and those taller than 180 cm or shorter than 140 cm
- Patients with severely altered mental status, spine deformities or history of laminectomy.
- Patients with inadequate sensory blockade and requiring conversion to general anaesthesia.

After approval by the Institutional Review Board, a bilingual written informed consent was obtained from all the participating patients. 200 patients of ASA grade I or II were randomly allocated to one of the two groups (B or F) of 100 patients each. Group B received bupivacaine 0.5% (H) in single bolus dose while, group F received bupivacaine 0.5% (H) in fractionated dose i.e. two-third of the calculated dose given initially followed by remaining one third dose after an interval of 90 seconds both doses given at a rate of 0.2ml/s.

All patients were premedicated with injection Ondansetron (0.1mg/kg intravenous [IV] and injection Ranitidine (1mg/kg) intravenous(IV) . Preloading was done by Lactate Ringers solution (10 ml/ kg). Standard monitors (pulse oximeter for SpO₂, heart rate (HR), non-invasive blood pressure, respiratory rate and ECG) were applied.

The procedure was carried out in the sitting position in L3-L4 or L4-L5 intervertebral space using a 25G Quincke spinal needle under all aseptic precautions, according to the standard institutional protocol. The single bolus group B received single bolus dose of bupivacaine. The fractionated dose group F received two-third of the total calculated dose given initially followed by one-third dose after 90s, both doses given at a rate 0.2ml/s. After injection of initial two-third dose, the syringe was kept attached to the spinal needle for remaining 90s after which remaining one third dose was administered. Thereafter, patient was placed in the supine position.

In this study, we assessed the hemodynamic stability [mean pulse rate and mean arterial blood pressure at 5minutes, 10minutes, 15minutes, 30minutes, 45minutes and 1hour after the induction till the end of surgery, the number of patients in whom vasopressors (Mephentermine /Ephedrine) had to be used Surgery was allowed when T₁₀ sensory block level and grade-IV motor block according to modified Bromage's scale were achieved. Patients not achieving block to this level were excluded from the study. Duration of surgery in all patients was around 40min to 1 hour.

Intraoperative fluid replacement was given as necessary depending on the blood loss and haemodynamic

parameters. Advanced equipments and drugs for resuscitation, airway management and ventilation were kept ready.

Supplementation with nasal oxygen at the rate of 3Lit./min was given to all patients. Intraoperative hypotension (>20% decrease in MAP from baseline value) was treated by injection Mephentermine/ Ephedrine in titrated doses with an increment of 3mg according to the response of the patient. Bradycardia (heart rate <50 beats/min) was treated with injection Atropine 0.01mg/kg IV.

The changes in pulse rate, mean arterial blood pressure, oxygen saturation (SpO₂) & respiratory rate were recorded at 0, 5, 10, 15, 30, 45 and 60min intervals up to the end point of surgery. Vital parameters were also monitored in postoperative period.

The observations recorded in the two groups were tabulated in master chart using Microsoft excel and Statistical Package for Social Sciences (SSPS ver. 21) was used to analyse the data. "Pearson Chi-square test" was applied for categorical data and continuous variables were analysed by "unpaired t test". Statistically significant difference in findings was considered when *p*-value was found to be <0.05. The final data was presented in the form of tables and graphs.

Results

The distribution of patients according to age, weight and height in both the groups was comparable (Table 1). Higher number of patients in fractionated dose group (85) compared to single bolus dose group (61) were hemodynamically stable and did not require vasopressors (*p* value<0.05) (Table 2).

Table 1: Comparison of different demographic variables

Group	Number	Age (years)	Weight (kg)	Height (cm)
		Mean ± SD	Mean ± SD	Mean ± SD
GROUP B	100	25.15 ± 2.43	56.02 ± 2.91	149.58 ± 3.81
GROUP F	100	24.82 ± 2.09	56.97 ± 4.17	149.64 ± 4.30

Table 2 : Intraoperative comparison of mean pulse rate between the two groups at different time intervals

Time Interval	GROUP B (n=100) (Mean±SD)	GROUP F (n=100) (Mean±SD)	't' value	P value
At induction	88.6±5.787	88.94±4.03	0.468 df=198	0.640
5min after induction	83.86±16.543	85.56±10.23	0.874 df=198	0.383
10 min after induction	79.39±22.084	81.99±18.434	0.904 df=198	0.367
15 min after induction	79.53±22.627	83.91±16.455	1.566 df=198	0.119
30 min after induction	93.69±3.852	94.08±3.341	0.765 df= 198	0.188
45 min after induction	88.32±6.791	87.71±5.91	0.677 df=198	0.499
1 hour after induction	83.35±7.52	84.7±6.93	1.32 df=198	0.189

The baseline pulse rate of the patients in the two groups were comparable. After induction, there was decrease in the pulse rate in both groups. The decrease in the pulse rate was more for bolus group as compared to

fractionated group at 5min, 10 minutes, 15minutes after induction. After 30 minutes of induction, pulse rates of the two groups got settled and were more or less the same. The differences in mean pulse rates of the two groups were statistically insignificant.

Table 3 : Intraoperative comparison of mean blood pressure between the two groups at different time intervals

Time interval	GROUP B (n=100) (Mean±SD)	GROUP F (n=100) (Mean±SD)	't' value	P value
At induction	89.08±5.063	90.17±4.37	1.651 df=198	0.100
5min after induction	81.22±18.28	85.91±14.864	1.99 df= 198	0.048
10 min after induction	80.02±19.67	90.00±14.700	4.064 df=198	0.000
15 min after induction	83. 57±22.36	90.86±11.027	2.923 df=198	0.004
30 min after induction	93.04±10.156	92.92±11.29	0.536 df=198	0.937
45 min after induction	85.82±9.958	86.18±11.113	0.891 df=198	0.088
1 hour after induction	85.49±7.49	85.66±7.60	0.294 df= 198	0.810

The mean arterial blood pressure decreased after induction in both the groups. The decrease in BP after induction was more for group B than for group F at 5min, 10min, 15 min after induction and the difference was statistically significant. But after 30 minutes till the end of surgery (1 hour), the mean BP for both the

groups were more or less same and was statistically insignificant.

The line diagram below shows that there is less fluctuation in mean BP in fractionated dose group than bolus dose group (i.e. better hemodynamic stability with fractionated dose group).

Table 4: Comparison of hemodynamic stability in both groups

	Group B	Group F
Hemodynamically stable (no vasopressor used)	61	85
Hemodynamically unstable (required vasopressors)	39	15

Discussion

One of the most common interventions operatively done in obstetrics is caesarean section. Mostly caesarean sections are done under spinal anaesthesia which is preferred due to rapid onset of sensory and motor block and also parturient can immediately see her baby while under subarachnoid block. So unless otherwise contraindicated spinal anaesthesia is preferred in elective caesarean section. But the most commonly seen complication is maternal hypotension due to which uteroplacental circulation is also hampered which in turn adversely affect the foetal outcome. So, various studies have been done to check the measures which can lead to less incidences of maternal hypotension.

C. Arzola et al[17], Nagata E et al[18], Zahir J et al[19] in their studies used fixed doses of bupivacaine. In many studies, calculated doses of bupivacaine 0.5% (H) according to different parameters like weight, height, body mass index of patients were used. Khalid Mandood Siddique et al in 2015, in his study, compared between the spinal anaesthetic doses based on height and weight versus height alone in 60 patients undergoing elective caesarean section. In his study, hypotension was observed more in the dosage group based on height (56.7%) than in the group in which dosage was based on both weight and height (26.7%) (p value = 0.018, statistically significant)[15].

Harten et al[7] in their study observed that the incidence of hypotension was less when dose of bupivacaine was adjusted according to height and weight of parturient and not when fixed dose was given.

In another study which done by Dutch anaesthetists[15], it was found that patient's height was a stronger

determinant for dose adjustment than weight and body mass index. In our study, we gave bupivacaine 0.5% heavy according to the height of the patient (0.07 mg/cm) and we got adequate results.

Fahmy et al [5] in their study also compared haemodynamic stability in patients who were given fractionated dose versus those who were given bolus dose and they found that better haemodynamic stability was achieved in patients who received fractionated dose. In our study we also got similar results.

Also we observed a decrease in pulse rate after induction in both the groups, and this was statistically insignificant. We used vasopressors and preloading in order to avoid hypotension. There are several studies which used different vasopressors to control maternal hypotension.

Kansal et al[20] compared mephentermine and ephedrine to control hypotension in spinal anaesthesia and found both to be equally effective.

Various studies such as those of Fahmy et al[5], Badheka et al[13], Patel et al[12] also found that better haemodynamic stability is achieved with fractionated dose.

In a similar study done by Badheka et al in 2017, the study was carried out in sixty patients undergoing elective LSCS[13]. Patients were divided into two groups. Group B patients received single bolus with injection bupivacaine 0.5% (heavy) and Group F patients received fractionated dose. They recorded and analysed the time of onset and regression of sensory and motor block, intraoperative haemodynamics and duration of analgesia. They found that all the patients were haemodynamically stable in Group F as compared to Group B. Duration of sensory and motor block and

duration of analgesia were longer in Group F compared to Group B, concluding that fractionated dose of spinal anaesthesia provides greater haemodynamic stability and longer duration of analgesia compared to bolus dose.

In another such study by Patel B et al in 2018 who did a comparison of fractionated versus bolus dose of Bupivacaine in spinal anaesthesia for 60 patients with PIH undergoing elective caesarean section.[12] Characteristic of sensory and motor block, duration of analgesia and hemodynamic stability were compared.

All the patients were haemodynamically stable in group F as compared to group B similar to our study. Duration of sensory and motor block and duration of analgesia were longer in group F as compared to group B.

In our study also we found that group of patients receiving fractionated dose of local anaesthetic were hemodynamically more stable as compared to the group receiving single bolus dose of local anaesthetic.

Rationale of Our Study

to evaluate whether hemodynamic stability is better with fractionated dose than with bolus dose.

Result

Result of our study and rationale justify each other. In our study fractionated dose provided better hemodynamic stability than single bolus dose.

Conclusion

It can be concluded that local anaesthetic when given in fractionated manner provide better hemodynamic stability than when given in single bolus dose. further studies can be done to compare fractionated dose and single bolus dose in high risk and critically ill patients.

Limitations of Study

We did not measure the neonatal outcome by any parameter like APGAR score and umbilical cord blood pH and uteroplacental perfusion. So we could not comment on the effect of fractionated dose of local anaesthetic on neonatal outcome and uteroplacental perfusion.

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