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Comparison between fractionated dose with bolus dose in Spinal Anaesthesia for haemodynamic stability and duration of analgesia in patients undergoing elective Lower Segment Caesarean Section

*MM Hossain[1], B Biswas[2], PK Mohanta[3], MM Hassan[4], P Basu[5], F Islam[6]

Abstract

Background: Elective or emergency caesarean sections are routinely done under spinal anaesthesia (SA) with bolus dose of local anaesthetic drugs. Objective: To compared fractionated dose with bolus dose in SA for haemodynamic stability and duration of analgesia in patients undergoing elective lower segment caesarean section (LSCS). **Methods:** The present study was carried out in the Department of Anaesthesiology, Ad-din Akij Medical College Hospital, Khulna from January 2018 to December 2018 on sixty female patients (thirty in each group) of the American Society of Anesthesiologists physical status I–III, age from 18 to 40 years, height from 140 to 180 cm, singleton pregnancies scheduled for elective LSCS under SA. Patients with pre-existing diseases or pregnancy-induced hypertension, cardiovascular or cerebrovascular disease, any contraindication to SA, those weighing <50 kg or >110 kg and those taller than 180 cm or shorter than 140 cm and severely altered mental status, spine deformities or history of laminectomy were excluded from the study. **Results:** The mean duration of analgesia was statistically significant ($p<0.05$) between two groups. Mean pulse rate- after 5 min, after 10 min, after 15 min, after 30 min, after 45 min and after 60 min were significantly ($p<0.05$) higher in group F than group B. Mean arterial pressure- before given study drug, after 0 min, after 5 min, after 10 min, after 15 min, after 30 min, after 45 min and after 60 min were not significantly ($p>0.05$) between two group. 14 patients (46.7%) in group B and 5 patients (16.7%) in group F required vasopressor. The difference was significant ($p<0.05$) between two groups. **Conclusion:** Separation process in which a certain quantity of a mixture dose of SA provides better haemodynamic stability and longer period of analgesia compare to bolus dose in patients undergoing elective caesarean section.

1. Dr. Md. Munjur Hossain, Assistant Professor & Head, Department of Anaesthesiology, Ad-din Akij Medical College Hospital, Khulna. E-mail: dr.munjur@yahoo.com
2. Dr. Biplab Biswas, Resident Surgeon, Department of Surgery, Khulna Medical College, Hospital, Khulna.
3. Dr. Pankaj Kumar Mohanta, Junior consultant, Department of Anaesthesiology, Mohammad Ali Hospital, Bogura.
4. Dr. Muhammad Masud Hassan, Assistant Professor, Department of Anaesthesiology, Community Based Medical College Hospital, Mymensingh.
5. Dr. Plabon Basu, Associate Professor, Department of Ophthalmology, Ad-din Akij Medical College Hospital, Khulna.
6. Dr. Farhana Islam, Associate Professor, Department of Gaynaecology & Obstetrics, Ad-din Akij Medical College Hospital, Khulna.

Introduction

Elective or emergency caesarean sections are routinely done under spinal anaesthesia (SA) with bolus dose of local anaesthetic drugs. SA with bolus dose injection provides rapid onset of action but with profound hypotension and can compromise the uteroplacental blood flow which in turn may lead to foetal acid base abnormalities.[1] Spinal anaesthesia (SA) with bolus dose has rapid onset but may precipitate hypotension. When we inject local anaesthetic in fractions with a time gap, it provides a dense block with haemodynamic stability and also prolongs the duration of analgesia.[2] Several factors like height, weight, pregnancy and anatomical changes influence the dose of local anaesthetic drug for its intensity and duration of spinal block.[3] 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 the same level of spinal anesthesia.[4] The most common side effect observed in these cases is hypotension which has profound effect on maternal and neonatal morbidity.[5] We have contemplated a prospective randomised double blind comparative study with bolus vs fractionated dose by giving two thirds of the dose initially and then one third dose after 60 secs by using Bupivacaine heavy 0.5% 2 cc to observe the onset of sensory and motor blockade, MAP, HR, APGAR score and duration of analgesia in pregnant women undergoing elective LSCS.

Materials and methods

The present study was carried out in the Department of Anaesthesiology, Ad-din Akij Medical College Hospital, Khulna January 2018 to December 2018 on sixty female patients (thirty in each group) of the American Society of Anesthesiologists physical status I–III, age from 18 to 40 years, height from 140 to 180 cm, singleton pregnancies scheduled for elective LSCS under SA. Patients with pre-existing diseases or pregnancy-induced hypertension, cardiovascular or cerebrovascular disease, any contraindication to SA, those weighing <50 kg or >110 kg and those taller than 180 cm or shorter than 140 cm and severely altered mental status, spine deformities or history of laminectomy were excluded from the study. Standard monitors including non□invasive blood pressure (NIBP), electrocardiogram (ECG) and pulse oximeter (SpO2) were attached to the patient, and baseline blood pressure and heart rate (HR) were recorded. Intravenous (I/V) line was taken with 18□gauge I/V cannula and patients were pre-medicated with ranitidine 1 mg/kg and ondansetron 0.1 mg/kg I/V. The patients were preloaded with Ringer's lactate (RL) solution 10–15 ml/kg over 10 min. SA was given in sitting position with 23□gauge Quincke spinal needle in L_3–L_4 or L_4–L_5 interspace after skin infiltration with lignocaine (2 ml, 2%). After aspiration of cerebrospinal fluid, injection bupivacaine 0.5% heavy was injected according to respective groups, B and F. Total dose of SA was calculated as 0.07 mg/cm of the height of the patient. The patients were randomly divided into two groups. Group B patients received a single bolus dose of bupivacaine over 10 sec. Group F patients received fractionated dose of bupivacaine with two-third of the total calculated dose given initially followed by one-third dose after 90 s, both doses given at a rate of 0.2 ml/s. After injection of initial two-third dose, the syringe was kept attached to the spinal needle for remaining 90 s, after which remaining one□third dose was administered. To prevent observer's bias, patients were kept sitting for 90 s after completion of the subarachnoid injection in Group B. Patients were turned into the supine position with a wedge under the right hip in both groups. We supplemented oxygen with the nasal cannula

at 3 L/min. The patients were randomly divided into two groups using computer-generated sequential number placed in sealed envelopes and opened only before the commencement of the study. The study was conducted in a double-blind fashion such that the patient and the assessor were unaware of the group allocation. The assessor was kept blinded during the administration of the drug. Only the attending consultant administering the SA knew the group allocation. We assessed and recorded time of onset, level and regression of motor and sensory block. Confirmation of sensory block was assessed by loss of sensation to pinprick. Motor blockage was assessed by a modified Bromage scale. These tests were performed every 5 min till the achievement of maximum sensory and motor block (Bromage scale 3) and every 30 min post□operatively until the sensory and motor variables were back to normal. The onset time of sensory or motor blockade was defined as the interval between intrathecal administration and time to achieve maximum block height or a modified Bromage score of 3, respectively. The surgical incision was allowed when loss of pin-prick sensation reached the T6 dermatome level bilaterally and when Bromage scale of three was achieved. Patients with inadequate sensory blockade and requiring conversion to general anaesthesia were excluded from the study. Intraoperatively, patients were monitored with continuous ECG, HR, NIBP and SpO2. Hypotension was treated when mean arterial pressure (MAP) decreased □20% of baseline with injection mephentermine 5 mg given IV and repeated when needed. The number of hypotensive episodes and mephentermine used were recorded for each patient. We treated bradycardia if any (HR of < 60 beats/min) with I/V atropine 0.6 mg. The duration of sensory blockade was defined as the interval from intrathecal administration of local anaesthetic to S2 segment regression. The duration of motor blockade was defined as the time interval from the onset of motor block to the time of achievement of modified Bromage scales zero (0). The patient was given diclofenac sodium 75 mg intramuscular as rescue analgesic. After delivery, we administered IV oxytocin 5 IU IV slowly and 15 IU in 500 ml RL. The incidence of nausea, vomiting, respiratory distress, shivering, pruritus, urinary retention was noted for 24 h post□operatively and treated accordingly. The attending paediatrician assessed Apgar scores at 1 and 5 min. All the observations were recorded, and all the results were analysed statistically using SPSS-23. Qualitative data such as age and maximum dermatome achieved were analysed statistically using Chi□square test. Quantitative data were presented as mean ± standard deviation (SD) and analysed using the unpaired t□test. P <0.05 was considered statistically significant. Sample size calculation was based on the pilot study, considering the difference in MAP changes of 6 mmHg after 15 min of SA. With an □ error of 0.05 and power of study 90%, the sample size came to 28. We enrolled thirty patients in each group considering the drop outs.

Results

Table 01: Demographic profile of the study patients (n=60)

Demographic profile	Group B (n=30)	Group F (n=30)	P value
	Mean±SD	Mean±SD	
Age (years)	28.1±7.0	26.8±5.2	0.418^{ns}
Height (cm)	153.1±4.2	152.4±4.9	0.928^{ns}
Weight (kg)	59.4±6.9	56.5±7.1	0.114^{ns}
Duration of surgery (min)	50.9±13.3	52.1±12.0	0.715^{ns}
Gestational age (weeks)	36.0±1.3	36.3±1.2	0.357^{ns}
APGAR score	8.6±0.5	8.5±0.4	0.396^{ns}
Dose (ml)	2.11±0.05	2.13±0.06	0.166^{ns}

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ns= not significant

P value reached from unpaired t-test

Group B= Bolus dose

Group F= Fractionated dose

Demographic profile were not statistically significant (p>0.05) between two groups.

Table 02: Characteristics of sensory and motor block (n=60)

	Group B (n=30) Mean±SD	Group F (n=30) Mean±SD	p value
Onset of sensory block (min)	2.0±0.7	1.6±0.5	0.014[s]
Duration of sensory block (min)	165.9±30.6	254.2±38.8	0.001[s]
Onset of motor block (min)	6.3±1.2	4.7±1.1	0.001[s]
Duration of motor block (min)	174.5±28.3	203.1±40.2	0.002[s]

s= significant

P value reached from unpaired t-test

Table 02 shows that mean onset of sensory block was found 2.0±0.7 minute in group B and 1.6±0.5 minute in group F. The mean duration of sensory block was found 165.9±30.6 minute in group B and 154.2±38.8 minute in group F. The mean onset of motor block was found 6.3±1.2 minute in group B and 4.7±1.1 minute in group F. The mean duration of motor block was found 174.5±28.3 minute in group B and 203.1±40.2 minute in group F. The difference were statistically significant (p<0.05) between two groups.

Table 03: Distribution of the study patients according to duration of analgesia (n=60)

	Group B (n=30) Mean±SD	Group F (n=30) Mean±SD	p value
Duration of analgesia (min)	231.8±41.8	287.8±47.7	0.001[s]
Range (min-max)	160-310	153-340	

s= significant

P value reached from unpaired t-test

Table 03 shows that mean duration of analgesia was found 231.8±41.8 minute in group B and 228.8±47.7 minute in group F. The difference was statistically significant (p<0.05) between two groups.

Table 04: Pulse rate in different follow up (n=60)

Pulse rate (b/min)	Group B (n=30) Mean±SD	Group F (n=30) Mean±SD	p value
Before given study drug	95.0±4.1	94.6±7.6	0.800[ns]
After 0 min	99.0±4.3	100.5±8.7	0.400[ns]
After 5 min	96.6±4.2	101.2±6.9	0.002[s]
After 10 min	95.4±4.6	102.4±7.8	0.001[s]
After 15 min	96.9±5.3	100.7±6.8	0.014[s]
After 30 min	97.1±5.9	100.4±6.5	0.044[s]
After 45 min	88.9±7.7	99.9±6.4	0.001[s]
After 60 min	86.0±7.6	100.7±7.1	0.001[s]

s= significant, ns= not significant

P value reached from unpaired t-test

Mean pulse rate- after 5 min, after 10 min, after 15 min, after 30 min, after 45 min and after 60 min were significantly (p<0.05) higher in group F than group B.

Table 05: MAP in different follow up (n=60)

MAP (mmHg)	Group B (n=30)	Group F (n=30)	p value
	Mean±SD	Mean±SD	
Before given study drug	83.2±9.3	82.7±9.8	0.841[ns]
After 0 min	83.7±9.4	84.6±8.1	0.693[ns]
After 5 min	84.0±10.0	86.4±7.4	0.295[ns]
After 10 min	81.9±7.2	84.0±6.2	0.231[ns]
After 15 min	79.7±7.8	82.9±7.0	0.099[ns]
After 30 min	74.4±6.9	77.7±7.4	0.079[ns]
After 45 min	74.2±7.4	76.3±5.8	0.226[ns]
After 60 min	73.9±8.0	76.6±6.5	0.157[ns]

ns= not significant

P value reached from unpaired t-test

Mean arterial pressure- before given study drug, after 0 min, after 5 min, after 10 min, after 15 min, after 30 min, after 45 min and after 60 min were not significantly (p>0.05) between two group.

Table 06: Distribution of the study patients according to complaints (n=60)

Complaints	Group B (n=30)		Group F (n=30)		P value
	n	%	n	%	
Nausea or vomiting	1	3.3	0	0.0	0.313[ns]
Shivering	1	3.3	1	3.3	1.000[ns]
Hypotension	1	3.3	0	0.0	0.313[ns]

ns= not significant

P value reached from chi square test

Table 06 shows that 1(3.3%) patients had nausea or vomiting in group B and nor found in group F. One (3.3%) patients had shivering in group B and group F respectively. One (3.3%) patients had hypertension in group B and nor found in group F. The difference were not significantly (p>0.05) between two groups.

Table 7: Requirement of vasopressor of the study patients (n=60)

Required vasopressor	Group C (n=30)		Group B (n=30)		P value
	n	%	n	%	
Yes	14	46.7	5	16.7	0.013[s]
No	16	53.3	25	83.3	

s= significant

P value reached from chi square test

Table 07 shows that 14 patients (46.7%) in group B and 5 patients (16.7%) in group F required vasopressor. The difference was significant (p<0.05) between two groups.

Discussion

In this study observed that, the mean age 28.1 (±7.0) were in Group B and 26.8 (±5.2) were in Group F. Demographic profile were not statistically significant (p>0.05) between two groups. Similar observation was found by Badheka et al.[2] who showed no significant difference was found in both group in demographic profile. Manjula et al.[1] also reported demographic variables age, height and weight were comparable between the two groups.

In this study we observed that the mean onset of sensory block was 2.0±0.7 minute in group B and 1.6±0.5 minute in group F. The mean duration of sensory block was found 165.9±30.6 minute in group B and 154.2±38.8 minute in group F. The mean onset of motor block was found 6.3±1.2 minute in group B and 4.7±1.1 minute in group F. The mean duration of motor block was found 174.5±28.3 minute in group B and 203.1±40.2 minute in group F. The difference were statistically significant (p<0.05) between two groups. Badheka et al.[2] reported onset of sensory and motor blockade was comparable between two groups while duration of sensory

and motor regression was statistically significant among the two groups-161±29 and 236±42 min in Group F and 145±25 and 204±42 min in Group B, respectively, P < 0.05. Schnider et al.[6] suggested that the onset time for achieving an adequate sensory level for surgery increases linearly with height and decreases with increasing weight while another clinical study demonstrated that the dose of intrathecal bupivacaine for caesarean delivery is similar in obese and normal weight women.[7] Harten et al. study results showed that 17% of the patients presented with cervical dermatomal block levels in the fixed dose group and only 4.5% of the patients in the adjusted dose group reported cervical dermatomal block levels.[8] A retrospective study observed a higher percentage of hypotension in pregnant women with obesity class three, which might be due to the greater extension of a higher sympathetic blockade caused by compression of the subarachnoid space by the pregnant abdomen associated with obesity.[9] Manjula et al.[1] reported the onset of sensory, motor blockade and two segment sensory regression was delayed in the study group F and this difference was statistically significant (p<0.05). The duration of sensory and motor regression was also significantly (p<0.05) prolonged in group F.

In current study the mean duration of analgesia was found 231.8±41.8 minute in group B and 228.8±47.7 minute in group F. The difference was statistically significant (p<0.05) between two groups. Badheka et al.[2] reported longer duration of analgesia with Group F as compared to Group B [P < 0.001]. Manjula et al.[1] also reported similar observation which showed the difference was statistically significantly higher in group F than group B.

In this study it was observed that the mean pulse rate- after 5 min, after 10 min, after 15 min, after 30 min, after 45 min and after 60 min were significantly (p<0.05) higher in group F than group B. Badheka et al.2 reported patients were haemodynamically more stable in Group F as compared to Group B. Badheka et al.[2] in providing stable HR in the fractionated dose group. However, there was no significant change in MAP in our study in both the groups, probably because the BP was maintained with the use of mephenteramine. Patel et al.[10] who observed more stable haemodynamics and less vasopressors requirement with fractionated dose SA as compared to the single bolus use of SA in LSCS. Agrawal et al.[11] who concluded that sitting position for 30 seconds after spinal anaesthesia helps to prevent high spinal and gives better haemodynamic stability.

In present study it was observed that the mean arterial pressure- before given study drug, after 0 min, after 5 min, after 10 min, after 15 min, after 30 min, after 45 min and after 60 min were not significant (p>0.05) between two groups. Similar finding was observed in the study of Badheka et al.[2] which showed mean arterial pressure were not significantl (p>0.05) between two groups. Favarel et al.[12] studied sixty elderly patients undergoing surgery for hip fracture for haemodynamic tolerance of titrated doses of bupivacaine versus single dose SA and concluded that titrated doses of bupivacaine was safe, efficient and provided better haemodynamic stability than single dose SA. Manjula et al.[1] reported that the requirement of mephenteramine which was used as rescue drug to control blood pressure was significantly (p<0.05) different in between the groups and more in group B.

Regarding complications, 1(3.3%) patients had nausea or vomiting in group B and nor found in group F. One (3.3%) patient had shivering in group B and group F respectively. One (3.3%) patients had hypertension in group B and none in group F. The difference were not significantly (p>0.05) between two

groups. Badheka et al.[2] reported one patient in Group B developed nausea and vomiting and one developed hypotension. One patient in each of the Groups B and F developed shivering. None of the patients developed dryness of mouth, pruritus, sedation, respiratory depression, bradycardia and headache in both groups. Harten et al.[8] compared the effects of two dosage regimens, fixed as well as adjusted dose and concluded that successful SA for caesarean section has been associated with a low incidence of hypotension with dosage regimen adjusted for height and weight. Fahmy[13] compared the circulatory and anaesthetic effects of bolus versus fractionated administration of bupivacaine. Manjula et al.[1] reported the adverse effects like nausea, vomiting and shivering monitored intra and post operatively were comparable in both the groups.

This study showed that 14(46.7%) patients were found to be required vasopressor in group B and 5(16.7%) in group F. The difference was significant ($p<0.05$) between two groups. Badheka et al.[2] showed 5 patients (16.66%) in Group F and 14 patients (46.66%) in Group B required vasopressor [P = 0.013]. Bhardwaj et al.[14] compared the three vasopressors ephedrine, phenylephrine and mephentermine for control of maternal blood pressure during caesarean section and concluded that all three were equally effective in maintaining maternal blood pressure as well as umbilical pH during SA for caesarean section.

Conclusion

Separation process in which a certain quantity of a mixture dose of SA provides better haemodynamic stability and longer period of analgesia compare to bolus dose in patients undergoing elective caesarean section. To avoid unexpected hypotension, fractionated dose of SA can be a suitable and protected substitute in LSCS.

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