Comparative study between fractionated and single bolus dose of local anaesthetic in elective lower segment caeserean section

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Abstract
Context: To evaluate whether Fractionated dose is an alternative to single bolus dose in spinal anaesthesia in terms of haemodynamic stability, total analgesic duration and quality of sensory and motor block.

Aims: We aim to compare between fractionated and single bolus dose of local anaesthetic in subarachnoid block in elective LSCS.

Settings and Design: This prospective comparative study was conducted at a tertiary care hospital in central India.

Materials and Methods: 200 healthy female patients were randomly divided into groups (100 in each) group F (fractionated group) and group B (single bolus group). Subarachnoid block was given in sitting position in both the groups with 0.5% hyperbaric bupivacaine according to the height of the patient (0.07mg/cm) height. Group B was given single bolus dose over 10 seconds. Group F received 2/3rd of the dose initially followed by 1/3rd dose after 90 sec, the rate was 0.2ml/sec in both the groups. In group F, syringe was kept attached to the spinal needle after 2/3rd dose for 90 sec, after which the remaining 1/3rd dose was given. Data assessed was onset, level and duration of sensory block. Onset of sensory block assessed by pin prick sensation. Onset, duration & regression of motor block was also assessed. Duration of analgesia and the number of hypertensive episodes was also noted.

Statistical Analysis used: Collected data was analysed using Microsoft excel and Statistical Package for Social Sciences (SPSS ver. 21).

Results: Significant statistical difference was found between the two groups in terms of haemodynamic stability, characteristic of block, time of first rescue analgesia and total duration of analgesia.

Conclusions: Fractionated group was found to be more haemodynamically stable with good quality sensory and motor block.

Introduction
Caesarean section is one of the most common operative interventions performed in obstetrics, whose development and application has saved lives of countless mothers and infants.

Each anaesthesia technique whether general or neuroaxial is laden with its inherent pros and cons. Regional anaesthesia should be chosen when possible as it has the least associated maternal morbidity, minimize neonatal exposure of drug and increase mother-child bonding by allowing the mother to enjoy birthing experience. Spinal anaesthesia in comparison to epidural is quicker, provide a dense block but, due to sympathetic block, is more related to maternal hypotension which may lead to decreased uteroplacental perfusion. The incidence of hypotension without preloading is 75-85% with bolus dose of spinal anaesthesia.¹ Thus we formulated this study to compare fractionated dose and single bolus dose of local anaesthetic in spinal anaesthesia for elective caesarean section for haemodynamic stability, quality of sensory & motor block and analgesic duration.

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, were included in the study after being approved from institutional review board.

Study Design
“A Prospective Randomized Comparative study”.

Inclusion Criteria
1. All patients with single live pregnancy scheduled for elective caesarean section.
2. Patients in age group 18-30 years.
3. Height between 140 to 180 cm.

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Exclusion Criteria
1. Patients with known contraindication to spinal anaesthesia.
2. Patients weighing more than 110 kg and those taller than 180 cm or shorter than 140 cm.
3. Patient with partial or no effect of spinal anaesthesia.

After approval by the Institutional Review Board, a bilingual written informed consent was obtained from all the participating patients. All patients of single live pregnancy scheduled for elective caesarean section with age group 18 to 30 years and height 140 to 160 cm were included in the study and patients with contraindications to spinal anaesthesia were excluded from study. Thus after inclusion and exclusion criteria, 200 patients formed the cohort which 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.

All patients were premedicated with injection Ondansetron (0.1mg/kg intravenous (IV) and injection Ranitidine (1mg/kg) intravenous (IV). Preloading was done by Lactate Ringer’s solution (10 ml/ kg). Standard monitoring (pulse rate, respiratory rate, NIBP, SPO2 & ECG) was done.

After taking all aseptic precautions, spinal block was given in sitting position in L3-L4 or L4-L5 inter vertebral space with 25G Quinke spinal needle, according to the standard institutional protocol. The group B received single bolus dose of Bupivacaine0.5%(H)and group F received the fractionated dose i.e. after calculating the total dose according to the height of the patient, 2/3rd of the dose was given initial, keeping the needle in situ and after an interval of 90sec, the remaining 1/3rd of the dose was administered. Patients were turned to supine position with a wedge under the right hip in both the groups without any tilt.

Data assessed were
1. Duration of analgesia was calculated, the time duration from the intrathecal block to the need of supplementation of first rescue analgesic based on VAS >4 the patient was given diclofenac sodium 75mg (i.m.) as rescue analgesia when Visual analogue score.[>4] characteristic of sensory block/onset, time of duration and regression of sensory block was noted. Onset of block was taken as the time from the end of intrathecal injection to loss of pain pricking sensation upto T10 segment. Duration of block was taken as the time interval from administration to regression up to S2segment.
2. Characteristic of motor block (onset, duration and regression) was noted. Time of onset of motor block was noted by modified Bromage scale, the time from the end of intrathecal injection to the development of grade IV motor block. Duration of block was calculated from the onset of block to the attainment of modified Bromage scale 0.
3. Pain score according to VAS score at 1 hour, 2 hours and 3 hours after spinal anaesthesia (till the completion of surgery).

Surgery was allowed when T10 block level was achieved. Patients not achieving sensory block up to T10 and grade-IV motor block, modified Bromage scale were excluded from the study. Duration of surgery in all patients was around 1 hour.

Intraoperative fluid replacement was given as necessary depending on the blood loss and haemodynamic parameters. Advance airway management equipments and drugs for resuscitation were kept ready.

All patients were supplemented with nasal oxygen at the rate of 3l/min. 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. Heart rate <50 beats/min) was considered as bradycardia and treated with inj-Atropine0.01mg/kg i.v.

Intensity of pain was assessed by Visual Analogue Scale (VAS) 0-10cm was used to assess the intensity of pain at induction, and in every 1 hour till 3hours (time when patient required rescue analgesics). The changes in haemodynamic parameters (pulse rate, MAP, SpO2) & respiratory rate was 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 using Microsoft excel and Statistical Package for Social Sciences (SPSS ver. 21) the recorded observation were analysed using Microsoft excel and SPSS ver.21 software. “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.

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

The mean onset of sensory block was much earlier in group F(71.53 ± 5.66sec), compared to group B(88.95±4.51sec) and was found to be statistically significant the mean regression of sensory block was much late in group F(170.53+-5.902min) compared to group B(152.34+4.67min) and was found to be statistically significant the mean duration of sensory block was more in group F(169.34+-5.88min) compared to group B(150.86+4.69min) the mean onset of motor block was faster in group F(88.95+4.51sec) compared to group B(116.20+-2.56sec) while the mean regression of motor block was prolonged in group F(152.34+4.64min) compared to group B(134.25+-8.70min) and was statistically significant (graph, table 3)

The mean onset of motor block in the single bolus dose group was 116.20±2.554 seconds while in the fractionated dose group, it was 88.95 ±4.516 seconds. The mean regression of motor block in the group B was 134.25+8.704 minutes, while in the group F, it was 152.34+4.676 minutes. The mean duration of motor block in the group B
was 132.31 ± 8.71 minutes, while in the group F, it was 150.86 ± 4.69 minutes (p<0.05) (Table 4).

The mean time taken for first supplementation of analgesics in the single bolus dose group was 2.61 ± 0.53 hrs, while in the fractionated dose group was 3.17 ± 0.377 hrs (p<0.05), thus group F needed late supplementation of analgesia and showed a longer duration of analgesia compared to group B. (Table 4). At 1 hour and 2 hours after spinal anaesthesia - there was a statistically insignificant association between pain scores of both groups.

At 3 hours after spinal anaesthesia - patients (65) in group B compared to 40 patients in group F had VAS score > 4 and required supplementation of rescue analgesics and this difference was statistically significant. Between 3rd hour and 4th hour after spinal anaesthesia, all patients developed pain due to regression of sensory block. So, all patients required rescue analgesics before 4th hour after spinal anaesthesia. So, VAS score was not assessed after 4 hours of spinal anaesthesia.

**Discussion**

Caesarean section is one of the most common operative intervention in obstetrics. Caesarean section is mostly done under spinal anaesthesia because of its rapid onset. The most common complication associated with subarachnoid block in such cases is maternal hypotension. Maternal hypotension is detrimental as it leads to decrease in uteroplacental circulation and adversely affect foetal outcome. Unadjusted doses of local anaesthetic is one of the cause which increases the chances of maternal hypotension in caesarean section under spinal anaesthesia. In this study we compared fractionated dose with single bolus dose of local anaesthetic in elective caesarean section. There are various parameters which predict the level of block and amongst them, the most significant determinants are height and weight. Harten et al in his study adjusted the dose of bupivacaine 0.5% heavy according to patients height and weight and they found that the incidence and severity of maternal hypotension was much less (50%) than in fixed dose group (71.7%).

**Table 1:** Comparison of different demographic variables

<table>
<thead>
<tr>
<th>Group</th>
<th>Number</th>
<th>Age (years) mean ± SD</th>
<th>Weight (kg) mean ± SD</th>
<th>Height (cm) mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group B</td>
<td>100</td>
<td>25.15 ±2.43</td>
<td>56.02 ±2.91</td>
<td>149.58 ±3.81</td>
</tr>
<tr>
<td>Group F</td>
<td>100</td>
<td>24.82 ±2.09</td>
<td>56.97 ±4.17</td>
<td>149.64 ±4.30</td>
</tr>
</tbody>
</table>

**Table 2:** Comparison of hemodynamic stability in both groups

<table>
<thead>
<tr>
<th></th>
<th>Group B</th>
<th>Group F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemodynamically stable (no vasopressor used)</td>
<td>61</td>
<td>85</td>
</tr>
<tr>
<td>Hemodynamically unstable (required vasopressors)</td>
<td>39</td>
<td>15</td>
</tr>
</tbody>
</table>

**Table 3:** Comparison of onset, regression and duration of sensory block in both groups

<table>
<thead>
<tr>
<th></th>
<th>Group B</th>
<th>Group F</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean onset of sensory block (in seconds)</td>
<td>88.95 ±4.516</td>
<td>71.53 ±5.66</td>
<td>0.000</td>
</tr>
<tr>
<td>Mean regression of sensory block (in minutes)</td>
<td>152.34 ±4.676</td>
<td>170.53 ±5.902</td>
<td>0.000</td>
</tr>
<tr>
<td>Mean duration of sensory block (in minutes)</td>
<td>150.86 ±4.69</td>
<td>169.34 ±5.88</td>
<td>0.000</td>
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</table>

**Table 4:** Comparison of onset, regression and duration of motor block in both groups

<table>
<thead>
<tr>
<th></th>
<th>Group B</th>
<th>Group F</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean onset of motor block (in seconds)</td>
<td>116.20 ±2.554</td>
<td>88.95 ±4.516</td>
<td>0.000</td>
</tr>
<tr>
<td>Mean regression of motor block (in minutes)</td>
<td>134.25 ±8.704</td>
<td>152.34 ±4.676</td>
<td>0.000</td>
</tr>
<tr>
<td>Mean duration of motor block (in minutes)</td>
<td>132.31 ±8.71</td>
<td>150.86 ±4.69</td>
<td>0.000</td>
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</tbody>
</table>

**Table 5:** Comparison of time taken for first supplementation of analgesics

<table>
<thead>
<tr>
<th></th>
<th>Group B</th>
<th>Group F</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time taken for first supplementation of analgesics (in hours)</td>
<td>2.61 ±0.53</td>
<td>3.17 ±0.377</td>
<td>0.000</td>
</tr>
</tbody>
</table>
A study was done by Dutch anaesthetists in July 2014 and they found patients height (60.4%) to be the strongest determining characteristic for dose adjustment in comparison to weight (13.5%) and body mass index (20.9%). In our study compared the dose of bupivacaine 0.5% heavy according to height of the patients (0.07mg/cm) and got effective spinal block in most of the cases. Similarly we considered height as the predictor for calculating the dose and used Bupivacaine in the dose of 0.07mg/cm height and got adequate results. Fahmy et al in their studies compared fractionated dose and single bolus dose for circulatory stability and concluded that there was lesser degree of hypotension when the same dose of local anaesthetic was given in a fractionated manner. We in our study found that fractionated dose group was more haemodynamically stable. Our study showed similar results as done by Fahmy et al. In our study, we also observed a decrease in pulse rate after induction in both the groups but it was statistically insignificant. Vasopressors are used to avoid the maternal hypotension. There are many studies which have used different vasopressors for the control of maternal hypotension. A. Kansal et al compared ephedrine and mephentramine for control of hypotension for spinal anaesthesia and concluded that both are equally effective. We, in our study used both ephedrine and mephentamine for control hypotension. In our study, there was faster onset, longer duration and late regression of sensory and motor block in fractionated dose group as compared to single bolus dose. Patients in fractionated group were found to be more hemodynamically stable as compared to single bolus dose group. Also, the duration of analgesic was prolonged in fractionated group as compared to single bolus group. The results of our study were comparable with previous studies done by Fahmy et al, Badheka et al, Patel et al. Many studies by Prabhakaran A et al, Hussain et al are available where they have used VAS score for assessment of pain intensity and requirement of rescue analgesics postoperatively. In our study, we also used VAS score to assess the pain intensity at different time intervals post operatively and time for first rescue analgesia requirement. We in our study found that patients in fractionated dose group were more comfortable and required late supplementation of rescue analgesic as compared to single bolus dose group.

Rationale of my study
To evaluate whether fractionated dose of local anaesthetic is better than bolus dose in terms of hemodynamic stability, duration of analgesia and adequacy of sensory and motor block.

Result
Result of our study, justify the rationale of study. In our study, when we compared fractioned dose and bolus dose we found that fractionated dose showed good haemodynamic stability, longer duration of analgesia and better sensory and motor block.

Conclusion
It can be concluded from our study that fractionating the dose of local anaesthetic can prolong the duration of analgesia, produce a quicker onset and late regression of sensory and motor block with circulatory stability and minimal requirement of vasopressors. Thus it can be considered as an alternative to single bolus dose of local anaesthetic in spinal anaesthesia. Further studies can be done to compare the same in critically ill and high risk obstetric patients.

Limitations of Study
In our study, we did not assess the neonatal outcome by any parameter like apgar score & umbilical cord blood ph & uteroplacental perfusion. Hence we were not able to comment on the neonatal outcome & uteroplacental perfusion.

Conflict of Interest: None.

Source of Funding: None.

References

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