

**Original Article:**

**Spinal Anaesthesia Induced Hypotension and Related Adverse Effects in Caesarean Section Delivery and Neonatal Outcome: A Comparison of Using Crystalloid Pre-Loading and Co-Loading in Caesarean Patients**

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**Abstract:**

**Background:** Volume loading by rapid infusion of crystalloid solution before/during induction of spinal anaesthesia may effectively reduce the incidence of anaesthesia induced hypotension.

**Objective:** To compare the efficacy of crystalloid pre-loading and co-loading to prevent hypotension and related adverse effects as well as poor neonatal outcome in caesarean section delivery under spinal anaesthesia.

**Methods:** This single blinded randomized controlled clinical trial was conducted in the Department of Anaesthesia, Analgesia & Intensive Care, Dhaka Medical College Hospital, Dhaka, between January 2013 and December 2014. A total of 90 patients were selected – 45 patients of group I received co-loading with Ringer's lactate solution, while another 45 patients of group II received a pre-loading of the same fluid. Blood pressure and heart rate were recorded. Ephedrine and adrenaline were administered as needed to treat hypotension. APGAR scores of the newborn were recorded at 1st minute and 5th minute after delivery. Adverse effects like nausea, vomiting, light headedness and shivering was observed all through during operation and post-operative phase in all patients, if any, and recorded.

**Results:** The incidence of hypotension was 17 (37.8%) in group I (co-loading) and 27 (60%) in group II (pre-loading), which was significantly higher in group II ( $p < 0.05$ ). Adverse effects – nausea, vomiting, light headedness and shivering was observed more in group II patients; however, the difference was not statistically significant. In neonates, APGAR score at 1 minute was found  $\leq 7$  in 18 (40.0%) from group I, while 28 (62.2%) from group II; the difference was statistically significant ( $p < 0.05$ ). No significant difference was observed in APGAR score at 5 minutes, as found  $\leq 7$  in 6 (13.3%) and 3 (6.7%) in group I and group II respectively.

**Conclusion:** Severity of hypotension, increased ephedrine requirement and poor APGAR score were evident in patients who received crystalloid pre-loading group (group II), which means crystalloid co-loading group (group I) procedure was more effective in preventing spinal anaesthesia induced hypotension and secured better neonatal outcome.

**Keywords:** Crystalloid pre-loading, crystalloid co-loading, spinal anaesthesia, hypotension, neonatal outcome, APGAR score.

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**Introduction:**

Spinal anaesthesia has become a commonly used technique for elective and emergency caesarean section operation, as it is relatively

cheaper, easily administered and rapidly acting technique, having good quality of sensory and motor block<sup>1,2</sup>. It helps the mother remain awake for the birth and comfortable afterwards as well

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as avoids complications and risks associated with general anaesthesia<sup>3,4</sup>. However, spinal anaesthesia is also not without disadvantages; it is associated with high incidence of hypotension, which is more common and profound in pregnant population that can result in both maternal and neonatal morbidities<sup>2-5</sup>. Spinal anaesthesia causes sympathetic blockade and this reduces blood pressure by systemic vascular resistance and venodilatation in the lower extremity of the body, which becomes more aggravated in pregnancy by the effect of gravid uterus and associated aorto-caval compression<sup>2,5,6</sup>. Moreover, increased sensitivity to spinal anaesthetics in pregnancy due to higher progesterone levels, hypotension induce more nausea and vomiting, cardiovascular collapse and loss of consciousness in the mother<sup>2,6</sup>. Besides, prolonged hypotension can cause fetal hypoxia and acidosis resulting in a possibility of lower APGAR score in newborns due to consequence of reduction in uterine blood flow, which is ultimately pressure dependent<sup>6</sup>. Hence, prevention of episodes of hypotension due to spinal anaesthesia for caesarean section operation always remains as an important issue for an anaesthesiologist. The practice of volume loading apparently reduce the high incidence of hypotension in obstetric patients, as first introduced over 50 years back<sup>7</sup>. Though some of the earlier studies demonstrated immense success of crystalloid preloading<sup>8,9</sup>, the results of those studies have been questioned by the other investigators<sup>10-12</sup>. In the recent past, co-loading has generated interest for the prevention of spinal-induced hypotension and suggested that it is more rational approach for the prevention of post spinal hypotension<sup>13,14</sup>. Co-loading might be physiologically more appropriate because the maximum effect can be achieved during the time of the block and possibly increase intravascular volume expansion during vasodilatation from the sympathetic blockade and limit fluid redistribution and excretion<sup>13,14</sup>. Hence, present study was designed to compare the efficacy of crystalloid pre-loading and co-loading to prevent spinal anaesthesia induced hypotension and related adverse effects in caesarean section delivery and neonatal outcome in those two groups.

#### Methods:

This single blinded randomized controlled clinical trial was conducted in the Department of Anaesthesia, Analgesia, Palliative and Intensive Care Medicine Care, Dhaka Medical

College Hospital, Dhaka, from January 2013 to December 2014. Our study population was all the patients admitted in Department of Obstetrics & Gynaecology in the same hospital who underwent caesarean section operation. However, convenient sampling technique was adopted. The patients were selected after fulfilling the following inclusion and exclusion criteria:

#### *Inclusion criteria:*

1. Patients (pregnant women) with singleton, uncomplicated pregnancy who underwent caesarean section done under spinal anaesthesia.

#### *Exclusion criteria:*

1. Patients with congenital heart disease, chronic hypertension, gestational hypertension, pre-eclampsia, eclampsia;
2. Patients contraindicated for spinal anaesthesia; and

3. Patients refused to participate in the study.

After fulfilling the inclusion and exclusion criteria, finally 90 pregnant women were allocated into two groups with 45 in each group. They were grouped by odd and even number and allocated to receive either crystalloid pre-loading or co-loading during caesarean section operation. The co-loading group was named group-I and pre-loading group was named group-II. Group II (pre-loading) received of 20ml/kg of Ringers lactate solution over a period of 20 minutes before spinal anaesthesia and group I (co-loading) received 20ml/kg of Ringers lactate solution after the spinal anaesthesia by pressurized infusion pump. In the operation theatre, blood pressure, heart rate was measured, heart and lung were examined and recorded. The anaesthesia procedure was explained to the patient. Intravenous access was secured with 18G IV cannula. Ringer's lactate fluid was infused at the rate of 5 drops per minute to keep the cannula patent and monitoring of electrocardiogram and pulse oximetry was applied. The patients of group II (pre-load) received 20ml/kg Ringer's lactate solution over a period of 20 minutes before spinal anaesthesia. Spinal anaesthesia was conducted with the patient in the right lateral position. With all aseptic preparation, the skin and subcutaneous tissue were infiltrated with local anaesthetics. Spinal anaesthesia was given using 2.5 ml of 0.5% of hyperbaric bupivacaine, injected slowly over 12 seconds at the L2-3 or L3-4 level with a 25G Quincke needle. Patients of group I (co-load) received same Ringers lactate fluid load of

20ml/kg fluid by pressurized infusion pump after observing the free flow of cerebrospinal fluid. After spinal anaesthesia injection, dressing was applied and immediately put into supine position. Urinary catheter was inserted in all patients, and a wedge was placed for 15 degree left lateral tilt. Once the fluid bolus was given, infusion rate decreased to a maintenance rate of 100ml/hour. The quality of the sensory block was assessed by swab soaked in alcohol. Surgery was proceeded after confirmation of block to T4 level. Blood pressure and heart rate were recorded in both the groups with 3-minute intervals from the beginning of the subarachnoid block for the first 20 minutes, and then with 5-minute intervals up to one hour. Spinal anaesthesia induced hypotension was defined as a decrease in the systolic arterial pressure (SAP) >20% from the baseline reading or a decrease of SAP to less than 80 mmHg as an absolute value. Hypotension was treated by bolus doses of ephedrine (5mg). If the systolic arterial blood pressure decreases to less than 80 mm of Hg or less than 80% of the calculated baseline value, 5 mg ephedrine doses were administered until systolic arterial pressure recovered to normal limit. The patients who did not respond with ephedrine, inj. adrenaline was given in doses of 10µg.

After delivery of the baby, all patients received 10 IU of Inj. oxytocin bolus and 20 IU was mixed in the Ringer's lactate solution, which was infused slowly. APGAR scores of the newborn were recorded at 1st minute and 5th minute after delivery. Adverse effects like nausea, vomiting, light headedness and shivering was observed all through during operation and post-operative phase in all patients, if any, and recorded.

Statistical analyses were done using the SPSS version 19.0 for Windows (SPSS Inc., Chicago, Illinois, USA). The mean values were calculated for continuous variables. The qualitative observations were counted by frequencies and expressed in percentages. Chi-Square test was used to analyze the categorical variables, while Student t-test was used for continuous variables. P values <0.05 was considered as statistically significant.

**Results:**

Most of the patients belonged to age group ≤30 years in both trial groups. The mean age was 24.4±4.4 years in group I (co-loading) and 25.5±4.0 years

in group II (pre-loading). Mean age difference was not statistically significant between the groups (Table 1). The incidence of hypotension was 17(37.8%) in group I (co-loading) and 27(60%) in group II (pre-loading), which was significantly higher in group II (p<0.05) (Table 2). Ephedrine was required in 17 cases (37.8%) in group I and 27 cases (60%) in group II. Mean ephedrine required was 9.2±3.6 mg in group I and 11.5±4.3 mg in group II. The difference was statistically significant (p<0.05) (Table 3). Adrenaline was administered in 1 case (2.2%) in group I and in 2 cases (4.4%) in group II. However, the difference was not statistically significant (p>0.05) (Table 3). Among the side effects of hypotension, nausea and vomiting were reported by 14(31.1%) and 3 (6.7%) in group I, while 12(26.7%) and 9(20.0%) in group II respectively. Light headedness was reported by 10(22.2%) and 11(24.4%), while shivering was reported by 9(20.0%) and 12(26.7%) of group I and group II respectively. However, the difference was not statistically significant among the variables between two groups (p>0.05) (Table 4). In the neonates, APGAR score at 1 minute was found ≤7 in 18(40.0%) from group I, while 28(62.2%) from group II, which was statistically significant (p<0.05). APGAR score at 5 minutes was found ≤7 in 6(13.3%) from group I, while in 3(6.7%) from group II. The difference was not statistically significant (p>0.05) (Table 5).

**Table 1:** Distribution of the study patients by age (n=90)

Age (years)	Group-I (n <sub>1</sub> =45)		Group-II (n <sub>2</sub> =45)		P value
	Frequency	%	Frequency	%	
≤30	38	84.4	37	82.2	0.211 <sup>NS</sup>
>30	7	15.6	8	17.8	
Mean±SD	24.4±4.4 (18-35)		25.5±4.0 (19-36)		

Figures in the parentheses indicate range. NS = not significant; P value reached from unpaired Student-t test.

**Table 2:** Distribution of the study patients by hypotension (n=90)

Hypotension	Group-I (n <sub>1</sub> =45)		Group-II (n <sub>2</sub> =45)		P value
	Frequency	%	Frequency	%	
No hypotension	28	62.2	18	40.0	0.034 <sup>S</sup>
Hypotension occurred	17	37.8	27	60.0	

S = significant; P value reached from Chi-square test.

**Table 3:** Ephedrine and adrenaline requirement in management of hypotension (n=90)

Medication	Group I	Group II	P value
Ephedrine Requirement	17 (37.8%)	27 (60.0%)	0.006 <sup>s</sup>
Mean Ephedrine Requirement (mg)	9.2±3.6	11.5±4.3	0.007 <sup>s</sup>
Adrenaline Requirement	1 (2.2%)	2 (4.4%)	0.500 <sup>NS</sup>

Figures in the parentheses indicate percentage. S = significant, NS = not significant;

P value reached from unpaired Student-t test.

**Table 4:** Distribution adverse effects of hypotension (n=90)

Complications	Group-I (n <sub>1</sub> =45)		Group-II (n <sub>2</sub> =45)		P value
	Frequency	%	Frequency	%	
<b>Nausea</b>					
Present	14	31.1	12	26.7	0.641 <sup>NS</sup>
Absent	31	68.9	33	73.3	
<b>Vomiting</b>					
Present	3	6.7	9	20.0	0.062 <sup>NS</sup>
Absent	42	93.3	36	80.0	
<b>Light headedness</b>					
Present	10	22.2	11	24.4	0.803 <sup>NS</sup>
Absent	35	77.8	34	75.6	
<b>Shivering</b>					
Present	9	20.0	12	26.7	0.454 <sup>NS</sup>
Absent	36	80.0	33	73.3	

NS = not significant; P value reached from Chi-square test.

**Table 5:** Neonatal outcome by APGAR score (n=90)

APGAR score	Group-I (n <sub>1</sub> =45)		Group-II (n <sub>2</sub> =45)		P value
	Frequency	%	Frequency	%	
<b>1 minute</b>					
≤7	18	40.0	28	62.2	0.034 <sup>s</sup>
>7	27	60.0	17	37.8	
<b>5 minutes</b>					
≤7	6	13.3	3	6.7	0.242 <sup>NS</sup>
>7	39	86.7	42	93.3	

S = significant, NS = not significant; P value reached from Chi-square test.

## Discussion:

In this present study, most of the patients belonged to age ≤30 years in both groups. The mean age was 24.4±4.4 years in group I (co-loading group) and 25.5±4.0 years in group II (pre-loading group). The difference was not statistically significant (p>0.05) between two groups. Dyer et al.<sup>14</sup> reported mean age 26.8±4.9 and 27.4±6.0 years for pre-load and co-load respectively, while Jacob et al.<sup>15</sup> found mean age 26.9±2.4 years in co-load and 26.7±2.6 years in pre-load group. Oh et al.<sup>16</sup> showed the mean age of patients in co-load group 33.7±4.0 years as compared to 33.5±3.5 years in pre-load group. The differences were not statistically significant in those studies and the results were found similar to our study.

In this present study, we observed episodes of hypotension more in group II (pre-loading) in comparison to group I (co-loading), which was statistically significant. Mojica et al.<sup>13</sup> conducted a randomized clinical trial to evaluate the efficacy of crystalloids in preventing spinal-induced hypotension (SIH) and cardiovascular side effects (CVSE) in a group of surgical patients. The incidence of SIH was similar in all treatment groups. However, compared to placebo, crystalloid administration at the time of spinal block resulted in a significant reduction in the proportion of patients developing CVSE from 9.9% to 2.3% (P<0.05). Administration of crystalloids at the time of spinal block seems to be effective because it provides additional intravascular fluids during the period of highest risk of CVSE after spinal anesthesia<sup>13</sup>. Dyer et al.<sup>14</sup> reported 84% hypotension in the pre-load group and 60% in the co-load group. Jacob et al.<sup>15</sup> reported that 60% of patients in the pre-loading group developed hypotension. Previous studies using 15 ml/kg of lactated Ringer's as pre-load in the obstetric population reported the incidence of hypotension as 55%, as studied by Gajraj et al.<sup>17</sup> and 45.5%, as found by Tercanli et al.<sup>18</sup>. However, Oh et al.<sup>16</sup> studied comparing systolic blood pressure between the two groups at baseline, with 1 minute interval and found that hypotension occurred in 83% cases in pre-loading group and 53% in the co-loading group, which was statistically significant (P=0.026).

We observed adverse effects like nausea, vomiting, light headedness and shivering more in group II patients; however, the difference was not statistically significant. Conversely, Jacob et al.<sup>15</sup> observed significant difference – nausea 19 vs. 10 and vomiting 14 vs. 6 in pre-load and co-load

respectively ( $P < 0.05$ ), while Oh et al.<sup>16</sup> observed nausea 60% and 27% respectively.

Dyer et al.<sup>14</sup> reported that the co-load group required a lower median dose ( $P = 0.03$ ) and a lower median number ( $P = 0.04$ ) of ephedrine doses for the treatment of maternal hypotension pre-delivery. Nevertheless, there was no difference in either the total cumulative dose, or in the total number of doses of ephedrine between groups. Jacob et al.<sup>15</sup> showed that the mean number of doses of ephedrine required 2.6 vs. 1.8 and the total dose of ephedrine used 14.2 mg vs. 12.6 mg in pre-load and co-load respectively which were statistically significant. Oh et al.<sup>16</sup> reported that smaller dose of ephedrine (7.5 mg) required in the co-load group than the pre-load group (15 mg).

Evidence suggested that neonatal outcomes in terms of APGAR score was not statistically significant between pre-load and co-load groups as recorded at birth, 1 minute and 5 minutes after birth, despite a difference in the episodes of hypotension among the groups<sup>15</sup>, unlike the findings of the present study. This reflects previous experience that transient decreases in blood pressure rapidly treated by vasopressor do not usually affect the fetal outcome<sup>19</sup>.

#### **Limitations of the study:**

This was a single-centre trial. The study population was selected from an urban hospital for a short period of time in Dhaka city. Hence, the results of the study may not be generalized and does not necessarily reflect the overall picture of the country. Small sample size was another limitation of the present study. The lack of a control group

or placebo group precluded determination of an absolute reduction in the incidence of hypotension (as we did not include a placebo for ethical reasons). Moreover, the study did not investigate the correlation between umbilical artery pH and spinal-delivery interval, uterine incision-delivery interval and duration of hypotension. APGAR score was taken for rapid evaluation of neonatal (fetal) outcome in place of umbilical blood pH and blood gas status as the same was not readily available in the Department of Obstetrics & Gynaecology facility.

#### **Conclusion:**

In summary, severity of hypotension, increased ephedrine requirement and poor APGAR score were evident in patients who received crystalloid pre-load, which means crystalloid co-load procedure was more effective in preventing spinal anaesthesia induced hypotension and secured better neonatal outcome. Further studies with larger sample and multi-centre trials along with high technical back up are recommended.

**Conflict of interest:** None declared.

**Ethical approval issue:** The study was approved by the Ethical Review Committee of Dhaka Medical College, Dhaka, Bangladesh.

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**Authors' contribution:** Concept and study design: TM; Data collection and compilation: TM, MHC, SA, MAKM, MM, SMAH, AS; Data analysis: TM, SMAH; Critical writing, revision and finalizing the manuscript: TM, MHC, SA, MAKM, MM, SMAH, AS.

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