



E-ISSN: 2664-8857

P-ISSN: 2664-8849

www.anesthesiologyjournal.in

IJAR 2025; 7(2): 41-45

Received: 01-07-2025

Accepted: 05-08-2025

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Preloading versus coload of crystalloids for prevention of spinal anaesthesia induced maternal hypotension during elective caesarean section: A comparative study

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DOI: <https://www.doi.org/10.33545/26648849.2025.v7.i2a.68>

Abstract

Objective: This study was conducted to compare the effectiveness of preloading and coload of crystalloids in prevention of spinal anaesthesia induced maternal hypotension during elective caesarean section and to determine the incidence of hypotension and vasopressor requirement for the maintenance of blood pressure in both groups.

Methods: A prospective comparative study was conducted among 66 patients who were divided into Group P (Preloading): 33 patients, for whom 15 ml/kg Ringer Lactate (RL) solution was given over 20 minutes prior to spinal anaesthesia; Group C (Coload): 33 patients, for whom 15 ml/kg RL solution was given over 20 minutes at the time of administration of spinal anaesthesia. Spinal anaesthesia was administered in a standardized manner with a dural puncture at L3-L4 level using 25 G Quincke Babcock spinal needle and administration of an assigned group of intrathecal drugs. Hypotension was treated by using incremental doses of injection ephedrine 3 mg intravenously and fluid bolus. Blood pressure was measured every 5 minutes for the first half an hour, then every 15 minutes till 120 minutes. The side effects of hypotension, APGAR score of infants, and overall duration of spinal anaesthesia are recorded and analysed.

Result: We observed that 5 out of the 33 patients (15.2%) in Group C and 13 out of the 33 patients (39.4%) in Group P had episode(s) of hypotension. On an average 1.2 gms of ephedrine was required in Group C, while 1.92 gms of ephedrine was needed for Group P. We observed a significant statistical difference between the incidence of hypotension ($p = 0.027$). There was no statistically significant difference in the mean age ($p = 1$), weight ($p = 0.80$), and height ($p = 0.87$). The baseline systolic blood pressure, mean arterial blood pressure and pulse rates were also similar in the two groups.

Conclusion: This study demonstrated that co-load is better than preload in the prevention of spinal anaesthesia-induced hypotension during caesarean section. A larger clinical trial in the Indian context is advisable.

Keywords: Pre-loading, co-loading, hypotension, spinal block

Introduction

Spinal anaesthesia is usually regarded as one of the most dependable regional block procedures available today. Spinal anaesthesia is also favoured since it avoids the need for a general anaesthetic and the possibility of a failed intubation procedure [1]. The major side effect of spinal anaesthesia is hypotension; the probability of such occurrence is 75% receiving the procedure. This causes foetal distress, foetal hypoxia and acidosis. Administration of crystalloids before spinal block called preloading has been common practice to prevent hypotension. Another technique to overcome maternal hypotension that come into practice is coload. Coload is the rapid intravenous administration of crystalloids at the maximal possible rate at the time of administration of spinal anaesthesia. We conducted this study to compare the effectiveness of preloading and coload in the prevention of spinal anaesthesia-induced maternal hypotension and compared the incidence of hypotension and vasopressor requirement in both groups.

Materials and Methods

After obtaining Institutional Research Committee, Ethical Committee approval and a written informed consent, a prospective comparative study was conducted among 66 patients posted for elective caesarean section under spinal anaesthesia/General Theatre complex, St. Stephen's Hospital, Tis Hazari, New Delhi. The study duration was from July 2019 to June 2020. Sample size was calculated using the formula $N = (\sigma_1^2 + \sigma_2^2) \times \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2}{(m_1 - m_2)^2}$ by taking data from the Singel *et al.* study where desired power = 0.8, alpha = 0.05, hypotension incidence 80% and significant if 50% decrease in incidence. m_1 = mean blood pressure (BP) in group S, m_2 = mean BP in group M, σ_1 = SD of BP in group S, σ_2 = SD of BP in group M, $Z_{1-\alpha/2} = 1.96$ (Normal varied value for $\alpha=5\%$), $Z_{1-\beta} = 1.28$ (normal varied value for power 90%)

The study subjects were adult patients aged 18-40 and belonging to ASA (American Society of Anaesthesiology) grade II. Patients with comorbid conditions such as chronic or pregnancy-induced hypertension, foetal distress, antepartum haemorrhage, eclampsia, anaemia, cardiovascular illness, and recalcitrant patients were excluded. Patients were then assigned to one of the two groups using a computer-generated random number table.

- Group C (Coloading): 33 patients, whom 15 ml/kg RL solution were be given over 20 minutes prior to spinal block
- Group P (Preloading): 33 patients, for whom 15 ml/kg RL solution was given over 20 minutes at the time of administration of spinal block

Before the surgery, every patient received standard monitoring of pulse oximetry, non-invasive arterial blood pressure, and electrocardiogram. Under all aseptic precautions, spinal anaesthesia was administered in a standardized manner with dural Singel puncture at L3-L4 level using 25 G Quincke Babcock spinal needle and administration of assigned group of intrathecal drugs as per patient group allotment. Surgery began once an appropriate level of the block was established, and the start time was recorded. Hypotension was treated by using incremental doses of injection ephedrine 3 mg intravenously and fluid bolus. Pulse, Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), and SpO₂ were recorded. BP was measured, every 5mins for the first half an hour, then every 15mins till 120mins after giving spinal anaesthesia, and then every 20 minutes till the completion of surgery. Characteristics of side effects and infant outcomes were recorded. Quantitative data was presented as mean +/-standard deviation. The student test measured quantitative variables like age, pulse, SBP, MBP, and spinal blockade characteristics. The chi-square/Fischer exact test compared proportions like side effects. P value < 0.05 was taken as the level of significance.

Results

A total of 66 parturient aged 20 to 35 years with ASA physical status II, who underwent lower segment Caesarean section under spinal anaesthesia were studied. Two groups of patients were observed as described. Group C (Coloading) consisted of 33 participants with mean age of 27.8 (SD 2.48) years, mean weight of 71.1 (SD 5.79) kg,

mean height of 1.6 (SD 0.04) and mean body mass index of 28.1 (SD 2.22) while group P (Preloading) consisted of 33 participants with mean age of 27.8 (SD 2.26) years, mean weight of 71 (SD 5.9) kg, mean height of 1.6 (SD 0.04) m and mean body mass index of 28.1 (SD 2.16). There was no statistically significant difference in the mean age ($p = 1$), weight ($p = 0.80$) and height ($p = 0.87$) between the two study groups.

We observed that 5 out of the 33 patients (15.2%) in group C (Coloading group) and 13 out of the 33 patients (39.4%) in group P (Preloading group) had episode(s) of hypotension (Table 1). We observed a significant statistical difference between the incidence of hypotension ($p = 0.027$). We also analysed that on an average 1.2 gms of ephedrine was required in the Coloading group, while 1.92 gms of ephedrine was required in the Preloading group which was statistically not significant. The proportions of the coloading and preloaded groups with complaints of nausea were 0% and 6.1% respectively (Table 1). The proportion with episodes of retching/vomiting were 0% and 3% respectively. There was no statistically significant difference in the proportion of both groups with complications related to SIH (Spinal Induced Hypotension). All the neonates in both groups had APGAR scores at 5 minutes ≥ 7 . There was no difference in foetal outcome between the groups.

Post-operative MAP, measured in 5 mins, 10 mins, 15 mins, 20 mins, 25 mins and 30 mins (fig 1). Intra-operative MAP we measured over 3 mins, 6 mins, 10 mins, 15 mins, 20 mins, 25 mins, 40 mins, 55 mins, 70 mins, 85 mins, 100 mins and 120 mins (fig 1). Even though there is no significant change in MAP in both groups, we observed that intra operatively and post operatively hypotension is less in the coloading group.

Discussion

Anaesthesia is the key part of all surgery. Spinal anaesthesia or spinal block is usually regarded as one of the most dependable regional block procedures available today. In pregnant women, smaller dosages of local anaesthetic are required for spinal anaesthesia, and the distribution of the local anaesthetic into the cerebrospinal fluid (CSF) is less predictable^[2]. Bolus intravenous fluid delivery, either as a preload or as a coload, to correct blood volume has been widely employed as a first-line treatment for various medical conditions^[2, 3].

Our findings indicate, that there was a statistically significant difference in the occurrences of hypotension ($p = 0.62$) between the coloading group and the preloading group and that the incidence of hypotension was lower in the coloading group than in the preloading group. According to the findings of Hai-Fang Ni *et al.*, coload may be more effective than crystalloid preload in reducing hypotension caused by delayed infusion time^[4]. Similarly, it has been seen in animal models that capillary hydraulic pressure increases over time as a result of crystalloid infusion, which may enhance the hydraulic pressure differential and fluid filtration from plasma into the interstitial space^[5].

Our results and observations are comparable with meta-analysis results reported by Hai-Fang Ni *et al.* in 2017 who analysed ten studies in which 824 cases were included and found that the incidence of hypotension was significantly higher in the preload group compared with the coload group^[4]. All studies applied spinal anaesthesia for caesarean section. Nine studies enrolled healthy parturient scheduled

for elective surgery and one for emergency delivery. Pooled data from ten studies showed that patients in the crystalloid preload group had more hypotensive episodes than those in the coload group (57.8% versus 47.1%, OR = 1.62, 95% CI = 1.11-2.37, and $P = 0.01$). They also reported that sensitivity analysis reflected that these findings were robust (with pooled ORs ranging from 1.49 (95% CI = 1.01-1.29) to 1.80 (95% CI = 2.18-2.60). In a study in 2017 by Rehmani *et al.* from Pakistan which includes 314 patients (157 in each group) reported similar findings. Their study which also looked at the comparison of efficacy of crystalloid preload and coload on reducing hypotension and improving APGAR score in patient receiving spinal anaesthesia for elective caesarean sections noted incidence of hypotension more in 67 patients (21.3%) of preloading group compared to 30 patients (9.6%) of coload group. Singhal *et al.* from Rajasthan in 2019 in a study of 62 parturient and reported that the incidence of hypotension was significantly lower in the coload study arm when compared to the preload study arm in a randomised controlled trial [6]. Similarly, a recent study in 2020 from India by Bharadwaj *et al.* observed that the systolic blood pressure dropped in both groups after spinal anaesthesia but drop was more in Preloading group [7]. They concluded that coload of crystalloid fluid is a better method than preloading of crystalloids for prevention of maternal hypotension after subarachnoid block. Another study from India also in 2020 by Borse *et al.* in Maharashtra, India also observed ASA grade I parturient posted for elective caesarean section and randomly allocated in two study groups of 30 each to receive either preload or coload with Ringer's lactate solution [8]. Hypotension was reported to be significantly less in coload group (36%) than preloading group (60%).

In our study ephedrine was used as a vasopressor. There are very few reports of adverse clinical outcomes for mother or baby after ephedrine use in obstetrics [9]. We observed mean bolus dose of ephedrine used was more in the preload than in the coload group in this study, although the difference was not statistically significant. We found that the minimum bolus dose was as low as 1 mg to a maximum

of 2 mg as reported between the two groups under study. Similar to our observation, other studies that reported no difference in the incidence of hypotension between the preload and coload group did not also find any difference in vasopressor use between the groups [10]. Jain *et al.* reported that similar to our study, and noted that mean no. of bolus doses of ephedrine administered was 1.43+1.72 in coload group and 1.27+1.74 in preload group which was insignificant.

It has been well documented that hypotension significantly increases the odds of developing nausea or vomiting during spinal anaesthesia ($p = 0.009$) [11]. Hypotension can induce brainstem ischaemia, which in turn activates the circulatory, respiratory and vomiting centres located in the medulla [12]. Another hypothesis is that hypotension leads to ischaemia in the intestines and the release of emetogenic substances (e.g. serotonin) [12]. Intraoperative nausea and vomiting during spinal anaesthesia is often observed in hypotension. We therefore also looked at nausea and vomiting as unfavourable or as an adverse event during spinal anaesthesia which is otherwise commonly reported to be ranging from 35% and 64.5% of parturients [13]. In our study only 2 patients in the preloading group reported nausea and only 1 patient reported vomiting, compared to no patient in the coload group reporting nausea or vomiting. There was no statistical significance between the two results.

We assessed foetal outcome using Apgar score. The median Apgar scores at 1 and 5 minutes were similar in both groups. Our study did not demonstrate any difference in the Apgar scores between the groups at 1 and 5 minutes as we did not have a newborn with low APGAR scores in either of the two groups. None of the other studies reviewed reported differences in the APGAR scores between the groups [14, 8, 15]. APGAR scores is expression of the neonate's physiological condition and has subjective components and the blood and tissue chemistry must be significantly affected before the score reflects it truly [16]. A more sensitive measure which may have been used are foetal lactate levels, blood gases and pH [17, 18]. Facilities for rapid blood biochemical analysis were not easily available at the time of this study.

Table 1: Clinical Characteristics

Variables	Coloading (N=33)	Preloading (N=33)	P Value
Number of Cases (%)	5(15.2)	13(39.4)	0.027
Ephedrine dose (gms)	1.2 gm (N=5)	1.92 gm (N=13)	0.54
Incidence of nausea N(%)	0	2(6.1%)	0.15
Incidence of vomiting N(%)	0	1(3%)	0.31
Neonatal APGAR score<7 at 1min N(%)	0	0	NA
Neonatal APGAR score<7 at 5min N(%)	0	0	NA

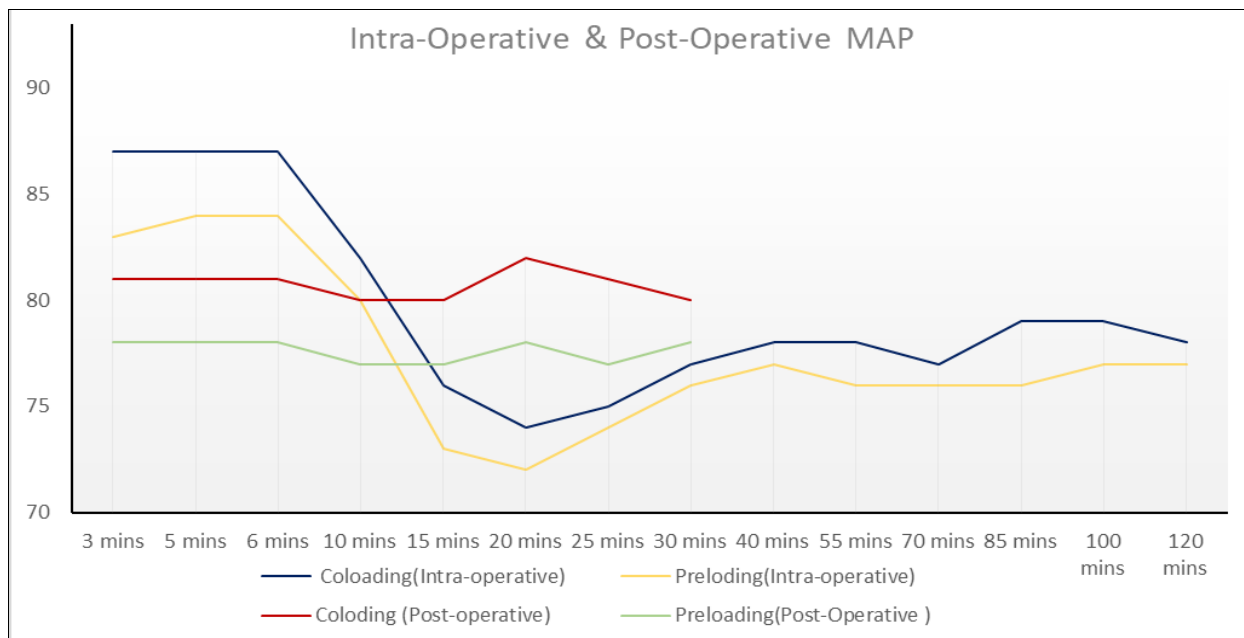


Fig 1: Intra-Operative MAP & Post-Operative MAP

Conclusion

The median bolus dose of ephedrine required for hypotension was 1.56 g. Although two parturient in the preloading group had minor emetic symptoms, the difference was insignificant. Foetal outcomes were also similar between the groups. This study demonstrated that coload is better than preload in the prevention of spinal anaesthesia-induced hypotension during caesarean section. More large clinical trials in the Indian context with adequate control groups, blood pressure contextualization, and foetal blood group recordings would be advisable for more robust study result.

Conflict of Interest

Not available

Financial Support

Not available

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How to Cite This Article

Appu AK, Kunnathadi F, Meethal AC, Velayudhan A. Preloading versus coload of crystalloids for prevention of spinal anaesthesia induced maternal hypotension during elective caesarean section: A comparative study. *International Journal of Anesthesiology Research.* 2025;7(2):41-45.

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