

Comparitive Evaluation of Crystalloid Preload and Crystalloid Coload on Hemodynamic Parameters in Patients Undergoing Elective Cesarean Section under Spinal Anesthesia

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Abstract

Aims and Objectives: To compare the effects of crystalloid preload and crystalloid coload on hemodynamic parameters in patients undergoing elective cesarean section under spinal anesthesia. *Materials and Methods:* One hundred patients with American Society of Anesthesiologists Physical Status I and II scheduled for elective cesarean section under spinal anesthesia were randomly allocated into two groups with fifty patients each. *Group P:* Received 15 ml/kg of Ringer's lactate solution over 20 minutes prior to spinal anesthesia. *Group C:* Received 15 ml/kg of Ringer's lactate solution over 20 minutes as soon as Cerebrospinal fluid (CSF) was tapped. Patients were assessed for hemodynamic changes, mean and total dose of vasopressor consumption in the intraoperative period. *Results:* The incidence of Hypotension was high in Group P (66%) when compared to Group C (36%) with *p* - value of 0.0027 which is statistically significant. Hypotension appeared early in Group P (6.85 ± 0.83) when compared to Group C (15.83 ± 0.92) minutes with significant *p* - value of < 0.001 . Group P also had higher incidence of nausea and vomiting (48% and 34%) when compared to Group C (18% and 12%) respectively with statistically significant difference. (*p* - value 0.0027 and 0.0014 respectively). The incidence of bradycardia and shivering was also high in Group P as compared to Group C though the difference is statistically insignificant. *Conclusion:* Crystalloid coload in the dose of 15 ml/kg is more effective than the crystalloid preload in the same dose for prevention of spinal hypotension in patients undergoing elective cesarean section.

Keywords: Crystalloid preload; Crystalloid coload; Elective cesarean section; Hemodynamic changes; Mean and total vasopressor consumption.

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Introduction

Regional anesthesia, especially Spinal Anesthesia (SA) is commonly used in patients undergoing

cesarean section due to its beneficial effects on both mother and fetus.¹ Spinal anesthesia is preferred over General anesthesia due to its distinct advantages such as avoidance of airway related complications, aspiration and neonatal depression.^{2,3}

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Spinal anesthesia is usually accompanied with hypotension (Spinal Hypotension) which is often defined as a Systolic blood pressure less than 100 mm Hg or a 20% drop in the baseline level.⁴ Spinal hypotension is a common physiological complication with an incidence rate of 25–75% among general population and a little higher incidence rate of 82% in parturients undergoing cesarean section.^{5,6} Higher rate of spinal hypotension in parturients is due to aortocaval compression as well as the higher level of block (T_4) required for cesarean section.⁷

Spinal hypotension is mainly due to sympathetic blockade leading to peripheral vasodilation and venous pooling of blood which in-turn leads to decreased venous return and cardiac output.⁸ Other maternal side effects associated with spinal anesthesia include nausea, vomiting, aspiration, altered sensorium, bradycardia and cardiac arrhythmias.^{2,3} Sustained maternal hypotension is associated with fetal hypoxia and acidosis as a result of placental hypoperfusion.⁹ Thus, prevention of spinal hypotension is of paramount importance to the attending anesthetist as both mother and fetus life is at risk.

Several prophylactic measures were investigated to offset the hypotensive effect of spinal anesthesia such as leg wrapping, elastic stockings, optimizing patient's position, intravenous fluids and vasopressors. Of all the methods, most commonly used technique was intravenous volume expansion with intravenous fluids before the initiation of spinal anesthesia, a technique commonly called "preload" which was first described by Wollman and Marx.^{10,11}

However, the efficacy of preload in preventing spinal hypotension was questioned by some studies and advised the rapid bolus infusion of intravenous fluids in the period just following the spinal injection, a technique commonly called "coload".¹²⁻¹⁵

Mercier et al. suggested fluid coload may be a more physiological and rational approach for prevention of Spinal hypotension because the increase in intravascular volume brought about by co-loading coincides with the time of maximal vasodilation. Crystalloids do not remain in the intravascular space but distribute rapidly into the extracellular space (75%) and hence, the timing of infusion may be the keynote to prevent spinal hypotension.¹⁶

However, a systematic review and meta-analysis involving eight studies on 518 patients for the effects

of preloading and coload on spinal hypotension observed a similar incidence of hypotension and nausea/vomiting between the two groups.¹⁷

Some studies showed that colloids may be more effective than crystalloids for preventing spinal hypotension. However, there are several disadvantages associated with colloids, such as cost, allergic reactions and their effects on coagulation system.⁸ Hence, crystalloids are still preferred over colloids by many anesthesiologists.

Based on the above studies, we hypothesized to conduct this study to evaluate the effect of crystalloid preload and crystalloid coload on hemodynamic parameters in patients undergoing elective cesarean section under spinal anesthesia. The rationale of this study was to identify safe fluid loading techniques to prevent spinal hypotension in patients undergoing elective cesarean section under spinal anesthesia.

Materials and Methods

Randomized, prospective, double blind study was conducted on 100 patients scheduled to undergo elective cesarean section at Major operation theatre MIMS, Mandya, Karnataka, India after obtaining approval from Institutional Ethical Committee and informed consent from patients.

Inclusion Criteria

1. ASA I & II patients undergoing elective cesarean section;
2. Age: 18–35 years;
3. Weight: 50–100 kgs;
4. Height: > 150 cm;
5. BMI < 30
6. Singleton pregnancy at term;
7. Uncomplicated pregnancy.

Exclusion Criteria

1. Spinal deformities;
2. Coagulation abnormalities;
3. Medical comorbidities such as Pregnancy Induced Hypertension (PIH), chronic hypertension, Gestational Diabetes Mellitus (GDM), cardiovascular diseases, severe anemia etc;
4. Patients posted for emergency cesarean section;

5. Infection at lumbar puncture site;
6. Allergic to local anesthetics;
7. Any other contraindications for regional anesthesia.

Preoperative assessment of patients including routine blood investigations and Electrocardiogram (ECG) were done a day prior to surgery. Patients were briefed about details of the study and informed consent was taken. Using computer generated random numbers patients were randomized into Group P (Preload Group) and Group C (Coload Group) each having 50 patients. The patients were kept nil per oral as per American Society of Anesthesiologists (ASA) guidelines.¹⁸

All patients received Tab. Ranitidine 150 mg orally on the night before surgery. On the day of surgery 50 mg Inj. Ranitidine and 10 mg Inj. Metoclopramide were given 2 hours prior to surgery.

For the study, all patients had two 18 G intravenous cannula, one for the administration of intravenous fluid and the other for administering intravenous drugs. On arrival to the major operation theatre, patient was connected to multiparameter monitor to record pulse rate, noninvasive blood pressure, ECG, and oxygen saturation (SpO₂). Under aseptic precautions, all study patients received spinal anesthesia in left lateral position at L3-L4/L4-L5 intervertebral space using 10 mg (2 cc) 0.5% Inj. Bupivacaine heavy with 25 G Quincke's spinal needle.

The patients in Group P received 15 ml/kg of Ringers lactate solution over 20 minutes prior to spinal block. The patients in Group C were given 15 ml/kg of Ringers lactate solution over 20 minutes as soon as Cerebrospinal fluid (CSF) was tapped. After the spinal injection, the patients were put into supine position with a 15 degrees wedge under the right hip. The sensory level was assessed using pin prick to 25 G needle every 5 minutes till the level stabilized for at least three consecutive readings. After achieving a block height of T5, surgeon was asked to start the surgery.

After infusion of predefined fluid in respective study group, Ringers lactate was started at maintenance rate of 10 ml/kg⁻¹/hr⁻¹ for the intraoperative period.

A two-operator technique was employed to prevent the observer bias. Randomization was performed by an Anesthetist intended to deliver the studied fluid and to initiate spinal anesthesia while interventions and monitoring were

performed by a second Anesthetist blinded to the group allocation.

All patients were continuously monitored for heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, SpO₂ by an investigator every 2 minutes for the first 10 minutes and every 5 minutes till 30 minutes and every 10 minutes till the end of surgery.

Maternal hypotension was defined as a fall in Systolic Blood Pressure (SBP) to less than 100 mm of Hg or Mean Arterial Pressure (MAP) less than 80% of the baseline value. Any episode of maternal hypotension was treated with a bolus dose of crystalloid fluid and Inj. Phenylephrine 25 µg IV repeated every 3 minutes until the blood pressure recovers to normal. The number of doses and the total dose of Phenylephrine required to treat hypotension was recorded.

Bradycardia was defined as a Heart rate less than 50 beats per minute and was treated with intravenous Inj. Atropine 0.6 mg. Any episode of nausea or vomiting was treated with a bolus dose of Inj. Ondansetron 4 mg IV. Continuous monitoring of oxygen saturation was done and supplemental oxygen was delivered through a facemask if SpO₂ falls below 94%. Inj. Oxytocin 20 IU intravenous infusion was administered to the mother once the baby was delivered. APGAR scores were determined at 1 and 5 minutes interval by the attending neonatologist who was unaware of the study group allocation. Fetal blood gas analysis was performed with ABL 90 FLEX analyzer (Radiometer, Copenhagen, Denmark) on blood samples collected from umbilical artery and umbilical vein.

The total blood loss and total intravenous fluid administered were also noted.

Statistical Analysis

Descriptive statistical analysis was done using SPSS® computer software-IBM SPSS Statistics version 26. Results on continuous measurements were presented as Mean ± SD and results on categorical measurements were presented in number and percentage. Student's *t*-test/*Z*-test was used to find the significance of study parameters on continuous scale while Chi-square test/Fishers exact test was used to find the significance of study parameters on categorical scale. Upper sensory level attained was compared with Mann-Whitney *U*-test. Significance was assessed at 5% level. Any *p* - value less than 0.05 (*p* < 0.05) was considered as statistically significant.

Results

The demographic data was comparable among the study groups and the difference was not statistically significant, as shown in (Table 1).

There was no statistically significant difference between the two groups as regards to baseline heart rate, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP), (Table 2).

Table 1: Demographic variables among study groups

Parameters	Mean \pm SD		<i>t</i> -test statistic value	<i>p</i> - value
	Group P (<i>n</i> = 50)	Group C (<i>n</i> = 50)		
Age (yrs)	25.22 \pm 2.65	24.80 \pm 2.75	0.777	0.439
Weight (kgs)	69.92 \pm 4.70	68.56 \pm 3.87	1.578	0.118
Height (cms)	165.40 \pm 4.48	165.94 \pm 3.18	-0.695	0.489
Body Mass Index	25.61 \pm 2.18	24.93 \pm 1.79	1.694	0.093
Gestational Age (wks)	38.59 \pm 0.43	38.44 \pm 0.36	1.841	0.069

Table 2: Comparison of preoperative characteristics among study groups

Parameters	Mean \pm SD		<i>t</i> - test statistic value	<i>p</i> - value
	Group P (<i>n</i> = 50)	Group C (<i>n</i> = 50)		
Baseline HR (bpm)	72.52 \pm 7.44	74.08 \pm 5.76	-1.173	0.244
Baseline SBP (mm Hg)	122.60 \pm 6.89	121.28 \pm 6.84	0.961	0.339
Baseline DBP (mm Hg)	74.96 \pm 5.60	74.32 \pm 6.53	0.524	0.602
Baseline MAP (mm Hg)	90.90 \pm 4.55	89.98 \pm 5.09	0.952	0.343

In Group P, the incidence rate of Hypotension was high (66%) when compared to Group C (36%) with *p* - value of 0.0027 which is statistically significant.

No significant difference was observed in mean arterial pressure between the two groups at different times studied, except at 6 and 15 minutes, which showed a significant difference between the two groups (*p*-value < 0.001 and

p-value < 0.001) respectively. Hypotension appeared early in Group P (6.85 \pm 0.83) when compared to Group C (15.83 \pm 0.92) minutes with *p* - value of < 0.001, Fig. 1. Similarly, the study of Heart rate also showed no significant difference among the study groups at different times except at 6 and 15 minutes which showed a statistically significant difference with *p* - value of 0.003 and *p* - value of 0.001 respectively, (Fig. 2).

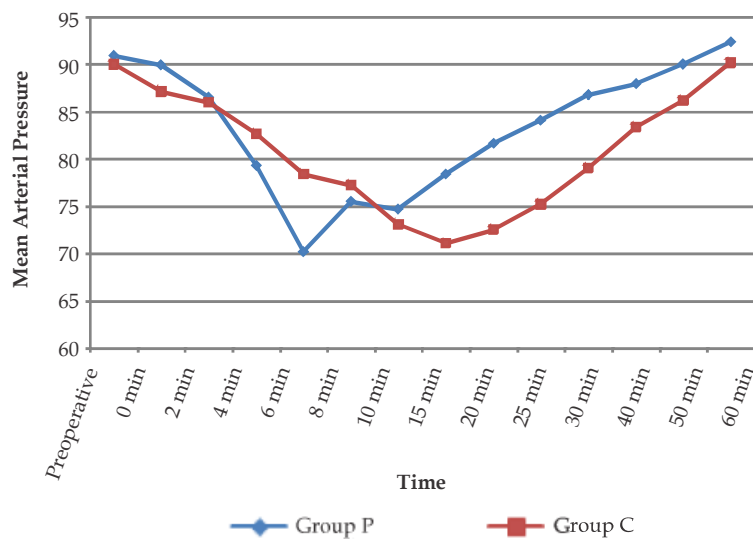


Fig. 1: Trends of Mean arterial pressure among study groups.

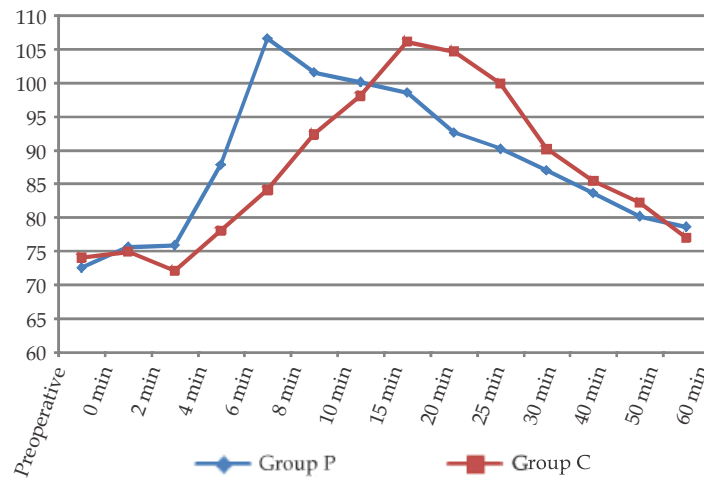


Fig. 2: Trends of Heart rate among study groups.

Group P had higher incidence of Nausea and vomiting (48% and 34%) when compared to Group C (18% and 12%) respectively with statistically significant difference. (*p* - value 0.0027 and 0.0014 respectively). The incidence rate of Bradycardia was also high in Group P (26%) when compared to Group C (16%) though the difference was statistically insignificant (*p* - value 0.2187). Patients complaining of shivering was also more in Group P (42%) when compared to Group C (30%) though the difference was statistically insignificant (*p* - value 0.2113).

Mean number of dose of Phenylephrine used to correct hypotension in Group P was 1.14 ± 1.74 when compared to Group C 0.51 ± 1.72 with *p* - value of < 0.001 which is statistically significant. Patients requiring single as well as double rescue dose of vasopressor to correct hypotension was

more in Group P when compared to Group C though the difference was statistically insignificant. The triple rescue dose requirement was also high in Group P as compared to Group C and the difference was statistically significant. (*p* - value = 0.0026)

The mean total cumulative dose of vasopressor to correct hypotension was high in Group P ($41.67 + 20.41$) as compared to Group C (34.72 ± 12.54) mcg though the difference was statistically insignificant (*p* - value = 0.196). The total intravenous fluids used to correct intraoperative hypotension was more in Group P (1780 ± 236) as compared to Group C (1395 ± 215) with statistically significant *p* - value of < 0.001 , (Table 3, Figs. 3 and 4).

No adverse neonatal outcome was observed in the study groups in terms of Apgar score and acid-base status, (Table 4).

Table 3: Comparison of intraoperative characteristics among study groups

Parameters	Group P (n = 50)	Group C (n = 50)	t-test statistic value/Z-test statistic value	p - value
Highest sensory block level	T5 (T3-T6)	T5 (T2-T6)	-0.20	0.8414
Total fluids (ml)	1780 ± 236	1395 ± 215	8.52	< 0.001
Blood loss (ml)	654 ± 186	690 ± 118	-0.115	0.25
Time to first hypotension (min)	6.85 ± 0.83	15.83 ± 0.92	-35.411	< 0.001
Hypotension (%)	33 (66.0)	18 (36.0)	3.01	0.0027
Nausea (%)	24 (48.0)	09 (18.0)	3.19	0.0014
Vomiting (%)	17 (34.0)	06 (12.0)	2.61	0.0096
Bradycardia (%)	13 (26.0)	08 (16.0)	1.23	0.2187
Shivering (%)	21 (42.0)	15 (30.0)	1.25	0.2113
Mean dose of Phenylephrine (No)	1.14 ± 1.74	0.51 ± 1.72	7.5	< 0.001
Single rescue dose of Phenylephrine	18	11	1.542	0.1235
Double rescue dose of Phenylephrine	08	07	0.28	0.7794
Triple rescue dose of Phenylephrine	07	0	3.06	0.0026
Total dose of Phenylephrine (mcg)	41.67 ± 20.41	34.72 ± 12.54	1.311	0.196

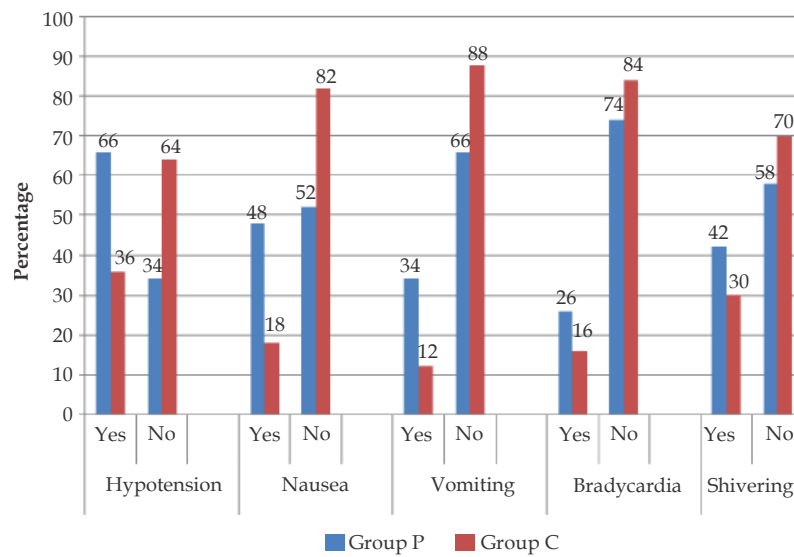


Fig. 3: Comparison of intraoperative characteristics among study groups.

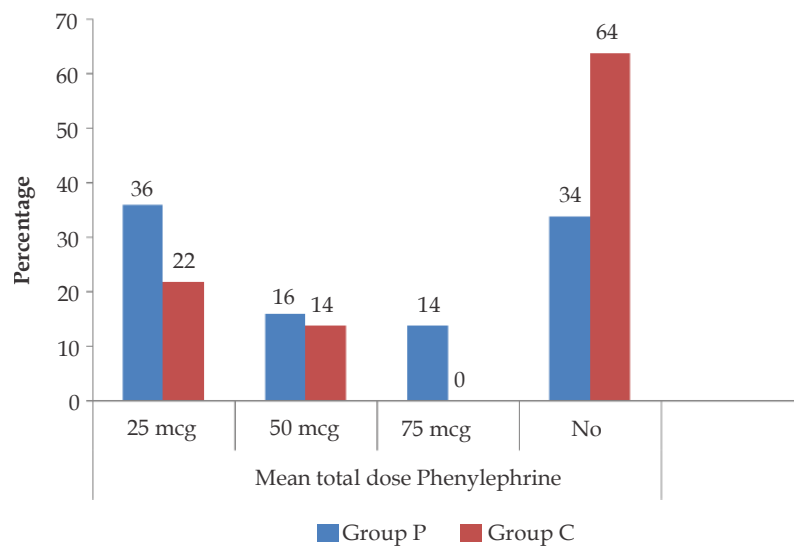


Fig. 4: Comparison of mean total cumulative dose of Phenylephrine use among study groups.

Table 4: Neonatal outcome among study groups

Parameter	Group P (n = 50)	Group C (n = 50)	t-test statistic value	p - value
APGAR score				
At 1 min	8.17 ± 0.73	8.20 ± 0.69	7.336	0.985
At 5 min	9.67 ± 0.47	9.65 ± 0.48	7.758	0.717
Umbilical Vein				
pH	7.34 ± 0.4	7.31 ± 0.2	0.474	0.636
pO ₂ (mm Hg)	30.6 ± 7.6	29.9 ± 7.7	0.457	0.648
pCO ₂ (mm Hg)	41.5 ± 5.4	41.8 ± 6.2	0.258	0.796
BE (Meq/ml)	-2.5 ± 1.7	-2.7 ± 2.0	0.538	0.591
Umbilical Artery				
pH	7.35 ± 0.4	7.37 ± 0.7	0.367	0.377
pO ₂ (mm Hg)	16.9 ± 4.7	17.2 ± 5.1	0.305	0.760
pCO ₂ (mm Hg)	52.5 ± 8.2	53.2 ± 7.9	0.434	0.664
BE (Meq/ml)	-2.5 ± 1.3	-2.4 ± 1.7	0.330	0.741

Discussion

Subarachnoid Block (SAB), a form of regional anesthesia is most commonly practiced for cesarean delivery. It has distinct advantages such as rapid onset of action, dense sensory and motor block as compared to epidural anesthesia, preservation of consciousness and airway reflexes of patients thus avoiding aspiration and failed intubation as well as better postoperative pain relief and neonatal outcome as compared to general anesthesia.^{1,2}

Spinal Hypotension remains a common and potentially very serious complication due to its detrimental effects on both mother and foetal outcomes. The fall in blood pressure is attributed mainly to the sympathetic blockade resulting in vasodilation of capacitance vessels and peripheral pooling of blood. This in-turn leads to decreased venous return and cardiac output.^{2,8} Preventive measures commonly practiced to avoid spinal hypotension in parturients include leg wrapping, elastic stockings, trendlenburg position, left lateral tilt, manual displacement of uterus, intravenous fluids and vasopressors. In spite of all these prophylactic measures the incidence of spinal hypotension in parturients can be as high as 53% to 82%.^{2,5}

Earlier studies conducted by Wollman SB, Marx GF et al. suggested the use of intravenous crystalloid fluids before the initiation of spinal anesthesia, a technique commonly referred as "Preload" for alleviating the hypotensive effects of spinal anesthesia.^{10,11} This fluid bolus was aimed at restoration of relative hypovolemia secondary to sympathetic blockade following spinal anesthesia thereby increasing the venous return to the heart and cardiac output. However, some studies reported an actual increase in cardiac output in obstetric population following spinal anesthesia thereby, questioned the rationale of infusing the crystalloid fluids before the administration of spinal anesthesia.^{12,19,20} Possible reasons proposed for the failure of preload technique in prevention of spinal hypotension include:

- a. Crystalloid preload infusion rapidly increases the capillary hydrostatic pressure thereby gets redistributed (75%) into the interstitial space without causing much increase in the central venous pressure;²¹⁻²³
- b. Crystalloid preload may induce atrial natriuretic peptide secretion, resulting in peripheral vasodilation and also increased rate of fluid excretion;²⁴

- c. Crystalloid preload infusion does not increase the intravascular volume at the actual time of maximum vasodilation;²⁵
- d. Crystalloid preload infusion in parturients has been reported to disrupt Glycocalyx which is a carbohydrate rich layer lining the endothelium which plays a major role in maintaining the integrity of endothelial layer of the vessel leading to the diffusion of fluid into the interstitial space.²⁶

Park GE, Hauch MA et al. studied the effects of three different doses of preload fluid volume prior to spinal anesthesia who compared 10, 20 and 30 ml/kg crystalloid preload and concluded there was no significant difference in the incidence of hypotension among three study groups.²⁷ Thus crystalloid preload infusion may not only fail to maintain hemodynamic stability after spinal anesthesia, but also may have a detrimental effect by decreasing the colloidal osmotic pressure leading to pulmonary edema in compromised patients.^{28,29}

Moreover American Society of Anesthesiologists (ASA) clinical practice guidelines recommendation concerning spinal anesthesia for cesarean delivery states:

"Although fluid preloading reduces the frequency of maternal hypotension, initiation of spinal anesthesia should not be delayed to administer fixed volume of intravenous fluid."³⁰

Dyer RA, Farina Z et al. conducted a study on fifty patients undergoing elective cesarean section for hypotension after spinal anesthesia. Patients were randomly allocated into two groups to receive either 20 ml/kg of crystalloid solution over 20 minutes prior to spinal anesthesia (preload) or an equivalent volume by rapid infusion immediately after spinal anesthesia (coload). Hypotension was observed more in the preload than coload group. Vasopressor requirement was also significantly high in the preload than coload group ($p = 0.047$). The median number of vasopressor dose used to correct hypotension was significantly high in preload than coload group ($p = 0.04$). Our study also observed, significantly higher incidence of hypotension in preload group (66%) than coload group (36%) with p - value = 0.0027. The mean number of dose of vasopressor used to correct hypotension was also significantly high in preload group as compared to coload group, (p - value = < 0.001).²⁰

Oh A-Y, Hwang J-W, Song I-A et al. conducted a similar study on sixty pregnant women posted for elective cesarean section for hypotension and

vasopressor requirement. Patients were allocated randomly into two groups to receive 15 ml/kg crystalloid fluid either prior to spinal block or after its administration. The incidence of hypotension was significantly higher in the preload group (83.3%) compared to the coload group (53.3%). (p - value = 0.026). The mean total cumulative dose of vasopressor consumption was significantly high in preload group (15.2 ± 11.9 mg) as compared to coload group (7.5 ± 8.6 mg), (p - value = 0.015). Even our study observed, similar results with higher incidence of hypotension in preload group (66%) as compared to coload group (36%) with p - value = 0.0027. The total cumulative dose of vasopressor consumption was also high in preload group (41.67 ± 20.41 mcg) as compared to coload group (34.72 ± 12.54 mcg) though the difference was statistically not significant, (p - value = 0.196).³¹ Similar results were also found in other studies.³²

Mercier FJ, Augè M et al. found that the infusion of crystalloid fluids at the actual time of intravascular volume deficit is more efficient in preventing spinal hypotension than prophylactic administration. They proposed not to use crystalloid preload as it was clinically ineffective. They concluded that the incidence and severity of hypotension can be decreased by combining a prophylactic vasopressor regimen with hydroxyethyl starch preloading, hydroxyethyl starch coload or crystalloid coload.¹⁵

However, contrary results were found in a study conducted by Bouchnak M, Ben Cheikh N, et al. where they reported a higher incidence of hypotension in the coload group (96.6%) than in the preload group (86.6%). They had compared the infusion of 20 ml/kg crystalloid given over 15 minutes as coload or preload in the obstetric population.³³ However, in our study we compared the infusion of 15 ml/kg of crystalloid fluid given over 20 minutes as coload or preload and observed completely contrary results as compared to this study. The wide variations in the incidence of hypotension in these studies may be due to the differences in the definitions of hypotension with different volumes and different rate of infusion of crystalloid fluids used in these studies.

A meta-analysis conducted by Banerjee A, Stocche RM comprising eight studies with five hundred and eighteen patients for hypotension in cesarean section found the incidence of hypotension to be 59.3% in coload group as compared to 62.4% in the preload group. They concluded that there is no significant inter group difference and hence, should not delay surgery in order to deliver

preload volume of fluid.¹⁷ Similar results were also observed in a study conducted by Jacob JJ, Williams AJ which concluded both preloading and coload strategy alone are ineffective in the prevention of hypotension in the obstetric population receiving spinal anesthesia and should be supplemented with vasopressor therapy for maintaining normal blood pressure.³⁴

The incidence of maternal nausea and vomiting has a direct correlation with the severity and duration of maternal hypotension during spinal anesthesia as observed by earlier studies.^{35,36} Our study observed a higher incidence of maternal nausea and vomiting in preload group (48% and 34%) which also experienced higher incidence of hypotension as compared to coload group (18% and 12%) respectively. This may be due to the stimulation of chemoreceptor trigger zone as a consequence of maternal hypotension.³⁷

Some studies also compared the hemodynamic changes in pregnant women after using colloid for either preload or for both preload and coload group. Though the hemodynamic changes are less with the use of colloid, one should be very careful for allergic reactions and its effects on coagulation system.^{8,38-40}

There was no evidence of any significant foetal acidosis as all the neonates had an umbilical arterial pH > 7.3. This may be due to the prompt treatment of hypotension with crystalloid fluid and vasopressors which maintained normal fetal perfusion.

The main limitation of this study is absence of a control group. Hence, the efficacy of preload in prevention of spinal hypotension in patients undergoing cesarean section cannot be assessed. In fact, the results of our study proposes the need for conducting more studies with larger sample size and a control group to establish safe fluid loading techniques to prevent spinal hypotension in patients undergoing elective cesarean section under spinal anesthesia.

Conclusion

We conclude that the crystalloid coload in the dose of 15 ml/kg is more effective than the crystalloid preload in the same dose for prevention of spinal hypotension in patients undergoing elective cesarean section. Surgery should not be delayed in view of preloading the patient as preloading alone is not effective in prevention of spinal hypotension and should be supplemented with vasopressors.

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