



Original Research Article

A randomized single-blinded comparative experimental study to test the influence of timing of intravenous fluid therapy on maternal hemodynamics during lower segmental caesarean section under spinal anaesthesia

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ABSTRACT

Background: Spinal anaesthesia-induced hypotension can be prevented by several techniques and methodologies, which is very important as the life of the mother and fetus is at risk. This study compared the efficacy of crystalloid administration 6 hours and half an hour before spinal anaesthesia on reducing hypotension.

Materials and Methods: After obtaining informed consent, 110 ASA 2 patients aged between 20 and 40 were scheduled for elective lower segmental caesarean section under spinal anaesthesia. Patients were randomly allocated into two groups. Group 1: Participants were kept nil per oral overnight, and Ringer's lactate was administered over half an hour before surgery. Group 2: participants were given ringer lactate. The amount was based upon the Holiday Segar formula (first 10 kg received 4ml/kg, 10-20 kg- 2ml/kg and remaining received 1 ml/kg) and given steadily over half an hour and 6 hours respectively in both groups. The incidence of hypotension and the need for rescue vasopressor in the two groups was recorded.

Results: The two groups were statistically comparable in terms of age, height and weight. The incidence of Hypotension in Group 1 was 12.7%, and in Group 2 was 25%, which was statistically insignificant. Seven out of 55 patients in Group 1 had SBP<20% from baseline, whereas in Group 2, 14 patients out of 55 patients had SBP <20% from baseline, which was statistically insignificant. The incidence of ephedrine usage was statistically insignificant in both groups.

Conclusion: This study's results showed no statistically significant difference in preventing hypotension whether the fluids were given as 6 hours or half an hour before surgery. Therefore, to deliver preload of fluid, it is unnecessary to delay surgery.

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1. Introduction

Spinal anaesthesia is a rapid and simple technique for pregnant women undergoing caesarean section. Spinal anaesthesia is a regional anaesthesia obtained by depositing the local anaesthetic agents in the subarachnoid space that act on the spinal nerve roots. Despite the advantages of spinal anaesthesia for caesarean section, the potential for hypotension with this technique poses a great threat to both

the mother and the fetus.^{1,2} If untreated, it can lead to maternal symptoms like nausea, vomiting, dizziness and serious fetal complications like bradycardia and acidosis secondary to placental hypo perfusion. Thus, prevention of hypotension is essential for better outcomes for both the mother and the fetus.^{3,4}

In pregnant women, hypotension induced by subarachnoid block occurs due to the thoracolumbar sympathectomy, which reduces systemic vascular resistance and increases venous pooling, thereby reducing preload and

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cardiac output.^{5–7} Effective sensory block up to the level of T4–T6 dermatome is the primary objective of the spinal anaesthesia technique, and it must be accomplished while minimizing maternal and neonatal side effects. Hypotension in spinal anaesthesia is caused by the sympathetic blockade, leading to vasodilatation and blood pooling. Preloading (Fluid administration before spinal anaesthesia) for hypotension prevention is a traditional practice in spinal anaesthesia.⁸

Fluid infused before or when starting the spinal anaesthesia is referred to as preloading and co-loading, respectively. Crystalloid solutions do not stay in the intravascular compartment but distribute proportionately into the extracellular compartment. Therefore, the timing of infusion is important to prevent hypotension because the volume-expanding effect is maximal immediately after the spinal anaesthetic is administered.^{9,10} Intravenous fluid loading is used to correct preoperative dehydration and increase preload, thereby reducing hypotension. The study aims to compare the efficacy of crystalloid administration 6 hours and half an hour before spinal anaesthesia on reducing hypotension.

2. Materials and Methods

A randomized single blinded experimental study was conducted in the hospital's Obstetric wards, Labour room and operation theatre unit for 18 months from January 2020 to June 2021. After obtaining institutional Ethics committee clearance, 110 patients were studied with 55 in each group. Sample size was calculated based on the study: 'Crystalloid co-load: A better option than crystalloid preload for prevention of post-spinal hypotension in elective caesarean section' study done by M Khan, Waqar-ul-Nisai, A Farooqi, N Ahmad, S Qaz which was published in The Internet Journal of Anesthesiology. 2013 Volume 32 Number 1. Scientific basis for sample selection used in this study is based on the formula:

$$N = \frac{(p_1 q_1 + p_2 q_2)(z\alpha + z\beta)^2}{(p_1 - p_2)^2}$$

$Z\alpha = 1.96$ at 95% significance $Z\beta = 0.84$ at 80% statistical power

$$p_1 = 70\% \quad p_2 = 40\%$$

2.1. Inclusion criteria

Patients scheduled to undergo an elective caesarean section, ASA grade II, aged between 20–40 years and those who gave informed consent were included.

2.2. Exclusion criteria

Emergency LSCS patients, ASA III and IV, Severe anaemia, coagulation defects, bleeding dyscrasias, previous surgeries on the spine or spinal deformities, raised ICP, infections over the lumbosacral region, history of hypersensitivity to

bupivacaine and morbidly obese patients were excluded.

The patient's medical, surgical, and obstetric history were obtained, and baseline blood pressure and heart rate measurements were recorded. The airway, CVS, and RS examinations were evaluated consistent with the American Society of Anaesthesiologists' (ASA) guidelines, and NPO instructions were given. Written and informed consent was obtained from every patient, and standard protocols were followed for anaesthesia in both groups of patients. All patients were kept nil per oral for 6 hours before the procedure according to ASA guidelines.

The parturients were randomly allocated into two groups. Group 1: Participants were kept nil per oral overnight, and Ringer's lactate was administered over half an hour before surgery. Group 2: participants were given ringer lactate 6 hours before surgery. Thalf an hour and 6 hours respectively.

Pre-anaesthetic check-ups were done systematically, and the patient's proforma was filled. The patient was reviewed preoperatively in OT, and parameters like heart rate, systolic, diastolic and mean arterial pressure were recorded. Both group patients were given Inj. Pantoprazole 40 mg I.V. and Inj. Metoclopramide 10 mg i.v slowly over 5 min.

The patient was shifted to the operation theatre in a supine position with a wedge under the right loin. Standard ASA monitors like a cardiograph, pulse oximeter, and non-invasive blood pressure monitor were connected. The immediate preoperative MAP, SBP, DBP, and HR were documented, and time was noted. Oxygen was given by face mask at the rate of 4 litres per minute. Under strict aseptic precautions spinal anaesthesia was induced in the sitting position, using a 26-gauge Quincke spinal needle. The needle was inserted into the L3–L4 space and, after withdrawal of the cerebrospinal fluid, 1.8 mL of 0.5% bupivacaine with 60mcg of buprenorphine was injected. The parturient was immediately placed supine with a 15° left lateral tilt. The level of spinal anaesthesia was assessed and recorded at 5 min after the block was given.

The parameters were assessed 5 minutes after the sub-arachnoid block, and after this recording, the MAP, SBP, DBP and HR were recorded every 5 minutes for 1 hour. After 1 hour, the same parameters were recorded every 15 mins till 2 hours after spinal anaesthesia was given. Surgical incision and baby delivery time were noted, and ten units of oxytocin infusion were given through the IV line after the baby's delivery. The patient was shifted to the recovery room after the procedure. Side effects such as nausea, vomiting and post-dural puncture headache were recorded and treated accordingly.

Statistical calculation was done using Statistical Package of Social Science (SPSS) version 20. Statistical analysis was performed, and quantitative data was expressed as mean (standard deviation). A comparison was made using an "independent sample t-test", and a p-value <0.05 was

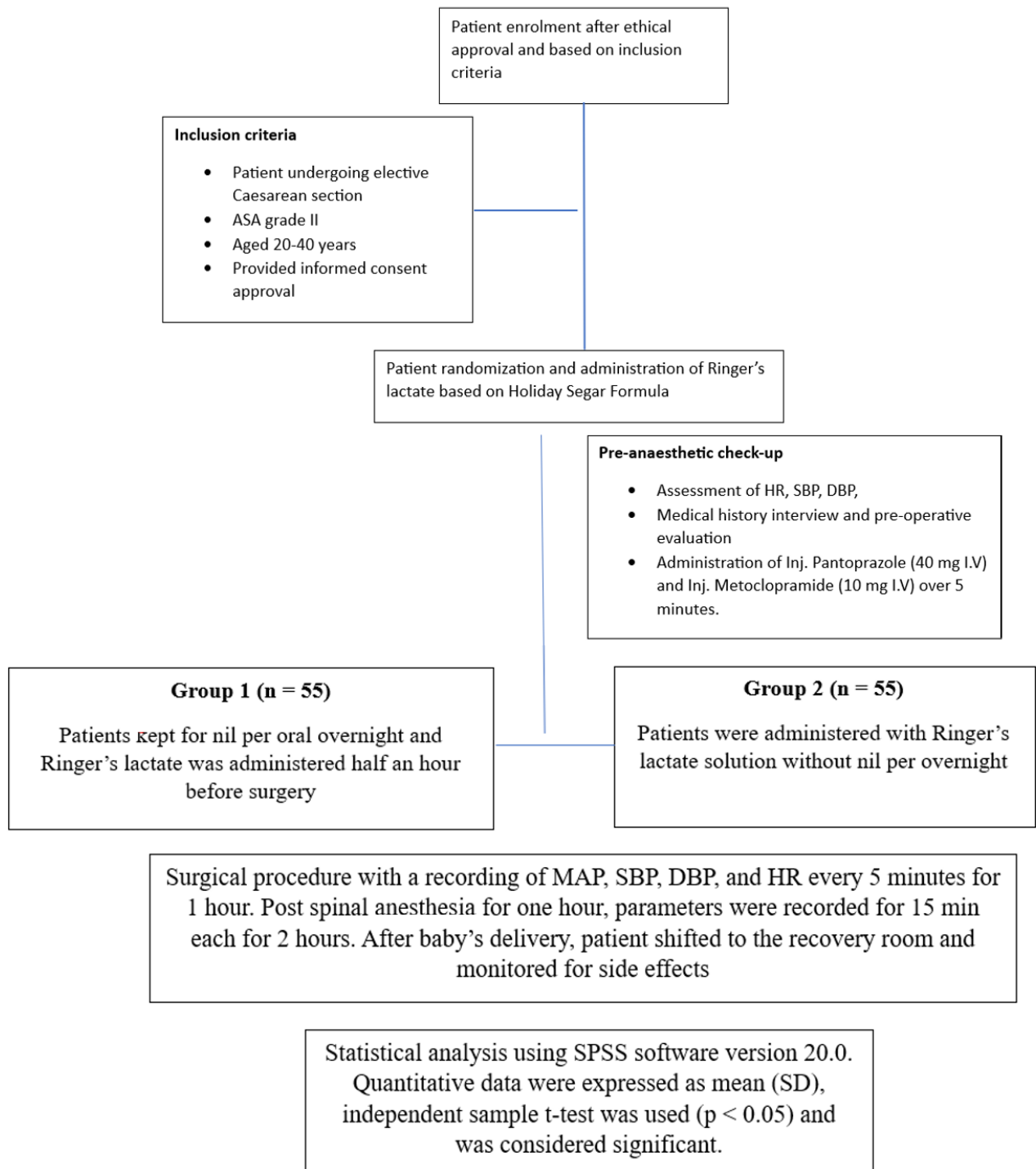


Diagram 1: Consort diagram

considered significant.

3. Results

One hundred ten parturients were enrolled in this study, with 55 patients in each group.

Table 1: Patient characteristics between groups

	Preload (n=55)	Coload (n=55)	P-value
Age (in years)	28.24±3.19	28.67±4.22	0.542
Height	157.75±3.46	156.96±3.38	0.233
Weight	68.27±8.31	69.98±8.66	0.293

Comparing the two groups' age, weight, and height shows that it is statistically insignificant.

Table 2: Hypotension, usage of ephedrine, nausea, and vomiting incidence between the Groups

		Group 1	Group 2	P-value
Hypotension	Yes	7	14	0.089
	No	48	41	
Ephedrine	6mg	7	11	0.781
	12mg	0	3	
Ephedrine used	Yes	7	14	0.089
	No	48	41	
Nausea	Absent	53	52	0.647
	Present	2	3	
Vomiting	Absent	52	54	0.308
	Present	3	1	

Seven out of 55 patients in Group 1 had SBP <20% from baseline. In Group 2, 14 out of 55 patients had SBP <20% from baseline, which was statistically insignificant. Comparing the HR between the two groups shows that HR is statistically insignificant (Figure 1).

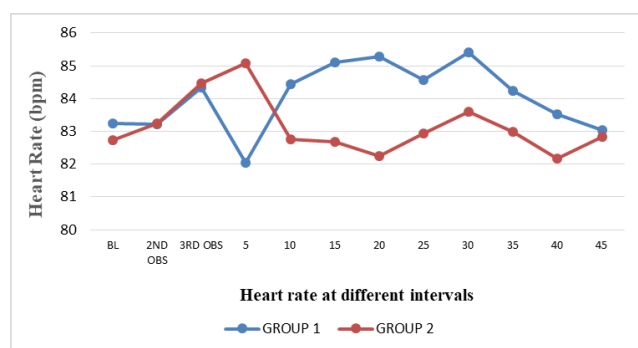


Fig. 1: Heart rate between groups

Comparison of the SBP at the 5th, 10th and 15th minute between the two groups shows that SBP is higher in Group 2 with a t value of -1.34, -0.309 and -0.108. SBP between the two groups was insignificant with a p value BP of 0.183, 0.758 and 0.914.

Comparison of the DBP at the 5th, 10th and 15th minute between the two groups shows that DBP is higher in Group 2 with a t value of -1.683, -0.626, and -1.738. A statistically insignificant p-value of 0.095, 0.533, and 0.085.

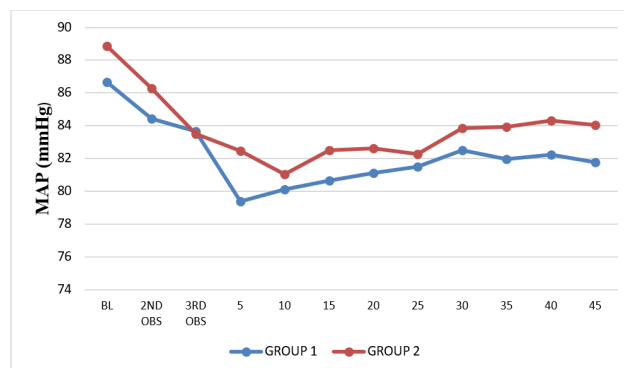


Fig. 2: Mean arterial blood pressure between group

Comparison of the MAP at the 5th, 10th and 15th minute between the two groups shows that MAP is higher in Group 2 with a t value of -1.752, -0.58, -1.351 and is statistically insignificant with a p-value of 0.083, 0.563, 0.18 (Figure 2).

The incidence of ephedrine usage was statistically not significant in both groups. The incidence of nausea and vomiting in Group 1 was 2 and 3, respectively, whereas, in Group 2, the incidence was 3 and 1, respectively. This difference in the incidence of nausea and vomiting between the two groups was statistically insignificant (Table 2).

4. Discussion

Spinal anaesthesia-induced hypotension occurs frequently in patients undergoing caesarean section. Hypotension is caused by arterial and venous vasodilatation resulting from the sympathetic block.^{11,12} The most effective strategy to reduce the incidence of hypotension remains a challenge to anesthesiologists. Fluid preloading and co-loading with crystalloid or colloid can effectively prevent spinal-induced hypotension. Other methods like using vasoactive agents¹ like ephedrine and phenylephrine, leg elevation and compression stockings are also used.

Preloading aims to fill the intravascular compartment and prevent hypotension caused by vasodilatation due to sympathetic blockade.⁸ Crystalloids and colloids are used to preload and coload. Though colloids have the advantage of maintaining intravascular volume and preventing hypotension effectively¹³ due to their long half-life, colloids are not widely used as they are costly, not readily available and associated with allergic reactions. The cause of hypotension after spinal anaesthesia depends on patient volume status, comorbidities, the volume of the drug, speed in which the drug was given etc.¹⁴ Vasopressor can be used to prevent and treat spinal-induced hypotension when different techniques for prevention of hemodynamic

instability are coupled.

In this study, ringer lactate was preferred over colloids because studies show that ringer lactate given after spinal anaesthesia increased cardiac output. Iso, crystalloids are inexpensive and have lower side effects like anaphylactic reactions than colloids.¹⁵ A study by Khan et al.¹⁶ concluded that a significantly lower incidence of post-spinal hypotension was found in the co-load group than in the preload group. Parturients in the co-load group required significantly fewer vasopressor doses than the preload group. In another study conducted by Banerjee et al.¹⁷ on a total of 518 patients undergoing elective Caesarean delivery under spinal anaesthesia, the timing of fluid loading did not impact the incidence of hypotension, concluding that delaying surgery to deliver a preload of fluid is unnecessary. The purpose of this meta-analysis was to determine whether the timing of the fluid infusion, before (preload) or during (coload) induction of spinal anaesthesia for Cesarean delivery, influences the incidence of maternal hypotension or neonatal outcome. My study was to determine two different timings in preload itself i.e., both the groups received fluid before the surgery itself, one group received half an hour before and the other group received 6 hours before.

In this study, the MAP between the two groups at the 5th, 10th and 15th minute shows that MAP is higher in Group 2 with a t value of -1.752, -0.58, -1.351. This is statistically insignificant with a p-value of 0.083, 0.563, 0.18. The vasopressor requirement in both groups does not show a statistically significant difference. The incidence of nausea (p=0.647) and vomiting (p=0.038) was statistically insignificant. In our study, the occurrence of hypotension in group 1 is 12.7%, and in group 2 is 25%, which is statistically insignificant (p= 0.089).

Kol IO et al.¹⁸ conducted a study that concluded that prophylactic administration of intravenous ephedrine during spinal anaesthesia for a cesarean section could prevent hypotension without significant maternal tachycardia or hypertension. In our study, ephedrine was used as the rescue vasopressor. Seven patients in group 1 required ephedrine (6mg), and 14 patients in group 2 required ephedrine, among which 11 patients required 6 mg and 3 required 12 mg.

5. Limitations

This study had several limitations. The sample size calculated for this study was small, so the p-value was insignificant. Neonatal outcome was not recorded. Advocating a non-blinding methodology was another drawback.

6. Conclusion

Results of this study showed that there was statistically no significant difference in preventing hypotension whether the

fluids were given 6 hours or half an hour before surgery. Therefore, to deliver a preload of fluid, it is unnecessary to delay surgery. The hypotension incidence was higher in Group 2 than in Group 1, but statistically, it was not significant, probably due to the small sample size.

7. Source of Funding

None.

8. Conflicts of Interest

There are no conflicts of interest.

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