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Research Article

Colloid-crystalloid preloading vs Crystalloid Only preloading: A Randomized Control Trial for Preventing Hypotension After Spinal Anaesthesia

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Abstract

Aim and Objective: To compare the effectiveness of colloid-crystalloid preloading and crystalloid-alone preloading in preventing hypotension in patients undergoing below-umbilicus surgeries under spinal anaesthesia.

Methodology: This randomized controlled study (RCT) was performed at Daya General Hospital in Thrissur, Kerala, from November 2020 to May 2022, focusing on adult patients undergoing elective procedures below the umbilicus. The study included participants aged 20 to 50, with a BMI ranging from 18 to 30, and classified them as either ASA grade I or II. Patients who didn't meet the requirements were those who had certain comorbidities, such as high or low blood pressure, electrolyte imbalances, ECG conduction abnormalities, those who were taking beta-blockers, were experiencing fluid overload, or were allergic to the study medications. Emergency cases and patients who chose not to participate were also excluded.

Result: This study evaluated the hemodynamic effects of colloid-crystalloid preloading versus crystalloid-only preloading in 200 patients undergoing surgeries below the umbilicus. Baseline characteristics between the two groups were comparable, ensuring validity. The colloid-crystalloid preloading group had more stable systolic blood pressure (SBP), and it dropped less after spinal anaesthesia. At 5 minutes, SBP was 123.12 ± 8.5 mmHg in the colloid-crystalloid preloading group, compared to 114.56 ± 5 mmHg in the crystalloid-only preloading group ($p < 0.01$). At 15 minutes, this group maintained a higher SBP (116.49 ± 8.2 mmHg vs. 110.78 ± 5.2 mmHg, $p < 0.01$). The diastolic blood pressure (DBP) was higher in the colloid-crystalloid preloading group and stayed higher at key intervals, at 15 minutes, DBP was 71.84 ± 8.6 mmHg in the colloid-crystalloid preloading group and 68.02 ± 6.7 mmHg in the crystalloid-only group ($p = 0.03$).

Conclusion: These results suggest that colloid-crystalloid preloading is better at keeping blood pressure stable and lowering episodes of hypotension than crystalloid-only preloading during the time after spinal anaesthesia.

Keywords: colloid-crystalloid, Spinal anaesthesia, spinal-induced hypotension

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Introduction

Spinal anaesthesia (SA), or subarachnoid blockade, is widely preferred for surgeries below the umbilicus, including caesarean sections, lower limb surgeries, and hemorrhoidectomy. This technique, involving a mix of sympathetic, sensory, and motor blockade, enables rapid anaesthesia delivery with lasting effects but can cause spinal-induced hypotension (SIH) due to sympathetic blockade and resulting vasodilation. The severity of SIH often necessitates preventive strategies to ensure safe outcomes during surgery. [1]

Fluid preloading, vasopressor administration, and patient positioning are common interventions to prevent SIH. Preloading with intravenous fluids aims to expand intravascular volume, counteracting the hypotensive effects of SA. Crystalloids, which disperse rapidly in extracellular spaces, and colloids, which stay longer in the intravascular compartment due to higher oncotic pressure, are the primary preloading solutions used. Research has shown that colloid preloading may outperform crystalloid preloading in maintaining stable blood pressure following SA, given its longer-lasting hemodynamic effects. [2]

Much of the existing literature has focused on preventing hypotension in obstetric patients undergoing caesarean sections, given their heightened risk due to pregnancy-related physiological changes. However, the principles can be extended to non-obstetric patients undergoing lower body surgeries. This study explores the effectiveness of colloid-crystalloid preloading versus crystalloid-only preloading in mitigating SIH in a broader surgical population. [3]

While numerous studies support colloid superiority for preloading, some evidence suggests that co-loading, administering fluids concurrently with SA, may offer superior hypotension prevention compared to preloading alone. This study aims to consolidate these varied insights, comparing the effects of colloid-crystalloid preloading versus crystalloid only preloading to offer an optimized approach to SIH management beyond obstetric applications. [4]

Material and method:

Study Area

This study was conducted at Daya General Hospital in Thrissur, Kerala, from November 2020 to May 2022.

Study Design and Population

The study was a randomized controlled trial (RCT) targeting adult patients undergoing elective surgeries below the umbilicus. Eligible participants were between the ages of 20 and 50, had a BMI of 18-30, and were classified as American Society of Anaesthesiologists (ASA) grades I or II. Exclusion criteria included patients with certain comorbidities, such as hypertension, hypotension, electrolyte imbalances, conduction defects on ECG, or chronic pain managed with opioids or analgesics. Patients on beta-blockers, those with fluid overload, and individuals with allergies to the study drugs were also excluded, along with those requiring emergency surgeries or those who declined participation.

Sample Size

Sample size calculations, based on previously observed hypotension rates of 55.3% and 36% for the two groups, indicated a need for 200 patients (100 per group) to achieve 95% confidence and 80% power.

Randomization and Blinding

Randomization was achieved using a computer-generated sequence. Patients were assigned to one of two groups, with blinding applied to both patients and the administering nurses. Nurses unaware of the study specifics provided preloading fluids 40 minutes before surgery. The investigator assessed the hemodynamic variations in each subject without the knowledge about the groups they belong to.

Procedure and Intervention

Following ethics committee approval, patients selected for the study were given detailed preoperative assessments. On the surgery day, an 18G IV line was placed, and preoperative monitors, including ECG, pulse oximetry (SpO_2), non-invasive blood pressure (NIBP), and heart rate (HR), were established. Patients in Group CC received a 500 ml dose of hydroxyethyl starch (HES) and 500 ml of balanced salt solution (BSS) as a preload, while Group C received a 1000 ml preload of BSS alone, administered 40 minutes pre-surgery. After preloading, a spinal block was induced at L2-3 or L3-4 level and surgery was proceeded after proper positioning and monitoring of patient and assessing level of block. Patients were also given 250ml/hr maintenance infusion of BSS after spinal anaesthesia.

Result

This study included 200 adult patients undergoing elective surgeries below the umbilicus, divided equally into two groups. One group received colloid-crystalloid preloading, while the other received only crystalloid preloading, allowing a comparative analysis of their hemodynamic stability during post-spinal anaesthesia.

Table 1: Baseline Characteristics of Patients

Variable	Colloid-Crystalloid preloading Group	Crystalloid-Only preloading Group	Total
Age (years)Mean ± SD	43±10.1	42±10.5	
Gender (M/F)			
Male	56(56%)	53(53%)	109
Female	44(44%)	47(47%)	91
Total	100	100	200(100)
ASA Classification			
1	86(86%)	90(90%)	176(88%)
2	14	10	24(12%)
Surgical Duration (min)Mean ± SD	43.4± 11.5	44.1± 10.2	

The baseline characteristics of the 200 participants were comparable between the colloid-crystalloid preloading group and the crystalloid-only preloading group. The mean age of participants was similar, at 43 ± 10.1 years for the colloid-crystalloid group and 42 ± 10.5 years for the crystalloid-only preloading group. Gender distribution was balanced, with 56 males (56%) and 44 females (44%) in the colloid-crystalloid preloading group, compared to 53 males (53%) and 47 females (47%) in the crystalloid-only preloading group, resulting in a total of 109 males and 91 females across both groups. Regarding ASA classification, 86 patients (86%) in the colloid-crystalloid preloading group were classified as ASA 1, while 14 patients (14%) were ASA 2; the crystalloid-only preloading group had 90 patients (90%) in ASA 1 and 10 patients (10%) in ASA 2, resulting in a total of 176 patients (88%) classified as ASA 1 and 24 patients (12%) as ASA 2 across both groups. The surgical durations were also comparable, with a mean of 43.4 ± 11.5 minutes for the colloid-crystalloid preloading group and 44.1 ± 10.2 minutes for the crystalloid-only preloading group, further supporting the similarity between the two groups in this randomized controlled trial.(Table 1)

SBP and DBP Distribution of study subjects during post-spinal anaesthesia.

Variables	Group	N	Mean	F	P	t
SBP -Baseline	C	100	122.81± 7.3	0.87	0.35	1.75
	CC	100	124.54± 6.6			1.75
SBP (5 MIN)	C	100	114.56± 5	18.76	0.00	8.58
	CC	100	123.12± 8.5			8.58
SBP (10 MIN)	C	100	113.52± 5.3	0.447	0.550	-2.87
	CC	100	115.82± 5.9			-2.87
SBP (15 MIN)	C	100	110.78± 5.2	32.02	0.00	-5.84
	CC	100	116.49± 8.2			-5.84
DBP -Baseline	C	100	73.5±7.8	0.016	0.9	-0.637
	CC	100	74.2±7.6			-0.637
DBP (5 MIN)	C	100	72.5±8.5	0.004	0.05	-0.41
	CC	100	73.0±10.3			-0.41
DBP (10 MIN)	C	100	72.63±8.7	0.98	0.322	-036
	CC	100	72.6±10.8			-036
DBP (15 MIN)	C	100	68.02±6.7	9.29	0.03	3.46
	CC	100	71.84+8.6			3.46

Systolic Blood Pressure (SBP) Distribution during Post-Spinal Aesthesia in the Colloid-Crystalloid preloading and **Crystalloid-Only** preloading Group

The systolic blood pressure (SBP) measurements revealed significant differences between the two groups over time. At baseline, the colloid-crystalloid preloading group exhibited a mean SBP of 124.54 ± 6.6 mmHg, compared to 122.81 ± 7.3 mmHg in the crystalloid-only preloading group, though this difference was not statistically significant (p = 0.87). After 5 minutes, the colloid-crystalloid preloading group showed a decrease (SBP) to 123.12 ± 8.5 mmHg, while the crystalloid-only preloading group experienced a significant drop to 114.56 ± 5 mmHg (p < 0.01). This suggests that colloid-crystalloid preloading maintains a higher SBP during post-spinal anaesthesia, indicating a protective effect against hypotension. At the 10-minute mark, SBP values for both groups were similar (CC: 115.82 ± 5.9 mmHg; C: 113.52 ± 5.3 mmHg, p = 0.55), indicating a stabilization phase. However, by 15 minutes, the colloid-crystalloid preloading group demonstrated a mean SBP of 116.49 ± 8.2 mmHg, significantly higher than the crystalloid-only preloading groups' 110.78 ± 5.2 mmHg (p < 0.01). This sustained difference highlights the effectiveness of the colloid-crystalloid preloading in reducing hypotensive episodes that occur over time following spinal anaesthesia. (Table 2, Fig 1)

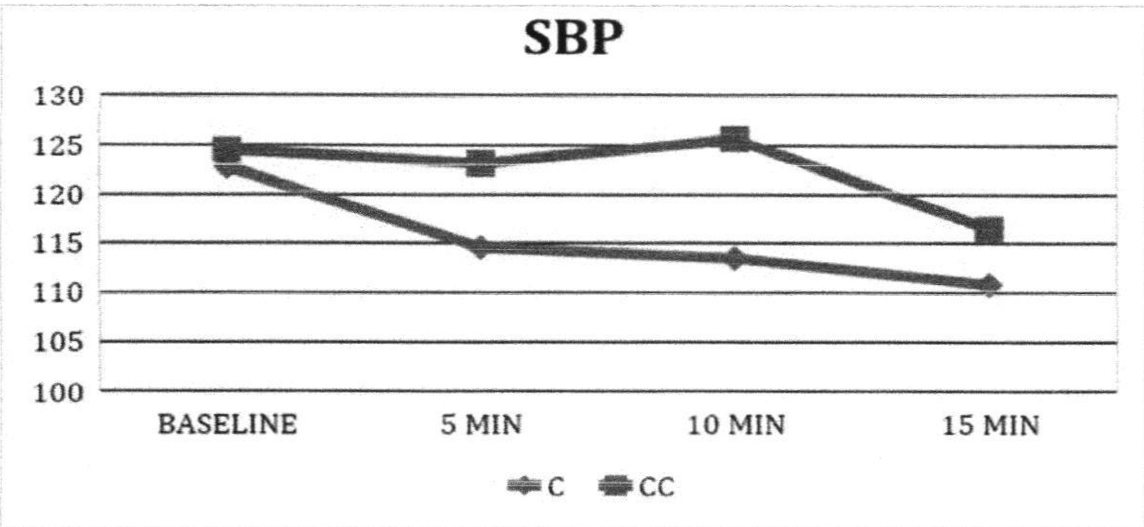

Figure 1: Line Diagram for comparison of SBP among groups about time Diastolic Blood Pressure (DBP) Distribution during post-spinal anaesthesia.

The diastolic blood pressure (DBP) results also indicated favourable outcomes for the colloid-crystalloid preloading group. Baseline DBP measurements were comparable between groups, with the colloid-crystalloid preloading group at 74.2 ± 7.6 mmHg and the crystalloid-only preloading group at 73.5 ± 7.8 mmHg (p = 0.9). After 5 minutes, the DBP was significantly higher in the colloid-crystalloid preloading group (73.0 ± 10.3 mmHg) compared to the crystalloid-only preloading group (72.5 ± 8.5 mmHg, p = 0.004), suggesting the superior effect of colloid-crystalloid preloading. At 10 minutes, both groups exhibited similar DBP values (p = 0.32), indicating that the initial hemodynamic stability provided by colloid-crystalloid preloading was being maintained. However, at 15 minutes, the colloid-crystalloid preloading group maintained a DBP of 71.84 ± 8.6 mmHg, while the crystalloid-only preloading group dropped DBP to 68.02 ± 6.7 mmHg (p = 0.03). This ongoing difference supports the idea that colloid-crystalloid preloading effectively lowers hypotension, highlighting its role in improving hemodynamic stability after spinal anaesthesia.(Table 2, Figure 2)

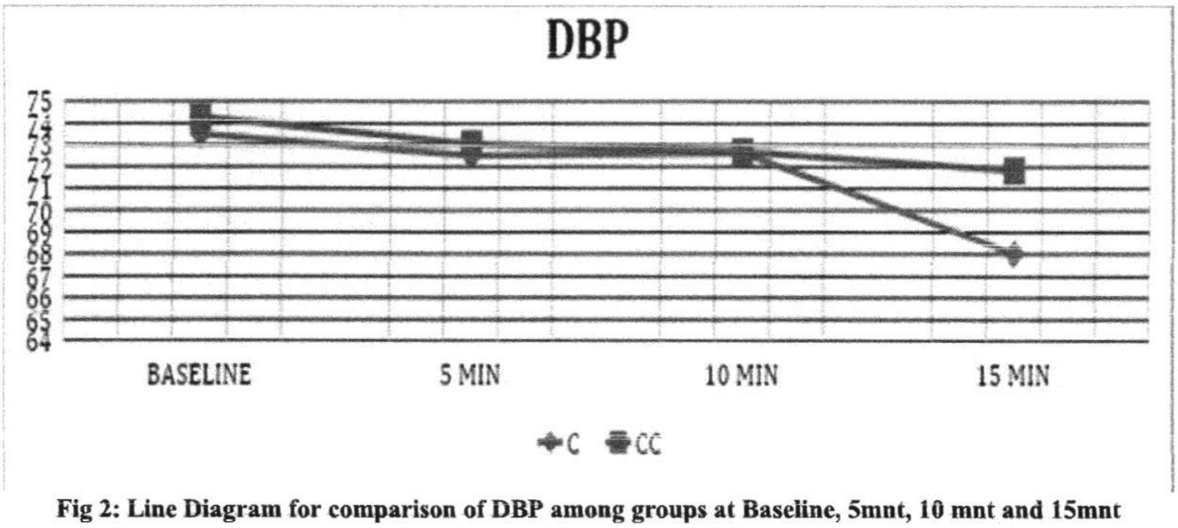

Fig 2: Line Diagram for comparison of DBP among groups at Baseline, 5mnt, 10 mnt and 15mnt

Discussion

Spinal anaesthesia is widely regarded as the technique of choice for surgeries performed below the umbilicus. However, the occurrence of post-spinal hypotension remains a significant concern, particularly in obstetric patients, with reported incidence rates ranging from 7.4% to 74.1% [5]. This condition is primarily attributed to induced sympathectomy, leading to decreased systemic vascular resistance and greater arterial vasodilation. If not addressed promptly, post-spinal hypotension can result in adverse effects such as nausea, vomiting, and more severe complications in obstetric patients, including fetal bradycardia and acidemia [6]. Given these risks, various methods—both pharmacological and non-pharmacological—have been explored to mitigate the effects of spinal hypotension.

In our randomized controlled trial, we examined the efficacy of a combination of hydroxyethyl starch (HES) and balanced salt solution (BSS) versus BSS alone in preventing post-spinal hypotension. Our findings indicate that the colloid-crystalloid preloading group-maintained blood pressure significantly better from baseline throughout the surgical procedure compared to the crystalloid-only preloading group. This outcome highlights the potential advantages of using HES.

Mercier et al. demonstrated that a mixed colloid-crystalloid preloading effectively improved the prevention of hypotension following spinal anaesthesia in parturient, suggesting that the combination approach may enhance hemodynamic stability [7].

Nevertheless, our study is not without limitations. One major limitation is the choice of crystalloid preloading as a control, which may not be ideal. Research suggests that crystalloid co-loading is more effective [8,9,10].

Conclusion:

The study results show that colloid-crystalloid preloading is better than crystalloid-only preloading at keeping blood pressure stable after spinal anaesthesia, especially during surgeries below the umbilicus. Significant differences in both SBP and DBP at different time points suggest that colloid-crystalloid preloading may provide better hemodynamic stability, lowering the number of hypotensive events. This has clinical implications because better stability may mean fewer interventions are needed, like giving vasopressors like phenylephrine, ephedrine, etc. This could improve patient safety and outcomes in below-umbilicus surgeries under spinal anaesthesia.

Conflict of interest: Nil

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