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Comparative Analysis of Phenylephrine Infusion, Bolus Usage, and Atropine Administration in Colloid vs. crystalloid Preloaded Groups in preventing hypotension after Spinal Anaesthesia: A randomized controlled trial

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Abstract

Purpose: *To compare the efficacy and outcomes of phenylephrine infusion and bolus usage, atropine administration, and the correlation between surgery duration in patients receiving colloid versus crystalloid preloading in preventing hypotension after spinal anaesthesia.*

Methodology: *This randomized double-blind study involved 200 patients (100 in each group: Group C – BSS (Balanced salt solution-crystalloid) alone, Group CC – HES (Hydroxyethyl starch-colloid)-BSS (crystalloid)combination). Preloading began 40 minutes before surgery, with Group C receiving 1L of BSS and Group CC receiving 500ml of HES and 500ml of BSS. Phenylephrine (PE) infusion started at 100 mcg/min post-spinal anaesthesia for 3 minutes, with continuation based on BP fluctuation for up to 15 minutes. Further management of BP fall (after 15 minutes of surgery till the surgery is over) was using PE (phenylephrine) boluses, which were administered as per an algorithm. Demographics and hemodynamic changes (BP, HR, MAP) were recorded at 5, 10, and 15 minutes post-spinal anaesthesia. Atropine was used for bradycardia (HR < 50 bpm), and total PE boluses were noted. Data were analyzed using Chi-square and Levene's test.*

Result: *In the comparison between groups for phenylephrine infusion duration, Group C had a slightly longer mean duration (4.11 minutes) compared to Group CC (3.79 minutes), but this difference was not statistically significant ($p = 0.11$). Phenylephrine (PE) infusion at 100 mcg/min showed significant effects on maintaining systolic blood pressure (SBP) in the first 5 minutes for both Group C ($p = 0.000$, $r = -0.368$) and Group CC ($p = 0.010$, $r = -0.257$), indicating a weak negative correlation. In terms of phenylephrine boluses, both groups showed similar patterns, with Group C having 81% of patients using no bolus and Group CC having 90%, though the difference was not significant ($p = 0.08$). Atropine usage was significantly higher in Group C (7%) compared to Group CC (3%), with a p-value of 0.034. Additionally, a significant relationship was found in Group C between the duration of phenylephrine infusion and the number of boluses used, while Group CC showed a stronger association between bolus use and atropine administration. For surgery duration, Group C showed no significant correlation with atropine usage ($p = 0.073$), whereas Group CC had a significant association ($p = 0.004$), with increased atropine use as surgery duration extended. Both groups showed a tendency for more phenylephrine boluses with longer surgeries, particularly those exceeding 60 minutes.*

Conclusion: *This study comparing colloid-crystalloid (HES-BSS) and crystalloid (BSS) preloading in preventing hypotension after spinal anesthesia found no significant difference in phenylephrine infusion duration or bolus requirements, though crystalloid (BSS) showed a slightly longer, non-significant infusion duration. Both groups needed more phenylephrine boluses in surgeries over 60 minutes. Colloid-crystalloid (HES-BSS) preloading was more effective overall, and phenylephrine (PE) infusion (100 mcg/min) effectively maintains SBP only in the first*

5 minutes in both groups.

Keywords: *Balanced salt solution-crystalloid, Diastolic blood pressure, Hydroxyethyl starch-colloid, Phenylephrine, Spinal Anaesthesia, Systolic blood pressure*

Introduction

Spinal anaesthesia (SA), a subarachnoid blockade, involves injecting local anaesthetic agents into the subarachnoid space, combining sympathetic, sensory, and motor blockades. First practised in 1898, SA is particularly suited for below-umbilicus surgeries, including lower limb procedures, caesarean sections, and haemorrhoidectomies. (1) The drugs typically used in SA include bupivacaine, lignocaine, and opioids like morphine and fentanyl. (l)While generally safe, SA may lead to minor complications (e.g., mild hypotension and bradycardia) and major complications (e.g., cardiac arrest or spinal epidural hematoma) due to its impact on autonomic nervous system control. (1,2)

Preloading and Co-loading Fluids: IV fluids, such as crystalloids and colloids, are standard for managing patient volume status during SA. Crystalloids (e.g., normal saline, Ringer's lactate) diffuse easily between intravascular and interstitial compartments. At the same time, colloids (e.g., hydroxyethyl starch, albumin) are larger molecules that remain in the vascular space longer, expanding plasma volume and sustaining blood pressure more effectively. Hydroxyethyl starch (HES) is particularly effective in maintaining plasma volume due to its modified structure, which resists breakdown in the bloodstream. However, high-molecular-weight (HMW) HES carries risks of altered haemostasis and nephrotoxicity, especially in critically ill patients. (3,4)

Use of Phenylephrine (PE): PE, a synthetic sympathomimetic, is commonly employed to counteract spinal-induced hypotension. Acting primarily on alpha-adrenergic receptors, PE increases peripheral vascular resistance, leading to elevated mean arterial pressure with minimal effects on cardiac output. Though effective, it may reduce renal blood flow. (5) It can cause baroreceptor-induced reflex bradycardia which is due to elevation of diastolic blood pressure.

This study aims to determine the comparative effectiveness of colloid-crystalloid and crystalloid-only preloading methods, each followed by PE infusion, in preventing post-SA hypotension in non-obstetric below-umbilicus surgeries, building upon prior research largely focused on obstetric cases. The findings will provide insights into optimal preloading and vasopressor strategies for minimizing hypotension associated with spinal anaesthesia.

Materials and Methods

Study Area: This study was conducted at Daya General Hospital, Thrissur, Kerala.

Study Duration: The study took place over a period from November 2020 to May 2022.

Study Design: A randomized controlled trial design was used to compare the effects of colloid-crystalloid (HES-BSS) versus crystalloid (BSS alone) preloading in the prevention of hypotension in patients undergoing spinal anaesthesia.

Study Population: Patients scheduled for elective surgeries below the umbilicus.

Sample Size Calculation: The sample size was calculated based on a prior study showing hypotension incidence rates of 55.3% and 36% in colloid-crystalloid and crystalloid groups, respectively, with a 95% confidence level and 80% power. Using standard sample size calculation formulas, the minimum required sample size was determined to be 200 patients, with 100 in each group.

Inclusion Criteria:

- Patients classified as ASA I or II by the American Society of Anesthesiologists.
- Age range: 20-50 years.
- BMI between 18 and 30.

Exclusion Criteria

- Patients with ECG changes indicating conduction defects.
- Patients with a history of hypotension, hypovolemia, hypertension, diabetes, or electrolyte imbalances.
- Patients with fluid overload or valvular stenotic lesions.
- Patients on beta blockers or with autonomic dysfunction.
- Patients with chronic pain on opioids or other analgesics.
- Known allergy to the study drugs.
- Emergency surgeries.
- Patient refusal to participate.

Randomization and Blinding

Patients who met the eligibility criteria were randomly assigned to either Group C (crystalloid preload only) or Group CC (colloid-crystalloid preload) using a computer-generated random number sequence. Nurses, who were blinded to the study groups, administered preloading 40 minutes before surgery. Phenylephrine infusion and bolus administration were managed by the investigator, who was also blinded to the group assignments. Patients were kept unaware of their assigned groups.

Study Procedures: Following Institutional Research and Ethics Committee approval, patients scheduled for elective below-umbilicus surgeries were randomly assigned to either Group C or Group CC. Informed consent was obtained from all participants, and no additional financial burden was imposed on them.

Preloading Protocol

- **Groups**: Patients were randomized into two preloading groups:
  - **Group C**: Crystalloid (Balanced Salt Solution, BSS alone).
  - **Group CC**: Colloid-crystalloid (Hydroxyethyl Starch, HES-BSS).
- **Fluid Preload Administration**: The patients in Group CC were preloaded with 500 millilitres (ml) of Hydroxyethyl starch (HES) and 500 ml of BSS. The patients in Group C would be preloaded with 1000 ml BSS. This was done 40 minutes before surgery.
- **Phenylephrine Administration Protocol**

1. **Initial Infusion**:
   - **PE Infusion Start**: After induction of spinal anaesthesia, phenylephrine infusion was initiated at 100 mcg/min for the first 3 minutes to rapidly counteract initial hypotensive effects.
   - **Maintenance Infusion Rate**: After 3 minutes, the infusion was adjusted (stopped if BP is greater than the baseline and continued if BP falls below baseline) based on real-time systolic blood pressure (SBP) monitoring for the next 12 minutes after ensuring vitals are stable.
   - **Bolus Dosage**: PE bolus was given as per an algorithm for any BP fall that may be encountered after 15 minutes. The total requirement of PE boluses and the advantage of PE infusion were assessed for each case. If SBP fell >20% or>30% below baseline, a PE bolus of 50 0r 100 mcg was administered respectively, with repeated boluses, if necessary, until SBP stabilized.
2. **Target SBP Range**: The goal was to maintain SBP within 80% of baseline, adjusting the infusion rate as needed or administering additional boluses if hypotension persisted.

Atropine Administration Protocol for Bradycardia

- **Definition of Bradycardia**: Bradycardia was defined as a heart rate (HR) <50 bpm.

- **Indications for Atropine Use**:
    - Bradycardia is a known side effect of PE due to reflex bradycardia. Higher PE doses or prolonged infusion durations were associated with increased atropine usage to counteract these effects.
    - **Atropine Dosage**: Atropine 0.6 mg was administered intravenously when HR fell below 50 bpm.
    - If bradycardia persisted after the initial dose, additional atropine doses were given as needed.

Monitoring and Documentation

- **Blood Pressure and Heart Rate**: Monitored at 1-minute intervals for the first 15 minutes after spinal anaesthesia and every 3 minutes thereafter until surgery completion.
- **PE and Atropine Correlations**: Documented all instances of PE bolus usage, infusion adjustments, and atropine administration, noting any associations with infusion duration or cumulative PE dosage.
- **Surgery Duration**: Recorded to evaluate the correlation between surgery length, PE requirements, and atropine usage, as prolonged surgeries tended to increase both PE and atropine needs.

Result

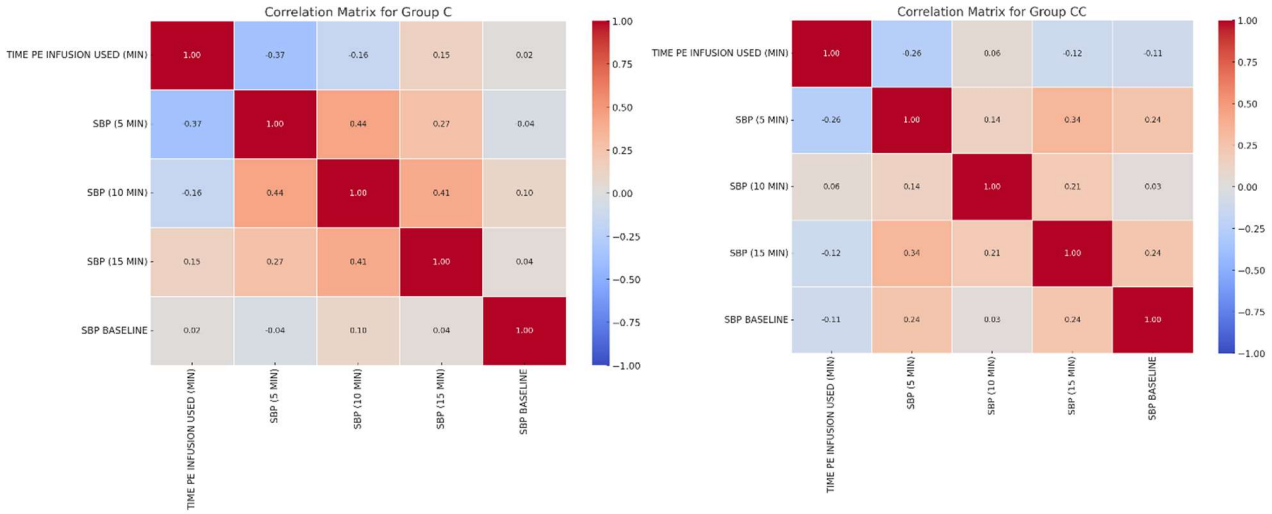
Comparison of Phenylephrine Infusion Between Groups: Table 1 compares the mean duration of phenylephrine infusion between two groups {Group C Crystalloid (Balanced Salt Solution, BSS alone) and Group CC: Colloid-crystalloid (Hydroxyethyl Starch, HES-BSS). and Group CC}. The results show a slight difference between the two groups. Group C had a mean of 4.11 minutes with a standard deviation of 2.90, while Group CC had a mean of 3.79 minutes with a standard deviation of 2.44. However, this difference is not statistically significant ($p = 0.11$), suggesting that the duration of phenylephrine infusion was similar between the two groups. (Table 1)

Table 1: Comparison of Phenylephrine Infusion in Both Groups

Group	N	Mean	Std. Deviation	Std. Error Mean	F	Sig.	t
C	100	4.11	2.90	0.29	2.54	0.11	.844
CC	100	3.79	2.44	0.24			

Correlation of Phenylephrine Infusion and SBP Changes: Phenylephrine (PE) infusion at 100 mcg/min showed significant effects on maintaining systolic blood pressure (SBP) in the first 5 minutes for both Group C ($p = 0.000$, $r = -0.368$) and Group CC ($p = 0.010$, $r = -0.257$), indicating a weak negative correlation. At 10 minutes, no statistical significance was observed in either group, but Group C showed a closer p-value ($p = 0.104$, $r = 0.439$) compared to Group CC ($p = 0.553$, $r = 0.207$), with weak positive correlations in both. Similarly, at 15 minutes, no significance was found for Group C ($p = 0.146$) or Group CC ($p = 0.247$, $r = 0.238$). Baseline SBP showed no significant correlation with PE infusion in either group (Group C: $p = 0.865$, Group CC: $p = 0.290$). Overall, PE infusion effectively maintained SBP only in the first 5 minutes, in both groups (Graph1)

Graph 1: Correlation matrices Between PE Infusion and SBP Among Group C and CC



Comparison of Number of Phenylephrine Boluses Used: In Group C, 81 % of the patients did not require any bolus, while 17 % used one bolus, and only 2 % used two boluses. In contrast, Group CC showed a slightly higher percentage (90%) of patients using no bolus, but fewer patients (7%) used one bolus and 3% used two. The difference between the groups is marginal, with a p-value of 0.08, which is not statistically significant. (Table 2)

Atropine Usage Comparison: In Group C, 92% of the patients did not require atropine, while only 7% used one atropine dose. In Group CC, 95% of patients did not require atropine, while only 3% used one dose and 2% used two doses. The difference between the groups is statistically significant (p = 0.034), suggesting that Group C patients were more likely to require atropine than those in Group CC. (Table 2)

Table 2: Comparison of Number of Phenylephrine Boluses Used and Atropine Usage Among Groups (Group C and CC)

Group	**0 PE Bolus**	**1 PE Bolus**	**2 PE Bolus**	**Total**	
C	81 (81.0%)	17 (17.0%)	2 (2.0%)	100 (100.0%)	
CC	90 (90.0%)	7 (7.0%)	3 (3.0%)	100 (100.0%)	X=4.840 P=0.08
Group	**0 Atropine**	**1 Atropine**	**2 Atropine**	**Total**	
C	89 (89.0%)	11 (11.0%)	0 (0.0%)	100 (100.0%)	X=6.767 P=0.034
CC	95 (95.0%)	3 (3.0%)	2 (2.0%)	100 (100.0%)	

Relationship Between Time for Phenylephrine Infusion and Boluses Used: When analyzing the time for

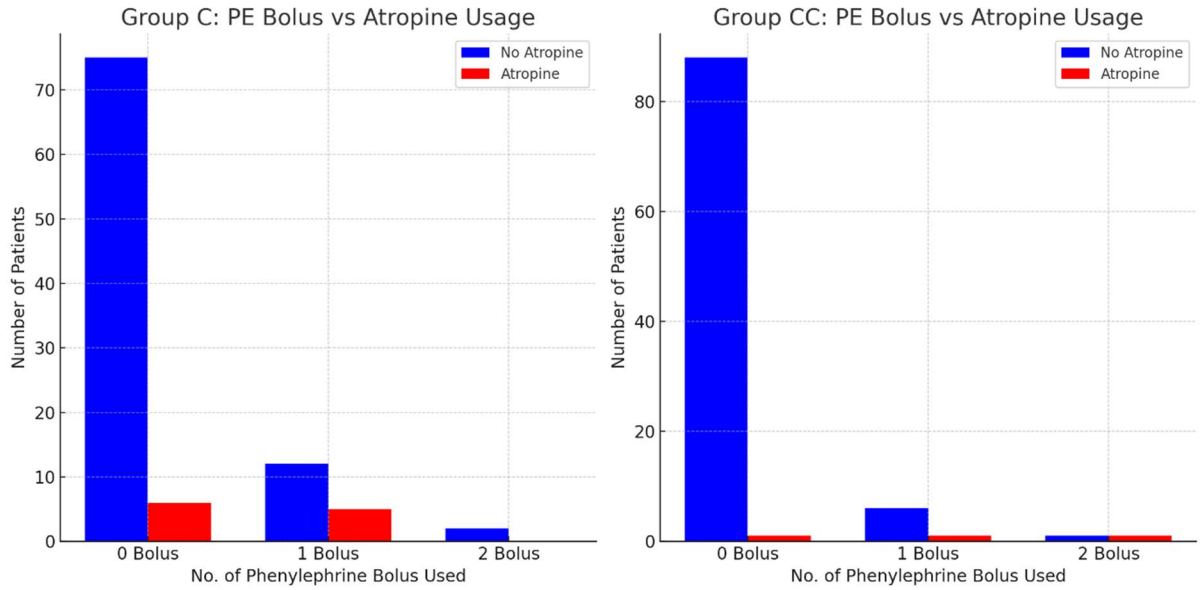
phenylephrine infusion and the number of boluses used, Group C showed a relatively stable usage pattern, with most patients using no bolus, especially for shorter infusion times (up to 5 minutes). However, in Group CC, a statistically significant relationship was found (p = 0.00). As the duration of the phenylephrine infusion increased, the likelihood of using boluses reduced.(Table 3)

Table 3: Comparison of Time for Phenylephrine Infusion and Number of Phenylephrine Boluses Used

Group	Time for Phenylephrine Infusion (min)	0 Bolus Used	1 Bolus Used	2 Bolus Used	Total	X p
C	3	70 (83.3%)	12 (14.3%)	2 (2.4%)	84	
	4	1 (100.0%)	0 (0.0%)	0 (0.0%)	1	
	5	2 (100.0%)	0 (0.0%)	0 (0.0%)	2	
	7	1 (100.0%)	0 (0.0%)	0 (0.0%)	1	
	8	1 (100.0%)	0 (0.0%)	0 (0.0%)	1	X=14.426a P=0.7
	9	1 (100.0%)	0 (0.0%)	0 (0.0%)	1	
	10	1 (33.3%)	2 (66.7%)	0 (0.0%)	3	
	11	1 (50.0%)	1 (50.0%)	0 (0.0%)	2	
	12	2 (100.0%)	0 (0.0%)	0 (0.0%)	2	
	15	1 (33.3%)	2 (66.7%)	0 (0.0%)	3	
CC	3	82 (93.2%)	5 (5.7%)	1 (1.1%)	88	
	4	1 (100.0%)	0 (0.0%)	0 (0.0%)	1	
	5	1 (100.0%)	0 (0.0%)	0 (0.0%)	1	
	7	1 (100.0%)	0 (0.0%)	0 (0.0%)	1	X=51.320b P=0.00
	8	1 (50.0%)	0 (0.0%)	1 (50.0%)	2	
	9	1 (100.0%)	0 (0.0%)	0 (0.0%)	1	
	10	0 (0.0%)	1 (100.0%)	0 (0.0%)	1	
	11	1 (50.0%)	1 (50.0%)	0 (0.0%)	2	
	12	1 (100.0%)	0 (0.0%)	0 (0.0%)	1	
	15	1 (50.0%)	0 (0.0%)	1 (50.0%)	2	

Correlation Between Phenylephrine Boluses and Atropine Usage: In Group C, the majority of patients (92.6%) who did not require atropine used any phenylephrine bolus, while a smaller percentage (29.4%) of those who used

one phenylephrine bolus required atropine. A statistically significant correlation was observed (p = 0.02). In Group CC, 97.8% of patients who did not require atropine used any phenylephrine bolus, with a significant portion of those who used boluses requiring atropine, particularly those using two boluses (33.3%). This relationship was highly significant (p = 0.00). (Graph 2)



Graph 2: Comparison of phenylephrine bolus usage versus atropine usage for both Group C and Group CC

Duration of Surgery and Atropine Usage: Group C showed no significant association between the duration of surgery and atropine usage (p = 0.073), suggesting that atropine usage did not significantly change based on surgery length. In contrast, Group CC showed a significant association between surgery duration and atropine use (p = 0.004). In this group, atropine usage increased as surgery duration extended, with a notable increase in patients requiring atropine for surgeries lasting more than 60 minutes. (Table 4)

Table 4: Comparison of Duration of Surgery (DOS) and Atropine Usage Among Groups (Group C and Group CC)

Group	Duration of Surgery (DOS)	Atropine Usage 0 (Count, %)	Atropine Usage 1 (Count, %)	Atropine Usage 2 (Count, %)	Total (Count, %)	
Group C						
	<= 3 hours	7 (87.50%)	1 (12.50%)	0 (0%)	8 (100%)	
	30-40 minutes	6 (100%)	0 (0%)	0 (0%)	6 (100%)	
	40-50 minutes	58 (93.50%)	4 (6.50%)	0 (0%)	62 (100%)	X=8.577 P=0.07
	50-60 minutes	10 (83.30%)	2 (16.70%)	0 (0%)	12 (100%)	
	>= 60 minutes	8 (66.70%)	4 (33.30%)	0 (0%)	12 (100%)	
	Total	89 (89.00%)	11 (11.00%)	0 (0%)	100 (100%)	

Group	Duration of Surgery (DOS)	Atropine Usage 0 (Count, %)	Atropine Usage 1 (Count, %)	Atropine Usage 2 (Count, %)	Total (Count, %)	
Group CC						
	<= 3 hours	25 (100%)	0 (0%)	0 (0%)	25 (100%)	
	30-40 minutes	6 (100%)	0 (0%)	0 (0%)	6 (100%)	X=22.438 0.004
	40-50 minutes	46 (100%)	0 (0%)	0 (0%)	46 (100%)	
	50-60 minutes	4 (100%)	0 (0%)	0 (0%)	4 (100%)	
	>= 60 minutes	14 (73.70%)	3 (15.80%)	2 (10.50%)	19 (100%)	
	Total	95 (95.00%)	3 (3.00%)	2 (2.00%)	100 (100%)	

Duration of Surgery and Phenylephrine Bolus Usage: Regarding the relationship between the duration of surgery and phenylephrine boluses used, Group C showed a pattern where longer surgeries led to more phenylephrine boluses used. Particularly, surgeries lasting over 60 minutes required more boluses (75% of these surgeries). Similarly, Group CC showed an increase in bolus use as surgery duration increased, with the percentage of patients using multiple boluses also increasing for surgeries lasting over 60 minutes. (Table 5)

Table 5: Phenylephrine Boluses Used (PE Bolus Usage)

Group	Duration of Surgery (DOS)	No. of Phenylephrine Boluses Used 0	No. of Phenylephrine Boluses Used 1	No. of Phenylephrine Boluses Used 2	Total
Group C					
	<=30 minutes	7 (87.50%)	1 (12.50%)	0 (0.00%)	8 (100%)
	30-40 minutes	6 (100.00%)	0 (0.00%)	0 (0.00%)	6 (100%)
	40-50 minutes	60 (96.80%)	2 (3.20%)	0 (0.00%)	62 (100%)
	50-60 minutes	7 (58.30%)	5 (41.70%)	0 (0.00%)	12 (100%)
	>=60 minutes	1 (8.30%)	9 (75.00%)	2 (16.70%)	12 (100%)
	Total	81 (81.00%)	17 (17.00%)	2 (2.00%)	100 (100%)
Group					

Group	Duration of Surgery (DOS)	No. of Phenylephrine Boluses Used 0	No. of Phenylephrine Boluses Used 1	No. of Phenylephrine Boluses Used 2	Total
CC					
	<=30 minutes	25 (100.00%)	0 (0.00%)	0 (0.00%)	25 (100%)
	30-40 minutes	6 (100.00%)	0 (0.00%)	0 (0.00%)	6 (100%)
	40-50 minutes	45 (97.80%)	1 (2.20%)	0 (0.00%)	46 (100%)
	50-60 minutes	3 (75.00%)	1 (25.00%)	0 (0.00%)	4 (100%)
	>=60 minutes	11 (57.90%)	5 (26.30%)	3 (15.80%)	19 (100%)
	Total	90 (90.00%)	7 (7.00%)	3 (3.00%)	100 (100%)

Discussion

This study compared the effects of colloid-crystalloid (HES-BSS) and crystalloid (BSS) alone preloading on hemodynamic stability and phenylephrine (PE) requirements for managing hypotension after spinal anaesthesia. Group C (crystalloids) had a slightly longer mean duration of phenylephrine infusion than Group CC (colloid-crystalloid), although the difference was not statistically significant. Additionally, a significant correlation was observed between phenylephrine infusion time and systolic blood pressure (SBP) at specific time points in Group C, indicating that crystalloids might require more frequent adjustments in PE infusion to maintain blood pressure stability.

Comparing these findings with other studies reveals consistent but varied patterns in the impact of preloading solutions and PE usage on hemodynamic management:

Ngan Kee et al. (2004) evaluated the effectiveness of varying doses of phenylephrine in preventing hypotension during cesarean delivery. Patients in the higher PE dose group (Group 100) experienced fewer hypotensive episodes than lower-dose groups (Groups 80 and 90), with a median of 0 episodes in Group 100 compared to 5 and 2 episodes in Groups 80 and 90, respectively. Additionally, the total dose of PE was significantly higher in Group 100, illustrating a direct relationship between the PE dose and stability in blood pressure, aligning with the increased PE requirements seen in Group C of our study. This finding highlights that higher PE doses and infusion times may be more necessary in groups with less stable fluid support, such as crystalloid preloads. (6)

Mercier et al. (2014) demonstrated that HES preloading significantly reduced both the incidence and severity of hypotension compared to RL (crystalloid) preloading, resulting in a 36.6% hypotension rate in the HES group versus 55.3% in the RL group. This supports our finding that colloid preloading might lead to fewer hypotensive events and reduced PE bolus needs, suggesting that HES provides better initial volume expansion and hemodynamic stability. (7)

Böttiger et al. (2016) found that HES preloading in elective cesarean delivery led to a statistically lower total PE requirement (1077.5 ± 514 mcg) compared to the crystalloid group (1477 ± 591 mcg, $p = 0.003$), with no significant difference in bradycardia or hypotension rates. This is consistent with our finding that Group CC (colloid) patients required fewer PE boluses and less atropine for reflex bradycardia, suggesting that HES may reduce the total PE

requirement while also enhancing heart rate stability. (8)

Ferré et al. (2016) observed that patients receiving prophylactic PE infusions had a delayed onset and lower frequency of hypotensive episodes compared to controls. Although the hypotensive patient count was similar, those receiving PE had fewer hypotensive events. Our study's findings support this approach, as the continuous infusion of PE, especially in crystalloids, helped mitigate rapid blood pressure drops, although adjustments were more frequent in the crystalloid group. (9)

Shah et al. (2018) reported a lesser and more stabilized drop in mean arterial pressure (MAP) when using phenylephrine infusions compared to conventional fluid preloads, indicating PE's superior efficacy in preventing hypotension after spinal anaesthesia. In our study, Group CC also exhibited fewer fluctuations in SBP due to the stable hemodynamic support provided by the colloid preload, reinforcing the value of PE infusions in groups with higher hypotensive risk. (10)

Overall, our findings align with existing literature, showing that colloid preloads may offer better volume support and reduce the frequency and duration of phenylephrine infusions. However, crystalloids, despite requiring higher PE doses, can still achieve comparable outcomes when PE is managed carefully. The increased atropine usage in the crystalloid group aligns with the increased PE doses required, as bradycardia is a side effect of phenylephrine. The literature indicates that colloid preloading, particularly HES, remains beneficial in reducing hypotension risk and PE requirements while minimizing the need for interventions like atropine.

Conclusion

This study evaluated the efficacy of colloid-crystalloid (HES-BSS) versus crystalloid (BSS) alone preloading in preventing hypotension following spinal anesthesia. No significant difference was observed in phenylephrine infusion duration or bolus requirements between the two groups. While the crystalloid (BSS) group showed a slightly longer infusion duration, this difference was not statistically significant. Both groups demonstrated a trend of increased phenylephrine bolus needs in surgeries lasting over 60 minutes. Colloid-crystalloid (HES-BSS) preloading appeared more effective than crystalloid alone in managing hypotension after spinal anesthesia, with phenylephrine infusion maintaining SBP effectively only in the first 5 minutes for both groups. However, atropine use was significantly higher in the Colloid-crystalloid group (Group CC), with a stronger association between bolus usage and atropine administration.

Conflict of interest: Nil

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