

Original Research

# Comparative Efficacy of Hydroxyethyl Starch and Haemaccel Preloading in Preventing Hypotension During Subarachnoid Block

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**Abstract:** Hypotension is a frequent complication of subarachnoid block (SAB) that frequently requires pharmacological treatment. The purpose of this study was to compare the relative efficacy of two pre-loaded colloid preparations, Hydroxyethyl Starch (HES 6%) and Haemaccel, in decreasing the frequency and severity of hypotension after subarachnoid block (SAB). A prospective randomised controlled trial was conducted with 200 patients who underwent elective lower abdominal and lower limb surgery under spinal anaesthesia in a tertiary care hospital. Patients were randomised into two groups: HA (Haemaccel) and HES (Hydroxyethyl Starch 6%). Inclusion criteria were ASA grade I and II patients, age between 20 and 65 years. Preloading with 10 ml/kg of either Haemaccel or HES 6% was given 15 minutes before spinal anaesthesia. Vital signs were observed, and hypotension was defined as systolic blood pressure (SBP) <90 mmHg or <70% of the baseline. Ephedrine and atropine were administered as needed for the treatment of hypotension and bradycardia. Hypotension incidence and ephedrine use were documented and compared between the groups. The baseline characteristics of the two groups were similar. Group-HA exhibited a higher pulse rate and more significant reductions in SBP and MAP at 10, 15, 20, and 25 minutes compared to Group-HES. There were no significant differences in the requirement for ephedrine or adverse events between the two groups. Nine patients in the Group-HA and four in the Group-HES required ephedrine administration. Although no serious complications occurred, Group-HA did experience a higher incidence of bradycardia, nausea, vomiting, and allergy. With these findings we conclude that Haemaccel and Hydroxyethyl Starch were efficacious in reducing hypotension following a subarachnoid block. However, more stable haemodynamic results were achieved in the Group-HES. Ephedrine requirements and overall safety profiles were comparable between the two colloid groups, indicating that either colloid may be used to effectively avoid hypotension.

**Keywords:** Hypotension; Subarachnoid Block; Haemaccel; Hydroxyethyl Starch 6%; Colloid Preloading

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## Introduction

Hypotension is the most common side effect of subarachnoid block commonly referred to as spinal anaesthesia, but its incidence varies from 15% to 33%. [1] The administration of large amounts of intravenous (IV) fluids preoperatively prior to spinal anaesthesia has become the rule in an effort to prevent this. [2,3] Spinal hypotension is primarily caused by a preganglionic sympathetic block, which leads to increased intravascular space capacity due to vasodilatation, decreased vascular resistance, and increased compliance of capacitance vessels. The local anaesthetic agent affects the preganglionic fibres in the thoracolumbar segment, leading to the sympathetic ganglia and chain. This results in the blockade of vasoconstrictor fibres in the arterioles, capillaries, and veins, causing major circulatory changes, particularly on the venous side. The peripheral veins and venules dilate, leading to increased venous compliance. When combined with the paralysis of skeletal muscles, this results in a loss of the muscular "milking" action on veins, as well as interference with the thoracic respiratory pump, reducing venous return and subsequently lowering cardiac output, leading to a drop in blood pressure.

Traditionally, crystalloid solutions have been administered prior to spinal anaesthesia to reduce hypotension; however, their short intravascular half-life and poor plasma-expanding properties limit their effectiveness. [4,5] Colloid solutions such as hydroxyethyl starch (HES) and polygeline/Haemaccel (HA) that persist in circulation for several minutes are generally more effective in the prevention of hypotension and hypovolaemia. Preloading with colloids such as 6% HES or HA has been found to be superior to crystalloid solutions in the prophylaxis against hypotension in patients having elective and emergency surgeries under spinal anaesthesia. The current study sought to assess haemodynamic alterations in spinal anaesthesia following preloading with these infusion solutions. The specific aims were to explore the ability of colloids to decrease the incidence of hypotension following spinal anaesthesia and to compare the effectiveness of 6% HES and HA in reducing both the incidence and severity of hypotension after a subarachnoid block. Even though crystalloid preloading is a common practice, it has been demonstrated to be of limited effectiveness, especially in minimizing hypotension in patients undergoing general surgery. [6,7] Improved hemodynamic stability has been reported by some studies with colloid infusion during spinal anaesthesia. [8-11] This study aimed to compare HES (6%) with HA, two popular colloid preparations, to determine which is more effective at minimising spinal anaesthesia-induced hypotension and sustaining optimal haemodynamic stability.

## Materials and Methods

A prospective randomised controlled study was performed on 200 patients who underwent elective operative procedures under spinal anaesthesia for lower limb and lower abdominal surgeries at a tertiary care centre. The inclusion criteria included elective cases of ASA grade 1 and 2 and patients aged 20–65 years. The exclusion criteria included all emergency cases, anaemia, coagulopathy, and bleeding disorders; back pain, spinal deformity, or history of spine operations; active skin lesions in the lumbosacral area; history of hypersensitivity; and any contraindication to subarachnoid block.

The research protocol was approved by the scientific and ethics committee of the hospital. A complete pre-anaesthetic examination was carried out, including the collection of a detailed medical history; clinical examination; evaluation of the cardiovascular, respiratory, and central nervous systems; and spinal examination. The patients were educated regarding the subarachnoid block technique, and consent was obtained. Routine investigations included complete haemogram, bleeding and clotting times, blood sugar, urea, serum creatinine, and urine analysis. Other investigations, such as ECG in patients above 40 years of age and chest radiography when necessary, were also performed. Patients were also given 0.2 mg/kg Diazepam at night prior to surgery to alleviate anxiety and were asked to fast from the night before.

A total of 200 ASA grade I and II patients undergoing lower abdominal and lower limb surgery under subarachnoid block were randomly allocated into two groups: Group-HA (administered 10 ml/kg HA) and Group-HES (administered 10 ml/kg of 6% HES). Baseline vital signs were measured in the supine

position using a mercury sphygmomanometer along with heart rate, systolic blood pressure (SBP), and diastolic blood pressure (DBP). Preloading fluids were given over 15 minutes within the pre-anaesthetic room through an 18G IV cannula. Pulse rate and blood pressure were measured following administration of the preloading fluids, after which the patients were taken to the operating theatre. Subarachnoid block was performed under aseptic precautions in the lateral decubitus position at interspace L3-L4 with a 25G spinal needle, giving 3.2 ml of 0.5% heavy bupivacaine. After the block, the patients were rotated to the supine position, and the level of anaesthesia was checked bilaterally by the pinprick test after 10 min.

Vital signs, such as pulse rate, SBP, DBP, and MAP, were observed at 2-minute intervals for the initial 10 minutes, 5-minute intervals for the next 50 min, and 10-minute intervals thereafter. Hypotension, defined as SBP <90 mmHg or <70% of the baseline, was treated with boluses of 6 mg IV ephedrine as needed. Bradycardia (heart rate <50/min) was treated with atropine 0.6 mg. After preloading, Ringer's lactate (1.5 ml/kg/hr) was used as maintenance fluid. The incidence of hypotension and the average dose of ephedrine used for treatment were noted. All information gathered was tabulated in Microsoft Excel 2016 and subsequently categorized and analyzed using SPSS software version 22.0. Descriptive statistics for the qualitative variables are expressed as frequencies and percentages. Quantitative data are expressed as mean and standard deviation. Statistical significance was considered at a p-value of <0.05, and a p-value of <0.01 was regarded as highly significant.

## Results

The groups were comparable in terms of age, weight, and sex distribution, with no significant differences ( $p > 0.05$ ). The baseline pulse rate and systolic blood pressure were also statistically similar between the two groups ( $p > 0.05$ ). Group-HA consisted of 47 patients who underwent gynaecological surgery and 53 patients who underwent general surgery, whereas Group-HES consisted of 51 patients who underwent gynaecological surgery and 49 patients who underwent general surgery. This indicates a comparable distribution of types of operations between the two groups. The surgery time was divided into four intervals: 30-50 mins, 60-80 mins, 90-110 mins, and more than 120 min. No significant differences were observed between the two groups regarding the duration of surgery (all  $p > 0.05$ ), indicating that the time spent during surgery was comparable between the two groups. (Table 1)

**Table 1.** Baseline characteristics and surgery information

Characteristics	Group-HA	Group-HES	P value	
Sex (M/F)	M = 50	M = 45	> 0.05	
	F = 50	F = 55		
Age	39.09 ± 8.76	37.73 ± 7.80	0.2475	
Weight	50.25 ± 6.22	50.60 ± 5.29	0.6687	
Baseline PR	75.91 ± 9.14	74.18 ± 8.18	0.1624	
Baseline SPB	123.21 ± 9.09	121.46 ± 10.51	0.1029	
Type of surgery	Gynaecology = 47	Gynaecology = 51		
	General Surgery = 53	General Surgery = 49		
Duration of Surgery	Mins	Group-HA	Group-HES	P value
(Time in Minutes)	30-50	69	18	0.329
	60-80	69	65	0.547
	90-110	11	9	0.637
	>120	7	8	0.788

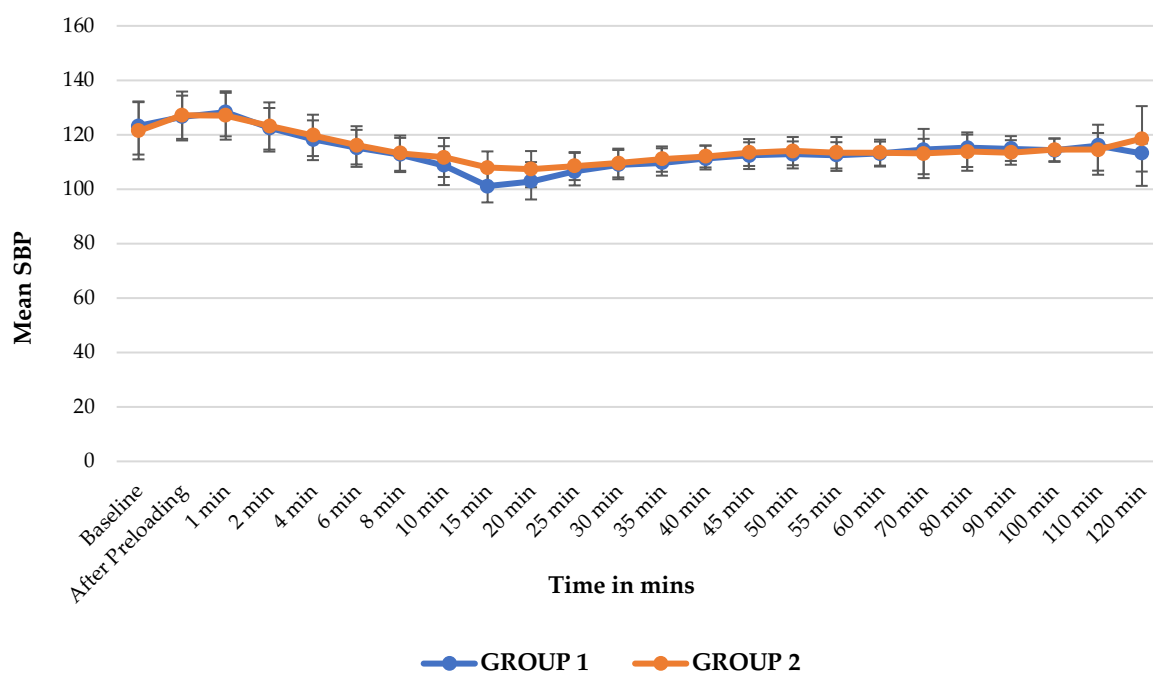
The change in pulse rate over time for both groups, from baseline and continuing in intervals up to 120 minutes is displayed in Table 2. In both groups, the pulse rate increased following preloading and during the initial period following spinal anaesthesia, although no significant differences were noted up to 15 min. A statistically significant difference ( $p < 0.05$ ) in pulse rate was noted at 20 and 25 min between the Group-HA and Group-HES, with the Group-HA having a higher pulse rate.

**Table 2.** Comparison of pulse rate between the groups

<b>Time</b>	<b>Group-HA Mean <math>\pm</math> SD</b>	<b>Group-HES Mean <math>\pm</math> SD</b>	<b>p value</b>
Baseline	74.18 $\pm$ 8.18	76.10 $\pm$ 9.15	0.1194
After Preloading	80.17 $\pm$ 8.51	82.59 $\pm$ 10.61	0.0768
1 min	83.41 $\pm$ 10.82	86.32 $\pm$ 12.22	0.0762
2 min	84.07 $\pm$ 10.95	85.89 $\pm$ 13.24	0.2908
4 min	83.59 $\pm$ 10.22	85.80 $\pm$ 13.63	0.1960
6 min	81.43 $\pm$ 9.78	84.33 $\pm$ 12.74	0.0725
8 min	80.09 $\pm$ 9.48	83.06 $\pm$ 12.57	0.0607
10 min	78.54 $\pm$ 9.36	81.46 $\pm$ 12.02	0.0567
15 min	76.96 $\pm$ 8.94	79.80 $\pm$ 12.48	0.0658
20 min	78.80 $\pm$ 11.77	74.99 $\pm$ 8.37	0.0090**
25 min	77.31 $\pm$ 11.80	73.65 $\pm$ 7.87	0.0106*
30 min	73.93 $\pm$ 7.26	74.96 $\pm$ 9.95	0.4041
35 min	72.51 $\pm$ 7.58	73.35 $\pm$ 9.03	0.4786
40 min	71.13 $\pm$ 7.56	72.07 $\pm$ 8.44	0.4120
45 min	70.69 $\pm$ 7.02	70.79 $\pm$ 8.17	0.9252
50 min	70.48 $\pm$ 6.99	70.81 $\pm$ 7.88	0.7743
55 min	69.37 $\pm$ 7.54	70.68 $\pm$ 7.68	0.2806
60 min	70.34 $\pm$ 5.79	71.61 $\pm$ 6.93	0.2400
70 min	69.57 $\pm$ 8.79	68.74 $\pm$ 9.90	0.7704
80 min	73.09 $\pm$ 10.12	68.50 $\pm$ 8.39	0.1858
90 min	75.83 $\pm$ 9.11	70.28 $\pm$ 7.65	0.1552
100 min	70.92 $\pm$ 7.73	70.62 $\pm$ 7.85	0.9206
110 min	73.00 $\pm$ 4.24	70.64 $\pm$ 7.54	0.6818
120 min	71.00 $\pm$ 5.66	70.00 $\pm$ 7.46	0.8679

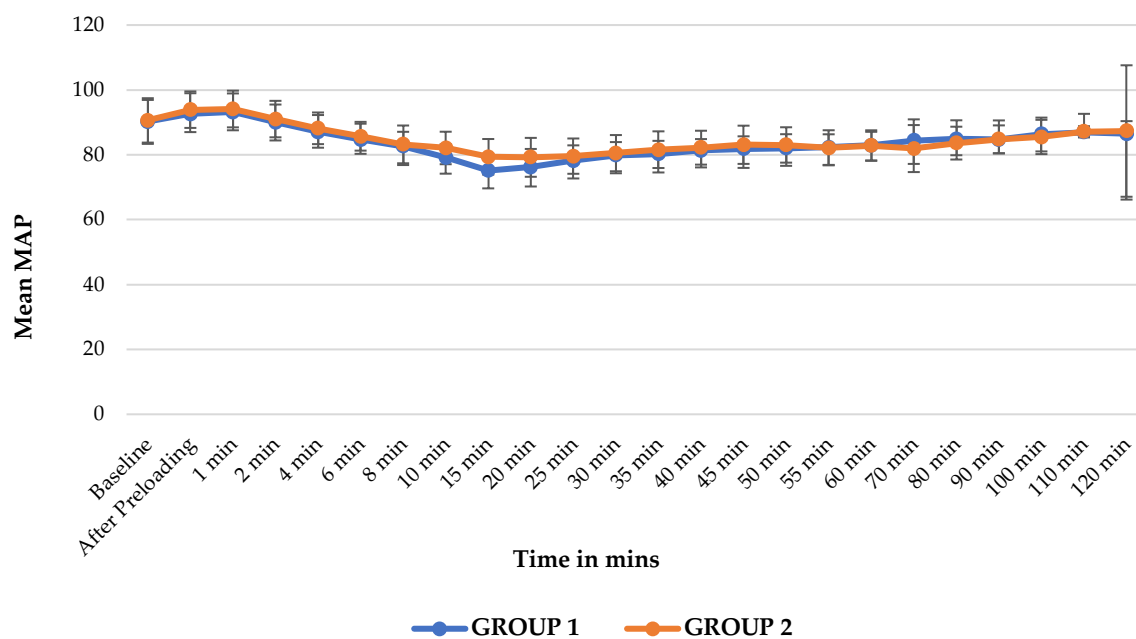
\*Significant ( $p < 0.05$ ); \*\*Highly significant ( $p < 0.01$ )

There were no differences in SBP between the groups during the early phase (up to 8 minutes). However, Group-HA always experienced a larger reduction in SBP than Group-HES from the 10th minute onwards, with significant differences at 10, 15, 20, and 25 min. (Figure 1)



**Figure 1:** Comparison of SBP between the groups

There were no significant differences in MAP during the first 8 minutes after spinal anaesthesia. Group-HA had a greater reduction in MAP at 10, 15, and 20 min than Group-HES, with statistical significance at these intervals. (Figure 2)



**Figure 2:** Comparison of MAP between the groups

None of the patients in either group had an SBP < 90 mmHg in the first 10 min. However, at the 15-minute interval, Group-HA had six patients and Group-HES had two patients with SBP < 90 mmHg. This pattern continued through the 25-minute mark, with more patients in Group-HA experiencing SBP < 90 mmHg. (Table 3)

**Table 3.** Number of patients with SBP < 90 mmhg in two groups of study

Time in mins	Group-HA	Group-HES
1 -10	0	0
15	6	2
20	1	1
25	2	1
30 - 120	0	0

Nine patients in the Group-HA and four in the Group-HES required ephedrine. There was no statistically significant difference in ephedrine dose requirement between the two groups ( $p > 0.05$ ), indicating that the need for treatment was similar in both groups. The Group-HA experienced bradycardia, nausea, vomiting, and allergies. Specifically, 1 patient had bradycardia, 2 patients had nausea and vomiting, and 2 patients had allergic reactions. In contrast, the Group-HES had one case of bradycardia, but no cases of nausea, vomiting, or allergic reactions. While the overall complication incidence was low in both groups, Group-HA experienced a higher incidence of adverse events such as nausea, vomiting, and allergic reactions compared to Group-HES. (Table 4)

**Table 4.** Complications and ephedrine dose requirements

Complications	Bradycardia	Nausea and Vomiting	Allergic reactions
Group-HA	1	2	2
Group-HES	1	0	0
Ephedrine dose requirements (mg)	Group-HA (No. of Patients)	Group-HES (No. of Patients)	p value
Nil	91	96	-
Single bolus (6 mg)	6	3	0.498
> One Bolus	3	1	0.621
Total Dose Required	9	4	0.152

## Discussion

The current study was conducted to compare and assess haemodynamic alterations in terms of pulse rate, SBP, and MAP in two groups (HA and HES) after spinal anaesthesia. The two groups were well-matched according to demographic features, i.e., age, weight, and sex distribution, and no differences were noted ( $p > 0.05$ ), indicating that baseline characteristics were equally matched. Which is in line with studies by Kumar and Prasad et al., the results also revealed uniform baseline characteristics (age, weight, sex) and surgery duration, without any differences. [12,13] Group-HA consisted of 47 patients who underwent gynaecological surgery and 53 patients who underwent general surgery, while the Group-HES consisted of 51 patients who underwent gynaecological surgery and 49 who underwent general surgery. The spread of the types of surgery was comparable between the two groups, such that any differences in haemodynamic variables were not affected by the nature of surgery. The length of

surgery was also similar between the two groups, reinforcing that the duration of the procedure did not affect the outcomes.

After spinal anaesthesia, the pulse rate increased in both groups, as expected following pre-blocking. However, at 20 and 25 min after anaesthesia, a notable difference was recorded between Groups-HA and Group-HES, with Group-HA having a greater pulse rate. This indicates that Group-HA might have had a stronger physiological reaction to spinal anaesthesia, possibly as a result of increased sympathetic stimulation or variation in anaesthetic techniques. For SBP, no differences between the groups were significant during the first 8 min. Nonetheless, Group-HA showed a much larger decrease in SBP beginning at the 10th minute, with significant differences at 10, 15, 20, and 25 min. This suggests a more intense haemodynamic response in Group-HA, which could be a result of the volume of fluid used or other variables involving spinal anaesthesia.

For MAP, similar to SBP, Group-HA had a greater reduction than Group-HES at 10, 15, and 20 min, the results of which were statistically significant at these time intervals. This trend is consistent with the differences in SBP, indicating that the total perfusion pressure (MAP) was more impacted in Group-HA in the early post-anaesthesia phase. Compared with earlier research, the SBP and pulse rate responses in both groups compared with Kumar's reported responses were similar, without any significant differences in initial baseline measurements or early post-preload responses. [12] Kumar, however, noted that pulse rate alterations were more consistent throughout time, with no significant differences after 15 minutes, but our study noted significant differences at 20 and 25 minutes following anaesthesia. [12] Prasad et al. documented significant differences at later intervals (60-90 minutes), which indicates that the hemodynamic response could be different based on anesthetic drugs or patient population. [13]

Clinically, neither group showed SBP < 90 mmHg in the initial 10 min following anaesthesia. The Group-HA had a greater number of patients with SBP < 90 mmHg at 15 min (6 patients vs. 2 in the Group-HES), and the trend continued to 25 min. This indicates that Group-HA had greater haemodynamic instability after spinal anaesthesia, which resulted in a greater requirement for pharmacologic intervention. In total, nine patients in Group-HA and four in Group-HES needed ephedrine. Although the ephedrine dose requirements were not significantly different, the greater frequency of ephedrine use in Group-HA suggests that Group-HA had greater haemodynamic instability. These results contrast with those of Kumar's study, which showed increased frequency of ephedrine use in the HA group was associated with more severe haemodynamic disturbances compared to the HES group. [12] The Group-HA had a greater number of side effects, such as bradycardia (1 patient), nausea and vomiting (2 patients), and allergic reactions (2 patients). Conversely, the Group-HES did not experience any cases of nausea, vomiting, or allergic reactions but had one case of bradycardia. These results imply that haemacel's decreased haemodynamic stability may be the cause of the increased rate of complications. Nevertheless, the overall complication incidence in both groups was low, and spinal anaesthesia was still comparatively safe in both groups. Several studies have evaluated the impact of various colloids and crystalloids as preload agents prior to spinal anaesthesia. Shroff et al. reported that HES was more effective and safer than polygeline for avoiding hypotension following spinal anaesthesia. Their research showed that HES led to fewer ephedrine-requiring patients, with a lower rate of hypotension (3.77%) as opposed to polygeline (12.24%). [14] This confirms our research, in which the Group-HES had fewer haemodynamic alterations than the Group-HA. Moreover, Vercauteren et al., noted that a combination of HES with Ringer's lactate was superior to the gelatin-Ringer's lactate combination in lowering vasopressor requirements in spinal anaesthesia. [15]

Sharma et al. and Karinen et al. also reported that HES was better than crystalloids (e.g., Ringer's lactate) to avert hypotension in spinal anaesthesia. [16, 17] Mortelmans et al., compared HES with modified gelatin and observed that HES increased intravascular volume more significantly, again supporting the idea that HES results in improved hemodynamic stability in spinal anaesthesia. [18] The efficacy of



intravascular colloid solutions in averting hypotension is because they remain in the intravascular compartment for a longer period. These results corroborate with those of Davies, wherein he proved that colloids are better in the prevention of hypotension than crystalloids. [19] The same results were found in Alimaian et al.'s study. [20] Other research, including Baraka et al. and Shapira et al., showed that HES or colloids such as Haemaccel was found to have a more beneficial effect on SBP and decreased the rate of hypotension when compared to crystalloid fluids. [9, 21] Verma et al.'s findings indicate that Haemaccel, being a colloid solution, was more effective than Ringer's Lactate, a crystalloid, in controlling haemodynamic stability and the development of hypotension after spinal anaesthesia. [22] Nonetheless, allergic reactions were the disadvantage observed with Haemaccel, but not HES. Colloid preloading is a more consistent method for treating hypotension in spinal anesthesia patients, providing a higher advantage for efficacy and patient outcome than crystalloids. [23]

## Conclusion

The Group-HA and Group-HES had comparable baseline characteristics, surgery type, and duration. The Group-HES showed more stable haemodynamic outcomes, whereas the Group-HA showed a higher pulse rate and greater drop in blood pressure at certain time points. While there were no statistically significant differences in ephedrine requirement, Group-HA did experience a higher incidence of certain adverse events. Overall, both colloids demonstrated effectiveness, with HES showing slightly more stable hemodynamic outcomes and fewer adverse events.

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