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A COMPARATIVE STUDY OF INTRAOPERATIVE HAEMODYNAMIC CHANGES FOLLOWING COLOADING WITH SUCCINYLATED GELATIN VERSUS RINGER'S LACTATE IN LOWER LIMB ORTHOPEDIC SURGERY UNDER SPINAL ANAESTHESIA

Anaesthesiology

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ABSTRACT

Introduction: Spinal anaesthesia is the most commonly administered regional anaesthesia for lower limb orthopedic surgery. Crystalloids and colloids are routinely used as coloading fluids and have considerable debate over their effectiveness in coloading during spinal anaesthesia. Aim of this study is to compare the haemodynamic alterations during spinal anaesthesia in lower limb orthopedic surgery when Ringer's lactate or succinylated gelatin is used for coloading.

Materials and methods: 120 patients between 18-65 years with American society of Anaesthesiologists (ASA) physical status 1 or 2, posted for elective lower limb orthopedic surgery under spinal anaesthesia were randomly distributed in two groups. Patients in group A received succinylated gelatin and group B received Ringer's lactate as coloading fluid. Haemodynamic alterations were recorded both intraoperatively and postoperatively up to 4 hours with amount of vasopressor consumed, if any. The patients were also observed for any side effects.

Results: In group B, there was a sharp decrease in heart rate with significant decrease in systolic, diastolic and mean arterial pressure. They had several episodes of hypotension and 58% of them required vasopressor. Steady decrease in heart rate with better maintaining of haemodynamic parameters was observed in group A.

Conclusion: Coloading with succinylated gelatin in case of lower limb orthopedic surgery under spinal anaesthesia provides significantly better haemodynamic stability compared to Ringer's lactate.

KEYWORDS

Spinal anaesthesia, succinylated gelatin, Ringer's lactate, coloading

INTRODUCTION:

Spinal anaesthesia (SA) is the most commonly administered anaesthesia for lower limb orthopedic surgery. Haemodynamic alterations during spinal anaesthesia are common and can cause significant morbidity and mortality.

SA causes pharmacological sympathectomy resulting in potential deleterious consequences for the patient. Hypotension following spinal anaesthesia mainly occurs due to peripheral vasodilatation and venous pooling of blood.[1] The clinicians have used various methods and techniques such as leg wrapping, elastic stockings, optimizing patient's position, intravenous fluids and vasopressor with varying degree of success.[1] Among these techniques, administration of intravenous fluids to optimize the blood volume has been the most popular and widely used as the first line of therapy.

The intravenous fluids can be used both before and during the administration of SA. In preloading, the fluid is given around 15-20 minutes prior to the administration of SA to load the intravascular compartment. However, preloading is gradually losing its popularity as it cannot prevent episodes of hypotension after SA like coloading which is defined as infusion of 15-20 ml/ kg/ hr of iv fluid simultaneously with the administration of SA.[1] Coloading seems to be more appropriate physiologically as the increase in intravascular volume brought about by coloading coincides with the time of maximal vasodilatation due to SA. But after preloading rapid redistribution of the fluid into the extravascular compartment decrease the effect of increase in the intravascular volume. Also, preloading induces the secretion of atrial natriuretic peptide (ANP) which causes peripheral vasodilatation and increases the rate of excretion of intravascular fluid.[1]

Crystalloids & colloids are routinely used for coloading & have considerable debate over their effectiveness in coloading. Crystalloid supporters highlight all the advantages such as easy availability, less reaction & less costly whereas colloid promoters mention about their intravascular expansion capability. Colloids have a longer half-life in the intravascular compartment compared to crystalloids and are able to maintain the increase in intravascular volume for longer durations. Too much crystalloid causes overloading of pulmonary circulation resulting in signs of over-hydration. To prevent this colloids have been tried. They have been observed to be more effective in preventing the hypotension following SA as compared to crystalloid solution.[2,3]

Though several studies have been conducted in pregnant patients using crystalloids and colloids for coloading, but there is scarcity of data regarding efficacy in terms of haemodynamic stability of either of the fluid in lower limb orthopedic surgery.[4-7] So this study was conducted to compare the haemodynamic stability of Ringer's lactate (RL) and succinylated gelatin when used for coloading in spinal anaesthesia during lower limb orthopedic surgery.

MATERIALS AND METHODS:

After obtaining the institutional ethics committee approval and written informed consent, this prospective, randomized, single centre study was conducted in orthopedic operation theatre (OT) of our institution after fulfilling the inclusion criteria. The study was conducted for 12 months having a sample size of 120 patients undergoing lower limb orthopedic surgery. Sample size was calculated assuming a two sided test with alpha error 0.1 and power of 0.9.

Patients having age 18-65 years of both sexes, weight of 40-80 kg, ASA grade 1 and 2, scheduled for elective lower limb orthopedic surgery were included. Patients having more than 2.5 liters blood loss during surgery were excluded from the study.

Randomization was done using sealed envelope containing computer generated random number allocated in two groups of 60 patients each. Patient in group A received succinylated gelatin (15 ml/kg) and group B received RL (15 ml/kg) over 15-20 min following SA.

On arrival at the OT intravenous cannulation was done in one of the upper limb with 18G cannula. Intravenous fluid was selected according to the group to which the patient belongs to.

All the basic monitors were attached to the patient and baseline parameters were recorded. Under strict aseptic preparations, dural puncture was performed at L3/L4 or L4/L5 inter vertebral space with 25G sterile disposable Quincke's type spinal needle, using standard midline approach in the sitting position with support of shoulder by one assistant. Free flow of CSF was confirmed and 3.0 ml of 0.5% bupivacaine heavy was injected at the rate of 0.2 ml/second and then the patient was turned to supine position. Coloading fluid was transfused over 15 to 20 minutes with a loading dose of 15 ml/kg and thereafter RL infusion was maintained at a rate of 10 ml/ kg/ hr. for the rest of the operative procedure in all patients. [8]

Baseline and intraoperative HR, SBP, DBP, MAP were recorded. Postoperative vitals were recorded upto 4 hours, incidence of adverse effect and vasopressor consumed were also recorded. Hypotension was defined as a decrease in mean arterial pressure by more than 25% from baseline level.[9] Plan of management to combat the hypotension was to increase the fluid infusion rate, administering 100% oxygen by mask & injection mephentermine sulphate 6 mg intravenous bolus by repeating till correction of hypotension. Bradycardia, if any, was managed by 0.6 mg of atropine injection intravenously.

STATISTICALANALYSIS:

Data were collected during study proforma and analysed by a biostatistician at the end of the study. Data entered in Microsoft Excel spread sheet, analyzed statistically using appropriate software SPSS20 (version 9). All values were expressed in mean ± standard deviation. Results were analyzed by unpaired student t test for parametric data. Comparision of haemodynamic status between the two groups were done and p value <0.05 was regarded as statistically significant. Fischer's exact test & chi-square tests were done for categorical data.

RESULTS:

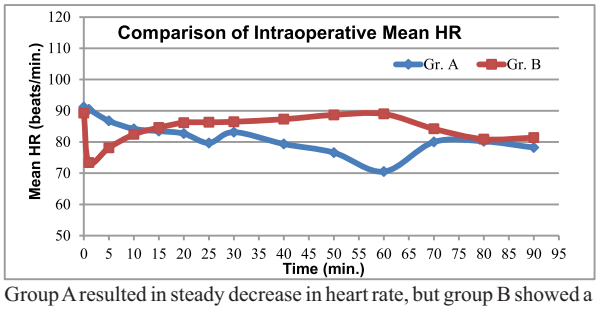
This prospective randomized study was conducted in 120 patients over 12 months who received either RL or succinylated gelatin for coloading during spinal anaesthesia in lower limb orthopaedic surgery.

Table 1. Demographic variables between two groups

	Gr. A	Gr. B	p value
Sex (M/F)	35/25	36/24	>0.05
Mean Age (years)	37.73±5.9	35.87±6.5	0.156
Mean Weight (kg)	58.67±3.7	58.45±6.4	0.103
Mean Height (cm)	165.03±8.03	165.27±7.45	0.869
Mean duration of operation (min.)	56.83±16.7	58±18.3	0.716
ASA class (I/II)	36/24	37/23	> 0.05

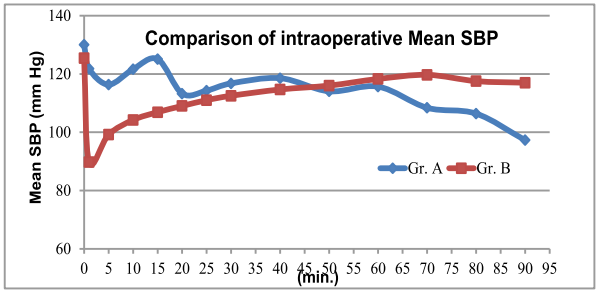
It has been seen that the two groups were comparable in terms of sex, age, weight, height, operation duration and ASA class distribution (Table 1).

Figure 1: Comparison of intraoperative Mean HR (in beats/min.)



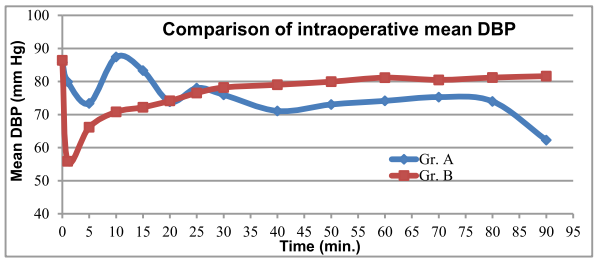
Group A resulted in steady decrease in heart rate, but group B showed a steep decrease in heart rate initially though both the groups recovered gradually ending in a similar status. It was found from the study that intraoperatively there was statistically significant difference in terms of heart rate between the two groups at 1, 5 ,25 ,40, 50 and 60 min. HR was higher in group B compared to group A throughout the study period except first 15 min. (Fig 1).

Figure 2: Comparison of intraoperative Mean SBP (in mm Hg)



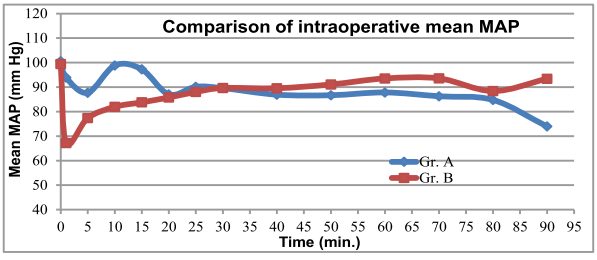
While comparing SBP between two groups, statistically significant difference was found in two groups (p 0.001) at 1, 5, 10, 15, 20, 30, 70, 80 and 90 min. SBP was higher in group A compared to group B in first half of the study period while reverse in second half (Fig 2).

Figure 3: Comparison of intraoperative Mean DBP (in mm Hg)



While comparing DBP intraoperatively, statistical significant difference was found at 5, 10, 15, 40, 50, 60, 70, 80, 90 min. Mean DBP was found to be higher in group A compared to group B in first part of the study period (Fig 3).

Figure 4: Comparison of intraoperative Mean MAP (in mm Hg)



Regarding MAP, group A getting colloid showed fewer episodes of hypotension compared to group B which showed 58% of patients requiring vasopressor (Fig 4 and Table 2).

Table 2: Comparing intra-operative vasopressor use between the two study groups

	Gr. A	Gr. B	P value
No. of patients receiving vasopressor	2	35	>0.05
% of patients receiving vasopressor	3.3	58.3	>0.05

No statistically significant difference regarding HR, SBP, DBP and MAP was observed between the two groups post operatively.

DISCUSSION:

There are various subtypes of colloid solutions, both natural and artificial. Among the colloids, gelatin, starch, dextran and albumin are the main subtypes. These are also known as volume expanders. Among these, both gelatin and starch (e.g., hydroxyethylstarch) are the most frequently used volume expanders. Though in terms of safety, gelatin is superior to starch. Among the various types of colloids, succinylated gelatin or Gelofusine™ bears similarity with Ringer's lactate in terms of pharmacokinetic properties. Succinylated gelatin is the shortest acting colloid among various colloids available and it is rapidly excreted by kidney and plasma half life is 2.5 hours. Gelofusine™ is 4% succinylated gelatin which has molecular weight of 30000 Dalton characterized by long stretched polypeptide chain which has significant negative charge created by succinylation. Succinylated gelatin is superior from other colloids in relation to rapid haemodynamic stabilization with sufficient duration of volume effect, short acting, better effect in microcirculation, no impairment in renal function, no influence in blood coagulation, no episodes of hyperchloremic acidosis, low incidence of anaphylaxis and no dose limit.[6]

While comparing intraoperative HR between the two study groups, it was found that after spinal anaesthesia, there was a sharp decrease in HR in patients receiving RL, which eventually stabilized thereafter and maintained almost steadily till the end of operation.

Whereas, in the group receiving succinylated gelatin, the heart rate steadily decreased and reached its nadir at 60 minutes, from which it increased gradually. This variation in heart rate in two groups can be explained by the types of fluid administered. In group B, patient received RL had several episodes of hypotension, which was treated by giving mephentermine which eventually caused tachycardia. But in group A, the patients received succinylated gelatin and had a fewer episodes of hypotension, so the compensatory increase in heart rate was not there. Also, towards the end of the surgery, heart rate in group A approaches towards baseline as the anxiety diminishes (Fig 1).

Both SBP and DBP showed statistically significant differences between the two groups, succinylated gelatin maintained more stable and sustainable blood pressure than the RL intraoperatively (Fig 2 and 3). Our study resembles Baraka et al. who found that blood pressure is maintained better with polymerized gelatin than NS.[10]

In group B, multiple episodes of hypotension were noted which supports the study of Riley et al., Yatish et al., Uemaya et al. and Siddik et al. who observed that hypotension was more common with RL compared to hexastarch.[11-14] Even Sukhminder et al. and Ripolles et al. also support the finding of having less episodes of hypotension with colloids.[15-16]

In the present study, the change in pattern of DBP is almost similar to that of SBP which shows that succinylated gelatin is able to maintain blood pressure without vasopressor support (only 3% needed vasopressor) whereas patients receiving RL had to maintain the blood pressure with vasopressor support (58%), reflecting the study of Siddik et al. [14] MAP followed the same trend corroborating the findings of Marhofer et al.[17].

From the observations and analyses of the present study, it can be inferred that coloading with succinylated gelatin in case of lower limb orthopedic surgery under spinal anaesthesia provides significantly better haemodynamic stability in terms of lower heart rate and higher systolic, diastolic and mean arterial pressure compared to RL without any increased incidence of adverse effect or complication.

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