

## COMPARATIVE STUDY OF HAEMODYNAMIC CHANGES BETWEEN 6% HYDROXYETHYLSTARCH 130/0.4 AND RINGER LACTATE COLOADING IN ELDERLY PATIENTS UNDERGOING LOWER LIMB ORTHOPAEDIC SURGERY UNDER SPINAL ANAESTHESIA

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### Abstract

**Background:** Anaesthesia for the lower limb surgeries could be either general or regional. Studies had shown that regional anaesthesia for lower limb surgery results in better postoperative outcomes, including improved respiratory function, less nausea vomiting, less pain and lower incidence of deep vein thrombosis. Among all the regional anaesthetic techniques spinal anaesthesia remained most preferred technique for its fast, predictable, profound, high quality sensory and motor block. However some complications like hypotension, bradycardia, post dural puncture headache, urinary retention were unavoidable and hypotension remained the most common one and found to be more in the elderly population with incidence of 25–82%. Treating spinal anaesthesia-induced hypotension included intravenous (IV) volume administration. IV Fluid infused before and at the time of spinal anaesthesia was referred to as preloading and coloadng respectively. Although merit of coloadng and the choice of fluid to be infused had remained a matter of debate, till today no definitive study had indicated any superiority of colloids over crystalloids decisively moreover large amount crystalloids to counter hypotension remained a threat to the cardiovascular overload for elderly patients. Role of vasopressors in elderly remained controversial too.

So this observational prospective study was undertaken to compare the efficacy of coloadng of infusion 6%HES 130/0.4 (colloid) and Ringer Lactate solution (crystalloid) to maintain the intra operative haemodynamics in elderly patients undergoing lower limb orthopaedic surgery under spinal anaesthesia.

**Objectives:** To assess and to compare the efficacy of infusion 6%HES 130/0.4 and infusion Ringer lactate solution coloadng in preventing the intra-operative hypotension.

**Materials and method:** On approval of the Ethics Committee of Burdwan Medical College (BMC&H), 80 patients were included and equally divided into two groups group A and group B where group A received 6% HES as coloadng fluid and group B received RL as coloadng fluid at the start of spinal anaesthesia. On entering Operation Theatre baseline parameters were noted for each patient and lumbar puncture for spinal anaesthesia was performed following strict aseptic precautions, in sitting position. Upon achieving adequate block episodes of hypotension were noted and treated according to the study protocol.

**Results:** Statistical analysis for Continuous and categorical variables were done using Mann-Whitney U test and Pearson's Chi Square test accordingly and p values less than 0.05 were considered significant.

In group A, 17.5 % patients developed one episodes of hypotension whereas in group B, 37.5% patients developed one episodes of hypotension which was statistically significant with p value 0.0465. In group A none of the patients developed further episodes of hypotension but in group B 5% affected patients developed one more episodes of hypotension and 2.5% affected patients developed two more episodes of hypotension.

Average intravenous dose of mephentermine required to treat hypotension was 1.05 mg for group A and 2.70 mg for group B and found to be statistically significant with p value 0.039. Total fluid consumption In group A was 654.95 ml whereas in group B was 976.73 ml and also found to be statistically significant with p value <0.001.

**Conclusion:** The study found that coloadng with 6% HES was significantly effective than Ringer Lactate solution in preventing episodes of hypotension in spinal anaesthesia induced elderly patients undergoing lower limb surgery without any noticeable adverse effect.

**Key Words:** spinal anaesthesia, lower limb surgery, elderly patients, coloadng

## Introduction:

International statistical data showed that reconstitution of lower extremity fractures remained the leading cause of surgery for the elderly<sup>1</sup>. Predictable physiological and metabolic changes in elderly patients could limit their ability to respond to surgical and anaesthetic stress<sup>2</sup>. Furthermore, co morbidities of increased age could contribute to perioperative adverse events and mortality<sup>3-5</sup>.

The choice of anaesthesia for the lower limb surgeries could be either general or regional anaesthesia. Studies had shown that regional anaesthesia for lower limb surgery had better postoperative outcomes, including improved respiratory function, less nausea vomiting, less pain and lower incidence of deep vein thrombosis<sup>6-8</sup>.

Among all the regional anaesthetic techniques, spinal anaesthesia remained the most preferred technique for its fast, predictable, profound, high quality sensory and motor block. However complications like hypotension, bradycardia, post dural puncture headache, urinary retention might be unavoidable and hypotension remained the most common for these elderly patients.

The degenerative lesions caused by ageing, (structural changes in arterioles, functional disorders of the autonomous nervous system and reduced response of baroreceptors to hypotension), rendered the elderly patients more susceptible to hypotensive episodes during spinal anaesthesia<sup>10</sup>

Fluid infusion before and at the time of spinal anaesthesia was referred as preloading and coloadng respectively<sup>11</sup>.

Both crystalloids and colloids had been in use for coloadng and the choice of fluid to be infused remained a matter of debate so far.

Some studies indicated about inability of crystalloids to expand intravascular space adequately by replacing intravascular deficit and stressed on colloids for their affectivity in volume expansion by remaining in circulation for longer period of time<sup>12,13,14,15</sup>.

This observational study was undertaken to assess and compare the efficacy of colloid (6% HES) co loading with crystalloid (ringer lactate) co loading in preventing hypotension in spinal anaesthesia induced elderly patient for lower limb surgery.

## MATERIALS AND METHODS:

On approval of the Ethics Committee of Burdwan Medical College (BMC&H), a prospective observational study was undertaken in the orthopedic operation theater(OT) where 80 elderly patients were included who complied with the inclusion criteria of the study for undergoing lower limb surgery under spinal anaesthesia. Routine investigations were reviewed. Participants were explained regarding study and written consents were taken.

80 participants were allocated into two equal groups, group A and group B where group A received 6% HES 130/0.4 at a dose of 7ml/kg body weight and group B received Ringer Lcatate solution at a dose of 12 ml/kg body weight as coloadng fluid administered simultaneously at the start of spinal anaesthesia.

On entering OT for all patients intravenous access using 18G intravenous cannulae were established for possible infusion at a rate of 90ml/min. Patients were monitored with Pulse oximeter, ECG, automatic oscillometric blood pressure cuff, temperature probe attached to multi parameter monitor. Baseline measures of heart rate(HR), Systolic blood pressure(SBP), Diastolic blood pressure (DBP), Mean arterial pressure(MAP), oxygen saturation(Spo2) and Respiratory rate (RR) were taken. SBP, DBP, MAP were taken as the mean of 3 readings within 10% of each other with the BP recorded from the dependent arm. Body weight was calculated from height of the patient using ideal body weight formula.

Lumbar puncture performed following strict aseptic precautions by midline approach with patient in sitting position with 26G Quincke's spinal needle. Spinal anaesthesia administered using Inj. bupivacaine 0.5% (hyperbaric with dextrose 80mg/ml), at L3-L4 or L4-L5 vertebral interspace. After establishing free flow of CSF through the needle, 2.5ml (12.5mg) of hyperbaric bupivacaine along with 25microgram(0.5ml) of inj fentanyl were injected into the subarachnoid space. Every patient was immediately turned supine on the table.

Co loading was started at the time of identification of CSF and the patients of Group A received 6% HES at a dose of 7ml/kg body weight and Group B received Ringer Lactate solution at a dose of 12ml/kg body weight. Each infusion was completed in 10 mins. Following completion of coloadng patients of both groups were infused with Ringer Lactate solution at a rate of 4ml/kg body weight/ hr as maintenance fluid till the end of the surgey. On achieving adequate

block surgeons were allowed for operation and oxygen @ 4L/min was supplemented through mask throughout surgery.

Hypotension was defined as a decrease of systolic blood pressure below 80% of baseline systolic blood pressure reading.<sup>18</sup>

Bradycardia was defined as heart rate less than 50 beats per minute and study period was defined as the first 60 minutes from the initiation of the subarachnoid block. SBP, DBP, MAP, HR, SPO2, RR, were noted at an interval of 3 minutes for the first 15 minutes, then at 5 minutes interval for the next 15 minutes and at 10 minutes interval for the rest of the duration of operation. SBP, DBP, MAP, HR, SPO2, RR were also noted at 0 minute which corresponded with the time of onset of subarachnoid block. Episodes of hypotension were corrected by additional fluid bolus and intravenous vasopressor, inj mephentermine 6mg bolus as per study protocol.

Further bolus doses of drugs were administered when SBP did not rise above 80% of baseline value, or whenever it was needed during the study period.

The time from intrathecal injection to the first episodes of hypotension, number of patients with hypotension, total episodes of hypotension, the

number of vasopressor boluses and total dose of injection mephentermine administered, any incidence of nausea vomiting or intraoperative bradycardia were recorded.

#### Results:

Assuming p value < 0.05 to be significant and considering effect to be two sided, we got  $Z_{\alpha}=1.96$ ; assuming power of study to be 90% we got  $Z_{1-\beta}=1.28$ ; considering an effect size (difference in SBP at 15 minutes between the groups) of 8 to be statistically significant it was found to be  $n > 2(Z_{\alpha} + Z_{1-\beta})^2 \times SD^2/d^2$  and  $n=40$  in each group and hence eighty patients were observed as a whole.

Continuous variables were expressed as mean, median and standard deviation and compared across the groups using Mann-Whitney U test. Categorical variables were expressed as number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for independence of attributes/ Fisher's exact test as appropriate. The statistical software SPSS version 20 was used for the analysis. An alpha error of 5% had been taken into consideration and p value less than 0.05 considered as significant.

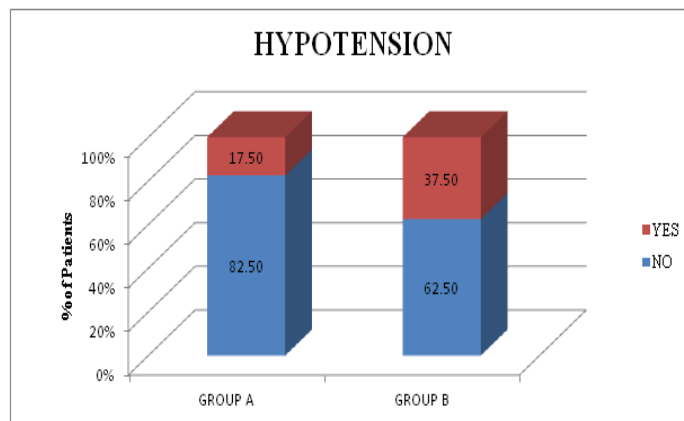
Table 1: showing demographic data where there was no significant variation seen

		GROUP		Total	p Value	Significance
		GROUP A	GROUP B			
AGE	60-65	29(72.5)	30(75)	59(73.75)	0.963	Not Significant
	66-70	9(22.5)	8(20)	17(21.25)		
	71-75	2(5)	2(5)	4(5)		
Total		40(100)	40(100)	80(100)		
SEX	Female				1.000	Not Significant
		15(37.5)	15(37.5)	30(37.5)		
	Male	25(62.5)	25(62.5)	50(62.5)		
Total		40(100)	40(100)	80(100)		

**Table 2: comparison of patients with hypotension between two groups.**

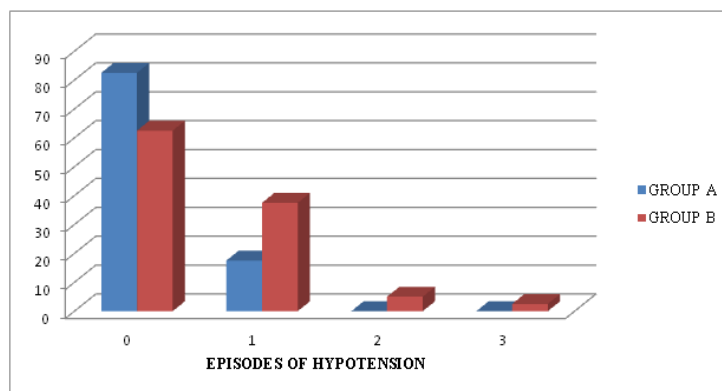
		GROUP		Total	p Value	Significance
		GROUP A	GROUP B			
HYPOTENSION	NO	33(82.5)	25(62.5)	58(72.5)	0.045	Significant
	YES	7(17.5)	15(37.5)	22(27.5)		
Total		40(100)	40(100)	80(100)		

Showing 7 patients out of 40 developed hypotension in group A whereas in group B 15 patients out of 40 developed hypotension. This difference was statistically significant with p value 0.045.

**Figure 1: comparison of percentage of patients with hypotension between two groups.****Table 3: comparison of distribution of total episodes of hypotension**

		GROUP		p Value	Significance
		GROUP A	GROUP B		
EPISODES OF HYPOTENSION	0	33(82.5)	25(62.5)	0.0465	Significant
	1	7(17.5)	15 (37.5)	0.0465	
	2	0(0)	2 (5)	NA	
	3	0(0)	1(2.5)	NA	
Total		40(100)	40(100)		

Showing the distribution of episodes of hypotension between the two group. In group A 17.5 % patients developed one episodes of hypotension whereas in group B 37.5% patients developed one episodes of hypotension .

**Figure 2: diagram showing the distribution of episodes of hypotension between two groups**

**Table 4: comparison of total dose of mephentermine between two groups.**

	GROUP							
	GROUP A			GROUP B				
	Mean	Median	Std. Deviation	Mean	Median	Std. Deviation	p Value	Significance
TOTAL DOSE OF MEPHENTERMINE	1.05	0.00	2.31	2.70	0.00	4.06	0.039	Significant

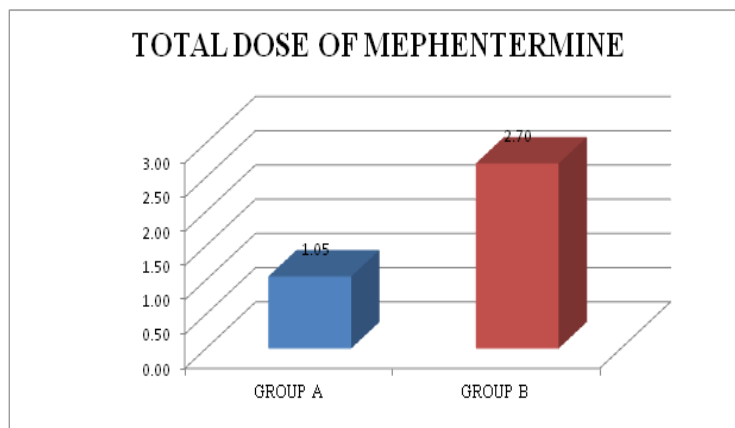
**Figure 3: comparison of average dose of mephentermine between two groups.**

Table 4 and figure 3 shows that average intravenous dose of mephentermine required to treat hypotension following spinal anaesthesia was 1.05 mg in group A and in group B was 2.70 mg and the difference was statistically significant with p value was 0.039.

**Table 5: comparison of total intraoperative fluid (coloadng + intraoperative maintenance fluid) between two groups.**

	GROUP							
	GROUP A			GROUP B				
	Mean	Median	Std. Deviation	Mean	Median	Std. Deviation	p Value	Significance
Total I.V fluid in 1 hr duration)	654.95	676.00	62.60	976.73	984.00	80.59	<0.001	Significant

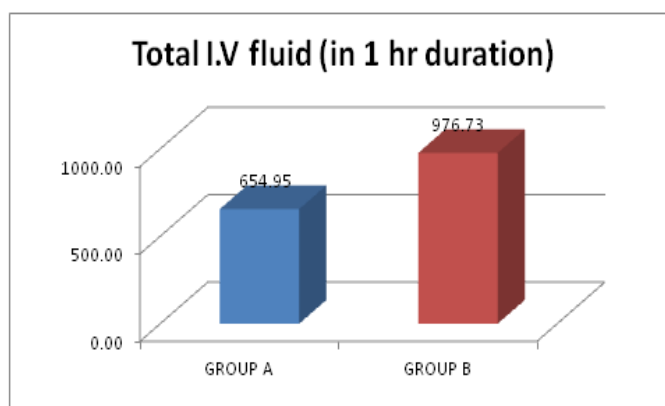
**Figure 4 : comparison of total intraoperative fluid (coloadng + intraoperative maintenance fluid) between two groups.**

Table 4 and figure 4 shows the comparison of volume of total intraoperative fluid (coload + intraoperative maintenance fluid). In group A it was 654.95 ml whereas in group B it was 976.73 ml and they were statistically significant with p value <0.001.

### Discussion:

Spinal anaesthesia normally blocks efferent sympathetic fibres thereby reducing SVR with peripheral pooling of blood and reduced cardiac output<sup>13</sup>. Physiologically baroreceptor mediated compensatory responses help in maintaining blood pressure. However if sensory level block gets extended beyond T8, release of catecholamines by the adrenals would be compromised and if gets extended beyond T2 ability for cardiac compensation would be lost. Elderly patients with lower limb fractures could become more susceptible to hypotension during spinal anaesthesia because of their pre-existing hypovolaemic state from blood loss<sup>15</sup>. More over these patients could present with many other co morbidities and could easily develop electrolyte imbalance perioperatively. Rapid infusion of fluid to maintain normotension could result in circulatory overload in elderly population. Studies done over decades had suggested that crystalloids infused rapidly might not be that effective as they diffuse mainly into the interstitial space<sup>14,15</sup>. The efficacy of colloid had been reported quite consistently in many studies. However, prophylactic administration of colloids never got popular due to their increased cost, possibility of derangement of coagulation, suppression of platelet activity and risk of anaphylaxis. Based on literary evidence, a common methodology had been practiced as pre-loading the patient with 10-20 ml/kg of intravenous fluids around 15-20 minutes prior to the administration of spinal anaesthesia so far. However due to inconsistent results and lack of evidence in benefits of pre-loading, the concept of co loading had gradually gained widespread acceptance among the clinicians. Studies with intravenous infusion of crystalloids as co loading fluid had shown to reduce the incidence of spinal induced hypotension.<sup>9</sup> Till date confusion remained about the type of fluid to be used for preloading but both colloids and crystalloids had been tried for co loading and colloids being preferred in elderly age group<sup>13, 14,15, 17</sup>.

In this present study it had been seen that the patients from two groups were comparable demographically in age, sex height, weight, surgical

interventions and other parameters (Table1) but there were definite changes in blood pressure (SBP,DBP,MAP) and heart rates in patients between two groups at different point of time of observation. It was also found that mephentermine, the drug used for maintaining desired level of BP as per study protocol also varied in term of consumption between the two groups at different point of observations. However interesting part of these observations was non significant changes of SBP, DBP and MAP in the whole study period except for a few particular points of time like at 15<sup>th</sup> and 20<sup>th</sup> min, where patients co loaded with colloids had shown significantly better maintenance of BP than the crystalloid co loading group. Many of the previous studies which have compared crystalloids and colloids as co loading fluid had shown no significant changes of outcome. Different studies have recommended 10 mg of 0.5% bupivacaine (heavy) and 25 microgram fentanyl as an optimum dose in spinal anaesthesia for elderly patients undergoing orthopaedic lower limb surgeries of moderate duration which was maintained in this study to avoid haemodynamic instability. One study, by Sivana U et al done in 2017 demonstrated that colloid co loading had been effective and superior to crystalloid co loading in preventing maternal hypotension during perioperative period with the help of CVP guidance in caesarean delivery. Another study done by Wani SA, Pandit BH, Ud DinM et al did not find any significant difference between colloid and crystalloids in preventing maternal hypotension during spinal anaesthesia induced LSCS. Here in the present study, however significant difference in maintaining BP around 15<sup>th</sup>, and 20<sup>th</sup> minutes post spinal block could possibly be due to the intravascular retention effect of colloids over crystalloids as main counter mechanism when the vasodilatation due to autonomic block was supposed to be the maximum with little scope for other compensatory mechanisms save vasoactive drug, mephentermine (Table-4). Here again it was also found that as a whole there were no significant difference in change of heart rates among the patients between these two groups during this period of observation. In this study it was also found that total number of patients who developed post spinal anaesthesia hypotension were significantly less in the group who received colloid co loading than the patients of crystalloid co loading group (Table-2). Moreover considering the distribution of episodes of hypotension it was clearly found that the first episode of hypotension occurred in more patients in the



crystalloid co loading group which was significantly higher than the patients of colloid co loading group (Table-3). All these findings could be due to the beneficial effect of colloid in maintaining intravascular volume more proficiently. These findings were shown to be corroborated with the findings of the study by Lofy EM, Moustafa AM, Feky EM et al where first episode of hypotension was found to be significantly higher in patients from crystalloid co loading group. Although a study done in 2016 by Gamal M, Elewa, Heba A et al, on elderly patients undergoing inguinal hernia repair without mesh could not establish any significant advantage of colloid co loading over preloading, the reason might be due to less fluid shift during perioperative period in hernia repair whereas in most of the orthopaedic lower limb surgeries, where chance of fluid shift is more rapid might have influenced the findings in this present study. A study by Xie RF et al, on elderly patients undergoing hip replacement surgery had clearly shown that colloid preloading 8ml/kg is significantly more effective than crystalloid preloading in maintaining cardiac output and thereby haemodynamic stability under spinal anaesthesia. In the present study although cardiac output could not be measured, yet maintenance of desired level of BP without much change in the heart rates in these elderly patients by colloid co loading 7ml/kg is very much comparable to the study of Xie RF and his colleagues. In this study it was also seen that even though the number of mephentermine boluses required to maintain desire BP as per study protocol, were similar in both the study groups, the total consumption of the vasoactive drug, mephentermine was significantly higher in crystalloid co loading group than the colloid co loading group and possibly due to increased requirement of the drug in significantly higher number of patients in that group. This finding is neither very explicable nor conclusive. Some of the studies had indeed shown conflicting reports regarding requirement of different vasoactive drugs like ephedrine or phenylephrine in patients receiving crystalloids but the study protocols did not match the present study. Mephentermine being readily available in this institution was preferred to phenylephrine to avoid unnecessary bradycardia. The present study had also shown that total amount of fluid infused during the study period considering both co loading and intraoperative maintenance fluid was significantly more in patients receiving crystalloid solution than colloid co loading patients and

corroborated with a few studies (Table 5), but this observation could not be of any significance as this study was not so designed. Cardiac output and central venous pressure monitoring could have been better guide for maintaining haemodynamic stability and appropriate fluid management but due to logistic reasons the present study had its limitation without these monitoring facilities. Urine output was also could not be monitored fearing chance of urinary infection. Immediate post operative coagulation profile were also not measured and blood supplements when needed could not be taken into consideration as that was beyond the scope of this study of one hour post induction. None of the patients from either group develop clinically significant bradycardia or hypertension during this study period. No nausea or vomiting, respiratory distress or significant pruritus was reported from any patient during the study.

### Conclusion:

From the present study it was found that Coloadng of infusion of 6% hydroxyethylstarch 130/0.4 (colloid ) was significantly more effective than coloadng of infusion of ringer lactate solution in preventing sequence of hypotension and in reducing the consumption of vasoactive drug following spinal anaesthesia in elderly patients undergoing lower limb surgery without much noticeable complications.

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