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Research Article

COMPARATIVE STUDY BETWEEN INTRA VASCULAR ADMINISTRATION OF 6% HETA STARCH, 3% HETA STARCH & RINGER LACTATE SOLUTION FOR PREVENTION OF HYPOTENSION DURING SPINAL ANAESTHESIA

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A R T I C L E I N F O

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A B S T R A C T

Background: Spinal anaesthesia is the more commonly administered procedure for pelvic, lower abdominal and lower limb procedures. It is popular because of simplicity and reliability of the technique as well as the relative rapidity with which adequate anaesthesia can be established. Hypotension is the most common complication of spinal anaesthesia. It results primarily from blockage of the sympathetic nervous system, which causes decrease in systemic vascular resistance and cardiac output. It is a common practice to give intravenous fluids, usually crystalloids, prior to central neuraxial block in order to prevent hypotension and this is usually referred as preloading, although the value of preloading with crystalloids is questioned. ***Aim of the Study:*** To compare the efficacy of a crystalloid to that of colloids in reducing the incidence and severity of hypotension in spinal anaesthesia, and also to find out if HES is a better colloid than ringer lactate. ***Methodology:*** A comparative study of volume preloading prior to subarachnoid block with Hetastarch (6%), Hetastarch (3%), Ringer`s lactate was undertaken at Osmania General Hospital, Hyderabad, after ethical committee clearance, institution approval and informed consent from the patients. **Conclusion:** It was observed from our study that 6% HES reduced the incidence of hypotension after spinal anaesthesia and also required lesser mean dose requirements of Mephentermine when compared to 3% HES and Ringer`s lactate. 3% HES when compared to Ringer`s lactate was better in terms of reducing the incidence and severity of hypotension following spinal anaesthesia.

INTRODUCTION

The introduction of local anaesthetic solutions into subarachnoid space produces spinal anaesthesia. Spinal anaesthesia has several advantages as compared to general anaesthesia; such as minimizing the risks of difficult intubation, decreasing the incidence of aspiration pneumonia, well postoperative pain relief. However spinal anaesthesia does have some drawbacks, especially of having high incidence of hypotension in up to 80 to 90 percent of cases. This may lead to nausea, vomiting, and even death of the patient[1]

Hypotension during spinal anaesthesia is common and can cause significant morbidity and mortality. Prior to spinal anaesthesia crystalloid administration is recommended to reduce the incidence of hypotension and this is referred to as preloading, although it's value has been questioned.[2-5] Crystalloid solutions have a short intravascular time and are poor plasma volume expanders, which may explain why hypotension associated with spinal anaesthesia cannot be completely eliminated by crystalloid preloading. Large volumes of crystalloid fluid can also decrease oxygen-carrying capacity, and may increase the risk of pulmonary and peripheral oedema during puerperium[6-8]. Colloids, which remain in the circulation for a longer period, seem to be an effective alternative

Heta starch is a synthetic colloid with a mean molecular weight of 450,000, which is widely used for volume expansion in-patients with trauma, shock or sepsis[9]. This study is made to compare the efficacy of crystalloid to colloid in reducing the incidence and severity of spinal induced hypotension and also to assess if Heta starch (6%) is a better colloid than 3% Heta starch in reducing spinal induced hypotension.

Aims and Objectives

1. To assess: if preloading with colloids in spinal anaesthesia reduces the incidence and severity of hypotension compared to crystalloids.

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2. To assess: if Heta starch 6% is a better colloid than3% Heta starch in reducing the incidence and severity of spinal induced hypotension.

METHODOLOGY

A comparative study of volume preloading prior to subarachnoid block with hetastarch (3%), Heta starch (6%), Ringer`s lactate was undertaken at Osmania general Hospital, Hyderabad included 90 inpatients during the period between December 2019 to November 2020, after ethical committee clearance, institution approval and informed consent from the patients.

Inclusion Criteria

- ASA physical status class 1 and 2.
- Age between 18 and 60 years.
- Weight between 40 and 80 Kgs.
- Who gave informed written consent

Exclusion Criteria

- Emergency surgeries.
- Severe anaemia, coagulation abnormalities and bleeding disorders.
- Patients with previous history of surgeries on the spine.
- Patients with spinal deformities.
- Patients with history of chronic backache
- Patients with active skin lesions over lumbosacral region
- Patients with obesity, chronic hypertension, diabetes, and heart disease

Pre-anaesthetic Evaluation

A thorough pre-anaesthetic evaluation was done with special emphasis on cardio respiratory, nervous system and endocrinal abnormalities. Previous anaesthetic exposure and drug sensitivity were enquired. A thorough general and systemic examination was carried out for baseline vital parameters, airway assessment, cardio-respiratory and CNS abnormalities. Special attention was paid for any kind of spinal deformities, active skin lesions over the lumbosacral area. Height and weight were recorded.

Preparation of Patients

Patients were advised to be nil orally from 10 p.m. onwards and were pre-medicated with oral diazepam 0.2 mg/kg (not exceeding 10 mg) on the previous day of surgery.

Patients were randomized into 3 groups of 30 patients each**:**

- Group A: Patients receiving preloading with 10ml/kg of Hetastarch (3%).
- Group B: Patients receiving preloading with 10ml/kg of Hetastarch(6%)
- Group C: Patients receiving preloading with 10ml/kg of Ringer`s lactate

Before shifting the patient to the operation table, anaesthesia machine was checked, emergency drugs and airway equipments were kept ready. Monitors were checked for their proper functioning.

Procedure

Patients were transported to O. T where 18G canula were inserted. Baseline heart rate, systolic blood pressure and diastolic blood pressure were measured in supine position using a mercury sphygmomanometer. Mean arterial blood pressure was derived from the formula, MAP = DBP + PP/3. The fluids were administered prior to spinal anaesthesia over duration of 15 minutes. After intravascular administration, pulse rate and blood pressure were measured.

With all aseptic conditions and patients in lateral position, spinal anaesthesia was performed at L3-L4 inter space with a 25 gauge spinal needle using 3ml of 0.5% bupivacaine heavy. The patient was turned to supine position, and the level of anaesthesia determined by pinprick method, bilaterally, after 10 minutes of intrathecal injection. Pulse rate, systolic and diastolic blood pressure was recorded at 5 min intervals for 1-hour duration and at the end of surgery.

Hypotension was defined as decrease in systolic blood pressure to both less than 100 mm of Hg and 75% of the baseline value whichever is greater. Hypotension was treated by an intravenous bolus of 6mg mephentermine repeated as necessary until the blood pressure was increased to >75 % of the baseline value. Bradycardia (heart rate less than 50/min) when encountered was treated with 0.6 mg of atropine. After preloading all patients were given ringer lactate at the rate of 1.5 ml/kg/hr as maintenance fluid. The number of patients developing hypotension as well the mean dose of mephentermine required for treatment was noted.

Monitoring the patient

The patients were monitored with ECG, pulse oximetry and blood pressure.

Drugs and Equipments used for the study

- Inj. Bupivacaine hydrochloride in dextrose (heavy) 0.5%.
- Spinal needle (Quincke type, 25G, 90 mm)
- Hypodermic needles (22G & 24G)
- Glass syringes (5, 2 ml each)
- Skin preparation set
- Sponge holding forceps
- Spirit bowl
- Gauze pieces
- Holed towel

Statistical Methods

The analysis of variance has been carried out to find the group significance difference of pulse rate, SBP and MAP between the three groups of patients. The Post hoc test by Tukey has been carried out to find the pair wise significance between the three groups. The Chi-square test has been used to find the significance of proportions of Mephentermine dose requirement between the three groups.

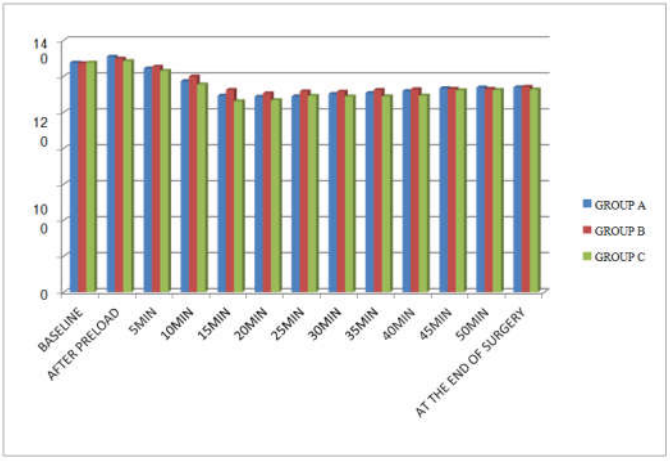
RESULTS

Table 1 The background characteristics of three groups

Background characteristics	Group A	Group B	Group C	Significance by one way ANOVA
SEX	M=16/30 F=14/30	M=15/30 F=15/30	M=17/30 F=13/30	P>0.05 By Chi-square
AGE	37.2±12.22	37±5.38	38.4±6.41	P>0.05
WEIGHT	58.3±4.74	60.9±3.85	60.9±3.82	P>0.05
Pulse at base line	76.8±7.6	76±6.9	76.6±6.92	P>0.05
Systolic pressure at baseline	127.6±6.73	127.26±7.79	127.67±6.68	P>0.05
Inference	The three samples are Age and Weight matched. Similarly Samples are matched with respect to Pulse rate and SBP at baseline.			

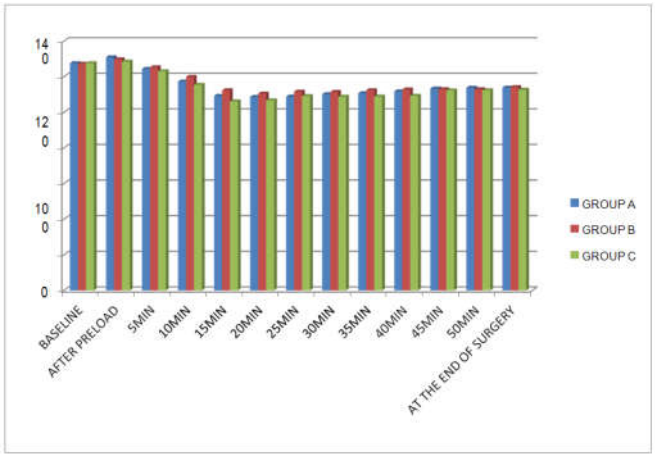
Table 2 Comparison of pulse rate between the three groups

Pulse rate at different time intervals	Group A (Mean ± SD)	Group B (Mean ± SD)	Group C (Mean ± SD)	Significance by one way ANOVA
Baseline	76.8±7.6	76.4±6.94	76.6±6.92	P=0.980(NS)
After preload	82.1±6.9	80.4±6.36	81.7±7	P=0.053(NS)
5min	84.4±8.1	81.9±7.2	84.9±7.4	P=0.267(NS)
10min	81±7	79±6.1	82±6	P=0.320(NS)
15min	78.7±6.4	77±6.7	79±6.2	P=0.271(NS)
20min	75.8±5.1	73.83±5.79	76.8±4.96	P=0.093(NS)
25min	74.1±4.3	72.4±4.93	75±4.7	P=0.094(NS)
30min	72.7±4.28	71.97±4.687	73.97±4.53	P=0.225(NS)
35min	72±5	71±4.4	73±5	P=0.336(NS)
40min	71±4	70±4.5	723±4	P=0.525(NS)
45min	70.7±4.4	70.1±4.13	71±4.6	P=0.603(NS)
50min	70±4	69±3.7	70±4	P=0.688(NS)
At end of surgery	70.1±2.4	69.2±2.72	70.8±3	P=0.086(NS)



Graph 1 Mean pattern of Systolic Blood Pressure (SBP) of the three groups

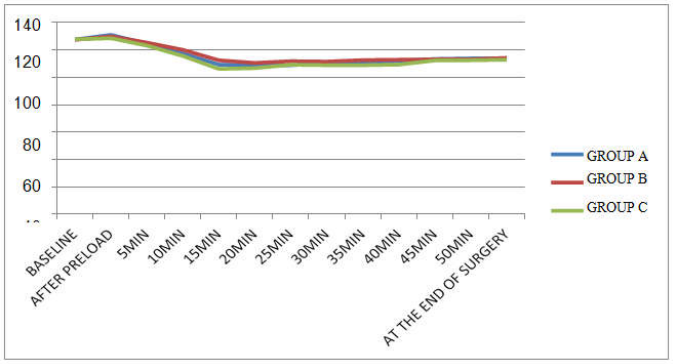
* Statistical Significance at 5%: ** Statistical significance at 1%: NS Not significant

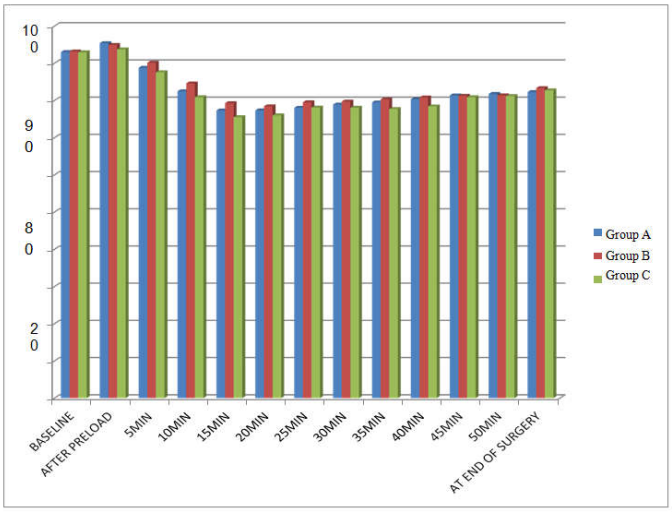


Graph 2 Mean pattern of Systolic Blood Pressure (SBP) of the three groups

* Statistical Significance at 5%: ** Statistical significance at 1%: NS Not significant

Graphical view of mean SBP in three groups





Graph 3 Mean pattern of Mean Arterial Pressure (MAP) of the three groups

Graphical view of MAP in three groups

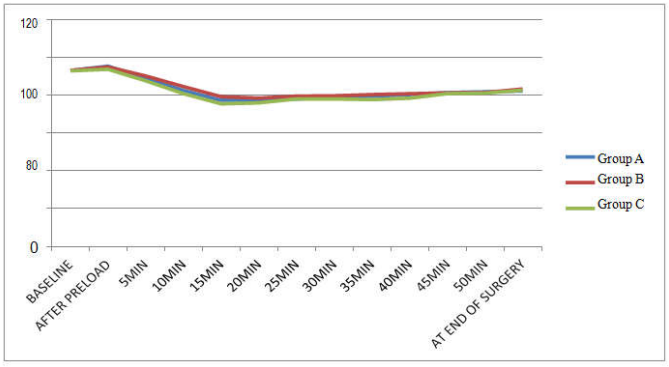


Table 3 Number of Patients with SBP<100 in three groups of study

Study period	Number & percentage of SBP <100		
	Group A	Group B	Group C
baseline	-	-	-
After preload	-	-	-
5min	-	-	-
10min	-	-	1
15min	1	-	5
20min	3	3	6
25min	3	1	2
30min	2	1	1
35min	1	-	1
40min	-	-	-
45min	-	-	-
50min	-	-	-
At the end of surgery	-	-	-

Table 4 Mephentermine dose requirements

DOSE IN MG	Number of Patients		
	Group A	Group B	Group C
No Dose Required	20	25	14
Single Dose	9	5	13
>1 bolus	1	-	3
Total Requirement	10	5	16

DISCUSSION

Spinal anaesthesia is the more commonly administered procedure for pelvic, lower abdominal and lower limb procedures. It is popular because of simplicity and reliability of the technique as well as the relative rapidity with which adequate anaesthesia can be established. In contrast to general anaesthesia, it avoids poly- pharmacy as well as situations of difficult intubation. This reduces considerably the morbidity and mortality.

Satisfactory analgesia for abdominal surgeries under spinal block requires sensory block from T6 to S5. This level of high thoracic block induces widespread vasodilatation with resultant hypotension. A significant number of patients suffer from disturbing hypotension and relative hypovolemia during this procedure.

In our study we randomized 90 patients into three groups with 30 patients each. Group A received 10ml/kg of 3%HES, group B received 10 ml/kg of 6%HES, group C received 10 ml/kg of Ringer`s lactate. Patients receiving 6%HES and 3%HES had a lower incidence of hypotension when compared to ringer lactate. Group A patients had a incidence of 33.3% of hypotension, group B had a incidence of 16.6% whereas ringer lactate group had the maximum incidence of hypotension of 53.3%. Also the mean dose of mephentermine required was less in the colloid groups compared to the ringer lactate group. Group A patients required a mean dose of 2.2mg, group B mean dose of 1mg and group C mean dose of 3.8 mg which was statistically significant. These findings are consistent with the findings of others who have compared colloid and crystalloid preloading prior to spinal anaesthesia.

A study by Sharma *et al*[10] has shown that intravenous infusion of 500 ml of 6% Heta starch is more effective than 1000 ml of lactated Ringer`s solution in attenuating spinal anaesthesia induced hypotension in women undergoing postpartum tubal ligation. Incidence of hypotension was 52% in the lactated Ringer`s solution and 16% in the Hetastarch group.

Karinen *et al*[11] study in 1995 aimed to compare the effect of Ringer`s lactate and Hydroxy ethyl starch preloading on the hemodynamic state during spinal anaesthesia on patients undergoing caesarean section. The study showed high incidence of maternal hypotension in the crystalloid (62%) group as compared to the colloid group (38%). In our study the incidence of hypotension in ringer lactate group was 53.3% and it was 16.6% in the 6%Hydroxyethyl group, 33.3%in 3%HES..

Baraka *et al* study[12] in 1994 compared intravascular administration of polymerized gelatin and isotonic saline before spinal anaesthesia for prevention of spinal anaesthesia induced hypotension. They reported a 11% incidence of hypotension after administration of 7 ml/kg of 3% gelatin compared with 52% after same volume of crystalloid in males undergoing transurethral resection of prostate under spinal anaesthesia.

Shapira *et al*[13] study in 1991 aimed to determine different aspects concerning hypotension and its prevention following spinal anaesthesia by preloading the patients with Haemaccel and ringer`s lactate respectively. They found that the systolic blood pressure decrease was significantly greater in the crystalloid group. The average decrease in systolic blood pressure in the Haemaccel group was 6 mm hg and in the ringer group it was 16 mmHg.

M.P Vercauteren *et al* (1996)[14] studied 90 patients undergoing elective caesarian section under spinal anaesthesia who received ringer lactate (LR) 1000 ml with up to 1000 ml of modified gelatin, LR 1000 ml with up to 1000 ml of hydroxyethyl starch 6%(HES) or only up to 1000 ml of 6% HES. Lumbar puncture was performed as soon as 500 ml of the colloid was infused. The incidence of hypotension, number of patients requiring a vasopressor and doses of ephedrine required to restore arterial pressure were significantly lower in favour of those receiving the crystalloid – HES combination.

In our study group A received 3%HES and group B received 6%HES. The incidence of hypotension was 33.3% in group A and 16.6% in the group B.

Also the mean dose of mephentermine required was significantly less in the 6%HES group.

Riley *et al* (1995)[15] conducted a study to determine whether preoperative administration of 6% hydroxyethyl starch decreases the incidence and severity of hypotension after spinal anaesthesia for elective caesarian section. Forty non laboring ASA grade I and II women having non urgent caesarian section were randomized to receive either 500 ml of 6% HES plus one litre of ringer lactate (n=20), or two litre of ringer lactate prior to induction of spinal anaesthesia. Hypotension occurred in 45% of patients who received HES Vs 85% of those who received only ringer lactate ($p< 0.05$) and minimum systolic blood pressure was lower in the ringer lactate group than in the HES group. In addition, the ringer lactate group had a higher maximum heart rate, a shorter mean time to hypotension and required more 5 mg doses of ephedrine for treatment of hypotension than HES group. They concluded that 6% of HES plus ringer lactate is more effective than ringer lactate alone.

In our study we measured the hemodynamic variables - heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure was derived from the formula MAP = DBP + 1/3 PP.

Satproedprai *et al* (1995)[16] studied the effect of preload infusion on cardiovascular system to prevent spinal hypotension in caesarian section in Chulalongkorn hospital during August 1993 to June 1994. 80 parturients of ASA class I and IE were included in the study and randomly allocated into two groups of 40 cases each, each receiving intravenously in 15 minutes either 10 ml per Kg of normal saline or 5 ml per Kg of polygeline solution as preloading fluids. The incidence of hypotension in normal saline treated group was 58% in comparison to 25% in polygeline group. The average doses of ephedrine used were 4.9 mg/case in normal saline group and 1.8 mg/case in polygeline group. It was therefore concluded that polygeline solution is more effective than normal saline in prevention of spinal anaesthesia induced hypotension.

H. A. Adriaensen (1996)[17] studied 90 patients undergoing elective caesarian section under spinal anaesthesia who received ringer lactate (LR) 1000 ml with up to 1000 ml of modified gelatin, LR 1000 ml with up to 1000 ml of hydroxyethyl starch 6% (HES) or only up to 1000 ml of 6% HES. Lumbar puncture was performed as soon as 500 ml of the colloid was infused. The incidence of hypotension, number of patients requiring a vasopressor and doses of ephedrine required to restore arterial pressure were significantly lower in favour of those receiving the crystalloid – HES combination.

Monica Kheterpal, R. L. Gairola, D. K. Singh, A. Lal (2001)[18] from the department of Anaesthesiology, Institute of Medical Sciences, Banaras Hindu University, Varanasi, compared the efficacy of colloids and crystalloids when used as preloading in prevention of combined spinal and epidural anaesthesia induced hypotension and concluded that colloids offset hypotension more effectively than crystalloids.

Idehen HO, Amadasun FE, Ekwere IT(2014)[19]. Compared intravenous colloid and colloid-crystalloid combination in hypotension prophylaxis during spinal anaesthesia for cesarean section. And found that crystalloid –colloid combination showed better efficacy in hypotension prophylaxis over colloid regimen in first 10min. beyond 10 min this combination has no advantage over colloids in maintaining haemodynamic parameters.

CONCLUSION

It can be concluded from the present study that colloids offset Hypotension and Hypovolemia more effectively than crystalloids (Ringer Lactate) in patients scheduled for elective surgery under spinal anaesthesia. Also it can be concluded that 6% Hydroxyethyl starch is a better colloid than 3% HES in preventing spinal anaesthesia induced hypotension.

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