

Comparing Lactated Ringer's and Hydroxyethyl Starch Preloading to Prevent Hypotension in Caesarean Section Spinal Anaesthesia: A Clinical Study

Dr Kangkan Sharma

MD Anaesthesiology. DM Cardiac Anaesthesiology. Senior Consultant Cardiac Anaesthesiology. Health City Hospital. Guwahati, India
(Corresponding Author)

Abstract: *This prospective, randomized study compared the efficacy of 500 mL 6% hydroxyethyl starch (HES 130/0.4) versus 1 L Lactated Ringer's (RL) solution as preloading fluids to prevent hypotension in 150 non-laboring ASA I and II women undergoing elective caesarean section under spinal anaesthesia. Patients were randomly assigned to receive either HES (Group A) or RL (Group B) before anaesthesia, with blood pressure monitored at regular intervals up to 60 minutes post-spinal block. Hypotension, defined as a systolic drop >30% or <90 mmHg, was managed with RL infusion and mephentermine boluses. Results showed hypotension in 17.33% of Group A versus 33.33% of Group B ($p=0.0381$), with Group A requiring significantly less mephentermine. We conclude that HES 130/0.4 outperforms RL in preventing hypotension, suggesting its potential for routine use.*

Keywords: Hydroxyethyl Starch, Ringer Lactate, Caesarean Section, Spinal Anaesthesia, Hypotension

1. Introduction

Hypotension is one of the commonest serious problems following spinal anaesthesia for caesarean, potentially endangering both mother and child [15]. Measures to decrease the incidence and severity of maternal hypotension include left uterine displacement, fluid preload, prophylactic vasoconstrictors, Trendelenburg position [16]. Acute hydration has become the cornerstone of prophylaxis for prevention of hypotension in obstetrics. Several studies have been done to evaluate the efficacy of different preloading solutions including crystalloids and colloids. In contrast to crystalloid, colloid remains for a longer period within the intravascular space. Crystalloid pre-hydration has poor efficacy for preventing hypotension [17], probably because it undergoes rapid distribution [2]. Thus, a preload with colloid provides a sustained increase in central blood volume and cardiac output, which overlaps with the hemodynamic events that follow the induction of spinal anaesthesia. However, some studies have encountered lack of benefit by volume preloading [17]. Given the frequency of caesarean sections and the risks hypotension poses to maternal and fetal outcomes, identifying an effective preloading strategy could improve safety and recovery, making this comparison clinically meaningful. This study has been undertaken to assess the efficacy of volume preloading and to compare the relative efficacy of ringer's lactate and HES 6% as preloading solution.

2. Aims and Objectives

We have selected this study to re-evaluate the relative efficacy of 6%hydroxyethyl starch and lactated ringer's solution as preloading fluid in prevention of hypotension in spinal anaesthesia for elective caesarean section. We have observed the following important parameters to achieve the goal of our study - - -

- 1) To compare the level of blood pressure (SBP, DBP, MAP) and heart rate in two groups.
- 2) Requirement of inj mephentermine and crystalloid to maintain blood pressure.

3. Methods

After obtaining Institutional Ethical Committee clearance and informed consent from patients this prospective, comparative randomized trial was conducted at caesarean section operation theatre of department of Obstetrics and Gynaecology under the Anaesthesiology Department of Assam Medical College and hospital Dibrugarh, from July 2012 to June 2013.

Sample size was determined based on prior studies, targeting a 15% difference in hypotension incidence with 80% power and $\alpha=0.05$. Subjects were randomly allocated to two groups containing 75 patients in each group. Group A ($n=75$) received 500 ml of 6% HES and group B ($n=75$) received 1000 ml of lactated ringers solution over 20 minutes just prior to subarachnoid block

After receiving the patient inside the operation theatre, baseline vital signs were recorded using BPL Ultima Multiparameter Monitor. Preloading of patient was started after securing IV line with 18 Gauge cannula. Group A received 6%HES 500 ml and group B received 1000 ml RL respectively over a period of 20 minutes just prior to the administration of spinal anaesthesia. Under all aseptic precautions, subarachnoid block was performed with 25G quincke type of spinal needle at the L2 - L3 or L3 - L4 interspace with the patient in left lateral position with 1.8 - 2.2ml of 0.5% hyperbaric bupivacaine. Immediately patient was turned and kept in supine position. All patients received oxygen by face mask[at]5 L/min till the delivery of the baby. Intra-operative intravenous infusion consisted of RL in all

patients. After delivery of baby 10 IU oxytocin was started as slow infusion. Infusion of lactated ringer continued throughout surgery and in the postoperative period.

The Following Observations Were Made

1. Maternal blood pressure, heart rate and mean arterial pressure were recorded at following intervals:

Pre - operative (baseline).

After preloading and just before subarachnoid block.

After subarachnoid block in supine position,

Every 5 minutes for first 30 minutes,

Thereafter every 10 minutes till end of surgery or upto 60 minutes.

2. Amount of mephentermine and ringer's lactate administered in both the groups

Hypotension: - was defined as decrease in systolic arterial pressure by >30% from baseline or <90 mmhg whichever is greater [15]. Hypotension was managed by increasing the rate of iv infusion. If not corrected inj. Mephentermine was administered.

Bradycardia (HR<15% of baseline or <60 bpm) was managed by inj. Atropine [4].

Statistical Methods

Difference between the mean for values of systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, dose of mephentermine, amount of RL were tested for statistical significance using unpaired 't' test at 5% level of significance. Fisher's exact test was used to determine p value of relative requirement of mephentermine frequency of complications and number of patients in ASA categories.

4. Results

Systolic blood pressure trends

Systolic blood pressure	Group A (mean± SD)	Group B (mean± SD)	p value	Significance
Preoperative (baseline)	120.43±8.94	122.75±5.85	.0621	NS
At the onset of preload	121.40±6.68	122.55±4.54	.2208	NS
After preload and just before SAB	123.03±6.46	124.32±4.22	.1488	NS
After SAB in supine position	122.92±6.94	123.88±4.25	.308	NS
5 mins after supine position	118.81±8.02	115.04±12.49	.0292	S
After 10 mins	113.77±9.97	105.21±11.82	<.0001	S
After 15 mins	114.37±9.63	106.84±7.59	<.0001	S
After 20 mins	115.41±8.08	110.63±9.18	.0009	S
After 25 mins	114.40±7.44	110.71±6.11	.0011	S
After 30 mins	115.85±6.77	111.51±6.82	.0001	S
After 40 mins	115.27±5.47	112.16±8.71	.0098	S
After 50 mins	119.73±5.28	115.60±6.26	<.0001	S
After 60 mins	121.12±4.61	115.97±6.98	<.0001	S

Systolic blood pressure changes: The mean baseline SBP was slightly higher in the RL group 122.75±5.85 mmHg compared to 120.43±8.94 mmHg in the HES group. The same trend was maintained throughout the period of preloading. These differences were not significant. just

before SAB the mean SBP was 123.03±6.46 mmHg in HES group and 124.32±4.22 in RL group. After SAB both the groups showed slightly decreasing trend in SBP which became statistically significant at 5 mins after LP and maintained upto 60 minutes.

Incidence of hypotension: In HES group 13 (17.33%) mother suffered from hypotension in comparison to 25 (33.33%) in RL group and this difference was significant (p=0.0381).

Comparing number of patients suffering from hypotension

Group	Hypotension present	Hypotension absent	p value
Group A	13	62	0.0381
Group B	25	50	

Diastolic blood pressure in two groups

Diastolic blood pressure	Group A (mean± SD)	Group B (mean± SD)	p value	Significance
Preoperative (baseline)	77.89±6.49	78.35±4.27	.6141	NS
At the onset of preload	76.53±5.28	76.67±4.48	.8678	NS
After preloading and just before SAB	78.64±4.24	78.09±3.69	.4008	NS
After SAB in supine position	77.47±4.59	76.17±4.56	.0854	NS
5 mins after supine position	75.09±6.01	70.96±9.38	.0016	S
After 10 mins	72.96±8.09	62.39±10.36	<.0001	S
After 15 mins	72.19±8.05	66.53±5.66	<.0001	S
After 20 mins	72.35±8.15	69.49±8.11	.0332	S
After 25 mins	72.17±7.65	69.91±4.99	.0333	S
After 30 mins	72.72±8.25	70.25±5.76	.0354	S
After 40 mins	71.03±7.02	65.64±8.41	<.0001	S
After 50 mins	75.60±7.82	72.19±5.52	.0024	S
After 60 mins	76.08±4.85	73.78±5.37	.0051	S

Diastolic blood pressure changes: - The mean baseline DBP was slightly higher in the RL group 78.35±4.27 mmHg compared to 77.89±6.49 mmHg in the HES group. The same trend was maintained throughout the period of preloading. These differences were not significant. Just before SAB the mean DBP was 78.64±4.24mmhg in HES group and 78.09±3.69 in RL group. After SAB both the groups showed slightly decreasing trend in DBP which became statistically significant at 5 mins after LP and maintained upto 60 minutes.

Mean arterial pressure in two groups

Mean arterial pressure	Group A (mean ±SD)	Group B (mean± SD)	P value	Significance
Preoperative (baseline)	92.09±6.41	93.15±4.12	.2329	NS
At the onset of preload	91.68±5.15	91.93±4.13	.7402	NS
After preloading and just before SAB	93.55±4.08	93.48±3.35	.9131	NS
After SAB in supine position	92.63±4.73	92.09±3.76	.4459	NS
5 mins after supine position	89.72±6.35	85.49±10.18	.0027	S
After 10 mins	86.56±8.54	76.65±10.25	<.0001	S

After 15 mins	86.25±8.03	79.96±5.57	<.0001	S
After 20 mins	86.69±7.58	83.36±8.08	.0101	S
After 25 mins	86.16±7.01	83.36±4.83	.005	S
After 30 mins	86.97±7.37	83.87±5.87	.0049	S
After 40 mins	85.76±5.95	81.16±7.87	<.0001	S
After 50 mins	90.33±6.58	86.69±5.59	.0004	S
After 60 minutes	91.11±4.06	87.77±5.72	<.0001	S

Mean arterial pressure changes: The mean baseline MAP was slightly higher in the RL group 93.15±4.12 mmHg compared to 92.09±6.41 mmHg in the HES group. The same trend was maintained throughout the period of preloading. These differences were not significant. Just before SAB the mean MAP was 93.55±4.08mmHg in HES group and 93.48±3.35mmHg in RL group. After SAB both the groups showed slightly decreasing trend in MAP which became statistically significant at 5 mins after LP and maintained upto 60 minutes.

Heart rate changes in two groups

Heart rate	Group A (mean± SD)	Group B (mean±SD)	P value	Significance
Preoperative (baseline)	79.42±5.67	79.86±5.11	.6184	NS
At the onset of preload	78.2±4.56	78.41±5.71	.8007	NS
After preload and just before SAB	77.8±4.63	78.21±5.91	.6342	NS
After SAB in supine position	85.17±4.80	85.64±4.92	.5574	NS
5 mins after supine position	78.76±4.23	79.45±5.82	.4052	NS
After 10 mins	78.05±3.42	79.38±6.66	.1250	NS
After 15 mins	77.05±2.82	78±4.77	.1409	NS
After 20 mins	77.09±6.33	78.63±4.7	.0974	NS
After 25 mins	76.17±2.99	77.38±5.55	.0978	NS
After 30 mins	76.72±8.78	77.07±4.62	.7626	NS
After 40 mins	76.51±8.31	77.2±5.86	.5559	NS
After 50 mins	76.25±6.65	76.95±3.93	.4380	NS
After 60 mins	75.61±6.38	76.27±4.75	.4780	NS

Heart rate changes: - The baseline heart rate were 79.42±5.67/min in HES and 79.86±5.11 / min in RL group. Both were comparable. HR remained stable during the preloading period. But around the period of SAB there was a sharp rise in HR in both the groups. But there was a decreasing trend in HR in both the groups. HR was comparable throughout the period in the two groups.

Total dose of mephentermine and lactated ringer's administered intra – operatively

Variable	Group A mean± SD	Group B mean± SD	P value	Significance
Mephentermine (mg)	.40±1.14	1.08±1.61	.0033	S
L R (in liter)	1015.87±105.70	1138±160.69	<0.0001	S

Table showing comparison of mephentermine requirement

Groups	Required (no of patients)	Not required (no of patients)	P value
Group A	9	66	0.0031
Group B	25	50	

Intra- operative fluid requirement in HES group 1015.87±105.70 ml was higher than RL group 1138±160.69 ml and it was statistically significant (p value <0.0001).

Nine patients in group A required injmephentermine in comparison to 25 patients in RL group. Amount of injmephentermine required was also higher in RL group in comparison to HES group which was statistically significant (p value 0.0033).

5. Discussion

In our study we have tried to see the benefit of preloading the patients with Hydroxyethyl starch 6% (130/0.4) in prevention of hypotension and compared it with Lactated ringer's solution. We administered 500ml HES in one group and 1000ml RL in the other group. There is no definite point defined at which hypotension should be treated. We took the point as decrease in systolic arterial pressure by >30% or <90 mmhg whichever was greater [4, 15]. Hypotension was managed by increasing the rate of intravenous fluid that is giving 200ml RL IV fast. If not corrected Injmephentermine 3mg IV was administered every 60 seconds till SBP of

>90mmhg was achieved. Bradycardia (HR<15% of baseline or 60 per minute) was treated with Inj atropine 0.3 mg IV.

The mean baseline SBP were comparable between both the groups, being 120.43±9.09 mmHg and 122.75±5.85 mmHg in Group A and Group B respectively. After the onset of preload, the SBP remained stable in both the groups till the end of preloading. This is similar to findings of **Hamaji et al (2013) [11]**, **Udeyana Singh et. Al (2009) [4]**, **Samiamadi - jebara et al (2008) [13]**.

The SBP remained unchanged at the time of LP. Post - spinal anaesthesia, SBP declined in both groups. SBP reached its nadir between 5 - 15 minutes after LP, which was statistically significant like studies of **Duggal Geetika et al (2012) [9]**, **Loubert C et al (2012) [8]**, **Bouchnak M (2012) [7]**, **SamiaMadi - jebara [13]**. But there was no significant difference in the study done by **Adilson hamaji et al (2013) [11]**, **mehndi fathi et al (2013) [7]**.

In the HES group percentage of patients suffering from hypotension is 17.33% and in the RL group it is 33.33% in our study. The study done by **Duggal Geetika et al (2012) [9]** found the incidence of hypotension to be 40% and 60% in HES group and RL group respectively. **Bouchnak M (2012) et al [7]** found 40% and 66% in HES RL group respectively. In 2011 **rufengxie et al [6]** found the incidence of hypotension to be similar. In 2011 **Frédéric J. Mercier, MD, phd [11]** found a 45% incidence of hypotension in the colloid group versus 85% in the crystalloid group in spinal

anesthesia for caesarean section. **UDEYANA SINGH AND USHA SAHA (2009) [4]**, compared HES 6% and RL preloading in spinal anaesthesia for caesarean section and did not find any significant hypotension (<30%) in any of the groups

The mean diastolic BP were comparable in the two groups during the period of preloading. But after subarachnoid block the mean diastolic BP followed a decreasing trend in both the groups upto 60 minutes like studies of **Udeyana Singh et al (2009) [4]**. In the study done by **Duggal Geetika (2012) [9]** diastolic BP became significantly higher in HES group after 30 minutes of SAB. But in the study done by **mehndi fathi et al (2013) [10]**, **adilson hamaji et al (2013) [11]**, this difference was not statistically significant.

The mean MAP were comparable in the two groups during the period of preloading like studies of **Udeyanasingh (2009) et al [4]**, **samiyadi - jebara (2008) et al [13]**. But after 5 minutes of SAB it was significantly higher in the HES group maintained upto 60 minutes from SAB.

In our study 9 patients in HES group and 25 patients in RL group required vasopressor Inj mephentermine. Amount of Inj mephentermine was also higher in RL group with a p value of 0.0033. in the study of **Duggal Geetika et al (2012) [9]** requirement of vasopressor was least in the colloid group. In the study done by **Udeyanasingh and Usha Saha (2009) [4]** not a single patient required vasopressor in both the groups. **SAMIA MADI - JEBARA et al in (2008) [13]** found requirement of inj ephedrine less in HES 6% group in comparison to LR group (p value 0.001). In a study published by **SAHAR M SIDDIK et al in (2000) [3]** more doses of ephedrine were required to treat hypotension 35.3mg in LR group in comparison to HES 10% 10.6mg with a p value <0.05.

The mean baseline heart rates were comparable in both the groups being 79.42±5.67 in HES group and 79.86±5.11 in RL group. The changing trends were also similar. The heart rates remained unchanged during the period of preloading. There was a sharp rise in heart rate at the time of LP in both the groups same as **Udeyana Singh et al 2009 [4]**., and this was attributed to apprehension and anxiety, posture change and the slight pain experienced by the patient at the time of LP. Following LP the HR decreased and became stable. None of the patient required inj atropine to treat bradycardia (<60 BPM). The stability of heart rate after LP can be explained by the onset of spinal blockade, consequent analgesia and relief of anxiety, loss of sensation of Braxton - Hicks contractions and the patient becoming comfortably settled in the OT table.

In our study the RL group required more IV fluid 1138±160.69 ml than the HES 6% group 1015.87±105.70 ml was higher and it was statistically significant (p value <0.0001). This is similar to the findings of **A. Feldheiser et al (2013) [12]**, **Udeyana Singh et al (2009) [4]** **A. M. Ovezov et al (2012) [14]**

6. Conclusion

This study demonstrates that preloading with 6% hydroxyethyl starch (HES 130/0.4) significantly lowers the incidence of hypotension in ASA I and II patients undergoing elective caesarean section under spinal anaesthesia compared to Lactated Ringer's solution (33.33% vs.17.33%, p=0.0381). It also reduces the need for intravenous fluids and vasopressors, suggesting HES as a more effective option. While not eliminating hypotension entirely, its routine use could enhance maternal safety and perioperative stability.

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