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Comparison of 6% Hydroxyl Ethyl Starch and Ringer's Lactate for Preloading in Caesarean Section under Spinal Anaesthesia

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Abstract

Background: Therefore the present study was undertaken to study on comparison of 6% hydroxyl ethyl starch with Ringer's Lactate for preloading in caesarean section under spinal anaesthesia. *Objectives:* To study the effects on heart rate and blood pressure after pre-load with 6% hydroxy ethyl starch and ringer's lactate in elective caesarean section after spinal anaesthesia. *Methods:* Total of one hundred patients belonging to ASA Grade I and II were included in the study during study duration. Patients in the age group of 18-35 years were selected. Through pre-operative examination was done one day prior to access the fitness for anaesthesia. Routine investigation like Haemoglobin, urine for sugar and albumin were done. Other investigations were carried out whenever necessary. The patients were randomly divided into two groups comprising of 50 patients in each group. Group A: received Lactated Ringer's solution 1000ml. Group B: received 500ml. of 6% Hydroxy Ethyl Starch. *Results:* There was no statistically significant difference found in pulse rate and blood pressure parameters at baseline between two groups ($p>0.05$). It was found that there is no statistically significant difference of pulse rate during first hour after the Subarachnoid injection between the two groups ($p>0.05$). It was found that, there is no statistically significant difference of changes in respiratory rate and SpO2 between the two groups ($P>0.05$). *Conclusion:* From the present study, it was conclude that, preloading subjects with 6% hydroxyl ethyl starch is useful than preloading with ringer lactate solution as it produces better hemodynamic stability to subjects.

Keywords: 6% Hydroxy Ethyl Starch, Lactated Ringer's Solution; Spinal; Hemodynamics.

Introduction

Delivery of a baby by caesarean section has become increasingly common. A number of factors account for the increased section rate. It has become commonly accepted that serious trauma to the baby can be eliminated by avoiding potentially difficult mid-forceps or vaginal breech delivery and performing a Caesarean section instead. The widespread use of electronic and biochemical foetal monitoring prior to and during labour has made it easier to identify a foetus in jeopardy and promptly deliver the baby by the abdominal route. The clinical impression that Caesarean section is less traumatic for the tiny foetus and concerns over potential lawsuits in cases of poor neonatal outcome, have also encouraged obstetricians to perform Caesarean sections with less positive indication than in the past.

To decrease the frequency and seriousness of spinal hypotension different moves have been utilized which incorporate Trendelenberg (head down) position, prophylactic vasopressors, leg rise and strapping, utilization of inflatable boots and preloading the patients with intravenous liquids with either crystalloid or colloid solution [1].

However, spinal anaesthesia is also not without its side effects. Through the years the high incidence of spinal hypotension has always been of great

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concern to the attending anaesthesiologist. Hypotension after spinal anaesthesia is one of the physiological effects of central neural blockade and can be a complication when allowed to go unnoticed or untreated. This hypotension if severe will have profound deleterious effect on the neonatal i.e hypoxia, acidosis and neonatal depression. To overcome these 100% oxygen by mask, left uterine displacement, prophylactic ephedrine and pre-loading with crystalloids is advocated.

Crystalloid arrangements, being of lower sub-atomic weight, enters the interstitial space because of absence of natural colloid osmotic weight and may bring about aspiratory edema which meddles with tissue oxygen trade. Despite what might be expected, colloids having higher atomic weight than crystalloids, have comparable osmolality as plasma stay bound to intravascular space with little extension of interstitial space [2].

Preloading with crystalloid solution will fill up the vasodilated (intravascular) compartments and prevent the fall after spinal anaesthesia. Since the crystalloid solutions expand the interstitial as well as intravascular compartment, these solutions may not always be an effective expander of plasma volume after spinal anaesthesia, since 75% of crystalloid solution diffuses into interstitial spaces which may lead to pulmonary oedema in the already over loaded circulation, which is seen with pregnancy, especially if large volumes are infused. Hence, we wanted to use another fluid which does not as readily diffuse into this interstitial space with its accompanying complications, this prompted us to use hydroxyl ethyl starch a colloid namely 6% hydroxyl ethyl starch as a preload.

Therefore the present study was undertaken to study on comparison of 6% hydroxyl ethyl starch with Ringer's Lactate for preloading in caesarean section under spinal anaesthesia.

Aims and Objectives

To study the effects on heart rate and blood pressure after pre-load with 6% hydroxy ethyl starch and ringer's lactate in elective caesarean section after spinal anaesthesia.

Material and Methods

This study was undertaken after obtaining approval of the Institutional ethics committee and written informed consent from the patients was obtained after explaining the procedure. Total of one hundred patients belonging to ASA Grade I and II were included in the study during study duration. Patients in the age group of 18-35 years were selected. Routine investigation like Haemoglobin, urine for sugar and albumin were done. Other investigations were carried out whenever necessary.

Exclusion Criteria were

1. All contraindications for spinal anaesthesia like Patients refusal, Local infections, Concomitant disease, Spinal deformities, Bleeding disorders, Increased intracranial tension, Systolic blood pressure less than 100mmHg etc.
2. Age less than 18 years or more than 35 years
3. Obesity,
4. Diabetes mellitus,
5. Pregnancy-induced hypertension.
6. Heart disease/respiratory disease
7. History of allergic reactions
8. Fetal distress, short stature,multiple gestations, placenta previa, abruption placenta.
9. Other than ASA-I and ASA-II

The patients were randomly divided into two groups comprising of 50 patients in each group.

Group A: received Lactated Ringer's solution 1000ml.

Group B: received 500ml. of 6% Hydroxy Ethyl Starch

Intravenously as volume pre-load given over a period of 20 mins. Prior to induction of spinal anaesthesia

Procedure

Pre-Medication

Inj.metaclopromide 10mg ½ half prior to anaesthesia. Inj. Ranitidine 50 mg intravenously. Pre-loading was done over a period of 20mins prior to sub-arachnoid block with: Lactated Ringer's solution 1000ml in Group A & 6% Hydroxy Ethyl Starch 500ml in Group B.

The patient was then given left lateral position. Complete asepsis was maintained. Lumbar puncture was performed at the level of L2-3 or L3-4 interspace with a 23G disposable lumbar puncture needle in left lateral position. On obtaining a free-flow of cerebro-spinal fluid 1.2cc of 5% xylocaine heavy was injected

into the sub-arachnoid space.

The patient was immediately positioned supine with left uterine displacement. We recorded upper level of spinal block which was assessed by pinprick method at 3, 5 and 10 mins. Oxygen supplementation was done with Hudson's mask with flow at 3 lit/ min. All patients given inj. Oxytocin 10 U by iv drip after birth of baby.

Monitoring

A base line pre-operative reading of pulse rate and arterial blood pressure and respiration was recorded. After sub-arachnoid block recording of heart rate and blood pressure, and respiration were made every minute for the 15 minutes and every 5 minutes thereafter. Oxygen saturation, electrocardiogram, urinary outputs were monitored throughout the study period.

Preoperative Fluid Infusions

Besides the pre-load fluid, the fluid used for maintenance was Lactated Ringer's solution 4ml/ kg/hr in all the patients.

Criteria for Hypotension

Decrease in arterial blood pressure by >30% of the preoperative blood pressure value was considered the criteria for hypotension.

Spinal Induced Hypotension was Corrected by

Leg raising and additional volumes of Ringer's Lactate solution was infused, 100% oxygen by mask. The cases where hypotension could not be corrected by above measures, Inj. Mephenteramine 3 mg I.V. was given. Additional doses of inj. Mephenteramine were given as and when required. We recorded total number of patients receiving inj. Mephenteramine and amount of additional Ringer's lactate solution to correct the spinal hypotension.

Statistical Analysis

Data was entered in Microsoft excel sheet. Descriptive statistics such as mean, SD and percentage was used. Data was analyzed using students t-test, chi square test wherever appropriate. P value of less than 0.05 was considered statistically significant

Results

The mean age of patient in Group A is 24.02 ± 3.56 and range of age is 19 to 33 years, while the mean age in Group B is 23.86 ± 3.96 and range of age is 19 to 33 years. This difference is statistically not significant. The mean height in Group A and Group B is 157.66 ± 6.97 and 153.24 ± 6.16 respectively and found that, difference is statistically not significant. The mean weight in Group A and Group B is 49.94 ± 3.53 and 51.62 ± 4.94 respectively and found difference is also statistically not significant.

There was no statistically significant difference found in pulse rate and blood pressure parameters at baseline between two groups (p>0.05).

Table 1: Comparison of baseline (preop) pulse rate and blood pressure in both groups

	Group A (n=50) Mean ± SD	Group B (n=50) Mean ± SD	t-value	p-value	Remarks
Pulse rate (beats / min)	83.68 ± 5.40	82.16 ± 7.27	1.18	0.24	No significant
systolic BP (mm of Hg)	120.24 ± 7.35	117.80 ± 8.16	1.57	0.12	No significant

Table 2: Comparison of changes in pulse rate during first hour after the Subarachnoid injection

Pulse Rate	Group A N=50 Mean ± SD	Group B N=50 Mean ± SD	t-value	p-value	Remarks
pre-op	83.68 ± 5.40	82.16 ± 7.27	1.18	0.24	NS
3 min	88.84 ± 4.49	88.02 ± 5.76	0.79	0.43	NS
5 min	87.30 ± 7.59	89.84 ± 5.54	1.90	0.06	NS
10 min	86.68 ± 11.31	89.96 ± 6.04	1.81	0.07	NS
15 min	88.96 ± 12.57	90.10 ± 7.55	0.55	0.58	NS
20 min	93.16 ± 10.00	90.40 ± 9.17	1.44	0.15	NS
25 min	92.44 ± 7.70	89.86 ± 9.01	1.54	0.13	NS
30 min	92.20 ± 7.77	90.10 ± 7.14	1.41	0.16	NS
45 min	92.26 ± 7.34	89.64 ± 6.92	1.84	0.07	NS
60 min	91.18 ± 5.69	89.64 ± 7.51	1.15	0.25	NS

Table 2: Comparison of changes in pulse rate during first hour after the Subarachnoid injection.

Pulse Rate	Group A N=50 Mean ± SD	Group B N=50 Mean ± SD	t-value	p-value	Remarks
pre-op	83.68 ± 5.40	82.16 ± 7.27	1.18	0.24	NS
3 min	88.84 ± 4.49	88.02 ± 5.76	0.79	0.43	NS
5 min	87.30 ± 7.59	89.84 ± 5.54	1.90	0.06	NS
10 min	86.68 ± 11.31	89.96 ± 6.04	1.81	0.07	NS
15 min	88.96 ± 12.57	90.10 ± 7.55	0.55	0.58	NS
20 min	93.16 ± 10.00	90.40 ± 9.17	1.44	0.15	NS
25 min	92.44 ± 7.70	89.86 ± 9.01	1.54	0.13	NS
30 min	92.20 ± 7.77	90.10 ± 7.14	1.41	0.16	NS
45 min	92.26 ± 7.34	89.64 ± 6.92	1.84	0.07	NS
60 min	91.18 ± 5.69	89.64 ± 7.51	1.15	0.25	NS

Table 3: Comparison of changes in systolic blood pressure during first hour after the Subarachnoid injection.

Blood Pressure	Group A N=50 Mean ± SD	Group B N=50 Mean ± SD	t-value	p-value	Remarks
pre-op	120.24 ± 7.35	117.80 ± 8.16	1.57	0.12	NS
3 min	109.60 ± 6.98	110.60 ± 8.40	0.65	0.52	NS
5 min	101.08 ± 6.72	105.64 ± 8.47	2.98	0.004	Significant
10 min	92.96 ± 6.78	100.04 ± 7.57	4.91	0.0001	Significant
15 min	86.92 ± 6.39	94.56 ± 8.19	5.19	0.0001	Significant
20 min	88.60 ± 5.47	91.52 ± 8.09	2.12	0.04	Significant
25 min	90.32 ± 4.79	93.08 ± 5.93	2.56	0.01	Significant
30 min	92.72 ± 5.94	95.84 ± 5.91	2.62	0.009	Significant
45 min	96.24 ± 4.56	98.04 ± 5.66	1.75	0.08	NS
60 min	99.76 ± 3.80	100.48 ± 5.26	0.78	0.43	NS

It was found that there is no statistically significant difference of pulse rate during first hour after the Subarachnoid injection between the two groups ($p>0.05$).

The above Table 3 shows that the difference of mean blood pressure preoperatively, at 3 min, at 45 min, at 60 min interval between groups was not statistically significant.

The mean blood pressure from 5 min to 30 min interval in both groups is as shown in the above table. It was found that there is statistically significant difference between two groups.

Table 4: Comparison of changes in respiratory rate during first hour after the Subarachnoid injection

Respiratory Rate	Group A n=50 Mean ± SD	Group B n=50 Mean ± SD	t-value	p-value	Remarks
pre-op	13.66 ± 0.89	13.54 ± 0.91	0.67	0.51	NS
3 min	13.54 ± 0.91	13.54 ± 0.91	0.0	1.0	NS
5 min	13.60 ± 0.88	13.66 ± 0.89	0.34	0.73	NS
10 min	13.48 ± 0.91	13.60 ± 0.88	0.67	0.50	NS
15 min	13.66 ± 0.89	13.48 ± 0.91	0.32	0.99	NS
20 min	13.46 ± 0.89	13.60 ± 0.90	0.44	0.78	NS
25 min	13.54 ± 0.91	13.54 ± 0.89	0.0	1.0	NS
30 min	13.66 ± 0.89	13.46 ± 0.89	1.12	0.26	NS
45 min	13.88 ± 0.91	13.60 ± 0.88	1.56	0.12	NS
60 min	13.60 ± 0.88	13.60 ± 0.86	0.0	1.0	NS

It was found that, there is no statistically significant difference of changes in respiratory rate between the two groups ($P>0.05$).

It was observed that, there is no statistically significant difference of changes in SpO2 between the two groups ($p>0.05$).

Out of 50 patients in Group A 21 (42%) patients had hypotension, while out of 50 in Group B only 9 had hypotension and it was found that, there is statistically difference between groups ($p=0.01$).

In Group A, 8 patients out of 21 with hypotension needed inj. Mephentermine, whereas in Group B only 2 out of 8 patients needed it. Statistically this difference is not significant ($p=0.82$).

Table 5 : Comparison of changes in SpO2 during first hour after the Subarachnoid injection.

Pulse Rate	Group A n=50 Mean ± SD	Group B n=50 Mean ± SD	t-value	p-value	Remarks
pre-op	98.04 ± 0.75	98.06 ± 0.77	0.13	0.89	NS
3 min	98.06 ± 0.77	98.18 ± 0.77	0.78	0.44	NS
5 min	98.10 ± 0.84	98.04 ± 0.75	0.37	0.71	NS
10 min	98.02 ± 0.81	98.10 ± 0.84	0.48	0.63	NS
15 min	98.04 ± 0.75	98.20 ± 0.81	1.02	0.31	NS
20 min	98.16 ± 0.82	98.24 ± 0.80	0.49	0.62	NS
25 min	98.06 ± 0.77	98.12 ± 0.77	0.39	0.69	NS
30 min	98.04 ± 0.75	98.16 ± 0.82	0.76	0.45	NS
45 min	98.20 ± 0.81	98.10 ± 0.74	0.52	0.64	NS
60 min	98.10 ± 0.84	98.36 ± 0.75	1.63	0.11	NS

Table 6: Incidence of hypotension

	Group A	Group B	χ^2 - value	p-value
No. of patients with hypotension	21 (42%)	9 (18%)	5.76	0.01
No. of patients required inj. Mephentermine	8 (16%)	2 (4%)	0.05	0.82

Discussion

Hypotension after spinal anaesthesia remains a common and potentially serious complication. Maternal hypotension is detrimental for the mother & also affects fetal outcome. Severe maternal hypotension may cause hypoxia, acidosis and neonatal depression. Thus it is important and relevant to prevent maternal hypotension or reduce its degree & duration at any cost.

Some of the techniques to achieve this include left lateral tilt or manual uterine displacement or both to relive aorto-caval compression, use of vasopressor prophylactically, preloading with IV fluids.

The commonly used pre-load ringer's lactate did not decrease the incidence of hypotension during spinal anaesthesia or prevent the severe form of hypotension. Hence, the aim of our study was Ringer's lactate versus 6% Hydroxy Ethyl Starch to compare the effects of crystalloids (RL) with a colloid (6% HES) pre-loading in preventing hypotension after spinal anaesthesia for caesarean section.

Heart Rate

The mean baseline heart rate were comparable in both groups being 83.68 ± 5.40 beats /min and 82.16 ±7.27 beats/min in Group A and B. There was comparable sharp rise in heart rate in both groups at time of LP which can be related to anxiety.

Rise in heart rate was continued from 5 to 20 min, reaching highest at 20 min in both group. This rise corresponds to period of hypotension, occurred after spinal anaesthesia. Rise in heart rate was more in group A, but there was no significant difference between two groups. After this, heart rate remained stable in both groups till end of surgery.

Tachycardia (pulse >15% of baseline or more than 100) seen in 5 patients (10%) in both groups. It was associated with hypotension.

Clinically significant fall in HR >15% from baseline occurred in 4 patients in group A and 3 patients in group B. Therefore treatment (atropine) was needed.

In most other studies tachycardia corresponded to the periods of hypotension, which occurred after spinal anaesthesia. This occurred between 3-10 min of LP in most patients were found in several studies (Rout et al 1992 [3] , Riley et al 1995 [4]).

Edward Riley et al [5] found rise in HR was more in group A(RL) than Group B(HES). Udeyana singh et al [5] found no significant change in HR in both groups.

Blood Pressure

Baseline blood was pressure comparable in both the groups being 120.24 ± 7.35 mm of Hg in Group A and 117.80 ± 8.16 mm of Hg in group B. BP remained relatively stable after preloading & during LP. Fall in BP started immediately after induction of spinal anaesthesia, in spite of preloading in both the groups.

However fall in BP in group A was significantly more during 5-20 min, than in group B ($p<0.05$). Rate of fall in BP was also seen more in Group A compared to group B. After this period (5-20 min) sys BP remain stable till end of surgery in both groups.

After reaching minimum level of 86.92 ± 6.39 mm of Hg at 15 min, sys BP in group A gradually increased

till end of surgery, but always remain lower than baseline value.

Similar trends were seen in group B, where minimum level of sys BP reached at 20 min (91.52 ± 8-09 mm of Hg) . Difference in fall in BP between two group was statistically significant during 5 min to 30 min ($p<0.05$).

This shows that preloading with 6% HES better in preventing onset, duration and degree of hypotension.

The time of decrease in BP corresponds to studies by other worker like Mathru et al [6], Rout et al [3], Riley et al [4], Ueyama et al [7] in whose SBP decreased maximally from baseline values at periods ranging 4 min-10 min after LP.

Similar findings were noted in studies of Mathru et al [6], French et al [8], Siddik et al [9]. Udeyana singh et al [5] found no significant change in BP in RL group & HES group.

Incidence and Severity

Incidence of hypotension was higher in group A- 36 patients (72%) than in group B – 23 patients (46%). It is statically significant ($p<0.01$).

All the patients were given RL 4ml/kg/hr as maintenance fluid throughout the cycle. In spite of preloading and this maintenance fluid the fall in BP had to be corrected by additional amount of RL.

In spite of the above treatment in some patients the fall was sever enough to warrant the use of inj Mephentermine iv. 28 patients (56%) in group A compared to 14 patients (28%) in group B required inj Mephentermine. Out of 28 patients in group A, 7 patients require 2 doses of inj Mephentermine . one such case noted in group A. this difference is also statistically significant ($p<0.05$).

Higher incidence of hypotension in RL preloaded group than colloid preloaded group also noted by Mathru et al [6], Hallworth et al [10], French et al [8], Siddik et al [9] in their studies. induced hypotension. Similar results also have been revealed in studies by Madi-Jebara S et al [11] and Ueyama H et al [7]. Which implied much effectiveness of Hetastarch solution in prevention from changes in cardiac indexes in patients undergoing spinal anesthesia.

Koski et al [12] noted no statistical difference in amount of vasopressor required in the groups. Thus demonstrating that fall in the BP cannot be totally inhibited through administration of plasma substitutes.

Complications

6% HES is known to cause allergic reactions, but in our study none of the patient had Urticaria, pruritis, anaphylaxis. The higher incidence of Nausea seen in group A – 5 patients (10%) compared to group B – only 1 patient (2%). None of patients had vomiting. No post-operative complications noted in any patients. Similar finding were observed by Riley et al [4], Udeyana et al [5] showed no adverse reaction to Hetastarch.

Moretti EW et al concluded that they're both 6% hetastarch in saline group and 6% hetastarch in balanced salt solution groups had significantly less incidence of nausea and vomiting, use of rescue antiemetics, severe pain, peri-orbital edema, double vision as compared to Ringer's lactate solution group [13].

Conclusion

From the present study, it was conclude that, preloading subjects with 6% hydroxyl ethyl starch is useful than preloading with ringer lactate solution as it produces better hemodynamic stability to subjects.

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