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A randomized controlled trial to compare crystalloid and colloid co-loading in preventing spinal hypotension in parturients undergoing caesarean section

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Abstract

Background: Spinal anaesthesia is the preferred technique for operative delivery in parturients, but associated hypotension can be detrimental for both mother and fetus. Different types (Crystalloid or colloid) and timings (preload or co-load) of fluids have been tried to decrease the incidence of hypotension. In our study, we planned to compare the efficacy of crystalloid co-loading and colloid co-loading in preventing hypotension in patients undergoing elective caesarean section under spinal anaesthesia.

Methods: 70 full term pregnant women with uncomplicated pregnancies scheduled for elective caesarean section under spinal anaesthesia were randomized to two groups to receive either crystalloid co-load or colloid co-load. Patients received either 15ml/kg of ringer's lactate or 8ml/kg of 6% hydroxyl ethyl starch after cerebrospinal fluid was tapped during spinal anaesthesia. Blood pressure, heart rate, and oxygen saturation were measured every two minutes for first 20 minutes and every five minutes till the end of procedure. Vasopressor was administered if systolic pressure was less than 80% of baseline pressure. APGAR scores, nausea, and vomiting were also monitored.

Statistical analysis: Student's t-test, chi-square test, fisher exact test.

Results: There was no statistically significant difference among the groups regarding systolic blood pressure and vasopressor requirements. The fall in diastolic blood pressure and mean arterial pressure was more in the crystalloid co-load group compared to the colloid co-load group. Neonatal outcomes and incidence of nausea and vomiting were comparable statistically among the two groups.

Conclusion: Colloid co-loading, even though better than crystalloid co-loading in preventing hypotension in pregnant patients undergoing caesarean section under spinal anaesthesia, they are ineffective as a single measure as incidence of hypotension in both the groups >50%.

Keywords: Co loading, Crystalloids, Colloids, Hypotension, Spinal anaesthesia, Caesarean section

Introduction

Single shot spinal anaesthesia has emerged as the technique of choice for routine caesarean delivery because of its simplicity, reliability and cost effectiveness.[1,2] But flipside of this technique is associated hypotension which can lead to undesirable maternal or fetal effects.[3] According to literature, incidence of obstetric spinal hypotension can range from 7 to 74%.[4] The deleterious effects of hypotension are syncope, nausea and vomiting in mother and placental hypoperfusion leading to hypoxia and acidosis in fetus.[5,6]

Parturients are more prone for hypotension due to higher level of block (T4) required for caesarean section, unique physiological and anatomical changes of pregnancy and increased susceptibility to the effects of sympathectomy due to reduced sensitivity to endogenous vasoconstrictors.[2]

Last three decades have seen extensive research aimed at preventing hypotension in obstetric spinal anesthesia.[7] The research has mainly involved different types of fluids like crystalloids and colloids and different vasopressors.[8] As usefulness of crystalloid preloading is being questioned by many studies,[9] we planned a study to compare the effectiveness of co loading with crystalloid and colloid in preventing hypotension in obstetric patients undergoing spinal anaesthesia for caesarean section.

Material and Methods

After obtaining approval from institutional ethical committee and written informed consent, 70 women with term singleton pregnancies, belonging to ASA physical status class 1 and 2, scheduled to undergo elective caesarean delivery under spinal anaesthesia were included in this prospective randomized study.

Parturients with pre-eclampsia, eclampsia, chronic hypertension, any major systemic disease, known fetal compromise or coagulopathies, extremes of height(<135 or >190 cms) or weight(<50 or >100 kg) or patients with contraindication to neuraxial anesthesia were excluded from the study.

Patients were randomized into two groups to receive crystalloid co load (group A) or colloid co load (group B) by computer generated random allocation.

Patients included in the study received ranitidine 150mg orally the previous night and on the morning of surgery. Two peripheral intravenous access (18 G) were secured. One was for co loading and another for maintenance fluid and oxytocin infusion.

Inside the operation theatre, routine non-invasive monitors like Non-invasive Blood Pressure (NIBP),

Electrocardiogram (ECG) and oxygen saturation probe were attached.

Spinal anesthesia was induced with patient in sitting position, L3-4 space with hyperbaric bupivacaine 0.5%, 2cc injected through 26 G quincke s needle. Co-loading commenced as soon as cerebrospinal fluid was tapped. Group a patients received a crystalloid (ringer's lactate) co load of 15ml/kg and group B patients received colloid(hydroxyl ethyl starch 6%) coload of 8 ml/kg. Co loading was completed within 10 minutes. Soon after induction of spinal anaesthesia patients were positioned supine with 15º left lateral tilt. Oxygen supplementation was done with Hudson's mask 6 lit/min. Highest level of sensory blockade was checked with pin prick method and in blockade T7 or above surgery was allowed to commence. Blood pressure (Systolic, diastolic and mean), heart rate and oxygen saturation were measured every two minutes for first 20 minutes and every five minutes thereafter till the completion of procedure. Vasopressor (ephedrine) 1 unit (6mg) administered intravenously if systolic pressure was <80% of the baseline pressure. Vasopressor repeated every one minute if hypotension persisted or recurred. If heart rate <50, glycopyrrolate 0.2 mg given intravenously.

After baby extraction, APGAR scores were noted down at 1 and 5 minutes. Oxytocin 10 units were given by slow intravenous infusion. The incidence of nausea and vomiting was measured on a three point scale of 1,2 and 3 with 1- no nausea and vomiting, 2-nausea but no vomiting and 3- both nausea and vomiting.[10] The patients were observed and actively questioned for presence of nausea. Nausea and vomiting not associated with hypotension was treated with injection ondansetron intravenously. The induction to delivery and uterine incision to delivery interval were also noted.

Following data were collected

1. Patient demographics (age, height, weight and duration of surgery)
2. Episodes of hypotension
3. Vasopressor requirements
4. Incidence of nausea and vomiting
5. Neonatal outcome indicated by APGAR scores

Any patients with inadequate blockade requiring general anaesthesia and excessive intraoperative bleeding were dropped from the study.

Statistical analysis: statistical analysis was done using software SAS 9.2. SPSS 15.0, Stata 10.1, Med Calc 9.0.1, Systat 12 nd R environment ver 2.11.1.

Student's t test (two tailed, independent) has been used to find the significance on metric parameters in intergroup analysis.

Chi square test / Fisher exact test has been used to find the significance of study parameters on categorical scale between two groups.

70 patients were enrolled and successfully completed the study. There were no significant differences between the groups regarding age, height, weight, duration of pregnancy and maximum sensory blockade. The incidence of hypotension was more in the crystalloid group (57.14%) compared to the colloid co loading group (54.2%).

The fall in diastolic blood pressure and mean arterial pressure was statistically significant in crystalloid co loading group compared to colloid co load group.

There is no statistically significant difference between systolic blood pressure and heart rate among the two groups. The number of vasopressor units required to treat hypotension among groups were comparable statistically.

Neonatal outcomes as measured by APGAR scores did not show any significant differences among the groups. The number of patients having side effects like nausea and vomiting was comparable among the two groups.

Table 1: Demographic data

	Crystalloid co load group	Colloid co load group	'P' value
Age (years)	24.31+/- 2.84	24.97+/- 2.65	0.320
Height (cms)	152.89 +/- 3.50	153.37+/- 2.72	0.520
Weight(kilograms)	61.03+/- 5.32	61.37+/- 6.34	0.807
Duration of surgery	37.00	38.01+/- 1.34	0.641
Maximum sensory blockade	T6 (T5-T7)	T6 (T5-T7)	0.89

Table 2: Secondary outcomes

	Crystalloid co load group	Colloid co load group	'P' value
APGAR score			
1 min	8.66+/- 0.48	8.69 +/- 0.47	0.803
5 min	9.97 +/- 0.17	10 +/- 0.00	0.321
Nausea and vomiting	3	3	-

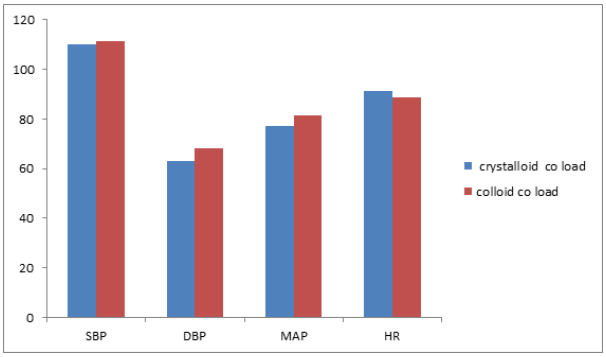

Fig. 1: Systolic BP, Diastolic BP, Mean BP & Heart Rate

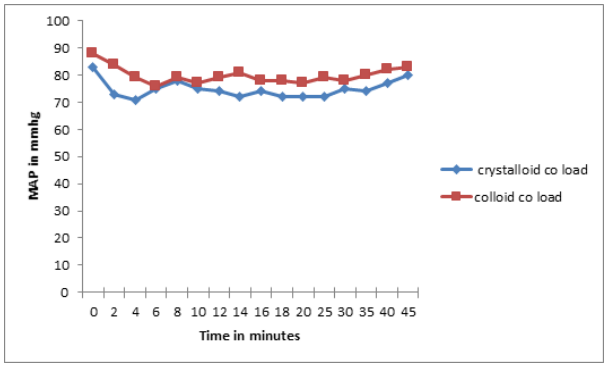

Fig. 2: Mean arterial pressure

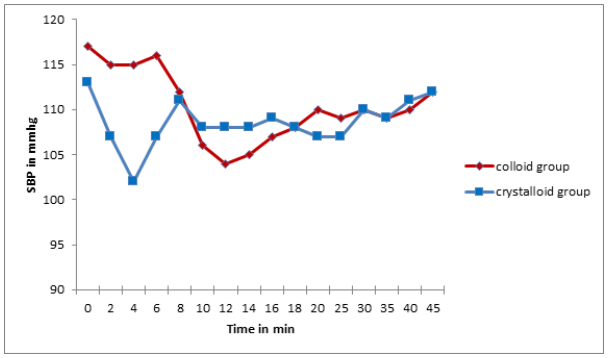

Fig. 3: Systolic blood pressure

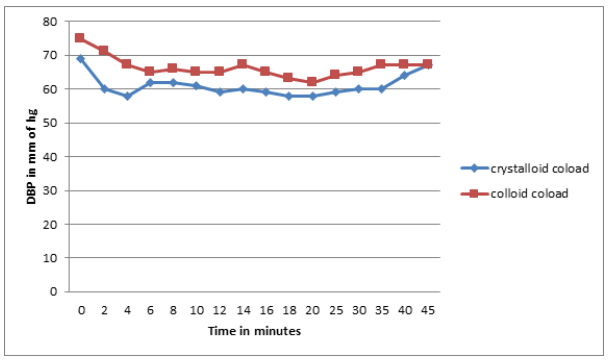

Fig. 4: Diastolic blood pressure

Discussion

Spinal anaesthesia has emerged as the most popular technique for operative delivery in pregnant patients.[11] But pharmacological sympathectomy leading to hypotension (incidence as high as 60-70%) can be deleterious both to fetus and parturient.[12] Several measures have been tried to prevent it, with varying degrees of success.[13] Most effective have been fluids (crystalloids and colloids) and vasopressors. Timing of fluid administration (preloading or co-loading) has been studied extensively.

To prevent hypotension following spinal anaesthesia, intravascular volume expansion can be achieved with either pre-loading or co loading with fluids. But studies suggest that preloading half hour prior to placement of subarachnoid block is ineffective due to the fluid redistribution and release of Atrial Natriuretic Peptide (ANP) leading to peripheral vasodilatation and increased excretion of fluid. Intravascular volume can be maintained by co loading, that is administration of intravenous fluids simultaneously with dural puncture so that infusion of fluids coincide with maximum vasodilatation due to spinal anaesthesia.[4,14,15] Studies have shown benefits of co loading as it is more physiological.[16,17,18] Co loading strategy was first described by Ewaldson and Hahn who proved its efficacy in non-obstetric population.[19]

As many studies have revealed the ineffectiveness of preloading with crystalloids,[20] we conceptualised a study to know the effectiveness of co-loading with crystalloid and colloid in preventing hypotension in parturients undergoing caesarean section under spinal anesthesia. Crystalloid co load and colloid preload have been shown to be effective, but there are not many studies directly comparing crystalloid co-load and colloid co load in caesarean section. Crystalloid used in our study was ringer's lactate solution and colloid was hydroxylethyl starch (6% HES 130/0.4) as it has better safety profile among the available colloids in terms of allergic reaction and interference with coagulation.

One of the initial trials proving usefulness of co-loading in obstetric patients was by Dyer et al who demonstrated decreased vasopressor requirement in the co-load group.[21] However crystalloid co loading has not been consistently efficacious in preventing hypotension.[22] Few studies supported the beneficial effects,[20] while few more did not prove its efficacy.[6] Banerjee et al concluded that timing of fluid loading did not have an impact on the incidence of hypotension but they showed that vasopressor requirement was reduced in colloid group as was the finding in our study.[6] Colloid co-loading does not have very much benefit compared to colloid pre-loading as colloids stay in the intravascular period for a longer period of time and offer more flexibility in their administration compared to crystalloids.[15,16,23] But colloids are expensive, have a potential for anaphylaxis (incidence of 0.06%), alterations in haemostasis and renal failure.[24,25] Thromboelastography in patients receiving 6% hydroxyl ethyl starch preloading has shown mild coagulation effects but clinical implications have not been documented.[26]

McDonald et al in their randomized controlled trial studied maternal cardiac output changes after crystalloid or colloid co-load in elective caesarean delivery following spinal anaesthesia. They found no differences in the cardiac output variables, vasopressor requirements or hemodynamics between two groups.[11] Our study in contrast had statistically significant difference in the mean arterial pressure among the groups with colloid co-loading group having less incidence of hypotension. They used a prophylactic phenylephrine infusion along with co-loading whereas in our study we used ephedrine as rescue vasopressor though not prophylactically. Similar to their study there was no statistically

significant difference in secondary outcomes like nausea, vomiting and APGAR scores among the groups.

Our results match with findings of Lotfy ME et al who studied colloid versus crystalloid co loading with spinal anesthesia during emergency caesarean section.[27] They found significant difference in mean arterial pressure among the groups, as evident in our study. Unlike our study, they had significant difference in the vasopressor requirements among groups. They also found difference in the incidence of nausea and vomiting while we did not. Smiley et al reported lower incidence of nausea and vomiting in the colloid group compared to crystalloid group.[28]

A recent meta-analysis (analysing 227 controlled trials) by Melchor J et al has shown the efficacy of colloids in decreasing the incidence of spinal hypotension in elective caesarean section patients compared to crystalloids.[9]

In our study, higher incidence of hypotension can be explained by lesser amount of fluids (8ml/kg of colloid and 15ml/kg of crystalloid) used for co loading and absence of a prophylactic vasopressor. Few studies have tried 15ml/kg of colloid co loading and 20 to 30ml/kg of crystalloid co loading. There are lot of variations in the incidence of hypotension in the studies done, as there are differences in the definition of hypotension, the administration rate and volume of fluids.

Neonatal outcomes, measured by APGAR scores, were not different among two groups in our study, results being similar to most of the studies done to compare the timing of fluid loading.[29] This is very important as neonatal outcomes directly reflect the adverse effects of hypotension. Recently it has been shown that term infants tolerate this placental perfusion variation without much adverse effects.

Limitations of our study are, prophylactic vasopressor was not used in both groups. Recent studies suggest use of a prophylactic phenylephrine infusion with co-loading has better efficacy in reducing the incidence of hypotension.[30,31] We did not have a control group as withholding fluids in caesarean section patients shall be against clinical practice.

As crystalloid preloading is being proved ineffective and obstetric operating rooms get busy with rapid turnover rates, co loading would be a more efficient method of fluid management. Time should not be lost to administer a fixed volume of fluid.[32]

Co loading, even though better with colloid compared to crystalloid, is inefficient as single intervention to prevent hypotension in parturients undergoing caesarean section under spinal anaesthesia.[33] It should be combined with a prophylactic vasopressor for lowering incidence of hypotension.

Research in last few years has empowered us with knowledge for choosing a fluid, timing of its administration and an appropriate vasopressor. Futuristic endeavours like searching for risk factors for spinal hypotension, technological advances to monitor hemodynamics in mother and closed loop vasopressor automated systems may help us to solve this 'holy grail' of obstetric anesthesia.[34,35]

We conclude that colloid co loading is better than crystalloid co loading in preventing hypotension in parturients undergoing caesarean section under spinal anaesthesia. Nevertheless we need to bear in mind the potential risks and expenses of colloid.

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