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A Prospective Randomised Study Comparing Crystalloid Preload and Coload in Parturients for Caesarean Section Under Subarachnoid Block

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Abstract

subarachnoid block.

Background and Aim: Regional anaesthesia is usually preferred over general anaesthesia in parturients undergoing caesarian section. Hypotension during spinal anaesthesia for caesarean section is a common complication. Here a study was designed to compare crystalloid preload and coload in parturients for caesarian section under

Material and Methods: 300 patients of age between 18-40yrs and weight 45-75Kg with ASA I/II Full term, singleton pregnancies undergoing elective caesarean section. Exclusion criteria includes any contraindication to spinal anaesthesia, diabetes, cardiovascular, cerebrovascular diseases, renal disorders, known fetal abnormalities.

This Prospective Randomized controlled study was conducted after institutional and ethics committee approval and written informed consent from patients recruited for the study were obtained. Preanaesthetic check done prior to surgery included physical examination and investigations as per requirement for the surgery. Tablet Ranitidine 150mg was administered orally the night before surgery. Inj. metoclopromide10 mg IV was given thirty minutes prior to surgery. All the patients had two intravenous cannulae, one for administration of fluid and the other for injecting drugs. On arrival in the operation room, non-invasive monitoring was instituted including ECG, NIBP and Spo2. Baseline heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) was calculated as the mean of three consecutive readings at 3min intervals during which the SBP did not vary by more than 10% from the average value. Patients were allocated into two groups randomly using computer generated random numbers. In Group P:n=150 (Preload) the patients received 15ml/kg of Ringer Lactate solution over a period of 15-20min before the subarachnoid block. Group C:n=150 (Coload) patients received 15ml/kg of Ringer lactate solution using a pressurised infusion system as soon as CSF was tapped to administer fluid at the maximal possible rate over20min.All patients received 10-12 mg of 0.5% hyperbaric bupivacaine intrathecally in the sitting position in L3-4 intervertebral space with 25 gauge Quinckes spinal needle. After the subarachnoid injection, the patients were made supine with a 15 degrees wedge under the right hip. The sensory level was assessed using pin prick using 25G needle every 5min till the level was stabilized for at least three consecutive readings. After achieving a block height of T 4-5, the surgery was allowed to commence. The following parameters were recorded every 2 minutes after the spinal injection till the first 10min, every 5min till the next 20min and every 10 min thereafter till the end of surgery: heart rate, systolic, diastolic, mean arterial pressures and Spo2. The values obtained in the first 60 minutes were used for statistical analysis. Maternal hypotension was defined as a systolic blood pressure < 20% of calculated baseline value. Hypotension was treated with additional rapid bolus infusion (approximately 100ml) of lactated Ringer solution. If

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not responsive, 6mg intravenous bolus of ephedrine to maintain systolic blood pressure at baseline value. In the event of excessive blood loss (>800ml as assessed by volume in suction bottle and weighing of swabs), the patient was excluded from study and treated appropriately. Bradycardia was defined as a heart rate <50beats/min and treated with atropine 0.6mg. After delivery of the baby,the mother was given infusion of 20U of pitocin in normal saline as routine practice. The person charting the hemodynamic parameters was not involved in the study and was unaware whether the patient had been pre-loaded or co-loaded. The number of doses of ephedrine required to treat hypotension was recorded. The total volume of fluid received by the patient during the duration of surgery was assessed. The attending neonatologist determined the APGAR scores of the baby at 1min and 5min after delivery."After data collection, data analysis is done with the help of SPSS software Ver 15 and Sigma Plot Ver 12.Quantitative data is presented with the help of Mean & Standard Deviation, comparison between the study groups is done with the help of Unpaired T test. Qualitative data is presented with the help of Frequency and Percentage table, association among study group is assessed with Chi-Square test (Fisher Exact test is applied for 2*2 table).P Value <0.05 is taken as significant.

Result: The incidence of hypotension, extra fluid boluses and number of ephedrine doses administered was higher in preload than coload group and difference was statistically significant.

The neonatal APGAR score, the mean heart rate in both preload group & co-load was statistically insignificant.

Conclusion: Crystalloidcoload is more efficient than crystalloid preload in prevention of hypotension in caesarean section following spinal anaesthesia.

Keywords: Crystalloid, coload, preload, Hypotension, subarachnoid block.

Introduction

Regional anaesthesia is usually preferred over general anaesthesia in parturients because it avoids the problems like airway manipulation, polypharmacy, postoperative respiratory problem, cognitive dysfunction etc. Subarachnoid block is a rapid, reliable, safe, most appropriate technique anaesthesia for parturients undergoing caesarean section due to its beneficial effects on both mother and fetus. Hypotension during spinal anaesthesia for caesarean section is a common complication, deleterious both to the mother and fetus which increases intra-operative and postmorbidity.² Sustained operative maternal hypotension is associated with fetal hypoxia and acidosis as a result of placental hypoperfusion.³ Without preventive measures, the incidence of post-spinal hypotension in parturients can be as high as 82%⁴ and with the use of various preventive measures, it has been reported as 53%⁵ to 80% 6. An alternative approach of fluid bolus at the time of administration administering intrathecal local anaesthetic termed as "co-load"8 has been evaluated. It may be more rational and physiologically more appropriate because the maximum effect can be achieved during the time when the block &consequent vasodilatation from sympathetic blockade & limit redistribution & excretion. The purpose of our study was to compare preload and co-load for the prevention of maternal hypotension. We compared the hemodynamic parameters, the requirement of fluid boluses & ephedrine for the treatment of hypotension & neonatal APGAR scores between the two groups.

Materials and Methods

After receiving approval from the hospital ethical committee and written informed consent, 300 patients in the age group of 18-40 years, weight 45-75Kg belonging to ASA I or II Full term, pregnancies undergoing singleton elective caesarean section (common indications being previous caesarean section, breech presentation. cephalopelvic disproportion, transverse lie etc) under spinal anesthesia were included in this study. The exclusion criteria included any contraindication to spinal anaesthesia, diabetes, cardiovascular, cerebrovascular diseases, renal disorders. known fetal abnormalities. Preanaesthetic check done prior to surgery included physical examination and investigations as per requirement for the surgery. Tablet Ranitidine 150mg was administered orally the night before surgery. Inj. metoclopromide10 mg IV was given thirty minutes prior to surgery. All the patients had two intravenous cannulae, one for administration of fluid and the other for injecting

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On arrival in the operation room, nondrugs. invasive monitoring was instituted including ECG, NIBP and Spo2. Baseline heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) was calculated as the mean of consecutive readings at 3min intervals during which the SBP did not vary by more than 10% from the average value. Patients were allocated into two groups randomly using computer generated random numbers. In Group P the patients received 15ml/kg of Ringer Lactate solution over a period of 15-20min before the subarachnoid block. Group C patients received 15ml/kg of Ringer lactate solution using a pressurised infusion system as soon as CSF was tapped to administer fluid at the maximal possible rate over20min. All patients received 10-12 mg of 0.5% hyperbaric bupivacaine intrathecally in the sitting position in L3-4 intervertebral space with 25 gauge Quinckes spinal needle. After the subarachnoid injection, the patients were made supine with a 15 degrees wedge under the right hip. The sensory level was assessed using pin prick using 25G needle every 5min till the level was stabilized for at least three consecutive readings. After achieving a block height of T 4-5, the surgery was allowed to commence. The following parameters were recorded every 2 minutes after the spinal injection till the first 10min, every 5min till the next 20min and every 10 min thereafter till the end of surgery: heart rate, systolic, diastolic, mean arterial pressures and Spo2. The values obtained in the first 60 minutes were used for statistical analysis. Maternal hypotension was defined as a systolic blood pressure < 20% of calculated baseline value. Hypotension was treated with additional rapid bolus infusion (approximately 100ml) of lactated Ringer solution. If not responsive, intravenous bolus of ephedrine to maintain systolic blood pressure at baseline value. In the event of excessive blood loss (>800ml as assessed by volume in suction bottle and weighing of swabs), the patient was excluded from study and treated appropriately. Bradycardia was defined as

a heart rate less than 50beats/min and treated with atropine 0.6mg. After delivery of the baby, the mother was given infusion of 20 U of pitocin in normal saline as routine practice. The person charting the hemodynamic parameters was not involved in the study and was unaware whether the patient had been pre-loaded or co-loaded. The number of doses of ephedrine required to treat hypotension was recorded. The total volume of fluid received by the patient during the duration of surgery was assessed. The attending neonatologist determined the APGAR scores of the baby at 1min and 5min after delivery."After data collection, data entry was done in Excel. Data analysis is done with the help of SPSS software Ver 15 and Sigma Plot Ver 12. Quantitative data is presented with the help of Mean & Standard Deviation, comparison between the study groups is done with the help of Unpaired T test.

Qualitative data is presented with the help of Frequency and Percentage table, association among study group is assessed with Chi-Square test (Fisher Exact test is applied for 2*2 table).

P Value < 0.05 is taken as significant.

Result

There was no statistically significant difference between two groups in demographic data i.eage, weight, ASA grade, distribution among study groups (table 1).

| Parameter | Group P | Group C | P value |
|-------------|---------------------|---------------------|---------|
| | (n=150) | (n=150) | |
| Age (years) | 24.73 | 24.87 <u>+</u> 3.12 | 0.692 |
| Weight (kg) | 69.20 <u>+</u> 3.57 | 69.20 <u>+</u> 3.57 | 1.0 |
| ASA I :II | 137:13 | 138:12 | 0.835 |

It is seen that during the entire observation period, there was no statistically significant difference between the mean heart rate of patients in preload and coload groups, p>0.05 (Figure 1).

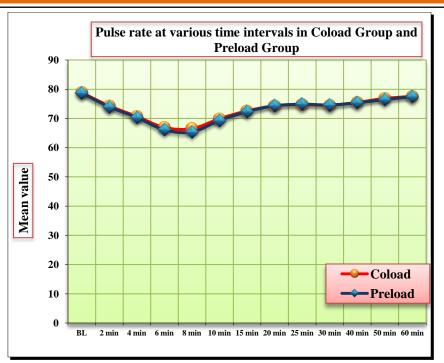


Fig 01

From Figure 2, the Systolic BP was not found to be statistically significant (p>0.05) except at 8 minutes, systolic BP in coload group was 105+_8.29 and in preload group was

102.84+_8.67(p=0.006).18.7% of patients from coload group developed systolic hypotension & 36% from preload group developed systolic hypotension.

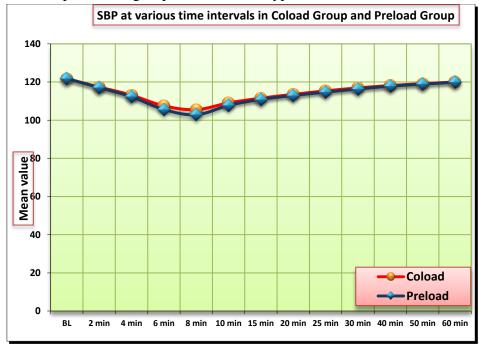


Fig 02

There was statistically insignificant difference between the mean diastolic BP of pre-load and coload groups, p>0.05.

It is seen that there was in significant difference of APGAR score at 1 minute and 5 minute between pre-load and co-load groups(p=1).

Figure 3, it is seen that there was statistically significant difference between the pre-load and co-load groups with respect to Ephedrine requirement.15.3% patients from co-load group versus 34% patients in the preload group required Ephedrine. (p <0.001).

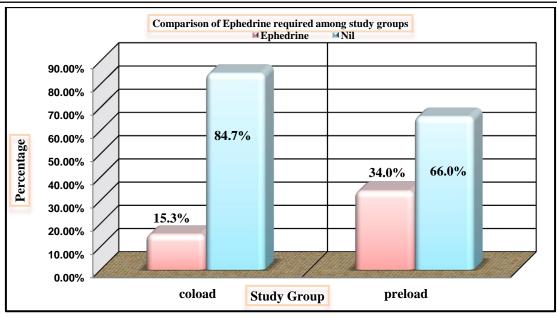


Fig 03

Figure 4,it is seen that there was statistically significant difference with respect to fluid boluses required to maintain BP. Mean fluid boluses(ml) given, in coload group was 1104.33 ± 155.7 and in

preload was 1187.77±198.77(p=<0.001). 18.7% patients in coload group versus 38 % patients in preload group required Fluid boluses.

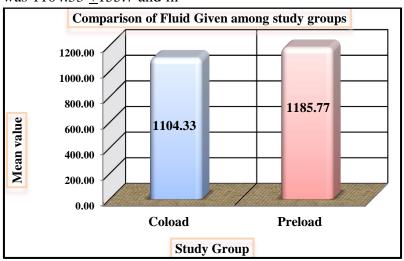


Fig 04

Discussion

Spinal anaesthesia is frequently used method for caesarean section because it is a simple technique and highly effective while avoiding morbidity and mortality associated with general anaesthesia 1 .Involvement of the cardiovascular system is the most important physiologic response to spinal anaesthesia which leads to higher incidence of maternal hypotension, fetal distress & maternal discomfort ⁹. Many studies have now questioned the value of traditional preloading techniques for prevention of spinal anesthesia induced hypotension during cesarean section. The first

study to challenge the role of preloading was that of Clark et al¹⁰, who studied the use of fluid loading, both with and without uterine displacement, comparing them with controls with neither prophylactic measure. One of the possible reasons for the decreased efficacy of crystalloid solutions as prophylaxis against spinal induced hypotension is that as much as 75% of any crystalloid diffuses into the interstitial space 11. The results from our study showed that the incidence of hypotension was lesser in the coload group as compared to the preload group (18.7% vs 36%) but this difference was not significant statistically.

Our results are comparable with Dyer et al⁸& Mojica et al¹² they reported that rapid crystalloid infusion of 20ml/kg after induction of spinal anaesthesia (coload) is relatively more effective than crystalloid preload of 20 ml/kg in preventing hypotension. Jacob et al¹³ also studied effect of crystalloid preload of 15ml/kg of Ringer Lactate solution & crystalloid coload of 15ml/kg of Ringer Lactate solution in parturient undergoing caesarean section & found the incidence of hypotension was similar between the two groups. Also Carvalho B et al¹⁴compared hetastarch preloading & coloading in parturients undergoing caesarean section, showed change in heart rate was statistically insignificant. The effects of varying the amount of crystalloid preload volume prior to spinal anesthesia were studied by Park et al¹⁵who compared 10, 20 and 30 ml/kg crystalloid preload and showed that there was no difference in the incidence of hypotension. A recent metaanalysis also concludes that the timing of fluid loading does not have impact on the incidence of hypotension¹⁶. The variation in incidence of hypotension in these studies may be explained by difference in volume of fluid administered & the different rates of fluid administration of the crystalloids. Although crystalloid is safe during pregnancy, large volume of crystalloid preload can lead to hemodilution and pulmonary oedema in susceptible parturient possibly because of increase in lung water during pregnancy¹⁷.Preload before spinal anaesthesia is rapidly redistributed & may induce atrial natriuretic peptide secretion resulting in vasodilatation followed by increased rate of excretion of preloaded fluid ¹⁸. Dyer et al.⁸ suggested that coloading might increase intravascular volume expansion during vasodilatation from the sympathetic blockade and limit fluid redistribution and excretion. In our study ,it is seen that duringthe mean heart rate in both preload group & coload was statistically insignificant (p=). In both groups, there was early onset of fall in heart rate till 8 minutes after this heart rate is settled to baseline, it was statistically insignificant(p>0.05). This result was comparable

with that of Jacob et al¹³, who studied effect of preload & coload of 15ml/kg of Ringer Lactate solution in parturients undergoing caesarean section ,the changes in the mean heart rate in preload group & coload group was statistically insignificant. There was statistically significant difference between the preload and coload groups with respect to Ephedrine requirement.15.3% patients from coload group versus 34% patients in the preload group required Ephedrine. (p < 0.001). This result is comparable to Dyer RA et at⁸where significantly more patients in preload group vasopressor (ephedrine) required (p=0.047). Ah-Young oh at al¹⁹ studied the effect of timing of crystalloid administration preload (15ml/kg)versus coload (15ml/kg) on maternal hypotension undergoing caesarean section during spinal anaesthesia showed smaller dose of ephedrine was required in coload group (p=0.015). It is seen that there was statistically significant difference with respect to fluid boluses required to maintain BP. Mean fluid boluses(ml) given, in co-load group was 1104.33 +155.7 and in pre-load was 1187.77+198.77 (p=<0.001). 18.7% patients in co-load group versus 38 % patients in pre-load group required Fluid boluses. Therefore it is commented that timing of fluid administration is important to prevent spinal hypotension. This increase in fluid requirement in preload group is may be because of rapid redistribution & excretion of crystalloid 18. our results are comparable to Jacob et al¹³, where patients in preload group received a larger total volume of crystalloid as compared to those in the coload group, however this difference was statistically not significant. Siddik Sayyid et al²⁰, compared colloid preload to coload during spinal anaesthesia for elective caesarean section there was no difference in the total requirement of Ringer Lactate solution at the time of hypotension. Our study revealed that despite 18-38 % incidence of hypotension, neonatal outcome in terms of APGAR score at 1 & 5 minutes was similar in both preload as well as coload group & difference was statistically not significant at 1min.&

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5min.after birth (p =1). Our results are comparable to Siddik-sayyid et al ²⁰, Jacob et al ¹³Dyer et al ⁸& Mojica et al ¹² they compared the effect of crystalloid coload & crystalloid preload for parturients undergoing caesarean section in under spinal anaesthesia showed, neonatal outcome was similar in both group. Our study had limitations. We studied only APGAR score to evaluate fetal outcome in place of umbilical blood pH and blood gas status as the same was not available in our obstetric facility. We did not investigate the correlation between umbilical artery pH, and spinal induction time to baby delivery time, uterine incision - delivery interval, as did Dyer et al ⁸.

Conclusion

We conclude as per our observation & results, that crystalloid coload is more efficient than crystalloid preload in prevention of hypotension in caesarean section following spinal anaesthesia. The preload group required more fluid boluses & ephedrine as compared to the coload group. Neonatal APGAR score remained equally good in both group.

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