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RESEARCH ARTICLE

COLLOID VERSUS CRYSTALLOID COLOAD FOR THE PREVENTION OF SPINAL ANEASTHESIA INDUCED HYPOTENSION OF ELECTIVE CAESAREAN SECTION

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ABSTRACT

Background: Spinal anaesthesia is the standard technique for elective caesarean section, but hypotension remains the main complication with this technique. This hypotension has detrimental effects on both mother and foetus. To prevent hypotension, crystalloid or colloid coload with vesopressor may be an alternate choice.
Aim: To compare the efficacy of crystalloid and colloid coload in presence of phenylephrine infusion for the prevention of spinal anaesthesia induced hypotension.
Methods: Forty subjects (40) are randomly allocated into two groups. Subjects were infused either crystalloid or colloid within 10 minutes after spinal anaesthesia (coload).Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP) and oxygen saturation were recorded in three minutes interval throughout the surgery. Continuous ECG monitoring was done. Adverse events (nausea, vomiting etc) if any were recorded in case report form (CRF). Phenylephrine infusion was continued at the rate of 40 mcg/min throughout the surgery.
Results: Demographic parameters were comparable. HR, SBP, DBP, MBP, Oxygen saturation all are comparable between the groups and within the group in various time period. There was no episode of nausea or vomiting and no requirement of rescue medication of phenylephrine 100 mcg intravenously.
Conclusion: There is no difference of efficacy of crystalloid and colloid, when use as coload with phenylephrine infusion for the prevention of spinal anaesthesia induced hypotension.
Key words: *spinal anaesthesia, crystalloid, colloid, hypotension*

INTRODUCTION

Spinal anaesthesia is the standard technique for elective caesarean section worldwide. However, hypotension remains the main complication with this technique. The incidence of hypotension is more than 80% without any prophylactic measures. This hypotension with or without bradycardia has detrimental effects on both mother (nausea, vomiting, dyspnoea etc) and foetus (acidosis, neurologic injuries, etc). [1]

This complication can be managed by multiple approaches like fluid therapy, use of vesopressor or simultaneous administration of fluid therapy and vesopressor.

Fluid infused before or at the time of induction of spinal anesthesia is referred to as "preloading" and "coloading," respectively.[2]

Early reports suggested that this complication could be prevented by infusing a bolus of fluid before induction of anesthesia, but this strategy, along with others that increase central blood volume, has met with limited success.[3]

Recently, some authors have suggested that fluid administration should take place at the time of induction of anesthesia for Cesarean delivery.[3]

Among the type of fluids (crystalloid or colloid) which one is better, is still not known.

Crystalloid has a short intravascular half-life because of its rapid distribution into the interstitial space. [4] In contrast to crystalloid, colloid remains for a longer period within the intravascular space.[5]

Phenylephrine, a pure α adrenergic agonist whose action is to counteract the decreased systemic vascular resistance induced by spinal anaesthesia, without increasing the heart rate. It has been found to be effective when given in infusion. Unlike ephedrine, phenylephrine is a rapidly acting potent vasoconstrictor with a short duration of action. Phenylephrine is more effective than ephedrine seen in controlled clinical trial.[1]

On this background, the study was conducted to determine the efficacy of crystalloid and colloid,when use as coloding along with vasoconstrictor-phenylephrine for the prevention of spinal induced hypotension.

MATERIALS AND METHODS

Ethical Considerations:

The study protocol, informed consent form (in Bengali, Hindi & English) and case report form (CRF) were submitted to the ethics committee of College of Medicine & JNM Hospital, Kolkata West Bengal for approval. Subject recruitment commenced only after approval was obtained. Written informed consent was taken from each participant. Illiterate individuals gave their fingerprint (left thumb impression) instead of signature in the presence of an appropriate witness.

Subject selection criteria:

The subjects who had willingly participated were enrolled on the basis of inclusion and exclusion criteria.

Pregnant mothers older than 18 years, ASA (American Society of Anaesthesiologists) physical status I or II, weighing more than 50 kg and less than 90 kg, having uncomplicated singleton pregnancy beyond 36 weeks, scheduled to had elective caesarean section under spinal anaesthesia were eligible for this study.

But patients who had suffering from hypertension (resting arterial pressure greater than 160/90 mm Hg.),had known coronary artery disease, cardiac valvular regurgitation and or stenosis, neuromuscular disorders or had a history of coagulation disorder or other systemic illness (renal disease, diabetes mellitus etc) were excluded from this study.

Study Setting:

The study was conducted in the Department of Anaesthesiology, College of Medicine & JNM Hospital (COMJNMH), Kalyani, Nadia, West Bengal.

Screening:

Through Obstetrics Indoor Department, COMJNMH.

Drug dispensing:

Gynecology Operation Theatre

Data compilation and Statistical analysis:

In Department of Pharmacology, COMJNMH.

Study Design:

The current study was designed as a prospective, interventional, randomized, double blind, with two parallel treatment groups and unicentric.

Study period:

The study was conducted from February 2013-April 2013.

Regulatory Considerations:

Since the study medication (crystalloid, colloid and phenylephrine) were already marketed in India at the time of study inception, no separate regulatory approval from the Drugs Controller General of India was sought.

Study Groups and Randomization:

A random number table generated by computer in blocks of 100. The large block size reduced the risk of allocation bias. The study coordinator was the only person with access to the randomization. According to the randomization sequence subjects fulfilling the selection criteria were received either crystalloid group (CR Group) or Colloid group (CO Group). Preprinted sheets within sealed sequentially numbered opaque envelopes contained information on group allocation.

Blinding:

Study was designed as double-blind study.

METHODS

After recruitment, a detailed medical history was taken followed by thorough clinical examination which included both general and systemic examination. After screening, the patients who fulfilled the selection criteria were randomized and allocated in either group.

Patients received no premedication. Before spinal anesthesia, two 18 gauge I.V. (intravenous) catheter were introduced in the vein of left and right forearm of each patient.

Non invasive blood pressure (BP), electrocardiography (ECG) and pulse oximetry were then attached for monitoring blood pressure (systolic, diastolic and mean arterial pressure), pulse rate and O2 saturation. Baseline measures of heart rate (HR), systolic BP (SBP), oxygen saturation were taken. SBP and baseline HR were taken as the mean of 3 readings within 10% of each other with the BP recorded from the dependent arm. Then, MBP (mean arterial blood pressure), SBP (systolic blood pressure), DBP (diastolic blood pressure), HR was recorded throughout the surgery in three minutes interval.

After that Patients were placed in sitting position and after antiseptic dressing and draping, a 25 gauge spinal needle was inserted in L3-4 vertebral interspace and hyperbaric bupivacaine 0.5%, 2.5 ml was administered intrathecally. Thereafter, patients were placed supine with left lateral uterine displacement at 15° angle. The crystalloid group received 15ml/kg Ringer Lactate (RL) and the colloid group received 7ml/kg 6% hetastarch. Each infusion was commenced at the time of spinal injection and completed within 10 minutes. No further fluid was given until after delivery. The phenylephrine infusion was also started at the time of spinal injection at a rate of 40 mcg/min and was either on or off according to BP measurements determined at 3-minutes intervals. The infusion continued if the BP was at or below baseline SBP (bSBP) and turned off if above baseline. Two successive readings of hypotension (SBP - ≤80% bSBP) were treated with phenylephrine 100 mcg from the rescue syringe. The phenylephrine infusion was stopped for 2 consecutive readings of bradycardia (HR <50 bpm) with SBP at bSBP. Atropine 0.6mg mg was administered for 2 consecutive readings of bradycardia. Motor block and the upper sensory level of anesthesia to light touch were also assessed. Monitoring was conducted before and at 3-minutes intervals throughout the surgery. Surgery was allowed to commence if a sensory block to touch at the T5 dermatome was present. No further assessments of block height were recorded once surgery commenced. Hypotensive episodes, defined as SBP <80% bSBP and hypertensive episodes defined as SBP ≥120% bSBP were recorded. The total dose of phenylephrine from the time of spinal injection to delivery was recorded. The presence of nausea and vomiting was measured on a 3-point scale of 1, 2, and 3 indicating no nausea and no vomiting, nausea only, and both nausea and vomiting, respectively. Assessments were done at 5-minute intervals, until 20 minutes after the spinal injection, and when the parturient complained of sickness.

STATISTICAL ANALYSIS

Continuous data were given as mean ± standard error of mean (±SEM). As the continuous data were not passing the normality test, non-parametric statistics were performed. Nonparametric Mann-Whitney test was employed to find the significant difference ($p<0.05$) between the two groups (intergroup comparison). Friedman's ANOVA test followed by Dunn's Multiple Comparison test as post hoc test was employed to find the significance in the intragroup

 ISSN: 2250-1177 CODEN (USA): JDDTAO

in various time periods. The computer software graph pad instat version 3.06.was used for all the statistical analysis.

RESULT AND ANALYSIS

Forty subjects (40) were randomized and equally distributed into two groups (20 subjects in each group) during the period of February 2013 to April. The patient's characteristics like age, weight, duration of surgery, baseline mean values are tabulated in table 1 and figure 1, 2, and 3.

Table 1: Shows subject characteristics and baseline values

PARAMETERS	GROUP CO (N=20)	GROUP CR (N=20)	*p* VALUE
AGE	23.1 ± 0.9	29.8 ± 7.1	0.79
WEIGHT	55.6 ± 1.2	58.3 ± 0.7	0.62
DURATION OF SURGERY	26.3± 1.52	25.7 ± 0.8	0.73
BASELINE HR	86.8 ± 2.78	90.7 ± 2.21	3.21
BASELINE SBP	125 ± 2.16	122 ± 4.2	0.56
BASELINE DBP	81.6 ± 1.75	76.3 ± 2.7	0.12
BASELINE MBP	94 ± 2.4	89.4 ± 3.04	0.44
BASELINE O2 SATURATION	98.7 ± 0.44	99.2 ± 0.134	0.48

***p* value <0.05 means significant. *p* value from non parametric Mann-Whitney test.**

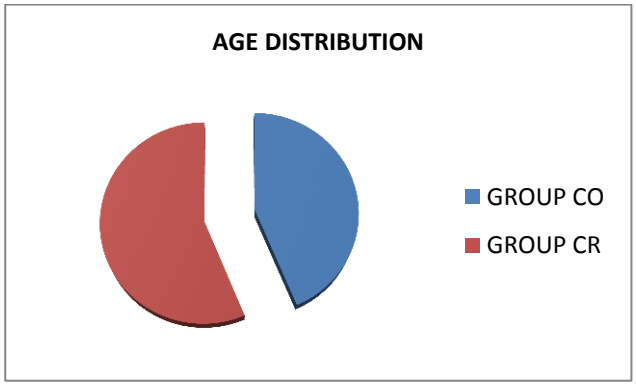

FIGURE 1: Shows age distribution in the study groups

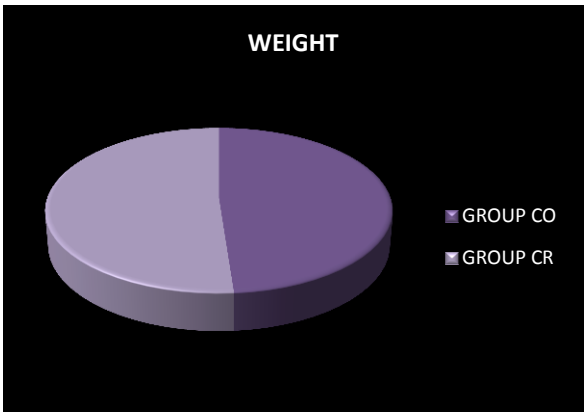

FIGURE 2: Shows distribution of weight between two groups

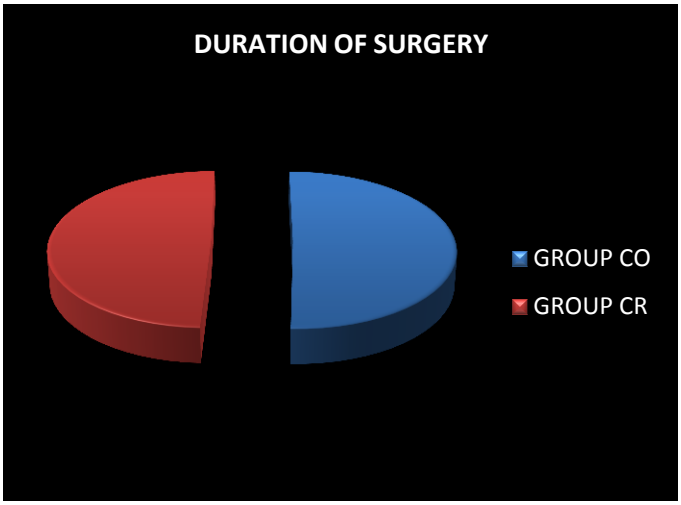

FIGURE 3: Shows duration of surgery between two groups

TOTAL REQUIREMENT OF PHENYLEPHRINE

The phenylephrine was infused throughout the operation at the rate of 40 mcg/minute. No rescue medication was needed in any subject. Table 2 and figure 4 show the requirement of phenylephrine.

TABLE 2: Shows total requirement of phenylephrine in both groups

PARAMETER	GROUP CO (N=20)	GROUP CR (N=20)	*p* VALUE
PHENYLEPHRINE (mcg)	1052 ± 61.11	1028 ± 32.13	0.44

p value >0.05 means non significant. p value from non parametric Mann-Whitney test.

 ISSN: 2250-1177 CODEN (USA): JDDTAO

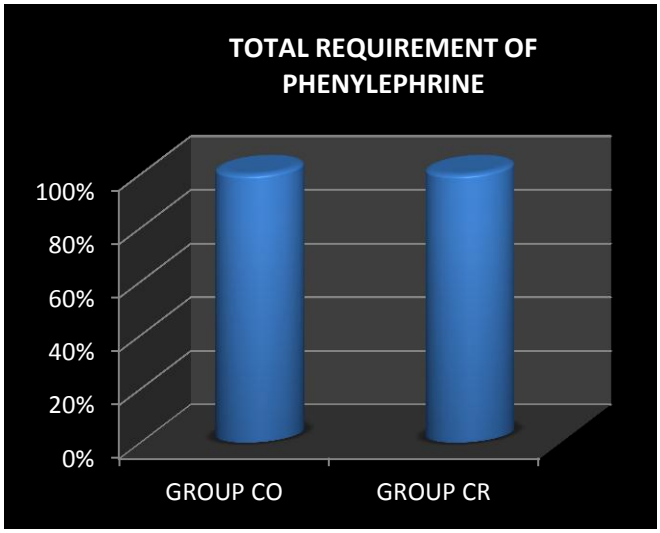

FIGURE 4: Total requirement of phenylephrine (in mcg) in two groups

HEART RATE (HR):

Heart rate was taken at baseline (HR1), then throughout the surgery in 3 minutes interval. Table 3 and figure 5 shows the comparison of the HR (beats/min) between two groups.

TABLE 3: Comparison of heart rate (beats/min) in intraoperative period in two groups

HEART RATE	GROUP CO (N=20)	GROUP CR (N=20)	*p* VALUE
H1	86.8 ± 2.78	90.7 ± 2.21	0.32
H2	82.72 ± 3.86	96 ± 4.68	0.37
H3	92.45 ± 5.18	91.8 ± 5.3	0.17
H4	84.72 ± 3.67	85 ± 4.36	0.54
H5	90.9 ± 3.99	81.6 ± 5.3	0.64
H6	92.7 ± 4.39	83.1 ± 3.68	0.16
H7	92.6 ± 3.66	88.34 ± 5.03	0.59
H8	94 ± 3.34	93 ± 1.2	0.71
H9	93.8 ± 2.81	94.6 ± 2.1	0.92

p value from Nonparametric Mann-Whitney test was employed to find the significant difference (p<0.05) between the two groups, and Friedman's ANOVA test was employed to find the significance in the intra-group in various time periods. p value >0.05 means non-significant.

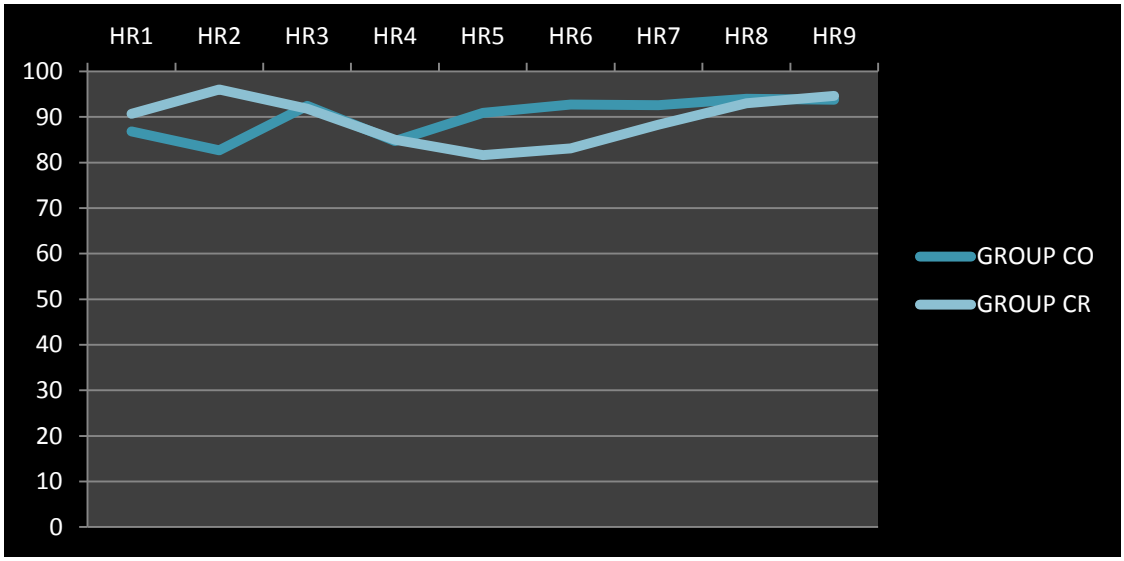

FIGURE 5: Shows the heart rate of both groups in various time periods

SYSTOLIC BLOOD PRESSURE (SBP)

SBP was taken at baseline (SBP1), then throughout the surgery in 3 minutes interval. Table 4 and figure 6 shows the comparison of the SBP (in mm of Hg) between two groups.

TABLE 4: Shows the comparison of SBP between two groups in various time periods

SYSTOLIC BLOOD PRESSURE	GROUP CO (N=20) [mm of Hg]	GROUP CR (N=20) [mm of Hg]	*p* VALUE
SBP 1	125 ± 2.16	122 ± 4.2	0.56
SBP 2	118 ± 3.9	113.7 ± 2.48	0.40
SBP3	121.5 ± 4.15	116.3 ± 2.23	0.32
SBP 4	115.1 ± 4.08	114.6 ± 2.32	0.96
SBP 5	114.4 ± 4.39	114.3 ± 3.58	0.90
SBP 6	114.12 ± 3.54	111.2 ± 2.92	0.71
SBP 7	115.34 ± 3.37	108.85 ± 3.12	0.24
SBP 8	110.89 ± 3.93	112 ± 3.05	0.64
SBP 9	109.8 ± 4.46	115.34 ± 2.90	0.39

p value from Nonparametric Mann-Whitney test was employed to find the significant difference (p<0.05) between the two groups, and Friedman's ANOVA test was employed to find the significance in the intra-group in various time periods. p value >0.05 means non significant.

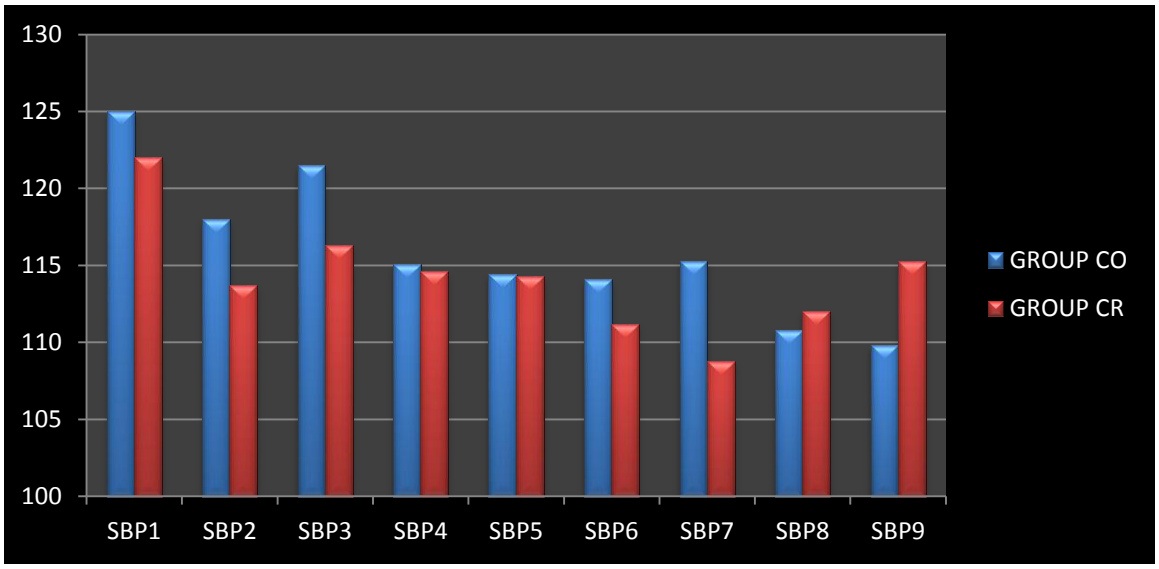

FIGURE 6: Shows the SBP (in mm of Hg) of both groups in various time periods

DIASTOLIC BLOOD PRESSURE (SBP)

DBP was taken at baseline (DBP1), then throughout the surgery in 3 minutes interval. Table 5 and figure 7 shows the comparison of the DBP (in mm of Hg) between two groups.

TABLE 5: Shows the comparison of DBP between two groups in various time periods.

SYSTOLIC BLOOD PRESSURE	GROUP CO (N=20)	GROUP CR (N=20)	*p* VALUE
SBP 1	81.6 ± 1.75	76.3 ± 2.72	0.12
SBP 2	78.6 ± 2.8	73 ± 2.60	0.17
SBP3	75.8 ± 2.49	70 ± 2.13	0.05
SBP 4	67.6 ± 3.0	67.2 ± 2.96	0.82
SBP 5	70.1 ± 3.17	66.7 ± 3.04	0.64
SBP 6	69.89 ± 3.34	67.5 ± 2.67	0.65
SBP 7	70.23 ± 3.15	61.85 ± 3.45	0.1
SBP 8	67.89 ± 4.45	62.67 ± 6.36	0.51
SBP 9	64.2 ± 6.19	69.67 ± 1.20	0.98

p value from Nonparametric Mann-Whitney test was employed to find the significant difference (p<0.05) between the two groups, and Friedman's ANOVA test was employed to find the significance in the intra-group in various time periods. p value >0.05 means non significant.

 ISSN: 2250-1177 CODEN (USA): JDDTAO

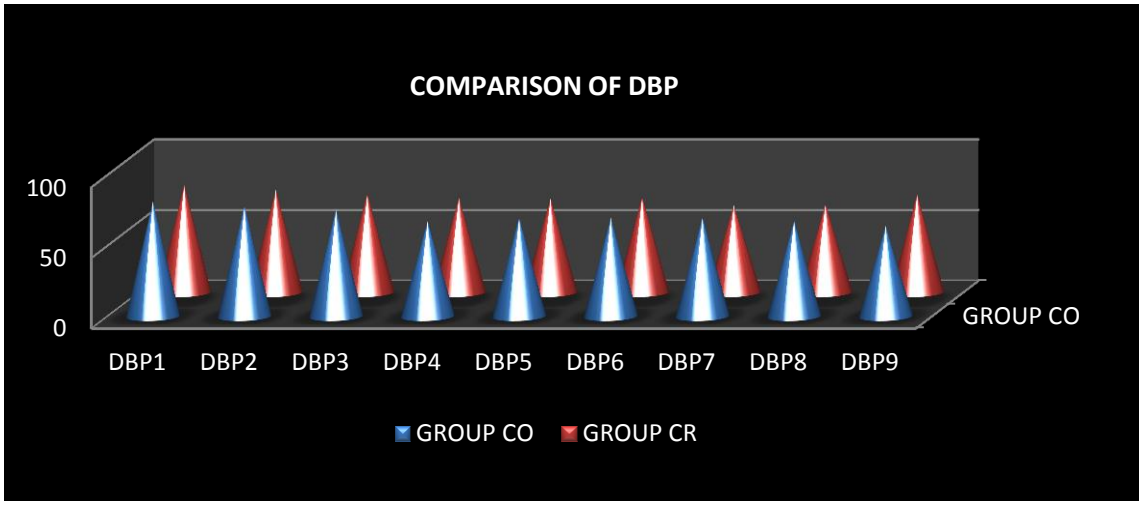

FIGURE 7: Shows the DBP (in mm of Hg) of both groups in various time periods

MEAN BLOOD PRESSURE (MBP)

MBP was taken at baseline (MBP1), then throughout the surgery in 3 minutes interval. Table 6 and figure 8 shows the comparison of the MBP (in mm of Hg) between two groups.

TABLE 6: Shows the comparison of MBP between two groups in various time periods

MEAN BLOOD PRESSURE	GROUP CO (N=20)	GROUP CR (N=20)	*P* VALUE
MBP 1	94 ± 2.4	89.4 ± 3.04	0.44
MBP 2	91.1 ± 3.2	83.6 ± 1.88	0.08
MBP3	89.3 ± 2.26	82.7 ± 2.64	0.1
MBP 4	83.3 ± 3.02	82.8 ± 2.7	0.87
MBP 5	84.6 ± 3.24	83.4 ± 2.68	0.84
MBP 6	84.56 ± 3.01	83 ± 2.68	0.9
MBP 7	85.12 ± 3.12	72.84 ± 3.63	0.05
MBP 8	82.12 ± 4.19	72 ± 8	0.4
MBP 9	80 ± 5.72	72 ± 5.2	0.57

p value from Nonparametric Mann-Whitney test was employed to find the significant difference ($p<0.05$) between the two groups, and Friedman's ANOVA test was employed to find the significance in the intra-group in various time periods. p value >0.05 means non significant.

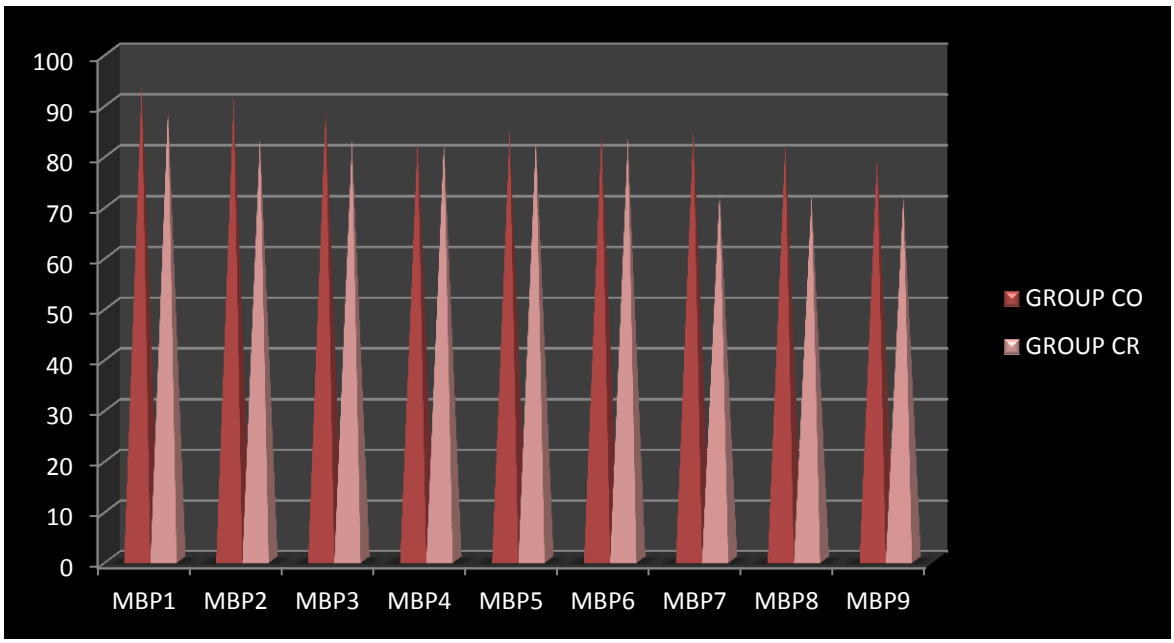

FIGURE 8: Shows the MBP (in mm of Hg) of both groups in various time periods

OXIGEN SATURATION (%)

Oxygen saturation was taken at baseline (OX1), then throughout the surgery in 3 minutes interval. Table 7 shows the comparison of the oxygen saturation between two groups in various time periods.

TABLE 7: Shows the oxygen saturation between two groups in various time periods

OXIGEN SATURATION	GROUP CO (N=20)	GROUP CR (N=20)	*p* VALUE
OX 1	98.7 ± 0.44	99.2 ± 0.13	0.42
OX2	99 ± 0.21	99.5 ± 0.16	0.09
OX3	98.6 ± 0.4	99.5 ± 0.16	0.06
OX4	99.3 ± 0.3	99.5 ± 0.16	0.7
OX5	98.8 ± 0.29	99.5 ± 0.22	0.3
OX6	98.88 ± 0.4	99.6 ± 0.16	0.12
OX7	98.88 ± 0.4	99.42 ± 0.29	0.28
OX8	98.75 ± 0.41	99.5 ± 0.28	0.3
OX9	99 ± 0.54	99.8 ± 0.21	0.31

p value from Nonparametric Mann-Whitney test was employed to find the significant difference ($p<0.05$) between the two groups, and Friedman's ANOVA test was employed to find the significance in the intra-group in various time periods. *p* value >0.05 means non significant.

ADVERSE EVENTS

Patients had no episode of hypotension or hypertension during the operation. There was no single episode of ECG abnormality. There was no complaining of nausea or vomiting by any subject during the study period.

DISCUSSION

Although spinal anaesthesia is the standard technique for elective caesarean section but hypotension (incidence 80%) remains the main complication without any prophylactic measures. This hypotension has detrimental effects on both mother and foetus.[1]

Fluid therapy is a prophylactic measure for prevention of spinal anaesthesia induced hypotension. Unfortunately, no fluid regimen alone has proven to be effective enough for preventing hypotension associated with spinal anesthesia during cesarean delivery.[6]

In a study, it was seen that there was no difference in the incidence of hypotension in women who received colloid administration before the initiation of spinal anesthesia compared with at the time of initiation of anesthesia. Both modalities are inefficient as single interventions to prevent hypotension.[6]

Another study suggested that applying fluid loading at the time of administering the intrathecal local anaesthesia (coload) may be more rational approach for the prevention of post spinal hypotension. Coload might be more physiologically more appropriate because maximal effect can be achieved during the time of the block.[7]

A randomized controlled study has shown that combining a phenylephrine infusion with a crystalloid coload, during spinal anesthesia for elective cesarean delivery, dramatically reduces hypotension compared with no coload.[2]

In several study it was found that preloading of colloid is much more effective than preloading of crystalloid for the prevention of spinal anesthesia induced hypotension. [8,9]

In our study we went to find out the role of colloid and crystalloid fluid therapy as coload in the presence of vasopressor phenylephrine for the prevension of spinal anesthesia induced hypotension during elective cesarean section.

40 subjects were randomly allocated into two groups and after completion of 40 subjects we found that there were comparable demographic profiles like age, weight and there were no statistical differences between baseline parameters of both groups.

Total requirement of phenylephrine in both Group CO and Group CR were comparable. Statistical analysis was done by non parametric Mann-Whitney test (*p* value 0.44).

The HR, SBP, DBP, MBP, and Oxygen saturation all are comparable within group (intra-group) in various time periods when analysed by nonparametric Friedman's ANOVA. All the parameters were also comparable between the groups when analysed by Nonparametric Mann-Whitney test.

There was no single episode of hypotension in any group, so there was no requirement of rescue medication.

This result collaborate with a randomized controlled trial (RCT), where it was found that no advantage in using colloid over crystalloid when used in combination with a phenylephrine infusion during spinal anesthesia for elective cesarean delivery. [2]

The main limitation of this study was that, there was absence of placebo group, so that it is impossible to determine absolute level of efficacy.

CONCLUSION

To conclude, there are no differences of efficacy between colloid and crystalloid, when use as coloading, in the presence of phenylephrine infusion, for the prevention of spinal anaesthesia induced hypotension in elective cesarean section.

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 ISSN: 2250-1177 CODEN (USA): JDDTAO