A COMPARATIVE STUDY OF CRYSTALLOID PRELOADING VERSUS EPHEDRINE INFUSION FOR PREVENTION OF HYPOTENSION DURING SPINAL ANAESTHESIA IN ELECTIVE CAESAREAN SECTION
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ABSTRACT: Anaesthesia to a parturient is not only unique but requires the highest degree of care because the anaesthesiologist has to look after two individuals, the mother and fetus. Caesarian section can be preferably performed under regional anaesthesia in elective or emergency circumstances because of inherent advantages. Parturient near term develop hypotension when they assume supine position because of aortocaval compression by the gravid uterus in supine position. This is compounded by spinal hypotension which may be detrimental to the mother and the resultant placentalhypoperfusion to the foetus. Ours was a clinical study comparing between crystalloid (ringer lactate) preloading v/s ephedrine infusion for prevention of hypotension during spinal anaesthesia in elective caesarean section” Methods: The study was conducted in sixty patients undergoing elective caesarean section. Patients selected were in the age group 20-35 years, ASA Grade I & II and weighing between 50-70 kgs. The selected patients were of a height between 145cm – 165cms. Patients were randomly allocated into two groups each comprising of thirty patients. Group I patients (preloading group) received preloading with 20ml/kg of Ringer lactate over 10-15min period preceding the subarachnoid block. Group II patients (Ephedrine infusion group) received infusion of ephedrine (50mg added to 500ml of ringer lactate) at a rate of 5mg/ min. for the first 2 min. and then the rate adjusted to 1mg/min. for the next 18 min. following spinal anaesthesia. After 20 min ephedrine infusion was stopped and plain Ringer lactate was continued as maintenance fluid and the study was conducted to compare falling in 1. Systolic blood pressure (SBP) 2. Mean arterial blood pressure (MAP) 3. diastolic blood pressure & pulse rate changes. RESULTS: The mean values of systolic blood pressure recorded preoperatively in Group I (109.73±5.77) and in Group II (109.00±7.47). This showed no statistical difference between the groups. The fall in SBP in Group I at 1 min. was 79.66±3.75. There was moderate fall in SBP in Group I. The fall in SBP in Group I was significant (P<0.05). There was moderate fall in DBP in Group I at 1 min (58.07±4.05). The fall in DBP is statistically not significant. (P>0.05). In Group-II, DBP raised at 1 min (81.13±3.81). The rise in DBP in Group-II was statistically significant. (P<0.05). The diastolic blood pressure was restored to near levels in Group I within 15 min and maintained throughout the intra-operative period with IV fluids and vasopressors (Ephedrine). Mention about sbp in group 2. There was moderate fall in MAP in Group I at 1 min (65.33±3.80). The fall in MAP was statistically significant. (P< 0.05). In Group-II, there was rise in MAP at 1 min (94.66±4.02). This rise in MAP in Group-II was statistically significant. (P < 0.05). All the parameters were comparable in the two groups and there was no significant statistical difference (P > 0.05). Tests of significance of the observed data from the two groups were carried out using “T” test and chi square test. P < 0.05 was taken as statistically significant.

KEYWORDS: Ephedrine, Elective caesarian section, Hypotention, Spinal Anaesthesia, Crystalloid solution.
INTRODUCTION: Anaesthesia to a pregnant women requires the highest degree of care because the anaesthesiologist has to look after two individuals, the mother and fetus. Caesarian section can be performed under general anaesthesia or regional anaesthesia in elective or emergency circumstances.

Regional anaesthesia remains the choice for caesarian section which requires blockade up to T4 level. Hypotension remains the commonest problem of spinal anaesthesia in obstetrics.

Ephedrine is an indirect-acting synthetic non-catecholamine. The pharmacological effects of this drug are due in part to endogenous release of norepinephrine (indirect acting), but the drug has direct stimulating effects on adrenergic receptors (direct acting).

The intravenous administration of ephedrine results in increases in systolic and diastolic blood pressure, heart rate, and cardiac output, thus reflecting α-receptor mediated peripheral arterial and venous vasoconstriction and increased myocardial contractility due to activation of β1-receptors. Uterine blood flow is not greatly altered when ephedrine is administered to restore blood pressure to normal after production of sympathetic nervous system blockade.

METHODOLOGY: After taking institutional ethical committee approval and written informed consent taken from the patient study was conducted in Sixty adult patients for elective caesarian section were randomly allocated into two groups each comprising of thirty patients. Patients selected were in the age group 20-35 years, ASA Grade I & II and weighing between 50-70 kgs. The selected patients were of a height between 145cm – 165cms. Study conducted at C. K. M Maternity Hospital, attached to Kakatiya Medical College, Warangal from October 2011 to May 2013.

Exclusion criteria:
1. Cardiovascular.
2. Respiratory disorders.
3. Hypotension.
4. Preeclampsia.
5. Diabetes.
6. Patients with hemoglobin concentration less than 10gm.
7. Contra indication to spinal anaesthesia.

Clinical history was obtained and thorough clinical examination was done in all patients. Biochemical investigations such as complete blood picture, haemoglobin, urine analysis, blood grouping, blood urea, serum creatinine and blood sugar were done in all cases.

Patients were explained about the technique and No premedication was given to any of the patient.

Patients were shifted to the operation theatre and baseline measurements of pulse rate, blood pressure and SPO2 were taken.

An 18 gauge cannula secured and Ringer lactate solution was used for preloading and giving additional boluses of IV fluids during events of hypotension. Another 20 gauge cannula was used for ephedrine infusion during spinal anaesthesia.

Group I patients (preloading group) received preloading with 20ml/kg of Ringer lactate over 10-15min period preceding the subarachnoid block.
Group II patients (Ephedrine infusion group) received infusion of ephedrine (50mg added to 500ml of ringer lactate) at a rate of 5mg/ min. for the first 2 min. and then the rate adjusted to 1mg/min. for the next 18 min. following spinal anaesthesia. After 20 min ephedrine infusion was stopped and plain Ringer lactate was continued as maintenance fluid.

Baseline recording of the pulse rate, blood pressure and SPO2 were taken before positioning the patients for subarachnoid block in Group-I (Preloading) and Group-II (Ephedrine infusion).

The following parameters were recorded:
1. Systolic blood pressure.
2. Diastolic blood pressure.
3. Mean arterial blood pressure.
4. Pulse rate.
5. Side effects like nausea and vomiting.

All blood pressures were monitored at 1Min, 5Min, 10Mins, 15Mins, 20Mins, 25Mins, 30Mins & at the end of the surgery to compare the fall in BP in two groups.

Statistics Analysis: Continuous data was analyzed by student’s t-test and categorical data by Chi-square test. Any possible significance has been determined considering it statistically significant if it’s P <0.05 % level of significance.

AGE DISTRIBUTION IN EACH GROUP-1

A total of 60 patients were studied with 30 in each group, The age varied from 20 years to 32 years, The mean age was 23.31 years.
THE DISTRIBUTION OF CASES STUDIED IN RELATION TO THEIR HEIGHT-2

Among the 60 patients studied, the height ranged from 145 to 163 cms. The mean height was 155.06 cms.

THE DISTRIBUTION OF CASES STUDIED IN RELATION TO THEIR WEIGHT-3

Among 60 patients studied the weight ranged from 48-68 Kgs. The mean weight was 58.19 Kgs.

RESULTS: The demographic data between two study groups were comparable.

DISCUSSION: Hypotension is common in elective or emergency caesarian sections after spinal anaesthesia. To prevent this many methods are followed. In these methods mainly volume preload (Jackson R, Reid JA, Thorburn J.).¹ and drug injections (Vasopressures) are used to prevent this hypotension.

Baseline recordings of pulse rate and blood pressure were recorded in the two groups before giving spinal anaesthesia.
HAEMODYNAMIC READINGS-1:

|       | Group-I         | Group-II        | P-Value |
|-------|-----------------|-----------------|---------|
| PR    | 88.06(4.61)     | 88.36(2.57)     | P > 0.05|
| SBP   | 109.73(4.61)    | 109.00(7.47)    | P > 0.05|
| DBP   | 73.27(3.58)     | 72.53(3.85)     | P > 0.05|
| MAP   | 85.06(3.83)     | 84.63(4.31)     | P > 0.05|

Table 1: Baseline recording

TRENDS OF PULSE RATE INTRAOPERATIVELY-4

The graph shows trends of pulse rate intra operatively. The mean pulse rate recorded pre-operatively in Group – I was 88.06±4.61, Group – II was 88.36±2.57. This showed no statistical difference between groups. The fall in the pulse rate in Group I (72.26±3.50) was not statistically significant (P > 0.05). The maximum rise in pulse rate was recorded in Group II at 5 min and 10 min. The mean values at 5 min. were 110.60±4.99 and at 10 min were 116.23±4.32. This rise in the pulse rate in Group II was statistically significant (P < 0.05).

There was a sudden fall in the haemodynamic recordings at 1 min after giving spinal anaesthesia.

The fall in the pulse rate was not statistically significant (P>0.05) in group I.

The rise in the pulse rate in Group II at 1 min was compared with pulse rate in Group I. This was statistically highly significant (P<0.001).

In Group I there was moderate fall in blood pressure. This was not statistically significant (P>0.05). In Group II the rise in blood pressure was significant statistically (P<0.05). Between Group I and Group II the difference in blood pressure was significant statistically (P<0.05).

The mean fall in blood pressure at 1 min in Group I was 80mmHg. There was moderate fall in blood pressure in Group I. In Group II there was rise in blood pressure at 1min (mean SAP 121mmHg) compared to baseline recording (mean SAP 109 mmHg).

The hemodynamic recordings were compared statistically every 5min. between the two groups.
The blood pressure reached near normal level after 15min in Group I. The blood pressure was maintained near normal levels in Group II after giving spinal anaesthesia.

In Group I and Group II the difference in blood pressure was statistically highly significant (P<0.001). In Group I there was maximum fall in blood pressure immediately after giving spinal anaesthesia and reached normal levels within 15min.

In Group II there was no fall in the blood pressure and the blood pressure maintained near normal levels throughout.

Between the groups, the maximum fall in blood pressure was recorded at 1 min. after the spinal anaesthesia. In group I the mean fall in SAP was 30mmHg. All these values were significant by chi square test.

In Group I, systolic blood pressure reached near normal levels within 20min after spinal anaesthesia. Mean SAP - pre operatively (107 mmHg) after 20 min (106 mmHg).

In group II, mean SAP pre-operatively (109 mm/Hg) and raised to 124 mmHg and maintained throughout surgery.

**TRENDS OF SYSTOLIC BLOOD PRESSURE INTRA OPERATIVELY-5**

This graph shows trends of systolic blood pressure intraoperatively in Group-I and Group-II. The mean values of systolic blood pressure recorded preoperatively in Group I (109.73±5.77) and in Group II (109.00±7.47). This showed no statistical difference between the groups. The fall in SBP in Group I at 1 min. was 79.66±3.75. There was moderate fall in SBP in Group I. The fall in SBP in Group I was significant (P < 0.05). The maximum rise in SBP recorded in Group II at 1 min 121.26±5.99 and maintained throughout the intraoperative period. The SBP was restored to normal levels in Group I within 15 min. and maintained near normal levels with IV fluid and vasopressors (Ephedrine).
OBSERVATIONS 1 MINUTE AFTER SPINAL ANAESTHESIA-2

|        | Group-I      | Group-II     | P-Value |
|--------|--------------|--------------|---------|
| PR     | 72.26(3.50)  | 98.56(2.02)  | P < 0.001 |
| SBP    | 79.66(3.75)  | 121.26(5.99) | P < 0.001 |
| DBP    | 58.07(4.05)  | 81.13(3.81)  | P < 0.001 |
| MAP    | 65.33(3.80)  | 94.66(4.02)  | P < 0.001 |

Table 2

The incidence of hypotension (decrease in systolic blood pressure more than 30mm Hg) in the preloading group 76% (23 in 30 patients) and in Group II (ephedrine infusion) 2 in 30 patients 6%.

Using the chi-square test, the incidence of hypotension was statistically significant in Group-I (P <0.05). In the Group-II the incidence of hypotension was not significant (P>0.05).

A similar study by S W Husaini, I F Russell, International Journal of Obstetric Anesthesia concluded that when ephedrine is infused prophylactically immediately following spinal anaesthesia for elective caesarean section, a 1000 ml crystalloid preload confers no advantages in terms of maternal blood pressure control or neonatal outcome.

In these trials hypotension was arbitrarily defined as decrease in systolic arterial pressure more than 30% of the baseline or less than 90mmHg.

Desalu I, Kushimo OT, concluded that prophylactic ephedrine given by standard infusion set was more effective than crystalloid prehydration in the prevention of hypotension during spinal anaesthesia for elective caesarean section.

Nevan M. El-Mekawy, concluded that intravenous infusion of ephedrine 1mg/min immediately after spinal anaesthesia for emergency caesarean sections, even if there is no enough time for proper prehydration, can control effectively the hypotension without episodes of hypertension or significant tachycardia.

TRENDS OF DIASTOLIC BLOOD PRESSURE INTRA OPERATIVELY-6
The infusion of intravenous fluid before administration of spinal anaesthesia as a prophylactic measure to prevent hypotension was extensively studied. Although it is possible that crystalloid prehydration may reduce the severity of hypotension, it cannot be relied on alone to prevent hypotension. The poor efficacy of crystalloid prehydration probably reflects rapid redistribution and limited augmentation of circulating volume (Clark RB, Thompson DS, Thomson CH).\(^5\)

In this study we evaluated the efficacy of preloading versus ephedrine infusion in prevention of spinal hypotension

### OBSERVATIONS 5 MINUTE AFTER SPINAL ANAESTHESIA-3

|          | Group-I     | Group-II    | P-Value   |
|----------|-------------|-------------|-----------|
| PR       | 77.90(3.95) | 110.60(4.99)| P < 0.001 |
| SBP      | 90.93(4.16) | 121.33(5.44)| P < 0.001 |
| DBP      | 66.00(4.61) | 81.87(3.19) | P < 0.001 |
| MAP      | 74.40(3.60) | 94.73(3.20) | P < 0.001 |

Table 3

### OBSERVATIONS 10 MINUTE AFTER SPINAL ANAESTHESIA-4

|          | Group-I     | Group-II    | P-Value   |
|----------|-------------|-------------|-----------|
| PR       | 78.76(2.72) | 116.23(4.32)| P < 0.001 |
| SBP      | 95.60(6.19) | 121.73(5.19)| P < 0.001 |
| DBP      | 67.67(4.61) | 82.47(3.39) | P < 0.001 |
| MAP      | 76.60(4.11) | 95.53(3.72) | P < 0.001 |

Table 4

Of all the vasopressors used for correction of hypotension in subarachnoid block, Ephedrine is the best choice for parturient (Ralston DH, Shneider SM, De Lorimier AA).\(^6\)

S M Burns, C M Cowan, et. al.\(^7\) reported a survey of practice of prevention and management of hypotension during spinal anaesthesia for elective caesarean section. Of the 558 respondents, 486(87.1%) stated that they routinely give a fluid preload. The fluid chosen by 405(83.3%) of the preloaders was Hartmann’s solution and the usual volume, chosen by 194(39.9%), was 1000 ml. Overall and in the treatment of hypotension, ephedrine was the sole vasoconstrictor selected by 531(95.2%) 41.

Ephedrine returns the uterine blood flow towards normal and reverses the foetal hypoxia associated with hypotension.
TRENDS OF MEAN ARTERIAL PRESSURE INTRA OPERATIVELY-7

**OBSERVATIONS 15 MINUTE AFTER SPINAL ANAESTHESIA-5**

|        | Group-I       | Group-II      | P-Value   |
|--------|---------------|---------------|-----------|
| PR     | 82.90(3.10)   | 115.93(3.83)  | P < 0.001 |
| SBP    | 100.40(4.73)  | 124.00(5.96)  | P < 0.001 |
| DBP    | 70.40(3.04)   | 83.20(4.05)   | P < 0.001 |
| MAP    | 80.33(3.17)   | 96.76(4.26)   | P < 0.001 |

In this study there was significant increase in heart rate in the Ephedrine infusion group. The change in SAP is related to the level of block and the risk of hypotension increased with height of block. Keeping in view the above facts, the level of sensory block was extended to T6 in all the cases and hence the difference in height among the two groups in our study did not affect the outcome of the study (Sancetta, S. M., Lynn, B., Simeone F. A., et al).

The study concludes that preloading alone has least protection against hypotension. The use of Ephedrine as vasoconstrictor is a very effective method in reducing the incidence, severity and duration of spinal hypotension and provides better haemodynamic stability and the results were comparable with previous studies mentioned (combined military hospital, Peshawar).

**OBSERVATIONS 20 MINUTE AFTER SPINAL ANAESTHESIA-6**

|        | Group-I       | Group-II      | P-Value   |
|--------|---------------|---------------|-----------|
| PR     | 84.63(1.47)   | 114.93(3.72)  | P < 0.001 |
| SBP    | 105.30(4.07)  | 124.33(6.47)  | P < 0.001 |
| DBP    | 72.27(2.33)   | 83.47(4.36)   | P < 0.001 |
| MAP    | 83.56(2.32)   | 97.00(4.71)   | P < 0.001 |

Fig. 7
END OF SURGERY-7

|       | Group-I     | Group-II    | P-Value  |
|-------|-------------|-------------|----------|
| PR    | 86.03(2.59) | 93.20(2.18) | P < 0.001|
| SBP   | 111.00(2.66)| 124.33(6.96)| P < 0.001|
| DBP   | 73.47(4.39) | 82.67(4.49) | P < 0.001|
| MAP   | 85.80(3.31) | 96.40(4.89) | P < 0.001|

Table 7

CONCLUSION: The present study concluded that preloading alone has least protection against hypotension. Ephedrine a vasopressor as a prophylactic infusion is the most effective method in preventing hypotension without adverse effects on the foetus.

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