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A COMPARATIVE STUDY OF INTRAMUSCULAR EPHEDRINE AND PHENYLEPHERINE AS PROPHYLAXIS FOR PREVENTION OF HYPOTENSION IN CAESAREAN SECTION UNDER SPINAL ANAESTHESIA.

Anaesthesiology

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ABSTRACT

Back ground and aims:- Spinal anesthesia has lower complication than general anesthesia in both mother and foetus, In which hypotension is major complication. This study was designed to evaluate and compare with prophylactic use of phenylephrine and ephedrine to reduce hypotension in caesarean section.

Method: - Eighty patients of the American society of anesthesiologists physical status grade I or II, scheduled for caesarean section under spinal anesthesia, were randomly allocated into two group A and B. Group A- received : 4 mg of phenylephrine and diluted upto 1.5 ml NS and group B – received : 1.5 ml of ephedrine 45 mg. Ten minute before of spinal anesthesia, The intramuscular injection of study medication was given into the right vastus lateralis muscle, data were analyzed with chi-square test for categorical variables in dependent sample. T- test and mann whitney U test for continuous variables was applied for analysis of the study.

Result :- In our study, incidence of hypotension was significant less in phenylephrine (10%) as compare of ephedrine group (27.5%) and incidence of nausea, vomiting was less in phenylephrine group as compared to ephedrine group. It was statistically significant ($P<0.05$).

Conclusion :- Phenylephrine was found to be better than ephedrine for prevention of spinal anaesthesia induced hypotension, nausea and vomiting.

KEYWORDS

Ephedrine, phenylephrine, Hypotension, Caesarian section

Introduction :- Spinal anesthesia has lower complication than general anesthesia in both mother and fetus,(1,2). Without prophylactic measures, hypotension is a frequent occurrence (up to 80% of the patients) during spinal anesthesia (3)

Systolic hypotension higher than 20% to 30% of patients baseline blood pressure can lead to maternal low perfusion pressure, manifest as nausea, vomiting, dizziness, and utero placental hypoperfusion with fetal hypoxia and acidosis, therefore, prevention and treatment of this complication with special medical agent for mantaning mother blood pressure and fetal circulation has been important issue for both anesthelogists and obstetrician. Ephedrine is the most commonly used drug among vasopressure, Ephedrine has mixed α and β adrenoreceptor activity. It maintains arterial pressure mainly by incressed in cardic output and heartrate as a result of its predominant activity on β1 adernoreceptor (14)

Phenylephirine is a adrenergic agonist, which acts by counteracting the decrease in systemic vascular resistance by spinal anesthesia, and has been found to be safe and effective (15). The onset of action both intramuscular ephedrine and phenylephrine is 15-20 minutes and duration of action last up to 2 hours.

Onset of action of bupivacain is 5-15 minutes so action of ephedrine and phenylepherine also 15-20 minutes and duration action are upto 2 hours.

In this randomized, double blind comparative study, we have evaluated inj. Phenylepherine 4 mg. i.m.with inj. Ephedrine 45 mg i.m. given 10 minutes prior to induction of spinal anesthesia. The aims and object of this study was to evaluate the symptoms like nausea, vomiting and requirement of rescue i.v. Vasopressor therapy in patients undergoing caesarian section delivery.

Methods:

This prospective, randomized, double-blind, study was done at a tertiary care center after the approval of the institutional ethical committee and obtaining written informed consent from all patients.

Eighty patients scheduled to undergo LSCS, aged between 18-35 years with the American society of anaesthesiologist (ASA) physical status grade I or II, height more than 140 cm. weight between 50-70 kg. Posted for LSCS under spinal anaesthesia were evaluated for this study.

All the patients underwent a thorough pre- operative examination, including history, general physical examination and necessary blood investigation patients with any contraindication to spinal anaesthesia or major neurological, cardiovascular, metabolic, respiratory, renal disease or coagulation abnormalities were, excluded from this study. After taking written informed consent, on the day of surgery, eighty patients were randomized into two groups of fourty patients using computerized randomization methods (Random allocation software) and the allocated group number of each patients was kept concealed in closed envelope, The patients and the anesthetist who were involved in randomization and drug prepation were masked about the information regarding further step at the study (drug administration, data collection and analysis.

All the patients were fasted for at last 6 hour before the procedure. In the operating room, a multipara meter monitor for electro cardiograph (ECG) heart rate(HR) oxygen saturation (spo2) and non- invasive blood pressure was attached and the baseline vital parameters were recorded. Intravenous (IV) line was secured with 18 gauge cannula and ringer lactate solution 10ml/kg was administered.

For double blinding study drug phenylephrine 4 mg (0.4 ml) of phenylephrine was taken form 1 ml syringe to 2 ml syringe and diluted up to 1.5 ml NS and study drug ephedrine 45mg (1.5ml of ephedrine in 2cc syringe).

Ten minutes before spinal anesthesia, the intramuscular injection of study medication was given into the right vastus lateralis muscle.

Under all aseptic precautions spinal anesthesia was given with 2.5 ml of 0.5% bupivacain heavy.

Vital parameter (pulse rate, blood pressure SPO2) and symptoms (nausea, vomiting) were monitored every 5 minutes for 30 minutes then every 10 minutes till the end of surgery.

Rescue intravenous bolus dose of Ephedrine 6 mg was given if patients developed hypotension nausea and vomiting Ringer lactate infusion was continue during the intra operative period.

Statistical analysis was done with the statistical programming software. Sample size was calculated at 80% study powder and, error of 0.05 assuming SD of 15.7 mg ephedrine as additional dose of ephedrine required as found in seed article for the minimal detectable difference of 10 mg of additional ephedrine dose 40 patients in each group are required as sample size. The qualitative and quantitative data was collected and analyzed by various test. Chi- square test for categorical variables independent sample T- test and mann whithney-U test for continuous variables was applied for analysis of the study. For all statistical test- a p – vaule less than 0.05 was taken to indicate a statistically significant difference.

Result -:

Eighty patients were enrolled and completed the study protocol, N=40 in each group.

Two groups were comparable with respect to age, weight and ASA status. (Table 1)

Heart rates were analyzed as basal and throughout the surgery at 5 minutes interval. Decline from in the basal heart rate was observed in phenylephrine group and increase heart rate in Ephedrine group. Difference in heart rate was not statistically significant across all measured times. (Table-2)

Basal vital were comparable. There was no significant difference in mean systolic blood pressure, preoperatively between both group except 15 minute and 30 minute intraopeartive where difference was statistically significant in both group. (Table 3)

There was no significant difference in diastolic pressure between both group except 5 minutes and 10 minutes after test drug injection and 30 minute in intraoperative period where difference between two groups was statistically significant (Table 4)

Basal vital were comparable in both group. There was no significant difference in MAP between two group except for 5 minutes after test drug injection and 15 minutes and 30 minutes in intraoperative period. (Table 5)

It was observed that incidence of nausea, vomiting was less in phenylephrine group as compared to ephedrine group. And it was statistically significant (P-<0.05) (table -6)

All the patients who developed hypotension, nausea or vomiting were administered rescue therapy.

Many patients required more than one dose of rescue ephedrine to treat hypotension, nausea or vomiting and few patients developed nausea and vomiting even without apparent hypotension. It was observed that these episodes were significantly less in phenylepherine group as compared to ephedrine group. (Table -7)

Discussion :-

The current incidence of hypotension following SAB is upto 80% of patients without prophylactic therapy (1). Various drugs and methods like preloading with intravenous (crystalloid – colloid) ephedrine, mephentrmine etc have been studied to prevent hypotension during spinal anesthesia with varying success (7). The usual approach to the use of vasopressors in this clinical setting is reactive rather than proactive, spinal anesthesia induced hypotension is allowed to develop and is they treated accordingly. A more logical approach to its prevention may be the administration of pre emptive vasopressors.

Measurement of SAP (Systolic arterials pressure) and MAP using noninvasive auto mated oscillometry has been found to be valid methods for noninvasive measurement of arterial pressure (Hutton pet al 1984) MAP was chosen rather than SAP. As this is component of arterial pressure that is most accurately determined by this methods. (Continuous invasive arterial pressure measurement is a more sensitive method of detecting hypotension, but is not usually indicated in healthy population).

In our study it was observed that incidence of hypotension was significant less in phenyleephrine (10%) as compare to ephedrine group (27.5%). (Table 6)

In the study done by Ayorinde BT et al (2001) (4), they found that the incidence of hypotension was significantly less in phenylepherine group (33%) as compare to control group (70%) also they found that the incidence of hypotension in phenylephrine 4 mg group was (33%) as compare to ephedrine group 45mg (48%). This difference was not stastically significant- In our study we found a statistically significance reductions in incidence of hypotension in phenylepherine group as compare to ephedrine group (P<0.05).

This difference might be because the study groups were different. The author given intramuscular injection just at the time of administration of spinal anesthesia where as we, in our study, gave the test drug 10 minutes before the administration of spinal anesthesia. Therefore maximum effect of test drug was achieved along the beginning of spinal anesthesia. The author also mentions that an earlier administration of drugs might have lad to further reduction in the incidence of hypotension. Significant reduced incidence of hypotension associated with phenylephrine group might suggest that peripheral vasodilatation is the predominant cause of hypotension due to spinal anesthesia. The fact that neither methods completely prevented the incidence of hypotension, so other mechanism might be operating to decrease the blood pressure.

The hypotension that accompanies spinal anesthesia is associated with nausea and vomiting, possibly due to a reduction in medullary blood flow to chemoreceptor's trigger zone, vasopressor drugs increase mean arterial pressure and presumably medullary blood flow as well. This reducing these symptoms (6) patients who developed nausea and vomiting intra-operatively were treated with rescue ephedrine 6 mg i.v. In our study incidence of nausea, vomiting was 10% in phenyl-ephedrine group as compared to 27.5% in ephedrine group. Looper DW et al (5) found that giving phenylephrine alone by infusion at cesarean delivery was associated with a lower incidence of maternal nausea and vomiting than giving ephedrine alone.

None of the patients in the present study developed tachycardia or bradycordia. In the study done by B KOHKI NISHIKAWA (3) bradycardia (heart-rate<50 bpm) after i.m. administration of phenylepherine was not observed. Also none of the patient in any group developed bradycardia in the study done by astride et at (2) in both studies phenylephrine and ephedrine were administration i.m. prophylactically.

The absence of hypertension, bradycardia and taechycardia in the present study might be due to the i.m. administration of these drugs suggesting that i.m. administration leads to better hemodynomic stability, than i.v. administration.

Conclusion:-

Phenylephrine and ephedrine was found effective in preventions of spinal anaesthesia induced hypotension, nausea and vomiting. Phenylephrine was found to be better than ephedrine for the same.

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Conflicts of interest

There are no conflicts of interest.

Table no. 1 Distribution of demographic variable

Variables		Group A (N=40)	Group B (N=40)	P Value
Age (Years)		25.08±3.12	25.23±3.47	0.839
Weight (kg)		57.25±4.35	55.50±3.74	0.608
ASA Grade	I	33	31	0.581
	II	7	9	

Values presented as mean ±SD, Group A = Phenylephrine Group B = Ephedrine,

ASA – American Society of anesthesiologists, SD = Standard deviation.

Table no. 2 Effect on Pulse Rate

	Group A (Mean+SD)	Group B (Mean + SD)	P Value
Basal	80.35±4.48	79.75±2.43	0.458
Just After Injection -5 minute	79.15±2.79	79.8±2.91	0.311
Just After Injection -10 minute	77.53±3.33	78.05±3.27	0.478
Intra-op -5 minute	80.35±4.65	79.95±2.43	0.630

Intra-op -10 minute	77.52±3.32	78.05±3.26	0.478
Intra-op -15 minute	78.70±5.06	76.53±6.31	0.093
Intra-op -20 minute	80.08±6.68	83.50±12.81	0.137
Intra-op -25 minute	78.98±3.74	80.33±7.61	0.317
Intra-op -30 minute	81.60±8.43	80.275±5.06	0.396
Intra-op -40 minute	79.30±2.74	79.20±2.76	0.871

Table no. 3 Effect on Systolic Blood Pressure

	Group A (Mean+SD)	Group B (Mean + SD)	P Value
Basal	123.27±2.60	123.5±2.83	0.712
Just After Injection -5 minute	123.53±3.00	123.70±2.79	0.788
Just After Injection -10 minute	123.03±3.30	123.73±3.18	0.336
Intra-op -5 minute	123.28±3.24	124.28±2.87	0.148
Intra-op -10 minute	123.43±2.83	123.30±2.75	0.841
Intra-op -15 minute	122.48±8.99	111.45±18.95	0.001
Intra-op -20 minute	121.03±10.40	115.95±15.85	0.094
Intra-op -25 minute	121.08±9.70	119.55±10.99	0.512
Intra-op -30 minute	123.95±.3.71	118.98±11.13	0.008
Intra-op -40 minute	123.70±2.79	123.80±3.12	0.880

Table no. 4 Effect on Mean Arterial Pressure

	Group A (Mean+SD)	Group B (Mean + SD)	P Value
Basal	94.08±2.12	94.22±2.12	0.671
Just After Injection -5 minute	93.61±1.59	94.65±1.94	0.0104
Just After Injection -10 minute	94.00±2.15	94.45±1.86	0.224
Intra-op -5 minute	94.27±2.41	94.36±2.35	0.862
Intra-op -10 minute	93.07±2.18	93.37±2.29	0.547
Intra-op -15 minute	91.69±6.23	86.45±12.09	0.017
Intra-op -20 minute	92.58±7.55	90.10±12.09	0.274
Intra-op -25 minute	91.50±6.49	88.88±10.06	0.169
Intra-op -30 minute	94.38±3.10	89.56±9.08	0.002
Intra-op -40 minute	94.63±1.94	94.10±1.92	0.229

Table no. 5 Effect on Diastolic blood Pressure

	Group A (Mean+SD)	Group B (Mean + SD)	P Value
Basal	79.08±3.25	79.5±2.78	0.531
Just After Injection -5 minute	78.65±2.79	80.13±2.46	0.014
Just After Injection -10 minute	79.48±2.52	78.33±2.20	0.032
Intra-op -5 minute	79.60±2.72	79.78±2.38	0.760
Intra-op -10 minute	78.08±3.17	78.53±2.84	0.505
Intra-op -15 minute	76.33±5.44	74.00±9.22	0.173
Intra-op -20 minute	78.35±6.61	76.88±10.43	0.452
Intra-op -25 minute	76.73±5.43	73.55±10.43	0.091
Intra-op -30 minute	79.50±3.62	74.25±9.53	0.001
Intra-op -40 minute	80.13±2.46	79.25±2.59	0.125

Table no. 6 Total no. of patients having Nausea and Vomiting in each group

	Group A (N=40)	Group B (N=40)	P Value
Total no. of patients	4(10%)	11 (27.05%)	<0.05

Table no. 7 Episodes of rescue IV

	Group A	Group B
5 minute	-	2
10 minute	-	-
15 minute	2	7
20 minute	2	5
25 minute	1	1
30 minute	2	2
40 minute	-	-
Total	7	17

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