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COMPARISON OF COADMINISTRATION OF 75 µg PHENYLEPHERINE VERSUS 5 mg EPHEDRINE WITH 3 UNITSOF OXYTOCIN FOR PREVENTION OF EXAGGERATED HYPOTENSION DUE TO OXYTOCIN IN LOWER SEGMENT CAESEREAN SECTION UNDER SPINAL ANAESTHESIA

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Abstract

BACKGROUND: Oxytocin, used as a uterotonic agent for prevention of post partum haemorrhage, causes hypotension and reflex tachycardia in parturients undergoing lower Segment Caesarean Section(LSCS). To prevent this hypotension various vasopressors like phenylepherine and ephedrine have been used.

This study is undertaken to know the effects of co-administration of phenylepherine and ephedrine with oxytocin in parturients undergoing LSCS under subarachnoid block.

METHODS: In this prospective double blind study, 150 parturients belonging to ASA I and II undergoing LSCS were randomized into three groups. Group A-3U Oxytocin+Phenylephrine75µg, Group B-3U Oxytocin+ Ephedrine 5mg, Group C- 3U Oxytocin+Normal saline, administered intravenously over 5 minutes after baby extraction. The incidence of hypotension, rescue vasopressor requirement and side effects were recorded. Statistical analysis was done with analysis of variance, Kruskal-Wallis, chi-square and fisher's exact test.

RESULTS: Demographic parameters were comparable in all three groups. The incidence of hypotension (Group A- 12%, Group B- 90%, Group C- 94%, P< 0.0001), magnitude of fall in Mean arterial pressure(Group A= 18.2 +/- 4.2 mmHg, Group B= 26 +/- 8.3 mmHg, Group C= 25.8 +/- 5.8 mmHg, P<0.0001) and rescue vasopressor requirement (Group A= 6 +/- 16.41µg, Group B= 45 +/- 15.15µg, Group C= 93 +/-24.76µg, P< 0.00076) were significantly lower in GroupA compared to Group B and Group C.

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CONCLUSION: Co-administration of 75 µg phenylepherine with 3U oxytocin reduces the incidence of exaggerated hypotension due to oxytocin compared to co-administration 5 mg ephedrine with 3U oxytocin in parturients undergoingLSCS under SAB.

KEYWORDS: Hypotension, Phenylepherine, Ephedrine, Oxytocin, Caesarean Section.

INTRODUCTION

Spinal anaesthesia was introduced into clinical practice by German Surgeon Karl August Bier in 1898 [1]. In the recent decades there has been a worldwide shift in obstetric anaesthesia practice in favour of regional anaesthesia with spinal anaesthesia being the most popular among them[2][3]. Today it is one of the most popular techniques for lower limb and lower abdominal procedures including caesarean section.

The incidence of hypotension in parturients undergoing caesarean under spinal anaesthesia has been reported in 85% of the patients [4]. Maternal hypotension may have detrimental effects on uterine blood flow, fetal well being and ultimately neonatal outcome as measured by umbilical artery pH and APGAR score.[5] Various measures like careful positioning and volume preloading with crystalloid or colloids have been used to prevent it[6-7]. Infusion of large volume of crystalloids over a short period of time carriesa risk of pulmonary oedema[8] and postoperative urinary retention.

Post partum haemorrhage (PPH) is one of the leading causes of maternal mortality with uterine atony being the cause in about 50% cases[9][10]. It can be reduced by proper use of uterotonic agents. Among the various uterotonics, oxytocin is most commonly used. Prophylactic routine use of oxytocin has been shown to reduce the incidence of PPH by 40%[11]. But oxytocin causes hypotension and reflex tachycardia as an adverse effect because oxytocin receptors are also found in the heart and large vessels.[12]

To prevent oxytocin induced hypotension various vasopressors like ephedrine, mephentermine and phenylepherine have been used[13][14]. Ephedrine is commonly used vasopressor in caesarean sections[15]. It has both direct and indirect action, stimulating mainly beta receptors (b1 and b2) increasing cardiac output, heart rate, systolic and diastolic blood pressure.[16] But it may worsen maternal tachycardia or precipitate arrthymia. Phenylepherine, a selective a_1 adrenergic agonist is as effective as ephedrine intreatment of hypotension[17]. It is associated with higher umbilical artery pH and less fetalacidosis [18]

Though there are studies comparing iv ephedrine with iv phenylepherine, the studies recommending a minimum effective dose of phenylephrine [19-20] and ephedrine required for coadministration with oxytocin to prevent exaggerated hypotension due to oxytocin are sparse. Hence this study is undertaken to know the beneficial effects of coadministration of phenylepherine and ephedrine with oxytocin in ASA I and II parturients undergoing LSCS under SAB.

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AIMS: To compare the effectiveness of coadministration of 75µg phenylepherine with 3U of oxytocin versus 5mg ephedrine with 3U of oxytocin for prevention of exaggerated hypotension due to oxytocin during Caesarean section under spinal anaesthesia.

MATERIAL AND METHODS

This is a Prospective, randomized double blind study. Parturients undergoing elective and emergency Lower Segment Caesarean Section underspinal anaesthesia at Bangalore Medical College and Research Institute attached hospitals.

Inclusion criteria

1) Parturients posted for elective and emergency Lower Segment Caesarean Section.
2) Parturients who give informed written consent.
3) Parturients belonging to ASA Grade I and II.

Exclusion criteria:

1) Complicated obstetrics with at increased risk of atony or excessive bleeding like known placenta previa, multiple gestation, prolonged labour, more than 2 previous LSCS, h/o PPH.
2) Cardiovascular instability like pre eclampsia, essential hypertension.

METHOD OF COLLECTION OF DATA: After obtaining informed written consent from the parturients, participation consent and, 150 parturients undergoing elective and emergency Caesarean section were randomly selected and allotted to one of the three groups of 50 each Group A - 3 units of Oxytocin + Phenylephrine75µg diluted to 10cc.Group B - 3 units of Oxytocin + ephedrine 5mg diluted to 10cc. Group C - 3units of Oxytocin + Normal saline diluted to 10cc.

Before shifting the parturients inside the OT, an 18G intravenous catheter was placed on the dorsum of parturient‟s non dominant hand and were preloaded with 10 ml/kg lactated Ringer solution warmed to 37˚C over 15 minutes before spinal anaesthesia. Premeditated with Inj ranitidine 50mg I.V and Inj metaclopromide10mg. On arrival to the operating room, standard monitors were connected to all patients. Baseline SBP, DBP, MAP, HR and SpO2 levels were recorded. Oxygen was delivered via a face mask at a rate of 4 L/min. Parturients were put in left lateral position and operating table was kept flat.

SAB was administered at L3/L4 or L4/L5 level using standard technique with 1.8 ml of 0.5 % hyperbaric bupivacaine + 25µg fentanly. All haemodynamic parameters such as SBP, DBP, MAP, HR and SpO_2 were recorded every 2 minutes. Two minutes after intrathecal injection, the level of sensory block was assessed using the loss of sensation to cold method and the motor blockade was determined using modified Bromage Scale. The level of sensory and motor blockade was checked every 2 min until the maximum level of the block was achieved. If parturient developed hypotension more than 20% of basal MAP before

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oxytocin infusion, was treated with injection phenylepherine 50mcg i.v bolus and excluded from the study. After extraction of the baby, group A received 3 units oxytocin+ phenylepherine 75 µg diluted to 10cc over 5 minutes, Group B received 3 units oxytocin + ephedrine 5mg diluted to 10cc over 5 minutes, group C received 3 units oxytocin + normal saline diluted to 10cc over 5 minutes. Heart rate, blood pressure and saturation were monitored every 2 minutes upto 10 minutes after oxytocin administration and then every 5 minutes till the end of surgery. Uterine tone was assessed by obstetricians at the end of oxytocin infusion and noted as either "adequate" or "inadequate". If uterus was not adequately contracted after the infusion, additional doses of oxytocin, methergine or prostadine was given and noted.

All the three groups received oxytocin infusion 10U/hr upto 4 hours. Hypotension is defined as fall in mean arterial pressure (MAP) >20% of baseline mean arterial pressure (MAP) and treated with phenylepherine of 50µg I.V bolus. Bradycardia is defined as fall in heart rate < 60 bpm and treated with atropine I.V 0.6mg.

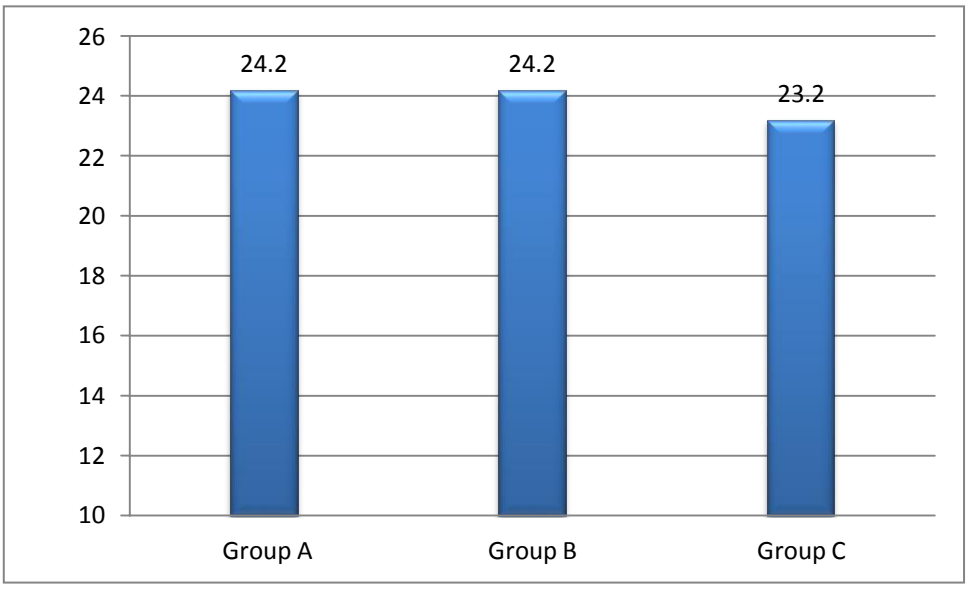
STATISTICAL ANALYSIS:

Summary statistics was done by means of proportions for categorical/ binary variables and mean, median, standard deviation, Inter Quartile Range (IQR) for continuous variables. Inferential statistics was done by using Chi square test/ fisher exact test, One way ANOVA with post hoc test and two way repeated measure ANOVA. Chi square test/ Fisher exact test are used comparing two or more independent proportions. Fisher exact is used when the number of expected numbers in > 25% cells is < 5. All statistical methods were done using SPSS 21.0 version for windows. $P < 0.05$ was considered statistically significant.

RESULTS

A total of 150 parturients were enrolled and randomly allocated into three groups Group A(n =50) received phenylepherine 75 µg and 3 U oxytocin , Group B (n=50) received ephedrine 5 mg and 3 U of oxytocin, Group C (n =50) received normal saline and 3 U of oxytocin IV infusion over 5 minutes after the extraction of baby.

Graph 1: AGE Distribution



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The age of the parturients ranged between 19 years to 36 years. The mean age in group A was 24.2 years with SD 3.4 , mean age in Group B was 24.2 years with SD 1.6 and mean age in Group C was 23.2 years with SD 2.3. The mean age in all the three groups was comparable.

TABLE 2: COMPARISON OF GESTATIONAL AGE

	GROUPS					
	Group A		Group B		Group C	
	Mean	SD	Mean	SD	Mean	SD
GESTATIONAL AGE IN WEEKS	39	1	38	1	39	1

The mean gestational age in Group A was 38 weeks with SD of 1, in Group B was 39 weeks with SD of 1 and in Group C was 39 weeks with SD of 1. The mean gestational age was comparable among all the three groups.

TABLE 3: COMPARISON OF INCIDENCE/ MAGNITUDE OF HYPOTENSION

		GROUPS						
		Group A (50)		Group B (50)		Group C (50)		
		n	%	n	%	n	%	p
No. of times rescue vasopressor given	Nil (0)	44	88.0	5	10.0	3	6.0	<0.0001
	One (1)	6	12.0	45	90.0	1	2.0	
	Two (2)	0	.0	0	.0	46	92.0	
Incidence of hypotension(%)		12%		90%		94%		
Dose of rescue vasopressor given(phenylepherine 50 µg)								
Mean +/-SD (95% CI)		6 +/- 16.4		45 +/- 15.15		93 +/- 24.76		
Median (IQR)		0(0-0)		50(50-50)		100(100-100)		

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On inter group comparison we found that the incidence of hypotension was 12% in group A, out of 50 parturients, 6 developed hypotension. In Group B out of 50 parturients, 45 parturients developed hypotension with the incidence of 90% and in Group C out of 50 parturients 47 parturients developed hypotension with the incidence of 94% , with a P value of < 0.0001 which was statistically significant.

The incidence of hypotension was least in group A (phenylepherine group) and maximum in group C (normal saline group). Rescue vasopressor requirement (phenylepherine 50 µg) was least in Group A, out of 50 parturients only 6 parturients received rescue vasopressor once, with a mean of 6 and SD of 16.41. In Group B out of 50 parturients 45 parturients received rescue vasopressor once with a of mean 45 and SD 15.15 . Median rescue vasopressor requirement in group A was found to be 0 (0-0), in group B was found to be 50 (50-50) and in group C was 100 (100-100). Maximum rescue vasopressor requirement was in Group C(normal saline group) out of 50 parturients 46 parturients received phenylepherine 100 µg(two doses) with mean requirement of 93 and SD of 24.76 with a P value of < 0.00076 which was statistically significant.

TABLE 4: MAGNITUDE OF CHANGE IN BLOOD PRESSURE

	GROUPS									
	A		B		C		Overall	A vs B	B vs C	A vs C
	Mean	SD	Mean	SD	Mean	SD				
Change of MAP	18.21	4.2	26.0	8.3	25.83	5.8	<0.0001	<0.001	1	<0.001
Change of DBP	23.42	8.2	34.3	16.7	27.74	6.5	<0.0001	<0.001	0.01	0.2
Change of SBP	16.89	5.9	26.5	14.9	24.36	5.9	<0.0001	<0.001	0.9	0.001

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The magnitude of change in mean arterial pressure (MAP) in group A (phenylepherine group) was 18.2 +/- 4.2 mmHg, in group B (ephedrine group) it was found to be 26 +/- 8.3 mmHg and in group C (normal saline group) it was found to be 25.83+/-5.8 mmHg. On inter group comparison we found that the magnitude of change in mean arterial pressure (MAP) was least in group A (phenylepherine group) which was statistically significant with P value of <0.001. The magnitude of change in MAP between group B and C was comparable, which was statistically not significant P > 0.05.

TABLE 5: COMPARISON OF NAUSEA /VOMITING

		GROUPS						
		Group A (50)		Group B (50)		Group C (50)		
		N	%	N	%	N	%	P
IO Nausea /Vomiting		2	4.0	10	20.0	21	42.0	<0.0001

The incidence of nausea and vomiting was highest in group C (normal saline group) 42 %, out of 50 parturients, 21parturients complained of nausea /vomiting. In group B, out of 50 parturients, 10 parturients complained of nausea /vomiting with the incidence of 20%. In group A(phenylepherine group), the incidence of nausea and vomiting was least (2%), out of 50 parturients only 2 of them experienced nausea/vomiting. There was significant statistical difference in the three groups with a P value of <0.0001.

TABLE 6: COMPARISON OF HAEMODYNAMIC PARAMETERS (IMMEDIATE POST OPERATIVE PERIOD)

	GROUPS						
	Group A		Group B		Group C		P
	Mean	SD	Mean	SD	Mean	SD	
IPO_HR	87	8	87	8	85	8	0.2
IPO_SBP	117	7	117	8	116	7	0.9
IPO_DBP	68	6	68	6	66	5	0.5
IPO_MAP	84	6	85	5	83	4	0.4
IPO_SPO2	100	1	100	0	100	0	0.3

All parameters : heart rate, systolic blood pressure, Diastolic blood pressure, mean arterial pressure and saturation were comparable among all three groups in immediatepost operative

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period. There was no significant difference among the three groups during immediate post operative period.

TABLE 7: COMPARISON OF HEART RATE DURING POST OPERATIVEPERIOD

	GROUPS					
	Group A		Group B		Group C	
	Mean	SD	Mean	SD	Mean	SD
PO_HR	87	8	87	8	85	8
PO_HR_30MIN	86	8	85	8	83	7
PO_HR_60MIN	87	8	84	8	83	8
PO_HR_90MIN	89	9	87	9	83	7
PO_HR_120MIN	89	10	87	9	85	7
PO_HR_150MIN	90	11	89	11	84	8
PO_HR_180MIN	90	11	89	10	83	8

In the post operative period, Heart rate among all the three groups was comparable. Therewas no significant difference among the three groups.

TABLE 8: COMPARISON OF SYSTOLIC BLOOD PRESSURE DURING POST OPERATIVE PERIOD

	GROUPS						
	Group A		Group B		Group C		P
	Mean	SD	Mean	SD	Mean	SD	
PO_SBP	117	7	117	8	116	7	0.9
PO_SBP_30MIN	115	12	119	6	118	7	0.04
PO_SBP_60MIN	117	14	119	8	118	17	0.6

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PO_SBP_90 MIN	117	13	120	6	119	7	0.5
PO_SBP_120 MIN	118	12	120	7	120	6	0.6
PO_SBP_150 MIN	117	11	119	6	120	7	0.1
PO_SBP_180 MIN	119	11	121	7	118	8	0.2

The SBP was comparable among all the three groups and there was no significant difference among three groups during post operative period.

TABLE 9: COMPARISON OF DIASTOLIC BLOOD PRESSURE DURING POST OPERATIVE PERIOD

	GROUPS						
	Group A		Group B		Group C		P
	Mean	SD	Mean	SD	Mean	SD	
PO_DBP	68	6	68	6	66	5	0.5
PO_DBP_30 MIN	68	5	67	6	67	7	0.6
PO_DBP_60 MIN	69	6	69	6	67	7	0.2
PO_DBP_90 MIN	68	7	68	6	67	8	0.7
PO_DBP_120 MIN	69	7	68	6	67	6	0.2
PO_DBP_150 MIN	68	6	69	6	67	6	0.5
PO_DBP_180 MIN	69	8	70	7	68	5	0.5

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The DBP was comparable among all the three groups and there was no significant difference among three groups during post operative period**.**

TABLE 10: COMPARISON OF MAP POST OPERATIVE PERIOD

	GROUPS						
	Group A		Group B		Group C		P
	Mean	SD	Mean	SD	Mean	SD	
PO_MAP	84	6	85	5	83	4	0.4
PO_MAP_30 MIN	84	6	85	4	84	5	0.3
PO_MAP_60 MIN	84	7	86	5	86	5	0.3
PO_MAP_90 MIN	86	7	86	4	85	4	0.4
PO_MAP_120 MIN	86	8	86	5	85	4	0.6
PO_MAP_150 MIN	86	7	86	5	85	7	0.5
PO_MAP_180 MIN	86	7	87	4	85	5	0.1

Mean arterial pressure (MAP) was comparable among all the three groups. There was no significant difference in MAP among three groups during post-operative period.

TABLE 11: COMPARISON OF S p O_2 POST OPERATIVE PERIOD

	GROUPS						
	Group A		Group B		Group C		P
	Mean	SD	Mean	SD	Mean	SD	
PO_MAP	84	6	85	5	83	4	0.4
PO_SPO2	100	1	100	0	100	0	0.3
PO_spo2_30MIN	100	1	100	0	99	3	0.1

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PO_spo2_60MIN	100	0	100	0	99	3	0.04
PO_spo2_90MIN	100	1	100	1	99	1	0.2
PO_spo2_120 MIN	99	1	99	1	99	1	1
PO_spo2_150 MIN	99	1	100	1	99	1	0.5
PO_spo2_180 MIN	100	1	100	1	100	1	0.5

SpO_2 was comparable among all three groups during post operative period. There was no significant difference among three groups.

DISCUSSION

Oxytocin causes hypotension and reflex tachycardia as an adverse effect because oxytocin receptors are also found in the heart and large vessels[12]. The principal effect of oxytocin seems to be on SVR, and hence a drug which directly increases SVR would counteract the effect of oxytocin. Some studies have shown that slower injection of oxytocin can effectively minimize the cardio-vascular effects of a bolus dose without compromising the therapeutic benefits.

There is no uniformity in the dose of oxytocin that is given for adequate uterine contraction. Susmita Bhattacharya et al [21], compared the haemodynamic effects of oxytocin 3 U I.V bolus over 15sec and 3 U oxytocin infusion over 5 min in 80parturients undergoing elective Caesarean section. They observed that there was significant rise in heart rate and significant decrease in MAP in bolus group compared to infusion group. 3 parturients in bolus group had EKG changes in the form of ST-T depression and 5 parturients complained of chest pain. Whereas no such complaints were found in infusion group.

In our study, we used 3U oxytocin over 5 min and we found that uterine contractions was adequate in all cases and no additional doses of uterotonic agent were needed. We did not observe ECG changes or chest pain even in control group. Though there was hypotension and decrease in the MAP there was no reflex tachycardia even in control group, this may be because of rescue vasopressor phenylepherine, which may have obtunded tachycardia effect in parturients who received 3U oxytocin infusion.

There are studies comparing the efficacy of different doses of phenylepherine and ephedrine to treat post spinal hypotension in elective LSCS. PA Hal et al [13], compared infusion of phenylepherine and ephedrine in 29 healthy parturients undergoing elective caesarean section under spinal anaesthesia in terms of maternal cardiovascular changes and neonatal acid base status. They found that infusion of phenylepherine 10µg/min is significantly less effective in

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maintaining systolic arterial pressure within 20% limit than ephedrine 1 mg/min and ephedrine 2mg/min.

In our study we compared coadministration of 3U oxytocin with 75µg phenylepherine versus 5mg ephedrine and we found that coadministration of 75µg phenylepherine with 3U oxytocin reduced the incidence of hypotension, number of episodes of hypotension and also rescue vasopressor requirement and it is better in preventing oxytocin induced hypotension compared to 5 mg ephedrine with 3U oxytocin in parturients undergoing LSCS.

A study was undertaken by Thomas D G et al [18], in 38 healthy women undergoing elective LSCS under spinal anaesthesia to compare the effectiveness of bolus phenylepherine 100µg and ephedrine 5mg for maintenance of arterial pressure. They observed that the median (range) number of boluses of phenylepherine and ephedrine was similar, and the maternal systolic blood pressure and cardiac output changes were similar in both groups, but the mean maximum percentage change in maternal HR was larger in the phenylepherine group than in ephedrine group as a consequence atropine was required in 11 /19 women in phenylepherine group compared with 2/19 women inephedrine group . They found that bolus phenylephrine is as effective as ephedrine in restoring maternal arterial pressure above 100mmHg.

In our study we observed that, on inter group analysis, the number of episodes of hypotension and median rescue vasopressor requirement was more in ephedrine group(5mg) compared to phenylepherine group(75µg), the magnitude of fall in MAP was least with phenylepherine 75µg (18.2 +/- 4.2 mmHg). We did not observe bradycardia in any of the three groups. None of the parturients required Inj atropine. This may be attributed to the administration of phenylepherine as infusion rather than bolus dose. Though there was hypotension in normal saline group who received 3U oxytocin over 5 minutes, there was no tachycardia , as phenylepherine, used to treat hypotension might have obtunded tachycardia effect.

Few authors have noted that phenylepherine 100µg had quicker control of BP compared to 6mg mephentermine and 6mg ephedrine. There are studies which have observed that the minimum vasopressor dose for preventing post spinal hypotension in LSCS and concluded that phenylepherine is more potent than ephedrine by a factor of 80 for equivalent maternal BP control [53]. In our study we compared 75µg phenylepherine vs 5mg ephedrine with coadministration of 3U oxytocin. We also found that coadministration 75µg phenylepherine with oxytocin is more potent than coadministration of 5mg ephedrine with oxytocin.

Robert A. Dyer et al [19], compared the haemodynamic effects of ephedrine, phenylephrine, and coadministration of phenylepherine with oxytocin in 43 parturients during spinal anesthesia posted for elective cesarean section in 43 parturients who receive 80 µg of phenylepherine or 10 mg epherine. A sub group 20 parturients were randomized to receive oxytocin compared with oxytocin plus 80µg phenylepherine following extraction of baby. They observed that mean cardiac output and maximum absolute response in cardiac output were significantly lower after phenylepherine administration than after ephedrine. Cardiac output changes correlated with heart rate changes. Coadministration of phenylepherine obtunded oxytocin induced decreases in systemic vascular resistance and increases in heart rate and cardiac output.

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In our present study, we observed that heart rate was comparable among the three groups, there was no incidence of bradycardia in any of the groups. We also found that, though incidence was hypotension, number of episodes of hypotension was more in control group, there was no reflex tachycardia. This could be attributed to the administration of rescue vasopressor, Phenylepherine in the control group. Phenylepherine is known to cause bradycardia when given as bolus and in higher doses(100µg). In our study we used 75µg phenylepherine as infusion. Hence we did not observe significant variations in the heart rate. On inte rgroup analysis, we also found that magnitude of fall in MAP was least with phenylepherine 75µg (18.2 +/- 4.2 mmHg).

Devika Rani et al [20], conducted a study to know the effects of coadministration of different doses of phenylepherine with oxytocin to prevent oxytocin induced hypotension in caesarean section under spinal anaesthesia. They observed that the incidence of hypotension, magnitude of fall in mean arterial pressure, rescue vasopressor requirement were significantly lower in phenylepherine 75µg group. They concluded that coadministration of 75 µg phenylepherine with 3 U of oxytocin reduces the incidence of oxytocin induced hypotension compared to 50 µg phenylepherine with 3U of oxytocin in parturients undergoing LSCS under spinal anaesthesia.

In our study we also observed that the incidence of hypotension, magnitude of fall in Mean arterial pressure and rescue vasopressor requirement were significantly lower in phenylepherine group (75µg). We found that, Coadministration of 75 µg phenylepherine with oxytocin is better in reducing the incidence of oxytocin induced hypotension compared to coadministration 5 mg ephedrine with oxytocin in parturients undergoing LSCS.

CONCLUSION

Coadministration of phenylepherine 75 µg with 3U of oxytocin after extraction of baby reduces the incidence of exaggerated hypotension due to oxytocin and rescue vasopressor requirement compared to coadministration of 5mg ephedrine with 3 U of oxytocin in parturients undergoing LSCS under spinal anaesthesia.

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