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COMPARATIVE STUDY OF TAB. NIFEDIPINE VERSUS TAB. LABETALOL IN HYPERSENSETIVE DISORDER OF PREGNANCY

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ABSTRACT:
Hypertension in pregnancy is the important cause of mortality and mortality in not only mother but also in fetus. The incidences of hypertensive disorders ranges from 2.8% of all pregnancies and contributes to 9% of maternal mortality in Asia and 12% in India [3,4] the Gestational hypertension is diagnosed when the BP exceeds 140/90 in the absence of protein urea or pathological edema. One hundred pregnant women having blood pressure ≥ 160/110 mmHg were selected and divided in two groups. The Group A treated with oral Tab. Nifedipine 10 mg and the Group B treated with oral Tab. Labetalol 100 mg. The most common complaints were pain in abdomen, epigastric pain, severe headache, visual disturbances.
The most common age group was 21 to 25 years in group A (62%0 and group B(64%) (p= 0.949) and mean age group A and group B was 22.00 ± 2.53 years and 22.34 ± 2.58 years (p= 0.507) respectively. Majority of the women in group A (80%) and group (62%) had primi para (p =0.076). The most common complaint was pain in abdomen 94% in group A vs 92% in group B (p = 0.500). It was observed that, 96% of the women in group B had onset of the blood pressure control within 30 minutes where as 94% of the women achieved the target blood pressure within 31 to 60 minutes(p< 0.001). The mean duration for the onset of blood pressure control was also significantly low in the group B compared to group A (29.40 ± 6.75 vs 52.80 ± 12.94 and p < 0.001) . The onset of blood pressure control in most of the women with group A (94%) and group B (86%) was achieved with two doses (p = 0.093) and mean number of doses required in group A and group B (2.08 0.34 vs1.96 0.46) was also comparable (p = 0.136)
Interpretation and conclusion is Tab. Nifedipine requires significant shorter duration for the onset of blood pressure control compared to Tab. Labetalol without additional doses.

Key words: Nifedipine, labetalol, hypertension

INTRODUCTION
Pregnancy induced hypertension (PIH) is one of the maternal disease that causes the most detrimental effects to the maternal, fetal, and neonatal organs.[1] Increase in systolic blood pressure(BP) of almost 30mmHg or increase in diastolic BP of about 15 mmHg over previously known BP is called PIH.[2]Pregnancy induced hypertension is defined as hypertension that develops as direct result of gravid state. Pregnancy induced hypertension can become a serious and life threatening obstetric complication.[3]It is one of the most common cause of both maternal and neonatal morbidity.[4]. The incidences of hypertensive disorders ranges from 2.8% of all pregnancies and contributes to 9% of maternal mortality in Asia and 12% in India [3,4]
Maternal complications due to very high blood pressure include eclampsia, cerebral haemorrhage, cortical blindness, cortical and tubular necrosis and abruption. It consequence these children are at risk of intrauterine growth, retardation and may be delivered prematurely.[5]
There have been many drugs that have been described in control of hypertension. The drug like Nifedipine and Labetalol have demonstrated comparable efficacy and a lower risk of overshoot hypotension as well as fetal distress when compared with hydralazine in randomized clinical trials. The antihypertensive drugs lower pressure,there is not enough evidence to show which drug is most effective when taken by pregnant women with hypertension.
Hence this attempt was taken to compare the effect of Tab.Nifedipine versus Tab. Labetalol in hypertensive disorder in pregnant women.

AIMS AND OBJECTIVES
To compare the effect of Tab. Nifedipine versus Tab. Labetalol in hypertensive disorder of pregnancy.
Objectives:
1. To assess the time taken to achieve target blood pressure in hypertensive pregnant women.
2. To evaluate the number of doses required to achieve target blood pressure in hypertensive disorder of pregnancy.

MATERIALS AND METHODS
A total 100 pregnant women with hypertension ≥160/110 mmHg were selected.

Inclusion Criteria--

1. Hypertension with systolic blood pressure ≥160 mmHg.
2. Hypertension with diastolic blood pressure ≥110 mmHg.

Exclusion criteria—

1. Pregnant women with maternal heart rate < 60.
2. Pregnant women with maternal heart rate > 120.
3. Women with cardiac disease, bronchial asthma, diabetes mellitus, Liver disorder.
4. Allergy to Nifedipine, Labetalol
5. In case if hypotension (BP ≤ 90/60mmHg) was developed in patient after treatment was excluded from trial.

Investigations---

- Hemoglobin
- Platelet count
- Random blood sugar
- Blood urea nitrogen
- Serum creatinine
- Serum uric acid

The selected women were randomly divided into two groups of 50 each based on computer generated randomization.

- ❖ Group A—Patients receiving oral Labetalol 100mg.
- ❖ Group B—Patients receiving oral Nifedipine 10mg.

Group A—

Pregnant women in this group received oral Labetalol 100 mg initially followed by repeated doses of 100 mg every 30 minutes for up to a maximum of 8 doses.

Group B—

Pregnant women in this group received oral Nifedipine10 mg initially followed by repeated doses of 10mg every 15 minutes for up to a maximum of 8 doses or until the therapeutic blood pressure goal of ≤ 140/90mmHg .

Dose: Maximum 8 doses

Outcome variable

1. Blood pressure monitoring
2. Time taken to achieve target blood pressure.
3. Number of doses required to achieve target blood pressure.

OBSERVATIONS AND RESULTS

Table no.1: Comparison of study population according to their age

Age Group (Years)	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
≤ 20	15	30.00	13	26.00
21-25	31	62.00	32	64.00
26-30	04	08.00	04	08.00
> 30	00	00.00	01	02.00
Total	50	100.00	50	100.00
P = 0.949				

Table no.2: Comparison of study population according to complaint of headache

Complaint of Headache	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
Yes	04	08.00	04	08.00
No	46	92.00	46	92.00
Total	50	100.00	50	100.00
P = 0.643				

Table no.3:Comparison of study population according to complaint of pain in abdomen

Complaint of Abdomen pain	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
Yes	47	94.00	46	92.00
No	03	06.00	04	08.00
Total	50	100.00	50	100.00
P = 0.500				

Table no4: Comparison of study population according to complaint bleeding per vagina

Complaint of Bleeding per vagina	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
Yes	00	00.00	01	02.00
No	50	100.00	49	98.00
Total	50	100.00	50	100.00
P = 0.500				

Table no5: Comparison of study population according to the parity

Parity	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
Primi	40	80.00	31	62.00
Multi	10	20.00	19	38.00
Total	50	100.00	50	100.00
P = 0.076				

Table no6: Comparison of study population according to the presentation

Presentation	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
Cephalic	49	98.00	49	98.00
Breech	01	02.00	01	02.00
Total	50	100.00	50	100.00
P = 0.753				

Table no 7: Comparison of study population according to the uterine contraction

Uterine contraction	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
Yes	47	94.00	45	90.00
No	03	06.00	05	10.00
Total	50	100.00	50	100.00
P = 0.357				

Table no 8: Comparison of study population according to the fetal heart rate

Fetal heart rate	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
Present	49	98.00	49	98.00
Absent	01	02.00	01	02.00
Total	50	100.00	50	100.00
P = 0.753				

Table no 9: Comparison of study population according to the number of drug doses given

Number of drug doses	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
01	00	00.00	05	10.00
02	47	94.00	43	86.00
03	02	04.00	01	02.00
04	01	02.00	01	02.00
Total	50	100.00	50	100.00
P = 0.093				

Table no 10: Comparison of study population according to the duration therapy

Duration of therapy(hours)	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
≤ 4	07	14.00	13	26.00
5-8	15	30.00	05	10.00
9-12	28	56.00	30	60.00
.>12	00	00.00	02	04.00
Total	50	100.00	50	100.00
P = 0.029				

Table no 11: Comparison of study population according to the duration of onset to control BP

Duration in minutes	Group A		Group B	
	Number of Pts	Percentage	Number of Pts	Percentage
≤ 30	07	00.00	48	96.00
31-60	47	94.00	02	04.00
61-90	02	04.00	00	00.00
91-120	01	02.00	00	00.00
Total	50	100.00	50	100.00
P = 0.001				

Table no 12: Comparison of study population according to clinical profile

Variables	Group A		Group B		P value
	Mean	SD	Mean	SD	
Age(Years)	22.00	2.53	22.34	2.58	0.507
Amenorrhoea	8.90	0.36	8.84	0.51	0.500
Height(Cms)	151.22	3.95	152.26	4.05	0.197
Weight(Kgs)	57.74	8.46	56.74	7.37	0.530
Pulse rate/minute	88.24	4.69	88.76	3.10	0.515
Respiratory rate/minute	15.92	1.45	15.76	1.44	0.581
Systolic blood pressure(mm Hg)	165.88	5.66	165.80	4.50	0.938
Daistolic blood pressure(mm Hg)	104.56	5.27	105.28	5.61	0.510
Fundal height	36.06	2.56	36.00	3.18	0.917
Haemoglobin(gm%)	9.65	1.74	9.86	1.81	0.557

Platelate count/Cumm	1.65	0.52	1.65	0.44	0.975
Random blood sugar(mg/dL)	87.90	9.48	89.80	10.69	0.350
Blood Urea(mg/DL)	21.10	2.31	21.30	2.39	0.672
Serum creatinine(mg/dL)	0.81	0.12	0.81	0.12	0.796
Serum uric acid	5.17	1.00	5.13	0.90	0.859
Number of Doses	2.08	0.34	1.96	0.45	0.136
Duration of therapy (hours)	8.10	3.23	7.75	4.42	0.648
Onset of BP control(Minutes)	52.80	12.94	29.40	6.75	< **0.001**

Table no 13: Comparison of study population according to clinical profile

Interval	Blood pressure	Group A (n=50) Mean	SD	Group B (n=50) Mean	SD	P value
0 Min	SBP DBP	165.88 104.36	5.66 5.25	165.80 105.28	4.50 5.61	0.938 0.399
15 Min	SBP DBP	159.04 92.92	4.84 3.57	151.00 92.68	6.28 4.19	**<0.001** 0.759
30 Min	SBP DBP	152.00 92.08	5.86 4.25	138.58 87.33	4.92 4.58	**<0.001** **<0.001**
45 Min	SBP DBP	141.56 90.88	4.87 3.11	135.90 88.38	3.67 2.87	**<0.001** **<0.001**
1 Hour	SBP DBP	137.12 89.44	5.16 2.94	142.54 88.98	7.00 4.54	**<0.001** 0.574
75 Min	SBP DBP	136.68 89.55	6.05 2.65	136.20 87.85	3.70 2.54	0.658 **0.004**
90 Min	SBP DBP	139.64 89.32	10.15 3.28	137.95 87.44	7.42 5.39	0.386 **0.063**
105 Min	SBP DBP	138.41 89.77	8.19 2.52	135.95 88.36	4.34 2.67	0.087 **0.016**
2 Hours	SBP DBP	140.36 88.86	7.26 4.21	142.51 89.95	5.92 4.46	0.142 0.260
2.5 Hours	SBP DBP	140.27 90.59	7.49 3.77	142.26 88.95	7.76 2.93	0.243 **0.030**
3 Hours	SBP DBP	139.12 89.53	7.86 2.46	135.11 89.05	4.57 2.74	**0.006** 0.410
3.5 Hours	SBP DBP	140.37 89.63	9.74 3.63	141.89 89.21	9.09 3.88	0.469 0.620
4 Hours	SBP DBP	137.77 89.91	7.05 2.72	142.74 88.84	6.23 4.76	**0.001** 0.229
5 Hours	SBP DBP	141.63 90.74	8.81 4.02	146.27 89.03	8.78 5.53	**0.021** 0.122
6 Hours	SBP DBP	140.60 89.49	8.45 3.06	141.84 88.81	7.68 4.28	0.496 0.425
7 Hours	SBP DBP	139.85 90.44	8.75 2.63	139.77 89.89	5.65 3.63	0.961 0.456
8 Hours	SBP	139.81	7.56	143.37	8.04	0.068

	DBP	89.68	3.27	88.97	5.03	0.497
9 Hours	SBP	141.36	10.23	148.31	6.78	**0.004**
	DBP	89.64	3.13	88.81	6.38	0.518
10 Hours	SBP	144.00	8.40	144.55	9.10	0.837
	DBP	89.36	3.11	87.55	5.31	0.175
11 Hours	SBP	144.36	10.03	144.00	4.50	0.912
	DBP	90.00	2.19	89.13	1.63	0.275
12 Hours	SBP	147.00	8.08	148.00	6.63	0.849
	DBP	85.50	6.40	89.20	6.72	0.429

DISCUSSION

1. In present study age ranged from 18 to 31 years. Maximum women in group A (62%) and group B(64%) were aged between 21 to 25 years (p = 0.949). The mean age in group A was 22.00±2.53 years and group B it was 22.34± 2.58 years (p=0.507)
2. The obstetric history revealed most of the women in group A and group B with Primi para (80% vs 62%) (p=0.076)
3. In the present study presenting complaints like headache(8% each in group A and group B; p=0.643), pain in abdomen (94% in group A vs 92% in group B and p=0.500), bleeding per vagina (2% in group B vs Zero in group A; p=500) .
4. The comparing of cephalic presentation in women with group A and group B (98% each with p=0.753). Also uterine contraction (94% vs 90% with p=0.357) and presence of fetal heart rate was (98%) of the women each in group A and group B (p=0.753).
5. The clinical profile comparable in group A and group B results p>0.050.
6. In this study majority of the women in group B((6%) had onset of the blood pressure control within 30 minutes while in group A (94%) required duration of 31 to 60 minutes. This difference was statistically significant. (p <0.001). The mean duration for the onset of blood pressure control was also significantly low in group B compared to group A (29.40± 6.75 vs 52.80 ± 12.94 minutes where p < 0.001). The mean systolic and diastolic blood pressure in group A at beginning was 168.55± 5.66 and 104.36± 5.25 mmHg which gradually came down to 132.12 ± 5.16 and 89.44 ± 2.94 mm Hg at one hour interval while in group B, the mean systolic and diastolic blood pressure in group A at beginning was 165.80± 4.50 and 105.28± 5.61 reduced to 138.58 ± 4.92 and 87.33 ± 4.58 at 30 minutes intervals. The mean systolic and diastolic blood pressure at 30 minutes interval were significantly low in group B compared to group A where p < 0.001.
7. The women in group A had maximum duration of 12 hours while in group B only 4 % women required > 12 hours of duration
8. The majority of the women in group A (94%) and group B(86%) required two doses for the control of blood pressure (p = 0.093). the mean number of doses required in group A were slightly high (2.08± 0.34) compared group B (1.96 ± 0.46) but difference was statistically insignificant (p = 0.136). It shows that the faster onset of target blood pressure in women with nifedipine did not require additional doses compared to oral labetalol.

CONCLUSION

On the basis of observations and results in present study concluded that Tab. Nifedipine 10 mg is highly effective in achieving target blood pressure of 140/90 mmHg compared to 100mg Tab.Labetalol due to rapid onset of control.

The number of doses required to achieve the target blood pressure of 140/90 for Tab.Nifedipine 10 mg and Tab. Labetalol 100mg were almost equal.

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