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To compare success rate of oral nifedipine and intramuscular progesterone in treating threatened preterm labor

[1]Dr. B S Meena, [2]Dr. Vacha Sardar, [3]Dr. Suman Mendiratta

[1]Senior professor & HOD, [2]Resident Doctor, [3]Senior professor

Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur, Raj.

Corresponding Author: Dr. Vacha Sardar**,** Resident Doctor, Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur, Raj.

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Abstract

Background: Threatened preterm labor (TPL) is the leading cause of hospitalization during pregnancy. Almost 50% of the women with the diagnosis of TPL would eventually have a preterm delivery.

Methods: This study was a prospective interventional study was done in the Department of Obstetrics and Gynaecology, SMS Medical College & associated Hospitals, Jaipur from June 2018 onwards.

Results: Out of 50 newborns delivered by mothers who were treated with Nifedipine (Group A),49(90%) newborns survived while 5(10%) died. On the other hand Out of 50 newborns delivered by mothers who were treated with progesterone (Group B), 48(96%) newborns survived while 2(4%) died. P value was 0.436 which was not significant. Mothers treated with nifedipine had more neonatal deaths, as compare to progesterone.

Conclusion: We conclude that In conclusion, oral nifedipine has similar therapeutic efficacy to im micronised progesterone injection in postponing the TPL There was significant high birth weight in a patients treated with progesterone. Future studies are needed to evaluate this treatment in larger population.

Keywords: Nifedipine, Progesterone, Threatened preterm labor (TPL).

Introduction

Threatened preterm labor (TPL) is the leading cause of hospitalization during pregnancy[1]. Almost 50% of the women with the diagnosis of TPL would eventually have a preterm delivery[2]. Although the majority of these preterm births took place in the developing countries, the rate has recently been increased in the developed world.[3] Since the preterm birth is the main cause of neonatal mortality and morbidity, multiple strategies have been introduced to improve the neonatal outcome by postponing the delivery. [4] Tocolytic agents are the primary therapeutic options for TPL. For decades, β agonists and magnesium sulfate have been used for the treatment of preterm labor. Recent studies have shown that nifedipine, a calcium-channel blocker, is a more effective and better tolerated tocolytic agent compared to traditional drugs. [5] Nifedipine is now the first choice for the suppression of preterm labor [6]

However the use of nifedipine is associated with some side effects such as a headache, dizziness, flushing, and peripheral edema, and is contraindicated in women with hypotension, congestive heart failure, and aortic stenosis. There are also some concerns about its adverse effect on fetus. Progesterone is a key hormone in the process of pregnancy, since its decline has been implicated in the initiation of labor. Previous studies have demonstrated the effectiveness of prophylactic progesterone for preterm labor in high-risk women. Prophylactic progesterone significantly reduces the risk of preterm birth, low birth weight, and neonatal complications. Based on these findings, progesterone might be used as a tocolytic agent in women with TPL.[7]

Material & Methods

Study Type: A randomised comparative study

Study Design: This study was a prospective interventional study was done in the Department of Obstetrics and Gynaecology, SMS Medical College & associated Hospitals, Jaipur from June 2018 onwards.

Duration of Study: February 2018 onwards till sample size achieved

Sample Size

The sample size is calculated at power 80% and alpha error 0.05 assuming SD of 2 in duration of NICU stay as observed in the study.

For minimal detectable difference of 1.22 in duration of NICU stay, 44 cases will be required in each group.

As there are two groups therefore (88) cases will be required for total sample size. It is further enhanced and rounded off to 100 cases assuming 10% drop out/lost to follow up, (50 cases) equally divided into 2 groups

Study Group

Group A: Patients who receive loading dose of 30 mg of oral nifedipine and continued with 10-20 mg every 4-6 hours until the pain relief.

Group B: Patients who receive 200 mg im progesterone (100 mg in each gluteus maximus muscle)

Inclusion Criteria

- Singleton pregnancy
- Women of Age >18
- Gestational age between 26-36. 6 wks by last menstrual period verified by USG.
- Willing to participate

Exclusion Criteria

- Cervical dilatation ≥3cm.
- Vaginal bleeding
- Vaginal discharge
- uterine over distention (due to polyhydramnios or multiple gestations)
- Fever > 38'c
- Fetal distress
- Blood pressure ≥ 140/90 and ≤ 100/60 mmhg
- Gestational age > 37
- Patients with hypotension
- Fetal congenital anomaly
- Non-cooperative patient
- Withdrawal from study
- Severely ill

Methodology

1. Singleton pregnant women at preterm attending antenatal clinic in department of obstetrics and gynecology in SMS Medical college, Jaipur.
2. Details of the study will be explained to the pregnant women and written informed consent will be taken from all the pregnant women.
3. Inclusion and exclusion criteria will be applied.
4. Period of gestation will be calculated by LMP in patients with regular cycles or by first trimester USG.

5. Nifedipine will be stated with a loading dose of 30 mg and continued with 10-20 mg every 4-6 hours until the pain relief.
6. Tocolysis will be provided with 200mg of intramuscular progesterone (100 mg in each gluteus maximus muscle) in the second group.
7. The uterine contractions will be carefully monitored for the next 24 hours. If no contraction will be encountered, the patient will be discharged home. Patients will be asked to limit their physical activity and alarmed of the signs and symptoms of preterm labor. Weekly perinatal visits will be scheduled until the delivery.
8. Maternal outcome will be seen in terms of type of labor
9. Fetal outcome will be seen as 5 minute APGAR score, birth weight, umbillcal artery pH.
10. Data collection and statistical analysis will be done.

Statistical Analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Observations and Results

Table: 1 Distribution of study subjects

Variable	Group		P value
	Nifedipine	Progesterone	
Age	25.7± 2.82	26.44± 2.96.	0.288
BMI	25.62±2.56	26.34±2.81	0.184
BISHOP score	1.82±0.72	1.46±0.5	0.012
H/O preterm birth	48 (96.00%)	44 (88.00%)	0.269

The mean age of mothers who were treated with Nifedipine (Group A) was 25.7± 2.82 and of the mothers who were treated with progesterone (Group B) was 26.44± 2.96. Mean BMI of mothers who were treated with Nifedipine (Group A) was 25.62±2.56 and of mothers who were treated with progesterone (Group B) was 26.34±2.81. P value is 0.184. Out of 50 mothers who were treated with Nifedipine (Group A) mean BISHOP score was 1.82±0.72 and out of 50 mothers who were treated with progesterone (Group B) mean bishop score was 1.46±0.5. P value is 0.012. Out of 50 mothers in group A only 2(4%) mothers had history of preterm birth and 48(96%) mothers had no history of preterm birth. On the other hand 6(12%) mothers out of 50 in group B had history of preterm birth. The P value is 0.269 which is not significant. (P>0.05)

Table 2: Distribution of study subjects in relation to neonatal death

Neonatal death	Group		P value
	Nifedipine	Progesterone	
No	45 (90.00%)	48 (96.00%)	0.436
Yes	5 (10.00%)	2 (4.00%)	

Out of 50 newborns delivered by mothers who were treated with Nifedipine (Group A),49(90%) newborns survived while 5(10%) died. On the other hand Out of 50 newborns delivered by mothers who were treated with progesterone (Group B), 48(96%) newborns survived while 2(4%) died. P value was 0.436 which was not significant. Mothers treated with nifedipine had more neonatal deaths, as compare to progesterone.

Discussion

The present study is a randomized comparative study carried out at department of obstetrics and gynaecology, SMS Medical College, Jaipur from June 2018 till sample size is reached. It consists of 2 groups

each group has 50 patients Group B which consists of patients who received loading dose of 30 mg oral nifedipine and continued 10-20 mg every 4 -6 hours until pain relief and group A consists of patients who received 200 mg im progesterone.

In the present study, the mean age of mothers of group A was 25.7±2.82 and of the mothers of group B was 26.44± 2.96.

In the study conducted by Bushra Ashraf. et.al 2019 [8]were a total of 276 patients, with 138 patients in either group. There was no significant difference in the baseline maternal demographics and clinical characteristics of the two groups. The age of the patients ranged between 16 and 45 yr with a mean age of 23.03±8.35 yr in group A and 23.16±8.37 yr in group B.

In the present study mean BMI of mothers of group A was 25.62±2.56 and of mothers of group B was 26.34±2.81. P value is 0.184 which is not significant. (P>0.05)

The mean BISHOP score of mothers of group A was 1.82±0.72 and of mothers of group B was 1.46±0.5. P value is 0.012. It is significant as P value is less than 0.05. (P>0.05)

In the present study patients treated with nifedipine had more neonatal deaths, which was (10%) as compare to progesterone which was 4%. P value was 0.436 which was not significant (p>0.05)

In the study conducted by Bushra Ashraf. et.al [8] patients treated with nifedipine had more neonatal deaths, which was 9.42%, as compared to progesterone which was 2.17%

Conclusion

We conclude that In conclusion, oral nifedipine has similar therapeutic efficacy to im micronised progesterone injection in postponing the TPL There was significant high birth weight in a patients treated with progesterone. Future studies are needed to evaluate this treatment in larger population.

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