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Original Research

Comparison of Feto-Maternal Outcomes between Nifedipine and Magnesium Sulfate in the Management of Preterm Labor

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Abstract: **Objective:** To compare the feto-maternal outcomes between the administration of nifedipine versus magnesium sulfate in the management of preterm labor. **Study design:** Randomized controlled trial **Study place and period:** Department of Obstetrics & Gynecology, Chaudhry Muhammad Akram Hospital, Lahore, from April 2025 to September 2025. **Methodology:** One hundred and ten pregnant females were enrolled and randomly assigned in two groups. In group-A, females received Nifedipine and in group-B, females received Magnesium sulfate. Females were followed by for outcomes including successful tocolysis and Low Apgar score of neonate at birth. All collected data will be recorded in proforma and analysed in SPSS v.26. **Results:** In this trial, we observed that the median age of females in nifedipine group was 30.00 (IQR: 12.00) years and in magnesium sulfate group was 27.00 (IQR: 17.00) years. Successful tocolysis was observed in 50 (90.9%) females in nifedipine group while in 41 (74.5%) in magnesium sulfate group ($p<0.05$). For low Apgar score, nifedipine group had less frequency of low Apgar score, 6 (10.9%) than magnesium sulfate group 15 (27.3%, $p<0.05$). **Conclusion:** In this trial, we observed that nifedipine is more effective in improving gestational age for delivery nearer or at term.

Keywords: Preterm labor, feto-maternal outcomes, nifedipine, magnesium sulfate, Apgar score, Successful tocolysis.

INTRODUCTION

Due to its correlation with poor feto-maternal outcomes, preterm labor—defined as the start of labor before 37 weeks of gestation—remains a major obstetric concern. [1] According to a study conducted in Pakistan, the estimated prevalence of preterm delivery is almost 21%.[2] Another study found that 5–10% of patients give birth before 37 weeks, while 1-2% of pregnancies end before 32 weeks.[3] Preterm delivery has been linked to a number of co-morbidities, such as broncho-pulmonary dysplasia, necrotizing enterocolitis, intra-ventricular hemorrhage, retinopathy of prematurity, and congenital abnormalities.[4, 5] In order to reduce the related risk of perinatal morbidity and mortality, treating preterm labor and preventing its occurrence are important objectives in the management of pregnancies.[6, 7]

Among the drugs used to postpone the commencement of preterm delivery include beta-2 agonists, prostaglandin synthetase inhibitors, calcium channel blockers, oxytocin receptor antagonist

(Atosiban), nitric oxide donors, and magnesium sulphate. However, because of their high cost or related adverse effects, the use of the majority of these medicines is limited.[8, 9] Nifedipine and magnesium sulfate are two tocolytic medications that are frequently used to treat premature labor. A calcium channel blocker called nifedipine works by preventing calcium from entering myometrial cells. This causes smooth muscle to relax, which in turn prevents uterine contractions. On the other hand, it is thought that magnesium sulfate causes tocolysis through a variety of mechanisms, such as interference with myometrial contractility, inhibition of prostaglandin synthesis, and blocking of calcium channels.[1, 10]

The relative effectiveness and safety of nifedipine and magnesium sulfate in the treatment of preterm labor are still up for discussion, despite their widespread use. There have been inconsistent results from earlier research; some have shown that one drug is better than the other, while others have found no discernible difference in feto-maternal outcomes. Further research into the relative efficacy of nifedipine and magnesium sulfate is necessary given the significance of optimizing management techniques for preterm labor. This study attempts to offer important insights into the best way to manage preterm labor by assessing their effect on feto-maternal outcomes.

MATERIALS AND METHODS

Upon receiving approval from the ethical committee as well as obtaining informed consent from the participants, this randomized controlled tria1 was conducted at Department of Obstetrics & Gynecology, Chaudhry Muhammad Akram Hospital, Lahore from April 2025 to September 2025. Sample size was calculated using WHO sample size calculator with following parameters:

- Significance level (α) = 5%
- Power of study (d) = 8%
- Expected frequency of successful tocolysis after nifedipine therapy = 72%[11]
- Expected frequency of successful tocolysis after magnesium sulfate therapy = 48%[11]

Calculated sample size (n) is 110 (55 in each group)
Non-probability consecutive sampling technique was applied to enroll the females with following characteristics:

Inclusion Criteria: Women of reproductive age: 15-45 years, with singleton pregnancy, presenting with preterm labor. Preterm labor was defined as onset of labor between gestational weeks 32 and 36, with regular painful uterine contractions lasting more than 1 hour and 1 or more contractions in 10 minutes, with effacement, intact membranes, and cervical dilation < 3cm on per vaginal examination, diagnosed by consultant obstetrician.

Exclusion Criteria: Females with history of previous use of nifedipine, history of hypersensitivity reaction to nifedipine, fetal distress at presentation, hypotension at presentation, cervical dilatation of 3cm or more, intrauterine fetal death, or multiple pregnancies were excluded.

Baseline characteristics such as maternal age, gestational age, gravidity, and parity were documented. Initially, females were informed about the risks and benefits of the treatment. Vital signs were checked for all females before administering a 500cc Ringer's solution via rapid infusion. If uterine contractions persist, females were randomly assigned to either the Nifedipine group (Group A) or the Magnesium sulfate group (Group B). Females in the Magnesium sulfate group received an intravenous 6g bolus of MgSO4 20%, followed by a continuous infusion of 2g/hour. Those in the Nifedipine group will receive an oral dose of 10 mg nifedipine every 20 minutes for three doses, followed by 10 mg orally every 6 hours. Treatment continued for 48 hours in both groups. Females' pulse rate and blood pressure were monitored every 30 minutes for the first 4 hours, and then every 4 hours up to 48 hours. Additionally, females in the Magnesium sulfate group were assessed for signs of MgSO4 toxicity at the same intervals. Fetal and maternal outcomes were determined in terms of successful tocolysis and low Apgar score. Successful tocolysis was noted in terms of "successful tocolysis" defined as cessation of uterine contractions and delay of delivery for ≥ 48 hours after treatment, assessed by consultant obstetrician. Low Apgar score <7 was assessed by consultant obstetrician at 1 and 5 minutes. All collected data was systematically recorded on a designated proforma.

Statistical analysis for the study was conducted using the SPSS software version 26.0. The normality of distribution for continuous variables was assessed using the Kolmogorov-Smirnov test. Continuous variables such as maternal age, gestational age, will be presented as mean and standard deviation. While categorical variables like gravidity, parity, successful tocolysis, and low APGAR score, were reported as frequency (%). Categorical variables, successful tocolysis, and low APGAR score were be analyzed using the Chi-square test or Fisher's exact test as appropriate. Potential confounding variables identified include maternal age, gestational age, and parity were controlled through stratification. After stratification, the effect of confounding variables on the primary outcomes was compared between the Nifedipine and Magnesium sulfate groups using the Chi-square test to ascertain any significance. All tests will be two-tailed, and a p-value ≤0.05 was considered as significant.

RESULT

In this trial, we observed that the median age of females in nifedipine group was 30.00 (IQR: 12.00) years and in magnesium sulfate group was 27.00 (IQR: 17.00) years. The median gestational age was similar in both groups 34.00 (IQR: 2.00) weeks. The median BMI of females was 25.00 (IQR: 6.00) vs. 26.00 (IQR: 8.00) kg/m^2 in both groups. In nifedipine group, there were 11 (20%) primigravida and in magnesium sulfate group, 20 (36.4%) were primigravida. In nifedipine group, the median blood pressure was 130.00 (IQR: 20.00) / 80.00 (IQR: 20.00) mmHg and in magnesium sulfate group, median blood pressure was 130.00 (IQR: 25.00) / 80.00 (IQR: 25.00). The pulse rate was less in nifedipine group than magnesium sulfate group. Table-I

In this trial, we observed successful tocolysis in 50 (90.9%) females in nifedipine group while in 41 (74.5%) in magnesium sulfate group. The difference was significant ($p<0.05$). The median Apgar score in nifedipine group was 8.00 (IQR: 2.00) while in magnesium sulfate group was 8.00 (IQR: 3.00) at 1 minutes ($p>0.05$). After 5 minutes of birth, the median Apgar score in nifedipine group was 8.00 (IQR: 2.00) while in magnesium sulfate group was 8.00 (IQR: 3.00) and difference was insignificant ($p>0.05$). But for low Apgar score, nifedipine group had less frequency of low Apgar score, 6 (10.9%) than magnesium sulfate group 15 (27.3%) and this difference was significant ($p<0.05$). Table-II

In this trial, we observed that when data was stratified for age factor, it was observed that in both age strata, the successful tocolysis was observed better with nifedipine than magnesium sulfate, although the difference was insignificant ($p>0.05$). Data was also stratified for gestational age and it was observed that in females given tocolysis at gestational age 32-34 weeks, the successful tocolysis was achieved better with nifedipine (100%) than magnesium sulfate (82.4%, $p<0.05$). But at gestational age 35-36 weeks, successful tocolysis was achieved in 75% cases with nifedipine while in 61.9% females with magnesium sulfate ($p>0.05$). In primigravida females, the successful tocolysis was insignificant in both groups (81.8% vs. 75%, $p>0.05$). But in multigravida females, successful tocolysis was observed in 93.2% with nifedipine while in 74.3% with magnesium sulfate ($p<0.05$). In obese females, nifedipine worked better and achieved successful tocolysis in 91.7% cases while with magnesium sulfate, successful tocolysis was achieved in 70% cases ($p<<0.05$). In non-obese females, the effectiveness was almost similar in both groups (90.3% vs. 80%, $p>0.05$). Among hypertensive females, nifedipine showed better successful tocolysis (94.7%) than magnesium sulfate (88.2%), although the difference was insignificant ($p>0.05$). In non-hypertensive females, successful tocolysis was achieved in 88.9% with nifedipine and in 68.4% with magnesium sulfate ($P<0.05$). Table-III
In this trial, we observed that when data was stratified for age factor, it was observed that in females aged 15-25 years, low Apgar score was observed in 9.1% cases with nifedipine while in 44% cases with magnesium sulfate ($p<0.05$). But in females delivered at age 26-45 years, the low Apgar score was almost similar in both groups ($p>0.05$). Data was also stratified for gestational age and it was observed that in females given tocolysis at gestational age 32-34 weeks, the low Apgar score was noted in 2.9% cases with nifedipine, while in 26.5% cases with magnesium sulfate ($p<0.05$). But at gestational age 35-36 weeks, low Apgar score was noted in 25% cases with nifedipine while in 28.6% females with magnesium sulfate ($p>0.05$). In primigravida females, the low Apgar score was nil with nifedipine while in 40% cases with magnesium sulfate ($p<0.05$). But in multigravida females, low Apgar score was observed in 13.6% with nifedipine while in 20% with magnesium sulfate ($p>0.05$). In obese females, nifedipine worked better and low Apgar score was observed less (8.3%) than magnesium sulfate (26.7%). In non-obese females, the low Apgar score observed less (12.9%) than magnesium sulfate (28%, $p>0.05$). Among hypertensive females, nifedipine showed less cases of low Apgar score (5.3%) than magnesium sulfate (41.2%, $p<0.05$). In non-hypertensive females, low Apgar score was noted in 13.9% with nifedipine and in 21.1% with magnesium sulfate ($P>0.05$). Table-IV

Table-I: Demographics and clinical assessment of females (n = 110)

	Group	
	Nifedipine	**Magnesium sulfate**
n	55	55
Age, years	30.00 (IQR: 12.00)	27.00 (IQR: 17.00)
Gestational Age, weeks	34.00 (IQR: 2.00)	34.00 (IQR: 2.00)
BMI, kg/m^2	25.00 (IQR: 6.00)	26.00 (IQR: 8.00)
Parity		
Primigravida	11 (20%)	20 (36.4%)
Parity 1	15 (27.3%)	7 (12.7%)
Parity 2	19 (34.5%)	21 (38.2%)
Parity 3	10 (18.2%)	7 (12.7%)
SBP, mmHg	130.00 (IQR: 20.00)	130.00 (IQR: 25.00)
DBP, mmHg	80.00 (IQR: 20.00)	80.00 (IQR: 25.00)
Pulse, bpm	82.00 (IQR: 17.00)	87.00 (IQR: 14.00)

Table-II: Comparison of feto-maternal outcomes in both groups (n = 110)

	Group		p-value
	Nifedipine	Magnesium sulfate	
n	55	55	
Successful tocolysis	50 (90.9%)	41 (74.5%)	0.023
Apgar score at 1 minute	8.00 (IQR: 2.00)	8.00 (IQR: 3.00)	0.231
Apgar score at 5 minute	8.00 (IQR: 2.00)	8.00 (IQR: 3.00)	0.095
Low Apgar score	6 (10.9%)	15 (27.3%)	0.029

Table-III: Comparison of successful tocolysis in both groups when controlled for effect modifiers (n = 110)

		Group		p-value
		Nifedipine	Magnesium sulfate	
Age (years)	15-25	19 (86.4%)	16 (64.0%)	0.079
	26-45	31 (93.9%)	25 (83.3%)	0.181
Gestational age (weeks)	32-34	35 (100%)	28 (82.4%)	0.009
	35-36	15 (75.0%)	13 (61.9%)	0.368
Parity	Primigravida	9 (81.8%)	15 (75.0%)	0.664
	Multigravida	41 (93.2%)	26 (74.3%)	0.020
BMI	Obese	22 (91.7%)	21 (70.0%)	0.049
	Non-obese	28 (90.3%)	20 (80.0%)	0.272
Hypertension	Present	18 (94.7%)	15 (88.2%)	0.481
	Absent	32 (88.9%)	26 (68.4%)	0.033

Table-IV: Comparison of low Apgar score in both groups when controlled for effect modifiers (n = 110)

		Group		p-value
		Nifedipine	Magnesium sulfate	
Age (years)	15-25	2 (9.1%)	11 (44.0%)	0.008
	26-45	4 (12.1%)	4 (13.3%)	0.885
Gestational age (weeks)	32-34	1 (2.9%)	9 (26.5%)	0.006
	35-36	5 (25.0%)	6 (28.6%)	>0.999
Parity	Primigravida	0 (0.0%)	8 (40.0%)	0.028
	Multigravida	6 (13.6%)	7 (20.0%)	0.449
BMI	Obese	2 (8.3%)	8 (26.7%)	0.157
	Non-obese	4 (12.9%)	7 (28.0%)	0.190
Hypertension	Present	1 (5.3%)	7 (41.2%)	0.016
	Absent	5 (13.9%)	8 (21.1%)	0.545

DISCUSSION

In this trial, we observed that Successful tocolysis (cessation of uterine contractions for at least 48 hours) was observed in 50 (90.9%) females in nifedipine group while in 41 (74.5%) in magnesium sulfate group ($p<0.05$). For low Apgar score, nifedipine group had less frequency of low Apgar score, 6 (10.9%) than magnesium sulfate group 15 (27.3%, $p<0.05$).

In a randomized controlled tria1 presented by Bhat et al., about 70% of females in the MgSO4 group and 57.5% of females in the Nifedipine group delivered near term or at term out of females, who earlier presented with preterm labor. At one minute, APGAR scores were less than seven in 50% of cases (MgSO4) and 56.5% of cases (Nifedipine), with no discernible difference ($p=0.642$). At five minutes, 57.1% (MgSO4) and 65.2% (Nifedipine) had scores less than seven ($p=0.557$).[12] Tocolytics are primarily used to avoid premature labor by essentially extending pregnancy by at least 48 to 72 hours. This allows for the delivery of two doses of corticosteroids, which aid in the development of the newborn's lungs.[13]

According to a study, 48% of the magnesium sulfate group and 72% of the nifedipine group postponed labor for more than 48 hours ($p=0.03$). [11] On the other hand, another study found that magnesium sulfate prevented labor for 48 hours in 88.80% of cases and nifedipine in 74% of cases ($p=0.003$).[14] According to Khooshideh et al., there was no discernible difference in birth within 24 hours (70% Nifedipine vs. 72.2%

MgSO4, p=0.65) or 48 hours (14.5% Nifedipine vs. 13.6% MgSO4, p=0.84) in 220 females with premature labor treated with either Nifedipine or MgSO4. There was no significant difference between APGAR scores <7 at 1 minute (10% Nifedipine vs. 9% MgSO4, p=0.81) and after 5 minutes (6.4% Nifedipine vs. 7.3% MgSO4, p=0.7).[15]

However, in a different study, Nikbakht et al. found that both medications were similarly successful in preventing labor and postponing delivery for more than seven days (56% vs. 64% with nifedipine vs. magnesium sulfate, respectively; p>0.05). For the treatment of preterm labor, the researcher found that oral nifedipine is a good substitute for magnesium sulfate with comparable effectiveness.[16] This contradiction may be due to different number of sample size and different population and health care system, as Iran has better healthcare system than Pakistan.

Other research have demonstrated these findings. In a randomized study, Lyell et al. also found that the primary result (arrest of preterm labor, which is defined as preventing delivery for 48 hours with uterine quiescence) was attained by more individuals who were given magnesium sulfate (87% compared with 72%, P=0.01). Delivery within 48 hours did not differ (7.6% magnesium sulfate versus 8.0% nifedipine, P=0.92).[17]

A meta-analysis of fifty publications with 6072 cases (n = 3,014 for magnesium sulfate and n = 3,058 for nifedipine) was carried out by Fan et al. Nifedipine was superior to magnesium sulfate in terms of delay to beginning of action, lengthening of gestation days, and higher neonatal Apgar scores. They came to the conclusion that nifedipine had a faster onset of action and a longer pregnancy than magnesium sulfate. However, more research is required to verify these medicines' long-term safety and effectiveness.[18]

Nifedipine demonstrated a stronger effect than a 4-gram IV dosage of magnesium sulfate, according to Costa et al.'s meta-analyses of 15 randomized studies. However, there was no discernible difference in the effectiveness of these tocolytics in extending pregnancy by 48 hours between nifedipine and a 6-gram intravenous dose of magnesium sulfate. Magnesium sulfate was also linked to greater negative medication responses. Large, well powered trials are needed to corroborate the evidence reported here, which has a moderate degree of assurance.[19]

Based on a meta-analysis of 40 trials, Zamani et al. also came to the conclusion that, given nifedipine's superiority over ritodrine and nitroglycerine and its comparable effectiveness to magnesium sulfate for tocolysis, the first drug line appears to be determined by these options' side effects. They found that there was no significant difference between nifedipine and magnesium sulfate at any of the time points (i.e., within the first 48 hours, for more than one week, and for 34 weeks and more).[20]

In this study, we observed few limitations including financial limitation and time limitation. Door to time limitation, we only observed short term outcomes that are also limited to only successful tocolysis and Apgar score. However, further parameters including adverse effects of trial drugs including headache, gastrointestinal disturbances, changes in hemodynamics and mode of delivery along with NICU admission. Further trials, could be done with large sample size and more number of outcome parameters.

CONCLUSION

It has been proved in this trial, that nifedipine is more effective in improving gestational age for delivery nearer or at term. For tocolysis, in future, we will implement the use of nifedipine and replace magnesium sulfate, because it provides better pregnancy prolongation with fewer maternal side effects and easier administration.

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