



## **Nifedipine compared to magnesium sulphate for treating preterm labor: A randomized clinical trial**

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### **Abstract**

**Background:** To evaluate comparison of Nifedipine and magnesium sulphate for treating preterm labor.

**Material and methods:** A total of 200 subjects with presence of preterm labour between twenty-four weeks to thirty-seven weeks of gestation. Pregnancies that were nulliparous or multiparous, had intact membranes, and displayed clinical indicators of premature labour met the inclusion criteria. Randomization of all the patients was done and all the patients were divided into two study groups- Nifedipine group and magnesium sulphate group. The success of tocolysis treatment and its side effects were evaluated in all patients who had not given birth forty-eight hours and more than 7 days (secondary tocolytic effects) after starting it. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software.

**Results:** Mean maternal age of nifedipine group and magnesium sulphate group was 31.5 years and 30.1 years respectively. In the nifedipine group, there were 5 patients who delivered after 24 hours, 10 patients who delivered after 48 hours, 5 patients who delivered after 72 hours, and 55 patients who delivered after 7 days. In the magnesium sulphate group, there were 8 patients who delivered after 24 hours, 8 patients who delivered after 48 hours, 6 patients who delivered after 72 hours, and 60 patients who delivered after 7 days. There was no statistically significant difference between the two groups with regard to this quality.

**Conclusion:** We concluded that the oral nifedipine is a suitable alternative for magnesium sulfate with the same efficacy and side effects in the management of preterm labor.

**Keywords:** Nifedipine, Magnesium sulfate, preterm labor.

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### **Introduction**

The incidence of preterm birth is nine percent to thirteen percent of births.<sup>1</sup> Tocolytic agents like beta mimetics, calcium channel blockers, oxytocin receptor antagonists, and magnesium sulfate are used to suppress preterm labor.<sup>2, 3</sup> Previous authors declared that MgSO<sub>4</sub> administration did not result in a statistical reduction in birth < 48 hours.<sup>5</sup> In addition,

MgSO<sub>4</sub> may be associated with an increase in maternal and neonatal adverse effects<sup>6</sup>. MgSO<sub>4</sub> is recommended as a neuroprotective drug for the neonate < 32 weeks<sup>7</sup>. Nifedipine as a calcium channel blocker is one of the best drugs for inhibition of preterm labor.<sup>8</sup> Ease of administration, maternal tolerance, low neonatal mortality and respiratory distress syndrome, and low maternal adverse effects are the advantages of nifedipine.<sup>9,10</sup> Nifedipine is a vasodilator and it may cause nausea, flushing, headache, dizziness, palpitations, and transient hypotension.<sup>11,12</sup> An optimal nifedipine dosing regimen for treatment of preterm labor has not been yet established.<sup>12</sup> Hence; the present study was conducted for comparing Nifedipine to magnesium sulphate for treating preterm labour.

### **Material and methods**

The present study was conducted for comparing Nifedipine to magnesium sulphate for treating preterm labour. A total of 200 subjects with presence of preterm labour between twenty-four weeks to thirty-seven weeks of gestation. Pregnancies that were nulliparous or multiparous, had intact membranes, and displayed clinical indicators of premature labour met the inclusion criteria. A cervical change and four or more uterine contractions lasting at least 30 seconds each are required to diagnose premature labour. Dexamethasone was given to patients whose gestational ages were below 34 weeks to promote foetal lung maturity. Randomization of all the patients was done and all the patients were divided into two study groups- Nifedipine group and magnesium sulphate group. A ten mg capsule was used to start the tocolysis process, which was subsequently repeated every 20 minutes up to a maximum dose of 30 mg during the first hour of treatment. After that, a ten mg capsule was used as the maintenance dose every six hours. Magnesium sulphate tocolysis was started with 10g (I.V.) and then 5g (I.M.) every four hours. Fetal heart rate, blood pressure, pulse rate, and uterine contractions were all monitored in all cases. The success of tocolysis treatment and its side effects were evaluated in all patients who had not given birth forty-eight hours and more than 7 days (secondary tocolytic effects) after starting it. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software.

### **Results**

Mean maternal age of nifedipine group and magnesium sulphate group was 31.5 years and 30.1 years respectively. In the nifedipine group, there were 5 patients who delivered after 24 hours, 10 patients who delivered after 48 hours, 5 patients who delivered after 72 hours, and 55 patients who delivered after 7 days. In the magnesium sulphate group, there were 8 patients who delivered after 24 hours, 8 patients who delivered after 48 hours, 6 patients who delivered after 72 hours, and 60 patients who delivered after 7 days. There was no statistically significant difference between the two groups with regard to this quality. In this particular trial, 18 patients in the nifedipine group and 15 patients in the magnesium sulphate group experienced a treatment failure and required the use of additional tocolytic drugs. There was likewise no statistically significant difference between the two groups with regard to this quality.

**Table 1:** Demographic and clinical data

Variable		Nifedipine group (%)	Magnesium sulphate (%)
Mean Maternal age (years)		31.5	30.1
Gravida	Primi	59	55
	Multi	41	45
Mean gestational age (weeks)		34.6	35.1

**Table 2:** Obstetric characteristics

Variable		Nifedipine group (%)	Magnesium sulphate (%)	p-value
Delivery	After 24 hours	5	8	0.64
	After 48 hours	10	8	0.81
	After 72 hours	5	6	0.27
	After 7 days	55	60	0.28
Treatment failure		18	15	0.32
Adverse events		7	3	0.14

## Discussion

Preterm labor is frequency uterine contractions, progressive effacement and dilation of the cervix prior to term gestation. Prevention and treatment of preterm labor is important because it is one of the most important causes of perinatal morbidity and mortality. Some studies showed that nifedipine in comparison with other tocolytics is associated with a more frequent successful prolongation of pregnancy and lower incidence of respiratory distress syndrome. In a recent study in which these two tocolytic agents Magnesium sulfate and Nifedipine were compared in terms of efficacy in preterm labour. The primary outcome was arrest of preterm labour, defined as prevention of delivery for 48 hours. Results showed that more patients assigned to magnesium sulfate achieved the primary outcome.<sup>9- 12</sup> Hence; the present study was conducted for comparing Nifedipine to magnesium sulphate for treating preterm labour. Mean maternal age of nifedipine group and magnesium sulphate group was 31.5 years and 30.1 years respectively. In the nifedipine group, there were 5 patients who delivered after 24 hours, 10 patients who delivered after 48 hours, 5 patients who delivered after 72 hours, and 55 patients who delivered after 7 days. In the magnesium sulphate group, there were 8 patients who delivered after 24 hours, 8 patients who delivered after 48 hours, 6 patients who delivered after 72 hours, and 60 patients who delivered after 7 days. There was no statistically significant difference between the two groups with regard to this quality. Nikbakht, R et al compared the efficacy and safety of magnesium sulfate and nifedipine in the management of preterm labor. 100 women with documented preterm labor were randomly assigned to receive magnesium sulfate (n=50) and nifedipine (n=50) as tocolytic therapy. Both drugs were equally effective in prevention of labor and delaying delivery >7 days, 56% vs. 64% in the nifedipine and magnesium sulfate groups, and the days gain in utero was no statistically different in two groups. 6% of nifedipine group and 2% of magnesium sulfate group required drug discontinuation due to severe symptoms. There were also no significant

differences in maternal characteristics between two groups. The total success rate and side effects were similar in two groups.<sup>11</sup>

In this particular trial, 18 patients in the nifedipine group and 15 patients in the magnesium sulphate group experienced a treatment failure and required the use of additional tocolytic drugs. There was likewise no statistically significant difference between the two groups with regard to this quality. Lyell DJ et al compared the efficacy and side effects of intravenous magnesium to oral nifedipine for acute tocolysis of preterm labor. One hundred ninety-two patients were enrolled. More patients assigned to magnesium sulfate achieved the primary outcome (87% compared with 72%,  $P=.01$ ). There were no differences in delivery within 48 hours (7.6% magnesium sulfate compared with 8.0% nifedipine,  $P=.92$ ), gestational age at delivery (35.8 compared with 36.0 weeks,  $P=.61$ ), birth before 37 and 32 weeks (57% compared with 57%,  $P=.97$ , and 11% compared with 8%,  $P=.39$ ), and episodes of recurrent preterm labor. Mild and severe maternal adverse effects were significantly more frequent with magnesium sulfate. Birth weight, birth weight less than 2,500 g, and neonatal morbidities were similar between groups, but newborns in the magnesium sulfate group spent longer in the neonatal intensive care unit (8.8+/-17.7 compared with 4.2+/-8.2 days,  $P=.007$ ). Patients who received magnesium sulfate achieved the primary outcome more frequently.<sup>12</sup>

## **Conclusion**

We concluded that the oral nifedipine is a suitable alternative for magnesium sulfate with the same efficacy and side effects in the management of preterm labor.

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