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Original Research Article

A comparative study on MgSO₄ and nifedipine as acute tocolytic agents in preterm labour

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ABSTRACT

Background: Preterm labour is a major cause of neonatal morbidity and mortality. Tocolysis helps delay delivery, allowing time for antenatal corticosteroids and in-utero transfer. Magnesium sulphate (MgSO₄) and nifedipine are commonly used agents, but comparative evidence is limited. To compare the efficacy and safety of MgSO₄ and nifedipine as acute tocolytics in preterm labour.

Methods: This randomized controlled trial at a tertiary care centre - GMC Akola, enrolled 100 women between 28–34 weeks of gestation with preterm labour. Participants were randomly allocated to receive either MgSO₄ (loading dose 4 g IV, followed by 1 g/hr infusion) or oral nifedipine (10 mg every 20 min up to 3 doses, then 20 mg every 4-6 hrs for 24 hrs). Outcomes assessed were uterine quiescence, prolongation of pregnancy ≥48 hrs, maternal side effects, and neonatal outcomes.

Results: Labour was arrested in 92% of women treated with MgSO₄ and 90% with nifedipine. MgSO₄ achieved slightly higher rates of uterine quiescence and prolongation beyond 48 hrs. NICU admissions were lower with MgSO₄ (38% vs 44%), as was neonatal mortality (10% vs 14%). Side effects were mild and comparable: hot flushes/lethargy with MgSO₄ and tachycardia/headache with nifedipine. No serious adverse events occurred.

Conclusion: Both MgSO₄ and nifedipine are effective and safe tocolytic agents. MgSO₄ offers a marginal advantage in prolonging gestation and provides fetal neuroprotection, whereas nifedipine is simpler to administer and cost-effective in low-resource settings.

Keywords: Preterm labour, Tocolysis, Magnesium sulphate, Nifedipine, Neonatal outcome

INTRODUCTION

According to the WHO, preterm is defined as babies born alive before 37 weeks of pregnancy are completed.¹ The preterm classification is typically used between 20-37 weeks with a further separation of early preterm between 20 and 33 weeks and late preterm between 33 and 37 weeks.² Preterm labor can cause premature birth. The earlier the prematurity, the greater is the health risk to the newborn. Premature newborns often need special care in the neonatal intensive care unit and can have long-term mental and physical disabilities. These conditions may be lifelong, like cerebral palsy, or may only manifest later in

the person's life as learning difficulties. The WHO records an estimated 13.4 Million babies were born preterm in 2020. That is more than 1 in 10 babies. Approximately 900000 children died in 2019 of complications of preterm birth. Many survivors face a lifetime of disability, including learning disabilities and visual and hearing problems.¹ The WHO also records a large disparity in the survival rate of preterm newborns in low-income and high-income countries. In low-income countries, it found that 90% of preterm newborns did not survive past a few days whereas this rate was 10% in high income countries. Tocolysis is an obstetric procedure carried out with the use of medications with the purpose of delaying the delivery

of a fetus in women presenting preterm contractions. These medications are administered with the hope of decreasing fetal morbidity and mortality. Tocolysis is intended to prolong gestation for two to seven days and works by creating a quiescent environment in the uterus. This is important to allow transportation to a higher care facility, to administer a fetal lung maturity scheme with antenatal corticosteroids.⁴ Tocolysis is not intended to increase gestation of the fetus to term but is focused on providing a window of time to support treatments that have been shown to improve outcomes for delivery.⁴

METHODS

A randomised clinical trial was carried out in the Department of Obstetrics and Gynaecology at Government Medical College Akola, Maharashtra between March 2023 to October 2024. The study population consisted of 100 pregnant women with gestational age between 28-34 weeks presenting with symptoms of preterm labour. Simple random sampling technique was employed using the lottery method. Group allocation was done using sequentially numbered opaque envelopes based on a computer-generated randomization table, 50 belonging to each group. This study is conducted for comparing nifedipine and magnesium sulphate in management of preterm labour. All pregnant patients coming with complaints of labour pains with gestational age more than 28 weeks and less than 34 weeks satisfying inclusion criteria will be enrolled in the study after taking proper consent.

Inclusion criteria

Pregnant women with singleton pregnancy with gestational age less than 34 weeks and more than 28 weeks in preterm labour (2 or more contractions in 10 mins lasting for 30 seconds with cervical changes 0-3 cm and with less than 50% effacement with intact membrane).

Exclusion criteria

Women with contraindication/hypersensitivity for MgSO₄ and nifedipine, twin pregnancy, severe fetal malformation or chromosomal abnormalities, intrauterine fetal demise, placental abruption, placenta previa, prom, maternal medical disease, chorioamnionitis, nonreassuring fetal status, intrauterine growth restriction, patients with cervical dilation more than or equal to 4 cm. After proper evaluation by history and proper examination, appropriate

candidates are selected for MgSO₄ /Nifedipine whoever fulfils the inclusion criteria. Patients consent for study is taken. Randomly dividing patients into two groups by using sequentially numbered opaque envelopes generated from a random numbers table. Vital signs are checked first for all patients, 500cc RL is then administered before giving MgSO₄ and Nifedipine. Patients will be monitored for attainment of uterine quiescence which is defined as one or less contraction in 10mins calculated manually from initiation of treatment. Patients will be monitored for preterm labour to subside, defined as 6 or less contractions per hour for 12 hours and no further cervical changes within 48 hours of initiation of tocolytic therapy. Patients will be monitored for continuation of pregnancy till 48 hrs by calculating time between treatment initiation and preterm delivery. Patients are monitored for adverse effects due 2 are kept on micronized progesterone therapy till term. Results are statistically analysed from the case sheet

RESULTS

In a current study with 100 participants, it is observed that 55% of patients of MgSO₄ group was between 18-25 years, 39% between 26-33 years and 5% between 34-40 years. While from Nifedipine group 54% belong in 18-25 year, 40% in 26-33 years, only 6% between 34-40 years. The distribution of patients based on gravida status in both study groups shows that Among women receiving MgSO₄, 35% were primigravida and 65% were multigravida. In the Nifedipine group, 29% were primigravida and 71% were multigravida. In a current study involving 100 patients, 50 were treated with nifedipine and 50 with MgSO₄. Both MgSO₄ and nifedipine were found to be equally effective in stopping labor and extending gestational age. Among the 50 patients who received MgSO₄, labor was halted in 46 cases, while labor was stopped in 45 cases out of the 50 patients treated with nifedipine.

However, it is found that MgSO₄ is found slightly superior in terms of: achieving quiescence and prolonging gestational age above 48 hours: 92% over 90% for nifedipine. In terms of NICU admissions, 38% of the MgSO₄ group required it, compared to 44% in the nifedipine group. As for neonatal mortality, 10% was observed in the MgSO₄ group, while 14% occurred in the nifedipine group. In the current study both MgSO₄ and Nifedipine exhibited similar rates of side effects (11-12%). MgSO₄ causes hot flushes (6%) and lethargy (6%), while Nifedipine led to tachycardia and headaches.

Table 1: Administration of MgSO₄ and nifedipine.

	Loading dose	Maintenance dose	Advantage	Side effect
MgSO₄	4 g administered iv slowly over 20-30 mins	1 g per hour via the intravenous route in 100 ml normal saline	Fetal neuroprotection, cost effective, easily available	Respiratory depression, MgSO ₄ toxicity
Nifedipine	10 mg orally every 20 mins upto 3 doses	20 mg orally every 4-6 hrs till 24 hours	Easy to administer, lesser side effects	Maternal tachycardia, hypotension

Table 2: Age distribution.

Age group (in years)	MgSO ₄ (n=50)	MgSO ₄ %	Nifedipine (n=50)	Nifedipine %
18–25	28	55	27	54
26–33	20	39	20	40
34–40	2	5	3	6

Table 3: Gravida status.

Gravida status	MgSO ₄ (n=50)	MgSO ₄ %	Nifedipine (n=50)	Nifedipine %
Primigravida	18	35	15	29
Multigravida	32	65	36	71

Table 4: Quiescence Achieved.

Above 48 hours	MgSO ₄	Nifedipine	Total
No	4	5	9
Yes	46	45	91
Total	50	50	100

Table 5: NICU admissions.

NICU admission	MgSO ₄	Nifedipine
No	35	31
Yes	15	19

Table6: Neonatal mortality.

Neonatal mortality	MgSO ₄	Nifedipine
No	45	43
Yes	5	7

Table 7 Side effects

Side effects	MgSO ₄	Nifedipine
Headache		5
Hot Flushes	3	
Lethargy	3	
None	44	40
Tachycardia		5

DISCUSSION

Quiescence achieved

In a current study involving 100 patients, 50 were treated with nifedipine and 50 with MgSO₄. It is found that MgSO₄ is found slightly superior in terms of achieving Quiescence and prolonging gestational age above 48 hours: 92% over 90% for Nifedipine. Similar to our study, research published in the Indian Journal of Obstetrics and Gynecology found no difference between the two drugs in terms of arresting labor.¹⁴ Similar results were found by research published by American journal of obstetrics and gynecology and journal of molecular biology.¹⁵ Lyell et al reported that magnesium sulfate achieved the primary

outcome more frequently than nifedipine. However, no differences were noted between drugs in delay of delivery, gestational age at delivery or major neonatal outcomes.¹⁶ Nikbakht et al performed a similar study, revealing that both drugs showed comparable effectiveness in preventing labor and postponing delivery for more than 7 days, with success rates of 56% in the nifedipine group and 64% in the magnesium sulfate group. The difference in the number of days gained in utero was not statistically significant between the two groups.¹⁷ Additionally, a 2023 study conducted at SDM Medical College in Dharwad, Karnataka, found that nifedipine successfully delayed delivery for up to 7 days in 80% of patients, while magnesium sulfate was effective in 67.5% of patients. Tabassum et al 2016 observed that preterm labour was

prevented for 48hrs in MgSO₄ group (88.80% patients) while in nifedipine group it was prevented for 74% patients.¹⁸ Glock et al in his comparative trial had found that both these drugs were equally effective in arresting labor and delaying delivery >48 hours, 92% versus 93%.¹⁹

Neonatal intensive care unit admission

Our study revealed that the majority of patients, 35 from the MgSO₄ group and 31 from the nifedipine group, did not require NICU admission, with APGAR scores at 5 minutes ranging from 8 to 10. However, 15 patients in the MgSO₄ group and 19 in the nifedipine group were admitted to the NICU due to respiratory distress and low birth weight. Among these, 5 from the MgSO₄ group and 7 from the nifedipine group experienced neonatal mortality.

Similar to the study, Singh et al observed that the maximum number of babies had an Apgar score between 8 and 10 at 5 minutes. Khooshideh et al also observed that there were no statistically significant differences in one-minute and five-minute Apgar scores in neonates. A study by Lyell et al suggested that Neonatal outcomes were not different between the groups. There were no differences in average birth weight. There were no differences in neonatal morbidities.

There was one neonatal death in the magnesium sulfate group, thought to be unrelated to magnesium sulfate.²¹ However, Grimes and colleagues showed that the risk of total paediatric mortality was significantly higher for infants exposed to magnesium sulphate and it should not be used for tocolysis.²² But evidence suggests that magnesium sulphate given before anticipated early preterm birth reduces the risk of cerebral palsy in surviving infants. In patients who require magnesium sulphate for neuro-protection, it may be suitable to use this therapy at tocolytic doses because it can serve both purposes.²³

Side effects

In present study, neither medication resulted in any serious side effects that would necessitate discontinuation of therapy. The majority of patients did not experience any side effects-44 patients from the MgSO₄ group and 40 patients from the Nifedipine group. In the MgSO₄ group, out of 50 patients, 3 experienced hot flushes, 3 had lethargy, while 5 experienced headaches and 5 had tachycardia with nifedipine, all of which did not require stopping the medication.

Glock et al in his comparative trial had found that Both study groups had a similar incidence of side effects, although 4 (10%) of magnesium sulfate-treated patients required drug discontinuation because of severe symptoms.¹⁹ A retrospective case series report on 355 patients (without a control group) reached a conclusion that, MgSO₄ was found to be a successful, inexpensive, and relatively nontoxic tocolytic agent that had few side

effects.²⁰ Nikbakht et al compared the efficacy and safety of magnesium sulfate and nifedipine in the management of preterm labor 6% of the 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.¹³

Limitations

The study was conducted with a relatively small sample size of 100 patients at a single tertiary care center, which may limit the generalizability of the findings to broader populations or different healthcare settings. Neonatal outcomes were assessed only up to the immediate postnatal period, without long-term follow-up. Patients with contraindications to tocolysis or those with multiple gestations, preeclampsia, or fetal anomalies were excluded, so the results may not apply to these higher-risk groups.

CONCLUSION

Both magnesium sulphate and nifedipine are as effective in arresting and prolonging gestational age and thus some benefit could be achieved from prolongation of pregnancy by enabling corticosteroid administration to accelerate fetal lung maturation which would help to reduce perinatal mortality and morbidity of fetus. However, in low resource settings nifedipine is a suitable alternative to magnesium sulphate as route of administration is per oral. Patients who received magnesium sulfate achieved the primary outcome more frequently and is slightly more effective in prolonging labour above 48hr. Also, with magnesium sulphate there is better neonatal outcome as it has neuroprotective function too.

However, patients with magnesium sulphate experienced hot flashes and lethargy while patients with nifedipine experienced tachycardia and headaches.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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