Section: Obstetrics & Gynaecology

Original Research Article

A HOSPITAL BASED PROSPECTIVE STUDY TO COMPARE THE TOCOLYTIC EFFICACY OF NIFEDIPINE AND MAGNESIUM SULPHATE IN PRETERM LABOUR AND EVALUATE THE MATERNAL SIDE EFFECT & NEONATAL OUTCOME AT TERTIARY CARE CENTRE

Ayesha Choudhary[1], Khushi Bansal[2], Divya Upadhyay[3]

[1]*Assistant Professor, Department of Obstetrics & Gynaecology, Government Medical College, Barmer, Rajasthan, India.*
[2]*Senior Resident, Department of Obstetrics & Gynaecology, Government Medical College, Chittorgarh, Rajasthan, India.*
[3]*Senior Resident, Department of Obstetrics & Gynaecology, SMS Medical College, Jaipur, Rajasthan, India.*

Received *: 03/09/2025*
Received in revised form *: 25/09/2025*
Accepted *: 10/10/2025*

Corresponding Author:
Dr. Ayesha Choudhary,
Assistant Professor, Department of Obstetrics & Gynaecology, Government Medical College, Barmer, Rajasthan, India.
Email: ayeshachoudhary2012@gmail.com

DOI: 10.70034/ijmedph.2025.4.452

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2025; 15 (4); 2505-2509

ABSTRACT

Background: Tocolysis refers to pharmacological inhibition of uterine contractions. Tocolysis helps in arrest of labour, provides sufficient time to transfer mother and foetus in utero to supportive neonatal intensive care facility. This study compares the tocolytic efficacy, side effects and neonatal outcome in patients with preterm labour who received nifedipine or magnesium sulphate as a tocolytic agent.

Materials & Methods: A comparative study of tocolytic efficacy of Nifedipine and Magnesium sulphate in preterm labour was undertaken in the Department of Obstetrics and Gynaecology in government medical college, Barmer, Rajasthan, India during one-year period. After fulfilling the inclusion and exclusion criteria 100 patients were included in this study. They were randomized into two group by simple randomization technique. One group received Nifedipine as tocolytic agent and the other received Magnesium sulphate. Statistical analysis was done by using chi square test.

Results: Our study showed that the mean age of the patients in $MgSO_4$ group was 28.16±8.29 years and mean age of the patients in Nifedipine group was 27.72±7.73 years. There was no statistically significant difference in the age among both the groups ($p>0.05$). Parity, booked/unbooked, gestational age was no statistically significant difference in parity status among both the groups ($p>0.05$, $p=1.00$, $P=0.825$ respectively). Maternal adverse effects were more with magnesium sulphate (56.66%) than nifedipine group (43.33%). Neonatal outcome was better in nifedipine group than with less number of NICU admission and RDS when compared to magnesium sulphate group.

Conclusion: Nifedipine is has ease of oral administration. Nifedipine is safer and better tolerated and more efficient tocolytic agent when compared to magnesium sulphate for tocolysis in preterm labour.

Keywords: Nifedipine, Magnesium Sulphate, Tocolytic Agents, Preterm Labour.

INTRODUCTION

Preterm labour is defined by WHO as the onset of labour after the gestation of viability (20 weeks to 28 weeks) and before 259 days or 37 completed weeks of pregnancy.[1] The pathogenesis of preterm labour is not well understood, and it is often not clear whether preterm labour represents early idiopathic activation of the normal labour process or results from a pathologic mechanism. Several theories exist regarding the initiation of labour including: oxytocin initiation, progesterone withdrawal and premature decidual activation.[2]

Complications associated with PTB include impaired health and growth, cognitive and psychological impairments, and early onset of chronic illnesses.

They are the most prevalent cause of neonatal mortality and the primary contributor to death among children under the age of 5, accounting for 36.1% and 17.7%, respectively.[3] Additionally, the high cost of treating PTB poses a significant economic burden for families and societies.[4] Therefore, timely intervention and medication are critical for the prevention and management of PTB as they are essential in reducing maternal and neonatal mortality rates and related complications.

Tocolysis refers to pharmacological inhibition of uterine contractions. Its use in preterm delivery aims to inhibit uterine contractions to prolong pregnancy and thus reducing perinatal morbidity and mortality. Tocolysis helps in arrest of labour, provides sufficient time to transfer mother and foetus in utero to supportive neonatal intensive care facility. It also gives time to give corticosteroids for foetal lung maturity.[5]

Tocolytics, including nifedipine and magnesium sulphate, are commonly used to prolong gestational age of pregnancy after the diagnosis of PTB clinically.[6] This provides an opportunity for women with imminent PTB to receive corticosteroids and magnesium sulphate, which can improve neonatal outcomes and protect foetal neurodevelopment.[7]

Nifedipine, a calcium channel blocker, has been shown to reduce the likelihood of delivery within 7days of treatment initiation and before 34 weeks of gestation, and may also reduce adverse neonatal outcomes.[8] However, separate research found that while nifedipine may extend gestation for 48 hours or 7days, it does not effectively prevent delivery prior to 37 weeks of gestation. Furthermore, there was no significant improvement in neonatal outcomes.[9]

Magnesium sulphate is widely regarded as the preferred tocolytic agent by many obstetricians and perinatologists due to its positive effects on achieving uterine quiescence rapidly, especially at higher doses.[10] However, some researchers have questioned magnesium sulphate's effectiveness as a tocolytic agent and raised concerns about its potential association with foetal and neonatal deaths.[11] Nevertheless, magnesium sulphate remains a widely used tocolytic agent. According to recent research, the results do not establish significant correlations between prenatal magnesium sulphate and adverse neonatal outcomes.[12] This study compares the tocolytic efficacy, side effects and neonatal outcome in patients with preterm labour who received nifedipine or magnesium sulphate as a tocolytic agent.

MATERIALS AND METHODS

A comparative study of tocolytic efficacy of Nifedipine and Magnesium sulphate in preterm labour was undertaken in the Department of Obstetrics and Gynaecology in government medical college, Barmer, Rajasthan, India during one-year period. After fulfilling inclusion and exclusion criteria cases were taken. They were randomized into two group by simple randomization technique. Total 60 cases were included in this study, 30 cases in each group.

Inclusion Criteria

- Age 18 – 35 years.
- Patient willing to give informed consent.
- Singleton pregnancy with cephalic presentation with gestational age 28-34 weeks.
- About 1-2 regular uterine contraction occurring in 10 minutes.
- Cervical effacement up to 80% and with dilatation < 2 cm with intact membranes.
- No previous administration of tocolytics.

Exclusion Criteria

- Patient not willing to give informed consent.
- Severe anaemia.
- PPROM
- Cervical dilatation more than 4 cm
- Obstetric complications like severe PIH, Eclampsia, seizure disorder, GDM, T2DM, Cardiac diseases, Antepartum haemorrhage, Hydramnios, Hyperthyroidism.
- Fetal complications like Chorioamnionitis, FGR, and fetus with Congenital anomaly, fetal distress and Oligohydromnios.
- Multifetal gestation
- Seropositive cases

Methods

Complete history of a patient regarding age, occupation, socioeconomic status, obstetric history, history of abortions, previous preterm birth, history of any medical disorders was taken.

Using Naegele's rule period of gestation is calculated from last menstrual period of the patient and was also assessed by clinical examination and obstetric ultrasound. Complete general physical examination was done. Vitals were noted. Other systemic examination was done.

In per abdominal examination uterine height, presentation, position, lie of the foetus and foetal heart rate were noted. Frequency and duration of uterine contraction were noted.

Per speculum examination was done to see any discharge, leak or bleed and bulging of membranes. High vaginal swab was taken for culture and sensitivity. In per vaginal examination position of the cervix, consistency, effacement, dilatation of cervix, membrane status and station of the presenting part were noted.

Routine and other investigations include CBC, urine routine, RBS, LFT, RFT, serum electrolytes, serological tests like HIV, HbsAg and VDRL, blood grouping and Rh typing, obstetric ultrasound examination, high vaginal swab for culture and sensitivity, urine for culture and sensitivity.

They were randomized into 2 groups – group A and group B by simple randomization technique.

Group A: Nifedipine group received initial dose of Nifedipine 20 mg orally followed by 10-20mg 3 to 4 times a day, adjusted according to the uterine activity for up to 48 hours.

Group B: Magnesium sulphate group received loading dose of magnesium sulphate 4 gm intravenous bolus over 10 to 15 minutes followed by maintenance dose 1g intravenous magnesium sulphate per hour for 24 hours.

In magnesium sulphate group pulse, blood pressure monitored hourly for 4 hours and four hourly for 24 hours. Urine output, respiratory rate, deep tendon reflex monitored 4 hourly. Side effects of magnesium sulphate were noted. In nifedipine group pulse, blood pressure monitored 2 hourly. Side effects of nifedipine were noted. In both the group uterine activity, FHR monitored hourly.

All the patients in both the groups received Injection. Betamethasone 12 mg intramuscularly 2 doses 24 hours apart.

After delivery of the baby, Apgar score at 1 and 5 minutes, gestational age, birth weight were noted. Babies who required NICU admission were also noted and these babies were followed till discharge. During the hospital stay perinatal complications were noted

Statistical analysis of 60 cases was done using Chi-square test and SPSS21.0v software was used for statistical calculation.

Table 1: Demographic variables of participants in both groups

Variables	Group A (Nifedipine) (N=30)	Group B (MgSO4) (N=30)	Total (N=60)
Age groups			
18 -20 years	7 (23.33%)	3 (10%)	10 (16.66%)
21 -25 years	14 (46.66%)	17 (56.66%)	31 (51.66%)
26 -30 years	8 (26.66%)	10 (30%)	18 (30%)
31 -35 years	1 (3.33%)	0 (0%)	1 (1.66%)
Parity			
Primi	16 (53.33%)	13 (43.33%)	29 (48.33%)
Multi	14 (46.66%)	17 (56.66%)	31 (51.66%)
Booked/Unbooked			
Booked	19 (63.33%)	19 (63.33%)	39 (63.33%)
Unbooked	11 (36.66%)	11 (36.66%)	22 (36.66%)
Gestational age (weeks)			
28 – 30	3 (10%)	2 (6.66%)	5 (8.33%)
31 – 32	11 (36.66%)	11 (36.66%)	22 (36.66%)
32 – 34	16 (53.33%)	17 (56.66%)	33 (55%)
Total side effect	13 (43.33%)	17 (56.66%)	-

Table 2: Neonatal outcomes

Neonatal outcome	Group A (Nifedipine) (N=30)	Group B (MgSO4) (N=30)	P value
Mean Gestational age at birth	34.5 weeks	33 week 2 days	P>0.05
Mean Birth weight (gm)	1956±472	1827±629	P>0.05
Mother side	11 (36.66%)	7 (23.33%)	P>0.05
NICU admission	18 (60%)	22 (73.33%)	P>0.05
Perinatal death	0 (0%)	1 (3.33%)	P>0.05
Respiratory distress syndrome	5 (16.66%)	11 (36.66%)	**P<0.05***

RESULTS

Our study showed that the mean age of the patients in $MgSO_4$ group was 28.16±8.29 years and mean age of the patients in Nifedipine group was 27.72±7.73 years. There was no statistically significant difference in the age among both the groups (p>0.05). Parity, booked/unbooked, gestational age was no statistically significant difference in parity status among both the groups (p>0.05, p=1.00, P=0.825 respectively) (table 1). There were more side effects among the $MgSO_4$ group compared to the nifedipine group but the difference was not statistically significant. (P>0.05) But there was statistically significant difference in pattern of side effects among both groups (P<0.05*). Flushing was seen only in $MgSO_4$ group and hypotension was more among nifedipine group (table 1).

In nifedipine group, the mean birth weight was 1956±472 grams, babies shifted to mother side were 11 (36.66%), NICU admission were 18 (60%) and respiratory distress syndrome were 16.66%. In magnesium sulphate group, the mean birth weight was 1827±629 grams, babies shifted to mother side were 7 (23.33%), NICU admission were 22 (73.33%), perinatal death was 1 (3.33%) and respiratory distress syndrome were 11 (36.66%). There was no statistically significant difference in NICU admission, perinatal death and babies shifted to mother side in both the groups (P-0.834). Birth weight was less in magnesium sulphate group, but it was not statistically significant (P-0.236). However, there was statistically significant more number of respiratory distress syndrome noted in magnesium sulphate group (P-0.043).

DISCUSSION

Tocolytics are an accepted component of the obstetric management of women with preterm labour and research continues to identify new tocolytic agents. Prevention and treatment of preterm labour

has significant impact on neonatal outcome. It Includes short term complications like RDS, and sepsis, intraventricular haemorrhage, necrotising enterocolitis, and long-term complications like neurodevelopmental problems and disability.

A wide variety of tocolytic drugs available which differs in their pharmacological principle. However, the choice of a tocolytic agent is assessed by its efficacy, safety and side effects. In our study we compared the tocolytic efficacy of nifedipine and magnesium sulphate. There is growing evidence by many studies that nifedipine is a better tocolytic with better efficacy and less adverse effects.

Magnesium sulphate (MgSO4) is the most common agent used for the treatment of preterm labour. It is used as primary tocolytic agent due to similar efficacy to terbutaline.[13]

In this study, we have compared the magnesium sulphate with oral nifedipine in acute tocolysis for at least 48 hours or more in preterm labour patients. The mean age of patients in our study was 27.72±7.73 years in group A and 28.16±8.29 years in group B. Majority of the patients 49 (81.66%) were between 21 to 30 years of age in both groups. These results were very much comparable with Taherian et al.[14]

In our study, majority of patients were primigravida i.e. 48.33%. Taherian et al[14] has also shown 50.05% primigravida in his study. So, the results of our study had shown the increase risk of preterm labour in younger primigravida females. Study conducted by Lyell et al[15] and Glock et al[6] have also reported that preterm labour usually develops in younger females & this may be associated with primiparity. Similar results noted in a study by Ramesh B et al in 2011-2012. This study included 100 patients in spontaneous preterm labour. This study compared the tocolytic efficacy and maternal adverse effects between intravenous magnesium sulphate and nifedipine. [17]

Lyell et al[15] in his randomized trial has shown opposite results as compared to this study i.e. 38.6.8% patients in nifedipine group and 49.2% patients in magnesium sulphate group delivered before discharge in the first 48 hours (primary tocolytic effect).

Marymkhooshideh et al in 2017[18] reported that magnesium sulphate had more maternal adverse effects than nifedipine. Hypotension was seen in 6.4% in nifedipine when compared to 1.8% in magnesium sulphate group.

In our study, prolongation of pregnancy was more in nifedipine group (73.33%) when compared to magnesium sulphate group (33.33%) with a P value (0.001). On comparing with the study done by Ramesh B et al in 2011-2012 on the tocolytic efficacy of magnesium sulphate was (62%) when compared to nifedipine (83%) with a P value (0.003) which was similar to our study.[17] Another study by Lyell DJ et al[15] in 2017 did a randomized controlled trail on 192 patients in preterm labour at 24 to 33 weeks and 6 days of gestation found that tocolytic efficacy of nifedipine (72%).

On comparing neonatal outcome, our study found a greater number of NICU admissions (73.33%) and RDS (36.66%) in magnesium sulphate group when compared to nifedipine group (60%) and (16.66%) respectively. Similar results were noted in a study by Lyell DJ et al[15] where NICU admission in magnesium group was (52%) and RDS was (23%) when compared to nifedipine which was (37%) and 19%) respectively. Shagufta et al in 2015, in her study found that a smaller number of NICU admissions in nifedipine (37.3%) when compared to magnesium sulphate (51.9%).[19] A study by Mittindorf et al in 2002 on association between the use of antenatal magnesium sulphate and its adverse neonatal outcome in preterm labour. This study showed that magnesium sulphate had a significant risk factor (p-0.03).[20]

CONCLUSION

Nifedipine demonstrates superior efficacy as a tocolytic agent compared with magnesium sulphate, with a rapid onset and extended period of gestation. However, no substantial difference was observed between magnesium sulphate and nifedipine in their ability to extend pregnancy for 48 hours or 7days or longer. Furthermore, nifedipine has been shown to have a lower incidence of maternal side effects compared with magnesium sulphate.

REFERENCES

1. Svigos JM, Dodd JM, Robinson JS. Threatened and actual preterm labour including mode of delivery. In: High risk pregnancy management options. 4th ed. Philadalphia: WB Saunders; 2011.p. 1065-74.
2. Goldenberg RL. Management of Preterm Labor. Obstet Gynecol. 2002;100(5):1020-35.
3. Perin J, Mulick A, Yeung D, et al. Global, regional, and national causes of under-5 mortality in 2000-19: an updated systematic analysis with implications for the Sustainable Development Goals. Lancet Child Adolesc Health 2022;6:106–15.
4. Ashorn P, Ashorn U, Muthiani Y, et al. Small vulnerable newborns— big potential for impact. The Lancet 2023;401:1692–706.
5. Aria F, Bhide AF, Arulukmaran S, Damania K, Daftary SNE. Practical Guide to High Risk Pregnancy and Delivery-E-Book. Philadelphia: Elsevier Health Sciences; 2012. pp135-42.
6. Lamont CD, Jørgensen JS, Lamont RF. The safety of tocolytics used for the inhibition of preterm labour. Expert Opin Drug Saf 2016;15:1163–73.
7. Wilson A, Hodgetts-Morton VA, Marson EJ, et al. Tocolytics for delaying preterm birth: a network meta-analysis (0924). Cochrane Database Syst Rev 2022;8:CD014978.
8. Conde-Agudelo A, Romero R, Kusanovic JP. Nifedipine in the management of preterm labor: a systematic review and meta analysis. Am J Obstet Gynecol 2011;204:134.
9. Hawkins JS, Wells CE, Casey BM, et al. Nifedipine for Acute Tocolysis of Preterm Labor: A Placebo-Controlled Randomized Trial. Obstet Gynecol 2021;138:73–8.
10. Lewis DF. Magnesium sulfate: the first-line tocolytic. Obstet Gynecol Clin North Am 2005;32:485–500.

11. Crowther CA, Brown J, McKinlay CJD, et al. Magnesium sulphate for preventing preterm birth in threatened preterm labour. Cochrane Database Syst Rev 2014;2014:CD001060.
12. Shepherd E, Salam RA, Manhas D, et al. Antenatal magnesium sulphate and adverse neonatal outcomes: A systematic review and meta-analysis. PLoS Med 2019;16:e1002988.
13. Haas DM, Imperiale TF, Kirkpatrick PR, Klein RW, Zollinger TW, Golichowski AM. Tocolytic therapy: a meta-analysis and decision analysis. Obstet Gynecol. 2009;113(3):585-94.
14. Taherian AA, Dehdar P. Comparison of efficacy and safety of nifedipine versus magnesium sulfate in treatment of preterm labor. J Res Med Sci. 2007;12(3):136-42.
15. Lyell DJ, Pullen K, Cambell L, Ching S, Druzen ML, Chitkera V, et al. Magnesium sulfate compared with nifedipine for acute tocolysis of preterm labour: a ramdomized controlled trial. Obstet Gynecol. 2007;110(1):61-7
16. Glock JL, Morales WJ. Efficacy and safety of nifedipine versus magnesium sulfate in the management of preterm labor: A randomized study. Am J Obstet Gynecol. 1993;169:960–4.
17. Ramesh B. Comparison of safety and efficacy of intravenous magnesium sulphate and oral nifedipine in treatment of preterm labour. Stanley Medical Journal. 2017 Oct 24;4(3):40-3.
18. Khooshideh M, Rahmati J, Teimoori B. Nifedipine versus magnesium sulfate for treatment of preterm labor: Comparison of efficacy and adverse effects in a randomized controlled trial. Shiraz E-Med J. 2017;18(6):e46875.
19. Tabassum S, Shahzadi U, Khalid A. Comparative Study of Efficacy of Magnesium Sulfate and Nifedipine in Suppression of Preterm Labour. Pakistan Journal of Medical and Health Sciences. 2016 Oct 1;10(4):1307-11.
20. Mittendorf R, Covert R, Boinan J, Khoshnood B, Lee KS, Siegler M. Is tocolytic magnesium sulphate associated with increased total paediatric mortality? The Lancet. 1997 Nov;1517-8.