A Comparative Study of Transdermal Nitroglycerine Patch and Oral Nifedipine in Preterm Labor

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Abstract

Background: Currently, the main goal for the use of tocolytic therapy is to delay the birth so as to allow the use of corticosteroids for accelerating fetal lung maturity and maternal transfer to a tertiary care center and thereby reducing neonatal morbidity and mortality. Aims and Objectives: The aims and objectives were to compare the safety and efficacy of transdermal nitroglycerine patch with oral nifedipine as a tocolytic agent to arrest preterm labor and prevent preterm birth. Materials and Methods: Based on the selection criteria, 50 patients were selected randomly in Group A and Group B. Group A women were given transdermal nitroglycerin patch, which delivered 10 mg Nitroglycerin (NTG) over 24 h and it was applied to the woman’s abdomen followed by another patch of 10 mg after 1 h if contractions persisted. After 24 h, it was replaced by a fresh patch. Group B women were given an oral loading dose of nifedipine 20 mg followed by a similar dose if contractions persisted after 1 h. A maintenance dose of 10 mg thrice daily was given if contractions were suppressed. Patients were monitored from the time of admission to the time of discharge. Results: The mean duration of prolongation of pregnancy in Group B (3.68 ± 1.91 days) was significantly more than Group A (2.78 ± 1.39 days). Headache was seen significantly more in Group A (42%) than group B (6%). Tachycardia, hypotension, and palpitation showed no statistically significant difference between them. There was no statistically significant difference in the birth weight of the babies in both the groups. Conclusion: Nifedipine is a safe and effective drug in prolonging preterm labor and has minimal maternal and neonatal side effects.

Keywords: Nifedipine, nitroglycerine patch, preterm labor

Résumé

Contexte: Actuellement, le principal objectif de l’utilisation de la thérapie tocolytique est de retarder la naissance afin de permettre l’utilisation de corticostéroïdes pour accélérer la maturité pulmonaire fœtale et le transfert maternel vers un centre de soins tertiaires et ainsi réduire la morbidité et la mortalité néonatales. Buts et objectifs: Les buts et objectifs étaient de comparer l’innocuité et l’efficacité du timbre transdermique de nitroglycérine avec la nifédipine par voie orale comme agent tocolytique pour arrêter le travail prématuré et prévenir l’accouchement prématuré. Matériel et méthodes: Sur la base des critères de sélection, 50 patientes ont été sélectionnées au hasard dans les groupes A et B. Les femmes du groupe A ont reçu un patch transdermique de nitroglycérine, qui a administré 10 mg de NTG en 24 h et appliqué sur l’abdomen de la femme suivi d’un autre patch de 10 mg après 1 h si les contractions ont persisté. Après 24 h, il a été remplacé par un nouveau patch. Les femmes du groupe B ont reçu une dose de charge orale de 20 mg de nifédipine suivie d’une dose similaire si les contractions persistaient après 1 h. Une dose d’entretien de 10 mg trois fois par jour était administrée si les contractions étaient supprimées. Les patients ont été suivis du moment de l’admission au moment de la sortie. Résultats: La durée moyenne de prolongation de la grossesse dans le groupe B (3,68 ± 1,91 jours) était significativement plus élevée que dans le groupe A (2,78 ± 1,39 jours). Les céphalées étaient significativement plus observées dans le groupe A (42%) que dans le groupe B (6%). La tachycardie, l’hypotension et les palpitations n’ont montré aucune différence statistiquement significative entre elles. Il n’y avait pas de

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difference statistiquement significative du poids à la naissance des bébés dans les deux groupes. Conclusion: La nifédipine est un médicament sûr et efficace pour prolonger le travail prématuré et a des effets secondaires maternels et néonatals minimes.

**Mots-clés:** Nifédipine, patch à la nitroglycerine, travail prématuré

**INTRODUCTION**

Preterm birth is a major challenge faced by obstetricians worldwide. Globally, an estimated 13 million babies are born before 37 completed weeks of gestation annually. It is the leading cause of infant morbidity and mortality. According to the report, India is among the top 10 countries that account for 60% of the world’s preterm births.

In two-third of preterm birth cases, preterm labor occurs following spontaneous onset of labor.

In about 45%–50% of cases of preterm labor, the etiology remains obscure. Hence, attempts at prevention have not been very encouraging, but the arrest of preterm labor continues to be the need of the hour. Obstetrician faces the challenge of survival of premature neonate as well as therapeutic alternatives available for the management of preterm labor.

By arresting preterm labor, we can reduce the maternal guilt and anxiety about the cause for preterm birth of their baby and financial burden of preterm birth and care around preterm birth for families and communities.

One of the effective treatments for preterm labor is nifedipine, which is a calcium channel blocker and is associated with improvement in neonatal outcomes. It is significantly more successful in prolonging pregnancy beyond 48 h and effective in delaying birth for up to 7 days. Nitroglycerine patches have also been reported to be as an effective tocolytic drug due to its safety profile with infrequent maternal and fetal side effects.

Efforts are directed toward finding alternatives that are safer, better tolerated, as well as efficacious in prolonging pregnancy. Both nitroglycerine and nifedipine have been shown to be effective in preterm labor. However, only a few studies have directly compared the safety and efficacy of oral nifedipine with transdermal nitroglycerine patches as tocolytic agents in preterm labor. The present study has been planned to compare the safety, efficacy, and perinatal outcome where transdermal nitroglycerine patch and oral nifedipine was used as tocolytic agents in preterm labor.

**MATERIALS AND METHODS**

The present prospective study was conducted in 100 pregnant women diagnosed with preterm labor attending the labor room and outpatient department of Bebe Nanki Hospital, Department of Obstetrics and Gynaecology, Government Medical College, Amritsar, Punjab, India, from March 2018 to June 2019 after obtaining their informed consent. The study was conducted after approval from the Institutional Ethics Committee, Government Medical College, Amritsar. Based on inclusion and exclusion criteria, 50 patients were selected by single-blinded randomized control trial in each group: Group A: nitroglycerine group and Group B: nifedipine group. Patients with singleton pregnancy with gestational age between 28 and 34 weeks having regular uterine contractions 4 in 20 min or 8 in a period of 1 h as per the ACOG criteria and cervical effacement >80% or dilatation of ≥3 cm with intact membranes were involved in the study. Patients with systemic diseases such as diabetes mellitus, cardiac diseases, liver or renal diseases, hypertension and hypotension, fetal complications such as chorioamnionitis (maternal fever, leukocytosis, and fetal tachycardia), Intrauterine growth restriction (IUGR), congenital anomaly, fetal distress, and intrauterine fetal death and patients hypersensitive/allergic to nitroglycerine and nifedipine drugs or any other contraindication to nitro compounds and calcium channel blockers were excluded from the present study.

**Procedure of the study**

**Group A nitroglycerine group**

Women were given the transdermal nitroglycerine patch, which delivered 10 mg NTG over 24 h. The patch was applied on the woman’s abdomen. If contractions persisted at the end of 1 h, an additional patch was applied. No more than two patches were worn simultaneously (20 mg). At the end of 24 h, these were replaced by a fresh patch. Mild headaches were treated with paracetamol. Patches remained in place for 12 h after the contractions had ceased.

**Group B nifedipine group**

Women were given an oral loading dose of nifedipine 20 mg. If contractions persisted at the end of 1 h, a similar dose was repeated. If labor was suppressed after the first or second dose, a maintenance dose of 10 mg three times daily adjusted according to uterine activity was given.

Patients were monitored from the time of admission to the time of discharge. Inability of the drug to prolong gestation for a minimum period of 48 h or persistence of uterine contractions even after 20 mg of NTG or 40 mg of nifedipine was considered to be a treatment failure. Under such circumstances, the therapy was discontinued and conventional treatment was provided by labor room team.

The sample size of 50 patients in each group was calculated on the basis of $\alpha$ error of 0.05 and power of 0.80. The results obtained were statistically analyzed using SPSS software. Significance was evaluated using Chi-square test and unpaired Student’s “$t$”-test. *$P < 0.05$ is statistically significant.
**RESULTS**

The maximum number of patients in Group A falls in 20–24 years age, i.e., 52%, whereas in Group B, maximum patients (52%) fall in 25–29 year age range. The mean age group in the study subject was 24.52 years in Group A and 24.26 years in Group B. History of preterm labor in a previous pregnancy was present in 24% (12 out of 50) of cases in Group A and 16% (8 out of 50) in Group B. There was no statistically significant difference in the history of preterm labor between the two groups of patients. History of previous abortion was present in 16% (8 out of 50) of cases in Group A and 24% (12 out of 50) in Group B patients. There was no statistically significant difference in both the group of patients.

The mean duration of prolongation of pregnancy varied with gestational age on admission considerably both in Group A and Group B. When the gestational age was between 32.1 and 34.0 weeks, the mean prolongation in Group A was 2.79 ± 1.41 days, and in Group B, it was 3.70 ± 1.77 days. The difference between them showed a statistically significant difference [Table 1].

A statistically significant difference was observed in the mean prolongation of pregnancy between both the groups when the station of presenting part was at −3 and −2, whereas statistically no significant difference found at −4 [Table 2].

Table 3 shows that the treatment delivery interval differed significantly in both the groups.

In patients with cervical dilatation 3 cm, the mean prolongation of pregnancy was higher in Group B than Group A, but the difference between them was statistically not significant. In patients with cervical dilatation >3 cm, the mean prolongation of pregnancy was significantly higher in Group B than Group A [Table 4].

Table 5 shows that there was no statistically significant difference in the birth weight of the babies of both the groups.

There was a statistically significant difference in Apgar score at 1 min and 5 min between both the groups [Table 6].

Neonatal jaundice was the most common complication – 40% in Group A and 44% in Group B, followed by respiratory distress syndrome (RDS) 12% in Group A and 10% in Group B. The mean duration of hospital stay was more in NTG group (15 days) than nifedipine group (14 days). There was no statistically significant difference in the neonatal outcomes and complications like birth asphyxia, neonatal jaundice, hypoglycemia, RDS, sepsis, need for neonatal intensive care unit (NICU) admission, and mean duration of stay [Table 7].

Headache was seen significantly more in Group A (42%) than Group B (6%). Tachycardia, hypotension, and palpitation showed no statistically significant difference between them [Table 8].

**DISCUSSION**

Tocolysis aims to gain time for administration of corticosteroids to attain fetal lung maturity and to reduce prematurity-related complications. The present study was carried out to compare the effectiveness of transdermal nitroglycerine patch and oral nifedipine as a tocolytic agent to arrest the preterm labor and prevent preterm birth.

When these data were compared with previous studies, baseline characteristics did not differ significantly. In the study by Amorim et al. (2009), pregnant women aged between 18 and 40 years with singleton pregnancies.[7]

The current study revealed that preterm labor was more common in primigravida of nitroglycerine group (40%) and second gravida (34%) of nifedipine group. There was no statistically significant difference in parity between the two groups. Similar results have also been observed by Dhawle et al.[8] and Rani et al.[8] Rani et al. observed that preterm labor

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**Table 1: Gestational age at admission and mean prolongation of pregnancy in Group A and Group B**

| Gestational age (in weeks) | Number of cases | Prolongation Mean (in days) | P |
|----------------------------|-----------------|-----------------------------|---|
|                            | Group A, n (%)  | Group B, n (%)              |    |
| 28.0-30.0                  | 3 (6)           | 3 (6)                       |    |
| 30.1-32.0                  | 8 (16)          | 10 (20)                     |    |
| 32.1-34.0                  | 39 (78)         | 37 (74)                     |    |
| Total                      | 50 (100)        | 50 (100)                    |    |
|                            | Group A         | Group B                     |    |
|                            | 2.67±1.154      | 4±3.46                      | 0.562 |
|                            | 2.75±1.48       | 3.5±2.12                    | 0.41  |
|                            | 2.79±1.41       | 3.70±1.77                   | 0.0152* |

*P value < 0.05 indicates statistically significant results

**Table 2: Relation of station of the presenting part and mean prolongation of pregnancy in Group A and Group B**

| Station of presenting part | Number of cases | Prolongation Mean (in days) | P |
|----------------------------|-----------------|-----------------------------|---|
|                            | Group A, n (%)  | Group B, n (%)              |    |
| −3                         | 14 (28)         | 20 (40)                     |    |
| −2                         | 26 (52)         | 22 (44)                     |    |
| −1                         | 10 (20)         | 8 (16)                      |    |
|                            | 2.64±0.928      | 4±1.85                      | <0.0001* |
|                            | 2.5±0.971       | 3.86±2.07                   | 0.0001* |
|                            | 1.70±2.96       | 2.375±1.06                  | 0.1322 |

*P value < 0.05 indicates statistically significant results

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is more commonly seen in primigravida and second gravida in both the groups. Forty-two percent in nifedipine group and 44% in the NTG group with preterm labor were observed to be primigravida. In the present study, the patients with gestational age between 28 and 34 weeks were recruited because majority of prematurity related complications occur before 34 weeks. Preterm labor leads to long-term morbidities in babies including neurodevelopmental handicap, cerebral palsy, seizure disorder, blindness, deafness, and nonneurological disorders such as bronchopulmonary dysplasia and retinopathy of prematurity. A review of literature revealed that gestational age at admission varied between 24 and 34 weeks in Amorim et al.’s study. Gestational age at entry differed considerably in each study group. In the study by Taherian and Dehedar, gestational age between 26 and 36 weeks was included in their study. In Kashanian et al.’s study, gestational age varied from 26 to 34 weeks. In concordance to our findings, Balasubramani and Kamatchi also found similar results. They also observed a history of preterm labor in 6% of patients of the nifedipine group and 5% of NTG group. Kashanian et al. found a history of previous abortion in 32.2% of patients in nifedipine group and 13.3% in the NTG group patients. Kashanian et al. found a history of previous abortion in 32.2% of patients in nifedipine group and 13.3% in the NTG group with no statistically significant difference between them. They also observed a history of preterm labor in 6.7% of patients of the nifedipine group and 5% of NTG group. The present study showed that the mean duration of prolongation of pregnancy decreases when the station of the presenting part is low in both the groups. Balasubramani and Kamatchi also found similar results.

Headache was seen more significantly in the NTG group (42%) than in the nifedipine group (6%) in our study. Tachycardia in 20%, hypotension in only 2%, and palpitation in 6% of women were observed in Group A and 28%, 4%, and 10% of women, respectively, in Group B. Dhawle et al. also observed that the total incidence of side effects was 48.7% with NTG against 34.88% with nifedipine which
was similar to our study. Headache was significantly more with NTG (41.5% versus 4.7%). There was no difference in the incidence of tachycardia or palpitations between the two groups. In the study by Amorim et al.,[3] no statistically significant difference in the frequency of side effects presented by patients was seen except for headache which was in about 30% of patients who received nitroglycerine and 8.3% of patients who received nifedipine. Papatsonis et al.[13] found the incidence of side effects with nifedipine to be significantly less when compared to ritodrine (18.9% versus 36%). Kashanian et al.[10] found that nifedipine was associated with side effects in 40% of patients as compared to 17.5% with atosiban. They also found the incidence of hypotension with nifedipine to be 27.7%. In contrast to these studies, Yasmin et al.[14] observed that most common adverse effects observed with nifedipine were headache (32%), followed by palpitations (8%) and hypotension (8%). NTG patch had a better side effect profile, with 48% of patients being asymptomatic; however, headache (32%) was the most frequent complaint with it.

The results of the present study showed that the treatment delivery interval differed significantly in both the groups. About 2% delivered on the same day of treatment in the nitroglycerine group, whereas the treatment delivery interval was prolonged in the nifedipine group. Our study demonstrated that nifedipine showed a longer mean duration of prolongation of pregnancy than the NTG group [Table 3]. Similar results showing more effective prolongation of pregnancy in the nifedipine group than NTG group were also shown in other studies conducted by Dhawle et al.[3] and Yasmin et al.[14]

Dhawle et al.[3] observed the mean prolongation of pregnancy more in nifedipine (34.46 days) than NTG (29.04 days). Yasmin et al.[14] found the prolongation of pregnancy beyond 48 h more with nifedipine (74%) than Nitroglycerine (GTN) (40%). Similarly, prolongation beyond 7 days was also more frequent with nifedipine (32%) as compared with GTN (24%). However, Iftikhar and Kanwal[15] observed no marked difference between both the groups. They observed that in nifedipine group, 80.60% of women had successful tocolysis as compared to NTG Group in which tocolysis was achieved in 86.2%.

Failure of acute tocolysis, defined as delivery within 48 h, was significantly more common with NTG (31.7%) as compared to nifedipine (11.6%) in the study conducted by Dhawle et al.[3] Dhawle et al. found a failure of acute tocolysis, significantly more common with NTG (31.7%) as compared to nifedipine (11.6%). Yasmin et al.[14] also observed the failure of acute tocolysis more with NTG (60%) as compared with nifedipine (28%). Our study also showed one case of failure of acute tocolysis in the NTG group, whereas no failure case was observed in the nifedipine group.

Current study results showed that there was no statistically significant difference in the birth weight of the babies in both the groups [Table 5]. Our study showed that in NTG group, the mean birth weight was 2.238 kg, whereas in the nifedipine group, the mean birth weight was 2.334 kg. Our results are in agreement with other studies carried out by Dhawle et al.[3] and Balasubramani and Kamatchi.[16] Dhawle et al. found that mean birth weights in the two groups were 2.11 kg (NTG) and 2.14 kg (nifedipine). Similarly, Balasubramani and Kamatchi observed that in nifedipine group, the mean birth weight was 2.32 kg, whereas in the NTG group, the mean birth weight was 2.19 kg with an insignificant difference between them. In contrast to it, Kashanian et al.[10] observed a significantly higher neonatal weight of 2634.39 ± 584.09 g in the NTG group than 2357.41 ± 857.12 g of the nifedipine group.

Cervical dilatation at the onset of tocolysis was the most important factor influencing the prolongation of pregnancy. Cervical dilatation in our study was in the range of 3 cm or >3. The mean prolongation of pregnancy at 3 cm cervical dilatation was significantly more than cervical dilatation >3 cm in the nitroglycerine group. However, the mean prolongation of pregnancy at 3-cm cervical dilatation was not significantly more than with cervical dilatation >3 cm in nifedipine group. Similar results had also been found by Dhawle et al.[3] and Balasubramani and Kamatchi[16] Dhawle et al. observed that when the cervical dilatation was <3 cm, there was no statistically significant difference between the two groups. However, when the cervical dilatation was >3 cm, nifedipine was significantly more effective in prolonging pregnancy compared to NTG (5.00 ± 5.45 days versus 0.56 ± 0.53 days; P = 0.015). Balasubramani and Kamatchi also found similar results that with 2 cm dilatation of cervix, the mean prolongation was 11 days in nifedipine group and 4 days in NTG group. When the cervical dilatation was 3 cm, the mean prolongation with Group I was 3.2 days and with Group II was 2.8 days (P = 0.0458, significant).

The present study showed that there was no statistically significant difference in the neonatal outcomes and complications such as birth asphyxia, neonatal jaundice, hypoglycemia, RDS, sepsis, need for NICU admission, and mean duration of stay. Neonatal jaundice was the most common complication 40% in Group A and 44% in Group B, followed by RDS 12% in the nitroglycerine group and 10% in the nifedipine group. Similar studies have also been reported by Dhawle et al.[3] Zulfiqar et al.,[16] and Yasmin et al.[14] Dhawle et al. reported an incidence of respiratory distress 17.1% in the NTG group and 9.3% in the nifedipine group and difference was not statistically significant. They also found that neonatal jaundice was the most common complication (48.8% of neonates from either group).[3] Zulfiqar et al. also observed that the incidence of respiratory distress was 76.7% in the nifedipine group and 63.3% in the NTG group and showed no statistically significant difference between both the groups.[16]

Our study showed that the mean 1-min Apgar score in newborns of nitroglycerine group was 4.46 and in nifedipine group was 5.02. At 5 min, Apgar score was 5.8 in nitroglycerine group newborn and it was 6.38 in nifedipine group. There was
a statistically significant difference between both the groups at 1 min and 5 min. Similar results had also been obtained by Balasubramani and Kamatchi[5] They observed that babies born in nifedipine group had mean Apgar score 5.02 and in NTG group, they had mean Apgar score 4.46 in 1 min, 5 min Apgar score was 6.38 in nifedipine group babies, and it was 5.8 in NTG group babies. Hence, it can be concluded that the neonatal outcome was good with nifedipine because it had better Apgar and lesser morbidity in neonates. However, the results obtained by Kashanian et al.[10] were not in concordance to the present study. They observed 8.5 ± 0.9 Apgar score of 5 min in the NTG group which was significantly more than 7.7 ± 1.7 of nifedipine group.

It should also be kept in mind that tocolysis is being used for preterm babies who are already prone to get admitted in the NICU for prematurity and prematurity-related problems, thus giving higher nursery admission rates as compared to term babies. As a secondary analysis, an economic evaluation of the trial was done. The cost of oral nifedipine is less when compared to transdermal nitroglycerine, which is costlier.

**Conclusion**

Tocolytic efficacy of oral nifedipine was comparatively better than transdermal nitroglycerin because of better acute tocolytic effect, reduced maternal complication, good neonatal outcome, and lower preterm delivery rate and with more prolongation of pregnancy. To conclude, oral nifedipine has a very good role to play in the treatment of acute tocolysis and for prolongation of pregnancy. Hence, it can be considered as the first-line drug of choice.

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**Conflicts of interest**

There are no conflicts of interest.

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