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EVALUATING THE EFFECTIVENESS OF ORAL NIFEDIPINE VERSUS TRANSDERMAL NITROGLYCERINE FOR TOCOLYSIS IN PRETERM LABOR: A PROSPECTIVE ANALYSIS

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Abstract

Introduction: Through this paper, we hope to improve the quality of evidence-based care for preterm labour and, in the process, the health of women and their babies. Neonatal outcomes, rates of preterm delivery within 48 hours, and the amount of time needed for successful tocolysis will all be included in the review. The results of this study have the potential to enhance the quality of preterm labour treatment and therefore improve the health of mothers and babies.

Aim and Objective: The purpose of this study is to evaluate and compare the tocolytic efficacy of transdermal nitroglycerine patches and oral Nifedipine tablets in the treatment of premature labour. Examining the tocolytic effect especially related to oral Nifedipine and comparing the effectiveness of these two therapies in preventing premature contractions are the main goals.

Methods and Material: The efficacy of tocolytics in treating premature labour was thoroughly investigated using a prospective trial that contrasted oral nifedipine with transdermal nitroglycerine patches. Through careful patient selection, randomization, and regular monitoring, the study prioritises patient safety and improves external validity, guaranteeing accurate comparisons between the two therapies.

Result: In this study, 120 pregnant women who were experiencing preterm labour were tested for tocolytic efficacy between nitroglycerine patches and oral nifedipine. The distributions of maternal age, gestational age, and parity were comparable. Nitroglycerine caused more headaches and hypotension, which led to a higher rate of discontinuations, but cervical dilation did not differ significantly. Because oral nifedipine is readily available and safe, its overall efficacy was comparable.

Conclusion: The nitroglycerine patch and oral nifedipine groups did not significantly differ in terms of obstetrical history or baseline indicators, according to the study. Despite the fact that the p-value was greater than 0.05, suggesting similar tocolytic effects, oral nifedipine was preferred due to its longer pregnancy extension and better safety record.

Keywords: Nitroglycerine patch, Tocolysis in Preterm, Analysis, Transdermal Nitroglycerine

I. INTRODUCTION

Preterm labour, which is characterised as the commencement of labour before 37 weeks of gestation, is still a major problem in obstetrics and raises the risk of morbidity and mortality for newborns. One of the most important interventions for postponing premature delivery and giving foetal lung maturation and other supporting measures more time is tocolysis, or the suppression of uterine contractions. Numerous tocolytic drugs, each with a distinct pharmacokinetic profile and adverse effect profile, have been used. Of them, transdermal nitroglycerine and oral nifedipine have shown promise, although there are few thorough trials that directly compare their efficacy in tocolysis. The calcium channel blocker nifedipine has been demonstrated to efficiently stop uterine contractions by lowering smooth muscle cells' intracellular calcium levels. Its oral administration offers a practical and easily accessible method of tocolysis. Conversely, the tocolytic effects of transdermal nitroglycerine, a nitric oxide donor, are achieved by encouraging smooth muscle relaxation. This delivery system provides a steady and regulated release of the drug.

In order to inform therapeutic decision-making, a comparative study is necessary, regardless of the particular benefits of each of these medications. Our prospective study intends to compare and comprehensively assess the efficacy of transdermal nitroglycerine and oral nifedipine for tocolysis in women who are at risk of premature labour. This study's main goals are to evaluate neonatal outcomes, the rate of preterm delivery within 48 hours of therapy initiation, and the time to successful

tocolysis. Assessing the tocolytic regimen's overall patient satisfaction, cost-effectiveness, and adverse effects on mothers are the secondary goals. Our research attempts to provide important insights into optimising preterm labour management tactics, ultimately improving maternal and newborn outcomes, by offering a thorough evaluation of these two frequently used tocolytic drugs. Given the continuous need for evidence-based strategies to address the difficulties related to preterm birth, this research is especially pertinent.

II. AIM and Objective

Aim:

To assess and contrast transdermal nitroglycerine patches' and oral nifedipine tablets' tocolytic efficacy in the treatment of premature labour.

Objective:

- **Analyse the Tocolytic Impact of Oral Nifedipine:**

Examine the effects of taking Nifedipine pills orally on avoiding and postponing premature contractions.

- **Evaluate the Transdermal Nitroglycerine Patch's Tocolytic Effect:**

Examine and describe the transdermal nitroglycerine patches' tocolytic efficacy, paying particular attention to how well they can prevent uterine contractions during premature labour.

- **Compare the Two Drugs' Tocolytic Effects:**

Compare the tocolytic efficacy of transdermal nitroglycerine patches and oral nifedipine tablets, taking into account variables like the duration of successful tocolysis and the prevalence of premature birth within 48 hours.

By addressing these goals, the study hopes to help doctors make well-informed decisions for the best management of preterm labour by offering insightful information on the relative benefits and efficacy of these two commonly used tocolytic drugs.

III. Method and Material

In order to evaluate the tocolytic efficacy of transdermal nitroglycerine patches and oral nifedipine in preterm labour, this prospective trial used a rigorous methodology. The date of the last menstrual period (LMP), accompanied by early urine pregnancy tests and/or ultrasounds performed before 20 weeks, was used to determine the gestational age, which is essential for correct assessment. A thorough physical examination, including sterile per speculum and per abdominal examinations, was part of the full evaluation, which also included demographic profile and a detailed medical history. Cervical dilatation was measured and ruptured membranes were ruled out using these exams.

Patients were randomised into two groups: Group B (transdermal nitroglycerine patch) or Group A (oral nifedipine). A strong dataset for analysis was produced by monitoring blood pressure, pulse rate, and uterine contractions hourly during the first 12 hours and then every 4 hours for the next 60.

- Patients in Group A were administered oral nifedipine (10 mg Tab Depin). An oral dose of 10 mg was added as a supplement if contractions continued after an hour after the loading dose of 30 mg. Oral maintenance doses of 10 mg every 6 hours were administered for 72 hours, unless certain conditions were satisfied to stop.
- Patients in Group B received treatment with a Nitroglycerine Transdermal Patch (Nitroderm 10). An extra patch was put, up to a maximum of two patches (20 mg) at once, if contractions continued after an hour. Following a 24-hour period, the patch was changed, and therapy was stopped in accordance with predetermined standards.

In order to support newborn outcomes, both groups got injection dexamethasone for foetal lung maturity, which is consistent with conventional practise. To ensure a fair allocation of instances between the two groups, computer-generated numbers were used throughout the randomization process. This approach decreased the possibility of selection bias and improved the study's internal validity. Thorough patient selection, randomization, and systematic monitoring in the research design paves the way for reliable comparisons of Oral Nifedipine and Transdermal Nitroglycerine Patch in the treatment of premature labour. Patient safety is ensured by the inclusion of clear criteria for therapy cessation, and the study's external validity and possible relevance to wider clinical contexts are improved by the regular use of standardised interventions like dexamethasone delivery.

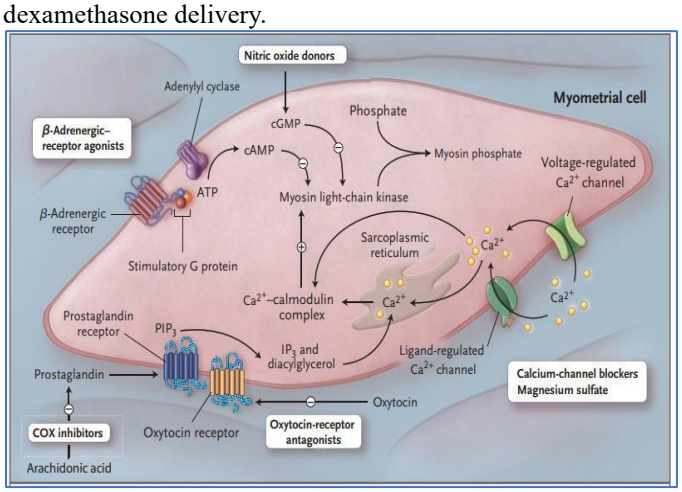

Figure 1: Representation of Mechanism of action of the Tocolysis

The modes of action for transdermal nitroglycerine and oral nifedipine-induced tocolysis are shown in Figure 1. Because oral nifedipine lowers intracellular calcium levels in smooth muscle cells, it decreases uterine contractions. Nitric oxide donor transdermal nitroglycerine facilitates smooth muscular relaxation. The figure 1 illustrates how these several pharmacological processes promote the tocolytic effects of each medication and play a part in delaying premature labour by suppressing preterm contractions.

Table 1: Summary of tocolytic effect of nifedipine by other compounds and the potential risks

Compound Combination	Modification of myometrial relaxation	Combination Risk
Nifedipine + Ritodrine	Heightened (In In Vivo Experiments Including Both Humans and Animals).	Cardiac Arrest, Pulmonary Edoema.
Nifedipine + Atosiban	Enhanced (In An In Vitro Human Study).	Nothing (Just Information Derived From In Vitro Experiments).

Nifedipine + Celecoxib	Reduced (In A Study Involving Humans.	Nothing (Just Information Derived From In Vitro Experiments).
Nifedipine + progesterone	Reduced (In Vivo Investigation In An Animal In Vitro) In A Human Research Conducted In Vivo, Unchanged.	Not Very Risky In Comparison To Monotherapy With Nifedipine.

- **Statistical Method**

This study's data analysis was strong, using a mix of descriptive and inferential statistical techniques to clarify the tocolytic effects of transdermal nitroglycerine patches and oral nifedipine in premature labour. Number (%) was used to represent categorical measurements, while Mean ± SD (Min-Max) was used to summarise continuous measurements. A thorough assessment of the study parameters was guaranteed by the use of relevant statistical tests, such as the Fisher Exact test for categorical variables and the Student t-test for continuous variables.

The normal distribution of dependent variables, random selection from the population, and the independence of cases in the samples were among the presumptions that underpinned the statistical analysis. The study's findings are more dependable and broadly applicable as a result of these presumptions. To evaluate the significance of research parameters on a continuous scale and enable inter-group comparisons between Oral Nifedipine and Transdermal Nitroglycerine Patch, the Student t-test, a two-tailed, independent analysis, was appropriately utilised. This approach illuminated distinctions between the two treatment modes by enabling a detailed analysis of metric parameters. Furthermore, a thorough examination of the significance of the study parameters was guaranteed by the application of the Chi-square and Fisher Exact tests for categorical variables, which provided information about any correlations or variations between groups.

There is strong confidence in the study's findings because the statistical analysis was rigorous and adhered to at the 95% level of significance. Overall, the study's validity and reliability are improved by the careful implementation of these statistical techniques, which also provide important evidence to support clinical judgements regarding the management of premature labour.

IV. RESULT AND DISCUSSION

The rates of pregnancy extension for the oral nifedipine and nitroglycerine patch groups are contrasted in Table 2. Three categories are used to classify the length of pregnancy prolongation: less than two days, two to seven days, and more than seven days. Within the total cases, the percentages for each group are displayed. The statistical significance of the observed differences is shown by the P value. P values above 0.05 indicate that there is no significant difference in pregnancy prolongation between the two groups.

Table 2: Comparison of the two study groups' respective rates of pregnancy prolongation

Prolongation of pregnancy (days)	**Oral Nifedipine**		**Nitroglycerine Patch (n=60)**		**P Value**
	Cases	%	**Cases**	%	
Less than 2 days	18	30	23	38.33	0.628
In between 2-7 days	35	58.33	31	51.67	
Greater than 7 days	7	11.67	6	100	
Total	60	100	60	100	

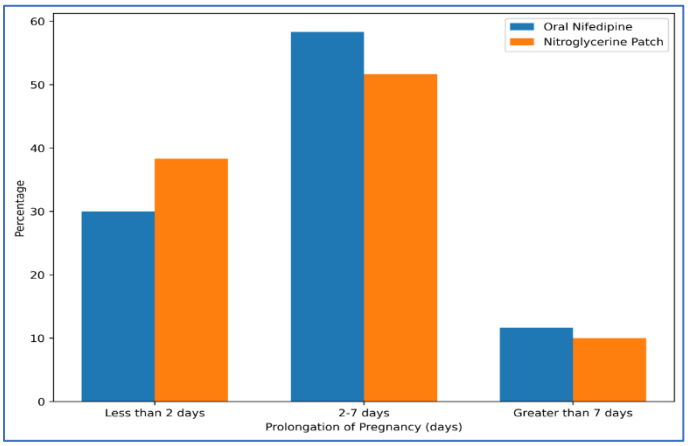

Figure 2: Representation of comparison of rates of pregnancy prolongation

The gestational ages (GA) of the two research groups at the time of reporting are contrasted in this table. Each GA category's average length in days is shown, along with P values that denote statistical significance. P values above 0.05 for every category in the data demonstrate that there are no statistically significant variations in gestational age at reporting between the two groups.

Table 3: Comparison of the two study groups' gestational ages (GA) at the time of reporting

GA during the reporting period	**Average Duration in days (maximum 7 days f/up)**		**P value***
	Nitroglycerine Patch (n=60)	**Oral Nifedipine (n=60)**	
Between 28-30 weeks	2.76±1.24	3.01±2.06	0.422
Between 30-32 weeks	2.67±2.76	3.49±2.22	0.075
Between 32-34 weeks	2.93±2.73	3.71±1.65	0.06
Between 35-36 weeks	3.06±1.69	3.53±2.26	0.209

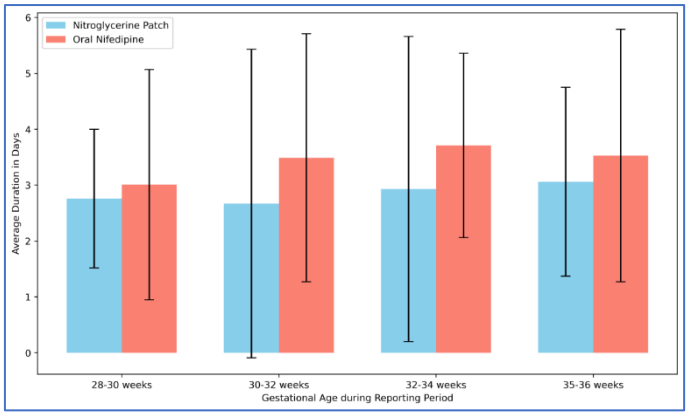

Figure 3: Representation of gestational ages (GA) at the time of reporting

The problems seen in both study groups are shown in table 4. For each complication, such as palpitations, tachycardia, hypotension, and severe headaches, the number of cases and percentages are given. The statistical significance of the observed differences is indicated by the P values. The findings indicate a substantial difference in complications between the two groups, with tachycardia, hypotension, and severe headaches showing P values less than 0.05.

Table 4: Comparison of the two research groups' complications

Complications	**Oral Nifedipine (n=60)**		**Nitroglycerine Patch (n=60)**		**P Value**
	Cases	**Percentage**	**Cases**	**Percentage**	
Severe Headache	4	6.67%	15	25.00%	0.005
Tachycardia	16	26.67%	5	8.33%	0.001
Hypotension	2	3.33%	8	13.33%	0.047
Palpitation	4	6.67%	2	3.33%	0.402

The treatment costs for Nitroglycerine Patch and Oral Nifedipine are contrasted in this table. For every treatment, it provides information on the mean cost per case, cost per unit, and content. The findings indicate that the cost per case for oral nifedipine is lower than that of nitroglycerine patches. The standard deviation sheds light on how differently each group's costs vary. All things considered; this data is essential for assessing the financial effects of every available treatment choice.

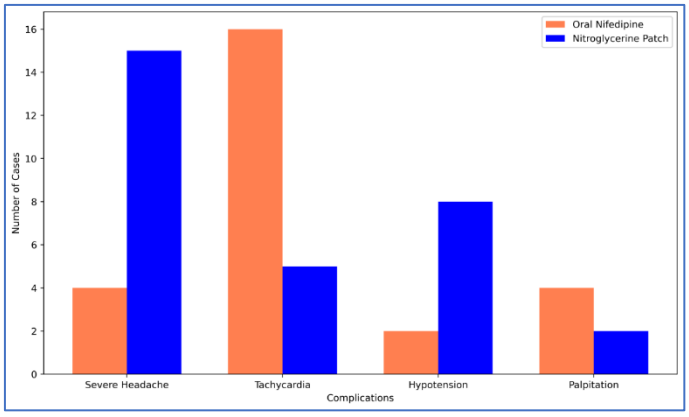

Figure 4: Representation of Comparison of the two research groups' complications

Table 5: Comparison of the two research groups' treatment costs

Treatment	**Content**	**Cost per Unit Approx.**	**Cost per case Mean**
Oral Nifedipine (n=60)	Cap Nifedipine (30 mg loading dosage), then 10 mg every eight hours for three days	Rs. 3.00 per 10mg tablet	Each patient costs Rs. 30.00, with a 2.12 standard deviation.
		The number of tablets needed varies from 8 to 11.	
Nitroglycerine Patch (n=60)	It takes one or two nitroglycerine patches.	Rs. 60 per patch	Patients costing Rs. 92.00 each, with a standard deviation of 10.37

Preterm labour, which is defined as beginning before 37 weeks of pregnancy, accounts for 7–12% of pregnancies and 70–80% of infant morbidity and death. It presents serious health hazards to the unborn child. The goal of tocolytics, such as nitroglycerine patches and oral nifedipine, is to postpone labour in order to give time for the administration of corticosteroids. In this study, the tocolytic effects were compared in 120 pregnant moms. The distributions of parity, gestational age, and maternal age were comparable amongst the groups. Cervical dilation did not significantly differ between the groups, however the nitroglycerine group experienced more headaches and hypotension, which resulted in more discontinuations. Overall, the tocolytic efficacy of both therapies was equivalent; however, due to its availability and safety profile, oral nifedipine was preferred.

V. Conclusion

The obstetrical history and baseline indicators in this extensive trial did not show any discernible differences between the study groups that were given the nitroglycerine patch and those that were given oral nifedipine. The study's internal validity is strengthened by the fact that there were no differences in the groups' gestational age, parity, Bishop's score, or cervical dilatation at the time of reporting. Interestingly, the statistical analysis did not show a significant difference because the p-value above 0.05, even though the oral nifedipine group

benefited from a longer duration of pregnancy extension. This finding highlights the need for cautious interpretation within the limitations of the study, even though it points to a noteworthy trend in favour of oral nifedipine. One important finding from the study was the substantial increase in headache and hypotension that occurred in the nitroglycerine patch group. On the other hand, tachycardia showed a strong correlation with the oral nifedipine group. The in-depth comprehension of the adverse effect profiles provides significant understanding of the safety factors related to every tocolytic drug. As a result, even though the study's results showed that the nitroglycerine patch and oral nifedipine had statistically comparable tocolytic effects, availability and side effect profiles were taken into account, which led to a recommendation that preferred the use of oral nifedipine for tocolysis. In addition to addressing the main research question, this nuanced conclusion offers insightful advice for physicians, highlighting the significance of choosing tocolytic agents holistically while managing preterm labour.

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