DOI: 10.7860/JCDR/2025/75829.20546

Original Article

Obstetrics and Gynaecology Section

A Comparative Study to Determine the Efficacy of Atosiban versus Nifedipine in Management of Preterm Labour

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ABSTRACT

Introduction: Preterm Labour (PTL) remains a significant challenge in obstetrics, contributing to neonatal morbidity and mortality. The management of PTL involves the use of tocolytic agents to delay delivery, thereby allowing for further foetal development.

Aim: To compare the tocolytic efficacy of Nifedipine and Atosiban in the management of PTL.

Materials and Methods: This prospective interventional study was conducted at Dr. DY Patil Medical College, Hospital, and Research Centre, Pune, Maharashtra, India from October 2022 to August 2024. Ninety pregnant women between 24 to 34 weeks of gestation, diagnosed with PTL, were assigned to receive either Atosiban (n=45) or Nifedipine (n=45) according to the inclusion criteria. The primary outcomes measured were the duration of pregnancy prolongation, neonatal outcomes and Neonatal Intensive Care Unit (NICU) admissions. Chi-square tests or t-tests were used to compare these categorical variables.

Results: Nifedipine was associated with a slightly higher percentage (36 cases, or 80%) achieving pregnancy prolongation for more than seven days compared to Atosiban (34 cases, or 75.56%). Nifedipine also demonstrated better neonatal outcomes and reduced NICU admissions (Nifedipine: 14 cases, or 31.11% vs. Atosiban: 20 cases, or 44.44%). However, Nifedipine was linked to a higher incidence of maternal side-effects , such as headache, hypotension and tachycardia, whereas Atosiban was better tolerated, with fewer reported side-effects . Atosiban was more frequently used in cases with earlier gestational ages, reflecting its utility in more acute clinical scenarios.

Conclusion: Both Atosiban and Nifedipine were effective in managing PTL, with each drug offering distinct advantages depending on the clinical scenario. Nifedipine was more effective in prolonging pregnancy and improving neonatal outcomes, while Atosiban was associated with fewer maternal side-effects and is preferred in acute cases.

Keywords: Calcium channel blocker, Maternal side-effects, Neonatal intensive care unit, Neonatal outcome, Oxytocin receptor antagonist, Prolongation of pregnancy, Tocolysis

INTRODUCTION

PTL is a significant contributor to neonatal morbidity and mortality worldwide [1]. A recent systematic review in The Lancet estimated that India has a preterm birth rate of 13.6% and is amongst one of the top five countries for the number of preterm births [2]. According to the National Family Health Survey 2015-16 (NFHS-4), a nationwide district-level demographic health survey, the infant mortality rate in India is 41 per 1,000 births [3]. Most of the infant mortality has been reported to be associated with preterm births [4]. Survival rates improve by approximately 3% with each additional day a baby remains in utero between 22 and 28 weeks of gestation [5]. Tocolytic therapy, which involves the use of medication to suppress premature uterine contractions, plays a vital role in delaying delivery [6]. This delay provides time for the administration of prenatal corticosteroids and facilitates the transfer of the mother to a tertiary care facility, both of which are associated with improved neonatal outcomes [7]. Prenatal corticosteroids have been shown to reduce the incidence of respiratory distress syndrome, intraventricular haemorrhage, necrotising enterocolitis, and other complications in preterm infants [8]. Additionally, in-utero transfer is linked to lower neonatal morbidity and mortality compared to postnatal transportation [9].

Mosler and Schwalm introduced the term “tocolysis,” which refers to a range of pharmacological agents designed to suppress PTL [5]. Despite some controversy surrounding their use, tocolytics are considered crucial for managing PTL in order to allow time for corticosteroid administration. Current tocolytic agents include nitric oxide donors, prostaglandin inhibitors, beta-agonists, calcium channel blockers and oxytocin receptor antagonists [10]. Atosiban, an oxytocin receptor antagonist, has recently emerged as a promising tocolytic option in India, offering a favourable safety profile for both mother and foetus [11]. Traditionally, Nifedipine, a calcium channel blocker, has been widely used for tocolysis due to its effectiveness in delaying delivery and reducing neonatal complications. However, its use can be associated with maternal side-effects such as hypotension and tachycardia [12].

Currently, it remains unclear which medication provides the best results. However, calcium channel blockers or oxytocin antagonists are recommended for initial tocolysis for 48 hours, as they offer the best efficacy relative to their side-effects [13,14]. The results of three small randomised trials comparing the oxytocin antagonist Atosiban with the calcium channel blocker Nifedipine reveal inconsistent findings [15-17]. This highlights the urgent need for further research to clarify these treatments and improve patient outcomes. This study aimed to evaluate and compare the efficacy and safety profiles of Atosiban and Nifedipine in the management of PTL, focusing on their ability to prolong pregnancy, maternal tolerability profile and improve neonatal outcomes. By assessing the comparative benefits of these two tocolytic agents, the study seeks to provide insights in optimising the management of PTL.

MATERIALS AND METHODS

This prospective interventional study was conducted at Dr. DY Patil Medical College, Hospital, and Research Centre, Pimpri Pune, Maharashtra, India from October 2022 to August 2024. The ethics

committee of the institute approved the study (Research Protocol No.- IESC/PGS/2022/136).

Inclusion criteria: Women aged 19-35 with a singleton pregnancy, gestational age between 24+0/7 to 34+0/7 weeks, and clinically diagnosed with PTL, including frequent uterine contractions and cervical alterations, were included in the study.

Exclusion criteria: Patients with multifoetal pregnancy, in active labour with >3 cm cervical dilation, having premature rupture of membranes, antepartum haemorrhage, a foetus with intrauterine growth restriction below the tenth percentile, non reassuring foetal status, signs of intrauterine infection or intrauterine foetal death, major foetal anomalies, or chromosomal abnormalities were excluded. Mothers with known uterine malformations, Rh incompatibility, comorbidities, or those already on other tocolytic treatments were also excluded from the study.

Sample size estimation: A total of 90 patients (45 in each group) were included in the study. The sample size was calculated by assuming an effect size of 0.6 (medium) and setting the α error at 0.05 and the power (1-β) error at 0.8, with an allocation ratio of N2/N1 being 1. The calculated sample size was 90. The software used for this calculation was G*Power version 3.1.

Methodology and parameters studied: Antenatal care (ANC) patients attending the Outpatient Department (OPD) or Inpatient Department (IPD) in the Department of Obstetrics and Gynaecology were included in the study. Ninety pregnant females in their 24+0/7 to 34+0/7 weeks of pregnancy with PTL were selected after a detailed history and clinical examination. They were informed about the purpose of the study, and informed consent was obtained from each participant. Subsequently, they were divided into the Atosiban or Nifedipine group according to the consultant's decision based on signs, symptoms and examination.

The initial dose of Atosiban was given as a single intravenous bolus of 6.75 mg/0.9 mL in 100 mL of isotonic normal saline. This was followed immediately by an intravenous infusion of 300 μg/min of Atosiban (37.5 mg/5 mL concentrate for solution for infusion) over three hours, and then 100 μg/min for a total of up to 48 hours [18]. Nifedipine was administered as a loading dose of 30 mg orally, followed by 10 mg to 20 mg every four to six hours [19]. Steroid cover was provided to all mothers receiving and responding to either tocolytic drug.

The primary outcomes measured were the duration of pregnancy prolongation, neonatal outcomes and NICU admissions. Secondary outcomes included maternal side-effects and gestational age at delivery [Table/Fig-1]. Data were collected on maternal age, history of previous preterm deliveries, gestational age at admission, duration of pregnancy prolongation, gestational age at delivery, maternal side-effects, and neonatal outcomes.

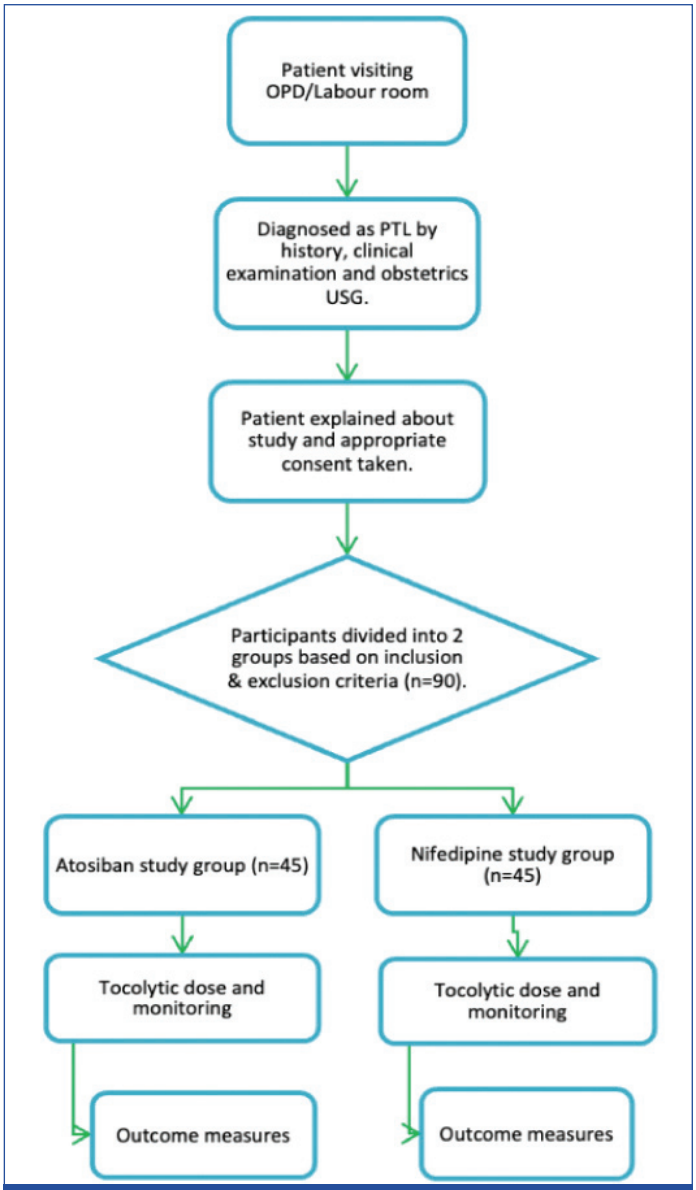
STATISTICAL ANALYSIS

Statistical analysis was conducted using Statistical Package for the Social Sciences (SPSS version 3.1) software, with p-values <0.05 considered statistically significant. The Chi-square test or t-test was used to compare these categorical variables.

RESULTS

The age distribution was similar in both groups, with most participants aged 21-25 years. A slightly higher proportion of participants in the Atosiban group (10 [22.22%]) had a history of previous preterm deliveries compared to the Nifedipine group (6 [13.33%]). Both groups had similar mean gestational ages at admission and delivery [Table/Fig-2].

Nifedipine was associated with a higher percentage of cases achieving more than seven days of pregnancy prolongation compared to Atosiban (36 [80%] vs. 34 [75.56%]). Both groups had an equal percentage of cases with more than 30 days of prolongation (4.44%) [Table/Fig-3].



[Table/Fig-1]: Study's flow chart.

Variable	Group A Atosiban (n=45)	Group B Nifedipine (n=45)	p-value (t-test & Chi-square Test)
Mean age (years)	25.37±3.09	24.95±3.03	0.510
Previous preterm delivery	10 (22.22%)	6 (13.33%)	0.012*
Mean gestational age at admission (weeks)	30.15±2.63	30.86±2.70	0.200
Mean gestational age at delivery (weeks)	32.86±3.04	33.75±2.83	0.150

[Table/Fig-2]: Baseline variables among group A and B.
*Significant p-value; Values calculated by using t-test and Chi-square test

Prolongation of pregnancy days	Group A Atosiban (n=45)	Group B Nifedipine (n=45)	p-value (Chi-square test)
<48 hours	6 (13.33%)	5 (11.11%)	1.00
48-72 hours	1 (2.22%)	2 (4.44%)	1.00
3-7 days	4 (8.89%)	2 (4.44%)	0.673
>7 days	34 (75.56%)	36 (80%)	0.800
Mean days of prolongation	16.53±7.14	17.24±8.10	0.001*

[Table/Fig-3]: Prolongation of pregnancy days in Group-A and Group-B.
*Significant p-value; Values calculated using Chi-square test

Nifedipine was associated with a higher incidence of side-effects such as headache (7 [15.56%] vs. 1 [2.22%], p-value=0.05), hypotension (5 [11.11%] vs. 1 [2.22%]), and tachycardia (3 [6.67%] vs. 1 [2.22%]) compared to Atosiban [Table/Fig-4].

Maternal side-effects	Group A Atosiban (n=45)	Group B Nifedipine (n=45)	p-value (Chi-square test)
Headache	1 (2.22%)	7 (15.56%)	0.050
Hypotension	1 (2.22%)	5 (11.11%)	0.191
Nausea and vomiting	2 (4.44%)	1 (2.22%)	1.00
Tachycardia	1 (2.22%)	3 (6.67%)	0.615
Palpitation	0	1 (2.22%)	1.00
Dizziness	0	1 (2.22%)	1.00

[Table/Fig-4]: Comparison of maternal side-effects in Groups A and B.
p-values calculated using Chi-square test

NICU admission rates were non significantly higher in the Atosiban group (20 [44.44%] vs. 14 [31.11%]). Nifedipine-treated infants had higher birth weights, with a greater proportion weighing more than 2.5 kg compared to Atosiban (12 [26.67%] vs. 8 [17.78%]) [Table/Fig-5].

Neonatal outcomes	Group A Atosiban (n=45)	Group B Nifedipine (n=45)	p-value (Chi-square test)
NICU admission	20 (44.44%)	14 (31.11%)	0.269
Mechanical ventilation	7 (15.56%)	4 (8.89%)	0.334
Respiratory distress syndrome	5 (11.11%)	2 (4.44%)	0.245
Intraventricular haemorrhage	2 (4.44%)	2 (4.44%)	1.00
Necrotising enterocolitis	1 (2.22%)	0	0.310
Sepsis	1 (2.22%)	1 (2.22%)	1.00
Apnoea	1 (2.22%)	0	0.317
Birth weight ≥2.5 kg	8 (17.78%)	12 (26.67%)	0.310

[Table/Fig-5]: Comparison of neonatal outcomes in Groups A and B.
p-values calculated using Chi-square test

DISCUSSION

This study aimed to evaluate and compare the efficacy of Atosiban and Nifedipine in the management of PTL, focussing on their impact on prolonging pregnancy and improving neonatal outcomes. The findings suggest that both drugs were almost equally effective in terms of efficacy; however, their safety profiles vary depending on clinical scenarios.

The age distribution in this study showed that the majority of participants were around 25 years old in both the Atosiban and Nifedipine groups. This demographic trend aligns with the findings of Singh P et al., on PTL management, who reported that young women aged over 18 years with gestational ages between 25-34 weeks are commonly affected by PTL [20]. The present study's alignment with these demographic patterns supports the generalisability of these findings to broader populations of women experiencing PTL.

A notable observation was the higher prevalence of previous preterm deliveries in the Atosiban group (22.22%) compared to the Nifedipine group (13.33%). This suggests that Atosiban is often chosen for patients with a history of PTL, potentially due to its effectiveness in acute scenarios. In contrast, Nifedipine was more commonly administered to patients without a history of preterm delivery, aligning with its use as a first-line treatment for less complicated cases. This pattern is supported by van Winden TMS et al., who highlighted that Nifedipine may offer protective benefits against adverse outcomes in children born to women without a history of PTL [21].

The gestational age at admission revealed that Atosiban was more frequently used at earlier gestational ages (28-31 weeks), while Nifedipine was used closer to term (32-34 weeks). This difference underscores the preference for Nifedipine in prolonging pregnancies closer to term, while Atosiban is used earlier to halt the progression of PTL. These findings are consistent with clinical practices reported by Gupta N et al., where Nifedipine was effectively utilised in later gestational weeks, highlighting its suitability for cases nearing term [22].

In terms of pregnancy prolongation, Nifedipine was associated with a slightly higher proportion of cases achieving more than seven days of prolongation (80%) compared to Atosiban (75.56%). This result indicates that Nifedipine may be more effective in sustaining pregnancy beyond the critical period, leading to improved neonatal outcomes. Present study findings align with Van Vliet EOG et al., who observed a slightly higher efficacy of Nifedipine over Atosiban in terms of the average number of days of delaying pregnancy and allowing better intrauterine growth for the foetus [23]. However, both drugs showed no significant difference in prolonging pregnancy (17.24 vs. 16.53). Salim R et al., showed similar results in the efficacy of both drugs in delaying pregnancy for 48 hours and seven days in PTL [15].

The gestational age at delivery further supports the efficacy of both drugs in delaying delivery to more viable gestational ages. The findings indicate that both drugs effectively prolong pregnancy to reduce neonatal morbidity and mortality. However, a slightly higher proportion of very preterm deliveries in the Atosiban group may be attributed to its use in more severe cases of PTL, where the risk of early delivery is higher despite tocolytic intervention. This observation was consistent with the study by Singh P et al., who found that Nifedipine is associated with longer pregnancy prolongation and a higher gestational age at delivery [20]. Additionally, Salim R et al., showed results of mean gestational age at delivery in their study that are similar to ours [15].

Maternal side-effects were more prevalent in the Nifedipine group, including headaches (15.56%), hypotension (11.11%), and tachycardia (6.67%). These side-effects are typical of calcium channel blockers like Nifedipine, which can cause vasodilation-related symptoms. In contrast, Atosiban, an oxytocin receptor antagonist, was better tolerated with fewer side-effects. This outcome supports findings from Kashanian M et al., which showed fewer cardiovascular side-effects with Atosiban [16]. The lower incidence of side-effects with Atosiban may make it a preferable choice for patients with contraindications to Nifedipine or those who experience significant side-effects, as supported by Al-Omari WR et al., in their study [17].

Regarding neonatal outcomes, NICU admission rates were higher in the Atosiban group (44.44%) compared to the Nifedipine group (31.11%). This difference could be due to the earlier gestational ages at delivery in the Atosiban group, as neonates born at earlier gestational ages typically require more intensive care. Despite this, the overall rates of severe neonatal complications, such as intraventricular haemorrhage and sepsis, were similar between the two groups, suggesting that both drugs provide comparable safety profiles. These findings are consistent with van Winden TMS et al., who reported similar neonatal outcomes between the two tocolytics, highlighting that Nifedipine may reduce NICU admissions but does not significantly alter the severity of neonatal complications [21]. Coomarasamy A et al., investigated the efficacy of Nifedipine versus Atosiban for tocolysis in a meta-analysis and demonstrated a significant reduction in neonatal Respiratory Distress Syndrome (RDS) with Nifedipine compared with Atosiban [24].

Lastly, birth weight outcomes showed that a higher percentage of infants in the Atosiban group were born with a weight of less than 2.5 kg (82.22%) compared to the Nifedipine group (73.33%). This likely reflects the earlier gestational ages at delivery in the Atosiban group. Studies by van Winden TMS et al., and Maher MA et al., also reported higher birth weights with Nifedipine, supporting its role in promoting longer gestational durations and improved neonatal outcomes [21,25].

Limitation(s)

The sample size was relatively small, potentially limiting the generalisability of the findings. The study was conducted at a

single tertiary care centre, introducing potential selection bias. Long-term neonatal outcomes were not assessed, which limits the understanding of the full impact of the treatments. Variability in clinical decision-making may have influenced the choice of tocolytic agent, thereby affecting the results.

CONCLUSION(S)

Atosiban and Nifedipine both showed similar effects in managing PTL, with each drug offering its own advantages. Nifedipine's ability to prolong pregnancy and improve neonatal outcomes makes it a valuable option for cases closer to term, while Atosiban's better side-effect profile may make it more suitable for acute intervention in patients with early PTL. Therefore, the choice of the first-line tocolytic agent can be determined based on the patient's profile, tolerability, and physician's preference. Further research with larger sample sizes and extended follow-up is needed to refine these findings and optimise PTL management strategies.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Sep 27, 2024
- Manual Googling: Oct 24, 2024
- iThenticate Software: Dec 17, 2024 (13%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Sep 26, 2024**
Date of Peer Review: **Oct 18, 2024**
Date of Acceptance: **Dec 19, 2024**
Date of Publishing: **Jan 01, 2025**