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Efficacy and Safety of Atosiban in Prevention of Preterm Labor: Experience from Bangladesh

Kazi Foyeza Akther[1]* and Mohammad Hosne Mobarak[2]

Abstract

Background: Preterm labor remains a leading cause of neonatal morbidity and mortality, particularly in low- and middle-income countries such as Bangladesh. Timely and safe tocolytic therapy is essential to delay delivery and improve perinatal outcomes. Atosiban, a selective oxytocin receptor antagonist, offers a targeted mechanism of action with a favorable safety profile; however, evidence from real-world clinical settings in South Asia remains limited.

Aim: To evaluate the effectiveness and safety of atosiban in the prevention of threatened preterm labor in a tertiary care hospital setting in Bangladesh.

Methods: This Phase IV, retrospective, observational cohort study included women presenting with threatened preterm labor between >28 and <34 weeks of gestation who were treated with atosiban from January to December 2023. Atosiban was administered as an intravenous bolus followed by continuous infusion for up to 48 hours. The primary endpoint was the proportion of women maintaining a viable pregnancy for at least 4–6 weeks after treatment. Secondary outcomes included requirement for additional management, maternal and neonatal adverse events, mode of delivery, and neonatal outcome. Data were analyzed using descriptive statistics, and exploratory subgroup analyses were performed.

Findings: A total of 48 women were enrolled in the study. The mean maternal age was 29.4 ± 4.6 years. Pregnancy prolongation for at least four weeks was achieved in 77.1% (37/48) of patients. Exploratory analyses demonstrated numerically higher pregnancy prolongation rates among women aged <30 years, those without a prior history of preterm labor, and those not requiring additional management. Maternal adverse events were reported in 16.7% of patients, with no serious adverse events observed. Normal vaginal delivery occurred in 60.4% of cases. Neonatal survival was 100%.

Conclusion: Atosiban demonstrated effective pregnancy prolongation with a favorable maternal and neonatal safety profile in women with threatened preterm labour. These findings support its use as a pragmatic tocolytic option in routine clinical practice within resource-constrained South Asian settings.

Keywords: Atosiban; Tocolytic agent; Preterm labor; Premature birth; Maternal mortality; Pregnancy prolongation; Perinatal outcomes.

Affiliation:

[1]MBBS, FCPS, MCPS Consultant, Department of Obstetrics & Gynaecology, BRB Hospitals Ltd. Dhaka, Bangladesh

[2]MBBS, FCPS, MCPS, DA Consultant Department of Anesthesiology, Continental Hospital PLC. Dhaka, Bangladesh

***Corresponding author:**
Kazi Foyeza Akther, MBBS, FCPS, MCPS Consultant, Department of Obstetrics & Gynaecology, BRB Hospitals Ltd. Dhaka, Bangladesh.

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Introduction:

Preterm labor remains a major public health challenge and a leading cause of neonatal morbidity and mortality worldwide. [1] Statistically, every year, there are 15 million (11.1%) preterm births of all births worldwide, and 13.3% of these births occur in South Asia alone. [2] In South Asia, including Bangladesh, preterm birth continues to be a critical contributor to adverse perinatal outcomes owing to scarcity of neonatal intensive care resources and no or delayed access to specialized obstetric care. [3-4]

Preterm labor, defined as the onset of labor between 20 and 36 weeks of gestation, is associated with significant neonatal complications such as respiratory distress syndrome, low birth weight, sepsis, intraventricular hemorrhage, and long-term neurodevelopmental impairment. [5] Maternal complications, including infection, hemorrhage, and increased cardiovascular risk, have also been reported. [6]

Early identification of women at risk is central to prevention strategies. Short cervical length measured by transvaginal sonography has emerged as a strong predictor of spontaneous preterm labor. [7] Moreover, in the Bangladeshi and broader South Asian context, additional risk factors such as gestational diabetes mellitus, urinary tract infections, multiple pregnancies, and previous preterm birth are frequently encountered during antenatal care. [8]

Atosiban, a selective oxytocin receptor antagonist, has been developed as a targeted tocolytic agent with fewer cardiovascular side effects compared with traditional tocolytics. [9] Following its recent approval in Bangladesh, real-world evidence on its effectiveness and safety in local populations remains limited. This study aims to evaluate the real-world effectiveness and safety of atosiban in preventing threatened preterm labor in a tertiary care setting in Bangladesh.

Methods

Study design and setting

This Phase IV, retrospective, observational cohort study was conducted at a BRB Hospital Ltd. in Dhaka, Bangladesh. Medical records of women treated with atosiban between 1 January 2023 and 31 December 2023 were reviewed.

Study population

Women presenting with threatened preterm labor who received atosiban during the study period were eligible. A total of 48 complete cases were included in the final analysis.

Eligibility criteria

Inclusion criteria

- Those who had a gestational age between >28 and <34 weeks.
- Patients who had a cervical length <2.5 cm on transvaginal sonography.
- Those who had one or more risk factors such as gestational diabetes mellitus, urinary tract infection, anemia, multiple pregnancy, prior preterm labor, or shortened cervical length.
- Were treated with atosiban for prevention of preterm labor.

Exclusion criteria

- Those women with gestational age ≥34 weeks.
- Those who had inevitable miscarriage due to organic cause.
- Patients with abnormal fetal heart rate, antepartum hemorrhage, preeclampsia, eclampsia, premature rupture of membranes or cervical cerclage.
- Those who had known contraindications to atosiban.
- Incomplete medical records were excluded.

Intervention

Atosiban was administered as an intravenous bolus of 6.75 mg over one minute, followed by an infusion of 18 mg/hour for three hours, then reduced to 6 mg/hour for up to 45 hours, in accordance with standard clinical practice.

Study endpoints

The primary endpoint was the proportion of women maintaining a viable pregnancy for at least 4–6 weeks following treatment. Secondary endpoints included requirement of additional management, maternal and neonatal adverse events, mode of delivery, and neonatal outcomes.

Data analysis

Data were analyzed using descriptive statistics. Continuous variables were summarized using mean ± standard deviation and range, while categorical variables were presented as counts and percentages. Exploratory subgroup analyses were performed descriptively to assess pregnancy prolongation across key baseline characteristics.

Ethical consideration

Ethical approval for this study was obtained from the Institutional Authority of BRB Hospitals Limited, Dhaka, Bangladesh. This study was conducted in accordance with applicable ethical guidelines and principles for biomedical research. As this was a retrospective, observational study, no additional intervention beyond standard clinical care was performed. Confidentiality of participant information was strictly maintained throughout the study. In addition, participants retained the right to withdraw their consent at any time and at any stage of the study without any effect

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on their standard medical care. No financial incentives or remuneration were provided for participation in the study.

Result

Table 1: Baseline maternal and obstetric characteristics (n=48)

Characteristics	Frequency/Percentage (n/%) or mean ± SD
Mean maternal age (years)	29.4 ± 4.6
Age group (years)	
20-24	7 (14.6)
25-29	18 (37.5)
30-34	16 (33.3)
≥ 35	7 (14.6)
Previous pregnancy	27 (56.3)
History of abortion	6 (12.5)
History of preterm labor/premature birth	5 (10.4)

The mean maternal age of the study population was 29.4 ± 4.6 years, with the majority of women belonging to the 25–29-year age group (37.5%), followed by those aged 30–34 years (33.3%). More than half of the participants (56.3%) had a history of previous pregnancy. In addition, a history of abortion was present in 12.5% of women, while 10.4% had a previous history of preterm labor or premature birth. [Table 1]

Table 2: Clinical presentation and need for additional management (n=48)

Characteristics	Frequency/Percentage (n/%)
Symptoms of preterm labor	48 (100)
Additional management required	15 (31.3)

It can be seen that, all 48 women (100%) presented with clinical symptoms of preterm labor at admission. Additional management alongside atosiban therapy was required in 31.3% of patients, indicating that most cases could be controlled without the need for further therapeutic interventions. [Table 2]

Table 3: Primary efficacy outcome (n=48)

Outcome	Frequency/Percentage (n/%)
Pregnancy prolonged ≥4 weeks	37 (77.1)
Pregnancy not prolonged ≥4 weeks	11 (22.9)

As evident, atosiban was mostly well tolerated since maternal adverse events were reported in only 16.7% patients. Importantly, no serious adverse events or treatment discontinuations due to drug-related complications were observed. [Table 3]

It was clearly visible that, pregnancy prolongation for at least four weeks was achieved in 80.0% of women aged <30 years compared with 73.9% among women aged ≥30 years. Among women with a previous history of preterm labor, pregnancy prolongation was observed in 60.0%, whereas a higher proportion (79.1%) of women without such history achieved the primary efficacy outcome. Besides, patients who required additional management demonstrated a lower rate of pregnancy prolongation 66.7% compared with those managed with atosiban alone 81.8%. These findings suggest numerically reduced efficacy in women with higher baseline obstetric risk or more severe clinical presentation. [Table 4].

Table 4: Exploratory sub-group analysis of pregnancy prolongation ≥ 4 weeks (n=48)

Subgroup	Pregnancy prolonged ≥ 4 weeks (n/%)	Not prolonged (n/%)
Age group (years)		
Age <30 (n=25)	20 (80.0)	5 (20.0)
Age >30 (n=23)	17 (73.9)	6 (26.1)
Previous preterm labor		
No (n=43)	34 (79.1)	9 (20.9)
Yes (n=5)	3 (60.0)	2 (40.0)
Additional management required		
No (n=33)	27 (81.8)	6 (18.2)
Yes (n=15)	10 (66.7)	5 (33.3)

It was clearly seen that, the primary efficacy outcome, prolongation of pregnancy for at least four weeks following atosiban administration, was achieved in 77.1% of women. Pregnancy could not be prolonged for four weeks in 22.9% of cases. [Table 5].

Table 5: Safety outcomes (n=48)

Safety-related outcomes	Frequency/Percentage (n/%)
Minor adverse events	8 (16.7)
Serious adverse events	0 (0.0)
Discontinuation of treatment as a result of adversities	0 (0.0)

Furthermore, it was evident that, normal vaginal delivery occurred in 60.4% of patients, whereas 39.6% underwent caesarean section. The observed distribution of delivery modes likely reflects obstetric indications rather than treatment-related effects. Lastly, neonatal survival was universal; all the 48 babies were alive. [Table 6].

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Table 6: Delivery and neonatal outcomes (n=48)

Delivery and neonatal outcomes	Frequency/ Percentage (n/%)
Mode of delivery	
Normal vaginal delivery	29 (60.4)
Caesarean section	19 (39.6)
Neonatal outcomes	
Alive	48 (100)

Discussion

Preterm labor continues to be a major contributor to neonatal morbidity and mortality in Bangladesh and other South Asian countries, where healthcare resources and access to advanced neonatal intensive care remain variable. Although atosiban has been widely studied in European and high-income settings, there is a relative paucity of real-world evidence from Bangladesh and neighboring countries, where patient profiles, risk factors, and healthcare delivery systems differ substantially. Following the recent approval of atosiban in Bangladesh, it was therefore important to evaluate its effectiveness and safety in routine clinical practice within a local tertiary care setting.

In the present study, the mean maternal age was 29.4 years, with the majority of women falling between 25 and 34 years of age. While 28% of 15–19-year-olds have begun childbearing, relevant studies expose that 64% of preterm deliveries occur in women aged 21-30, followed by a substantial 24% in those under 20 years of age. [10] In addition, similar age profiles have been documented in Indian hospital-based cohorts evaluating tocolytic therapies, suggesting comparable reproductive demographics across South Asia. [11]

Furthermore, more than half of the women in this study had a history of previous pregnancy, while a smaller proportion had a history of abortion or previous preterm labor. The relatively lower prevalence of prior preterm birth in this cohort may reflect improved antenatal surveillance and earlier identification of cervical shortening, which is increasingly emphasized in urban tertiary centers in Bangladesh. A comprehensive review explained that several low-cost interventions in low- and middle-income countries such as multiple micronutrient supplementation and enhanced quality of antenatal care resulted in significant reductions in preterm births. [12]

All women in this study presented with clinical symptoms of preterm labor, consistent with the inclusion criteria and standard diagnostic practices. Approximately one-third of patients required additional management alongside atosiban therapy. This finding aligns with real-world reports from South Asian settings, where concomitant use of antibiotics, corticosteroids, or supportive therapies is often necessary due to the high prevalence of infection-related and metabolic risk factors such as urinary tract infection and gestational diabetes mellitus. [13] Recent study in Oman has similarly reported that 25–40% of women treated for threatened preterm labor required adjunctive management, reflecting disease severity rather than treatment failure. The fact that the majority of women in our cohort were managed successfully with atosiban alone suggests adequate efficacy in less complicated cases. [14]

Furthermore, pregnancy prolongation of at least four weeks was achieved in 77.1% of women in this study. This outcome is clinically significant in the Bangladeshi context, where even modest prolongation of gestation can substantially improve neonatal survival and reduce complications associated with prematurity. [15]

Comparable pregnancy prolongation rates have been reported in Asian observational studies evaluating atosiban, with reported success rates generally ranging between 70% and 80%. These findings are consistent with international studies conducted in East Asia, although direct comparisons should be interpreted cautiously due to differences in study design and patient populations. [14, 16] Nevertheless, the observed efficacy in this Bangladeshi cohort reinforces the applicability of atosiban in routine regional practice.

Exploratory subgroup analyses revealed numerically higher pregnancy prolongation rates among women aged below 30 years, those without a prior history of preterm labour, and those not requiring additional management. These trends are biologically plausible and consistent with regional literature, where higher baseline obstetric risk and disease severity have been associated with reduced responsiveness to tocolytic therapy. Similar observations have been reported in Indian and South American studies, where women with recurrent preterm labor or multiple co-morbidities demonstrated lower pregnancy prolongation rates despite tocolytic use. [13, 17] While these findings in our study are descriptive and exploratory, they provide useful clinical insights for patient counseling and risk stratification in resource-limited settings.

In addition, atosiban was well tolerated in this cohort, with a low incidence of maternal adverse events and no reported serious adverse events. This favorable safety profile is particularly important in the South Asian context, where traditional tocolytics such as β-agonists and calcium channel blockers are often associated with cardiovascular side effects that may limit their use. [18] Moreover, regional studies from Bangladesh have similarly highlighted the tolerability advantages of atosiban compared to other tocolytics. [19] International randomized trials have consistently

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demonstrated comparable efficacy with fewer maternal adverse effects, and our findings support these conclusions in a real-world Bangladeshi population. [20]

Moreover, the majority of women in this study delivered vaginally, while caesarean section was performed in approximately two-fifths of cases. This distribution is consistent with regional obstetric practices, where mode of delivery is largely determined by obstetric indications rather than prior tocolytic exposure. Studies from African region have reported similar delivery patterns among women treated for preterm labor. [21] In addition, neonatal survival in this cohort was 100%, which compares favorably with regional reports and reflects both effective pregnancy prolongation and improved perinatal care in tertiary centers. [10]

Limitations

Firstly, the retrospective nature of the study limits causal inference. Secondly, the sample size was modest, and exploratory subgroup analyses were not powered for statistical significance testing. Finally, long-term neonatal outcomes were not assessed.

Conclusion

Atosiban demonstrated favorable effectiveness and safety in preventing threatened preterm labor. These findings support the use of atosiban as a valuable tocolytic option in Bangladesh and similar South Asian settings, while highlighting the need for larger prospective studies to further validate these observations.

Conflict of interest

The authors declared no conflict of interest.

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