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Research Article

Duration of Pregnancy Prolongation with Atosiban in Twin Pregnancies Diagnosed with Threatened Preterm Labor

Nguyen Thi Yen [1,*], Ho Minh Tuan [1], Nguyen Thi Cam Nhung [1], Nguyen Hong Hoa [2]

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ABSTRACT

Background: Twin pregnancy is a high-risk condition associated with numerous maternal and fetal complications. Common complications include hypertensive disorders, preterm birth, congenital abnormalities, and those specific to twin gestations. Among these, preterm birth is the most prevalent, with a rate exceeding 50% in twin pregnancies, 10.8 times higher than in singleton pregnancies. Preterm birth not only leads to significant neonatal morbidity and mortality but also imposes a substantial economic burden for neonatal care. Approximately 70% of preterm infant deaths occur in the neonatal period, and 50% of these children die within the first five years of life. The cornerstone of managing threatened preterm labor focuses on preventing or inhibiting uterine contractions, thereby prolonging pregnancy to allow for the administration of corticosteroids for fetal lung maturation, magnesium sulfate for fetal neuroprotection, and transfer to a tertiary care center. Atosiban is a highly effective tocolytic agent with minimal maternal and fetal side effects.

Methods: This was a retrospective case series study of 81 pregnant women with twin gestations diagnosed with threatened preterm labor, who were treated with Atosiban at Tu Du Hospital.

Results: The mean pregnancy prolongation was 120 hours. The rate of pregnancy prolongation for $\geq$ 48 hours was 88.9%. The incidence of adverse effects from Atosiban was low (2.5%).

Conclusion: Atosiban is a highly effective and well-tolerated tocolytic agent for the management of threatened preterm labor in women with twin pregnancies.

Key words: Preterm birth, twin pregnancy, tocolysis, Atosiban

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INTRODUCTION

The global prevalence of preterm birth has been on the rise, increasing from 9.8% in 2000 to 10.6% in 2014.[1] According to research by Martin in the United States, the preterm birth rate was 9.8% in 2016 and rose to 10.2% in 2019.[2] In Australia, the rate was 8.7% in 2017, with the rate among twin pregnancies being 66%.[3] Multiple gestation is identified as one of the highest risk factors for preterm birth. The rate of preterm birth in twin pregnancies can exceed 50%, which is 10.8 times higher than in singleton pregnancies.[4] Preterm birth not only causes numerous complications for the newborn but also represents a significant economic burden for the care of a premature infant.[5]

Preterm birth, particularly in twin pregnancies, remains a major challenge in modern obstetrics, associated with numerous risks for both mother and baby.[6] Tocolytic drugs play a crucial role in delaying delivery, providing a crucial window of opportunity for other interventions to take effect.[7] Among tocolytics, Atosiban—an oxytocin receptor antagonist—has garnered increasing attention due to its high efficacy and favorable side-effect profile.

METHODS

Study Design: A retrospective case series study.

Study Population: All pregnant women with twin gestations between 24 weeks and 33 weeks 6 days of gestation, who were diagnosed with threatened preterm labor and treated with Atosiban at Department of Obstetrics A, Tu Du Hospital, from January 2019 to December 2021.

Inclusion Criteria: Pregnant women with twin pregnancies admitted to TD Hospital with medical records satisfying the following conditions:

- Age of 18 years or older.
- Viable twin pregnancy with a gestational age from 24 weeks to 33 weeks and 6 days, determined by the last menstrual period, first-trimester ultrasound, or the date of embryo transfer.
- Diagnosed with threatened preterm labor.
- Indicated for treatment with Atosiban and have completed part or all of the treatment protocol.

Exclusion Criteria: Cases with medical records noting the following:

- Premature rupture of membranes or chorioamnionitis.
- Conditions requiring termination of pregnancy,

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such as: fetal distress, placental abruption, bleeding placenta previa, or severe pre-eclampsia.
- Congenital fetal anomalies.
- Intrauterine fetal demise.
- Allergy to any component of the medication.
- Prior use of other tocolytic agents.

Data Collection: A list of pregnant women with twin pregnancies who were admitted and treated for threatened preterm labor with Atosiban at Department of Obstetrics A, Tu Du Hospital, was compiled. Medical records were retrieved from the archives using admission and storage codes. Data were collected from the medical records based on a predesigned data collection form, including maternal demographic information, clinical and subclinical symptoms at admission, and the progression of treatment as documented by physicians and midwives.

Our study included women with twin gestations from 24 weeks to 33 weeks 6 days at Tu Du Hospital who were diagnosed with threatened preterm labor, meeting the criteria of $\geq$4 uterine contractions per 20 minutes and a cervical dilation of <3 cm. They received tocolysis with Atosiban, administered as an initial 6.75 mg bolus, followed by a loading infusion of 300 μg/minute for 3 hours, and subsequently a maintenance infusion of 100 μg/minute for 45 hours.

Data Analysis:
- Data were coded and entered using EpiData 3.1 software.
- Data were processed and analyzed using R statistical software.
- Independent and dependent variables were described using proportions, frequencies, or presented in frequency distribution tables.
- Descriptive statistics and univariate analysis were performed. All statistical tests were conducted with a 95% confidence interval, and a result was considered statistically significant if $p<0.05$.

Study Objectives:
- Primary Objective: To describe the efficacy of Atosiban in inhibiting uterine contractions in pregnant women with twin gestations between 24 and 33 weeks 6 days of gestation diagnosed with threatened preterm labor.
- Secondary Objectives: To investigate factors associated with the efficacy of Atosiban tocolysis in this population and to describe the adverse effects of the drug.
- Success Criteria: Cessation or reduction of uterine contractions within 48 hours of initiating Atosiban and pregnancy prolongation of $\geq$ 48 hours.
- Failure Criteria: Failure to inhibit uterine contractions, resulting in delivery before 48 hours from the start of Atosiban, or discontinuation of treatment due to maternal adverse effects.

RESULTS

A total of 81 pregnant women were included in the study. The mean maternal age at admission was 28.7 $\pm$ 4.8 years. The mean gestational age was 29.9 $\pm$ 2.6 weeks, which is the typical gestational age range for initiating tocolysis to delay delivery for the completion of corticosteroid therapy and fetal neuroprotection. In this study, dichorionic-diamniotic (DCDA) and monochorionic-diamniotic (MCDA) twin pregnancies accounted for 53.1% and 36.9% of cases, respectively. There were no cases of monochorionic-monoamniotic (MCMA) twins.

Prior to treatment, 67.9% of patients had a cervical dilation of $\leq$ 1 cm, while 32.1% had a dilation of 2 – $\leq$ 3 cm. The majority of patients (74.1%) had a cervical effacement of < 60%, while 25.9% had an effacement of $\geq$ 60%.

Table 1: Cervical Characteristics Before Treatment*

Characteristic	Frequency (n)	Percentage (%)
Cervical Dilation		
<1 cm	29	35.8
1 cm	26	32.1
2 – $\leq$ 3 cm	26	32.1
Cervical Effacement		
< 60%	60	74.1
$\geq$ 60%	21	25.9

*Source: Calculated by the authors

Before treatment, 100% of cases had a uterine contraction intensity of $\geq$ 60 mmHg, with a mean of 73.7 $\pm$ 16.5 mmHg. The mean contraction frequency was 3.0 $\pm$ 0.9 contractions per 10 minutes, with 28.4% (23) of women having more than 4 contractions per 10 minutes. After treatment, 42 cases (51.9%) had complete cessation of uterine contractions, 24 cases (29.6%) had 1–2 contractions, and only 3 cases (3.7%) still had 4–5 contractions. After tocolysis, only 27.2% of cases had a contraction intensity of $\geq$ 60 mmHg, and 54.4% experienced a complete reduction in contraction intensity. After the second vial of Atosiban, the mean frequency and intensity decreased significantly to 1.8

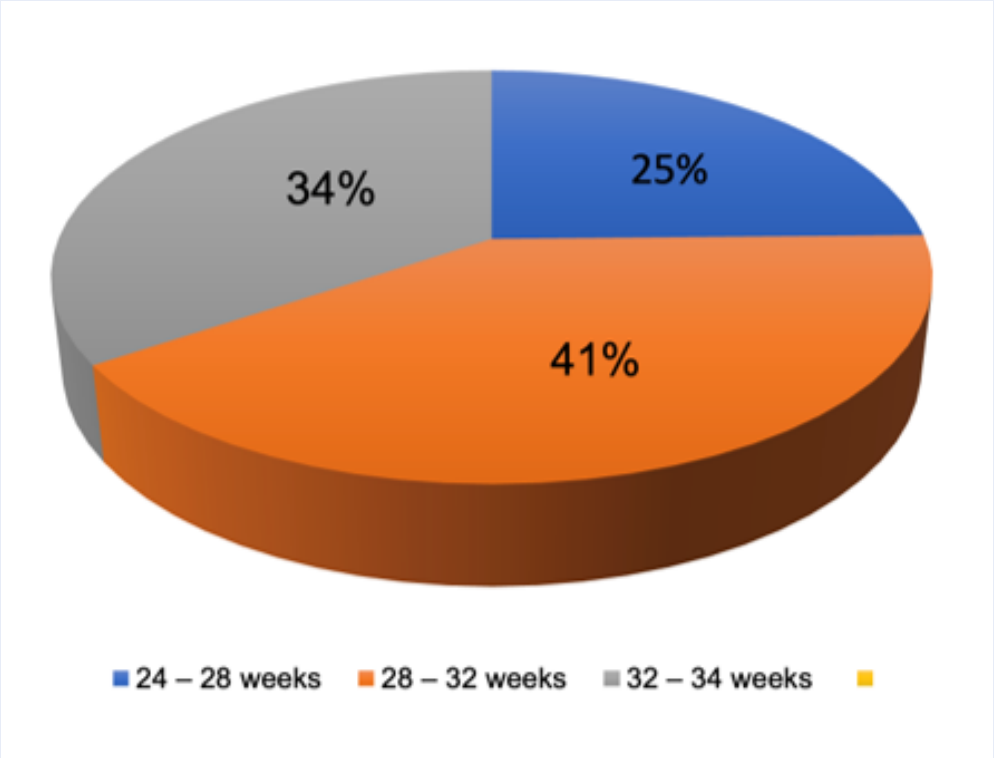

Figure 1: Chart of gestational ageat admission (Source: Generated by the authors using Microsoft Excel 2019)

± 1.2 contractions and 51.1 ± 24.0 mmHg, respectively. The mean number of Atosiban vials required to achieve tocolysis was 4.7 ± 2.2.

Pregnancy Prolongation The rate of pregnancy prolongation for ≥ 48 hours with Atosiban for threatened preterm labor in twin pregnancies was 88.9%.

Table 2: Durationof Pregnancy Prolongation*

Duration of Pregnancy Prolongation	Frequency (n)	Percentage (%)	Cumulative
< 48 hours	9	11.1	11.1
48 hours - 7 days	55	67.9	79.0
≥7 days	17	21.0	100
Total	81	100	100

*Source: Calculated by the authors

The mean pregnancy prolongation for the 81 subjects was 120.0 ± 73.4 hours (5.0 ± 3.1 days). The shortest prolongation was 4 hours, and the longest was 407 hours (17 days). The results show that 88.9% of patients achieved pregnancy prolongation of ≥ 48 hours, with only 9 cases (11.1%) delivering in < 48 hours.

In our study, most cases were treated with a single course of Atosiban. Only 8 cases required a repeat course to suppress contractions, with a maximum of 4 courses administered to one patient. Cases receiving a single course of Atosiban had a mean pregnancy prolongation of 112.3 ± 69.8 hours, whereas those receiving two or more courses had a mean prolongation of 189.5 ± 72.4 hours. This difference was statistically significant (=0.0041). The mean pregnancy prolongation in the group with ≥2 courses was 77.2 hours longer (95% CI: 25.2 – 129.1) than in the single-course group. Among these 8 cases, 5 delivered at Tu Du Hospital due to progressive labor, hypertonic contractions, or anhydramnios with twin-to-twin transfusion syndrome (TTTS) at a gestational age of primarily 28–32 weeks. The remaining 3 cases were stabilized and discharged for continued outpatient monitoring.

Of the 81 study subjects, 38 delivered at Tu Du Hospital. The gestational age group of 28–32 weeks accounted for the largest proportion of deliveries (44.7%), while the 34–37 week group was the smallest (Figure 3). The majority of women (63.2%) delivered via cesarean section.

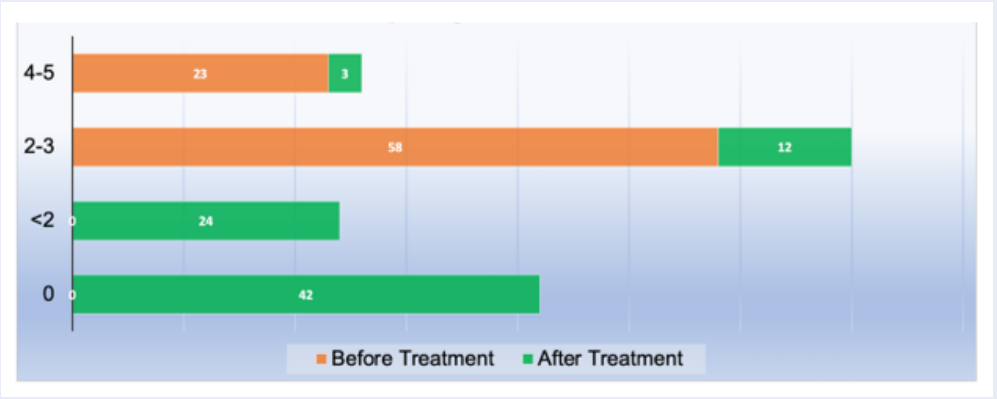

Figure 2: Chart of contraction frequency before and after Atosiban treatment (Source: Generatedby the authors using Microsoft Excel 2019)

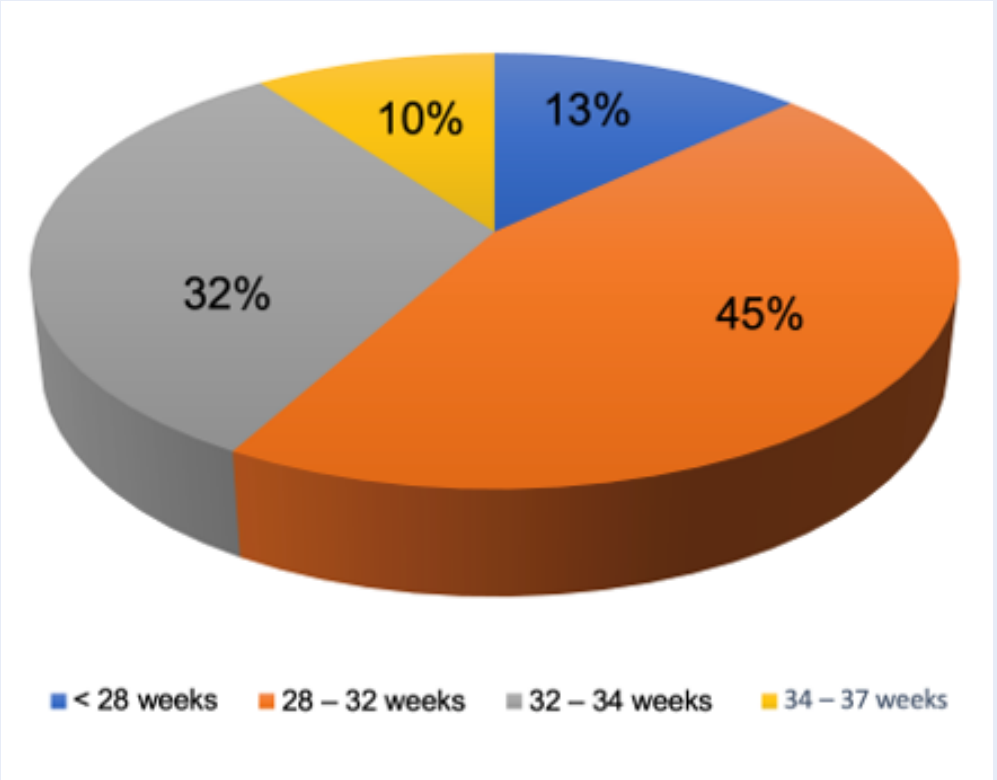

Figure 3: Distribution of Gestational age at Delivery (Source: Generated by the authors using Microsoft Excel 2019)

Table 3: AssociationBetween Success Rate and Labor Characteristics*

Characteristic	Success	Failure	OR	P-value
Cervical Dilation				
≤ 1 cm	51 (70.8%)	5 (55.6%)	3.04 (0.58 – 16.64)	0.138 (Fisher)
2 – 3 cm	21 (29.2%)	4 (44.4%)		
Cervical Effacement				
Thick (< 60%)	57 (79.2%)	3 (33.3%)	7.6 (1.38 – 50.81)	0.008 (Fisher)
≥ 60%	15 (20.8%)	6 (66.7%)	1	
Contraction Frequency				
1 – 2 contractions	25 (34.7%)	4 (44.4%)	1	0.777 (Fisher)
3 – 4 contractions	45 (62.5%)	5 (55.6%)		
≥ 5 contractions	2 (2.8%)	0 (0%)		

*Source: Calculated by the authors

The success rate was higher in the group with cervical dilation ≤ 1 cm compared to the 2–3 cm group; however, this difference was not statistically significant (=0.138). A thick cervix (< 60% effaced) was associated with a significantly higher treatment success rate compared to a cervix with ≥ 60% effacement (OR = 7.6; 95% CI: 1.38 – 50.81; =0.008). Contraction frequency was not significantly associated with the treatment efficacy of Atosiban (>0.05).

Rate of Adverse Effects

The baseline vital signs of the participants in our study were mostly stable before treatment. The mean maternal pulse was 91.8±9.7 bpm, with 87.7% of patients having a pulse ≤100 bpm and 12.3% having a pulse >100 bpm. The mean systolic blood pressure was 110.1 mmHg, and the mean diastolic blood pressure was 68.3 mmHg; there were two cases of hypertension. The mean temperature at admission was 37°C.

In our study, the mean fluctuation in maternal pulse was 7.7 bpm, with a maximum fluctuation of 38 bpm. This maximum change was observed in a patient who presented with a heart rate of 127 bpm and more than five contractions before treatment. Among the 10 cases with a pre-treatment heart rate >100 bpm, the heart rate normalized during monitoring without specific intervention. Only one patient had a pre-existing diagnosis of hyperthyroidism during pregnancy. Systolic and diastolic blood pressures fluctuated by a mean of 8.5 mmHg and 6.8 mmHg, respectively. The temperature varied by 0.2°C during the treatment period.

During treatment, no patient reported symptoms of nausea, vomiting, headache, or dizziness. There were no cases of hypotension or injection site reactions. Three cases of tachycardia were recorded: one patient with fever was diagnosed with bronchitis and monitored for chorioamnionitis; one patient with pre-existing hyperthyroidism presented with sinus tachycardia upon admission; and one case experienced transient tachycardia at 106 bpm, which later resolved spontaneously.

DISCUSSION

The mean gestational age at admission for treatment was 29.9 ± 2.6 weeks. The highest gestational age was 33 weeks and 4 days, and the lowest was 24 weeks. This is a common gestational age range for initiating tocolysis to delay delivery, allowing for the completion of corticosteroid therapy and fetal neuroprotection in cases of threatened preterm birth. In our study, 49.4% of patients received corticosteroid therapy during this Atosiban treatment course. It is possible that because many participants in our study had long-awaited pregnancies or underwent assisted reproduction, consent for the use of corticosteroids and Atosiban was more readily obtained.

Our finding of an 88.9% rate of pregnancy prolongation for $\geq$ 48 hours is slightly lower than that reported in previous Vietnamese studies on Atosiban efficacy, such as Phan Ha Minh Hanh at My Duc Hospital (94.6%), Doan Chau Quynh (93.5%), and Nguyen Huu Tien at Binh Dinh Provincial General Hospital (92.1%).[8–10] This discrepancy may be due to our study population consisting entirely of twin pregnancies, which carry a higher intrinsic risk of preterm birth. Additionally, the studies by Doan Chau Quynh and Nguyen Huu Tien had inclusion criteria with a lower baseline uterine contraction frequency than ours.

Our results are comparable to those of Ly Thanh Truong Giang at Hue Central Hospital (88.6%) and Nguyen Manh Thang in 2021 at the National Hospital of Obstetrics and Gynecology (86.4%). In Ly Thanh Truong Giang's study, the prolongation rate was higher in singleton pregnancies (92.9%) compared to twin pregnancies (71.4%), although this difference was not statistically significant.[11]

Prior to treatment, 100% of participants in our study had a contraction intensity $\geq$ 60 mmHg, with a mean of 73.7 $\pm$ 16.5 mmHg. The mean contraction frequency was 3.0 $\pm$ 0.9 contractions per 10 minutes, and 28.4% of women had more than 4 contractions per 10 minutes before treatment. Both the mean frequency and intensity in our study were higher than in studies by Ly Thanh Truong Giang (1.9 $\pm$ 0.8 contractions/10 min), Dewan (4 contractions/30 min), and Doan Chau Quynh, where 51.6% of participants had only 1–2 contractions/10 min before treatment, and only 12.9% had $\geq$ 5 contractions. As our study population consisted exclusively of twin pregnancies, uterine activity was expectedly higher than in the singleton-predominant cohorts of other studies. This may also explain why the mean time to achieve tocolysis was longer in our study. Specifically, the mean number of Atosiban vials required was 4.7 $\pm$ 2.2, indicating lower initial efficacy compared to the study by Ly Thanh Truong Giang, where tocolysis was achieved in an average of 3.6 $\pm$ 1.33 hours, versus approximately 15 hours in our study.

However, the aforementioned studies did not exclusively enroll twin pregnancies, likely due to a lack of data on tocolysis specifically in twin gestations in Vietnam. Our study's rate of pregnancy prolongation for $\geq$48 hours is higher when compared to the twin pregnancy subgroup in the study by Doan Chau Quynh,[9] which reported a prolongation rate of 68.6% for twins alone. Our rate is also higher when compared specifically to the twin pregnancy cohort in the 2010 study by Pham Thi Ngoc Diep,[12] which had a prolongation rate of 72.7%. In summary, the rate of pregnancy prolongation for $\geq$48 hours in our study appears to be higher than previously reported in similar Vietnamese studies on the efficacy of Atosiban in twin pregnancies.

After the second vial, we observed a substantial decrease in mean contraction frequency and intensity, from 3.0 $\pm$ 0.9 contractions to 1.8 $\pm$ 1.2 contractions, and from 73.7 $\pm$ 16.5 mmHg to 51.1 $\pm$ 24.0 mmHg, respectively. Overall, 61.7% of patients had a reduction in contraction frequency, and 52.8% had a reduction in intensity. Only 7 cases (8.6%) showed an increase in frequency or intensity after the second vial.

Eight patients required repeat courses of Atosiban for tocolysis, with a maximum of four courses administered to one patient. The mean duration of pregnancy prolongation in the group receiving two or more courses of Atosiban was 77.2 hours longer (95% CI: 25.2 – 129.1) than in the group receiving only one course. Among these eight cases, five women delivered at Tu Du Hospital due to progressive labor, hypertonic contractions, or anhydramnios with twin-to-twin transfusion syndrome, primarily between 28 and 32 weeks of gestation. The remaining three cases were stabilized and discharged for continued outpatient monitoring.

The primary goal of tocolytic therapy is to prolong pregnancy long enough to achieve the optimal effects of corticosteroid administration for fetal lung maturation, magnesium sulfate for fetal neuroprotection, or to allow for transfer to a tertiary care center. Maintenance tocolytic therapy has not been shown to be effective in preventing preterm birth or improving neonatal outcomes. Therefore, maintenance tocolysis is not routinely recommended. However, as there are no specific recommendations for twin pregnancies, the use of more than one course of Atosiban remains a subject of debate and lacks consensus in clinical practice.

Besides efficacy, safety for both the mother and fetus is a paramount concern. An ideal tocolytic agent should delay delivery without causing significant maternal or fetal side effects, and it should be cost-effective. During treatment in our study, no patients reported nausea, vomiting, headache, or dizziness. There were no instances of hypotension or injection site reactions. Three cases of tachycardia were noted: one was associated with fever in a patient diagnosed with bronchitis and monitored for chorioamnionitis; one was sinus tachycardia in a patient with pre-existing hyperthyroidism; and one was a transient episode of tachycardia at 106 bpm that subsequently resolved spontaneously.

Of the 38 women who delivered at Tu Du Hospital, no cases of stillbirth were recorded. At 1 minute after birth, 13.2% of neonates had an Apgar score ≥7, while 86.8% had an Apgar score <7. At 5 minutes, the Apgar scores improved, with 55.3% of neonates scoring ≥7 and 44.7% scoring <7. The high rate of Apgar scores <7 at 1 minute (86.8%) is likely attributable to prematurity, as 90% of the infants in our study were born at <34 weeks of gestation. However, following active resuscitation, the Apgar scores at 5 minutes showed significant improvement, with the percentage of scores <7 decreasing to 44.7%.

CONCLUSIONS

This study on the efficacy of Atosiban for threatened preterm labor in 81 women with twin pregnancies between 24 and 33 weeks 6 days of gestation shows a mean pregnancy prolongation of 120.0 ± 73.4 hours (5.0 ± 3.1 days). The shortest prolongation was 4 hours and the longest was 407 hours (17 days). The results indicate that 88.9% of pregnancies were prolonged for ≥ 48 hours. The rate of adverse effects was low, with only 2 cases of maternal tachycardia (2.5%) recorded. Pre-treatment cervical effacement was significantly associated with the success rate of Atosiban tocolysis.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest in conducting this research.

AUTHOR CONTRIBUTIONS

Nguyen Thi Yen: Conceptualization, Methodology, Formal analysis, Writing - Review & Editing.
Ho Minh Tuan: Software, Validation, Formal analysis, Writing - Original Draft.
Nguyen Thi Cam Nhung: Software, Investigation.
Nguyen Hong Hoa: Writing - Review & Editing, Supervision.

ETHICS IN BIOMEDICAL RESEARCH

This was a retrospective study utilizing only pre-existing information from the medical records of patients who had already been treated and discharged. The study did not interfere with the diagnosis or treatment process of any patient.

All information regarding the study participants was kept strictly confidential and used solely for scientific purposes.

The study was conducted after receiving approval from the Ethics Committee in Biomedical Research of the University of Medicine and Pharmacy at Ho Chi Minh City and Tu Du Hospital.

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Bài nghiên cứu

Thời gian kéo dài thai kỳ của atosiban trên sản phụ song thai có chẩn đoán dọa sinh non

Nguyễn Thị Yến [1,*], Hồ Minh Tuấn [1], Nguyễn Thị Cẩm Nhung [1], Nguyễn Hồng Hoa [2]

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TÓM TẮT

Đặt vấn đề: Song thai là một thai kỳ tiềm ẩn nhiều nguy cơ cho cả mẹ và thai. Nhiều biến chứng thường gặp trong song thai như rối loạn huyết áp, sinh non, dị tật bẩm sinh hay những biến chứng đặc hiệu trên song thai. Trong đó, nguy cơ sinh non là thường gặp nhất, tỷ lệ sinh non ở song thai chiếm trên 50%, gấp 10,8 lần so với đơn thai. Sinh non không chỉ gây nên nhiều biến chứng cho trẻ sơ sinh mà còn là gánh nặng về kinh tế cho việc chăm sóc một trẻ sơ sinh non tháng. Có khoảng 70% trẻ sinh non tử vong ở giai đoạn sơ sinh và 50% tử vong trong vòng 5 năm đầu đời. Chìa khóa điều trị dọa sinh non được tập trung vào việc ngăn ngừa hoặc ức chế cơn gò tử cung, kéo dài thời gian để sử dụng corticosteroid trưởng thành phổi, magnesium sulfate để bảo vệ não thai nhi và chuyển đến cơ sở chăm sóc đặc biệt. Atosiban là thuốc có hiệu quả cao trong điều trị cắt cơn gò tử cung và ít ảnh hưởng lên mẹ và thai.

Phương pháp: Báo cáo loạt ca hồi cứu trên 81 sản phụ song thai được chẩn đoán dọa sinh non và được điều trị bằng Atosiban tại bệnh viện Từ Dũ.

Kết quả: Thời gian kéo dài thai kỳ trung bình là 120 giờ. Tỷ lệ kéo dài thai kỳ ≥ 48 giờ chiếm 88,9%.Tác dụng không mong muốn của Atosiban chiếm tỷ lệ thấp (2,5%).

Kết luận: Atosiban là thuốc hiệu quả cao và ít tác dụng phụ trong việc giảm gò tử cung trong điều trị dọa sinh trên sản phụ song thai.

Từ khoá: Sinh non, song thai, giảm gò, Atosiban

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