

PROGESTERONE VERSUS RITODRINE IN MANAGEMENT OF PRETERM LABOR

By

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ABSTRACT

Background: Preterm labor (PTL) and delivery remain a significant problem in contemporary obstetric practice. Although the exact cause remains unclear, it is most likely to be multifactorial in nature. Progesterone may be effective in prevention of premature birth in some high risk populations. Women with arrested premature labor are at risk of recurrent labor and maintenance therapy with standard tocolytics has not been successful.

Objective: To compare the efficacy and safety of beta-sympathomimetics (Ritodrine) and Progesterone for maintenance tocolysis after arrested preterm labor for prolongation of pregnancy and prevention of recurrence of preterm labor.

Subjects and methods: This study was a case-control study which was carried out to evaluate the efficacy and safety of beta-sympathomimetics (Ritodrine) and Progesterone for maintenance tocolysis after arrested preterm labor. This study was carried out on 100 pregnant women attending Sohag Teaching Hospital and Al-Azhar University Hospital (Al-Hussein) in gestational age between 28 and 37 weeks, from August 2019 to August 2020. Patients were divided into two equal groups: Group (A) received oral ritodrine (yutopar), and Group (B) received progesterone vaginal suppository (prontogest 400).

Results: Among participants in Group A, there were 41 (82%) multigravida and 9 (18%) primigravida, while in Group B there were 45 (90%) multigravida and 5 (10%) primigravida. The mean maternal age in Group A was 25.52 (± 3.94 SD) with range (19-32), while the mean maternal age in Group B was 26.64 (± 3.84 SD) with range (21-32). There were 27 (54%) in Group A who had Previous PTL or abortion while there were 21 (42%) in Group B only. There was a high statistically significant difference between the studied groups as regard outcome babies.

Conclusion: Progesterone has the upper hand on ritodrine in maintenance tocolysis. Also, it showed that neonatal outcomes were better with progesterone and the maternal side effects were fewer with progesterone than ritodrine.

Keywords: Preterm labor, Tocolysis, Ritodrine, Progesterone.

INTRODUCTION

Despite advances in perinatal medicine, the incidence of preterm birth continues to increase. The primary goal of tocolytic therapy is to reduce neonatal morbidity and mortality. While studies have demonstrated prolongation of

pregnancy, no tocolytic drug has been shown to improve neonatal outcomes (*Simhan et al., 2018*).

Preterm birth (PTB) is currently the leading cause of childhood mortality in children under 5 years (*Harrison and Goldenberg, 2015*). In 2010, 14.9 million

babies were born preterm, accounting for 11.1% of all births worldwide. Rates of PTB range from approximately 5% of births in European countries, to 18% in certain African countries (*Blencowe et al., 2012*).

Much of the economic burden can be attributed to neonatal intensive care, often followed by ongoing health care and educational requirements, in addition to the emotional impact experienced by families (*Howson et al., 2013*).

Preterm labor (PTL) can be initiated by multiple mechanisms, including infection or inflammation, uteroplacental ischemia or hemorrhage, uterine over distension or stress (*Goldenberg et al., 2010*).

Maternal risk factors include extremes in maternal age, body mass index (BMI), multiple gestations, the use of assisted reproductive technologies, history of PTB and low socioeconomic status (*Rubens et al., 2014*).

In general, tocolytic therapies are largely ineffective at substantially delaying delivery and reducing neonatal mortality (*Haas et al., 2012*).

The most commonly used tocolytic agents are beta-adrenergic agonists. Meta-analysis has shown that beta-adrenergic agonists, especially ritodrine are associated with a postponement of delivery 24, 48 hours and 7 days. However such a delay has not been associated with a significant reduction in either perinatal mortality or morbidity. The great incidence of usually mild but potentially severe side effects of beta-sympathomimetics has led to the search for better drugs. Progesterone is useful in

allowing pregnancy to reach term (*Elovitz et al., 2011*).

Several trials have reported the benefits of vaginal progesterone administration for reducing the rates of PTB and improving neonatal outcome. However, these studies had limited information on the long term outcome of these infants (*Dodd et al., 2013*).

The aim of this study was to compare the efficacy and safety of beta-sympathomimetics (Ritodrine) and Progesterone for maintenance tocolysis after arrested preterm labor for prolongation of pregnancy and prevention of recurrence of preterm labor.

PATIENTS AND METHODS

This was a case-control study carried out to evaluate the efficacy and safety of beta-sympathomimetics (Ritodrine) and Progesterone for maintenance tocolysis after arrested preterm labor. This study was carried out to pregnant women attending Sohag Teaching Hospital and Al-Azhar University Hospital (Al-Hussein) in gestational age between 28 and 37 weeks, from August 2019 to August 2020.

Group A: received oral Ritodrine 10 mg tablet was given every 12 hours till 37 weeks of pregnancy or till deliver whichever occurred early.

A total of 100 pregnant women was included in the study and divided into two equal groups:

Group B: received progesterone pessaries containing 400 mg natural progesterone per pessary. It was used by the patient as one pessary per vaginum at bed-time until

37 weeks or till delivery whichever occurred early.

All regimens of administration started after stoppage of acute attack of preterm labor whatever the method of management.

Inclusion criteria: History of painful regular uterine contractions associated with bouts of diarrhea or associated with menstrual like cramps, singleton pregnancy, intact membranes, the dating of pregnancy confirmed through first ultrasound scanning or last menstrual period and cervical dilation of 3 cm or less.

Exclusion criteria: Acute attack of preterm labor, cervical dilation >3 cm, hypotension (less than 80 mmHg systolic or 50 mmHg diastolic), major fetal congenital anomalies, unreassuring traces of fetal cardiotocography, ante-partum hemorrhage or history of recurrent vaginal bleeding, rupture of membranes, multiple pregnancy, polyhydramnios, chorioamnionitis, unexplained pyrexia, medical disorders, i.e. diabetes, cardiac disease, sensitivity or contraindications to ritodrine and other tocolytic therapy during this pregnancy.

All patients were subjected to:

1. Informed written consent.
2. History taking: Personal history, present history, obstetric history, menstrual history, past history and family history.
3. General examination: With special attention to blood pressure, pulse and temperature, Blood pressure for all the patients should be above 100/60 mmHg before commencement of treatment.

4. Abdominal examination: To palpate the uterine contractions and monitoring of the fetal heart rate.
5. Sonographic assessment: To estimate the gestational age, amount of liquor and exclude placenta previa, placental abruption and major fetal congenital anomalies. Several ultrasound parameters will be used to estimate gestational age including biparietal diameter (BPD), head circumference (HC), and femur length (FL).
6. Pelvic examination: To assess the state of membranes and exclude their rupture through examination with a sterile Cusco speculum, to exclude vaginal bleeding and assess the state of the cervix.
7. Urine analysis: To detect urinary tract infection.
8. Administration of tocolytic agent in the form of vaginal progesterone, or oral ritodrine. If the women were stable and undelivered after 48h of maintenance tocolysis, they would be discharged and followed-up in the antenatal care clinic.

All patients were discharged with the following instructions: - Avoid intercourse, heavy work and carrying heavy things. - Return back to the hospital if developed symptoms of preterm labor. - At every visit, fetal growth was assessed clinically and patients were evaluated for side-effects. - Maintenance tocolysis was given until 37 weeks or to the onset of spontaneous labour, whichever occurred earlier.

9. Follow up of the patient weekly in the obstetric outpatient clinic until delivery

to detect the date and mode of delivery and the outcome.

Statistical analysis:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5%

level. Chi-square test was used for categorical variables, to compare between different groups. Fisher's exact correction for chi-square was used when more than 20% of the cells have expected count less than 5. Student t-test was used for normally distributed quantitative variables, to compare between two studied groups. Mann Whitney test was used for abnormally distributed quantitative variables, to compare between two studied groups. A p value of ≤ 0.05 was considered statistically significant for all analyses.

RESULTS

Among participants in Group A, there were 41 (82%) multigravida and 9 (18%) primigravida, while in Group B there were 45 (90%) multigravida and 5 (10%) primigravida. The mean maternal age in Group A was 25.52 (± 3.94 SD) with range (19-32) while the mean maternal age in Group B was 26.64 (± 3.84 SD) with range

(21-32). There were 27 (54%) in Group A who had Previous PTL or abortion while there were 21 (42%) in Group B only. There was no statistically significant difference between the studied groups as regard Parity, Maternal age or Previous PTL or abortion (**Table 1**).

Table (1): Comparison between the two studied groups according to obstetric history

Obstetric history	Group A (n = 50)		Group B (n = 50)		p
	No.	%	No.	%	
Parity					
MG.	41	82.0	45	90.0	0.249
PG.	9	18.0	5	10.0	
Maternal Age (years)					
Min. – Max.	19.0 – 32.0		21.0 – 32.0		0.153
Mean \pm SD.	25.52 \pm 3.94		26.64 \pm 3.84		
Median (IQR)	26.0 (21.0 – 29.0)		26.0 (23.0 – 30.0)		
Previous PTL or abortion					
No	23	46.0	29	58.0	0.230
Yes	27	54.0	21	42.0	

χ^2 : Chi square test, t: Student t-test.

p: p value for comparing between the studied groups.

Group A: Oral ritodrine (yutopar).

Group B: Progesterone vaginal suppository (prontogest 400).

Among participants in Group A, there were 8 (16%) have asymptomatic bactiuria in urine analysis (U.A) while there were 7 (14%) in Group B. The mean frequency of recurrence of cases in Group A was 2.45 (± 1.12 SD) with range (0.7-4.2), while the mean frequency of recurrence in Group B was 1.96 (± 0.61 SD) with range (0.8-3). The mean Gestational age at delivery of cases in Group A was 34.74 (± 3.02 SD) with range (28-38), while the mean gestational age at delivery in Group B was 36.2 (± 2.53 SD)

with range (28-38). The mean tocolysis duration of cases in Group A was 1.27 (± 0.51 SD) with range (0.48-2.29) while the mean tocolysis duration in Group B was 4.29 (± 2.62 SD) with range (0.7-8.61). There was a statistically significant difference between the studied groups as regards tocolysis duration. There was a statistically significant difference as regards frequency of recurrence, and gestational age at delivery and there was no statistically significant difference as regard U.A (Table 2).

Table (2): Comparison between the two studied groups according to different parameters

Parameters	Group A (n = 50)		Group B (n = 50)		p
	No.	%	No.	%	
U.A (Asymptomatic bactiuria).					
No	42	84.0	43	86.0	0.779
Yes	8	16.0	7	14.0	
Frequency of recurrence					
Min. – Max.	0.70 – 4.20		0.80 – 3.0		0.008*
Mean \pm SD.	2.45 \pm 1.12		1.96 \pm 0.61		
Median (IQR)	2.45 (1.50 – 3.40)		1.95 (1.60 – 2.50)		
Gestational age at delivery (weeks)					
Min. – Max.	28.0 – 38.0		28.0 – 38.0		0.010*
Mean \pm SD.	34.74 \pm 3.02		36.20 \pm 2.53		
Median (IQR)	36.0 (33.0 – 37.0)		37.0 (36.0 – 38.0)		
Tocolysis duration					
Min. – Max.	0.48 – 2.29		0.71 – 8.61		<0.001*
Mean \pm SD.	1.27 \pm 0.51		4.29 \pm 2.62		
Median (IQR)	1.17 (0.85 – 1.75)		4.55 (1.69 – 6.75)		

χ^2 : Chi square test, t: Student t-test, U: Mann Whitney test.

p: p value for comparing between the studied groups.

*: Statistically significant at $p \leq 0.05$.

Group A: Oral ritodrine (yutopar).

Group B: Progesterone vaginal suppository (prontogest 400).

Among the babies delivered in Group A, there were 20 (40%) entered Incubation, 14 (28%) discharged, and 16 (32%) end. Among the babies delivered in Group B, there were 12 (24%) entered

Incubation, 35 (70%) discharged, and 3 (6%) end. There was a statistically significant difference between the studied groups as regards outcome babies (Table 3).

Table (3): Comparison between the two studied groups according to outcome

Outcome	Group A (n = 50)		Group B (n = 50)		p
	No.	%	No.	%	
Incubation	20	40.0	12	24.0	<0.001*
Discharged	14	28.0	35	70.0	
END	16	32.0	3	6.0	

χ^2 : Chi square test.

p: p value for comparing between the studied groups.

*: Statistically significant at $p \leq 0.05$.

Group A: Oral ritodrine (yutopar).

Group B: Progesterone vaginal suppository (prontogest 400).

Among the cases of Group A, there were 13 (26%) had hypotension, 7 (14%) had palpitation, 9 (18%) had tachycardia, 6 (12%) had flushing and redness and 50 (100%) had atonic postpartum hemorrhage (PPH). Among the cases of Group B, there were 2 (4%) had hypotension, 5 (10%) had palpitation, 4 (8%) had tachycardia, 2 (4%) had nausea

and vomiting, and 50 (100%) had atonic post-partum hemorrhage (PPH). There was a statistically significant difference between the studied groups as regard hypotension and flushing and redness, while there was no statistically significant difference as regards palpitation, tachycardia, nausea and vomiting and atonic PPH (Table 4).

Table (4): Comparison between the two studied groups according to maternal side effects and complications

Maternal side effects and complications	Group A (n = 50)		Group B (n = 50)		p
	No.	%	No.	%	
Hypotension	13	26.0	2	4.0	0.002*
Palpitation	7	14.0	5	10.0	0.538
Tachycardia	9	18.0	4	8.0	0.137
Nausea & vomiting	0	0.0	2	4.0	^{FE} p=0.153
Flushing and redness	6	12.0	0	0.0	^{FE} p=0.012*
Constipation	0	0.0	0	0.0	–
Atonic PPH	50	100.0	50	100.0	–

χ^2 : Chi square test, FE: Fisher Exact.

p: p value for comparing between the studied groups.

*: Statistically significant at $p \leq 0.05$.

Group A: Oral ritodrine (yutopar).

Group B: Progesterone vaginal suppository (prontogest 400).

DISCUSSION

In Group A there were 82% multigravida and 18% primigravida, while in Group B there were 90% multigravidas and 10% primigravida. The mean maternal age in Group A was 25.52 (± 3.94 SD) with range (19-32) while the

mean maternal age in Group B was 26.64 (± 3.84 SD) with range (21-32). There were 54% in Group A had previous PTL or abortion, while there were 42% in Group B only. There was no statistically significant difference between the studied

groups as regard parity, maternal age or previous PTL or abortion.

In the study of *Mohie-Eldin et al. (2017)*, they concluded that when comparing patient characteristics in the two study groups there was no statistically significant difference between study groups as regards the age, parity, gestational age at admission and number of previous preterm labor. Also, there is no statistically significant difference in Hb level and presence of asymptomatic bacteruria in between patients included in the study groups with a special noting that anemic patients in this study were associated with urinary tract infection which is consistent with our results as regard the aforementioned parameters.

In the study of *Khalid et al. (2019)*, there was no significant difference in terms of mean age, maternal history, BMI, HB level, and history of PTL.

The early detection of pregnant women at high risk for preterm delivery could be the best way to prevent preterm birth. In the present study, 100 eligible pregnant women with a gestational age between 28 weeks and 37 weeks were included, out of which for maintenance tocolysis, 50 received oral ritodrine, 50 women received progesterone pessaries.

In our study, in Group A there were 16% with asymptomatic bacteriuria in U.A, while there were 14% in Group B. There was a statistically significant difference between the studied groups as regards tocolysis duration, frequency of recurrence and gestational age at delivery, and there was no statistically significant difference as regards U.A.

Mohie-Eldin et al. (2017) concluded that there was a statistically significant difference between the study groups with higher percentage of recurrence in ritodrine group (80%) if compared with and progesterone group (40%). There was a statistically significant difference between both groups as regards tocolysis duration and median gestational age.

Freak-Poli et al. (2011) reported that incidence of delivery before 34 weeks of gestation was 19.2% in progesterone group compared with 34.4% in placebo group and the difference was statistically significant. Uterine contractions were more frequently found among placebo group than in the progesterone group (54.3% Vs 23.6%) respectively. As regard the mean gestational age at delivery, there was a statistically significant difference between the three study groups with higher mean in progesterone group if compared to ritodrine group but there is no significant difference compared to ritodrine group. As regard prolongation of gestation to 37 weeks or more, there was a statistically significant difference between the study groups with more prolongation of gestational age in progesterone group (60%) if compared to ritodrine group (23.3%).

However, these results were not in agreement with the results reported by *O'Brien et al. (2010)* who reported that progesterone did not decrease the frequency of preterm birth rates (<32 weeks of gestation). As regards frequency of recurrence of attacks of preterm labour there was a statistically significant difference between the study groups with higher mean of recurrence in ritodrine

group (2.5 ± 1.13) if compared to both and progesterone group.

On the other hand, study was done by *Papatsonis et al. (2012)* to compare the efficacy with ritodrine in the management of preterm labor, Regarding tocolysis duration, our results came in accordance with the randomized, multi-centric trial done by *Van De Water et al. (2010)*.

Comparison between the two studied groups according to outcome, the babies delivered in Group A were 40% entered Incubation, 28% discharged, and 32% end. Among the babies delivered in Group B there were 24% entered Incubation, 70% discharged, and 3 (6%) end.

In the study of *Mohie-Eldin et al. (2017)*, the neonatal outcome in the studied group of patients the babies delivered in Group A (ritodrine group) were 40% entered Incubation, 30% discharged, and 30% end. Among the babies delivered in Group B there were 33.3% entered Incubation, 60% discharged, and 6.7% end. They concluded that, there was no statistically significant difference between the two study groups, but there was a statistically significant difference between progesterone group if compared to ritodrine group as 60% of babies discharged together with the mother to the home, 33.3% of babies were incubated and 6.7% of babies develop early neonatal death. However, in ritodrine group, 30% of babies were taken to the home, 40% were incubated, and 30% of babies develop early neonatal death which comes in correlation with our results.

Papatsonis et al. (2012) supported the previous work on ritodrine for treatment of preterm labor with respect to neonatal

outcome. There were no significant differences in umbilical artery pH values and Apgar scores between groups. Progesterone was associated with lower admission rates to the NICU (49% versus 66%) compared with ritodrine, and lower incidences of RDS (21% versus 37%), intracranial bleeding (18% versus 31%), and neonatal jaundice (52% versus 67%) which is consistent with our results.

There was a statistically significant difference between the studied groups as regard hypotension and flushing and redness while there was no statistically significant difference as regard Palpitation, tachycardia, nausea and vomiting and atonic PPH.

Mohie-Eldin et al. (2017) concluded that difference between the two study groups as regards maternal side effects as tachycardia and palpitation were more common in patients receiving ritodrine than in other patient groups, while flushing and redness were more common in ritodrine group (16.6%) than progesterone groups (10%) but without significant difference between the two groups. Also there was a higher incidence of hypotension in ritodrine group. However, no women in our study discontinued medication due to adverse effects or medication intolerance. As regards, maternal postpartum complications, atonic postpartum hemorrhage was the main complication of tocolysis, but there was no statistically significant difference between the two study groups on incidence of postpartum hemorrhage which consistent with our study.

CONCLUSION

There was overall difference between progesterone, and ritodrine in their efficacy as maintenance tocolysis for prevention of recurrence of preterm labor. Progesterone has the upper hand on ritodrine in maintenance tocolysis. Neonatal outcomes were better with progesterone, and the maternal side effects were fewer with progesterone than ritodrine.

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مقارنة بين استخدام عقار البروجسترون و عقار الريتودرين في علاج الأم الولادة المبكرة

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خلفية البحث: لا يزال المخاض والولادة قبل الأوان يمثلان مشكلة كبيرة في ممارسة التوليد المعاصرة. على الرغم من أن السبب الدقيق لا يزال غير واضح، فمن المرجح أن يكون متعدد العوامل بطبيعته. عقار البروجسترون مفيد في السماح بالحمل للوصول إلى نهايته الطبيعية الفسيولوجية. ففي الدراسات التجريبية على الحيوانات منع علاج ميدروكسي بروجسترون المخاض وامتلك نشاطاً مضاداً للالتهابات في الجسم، علاوة على ذلك فإن مضادات البروجسترون المعطاة في الحمل المكتمل تزيد من معدل المخاض العفوي الفسيولوجي.

الهدف من البحث: مقارنة فعالية وسلامة محاكيات بيتا الودية (ريتودرين) والبروجسترون من أجل تثبيط المخاض بعد أن يتم إيقاف الام المخاض الحادة لإطالة فترة الحمل اكبر فترة ممكنة وأيضا منع تكرار الام المخاض.

المريضات وطرق البحث: هذه الدراسة تم إجراؤها على 100 سيدة من الحوامل في مستشفى سوهاج التعليمي ومستشفى الحسين الجامعي في عمر الحمل بين 28 و 37 أسبوعاً، خلال الفترة من أغسطس 2019 إلى أغسطس 2020، مقسمة إلى مجموعتين متساويتين: المجموعة (أ): تناولن الريتودرين (يوتوبار) عن طريق الفم، و المجموعة (ب): تلقين البروجسترون كأفماع مهبلية (برونتوجيست 400).

نتائج البحث: بين المشاركون في المجموعة (أ) كان هناك 41 (82%) متعددة الحمل و 9 (18%) حوامل لأول مرة، بينما في المجموعة (ب) كان

هناك 45 (90%) متعددة الحمل و 5 (10%) حوامل لأول مرة. وكان متوسط عمر الأم في المجموعة (أ) 3.94 ± 25.52 فى النطاق (19-32), بينما كان متوسط عمر الأم في المجموعة (ب) 3.84 ± 26.64 فى النطاق (21-32). ولم يكن هناك فرق يعتد به إحصائياً بين المجموعات المدروسة فيما يتعلق بعدد الولادات السابقة، أو عمر الأم أو الإجهاضات السابقة، مع وجود فروق ذات دلالة إحصائية عالية بين المجموعات المدروسة فيما يتعلق بمدة استخدام مثبطات المخاض. ولم يكن هناك فرقا يعتد به إحصائياً فيما يتعلق بتكرار الاجهاض وعمر الحمل عند الولادة، ولم يكن هناك فرقا يعتد به إحصائياً فيما يتعلق بوجود التهابات فى مجرى البول.

الاستنتاج: البروجسترون له اليد العليا على الريتودرين فى تحلل المخاض. كما أظهرت أن نتائج حديثي الولادة كانت أفضل مع البروجسترون وأن الآثار الجانبية للأم كانت أقل مع البروجسترون من الريتودرين.

الكلمات الدالة: المخاض المبكر، مثبطات المخاض، ريتودرين، البروجسترون.