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Comparative Study between Cervical Cerclage and Progesterone for Preventing Pre-Term Labour in Women with History of Pre-Term Labour

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Abstract

Background: Pre-term delivery is on of the main complications of gestation accompanying with perinatal mortalities and morbidities. Implementation of approaches to avoid spontaneous pre-term delivery (s-PTB) is progressively standardized, Progesterone and cervical cerclage utilized for the inhibition of pre-term labour.

Aim of Study: To compare cervical cerclage and progesterone for prevention of pre-term labour in females with history of pre-term labour.

Subjects and Methods: This work is a randomized controlled trial, was carried at Obstetrics and Gynecology Dep. of El Hussein Hospitals of Al-Azhar Faculty of Medicine, on 400 females, from March 2020 till March 2021.

Results: A significant change was found among the study groups according to 1ry outcome as regards Mean GA at delivery.

Conclusion: The vaginal progesterone is successful as cervical cerclage in preventing pre-mature labour but its usage is better in clinical as it's noninvasive method and economic.

Key Words: *Pre-term labour – Progesterone – Short cervix.*

Introduction

PRE-TERM delivery, as well called pre-mature delivery, is the delivery of a baby at before the 37th week gestational-age of (GA) **[1]**.

Pre-mature newborns have higher risk for cerebral palsy, postponements in growth, hearing difficulties and sight complications. These dangers are higher with earlier delivery **[2]**.

The reason of pre-term delivery is frequently unknown. Risk factors comprise DM, hypertension, multiple baby pregnancy, body mass index, and vaginal infections, smoking and psychological stress, between others **[3]**. It is suggested that labour not be medically persuaded pre 39 th GA week except essential for other medical causes. Similar recommendations apply to cesarean-section (CS) **[4]**.

In women at risk, the progesterone hormone, if taken throughout gravidity, might avoid pre-term delivery **[5]**.

Evidences doesn't support the utility of bed rest. It is assessed that at minimum 75% of pre-term babies can survive with suitable treatments, and the rate of survival is maximum between the babies delivered the latest. In females who may be delivered from 24 to 37 th GA week, corticosteroids progress outcome **[6]**. A number of drugs, counting nifedipine, can postpone birth so that a mother can had more medical care and the corticosteroids have elevated chance of exertion **[7]**.

Pre-term delivery is the commonest reason of mortality between newborns all over the world. About 15 million newborns are pre-term yearly (5-18% of all births) **[8]**. About 0.5% of deliveries are very early peri feasible deliveries, and these responsible for most of the mortalities. In several nations, rates of pre-mature deliveries have elevated from the 1990 to 2010.

Cervical cerclage, as well named a cervical stitch, is a therapy for cervical ineffectiveness or deficiency, when the cervix begins to reduce and open too early throughout a gestation resulting in either late abortion or pre-term delivery. Frequently, the intervention is performed in the 1 st or 2nd trimester of gestation, for a female who has had one or more late abortion in the past. The word

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"cerclage" means "hoop" in French, as in the metal hoop surrounding a tub [9].

Employing a cerclage conferred further profit more than vaginal progesterone only for females with very short cervixes and singleton gestations, in a new report. Those who have rescue cerclage besides vaginal progesterone had a 92% total decrease in s-PTB rates, and babies had lesser admissions to neonatal-ICU and lesser complications [10].

This work aimed to compare cervical cerclage and progesterone for preventing pre-term labour in females with history of pre-term labour.

Patients and Methods

This work was a randomized controlled trial carried at Obstetrics and Gynecology Department of Al Sayed Galal Bab Al Sharia Obstetrics and Gynecology Hospital for 400 females were included in the study from March 2020 till March 2021.

The preparatory phase was Two month, Design of examination sheet was Four months, Review of literature was Two months and Collection, organization, entering of data and statistical analysis was Four months.

Inclusion criteria: (High-risk for pre-term labourwith one of the following criteria), history of pre-term labour, 2nd trimester abortion (between 16 and 37 week of GA), singleton pregnancy with short cervical extent (less than 2.5cm), on US at 16+0 to 24+0 weeks GA and 3-Earlier prophylactic cervical cerclage.

Exclusion criteria: Congenital irregularities in the embryo revealed throughout the following-up, sign of imminent birth, or contractions of uterine, sign of membrane ruptures, or amniotic infections, uterine embryo mortality and uterine or cervical irregularities.

Randomization: Was ensured using sealed envelope technique closed envelopes containing letter C for Cervical Cercelage group and letter P for progesterone group and then participants choose randomly.

Methods:

Detailed personal, obstetric and medical history including: Personal history including age, smoking and level of education Obstetric history including gravidity, parity, number of abortions, modes of delivery in previous pregnancies, 1st day of the last ordinary menstrual period and the gestational age, onset, duration and frequency of labour pains, urinary symptoms (dysurea, frequency, urgency), vaginal discharge (color, itching). Medical history including Present or Past history of any chronic illnesses (renal, hypertensive, diabetics, hepatic, cardiac...).

Labouratory investigations: CBC, random Blood Sugar, liver, thyroid and kidney function.

Gestational age (GA) was determined on base of the previous menstrual period with steady cycles or the 1st trimester US. At the 1st antenatal visit, the cases were regularly screened and managed for Neisseria Gonorrhea and Chlamydia Trachomatis. Symptomatic Bacteriological Vaginosis was as well managed with specific antibiotics and repeated cultures were performed to confirm the efficacy of treatment. Women who have higher risk for PTB have been screened through TVS (Trans-vaginal Ultra-sound) of cervix every 2 weeks amid 14-24 weeks.

Cervical extent was calculated by qualified sonographers via standard methods. The woman's bladder was evacuated before visualizations of cervix, minimum pressure essential was utilized to get clear images of cervical canal in mid-sagittal level.

All women in the study were advice to reduce physical activity for the remaining days of their pregnancy. They were given prophylactic steroids (two doses of Dexamethasone, 12mg intramuscularly, 12h apart) for fetal lung maturation at 28 weeks of pregnancy.

Primary outcome measure was PTB <34 weeks GA.

Secondary outcome includes: PTB at <37 weeks, <35 weeks, and <28 weeks. Newborn outcomes include neonatal mortality, NICU admissions, length of NICU and comorbidities (any RDS, intra-ventricular haemorrhage, necrotizing enterocolitis or sepsis).

Ethical committee: Consent from the ethical committee of the faculty was attained and agreement from IRB was taken.

Statistical analysis of the data: Collected data analyzed via SPSS-20 program (IBM-USA). Qualitative data have been presented as numbers and percentage. The Kolmogorov-Smirnov test has been utilized to verify the data with normal distributions Quantitative data have been presented as range (min and max), mean, SD, median and inter-

quartile range (IQR). The level of Significance was 5% level. The utilized examinations were: Chi-square testing: For categorical parameters, for comparing amid various groups. Fisher's Exact or Monte Carlo correction: Correction for chi-square when >20% of the cells have expected count <5. Student *t*-testing: For quantitative data with normal distribution, for comparison among 2 groups. Mann Whitney test: For quantitative data with abnormal distribution, for comparison among 2 groups.

Results

A significant change was found among the study groups regarding miscarriage history, non-significant change was found amid both groups regarding full history of patients. Table (1).

Table (1): Comparison between the two studied groups regarding full history of cases.

Full history of patients	Cerclage group (n=200)		Vaginal progesterone group (n=200)		Test of sig.	*p*
	No.	%	No.	%		
Age (years):						
- Min. – Max.	20-35		20-35		*t*=	0.178
- Mean ± SD.	28.17±4.63		27.55±4.64		1.349	
- Median (IQR)	28 (24.75-32)		28 (24-31)			
BMI (kg/m²):						
- Min. – Max.	23.4-32		22.5-32.3		*t*=	0.557
- Mean ± SD.	27.63±2.35		27.48±2.7		0.588	
- Median (IQR)	27.55 (25.58-29.43)		27.35 (25.2-30)			
Parity:						
- Min. – Max.	1-4		1-4		U=	0.780
- Mean ± SD.	2.07±1.06		2.07±1		19690	
- Median (IQR)	2 (1-3)		2 (1-3)			
Medical complications:						
- No	200	100.0	200	100.0	—	—
History of abortion:						
- No	125	62.5	144	72.0	χ^2 =	0.043
- Yes	75	37.5	56	28.0	4.098*	

χ^2 : Chi square testing.
t : Student *t*-testing.
U : Mann Whitney testing.
* : Statistical significance at *p*-value ≤0.05.
IQR : Inter quartile range.

A nonsignificant change was found among the study groups according to 1 st visit as regards GA and CL. Table (2).

A nonsignificant change was found among the study groups according to GA or extreme short cervix visit as regards CL. Table (3).

Table (2): Comparing among the study groups as regard 1 st visit.

1 st visit	Cerclage group (n=200)	Vaginal progesterone group (n=30)	*t*	*p*
GA:				
Min. – Max.	10-12	10-12	0.368	0.713
Mean ± SD.	10.97±0.8	10.94±0.83		
Median (IQR)	11 (10-12)	11 (10-12)		
CL:				
Min. – Max.	18-21	18-21	1.214	0.226
Mean ± SD.	19.35±0.62	19.44±0.84		
Median (IQR)	19 (19-20)	19 (19-20)		

t : Student *t*-testing.
*: Statistical significance at *p*-value ≤0.05.
IQR: Inter quartile range.

Table (3): Comparing among the study groups as regard extreme short cervix visit.

Extreme short cervix visit	Cerclage group (n=200)		Vaginal progesterone group (n=30)		Test of sig.	*p*
	No.	%	No.	%		
GA:						
Min. – Max.	15-26		15-26		*t*=	0.408
Mean ± SD.	20.41±3.58		20.7±3.42		0.829	
Median (IQR)	20 (17-23)		21 (18-24)			
CL:						
No measurable cervix	83	41.5	70	35.0	χ^2 =	0.181
Yes	117	58.5	130	65.0	1.789	
Min. – Max.	2-10		2- 11		*t*=	0.064
Mean ± SD.	6.02±2.28		6.38±2.06		1.862	
Median (IQR)	6 (4-8)		6 (5-8)			

χ^2 : Chi square testing. *: Statistical significance at *p*-value ≤0.05.
t : Student *t*-testing. IQR: Inter quartile range.

A nonsignificant change was found among the study groups as regards genitourinary microbiological screening. Table (4).

Table (4): Comparing among the study groups as regard genitourinary microbiological screening.

Genitourinary microbiological screening	Cerclage group (n=200)		Vaginal progesterone group (n=30)		χ^2	*p*
	No.	%	No.	%		
No	105	52.5	112	56.0	0.494	0.482
Yes	95	47.5	88	44.0		
Trichomonas	45	47.4	42	47.7	1.532	0.675
Bacterial vaginosis	20	21.1	13	14.8		
Urinary tract infection	20	21.1	23	26.1		
GC/Chlamydia	10	10.5	10	11.4		

χ^2 : Chi square testing.
* : Statistical significance at *p*-value ≤0.05.

A significant change was found among the study groups according to 1ry outcome as regards Mean GA at delivery. Table (5).

Table (5): Comparing among the study groups as regard 1ry outcome.

1ry outcome	Cerclage group (n=200)	Vaginal progesterone group (n=30)	*t*	*p*
Mean GA at delivery:				
Min. – Max.	24-41	24-41	2.786*	0.006*
Mean ± SD.	35.52±5.33	34.17±4.31		
Median (IQR)	38 (34-40)	34 (31-38)		

t : Student *t*-testing.
*: Statistical significance at *p*-value ≤0.05.
IQR: Inter quartile range.

A nonsignificant change was found among the study groups according to secondary outcome. Table (6).

Table (6): Comparing among the study groups as regard 2ry outcome.

2ry outcome	Cerclage group (n=200)		Vaginal progesterone group (n=30)		Test of sig.	*p*
	No.	%	No.	%		
Apgar:						
1 min:						
Min. – Max.	2-10		2-10		*t*=0.358	0.721
Mean ± SD.	6.53±2.31		6.61±2.15			
Median (IQR)	7 (4-8)		7 (5-8)			
5 min:						
Min. – Max.	4-10		4-10		*t*=0.724	0.469
Mean ± SD.	7.94±1.64		7.82±1.68			
Median (IQR)	8 (7-9)		8 (7-9)			
NICU admission:						
No	14	46.7	16	53.3	χ^2=2.216	0.137
Yes	16	53.3	14	46.7		
Length of NICU stay:						
Min. – Max.	1-50		2-50		U=1950	0.353
Mean ± SD.	23.73±13.74		21.29±12.03			
Median (IQR)	21 (15-35.5)		21 (11-30)			
Stillbirths/NND:						
No	199	99.5	197	98.5	χ^2=1.008	FE *p*=
Yes	1	0.5	3	1.5		0.315

χ^2 : Chi square testing. U: Mann whitney testing
FE: Fisher exact. *: Statistical significance at
t : Student *t*-testing. *p*-value ≤0.05.
IQR: Inter quartile range.

Discussion

Pre-term labour (PTL) refers to a delivery that occurs before 37 weeks of gestation. Pre-term delivery is the main reason for newborn mortality (mortality within 28-day of birth). It is accountable for 27 percent of newborn mortality universally, including more than one million mortalities yearly **[11]**.

In the current work we found that there was significant change among the 2 study groups regarding miscarriage history, groups were comparable in terms of age (years), BMI (kg/m ^{2}) and parity.

Matching our results, AbdElzaher et al., **[12]** showed that there was statistically insignificant variance among the studied groups as regard age, BMI and parity.

In agreement with our results, Abd Elaal, **[13]** showed that a nonsignificant change was found among the study groups regarding age and parity.

In contrast to our results, Abd Elaal, **[13]** reported that a nonsignificant change was found among the study groups regarding Number of abortions.

In our results we found that that a nonsignificant change was found among the study groups according to 1 st visit as regards GA and CL.

In agreement with our findings Naim et al., **[14]** showed that a nonsignificant change was found among the study groups as regard each of GA and CL.

These results are in agreement with those of AbdElzaher et al., **[12]** who showed that a nonsignificant change was found among the study groups as regard GA and CL.

In disagreement with our findings, Abd Elaal et al., **[13]** reported that there was significant change among study groups as regard GA (p<0.001).

In our study we found that a significant change was found among the study groups according to 1ry outcome as regards Mean GA at delivery.

In disagreement with our findings, AbdElzaher et al., **[12]** showed that the rate of primary outcomes impulsive birth pre 34 weeks of GA was 10 patients (21.2%) in cervical cerclage group and 13 patients (27.1%) in the vaginal progesterone group (p=0.392) nonsignificant change amid both groups.

In agreement with our results, Abd Elaal et al., **[13]** revealed that a significant change was found among the study groups according to 1ry outcome as regards GA. The rate of pre-term birth <37 week and ≤34 week in twin and triplet gestations was significantly inferior in the combination than that in the progesterone and cerclage groups (χ^2=7.855, 7.451; p=0.019, 0.024, respectively).

Naim et al., **[14]** showed that that either vaginal progesterone only or cerclage only reduced the

risk for pre-term labour significantly compared to control. Moreover, combination of cerclage and vaginal progesterone resulted in higher decrease of pre-term labour.

In the present study we revealed that the studied groups were comparable as regard secondary outcome.

AbdElzaher et al., [12] showed that the average GA at the time of birth was 36+3 weeks in cervical cerclage group and 35+3 weeks in vaginal progesterone group (p=0.392). There was also nonsignificant change in GA at birth when analyzed for the studied groups.

In the present study we revealed that there was nonsignificant variance between both groups regarding NICU admission and NICU stay length and these findings were in harmony with that of AbdElzaher et al., [12].

Abd Elaal et al., [13] showed that the concurrent use of vaginal progesterone and cervical cerclage was significantly effective in reducing the risk of PTL in twins and triplets gestation and was significantly associated with better perinatal outcomes (significantly higher mean birth weight, higher mean Apgar score, lower rate of NICU admission).

In our results we revealed that the studied groups were comparable as regard Apgar score.

Abd Elaal et al., [13] showed that the mean Apgar score in the combination group was significantly more than that in the progesterone and cerclage groups (F=6.047, p=0.003). Multiple comparisons showed that the difference in the Apgar score was not statistically significant between the progesterone and the cerclage groups (t=0.041, p=1.000), significant among the combination and the cerclage groups (t=1.252, p=0.013), and significant among the combination and the progesterone groups (t=1.222, p=0.023).

In our study both intervention were accompanied with a significant decrease in the risk of preterm delivery <34 weeks of GA if compared with females with history of pre-term labour pre the 34th week (p=0.001), this agree with Berghella et al., [15], randomized trials allocated to receive vaginal progesterone vs. placebo/no intervention, or cerclage vs. no cerclage for the avoidance of pre-term delivery.

Briery et al., [16] showed that the indirect comparison of meta-analysis shows trends to better outcome with vaginal progesterone treatment in comparison to cerclage RR > 1.0, but these didn't reach statistical significance as the 95% CIs overlap 1.

Conde-Agudelo et al., [17] reported that babies whose moms treated with vaginal progesterone had a significantly inferior risk of composite newborn morbidities and NICU admission than placebo group. Cases who were allocated to cerclage revealed a significant decrease in the risk of PTB at <37, <35, and <28 weeks of GA and a delivery weight of <1.5kg in comparison to those who didn't receive cerclage. Vaginal progesterone and cerclage are similarly effective in reducing the risk of PTL in high-risk pregnancy (previous spontaneous PTB, short cervical extent <2.5cm in 2 nd trimester).

Rode et al., [18] reported that in 677 cases with diamniotic twin pregnancy, treatment with vaginal progesterone 200mg pessaries starting at 20-24 weeks till 34 weeks weren't accompanied with significant influence on occurrences of PTL or perinatal complications in comparison with placebo.

Regarding outcome, we found that either vaginal progesterone only or cerclage only reduced the risk for pre-term labour significantly compared to control. Our findings were comparable to that of Alfirevic et al., [9] as their results suggested comparable efficiency of presently obtainable treatments (vaginal progesterone and cerclage) for cases with singleton gestation who have at minimum one prior pre-term delivery and a reduced cervical length measured by TVS.

Comparison of utilization of cervical cerclage and vaginal progesterone, showed that nonsignificant variance. But using vaginal progesterone has many advantages. Firstly, it is non-invasive technique with easy administration. Secondary, the patients do not suffer from surgical procedure adverse such as anesthesia, pain and complication. Thirdly, using vaginal progesterone saves time for patients and doctors. Lastly, its cost is lesser than cervical cerclage. From above mentioned reasons, it is clear that using vaginal progesterone is superior in management of premature labour.

This not with standing, the study had a few limitations. small sample size so it is recommended to conduct another study with large sample size. Confidently our results will inspire other groups to publish their findings of large sample size with obviously agreed-upon, and re-producible, protocols and comprehensive following-up that will complement the data offered here. We as well hope that international collaborations will be setup to examine these therapies in satisfactorily powered

randomized trials, concerning both low- and high-risk females.

Either vaginal progesterone or cerclage is similarly efficient for prevention PTB in cases with a high risk of PTL (singleton pregnancy, a sonographic short cervical length <2.5cm in the 2 nd trimester, and a history of preceding s-PTB) and in improving the composite perinatal morbidities and mortalities. Selection of the best intervention needs to consider opposing conditions, cost, and case/clinician favorites.

Conclusion:

The vaginal progesterone is operative as cervical cerclage in avoidance of pre-mature labour but its usage is better in clinical as it's noninvasive method and lesser cost.

Recommendations:

More studies on larger sample size to highlight our findings, more cases, lengthier following-up, and multi-center practice are all essential to precisely find out the function of cervical cerclage and progesterone for prevention of pre-term labour in cases with history of pre-term labour, cases at PTL risk must be stimulated to contribute in investigations on the utility of progesterone in dropping the risks of PTL. Females must be knowledge able about the deficiency of accessible data for many newborn outcomes and about the deficiency of comparative data on dosing and route of administrations. Females with short cervix must be knowledgeable of the single large RCT viewing the advantage of progesterone in avoiding PTL.

Conflict of interest: No conflicts of interest.

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دراسة مقارنة بين البروجسترون وعملية ربط عنق الرحم فى السيدات اللآتى لديهن تاريخ مرضى للولادة المبكرة

الخلفية: العلمية لا تزال آليات الولادة المبكرة غير واضحة. يمكن أن يرتبط إما بتنشيط سابق لأوانه لعملية الانقباض الفسيولوجية أو بعامل مرضى مسؤول عن تقلصات الرحم، مما يؤدى إلى الولادة المبكرة.

تطويق عنق الرحم هو إجراء جراحى معروف يتم إجراؤه أثناء الحمل. يتضمن وضع خيط (غرزة) حول عنق الرحم، بهدف توفير الدعم الميكانيكى لعنق الرحم وبالتالى تقليل خطر الولادة المبكرة. لا تزال فعالية وسلامة هذا الإجراء موضع خلاف.

لطالما اعتبر البروجسترون من العوامل المهمة فى الحفاظ على هدوء الرحم وقد استخدم على نطاق واسع فى الوقاية الأولية والثانوية من الولادة المبكرة. لذلك اخترنا هذا العامل الدوائى كعقار فعال لدراستنا.

الهدف من الدراسة: تهدف الدراسة إلى المقارنة بين تطويق عنق الرحم والبروجسترون للوقاية من الولادة المبكرة عند النساء اللواتى لديهن تاريخ من الولادة المبكرة.

المرضى وطرق البحث: هذه الدراسة عبارة عن تجربة عشوائية مضبوطة، أجريت فى قسم أمراض النساء والولادة بمستشفى الحسين بكلية طب الأزهر، على ٤٠٠ أنثى، من مارس ٢٠٢٠ حتى مارس ٢٠٢١.

أظهرت النتائج الرئيسية للدراسة ما يلى: كان هناك فرق ذو دلالة إحصائية بين المجموعات المدروسة فيما يتعلق بتاريخ الإجهاض، ولا يوجد فرق كبير بين المجموعتين المدروستين فيما يتعلق بالتاريخ الكامل للمرضى. لم يكن هناك فرق معنوى بين المجموعتين المدروستين حسب الزيارة الأولى فيما يتعلق بعمر الحمل وطول عنق الرحم. لم يكن هناك فرق معنوى بين المجموعتين المدروستين فيما يتعلق بالفحص الميكروبيولوجى البولى التناسلى. كان هناك فرق معنوى بين المجموعتين المدروستين وفقاً للولادة الأولى فيما يتعلق بمتوسط عمر الحمل عند الولادة. لم يكن هناك فرق معنوى بين المجموعتين المدروستين تبعاً للنتيجة الثانوية.

بناء على نتائجنا، نوصى بإجراء مزيد من الدراسات على المرضى الأكبر حجماً وفترة المتابعة الأطول للتأكيد على استنتاجنا.

النتائج: تم العثور على تغيير كبير بين مجموعات الدراسة وفقاً لنتيجة 1ry فيما يتعلق بمتوسط GA عند الولادة.

الاستنتاج: بروجسترون المهبلى ناجح كتطويق عنق الرحم فى منع المخاض قبل النضج ولكن استخدامه أفضل من الناحية السريرية لأنه طريقة غير باضعة واقتصادية.