ORIGINAL ARTICLE

Cervical Cerclage versus Progesterone for Preventing Preterm Birth and Their Outcome in Patients with History of Preterm Labor

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Abstract

Background: ***An enormous public health burden has resulted from preterm delivery, which is still a major contributor to the worldwide waste of human resources in the form of premature infants.***

Objective: ***In order to determine whether the use of progesterone injections once weekly or the implantation of a preventative cervical cerclage increases the duration of a singleton pregnancy in women who are at high risk of miscarriage due to a history of complications, an ultrasound finding of a "short cervix," or other physical examination findings.***

Methods: ***Using inclusion and exclusion criteria, a prospective randomized controlled comparative study involving 100 pregnant women with a history of preterm labor was carried out at tertiary care hospitals in the UAE from June 2022 to April 2024. The hospitals in question were Al-Hussein University Hospital, Sayed Galal University Hospital, and Sheikh Zayed Hospital.***

Results: ***There is a statistically significant distinction among the groups when it comes to abortion history, but no difference when it comes to patients' comprehensive medical histories or the first visit when it comes to GA and CL. In terms of the first outcome, specifically the Mean GA at delivery, a statistically significant difference was found between the two groups.***

Conclusion: ***In high-risk pregnant women with a singleton, a history of spontaneous preterm birth, or a sonographic short cervix during the middle trimester, intramuscular progesterone therapy was more effective than cervical Cerclage in preventing premature delivery and enhancing perinatal outcomes. A non-invasive and straightforward approach, intramuscular 17a-hydroxyprogesterone caproate spares patients and doctors the agony and complications of anesthesia while also saving time and money compared to cervical Cerclage.***

Keywords: Preterm Birth; Cervical Cerclage; IM Progesterone

1. Introduction

According to the World Health Organization(WHO), a baby is considered preterm if it is born before the mother reaches 37 weeks of gestation or less than 259 days after her last menstrual cycle.[1] In 2010, there were around 135 million live births globally; however, 14.9 million of these newborns were born prematurely, giving the preterm delivery rate 11.1%, according to the most recent figures from the World Health Organization. Sixty percent of premature births occur in Asia and Africa combined; 12.8% occur in sub-Saharan Africa, and 13.5% in Asia.[2]

A major contributor to the worldwide waste of human resource potential in the newborns that make it through the first trimester is preterm delivery, which has created a heavy public health burden. Preterm births account for the largest proportion of newborn mortality, accounting for as much as 35% of the over 3 million deaths that occur each year on a global scale. Although pneumonia is the leading cause of mortality among children under five, premature delivery ranks second.[3]

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The structural narrowing and dilation of the cervix that can occur too early during pregnancy might cause miscarriage or premature delivery. "Cervical insufficiency" is the medical term used to describe the condition in which the uterus does not contract.[4]

When the cervix is unable to maintain a gestational sac within the uterus until delivery, this condition is known as cervical insufficiency. Consistent episodes of miscarriage in the second trimester of pregnancy are a hallmark of cervical insufficiency. These episodes are characterized clinically by painless cervix dilatation, bulging, rupture of fetal membranes, and expulsion of usually live fetus or fetuses, with minimal to no uterine activity.[5]

A surgical procedure called cervical Cerclage is used to suture the cervical neck of a pregnant woman. Several signs and symptoms necessitate the placement of cerclages during pregnancy. One option is to implant cervical Cerclage as an emergency procedure when a woman is physically threatened with abortion and presents to the hospital. Another option is to prearrange the procedure based on the patient's medical history or if a transvaginal ultrasound reveals that the cervical length is too short. Women who have experienced premature birth in the past and have a cervix that is shorter than 25mm, or who have cervical insufficiency either historically or now, may be eligible for this procedure.[6]

A sex steroid called progesterone is naturally created by the corpus luteum and the placenta during the time a woman is in her second or third trimester of pregnancy. Today, the mainstay in the fight against preterm births is progestogens, which are substances with an activity similar to progesterone.[7]

Epiprogesterone 17-α-hydroxy. It is a synthetic progestogen called caproate. Instead of being created by the human body, the "caproate molecule" is synthesized in a lab by adding it to 17-α-hydroxyprogesterone. By incorporating the caproate molecule, the drug's half-life is extended. This process alters the drug's structure, which in turn changes its pharmacological or physiological effects.[8]

Even though 17-alpha hydroxyprogesterone caproate is given as a preventative measure, recurrent preterm births can still occur in up to 30% of recipients who do not respond to 17-α-hydroxyprogesterone.[9, 10]

The purpose of this study is to determine whether women who are at high risk of miscarriage due to a history of complications, an ultrasound diagnosis of a "short cervix," or a physical exam can benefit from progesterone weekly injections or preventative cervical cerclage insertion in order to prolong the duration of a single pregnancy.

2. Patients and methods

From June 2022 through April 2024, a total of one hundred pregnant women with a history of preterm labor participated in this prospective randomized controlled comparative study. This study was performed at Sheikh Zayed hospital and El-Hussein and El-Sayed Galal University hospitals. The study was approved by the ethical committee and all patients provided written consent.

Inclusion criteria:

Women who are under the age of 40 and above the age of 20 who are carrying a single live fetus, experiencing premature labor(characterized as labor that begins between 28 and 34 weeks gestation) at least once Whole cell membrane Included at 12-weeks of gestational age, Women who don't smoke or drink Most people's body mass index falls between 20 and 25. Unintentional pregnancies or those induced by ovulation stimulants(ART-free), Women who have not been previously diagnosed with uterine abnormalities through HSG, no prior experience with uterine scarring(such as a CS or myomectomy), no history of hypertension, diabetes, or ablative or excisional cervix operations.

Exclusion criteria:

Birth defects found in the developing baby during the follow-up Obstetric myoma Membrane rupture during follow-up, polyhydramnios, During the follow-up, a placenta previa was detected. During the follow-up, an accidental bleeding occurs. Intrauterine Fetal Defects(IUFD), Gestational Diabetes Mellitus(DM) identified during pregnancy follow-up, and Pre-Eclampsia Diagnosis(UPS or albumin in urine).

Mode of delivery:

Either vaginal delivery or cesarean section.

Type of cerculage:

Cervical cerculage 'McDonald's operation'

Sample size justification:

MedCalc® version 12.3.0.0 program "Ostend, Belgium" was used for calculations of sample size, statistical calculator based on 95% confidence interval and power of the study 80% with α error 5%, According to Galal et al.[11] 2 groups were selected each group was 30-patients, group A received cidulot depot 250 IM weekly starting at 20 weeks and group-B cervical cerclage was done at 13-14 weeks, showed that preterm labour (<37 weeks=11 versus 20 in group-B) with the percent 36.6% versus 66.6% in group-B, So it can be relied upon in this study, based on this assumption, sample size was calculated according to these values produced a minimal samples size of 86 cases were enough to find such a difference. Assuming a drop-out ratio of 14%, the sample size

was 100 cases, subdivided into two groups: Group A: n=50 and Group B: n=50.

Study Procedures: All participants were submitted to the following:

A full detailed history focusing on the present and past history of the same condition, age, gravidity, Parity, BMI, and Drug history. In order to determine gestational age, which is expressed in weeks, the first day of the last menstrual cycle and the confirmation of the first trimester of pregnancy through ultrasound were used.

Examination: including Fetal Sex: female fetus and Fetal Weight

Investigations:

The following tests are performed during pregnancy: obstetric ultrasound to determine the number of fetuses, viability, gestational age, placental location, and cervical length; complete blood count(CBC), fasting blood sugar(FBS) at 24 weeks; complete urine analysis every 2 weeks; beginning at 24-weeks, a single course of dexamethasone 0.5 mg intramuscularly every 12 hours for 48 hours to improve fetal lung maturity; documentation of receiving tocolytic drugs or not; and the time of delivery.

Patients were randomly allocated to two groups:Our first group of 50-individuals received 17 OH progesterone(cidulot depot 250mg) intramuscularly once weekly beginning at 16–20 weeks gestational age and continuing until 36 weeks. Our second group of 50-patients had cervical Cerclage (McDonald's procedure) performed between 12 and 14-weeks.

Statistical analysis:

For numerical parametric variables, the analysis was carried out using SPSS for Windows v20.0. For numerical non-parametric variables, the range, median, and inter-quartile range were used. For categorical variables, the number and percentage were used. A 0.05 level of significance is used.

3. Results

Table 1. Comparison of the two groups under study based on patient histories.

FULL HISTORY OF PATIENTS	PROGESTERONE IM GROUP (N=50)	CERCLAGE GROUP (N=50)	TEST OF SIG.	P
AGE(YEARS)				
RANGE	22-37	21-38	0.220	0.826
MEAN±SD.	29.23±4.78	29.02±4.77		
BMI(KG/M²)				
RANGE	20.1-24.5	20.0-25	1.452	0.149
MEAN±SD.	23.79±1.55	23.31±1.75		
PARITY				
RANGE	1-4	1-4	0.582	0.386
MEDIAN(IQR)	2(1-3)	2(1-3)		
HISTORY OF ABORTION				
NO	36(72.0%)	29(58.0%)	4.261	0.039*
YES	14(28.0%)	21(42.0%)		

According to Table 1, there was a statistically significant distinction among the two groups under study in terms of the history of abortions(p-value p<0.05); however, there was no statistically significant distinction among the two groups in terms of the patients' complete medical histories(p-value p>0.05).

Table 2. Comparison of the two groups under study based on the first visit

1ST VISIT	PROGESTERONE IM GROUP (N=50)	CERCLAGE GROUP (N=50)	T	P
GA "WKS."				
RANGE	10-12	10-12	-	0.702
MEAN±SD.	10.99±0.81	11.05±0.75	0.384	
CL				
RANGE	18-21	18-21	-	0.543
MEAN±SD.	19.97±0.87	20.08±0.93	0.611	

According to the first visit, there was no statistically significant distinction among the two groups under study in terms of GA and CL, as indicated by the p-value(p>0.05) in Table (2).

Table 3. Comparison of the two groups under study based on extremely brief cervix visits

EXTREME SHORT CERVIX VISIT	PROGESTERONE IM GROUP (N=50)	CERCLAGE GROUP (N=50)	TEST OF SIG.	P-VALUE
GA "WKS."				
RANGE	15-26	15-26	0.416	0.678
MEAN±SD.	21.32±3.52	21.02±3.69		
CL				
NO MEASURABLE CERVIX	18(36.0%)	21(42.0%)	0.168	0.682
YES	32(64.0%)	29(58.0%)		
RANGE	2-12	3-10	0.827	0.4104
MEAN±SD.	6.57±2.12	6.20±2.35		

According to GA and severe short cervix visit with regard to CL, there was no statistically significant distinction among the two groups under study, as indicated by the p-value(p>0.05) in Table (3).

Table 4. Genitourinary microbiological screening comparison of the two groups under study

GENITOURINARY MICROBIOLOGICAL SCREENING	PROGESTERONE IM GROUP (N=50)	CERCLAGE GROUP (N=50)	X²	P
NO	28(56.0%)	26(52.0%)	0.0403	0.841
YES	22(44.0%)	24(48.0%)		
TRICHOMONAS	10(45.5%)	11(45.8%)	0.553	0.907
BACTERIAL VAGINOSIS	3(13.6%)	5(20.8%)		
URINARY TRACT INFECTION	6(27.3%)	5(20.8%)		
GC/CHLAMYDIA	3(13.6%)	3(12.5%)		

With a p-value of p>0.05, Table (4) demonstrates that there was no discernible difference in genitourinary microbiological screening between the two groups under study.

Table 5. Comparison of the two groups under study based on the results of 1ry

1RY OUTCOME	PROGESTERONE IM GROUP (N=50)	CERCLAGE GROUP (N=50)	T	P
MEAN GA AT DELIVERY				
RANGE	25-41	24-41	4.577	0.003*
MEAN±SD.	36.83±2.15	34.27±3.32		

According to the 1ry outcome regarding Mean GA at delivery, Table (5) demonstrates that there

was a statistically significant distinction between the two groups under study, with a p-value of less than 0.05.

Table 6. Comparison of the two groups under study based on the 2ry result.

2RY OUTCOME	PROGESTERONE IM GROUP (N=50)	CERCLAGE GROUP (N=50)	TEST OF SIG.	P-VALUE
APGAR 1 MIN				
RANGE	2-10	2-10	0.461	0.619
MEDIAN(IQR)	7(5-8)	7(4-8)		
APGAR 5 MIN				
RANGE	4-10	4-10	0.929	0.376
MEDIAN(IQR)	8(7-9)	8(7-9)		
NICU ADMISSION				
NO	27(54.0%)	23(46.0%)	0.360	0.548
YES	23(46.0%)	27(54.0%)		
LENGTH OF NICU STAY				
RANGE	2-49	1-47	-	0.346
MEAN±SD.	21.35±12.07	23.80±13.78	0.946	
STILLBIRTHS/NND				
NO	48(96.0%)	49(98.0%)	0.000	1.000
YES	2(4.0%)	1(2.0%)		

According to secondary outcomes regarding Apgar 1 and Apgar 5-minutes, NICU admission, length of NICU stay, and stillbirths/NDN, Table(6) demonstrates that there was no statistically significant distinction among the two groups under study, with a p-value of P>0.05.

4. Discussion

The results of the current study showed that there was a statistically significant distinction between the groups under study with respect to the history of abortion(p-value p<0.05); however, there was no statistically significant distinction between the two groups with respect to the full history of patients(p-value p>0.05); and there was no significant distinction between the two groups with respect to the GA and cervical length at the first visit(p>0.05).

These results are consistent with earlier research. Abdelsattar et al.,[12] compared the efficacy of using cervical Cerclage versus progesterone to prevent preterm labor in 120 pregnant women at high risk of preterm birth. The trial found that both groups fared significantly better in terms of reducing the risk of miscarriage, but no better in terms of maternal age, body mass index(BMI), or parity. Furthermore, there was no statistically significant change in GA or cervical length across the study groups based on the first visit.

This agreed with the study of Kindinger et al.,[13] that found that the mean pre-cerclage cervical length assessed by transvaginal ultrasonography was 29.28±5.54, and the mean post-cerclage cervical length was 31.68±4.21(p<0.001).

Among the two groups, we performed genitourinary microbiological screening. The findings of the screening showed that neither the Progesterone IM Group nor the Cerclage Group had any infections, with no statistically significant difference between the two groups (x^2=0.0403, p=0.841). Results showed that 44.0 percent of the Progesterone IM group and 48.0 percent of the Cerclage group had infections. The percentage of patients with Trichomonas was 45.5% in the Progesterone IM group and 45.8% in the Cerclage group(x^2=0.553, p=0.907). However, bacterial vaginosis was observed in 20.8% of the cervical group and 13.6% of the progesterone intramuscular group. In the Progesterone IM group, 27.3% of the patients were found to have an infection of the urinary tract, whereas in the Cerclage group. And lastly, 13.6% of the Progesterone IM group and 12.5% of the Cerclage group tested positive for GC/Chlamydia.

According to what we've discovered, Abdelsattar et al.,[12] turned shown that there was no discernible shift in genitourinary microbiological screening among the research groups.

Our study found that there was a statistically significant difference between the groups when it came to the gestational age(GA) at delivery. The Progesterone IM Group had an average GA at 36.83±2.15 weeks, while the Cerclage Group had an average GA at 34.27±3.32 weeks(t=4.577, p=0.003).

Both the Royal College of Obstetricians and Gynecologists in the United Kingdom and the American College of Obstetricians and Gynecologists suggest cervical Cerclage to women who have a history of spontaneous preterm birth(PTB) or who have a low cervical length. Cervical Cerclage is known to reduce the risk of PTB by around 20%. In order to prevent ascending infections, this method mechanically supports a weak cervix and aids in keeping the cervical mucous barrier intact.12 Progesterone therapy, on the other hand, has a number of advantages over cervical Cerclage, including being less intrusive, less time-consuming, less expensive, and requiring no anesthesia or its risks.[12]

While progesterone's exact function during pregnancy is still unknown, what is known is that it has a dual effect on the myometrium: first, it inhibits the replacement of estrogen receptors in the cytosol, which reduces estrogen's action, and second, it affects the uterine biosynthetic processes directly through its own cellular receptor. So, progesterone keeps the contractile capacity in check; rats and rabbits given the hormone show signs of tension in their electrically stimulated uteruses.[14]

However, Wood et al.,[15] 198 women did not receive 17P prior to the previous CL, but 211 women who underwent screening did receive it, as part of a retrospective cohort research. Whether patients were given 17P before their last cervical length or not had no effect on the shortest mid-trimester cervical length, according

to the study. Furthermore, there was almost no difference in the rates of cervical length shortening to less than 25mm across these categories. Despite the indications of Cerclage, 17P did not lengthen gestation in high-risk women who underwent cervical length screening. The opposite was true: patients who had 17P were, on average, one week ahead of schedule compared to those who didn't.

In agreement with our results, Abdelsattar et al.,[12] found that the average GA at delivery for the group receiving Cerclage was 35.52±5.33 weeks, while for the group receiving Vaginal Progesterone it was 34.17±4.31 weeks. The Cerclage group had a median GA at delivery of 38(34-40) weeks, while the Vaginal Progesterone group had a median GA of 34(31-38) weeks. Statistical analysis revealed a noteworthy distinction between the categories(t=2.786, p=0.006).

This is consistent with previous work performed by Abd Elaal et al study[16], because they found that the groups investigated had significantly different GA levels. The incidence of premature labor(defined as beginning before 34-weeks of gestation) was significantly lower in cerclage groups.

Recently, Ismail et al.,[17] compared the effectiveness of vaginal and intramuscular progesterone with cervical Cerclage in preventing preterm birth in 120-pregnant women with a history of preterm birth. The results showed that the cerclage group experienced a significantly increased cervical length from 1.877+0.41cm to 2.18+0.31cm, with a P-value of less than 0.001. Mean GA at delivery, however, did not differ significantly across the research groups(36.27+4.97) as opposed to 35.0+5.47.

Our study found no statistically significant distinction between the two groups in terms of foetal outcome when it came to secondary outcomes such as Apgar 1-minute, Apgar 5-minute, neonatal intensive care unit admission, length of neonatal intensive care unit stay, and stillbirths/NND(p-value>0.05).

In concordance with our findings, Abdelsattar et al.,[12] found that when it came to NICU admission and NICU stay time, there was no significant difference between the two groups.

Also, Ismail et al.,[17] found no statistically significant distinction in the rates of admission to the NICU between the two groups.

In addition, Abd Elaal et al.,[16] found no statistically significant difference in newborn morbidity between the cerclage and progesterone groups(t=0.041, p=1.000).

As regards neonatal outcome, Fahmy et al.,[18] found that 22 cases (19.8%) had overall morbidity and 5 cases (4.5%) had death. Five newborns(4.5%) died because they were born with an extremely low birth weight(<2500g). Three of the babies also died from sepsis, and two babies(1.8%) died because their gestational age was less than 30 weeks. In addition, compared to the progesterone group, the cerclage group had a considerably reduced number of newborns admitted to the NICU(P<0.001).

Also, compared to the progesterone groups, the cerclage group had a higher mean Apgar score(7.79 vs. 7.72). Statistical analysis revealed no statistically significant difference in Apgar scores between the progesterone and cerclage groups(P=0.809).

Patients in the vaginal progesterone or cervical cerclage groups did not have any major side effects. This could be because of the brief duration of the study, the small number of participants in the progesterone group, or the low daily dose of progesterone. To learn more about the long-term side effects, researchers continue to do follow-ups.

4. Conclusion

When compared to cervical Cerclage, intramuscular progesterone therapy had a more favorable effect on fetal outcome(NICU, Apgar score, Mortality, and Morbidity), as well as on improving perinatal outcomes for high-risk women who were carrying a singleton, had a history of spontaneous preterm births, or had a sonographically short cervix during the mid-trimester

A non-invasive and straightforward approach, intramuscular 17α-hydroxyprogesterone caproate spares patients and doctors the agony and complications of anesthesia while also saving time and money compared to cervical Cerclage.

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