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# Study of the Effectiveness of Cervical Cerclage versus Progesterone in Preterm Labor. A Comparative Clinical Trial

Anwer Ezzat Ismael<sup>1</sup>, Walid Abdallah<sup>1</sup>, Hudi Alshareef Thabit<sup>2\*</sup>, Wafaa Mohamed Diab<sup>1</sup>

<sup>1</sup>Department of Obstetrics and Gynecology, Faculty of Medicine, Zagazig University, Egypt.

<sup>2</sup>MBCCH, Faculty of Medicine, Benghazi University, Libya.

**Corresponding author:** Hudi Alshareef Thabit

#### E-mail:

hudathabit67@gmail.com

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### ABSTRACT

**Background:** Patients with a singleton pregnancy, a history of spontaneous preterm delivery, and a short cervix may benefit from preterm birth prevention strategies that involve vaginal progesterone treatment as well as the placement of a cervical cerclage. Clinical use of vaginal progesterone is preferred over cervical cerclage because it is less expensive and does not require invasive surgery to prevent premature labor. This study aims at comparing the efficacy of using both vaginal and intramuscular progesterone versus cervical cerclage for prevention of the preterm birth among females with previous history of preterm birth.

**Methods:** One hundred and twenty pregnant females with an increased risk of preterm labor (assessed by a previous preterm birth (PTB) or transvaginal ultrasound (TVUS) findings of a shortened cervix which is less than 25 mm participated in this randomized controlled study at the Obstetrics and Gynecological Department of Zagazig University Hospital. Group A: 62 pregnant women had progesterone therapy in the form of vaginal suppositories 400mg twice per day and intramuscular long-acting progesterone per week at 13 weeks to 37 weeks gestational age. Group B: (Cervical Cerclage group) 58 pregnant women who had Cervical Cerclage at 13 weeks' gestation without progesterone. All data regarding the timing of labor onset, along with maternal and neonatal complications were documented.

**Results:** Cervical length is significantly increased in the cerclage group from 1.877+.41 cm to 2.18+.31 cm with P value <0.001 after doing the cerclage. When compared to the cervical cerclage, progesterone use yielded similar effects with non-statistically significant differences in terms of method of delivery, pregnancy fate, and neonatal outcomes.

**Conclusion:** The progesterone is successful as cervical cerclage in preventing preterm labor, but its usage could be better in clinical as it's noninvasive method and economic.

Keywords: Cervical Cerclage, Progesterone, Preterm Labor.

### **INTRODUCTION**

Preterm birth, often known as preterm labor, occurs when a baby is delivered before 37 weeks of gestation [1]. Many nations, especially those with lesser incomes, do not have enough statistics to determine the true prevalence of preterm delivery. About 15 million newborns are delivered prematurely every year, or about 11 % of all births, according to estimates based on data from 184 countries [2]. Births that occur before 37 weeks of pregnancy are considered preterm as defined by the World Health Organization. Extreme preterm birth occurs before 28 weeks of pregnancy, very preterm birth occurs between 28 and 32 weeks, and moderate to late preterm delivery occurs between 34 and 37 weeks. Medically unnecessary induction of labor or elective cesarean sections are two common causes of preterm birth that a healthcare provider may choose to facilitate. While it is no longer considered preterm to have a baby born after 37 weeks of pregnancy, experts advise waiting until 39 weeks are reached to give birth for the best possible health outcomes for both mother and child [3].

Many preterm births have no clear cause. Nonetheless, numerous things put women in danger, including diabetes, hypertension, repeated pregnancies, a high BMI, vaginal infections, smoking, and psychological stress [4]. Recurrent spontaneous preterm birth is also linked to having a history of preterm birth. One of the strongest and most accurate indicators of preterm birth in asymptomatic females with a singleton or twin mid-trimester gestation is а transvaginal sonographic cervical length of equal to or less than 25mm [5].

Preterm cervix shortening and opening can cause a late abortion or preterm delivery, a procedure known as cervical cerclage (also known as a cervical stitch) is used to treat the condition. If a woman has already had one or more late abortions, the intervention is usually performed in the first or second trimester of pregnancy. Cerclage, the French term for "hoop," describes the metal hoop that surrounds a tub [6]. For women with extremely short cervixes and uncomplicated pregnancies, using a cerclage was more beneficial than using vaginal progesterone, according to a recent study [7]. However, practical use of vaginal progesterone is preferred due to its noninvasive nature and lower cost than cervical cerclage for the prevention of premature labor [8].

Therefore, we did this work comparing the efficacy of vaginal and intramuscular progesterone versus cervical cerclage for prevention of the preterm birth among females with previous history of preterm birth.

### METHODS

One hundred and twenty pregnant females with an increased risk of preterm labor (assessed by a previous preterm birth (PTB) or transvaginal ultrasound (TVUS) findings of a shortened cervix which is less than 25 mm participated in this randomized controlled study at the Obstetrics and Gynecological Department of Zagazig University Hospital in duration from 1st of October 2022 till end of May 2023.

We included females aged from 18 to 34 years with Gestational age ranging from 13 to 24 weeks with ultrasound confirmation and an exact date based on the final day of a woman's period, with a history of 2 or more than spontaneous preterm birth or short cervix (less than 25mm), on the US at 13 to 22 weeks GA or who had single tone pregnancy.

Females who had any of the following were excluded from the study: multiple pregnancies, fetal abnormalities diagnosed by ultrasound at firsttrimester scan (13weeks), clinical evidence suggesting chorioamnionitis, preterm premature rupture of membranes, uterine malformation diagnosed by ultrasonography, and those who had rescue cerclage.

After institutional review board approval of IRB (#9849/21-9-2022), written informed consent was obtained from all participants. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

The selected women were randomized into two groups, Group A (progesterone group): 70 Pregnant females treated with progesterone therapy in the form of vaginal suppositories 400mg (Prontogest) twice per day and intramuscular long-acting progesterone per week at 13 weeks till 37 weeks' gestational age or the date of preterm birth as guideline no 398 done by Jain et al [9], and Group B (Cervical Cerclage group) included 70 pregnant females treated with cervical cerclage at 13 weeks' gestation without progesterone.

All the participating pregnant women were subjected to complete history taking (medical and obstetric history) including personal data, and obstetric history (gravidity, birth defects, abortions, and parity previous birthing methods, the first day of the last menstrual cycle, urinary symptoms (dysuria, frequency, urgency), and vaginal discharge, the gestational age upon diagnosis of the short cervix, the onset, length, and frequency of labor pains, (color as well as itching).

General. abdominal as well and local examination was performed for the detection of vital signs to exclude chorioamnionitis. Routine laboratory investigations for pregnant women including complete blood count (CBC), random blood sugar, liver, thyroid, and kidney function obtained. Transabdominal were ultrasound examination for estimation of the gestational age. fetal growth as well as the fetal biophysical profile during the antenatal follow-up and targeted, transvaginal ultrasonographic scan for measurement of cervical length (stated in mm and derived from a sagittal section measurement of the distance between the external and internal os [10] and exclusion of any funneling or herniation of amniotic sac through the cervix.

The McDonald technique was used for all cerclage procedures during the study period, each one was finished with a single piece of 5-mm Mersilene tape, polyester fiber suture on a 48-mm, tapered-point CTX needle. The needle's curvature fraction was half a circle, and the curvature fraction was calculated by dividing the length of the needle by the curvature of the tape. The McDonald technique involves tying an anterior suture around the cervix like a purse string. With the McDonald technique, para-cervical tissue is not dissected. After a diagnosis of an extremely short cervix, females in the cerclage group were admitted for observation, anti-inflammatory medication with indomethacin, intravenous (IV) hydration and IV antibiotics the night before the surgery. The spinal anesthetic was used for the surgeries. Before surgery, women were given a loading dose of indomethacin (50 mg) and cefazolin (2.0 g). Cefazolin 2 g IV piggyback was given for 24 hours, and they were also kept on indomethacin 25 mg every 6 hours for 48 hours after surgery. If labor progressed, a major membrane rupture occurred, or chorioamnionitis was present, the knots of the cerclage procedure were cut at around 36 weeks of gestation (figures 1, 2 and 3).

Vaginal suppositories (Prontogest) 400mg twice per day and intramuscular progesterone (long acting) per week were administered at 13 weeks till 37 weeks gestational age, the date of preterm birth or clinical chorioamnionitis.

The studied cases were interviewed every two weeks. Qualified sonographers used manufacturing standard methods to determine cervical extent. After the patient's bladder was emptied, the smallest amount of force was applied to successfully obtain mid-sagittal views of the cervix. Participants were instructed to limit their activity levels for the duration of their pregnancies. At 28 weeks of pregnancy, they were administered preventive steroids (Dexamethasone, 12mg intramuscularly, twice, 24 hours apart) to aid in fetal lung maturation.

Participants in the progesterone group were asked about any negative reactions or symptoms they had after receiving progesterone (either vaginally or intramuscularly) during the follow-up appointments. In addition, those in the cerclage group were queried on the occurrence of any adverse effects. Ultrasound measurements of the cervix and the uterus were taken transvaginally and transabdominally every four weeks from the time of enrollment until 37 weeks.

Patients who were diagnosed with PTL during the trial period were allowed to receive treatment and remain in the study until delivery as long as rupture of the membranes did not occur. Hospitalization, hydration, bed rest, brief tocolysis, and steroids were all part of the standard procedure for treating PTL. The time of labor beginning, as well as any complications experienced by the mother or newborn, were recorded at the time of delivery.

Primary outcomes included births that occur before 37 weeks and the average number of days a baby stays in the neonatal intensive care unit (NICU).

Secondary outcomes: the admission of a newborn to the intensive care unit is part of the overall neonatal morbidity rate.

### Statistical analysis:

IBM's statistical analysis software, SPSS, version 20.0, was used to process the data. Qualitative data was represented with numerical and percentage-based language. Quantitative information was summarized by means and standard deviations.

#### RESULTS

Maternal age, gestational age, parity, as well as body mass index at first examination show no statistically significant differences between the two groups (Table 1). Neither group differs significantly from the other concerning the risk variables of spontaneous PTB, including abortion and PTB before 32 weeks of gestation in the past (Table 2).

Cervical length is significantly increased in the cerclage group from 1.877+.41 cm to 2.18+.31 cm with P value <0.001 after doing the cerclage (Table 3 and figure 4). In terms of pregnancy fate and delivery methods, no significant differences were found between both groups (Table 4). When comparing newborn outcomes between the two groups, no statistically significant differences were found (Table 5).

**Table 1:** Comparison between cerclage and progesterone groups as regard patient characteristics

	Cerclage group N=58	progesterone group N=62	Test of significance	Value of test	P Value
Age					
(mean <u>+</u> SD)	30 <u>+</u> 3.93	29 <u>+</u> 5.64	t test	1.11	0.26 (NS)
Parity					
(NO %)					0.149 ( <b>NS</b> )
Nullipara	17 29.3%	26 41.9%	$X^2$	2.08	
Multipara	41 70.7%	36 58.1%			
Gestational age	13.3 <u>+</u> 2.78	13.6 <u>+</u> 1.72	t test	0.715	0.47
at start of					(NS)
examination					
(mean <u>+</u> SD)					
BMI	25.5 <u>+</u> 3.22	25.88 <u>+</u> 2.26	t test	0.75	0.4
(mean <u>+</u> SD)					(NS)

BMI: Body mass index

**Table 2:** Comparison between cerclage and progesterone groups as regard risk factors for spontaneous preterm birth

Risk factors	Cerclage N=58	group	progesterone group N=62		Test of significance	Value of test	P Value
	NO	%	NO	%			
Previous abortion	16	27.5%	19	30.4%	Chi- Square	0.14	0.7 ( <b>NS</b> )
Previous PTB<32w	30	51.7%	40	64.5%	Chi- Square	2.02	0.15 (NS)
Previous PTB<36w	28	48.3%	22	35.5%	Chi- Square	2.02	0.15 (NS)
Digital examination							
Closed	44	75.8%	50	80.6%	Chi- Square	0.4	0.52
Opened	14	24.2%	12	19.4%			( <b>NS</b> )
Sonographic criteria							
Cervical length							
(mean <u>+</u> SD)	1.877 <u>+</u> .41	l	1.986 <u>+</u> .141		Chi- Square	4.00	527 ( <b>NS</b> )
Funneling	17	29.3%	19	30.4%	Chi- Square	0.03	0.87 (NS)
Previous cerclage	16	27.5%	19	30.4%	Chi- Square	0.14	0.7 (NS)
UTI	17	29.3%	20	32.2%	Chi- Square	0.12	0.72 (NS)

PTB; Preterm birth UTI: Urinary tract infection

Table 3: Comparison between sonographic examination of the cervix before and after cerclage

	Pre cerclage	Post cerclage	Test of significance	Value of test	P Value
Cervical length (Cm)					
(mean <u>+</u> SD)	1.877 <u>+</u> .41	2.18 <u>+</u> .31	Paired t test	10.352	.000 ( <b>HS</b> )
short cervix<2.5cm					
N=44	2.05 <u>+</u> 0.19	2.31 <u>+</u> 0.19	Paired t test	10.5	0.000 ( <b>HS</b> )
(mean <u>+</u> SD)					
Extremely short cervix<1.5cm					
N=14	1.17 <u>+</u> 0.27	1.69 <u>+</u> 0.17	Paired t test	8.2	0.000 ( <b>HS</b> )

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(mean <u>+</u> SD)					
Funneling (mm)					
(NO %)	17 29.3%	12 20.6%	McNemar	1.11	0.29 (NS)
Internal os (mm)					
(mean <u>+</u> SD)	6.7 <u>+</u> 1.5	6.1 <u>+</u> 1.3	Paired t test	7.2	.0243 <b>(S</b> )

**Table 4:** Comparison between cerclage and progesterone groups as regard fate of pregnancy, mode of delivery

	Cerclage N=58	group			Test of significance	Value of test	P Value
	NO	%	NO	%			
PTB<32w	3	5.1%	3	4.8%	Fisher's		0.62 (NS)
PTB<36w	8	13.7%	7	11.3%	$\chi^2$	0.17	0.67 (NS)
Abortion	3	5.1%	2	3.2%	Fisher's		0.46 (NS)
FT	44	75.8%	50	80.6%	Chi-Square	0.4	0.52 (NS)
Vaginal	44	75.8%	50	80.6%	Chi- Square	0.4	0.52
C.S	14	24.2%	12	19.4%			(NS)

Table 5: Comparison between cerclage and progesterone groups as regard neonatal outcome

	Cerclage group N=58	progesterone group N=62	Test of significance	Value of test	P Value
Gestational age at delivery (mean <u>+</u> SD)	36.27 <u>+</u> 4.97	35.0 <u>+</u> 5.47	t test	1.32	0.18 (NS)
Birth weight (mean <u>+</u> SD)	2725.0 <u>+</u> 502.65	2518.9 <u>+</u> 656.94	t test	1.92	0.057 ( <b>NS</b> )
ICU admition (NO %)	8 13.79%	6 9.67%	$\chi^2$	0.49	0.48 (NS)
Neonatal mortality (NO %)	2 3.4%	2 3.2%	Fisher's		0.66 (NS)
Neonatal morbidity (NO %)	4 6.89%	5 8.1%	Fisher's		0.54 (NS)
Norma; Neonatal (NO %)	44 75.88%	49 79.0%	$\chi^2$	0.17	0.67 (NS)

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**Figure 1:** 1st step of cervical cerclage, identification of the uterine cervix and grasping the upper and lower lips with ring forceps.



Figure 2: 2nd step of cervical cerclage, taking 4bites with cervix set tape, taking caution to avoid Paracervical vessels.

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### DISCUSSION

Live birth before 37 weeks of pregnancy is considered preterm labor. A healthcare provider can induce labor or perform an elective cesarean section to cause preterm labor [3]. There were 2.6 million newborn fatalities in 2016, with complications during labor accounting for 35 percent of these deaths worldwide [12].

Women carrying a singleton, who have a history of spontaneous preterm delivery, and who have a sonographically short cervix at the midpoint of their pregnancy benefit equally from progesterone and cerclage for preventing premature labor and enhancing perinatal outcomes. Adverse events, the cost-effectiveness of therapies, and patient/doctor preferences will all play a role in determining the course of treatment [4].

Maternal age, gestational age, parity, as well as body mass index were not significantly different between the two groups at the baseline. In accordance with our findings, Abd Elzaher et al [12] found no statistically significant differences in age, BMI, or parity across the groups they analyzed. Contrary to our results, Abd Elaal et al [13] found statistically significant differences in GA between the research groups (p<0.001).

In our study regarding cervical length measurement, it was relatively shorter with a mean length of 1.877 mm  $\pm$  4.1 SD before cerclage these findings agree with the findings of many authors who found that cervical shortening increases the risk of cervical incompetence and then preterm labor that could follow.

Also, NICE [14] reported that when a cervical length measurement  $\geq$ 35 mm in the current pregnancy is observed in a patient with a history of abortion before 26 weeks, the cause of prior PTL or mid trimestric abortion is something other than short cervix (e.g. fetal anomaly, abruptio placentae, trauma, second trimester bleeding or acute pyelonephritis).

In this study, the change in cervical length measurement after cerclage showed an increase in cervical length post cerclage with a statistically significant difference in the cerclage group. the same is also noted in the subgroups of short cervix<2.5cm and extremely short cervix <1.5cm. This agrees with the study of Kindinger et al [15] that found that the mean pre-cerclage cervical length assessed by transvaginal ultrasonography, was  $29.28\pm5.54$ , and the mean post-cerclage cervical length was  $31.68\pm4.21$  (p<0.001). Also, the study of Karaen et al [16] as well as Vintzileos and

Visser [17] found that therapeutic Mcdonald cerclage results in a significant cervical lengthening increase as measured by transvaginal ultrasonography.

In our study, as regards the fate of pregnancy there were no statistically significant differences in the rates of PTB < 32 weeks, PTL <36 weeks, full term, and abortion.

Also, Conde-Agudelo et al [18] performed a meta-analysis of 4 properly conducted trials that included a total of 305 cerclage patients and 302 progesterone and found that both did not prevent PTL in women with a shortened cervical length. Also, the study of Hassan et al [19] found that progesterone among females with a short cervix did not reduce the rate of spontaneous PTL.

However, these results disagree with the study of Heath et al [20]. that found that the cerclage group had a far lower rate of spontaneous birth before 32 weeks of gestation (5% vs. 52%) than the progesterone group.

Our study found that mean birth weight (2725.0 + 502.65) in the cerclage group versus (2518.9 + 656.94 SD) in the progesterone group respectively, indicating that no statistically significant, there were no differences in neonatal morbidity, neonatal mortality, and ICU admission in cerclage group versus progesterone group. and this was following Roeckner et al [21] who noted that there was no evidence that cerclage was a major contributor to adverse fetal outcomes.

Disagree with our study, Newman et al [22] found that the cerclage group had a significantly higher birth weight than the progesterone group (p=.004).

We found no statistically significant differences in mean GA at delivery between the study groups. (36.27+4.97 versus 35.0+5.47)

In agreement with our findings, AbdElzaher et al [12] revealed that the cervical cerclage group had a mean GA of 36+3 weeks at birth, while the progesterone group had a GA of 35+3 weeks, when comparing the birth GA of the different groups, we could not find any statistically significant differences.

Our findings were not in agreement with Abd Elaal et al study [13], since they detected significant changes in GA between the groups studied. Cerclage groups had a markedly lower rate of preterm labor of less than 34 weeks of gestation.

No statistically significant difference in NICU admission rates was seen between the two groups, as assessed in our study, which is consistent with those shown by Abd Elzaher et al [12].

In accordance with our results, Abd Elaal et al [13] found that using progesterone and a cervical cerclage at the same time greatly decreased the risk of preterm labor and was significantly linked to improved perinatal outcomes (mean Apgar score, mean birth weight, as well as lower NICU admission rates were significantly higher).

Abd Elaal et al [13] showed that comparing the progesterone and cerclage groups, there was no significant difference in neonatal morbidity (t=0.041, p=1.000), compared to the progesterone and cerclage groups, the combination group had considerably lower rates of newborn morbidity (F=6.047, p=0.003).

In our study, females who had a history of preterm labor before the 34th week of GA were significantly less likely to have a baby prematurely if they received either intervention, in the same line, Berghella et al [18] observed a significant reduction in PTL in both the progesterone and cerclage groups, compared to the placebo/no intervention group and the no cerclage group, for the prevention of premature delivery.

In addition to contrasting with our findings, among 677 women, Rode et al [23] did not find any statistically significant difference in the use of progesterone 200mg beginning at 20-24 weeks and continuing until 34 weeks, compared to the use of placebo.

The current study results showed that the likelihood of having a premature birth was greatly lowered with either progesterone or cerclage. The results we obtained were like those found by Alfirevic et al [6]. Considering cases of singleton pregnancies with a short cervical length as indicated by TVS and a history of preterm delivery, their findings revealed that the currently available therapies (progesterone and cerclage) are equally effective.

There was no statistically significant difference between cerclage and progesterone use. There are numerous benefits of utilizing progesterone: It's a simple, painless, and noninvasive method, anesthesia, pain, and complications are not experienced by the patients, utilizing progesterone saves a great time for doctors as well as patients, and finally, compared to cervical cerclage, it's more affordable [4].

Thus, in cases with a high risk of preterm labor, cervical length of less than 2.5 cm in the second trimester by sonography, and a history of prior spontaneous preterm birth; either vaginal progesterone or cerclage is equally efficient for prevention of preterm labor and in improving the perinatal morbidities and mortalities. Conditions, cost, and case/clinician preferences all play a role in making the optimum intervention choice [4].

### CONCLUSION

The progesterone is successful as cervical cerclage in preventing preterm labor, but its usage could be better in clinical as it's noninvasive method and economic.

**Study limitations:** The current study was done in one center on a relatively small sample size, Cervical cerclage and progesterone for the prevention of preterm labor require additional research, including longer follow-up and multicenter practice.

**Conflict of interest:** Non to declare.

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#### APPENDIX



Figure 3: 3rd step of cervical cerclage: the tape is then ligated and cut.

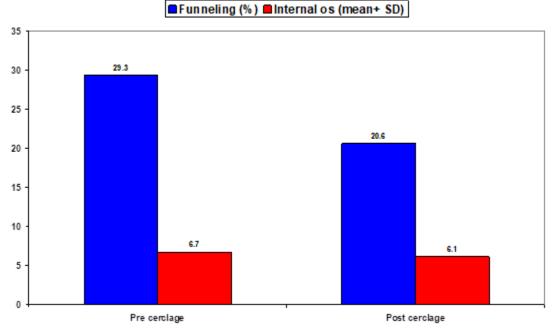


Figure 4: 3rd step of cervical cerclage: the tape is then ligated and cut

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