

# Gestational and Neonatal Outcomes of a New Three-Step Procedure for Emergency Cerclage

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## Research Article

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# Abstract

**Background:** The objective of our study was to evaluate a new technique for emergency cerclage performed in a cohort of patients with cervical incompetence in the second trimester of pregnancy. Design: Prospective observational study in Regional university hospital. Population: Twenty-four pregnant women at 15 to 24 weeks gestation with cervical dilatation and bursa prolapse

**Methods:** Depending on the clinical condition of the patient, a new emergency cerclage was performed with a technical consisting of a first cerclage in a purse-string and a second occlusive cerclage located inferiorly to the first one. The technique ended with the performance of a cervical cleisis, depending on the presence or absence of prolapse of the vaginal bag. This procedure is called the Three-Step Procedure for Emergency Cerclage (TSEC). Outcome measure: The latency period to delivery

**Results:** Latency from procedure to delivery, pregnancy duration, infant birth weight, rate of premature amniorrhexis. The mean latency from procedure to delivery was 14 weeks + 6 days, the mean weight of the newborns was 2550 g, and the mean age at delivery was 35 weeks. The neonatal survival rate was 95.8%. The rate of premature amniorrhexis <34 weeks was 8.3% (two cases) with successful perinatal outcomes. There were significant differences ( $p < 0.05$ ) between groups when we sub-divided the cohort in terms of history of conization, preterm delivery, and bursal prolapse. The multivariate regression model showed that best predictor variables for latency to delivery were cervical dilatation at diagnosis, the use of the three step cerclage, cervical length after the procedure, and gestational age at diagnosis.

**Conclusion:** The excellent results obtained with the TSEC procedure in terms of the latency from procedure to delivery, gestational age at delivery, birth weight, and few reported complications, highlight the importance of collecting new data on this promising novel procedure.

## Background

Preterm delivery accounts for 70–80% of neonatal mortality, and intensive care, support after hospital discharge, and care during childhood impose a great cost on health systems in developed countries (1,2,3,4). Women who present with cervical shortening are considered at high risk of preterm delivery (5). Although the incidence of cervical insufficiency is difficult to establish due to the lack of clear diagnostic criteria, this pathology could be responsible for approximately 10–25% of gestational losses in the second trimester (6).

Cervical insufficiency is defined by an open cervical ostium and bulging amniotic membranes, without pain or other symptoms of threatened abortion (external bleeding or uterine contractions) (1). Multiple observational studies have highlighted the efficacy of emergency cerclage in these patients, evidenced by prolonged pregnancy duration. Both a bibliographic review published by Namouz (7) and a recent meta-analysis by Chatzakis (8) concluded that emergency cerclage in pregnant women with painless cervical dilatation decreases preterm births, prolongs pregnancy, and decreases neonatal deaths and fetal losses without increasing the risk of chorioamnionitis and preterm premature rupture of membranes.

Various techniques have been described for performing cerclage, including that described by Shirodkar (9) and McDonald (10) in the 1950s, which are still performed today. Shirodkar initially introduced a transvaginal cervical cerclage to be performed after detection of a gradually yielding cervix, even on women in the seventh month of pregnancy. McDonald performed transvaginal cerclage on women with cervical dilatation and bulging amniotic membranes during the second trimester of pregnancy (10). Throughout the years, modifications to the original techniques have been introduced (11), including the level of the cerclage (12) and the suture materials used (13).

There is considerable controversy regarding the cerclage success rate and maternal-fetal outcomes. Bayrak et al. (14) reported that in 27 patients who received emergency McDonald cerclage, 63% reached week 28 with the average prolongation of pregnancy being 64 days. Curti et al. (15) reported on 37 women between 17–27 weeks' gestation with cervical dilatation. A Shirodkar cerclage was performed and the average prolongation of pregnancy was 43 days and the average gestational age at delivery was 29 weeks. Studies have been carried out to compare the benefits of various techniques ; however, no technique has been found to be superior to the others. Basbug in a recent study ,compared the efficacy of modified Shirodkar and McDonald rescue cerclage techniques in women with singleton pregnancies. The study sample included 47 women who presented cervical incompetence and cervical dilatation with fetal membranes prolapsed into the vagina. The outcomes were compared by cerclage technique used, Shirodkar or McDonald. Both groups had similar delivery rates after 28, 32, and 37 weeks, and concluded that the effects of the McDonald and modified Shirodkar cerclage procedures on prolonging pregnancy and improving the live birth rate were similar. (16)

Following a review of the literature on perinatal outcomes in patients who required emergency cerclage, we found that despite the treatments applied, the rates of prematurity and related complications remain high, and none of the cerclage techniques described so far have shown to be superior to the others. This is why we see the need to continue with the research into new technical modifications that can improve these results.

This study aimed to evaluate pregnancy outcomes in pregnant patients with cervical dilatation and prolapsed fetal membranes in the second trimester of pregnancy who were treated with a novel three step procedure for emergency cerclage (TSEC) developed at our hospital.

## Methods

### Study design

Prospective observational study. During the 2015–2020 period, all pregnant women between 15 and 24 weeks of gestation who presented with clinical cervical modification with or without membrane prolapse, or who were diagnosed with this condition after ultrasound diagnosis, were offered the option of undergoing emergency cerclage to prevent a preterm delivery.

### Study population

Twenty-four pregnant women at 15 to 24 weeks gestation with cervical dilatation and bursa prolapse.

This procedure was offered only when one of the following clinical criterion was met: 1) cervical length <15 mm, measured with a 2.5–6.0 MHz transvaginal ultrasound probe (measurement had to be taken in the lithotomy position with the bladder completely empty, the shortest measurement was recorded) or 2) examination finding of a cervical dilatation between 1–4 cm, with visualization of the membranes at or exceeding the level of the external cervical os. Cerclage was not performed in the presence of fetal anomalies, bacterial vaginosis, uterine contractions, preterm premature rupture of membranes, active labor, and clinical symptoms or laboratory findings that suggest chorioamnionitis.

All patients underwent a 24-h observation period to rule out chorioamnionitis, bacterial vaginosis, and active labor before the surgery. In addition, vaginal ovules with clorhexidina were used 24 h before the operation.

Premature rupture of membranes (PROM) was determined using Actim<sup>®</sup> PROM (Medix Biochemica, Espoo, Finland) or by the direct identification of amniotic fluid thru the cervix and sonographic characteristics of oligohydramnios or anhydramnios. Chorioamnionitis was defined by fever >38°C, significantly elevated maternal serum leukocyte count

(>15000/mm<sup>3</sup>) (11), and the combination of positive amniotic Gram stain and glucose <5 mg/dl. Bacterial vaginosis was diagnosed by purulent vaginal discharge detected during the speculum examination on admission. Active labor was defined as the presence of regular uterine contractions, three or more in 10 minutes with cervical modifications.

Patients who underwent the procedure were informed that the surgeon may choose to make adaptations to the conventional cerclage techniques depending on the clinical conditions.

All patients provided the necessary consent to undergo cerclage and for participation in the study. This study was approved by the Ethical Committee of the Hospital Regional Universitario de Málaga.

### **Operative procedure**

After making the diagnosis of cervical incompetence, our group decided to apply a modification to the cerclage technique consisting of:

1. A first cerclage in a purse-string suture to ensure the reduction of the bag
2. A subsequent occlusive cerclage to ensure good cervical competence
3. To this technique a posterior cervical cleisis would be added depending on the cervical dilation and the degree of prolapse (TSEC)

The TSEC was reserved for those patients with dilation greater than 3 cm with a prolapsed bag, while the McDonald-type cerclage was performed in those patients with greater cervical length and less dilation, reserving double cerclage without cleisis for the remaining patients.

The technique for performing the TSEC was performed as follows:

1. The cervix was exposed using Sim's specula, after washing and asepsis of the vagina with chlorhexidine.
2. The bag was reduced using a swab impregnated with sterile lubricant, until both cervical lips were exposed (normally the lower lip proves more difficult) and then pulled up using a Foester clamp.
3. A Foley catheter was prepared and cut at the distal end, at the level of the upper edge of the inflated balloon. It was important not to leave any edges that could damage the amniotic sac.
4. The Foley catheter was inserted and then filled depending on the degree of cervical dilation and the stage of the procedure. To do this, a third assistant helped to increase or reduce the drainage flow, depending on the stage of the procedure. This initially corrected the prolapse. It was then reduced in order to cross the cervical canal and later, once past the internal cervical os, the volume was increased again to fix the reduction of the bag and to facilitate safe cerclage (Fig. 1).
5. The first cerclage was performed using Prolene 1. A purse-string suture was placed as cranially as possible and as close as possible to the level of the internal cervical os, with care taken not to damage the bladder. The suture was applied superficially, without going too deep into the cervical stroma, since the aim of this step is to keep the bag reduced once the Foley catheter had been removed, and to leave a segment of the cervix free on which to perform a second cerclage, so conglutination is completely guaranteed (Fig. 2).
6. The tobacco pouch seam was then closed while the Foley catheter was simultaneously deflated and removed, ensuring that the cervix was completely closed.
7. A second cerclage was performed with Mersilene tape, which was attached approximately 1 cm below the previous cerclage. The stitches in this suture were designed to conglutinate the cervix, including the anterior and posterior lips at both commissures (8 to 11 o'clock on the left edge and 4 to 1 o'clock on the right edge). The point applied on

the lower edge extended from 7 to 5 o'clock, and it was positioned as cranially as possible. The knot was located at 12 o'clock (Fig. 3)

8. The cervix was closed at the cervical os using Vycril 0. Two double stitches were applied in both commissures (Fig. 4), plus a third in the central area (Fig. 5).

TSEC has a number of differences with respect to the techniques described so far.

1. The aim of the first suture is to reduce the prolapse, isolate and protect the amniotic sac and provide the widest possible portion of cervix on which to apply the second cerclage, with the aim of containing the product of gestation and restoring the functionality and competence of the cervix. This is why this first step can be done with smaller sutures of 1 or 0 and with shorter needles. This facilitates access and execution of the suture as close as possible to the internal cervical os, especially in situations where the cervix is very shortened and dilated. In addition, as its main objective is not to restore cervical functionality but to keep the pouch reduced, we can superficially affect the cervical tissue without going deep into it, which avoids possible accidental ruptures or lacerations of the pouch, as well as injuries to neighbouring organs (bladder, ureter or rectum). Unlike the Shirodkar technique, it is not necessary to detach or reject the bladder from the cervix, which makes it technically simpler and avoids possible complications associated with this approach.
2. The second suture, as we have mentioned, has a functional objective of containment, but unlike what happens when performing the McDonald's technique, by having a completely free cervical stump, the application of the suture will be performed medially and covering the entire cervical diameter, thus joining both lips with what we understand we can give more strength to this suture, also requiring only three points as a triangle around the theoretical cervical canal.
3. Finally, we finish the procedure by adding a cervical cleisis, which although as an isolated technique had already been applied, we believe that added to the previous steps, especially in patients with advanced dilatation and exposure of the amniotic sac, can offer additional protection against possible contamination or ascending infections, which are one of the main risks to be avoided in these patients.

Once the cerclage was performed, we evaluated its correct application using ultrasonographic visualization of the location of the suture, correct reduction of the pocket, and verification of a cervical length of >20 mm.

All patients were given ceftriazone intravenously in the operation room. Patients with bulging membranes at diagnosis, were given additional prophylactic erythromycine and ampiciline IV during the first 48 h after the procedure.

Prophylactic tocolysis was indicated with 50 mg transrectal indomethacin every 6 h during the first 48 h, keeping the patient on Trendelenburg for the first 24–48 h. The patients were discharged after 72 h. Prior to hospital discharge, an ultrasound reevaluation of the cervix was performed to confirm correct placement of the cerclage and the absence of cervical dilation or bag prolapse.

Cerclage removal was performed on an outpatient basis by sectioning the knots at week 37, if labor began, or when any circumstance that required termination of pregnancy occurred.

The main outcome measure was the mean latency until delivery from the placement of the different cerclages, as well as perinatal outcomes. The latency period was defined as the time elapsed from the application of cerclage to delivery. Other main outcomes included immediate maternal complications, including rupture of membranes, pregnancy loss, excessive blood loss during the procedure (more than 25 ml), or cervical injury.

Other evaluated outcomes were gestational age at delivery, time elapsed from the application of cerclage, birth weight, and neonatal outcomes.

## Statistical Analyses

We performed an initial analysis of the frequency distribution of the independent variables. Subsequently, a bivariate analysis was performed to identify associations between variables. For bivariate analyses, we used the independent sample t-test to compare the mean values in two groups/categories of women when conditions of normality were present, and a Mann Whitney U test for the rest of cases. For comparisons between a greater number of groups, we used either a single-factor ANOVA or the non-parametric Kruskal–Wallis test according to the conditions of homoscedasticity that were evaluated using Levene's test. The chi-square test was used to compare qualitative variables. To analyze the relationship between quantitative variables, the Pearson's correlation coefficient was used. The significance level was set at  $p < 0.05$ . We used logistic regression models to predict the results of the main dependent variable, latency to delivery. The models were constructed using the Intro procedure, including the sociodemographic and obstetric variables that were shown first to be significantly associated, using the typical stopping p-value thresholds for explanatory modeling.(17)

## Results

A total of 24 women between 15 and 24 weeks' gestation underwent cerclage. Of these 24 women, 22 underwent TSEC, and a decision was made to perform cervical cleisis in 11 patients due to their advanced cervical modification and degree of prolapse of the amniotic membranes. The remaining two patients underwent a McDonalds-type cerclage given the most favorable clinical findings.

The mean age of our patients was 33.3 years. Of our sample, 54% had no previous delivery, and 946% were multiparas. (Table 1)

Table 1  
Characteristics demographics.

Variables	Patients(N = 24)
Age	33.3 ± 5.5
Parity	3 (12.5%)
Nulliparous/primiparous	13 (4.52%)
Multiparous	11 (45.8%)

The mean gestational age at diagnosis was 20 weeks + 1 day ± 3 weeks + 4 days). The mean cervical length at diagnosis was 10.83 ± 7.92 mm and the mean cervical dilatation was 2.57 cm. After cerclage, the mean cervical length was 22.85 ± 8.23 mm.

Twenty-one patients (87.5%) presented with bulging amniotic membranes. In 14 patients, the membranes did not extend beyond the external cervical os, and in seven cases, there was complete prolapsed membranes into vagina. Despite this, no case of accidental amniorrhaxis occurred during surgery (Table 2).

Table 2  
Characteristics of our patients (n = 24)

	N (%)
Previous abortion	1 (45.8%)
Previous conization	3 (12.5%)
Previous premature delivery	5 (20.8%)
Previous chorioamnionitis	2 (8.3%)
Previous cervical incompetence	3 (12.5%)
Previous prolapsed membranes	3 (12.5%)

After the intervention, four cases of chorioamnionitis were diagnosed, which represents 16.4%. Within this group, one case of stillbirth was recorded at week 24 of pregnancy, which occurred 4 weeks after cerclage. The woman had a satisfactory evolution without adverse events. In the rest of the cases in which chorioamnionitis developed, the evolution of the newborn and the mother were satisfactory, with no infectious pathology after delivery or subsequent sequelae, with a disease-free survival of 75% for the newborns and 100% for mothers.

The prematurity rate (defined as birth before 37 weeks) was of 54.2% (Table 3).

Table 3  
Pregnancy outcomes

	N (%)
Chorioamnionitis	4 (16.4%)
Birth after 28 weeks	21 (87.5%)
Birth after 34 weeks	19 (79.1%)
Birth after 37 weeks	11 (45.8%)
Neonatal survival	23 (95.8%)

The rate of premature amniorrhexis < 34 weeks was 8.3% (two cases) with successful perinatal outcomes.

Table 4 shows the latency period to delivery, as well as the increase in gestational age at delivery.

Table 4  
Duration of pregnancy and perinatal outcomes

		MEAN (RANGE)	SD
Gestation at delivery (weeks + days)	35 (24 + 1–40 + 5)	± 4 + 5	
Interval to delivery (days)	14 + 6 (2–26 + 5)	± 7	
Birth weight (g)	2550 (580–3880)	± 947.266	
SD, standard deviation			

The cesarean delivery rate was 20.8% (five cases) and the vaginal delivery rate was 58.3%. There were no cases of cervical dystocia due to scar tissue which prevented cervical dilation.

We observed significant positive correlations between cervical length after the intervention and gestational age (g.a.) at delivery and between cervical length at diagnosis and latency with  $r = 0.48$  ( $p < 0.05$ ). On the other hand, negative significant correlations were found between dilatation at diagnosis and g.a. at delivery, and latency duration with  $r = -0.68$  ( $p < 0.001$ ).

In the bivariate analyses, there was a significantly shorter mean duration of pregnancy in women with chorioamnionitis than those without chorioamnionitis. The median interval to delivery was 7 weeks + 1 day in women with chorioamnionitis and 16 weeks + 1 day in women without chorioamnionitis ( $p < 0.007$ ). A similar finding was revealed when gestational weeks at delivery was compared in the two groups of women, with a significantly shorter median duration of pregnancy in the group with chorioamnionitis (28 weeks + 1 day vs. 36 weeks + 3 days;  $p < 0.003$ ). The median neonatal birth weight in the chorioamnionitis group was  $1285 \pm 327.26$  g, compared to  $2803 \pm 815.50$  g in the control group, and this difference was significant ( $p < 0.002$ ) (Table 5).

Table 5  
Bivariate analyses

	Chorioamnionitis			Preterm birth			Conization			Prolapsed Membranes		
	+	-	P-value	+	-	p-value	+	-	p-value	+	-	p-value
Gestational at diagnosis, weeks + days	15+ 4	20+ 3	NS	19	20+ 3	$p < 0.01$	14+ 2	21+ 1	$p < 0.007$	17+ 4	20+ 3	NS
Gestation at delivery, weeks + days	28+ 1	36+ 3	$p < 0.003$	36	34+ 5	$p < 0.05$	38+ 2	34+ 3	$p < 0.001$	32+ 4	35+ 1	NS
Interval to delivery, weeks + days	7+1	16+ 1	$p < 0.007$	17	12	NS	24	13+ 3	NS	5+6	16	$p < 0.01$
Birth weight, g	1285 $\pm$ 327.3 g	2803 $\pm$ 815.5 g	$p < 0.002$	2628	2529	NS	2943	2493	NS	1376	2717	$p < 0.01$
Data are presented as median or mean $\pm$ standard deviation.												
R square 90% ( $p = 0.1$ )												

Women with membranes bulging beyond the external os (12.5%) showed a mean latency to delivery after cerclage placement of 5 weeks + 6 days compared to 16 weeks in the control group ( $p < 0.01$ ; dof 27.2) and the median neonatal birth weight was 1376 g compared to the control group (2717 g) ( $p < 0.01$ ; dof 423.71) (Table 5).

Diagnosis occurred significantly earlier in patients with a previous preterm birth (19 weeks vs. 20 weeks + 3 days [ $t = 0.79$ ;  $p < 0.01$ ; dof = 22]). In addition, the mean gestation at delivery was 36 weeks in patients with a previous preterm birth compared to 34 weeks + 5 days in the control group ( $p < 0.05$ ) (Table 5).

When we compared patients with a previous conization with those without a previous conization, women with previous conization showed a longer interval to delivery (24 weeks vs. 13 weeks + 3 days [ $t = -2.8$ ;  $p < 0.007$ ; dof = -117.18]).

Similarly, women with a previous conization showed a longer total gestation compared to women with no conization (38 weeks + 2 days vs. 34 weeks + 3 days [t = -1.3; p < 0.001; dof 21.49) (Table 5)

After multivariable analysis, the best predictive fitting model for prediction of latency to delivery included cervical dilatation, cervical length after the intervention, our technique for cerclage, and gestational age at delivery (Table 6, Fig. 6).

Table 6  
Multiple regression for latency

Constant	B	Std Error	Standardized coefficients Beta	t	Sig	95% Lower bound	95% Upper bound
Cervical dilatation	-18.91	0.86	-0.49	-2.71	0.02	-34.27	-3.544
Three step cerclage	43.782	24.073	0.185	1.819	0.096	-9.20	96.767
Length after cerclage	2.110	0.655	0.360	3.223	0.008	0.669	3.551
Gestational days at diagnosis	1.260	0.251	-0.660	5.024	0.000	1.812	-0.708
Dependent variable: interval to delivery							

## Discussion

To date, the treatments used in patients with cervical insufficiency diagnosed in the second trimester have failed to prevent a high rate of prematurity with its attendant neonatal consequences. None technique for emergency cerclage has been shown to be superior to others.

In the present study, we analyzed the results of emergency cerclages performed in the second trimester of pregnancy in patients treated at our hospital using our cerclage technique which included certain technical variants that we considered potentially beneficial for patients. We have called our novel technique, the “three-step procedure for emergency cerclage (TSEC).”

Our main objective was to evaluate how the application of our novel cerclage technique could prolong the duration of pregnancy. The results obtained are favorable compared to those reflected in the literature, not only in relation to the prolongation of pregnancy, but also in terms of variables such as neonate birth weight and the rate of maternal and fetal complications.

In our trial, the mean gestational age at cerclage was 20 weeks + 1 days and the interval to delivery after cerclage was 14 weeks + 6 days. Fortner et al. (17) reported a latency rate of 5 weeks + 3 days. On the other hand, Basbug et al. (16) who performed cerclage with the Schirodkar technique reported a latency until delivery of 11 weeks + 3 days. Daskalakis et al. (18) reported on 46 patients with bulging fetal membranes. Seventeen patients were treated with bed rest and 29 were treated with McDonalds cerclage and an increase in median prolongation of pregnancy of 8.8 weeks was observed in the group who underwent emergency cerclage. Ventolini et al. (19) enrolled 56 women who underwent Schirodkar cerclage. The mean gestational age at cerclage was 19 weeks + 4 days and the latency to delivery was 9 weeks + 1 day.

Our rate of preterm amniorrhexis in the pregnancies where cerclage was applied was 8.2%, and this rate is much lower than rates reported in the existing literature of around 25% (20). Stupin et al. (21) performed a double cerclage plus type cleisis (Szendi / Saling) as well as McDonalds-type cerclage in their sample, and reported a total of eight patients in

whom amniorrhexis occurred during the technique, as well as three cases of cervical lacerations during the removal of the cerclage. In our study, there were no cases of accidental amniorrhexis during the procedure or any notable complications in its removal, nor did we observe any influence on the evolution of the subsequent delivery.

Gupta et al. (22) reported a chorioamnionitis rate of 46% and Abo-Yaoub et al. (23) reported a rate of 16.2%. Likewise, Freire et al. (24) reported a rate of 23.5%. Our chorioamnionitis rate was 16%, which is lower than that reported in other studies. Analysis of the cases that developed clinical chorioamnionitis revealed significant differences in terms of the duration of pregnancy (7 weeks + 1 days vs. 16 weeks + 2 days), indicating that this is the main determining factor for predicting the final results in our cerclages.

One of the most outstanding findings was that in conized patients, the results were very satisfactory with latency time to delivery even higher than that in non-conized patients. Even though our sample was very limited, the differences found between the two groups are significant, and we suggest that this type of cerclage could be particularly beneficial in this group of patients.

It is especially important to evaluate how cerclage is able to prevent extreme prematurity in these patients. In his study, Aoki (25) succeeded in prolonging pregnancies beyond 28 weeks in 66% of his patients. Bayrak (14) reported similar numbers (63%), as did Pereira (62%) (26). In our study, 87.5% of the pregnant women who underwent cerclage managed to exceed 28 weeks of gestation.

There are very few reports on pregnancies that reach full-term. Ventollini (19) reported that 23% of pregnancies exceeded 38 weeks; however, Basbug (16) reported a lower figure of 13.6%. In our sample, 11 patients exceeded 37 weeks of gestation, which represents 45.8% of the total.

Birth weight is an important indicator of perinatal outcomes, and there are many reports on this in the literature. One study that stands out is that by Hordnes (27) which was published in 1996 and reported an average birth weight of 2252 g; however, it should be noted that the number of patients in that study was small. However, larger and more recent studies, such as the study by Fortner (19) reported an average birth weight of 1190 g. In 2010, Gupta (22) reported an average birth weight of 1937 g. The results of our study are very favorable since we found an average birth weight of 2550 g.

After analysing all the above data, we can conclude that using our TSEC technique we could obtain a longer latency period that would result in lower prematurity rates. These results would be especially beneficial in patients with poor prognosis (prolapsed membranes, cervical dilatation, conization patients), in which most of the studies have been unsatisfactory. It is an easily applicable technique and we find of particular interest the low or null incidence of complications during its performance. The efficacy of the technique and the low or null incidence of complications has led to a drastic reduction in the hospital stay of these patients, making TSEC a beneficial technique from a cost-effective point of view.

## Conclusion

The cerclage is a technique of proven usefulness in patients with cervical dilation in the second trimester of pregnancy for the prevention of preterm delivery. It prolongs pregnancy and prevents poor perinatal outcomes derived from prematurity.

So far, no technique has been proven as superior to the rest. In this study, we have presented our results of our novel technique which introduces certain modifications—the TSEC.

Most of the studies to date, and the present study, report on a small number of recruited patients. This fact, together with the fact that most studies, including the present study, are observational, prevents us from obtaining definitive conclusions. These are the main limitations of this research, and larger studies are required to confirm our findings.

Despite this, the good results in terms of latency until delivery after cerclage, gestational age at delivery, birth weight, and minimization of complications reported in our work compels us to continue to evaluate the results of our technique which may provide significantly better outcomes for neonates and mothers.

## Abbreviations

TSEC: Three-Step Procedure for Emergency Cerclage, PROM: Premature rupture of membranes.

## Declarations

**Ethics approval and consent to participate:** The research has been carried out in accordance with the Declaration of Helsinki. This original contribution was approved by the ethics committee of Regional University Hospital ( Málaga. Sapin) and the consent for participation was obtained in writing. The committee's reference number is 15032021/50.

**Consent for publication** The authors have obtained the patients' signed consent to publication. This work has not been published before and it is not under consideration for publication anywhere else.

**Availability of data and materials.** The datasets used to support the findings of this study are available from Hospital Regional Universitario Málaga Spain upon reasonable request and signing a data access agreement subject to approval from the study principal investigators.

**Competing interests:** In this study, there is no conflicts of interest

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**Authors' contributions:** The information related to the cases can be obtained from the corresponding authors (MGC and LSM) upon reasonable request. MGC and LSM also data collection and manuscript writing. EGM and JSJL., editing and writing The data were collected during the patients' hospital admission by the investigators who provided direct assistance. These data are stored in the computerized support system of electronic medical records of the Andalusian health system.

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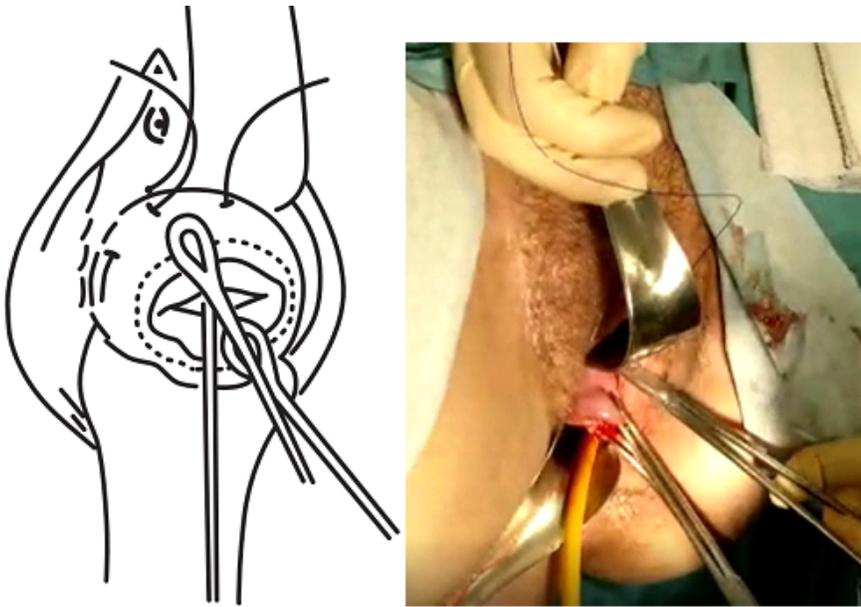
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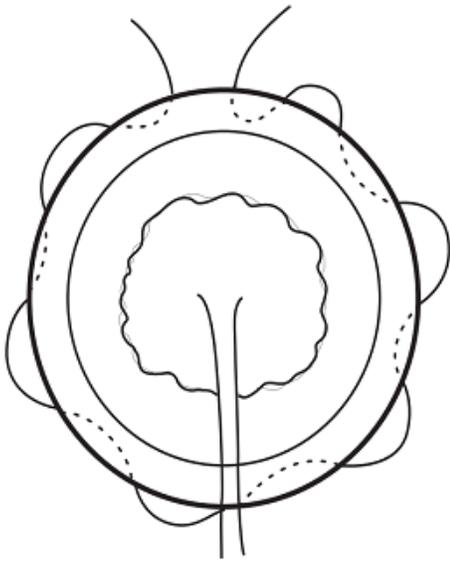
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## Figures



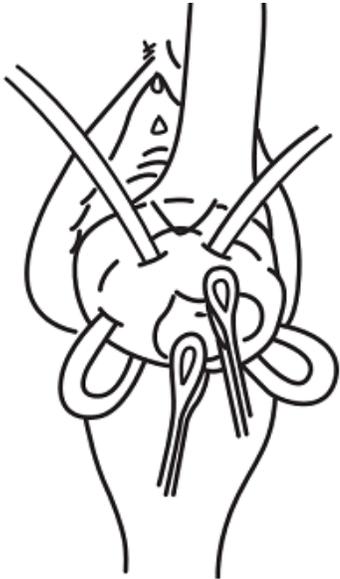
**Figure 1**

Reduction of prolapsed membranes



**Figure 2**

Purse-string sutures



**Figure 3**

Second occlusive suture (Mersilene)



**Figure 4**

Cervical cleidotomy



**Figure 5**

Cervical cleidotomy

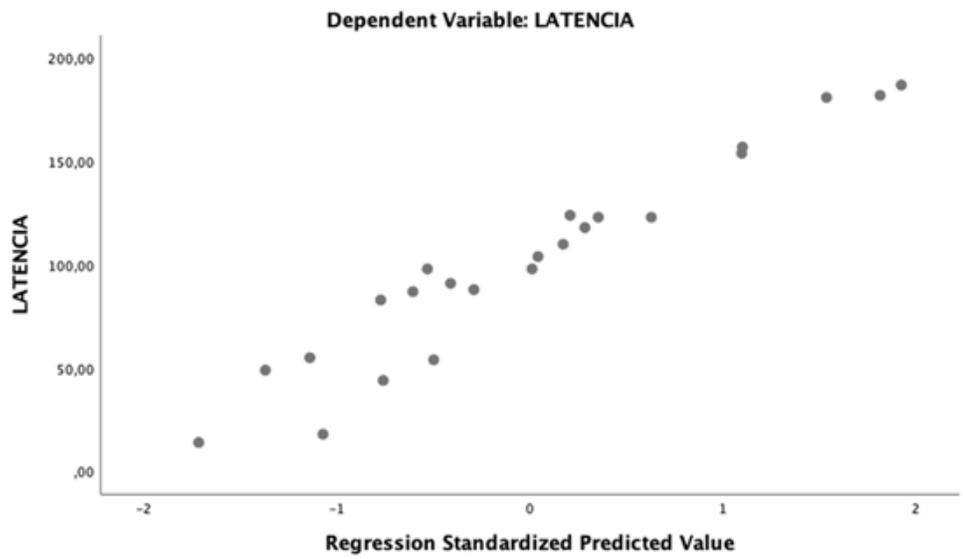


Figure 6

Best fitting predictive model of logistic regression of the interval to delivery