Transvaginal Cervical Cerclage in Cervical Insufficiency: Outcomes of 77 Pregnancies: Single Institution Retrospective Study

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Abstract

Background: Cervical insufficiency is a major cause of second-trimester pregnancy loss and spontaneous preterm delivery. Cervical cerclage is a surgical procedure that can be performed in an attempt to maintain the structural integrity of the cervix in order to prolong gestation and improve obstetrical outcomes.

Objective: The aim of the study was to investigate the effectiveness of the transvaginal cervical cerclage (TVCs).

Materials and methods: A single-institution retrospective study included 106 pregnant women (93 singleton pregnancies and 13 twin pregnancies) who underwent transvaginal cerclage between 2015 and February 2022. Data extracted included patient demographics, gestation of suture insertion, gestation at delivery, mode of delivery, pregnancy outcomes and details about the suture insertion. The main outcomes of pregnancy which were evaluated were live birth rate and gestation at delivery.

Results: During the study period, 106 women underwent transvaginal cerclage between 14 and 30 weeks of gestation. Cervical cerclages were done by the McDonald (n=105) or the Shirodkar technique (n=1). Regarding the mode of the delivery, cesarean section was performed in 59 cases (77%), in 18 cases it was vaginal delivery (23%). The outcomes of 77 pregnancies (88 babies) were analyzed. The live birth rate was 97.7%, a mean gestational age at delivery of 36 weeks; the preterm birth rate at <32 weeks was 19.5%, only 1.3% women delivered before 24 weeks.

Conclusion: Placement of transvaginal cerclage appears to reduce preterm delivery before 32 weeks and improve neonatal survival. It appears to be a safe and effective procedure.

Keywords: Cerclage, Cervical; Uterine cervical incompetence; Premature birth.

Introduction

Preterm birth remains to be one of the main causes of perinatal mortality and morbidity of the newborns. WHO (World Health Organisation) defines preterm birth as babies born alive before 37 weeks of pregnancy are completed [1]. Globally, prematurity is the leading cause of death in children under the age of 5 years. In almost all countries with reliable data, preterm birth rates are increasing currently ranging from 5 to 18% of live births [1]. An estimated 15 million babies are born too early every year, which is more than 1 in 10 babies. Approximately 1 million children die each year due to complications of preterm birth [2]. The reason for nearly 15% of recurrent miscarriages and preterm deliveries is cervical insufficiency, which concerns relatively 1% of all pregnancies [3].

Cervical insufficiency, also called cervical incompetence or cervical weakness is a medical condition in which the cervix begins to dilate and efface before the pregnancy has reached term. There are various definitions of cervical weakness, but...
the one commonly used is the inability of the uterine cervix to retain a pregnancy in the absence of the signs and symptoms of clinical contractions, or labor, or both [4]. Cervical weakness usually occurs during the middle of the second or early third trimester, depending upon the severity of it [5]. Main treatment of cervical insufficiency in pregnancy is the placement of the cervical cerclages. It is performed to stop the progress of dilation of the cervix and to close it. The treatment consists of a strong suture sewn into and around the cervix early in the pregnancy and then removed towards the end of the pregnancy when the greatest risk of miscarriage has passed [6].

The most common type of transvaginal cervical cerclage is the McDonald cerclage. It was described in 1957 and was developed by I.A. McDonald [7]. It is a purse-string nonabsorbable suture placed at cervicovaginal junction [8]. That type of cervical cerclage is usually placed between 16 and 18 weeks and is removed about 37 th weeks. Less common technique is the Shirodkar cerclage which is technically more difficult than the McDonald’s. It was proposed in 1955 [9]. The difference between those procedures is mainly the fact that placing the Shirodkar cerclage requires dissection of the bladder and the rectum which leads to more complications [10]. If the transvaginal cervical cerclage fails, a transabdominal approach can be used. That procedure can also be carried out if a woman has a short scarred cervix. The stitches are placed at the level of internal cervical os. They can be placed either at the early stages of pregnancy, around 12th weeks or even before pregnancy [9].

There are three indications for placing cerclage: history-indicated cerclage (HIC), ultrasound-indicated cerclage (UIC) and physical examination-indicated cerclage (PEIC) [11]. HIC is placed between 12 and 14 weeks in women who have poor obstetric history. The criteria includes 2 or more subsequent spontaneous pregnancy loss between 16 and 28 weeks, 3 or more preterm births or second trimester loss between 14 and 24 weeks [11]. UIC is placed when the cervical length in transvaginal ultrasound is shorter than 25 mm. Suggested gestational age of placement of the cerclage is between 16 and 23 weeks [11]. PEIC is placed when cervical dilatation is found during manual examination or using speculum. The procedure should be carried out between 16 and 23 weeks [11]. Although cervical cerclage is a worldwide known and commonly performed procedure the effectiveness of it is still unclear. There are numerous studies in which results are conflicting. This article proves the usefulness of the cerclage in cervical insufficiency in preventing preterm birth.

Materials and methods

The study was based at the 2nd Department and Clinic of Gynaecology and Obstetrics, Wroclaw Medical University in Poland. The study was in compliance with the Helsinki Declaration and the authorization to perform this study was obtained from the Wroclaw Medical University Ethical Committee (approval number: 19-285A). Before subject recruitment and data collection the informed consent was obtained from each participant. Data processing was conducted anonymously and in strict confidence.

KS-MEDIS system and case notes were used for obtaining information. The records of all patients who underwent transvaginal cerclage insertion from November 2015 to February 2022 were reviewed. Information such as patient age, parity, history, gestation at delivery, gestation of suture insertion and type of delivery were collected. Information gathered also included delivery outcomes, the type of suture inserted, perioperative treatment and complications which seemed connected to the suture placement.

The prolongation of pregnancy, complications and outcomes of pregnancy were evaluated. The primary outcome of interest was live birth and the secondary outcome was the delivery at ≥32 weeks gestation.

Statistical analysis was done using Microsoft Excel.

Results

Over 6 years, a total of 106 women underwent insertion of TVCs (transvaginal cerclages). The mean age was 31.6±4.5 years (range 17-43 years). 13/106 (12%) pregnancies were twin pregnancies and 93/106 (88%) were singleton pregnancies. In 34 cases (32%) it was the 1st pregnancy, in 33 cases (31%) the 2nd, in 22 cases (21%) the 3rd, in 9 cases (8%) the 4th, in 3 cases (3%) the 5th, in 4 cases (4%) the 6th and in 1 case (1%) the 8th pregnancy. The mean gestation at the time of the procedure was 23,1±3,7 (range 14-30) weeks.

Cervical cerclages were done by the McDonald technique in 105 cases and the Shirodkar technique in one case - in a patient after double conization of the cervix.

All cases were performed technically successfully with no surgical or anaesthetic complications. Membrane rupture did not occur at the time of cerclage placement in any patient. All patients had similar management (hospitalisation, bed rest, progesterone treatment). 35/106 women (33%) received antibiotics. In 10 cases it was necessary to repeat the cerclage during the pregnancy.

During data analysis, one pregnancy was excluded because it ended for the reason not relating to the cerclage. The patient was presenting symptoms of intrauterine infection and regarding her safety and health it was needed to remove the cerclage and induce the labour. She delivered the baby without any signs of life. 29 women gave birth in other hospitals therefore we don’t have information about the delivery.

The outcomes of 77 pregnancies (88 babies, 11 sets of twins) were analyzed. The live birth rate was 86/88 (97,7%). The two neonatal deaths (2,3%) include two patients who required repeated insertion of TVCs. One patient received TVCs in 20th weeks and in 24 weeks considering the slippage of the previously placed suture and the progressive dilation of the cervix with bulging of the fetal membranes into the vagina, she was qualified for the next cervical suture. Due to ineffectiveness of emergency sutures and contractile activity of the uterus, despite intravenous tocolysis, it was impossible to stop the progressive delivery. Second patient had cerclages placed in 16 weeks. In 20 weeks she was admitted to the clinic due to shortening and dilation of the cervix, although the physical examination revealed an intact cerclage. It was removed, another cerclage was placed and the patient was treated with tocolytics and antibiotics. Despite the treatment, signs of intrauterine infection and intense contractions were observed and the patient was diagnosed with intrauterine death (IUD). Regarding the mode of the delivery, cesarean section was performed in 59 cases (77%), it was a planned procedure in 32 cases and an emergency procedure in 27 cases. 18 women underwent vaginal delivery (23%). The median gestation at delivery was 36 weeks (range 23-42 weeks); 62/77 (80,5%) women delivered after 36 weeks, all with babies alive and well and 47/77 (61%) women delivered after 37 weeks. 15
patients delivered between 23 and 32 weeks gestation. All of these deliveries occurred due to preterm labour or preterm rupture of membranes and therefore their cerclages were deemed suboptimal (average gestational age 27.4±2.66 weeks). In terms of obstetric complications, 7(9.2%) patients experienced gestational diabetes, 1(1.3%) preeclampsia, 1(1.3%) gestational hypertension, 21(27.6%) secondary anaemia. Our results suggest that TVCs in women with cervical incompetence appeared to produce encouraging results, with 80.5% women delivering after 32 weeks and 97.7% women producing live births.

**Table 1: Demographic factors.**

<table>
<thead>
<tr>
<th>Age</th>
<th>31.6±4.5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiparous women</td>
<td>34(32%)</td>
</tr>
<tr>
<td>Primiparous women</td>
<td>72(68%)</td>
</tr>
<tr>
<td>Twin pregnancies</td>
<td>13(12%)</td>
</tr>
<tr>
<td>Singleton pregnancies</td>
<td>93(88%)</td>
</tr>
<tr>
<td>GA at cerclage placement</td>
<td>23,1±3.7 (range 14-30) weeks</td>
</tr>
</tbody>
</table>

**Table 2: Outcome.**

<table>
<thead>
<tr>
<th>Mean gestational age</th>
<th>Outcome</th>
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</thead>
<tbody>
<tr>
<td>Delivery 13-24 weeks</td>
<td>1(1,3%)</td>
</tr>
<tr>
<td>24.1-28 weeks</td>
<td>6(7,8%)</td>
</tr>
<tr>
<td>28.1-32 weeks</td>
<td>8(10,4%)</td>
</tr>
<tr>
<td>32.1-37 weeks</td>
<td>26(33,8%)</td>
</tr>
<tr>
<td>&gt;37.1 weeks</td>
<td>36(46,7%)</td>
</tr>
<tr>
<td>Live birth rate (%)</td>
<td>97,7</td>
</tr>
<tr>
<td>Vaginal delivery rate (%)</td>
<td>23</td>
</tr>
</tbody>
</table>

**Discussion**

Our study focused on patients with cervical insufficiency during pregnancy. In this group of patients, insertion of TVCs was highly effective. Based on our study, we can conclude that this procedure extends the duration of pregnancy, making it possible to reduce the number of premature births. The vast majority of pregnancies that were the subject of the study ended in the birth of alive and healthy neonates.

The effectiveness of inserting the cervical cerclages varies from different aspects, mainly as: whether it is a singleton or twin pregnancy, the type of indication and cervical length. A significant amount of literature has attempted to evaluate the efficacy of TVCs placement in singleton pregnancies. In singleton pregnancies, insertion of a cerclage appears to prolong gestation and improve outcomes compared to expectant management [12,13]. For patients with twin pregnancies, it is unclear in which circumstances a cervical cerclage may improve outcomes. It is not routinely indicated but appears to be beneficial in subjects with a history of preterm birth or very short cervix or dilated cervix. There are some studies proving its utility for the reduction of preterm birth and the prolongation of pregnancy. Further studies are required to set the detailed management in women with twin pregnancy [14].

Another factor that determines the success of the treatment is the indication - whether it is an history indicated (elective), ultrasound indicated or rescue cerclage. Elective and ultrasound indicated cervical cerclage appear to have low complication rates and high live-birth rates. Rescue cerclage has a significantly higher complication rate and is associated with a high loss rate. More studies are required to determine whether this intervention actually prolongs pregnancy [15].

Gravid patients who were assigned to apply the cerclage are expected to have longer cervixes if the procedure was conducted correctly. The studies show that those women whose cervix length is longer after the use of cerclage have bigger chances to deliver on time than those whose cervix is the same size or smaller after the cerclage [16].

Many researches proved the effectiveness of the cervical cerclage in preventing recurrent second term miscarriages or extreme preterm delivery. In the Danish studies it was proved that compliance of prophylactic cerclage declined the number of situations mentioned in the previous sentence significantly [adjusted odds ratio (OR) 0.47; 95% CI 0.29-0.76] [17]. The effectiveness is the highest among women with a shortened cervix and with burdened obstetric history [18] but it decreases with greater dilatation [19]. The research conducted by Owen, in which women were assigned to cerclage were cervical length below 25 mm proved that there was a significant interaction between cervical length and cerclage. The rate of survival among newborns was also higher in the group in which cerclage was applied [20]. It enables conservation of correct development of the fetus. Other studies that proved the accuracy of the cerclage were conducted among others by Korb [21] and Andrews [22].

The removal of the McDonald cerclage is not problematic for experienced obstetrician. If the pregnancy was planned to be terminated via cesarean section it can be removed directly before the operation [23]. In the studies of Alabi-Isama patients have removed cerclage in 37 weeks of gestational age and the average time from the removal to delivery was about 14 days which allowed children to be born on time. Only 3% of the women gave birth during the first 24 hours and 11% during the first 48h [24].

As an invasive medical procedure cervical cerclage is connected with some complications such as premature pre-labour rupture of the membranes, which involves 1-8% of pregnant women who underwent this type of treatment [20]. In 3-13% of the patients may occur seam slippage, and in 1-13% cervical trauma [23]. According to Suzuki cervical cerclage is an independent risk factor of intrapartum cervical lacerations in vaginal deliveries [26]. The threat is also chorioamnionitis which is dangerous to both the woman and the fetus [27], hemorrhage from birth canal or vesicovaginal fistula [25].

The problem can also occur during removing the cerclage but it is a very rare condition (about 1%) [28]. Some studies claim that application of cerclage leads to an increased amount of cesarean section due to the pregnant woman's sense of 'medicalizing' their pregnancy and due to threat of further complications during delivery [27].

**Conclusion**

The main determinant of success for a cervical cerclage procedure is the capability of preventing preterm birth and related adverse outcomes. This study provides evidence of the effec-
tiveness of inserting TVCs in prolonging the pregnancy and reducing preterm birth rate. Transvaginal cerclage placement is a safe and effective procedure which results in favorable obstetric outcomes for women with cervical insufficiency.

Declarations

Conflict of interest: No conflict of interest is declared by the authors.

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