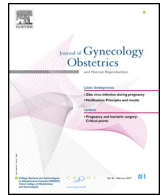




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Original Article

## Evaluation of a new technique of prophylactic cervical cerclage simplified from the Shirodkar cerclage: A pilot study

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### ABSTRACT

**Introduction.** – In terms of prophylactic cerclage, the simplest and most commonly used technique is the McDonald cervical cerclage. Cervico-isthmic cerclage techniques may have better results, but are more difficult to achieve. A simplified Shirodkar technique would have the advantage of being “cervical high” while remaining easy to achieve.

**Objective.** – To compare the results of high cervical cerclage, according to a simplified Shirodkar technique, with those of a classic McDonald cerclage, in the case of women at high risk of prematurity in an exploratory study.

**Methods.** – A comparative, retrospective study of prophylactic cerclage was conducted according to one or the other technique performed in a university hospital from 2006 to 2013. Women were included only if they had a history of at least two late miscarriages and/or premature delivery before 33 weeks. The primary outcome was the rate of delivery before 35 weeks.

**Results.** – Our study involved 38 women: 24 in the McDonald cerclage group and 14 in the simplified Shirodkar cerclage group. The two groups were comparable for their obstetric and general characteristics. The percentage of preterm deliveries before 35 weeks was similar in both groups (7.1% and 25.0% in the Shirodkar and McDonald groups respectively;  $P = 0.17$ ). No significant difference was observed in the rate of surgical complications or hospitalizations during the pregnancies.

**Conclusion.** – In this study, we were unable to demonstrate an advantage to using the simplified Shirodkar technique – high cervical cerclage – compared with use of the McDonald technique – classical cerclage.

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### Introduction

Spontaneous preterm deliveries are a major cause of perinatal mortality and morbidity [1]. To reduce the risk of preterm birth in women at high risk of preterm birth [2], several cerclage techniques have been developed since the 1950s [3–6].

However, while certain data support the effectiveness of cerclage in cases of repeated history of premature birth [7], few studies have compared different cerclage techniques. Cervical cerclage techniques are less binding [6,8–10], but may be less effective than cervico-isthmic cerclage techniques [8,11–13].

The most commonly used cervical cerclage technique used is the one described by McDonald [3,14]. It is an easy technique,

and involves positioning a temporary thread at the middle part of the cervix via the vagina; the thread is then removed in late pregnancy.

Regarding the cervico-isthmic techniques [4–6,15,16], Shirodkar, followed by others, have described the application of a temporary strip that is placed on the uterine isthmus, which is therefore higher and closer to the internal orifice, vaginally or abdominally. In the initial Shirodkar technique [4], the prior dissection of the vesicouterine space allows both access to the uterine isthmus and concealment of the strip. As regards to abdominal approach techniques [6,15,17–19], both laparotomic [6] and laparoscopic [15,18,19] approaches have been described. Such techniques require not only a bladder dissection but also the placement of a strip around the cervix so as to avoid the uterine vessels, thus increasing both the complexity and hemorrhagic risk of the intervention [6,15,17].

Furthermore, the strip is permanent, so an elective cesarean section is necessary at the end of the pregnancy [5].

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We are interested in a technique involving a simplified high cervical cerclage – named “simplified Shirodkar” – rather than the earlier cervico-isthmic Shirodkar technique [20]. We conducted a pilot study – exploratory – to compare the results of this new technique to that of McDonald use usually in the same indications in our center.

## Methods

This was a retrospective and comparative single-center study conducted between January 2006 and January 2013 in a university hospital providing high level of care maternity care. Women who met the inclusion criteria were those who had undergone a prophylactic cerclage during the study period. Eligible women were identified from our maternal hospital-discharge records by diagnostic and procedure codes (International Classification of Diseases, 10th Revision). To obtain as high a statistical contrast as possible, we chose to conduct this study only in patients at high risk and with an indication of cerclage recommended at the time of this study period [21]. The inclusion criteria also required that the women should have a history of at least two – consecutive or not – late spontaneous miscarriages between 16 and 21 weeks and/or premature deliveries between 22 and 32 + 6 weeks. Exclusion criteria were multiple pregnancies, emergency cerclage, therapeutic cerclage, and cerclage techniques other than McDonald and simplified Shirodkar.

The following maternal and neonatal data needed for our analysis were gathered from the medical records: occupation, marital status, smoking status, obstetric history, history of cone biopsy, uterine malformation or cervical incompetence, maternal age, IMC in early pregnancy, cerclage characteristics and complications, complications during pregnancy, gestational age at cerclage removal, gestational age at delivery, type of labor, cesarean section and neonatal outcome, birth weight, Apgar score, and NICU transfer. Immediate surgical complications of the cerclage were defined by the occurrence of a preterm rupture of membranes or hyperthermia within 72 hours after the intervention. Other events of the pregnancy studied were hospitalizations for preterm labor, the use of a tocolytic treatment, premature rupture of membranes, antenatal signs of chorioamnionitis, and fetal death. Chorioamnionitis was defined as the presence of at least one of the following signs: maternal fever  $> 38^{\circ}\text{C}$ , vaginal bleeding, pus or foul-smelling vaginal discharge, maternal tachycardia  $> 100$  bpm, fetal tachycardia  $> 160$  bpm, maternal CRP  $> 15$  mg/L, and maternal leucocytes  $> 15,000/\text{mm}^3$ .

Women with a simplified Shirodkar cerclage were compared with women who had a McDonald cerclage. All cerclages were performed under general or regional anesthesia. Women were considered to be in the McDonald group if they had received a cerclage using the technique described by McDonald [3,14] – that is to say, by weaving a braid through the connection of the middle-third/upper-third of the cervix, by passing six or four cardinal points, and by tying the two strands at the front of the cervix (Mersutures F 1513, Ethicon®, Issy-les-Moulineaux, France). Women were considered in the simplified Shirodkar group if they had undergone the technique described by Raynal et al. [20]. This involves handling the cervix rather firmly using four Allis clamps and then placing – sufficiently deep in the cervix – a strip of 5 mm thickness high on the cervix, in the angles of reflection of the vagina with the bladder forward and with the pouch of Douglas behind. The technique is facilitated by the nature of the doubly crimped thick strip, which allows starting the strap at about a radius of 6 hours back and strongly tying the knot on a radius of 12 hours before (Mersutures RS 22U, Ethicon®, Issy-les-Moulineaux, France) (Appendix A).

The primary outcome defined before the study was the rate of delivery at  $< 35$  weeks. The secondary outcomes were the

percentage of deliveries at  $< 24$ , 28, 32, and 37 weeks, operative complications, premature rupture of membranes before 37 weeks, chorioamnionitis during pregnancy, perinatal mortality (22 weeks of gestation–7 days after delivery), neonatal mortality (infants who were born alive but died before 28 days of life).

With no previous data on the simplified Shirodkar technique, the study was exploratory. A descriptive analysis of the two groups of women was carried out, and then compared. Comparisons between percentages were calculated using the chi-square or Fisher's exact test, depending on the number of women in each group. The mean comparisons were performed using the Student *t*-test, and the median test comparisons by the Kruskal-Wallis test, according to the normal distribution (or not) of the quantitative variables. A difference was considered significant if  $P < 0.05$ . The analyses were performed using STATA software version 13.0.0 (Copyright 1985–2013 StataCorp LP, StataCorp, College Station, Texas 77845, USA).

## Results

During the study period, 114 women underwent a cervical cerclage, and 38 met the predefined inclusion criteria: 24 in the McDonald group and 14 in the simplified Shirodkar group (Fig. 1).

Women in both groups were comparable regarding their general characteristics (Table 1). Maternal age was a little higher in the simplified Shirodkar group, but without a significant difference (33.1 years vs. 30.9 years,  $P = 0.15$ ). Regardless of the group, less than one in two women had a professional activity and the majority lived alone. The women also had similar anthropometric and socio-economic characteristics.

The women did not differ regarding their obstetric history (Table 2), particularly regarding the number of late miscarriages or premature deliveries ( $2.5 \pm 1.2$  vs.  $2.3 \pm 0.5$ ,  $P = 0.40$ ). Over half of the patients had previously had a cerclage. However, the women in the simplified Shirodkar group had a little more history of perinatal death than the patients in the McDonald group ( $1.5 \pm 1.0$  vs.  $1.0 \pm 1.0$ ,  $P = 0.04$ ).

The median gestational age at cerclage was similar between the simplified Shirodkar group and the McDonald group ( $13.0 \pm 2.0$  vs.  $14.0 \pm 2.0$ ,  $P = 0.22$ ) (Table 3). Most of the cerclages had been performed under general anesthesia. The two groups did not differ in terms of those who had received antibiotics – less than a quarter of the women – and those who had received progesterone after the cerclage – less than a third of cases. Regarding the immediate operative complications, only one patient had premature rupture of membranes the day after the cerclage in the simplified Shirodkar group. After a pregnancy marked by repeated antibiotic treatment, the woman was delivered after an induced labor for premature rupture of membranes at 35 weeks. No woman presented with hyperthermia within 72 hours of the cerclage.

Complications and pregnancy outcomes are described in Table 4. Regarding the primary outcome, the percentage of deliveries before 35 weeks did not differ according to the cerclage technique (7.2% vs. 25.0%  $P = 0.17$ ). Similarly, no significant differences were found in the analysis at different gestational age thresholds. Regarding the secondary outcomes, no difference was found in hospital admissions for preterm labor or use of tocolytics during pregnancy. Three women had antenatal signs of chorioamnionitis, all in the McDonald group, with two in the case of a premature rupture of membranes leading to a birth at 27 and 28 weeks, respectively, and the other outside of a context of membrane rupture followed by delivery at 30 weeks. Finally, the use of cesarean section was no different according to the cerclage technique used.

Our study revealed no differences between techniques in terms of perinatal and neonatal complications (Table 5). Regarding

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