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Case-controlled Study

Pre-Cerclage cervical length predicts long-term pregnancy sustenance: A case-control study

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ABSTRACT

Background: This study aimed to assess a predictor of long-term pregnancy sustenance post cervical cerclage in women with or without a medical history of cervical insufficiency.
Materials and methods: We included pregnant women who underwent cerclage at 12–25 weeks gestation in four perinatal medical centers between January 2009 and December 2010. We classified the cerclage modality as ultrasound-indicated cervical cerclage if the pre-cerclage CL was <25 mm because the prophylactic and therapeutic cerclage definitions varied among institutions. The procedure was deemed successful if the pregnancy continued for more than 13 weeks post cerclage. We compared the outcomes of women who underwent successful and unsuccessful cerclage and investigated whether the pre-cerclage CL could predict pregnancy outcomes in women who underwent successful cerclage using receiver-operating characteristic curves.
Results: We screened 114 pregnant women; 91 met the inclusion criteria. Pre-cerclage CL was a moderately accurate predictor of long-term pregnancy sustenance in the successful group (optimal cut-off value: 17 mm; area under the curve: 0.76; P = 0.0016). Approximately 87% of patients with a pre-cerclage CL ≥ 17 mm sustained their pregnancies for more than 13 weeks post cerclage; however, 64% of patients with a pre-cerclage CL < 17 mm did not.
Conclusion: We speculate that the use of other treatment options in addition to cerclage in women with a pre-cerclage CL < 17 mm may result in a successful pregnancy.

1. Introduction

Cervical insufficiency is a condition in which the cervix dilates in the second trimester of pregnancy without symptoms or signs of labor, such as uterine contractions or amniotic fluid leakage. Cervical insufficiency is clinically diagnosed in patients with a previous typical spontaneous abortion that may be associated with a short cervical length (CL) on transvaginal ultrasonography. For patients with cervical insufficiency, cervical cerclage is performed prophylactically or therapeutically under the following conditions: prophylactic cerclage for preterm high-risk pregnant women, ultrasound-indicated cerclage for pregnant women with short CLs, and urgent cerclage for pregnant women presenting with cervical dilation <3 cm and a visible amniotic membrane. Therapeutic cervical cerclage can be performed in the latter two conditions to prevent premature birth due to cervical insufficiency [1].

There are two operative procedures for cervical cerclage which are well-known as Shirodkar's and McDonald's operation. These operations were developed for the therapy of cervical insufficiency in the 1950s. Both operations are recognized as a universal and promising therapy and largely remain unaltered since developed. In general, Shirodkar's

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operation is used for both prophylactic and therapeutic cervical cerclage while McDonald's operation tends to be used for therapeutic cerclage.

Transvaginal ultrasonographic CL measurements are more objective than a pelvic examination and may lead to an early diagnosis of threatened preterm birth [2], especially if ultrasonography shows a shortened CL [3]. A CL < 25 mm at 20–24 weeks gestation is a risk factor for preterm birth, with 42% of preterm births occurring earlier than 37 weeks of gestation and 33% occurring earlier than 34 weeks of gestation [4]. Prophylactic cervical cerclage is recommended for singleton pregnancies in women with a history of preterm birth at <34 weeks gestation and a pre-cerclage CL < 25 mm before 24 weeks gestation [5]. Although ultrasound-indicated cervical cerclage is effective in pregnant women with a CL ≤ 10 mm who have no preterm birth history, it is ineffective in women with singleton pregnancies with a CL ≤ 25 mm who have no preterm birth history [6]. Additionally, ultrasound-indicated cervical cerclage did not prolong the gestational period among Japanese pregnant women with a pre-cervical CL < 25 mm between 16 and 26 weeks of gestation. However, it decreased the hospitalization length [7]. Therefore, in Japan, ultrasound-indicated cervical cerclage may benefit pregnant women (gestation, between 16 and 26 weeks; CL, <25 mm) who do not have vaginosis or cervicitis.

We sought to investigate the usefulness of cervical cerclage in pregnant women with cervical insufficiency and evaluate the predictive factors associated with successful cervical cerclage.

2. Materials and Methods

This study retrospectively reviewed data from pregnant women who underwent cerclage from January 2009 to December 2010 in four perinatal medical centers in Kitakyushu City, Japan. We included pregnant women who underwent cerclage at 12–25 weeks of gestation due to threatened abortion or premature delivery associated with cervical insufficiency. The threatened abortion or premature delivery associated with cervical insufficiency was diagnosed if previous abortion or premature delivery had been diagnosed as cervical insufficiency or if transvaginal ultrasound showed the cervical length less than 25 mm in this pregnancy. Specialist physicians certified by the Japan society for obstetrics and gynecology performed the cervical cerclage, with different surgeons and teams across the four perinatal medical centers.

The local ethics committee approved this study (approval number: UOEHCRB19-037). The institutional ethics review board waived written informed consent as an opt-out policy. All procedures followed the relevant guidelines and regulations of the institutional ethics review board and the Declaration of Helsinki.

First, we analyzed the main factors leading to non-term birth by grouping the patients into non-term and term birth groups (Fig. 1, Grouping 1). We collected the following data from medical records: the maternal age at cervical cerclage, gravidity, parity, maternal height and weight, smoking history, history of a cervical cone biopsy, history of premature birth and cervical cerclage, white blood cell (WBC) count, C-reactive protein (CRP) level, gestational age at cerclage, pre-and post-cerclage CL, blood loss volume during cerclage, cerclage procedure duration, post-cerclage hospital length of stay, and post-cerclage ritodrine administration period.

Second, we analyzed the factors associated with successful cervical cerclage. This study classified the cerclage procedure modality as ultrasound-indicated cervical cerclage if the pre-cerclage CL was <25 mm because the prophylactic and therapeutic cerclage definitions varied among the institutions. Additionally, we defined successful cerclage as a pregnancy latency ≥13 weeks from cerclage to delivery [8]. Furthermore, a pregnancy latency of ≥13 weeks was considered a promising duration to obtain significantly improved pregnancy outcome, since this means that a 14 week gestation at cerclage may reach to a 27 week gestation at delivery. Therefore, we divided the patients into two groups (pregnancy latency ≥13 weeks and <13 weeks) and explored clinical factors between the successful and unsuccessful cerclage groups (Fig. 1, Grouping 2). Moreover, receiver operating characteristic (ROC) curves were used to calculate the pre-cerclage CL cut-off value required to predict if pregnancy could be sustained for >13 weeks after cerclage. Thus, we extracted significant factors for a successful cervical cerclage for long-term pregnancy sustenance in women with cervical insufficiency.

Statistical analyses were performed using JMP software (JMP version 11; SAS Institute Inc., Cary, NC, USA). The chi-square test, Fisher's exact test, and Wilcoxon rank-sum test were used for group comparisons. Statistical significance was set at $P < 0.05$.

This work has been reported in line with the STROCSS criteria [9].

3. Results

We identified 114 pregnant women who underwent cerclage during the study period; 91 patients met the inclusion criteria. We excluded 15 women with unknown pregnancy outcomes and eight women with multiple gestations (Fig. 1). Of the included patients, 60 (65.9%) and 31 (34.1%) women had term and non-term births, respectively. Furthermore, in the non-term birth group, 26 (83.9%) and five (16.1%) women had preterm births and abortions after cerclage, respectively. No serious complications, such as membrane rupture, uncontrollable bleeding, or bladder and/or rectum injuries, occurred during cerclage.

There were no significant differences in the baseline characteristics between the non-term and term birth groups (Table 1). In addition, the proportion of patients with a history of cervical cone biopsy and preterm birth was not significantly different between the groups. However, the proportion of patients with cervical insufficiency was slightly higher in

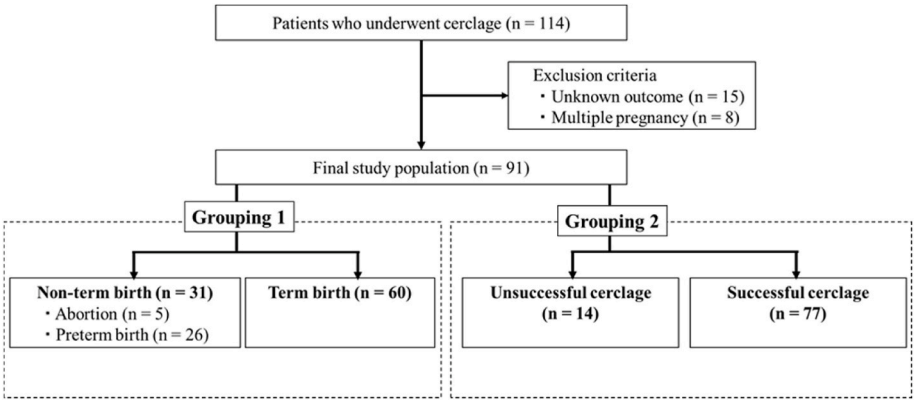

Fig. 1. Flow chart depicting participant selection and classification. Grouping 1 compared women with non-term and term births. Grouping 2 compared women who underwent unsuccessful and successful cerclage. Successful cerclage was defined as a cerclage-sustained pregnancy of 13 weeks or more.

Table 1
Baseline characteristics.

	Non-term births (n = 31)	Term births (n = 60)	P-value
GW at delivery	32 w 4 d [24 w 6 d–36 w 0 d]	38 w 4 d [37 w 3 d–39 w 4 d]	NA
Maternal age (years)	33 [28–36]	34 [27–38]	0.39
Gravidity	3 [2–4]	3 [2–5]	0.35
Parity	1 [0–2]	1 [1–2]	0.33
H (cm)	157 [154–162]	159 [154–161]	0.33
BW (kg)	54 [50–58]	52 [48–63]	0.91
Smoker (%)	2 (6.5%)	8 (13%)	0.37
History of CB (%)	2 (6.5%)	10 (17%)	0.18
History of PB (%)	13 (42%)	26 (43%)	0.81
History of CI (%)	4 (13%)	27 (45%)	0.06

Data are presented as medians [interquartile ranges] or numbers and percentages. P-values were calculated using the Wilcoxon rank-sum test. Non-term births included abortions and preterm births. Abbreviations: GW, gestational weeks; H, height; BW, body weight; CB, cone biopsy of the uterine cervix; PB, preterm birth; CI, cervical insufficiency; NA, not applicable; w, weeks; d, days.

the term birth group than in the non-term birth group, with a borderline significant difference (P = 0.06).

Table 2 presents the clinical conditions of the non-term and term birth groups. The ultrasound-indicated cervical cerclage rate was significantly higher in the non-term birth group than in the term birth group (68% vs. 38%, P < 0.01). Moreover, the post-cerclage hospitalization duration and tocolytic agent use were significantly longer in the non-term birth group than the term birth group (19 vs. 8 days, P = 0.03; 8 vs. 0 days, P < 0.01, respectively). Pregnancy latency from cerclage to delivery was significantly shorter in the non-term birth group than in the term birth group (228 vs. 270 days, P < 0.01). However, inflammatory marker levels (WBC and CRP) were normal in both groups, with no significant between-group difference (P > 0.05).

Table 3 presents the patients' clinical conditions in the successful and unsuccessful cerclage groups. There were no differences in the proportion of patients with a history of cervical cone biopsy, preterm birth, and cervical insufficiency between the groups. However, the rate of ultrasound-indicated cervical cerclage was significantly higher in the unsuccessful group than in the successful group (79% vs. 43%, P = 0.01). Inflammatory marker levels were normal in both groups, with no significant between-group difference (P > 0.05).

ROC curve analysis determined a 17-mm CL cut-off value for pregnancy sustenance for more than 13 weeks post cerclage (Fig. 2). We found that 87% of patients with a pre-cerclage CL ≥ 17 mm sustained their pregnancies for more than 13 weeks post cerclage, and 64% of patients with a pre-cerclage CL < 17 mm did not.

Table 2
Clinical findings in the non-term and term birth groups.

	Non-term births (n = 31)	Term births (n = 60)	P-value
WBC (/μL)	7970 [6800–10,560]	7970 [6300–8740]	0.16
CRP (mg/dL)	0.24 [0.1–0.3]	0.125 [0.0–0.4]	0.58
GW at cerclage	18 w [14–20]	15 w [14–19]	0.16
Pre-cerclage CL (mm)	21 [13–33]	30 [19–38]	**0.03***
Prophylactic cerclage	10 (32%)	37 (62%)	< **0.01***
Therapeutic cerclage	21 (68%)	23 (38%)	< **0.01***
Blood loss of operation (g)	30 [10–7]	30 [20–50]	0.83
Operation time (min)	30 [16–35]	22 [15–30]	0.10
Post-cerclage CL (mm)	33 [25–38]	36 [28–41]	0.23
CL from suture to EOS (mm)	16 [14–19]	16 [14–20]	0.85
Hospitalization (day)	15 [7–69]	8 [7–11]	**0.03***
Duration of RIT use (day)	7 [1–28]	0 [0–4]	< **0.01***
Pregnancy latency (day)	112 [52–119]	155 [128–174]	< **0.01***

Data are presented as medians [interquartile ranges] or numbers and percentages. The P-value was calculated using the Wilcoxon rank-sum test; * indicates statistical significance. Non-term births included abortions and preterm births. Pregnancy latency was defined as the duration from cerclage to delivery. WBC, white blood cells; CRP, C-reactive protein; GW, gestational weeks; CL, cervical length; EOS, external OS; RIT, Ritodrin; w, weeks.

Table 3
Clinical findings in the unsuccessful and successful cerclage groups.

	Unsuccessful cerclage (n = 14)	Successful cerclage (n = 77)	P-value
GW at delivery	24 w 6 d [21 w 2d–36 w 5 d]	38 w 0 d [36 w 6 d–39 w 5 d]	NA
Maternal age (year)	35 [28–38]	33 [28–36]	0.35
Gravidity	2.5 [1.8–5]	3 [2–4]	0.71
Parity	1 [0.8–2]	1 [1–2]	0.49
History of CB	0 (0%)	12 (16%)	0.20
History of PB	4 (29%)	35 (45%)	0.23
History of CI	1 (7.1%)	21 (27%)	0.07
WBC (μ/L)	7600 [6520–8800]	8340 [6660–12,600]	0.15
CRP (mg/dL)	0.21 [0.07–0.34]	0.1 [0.09–0.33]	0.53
Prophylactic cerclage	3 (21%)	44 (57%)	**0.01***
Therapeutic cerclage	11 (79%)	33 (43%)	**0.01***
Operation time (min)	27.5 [14–61]	35 [5–75]	0.96
Pregnancy latency (day)	43 [11–84]	147 [119–171]	NA

Data are presented as medians [interquartile ranges] or numbers and percentages. The P-value was calculated using the Wilcoxon rank-sum test; * indicates statistical significance. The successful group included women whose pregnancy latency was 13 weeks or more after cerclage. Pregnancy latency was defined as the duration from cerclage to delivery. GW, gestational weeks; CB, cone biopsy of the uterine cervix; PB, preterm birth; CI, cervical insufficiency; WBC, white blood cells; CRP, C-reactive protein; NA, not applicable; w, weeks; d, day.

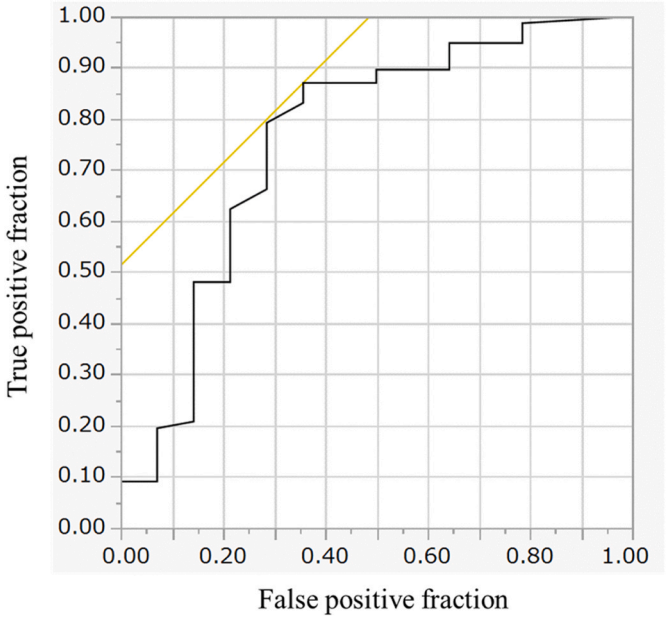

Fig. 2. Receiver operating characteristic (ROC) curve. An ROC curve was created to predict long-term pregnancy latency (13 weeks or more) after cerclage. The pre-cerclage cervical length cut-off value to obtain long-term pregnancy latency was 17 mm (area under the curve: 0.76, P-value: 0.0016).

4. Discussion

Pregnant women with a history of typical spontaneous abortion associated with cervical insufficiency undergo prophylactic cervical cerclage. However, a patient's medical history alone is insufficient to diagnose cervical insufficiency in pregnant women with actual cervical insufficiency [10]. In this study, prophylactic cerclage was significantly associated with term birth, but a history of preterm birth was not significantly associated with preterm birth and abortion. Although we could not evaluate whether pregnant women who underwent prophylactic cerclage indeed had cervical insufficiency, prophylactic cerclage is a promising therapy for cervical insufficiency diagnosed using a patient's medical history.

In this study, therapeutic cerclage was significantly associated with preterm birth and abortion. Unsurprisingly, the therapeutic cerclage outcome was worse than that of prophylactic cerclage. However, therapeutic cerclage is not useless for women with cervical insufficiency diagnosed during pregnancy. This study's principal and novel finding is that therapeutic cerclage is a promising strategy for pregnant women with cervical insufficiency and a pre-cerclage CL $\geq$ 17 mm as it results in long-term pregnancy sustenance (>13 weeks post cerclage). However, therapeutic cerclage is only effective in pregnant women with a pre-cerclage CL $\leq$ 10 mm without a history of preterm birth [5]. In a previous study, a cerclage group consisting of pregnant women with CLs $\leq$15 mm at 22–24 weeks gestation had fewer preterm births before 32 weeks than the non-cerclage group [11]. The exact reason for the discrepancy between our findings and those of previous studies is unknown; however, it may have been influenced by differences in the definitions of successful cervical cerclage and therapeutic cerclage indications between the studies.

The 2020 Guideline for Obstetrical Practice in Japan recommends obtaining WBC and serum CRP levels before cervical cerclage as cervicitis and intrauterine infection can render cerclage ineffective [12]. Furthermore, a high pre-cerclage cervical interleukin 8 (IL-8) level significantly increases the preterm birth rate; in women with subclinical cervicitis associated with elevated IL-8 levels, cerclage exerts a counterproductive effect on pregnancy outcomes [13].

As the physicians abided by the 2020 Guideline for Obstetrical Practice in Japan, all patients in our study had normal pre-cerclage WBC and CRP levels, which were not significantly associated with preterm birth, abortion, and unsuccessful cervical cerclage [15]. Although cervical IL-8 levels were not measured in our study population, 87% of women with normal WBC and CRP levels and a pre-cerclage CL $\geq$ 17 mm sustained their pregnancies for >13 weeks post cerclage. Hence, the measurement of cervical IL-8 levels before cerclage may be unnecessary.

ROC curve analysis in the present study indicated that 64% of patients with a pre-cerclage CL < 17 mm did not sustain their pregnancies for up to 13 weeks post cerclage. Thus, pregnant women with a severely shortened pre-cerclage CL are likely to have a preterm birth even if the cerclage is performed appropriately. The use of an Arabin pessary in addition to cervical cerclage is reportedly an option to prevent preterm birth in patients with a CL less than the third percentile [14,15]. Furthermore, a previous study reported that using vaginal progesterone in addition to cervical cerclage in women with a CL < 10 mm significantly decreased the overall spontaneous preterm birth rate and overall neonatal morbidity and mortality. Moreover, the same study showed that the average pregnancy latency was 14 weeks in patients who underwent a combination of cerclage and vaginal progesterone administration; the pregnancy latency period was two times longer than that of patients who received only vaginal progesterone [16]. Thus, additional treatments, such as an Arabin pessary and vaginal progesterone, may improve pregnancy outcomes.

This study had five limitations. First, this was not a randomized controlled trial. Therefore, we could not adequately verify the true efficacy of cerclage. Second, in this study, the therapeutic cerclage group may have included a small number of prophylactic cerclage cases, potentially improving pregnancy outcomes. Third, we defined efficacious cerclage as one that enabled the pregnancy to continue for at least 13 weeks. Hence, the pregnancy outcomes may differ with various efficacious cerclage definitions. Fourth, as described in the introduction, physicians in the four perinatal medical centers may have performed cerclage for different indications (i.e., with differential degrees of uterine contraction before cerclage), as there is no well-established clinical indication for cerclage. Lastly, the cervical cerclage such as Shirodkar's and McDonald's operation are universal and well-established operation, however, the surgeon, and their relative experience and proficiency, may differ across the four perinatal medical centers, which may affect the over-all outcome of the operation.

In conclusion, the pre-cerclage CL predicts long-term pregnancy sustenance regardless of a medical history of cervical insufficiency. We speculate that the use of other treatment options in addition to cerclage in women with a pre-cerclage CL < 17 mm may result in a successful pregnancy.

Ethical approval

The ethics committee of the University of Occupational and Environmental Health, Japan, approved this study (approval number: UOEHCRB19-037).

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