Pre-Cerclage Cervical Length—A Reliable Predictor of Long-Term Pregnancy Sustenance After Therapeutic Cervical Cerclage: A Retrospective Study

Emi Kondo  
National hospital organization Kokura Medical Center

Eiji Shibata (✉ age-s@med.uoeh-u.ac.jp)  
University of Occupational and Environmental Health University of Occupational and Environmental Health

Toshihide Sakuragi  
University of Occupational and Environmental Health University of Occupational and Environmental Health

Yukiyo Aiko  
Kyushu Hospital

Takeshi Kawakami  
Kyushu Hospital

Takeshi Takashima  
Kitakyushu Municipal Medical Center

Kiyoshi Yoshino  
University of Occupational and Environmental Health University of Occupational and Environmental Health

Naofumi Okura  
National hospital organization Kokura Medical Center

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Abstract

Background: The indication of therapeutic cerclage is still controversial. The purpose of this study was to assess pregnancy outcomes after cervical cerclage in women with shortened cervical length (CL) during pregnancy and/or with a medical history of cervical insufficiency.

Methods: We included pregnant women who underwent cerclage in four perinatal medical centers between January 2009 and December 2010. We compared the outcomes of cerclage in terms of non-term and term births, as well as successful and unsuccessful cerclages. Cervical cerclage was defined as successful if pregnancy was continued for more than 13 weeks post-cerclage. Therapeutic and prophylactic cerclages were performed in pregnant women with pre-cerclage CL < 25 mm and ≥ 25 mm, respectively.

Results: We screened 114 pregnant women, of whom 91 were included; 15 and 8 women were excluded for unknown pregnancy outcomes and multiple gestation, respectively. The rate of therapeutic cerclage was significantly higher in the non-term birth (68% vs. 38%, p <0.01; non-term group vs. term birth group), unsuccessful cerclage (79% vs. 43%, p =0.01; unsuccessful cerclage vs. successful cerclage) groups. Inflammatory marker levels (white blood cell count and C-reactive protein) were normal in both group sets, albeit no significantly different between-group differences. Receiver-operating characteristic curve analysis revealed that 87% of patients with pre-cerclage CL ≥ 17 mm sustained their pregnancies for more than 13 weeks post-cerclage. However, 64% of patients with pre-cerclage CL < 17 mm did not sustain their pregnancies for more than 13 weeks post-cerclage.

Conclusions: Therapeutic cerclage should be performed in patients with cervical insufficiency having CL ≥ 17 mm, for long-term pregnancy sustenance.

Background

Cervical insufficiency is a condition in which the cervix dilates in the second trimester of pregnancy without symptoms or signs such as uterine contractions and amniotic fluid leakage. However, the etiology of this disease has not been fully elucidated. Cervical insufficiency is clinically diagnosed in patients with a previous typical spontaneous abortion that may be associated with cervical length (CL) shortening on transvaginal ultrasonography. Cervical cerclage is performed as a prophylactic or therapeutic modality for patients with cervical insufficiency. Cervical cerclage can be performed under the following three 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 abovementioned conditions to prevent premature birth from cervical insufficiency1.

Transvaginal ultrasonographic CL measurement is more objective than pelvic examination, and can potentially lead to an early diagnosis of threatened preterm birth2. A shortened CL on transvaginal
ultrasonography is related to preterm birth\(^3\). Moreover, when the CL is \(\leq 30\) mm or \(\leq 26\) mm at 24 weeks of gestation, the odds ratio for preterm birth at \(< 35\) weeks’ gestation increased to 3.79 and 6.19, respectively. Using receiver-operating characteristic (ROC) curve analysis, a previous study reported a cutoff CL of 25 mm for preterm birth occurring at 15–24 weeks of gestation\(^4\).

However, cervical insufficiency is asymptomatic, therefore, cervical shortening and dilation are difficult to detect in appropriate timing. Pregnant women with severely dilated cervix associated with bulging of amniotic membrane cannot undergo cerclage, and thus preterm birth is unavoidable for them. In singleton pregnancies without prior spontaneous preterm birth, cerclage for pregnant women with CL \(< 25\)mm does not seem to prevent preterm delivery or improve neonatal outcome, however, cerclage for pregnant women with CL \(< 10\)mm seems to be efficacious in the second trimester\(^5\). Therefore, for therapeutic cervical cerclage to be successful, it is crucial to detect a shortened CL using transvaginal ultrasonography, and perform cervical cerclage before severe cervical dilation occurs\(^5\). However, there is no established consensus regarding the clinical indications for therapeutic cervical cerclage.

In this study, we sought to investigate the usefulness of cervical cerclage in pregnant women with cervical insufficiency, and to evaluate the predictive factors for successful cervical cerclage.

**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: University of Occupational and Environmental Health, Kitakyushu Municipal Medical Center, Japan Community Health Care Organization Kyushu Hospital, and National Hospital Organization Kokura Medical Center.

Cervical cerclage was performed under the following two conditions: prophylactic cerclage for pregnant women with a medical history of cervical insufficiency, and therapeutic cerclage for pregnant women with CL shortening and/or incidentally observed cervical dilation. In this study, we defined prophylactic and therapeutic cerclages as cerclages performed in pregnant women with a CL \(\geq 25\) mm and \(< 25\) mm\(^6\), respectively.

First, we analyzed the main factors leading to non-term birth. We grouped the patients into non-term and term birth groups (Fig. 1; Grouping 1). The following parameters were collected from medical records: maternal age at cervical cerclage, gravidity, parity, maternal height, maternal weight, smoking history, history of cervical cone biopsy, history of premature birth and history of cervical cerclage, white blood cell count (WBC), C-reactive protein (CRP) level, gestational age at cerclage, pre-cerclage CL, 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. Based on findings from a previous study, we defined successful cerclage as pregnancy latency \(\geq 13\) weeks from cerclage to
delivery\textsuperscript{7}. Furthermore, pregnancy latency $\geq 13$ weeks was thought to be sufficient to obtain significantly improved pregnancy outcomes. Therefore, we divided the patients into two groups (those with pregnancy latency $\geq 13$ weeks and $< 13$ weeks), and explored clinical factors between successful and unsuccessful cerclage groups (Fig. 1; Grouping 2). Moreover, ROC curves were used to calculate the pre-cerclage CL cut-off value required to determine whether pregnancy could be sustained for more than 13 weeks after cerclage.

Thus, we extracted significant factors for successful cervical cerclage; that is for long-term pregnancy sustenance in women with cervical insufficiency.

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

**Results**

We collected data from 114 pregnant women who underwent cerclage. Overall, 91 patients met the inclusion criteria; we excluded 15 and 8 women with unknown pregnancy outcomes and multiple gestation, respectively (Fig. 1). Of the included patients, 60 (65.9\%) and 31 (34.1\%) had term and non-term births, respectively. Furthermore, in the non-term birth group, 26 (83.9\%) and 5 (16.1\%) had preterm birth and abortion after cerclage, respectively. In our sample population, no serious complications occurred during cerclage, such as rupture of membranes, uncontrollable bleeding, or injuries to the bladder and/or rectum.

There were no significant differences in baseline characteristics between the non-term and term birth groups (Table 1). The proportion of patients with previous cervical cone biopsy and preterm birth was not significantly different between the two groups. However, the proportion of patients with cervical insufficiency was slightly higher in the term than in the non-term birth group, with a borderline significant difference.


Table 1
Baseline characteristics of the study population

|                          | Non-term birth (n = 31) | Term birth (n = 60) | P-value |
|--------------------------|-------------------------|---------------------|---------|
| GW at delivery           | 32w4d [24w6d-36w0d]     | 38w4d [37w3d-39w4d] | 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    |
| BH (cm)                  | 157 [154–162]           | 159 [154–161]       | 0.33    |
| BW (kg)                  | 54 [50–58]              | 52 [48–63]          | 0.91    |
| Smoker (%)               | 2 (2.5%)                | 8 (10%)             | 0.37    |
| History of CB (%)        | 2 (2.2%)                | 10 (11%)            | 0.18    |
| History of PB (%)        | 13 (14%)                | 26 (26%)            | 0.81    |
| History of CI (%)        | 4 (4.4%)                | 27 (30%)            | 0.06    |

Data are presented as median [interquartile range] or number and percentage. P-values were calculated using the Wilcoxon rank sum test. Non-term births included abortion and preterm birth.

GW, gestational weeks; BH, body height; BW, body weight; CB, cone biopsy of the uterine cervix; PB, preterm birth; CI, cervical insufficiency; NA, not applicable; w, week; d, day

Table 2 shows the clinical conditions of the non-term and term birth groups. The rate of therapeutic cerclage was significantly higher in the non-term birth group (68% vs. 38%, p < 0.01; non-term group vs. term birth group). Moreover, the post-cerclage durations of hospitalization and tocolytic agent use were significantly longer in the non-term group (19 vs. 8 days, p = 0.03 [hospitalization]; 8 vs. 0 days, p < 0.01 [tocolytic agent use]: non-term group vs. term birth group). Pregnancy latency from cerclage to delivery was significantly shorter in the non-term birth group (228 vs. 270 days, p < 0.01; non-term vs. term birth group). However, inflammatory marker levels (WBC and CRP) were normal in both groups, with no significant between-group difference.
| Non-term birth (n = 31) | Term birth (n = 60) | P-value |
|------------------------|---------------------|---------|
| WBC (/µL)              | 7970 [6800–10560]   | 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         | 18w [14–20]         | 15w [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(81%)             | 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 median [interquartile range or number and percentage. The P value was calculated using the Wilcoxon rank sum test, and a P value less than 0.05* was considered significant. Non-term births included abortion and preterm birth. Pregnancy latency was defined as the duration from cerclage to delivery. GW, gestational weeks; CL, cervical length; EOS, external OS; RIT, Ritodrin; w, weeks.

Table 3 shows the clinical conditions of patients in the successful and unsuccessful cerclage groups. There were no differences in the proportions of patients with previous cervical cone biopsy, preterm birth, and cervical insufficiency between the two groups. The rate of therapeutic cerclage was significantly higher in the unsuccessful group (79% vs. 43%, p = 0.01; unsuccessful vs. successful cerclage group). Inflammatory marker levels were normal in both groups, with no significant between-group difference.
Table 3
Comparison of clinical findings in the unsuccessful and successful groups.

|                                | Unsuccessful cerclage (n = 14) | Successful cerclage (n = 77) | P-value |
|--------------------------------|--------------------------------|-----------------------------|---------|
| GW at delivery                 | 24w6d [21w2d-36w5d]            | 38w0d [36w6d-39w5d]         | 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 (13%)                    | 0.20    |
| History of PB                  | 4 (4.4%)                      | 35 (38%)                    | 0.23    |
| History of CI                  | 1 (1.1%)                      | 21 (23%)                    | 0.07    |
| WBC (µ/L)                      | 7600 [6520–8800]              | 8340 [6660–12600]           | 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 median [interquartile range] or number and percentage. The P value was calculated using the Wilcoxon rank sum test, and a P value less than 0.05* was considered significant. The successful group included pregnant 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; NA, not applicable; w, week; d, day.

ROC curve analysis showed a CL cut-off value of 17 mm for pregnancy sustenance for more than 13 weeks post-cerclage (Fig. 2). We found that 87% of patients with pre-cerclage CL \( \geq 17 \) mm sustained their pregnancies for more than 13 weeks post-cerclage. However, 64% of patients with pre-cerclage CL < 17 mm sustained their pregnancies for more than 13 weeks post-cerclage.

**Discussion**

Prophylactic cervical cerclage is performed in pregnant women with a medical history of previous typical spontaneous abortion associated with cervical insufficiency. The use of the medical history is insufficient
to diagnose cervical insufficiency in pregnant women with true cervical insufficiency\textsuperscript{8,9}.

In the present study, prophylactic cerclage was significantly associated with term birth; nevertheless, a history of preterm birth was not significantly associated with the occurrence of preterm birth and abortion. Although we could not evaluate whether pregnant women who underwent prophylactic cerclage truly had cervical insufficiency, prophylactic cerclage should be considered as a promising therapy for cervical insufficiency diagnosed using a typical medical history.

Preterm birth was significantly reduced after therapeutic cerclage among high-risk pregnant women with a history of preterm birth\textsuperscript{10}. Therapeutic cerclage reduces neonatal morbidity and mortality in pregnant women having a history of spontaneous preterm birth with gestational age < 34 weeks, or in women with ongoing singleton pregnancies having a CL less than 25 mm at a gestational age < 24 weeks\textsuperscript{11}. Further, therapeutic cerclage is reportedly effective in pregnant women with a CL ≤ 10 mm having no preterm birth history, albeit not effective in women with singleton pregnancies having no preterm birth history and with a CL ≤ 25 mm\textsuperscript{5}. According to a Japanese randomized controlled trial (RCT), the gestational period was not significantly prolonged after therapeutic cerclage; however, the proportion of patients requiring preterm birth management was significantly reduced in pregnant women with a short CL ≤ 25.0 mm who underwent therapeutic cerclage between 16- and 26-week gestations\textsuperscript{12}. In contrast to these previous study findings, several studies have reported negative effects of therapeutic cerclage in pregnant women with a shortened CL and without a preterm birth history\textsuperscript{13}. Thus, there is no established consensus regarding the clinical indications for therapeutic cervical cerclage.

In the present study, therapeutic cerclage was significantly associated with preterm birth and abortion. Obviously, the outcome of therapeutic cerclage is worse than that of prophylactic cerclage. However, therapeutic cerclage is not a useless therapy for women with cervical insufficiency diagnosed during an ongoing pregnancy. The principal new finding of this study is that therapeutic cerclage is a promising therapeutic strategy for pregnant women with cervical insufficiency having a pre-cerclage CL ≥ 17 mm, as it produces a long-term pregnancy sustenance > 13 weeks post-cerclage. However, therapeutic cerclage is effective only in pregnant women with a pre-cerclage CL ≤ 10 mm and without a history of preterm birth\textsuperscript{5}. In a previous study, a cerclage group, having pregnant women with CL ≤ 15 mm at 22 to 24 weeks' gestation, had fewer preterm births before 32 weeks of gestation compared with a non-cerclage group\textsuperscript{13}. We do not know the exact reason for this discrepancy between our findings and previous study findings. The abovementioned discrepancy may have been influenced by the difference in outcomes of successful cervical cerclage and indications of therapeutic cerclage between the studies.

Guideline for Obstetrical Practice in Japan 2020 recommend the measurement of WBC and serum CRP levels before cervical cerclage, as cervicitis and intrauterine infection can render cerclage ineffective\textsuperscript{14}. Furthermore, high pre-cerclage cervical interleukin 8 (IL-8) levels significantly increase the rate of preterm birth, and cerclage exerts a counterproductive effect on pregnancy outcomes in women with subclinical cervicitis associated with high IL-8 levels\textsuperscript{15}.
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. The pre-cerclage WBC and CRP levels were normal range in all patients because physicians abided by Guideline for Obstetrical Practice in Japan 2020\textsuperscript{14}. Cervical IL-8 levels were not measured in our study population. Eighty-seven percent of pregnant women with normal WBC and CRP levels and pre-cerclage CL ≥17 mm sustain their pregnancies for > 13 weeks post-cerclage; hence, it may be unnecessary to measure cervical IL-8 levels before cerclage.

ROC curve analysis in the present study revealed that 64\% of patients having pre-cerclage CL < 17 mm sustained their pregnancies for up to 13 weeks post-cerclage. Thus, pregnant women with severely shortened pre-cerclage CL are likely to have a preterm birth, even if the cerclage procedure is performed appropriately. The use of Arabic pessary, in addition to cervical cerclage, is reportedly an option for preventing preterm birth in patients with CL less than the third percentile\textsuperscript{16,17}. A previous study reported that, in addition to cervical cerclage, the use of vaginal progesterone in women with shortened CL < 10 mm significantly decreases overall spontaneous preterm birth rates 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; there was a two-fold prolongation in the pregnancy latency period with respect to that of patients who received only vaginal progesterone\textsuperscript{18}. Thus, additional treatments such as the use of Arabic pessary and vaginal progesterone may contribute to better pregnancy outcomes.

This study had three serious limitations. First, this study was not an RCT; therefore, the true efficacy of therapeutic cerclage was not adequately verified. Second, we defined efficacious cerclage as one that enabled the maintenance of pregnancy for at least 13 weeks; hence, the pregnancy outcomes may be different if different definitions of efficacious cerclage are used. Lastly, as described in the introduction, physicians in the four perinatal medical centers might have performed therapeutic cerclage for different indications (i.e., with differential degrees of uterine contraction before cerclage), as there is no well-established clinical indication for therapeutic cerclage.

**Conclusions**

Therapeutic cerclage should be performed in pregnant women with pre-cerclage CL ≥ 17 mm. Furthermore, we speculate that the use of other treatment options in addition to therapeutic cerclage may produce successful pregnancy outcomes if the pre-cerclage CL is < 17 mm.

**Abbreviations**

CL
cervical length
CRP
C-reactive protein
Declarations

Ethics approval and consent to participate:

This study was approved by the ethics committee of the University of Occupational and Environmental Health, Japan (approval number: UOEHCRB19-037). The written informed consent was waived, as an opt-out policy was approved by the institutional ethics review board. All procedures were performed in accordance with the relevant guidelines and regulations of the institutional ethics review board and the Declaration of Helsinki.

Consent for publication:

Not applicable

Availability of data and materials:

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests:

The authors declare that they have no competing interests.

Funding:

Not applicable.

Authors' contributions:

Emi Kondo and Eiji Shibata were responsible for the design of the study and wrote the manuscript. All authors read and approved the final version of the manuscript.

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**Figures**

**Figure 1**

Flow chart for selecting final studied population and grouping for comparison. Grouping 1 was used for the comparison of non-term and term birth groups. Grouping 2 was used to compare the unsuccessful and successful cerclage groups. Successful cerclage was defined as a cerclage-sustained pregnancy for 13 weeks or more.
Figure 2

ROC (receiver operating characteristic) curve An ROC curve was created to predict long-term pregnancy latency (13 weeks or more) after cerclage. The cut-off value of pre-cerclage cervical length was 17 mm for obtaining long-term pregnancy latency (AUC: 0.80, P value < 0.01).