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Prophylactic Cerclage to Prevent Preterm Birth after Conization: A Cohort Study Using Data from the National Health Insurance Service of Korea

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Purpose: To investigate potential differences in the frequency of preterm births (PTB) between pregnancies with or without prophylactic cerclage in women with a history of conization.

Materials and Methods: We identified women who had their first singleton delivery after conization between 2013 and 2018 using records in the National Health Insurance Service of Korea claims database. We only included women who had undergone a health examination and interview within 2 years before delivery. We used timing of maternal serum alpha-fetoprotein (MSAFP) tests to differentiate early (before) from late (after the MSAFP test) cerclage. The frequency of adverse pregnancy outcomes, including PTB, preterm labor and premature rupture of membranes, antibiotics and tocolytics use, cesarean delivery, and number of admissions before delivery, were compared.

Results: A total of 8322 women was included. Compared to the no cerclage group (n=7147), the risks of adverse pregnancy outcomes were higher in the cerclage group (n=1175). After categorizing patients with cerclage into two groups, the risk of PTB was still higher in the early cerclage group than in the no cerclage group after adjusting for baseline factors (4.48%, 30/669 vs. 2.77%, 159/5749, odds ratio 2.42, 95% confidence interval 1.49, 3.92). Other adverse pregnancy outcomes were also more frequent in the early cerclage group than the no cerclage group.

Conclusion: Early cerclage performed before MSAFP testing does not prevent PTB in pregnancy with a history of conization, but increases the risk of adverse pregnancy outcomes, including PTB.

Key Words: Conization, cervical cerclage, preterm birth, preterm labor, prevention, epidemiology

INTRODUCTION

It is widely accepted that conization or loop electrosurgical excision procedure to remove cervical intraepithelial lesions is associated with an increased risk of preterm birth.[1-6] Although the reason for this increase is unclear, cervical cerclage is widely performed to prevent preterm birth in patients with a previous history of conization. Currently, the practice of prophylactic cerclage is not based on firm evidence. Several retrospective case-control and cohort studies, as well as a systematic review, have indicated that the cerclage procedure may not prevent preterm birth.[7-9] One retrospective cohort study even reported that the risk of early preterm birth (≤34 weeks of gestation) is increased with cerclage.[10] However, those studies suffered from a small number of subjects. To overcome the limitation of small sample sizes, Cho, et al.[11] used the claims database of the National Health Insurance Service (NHIS) of Korea to look at the risk of preterm birth after conization.[11] In the report, they in-

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cluded more than 1000 subjects and found that the cerclage is associated with an increased risk of preterm birth in women who have undergone conization. However, the timing of the procedure may matter because if the cerclage was performed when they had symptoms of cervical insufficiency, such as cervical dilatation and bulging membranes, an increased risk of preterm birth may have already been present. Therefore, it would be very informative to evaluate the risk of preterm births according to the timing of the procedure.

The purpose of this study was to determine if the risk of preterm birth is higher in patients with cerclage after conization before pregnancy, compared to patients without cerclage, and to evaluate if there is a difference in the risk of preterm birth according to the timing or indications of cerclage after conization using the NHIS claims database.

MATERIALS AND METHODS

Study population

We performed a retrospective cohort study of customized health information from the NHIS claims database, which covers about 97% of the entire population of Korea (the remaining 3% are covered by Medical Aid). The NHIS data can be extracted and used for research purposes upon request (https://nhiss.nhis.or.kr). We identified all women who underwent conization procedures between 2002 and 2018 and had a singleton delivery between 2013 and 2018 using diagnoses based on the International Classification of Disease, 10th revision codes (ICD-10) and procedure codes.

As part of the NHIS program, subscribers and beneficiaries who satisfy specific criteria are invited to participate in a biannual National Health Screening Examination (NHSE), and their screening results are recorded in the NHIS database. The NHSE program includes a health examination and interview, which encompasses questions regarding demographic, socioeconomic, and lifestyle status. We only included subjects who had taken part in the NHSE program within 2 years before their first delivery after cerclage. Women with multiple pregnancies, patients on Medical Aid, and a second or more pregnancies after conization were excluded from the study.

As this study used the NHIS claims database and no identifiable patient information was used, informed consent was not obtained. The Ethics Committee of National Health Insurance Service Ilsan Hospital approved this study (approval number: NHIMC 2020-12-034, date of approval: Jan 17, 2021).

Identification of outcomes and baseline characteristics

The primary outcome was frequency of preterm births. The secondary outcomes were frequency of preterm labor and preterm premature rupture of membranes (PROM), length of stay at admission and number of admissions before delivery, antibiotics use, tocolytics use, and the rate of cesarean delivery. Preterm birth was defined as birth before 37 weeks of gestation, and ICD-10 codes O60.1 and O60.3 were used to search the database. For the identification of preterm labor and preterm PROM, the ICD-10 codes O60.x and O42.x were used, respectively.

We collected baseline factors from NHSE data to adjust for possible confounders and included the following variables: age, body mass index (BMI), exercise, alcohol consumption, and smoking. BMI was calculated using height and weight measurements, and it was categorized as low weight (<18.5 kg/m^2), normal weight (18.5–22.9 kg/m^2), overweight (23.0–24.9 kg/m^2), and obese (≥25 kg/m^2), which was adopted from cutoffs established for South Korean adults, proposed by the Korean Society for the Study of Obesity.[12] Economic status was categorized into four groups: low, low-middle, middle-high, and high. Alcohol consumption was categorized as non-drinker or active drinker: active drinker was defined as drinking alcohol more than four times per week or more than four drinks at a time. Prepregnancy smoking was categorized as current (at the time of NHSE health interview) or non-smoker. The exercise was also categorized as non- or active, and active exercise was defined as more than three high-intensity workouts per week or more than five intermediate workouts per week. Residential area was divided into three categories: Capital area (Seoul, Gyeonggi), Metropolitan area (Incheon, Daejeon, Gwangju, Busan, Daegu, Ulsan), and Others. Diagnosis of hypertension before pregnancy was based on the relevant ICD-10 code and prescription information. Charlson comorbidity index was calculated as a measure of comorbid disease status. To do so, a weighted score was assigned to each of 17 comorbidities based on 1-year mortality. The sum of the index score is an indicator of disease burden and a strong estimator of mortality. We calculated the index using appropriate ICD-10 codes.[13]

Differentiation of the type of cerclage

As most prophylactic cerclages are performed at or before 14 weeks of gestation, we categorized cerclages using the timing of maternal serum alpha-fetoprotein (MSAFP) testing, which is usually performed between 15 and 20 weeks of gestation. Cerclages performed at or before the MSAFP test were considered as early cerclages, and those performed after the test were considered as late cerclages. First, the frequencies of pregnancy outcomes were compared between the cerclage and no cerclage groups. Then, outcomes between early cerclage and no cerclage groups were compared.

Statistical analysis

Continuous and categorical variables were compared using Student's t-test and chi-square test, respectively. Logistic regression analyses were performed to account for possible confounders, such as maternal age, years from conization to delivery, level of income, residential area, Charlson comorbidity index, smoking, drinking, exercise, and BMI. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. Statistical analyses

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were performed using SAS version 9.4 (SAS Institute, Inc., Cary, NC, USA). A p value <0.05 was considered significant.

RESULTS

There were 2354129 deliveries from 1893636 women between 2013 and 2018 in Korea and 861047 women who received NHSE within 2 years before delivery. We included 8322 subjects in the analysis after excluding second deliveries after conization, patients with missing values for the variables in the NHSE questionnaires, multiple pregnancies, and Medical Aid recipients among 14050 women who received conization before delivery during this period (Fig. 1).

Table 1 shows the baseline characteristics of the study population. Maternal age, years from conization to delivery, residential area, Charlson comorbidity index, and pregnancy history before the first pregnancy after conization differed between the cerclage and no cerclage groups. Level of income, smoking, drinking, and exercise were not different between the two groups.

We compared the outcomes between cerclage and no cerclage groups (Table 2). The frequency of admissions before delivery was 99.66% in the cerclage group and 19.73% in the no cerclage group. The mean number of admissions was 0.25±0.59 in the no cerclage group and 1.44±0.76 in the cerclage group. Antibiotics and tocolytics use was more frequent in the cerclage group. Preterm birth was significantly more frequent in the cerclage group than in the no cerclage group (8.34% vs. 3.15%, p<0.0001). Cesarean delivery, preterm labor, and preterm PROM were more frequent in the cerclage group than in the no cerclage group, the differences in which were all statistically significant.

We stratified patients according to the timing of surgery using MSAFP testing. After removing the patients without information on the timing of the MSAFP testing, there were 5749 women without cerclage, 669 women with cerclage before the MSAFP measurement, and 291 women with cerclage after the MSAFP measurement. Fig. 2 illustrates the number of patients who underwent cerclage according to the days from MSAFP testing. The histogram shows bimodal characteristics with peak incidence on the day of MSAFP testing.

Table 3 shows the outcomes of the patients according to the timing of cerclages. The number of admissions was higher in both the early cerclage (1.41±0.76) and late cerclage (1.47±0.77) groups than in the no cerclage group (0.26±0.6). The frequency of admission was nearly 100% in both the early and late cerclage groups, compared to only 20.39% in the no cerclage group. The frequency of preterm births was higher even after adjustment for maternal age, years from conization to delivery, level of income, residential area, Charlson comorbidity index, smoking, drinking, exercise, and BMI in both the early (2.77% vs.

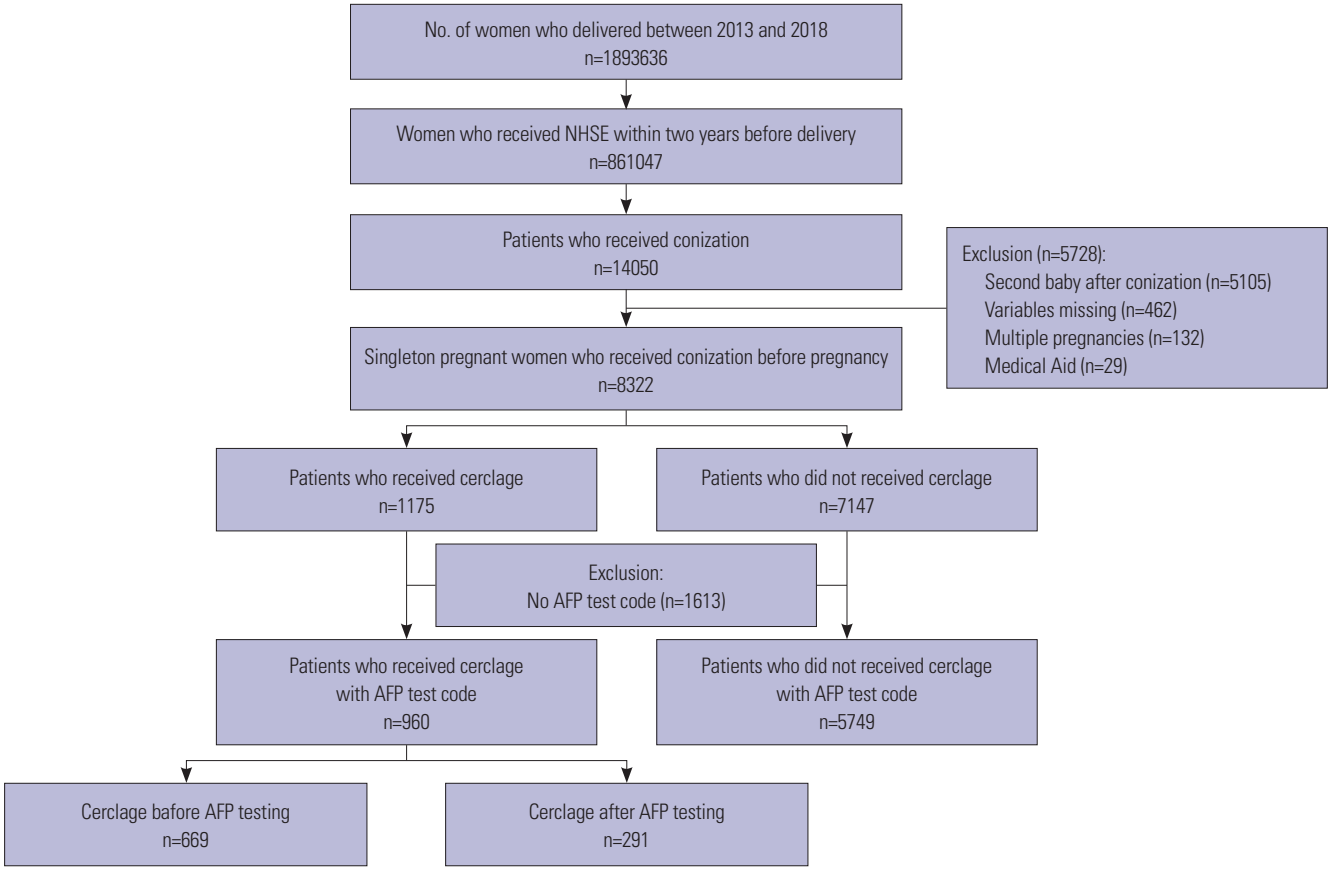

Fig. 1. Flow diagram of patient selection. NHSE, National Health Screening Examination; AFP, alpha-fetoprotein.

Table 1. Baseline Characteristics of the Study Population

	No cerclage (n=7147)	Cerclage (n=1175)	*p* value
Age (yr)	33.63±4.03	33.90±3.98	0.0356
Years from conization to delivery	4.06±2.81	3.69±2.61	<0.0001
Income level			0.1845
Low	1016 (14.22)	194 (16.51)	
Middle-low	1924 (26.92)	304 (25.87)	
Middle-high	2725 (38.13)	448 (38.13)	
High	1482 (20.74)	229 (19.49)	
Location			<0.0001
Capital area	3922 (54.88)	427 (36.34)	
Metropolitan area	1720 (24.07)	330 (28.09)	
Others	1505 (21.06)	418 (35.57)	
Charlson Comorbidity Index			<0.0001
0	4312 (60.33)	660 (56.17)	
1	1956 (27.37)	317 (26.98)	
2+	879 (12.30)	198 (16.85)	
Pregnancy Hx before the first pregnancy after conization			<0.0001
No	5031 (70.39)	213 (18.13)	
Yes	2116 (29.61)	962 (81.87)	
Smoking			0.2358
No	6784 (94.92)	1105 (94.04)	
Yes	363 (5.08)	70 (5.96)	
Drinking			0.2795
No	5668 (79.31)	915 (77.87)	
Yes	1479 (20.69)	260 (22.13)	
Exercise			0.2287
No	4339 (60.71)	691 (58.81)	
Yes	2808 (39.29)	484 (41.19)	
BMI			0.2532
Underweight (<18.5)	807 (11.29)	123 (10.47)	
Normal (18.5–22.9)	4324 (60.50)	693 (58.98)	
Overweight (23.0–24.9)	1020 (14.27)	171 (14.55)	
Obese (25.0 or over)	996 (13.94)	188 (16.00)	

Hx, history; BMI, body mass index.
Data are presented as a n (%) or mean±standard deviation.

4.48%, *p*=0.0179; adjusted OR 2.42, 95% CI 1.49, 3.92) and late cerclage group (2.77% vs. 11%, *p*<0.0001; adjusted OR 4.82, 95% CI 3.18, 7.3), compared to the no cerclage group. Antibiotics and tocolytics use, preterm labor, and cesarean delivery also were more frequent in the early cerclage group than in the no cerclage group, and the differences were statistically significant. The risk of preterm PROM was higher in the early cerclage group, with an OR of 1.62 (95% CI 1.31, 2.01), and in the late cerclage group, with an OR of 1.74 (95% CI 1.33, 2.27), compared to the no cerclage group, after adjustment.

DISCUSSION

The principal finding of this study is that there is an increased risk of preterm birth in women who undergo a cerclage after conization, compared with no cerclage. Even when the risk of preterm birth was compared between early and no cerclage using the timing of MSAFP testing, the risk of preterm birth was increased. As prophylactic cerclages are usually performed at

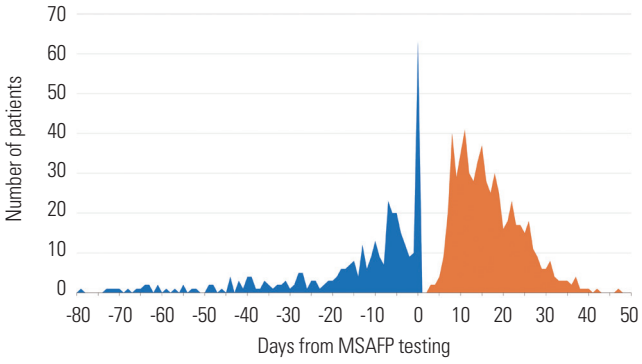

Fig. 2. Area plot of the number of the patients who underwent cerclage at the days from the MSAFP testing (x-axis). The zero in the x-axis represents the day of MSAFP testing. The positive numbers in the x-axis represent the days after MSAFP testing (orange area, late cerclages: n=291). The negative numbers represent the days before the MSAFP testing (blue area, early cerclages: n=663). Patients who undertook cerclage between -80 and -118 days from MSAFP testing were omitted from the plot (n=6). MSAFP, maternal serum alpha-fetoprotein.

Table 2. Patient Outcomes in the Cerclage and No Cerclage Groups

	No cerclage (n=7147)	Cerclage (n=1175)	*p* value	Unadjusted OR (95% CI)	Adjusted OR (95% CI)*
No. of admissions	0.25±0.59	1.44±0.76	<0.0001		
Admissions before delivery	1410 (19.73)	1171 (99.66)	<0.0001		
Antibiotics use	230 (3.22)	159 (13.53)	<0.0001	4.71 (3.81, 5.82)	6.11 (4.73, 7.9)
Tocolytics use†	316 (4.42)	259 (22.04)	<0.0001	6.11 (5.12, 7.3)	8.76 (6.93, 11.06)
Cesarean delivery‡	2901/6594 (43.99)	545/1042 (52.3)	<0.0001	1.4 (1.23, 1.59)	1.6 (1.38, 1.85)
Preterm labor	803 (11.24)	419 (35.66)	<0.0001	4.38 (3.81, 5.04)	5.97 (5.03, 7.07)
Preterm birth	225 (3.15)	98 (8.34)	<0.0001	2.8 (2.19, 3.58)	4.02 (3.01, 5.37)
Preterm PROM	1639 (22.93)	307 (26.13)	0.0182	1.19 (1.03, 1.37)	1.72 (1.47, 2.02)

OR, odds ratio; CI, confidence interval; PROM, premature rupture of membranes.
Data are presented as a n (%) or mean±standard deviation.
*Adjusted for maternal age, years from conization to delivery, level of income, residential area, Charlson comorbidity index, smoking, drinking, exercise, and body mass index, †Hypertension was additionally adjusted, ‡Type of delivery was not identified in 683 deliveries.

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Table 3. Patient Outcomes according to the Timing of Cerclages

	No cerclage (n=5749)	Early cerclage (n=669)				Late cerclage (n=291)			
	n (%)	n (%)	*p* value*	Unadjusted OR (95% CI)	Adjusted OR† (95% CI)	n (%)	*p* value‡	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
No. of admissions	0.26±0.6	1.41±0.76	<0.0001			1.47±0.77	<0.0001		
Admissions§	1172 (20.39)	666 (99.55)	<0.0001			291 (100)			
Antibiotics use	197 (3.43)	68 (10.16)	<0.0001	3.19 (2.39, 4.25)	4.04 (2.8, 5.83)	55 (18.9)	<0.0001	6.57 (4.74, 9.1)	7.22 (5.12, 10.19)
Tocolytics use‖	267 (4.64)	125 (18.68)	<0.0001	4.72 (3.75, 5.94)	6.32 (4.57, 8.75)	84 (28.87)	<0.0001	8.33 (6.29, 11.04)	10.45 (7.62, 14.33)
Cesarean delivery¶	2314/5294 (43.71)	316/601 (52.58)	<0.0001	1.43 (1.21, 1.69)	1.75 (1.44, 2.12)	141/255 (55.29)	0.0004	1.59 (1.24, 2.05)	1.73 (1.33, 2.25)
Preterm labor	663 (11.53)	196 (29.3)	<0.0001	3.18 (2.64, 3.83)	4.07 (3.23, 5.12)	141 (48.45)	<0.0001	7.21 (5.65, 9.2)	8.25 (6.39, 10.66)
Preterm birth	159 (2.77)	30 (4.48)	0.0179	1.65 (1.11, 2.46)	2.42 (1.49, 3.92)	32 (11)	<0.0001	4.34 (2.91, 6.48)	4.82 (3.18, 7.3)
Preterm PROM	1336 (23.24)	163 (24.36)	0.5464	1.06 (0.88, 1.28)	1.62 (1.31, 2.01)	87 (29.9)	0.0111	1.41 (1.09, 1.82)	1.74 (1.33, 2.27)

OR, odds ratio; CI, confidence interval; PROM, premature rupture of membranes.
Data are presented as a n (%) or mean±standard deviation.
*Comparison between no cerclage and early, †Adjusted for maternal age, years from conization to delivery, level of income, residential area, Charlson comorbidity index, smoking, drinking, exercise, and body mass index, ‡Comparison between no cerclage and late, §Admissions before delivery, ‖Hypertension was additionally adjusted, ¶Mode of delivery was not identified in 558 deliveries.

this time (before MSAFP testing), we believe that "early" cerclage represents "prophylactic" cerclage.

Since the introduction of the procedure, prophylactic cerclage has been the gold standard treatment in women with an incompetent internal os of the cervix, which is classified as history-indicated cerclage. The rationale behind the procedure is to give structural support to the weakened cervix.[14] However, the efficacy of cerclages in this patient population has not been consistent in well-designed clinical studies: two randomized trials failed to show an effect for history-indicated cerclage in reducing preterm births.[15,16] Only one randomized trial published nearly three decades ago showed a 4% risk reduction in preterm births without significant benefits to neonatal outcomes, including neonatal death, stillbirth, and miscarriage.[17]

The practice of cerclage in patients with a history of cervical conization is not based on consistent evidence as well. Several retrospective studies have examined the effect of cerclage on preventing preterm birth in patients with a history of conization. Some reported no difference in the risk of preterm birth,[7,8,18] while others reported a nonsignificant increased risk of preterm birth in patients with cerclage.[19] In one paper, Zeisler, et al.[19] concluded that prophylactic cerclage should be used more sparingly in women with a history of conization because it tends to induce preterm uterine contractions. In an individual patient-level data meta-analysis, a small number of patients who underwent cerclage after cone biopsy was included.[20] Therein, a nonsignificant increased risk of preterm birth was reported in the cerclage group. The report by Miyakoshi, et al.[18] has been the largest retrospective study to address the risk of preterm birth in patients with prophylactic cerclage after conization. Although they did not indicate the timing of the procedure, there was no difference in preterm birth in women with or without prophylactic cerclage.

We argue that the practice of prophylactic cerclage is not evidence-based and is also unethical considering various complications that occurred in the prophylactic cerclage group. In our study, hospital admission was increased, which would be expected. Antibiotics and tocolytics use was also increased. Preterm labor, preterm PROM, and cesarean delivery rates were increased in the prophylactic cerclage group after adjusting for baseline characteristics. These complications might have been reduced if it had not been for the prophylactic cerclage.

There are strengths to this study. First, our report included data from a cohort including more than 1.8 million births for the entire population of Korea. Therefore, the number of subjects is larger than any other studies on this issue. Second, we not only analyzed the risk of preterm birth in patients who underwent cerclage after conization, but also categorized risk according to the timing of the cerclage, which enabled us to analyze the risk of preterm birth in the prophylactic cerclage group. As we used NHSE study data that contained demographic, socioeconomic, and comorbidity information, we could adjust for possible confounders. In contrast, there are several limitations

to consider in interpreting our results. The NHIS data do not provide detailed information on the patients' condition. Although we used the timing of MSAFP testing to differentiate between types of cerclage, the classification might have been incorrect in some of the patients. It seems that a significant number of late cerclages were included within 1–2 weeks after MSAFP testing. The prophylactic cerclage might have been decided after MSAFP testing. Second, the diagnoses of maternal complications were based on insurance claims data from the NHIS database. As the data were designed for cost claim issues and not for research purposes, there may be some misclassifications in the diagnosis. Third, we used the ICD-10 codes O60.1 and O60.3 to search for cases of preterm birth. As a result, indicated, as well as spontaneous preterm, births might have been included in the data. Fourth, physicians may decide to perform cerclage based on cervical length. However, such data could not be obtained from the NHIS claims database. Lastly, data collected from the NHSE questionnaire are limited to pre-pregnancy status. Therefore, the data may not reflect the effects of certain behaviors during pregnancy, such as smoking, exercise, and alcohol consumption.

In conclusion, early cerclage performed before MSAFP testing during pregnancy with a history of conization does not prevent preterm birth, but increases the risk of adverse pregnancy outcomes, including admission before delivery, preterm labor, preterm PROM, antibiotics, and tocolytics use, and cesarean delivery. We suggest that cerclage procedures in women with a previous history of conization should not be performed routinely until supported by sound evidence.

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AUTHOR CONTRIBUTIONS

Conceptualization: Eui Hyeok Kim, Hyun Soo Park, and Jisun Yoon. Data curation: Eui Hyeok Kim, Sang Ah Lee, and Hyun Soo Park. Formal analysis: Hyun Soo Park and Sang Ah Lee. Funding acquisition: Eui Hyeok Kim and Hee-Sun Kim. Investigation: Hyun Soo Park and Eui Hyeok Kim. Methodology: Eui Hyeok Kim and Jisun Yoon. Project administration: Hyun Soo Park and Hee-Sun Kim. Resources: Hyun Soo Park, Hee-Sun Kim, and Jisun Yoon. Software: Sang Ah Lee. Supervision: Eui Hyeok Kim and Jisun Yoon. Validation: Eui Hyeok Kim and Sang Ah Lee. Visualization: Hyun Soo Park. Writing—original draft: Hyun Soo Park and Eui Hyeok Kim. Writing—review & editing: Hyun Soo Park and Eui Hyeok Kim. Approval of final manuscript: all authors.

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