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To cite this article: Jee Yoon Park, Kyong-No Lee, Hyeon Ji Kim, Kiroong Choe, Aeri Cho, Bohyoung Kim, Jinwook Seo, Hayan Kwon, Jong Woon Kim, Jin-Gon Bae, Ji-Hee Sung, Se Jin Lee, Young Mi Jung, You Jung Han, Subeen Hong, Jin-Hoon Chung, Hye-Sung Won & Jong Kwan Jun (2024) Pregnancy outcomes of cerclage in twin gestations: a multicenter retrospective cohort study, The Journal of Maternal-Fetal & Neonatal Medicine, 37:1, 2355495, DOI: [10.1080/14767058.2024.2355495](https://doi.org/10.1080/14767058.2024.2355495)

To link to this article: <https://doi.org/10.1080/14767058.2024.2355495>



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Published online: 16 Jun 2024.



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## Pregnancy outcomes of cerclage in twin gestations: a multicenter retrospective cohort study

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### ABSTRACT

**Objectives:** To determine the effects of cerclage on twin pregnancies.

**Methods:** A multicenter, retrospective, cohort study was conducted at 10 tertiary centers using a web-based data collection platform. The study population included twin pregnancies delivered after 20 weeks of gestation. Patients with one or two fetal deaths before 20 weeks of gestation were excluded. Maternal characteristics, including prenatal cervical length (CL) and obstetric outcomes, were retrieved from the electronic medical records.

**Results:** A total of 1,473 patients had available data regarding the CL measured before 24 weeks of gestation. Seven patients without CL data obtained prior to cerclage were excluded from the analysis. The study population was divided into two groups according to the CL measured during the mid-trimester: the CL  $\leq 2.5$  cm group ( $n = 127$ ) and the CL  $> 2.5$  cm group ( $n = 1,339$ ). A total of 127 patients (8.7%) were included in the CL  $\leq 2.5$  cm group, including 41.7% (53/127) who received cerclage. Patients in the CL  $> 2.5$  cm group who received cerclage had significantly lower gestational age at delivery than the control group (hazard ratio (HR): 1.8; 95% confidence interval (CI): 1.11–2.87;  $p = .016$ ). Patients in the CL  $\leq 2.5$  cm group who received cerclage had a significantly higher gestational age at delivery than the control group (HR: 0.5; 95% CI: 0.30–0.82;  $p$  value = .006).

**Conclusions:** In twin pregnancies with a CL  $\leq 2.5$  cm, cerclage significantly prolongs gestation. However, unnecessary cerclage in women with a CL  $> 2.5$  cm may result in a higher risk of preterm labor and histologic chorioamnionitis although this study has a limitation originated from retrospective design.

### ARTICLE HISTORY

Received 22 February

2024

Revised 7 May 2024

Accepted 10 May 2024

### KEYWORDS

Cerclage; twin pregnancy; preterm birth; cervical length; acute cervical insufficiency

### Introduction

Twin pregnancies account for approximately 3% of all live births and are mostly a result of the increased use of assisted reproductive technology (ART) [1,2]. The

proportion of preterm births in twin pregnancies is much higher than that in singleton pregnancies; therefore, more neonates suffer from morbidities and complications caused by preterm birth [3–5]. Several methods are used to prevent preterm birth, including

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the use of progesterone and cervical cerclage; however, most guidelines focus on singleton pregnancies [6,7].

Although cerclage is an acceptable treatment for acute cervical insufficiency and is used to prolong pregnancy, a meta-analysis reported that ultrasound-indicated cerclage in twin pregnancy increases the risk of preterm birth before 34 weeks of gestation, causing clinicians to hesitate regarding the use of cerclage for twin pregnancies with a short cervical length (CL) during the mid-trimester [8]. Physical examination-indicated cerclage before 24 weeks of gestation in twin pregnancies has been recommended to reduce the risk of preterm birth [9]. However, the indications for cerclage are mixed or inconsistent in previous studies. Several retrospective studies have reported prolonged pregnancy after cerclage in twin pregnancies with acute cervical insufficiency; however, the definitions of physical examination-indicated cerclage vary [10–12].

A previous study regarding twin pregnancies with cervical dilatation diagnosed by physical examination reported that 20% had prolapsed membranes beyond the external orifice of the uterus [11]. Several Korean studies regarding twin pregnancies with short CL have been reported. A cohort study comparing ultrasonography-indicated cerclage in twin pregnancies with that in singleton pregnancies reported comparable outcomes between twin and singleton pregnancies [13]. Another study reported that the use of a cervical pessary when the CL was  $<15$  mm was associated with the prolongation of twin pregnancies [14]. However, cervical pessaries are not typically used for short CL, even for singleton pregnancies, and its therapeutic effect remains unclear [15].

Based on the conflicting results of previous studies, the safety and efficacy of cerclage in twin pregnancies with a short CL prior to 24 weeks of gestation requires further investigation. This study assessed the outcomes of twin pregnancies based on the CL and the use of cerclage.

## Materials and methods

A multicenter, retrospective, cohort study was conducted by the Committee of Research for Multifetal Pregnancy of the Korean Society of Maternal Fetal Medicine at 10 university-affiliated medical centers using a web-based data collection platform. Twin pregnancies delivered after 20 weeks of gestation between January 2019 and July 2021 were included. Patients with one or two fetal deaths before 20 weeks of gestation were excluded. Maternal characteristics recorded

during prenatal checkups and obstetric outcomes were retrieved from the electronic medical records of each center, and all data were merged using a web-based platform accessed only by the committee members. The web-based data collection platform was designed for this study by the Computer Science and Engineering team at Seoul National University to standardize the definitions or indications of data collected from various centers and to make the analysis of large data easier. The study protocol was approved by the Institutional Review Board of each participating center and followed the principles of the Declaration of Helsinki.

The data of patients with available CL measurements obtained prior to 24 weeks of gestation were analyzed. The maternal age, parity, and obstetric history (including history of spontaneous preterm delivery before 37 weeks of gestation, height, weight at delivery, pre-pregnancy weight, chorionicity, use of ART, hypertensive disorder during pregnancy, gestational diabetes mellitus, pregestational diabetes mellitus, and use of insulin) were analyzed. As much data as possible regarding the variables or outcomes associated with preterm birth were collected. CL measurements obtained during prenatal checkups were divided into five categories: before 20 weeks, 20 + 0 to 23 + 6 weeks, 24 + 0 to 27 + 6 weeks, 28 + 0 to 31 + 6 weeks, and 32 + 0 to 36 + 0 weeks of gestation. The presence of preterm premature rupture of membranes (PPROM), use of tocolytics for preterm labor, and administration of antenatal corticosteroids, progesterone supplementation, or antibiotics were checked. The study population was divided into two groups with according to CL measured before 24 weeks of gestation with the reference value of 2.5 cm. In both groups, patients were reviewed to check whether they had received cerclage operation or not during the remaining pregnancy period. When cerclage was performed, the indications and the gestational age were thoroughly reviewed. The maternal baseline characteristics and outcomes were compared according to the presence of cerclage operation in each group (either short CL  $\leq 2.5$  cm group or the group with CL  $> 2.5$  cm). The gestational age at delivery and the proportion of preterm births, which were the primary outcomes of this study, were compared according to the use of cerclage. Patients for whom cerclage was performed prior to 24 weeks of gestation were excluded from the study.

Continuous variables were compared using Student's *t*-test or Mann–Whitney *U*-test, and proportions were compared using the Chi-square test or Fisher's exact test. The generalized Wilcoxon test for survival analysis was used to examine the interval from CL measurement to delivery and gestational age at delivery. The

Cox proportional hazard model was used to determine the hazard ratios (HRs) of the interval from CL measurement to delivery and gestational age at delivery according to the use of cerclage with adjustment for confounding factors. Statistical significance was set at  $p < .05$ . All statistical analyses were performed using SPSS version 22 (IBM SPSS Inc., Armonk, NY).

## Results

A total of 2,638 twin pregnancies were reported at the 10 participating centers, including 1,473 with available data regarding CL measured before 24 weeks of gestation (Figure 1). Seven patients who underwent

cerclage prior to the measurement of CL were excluded from the analysis. A total of 127 patients had a CL  $\leq 2.5$  cm. Among the patients with a CL  $\leq 2.5$  cm, 41.7% (53/127) received cerclage (Table 1). Among the patients with a CL  $> 2.5$  cm before 24 weeks of gestation, 1.4% (19/1339) received cerclage (Table 1). Among patients with a CL  $\leq 2.5$  cm, the mean maternal age was significantly higher in patients without cerclage than in those with cerclage (36 years vs. 34 years,  $p = .020$ ). In patients who had received cerclage operation ( $N = 72$ ), McDonald technique was majority, which had a rate of 72.2% (52/72), and 20 cases (27.8%) received modified Shirodkar's operation. About one-third (24/71) had two suture knots and one suture

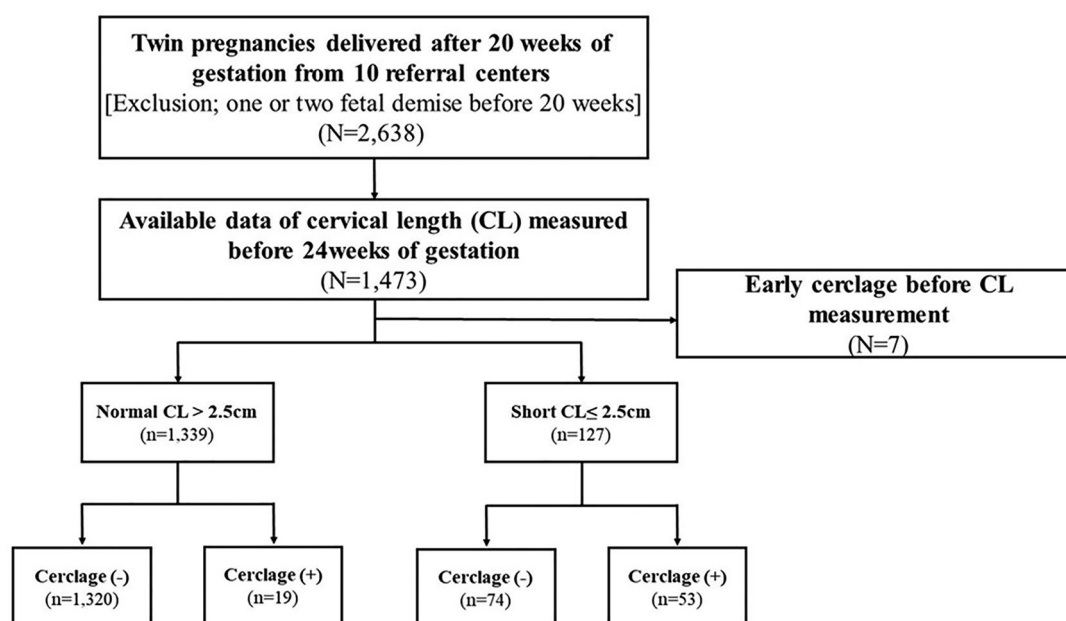


Figure 1. Study flowchart.

Table 1. Maternal baseline characteristics.

Variables	CL $> 2.5$ cm (N = 1339)			CL $\leq 2.5$ cm (N = 127)		
	Cerclage (-) (n = 1320)	Cerclage (+) (n = 19)	p Value	Cerclage (-) (n = 74)	Cerclage (+) (n = 53)	p Value
Maternal age (years)	36 $\pm$ 3.4	36 $\pm$ 3.5	.731	36 $\pm$ 4.1	34 $\pm$ 4.3	.020
Nulliparity	81.5% (1076/1320)	73.7% (14/19)	.375	81.1% (60/74)	81.1% (43/53)	>.999
Past history of PTB	2.7% (35/1320)	0 (0/19)	>.999	5.4% (4/74)	9.4% (5/53)	.489
Height (cm)	162 $\pm$ 5.1	161 $\pm$ 4.2	.177	161 $\pm$ 5.3	162 $\pm$ 5.3	.323
Weight at delivery (kg)	72 $\pm$ 10.6	68 $\pm$ 9.6	.110	71 $\pm$ 11.3	70 $\pm$ 11.4	.345
Pre-pregnancy BMI (kg/cm <sup>2</sup> )	22 $\pm$ 3.6	23 $\pm$ 4.4	.163	23 $\pm$ 4.1	23 $\pm$ 4.9	.958
Monochorionicity	17.6% (232/1320)	15.8% (3/19)	>.999	23.0% (17/74)	20.8% (11/53)	.831
ART	79.3% (1047/1320)	84.2% (16/19)	.779	67.6% (50/74)	77.4% (41/53)	.240
IVF-ET	70.3% (928/1320)	78.9% (15/19)	.613	64.9% (48/74)	67.9% (36/53)	.849
IUI	6.8% (90/1320)	5.3% (1/19)	>.999	2.7% (2/74)	9.4% (5/53)	.128
Hypertensive disorder	10.1% (133/1320)	15.8% (3/19)	.431	9.5% (7/74)	1.9% (1/53)	.138
GDM	13.5% (178/1320)	32.1% (4/19)	.313	13.5% (10/74)	22.6% (12/53)	.235
Pregestational DM	0.4% (5/1320)	0 (0/19)	>.999	1.4% (1/74)	0 (0/53)	>.999
Insulin use	2.2% (29/1320)	5.3% (1/19)	.352	5.4% (4/74)	1.9% (1/53)	.400

Abbreviations. CL, cervical length; PTB, preterm birth; BMI, body mass index; ART, assisted reproductive technology; IVF-ET, *in vitro* fertilization and embryo transfer; IUI, intrauterine insemination; GDM, gestational diabetes mellitus; DM, diabetes mellitus. Values are expressed as mean  $\pm$  standard deviation or proportion (n/N).

know was found in 65.3% (47/71). Tocolytics were given in 44.4% (32/65) before cerclage and in 58.3% (42/65) immediately after cerclage. For cerclage operation, antibiotics were administered in 58.3% (42/72), however, the regimens or combinations varied according to the attending physician or the institution.

Among patients with a CL >2.5cm, the rate of preterm labor treated with tocolytics was significantly higher in the patients who received cerclage than in those who did not (63.2% vs. 21.8%,  $p < .001$ ) (Table 2). The mean gestational age at CL measurement was not significantly different between patients who received cerclage and those who did not; however, the mean CL was shorter in patients who received cerclage than in patients without cerclage (3.1cm vs. 3.8cm,  $p < .001$ ). Patients who received cerclage were more likely to be administered antenatal corticosteroids, progesterone supplementation, and antibiotics than the control group (all  $p < .05$ ). The mean gestational age at delivery was significantly lower among patients with a CL >2.5cm who received cerclage than among those who did not (33.8 weeks vs. 35.9 weeks,  $p = .002$ ). The rate of preterm births before 34 weeks of gestation was 42.1% among patients who received cerclage and 10.8% among those who did not ( $p = .001$ ). The proportion of patients with histological chorioamnionitis was significantly higher among those who received cerclage than in the control patients (33.3% vs. 9.7%,  $p = .006$ ).

Among patients with a CL  $\leq$  2.5cm, those who underwent cerclage had a shorter mean CL than the control patients (1.1cm vs. 1.9cm,  $p < .001$ ) (Table 2). The proportions of PPROM, preterm labor with

tocolytics, and administration of antenatal corticosteroids for fetal lung maturation were not significantly different between patients who received cerclage and control patients (all  $p > .05$ ). Patients who received cerclage were significantly more likely to be administered progesterone or antibiotics than the control patients (both  $p < .05$ ). The rates of preterm births before 28 and 34 weeks of gestation and the placental pathologies were comparable between those who received cerclage and those who did not.

Among patients with CL >2.5cm, those who received had a shorter interval from CL measurement to delivery although the difference did not reach statistical significance (HR: 1.6; 95% confidence interval (CI): 1.00–2.56;  $p = .052$ ) (Figure 2(A)). Patients who underwent cerclage had a significantly lower gestational age at delivery than the control group (HR: 1.8; 95% CI: 1.11–2.87;  $p = .016$ ) (Figure 2(B)). Patients with a CL  $\leq$ 2.5cm who received cerclage had a significantly longer interval from CL measurement to delivery than the control patients (HR: 0.5; 95% CI: 0.30–0.82;  $p = .006$ ) (Figure 3(A)). These patients who received cerclage had a significantly greater gestational age at delivery compared to the control patients (HR: 0.5; 95% CI: 0.30–0.82;  $p = .006$ ).

## Discussion

The effect of cerclage on pregnancy outcomes differed according to CL measured before 24 weeks of gestation. Among patients with a CL  $\leq$ 2.5cm, the cerclage significantly prolonged pregnancy despite the shorter CL among patients who underwent cerclage compared to

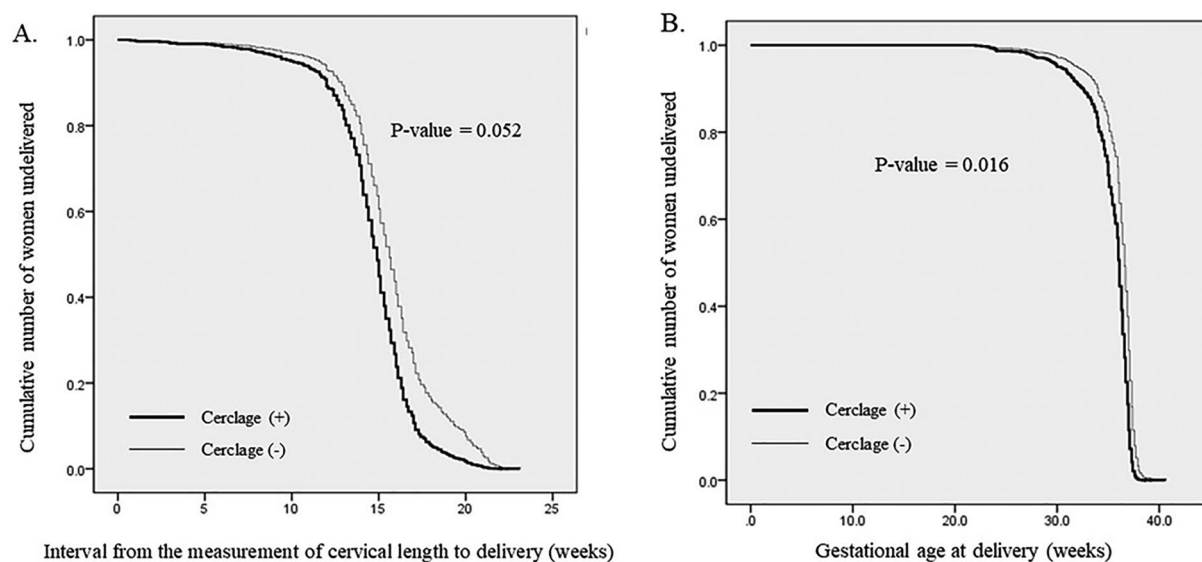
**Table 2.** Obstetric outcomes.

Variables	CL >2.5cm (N = 1339)			Short CL $\leq$ 2.5cm (N = 127)		
	Cerclage (–) (n = 1320)	Cerclage (+) (n = 19)	p Value	Cerclage (–) (n = 74)	Cerclage (+) (n = 53)	p Value
PPROM	11.7% (154/1320)	21.1% (4/19)	.268	20.3% (15/74)	34.0% (18/53)	.102
PTL with tocolytics	21.8% (288/1320)	63.2% (12/19)	<.001	59.5% (44/74)	58.5% (31/53)	>.999
Clinical chorioamnionitis	0.8% (10/1320)	5.3% (1/19)	.146	1.4% (1/74)	1.9% (1/53)	>.999
CL (cm)	3.8 $\pm$ 0.61	3.1 $\pm$ 0.41	<.001	1.9 $\pm$ 0.68	1.1 $\pm$ 0.71	<.001
GA at measurement (weeks)	20.4 $\pm$ 1.97	20.1 $\pm$ 1.96	.244	21.2 $\pm$ 1.85	20.7 $\pm$ 1.83	.084
Interval from measurement to delivery (weeks)	15.5 $\pm$ 3.01	13.7 $\pm$ 3.90	.100	11.2 $\pm$ 5.9	12.2 $\pm$ 5.5	.219
GA at cerclage (weeks) <sup>a</sup>	NA	22.3 $\pm$ 1.66		NA	20.9 $\pm$ 2.11	
Antenatal corticosteroids	26.0% (343/1320)	52.6% (10/19)	.015	56.8% (42/74)	58.5% (31/53)	.858
Progesterone supplementation	13.5% (178/1320)	57.9% (11/19)	<.001	36.5% (27/74)	60.4% (32/53)	.011
Antibiotics use	11.7% (155/1320)	47.4% (9/19)	<.001	36.5% (27/74)	62.3% (33/53)	.007
GA at delivery (weeks)	35.9 $\pm$ 2.32	33.8 $\pm$ 3.80	.002	32.4 $\pm$ 5.24	32.9 $\pm$ 5.18	.284
PTB before 28 weeks	20% (27/1320)	10.5% (2/19)	.062	23.0% (17/74)	24.5% (13/53)	.836
PTB before 34 weeks	10.8% (142/1320)	42.1% (8/19)	.001	41.9% (31/74)	39.6% (21/53)	.856
Cesarean section	84.7% (1118/1320)	78.9% (15/19)	.517	75.7% (56/74)	73.6% (39/53)	.837
Histologic chorioamnionitis	9.7% (113/1163)	33.3% (6/18)	.006	18.1% (13/72)	24.5% (12/49)	.493
Funisitis	1.3% (15/1163)	5.6% (1/18)	.219	9.7% (7/72)	8.2% (4/49)	>.999

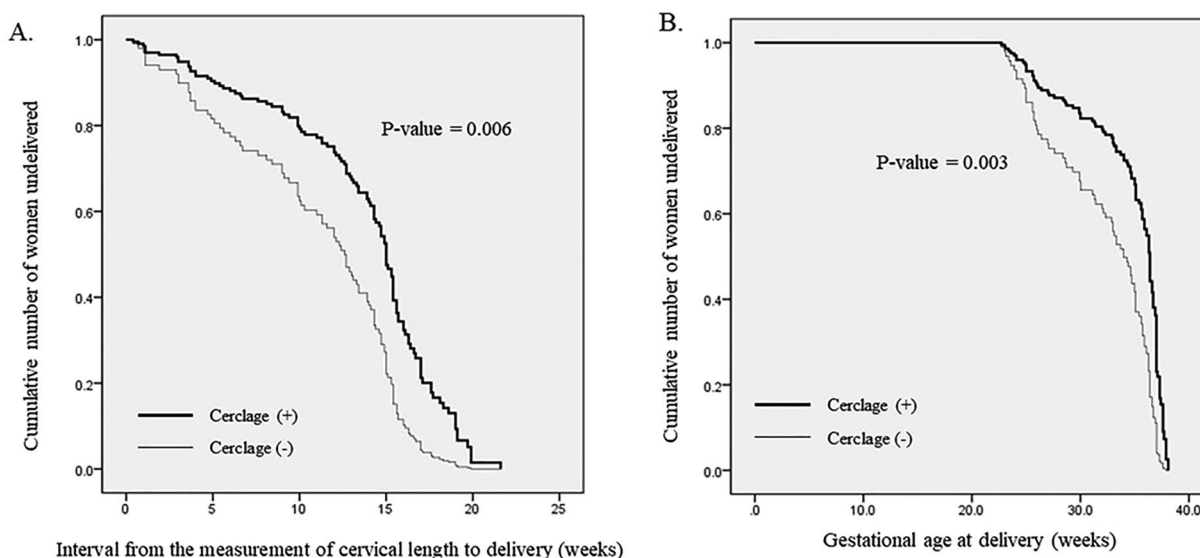
Abbreviations. PPROM, preterm premature rupture of membranes; PTL, preterm labor; CL, cervical length; GA, gestational age; PTB, preterm birth; NA, not available.

Values are expressed as mean  $\pm$  standard deviation or proportion (n/N).

<sup>a</sup>The difference of the mean value for gestational age at cerclage between cervical length >2.5cm group and cervical length  $\leq$ 2.5cm group was statistically significant ( $p = .016$ ).



**Figure 2.** Survival curves according to cerclage in patients with cervical length (CL) >2.5 cm measured before 24 weeks of gestation. (A) Interval from CL measurement to delivery; (B) gestational age at delivery.



**Figure 3.** Survival curves according to cerclage in patients with cervical length (CL)  $\leq$ 2.5 cm measured before 24 weeks of gestation. (A) Interval from CL measurement to delivery; (B) gestational age at delivery.

those who did not. This result suggests that ultrasound-indicated cerclage for short CL could be beneficial in twin pregnancies as well as singleton pregnancies. However, among patients with a CL >2.5 cm, cerclage did not prolong pregnancy. Among patients with a CL >2.5 cm, the rates of preterm labor with the administration of tocolytics and histological chorioamnionitis were higher among patients who received cerclage than in control patients. As all data regarding CL used for the analysis were measured prior to the cerclage operation and the pregnancy outcomes were determined after the cerclage, the occurrence of preterm labor and histologic

chorioamnionitis could be considered consequences of cerclage. This result suggests that cerclage in patients with twin pregnancies and a CL >2.5 cm or in those who are not diagnosed with a high-risk of preterm birth may be unnecessary or even harmful.

The investigation of the use of cerclage to prevent preterm birth in twin pregnancies is difficult in well-designed prospective studies. Several women with twin pregnancies conceived via IVF after multiple failed pregnancies and are reluctant to participate in the observation group of a randomized controlled trial. Therefore, a national, multicenter study that analyzes

medical practices in clinical settings is important. A previous meta-analysis reported that cerclage is associated with a higher risk of preterm birth in twin pregnancies [16]. However, the results of other studies support the use of cerclage for certain conditions, such as advanced cervical dilatation or bag bulging, is beneficial in twin pregnancies and does not compromise the pregnancy outcomes [17,18]. These findings suggest that cerclage may be beneficial only for twins with advanced cervical insufficiency. Therefore, the indications for cerclage must be thoroughly reviewed to establish guidelines regarding cerclage in twin pregnancies.

In this study, data were collected from multiple referral hospitals so that the bias of attending physicians could not critically affect the outcome and analyzed the presence of cerclage only in patients with available CL measurements prior to cerclage to examine the effects of cerclage. Cerclage is dependent on the surgeon's skills and experience. National cohort data from several medical centers are essential for investigating the effects of cerclage in twin pregnancies. The results of this relatively large study suggest that cerclage may be beneficial to prolong pregnancy in twin pregnancies with a CL  $\leq 2.5$  cm but may be harmful when performed inadequately although there is a certain limitation caused by retrospective design. A randomized controlled trial is the best study type to determine the effect of cerclage by comparing data of women who receive cerclage group with those who do not; however, a trial regarding this topic is extremely difficult to conduct. Previous studies have reported negative or insufficient results regarding the efficacy of ultrasonography-indicated cerclage in twin pregnancies. A meta-analysis using individual patient-level data from three randomized controlled trials reported that cerclage in twin pregnancies with a short CL was associated with an increased risk of preterm birth and perinatal death compared to that in control patients who did not receive cerclage [16]. A trial in which negative results are predicted makes it difficult for pregnant women to consent to participate; therefore, the conduction of a randomized controlled trial regarding this topic is difficult. Although the results are indirect and are limited by the retrospective nature of the study, the findings of the current study may be useful when counseling women with twin pregnancies with a high risk for preterm birth and to decrease the use of unnecessary interventions.

### Acknowledgements

We are thankful to all the researchers who participated in this project. The 10 centers in this multi-center study have

approval of IRB and the project numbers are as follows: B-2108-705-110 for Seoul National University Bundang Hospital; 4-2021-0961 for Severance Hospital, Yonsei University College of Medicine; CNUH-2021-310 for Chonnam National University Medical School; 2021-08-051-002 for Keimyung University Dongsan Medical Center; 2021-08-009 for Samsung Medical Center; KNUH-B-2021-08-026 for Kangwon National University Hospital; 2108-027-1242 for Seoul National University Hospital; GCI 2021-08-009 for CHA Gangnam Medical Center; KC21RIDI0598 for Seoul St. Mary's Hospital; 2021-1621 for Asan Medical Center, University of Ulsan College of Medicine.

### Disclosure statement

No potential conflict of interest was reported by the author(s).

### Funding

This study was supported by a grant from the multicenter research project funded by the Korean Society of Maternal Fetal Medicine, Republic of Korea.

### Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to their containing information that could compromise the privacy of research participants.

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