

## Cervical cerclage for prevention of preterm birth

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#### RESEARCH ARTICLE

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# Cervical cerclage for prevention of preterm birth: the results from A 20-year cohort

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#### ABSTRACT

Cerclages can be used to prevent preterm birth, although their effectiveness and safety is disputed. We aimed to describe obstetric outcomes after cerclage procedures. We included 156 singleton pregnancies and six multiple pregnancies. In singleton pregnancies with history-indicated, short cervix-indicated and emergency cerclages, respectively 84.6, 76.5 and 43.8% resulted in late preterm or term deliveries. In singletons, the following complications were reported: excessive bleeding in one emergency cerclage procedure and three re-cerclage procedures in the history-indicated cerclage group. No perioperative rupture of membranes occurred in singletons. When comparing results of experienced and less-experienced gynaecologists; 90.7% and 94.4% for the two experienced gynaecologist as compared to 85.0% for the group of less-experienced gynaecologists. In conclusion, cerclages in singletons result in few cerclage-associated complications and a high take home child rate, when performed by experienced gynaecologists.

#### **IMPACT STATEMENT**

- What is already known on this subject? Prematurity is the leading cause of perinatal and neonatal mortality and morbidity worldwide. Cervical cerclages can be used to prevent preterm birth, although their effectiveness and safety is disputed.
- What the results of this study add? In our cohort study, singleton pregnancies with cerclages seem to have satisfactory obstetric outcomes. We found a very low prevalence of cerclage-associated complications in singleton pregnancies, for both history-indicated, short cervix-indicated and emergency cerclages. Additionally, take home child rates in singleton pregnancies were remarkably higher when cerclage procedures were performed by experienced gynaecologists, compared to less experienced gynaecologists.
- What the implications are of these findings for clinical practice and/or further research? Based on the observed difference in take home child rates, we advise all cerclage procedures to be performed by experienced gynaecologists only. This may mean that women with an indication for cerclage will be referred to a more experienced colleague, either in the same, or in another hospital. To ensure treatment by an experienced gynaecologist, simulation-based training could also provide a solution.

**Abbreviations:** DES: Diethylstilbestrol; GA: Gestational age; IQR: Interquartile range; PTB: Preterm birth; ROM: Rupture of membranes; SD: Standard deviation

#### Introduction

In 2014, 10.6% of all births, corresponding with 15 million infants worldwide, were preterm (before a gestational age (GA) of  $37^{+0}$  weeks) (World Health Organization 2015; Chawanpaiboon et al. 2019). Prematurity is the leading cause of perinatal and neonatal mortality and morbidity worldwide; over one third of all neonatal deaths in 2015 was caused by prematurity (World Health Organization 2015; Liu et al. 2016).

Unfortunately, the percentage premature births is still rising (Chawanpaiboon et al. 2019).

Preterm birth (PTB) is associated with multiple risk factors: previous PTB, second trimester miscarriage, previous cervical procedures, shortened cervical length before or during pregnancy and hypoplastic cervix due to maternal intra-uterine exposure to diethylstilbestrol (DES) (Ludmir et al. 1987; Owen et al. 2004; Di Renzo et al. 2011; Simoens et al. 2012; Koullali

**KEYWORDS** 

Cerclage; cervical suture; cervical stitch; McDonald; complication; preterm birth



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Figure 1. The cervical canal is closed after completion of a cervical cerclage procedure. The suture is knotted on top of a collar button.

et al. 2016). One of the proposed mechanisms leading to PTB is cervical insufficiency. Some researchers define cervical insufficiency as the inability of the uterine cervix to retain a pregnancy in the second trimester in the absence of evident contractions (American College of Obstetricians and Gynecologists 2014). However, up to now, no agreement has been reached on the exact definition and diagnosis of cervical insufficiency (Romero et al. 2006; Alfirevic et al. 2017).

Multiple strategies to prevent PTB are known, including cervical cerclage procedures (American College of Obstetricians and Gynecologists 2014). Cervical cerclage is a surgical procedure in which a non-absorbable suture is used to provide mechanical support to the cervix (McDonald 1957). Cerclage procedures are not without risks; rupture of membranes (ROM), spontaneous induction of labour or bleeding may occur (Alfirevic et al. 2017). Besides, intra-uterine infection, possibly leading to PTB and/or maternal sepsis, may occur postoperatively (Bauer et al. 2013).

The effectiveness and safety, and the exact group of women who may benefit from cerclages are still under debate (Alfirevic et al. 2017). Indications for cerclage procedures are often not completely reported and results regarding effectiveness may be contradictive (Althuisius et al. 2003; Alfirevic et al. 2017; Berghella et al. 2017). As a result, gynaecologists may become more reluctant to offer cerclages to women at risk of PTB (Suhag et al. 2015). Therefore, our main objective in this retrospective cohort study was to describe obstetric outcomes after cerclage procedures according to the indication in a tertiary care hospital as well as the prevalence of cerclage-associated complications. In addition, we aimed to examine whether the operating gynaecologists' experience with cerclage procedures affected the outcomes.

#### **Material and methods**

We included all pregnancies between January 1<sup>st</sup> 2000, until June 30<sup>th</sup> 2020 in which a cervical cerclage procedure was performed at the Máxima MC, Veldhoven, The Netherlands (a tertiary care referral hospital). Data were collected from electronic and paper patient files. Women in whom the cerclage procedure was performed twice within one pregnancy (recerclage), were only included once (the first procedure), whereas the re-cerclage was reported as complication of the first procedure. When GA at the time of delivery was missing, the pregnancy was considered lost-to-follow-up.

All pregnancies were divided into three groups; 1) pregnancies with history-indicated cerclage, 2) pregnancies with short cervix-indicated cerclage or 3) pregnancies with emergency cerclage. History-indicated cerclages were planned procedures. Indications for history-indicated cerclages were previous PTB, previous cervical procedures (i.e. conisation or loop electrosurgical excision procedure) or maternal intrauterine DES exposure. Short cervix-indicated cerclages were all cerclage procedures performed because of a short cervical length based on vaginal examination (i.e. subjective assessment) or transvaginal ultrasound measurement (i.e. objective assessment, cut-off value <30 mm), but without dilation or protruding membranes. Emergency cerclages were all cerclage procedures performed in the presence of cervical dilation or protruding membranes.

Cerclage procedures were performed by trained gynaecologists or under direct supervision of a trained gynaecologist. All cerclages were vaginal cerclages according to McDonald's procedure (Figure 1) (McDonald 1957). The suture is placed as close as possible to the level of the internal cervical os, though no dissection is involved in this technique. A balloon catheter was used to replace the protruded membranes into the uterus in emergency cerclages only (Figure 2). Perioperative, tocolytics or antibiotic prophylaxis were administered according to the clinical judgement of the operating gynaecologist. Cerclage procedures were only considered in the absence of signs of intra-uterine infection (i.e. absence of fever, elevated C-reactive protein or elevated white blood cell count), contractions and vaginal blood loss (National Institute for Health and Care Excellence 2019). Removal of cerclages took place between 36<sup>+0</sup> and 37<sup>+0</sup> weeks GA, unless it was removed earlier due to signs of infection, spontaneous contractions or ROM.

Some pregnancies with a cerclage were also treated with progesterone to prevent PTB. This prophylactic treatment consisted of vaginal progesterone administration (200 mg daily) from  $16^{+0}$  until  $36^{+0}$  weeks GA. Additional treatment with progesterone to prevent PTB was started according to the hospital's protocol at the time. Pessaries were not used as prophylaxis of PTB.

The primary outcomes were PTB rate and the risk of perioperative complications in singleton pregnancies after history-indicated, short cervix-indicated and emergency



Figure 2. Emergency cerclage procedure. The protruding membranes are visualised and gently pushed back into the uterus using an inflated balloon catheter. After replacement of the protruded membranes, the cerclage sutures are placed in accordance with McDonald's technique. The suture is pulled tight while simultaneously deflating and slowly withdrawing the catheter.

cerclage. Additionally, we examined whether the operating gynaecologists' experience with cerclage procedures affected the outcomes. PTB was subclassified based on the GA at delivery in accordance with the WHO subclassification: immature birth ( $<24^{+0}$  weeks GA), extreme PTB ( $24^{+0}$ - $27^{+6}$  weeks GA), very PTB (28<sup>+0</sup>-31<sup>+6</sup> weeks GA), moderate to late PTB  $(32^{+0}-36^{+6})$  weeks GA) and term birth ( $\geq 37^{+0}$  weeks GA). Perioperative complications were defined as complications (i.e. bleeding, ROM) occurring during or up to 24 hours after the cerclage procedure. The necessity for a second cerclage procedure within the same pregnancy was considered a complication as well, though its occurrence was not restricted to 24 hours after the initial cerclage procedure. Moreover, we reported complications occurring within 1 to 7 days postoperatively. Gynaecologists were considered experienced in performing cerclage procedures when they judged themselves to be experienced and whose department head agreed with this judgement. Secondary outcomes were GA at delivery, pregnancy prolongation (days between cerclage procedure and delivery), take home child rate (number of neonates discharged alive) and reasons for cerclage removal before 36<sup>+0</sup> weeks GA.

We used descriptive statistics for baseline characteristics and study outcomes. All outcomes were described for the three groups: history-indicated, short cervix-indicated and emergency cerclages. We additionally described subgroups of pregnancies that received additional treatment with either vaginal progesterone, perioperative tocolytics or perioperative antibiotics. Subgroups were also reported according to operating gynaecologists (gynaecologist A to C). Gynaecologists A and B correspond to two gynaecologists, whereas gynaecologist C corresponds to all other operating gynaecologists during the study period. Multiple pregnancies were not included in all aforementioned analyses and were reported separately in order to reduce heterogeneity. All analyses were conducted in SPSS software (version 26, IBM corp., Armonk, NY).

#### Ethical approval

The Daily Board of the Medical Ethics Committee of Máxima MC confirmed that the rules laid down in the Medical Research Involving Human Subjects Act do not apply to this research (METC-number N19.111).

#### Results

We included 156 singleton pregnancies and six multiple pregnancies (total 162 pregnancies) in which a cerclage procedure was performed. In total, there are 39 women who were included for more than one pregnancy with a cerclage (89 out of 162 included pregnancies were from these 39 women). Of these 39 women, the first cerclage procedure was either history-indicated, short cervix-indicated or an emergency cerclage. The subsequent cerclage procedures were all history-indicated. Most singleton pregnancies received history-indicated cerclages (n = 123), while a minority received short cervix-indicated cerclages (n = 17) or emergency cerclages (n = 16). Baseline characteristics are presented in Table S1.

In singleton pregnancies with history-indicated cerclages, almost one third received a cerclage based on a history of one immature birth (Table S2). For singleton pregnancies with short cervix-indicated cerclages, the majority had a history of PTB (64.7%), whereas a history of PTB was present in 31.3% of pregnancies with emergency cerclages (Table S2).

All perioperative and obstetric outcomes of singleton pregnancies with cerclages, divided into history-indicated, short cervix-indicated and emergency cerclages, are presented in Table 1. In singleton pregnancies with history-indicated, short cervix-indicated and emergency cerclages, respectively 84.6, 76.5 and 43.8% resulted in late preterm or term deliveries. Three re-cerclage procedures were performed in the history-indicated cerclage group and one emergency cerclage procedure was complicated with excessive bleeding from the cervix (1500 cc). No perioperative ROM occurred in any singleton pregnancy, including the three re-cerclage procedures. A total of four cerclages (of which three emergency cerclages) was removed before 36<sup>+0</sup> weeks GA due to suspected infection (2.6%). Two of these four cerclages were removed due to suspicion of infection within one week after the cerclage procedure. Both women delivered within one day after removal of the cerclage. The median GA at delivery was 38<sup>+5</sup> weeks GA for pregnancies with history- and short cervix-indicated cerclages, whereas this was 29<sup>+6</sup> weeks GA for emergency cerclages. The take home child rates were 91.1, 94.1 and 81.3% for history-indicated, short cervix-indicated and emergency cerclages, respectively. Reasons for foetal or neonatal mortality in the history-indicated cerclage

	History-indicated cerclage	History-indicated cerclage		
	based on previous immature	based on DES exposure or	Short cervix-indicated	
	or preterm birth ( $n = 113$ )	cervical procedures ( $n = 10$ )	cerclage ( $n = 17$ )	Emergency cerclage ( $n = 16$ )
GA at delivery				
GA <24 <sup>+0</sup>	6 (5.3)	0 (0.0)	0 (0.0)	3 (18.8)
GA 24 <sup>+0</sup> -27 <sup>+6</sup>	2 (1.8)	0 (0.0)	3 (17.6)	3 (18.8)
GA 28 <sup>+0</sup> -31 <sup>+6</sup>	10 (8.8)	1 (10.0)	1 (5.9)	3 (18.8)
GA 32 <sup>+0</sup> -36 <sup>+6</sup>	11 (9.7)	1 (10.0)	1 (5.9)	2 (12.5)
$GA > 37^{+0}$	84 (74.3)	8 (80.0)	12 (70.6)	5 (31.3)
GA at delivery (weeks + days)	38 <sup>+5</sup> [2 <sup>+6</sup> ]	38 <sup>+6</sup> [2 <sup>+6</sup> ]	38 <sup>+5</sup> [6 <sup>+5</sup> ]	29 <sup>+6</sup> [12 <sup>+1</sup> ]
	Range $15^{+4} - 41^{+1}$	Range $28^{+0} - 40^{+4}$	Range $26^{+1} - 42^{+4}$	Range $22^{+1} - 40^{+4}$
Pregnancy	25 <sup>+1</sup> [4 <sup>+1</sup> ]	25 <sup>+6</sup> [2 <sup>+5</sup> ]	18 <sup>+2</sup> [8 <sup>+4</sup> ]	9 <sup>+6</sup> [11 <sup>+6</sup> ]
prolongation (weeks $+$ days)	Range $1^{+6} - 28^{+4}$	Range 13 <sup>+5</sup> -26 <sup>+6</sup>	Range $4^{+0} - 25^{+5}$	Range $0^{+1} - 19^{+6}$
Take home child rate	102 (90.3)	10 (100.0)	16 (94.1)	13 (81.3)
Perioperative complications				
None	110 (97.3)	10 (100.0)	17 (100.0)	15 (93.8)
ROM	0 (0)	0 (0.0)	0 (0.0)	0 (0.0)
Excessive bleeding (1500cc)	0 (0)	0 (0.0)	0 (0.0)	1 (6.3)
Second cerclage procedure within one pregnancy	3 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
Reasons for removal of $CA_{36^{+0}}$				
Suspicion of infection	1 (0.9)	0 (0 0)	0 (0)	3 (19.9)
Suspicion of infection	16 (14 2)	1 (10.0)	5 (29 4)	6 (37.5)
or ROM	10 (14.2)	1 (10.0)	J (29.4)	(27.5)
Spontaneous loss	2 (1.8)	0 (0.0)	0 (0)	2 (12.5)
Other	6 (5.3)	1 (10.0)	0 (0)	0 (0.0)

Table 1. Obstetric and perioperative outcomes for singleton pregnancies with history-indicated, short cervix-indicated and emergency cerclages.

All data are provided as number (%) or median [IQR].

group were; intra-uterine demise (n = 1), trisomy 18 (n = 2), hypoplastic left heart syndrome (n = 1) and immaturity (n = 7). One neonate died of necrotising enterocolitis in the short cervix-indicated cerclage group and three neonates were born immature in the emergency cerclage group.

When comparing pregnancies with cerclages only and pregnancies with cerclages and progesterone prophylaxis, outcomes were comparable (Table 2). Pregnancies in which perioperative antibiotic treatment was started, resulted in earlier deliveries as compared to pregnancies without antibiotic treatment (median GA at delivery  $33^{+6}$  and  $38^{+4}$  weeks, respectively). A similar observation was seen in pregnancies with a cerclage procedure treated with perioperative tocolytics compared to no perioperative tocolytics (median GA at delivery  $32^{+4}$  and  $38^{+5}$  weeks, respectively). In 8.0% (n = 2) of pregnancies that received perioperative antibiotics, cerclages were removed preterm due to suspected infection whereas this was the case in 1.5% (n = 2) of pregnancies without perioperative antibiotic treatment (Table 2).

Obstetric outcomes and cerclage-associated complications were compared between different operating gynaecologists (Table 3). One experienced gynaecologist (A) performed 75.6% of all cerclage procedures in singleton pregnancies. Another 11.5% were performed by a second gynaecologist (B) and 12.8% by a variety of other gynaecologists (C) with less experience. Gynaecologist C performed 18 (90.0%) history-indicated cerclage procedures and two (10.0%) short cervix-indicated cerclages procedures. The two experienced gynaecologists performed emergency cerclages as well (Table 3). The take home child rates were 90.7, 94.4 and 85.0% for gynaecologist A, B and C, respectively.

Cerclage procedures were performed in six multiple pregnancies (five twin and one triplet pregnancy). Data of these pregnancies are presented in Table S3. One cerclage procedure was complicated by ROM. Additionally, in another multiple pregnancy, a re-cerclage procedure was performed which was complicated by perioperative ROM as well. During this re-cerclage procedure, two centimetre dilation with protrusion of membranes was noted.

#### Discussion

In our cohort study, singleton pregnancies with cerclages seem to have satisfactory obstetric outcomes. We found a very low prevalence of cerclage-associated complications in singleton pregnancies, for both history-indicated, short cervix-indicated and emergency cerclages. Cerclage-associated complications were more common in multiple pregnancies with cerclages. Additionally, take home child rates in singleton pregnancies were remarkably higher when cerclage procedures were performed by experienced gynaecologists, compared to less experienced gynaecologists.

Strengths of our study are that it is a relatively large cohort study using data with high completeness, reporting in detail the baseline characteristics, the GA of the cerclage procedures, the use of perioperative antibiotics and/or tocolytics, the use of progesterone prophylaxis, and obstetrical and neonatal outcomes. In contrast to other articles, indications for cerclage procedures are explicitly reported. The effectiveness of cerclages is still under debate (Alfirevic et al. 2017) and it remains unclear which women would benefit most. When describing obstetric outcomes after cerclage procedures, it is thus important that outcomes are split according to baseline characteristics.

In our study, 87% of the described cerclage procedures were performed by two experienced gynaecologists. We were therefore able to describe the outcomes of cerclage

Table 2. Obstetric outcomes in singleton pregnancies with cerclage and additional treatment with either progesterone, antibiotics or tocolytics.

	Additional treatment with progesterone		Additional treatment with perioperative antibiotics		Additional treatment with perioperative tocolytics	
	Cerclage only $(n = 101)$	Cerclage and progesterone (n = 55)	Cerclage only (n = 131)	Cerclage and perioperative antibiotics $(n = 25)$	Cerclage only $(n = 138)$	Cerclage and perioperative tocolytics (n = 18)
GA at delivery						
GA <24 <sup>+0</sup>	6 (5.9)	3 (5.5)	6 (4.6)	3 (12.0)	7 (5.1)	2 (11.1)
GA 24 <sup>+0</sup> -27 <sup>+6</sup>	4 (4.0)	4 (7.3)	3 (2.3)	5 (20.0)	5 (3.6)	3 (16.7)
GA 28 <sup>+0</sup> -31 <sup>+6</sup>	10 (9.9)	5 (9.1)	11 (8.4)	4 (16.0)	11 (8.0)	4 (22.2)
GA 32 <sup>+0</sup> -36 <sup>+6</sup>	11 (10.9)	4 (7.3)	14 (10.7)	1 (4.0)	14 (10.1)	1 (5.6)
${ m GA}>$ 37 $^{+0}$	70 (69.3)	39 (70.9)	97 (74.0)	12 (48.0)	101 (73.2)	8 (44.4)
GA at	38 <sup>+4</sup> [5 <sup>+5</sup> ]	38 <sup>+2</sup> [5 <sup>+2</sup> ]	38 <sup>+4</sup> [2 <sup>+5</sup> ]	33 <sup>+6</sup> [12 <sup>+4</sup> ]	38 <sup>+5</sup> [3 <sup>+0</sup> ]	32 <sup>+4</sup> [12 <sup>+4</sup> ]
delivery	Range $15^{+4} - 42^{+4}$	Range $17^{+4} - 40^{+5}$	Range $15^{+4} - 42^{+4}$	Range $22^{+1} - 40^{+5}$	Range $15^{+4} - 42^{+4}$	Range $23^{+0} - 40^{+4}$
(weeks $+$ days)	5	5	5	5	5	5
Pregnancy	24 <sup>+4</sup> [7 <sup>+1</sup> ]	24 <sup>+2</sup> [10 <sup>+0</sup> ]	24 <sup>+6</sup> [6 <sup>+3</sup> ]	15 <sup>+5</sup> [18 <sup>+4</sup> ]	24 <sup>+6</sup> [6 <sup>+4</sup> ]	13 <sup>+1</sup> [11 <sup>+6</sup> ]
prolongation	Range $0^{+1} - 28^{+4}$	Range $4^{+0} - 27^{+6}$	Range $1^{+6} - 28^{+1}$	Range $0^{+1} - 28^{+4}$	Range $0^{+2} - 28^{+4}$	Range $0^{+1} - 27^{+6}$
(weeks + days)	5	5	5	5	5	5
Take Home Child Rate	90 (89.1)	51 (92.7)	120 (91.6)	21 (84.0)	126 (91.3)	15 (83.3)

All data are provided as number (%) or median [IQR].

Table 3.	Obstetric and	perioperative	outcomes in	singleton	pregnancies fo	r different	operating	gynaecologist
								J/ · · · · J · ·

	Gynaecologist A ( $n = 118$ )	Gynaecologist B ( $n = 18$ )	Gynaecologist C (n = 20)
GA at cerclage procedure (weeks + days)	14 <sup>+0</sup> [1 <sup>+6</sup> ]	14 <sup>+6</sup> [6 <sup>+4</sup> ]	14 <sup>+0</sup> [1 <sup>+4</sup> ]
5 1 4 7 7	Range $10^{+0} - 24^{+1}$	Range $11^{+6} - 22^{+6}$	Range $12^{+0} - 21^{+2}$
History-indicated cerclage	95 (80.5)	10 (55.6)	18 (90.0)
Short Cervix-indicated cerclage	11 (9.3)	4 (22.2)	2 (10.0)
Emergency cerclage	12 (10.2)	4 (22.2)	0 (0.0)
Nulliparous women	12 (10.2)	4 (22.2)	1 (5.0)
Progesterone	39 (33.1)	7 (38.9)	9 (45.0)
Perioperative antibiotics	11 (9.3)	8 (44.4)	6 (30.0)
Perioperative tocolytics	8 (6.8)	5 (27.8)	5 (25.0)
GA at delivery			
$GA < 24^{+0}$	8 (6.8)	1 (5.6)	0 (0.0)
GA 24 <sup>+0</sup> -27 <sup>+6</sup>	6 (5.1)	0 (0.0)	2 (10.0)
GA 28 <sup>+0</sup> -31 <sup>+6</sup>	12 (10.2)	0 (0.0)	3 (15.0)
GA 32 <sup>+0</sup> -36 <sup>+6</sup>	12 (10.2)	2 (11.1)	1 (5.0)
$GA \ge 37^{+0}$	80 (67.8)	15 (83.3)	14 (70.0)
GA at $\overline{delivery}$ (weeks + days)	38 <sup>+3</sup> [5 <sup>+6</sup> ]	38 <sup>+5</sup> [2 <sup>+2</sup> ]	39 <sup>+1</sup> [8 <sup>+0</sup> ]
	Range $15^{+4} - 42^{+4}$	Range $23^{+0} - 40^{+4}$	Range $24^{+0} - 40^{+5}$
Pregnancy prolongation (weeks + days)	24 <sup>+2</sup> [8 <sup>+2</sup> ]	22 <sup>+6</sup> [7 <sup>+1</sup> ]	25 <sup>+1</sup> [9 <sup>+1</sup> ]
	Range $0^{+2} - 28^{+1}$	Range $0^{+1}$ -26 <sup>+4</sup>	Range $7^{+1} - 28^{+4}$
Take Home Child Rate	107 (90.7)	17 (94.4)	17 (85.0)
Perioperative complications			
None	115 (97.5)	18 (100.0)	19 (95.0)
ROM	0 (0.0)	0 (0.0)	0 (0.0)
Excessive bleeding (>1000cc)	1 (0.8)	0 (0.0)	0 (0.0)
Second cerclage procedure within one pregnancy	2 (1.7)	0 (0.0)	1 (5.0)
Reasons for removal of cerclage $<$ GA 36 <sup>+0</sup>			
Suspicion of infection	2 (1.7)	2 (11.1)	0 (0.0)
Spontaneous contractions or ROM	25 (21.2)	0 (0.0)	3 (15.0)
Spontaneous loss	4 (3.4)	0 (0.0)	0 (0.0)
Other	5 (4.2)	0 (0.0)	2 (10.0)

All data are provided as number (%) or median [IQR].

procedures performed by experienced obstetric medicine specialists.

Ideally, we would also report neonatal morbidity, since this outcome is more important than the GA at delivery with regard to the effectiveness of cerclages (Alfirevic et al. 2017). Unfortunately, we were unable to do so due to the study design. However, the incidence of adverse neonatal outcomes significantly decreases with increasing GA at delivery (Bastek et al. 2008). Therefore, GA at delivery was considered a suitable outcome measure.

The study was done in a tertiary care referral hospital, which might have led to a selection of more high-risk pregnancies to be included in our cohort. Nonetheless, pregnancies with cerclages had satisfactory obstetric outcomes in our cohort. However, due to the nature of the study, no conclusions can be drawn regarding the effectiveness of cerclages.

In our study, perioperative ROM did not occur at all in singleton pregnancies with either history-indicated, short cervix-indicated or emergency cerclages. In existing literature, perioperative ROM is relatively uncommon in non-emergency cerclage procedures as well, whereas this may exceed to 19.4% in emergency cerclage procedures (Barth et al. 1990; Mitra et al. 1992; Wong et al. 1993; Aarts et al. 1995; Caruso et al. 2000; Harger 2002; Drassinower et al. 2011). The large number of procedures performed by a single experienced gynaecologist in our study may have contributed to a low complication rate. Moreover, risks on perioperative complications may have been low in our cohort due to adherence to strict criteria for

cerclage indications; cerclages were only considered in the absence of signs of intra-uterine infection, uterine contractions and vaginal blood loss. The use of a team approach may also have contributed to the strict selection of eligible women.

Contrary to what is known in literature (Berghella et al. 2017), pregnancies in which perioperative antibiotic treatment was started, resulted in earlier deliveries as compared to pregnancies without antibiotic treatment. The same applies to treatment with perioperative tocolytics. Most likely this can be attributed to selection bias in our cohort.

In addition, in our cohort, outcomes were comparable for pregnancies with and without additional prophylactic treatment with progesterone, while other studies suggest a possible beneficial effect of a multifactorial approach (i.e. additional treatment with progesterone in pregnancies with cerclages) (Stetson et al. 2016). As we believe some degree of selection bias is present in our cohort, this might explain why this possible beneficial effect is not reflected in our cohort. It would be interesting to analyse the use of progesterone, perioperative antibiotics and perioperative tocolytics for each type of cerclage indication (history-indicated, short cervix-indicated and emergency cerclage) separately, however, these analyses would be more suitable for a larger population of a prospective study.

The GA at delivery that is considered immature must be taken into account when interpreting the results. In 2000, active care was common practice for neonates born from a GA of  $26^{+0}$ , whereas nowadays in the Netherlands, neonates may be actively cared for from a GA of  $24^{+0}$  weeks (Nederlandse Vereniging voor Kindergeneeskunde 2010). Besides, neonatal care has improved over decennia. Since pregnancies in this study originated from the year 2000 and further, the results could show an underestimation of the take home child rates nowadays. On the other hand, the provided data originate from a tertiary care hospital where care for the prematurely born neonate is facilitated by the presence of a neonatal intensive care unit. Hospitals without a neonatal intensive care unit may have less favourable neonatal outcomes.

Multiple pregnancies with cerclages have less favourable obstetric outcomes, although we describe only a small selected group. The effectiveness of cerclages in multiple pregnancies is thus still under debate. Besides, we described a higher complication rate in multiple pregnancies, which highlights the importance of the debate.

In our study, 87% of the described cerclage procedures were performed by two experienced gynaecologists (gynaecologist A and B), whereas 13% of procedures were performed by a variety of other gynaecologists with less experience (gynaecologist C). When comparing results of the two experienced gynaecologists to the results of the group gynaecologists with less experience, a remarkably smaller take home child rate is observed for all singleton pregnancies treated by the gynaecologists with less experience (90.7, 94.4 and 85.0% respectively). Data were not corrected for differences in baseline characteristics between groups, although the GA at the time of the cerclage procedures seem comparable between different groups and no emergency cerclages were performed in the group with less experienced gynaecologists,

indicating that the take home child rates were not negatively influenced by the indication for cerclage. Based on the observed difference in take home child rates, we advise all cerclage procedures to be performed by experienced gynaecologists only. This may mean that women with an indication for cerclage will be referred to a more experienced colleague, either in the same, or in another hospital. To ensure treatment by an experienced gynaecologist, simulation-based training could also provide a solution. Simulation-based training for cerclage procedures can contribute to an increased exposure of gynaecologists to the procedure (Nitsche and Brost 2012, 2013). This allows for both obtaining and maintaining proficiency of the vaginal cerclage procedure, especially since its use is diminishing (Suhag et al. 2015).

#### Conclusion

Cerclages in singleton pregnancies result in few cerclageassociated complications and a high take home child rate, when performed by experienced gynaecologists.

#### Disclosure statement

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#### Data availability statement

The data that support the findings of this study are available from the corresponding author, MF, upon reasonable request.

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