

Review of Outcomes for Vaginal-Approach Cervical Cerclage in Women at Risk of Spontaneous Preterm Birth

R. O’Keeffe, A. Redmond, L. Leuthe, S. Corcoran

The National Maternity Hospital, Holles Street, Dublin 2, Ireland.

Abstract

Aim

Cervical cerclage(CC) is recognised to reduce the risk of recurrent spontaneous preterm birth(PTB). Insertion of cerclage is not without risk so should be targeted to pregnancies likely to benefit. The aim of this study is to describe the indications, complications from and outcomes in the pregnancies where a CC has been sited.

Methods

Retrospective cohort study of all women undergoing vaginal-approach CC in a tertiary referral centre with a dedicated PTB Service between January 2018 and January 2022.

Results

62 patients were included. 33%(n=20) were inserted on the basis of patient-history alone, 67%(n=42) were ultrasound-indicated. All cerclages were inserted prior to 24 weeks. Complications included; Rupture of Membranes(ROM): 1%(n=1), Non-Substantial Antepartum Haemorrhage(NSAPH): 5%(n=4), Infection: 5%(n=3), Chorioamnionitis: 8%(n=5), Preterm-Premature Rupture of Membranes(PPROM): 16%(n=10), Difficult suture removal: 3%(n=2), Stillbirth: 1%(n=1). 68%(n=42) of women had their cerclage electively removed between 36 – 37weeks. 76%(n=47) of patients delivered after 37 weeks, 6%(n=4) delivered between 34 – 36+6weeks, 15%(n=9) delivered below 34weeks and 3%(n=2) delivered below 24 weeks.

Discussion

Despite being a relatively simple procedure CC is not without risk. Reported adverse events associated with cervical cerclage include vaginal bleeding, PPRM, infection and difficulty in cerclage removal. The reported incidences of each of these complications in the literature are similar to our findings. Potential hazards of CC need to be weighed against the possible benefits.

Introduction

Spontaneous preterm birth (PTB) is one of the leading causes of perinatal morbidity and mortality¹. PTB has a significant effect on the individual baby, the family and the wider society.

Preventive therapies targeted towards women with risk factors such as a prior PTB or a short cervix have now been shown definitively to reduce the rate of PTB in this select subgroup². Vaginal-approach cervical cerclage (VACC) is one of the treatments employed in this high-risk group^{3,4}. It is a surgical technique which involves placing a suture around the cervix in a pregnant woman³. It can be placed in an elective or emergency setting. Shirodkar and McDonald are two specific insertion techniques used. Studies have shown the comparative efficacy of both techniques and the choice of technique should be at the discretion of the operator⁶.

Cervical cerclage (CC) is not without risk so should be targeted to pregnancies likely to benefit⁸. Adverse events include bleeding, preterm - premature rupture of membranes (PPROM), infection and difficulty in removal have all been reported in the literature⁸. Potential hazards of CC need to be weighed against the possible benefits.

The development of a specific pre-term birth surveillance clinic at The National Maternity Hospital over the last ten years has seen the use of these therapies increase. The purpose of this study is to review the cases of CC and to describe the indications, the complications and the outcomes in the singleton pregnancies where a VACC has been sited.

Methods

The National Maternity Hospital, Dublin is a tertiary referral centre with approximately 8,000 deliveries annually. The hospital runs a dedicated Preterm Birth Service.

This was a retrospective cohort study of all women with singleton pregnancies who underwent a VACC in The National Maternity Hospital, Dublin between January 2018 – January 2022. Women who were currently pregnant or with incomplete follow up information were excluded from the analysis. This study was approved by the Ethics Board from The National Maternity Hospital (approval number: EC15.2022, date: 12th May 2022) and the requirement for informed consent was waived due to the retrospective nature of this study.

The study participants were identified from institutional clinical database for CC held in the preterm birth clinic. We retrospectively reviewed each electronic medical record to obtain the maternal demographic characteristics and clinical data.

The primary aim of the study was to describe the indications for and complications of insertion of elective VACC. The secondary outcome of interest was the incidence of procedure-related complications and outcomes in the pregnancies where a cerclage was inserted. Outcomes of the pregnancy such as gestation at removal of cerclage, reasons for removal and gestation at delivery were also described.

Results

72 patients were found to fit the criteria. 10 patients were excluded due to either ongoing pregnancies or incomplete follow up. 62 patients therefore were included. Table 1 shows the maternal demographics, indication for insertion and obstetric history.

Indication for Insertion

33% (n=20) of CC were inserted based on patient history alone. 5% (n=1) of women in this group had three or more previous PTB. 67% (n=42) were ultrasound indicated. 40 out of 42 of these patients (95%) had experienced cervical shortening and had a cervical length of below 25mm. All cerclages were inserted prior to 24 weeks.

Table 1: Maternal Characteristics

History	Indicated	Cerclage
		20 (33%)
Ultrasound Indicated	Cerclage	42 (67%)
Time of insertion (gestational week)		15 (9 – 23)
Age of patient (years)		34 (21 – 43)
Mean BMI		26.2 (18.5 – 39.06)
Nulliparous		21 (34%)
Multiparous		41 (66%)
Current smoker		14 (23%)

Indication for Removal

The indications for removal are listed in Table 2. 68% (n=42) of patients had their CC electively removed between 36 – 37 weeks. 3% of patients (n=2) had their CC removed at pre-labour caesarean section.

10% of patients had their cerclage removed due to PPRM (n=6), while 6% (n=4) of patients had it removed due to concerns of chorioamnionitis. 11% (n=7) had their cerclage removed due to pains.

One patient had the cerclage removed due to bleeding. This patient was admitted to the hospital at 32+1 weeks following a non-substantial antepartum haemorrhage (NSAPH) at home. They had a known low-lying placenta. The cerclage was removed at 32+4 weeks due to ongoing concerns with vaginal bleeding and PPROM. She had an emergency caesarean section (EMCS) and delivered at 33+6 weeks.

Table 2: Indication for Removal

Indication for Removal	Number of patients (%)
Elective removal	42 (68%)
Elective at Caesarean Section	2 (3%)
Pains	7 (11%)
PPROM	6 (10%)
Infection/Chorioamnionitis	4 (6%)
Bleeding	1 (1%)

Gestation at Delivery

Table 3 shows the outcomes of delivery. 76% of patients (n=47) delivered after 37 weeks. Of these, 53% (n=25) had spontaneous vaginal deliveries (SVD), 9% (n=4) had instrumental deliveries, 28% (n=13) had elective lower-segment caesarean sections and 10% (n=5) had EMCS.

6% (n=4) of women delivered between 34 – 36+6 weeks. All of these patients had SVD. 15% (n=9) of patients delivered between 24 – 34 weeks. Of these, two-thirds (n=6) of women had SVD while a third (n=3) had an EMCS.

2 patients (3%) delivered below 24 weeks. Both patients had SVD. One patient presented with PPROM, pyrexia and pains at 20+2 weeks. Fetal heart had been noted on transabdominal ultrasound. CC was removed. The patient had a SVD shortly after removal. The baby was born with no signs of life at delivery. The other patient experienced a neonatal death one day after delivery at 23+3 weeks.

Table 3: Outcomes of Delivery

Gestation at Delivery (weeks)	Number of patients (%)	Spontaneous Vaginal Delivery	Instrumental Delivery	Elective LSCS	Emergency LSCS
Above 37	47 (76%)	25 (53%)	4 (9%)	13 (28%)	5 (10%)
34 – 36+6	4 (6%)	4 (100%)	0 (0%)	0 (0%)	0 (0%)
Below 34	9 (15%)	6 (70%)	0 (0%)	0 (0%)	3 (30%)
	2 (3%)	2 (3%)	0 (0%)	0 (0%)	0 (0%)

Below 24 (failure of cerclage)					
--------------------------------	--	--	--	--	--

Complications

16% (n=10) of patients had reported PPROM. PPROM occurred on average at 30+2 weeks (20+2 to 36+3 weeks), with 50% (n=5) over 32 weeks. CC was removed within 24-hours in 80% of cases (n=8), with the remaining 20% (n=2) being removed within 48-hours. 40% of these patients (n=4) had clinical or biochemical signs of chorioamnionitis. 2 further patients (20%) had chorioamnionitis confirmed histologically with growth on microbiological cultures.

There was one patient that experienced an intra-uterine death (1%). CC was removed at 27+5 weeks due to PPROM. Intra-uterine death was confirmed on departmental ultrasound at 28+1 weeks following an absent fetal heart on auscultation. This was further complicated by chorioamnionitis, and the patient had an EMCS.

There were two (3%) reported incidents of difficult suture removal. The first patient was a 35-year-old woman, nulliparous with a history of three previous LLETZ procedures. A routine cerclage removal was planned for 36 weeks however the stitch was unable to be visualised on examination and therefore was unable to be removed in an outpatient setting. The patient was booked to have the cerclage removed a week later under spinal anaesthesia in theatre. There was granulation tissue reported intraoperatively at the site of the knot, but the cerclage was thought to have been removed. The patient returned the following week at 38 weeks with regular contraction-like pains. On vaginal examination the suture was still present. It was removed and the patient went on to have an instrumental delivery.

The second patient, a 36-year-old woman, attended the Emergency Department at 20 weeks with pains and bulging membranes. PPROM was confirmed and cerclage removal was attempted. Removal was initially unsuccessful. However, on the third attempt the cerclage was removed routinely.

Four patients (5%) experienced a NSAPH requiring hospital admission. All patients were rhesus positive and reported NSAPH between 26–32 weeks. Three patients were admitted for observations for 24-hours and then discharged home. One patient, a 35-year old woman, with a history of one previous caesarean section was admitted at 27+3 weeks with NSAPH and regular pains. She had a cerclage inserted at 20 weeks due to a short cervix (1.7cm in length). Bulging membranes were noted on speculum examination and considering this and her regular pains the CC was removed. The patient had a 100ml bleed post-procedure. She had a SVD of a liveborn infant later that day.

Two of the women that were discharged home following 24-hours of observations both represented to hospital within one week. They both had concerns of chorioamnionitis and had EMCS. The fourth patient had her cerclage removed electively at 36 weeks and had a SVD at 38 weeks.

Table 4 summarises our findings of the complications associated with VACC.

Table 4: Complications Associated with Vaginal-Approach Cervical Cerclage

Complications	Number of patients (%)
Intraoperative bleeding (>200mls)	0 (0%)
Intraoperative ROM	1 (1%)
NSAPH ^a	4 (5%)
Infection ^b	3 (5%)
Clinical chorioamnionitis ^c	5 (8%)
PPROM ^d	10 (16%)
Difficult removal of suture	2 (3%)
Intra-uterine death ^e	1 (1%)

a: non-substantial antepartum haemorrhage in pregnancy,
b: positive high vaginal swab culture within 2weeks of insertion.
c: associated with signs of infection such as pyrexia or raised WCC
d: preterm premature rupture of membranes, e: stillbirth at 28+1 weeks of gestation.

Discussion

Several studies have shown that the use of VACC reduces the risk of recurrent sPTB^{9,10}. Overall our outcomes from CC insertion is good. A total of 71% of patients had their CC removed electively, either between 36-37 weeks or during pre-labour caesarean section. This is in keeping with the most recent RCOG greentop guidelines on CC⁷.The majority of patients (76%) proceeded to a term delivery with 53% of these patients having a SVD.

The RCOG recently updated their Green-top guidelines (February 2022) on CC and there are three well-accepted indications for VACC placement⁷. A history indicated (HIC) or prophylactic cerclage may be inserted in singleton pregnancies in women with a history of three or more previous sPTB⁷. As previously mentioned, 33% (n=20) of our patients had CC inserted based on patient history alone. 5% (n=1) of women in this group had three or more previous sPTB. However, these were women that had cerclages inserted prior to the new guidelines. We have now updated our criteria for insertion based on the most up-to-date guidelines.

An ultrasound indicated cerclage (UIC) may be considered for women with a history of spontaneous second trimester loss or sPTB if the cervical length in a current singleton pregnancy is $<25\text{mm}$ ⁷. 67% (n=42) of cerclages were ultrasound indicated. 40 out of 42 of these patients (95%) had experienced cervical shortening and had a cervical length of below 25mm.

However, despite being a common and relatively simple procedure, CC insertion is not without risk. Reported adverse events include bleeding, PPROM, infection and difficulty in removal have all been reported in the literature⁸. The reported incidences of each of these complications in the literature are similar to our findings^{11,12,13,15}.

PPROM is considered the most frequent complication following cerclage insertion, and reportedly occurs in up to 38% of cases^{10,14}. Our data showed 16% of women with cerclages had PPROM. However, given that the rate of PROM in all pregnancies is 3%¹⁰, our rate of 16% may not be excessive in a subgroup of high-risk patients. Therefore PPROM cannot be solely attributed to insertion of CC.

Drassinower et al.¹⁵ retrospectively evaluated the perioperative and postoperative (up to 2 weeks after cerclage) complications of cerclage insertion. They looked at women who underwent either history-indicated or ultrasound-indicated cerclage. They found no perioperative complications among the women who underwent history-indicated cerclages. They found two perioperative complications among the 89 women who underwent ultrasound-indicated cerclages: one case of unsuccessful regional anaesthesia and one case of vaginal bleeding and preterm labour 2-weeks postoperatively.

To et al.¹⁶ described the perioperative complications in women undergoing ultrasound-indicated cerclage insertion. They found one case of intraoperative rupture of membrane (ROM) in 123 procedures. Similarly, in a randomised controlled trial by Owen et al.¹⁷, they reported one case of intraoperative ROM, one case of bleeding postoperatively and two cases of anaesthetic complications in 153 procedures. We found one case of intraoperative ROM in our study of 62 patients undergoing elective cerclage insertion. Therefore, these findings in the literature are consistent with ours, that intraoperative ROM rarely occurred in women undergoing elective cerclage insertion.

Cerclage insertion has been associated with chorioamnionitis and other intrauterine infections¹⁸. We found that 8% of women had clinical chorioamnionitis in their pregnancy. Moreover, Treadwell et al. reviewed 482 cases and found that postoperative infections occurred in 6.6% of cases of cerclage¹⁹. These findings are similar to ours as we found 5% of women complained of vaginal discharge and had a positive HVS culture within 2 weeks of insertion of CC.

Our study has some limitations. It is a retrospective review and had a relatively small sample size. . The strengths of our study are that it was performed in a single institution, we completed a detailed review of each medical chart and that many patients were followed to delivery.

We can conclude that potential hazards of CC insertion need to be weighed against the possible benefits. The findings of this study will help us to counsel our patients on the potential risks and benefits of cervical cerclage insertion. It may therefore have clinical implications for getting adequately informed consent from these women.

Declarations of Conflicts of Interest:

None declared.

Corresponding Author:

Rachel O’Keeffe,
The National Maternity Hospital,
Holles Street,
Dublin 2.
E-Mail: rachelokeeffe1993@gmail.com

References

1. Eleje GU, Eke AC, Ikechebelu JI, Ezebialu IU, Okam PC, Ilika CP. Cervical stitch (cerclage) in combination with other treatments for preventing spontaneous preterm birth in singleton pregnancies. *Cochrane Database Syst Rev.* 2020 Sep 24;9(9):CD012871.
2. Shimrit Shor, Ariel Zimmerman, Ron Maymon, Michal Kovo, Maya Wolf, Ifat Wiener, Jacob Bar & Yaakov Melcer. Combined therapy with vaginal progesterone, Arabin cervical pessary and cervical cerclage to prevent preterm delivery in high-risk women. *The Journal of Maternal-Fetal & Neonatal Medicine*, 2021;34:13, 2154-2158.
3. Alfirevic Z, Stampalija T, Medley N. Cervical stitch (cerclage) for preventing preterm birth in singleton pregnancy. *Cochrane Database Syst Rev.* 2017 Jun 6;6(6):CD008991.
4. Yorifuji T, Makino S, Yamamoto Y, Tanaka T, Itakura A, Takeda S. Effectiveness of delayed absorbable monofilament suture in emergency cerclage. *Taiwanese Journal of Obstetrics & Gynecology* 2014;53(3):382-4.
5. Odibo AO, Berghella V, To MS, et al. Shirodkar versus McDonald cerclage for the prevention of preterm birth in women with short cervical length. *Am J Perinatol.* 2007;24(1):55–60.
6. Shennan, A, Story, L, Jacobsson, B, Grobman, WA; the FIGO Working Group for Preterm Birth. FIGO good practice recommendations on cervical cerclage for prevention of preterm birth. *Int J GynecolObstet.* 2021; 155: 19– 22.

7. Shennan, AH, Story, L; the Royal College of Obstetricians, Gynaecologists. Cervical Cerclage. BJOG 2022; 129: 1178– 1210.
8. Kuruma, A., Hayashi, S., Koh, I., Yamamoto, R., Mitsuda, N. and Ishii, K. Incidences of complications associated with cervical cerclage by indication of the procedure. J. Obstet. Gynaecol. Res., 2022;48: 73-79.
9. Alfirevic Z, Owen J, Carreras Moratonas E, Sharp AN, Szychowski JM, Goya M. Vaginal progesterone, cerclage or cervical pessary for preventing preterm birth in asymptomatic singleton pregnant women with a history of preterm birth and a sonographic short cervix. Ultrasound Obstet Gynecol. 2013;41:146–151
10. Lee KN, Whang EJ, Chang KH, Song JE, Son GH, Lee KY. History-indicated cerclage: the association between previous preterm history and cerclage outcome. Obstet Gynecol Sci. 2018 Jan;61(1):23-29.
11. J.H. Harger. “Cervical cerclage: patient selection, morbidity, and success rates.” Clin Perinatol. 1983;(10):321-341.
12. M. Kurup, J.W. Goldkrand. “Cervical incompetence: elective, emergent, or urgent cerclage. “Am J Obstet Gynecol. 1999;(181):240-246
13. W.A Peters III, S. Thiagarajah, G.M. Harbert Jr. “Cervical cerclage: twenty years’ experience.” South Med J. 1979;(72):933-937
14. Brown R, Gagnon R, Delisle MF, Maternal Fetal Medicine Committee Cervical insufficiency and cervical cerclage. J Obstet Gynaecol Can. 2013;35:1115–1127.
15. Drassinower D, Poggi SH, Landy HJ, Gilo N, Benson JE, Ghidini A. Perioperative complications of history-indicated and ultrasound-indicated cervical cerclage. Am J Obstet Gynecol. 2011;205(1):53.
16. To MS, Alfirevic Z, Heath VCF, Cicero S, Cacho AM, Williamson PR, et al. Cervical cerclage for prevention of preterm delivery in women with short cervix: randomised controlled trial. Lancet. 2004;363(9242):1849-53
17. Owen J, Hankins G, Iams JD, Berghella V, Sheffield JS, Perez-Delboy A, et al. Multicenter randomised trial of cerclage for preterm birth prevention in high-risk women with shortened midtrimester cervical length. Am J Obstet Gynecol. 2009;201(4):375.
18. Simcox R, Shennan A. Cervical cerclage: a review. Int J Surg. 2007;5(3):205–209.
19. Treadwell MC, Bronsteen RA, Bottoms SF. Prognostic factors and complication rates for cervical cerclage: a review of 482 cases. Am J Obstet Gynecol. 1991;165(3):555–558.