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Cervical Cerclage

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Cervical Cerclage

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This is the second edition of this guideline; the first edition was published in 2011 under the same name. It supplements NICE guideline NG25 *Preterm labour and birth*.

1. Key recommendations

- Women with singleton pregnancies and three or more previous preterm births should be offered a history-indicated cervical cerclage. [Grade B]
- Women with a singleton pregnancy and a history of spontaneous second trimester loss or preterm birth who have not undergone a history-indicated cerclage may be offered serial sonographic surveillance, as those who experience cervical shortening may benefit from ultrasound-indicated cerclage while those whose cervix remains long (greater than 25mm) have a low risk of second-trimester loss/preterm birth. [Grade B]
- For women with a singleton pregnancy and no other risk factors for preterm birth, insertion of cervical cerclage is not recommended in women who have an incidentally identified short cervix. [Grade B]
- In women with a previous unsuccessful transvaginal cerclage, insertion of a transabdominal cerclage may be discussed and considered. [Grade D]
- In women with a singleton pregnancy insertion of a emergency cerclage may delay birth by an average of 34 days, compared with expectant management/bed rest alone in suitable cases. It may also be associated with a two-fold reduction in the chance of birth before 34 weeks of gestation. However, there are only limited data to support an associated improvement in neonatal mortality or morbidity. [Grade B]
- The choice of transvaginal cerclage technique (high cervical insertion with bladder mobilization or low cervical insertion) should be at the discretion of the surgeon [Grade C], but the cerclage should be placed as high as is practically possible. [Grade C]

2. Background and scope

Cerclage remains one of the standard options for prophylactic intervention in the care of women at risk of preterm birth and second trimester fetal loss and is used by most obstetricians, despite difficulties in identifying the population of women who would most benefit. The procedure, a stitch inserted into the cervix, was first performed in 1902 in women with a history of second trimester loss or spontaneous preterm birth suggestive of cervical insufficiency, with the aim of preventing recurrent loss.

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Cervical insufficiency is an imprecise clinical diagnosis frequently applied to women with such a history, where it is assumed that the cervix is 'weak' and unable to remain closed during the pregnancy. Recent evidence suggests that, rather than being a dichotomous variable, cervical integrity is likely to be a continuum influenced by factors related not solely to the intrinsic structure of the cervix but also to processes driving premature effacement and dilatation. While cerclage may provide a degree of structural support to a 'weak' cervix, its role in maintaining the cervical length and the endocervical mucus plug as a mechanical barrier to ascending infection may be more important.

There is lack of consensus on the optimal cerclage technique, timing of suture placement, the role of amniocentesis before emergency cerclage insertion and optimal care following insertion. Complications are not well documented and often difficult to separate from risks inherent to the underlying condition. The purpose of this guideline is to review the literature and provide evidence-based guidance on the use of cerclage in women at risk of preterm birth and second trimester loss. This guideline supplements NICE guideline [NG25] Preterm labour and birth.[1]

Within this document we use the terms woman and women's health. However, it is important to acknowledge that it is not only people who identify as women for whom it is necessary to access women's health and reproductive services in order to maintain their gynaecological health and reproductive wellbeing. Gynaecological and obstetric services and delivery of care must therefore be appropriate, inclusive and sensitive to the needs of those individuals whose gender identity does not align with the sex they were assigned at birth.

3. Identification and assessment of evidence

This Royal College of Obstetricians and Gynaecologists (RCOG) guideline was developed in accordance with the standard methodology for producing RCOG Green-top Guidelines.[2]

The Cochrane Library (including the Cochrane Database of Systematic Reviews), DARE, EMBASE, TRIP, Medline and PubMed (electronic databases) were searched for relevant randomized control trials, systematic reviews and meta-analyses. The search was restricted to articles published between 2011 and April 2020. The databases were searched using the relevant MeSH terms, including all subheadings and this was combined with a keyword search. Search words included 'cervical cerclage', 'cervical suture', 'cervical stitch', 'midtrimester miscarriage', 'McDonald cerclage', 'Shirodkar cerclage', 'infection and cerclage', 'tocolytics and cerclage' and 'inflammatory mediators and cerclage'; the search was limited to humans and the English language. The National Library for Health and National Guidelines Clearing House were also searched for relevant guidelines and reviews. The full search strategy is available to view online as supporting information (Appendices S1 and S2).

4. Definitions

Previous terminology (prophylactic, as a planned procedure, emergency, urgent, rescue) of cervical sutures/cerclage can be ambiguous. More appropriate nomenclature based on indication for cervical suture is recommended. The terms below are increasingly used in the scientific literature.

History-indicated cerclage

Insertion of a cerclage as a result of factors in a woman's obstetric or gynaecological history, which increase the risk of spontaneous second trimester loss or preterm birth.[3] A history-indicated suture is performed as a prophylactic measure in asymptomatic women and usually inserted as a planned procedure at 11–14 weeks of gestation.

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Preterm Birth

Birth before to 37^{+0} weeks' gestation.

Ultrasound-indicated cerclage

Insertion of a cerclage as a therapeutic measure in cases of cervical length shortening seen on transvaginal ultrasound.[3] Ultrasound-indicated cerclage is performed on asymptomatic women who do not have exposed fetal membranes in the vagina. Sonographic assessment of the cervix is usually performed between 14 and 24 weeks of gestation by transvaginal scan and with an empty maternal bladder.

Emergency cerclage (also known as physical exam-indicated or emergency cerclage)

Insertion of cerclage as a salvage measure in the case of premature cervical dilatation with exposed fetal membranes in the vagina.[3] This may be discovered by ultrasound examination of the cervix or as a result of a speculum/physical examination performed for symptoms such as vaginal discharge, bleeding or 'sensation of pressure'. It can be considered up to 27^{+6} weeks gestation.[1]

Transvaginal cerclage (McDonald)

A transvaginal purse-string suture placed at the cervical isthmus junction, without bladder mobilization.[4]

High transvaginal cerclage requiring bladder mobilization (including Shirodkar)

A transvaginal purse-string suture placed following bladder mobilization, to allow insertion above the level of the cardinal ligaments.[5]

Transabdominal cerclage

A suture performed via a laparotomy or laparoscopy, placing the suture at the cervicoisthmic junction.[6]

Occlusion cerclage

Occlusion of the external os by placement of a continuous non-absorbable suture. The theory behind the potential benefit of occlusion cerclage is retention of the mucus plug.[7]

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5. History-indicated cerclage

5.1. *When should a history-indicated cerclage be offered?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Women with singleton pregnancies and three or more previous preterm births should be offered a history-indicated cervical cerclage	1+	B	A subgroup analysis of the Medical Research Council (MRC)/RCOG multicentre trial found benefit was only conferred for women with a history of three or more previous preterm births and/or second trimester losses
History-indicated cerclage should not routinely be offered to women with less than three previous preterm births and/or second trimester losses without additional risk factors	1+	B	Subgroup analysis of the MRC/RCOG multicentre trial showed no benefit conferred
It is unknown if the specific characteristics of the previous adverse event are helpful in the decision to place a history-indicated cerclage. (e.g. painless dilatation, rupture of membranes, prior cervical surgery)	4	GPP	Good quality data are currently lacking to inform this practice

Cochrane review concluded that, in women with a singleton pregnancy, there was a significant reduction in preterm births compared to controls before 37, 34 and 28 weeks of gestation in women who had cerclage compared to no cerclage (average risk ratio [RR] 0.77, 95% confidence interval [CI] 0.66–0.89, incorporating nine studies with 2415 women). Subgroup analysis (assessing history-indicated; short cervix based on one off ultrasound in women at high risk; short cervix found by serial scan measurements in women at high risk; examination indicated; and short cervix found on scan in populations with low or mixed risk) had too few numbers to draw significant conclusions.[3]

Evidence level 1+

There is no evidence to suggest an effect on perinatal death. Although the authors concluded that cerclage probably leads to a reduced risk of perinatal death when compared to no cerclage, the CI crossed the line of no effect (RR 0.82, 95% CI 0.65–1.04, based on 10 studies including 2927 women). When stillbirths and neonatal deaths were considered separately the number of events and sample size were reduced considerably. Neonatal morbidity was similar with and without cerclage.[3]

Evidence Level 1+

A pre-specified subgroup analysis of an international multicentre trial, which recruited 1292 women to cerclage or no cerclage, coordinated by the MRC and RCOG, found that only women with a history of three or more pregnancies ending before 37 weeks of gestation (n = 104) benefitted from cerclage, which halved the incidence of preterm birth before 33 weeks of gestation (15% versus 32% $P > 0.05$). No effect was observed in those with only one (birth before 33 weeks of gestation in the cerclage group 14% versus 17% in the expectant group) or two previous early births (birth before 33 weeks of gestation in the cerclage group 12% versus 14% in the expectant group).[8]

Evidence level 1+

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Subgroup analysis of this study also found no benefit for a history-indicated cerclage in women with previous cervical surgery or uterine abnormalities; the authors concluded that the relatively small numbers in each group limited the reliability of these results.[8]

Evidence level 1+

The studies that have examined the use of pre-pregnancy techniques (e.g. hysterography, cervical resistance indices, insertion of cervical dilators) to assess cervical weakness were observational and not designed to test the hypothesis that their use optimized the selection of women for history-indicated cerclage.[9,10]

Evidence level 3

6. Ultrasound-indicated cerclage

6.1. *When should an ultrasound-indicated cerclage be offered?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
For women with a singleton pregnancy and no other risk factors for preterm birth, insertion of cervical cerclage is not recommended in women who have a short cervix incidentally identified on a late second trimester ultrasound scan	**1++**	**B**	A number of randomized controlled trials (RCTs) and a meta-analysis have found no benefit of cerclage in women with a cervical length less than 25 mm with no other risk factors for preterm birth

To et al.[11] screened 47 123 women at 22–24 weeks of gestation using transvaginal ultrasound to measure cervical length; in 470 women (1%), the cervix was 15 mm or less. Of these women, 253 (54%) agreed to participate in a randomized study comparing Shirodkar cerclage (n = 127) with expectant management (n = 126). The incidence of preterm birth before 33 weeks of gestation was similar in both groups, at 22% (28 of 127) in the cerclage group versus 26% (33 of 126) in the control group (RR 0.84; 95% CI 0.54–1.3; P = 0.44), with no significant differences in perinatal or maternal morbidity or mortality.

Evidence level 1++

This was further confirmed in an individual patient data (IPD) meta-analysis of four RCTs of cerclage versus expectant management in women with a short cervix (in which women from the previously discussed RCT were included). This meta-analysis reported no overall evidence of benefit of cerclage in women with cervical length less than 25mm who had no other risk factors for spontaneous preterm birth.[12]

Evidence level 1++

Routine surveillance of women at low risk is not currently recommended by the National Screening Committee.

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6.1.1. Women with a singleton pregnancy and a history of spontaneous second trimester loss or preterm birth

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Women with a history of one or more spontaneous second trimester loss or preterm births who are undergoing ultrasound surveillance of cervical length should be offered cerclage if the cervix is 25mm or less at gestations less than 24 weeks	1++	A	A meta-analysis including data from four RCTs shows that an ultrasound indicated cerclage for cervical shortening (less than 25 mm) in the presence of a history of one or more spontaneous second trimester losses or preterm births, reduces preterm birth prior to 35 weeks gestation
An ultrasound-indicated cerclage is not recommended for funnelling of the cervix (dilatation of the internal os on ultrasound) in the absence of cervical shortening to 25 mm or less (the closed length of the cervix)	2++	C	Observational studies have indicated no association between preterm birth and funnelling alone in the absence of a short cervix

An RCT of ultrasound-indicated cerclage with singleton pregnancies with a history of spontaneous preterm birth between 17^{+0} and 33^{+6} weeks of gestation, who were found to have a cervical length of less than 25mm detected during serial sonographic examinations between 16^{+0} and 21^{+6} weeks of gestation, reported that when compared with expectant management, cerclage reduced pre-viable birth (at less than 24^{+0} weeks of gestation: 6.1% versus 14%; $P = 0.03$) and perinatal death (8.8% versus 16%; $P = 0.046$) but did not prevent birth at less than 35^{+0} weeks of gestation (32% versus 42%; odds ratio [OR] 0.67; 95% CI 0.42–1.07) unless cervical length was less than 15 mm (OR 0.23; 95% CI 0.08–0.66).[13]

Evidence level 1++

Similar results were reported from a meta-analysis that included 607 pregnancies from four RCTs of ultrasound-indicated cerclage.[14] This study reported that in the subgroup of women with singleton pregnancies with a history of preterm second trimester loss (16^{+0}–23^{+0} weeks of gestation) or birth before 36 weeks of gestation, cerclage resulted in a significant reduction in birth before 35 weeks of gestation (RR 0.57; 95% CI 0.33–0.99 and RR 0.61; 95% CI 0.40–0.92, respectively) when compared with expectant management; this reduction was of a similar magnitude to that observed in the previous study.[13]

Evidence level 1++

There are no studies evaluating ultrasound-indicated cerclage performed solely on the presence of funnelling. However, studies have demonstrated that funnelling is a function of cervical shortening and does not appear to independently add to the risk of preterm birth associated with cervical length.[15,16]

Evidence level 2++

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6.2. *Who should be offered serial sonographic surveillance with a view to ultrasound-indicated cerclage?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Women with a history of spontaneous second trimester loss or preterm birth who have not undergone a history-indicated cerclage may be offered serial sonographic surveillance, as those who experience cervical shortening (less than 25mm) may benefit from ultrasound-indicated cerclage (see 6.1)	**2++**	**B**	A meta-analysis showed similar incidences of preterm birth with history and ultrasound indicated cerclage in women at high risk

In studies where serial sonographic surveillance of cervical length has been carried out in women with a history of second trimester loss and/or spontaneous preterm birth, 40%–70% of women maintain a cervical length of more than 25mm before 24^{+0} weeks of gestation.[8,13,16–19] In three of these studies, 90% of women who maintained a cervical length of more than 25mm (and therefore did not receive cerclage) gave birth after 34 weeks of gestation. This suggests that serial sonographic surveillance may differentiate between women with a prior second trimester loss/preterm birth who might benefit from cerclage and women who do not need intervention

Evidence level 2++

A meta-analysis by Berghella et al.[20] compared pregnancy outcomes in singleton gestations with prior preterm birth that were managed either by cervical length screening with cerclage for short cervical length or history-indicated cerclage. Cervical length screening with cerclage for short cervical length was associated with similar incidences of preterm birth before 37 weeks (31% compared with 32%, RR 0.97; 95% CI 0.73–1.29), preterm birth before 34 weeks (17% compared with 23%, RR 0.76; 95% CI 0.48–1.2) and perinatal mortality (5% compared with 3%, RR 1.77; 95% CI 0.58–5.35) compared with history-indicated cerclage. In the transvaginal ultrasound group, only 42% developed a short cervix and required cerclage. These data support the recommendation that women with a previous second trimester loss/preterm birth can be safely cared for by serial ultrasound surveillance and that this may reduce the number of cerclages performed

Evidence level 2++

Ultrasound surveillance of cervical length is advocated in women at high and intermediate risk in Element 5 of the Saving Babies Lives Care Bundle,[21] the timing of which is dependent on the women's history.

Women at high risk include:

- those with a previous preterm birth or second trimester loss (16–34 weeks' gestation)
- previous preterm prelabour rupture of membranes (PPROM) less than 34 weeks
- previous use of cerclage
- known uterine variant
- intrauterine adhesions

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- history of trachelectomy.

These women are recommended to be reviewed by a preterm prevention specialist by 12 weeks where possible, or with the dating scan whichever is sooner, and offered transvaginal cervix scanning as a secondary screening test every 2–4 weeks between 16 and 24 weeks.

Women at intermediate risk include:

- women including those who have a history of a previous full dilatation C-section
- significant cervical excisional surgery i.e. large loop excision of the transformation zone (LLETZ) with an excision depth greater than 1 cm, more than one procedure or a cone biopsy.

These women should undergo a single transvaginal cervix scan no later than 18–22 weeks as a minimum. These timings are based on a consensus of experts from the UK Preterm Clinical Network.[22]

Evidence level 4

There is, however, uncertainty as to how to care for these women if a short cervix is identified in women who have had serial screening but do not have a history of a previous preterm birth; an ultrasound indicated cerclage may be considered.

7. Can cervical cerclage be recommended in any other groups of women considered at increased risk of preterm birth?

7.1. Multiple pregnancy

Recommendation	Evidence quality	Strength	Rationale for the recommendation
The insertion of a history- or ultrasound-indicated cerclage in women with multiple pregnancies is not recommended	**1++**	**B**	Data from meta analyses indicates no benefit of cerclage in multiple pregnancies without additional risk factors

A meta-analysis of five trials assessed the use of cerclage in multiple pregnancies; 122 women had twin pregnancies and six had triplet pregnancies. Included studies assessed history-indicated cerclage, ultrasound indicated cerclage and physical exam-indicated cerclage. No statistical difference in perinatal death was found between cerclage and no cerclage (19.2% versus 9.5%; RR 1.74, 95% CI 0.92–3.28, five trials $n = 262$), significant neonatal morbidity (15.8% versus 13.6%; average RR 0.96, 95% CI 0.13–7.10, three trials $n = 116$) or composite perinatal death and neonatal morbidity (40.4% versus 20.3%; average RR 1.54, 95% CI 0.58–4.11, three trials $n = 116$). No significant differences were found in secondary outcomes such as preterm birth less than 34 weeks, birth weight below 2500 g, respiratory distress syndrome, caesarean section rates and maternal side-effects. Subgroups were also assessed: ultrasound indicated cerclage was associated with an increased risk of low birth weight (below 2500 g) compared to no cerclage (average RR 1.39, 95% CI 1.06–1.83), very low birth weight (below 1500g) (average RR 3.31, 95% CI 1.58–6.91) and respiratory distress syndrome (average RR 5.07, 95% CI 1.75–14.7). However, the numbers in these subgroups were small so results should be interpreted with caution.[23]

Evidence level 1++

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Jarde et al.[24] also assessed the efficacy of twin pregnancies treated with progesterone, pessary or cerclage in a meta-analysis. No intervention significantly reduced the risk of preterm birth less than 34 or 37 weeks' gestation, or neonatal death compared to a control group.

Evidence level 1+

Data from a multicentre retrospective cohort study in twins, where women with a cervix less than 25mm between 16 and 24 weeks' gestation either had ultrasound indicated cerclage (n = 57), or no cerclage (n = 83) found that there were no differences in gestational age at birth or spontaneous preterm birth less than 28 weeks (12 versus 20 adjusted OR 0.3 95% CI 0.68–1.37). In the subgroup of women with cervical length less than 15 mm (cerclage n = 32 and controls n = 39) the interval between diagnosis to birth was significantly prolonged (12.5 ± 4.5 versus 8.8 ± 4.6 weeks, $P < 0.001$); spontaneous preterm birth less than 34 weeks was significantly decreased (16 versus 31 adjusted OR 0.51; 95% CI 0.31–0.83) as was admission to neonatal intensive care unit when the ultrasound indicated group was compared with the control group. However, there was no difference in rates of preterm birth at gestations less than 32 weeks, less than 28 weeks and less than 24 weeks and no effect on perinatal mortality (11.3% versus 16.6% P = 0.46). Numbers in this study are small and further RCTs are therefore required to assess the effect of ultrasound indicated cerclage based on different cervical lengths.[25]

Evidence level 2++

STOPPIT-2 is a randomised trial of the Arabin pessary to prevent preterm birth in twin pregnancies with a short cervix. Data collection is now complete and the results are currently being analysed.[26]

7.2. *Cervical surgery, trauma and uterine abnormalities*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
The role of history- or ultrasound-indicated cerclage is uncertain in other high-risk groups, who display no additional risk factors, such as women with Mullerian anomalies, previous cervical surgery (cone biopsy, LLETZ or destructive procedures such as laser ablation or diathermy) or multiple dilatation and evacuation	**1+**	**B**	An IPD meta-analysis showed no difference in preterm birth before 35 weeks

Local excisional treatment of the cervix has been shown to be associated with an increased risk of preterm birth. A meta-analysis of 27 retrospective cohort studies showed an increased risk of preterm birth less than 37 weeks' gestation when cold knife conisation was compared to no treatment (14% versus 5%; RR 2.59, 95% CI 1.8–3.72) and LLETZ versus no treatment (11% versus 7%; RR 1.7, 95% CI 1.24–2.35). No increased risk was associated with laser ablation.[27] Women with cervical intraepithelial neoplasia have been shown to have an increased background risk of preterm birth compared to the general population (5.9% versus 5.6%; RR 1.24, 95% CI 1.14–1.35) but the risk of preterm birth is higher in women who have undergone more than one treatment (13.2% versus 4.1%; RR 3.78, 95% CI 2.65–5.39) and with increasing depth of excision (≤ 10–12mm: 7.1% versus 3.4%; RR 1.54, 95% CI 1.09–2.18; ≥10–12mm: 9.8% versus 3.4%; RR 1.93, 95% CI 1.62–2.31; ≥15–17mm: 10.1% versus 3.4%; RR 2.77, 95% CI 1.95–3.93; ≥20mm: 10.2% versus 3.4%; RR 4.91, 95% CI 2.06–11.68).[28]

Evidence level 1+

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Kindinger et al.[29] aimed to develop a screening model to differentiate women into high and low risk for preterm birth after excisional treatment for cervical intraepithelial neoplasia. Longitudinal cervical length data from 725 pregnant women post treatment attending preterm surveillance clinics over a ten-year period was analysed. Of these, 13.5% of women received an ultrasound indicated cerclage and 9.7% gave birth prior to 37 weeks' gestation; 24.5% of these despite receiving cervical cerclage. Accuracy parameters of interval reduction in cervical length between longitudinal second trimester measurements were undertaken and a reduction in cervical length of less than 10% between measurements identified women at low risk of preterm birth who did not require further surveillance. However, the study was retrospective and a direct comparison population was lacking. Prospective studies are required to investigate this further.

Evidence level 2+

A consensus of experts from the UK Preterm Clinical Network has recommended women with a history of significant cervical excisional surgery i.e. LLETZ where greater than 10mm excised, or more than one LLETZ procedure, or a cone biopsy should be referred to a preterm birth prevention specialist and a single transvaginal cervical scan should be performed between 18–22 weeks as a minimum. Women with a known uterine variant should be referred to a preterm prevention specialist by 12 weeks' gestation where possible and offered transvaginal screening every 2–4 weeks between 16 and 24 weeks' gestation.[22]

Evidence level 4

The existing published studies are either inadequately controlled or include insufficient numbers to be able to make evidence-based recommendations regarding efficacy of cerclage in these groups of women. The IPD meta-analysis of ultrasound-indicated cerclage[14] (subgroup analysis of those women with a history of cone biopsy [$n = 64$] or more than one dilatation and evacuation [$n = 131$]) showed no difference in preterm birth before 35 weeks of gestation in the cerclage group compared with the expectant management group (RR 1.18, 95% CI 0.57–2.45 and RR 0.91, 95% CI 0.57–1.47, respectively); however, the authors concluded that the results should be interpreted with caution owing to the small numbers of women. There were insufficient women with Mullerian anomalies or diethylstilbestrol exposure to perform subgroup analyses.

Evidence level 1–

The MRC/RCOG study of history-indicated cerclage reported that, in a subgroup analysis of women with a history of cone biopsy or cervical amputation ($n = 138$), there was no significant difference in birth before 33^{+0} weeks of gestation in the cerclage group compared with the expectant group (19% versus 22%).[8]

Evidence level 1+

7.3. *Women with raised BMI*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Cerclage is effective in women with a raised BMI	**1–**	**B**	A secondary analysis of an RCT showed no evidence cerclage was less effective in women with a raised BMI

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A secondary analysis of a multicentre RCT included women with an increased BMI (above 25kg/m^2) and cervical shortening (less than 25 mm) who were randomly assigned to cerclage or no cerclage. BMI has purported to be associated with preterm birth due to a heightened inflammatory response. In the cerclage group (n = 148) BMI had no effect but in the non-cerclage group (P = 153), increasing BMI was inversely associated with gestational age at birth; however, the result was driven by several women with an extremely high BMI (above 47kg/m^2).[30]

Evidence level 1–

8. Transabdominal cerclage

8.1. *When should a transabdominal cerclage be considered?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
In women with a previous unsuccessful transvaginal cerclage, insertion of a transabdominal cerclage may be discussed and considered	**1+**	**A**	Evidence is derived from a multi-centre RCT randomising women to trans abdominal cerclage high vaginal or low vaginally placed cerclage
Transabdominal cerclage can be performed pre-conceptually or in early pregnancy. Pre-conceptual procedures may be more effective and are not associated with sub-fertility	**4**	**GPP**	Pre-conceptional insertion should be considered as it does not affect fertility rates and technically may be easier with lower anaesthetic and fetal risks

A transabdominal cerclage is usually inserted following an unsuccessful vaginal cerclage or extensive cervical surgery. The MAVRIC study, a multicentre randomized controlled trial of transabdominal versus transvaginal cerclage randomized women to receive transabdominal cerclage, high vaginal cerclage or low vaginal cerclage either before conception or at less than 14 weeks of gestation. The data for 111 of 139 women who were recruited and who conceived were analysed: 39 had transabdominal cerclage, 39 had high vaginal cerclage and 33 had low vaginal cerclage. Rates of preterm birth less than 32 weeks' gestation were significantly lower in women who received transabdominal cerclage compared with low vaginal cerclage (8% versus 33%, RR 0.23: 95% CI, 0.07–0.76; P = 0.0157). The number needed to treat to prevent one preterm birth was 3.9 (95% CI, 2.32–12.1). There was no difference in preterm birth rates between high and low vaginal cerclage.[31] However, a previous retrospective study has indicated that the higher a cerclage is placed in cases of short cervix the lower the subsequent odds of preterm birth.[32]

Evidence level 2–

There are no RCT studies directly comparing the insertion of a pre-conceptual transabdominal cerclage with insertion in early pregnancy. Tulandi et al.[33] evaluated 16 studies of abdominal cerclage involving 678 cases, finding no difference in the live birth rate when the cerclage was performed before or during pregnancy. However, pre-conceptual insertion should be considered when possible because of reduced anaesthetics risk and the technical advantage of operating on the uterus of a woman who is not pregnant. Furthermore, there is no evidence that pre-conceptual transabdominal cerclage has any detrimental impact on fertility or care and treatment of early miscarriage.

Evidence level 2+

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Subgroup analysis of an RCT comparing abdominal cerclage with vaginal cerclage (low or high) included women with a history of previous second trimester loss or preterm birth despite having a previous low vaginal cerclage. Women in the abdominal cerclage group had the surgery before conception. There was no difference between time to conception between the two groups (hazard ratio 1.34; 95% CI 0.72–2.5 $P = 0.35$); rates of conception at 6, 12 and 18 months were similar.[34]

Evidence level 1+

8.2. *Should an abdominal cerclage be performed laparoscopically?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Laparoscopic and open abdominal cerclage have similar efficacy. The laparoscopic approach is associated with fewer complications, and can be considered where suitable surgical expertise is available	**2+**	**C**	A meta-analysis has indicated no difference in second trimester loss or birth rates after 34 weeks between insertion laparoscopy or laparotomy

Tulandi et al.[33] evaluated the efficacy of abdominal cerclage via laparoscopy versus laparotomy including 16 studies and a total of 678 cases. They found no difference in the rates of third trimester birth and live birth rates via laparoscopy or laparotomy (97.3%–100% and 100% respectively).

Evidence level 1+

A prospective cohort study assessed women who underwent laparoscopic abdominal cervical cerclage and compared them with a historical cohort of women who underwent the same procedure via laparotomy. Fetal survival rate post cerclage was similar in the two groups (98% versus 100%) but complications were more common in the laparotomy group (22% versus 2%). There were no conversions to laparotomy in the laparoscopy group.[35]

Evidence level 2+

A meta-analysis including six studies using the laparoscopic approach and 26 studies using the abdominal approach found no difference in second trimester loss (8.1% laparoscopic versus 7.8%) or birth rates after 34 weeks (78.5% versus 84.8%) in the two groups. However, this was not a direct comparison of the two modalities.[36] A further meta-analysis comparing laparoscopic versus open abdominal cerclage found no difference in third trimester birth or live birth rates.[33]

Evidence level 2+

Case reports have also been published regarding the insertion of an abdominal cerclage using a robotic assisted technique.[37,38] Further studies are needed to assess its efficacy

Evidence level 3

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8.3. *How should women who experience delayed miscarriage or fetal death be cared for?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Decisions on care and treatment in cases of delayed miscarriage or fetal death in women with an abdominal cerclage can be difficult and women's decision making should be aided by a senior obstetrician	**4**	**GPP**	No studies have been performed but senior clinicians should be involved in these decisions
Complete evacuation through the stitch by suction curettage or by dilatation and evacuation (up to 18 weeks of gestation) may be performed; alternatively, the suture may be cut, usually via a posterior colpotomy. Failing this, a hysterotomy may be required or caesarean section may be necessary; the woman's decision should be aided by a senior obstetrician	**4**	**D**	Case reports have been published regarding evacuation through a transabdominal cerclage or cutting of the suture

Carers should be aware of the potential psychological sequelae associated with fetal death and miscarriage, and women and their families supported by debriefing services and the offer of counselling. Families should also be signposted to the relevant patient support groups.

There are no studies evaluating the different methods of uterine evacuation in the event of fetal demise or the need to terminate a pregnancy. The use of techniques described above has been reported by experienced clinicians and in case reports.[39,40] Evidence level 3

9. Emergency cerclage

9.1. *When should a rescue cerclage be discussed and considered?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
The decision to place a emergency suture should be individualised, taking the parents' views carefully into account. The balance is between a useful prolongation of pregnancy with its reduced neonatal morbidity and mortality, against the possibility of prolonged severe neonatal morbidity in a baby that might otherwise die. The woman's decision should be aided by a senior obstetrician	**2+**	**D**	Individualisation of care is paramount considering the risks and benefits.
Insertion of a emergency cerclage may delay birth by approximately 34 days in suitable cases (CI = 18–50 days), compared with expectant management/bed rest alone. It may	**2–**	B	A systematic review including cohort studies (both prospective and retrospective) and RCTs.

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(Continued)

Recommendation	Evidence quality	Strength	Rationale for the recommendation
also be associated with a two-fold reduction in the chance of birth before 34 weeks of gestation. However, there are only limited data to support an associated improvement in neonatal mortality or morbidity			
Advanced dilatation of the cervix (more than 4cm) or membrane prolapse beyond the external os appears to be associated with a high chance of cerclage failure	**3**	**D**	Data are derived from uncontrolled studies

Eshanipor et al.[41] undertook a systematic review to estimate the effectiveness of physical examination-indicated cerclage in the presence of cervical dilatation and exposed membranes in the second trimester. Both cohort studies and RCTs were included comparing women who underwent expectant management with cervical dilatation between 14 and 27 weeks' gestation. Ten studies were included although only one was an RCT, two were prospective cohort studies and seven were retrospective cohort studies; 64% (485) underwent cerclage and 36% (272) had expectant management. Cerclage was associated with increased neonatal survival (71% compared with 43%; RR 1.65, 95% CI 1.19–2.28) and prolongation of pregnancy (mean difference 33.98 days, 95% CI 17.88–50.08). Birth at all preterm gestations except those prior to 24 weeks was reduced. However, details regarding the exact degree of dilatation at time of cerclage were not given. Randomised controlled trials are warranted to identify the women most likely to benefit from emergency cerclage

Evidence level 2+

There is no clear evidence that the gestation at which the cerclage is inserted affects the magnitude of prolongation of the pregnancy; however, consideration should be given to the fact that, in cases presenting before 20 weeks of gestation, insertion of a emergency cerclage is highly likely to result in a preterm birth before 28 weeks of gestation. Furthermore, emergency cerclage can rarely be justified beyond 24 weeks' gestation due to the potential risk of iatrogenic membrane rupture and subsequent preterm birth.

The aforementioned studies have not provided an analysis of prolongation of pregnancy in relation to cervical dilatation. However, several other uncontrolled studies have suggested the presence of membrane prolapse beyond the external os and/or cervical dilatation greater than 4cm are significant predictors of cerclage failure. In view of the absence of a control group in these studies, it is not clear whether this observation relates to treatment failure or a more advanced underlying process that makes this group of women inherently more likely to give birth.[42-44]

Evidence level 2–

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9.2. *What are the contraindications to cerclage insertion?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
The contraindications to cerclage insertion are: • active preterm labour • clinical evidence of chorioamnionitis • continuing vaginal bleeding • PPROM • evidence of fetal compromise • lethal fetal defect • fetal death	**4**	**GPP**	It is important to offer the procedure to the women most likely to benefit

9.3. *What information should be given to women before cerclage insertion?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Before history- or ultrasound-indicated cerclage insertion women should be given verbal and written information about potential complications. **Before any type of cerclage insertion, women should be informed of the following:**			
• There is a small risk of intraoperative bladder damage, cervical trauma, membrane rupture and bleeding during insertion of cervical cerclage.	**2–**	**D**	Date limited to case series and case reports
• Cervical cerclage may be associated with a risk of cervical laceration/trauma if there is spontaneous labour with the suture in place.	**2–**	**D**	Data are limited to case reports and series
• High vaginal cerclage, inserted with bladder mobilisation, usually requires anaesthetic for removal and therefore carries the risk of an additional anaesthetic.	**4**	**GPP**	
For women undergoing non-"emergency" cerclage:			
• Vaginal cerclage insertion is not associated with an increased risk of PPROM, chorioamnionitis, induction of labour or caesarean section.	**1+**	**B**	There is no evidence to suggest there is a correlation from existing studies
• The insertion of a cervical suture is not associated with an increased risk of preterm birth or second trimester loss.	**1+**	**B**	An IPD meta-analysis showed no increase in preterm birth or second trimester loss
• Cervical cerclage may be associated with a risk of cervical laceration/trauma if there is spontaneous labour with the suture in place.	**1+**	**B**	An IPD meta-analysis showed a doubling of the risk of pyrexia but no apparent increase in chorioamnionitis

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Although women are often routinely informed of a number of potential complications associated with cerclage insertion, including PPROM, second trimester loss, preterm labour, infection, bleeding and bladder or cervical damage, there is little published evidence to support this. None of the randomized studies of cervical cerclage have been designed or adequately powered to assess the risk of maternal morbidity and, to date, none of the larger studies of history- or ultrasound-indicated cerclage have reported an increase in PPROM, preterm birth or second trimester loss.[8,13,45] Intraoperative complications including bladder damage, cervical trauma, membrane rupture and bleeding are reported but are rare (less than 1%).[8,11,13] Fistula formation has been reported as a late, rare complication.[46]

Evidence level 2–

An IPD meta-analysis of seven randomized studies of cerclage insertion (combining data from studies of both history-indicated and ultrasound-indicated cerclage) found that cerclage was associated with an increased risk of maternal pyrexia (OR 2.35; 95% CI 1.37–4.05), but there was no evidence of an increase in chorioamnionitis (OR 0.73; 95% CI 0.36–1.46), PPROM (OR 0.92; 95% CI 0.62–1.35), induction of labour or caesarean birth (OR for spontaneous labour for no cerclage 0.81; 95% CI 0.65–1.02).[47]

Evidence level 1+

In a retrospective review of 251 cerclages (including 49 rescue and 202 history-indicated sutures) over a 7.5–year period, cervical laceration requiring suturing at the time of birth was reported in 11% of Shirodkar and 14% of McDonald procedures, which was higher than that reported in 55 688 other births occurring during the same period (2%).[48] Although this was statistically significant ($P < 0.025$), this result is highly susceptible to reporting bias

Evidence level 2–

Several case series have reported high risks of membrane rupture and infection associated with emergency cerclage; however, the lack of a control group makes it difficult to separate the procedure-related risk from that inherent to the underlying condition.[49]

Evidence level 2–

Prior to cerclage insertion, women should be given appropriate verbal and written information; patient information can be found on the RCOG website.[50]

10. Pre-operative management

10.1. What investigations should be performed before insertion of cervical cerclage?

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Women should be offered a first trimester ultrasound scan and screening for aneuploidy before the insertion of a history-indicated suture to ensure both viability, singleton pregnancy, and the absence of lethal/major fetal anomaly	**4**	**GPP**	This is considered good practice
Before ultrasound-indicated or emergency cerclage, it is preferable to ensure an anomaly scan has been performed	**4**	**GPP**	This is considered good practice

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(Continued)

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Maternal white cell count and C-reactive protein to detect chorioamnionitis before insertion of a emergency cerclage can be used to aid management. The decision to perform these tests should be based on the overall clinical picture, but in the absence of clinical signs of chorioamnionitis, the decision for emergency cerclage need not be delayed	**2–**	**D**	There is limited evidence to inform this however it is good practice to ensure there are no signs of developing infection in the mother

Several studies have linked a raised maternal C-reactive protein level with histological evidence of chorioamnionitis in cases of preterm labour or PPROM, however the sensitivity and specificity are considered poor and they should be used in conjunction with clinical features.[51,52] In an uncontrolled retrospective review of 17 cases of emergency cerclage, the authors reported that a preoperative C-reactive protein value below 4.0 mg/dl and a maternal white cell count less than 14 000/microlitre were associated with prolongation of pregnancy compared with women with values above these cut-offs. Interpretation of these results was confounded by the degree of cervical dilatation, such that those women with higher values also had more advanced cervical dilatation

Evidence level 2–

10.2. *Should amniocentesis to detect infection be performed before rescue or ultrasound-indicated cerclage?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
There is insufficient evidence to recommend routine amniocentesis before rescue or ultrasound-indicated cerclage as there are no clear data demonstrating improved outcomes	**4**	**GPP**	There is no evidence to support routine amniocentesis prior to emergency cerclage
In selected cases where there is suspicion of intra-amniotic infection, amniocentesis may be performed to aid the decision about emergency cerclage, as the presence of infection is associated with a poor prognosis	**3**	**D**	No RCTs have investigated the use of amniocentesis prior to emergency cerclage but it may be considered on an individual basis
Amniocentesis before emergency cerclage does not appear to increase the risk of preterm birth before 28 weeks of gestation but there is likely to be some risk to from the procedure	**2+**	**D**	This is based on limited numbers of women

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Several studies have reported an association between poor pregnancy outcome and the presence of intra-amniotic infection/inflammation, diagnosed by amniocentesis, in women presenting with a dilated cervix, whether or not they undergo emergency cerclage.[53,54] However, none of these studies were randomized and are therefore susceptible to selection bias, with the majority of women undergoing amniocentesis at the discretion of the individual physician. Rates of intra-amniotic infection vary from 13% to 51% depending on the criteria used to define a 'positive' result and the population selected.[55-57] Furthermore, the low specificity of amniocentesis could deny women cerclage who may have benefited from the procedure. The incidence of intra-amniotic infection in ultrasound-indicated cerclage is about 1–2%.

Evidence level 3

Airoldi et al.[55] identified 122 women between 15^{+0} and 25^{+6} weeks of gestation with a dilated cervix (1–4 cm). Twenty-four (20%) of these had an amniocentesis performed. Following multivariate regression analysis, the authors concluded that an amniocentesis did not independently contribute to preterm birth before 28 weeks of gestation ($P = 0.90$).

Evidence level 2+

10.2.1. Is amnioreduction before emergency cerclage recommended?

Recommendation	Evidence quality	Strength	Rationale for the recommendation
There is an absence of data to either refute or support the use of amnioreduction before insertion of a emergency cerclage and this should therefore not be carried out	**3**	**D**	Data are currently lacking.

Several small studies have reported successful prolongation of pregnancy using amnioreduction before cerclage, but the absence of a valid control group makes it impossible to draw any evidence-based conclusion as to its contribution to the outcome.[58-60]

Evidence level 3

10.2.2. Should a latency period be observed between presentation and insertion of a rescue or ultrasound-indicated cerclage?

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Each case should be managed on an individual basis	**4**	**GPP**	There are no studies to support immediate versus delayed cerclage insertion in either rescue or ultrasound-indicated procedures

The interval between presentation and suture insertion varies between studies. Any delay must balance the risk of inserting a suture in a cervix that is inevitably going to continue dilating against the increased risk of ascending infection.

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10.2.3. Should routine genital tract screening for infection be carried out before cerclage insertion?

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Routine genital tract screening should not be undertaken before cerclage insertion	**4**	**GPP**	Data are currently lacking to support this practice
In the presence of a positive culture from a genital swab, antimicrobial therapy should be decided on an individual basis after discussion with the microbiology team	**4**	**GPP**	This should be considered on an individual basis

No prospective studies have assessed the benefit of microbial screening prior to cerclage insertion. However, a small retrospective study of 65 consecutive cases found variable colonization and antibiotic sensitivities and no antibiotic would empirically treat all pathogens.[61]

Evidence level 3

11. Operative issues

11.1. Should perioperative tocolysis be used for insertion of cerclage?

Recommendation	Evidence quality	Strength	Rationale for the recommendation
There is no evidence to support the use of routine perioperative tocolysis in women undergoing insertion of cerclage; this should be considered on an individual basis	**4**	**GPP**	There are no data to support the use of tocolysis at the time of cerclage insertion at present

In most of the existing randomized studies, the majority of women allocated cerclage also received perioperative tocolysis, most commonly indomethacin. Consequently, there is no control group available for comparison. However, a retrospective cohort study involving 101 women who underwent ultrasound-indicated cerclage reported that the rate of preterm birth before 35 weeks of gestation was not significantly different in women who received indomethacin for 48 hours following the procedure compared with those who did not (39% versus 34%).[62] There is a paucity of adequately powered trials to compare the use of perioperative tocolytic with cerclage alone.

Evidence level 4

11.2. Should perioperative antibiotics be given?

Recommendation	Evidence quality	Strength	Rationale for the recommendation
The decision for antibiotic prophylaxis at the time of cerclage placement should be at the discretion of the operating team	**1–**	**C**	Data to support antibiotic use are limited to one RCT also assessing the use of indomethacin

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An RCT was conducted evaluating perioperative indomethacin and antibiotic administration at the time of examination indicated cerclage. Fifty-three women were enrolled and three were lost to follow up. A greater proportion of pregnancies were prolonged by 28 days among women who received indomethacin and perioperative antibiotics ($P = 0.01$).[63] However numbers were limited and concerns have been raised regarding the use of indomethacin due to premature closure of the ductus arteriosus in the baby.

Evidence level 1−

11.3. *What method of anaesthesia should be employed for the insertion of cerclage?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
The choice of anaesthesia should be made by the operating team in conjunction with the woman	**2+**	**B**	Data from a multicentre retrospective cohort study indicates that both general and regional anaesthesia are safe. The decision should be made on a case by case basis and justified

There are no RCTs comparing general with regional anaesthesia for insertion of cervical cerclage. A multicentre retrospective cohort study of 487 cases of cervical cerclage compared the type of anaesthesia with obstetric outcomes, finding that both general and regional anaesthesia could be safely used. General anaesthetic was associated with a shorter recovery time but a higher demand for opioid and non-opioid analgesia.[64] The choice of anaesthesia should be made on a case by case basis.

Evidence level 2+

11.4. *Can cerclage be performed as a day-case procedure?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Elective transvaginal cerclage can safely be performed as a day-case procedure	**2+**	**C**	A retrospective study has shown no difference in short term complications between day case and inpatient procedures

Golan et al.[65] retrospectively compared 125 cases of elective outpatient cerclage with 101 cases of inpatient cerclage, during which women received complete bed rest in hospital for 48 hours postoperatively. There was no significant difference in short-term complications or pregnancy outcome, but hospital stay was significantly shorter for those managed as planned day cases.

Evidence level 2+

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11.5. *Which technique and material should be used?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
The choice of suture material should be at the discretion of the surgeon; a non-absorbable suture should be used	**4**	**GPP**	Trials are currently in progress to inform the use of suture material at present this should be at the discretion of the surgeon
The choice of transvaginal cerclage technique (high cervical insertion with bladder mobilization or low cervical insertion) should be at the discretion of the surgeon, but the cerclage should be placed as high as is practically possible	**2+**	**C**	Secondary analysis of data and small RCTs have found no difference in outcomes between the techniques of cerclage. This should therefore be at the discretion of the surgeon
There is no difference between using two purse-string sutures and one single suture and should be at the discretion of the surgeon	**1+**	**B**	Limited data from small RCTs indicates there is no evidence to support the placement of two sutures in preference to one
The insertion of cervical occlusion suture in addition to the primary cerclage is not routinely recommended	**1–**	**C**	There is no evidence to support this practice. One RCT has been performed but was stopped due to slow recruitment and lack of efficacy

There is insufficient evidence to support any specific technique for cerclage insertion. One small RCT compared Shirodkar (n = 34) and McDonald Cerclage (n = 34) versus bed rest (n = 30) in women with no evidence of infection. No difference in the preterm birth or perinatal outcomes was found between the three groups.[66]

Evidence level 1–

In a secondary analysis of singleton pregnancy data from four randomized trials of cervical cerclage in women with a short cervix, there was no significant difference in the rate of birth before 33 weeks of gestation in those with a McDonald cerclage compared with those with a Shirodkar suture, once adjusted for confounding factors (OR 0.55; 95% CI 0.2–1.3).[67] These results should be interpreted with caution since the study was not sufficiently powered to detect a statistically significant difference in this outcome.

Evidence level 2+

A secondary analysis was conducted from a multicentre trial of ultrasound indicated cerclage for short cervical length in which women with a prior spontaneous preterm birth 16–34 weeks with a singleton pregnancy and cervical length less than 25mm between 16 and 23 weeks were randomized to McDonald cerclage or no cerclage. Outcomes of women who underwent cerclage were analysed by the type of suture material comparing polyester braided thread to mersilene tape. One hundred and thirty-eight women were included: 84 had polyester braided thread, 56 had mersilene tape; eight had monofilament and were excluded from the analysis. Rates of preterm birth less than 35 weeks were similar between polyester braided thread and mersilene tape.[68] An RCT is currently ongoing assessing the type of suture material.[69]

Evidence level 2+

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Two RCTs have been performed comparing the efficacy of single versus double cerclage. Both concluded there was no significance in preterm birth rates. One, comprising of 33 women, found that the preterm birth rate less than 34 weeks was comparable between the two groups (10.5% versus 35.7%; $P = 0.106$).[70] The second found there was no significant difference in prolongation of the pregnancy between single and double cerclage, however, preterm birth less than 33 weeks was not experienced by any of the women in the double cerclage group and five in the single cerclage group.[71] The total number of participants in both studies was very small so limited conclusions can be drawn. Further RCTs are warranted to assess whether double cerclage may be superior to single.

Evidence level 1–

There are limited data on the role of cervical occlusion at the time of cerclage. The only multi centre RCT was stopped early due to slow recruitment and an interim analysis showing no benefit of occlusion.[72]

Evidence level 1–

12. Adjuvant management

12.1. Bed rest

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Bed rest in women who have undergone cerclage should not be routinely recommended but should be individualised, taking into account the clinical circumstances and potential adverse effects that bed rest could have on women and their families, in addition to increased costs for the healthcare system	**4**	**GPP**	Limited data exists to support the use of bed rest but individualisation of care should be considered as well as the risks associated with prolonged immobilization

There are no studies comparing bed rest in women undergoing cervical cerclage. A Cochrane review of bed rest in women at high risk of preterm birth identified only one randomized cluster study of uncertain methodological quality. A comparison was made between 432 women prescribed bed rest and 834 women prescribed no intervention/placebo. Preterm birth before 37 weeks of gestation was similar in both groups (7.9% in the intervention group versus 8.5% in the control group: RR 0.92; 95% CI 0.62–1.37).[73]

Evidence level 1–

12.2. Sexual intercourse

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Abstinence from sexual intercourse following cerclage insertion should not be routinely recommended	**4**	**GPP**	There is no evidence to recommend abstinence from sexual intercourse

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There are no studies evaluating the effect of sexual intercourse on the risk of second trimester loss or preterm birth in women with cervical cerclage.

12.3. *Is there a role for post-cerclage serial sonographic surveillance of cervical length?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
While routine serial sonographic measurement of the cervix is not recommended it may be useful in individual cases following ultrasound-indicated cerclage to offer timely administration of steroids or in utero transfer	**3**	**D**	This is considered good practice
In the presence of history-indicated cerclage additional ultrasound-indicated cerclage is not routinely recommended as, compared with expectant management, it may be associated with an increase in both pregnancy loss and birth before 35 weeks of gestation	**3**	**D**	Data are limited to retrospective studies with small numbers
The decision to place a emergency cerclage following an elective or ultrasound-indicated cerclage should be made on an individual basis taking into account the clinical circumstances	**4**	**GPP**	Care should be individualised

Several studies have shown a significant increase in cervical length following the insertion of elective, ultrasound-indicated and emergency cerclage.[32,74-77] A number of retrospective studies have indicated that the higher the cerclage is placed the lower the risk of subsequent preterm delivery.[32,78]

Evidence level 2–

In a retrospective cohort study involving 24 women with a history-indicated cerclage and subsequent cervical length shortening to less than 25mm on ultrasound, 19 women had expectant management and five women underwent insertion of a reinforcing cerclage.[79] Repeat suture insertion was associated with a significantly earlier gestational age at birth (21 versus 33 weeks of gestation; $P = 0.002$) and an increased second trimester loss rate (80% versus 15%; $P = 0.01$). However, the numbers are small and selection criteria for choosing expectant management over repeat suture insertion were not defined and hence these results may be subject to bias. This finding was supported by a further retrospective cohort study by Simcox et al.[80] which assessed 25 women with a previous cerclage and evidence of membranes prolapsing through the first suture. Of these women, 13 had a second reinforcing suture and 12 had expectant management. Women with a reinforcing cerclage were more likely to give birth at an earlier gestation compared with those who had expectant management (26^{+0} [$\pm 5^{+1}$] compared with 31^{+1} [$\pm 7^{+0}$] weeks $P = 0.047$). Numbers are, however, again limited.

Evidence level 3

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12.4. *Is fetal fibronectin testing useful following insertion of a cervical cerclage?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Routine fetal fibronectin testing is not recommended post-cerclage. However, the high negative predictive value of fetal fibronectin testing for subsequent birth at less than 30 weeks of gestation in asymptomatic high-risk women with a cerclage in place may provide reassurance to women and clinicians in individual cases	**2+**	**C**	Limited data exist indicates however, there is a high negative predictive value of fetal fibronectin following cerclage

In a retrospective observational study involving 910 asymptomatic women at high risk of preterm birth, including 159 with a cervical cerclage in place, fetal fibronectin testing for the prediction of birth before 30 weeks of gestation was shown to have a similar negative predictive value in both groups (over 98%) but a significantly lower specificity (77% versus 90%; $P < 0.001$) in those with a suture.[81] Evidence level 2+

A further small study by Benson et al.[82] undertook 71 fibronectin tests in women presenting with symptoms of labour post cervical cerclage between 23 and 34 weeks' gestation finding the sensitivity, specificity, positive predictive value and negative predictive value for birth within 2 weeks of fFN testing were 100, 78, 28 and 100% respectively. Evidence level 2+

Although other tests are commercially available for the prediction of preterm birth, such as Partosure and Actim Partus no studies to date have evaluted their use following cervical cerclage insertion.

12.5. *Should women receive supplement progesterone following cerclage?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
Routine use of progesterone supplementation following cerclage is not recommended	**4**	**GPP**	NG 25 recommendation

Current NICE guidelines do not advise progesterone administration following cervical cerclage.[83] Evidence level 4

One RCT of 100 women compared the use of emergency cerclage in women in addition to progesterone treatment. Those with cerclage and progesterone had in increase in pregnancy prolongation compared to progesterone alone (28.44 $\pm$ 12.73 days versus 9.96 $\pm$ 3.27). Neonatal outcomes, early neonatal deaths were also lower in this group.[84] However, it should be noted the entry criteria was defined as 'true Evidence level 1−

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labour pains and diagnosed as starting preterm labour' and no details regarding dilatation or cervical length were reported.

Jarde et al.[85] assessed whether combining interventions improved outcome in a systematic review. This included both randomized and non-randomized studies where asymptomatic women at risk of preterm birth received any combination of progesterone, pessary, cerclage or pessary compared with either one or no intervention. No differences in preterm birth before 37 weeks were found when comparing cerclage and progesterone with cerclage alone (RR 1.04, 95% CI 0.71–2.42).

Evidence level 2+

There are no comparative studies on the use of progesterone in women who have undergone cerclage. In an RCT of ultrasound-indicated cerclage involving 302 women with singleton pregnancies and a history of spontaneous preterm birth between 17^{+0} and 33^{+6} weeks of gestation, an analysis of the woman's recorded intention to use supplemental progesterone did not appear to have any effect on birth before 35^{+0} weeks of gestation (OR 0.97; 95% CI 0.6–1.6).[13]

Evidence level 1+

12.6. *Should women be offered an Arabin pessary or progesterone instead of a cerclage?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
There is no evidence that either progesterone or Arabin pessary alone are more or less effective than cervical cerclage	**1–**	**C**	Data are currently lacking but trials are ongoing

Multiple studies have compared different agents (cerclage, progesterone and pessaries) for the prevention of preterm birth, however these often do not control for clinician preference and many of the studies are retrospective in nature.

The 2017 Cochrane review assessed the efficacy of cerclage versus progesterone in high risk women for preventing preterm birth. Two trials were included comprising of 129 women with a short cervix on ultrasound. However, numbers were too small to detect significant differences.[3]

Evidence level 1–

A meta-analysis was undertaken by Jarde assessing the effectiveness of progesterone, cerclage and Arabin pessary insertion for preventing preterm birth in singleton pregnancies, which included 36 trials (9425 women). Progesterone was most effective, reducing preterm birth less than 34 weeks (OR 0.44; 95% CI 0.22–0.79; NNT 9), less than 37 weeks (OR 0.58; 95% CI 0.41–0.79; NNT 9) and neonatal death (OR 0.5; 95% CI 0.28–0.58) compared with control but the data was heterogeneous and the indication for treatment included women with just a history of previous preterm birth and others who had a sonographically short cervix. Results should therefore be interpreted with caution.[86]

Evidence level 1+

Conde-Agudelo et al.[87] also compared the efficacy of vaginal progesterone and cerclage in preventing preterm birth and adverse perinatal outcomes in women with a singleton gestation, previous spontaneous preterm birth and short cervix undertaking a meta-analysis of RCTs comparing vaginal progesterone to placebo/no treatment or cerclage to

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no cerclage in women with a singleton gestation, previous spontaneous preterm birth and a sonographic cervical length less than 25 mm. Five trials comparing vaginal progesterone versus placebo and five comparing cerclage versus no cerclage were included. Both progesterone and cerclage were equally effective for preventing preterm birth and improving perinatal outcomes. However, cerclage and progesterone were not compared directly.

A number of randomized controlled trials are planned comparing the efficacy of cerclage versus pessary versus progesterone.[83,88]

13. When should the cerclage be removed?

Recommendation	Evidence quality	Strength	Rationale for the recommendation
A transvaginal cervical cerclage should be removed before labour, usually between 36^{+1} and 37^{+0} weeks of gestation, unless birth is by pre-labour caesarean section, in which case suture removal could be delayed until this time	**4**	**GPP**	This is considered good practice
In women presenting in established preterm labour, the cerclage should be removed to minimize potential trauma to the cervix	**4**	**GPP**	This is considered good practice
A high (inserted with bladder mobilization) cervical cerclage will usually require anaesthesia for removal	**4**	**GPP**	This is considered good practice
All women with a transabdominal cerclage require birth by caesarean birth, and the abdominal suture may be left in place following birth	**4**	**GPP**	This is considered good practice

There are no studies comparing elective removal of transvaginal cerclage with removal in labour. However, in the absence of preterm labour, elective removal at 36–37 weeks of gestation is advisable owing to the potential risk of cervical injury in labour and the minimal risk to a neonate born at this gestation.

There are no studies regarding the use of anaesthesia in the removal of a cerclage inserted with bladder mobilization but, given that the technique involves burial of the suture, an anaesthetic is likely to be necessary for removal. Decisions regarding use of anaesthetic should be taken jointly with the woman.

There are no published studies on long-term outcome comparing a policy of removing a transabdominal cerclage to it remaining in place. However, if further pregnancies are contemplated, it is reasonable to recommend leaving the cerclage in place. There have been anecdotal reports of suture 'pulling through' prior to labour, and a vaginal birth can occur safely if this is identified.

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13.1. *Should the cerclage be removed following PPROM?*

Recommendation	Evidence quality	Strength	Rationale for the recommendation
In women with PPROM between 24 and 34 weeks of gestation and without evidence of infection or preterm labour, delayed removal of the cerclage for 48 hours can be considered to facilitate in utero transfer	**4**	**GPP**	Care should be individualised
Delayed suture removal until labour ensues, or birth is indicated, is associated with an increased risk of maternal/fetal sepsis and is not recommended	**1–**	**C**	Data are derived from one RCT which was terminated early but interim analysis indicated there is no increased prolongation of pregnancy
Given the risk of neonatal and/or maternal sepsis and the minimal benefit of 48 hours of latency in pregnancy with PPROM before 23 and after 34 weeks of gestation, delayed suture removal is unlikely to be advantageous in this situation	**1–**	**C**	Data are derived from the same RCT and there was a suggestion leaving the cerclage in place was associated with higher rates of chorioamnionitis

A multicentre RCT conducted by Galyean et al.[89] assessed women where a cerclage was placed less than 24 weeks' gestation in singleton or twin pregnancies with a subsequent rupture of membranes between 22 and 33 weeks' gestation. Women were then randomized to retention or removal of the cerclage. Expectant management was then performed and birth expedited in the presence of chorioamnionitis, fetal distress or other medical or obstetric indications. The study was terminated after 56 women were recruited in 10 years as, even if the intended sample size of 142 was reached, interim statistical analysis demonstrated that it was unlikely that leaving a cerclage in situ after PPROM would prolong gestation. There was also the suggestion that leaving the suture in place was associated with higher rates of chorioamnionitis and no benefit in terms of steroid administration.

Evidence level 1–

14. Recommendations for future research

- To further assess the role of combination therapies in the management of women at high risk of preterm delivery, specifically progesterone with cerclage.
- To further evaluate the role of cerclage in specific women with cervical damage i.e. women with isolate loop excisions, cone biopsies and full dilatation C-sections
- To assess the role of adjuvant diagnostics and therapies at the time of cerclage such as anti-inflammatory biomarkers and antibiotics.
- The details of surgical intervention including women undergoing transabdominal cerclage such as the role of operator experience and surgical technique.

15. Suggested audit topics

- Number of women referred to a consultant obstetrician (or a specialist prematurity clinic) before 12 weeks of gestation as a proportion of those eligible for history indicated cerclage (100%).

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- Percentage of women having cerclage in line with indications in local protocols (greater than90%).
- Proportion of women offered aneuploidy screening before history-indicated cerclage insertion (100%).

16. Useful links and support

- *Cervical Stitch* RCOG Patient Information Leaflet [https://www.rcog.org.uk/en/patients/patient-leaflets/cervical-stitch/]
- Tommy's Charity information regarding cervical incompetence [https://www.tommys.org/pregnancy-complications/prem-birth/treatment/cervical-incompetence]
- NICE guideline [NG25] *Preterm labour and birth* [https://www.nice.org.uk/guidance/ng25]

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Cervical cerclage literature search strategy.
Appendix S2. Cervical cerclage search strategy top up.

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The final version is the responsibility of the Guidelines Committee of the RCOG.

The guideline will be considered for update 3 years after publication, with an intermediate assessment of the need to update 2 years after publication.

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