

Cervical Insufficiency and Cervical Cerclage

This clinical practice guideline has been prepared by the Maternal Fetal Medicine Committee, reviewed by the Clinical Practice Obstetrics Committee, and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

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Key words: Cervical insufficiency, cervical incompetence, cervical cerclage, preterm delivery, prematurity, Shirodkar cerclage, MacDonald cerclage, abdominal cerclage, rescue cerclage, cervical shortening, trans-vaginal ultrasound, cervical length

Abstract

Objective: The purpose of this guideline is to provide a framework that clinicians can use to determine which women are at greatest risk of having cervical insufficiency and in which set of circumstances a cerclage is of potential value.

Evidence: Published literature was retrieved through searches of PubMed or MEDLINE, CINAHL, and The Cochrane Library in 2012 using appropriate controlled vocabulary (e.g., uterine cervical incompetence) and key words (e.g., cervical insufficiency, cerclage, Shirodkar, cerclage, MacDonald, cerclage, abdominal, cervical length, mid-trimester pregnancy loss). Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies. There were no date or language restrictions. Searches were updated on a regular basis and incorporated in the guideline to January 2011. Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

Values: The quality of evidence in this document was rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care (Table).

Recommendations

1. Women who are pregnant or planning pregnancy should be evaluated for risk factors for cervical insufficiency. A thorough medical history at initial evaluation may alert clinicians to risk factors in a first or index pregnancy. (III-B)
2. Detailed evaluation of risk factors should be undertaken in women following a mid-trimester pregnancy loss or early premature delivery, or in cases where such complications have occurred in a preceding pregnancy. (III-B)
3. In women with a history of cervical insufficiency, urinalysis for culture and sensitivity and vaginal cultures for bacterial vaginosis should be taken at the first obstetric visit and any infections so found should be treated. (I-A)
4. Women with a history of three or more second-trimester pregnancy losses or extreme premature deliveries, in whom no specific cause other than potential cervical insufficiency is identified, should be offered elective cerclage at 12 to 14 weeks of gestation. (I-A)

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Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care

Quality of evidence assessment*	Classification of recommendations†
I: Evidence obtained from at least one properly randomized controlled trial	A. There is good evidence to recommend the clinical preventive action
II-1: Evidence from well-designed controlled trials without randomization	B. There is fair evidence to recommend the clinical preventive action
II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group	C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category	D. There is fair evidence to recommend against the clinical preventive action
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	E. There is good evidence to recommend against the clinical preventive action
	L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

*The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.¹⁵⁶

†Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.¹⁵⁶

5. In women with a classic history of cervical insufficiency in whom prior vaginal cervical cerclage has been unsuccessful, abdominal cerclage can be considered in the absence of additional mitigating factors. (II-3C)
6. Women who have undergone trachelectomy should have abdominal cerclage placement. (II-3C)
7. Emergency cerclage may be considered in women in whom the cervix has dilated to < 4 cm without contractions before 24 weeks of gestation. (II-3C)
8. Women in whom cerclage is not considered or justified, but whose history suggests a risk for cervical insufficiency (1 or 2 prior mid-trimester losses or extreme premature deliveries), should be offered serial cervical length assessment by ultrasound. (II-2B)
9. Cerclage should be considered in singleton pregnancies in women with a history of spontaneous preterm birth or possible cervical insufficiency if the cervical length is \leq 25 mm before 24 weeks of gestation. (I-A)
10. There is no benefit to cerclage in a woman with an incidental finding of a short cervix by ultrasound examination but no prior risk factors for preterm birth. (II-1D)
11. Present data do not support the use of elective cerclage in multiple gestations even when there is a history of preterm birth; therefore, this should be avoided. (I-D)
12. The literature does not support the insertion of cerclage in multiple gestations on the basis of cervical length. (II-1D)

INTRODUCTION

Cervical insufficiency may be present in up to 1% of obstetric populations, and it therefore represents a concern frequently enough that a guideline to address the dilemmas in its management is overdue. Despite having been part of obstetric practice for over a century, both the

role of cervical cerclage and indications for it remain ill-defined and controversial, with wide practice variations in different clinical settings. In part, the lack of clarity that surrounds cerclage is fostered by uncertainty in identifying those patients who will truly benefit from its use (i.e., those with true cervical insufficiency or truly increased risk of early preterm delivery).^{1,2}

Cervical insufficiency has no consistent definition, but is usually characterized by dilatation and shortening of the cervix before the 37th week of gestation in the absence of preterm labour, and is most classically associated with painless, progressive dilatation of the uterine cervix in the second or early third trimester resulting in membrane prolapse, premature rupture of the membranes, mid-trimester pregnancy loss, or preterm birth.^{3,4} Cervical insufficiency arises from the woman's inability to support a full-term pregnancy due to a functional or structural defect of the cervix.¹

The incidence of true cervical insufficiency is estimated at less than 1% of the obstetric population. In Denmark from 1980 to 1990, cervical insufficiency was diagnosed in 4.6 per 1000 women,² and it is estimated to occur in 8% of women with recurrent mid-trimester losses.⁵ A variety of risk factors have been identified and are divided here into those that may be identified from prior maternal history and those that may arise in the index pregnancy itself.

The classic history that raises the suspicion of cervical insufficiency is that of recurrent mid-trimester

pregnancy losses. A previous preterm pre-labour rupture of membranes at less than 32 weeks should be noted, as should a prior pregnancy with a cervical length measurement of less than 25 mm prior to 27 weeks of gestation.⁶ Any history of prior cervical trauma (e.g. repeated therapeutic abortion, repetitive cervical dilatation, cone biopsy, cervical tears and lacerations, trachelectomy) should also be noted. A risk factor reducing in incidence is that of the mother herself having been exposed to diethylstilbestrol in utero.⁶ A variety of other maternal risk factors include the presence of a congenital uterine anomaly or a maternal connective tissue disease or abnormalities, e.g. Ehlers-Danlos syndrome,⁷ that impacts upon the integrity of normal collagen development and function. Recently, polycystic ovarian syndrome has been suggested as a risk factor for cervical insufficiency, especially in women of South Asian or Black origin.⁸ In many cases, especially when clinical features and findings lead to suspicion of the diagnosis in the first pregnancy, these risk factors may not be present and the cause may remain idiopathic.⁹⁻¹²

In the index pregnancy, findings indicative of possible cervical insufficiency include cervical funnelling, cervical shortening,¹² and overt cervical dilatation.¹³ Even in the absence of funnelling, a cervical length determined by ultrasound to be < 25 mm prior to 27 weeks^{10,11} increases the risk of pregnancy loss or preterm birth.

Up to 85% of the cervix's dry weight is collagen. Petersen and Uldbjerg examined cervical collagen in non-pregnant women with previous cervical insufficiency and found that they had markedly lower median cervical hydroxyproline concentrations than parous women without cervical insufficiency.¹⁴ The causes of this have yet to be ascertained, but this seems to be a key factor in understanding the mechanism of cervical failure in such cases.

In addition to its mechanical strength, the cervix may also play a role in protecting the uterine contents from ascending infection,^{4,15} with one key factor in this being the role of the cervical mucous as a barrier between the uterus and ascending infection. Data suggest that 80% of cases of acute cervical insufficiency may be associated with intra-amniotic infection.¹⁶

DIAGNOSIS OF CERVICAL INSUFFICIENCY

There is no diagnostic test for cervical insufficiency. Although many tests have been reported or are used (assessment of the cervical canal width by hysterosalpingogram, assessment of the ease of insertion of cervical dilators [size 9 Hegar] without resistance, the

force required to withdraw an inflated Foley catheter through the internal os, the force required to stretch the cervix using an intracervical balloon) none of these meet the criteria required for a diagnostic test.¹⁷⁻²¹ Part of the diagnosis is based upon the exclusion of other causes of preterm delivery or mid-trimester pregnancy loss. In recent practice, transvaginal ultrasonography has been increasingly used as a demonstrably valid and reproducible method of cervical assessment, and cervical shortening correlates with the risk of preterm delivery.^{12,22-25}

Without a reliable diagnostic test, it becomes necessary to screen for or to predict the likelihood of cervical insufficiency. This process is based upon the identification and recognition of key risk factors in the woman's history and in the index pregnancy.

The most common factors in the patient history that indicate she may be at risk are a prior second trimester pregnancy loss or a prior preterm birth. It should be noted, however, that although in some situations there may be a continuum between cervical insufficiency and preterm labour and delivery, in others these are distinct and unrelated processes. A history of preterm labour or the identification of factors that increase the risk for preterm birth do not always necessarily indicate risk for cervical insufficiency.^{26,27}

A history of prior cervical surgery, e.g. loop electrosurgical excision procedure (LEEP), may also present a risk for cervical insufficiency. In such patients there may also be a role for cervical length assessment by ultrasound. In patients who have had a prior LEEP, a 30 mm cervical length has a positive predictive value for preterm birth of 54%, but a negative predictive value of 95%.²³ However, because of the low overall frequency of cervical insufficiency even in this group, some data do not support the routine use of mid-trimester ultrasound in such women.²³ Other forms of cervical trauma, for example cervical tears, may also be significant.²⁸

Less frequent in current practice is the identification of women who were exposed to diethylstilboestrol when in utero themselves.²⁹⁻³¹

The key finding in the current pregnancy is the identification of cervical shortening. Cervical length assessment by ultrasound is an established means of assessing the risk for preterm labour and delivery (cervical length < 25 mm).^{11,12,22,25,32,33}

Patients may also be found to have cervical dilatation rather than just shortening, or they may present with preterm membrane rupture. Identification of cervical dilatation in

the absence of a maternal history of contractions, with or without membrane rupture, is considered tantamount to a diagnosis of cervical insufficiency. Models based on the recognition of these two main risk factors (cervical shortening and cervical dilatation) have been described and may be of value in determining which patients are at greatest risk, but further assessment of such screening tools is required.³⁴

Recommendations

1. Women who are pregnant or planning pregnancy should be evaluated for risk factors for cervical insufficiency. A thorough medical history at initial evaluation may alert clinicians to risk factors in a first or index pregnancy. (III-B)
2. Detailed evaluation of risk factors should be undertaken in women following a mid-trimester pregnancy loss or early premature delivery, or in cases where such complications have occurred in a preceding pregnancy. (III-B)

MANAGEMENT OF CERVICAL INSUFFICIENCY

The management of cervical insufficiency can be viewed as falling broadly into two main types: those in which it is clear that surgical intervention in the form of cerclage is indicated, and those in which a conservative path will be pursued.

Indications for the insertion of a cerclage may arise from the clinical history or the finding of cervical shortening and/or dilatation in the index pregnancy, and therefore may be divided into prophylactic cerclage versus therapeutic cerclage. Alternatives to cerclage include the cervical pessary; some data suggest this may be of benefit in some cases, but these data are sparse and conflicting. Further investigation of such techniques is required before they can be considered as part of a guideline for the management of cervical insufficiency.³⁵

Prophylactic Transvaginal Cerclage

Consider elective cerclage if there appears to be a high risk of cervical insufficiency based on the woman's obstetric history. The level of risk is typically determined by identifying and assessing the significance of the risk factors described in the "Diagnosis of Cervical Insufficiency" section. Most frequently the assessment of risk will be founded upon a history of second-trimester pregnancy losses or early preterm deliveries in the absence of other mitigating risk factors.^{36–38} Therefore a detailed evaluation of risk factors should be undertaken in women presenting with a history of a mid-trimester pregnancy loss or early premature delivery.

Data from the UK MRC/RCOG RCT³⁶ did not demonstrate the benefit of cerclage after 1 or 2 prior deliveries preceding 33 weeks' gestation; however, the numbers were small and this might have had an impact on the observed effect, particularly in the case of mid-trimester losses as opposed to premature deliveries. The benefit of cerclage after 2 or 3 mid-trimester losses alone, as opposed to losses and deliveries up to and including 33 weeks, is undefined. The findings of this UK study might be influenced by the inclusion of cases in which the treating obstetrician was unsure that the cerclage would be of benefit. However, other smaller studies also failed to demonstrate the benefit of cerclage.^{37,38} A recent Cochrane review analyzed data from 12 studies of women considered at sufficient risk to justify cerclage who were randomized to cerclage, alternative treatments (e.g., progesterone), or no treatment. This analysis presents somewhat conflicting findings in reporting that although cerclage has a statistically significant effect on reducing preterm birth rates, there is no significant impact on perinatal morbidity and mortality. Furthermore cerclage was associated with increased maternal morbidity and Caesarean section rates (the latter perhaps also accounting for a non-significant increase in respiratory morbidity amongst infants born to women with a cerclage).³⁹

A prophylactic cerclage is normally placed between 12 and 14 weeks' gestation. Although placement can be delayed, the gestational age of prior pregnancy losses should be taken into account, particularly in women whose losses present at progressively earlier gestations.

Prerequisites for prophylactic cerclage placement

Prior to placement of a cerclage it is essential to confirm the viability of the pregnancy by ultrasound. It is wise therefore, at the same time to exclude significant malformations and determine whether there is a significantly elevated aneuploidy risk by first trimester ultrasound nuchal translucency screening, if possible combined with serum marker screening. In cases found to be at elevated risk for aneuploidy or with fetal malformations, placement may be delayed until after karyotype results are obtained (using chorionic villus sampling for earlier karyotype determination than amniocentesis, where available) or until a more detailed ultrasound assessment is performed.

Before admission for cerclage, urinalysis for culture and sensitivity and vaginal cultures for bacterial vaginosis should be taken and any infections found should be treated.^{16,40–46} Microbial invasion of the amniotic cavity has been reported to occur in around 50% of women with cervical insufficiency and exposed fetal membranes.^{45,47} Amniocentesis has therefore been suggested for evaluating and treating such colonization

prior to cerclage placement; however, no clear benefit in prolonging pregnancy has been shown for amniocentesis over cerclage alone, and therefore its routine use is not advised.⁴⁸

Cerclage techniques and materials

The two main techniques of transvaginal cerclage involve the MacDonald approach and the Shirodkar approach. In the MacDonald approach the suture is inserted as close as possible to the junction of the cervix with the vagina, with no dissection of tissue planes.⁴⁹ In the Shirodkar approach a sub-epithelial suture is inserted above the junction of the cervix with the vagina with dissection of the bladder and rectum; this allows for higher placement (closer to the internal cervical os) of the suture than the MacDonald approach.⁵⁰

There are no data to indicate an advantage of one technique over another, so the choice between a MacDonald approach or modification thereof or a Shirodkar approach or modification thereof should be left to the discretion and skills of the surgeon.^{51–55} Both techniques, influenced by patient selection, are associated with an increased Caesarean section rate, which is perhaps marginally higher following the Shirodkar approach, although this data has not been replicated.⁵⁶

Two forms of double cerclage are also described. The first simply involves the insertion of two cervical cerclages in an attempt to buttress the cervix more strongly. This has been shown to be of no benefit.⁵⁷ In the second double cerclage, a second occlusive suture is placed at the external os to retain the mucous plug and help the cervix maintain itself as a barrier to infection. Only limited data regarding this are available at present.⁵⁸

No data indicate any advantage or disadvantage of particular suture materials. The most frequently used is a braided Mersilene tape, although some surgeons use Prolene. Meshes are also reportedly used, but no comparisons have been made with existing techniques.^{59,60} There are data indicating that delayed absorbable suture materials may also be used, but the benefits or disadvantages of different materials still require greater evaluation.⁶¹

Unless it is contraindicated, regional anaesthesia is usually preferred to general anaesthesia in light of its lesser associated risks.^{62,63}

It should be noted that for prophylactic cerclage, no randomized trials have presented findings free of confounding variables to support the routine use of tocolytics,^{64,65} corticosteroids, or antibiotics,^{66–68} although for cerclages placed in gestations close to fetal viability, corticosteroid usage should be considered. Similarly, data on the use of progesterone in women who have a

cerclage in place are limited. The use of progesterone with cerclage is not new, but despite more recent data for the use of progesterone therapy in women at risk of preterm delivery, overall data do not presently support this approach. Although one early study implied a benefit to progesterone, it was an uncontrolled cohort study,⁶⁹ and a contemporaneous controlled cohort evaluation demonstrated a reduction in hospital admission, but not in the rate of pregnancy loss.⁷⁰ A more recent study of 17-alpha-hydroxyprogesterone caproate in women with cerclage essentially demonstrated no advantage, although this study was retrospective and the criteria for cerclage placement were ill-defined.⁷¹ Two further studies also indicated that 17-alpha-hydroxyprogesterone caproate injections do not provide additional benefit for the prevention of preterm birth in women who received an ultrasound-indicated cerclage.^{72,73}

There are no specific data comparing the efficacy of systemic and vaginal progesterones in women with a cerclage in place.

Complications

Three randomized clinical trials have shown that cerclage is associated with increased medical interventions and doubles the risk of puerperal pyrexia.^{36–38} The use of tocolytics increases with cerclage, as does the rate of hospital admissions, and one study found a higher rate of Caesarean sections.³⁷ However, the risk and nature of complications is influenced by whether the cerclage is inserted electively or as an emergency with membranes bulging through the cervix. The complications reported with cerclage include sepsis, premature rupture of membranes, premature labour, cervical dystocia, cervical laceration at delivery (11% to 14%),^{74–76,77} and hemorrhage.

However, meta-analysis of a number of studies has not confirmed higher rates of chorioamnionitis or preterm pre-labour membrane rupture in women managed with cerclage than in those managed by other means.⁷⁸ Although cervical dystocia is frequently cited as a complication of cerclage due to cervical scarring,⁷⁹ data do not support its being truly attributable to cerclage⁸⁰; the increased risk of cervical laceration, however, although it appears to be unrelated to the timing of the removal of the cerclage, can be attributed to the cerclage.^{74–76,81}

Recommendations

3. In women with a history of cervical insufficiency, urinalysis for culture and sensitivity and vaginal cultures for bacterial vaginosis should be taken at the first obstetric visit and any infections so found should be treated. (I-A)

4. Women with a history of three or more second trimester pregnancy losses or extreme premature deliveries, in whom no specific cause other than potential cervical insufficiency is identified, should be offered elective cerclage at 12 to 14 weeks of gestation. (I-A)

Cerclage follow-up

Lengthening of the cervix following cerclage has been observed, and the immediate assessment of the cervix following suture placement may correlate with gestational age at delivery⁸²⁻⁸⁴; however, the data are inconsistent on the efficacy of continued cervical length assessment post cerclage in determining when delivery might occur.^{85,86} This is somewhat supported by the inconsistency in studies evaluating whether the placement of a second suture is beneficial in women whose cervix is found to shorten further post cerclage placement, with two studies demonstrating contradictory effects of such a measure.^{87,88} Therefore at present routine post-cerclage follow-up by ultrasound is not recommended. The positive predictive value of fibronectin as a predictor of preterm delivery appears to be adversely affected by a cerclage, although the negative predictive value is not.⁸⁹

Removal of cerclage

The cerclage is generally removed electively at 36 to 38 weeks' gestation. Removal can usually be performed without anaesthesia or with only short-acting narcotics, such as Fentanyl administered intravenously. The onset of premature labour unresponsive to tocolysis and or a strong suspicion of sepsis are indications for emergency removal of the cerclage.

A number of studies have addressed the question of cerclage removal with premature membrane rupture and no associated contractions. Meta-analysis has shown an increased neonatal mortality rate with delayed removal, with sepsis the principal cause; therefore a policy of removal within 48 hours (allowing time for corticosteroid administration if appropriate) is advocated.⁹⁰⁻⁹³ C-reactive protein estimation may be used as a predictor of chorioamnionitis following preterm membrane rupture and may therefore aid the decision between immediate or delayed (< 48 hours) suture removal.^{94,95} Incidentally, it should be noted that clear documentation of the cerclage placement, specifically knot placement and number, will facilitate the removal of the cerclage prior to delivery.

Prophylactic Transabdominal Cerclage

In women with a good history of cervical insufficiency in whom prior vaginal cerclage has been unsuccessful, abdominal cerclage can be considered in the absence of

additional mitigating factors.⁹⁶⁻¹⁰⁰ This should also be considered for women who have undergone trachelectomy or who have had an effective trachelectomy.^{101,102} The placement of an abdominal suture may be undertaken by either laparoscopic or open surgical techniques. The former is generally preferred in current practice,^{103,104} although both techniques are associated with higher maternal morbidity than a transvaginal cerclage approach. Abdominal cerclage should be undertaken by a surgeon experienced in the placement of such sutures. A prophylactic abdominal cerclage is often inserted at the same time as a trachelectomy is performed in women of reproductive age who plan to pursue the option of childbirth.¹⁰⁵

Recommendations

5. In women with a classic history of cervical insufficiency in whom prior vaginal cerclage has been unsuccessful, abdominal cerclage can be considered in the absence of additional mitigating factors. (II-3C)
6. Women who have undergone trachelectomy should have abdominal cerclage placement. (II-3C)

Emergency Cerclage

An emergency (or salvage or rescue) cerclage is typically one placed in a woman whose cervix is already dilated. Emergency should be considered when there is clinical or sonographic identification of a cervix dilated > 1 to 2 cm with no perceived uterine contractions (with or without membranes bulging through the external os).^{106,107} It is important to note that there must be no clinical evidence of chorioamnionitis. Although some groups advocate amniocentesis prior to emergency cerclage in order to both exclude infection and aid in reducing intrauterine pressure, no randomized studies confirm the effect of this approach.^{108,109}

A small randomized clinical trial has shown prolongation of pregnancies by 4 weeks with emergency cerclage placement,¹¹⁰ and other observational studies have reported pregnancy prolongation of between 6 and 9 weeks with emergency cerclage placement compared with under 4 weeks with conservative management (bed rest).¹¹¹⁻¹¹⁴ Scoring systems have been considered to evaluate which cases will benefit from emergency cerclage (based on cervical effacement, dilatation, and membrane prolapse).^{115,116} The benefit of cerclage even with cervical dilatation to 4 cm has been shown and should be considered, and the scoring systems can be used to counsel patients about the likely outcome of undergoing emergency cerclage.

Adjunctive measures

The administration of a course of indomethacin prior to cerclage placement might reduce protruding membranes

through its effect on reducing fetal urine production (thereby reducing intrauterine pressure) and through its tocolytic value.¹¹⁰ Bed rest with or without Trendelenburg may further help to reduce bulging membranes and facilitate suture placement, as may using a Foley balloon inserted into the cervix and then inflated to mechanically reduce the membranes.¹¹⁷ Broad-spectrum antibiotic coverage is usually prescribed, although there are no data to support this.

Amniocentesis may have a greater role to play in emergency cerclage than in prophylactic cerclage. The first potential benefit of amniocentesis in emergency cases is in identifying those women who may not benefit from cerclage, based upon evidence of infection¹⁰⁹ or on a more complex evaluation of proteomic markers that investigates infection as well as other factors believed to affect the efficacy of cerclage.^{109,118} Its second benefit is in removing a larger volume of amniotic fluid (cf. amniodrainage), permitting bulging membranes to withdraw into the cervix by reducing intrauterine pressure and thereby facilitating cerclage placement.¹¹⁹⁻¹²¹

Cerclage removal

The criteria for removal of an emergency cerclage are the same as for a prophylactic cerclage.

Recommendation

7. Emergency cerclage may be considered in women in whom the cervix has dilated to < 4 cm without contractions before 24 weeks of gestation. (II-3C)

Cervical Pessary

The use of pessaries in the management of cervical insufficiency or preterm delivery is not new, with the use of a glass pessary having first been described in 1977.¹²² Since then various designs and materials have been used and reported.¹²³⁻¹²⁹ Although many of these reports and reviews showed promise, a Cochrane review found no studies suitable for inclusion in an analysis of the benefits of this technique.³⁵ Since then a number of studies have been undertaken, some of which are still in progress. Two recent studies have again suggested a benefit of cervical pessaries in the management of cervical insufficiency, preterm delivery, or short cervix.^{130,131} However, to date the data supporting such techniques in the routine management of cervical insufficiency remain insufficient.

CONSERVATIVE OBSERVATIONAL MANAGEMENT

A conservative strategy including cervical length assessment may be adopted in the management of women considered to have cervical insufficiency, but whose

history is not considered to indicate enough risk to warrant immediate prophylactic cerclage.¹³² In such women, ultrasound cervical length assessment will identify a cohort who is at increased risk of a further pregnancy loss or preterm delivery, some of whom may then benefit from the subsequent placement of a cerclage. Conservative management should be based on and include the following steps:

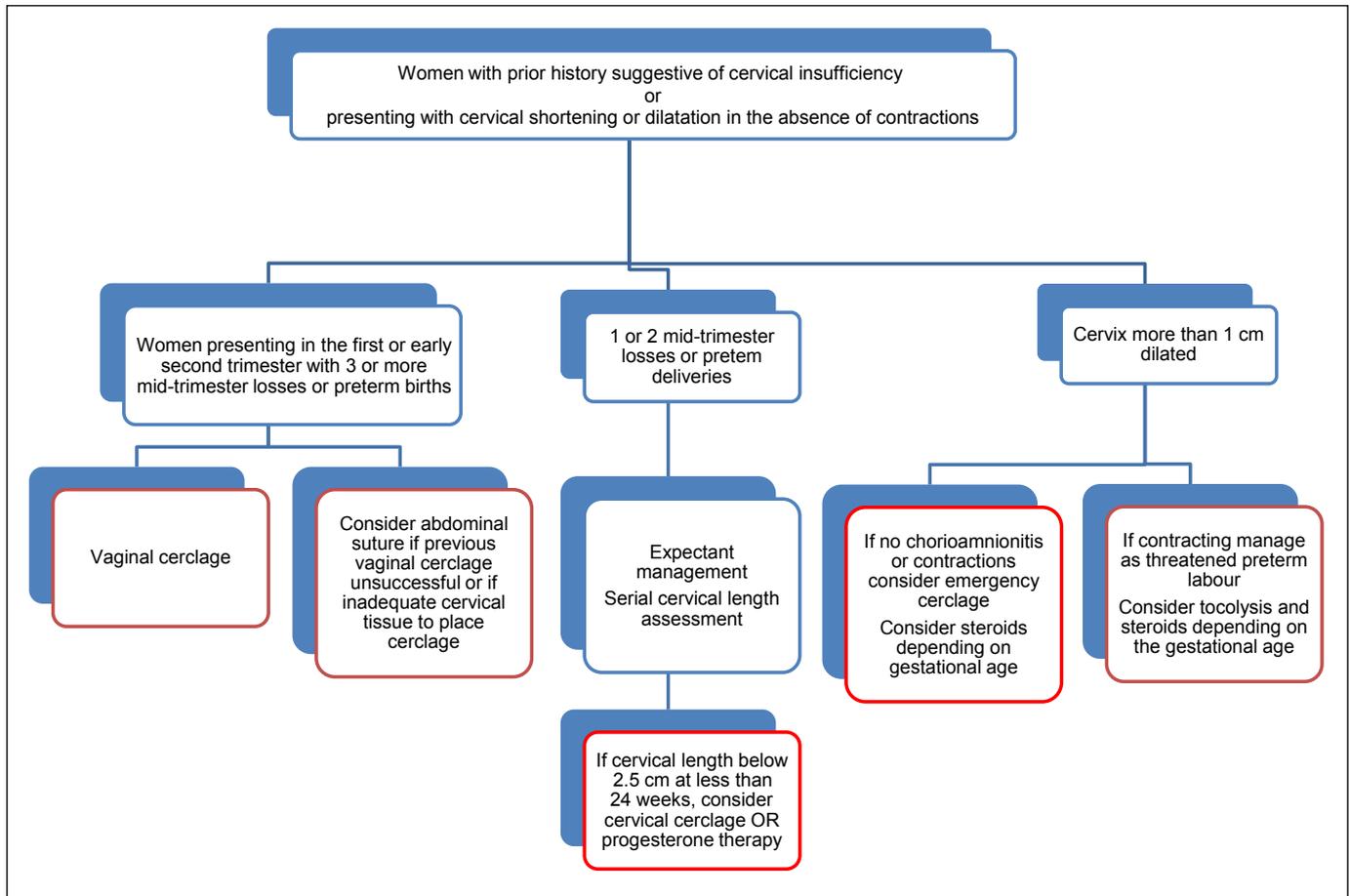
1. Urine for culture and sensitivity and vaginal cultures for bacterial vaginosis⁴⁰⁻⁴² should be taken at the first obstetric visit, and any infections found should be treated.^{16,40-46}
2. Serial transvaginal ultrasonography should be performed every 7 to 14 days from 16 weeks of gestation or at least 2 weeks prior to the gestational age of the earliest preceding pregnancy loss.¹³³
3. Consider advising the patient to reduce physical activity, especially those with physical employment, prolonged periods of standing, or frequent and repetitive lifting, although there are no data to confirm or deny the efficacy of bed rest in such cases.¹³⁴
4. Strongly encourage the cessation of smoking with referral to support programs.
5. Beyond 23 weeks consider the prophylactic use of corticosteroids if there are signs or symptoms suggestive of an increased risk of preterm delivery.

Ultrasound assessment of cervical length

Ultrasound has been shown reliably and reproducibly to allow estimation of cervical length. The length of the cervix as measured by ultrasound has in turn been demonstrated to be a useful tool in the prediction of the risk of preterm delivery.^{12,25,33,135} Transvaginal ultrasonography is the gold standard technique of assessment, but if this cannot be performed then an assessment may be made either abdominally or transperineally.¹³⁶

Assessment of the cervix typically reports the cervical length and identifies any evidence of cervical funnelling. Although funnelling is typically reported when the cervix is assessed, it should be noted that data do not support the placement of a cerclage on the basis of funnelling, but rather on residual cervical length.¹² Transfundal pressure created by applying fundal pressure in the direction of the uterine axis for 15 seconds is more effective than coughing or standing in eliciting cervical changes and signs of progressive second trimester cervical shortening during active assessment of the cervix.¹³⁷⁻¹³⁹

Flow diagram



Recommendations

8. Women in whom cerclage is not considered or justified, but whose history suggests a risk for cervical insufficiency (1 or 2 prior mid-trimester losses or extreme premature deliveries), should be offered serial cervical length assessment by ultrasound. (II-2B)

Cerclage Based on Ultrasound Measurement of Cervical Length

Data do not support the placement of a cerclage in women in whom there is an incidental finding by ultrasound of cervical shortening (≤ 25 mm) and who are not otherwise considered to be at risk of mid trimester loss or of preterm delivery.¹⁴⁰⁻¹⁴² Women considered to be at risk (because, e.g., of a history of mid-trimester loss or early preterm delivery) should be offered cerclage if their cervical length is ≤ 25 mm before 24 weeks of gestation.^{140,143-147}

Recommendations

9. Cerclage should be considered in singleton pregnancies in women with a history of spontaneous preterm birth or possible cervical

insufficiency if the cervical length is ≤ 25 mm before 24 weeks of gestation. (I-A)

10. There is no benefit to cerclage in a woman with an incidental finding of a short cervix by ultrasound examination but no prior risk factors for preterm birth. (II-1D)

Progesterone

Progesterones have been used historically and more recently in the prevention of preterm birth. The possible efficacy of progesterones in cervical insufficiency has often been extrapolated from that in preterm birth, but this may not be appropriate.

At present no data support the use of progesterone together with cerclage. The data comparing cerclage and progesterone in isolation are limited and perhaps inapplicable to the question of using progesterones for cervical insufficiency. One study reported no significant difference in the rate of preterm birth between women treated with progesterone or by cerclage; however, the indication for intervention was a short cervix on ultrasound screening, and by the criteria presented in this guideline, cerclage would not have been

indicated in many of the cases included.¹⁴⁸ However, a study evaluating the effects of progesterone on cervical length in women considered at risk of preterm birth suggests that progesterone helps preserve cervical length,⁷⁰ and thereby reduces the risk of preterm birth; this finding also supports the use of vaginal progesterones.^{149,150} The role of progesterone in mid-trimester loss remains unclear, therefore its routine use is not recommended and further evaluation is needed. Further information regarding the use of progesterones to prevent preterm birth may be found in the SOGC guideline, “The Use of Progesterone for Prevention of Preterm Birth.”¹⁵¹

Multiple Gestations

Because twins and higher-order multiple gestations are at increased risk of preterm delivery, it has been speculated that cerclage placement may improve their perinatal outcomes. However, elective cerclage placement in multiple pregnancies without additional risk factors has not been shown to benefit pregnancy outcomes in this group.¹⁵²

Furthermore, although ultrasound cervical length assessment in this group may predict an increased risk of early delivery,¹⁵³ in contrast to singleton gestations, data have shown no benefit in the placement of cerclage in multiple gestations with ultrasound-identified cervical shortening.^{143,154,155} Indeed, a meta-analysis has shown a relative risk increase of 2.15 for preterm delivery (< 35 weeks) in such pregnancies with an ultrasound-indicated (cervical length < 25 mm) cerclage.¹⁴³

Recommendations

11. Present data do not support the use of elective cerclage in multiple gestations even when there is a history of preterm birth; therefore, this should be avoided. (I-D)
12. The literature does not support the insertion of cerclage in multiple gestations on the basis of cervical length. (II-1D)

SUMMARY

The decision on how best to minimize the risk of recurrent mid-trimester pregnancy loss (loss between 14 and 26 weeks) or extreme preterm birth in women who are deemed at increased risk, either by virtue of their medical history or the findings of a short or dilated cervix, should be personalized, based on the clinical circumstances, the skills and expertise of the clinical team, and the woman's informed consent (Figure).

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