The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN–GYNECOLOGISTS

NUMBER 142, FEBRUARY 2014

Cerclage for the Management of Cervical Insufficiency

The inability of the uterine cervix to retain a pregnancy in the second trimester is referred to as cervical insufficiency. Controversy exists in the medical literature pertaining to issues of pathophysiology, screening, diagnosis, and management of cervical insufficiency. The purpose of this document is to provide a review of current evidence of cervical insufficiency, including screening of asymptomatic at-risk women, and to offer guidelines on the use of cerclage for management. The diagnosis and management of other cervical issues during pregnancy, such as short cervical length, are discussed more in-depth in other publications of the American College of Obstetricians and Gynecologists.

Background

Definition

The term cervical insufficiency is used to describe the inability of the uterine cervix to retain a pregnancy in the absence of the signs and symptoms of clinical contractions, or labor, or both in the second trimester. Based on current data, the ultrasonographic finding of a short cervical length in the second trimester is associated with an increased risk of preterm birth but is not sufficient for the diagnosis of cervical insufficiency.

Pathophysiology

The pathophysiology of cervical insufficiency is still poorly understood. Factors that may increase the risk of cervical insufficiency include surgical trauma to the cervix from conization, loop electrosurgical excision procedures, mechanical dilation of the cervix during pregnancy termination, or obstetric lacerations, although data confirming these associations are inconsistent (1–4). Other proposed etiologies have included congenital müllerian anomalies, deficiencies in cervical collagen and elastin, and in utero exposure to diethylstilbestrol. However, these factors are not associated specifically with cervical insufficiency and are not indications for the use of cervical cerclage.

Diagnosis

The diagnosis of cervical insufficiency is challenging because of a lack of objective findings and clear diagnostic criteria. Diagnosis is based on a history of painless cervical dilation after the first trimester with subsequent expulsion of the pregnancy in the second trimester, typically before 24 weeks of gestation, without contractions or labor and in the absence of other clear pathology (eg, bleeding, infection, ruptured membranes). Recently, attempts have been made to use assessment of cervical length in the second trimester and the identification of cervical shortening as an ultrasonographic diagnostic marker

Committee on Practice Bulletins—Obstetrics. This Practice Bulletin was developed by the Committee on Practice Bulletins—Obstetrics with the assistance of Orion Rust, MD and Anthony Odibo, MD, MSCE. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

of cervical insufficiency. However, short cervical length has been shown to be a marker of preterm birth in general rather than a specific marker of cervical insufficiency. Nonetheless, cerclage may be effective in particular circumstances (to be discussed later in this document) when a short cervix is found.

Various diagnostic tests in the nonpregnant woman have been suggested to confirm the presence of cervical insufficiency, including hysterosalpingography and radiographic imaging of balloon traction on the cervix, assessment of the patulous cervix with Hegar or Pratt dilators, the use of a balloon elastance test, and use of graduated cervical dilators to calculate a cervical resistance index (5–7). However, none of these tests have been validated in rigorous scientific studies, and they should not be used to diagnose cervical insufficiency.

Treatment Options

Historically, several nonsurgical and surgical modalities have been proposed to treat cervical insufficiency. Certain nonsurgical approaches, including activity restriction, bed rest, and pelvic rest have not been proved to be effective for the treatment of cervical insufficiency and their use is discouraged (8, 9). Another nonsurgical treatment to be considered in patients at risk of cervical insufficiency is the vaginal pessary. Evidence is limited for potential benefit of pessary placement in select high-risk patients (10–12).

Surgical approaches include transvaginal and transabdominal cervical cerclage. The standard transvaginal cerclage methods currently used include modifications of the McDonald and Shirodkar techniques. The superiority of one suture type or surgical technique over another has not been established (13, 14). In the McDonald procedure, a simple purse-string suture of nonresorbable material is inserted at the cervicovaginal junction (15). Retrospective studies have not demonstrated the benefit of the placement of an additional stitch for reinforcement or to restore cervical mucus (16). The Shirodkar procedure involves the dissection of the vesicocervical mucosa in an attempt to place the suture as close to the cervical internal os as might otherwise be possible. The bladder and rectum are dissected from the cervix in a cephalad manner, the suture is placed and tied, and mucosa is replaced over the knot (17, 18). Nonresorbable sutures should be used for cerclage placement using the Shirodkar procedure.

Transabdominal cervicoisthmic cerclage generally is reserved for patients in whom cerclage is indicated based on the diagnosis of cervical insufficiency but cannot be placed because of anatomical limitations (eg, after a trachelectomy), or in the case of failed transvaginal cervical cerclage procedures that resulted in second-trimester pregnancy loss (19). Transabdominal cerclage can be accomplished through open laparotomy or operative laparoscopy depending on physician experience, or patient preference. No evidence exists to suggest that one surgical approach for cervicoisthmic cerclage placement has an advantage over the other techniques (20). Abdominal cerclage procedures usually are performed in the late first trimester or early second trimester (10–14 weeks of gestation) or in the nonpregnant state (20, 21). The stitch can be left in place between pregnancies with subsequent cesarean delivery.

Clinical Considerations and Recommendations

▶ ***In which patients is cerclage indicated based on obstetric history or physical examination findings?***

Cerclage placement may be indicated based on a history of cervical insufficiency, physical examination findings, or a history of preterm birth and certain ultrasonographic findings (see Box 1). The safety and efficacy of cerclage in the treatment of patients with cervical insufficiency after fetal viability have not been adequately assessed. Cerclage should be limited to pregnancies in the second trimester before fetal viability has been achieved.

Box 1. Indications for Cervical Cerclage in Women With Singleton Pregnancies ⇦

History

- History of one or more second-trimester pregnancy losses related to painless cervical dilation and in the absence of labor or abruptio placentae
- Prior cerclage due to painless cervical dilation in the second trimester

Physical Examination

- Painless cervical dilation in the second trimester

Ultrasonographic Finding With a History of Prior Preterm Birth

- Current singleton pregnancy, prior spontaneous preterm birth at less than 34 weeks of gestation, and short cervical length (less than 25 mm) before 24 weeks of gestation

History-Indicated Cerclage

Patient selection for history-indicated cerclage (also known as prophylactic cerclage) is based on classic historic features of cervical insufficiency (see Box 1). History-indicated cerclage can be considered in a patient with a history of unexplained second-trimester delivery in the absence of labor or abruptio placentae. History-indicated cerclages typically are placed at approximately 13–14 weeks of gestation.

Three randomized controlled clinical trials have reported on the efficacy of history-indicated cerclage in women chosen because of various historical features alone. Two of the trials that compared cerclage with no cerclage for women with a history of preterm birth found no significant improvement in outcomes among women treated with cerclage (22, 23). The third trial, an intent-to-treat study of 1,292 women with singleton pregnancies at risk of preterm delivery, found that there were fewer deliveries before 33 weeks of gestation in the cerclage group (83 [13%] compared with 110 [17%], P=.03) (24).

Physical Examination-Indicated Cerclage

Women who present with advanced cervical dilation in the absence of labor and abruptio placentae have historically been candidates for examination-indicated cerclage (known as emergency or rescue cerclage). Limited data from one small randomized trial and retrospective studies have suggested the possibility of benefit from cerclage placement in these women (25–34). Thus, after clinical examination to rule out uterine activity, or intraamniotic infection, or both, physical examination-indicated cerclage placement (if technically feasible) in patients with singleton gestations who have cervical change of the internal os may be beneficial. Nevertheless, given the lack of larger randomized trials that have demonstrated clear benefit, women should be counseled about the potential for associated maternal and perinatal morbidity.

▶ *What is the role of ultrasonography in managing women with a history of cervical insufficiency?*

Since transvaginal ultrasound became widely available for cervical length assessment, numerous studies have compared perinatal outcome in cerclage patients treated with history-indicated cerclage versus those monitored with serial transvaginal ultrasound examinations who have been treated with an ultrasound-indicated cerclage as needed. Two recent summaries of the results of these multiple studies have drawn the following conclusions, which are limited to singleton pregnancies:

- Most patients at risk of cervical insufficiency can be safely monitored with serial transvaginal ultrasound examinations in the second trimester (35, 36).
- Unnecessary history-indicated cerclage procedures can be avoided in more than one half of the patients (35, 37).
- Duration of surveillance should begin at 16 weeks and end at 24 weeks of gestation (35).

Ultrasound-indicated cerclage often is recommended for women who have changes on transvaginal ultrasound examination that are consistent with a short cervical length with or without the presence of funneling. These women usually undergo an ultrasound examination because they have risk factors for early delivery. Although patients usually are asymptomatic, some may report nonspecific symptoms, such as backache, uterine contractions, vaginal spotting, pelvic pressure, or mucoid vaginal discharge. Meta-analyses of multiple randomized trials that compared cerclage versus no cerclage in patients with short cervical length during the second trimester have reached the following conclusions (36, 38):

- Although women with a current singleton pregnancy, prior spontaneous preterm birth at less than 34 weeks of gestation, and short cervical length (less than 25 mm) before 24 weeks of gestation do not meet the diagnostic criteria for cervical insufficiency, available evidence suggests that cerclage placement may be effective in this setting. Cerclage is associated with significant decreases in preterm birth outcomes, as well as improvements in composite neonatal morbidity and mortality, and may be considered in women with this combination of history and ultrasound examination findings (38, 39).
- Cerclage placement in women without a history of prior spontaneous preterm birth and with a cervical length less than 25 mm detected between 16 weeks and 24 weeks of gestation has not been associated with a significant reduction in preterm birth (40).

▶ *Which patients should not be considered candidates for cerclage?*

Incidentally detected short cervical length in the second trimester in the absence of a prior singleton preterm birth is not diagnostic of cervical insufficiency, and cerclage is not indicated in this setting. Vaginal progesterone is recommended as a management option to reduce the risk of preterm birth in asymptomatic women with a singleton gestation without a prior preterm birth with an incidentally identified very short cervical length less than or equal to 20 mm before or at 24 weeks of gestation (41).

Cerclage may increase the risk of preterm birth in women with a twin pregnancy and an ultrasonographically detected cervical length less than 25 mm and is not recommended (36, 42). In addition, evidence is lacking for the benefit of cerclage solely for the following indications: prior loop electrosurgical excision procedure, cone biopsy, or müllerian anomaly.

▶ *Is cerclage placement associated with an increase in morbidity?*

Overall, there is a low risk of complications with cerclage placement. Reported complications include rupture of membranes, chorioamnionitis, cervical lacerations, and suture displacement. The incidence of complications varies widely in relation to the timing and indications for the cerclage. A cerclage in the presence of membrane rupture or dilation generally is associated with an increased risk of complications. Life-threatening complications of uterine rupture and maternal septicemia are extremely rare but have been reported with all types of cerclage (24, 43).

Compared with transvaginal cerclage, transabdominal cerclage carries a much greater risk of hemorrhage, which can be life threatening, in addition to all the other complications associated with abdominal surgery (21, 44, 45). Furthermore, it generally precludes the performance of uterine evacuation or vaginal delivery. However, transabdominal cerclage is not an indication for otherwise nonindicated delivery before 39 weeks of gestation.

▶ *Is there a role for additional perioperative interventions and postoperative ultrasonographic assessment with cerclage placement?*

Neither antibiotics nor prophylactic tocolytics has been shown to improve the efficacy of cerclage, regardless of timing or indication (34, 45). In addition, further ultrasonographic surveillance of cervical length after cerclage placement is not necessary (26, 46).

▶ *When is removal of transvaginal McDonald cerclage indicated in patients with no complications, and what is the appropriate setting for removal?*

In patients with no complications, transvaginal McDonald cerclage removal is recommended at 36–37 weeks of gestation. In cases of a planned vaginal delivery, intentional deferral of cerclage removal until the time of labor is not recommended. Cerclage removal is not an indication for delivery. For patients who elect cesarean delivery at or beyond 39 weeks of gestation, cerclage removal at the time of delivery may be performed; however, the possibility of spontaneous labor between 37 weeks and 39 weeks of gestation must be considered. Patients typically do not go into labor after in-office cerclage removal (47). In most cases, removal of a McDonald cerclage in the office setting is appropriate.

▶ *How should women with cerclage and preterm premature rupture of membranes be managed?*

There are no prospective studies with which to guide the care of women with preterm premature rupture of membranes (PROM) who have a cervical cerclage. Results from retrospective studies have not been consistent, but generally have found that cerclage retention for more than 24 hours after preterm PROM is associated with pregnancy prolongation (48); however, because of the nonrandomized nature of the reports, it is unclear how factors (such as labor or infection) contributed to decisions for cerclage removal, which may have yielded biased results. In some, but not all studies, cerclage retention with preterm PROM has been associated with increased rates of neonatal mortality from sepsis, neonatal sepsis, respiratory distress syndrome, and maternal chorioamnionitis (48, 49). A firm recommendation on whether a cerclage should be removed after premature PROM cannot be made, and either removal or retention is reasonable. Regardless, if a cerclage remains in place with preterm PROM, prolonged antibiotic prophylaxis beyond 7 days is not recommended.

▶ *Should cerclage be removed in women with preterm labor?*

The diagnosis of preterm labor may be more difficult in patients with cerclage. In a patient who presents with symptoms of preterm labor, clinical judgment about cerclage removal is advised. Routine management of preterm labor should be followed for patients with symptomatic preterm labor (50). If cervical change, painful contractions, or vaginal bleeding progress, cerclage removal is recommended.

Summary of Recommendations and Conclusions

The following recommendations are based on good or consistent scientific evidence (Level A):

- Although women with a current singleton pregnancy, prior spontaneous preterm birth at less than

34 weeks of gestation, and short cervical length (less than 25 mm) before 24 weeks of gestation do not meet the diagnostic criteria for cervical insufficiency, available evidence suggests that cerclage placement may be effective in this setting. Cerclage is associated with significant decreases in preterm birth outcomes, as well as improvements in composite neonatal morbidity and mortality, and may be considered in women with this combination of history and ultrasonographic findings .

- Cerclage placement in women without a prior spontaneous preterm birth and a cervical length less than 25 mm detected between 16 weeks and 24 weeks of gestation has not been associated with a significant reduction in preterm birth.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Certain nonsurgical approaches, including activity restriction, bed rest, and pelvic rest have not been proved to be effective for the treatment of cervical insufficiency and their use is discouraged.
- The standard transvaginal cerclage methods currently used include modifications of the McDonald and Shirodkar techniques. The superiority of one suture type or surgical technique over another has not been established.
- Cerclage may increase the risk of preterm birth in women with a twin pregnancy and an ultrasonographically detected cervical length less than 25 mm and is not recommended.
- Neither antibiotics nor prophylactic tocolytics have been shown to improve the efficacy of cerclage, regardless of timing or indication.
- A history-indicated cerclage can be considered in a patient with a history of unexplained second-trimester delivery in the absence of labor or abruptio placentae.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Cerclage should be limited to pregnancies in the second trimester before fetal viability has been achieved.
- Transabdominal cervicoisthmic cerclage generally is reserved for patients in whom a cerclage is indicated based on the diagnosis of cervical insufficiency but cannot be placed because of anatomical limitations (eg, after a trachelectomy), or in the case of failed transvaginal cervical cerclage procedures that resulted in second-trimester pregnancy loss.
- After clinical examination to rule out uterine activity, or intraamniotic infection, or both, physical examination-indicated cerclage placement (if technically feasible) in patients with singleton gestations who have cervical change of the internal os may be beneficial.
- In patients with no complications, transvaginal McDonald cerclage removal is recommended at 36–37 weeks of gestation.
- For patients who elect cesarean delivery at or beyond 39 weeks of gestation, cerclage removal at the time of delivery may be performed; however, the possibility of spontaneous labor between 37 weeks and 39 weeks of gestation must be considered.
- In most cases, removal of a McDonald cerclage in the office setting is appropriate.

Proposed Performance Measure

Percentage of women with a current singleton pregnancy, prior spontaneous preterm birth at less than 34 weeks of gestation, and short cervical length (less than 25 mm) before 24 weeks of gestation who are counseled about cerclage

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The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 2000–June 2013. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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Cerclage for the management of cervical insufficiency. Practice Bulletin No. 142. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:372–9.