

CERVICAL

10 MANAGEMENT CONTROVERSIES

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A number of placement and follow-up strategies remain unproven. An expert offers clinical perspective and summarizes published data on 10 key questions.

Ithough it has become the basic management tool for cervical incompetence, cervical cerclage especially emergent cerclage—remains a procedure with well-defined risks and questionable benefits. Thus, it should be used judiciously.

This article addresses 10 particularly controversial questions about this intervention.

Indications

The only generally accepted indication for elective cerclage placement is a history suggestive of cervical incompetence. For emergent cerclage, the primary indication is premature effacement or dilatation of the cervix in the absence of labor prior to 28 weeks' gestation. Asymptomatic women with a history of midtrimester delivery and sonographic evidence of cervical shortening or funneling also may benefit from emergent cerclage placement.

Contraindications

Absolute contraindications to cervical cer-clage include uterine contractions or labor, unexplained vaginal bleeding, intrauterine or vaginal infection, rupture of fetal membranes, intrauterine fetal demise, major fetal anomaly, and a gestational age beyond 28 weeks.

Factors such as placenta previa, a mucopurulent cervical discharge with membrane opacification, fetal membranes prolapsing through the cervical os, and intrauterine fetal growth restriction may be regarded as relative contraindications to emergent cerclage.

CONTROVERSY 1

What is the role

of antibiotics, tocolytics, and progestins?

Antibiotics. Disagreement remains over the advisability of administering antibiotics at the time of prophylactic cerclage placement, which is generally 10 to 15 weeks' gestation. Unfortunately, we lack sufficient data to refute or support this strategy. Because cultures do not always identify potentially pathogenic organisms, and because some "normal" flora can become pathogenic under some circumstances, my practice is to administer a prophylactic antibiotic 30 minutes prior to the procedure. Since there is no "correct" choice of antibiotic, reasonably broad-spectrum coverage is generally desirable. Cefazolin, ampicillin, erythromycin, and clindamycin all are appropriate selections for this purpose.

Because the risk of infection is greater in emergent cerclage, given the greater exposure of the membranes to vaginal flora, my practice is to administer prophylactic antibiotics during the perioperative period. If the emergent cerclage is placed close to the limits of fetal viability, I give combined antibiotic therapy. Again, however, we lack sufficient data to definitively justify this approach. The risks and benefits must be discussed with the patient and her family, with all parties agreeing on the appropriate course.

Tocolytic therapy is a bit less controversial in regard to prophylactic cerclage. At 10 to 15 weeks' gestation, preterm labor is unlikely. Thus, tocolytics are not called for, though sometimes they are given perioperatively to reduce cramping. As with the antibiotics controversy, data are insufficient to support or condemn this practice.

One or 2 doses of indomethacin at the time of cerclage placement has been anecdotally reported to reduce cramping and, potentially, local inflammatory response; again, evidence is lacking. The risks of such an approach are negligible. Nevertheless, they should be reviewed with the patient, along with benefits.

Prophylactic tocolytic therapy may be employed in the setting of emergent cerclage, especially if the procedure is performed at the limits of fetal viability when corticosteroid CONTINUED

CERVICAL CERCLAGE 10 controversies

- 1. What is the role of antibiotics, tocolytics, and progestins?
- 2. When is transabdominal cerclage an option?
- 3. After placement, what follow-up is necessary?
- 4. What is the optimal time for removal?
- 5. Should the cerclage be removed if the membranes rupture?
- 6. Should a cerclage be placed in a woman with a short cervix?
- 7. Should all DES-exposed women be offered prophylactic cerclage?
- 8. What is the role of cervical cerclage in multiple gestations?
- 9. Should a cerclage be placed prior to pregnancy?
- 10. Is there a role for permanent cerclage placement?

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administration is being considered. Whether this approach prolongs pregnancy or improves outcomes is unclear.

Progestins have enjoyed episodic popularity as a means of reducing preterm birth. For this reason, clinicians have given progesterone as an adjunct to cerclage placement, either as an

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ongoing or perioperative regimen. The data that do exist suggest that the role of progestins—if there is one—may be to deter preterm labor rather than to reduce cervical incompetence. Therefore, progestins should not be used therapeutically as an acute intervention. For these reasons, progestins are not routinely given as an adjunct to cerclage.

CONTROVERSY 2

When is transabdominal cerclage an option?

Transabdominal cervicoisthmic cerclage (TAC) was developed for patients in whom placement of a transvaginal cerclage was technically impossible or in whom a prior cerclage had been unsuccessful. It was first described by Benson and Durfee, who published the results of their initial 10 cases in 1965. The perinatal salvage rate in this series was 11% (5 viable infants out of 45 pregnancies) before and 82% (11 of 13) after TAC placement.

Since that series, a number of investigators have used TAC in selected patients with cervical incompetence, and have reported similar results.²⁻⁴ These data suggest that, in selected patients, TAC is safe and effective at reducing the incidence of second-trimester pregnancy loss due to cervical incompetence.

There is no evidence, however, that TAC is superior to transvaginal cerclage as an initial

procedure in the management of cervical incompetence. Furthermore, TAC is associated with far more morbidity than transvaginal cerclage. Not only does it require a laparotomy for placement, but subsequent cesarean delivery is necessary. For these reasons, TAC should be reserved for patients with documented cervical incompetence who have either failed previous transvaginal cerclage or in whom a transvaginal cerclage is technically impossible to place, e.g., when there is little of the anatomic cervix to work with.

Multiple cervical therapies for dysplasia, prior Manchester-Fothergill operation, or severe adenosis secondary to diethylstilbestrol (DES) exposure are other examples of situations in which the transvaginal approach to cerclage may be impossible.

■ CONTROVERSY 3

After placement, what follow-up is necessary?

Many approaches have been employed in the prophylactic-cerclage patient, all of them unencumbered by data. Empirically, many patients benefit from the freedom to carry on routine activities until 16 weeks' gestation, at which time various restrictions are imposed, depending on the risk of preterm delivery.

The most frequently employed follow-up today is the ultrasound examination to assess cervical length, although its superiority to digital examination is not well-substantiated. Nevertheless, a cervical length that appears to be normal on ultrasound is very reassuring for the patient, and the benefit of such reassurance is difficult to quantify—but probably real.

After 24 weeks' gestation, the need for follow-up of the cervix diminishes, since further surgical intervention would be unlikely. After this gestational age, surveillance will be mainly for preterm labor. Because it often is difficult to distinguish cervical incompetence from preterm labor, close surveillance for the latter is prudent and justified.

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When it comes to emergent cerclage, patients initially tend to be hospitalized. Since the underlying problem necessitating the cerclage (infection, incompetence, concealed

Retention of the cerclage may prolong latency, allowing for a more favorable gestational age at delivery. On the other hand, it also may provide a nidus for infection.

abruption) is rarely clear, the need for caution is greater. These patients generally benefit from close ultrasound surveillance and, as gestation progresses, close surveillance for preterm labor. Additional restrictions such as bed rest generally are imposed as well, but we lack data proving that they improve pregnancy outcome.

CONTROVERSY 4

What is the optimal time for removal?

Since the purpose of cerclage placement is to prevent prematurity, I generally recommend delaying removal until 37 weeks' gestation, when the definition of "term" is met. There is no standard of care attached to this gestational age, and removal at 36 or 38 weeks is perfectly acceptable.

Too-early removal should be avoided, as this increases the possibility of a significantly premature delivery. It also is inadvisable to delay removal beyond 38 weeks, when the benefits of prolonging gestation are negligible and the risk of cervical damage with initiation of labor closer to term is increased.

Of course, if increased uterine activity at an earlier gestational age places the cerclage under tension, earlier removal is justified.

CONTROVERSY 5

Should the cerclage be removed if the membranes rupture?

The presence of a cerclage does not appear to increase the incidence of preterm premature rupture of membranes (PROM) remote from

placement. On occasion, however, preterm rupture occurs with a cerclage in place. Retention of the cerclage may prolong latency, allowing for a more favorable gestational age at delivery. On the other hand, a retained cerclage may provide a nidus for infection.

Ludmir et al⁵ conducted a retrospective analysis of prophylactic McDonald cerclage in 30 singleton pregnancies complicated by preterm PROM between 24 and 32 weeks' gestation. In 20 cases (67%), the cerclage was removed at presentation at the discretion of the attending obstetrician; in the remaining 10 cases (33%), the cerclage was retained until delivery. The difference in likelihood of delivery within 24 hours of presentation between the 2 groups was significant: 30% (6 of 20) in the removed versus 0% (0 of 10) in the retained group. The neonatal mortality rate in the retained group was 70% (7 of 10), however, compared with 10% (2 of 20) in the removed group (P < .001). Seventy-one percent of neonatal deaths (5 of 7) in the retained group were the result of early neonatal sepsis, compared with 5% (1 of 20) in the removed group (P < .001). Neonatal mortality was not examined by gestational age.

A more recent retrospective analysis of pregnancy outcomes in 81 patients with preterm PROM and preexisting cerclage between 24 and 35 weeks' gestation suggested that the decision to remove or retain the cerclage had no effect on latency or perinatal outcome. Comparison of the cerclage patients with 162 control subjects with preterm PROM but no cerclage suggested that gestational age at presentation was the most important determinant of pregnancy outcome.

In light of these data, Ob/Gyns should individualize the management of patients with preterm PROM and a preexisting cerclage, weighing the risk of infection against those of precipitating an extremely premature delivery with cerclage removal.

In my own practice, I have changed from being a staunch advocate of cerclage removal to a supporter of either approach, depending

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on individual practice style (my style remaining one of removal in the setting of preterm PROM, provided that such removal can be easily accomplished).

It is unlikely that a patient with a short cervix and no history of adverse pregnancy outcome would benefit from cerclage.

Again, we are hampered in decision-making by a paucity of data to support or refute either approach. I would emphasize the importance of dialogue, making sure the patient is aware of her options before a course of action is decided upon.

CONTROVERSY 6

Should a cerclage be placed in a woman with a short cervix?

In recent years, a number of screening tests have been introduced to identify women at increased risk of preterm delivery: biochemical tests such as fetal fibronectin,7,8 hormonal tests such as salivary estriol,9 and serial cervical ultrasound examinations to assess cervical length and the presence or absence of membrane funneling.10,11 Real-time sonographic evaluation of the cervix has demonstrated a strong inverse correlation between cervical length and preterm delivery.10,111 If the cervical length is below the 10th percentile for gestational age, the pregnancy is at a 6-fold increased risk of delivery prior to 35 weeks.¹⁰ A cervical length of 15 mm or less at 23 weeks occurs in less than 2% of low-risk women, but is predictive of delivery prior to 28 weeks and 32 weeks in 60% and 90% of cases, respectively.10

Several retrospective studies suggest that placement of a cervical cerclage in asymptomatic women with short cervical length may improve perinatal outcome. Done study reported a 10-fold reduction in the incidence of delivery prior to 32 weeks' gestation in women treated with cerclage, with preterm-

delivery rates of 52% and 5% for women in the control and cerclage groups, respectively.¹³ These women were identified via endovaginal ultrasound as having a reduced cervical length prior to 24 weeks' gestation.

According to more recent data, however, cerclage is not indicated in women with evidence of cervical shortening. Indeed, 1 study showed a higher rate of preterm PROM in women undergoing cerclage, compared with those without cerclage (65.2% versus 36.5%; P < .05). Further studies are needed.

In essence, clinicians must tabulate all of the risks for preterm birth before selecting a course of action, with the final decision residing in a risk-benefit analysis that involves the patient. For example, it is unlikely that a patient with a short cervix (found incidentally on ultrasound) and no history of adverse pregnancy outcome would benefit from cerclage. She may, however, benefit from other screening modalities, such as ultrasound surveillance of cervical length until 24 weeks, and possibly fetal fibronectin determinations to better assess her absence of risk for preterm delivery.

On the other hand, a patient with a history of prior idiopathic preterm delivery who is found via ultrasound to have a shortened cervix may benefit from early cerclage placement.

CONTROVERSY 7

Should all DES-exposed women be offered prophylactic cerclage?

In utero exposure to DES alters the structure of the cervix in up to 69% of women. ¹⁸ For example, the endocervical canal is narrower, and the demarcation between it and the lower uterine segment is less clear than in unexposed women. In addition, the cervix does not protrude as far into the vagina as in unexposed women. These and other changes can resemble alterations associated with an incompetent cervix.

Women exposed to DES are 2.6 to 6.7 times more likely than unexposed women to

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experience premature delivery.¹⁸ Even so, most experts have concluded that prophylactic cerclage is not indicated in patients with a history of in utero exposure to DES unless those women have experienced a previous pregnancy loss or have clear evidence of cervical shortening. One reason is the fact that the DES-exposed cervix responds differently to surgery. Further studies are required to clarify this issue.

CONTROVERSY 8

What is the role of cervical cerclage in multiple gestations?

Although multiple gestations face an increased risk of preterm delivery, there is no reliable evidence that prophylactic cerclage is helpful in uncomplicated twin pregnancies. ¹⁹⁻²² In fact, a randomized trial of the issue failed to reveal any advantage, ²⁰ as did 2 randomized trials involving women at high risk of preterm delivery that included patients with twins. ^{21,22} (Women with a

classic history of cervical incompetence were excluded from the latter trial.)²²

Because the data do not clearly support the use of cervical cerclage in higher-order

Complications such as infection and erosion of the cerclage into adjacent organs suggest that the cerclage should be removed once its function has been fulfilled.

multiple gestations, it is not recommended at this time. However, it appears that prophylactic cerclage may reduce extremely premature births in triplet pregnancies.²³

CONTROVERSY 9

Should a cerclage be placed prior to pregnancy?

Cerclage placement prior to pregnancy is predicated on the assumption that avoiding manip-

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ulation of the cervix during pregnancy is desirable. This is particularly true in circumstances when the more elaborate cerclage procedures are necessary, such as abdominal or Shirodkar techniques. With these modalities, blood loss may be greater during pregnancy, and cervical manipulation may be more extensive.

Data to support or condemn this approach are insufficient, but certain practical considerations are worth mentioning. The most frequently cited risk of cerclage placement during pregnancy is loss of the pregnancy. Anatomic injury to surrounding structures may occur in either the pregnant or nonpregnant state. Placement prior to pregnancy also can be problematic if subsequent pregnancy loss occurs or a fetal anomaly is diagnosed especially in the case of abdominal cerclage. In extreme circumstances, the need for uterine evacuation via hysterotomy could arise. There is also the theoretical risk of reduced fertility due to increased inflammation of the cervix if the cerclage is placed prior to conception.

For these reasons, coupled with improved techniques of ultrasound diagnosis and obstetric anesthesia, I opt for placement of cerclage in the late first trimester of pregnancy.

CONTROVERSY 10

Is there a role for permanent cerclage placement?

By and large, permanent cerclage placement is not recommended. Complications, including infection and erosion of the cerclage into adjacent organs, suggest that the cerclage should be removed once its function has been fulfilled. The issue of permanent cerclage placement arises almost exclusively in regard to abdominal cerclage—less often to the "true" (as opposed to modified) Shirodkar cerclage. Since cesarean delivery is necessary in cases of abdominal cerclage, the cerclage may be removed when the patient experiences what she has determined will be her final delivery.

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