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Society for Maternal-Fetal Medicine Consult Series #65: Transabdominal cerclage

Society for Maternal-Fetal Medicine (SMFM); Lorene Temming, MD, MSCI; and Emad Mikhail, MD; SMFM Publications Committee

The American Association of Gynecologic Laparoscopists (AAGL) and the American College of Obstetricians and Gynecologists (ACOG) endorse this document.

Cerclage is the mainstay of treatment for cervical insufficiency. Although transabdominal cerclage may have advantages over transvaginal cerclage, it is associated with increased morbidity and the need for cesarean delivery. In this Consult, we review the current literature on the benefits and risks of transabdominal cerclage and provide recommendations based on the available evidence. The following are Society for Maternal-Fetal Medicine recommendations: (1) we recommend that transabdominal cerclage placement be offered to patients with a previous transvaginal cerclage placement (history or ultrasound indicated) and subsequent spontaneous singleton delivery before 28 weeks of gestation (GRADE 1B); (2) we recommend maternal-fetal medicine consultation for counseling patients who may be candidates for transabdominal cerclage and those who have undergone transabdominal cerclage (Best Practice); (3) we suggest that both laparoscopic transabdominal cerclage and open transabdominal cerclage are acceptable and the decision of approach may depend on gestational age, technical feasibility, available resources, and expertise (GRADE 2B); (4) we suggest that transabdominal cerclage can be performed before pregnancy or in the first trimester of pregnancy with similar fetal outcomes. If a patient with an indication for transabdominal cerclage presents after the first trimester of pregnancy, transabdominal cerclage can still be considered before 22 weeks of gestation (GRADE 2C); (5) we recommend that routine transvaginal cervical length screening not be performed for patients with a transabdominal cerclage in situ (GRADE 1C); (6) we suggest that for individuals at risk of recurrent spontaneous preterm birth, including those with a transabdominal cerclage in situ, a risk-benefit discussion of supplemental vaginal progesterone be undertaken with shared decision-making (GRADE 2C); (7) we suggest that pregnancy loss be managed with dilation and curettage or dilation and evacuation with a transabdominal cerclage in situ or via usual obstetrical management after laparoscopic removal of the transabdominal cerclage, depending on gestational age and resources available (GRADE 2C); and (8) we suggest cesarean delivery between 37 0/7 and 39 0/7 weeks of gestation for patients with a transabdominal cerclage in situ (GRADE 2C).

Key words: cervical insufficiency, laparoscopic transabdominal cerclage, preterm birth, transabdominal cerclage

Introduction

Preterm birth remains a leading cause of neonatal morbidity and mortality. Cervical insufficiency, commonly defined as the inability of a cervix to retain a pregnancy, is an important cause of preterm birth.[1] Cervical insufficiency complicates 0.05% to 1.00% of pregnancies and is characterized by painless cervical dilation leading to early delivery, typically in the middle of the second trimester of pregnancy.[2] The underlying physiology of cervical insufficiency is poorly understood. There are several innate risk factors for cervical insufficiency, including müllerian anomalies and diseases with abnormal collagen, such as Ehlers-Danlos syndrome. In addition, various acquired risk factors for cervical insufficiency have been described, including cervical trauma, prolonged second stage of labor, repeated mechanical dilation, and loop electrosurgery excision procedures (LEEPs) or cold knife conization procedures.[1]

The diagnosis of cervical insufficiency is based on a history of one or more second-trimester losses after painless cervical dilation in the absence of labor or abruption.[1] Cerclage is the mainstay of treatment for cervical insufficiency. There is clear evidence of benefit in patients with a history of preterm birth before 34 weeks of gestation and a cervical length of <25 mm and in patients with an advanced

Corresponding author: Society for Maternal-Fetal Medicine (SMFM) Publications Committee. pubs@smfm.org

cervical dilation before 24 weeks of gestation.[3–5] The use of a cerclage in patients without a history of preterm birth who are found to have a short cervix in the second trimester of pregnancy is less clear, with a recent meta-analysis finding that there was no benefit of the use of a cerclage for patients without a history of preterm birth and transvaginal cervical length of <25 mm.[6] However, the same meta-analysis showed some benefit for some subgroups of patients: those with a transvaginal cervical length of <10 mm, those who received tocolysis as additional therapy to cerclage, and those who received antibiotics as additional therapy to cerclage.[6]

Cerclage is typically performed via a vaginal approach. The most commonly used techniques are modifications of methods originally described by McDonald[7] and Shirodkar.[8] A McDonald cerclage consists of the placement of a nonabsorbable suture at the cervicovaginal junction, whereas the Shirodkar technique describes the dissection of the vesicocervical mucosa to place a nonabsorbable suture as close to the cervical internal os as possible.[7,8] Evidence does not show an advantage of 1 technique or suture type over another in terms of efficacy of preterm birth prevention. A recent meta-analysis suggested the preferential use of a McDonald cerclage as there is improved ease of placement and removal and comparative efficacy to a Shirodkar cerclage.[1,9] A cerclage is typically placed during pregnancy for 3 main indications: (1) history of at least 1 second-trimester loss in the absence of labor or abruption, (2) painless cervical dilation, or (3) history of previous preterm birth before 34 weeks of gestation and transvaginal cervical length of <25 mm.[3–6]

In addition, a cerclage can be placed transabdominally. Benson and Durfee[10] first described this technique in 1965. There are some advantages to transabdominal cerclage (TAC) placement. Using an abdominal approach, a cerclage can be placed at the cervicoisthmic junction, which may provide greater structural support to the cervix.[11] In addition, TAC avoids the presence of a foreign body in the vagina, which may decrease the risk of preterm rupture of membranes or intra-amniotic infection.[12] However, TAC is a more morbid and complicated surgery than transvaginal cerclage, as it involves abdominal access and dissection with potentially increased bleeding risks.[12] In addition, TAC placement typically necessitates cesarean delivery, exposing the patient to another abdominal surgery.

What are indications for transabdominal cerclage?

Because TAC is associated with both increased morbidity of placement and the need for cesarean delivery, it is not offered as a first-line treatment to patients with cervical insufficiency. Alternatively, it is typically offered to patients in whom a transvaginal cerclage would be exceedingly difficult to place for anatomic reasons or patients with a history of an unsuccessful vaginal cerclage placement in a previous pregnancy.[13]

There are several situations where TAC may be considered for anatomic reasons. These have included patients with an extensively amputated cervix without ample cervix to perform a transvaginal cerclage, such as in patients with recurrent LEEPs or trachelectomy[14] and in patients with a congenitally extremely short cervix.[14]

More commonly, TAC is used for patients with unsuccessful transvaginal cerclage. Previous unsuccessful transvaginal cerclage is a spontaneous preterm delivery before 28 weeks of gestation despite transvaginal cerclage. Spontaneous preterm deliveries are those that result from preterm labor or preterm premature rupture of membranes.[1] In addition, a retrospective study demonstrated that TAC reduced the risk of recurrent preterm birth compared with repeat transvaginal cerclage in patients who had a previous delivery before 33 to 34 weeks of gestation with a transvaginal cerclage in place.[12]

The use of TAC in the prevention of preterm birth was evaluated in a recent randomized controlled trial (RCT), the Multicentre Abdominal vs Vaginal Randomized Intervention of Cerclage (MAVRIC) study.[15] The MAVRIC trial compared the use of a TAC, high vaginal cerclage, and low vaginal cerclage among patients with previous miscarriage or preterm birth between 14 and 28 weeks of gestation with a transvaginal cerclage in situ at the time of previous delivery. Patients who delivered early with previous examination-indicated cerclages were excluded. Patients were randomized in a 1:1:1 ratio to TAC, high vaginal cerclage, or low vaginal cerclage. TAC was performed as an open procedure either before pregnancy or up to 14 weeks of gestation; high vaginal cerclage and low vaginal cerclage were performed between 10 and 16 weeks of gestation. Preterm birth rates before 32 weeks of gestation were significantly lower with TAC compared with low vaginal cerclage (8% vs 33%; relative risk [RR], 0.23; 95% confidence interval [CI], 0.07–0.76; P=.0157) and high vaginal cerclage (8% vs 38%; RR, 0.2; 95% CI, 0.06–0.64; P=.0024).[15] The number needed to treat (NNT) to prevent 1 preterm birth when TAC was compared with low vaginal cerclage was 3.9 (95% CI, 2.32–12.10); when TAC was compared with high vaginal cerclage, NNT was 3.2 (95% CI, 2.0–7.4).[15] **We recommend that TAC placement be offered to patients with a previous transvaginal cerclage placement (history or ultrasound indicated) and subsequent spontaneous singleton delivery before 28 weeks of gestation (GRADE 1B).**

What is the role of maternal-fetal medicine subspecialists in transabdominal cerclage?

Maternal-fetal medicine (MFM) subspecialists should be involved in identifying and counseling patients eligible for TAC. Eligible candidates for TAC may be identified after the index pregnancy where transvaginal cerclage is unsuccessful. In these cases, MFM subspecialists can assist with counseling, and a TAC may be placed before any future pregnancies. Furthermore, patients may be identified early in a current pregnancy based on a history of cervical insufficiency and either previous unsuccessful transvaginal

cerclage or anatomic factors making transvaginal cerclage impossible. MFM subspecialists are well suited to counsel regarding the risks and benefits of TAC, the timing of TAC placement, and the management of pregnancy after TAC. MFM subspecialists can be involved in placing a TAC or can refer to other surgeons to perform the procedure, depending on local resources and level of experience. **We recommend MFM consultation for counseling patients who may be candidates for TAC and those who have undergone TAC (Best Practice).**

How is transabdominal cerclage placed?

The technique of TAC placement was first described as an open procedure by Benson and Dupree[10] in 1965. TAC placement is typically performed under spinal or regional anesthesia, and a Pfannenstiel incision is used. The uterus is exteriorized, and the surgeon identifies and palpates the uterine vessels bilaterally. The surgeon retracts the uterine vessels laterally to create an avascular space between the uterus and the vessels in the broad ligament at the level of the internal os of the cervix. Typically, a nonabsorbable thick braided 5-mm suture is guided through this space using a right-angle clamp. The suture may be tied anteriorly or posteriorly, and it is left in place.[16,17] There is no clear evidence regarding the benefit of tocolysis for TAC placement.[16] Open TAC placement requires 2 laparotomies: one at the time of cerclage placement and one at the time of cesarean delivery. The risks of open TAC placement are similar to other open procedures and are discussed in further detail below. In addition, hospital admission and recovery time are similar to that of other open procedures.

In the past 10 to 15 years, a minimally invasive surgical approach for TAC placement has been developed and increased in availability and popularity. The use of conventional laparoscopy, robotic surgery, and single-incision laparoscopy for TAC placement has been described.[18,19] Many different techniques are reported for laparoscopic TAC placement; most describe a 3-port laparoscopic approach, some with a fourth suprapubic assistant port.[18,20] Most use a nonabsorbable thick braided 5-mm suture, a straightened needle, and a uterine manipulator.[18] Most dissect the uterovesical and paravesical spaces and make a window in the broad ligament through which the suture is placed, with some placing the knot anteriorly and some posteriorly.[18] An exact description of the procedure is beyond the scope of this Consult, but we refer readers to the reference of Zhao et al,[20] which includes a video description. There is no clear evidence for tocolysis in the setting of laparoscopic TAC placement.

In addition, there is a recent description of modified laparoscopic TAC placement with the nonabsorbable thick braided suture tied in the vagina, which enabled vaginal removal at term and allowed for an attempt at normal spontaneous vaginal delivery.[21] Using this technique, a series of 26 pregnancies had favorable obstetrical outcomes, with a neonatal survival rate of 100%, term deliveries of 81.5%, and vaginal delivery achieved in 21 pregnancies.[21] Although vaginal delivery has potential benefits for patients, there is also value in using a single TAC for multiple pregnancies with the TAC left in situ during cesarean delivery. Future studies should evaluate vaginal removal of a TAC prospectively and from a cost-effectiveness standpoint.

Several studies have evaluated whether there are advantages of laparoscopic TAC placement compared with open TAC placement. Smith et al[22] and Kim et al[23] compared laparoscopic TAC placement with open TAC placement. They found that laparoscopic TAC placement procedures are associated with less risk of blood loss as they hypothesize that there is increased visualization and less risk of uterine vessel injury. Furthermore, they found that although laparoscopy was associated with longer operative time, it required a shorter hospital stay and quicker return to activity for the patient.[22,23] In contrast, in a larger systematic review, Burger et al[24] found no difference in blood loss, operative time, or hospital stay when laparoscopic TAC placement was compared with open TAC placement. A more recent systematic review by Hulshoff et al[25] found that laparoscopic TAC placement was associated with less blood loss and a shorter hospital stay compared with open TAC placement; however, laparoscopic TAC placement was associated with a longer operation duration. There are similar rates of pregnancy and miscarriage after laparoscopic and open TAC placement.[18]

Other studies have compared the efficacy of preterm birth prevention between open and laparoscopic TAC procedures. A meta-analysis of available retrospective studies compared laparoscopic TAC (n=728) with open TAC (n=1116) and found that laparoscopic TAC had a higher rate of deliveries at >34.0 weeks of gestation (82.9% vs 76.0%; $P<.01$) and a lower rate of deliveries at 23.0 to 33.6 weeks of gestation (6.8% vs 14.8%; $P<.01$).[18] When first-trimester losses were excluded, neonatal survival was higher in the laparoscopic group (96.5% vs 90.1%; $P<.01$).[18] A more recent meta-analysis comparing laparoscopic TAC (n=1869) and open TAC (n=1529) found that gestational age at delivery (overall, 36.6 weeks of gestation) was not statistically different between the 2 approaches. When first-trimester losses were excluded, fetal survival did not differ significantly between the groups.[25] In several smaller retrospective studies and meta-analyses, gestational age at delivery and neonatal survival were similar when laparoscopic TAC was compared with open TAC.[22–24] Delivery rates after 34 weeks of gestation ranged from 78.5% to 82.9% with the laparoscopic approach and 76% to 84.8% with the open approach.[18,22–24,26,27] Neonatal survival rates ranged from 96.4% to 98.5% with laparoscopic TAC and 90.8% to 98.0% with open TAC.[18,22–24,26,27]

Several operative complications have been described with both laparoscopic TAC placement and open TAC placement. There are reports of pelvic infection, small bowel injury, bladder injury, laceration of uterine vessels, and insufficient tightening of the cerclage in both open and laparoscopic procedures. In open procedures, there was a

complication rate of 3.7% in a series of 300 cases performed by a single surgeon[27] and 1.2% in a systematic review.[18] In laparoscopic procedures, there are reports of uterine perforation with uterine manipulator in addition to the previously mentioned complications. Complication rates of laparoscopic TAC placement range from 0.7% to 4.5%.[18,24,26,28] Complication rates are similar when laparoscopic and open TAC procedures are directly compared.[18,22,24] There are several cases of rarer complications that occur in pregnancy after TAC placement, in both laparoscopic TAC and open TAC, including cases of spontaneous uterine rupture, uterine rupture with term labor, and uterine dehiscence noted at the time of cesarean delivery.[27,29] In addition, there is a report of TAC erosion into the vagina 7 years after the procedure was performed.[30]

In summary, both laparoscopic TAC and transabdominal TAC are acceptable approaches[13]; complication rates of both laparoscopic and open procedures are rare and similar. Although there is some inconsistent evidence suggesting the benefit of laparoscopic TAC, the 2 approaches have yet to be compared prospectively. A large RCT is needed to answer the question of the optimal approach. **We suggest that both laparoscopic TAC and open TAC are acceptable and the decision of approach may depend on gestational age, technical feasibility, available resources, and expertise (GRADE 2B).**

What is the ideal time for transabdominal cerclage placement?

A TAC can be placed before pregnancy or early in pregnancy. There are some advantages to an interval, pre-pregnancy TAC placement. Primarily, the uterus is smaller, which makes accessing the cervicoisthmic junction easier. In addition, the surgical risks related to anesthesia and blood loss do not have the potential to affect pregnancy when interval TAC is performed. Nevertheless, it is sometimes not possible to place a TAC before pregnancy as a patient with indications for TAC may present when already pregnant.

A recent systematic review showed that more laparoscopic TAC procedures are performed before pregnancy (71.1% before pregnancy vs 28.9% during pregnancy), whereas more open TAC procedures are performed during pregnancy (18.6% before pregnancy vs 81.4% during pregnancy).[18] These findings demonstrate a preference for open TAC placement during pregnancy, likely related to easier placement with a gravid uterus. Tulandi et al[31] performed a meta-analysis evaluating 678 cases of cerclage, with some performed before pregnancy and some during pregnancy. They found that the live birth rate was similar between cerclage procedures performed before and during pregnancy. There was some evidence of increased complication rates in the during pregnancy cerclage group, although this was likely attributable to the near-exclusive use of laparotomy during pregnancy. Similarly, Dawood et al[32] compared 59 pre-pregnancy open TAC procedures to 62 during pregnancy open TAC procedures and found that the overall rate of neonatal survival was similar. However, patients in the pre-pregnancy group were more likely to deliver after 34 weeks of gestation.[32] Moreover, there were fewer preterm deliveries in the pre-pregnancy group and increased rates of surgical complications, including quantified blood loss of >500 mL in the during pregnancy group.[32]

The question of the best approach and timing when a patient who needs a TAC presents during pregnancy merits further research. In most studies, a TAC is placed in the first trimester of current pregnancies. The MAVRIC trial evaluated an open approach in pregnant patients before 14 weeks of gestation,[15] although other studies have included placements up to 22 weeks of gestation.[33,34] The choice of approach may be influenced by gestational age and technical feasibility. It is unclear whether the open or laparoscopic approach is more beneficial when performed during pregnancy. Of note, the MAVRIC trial compared an open TAC to a high vaginal cerclage, which was placed high in the cervix by mobilizing the bladder, similar to a Shirodkar cerclage. Other authors have described transvaginal cerclage placement at the cervicoisthmic junction and found that obstetrical outcomes with transvaginal cervicoisthmic cerclage were similar to transabdominal cervicoisthmic cerclage.[35] This vaginal approach is different from the high vaginal technique described in the MAVRIC trial, which was found to be less efficacious than TAC. Future studies could compare transvaginal cervicoisthmic cerclage to TAC in the already pregnant population.

Substantial healthcare disparities exist regarding access to care in the interpregnancy period for low-income individuals.[36] Consultation and surgical planning for TAC placement might occur during the interpregnancy period, specifically if pre-pregnancy TAC is desired. Access to continuous insurance coverage is necessary for individuals to receive appropriate care, and without it, there are detrimental gaps in access to physician care.[37]

Regarding future fertility, a recent secondary analysis of the MAVRIC study demonstrated no difference in the time to pregnancy after randomization between those with TAC performed before pregnancy and high vaginal or low vaginal cerclage performed during pregnancy.[38] The rates of pregnancy at 6, 12, and 18 months were similar between both groups.[38] Some evidence suggests that pre-pregnancy TAC is associated with lower maternal risks, possibly because of the increased ability to perform pre-pregnancy TAC laparoscopically. **We suggest that TAC can be performed before pregnancy or in the first trimester of pregnancy with similar fetal outcomes. If a patient with an indication for TAC presents after the first trimester of pregnancy, TAC can still be considered before 22 weeks of gestation (GRADE 2C).**

How should pregnancy with abdominal cerclage in situ be managed?

MFM subspecialists can counsel regarding the placement of a TAC and can assist in the management of pregnancy with a

Summary of recommendations

No.	Recommendation	GRADE
1	We recommend that TAC placement be offered to patients with a previous transvaginal cerclage placement (history or ultrasound indicated) and subsequent spontaneous singleton delivery before 28 weeks of gestation.	1B
2	We recommend MFM consultation for counseling patients who may be candidates for TAC and those who have undergone TAC.	Best Practice
3	We suggest that both laparoscopic TAC and open TAC are acceptable and the decision of approach may depend on gestational age, technical feasibility, available resources, and expertise.	2B
4	We suggest that TAC can be performed before pregnancy or in the first trimester of pregnancy with similar fetal outcomes. If a patient with an indication for TAC presents after the first trimester of pregnancy, TAC can still be considered before 22 weeks of gestation; TAC in the second trimester of pregnancy is more commonly performed as an open procedure.	2C
5	We recommend that routine transvaginal cervical length screening not be performed for patients with a TAC in situ.	1C
6	We suggest that for individuals at risk of recurrent spontaneous preterm birth, including those with a TAC in situ, a risk-benefit discussion of supplemental vaginal progesterone be undertaken with shared decision-making.	2C
7	We suggest that pregnancy loss be managed with D&C or D&E with a TAC in situ or via usual obstetrical management after laparoscopic removal of the TAC, depending on gestational age and resources available.	2C
8	We suggest cesarean delivery between 37 0/7 and 39 0/7 weeks of gestation for patients with a TAC in situ.	2C

D&C, dilation and curettage; *D&E*, dilation and evacuation; *MFM*, maternal-fetal medicine; *TAC*, transabdominal cerclage.

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TAC in situ. Of note, a question that frequently arises in the care of pregnancy with a TAC in situ is if there is utility in following cervical length after a TAC is placed. This has not been clearly evaluated in the setting of TAC. However, several studies have evaluated the value of follow-up cervical length measurement after transvaginal cerclage placement. Those studies demonstrated that although cervical shortening after cerclage may increase the risk of preterm birth, cervical length, whether measured above or below the cerclage, does not directly correlate with the outcomes.[39–46] Furthermore, rescue cerclage does not improve outcomes in the setting of a short cervix after cerclage.[39,47,48] Rescue cerclage in the setting of TAC may be even more challenging and less likely to be successful given the potential anatomic considerations and patient history that led to TAC in the first place. **We recommend that routine transvaginal cervical length screening not be performed for patients with a TAC in situ (GRADE 1C).**

The question may arise if patients with a TAC in situ should be treated with progesterone. In the MAVRIC trial, progesterone was used in 27% of patients (17% of those with TAC, 28% of those with high vaginal cerclage, and 48% of those with low vaginal cerclage).[15] This question is more challenging given that the US Food and Drug Administration has withdrawn approval of intramuscular 17-alpha hydroxyprogesterone caproate after a confirmatory trial failed to verify clinical benefit.[49,50] Although the efficacy of vaginal progesterone for the prevention of recurrent preterm birth has been investigated,[51,52] the benefit of adding vaginal progesterone to the treatment regimen of patients with cerclage is unknown. **We suggest that for individuals at risk of recurrent spontaneous preterm birth, including those with a TAC in situ, a risk-benefit discussion of supplemental vaginal progesterone be undertaken with shared decision-making (GRADE 2C).** This discussion can consider the historical use of progesterone in many patients with TAC, the lack of short-term safety concerns regarding progesterone, and the overall uncertainty regarding the benefit of progesterone use.

In addition, pregnancies with TAC are subject to pregnancy loss for various reasons, including spontaneous abortion, missed abortion, incomplete abortion, therapeutic abortion, and failure of TAC associated with preterm dilation or rupture of membranes. Pregnancy loss can be managed via dilation and evacuation (D&E) with a TAC in situ. A large retrospective study of 142 patients with TAC found that 14 patients subsequently underwent 19 D&E procedures, with 15 of those procedures occurring at $<$12 weeks of gestation and 4 of those procedures occurring between 12 and 19 weeks of gestation.[53] In these cases and another case report of D&E at 19 weeks of gestation, osmotic dilators and standard surgical techniques were used, and no major complication was noted.[53,54] In both studies, there are several reports of successful term or near-term deliveries in subsequent pregnancies after both first- and second-trimester dilation and curettage (D&C) for the treatment of pregnancy loss.[53,54] In addition, there are several case reports of fetal demise at advanced gestational ages delivered vaginally after laparoscopic removal of the TAC.[55,56] These data suggest that pregnancy loss can be managed with D&E and laparoscopic removal of the TAC. **We suggest that pregnancy loss be managed with D&C or D&E with a TAC in situ or via usual obstetrical management after laparoscopic removal of the TAC, depending on gestational age and resources available (GRADE 2C).**

Society for Maternal-Fetal Medicine grading system: GRADE recommendations[61,a]

GRADE of recommendation	Clarity of risk and benefit	Quality of supporting evidence	Implications
1A. Strong recommendation, high-quality evidence	Benefits outweigh risks and burdens, or vice versa	Consistent evidence from well-performed, RCTs, or overwhelming evidence of some other form Further research is unlikely to change confidence in the estimate of benefit and risk	Strong recommendation that can apply to most patients in most circumstances without reservation Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present
1B. Strong recommendation, moderate-quality evidence	Benefits outweigh risks and burdens, or vice versa	Evidence from RCTs with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design Further research (if performed) is likely to have an effect on confidence in the estimate of benefit and risk and may change the estimate	Strong recommendation that applies to most patients Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present
1C. Strong recommendation, low-quality evidence	Benefits seem to outweigh risks and burdens, or vice versa	Evidence from observational studies, unsystematic clinical experience, or RCTs with serious flaws Any estimate of effect is uncertain	Strong recommendation that applies to most patients Some of the evidence base supporting the recommendation is, however, of low quality
2A. Weak recommendation, high-quality evidence	Benefits are closely balanced with risks and burdens	Consistent evidence from well-performed RCTs or overwhelming evidence of some other form Further research is unlikely to change confidence in the estimate of benefit and risk	Weak recommendation; best action may differ depending on circumstances or patients or societal values
2B. Weak recommendation, moderate-quality evidence	Benefits are closely balanced with risks and burdens; there are some uncertainties in the estimates of benefits, risks, and burdens	Evidence from RCTs with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design Further research (if performed) is likely to have an effect on confidence in the estimate of benefit and risk and may change the estimate	Weak recommendation; alternative approaches likely to be better for some patients under some circumstances
2C. Weak recommendation, low-quality evidence	There are uncertainties in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens	Evidence from observational studies, unsystematic clinical experience, or RCTs with serious flaws Any estimate of effect is uncertain	Very weak recommendation, other alternatives may be equally reasonable
Best practice	Recommendation in which either (1) there is an enormous amount of indirect evidence that justifies strong recommendation (direct evidence would be challenging, and inefficient use of time and resources, to bring together and carefully summarize) or (2) recommendation to the contrary would be unethical		

RCT, randomized controlled trial.

[a] Adapted from Guyatt et al.[62]

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Guidelines
The content of this document reflects the national and international guidelines related to cerclage

Organization	Title	Year of Publication
American College of Obstetricians and Gynecologists	Practice Bulletin No.142: Cerclage for the management of cervical insufficiency[1]	2014
American College of Obstetricians and Gynecologists	Committee Opinion No. 831: Medically indicated late-preterm and early-term deliveries[58]	2021
Royal College of Obstetricians and Gynaecologists	Cervical cerclage[13]	2022
The Joint Commission	Specifications manual for Joint Commission national quality measures (v2023a1)[59]	2022

There are limited reports of unsuccessful TAC with preterm dilation or rupture of membranes. A retrospective study that evaluated 8 of 96 patients (7%) with unsuccessful TAC did not identify any specific risk factors for failure.[57] Moreover, there are several case reports of successful pregnancies after unsuccessful TAC using the same TAC in future pregnancies with successful term or late preterm deliveries.[53,54] Subsequent term or late preterm delivery occurred in these cohorts after D&C or D&E were performed.[53,54] These findings suggest that the etiology of preterm dilation or rupture of membranes in the setting of TAC is complex and that the patient does not necessarily need TAC revision or removal after unsuccessful TAC.[53,54]

Finally, the timing of delivery with a TAC in situ must be considered. There are several reports of uterine dehiscence or even uterine rupture with labor in patients with a TAC.[27–29] For this reason, cesarean delivery before the onset of labor is advisable. The timing could be considered similar to previous myomectomy (generally recommended at early term from 37 0/7 to 38 6/7 weeks of gestation).[58,59] Expert opinion varies, with some delivering at 37 weeks of gestation and some delivering as late as 39 0/7 weeks of gestation.[28] After cesarean delivery, a TAC should generally be left in situ for future pregnancies. Subsequent pregnancies with repeated use of the same TAC have similarly good survival rates and rates of term birth, and long-term complications of a retained TAC are rare.[60] The long-term management of a TAC in situ after completion of childbearing is not well defined. There are no outcome data to support routine TAC removal. However, for patients undergoing a tubal ligation at the time of cesarean delivery or who are certain they do not wish future children, suture removal can be considered, provided it is not anticipated to involve significant dissection and blood loss. **We suggest cesarean delivery between 37 0/7 and 39 0/7 weeks of gestation for patients with a TAC in situ (GRADE 2C).**

Conclusion

TAC placement is a highly effective method for preventing preterm birth in patients with cervical insufficiency and previous unsuccessful transvaginal cerclage placement or in whom a transvaginal cerclage would be very challenging to place. A TAC should be considered in patients with previous delivery before 28 weeks of gestation with a transvaginal cerclage in situ. Minimally invasive approaches to TAC placement may decrease blood loss and length of hospital stay and appear to be as effective as open approaches, although this has not been studied prospectively. Counseling regarding TAC placement and management of pregnancies with a TAC in situ should be performed by an MFM subspecialist. Early pregnancy loss in the setting of TAC placement can be managed with D&C or D&E without compromising the TAC. Later pregnancy loss can be managed with laparoscopic removal of the TAC and usual obstetrical management. Patients with a TAC in situ should be delivered between 37 0/7 and 39 0/7 weeks of gestation.

There are several areas of future research regarding TAC. It is important to continue evaluating long-term morbidity associated with TAC, including chronic pelvic pain and morbidity associated with repeat surgeries for TAC placement, cesarean delivery, and potentially TAC removal. This long-term morbidity should be compared with the reduced morbidity of fewer unsuccessful pregnancies in patients with a TAC to determine the cost-effectiveness of TAC placement.

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