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Clinical Guidelines

Cervical preparation for second-trimester surgical abortion prior to 20 weeks' gestation

SFP Guideline #2013-4

Abstract

For a dilation and evacuation (D&E) procedure, the cervix must be dilated sufficiently to allow passage of operative instruments and products of conception without injuring the uterus or cervical canal. Preoperative preparation of the cervix reduces the risk of cervical laceration and uterine perforation. The cervix may be prepared with osmotic dilators, pharmacologic agents or both. Dilapan-S™ and laminaria are the two osmotic dilators currently available in the United States. Laminaria tents, made from dehydrated seaweed, require 12–24 h to achieve maximum dilation. Dilapan-S™, made of synthetic hydrogel, achieves significant dilation within 4 h and is thus preferable for same-day procedures. A single set of one to several dilators is usually adequate for D&E before 20 weeks' gestation. Misoprostol, a prostaglandin E_1 analogue, is sometimes used instead of osmotic dilators. It is generally regarded as safe and effective; however, misoprostol achieves less dilation than overnight osmotic tents. The literature supports same-day cervical preparation with misoprostol or Dilapan-S™ up to 18 weeks' gestation. As the evidence regarding alternative regimens increases, highly experienced D&E providers may consider same-day regimens at later gestations utilizing serial doses of misoprostol or a combination of osmotic and pharmacologic agents. Misoprostol use as an adjunct to overnight osmotic dilation is not significantly beneficial before 19 weeks' gestation. Limited data demonstrate the safety of misoprostol before D&E in patients with a prior cesarean delivery. Mifepristone, a progesterone receptor antagonist, is also effective for cervical preparation prior to D&E, although data to support its use are limited. The Society of Family Planning recommends preoperative cervical preparation to decrease the risk of complications when performing a D&E. Since no single protocol has been found to be superior in all situations, clinical judgment is warranted when selecting a method of cervical preparation.

Keywords: Dilation and evacuation; Cervical dilation; Dilator; Laminaria; Dilapan; Lamicel; Misoprostol; Mifepristone; Cervical priming

This document revises and replaces the previous version, originally published in #2007-2. Approaches to cervical preparation prior to dilation and evacuation (D&E) have changed over the past 6 years, with increased emphasis on regimens that avoid overnight placement of osmotic dilators. These practice recommendations have been updated to reflect increasing evidence demonstrating the safety of regimens that accomplish cervical preparation and D&E within a single day. The use of Dilapan-S™ and misoprostol for cervical preparation on the same day as D&E has increased. Medical evidence now supports the use of misoprostol and Dilapan-S™ for cervical preparation on the same day as D&E as safe alternatives to overnight osmotic dilation up to 18 weeks' gestation. More recent studies support the safety of same-day cervical preparation before D&E at later gestations; however, the literature is limited. In addition, mifepristone is being evaluated as an alternative to overnight osmotic dilatation early in the second trimester.

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Background

Roughly 11% of abortions performed in the United States occur in the second trimester [1]. Pregnancies may be terminated in the second trimester by labor induction, D&E, hysterotomy and hysterectomy. Because D&E is safe, cost effective and efficient, it is the most common means of second-trimester abortion in the United States [2].

During D&E, the cervix must be dilated sufficiently to allow passage of operative instruments and fetal parts without injuring the cervical canal. The minimum dilation required to pass most forceps used for D&E ranges from 14 to 19 mm, although wider dilation is often required to remove products of conception at advanced gestations [3]. The cervical dilation needed for D&E increases with gestational age. Neither the minimal nor the ideal degree of dilation required for D&E at each gestational age has been determined.

Though the cervix may be mechanically dilated at the time of D&E, the degree of dilation needed for later procedures may require additional force, potentially increasing risk of cervical trauma and other complications. During D&E, perforation of the uterus occurs in 0.2–0.3% and cervical laceration occurs in 0–1% [4–6]. Insufficient cervical dilation is a strong predictor of major complications of D&E [7]. The risk of uterine and cervical trauma can be minimized with preoperative preparation of the cervix to achieve baseline dilation and softening [4–8].

The cervix may be prepared with osmotic cervical dilators (e.g., laminaria tents) or pharmacologic agents (e.g., misoprostol). Osmotic dilators are dehydrated rods placed in the cervical canal that absorb fluid within the cervix and slowly expand in situ to cause dilation. This expansion exerts radial pressure on the cervical canal, which, in addition to physical dilation, may induce prostaglandin synthesis that softens the cervix and makes subsequent mechanical dilation easier [9–12]. Two types of osmotic dilators are currently available in the United States: laminaria and Dilapan-S™. Table 1 compares the features of these products. In addition, the drugs misoprostol and mifepristone may be used as cervical priming agents prior to second-trimester surgical abortion.

Osmotic dilators: Laminaria, Dilapan-S™ and Lamicel®

Laminaria

The stems of the seaweed *Laminaria japonica* and *Laminaria digitata* are dehydrated and made into cervical tents that are then sterilized. Several suppliers currently manufacture laminaria tents in a range of sizes (Table 1). When placed, they may swell to 3–4 times their initial diameter. For example, a 3-mm laminaria tent achieves approximately 1 cm dilation in situ overnight [13–15]. Most of this dilation occurs in the first 6 h, although the maximum effect is not achieved for 12–24 h [9,16,17].

Since laminaria tents are made from natural resources, drawbacks include variability in the product, potential allergy and theoretical transmission of infection. There are no modern reports of laminaria tents transmitting infection, and numerous studies demonstrate that infectious morbidity is not increased by their use [18–21]. The greatest limitation of laminaria use for cervical preparation is the time required to achieve dilation, usually necessitating a 2-day abortion procedure. Faster acting synthetic dilators were developed to enable D&E to be performed in 1 day.

Table 1
Characteristics of currently available osmotic dilator tents: Laminaria [13] and Dilapan-S™ [22,23]

	Laminaria	Dilapan-S™
Diameter	2–10 mm	3 and 4 mm
Length	60–85 mm	55 and 65 mm
Time to minimal effect	6 h	2 h
Time to maximum effect	12–24 h	4–6 h
Maximum dilation achieved	3 times dehydrated diameter	4 times dehydrated diameter

Dilapan-S™

Dilapan-S™ is a synthetic osmotic dilator made of a polyacrylate-based proprietary hydrogel (Aquacryl) [22]. Tents come in two diameters and two lengths (Table 1). Compared to laminaria, Dilapan-S™ achieves cervical dilation in a shorter timeframe and rapidly swells to 3–4 times its initial diameter in situ. One 4-mm dilator can result in 7.8–10 mm or 10–11.2 mm of cervical dilation within 2 or 4 h, respectively. After 24 h, one 4-mm Dilapan-S™ expands to 12.7–14.6 mm [22,23]. Unlike laminaria, Dilapan-S™ shortens as it swells; thus, the longer 65-mm tent is recommended for most patients to ensure that the internal cervical os is adequately dilated [22–24].

Dilapan-S™ was designed with a stronger core than its predecessor (original Dilapan™) to decrease risk of tent fragmentation during removal. Although no published studies have addressed rates of fragmentation and other complications in the reformulated product, anecdotal reports suggest that dilator entrapment or fracture occur rarely.

Lamicel®

Lamicel®, another effective synthetic osmotic dilator, has not been manufactured since 2008.

Medications for cervical priming: Mifepristone and misoprostol

Over the past decade, there has been increased interest in preparing the cervix for D&E without overnight osmotic dilation. Many women find dilator insertion painful and anxiety producing. Patients, especially those traveling long distances for care, may prefer completing an abortion in a single day. In a randomized trial of same-day priming with misoprostol vs. overnight laminaria, women stated a strong preference for having their procedure completed in a single day [25]. Same-day regimens also have the potential to improve convenience and decrease expenses for both the patient and the provider. However, medical regimens may be more unpredictable in terms of the dilation achieved, the time needed to achieve adequate preparation and the risk of spontaneous delivery before D&E; thus, they may not be feasible or appropriate in some clinical settings.

Misoprostol

Misoprostol, an inexpensive prostaglandin E_1 analogue, is commonly used as an *off-label* alternative or adjunct to osmotic dilators prior to D&E. Side effects include cramping, nausea, vomiting, diarrhea, fever and chills. Doses range from 200 to 800 mcg, with 400 mcg being used most commonly. In the United States, misoprostol is labeled only for oral administration and approved solely for treatment of gastrointestinal disorders; however, when used *off-label* for cervical priming prior to D&E, misoprostol may be administered po, buccally, sublingually or vaginally [26].

Mifepristone

Mifepristone, a progesterone receptor antagonist, may be used for cervical priming before D&E. A 200-mg dose of mifepristone administered po 24–48 h before surgery achieves cervical softening, decreases force required for mechanical cervical dilation and increases uterine response to misoprostol when given prior to abortion [27–31]. The safety and efficacy of mifepristone used alone for cervical preparation prior to D&E has not been well studied.

In the United States, mifepristone is approved for use only up to 7 weeks' gestation in conjunction with misoprostol for first-trimester medication abortion, and labeling restrictions require administration by a clinician; however, it is used *off-label* for cervical preparation at later gestations [32,33]. There may be institutional and legislative barriers regarding *off-label* use; however, mifepristone is being used routinely in a growing number of US clinics and hospitals. Of note, mifepristone is significantly more expensive than misoprostol in the United States.

Clinical Questions and Recommendations

1. Does use of osmotic dilators decrease the risk of complications of D&E?

A prospective cohort study of more than 11,000 second-trimester D&E procedures demonstrated the protective effect of laminaria [6]. The rate of cervical laceration in patients between 18 and 20 weeks' gestation declined from 5% to 1.6% (p=0.002) when laminaria tents were placed 5–24 h preoperatively. Laminaria also decreased the rate of cervical laceration between 14 and 18 weeks from 0.8% to 0.4%; however, this result was not statistically significant.

2. What are the risks of using osmotic dilators before D&E?

Complications from use of osmotic dilators are rare. Risks include infection, pain, vasovagal reactions, allergies, bleeding, inadequate cervical dilation, cervical perforation, rupture of membranes and labor prior to planned surgery [21]. Women often rate levels of pain during insertion as moderate, even when a cervical block is used [29], and vasovagal reactions may occur [34,35]. Allergic reactions and anaphylaxis have been reported following insertion of laminaria tents but not synthetic dilators [21,36–38]. The package label warns that, because laminaria tents are dried seaweed, patients with seafood allergy may have an allergic response [13]. If dilators are not placed correctly, the internal cervical os may not dilate. The dilators may create a false passage and perforate the cervix. Amniotic membranes may be inadvertently ruptured during insertion, although this occurs infrequently. Last, osmotic dilators can lead to labor or precipitous delivery prior to the scheduled surgical time. These complications occur rarely.

Bacterial contamination from upward migration of vaginal and cervical flora is a theoretical concern [39]. Package labeling recommends that broad-spectrum antibiotics be given at the time of laminaria insertion due to theoretical risk of infection [13]; however, the Dilapan-S™ label does not recommend antibiotic prophylaxis for the synthetic product. No studies have examined the necessity of antibiotic prophylaxis, and practices vary among clinicians. There are a few case reports of bacteremia and toxic shock syndrome following laminaria placement [21,39,40]. Despite these isolated reports, medical evidence demonstrates that overall infectious morbidity is not increased when using osmotic dilators before D&E [16,18–21].

Cervical dilators are occasionally difficult to remove [21,22,41,42]. When tents swell within a noncompliant cervix, the portion within the canal may remain minimally dilated, while portions within the uterine cavity and the vagina swell significantly, creating an hourglass or "dumbbell" shape. This may result in inadequate dilation of the cervical internal os and difficult tent removal. Osmotic tents may fragment during attempted removal when cervical dilation is inadequate; however, this occurs rarely. Osmotic dilators may also migrate into the uterine cavity. Whole or fragmented dilators may be removed from the uterus with suction or forceps. If fragments of or whole tents are inadvertently retained within the cavity, later complications, including pain and bleeding, may develop [42].

3. Which osmotic dilator is preferred for preparation of the cervix for D&E?

Overall, the choice of osmotic dilator will fall to individual clinician preference. Some clinicians choose to use laminaria and Dilapan-S™ at the same time, which anecdotally makes removal easier. Consideration should be given to gestational age as well as to intended length of preparation. When trying to shorten the time for cervical preparation, Dilapan-S™ is preferred as it acts more rapidly [9,16,17,22,23,43,44].

4. Can misoprostol be used as an alternative to osmotic dilators for cervical preparation prior to D&E?

Misoprostol, a prostaglandin E_1 analogue, administered buccally or vaginally, has been used as an alternative to osmotic dilators prior to early second-trimester surgical abortion for more than a decade. In a survey of National Abortion Federation member clinics throughout North America in 2001, researchers found that roughly 40% routinely used misoprostol in place of osmotic dilators prior to 16 weeks' gestation [45]. At later gestational ages, fewer clinics omit osmotic dilator tents, with only 12% routinely using misoprostol alone between 18 and 20 weeks.

Misoprostol achieves less cervical dilation than osmotic tents and may increase the likelihood of inadequate dilation, though rarely resulting in a challenging or failed abortion [25,43,44,46,47]. In a retrospective case series of more than 2200 D&Es between 12 and 23 6/7 weeks' gestation that

used various cervical preparation regimens, including varying doses of misoprostol, difficult or inadequate dilation was encountered in 2% after overnight laminaria (n=946) and in 18% of women (up to 18 weeks) treated with misoprostol alone (n=1260, p<.004). Of note, all women past 18 weeks' gestation received overnight laminaria. The abortion procedure was completed in 99.8% of cases, with a low rate of serious complications [46].

No studies have been sufficiently powered to determine if the difficult dilation encountered more commonly with misoprostol alone results in increased rates of cervical laceration or uterine perforation [25,43,44]. The largest case series to date includes outcomes from 6620 abortions performed at Planned Parenthood of Los Angeles between 12 and 16 weeks using 400 mcg of misoprostol administered vaginally or buccally 90 min prior to D&E [48]. The uterine perforation rate was 0.45%, and no cervical lacerations occurred. No other serious complications of second-trimester abortion increased.

Only one small randomized trial (n=84) has compared the use of laminaria placed overnight to 400 mcg of misoprostol placed vaginally 3–4 h before D&E at 13–16 weeks' gestation [25]. Most subjects preferred a same-day regimen to overnight treatment; however, surgeons' satisfaction with cervical preparation was much lower when misoprostol was used (37% vs. 95%, p<.001). Less preoperative dilation was achieved with misoprostol than with overnight laminaria (33 *Fr* vs. 43 *Fr*, p<.001), and procedures in the misoprostol group were more likely to require additional mechanical dilation (80% vs. 21%, p<.001). Physicians rated 27% of the misoprostol procedures as moderate to markedly difficult vs. 5% in the laminaria group (p=.01); however, 98.8% of all procedures were completed on the first attempt. These differences were pronounced in nulliparous patients but not statistically significant in parous women. One uterine perforation and two superficial cervical lacerations occurred in the misoprostol group (n=42), with none in the laminaria group (n=42).

In the only randomized controlled trial studying same-day regimens, 400 mcg of misoprostol placed buccally was compared to a single Dilapan-S™ inserted 3–4 h prior to surgical abortion at 12–15 weeks' gestation [44]. Similar baseline dilation was achieved; however, subsequent mechanical dilation was rated to be easier after Dilapan-S™ (p=.015). Patient satisfaction, procedure time and complication rates were similar between groups. There were no major complications.

A large case series detailed three highly trained clinicians' experiences with a multidose misoprostol regimen as an alternative to overnight dilation at 17–23 weeks in 1081 patients in an outpatient pregnancy termination clinic [47]. The rate of major complications was less than 2% and consistent with complication rates in the literature. The misoprostol regimen used varied by provider. The most common regimen was 400 mcg vaginally or buccally every 2 h until adequate cervical preparation was achieved as judged subjectively by the surgeon. The average total misoprostol dose was 1200 mcg (range, 200–2400 mcg). Only two procedures were not completed within a single day, and more than 95% were completed in 7 h or less. The incidence of labor induction and spontaneous delivery was not discussed.

In summary, randomized trials demonstrate that tent placement more effectively dilates and prepares the cervix before D&E than misoprostol [25,44]; however, no studies demonstrate that using misoprostol in lieu of osmotic dilators increases the rate of rare but serious complications. Protocols using misoprostol or Dilapan-S™ on the same day as D&E are safe and effective prior to 18 weeks' gestation [46,48]. Protocols used by highly experienced D&E providers demonstrate that overnight osmotic dilation may be avoided at later gestations as well [47,49]. Misoprostol use for cervical priming is less predictable than osmotic dilation, and thus, the provider must be prepared for challenging or inadequate cervical dilation, the need for urgent D&E in cases of more rapid response to cervical priming or the increased possibility of out-of-clinic delivery if misoprostol is administered at home. Patients prefer same-day misoprostol to overnight osmotic dilators, but no difference in satisfaction is noted when same-day regimens of misoprostol and dilators are compared. Given these considerations, patient preference should be considered when feasible.

5. Is adjuvant misoprostol necessary or beneficial after placement of osmotic dilators?

Misoprostol is a useful adjuvant to overnight osmotic dilators late in the second trimester, but routine use at earlier gestations is unnecessary when osmotic tents are placed. Though use of misoprostol as an adjunct to overnight dilation has become common [45], only one randomized study has assessed the efficacy of this practice. Edelman et al. conducted a double-blind, placebo-controlled trial to assess the potential benefit of adjunctive preoperative buccal misoprostol between 13 and 20 6/7 weeks' gestation following overnight laminaria [50]. Subjects (n=125) were treated with 400 mcg of buccal misoprostol or placebo 90 min prior to D&E. Adjunctive misoprostol increased preoperative cervical dilation only for subjects at 19 weeks' gestation or beyond (54 *Fr* vs. 49 *Fr*, p=.01). Misoprostol significantly improved perceived ease of subsequent dilation at 16 or more weeks' gestation; however, there was no difference in procedure time, estimated blood loss or complication rates between groups.

The combination of Dilapan-S™ with adjuvant misoprostol may prepare the cervix to allow same-day procedures later in the second trimester. Lyus et al. reviewed the outcome of 274 D&Es between 18 and 21 6/7 weeks' gestation performed under general anesthesia by four experienced surgeons using a combination of 1–3 Dilapan-S™ and 400 mcg of adjuvant misoprostol placed vaginally 3–4 h preoperatively [49]. One cervical laceration (0.3%) occurred, and one patient passed the fetus prior to the scheduled D&E.

6. Can mifepristone be used as an alternative or adjuvant to osmotic dilators for cervical preparation prior to D&E?

Mifepristone has been evaluated as a potential replacement for overnight osmotic dilation in a few small trials. Mifepristone is superior to laminaria for cervical priming prior to second-trimester labor induction and is recommended by the Society of Family Planning, the American College of Obstetricians and Gynecologists and the Royal College of Obstetricians and Gynaecologist for this purpose [28,51,52]. Mifepristone avoids the discomfort of osmotic dilator insertion and gastrointestinal side effects of misoprostol; however, it requires a multiple-day protocol for cervical preparation [27,28]. The risk of spontaneous expulsion of the fetus prior to D&E increases, especially when mifepristone is followed by misoprostol [27].

A randomized noninferiority trial (n=50) compared 200 mg of mifepristone administered po to placement of 3–6 laminaria tents 24 h prior to D&E between 14 and 16 weeks' gestation [29]. Cervical dilation after priming was much less in the mifepristone group; however, additional mechanical dilation took less than 2 min on average and was informally described as usually "easy." No complications were reported.

A large randomized trial assessed the effect of mifepristone pretreatment 48 h prior to 600 mcg misoprostol, given sublingual or vaginally, on the day of D&E to 20 weeks' gestation (n=900) [27]. Subjects who received mifepristone prior to misoprostol had greater preoperative cervical dilation, easier mechanical dilation and shorter surgical times. The risk of spontaneous expulsion of the fetus during the 48 h following mifepristone and before D&E was 0.4%; however, pretreatment with mifepristone significantly increased the risk of vaginal delivery following misoprostol fivefold (1.3% vs. 6.2%, p<.01).

One series from a clinic in Australia (n=21) reported a higher risk of cervical laceration (19%) at the time of D&E between 17 and 22 weeks associated with the use of mifepristone in addition to misoprostol and osmotic dilators [53]. This has not been reported in other studies using mifepristone prior to D&E [27,29].

7. How many osmotic dilators should be placed?

The number of tents placed varies greatly among clinicians and depends on provider experience, gestational age, parity, the compliance of the cervix and whether Dilapan-S™ or laminaria tents are used [3,14,54,55]. Some providers may attempt to place more osmotic dilators for challenging cases, such as those involving adolescents, patients with no prior vaginal birth or women with scarring from treatment of cervical dysplasia. Protocols recommend increasing numbers of dilators with increasing gestational age. Compared with the number of laminaria, approximately half the number of Dilapan-S™ is needed because of the increased dilation achieved by the former [3,41,55]. In a review of D&Es performed after 20 weeks' gestation (n=147), the need for intraoperative mechanical cervical dilation and the rates of uterine and cervical damage decreased as more tents were used [56]. Specific protocols, usually based on provider or clinic experience, have not been compared in randomized clinical trials and none is clearly superior.

Package labeling offers some guidelines; however, these are not based on data from published clinical trials. The package labeling for laminaria refers to insertion of a single tent but does not specifically preclude multiple tent placement [13]. The US package labeling for Dilapan-S™ states that one tent should be placed 4 h prior to D&E up to 16 weeks' gestation [22]. Though the US label does not mention placement of multiple tents or use beyond 16 weeks' gestation, the package insert for Dilapan-S™ used internationally recommends two tents at 13–15 weeks, three at 16–18 weeks and four at 18 weeks' gestation and beyond. Overnight placement is recommended beyond 18 weeks' gestation [23].

A few small studies demonstrate that a single Dilapan-S™ placed 3–4 h prior to D&E may be sufficient up to 18 weeks' gestation [43,44]. Additional mechanical dilation was described as "somewhat" or "very difficult" in 10% of subjects before 15 weeks (n=60) and 18% of those at 16–18 weeks' gestation (n=45) [43,44]. Approximately half of subjects in each study were nulliparous. No cervical lacerations or uterine perforations occurred. However, in a case series of 80 women who received a single Dilapan 6 h before D&E at 15–20 weeks' gestation, two nulliparous women sustained cervical lacerations requiring suture [57].

Although studies demonstrate that a single set of dilators is generally sufficient prior to 20 weeks' gestation [43,44,46,49,53], some clinicians place serial sets over 1–2 days, especially at later gestations or to achieve advanced dilation to allow intact extraction of the fetus [3,55]. More tents may be placed with each successive set due to increasing cervical dilation and softening [58,59]. Stubblefield et al. conducted a randomized study comparing a 1-day protocol (18–22 h) vs. a 2-day protocol (48 h) prior to D&E at 17–19 weeks gestation (n=60) [59]. Greater dilation was achieved with the 2-day regimen than with the overnight regimen (22.4 vs. 18.2 mm diameter, p<.001). However, the authors questioned whether the small clinical benefit was outweighed by the additional patient inconvenience and discomfort entailed in placement of a second set of dilators. The gestational age at which 2 days of osmotic dilation is needed or beneficial has not been determined.

8. How long should osmotic dilators be left in situ?

The length of time dilators that should be retained varies according to the dilator being used and the degree of dilation needed to complete the procedure. Laminaria tents dilate more slowly and, for this reason, they are often left in place overnight. Though Dilapan-S™ achieves its effect more quickly, it is also commonly left in situ overnight as well

when used in clinics that cannot accommodate same-day procedures. No studies directly compare complication rates by the duration tents that are left in place.

Prior to 18 weeks' gestation, overnight dilation is not necessary [34,43,44,48]. Protocols using Dilapan-S™ on the same day prior to D&E at 12–18 weeks wait 3–4 h between insertion and further instrumentation [43,44]. As previously discussed, overnight dilation is usually recommended after 18 weeks regardless of tent selection. However, experienced providers report using a combination of Dilapan-S™ and misoprostol 3–4 h before D&E in gestations up to 21 6/7 weeks when a same-day protocol is desired [49].

The package labeling for both tents indicates that osmotic dilators should not be left in place for more than 24 h [13,22]. Nonetheless, dilators are sometimes left in place longer without reports of increased infection rates. Hern reported a 2% postoperative infection rate in patients treated with serial laminaria for a median time of 41 h [58]. Others reported no complications with tents in place for 48 h [58–60].

9. What are the pregnancy outcomes if the patient chooses to continue her pregnancy after osmotic dilators, prostaglandin analogues, or mifepristone are used for cervical preparation?

Patients who decide to continue their pregnancy following cervical preparation with osmotic tents, misoprostol or mifepristone in the second trimester should be counseled about the additional risks of miscarriage and preterm birth resulting from the initiation of the abortion process. However, they should also be advised of the possibility for an uncomplicated pregnancy and a live term birth.

Limited data are available on pregnancy outcome subsequent to removal of laminaria tents, with none available specifically following Dilapan-S™ removal. A report of two cases demonstrates that osmotic cervical dilation can reverse and that pregnancies may continue despite intentional dilation up to 2 cm [61]. The largest published series of women who continued their pregnancies after laminaria removal includes only 17 women, of whom 14 (82%) delivered healthy, term infants [62]. Two delivered prematurely and one miscarried 2 weeks after tent removal. With preterm cervical dilation, exposed membranes and the presence of a foreign body, there is a theoretical increased risk of ascending infection. However, the miscarriage and preterm deliveries noted in this series were not attributed to infection. Of note, prophylactic antibiotics were administered at the time of dilator insertion and were continued after tent removal in most of these women [61,62].

If a woman decides to continue her pregnancy after mifepristone or misoprostol exposure, the potential for an increased risk of spontaneous abortion, preterm labor and teratogenesis should be addressed. The risk of teratogenic effects is minimized in the second trimester once organogenesis is complete. No studies exist to confirm or exclude mifepristone or misoprostol as a teratogen beyond the first trimester.

Misoprostol use in the first trimester of pregnancy may be associated with fetal anomalies, specifically Moebius Syndrome, a rare congenital facial paralysis, with or without limb defects [63,64]. Bernard et al. prospectively followed 105 pregnancies exposed to mifepristone alone or in combination with misoprostol for attempted first-trimester abortion [65]. Of the 59 women who also received misoprostol and continued their pregnancy following failed medication abortion, 49 had term live births, 8 had preterm live births and 2 had spontaneous abortions. Four had congenital anomalies, including 1 with Moebius Syndrome, 1 with multiple severe anomalies and 2 with minor anomalies.

Mifepristone by itself may result in abortion; however, initial studies found that repeated doses are often required [31]. In Bernard's series of first-trimester patients, 17% (n=46) of those wanting to continue their pregnancy following mifepristone ingestion ultimately aborted spontaneously [65]. There are few data regarding the effect of isolated mifepristone exposure in the second trimester on pregnancy outcome. Carbonell reported that 0.4% of 450 women administered 200 mg of mifepristone for cervical priming prior to second-trimester abortion delivered spontaneously within the 48-h interval before misoprostol administration [27].

One brief case series reports that 4 of 5 patients treated with serial intramuscular progesterone injections following first-trimester mifepristone administration delivered healthy term infants, suggesting that the effects of mifepristone may be reversed [67]. One woman completed her abortion soon after the first progesterone injection.

In contrast to isolated misoprostol exposure, there is no reported pattern of congenital anomalies following mifepristone exposure. The package insert notes that, of the 36 patients with known outcome following mifepristone administration alone, 1 terminated an anomalous fetus with sirenomelia and cleft palate [66]. In the abovementioned study by Bernard, two infants had congenital anomalies following isolated first-trimester mifepristone exposure (one with Claude Bernard-Horner Syndrome and the other with hydrocephalus with an adductus thumb) [66]; however, these anomalies could have been secondary to other medical risk factors.

10. Does the use of misoprostol or mifepristone increase the risk of cesarean scar rupture when used for cervical priming before D&E?

Since uterine scar rupture is rare in the second trimester, no study has sufficient power to address the overall risk of this complication and determine if risk is significantly increased by misoprostol administration. The slight risk of uterine rupture is outweighed by the risk of cervical laceration and uterine perforation resulting from inadequate cervical preparation. Thus, the use of mifepristone or misoprostol for cervical preparation prior to D&E should not be restricted in women with prior uterine surgery.

Many studies of misoprostol use prior to D&E include women with prior cesarean section with no resultant uterine rupture [27,43,46–48,58]. A single case report of a uterine rupture during D&E preceded by overnight laminaria and 2 doses of preoperative misoprostol was found in the published literature [68]. This patient was at 23 weeks' gestation and had 2 prior cesarean deliveries. Rupture of a prior uterine scar has been reported in the second trimester after misoprostol use for labor induction; however, this outcome is also rare [69]. No studies address uterine scar location (i.e., low transverse vs. classical vertical incision) or risk in subjects with a prior transmural myomectomy. None address the risk of mifepristone administration for cervical priming in women with a uterine scar, though there are no reports of uterine scar rupture following mifepristone alone.

11. Should cervical dilators be placed in the setting of ruptured membranes?

There is no contraindication to placement of tents following ruptured membranes; however, package labeling states that osmotic tents should not be placed in the case of evident genital tract infection [22]. A retrospective case–control study of 34 women with mid-trimester premature rupture of membranes showed that overnight laminaria placement prior to D&E did not result in rates of infection higher than those among controls with intact membranes [70]. Of note, all subjects were treated with a 5-day course of broad-spectrum oral antibiotics. In the absence of more extensive data, the Society of Family Planning recommends cervical preparation prior to D&E in cases with ruptured membranes and endorses the use of osmotic dilators for this purpose. When clinically indicated, osmotic dilators may be used *off-label* in cases of chorioamnionitis to hasten surgical uterine evacuation; however, this practice has not been reported in the medical literature.

12. May dilators be placed in patients with a placenta previa?

Osmotic dilators are not contraindicated in patients with placenta previa. Despite theoretical concern for hemorrhage, no significant bleeding was noted during or after laminaria placement in two case series. In one series, tents were placed at up to 24 weeks' gestation in 8 subjects with complete previa with no increase in bleeding or transfusions [71]. Thomas et al. studied 131 women who underwent outpatient dilator placement and mid-trimester D&E [72]. Those with previa had an increased operative blood loss of approximately 20 mL, but there was no difference in operative time, hemorrhage or infection. These studies do not address outcomes in the subset of women with placenta previa who were already bleeding prior to dilator insertion. Women who are bleeding are commonly admitted for observation following tent insertion.

Conclusions and Recommendations

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

1. Cervical preparation is recommended prior to second-trimester D&E to decrease risk of cervical trauma.
2. Osmotic dilators (laminaria and Dilapan-S™) are safe and effective for cervical preparation prior to D&E.
3. Use of osmotic dilators does not increase infectious morbidity.
4. When osmotic dilator placement and D&E are to be performed on the same day, Dilapan-S™ is preferred over laminaria tents to achieve adequate priming more quickly.
5. Osmotic dilators achieve more preoperative dilation than mifepristone or misoprostol.

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

1. Prior to 20 weeks' gestation, adequate cervical preparation may be achieved with a single set of osmotic dilators.
2. Dilapan-S™ placed 3–4 h prior to D&E is a safe alternative to overnight dilator placement up to 18 weeks' gestation.
3. Use of misoprostol or mifepristone as an alternative to osmotic tents increases risk of inadequate cervical dilation; however, this has not been shown to increase the rate of rare, severe complications, such as uterine perforation and cervical lacerations.
4. Routine use of adjunctive buccal misoprostol in addition to osmotic dilators is not recommended before 16 weeks' gestation but may be considered when difficult cervical dilation is anticipated or at later gestational ages.
5. Misoprostol may be given in the second trimester prior to D&E to women with a prior cesarean delivery.
6. Use of mifepristone, especially when combined with misoprostol, increases the rate of spontaneous vaginal delivery prior to D&E.

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

1. Only experienced providers capable of managing difficult cervical dilation should use protocols omitting osmotic tent placement prior to D&E.
2. Overnight placement of osmotic dilators is recommended after 18 weeks' gestation. Highly experienced D&E providers may consider same-day procedures at later gestations utilizing a combination of osmotic and pharmacologic agents or serial doses of misoprostol, if needed, to accommodate the time constraints of patients and staff.
3. Mifepristone may be administered for cervical priming in women with prior cesarean delivery.

4. The choice of number and type of osmotic dilators and length of preoperative treatment depend on gestational age, provider experience and patient risk factors. While increasing numbers of osmotic dilators are indicated for cervical preparation at later gestational ages, no single protocol has been proven ideal or applicable for all clinical situations.

Important Questions To Be Answered

Despite advances in second-trimester surgical abortion techniques over the past three decades, the ideal cervical preparation before second-trimester D&E remains unknown. Future studies should focus on clarifying the gestational age at which osmotic dilation is required and when overnight placement is needed. The use of misoprostol and mifepristone as alternatives or adjuncts to osmotic dilators prior to D&E warrants further study through randomized comparative trials. Finally, the side-effect profile, patient and provider satisfaction and the costs of the various mechanisms of cervical preparation warrant further investigation. Fortunately, a large multicenter randomized clinical trial is underway in the United States to address many of these outstanding issues. In addition, experienced providers who have been providing later D&Es without overnight osmotic dilation are strongly encouraged to publish case series of their experiences and outcomes with alternative cervical preparation regimens.

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Sources

The PubMed database was used to identify references published between 1966 and August 2013. The database was searched for the following terms: laminaria, Lamicel®, Dilapan™, second-trimester pregnancy, D&E, induced abortion, mifepristone, misoprostol and cervical priming. Only English-language abstracts were included. The abstracts were reviewed and relevant articles were obtained. Additional references cited in these journal articles were reviewed. Contemporary textbooks and published women's health guidelines were also consulted.

Authorship

These guidelines were prepared by Michelle C. Fox and Colleen M. Krajewski and were reviewed and approved by the Board of the Society of Family Planning.

Conflict of Interest Statement

Michelle C. Fox and Colleen M. Krajewski report no significant relationships with industry relative to these guidelines. The Society of Family Planning receives no direct support from pharmaceutical companies or other industries.

Intended Audience

This guideline has been developed by the Society for Family Planning for its members and other clinicians who perform surgical second-trimester abortions. This guideline may be of interest to other professional groups that set practice standards for family planning services. The purpose of this document is to review the medical literature evaluating common means of cervical preparation for second-trimester surgical abortion prior to 20 weeks' gestation. This evidence-based review should guide clinicians in preparing the cervix prior to D&E, although it is not intended to dictate clinical care.