

Clinical Guidelines

Cervical preparation for surgical abortion from 20 to 24 weeks' gestation

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Abstract

Although less than 2% of abortions in the United States occur after 20 weeks, procedures performed at more advanced gestations are associated with increased morbidity and mortality. Adequate cervical preparation before dilation and evacuation (D&E) at 20 or more weeks' gestation reduces procedural risk. However, few clinical trials have included sufficient information on best practices for cervical preparation in this gestational age range. For procedures at 20 or more weeks' gestation, at least 1 day of cervical preparation is recommended. Evidence is less clear that the procedure is faster or safer with the use of either serial dilation over more than 1 day or adjuvant misoprostol. Osmotic dilators are preferable to misoprostol, but there are insufficient data to support either laminaria or Dilapan as the preferred dilator. Fewer Dilapan are needed to gain the same amount of dilation as laminaria. The Society of Family Planning recommends preoperative cervical preparation before D&E between 20 and 24 weeks. Further studies are needed to clarify the best means to prepare the cervix to minimize abortion complications and improve outcome in this gestational age range.

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Background

In the United States, 1.4% of abortions take place after 20 weeks' gestation [1]. The majority of these procedures are performed from 20 to 23 weeks' gestation [2]. Most second-trimester abortions in the USA (87%) are accomplished by dilatation and evacuation (D&E) [1]. Cervical preparation before surgical abortion at 20–24 weeks is essential to reduce complications since the fetal parts are both larger and more calcified as compared to earlier gestations.

Procedural complications increase with advancing gestational age [1,2]. Morbidity and mortality of induced abortion increase an average of 20% per week [3]. A rare but serious D&E complication, uterine perforation, occurs in only 0.2–0.4% of surgical abortions between 12 and 26 weeks [4] with an increase in relative risk of 1.4 with each additional 2 weeks of gestation [5]. In a review of almost 12,000 patients undergoing D&E between 12 and 26 weeks, blood loss exceeding 500 ml and cervical laceration were the most

common complications, each affecting approximately 0.9% of the patients [4]. In those women with 19–26 weeks' gestation, cervical laceration was significantly reduced ($p < .05$) when laminaria were used.

Three methods can be used to open the cervix in this gestational age range: mechanical dilation alone with graduated rigid dilators, preoperative placement of osmotic dilators and preoperative use of ripening agents. In some circumstances, the latter two options may include subsequent use of mechanical dilation.

Mechanical dilation

Early in the development of D&E, mechanical dilation without cervical preparation was observed to increase both the short- and long-term morbidity of procedures requiring significant dilatation such as advanced second trimester gestations. Mechanical dilation using graduated Pratt,

Denniston or other dilators may be used at 20–24 weeks for augmenting the dilatation obtained by osmotic dilators and/or cervical ripening agents.

Osmotic dilators

Laminaria

A tent composed of dried, compressed seaweed stem, absorbs fluid to expand gradually and also assists in ripening the cervix by endogenous prostaglandin release [6]. A clinical effect is measurable in 3 h but does not achieve full potential until 12–24 h [7–9].

Dilapan

A hygroscopic rod dilator made from hydrophilic polymers, is superior to laminaria in dilating properties [10], but initially was prone to fracture [11,12]. In 2002, the initial formulation was replaced by Dilapan-S, which dilates at a faster rate and to a larger extent than laminaria and is synthesized with a stronger core intended to reduce fragmentation.

Lamicel®

A sterile polyvinyl sponge with magnesium sulfate, does not elicit cervical wall tension. In contrast to laminaria and Dilapan, its action is largely chemical. While the manufacturer claims that it softens the cervix in 30 min and achieves adequate cervical dilation in a few hours, it is not believed to achieve adequate dilation alone for procedures at 20–24 weeks' gestation when at least 2 cm of dilation is commonly recommended [13].

Ripening agents

Prostaglandins

Prostaglandins were first used in 1970 to soften and dilate the cervix before uterine evacuation [14,15]. Prostaglandin receptors are present throughout pregnancy and help initiate uterine contractions [16]. Misoprostol, a PGE₁ analogue that can be administered orally, vaginally or buccally, has become the most commonly used prostaglandin analogue. Misoprostol offers a relatively inexpensive and chemically stable agent for cervical ripening [17].

Antiprogesterones

Antiprogesterones, such as mifepristone, are synthetic steroids that bind to progesterone receptors and prevent endogenous progesterone from reaching its target [18,19]. Mifepristone elicits significant cervical dilatation and softening without initiating contractions, leading to less concern about precipitating labor induction when preparing a cervix for D&E. No studies have examined its use before D&E at 20–24 weeks' gestation, either alone or as an adjuvant to other cervical ripening agents.

Despite common recommendations for cervical dilation or preparation before D&E [20,21], a number of questions remain unanswered. This document reviews current evidence on cervical preparation for D&E at 20–24 weeks' gestation.

Clinical questions and recommendations

1. Does the use of osmotic dilators decrease the risk of complications with D&E at 20–24 weeks' gestation?

Adequate pre-procedure cervical dilation reduces D&E morbidity. Mechanical dilation alone is associated with more complications than osmotic dilation with laminaria [20–24]. Cervical laceration with hemorrhage is one of the most commonly cited serious D&E complications [4,20,25,26]. Data from retrospective studies suggest that cervical preparation with osmotic dilators decreases the risk of cervical laceration at 20–24 weeks' gestation [4].

One of the largest series describing how to decrease cervical injury from abortion only included procedures performed at less than 12 weeks' gestation [20,27]. Prospective series with women greater than 12 weeks' gestation include little to no information specifically about the 20–24 weeks range [28]. A retrospective series of 11,747 D&E procedures completed between 1972 and 1981 evaluated the incidence of cervical laceration requiring repair [4]. Between 20 and 26 weeks' gestation, 10% of cases using mechanical dilation alone required repair, the majority of which were reported to be in the distal cervical canal and were less than 2 cm long. After the introduction of laminaria tents for cervical preparation, the incidence of cervical laceration requiring repair decreased significantly to 1.2% ($p < .05$) for procedures between 20 and 26 weeks. No studies have evaluated the long-term effects of cervical laceration, if any, on future pregnancy outcome.

The associations between gestational age, parity, provider experience and the use of cervical dilators to decrease procedure risk are still poorly understood, especially for procedures at 20–24 weeks. Although conventional wisdom holds that cervical injuries are more common in teenagers [21,29], no data examine this risk for teens having abortions at 20–24 weeks' gestation. Additionally, the association between cervical injury and parity is unclear [20,23,27,30,31]. Although studies suggest that nulliparous women benefit more from laminaria placement before surgical abortion between 13 and 16 weeks' gestation than do parous women [32], research has not investigated this association independently above 17 weeks' gestation. Cervical preparation with osmotic dilators results in a nonsignificant trend towards a reduced risk of uterine perforation above 19 weeks' gestation [5,27]. Additionally, evidence suggests higher rates of cervical injury and uterine perforation when abortions are performed by inexperienced providers [21,27].

No studies have examined whether osmotic dilators before D&E at 20–24 weeks increase or decrease the risks of

infection or hemorrhage. Retrospective evidence suggests that cervical preparation with osmotic dilators before surgical abortion at 20–24 weeks may reduce the risk of cervical laceration.

2. *What are the risks of using osmotic dilators as cervical preparation before D&E at 20–24 weeks' gestation?*

No significant clinical risks of using osmotic dilators before D&E at 20–24 weeks' gestation have been documented. Onset of labor is a potential rare complication after placement of osmotic dilators. The exact incidence is not known. Labor onset occurred in about 1 in 500 cases in a series of 1000 D&E procedures performed between 17 and 25 weeks' gestation using serial laminaria and adjunctive urea [25]. This rate is slightly higher than estimates of 1 in 2000 to 3000 abortions at 14–18 weeks' gestation [13]. Still, the relative infrequency of labor demonstrates that inpatient hospitalization for observation is not necessary following dilator placement. No data address whether the risk of labor changes in women at 20–24 weeks' gestation when more dilators are placed or when serial placement is used.

Other possible immediate and long-term risks of osmotic dilators include difficult removal, fragmentation and displacement of the dilators within the uterus [11,33], hypersensitivity reactions [34], infectious morbidity [11,35,36], vasovagal reactions, incidental rupture of amniotic membranes during placement, perforation of the cervix, and possible future cervical incompetence [12,13,26,37–39]. Information regarding these potential risks of cervical osmotic dilator placement has been addressed by the Society of Family Planning in two previous reviews [40,41].

Interesting data exist about future pregnancy risk when focusing on procedures from 20 to 24 weeks' gestation. In a retrospective review of 600 patients who underwent D&E between 14 and 24 weeks after approximately 24 h of cervical preparation with laminaria, 96 subsequent pregnancies were identified. Increased risk of subsequent cervical incompetence or preterm delivery was not identified after second-trimester cervical dilation and surgical abortion. However, subsequent preterm delivery appeared to be correlated with a lower gestational duration at the time of previous second-trimester surgical abortion. Specifically, women who had had a previous surgical abortion completed with a median gestational age of 20 weeks had a significantly lower risk of preterm delivery compared to those at a median of 18 weeks. These findings led the authors to hypothesize that future cervical incompetence may be related to the degree of cervical trauma that occurs during the abortion itself rather than to the amount of cervical dilation obtained through osmotic dilation [42].

The benefits of cervical dilation by osmotic dilation appear to outweigh any risks associated with their placement. Placement of osmotic dilators is generally safe and recommended before D&E at 20–24 weeks' gestation.

3. *Which osmotic dilator is preferred for preparation of the cervix for D&E at 20–24 weeks' gestation?*

Data comparing osmotic dilators used for cervical preparation before surgical abortion at 20–24 weeks' gestation are scant. The largest trial comparing overnight laminaria to overnight Dilapan included 1001 subjects between 13 and 25 weeks' gestation [11]. Laminaria or Dilapan were used for cervical preparation on an every-other-case basis. Women were excluded if they had a history of cervical surgery or multiple cesarean sections, presence of cervical scarring, serious current illness or active vaginal bleeding. Additionally, any woman who was “judged to require multiple applications of dilators” was excluded from the study. The data were not stratified by gestational age; thus, it is not clear which results pertain to cases performed at 20 weeks or greater. No differences were found in procedure time, blood loss or need for additional dilation. Approximately twice as many laminaria were required to achieve the same amount of dilation achieved with Dilapan, but women were more likely to have “cervical dilation deficiency” (defined as “poor to no dilation” or “fractured or retained dilator”) when Dilapan were used.

Earlier data indicated that patients might experience more pain after placement of Dilapan, presumably due to rapid dilation [43]. When Dilapan expands in an hourglass shape, removal may be more difficult. Based on anecdotal experience, some providers recommend placing a laminaria tent or Lamichel with Dilapan to facilitate removal [12,44]. No data exist to validate this approach. Additionally, no studies have directly compared laminaria to Dilapan-S for use at 20–24 weeks' gestation since its reformulation and reintroduction to clinical practice.

Overall, evidence is insufficient to recommend one osmotic dilator over another before D&E from 20 to 24 weeks. However, fewer Dilapan than laminaria may be needed to achieve equivalent dilation.

4. *How many osmotic dilators should be placed?*

No data address the question of how many osmotic dilators to use before D&E at 20–24 weeks' gestation nor whether specific sizes of dilators should be used. Additionally, no evidence addresses these questions for nulliparous women and teens, both groups at higher risk of complications with D&E [20,21,27,30,45–47]. Some experts recommend placing as many dilators as possible until resistance is met or until they fit snugly [11,34]. Most suggest a larger number of dilators as gestational age advances since the cervix must accommodate larger forceps [44].

One study including second-trimester surgical abortion patients suggested that a given number of laminaria will create greater dilation at later gestations, presumably because of increasing cervical compliance as the pregnancy advances [48]. A retrospective review in 147 women examined the degree of dilatation achieved with overnight Dilapan-S, with or without misoprostol, before abortion between 20 and 24 weeks. The results suggested that two or three dilators

were superior to a single dilator. Women with a single dilator were almost 1.8 times (95% CI 1.4–2.3) as likely to require additional mechanical cervical dilation [49]. No differences were noted in complications between the two groups, but the study was not powered to determine differences in complications [22].

Overall, sufficient data do not exist for guidance about the exact number of dilators that should be used when preparing the cervix for late second-trimester D&E or about the significance of this number in correlation to important clinical outcomes.

5. How long should osmotic dilators be left in situ before D&E at 20–24 weeks' gestation?

No evidence-based recommendations can be made about how long dilators should be left in place. Some experts recommend leaving a single set in place for 18–48 h or replacing them with a second set after 18–24 h [13]. No studies have addressed the theory that increased cervical softening may occur with longer duration of dilator retention.

In a small retrospective review, women treated with two to three Dilapan-S with or without adjuvant misoprostol the day before a 20–24 week D&E had no more complications than women treated with one to two Dilapan-S dilators with or without misoprostol on the same day of the procedure [49]. In this retrospective chart review of 147 abortion cases, there was a nonstatistically significant overall risk reduction of 2.63% (95% CI –7.9% to 13.2%) between cervical preparation achieved with overnight Dilapan-S with or without misoprostol compared to cervical preparation achieved with same-day Dilapan-S with or without misoprostol. The small size, retrospective nature and variation in cervical preparation protocols make it difficult to draw any definitive conclusions from this study. This study is an example of the insufficient literature available to address these clinical issues.

The evidence is insufficient to determine an optimal time for osmotic dilators to be left in situ before D&E at 20–24 weeks.

6. Are multiple days of cervical preparation warranted before procedures at 20 weeks or greater gestation and if so, when?

Expert opinion holds that at least 1 day of cervical preparation is necessary for late second-trimester surgical abortions and several experienced providers have published recommendations [11,13,26,44]. No randomized trials have explored this topic. Based on results from studies in earlier gestations, serial laminaria appear safe [50]. In 172 women at 18–22 weeks' gestation who had two sets of laminaria placed the day before D&E (the second set 6 h after the first), 92% had at least 18 mm of dilation and none experienced cervical injury [51].

Some providers describe that two or three sets of dilators are helpful especially for patients with noncompliant cervixes, such as younger or nulliparous women

[13,21]. Overall, there is no evidence to determine whether multiple days of cervical preparation leads to a reduction in abortion complications.

7. Should misoprostol be used as an alternative or adjunct to osmotic dilators for cervical preparation before D&E at 20–24 weeks' gestation?

Data suggest that misoprostol is best used as an adjunct to osmotic dilators rather than alone as cervical preparation for surgical abortion at 20–24 weeks. In a previously described trial, the addition of misoprostol to Dilapan-S did not significantly increase or decrease the number of procedure-related cervical or uterine complications [49]. Moreover, the additional misoprostol did not decrease the need for further cervical dilation. The study did not evaluate other outcomes such as the need for additional dilation, procedure time or blood loss.

A retrospective study of 2218 elective D&E procedures between 12 and 23 6/7 weeks (19% of which were ≥ 20 weeks' gestation) found that the use of buccal misoprostol with or without laminaria is effective and safe [5]. Additional dilatation was required more frequently when buccal misoprostol was used alone compared with the combination of buccal misoprostol and laminaria (70% vs. 13%, $p < .001$). When the results were stratified by gestational age, additional dilation was needed between 18 and 23 6/7 weeks 28% of the time when buccal misoprostol was used alone and only 12.3% of the time when buccal misoprostol was used with laminaria (RR 0.44, 95% CI 0.27–0.72), representing a 56% reduction in need for additional mechanical dilation. Paradoxically, women who received a 400-mcg dose of buccal misoprostol were 94% less likely to need additional dilation compared to patients who received a 600-mcg dose (RR 0.06, 95% CI 0.03–0.12). Because this trial was not randomized, strict conclusions about the clinical relevance of this finding cannot be made.

In a randomized controlled trial comparing cervical preparation with laminaria alone to cervical preparation with laminaria plus 400 mcg buccal misoprostol between 13 and 20 6/7 weeks, a subanalysis of gestations between 19 0/7 and 20 6/7 weeks ($n=29$) demonstrated that adjunctive misoprostol resulted in a significant improvement in dilation over placebo ($p=.01$) [52].

Overall, limited data suggest that misoprostol as an adjunct to osmotic dilators may result in greater cervical dilation compared to misoprostol alone. The optimal dose and route of adjuvant misoprostol are unknown. Moreover, whether this additional treatment decreases patient risk has not been determined.

8. What are the risks of using osmotic dilators with misoprostol for cervical preparation between 20 and 24 weeks for women with a uterine scar?

A case report of a uterine rupture after overnight laminaria and two doses of 400 mcg misoprostol before a

planned 23-week D&E in a patient with two previous cesarean deliveries [53] suggests possible risk. However, there are little prospective data to demonstrate that women with a uterine scar have an increased risk of uterine complications after using osmotic dilators with adjuvant misoprostol as cervical preparation for D&E. A large retrospective study of D&E procedures using buccal misoprostol alone or in conjunction with laminaria between 12 and 23 6/7 weeks (19% of which were ≥ 20 weeks' gestation) found that women with a history of cesarean delivery were three times as likely to experience some adverse event (OR 3.11, 95% CI 1.14–7.98), none of which was explained by uterine rupture or scar dehiscence [5].

Although few studies have examined the use of misoprostol before a D&E in women with a uterine scar, we can look at second-trimester misoprostol induction abortion literature to extrapolate about relative safety, especially since women undergoing induction abortion are likely to receive a larger total dose of misoprostol than would be used for cervical preparation before D&E. The majority of studies addressing risk of uterine rupture or scar dehiscence in the second trimester before misoprostol induction termination find no associated risk. Bhattacharjee et al. [54] found no uterine rupture or scar dehiscence among 80 patients with prior uterine scars undergoing induction termination with misoprostol between 13 and 26 weeks. Similarly, Daskalakis et al. [55] found no uterine rupture or scar dehiscence among 108 misoprostol induction termination patients between 17 and 24 weeks nor did Dickinson [56] who looked at 720 similar patients between 14 and 28 weeks. These results were also observed by Rouzi [57] in 10 patients undergoing medical induction for fetal demise at a mean gestation of 20 weeks. In addition to case reports of uterine rupture [53,58], one retrospective study of second-trimester induction termination found a significantly higher risk of both blood transfusion (OR 2.3; 95% CI 1.1–5.0) and uterine rupture (OR 20.9; 95% CI 41.1–104) among women who had a prior cesarean [59]. Other studies mention second-trimester uterine rupture and increased induction complications in women with previous uterine scars [22,60].

Overall, no data suggest that using misoprostol in conjunction with osmotic dilators as cervical preparation for surgical abortion at 20–24 weeks in women with a uterine scar markedly increases D&E risks such as cervical laceration or uterine perforation, rupture, or dehiscence. However, more definitive studies of the safety of adjuvant misoprostol are needed.

Conclusions and recommendations

The following recommendation is based on good and consistent scientific evidence (Level A):

1. The safety of D&E procedures at 20–24 weeks' gestation is improved by preoperative cervical preparation.

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

1. Buccal misoprostol 400 mcg is an adequate dose for cervical ripening when used as an adjunct to osmotic dilation before D&E at 20–24 weeks' gestation. Use of adjuvant misoprostol may decrease the need for additional dilation in these procedures. Higher doses of buccal misoprostol do not appear to decrease the need for additional dilation.
2. Using adjuvant misoprostol with osmotic dilators before D&E at 20–24 weeks' gestation is not associated with significant procedure-associated risks and may aid in cervical dilation.

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

1. More osmotic dilators are needed for cervical preparation before D&E as the gestational age advances between 20 and 24 weeks.
2. Decisions about the number of dilators to place should be individualized, taking into consideration factors such as a woman's cervical compliance, parity and gestational duration. Decisions about additional time for dilator retention, serial dilator placement or adjuvant misoprostol also should be individualized.
3. Approximately half the number of Dilapan are necessary to achieve a given amount of cervical dilatation as compared to laminaria.

Important questions to be answered

Additional research is needed to determine the best approach to obtaining adequate cervical dilation before D&E at 20–24 weeks. Little high-quality evidence is available to guide clinical decision making. Better designed studies are needed comparing types of osmotic dilators and the effects of serial dilators. Other studies should address the efficacy and safety of adjuvant treatments such as misoprostol or mifepristone in improving cervical preparation, including women with a prior uterine scar. Although a more dramatic change in D&E clinical practice and patient convenience, with possible resultant increased risk, would result from research into same-day cervical preparation with Dilapan-S and/or misoprostol, current clinical consensus recommends at least 1 day of cervical preparation for D&E procedures at 20–24 weeks.

To further complicate research efforts aimed at guiding decisions about cervical preparation before D&E at 20–24 weeks' gestation, US researchers may be concerned that serial applications of osmotic dilators or adjuvant misoprostol use may be interpreted as intent to perform a “partial birth abortion,” which is a federal crime [61,62]. The federal ban creates an obstacle to research on this topic. Investigators who use preoperative feticidal agents introduce a confounder because feticide itself may have an impact on the safety of

D&E at 20–24 weeks, including the safety and efficacy of cervical preparation.

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Sources

MEDLINE and EMBASE databases were searched from 1966 to 2007, including the following MeSH terms and text words: induced abortion, surgical abortion, termination, second-trimester, midtrimester, evacuation, hygroscopic tents, priming, cervical ripening, cervical dilation, osmotic dilator, meteneprost, dinoprostone, hydrophilic polymer, sulprostone, laminaria, Dilapan, Lamichel, hypan, gemeprost, prostaglandin and misoprostol. English-language abstracts were reviewed for relevance, with articles and contemporary chapters reviewed for any additional references. An automatic e-mail notification update was created on this topic to continue to review any new articles published during the course of preparing the guidelines. Non-English articles were excluded.

Authorship

These guidelines were prepared by Sara Newmann, MD, MPH; Andrea Dalve-Endres, MD; and Eleanor A. Drey, MD, EdM; and were reviewed and approved by the Board of the Society of Family Planning.

Conflict of Interest Statement

Sara Newmann, MD, MPH; Andrea Dalve-Endres, MD; and Eleanor A. Drey, MD, EdM, 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 Society of Family Planning guideline was developed for its members and other clinicians who perform surgical abortion procedures at 20 to 24 weeks or who care for women undergoing these procedures. 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 from 20 to 24 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.