



Review Article

Society of Family Planning clinical recommendations: Cervical preparation for dilation and evacuation at 20–24 weeks' gestation ☆☆☆

Justin T. Diedrich ^{a,*}, Eleanor A. Drey ^b, Sara J. Newmann ^b^a Department of Obstetrics & Gynecology, University of California, Irvine, United States^b Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco, United States

ARTICLE INFO

Article history:

Received 19 June 2019

Received in revised form 2 January 2020

Accepted 4 January 2020

Keywords:

Abortion

Cervical preparation

Second-trimester

Misoprostol

Dilation

Mifepristone

Dilation & evacuation

ABSTRACT

Although only 1.3% of abortions in the United States are between 20 and 24 weeks' gestation, these procedures are associated with elevated risks of morbidity and mortality. Adequate cervical preparation before dilation and evacuation (D&E) at 20–24 weeks' gestation reduces procedural risk. For this gestational range, at least one day of cervical preparation with osmotic dilators is recommended before D&E. The use of overnight osmotic dilators alone is sufficient for most D&Es at 20–24 weeks' gestation. Dilapan-S[®] dilators require a shorter time to achieve maximum dilation, may be more effective than laminaria and may increase the likelihood of success on the first D&E attempt. The use of adjunctive mifepristone administered one-day pre-operatively at the time of osmotic dilator placement, should be considered because evidence demonstrates that it makes D&E subjectively easier at 20–24 weeks without increasing side effects. While older studies suggest that two-days of serial osmotic dilators provide greater dilation than one day of dilators, adjunctive mifepristone may be comparable to a second day of dilators. Adjunctive misoprostol administered on the day of D&E does not appear to affect initial cervical dilation and procedure time and compared with mifepristone is associated with more side effects, such as pain and nausea. Using overnight mifepristone and same-day misoprostol without osmotic dilators at 20–24 weeks' gestation lengthens D&E procedure time and appears to increase immediate complications, at least among less experienced providers. Some evidence shows the feasibility of same-day cervical preparation before D&E at 20–24 weeks using Dilapan-S[®] with adjunctive misoprostol or serial repeat dosing of misoprostol, but same-day preparation should be limited to providers with significant experience with these regimens. The Society of Family Planning recommends preoperative cervical preparation before D&E at 20–24 weeks' gestation. Further studies are needed to clarify the best means of preparing the cervix in order to minimize abortion complications and improve outcomes in this gestational range.

© 2020 Elsevier Inc. All rights reserved.

Contents

1. Introduction	287
2. Background	287
2.1. Osmotic dilators	287
2.2. Pharmacologic and other methods	287
3. Clinical questions	287
4. Conclusions	290
5. Recommendations	290
6. Recommendation for future research	291

* Disclosures: Dr. Diedrich is a contraceptive trainer for Merck and Sebela. Dr. Drey has nothing to disclose. Dr. Newmann has nothing to disclose.

☆☆ Conflict of Interest Statement: Dr. Diedrich is a contraceptive trainer for Merck and Sebela. Dr. Drey and Dr. Newmann have no conflicts of interest to disclose. The Society of Family Planning receives no direct support from pharmaceutical companies or other industries.

* Corresponding author.

E-mail address: info@societyfp.org (J.T. Diedrich).

7. Sources	291
8. Intended audience	291
9. Authorship	291
References	291

1. Introduction

In the last several years, multiple randomized trials have evaluated methods of cervical preparation before dilation and evacuation (D&E) abortion. The results of these trials have led to improvements in cervical preparation. The Society of Family Planning (SFP) is writing this update due to new evidence regarding cervical dilation before D&E at 20–24 weeks, including data on the use of the anti-progesterone mifepristone, use of osmotic dilators with and without misoprostol, and side effects of misoprostol. As a result, we are able to refine our 2008 recommendations [1]. This document synthesizes evidence from studies that used varying methodologies and patient populations. The gestational age of interest for these recommendations is 20–24 weeks, which is the range with the most consistent data reported in previous studies (20–24 weeks, inclusive). However, data from some studies using gestational ages outside the range of interest (12–26 weeks, inclusive) are included in these recommendations.

2. Background

Approximately 1.3% of abortions take place after 20 weeks' gestation in the United States each year [2]. Despite a recent decrease in the number of abortions occurring annually in the United States, the proportion of second-trimester abortions has remained relatively consistent. The vast majority of second-trimester surgical abortions are provided by D&E. Although complications from D&E are rare, the rate of such complications increases with gestational duration [3,4]. In a review of almost 12,000 patients undergoing D&E at gestations of up to 26 weeks, the most common complications included cervical laceration and blood loss of more than 500 mL, each of which occurred in less than 0.9% of patients [5].

D&E is a safe procedure, with rates of morbidity and mortality significantly lower than those associated with childbirth [5–7]. Decades of data and practice demonstrate that to minimize risk, the uterine cervix must be prepared before the procedure [8]. Three main methods are available to dilate or soften the uterine cervix before D&E: mechanical dilation with rigid dilators, preoperative placement of osmotic dilators, and preoperative administration of pharmacologic agents.

Before the advent and study of other methods, mechanical dilation was used without cervical preparation, generally with graduated rigid Pratt, Denniston, Hegar, or other mechanical dilators. Compared with use of osmotic dilators or pharmacologic agents, use of mechanical dilation alone is associated with higher risks of short- and long-term morbidity, especially because D&Es at advanced gestations require greater cervical dilatation [9,10]. In contemporary abortion practice, after 14 weeks' gestation, most providers use mechanical dilation only in conjunction with other methods of cervical preparation.

2.1. Osmotic dilators

Two types of osmotic dilators are available for cervical preparation. The dried, rolled, sterilized seaweed stems of *Laminaria japonica* expand slowly by absorbing fluid. The maximum clinical effect of this method is achieved after 24 h [11,12], with laminaria

expanding to approximately 2.7–2.9 times their dry diameter [12]. Dilapan, a synthetic osmotic dilator, dilates the cervix more quickly, evenly and consistently than laminaria. Although these synthetic dilators initially were prone to fracture [13,14], they were reformulated in 2002 and replaced with Dilapan-S®. Dilapan-S® not only dilates faster than the previous formulation but has a stronger core to reduce fragmentation. Dilapan-S® dilates to almost its maximum diameter (3.3–3.6 times its dry diameter) in 4–6 h, but continues to dilate over the course of 24 h [12].

2.2. Pharmacologic and other methods

Prostaglandins and anti-progesterones are pharmacologic agents frequently used for cervical preparation. The most common prostaglandin used for cervical ripening is misoprostol, a PGE₁ analogue, which is relatively inexpensive and stable at room temperature. The World Health Organization recognizes misoprostol as one of the essential core medications necessary for basic health care [15]. Although it can be used by different routes for other purposes, to prepare the cervix before D&E misoprostol primarily is administered buccally, vaginally, or sublingually. Serum levels are lower for the buccal route, but similar uterine tone is produced with all three routes [16,17].

Mifepristone is an anti-progesterone steroid that binds avidly to progesterone receptors to cause significant cervical ripening [18,19]. Typically given orally 24–48 h before D&E, mifepristone does not have misoprostol's gastrointestinal or pyrexia side effects.

3. Clinical questions

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

Preoperative cervical preparation reduces D&E morbidity. Mechanical dilation alone is associated with more complications than the use of osmotic dilators [9,20]. Cervical laceration with hemorrhage is one of the most commonly cited serious complications of D&E through 24 weeks' gestation [4,20,21]. Evidence from a large retrospective study that looked at complications before and after the introduction of osmotic dilators suggests that cervical preparation with osmotic dilators before D&E decreases the risk of cervical laceration [20]. This series of 11,747 D&Es completed between 1972 and 1981 evaluated the incidence of cervical laceration requiring repair at gestations of more than 19 weeks. Ten percent of all D&Es using mechanical dilation alone resulted in a cervical laceration needing repair. After the use of osmotic dilators was introduced, repaired cervical laceration decreased significantly, to 1.2% ($p < 0.05$). Early data on abortion morbidity show cervical injuries are more common among adolescent patients at any gestation [22]. However, no recent data examine this risk for adolescents undergoing an abortion after 20 weeks of gestation. Several large reviews of abortion complications have not found an association between cervical injury and parity or prior vaginal delivery [7,10,27,29].

Although uterine perforation is a rare complication, cervical preparation with osmotic dilators may decrease this risk as well. In a study describing more than 67,000 surgical abortions in which the incidence of uterine perforation was found to be 0.9 per 1000

abortions, the use of laminaria for dilation had a protective effect, although this effect was not statistically significant (RR 0.17, 95% CI, 0.02–1.20) [22]. Evidence also suggests a higher incidence of cervical injury and perforation when abortions are completed by inexperienced providers; it is unclear whether osmotic dilation modifies this risk [9,22]. No studies have examined whether use of osmotic dilators at 20–24 weeks' gestation affects the incidence of infection or hemorrhage.

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

Onset of labor or extramural delivery are potential rare complications after placement of osmotic dilators, with the exact incidence unknown. However, when a feticidal agent is used in conjunction with osmotic dilators, the reported incidence of expulsion or contractions leading to hospitalization ranges between 0.3% and 1.9%. Intra-amniotic digoxin causes a higher incidence of extramural delivery than intra-fetal injections [23–25].

No trials have directly examined the risk of infection after the placement of osmotic dilators for D&E at 20–24 weeks of gestation. Case reports of infection attributable to osmotic dilator placement alone are rare [14,26,27]. Antibiotic prophylaxis usually is administered at the time of dilator placement, which likely contributes to the low incidence of infection.

Currently, no data link use of osmotic dilators followed by D&E with an increased risk of preterm birth in subsequent pregnancies. A retrospective, case-control study evaluated patients who underwent D&E at 12–24 weeks' gestation and compared them with patients who did not have a prior D&E. Cases included 85 patients with a prior D&E and 170 controls. Patients with a prior D&E delivered slightly earlier (38.9 weeks vs. 39.5 weeks, $p = 0.001$). However, no statistically significant difference was found in terms of birth weight, spontaneous preterm delivery, abnormal placentation, or complications overall [28]. A retrospective review of 600 patients who underwent D&E at 14–24 weeks' gestation (average 19 weeks) after approximately 24 h of cervical preparation with laminaria identified 96 subsequent pregnancies. The researchers did not find an association of D&E with preterm birth [29]. Another retrospective cohort study described the subsequent pregnancies of patients who underwent pregnancy termination at 17–24 weeks for preterm premature rupture of membranes (without signs of labor or cervical dilatation), fetal anomalies, or fetal demise. Patients had a choice of labor induction or D&E. Those who underwent D&E after 1–2 days of osmotic dilation with laminaria had a lower incidence of preterm birth than those who underwent induction (6.9% vs. 30.2%, $p < 0.01$) [31]. The 6.9% rate of preterm birth reported in this study is substantially lower than the overall risk of preterm birth in the United States, which is 12% [30]. The authors concluded that D&E is not associated with subsequent preterm birth.

3. What type of osmotic dilator is preferable for preparation of the cervix before D&E at 20–24 weeks' gestation?

Both laminaria and Dilapan-S[®] are safe and effective osmotic dilators for cervical preparation. Dilapan-S[®] dilates more quickly and to a larger diameter than laminaria, requiring less time and fewer dilators for the same dilation effect and making their use an option for same-day cervical preparation in early second-trimester cases. Ultimately, osmotic dilator choice is based on individual provider preference, with little available information comparing the two. Dayananda and colleagues completed a double-blinded trial that randomized patients ($N = 180$) to overnight laminaria or overnight Dilapan-S[®] [31]. They stratified by gestational duration, with an early cohort at 18–20 6/7 weeks

and a late cohort at 21–23 6/7 weeks. The primary outcome was operative time. Secondary outcomes included number of dilators placed, initial dilation, need for mechanical dilation, ability to complete procedure on first attempt, acceptability, and complications. Although no differences were found in operative time in either the early ($p = 0.60$) or the late ($p = 0.78$) gestational cohorts or in initial dilation and patient satisfaction, 24 D&Es were unable to be completed on the first attempt. Of those, 75% had received laminaria, suggesting a greater degree of efficacy when Dilapan-S[®] is used for cervical preparation instead of laminaria. In addition, Dilapan-S dilates more rapidly, which may be preferable when attempting to shorten the preoperative duration.

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. In addition, no studies address these questions specifically for nulliparous patients or adolescents, both groups at higher risk of D&E complications [9,23,34–37]. Some experts recommend placing as many dilators as possible until resistance is met or until they fit snugly [13]. Most suggest increasing the number of dilators used as gestational duration advances because the cervix must accommodate larger forceps and the fetal parts are larger [32]. Dilapan-S[®] osmotic dilators achieve greater dilation than laminaria, which means fewer may be necessary at a given gestation.

One prospective investigation from 1996 that included gestations through 19 weeks observed the dilation achieved after overnight use of laminaria. The authors found that laminaria expanded more at later gestations than at earlier gestations, which they hypothesize is the result of greater cervical compliance as the pregnancy advances [33]. A review of 147 patients described the degree of dilation achieved with overnight Dilapan-S[®], with or without misoprostol, before D&E at 20–24 weeks' gestation. The results suggested that two or three dilators were superior to a single dilator. Patients with a single dilator were almost 1.8 times (95% CI 1.4–2.3) as likely as those with 2–3 to require additional mechanical cervical dilation [34]. No differences in complication rates were noted between the two groups, but the study did not have adequate power to examine this outcome.

Overall, the available data are not sufficient to provide guidance about the exact number of dilators to use when preparing the cervix for late second-trimester D&E or about the effect of this number on important clinical outcomes. In a 2013 cross-sectional survey of abortion facilities in the United States, White and colleagues assessed second-trimester surgical abortion practices. Of 703 facilities across the country, 383 (54%) responded. In the second trimester, 85% of clinicians used osmotic dilators for cervical preparation. Also, 75% used misoprostol, while only 8% used mifepristone. About 75% combined dilators and misoprostol [35].

5. Are multiple days of cervical preparation warranted before D&Es at 20–24 weeks' gestation, and if so, when?

Previous data from a 1982 RCT [36] showed two days of laminaria produced more dilation than a single day. However, new data suggest alternatives to this practice. Recent studies have shown that overnight cervical preparation can be effective before D&Es at 20–24-weeks' gestation. A randomized controlled trial by Shaw and colleagues among patients between 19 and 23 6/7 weeks' gestation compared overnight laminaria and mifepristone to two days of serial laminaria [37]. All patients also received misoprostol on the day of their procedure. This non-inferiority trial set a 5-min difference in procedure time as being clinically significant. Mean procedure times were similar in the two groups (11 min and 52 s

among mifepristone with overnight dilators vs. 10 min and 56 s among patients receiving two days of dilators without mifepristone). The 95% CI for change in procedure time was $-4:09$ to $+2:16$ min. Patients were much more satisfied with overnight preparation with laminaria and mifepristone than with two days of osmotic dilators. This suggests two-day dilation is not necessary for routine cases. However, some cases may warrant greater dilation (for example, in certain fetal anomalies or for a more intact specimen) and some cervixes may be less responsive, requiring additional time or dilators; therefore, care must be individualized.

In a multicenter, randomized controlled trial by Goldberg and colleagues [38], subjects between 16 and 23 6/7 weeks' gestation were randomized to one of three arms: overnight dilators alone, overnight dilators with mifepristone, and overnight dilators with preoperative misoprostol. Of 300 participants, only two (one in the dilator-with-mifepristone group and one in the dilator-with-misoprostol group) did not have adequate dilation to complete the D&E on day 2. One day of overnight dilators with or without adjuvant pharmacologic therapy is sufficient for most D&Es in this gestational range.

6. Is there evidence to support use of misoprostol or mifepristone as an adjuvant to overnight osmotic dilators for D&E at 20–24 weeks' gestation?

A randomized controlled trial by Drey and colleagues included 196 patients at 21–23 weeks' gestation who were randomized to receive 3–4 h of 400 mcg of buccal misoprostol versus placebo in addition to overnight laminaria [39]. The procedural duration in the laminaria-plus-misoprostol cohort was on average 1.7 min shorter than in the placebo group ($p = 0.02$), with slightly greater initial cervical dilation (75 mm vs. 73 mm, $p = 0.04$). However, the physicians did not find the D&Es to be subjectively easier, and the median procedural durations did not differ. Patients who received misoprostol reported significantly more pre-procedural pain than those receiving placebo (52% vs. 11%, $p < 0.001$).

In the multicenter randomized controlled trial by Goldberg and colleagues, patients between 16 and 23 6/7 weeks' gestation were randomized to one of three arms: overnight dilators alone, overnight dilators with 200 mg mifepristone, and overnight dilators with 400 mcg misoprostol given approximately 3 h preoperatively [38]. This trial included an early cohort (152 participants at 16–18 6/7 weeks) and a late cohort (148 participants at 19–23 6/7 weeks), all of whom initially received a mix of Dilapan-S[®] and 4 mm laminaria based on provider preference. The primary outcome of operative time—defined as placement of the first instrument in the uterus to removal of the last instrument—did not differ among the three arms in either gestational cohort. By contrast, a shorter total procedure time (speculum in to speculum out) was noted with adjuvant mifepristone in the later cohort, which was largely due to less time managing postoperative bleeding and complications. In addition, the D&Es in the mifepristone arm were subjectively easier, had a trend toward fewer complications (compared with the dilators-alone arm), and resulted in fewer side effects than in the misoprostol arm. However, the study was not powered to evaluate complications. Although complications did not differ significantly across groups, the frequency of complications with dilators alone (10%, 95% CI 4.2–16.0) was higher than with adjuvant misoprostol (2%, 95% CI 0–4.7) or adjuvant mifepristone (2%, 95% CI 0–4.8). Patients who received misoprostol had significantly more pain, fever, and chills.

In a recently published systematic review and meta-analysis, Cahill and colleagues evaluated the effect of adjuvant misoprostol with overnight dilators for D&E after 16 weeks [40]. Only three studies met inclusion criteria, including the two studies described above [38,39]. (The third study only included patients at 16–20 weeks of

gestation.) The Cahill review shows that based on current evidence adjunctive misoprostol with osmotic dilators after 16 weeks does not significantly shorten procedure time or decrease need for mechanical dilation, but further research is needed to determine the effect of misoprostol on complications and blood loss.

No studies have shown increased bleeding, atony, or complications with adjunctive mifepristone for D&E after 20 weeks' gestation when used with osmotic dilators [37,38]. However, these studies did not have adequate power to find differences in complications or blood loss.

No data are available to define the most effective interval between mifepristone and the D&E procedure at 20–24 weeks' gestation. However, Casey and colleagues' randomized controlled trial among patients undergoing same-day termination between 14 and 19 6/7 weeks' gestation suggested that 4–6 h was insufficient for mifepristone to improve cervical ripening [41]. Their participants had cervical ripening with misoprostol and either mifepristone or placebo administered 4–6 h before D&E, with no significant difference in procedure times or initial cervical dilation with the addition of mifepristone.

As noted in the study by Goldberg and colleagues, approximately 18–24 h of preparation with mifepristone 200 mg and osmotic dilators the day before D&E was sufficient to make procedures significantly easier and faster, when measuring total procedure time from speculum placement to removal of all instruments from the vagina [38]. This trial suggests that 18–24 h is sufficient to achieve adjuvant mifepristone's cervical ripening effects in patients at gestational ages of up to 23 6/7 weeks. At the time of publication, the authors are not aware of data describing longer intervals of mifepristone use at this gestation.

In summary, adjuvant mifepristone for D&E at 20–24 weeks' gestation has been shown to decrease procedure time and improve providers' sense of ease of procedure without increasing side effects. Based on individual study data, adjuvant misoprostol may increase initial dilation and shorten procedure time slightly; however, a recent meta-analysis [40] shows no benefit to using adjuvant misoprostol in terms of bleeding or procedure time and that it is associated with increased patient side effects.

7. Does prior hysterotomy increase risks of cervical preparation before D&E at 20–24 weeks' gestation?

Prior cesarean delivery has been described as an independent risk factor for adverse events during D&E in general [42]. A case report of 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 suggests a possible elevation in risk [43]. However, little prospective data demonstrate that patients 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&Es using buccal misoprostol alone or in conjunction with laminaria between 12 and 23 6/7 weeks' gestation ($N = 2218$, 19% of which were at ≥ 20 weeks) found that patients with a history of cesarean birth were three times as likely as those without such a history to experience an adverse event (OR 3.11, 95% CI 1.14–7.98), of which none were uterine rupture or scar dehiscence. The study did not identify which specific adverse events occurred among those with or without a history of prior cesarean. The adverse events included cervical laceration; spontaneous rupture of membranes pre-procedure; spontaneous delivery of placenta or fetus before D&E; hemorrhage; fever, fainting, nausea or vomiting; incomplete dilation, suspected perforation; incomplete abortion; and sepsis [44]. In the labor induction literature, providers often use misoprostol by itself or in conjunction with mifepristone (without osmotic dilators) without an elevated risk of cesarean

scar dehiscence or rupture at 20–24 weeks' gestation among patients with one prior cesarean [45]. Patients with a uterine scar undergoing D&E at 20–24 weeks' gestation are at elevated risk of adverse events, but no data exist to attribute the elevated risk to cervical preparation.

8. *Does evidence support the use of same-day cervical preparation at 20–24 weeks' gestation?*

Some evidence supports the use of same-day misoprostol as cervical preparation at 20 weeks' gestation and possibly later. A case series of patients undergoing same-day cervical preparation before D&E included 229 patients at 20 weeks' gestation and an additional 17 patients at 21–23 weeks' gestation [46]. None of the patients had had a prior cesarean. All patients received a loading dose of 200–600 mcg misoprostol, with dose and route (vaginal vs. buccal) dependent on the provider. Additional doses of misoprostol were given every 2 h after examination. Patients received an average of 3 doses of misoprostol (range 1–5). The median time from administration of buccal misoprostol until D&E completion was approximately 5 h. One cervical laceration occurred at 20 weeks, with no complications in the subset of patients at 21–23 weeks' gestation. However, given the study design and small numbers, we cannot draw conclusions about operative time, procedure difficulty, complications, or patient satisfaction, especially at gestations of more than 20 weeks.

In a review of D&Es done by the British Pregnancy Advisory Service, Lyus and colleagues [47] describe D&Es completed at 18–21 6/7 weeks' gestation using 400 mcg vaginal misoprostol and 1–3 synthetic dilators for an average of 3 h and 40 min before the D&E. The cohort included 274 patients at an average of 20 weeks' gestation, none of whom required mechanical dilation. The four experienced providers who completed all the procedures had only two immediate complications: a cervical laceration requiring suture and a fetal expulsion before D&E.

In 2007, a retrospective study published by Poon and colleagues [34] described cervical preparation practices of abortion providers at King's College Hospital in the UK. Their initial same-day protocol for cervical preparation through 23 6/7 weeks' gestation utilized one or two Dilapan and up to 800 mcg vaginal misoprostol, with the D&E procedure completed 4–7 h later. Of the 34 patients who received this protocol, six patients (18%) required no further dilation and the remaining 28 required mechanical dilation. Three patients had cervical damage requiring repair, and two patients had heavy bleeding requiring an overnight stay.

Some evidence shows the feasibility of same-day cervical preparation before D&E at 20–24 weeks' gestation, but only experienced providers should offer these procedures. Further studies should evaluate safety, procedure time, complications, patient acceptability, and ideally, any long-term sequelae of same-day D&Es at gestations of more than 20 weeks.

9. *Does evidence support use of mifepristone alone or mifepristone with misoprostol at 20–24 weeks' gestation without osmotic dilators?*

Shaw's randomized controlled trial of 75 patients receiving a D&E between 19 and 23 6/7 weeks' gestation randomized participants into three groups: overnight 200 mg mifepristone without dilators and 400 mcg buccal misoprostol on the day of surgery; overnight dilators with overnight mifepristone and misoprostol on the day of surgery; and overnight dilators with overnight placebo and misoprostol on the day of surgery [48]. Procedure time was significantly longer ($p < 0.01$) in the mifepristone-misoprostol group without dilators (18.5 min) than in the group with dilators, mifepristone, and misoprostol (12 min) and the group

with dilators, misoprostol, and placebo (13 min). They observed a nonstatistically significant difference in complications ($p = 0.20$) between the mifepristone-misoprostol group without dilators (2 perforations and 5 cervical lacerations) and the group with dilators, mifepristone and misoprostol (1 perforation); and the group with dilators, misoprostol, and placebo (1 cervical laceration). Of note, almost all complications (6 of 7) occurred during D&Es provided by gynecologists undergoing additional Family Planning training, while one perforation occurred during a procedure done by an attending surgeon. Based on this study, while overnight mifepristone plus same-day misoprostol without dilators may be feasible, the high frequency of observed complications is concerning. However, the study was not powered to assess complications.

Eliminating dilator use before procedures in the late second trimester is feasible and may decrease discomfort and dilator-related preoperative time for patients. However, procedure time is lengthened, complications may be more frequent and provider experience may affect risk. We have no information about potential impact on subsequent pregnancy outcomes.

4. Conclusions

Significant new research can help guide our cervical preparation choices. As of 2013, the majority of U.S. abortion providers used a combination of misoprostol and osmotic dilation before late second-trimester D&E, and numbers of dilators used and duration of use varies. Dilapan-S[®] requires a shorter time to achieve maximum dilation and may be more effective than laminaria for cervical preparation before late second-trimester D&E. One day of overnight dilators with or without adjuvant pharmacologic therapy is sufficient for most D&Es at 20–24 weeks' gestation. Current evidence supports the use of mifepristone as an adjuvant to osmotic dilators for D&E at 20–24 weeks' gestation. By contrast, procedure time appears to lengthen and complications increase when mifepristone and misoprostol are used without osmotic dilators at 20–24 weeks' gestation. Adjuvant mifepristone has been shown to decrease procedure time and improve providers sense of ease of procedure without increasing side effects for D&E at 20–24 weeks' gestation. Addition of misoprostol does not suggest benefit and causes more cramping and pain. Patients with a uterine scar undergoing D&E at 20–24 weeks' gestation are at elevated risk of adverse events, but no data exist to attribute the increased risk to cervical preparation. While there is evidence that same-day cervical preparation before D&E at 20–24 weeks' gestation may be feasible, this practice should be limited to providers with significant experience with these regimens. Use of mifepristone and misoprostol alone without dilator use before procedures in the second trimester is possible, but procedure time is lengthened and complications may be more frequent.

5. Recommendations

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

- Cervical preparation always should be used before D&E at 20–24 weeks' gestation to reduce D&E risks, including cervical laceration and hemorrhage.

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

- One day of overnight osmotic dilators, with or without adjuvant pharmacologic therapy, is sufficient to be able to complete most D&Es at 20–24 weeks' gestation.

- Dilapan-S® requires a shorter time to achieve maximum dilation and may be more effective than laminaria for cervical preparation before second-trimester D&E.
- Adjuvant mifepristone should be considered, because it makes D&Es subjectively easier at 20–24 weeks' gestation without adding side effects.
- Using mifepristone and misoprostol without osmotic dilators at 20–24 weeks' gestation lengthens D&E procedure time and appears to increase immediate complications. Pharmacologic-only regimens without adjuvant osmotic dilators should not be implemented widely without further research supporting their use.
- Use of misoprostol for cervical preparation before D&E at 20–24 weeks' gestation does not increase the risk of uterine scar dehiscence.
- Adjuvant misoprostol for patients who received uncomplicated dilator insertions the day before D&E does not appear to significantly decrease procedure time or decrease need for initial dilation, and it increases side effects, such as pain, cramping, and nausea.
- Current retrospective data do not show an association between history of osmotic dilation before D&E and subsequent preterm birth.

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

- Consider using more osmotic dilators as gestational duration advances.
- Some evidence shows the feasibility of same-day cervical preparation before D&E at 20–24 weeks' gestation with synthetic dilators plus adjunctive misoprostol or serial doses of misoprostol, but this should be limited to providers with significant experience with these regimens.

6. Recommendation for future research

Additional research is needed to address concerns about the association between abortion and subsequent preterm birth, especially to assess the effects of various cervical preparation regimens. Research on mifepristone has added significantly to the ability to provide safe, efficient cervical preparation before D&E. The use of mifepristone without osmotic dilators should be studied to offer more options to patients and decrease the need for a separate procedure to place osmotic dilators. Larger studies of risk and complications among subgroups associated with higher risk cervixes, such as nulliparas or younger patients, could be helpful in optimizing cervical preparation for these patients. While current data favor adjunctive mifepristone over misoprostol for cervical preparation, future research should evaluate whether misoprostol may be of benefit by increasing uterine tone and decreased bleeding.

7. Sources

MEDLINE and EMBASE databases were searched from 1966 to 2018. 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. We excluded non-English articles.

8. Intended audience

This Society of Family Planning Clinical Recommendation was developed for its members and other clinicians who provide

D&Es at 20–24 weeks' gestation or who care for patients undergoing these procedures. This recommendation 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 D&Es at 20–24 weeks' gestation. This evidence-based review should guide clinicians in preparing the cervix before D&E, although it is not intended to dictate clinical care.

9. Authorship

These guidelines were prepared by Justin T. Diedrich, MD, MSCI; Eleanor A. Drey, MD, EdM; and Sara J. Newmann, MD, MPH; and were reviewed and approved by the Board of the Society of Family Planning.

References

- [1] Newmann S, Dalve-Endres A, Drey EA. Clinical guidelines. Cervical preparation for surgical abortion from 20 to 24 weeks' gestation. *Contraception* 2008;77:308–14.
- [2] Jatlaoui TC, Boutot ME, Mandel MG, Whiteman MK, Ti A, Petersen E, et al. Abortion Surveillance – United States, 2015. *MMWR Surveill Summ* 2018;67:1–45.
- [3] Grossman D, Blanchard K, Blumenthal P. Complications after second trimester surgical and medical abortion. *Reprod Heal Matters* 2008;16:173–82.
- [4] Autry AM, Hayes EC, Jacobson GF, Kirby RS. A comparison of medical induction and dilation and evacuation for second-trimester abortion. *Am J Obstet Gynecol* 2002;187:393–7.
- [5] Zane S, Creanga AA, Berg CJ, Pazol K, Suchdev DB, Jamieson DJ, et al. Abortion-related mortality in the United States: 1998–2010. *Obstet Gynecol* 2015;126:258–65.
- [6] Creanga AA, Berg CJ, Syverson C, Seed K, Bruce FC, Callaghan WM. Pregnancy-related mortality in the United States, 2006–2010. *Obstet Gynecol* 2015;125:5–12.
- [7] Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. *Obstet Gynecol* 2012;119:215–9.
- [8] Newmann S, Dalve-Endres A, Diedrich J, Drey E, Meckstroth K, Steinauer JE. Cervical preparation for second trimester surgical abortion. *Cochrane Database Syst Rev* 2008. <https://doi.org/10.1002/14651858.CD007310>.
- [9] Schulz KF, Grimes DA, Cates W. Measures to prevent cervical injury during suction curettage abortion. *Lancet (London, England)* 1983;1:1182–5.
- [10] Grimes DA, Schulz KF. Morbidity and mortality from second-trimester abortions. *J Reprod Med* 1985;30:505–14.
- [11] Eaton CJ, Cohn F, Bollinger CC. Laminaria tent as a cervical dilator prior to aspiration-type therapeutic abortion. *Obstet Gynecol* 1972;39:535–7.
- [12] Druneč T, Reidingerová M, Plisová M, Dudič M, Gdovinová D, Stoy V. Experimental comparison of properties of natural and synthetic osmotic dilators. *Arch Gynecol Obstet* 2015;292:349–54.
- [13] Hern WM. Laminaria versus Dilapan osmotic cervical dilators for outpatient dilation and evacuation abortion: Randomized cohort comparison of 1001 patients. *Am J Obstet Gynecol* 1994;171:1324–8.
- [14] Lichtenberg ES. Complications of osmotic dilators. *Obstet Gynecol Surv* 2004;59:528–36.
- [15] World Health Organization. WHO model list of essential medicines – 19th list (April 2015). 2015. doi:10.1016/S1473-3099(14)70780-7.
- [16] Goldberg AB, Greenberg MB, Darney PD. Misoprostol and pregnancy. *N Engl J Med* 2001;344:38–47.
- [17] Meckstroth KR, Whitaker AK, Bertisch S, Goldberg AB, Darney PD. Misoprostol administered by epithelial routes: drug absorption and uterine response. *Obstet Gynecol* 2006;108:582–90.
- [18] Cadepond F, Ulmann A, Baulieu EE. RU486 (mifepristone): mechanisms of action and clinical uses. *Annu Rev Med* 1997;48:129–56.
- [19] Baulieu EE. RU 486 (mifepristone). A short overview of its mechanisms of action and clinical uses at the end of 1996. *Ann N Y Acad Sci* 1997;828:47–58.
- [20] Peterson WF, Berry FN, Grace MR, Gulbranson CL. Second-trimester abortion by dilatation and evacuation: an analysis of 11,747 cases. *Obstet Gynecol* 1983;62:185–90.
- [21] Hern WM. Serial multiple laminaria and adjunctive urea in late outpatient dilatation and evacuation abortion. *Obstet Gynecol* 1984;63:543–9.
- [22] Grimes DA, Schulz KF, Cates WJ. Prevention of uterine perforation during curettage abortion. *JAMA J Am Med Assoc* 1984;251:2108–11.
- [23] Molaei M, Jones HE, Weiselberg T, McManama M, Bassell J, Westhoff CL. Effectiveness and safety of digoxin to induce fetal demise prior to second-trimester abortion. *Contraception* 2008;77:223–5.
- [24] Steward R, Melamed A, Kim R, Nucatola D, Gatter M. Infection and extramural delivery with use of digoxin as a fetocidal agent. *Contraception* 2012;85:150–4.
- [25] Dean G, Colarossi L, Lunde B, Jacobs AR, Porsch LM, Paul ME. Safety of digoxin for fetal demise before second-trimester abortion by dilation

- and evacuation. *Contraception* 2012;85:144–9. <https://doi.org/10.1016/j.contraception.2011.05.016>.
- [26] Gusdon JP, May WJ. Complications caused by difficult removal of laminaria tents. *Am J Obstet Gynecol* 1975;121:286–7.
- [27] Sutkin G, Capelle SD, Schlievert PM, Creinin MD. Toxic shock syndrome after laminaria insertion. *Obstet Gynecol* 2001;98:959–61.
- [28] Jackson JE, Grobman WA, Haney E, Casele H. Mid-trimester dilation and evacuation with laminaria does not increase the risk for severe subsequent pregnancy complications. *Int J Gynecol Obstet* 2007;96:12–5.
- [29] Kalish RB, Chasen ST, Rosenzweig LB, Rashbaum WK, Chervenak FA. Impact of midtrimester dilation and evacuation on subsequent pregnancy outcome. *Am J Obstet Gynecol* 2002;187:882–5.
- [30] March of Dimes, PMNCH, Save the Children, WHO. Born too soon. In *The Global Action Report on Preterm Birth*. CP Howson, MV Kinney, JE Lawn Eds World Heal Organ Publ Geneva 2012. doi:http://whqlibdoc.who.int/publications/2012/9789241503433_eng.pdf.
- [31] Dayananda I, Colarossi L, Porsch L, Balakumar K, Dean G. Laminaria compared with Dilapan-S™ for cervical preparation before dilation and evacuation at 18–24 weeks of gestation: a randomized controlled trial. *Contraception* 2016;94:388.
- [32] Hammond C, Chasen S. Dilation and evacuation. In: Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield PG, Creinin MD, editors. *Management of Normal and Abnormal Pregnancy: Comprehensive Abortion Care*. Blackwell Publishing; 2009. p. 157–77.
- [33] Munsick RA, Fineberg NS. Cervical dilation from multiple laminaria tents used for abortion. *Obstet Gynecol* 1996;87:726–9.
- [34] Poon LCY, Parsons J. Audit of the effectiveness of cervical preparation with Dilapan prior to late second-trimester (20–24 weeks) surgical termination of pregnancy. *BJOG Int J Obstet Gynaecol* 2007;114:485–8.
- [35] White KO, Jones HE, Shorter J, Norman WV, Guilbert E, Lichtenberg ES, et al. Second-trimester surgical abortion practices in the United States. *Contraception* 2018;98:95–9.
- [36] Stubblefield PG, Altman AM, Goldstein SP. Randomized trial of one versus two days of laminaria treatment prior to late midtrimester abortion by uterine evacuation: a pilot study. *Am J Obstet Gynecol* 1982;143:481–2.
- [37] Shaw KA, Shaw JG, Hugin M, Velasquez G, Hopkins FW, Blumenthal PD. Adjunct mifepristone for cervical preparation prior to dilation and evacuation: a randomized trial. *Contraception* 2015;91:313–9.
- [38] Goldberg AB, Fortin JA, Drey EA, Dean G, Lichtenberg ES, Bednarek PH, et al. Cervical preparation before dilation and evacuation using adjunctive misoprostol or mifepristone compared with overnight osmotic dilators alone: a randomized controlled trial. *Obs Gynecol* 2015;126:599–609.
- [39] Drey EA, Benson LS, Sokoloff A, Steinauer JE, Roy G, Jackson RA. Buccal misoprostol plus laminaria for cervical preparation before dilation and evacuation at 21–23 weeks of gestation: A randomized controlled trial. *Contraception* 2014;89:307–13.
- [40] Cahill E, Henkel A, Shaw J, Shaw K. Misoprostol as an Adjunct to Overnight Osmotic Dilators Prior to Second Trimester Dilation and Evacuation: A Systematic Review and Meta-Analysis. *Contraception* 2020;101:74–78. Doi: <https://doi.org/10.1016/j.contraception.2019.09.005>.
- [41] Casey FE, Ye PP, Perritt JD, Moreno-Ruiz NL, Reeves MF. A randomized controlled trial evaluating same-day mifepristone and misoprostol compared to misoprostol alone for cervical preparation prior to second-trimester surgical abortion. *Contraception* 2016;94:127–33.
- [42] Frick AC, Drey EA, Diedrich JT, Steinauer JE. Effect of prior cesarean delivery on risk of second-trimester surgical abortion complications. *Obstet Gynecol* 2010;115:760–4.
- [43] Berghahn L, Christensen D, Droste S. Uterine rupture during second-trimester abortion associated with misoprostol. *Obstet Gynecol* 2001;98:976–7.
- [44] Patel A, Talmont E, Morfesis J, Pelta M, Gatter M, Momtaz MR, et al. Adequacy and safety of buccal misoprostol for cervical preparation prior to termination of second-trimester pregnancy. *Contraception* 2006;73:420–30.
- [45] Borgatta L, Kapp N. Clinical guidelines. Labor induction abortion in the second trimester. *Contraception* 2011;84:4–18.
- [46] Maurer KA, Jacobson JC, Turok DK. Same-day cervical preparation with misoprostol prior to second trimester D & E: a case series. *Contraception* 2013;88:116–21.
- [47] Lyus R, Lohr PA, Taylor J, Morroni C. Outcomes with same-day cervical preparation with Dilapan-S osmotic dilators and vaginal misoprostol before dilation and evacuation at 18 to 21+6 weeks' gestation. *Contraception* 2013;87:71–5.
- [48] Shaw KA, Lerma K, Shaw JG, Scrivner KJ, Hugin M, Hopkins FW, et al. Pre-operative effects of mifepristone (POEM) for dilation and evacuation after 19 weeks gestation: a randomised controlled trial. *BJOG* 2017.