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Clinical Guidelines

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

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Abstract

Roughly 11% of induced abortions in the United States are performed after 14 weeks of gestation, most commonly by dilation and evacuation (D&E). For a 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, prostaglandin analogues, or both. Osmotic dilators currently available in the United States include Dilapan-STM, Lamicel[®], and laminaria. Laminaria tents are made from dehydrated seaweed and require 12–24 h to achieve greatest dilation. The synthetic products, Dilapan-STM and Lamicel[®], achieve maximum effect within 6 h. Dilapan-STM achieves greater dilation than the others and, thus, requires fewer dilators to be placed but may be more difficult to remove. For same day procedures, Dilapan-STM and Lamicel® are preferable to laminaria. A single set of one to several dilators is usually adequate for D&E before 20 weeks of gestation. Additional sets over 1-2 days may be needed in challenging cases. Misoprostol, a prostaglandin analogue, is sometimes used instead of osmotic dilators; however, the data to support such use are limited. Misoprostol is inferior to overnight dilation with laminaria for cervical priming prior to D&E. Misoprostol use as an adjunct to overnight osmotic dilation is only marginally beneficial for priming beyond 16 weeks and does not truly demonstrate any benefit before 19 weeks of gestation. Limited data demonstrate the safety of misoprostol prior to D&E in patients with a uterine scar. The Society of Family Planning recommends preoperative cervical preparation to decrease the risk of complications when performing a D&E prior to 20 weeks of gestation. The three currently available osmotic dilators (laminaria, Lamicel[®], and Dilapan-STM) are safe and effective for this use. Since no single protocol has been found to be superior, clinical judgment is warranted when selecting a method of preoperative cervical preparation. © 2007 Elsevier Inc. All rights reserved.

Keywords: Dilation and Evacuation; Cervical dilation; Dilator; Laminaria; Dilapan; Lamicel; Misoprostol

Background

Approximately 1.29 million legal abortions are performed in the United States each year, most of which occur early in the first trimester [1]. Roughly 11% of pregnancies terminated in the United States end in the second trimester, with only 1.4% at 21 weeks and beyond [2]. Pregnancies may be terminated in the second trimester by labor induction, dilation and evacuation (D&E), hysterotomy, and hysterectomy. Because D&E is safe, cost-effective and efficient, it is the most common means of second trimester elective abortion. In 2003, more than 98% of all second-trimester abortions in the United States were performed by D&E [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, though wider dilation is often required to remove products of conception at advanced gestations [3]. The cervical dilation needed for D&E increases with gestation. Both the minimal and the ideal degree of dilation required for D&E at each gestation age has not been determined.

Though the cervix may be manually dilated at the time of D&E, the degree of dilation needed for later procedures may require additional force, increasing risk of cervical trauma and other complications. Reported complications of D&E include cervical laceration, uterine perforation, retained products of conception, infection and hemorrhage. During midtrimester D&E, perforation of the uterus occurs in 0.2–0.3% and cervical laceration occurs in 0–1% [4–7]. The risk of uterine and cervical trauma can be minimized with preoperative preparation of the cervix to achieve baseline dilation and softening [7–9]. The cervix may be prepared with osmotic or hygroscopic cervical dilators (e.g., laminaria tents), and/or prostaglandin analogues (e.g., misoprostol).

Osmotic dilators are tents placed into the cervical canal that slowly expand to dilate and soften the cervix. Three types of osmotic dilators are currently available in the United States: laminaria, Lamicel[®], and Dilapan-STM. Additionally, prostaglandin analogues, most commonly misoprostol, may be used as cervical priming agents prior to induced abortion.

Osmotic dilators: laminaria, Lamicel[®], DilapanTM, and Dilapan-STM

Laminaria

The stems of the seaweed *Laminaria japonica* and *L. digitata* may be dehydrated and made into cervical tents. Currently available laminaria tents are manufactured by several suppliers. Tent size ranges from 2 to 10 mm in diameter and 60–85 mm in length (MedGyn: Lombard, IL, USA, and Norscan: Westlake Village, CA, USA). When placed, they absorb fluid within the cervix and slowly swell 3–4 times their dehydrated diameter. For example, a 3-mm laminaria tent achieves approximately 1 cm dilation in situ overnight [10,11]. Most of this dilation occurs in the first 6 h, though the maximum effect is not achieved for 12–24 h [12–14]. This slow dilation exerts radial pressure on the cervical canal, which, in addition to physical dilation, may induce prostaglandin synthesis and cervical ripening, thus making subsequent manual dilation easier [13,15–18].

Since laminaria tents are made from natural resources, drawbacks include lack of uniformity in the product and theoretical risk of infection. The dilation achieved by a specific size tent is unpredictable. Historically, there were concerns that laminaria tents may harbor infectious organisms, and the package labeling cautions that residual bacterial spores could persist even after sterilization [19]. There are no modern reports of single-use laminaria tents transmitting infection, and numerous studies demonstrate that infectious morbidity is not increased by their use [13,20–23]. No studies have been performed that address whether antibiotic administration at the time of laminaria insertion is beneficial. The greatest limitation of laminaria use for cervical preparation is the time it takes to achieve dilation. Overnight placement is often needed, resulting in a 2-day abortion procedure. Fasteracting synthetic dilators, including Lamicel and Dilapan and Dilapan, were developed to address these concerns.

Lamicel®

The use of Lamicel[®], a synthetic osmotic dilator, was first reported in 1982 [24,25]. Lamicel[®] is a dehydrated polyvinyl alcohol sponge embedded with 450 mg of magnesium sulfate. Lamicel[®] works faster than laminaria with cervical ripening effects occurring within 2 h and maximizing at 6 h [26]. Lamicel[®] tents are 67 mm long and 3 or 5 mm in diameter [25]. Lamicel[®] swells 3–4 times its dehydrated diameter. Even when maximally dilated, however, the sponge is compressible and does not exert radial force within the cervix [16]. Lamicel[®] may work by inciting prostaglandin synthesis [27] or by stimulating collagenolytic activity within

the cervical stroma [28], but the exact mechanism of action is unclear. Serum magnesium levels are not increased with Lamicel® in place [29]. The necessity of magnesium within the sponge is questioned by one study that showed that identical tents of polyvinyl alcohol without added magnesium produced a similar degree of cervical priming [30].

Because Lamicel does not exert radial force, it may not achieve as much dilation as other cervical tents. One 5 mm Lamicel placed 6 h prior to midtrimester abortion only dilates the cervix approximately 8 mm [31]; however, the ripening effect makes subsequent dilation easier to achieve [26,32–34]. Lamicel is effective as a cervical preparation agent when placed a few hours prior to surgical evacuation of gestations up to 16 weeks [32,33]. When used overnight, Lamicel is effective up to 17 weeks of gestation [24]. Lamicel is not commonly used as the sole means of cervical preparation in the late second trimester due to concerns that the compressible sponges will result in inadequate dilation [3].

DilapanTM and Dilapan-STM

DilapanTM is a synthetic osmotic dilator made of a polyacrylate-based proprietary hydrogel (Aquacryl) [35]. Dilapan™ use for abortion was first reported in 1982 [36]. It was removed from the United States market from 1995 to 2002 and reintroduced after reformulation as Dilapan-STM. Dehydrated Dilapan-STM is available in diameters of 3 and 4 mm and lengths of 55 and 65 mm. It rapidly swells 3-4 times in diameter in situ. A significant effect is noted within 2 h with one 4-mm dilator producing 7.8-10 mm of cervical dilation. Most dilation is achieved within 4-6 h; however, the device continues to expand up to 24 h in situ. One 4-mm Dilapan-STM expands to 12.7–14.6 mm when left in place for 24 h [35]. Of all the available cervical osmotic dilators, Dilapan-STM achieves the greatest cervical dilation in the shortest timeframe. Unlike the other available dilators, it shortens by 18% as it swells; thus, the longer tent is recommended for most patients to insure that the internal cervical os is adequately dilated [35].

The greatest disadvantage of the older formulation of DilapanTM was its propensity to break during removal, increasing the risk of retained fragments. Dilator entrapment and fragmentation occurred in 4–12% of reported procedures using the older device [33,37,38]. In contrast, fragmentation is a rare complication of laminaria and has not been reported for Lamicel[®] [23,39]. The newer device, Dilapan-STM, was designed with a stronger core to decrease this problem. Although no published studies have addressed fragmentation and other complication rates in the reformulated product, there are anecdotal reports of fracture with Dilapan-STM [35].

Clinical questions and recommendations

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

In a review of over 15,000 first-trimester abortions performed by multiple clinicians, Shulz et al. [40] showed

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