Other Mechanical Methods for Pre-Induction Cervical Ripening.

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Other mechanical methods for pre-induction cervical ripening

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ABSTRACT

Pre-induction cervical ripening is an important part of the labor induction process in women with an unfavorable cervix. This can be achieved either by pharmacologic or mechanical methods of cervical ripening. While the Foley catheter is the most commonly used mechanical method for labor induction, other mechanical methods are also available. This article reviews the safety profiles of osmotic dilators, extra-amniotic saline infusion, double-balloon catheters, and also compares their efficacy to that of other mechanical and pharmacologic cervical ripening methods. While mechanical methods have been shown to be safe and effective for cervical ripening, none of these alternatives has been shown to be superior to the Foley catheter.

Introduction

Labor induction is one of the most common obstetric procedures, occurring in 23.3% of pregnancies in 2012.[1] This is often performed by the administration of oxytocin or prostaglandins, or by other techniques including amniotomy or membrane stripping.[2] In women with an unfavorable cervix, often defined as a Bishop score less than 6, this process requires the additional step of cervical ripening. Methods of cervical ripening can be broadly categorized into pharmacologic and mechanical methods. Current mechanical methods include the Foley balloon catheter, osmotic dilators, extra-amniotic saline infusion, and double-balloon catheters. Pharmacologic methods are discussed in another chapter.

Historical mechanical dilators

Mechanical forces to dilate the cervix have been used since primitive times, most often to aid in the removal of uterine contents during pregnancy termination.[3,4] Rigid cervical dilators were primarily used, with numerous variations of the surgical instrument.[4] In the late 1800s, mechanical techniques were developed, these included bougies, the Braun's colpeurynter, and the Champetier de Ribes' metreurynter; the latter two using rubber balloons inserted into the lower uterine segment and attached to an external weight.[3] Over time, this process was extrapolated for cervical ripening prior to labor, with today's version being the Foley catheter.[3]

In 1863, Sloan described the use of seaweed, specifically the dried stem of *Laminaria digitata*, as a tent that expanded in length and diameter with the absorption of water.[3,4] Early uses of seaweed included the treatment of dysmenorrhea, primary infertility, and pyometria and prior to uterine exploration.[4] Over time, however, the natural seaweed tents became associated with a high rate of sepsis due to poor packaging, pollution of the areas where the seaweed was harvested, porous nature making it difficult to sterilize, and blockage of tissue secretions.[4] Subsequently, synthetic tents

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were designed to imitate the properties of Laminaria but without the risk of infections. Modern-day sterilization techniques have eliminated the infectious morbidity of Laminaria.

This review addresses the mechanical methods of cervical ripening other than the Foley catheter, including natural (*Laminaria*) and synthetic (Lamicel and Dilapan) osmotic dilators, extra-amniotic saline infusion (EASI), and the double-balloon catheter. The Foley catheter for cervical ripening has been addressed in another chapter of this issue.

Mechanical cervical ripening—mechanisms of action

Cervical ripening occurs throughout gestation, with progressive softening of the cervix secondary to remodeling of the extracellular matrix.[5,6] Closer to term, there is a breakdown of the cervical collagen that results in effacement of the cervix. This allows the cervix to dilate in response to uterine contractions.[6,7] This process is likely regulated by both endocrine factors (estrogen, progesterone, relaxin, androgens, and prostaglandins) and inflammatory responses.[5–12]

Mechanical methods lead to cervical ripening both by direct mechanical dilation of the cervix and stimulation of prostaglandin release from the amnion, chorion, and decidua.[6,7] Myometrial stretching has been shown to increase the production of COX-2, which is a prostaglandin precursor.[13,14] Another potential mechanism is the production of an inflammatory reaction at the level of the cervix that leads to cervical remodeling by release of inflammatory cytokines (such as IL-1 and IL-8) and matrix metalloproteases.[5,6,8]

Osmotic dilators

Osmotic cervical dilators are made of hygroscopic materials that readily absorb water resulting in their swelling. When placed in the cervix, they swell and lengthen, thereby progressively dilating the cervix. They are made from seaweeds (*Laminaria japonica* or *Laminaria digitata*) or from synthetic hydrophilic materials. Synthetic dilators include Lamicel (Medtronic Xomed, Inc; Jacksonville, FL) and Dilapan-S (JCEC Company, Inc; Kendall Park, NJ). Osmotic dilators are inserted into the cervical canal under direct visualization during a sterile speculum examination. The cervix should be cleansed with a sterile solution prior to insertion. Using sponge forceps, the dilators should be inserted such that the tip is just inside the internal os and the string is still visible in the vagina.[15] Osmotic dilators range in size from 2 to 10 mm. Often the maximum number of dilators that can be inserted without causing significant pressure to the cervical wall are used.

Laminaria are hygroscopic rods made from the stem of sterile seaweed (*Laminaria japonica or Laminaria digitata*). Dilapan-S is a synthetic hygroscopic dilator made of compresses polyacrylonitrile sponges. Both Laminaria and Dilapan-S function by active and passive cervical dilation. They absorb water from the cervix thereby increasing their diameter by which in turn stretches the cervix.[3] The cervical stretching also stimulates the release of prostaglandins, aiding in the ripening process.[3] Most of the increment in size of Laminaria occurs in the first 6 h, however it can be used for 12–24 h for maximum expansion.[6] Dilapan-S exerts a greater mechanical force on the cervix compared to Laminaria, as well as acts significantly faster, reaching two to three times its original diameter within 2–4 h.[3]

Lamicel is composed of compressed polyvinyl acetal sponges containing up to 500 mg of magnesium.[3] It also works by extracting fluid from the cervical tissue and softening the cervix, but has an additional property of magnesium-induced cervical stroma collagenolysis.[16] It may also increase the sensitivity of the cervix to prostaglandin E2 (PGE2).[17] Lamicel can increase up to three to four times its diameter in the first 2–4 h, while exerting significantly less mechanical force on the cervix compared to Laminaria.[3] Lamicel is currently not approved for use beyond gestational age of 23 weeks and 6 days in the United States.

Effectiveness of osmotic dilators

Osmotic dilators versus placebo

A 2012 Cochrane review on methods of mechanical dilation for induction of labor found no significant difference in risk of cesarean section between Laminaria and placebo (RR = 0.98, 95% CI: 0.74–1.30).[18] A randomized, controlled, double-blind study evaluated the safety and efficacy of pre-induction cervical ripening with *Laminaria japonica* versus no ripening prior to amniotomy on day 2. Laminaria use did not improve rates of cesarean delivery or mean length of induction.[19] In a comparison of Dilapan and no pretreatment before oxytocin induction, Dilapan resulted in a significant difference in median Bishop score but no significant difference in length of labor or in the cesarean section rate were observed.[20]

Laminaria versus Dilapan

In a randomized study comparing Dilapan to *Laminaria japonicum*, fewer Dilapan diliators were needed to achieve significant cervical ripening than *Laminaria*. Dilapan was also associated with a trend towards a shorter induction to delivery interval; however, there were no differences in mode of delivery.[21]

Osmotic dilators versus prostaglandins

There are a number of studies that compare osmotic dilators to different prostaglandins for cervical ripening (vaginal PGE2, intracervical PGE2, or misoprostol). One consistent finding was a similar rate of cesarean delivery for both methods.[22–25] The results are mixed with respect to cervical ripening to delivery interval, with one report finding no significant difference,[26] and another noting a longer induction time to delivery with Laminaria.[22] Osmotic dilators have been consistently associated with lower rates of hyper stimulation, both with and without change in the fetal heart rate; however, no differences in operative delivery for fetal distress have been reported.[22,23,26] A 2012 Cochrane Review on methods of mechanical cervical ripening included 11 studies (1397 women) and found no difference in rates of cesarean delivery

or time to delivery, but reported higher rates of hyper stimulation with prostaglandins.[18]

Several studies compared the use of prostaglandin E2 gel with and without an osmotic dilator. There were no differences in rates of vaginal delivery within 24 h,[27] need for oxytocin administration,[28] hyperstimulation,[29] or cesarean delivery.[18,27,28]

Osmotic dilators versus oxytocin

There are only a few studies that have evaluated Laminaria with and without oxytocin to oxytocin alone, and these consistently found no differences in rate of cesarean delivery.[29–31] However, Jagani et al.[29] noted that Laminaria alone was associated with a longer induction to delivery time compared to oxytocin alone, whereas Lyndrup et al.[31] found similar efficacy with Lamicel and oxytocin versus oxytocin alone.

Osmotic dilators versus Foley balloon

There are no reports of osmotic dilators versus the intracervical Foley balloon alone. Lin et al.[32] compared Laminaria followed by oxytocin to the cervical Foley with extra-amniotic saline infusion (EASI) and oxytocin. This was a small study (26 subjects per arm); however, they found a significantly shorter induction to delivery time by 4 h in the EASI and oxytocin group. There were no significant differences in the rate of cesarean delivery; however, fewer cesarean deliveries were performed for failed induction in the EASI group.[32]

Safety of osmotic dilators

Historically, Laminaria use was associated with an increased risk of sepsis; however, recent sterilization techniques have significantly reduced this risk.[4] Currently, osmotic dilators are most often used for cervical ripening prior to first and second trimester dilation and evacuation (D&E) procedures. This process has been associated with decreased risk of cervical laceration and uterine perforation, without significant risks other than pain with insertion.[33–35]

The data regarding risk of infection with osmotic dilators for pre-induction cervical ripening is more mixed. A Cochrane review on cervical ripening found increased odds of chorioamnionitis or endometritis with osmotic dilators, but when the outcomes were assessed individually, these results were not significant.[18] Another systematic review included randomized controlled trials using Laminaria or other hygroscopic dilators, as well as other mechanical methods of cervical ripening.[37] When outcomes were individually assessed, the only significant finding was an increase in risk of endometritis with other hygroscopic dilator use.[37] Two other reports comparing osmotic dilators to pharmacologic methods found increased risk of infections with osmotic dilator use, specifically endometritis,[27,36] chorioamnionitis,[27] and neonatal sepsis.[36]

Other potential complications of osmotic dilators include hypersensitivity/anaphylaxis and retention of whole or fragmented product. A recent case series outlined a total of 10 cases of hypersensitivity, of which eight met criteria for true anaphylaxis.[38] In these cases, the reaction time ranged from immediate to 3 h after placement, almost all patients had prior exposure to Laminaria.[38] There are no reports of hypersensitivity related to synthetic osmotic dilator use. There are a number of reports of retained fragments of Dilapan, which can occur as the result of mechanical stress.[33] This occurred more frequently with an earlier version of Dilapan, which was removed from the market in 1995. Dilapan became available for use again in 2002 with a significantly lower rate of complications. Laminaria can also be retained, but this is less common as they are less likely to fragment.[39]

Extra-amniotic saline infusion (EASI)

Extra-amniotic saline infusion was first described in the late 1970s as a method for midtrimester pregnancy termination as well as for induction in the setting of fetal demise.[32,40] This was then extrapolated for use in the third trimester labor inductions. Extra-amniotic saline is infused through a transcervical Foley catheter, theoretically stripping the membranes and resulting in an increased release of prostaglandins and cytokines.[17] Varying rates of saline infusion have been reported, with earlier studies using 60 ml/h[40,41] and more recent reports using 30–40 ml/h.[42,43]

Effectiveness of EASI

EASI versus prostaglandins

A number of studies have compared EASI with and without concomitant oxytocin to prostaglandins. Compared to prostaglandins, EASI has consistently been shown to significantly improve the post-ripening Bishop score as well as shorten the time of cervical ripening.[40,41,44–46,48,49] The data is mixed for the outcome of induction to delivery interval. Three reports found that EASI was associated with a 3–5 h shorter interval to delivery,[45,46,50] while others found no differences in time to delivery.[40,41,44,48,49] A single study by Lyndrup et al. found that EASI was associated with an increased risk of failed vaginal delivery in 24 h and therefore an increased rate of cesarean delivery. However, subgroup analysisfound that this result was most pronounced in multiparous patients, with primiparous patients with unfavorable cervices having similar results for both study groups.[47] In all other reports, the rate of cesarean delivery is similar for both EASI and PGE2 study groups.[40,41,44–46,48–50]

EASI versus Foley Balloon

Three randomized controlled trials have compared the cervical Foley balloon with and without EASI. Karjane et al.[43] noted that the Foley balloon with EASI was associated with a shorter time from induction to delivery compared to the Foley balloon alone, but with no difference in cesarean delivery rate. Reports by Lin et al.[42] and Guinn et al.[51] found that there were no differences between Foley balloon with and without EASI for induction to delivery interval, proportion of women achieving vaginal delivery within 24 h, or rate of cesarean delivery.

The Cochrane Review on mechanical methods of cervical ripening concluded that there is insufficient data to support the use of extra-amniotic saline infusion.[18]

Safety of EASI

Although chorioamnionitis and/or endometritis have been evaluated as outcomes in many studies on EASI, none of these was adequately powered for this outcome. The Cochrane Review on mechanical methods of cervical ripening did not find an increased risk of chorioamnionitis or endometritis with use of EASI (three studies).[18] Another systematic review included these three studies as well as six others to assess infections morbidity.[37] In nine studies, there were no increased odds of maternal infection with EASI (OR = 1.05, 95% CI: 0.73–1.50). Seven of these found no increased risk of chorioamnionitis (OR = 1.07, 95% CI: 0.72–1.60) or endometritis (OR = 0.91, 95% CI: 0.43–1.94).[37] Similarly, the three randomized trials comparing Foley with and without EASI found no differences in rates of chorioamnionitis or endometritis.[42,43,51]

Double-balloon catheter

A cervical double-balloon catheter was first described by Atad et al.[52] in 1991, as a method to ensure that the intracervical PGE2 gel remained in place. In this study, the authors found that the use of a double-balloon catheter was associated with improved cervical ripening and a shorter induction to delivery time when compared to PGE2 gel, without benefit of adding intracervical PGE2 gel through the device.[52] The authors proposed that the mechanism was superior to that of a single balloon Foley catheter because the force of dilation occurs from both the internal and external cervical os, whereas the Foley can only exert force on the internal os when placed on traction.[52,53]

The original double-balloon catheter was marketed as the "Atad Ripener Device" and approved by the FDA in 2005 (Atad Developments and Medical Services Ltd; Israel). The device is an 18-French natural latex, 3-lumen catheter with double balloons 2-cm apart at the distal end.[52] These balloons each have a capacity of 80 ml. The catheter is inserted into the cervix such that both balloons are within the cervix. The internal balloon is then partially inflated, followed by traction to appropriately place this balloon at the internal os. The external balloon is then partially inflated in a similar fashion. Both balloons are then inflated to their capacity, and the device taped to the patient's leg.[52] The device can be left in place for up to 12 h. The Cook Cervical Ripening Balloon (Cook Inc; Bloomington, IN) was approved by the FDA in 2013. This is an 18-French silicone double-balloon catheter that comes with an optional stylet to aid with insertion. These balloons also have a capacity of 80 ml, and insertion is identical to that of the Atad catheter.

Effectiveness of the double-balloon catheter

Double-balloon catheter versus PGE2

In the initial study by Atad et al.,[52] the double-balloon catheter resulted in shorter induction to delivery times. In a subsequent study, Atad et al. compared the double-balloon catheter, PGE2, and oxytocin. They found that the double-balloon catheter and PGE2 were equivalent in terms of change in Bishop score, time to delivery, and rate of vaginal delivery, but both were superior to oxytocin alone for these outcomes.[54] Two recent reports found that the double-balloon catheter was associated with a higher rate of delivery within 24 h, without a difference in mode of delivery.[55,56] In contrast, one report examining PGE2 and the double-balloon catheter in patients with oligohydramnios found a shorter induction to delivery time in the PGE2 group; however, they did not assess time to vaginal delivery as an outcome.[57]

Double-balloon catheter versus single balloon catheter

Pennell et al. compared the single balloon catheter, double-balloon catheter, and PGE2 gel. The double-balloon catheter resulted in a 1-h longer induction to delivery time due to a longer time to active labor, but there were no differences in mode of delivery. The authors also found that the single balloon catheter was associated with the lowest pain scores, as well as the lowest cost (attributed to the cost of the ripening device, with no differences in length of stay or postnatal complications).[58] Another randomized controlled trial comparing the single and double-balloon catheters found no differences in induction to delivery times or rates of cesarean delivery regardless of parity; however, there was a higher rate of operative delivery (vacuum or cesarean section) in the double-balloon catheter group. This group also had a higher rate of the composite adverse neonatal outcome that included intrapartum fever, malpresentation, and cord prolapse.[59] In summary, the double-balloon catheter appears to be comparable to the single balloon catheter in terms of efficacy; however, it has a significantly higher cost, has been associated with increase pain scores, and may be associated with an increased risk of adverse labor outcomes.

Conclusions

Pre-induction cervical ripening is an important step in the process of labor induction in women with an unfavorable cervix. This article has reviewed alternatives to the cervical Foley catheter, which is currently the most commonly used mechanical method of cervical ripening. Laminaria is no longer used for pre-induction cervical ripening, but has an important role in reducing the risks associated with cervical dilation prior to dilation and evacuation procedures. At the present time, the data does not support any added benefit to the use of extra-amniotic saline infusion or a double-balloon catheter when compared to the Foley catheter alone. The Foley catheter should continue to be the primary method of mechanical cervical ripening, based on its efficacy, low cost, association with lower rates of uterine contractile abnormalities, and improved pain scores.

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