Intracervical Foley balloon catheter for cervical ripening and labor induction: A review

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**Abstract**

Labor induction is a common obstetric practice. Optimal methods of both ripening and induction are debated. This article assesses the intracervical Foley balloon catheter through review of literature, including meta-analyses, randomized controlled trials, and retrospective data. Discussion includes comparison of Foley balloon catheters to pharmacologic agents, safety profile in various clinical scenarios, and cost-effectiveness.

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**Introduction**

Approximately 20% of laboring women undergo induction for maternal or fetal indications.\cite{1} Labor can be induced by mechanical methods, such as intracervical Foley balloon catheters, hygroscopic dilators such as Laminaria and Dilapan, and amniotomy. It can also be accomplished with the use of exogenously administered prostaglandins, such as misoprostol and dinoprostone. All of these options ripen the cervix, thus softening the cervix and preparing it for labor.

Mechanical methods of cervical ripening and labor induction are safe and effective. One of the most effective induction tools is the Foley balloon catheter. To understand how the Foley balloon catheter incites cervical change, one must understand the structure of the cervix and how labor begins and progresses.

Remodeling of the cervix occurs in 4 phases: softening, ripening, dilation, and repair after delivery. Softening occurs throughout gestation. Ripening is defined as the peak of cervical tissue loss of tensile strength and structure. Dilation proceeds once the cervix is ripe and causes both the external and internal cervical os to open.\cite{2,3}

The cervix contains extracellular fibrous tissue matrices composed of types 1 and 3 collagen, glycosaminoglycans, and matrix proteins. During parturition, these matrices are degraded and remodeled. The tissue tensile strength decreases because of degradation of collagen cross-links. As labor progresses, endogenous prostaglandins are released that stimulate stretch forces on myometrial cells and the overlying amnion. E-cadherin is up-regulated by cervical epithelial cells, which further increases tissue breakdown. Progesterone synthesis declines, while estradiol concentrations increase. This increases the concentration of aquaporins and gap junctions. Cervical water content subsequently increases, which further remodels the cervical extracellular matrices.\cite{4} As prostaglandins circulate, local inflammatory responses cause alterations in tissue gene expression. All of these mechanisms help to soften, efface, and subsequently dilate the cervix.\cite{5}

**Purpose**

Cervical ripening is often required to make the cervix more favorable for induction. In women with low Bishop scores...
(a score less than 6 is called an unfavorable cervix and likely requires ripening), a favorable option is to ripen the cervix with a Foley bulb transcervical catheter. The Foley bulb softens and stretches the cervix mechanically and stimulates endogenous prostaglandin release.5

Methods

Typically, a standard 16-F latex or latex-free Foley catheter is used. There is also a specialized Cook catheter, which small studies have shown to be less efficacious and more costly.6 The Foley bulb is placed into the internal cervical os. This can be accomplished digitally or visually with a speculum and ring forceps. The balloon is filled with 30–60 ml of sterile water. The Foley catheter is taped to tension on the patient’s medial thigh in order to exert pressure on the internal cervical os. Care must be taken to avoid placing the balloon too far; if the balloon is behind the fetal head, it cannot exert tensile force on the cervix. Proper positioning of the balloon can be easily assessed with bedside trans-abdominal ultrasound. A form of Foley catheter balloon has a double balloon, which exerts pressure on the external and internal cervical os simultaneously.

In some protocols, pitocin is used to augment labor after spontaneous expulsion or removal of the Foley balloon catheter. Other protocols use pitocin concomitantly with the Foley balloon catheter.7

Research

Foley catheter balloons are often preferred to pharmacologic agents. There is less uterine hyperstimulation and tachysystole with mechanical methods.8-10 The PROBAAT trial, a randomized controlled trial of 824 women, compared Foley catheters to dinoprostone gel for cervical ripening.11 Outcomes were measured by cesarean section rate, maternal and neonatal morbidity, and time from intervention to birth. The rate of cesarean section was essentially the same [93 (23%) Foley bulb versus 82 (20%) dinoprostone gel]. The women in the Foley balloon catheter group had fewer rates of operative vaginal deliveries due to fetal distress and reduced neonatal intensive care unit admissions. A meta-analysis of 27 randomized controlled trials comparing Foley balloon catheters to locally applied prostaglandins echoed those results, indicating that prostaglandins have a significantly higher risk of uterine contractile abnormalities [RR = 2.35; 95% confidence interval (CI): 1.41–3.90; P < 0.001].12

Another important factor is the low cost of Foley balloon catheter induction,13 especially considering its clinical efficacy and favorable safety profile.

Arguments in favor of pharmacologic ripening quote studies that have shown lower rates of vaginal delivery within 24 hours with use of a Foley catheter balloon. However, the authors of 2 large meta-analyses quoted most often commented that the studies they included in their meta-analyses were insufficiently powered to detect statistically significant effects on vaginal delivery rates.12,13 Further, a randomized controlled trial comparing Foley balloon catheter and subsequent pitocin use versus oral misoprostol showed that misoprostol leads to longer induction-to-delivery times in nulliparous women. Rates of labor induction are rising quickly. The ARRIVE trial is currently randomizing women to elective induction of labor at 39 weeks versus expectant management and analyzing neonatal morbidity and mortality.14 With the rise in labor induction for elective inductions in addition to maternal and neonatal indications, outpatient Foley catether cervical ripening is an attractive option to reduce inpatient hospital stays. Ongoing research will determine if this method safely improves patient satisfaction and decreases hospital stay length and cost.15

A concern with Foley balloon catheter ripening is the risk of infection. Large randomized controlled trials show mixed data: Jozwiak et al.11 examined infection rates in both mother and baby in the PROBAAT trial and found that infection rates were the same with use of Foley balloon or dinoprostone gel. However, a meta-analysis of randomized controlled trials that specifically studied maternal and neonatal infection rates showed increased rates of maternal infection in women induced by Foley catheter [OR = 1.50; 95% CI: 1.07–2.09] compared with pharmacologic agents.16

Prior cesarean section

Controversy surrounds use of Foley catheter balloons in women desiring trial of labor after cesarean section. Bujold et al. studied women with a prior low transverse cesarean section. Their results showed no significant difference in uterine rupture rates between women induced with a Foley catheter balloon versus women who entered labor spontaneously.17 However, in a retrospective analysis of 972 women attempting trial of labor after a prior low transverse cesarean section, Hoffman et al.18 demonstrated a significantly increased uterine rupture rate with Foley catheter balloon (6.52%) pre-induction cervical ripening versus spontaneous labor (1.87%).

Ruptured membranes

It is unclear whether Foley balloon catheters decrease time from induction to delivery and cesarean section rates in women with premature rupture of membranes and preterm premature rupture of membranes without labor. Retrospective data of women induced by Foley balloon catheter and misoprostol showed that Foley balloon catheters may shorten time to delivery.19 Since Foley balloon catheters are foreign objects, they predispose women to intrauterine infection. However, the risk of chorioamnionitis may be decreased if the time from induction to delivery is shortened. The upcoming FOLCROM trial investigates use of Foley balloon catheters for cervical ripening followed by pitocin augmentation versus pitocin alone.

Conclusion

Intracervical Foley balloon catheters are a relatively safe and effective way to ripen the cervix compared to other cervical
ripening agents. Due to their low cost and lower rates of uterine hyperstimulation, they are an excellent tool to use both in prospering and developing countries. Numerous studies show that Foley balloon catheters are equivalent to pharmacologic methods with rates of failed induction of labor and cesarean section. However, their safety profile makes them an attractive alternative, even as an option for outpatient pre-induction cervical ripening. This obstetric strategy will be discussed in a further article.

REFERENCES