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Hot Topics in Obstetrical Care

Tuesday, March 12th, 12:15pm- 1pm EST

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- **May 14th, 2019 @ 12:15pm** Venous Thromboembolism and Pulmonary Embolism & VT Dept. of Health Topic
- **June 11, 2019 @ 12:15pm** Severe Maternal Morbidity & VT Dept. of Health Topic

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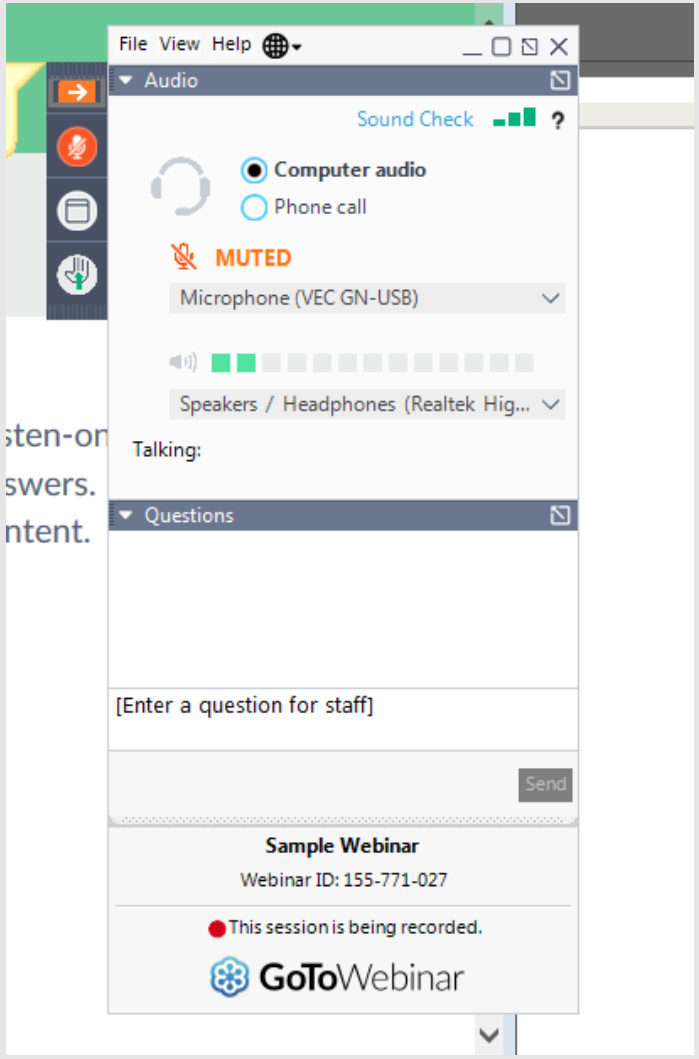

Updates in induction and cervical ripening

Marjorie Meyer MD

University of Vermont

VCHIP Webinar

Should we discuss induction at 39 weeks with all patients?

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 9, 2018 VOL. 379 NO. 6

Labor Induction versus Expectant Management in Low-Risk Nulliparous Women

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ABSTRACT

BACKGROUND

The perinatal and maternal consequences of induction of labor at 39 weeks among low-risk nulliparous women are uncertain.

METHODS

In this multicenter trial, we randomly assigned low-risk nulliparous women who were at 38 weeks 0 days to 38 weeks 6 days of gestation to labor induction at 39 weeks 0 days to 39 weeks 4 days or to expectant management. The primary outcome was a composite of perinatal death or severe neonatal complications; the principal secondary outcome was cesarean delivery.

RESULTS

A total of 3062 women were assigned to labor induction, and 3044 were assigned to expectant management. The primary outcome occurred in 4.3% of neonates in the induction group and in 5.4% in the expectant-management group (relative risk, 0.80; 95% confidence interval [CI], 0.64 to 1.00). The frequency of cesarean delivery was significantly lower in the induction group than in the expectant-management group (18.6% vs. 22.2%; relative risk, 0.84; 95% CI, 0.76 to 0.93).

CONCLUSIONS

Induction of labor at 39 weeks in low-risk nulliparous women did not result in a significantly lower frequency of a composite adverse perinatal outcome, but it did result in a significantly lower frequency of cesarean delivery. (Funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development; ARRIVE ClinicalTrials.gov number, NCT01990612.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Grobman at the Department of Obstetrics and Gynecology, Northwestern University, 250 E. Superior St., Suite 05-2175, Chicago, IL 60611, or at w-grobman@northwestern.edu.

*A list of other members of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network is provided in the Supplementary Appendix, available at NEJM.org.

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DOI: 10.1056/NEJMoa1800566

Eligibility Criteria

Inclusion Criteria

- Nulliparous - no previous pregnancy beyond 20 weeks 0 days
- Singleton gestation. Twin gestation reduced to singleton, either spontaneously or therapeutically, is not eligible unless the reduction occurred before 14 weeks 0 days project gestational age (see below).
- Gestational age at randomization between 38 weeks 0 days and 38 weeks 6 days inclusive based on clinical information and evaluation of the earliest ultrasound as described below

Exclusion Criteria

- Project gestational age at date of first ultrasound is > 20 weeks 6 days
- Plan for induction of labor prior to 40 weeks 5 days
- Plan for cesarean delivery or contraindication to labor
- Breech presentation
- Signs of labor (regular painful contractions with cervical change)
- Fetal demise or known major fetal anomaly
- Heparin or low-molecular weight heparin use during the current pregnancy
- Placenta previa, accreta, vasa previa
- Active vaginal bleeding greater than bloody show
- Ruptured membranes
- Cerclage in current pregnancy
- Known oligohydramnios, defined as amniotic fluid index < 5 cm or maximal vertical pocket < 2 cm
- Fetal growth restriction, defined as EFW < 10th percentile
- Known HIV positivity because of modified delivery plan
- Major maternal medical illness associated with increased risk for adverse pregnancy outcome (e.g. any diabetes mellitus, lupus, any hypertensive disorder, cardiac disease, renal insufficiency)
- Refusal of blood products
- Participation in another interventional study that influences management of labor at delivery or perinatal morbidity or mortality
- Delivery planned elsewhere at a non-Network site

4.4 Study Procedures

Women randomized to induction of labor will undergo induction via oxytocin at 39 weeks 0 days to 39 weeks 4 days. Those with an unfavorable cervix (modified Bishop score < 5) will first undergo cervical ripening (method left to the discretion of the patient's physician) in conjunction with or followed by oxytocin stimulation unless a contraindication arises.

Women randomized to expectant management will have at least weekly follow-up visits with their providers and, unless a medical indication is present, will continue pregnancy until at least 40 weeks 5 days of gestation. Antepartum fetal testing will be initiated no later than 41 weeks 6 days according to policies at each center. All patients will undergo induction via oxytocin by 42 weeks 2 days.

SMFM Statement on Elective Induction of Labor in Low-Risk Nulliparous Women at Term: the ARRIVE Trial

Society of Maternal-Fetal (SMFM) Publications Committee

A Randomized Trial of Induction Versus Expectant Management (ARRIVE) was conducted by the Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network from March 2014 to August 2017.This large multicenter, unmasked, randomized controlled trial was performed to test the hypothesis that elective IOL at 39 weeks of gestation, compared with expectant management among low-risk nulliparous women, reduces the risk of a composite outcome of perinatal death or severe neonatal morbidity. Nulliparous women with reliable dating and no obstetric or medical complications were eligible, regardless of favorability of cervical examination. The purpose of this document is to review the findings of the recent randomized trial and to provide guidance for implementation of the study findings.

Summary of Recommendations

	Recommendations
1	It is reasonable to offer elective induction of labor to low-risk nulliparous women ≥39 weeks 0 days of gestation. We recommend that providers who choose this approach ensure that women meet eligibility criteria of the ARRIVE trial.
2	We recommend against offering elective induction of labor to women under circumstances that are inconsistent with the ARRIVE study protocol unless performed as part of research or quality improvement.
3	We recommend that further research be conducted to measure the impact of this practice in settings other than a clinical trial.

2018

Induction of Labor at 39 Weeks of Gestation vs. Expectant Management for Low-Risk Nulliparous Women: A Cost-Effectiveness Analysis

Ms. Alyssa R. Hersh, BS, BA, Ms. Ashley E. Skeith, BS, Dr. James A. Sargent, MD, Dr. Aaron B. Caughey, MD PhD

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DOI: https://doi.org/10.1016/j.ajog.2019.02.017

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AJOG at a Glance:

- This study found that induction of labor for low-risk, nulliparous women at 39 weeks of gestation is cost-effective with our baseline model inputs, resulting in better outcomes yet higher costs, with an incremental cost-effectiveness ratio of $87,692 per QALY, which is below the commonly used threshold of $100,000/QALY.
- Small changes in multiple model inputs were highly impactful to the cost-effectiveness of the model lead elective induction to not be cost effective 65% of the time as costs and pregnancy outcomes vary widely across the United States, these findings suggest the cost-effectiveness may vary based on institutional policies and patient populations.

Keywords: low-risk nulliparous women; induction of labor; mode of delivery; cesarean section; health care resources; obstetric outcomes; decision analysis

Condensation: Induction of labor at 39 weeks of gestation is marginally cost-effective for low-risk nulliparous women compared to expectant management.

Labor Induction: *Current Commentary*

Elective Induction at 39 Weeks of Gestation and the Implications of a Large, Multicenter, Randomized Controlled Trial

Caroline Marrs, MD, Mauricio La Rosa, MD, Aaron Caughey, MD, PhD, and George Saade, MD

TRIAL TO BEDSIDE: HOW SHOULD WE COUNSEL PATIENTS?

The results of the ARRIVE trial disrupt the traditional wisdom that awaiting spontaneous labor after 38 6/7 weeks of gestation in low-risk women is preferable to induction and support a shift in obstetric practice. Expectant management should no longer be considered the default and elective induction the exception.

Low-risk nulliparous women should be informed that there is strong evidence supporting the neonatal and maternal safety of elective induction, as well as the lower risk of cesarean delivery and hypertensive disorders of pregnancy with induction. They should be counseled that the rate of cesarean delivery is decreased by 16% with elective induction compared with expectant management, whether or not the patient has a favorable cervix. As with all shared medical decision-making, the clinician's responsibility is to inform the patient but the decision is ultimately hers. However, it is inappropriate to withhold this information from patients.

IMPLICATIONS FOR POLICIES

Although one RCT does not warrant a swift and sweeping policy of mandating elective induction at 39 weeks of gestation at the hospital or system level, these results do call into question the validity of current policies that discourage or even forbid elective induction at any gestational age. Hospitals or practices that strictly forbid all elective inductions should reconsider their position.

2019

The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 597 • May 2014 (Reaffirmed 2016)

Committee on Obstetric Practice

The Society for Maternal-Fetal Medicine endorses this document. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Labor Induction or Augmentation and Autism

ABSTRACT: Functional oxytocin deficiency and a faulty oxytocin signaling pathway have been observed in conjunction with autism spectrum disorder (ASD). Because exogenous synthetic oxytocin commonly is administered for labor induction and augmentation, some have hypothesized that synthetic oxytocin used for these purposes may alter fetal oxytocin receptors and predispose exposed offspring to ASD. However, current evidence does not identify a causal relationship between labor induction or augmentation in general, or oxytocin labor induction specifically, and autism or ASD. Recognizing the limitations of available study design, conflicting data, and the potential consequences of limiting labor induction and augmentation, the Committee on Obstetric Practice recommends against a change in current guidance regarding counseling and indications for and methods of labor induction and augmentation.

Should we discuss induction at 39 weeks with all patients?

It is reasonable to discuss the risks and benefits and offer patient induction at 39 weeks to low risk patients

Do not need to recommend or encourage induction if patient does not want to be induced

Hospital policies should not prohibit induction at 39 weeks in low risk women

Cervical Ripening prior to induction:

Bishop <7
Shortens duration of labor
No change in cesarean rate

This holds true for all the data about cervical ripening methods:
No change in cesarean

30 cc foley

Cook double balloon catheter
Each 80 cc (some patients do not tolerate highest volume)
(about $80)

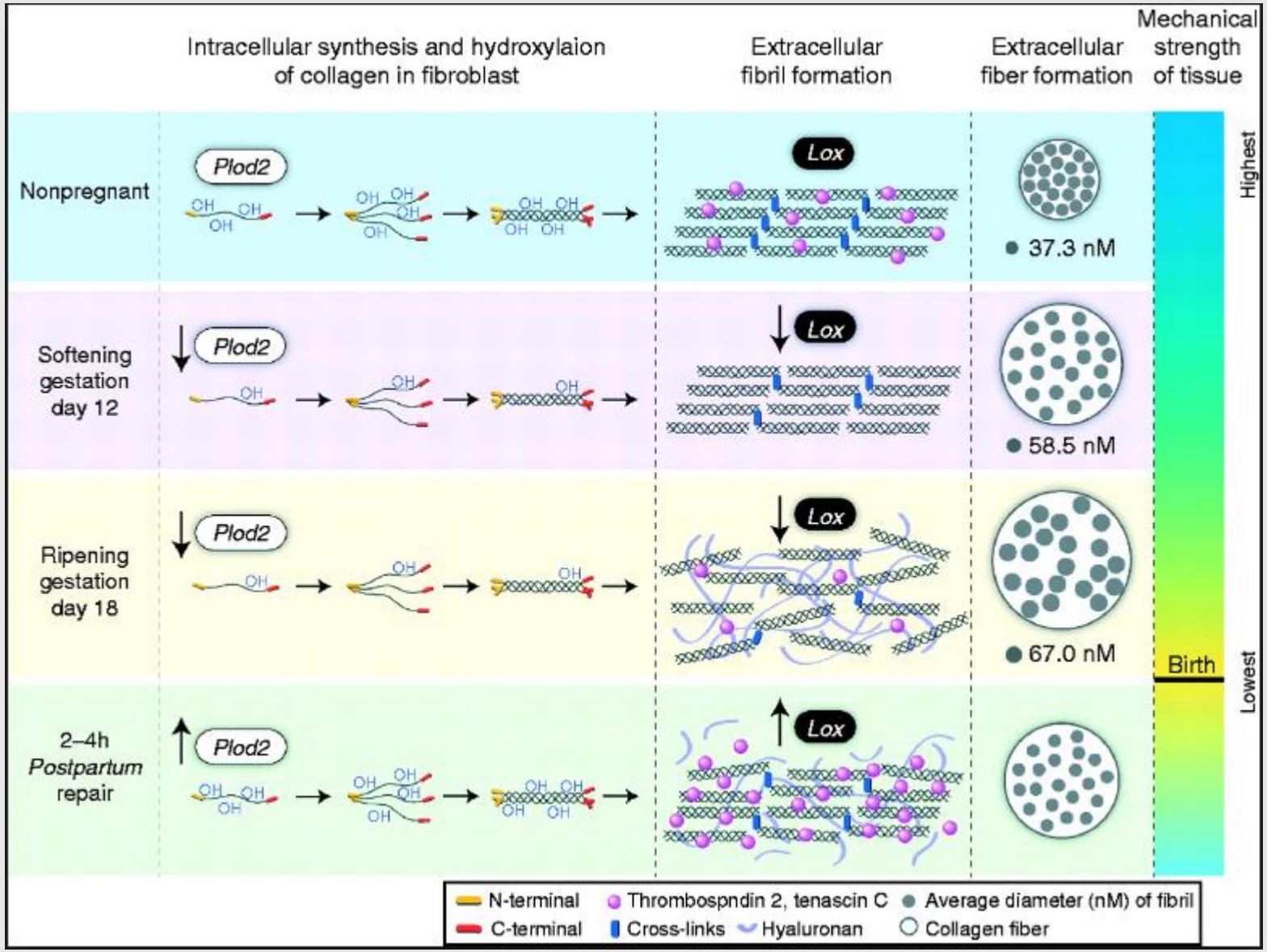
60 cc foley

(about $10)

?FDA approved can see how to buy

Prepadil
About $175

Cervical remodeling for labor is a process: fastest might not always be better.
Keep on the lookout for protocols that can give women a couple days for this process as outpt



Are cervical ripening balloons safe?

DOI: 10.1111/1471-0528.15047
www.bjog.org

Systematic review

Safety of the balloon catheter for cervical ripening in outpatient care: complications during the period from insertion to expulsion of a balloon catheter in the process of labour induction: a systematic review

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Background It has been suggested that cervical ripening with a balloon catheter for labour induction can be done in an outpatient setting in low-risk pregnancies. Introduction of such an approach needs to be accompanied with monitoring of potential complications. Therefore the existence and frequency of any associated adverse event during cervical ripening needs to be established.

Objective To assess the complication rate during cervical ripening with balloon induction.

Search strategy We searched Embase, Medline, Cochrane Collaboration and CINAHL using keywords 'induction of labour', 'cervical ripening', 'balloon catheter', 'Foley balloon', 'transcervical balloon'.

Selection criteria We included randomized controlled trials and cohort studies containing original data on fetal and maternal morbidity in pregnant women during cervical ripening with a balloon catheter. Only articles for which authors were able to give data for this exact time frame were included.

Data collection and analysis Two reviewers assessed independently the eligibility of included studies, extracted data and performed a quality assessment. A meta-analysis was performed to calculate the estimated prevalence of the adverse events.

Main results In total 26 studies were included reporting on 8292 women. The estimated prevalence of the analysed adverse events in the random effects model was between 0.0 and 0.26%, of which 'pain/discomfort' had the highest prevalence.

Conclusion This study suggests the risk of adverse events during the period between insertion and expulsion of a balloon catheter in cervical ripening to be low. These data facilitate further evaluation and implementation of this procedure in an outpatient setting for low-risk pregnancies.

Keywords Balloon catheter, cervical ripening, complications, induction of labour, outpatient care, safety, systematic review.

Tweetable abstract Balloon catheter for cervical ripening appears to be safe enough to evaluate its use in the outpatient setting.

Cervical Ripening Balloons are safe
Insufficient evidence for outpatient use

<u>Review:</u>
26 studies
N=8292 women
Adverse outcome 0-0.2%: pain and discomfort highest prevalence

Table 2. Adverse events during cervical ripening phase time frame with a transcervical balloon catheter

Adverse events	No. of studies reporting on adverse event (Total sample size)	Occurrence of AE in ripening period	Reference numbers of studies that report on occurrence of AE in ripening period
Pain, discomfort	17 (5754)*, ***	31***	10,14–17,22
Unintended amniotomy	12 (2989)	19	18,19
Vaginal bleeding	18 (6566)*	18**	7,10,15,17–22,37
Balloon displacement	10 (2397)	12	8,9,20,37
Non-reassuring fetal heart rate	17 (5351)	15	9,18,19,23,24
Allergic reaction	16 (6832)	2	15,20
Voiding problems	10 (3522)*	2	10
Balloon rupture	12 (3222)*	1	10
Uterine hypertonus	14 (3707)	1	7
Uterine hyperstimulation	20 (4812)	1	23
Decreased fetal movements	11 (4318)*	1	10
Malpresentation	16 (6046)	4	24,25,33
Intrapartum infection	15 (5023)	0	–
Placental abruption	16 (6154)*	0	–
Uterine tachysystole	19 (4450)	0	–
Uterine rupture	23 (7916)	0	–
Cord prolapse	21 (6960)	0	–
Fetal death	24 (8189)	0	–
Maternal death	22 (6875)	0	–
Genital laceration	13 (4420)	0	–

AE, adverse event; DBC, double balloon catheter.
*Kruit et al.[10]: only data for outpatient group on this adverse events.
**de Oliveira e Oliveira et al.[17]: one women with vaginal bleeding, this woman was excluded from their analysis but included in this review. The sample size of the intention-to-treat was maintained.
***Salim et al.[16]: only data for DBC group on this adverse event; one women with discomfort in the DBC group, this woman was excluded from their analysis but included in this review. The sample size of the intention-to-treat was maintained.

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journal homepage: www.elsevier.com/locate/ejogrb

Review article

Risk of maternal, fetal and neonatal complications associated with the use of the transcervical balloon catheter in induction of labour: A systematic review☆

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ABSTRACT

Induction of labour is one of the most frequently applied obstetrical interventions globally. Many studies have compared the use of balloon catheters with pharmacological agents. Although the safety of the balloon catheter is often mentioned, little has been written about the total spectrum of maternal and fetal morbidity associated with induction of labour using a balloon catheter. We evaluated the safety of labour induction with a transcervical balloon catheter by conducting a literature review with pooled risk assessments of the maternal, fetal and neonatal morbidity.

We searched Medline, EMBASE and CINAHL as well as the Cochrane database using the Keywords 'induction of labour', 'cervical ripening', 'transcervical balloon', 'balloon catheter' and 'Foley balloon'. We did not use language or date restrictions. Randomized and quasi-randomized controlled trials as well as observational studies that contained original data on occurrence of maternal, fetal or neonatal morbidity during induction of labour with the balloon catheter were included. Studies were excluded if the balloon catheter was used concurrently with oxytocin and concurrently or consecutively with misoprostol, dinoprostone or extra-amniotic saline infusion. Study selection and quality assessment was performed by two authors independently using a standardized critical appraisal instrument. Outcomes were reported as weighted mean rates.

We detected 84 articles reporting on 13,791 women. The overall risk of developing intrapartum maternal infection was 11.3% (912 of 8079 women), 3.3% (151 of 4538 women) for postpartum maternal infection and 4.6% (203 of 4460 women) for neonatal infection. Uterine hypercontractility occurred in 2.7% (148 of 5439) of the women. Uterine rupture after previous caesarean section occurred in 1.9% of women (26 of 1373), while other major maternal complications had an occurrence rate of <1%. The risk for developing minor maternal complications was <2%. The risk of developing a non-reassuring fetal heart rate was 10.8% (793 of 7336 women), 10.1% (507 of 5008 women) for fetal distress and 14.0% (460 of 3295 women) for meconium stained liquor. Neonatal death occurred in 0.29% (6 of 2058) of the deliveries and NICU admission in 7.2% (650 of 9065 deliveries). This review shows that labour induction with a balloon catheter is a safe intervention, with intrapartum maternal infection being the only reasonable risk above 10%.

Infection

Maternal intrapartum infection (intrapartum infection in general/suspected, chorioamnionitis, intrapartum fever >38° C, use of antibiotics); postpartum maternal infection (postpartum infection in general/suspected; puerperal fever >38° C; endomyometritis; urinary tract infection; wound infection; use of postpartum antibiotics); neonatal infection/sepsis (in general/suspected/proven, clinical sepsis, neonatal fever >38° C).

Abnormal uterine activity

Tachysystole; hyperstimulation; hypertonus; uterine hyperstimulation syndrome; excessive uterine activity.

Hemorrhage

Intrapartum hemorrhage (bleeding after insertion, antepartum bleeding); postpartum hemorrhage (unspecified volume, > 500 mL, >1000 mL).

Major maternal

Uterine rupture/scar dehiscence; placental abruption; cord prolapse; malpresentation; maternal death.

Minor maternal

Balloon rupture; displacement of the balloon; nausea/vomiting; pain/discomfort; voiding problems; genital lacerations/birth canal injury; allergic reaction; unintended amniotomy.

Fetal

Non-reassuring fetal heart rate (in general/during ripening/as indication for CS/assisted deliveries, fetal CTG abnormalities, fetal tachycardia, fetal bradycardia, late decelerations); suspected fetal distress (unspecified/as indication for CS/assisted deliveries); meconium stained liquor; fetal death.

Neonatal

NICU/ward admission; low Apgar score; low pH; meconium aspiration syndrome; asphyxia; encephalopathy.

Both studies that provided a definition as well as studies that did not give definitions for the adverse events were included.

Review:
84 articles
13, 791 women

Single and double balloon reported separately

Infection rate about 10% (exclude PROM)

Are cervical ripening balloons safe?

Cervical ripening balloons appear to be safe

Do not increase risk of bleeding or infection

All inpatient

European Journal of Obstetrics & Gynecology and Reproductive Biology 229 (2018) 70–75

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journal homepage: www.elsevier.com/locate/ejogrb

Full length article

Synthetic osmotic dilators in the induction of labour—An international multicentre observational study

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ABSTRACT

Introduction: To evaluate the effects of synthetic osmotic dilators (Dilapan-S/ Dilasoft) in women who required induction of labour in a large prospective multicentre international observational study.

Materials and methods: Primary outcomes were duration of Dilapan-S/Dilasoft insertion (hours), total induction - delivery interval (hours) and the rate of vaginal deliveries within 24 h (%). Secondary outcomes were the number of dilators inserted, Bishop score increase after extraction of Dilapan-S/ Dilasoft, complications during induction (uterine contractions, uterine tachysystole and hyperstimulation, effect on the fetus) and post induction (infections and neonatal outcomes), agents / procedures used for subsequent induction of labour, immediate rate of spontaneous labours following cervical ripening period, rate of spontaneous vaginal deliveries, rate of instrumental vaginal deliveries and caesarean sections.

RESULTS: Total of 543 women were recruited across 11 study sites, of which, 444 women were eligible for analysis. With Dilapan-S/Dilasoft use of <12 h (n = 188) the overall vaginal delivery rate was 76.6% with 45.7% of these births occurring within 24 h, 66% within 36 h and 75.5% within 48 h from insertion of Dilapan-S/Dilasoft. The mean insertion-delivery interval for this group was 24.3(±10.4) hours. With Dilapan-S/Dilasoft use of >12 h (n = 256), the overall vaginal delivery rate was 64.8%, with 16% of these births occurring within 24 h, 48.4% within 36 h and 54.7% within 48 h from insertion of Dilapan-S/Dilasoft. The mean insertion-delivery interval for this group was 39.1(±29.2) hours. The mean gain in the Bishops score was +3.6(±2.3). The mean number of Dilapan-S/Dilasoft dilators used was 3.8 (±1.1). The overall rate of caesarean section was 30.1%. The overall complication rate was low including infection risk. No adverse neonatal outcome was attributable to the use of Dilapan-S/Dilasoft.

Table 3
Bishop score.

Bishop score	Mean	SD	Mean Gain
All women (N = 444)			
Bishop score prior to insertion	2.9	(±1.2)	3.6
Bishop score after extraction	6.5	(±2.3)	
Nulliparas (N = 289)			
Bishop score prior to insertion	2.9	(±1.3)	3.7
Bishop score after extraction	6.6	(±2.3)	
Women with previous caesarean section (N = 41)			
Bishop score prior to insertion	2.6	(±1.1)	3.8
Bishop score after extraction	6.4	(±1.7)	
Multiparas (N = 114)			
Bishop score prior to insertion	2.9	(±1.1)	3.5
Bishop score after extraction	6.3	(±2.3)	

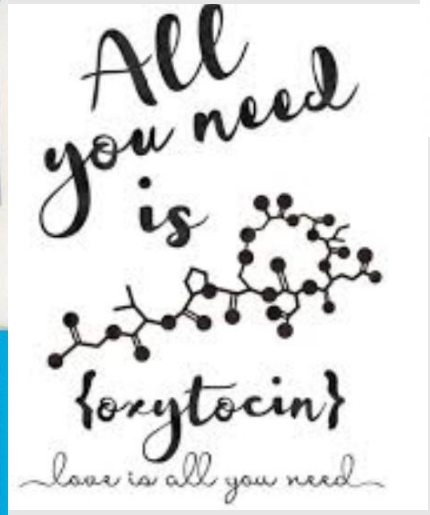
Will be emerging

Apparently FDA approved

Not ready for prime time

Bishop scores still <7

Focus on comparative studies of usual induction methods versus ripening with cervical ripening balloons or foley (with or without miso or oxytocin)



DOI: 10.1111/1471-0528.14256
www.bjog.org

Systematic review

Double-balloon catheter versus prostaglandin E2 for cervical ripening and labour induction: a systematic review and meta-analysis of randomised controlled trials

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Accepted 6 July 2016. Published Online 17 August 2016.

Background Induction of labour has become an increasingly common procedure. Ripening methods, including mechanical devices and pharmacological agents, improve the success rate of labour induction.

Objective To compare the efficacy and safety of the double-balloon catheter with prostaglandin E2 agents used for labour induction.

Search strategy We searched electronic sources from MEDLINE, Embase and Web of Science, the Cochrane Library Database of Systematic Reviews, and ClinicalTrials.gov website.

Selection criteria Only randomised controlled trials comparing the PGE2 agents with the double-balloon catheter for cervical ripening and labour induction in women with unfavourable cervices were included in the analysis.

Data collection and analysis The main outcomes included the vaginal delivery rate within 24 hours and risk of caesarean section. We calculated relative risks and mean differences using fixed- and random-effects models.

Main results Nine studies (1866 patients) were included in this systematic review. Both the double-balloon catheter and PGE2 agents were comparable with regard to rate of caesarean section (RR 0.92; 95% CI 0.79, 1.07), vaginal delivery within 24 hours (RR 0.95; 95% CI 0.78, 1.16) and maternal adverse events, but the risk of excessive uterine activity (RR 10.02; 95% CI 3.99, 25.17) and need for neonatal intensive care unit admissions (RR 1.31; 95% CI 1.01, 1.69) were significantly increased in women who received PGE2 agents.

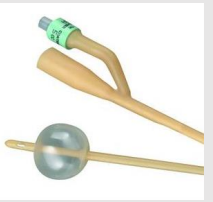
Conclusions The double-balloon catheter demonstrated greater safety and cost-effectiveness than PGE2 agents for cervical ripening and labour induction. The efficacy profiles of both methods were similar.

Keywords Cervical ripening, double-balloon catheter, induction of labour, prostaglandin E2.

Tweetable abstract Double-balloon catheter versus prostaglandin E2 for cervical ripening and labour induction

Linked article: This article has journal club questions by J Jardine, p. 900 in this issue. To view these visit https://doi.org/10.1111/1471-0528.14554.

Please cite this paper as: Du YM, Zhu LY, Cui LN, Jin BH, Ou JL. Double-balloon catheter versus prostaglandin E2 for cervical ripening and labour induction: a systematic review and meta-analysis of randomised controlled trials. BJOG 2017;124:891–899.



N=9 studies
N=1866 patients

<u>No difference:</u>
Cesarean
Vaginal birth <24 hrs
Maternal adverse events

<u>Increased in gel:</u>
NICU admissions
Tachysystole

Should oxytocin be started with the balloon placement or should it be held for ripening?

A randomized trial of Foley balloon induction of labor trial in nulliparas (FIAT-N)

Katherine A. Connolly, MD; Katherine S. Kohari, MD; Patricia Rekawek, MD; Brooke S. Smilen; Meredith R. Miller, MPH; Erin Moshier, MS; Stephanie H. Factor, MD, MPH; Joanne L. Stone, MD; Angela T. Bianco, MD

BACKGROUND: With an increasing rate of induction of labor, it is important to choose induction methods that are safe and efficient in achieving a vaginal delivery. The optimal method for inducing nulliparous women with an unfavorable cervix is not known.

OBJECTIVE: We sought to determine if induction of labor with simultaneous use of oxytocin and Foley balloon vs sequential use of Foley balloon followed by oxytocin decreases the time to delivery in nulliparous women.

STUDY DESIGN: We conducted a randomized controlled trial of nulliparous women presenting for induction at a single institution from December 2013 through March 2015. After decision for induction was made by their primary provider, women with gestational age ≥24 weeks with a nonanomalous, singleton fetus in vertex presentation with intact membranes were offered participation. Exclusion criteria included history of uterine surgery, unexplained vaginal bleeding, latex allergy, or contraindication to vaginal delivery. Participants were randomized to either simultaneous (oxytocin and Foley balloon) or sequential (oxytocin after expulsion of Foley balloon) induction group. The primary outcome was time from induction to delivery. Secondary outcomes included mode of delivery, estimated blood loss, postpartum hemorrhage, chorioamnionitis, and composite neonatal outcome. Maternal and neonatal outcomes were collected via chart review. Analyses were done on an intention-to-treat basis.

RESULTS: A total of 166 patients were enrolled; 82 in the simultaneous and 84 in the sequential group. There were no differences in baseline characteristics in the 2 groups. Patients who received simultaneous oxytocin with insertion of a Foley balloon delivered significantly earlier (15.92 vs 18.87 hours, $P = .004$) than those in the sequential group. There was no difference in rate of cesarean delivery, estimated blood loss, postpartum hemorrhage, chorioamnionitis, or composite neonatal outcome.

CONCLUSION: Simultaneous use of oxytocin and Foley balloon for induction of labor results in a significantly shorter interval to delivery in nulliparas.

Key words: Foley balloon, induction of labor, oxytocin

N=166
Randomized

Oxytocin+foley simultaneous:
16 hours

Foley 12 hrs (or expulsion) then oxytocin sequential:
19 hours

P=0.004

OBSTETRICS

Cervical ripening balloon with and without oxytocin in multiparas: a randomized controlled trial

Alison M. Bauer, MD; Justin R. Lappen, MD; Kimberly S. Gecsi, MD; David N. Hackney, MD, MS

BACKGROUND: The optimal method for induction of labor for multiparous women with an unfavorable cervix is unknown.

OBJECTIVE: We sought to determine if induction of labor with simultaneous use of oxytocin and a cervical ripening balloon, compared with sequential use, increases the likelihood of delivery within 24 hours in multiparous women.

STUDY DESIGN: We performed a randomized controlled trial from November 2014 through June 2017. Eligible participants were multiparous women with a vertex presenting, nonanomalous singleton gestation ≥34 weeks undergoing induction of labor. Women were excluded for admission cervical examination >2 cm, ruptured membranes, chorioamnionitis or evidence of systemic infection, placental abruption, low-lying placenta, >1 prior cesarean delivery, or contraindication to vaginal delivery. Patients were randomly allocated to the following cervical ripening groups: simultaneous (oxytocin with cervical ripening balloon) or sequential (oxytocin following cervical ripening balloon expulsion). The primary outcome was delivery within 24 hours of cervical ripening balloon placement. Secondary outcomes included induction-to-delivery interval, time to cervical ripening balloon expulsion, mode of delivery, and adverse maternal or neonatal outcomes.

RESULTS: In all, 180 patients were randomized (90 simultaneous, 90 sequential). Baseline demographic and obstetric characteristics were similar between study groups. Women in the simultaneous group were significantly more likely to deliver within 24 hours of cervical ripening balloon placement compared to the sequential group (87.8% vs 73.3%, $P = .02$). The simultaneous group also had a significantly shorter induction-to-delivery interval and greater cervical dilation at cervical ripening balloon expulsion. There were no differences in mode of delivery, chorioamnionitis, or adverse maternal or neonatal outcomes.

CONCLUSION: In multiparous women with an unfavorable cervix, the simultaneous use of cervical ripening balloon and oxytocin results in an increased frequency of delivery within 24 hours and a shorter induction-to-delivery interval.

Key words: cervical ripening balloon, Foley balloon, induction of labor, labor induction, multipara, oxytocin

N=180 pateints
Randomized

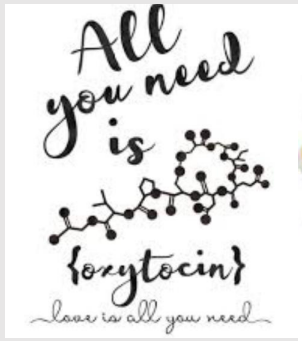
Delivery <24 hrs:

Oxytocin+balloon simultaneous: 88%

Balloon followed by oxytocin: 73%

P=0.02

Should oxytocin be started with the balloon placement or should it be held for ripening?
Start oxytocin with the placement of balloon for most efficient delivery timing



Misoprostol or oxytocin with or without balloon versus balloon followed by misoprostol or oxytocin

Misoprostol or oxytocin with or without balloon versus balloon followed by misoprostol or oxytocin

Do cervical ripening balloons improve induction time in women with PROM?

A randomized trial of Foley Bulb for Labor Induction in Premature Rupture of Membranes in Nulliparas (FLIP)

Jennifer M. H. Amorosa, MD; Joanne Stone, MD; Stephanie H. Factor, MD, MPH; Whitney Booker, MD; Meredith Newland; Angela Bianco, MD

BACKGROUND: In premature rupture of membranes (PROM), the risk of chorioamnionitis increases with increasing duration of membrane rupture. Decreasing the time from PROM to delivery is associated with lower rates of maternal infection. The American College of Obstetricians and Gynecologists suggests that all women with PROM who do not have a contraindication to vaginal delivery have their labor induced instead of being managed expectantly. Although the use of oxytocin for labor induction has been demonstrated to decrease the time to delivery compared with expectant management, no studies have evaluated the effectiveness of cervical ripening with a Foley bulb to additionally decrease the time to delivery.

OBJECTIVE: To determine whether simultaneous use of an intracervical Foley bulb and oxytocin decreases time from induction start to delivery in nulliparous patients with PROM compared with the use of oxytocin alone.

STUDY DESIGN: A randomized trial was conducted from August 2014 to February 2016 that compared the use of concurrent Foley bulb/oxytocin vs oxytocin alone in nulliparous patients ≥34 weeks' gestational undergoing labor induction for PROM. Our primary outcome was time from induction to delivery. Secondary outcomes were mode of delivery, tachysystole, chorioamnionitis, postpartum hemorrhage, Apgar scores, and admission to the neonatal intensive care unit.

RESULTS: A total of 128 women were randomized. Baseline characteristics were similar between groups. We found no difference in induction-to-delivery time between women induced with concurrent Foley bulb/oxytocin vs oxytocin alone (median time 13.0 hours [interquartile 10.7, 16.1] compared with 10.8 hours [interquartile range 7.8, 16.6], respectively, $P = .09$). There were no significant differences in mode of delivery, rates of postpartum hemorrhage, chorioamnionitis, or epidural use. Both groups had similar rates of tachysystole as well as total oxytocin dose. There were no differences in neonatal birth weight, Apgar scores, cord gases, or admissions to the neonatal intensive care unit.

CONCLUSION: This is the first randomized trial to compare concurrent Foley bulb/oxytocin vs oxytocin alone in nulliparous patients undergoing induction of labor for PROM. We found no difference in time from induction to delivery in patients induced with concurrent Foley bulb/oxytocin vs oxytocin alone. In nulliparous patients with PROM, this study suggests that addition of a Foley bulb to oxytocin does not decrease the time from induction start to delivery.

Key words: Foley bulb, induction of labor, labor induction, nulliparous, premature rupture of membranes, PROM

American Journal of Obstetrics & Gynecology SEPTEMBER 2017

N=128 women
Nulliparous

Foley+oxytocin (simultaneous): 13 hrs

Oxytocin: 11 hours

P=0.09

No difference:
Cesarean
PPH
Chorio
tachysystole

Original Research

Foley Plus Oxytocin Compared With Oxytocin for Induction After Membrane Rupture

A Randomized Controlled Trial

A. Dhanya Mackeen, MD, MPH, Danielle E. Durie, MD, Monique Lin, MD, Christopher K. Huls, MD, Emma Qureshey, MD, Michael J. Paglia, MD, PhD, Haiyan Sun, MS, and Anthony Sciscione, DO

OBJECTIVE: To evaluate the use of a transcervical Foley catheter plus oxytocin infusion compared with oxytocin infusion alone for labor induction and cervical ripening in women 34 weeks of gestation or greater with prelabor rupture of membranes.

METHODS: This is a randomized, multicenter trial of women with a live, singleton gestation at 34 weeks of gestation or greater with prelabor rupture of membranes, an unfavorable cervical examination (less than 2 cm or 80% effaced), and no contraindication to labor. Participants were randomly allocated to a transcervical Foley catheter inflated to 30 cc with concurrent oxytocin infusion or oxytocin infusion alone. Oxytocin administration was standardized across sites. The primary study outcome was interval from induction to delivery. To detect a 2.5-hour difference in the interval from induction to delivery, we required outcome data on 194 women, assuming 80% power and a two-tailed α of 5%. Analysis was by intent to treat.

RESULTS: We enrolled 201 women: 93 were allocated to Foley and 108 to oxytocin. Demographics were similar between the groups. Time to delivery was not significantly different between groups: in the Foley group, it was 13.9 hours (±6.9 SD) compared with 14.4 hours (±7.9 SD) in the oxytocin group (P=.69). There were more cases of clinical chorioamnionitis (8% compared with 0%, P<.01) in the Foley group compared with the oxytocin group. There were no differences for other infectious morbidities or any other variable studied.

CONCLUSION: In patients with prelabor rupture of membranes, the use of a transcervical Foley catheter in addition to oxytocin does not shorten the time to delivery compared with oxytocin alone, but may increase the incidence of intraamniotic infection.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, NCT01973036.

(Obstet Gynecol 2018;131:4–11)

DOI: 10.1097/AOG.0000000000002374

From the Department of Obstetrics and Gynecology, Division of Maternal-Fetal Medicine and Biostatistics Core, Geisinger, Danville, Pennsylvania; the Department of Obstetrics and Gynecology, Division of Maternal-Fetal Medicine, Lehigh Valley Health Network, Allentown, Pennsylvania; the University of Colorado School of Medicine, Aurora, Colorado; the University of Arizona College of Medicine, Phoenix at Banner University Medical Center, Phoenix, Arizona; and Christiana Care Health System, Newark, Delaware.

Both Geisinger and Lehigh Valley Health Network received small internal grants to assist with the conduct of the study at those individual sites. The internal grant at Geisinger was also applied for the statistical analyses for the entire study.

Presented at the 37th Annual Meeting of the Society for Maternal-Fetal Medicine, January 23–28, 2017, Las Vegas, Nevada.

The authors thank Natacha Antunes, Kristina Blessing, Ana Bodea Braescu, Dr Kendra Gray, Vicki Greenberg, Carrie Kitto, Dr Sandra Madueke-Laveaux, Gloria Mullen, Dr Roger Packard, Dr Trevor Quinor, Rachel Rodel, Duane Shaffer, Mallory Snyder, and Mary Sobotor for assisting with the conduct of

N=201 patients

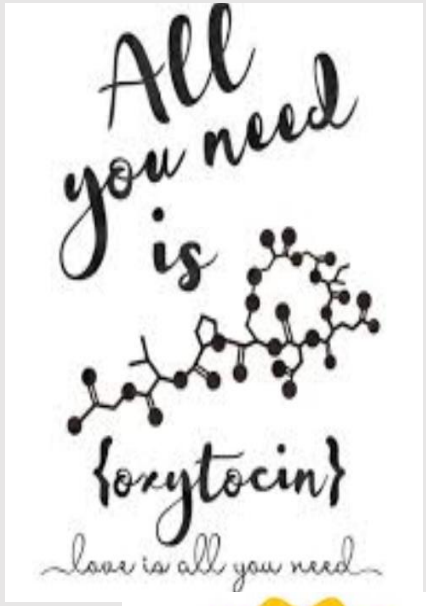
Foley+oxytocin (simultaneous): 14 hours

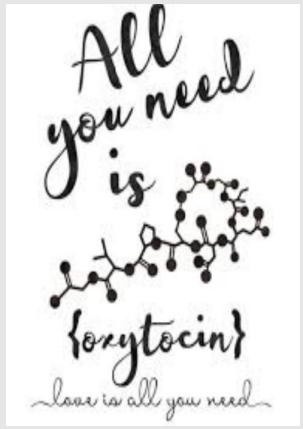
Oxytocin: 14 hours
P=0.69

Clinical chorio:
Increased with foley: 8% vs 0%

Foley may increase chorioamnionitis with PROM

Do cervical ripening balloons improve induction time in women with PROM?
NO: and might INCREASE intraamniotic infection





OBSTETRICS

Tension compared to no tension on a Foley transcervical catheter for cervical ripening: a randomized controlled trial

Gary Fruhman, MD; Jeffrey A. Gavard, PhD; Erol Amon, MD, JD; Kathleen V. G. Flick, MD; Collin Miller, MSW; Gilad A. Gross, MD

BACKGROUND: Cervical ripening of an unfavorable cervix can be achieved by placement of a transcervical catheter. Advantages of this method include both lower cost and lower risk of tachysystole than other methods. Despite widespread use with varying degrees of applied tension, an unanswered question is whether there is an advantage to placing the transcervical catheter to tension compared with placement without tension.

OBJECTIVE: The purpose of this study was to determine whether tension placed on a transcervical balloon catheter that is inserted for cervical ripening results in a faster time to delivery.

STUDY DESIGN: This was a prospective, randomized controlled trial; 140 women who underwent cervical ripening (Bishop score, ≤6) were assigned randomly to a balloon catheter with applied tension vs no tension. Tension was created when the catheter was taped to the patient's thigh and tension was reapplied in 30-minute increments. There were 67 patients in the tension group and 73 patients in the no tension group. Low-dose oxytocin (maximum, 6 mU/min) was administered after catheter placement. The primary outcome was time from catheter insertion to delivery. A secondary outcome was time from insertion to catheter expulsion. The Kolmogorov-Smirnov test was used to determine whether the data were distributed normally. Survival curves that used lifetables were constructed from time of catheter insertion to delivery and from time of catheter insertion to catheter expulsion and were compared with the use of the Wilcoxon (Gehan) Breslow statistic. A probability value of $<.05$ was set to denote statistical significance.

RESULTS: Baseline characteristics were similar between groups. The median time from catheter insertion to delivery was not significantly different between the tension group and the no tension group (16.2 vs 16.9 hours; $P=.814$). The median time from catheter insertion to expulsion, however, was significantly less in the tension group vs the no tension group (2.6 vs 4.6 hours; $P<.001$), respectively. Vaginal delivery within 24 hours was not significantly different between the tension and no tension groups (41/52 [79%] vs 37/52 [71%]; $P=.365$) nor were there significant differences in cesarean delivery rates between the tension and no tension groups (17/67 [25%] vs 27/73 [37%]; $P=.139$).

CONCLUSION: Application of tension did not result in faster delivery times but did result in faster times to catheter expulsion.

Key words: cervical ripening, Foley bulb, induction of labor, tension, transcervical catheter

Tension by taping to thigh (other trials hung a bag at end of bed)

Foley insertion to delivery:
Tension: 16 hrs
No tension: 16 hrs

Faster expulsion but not faster delivery

(other trials increased discomfort)

No need to apply tension to foley by tape or hanging

Double balloon versus foley (30 or 60 cc)

doi:10.1111/jog.13086 J. Obstet. Gynaecol. Res. Vol. 42, No. 11: 1489–1494, November 2016

Use of the Foley catheter versus a double balloon cervical ripening catheter in pre-induction cervical ripening in postdate primigravidae

Waleed Ali Sayed Ahmed, Zakia Mahdy Ibrahim, Osama Elsayed Ashor, Mariam Lotfi Mohamed, Magdy Refaat Ahmed and Amal Mohamed Elshahat

Department of Obstetrics and Gynecology, Faculty of Medicine, Suez Canal University, Ismailia, Egypt

Abstract

Aim: To compare the efficacy of two mechanical devices for pre-induction of labor cervical ripening: the Foley catheter and the Cook cervical ripening balloon.

Methods: This interventional study included 78 postdate primigravid women randomly allocated into two groups: the Foley or Cook balloon catheter. Removal of the catheters was planned approximately 12 h after insertion if spontaneous expulsion had not occurred. The main outcome measures included changes in Bishop score, insertion to delivery time, mode of delivery and occurrence of adverse effects.

Results: Spontaneous expulsion of the Foley catheter was encountered more frequently than the Cook (89.2% *vs* 78.4%; $P = 0.03$). However, the median Bishop score was significantly higher when using the Cook compared with the Foley catheter after balloon removal (6 *vs* 5; $P = 0.03$). The duration from balloon insertion to expulsion and from insertion to delivery was significantly shorter in the Foley group compared with the Cook balloon group (6:19 ± 2:1 *vs* 7:26 ± 2:25 h; $P = 0.03$ and 13:50 ± 4:00 *vs* 15:16 ± 4:30 h; $P = 0.03$, respectively). There were no significant differences in other outcomes, such as the amount of oxytocin units used, mode of delivery, pain encountered during or after insertion and overall patient satisfaction.

Conclusions: Use of the Cook cervical ripening catheter results in greater cervical ripening compared with the Foley catheter. However, the duration from balloon insertion to expulsion and then delivery were significantly shorter when using the Foley catheter; therefore, we recommend its use, particularly in low resource settings.

Key words: cervical ripening, Cook cervical ripening balloon, Foley catheter, induction of labor.

N=78
Nulliparous
All catheters removed at 12 hrs if not expelled

Spontaneous expulsion:
Foley: 89%
Double balloon: 78%
P=0.03

Bishop score:
Foley: 5
Double balloon: 6
P=0.03

Insertion to delivery:
Foley: 14 hrs
Double balloon: 15 hrs
P=0.03

No difference:
Cesarean
Oxytocin used
Pain; pt satisfaction

Journal of Perinatology (2018) 38:217–225
https://doi.org/10.1038/s41372-017-0005-7

ARTICLE

Comparison of single- and double-balloon catheters for labor induction: a systematic review and meta-analysis of randomized controlled trials

Raed Salim[1,2] · Naama Schwartz[3] · Noah Zafran[1,2] · Sivan Zuarez-Easton[1] · Gali Garmi[1,2] · Shabtai Romano[1,2]

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Abstract

Objective There is a paucity of head-to-head randomized trials that compare single- and double-balloon catheters, and the results of the available data in terms of time from catheter insertion to delivery and delivery mode are mixed. This meta-analysis of randomized controlled trials compares the efficacy of single- and double-balloon catheters in women undergoing labor induction.

Study design Searches were made in MEDLINE, EMBASE, PubMed, ClinicalTrials.gov, and the Cochrane Library from inception through June 2016. Peer-reviewed randomized and quasi-randomized trials that compared single- and double-balloon catheters head-to-head for cervical ripening or labor induction were identified. Eligible study populations consisted of women with singleton pregnancies that had any indication for labor induction and were randomly assigned to undergo induction with a single- or a double-balloon catheter. The primary outcome was time from catheter insertion to delivery and delivery mode. The secondary outcomes were intrapartum fever or chorioamnionitis, woman's satisfaction, and neonatal Apgar score.

Results Of the 520 records identified, five randomized trials (996 women; 491 with single-balloon and 505 with double-balloon catheters) were considered eligible and included in the meta-analysis. Time from catheter insertion to delivery did not differ between the two types of catheter ($p = 0.527$; WMD −0.87; 95% CI: −3.55, 1.82). The incidence of cesarean delivery also did not differ ($p = 0.844$; RR 0.97; 95% CI: 0.69, 1.35). Delivery within 24 h, delivery mode, incidences of intrapartum fever or chorioamnionitis, and neonatal Apgar score <7 at 5 min did not differ between the two types of catheter as well. Women who were induced with the single-balloon catheter were more satisfied ($p = 0.029$; WMD 0.56; 95% CI: 0.06, 1.06).

Conclusion Time from catheter insertion to delivery and delivery mode were comparable between the two types of catheter.

N=5 trials
N=996 patients

Insertion to delivery:
No difference

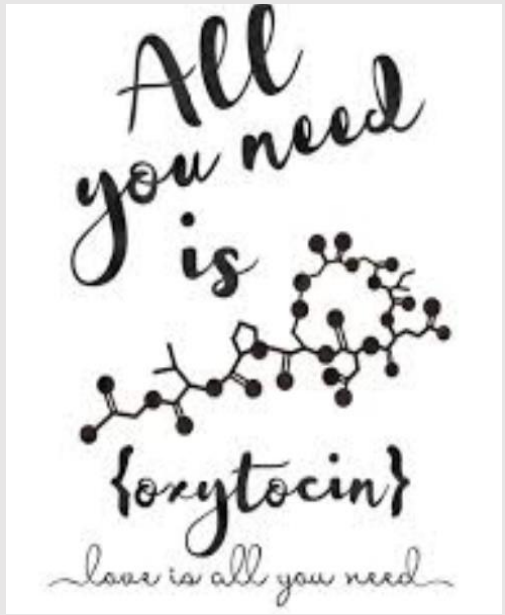
Cesarean:
No difference

No difference:
Deli very <24 hrs
Chorioamnionitis
Fever
Low APGAR

Foley: better patient satisfaction
(p=0.029)

Double balloon versus foley (30 or 60 cc)

Big Picture: multiple groups



Original Research

Mechanical and Pharmacologic Methods of Labor Induction

A Randomized Controlled Trial

Lisa D. Levine, MD, MSCE, Katheryne L. Downes, PhD, MPH, Michal A. Elovitz, MD, Samuel Parry, MD, Mary D. Sammel, ScD, and Sindhu K. Srinivas, MD, MSCE

OBJECTIVE: To evaluate the effectiveness of four commonly used induction methods.

METHODS: This randomized trial compared four induction methods: misoprostol alone, Foley alone, misoprostol–cervical Foley concurrently, and Foley–oxytocin concurrently. Women undergoing labor induction with full-term (37 weeks of gestation or greater), singleton, vertex-presenting gestations, with no contraindication to vaginal delivery, intact membranes, Bishop score 6 or less, and cervical dilation 2 cm or less were included. Women were enrolled only once during the study period. Our primary outcome was time to delivery. Neither patients nor health care providers were blinded to assigned treatment group because examinations are required for placement of all methods; however, research personnel were blinded during data abstraction. A sample size of 123 per group (n=492) was planned to compare the four groups pairwise ($P \leq .008$) with a 4-hour reduction in delivery time considered clinically meaningful.

RESULTS: From May 2013 through June 2015, 997 women were screened and 491 were randomized and analyzed. Demographic and clinical characteristics were similar among the four treatment groups. When comparing all induction method groups, combination methods achieved a faster median time to delivery than single-agent methods (misoprostol–Foley: 13.1 hours, Foley–oxytocin: 14.5 hours, misoprostol: 17.6 hours, Foley: 17.7 hours, $P<.001$). When censored for cesarean delivery and adjusting for parity, women who received misoprostol–Foley were almost twice as likely to deliver before women who received misoprostol alone (hazard ratio 1.92, 95% confidence interval [CI] 1.42–2.59) or Foley alone (hazard ratio 1.87, 95% CI 1.87 1.39–2.52), whereas Foley–oxytocin was not statistically different from single-agent methods.

CONCLUSION: After censoring for cesarean delivery and adjusting for parity, misoprostol–cervical Foley resulted in twice the chance of delivering before either single-agent method.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, https://clinicaltrials.gov, NCT01916681.

From the Maternal and Child Health Research Program, Department of Obstetrics & Gynecology, and the Department of Biostatistics and Epidemiology, Center for Clinical Epidemiology and Biostatistics, and Women's Health Clinical Research Center, University of Pennsylvania Perelman School of Medicine, Philadelphia, Pennsylvania.

(Obstet Gynecol 2016;128:1357–64)
DOI: 10.1097/AOG.0000000000001778

N=491

4 groups:

Miso alone
Foley alone
Miso+foley (simultaneous)
Foley+Oxytocin (Simultaneous)

Using foley with uterotonic worked faster than uterotonic alone
(M+F: 13 hrs; F+O: 15 hrs
M:18 hrs; F: 18 hrs)

Miso+foley more likely to deliver <24 hrs compared to miso alone or foley alone

Foley+oxytocin no different from miso alone or foley alone

Big Picture: multiple groups

BUNDLE IS BETTER

Where are we with inductions in 2019:

- We should discuss induction at 39 weeks in low risk women:
- not mandate or even recommend; simply offer as an option

- We should not have policies that forbid induction at 39 weeks

- Patients still need to be prioritized for induction and low risk is still low risk

- The most efficient induction methods include balloon placement (foley or double balloon) simultaneously with uterotonic (oxytocin or miso): modest shortening; no improvement in cesarean

Big Picture: multiple groups

BUNDLE IS BETTER

Questions?

This webinar was recorded and will be available to view within 5 days at vchipobstetrics.org

OB/GYN Webinar Series 2018-2019
Upcoming Webinar:

-**April 18th, 2019 @12:15pm** Acute Pain Control for Opioid Dependent Patients following delivery &VT Dept. of Health Topic

-**May 14th, 2019 @ 12:15pm** Venous Thromboembolism and Pulmonary Embolism & VT Dept. of Health Topic

-**June 11, 2019 @ 12:15pm** Severe Maternal Morbidity & VT Dept. of Health Topic

To Register visit: vchipobstetrics.org

Contact: Amanda.slater@uvmhealth.org

Thank you!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