Promoting Primary Vaginal Deliveries Initiative

The Safety and Benefits of Outpatient Cervical Ripening: An "Old Technique" for Modern Times

David C. Lagrew, Jr., M.D.

PROVIDE Collaborative Session Webinar
Partnering to Improve Health Care Quality
for Mothers and Babies

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Agenda

December 13, 2018

- The Safety and Benefits of Outpatient Cervical Ripening: An "Old Technique" for Modern Times

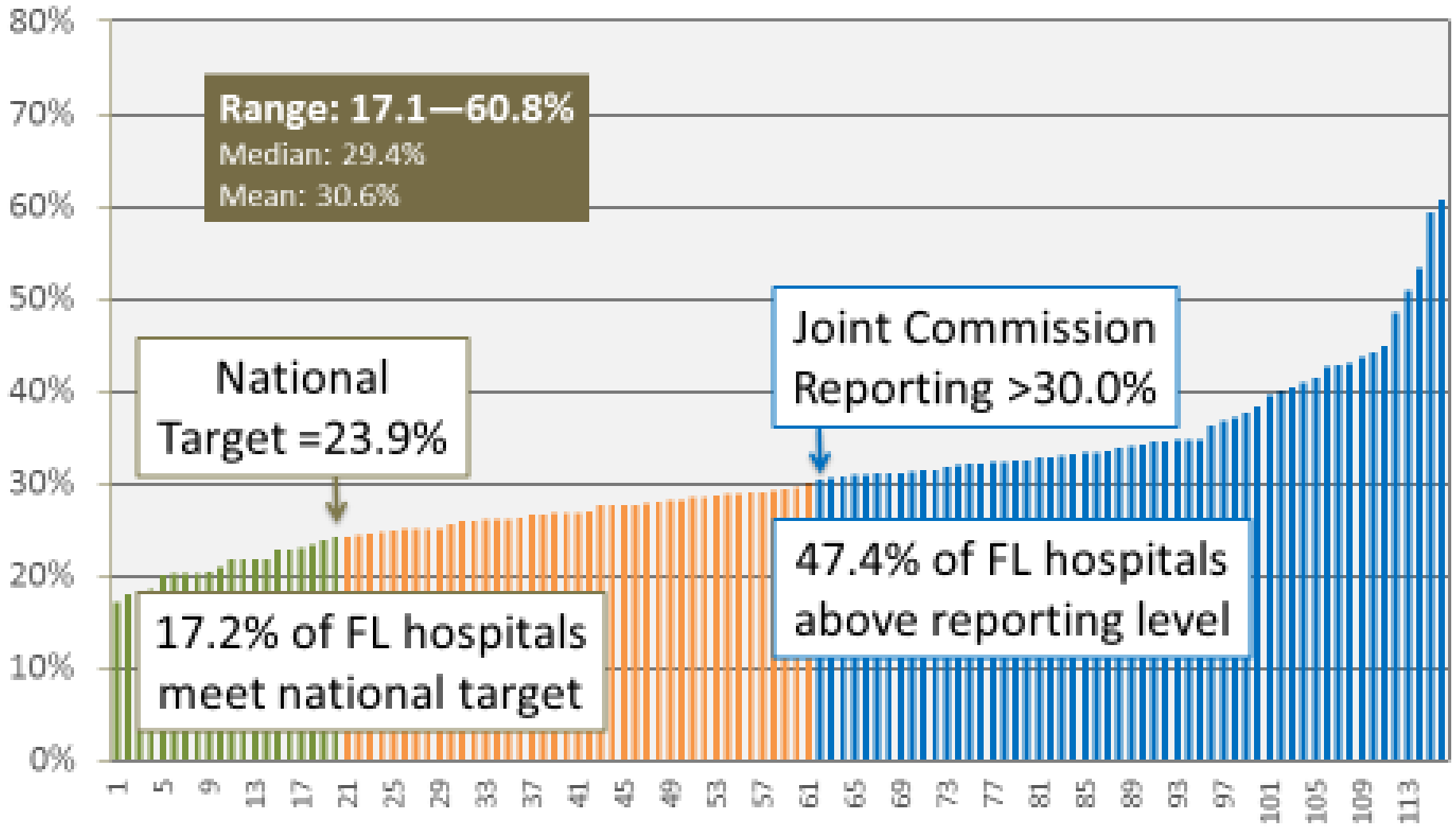
Objectives:

- Describe process for selecting candidates for outpatient cervical ripening
- Describe tools and procedures used
- Discuss ways to overcome barriers to implementation
- Discuss safety and benefits

*Pro*moting Primary *V*aginal *De*liveries (PROVIDE) Initiative

- Stakeholders across Florida and the U.S. have noted increasing primary cesarean delivery rates, that impact morbidity, mortality, and health care costs.
- Launched October 2017 with 42 hospitals, will be offered to additional hospitals and extended through June 2021.
- The goal is to improve maternal and newborn outcomes by applying evidence-based interventions to promote primary vaginal deliveries at Florida delivery hospitals and reduce Nulliparous Term Singleton Vertex Cesareans for low risk women.
- Offers initiative participants resources via On-Site Consultation, Webinars, Website Resources, Telephonic and Electronic Technical Assistance, and Data Reporting.

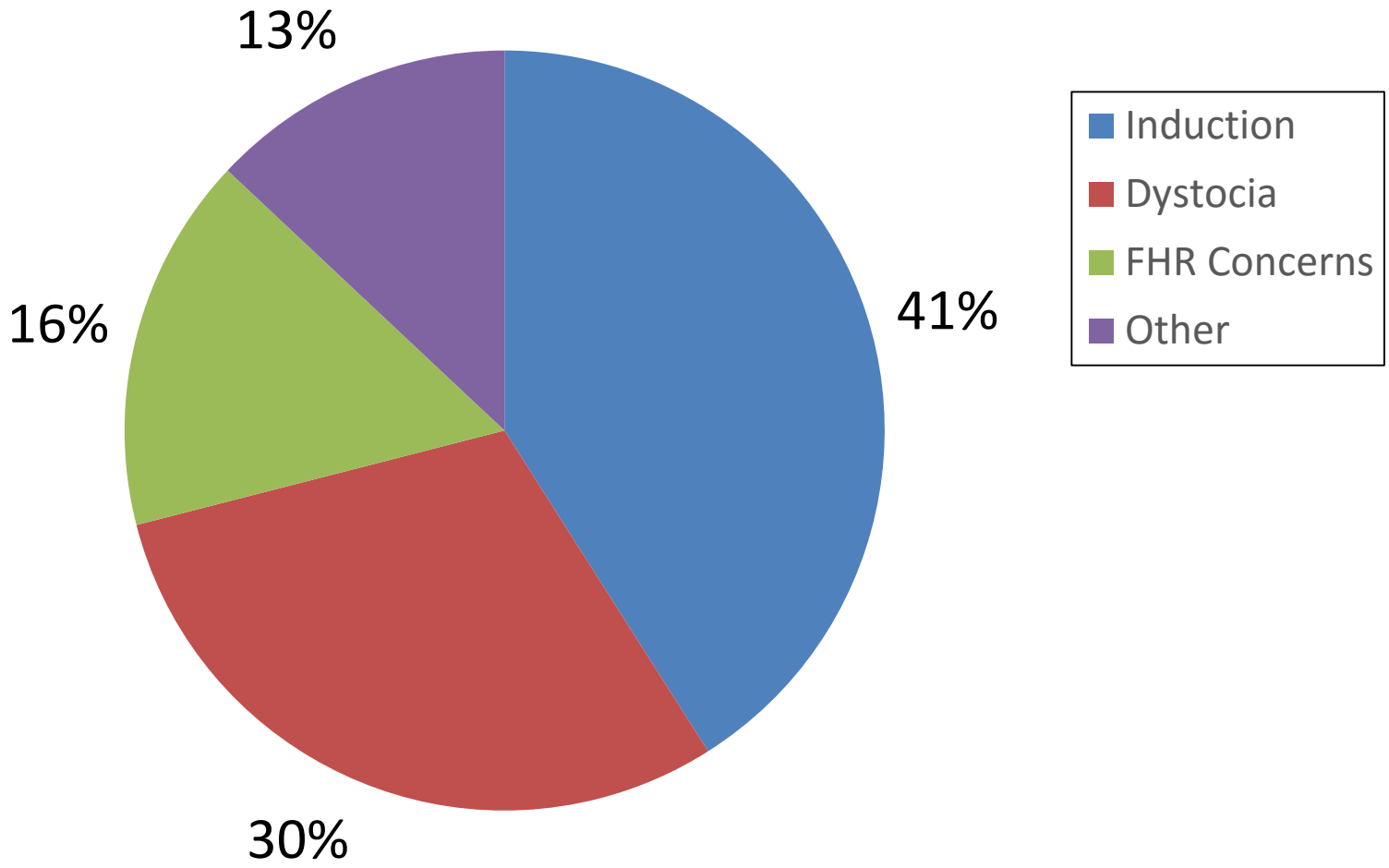
2017 NTSV Cesarean Rates, 116 FL Hospitals



Source: FL Vital Records, 2017

Partnering to Improve Health Care Quality for Mothers and Babies

PROVIDE Baseline Data: NTSV Cesarean Deliveries Performed Not Meeting Criteria by Category



*Other: cases in the Induction and Labor Dystocia categories where the cervical dilation at the time of delivery is unknown. Also cases in FHRC category where the FHRC category was Other

Inductions Present Challenges

- Largest focus areas in the PROVIDE initiative
- Hospitals report a wide range of induction policies
- Failed inductions are frustrating for everyone
- Frequent requests for evidence-based tools and methods related to induction

David C. Lagrew Jr. M.D.

- Regional Exec. Medical Director, Women's & Children's Institute Providence St. Joseph Health-Southern California
- Board Certified OB/GYN with specialty in Maternal/Fetal Medicine
- President, Pacific Coast OB/GYN Society
- Member CMQCC Exec. Committee and serves on several of their expert panels
- Co-authored National Bundle for Safe Reduction of Primary Cesarean Births
- Numerous publications and national presentations

The Safety and Benefits of Outpatient Cervical Ripening

An “Old Technique” for Modern Times

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Regional Executive Medical Director

Women’s and Children’s Institute PSJH-SoCal

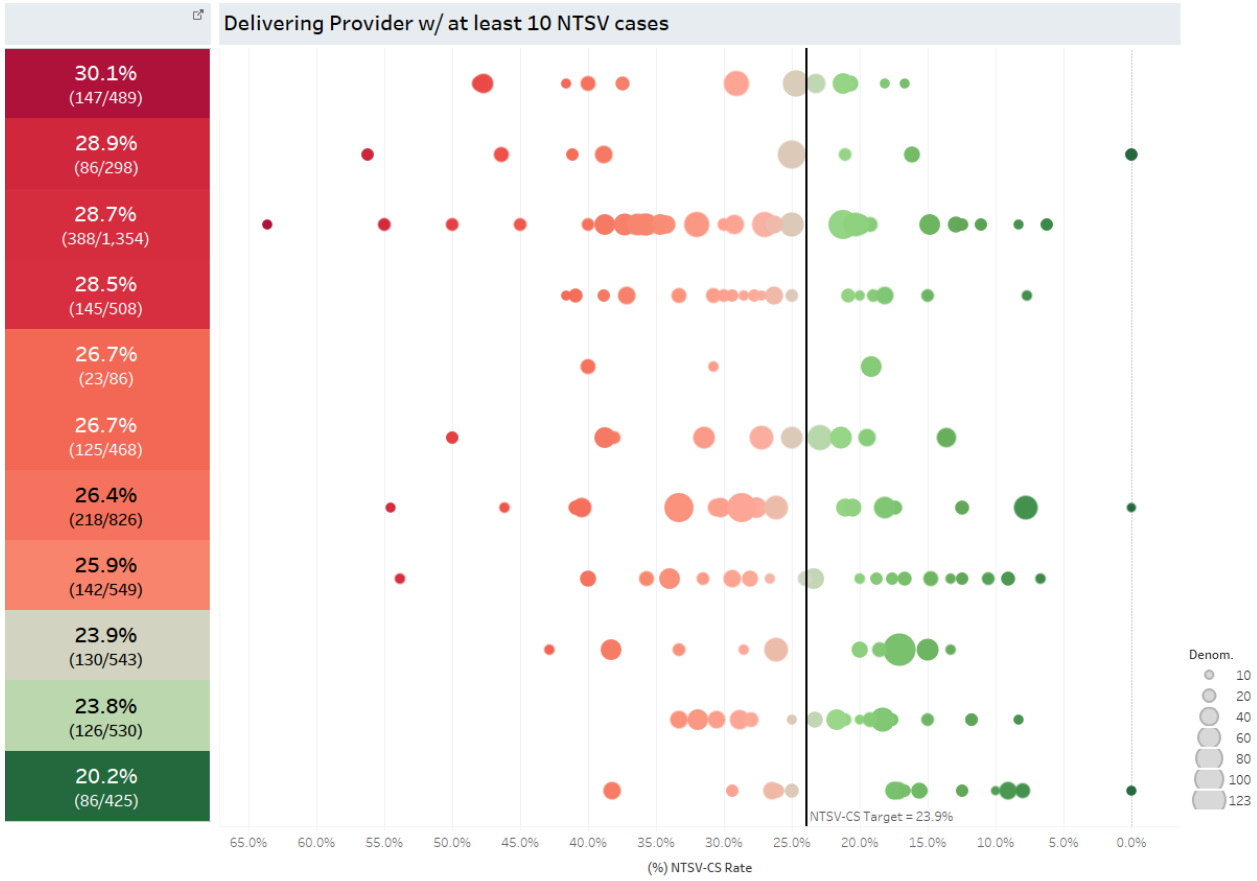
Providence St. Joseph Health

I have no conflicts to disclose

On the road to shorter, easier, safer and more successful labors

BACKGROUND

Year to date-We have a lot of variation!



Length of First Stage of Labor and Complications

- Of the 10,661 nulliparous women meeting study criteria, the median (50th percentile) length of the first stage was 10.5 hours.
- Compared with women with a first stage between 2.8 and 30 hours (5th to 95th percentile thresholds), the risk of cesarean delivery was higher (6.1% compared with 13.5%; adjusted odds ratio [OR], 2.28, 95% confidence interval [CI], 1.92-2.72) in women with a first stage longer than 30 hours (greater than the 95th percentile).
- These women also had higher odds of chorioamnionitis (12.5% compared with 23.5%; adjusted OR, 1.58; 95% CI, 1.25-1.98) and neonatal admission to the neonatal intensive care unit (4.7% compared with 9.8%; adjusted OR, 1.53; 95% CI, 1.18-1.97) but no other associated adverse neonatal outcomes.

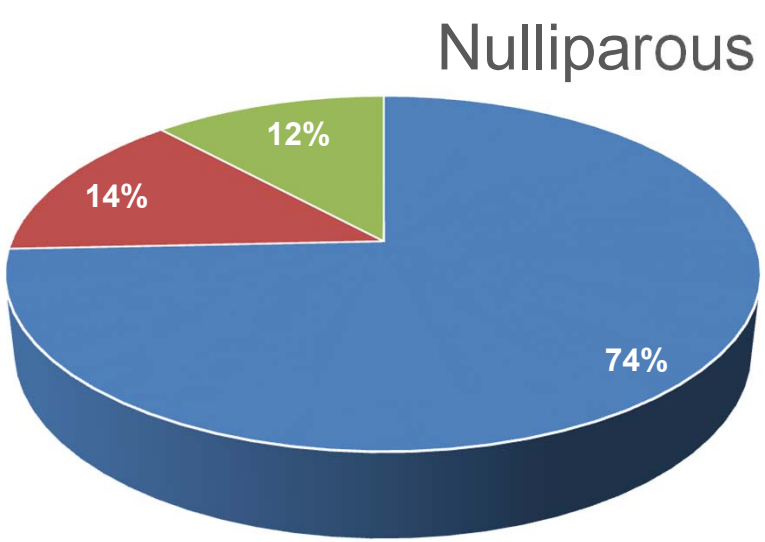
Cheng Y et al, Obstet Gynecol. 2010 Nov;116(5):1127-35.

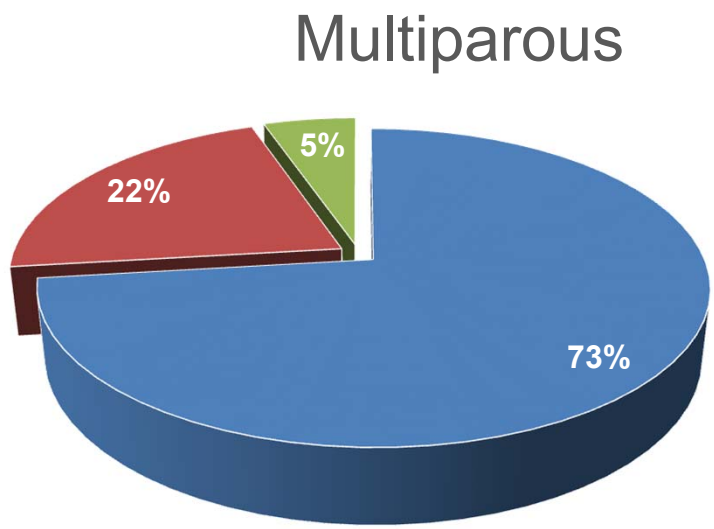
TTD = Time of Delivery – Time of Admission

Decreasing TTD should decrease complications and costs!

Nuance: Need to correct for antepartum patients or protracted diagnoses patients

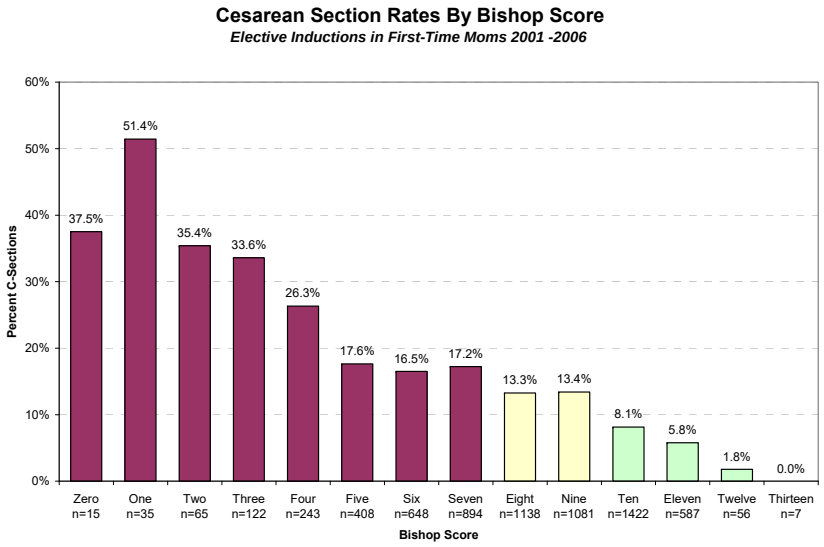
Breakdown by Labor Type



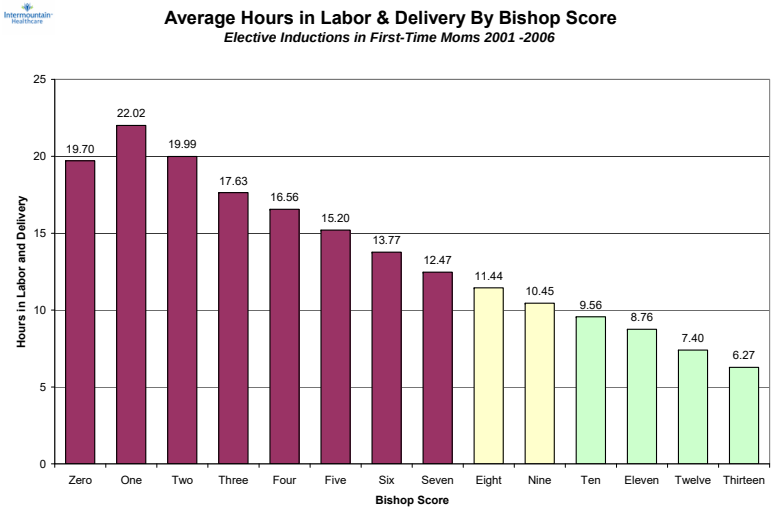


- Spontaneous
- Ind with Ripening
- Ind without Ripening

Providence St.Joseph Health

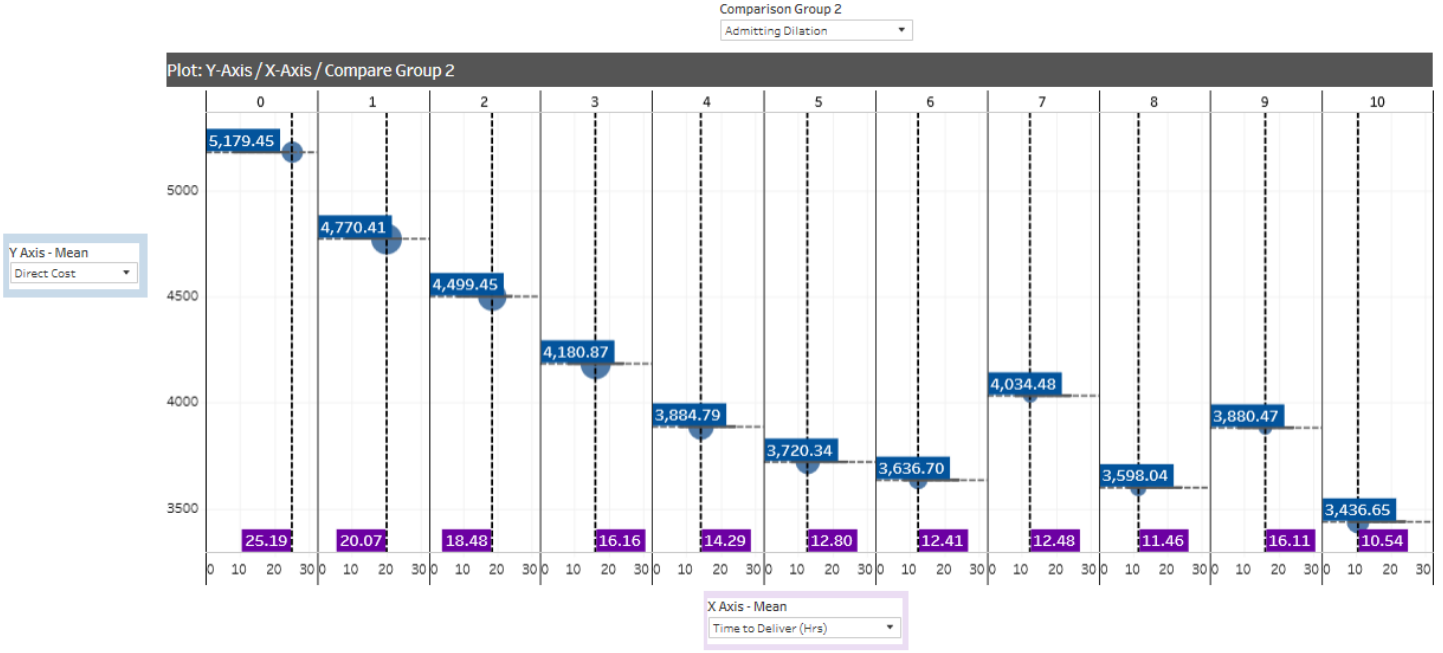


Intermountain® Healthcare



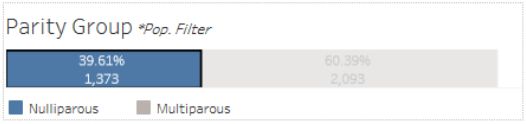
Other's results are similar!

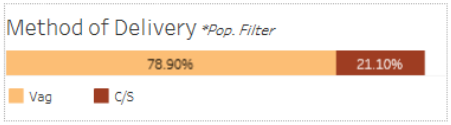
TTD v. Admitting Dilation v. Direct Cost – Nulliparous View



Volume By Cmpare Group 2

Compare Gr..	Select Level	0	1	2	3	4	5	6	7	8	9	10
Grand Total		47	99	84	95	66	61	37	23	28	19	52
	SJHS Legacy	47	99	84	95	66	61	37	23	28	19	52





	<4	>/= 4
Avg. Direct Cost	$4,587.21	$3,719.82
Avg. TTD (Hours)	19.26	12.75

Providence St. Joseph Health

PSJH OC/HD Service Area (n=8,022)

	Spontaneous Labor	Induced without PG	Induced with PG
Nulliparous TTD (hours)	13	17	23
Nulliparous CSR	17.3%	26.1%	32.9%
Multiparous TTD (hours)	7	12	16
Multiparous CSR	5.1%	5.0%	8.8%

ARRIVE TRIAL

Should we be inducing everyone at 39 weeks?

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.

N Engl J Med 2018;379:513-23.
DOI: 10.1056/NEJMoa1800566

Cost Containment to Buffer Added TTD for elective inductions

1) Strict scheduling process and careful review of clinical data to limit burden
2) LEAN processes of induction to assure admission with complete information, timely start to oxytocin
3) Outpatient cervical ripening in patients whom appropriate (since these are low risk should be majority of patients)
4) Active management of labor with prompt augmentation for arrest disorders

Two Major Strategies to Reduce TTD

- AVOIDING LATENT PHASE ADMISSIONS
  - Key Strategy: Standard protocol for not admitting patient prior to 4 cm without maternal or fetal indication when presenting in latent phase.
  - Associated changes: Scripted SBAR communications with MD, patient support tools/plans, associated education
- OUTPATIENT CERVICAL RIPENING
  - Key Strategy: Utilization of balloon cervical ripening instead of PG for patients without maternal or fetal indication.
  - Associated changes: Tags onto scheduling processes, education of providers, induction workflow improvement, changes in CPN to track type of cervical ripening.

Committee Opinion 687: Latent Phase Admission

- Observational studies have found that admission in the **latent phase of labor is associated with more arrests and cesarean deliveries in the active phase and with an increase in the use of oxytocin, intrauterine pressure catheters, and antibiotics for intrapartum fever.**
- A randomized controlled trial (RCT) that compared admission at initial presentation to the labor unit (immediate admission) versus admission when in active labor (delayed admission) **found that those allocated to the delayed admission group had lower rates of epidural use and augmentation of labor, had greater satisfaction, and spent less time in the labor and delivery unit.** Although there were no significant differences between study groups in operative vaginal or cesarean deliveries or newborn outcomes, the study was underpowered to assess these outcomes

Obstet Gynecol VOL. 129, NO. 2, FEBRUARY 2017

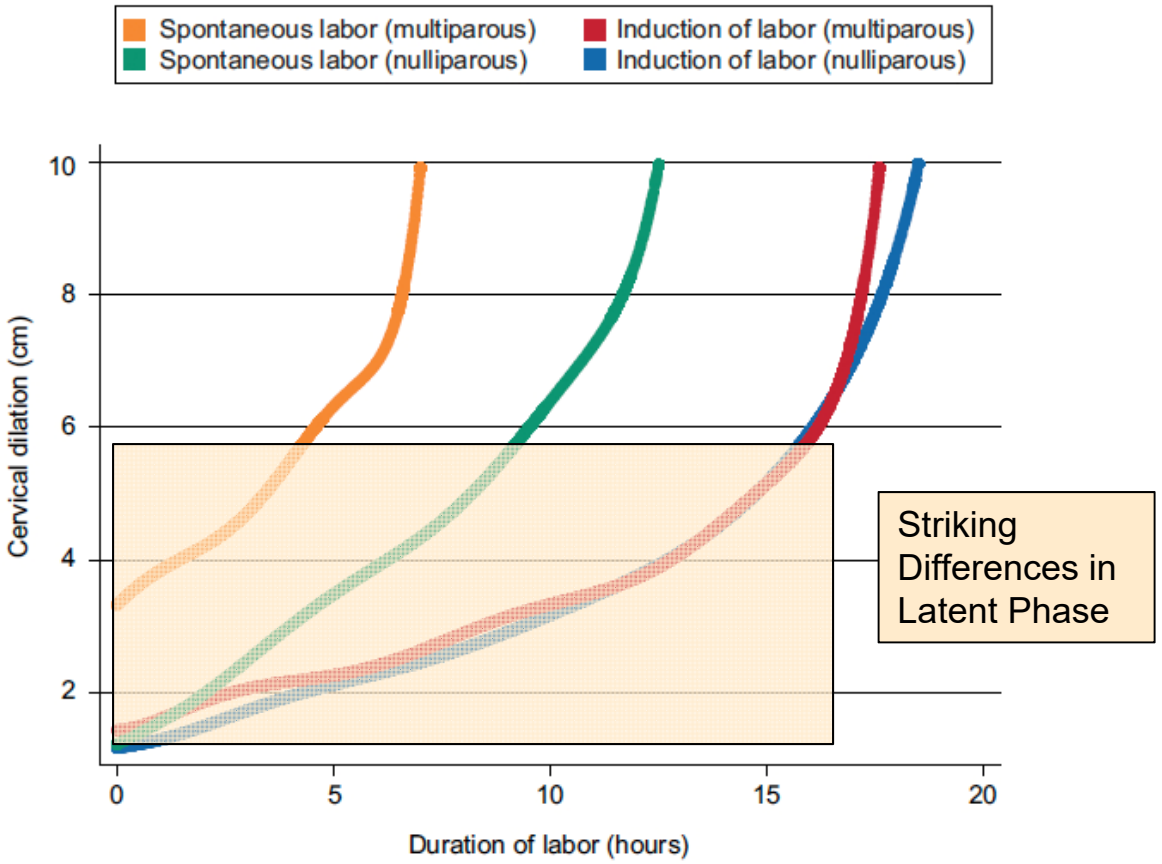


Fig. 1. Average labor curves stratified by parity and type of labor onset.

Harper. Normal Labor in Induction. Obstet Gynecol 2012.

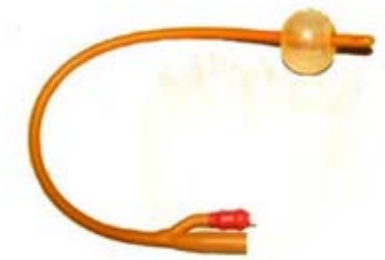
23

Why reduce latent phase admissions?

- The length of latent phase can be measured in hours and days.
- It is the most variable time of “labor”
- New labor curve guidelines of using 6 cm as the start of active phase means that several hours of latent phase have been added.
- Studies in labors with reassuring maternal/fetal screening show no medical benefit for patients.
- Perceived length of labor is increased and admissions in early latent phase can lead to “unnecessary augmentations/inductions”.
- Requires reeducation of staff, providers and patients.

CERVICAL RIPENING

Cochrane Review: Mechanical methods for induction of labor



- **Mechanical methods results in similar cesarean section rates as prostaglandins**, ***with a lower risk of hyper-stimulation***.
- Mechanical methods do not increase the overall number of women not delivered within 24 hours, (exception-multiparous women had lower rates of vaginal delivery within 24 hours when compared with vaginal PGE2.
- Compared with oxytocin, mechanical methods reduce the risk of cesarean section.

Jozwiak et al Cochrane Database Syst Rev. 2012 Mar 14;(3):CD001233.

What if outpatient?

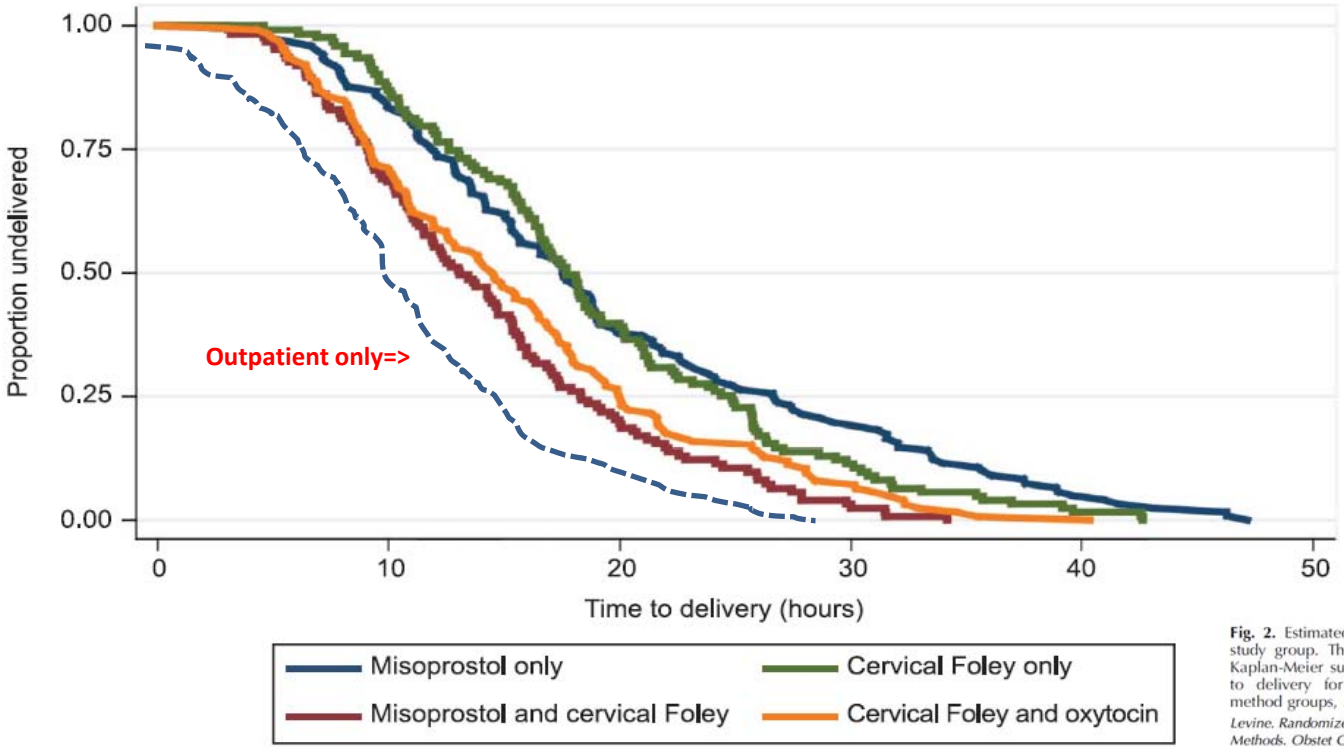


Fig. 2. Estimated time to delivery by study group. This figure displays the Kaplan-Meier survival curves for time to delivery for the four induction method groups, $P<.001$.

Levine. Randomized Trial of Four Induction Methods. Obstet Gynecol 2016.

Why outpatient balloon cervical ripening?

- Reduces the perceived length of the induction for patient, staff and providers.
- By reducing cost and burden can use more liberally and therefore increase ripening which theoretically reduces lengths of labor and cesarean section.
- Studies show a reduction of 9 hours in labor and delivery and patients sleep 5 hours longer.
- Downside: Burden on MD office/clinic, may lead to more elective inductions by making easier.

TABLE 1 Comparison of Foley balloon to other methods of cervical ripening/ induction (prostaglandin and oxytocin)

	FB vs PG		FB vs Oxytocin		FB+PG vs PG	
	RR	95% CI	RR	95% CI	RR	95% CI
Cesarean delivery	1.01	0.90–1.13	0.57*	0.38–0.88*	0.92	0.79–1.08
No vaginal delivery within 24 hours	1.26	0.94–1.68	NA	NA	0.45*	0.28–0.71*
Hyperstimulation without FHR change	0.19*	0.08–0.43*	0.20	0.01–4.11	0.53*	0.35–0.78*

*Significant results
Abbreviations: FB, Foley balloon; PG, prostaglandin; RR, relative risk

Contemporary OBGYN The transcervical Foley balloon
Tania F. Esakoff, MDSarah J. Kilpatrick, MD, PhD Nov 1, 2013

PATIENT HANDOUT

If your doctor recommends a transcervical Foley balloon for induction

BY TANIA F. ESAKOFF, MD,
AND SARAH J. KILPATRICK, MD, PHD

Why does my doctor want to use a Foley balloon?

The Foley balloon is one of the methods currently used to help dilate the cervix and prepare it for labor.

Is the balloon painful?

Although every individual has a different pain threshold, most patients don't consider the balloon painful and tolerate the insertion well.

Is it safe for my baby?

The Foley balloon is thought to be a safe method of cervical ripening.

I've heard of Pitocin being used to induce labor. Why does my doctor want to use a Foley balloon instead?

Foley balloons help soften and dilate the cervix in preparation for labor. Oxytocin (also known as Pitocin) causes uterine contractions.

How soon after the Foley balloon is inserted can I expect to deliver?

The exact time of delivery after induction differs from patient to patient. Most women deliver within 24 hours of insertion of the Foley balloon.

TABLE 3 **Cost comparison of various cervical ripening methods**

Device	Foley balloon	Cook balloon	Misoprostol (100 mcg)	Dinoprostone vaginal insert (10 mg)
Price	$3.00	$41.00	$1.09	$218.94

30 ml versus 60 ml Balloon

Table 2. Labor, Delivery, and Neonatal Outcomes

	30-mL Balloon	60-mL Balloon	*P*
Labor and delivery			
Time to expulsion of FB* (h)	3.1 (1.9–5.8)	3.9 (2.4–6.5)	.068
Dilation after expulsion (cm)*	3 (3–4)	4 (3–4)	<.01
Time to active labor (h)*	10.4 (6.5–19.3)	10.5 (5.3–16.3)	.44
Delivery time (h)*	20.0 (13.9–30.0)	18.8 (12.0–27.1)	.37
Delivery within 12 h	13 (14)	25 (26)	.04
Delivery within 24 h	60 (64)	65 (66)	.72
Delivery method			
SVD	62 (66)	62 (63)	.71
Vacuum-assisted vaginal	3 (3)	6 (6)	
Forceps-assisted vaginal	9 (10)	7 (7)	
Cesarean	20 (21)	23 (23)	

Delaney et al Labor Induction With a Foley Balloon Obstet Gynecol VOL. 115, NO. 6, JUNE 2010

Double Balloon vs. Single Balloon Meta-Analysis

- 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).

Salim R et al. J Perinatol. 2018 Mar;38(3):217-225.

Double Balloon vs. Single Balloon Meta-Analysis

- To compare the efficacy of single- versus double-balloon catheter (SBC vs. DBC) for cervical ripening and labor induction with an unfavorable cervix.
- Regardless of parity, pooled analyses of the six trials (n = 1060 women) found that mean intervention to birth time, vaginal delivery and cesarean section rates, and maternal satisfaction to the procedure were similar for both studied groups (SBC vs. DBC).
- Measured primary outcome measures were similar regardless of the type of device used for labor induction of singleton pregnancies.

Lajusticia H et al. Arch Gynecol Obstet. 2018 May;297(5):1089-1100.

Double Balloon vs. Single Balloon Meta-Analysis

- Searched Embase, PubMed and the Cochrane Library for randomized or quasi-randomized controlled trials to compare the use of single-balloon to double-balloon catheters.
- There were no significant differences in the rate of cesarean (RR 1.09, 95% CI 0.86, 1.38; P = 0.48), or vaginal deliveries within 24 h (RR 0.94, 95% CI 0.82, 1.09; P = 0.42), the mean time to delivery (MD 0.39, 95% CI -0.90, 1.68 h; P = 0.55) or Bishop score improvement (MD 0.62, 95%CI -0.18, 1.42; P = 0.13) between the groups.
- The Foley catheter is significantly cheaper, widely available and accessible, has a longer history of use and remains the logical choice over the double-balloon catheter for cervical ripening.

Yang F et al. J Obstet Gynaecol Res. 2018 Jan;44(1):27-34.

IS IT SAFE TO RIPEN THE CERVIX WITH A BALLOON OUTPATIENT?

Conservative View (Looking at all ripening methods)

- Induction of labor is one of the most commonly performed obstetric procedures. Many patients undergoing labor induction require **cervical ripening**. In an era where cost and patient satisfaction have become paramount, the idea of **outpatient cervical ripening** is appealing; provided it can be performed in a safe and cost effective manner. The ideal agent would induce adequate **cervical ripening** without causing significant uterine contractions/labor. Various methods have been studied including administration of misoprostol, PGE2, nitric oxide donors, use of Foley balloon catheters and acupuncture. Each method has its strengths and limitations; however, larger studies of **outpatient cervical ripening** that are specifically powered for rare adverse maternal and fetal outcomes are needed before definitive recommendations can be made.

Amorosa, Jennifer M.H.; Stone, Joanne L. SEMIN PERINATOL, Oct 2015; 39(6): 488-494.

Up-to-Date Latest on Balloon Catheter

- There are **no absolute contraindications** to mechanical methods of cervical ripening in women who are candidates for labor and vaginal delivery. A **low-lying placenta is a relative contraindication** since the edge of the placenta may be disrupted by manipulation during placement of the device.
- Some practitioners do not place mechanical devices for cervical ripening in women with ruptured membranes, some remove the device if membranes rupture at any time after placement, and others limit the duration of cervical ripening to 12 hours if membranes rupture after placement. While there is not total consensus on optimal management in this setting, the package insert for the Cook Cervical Ripening Balloon lists ruptured membranes as a contraindication to placement and an indication for deflation and removal.
- **Mechanical methods of cervical ripening do not cause systemic side effects** and are associated with a lower rate of tachysystole than prostaglandins.
- **Oxytocin can be started concurrently** or after the catheter has been extruded or removed.

Obtained 10/16/2018 From <https://www.uptodate.com/contents/techniques-for-ripening-the-unfavorable-cervix-prior-to-induction?search=cervical%20ripening%20balloon&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#references>

Up-to-Date Latest on Outpatient Balloon Catheter

- Investigators in the United States have reported that outpatient pre-induction cervical ripening using a balloon catheter can be safely performed in properly selected patients [43,44,80]. The procedure has been limited to low-risk women with a singleton, live, vertex fetus at ≥37 weeks of gestation; exclusion criteria have included previous cesarean delivery, gestational hypertension or preeclampsia, pregestational diabetes, fetal growth restriction, rupture of membranes, and factors that could preclude prompt return to the hospital in the event of a problem.

Obtained 10/16/2018 From <https://www.uptodate.com/contents/techniques-for-ripening-the-unfavorable-cervix-prior-to-induction?search=cervical%20ripening%20balloon&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#references>

Adverse Event Frequency

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

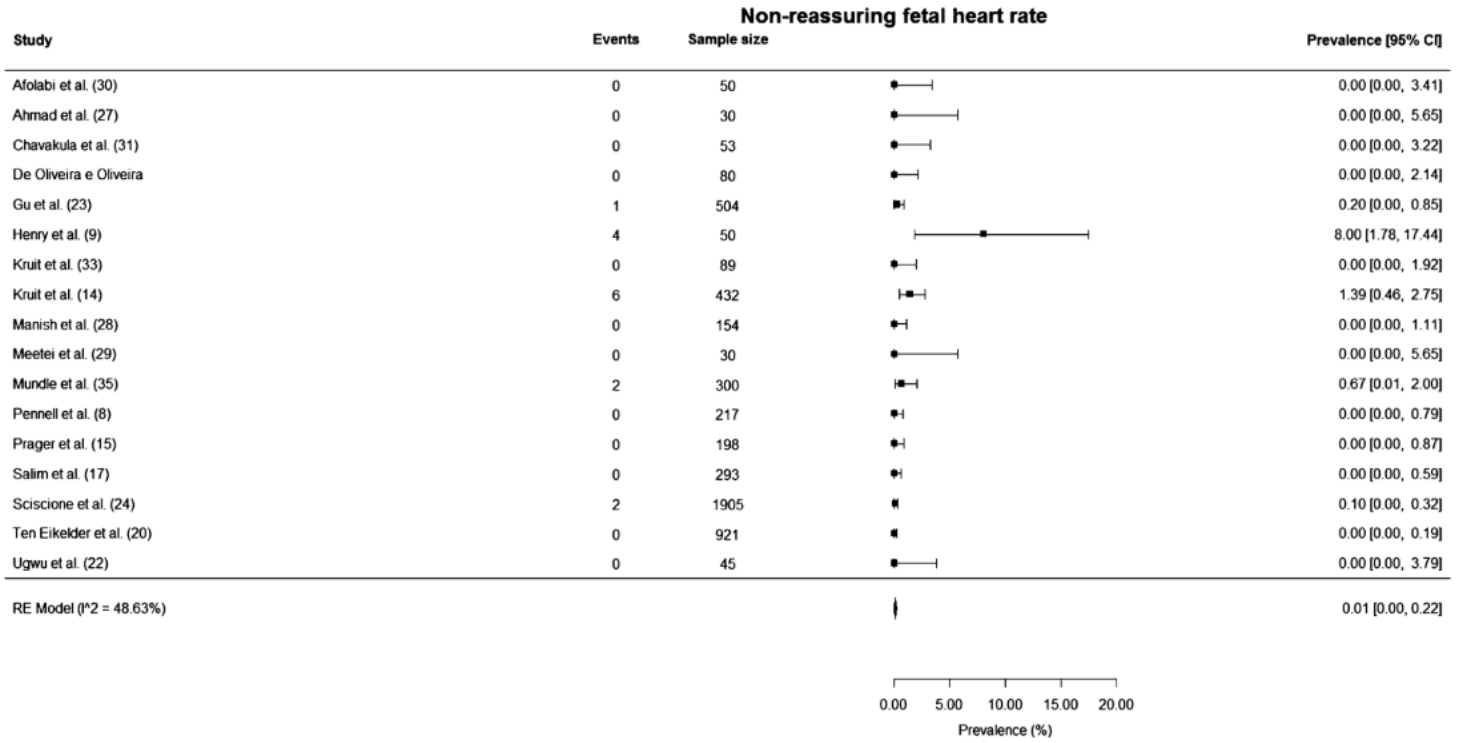
Adverse events	No. of studies reporting on adverse event (Total sample size)	Occurrence of AE in ripening period	Reference numbers of studies that report on occurrence of AE in ripening period
Pain, discomfort	17 (5754)*, ***	31***	10,14–17,22
Unintended amniotomy	12 (2989)	19	18,19
Vaginal bleeding	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.

Event	
Pain	**1:185**
Bleeding	**1:364**
Rupture of Membrane	**1:157**
NRFHR	**1:365**
Uterine Hypertonus	**1:3,707**
Tachysystole	**1:4,812**
Fetal Death	**0:8189**

Diederen,M., et al BJOG 2018; 125:1086-95.

NRFHR Limited to a few studies



Diederen,M., et al BJOG 2018; 125:1086-95.

40

NRFHR with Balloon Ripening

Table 1 Main indication for IOL ($n = 432$)

	n	Percent
Post-term pregnancy	266	61.6
Pre-eclampsia/hypertension	56	13
Intrauterine growth restriction	23	5.3
Gestational diabetes	29	6.7
DM I	3	0.6
Oligohydramnion	19	4.4
Obstetric cholestasis	16	3.7
Maternal disease[a]	3	0.6
Foetal disease[b]	4	1
Psychosocial reasons[c]	3	0.6
Decreased foetal movement	6	1.4
LGA	4	0.9

DM I diabetes mellitus type 1, *LGA* large for gestational age
[a]Back pain, heart transplantation, difficulty urinating, ulcerative colitis
[b]Heart malformation, Catc-22 h, suspected distress
[c]Maternal exhaustion, fear of labour, maternal preference

- **METHODS:**
- This clinical retrospective study of 432 nulliparous women with singleton pregnancy and intact amniotic membranes at or beyond 37 gestational weeks scheduled for induction of labour by Foley catheter was conducted over the course of one year, between January 2012 and January 2013, in Helsinki University Hospital. The main outcome measures were caesarean section rate and maternal and neonatal infections. Univariate and multivariate logistic regressions were used to estimate relative risks by odds ratios with 95% confidence intervals.
- **RESULTS:**
- The caesarean section rate was 39.1% (n = 169). In multivariate regression analysis, the factors associated with caesarean section were the need for oxytocin for labour induction [OR 2.9 (95% CI 1.8-4.5) p < 0.001] and early epidural analgesia [OR 9.9 (95% CI 2.1-47.5), p = 0.004]. The maternal intrapartum infection rate was 6.3%, and the clinical neonatal infection rate was 2.8%. In multivariate analysis, gestational diabetes was associated with maternal intrapartum infection [OR 4.3 (95% CI 1.7-11.0, p = 0.002] and early epidural analgesia with neonatal clinical sepsis [OR 10.5 (95% CI 1.4-76), p = 0.02].

Kruit H, et al Management of Foley catheter induction among nulliparous women: a retrospective study. BMC Pregnancy Childbirth. 2015 Oct 27;15:276.

Is monitoring necessary?

- No biologic plausibility and cost is an issue to discuss
- *Clearly if the patient has an indication for FHR monitoring they should have NST.*
- Debatable for low risk patients since data and experience suggest risk of stillbirth or bad outcome extremely low
- Risk of random stillbirth 39-41 weeks
  - (1/2000 SB/week / 7 days/week * 0.5 days) = 1/28,000 rate (NNT = 28,000)
  - Assumes monitoring would have prevented the stillbirth
- Cost $28 M for one hour strip or $336 M for continuous

42

TECHNIQUE AND TIPS

43

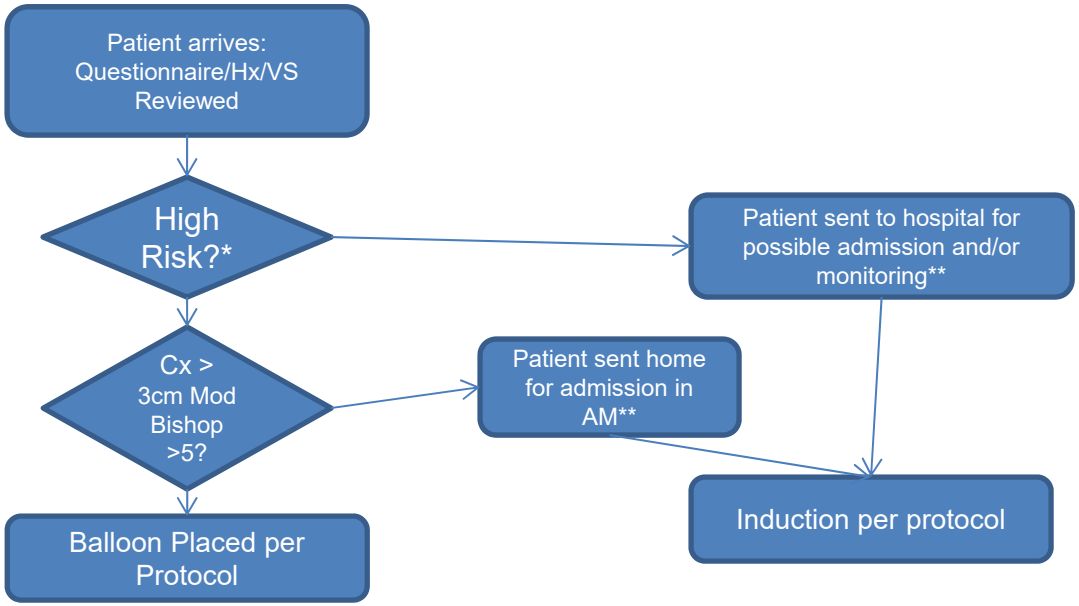
Modified Bishop Score ARRIVE Trial

Unfavorable considered score of less than 5

Scoring System for the Modified Bishop Score				
Using cervical length				
Fetal station (in relation to the ischial spines)	-3 cm	-2 cm	-1 - 0 cm	1 - 2 cm
	0	1	2	3
Cervical dilation	0 cm	1-2 cm	3-4 cm	>4 cm
	0	2	4	6
Cervical length*	3 cm (>2.5cm)	2 cm (>1.5 -2.5cm)	1 cm (>0.5 -1.5 cm)	0 cm (≤ 0.5 cm)
	0	1	2	3
Cervical Effacement*		0%-<25%	25%-<75%	≥ 75%
		1	2	3

*Either cervical length or cervical effacement was used in the determination of modified Bishop score based on which was used in documentation of the cervical examination.

In Office Balloon Placement



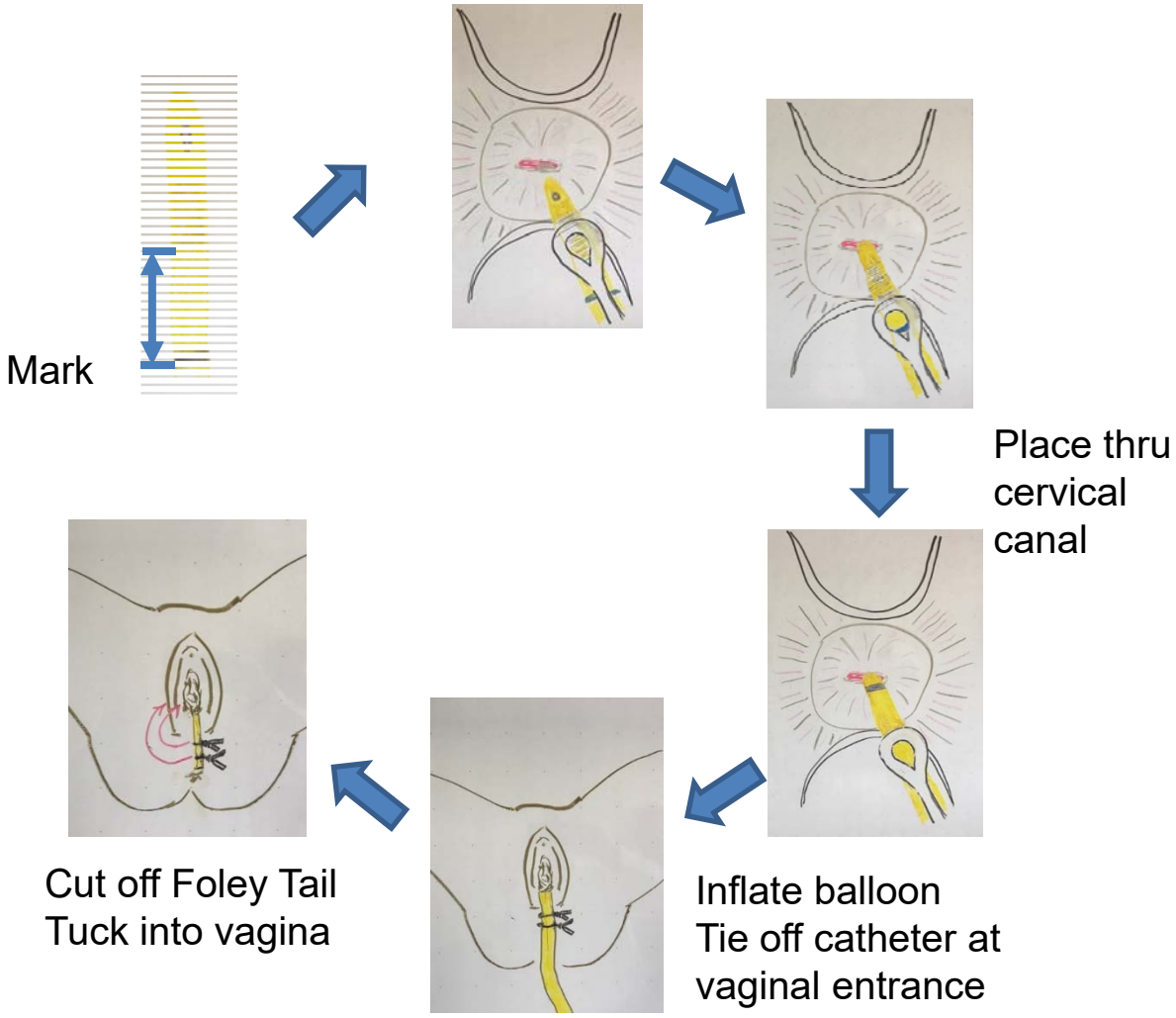
*Positive questionnaire, abnormal vital signs or history (Preeclampsia, Premature Rupture of Membranes, Equivocal AP Testing, Oligohydramnios, etc.)
** Patients admitted into hospital, if no prior uterine surgery or other complication consider combination cervical ripening with misoprostol and foley catheter balloon

Patient Questionnaire

- Has you felt good fetal movement over the last 24 hours?
- Have you been having any contractions or strong back ache in the last 24 hours?
- Have you had any evidence of increased cervical discharge or spotting?
- Have you had any bleeding during the pregnancy or been told your placenta was near your cervix (placenta previa)?
- Have you been told you have low or borderline low amniotic fluid levels?

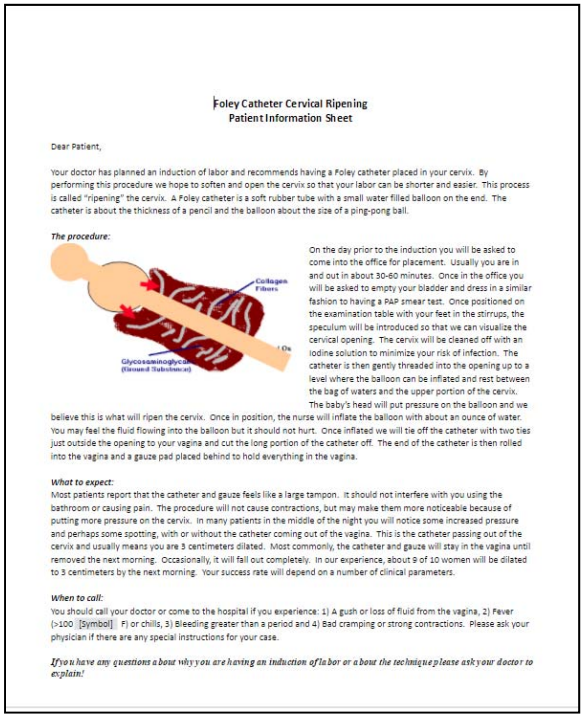
Equipment List

1. LARGE Graves speculum
2. Betadine swabs
3. Ring forceps
4. 16 French Foley catheter with 30 cc balloon
5. 30 cc syringe and 19 G needle
6. 30 cc vial Normal Saline
7. Scissors
8. Umbilical tape
9. Sterile gloves
10. OR Marker pen


Mark
Place thru cervical canal
Inflate balloon
Tie off catheter at vaginal entrance
Cut off Foley Tail
Tuck into vagina

The patient is sent home

- The patient is then sent home with instructions and informed she is likely to notice mild cramping and spotting when the catheter passes through the cervix when catheter dilation is complete in about 6-8 hours.



Foley Catheter Cervical Ripening
Patient Information Sheet

Dear Patient,

Your doctor has planned an induction of labor and recommends having a Foley catheter placed in your cervix. By performing this procedure we hope to soften and open the cervix so that your labor can be shorter and easier. This process is called "ripening" the cervix. A Foley catheter is a soft rubber tube with a small water filled balloon on the end. The catheter is about the thickness of a pencil and the balloon about the size of a ping-pong ball.

The procedure:

On the day prior to the induction you will be asked to come into the office for placement. Usually you are in and out in about 30-60 minutes. Once in the office you will be asked to empty your bladder and dress in a similar fashion to having a PAP smear test. Once positioned on the examination table with your feet in the stirrups, the speculum will be introduced so that we can visualize the cervical opening. The cervix will be cleaned off with an iodine solution to minimize your risk of infection. The catheter is then gently threaded into the opening up to a level where the balloon can be inflated and rest between the bag of waters and the upper portion of the cervix. The baby's head will put pressure on the balloon and we believe this is what will ripen the cervix. Once in position, the nurse will inflate the balloon with about an ounce of water. You may feel the fluid flowing into the balloon but it should not hurt. Once inflated we will tie off the catheter with two ties just outside the opening to your vagina and cut the long portion of the catheter off. The end of the catheter is then rolled into the vagina and a gauze pad placed behind to hold everything in the vagina.

What to expect:

Most patients report that the catheter and gauze feels like a large tampon. It should not interfere with you using the bathroom or causing pain. The procedure will not cause contractions, but may make them more noticeable because of putting more pressure on the cervix. In many patients in the middle of the night you will notice some increased pressure and perhaps some spotting, with or without the catheter coming out of the vagina. This is the catheter passing out of the cervix and usually means you are 3 centimeters dilated. Most commonly, the catheter and gauze will stay in the vagina until removed the next morning. Occasionally, it will fall out completely. In our experience, about 9 of 10 women will be dilated to 3 centimeters by the next morning. Your success rate will depend on a number of clinical parameters.

When to call:

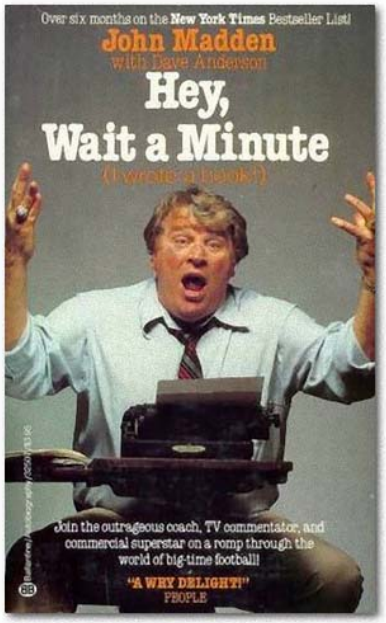
You should call your doctor or come to the hospital if you experience: 1) A gush or loss of fluid from the vagina, 2) Fever (>100 [Symbol] F) or chills, 3) Bleeding greater than a period and 4) Bad cramping or strong contractions. Please ask your physician if there are any special instructions for your case.

If you have any questions about why you are having an induction of labor or about the technique please ask your doctor to explain!

Providence St. Joseph Health

Convincing Providers and Staff

- Obviously, these changes reduce costs and can lead to resistance by providers and staff as mere cost reduction.
- This can be addressed by:
  - Reminding them that our nursing staff is often inundated with too many patients and cannot give attention to those patients who need their bedside time.
  - Cost reduction can lead to growth of the unit in a value based care environment.
  - These particular changes can enhance the birth process by shortening the perceived length of labor, reducing the need for augmentation and cesarean section.



Providence St. Joseph Health

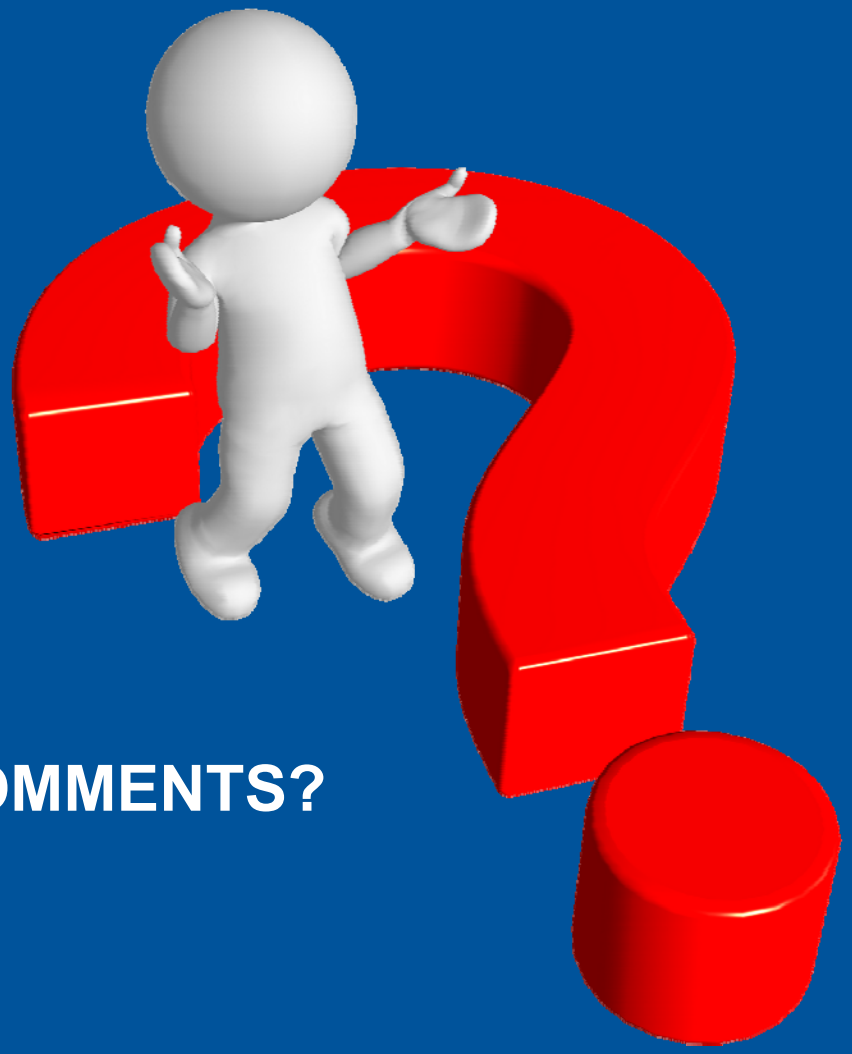
Lessons Learned From Experience
Outpatient Balloon Ripening

- Majority of patients can have balloon placed/ stenosis rare
- Proper placement above internal os has very good success
- Low Risk Patients: No fetal monitoring needed since no tachysystole risk but poorly documented and therefore starting with monitoring is reasonable and for sure monitoring for high risk patients is recommended
- If inpatient for monitoring you can use misoprostol or oxytocin and Foley balloon concurrently (not double balloon)
- Only about 5% come in labor before morning
- Balloon usually sitting in vagina in the morning, can have induction started if balloon not expelled
- Patients much happier with the process and cramping
- Relieves significant burden on patients, L&D Staff and Physicians (9-12 hours less admission time and 4-5 hours more sleep)

51

Diversity Considerations

- Many ethnic groups may need translated patient information forms
- No data suggest that this will work better or worse based on cultural differences
- Care should be taken to ensure ability for the patients to return to the unit with outpatient cervical ripening.



QUESTIONS OR COMMENTS?

Patient Information

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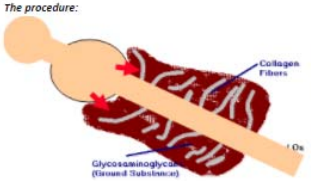

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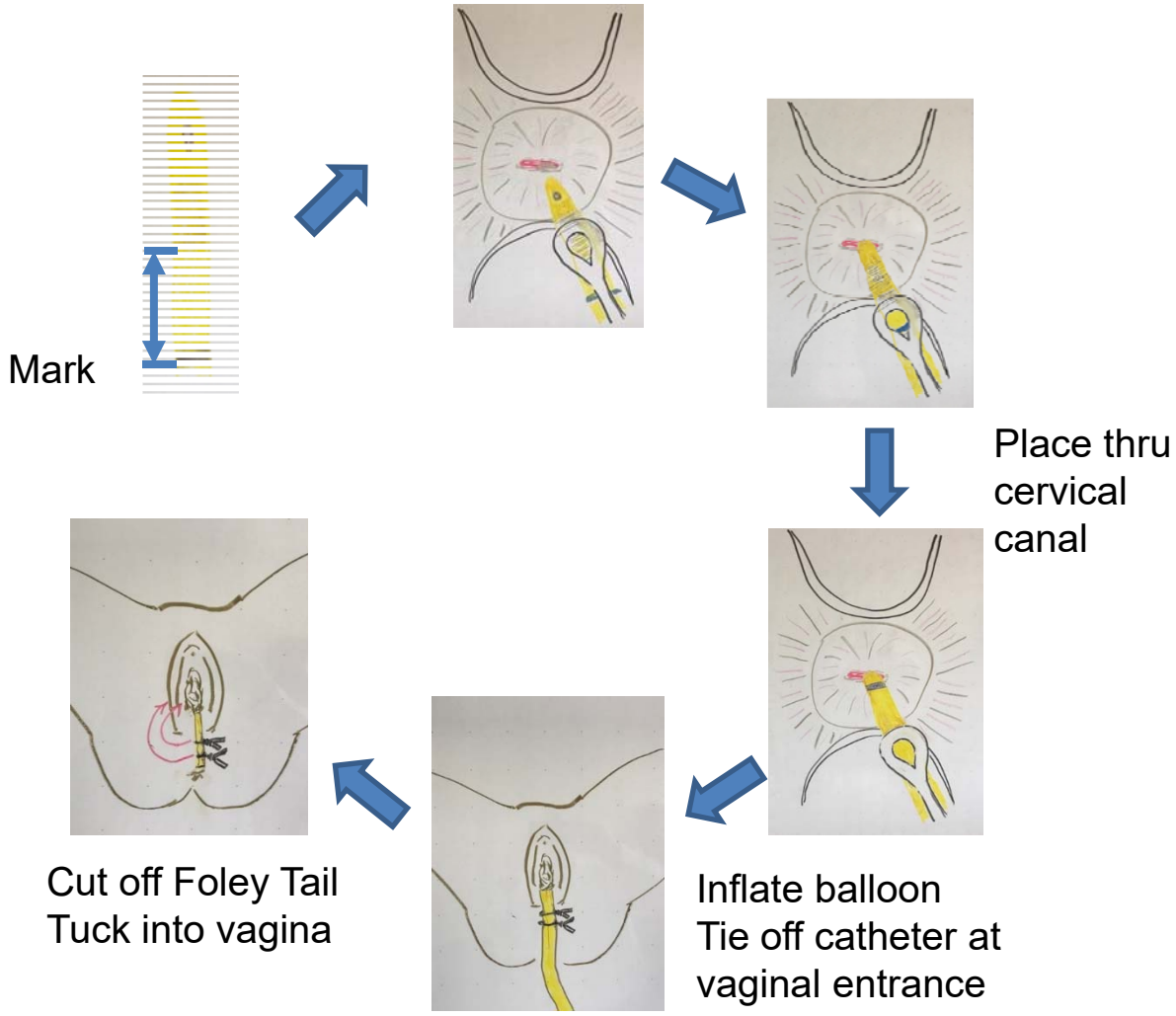
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Place thru cervical canal
Inflate balloon
Tie off catheter at vaginal entrance
Cut off Foley Tail
Tuck into vagina

Partnering to Improve Health Care Quality
for Mothers and Babies

Q & A

- If you have a question, please enter it in the “Chat/Question Box” or “Raise Your Hand” (click hand button) to be un-muted.
- We can only unmute you if you have dialed your Audio PIN (shown on the GoToWebinar side bar—enter you PIN plus #).
- Other questions: FPQC@health.usf.edu
- Website: FPQC.org go to current projects and select PROVIDE for resources and archived webinars