



Induction of Labor - Risk, Benefits and Techniques for Increasing Success

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Neither Dr. Main nor Dr. Lagrew have any any conflicts or disclosures





Preface

This story is all about the Cervix....





Key Take Home Messages

- Central importance of cervical ripeness
- Discordancy of Cesarean risk estimates between observational studies and RCTs
- Extremely large hospital-level variation in rates of CS after labor induction
- How you perform the induction is critical
- New ACOG guidelines
- Outpatient approach to cervical ripening





We will not cover...

- Direct comparisons of products, e.g. misoprostol, prostaglandin inserts, double and single cervical balloons
- AROM, membrane stripping, breast stimulation
- Patient education: engagement and expectations



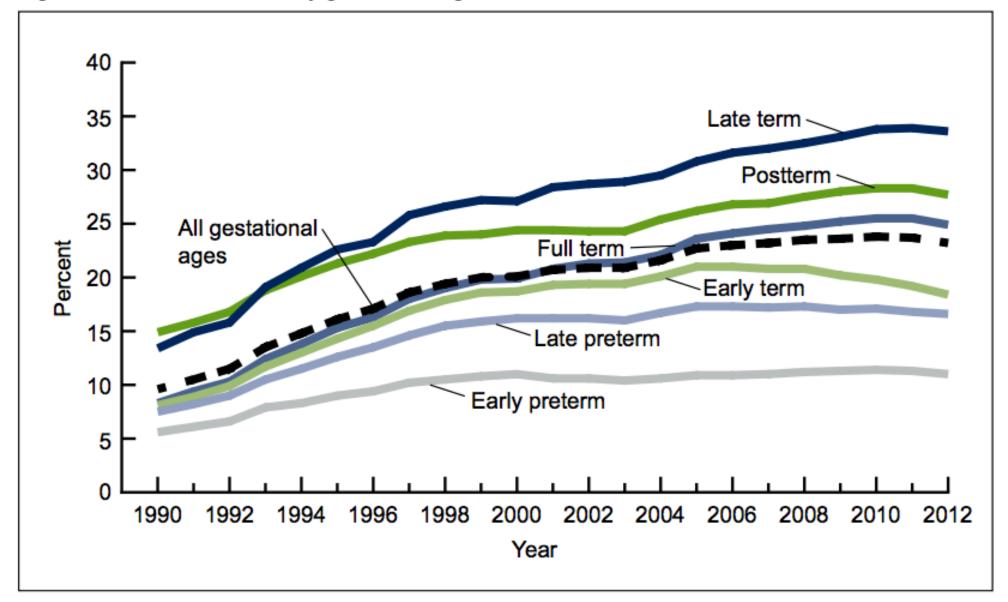


Oxytocin

- 1906: Sir Henry Dale found that extracts form the human posterior pituitary gland contracted the uterus of a pregnant cat and coined the term term oxytocin from two Greek words meaning "swift birth".
- 1953: Oxytocin was the first ever polypeptide to be sequenced and synthesized by Vincent du Vigneaud, earning the Nobel Prize in 1955.
- 1962: Approved by the FDA for use in supporting milk production but widely used for other indications...



Figure 1. Induction of labor, by gestational age: United States, 1990–2012



NOTES: Singletons only. Early preterm is less than 34 weeks of gestation; late preterm is 34–36 weeks; early term is 37–38 weeks; full term is 39–40 weeks; late term is 41 weeks; postterm is 42 weeks or more. Access data table for Figure 1 at: http://www.cdc.gov/nchs/data/databriefs/db155 table.pdf#1.

SOURCE: CDC/NCHS, National Vital Statistics System.



NEW ACOG STANDARD LABOR DEFINITIONS (2014)

LABOR	Uterine contractions resulting in cervical change (dilation and/or effacement) Phases: • Latent phase – from the onset of labor to the onset of the active phase • Active phase – accelerated cervical dilation typically beginning at 6 cm		
AUGMENTATION OF LABOR	The stimulation of uterine contractions using pharmacologic methods or artificial rupture of membranes to increase their frequency and/or strength following the onset of spontaneous labor or contractions following spontaneous rupture of membranes. If labor has been started using any method of induction described below (including cervical ripening agents), then the term, Augmentation of Labor, should not be used.		
INDUCTION OF LABOR	The use of pharmacological and/or mechanical methods to initiate labor (Examples of methods include but are not limited to: artificial rupture of membranes, balloons, oxytocin, prostaglandin, Laminaria, or other cervical ripening agents) Still applies even if any of the following are performed: • Unsuccessful attempts at initiating labor • Initiation of labor following spontaneous ruptured membranes without contractions		

Menard MK, Main EK, Currigan SM. Executive Summary of the reVITALize Initiative: Standardizing Obstetric Data Definitions. Obstet Gynecol 2014 July; 124:150-3.



Induction Definitions: Key Points

- Induction of labor includes <u>all cases</u> with <u>any</u> of the following:
 - Cervical ripening using medications (e.g. prostaglandins including misoprostol)
 - Cervical ripening using mechanical methods (e.g. balloons or other cervical dilators)
 - Artificial rupture of membranes <u>before the onset of labor</u>
 - Oxytocin/Pitocin® <u>before the onset of labor</u>. Note, if oxytocin is used in the setting of irregular contractions with intact membranes without cervical change, then it would be considered an Induction of Labor.
- Augmentation of labor occurs ONLY:
 - After the onset of <u>spontaneous labor</u>, <u>defined as contractions</u> <u>with</u> <u>cervical change</u>, or
 - After <u>spontaneous rupture of membranes with contractions (with or without cervical change)</u>.
 - Note, if there is spontaneous rupture of membranes and <u>no contractions</u> then administration of oxytocin is considered an induction of labor.





Bishop Score for Cervical Ripeness

Cervical Assessment						
Score:	0	1	2	3		
Dilation (cm)	0	1-2	3-4	5-6		
Effacement(%)	0-30	40-50	60-70	80+		
Station	-3	-2	-1/0	+1/+2		
Consistency	Firm	Medium	Soft			
Position	Post.	Mid.	Ant.			

(Bishop EH: Obstet Gynecol 1964, 24:266-8)



Bishop Score

- "In many clinics, elective induction of labor has become a frequent and acceptable procedure justified by reportedly satisfactory results." (EH Bishop, 1965)
- Due to the unpredictability of nulliparous labor even with favorable conditions, there is "no justification for labor induction during the first pregnancy"
- "Score of 9 or more will have a safe and successful labor"





Modified Bishop Score

- Modified to make it applicable to more patients and improve predictability
- Most important change was to subtract one point for nullips and add one point for each prior vaginal birth
- Predictive Value:

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Score: 0-4 50% failure rate
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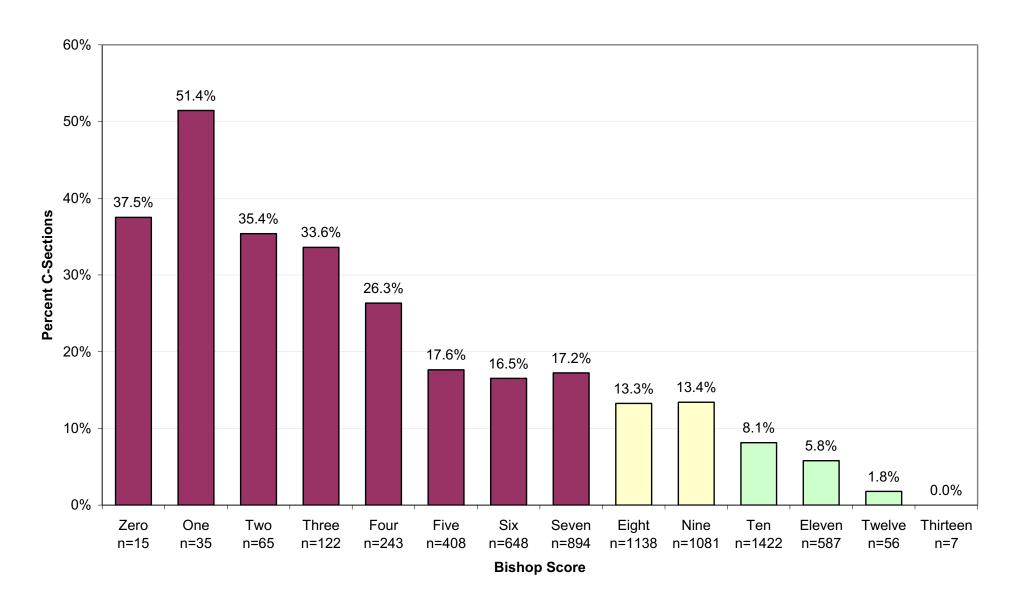
5-9 10% failure rate

10-13 0% failure rate



Cesarean Section Rates By Bishop Score

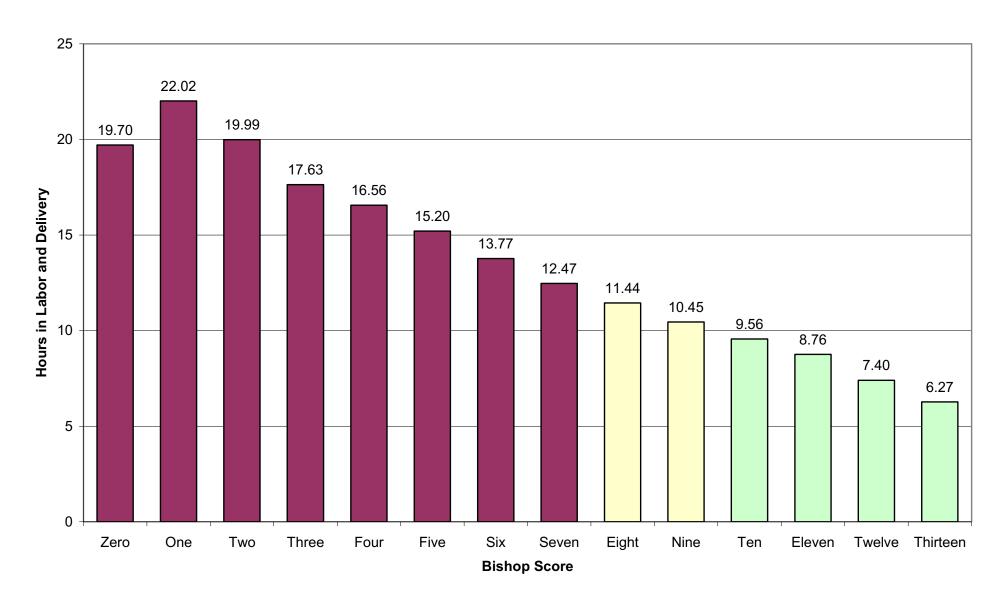
Elective Inductions in First-Time Moms 2001 -2006





Average Hours in Labor & Delivery By Bishop Score

Elective Inductions in First-Time Moms 2001 -2006





Comparison of Cesarean Rates Among Nullips with Spontaneous Labor to Those with Labor Induction

- Ehrenthal: Crude OR 2.67, Adj. OR 1.93
 - □ Obstet Gynecol 2010; 116:35
- Seyb: Adj. OR 1.89
 - □ Obstet Gynecol 1999; 94:600
- Glantz: Adj. OR 1.90
 - □ J Reprod Med 2005; 50:235
- Vahratian: Adj OR 3.50 if cervical ripening needed
 - □ Obstet Gynecol 2005; 105:696



Inductions in Postdates Pregnancies

- Formal Meta-analysis of 8 RCTs
- Induction favored:
 Fewer CS: RR 1.17 (1.07--1.29)
 Fewer Mec Stained Fluid: RR 1.67 (1.23--2.26)
- Conclusion: Elective induction at 41 weeks is associated with lower CS and MSF, but concerns about translation of these findings into actual practice (studies were performed in academic centers)
- Not stratified by parity





Inductions in women with Preeclampsia

- Dutch HYPITAT trial: RCT induction vs expectant management at 37 wks (~378 women each arm)—No difference in the CS rate and fewer maternal and neonatal morbidities if induced at 37 weeks (or at diagnosis) (population was 71% nullips)
- CS rate was impressively low! 14% / 19% in the two groups
- FYI, Dutch women are the tallest in the world (average over 5'7")

ajog.org November 2015

Systematic Reviews

OBSTETRICS

Induction of labor at full term in uncomplicated singleton gestations: a systematic review and metaanalysis of randomized controlled trials

Gabriele Saccone, MD; Vincenzo Berghella, MD

- Meta-analysis of 5 medium RCTs: 39-41wks
- Similar rates of CS: 9.7% v. 7.5% (Ind v Spon)
- Similar rates of Chorio: 9.6%v. 8.0%

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- Similar rates of CS: 9.7% v. 7.5% (Ind v Spon)
- Similar rates of Chorio: 9.6%v. 8.0%
- 2 RCT did sub-analyses of Nullips (100 each arm)
- Rates of CS: 25.5% v. 15.3% (Ind v Spon)
- RR: 1.67 (0.94-2.95)





NEJM: Randomized Trial of Labor Induction in Women ≥35 Years of Age

- UK Academic Centers, all nulliparous, 35-39 years of age 304/314 women in each group
- No difference in CS rate: 32% v 33%
- No difference in maternal or infant outcomes (not powered enough for stillbirth detection)





Large Population Study in Australia

- 42,950 NTSV births <41 weeks gestation without any medical or obstetrical complications; Compared spontaneous labor with or without augmentation, and each form of induction ripening
- Further adjusted for age, epidural, birthweight, and payment status
- Risk of Cesarean Delivery:
 Spontaneous v. Induced: RR 2.54
 Any cervical ripening: Adj RR 2.78-4.06





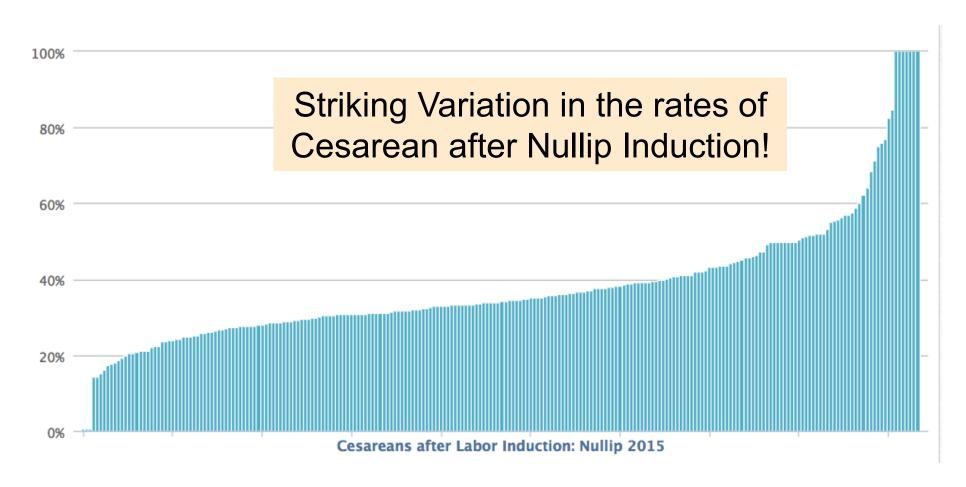
What to do when there is conflicting data?

- Retrospective studies vs. RCTs with selected populations
- How can you pick from the literature?
 - Is my setting and patient population the same?
 - Does my hospital have strict induction protocols like the ones used in the RCTs?
 - Are my results similar?
- Where are ACOG guidelines?



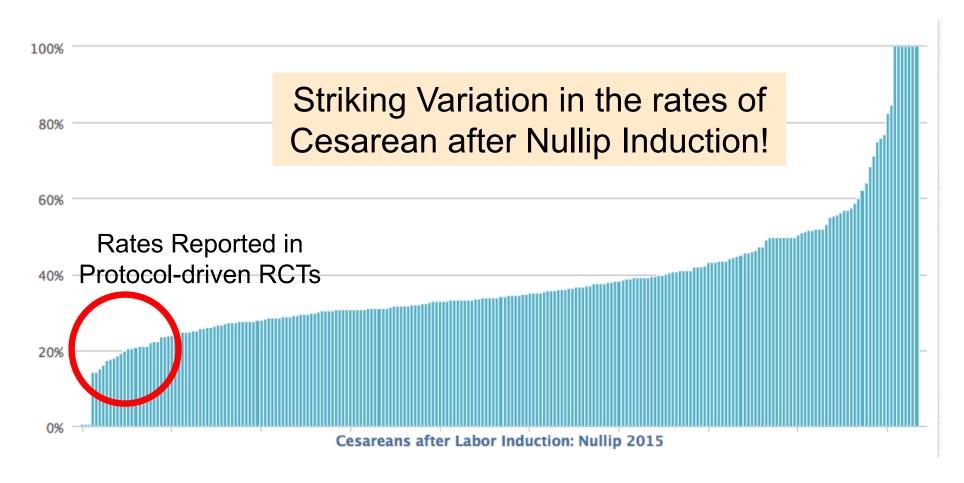


Cesarean Rate for Nullip Inductions 244 California Hospitals-- 2015 (CMQCC Maternal Data Center)



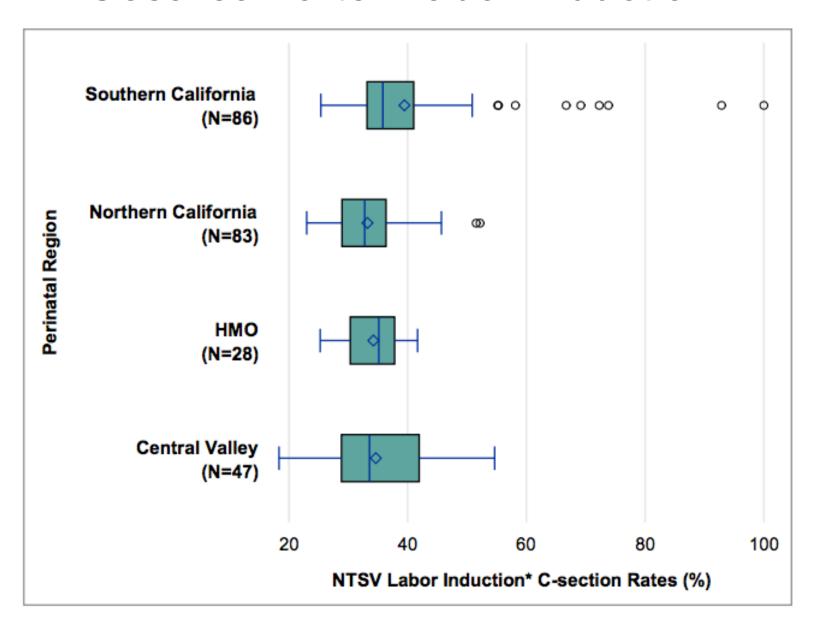


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Large Variation in Hospital Rates of Cesarean after Labor Induction







OBSTETRIC CARE CONSENSUS

Number 1 · March 2014

Safe Prevention of the Primary Cesarean Delivery

New National Guidelines for Defining Labor Abnormalities and Management Options

Table 3. Recommendations for the Safe Prevention of the Primary Cesarean Delivery

Recommendations	
Induction of labor	
Before 41 0/7 weeks of gestation, induction of labor generally should be performed based on maternal and fetal medical indications. Inductions at 41 0/7 weeks of gestation and beyond should be performed to reduce the risk of cesarean delivery and the risk of perinatal morbidity and mortality.	Strong
Cervical ripening methods should be used when labor is induced in women with an unfavorable cervix.	Strong red
If the maternal and fetal status allow, cesarean deliveries for failed induction of labor in the latent phase can be avoided by allowing longer durations of the latent phase (up to 24 hours or longer) and requiring that oxytocin be administered for at least 12–18 hours after membrane rupture before deeming the induction a failure.	Strong red

Safe prevention of the primary cesarean delivery. Obstetric Care Consensus No. 1. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:693–711.

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Strong Recommendation, High Quality Evidence	
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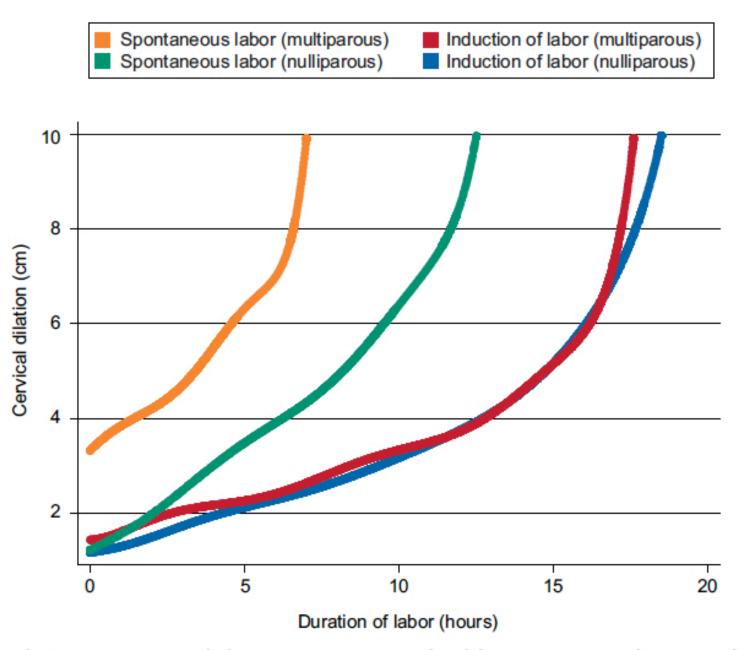


Fig. 1. Average labor curves stratified by parity and type of labor onset.

Harper. Normal Labor in Induction. Obstet Gynecol 2012.

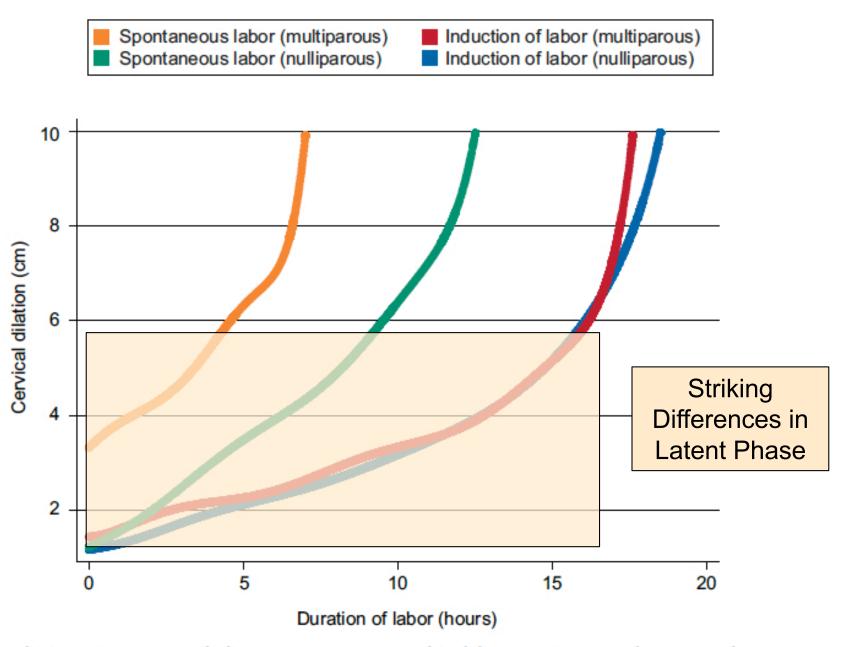


Fig. 1. Average labor curves stratified by parity and type of labor onset.

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The American College of Obstetricians and Gynecologists



Ten Things Physicians and Patients Should Question



Don't schedule elective, non-medically indicated inductions of labor or Cesarean deliveries before 39 weeks 0 days gestational age.

Delivery prior to 39 weeks 0 days has been shown to be associated with an increased risk of learning disabilities and a potential increase in morbidity and mortality. There are clear medical indications for delivery prior to 39 weeks 0 days based on maternal and/or fetal conditions. A mature fetal lung test, in the absence of appropriate clinical criteria, is not an indication for delivery.



Don't schedule elective, non-medically indicated inductions of labor between 39 weeks 0 days and 41 weeks 0 days unless the cervix is deemed favorable.

Ideally, labor should start on its own initiative whenever possible. Higher Cesarean delivery rates result from inductions of labor when the cervix is unfavorable. Health care practitioners should discuss the risks and benefits with their patients before considering inductions of labor without medical indications.



Don't perform routine annual cervical cytology screening (Pap tests) in women 30–65 years of age.

In average risk women, annual cervical cytology screening has been shown to offer no advantage over screening performed at 3-year intervals. However, a well-woman visit should occur annually for patients with their health care practitioner to discuss concerns and problems, and have appropriate screening with consideration of a pelvic examination.



Don't treat patients who have mild dysplasia of less than two years in duration.

Mild dysplasia (Cervical Intraepithelial Neoplasia [CIN 1]) is associated with the presence of the human papillomavirus (HPV), which does not require treatment in average risk women. Most women with CIN 1 on biopsy have a transient HPV infection that will usually clear in less than 12 months and, therefore, does not require treatment.



Don't screen for ovarian cancer in asymptomatic women at average risk.

In population studies, there is only fair evidence that screening of asymptomatic women with serum CA-125 level and/or transvaginal ultrasound can detect ovarian cancer at an earlier stage than it can be detected in the absence of screening. Because of the low prevalence of ovarian cancer and the invasive nature of the interventions required after a positive screening test, the potential harms of screening outweigh the potential benefits.

Released March 2016





The American College of Obstetricians and Gynecologists



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Released March 2016





"Elective" Inductions 39-41wks

- "First do no harm": are the risks minimal? What's my rate?
- First births + need for cervical ripening = Trouble
- Should elective inductions be limited to Bishop scores > 6 or 8?
- Should elective inductions not have cervical ripening?
- A nullip with a long hard cervix at 40wks has no easy choices...
- CAVEAT: Induced labor has a different shaped labor curve and longer stages





Keys for Induction Success

- Who you choose (parity and cervical ripeness)
- How you perform the induction
- Follow your success rates!





Outpatient Balloon Cervical Ripening

David Lagrew MD

Executive Medical Director, Women's Health

St. Joseph Hoag Health





Checklist-based Protocol for Oxytocin Administration

- Mean time of infusion to delivery was 8.5 +/- 5.3 hours versus 8.2 +/- 4.5 hours (NS)
- Newborn index of adverse outcome were significantly fewer in the post protocol group (31 vs 18, P = .049).
- System wide decline in the rate of primary cesarean delivery from 23.6% in 2005 to 21.0% in 2006.

Clark S, Belfort M, Saade G, Hankins G, Miller D, Frye D, Meyers J. Implementation of a conservative checklist-based protocol for oxytocin administration: maternal and newborn outcomes. Am J Obstet Gynecol. 2007 Nov;197(5):480.e1-5.





Patient Safety Checklist 🗸

Number 2 • November 2011

	CTION	OF LABO	R				Reaffirmed	
Patient				Date of birth MR #			MR #	
Physician or certified nurse-midwife				Last menstrual period				
Gravidity/Parity								
Estimated date of deli	very		Best estimat	ed gestational	age at delive	ту		
ndication for induction	on		_					
Fetal Presentation (1	1)							
☐ Vertex								
Other								
☐ If other, pl	hysician	or certified r	nurse-midwife n	otified				
Estimated fetal weig	ght							
☐ Patient has a con	npleted n	nedical histo	ry and physical e	examination				
☐ Known allergi								
☐ Medical factor								
☐ Pertinent pren							, 3)	
☐ Other special	concern	s identified (eg, medical prob	lems and speci	al needs):		_	
☐ Patient counseled	d about r	isks and ben	efits of induction	of labor (1)				
☐ Consent form	signed a	as required by	y institution					
Bishop Score (see be	elow) (1):	_					
			Bisho	p Scoring Syst	tem			
				Factor				
	Score	Dilation (cm)	Position of Cervix	Effacement (%)	Station*	Cervical Consistency		
	0	Closed	Posterior	0-30	-3	Firm		
	1	1–2	Midposition	40-50	-2	Medium		
		2.4	Anterior	60-70	-1, 0	Soft		
	2	3-4	7 411001101					

Every Woman with a Labor Induction Should have a Patient Safety Checklist





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.



Timing of Adverse Events with Foley Catheter for Cervical Ripening

- What is the risk for adverse events between Foley insertion and 6AM the following day in a low risk population (no prior CS, HTN, DM, or PPROM)?
- 1,905 women observed as inpatients
- Zero rates of: CS for non-reassuring fetal tracing, vaginal bleeding, placental abruption, or intrapartum stillbirth
- This large cohort supports the outpatient use of Foley cervical ripening





- Mechanical methods as effective with respect to achieving ripeness and cesarean delivery rates in controlled studies
- 2. Balloon ripening can be used outpatient since tachysystole is not associated
- Better experience comes from patients having less cramping and not spending the night in the hospital
- 4. Less cost since monitoring and nursing care not used for 8-12 hours while awaiting ripening of the cervix





- METHODS: RCT of term IOL (N=101)--outpatient care using Foley catheter (OP, n=50) or inpatient care using vaginal PGE2 (IP, n=51). OP group had Foley catheter inserted and were discharged home. IP group received 2 mg/1 mg vaginal PGE2 if nulliparous or 1 mg/1 mg if multiparous.
- **RESULTS:** OP group had shorter hospital stay prior to birth (21.3 vs. 32.4 hrs, p<.001), IP were more likely to achieve vaginal birth within 12 hours of presenting to Birthing Unit (53% vs. 28%, p=.01). Vaginal birth rates (66% OP Vs. 71% IP), total induction to delivery time (33.5 hrs vs. 31.3 hrs) were similar. OP group felt less pain (significant discomfort 26% Vs 58%, p=.003), and had more sleep (5.8 Vs 3.4 hours, p<.001), during cervical preparation, but were more likely to require oxytocin IOL (88 Vs 59%, p=.001).

Henry A et al BMC Pregnancy Childbirth. 2013 Jan 29;13:25.





Outpatient as Effective as Inpatient Foley Catheter for Cervical Ripening

- Sixty-one women were randomized into the outpatient group, and 50 women into the inpatient group.
- The median Bishop score at entry was 3.0 for each group. The mean change in Bishop scores after catheter placement was not different between the inpatient and outpatient groups (3.0 versus 3.0).
- The maximum dose of oxytocin, time of oxytocin, epidural rate, induction time, 1-minute and 5-minute Apgar scores, and cord pH were not significantly different. The outpatient group on average avoided 9.6 hours of hospitalization.
- There were no adverse events or maternal morbidity in either group.

Sciscione AC et al Obstet Gynecol. 2001 Nov;98(5 Pt 1):751-6.



Mechanical and Pharmacologic Methods of Labor Induction

- 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
- Results: Median time to delivery: misoprostol—Foley: 13.1 hours, Foley—oxytocin: 14.5 hours, misoprostol: 17.6 hours, Foley: 17.7 hours, (p=.001)
- 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.



What if outpatient?

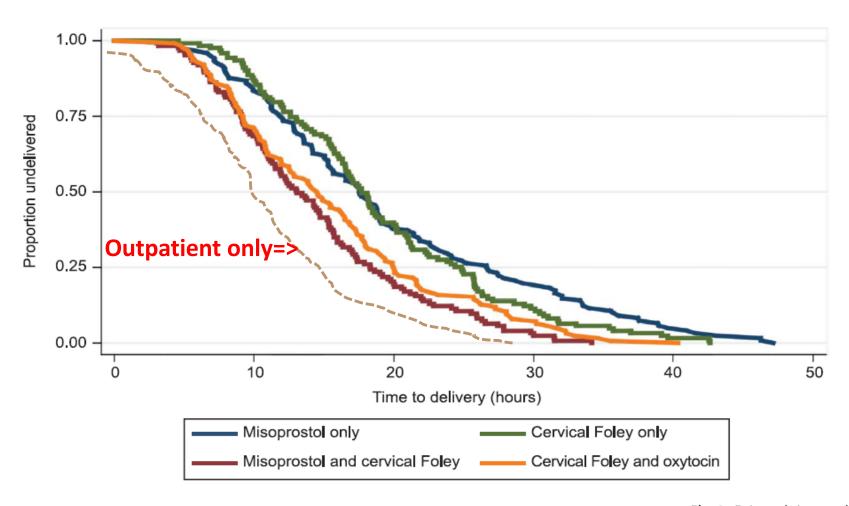


Fig. 2. Estimated time to delivery by study group. This figure displays the Kaplan-Meier survival curves for time to delivery for the four induction method groups, *P*<.001.





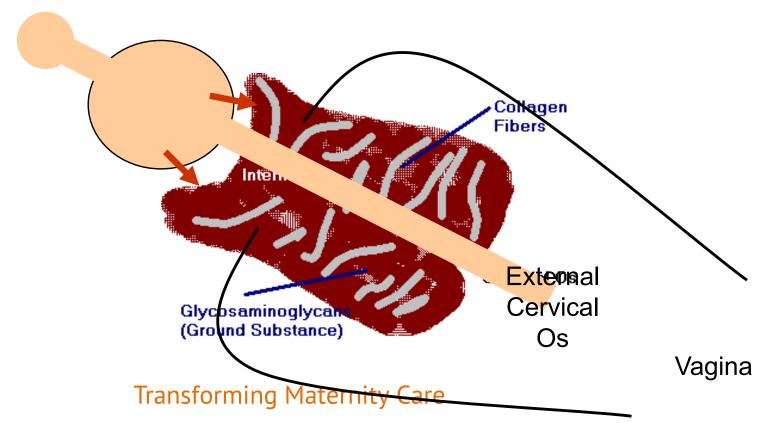
Our Technique Summary

- Patient seen in labor and delivery where navigator reviews documentation, labs and orders, explains induction procedure in detail (saving time in morning of induction); preinduction checklist done
- Patient goes to office/ clinic afternoon prior to scheduled induction and balloon placed
- Patient arrives 0600 or 0700 of the morning of induction IV started and infusion after hospital checklist completed





The catheter is inserted just inside the internal cervical os. The balloon rests on the internal os and puts pressure down. The patient usually feel minimal cramping since the balloon elevates the amniotic sac and vertex.

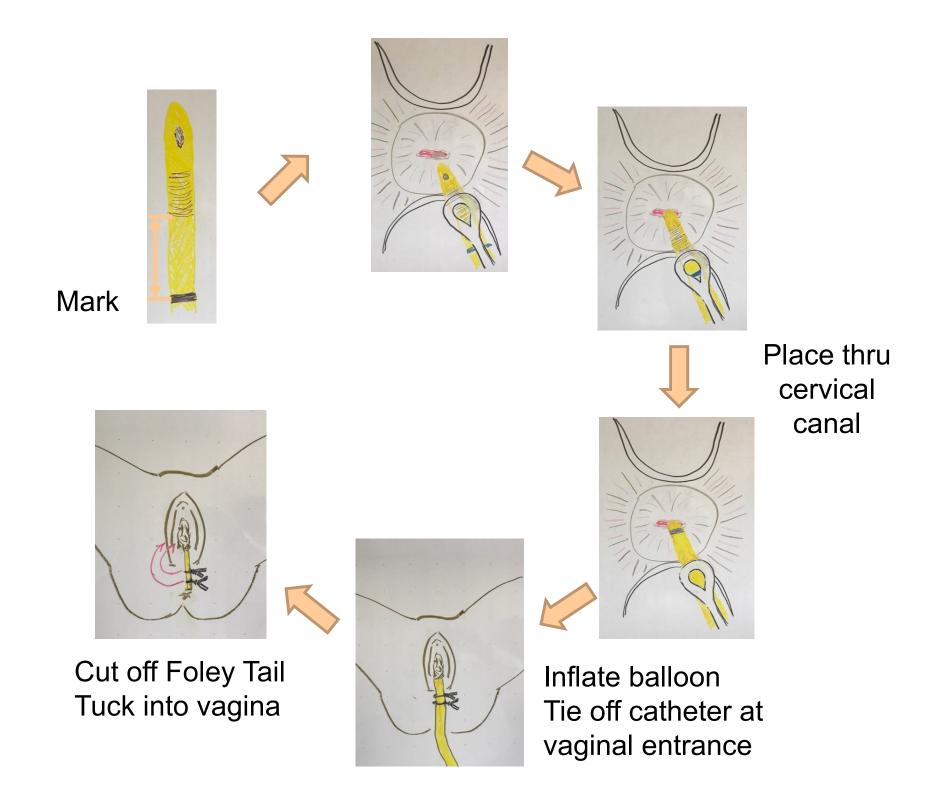






Office Equipment List

- 1. Graves speculum
- 2. Betadine swabs
- 3. Ring forceps
- 4. 16 French Foley catheter with 30 cc balloon (60 cc)
- 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





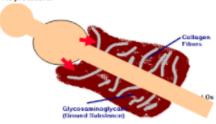
Patient Information

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 lodine 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 infliated 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 cal

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!



Shifted Burden...

- Obvious that this adds some burden to the office/ clinic in terms of time and costs.
- Consider a hospital supplied package (catheter, syringe, needle, saline, ties, marker)
- One reason for using Foley balloon is much lower cost than Cook catheter and no strong evidence double balloon is more effective (more studies needed to determine which patients would benefit from this device)



Lessons Learned From Experience

- Majority of patients can have balloon placed/ stenosis rare
- Proper placement above internal os has very good success
- No fetal monitoring needed since no tachysystole risk, monitoring only for other indications
- If <u>inpatient</u> for monitoring you can use misoprostol or oxytocin and Foley balloon concurrently
- 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 less tired since slept at home
- Relieves significant burden on L&D Staff and Physicians



Keys for Safe Successful Inductions

- Follow ACOG guidelines—avoid elective inductions in nullips with an unfavorable cx
- Follow your hospital's and your personal success rates for induction—Aim for 20%'s
- Remember, how you perform the induction is critical (standard guidelines, lots of patience!)
- Strongly consider outpatient approach to cervical ripening



Thank You!





We are happy to take questions