CMQCC
California Maternal
Quality Care Collaborative

Induction of Labor Beyond the Arrive Trial - Risk, Benefits and Techniques for Increasing Success

Elliott Main, MD
Medical Director, CMQCC
Clinical Professor, OB/GYN
Stanford University

David Lagrew, MD
Executive Medical Director
Providence St. Joseph
Health-Southern California

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

Preface

This story is all about the Cervix….

And about Parity!

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…

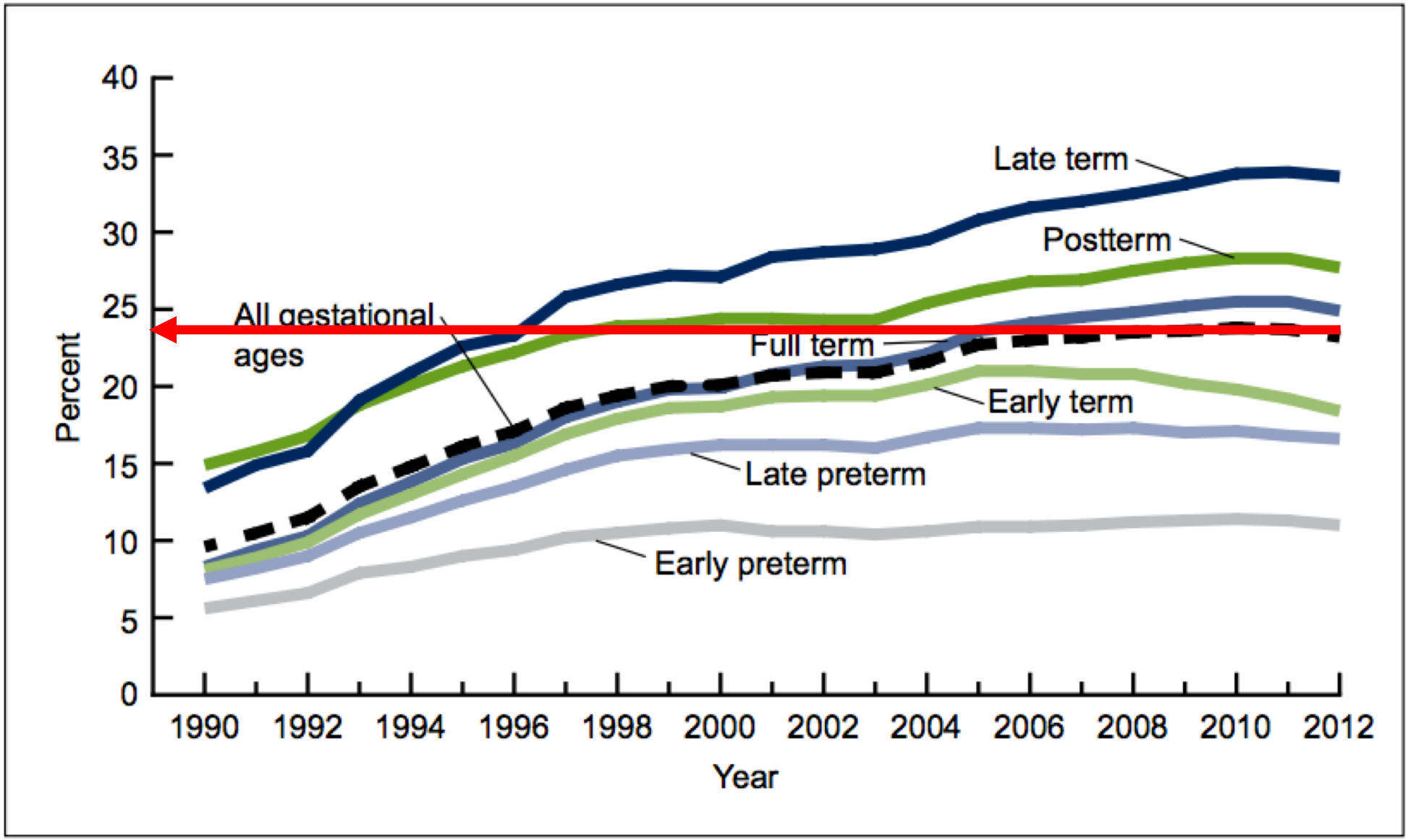
- Direct comparisons of products, e.g. misoprostol, prostaglandin inserts, double and single cervical balloons
- AROM, membrane stripping, breast stimulation
- Patient education: engagement and expectations

All of which are important…

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 all cases with any 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 before the onset of labor
  - Oxytocin/Pitocin® before the onset of labor. 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 spontaneous labor, defined as contractions with cervical change, or
  - After spontaneous rupture of membranes with contractions (with or without cervical change).
    Note, if there is spontaneous rupture of membranes and no contractions then administration of oxytocin is considered an induction of labor.

Link to full set of definitions: http://download.lww.com/wolterskluwer_vitalstream_com/PermaLink/AOG/A/AOG_124_1_2014_05_28_MENARD_14-107_SDC3.pdf

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."
- Due to the unpredictability of nulliparous labor even with favorable conditions, there is "no justification for labor induction during the first pregnancy"
- In multips, "a score of 9 or more will have a safe and successful labor"

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

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:

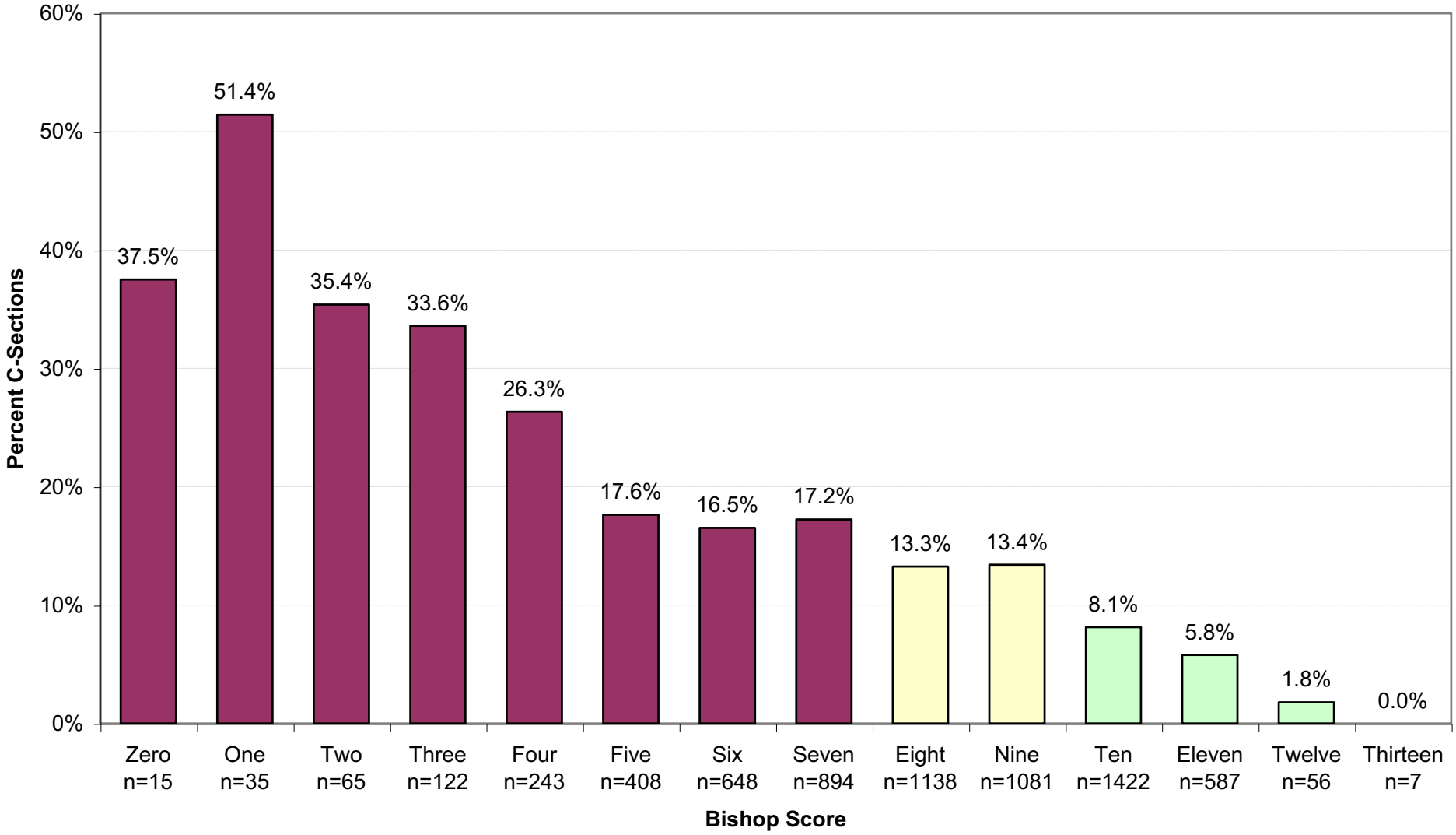
Score:		
	0-4	50% failure rate
	5-9	10% failure rate
	10-13	0% failure rate

(Hughey MY, McELin TW, Bird CC. An evaluation of preinduction scoring systems. Obstet Gynecol 1976, 48:635)

Intermountain Healthcare

Cesarean Section Rates By Bishop Score

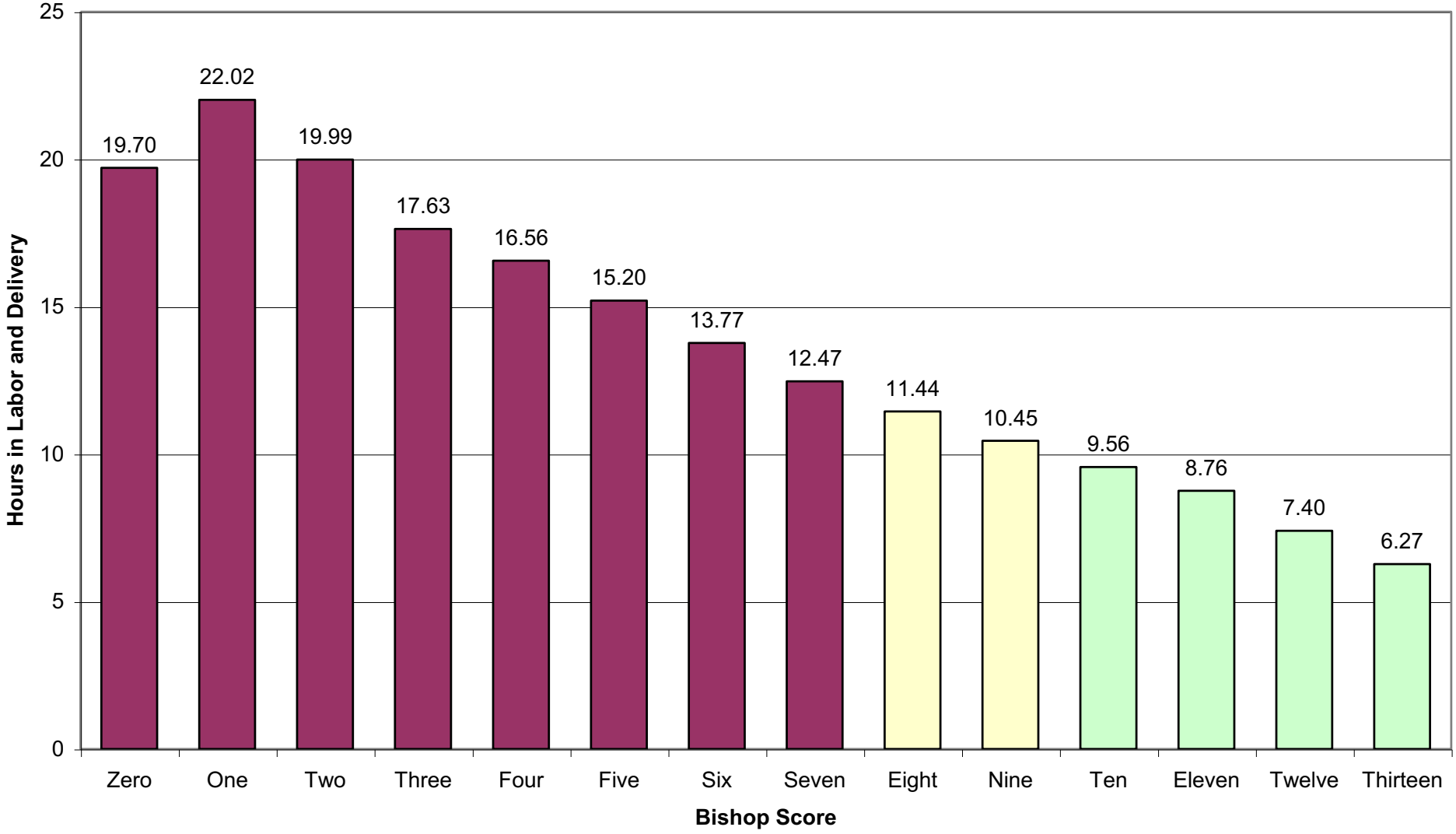
Elective Inductions in First-Time Moms 2001 -2006



Intermountain Healthcare

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

What is the Best Way of Looking at Population Data?

- "Induced vs Not-Induced" for all term GA can introduce bias (as not-induced may later become induced for reason…)
- "Induced at 39 weeks vs Expectant Management" appears better (but also can have bias as it includes pregnancies that go beyond 41, 41 and even 43 weeks…)
- Analyses using "Induced at 39 weeks vs Expectant Management" typically show no increased risk of induction

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

(Caughey AB etal. Ann Intern Med 2009 151:2523)

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")

Koopmans CM etal; *Lancet* 2009; 374(9694):979-88. (1st of 4 HYPITAT articles)

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%

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%

- 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)

(Walker KF etal. N Eng J Med 2016; 374:813-22)

The Arrive Trial: Keys
more details to come

- University hospitals
- All with strong induction of labor guidelines
- All with formal standards for “failed” induction: >15 hours of ROM with Oxytocin
- Very low risk population

- But overall, very impressive results!

(Grobman W, etal. 2018 Presentation at SMFM)

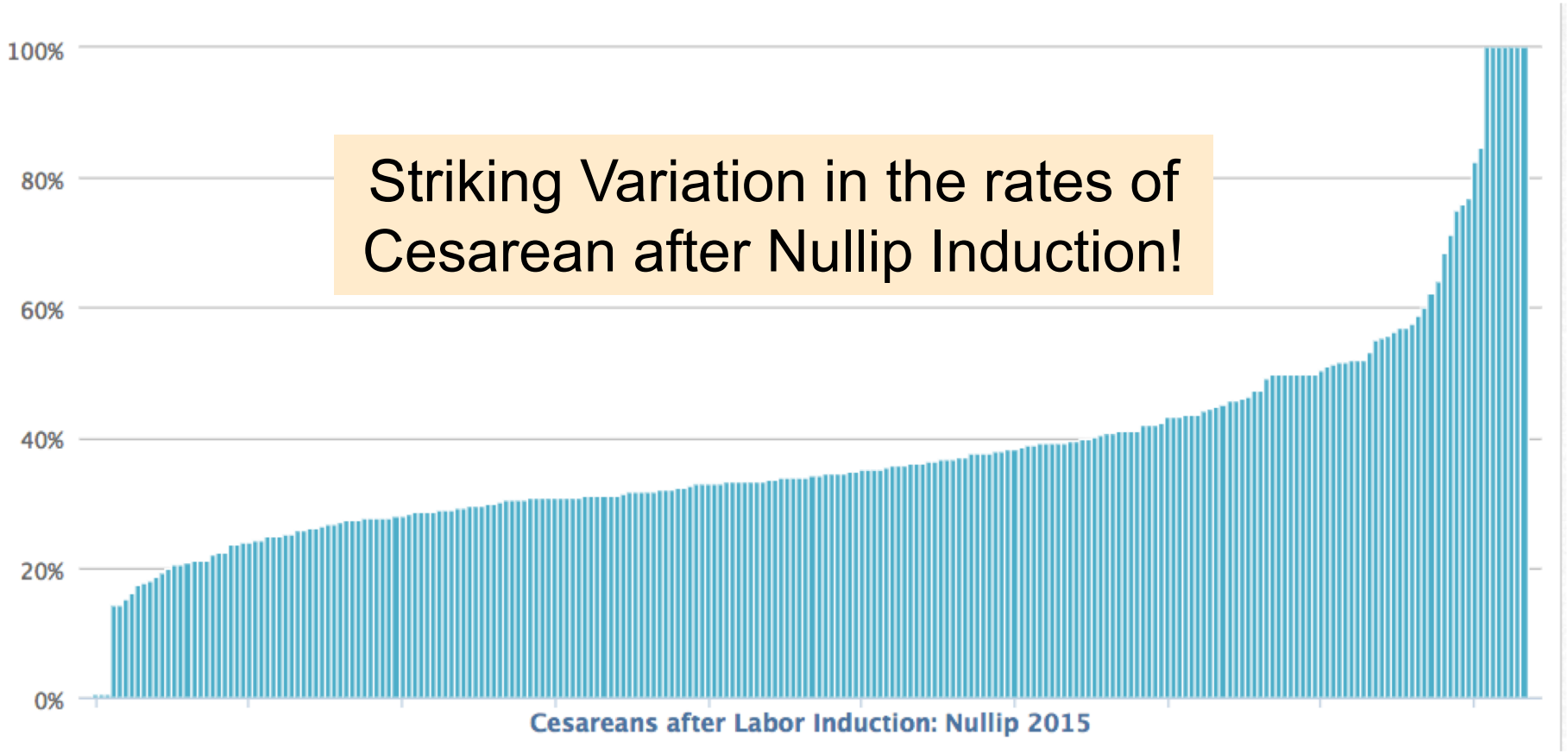
What to do when there is conflicting data?

- 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?

What Are the CS Rates with Labor Induction in "Average" Hospitals?

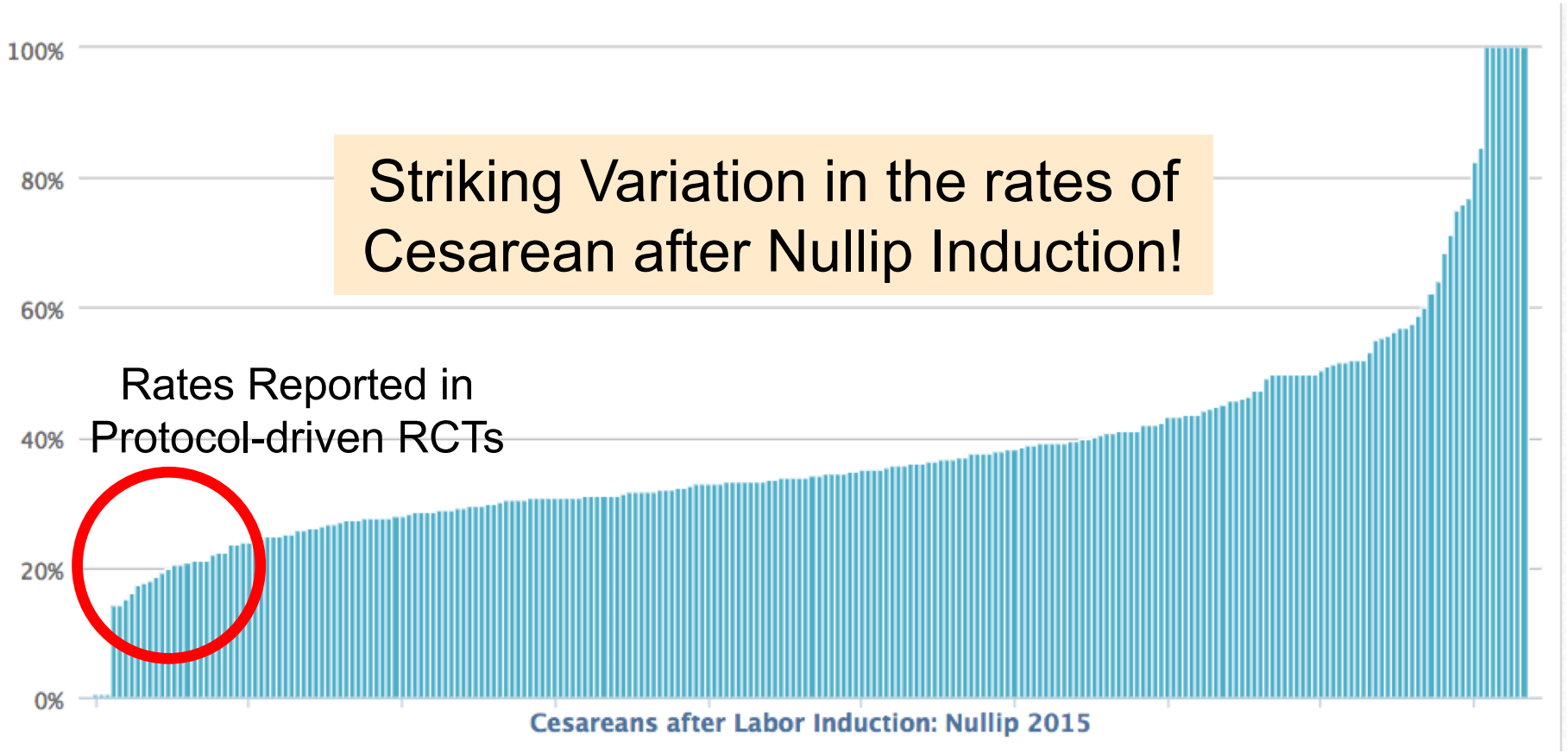
Cesarean Rate for Nullip Inductions 244 California Hospitals-- 2015

(CMQCC Maternal Data Center)



Cesarean Rate for Nullip Inductions 244 California Hospitals-- 2015

(CMQCC Maternal Data Center)



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

Society for Maternal-Fetal Medicine

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	Grade
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 rec
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 rec

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

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

Recommendations	Grade
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	Strong
Cervical ripening methods should be used when labor is induced in women with an unfavorable cervix.	Strong rec
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 rec

Strong Recommendation, High Quality Evidence

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

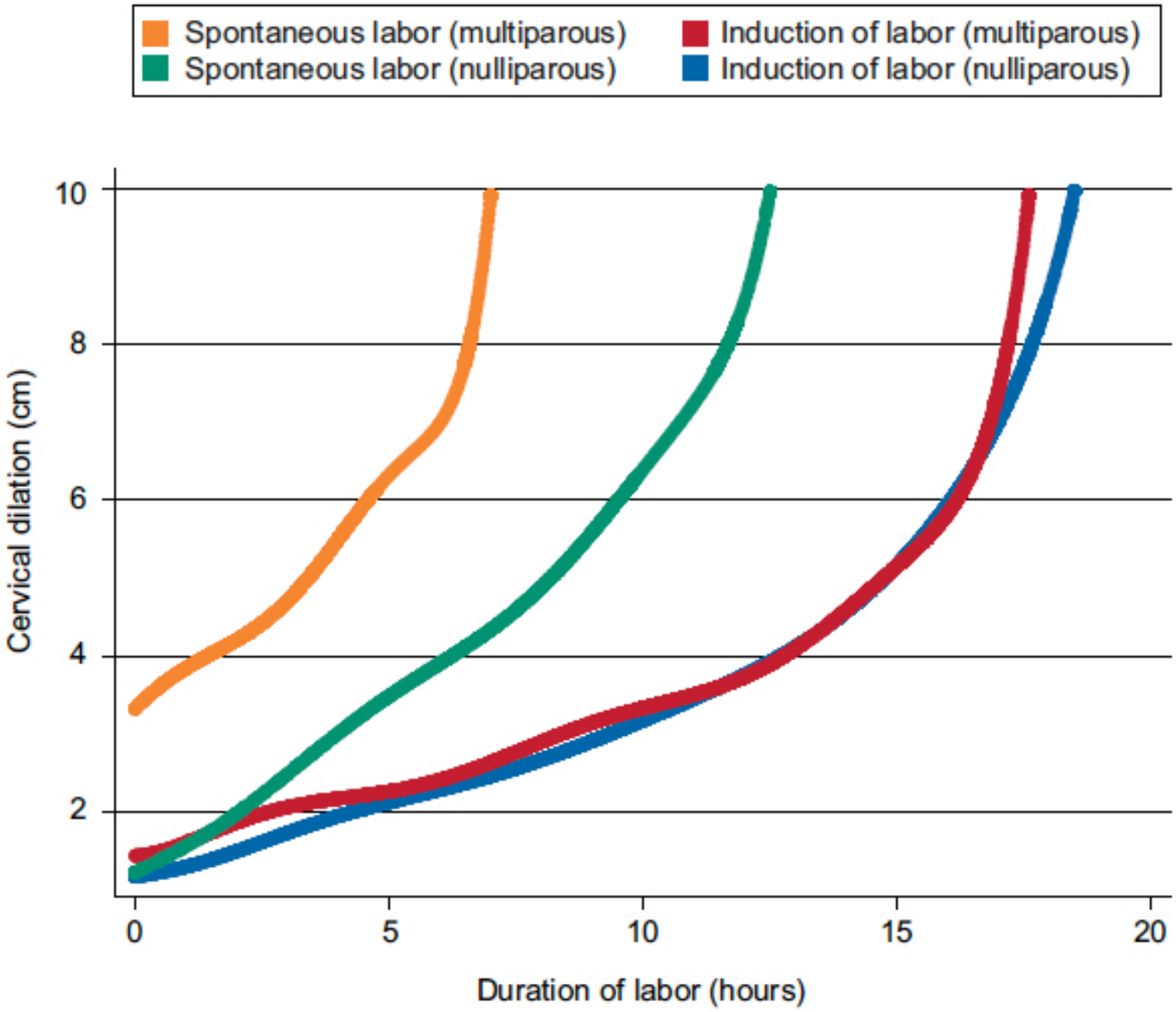


Fig. 1. Average labor curves stratified by parity and type of labor onset.

Harper. Normal Labor in Induction. Obstet Gynecol 2012.

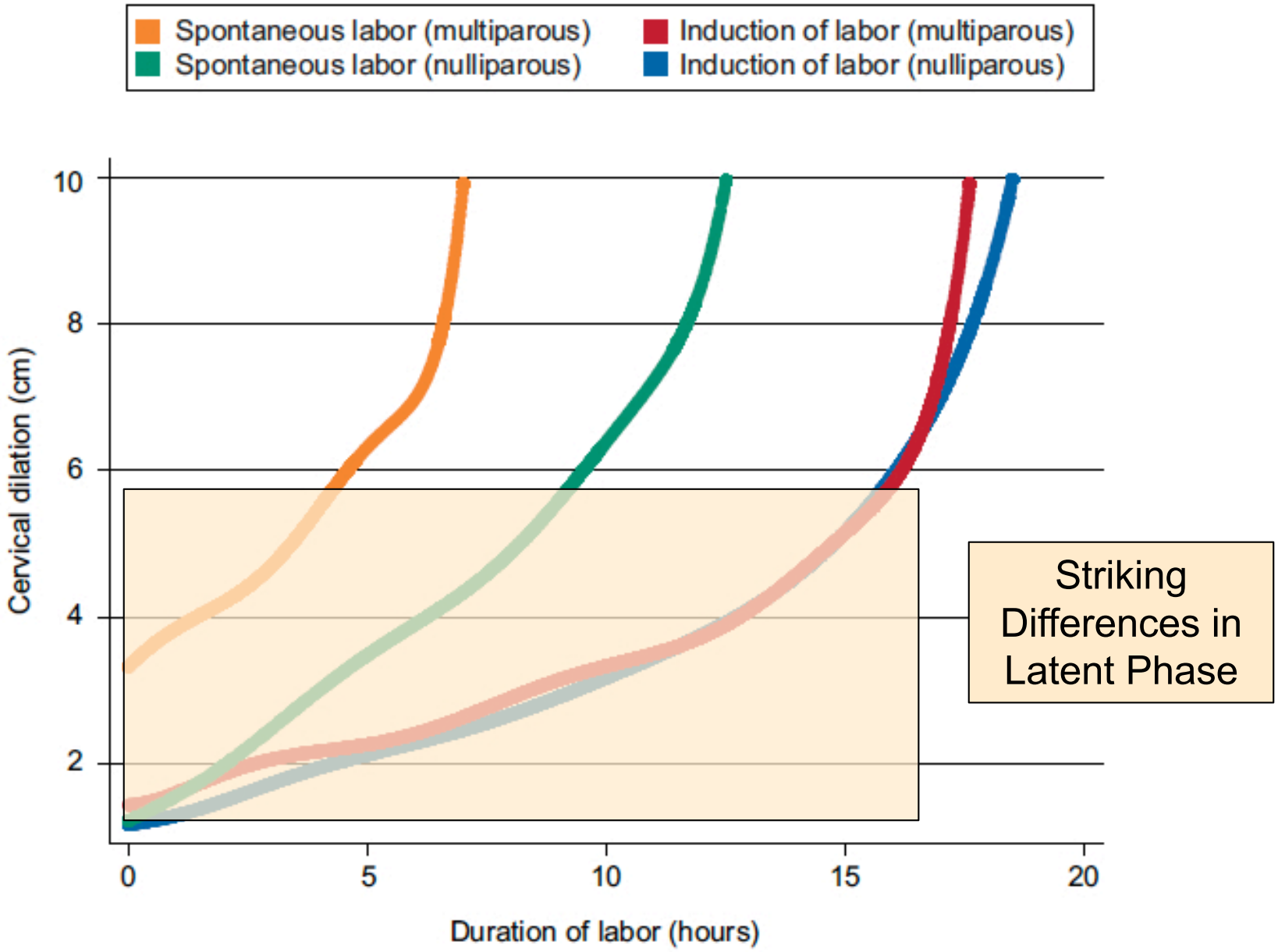
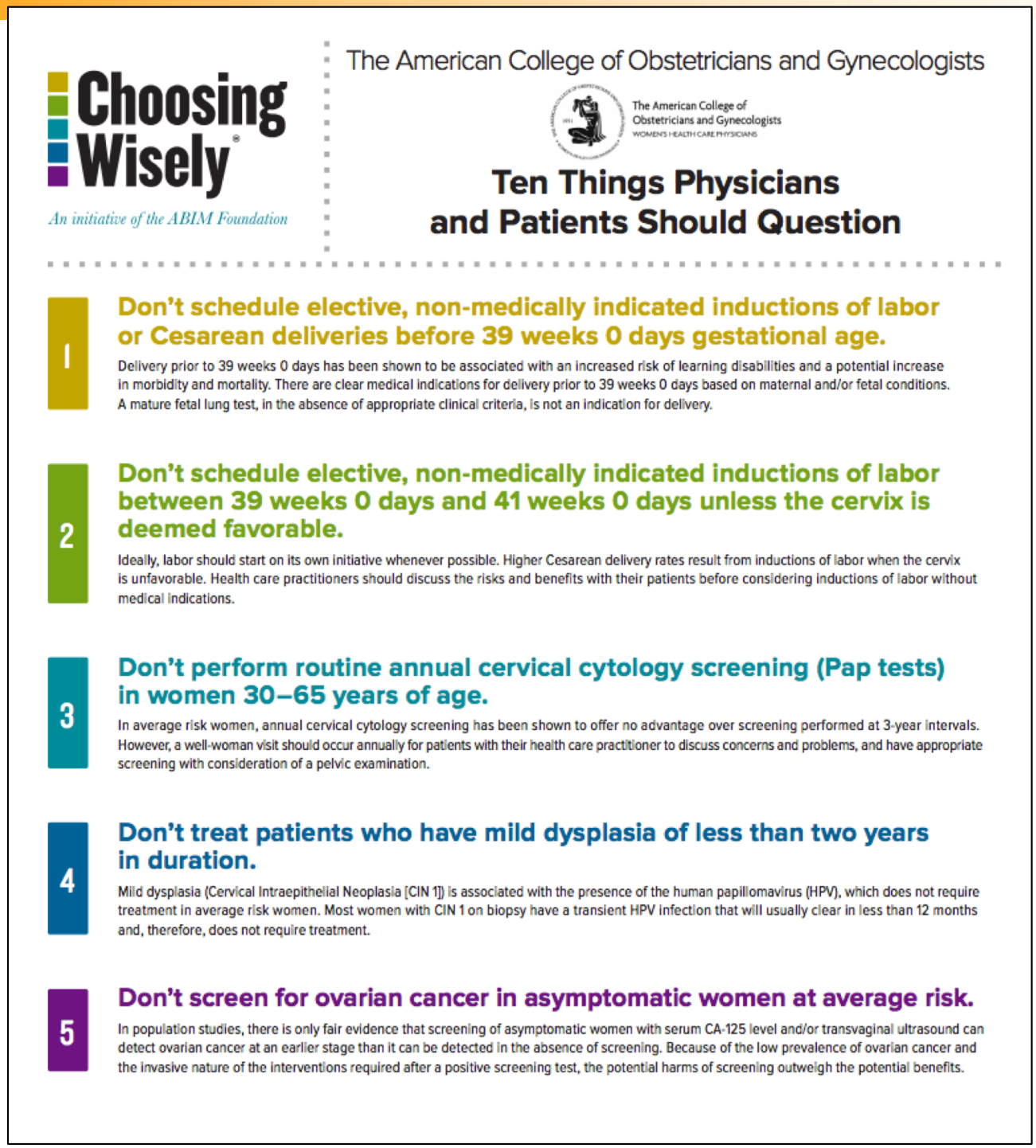


Fig. 1. Average labor curves stratified by parity and type of labor onset.

Harper. Normal Labor in Induction. Obstet Gynecol 2012.



Choosing Wisely®

An initiative of the ABIM Foundation

The American College of Obstetricians and Gynecologists

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

Ten Things Physicians and Patients Should Question

1 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.

2 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.

3 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.

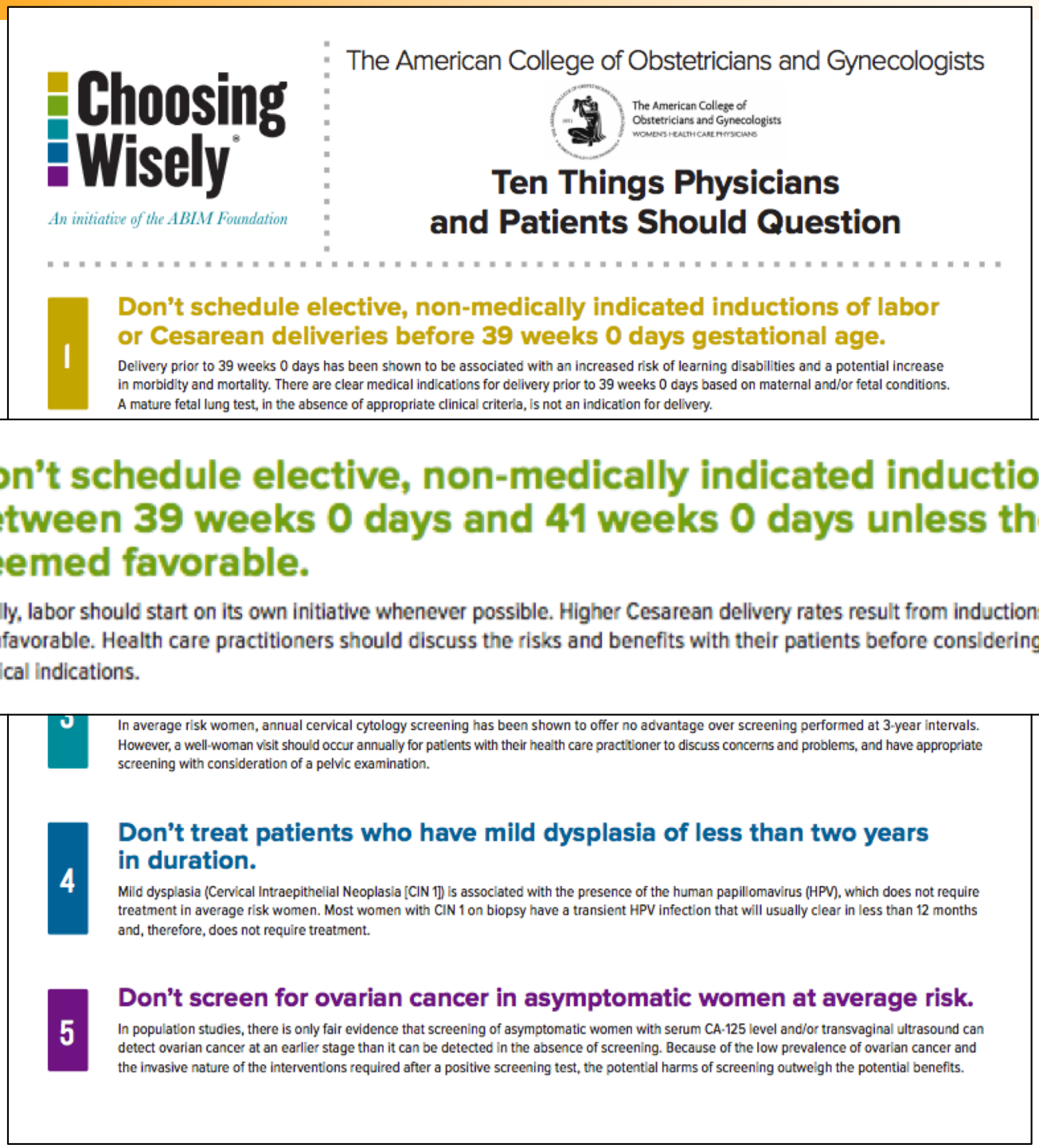
4 Don't treat patients who have mild dysplasia of less than two years in duration.

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.

5 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



Choosing Wisely®
An initiative of the ABIM Foundation

The American College of Obstetricians and Gynecologists

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

Ten Things Physicians and Patients Should Question

1 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.

2 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.

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.

4 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.

5 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

"Elective" Inductions 39-41wks

- "First do no harm": are the risks minimal? That depends---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!

CMQCC
California Maternal
Quality Care Collaborative

ARRIVE TRIAL
Finally answered?

David Lagrew MD
Executive Medical Director
PSJH Southern California

ARRIVE TRIAL SUMMARY

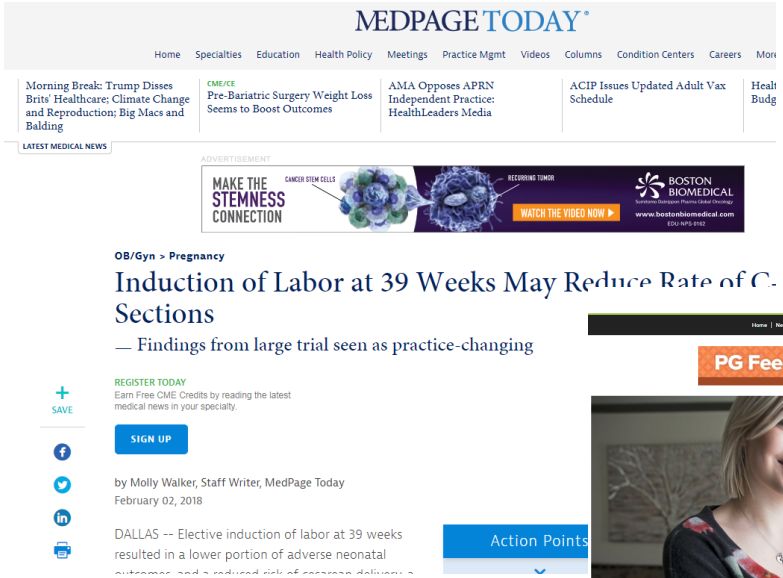
- The ARRIVE Trial was released on February 1st at the Society for Maternal Fetal Medicine Annual Meeting
- The ARRIVE trial was a randomized controlled trial comparing labor induction at 39 weeks to expectant management to 42 2/7 weeks among low risk nulliparous women
- The primary outcome was a composite of perinatal outcomes and the secondary outcome was cesarean birth
- The trial included 3,000 women in each arm and was performed in University hospitals belonging to the NICHD Maternal Fetal Medicine Network

Grobman WA, etal. A randomized trial of elective induction of labor at 39 weeks compared with expectant management of low-risk nulliparous women. Am J Obstet Gynecol 2018; 218:S601.

Main Results

- Delivery in the IOL group was significantly earlier than in the EM group (**39.3 weeks** [IQR 39.1 to 39.6] vs **40.0 weeks** [IQR 39.3 to 40.7]; *P* < .001)
- Preeclampsia and gestational hypertension occurred in **9%** of the IOL group versus **14%** of the EM group
- Among newborns, 3% in the IOL group needed respiratory support versus 4% in the EM group
- The primary (adverse) perinatal outcome occurred in 4.4% of the IOL group versus 5.4% of the EM group (RR 0.81, 95% CI 0.64 to 1.01; ***P* = .06**)
- **Frequency of CD also was significantly lower in the IOL group (18.6% vs 22.2%; RR 0.84, 95% CI 0.76 to 0.93)**

Immediate News:



MEDPAGE TODAY

Home Specialties Education Health Policy Meetings Practice Mgmt Videos Columns Condition Centers Careers

Morning Break: Trump Disses Brits' Healthcare; Climate Change and Reproduction; Big Macs and Balding

CME/CE
Pre-Bariatric Surgery Weight Loss Seems to Boost Outcomes

AMA Opposes APRN Independent Practice: HealthLeaders Media

ACIP Issues Updated Adult Vax Schedule

LATEST MEDICAL NEWS

ADVERTISEMENT

MAKE THE STEMNESS CONNECTION — CANCER STEM CELLS — RECURRING TUMOR — WATCH THE VIDEO NOW — BOSTON BIOMEDICAL — www.bostonbiomedical.com

OB/Gyn > Pregnancy

Induction of Labor at 39 Weeks May Reduce Rate of C-Sections

— Findings from large trial seen as practice-changing

SAVE

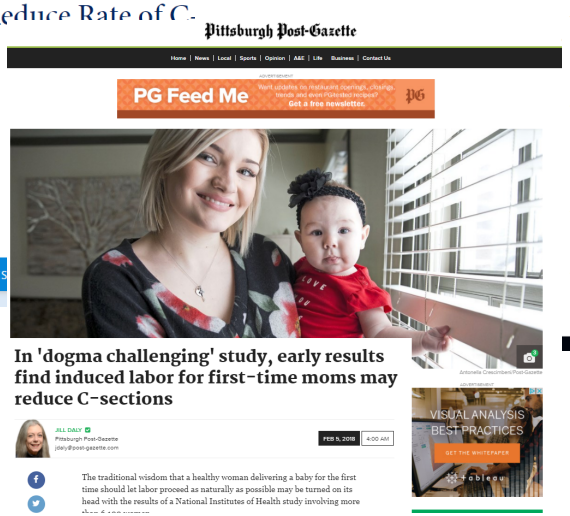
REGISTER TODAY
Earn Free CME Credits by reading the latest medical news in your specialty.

SIGN UP

by Molly Walker, Staff Writer, MedPage Today
February 02, 2018

DALLAS -- Elective induction of labor at 39 weeks resulted in a lower portion of adverse neonatal

Action Points



Pittsburgh Post-Gazette

Home | News | Local | Sports | Opinion | A&E | Life | Business | Contact Us

PG Feed Me — Get a free newsletter.

In 'dogma challenging' study, early results find induced labor for first-time moms may reduce C-sections

JILL DALY
Pittsburgh Post-Gazette
jdaly@post-gazette.com

FEB 5, 2018 4:00 AM

The traditional wisdom that a healthy woman delivering a baby for the first time should let labor proceed as naturally as possible may be turned on its head with the results of a National Institutes of Health study involving more

VISUAL ANALYSIS BEST PRACTICES — GET THE WHITEPAPER — tableau

NIH National Institutes of Health
Turning Discovery Into Health

Search

Health Information | Grants & Funding | News & Events | Research & Training

Home > News & Events > News Releases

NEWS RELEASES

Media Advisory Thursday, February 1, 2018

Induced labor after 39 weeks in healthy women may reduce need for C section

NIH-funded study suggests this approach may also reduce risk of preeclampsia, need for newborn respiratory support.

What

Healthy first-time mothers whose labor was induced in the 39th week of pregnancy were less likely to have a cesarean delivery, compared to a similar group who were not electively induced at 39 weeks, according to a study funded by the National Institutes of Health. Women in the induced group were also less likely to experience pregnancy-related blood pressure disorders, such as preeclampsia, and their infants were less likely to need help breathing in the first 3 days.

The study results will be presented at the annual meeting of the Society for Maternal-Fetal Medicine in Dallas on Feb. 1 at 11 a.m. EST.

Current guidelines recommend against elective induction of labor — inducing labor without a medical reason — in women in their first pregnancy prior to 41 weeks because of concern of increased need for cesarean delivery. Elective induction at 39 weeks, however, has become more common in recent years. NIH's *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) funded this study to determine whether elective induction is beneficial or harmful compared to expectant management (waiting for labor to begin naturally and intervening if problems occur).

Interesting Findings

- Certain perinatal complications such as neonatal seizures and 3rd or 4th degree lacerations were higher in the IOL group and most of the difference was made in a mixed diagnosis of respiratory findings
- The incidence of preeclampsia was raised from 9.1% to 14.3% despite there only being an average of 5 more days of gestational length
- The NTSV cesarean section rates were lower than vast majority of US hospitals in both IOL (18.6%) and EM group (22.2%) suggesting that the methods of conducting inductions and calling cesareans was not practiced in most hospitals.
- TTD not given and impact on L & D resources not discussed in abstract

Same group, same month, *different publication*…

- Study Design: This study is based on data from an obstetric cohort of women delivering at 25 US hospitals from 2008 through 2011. Nulliparous women who had a term singleton gestation in the cephalic presentation were eligible for this analysis if they underwent a labor induction.
- THEY HAD A CSR OF 33% IN THIS GROUP!

Grobman et al, American Journal of Obstetrics & Gynecology 2018 218, 122.e1-122.

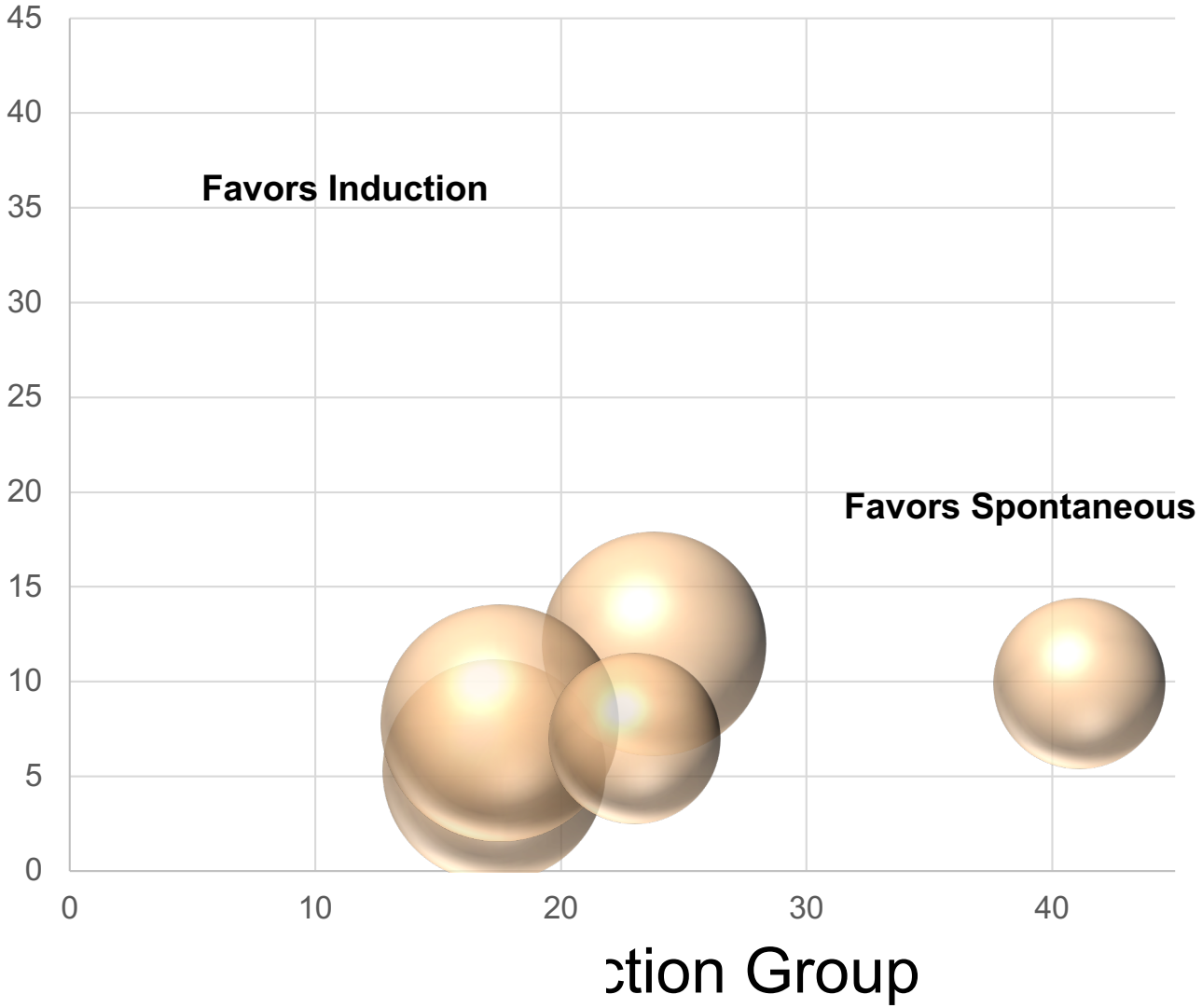
Wait for the paper, so we know:

- What were the protocols for induction and labor management?
- What was the impact on length of labor and if generalized could the typical US hospital achieve the same results without significantly over burdening their staffing and room constraints?
- Why were certain complications so frequent (preeclampsia and chorioamnionitis)?
- What were the rates of CS in induced versus spontaneous labor patients?

Retrospective: Spontaneous Labor vs. Induction

- Maslow et al in 2000 found, after reviewing 1,135 nulliparous women with low-risk, singleton, vertex pregnancies, that elective induction of labor (IOL) was associated with a 2.4x higher risk of cesarean delivery when compared to women in spontaneous labor, as well as increased cost and hospital time.
- Lee et al in 2015 found, after reviewing 1,375 pregnancies, a risk of cesarean of 17.3% in induced women compared to 5.3% in women who presented with spontaneous labor. This increased risk was confounded by many risk factors, including nulliparity and lower Bishop scores.
- Vrouenraets et al in 2005 found, in a prospective study of 1,389 women, a cesarean delivery rate of 12% among women in spontaneous labor compared to a rate of 23.4% among women induced for medical reasons and 23.8% among women induced electively.
- Seyb et al in 1999 found, in a prospective cohort study of 1,561 women, a cesarean delivery rate of 7.8% among women in spontaneous labor compared to a rate of 17.7% among women induced for medical reasons and 17.5% among women induced electively.
- Prysak et al in 1998 found, in a retrospective case-control study of 461 pairs of women, a 1.81-fold increased risk of cesarean delivery among women who were electively induced, with an even higher risk among nulliparous women (OR=6.14).
- Rattigan et al in 2013 found, in a retrospective analysis of 807 women, that women who had elective inductions had a cesarean delivery rate of 41.1% compared to 9.9% for women presenting with spontaneous labor.
- Vahratian et al in 2005 found, in a single institution review of 2,200 women, that elective induction in women with unfavorable cervices increased the risk of cesarean delivery by 3.5-fold.
- Luthy et al in 2004 found, in a single institution cohort study of 3,215 term, singleton, cephalic nulliparous pregnancies, a 1.78-fold higher risk of cesarean delivery with elective induction.
- Levine et al in 2014 found, in a retrospective cohort study of 862 women, a cesarean rate of 23% in induced women, compared to a rate of 7% in spontaneous laborers.
- Ehrenthal et al in 2010 found, in a retrospective cohort study of 7,804 women, that elective induction increased the risk of cesarean by 1.93-fold in nulliparous women.

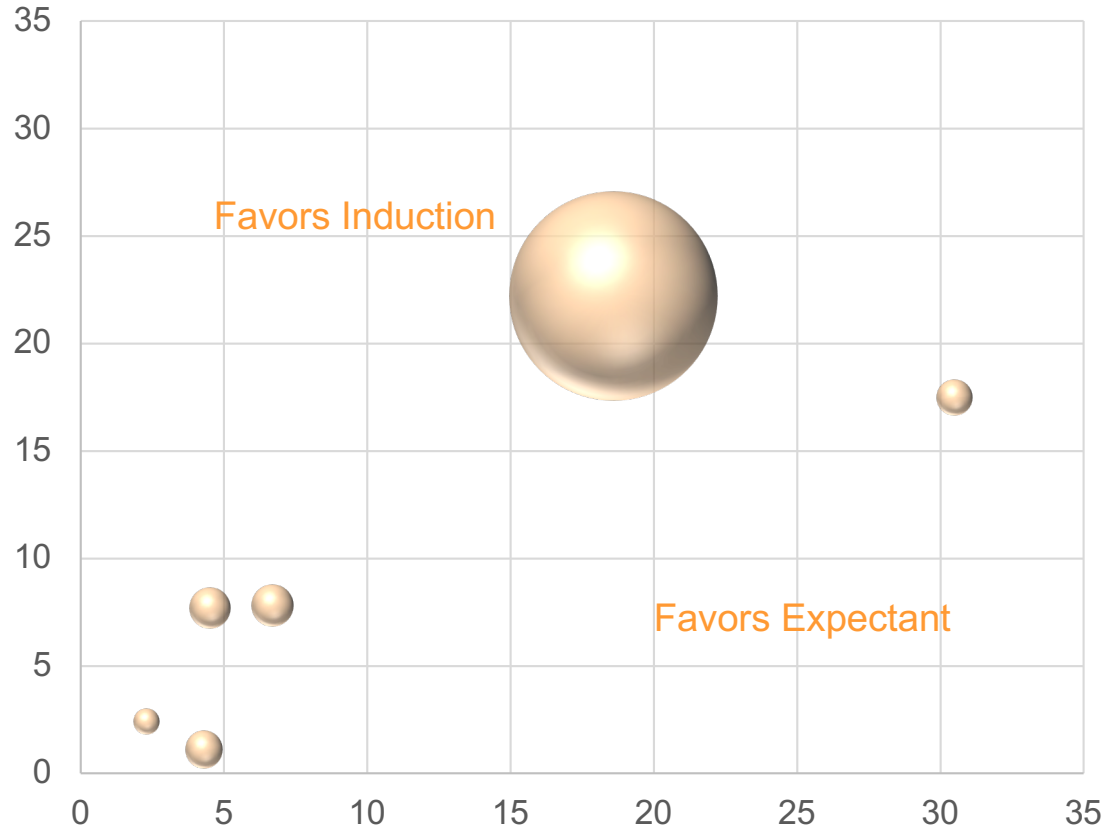
Induction CSR vs. Spontaneous Labor



Elective Induction at 39 weeks Trials

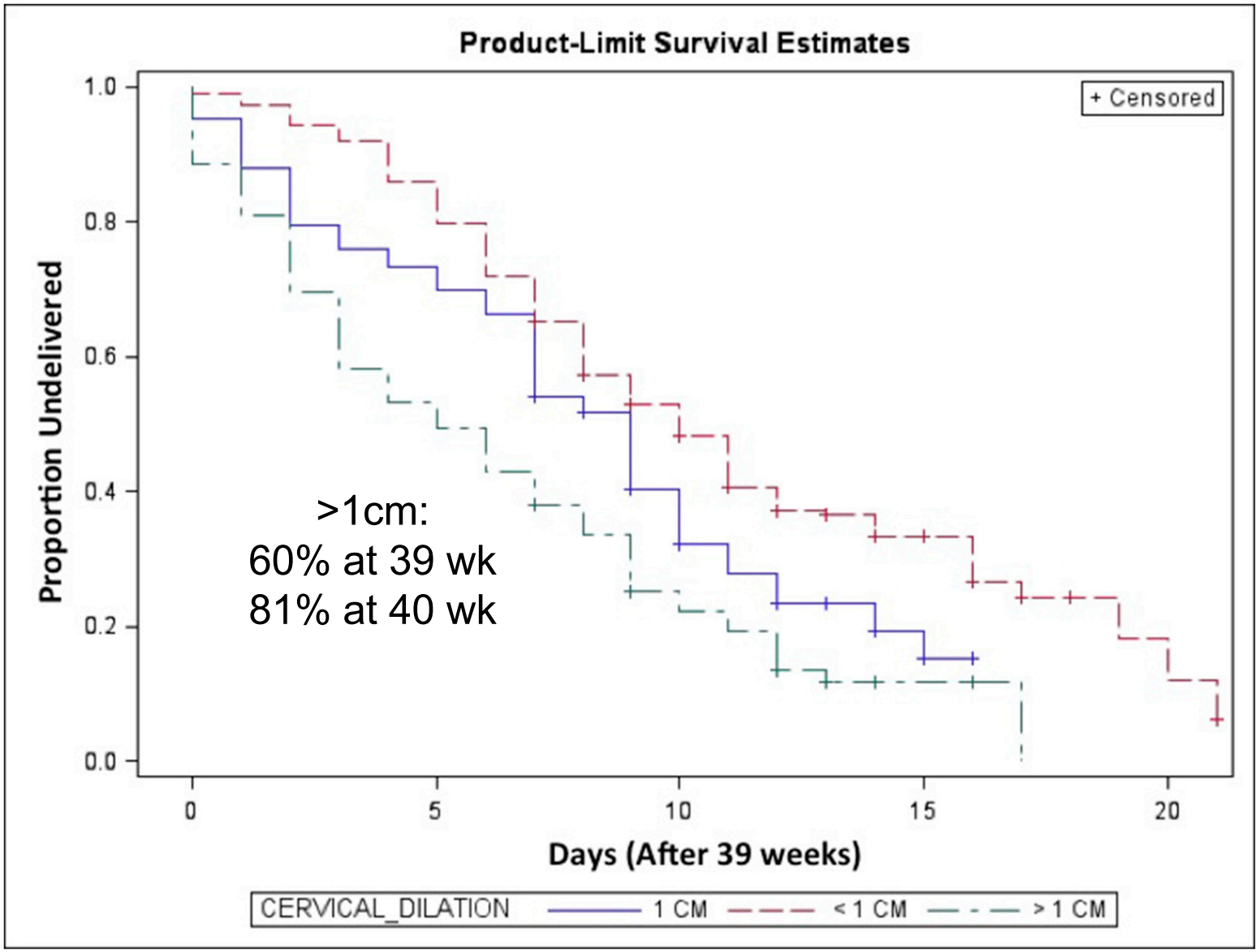
- Cole et al, 1975: 228 women, induced: 4.5%, expectant management: 7.7%
- Martin et al, 1978: 184 women, induced: 4.3%, expectant management: 1.1%
- Tyllskar et al, 1979: 84 women, induced: 2.3%, expectant management: 2.4%
- Nielsen et al, 2005: 226 women, induced: 6.7%, expectant management: 7.8%
- Miller et al, 2014: 162 women, induced: 30.5%, expectant management: 17.5%
- Grobman et al, 2018: 6000 women, induced: 18.6%, expectant management: 22.2%

RCT Results for Elective Induction



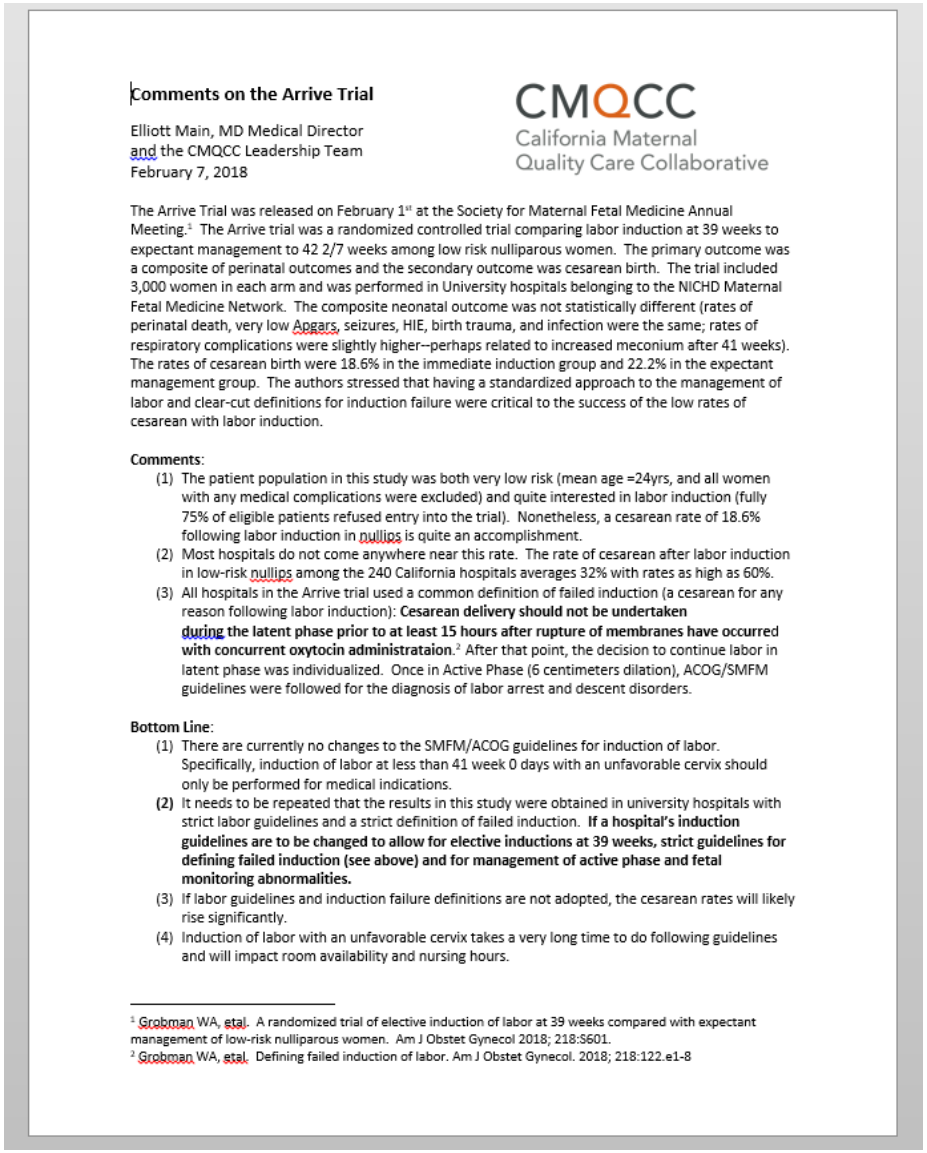
If Elective Induction works here's possibly why:

- CSR increases with gestational age
  - Rate of larger infants increases
  - Rate of placental insufficiency/SGA increases
- Increased CSR of "Indicated" over "Elective" Induction
- Rate of conditions, not allowing further expectant management, forcing induction with very unripe cervix (rate of preeclampsia)



Penelli et al AJOG Volume 218, Issue 1, Supplement, Pages S247–S248

CMQCC response:



Comments on the Arrive Trial

CMQCC
California Maternal
Quality Care Collaborative

Elliott Main, MD Medical Director
and the CMQCC Leadership Team
February 7, 2018

The Arrive Trial was released on February 1st at the Society for Maternal Fetal Medicine Annual Meeting.[1] The Arrive trial was a randomized controlled trial comparing labor induction at 39 weeks to expectant management to 42 2/7 weeks among low risk nulliparous women. The primary outcome was a composite of perinatal outcomes and the secondary outcome was cesarean birth. The trial included 3,000 women in each arm and was performed in University hospitals belonging to the NICHD Maternal Fetal Medicine Network. The composite neonatal outcome was not statistically different (rates of perinatal death, very low Apgars, seizures, HIE, birth trauma, and infection were the same; rates of respiratory complications were slightly higher--perhaps related to increased meconium after 41 weeks). The rates of cesarean birth were 18.6% in the immediate induction group and 22.2% in the expectant management group. The authors stressed that having a standardized approach to the management of labor and clear-cut definitions for induction failure were critical to the success of the low rates of cesarean with labor induction.

Comments:

(1) The patient population in this study was both very low risk (mean age =24yrs, and all women with any medical complications were excluded) and quite interested in labor induction (fully 75% of eligible patients refused entry into the trial). Nonetheless, a cesarean rate of 18.6% following labor induction in nullips is quite an accomplishment.

(2) Most hospitals do not come anywhere near this rate. The rate of cesarean after labor induction in low-risk nullips among the 240 California hospitals averages 32% with rates as high as 60%.

(3) All hospitals in the Arrive trial used a common definition of failed induction (a cesarean for any reason following labor induction): **Cesarean delivery should not be undertaken during the latent phase prior to at least 15 hours after rupture of membranes have occurred with concurrent oxytocin administrataion.**[2] After that point, the decision to continue labor in latent phase was individualized. Once in Active Phase (6 centimeters dilation), ACOG/SMFM guidelines were followed for the diagnosis of labor arrest and descent disorders.

Bottom Line:

(1) There are currently no changes to the SMFM/ACOG guidelines for induction of labor. Specifically, induction of labor at less than 41 week 0 days with an unfavorable cervix should only be performed for medical indications.

(2) It needs to be repeated that the results in this study were obtained in university hospitals with strict labor guidelines and a strict definition of failed induction. **If a hospital's induction guidelines are to be changed to allow for elective inductions at 39 weeks, strict guidelines for defining failed induction (see above) and for management of active phase and fetal monitoring abnormalities.**

(3) If labor guidelines and induction failure definitions are not adopted, the cesarean rates will likely rise significantly.

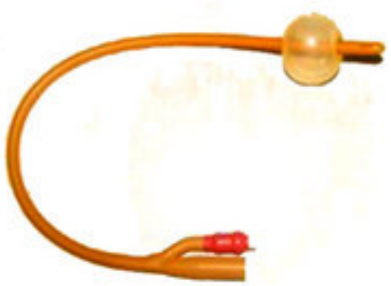
(4) Induction of labor with an unfavorable cervix takes a very long time to do following guidelines and will impact room availability and nursing hours.

---

[1] Grobman WA, etal. A randomized trial of elective induction of labor at 39 weeks compared with expectant management of low-risk nulliparous women. Am J Obstet Gynecol 2018; 218:S601.
[2] Grobman WA, etal. Defining failed induction of labor. Am J Obstet Gynecol. 2018; 218:122.e1-8

Summary

- Making recommendations and incorporating into clinical practice will require waiting for review of the full publication to see if these questions can be answered.
- The generalizability of the results is still very much in question and the cost/resource questions must be addressed.
- Can we use the results to lower cesarean section rates by showing that a carefully followed protocol for induction of labor and elective induction at 39 weeks?



CMQCC
California Maternal
Quality Care Collaborative

Outpatient Balloon 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.

Rationale of Outpatient Balloon

1. 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
3. 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

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.

What if outpatient?

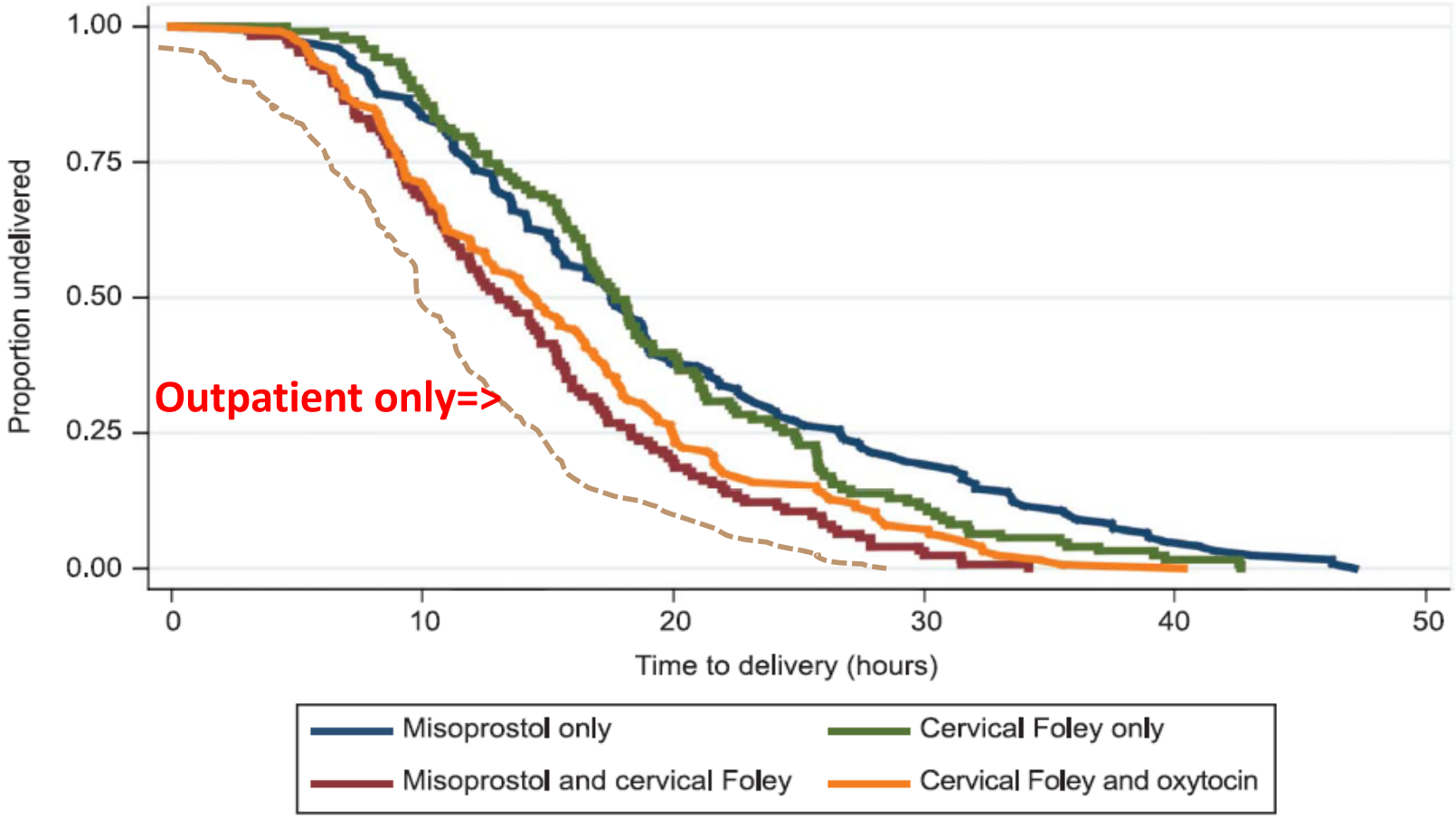


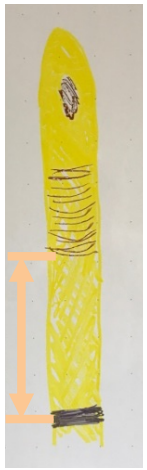
Fig. 2. Estimated time to delivery by study group. This figure displays the Kaplan-Meier survival curves for time to delivery for the four induction method groups, $P<.001$.

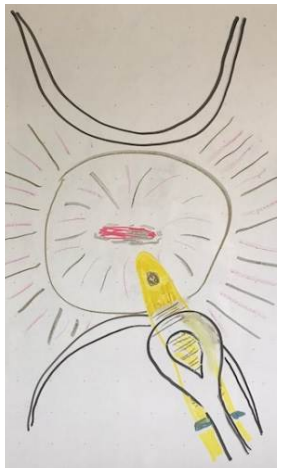
Levine. Randomized Trial of Four Induction Methods. Obstet Gynecol 2016.

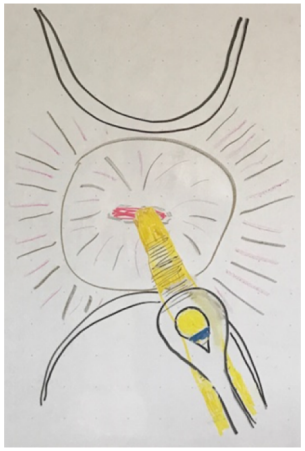
Our Technique Summary

- Patient seen in labor and delivery where navigator reviews documentation, labs and orders, explains induction procedure in detail (saving time in morning of induction); pre-induction 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

Mark

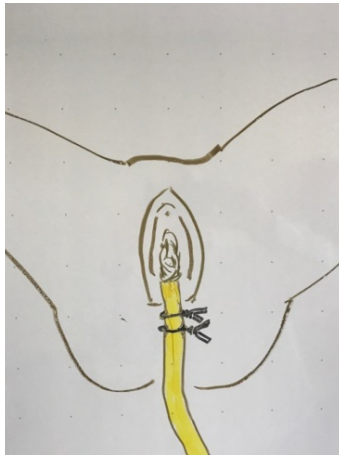


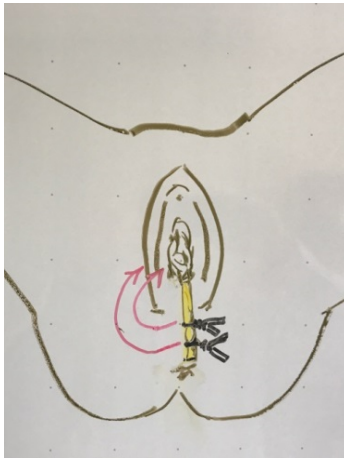




Place thru cervical canal

Inflate balloon
Tie off catheter at vaginal entrance





Cut off Foley Tail
Tuck into vagina

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