What’s the Deal With (Elective) Labor Inductions?

Ware Branch, MD

“At the heart of obstetrical care is a seemingly simple calculus: when are the benefits of delivery [and for whom] greater than the benefits of continued care [for the mother and baby]?”

William Grobman, MD
Disclosures

• UCB Pharmaceuticals Advisory Board, 2016
Objectives

- Evaluate the evidence for and against elective induction of labor
- Assess the cost of elective labor inductions
- Compare the methods of cervical ripening and labor induction
- Discuss future needs regarding elective labor induction
## Elective Induction

### Why?

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Patient desire and convenience</td>
<td></td>
</tr>
<tr>
<td>Physician work efficiency and lifestyle</td>
<td></td>
</tr>
<tr>
<td>Improved outcomes</td>
<td></td>
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<tr>
<td>Improved L&amp;D efficiency</td>
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</tr>
</tbody>
</table>
Figure 1. Induction of labor, by gestational age: United States, 1990–2012

NOTES: Singleton 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.

Percent of All Deliveries that are Elective Inductions, Medically Indicated Inductions and Spontaneous Labor

- % Elective
- % Indicated
- % Spontaneous
Elective Induction Versus Expectant Management

Pertinent Outcomes

- Cesarean delivery (CD)
- Operative vaginal delivery (OVD) and serious obstetrical lacerations
- PP hemorrhage
- Infection
  - Chorioamnionitis
  - Sepsis
- Time in labor
- Hospital length of stay

- Feto-neonatal death
- Feto-neonatal morbidities
  - Hypoxic encephalopathy
    - Poor Apgar scores, abn cord gases, seizures/organ dysfunction
  - Respiratory morbidities
  - Infection
  - Hyperbilirubinemia
- NICU admission / LOS
- Hospital LOS
Systematic Review: Elective Induction of Labor Versus Expectant Management of Pregnancy

- Analysis of 11 RCTs and 25 observational studies
  - Only included studies of pregnancies 37\(^0\) – 41\(^6\) weeks
  - Of RCTs, control groups: expectant management in 9 and spontaneous labor in 2
- Most RCTs were of pregnancies beyond 40 weeks
- Details of only 506 nulliparous women were reported in the trials

Systematic Review: Elective Induction of Labor Versus Expectant Management of Pregnancy

Comparison of cesarean delivery reported by the randomized, controlled trials of elective induction of labor versus expectant management, stratified by study location

Systematic Review: Elective Induction of Labor Versus Expectant Management of Pregnancy

- Expectant management → 22% increase in CD (OR, 1.22 [95% CI, 1.07 to 1.39]) and an absolute risk difference of 1.9 percentage points
  - For nulliparas, OR for CD 1.67 (0.81-3.46)
- Different than findings in observational studies

“Beyond [CD], …examination of most other outcomes demonstrates no statistically significant differences and provides low or insufficient evidence. Thus, the safety of elective induction labor requires further investigation.”
Maternal and Neonatal Outcomes in Electively Induced Low Risk Pregnancies

- Retrospective, cross-sectional study from 12 US institutions 2002-2008 (Consortium on Safe Labor)
  - 13,242 term electively induced labors in low risk, term pregnancies (~10% of low risk deliveries)
  - Compared to expectantly managed pregnancies

Am J Obstet Gynecol. 2014;211:249.e1
# Maternal and Neonatal Outcomes in Electively Induced Low Risk Pregnancies

## Neonatal Complication Composite

<table>
<thead>
<tr>
<th>Week of Gestation</th>
<th>Elective Induction</th>
<th>Expectant Management</th>
<th>Adj OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nulliparous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>109/1576</td>
<td>2451/26,605</td>
<td>0.750 (0.613-0.917)</td>
</tr>
<tr>
<td>40</td>
<td>137/2124</td>
<td>743/7447</td>
<td>0.652 (0.535-0.795)</td>
</tr>
<tr>
<td></td>
<td>Multiparous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>179/5987</td>
<td>988/19,749</td>
<td>0.590 (0.494-0.705)</td>
</tr>
<tr>
<td>40</td>
<td>75/1987</td>
<td>232/4645</td>
<td>0.756 (0.564-1.012)</td>
</tr>
</tbody>
</table>

Am J Obstet Gynecol. 2014;211:249.e1
Maternal and Neonatal Outcomes in Electively Induced Low Risk Pregnancies

- For maternal and neonatal morbidities, no outcome was worse with elective induction
- The composite neonatal morbidity was reduced with elective induction at term
- Several maternal outcomes were reduced with elective induction
  - Infectious morbidity
  - Obstetrical lacerations
  - Shoulder dystocia

Am J Obstet Gynecol. 2014;211:249.e1
Elective Induction Compared with Expectant Management in Term Nulliparas with a Favorable Cervix

- Retrospective cohort study of nulliparous women at 39°-40° weeks at a single institution
  - Elective induction group
    - Bishop score of at least 5 (medical record review)
    - No indication for induction
  - Randomly selected controls were women at 39+ weeks being expectantly managed
- Primary outcome = cesarean delivery

### Elective Induction Compared with Expectant Management in Term Nulliparas with a Favorable Cervix

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Expectantly Managed (N=294)</th>
<th>Elective Induction (N=295)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cesarean</td>
<td>20.1%</td>
<td>20.8%</td>
<td>0.84</td>
</tr>
<tr>
<td>Chorioamnionitis</td>
<td>9.5%</td>
<td>10.9%</td>
<td>0.59</td>
</tr>
<tr>
<td>Operative vaginal delivery</td>
<td>21.3%</td>
<td>20.2%</td>
<td>0.77</td>
</tr>
<tr>
<td>3rd or 4th degree laceration</td>
<td>12.6%</td>
<td>9.5%</td>
<td>0.24</td>
</tr>
<tr>
<td>Postpartum hemorrhage</td>
<td>3.4%</td>
<td>4.1%</td>
<td>0.66</td>
</tr>
</tbody>
</table>

Elective Induction Compared with Expectant Management in Term Nulliparas with a Favorable Cervix

<table>
<thead>
<tr>
<th>Neonatal Outcomes Stratified by Study Group</th>
<th>Expectantly Managed (N=294)</th>
<th>Elective Induction (N=294)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apgar &lt;7 at 5 min</td>
<td>0.7%</td>
<td>0.7%</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>NICU admission</td>
<td>1.4%</td>
<td>1.7%</td>
<td>0.73</td>
</tr>
<tr>
<td>UmA pH &lt;7</td>
<td>1.2%</td>
<td>0.5%</td>
<td>0.34</td>
</tr>
</tbody>
</table>

Randomized Trial of Labor Induction in Women 35 Years of Age or Older

- **Patients**
  - Low risk primigravidas $\geq 35$ yrs old
  - Singleton, cephalic fetus
  - Without regard to Bishop Score

- **Intervention**
  - Induction at $39^0-39^6$

- **Controls**
  - Expectant management until $41^0$

- **Primary outcome**
  - Cesarean delivery

Randomized Trial of Labor Induction in Women 35 Years of Age or Older

Cesarean Delivery
Assisted Vaginal Delivery
Fetal Distress
Maternal Complications*

* Hemorrhage requiring transfusion, systemic infection

## Neonatal Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Induction (N=304)</th>
<th>Expectant (N=314)</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liveborn</td>
<td>304</td>
<td>314</td>
<td></td>
</tr>
<tr>
<td>Low birth weight (&lt;2500 g)</td>
<td>4</td>
<td>6</td>
<td>0.68 (0.19–2.4)</td>
</tr>
<tr>
<td>UmA pH &lt;7.0</td>
<td>1</td>
<td>1</td>
<td>0.89 (0.05–14.6)</td>
</tr>
<tr>
<td>Adm to NICU &gt;4 days</td>
<td>6</td>
<td>7</td>
<td>0.88 (0.26–3.06)</td>
</tr>
<tr>
<td>Hypoxia</td>
<td>2</td>
<td>2</td>
<td>1.03 (0.14–7.50)</td>
</tr>
<tr>
<td>Suppl oxygen required</td>
<td>9</td>
<td>7</td>
<td>1.32 (0.58–2.99)</td>
</tr>
</tbody>
</table>
Elective Induction of Labor Compared vs Expectant Management of Nulliparous Women at 39 Weeks

- RCT of 161 nulliparas with BS of 5 or less
  - Randomized in 38th week; induction in 39th week
  - Foley or misoprostol $\rightarrow$ oxytocin
- Primary outcome: Cesarean delivery

Obstet Gynecol 2015; 126:1258
Elective Induction of Labor Compared vs Expectant Management of Nulliparous Women at 39 Weeks

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Induction (N=82)</th>
<th>Expectant Care (N=79)</th>
<th>RR (95% CI) or P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cesarean Delivery</td>
<td>25 (31%)</td>
<td>14 (18%)</td>
<td>1.72 (0.97-3.06)</td>
</tr>
<tr>
<td>NR FHRT</td>
<td>4 (16%)</td>
<td>5 (36%)</td>
<td>0.49 (0.14-1.40)</td>
</tr>
<tr>
<td>Arrest of dilation</td>
<td>18 (72%)</td>
<td>5 (36%)</td>
<td>2.02 (0.96-4.24)</td>
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<tr>
<td>Arrest of descent</td>
<td>3 (12%)</td>
<td>3 (21%)</td>
<td>0.56 (0.13-2.4)</td>
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<tr>
<td>Apgar &lt; 5 at 5 min</td>
<td>0</td>
<td>1 (1%)</td>
<td>0.49</td>
</tr>
<tr>
<td>NICU Admission</td>
<td>5 (6%)</td>
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<td>0.96 (0.29-3.2)</td>
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Economic Implications of Method of Delivery

  - Spontaneous labor
  - Induced labor
  - Cesarean without labor
- Compared costs that included
  - Physician fees, nursing hours in L&D, postpartum and neonatal intensive care units, epidural use, induction of labor agents, and consumables

Economic Implications of Method of Delivery

- Compared to spontaneous labor, induced labor was 16% more costly per case
  - Cesarean without labor only 4% more costly per case
- No accounting for long term implications of cesarean

Elective Induction Compared with Expectant Management in Term Nulliparas with a Favorable Cervix

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<tr>
<td>Hours in L&amp;D</td>
<td>9.0 (±5.1)</td>
<td>12.7 (±4.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Labor &gt; 12 hours</td>
<td>30.3%</td>
<td>47.6%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Delivery 6 am – 6 pm</td>
<td>54%</td>
<td>48%</td>
<td>0.20</td>
</tr>
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### Elective Induction of Labor Compared vs Expectant Management of Nulliparous Women at 39 Weeks

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<tr>
<td>LOS in L&amp;D (min)</td>
<td>1,521 ± 567</td>
<td>1,068 ± 553</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Cost-Effectiveness of Elective Induction in Nulliparas at 41 Weeks

- Decision analysis comparing induction to expectant management in 200,000 women
- Assumptions
  - Fetal demise rate of 0.12% in 41st wk
  - CS rate of 27% in induced women
  - Others
    - Probability of preeclampsia
    - Probability of maternal mortality
    - Probability of spontaneous labor
    - Probability of non-reassuring fetal surveillance

Cost-Effectiveness of Elective Induction in Nulliparas at 41 Weeks

- Induction superior to expectant management with regard to health effectiveness
  - Fetal death
  - Shoulder dystocia
  - Meconium aspiration syndrome
- Induction slightly more expensive, but with favorable cost ($10,945) per Quality-Adjusted Life Year

Elective Induction vs Expectant Management

Where Are We?

- Similar CD rates
- No obvious increase in maternal or fetal-neonatal morbidity
  - But studies underpowered
- Increased time and materials in L&D → more expensive per case, but
- Favorable cost per QALY (at least by 41 weeks)
Elective Induction vs Expectant Management

What We Could Really Use

- Better understanding of potential benefits vs risks of elective induction
  - Especially in unfavorable patients
- Better understanding of costs of elective induction
A Randomized Trial of Induction Versus Expectant Management (ARRIVE)

NCT01990612

- Induction at 39\(^0\)-39\(^4\) versus expectant management until >40\(^5\) weeks in nulliparas
- Primary outcome – severe neonatal morbidity and perinatal mortality
- Numerous secondary outcomes
We all want favorable maternal and neonatal outcomes, but what are the real goals of elective labor induction?

- Patient convenience and satisfaction
- Physician convenience and satisfaction
- Nurse convenience and staffing efficiency
- Facility convenience and budgetary accommodation
IMC L&D Patient Arrival Times - Total

9/1/2013 - 8/31/2014

Number of Patients

Hour of Day

- Sunday Average
- Monday Average
- Tuesday Average
- Wednesday Average
- Thursday Average
- Friday Average
- Saturday Average
- Daily Average
The Goals for Most Patients and Providers
What are the Real Goals of the Labor Induction?

Same day delivery (≤6-8 hours)?

Next day delivery (≤12-24 hours)?

Ground shipping delivery (within 2-4 days)?
Same day delivery ($\leq 6-8$ hours)?

Next day delivery ($\leq 12-24$ hours)?

Ground shipping delivery (within 2-4 days)?
The Easy Case
(Same day delivery)

- Healthy, term multipara with previous term vaginal deliveries, favorable cx (Bishop score ≥8)

- Needed:
  - Room in the inn among other guests and tasks
  - Adequate nursing staff
  - Induction with oxytocin
  - Timely (and safe) amniotomy
Feto-Neonatal and Maternal Risks at Term

42 y/o G1 (IVF-ET), BMI 43, mild GHTN, cx closed and thick

37 y/o G1, BMI 35, GDM on oral agent and insulin, cx closed/50

24 y/o G1, BMI 30, no medical problems, cx 1/long

35 y/o P1 (vag), BMI 30, no medical problems, cx 1/50 and soft

32 y/o P2 (vag), BMI 26, no medical problems, cx 3 cm
The Problem
Average and Median Hours in Labor By Patient Type:

Jan 2012 - Sep 2016

<table>
<thead>
<tr>
<th>Type</th>
<th>Average</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective</td>
<td>16.35</td>
<td>15.02</td>
</tr>
<tr>
<td>Indicated</td>
<td>10.54</td>
<td>9.7</td>
</tr>
<tr>
<td>Spontaneous</td>
<td>5.51</td>
<td>4.72</td>
</tr>
</tbody>
</table>

Multiparous:

- Elective: 7.34
- Indicated: 9.25
- Spontaneous: 7.975

Nulliparous:

- Elective: 11.70
- Indicated: 10.45
- Spontaneous: 10.54
Methods of Cervical Ripening

- Pharmacologic
  - Oxytocin
  - Misoprostol
  - PGE2

- Mechanical
  - Foley
  - Double balloon
  - Others
Effectiveness

Safety

Cost

Ease of Procurement and Administration

Patient Satisfaction
ACOG Practice Bulletin 107
August 2009

• Effective methods of cervical ripening include
  – PGE1 (misoprostol) and PGE2 (dinoprostone)
  – Mechanical dilation, including Foley catheters (14-26 French with inflation volumes of 30-80 mL)
• Insufficient evidence regarding delivery <24 hrs comparing mechanical methods to prostaglandins
## Duration of Labor for Cervical Dilation to the Next Centimeter in Nulliparas (hours, 50th, 95th centiles)

<table>
<thead>
<tr>
<th>Interval</th>
<th>Starting oxytocin</th>
<th>Continuing oxytocin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low dose (&lt;4)</td>
<td>High dose (4 and 4)</td>
</tr>
<tr>
<td>4-5 cm</td>
<td>3.3 (12.3)</td>
<td>3.2 (12.0)</td>
</tr>
<tr>
<td>5-6 cm</td>
<td>2.2 (7.6)</td>
<td>2.1 (7.0)</td>
</tr>
<tr>
<td>6-10 cm</td>
<td>1.6 (4.7)</td>
<td>1.5 (4.4)</td>
</tr>
</tbody>
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Data derived from 87,743 patients in 5 institutions (CSL); oxytocin use estimated to start at or before start of the interval

Zhang et al. Submitted for publication 2017
## Duration of Labor for Cervical Dilation to the Next Centimeter in Multiparas (hours, 50th, 95th centiles)

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<td>High dose (4 and 4)</td>
</tr>
<tr>
<td>4-5 cm</td>
<td>3.0 (11.4)</td>
<td>2.9 (11.0)</td>
</tr>
<tr>
<td>5-6 cm</td>
<td>1.9 (6.5)</td>
<td>1.8 (6.0)</td>
</tr>
<tr>
<td>6-10 cm</td>
<td>1.1 (3.3)</td>
<td>1.0 (3.1)</td>
</tr>
</tbody>
</table>

Data derived from 87,743 patients in 5 institutions (CSL); oxytocin use estimated to start at or before start of the interval

Zhang et al. Submitted for publication 2017
Cervical Ripening
The Current Bottom Line

- Mechanical versus Pharmacologic
  - Similar outcomes with regard to cesarean and length of labor
  - More hyperstimulation/tachysystole with prostaglandins
- Patience is a virtue
RCT of Mechanical and Pharmacologic Methods of Labor Induction

- **Design:** RCT
- **Subjects:** Term patients undergoing induction, BS ≤ 6 and Cx < 2 cm
- **Interventions:** (1) Misoprostol, (2) Mistoprostol+Foley, (3) Foley, (4) Foley+Oxytocin
- **Primary outcome:** Time to delivery

Levine et al. Obstet Gynecol 2016, Nov 3
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Misoprostol (N=120)</th>
<th>Misoprostol+ Foley (N=123)</th>
<th>Foley (N=123)</th>
<th>Foley+ Oxytocin (N=125)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cesarean (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>24%</td>
<td>28%</td>
<td>28.5%</td>
<td>30%</td>
</tr>
<tr>
<td>Multiparous</td>
<td>33%</td>
<td>44%</td>
<td>41%</td>
<td>40.5%</td>
</tr>
<tr>
<td></td>
<td>12%</td>
<td>4%</td>
<td>10%</td>
<td>16%</td>
</tr>
<tr>
<td>Time to VD (med h)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VD &lt;24 hrs (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>70%</td>
<td>88%</td>
<td>73%</td>
<td>84%</td>
</tr>
<tr>
<td>Multiparous</td>
<td>54%</td>
<td>81%</td>
<td>57.5%</td>
<td>78%</td>
</tr>
<tr>
<td></td>
<td>92%</td>
<td>98%</td>
<td>96%</td>
<td>92%</td>
</tr>
<tr>
<td>VD &lt;12 hrs (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>26%</td>
<td>45%</td>
<td>22%</td>
<td>41%</td>
</tr>
<tr>
<td>Multiparous</td>
<td>13%</td>
<td>27%</td>
<td>11%</td>
<td>26%</td>
</tr>
<tr>
<td></td>
<td>44%</td>
<td>70%</td>
<td>38%</td>
<td>63%</td>
</tr>
</tbody>
</table>

Levine et al. Obstet Gynecol 2016, Nov 3
<table>
<thead>
<tr>
<th>Method</th>
<th>HS/TS with CTG Changes</th>
<th>Overall CD</th>
<th>CD for fetal distress</th>
<th>AS &lt; 7 at 5min</th>
<th>Arterial Cord pH&lt;7.10</th>
<th>NICU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foley (N=111 in 2 studies)</td>
<td>0</td>
<td>32%</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>1%</td>
</tr>
<tr>
<td>Dinoprostone insert (N=728 in 3 studies)</td>
<td>5%</td>
<td>30%</td>
<td>NA</td>
<td>0.9%</td>
<td>NA</td>
<td>13%</td>
</tr>
<tr>
<td>Intracx PGE2 (N=334 in 6 studies)</td>
<td>1%</td>
<td>27%</td>
<td>4%</td>
<td>4%</td>
<td>NA</td>
<td>4%</td>
</tr>
<tr>
<td>Intravag PGE2 (282 in 5 studies)</td>
<td>NA</td>
<td>9%</td>
<td>NA</td>
<td>1%</td>
<td>NA</td>
<td>2%</td>
</tr>
<tr>
<td>Intravag misoprostol (N=197 in 5 studies)</td>
<td>2.2%</td>
<td>20%</td>
<td>6.8%</td>
<td>1%</td>
<td>NA</td>
<td>10%</td>
</tr>
<tr>
<td>Oral misoprostol (N=99 in 2 studies)</td>
<td>NA</td>
<td>19%</td>
<td>NA</td>
<td>1%</td>
<td>NA</td>
<td>5%</td>
</tr>
</tbody>
</table>
• Outpatient cervical ripening
  – Limited safety information available
  – Larger controlled studies needed to establish an effective and safe dose and vehicle for PGE2
  • Outpatient use may be appropriate in carefully selected patients
  – Mechanical methods may be particularly appropriate in the outpatient setting
Recommended fetal surveillance with prostaglandin agents

- General
  - Uterine activity and FHR monitoring continuously for an initial observation period - further monitoring governed by individual indications for induction and fetal status

- PGE2 gel
  - Continuous FHR and uterine activity monitoring for 30 minutes - 2 hrs
    - Uterine contractions usually are evident in the first hour and exhibit peak activity in the first 4 hours
  - FHR monitoring should be continued if regular uterine contractions persist
Induction of labour at term with oral misoprostol versus a Foley catheter (PROBAAT-II): a multicentre randomised controlled non-inferiority trial

- Open-label, randomized trial in 29 facilities
- Subjects scheduled for induction
  - Term with Bishop score <6
  - Scheduled for induction
- Interventions: oral misoprostol vs foley
- Primary outcome – a composite
  - Neonatal asphyxia (UmbA pH ≤7.05 or 5-min Apgar <7
  - Postpartum hemorrhage (1000 mL or more)
- Numerous secondary outcomes

Lancet 2016;387:1619
Induction of labour at term with oral misoprostol versus a Foley catheter (PROBAAT-II): a multicentre randomised controlled non-inferiority trial

- **Oral misoprostol**
  - 50 mcg q4 hrs up to 3 times daily
  - Fetal condition and uterine activity monitor X 1 hr before each dose
  - Continued up to 4 days or until Bishop score 6 or greater

- **Foley**
  - 16 or 18 F filled with 30 mL
  - External end taped to subject thigh without traction
  - Cx ripeness assessed every 12 hrs or when Foley expelled
    - Routinely replaced at 48 hrs
  - Continued up to 4 days or until Bishop score 6 or greater

Lancet 2016;387:1619
**Induction of labour at term with oral misoprostol versus a Foley catheter (PROBAAT-II): a multicentre randomised controlled non-inferiority trial**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Misoprostol (N=924)</th>
<th>Foley (N=921)</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Composite</td>
<td>113 (12.2%)</td>
<td>106 (11.5%)</td>
<td>1.06 (0.86–1.31)</td>
</tr>
<tr>
<td>Hyperstimulation with FHRT changes</td>
<td>26 (2.8%)</td>
<td>22 (2.4%)</td>
<td>1.18 (0.67–2.06)</td>
</tr>
<tr>
<td>Cesarean delivery</td>
<td>155 (16.8%)</td>
<td>185 (20.1%)</td>
<td>0.84 (0.69–1.02)</td>
</tr>
<tr>
<td>Operative vaginal delivery</td>
<td>125 (13.5%)</td>
<td>88 (9.6%)</td>
<td>1.41 (1.09–1.83)</td>
</tr>
</tbody>
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**Induction of labour at term with oral misoprostol versus a Foley catheter (PROBAAT-II): a multicentre randomised controlled non-inferiority trial**

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<tr>
<td>FTP in 1st stage → CD</td>
<td>57 (6.2%)</td>
<td>98 (10.6%)</td>
<td>0.58 (0.42–0.79)</td>
</tr>
<tr>
<td>NRFHT → operative vaginal delivery in 2nd stage</td>
<td>32 (3.5%)</td>
<td>13 (1.4%)</td>
<td>2.45 (1.30–4.64)</td>
</tr>
<tr>
<td>Oxytocin use</td>
<td>623 (68.4%)</td>
<td>740 (80.3%)</td>
<td>0.85 (0.81–0.90)</td>
</tr>
<tr>
<td>SROM</td>
<td>258 (27.9%)</td>
<td>91 (9.9%)</td>
<td>2.84 (2.27–3.54)</td>
</tr>
</tbody>
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Induction of labour at term with oral misoprostol versus a Foley catheter (PROBAAT-II): a multicentre randomised controlled non-inferiority trial

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<tr>
<td>Induction to birth (hrs)</td>
<td>29 (17-48)</td>
<td>30 (20-40)</td>
<td>NA</td>
</tr>
<tr>
<td>Delivery &lt;24 hrs</td>
<td>367 (39.7%)</td>
<td>278 (30.2%)</td>
<td>1.32 (1.16-1.49)</td>
</tr>
<tr>
<td>Delivery &lt;36 hrs</td>
<td>575 (62.2%)</td>
<td>623 (67.6%)</td>
<td>0.92 (0.86-0.98)</td>
</tr>
<tr>
<td>Delivery &lt;48 hrs</td>
<td>690 (74.7%)</td>
<td>740 (80.3%)</td>
<td>0.93 (0.89-0.98)</td>
</tr>
</tbody>
</table>

Lancet 2016;387:1619
Elective Induction vs Expectant Management

What We Could Really Use

- An easy to implement, safe, and reasonably inexpensive method of outpatient cervical ripening that
  - Results in or allows active labor within a predictable time-frame
- An efficient, strategically-scheduled L&D that
  - Easily adjusts beds and staffing to account for scheduled inductions and spontaneous labors
- Provider scheduling/care that
  - Accommodates scheduling concerns and ensures proper oversight and immediate presence for labor complications and deliveries