Trial of Labor after Cesarean Delivery: Which Patients? Which Hospitals?
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Disclosures

• I have not had a cesarean delivery
• I do not get paid more money for doing cesarean deliveries
• I did help write ACOG PB #115

…and have nothing else to disclose

TOLAC: What’s New and What’s Not

• Context and Definitions
• Which Patients?---What’s New in PB 115
• Which Hospitals?: Ethics, Risks and “Immediately Available”
• What’s the Problem?: A Pragmatic Look at the TOLAC map

Context: Trends

[Graph showing rates of vaginal birth after cesarean (VBAC rate), total cesarean deliveries (CD rate), and primary cesarean deliveries (Primary CD) over time.]
Local Data:

- VBAC Rate 2002 = 37%
- VBAC Rate 2012 = 24%
- VBAC Rate 2013 = 20.2%*

* Different Denominator

Context: NIH

- Conclusions
  - Many critical gaps in definitions, outcomes, available data
  - “Trial of labor is a reasonable option for many women with one prior cesarean…”
  - TOLAC and ERCD have different and important risks for a mother and her fetus
  - “This poses a profound ethical dilemma…”
Context: NIH

• Conclusions
  – “We are concerned about the barriers women face in gaining access to clinicians and facilities that are able and willing to offer a trial of labor”
  – “We are concerned that medico-legal considerations add to, and in many cases exacerbate, these barriers”
  – Recommend that ACOG and SOAP re-examine requirements for resources needed to conduct TOLAC/VBAC

Which Patients?

• Depends on the numbers
  – Chances of VBAC if TOLAC
  – Chance of morbidity and mortality if TOLAC
  – How many planned future pregnancies

Numbers That Patients and Providers Need

• Chance of VBAC if TOLAC: 60-80%
  – 74% in summary meta-analysis from AHRQ

Numbers That Patients and Providers Need

• Chance of VBAC modified by several factors
• There are available prediction models
  – Will push PPV/NPV 10-20% from average

Selected Clinical Factors Associated with Trial of Labor After Previous Cesarean Delivery Success
- Increased Probability of Success (Strong predictors)
  - Prior vaginal birth
  - Spontaneous labor
- Decreased Probability of Success (Other predictors)
  - Recurrent indication for initial cesarean delivery (labor dystocia)
  - Increased maternal age
  - Non-white ethnicity
  - Gestational age greater than 40 weeks
  - Maternal obesity
  - Preeclampsia
  - Short interpregnancy interval
  - Increased neonatal birth weight
Numbers That Patients and Providers Need

- Chance of VBAC modified by several factors
- There are available prediction models
  - Knowing that chance of VBAC are 95% v 75% v 65% may be important to some decisions

Numbers That Patients and Providers Need

- Risks of TOLAC
  - For the mother include risk of hemorrhage, infection, injury to pelvic organs, hysterectomy, death
    - Most maternal risks with TOLAC occur when cesarean delivery becomes necessary: risk therefore tied to chances of VBAC
  - For the neonate include respiratory complications, infection, HIE, death

Maternal Morbidity and Mortality

Table 1. Composite Maternal Risks from Elective Repeat Cesarean Delivery and Trial of Labor After Previous Cesarean Delivery

<table>
<thead>
<tr>
<th>Maternal Risk</th>
<th>EROD (%)</th>
<th>TOLAC (%)</th>
</tr>
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<tbody>
<tr>
<td>One CD</td>
<td>Two or more CDs</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>1.5-2.1</td>
<td>2.9</td>
</tr>
<tr>
<td>Operative injury</td>
<td>0.42-6</td>
<td>0.4</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>1.4-4</td>
<td>0.7-1.7</td>
</tr>
<tr>
<td>Hydration</td>
<td>0.2-0.3</td>
<td>0.2-0.5</td>
</tr>
<tr>
<td>Uterine rupture</td>
<td>0.4-0.5</td>
<td>0.7-0.9</td>
</tr>
<tr>
<td>Maternal death</td>
<td>0.9-0.04</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Abbreviations: CD, cesarean delivery; EROD, elective repeat cesarean delivery; TOLAC, trial of labor after cesarean delivery; VBAC, vaginal birth after cesarean.
Neonatal Morbidity and Mortality

Numbers That Patients and Providers Need

- Risk of uterine dehiscence
  - 0.3-0.9% for single prior low transverse hysterotomy
  - Higher for classical cesarean (data limited, ? 6-10%)
  - Reported data limited in some series by including symptomatic rupture and asymptomatic separations and by failure to stratify by type of prior hysterotomy

TOLAC Outcomes: Not ALL VBACs

Immediately Available
The following recommendations are based primarily on consensus and expert opinion (Level C):

- Because uterine rupture may be catastrophic, VBAC should be attempted in institutions equipped to respond to emergencies with physicians immediately available to provide emergency care.

Summary of Recommendations
The following recommendations are based on good and consistent scientific evidence (Level A):

- Most women with one previous cesarean delivery with a low-transverse incision are candidates for and should be counseled about VBAC and offered TOLAC.
• Expanded indications for TOLAC
  – Two or more prior cesareans
  – Low vertical or unknown scar
  – Multiples
  – Postdates (induction)
  – Breech (version OK!)

Candidates for TOLAC?: Special Cases

• More than one prior scar
  – Conflicting results from past and recent studies
    • MFMU ‘06: Rupture 0.9 v 0.7%
    • Macones ‘05: Rupture 0.9 v 1.8%
  – Risk of major morbidity with TOLAC seems higher if more than one past c/s (e.g. 2.1 v 3.2%)  
  – Chances of VBAC unaffected by # of c/s
  – “Reasonable” to TOLAC: counsel informed by chances of VBAC

Candidates for TOLAC?: Special Cases

• Low Vertical Scar
  – Similar chance of VBAC
  – Limited data “do not show consistent risk of rupture or maternal or perinatal morbidity”
  – Providers and patients “may choose” to proceed with TOLAC

• Unknown scar: No demonstrable difference from low transverse
  – Temper with common sense

“The absolute risk of complications is quite small….A VBAC attempt still seems reasonable in appropriately counseled and managed women with 2 prior cesareans”
Candidates for TOLAC?: Special Cases

- Twins: Less Likely to choose TOLAC but similar outcomes to singletons

<table>
<thead>
<tr>
<th>Induction</th>
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<tbody>
<tr>
<td>- Appears to be a gradient of risk of rupture: spontaneous &lt; oxytocin augmentation &lt; oxytocin induction &lt; oxytocin + prostaglandin induction</td>
</tr>
<tr>
<td>- Small case series suggest PGE1 should be avoided</td>
</tr>
<tr>
<td>- Risk of rupture may increase with increasing doses of oxytocin but indentifying a threshold dose is challenging</td>
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</tbody>
</table>

Risk of Uterine Rupture: MFMU Study

<table>
<thead>
<tr>
<th>Table 3. Rate of Uterine Rupture According to Labor Status</th>
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</thead>
<tbody>
<tr>
<td>Type of Labor</td>
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<tr>
<td>----------------</td>
</tr>
<tr>
<td>Spontaneous</td>
</tr>
<tr>
<td>Augmented</td>
</tr>
<tr>
<td>Induced</td>
</tr>
<tr>
<td>With any prosta-glandin, with spontaneous rupture</td>
</tr>
<tr>
<td>With any prosta-glandin, with induced rupture</td>
</tr>
<tr>
<td>With rupture &amp; &gt;20 cm cervix</td>
</tr>
<tr>
<td>With rupture &amp; ≤20 cm cervix</td>
</tr>
<tr>
<td>Not specified</td>
</tr>
</tbody>
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Landon NEJM, 2005

Can We?: Management of TOLAC

Drilling Down

<table>
<thead>
<tr>
<th>Table 2. Maternal Health Outcomes Stratified by Obstetric History and Type of Labor</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Prior Vaginal Delivery</td>
</tr>
<tr>
<td>---------------------------</td>
</tr>
<tr>
<td>Induced Labor</td>
</tr>
<tr>
<td>Induced Labor</td>
</tr>
<tr>
<td>Yaginal delivery</td>
</tr>
<tr>
<td>Uterine rupture</td>
</tr>
<tr>
<td>Vaginal delivery</td>
</tr>
<tr>
<td>Cesarean section</td>
</tr>
<tr>
<td>Bladder tear</td>
</tr>
<tr>
<td>Hemorrhage</td>
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<tr>
<td>Venous thrombosis</td>
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</tbody>
</table>

Grobman Ob/Gyn, 2007
Can We?: Management of TOLAC

- Induction
  - Incremental risk is not large
  - “Induction of labor for maternal or fetal indications remains an option for women undergoing TOLAC”
- Prostaglandins
  - PGE1 should not be used in the third trimester with past uterine scar
  - PGE2 to minimize the risk of rupture, select those with the greatest chance of VBAC and avoid sequential use with oxytocin

Can We?: Management of TOLAC

- Epidural
  - Yes: the Geneva convention applies in labor
  - Does not appear to reduce VBAC
  - Most common sign of rupture is FHR abnormalities
- Version
  - Limited data suggest it is not contraindicated
  - Similar success rates reported
“Immediately Available”: Limits and Arguments

- Available data largely from centers with immediately available
- Comparative data of immediately available to other standards is not available
- Limits access to/availability of TOLAC

Managing TOLAC: Needed Resources

- Emergencies can happen and be unexpected
- Sometimes minutes may make a difference – With occlusion, cord pH may drop as rapidly as .01/minute

Managing TOLAC: Evidence for Needed Resources
But…
Risk, TOLAC and the Ethics of Patient Choice

• Incremental risk likely to be small
• Given likely small absolute risk, respect for autonomy argues that appropriately patients and providers may choose TOLAC in settings with more limited resources
  – Counseling/informed consent is key
  – Respect for autonomy should not be an excuse to avoid providing resources

Immediately Available?

• “Recommends” that TOLAC be undertaken at facilities where staff are immediately available for emergency care (Level C---expert opinion)

Immediately Available?

• Respect for autonomy supports the concept that patients should be allowed to accept increased levels of risk

Reactions to PB 115

• No patient should be/ can be forced to have a cesarean regardless of facility’s TOLAC resources
• Change in policy is not meant to limit facilities’ appropriate efforts to provide recommended resources or respond to unexpected emergencies

Overall, I think the new practice bulletin is going to be much more agreeable to advocates and useful as a tool in encouraging hospitals and providers to reconsider their VBAC practices. We look forward to hearing your take in the comments.
Reactions to PB 115

"It is unclear how women will be at liberty to choose TOLAC when facilities continue to refuse them this option citing compliance with 2010 guidelines."

Does Immediately Available Limit TOLAC?

- For some women: Yes
  - Particularly in rural areas only covered by smaller volume facilities
- But, as a matter of public health, the issue is not just the number of sites that offer TOLAC but the number of women covered by those sites
  - Many women deliver at or have ready access to centers that support TOLAC
- The issue is clearly not all access: at sites that support/encourage TOLAC many chose ERCD

The Ethics of Vaginal Birth After Cesarean

- Described a recommendation for “immediately available”
  - Hospitals wishing to do VBAC must be prepared for emergency surgery
- Many hospitals still won’t offer VBAC and women won’t have this choice
  - Is repeat cesarean under such circumstances, voluntary?
- This is a situation that should be of great concern to obstetricians and the bioethics community

The Conundrum of Access to TOLAC

- Let’s Not Conflate Numbers of TOLAC Centers with Access
  - One center with 3000 deliveries/year and supporting TOLAC will provide greater access than 5 centers doing 500 deliveries/year who do not
- I am unaware of a map describing TOLAC centers in relation to U.S. population
- Referral and referral networks are an important, potential solution
MA Example: # of Annual Deliveries by Hospital ICAN VBAC Status

- Allowed: 59,050 (81%)
- De facto Ban: 6,480 (9%)
- Banned: 7,386 (10%)
- Total: 72,916

Must Every Maternity Hospital Offer TOLAC?

- Clearly we don’t expect every facility to offer every medical treatment/procedure
  - In many cases a path for referral is sufficient
- Is birth/TOLAC different?
  - “Natural” condition not a disease
  - Unpredictable---limiting ready distant transfer

Must Every Maternity Hospital Offer TOLAC?: Ethical Answers

- Difficult for me to construct an ethical argument obliging such
  - Particular when safe alternatives exist
- When geography limits access/choices to treatment
  - Are patients who choose to live in such areas obliged to accept some limits in the care they receive?
  - Are providers who practice in such areas obliged to tolerate different risks?

Optimizing Access

- TOLAC Centers---Can we identify/create a national network of centers of TOLAC Excellence?
  - Do we or can we have a TOLAC center within 25 mi of 90% of population?
What Are Facilities to Do?

- Make a genuine effort to marshal needed resources to make TOLAC as safe as possible in their setting
  - In many cases this will mean having resources immediately available
  - This may include antenatal referral of appropriate patient
- Consider plans/protocols for accessing resources whether readily or immediately available
  - Emergency drills
  - Anticipate problems and access resources before emergencies arise

Can We Increase VBAC Rates

- One way to increase national rates of TOLAC/VBAC is to increase uptake/interest among women who are delivering at centers that already support and encourage this option
- Patient Education
  - Understand first why don’t patients elect TOLAC
  - Then consider how to promote acceptance among appropriate candidates

Conclusion: Nothing New

Summary of Recommendations
The following recommendations are based on good and consistent scientific evidence (Level A):

- Most women with one previous cesarean delivery with a low-transverse incision are candidates for and should be counseled about VBAC and offered TOLAC.

Practice Bulletin No. 115
Definitions

• **Trial of Labor (TOLAC):** Trial of labor in women who have had a previous cesarean delivery *regardless of outcome*

• **Vaginal Birth After Cesarean (VBAC):**
  Vaginal birth after a prior cesarean delivery
  – Not “successful VBAC”

A Gradient of Risk

- **TOLAC**
  - CS after TOLAC: Highest
  - CS without TOLAC: Middle
  - VBAC: Lowest

- **ERCD**

Population Risk Depends on Chances of VBAC

- **CS after TOLAC**
- **CS without TOLAC**

Patients choose this

Not this
Numbers That Patients and Providers Need

- Chance of VBAC if TOLAC: 60-80%
  - 74% in summary meta-analysis from AHRQ

Neonatal Morbidity and Mortality

- Moderate Risk of Respiratory Morbidity
- Rare, rare risk of Death or HIE

And What About Them Lawyers?

- Shared decision making over time—*informed* consent
- Careful documentation
- Willingness to continually re-evaluate plans