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What We Have Learned About Trial of Labor After Cesarean Delivery from the MFMU Cesarean Registry

Mark B. Landon, MD¹, William A. Grobman, MD, MBA², and for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network

¹The Ohio State University College of Medicine, Columbus OH, Mark.Landon@osumc.edu

²Prentice Women's Hospital, Chicago IL, w-grobman@northwestern.edu

Abstract

The cesarean delivery rate in the United States has risen steadily over the past five decades such that approximately one in three women now undergo cesarean section. The rise in repeat operations and accompanying decline in trial of labor after cesarean (TOLAC) have been major contributors to this phenomenon. The appropriate use of TOLAC continues to be a topic of interest with the recognition that most women with a history of prior cesarean are candidates for trial of labor. The NICHD MFMU Network Cesarean Registry conducted from 1999–2002 provided contemporary data concerning the risks and benefits of TOLAC which in turn have helped inform practitioners and women considering their options for childbirth following cesarean delivery.

Introduction

Prior to 2010, there had been a progressive rise in the overall cesarean delivery rate to over 30 percent in the United States. Efforts to reduce the number of cesarean births, although initially successful, failed to achieve the 1990 U.S. Public Health Service goals. These goals included achieving an overall cesarean rate of 15 percent and a rate of vaginal birth after cesarean (VBAC) of 35 percent by the year 2000. The Healthy People 2000 report proposed a target rate of VBAC of 37 percent. In the early 1980s, as the number of repeat cesareans began to rise, VBAC was recommended in clinical management guidelines as a method to help reduce the overall cesarean rate. This recommendation resulted in a rise of VBAC from 3 percent in 1981 to 31 percent in 1998. With the trial of labor after cesarean (TOLAC) being more widely applied, reports of adverse outcomes associated with uterine rupture surfaced. The concerns about maternal and perinatal morbidity associated with TOLAC challenged the safety and appropriateness of this procedure. These issues, along with medicolegal concerns and the introduction of more stringent criteria for TOLAC, led to a substantial decline in the rate of VBAC to 12.7 percent in 2002.

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In 2003, a report by the Agency for Health Care Research and Quality concluded that the magnitude of risk of uterine rupture and its attendant morbidity remained uncertain, owing to methodologic deficiencies in various studies and differences among these reports with respect to definitions and the ascertainment of uterine rupture. In essence, the data were of insufficient quality to make recommendations concerning the optimal route of childbirth for women with prior cesarean delivery. The MFMU Network embarked upon a prospective cohort study from 1999 through 2002 at 19 academic medical centers to assess the risks of uterine rupture and neonatal and maternal morbidity associated with TOLAC as compared with repeat elective cesarean delivery.¹ The cesarean registry was originally planned as three-year study in order to collect sufficient data about rare and uncommon outcomes such as uterine rupture. However, because the rate of TOLAC declined during the first three years of the study period (1999, 48.3 percent; 2000, 42.7 percent; 2001, 34.4 percent), data were collected for an additional year.

Methodology

The registry included all women who had a pregnancy at 20 weeks or more of gestation or whose infant weighed at least 500 g. The labor and delivery logbook or database at each participating center was screened daily to identify cases. Medical records for each woman were reviewed by trained study nurses. Demographic data, details of obstetric history, and information concerning antepartum and intrapartum events were recorded. The prospective nature of the study allowed treating physicians to be contacted to resolve questions about complications of delivery. Neonatal data were collected up to 120 days following delivery or at the time of hospital discharge. Additional detailed data were collected for all infants admitted to the neonatal intensive care unit. A separate data collection form was used for all infants who had a clinical diagnosis of hypoxic ischemic encephalopathy (HIE), for all cases of uterine rupture, and for all infants with seizures, cardiopulmonary resuscitation, umbilical artery pH less than 7.0, head imaging at term, or 5-minute Apgar score less than 4. All instances of uterine rupture and HIE of the newborn underwent secondary review by local study investigators and a final central review by two of the investigators to ensure accurate diagnoses.

Maternal and perinatal outcomes were compared between women who had a TOLAC (n=17,898) and those who underwent scheduled repeat operation (n=15,801) without labor or who had obvious indications for repeat cesarean such as prior classical incision, abnormal presentation, placenta previa, prior myomectomy, non-reassuring antepartum fetal status or any other medical condition precluding TOLAC (n= 9013). Women presenting in labor with cervical dilation of at least 4 cm, as well as those receiving oxytocin, were classified as having undergone a TOLAC. Women presenting in early labor (n= 3276) without obvious indications for a planned repeat cesarean delivery and who subsequently underwent cesarean delivery were excluded from the analysis owing to the difficulty in distinguishing between a failed intended TOLAC and planned cesarean delivery.

Success Rates for TOLAC

The overall success rate for TOLAC has been reported to be in the 60–80 percent range. We confirmed this probability in our study as the success rate was 13,139/ 17,898 or 73.4 percent. Using the extensively collected data in the registry, we sought to identify precisely which factors were associated with success when controlling for multiple potential confounders.² We found that women with previous vaginal birth had an 86.7 success rate compared with 60.9% in women without such a history (OR 4.2 (95% CI 3.8–4.5, $p < 0.001$). In addition, VBAC success rates also increased with increasing number of prior VBACs: 63.3%, 87.6%, 90.9%, 90.6%, and 91.6% for those with 0, 1, 2, 3, and 4 or more prior VBACs.³ TOLAC success rates were predictably affected by previous indication for cesarean, need for induction, cervical dilation at admission, and birthweight. Rates were also affected by race/ethnicity and body mass index. Multivariable regression analysis identified several factors that were independently associated with TOLAC success: previous vaginal delivery (OR 3.9, 95 % CI 3.6–4.3), previous indication not being dystocia (OR 1.7, 95 % CI 1.5–1.8), spontaneous labor (OR 1.6: 95 % CI 1.5–1.8), birthweight < 4000g (OR 2.0, 95% CI 1.8–2.3) and white race (OR 1.8; 95% CI 1.6–1.9). The success rate in obese women (BMI >30) was lower (68.4%) than in non-obese women (79.6%). Using these data, we developed a prediction model for VBAC among women with one prior cesarean and a term singleton gestation undergoing TOLAC that is based on factors that could be assessed at the first prenatal visit. These included the variables of age, body mass index, race and ethnicity, prior vaginal delivery, prior VBAC, and a recurrent indication for the cesarean delivery.⁴ After development and internal validation, the model has been found to be accurate and has been validated in multiple populations other than the MFMU study population. The calculator is available on line at: <https://mfm.bsc.gwu.edu>. (Figure 1) Because circumstances at the time of admission for delivery may affect the chance of successful TOLAC, a second calculator was created to take these additional factors into account. This second calculator also is available using a link at the same website. The additional factors include BMI at delivery, cervical status, need for induction, and the presence or absence of preeclampsia. The MFMU Network also reported in a separate analysis that the TOLAC success rate was 66% in women with multiple prior cesareans compared to 74% with a single prior operation.⁵ The rate of success in 186 twin gestations reported by Varner et al. for the MFMU Network was 64.5%.⁶

Uterine Rupture and Risk Factors

Prior to the MFMU study, terminology, definitions and ascertainment for uterine rupture varied significantly in the existing VBAC literature. The investigators of the MFMU Network recognized that it was critical to differentiate between uterine rupture and uterine scar dehiscence. This distinction is clinically relevant because dehiscence most often represents an occult scar separation observed at laparotomy in women with a prior cesarean and is not associated with excessive morbidity in most cases. In our study, we found a rupture rate of 0.69%, with 124 symptomatic ruptures occurring in 17,898 women undergoing TOLAC. These data reflected rupture rates of 2/102 (2.0 percent) for those with a prior low vertical incision and 15/3206 (0.5 percent) for those with an unknown type of incision. Two uterine ruptures were recorded in 105 women with a prior classical, inverted T,

or J incision who presented in advanced labor or refused a repeat operation. Antecedent obstetric history may also affect the risk for uterine rupture. A history of prior preterm cesarean may indicate possible involvement of the muscular portion of the uterus and a greater risk for subsequent rupture with TOLAC. In a secondary analysis of the MFMU Cesarean registry data, we found that a prior preterm delivery was significantly associated with an increased risk of uterine rupture, although the risk remained less than 1% (0.58% compared to 0.28%, $p < 0.001$).⁷

In addition to the type of uterine scar and prior obstetric history, rates of uterine rupture have been associated with the number of prior cesarean deliveries, prior vaginal delivery, and labor management including induction and the use of oxytocin augmentation. A meta-analysis has suggested a nearly three-fold increased risk for uterine rupture (1.59 % vs 0.72%) in women with multiple compared to one prior cesarean.⁸ In contrast, we found no significant difference in rupture rates in women with one prior cesarean (115/16916 (0.7%) versus multiple prior cesareans (9/975 (0.9%)).⁵ Our study, however, was only powered to detect a three-fold increased risk.⁹ In light of these data, the American College of Obstetricians and Gynecologists (ACOG) considers it reasonable to offer TOLAC to women with more than one prior cesarean delivery and to counsel such women based on the combination of other factors that affect their probability of achieving VBAC.¹⁰

Prior vaginal delivery, either before or after a prior cesarean delivery, appears to be highly protective against uterine rupture in women undergoing TOLAC. A previous report found a 0.2% rupture rate in women with prior vaginal birth compared to 1.1% in those with no prior vaginal deliveries.¹¹ The MFMU Network confirmed this protective effect inasmuch as the rupture rate was 0.5 percent with prior vaginal delivery with an OR of 0.62 (95% CI, 0.43–0.90) compared to women without prior vaginal delivery.⁵

Induction of labor may be associated with an increased risk for uterine rupture compared with spontaneous labor. A population-based cohort study reported a rate of uterine rupture of 24/2236 (1.0%) for women undergoing induction compared with 56/10,789 (0.5%) in women with spontaneous onset of labor.¹² The MFMU Network study also noted the risk for uterine rupture in the setting of induction was elevated nearly three-fold (OR 2.86; 95% CI, 1.75–4.76) although the attributable risk of rupture related to labor induction was relatively small (i.e., 0.6% given the 1.0 versus 0.4 percent rates that were seen in those induced versus those in spontaneous labor). A secondary analysis from our study of the 11,187 women with one prior cesarean undergoing induction showed an increased risk of uterine rupture in women with no prior vaginal delivery, but no such a risk in women who had a history of prior vaginal delivery.¹³ In this analysis, the need for cervical ripening, which has been suggested to be a factor in other studies, did not affect the frequency of uterine rupture.¹⁴ Based on these cumulative data, ACOG continues to consider induction of labor for maternal or fetal indications to be an option for women undergoing TOLAC.

There remains conflicting data as to whether certain induction methods differentially increase the risk for uterine rupture. Lydon Rochelle first reported an increased risk for uterine rupture with the use of prostaglandins for labor induction. Uterine rupture was noted in 0.8% of women induced without prostaglandins compared to 2.5% in those receiving a

prostaglandin agent.¹² Unfortunately, the type of prostaglandin employed was not specified in this study. The data from the MFMU Network, as well as from another large contemporary study, did not confirm the increased risk for uterine rupture when prostaglandins alone are used for induction.^{1, 15} (Table 1). Interestingly, the MFMU Network study found no cases of uterine rupture when misoprostol (n=52) or any prostaglandin agent (n=227) was used alone for induction. The use of misoprostol during the study period antedated the recommendation that it not be used in women with a prior cesarean because of concerns for uterine rupture. Unfortunately, many VBAC reports fail to specify the prostaglandin agent used or whether oxytocin was employed in the induction process as well. We found that the risk of uterine rupture with use of any prostaglandin with or without oxytocin to be 13/926 (1.4%). These data, while limited, have led to the conclusion that sequential use of prostaglandins and oxytocin be avoided in women undergoing TOLAC.¹⁰

The debate as to whether oxytocin used for labor augmentation in contemporary obstetric practice is associated with an increased risk of uterine rupture continues. The rate of rupture was 52/6009 (0.9%) in women receiving oxytocin augmentation compared to 24/6685 (0.4%) in those without augmentation in the MFMU Network study. Cahill and colleagues have reported a dose response relationship between maximal oxytocin dose and the risk for uterine rupture among women undergoing TOLAC.¹⁶ A limitation of their report is that it includes both women undergoing induction and those receiving oxytocin augmentation. At a maximal dose of oxytocin (20 milliunits/min), the authors noted a rupture rate of 2.07%. Unfortunately, we did not collect information concerning oxytocin dosage in the MFMU Network study. Nonetheless, from available data, it appears that oxytocin can be used for labor augmentation in women undergoing TOLAC.

Risks Associated With TOLAC

The most serious sequelae of uterine rupture includes perinatal death, HIE and hysterectomy. Citing six perinatal deaths in 74 uterine ruptures among 11 studies, Guise and colleagues calculated 0.14 additional perinatal deaths per 1000 women undergoing TOLAC.¹⁷ This figure is remarkably similar to that for our study in which two neonatal deaths were recorded among 124 ruptures for an overall perinatal death rate of 0.11 per 1000 TOLACs. A review of 880 uterine ruptures over 20 years in studies of varying quality showed a rate of 0.4 per 1000³⁷.

Perinatal hypoxic brain injury is an adverse outcome associated with uterine rupture, however estimates of the frequency of this complication have been few and hampered by inconsistent definitions or the use of surrogates such as Apgar scores or cord gas values. We found a statistically significant increase in the rate of HIE related to uterine rupture among the offspring of women undergoing TOLAC at term compared to the children of women who underwent planned cesarean delivery (0.46 per 1000 versus no cases respectively). In 114 cases of uterine rupture at term, seven infants (6.2%) were diagnosed with HIE, and two of the .24 .24% se infants died in the neonatal period. (Table 2)

Other maternal complications such as endometritis (2.9 versus 1.8 %) and transfusion (1.7 versus 1.0 %) are significantly more common with TOLAC compared to an planned repeat cesarean. However, the frequencies of hysterectomy (0.2 versus 0.3 %) and maternal death (0.02 versus 0.04%) were not more common in our study with TOLAC versus planned repeat operation. Because of the possibility of uncontrolled confounding in the analyses that had been done, we attempted to produce a more minimally biased cohort by performing propensity analysis in order to determine more precisely the comparative risks of spontaneous labor and planned repeat cesarean delivery.¹⁹ In this analysis, the rates of endometritis and wound complication were higher among women who underwent a planned cesarean delivery. It is noted that these comparisons are for entire populations of women, and may not hold for a given individual. It is well accepted and confirmed by the MFMU Network analyses that that most of the excess adverse events following TOLAC are attributable to the group of women who require a repeat operation following labor.

Cost Effectiveness of TOLAC

The economic burden of routine repeat cesarean delivery has prompted investigators to consider whether TOLAC is a cost-effective strategy. Most analyses have incorporated quality-adjusted life years as the measure of effectiveness and then determined cost effectiveness as a function of various TOLAC success rates. In one such study, the choice of planned repeat cesarean instead of TOLAC resulted in 1591 additional cesareans at a cost of \$ 2.4 million per 100,000 women.²⁰ This study used summary point estimates from published observational studies which may have been biased due to the nonrandom nature of the choice to attempt either TOLAC or planned repeat cesarean delivery. A more recent analysis from our data attempted to rectify this limitation using propensity analysis and also included probabilities of outcomes throughout a woman's reproductive life that were contingent upon her initial choice regarding TOLAC.²¹ Utilizing this approach, TOLAC was found to be cost effective over a wide variety of clinical scenarios, including even when the probability of VBAC was as low as 43%.

Counseling for TOLAC

Regardless of approach to delivery, a pregnant woman with a history of prior cesarean delivery is at risk for both maternal and perinatal complications compared to a woman without such a history. Counseling a woman with a prior cesarean about her approach to delivery in a subsequent pregnancy should include a discussion about the most common complications for both TOLAC and repeat cesarean delivery, and an attempt should be made to include individualized risk assessment for the likelihood of VBAC and the comparative risks of maternal and perinatal morbidity. Plans for future childbearing and the risks for multiple cesareans including risks for placenta previa and accreta should also be considered. Our analyses indicate that the risk for placenta accreta is significantly increased with successive repeat operations.²² We found that placenta accreta is present in 15/16201 (0.24%), 49/15808 (0.31%), 36/6324(0.57%), 31/1452 (2.13%), 6/258 (2.33%), and 6/89 (6.74%) of women undergoing their first, second, third, fourth, fifth, sixth or more cesarean deliveries, respectively.

Estimates of the likelihood of VBAC success can be provided from the MFMU Network prediction tool as previously discussed. While there is no reliable prediction model for an individualized risk for uterine rupture, a consideration of individual specific risk factors that are associated with uterine rupture should be discussed as well. Contemporary data from the MFMU Cesarean Registry have helped to facilitate a discussion of both the likelihood of VBAC and the risks associated with uterine rupture. Whenever possible, risks should be detailed in absolute rather than relative terms in order to truly inform women of the choices for delivery and enhance shared decision making. Based on the available evidence, TOLAC should continue to be an option for most women with prior cesarean delivery. The MFMU Network data indicate that the attributable risk for a serious adverse perinatal outcome (perinatal death or HIE) at term appears to be about 1 per 2000 TOLACs. When one additionally considers the maternal risk of hysterectomy attributable to uterine rupture, the risk for any one of these adverse events is still about 1 in 1250 cases.

The decision to elect TOLAC may also increase the risk for perinatal death beyond HIE related to uterine rupture or intrapartum events. For women awaiting spontaneous labor beyond 39 weeks, there is a small but recognized possibility of stillbirth that would be avoidable with scheduled repeat operation at 39 weeks.

In summary, the MFMU Cesarean Registry has provided a wealth of information concerning the contemporary management of women with a history of prior cesarean delivery. This information is vital to providing a meaningful discussion with women considering their options for childbirth.

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Figure 1.

Legend: Predictive graphic nomogram for probability of vaginal birth after cesarean delivery resulting from a trial of labor. BMI, body mass index.

Reprinted from "Development of a Nomogram for Prediction of Vaginal Birth After Cesarean Delivery," by Grobman WA et al. *Obstet Gynecol* 2007;109:806–12

Table 1

Rates of Uterine Rupture According to Labor Status.

Type of Labor	No. of Patients	Uterine Rupture <i>no. (%)</i>	Odds Ratio (95% CI)*	P Value
Spontaneous	6685	24 (0.4)	1.00	---
Augmented	6009	52 (0.9)	2.42 (1.49–3.93)	<0.001
Induced	4708	48 (1.0)	2.86 (1.75–4.67)	<0.001
With any prostaglandins with or without oxytocin	926	13 (1.4)	3.95 (2.01–7.79)	<0.001
With prostaglandins alone	227	0	---	---
With prostaglandins	1691	15 (0.9)	2.48 (1.30–4.75)	0.004
With oxytocin alone	1864	20 (1.1)	3.01 (1.66–5.46)	<0.001
Not classified	496	0	---	---

Adapted from “Maternal and Perinatal Outcomes Associated with a Trial of Labor after Prior Cesarean Delivery,” by Landon MB et al. *N Engl J Med* 2004;351:2581–9.

Table 2

Perinatal Outcomes after Uterine Rupture in Term Pregnancies

Outcome	Term Pregnancies with Uterine Rupture (n = 114) no. (%)
Intrapartum stillbirth	0
Hypoxic-ischemic encephalopathy	7 (6.2)
Neonatal death	2 (1.8)
Admission to the neonatal intensive care unit	46 (40.4)
5-Minute Apgar score $\leq$ 5	16 (14.0)
Umbilical-artery blood pH $\leq$ 7.0	23 (33.3)

Adapted from “Maternal and Perinatal Outcomes Associated with a Trial of Labor after Prior Cesarean Delivery,” by Landon MB et al. *N Engl J Med* 2004;351:2581–9.