Data supplement to: Guideline showcases AAFP's commitment to evidence-based, patient-centered care. *Ann Fam Med.* Borgemeyer 3: 378.
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The American Academy of Family Physicians

Trial of Labor After Cesarean (TOLAC), Formerly Trial of Labor Versus Elective Repeat Cesarean Section for the Woman With a Previous Cesarean Section

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A Review of the Evidence and Recommendations by the American Academy of Family Physicians

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Trial of Labor After Cesarean (TOLAC), Formerly Trial of Labor Versus Elective Repeat Cesarean Section for the Woman With a Previous Cesarean Section

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These recommendations are provided only as an assistance for physicians making clinical decisions regarding the care of their patients. As such, they cannot substitute for the individual judgment brought to each clinical situation by the patient's family physician. As with all clinical reference resources, they reflect the best understanding of the science of medicine at the time of publication, but they should be used with the clear understanding that continued research may result in new knowledge and recommendations.

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Executive Summary

The American Academy of Family Physicians Commission on Clinical Policies and Research convened a panel to systematically review the available evidence on trial of labor after cesarean delivery (TOLAC) using the Agency for Healthcare Research and Quality Evidence Report on Vaginal Birth After Cesarean (VBAC). The panel's objective was to provide an evidence-based clinical practice guideline for pregnant women and their families, maternity care professionals, facilities, and policy-makers who care about trial of labor and maternity care for a woman with one previous cesarean. The recommendations are as follows:

Recommendation 1: Women with one previous cesarean delivery with a low transverse incision are candidates for and should be offered a trial of labor (TOL). **(Level A)**

Recommendation 2: Patients desiring trial of labor after previous cesarean (TOLAC) should be counseled that their chance for a successful vaginal birth after cesarean (VBAC) is influenced by the following: **(Level B)**

Positive Factors (increased likelihood of successful VBAC)
- Maternal age <40 years
- Prior vaginal delivery (particularly prior successful VBAC)
- Favorable cervical factors
- Presence of spontaneous labor
- Nonrecurrent indication that was present for prior cesarean delivery

Negative Factors (decreased likelihood of successful VBAC)
- Increased number of prior cesarean deliveries
- Gestational age >40 weeks
- Birth weight >4,000 g
- Induction or augmentation of labor

Recommendation 3: Prostaglandins should not be used for cervical ripening or induction as their use is associated with higher rates of uterine rupture and decreased rates of successful vaginal delivery. **(Level B)**

Recommendation 4**:** TOLAC should not be restricted only to facilities with available surgical teams present throughout labor since there is no evidence that these additional resources result in improved outcomes. **(Level C)**

At the same time, it is clinically appropriate that a management plan for uterine rupture and other potential emergencies requiring rapid cesarean section should be documented for each woman undergoing TOLAC. **(Level C)**

Recommendation 5: Maternity care professionals need to explore all the issues that may affect a woman's decision including issues such as recovery time and safety. **(Level C)**. No evidence based recommendation can be made regarding the best way to present the risks and benefits of trial of labor after previous cesarean delivery (TOLAC) to patients.

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INTRODUCTION

For many women, trial of labor after cesarean (TOLAC) delivery is a preferred alternative to elective repeat cesarean delivery (ERCD). In 1995, the American Academy of Family Physicians (AAFP) developed an evidence based, patient-centered clinical policy on trial of labor (TOL) versus ERCD for the woman with a previous cesarean delivery.[1] In 2001, because of new evidence, the AAFP Commission on Clinical Policies and Research decided there was a need for an updated policy or clinical practice guideline and successfully nominated this topic to the Agency for Healthcare Research and Quality (AHRQ) for an evidence review. In 2003, after publication of AHRQ Evidence Report Number 71,[2] the AAFP established a TOLAC Clinical Practice Guideline Panel (TOLAC Panel) composed of family physicians who were well-versed in practice guideline development and maternity care. The TOLAC Panel was charged with examining the evidence and developing a clinical practice guideline for pregnant women and their families, maternity care professionals, facilities, and policy-makers who care about TOLAC and maternity care. This TOLAC Clinical Practice Guideline is the product of the TOLAC Panel's work. The TOLAC Clinical Practice Guideline was peer-reviewed before being reviewed and approved by the Commission on Clinical Policies and Research (CCPR) and approved by the AAFP Board of Directors. This TOLAC Clinical Practice Guideline replaces the 1995 policy on TOLAC previously approved by the Academy. The TOLAC Clinical Practice Guideline describes the historical context for TOLAC, the methods used to review the literature, the results of the review, the evidence-based recommendations, and recommendations for further research in this area.

BACKGROUND

First attributed to Craigin, the dictum "once a cesarean, always a cesarean" dominated American obstetrical practice for much of the twentieth century.[3] Cesarean section became more widely accepted as improvements in anesthesia, blood banking, and the technique of the surgery itself occurred.[4]

The rate of cesarean birth tripled from 5.5% in 1970 to 16.5% in 1980, which prompted the convening of a National Institutes of Health (NIH) Consensus Development Conference on Cesarean Childbirth. The conference panel concluded: "In hospitals with appropriate facilities, services, and staff for prompt emergency cesarean birth, a proper selection of cases should permit a safe trial of labor and vaginal delivery for women who have had a previous low-segment transverse cesarean birth." [5]

Subsequent policy statements by the American College of Obstetricians and Gynecologists (ACOG) encouraged a TOL in women whose prior cesarean delivery involved a low transverse uterine incision.[6, 7] From the early 1980s to the mid-1990s, increasing comfort with the relative safety of TOLAC and rising managed care pressures to control costs appeared to shift options for a woman with a single previous low transverse cesarean from "You must have a repeat cesarean," to "You may have a trial of labor," to "You must have a trial of labor."

In the early 1990s, concerned that choices for women were being inappropriately limited, the AAFP conducted a comprehensive review and meta-analysis of 292 VBAC studies.[1,8] The AAFP meta-analysis showed that women who chose TOLAC had a symptomatic rupture rate that was 24 per 10,000 (0.24%) higher than in women who chose ERCD. While overall maternal outcomes were slightly better with TOLAC, infant outcomes were slightly better with ERCD. The outcomes were thought to be sufficiently similar that the AAFP concluded that the preferences of the woman should determine the mode of delivery. The AAFP 1995 policy recommended that "A trial of labor should be encouraged, but a decision by the woman in favor of elective repeat cesarean section should be supported."[9, 10]

A 1996 population-based study of 6,138 women in Nova Scotia reported that the symptomatic uterine rupture rate in women who underwent TOLAC was 27 per 10,000 (0.27%) higher than women who chose ERCD.[11] Against the backdrop of expanding criteria for and rising rates of TOLAC, this study heightened

concerns about higher-than-expected uterine rupture rates. These concerns resulted in the issuance of a Practice Bulletin by ACOG in 1999 that narrowed the circumstances for allowing TOLAC.[12] Most controversial was the bulletin's consensus statement that patients attempting VBAC should have "physicians immediately available to provide emergency care." This provision has been interpreted as requiring the constant presence of a surgical team for the TOLAC patient. Preliminary experience indicates that this requirement has decreased access to TOLAC services and reversed the rise in VBAC rates.[13] The continuing controversy surrounding TOLAC stimulated the federal government to award a contract for an evidence review on VBAC.[2] ACOG's Practice Bulletin Number 54, released in 2004, continues to support a TOLAC for VBAC patients and preserves the "immediately available" statement. The bulletin also discourages the use of prostaglandins for induction of labor in VBAC patients.[14]

Table 1 shows that the overall cesarean rate is inversely related to the rate of VBAC. Repeat cesarean accounts for about one-third of all cesarean deliveries. More than 1 in 4 U.S. babies are now born by cesarean, which is the highest rate of cesarean delivery ever recorded in the United States.

METHODS

AHRQ Evidence Report

The TOLAC Panel used the AHRQ Evidence Report Number 71[2] as the basis for constructing this TOLAC Clinical Practice Guideline. A full description of the methods used in the AHRQ systematic review can be found in that document.[2] A brief description of these methods and additional methods specific to this TOLAC Clinical Practice Guideline are given below.

The Oregon Evidence-based Practice Center (EPC) systematically reviewed published literature to compare the benefits and harms of a TOLAC to an ERCD and to examine factors influencing decision-making. A technical advisory panel composed of family physicians, nurse midwives, obstetricians, patients, and payers worked with the EPC to develop the analytic framework and key questions addressed in the evidence report and to ensure that the scope of the project addressed clinical questions and issues that arise in routine practice. Ten key questions were identified that encompassed comparison of outcomes between TOLAC and ERCD and the factors influencing the decision to undergo TOLAC.

The EPC review was restricted to studies published between the 1980 NIH Consensus Development Conference on Cesarean Childbirth and March 2002. Databases searched included MEDLINE, HealthSTAR, Cochrane systematic reviews and controlled trials registries, Database of Abstracts of Reviews of Effects, National Centre for Reviews and Dissemination, and Excerpta Medica database databases. Search strategies are presented as appendices in the full evidence report. In all, 15,370 citations were retrieved.[2]

Studies were included for review if they identified a group of patients with prior cesarean. Studies were excluded if they focused on the following: nulliparous patients, vertical, lower-vertical, classical or classic cesarean incision, an inability to differentiate outcomes based upon scar type, vaginal breech delivery, preterm delivery, multifetal pregnancy, or low birth weight, and for patients with particular conditions such as gestational diabetes, human immunodeficiency virus (HIV), and preeclampsia. Studies conducted in undeveloped or developing countries were excluded as were case reports, editorials, letters, and non-English-language papers. In this systematic review, 1,661 articles were selected for full-text review, and 180 studies were abstracted and included in the evidence report.

Internal validity of individual studies was assessed using the United States Preventive Services Task Force (USPSTF) criteria,[15] and were modified for some specific key questions. Large population-based and prospective cohort studies were included because randomized controlled trials (RCTs) of delivery method have not been done.

Where appropriate, meta-analysis was performed. To reduce potential bias, only studies of fair or good quality were included in analyses. For many questions, because of the limited number of studies of fair to good quality, only a narrative summary was produced in the evidence report.

Updated Evidence Review

Because two years had passed since the original evidence review, the TOLAC Panel conducted a systematic update of the evidence by reviewing studies published since the AHRQ evidence report. The update followed the same procedure as the AHRQ evidence report, used the same search strategies, and retrieved the abstracts of all English-language publications through March 2004. Studies were identified by search category as defined in Table 2 and were read by two reviewers who applied the same inclusion and exclusion criteria defined in the initial report, and assigned remaining studies to the appropriate key question(s). Studies selected for full review were retrieved and evaluated for study quality using the same criteria as that of the initial report.

The results of the full review by key question are presented in Table 3. The updated search yielded only seven studies that received a fair to good rating. Only key questions 1 and 8 identified more than one study (three each). The new studies for key questions 1 and 8 did not address identical outcomes or have the same study focus. Accordingly, without a body of new evidence for any key question, the TOLAC Panel determined that there was no support for any substantive change to the original report. Therefore, the original evidence report was used as the evidence source for this guideline.

RESULTS

The TOLAC Panel carefully reviewed the ten key questions addressed in the AHRQ evidence report and recognized that these questions were designed to maximize retrieval and critical review of all the scientific evidence. They were not, however, stated in a way that reflects how maternity care professionals normally approach a patient. The TOLAC Panel therefore restated these questions so as to render them clinically relevant. These restated questions with relevant subquestions were as follows:

Restated Key Questions

1. Should TOLAC be recommended and attempted?
- A. What are the benefits and harms of TOLAC?
- B. What patient characteristics influence beneficial or harmful outcomes?

2. What management strategies influence outcomes?
- A. How should labor be planned and managed in TOLAC patients?
- B. How quickly and what actions need to be taken if problems arise?
- C. What services need to be available during labor and delivery in the facility?
- D. What factors are associated with patient satisfaction with the birthing experience?

3. What are the issues to discuss with patients?
- A. What is the best way to present the risks and benefits to help patients understand?
- B. What kind of information influences patient decisions?

Table 4 provides the crosswalk between the restated questions and the 10 key questions addressed in the AHRQ evidence report. This allowed the TOLAC Panel to review the evidence in a reorganized fashion. It should be noted that some restated questions did not fully match with the question addressed in the AHRQ evidence report. For some questions, no reliable evidence could be found to support an answer. The evidence for each of the restated questions is provided below.

Review of Evidence

1. Should TOLAC be recommended and attempted?

A. What are the benefits and harms of TOLAC?

(1) What is the likelihood of vaginal delivery with TOLAC?

Summary: 76% of women who attempt TOLAC are successful in having a vaginal birth. The likelihood of success is reduced to 63% if oxytocin induction or augmentation is used and to 51% if prostaglandin ripening or induction is used. ***Quality of Evidence: Fair-Good***

Evidence: Reports of successful TOLAC rates range from 60%-82%, with the largest population-based study[11] reporting a 60.4% likelihood of success. The combined vaginal delivery rate for all prospective cohort studies, largely conducted in university or tertiary-care settings, was 75.9% (95% CI 69.9-81.5). Seven fair- or good-quality observational studies compared vaginal delivery rates for spontaneous labor and induced or augmented labor. All found a reduction in success when induction or augmentation was used, with five detecting a statistically significant reduction. Three fair- quality studies compared use of prostaglandins with spontaneous labor. The largest published study comparing prostaglandins (any type) with spontaneous labor[16] found a significantly lower rate of successful TOLAC among patients induced with prostaglandin E2 (PGE2) (51.4%) than in those undergoing spontaneous labor (76.9%)

(2) What are the maternal outcomes including uterine rupture for TOLAC compared with ERCD?

Summary:

(a) Maternal death rates do not differ between TOLAC and ERCD. ***Quality of Evidence: Fair***

(b) Hysterectomy rates do not differ between TOLAC and ERCD. ***Quality of Evidence: Fair-Poor***

(c) Infection rates are slightly increased in ERCD (6.4%-9.7%) vs TOLAC (5.3%-6.8%) [11, 17] and in a TOLAC resulting in a cesarean delivery (unsuccessful TOL) vs a successful TOL. ***Quality of Evidence: Poor***

(d) There is no significant difference in asymptomatic uterine rupture (sometimes referred to as uterine dehiscence) in TOLAC versus ERCD. ***Quality of Evidence: Fair-Poor***

(e) There is a small but significant increase in symptomatic uterine rupture in TOLAC vs ERCD (2.7 per 1,000). There is no significant increase in uterine rupture associated with induction or augmentation.[2] The risk of hysterectomy due to uterine rupture is 4.8 per 10,000.[2] ***Quality of Evidence: Fair-Poor***

Evidence: There is no direct evidence comparing the risks and benefits of TOLAC relative to ERCD in similar patients. Several fair- and good-quality cohort studies provide indirect evidence about the relative benefits and harms for mothers. Four major maternal

complications noted were: (1) maternal death; (2) major maternal hemorrhage, defined as requiring transfusion or hysterectomy; (3) maternal infection, including endomyometritis, wound infection, and/or postpartum/puerperal fever; and (4) uterine rupture.

Six studies examined maternal deaths. The largest population-based study found no maternal deaths in 6,138 women in either TOLAC or ERCD groups.[11] Combining the remaining cohort studies of 19,000 patients revealed that there were two deaths each in the TOLAC and ERCD groups.

Two good-quality studies provided information on transfusion rates. One found no significant difference, with rates of maternal hemorrhage requiring transfusion at about 1 percent for both groups (1.1 in TOLAC vs 1.3 in ERCD).[11] The other study found a statistically significant increase in transfusion for ERCD (0.72 in TOLAC vs 1.72 in ERCD).[16]

Studies evaluating maternal infection rates are of limited usefulness because of their lack of explicit definitions and because they combined sites and sources of infection. No study provided data on the risk of infection in spontaneous TOLAC (without augmentation). Two studies defined infection clearly, although they both combined puerperal infection and abdominal wound infection. These studies compared the incidence of maternal infection in TOLAC with that in ERCD and found infection rates increased in ERCD (5.3%-6.8% in TOLAC vs 6.4%-9.7% in ERCD).[11, 17] Subgroup analyses in one study found that women who had a TOLAC but did not deliver vaginally had significantly higher infection rates than women who were able to deliver vaginally (8% in failed TOL vs 3.5% in successful TOL).[11]

The definition of uterine rupture is used inconsistently and ambiguously in published studies. Three studies compared rates of asymptomatic uterine rupture in TOLAC with those in ERCD. Asymptomatic rupture was defined as an asymptomatic separation of the uterine scar that is an incidental finding at cesarean or upon manual exploration of the uterus following vaginal delivery. For these three studies, there was no statistically significant difference between the rates in TOLAC vs those in ERCD. The report found one good- and one fair-quality observational study that compared the rate of symptomatic rupture in TOLAC vs that in ERCD. When combined, the data suggest an increased risk of symptomatic uterine rupture for TOLAC (2.7 per 1,000) compared with ERCD.[11,18]

(3) What are the infant outcomes attributed to TOLAC vs ERCD?

Summary: There may or may not be a slightly increased risk of infant death for TOLAC compared with ERCD; this is uncertain because the quality of evidence for this finding is poor.

No study measured infant death directly attributable to a mother's choice of TOLAC or ERCD. The rate of infant death varied considerably in the two reports that evaluated it, from 12.9 per 10,000[19] to 90 per 10,000[11] for TOLAC compared with 1.1 per 10,000[19] to 50 per 10,000[11] for ERCD. The risk of perinatal death due to uterine rupture is 1.5 per 10,000.[2] ***Quality of Evidence: Poor***

Evidence: There is no direct evidence comparing the risks and benefits of TOLAC with those of ERCD for newborns with similar maternal risk factors. There were insufficient data to compare infant Apgar scores for TOLAC vs ERCD; only 1 fair-quality cohort study reported that more infants born from TOLAC had 5 minute Apgar scores less than 7 (1.47% in TOLAC vs 0.68% in ERCD, P =0.004).[20]

(4) What is the impact of TOLAC vs ERCD on maternal or infant health status and health-related quality of life?

Summary: No relevant studies were found that address the health status and health-related quality of life for VBAC and repeat cesarean patients.[2]

B. What patient characteristics influence beneficial or harmful outcomes?

(1) Are risk-assessment tools useful in prospectively identifying beneficial or harmful outcomes?

Summary: Risk-assessment tools may predict the likelihood of successful TOLAC. ***Quality of Evidence: Fair-Good***

Evidence: The EPC report identified two validated scoring systems, one by Flamm and Geiger and the other by Troyer and Parisi.[21, 22] Both systems were developed to use at admission for delivery; Flamm, however, was developed in a larger population (2,502 vs 264) and uses a 10-point vs 4-point scoring system to more strongly weight factors such as previous vaginal deliveries before and after the first cesarean and more than 75% effacement at admission. Only the study by Flamm and Geiger received a good-quality rating. Using the Flamm and Geiger scoring system, low scores (0-2) predicted a 49% likelihood of successful TOLAC, while high scores (8-10) reflected a 95% chance of success. A recently published retrospective study by Dinsmoor and Brock was not reviewed in the evidence report but was included in our update.[23] This study assessed the performance of the Flamm and Geiger system and that of Troyer and Parisi plus that of an additional scoring system by Alamia et al; which, unlike the other two, was not designed to evaluate TOLAC success but, rather, risk of uterine rupture.[24] The sample size was very small--153 subjects, 117 (76.7%) had a successful TOLAC. Thus, information on failed TOL was based on only 36 women. In addition, the study was composed of a select population of primarily indigent women. While the authors of the study found that patients with unfavorable scores still had a 48%-56% chance of a successful TOLAC, favorable scores (7 or greater in Flamm and Geiger, 0 in Troyer and Parisi, and 8 or greater in Alamia) uniformly predicted vaginal delivery in 97%-100% of eligible patients.

(2) What factors influence the route of delivery?

Summary: Factors significantly associated with increased likelihood of vaginal delivery include: maternal age <40 years, prior vaginal delivery (particularly prior successful VBAC), a nonrecurrent indication for the prior cesarean delivery, and favorable cervical factors. Factors significantly associated with decreased likelihood of vaginal delivery (failed TOL) include: increased number of prior cesarean deliveries, gestational age >40 weeks, birth weight >4,000 g, and augmentation of labor. ***Quality of Evidence: Fair-Good***

Evidence: There were 96 studies examining individual factors that influence route of delivery, but 83 were of poor-quality, most because they did not adjust for important confounders. Individual factors that influenced route of delivery fell into four general categories: demographic, past obstetric, current obstetric, and non clinical.

Demographic factors: Within the category of maternal demographics, the only subcategory on which evidence had been gathered was maternal age. Three fair- to good-quality studies found conflicting results on the effect of age. However, the only study to find increasing likelihood of vaginal delivery with increasing age exclusively included mothers younger than 35 years of age. The only study with statistically significant findings was Flamm,[21] which found a 2.58-times increased likelihood (95% CI 1.55-4.3) of TOLAC success in mothers younger than 40 compared with that in those 40 or older.

Past obstetric factors: Prior vaginal delivery was consistently associated with increased likelihood of successful TOLAC, and more so when the prior vaginal delivery occurred after the cesarean. Studies by Flamm[21] and Weinstein[25] reported adjusted odds ratios (ORs) of 1.53, (95% CI 1.12-2.1) and 1.8, (95% CI 1.1-3.1), respectively, when vaginal delivery occurred before the prior cesarean delivery Flamm[21] and Macones[26] found much higher odds ratios when the vaginal delivery came after the cesarean delivery adjusted OR 3.39, (95% CI 2.25-5.11) and 7.69, (95% CI 3.23-20), respectively. A single fair-quality study was identified that demonstrated that the likelihood of successful TOLAC decreased with increasing numbers of prior cesarean deliveries adjusted OR 0.43, (P<.05).[27] Two fair quality studies found that higher likelihood of TOLAC success was associated with a nonrecurring indication for the index cesarean.[21,25] Flamm[21] reported an adjusted OR of 1.93, (95% CI 1.58-2.35) for nonrecurrent vs recurrent indications, and although Weinstein[25] reported a nonsignificant adjusted OR of 0.8, (95% CI 0.3-2.0) when comparing recurrent vs nonrecurrent indications, that finding was consistent with that reported by Flamm.

Current obstetric factors: For current obstetric factors, two fair quality studies found a negative association between gestational age and the likelihood of VBAC.[27, 28] Pickardt[27] reported an adjusted OR of 0.81 (P<0.05), and Zelop[28] reported an adjusted OR of 0.67 (95% CI 0.56-0.83 for spontaneous labor).

There were only two fair-quality studies examining likelihood of VBAC with birth weights greater than 4,000 g.[25,29] The study by Zelop[29] found nearly half the likelihood of successful vaginal birth for birth weights greater than 4,000 g, with adjusted OR of 0.59 (95% CI 0.45-0.77) The study by Weinstein[25] was underpowered to detect a difference, reporting an adjusted OR of 0.95 (95% CI 0.17-5.0). Four fair-quality studies examined the influence of cervical dilation, and three of them found greater likelihoods of VBAC with higher cervical dilation.[21.26,27] Adjusted OR and 95% CI were as follows: for Flamm,[21] 2.16 (95% CI 1.66-2.82); for Macones,[26] 1.87 (95% CI 1.14-3.23); and for Pickhardt,[27] 1.62, P<0.05. Two-fair quality studies were identified that examined cervical effacement, and both found higher likelihoods of VBAC with greater cervical effacement, Flamm reporting an adjusted OR of 2.72 (95% CI 2.0-3.71) when >75% effaced and McNally reporting an adjusted OR of 5.0 (95% CI 1.28-19.23) when 100% effaced.[21,30] The evidence report identified two fair-quality studies that provided information on labor augmentation. One found that those with augmentation were statistically significantly less likely to have VBAC (adjusted OR of 0.47 and 95% CI 0.25-0.88)[26] while the other did not find any association.[31] Only one fair-quality study examined the effect of epidural use, and it found a statistically nonsignificant reduction in VBAC.[30]

2. What management strategies influence outcomes?

A. How should labor be planned and managed in TOLAC patients?

This question was not addressed in the evidence report.

B. How quickly and what actions need to be taken if problems arise?

This question was not addressed in the evidence report.

C. What services need to be available during labor and delivery in the facility?

Summary: No resource conditions or practice management characteristics that influence the risk of TOLAC or ERCD or their attendant complications were identified.[2] ***Quality of Evidence: Poor***

Evidence: No good evidence exists regarding the influence of the type or characteristics of the maternity care professional on VBAC rates or outcomes. This is in part due to patient selection bias (patient's choice of one type of maternity care professional over another).[2] Studies of hospital characteristics consistently indicated that teaching hospitals had higher VBAC rates. No comparisons were reported regarding the safety of a TOL in women with a prior cesarean delivery in different hospital settings. Studies of maternity-care professional and hospital characteristics focused exclusively on VBAC rates rather than on the safety of the procedure and, therefore, provided no evidence to address this question. There are conflicting studies on the relationship of a neonatal intensive care unit (NICU) to VBAC or ERCD rates. Patient selection bias confounded all comparison studies.

D. What factors are associated with patient satisfaction with the birthing experience?

No good-quality studies permitted conclusions regarding factors that influence patient satisfaction with the childbirth experience.[2]

3. What are the issues to discuss with patients?

A. What is the best way to present the risks and benefits to help patients understand?

This question was not addressed in the evidence report.

B. What kind of information influences patient decisions?

Summary: Several factors appeared to increase a patient's likelihood of choosing TOLAC: white race, prior vaginal delivery, and low levels of anxiety during pregnancy; social motives (recovery time to being able to care for baby or other children at home); and safety of mother or baby. ***Quality of Evidence: Fair.***

The influence of TOLAC counseling on the woman's decision is unclear from current studies.[2] There was no evidence that evaluated the effect of cost on patient decisions. TOLAC appears to be more cost-effective and has a higher resulting quality of life, especially when the prior probability of successful TOLAC >76%. ***Overall Quality of Evidence: Fair***

Evidence: Only one study examined the effect of race on preference, and two studies examined prior vaginal delivery as a predictor for TOLAC preference. Social motives appeared more often in studies as the primary reason for selecting TOLAC or ERCD rather than careful weighing of maternal or infant health. Six of the seven studies that reported women's reasons for choosing TOLAC found easier recovery to be a strong reason. Two of ten studies cited convenience as a primary reason for ERCD. Safety of mother and/or child was cited as an important reason in only four of the eleven studies

reporting reasons. Two studies, one fair- and one good-quality, demonstrated greater cost-effectiveness when the prior probability for vaginal delivery was ≥76%.

CONCLUSIONS AND RECOMMENDATIONS

Building on the reviewed evidence, the AAFP TOLAC Policy Team developed the following recommendations. The strength of recommendations is based on the SORT categorization system described in Table 5. The following recommendations are based on the evidence reviewed above. They are organized to respond to the restated key clinical questions posed by the TOLAC Panel.

1. Should TOLAC be recommended and attempted?

Recommendation 1: Women with one previous cesarean delivery with a low transverse incision are candidates for and should be offered a trial of labor (TOL). **(Level A)**

A discussion of benefits and harms attributed to each delivery method (TOLAC and ERCD) is essential in the process of informed consent. Current evidence suggests that:

A. Successful vaginal delivery rates when attempting TOLAC ranges from 60%-82% with the largest population based study reporting a rate of 60.4%.

B. Maternal death rates (2 per 19,000) do not differ between TOLAC and ERCD.

C. Hysterectomy rates do not differ between TOLAC and ERCD.

D. Maternal infection rates are increased in ERCD (8.6%-9.7%) vs TOLAC (6.6%-6.8%) and in unsuccessful TOL vs successful TOL.

E. There appears to be no significant difference in asymptomatic uterine rupture (sometimes referred to as uterine dehiscence) in TOLAC vs ERCD.

F. There is a small but significant increase in symptomatic uterine rupture in TOLAC vs ERCD.

G. There is no significant increase in uterine rupture associated with induction or augmentation.

H. There may or may not be a slight increased risk of infant death for TOLAC compared with ERCD; this is uncertain because the quality of the evidence for this finding is poor.

Recommendation 2: Patients desiring trial of labor after previous cesarean (TOLAC) should be counseled that their chance for a successful vaginal birth after cesarean (VBAC) is influenced by the following: **(Level B)**

<u>Positive Factors (increased likelihood of successful VBAC)</u>
Maternal age <40 years
Prior vaginal delivery (particularly prior successful VBAC)
Favorable cervical factors
Presence of spontaneous labor
Nonrecurrent indication that was present for prior cesarean delivery

Negative Factors (decreased likelihood of successful VBAC)
- Increased number of prior cesarean deliveries
- Gestational age >40 weeks
- Birth weight >4,000 g
- Induction or augmentation of labor

Recommendation 3: Prostaglandins should not be used for cervical ripening or induction as their use is associated with higher rates of uterine rupture and decreased rates of successful vaginal delivery. **(Level B)**

2. What management strategies influence outcomes?

***Recommendation 4*:** TOLAC should not be restricted only to facilities with available surgical teams present throughout labor since there is no evidence that these additional resources result in improved outcomes. **(Level C)**

At the same time, it is clinically appropriate that a management plan for uterine rupture and other potential emergencies requiring rapid cesarean section should be documented for each woman undergoing TOLAC. **(Level C)**

Much of the controversy on VBAC has centered on the management of labor, the timeliness of operative delivery, the risk of uterine rupture and its attendant consequences, and the potential for infant morbidity and mortality. Concerns have been raised about the impact of the immediately available policy on access to VBAC services. One consequence of the immediately available policy appears to be that some hospitals have discontinued VBAC services entirely, forcing women to present late in labor, to travel to another facility that allows VBAC, or to submit to a scheduled repeat cesarean delivery that they may not have wanted. This could result in adverse outcomes for women and babies beyond inconvenience.

Some have questioned the assumptions that seem to underpin the immediately available policy. For example, the policy assumes that having a surgical team immediately available will reduce morbidity or mortality from uterine rupture. The AAFP TOLAC Panel felt this was a debatable assumption. Similarly, the ACOG policy suggests that one rare obstetrical catastrophe (e.g., uterine rupture) merits a level of resource that has not been recommended for other rare obstetrical catastrophes (e.g., shoulder dystocia, abruptio placenta, cord prolapse) that may actually be more common. However, it may be argued that, while these other catastrophes are largely not predictable, permitting a TOL in a mother with a previous cesarean is a planned event that may demand a different degree of preparedness.

While adverse consequences of a TOLAC are distinctly uncommon and must be balanced against attendant risks associated with ERCD, current risk management policies across the United States restricting a TOL after previous cesarean section appear to be based on malpractice concerns rather than on available statistical and scientific evidence. The TOLAC Panel found no systematic evidence suggesting that improved outcomes for TOLAC patients resulted from restricting a woman's ability to undergo a TOLAC based on the availability of resources not usually present for other women in labor, the institutional setting, or the timeliness of operative delivery.

Any effort to limit the accessibility of TOLAC by requiring restrictive conditions during labor is likely to limit access to vaginal delivery for many women. Given the potential negative impact on access to care and the absence of evidence, no recommendations can be made as to whether a difference in intensity of care should be required for patients attempting a VBAC until more definitive evidence is provided demonstrating the benefits of more restrictive services for women undergoing a TOLAC.

Our recommendation significantly differs from current ACOG policy [14] because we could find no evidence to support a different level of care for TOLAC patients. Without good-quality evidence, we believe that

different levels of resources cannot be advocated because their potential for unintended harms cannot be evaluated against their purported benefits.

3. What is the best way to present the risks and benefits to help patients understand?

Recommendation 5: Maternity care professionals need to explore all the issues that may affect a woman's decision including issues such as recovery time and safety. **(Level C)**. No evidence based recommendation can be made regarding the best way to present the risks and benefits of trial of labor after previous cesarean delivery (TOLAC) to patients.

The impact of counseling on patient decisions and outcomes of TOL after previous cesarean delivery is unfortunately unclear at present. A nonexhaustive list of issues of concern may include the ability of the mother to care for a newborn baby and other children at home, ease and timeliness of recovery including in-hospital time, partner involvement in delivery process, ability to schedule a delivery vs unplanned delivery date, safety to mother and baby, and effect on future childbearing. Other important concerns may include mother-infant bonding and breastfeeding success. Risk-assessment tools may be useful both in providing additional data predicting likelihood of VBAC and in assisting with counseling.

FUTURE RESEARCH

There remains much that is not known about VBAC that is important to women and their maternity care professionals. Research should be pursued on the following:

1. **Development of common reporting criteria for uterine rupture and other complications**. Currently, studies evaluating uterine rupture rate vary considerably in their definition of uterine rupture and the severity of rupture. A universally accepted graded classification system that ranges from incomplete and asymptomatic scar separation to complete uterine wall rupture with fetal and maternal compromise would allow for more useful comparisons across studies. The grading system also should distinguish between clinical variations that have implications for their impact on the maternal and infant outcomes, as well as the urgency of intervention.

2. **Development of instruments that allow for the measurement of quality of life in mothers, infants, and their families.** Current instruments that focus on health-related quality of life include scales of physical and psychological functioning, but do not account for the ability of a woman to care for a newborn or the rest of her family. Ignoring this vital function may invalidate current tools for the population of women who have just had a baby. Other pertinent measures overlooked by current measures of quality of life include acute events such as postcesarean incisional pain compared to problems associated with postvaginal delivery, perineal pain, and long-term issues such as pelvic floor dysfunction.

3. **Development and validation of better tools to identify women likely to have a safe and successful VBAC**. Competing tools that have been developed retrospectively need more careful evaluation in a broader population of women at risk to identify the patient characteristics and management strategies that result in the best outcomes.

4. **Further investigation of factors that may help to identify women who are at higher risk for uterine rupture due to previous surgical history**, such as short interdelivery interval,[32, 33] single layer uterine closure[34, 35] and postoperative fever.[36]

5. **Development and validation of more specific decision support tools for VBAC**. VBAC represents an excellent opportunity in the nascent field of decision science to develop shared decision-making tools. The decision to undergo TOLAC often means balancing many factors

including the probabilities of low-frequency but high-severity adverse outcomes, personal values, convenience the needs of at least two patients, maternity care professional preferences and practice styles, and economics.

6. **Evaluation of the resources needed and the time required to intervene in cases of uterine rupture**. While conventional wisdom dictates that immediate emergency cesarean capabilities are required in cases of uterine rupture, there is little evidence to guide whether more rapid emergency intervention or additional resources will improve outcomes when a woman is attempting a VBAC.

7. **Evaluation of existing or new technologies that could be used to identify higher risk women for TOLAC or minimize the risk of rupture in those choosing to undergo a VBAC**. These include:

   A. Evaluating the performance characteristics of various monitoring systems to predict uterine rupture and prevent morbidity and mortality;

   B. Assessing whether imaging techniques such as ultrasound or magnetic resonance imaging.I can help predict rupture risk by locating the placenta in relation to the uterine scar;

   C. Assessing whether examination of the thickness of the lower uterine segment either before labor or serially during labor can identify patients at higher risk for uterine rupture.

ADDENDUM

Since the completion of the literature search and the TOLAC guideline, more than 100 studies meeting search criteria have been published. These include a widely publicized, large study examining the outcomes of women undergoing a TOLAC compared with those choosing ERCD in 19 large U.S. teaching institutions.[37] This cohort study showed that the symptomatic rupture rate during a TOLAC was 0.7%, a value consistent with the literature reviewed in the AHRQ evidence report. The only other maternal outcome that differed between groups was the rate of endometritis which was higher in the TOLAC group (odds ratio 1.62). In examining neonatal outcomes, babies born after labor were more like to have hypoxic-ischemic encephalopathy (HIE) (0.08%) than those with elective cesarean (0%).

The results of this trial are important but the study had several limitations. Nearly all low-birth-weight deliveries occurred in the TOLAC group. Similarly, women in the TOLAC group were nearly 3 times as likely to deliver prematurely (<37 weeks). This raises questions regarding comparability of groups. Also, as HIE is more common in premature children, this factor, rather than route of delivery, may account for many of the observed neonatal differences. Second, during the time that this cohort was studied, prostaglandin was still used for induction of women with a prior cesarean delivery. The rate of uterine rupture with prostaglandins was twice that seen when no prostaglandins were used, which limits the applicability of the information given the current recommendation that prostaglandins be avoided. The results of this study would not have substantially altered the group's conclusions.

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Table 1. Rates of Cesarean Deliveries, Primary Cesarean Deliveries and Vaginal Birth After Cesarean (VBAC)

Year	Total Cesarean Rate	Primary Cesarean Rate	VBAC Rate
1970	5.5%		
1980	16.5%		
1990	22.7%	15.5%	19.9%
1992	22.3%	14.6%	22.6%
1994	21.2%	14.7%	26.3%
1996	20.7%	15.2%	28.3%
1998	21.2%	15.9%	26.3%
2000	22.9%	16.1%	20.7%
2002	26.1%	18.0%	12.4%

Adapted from *Natl Vital Stat Rep* 2003;51:1-20.

Table 2. Results of Updated Search (March 2002-March 2004)

Using the search strategies described in Appendix D of the Agency for Healthcare Research and Quality evidence report, the following numbers of studies were identified.

Search Results By Topic										
Search Results	Spontaneous labor	Elective repeat cesarean section	Induction and augmentation	Predictors	Patient satisfaction, health status and patient preference	Economics/Cost	Access	Medicaid	Laws	Guidelines
Articles retrieved from search	53	61	205	115	42	17	57	4	8	54
Articles selected for full-text review	27	11	14	50	17	6	16	2	7	8

Table 3. Results of Updated Review by Key Question

Articles that were selected for updated review were assigned to the following key questions as appropriate.

Updated Results by Key Questions (KQ)										
	KQ1	**KQ2**	**KQ3**	**KQ4**	**KQ5**	**KQ6**	**KQ7**	**KQ8**	**KQ9**	**KQ10**
Articles reviewed	12	11	12	9	2	1	3	15	3	3
Articles with fair to good ratings that were found to contribute new information to evidence report and applicable to the key question	3	1	1	1	0	0	1	3	0	1

Table 4. Restated Clinical Questions and Relevant Related Questions

Restated Clinical Question and Relevant Related Question	Agency for Healthcare Research and Quality Evidence Report Key Question (KQ Number)
1. Should TOLAC be recommended and attempted?	
A. What are the benefits and harms of TOLAC?	**KQ1.** What is the frequency of vaginal delivery in women who undergo a trial of labor (TOL) (spontaneous onset, induced, and augmented) after prior low transverse cesarean (LTCS) or unknown scar? **KQ3.** What are the relative harms associated with a TOL (spontaneous onset, induced, and augmented) and repeat cesarean? **KQ4.** What is the incidence of uterine rupture, and are there methods for preventing major morbidity and mortality due to uterine rupture? **KQ5**. What are the health status and health-related quality of life for vaginal birth after cesarean (VBAC) and repeat cesarean patients?
B. What patient characteristics influence beneficial or harmful outcomes?	**KQ1.** What is the frequency of vaginal delivery in women who undergo a TOL (spontaneous onset, induced, and augmented) after prior LTCS or unknown scar? **KQ2.** How accurate are risk-assessment tools for identifying patients who will have a vaginal delivery after a TOL? **KQ8.** What individual factors influence route of delivery?

2. What management strategies influence outcomes?	
A. How should labor be planned and managed in TOLAC patients?	**KQ1.** What is the frequency of vaginal delivery in women who undergo a TOL (spontaneous onset, induced, and augmented) after prior LTCS or unknown scar? **KQ4.** What is the incidence of uterine rupture, and are there methods for preventing major morbidity and mortality due to uterine rupture? **KQ10.** How do legislation, policy, guidelines, provider characteristics, insurance type, and access to care affect health outcomes for VBAC candidates?
B. How quickly and what actions need to be taken if problems arise?	**KQ10.** How do legislation, policy, guidelines, provider characteristics, insurance type, and access to care affect health outcomes for VBAC candidates?
C. What services need to be available during labor and delivery in the facility?	**KQ4.** What is the incidence of uterine rupture, and are there methods for preventing major morbidity and mortality due to uterine rupture? **KQ10.** How do legislation, policy, guidelines, provider characteristics, insurance type, and access to care affect health outcomes for VBAC candidates?
D. What factors are associated with patient satisfaction with the birthing experience?	**KQ6.** Regarding VBAC and repeat cesarean, what factors influence patient satisfaction/dissatisfaction with the childbirth experience?
3. What are the issues to discuss with patients?	
A. What is the best way to present the risks and benefits to help patients understand?	**KQ9.** What factors influence a patient's decision-making regarding VBAC or elective repeat cesarean delivery (ERCD)?
B. What kind of information influences patient decisions?	**KQ7.** How are economic outcomes related to VBAC and repeat cesarean delivery (CD), and their respective complications? **KQ9.** What factors influence a patient's decision-making regarding VBAC or ERCD?

Table 5. Strength of Recommendation (SORT)

Strength of Recommendation	Definition
A	Recommendation based on consistent and good-quality, patient-oriented evidence.*
B	Recommendation based on inconsistent or limited-quality, patient-oriented evidence.*
C	Recommendation based on consensus, usual practice, opinion, disease-oriented evidence, or case series for studies of diagnosis, treatment, prevention, or screening*

*Patient-oriented evidence reflects outcomes that matter to patients: morbidity, mortality, symptoms, costs, and quality of life. Disease-oriented evidence reports intermediate, physiologic, or surrogate end points that may or may not reflect outcomes of importance to patients (e.g., blood pressure, blood chemistry, physiologic function, and pathologic findings). Adapted from how recommendations are graded for strength, and underlying individual studies are rated for quality Table 1.[38]

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