Complete Summary

GUIDELINE TITLE

Trial of labor after cesarean (TOLAC), formerly trial of labor versus elective repeat cesarean section for the woman with a previous cesarean section.

BIBLIOGRAPHIC SOURCE(S)

Wall E, Roberts R, Deutchman M, Hueston W, Atwood LA, Ireland B. Trial of labor after cesarean (TOLAC), formerly trial of labor versus elective repeat cesarean section for the woman with a previous cesarean section. Leawood (KS): American Academy of Family Physicians (AAFP); 2005 Mar. 18 p. [38 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Trial of labor versus elective repeat cesarean section for the woman with a previous cesarean section. Am Fam Physician 1995 Nov 1;52(6):1763-5.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Pregnancy, previous cesarean section

GUIDELINE CATEGORY

Counseling
Management
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Hospitals
Physicians

GUIDELINE OBJECTIVE(S)

To provide an evidence-based clinical practice guideline for pregnant women with one previous cesarean and their families, for the maternity care professionals attending their labor and delivery, for the maternity care facilities where they will labor and deliver, and for policy-makers who care about trial of labor and maternity care for a woman

TARGET POPULATION

Pregnant women with one previous cesarean section

INTERVENTIONS AND PRACTICES CONSIDERED

1. Trial of labor after cesarean (TOLAC)
2. Discussion of benefits and harms attributed to each delivery method
3. Counseling patients on positive and negative factors linked to success of vaginal birth after cesarean
4. Refraining from use of prostaglandins for cervical ripening or induction
5. Restriction of TOLAC to facilities with available surgical teams present throughout labor (considered but not recommended)

MAJOR OUTCOMES CONSIDERED

- Successful vaginal birth rates after TOLAC (trial of labor after cesarean)
- Maternal outcomes:
    - Maternal death rates
    - Hysterectomy rates
    - Symptomatic and asymptomatic uterine rupture
    - Postpartum hemorrhage
    - Infection rates
- Neonatal outcomes:
    - Infant death
    - Apgar scores
- Predictive values of risk-assessment tools
- Demographic, obstetric factors for increased likelihood of successful vaginal delivery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Agency for Healthcare Research and Quality (AHRQ) Evidence Report

The Oregon Evidence-based Practice Center (EPC) review was restricted to studies published between the 1980 National Institutes of Health (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.

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.

Internal validity of individual studies was assessed using the United States Preventive Services Task Force (USPSTF) criteria, 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.

Updated Evidence Review

Because two years had passed since the original evidence review, the Trial of Labor After Cesarean (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 of the original guideline document 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 of the original guideline document. 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.

NUMBER OF SOURCE DOCUMENTS

Data from 224 studies were abstracted and included in the evidence tables.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

A set of design-specific criteria developed by the current U.S. Preventive Services Task Force and additional criteria developed by the National Health Service (NHS) Centre for Reviews and Dissemination, based at the University of York in England, were used to rate the quality of the evidence. In general, studies were rated good if they met all criteria, fair if they addressed some but not all criteria, and poor if they had a "fatal flaw."

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Oregon Evidence-based Practice Center (EPC) systematically reviewed published literature to compare the benefits and harms of a trial of labor after cesarean (TOLAC) to an elective repeat cesarean delivery (ERCD) and to examine factors influencing decision-making.

Data Abstraction

Included study designs were determined by topic area. Study designs of included articles consisted of randomized controlled trials, cohort studies, case-control studies, cross-sectional studies, large case series (more than 10 subjects), and economic or decision models. All data were abstracted by the lead investigator for the topic. If the lead investigator encountered difficulty in finding or interpreting information in the published report, a second investigator reviewed the article and a consensus was reached.

Assessment of Study Quality

To assess the internal validity of individual studies, the EPC applied a set of design-specific criteria developed by the current U.S. Preventive Services Task

Force and additional criteria developed by the National Health Service (NHS) Centre for Reviews and Dissemination, based at the University of York in England. In general, studies were rated good if they met all criteria, fair if they addressed some but not all criteria, and poor if they had a "fatal flaw." Investigators were asked to use the study quality ratings as previously described to determine for their topic which quality components were most important in assessing internal validity. This process allowed for some individual topic fit for fatal flaws, etc. A second investigator independently rated all included articles, and disagreements were resolved by consensus.

Data Synthesis

Where appropriate, meta-analysis was performed using WinBugs® or StatsDirect® software. To reduce potential bias, only studies of fair or good quality were included in the analyses.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A technical advisory panel composed of family physicians, nurse midwives, obstetricians, patients, and payers worked with the Oregon Evidence-based Practice Center (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 trial of labor after cesarean (TOLAC) and elective repeat cesarean delivery (ERCD) and the factors influencing the decision to undergo TOLAC.

The TOLAC Panel carefully reviewed the ten key questions addressed in the Agency for Healthcare Research and Quality (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 in the original guideline document 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.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

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).

COST ANALYSIS

For a trial of labor (TOL) success probability of 76 percent or greater, TOL is more cost-effective and provides higher quality of life.

Further evaluation is needed of the sensitivity of the probability cut point of 76 percent to other potential predictor variables.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was peer-reviewed before being reviewed and approved by the Commission on Clinical Policies and Research (CCPR) and approved by the American Academy of Family Physicians (AAFP) Board of Directors. Some of the external peer reviewers are acknowledged in the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of recommendations (A, B, and C) are defined at the end of the "Major Recommendations" field.

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.

Definitions:

Grade of Recommendations

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*

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The policy was based primarily on a comprehensive review of published reports. The evidence base was comprised chiefly of large population-based and prospective cohort series. There were no randomized controlled trials which directly compared trial of labor (TOL) to elective repeat cesarean delivery (ERCD).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The guideline recommendations may aid pregnant women and their families, maternity-care professionals, facilities, and policymakers in decision-making about repeat cesarean or trial of labor.

POTENTIAL HARMS

Risks of vaginal birth after cesarean (VBAC) and elective repeat cesarean delivery (ERCD) include uterine rupture, hysterectomy, bleeding, infection/fever, incontinence, and maternal and fetal death.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 Apr (revised 2005 Mar)

GUIDELINE DEVELOPER(S)

American Academy of Family Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

No external funding used.

GUIDELINE COMMITTEE

Trial of Labor After Cesarean (TOLAC) Policy Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Team Members: Eric Wall, MD, MPH, LifeWise Health Plan of Oregon; Richard Roberts, MD, JD, Department of Family Medicine, University of Wisconsin-Madison; Mark Deutchman, MD, Department of Family Medicine, University of Colorado Health Sciences Center; William Hueston, MD, Department of Family Medicine, Medical University of South Carolina; Lesley A. Atwood, MD, Allina Medical Clinic-Hastings; and Belinda Ireland, MD, MS, Clinical Sciences Analyst, American Academy of Family Physicians

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Trial of labor versus elective repeat cesarean section for the woman with a previous cesarean section. Am Fam Physician 1995 Nov 1;52(6):1763-5.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Family Physicians (AAFP) Web site.

Print copies: Available from American Academy of Family Physicians, 11400 Tomahawk Creek Parkway, Leawood, KS 66211.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Vaginal Birth After Cesarean (VBAC). Summary. Evidence Report/Technology Assessment: Number 71. Agency for Healthcare Research and Quality, Rockville, MD.

Electronic copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Web site:

- HTML Format
- Portable Document Format (PDF)

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 30, 1998. The information was verified by the guideline developer on December 1, 1998. This NGC summary was updated by ECRI on August 29, 2005. The updated information was verified by the guideline developer on September 20, 2005.

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Date Modified: 9/22/2008