

# Uterine Rupture: Effects of Single versus Two-Layer Suturing of Uterus after Primary Cesarean Section A Prospective Observational Study

*Holly Campbell, MS IV*

## A. Study Purpose and Rationale

Over the past three decades, the cesarean section rate has increased from 5% to almost 25%<sup>1-3</sup>. Repeat cesarean section is the leading indication for cesarean birth, accounting for one third of all abdominal deliveries in the United States. In recent years, there have been tremendous efforts to decrease these high rates of cesarean births by various groups, including the National Institutes of Health, the American College of Obstetrics and Gynecology, and several managed health organizations

These efforts have resulted in an increase in the vaginal birth after cesarean section (VBAC) rate from 3% in the early 1980's to 27% in the late 1990's<sup>5</sup>. Encouraged by this trend, the Department of Health and Human Services has proposed a 37% target cesarean section rate by the year 2010 for eligible women with one previous low transverse cesarean section. In current practice, trial of labor after a previous cesarean birth with a low transverse uterine incision is an accepted approach to avoid a repeat cesarean delivery<sup>4</sup>.

However, concern exists that a trial of labor may, in fact, increase the risk of maternal complications as compared with elective cesarean delivery, since the majority of serious complications associated with cesarean section occur in women with an unsuccessful VBAC<sup>6</sup>. Among the potential problems associated with a trial of labor after previous cesarean section there is a small but significant risk of catastrophic uterine rupture with poor outcome for both mother and infant<sup>7-9</sup>. Complications of uterine rupture include life-threatening hemorrhage, peripartum hysterectomy, major operative injury, massive blood transfusion, hypoxic fetal injury, neurologic compromise, and death<sup>6, 8-11</sup>.

To date, there are no randomized trials that demonstrate maternal or perinatal outcomes are improved with VBAC compared to an elective repeat cesarean section. Meta-analysis of studies conducted in the United States in the 1980's comparing trial of labor following cesarean section did not find an increased risk of uterine rupture based in the 11 studies (6328 births) examining this issue<sup>19</sup>.

Yet these analyses seem contradict a recently published population-based retrospective cohort analysis done in Washington State, which found a tripling of the risk of uterine rupture with trial of labor compared with repeat cesarean section in women with one prior cesarean delivery<sup>12</sup>. Similarly, a near doubling of risk with a trial of labor was reported in California in 1995 and in a recent evaluation in Switzerland<sup>13</sup>.

A possible explanation for these risk differentials may be due to changes in clinical practice. Beginning in the late 1980's, some physicians began to adopt a single-layer closure technique of the uterine incision, rather than closing with the traditional double-layer closure method<sup>14</sup>.

A single randomized study has been conducted to date, comparing these closure methods. Their finding was that single-layer closure was associated with reduced operating times (5.6 minutes). However, there were no significant differences in use of suture materials, infection rates, blood loss, or transfusion requirement<sup>15</sup>. A Cochrane review of single- versus double-layer closure reported no studies examining the safety in relation to uterine rupture in subsequent births<sup>16</sup>.

Currently, there is no standard of practice recommending either a single- or double-closure method, and in actual clinical practice, preference varies widely between physicians and across institutions.

This study will attempt to establish the efficacy of double-layer closure over a single-layer closure in women attempting to deliver vaginally following a cesarean delivery, as evidenced by lower rates of uterine rupture.

## B. Design and Statistical Analysis

This will be a prospective study of women presenting with their first pregnancy after a primary cesarean section via low transverse uterine incision for any indication and who elect to undergo a trial of labor. After screening and consent, the operative reports of women participating in the study will be obtained from the hospital that performed the surgery. The method of closure, single- versus double-layer technique, will be recorded and used to separate the women into two groups.

These groups will be followed for the remainder of their pregnancy to ascertain the rate of uterine rupture as the primary outcome. The frequency of the primary outcome will then be compared in the two groups.

For the purpose of the study, uterine rupture is defined as complete disruption of the layers of the uterus in association with one of the following: intraperitoneal or vaginal hemorrhage, need for hysterectomy, bladder injury caused by uterine scar disruption, or extrusion of any portion of the fetal-placental unit<sup>18</sup>. As per usual management of the laboring patient, study subjects will be monitored for signs of uterine rupture including nonreassuring fetal heart rate pattern, abdominal pain, loss of station of the presenting part, vaginal bleeding, and hypotension.

To participate in the study, patients must be eligible for a trial of labor, as outlined by the College of Obstetrics and Gynecology. Patients must have a clinically adequate pelvis and no other uterine scars or previous uterine rupture<sup>4</sup>. Contraindications which would exclude patients from participation include prior classical or T-shaped uterine incision, other transfundal surgery, contracted pelvis, medical or obstetric complication that precludes vaginal delivery (i.e. active genital herpes, prior uterine rupture, placenta previa, malpresentation) and inability to perform emergency cesarean delivery due to surgeon unavailable, anesthesia, sufficient staff, or facility<sup>4</sup>.

Data from all patients enrolled in the study who undergo labor will be tabulated, regardless of actual mode of delivery. Therefore, patients attempting to deliver vaginally who fail a trial of labor and deliver via cesarean will not be excluded. However, women undergoing operative (forceps) delivery will be excluded, since this method of delivery is an independent risk factor for uterine rupture. In addition, pre-term (<37 weeks gestation) and multiple gestation pregnancies will be excluded, based on differences in management and in rupture rates compared to term singleton deliveries.

Other variables that may influence rupture rates will also be collected and examined. These include maternal gravidity and parity, type of induction agent used (oxytocin or prostaglandin), fetal presentation, gestational age and birthweight.

A rate of uterine rupture of 0.3% reported in 1979, before the introduction of single-layer closure, will be used to estimate the expected rate of rupture following a double-layer closure. This is inferred based on the findings of a meta-analysis which found no difference in the rates of uterine rupture<sup>19</sup> at a time when few, if any, closures were single-layer. This analysis, which included 31 studies with a total of 11,417 trials of labor and evaluated the association between birth route after a cesarean and maternal morbidity and mortality, played a pivotal role in the movement towards VBAC.

The effect of a single-layer closure on uterine rupture rates has been conservatively estimated at 2%, using the ACOG rate (1-2%) and a weighted average of rates reported by Lyndon-Rochelle, et al<sup>4, 12</sup> (3.7%). To detect the difference in rupture rates between these two groups, at a p-value < 0.05, alpha of 0.05, and a power of 80%, this study will require enrollment of 1458 subjects (729 per group). Based on the institution's birth statistics for 2000, it is expected that there will be approximately 400 patients presenting who meet eligibility criteria annually. Assuming a high rate of enrollment, data will be collected over a 3-4 year period.

The chi-square test will be used to compare the rates of rupture in the two groups. A secondary analysis using multiple logistic regression will also be performed, to determine the influence of the following characteristics on outcome: maternal gravidity and parity, type of induction agent used (oxytocin or prostaglandin), fetal presentation, gestational age and birthweight.

### **C. Study Procedure and Data Collection**

Eligible patients will be identified during intake at the time of presentation for prenatal care. As per routine, prenatal care providers (Physician, Clinical Nurse Midwife, or Physician Assistant) will collect patient's obstetrical history; identifying patients appropriate for study inclusion. Providers will be provided with copies of a consent form with a data sheet attached.

The provider may elect to obtain consent at that time, or have the clinic nurse consent the patient. If this does not take place, they have the option of completing the data sheet exclusively. All forms will be placed in a secure, locked box, to be collected by the investigators. Unconsented patients will be offered inclusion in the study on a subsequent visit by the investigators.

Following standard practice, the patient's provider will obtain documentation of prior operative procedure. Investigators will assist in the collection of this data, when necessary. Review of the operative note will identify the prior closure method and separate the women into two groups.

Data sheets collected at the time of consent will be filed according to patient's expected date of delivery. These will be used to request medical records and collect data on pregnancy outcome and study variables.

Any patient presenting to the labor floor without prior care within the study facility network will be screened for inclusion by house staff. Data sheets and consent will be available in the labor and delivery suite for this purpose. Operative notes may be reviewed subsequent to delivery in some of these patients, particularly when their prior delivery occurred at an outside institution. Data collection from index pregnancy will be obtained as with other patients.

### **D. Study Drugs**

None.

### **E. Medical Device**

None.

### **F. Study Questionnaires**

None.

### **G. Study Subjects**

Women presenting for prenatal care at the Audubon clinic, private offices located at the Atchley Pavilion, East 60<sup>th</sup> Street offices, or off-site private offices who plan to deliver at the study site are eligible, provided their immediately preceding delivery was a primary cesarean section via low transverse uterine incision and they have no other uterine scars.

### **H. Recruitment of Subjects**

Medical providers (MD, CNM or PA) will screen women with prior cesarean section for eligibility during routine prenatal care or at time of delivery. These patients will be explained the purpose of the study during the visit and given the opportunity to participate.

### **I. Confidentiality of Study Data**

Any information obtained during this study will be kept confidential. All study subjects will be assigned a unique study identification number for use in data recording and processing. Only study investigators will have access to the list, which coordinates study identification numbers with patient names.

**J. Potential Conflict of Interest**

None.

**K. Location of Study**

Sloane Hospital for Women, at New York-Presbyterian Medical Center (Columbia Campus) located on Broadway and 166<sup>th</sup> Street, New York, NY.

**L. Potential Risks**

Individual patients will not assume any increased risks from enrollment in this study.

**M. Potential Benefits**

Individual patients will not benefit from enrollment in this study.

**N. Alternative Therapies**

Not Applicable.

**O. Compensation to Subjects**

None.

**P. Costs to Subjects**

None.

**Q. Minors as Research Subjects**

Minors presenting with pregnancy are considered "emancipated minors" in New York State, conferring the same status as an adult. This includes the right to consent to participate in a research study.

**R. Radiation or Radioactive Substances**

None.

**S. References**

1. Curtin SC. Rates of cesarean birth and vaginal births after previous cesarean, 1991-95. *Monthly Vital Statistics Report*, volume 45, number 11, supplement 3. Hyattsville, Maryland: National Center for Health Statistics, 1997.
2. Center for Disease Control. Rates of cesarean delivery- United States, 1991. *MMWR Morb Mortal Wkly Rep* 1993;42:285-289.

3. Stafford RS. Alternative strategies for controlling rising cesarean rates. *JAMA* 1990;263:683-687.
4. American College of Obstetricians and Gynecologists. Vaginal birth after previous cesarean section. *ACOG Practice Bulletin*, Number 5. Washington, DC, July 1999.
5. Ventura SJ, Martin JA, Curtin SC, Mathews TJ. Birth: final data for 1997. *Natl Vital Stat Rep* 1999;47:1-83.
6. McMahon MJ, Luther ER, Bowes WA, Olshan AF. Comparison of a trial of labor with an elective second cesarean section. *N Engl J Med* 1996;335:689-95.
7. Paul RH, Miller DA. Cesarean birth: how to reduce the rate. *Am J Obstet Gynecol* 1995;172:1903-1911.
8. Scott JR. Mandatory trial of labor after cesarean delivery: an alternative viewpoint. *Obstet Gynecol* 1991;77:811-814.
9. Jones RO, Nagashima AW, Harnett-Goodman MM, Goodlin RC. Rupture of low transverse cesarean scars during trial of labor. *Obstet Gynecol* 1991;77:815-817.
10. Leung AS, Farmer RM, Leung K, Medearis AL, Paul RH. Risk factors associated with uterine rupture during trial of labor after cesarean delivery: a case-control study. *Am J Obstet Gynecol* 1993;168:1358-1363.
11. Fraser W, Maunsell E, Hodnett E, Moutquin JM. Randomized controlled trial of prenatal vaginal birth after cesarean section education and support program. Childbirth Alternatives Post-Cesarean Study Group. *Am J Obstet Gynecol* 1997;176:419-425.
12. Lyndon-Rochelle M, Holt VL, Easterling TR, Martin DP. Risk of uterine rupture during labor among women with a prior cesarean delivery. *N Engl J Med* 2001;345:3-8.
13. Josefson D. Vaginal delivery after cesarean section triples risk of uterine rupture. *BMJ* 2001;323:68.
14. Bivins HA, Gallup DG. Cesarean closure techniques: which works best? *Obstet Gynecol Mgmt* 2000;12:98.
15. Hauth JC, Owen J, Davis RO. Transverse uterine incision closure: one versus two layers. *Am J Obstet Gynecol* 1992;167:1108-1111.
16. Enkin MW, Wilkinson C. Single versus two layer suturing for closing the uterine incision at cesarean section (Cochrane Review). In: *The Cochrane Library*, Issue 1, 2002. Oxford: Update Software.
17. Depp R. Cesarean Delivery. In: Gabbe SG, Niebl JR, Simpson JL, editors. *Obstetrics: normal and problem pregnancies*. 3<sup>rd</sup> ed. New York: Churchill Livingstone; 1996. P. 606-607.

18. Zelop CM, Shipp TD, Repke JT, Cohen A, Lieberman E. Effect of previous vaginal delivery on the risk of uterine rupture during a subsequent trial of labor. *Am J Obstet Gynecol* 2000;183 (5):1184-1186.
19. Rosen MG. Dickinson JC. Westhoff CL. Vaginal birth after cesarean: a meta-analysis of morbidity and mortality. *Obstetrics & Gynecology*. 77(3):465-70, 1991 Mar.