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Variables in VBAC Success: A Retrospective Review of Trial of Labor After Cesarean (TOLAC) and Labor Support

A Thesis Presented
by
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Abstract

For most of the 20th century, the saying “once a cesarean, always a cesarean” was a rule in the United States. Today, the National Institutes of Health (NIH) opposes the dictum and urges women to consider trial of labor after cesarean (TOLAC). However, the factors that lead to a successful outcome remain unclear, as research continues to be conducted in hopes of creating a predictive model for vaginal birth after cesarean (VBAC) success.

The NIH’s request for more research in this area of obstetrics led to this retrospective cohort study of all TOLACs at Marin General Hospital (MGH) from 2000-2013. All labor trials were studied for patient demographics, details of labor, maternal and neonatal morbidities, insurance, and provider type. After confirming the quality of the data, verifying inclusion criteria and ignoring cases with missing data, a data set of 745 TOLACs with 13 explanatory variables of interest was prepared. A forward stepwise (Likelihood Ratio) binary logistic regression was run in IBM® SPSS® Statistics in order to create a model that could determine which variables were most predictive of delivery outcome in TOLAC patients.

Ultimately, seven variables were predictive and were included in the model. Of the seven, the most predictive variable in determining VBAC success was provider type. The model concluded that a woman’s odds of having a successful VBAC were almost four times greater if she began her delivery with a certified nurse midwife, than if she began her deliver with a physician (odds ratio 0.27, 95% CI 0.17-0.44; $p < 0.01$). The results from this study mimic the results of other models, and introduce labor support as a key factor in predicting VBAC success.

Historical Background

I. The Evolution of Cesarean Sections

Prior to the mid-1800s, many aspects of labor and delivery were obscure and misunderstood. Cesarean sections were minimally performed and were reserved for medical cases where the woman had no other way of being delivered. The surgery was rarely advocated for and was most often criticized or opposed for its maternal mortality rate due to hemorrhage, infection, or both (Low, 2009). Eventually, when medical research and technology flourished during the second half of the 19th century, these complications were addressed. Essential developments in anesthesia, surgical intervention, and antisepsis improved both the safety and the experience of the surgery for patients, and led to a slow decrease in maternal mortality rates through the end of the 19th century and into the 20th century (Low, 2009).

Anesthesia as a strategy to eliminate complications was introduced in obstetrics following the first public demonstration of surgical anesthesia in 1847 (Boothby, 1912). Physicians became particularly familiar with chloroform and ether as compounds with significant anesthetic qualities, and by 1850, the use of chloroform during surgery had propagated across Europe. Concurrently, many medical leaders opposed the use of anesthetic agents for pain relief during labor, calling the method unethical. Nonetheless, the greater medical community valued the new drugs. With obstetrical anesthesia, patients were calmer and physicians could prioritize careful technique over speed. The drugs were further supported when Queen Victoria asked to have chloroform administered to her during the births of her last two children in 1853 and 1857 (Ramsay, 2006).

Around the same time, improvements in surgical techniques revolutionized the methodology of surgical deliveries. Up until the mid-1800s, the uterine incision made during a cesarean section was never sutured closed. Instead, it was generally held that the womb would contract and retract in such a way that hemostasis would occur and sutures need not be used. This was standard procedure for cesareans at the time as it was assumed that the sutures would tear through the muscle during retraction, causing more maternal complications. However, beginning in 1871, following the success of silver wire sutures in vaginal delivery and the acceptance of uterine closure, the same wires were implemented in suturing the uterus after surgery. The application of uterine sutures after every cesarean then became common practice, and physicians concluded that it would probably diminish the rate of maternal mortality (Walton, 1878).

While anesthesia and the improvement of surgical techniques aided in decreasing the likelihood of maternal mortality, antisepsis seems to have been the most effective strategy in attacking the problem. Antisepsis is the prevention of infection by inhibiting or arresting the growth and multiplication of germs (infection agents), and given the high rates of intrauterine infection associated with surgical deliveries in the 19th century, the development of scrupulous antisepsis was necessary (Low, 2009). Principles of prevention and limitation of infection eventually became the focus of obstetric practice, playing a significant role in further reducing the maternal mortality rate (Low, 2009). Ultimately, with the advancement of medical care as a whole and the development of these three strategies, the use of cesarean deliveries increased between 1920 and 1950, and was enthusiastically embraced in different hospitals (Low, 2009).

II. The Rising Rate of Cesarean Sections

In 1970, the United States Cesarean rate sat at 5.5% but had tripled by 1980. Between 1984 and 2001, the rate minimally fluctuated above and below 21% (Kizer and Ellis, 1988). Since then, the cesarean rate has steadily increased. The Center for Disease Control and Prevention has recently reported it to be 32.8% (Martin et al., 2013). This soaring cesarean rate has been under investigation for decades and doesn't seem to be declining. Explanations for the rising rate include "our reliance on electronic fetal monitoring, pressure from health consumers to salvage small babies even at the very margins of viability, fear of litigation, decreasing expertise in operative vaginal deliveries and, in the West, lifestyle choices" (Ugwumadu, 2005).

In the 1960s, there was a greater emphasis placed on the health of the fetus. With the declining overall birth rate at the time, the focus was on favorable pregnancy outcomes and improved fetal outcomes. And with the impressive advances in medical care and the relative safety of cesarean sections, the easier it was to elect to perform the surgery. Eventually, cesarean deliveries were being performed to improve fetal outcomes. Additionally, studies were being published suggesting that cesarean deliveries improved the outcomes of various complications of pregnancy, which meant that more cesareans were being performed on women with breech presentations (fetal buttocks presented first during delivery) or fetal distress (NIH Consensus Statement, 2006). Physicians also elected to do the surgery when they were faced with abnormal fetal presentations that formerly required manipulative delivery. Eventually, the frequency of surgical intervention by physicians presented with complicated pregnancies rose (NIH Consensus Statement, 1980). And following the rise in primary cesarean rate came a rapid increase in the number of repeat cesareans.

III. The VBAC Controversies

For the greater part of the 20th century, the medical community believed in routine repeat cesarean deliveries for women that had previously undergone a cesarean delivery. Edwin Cragin coined the phrase “once a cesarean, always a cesarean” in 1916 to describe obstetricians’ management of patients with a prior cesarean delivery in the United States. The famous phrase emphasizes the idea that a repeat cesarean might be the risk associated with a primary cesarean, as Cragin urges his colleagues to practice sound obstetrics to avoid having to resort to surgery. Almost a century later, Flamm (1997) identifies and addresses five controversies with Cragin’s famous rule, as he describes the positive aspects that are associated with vaginal birth after cesarean (VBACs), but that tend to be overlooked.

(1) *The historical controversy*: Flamm references a literature review from 1950 to 1980 that confirms the relative safety of VBAC, and reports a 0.7% incidence of uterine rupture, a 0.93 perinatal (immediately before and after birth) mortality, and no maternal deaths in more than 5000 VBAC attempts (Lavin et al., 1982). Additionally, he reports that the percentage of women with a previous cesarean who delivered vaginally in the United States increased from 3.4% in 1980 to almost 25% in 1993 (Flamm, 1997).

(2) *The risk controversy*: Large cohort studies from 1987 and 1990 confirm that the risk of uterine rupture during trial of labor is approximately 1% (Flamm et al., 1990). Additionally, Phelan et al. (1987) conclude that the benefits associated with a trial of labor in after cesarean delivery (TOLAC) far outweigh the risks. Flamm also notes that a trial of labor should not be managed in a cavalier or superficial manner and should appropriately account for risk. During a VBAC attempt, a physician must be prepared for all possible outcomes.

(3) *The benchmark controversy*: The safety of TOLAC has been well documented since the mid-1960s, as more than 50 studies have confirmed that trial of labor carries little risk; however, little research had been done comparing risk of TOLAC and risk of cesarean (Lavin et al., 1982). An ideal benchmark study may never be conducted, as assigning women to VBAC or cesarean may not be feasible; however, large prospective cohort studies suggest that a vast majority of pregnancy outcomes will be favorable with either elective repeat cesarean or trial of labor.

(4) *The ethical controversy*: With the growing influence of managed care, the ethical challenge involved in offering, recommending, or performing a cesarean will continue to increase. Flamm notes the advantages of a repeat cesarean for both the physician and patient, including convenience, time-savings, and sometimes compensation for the provider. Physicians are left to determine what they constitute as appropriate counseling.

(5) *The legal controversy*: Large malpractice claims are involved in failed vaginal birth after cesarean attempts. Flamm challenges this controversy by asserting that legal action can be avoided by approaching vaginal birth after cesareans with greater caution rather than simply returning to the days of “once a cesarean, always a cesarean.”

(6) *The appropriate-hospital controversy*: Thousands of VBACs with similarly positive outcomes have taken place in hospitals with anesthesiologists and physicians immediately available. And though it might be tempting to conclude that hospitals without immediately available cesarean teams are not equipped to handle obstetric cases, Flamm ascertains that this isn't true. While it may be sensible to refer VBAC patients to centers with immediate Cesarean capabilities, this should not be mandated.

Introduction

The dictum “once a cesarean, always a cesarean” was well followed in the United States for the greater part of the 20th century. By 1980, 98 percent of women who’d had a previous cesarean delivery (CS) underwent a routine repeat cesarean for any subsequent pregnancy. Decades later, this old maxim still holds true for some and contributes to the overall rise in cesarean delivery rates seen today (Cunnigham et al., 2010).

In 1980, the National Institutes of Health (NIH) publicly called the maxim into question and suggested that this practice may not always be necessary (NIH Consensus Statement, 1980). The NIH examined the need of routine repeat cesarean delivery and defined situations in which vaginal birth after cesarean (VBAC) could be considered. And from studies done after 1960, it was confirmed that women who had previously undergone cesarean delivery could safely attempt a trial of labor (TOLAC) to have a vaginal delivery in subsequent pregnancies (Guise et al., 2010).

Thirty years later, the NIH began requesting that more women be offered trial of labor after cesarean (TOLAC) in hopes of decreasing the rates of cesarean delivery. However, little is known about factors that could predict the delivery outcome of an attempted VBAC, which means that women cannot be guaranteed a successful outcome from a TOLAC. Because of this uncertainty, the NIH requests that research be done to formulate predictive models for women hoping to attempt vaginal birth after cesarean (NIH Consensus Statement, 1980).

While a variety of medical and non-medical factors have been said to be associated with successful VBACs, no model has been able to use these factors to consistently predict delivery outcomes. Though the findings that confirm strong associations between factors and

VBAC success are not yet sufficient in developing a predictive model, they do suggest that there may be promise in the development of models to predict ideal VBAC patients.

Vaginal birth after cesarean is an important issue to explore in order to assess the value of the popular maxim, “once a cesarean, always a cesarean.” As many researchers have confirmed, it seems that vaginal births after cesareans might become more widely attempted if VBAC successes could be predicted (Cunningham et al., 2010). Naturally, it appears that women are apprehensive about TOLACs because they cannot be sure of delivery outcome. The challenge is to provide women who want to attempt VBAC a more individualized risk assessment during TOLAC (O’Brien-Abel, 2003). If it could be known whether or not a woman would have a successful VBAC, perhaps more women would attempt knowing they’d succeed.

I. Uterine Rupture in TOLACs and Cesarean Deliveries

Risks involved in TOLAC have been a topic of debate in obstetrics and have been deterring women from attempting VBACs for decades. A significant medical factor that has been heavily referenced as a reason to avoid TOLAC is concern about uterine rupture. This potentially catastrophic event involves a full-thickness disruption of the uterine wall and frequently results in life-threatening maternal and fetal compromise. Although a uterine scar is a well-known risk factor for uterine rupture (most of which arise from prior cesarean delivery), the majority of events involving the disruption of uterine scars result in uterine scar dehiscence, rather than uterine rupture. Uterine scar dehiscence is more common than uterine rupture, and involves the disruption and separation of a preexisting uterine scar. Typically,

uterine scar dehiscence does not result in major maternal or fetal complications, as the fetus, placenta, and umbilical cord remain contained within the uterine cavity.

While these risks appear alarming, the overall incidence of uterine rupture and uterine dehiscence is very low, even in high-risk subgroups. The rate of uterine rupture for all women is said to be approximately 0.07% (Gregory et al., 1999). In comparison, the rate of uterine rupture among women attempting VBAC is higher, and has been clinically determined to be approximately 0.5-0.9% after TOLAC (Gregory et al., 1999). These numbers represent an association that has been studied, which relates TOLAC with a higher risk of uterine rupture (Macones et al., 2005). And in women with multiple prior cesarean deliveries undergoing trial of labor, the rate of uterine rupture is even greater, 1.4% (Landon et al., 2004).

However, absolute risks are still incredibly low. In fact, researchers have found that the overall risk for perinatal mortality and morbidity with trial of labor is similar to that for any woman delivering her first child (Scott, 2010). One study confirmed that minor complications were more common among a group of women who opted for an elective repeat cesarean than among a group of women who attempted VBAC (Macones et al., 2005).

Ultimately, neither TOLAC nor elective repeat cesarean is risk-free. As researchers investigate the risks involved in TOLAC, they should also consider those involved in cesarean deliveries. Most of the literature focuses on the risk of uterine rupture in women attempting VBAC and assumes that risk of uterine rupture would not be included in elective repeat cesarean delivery. And yet, elective repeat cesarean delivery does not guarantee the prevention of uterine rupture, or the prevention of a number of other risks (Guise et al., 2004). For instance, the rate of infection is greater for all cesarean deliveries than for all

vaginal deliveries, as risk that is often ignored when considering these two methods of delivery (NIH Consensus Statement, 2006).

One 1987 study investigated the benefits associated with TOLAC and found that the benefits far outweighed the risks, as women with a trial of labor had significantly less maternal morbidity when contrasted with the group without trial of labor. The authors of the study went on to conclude that the policy “once a cesarean, always a cesarean” should be abandoned (Phelan et al., 1987).

Essentially, perceptions of high risk for uterine rupture cause many patients and practitioners to avoid vaginal birth after cesarean, when in fact the level of risk is low and manageable much like the level of risk in cesareans (Guise et al., 2004). The NIH reported, “the best evidence suggests that VBAC is a reasonable and safe choice for the majority of women with prior cesarean delivery” (Cunningham, 2010). In order to increase the rate of VBAC, patients and providers must better understand the risks and benefits of TOLAC, and be prepared to fully manage the term of labor.

II. Access to VBAC

In 1998, following a widely publicized study claiming that major complications are almost twice as likely among TOLAC patients as among patients that elect to have a second cesarean section (odds ratio 1.8, 95% CI 1.1-3.0), changes were made to the American College of Obstetricians and Gynecologists VBAC guidelines (McMahon et al., 1996). The College in turn limited TOLAC to women with one or two prior cesareans and recommended that a physician and anesthesia be “readily available” at the time of the VBAC attempt (Barger et al., 2013). Eventually, increasing malpractice concerns around TOLAC urged

ACOG to re-issue these guidelines in 1999, replacing “readily available” with “immediately available” (ACOG Practice Bulletin, 1999 and Barger et al., 2013). Between 1996 and 2010, the cesarean delivery rate rose from 21% to 32.8% and the VBAC rate dropped from 28% to 8% (Martin et al., 2012 and Cox, 2011).

Then in 2010, the NIH addressed questions regarding TOLAC in their Conference Consensus Statement, concluding that both TOLAC and elective repeat cesarean delivery carry important risks and benefits (Cunnigham et al., 2010). Furthermore, it was noted that TOLAC “is a reasonable option for many pregnant women” and that efforts must be made to ensure that women receive the support they need to make informed decisions about a trial of labor versus an elective repeat cesarean (Cunnigham et al., 2010).

However, even after the NIH published these findings that encouraged hospitals to decrease barriers to TOLAC, and ACOG issued a statement that encouraged less restrictive TOLAC guidelines, access to TOLAC remains restricted (Barger et al., 2013). For example, in a survey of access to trial of labor in California, the VBAC rates of hospitals permitting TOLAC was below 2%. The availability of VBAC services has significantly decreased, especially among small or more isolated hospitals (Roberts, 2007). This has been described as being a result of obstetricians’ reluctance to perform VBACs, which is most likely due to a combination of factors: “fear of liability, previous experience with a uterine rupture from TOLAC, involved with a cesarean related malpractice case, insurance carriers not allowing TOLAC, and convenience of scheduled repeat cesareans” (Barger et al., 2013).

In more recent surveys of hospitals and administrators, approximately 30% of hospitals stated that they’d stopped offering VBAC services all together (Gregory, 2010). In one particular hospital, where VBAC was still offered, 49% of the physicians that

participated in a survey reported performing more cesareans than five years earlier. The primary reasons for this increase were the risk of liability, and patient preference for the delivery method (Coleman et al., 2005).

While it appears that physicians are aware of the risks and benefits of TOLAC, a retrospective cohort study displays doubts regarding who should be offered trial of labor and what predicts successful VBAC, resulting in a decreased access to TOLAC across the United States (Coleman et al., 2005).

III. Factors Influencing VBAC Success

Of all attempted VBACs in the U.S., studies have demonstrated a probability of a successful VBAC that ranges between 60 and 80 percent (Grobman, 2010). Chances for a woman's success may vary significantly on the basis of her particular characteristics and history and factors that influence benefits and harms may include patient-specific factors, cultural and societal factors, health care provider type and professional resources, and ethical issues (Grobman, 2010).

Many models have been created that attempt to predict VBAC success; however, they are not typically predictive. Rather, these models are statistically significant and describe associations between certain factors and rates of VBAC success. In the NIH Consensus Statement from 2010, research from a variety of studies culminated in a list of demographic and obstetric factors associated with the likelihood of VBAC success (Cunningham et al., 2010). Each of the studies presented provide a model that can be used to guide decisions related to TOLAC. These prediction models are meant to give patients contemplating TOLAC individual chance of success to help them reach a better-informed decision

(Costantine et al., 2009). However, not one model has yet accurately calculated/predicted TOLAC outcome.

Nevertheless, research is still uncovering important information about TOLACs and VBAC success. Many studies are evaluating large cohorts and discovering what variables and factors may be involved in assessing VBAC success (Costantine et al., 2009). And given the variety of models that are being generated, it is possible to compare and contrast them in order to better understand what factors are consistently being associated with VBAC success, and which ones are not.

Thus far, a number of factors have been found to be of great importance across all models. The strongest demographic predictors of VBAC are race and ethnicity. Non-Hispanic white women seem to have higher rates of VBAC success than Hispanic and African-American women (Cunnigham et al., 2010). Additionally, the factor that has been most widely tied to increased rates of VBAC success is prior vaginal delivery (Costantine et al., 2009).

Other factors have been associated with decreased rates of VBAC success, such as increasing maternal age, single marital status, and less than 12 years of education. It has also been noted that delivery at private or rural hospitals or in the presence of disease are also associated with decreased likelihood of VBAC success. Additionally, gestational age greater than 40 weeks, labor augmentation, and labor induction are associated with a decreased rate of VBAC success (Blanchette et al., 2001 and Guise et al., 2004). Though many models include epidural use as a factor that may be associated in some way with VBAC success, the NIH reports that these data regarding epidural analgesia and VBAC are inconsistent (Cunnigham, 2010).

A variety of screening tools have been proposed for predicting VBAC, all of which take into account important factors that seem to be associated with VBAC success, and while these models may be capable of roughly predicting the likelihood of successful TOLAC at the population level, the models are not accurate in predicting the likelihood of successful TOLAC or the risk of uterine rupture at the individual level.

In an effort to address these predictive models and consider the factors that have been said to be associated with VBAC success, a retrospective review was done on all trials of labor after cesarean from 2000 to 2013 at a Marin General Hospital (MGH), a small community hospital in Northern California. This research aims to elucidate VBAC success and better explain the associations between a variety of factors and delivery outcome. Specifically, labor support is the focus of this model, as analyses from other research typically exclude the variable of “provider”. The purpose of this study is to ultimately examine what role labor support plays in predicting VBAC success, if any.

This investigation involved two disparate types of labor support, midwifery care and physician care. Focusing primarily on the role labor support plays on VBAC success, a new model was generated from data collected at Marin General Hospital. Essentially, it was hypothesized that patients with midwifery care for their labor support would typically have more successful rates of VBAC. This was predicted given the different roles that these two healthcare professionals typically play in a hospital. Physicians have many patients to see and are prepared to perform a repeat cesarean delivery if labor stalls or becomes complicated. However, midwives are not capable of performing cesarean deliveries, and are more equipped to invest the time and energy that is necessary to support a woman through TOLAC.

Methods and Materials

I. Consent Process and Documentation

Consent was not required for this study because it was a retrospective cohort study. Instead, personal identifying information and personal health information were protected and encrypted at each step. All researchers were approved by Marin General Hospital's Institutional Review Board (IRB) to study the effects of epidural analgesia on birth outcome in vaginal birth after cesarean patients. Further approval to study labor support in this same cohort was granted by Karin Ludwig, MGH IRB Member/Specialist, under the umbrella of Dr. Lizellen La Follette's IRB approval (Appendix).

II. Validation Study

Retrospective chart review was started on women with a history of prior cesarean birth who delivered at Marin General Hospital (MGH) between 1994 and 2013. The first step was to run a short validation study to confirm the quality of the data in the electronic medical records of Ponder's, a Sutter Health data collection system used by MGH until 2012. For the cases occurring between July 2012 and 2013, data extraction was done via Horizon Patient Folder (HPF), an electronic patient medical record system implemented by MGH.

The validation study was performed by randomly selecting ten charts from each year starting from 1994 and ending in 2013. In order to pull the correct and relevant charts for delivery by the hospital's storage facility for review, CPT codes were used as an identifier. The Current Procedural Terminology (CPT) codes are used by healthcare professionals to describe and bill medical visits, and are developed and maintained by the American Medical

Association. The CPT codes used to select the valid medical records for the validation study were:

- 59610: Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
- 59612: Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps)
- 59614: Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care
- 59618: Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
- 59620: Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery
- 59622: Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care

Once the 10 medical charts per year were randomly chosen, MGH's health information management (HIM) department requested their delivery by the hospital's storage facility. Each medical record was then evaluated for the quality of the data and inclusion of variables to be researched during the main study. Ultimately, 25 variables were extracted from Ponder's, and 13 additional variables of interest had to be manually entered into our spreadsheet.

The 24 variables available in Ponder's were extracted by the system and organized in a Microsoft® Excel spreadsheet. Of these variables, 17 were continuous: "birth date (mom)," "admit date to hospital (mom)," "admit time to hospital (mom)," "gestational age at admission," "admit weight in kg (mom)," "gestational age at delivery," "birth weight in grams," "cord gas artery pH," "Apgar score at 1 minute," "Apgar score at 5 minutes," "Apgar score at 10 minutes," "10 cm dilation time," "epidural start date," "cervical dilation at epidural," "oxytocin start date," "rupture of membranes time," and "discharge date (mom)." The other seven variables were nominal: "medical record number", "last name, first

name (mom),” “VBAC attempted (yes, no),” “labor analgesia (yes, no),” “intrauterine pressure catheter (yes, no),” “method of delivery (type of vaginal delivery, type of cesarean delivery),” and “delivery outcome (live birth, fetal death).”

Data from 13 additional variables that had not been extracted from the electronic medical records were also recorded for all of the cases. These variables were again both continuous and nominal: “admit height in inches (mom),” “body mass index at first prenatal visit (BMI),” “duration of oxytocin in hours,” “prior baby size in grams,” “cervical dilation at cesarean section,” “duration of the second stage of labor,” “prior vaginal delivery (yes, no),” “indication for repeat cesarean section (arrest of descent, etc.),” “labor induced (yes, no),” “neo-natal intensive care unit (NICU) admission (yes, no),” “payer mix (private, public insurance),” “provider (MD, CNM),” and “maternal morbidities (hemorrhage, etc.).”

At the conclusion of the validation study, 130 cases of TOLAC had been reviewed, and data on 37 variables of interest had been gathered for each case. Seventy (35%) of the charts that had requested could not be found in storage or in HPF, and it became clear that there would be holes in the study. The missing charts in question were mostly from 1994 to 1999. Upon further investigation, it was discovered that the hospital had destroyed these earlier records. This resulted in large amounts of missing data for cases prior to 2000.

III. Data Collection

The validation study confirmed that the medical records’ data from Ponder’s were high quality and contained all the variables necessary to run the retrospective study. This allowed for the retrospective chart review to begin on the 1,656 cases of TOLAC that had been identified by the CPT codes in Ponder’s.

However, all cases of TOLAC that had occurred prior to 2000 (746 cases) were excluded from the study before moving forward. With so many charts missing from 1994 through 1999, the study's sample size had to be adjusted in order to reflect consistent practice. At this point, the data included 910 medical records from 2000 to 2013, all containing one of the six CPT codes of interest. This data set represented all cases of TOLAC occurring after 2000, as described in the electronic data set.

Next, all physical charts for each of the 910 cases were delivered by the hospital's storage facility in order to be reviewed. The reliable validation study cases that had already been reviewed were used as templates, and the remaining cases were checked. For each case, the respective medical record was looked over, the Ponder's data were verified, and the correct information was recorded into the data sheet that now contained all variables that could possibly be of interest for the study. All TOLACs were reviewed for delivery details including assisted vaginal birth, indication for and dilation at C-section, maternal and neonatal morbidities. Finally, the data set was completely de-identified in order to protect personal health information (PHI). This was done by assigning a randomized identified number to each case.

Once all 910 TOLAC cases were carefully reviewed for accurate and complete data collection, each case was checked for certain inclusion criteria. These criteria were: full term gestation (≥ 37 weeks gestation), a singleton gestation, at least one prior cesarean, and vertex presentation at the time of delivery. Cases were excluded from the study if medical records did not contain one of the six qualifying CPT codes, or did not match the aforementioned criteria.

Additionally, cases that resulted in a cesarean, i.e. a failed VBAC, were carefully studied to confirm that each case reflected a true trial of labor. In some instances, Ponder's falsely identified a case as a TOLAC when an incorrect CPT code was used to describe a delivery. For this reason, progress notes and nurses' notes were thoroughly assessed. Cases where a TOLAC did not happen were ultimately eliminated from the study. These cases included non-laboring cases (e.g. sectioned at 1-2cm for floating head,), breech deliveries, deliveries at less than 37 weeks, and elective repeat cesareans. After correcting the data for these false TOLACs, we were left with 829 true cases of TOLAC at MGH between 2000 and 2013.

Of 829 cases that fit the inclusion criteria, 745 had complete data. Thus, 84 cases with missing values were excluded from the analysis. This included 1 case with no record of mother's gestational age, 41 cases with no record of mother's BMI (either due to missing height or weight), 36 cases with no record of mother's prior baby size, and 6 cases with no record of the duration of the second stage of labor. Given the large sample size of the data set, it was assumed that the exclusion of these records with missing data would not affect the results.

IV. IBM® SPSS® Statistics Data Set

Next, the data from the Microsoft Excel spreadsheet were revised for consistency. All nominal variables were verified to be dichotomous so that all of these variables could only have two possible categories. For example, where the type of cesarean or vaginal delivery had been recorded, the data were fixed to simply say "CS" or "VBAC," respectively.

Regardless of the details of a vaginal delivery, whether a cephalic spontaneous delivery or an

assisted vaginal delivery either by a vacuum or forceps, the spreadsheet was looked over and these cases were marked “VBAC.” Similarly, regardless of the details of a cesarean section delivery, whether a low transverse cesarean section or a low vertical cesarean section, the spreadsheet was reviewed and these cases were marked “CS.”

Upon completion of these revisions, the Excel file was imported into SPSS. Variables that were not of interest to the study were excluded from the SPSS data set and averaged variables were preferred over raw data. Ultimately, 13 variables were left in the SPSS file upon completion of the data review along with the response variable (delivery type):

- ¹ Delivery type: cesarean (0) or vaginal (1)
- ² Gestational age
- ³ BMI mother: first prenatal visit
- ⁴ Prior baby weight in grams – last birth mother had
- ⁵ Birth weight in grams
- ⁶ Duration of second stage of labor
- ⁷ Apgar average – tone, respiratory rate, color, cry after 1 minute, 5 minutes, and 10 minutes (if applicable): gives you a score of 0-10 (8-9 are great)
- ⁸ Epidural: no (0) or yes (1)
- ⁹ Oxytocin: no (0) or yes (1)
- ¹⁰ IUPC: no (0) or yes (1)
- ¹¹ Prior vaginal delivery: no (0) or yes (1)
- ¹² Labor augmentation/induction: no (0) or yes (1)
- ¹³ Payer mix: public insurance (0) or private/paid themselves (1)
- ¹⁴ Provider: delivered by certified nurse midwife (0) or obstetrician (1)

Following this clean up, all nominal variables were given a binary code, as this is typically preferred in SPSS. For example, a code of “0” for “CS” and “1” for “VBAC” was used here.

V. Chi-Square Tests for Associations (Delivery Type by Provider)

After all the data were prepared in SPSS, an initial statistical analysis was performed to test for the association between the response variable (delivery type) and the explanatory variable of greatest interest in this study, provider (CNM v. MD) (Laerd Statistics).

For this analysis, a new file was created in SPSS that included only three variables: (1) delivery type, which was the mode of delivery (CS/VBAC); (2) provider, which was the principal healthcare professional present at the start of the delivery (CNM/MD); and (3) frequency, which was the number of deliveries for each cell combination. In this analysis, cases were weighted since each line represented more than one case.

VI. Forward Stepwise (Likelihood Ratio) Binary Logistic Regression

Next, a logistic regression was run in SPSS to build a model that would predict delivery type based on the 13 explanatory variables previously described. Because it was not clear which variables were most predictive simply by looking at the data, or based on prior research, a forward stepwise entry method was chosen, along with the Likelihood Ratio (LR) criterion, which is considered the criterion least prone to error (Methods of Logistic Regression, 2011). This forward stepwise selection (Likelihood Ration) method added explanatory variables one at a time to a basic model (which only included the constant β_0).

Again, a new file was created in SPSS with all 13 variables included. For the dependent variable in this logistic regression, the response variable was coded “0” for “CS”, and “1” for “VBAC.” Similarly, the other dichotomous explanatory variables were appropriately coded, as described in the creation of the SPSS data set.

SPSS was then used to run the binary logistic regression. The response/dependent variable was marked as CS/VBAC, and all other explanatory variables were marked as covariates. The seven categorical variables were further tagged as categorical covariates. Finally, statistics and plots of interest were requested and generated in the output.

Results

Between 2000 and 2013, 35% of women with a history of cesarean delivery who were admitted to MGH attempted VBAC, and of these TOLAC cases, 74.4% were successful in delivering vaginally. Additionally, the rate of rupture in these TOLAC cases was 0.2% and the rate of low Apgar was 0.7%.

Of the 745 cases of VBAC attempt, 34.8% began their delivery with a nurse midwife (CNM), while the other 65.2% began their delivery under the care of a physician (MD). Of these midwife deliveries, 86.3% resulted in a successful VBAC, and of the physician deliveries, 67.5% resulted in a successful VBAC. This was a statistically significant association ($\chi^2(1) = 34.64$, $\phi = 0.216$, $p < 0.0005$).

The logistic regression model was also statistically significant, $\chi^2(7) = 148.991$, $p < 0.0005$. The model explained 18.1% (Nagelkerke R^2) of the variance in delivery type and correctly classified 79.9% of cases. Sensitivity was 36.6%, specificity was 94.8%, positive predictive value was 81.3%, and negative predictive value was 70.7%.

Of the 13 predictor variables, only seven added significantly to the model: birth weight, duration of the second stage of labor, epidural use, prior vaginal delivery, labor induction, insurance, and provider (Table 1).

Table 1. Logistic regression predicting likelihood of successful VBAC based on seven explanatory variables (birth weight, duration of second stage of labor, epidural, prior vaginal delivery, labor induced, payer mix, and provider).

	<i>B</i>	SE	Wald	<i>df</i>	<i>p</i>	Odds Ratio	95% CI for Odds Ratio	
							Lower	Upper
Birth weight	0.00	0.00	15.17	1	0.00	1.00	0.99	1.00
2 nd stage	0.45	0.08	29.29	1	0.00	1.57	1.34	1.85
Epidural	-0.68	0.23	8.97	1	0.00	0.51	0.33	0.79
PriorVagDeliv.	1.46	0.23	40.65	1	0.00	4.30	2.75	6.74
Labor induction	-0.49	0.20	5.98	1	0.01	0.61	0.41	0.91
Payer mix	0.77	0.21	13.66	1	0.00	2.16	1.44	3.24
Provider	-1.31	0.25	28.18	1	0.00	0.27	0.17	0.44
Constant	4.49	0.81	30.76	1	0.00	88.71		

Note: Epidural is for epidural compared to no epidural. PriorVagDeliv. is for prior vaginal delivery compared to no prior vaginal delivery. Labor induced is for labor induced compared to labor not induced. Payer mix is for private insurance compared to public insurance. Provider is for physician compared to certified nurse midwife.

Provider had the largest individual impact on delivery ($\chi^2 = 28.2$, $df = 1$, $p < 0.01$).

The odds ratio for “provider” was 0.27, meaning that the odds of having a successful VBAC with a physician were 72.9% less than having a successful VBAC with a midwife.

Prior vaginal delivery also significantly affected VBAC success ($\chi^2 = 40.65$, $df = 1$, $p < 0.01$). The odds ratio for “prior vaginal delivery” was 4.30, which means that the odds of having a successful VBAC were 4.30-fold greater for a woman who had a prior vaginal delivery at any point, than for a woman who had never had a prior vaginal delivery.

Duration of the second stage of labor (hours between getting to 10cm dilation and delivering) also significantly affected VBAC success ($\chi^2 = 29.29$, $df = 1$, $p < 0.01$). The odds ratio for “duration of the second stage of labor” was 1.57, which means that the odds of having a successful VBAC were 1.57-fold greater with each hour increase in the duration of the second stage

Birth weight of the baby also significantly affected VBAC success ($\chi^2 = 15.17$, $df = 1$, $p < 0.01$). The odds ratio for “birth weight” was 0.999, meaning that the odds of having a successful VBAC were 0.999-fold greater with each gram increase in birth weight.

Labor induction was the fifth most predictive variable and significantly affected VBAC success ($\chi^2 = 5.98$, $df = 1$, $p < 0.01$). The odds ratio for “labor induction” was 0.611, which means that the odds of having a successful VBAC were 0.611-fold greater for a woman who had an induced labor, than for a woman who did not.

Payer mix also significantly affected VBAC success ($\chi^2 = 13.66$, $df = 1$, $p < 0.01$). The odds ratio for “payer mix” was 2.16, meaning that the odds of having a successful VBAC were 2.16-fold greater for a woman who had private insurance, than for a woman who had public insurance.

Finally, epidural use was the last variable that significantly affected VBAC success ($\chi^2 = 8.97$, $df = 1$, $p < 0.01$). The odds rate for “epidural use” was 0.51, implying that the odds of having a successful VBAC were 0.51 times greater for a woman who had an epidural, than for a woman who did not.

With no independent variables in the model, the null model success was 74.4%. Contrastingly, the full model success was 79.9%.

Discussion

The present study generates a model that includes a variety of patient-specific factors that could potentially be involved in predicting VBAC success. Many of these variables have been previously studied and are known to be associated with TOLAC outcome, while a key explanatory variable in this study appears to be disregarded in the majority of the literature on VBACs.

The model generated in this study confirms the majority of the findings regarding factors associated with VBAC success. However, the association between VBAC success and the insurance variable, which was added in the sixth step, does not reflect expected results or findings in the literature. The odds ratio for this variable says that having a successful VBAC was 2.16-fold greater for a woman who had private insurance, than for a woman who had public insurance. This was unexpected given that midwives had the greatest rates of VBAC success, rather than physicians, and midwives were typically caring for patients with public insurance. However, this could be explained by the fact that women with private insurance may have been more capable of attempting VBAC given their coverage, while women with public insurance might have been advised to deliver by cesarean section for legal and malpractice reasons.

Typically, variables that are associated with decreased rates of VBAC success include labor induction, birth weight, and at times epidural use (Harper et al., 2008). This model, along with a variety of other models that have been proposed over the past two decades, confirms these findings (Srinivas et al., 2007 and Eden et al., 2010). Similarly, this model confirms that prior vaginal delivery and increased duration of the second stage of labor are

associated with increased rates of VBAC success (Harper et al., 2008 and Srinivas et al., 2007 and Eden et al., 2010).

Ultimately, this research illustrates a new finding: providers play a role in VBAC success. Patients that began their delivery with a nurse midwife had increased odds of having a successful VBAC (Table 1). The logistic regression identifies provider to be the most predictive variable in the model, as it was the first factor to be included in the forward stepwise regression. Additionally, the odds ratio for provider implies that the odds of having a successful VBAC are 3.7-fold greater for a woman delivering with a midwife (OR 0.27, 95% CI 0.17-0.44; $p < 0.01$).

This result supported the hypothesis that women with a midwife for a provider would have greater odds of having a successful VBAC than women delivering with a physician. Type of care varies depending on labor support, and so delivery outcome should too. In hospitals like MGH, physicians are generally only working 12-hour shifts, while midwives work 24-hour shifts. This allows midwives greater amounts of time to commit to their patients, and to see deliveries through. Additionally, physicians perform cesareans and other surgical procedures that midwives cannot. Ultimately, physicians tend to have less time per individual patient, while midwives are more capable of focusing on one patient at a time and can see a VBAC attempt through.

Given these simple differences in roles, variances in care and potential birth outcomes exist as well. A study was conducted that demonstrated longer durations of normal labor for patients in the care of obstetricians, and normal durations of labor for patients in the care of nurse midwives (Heres et al., 2000). The explanations of these results were that stress levels are associated with these different providers. Presumably, the longer duration of normal labor

was prolonged by an increased level of stress that was not found in patients delivering with midwives (Heres et al, 2000).

Essentially, type of care has been found to differ greatly between these two types of providers, and this new model now depicts how it relates to VBAC success. In order to identify whether or not this relationship between midwives and increased VBAC success might appear to exist elsewhere, more models must be created from similar data. However, a look into the statistics of VBAC success and midwifery care in other countries could also help to better understand what this association means.

Typically, publications from Europe describe the majority of women with a prior cesarean as attempting VBAC. In the United States, the VBAC attempt rate has been fluctuating around eight percent in recent years (Cox, 2011 and MacDorham et al., 2011). Contrastingly, the VBAC attempt rate has been consistently high in Europe, and ranges from 30 to 55% depending on the country (Case et al., 1971 and Selo-Ojeme et al., 2011). Of these attempts, the success rates range from 70-75%.

What is of great interest in these results is that unlike the U.S., Europe relies heavily on nurse midwives (Gregory, 2010). Not only does Europe tend to have greater amounts of midwifery care, but Europe also has greater rates of VBAC attempt and VBAC success. More research would have to be conducted in order to better understand whether or not provider is a predictive variable in determining VBAC success in Europe; however, for the sake of this study, this relationship is noteworthy.

Given the findings from this model, more research is needed to better understanding how labor support might affect VBAC success, and why this might be. The NIH has requested similar research: “the effects of medical training, hospital policy, and ethical and

legal concerns on the choice of delivery procedure are currently unexamined subjects deserving greater scrutiny by means of combination of epidemiological, economic, and social science methods” (NIH Consensus Statement, 1980). Essentially, physician and midwifery practice must be better understood in order to assess the ways in which labor support are associated with VBAC success.

Given that similar results have not yet been described in the literature about VBACs, provider care should begin to be included as a variable in the models that are being developed to predict VBAC success. Findings by investigators suggest that there may be promise in the development of models to predict ideal VBAC candidates or patients at increased risk for adverse events; perhaps these models could be made more accurate with labor support included as an explanatory variable (NIH Consensus Statement, 1980).

In 2013, models continue to be proposed, but not one has been integrated into standard obstetrical practice. Expectantly, by including labor support as a factor associated with VBAC success, creating an accurate predictive model may be increasingly probable. However, until a final model can correctly depict likelihood of delivering vaginally by trial of labor, patients need to be receiving all pertinent information in choosing whether or not to attempt VBAC.

Because of the complexity of these situations, the potential for biased recommendations, and the risks involved in TOLACs and cesareans, women should be fully informed of their options, and actively participate in the decision making process. Additionally, women with no pregnancy complications and with one previous (low-transverse incision) cesarean delivery should be counseled about VBAC and offered TOLAC

in all hospitals with the necessary equipment for cesarean delivery (ACOG Practice Bulletin, 2010).

Hopefully, if models can continue to be generated with an increased focus on labor support as a variable, and women can be counseled about vaginal birth after cesarean as a safe and alternative method to repeat cesarean delivery, then perhaps cesarean rates can eventually be reduced by widespread VBACs. In the meantime, the NIH or another appropriate Federal agency should create a website that will provide women with up-to-date information on the benefits and risks of all modes of delivery, including VBAC. This would allow women to be made aware of their options regardless of biased recommendations from providers, and ideally influence the national VBAC attempt rate and success rate.

Appendix:



MARIN GENERAL HOSPITAL
INSTITUTIONAL REVIEW BOARD

*CONTINUING REVIEW
EXPEDITED APPROVAL*

July 23, 2014

To: Lizellen La Follette, M.D.

The Marin General Hospital Institutional Review Board reviewed and approved your request to continue the following study and related documents for an additional year:

Study	The Effects of Epidural Analgesia on Birth Outcome in Vaginal Birth After Cesarean Patients: a Bivariate Logistic Regression
Document	◆ Continuing Review Application, signed 7/1/14 ◆ Protocol version 0414
Process	The expedited review is performed in accordance with the requirements set forth in 45 CFR 46.110 and 21 CFR 56.110, and Federal Register Expedited Review Category #5 – Research involving materials that have been collected or will be collected solely for nonresearch purposes.

The IRB review requirement of quarterly increments has been waived; and the Study Approval Period is **July 23, 2014 to April 22, 2015**. If the project is to continue, it must be reviewed prior to the expiration date. If the IRB has not reviewed and approved the continuation of this study by the expiration date, **all research activities must stop** (unless the IRB finds that it is in the best interest of the subject to continue participation).

CONDITIONS: Failure to adhere to these conditions will result in withdrawal of approval and suspension of research.

- ◆ Any modification to the research plan, consent document, recruitment materials, or other study-related documents must receive prior approval.
- ◆ Emergency changes to protect the subject's safety shall be reported to the IRB immediately.
- ◆ All Serious Adverse Events must be reported to the IRB in writing within five (5) days of knowledge of the incident. Any participant death, regardless of the status of study relationship, must be reported.
- ◆ All study deviations must be reported to the IRB with five (5) working days of knowledge of the event.

NOTICE:

The Marin General Hospital District does not indemnify any investigator in legal actions arising from research activities involving humans even though the activities had current IRB approval.

Thank you for your cooperation in our shared responsibility in protecting the rights and welfare of human participants in research.

Sincerely,

Karin Ludwig
MGH IRB Member/Specialist

250 Bon Air Road, Greenbrae, CA 94904

(415) 925-7965

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