OBSTETRICS

Third- and fourth-degree perineal lacerations: defining high-risk clinical clusters

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OBJECTIVE: Statistical methods that measure the independent contribution of individual factors for third-/fourth-degree perineal laceration (TFPL) fall short when the clinician is faced with a combination of factors. Our objective was to demonstrate how a statistical technique, classification and regression trees (CART), can identify high-risk clinical clusters.

STUDY DESIGN: We performed multivariable logistic regression, and CART analysis on data from 25,150 term vaginal births.

RESULTS: Multivariable analyses found strong associations with the use of episiotomy, forceps, vacuum, nulliparity, and birthweight. CART ranked episiotomy, operative delivery, and birthweight as the more discriminating factors and defined distinct risk groups with TFPL rates that ranged from 0-100%. For example, without episiotomy, the rate of TFPL was 2.2%. In the presence of an episiotomy, forceps, and birthweight of >3634 g, the rate of TFPL was 68.9%.

CONCLUSION: CART showed that certain combinations held low risk, where as other combinations carried extreme risk, which clarified how choices on delivery options can markedly affect the rate of TFPL for specific mothers.

Key words: classification and regression, episiotomy, perineal laceration

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A considerable challenge that faces all obstetricians involves distilling the myriad of published reports to choose the best tests and treatments for our patients. In addition to an ever-growing number of randomized clinical trials to consider, the increasing prevalence of high-quality observational studies and abundant metaanalyses add to the clinician's task.[1,2]

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★ EDITORS' CHOICE ★

When the conditions of a certain study are similar to our clinical circumstances, we might expect to obtain similar results over the course of many patients. Although this is important from an overall healthcare perspective, clinicians are often left with 2 problems. Sometimes the particular patient before us is not similar to the average patient and generalizing the study results to her particular situation is unsatisfactory. Furthermore, an odds ratio (OR) for one factor vs another does not communicate the prime piece of information for which our patient asks, namely, what is the actual rate of complication that she may expect to experience. The objective of this report was to demonstrate results from a statistical method that can help with these 2 problems with the use of the well-understood issue of third- and fourth-degree perineal laceration (TFPL).

Many years ago, Koss and Feinstein[3] noted that clinicians in practice often grouped patients with certain signs and symptoms and made decisions based on these groups, rather than relying solely on arithmetic scores representing the whole population. They were among the first in clinical epidemiology to use classification and regression trees (CARTs) to consolidate similar subgroups of patients and provide their specific risks.[3-5] Since then, CARTs have been used extensively in this area.[6-8] It should be noted that the acronym *CART* is used in several contexts with different meanings: sometimes as an abbreviation for the seminal book by Breiman et al,[9] and other times as the name of proprietary software that is based on the same book. We use CART here as an abbreviation for the general tree-growing method.

CARTs, which also are described as recursive partitioning methods, are statistical methods that examine a dataset to find the best variables and associated cutoff points to group the data into those with and without the outcome in question. Factors that are both frequent and discriminating rise in importance and result in groupings that bear resemblance and relevance to everyday clinical practice. From all variables under consideration CART selects the single factor that best separates the groups with and without the problem to form the first

TABLE 1
Characteristics of the study group

Variable	Partially complete dataset[a]	Records with data present, n (%)	Entirely complete dataset[b]	*P* value
Maternal age, y[c]	26.6 ± 6.2	14,426	26.3 ± 6.3	< .001
Maternal height, cm[c]	164.0 ± 7.4	7449	164.0 ± 7.4	.96
Body mass index, kg/m[2c]	31.2 ± 6.2	7203	31.0 ± 6.1	.09
Birthweight, g[c]	3435 ± 348	14,115	3300 ± 431	<. 001
Second stage, min[c]	62.0 ± 86.3	4423	63.2 ± 70	.382
Nulliparity, n (%)	4906 (33.9)	14,458	5127 (47.9)	< .001
Maternal diabetes mellitus or hypertension or thyroid disease, n (%)	1475 (10.2)	14,458	1217 (11.4)	.003
Labor induction, n (%)	5531 (38.3)	14,458	4377 (40.9)	< .001
Labor augmentation with oxytocin, n (%)	7031 (48.6)	14,458	5700 (53.3)	< .001
Epidural, n (%)	8605 (59.5)	14,458	8165 (76.4)	< .001
Forceps, n (%)	73 (0.5)	14,458	79 (0.7)	.020
Vacuum, n (%)	1203 (8.3)	14,458	1043 (9.8)	< .001
Midwife delivered, n (%)	325 (2.3)	14,302	314 (2.9)	.001
Episiotomy, n (%)	1269 (8.8)	14,458	1251 (11.7)	< .001
Fetal heart rate described as "concerning", n (%)	1736 (12)	14,458	1149 (10.7)	.002
Third-/fourth-degree perineal laceration, n (%)	411 (2.8)	14,458	471 (4.4)	< .001

[a] n = 14,458; [b] n = 10,692; [c] Data are given as mean ± SD.

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branch point or node. Once the first node has been formed, the same procedure is applied to each "child" node, which finds the next most discriminating factor, hence the term *recursive*. At each junction, CART also searches for the optimal cutoff point if that variable is continuous. Splitting stops when the statistical process determines no further discriminating advantage with any of the remaining factors. Contrary to multivariable logistic regression analysis, where the goal is to isolate the independent effect of specific factors, in CART there is no attempt to identify independence, rather the goal is to define and rank the most predictive clinical groupings.

CART applications are developing in a wide range of clinical situations, such as the prediction of outcomes with obesity, a diagnosis of Alzheimer's disease, the prediction of cardiovascular disease, and the identification of subgroups with different risks in epidemiologic investigations.[10-17] Examples of applications in obstetrics include assessment of electronic fetal monitoring tracings, prediction of outcomes of low birthweight babies, or antenatal risk assessment.[18-22]

In this study, we have examined a well-understood clinical problem, TFPL, first with the use of a standard multivariable logistic regression analysis to assess independent risk factors and then with the use of CART to determine the most discriminating clinical risk groups and their associated risks.

MATERIALS AND METHODS

This project was deemed to qualify for exempt status by the MedStar Research Institute institutional review board. The retrospective analysis was performed on data from women with vaginal births and live singleton, cephalic-presenting babies at a gestational age of ≥37 weeks and delivering between January 1, 2004, and December 31, 2008, at 1 of 4 acute care, teaching and research hospitals of Medstar Health System, which is a not-for-profit regional health care system. The hospitals with obstetrics services are in the Baltimore-Washington, DC corridor, and consist of 1 university hospital and 2 academic community teaching hospitals with level 3B or C neonatal intensive care units, and 1 academic community teaching hospital with a level 2 neonatal intensive care unit. Three of the 4 hospitals serve as regional referral centers.

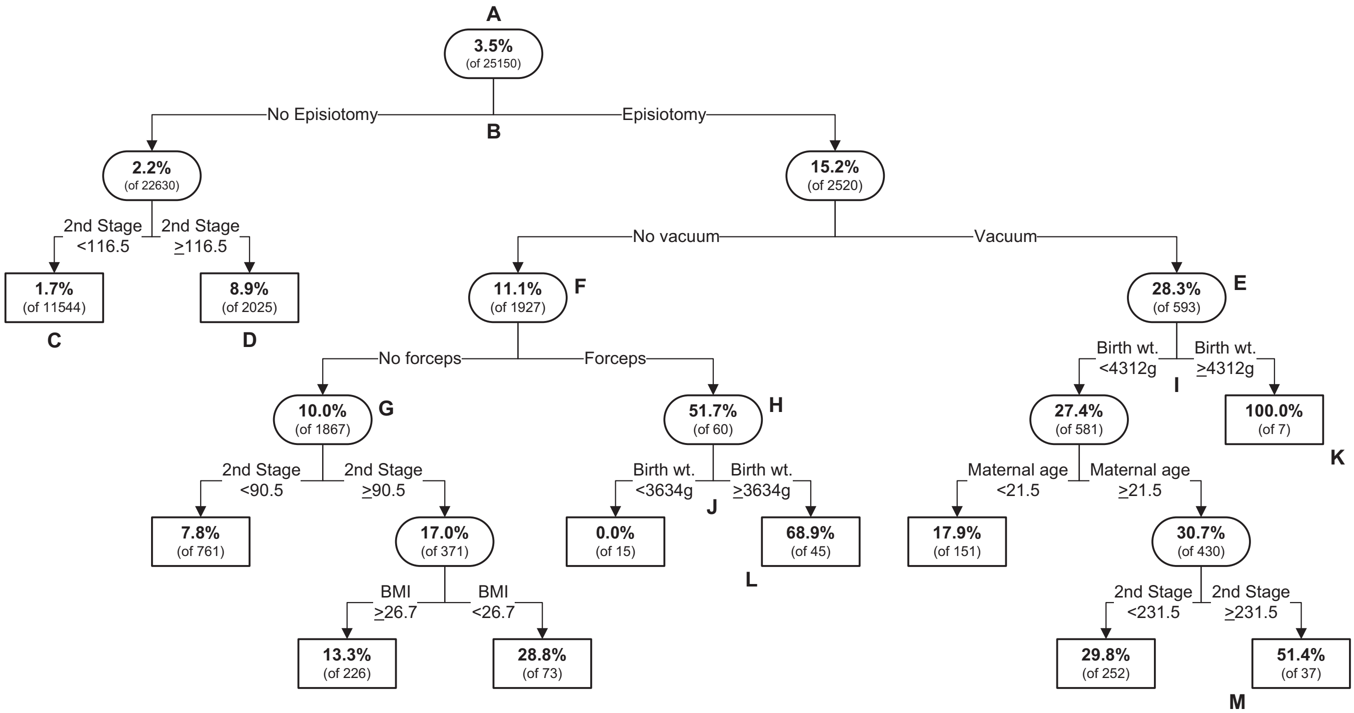
Data were extracted from 25,150 records with PeriBirth software (PeriGen, Princeton, NJ), an intelligent electronic medical record and decision support application introduced during this period. We selected 16 study variables that were based on risk factors described in the literature (Table 1).[23,24]

The multivariate analysis was confined to the 10,692 records in which study variables were 100% complete in each record.

Although the other 14,458 records were missing data in ≥1 fields, they had a high degree of completeness for all but 3 variables. body mass index, height, and second-stage duration were available in 31-52% of these records. Birth-

FIGURE

CART analysis shows the hierarchy of factors, the percentage of perineal laceration, and number of records at each node



BMI, body mass index; *CART*, classification and regression tree; *wt*, weight.

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weight, maternal age, and midwifery/physician presence at delivery were complete in 98%. The remaining 10 variables were complete in 100% of these partial records.

CARTs could use some records with partial data because these records contained data on most variables. In addition, CART uses a technique that is based on local multiple imputations to handle missing data and to reduce bias. The number of records that contributed at each CART node is indicated within parentheses in the Figure. The characteristics of the study group with respect to the 16 variables are summarized in Table 1.

We subjected both the total 25,150 dataset that included partially incomplete records (14,458) and the records with complete data (10,692) to univariate analysis for the 16 variables that are shown in Table 2. The variable "hospital" was included to provide an opportunity to see whether there were additional unmeasured factors within each institution that were associated with TFPL.

The multivariable analysis was conducted with only the complete dataset. Many of the 16 variables are interrelated; to minimize any bias by excluding a factor, we included all 16 variables in the multivariable analysis.

All data analyses were performed using the R Software Package (version 2.10.1; The R Foundation for Statistical Computing). The CART analysis, in particular, relied on the R package "rpart"; this is based on the work by Breiman et al[9] and obtains a tree by pruning a large tree according to the 1-SE rule.

RESULTS

Univariate analysis of both the total dataset and complete datasets showed very similar relative risks (Table 2). All relative risks from the total dataset fell with 95% confidence interval of the relative risks that were calculated in the complete dataset except for second-stage duration, where the difference was small and in the same positive direction.

Table 3 provides a summary of the results of the multivariate analysis and shows the 10 factors that reached statistical significance for independent association with TFPL. Among the potentially modifiable variables, forceps lead the list, followed by use of episiotomy and vacuum.

Of note, the hospital where the birth occurred no longer showed any association with TFPL. That is, once the maternal, fetal, and clinician variables were considered, the hospital of birth had no effect on the rate of TFPL.

We did not use distinct predetermined cutoffs for the continuous variables. In this method, the OR for TFPL between 2 specific levels of a continuous variable was given by the OR for that variable raised to the power of the difference, that is OR $^{\Delta}$, where Δ was the difference between the 2 specific levels. For example, the OR for 2 situations in which 1 baby weighs 500 g more than another is given by OR for birthweight: 1.002, raised to 500, or 1.002^{500} or 2.72.

TABLE 2
Variables that were examined by univariate analysis, the relative risk ratios, and 95% CI for third- /fourth-degree perineal laceration

	Univariate analysis relative risk (95% CI)	
Variable	25,150 subjects, including records with incomplete data	10,692 subjects, including only records with complete data
Episiotomy	7.91 (6.87–9.10)[a]	7.16 (6.91–8.69)[a]
Maternal age	1.028 (1.017–1.039)[a]	1.035 (1.02–1.05)[a]
Maternal height	0.983 (0.973–0.993)[a]	0.987 (0.975–0.998)[a]
Body mass index	0.965 (0.951–0.979)[a]	0.971 (0.954–0.987)[a]
Birthweight	1.001 (1.0007–1.00103)[a]	1.001 (1.0007–1.0011)[a]
Second stage	1.006 (1.0055–1.007)[a]	1.008 (1.007–1.009)[a]
Labor augmentation with oxytocin	1.40 (1.23–1.61)[a]	1.19 (0.99–1.44)
Labor induction	1.07 (0.94–1.23)	0.99 (0.82–1.19)
Epidural	1.27 (1.09–1.47)[a]	1.13 (0.90–1.41)
Midwife delivered	0.042 (0.0059–0.298)[a]	0 (0–inf)
Maternal diabetes mellitus or hypertension or thyroid disease	1.13 (0.92–1.39)	1.21 (0.92–1.59)
Nulliparity	6.11 (5.18–7.21)[a]	5.84 (5.57–7.47)[a]
Fetal heart rate described as “concerning”	0.92 (0.74–1.14)	0.92 (0.67–1.25)
Forceps	17.07 (12.19–23.91)[a]	15.78 (9.97–24.98)[a]
Vacuum	6.25 (5.50–7.23)[a]	5.99 (4.89–7.31)[a]
Hospital		
2 vs 1	2.82 (2.31–3.43)[a]	3.11 (2.35–4.11)[a]
3 vs 1	1.40 (1.18–1.67)[a]	1.57 (1.22–2.01)[a]
4 vs 1	1.84 (1.52–2.23)[a]	1.90 (1.41–2.57)[a]

CI, confidence interval.

[a] Statistical significance, $P < .05$.

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The Figure shows the results from the CART analysis. The following descriptions highlight certain positions on these branches to illustrate key aspects of CART.

The tree begins at position A; the rate of TFPL was 3.5% in the entire study population.

Position B shows that the use of episiotomy was the single most discriminating factor. In the absence of episiotomy, the rate of TFPL was 2.2 %; whereas in the presence of an episiotomy, the rate rose to 15.2%. It is important to point out that the use of episiotomy reflects a host of conditions and preferences that are known to the delivering clinician and include some conditions and preferences that are not covered explicitly in this analysis. For example, the state of the fetal heart rate at that moment and nulliparity are 2 of many considerations that could influence clinicians to do an episiotomy. The CART technique was not given information about the current fetal heart rate, but it did have access to parity information. It is certainly plausible that both may have influenced the clinical decision to do an episiotomy. However, with respect to the task of most efficiently partitioning the study group into those with and without TFPL based on the 16 selected variables, the presence or absence of episiotomy was the most discriminating factor. In the absence of an episiotomy, the only other factor that provided additional discrimination with respect to TFPL was the duration of second stage (positions C and D).

Following down the branch “with episiotomy,” the next most discriminating factor was the use of vacuum, which was associated with a 28.3% rate of TFPL (position E), compared with 11.1% when delivery occurred without vacuum (position F). The effect seen with use of forceps is demonstrated at (positions G and H).

The variables birthweight and second-stage duration appear in multiple branches, but with different thresholds. At each junction, CART not only searches for the next most discriminating variable but also for its optimal threshold if that variable is continuous. For example, the 4312-g threshold for birthweight with use of vacuum (position I) is much higher than the 3634 g threshold that is seen with the use of forceps (position J). These cutoff points must be viewed with reason by clinicians. Clearly, being close to the threshold is not the same as being far from it.

Some variables (nulliparity and maternal height) that have been found to be significant in the multiple regression analysis were not identified to form nodes with the tree approach. As explained previously the role of these factors may be buried within others.

Three terminal nodes (positions K, L, and M), also named *leaves* of the tree, show extreme rates of TFPL. Position K, which is defined by the use of vacuum with an episiotomy and a baby who weighs >4312 g, occurs rarely; however, when it does happen, all mothers experience a TFPL. TFPL rates of 68.9% (position L) and 51.3% (position M) leaves are also excessive.

Defining leaves and their associated complication rates demonstrates how CART can provide useful information to help choose if and when to do an episiotomy or use vacuum or forceps. For instance, a clinician might notice that the leaf that is defined by a second stage of >116.5 minutes without an episiotomy has a rate of TFPL of 8.9%. It may be tempting to shorten that second stage with an episiotomy. This would result in a lower rate of TFPL only if the patient with an episiotomy ends up in 2 other leaves, a spontaneous delivery with a second stage of <90.5 minutes where the rate of TFPL was 7.8%, or that very rare leaf of 15 mothers for whom delivery occurs with forceps in a baby who weighs <3634 g. All other leaves in the episiotomy branch have higher rates of TFPL.

TABLE 3

Adjusted odds ratios and the 95% CI from the multivariable analysis for factors that attained statistical significance

Variable (number with missing data)	Multivariable analysis adjusted odds ratio (95% CI) for 10,692 subjects that included only records with complete data[a]
Forceps	10.94 (6.41–18.69)
Nulliparity	5.11 (3.85–6.79)
Episiotomy	3.73 (3.01–4.62)
Vacuum	3.32 (2.63–4.19)
Maternal age	1.06 (1.04–1.07)
Second stage	1.003 (1.002–1.004)
Birthweight	1.002 (1.001–1.0023)
Body mass index	0.97 (0.95–0.99)
Maternal height	0.96 (0.95–0.97)
Labor augmentation with oxytocin	0.74 (0.60–0.91)

CI, confidence interval.

[a] Statistical significance, $P < .05$.

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COMMENT

This report demonstrates how 2 statistical methods identify the independent risk factors and combinations of factors that are especially hazardous for TFPL. Consistent with past reports, multivariable analyses indicated strong and independent association with forceps, nulliparity, episiotomy, vacuum, birthweight, and lesser contributions of 5 other factors.[23-30] This type of analysis is important because clinicians must know which variables are true risk factors, as opposed to those factors the apparent effect of which is actually related to another associated condition.

CART selected episiotomy and operative delivery techniques to define its top branches and produced estimates of risk that depended on the specific combinations with other factors. Moreover, it provided some guidance about thresholds for factors that span a continuum. Its results were more nuanced and demonstrated that it was not the mere presence or absence of a risk factor that defined outcome. For example, it identified a relatively rare situation in which even the presence of 2 major independent risk factors (the use of forceps and episiotomy) was associated with no TFPL and other situations in which the rate of TFPL was very excessive. Even if all 89 mothers who comprised the high-risk leaves (positions K, L, and M) with their extreme rates of TFPL underwent cesarean delivery, there would be a negligible impact on the cesarean delivery rate among the 25,150 vaginal births.

CART analysis is valuable because its risk leaves reflect clinical reality in situations in which the decision to perform episiotomy or to use operative delivery techniques often is based on multiple interacting factors (such as a long second stage with a suspected large baby in an older mother with a high body mass index); it is useful to know which constellations of factors portend extreme risk. Furthermore, the tree demonstrates how risks could change depending on the actions that are taken. For example, shortening the second stage with episiotomy would cause another branch to be traversed, with its own risks.

Generalization of these study results to another clinical practice would be appropriate if the characteristics of the pregnancies and clinicians were to match those described in this study. We were unable to study all potential factors that are associated with TFPL, such as the position of the head at the time of delivery. More variables would require an even larger database to measure their effects adequately. Nevertheless, with 25,150 records and 16 variables, clear patterns emerged in this contemporary multicenter study group.

Missing data presents a problem for all statistical methods. Overall, 91% of all data fields were complete, and most of the missing data was confined to 3 parameters. Very similar relative risk calculations that were based on the complete data set vs the total dataset that included incomplete records provided reassurance that incomplete data did not introduce major bias.

Medical decisions have always involved weighing factors, assessing options, and comparing risks to benefits. Clinicians call this experience our clinical judgment. Other clinicians might view this process more mathematically and see it as an exercise in probability assessment. Patient safety professionals take yet another perspective by searching to identify the real-life constellations of factors that consistently herald adverse outcome. This article demonstrates how 2 statistical methods help to sort out the independent risk factors and combinations of factors that are especially hazardous.

Although we have focused on a specific and common obstetric issue, one can imagine easily how these statistical techniques could be applied to other problems, where the determinants of outcome may include system factors (such as levels of staffing) or clinical actions (such as delayed intervention) and standard health parameters. One challenge for medical informatics is to distill the mass of detailed information that is gained from hundreds of thousands of births and to identify these "toxic" constellations. Modern intelligent electronic medical records are then well positioned to search for these situations going forward and to warn clinicians in time so that they can change pathways and minimize untoward consequences. ■

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