Risk Factors for Anal Sphincter Tear During Vaginal Delivery

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OBJECTIVE: To identify risk factors associated with anal sphincter tear during vaginal delivery and to identify opportunities for preventing this cause of fecal incontinence in young women.

METHODS: We used baseline data from two groups of women who participated in the Childbirth and Pelvic Symptoms (CAPS) study: those women who delivered vaginally, either those with or those without a recognized anal sphincter tear. Univariable analyses of demographic and obstetric information identified factors associated with anal sphincter tear. We calculated odds ratios (ORs) for these factors alone and in combination, adjusted for maternal age, race, and gestational age.

RESULTS: We included data from 797 primaparous women: 407 with a recognized anal sphincter tear and 390 without. Based on univariable analysis, a woman with a sphincter tear was more likely to be older, to be white, to have longer gestation or prolonged second stage of labor, to have a larger infant (birth weight/head circumference), or an infant who was in occiput posterior position, or to have an episiotomy or operative delivery. Logistic regression found forceps delivery (OR 13.6, 95%)

confidence interval [CI] 7.9–23.2) and episiotomy (OR 5.3, 95% CI 3.8–7.6) were strongly associated with a sphincter tear. The combination of forceps and episiotomy was markedly associated with sphincter tear (OR 25.3, 95% CI 10.2–62.6). The addition of epidural anesthesia to forceps and episiotomy increased the OR to 41.0 (95% CI 13.5–124.4).

CONCLUSION: Our results highlight the existence of modifiable obstetric interventions that increase the risk of anal sphincter tear during vaginal delivery. Our results may be used by clinicians and women to help inform their decisions regarding obstetric interventions.

(Obstet Gynecol 2007;109:29-34)

LEVEL OF EVIDENCE: II

n healthy young women, anal sphincter tear at vaginal delivery is the most common precursor of fecal incontinence^{1,2} and may also be a marker for the development of subsequent pelvic dysfunction. Anal sphincter tears occur in 2–19% of vaginal deliveries in the United States.^{3–5} Factors associated with anal sphincter tear include nulliparity,^{3,5–8} midline episiotomy,^{3–5,7,8} and operative vaginal delivery.^{3–9} Three to 6 months after obstetric anal sphincter tear, 29–53% of women report incontinence of flatus, and 5–10% report incontinence of stool.^{3,10–13} Long-term compromise of fecal continence has also been confirmed.¹⁴

Many studies of the association between sphincter tears and subsequent fecal incontinence symptoms have been conducted in Europe in centers where mediolateral episiotomy is commonly used. Sphincter tears occurring in conjunction with mediolateral episiotomy are likely to differ anatomically and perhaps functionally from those with midline episiotomy. Because midline episiotomy is the predominant practice in the United States, we cannot apply study findings from Europe to American women.

The Childbirth and Pelvic Symptoms (CAPS) study was a prospective cohort study performed by the Pelvic Floor Disorders Network (a cooperative



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Supported by grants from the National Institute of Child Health and Human Development (U01 HD41249, U10 HD41268, U10 HD41248, U10 HD41250, U10 HD41261, U10 HD41263, U10 HD41269, and U10 HD41267) and the National Institute of Diabetes, Digestive and Kidney Diseases (K24 DK068389).

The authors thank Dr. Robert Park, the Chair of the Pelvic Floor Disorders Network Steering Committee, for his advisory role in the development of the project.

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agreement research network sponsored by the National Institute of Child Health and Human Development) that examined the relationship between anal sphincter tears and pelvic symptoms after delivery in primiparous American women. The objective of this analysis was to identify risk factors associated with anal sphincter tear in women enrolled in the Childbirth and Pelvic Symptoms study who delivered vaginally. Given the potentially devastating and lifelong effects of anal sphincter tear at vaginal delivery, knowledge of modifiable risk factors may provide an opportunity to reduce the likelihood of fecal incontinence in otherwise healthy young women.

PARTICIPANTS AND METHODS

This analysis used baseline data from the Childbirth and Pelvic Symptoms study. The design and methods of this study have been reported in detail¹⁵ and are briefly summarized here. Each institution in the Pelvic Floor Disorders Network, including the data coordinating center, received institutional review board approval for this study, and all women provided written informed consent. The subjects in the Childbirth and Pelvic Symptoms study included three groups of primiparous women in hospital after a term, singleton delivery. Two groups of subjects delivered vaginally, either with or without clinical evidence of anal sphincter tear (sphincter tear and vaginal control groups, respectively). The third group delivered by cesarean without labor (cesarean control group). Because of the focus of this analysis, data from the cesarean group will not be presented. The first cohort included women with anal sphincter tear that was clinically recognized (ie, third- or fourth-degree perineal tear) and repaired at delivery (Sphincter Tear group). The second cohort was a control group that included women who delivered vaginally *without* a clinically recognized anal sphincter tear (Vaginal Control group). Research coordinators reviewed delivery logs daily to identify all potential participants with a sphincter tear or used an alternate method approved by the local ethics review board. An eligible woman *with* an anal sphincter tear (index case) was approached for enrollment. If she declined, the next eligible woman with a sphincter tear was approached until a woman in this cohort was enrolled. Then, the next woman who delivered *without* an anal sphincter tear (Vaginal Control) was identified and approached for study participation.

While in the hospital, the clinical site research coordinator interviewed consenting participants about ethnicity, marital or living status, and education level and abstracted demographic and clinical information from their hospital charts. Exclusion criteria included a history of inflammatory bowel disease, prepregnancy anal-rectal surgery, prepregnancy fecal incontinence, or presence of a neurological condition that would predispose to urinary or fecal incontinence.

To identify factors associated with anal sphincter tear, variables were compared with the outcome (sphincter tear) using Fisher exact test or χ^2 test for categorical variables or two-sample t tests for continuous variables. In addition to examining certain variables as continuous, cutoffs of clinical importance were used to create dichotomous variables. Pregnancy was defined as prolonged when greater than 41 weeks; macrosomia when the infant birth weight greater than 4,000 g; and prolonged second stage of labor when longer than 2 hours (even when an epidural was in place). After identifying significant variables, we calculated odds ratios (ORs) with 95% confidence intervals (CIs) adjusted for maternal age, race, and gestational age. We were particularly interested in six factors that would be known to the clinician before delivery and that could be considered modifiable (or actions affecting delivery could be modified by taking this variable into account): forceps, vacuum, episiotomy, prolonged second stage of labor, fetal position occiput posterior at the time of crowning, and epidural use. These variables were analyzed alone and in different combinations that would be clinically relevant. To determine potential combinations, models were built in a stepwise manner where multiple options were tested at each level to determine the best subset(s) with a specific number of independent variables. In the results we present, only models that improved the odds ratio were associated with a sphincter tear.

Results are presented as mean±standard deviation for continuous variables or as percentages for categorical variables. All tests were two-tailed and, because of the number of comparisons, were considered statistically significant at the 1% level. With the number of subjects provided by the Childbirth and Pelvic Symptoms study, we had 80% power to identify the following differences between the two study groups: a change of 0.2 standard deviations when the outcome measure was continuous; a change from 50% to 62% or from 20% to 29% or from 10% to 16% when the outcome measure was dichotomous. These percentages are a guide to how large the difference would have to be between having the factor in the tear group and having the factor in the control group in order for there to be 80% power to obtain significance.

OBSTETRICS & GYNECOLOGY



RESULTS

The report includes data from 797 primiparous women who delivered vaginally, 407 with recognized anal sphincter tear and 390 without. Table 1 depicts the maternal, infant, and delivery characteristics of women with sphincter tears compared with the vaginal control group. Women with anal sphincter tears were somewhat older and more likely to be of white race. Deliveries were more likely to result in anal sphincter tear when they occurred at later gestational age or with infants of heavier birth weight, larger head circumference, or in occiput posterior position. An anal sphincter tear was more likely with prolonged second stage of labor, episiotomy, or operative delivery. Although epidural was not associated with anal sphincter tear by univariable analyses (Table 1), it was included in regression models as a clinically relevant variable. As can be seen in Table 2, epidural was significantly associated with anal sphincter tear when the analysis was adjusted for maternal age, race, and gestational age.

Table 2 also demonstrates the effect of combining different variables of clinical relevance (except that Table 2 does not include combinations that did not increase the OR from simpler analyses). Forceps delivery and episiotomy, examined singly in adjusted analyses, were strongly associated with anal sphincter tear, with OR 13.6 and 5.3, respectively. When analyzed together (ie, women who had anal sphincter tear delivered by forceps with episiotomy compared with women who did not have intervention by vacuum or forceps, an episiotomy, or an occiput posterior positioning), the association was even stronger, with OR 25.3. Adding a third variable, prolonged second stage of labor, did not increase the OR further (OR 24.4), but adding epidural to forceps and episiotomy increased the OR to 41.0. Similarly, adding

 Table 1. Maternal, Infant, and Delivery Characteristics of 797 Primiparous Women With and Without Anal Sphincter Tear After Vaginal Delivery

	Sphincter Tear	Vaginal Control	P*	
Characteristic	(n=407)	(n=390)		
Maternal				
Age (y)	27.6 ± 6.0	25.8 ± 5.7	<.001	
Race				
White	298 (73)	258 (66)	.002†	
Black	62 (15)	95 (24)		
Other	47 (12)	37 (9)		
Body mass index (kg/m ²)				
Prepregnancy	24.6 ± 5.6	25.3 ± 5.7	.10	
Predelivery	31.2 ± 6.2	31.8 ± 6.5	.11	
Diabetes	5(1)	0	.06	
Infant				
Gestational age at delivery (wk)	39.9 ± 1.1	39.6 ± 1.1	.003	
Prolonged gestation [‡]	48 (12)	27 (7)	.021	
Birth weight (g)	$3,560 \pm 444$	$3,358 \pm 417$	<.001	
Macrosomia [§]	69 (17)	25 (6)	<.001	
Head circumference (cm)	34.6 ± 1.6	34.0 ± 1.8	<.001	
Labor and delivery				
Second-stage labor (h)	1.9 ± 1.4	1.4 ± 1.1	<.001	
Prolonged second stage	138 (34)	66 (17)	<.001	
Fetal head position OP	52 (13)	21 (5)	<.001	
Epidural analgesia	366 (90)	336 (86)	.10	
Episiotomy	204 (50)	98 (26)	<.001	
Forceps	122 (30)	25(6)	<.001	
Vacuum	101 (25)	38 (10)	<.001	
Either forceps or vacuum	210 (52)	62 (16)	<.001	
Both forceps and vacuum	13 (3)	1(0.3)	.002	

OP, occiput posterior.

Data are expressed as mean±standard deviation or n (%).

* Probability was assessed with the Fisher exact test for categorical variables; a two-sample *t* test was used for continuous variables.

[†] Fisher exact test comparing white to black race among women with and without sphincter tears.

* Prolonged gestation is defined as greater than 41 weeks.

[§] Macrosomia is defined as greater than 4,000 g.

Prolonged second stage is defined as longer than 2 hours.

¹ Midline: 188 of 204 (92%) for sphincter tear group; 87 of 98 (89%) for vaginal control group; denominator is those who had an episiotomy.

VOL. 109, NO. 1, JANUARY 2007

FitzGerald et al Risk Factors for Anal Sphincter Tear 31



Characteristic	Number With Factor in Sphincter Tear Group	Number With Factor in Vaginal Control Group	Estimated OR for Factor Being Related to Tear	95% Lower Confidence Limit for OR	95% Upper Confidence Limit for OR
No vacuum, forceps, episiotomy or OP (reference					
group)	91	235	1.0		
Forceps	122	25	13.6	7.9	23.2
Fetal position OP	52	21	7.0	3.8	12.6
Vacuum	101	38	6.3	4.0	10.1
Prolonged second stage	138	66	5.6	3.6	8.6
Episiotomy	220	103	5.3	3.8	7.6
Epidural	366	336	3.2	1.6	6.2
Forceps + episiotomy	63	6	25.3	10.2	62.6
Prolonged second stage + forceps + episiotomy	32	3	24.4	6.9	86.5
Epidural + forceps + episiotomy	61	4	41.0	13.5	124.4
Prolonged second stage + epidural + forceps					
+ episiotomy	32	2	40.6	8.6	191.8
OP + forceps	26	3	21.6	6.2	75.6
OP + vacuum	15	4	9.7	3.0	30.8
OP + episiotomy	33	5	15.9	5.8	43.2
OP + episiotomy + forceps	18	1	33.8	4.8	239.5
OP + episiotomy + epidural + forceps	17	0	∞	_	-

Table 2.	Multivariable	Analysis With	Anal Sphir	ncter Tear a	s Primary	Outcome,	Controlling for	or Maternal
	Age, Race, an	d Gestational	Age		,		0	

OR, odds ratio; OP, occiput posterior

prolonged second stage of labor as a fourth variable did not increase the OR further (OR 40.6).

Fetal occiput posterior position alone and in combination with some other factors was associated with a greater likelihood of anal sphincter tear. Of interest, occiput posterior position with forceps had an increased OR (21.6) over either factor singly (7.0 and 13.6, respectively), whereas occiput posterior position with vacuum had a somewhat lower OR (9.7). The combination of occiput posterior position with forceps and episiotomy yielded an even higher OR (33.8).

DISCUSSION

Several studies have documented the relatively poor anatomic and functional outcomes after primary repair of anal sphincter tears at delivery, with persistent anal sphincter defects well documented on ultrasonic imaging, even after apparently successful primary repair at the time of delivery. Even when the repaired sphincter appears intact, symptoms of anorectal dysfunction can be present.^{2,18} Moreover, the long-term success of subsequent anal sphincteroplasty for the treatment of fecal incontinence is discouraging, with fecal continence rates of less than 20% after 5 or more years.¹⁹ Indeed, it appears that anal sphincter function is never entirely restored by primary repair of anal sphincter tear at delivery, highlighting the importance of preventing the injury.

The findings of this analysis highlight the existence of potentially modifiable obstetric interventions that increase the occurrence of anal sphincter tear at vaginal delivery. We identified six variables known to the clinician before delivery that could be used in decision making to potentially decrease anal sphincter damage: forceps, fetal position occiput posterior, vacuum, prolonged second stage of labor, episiotomy, and epidural use. Analyzing combinations of these factors identified only a few patterns where anal sphincter tear was substantially more likely than when considering these factors singly. When clinicians recognize the potential confluence of these factors-for example, in a primiparous woman with the fetus in occiput posterior position and outlet dystocia in the second stage of labor, such that operative delivery (vaginal or abdominal) may be indicated-it seems prudent to consider the increased risk of anal sphincter tear and discuss this possibility with the patient as an outcome of attempted operative vaginal delivery.

Conservative use of episiotomy seems advisable given the preponderance of evidence, both in this study and others, to support its association with anal sphincter tear and its potentially devastating longterm sequelae.^{3–5,7–9,16} Although trials have been conducted comparing restricted with liberal use of episiotomy, all trials except one were performed in regions where mediolateral episiotomy is the predominant obstetric practice. Randomized trials comparing

OBSTETRICS & GYNECOLOGY



mediolateral and midline episiotomy have yet to be performed, although this seems like critical missing information needed to guide clinical decisions. Operative vaginal delivery, both by forceps and by vacuum, has been consistently identified as a risk factor for anal sphincter tear,^{3,5} with forceps-assisted vaginal deliveries associated with a greater risk for anal sphincter tear than vacuum delivery.^{2,17} Our analysis adds to this literature in its quantification of the odds of sphincter tear when there is a confluence of several risk factors.

Although the use of routine episiotomy²⁰ and the choice of forceps for operative vaginal delivery^{21,22} have decreased, they have not disappeared. There is likely to always be some justification for the use of forceps and episiotomy in the hands of the experienced obstetrician, who must balance the risks to mother and baby at the time of delivery–ie, fetal indications for operative vaginal delivery will always exist. Counseling patients about the risk of anal sphincter tear with interventions in the second stage of labor seems appropriate before undertaking these interventions. Because discussion of interventions can be difficult or impossible during labor, such counseling may be more properly conducted during prenatal visits.

Our results can be used by clinicians and women to help inform their decisions at the time of prenatal visits and may have some relevance to decision making during labor and delivery. However, our results cannot be used to fully inform intrapartum decisions, such as whether or not to perform episiotomy or operative vaginal delivery because critically important factors, including fetal well-being and maternal status, were not considered. Finally, we cannot say whether avoidance of episiotomies and operative vaginal deliveries would have prevented anal sphincter tear in any given subject.

Strengths of our study include a large sample size across multiple centers that include both academic and private practitioners from across the country. Black women were well represented in this study although women of Hispanic ethnicity were underrepresented. Our study population was also limited to primiparous women, and studies that have included both primiparous and multiparous women uniformly identify primiparity as a strong risk factor for anal sphincter tear. However, that information is not particularly useful in clinical decision making because primiparity is not modifiable. It seems more useful from a clinical standpoint to consider the risks of anal sphincter tear for primiparous and multiparous women separately and to inform patients accordingly. Given the significant immediate and long-term morbidity associated with perineal injury at vaginal delivery, future efforts will need to expand to identify factors that can be used to predict and avoid such injury. One approach might be to develop more complex risk models that combine multiple parameters to improve positive predictive value. For example, one study identified higher risk of perineal trauma with vacuum delivery; adding fetal occiput posterior position increased the risk by a factor of four.²³ The ideal model would include all parameters that are available before labor. A promising area for future research in this area may be imaging to define pelvic architecture because there is evidence of differences in the bony pelvis among women with and those without pelvic floor disorders.²⁴ Such differences might impact the progress of labor²⁵ and predispose to maternal trauma. Because the currently identified risk factors for anal sphincter tear are also associated with dystocia, other measures of labor progress, such as the labor curve, may similarly be pursued as potentially valuable predictors of maternal trauma. Obstetric research has achieved significant improvements in fetal and neonatal well-being; further efforts are now needed to similarly improve maternal well-being after delivery.

REFERENCES

- 1. Lamah M, Kumar D. Fecal incontinence. Dig Dis Sci 1999;44: 2488–99.
- Sultan AH, Kamm MA, Hudson CN, Thomas JM, Bartram CI. Anal-sphincter disruption during vaginal delivery. N Engl J Med 1993;329:1905–11.
- Angioli R, Gomez-Marin O, Cantuaria G, O'Sullivan MJ. Severe perineal lacerations during vaginal delivery: the University of Miami experience. Am J Obstet Gynecol 2000;182: 1083–5.
- Fenner DE, Genberg B, Brahma P, Marek L, DeLancey JO. Fecal and urinary incontinence after vaginal delivery with anal sphincter disruption in an obstetrics unit in the United States. Am J Obstet Gynecol 2003;189:1543–9; discussion 1549–50.
- Handa VL, Danielsen BH, Gilbert WM. Obstetric anal sphincter lacerations. Obstet Gynecol 2001;98:225–30.
- De Leeuw JW, Struijk PC, Vierhout ME, Wallenburg HC. Risk factors for third degree perineal ruptures during delivery. BJOG 2001;108:383–7.
- 7. Jander C, Lyrenas S. Third and fourth degree perineal tears: predictor factors in a referral hospital. Acta Obstet Gynecol Scand 2001;80:229–34.
- Burrows LJ, Cundiff GW, Leffler KS, Witter FR. Predictors of third and fourth degree perineal lacerations. J Pelvic Med Surg 2004;10:15–7.
- Donnelly V, Fynes M, Campbell D, Johnson H, O'Connell PR, O'Herlihy C. Obstetric events leading to anal sphincter damage. Obstet Gynecol 1998;92:955–61.
- Crawford LA, Quint EH, Pearl ML, DeLancey JO. Incontinence following rupture of the anal sphincter during delivery. Obstet Gynecol 1993;82:527–31.

VOL. 109, NO. 1, JANUARY 2007

FitzGerald et al Risk Factors for Anal Sphincter Tear 33



- Haadem K, Dahlstrom JA, Lingman G. Anal sphincter function after delivery: a prospective study in women with sphincter rupture and controls. Eur J Obstet Gynecol Reprod Biol 1990;35:7–13.
- Signorello LB, Harlow BL, Chekos AK, Repke JT. Midline episiotomy and anal incontinence: retrospective cohort study. BMJ 2000;320:86–90.
- Zetterstrom JP, Lopez A, Anzen B, Dolk A, Norman M, Mellgren A. Anal incontinence after vaginal delivery: a prospective study in primiparous women. Br J Obstet Gynecol 1999;106:324–30.
- Haadem K, Ohrlander S, Lingman G. Long-term ailments due to anal sphincter rupture caused by delivery: a hidden problem. Eur J Obstet Gynecol Reprod Biol 1988;27:27–32.
- Borello-France D, Burgio KL, Richter HE, Zyczynski H, FitzGerald MP, Whitehead W, et al. Fecal and urinary incontinence in primiparous women. Obstet Gynecol 2006;108: 863–72.
- De Leeuw JW, Vierhout ME, Struijk PC, Hop WC, Wallenburg HC. Anal sphincter damage after vaginal delivery: functional outcome and risk factors for fecal incontinence. Acta Obstet Gynecol Scand 2001;80:830–4.
- Caughey AB, Sandberg PL, Zlatnik MG, Thiet MP, Parer JT, Laros RKJ. Forceps compared with vacuum: rates of neonatal and maternal morbidity. Obstet Gynecol 2005;106:908–12.
- Belmonte-Montes C, Hagerman G, Vega-Yepez PA, Hernandez-de-Anda E, Fonseca-Morales V. Anal sphincter injury after vaginal delivery in primiparous females. Dis Colon Rect 2001;44:1244–8.
- Halverson AL, Hull TL. Long-term outcome of overlapping anal sphincter repair. [comment]. Dis Colon Rect 2002;45: 345–8.
- 20. Graham ID, Carroli G, Davies C, Medves JM. Episiotomy rates around the world: an update. Birth 2005;32:219–23.
- Bofill JA, Rust OA, Perry KG, Roberts WE, Martin RW, Morrison JC. Operative vaginal delivery: a survey of fellows of ACOG. Obstet Gynecol 1996;88:1007–10.
- Bofill JA, Rust OA, Perry KG, Roberts WE, Martin RW, Morrison JC. Forceps and vacuum delivery: a survey of North American residency programs. Obstet Gynecol 1996;88:622–5.

- Benavides L, Wu JM, Hundley AF, Ivester TS, Visco AG. The impact of occiput posterior fetal head position on the risk of anal sphincter injury in forceps-assisted vaginal deliveries. Am J Obstet Gynecol 2005;192:1702–6.
- Handa VL, Pannu HK, Siddique S, Gutman R, Van Rooyen J, Cundiff G. Architectural differences in the bony pelvis of women with and without pelvic floor disorders. Obstet Gynecol 2003;102:1283–90.
- Zaretsky MV, Alexander JM, McIntire DD, Hatab MR, Twickler DM, Leveno KJ. Magnetic resonance imaging pelvimetry and the prediction of labor dystocia. Obstet Gynecol 2005;106:919–26.

APPENDIX

Pelvic Floor Disorders Network Members

The following were the members of the Pelvic floor Disorders Network at the time of the CAPS study:

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