OBSTETRICS

Outcomes associated with a structured prenatal counseling program for shoulder dystocia with brachial plexus injury

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OBJECTIVE: We examined outcomes that were associated with a novel program to identify patients who are at high risk for shoulder dystocia with brachial plexus injury.

STUDY DESIGN: The program included a checklist of key risk factors and a multifactorial algorithm to estimate risk of shoulder dystocia with brachial plexus injury. We examined rates of cesarean delivery and shoulder dystocia in 8767 deliveries by clinicians who were enrolled in the program and in 11,958 patients of clinicians with no access to the program.

RESULTS: Key risk factors were identified in 1071 of 8767 mothers (12.2%), of whom 40 of 8767 women (0.46%) had results in the

high-risk category. The rate of primary cesarean delivery rate was stable (21.2-20.8%; $P = .57$). Shoulder dystocia rates fell by 56.8% (1.74-0.75%; $P = .002$). The rates of shoulder dystocia and cesarean birth showed no changes in the group with no access to the program.

CONCLUSION: With the introduction of this program, overall shoulder dystocia rates fell by more than one-half with no increase in the primary cesarean delivery rate.

Key words: brachial plexus injury, risk assessment, shoulder dystocia

Shoulder dystocia, a relatively rare and usually uncomplicated problem, presents a counseling dilemma for clinicians. Almost all mothers at term will possess at least 1 of the 10 risk factors listed in the American College of Obstetricians and Gynecologists practice bulletin no. 40 on shoulder dystocia.[1] In contrast, <2% of mothers will meet the standard fetal weight-based intervention criteria of 5000 g or 4500 g with maternal diabetes mellitus. The occasional serious injury that is associated with shoulder dystocia creates an even greater dilemma for clinicians. It is unrealistic and unreasonable to expect clinicians to raise the

specter of shoulder dystocia with persistent brachial plexus injury (BPI), which is a rare and catastrophic event, with mothers, especially when recommended criteria for offering prophylactic cesarean delivery will seldom be met.

Thus, there is a need for a method to identify the small subset of women who are truly at elevated risk for shoulder dystocia with BPI. Such a method should not increase the cesarean delivery rate unduly.

It is well established that high birthweight is associated with more shoulder dystocia. However, it is not possible to chose a particular threshold that has both high sensitivity and low false-positive rates to distinguish which mothers will experience shoulder dystocia in general from mothers with uncomplicated vaginal births or even from those who will also have BPI.[1-7] The average weight of babies with shoulder dystocia is approximately 4000 g or well within the normal range of term birthweights.[1,2,8-14]

Although it is impossible to predict with certainty who will also experience BPI, certain combinations of factors do carry added risk. For example, Mehta et al[15] demonstrated that both an elevated maternal body mass index and fetal weight of >4500 g raised the rate of as-

sociated BPI when shoulder dystocia does occur. Gudmundsson et al[16] found that the presence of a large baby in a short stature mother was associated with a much greater rate of neonatal injury than was seen with the same sized babies in tall mothers.

Using modern statistical methods, other researchers have examined large datasets of cases with BPI and have found strong associations with certain combinations of maternal and fetal size.[17-19] One of these statistical approaches is available in a web-based program that gives the doctor an estimation of a mother's personal risk based on her own factors, which in turn facilitates planning the delivery method.[18]

The estimation of risk has limitations that include the well-known imprecision that is related to the estimation of fetal weight before birth, In addition, other risk factors may become apparent during labor. This statistical method does provide a consistent way to consider the imperfect and incomplete information that is available before labor. This prospective observational study examines trends in interventions and outcomes in a period that spans 4 years after the introduction of a 3-step program to help clinicians to identify mothers who are at greatest risk for

shoulder dystocia with BPI, to estimate that likelihood, and to discuss delivery options with the mothers.

MATERIALS AND METHODS

The study was carried out in 2 urban teaching tertiary care hospitals in New Jersey. The insurance carrier of a group of clinicians made available this 3-step program. All pregnancies with a singleton baby at a gestational age of ≥36 weeks that were delivered at these 2 institutions were included in the study. Antepartum stillbirths were excluded. *Shoulder dystocia* was defined clinically as a delivery that requires the use of specialized maneuvers, beyond gentle downward traction of the head, to deliver the shoulders.

The risk assessment method that was used in our current study was developed with the use of retrospective data from births with shoulder dystocia with persistent BPI.[18] With the use of a statistical technique that is similar to the methods that estimate likelihood of Trisomy 21 on the basis of multiple serum and ultrasonic markers, this method combines several factors about mother and baby to estimate the risk of shoulder dystocia with persistent BPI.

Before commencing the program, policies were established regarding criteria for formal quantitative risk assessment, counseling, and the development of a specialized consent form that was used to document the patient's choice for delivery method. After user training, the program was commenced in a staggered fashion in the offices of participating clinicians. Operationally, the program included 3 steps.

Step 1: checklist of key risk factors

At approximately 36-37 weeks' gestation a simple paper checklist of key risk factors was used to identify women who then were recommended for a formal quantitative risk assessment.

Step 2: quantitative risk assessment

A secure website housed the risk assessment algorithms and maintained the testing records for each clinician. Here 7 data points were entered: previous vaginal birth, maternal diabetes mellitus, previous shoulder dystocia, mother's height and weight, gestational age, and estimated fetal weight. The application then estimated the risk of shoulder dystocia with BPI and provided the results in both numeric and graphic form. Results were grouped in 3 categories: low, intermediate, and high risk. The guidelines on usage suggested that cesarean delivery be offered when the results fell in the high-risk category and that usual care be planned for labor and delivery when results were in the low-risk category. Intermediate results were shared with the mother and considered during the management of labor, at which time additional risk factors that are related to labor progress could appear.

Step 3: discussion and documentation of planned delivery method

The website also contained specialized documents that included consent forms so that a mother could attest to understanding her own risk, the limitations of estimating fetal weight, available delivery options, and her preference for delivery method when the test results were elevated. A delivery summary template that included the elements that should be documented when shoulder dystocia occurs was also available.

In keeping with a fundamental tenet of medicine (Primum non nocere [First, do no harm]), our primary objective was to measure the impact on primary cesarean delivery rates. Our secondary objective was to examine trends in overall shoulder dystocia rates and the rates of shoulder dystocia with associated complications. Given the natural incidence of shoulder dystocia with permanent BPI that ranges from 1 in 5-10,000 vaginal births, we knew it would be impossible to draw confident conclusions regarding this particular complication without studying approximately 250,000 births.

We examined trends in interventions that included the rates of primary and repeat cesarean delivery, induction of labor and outcomes (such as rates of shoulder dystocia), perineal laceration, and low 5-minute Apgar scores.

The perceived need for ancillary delivery maneuvers, which defined shoulder dystocia, is to a degree a subjective clinical call. Thus, changing shoulder dystocia rates are always open to interpretation as to whether the actual condition was changing or possibly only diagnostic criteria were applied differently. Therefore, we also examined a subset of the total shoulder dystocia group that had an additional objective marker of a difficult shoulder dystocia delivery, namely those deliveries with any BPI or a need for immediate intubation, bag and mask ventilation, or fracture. We examined trends in the rate of this subset of "complicated" shoulder dystocia.

To determine whether rates of shoulder dystocia were decreasing naturally in these hospital settings, we examined the rates of shoulder dystocia among the patients of clinicians who did not have access to the risk assessment program over the same time period and used exactly the same inclusion criteria and definitions.

Obstetric outcomes were measured with the use of the institutional perinatal database that extracts data from the electronic medical record (PeriBirth; PeriGen, Princeton, NJ). In addition, the pediatric records for all babies who were noted to have shoulder dystocia were examined to ascertain the presence or absence of associated injury. This study received institutional review board approval.

The differences between proportions were analyzed by a χ^2 test or Fisher exact test, where appropriate. Comparisons of means were performed with the use of an unpaired t test. Trends were evaluated by χ^2 test for linear trend. All tests were 2-tailed; a probability value of < .05 was considered to be significant. Statistical analysis was performed with GraphPad Prism software (version 5.03 for Windows; GraphPad Software, San Diego CA).

RESULTS

Between November 2007 and June 2011, 8767 mothers were delivered by the clinicians who were enrolled in the 3-step program. Clinicians joined the program at staggered times. Apart from standardized training sessions and periodic feedback on use rates, there was no other formal process control. A total of 1071 of these mothers (12.2%) proceeded to step

TABLE 1
Maternal and fetal characteristics

Variable	With quantitative risk assessment (n = 1071)	Without quantitative risk assessment (n = 7697)	P value
Nulliparity, %	58.5	43.0	< .0001
Diabetes mellitus, %	10.8	3.7	< .0001
Induction, %	40.5	30.6	< .0001
Gestational age, y[a]	39.7 ± 0.9	39.3 ± 1.1	< .0001
Previous cesarean delivery, %	3.6	21.6	< .0001
Mean body mass index, kg/m^{2a}	33.6 ± 5.9	29.9 ± 4.7	< .0001
Body mass index, %			
>35, kg/m^2	35.9	11.2	< .0001
>40, kg/m^2	13.4	3.4	< .0001
Mean birthweight, g[a]	3657 ± 414	3401 ± 441	< .0001
Birthweight, %			
>4000 g	20.2	8.4	< .0001
>4500 g	1.5	0.8	.0213
>5000 g	0.09	0.05	.59

[a] Data are given as mean ± SD.

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2 (the quantitative risk assessment). As expected, they were significantly different from the others in several ways because they were selected on the basis of key risk factors for shoulder dystocia. As is outlined in Table 1, this group of mothers and babies were heavier and were more likely to have diabetes mellitus, to be nulliparous, or to have undergone induction of labor and less likely to have had a previous cesarean birth.

Despite the presence of ≥1 key risk factors, 923 of the 1071 patients (86.1%) who completed step 2 received results in the low-risk category. That is, most pa-tients who underwent step-2 testing received reassuring results, despite the presence of ≥1 shoulder dystocia risk factors. Another 108 patients (10.1%) fell in the intermediate-risk category, and 40 patients (3.7%) fell in the high-risk category.

The 40 women with high-risk results represent 0.46% of the 8767 total women in the study. In this smaller group, 34 of 40 women (85%) delivered by cesarean. There was 1 severe shoulder dystocia among the 6 mothers who delivered vaginally. This baby weighed 4185 g and had Apgar scores of 1 and 5 with bag and mask ventilation for 5 minutes. The baby did not have a BPI or central neurologic signs.

The trends in rates of interventions and outcomes are summarized in Tables 2 and 3. Over the course of the study period, the rate of quantitative risk assessment increased from 6.4-16.7%. Primary cesarean delivery rates were stable. Repeat cesarean delivery rates and consequently the total cesarean delivery rates increased. Only 0.4% of women had both a previous cesarean birth and a formal quantitative risk assessment, so the potential contribution of this test to the overall repeat cesarean delivery rate could not have been more than this. Although the overall induction rates remained stable, induction rates for "macrosomia" fell substantially.

Trends in outcomes are summarized in Table 3. Over the study period, the rates of shoulder dystocia rates fell by more than one-half, and this downward trend reached high statistical significance. The trend in "complicated" shoulder dystocia rates did not reach statistical significance at the .05 level but showed an encouraging pattern. Third- and fourth-degree perineal laceration rates also fell during the study period. There was no significant trend in low 5-minute Apgar rates.

There were no cases of persistent BPI in the deliveries of mothers who had a quantitative risk assessment. There was only 1 persistent BPI in the entire study population. This mother was a policy violation in that she clearly qualified for a quantitative risk assessment but did not receive one. Retrospective calculation of her risk with her own parame-

TABLE 2
Intervention trends during the study period

Analysis year	Births at ≥36 wk, n	Quantitative risk assessment, %	Cesarean delivery, %			Induction, %	Induction for macrosomia, %
			Primary	Repeat	Total		
1	2753	6.4	21.2	15.9	37.2	33.0	1.02
2	2343	13.9	22.7	16.8	39.4	31.9	0.47
3	2464	15.0	21.0	20.0	41.0	30.5	0.45
4	1207	16.7	20.8	20.0	40.8	31.8	0.33
P value		< .0001	.5721	< .0001	.0043	.14	.0038

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TABLE 3
Outcome trends during the study period

Analysis year	Births at ≥36 wk, n	Shoulder dystocia rate, %		Complicated shoulder dystocia rate per total births, %	Third-degree perineal laceration per vaginal births, %	Fourth-degree perineal laceration per vaginal births, %	5-min Apgar score <7, %
		Per total births	Per vaginal births				
1	2753	1.74	2.78	0.22	7.06	1.91	0.44
2	2343	1.66	2.75	0.21	4.44	1.76	0.38
3	2464	0.97	1.65	0.12	2.41	0.28	0.41
4	1207	0.75	1.26	0.00	3.22	1.54	0.17
P value		.002	.0046	.101	< .0001	.0100	.3156

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ters placed her well in the high-risk category. Her result remained high, even when we used a fetal weight underestimated by 500 g.

Among the 11,958 patients of clinicians who did not have access to the 3-step program, trends were stable for rates of shoulder dystocia (1.06-0.87%; $P = .221$) and for complicated shoulder dystocia (0.14-0.23%; $P = .56$).

COMMENT

In this observational study, a step-wise approach to estimate the risk of shoulder dystocia with BPI ultimately identified 0.46% of mothers to be at very elevated risk for shoulder dystocia and BPI. This method represents a significant advance over the current approach in which ≥1 of the American College of Obstetricians and Gynecologists risk factors for shoulder dystocia are found in almost all women at term; there is little guidance on how to further determine who is at risk for associated BPI.

Introduction of this program was not associated with an increase in the primary cesarean delivery rate. Moreover, shoulder dystocia rates fell by more than one-half over the course of the study. We are unaware of any previous report that described a clinical intervention that was associated both with a reduction in shoulder dystocia rates and no increase in the primary cesarean delivery rate.

Other potentially undesirable associations such as rising rates of perineal lacerations or low 5-minute Apgar scores were not observed as the frequency of these events either decreased or was stable.

It will take time to ascertain the impact on the most critical subset of the shoulder dystocia group, namely those women with persistent BPI, because of its more uncommon occurrence. Nevertheless, early indications regarding the trends in the "complicated" shoulder dystocia group were encouraging.

Prospective studies such as this have both strengths and weaknesses. Observational studies are limited with respect to ascertaining cause-and-effect relationships. It is possible that unmeasured factors during the course of the study affected the outcomes. However, a major factor that influences shoulder dystocia incidence is the rate of primary cesarean delivery, which was stable during the study period. Furthermore, the rates of shoulder dystocia in the patients of clinicians without access to the 3-step program were unchanged. When these results are generalized to other settings, results may differ, especially if patient characteristics or clinical practices are very different from those in this study.

What is the relevance of these results in face of the widespread adoption of shoulder dystocia drills? Quantitative risk assessment and shoulder dystocia team training are complementary approaches. Reports vary regarding the effect of maneuvers and drills on rates of associated injury.[20-25] This is consistent with experience in many other areas such as sports, the military, or the arts, where improvements with practice are greatest when the starting performance level is poor and least when a high level of performance already exists. This prenatal

counseling program is targeted to identify and remove cases with the most marked risk of injury; drills prepare teams to handle the unanticipated cases. These 2 approaches have potential to be very synergistic.

This 3-step program was seen to be a feasible method to identify a very small subset of women at significantly elevated risk for shoulder dystocia with BPI and to involve them in the decision regarding delivery method. Furthermore, results exceeded our expectations in that there was a large drop in the rate of shoulder dystocia in general, with no change in the primary cesarean delivery rate. We will continue to monitor these results to evaluate the impact on shoulder dystocia with persistent BPI.

Uncertainty is a known major cause of either the underuse or overuse of interventions and technology in medicine.[26] Cesarean section delivery and shoulder dystocia are not exceptions. These study results demonstrate how less uncertainty about a serious complication of birth can assist clinicians and mothers to make more confident choices about delivery methods. ∎

REFERENCES
1. American College of Obstetricians and Gynecologists. Shoulder dystocia: ACOG practice bulletin, no. 40. Washington, DC: The College; 2002.

2. Royal College of Obstetricians and Gynaecologists. Shoulder dystocia: green-top guideline 2005, No. 42. London: RCOG Press; 2005.
3. Rouse DJ, Owen J, Goldenberg RL, Cliver SP. The effectiveness and costs of elective cesarean delivery for fetal macrosomia diagnosed by ultrasound. JAMA 1996;276:1480-6.
4. Acker DB, Sachs BP, Friedman EA. Risk factors for shoulder dystocia. Obstet Gynecol 1985;66:762-8.
5. Nesbitt TS, Gilbert WM, Herrchen B. Shoulder dystocia and associated risk factors with macrosomic infants born in California. Am J Obstet Gynecol 1998;179:476-80.
6. Gherman RB, Ouzounian JG, Satin AJ, Goodwin TM, Phelan JP. A comparison of shoulder dystocia-associated transient and permanent brachial plexus palsies. Obstet Gynecol 2003;102:544-8.
7. Chauhan SP, Cole J, Laye MR, et al. Shoulder dystocia with and without BPI: experience from three centers. Am J Perinatol 2007;24:365-71.
8. Ouzounian JG, Gherman RB. Shoulder dystocia: are historic risk factors reliable predictors? Am J Obstet Gynecol 2005;192:1933-5.
9. Chauhan SP, Christian B, Gherman RB, Magann EF, Kaluser CK, Morrison JC. Shoulder dystocia without versus with brachial plexus injury: a case-control study. J Matern Fetal Neonatal Med 2007;20:313-7.
10. Baskett TF, Allen AC. Perinatal implications of shoulder dystocia. Obstet Gynecol 1995;86:14-7.

11. Belfort MA, Dildy GA, Saade GR, Suarez V, Clark SL. Prediction of shoulder dystocia using multivariate analysis. Am J Perinatol 2007;24:5-10.
12. Baskett TF. Shoulder dystocia. Best Pract Res Clin Obstet Gynaecol 2002;6:57-68.
13. Mehta SH, Blackwell SC, Hendler I, et al. Accuracy of estimated fetal weight in shoulder dystocia and neonatal birth injury. Am J Obstet Gynecol 2005;192:1877-80.
14. Ginsberg NA, Moisidis C. How to predict recurrent shoulder dystocia. Am J Obstet Gynecol 2001;184:1427-9.
15. Mehta SH, Blackwell SC, Bujold E, Sokol RJ. What factors are associated with neonatal injury following shoulder dystocia? J Perinatol 2006;26:85-8.
16. Gudmundsson S, Henningsson AC, Lindqvist P. Correlation of birth injury with maternal height and birthweight. BJOG 2005;112:764-7.
17. Dyachenko A, Ciampi A, Fahey J, Mighty H, Oppenheimer L, Hamilton EF. Prediction of risk for shoulder dystocia with neonatal injury. Am J Obstet Gynecol 2006;195:1544-9.
18. Hamilton EF, Ciampi C, Dyachenko A, Lerner HM, Miner L, Sandmire HF. Is shoulder dystocia with brachial plexus injury preventable? Fetal Matern Med Rev 2008;19:293-310.
19. Hoffman M, Bailit J, Wilkins I, et al. Predictors of shoulder dystocia with and without neonatal injury using multivariable modeling.

Am J Obstet Gynecol 2011:204(suppl):S129-30.
20. Walsh JM, Kandamany N, Ni Shuibhne N, Power H, Murphy JF, O'Herlihy C. Neonatal brachial plexus injury: comparison of incidence and antecedents between 2 decades. Am J Obstet Gynecol 2011;204:324-6.
21. Inglis SR, Feier N, Chetiyaar JB, et al. Effects of shoulder dystocia training on the incidence of brachial plexus injury. Am J Obstet Gynecol 2011;204:322-3.
22. Grobman WA, Miller D, Burke C, Hornbogen A, Tam K, Costello R. Outcomes associated with introduction of a shoulder dystocia protocol. Am J Obstet Gynecol 2011;205:513-7.
23. Draycott TJ, Crofts JF, Ash JP, et al. Improving neonatal outcome through practical shoulder dystocia training. Obstet Gynecol 2008;112:14-20.
24. Hoffman MK, Bailit JL, Branch DW, et al. A comparison of obstetric maneuvers for the acute management of shoulder dystocia. Obstet Gynecol 2011;117:1272-8.
25. MacKenzie IZ, Shah M, Lean K, Dutton S, Newdick H, Tucker DE. Management of shoulder dystocia: trends in incidence and maternal and neonatal morbidity. Obstet Gynecol 2007;110:1059-68.
26. McNeil BJ. Shattuck lecture: hidden barriers to improvement in the quality of care. N Engl J Med 2001;345:1612-20.