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Decreased rates of shoulder dystocia and brachial plexus injury via an evidence-based practice bundle

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Abstract

Objective—To evaluate whether a standardized approach to identify pregnant women at risk for shoulder dystocia (SD) is associated with reduced incidence of SD and brachial plexus injury (BPI).

Methods—Between 2011 and 2015, prospective data were collected from 29 community-based hospitals in the USA during implementation of an evidence-based practice bundle, including an admission risk assessment, required "timeout" before operative vaginal delivery (OVD), and low-fidelity SD drills. All women with singleton vertex pregnancies admitted for vaginal delivery were included. Rates of SD, BPI, OVD, and cesarean were compared between a baseline period (January 2011–September 2013) and an intervention period (October 2013–June 2015), during which there was a system-wide average bundle compliance of 90%.

Results—There was a significant reduction in the incidence of SD (17.6%; P=0.028), BPI (28.6%; P=0.018), and OVD (18.0%; P<0.001) after implementation of the evidence-based practice bundle. There was a nonsignificant reduction in primary (P=0.823) and total (P=0.396) cesarean rates, but no association between SD drills and incidence of BPI.

Conclusion—Implementation of a standard evidence-based practice bundle was found to be associated with a significant reduction in the incidence of SD and BPI. Utilization of low-fidelity drills was not associated with a reduction in BPI.

Graphical abstract

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Author contributions
All authors made substantial contributions to the study conception and design, and to data acquisition, analysis, and interpretation, including drafting and revising the manuscript for important intellectual content. All authors gave final approval to the version submitted. All authors agree to be accountable for all aspects of the work.

Conflict of interest
The authors have no conflicts of interest.

Synopsis: In a multicentered community-based hospital system, implementation of risk assessment tools was associated with decreased rates of shoulder dystocia and brachial plexus injury.

Keywords

Brachial plexus injury; Patient safety; Shoulder dystocia

1 INTRODUCTION

Shoulder dystocia is an obstetric emergency defined as “delivery that requires additional obstetric maneuvers following failure of gentle downward traction on the fetal head to effect delivery of the shoulders” [1]. The reported prevalence of shoulder dystocia among all vertex vaginal deliveries in the USA is 0.6%–2% [1,2], and the incidence seems to be increasing [2]. The most common major neonatal morbidity of shoulder dystocia is brachial plexus injury, with a frequency of 1.5 per 1000 births in the USA and 1.4 per 1000 births worldwide [3,4]. Transient neonatal brachial plexus injury occurs in 1.01%–16.8% of clinically apparent cases of shoulder dystocia [3], with approximately 10% of all cases resulting in persistent injury [1]. Although cases of shoulder dystocia are often unpredictable, several risk factors have been well documented [1]. Ideally, this information should be used to modify obstetric care and reduce maternal and neonatal morbidity with minimal or no effect on cesarean delivery rates.

Operative vaginal delivery is a known risk factor for shoulder dystocia, especially in the setting of fetal macrosomia [1,5]. Although the frequency of operative vaginal delivery has steadily decreased from 9.0% in 1990 to 3.3% in 2013 across the USA [6], the operative vaginal delivery rate in California from June 2013 to June 2015 was 7.3% (Maternal Data Center, California Maternal Quality Care Collaborative) [7]. Owing to the known risks of maternal and neonatal morbidity, it is essential that providers select appropriate candidates for this procedure [5,8].

Guidelines from the USA [1,3] and UK [9] indicate that neonatal brachial plexus injury might provide an excellent example of when standardization of care would improve maternal and neonatal outcomes. As a result, use of checklists, simulation drills, and debriefing to improve responder confidence, in addition to preparedness to handle shoulder dystocia, have been recommended [3,9–11].

It was considered that an evidence-based safety bundle constructed from these strategies might be associated with a reduction in shoulder dystocia and brachial plexus injury. The aim of the present study was therefore to evaluate the effectiveness of such a safety initiative to reduce the incidence of shoulder dystocia and brachial plexus injury.

2 MATERIALS AND METHODS

The present study evaluated maternal and neonatal data that were prospectively collected from 29 Dignity Health System community-based maternity units in Arizona, California, and Nevada, USA, between January 1, 2011, and June 30, 2015, as part of a program of ongoing clinical patient safety monitoring. Dignity Health does not require institutional review board approval for quality improvement projects.

The 29 study hospitals varied in size from a small rural center with fewer than 200 deliveries per year to large urban hospitals with approximately 4000–5000 deliveries per year. There were approximately 60 000 deliveries annually within the hospital system. Women with singleton vertex pregnancies admitted for a planned vaginal delivery either by induction of labor or in spontaneous labor were included in the study. The exclusion criteria were non-vertex presentation for a planned vaginal delivery, multiple pregnancy, known fetal demise, preterm delivery (<34 weeks), or a known fetal anomaly.

In January 2012, the health system implemented five programs designed to improve patient care and documentation: first, reduction of early elective deliveries at less than 39 weeks; second, oxytocin pre- and in-use checklists; third, a planned vaginal delivery admission tool; fourth, a standardized nurse and physician shoulder dystocia delivery record; and fifth, an elective operative delivery pre-use checklist.

The primary purpose of the vaginal delivery admission tool was to facilitate an efficient handover between cross-covering physicians allowing notification of risks for shoulder dystocia for all patients (Box 1). For example, if a patient screened positive in the "estimated fetal weight/previous history of shoulder dystocia" portion of the admission tool, the physician had to document informed consent in the medical record for a vaginal delivery or offer cesarean delivery. If risk factors were identified in the "maternal history and pregnancy status" section, the physician was notified and the patient counseled as needed.

The operative vaginal delivery pre-use checklist was used to highlight characteristics that are associated with an increased risk of shoulder dystocia, and so functioned as a "timeout" before an attempt at vaginal delivery (Box 2). If, after completing the "timeout," the provider felt that the patient was a poor candidate for operative vaginal delivery, cesarean delivery was offered.

During implementation of the tool and checklists, low-fidelity simulations were also carried out for all labor and delivery nursing staff, and physician participation was recommended. The simulations included didactic education, followed by drills using a pelvis manikin or a basic full manikin (Noelle, Gaumard Scientific, Miami, FL, USA). The drills were followed by a debriefing session.

In addition to the vaginal delivery admission assessment of risk factors, the shoulder dystocia bundle included completion of a detailed delivery form signed by both the delivery nurse and physician for deliveries in which shoulder dystocia occurred. The operative vaginal delivery bundle comprised: an elective pre-assessment form; documentation of informed consent if indicated; documentation of position, station, and estimated weight of fetus before elective operative delivery; adherence to number of pop-offs in the case of vacuum-assisted delivery; and an "exit strategy" in the event of a documented failed operative vaginal delivery.

During the implementation of both bundles, additional information was collected if clinically necessary, including documentation of the 5-minute Apgar score, umbilical cord gas data, histopathologic assessment of the placenta for a 5-minute Apgar score of less than 7, and evaluation of birth trauma.

A 6-month period was allowed for the hospitals to adopt the bundles, for members of the team to practice their roles, and to determine how the different aspects of the protocols were integrated. The initiative was then launched officially. Compliance monitoring was evaluated by using a multi-element scorecard that recorded an "all-or-none" score for the bundle [12]. Thus, bundle compliance was determined as 100% if all elements were completed for a patient, or 0% if any single or multiple items of the bundle were missed. For example, if five women had an operative vaginal delivery, and four of the five had all elements completed while one had an element missing, the compliance would be 80%. Monthly scorecards were shared among all hospitals.

All analyses were performed with SAS version 9.4 (SAS Institute, Cary, NC, USA). Continuous variable data were expressed as the rate per month aggregated quarterly for statistical analysis. The incidence of shoulder dystocia and brachial plexus injury in the periods before and after 90% bundle compliance were compared by *t* test. Wilcoxon signed rank test was used to compare shoulder dystocia incidence before and after implementation of practice drills. Pearson correlation was used to examine the associations between shoulder dystocia or brachial plexus injury incidence and bundle compliance rates, and those between shoulder dystocia or brachial plexus injury incidence and nurse or physician attendance rates at the drill practice sessions. Differences in primary and total cesarean rates were compared by *t* test between the time periods. Demographic characteristics, adjusted for total deliveries, were compared across the time periods by analysis of variance. $P<0.05$ was considered statistically significant.

3 RESULTS

The timeline of the study is shown in Figure 1. From January 2011, data on shoulder dystocia and brachial plexus injury were prospectively collected. In January 2012, the shoulder dystocia and operative vaginal delivery bundles were released. Full implementation at all sites with more than 90% compliance was achieved in September 2013. The baseline period comprised the pre-bundle data and data collected during bundle rollout, totaling 33 months (January 1, 2011, to September 30, 2013). The study period comprised 21 months after all sites had attained 90% all-or-none bundle compliance (October 1, 2013, to June 30, 2015). Standardized simulation sessions were in place in all maternity units by January 2014, with mandatory participation for labor and delivery nursing staff. Physicians were encouraged to participate.

During the 33-month baseline period, there were 168 579 births, of which 116 642 were vaginal deliveries. There were 1926 cases of shoulder dystocia, yielding a rate of 1.7 per 100 vaginal births. There were 250 cases of brachial plexus injury, yielding a rate of 2.1 per 1000 vaginal births. The rate of operative vaginal delivery was 6.1 per 100 births, and that of primary and total cesarean was 16.6 and 32.5 per 100 births, respectively.

In the 21-month period after 90% compliance was attained in all hospitals, there were 103 232 births, of which 70 178 were vaginal deliveries. As compared with baseline, there were significant reductions in the rates of shoulder dystocia, brachial plexus injury, and operative vaginal delivery (Table 1). The shoulder dystocia rate decreased by 17.6% (n=997; P=0.028), from 1.7 to 1.4 per 100 vaginal births; the brachial plexus injury rate decreased by 28.6% (n=105; P=0.018), from 2.1 to 1.5 per 1000 births; and the operative vaginal delivery rate decreased by 18.0% (n=3509; P<0.001), from 6.1 to 5.0 per 100 births. There was a nonsignificant decrease in primary and total cesarean rates (respectively, 16.5 per 100 births, P=0.823; and 30.1 per 100 births, P=0.396). Maternal demographic data, adjusted to total births, were evaluated from January 2011 to June 2015, but showed no significant change in age, ethnic origin, or incidence of diabetes (data not shown). The incidence of gestational diabetes increased over the course of the study, but the change was not significant (P=0.406).

As the rate of bundle compliance increased, there was significant decrease in the incidence of both shoulder dystocia (P=0.013) and brachial plexus injury (P<0.001), suggesting that bundle compliance was related to the outcomes noted. Furthermore, there was significant correlation between attaining 90% bundle compliance or higher, and the reduction of brachial plexus injury in the successive years 2013, 2014, and 2015 (respectively, r=−0.39, P=0.042; r=−0.40, P=0.033; and r=−0.43, P=0.024). In the same period, the increase in bundle compliance to 90% or greater was associated with a decrease in operative vaginal delivery rate (r=−0.33; P=0.017).

During the last 6 months of the study period, 66% of nurses (836/1260) and 13.7% of physicians (62/454) participated the in low-fidelity shoulder dystocia drills. Although there was an overall decrease in the incidence of shoulder dystocia after the implementation of drills, participation in the low-fidelity shoulder dystocia drills by nurses (r=−0.21; P=0.263) or physicians (r=−0.13; P=0.511) (Table 2) was not correlated with the incidence of shoulder dystocia or brachial plexus injury.

4 DISCUSSION

In the present large community-based multicentered prospective study, the implementation of evidence-based practice bundles for patients at risk for shoulder dystocia and use of operative vaginal delivery was found to be associated with a significant decrease in the incidence of shoulder dystocia and brachial plexus injury. Equally important, the use of these bundles within the 29 maternity centers was not associated with a change in the rate of primary or total cesarean delivery. The association between the bundle and outcome is supported by the strong correlation between bundle compliance and the rates of both shoulder dystocia and brachial plexus injury. Although creating, and engaging nurses and physicians in, low-fidelity drills probably improved team work and communication, the study did not find these activities to be associated with decreased rates of shoulder dystocia or brachial plexus injury.

Several studies have evaluated the impact of shoulder dystocia protocols and drills on maternal and neonatal outcomes with mixed results [13–19]. The present findings are consistent with those of Grobman et al. [15], who found that a standardized shoulder dystocia protocol with defined roles, general announcements, and improvement of documentation during the event decreased the rate of brachial plexus injury. As compared with Grobman et al.'s study, the present study had a large diverse practice of community hospitals affiliated with a health system, highlighting the importance of setting a standard protocol in all maternity units. The step-by-step use of uniform bundle elements in the study hospitals is consistent with the findings of Goffman et al. [16], who suggested that a standardized note template would probably be more effective in documenting shoulder dystocia events.

In a review of specific policies and procedures targeted to managing shoulder dystocia in a cohort of 25 hospitals in the Maternal–Fetal Medicine Units Network, Bailit et al. [13] found no associated decrease in the incidence of shoulder dystocia. That study did not examine the quality of the protocol or team simulation, or assess compliance, and there was no standard protocol agreement among the 25 institutions. By contrast, the present study highlights the importance of compliance testing and active hospital engagement with feedback to provide guidance for improvement.

The importance of uniformly assessing patients at risk for shoulder dystocia has been highlighted by MacKenzie et al. [14], who found that absence of a standardized risk assessment resulted in an increased incidence of shoulder dystocia and brachial plexus injury. This was observed during the same time that low-fidelity simulation drills were implemented in their hospital system [14]. When low-fidelity drills were considered alone in the present study, there was no significant change in the incidence of shoulder dystocia or brachial plexus injury. Nevertheless, the drills are likely to have improved communication among staff members despite the lack of an association with decreased brachial plexus injury. In low-resource settings, especially small obstetric care centers with low volume, it is important to perform shoulder dystocia drills to help maintain competence in skills [20].

The strengths of the present study are the large population of patients and the prospective collection of data in a standardized manner from several community-based hospitals. This design yielded sufficient numbers of patients to assess the impact of interventions on rare complications such as shoulder dystocia and the resultant brachial plexus injury. The hospital system includes various locations and maternity center sizes, demonstrating that these changes are applicable to different practice settings in most maternity units in high-income countries. The relatively short time taken to achieve 90% compliance with the bundle elements enforces the impact that can be made to reduce these obstetric complications.

The study has some limitations. First, there was a lack of patient-level data. Owing to an absence of birth certificate data, it was not possible to ascertain whether other changes in obstetric management or differences in fetal weight might have contributed to the decreased incidence of shoulder dystocia and brachial plexus injury. Nonetheless, the limited demographic data available did not change significantly change over the study period. Second, there was a low rate of physician participation in the shoulder dystocia drills, which meant that it was hard to determine the real impact that such drills might make in decreasing rare events. Third, the study baseline included the period of implementation of the bundle

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until all sites reached 90% compliance. Some sites might have reached the compliance goal earlier than September 2013, but the aim was to assess the impact over the entire hospital system because the number of hospital deliveries varied greatly, consistent with a wide variation in the degree of compliance until the end of the baseline period. Fourth, multiple interventions were implemented during the timeframe of the study; however, we considered that the two bundles reported in the study had the most impact. Last, data from long-term neonatal sequelae were not available to quantify the amount of permanent brachial plexus injury following shoulder dystocia, or to determine whether the interventions had similar effects in decreasing this serious neonatal morbidity.

In summary, the study found that the use of evidence-based interventions was associated with a decrease in the rates of shoulder dystocia and brachial plexus injury. Application of a pre-delivery risk analysis, standardized documentation, and assessment before operative vaginal delivery decreased one of the more significant neonatal morbidities. Although low-fidelity drills might improve team cohesiveness, they were not demonstrated to decrease the rates of shoulder dystocia or brachial plexus injury in the hospital system studied. By implementing the vaginal delivery checklist, providers in low-resource countries might be able to triage the high-risk patients who would benefit from delivering in a hospital setting. The 29 hospitals in the study system ranged in annual delivery volume from 150 to 5000, suggesting that the findings might be applicable to delivery units in all economic environments.

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Box 1

Planned vaginal delivery admission assessment.

Maternal history and pregnancy status (answer: yes/no)
Pre-pregnancy weight >90 kg or BMI >35
Maternal height <1.52 m
Maternal history of macrosomic newborn (>4000 g)
Length of pregnancy >41^{+0} weeks
Fetus thought to be large for gestational age or estimated fetal weight >4000 g
Estimated fetal weight/history of shoulder dystocia (answer: yes/no)[a]
Is the estimated fetal weight >4250 g (diabetic patient) OR >5000 g (non-diabetic patient)
Previous history of shoulder dystocia or "difficult birth"

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters).

[a]If the response is yes to either question, informed consent must be obtained and documented in the patient's medical record.

Box 2

Elective operative vaginal delivery pre-use checklist.

Maternal history and pregnancy status (answer: yes/no)
Pre-pregnancy weight >90 kg or BMI >35
Maternal height <1.52 m
Maternal history of macrosomic newborn (>4000 g)
Gestational age of this pregnancy >41^{0} weeks
Fetus thought to be large for gestational age or estimated fetal weight > 4000 grams
Current examination
Station of the fetal head
Position of the fetal head
Indications and delivery details
Indication for operative vaginal delivery
Planned delivery type (forceps/vacuum)
Risks/benefits and alternatives discussed with patient (informed consent: yes/no)
Anesthesia support team notified/present (yes/no)
Neonatal support team notified/present (yes/no)
Operating room team notified/present (yes/no)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters).

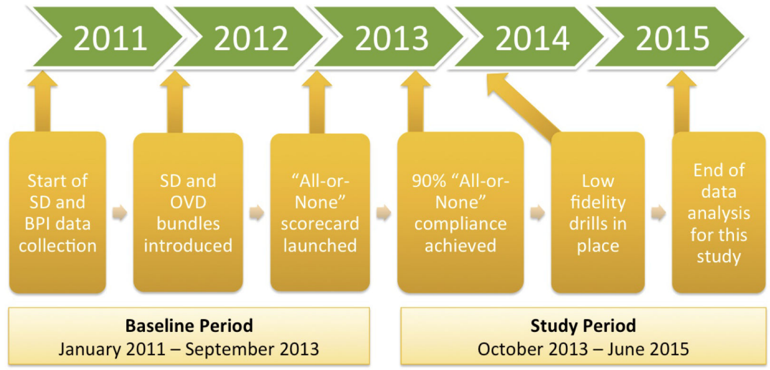

Figure 1.

Timeline of data collection. Abbreviations: SD, shoulder dystocia; BPI, brachial plexus injury; OVD, operative vaginal delivery.

Table 1

Outcomes after applying evidence-based practice bundles.

Outcome	Baseline (January 2011 to September 2013)	Study period (October 2013 to June 2015)[a]	*P* value
Total births	168 579	103 202	
Total vaginal births	116 642	70 178	
Shoulder dystocia			0.028
Total number	1936	997	
Per 100 births	1.7	1.4	
Brachial plexus injury			0.018
Total number	250	105	
Per 1000 births	2.1	1.5	
Operative vaginal delivery			<0.001
Total number	7116	3509	
Per 100 births	6.1	5.0	
Primary cesarean			0.823
Total number	9095	5126	
Per 100 births	16.6	16.5	
All cesarean			0.396
Total number	54 788	31 064	
Per 100 births	32.5	30.1	

[a]Outcomes at 90% all-or-none bundle compliance.

Table 2

Effects of applying low-fidelity drills.

Outcome	**Total no. of cases**	**Rate of cases**[a]	***P* value**
Shoulder dystocia			0.189
Before drills	249	5.66 ± 3.89	
After drills	201	4.57 ± 3.85	
Brachial plexus injury			0.752
Before drills	24	1.09 ± 1.07	
After drills	27	1.23 ± 0.95	

[a]Mean ± SD value per 100 births (shoulder dystocia) or per 1000 births (brachial plexus injury).