OBSTETRICS

Implementation of a conservative checklist-based protocol for oxytocin administration: maternal and newborn outcomes

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OBJECTIVE: The purpose of this study was to examine the effects of a conservative and specific checklist-based protocol for oxytocin administration on maternal and newborn outcome. The protocol was based on maternal and fetal response to oxytocin rather than infusion rate.

STUDY DESIGN: This was a retrospective chart review and data extraction of the last 100 patients receiving oxytocin before implementation of the protocol and the first 100 patients receiving oxytocin after protocol implementation.

RESULTS: The 2 groups were demographically similar. For the pre- and postprotocol groups, the mean time of infusion to delivery was 8.5 ± 5.3 hours versus 8.2 ± 4.5 hours (NS), the maximum oxytocin infusion rate was 13.8 ± 6.3 mU/min versus 11.4 ± 6.1 mU/min (P = .003) and the cesarean delivery rate was 15% versus 13% (NS). Every index of newborn outcome was improved in the post-protocol group, but these differences did not individually reach statistical significance. However, newborns with any index of adverse outcome were significantly fewer in the post protocol group (31 vs 18, P = .049). System wide implementation of this program was associated with a decline in the rate of primary cesarean delivery from 23.6% in 2005 to 21.0% in 2006.

CONCLUSION: Implementation of a specific and conservative checklist-based protocol for oxytocin infusion based on maternal and fetal response results in a significant reduction in maximum infusion rates of oxytocin without lengthening labor or increasing operative intervention. Cesarean delivery rate declined system-wide following implementation of this protocol. Newborn outcome also appears to be improved.

Key words: cesarean delivery, medication safety, oxytocin

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Oxytocin is one of the most commonly administered drugs in obstetrics. Although this agent, when carefully administered, is generally safe, adverse perinatal outcomes related to fetal hypoxia may occur in the presence of uterine hyperstimulation.[1] Due to a lack of outcomes based data demonstrating the clear superiority of any specific regimen of oxytocin administration, current guidelines in this regard are nonspecific.[2-4] While no single regimen of oxytocin administration has been demonstrated superior in terms of clinical outcomes, one of the most fundamental principles of quality improvement is that, in general, greater practice variation is associated with poorer outcomes than more uniform practice patterns.[5,6] In recent decades, the airline industry has established an enviable record of safety, due, in large part, to the extensive use of a uniform, checklist-based approach to the management of certain high risk situations.[7,8] We examined the effects of implementation of a conservative uniform checklist-based system of oxytocin administration in a large, tertiary level facility.

★ EDITORS' CHOICE ★

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Materials and Methods

The Hospital Corporation of America is the nation's largest single health care delivery organization, with 125 obstetric facilities in 20 states. In 2004, the Perinatal Safety Division assisted with the establishment of a system wide uniform, checklist-based protocol for oxytocin administration by work groups composed of representative practicing physicians, nurses, and pharmacists from the entire organization, as well as consultants from other institutions in areas served by our hospitals. With respect to mandated response to both fetal heart rate abnormalities and uterine contraction patterns, the protocols were purposefully far more conservative than would be required by current standard of care (Tables 2 and 3).[4] These protocols were then piloted in select facilities to further refine the safety and practicality of the checklists. The resultant checklist based protocols were then presented for adoption by individual departments of obstetrics and gynecology in each of our

TABLE 1
Oxytocin in-use checklist

Demographic/clinical factor	Prechecklist	Postchecklist
Maternal age	27.2±5.2	27.5±5.2
Parity	1.1±1.2	1.3±1.2
Gestational age (wk)	38.8±1.7	39.0±1.4
Oxytocin onset to delivery (h)	8.7±4.3	8.6±4.5
Total time oxytocin infused (h)	8.5±5.3	8.2±4.5
Maximum oxytocin dose (mU/min)	13.8±6.3	11.4±6.1 (0.003)*
Latent phase length (h)	5.8±3.3	5.5±3.2
Active phase length (h)	2.1±1.3	2.3±1.8
Second stage length (h)	0.69±0.69	0.74±0.92
Birthweight	6.998±1.259	7.421±1.231 (0.017)*
Apgar 1 minute	7.6±1.1	7.9±0.88 (0.048)*
Apgar 5 minutes	8.7±1.0	8.8±0.98
Cervical ripening agents	16	10
Cesarean delivery	15	13
Cesarean for fetal heart rate abnormalities	6	3
Operative vaginal delivery	11	10
Cesarean for labor arrest	9	9
Newborn intensive care admission	16	11
Respiratory distress	13	6
Sepsis suspected	2	1
Sepsis confirmed	6	2
Mean days in newborn intensive care	2.29	0.81
Mean newborn intensive care days for those admitted to NICU	14.3±10.4	7.4±5.7
Infants with 1 or more newborn complication	30	18 ($P = .049$)*

facilities. These protocols are designed as default models of oxytocin administration, to be automatically implemented and uniformly followed in the absence of a specific physician order to the contrary. Individual variations from protocol are allowed as long as the physician prospectively documents her/his rationale for such an alternative approach in the medical record. The protocols are designed for use in singleton, vertex, term labor in women with an unscarred uterus. Medical indications for induction did not exempt the patient from protocol use. Uniform protocols for oxytocin mixing and infusion were utilized.

St Mark's Hospital is a tertiary level, nonteaching referral facility in Salt Lake City, UT, with an annual delivery volume of approximately 3700. The checklist-based protocols were adopted by the department of Obstetrics and Gynecology at St Marks hospital and implemented March 1, 2005. As part of our ongoing internal patient safety and quality assurance program, we collected data regarding clinical course of labor and maternal/newborn outcomes in the last 100 patients receiving oxytocin prior to the adoption of the protocol and the first 100 patients receiving oxytocin after the introduction of the protocol. Institutional review board approval for publication of this analysis was obtained. Our working hypothesis was that such uniform, highly conservative practice would not significantly prolong labor or increase the intervention rate and would improve perinatal outcomes. Based upon the composite morbidity found in the pre-protocol group, we calculated that 100 patients in each group would give our analysis an 80% power to demonstrate a 50% reduction in composite adverse outcome at an alpha error of 0.05. Data extraction was undertaken by a single, experienced labor and delivery nurse from an institution in a different state. Univariate (Chi-square, Fisher exact, Student *t*, or Mann-Whitney rank sum test as appropriate) and multivariate analyses were performed.

RESULTS

All patients were delivered within a single month both before and after the protocol institution. During this period of time, there were no variations from protocol ordered by the attending physician. Demographic and clinical data are presented in Table 1. The only significant difference was a small but significant increased birthweight in the checklist managed group. The maximum dose of oxytocin used to achieve delivery was significantly lower in the checklist managed group. There was no difference in the length of any stage or phase of labor, total time of oxytocin administration, or rate of operative vaginal or abdominal delivery.

Following analysis of these data, these same protocols were implemented throughout the Hospital Corporation of America system. During the first year of system wide implementation of this protocol (2006), the primary cesarean delivery rate in approximately 220,000 deliveries fell from 23.6% (1995) to 21.0% (1996) in contrast to an annual increase in rate of primary cesarean of 1-4% in previous years (Figure).

A comparison of newborn outcomes demonstrated a statistically significant difference in 1 minute Apgar scores, with improved 1 minute Apgar scores in the checklist managed group. In addition,

fewer newborn complications were seen for every category analyzed, although individually, these did not reach statistical significance. However, when patients suffering any newborn complication requiring NICU admission or Apgar score < 8 were compared to those suffering no complication, significantly improved newborn outcome was seen in the checklist managed group (Table 1).

COMMENT

Current guidelines for oxytocin use are nonspecific, and current standard of care allows for a wide range of oxytocin doses and infusion rates.[4] This reflects a lack of evidence-based data to support safety or efficacy benefits of any specific regimen of oxytocin administration. On the other hand, one of the basic principles of quality process improvement is that process uniformity will generally result in product or outcome improvement, compared to processes that are highly variable.[5,6] This principle has been utilized with great success by the airline industry, which has developed highly standardized, checklist-based protocols for the management of a number of critical in-flight situations.[8] Indeed, the aircraft checklist has long been regarded as a foundation of pilot standardization and cockpit safety.[8] Such checklists were not developed as a result of randomized trials of various approaches but rather by pilots and other airline professionals on the basis of consensus "best practice." This approach has resulted in a dramatic decrease in aircraft errors and accidents since its institution several decades ago.[7] In contrast, according to the Institute of Medicine, medical errors have increased by 257% over a similar time period.[9] Further, even less specific, non-checklist-based best practice rules are only followed in the treatment of only about half of patients in the United States.[10] Accordingly, we sought to standardize our system wide approach to the administration of oxytocin, the drug most commonly implicated in avoidable medication related adverse outcomes, with the use of a highly specific checklist-based protocol (Tables 2 and 3).

TABLE 2
Pre-oxytocin checklist

HCA

HCA Perinatal Safety Initiative
Pre-Oxytocin Checklist
For Women with Term-Singleton Babies

"This Pre-Oxytocin checklist represents a guideline for care: however, individualized medical care is directed by the physician"

If the following checklist cannot be completed, Oxytocin should not be initiated

Date and time completed _____

1. ☐ Physician or Midwife Order on chart
2. ☐ Current history and physical on the chart*
3. ☐ Prenatal Record on chart*
4. ☐ Indication for induction is documented
5. ☐ Pelvis is documented by physician to be clinically adequate (should be on prenatal record)*
6. ☐ Estimated fetal weight within past week (clinical or ultrasound) less than 4500grams in a non-diabetic woman or less than 4250 grams in a diabetic woman*
7. ☐ Gestational age documented
8. ☐ Consent signed (General L&D consent)
9. ☐ Physician with C-section privileges is aware of the induction and readily available and this is documented in the medical record
10. ☐ Status of the cervix is assessed and documented
11. ☐ Presentation is assessed and documented (physician required to come in if nurse unable to determine)
12. ☐ Fetal Assessment completed and indicates: (complete all below)
    - ☐ A minimum of 30 minutes of fetal monitoring is required prior to starting Oxytocin
    - ☐ At least 2 accelerations (15 bpm x 15 sec) in 30 minutes are present, or a biophysical profile of 8 of 10 is present within the past 4 hours or adequate variability.**
    - ☐ No late decelerations in the last 30 minutes
    - ☐ No more than 2 Variable deceleration exceeding 60 seconds and decreasing greater than 60 bpm from baseline within the previous 30 minutes prior to starting Oxytocin infusion.

*May be delayed for non-elective admissions.

** This document does not apply to a formal Oxytocin challenge test without the intent to induce or augment labor.

**There will be some situations in which alterations in management from that described in the protocol are clinically appropriate. If, after reviewing the fetal heart rate strip and course of labor the responsible physician feels that in his or her judgment, continued use of Oxytocin is in the best interest of the mother and baby, the physician should write or dictate a note to that effect and order the Oxytocin to continue. The RN will continue to provide safe, high quality nursing care.

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The primary concern expressed by some physicians was that the conservatism built into these checklist-based protocols would unduly delay delivery or increase the need for operative intervention. Interference with physician autonomy was also a frequently cited concern. The latter concern is remarkably similar to observations of the initial response of pilots to flight protocols, where "pilot desire to be unique" and "pilot desire to demonstrate unusual competence" were frequent initial objections. Such objections have largely disappeared in the airline industry as the safety record of this industry has improved dramatically, in large part as a result of such checklists.[7,8]

In practice, the institution of this protocol neither prolonged labor nor increased the need for operative intervention despite a significant reduction in the maximum infusion rate of oxytocin. Our goal in developing this protocol was to

TABLE 3
"In use" oxytocin checklist

HCA

HCA Perinatal Safety Initiative

Recommended Oxytocin "In Use" Checklist for Women with Term Singleton- Babies

"This Oxytocin "In Use" Checklist represents a guideline for care; however, individualized medical care is directed by the physician."

Checklist will be completed every 30 minutes. Oxytocin should be stopped or decreased if the following checklist cannot be completed.

Date and time completed _____

☐ **Fetal Assessment indicates:**

☐ At least 1 acceleration of 15 bpm x 15 seconds in 30 minutes or adequate variability for 10 of the previous 30 minutes.

☐ No more than 1 late deceleration occurred.

☐ No more than 2 Variable decelerations exceeding 60 seconds in duration and decreasing greater than 60 bpm from the baseline within the previous 30 minutes.

☐ **Uterine Contractions**

☐ No more than 5 uterine contractions in 10 minutes for any 20minute interval

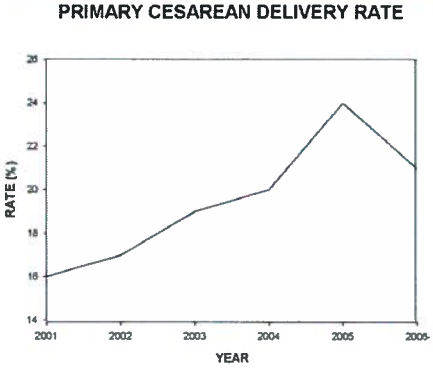
☐ No two contractions greater than 120 seconds duration

☐ Uterus palpates soft between contractions

☐ If IUPC is in place, MVU** must calculate less than 300 mm Hg and the baseline resting tone must be less than 25 mm Hg.

***If Oxytocin is stopped the Pre-Oxytocin Checklist will be reviewed before Oxytocin is reinitiated.**
**** MVU = Montevideo Units**

FIGURE
Primary cesarean delivery rate, Hospital Corporation of America



Clark. Checklist-based protocol for oxytocin. AJOG 2007.

improve practice and outcomes without regard to the cesarean delivery rate. All educational and policy initiatives were based upon the premise that the only metric of importance is the number of healthy mothers who take home healthy babies and that cesarean delivery is best viewed as a process, not an outcome. This premise, coupled with recommendations for a more conservative approach to issues such as abnormal fetal heart rate patterns and operative vaginal delivery, would have been expected to increase the rate of primary cesarean delivery. In practice, however, we saw a *decline* in the rate of primary cesarean delivery throughout our system associated with the uniform implementation of this protocol (Figure). In light of both national trends and our own system-wide data and patient safety initiatives, we believe this to be most likely a result of less hyperstimulation associated with the use of this oxytocin protocol. While our data do not allow a definitive conclusion regarding the cause of the decreased primary cesarean rate, it is clear that system-wide implementation of this protocol did not increase the primary cesarean delivery rate.

In addition, we found improvement in every index of newborn outcome examined in the protocol managed group, although, due to small sample size, only 1 minute Apgar score reached individual statistical significance. Overall adverse outcomes were, however, significantly lower in the protocol managed group. While statistically significant, these differences were not clinically dramatic; 1 minute Apgar score, for example, correlates poorly with long-term newborn outcome.[11] Further, while the combined outcome groups did demonstrate statistically significant improvement using the protocol, the *P* value was just under .05. Thus, while our data unequivocally demonstrate that this protocol does not prolong labor or increase the rate of cesarean delivery, we feel justified only in saying that this protocol appears to improve newborn outcomes. However, the 17% reduction in maximum oxytocin dose seen with protocol use was highly significant ($P = .003$). The only known adverse effect of exogenous oxytocin on the fetus is dose-related hyperstimulation. Thus, achievement of equivalent intervention rates and labor duration with a 17% reduction in the maximum dose of oxytocin certainly suggests that such improved outcomes would be born out more dramatically in a larger series. Similar labor outcomes with a lower dose of oxytocin seem in themselves a desirable goal.

In designing this checklist-based system, we chose to focus on uterine and fetal response to oxytocin, rather than on any specific dosing regimen, given the known variation in dose response of the

drug. In the absence of hyperstimulation or signs of fetal intolerance of labor, we felt the dose to be virtually irrelevant; thus, the protocol allows for any of the wide range of low or high dose oxytocin regimens approved by the American College of Obstetricians and Gynecologists.[4] Our outcomes support such recommendations and validate our assumption in this regard. Current nursing recommendations for formal charting during labor every 30 minutes. Thus, these protocols did not increase the time required for nurse charting, rather, they simply offered a standard approach to evaluation and charting. After stopping oxytocin, resumption was allowed as soon as criteria for oxytocin inititation were once again met (Tables 2 and 3).

Several definitions of hyperstimulation have been offered in the literature, some based on specific patterns of uterine activity, and others implying that oxytocin may be continued, regardless of the nature of resultant contractions, until fetal heart rate patterns suggesting frank asphyxia are obtained.[4] We purposefully did not utilize this confusing term; rather, we defined in a very simple manner fetal heart rate and uterine contraction patterns, which our work group felt to be indications for slowing, or stopping, the oxytocin infusion.

It should be noted that our protocols were considerably more conservative in terms of mandating a decrease in oxytocin dose based on abnormal patterns of fetal heart rate or uterine activity that would generally be required by the standard of care.[4] However, in most of our facilities patients are cared for by nurses with different levels of experience; periodic shift changes and lack of 24-hour in-house obstetricians or residents are also realities in most hospitals in the United States. Given these variables, many physicians were favorably inclined toward the use of such protocols as default procedures, allowing them to be assured that with even a basic level of nursing fetal monitoring skills and the ability to count, it is virtually impossible for a patient to be injured by oxytocin if these conservative protocols are followed. In a larger patient population, we foresee numerous situations in which a physician's order to deviate from the protocol may be entirely appropriate. Our design group of practicing physicians and nurses felt, however, that such circumstances would clearly require physician awareness and examination of the specific monitor pattern and overall clinical situation; under such circumstances, we did not feel it unreasonable to ask a physician to articulate her/his rationale for the clinical judgment to deviate from the protocol.

We wish to emphasize that the uniform practice pattern achieved with our protocols is probably as important as the actual details of the protocols themselves. Thus, other criteria for discontinuing oxytocin within a framework of an alternative checklist-based protocol may well have given equivalent results. However, our data support the use of specific checklist-based protocols as one appropriate way to manage oxytocin administration. Labor is not prolonged, cesarean deliveries are not increased, and newborn outcomes appear to be improved. ■

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