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Managing high dose oxytocin via a standardized protocol: An institutional experience

Robert Shapiro, Sandra Dayaratna, Melanie Clemmer, Leo Brancazio

ABSTRACT

Aims: Oxytocin has been on the Institute for Safe Medication Practices (ISMP) high alert medication list since 2007. This raises concern over the safety of oxytocin, especially in higher dose regimens. However, expediting delivery using high dose oxytocin would facilitate care for more patients by decreasing length of hospitalization. Drawing off the experience from the aviation industry, standardized protocols have been shown to increase both safety and efficiency. A high dose, standardized oxytocin protocol may expedite labor without sacrificing patient safety. We evaluated the impact of a high dose oxytocin protocol for labor induction with a hypothesis that length of hospitalization would decrease without adverse obstetrical or maternal outcomes. We further hypothesized that education regarding the use of high dose oxytocin would increase nursing compliance with the protocol. Methods: A retrospective cohort study involving 277 obstetric patients >35 weeks gestation who received oxytocin before protocol and 109 patients after protocol for induction / augmentation of labor. Oxytocin orders were standardized into a "low" and "high" dose protocol. Educational sessions were held to explain the safety and efficacy of these regimens. Obstetric interventions, outcomes, and nursing compliance with oxytocin orders were evaluated before and after standardization. Results: A comparison of intra-partum interventions and outcomes at the time of delivery showed no difference in the rate of occurrence in the before or after protocol implementation (p >0.05). While the overall percentage of patients receiving the high dose oxytocin protocol as ordered improved from 52.8% before protocol implementation to 66.7% after implantation, this difference was not significant (p >0.05). The high dose protocol (6x6) was the only treatment where the patients did not always get oxytocin administered as ordered. The rate of maternal infectious morbidity was reduced almost by half after protocol standardization (5.8% before versus 2.8% after). However, this was not statistically significant (p = 0.21). A significant barrier to implementation of the high dose protocol was nursing compliance with the standard orders (47% before protocol/33% after protocol). Upon further questioning, it was identified this was due to nursing concerns about possible adverse side effects in high risks obstetrical patients. Conclusion: We found no significant difference between the low and high dose protocols as far as the outcome/intervention parameters studied. Nursing compliance proved to be a barrier to implementation of the high dose protocol.

Keywords: High dose oxytocin, Protocol

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INTRODUCTION

Almost four million births occurred in the United States in 2011 and almost one quarter of them were the product of induction of labor [1]. In the United States, induction of labor for singleton births reached a high of 23.8% in 2010, then declined in 2011 (23.7%) and 2012 (23.3%) [2] oxytocin, the only agent available for induction of labor, has been associated with arrhythmias, blood pressure changes, uterine tachysystole, hyponatremia as well as other maternal and fetal adverse effects [1]. Despite these risks, there is variation in the way infusions of oxytocin are run in hospitals. West Virginia University Hospital is a tertiary level, teaching hospital in Morgantown, West Virginia with an annual delivery volume of approximately 1500 babies. The induction rate is 23.4%. Traditionally at our institution, provider preference dictated the way in which oxytocin was administered. There was however some resistance from nursing to use higher dose oxytocin regimens. This may in part be due to declarations such as the 2007 one by the Institute for Safe Medication Practices (ISMP) which added intravenous oxytocin to its list of high-alert medications [3]. Also, the Association of Women's Health Obstetric and Neonatal Nurses (AWHONN) introduced a guideline for professional registered nurse staffing for perinatal units in September 2010, recommending that patients on oxytocin should have a 1:1 nurse to patient ratio [4]. Such attempts to regulate oxytocin administration may have caused concerns about high dose regimens. Low dose oxytocin administration is not without its own set of risks, of course. Low dose regimens have been linked to increased length of induction, higher cesarean section rates, higher infectious morbidity, and higher health care costs due to longer lengths of hospitalization [5–7]. Since we provide high risk obstetrical care for much of West Virginia, and parts of Maryland and Pennsylvania, we are interested in providing safe obstetrical care and at the same time limiting hospital stays in order to enhance access. We hypothesized that a high dose oxytocin protocol for our labor inductions or augmentations would decrease length of hospitalization by expediting delivery without causing any adverse obstetrical or maternal outcomes. We further hypothesized that education regarding the use of high dose oxytocin would increase nursing compliance with the protocol.

MATERIALS AND METHODS

This retrospective cohort study was performed at Ruby Memorial Hospital, West Virginia University, Morgantown, West Virginia. Potential patients were identified from all patients delivering and discharged between (1/1/2011 and 6/29/2011: before) and (8/1/2011 to 9/30/2011: after). A total of 322 patients were identified in the before and 119 patients in the after standardization groups, respectively. Subjects with multiple gestations and augmentation prior to 35 weeks of gestation were excluded, leaving a total study population of 277 patients before and 109 patients after implementation. Patient demographics were collected from electronic medical records. The following demographics were recorded: Age (years) on the day of admission for delivery, ethnicity, marital status, highest education completed and tobacco use (Table 1). Relevant clinical information: whether or not this pregnancy was complicated by pre-eclampsia, gravidity, parity, and occurrence of prior C-section, was also collected from electronic medical records. The use of terbutaline for tachysystole, forceps or vacuum for assisted vaginal deliveries, incidence of cesarean section, maternal infections as a clinical diagnosis of either chorioamnionitis or endometritis, NICU admission of the infant for any indication, and length of hospital stay post-delivery in both groups were identified from patient medical charts. In addition, we evaluated nursing compliance with the ordered protocol.

Sample size calculations for the after standardization group were based on the frequency of occurrence of maternal morbidity in the before standardization group. To achieve 80% power a minimum of 108 patients were required. This study was IRB exempt because it was implemented as a quality improvement project.

Oxytocin at our institution is premixed in a concentration of 30 U/500 mL of normal saline. Before implementation of the protocol, oxytocin was administered in four different ways. The low dose protocol started at 2 mU and increased by 2 mU every 30 minutes to a maximum of 18 mU and the high dose protocol started at 6 mU and increased by 6 mU every 30 minutes to a maximum of 36 mU, both derived per ACOG recommendations [2]. Other ways that oxytocin was prescribed before protocol implementation included doubling the dose every 30 minutes and a combination which was written per the prescribing physician's desire. After implementation of the protocols, the only available options were a low and high dose protocol.

Educational sessions were held with nurses and clinicians to provide instruction on the new protocols as well as address any safety concerns. Once all nursing and physician staff was educated on the new oxytocin protocols, the protocols were implemented.

Pearson's chi-square test was used for most statistical analyses. When the sample size was inadequate for analysis by chi-square then Fisher's exact test was utilized and reported. Significance was determined to be $p < 0.05$ for all tests. A non-parametric t-test, the Wilcoxon Rank Sum test was used to compare length of stay as outlier's precluded normal distribution and transformation was inadequate. All statistics were categorized and completed

using intent to treat. Data were analyzed using JMP and SAS software (JMP®, Version Pro 11, SAS Institute Inc., Cary, NC, Copyright ©2013; SAS®, Version 9.3, SAS Institute Inc., Cary, NC, Copyright ©2002–2010).

RESULTS

A total of 277 patients with singleton gestations and labor induction or augmentation after 35 weeks of gestation were identified prior to protocol

Table 1: Demographic information and relevant obstetrical history for patients in the before and after standardization groups

		Before Standardization	After Standardization	
Demographic/		**n = 277**	**n = 109**	
Clinical Factor		**n (%)**	**n (%)**	**p-value**
Age (years)	≤ 19	28 (10.1%)	14 (12.8%)	0.208
	20–29	154 (55.6%)	53 (48.6%)	
	30–39	89 (32.1%)	42 (38.5%)	
	≥ 40	6 (2.2%)	0 (0%)	
Ethnicity	Caucasian	247 (89.2%)	97 (89.0%)	0.998
	Asian	7 (2.5%)	3 (2.8%)	
	African American	4 (1.4%)	1 (0.9%)	
	Multiracial	2 (0.7%)	1 (0.9%)	
	Other	4 (1.4%)	2 (1.8%)	
	Not recorded	13 (4.7%)	5(4.6%)	
Marital Status	Married	182 (65.7%)	70 (64.2%)	0.540
	Single	88 (31.8%)	38 (34.9%)	
	Divorced/Separated	7 (2.5%)	1 (0.9%)	
Education	Some HS	24 (10.0%)	16 (16.2%)	0.164
	Completed HS	59 (24.7%)	19 (19.2%)	
	Some College	56 (23.4%)	31 (31.3%)	
	Completed College	47 (19.7%)	13 (13.1%)	
	Advanced Degree	53 (22.2%)	19 (19.2%)	
	Not recorded	38	11	
Tobacco Use	Never	185 (66.8%)	64 (58.7%)	0.205
	Former	39 (14.1%)	18 (16.5%)	
	Current	53 (19.1%)	26 (23.9%)	
	Never Assessed	0 (0%)	1 (0.9%)	
Pre-Eclampsia	None	257 (92.8%)	100 (91.7%)	0.831
	Mild	13 (4.7%)	5 (4/6%)	
	Severe	7 (2.5%)	4 (3.7%)	
Gravidity	1	131 (47.3%)	42 (38.5%)	0.080
	2	72 (26.0%)	32 (29.4)	
	3	42 (15.2%)	16 (14.7%)	
	4	24 (8.7%)	9 (8.3%)	
	≥5	8 (2.9%)	10 (9.2%)	
Parity	0	156 (56.3%)	54 (49.5%)	0.113
	1	74 (26.7%)	32 (29.4%)	
	2	38 (13.7%)	13 (11.9%)	
	3	7 (2.5%)	6 (5.5%)	
	≥4	2 (0.7%)	4 (3.7%)	
Prior C/S	No	264 (95.3%)	107 (98.2%)	0.250
	Yes	13 (4.7%)	2 (1.8%)	

implementation and 109 after protocol implementation. No differences were identified in patient demographics at the time of admission, current diagnosis of pre-eclampsia, gravidity, parity, or prior cesarean section as the two populations were very homogeneous (Table 1). The average gestational age at delivery was 38w6d for the before protocol implementation and 39w 6d for the after protocol implementation groups.

A comparison of interventions at the time of delivery (use of Terbutaline, forceps, vacuum, or cesarean section) showed no difference in the rate of occurrence in the before or after protocol implementation for each specific type of intervention or all types of intervention combined (Table 3, p >0.05). Although fewer babies were admitted to the NICU for any indication after standardization (7.2% before versus 6.4% after) this difference was not significant (p >0.05). Days spent in the hospital after delivery did not differ before or after standardization (3.0±1.8 days and 3.2±2.2, respectively; p = 0.6). Although the rate of maternal infectious morbidity was reduced almost by half after protocol standardization (5.8% before versus 2.8% after), this was not statistically significant (Table 3, p = 0.21).

The number and percentage of patients receiving oxytocin using the low dose, high dose or other doses are shown in Table 2. Both before and after implementation of the protocol, the low dose oxytocin treatment was ordered most frequently (p = 0.005). With the elimination of individualized oxytocin ordering, physicians more frequently opted for the high dose (6x6) oxytocin treatment after standardization (Table 2). While data was analyzed by treatment option as an intent to treat, it was noted that some of the patients in the high dose group did not have their oxytocin run as ordered by the physician (n = 25 before and n = 10 after). All of the patients in the low dose group had their oxytocin run as ordered. While the overall percentage of patients receiving the high dose oxytocin protocol as ordered improved from 52.8% before protocol implementation to 66.7% after implantation, this difference was not significant (p >0.05). The high dose protocol (6x6) was the only treatment where the patients did not always get oxytocin administered as ordered.

We found no difference between the low and high dose protocols as far as the clinical outcome parameters studied, except a trend toward lower infectious morbidity. We also found that a significant barrier to implementation of the high dose protocol was nursing compliance with the standard orders. Upon further questioning, it was identified this was due to nursing concerns about possible adverse side effects in high risks obstetrical patients.

Table 2: Frequency of use for each Pitocin treatment options before and after standardization of the protocol, N (% of total)

Treatment	Before (n =277)	After (n = 109)
High (6x6)	53 (19.1%)	30 (27.5%)
Low (2x2)	192 (69.3%)	77 (70.6%)
Double	26 (9.4%)	0 (0.0%)
Combination	6 (2.2%)	2 (1.8%)

Table 3: Obstetrical outcomes in the before and after protocol standardization groups.

Delivery Intervention	Before (n = 277)	After (n = 109)	p-value
Terbutaline	20 (7.2%)	9 (8.3%)	0.728
Forceps	5 (1.8%)	2 (1.8%)	0.984
VAVD	11 (4.0%)	7 (6.4%)	0.304
Cesarean	52 (18.8%)	17 (15.6%)	0.464
Total	88 (31.8%)	35 (32.1%)	0.948
Outcomes			
NICU	20 (7.2%)	7 (6.4%)	0.78
Length of Stay (in days)	3.0±1.8	3.2±2.2	0.60
Maternal Infectious Morbidity	16 (5.8%)	3 (2.8%)	0.21

DISCUSSION

Most studies that evaluate protocol implementation advocate education as primary means to change practice patterns. Krening et al. developed a quality-based oxytocin protocol to decrease the risk of exposure to the drug and thereby decrease potential morbidity. After competency training, the outcomes from the protocol included shorter lengths of labor, decreased tachysystole, and decreased incidence of cesarean section [8].

Educational advocacy of a high dose oxytocin regimen was not enough to change nursing practice patterns during the course of our study. This is somewhat surprising given that practicing nurses and physicians had considerable input into the development of the high dose oxytocin protocol before data were obtained from the current study.

Drawing from experience in the aviation industry, standardized protocols have been applied in various health care settings and operating rooms [9]. Strict adherence to safety protocols has been widely shown to reduce errors in patient care and prevent untoward outcomes, such as infection [10].

After the oxytocin protocol was implemented in our study, overall infectious morbidity decreased by about 50 %, irrespective of high or low dose. Even though this did not reach statistical significance, this is still relevant given the large role infection plays in prolonged hospitalization, intensive care admission, and adverse maternal/neonatal outcomes. According to Pfitscher et al., of the Brazilian Network for Surveillance of Severe Maternal Morbidity, infection was responsible for one-fourth of all maternal near misses and nearly half of all maternal deaths [11].

One of the limitations of this study is that it remains unknown why the high-dose oxytocin protocol was not implemented even though it was ordered, other than anecdotal concerns from individual nurses.

Sometimes, institutional protocols may be perceived differently by various health care providers. Johns Hopkins surveyed their obstetric providers regarding whether clinical protocols resulted in better practice and improved patient safety. Their results showed that although clinical protocols were generally well received, significant differences exist among provider attitudes toward the importance of such protocols ensuring patient safety [12]. Given this study is a retrospective cohort, it does not allow for a contemporaneous control group for comparison. Even a year difference has resulted in a change in practice as can be seen by the impact of the March of Dimes initiative to decrease late preterm deliveries [13], which happened before the implementation of the standardized protocol. This resulted in a change in the average gestational age for the two groups. Our hospital initiated a policy in accordance with the March of Dimes initiative to decrease late preterm deliveries. This is reflected in the gestational age difference between the two arms of the study. Also, variables such as length of hospitalization, infectious morbidity, and maternal/neonatal complications could be influenced by confounding factors other than oxytocin dosage, especially in a high risk obstetrical population.

Most professional medical organizations like the American College of Obstetrics and

Gynecology (ACOG) incorporate evidence based medicine into clinical practice guidelines, as a service to healthcare providers [14]. Individual autonomy, lack of experience, and an overall tendency to resist change have all been linked as potential barriers to standardized protocols, despite their evidence based approach [15]. As seen in our study, education alone may not be enough to sway practice styles. Compared to low dose Oxytocin, a high dose oxytocin protocol may be an effective means to expedite delivery, decrease length of hospitalization, and improve overall efficiency [16]. However, if it is perceived as dangerous despite evidence based studies to the contrary, it does not really matter. Further studies are needed to address the efficacy of treatment protocols within the obstetric population and how to better implement them.

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Author Contributions

Robert Shapiro – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published
Sandra Dayaratna – Substantial contributions to conception and design, Acquisition of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published
Melanie Clemmer – Substantial contributions to conception and design, Acquisition of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published
Leo Brancazio – Substantial contributions to conception and design, Acquisition of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published

Guarantor

The corresponding author is the guarantor of submission.

Conflict of Interest

Authors declare no conflict of interest.

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