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Oxytocin Use in Labor

Legal Implications

Susan Drummond, MSN, RN, C-EFM

ABSTRACT

Oxytocin is one of the most commonly used medications in obstetrics and has been associated with claims of negligence in cases of adverse outcomes. Errors involving intravenous oxytocin administration for induction or augmentation of labor are most commonly dose related and include failure to avoid or treat tachysystole or failure to asses or treat a fetal heart rate pattern indicative of disruption in oxygenation. Clinicians should be knowledgeable regarding pharmacokinetics of oxytocin and the effect of uterine contractions on fetal oxygenation as well as safe titration of oxytocin to achieve the desired effect while minimizing harm.

Key Words: fetal oxygenation, oxytocin, patient safety, tachysystole

Oxytocin is one of the most frequently used medications in obstetric practice. Sir Henry Dale discovered it in 1909 and named it "oxytocin," using the Greek words for "quick" and "birth."[1] Vincent du Vigneaud synthesized oxytocin in 1954, and his work, the first synthesis of any peptide hormone, resulted in his winning the Nobel Prize in Chemistry in 1956.[2] Before 1990, induction of labor occurred in less than 10% of singleton births. After nearly 20 years of consecutive increases, labor induction for singletons reached a high of 23.8% in 2010 and then started to decline. By 2012, the rate was 23.3%.[3] The decreasing rate is largely attributed to the nationwide decrease in elective inductions prior to 39 completed weeks of gestation.[4]

In most instances, vaginal delivery poses less risk than delivery by cesarean section. Delivery before the onset of spontaneous labor is indicated when the maternal and/or fetal risks of continuing the pregnancy outweigh the maternal/fetal risks of delivery.[4] A Cochrane review that included 61 trials found that when oxytocin inductions were compared with expectant management, more women in the induction group delivered vaginally within 24 hours.[5] In another review, women induced at 37 to 40 completed weeks were less likely to have a cesarean delivery than those in the expectant management group.[6] No convincing evidence exists that elective induction is associated with a considerable increase in the rate of cesarean delivery.[7,8] Postterm pregnancy (>42 completed weeks) has been associated with higher risks of macrosomia, birth injury, and stillbirth. The World Health Organization recommends induction of labor for women who are at or beyond 41 weeks' gestation.[9] However, indications for induction of labor are not absolute. Both maternal and fetal factors are considered when planning a scheduled delivery. In general, a contraindication for induction is the same as a contraindication for spontaneous labor.

Oxytocin is also widely utilized for labor augmentation. Although the frequency of oxytocin use varies widely among hospitals in the United States, it may be used in as many as 50% of laboring women.[10] While issues related to oxytocin use in labor have long been seen frequently as allegations in medical malpractice cases, a recent trend of plaintiffs' allegations regarding uterine activity and head compression during labor makes it clear that oxytocin use and clinical management of uterine activity during labor are areas of great importance in the defense of perinatal malpractice claims.[11] This article

Author Affiliation: Department of OBGYN, Vanderbilt University School of Medicine, Nashville, Tennessee.

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Corresponding Author: Susan Drummond, MSN, RN, C-EFM, Department of OBGYN, Vanderbilt University School of Medicine, B-1100 MCN, 1161 21st Ave S, Nashville, TN 37232 (susan.drummond@vanderbilt.edu).

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discusses the legal implications of oxytocin when used in obstetric practice, including dosing, assessment and management of uterine activity, effects of uterine activity on fetal oxygenation, and recommendations for safe nursing practice.

OXYTOCIN ADMINISTRATION AND TITRATION

For labor induction or augmentation, oxytocin is used as an intravenous infusion of a dilute solution. While there is no universal standard for dilution, clinicians must be aware of and document the dosage titrated in milliunits per minute (mU/min). A common approach is to make a solution of 30 units of oxytocin in 500 mL of crystalloid to allow the infusion pump setting (milliliters/hour or mL/h) to match the dose administered (mU/min). This regimen essentially eliminates the risk of arithmetic errors in dosing and therefore promotes patient safety. The goal of oxytocin usage is to promote contractions that result in a labor pattern similar to spontaneous labor. Oxytocin has a relatively short plasma half-life, approximately 3 to 6 minutes.[12] Uterine response occurs within 3 to 5 minutes, and steady levels of plasma are achieved by 40 minutes.[13] Whether used for induction or augmentation of labor, oxytocin dosing is titrated to stimulate a uterine contraction pattern that is similar to that seen with spontaneous labor. The dose is generally increased every 15 to 30 minutes until regular contractions of moderate strength and lasting approximately 60 to 90 seconds are occurring every 2 to 3 minutes.[14] The association of an infused rate of oxytocin to natural levels occurring during labor has also been described. An infusion rate of 4 to 6 mU/min achieves serum levels consistent with the spontaneous level of oxytocin during the first stage of labor.[15] It has been reported that discontinuation of oxytocin (when utilized for induction of labor) once the active phase of labor is achieved does not prolong the active phase, as labor is likely self-sustaining at this point.[16,17] This may not be an appropriate plan for all inductions, but consideration could be made to maintaining or decreasing the rate when there is evidence of adequate labor as opposed to continuing or increasing the dosage.

The number and function of oxytocin receptor sites in uterine smooth muscle are an important consideration in understanding uterine response to oxytocin. Receptor sites increase in number as gestation progresses and further increase during labor. These sites can get oversaturated, leading to decreased muscle function. Myometrial samples from women who underwent cesarean section following labor were analyzed. Samples after 12 hours of labor contained approximately 50 times less oxytocin receptors than samples from women in labor for less than 12 hours.[18] Not only does decreased sensitization to oxytocin result in less effective labor but it may also increase the risk of postpartum hemorrhage (PPH) from uterine atony.[19] In one study, severe PPH was more likely when oxytocin was infused for a longer duration prior to birth. Exposure to 20 mU/min of oxytocin for 4.2 hours or more significantly increased the odds of sever PPH.[20] Therefore, administering oxytocin at the lowest effective dose for the shortest duration possible to achieve the desired effect on labor may help reduce clinically significant PPH.[21] This is consistent with one of the basic tenets of pharmacology, that of utilizing the lowest possible dose of a drug to achieve its desired result. Given that the legal standard of care is based on reasonableness, it would seem prudent to adhere to a lower dosage of oxytocin as long as it was effective.

A variety of dosing regimens for oxytocin have been proposed in the literature. The American College of Obstetrics and Gynecology (ACOG) advocates a low-dose regimen starting at 0.5 to 2 mU/min, with incremental increases of 1 to 2 mU every 15 to 40 minutes. A suggested high-dose regimen begins at 6 mU/min, with increases of 3 to 6 mU every 15 to 40 minutes.[4] Additional studies have investigated the impact of a high-dose regimen (starting dose of 4 mU/min, with increases of 4 mU/min every 30 minutes) on outcomes. Higher-dose regimens are associated with a slightly shorter duration of labor without increasing the cesarean section rate or adverse neonatal outcomes.[10,22] However, there is an increase in episodes of tachysystole associated with higher-dose approaches. This, along with the previously noted increase in PPH, warrants thoughtful consideration of both dosing and titration. In both low-dose and high-dose protocols, the dose is typically increased until labor progress is achieved (as evidenced by cervical change and/or fetal descent); or moderate-strong contractions occur every 2 to 3 minutes; or uterine activity reaches 200 to 250 MVU (Montevideo units).[14] Although a numeric value for the maximum dose of oxytocin has not been established, sustained doses higher than 20 mU are associated with a greater risk of PPH and may pose defensibility issues should litigation occur. While an ideal guideline has not been established, hospitals and hospital systems are encouraged to develop standardized guidelines for oxytocin administration and usage.

ASSESSMENT OF UTERINE ACTIVITY

In 2008, the ACOG and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) published a workshop report on electronic fetal monitoring (EFM).[13,14] The report stated that uterine contractions are quantified as the number of contractions

present in a 10-minute window, averaged over 30 minutes.[23,24] Two summary terms related to the frequency of uterine contractions were defined. Uterine contraction frequency is considered *normal* when there are 5 or fewer contractions in 10 minutes, averaged over a 30-minute window. When uterine contraction frequency is more than 5 contractions in 10 minutes, averaged over a 30-minute window, it is called *tachysystole*. The report states that tachysystole should be qualified as to the presence or absence of associated fetal heart rate (FHR) decelerations and applies to spontaneous as well as induced labors. The report went on to state that other characteristics of uterine activity were equally important; these included duration, intensity, and relaxation time.[23,24] For example, a pattern of uterine activity where there are an average of 4 contractions in 10 minutes over 30 minutes will never be tachysystole, but if the contractions are palpably moderate and 2 minutes in duration, they may interfere with adequate fetal oxygenation and the uterine activity would be considered excessive. This makes it clear that a complete evaluation of uterine activity includes much more than the frequency of uterine contractions. Titration of oxytocin and management of uterine activity require all clinicians be knowledgeable of definitions for uterine activity as well as the physiology of uterine activity and fetal oxygenation. Definitions of uterine activity in labor are listed in Table 1.

EFFECT OF UTERINE ACTIVITY ON FETAL OXYGENATION

Labor is defined as uterine contractions that produce cervical dilation and effacement. Oxygenated blood leaving the maternal heart travels through the systemic vasculature to the uterine artery and finally to the spiral arteries before entering the intervillous space of the placenta. Uterine contractions cause intramyometrial pressures (IMP) to rise, which leads to diminished blood through the spiral arteries. When the IMP equals the mean arterial pressure, blood flow stops.[25] As the contraction eases, blood flow through the spiral arteries resumes and by the end of the contraction blood flow is back to normal. One might equate this to an adult holding his breath briefly and intermittently with normal breathing between. For a normally grown term fetus with a well-functioning placenta, this interruption is trivial and well tolerated. The healthy, term fetus is physiologically developed to withstand these normal transitory changes through a variety of beneficial mechanisms, including shunts in the fetal cardiovascular system and fetal hemoglobin's increased affinity for oxygen. These and other mechanisms are adequate for the fetus to tolerate disruption posed by normal labor without a change in fetal oxygen saturation. However, if contractions are too frequent, resulting in relaxation time between contractions being shortened or incomplete, fetal hypoxemia may ensue. This can also occur with normal relaxation times if resting tone is elevated. In addition, the fetus who enters labor in a less than optimal state (ie, intrauterine growth restriction, prematurity, etc) may not even tolerate normal uterine activity.

Bakker and colleagues[26] reported an increased incidence of fetal acidemia where there was excessive uterine activity during the first or second stage of labor, stressing the importance of relaxation time. Johnson et al[27] demonstrated incomplete recovery of fetal oxygen saturation (Sao *x*) to baseline levels when contractions were occurring every 2 minutes or more. Peebles et al[28] observed that contractions occurring at intervals less than 2 minutes were associated with a decrease in fetal cerebral oxygenation as detected via near infrared spectroscopy.[28] Fetal SaO_2 initially rises at the beginning of a contraction; after initial increase, O_2 saturation declines and persists until the contraction has ceased. An example of fetal SaO_2 response to uterine activity is illustrated in Figure 1.

Ideal contraction interval in which fetal cerebral O_2 saturation remains stable or even increases is 2.3 minutes or longer.[29] Simpson and James[30] also noted decreasing fetal SaO_2 over a 30-minute period when 5 or

Table 1. Definitions of uterine activity in labor

Frequency	The time from beginning of one contraction to beginning of the next contraction (may be expressed as the number of contractions in a 10-min window). Frequency of contractions is considered *normal* if the frequency is ≤5 in 10 min, averaged over a 30-min window; it is considered *tachysystole* if the contraction frequency is >5 in 10 min, averaged over a 30-min window.
Duration	The time between the onset and the offset of a contraction.
Intensity	A value calculated by subtracting the resting tone from the peak of the contraction in mm Hg; it can only be accurately determined with an intrauterine pressure catheter.
Resting tone	The intrauterine pressure when the uterus is not contracting (may be measured by palpation when using a tocotransducer or in mm Hg when using an intrauterine pressure catheter).
Relaxation time	The time from the end of one contraction until the beginning of the next.
Montevideo units	A calculated value obtained by adding the intensities of all contractions in a 10-min window.[24,29]

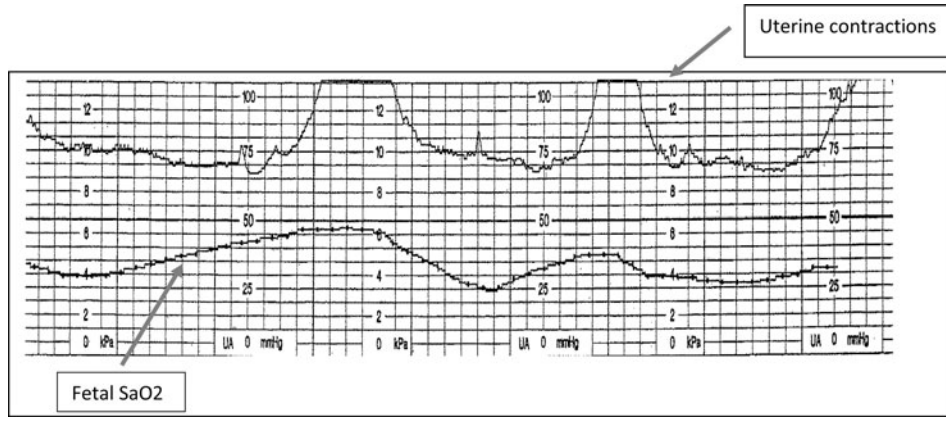

Figure 1. Fetal Sao_2 response to uterine activity. Note that fetal Sao_2 is maintained through the majority of the contraction but once it starts decreasing, it takes 50 to 60 seconds of relaxation time before Sao_2 starts to rise again.

more contractions occurred. The phase and stage of labor are also important when managing uterine activity and titrating oxytocin. In latent-phase labor, when contractions are fewer in frequency and lesser in intensity, labor has essentially no effect of fetal base deficit. But as labor progresses and contractions become closer and stronger, fetal base deficit is affected because of normal oxidative stress. Base deficit may increase by 1 every 3 hours in active phase of the first stage and by 1 every hour in the second stage with active pushing.[31] Thus, a clinician who attempts to create a second-stage contraction pattern during the latent phase of labor in an induction of labor may be setting up the fetus for acid-base deterioration later in labor. Some clinicians have the impression that if the mother is not feeling the contractions, they are not having any effect on the fetus, but this is neither scientific nor logical. Maternal discomfort is a subjective measure, not objective, and the effect of uterine contractions on fetal acid-base and oxygenation is well documented.

Evidence clearly supports avoiding or promptly treating tachysystole or other types of excessive uterine activity.[26,27,30] Intervening for tachysystole by decreasing or discontinuing oxytocin is advised by the ACOG.[4] Knowledge of the effects of excessive uterine activity on fetal oxygenation demands intervening at the time it is noted, rather than waiting to intervene until there is evidence of interrupted fetal oxygenation. Most cases of excessive uterine activity are oxytocin dose related and will be resolved by decreasing the infusion rate. Research has demonstrated that collective use of discontinuing oxytocin, lateral positioning, and an intravenous fluid (IVF) bolus of approximately 500 mL may be more effective in resolving oxytocin-induced tachysystole more rapidly than just 1 or 2 of the aforementioned interventions.[30] A meta-analysis of 11 randomized clinical trials demonstrated that low-dose oxytocin protocols in which doses were not increased more frequently than every 30 minutes resulted in fewer episodes of tachysystole and higher rates of spontaneous vaginal birth.[32] Preventing tachysystole with careful low-dose oxytocin titration and promptly treating it when it occurs will decrease the risk of injury to the fetus and therefore decrease the risk of litigation. It is imperative to also note contraction duration and intercontraction interval/relaxation time. Patient A may be having 5 contractions in 10 minutes, with each contraction lasting 60 seconds, therefore giving 60 seconds of relaxation time between each. Patient B may also be having 5 contractions in a 10-minute period, but each contraction is lasting 90 seconds. This results in only 30 seconds of relaxation time between each. Although neither patient meets the criteria for tachysystole, patient B may show signs of fetal hypoxemia due to the shortened time available for oxygen to be replenished.

Oxytocin was added to the list of high-alert medications designated by the Institute for Safe Medication Practices in 2007; the medications on this list are defined as those "bearing a heightened risk of harm when used in error."[33] This designation does not deem the medication *dangerous*, but it alerts the nurse to be vigilant about dose titration while carefully observing the maternal and fetal response. Of note, 2 other medications commonly used in obstetric practice are on the list: magnesium sulfate and insulin. These medications are clearly capable of posing harm when given in incorrect dosages, but when used correctly not only are not dangerous but are also beneficial. As noted earlier, using the lowest possible dose to achieve the desired effect is the goal.

OXYTOCIN IN LITIGATION

Oxytocin remains one of the most commonly used medications in obstetric practice and clearly has been associated with claims of medical negligence in cases of adverse outcomes. Injudicious use of oxytocin is a common allegation in malpractice claims. In one study of 77 obstetric malpractice cases, 68.5% had this claim.[34] Another study revealed that oxytocin is in the top 10 medications associated with medication errors and the most common obstetric medication associated with harm.[35] In the United States, the patient alleging medical malpractice must generally prove 4 requirements: (1) duty by the physician/nurse to provide care or treatment to the patient; (2) a breach of this duty by failing to adhere to standards of the profession; (3) a causal relationship between the breach and injury to the patient; and (4) the existence of damages that flow from the injury.[36] Nurses are often accused of breaching the standard of care regarding use of oxytocin. The allegations may read "administering extremely high doses of oxytocin" or "causing excessive uterine activity." Standard of care is typically defined as the care that a reasonable similarly trained professional would provide in a similar situation. Meeting the standard of care means providing "reasonable" care to the patient. The following case example is provided as an illustration.

CASE EXAMPLE

A 26-year-old G1 at 41$^5/_7$ weeks with scheduled induction of labor due to prolonged pregnancy. On admission, FHR tracing was category I. Following cervical ripening with misoprostol, labor induction was started with oxytocin at 2 mU/min. Hospital guidelines stated to "increase oxytocin at 1-2 mu/min q 30 min" to achieve a "normal labor pattern." In Figure 2A, the patient is in active labor, with the most recent cervical examination of 6 cm/80%/−1. There are 6 contractions in 10 minutes; this is representative of the frequency of contractions over the last 1 to 2 hours. Oxytocin is infusing at 14 mU/min. RN documents increasing oxytocin to "achieve normal labor pattern." The fetus is tolerating the uterine activity at this time with accelerations noted and no decelerations. Ignoring uterine tachysystole, the nurse continued to increase the oxytocin, although the patient was making adequate cervical change.

Four hours later, dilation is complete and the patient is pushing. Oxytocin has been maintained at 18 mU/min for the past 2 hours. Figure 2B reveals a tracing that is barely interpretable, with recurrent decelerations likely and no ability to accurately assess variability and rule out fetal metabolic acidemia. There is evidence of closed glottis pushing and a lack of adequate relaxation time. The nurse documented that the tracing had minimal/moderate variability at this time, nothing was noted about interventions or abnormal uterine activity, and the oxytocin dose remained unchanged. At delivery, the infant had Apgar scores of 2 at 1 minute and 3 at 5 minutes and was later diagnosed with hypoxic ischemic encephalopathy. Continuing to increase oxytocin with uterine tachysystole and failing to discontinue or decrease oxytocin with a tracing that has evidence of decelerations and little other interpretable data are unreasonable and therefore below the standard of care for an obstetric nurse. The plaintiff's attorney did not have much difficulty demonstrating these standard-of-care violations during deposition, and the case was settled for an undisclosed sum.

PROMOTING SAFE USE OF OXYTOCIN

Imprudent use of oxytocin is a common allegation in malpractice claims, and it is the most common obstetric medication associated with harm.[35] Yet, alternatives to oxytocin augmentation are not always considered by clinicians. The consideration of muscle hydration in the correction of dysfunctional labor is one example. Many labor and delivery units administer 125 mL/h of plain IVF to patients in labor. This is routine regardless of the patient's additional oral intake. More aggressive hydration (250 mL/h vs 125 mL/h) has been shown to decrease labor duration and reduce the need for oxytocin administration.[37,38] Additional evidence also suggests a similar beneficial effect of administering glucose-containing IVF in shortening labor and avoiding oxytocin use.[39] In one study, more aggressive hydration (250 mL/h) with normal saline was compared with the same rate of normal saline with 5% dextrose. The group of patients who received the glucose-containing solution had significantly shorter labor duration with no difference in the rate of cesarean delivery, instrumental delivery, Apgar scores, or arterial cord pH.[40] Clear liquids taken orally may also aid in keeping the patient well hydrated, and encouraging clear liquids is reasonable for uncomplicated low-risk labors.[41]

Appropriate nurse-to-patient ratios are a critical consideration when oxytocin is used. The AWHONN published updated staffing guidelines in 2010 and recommended a 1:1 nurse-to-patient ratio for patients receiving oxytocin for induction/augmentation of labor.[42] A retrospective analysis of more than 200 000 perinatal outcomes in women receiving oxytocin for induction or augmentation of labor found no relation between the frequency of 1:1 nurse-to-patient ratio and improved perinatal outcomes.[43] However, benefits of receiving continuous support during labor have been reported and include shorter labors, decreased need for oxytocin, and increased satisfaction with the childbirth

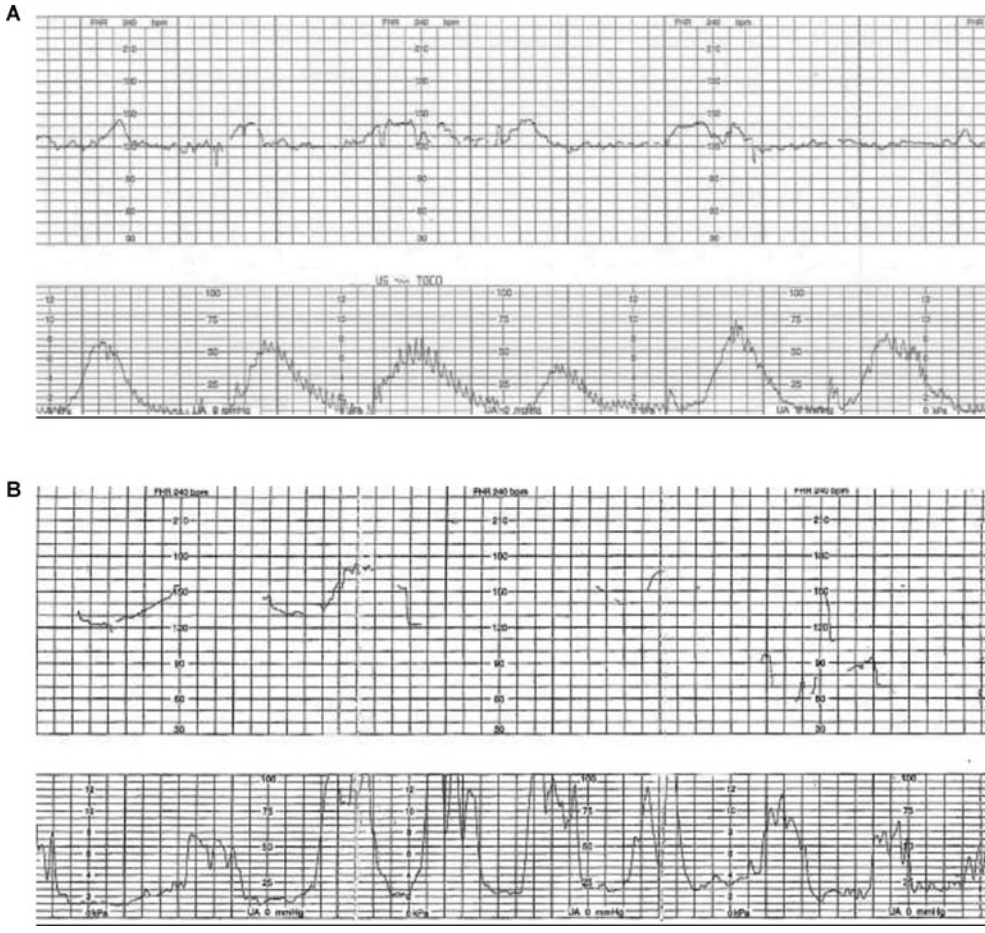

Figure 2. (A) Note that uterine tachysystole is occuring but evidence of adequate fetal oxygenation is present at this time. (B) Continued tachysystole has resulted in disruption of oxygen delivery to the fetus.

experience.[44,45] Each hospital must make individual decisions regarding staffing patterns and nurse-to-patient ratios taking into account patient acuity. A patient without risk factors in term labor who requires oxytocin augmentation represents a very different acuity level than a preterm patient with preeclampsia and a severe range of blood pressures undergoing induction of labor with oxytocin. The acuity level of any given patient may change during the labor process, necessitating a change in staffing patterns.

Thorough and ongoing assessment of uterine activity and FHR patterns is essential to guide titration of oxytocin. Use of an oxytocin pre-use and/or in-use checklist has been proposed as a method of increasing safety.[46,47] But one researcher found higher rates of chorioamnionitis, longer median time from admission to delivery, and more cesarean deliveries performed for labor dystocia after implementing a checklist-based oxytocin protocol.[48] Whether or not a checklist is used, one must not ignore the significance of critical thinking by the nurse managing the titration of oxytocin for induction or augmentation of labor. The process of critical thinking is stimulated by integrating the essential knowledge, experiences, and clinical reasoning that support professional practice. If a checklist is used, it must be designed to promote patient safety without unduly burdening the nurse with yet another task. A poorly designed or overly lengthy checklist can harm performance just as easily as a good one can improve it. In addition, charting FHR and uterine activity assessments in a flow sheet and on a checklist can potentially be a legal liability if the dual documentation creates a discrepancy. In reports where authors suggest that the use of an oxytocin checklist improved outcomes, it is worth considering whether the checklist made the difference or whether education of staff when implementing the checklist made the difference. No flow sheet or checklist exists that can take the place of a well-educated labor nurse using critical thinking at the bedside to make determinations on oxytocin titration.

Table 2. **Promoting safe nursing practice in oxytocin administration**

- Standard pharmacy preparation of oxytocin infusion
- Multidisciplinary education regarding pharmacokinetics of oxytocin and the effect of uterine contractions on fetal oxygenation
- Physician with cesarean section privileges readily available to respond to an emergency
- Promotion of uterine muscle function through adequate hydration and patient positioning
- Frequent nursing presence at the bedside to fully assess uterine activity and fetal heart rate response
- Once active labor is established, consider decreasing oxytocin to the lowest amount necessary for maintenance
- Promptly treat excessive uterine activity, regardless of any changes in the fetal heart pattern
- Consider the use of intrauterine pressure catheters when the contraction frequency seems adequate but is not resulting in labor progress
- Encourage multidisciplinary collaboration when developing oxytocin guidelines
- Consider low-dose, low-frequency dosing to avoid tachysystole and decrease risk of PPH
- Utilize correct definitions for the parameters of uterine activity evaluation
- Include recognition of all types of excessive uterine activity in oxytocin titration as opposed to a focus only on summary terms normal/tachysystole, as these only apply to contraction frequency
- Dosing should be documented and discussed in milliunits per minute regardless of dilution
- Standardize oxytocin dosing to decrease potential for error; do not allow a variety of dosing regimens[14,23,24,26,50]

Abbreviation: PPH, postpartum hemorrhage.

Hospitals are encouraged to develop uniform guidelines for the administration of oxytocin. The literature supports that standardization of procedures leads to fewer adverse events and decreased litigation.[49] It is crucial to remember that guidelines are suggestions for care, not rules, and having unit-based guidelines for oxytocin administration is not a substitute for critical thinking and nursing judgment.

When needed for induction or augmentation, nurses should carefully titrate the medication with vigilant assessment of uterine activity and fetal response. Knowledge of the National Institute of Child Health and Human Development terminology for interpreting EFM tracings and patterns that indicate fetal hypoxemia is essential for all clinicians involved in caring for the patient undergoing induction or augmentation of labor. Avoid tachysytole as well as other types of excessive uterine activity if possible and promptly treat it when it occurs. Maintain open communication with obstetric care providers regarding labor progress and any indications in the EFM tracing of disruption in fetal oxygenation. A summary of collaborative, evidence-based recommendations for safe administration of oxytocin is found in Table 2.

CONCLUSION

If there is no contraindication to labor, there is no contraindication to carefully administered oxytocin. Disagreement regarding the use of oxytocin is a common cause of dissonance between physicians and labor nurses.[36] All who provide care to patients in labor must be knowledgeable regarding management of uterine activity, careful titration of oxytocin, and the effects of uterine activity on fetal oxygenation. Multidisciplinary education regarding physiology of uterine contractions, pharmacokinetics of oxytocin, definition of normal uterine activity versus tachysytole, and institutional guidelines for the administration of oxytocin is essential. A physician in an office setting must be able to trust the labor nurse at the bedside to safely administer oxytocin while monitoring maternal and fetal response. If the nurse discontinues oxytocin due to concerns for fetal oxygenation, the physician must be able to trust the knowledge and judgment of the nurse. In addition, the nurse must be able to trust the physician to come to the patient's bedside if needed for evaluation of labor progress or fetal status. When nurses and physicians who are working together in a labor and delivery unit are jointly educated, increased trust regarding oxytocin use in labor management will ultimately ensue. Appropriate administration of oxytocin, open communication, and trust will promote safe patient care and therefore decrease the risk of litigation.

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