OBG MANAGEMENT

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Reducing the legal risks of labor induction and augmentation

Specific tactics minimize the chance of adverse oxytocin-related outcomes—and a flurry of allegations

IN THIS ARTICLE

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WHAT'S YOUR VERDICT?

Does this patient have grounds for a lawsuit?

At 41 weeks' estimated gestation, Elena, a 32-year-old primipara with an uneventful antepartum course, is scheduled for induction of labor for postdates. On admission she is 1 cm dilated and 70% effaced, with the fetal vertex at –3 station. Fetal heart rate monitoring shows a normal baseline, moderate variability, and accelerations. No decelerations are observed.

After the membranes are ruptured artificially, labor progresses slowly, and chorioamnionitis is suspected.

Fetal tachycardia with minimal variability and variable decelerations develops. Oxytocin is titrated to achieve uterine contractions every 2 minutes. Elena eventually becomes completely dilated and pushes for 95 minutes. During this time, the fetal variable decelerations increase in duration, with loss of variability and continued tachycardia.

Because of these findings, delivery is expedited with a vacuum extractor. The newborn is depressed, admitted to the neonatal intensive care unit for respiratory support to "rule out sepsis," and is later found to have neurologic injury.

In your opinion, does Elena have grounds for a lawsuit?

If such a case spurs a lawsuit, as it often will, the plaintiff's attorney is likely to declare any or all of these allegations:

- failure to discontinue oxytocin in light of nonreassuring fetal heart rate
- failure to identify and respond to uterine hyperstimulation
- failure to identify and respond to fetal distress
- failure to react in a timely manner to fetal distress
- inappropriate delivery method
- failure to use a fetal scalp electrode
- failure to recognize and act upon arrest of dilatation in a timely manner

These allegations are only the most probable ones in circumstances such as Elena's. When unanticipated morbidity or death occurs after oxytocin is used, physicians and nurses may find themselves facing any of the 18 allegations listed in the **TABLE** on page 33—or even others.

In court, these allegations will be based on the opinions of independent physicians, certified nurse-midwives, and registered nurses with the education, experience, and credentials to qualify as "experts." Courts usually allow experts when the substance of the allegations is beyond the public's general knowledge.

Although allegations often include inaccuracies, erroneous assumptions, and

conclusions based on "information and belief" rather than scientific evidence, they remain part of the claim until disproved over the course of the legal proceedings.

Elective inductions can spell trouble

Although the rate of induction has more than doubled since 1989, to 20.6% of births or more than 840,000 pregnancies in 2003,[1] still no consensus exists for patient selection. In some centers, inductions are reserved for women with medical indications only, whereas in others, more than half are elective.[2]

Because of this divergence, when there is a negative outcome after an elective induction, the obstetrician can anticipate an allegation of unnecessary induction due to lack of a medical indication.

TABLE

18 common allegations in oxytocin-related litigation

1.	Unnecessary induction due to lack of medical indication
2.	Failure to establish fetal well-being prior to initiating oxytocin
3.	Failure to adequately monitor fetal heart rate during oxytocin infusion
4.	Failure to adequately monitor uterine contractions
5.	Failure to place a spiral electrode and/or intrauterine pressure catheter
6.	Failure to discontinue oxytocin in light of nonreassuring fetal heart rate
7.	Failure to identify and respond to fetal distress
8.	Delay in identifying and responding to nonreassuring fetal heart rate
9.	Failure to notify provider of nonreassuring fetal heart rate
10.	Failure to identify and respond to uterine hyperstimulation and/or elevated resting tone
11.	Inappropriate titration of oxytocin not based on accepted protocols
12.	Administration of oxytocin without a physician's order
13.	Failure to follow physician's order
14.	Failure to order a cesarean section when fetal heart rate became nonreassuring
15.	Delay in cesarean section after being ordered by the physician
16.	Failure to follow hospital policies and procedures
17.	Inadequate policies and procedures governing oxytocin administration
18.	Failure to initiate chain of command

Fetal monitoring

Proven or not, it's the norm

Although we lack overwhelming proof of its superiority to intermittent auscultation,[3] electronic fetal monitoring (EFM) is used in most labor and delivery settings during oxytocin administration for induction or augmentation of labor—and fetal heart rate and uterine activity typically guide initiation and titration of oxytocin.

Nevertheless, because EFM is the unofficial standard, an obstetrician who chooses to use intermittent auscultation of fetal heart rate during oxytocin infusion can anticipate strong criticism if the delivery results in a compromised neonate.

A 2005 Cochrane review[4] of 18,561 births compared EFM with intermittent auscultation in labor and delivery and found fewer neonatal seizures in the EFM group but no differences in Apgar scores of less than 4 and 7, NICU admissions, perinatal deaths, or cerebral palsy.

"Default" intervals

Not only is the type of fetal monitoring important, but also how closely and how often the strip is evaluated. However, no studies have determined the optimal frequency of EFM interpretation during normal labors, let alone those induced or augmented with oxytocin. Furthermore, no single best methodology has been identified. Rather, the "default" timing of EFM interpretation has been loosely based on the historical practice of evaluating and documenting intermittent auscultation at 30-minute intervals during active labor and 15-minute intervals during the second stage for low-risk patients. For high-risk patients, the intervals have been every 15 minutes during the active phase and every 5 minutes during the second stage.

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FAST TRACK

The only thing electronic fetal monitoring can identify with high specificity is the oxygenated fetus that is not experiencing metabolic acidemia

What will expert witnesses look for?

After adverse outcomes, the EFM tracing will be examined closely by "experts" looking for evidence that it contained abnormalities demonstrating fetal compromise or predicting the infant's injury or death.

These experts also scrutinize the actions of physicians and nurses for appropriateness, timeliness, and effectiveness; the timing of the decision for expedited delivery; and the events occurring between that decision and the time of delivery or abdominal skin incision.

The monitor's shortcomings

Many courts now require experts to base their opinions on reliable scientific studies; however, in malpractice claims involving EFM, expert interpretation often is based on the expert's own personal or institutional experience or common practices rather than scientific evidence.

One of the most pervasive public misconceptions is that fetal monitoring can reliably detect when a fetus lacks sufficient oxygen, is experiencing a physiologically stressful labor that is depleting oxygen reserves, or is becoming asphyxiated. In reality, the positive predictive value (ability of the technology to identify the compromised fetus without including healthy fetuses) is very low: 0.14%. Thus, of 1,000 fetuses with nonreassuring tracings, only 1 or 2 are actually compromised.[5] This may explain why providers and nurses are reluctant to deem all nonreassuring recordings as accurate.

The only thing EFM reliably identifies with a high degree of specificity is the oxygenated fetus that is not experiencing metabolic acidemia. Recordings with "nonreassuring" features are statistically unlikely to imply a diagnosis of fetal metabolic acidosis, hypoxemia, or stress or distress.

Should EFM precede oxytocin?

No minimal duration of monitoring prior to oxytocin administration has been consistently determined. Researchers do not even agree that initial monitoring of the fetus scheduled for induction has benefit.

This does not mean that oxytocin can be started without knowledge of the maternal and fetal condition—only that the best timing and methods of assessment prior to induction of labor are unknown.

What is "nonreassuring"?

Starting oxytocin in a woman with a "nonreassuring" tracing opens the OB to criticism. This is the most contentious aspect of medical and nursing management because we lack standardized definitions of "reassuring" and "nonreassuring."

Nurses typically label a tracing nonreassuring based solely on decelerations or other variant patterns such as tachycardia. However, while a tracing's individual characteristics may reflect a variety of etiologies (one of which is decreased uteroplacental perfusion), variability and/or accelerations signify an overall reassuring status, or fetal tolerance of labor.

Physicians generally examine the tracing in light of other clinical factors, such as labor progress, historical data, or parity—and also in light of any specific actions that have been taken and the expected time of their peak effect.

When to notify the OB

Another contentious issue in labor induction is exactly when nurses should notify the physician of a nonreassuring fetal heart rate. Unfortunately, there is no consensus about this question, either; again, most EFM tracings requiring nursing intervention exhibit an overall reassuring status.

Because evaluation of nonreassuring findings may take several minutes, nurses usually notify the physician when their assessment is complete. If the worrisome tracing resolves after intervention, a nurse may appropriately postpone notification until the next opportunity for communication with the physician.

Uterine monitoring

Can monitoring predict rupture?

In cases involving uterine rupture and/or

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placental abruption, experts may allege that the event could have been predicted with an intrauterine pressure catheter. However, in a study of "controlled" uterine rupture (recording of intrauterine pressure before and during uterine incision at the time of cesarean section), Devoe et al[6] found no real differences in contraction frequency or duration, peak contraction pressures, or uterine resting tone prior to and after uterine "rupture" (incision).

We also lack prospective studies demonstrating that intrauterine pressure catheterization can predict placental abruption. Placement of the device purely for this reason is not indicated.

Titration of oxytocin

No consensus on frequency or intensity of contractions

Criticism of the method of oxytocin titration is common in malpractice claims because no data satisfactorily define adequate frequency or intensity of contractions.

Nor do we have widely accepted terminology to describe uterine activity. For example, hyperstimulation is sometimes defined as increased frequency of contractions with an abnormal fetal heart rate tracing, and sometimes as increased frequency of contractions without a nonreassuring fetal heart rate. The same inconsistencies hold true for the terms "hypertonus," "tetany," "tachysystole," and others.

"Adequate labor pattern" has been defined as 3 to 5 contractions in 10 minutes or 7 contractions in 15 minutes,[7] even though these criteria are based on limited data. Although clinically adequate labor is defined by cervical dilatation and effacement with fetal descent, this definition frequently leaves us titrating oxytocin by "trial and error." Fortunately, the half-life of oxytocin is short, and we can use fetal and uterine response to guide titration.

No definitive predictors of rupture, abruption, asphyxiation

When uterine rupture, placental abruption, and/or variant fetal heart patterns occur with hyperstimulation or elevated resting tone, the possibility of a cause-and-effect will be explored in legal claims. Although uterine rupture has been attributed to oxytocin in older, nonprospective, uncontrolled studies, more recent investigations[8] failed to confirm this link.

The effect of uterine hyperstimulation on fetal oxygenation is even less well established. Contractions increase placental vascular resistance, which in turn decreases uteroplacental blood flow. This phenomenon has been demonstrated in studies utilizing Doppler velocimetry,[9] radioangiography,[10] and fetal pulse oximetry.[11] However, none have been able to quantify, in millimeters of mercury, the intensity of uterine contractions or baseline tonus required to compromise fetal oxygenation.

Risk-reducing tactics

These strategies[12] do not represent the standard of care, but may help reduce liability:

- Routinely assess fetal heart rate during examination of the laboring patient.
- Document EFM interpretation comprehensively. Include baseline, variability, accelerations, decelerations, and uterine activity, as well as overall impression.
- Date and time every entry.
- When notified of a finding, detail the notification, as well as the orders and plan of care communicated to the nurse.
- Develop a mechanism for documentation when you are located outside the hospital (eg, progress notes that are later posted in the chart).
- Use digital storage and retrieval with central monitoring of displays to allow physicians to observe EFM tracings via remote access.
- Use handheld PDA-type displays.
- Go to the bedside to evaluate a patient when nurses ask you to do so. Document date and time, and the fetal heart rate interpretation.
- Decrease or discontinue oxytocin when variant fetal heart rate patterns suggest

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FAST TRACK

Go to the patient's bedside when summoned, and document the date, time, and fetal heart rate interpretation

6 RISK-REDUCING STRATEGIES

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As obstetricians, we are fortunate to participate in the most basic aspect of the human condition: the need to reproduce. Sometimes it is easy to overlook this fact, given the routine nature of many of our practices.

A case in point: oxytocin administration to induce or augment labor, an everyday occurrence in virtually all labor and delivery suites. Oxytocin is so ubiquitous, it can be easy to use it less than meticulously. Although the risks associated with its use are largely recognized, and the appropriate responses well known, a few points bear repeating.

Twin challenges: Protect and document

Safe and judicious use of oxytocin involves 2 challenges: minimizing medical risks to mother and fetus, and creating a supportive medical record. As in all aspects of medical care, we are required to know how to handle the clinical situation, and to document our skill, knowledge, and experience. Nowhere is this of greater concern than in the management of labor and delivery.

Here are 6 additional strategies for reducing legal risks of oxytocin use in labor.

1. Start with a written note

I suggest entering a written note into the record prior to administering oxytocin, outlining the reasoning behind the decision to proceed. Taking this pretreatment pause or "time out"—as the Joint Commission on Accreditation of Healthcare Organizations calls it—provides an opportunity to consider the risks, benefits, and alternatives of oxytocin use. This note should include the medical indication.

2. Conduct a comprehensive consent process

A passive signature on a general consent form is a minimalist way of demonstrating patient consent. By beginning the charting at the time of the consent discussion, you can demonstrate your consideration of the patient's understanding and desires, not to mention your adherence to the highest standards of care.

Was an alternative approach possible? The patient should have the benefit of your opinion as well as a discussion of other reasonable strategies. Involving her in an active discussion is a fundamental component of informed consent—especially since improper consent is a frequent allegation in malpractice actions.

3. Describe both uterine and fetal responses

Because oxytocin directly affects uterine activity and indirectly affects placental perfusion, any chart notation needs to include references to both. For example, the comment that "contractions are every 2 minutes" requires the additional observation that the fetal heart rate tracing "is reassuring," … "unchanged from earlier," … or "demonstrates changes that are being evaluated."

Whether a notation is made at the time of a routine labor check or when the physician is called to the bedside, comments on both uterine activity and fetal response are needed.

4. Discontinue oxytocin when the uterus overreacts

On occasion, excessive uterine activity may occur when oxytocin is first administered. Excessive uterine activity on a continuing basis can lead to fetal asphyxia. Although reducing the oxytocin dose will ultimately diminish uterine activity, I teach residents to discontinue oxytocin completely as soon as excessive uterine activity occurs.

Because this is a clinically important intervention, the medical record should be notated.

5. Adjust oxytocin to reflect changes in labor patterns

It makes good sense to avoid further oxytocin increases once the patient is in active labor (ie, progressive cervical change) and to decrease doses when contractions occur more frequently than every 2 minutes, even in the face of a reassuring fetal heart rate. This is not a situation in which, "if a little is good, a lot is better."

6. Consider including a labor curve

Adding a labor curve or partograph to the chart can be a further safeguard, as it makes it easy to identify prolonged labors and potential complications in a timely manner.

All 6 strategies help demonstrate and preserve your hard work and concern for the patient. As always, adherence to principles of sound care and communication is the bedrock of successful obstetrics. There is no substitute.

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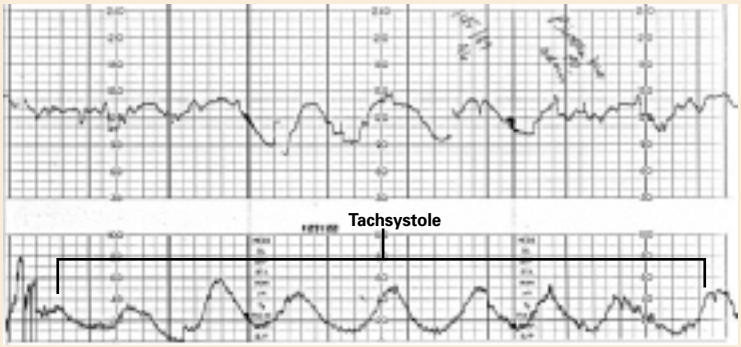
decreased uteroplacental perfusion (**FIGURE 1**).

- Avoid further increases in oxytocin once adequate labor (progressive cervical change) is established.
- Consider decreasing oxytocin—or avoid further increases—when uterine contractions are more frequent than 5 in 10 minutes or 7 in 15 minutes (**FIGURE 2**).
- Use National Institute of Child Health and Human Development terminology in verbal communications with nurses and physicians (see the Web version of this article for a downloadable PDF file of this terminology).

FIGURE 1

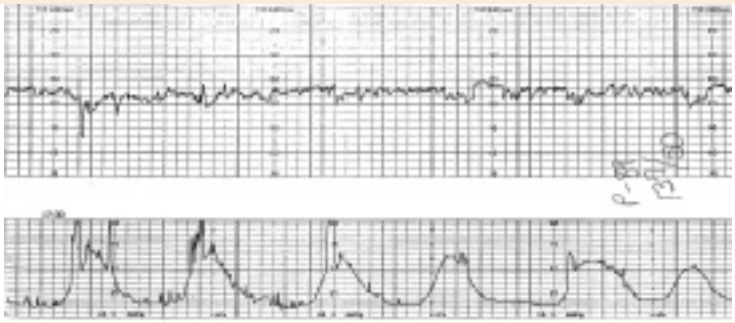
Tachysystole with decelerations signifies uterine hyperstimulation



Decrease or discontinue oxytocin when variant fetal heart rate patterns suggest decreased uteroplacental perfusion. This tracing shows uterine hyperstimulation (tachysystole with decelerations).

FIGURE 2

Titrate oxytocin to "normalize" contractions



Consider decreasing oxytocin—or avoid further increases—when uterine contractions are more frequent than 5 in 10 minutes or 7 in 15 minutes. This tracing shows 6 uterine contractions in 10 minutes. The fetal heart rate channel demonstrates moderate variability and, therefore, fetal tolerance of a frequent contraction pattern.

Why policies and procedures are a double-edged sword

Although policies and procedures are intended to help guide health care assessments and interventions, they are routinely subpoenaed and entered as evidence in an attempt to define the standard of care. Failure to follow these policies and procedures may be viewed by expert witnesses as a breach in that standard.

Use of oxytocin requires a medical or nursing professional to make judgments based on training, experience, and knowledge. Although policies and procedures cannot address every possible scenario or replace informed judgment, physicians and nurses are routinely criticized for failing to administer oxytocin or otherwise proceed exactly as outlined.

Some reasons policies and procedures should not be viewed as standard of care:

- They are typically written by a person in an administrative position who does not actually provide the care outlined.
- They are usually not routinely updated as new literature is published.
- Since they do not provide guidelines for unanticipated or unusual situations, deviation from policy is reasonable and even necessary in many scenarios.
- They are rarely written to reflect "reasonable" care; instead, they suggest an "ideal" level of care.

Reasonable protocols. Every physician and health care provider should be familiar with the hospital's policies and procedures and help hospital personnel revise those that appear to limit the physician's ability to easily adjust care or exercise judgment. Among the suggestions:

- Make all recommendations practical. This means they can be followed most of the time in most situations.
- Avoid terms such as "mandatory," "always," "never," "should," or "must."
- Limit recommendations that can be considered "endpoints" for increas-

ing oxytocin, such as: "Increase oxytocin until contractions are 2 to 3 minutes apart and 60 seconds in duration." Recommendations written in this fashion are difficult to follow clinically; although the criteria may be met, labor may not progress, warranting an increase in oxytocin beyond the endpoints in the guidelines. Guidelines that discuss considerations for decreasing or discontinuing the drug would be better.

It also is important to foster understanding among medical and nursing staff that policies and procedures are guidelines and that medical and nursing judgment supersedes policy recommendations. ■

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