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## Do you need to review the images of an ultrasound study?

Patient sues obstetrician, claiming ultrasounds were misread following intrauterine fetal demise because of undetected cord and growth restriction.

### The Case

A 20-year-old G2P1001 presented to her obstetrician on December 13, at 19 weeks and 6 days (19w6d), for her initial obstetrical visit. The pregnancy was a short interval one, as the woman had delivered a baby 10 months earlier. The prior pregnancy was reasonably uncomplicated, with threatened preterm labor at 36 weeks of gestation; the patient subsequently delivered at 38w1d a 7 lb 9 oz healthy female baby. During that pregnancy, all genetic screening and infection history were negative. The patient had 4 ultrasounds during the pregnancy at 9w3d, 11w3d, 19w5d, and 25w3d.

The current pregnancy was complicated by obesity, and the patient had a body mass index of 41.5 kg/m<sup>2</sup>. She suffered from sleep apnea. Her surgical history included a laparoscopic cholecystectomy. Again, her genetic history and infection history were negative.

Her initial examination at this first visit revealed a fundal height of 22 cm. Results of her examination were reported as normal, except for bacterial vaginosis and group B streptococcus in her urine. The remainder of her antepartum screening was negative, including ureaplasma, herpes simplex virus (HSV), *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, HIV, and thyrotropin; the screening was also negative for cystic fibrosis. Her rubella status was negative, with a plan to immunize her post partum. Results of her 1-hour diabetes screen at 27w4d were normal.

The patient underwent an ultrasound on December 13, at 20w2d, which was consistent with her dates, with an estimated date of delivery of April 30. Because of the fetal position and body habitus a complete heart evaluation, facial profile, and assessment of the lips were not possible. The report indicated that results of the “level 2” ultrasound

were normal, noting the limitations. A repeat study was recommended in 2 to 3 weeks. A follow-up ultrasound study performed on January 10, at 24w2d, was consistent with her dates, with an estimated gestational age (EGA) of 24w3d. The heart, lips, and facial profile were normal. Interval growth was also normal.

The patient had antepartum visits at 25w2d, with a fundal height of 25 cm; 28w2w, with a fundal height of 28 cm; and 31w2d, with a fundal height of 31 cm. Additional ultrasounds were not performed during this pregnancy.

At 34w0d the patient presented in premature labor to a hospital where the primary obstetrician did not deliver. On presentation her cervix was 8 cm, 100% effaced, and at a -1 station. Fetal heart tones were not heard. A bedside ultrasound confirmed no cardiac activity, consistent with an intrauterine fetal demise.

The patient progressed in labor and

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delivered via a spontaneous vaginal delivery at 8:09 AM a 1530 g (3 lb 6 oz) female baby, with an Apgar score of 0 at 1 minute and 0 at 5 minutes. There were no gross abnormalities, noting a normal appearing placenta with 3 vessels. A screen for toxoplasmosis, rubella, cytomegalovirus, and HSV was negative.

The patient sued the original obstetrician, claiming the ultrasounds were misread.

An autopsy revealed a baby weighing 1498 g, with extensive skin sloughing. Further findings included bilateral pleural effusions, ascites, and multiorgan autolysis. There were no internal or external congenital malformations. The placenta revealed an umbilical cord with 2 vessels (2Vs) and degenerative changes. The fetal membranes had no significant pathologic changes. A fetal weight at 34 weeks of 1498 g is below the fifth percentile, consistent with intrauterine growth restriction (IUGR).

The patient did not return to her original obstetrician for postpartum care. She experienced significant postpartum depression requiring counseling and medical therapy.

The patient sued the original obstetrician, claiming that the ultrasounds were misread. Had the 2V cord been recognized, repeat ultrasounds would have been performed. Further, when intrauterine growth restriction was observed, more aggressive testing and earlier delivery would have been pursued, saving the life of the baby.

During discovery, the plaintiff's maternal fetal medicine expert

testified that both ultrasounds were misread. A 2V cord was obvious on both studies. This finding is associated with an increased risk of aneuploidy and various structural fetal anomalies. As such, the patient would have been referred to a maternal fetal medicine specialist for a detailed anatomic survey. Based on the autopsy findings, this likely would have been normal. However, the presence of a 2V cord also increases the risk of IUGR. As such, if the cord had been recognized, the patient would have undergone serial ultrasounds, which would have detected the lagging growth of the fetus. Doppler assessment and antepartum testing would have been performed, likely indicating the need for earlier delivery, which more likely than not would have resulted in a viable baby.

The defense experts opined that there was no indication for additional ultrasound studies, as the patient's fundal height was appropriate for her EGA at all antepartum appointments. Further, they argued that there can be secondary atrophy or atresia of a previously developed vessel, which may account for the incidence of a 2V cord being 4 times higher in autopsy reports than on antepartum ultrasound. Even if the 2V cord were present, as an isolated finding with no aneuploidy or structural abnormalities, the pregnancy prognosis is relatively good. Further, the value of Doppler velocimetry in identifying babies at risk for intrauterine death is also controversial.

During the obstetrician's deposition, the plaintiff's counsel gained an admission that the obstetrician relied on the sonographer's preliminary

findings and, in fact, did not independently review the images in the 2 studies. Of note, in the electronic record, the 2 antenatal ultrasounds were signed by the sonographer, who was registered diagnostic medical sonographer-certified, and by the physician.

The plaintiff's experts opined that the physician must review the study images, interpret the findings, and make appropriate recommendations. It is beyond the scope of a sonographer's practice to interpret ultrasound studies. An independent review of the study images revealed a 2V umbilical cord on both antepartum ultrasound studies.

The case proceeded to trial. After a 6-day trial, the jury found for the plaintiff in the amount of \$1.2 million. Upon polling the jury, it was found that a key factor in their decision was the lack of the physician personally reviewing the ultrasound images in each study.

Discussion

1 What is a level 2 scan? The standard second-trimester ultrasound versus a detailed anatomic survey

This physician indicated that a level 2 scan was performed at 20w2d. The concept of a level 1 and level 2 obstetrical ultrasound no longer applies. The current terminology is a Standard Obstetric Ultrasound Examination (current procedural terminology [CPT] 76805), and a Detailed Obstetric Ultrasound Examination (CPT 76811).

The level 2 scan referred to an anatomic evaluation of the fetus, beyond the assessment of a level 1 scan, which included fetal position,

placental location, amniotic fluid assessment. The evaluation also included the determination of the EGA using the biparietal diameter, head circumference, femur length, and fetal weight with inclusion of the abdominal circumference. The level 1 scan of the past would now be classified as a limited study (CPT 76815), as it does not include all elements of the standard obstetric ultrasound.

**The standard second-trimester ultrasound study (CPT 76805) is, in fact, an anatomic survey, requiring an extensive evaluation of fetal anatomy, including the following<sup>1</sup>:**

Head, face, and neck, including the lateral cerebral ventricles, choroid plexus, midline falx, cavum septa pellucida, cerebellum, cisterna magna, upper lip, and nuchal fold (16-10 weeks of gestation);

Chest and heart, including the 4-chamber view, the outflow tracts, and the 3-vessel and 3-vessel trachea views (when feasible);

Abdomen, including stomach, kidneys, bladder, cord insertion, and number of umbilical cord vessels;

Spine, including the cervical, thoracic, lumbar, and sacral segments;

Extremities: legs, arms, feet, and hands — present or absent;

External genitalia for multiple pregnancies or when medically indicated; and

Maternal anatomy, including the uterus, adnexal structures, and cervix.

The detailed obstetric ultrasound examination (CPT 76811) is an “indication driven” study, appropriate only when specific indications are present, such as finding a fetal abnormality on the standard study or when a fetus is at risk for an inher-

able abnormality.<sup>2</sup>

A 76811 study requires additional training, usually obtained in appropriate fellowships in maternal fetal medicine (MFM) or radiology.

Thus, the detailed fetal anatomic examination should rarely occur outside referral practices with special expertise in identifying and diagnosing fetal anomalies.<sup>3</sup>

In fact, some insurers will not pay for CPT 76811 unless it is interpreted by a MFM specialist (taxonomy code 65) or a radiologist (taxonomy code 47). One must check with individual payors to determine their reimbursement guidelines.

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## 2 Who is responsible for interpreting ultrasound studies?

This seems like a simple question to which the answer would be the physician. However, many physicians rely on their sonographer to identify abnormalities and make recommendations for further evaluation. As such, the “interpreting” physician merely signs off on the preliminary report of the sonographer. It is beyond the scope of practice for sonographers to interpret studies. Their responsibility is to obtain appropriate images that allow the physician to interpret the study, document their impression, and make follow-up recommendations.<sup>4</sup> Relying on the sonographer’s interpretation subjects physicians to an increased risk of liability for a missed diagnosis, such as in this case. In this litigation, the physician’s

admission that study images were not personally reviewed was critical to the success of the plaintiff’s case and the subsequent judgment.

## 3 Who is responsible for billing for ultrasound studies?

Although not a part of this liability action, the physician was subsequently accused of billing for procedures that were not performed. Billing for ultrasound procedures is ultimately the responsibility of the physician. Sonographers may suggest appropriate codes and billing personnel submit the codes, but it is the physician who is ultimately responsible for appropriate and correct billing. Submitting a bill for reimbursement requires appropriate supervision of the sonographer, appropriate review of the study images, documentation of the findings and impressions, and follow-up recommendations. Submitted diagnosis codes should support the performance of the billed ultrasound study or studies.

In addition, image retention for the applicable statute of limitations is required for appropriate billing. Thus, signing a report without reviewing the images, the diagnoses, and the procedures billed, or not retaining the images, could result in a claim of fraud, subjecting physicians to civil and monetary penalties, some of which can be extensive. Sonologists, in other words the interpreting physicians, should familiarize themselves with the guidelines for training<sup>5</sup> and documentation of ultrasound examinations.<sup>6</sup> ■

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