Failure to diagnose fetomaternal hemorrhage

Ob-gyn closed claim study

By Tanya Babitch,
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Presentation
A 24-year-old woman came to her ob-gyn in January for confirmation of her first pregnancy. Pregnancy was confirmed with an estimated due date in mid-September. Prenatal profile testing revealed that the patient was Rh-negative.

Physician action
The patient’s first two trimesters were generally uneventful, other than intermittent complaints of nausea, vomiting, heartburn, tension headaches, upper respiratory infection, and a urinary tract infection that was treated with nitrofurantoin. A 20-week ultrasound revealed a low lying placenta, and the 28-week ultrasound showed a marginal placenta previa with the baby in the frank breech position. The first RhoGAM injection was given at 28 weeks gestation. Repeat antibody screening was negative. A 32-week sonogram revealed a marginally low-lying placenta and estimated fetal weight of 5 pounds. No gross fetal abnormalities were noted.

On July 22, at 33 weeks gestation, the patient came to the hospital with complaints of spotting. The patient was examined by a covering ob-gyn, and admitted to the hospital for observation. Ultrasound revealed slightly enlarged fetal ventricles. Non-stress testing was considered reassuring. The patient experienced occasional contractions with variable decelerations during the night. She was evaluated by her ob-gyn the next day. The ob-gyn ordered 1 ampule of RhoGAM. Per hospital protocol, the lab performed a Kleihauer-Bekte (K-B) test to determine the RhoGAM dosage required.

That evening, K-B test results indicated that 4.22%, or an estimated 212 ml of the blood within the maternal circulation was fetal in origin. Nursing staff notified the ob-gyn at 3 a.m. on July 24 that the fetal screen indicated that she needed 8 ampules of RhoGAM due to significant fetal-maternal bleed. The ob-gyn felt that this test result was inconsistent with the patient’s clinical picture, and asked that the lab supervisor repeat the test.

Repeat test results, available the next morning, confirmed that 4.24% of the maternal blood was fetal and that 8 ampules of RhoGAM were required. The ob-gyn asked that the screen be redone a third time, and results confirmed the original findings. The physician doubted the accuracy of the test results because the estimated fetal blood loss was in excess of the baby’s estimated entire blood volume of 192 cc.

She consulted a perinatologist, who agreed that the results were difficult to believe and suggested that the K-B testing be repeated by an expert. The ob-gyn chose to give the patient one ampule of RhoGAM, but consulted with a pathologist who agreed to repeat the K-B test at a lab outside the hospital. A hemoglobin electrophoresis was also ordered.

The patient was discharged from the hospital on July 24, with instructions to return to the ob-gyn’s office on July 28. The outside lab tests were completed on July 25, and the results confirmed the accuracy of the previous K-B tests. However, these results were not communicated to the ob-gyn or entered into the hospital’s computer system. On July 25 the patient called to report that she was “doing great,” and was informed by the staff that they were still researching her condition and had not yet received her test results.

On August 1, the patient reported intermittent light brown spotting, contractions, and decreased fetal movement. She was asked to return to the practice. A repeat non-stress test was reactive. K-B testing showed

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4+ fetal cells on maternal circulation, greater than the entire estimated blood volume of the fetus. The physician also mentioned that hemoglobin electrophoresis was pending, unaware that it had been received by the hospital. The patient returned for lab work on August 6. The ob-gyn discussed the case with two outside perinatologists, who suggested that she order indirect Coombs, CBC, and AST testing. The testing was ordered, but results of these tests did not make it into the patient’s medical record.

On August 7, the patient called the practice to report decreased fetal movement, and was instructed to go directly to the hospital. She was admitted for a non-stress test that revealed a non-reassuring baseline and minimal fetal heart rate variability. Due to the patient’s previous complications, the decision was made to perform a cesarean delivery. Preoperative diagnosis was uterine irritability, non-reassuring fetal heart rate, and questionable fetomaternal hemorrhage.

The ob-gyn delivered a 5-pound, 8-ounce female infant with Apgar scores of 8 and 8. The baby was tachypneic and was placed on an oxyhood and given oxygen. She was severely anemic with a hemoglobin/hematocrit of 5.1/17. She was given a partial exchange transfusion with packed red blood cells. After 60 ml her hemoglobin/hematocrit increased to 8/25. The placenta appeared abnormal with large cotyledons and possible infarction. The cord pH was 7.396.

The infant was transferred to a children’s hospital on August 11, and was diagnosed upon arrival with metabolic acidosis. A CT of the brain showed diffuse edema, and EEG was abnormal due to the presence of excessive background suppression. During the course of treatment, the baby experienced significant hypertension, contractures, multiple episodes of apnea and possible seizures. Her condition was complicated by pulmonary edema. Treating physicians felt that a fetomaternal hemorrhage caused the severe anemia and resulting hypoxic brain injury.

The child has spastic quadriparesis, mental retardation, feeding difficulties that require a G-button, and problems with temperature regulation. She is significantly impaired and will require extensive medical care for the rest of her life.

Allegations

The plaintiffs filed a lawsuit alleging that the ob-gyn negligently ignored the repeated K-B test results that revealed chronic fetal to maternal blood transfusion. They alleged the results of the testing warranted extensive RhoGAM administration and emergent delivery, and contended that the baby sustained global brain injury that could have been avoided. They also claimed that the mother became Rh sensitized due to the administration of inadequate amounts of RhoGAM, which could make it risky for her to attempt pregnancy in the future.

Legal implications

Physicians who reviewed this case for the defense stated that it was reasonable for the ob-gyn to question the initial K-B test results. The results from the non-stress test did not indicate that immediate delivery was warranted. However, the reviewers’ opinions were mixed about whether it was reasonable for the ob-gyn to ignore the repeat test results. Generally, they agreed that had the ob-gyn relied on the test results, she could have delivered the baby earlier or performed an intrauterine blood transfusion. The ob-gyn attempted to have the test results confirmed with additional testing by an outside lab, but the results were not reported to her. One physician felt that it was likely that the brain injury occurred long before the mother’s hospitalization, and felt that the actions of the ob-gyn might have had nothing to do with the baby’s outcome.

The plaintiff’s expert stated that the ob-gyn was negligent in disregarding the repeat K-B test results and failing to recognize them as substantial evidence of fetomaternal hemorrhage. He felt that the ob-gyn’s calculations of fetal blood volume failed to consider factors such as placental blood, the potential for fetal red blood cell production compensating for fetomaternal hemorrhage by extramedullary hematopoiesis, and increased bone marrow production of red blood cells. He stated that if the ob-gyn had correctly assessed the evidence and acted on it, an early delivery could have prevented the baby’s brain damage.

Disposition

Due to the potential difficulty of convincing a jury that the brain injury may not have been caused by the actions of the ob-gyn, and the highly sympathetic nature of the damages, the case was settled on behalf of the ob-gyn.

Risk management considerations

Fetomaternal hemorrhage, an extremely rare condition, presented a substantial challenge to the ob-gyn. All physicians who reviewed this case felt that questioning the initial K-B test result was completely reasonable. Taking the clinical picture into account, the first set of results seemed implausible. Diagnosing a chronic fetomaternal hemorrhage can be extremely challenging, especially in the absence of obvious fetal distress. Unfortunately, the outside test results that confirmed a substantial fetomaternal hemorrhage were completed on July 25, but the ob-gyn was not aware that the results had been received. The results were printed on August 1, but still not reported to the ob-gyn. It is arguable whether acting on the test results at that time would have had any effect on the baby’s outcome, but it may have assisted the physician’s defense in this case.

As illustrated in this case, developing, implementing, and consistently following procedures for monitoring and acting on test results can assist physicians and may prevent test results from being overlooked. Such protocols can enhance patient safety and reduce liability for physicians.

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TMLT continues fight to maintain medical liability reform

by Dana Leidig, ABC

On September 13, 2003, the citizens of Texas voted on Proposition 12 which determined whether the Texas Legislature should have the right to set caps on non-economic damages in medical liability cases. This legislation passed and along with House Bill 4, dramatically reformed the medical liability system in the state. In February 2008, the Texas Medical Association (TMA) along with John McKeever, MD, filed suit in Travis County in response to a liability lawsuit filed against Dr. McKeever in Nueces County claiming the $250,000 non-economic damage cap is unconstitutional. The appeal process for constitutional challenges to the 2003 tort reforms allows that, regardless of the county of origin of the plaintiff’s constitutional challenge, the defendant physician may file a suit in Travis County to address the issue. This case was heard in Travis County and a declaratory judgment action determined the cap to be constitutional.

This was not the only constitutional challenge mounted in 2008, though none have yet proved successful. These early challenges may be harbingers of a bigger, more organized storm to come when the Texas Legislature convenes in January 2009. There may be a strong effort by opponents of medical liability reform to weaken important aspects of this legislation. In order to keep the 2003 reforms that have helped cut both non-meritorious claim frequency and medical liability premiums in half and brought approximately 7,000 new physicians to Texas, it is essential that the strong coalition that achieved these landmark reforms six years ago remain active and vocal.

Grassroots efforts work

In the fall of 2001, TMLT and the TMA, the Texas Hospital Association, many county medical societies and specialty societies, physician groups, and other stakeholders joined together to form the Texas Alliance for Patient Access (TAPA). TAPA was dedicated to solving the problems of declining access to health care in Texas by analyzing medical liability laws and proposing changes that could reform the medical liability system. At that time, TAPA members worked tirelessly throughout the state to educate physicians about the issues. TMLT executives were part of the team, traveling from Brownsville to El Paso, Dallas to Houston to Texarkana to make presentations to physicians working in these locales.

In conjunction with TAPA, TMLT executives were also part of the team making presentations to the Texas House Insurance Committee to help legislators understand the critical nature of the issues. As physicians became more informed, the battle heated up. In April 2002, physicians attired in their white coats participated in an organized demonstration in the Rio Grande Valley and later in a white coat march on the state capitol to draw public attention to medical liability issues.

Achievements we cannot afford to lose

According to the Pacific Research Institute’s Tort Liability Index: 2008 Report, “the states that have the best overall tort rules on the books, and that will be heading in the right direction if the rules are fully implemented, are Colorado, Texas, Ohio, Georgia, Indiana, Florida, and Michigan.” It is vital to keep the Texas medical liability reforms intact and unchanged in order to control costs and encourage competition in the medical liability insurance industry. In the years following medical liability reform, the number of medical liability insurance carriers grew from 4 to 30, providing physicians greater choice and encouraging responsible rate setting among carriers.

What reforms mean for physicians

After five years, the positive effects of medical liability reform for both physicians and patients are clear: lower medical liability rates, decreased claims frequency and fewer non-meritorious lawsuits, more physicians moving to Texas, expansion of health care services, and greater access to health care for patients.

TMLT was the first medical liability carrier to lower rates for Texas policyholders. Subsequently, other medical liability insurance carriers followed with rate reductions. TMLT has decreased rates six times since medical liability reform was enacted, including a 4.7% average rate reduction effective January 1, 2009 setting the trends for other carriers. The cumulative premium savings by TMLT policyholders will exceed $275 million since January 2004. TMLT was also able to return savings to its policyholders through dividends. Since the first dividend was declared in 2005, TMLT policyholders have saved approximately $105 million with dividend credits off renewal premiums.

Claims frequency at TMLT—including mass litigation—has declined from 22.82% in 2002 to 9.46% in 2007. The number of cases taken to trial has also declined from 76 in 2002 to 49 in 2007. The percentage of claims closed without indemnity has increased from 86.89% in 2002 to 89.42% in 2007. Bob Fields, president and CEO of TMLT, stated in the 2007 annual report that in 2007 there were fewer frivolous and non-meritorious claims to defend.

These good results must be guarded carefully however. They are largely the result of the $250,000 cap on non-economic damages. According to TAPA, “any change to the non-economic damage cap will increase cost and frequency of suits and would reduce access to care.”

More physicians are available for Texans in their communities. According to an article published by the TMA, “The Texas Medical Board licensed a record 3,621 new doctors this fiscal year; 9 percent more than last year’s previous record of 3,324. Texas has licensed 14,499 new physicians post-reform.” This includes specialties such continued on page 4
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as neurosurgery, orthopedic surgery, trauma surgery, emergency medicine, obstetrics, and pediatric subspecialties whose numbers in Texas were declining before tort reform. TMA’s article also states that many physicians are now confident in offering services to patients considered high risk. “Many physicians report adding new in-office procedures and testing, nursing home coverage, and after-hours services. Others say they are now providing more charity care, participating in volunteer programs, and accepting more Medicaid and Medicare patients because of the liability reforms.”

On-call for tort reform

As the legislative session opens in January 2009, physicians must again be prepared to defend medical liability reforms. The importance of keeping these reforms intact cannot be overemphasized. Your local county medical or specialty society can provide you with information as the legislative year progresses, or visit www.texmed.org for current news on the issues. The TMA web site also is a good resource for materials suitable for making presentations to physician groups. The TAPA web site, www.tapa.info, will have legislative updates as well as a library of news articles from around the state. Stay informed. Write letters to your state senator and representative expressing your concerns and encourage your colleagues to do the same. Lawmakers need to be reminded how much medical liability reform has meant to physicians and their medical practices, and to patients who have greatly improved access to health care.

Sources


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