

Expert Outlines Litigation Risks Related to ART

BY SHERRY BOSCHERT
San Francisco Bureau

CABO SAN LUCAS, MEXICO — Higher rates of complications in babies born through assisted reproductive technology have led to malpractice lawsuits, Aubrey Milunsky, M.B., said at a conference on obstetrics, gynecology, perinatal medicine, neonatology, and the law.

"There is a medicolegal industry that is evolving at break-neck speed" related to ART, said Dr. Milunsky, who chaired the conference and is professor of human genetics, pediatrics, ob.gyn., and pathology at Boston University. ART plays a role in approximately 1% of the 4 million births in the United States each year, said Dr. Milunsky, who is also director of the Center for Human Genetics, Boston.

Compared with naturally conceived pregnancies, ART pregnancies carry nearly a threefold increased risk for low birth weight and more than a fivefold increased risk for fetal or infant death. Singletons delivered after ART are 40% more likely to be small for gestational age, 54% more likely to be delivered by cesarean section, and 27% more likely to require intensive care, compared with naturally conceived singletons. Multifetal pregnancies are more common with ART.

Maternal serum screening produces more false-positive results in ART pregnancies than in naturally conceived ones.

The overall rate of birth defects is 40%-200% higher in ART pregnancies than the background rate of 3%-4% in the general population. Three rare "imprinting" birth defects (disorders that appear to develop more in one sex

than in the other) have been reported in a handful of ART pregnancies: Beckwith-Wiedemann syndrome, Angelman's syndrome, and retinoblastoma.

When parents have gone to such great lengths to conceive a child through ART and are desperate to have a successful pregnancy, anything less than a "perfect" baby may be extra disappointing, and complications may seem extra burdensome, he added.

Sean Tipton, spokesman for the American Society for Reproductive Medicine in Washington, commented in a subsequent telephone interview, "We're not aware of any explosion in litigation in this area. It's certainly not news to anyone that children of infertility patients are not as healthy as children of healthy people."

Complications in ART pregnancies could be attributed to the underlying cause of the infertility, the advanced age of many women who seek ART, or issues related to multiple gestations, he said.

At the meeting, Dr. Milunsky highlighted some of the key areas for potential litigation related to ART:

► **Informed consent.** It is difficult and probably rare to get truly informed consent for all stages of ART a patient may go through, such as hormonal therapy, intracytoplasmic sperm injection, manipulation of the gamete or zygote in vitro, or insertion of cells into the womb.

► **Extreme prematurity.** Birth weights under 2,500 g are 70% more common in ART singletons than in naturally conceived ones. "Even though the technology is so phenomenal in terms of saving them ... the outcome is intellectually disastrous" for many of the extremely small babies, he said. As in non-ART pregnancies, damaged ba-

bies lead to lawsuits that often try to pin the blame on medical personnel.

► **Erroneous diagnosis.** Chromosomal testing of a blastomere biopsy can miss problems absent in one cell but present in others. "It's surprising, if not amazing, how often the embryo is made up of two sets of cells—normal and abnormal," he said.

When a fertilized egg multiplies into 8-16 cells in vitro, a gene analysis for cystic fibrosis (CF) typically involves one of those cells. But in some cases allele dropout occurs in the cell chosen for analysis, giving the false impression that the cell—and hence the blastomere—does not contain a CF mutation. At least two lawsuits resulted from missed CF diagnoses due to allele dropout.

► **Genetic counseling.** Failure to refer both parents for genetic counseling results in inadequate information gathering. "People undergoing ART rarely have a full genetic evaluation, I find," Dr. Milunsky said at the meeting, sponsored by Boston University and the Center for Human Genetics.

► **Targeted ultrasound.** Given the higher risks for complications in ART pregnancies, targeted ultrasound should be done during the second trimester in all ART pregnancies to search for detectable abnormalities.

► **Chorionic villus sampling/amniocentesis.** Don't let the parents' drive to succeed in pregnancy keep you from offering invasive testing, which can endanger the pregnancy. Your responsibility is to communicate any increased risk to the parents and give them options for management. "Let them make the choice, and you make the documentation," he said. ■

Fourth-Degree Tears More Likely to Result in Bowel Symptoms

BY MICHELE G. SULLIVAN
Mid-Atlantic Bureau

WHITE SULPHUR SPRINGS, W.VA. — Women who experience a fourth-degree tear during delivery are significantly more likely to have persistent anal sphincter defects leading to fecal urgency or incontinence than are women with a third-degree tear, Catherine M. Nichols, M.D., said at the annual meeting of the South Atlantic Association of Obstetricians and Gynecologists.

Third-degree tears are much more likely to heal without persistent sphincter defects, which are associated with up to an 18-fold increase in the development of new postpartum bowel symptoms, said

Dr. Nichols of Virginia Commonwealth University in Richmond.

Her prospective cohort study included 56 primiparous women, of whom 39 experienced a third-degree tear and 17 a fourth-degree tear at delivery.

There were no significant demographic differences between the groups. The mean age of the women was 25 years.

Infant birth weight (median about 3,400 grams) was similar in the two groups. Women who had a fourth-degree tear had a longer second stage of labor than did those with a third-degree tear (133 minutes vs. 78 minutes). Forceps deliveries occurred in 21% of the third-degree group and 47% of the fourth-degree group. Shoulder dystocia was more common in the fourth-degree group (24% vs. 13%), as was persistent occiput posterior position (24% vs. 13%) and midline episiotomy (76% vs. 49%).

After delivery, all of the women completed the Manchester Modified Bowel Function questionnaire to assess pre-delivery bowel function. At 6 weeks postpartum, all women were examined at a dedicated perineal clinic, where they completed another questionnaire to assess new bowel symptoms and received a pelvic exam and an endoanal ultrasound exam to determine the state of both internal and external anal sphincters.

Of the 56 women, 21 (38%) reported new bowel symptoms, which were incontinence to liquid stool or gas (14 women) and fecal urgency (19 women). Among those reporting new symptoms, 59% had a fourth-degree tear and 28% had a third-degree tear.

Disruption of both sphincters was more common among fourth-degree-tear patients. (See box.)

Conversely, most women with third-degree tears had both sphincters intact. Intact internal sphincters were found in significantly more women with third-degree tears than in those with fourth-degree tears.

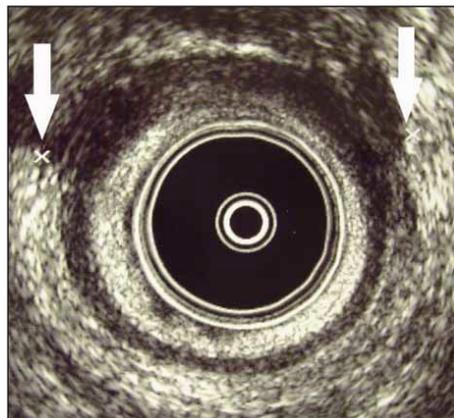
Intact external sphincters were found in a total of 67% of women who had third-degree tears and in 41% of those with fourth-degree tears. This difference, however, was not statistically significant.

There was a very strong correlation between sphincter disruption and the development of new symptoms. Women with an isolated defect of the external sphincter were 15.7 times more likely than those with no defects to report symptoms, and women with combined defects were 18.7 times more likely to report new symptoms, Dr. Nichols said at the meeting. ■



Of those with new bowel symptoms, 59% had a fourth-degree tear, and 28% had a third-degree tear.

DR. NICHOLS



Arrows indicate an area of disruption in the external anal sphincter (circular hyperechoic region). The internal anal sphincter (adjacent circular hypoechoic region) remains intact.

