OBG MANAGEMENT

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Membrane sweeping and GBS: A litigious combination?

Although it led to a defense verdict, a recent lawsuit suggests sweeping in a colonized patient can expose you to litigation

We've all done it. Stripping the membranes is an old, familiar method of separating the fetal membranes from the lower uterine segment, which is thought to trigger the local production of prostaglandins and hasten the start of contractions.[1]

Membrane stripping is a focus of controversy when it comes to the issue of group B streptococcus (GBS). This article looks at the literature on the subject and presents a recent legal case in which a woman colonized with GBS claimed membrane stripping was the proximate cause of her infant's death. In the case, experts for the plaintiff testified that membrane sweeping in a women colonized with GBS is below the standard of care, despite evidence to the contrary. The case, which involved a 2-week jury trial, resulted in a defense verdict.

The legal case

A 22-year-old primigravida presented at just over 39 weeks' gestation, reporting spontaneous rupture of membranes 1 hour earlier.

IUGR and Group B strep

Her antenatal course had been complicated by intrauterine growth restriction (IUGR), detected by ultrasound at 34 weeks' gestation. Because of the IUGR, the fetus was being evaluated twice weekly with nonstress tests and amniotic fluid measurements. At 35 weeks, testing for GBS colonization was positive. At 37 weeks, the membranes were stripped to facilitate cervical ripening because of the diagnosed IUGR.

On admission, she was noted to be afebrile with stable vital signs. She was given antibiotics for the GBS and examined. The membranes were grossly ruptured, with clear fluid pooling in the vagina; the cervix was dilated 3 cm with 80% effacement; and the fetus was at –1 to –2 station.

Although the woman was noted to be contracting every 2 minutes, she was barely aware of the contractions. The fetal heart tracing was initially reassuring, with good variability and no decelerations. She was allowed to walk around for 30 minutes.

Sudden fetal bradycardia

Shortly after the patient was placed back on the fetal heart rate monitor, 52 minutes after her initial presentation and approximately 2 hours after rupture of membranes, a marked and sudden fetal bradycardia was noted.

Emergent cesarean section was performed with a low transverse incision. Eighteen minutes after the onset of the bradycardia, a male infant weighing 3,510 g was delivered, with Apgar scores of 0, 2, and 0, at 1, 5, and 10 minutes, respectively. The umbilical cord arterial pH was 6.97. Pediatricians tried to resuscitate the

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baby, but intubation revealed immediate return of bright red blood. Despite aggressive intervention, including CPR, respiratory support, antibiotics, and inotropic agents, the infant died at 1 hour of life.

Cause of death: GBS pneumonia

An autopsy revealed bilateral massive consolidation of the lungs due to hemorrhagic bronchopneumonia. Tissue and blood cultures of the spleen, lung, and placenta all grew GBS, as did umbilical cord blood cultures. The cause of death: respiratory failure due to overwhelming GBS pneumonia.

The mother's postpartum course was complicated by a fever of 100.8°F on the second postoperative day, for which she was treated with intravenous ampicillin, gentamicin, and clindamycin. She was discharged home on the 4th postoperative day.

"Data insufficient" for or against

Many practitioners strip the membranes at term to keep patients from passing their due dates. When the membranes are stripped at 40 weeks' gestation, two thirds of women enter spontaneous labor within 72 hours; without membrane stripping, only one third of women do.[2] The strategy also decreases the chance that pregnancies will go past 42 weeks' gestation.[3]

Even more important, studies have found membrane stripping to be safe.[3–5] The risk of maternal and neonatal infections does not increase with the procedure, according to a Cochrane Review of 2,797 women in 22 different studies.[5]

The latest statement on the subject from the American College of Obstetricians and Gynecologists (ACOG) is a Committee Opinion published in December 2002—which came after the neonatal death in this case. It says the risks of membrane stripping in women colonized with GBS "have not been investigated in well-designed prospective studies. Therefore, data are insufficient to encourage or discourage this practice in women known to be GBS-colonized."[6]

Expert testimony

Plaintiff

The main witnesses for the plaintiff were a perinatologist and an obstetrician who specializes in infectious diseases. They opined that the infant's death was caused by the membrane stripping, given that the mother was known to be colonized with GBS.

The perinatologist said his opinion was based on the statements of the infectious disease specialist, who in turn cited a poster presentation at the Infectious Diseases Society for Obstetrics and Gynecology meeting in 2001[7]—which occurred a year after the neonatal death. The poster presentation was a series of 8 cases of perinatal sepsis following membrane stripping; the cases occurred between 1993 and 2000 and were provided by a parents' group with affected children, "The Jesse Cause."

Only the perinatologist appeared at trial. When asked to identify a single piece of published, peer-reviewed literature documenting an increased risk of neonatal GBS with membrane stripping, he was unable to do so.

Defense

An expert testified that, although GBS colonization occurs in 20% of all pregnancies, there are no data—prospective, retrospective, or controlled—to suggest that membrane sweeping in GBS-positive patients is associated with GBS sepsis of the newborn, and that membrane sweeping was appropriate in a woman with a fetus affected by unexplained IUGR.

The jury returned a defense verdict after less than 1 day of deliberation. It was not appealed.

Medicolegal lessons

As this case demonstrates, expert witnesses sometimes testify on a plaintiff's behalf despite clear data refuting their statements. ObGyns should be aware that even a practice with a long history, such as membrane stripping, may be proclaimed outside the standard of care by

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Cochrane Review: Membrane sweeping does not increase risk of maternal and neonatal infection

Randomized controlled trials prove 2 advantages of membrane sweeping

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Lower risk of postterm pregnancy

de Miranda E, van der Bom JG, Bonsel GJ, Bleker OP, Rosendaal FR. Membrane sweeping and prevention of post-term pregnancy in low-risk pregnancies: a randomized controlled trial. BJOG. APRIL 2006;113:402–408.

The conclusion of this herculean randomized controlled trial is unequivocal: Sweeping the membranes at 41 weeks' gestation, regardless of parity, significantly reduces the likelihood a pregnancy will reach 42 weeks. Number needed to treat: 6.

Risks of postterm pregnancy are numerous: greater likelihood of longer labor, cesarean section or operative vaginal delivery, infection, postpartum hemorrhage, shoulder dystocia, stillbirth or neonatal death, and meconium aspiration, to name a few. So any strategy to prevent it—particularly one that is easy and inexpensive—is welcome. The only adverse effect of membrane sweeping is increased bleeding; otherwise, the rates of peripartum complications are similar in women with or without the intervention.

Until 2006, studies of membrane sweeping were not randomized. Empiric evidence has suggested that membrane sweeping is ineffective. As a result, many clinicians eschewed the practice. According to the American College of Obstetricians and Gynecologists (ACOG) practice bulletin on postterm pregnancy,[8] management options at 41 weeks' gestation are limited to labor induction or expectant management with antepartum surveillance.

The de Miranda study was conducted at 51 primary care midwifery practices in the Netherlands.

Strengths. In addition to the randomized, controlled design, the trial's strengths are:

- Subanalysis of the data based on parity, on whether the gestational age was determined by ultrasound before 18 weeks, and whether the Bishop score was below 6 or at 6 or above
- Participation by several midwives reflected real clinical practice

In addition, almost 90% of patients who underwent the intervention said they would choose it again in the next pregnancy.

Weaknesses. The de Miranda study does have weaknesses:

- Patients randomized to the control group did not undergo a vaginal examination to determine whether they had a cervix favorable for labor induction. This omission seems unacceptable and contrary to ACOG recommendations.[8]
- The perinatal mortality rate (for all women in the study) was 5.4 per 1,000 births, which is higher than the 1.0 to 3.1 per 1,000 quoted in the ACOG practice bulletin.

There also is some question of which management strategy women prefer, because an earlier study by the Canadian Multicenter Postterm Pregnancy Trial Group[9] reported that women assigned to induction were significantly more satisfied than those allocated to observation.

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The only adverse effect of membrane sweeping was increased bleeding

such witnesses. We consider this kind of testimony unethical.

Until we have more data confirming or refuting the association between membrane sweeping (in cases of GBS colonization) and neonatal sepsis, or the medicolegal system changes, obstetricians should proceed with caution. We counsel our patients thoroughly and document the discussion. ■

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Spontaneous delivery is more likely

Tan PC, Jacob R, Omar SZ. Membrane sweeping at initiation of formal labor induction. A randomized controlled trial. Obstet Gynecol. **MARCH 2006**;107:569–577.

The Tan trial randomized 274 women scheduled for induction at term to membrane sweeping or no membrane sweeping at the initiation of induction. Although roughly 1 in 5 deliveries are induced, induction leads to spontaneous vaginal delivery much less often than does spontaneous labor. The Tan study sought to determine whether membrane sweeping increases the likelihood of spontaneous vaginal delivery. Swept women had:

- Higher spontaneous vaginal delivery rate (69% vs 56%, *P*=.041)
- Shorter induction-to-delivery interval (mean 14 vs 19 hours, *P*=.003)
- Fewer requirements for oxytocin (46% vs 59%, *P*=.037)
- Shorter duration of oxytocin infusion (mean 2.6 vs 4.3 hours, *P*=.001)
- Greater satisfaction with the birth process

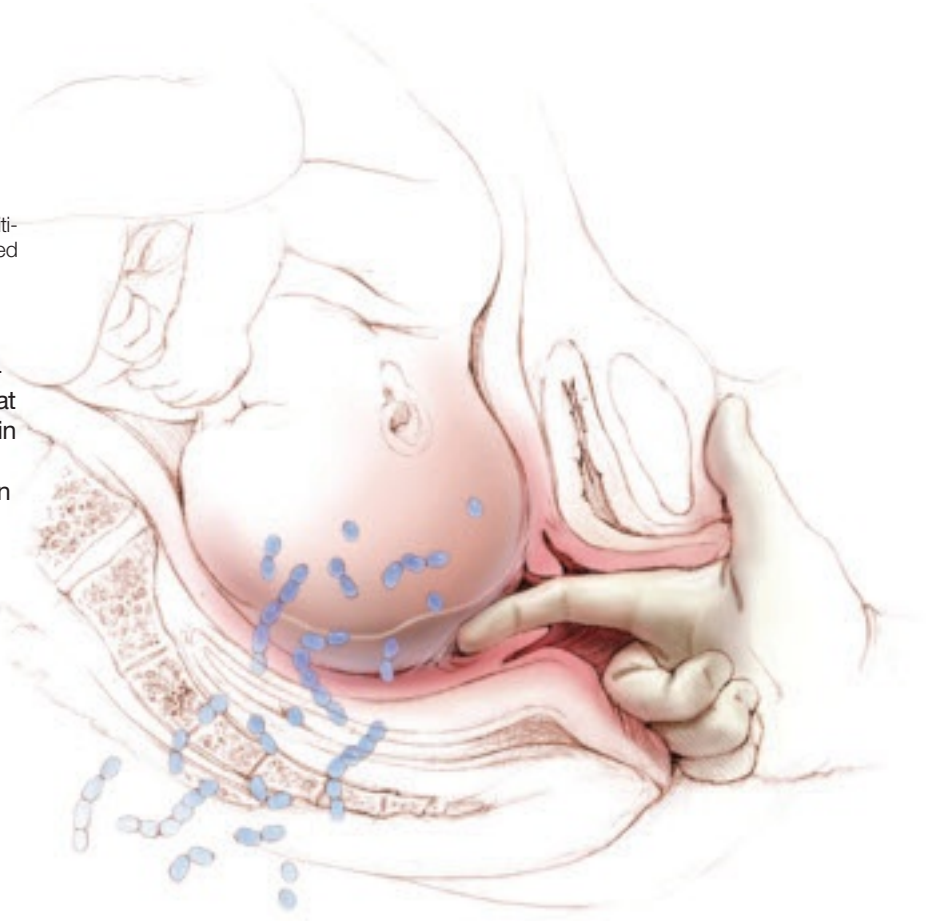

IMAGE: KIMBERLY MARTENS

To sweep the membranes, the clinician inserts a finger through the cervix and physically separates the fetal membranes from the lower uterine segment.This maneuver is thought to stimulate production of prostaglandins and hasten the start of contractions

Recommendations

These trials are sufficient reason to undertake membrane sweeping every 48 hours in women who strongly desire expectant management at 41 weeks' gestation

Counsel patients about the risks of observation

Test fetal well-being twice weekly

Sweeping may ease labor induction

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Swept women had more spontaneous vaginal deliveries and shorter induction intervals

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