Evaluation And Confirmation of Ruptured Membranes At Term

Randall Morgan MD MBA
21 yr old G1 P0 39 1/7 weeks comes to your office for prenatal visit and says she has been leaking for the past hour. You confirm or negate ROM by

- **A.** History, exam (if gross pooling & leaking from cervix confirm ruptured membranes)
- **B.** History, exam (if no gross pooling or leaking from cervix-add fern, nitrazine)
- **C.** History, exam (if no gross pooling & leaking from cervix-add fern, nitrazine & Amnisure)
- **D.** History, exam (if no gross pooling or leaking from cervix-add Amnisure)
- **E.** History, exam (if no gross pooling or leaking from cervix-transfer to hospital for Amnisure)
- **F.** A & B
- **G.** A & C
A 21 yr old G1 P0 39 1/7 weeks comes to the birth rooms and says she has been leaking for the past hour. You confirm or negate ROM by

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- E. A & B
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Premature Rupture of Membranes

Preterm delivery occurs in approximately 12% of all births in the United States and is a major factor that contributes to perinatal morbidity and mortality (1, 2). Preterm premature rupture of membranes (PROM) complicates approximately 3% of all pregnancies in the United States (3). The optimal approach to clinical assessment and treatment of women with term and preterm PROM remains controversial. Management hinges on knowledge of gestational age and evaluation of the relative risks of delivery versus the risks of expectant management (eg, infection, abruptio placentae, and umbilical cord accident). The purpose of this document is to review the current understanding of this condition and to provide management guidelines that have been validated by appropriately conducted outcome-based research when available. Additional guidelines on the basis of consensus and expert opinion also are presented.
Goals and objectives

1. participant will be able to discuss methods to confirm or negative ruptured membranes

2. participant will be able to discuss false positive/negatives of available methods to confirm ruptured membranes

3. Participant will be able to discuss how to confirm or negative ruptured membranes if there is a testing discrepancy.
How is premature rupture of membranes diagnosed?

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1. “Most cases of premature rupture of membranes can be diagnoses on basis of patient’s history & physical.”

2. “The diagnosis of membrane rupture typically is confirmed by
   - the visualization of amniotic fluid passing from the cervical canal & pooling in the vagina
   - A basic pH test of vaginal fluid
   - Or aborization (ferning) of dried vaginal fluid
Basic pH testing (Nitrazine testing)

- Normal pH of vagina is 4.5-6.0
- Amniotic fluid pH usually 7.1-7.3
- False positive semen, alkaline antiseptics, bacterial vaginosis
- False negative – prolonged membrane rupture, minimal residual fluid
How is premature rupture of membranes diagnosed?

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“In equivocal cases, additional tests may aid in the diagnosis.”

1. “Ultrasonic, examination of amniotic fluid volume may be a useful adjunct, but is non diagnostic.”

2. Fetal fibronectin is a sensitive but nonspecific test for ruptured membranes; a negative test is strongly suggestive of intact membranes, but positive test result is not diagnostic of PROM.”
How is premature rupture of membranes diagnosed?

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- In equivocal cases, additional tests may aid in the diagnosis.

  3. “Several commercially available tests for amniotic fluid proteins are currently on the market, with **high reported sensitivity** for PROM. However, **false-positive** test result rates of 19-30% have been reported in patients with clinically intact membranes and symptoms of labor. These test kits should be considered ancillary to standard methods of diagnosis.”
How is premature rupture of membranes diagnosed?

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➢ "If the diagnosis remains unclear after a full evaluation, membrane rupture can be diagnosed unequivocally with ultrasonographically guided transabdominal instillation of indigo carmine dye, followed by the passage of blue-dyed fluid into the vagina, which is documented by a stained tampon or pad."

➢ Maternal urine will also turn blue
21 yr old G1 P0 39 1/7 weeks comes to the birth rooms and says she has been leaking for the past hour. She has no pooling or leaking of fluid from her cervix. You confirm ROM if

- A. nitrazine +, fern +,
- C. nitrazine +, fern -
- D. nitrazine +, fern -, Amnisure +
- E. nitrazine -, fern +
- F. nitrazine -, fern +, Amnisure +
- F. nitrazine -, fern -, Amnisure +
Confirmation of ruptured membranes if

- Fluid was seen leaking from cervical os
- Or 2 of the following conditions were present
  - Pooling
  - Positive nitrazine
  - Positive ferning

184 patients tested (11-42 weeks)

- 76% ruptured membranes by conventional test
- 88% ruptured using Placental Alpha-Microglobulin-1 assay
- 87% were ruptured on initial presentation
Measurement of Placental Alpha-Microglobulin-1 in Cervicovaginal Discharge to Diagnose Rupture Of Membranes

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrazine</td>
<td>88.1</td>
<td>87.5</td>
<td>97.9</td>
<td>52.5</td>
</tr>
<tr>
<td></td>
<td>(0.817-0.925)</td>
<td>(0.665-0.967)</td>
<td>(0.935-0.995)</td>
<td>(0.363-0.682)</td>
</tr>
<tr>
<td>Amnisure</td>
<td>98.7</td>
<td>87.5</td>
<td>98.1</td>
<td>91.3</td>
</tr>
<tr>
<td></td>
<td>(0.951-0.998)</td>
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<td>(0.942-0.995)</td>
<td>(0.705-0.985)</td>
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Measurement of Placental Alpha-Microglobulin-1 in Cervicovaginal Discharge to Diagnose Rupture Of Membranes
*chart review performed to determine if truly ruptured (authors did not describe method)

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<th>Amnisure+ Nitrazine – n=21</th>
<th>Amnisure– Nitrazine + n=4</th>
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<td>139 (100%)</td>
<td>18 (86%)</td>
<td>1 (25%)</td>
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<td>No ROM</td>
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<td>3 (14%)</td>
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Lee’s conclusion.. Placental Alpha-Microglobulin-1 is rapid, accurate for confirming ROM and appears superior to conventional clinical assessment (pooling, nitrazine, ferning) and the nitrazine test alone.”
“How is premature rupture of membranes diagnosed?

However, false positive test results rates of 19-30% have been reported in patients with clinically intact membranes and symptoms of labor.”
Objective: “This study was conducted to examine the frequency and clinical significance of a positive Amnisure test in patients with preterm labor and intact membranes by sterile speculum exam.

- Retrospective, cohort, < 35 weeks, singleton, in preterm labor
- 96 patients met criteria
The clinical significance of a positive Amnisure test in women with preterm labor and intact membranes.

The Journal of Maternal-Fetal and Neonatal Medicine, 2012;25(9):1690-1698

- Diagnosis of ROM
  - Leakage of amniotic fluid from the cervical os was seen on speculum examination
  - Or Two of the following 3 signs were present
    - Pooling of amniotic fluid in posterior vaginal fornix
    - Positive nitrazine test
    - Positive ferning test
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- 17/90 (19%) had positive Amnisure and were not ruptured
The clinical significance of a positive Amnisure test in women with preterm labor and intact membranes.

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- 17/90 (19%) had positive Amnisure and were not ruptured

- Conclusions If + amnisure and not ruptured
  - Higher incidence of earlier preterm delivery
  - Intra-amniotic infection
  - Apgars < 7 both 1 & 5 minutes
  - “A positive Amnisure in patients without symptoms or signs of ROM should not be taken as indicator that membranes have ruptured”.
The clinical significance of a positive Amnisure Test™ in women with term labor with intact membranes

Lee et al. The Journal of Maternal-Fetal and Neonatal Medicine, April 2009, 22 (4): 305-310

- 4 study groups of term nulliparous women
  1. not in labor without clinical evidence of ROM (125)
  2. in labor without clinical ROM with a negative Amnisure test (56)
  3. in labor without clinical ROM with a positive Amnusure (25)
  4. In labor with clinical ROM (30)
The clinical significance of a positive Amnisure Test™ in women with term labor with intact membranes


- 4 study groups of term nulliparous women
  - Ruptured membranes diagnosed if:
    - 1. if the leakage of amniotic fluid was seen on speculum examination
      - Or
    - 2 of the following were present
      - A. pooling of amniotic fluid in the vaginal fonix
      - Positive nitrazine
      - Positive ferning test
The clinical significance of a positive Amnisure Test™ in women with term labor with intact membranes

4 study groups of term nulliparous women (excluded if premature ROM)

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The clinical significance of a positive Amnisure Test™ in women with term labor with intact membranes


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  - 2. in labor without clinical ROM with a negative Amnisure test (56)
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  - 4. In labor with clinical ROM (30)

- Positive Amnisure in women in labor without ROM 25/81 = 30.9%
- Negative Amnisure in women not in labor without ROM 6/125 = 4.8%
- If Amnisure + & no clinical ROM shorter interval from admission to delivery
21 yr old G1 P0 39 1/7 weeks comes to your office for prenatal visit. She has been leaking for the past hour. ROM confirmed by amniotic fluid leaking from her cervix. By speculum exam her cervix is 3 cm and looks 50% effaced. She is not contracting. FHT 140, reactive & no periodic changes

- 1. perform digital exam and start oxytocin induction of labor
- 2. perform digital exam and wait 6 hours to induce labor if she has not gone into labor spontaneously
- 3. not perform digital exam and start oxytocin induction of labor
- Not perform digital exam and start oxytocin of labor at 6 hours if she has not gone into labor spontaneously
How is premature rupture of membranes diagnosed?

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“Because digital cervical examinations increase the risk of infection and add little information to that available with speculum examination, digital examinations generally should be avoided unless the patients appears to be in active labor or delivery seem imminent. Sterile speculum examination provides an opportunity to inspect for cervicitis and umbilical cord prolapse, assess cervical dilation and effacement, and obtain cultures as appropriate.”
How is premature rupture of membranes diagnosed?

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- Reference
- Good correlation between speculum findings and digital exam (Munson et al Am J OB GYN 2000;183:1003-7)
Conclusions
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- **Level A**
- Patients with PROM before 34 0/7 weeks of gestation should be managed expectantly if no maternal or fetal contraindications exist.

- **Level B**
- For women with PROM at 37 0/7 weeks of gestation or more, if spontaneous labor does not occur near the time of presentation in those who do not have contraindications to labor, labor should be induced.
- At 34 0/7 weeks or greater gestation, delivery is recommenced for all women with ruptured membranes.
What did we learn?
Etiology of premature rupture of membranes

- 8% of term pregnancies are complicated by PROM
- Hannah-randomized to induction vs. expectant
  - ½ deliver within 5 hours of PROM
  - 95% deliver within 28 hours PROM