Evidence Table

Clinical Area: AmniSure (ROM) Rupture Of fetal Membranes Test

Study Type: Comparison of diagnostic tests.
Study Aim: To compare AmniSure rapid immunoassay with standard methods of diagnosing rupture of fetal membranes (ROM).

Outcomes

*Primary:* Sensitivity, specificity, positive predictive value, and negative predictive value.

Design:

- **Number of subjects:** N=203.
- **Description of study population:** Study participants were recruited from two hospitals in California. No characteristics other than the inclusion/exclusion criteria were provided.
- **Inclusion criteria:** Pregnant women between 15.0 and 42.0 weeks of gestation, presenting with signs and/or symptoms of membrane rupture.
- **Exclusion criteria:** Women with active vaginal bleeding from any source and/or placenta previa were excluded.
- **Power:** Not discussed.
- **Procedure:** Study participants underwent a clinical examination and the standard tests used to diagnose ROM. These included visual pooling of amniotic fluid, Nitrazine test (to determine alkaline pH of vaginal secretions), and microscopic ferning. The diagnosis of membrane rupture required coinciding positive results of two of these standard tests. AmniSure testing was then performed by a second examiner blinded to the results of the other tests. In case of discrepancy of the results between AmniSure and the control tests, the diagnosis was verified by either retesting or by sonographic evidence of low fluid. After delivery the clinical record of the patients were examined to determine whether the patient had premature rupture of the membranes (PROM) or preterm premature rupture of the membranes (PPROM).

Validity:

- **Independent blind comparison with a gold standard or follow-up of those not receiving the gold standard test?** AmniSure was compared to other standard tests. The physicians performing the AmniSure tests were blinded to the results of the standard tests, and vice versa.
- **Was “normal” defined?** Yes.
- **Appropriate spectrum of disease?** Patients with signs and/or symptoms of preterm rupture of membranes were included. The authors did not indicate if all the spectrum of patients with membrane rupture were included.
Methods described in enough detail to enable you to replicate the test? Yes.
Reproducible results? Yes.

Conclusions regarding validity of methods:
The authors compared the AmniSure test to other tests which might not be very accurate especially with passage of time from membrane rupture.

Results:
89/203 (43.8%) patients were diagnosed with ruptured membranes using the standard tests (control methods), and 114 (56.2%) were diagnosed as not having ruptured membranes.

Sensitivity, specificity, positive and negative predictive values of AmniSure test*

<table>
<thead>
<tr>
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<th>Value (%)</th>
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<tbody>
<tr>
<td>Sensitivity</td>
<td>98.9%</td>
</tr>
<tr>
<td>Specificity</td>
<td>100.0%</td>
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<tr>
<td>Positive predictive value</td>
<td>100.0%</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>99.1%</td>
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*In seven cases the control tests and AmniSure gave discrepant results. Verification of the results among these patients was made by retesting or ultrasonography.
The authors indicate that in 4 of these cases repeat examination showed that the control tests produced false negative results and that AmniSure was the accurate test.

Authors’ Conclusions:
The authors concluded, “AmniSure is a rapid bedside strip test that can detect rupture of fetal membranes with a high degree of predictive accuracy”. They recommended more studies to confirm their findings.

Reviewer’s Conclusions:
In this trial the performance of AmniSure was blindly compared to that of standard tests used for diagnosis of premature membrane rupture, and the results show that it was highly accurate compared to these tests. However, as reported by researchers these standard tests may be less accurate with passage of time from membrane rupture. The authors did not provide any patient characteristics or data to indicate the duration from experiencing any signs or symptoms of membrane rupture to testing. The test was not compared to clinical findings at delivery, which may give a more accurate diagnosis of premature rupture than the standard tests used.