

Diagnostic reliability of Speculum Exam

Sir,

In 1997 Ladfors *et al.* (1) published a study in which they assessed the diagnostic accuracy of sterile speculum examination for the diagnosis of rupture of the membranes (ROM) in pregnancy. The authors reported a 12% false negative rate which has been quoted in several recent articles (2-4). As part of our work for NICE's Medical Technology Evaluation Programme (www.nice.org.uk/mt) we have reviewed the data in the original publication and concluded that this rate has been interpreted inappropriately.

The authors compared speculum exam with diamine oxidase (DAO) as a reference test. A diagnostic reliability of 100% was assumed for DAO in both the original study and our recalculation. Patients admitted to a labour and delivery unit with self-reported suspicion of ROM, were given a sterile speculum exam at admission. Women in whom amniotic fluid could be seen were excluded from the rest of the study and a sample for DAO testing was collected from the remaining subjects. Of 2099 women who were initially eligible for the study, 1580 had amniotic fluid visualised at the initial speculum exam. However, 43 of these 1580 had 'signs of intact membranes at delivery' suggestive of false positive results for the initial speculum exam. Of the remaining 519 patients with no visualised amniotic fluid, 456 had a negative DAO test and 63 had a positive result.

The authors use the 63 positive DAO tests from the 519 negative speculum results to determine a 12% false negative result. However this only takes into account the patients in whom the speculum exam was negative and is not the standard method by which false negative rates are calculated. The false negative rate should be calculated as the proportion of patients with ROM who have a negative speculum test result. The tables below show that the false negative rate is closer to 4% than the 12% quoted in the original study. Tables 1a and 1b model the data on the assumption that the 1580 women with a positive speculum examination result would have had a positive DAO test if they had also been tested. The false negative rate in this case is then $63/1643$ or 3.8%. Tables 2a and 2b includes the 43 women with signs of intact membranes as false positive results so that the false negative rate calculated in this manner is $63/1600$ or 3.9%. The diagnostic performance of the speculum examination in these two models ranges are: sensitivity (96.1-96.2%), specificity (91.4-100.0%), false positive rate (0.0-8.6%) and false negative rate (3.8-3.9%).

Table 1a: Outcome frequency with no false positives

| | | Speculum | | |
|-----|-------|----------|------|-------|
| | | + ve | - ve | Total |
| DAO | + ve | 1580 | 63 | 1643 |
| | - ve | 0 | 456 | 456 |
| | Total | 1580 | 519 | 2099 |

Table 1b: Diagnostic accuracy with no false positives

| | |
|----------------------------|----------------------|
| Sensitivity | 96.2% (1580/1643) |
| Specificity | 100% (456/456) |
| False positive rate | 0% (0/456) |
| False negative rate | 3.8% (63/1643) |

Table 2a: Outcome frequency with 43 false positives

| | | Speculum | | |
|-----|-------|----------|------|-------|
| | | + ve | - ve | Total |
| DAO | + ve | 1537 | 63 | 1600 |
| | - ve | 43 | 456 | 499 |
| | Total | 1580 | 519 | 2099 |

Table 2b: Diagnostic accuracy with 43 false positives

| | |
|----------------------------|----------------------|
| Sensitivity | 96.1% (1537/1600) |
| Specificity | 91.4% (456/499) |
| False positive rate | 8.6% (43/499) |
| False negative rate | 3.9% (63/1600) |

Susan Peirce^{1*}, Alistair Ray¹, and Grace Carolan-Rees²

1 Research Associate, Cedar, Cardiff University, Cardiff

2 Director, Cedar University Hospital of Wales, Cardiff, UK

***Corresponding Author:**

Susan Peirce

E-mail: susan.peirce@wales.nhs.uk

References:

1. Ladfors L, Mattsson LA, Eriksson M, Eriksson M, Fall O.. (1997) Is a speculum examination sufficient for excluding the diagnosis of ruptured fetal membranes? *Acta Obstet Gynecol Scand* .1997;76:739-42.
2. El-Messidi A and Cameron A. Diagnosis of premature rupture of membranes: inspiration from the past and insights for the future. *J Obstet Gynaecol Can*. 2010;32: 561-9
3. van der Ham DP, van Teeffelen ASP, Mol BWJ. Prelabour rupture of membranes: overview of diagnostic methods. *Curr Opin Obstet Gynecol*. 2012;24: 408-12.
4. Neil PRL and Wallace EM. Is Amnisure® useful in the management of women with prelabour rupture of the membranes? *Aust N Z J Obstet Gynaecol*. 2010;50:534-8.