



BACKGROUND

Premature Rupture of the Membranes

In a normal birth the foetal membranes (chorionic and amniotic) rupture during labour. In 6 – 12% of pregnancies, however, the membranes rupture spontaneously before labour begins, a process known as premature rupture of the membranes, or PROM. If PROM occurs when pregnancy is at term, labour will usually follow or be induced to avoid infection. In 2-3%, however, PROM occurs before 37 weeks gestation, and in these cases a clinical decision must be made as to whether delivery should be induced with the resultant risks to the infant, or to allow the pregnancy to proceed with the risk of infection of the remaining amniotic fluid

Causes of PROM

Clinical variables

Cervical incompetence

Multiple pregnancies

Polyhydramnios

Antepartum haemorrhage

Heavy smoking

Physical properties of membranes

Infection

Acute inflammation of the placental membranes is twice as common when membranes rupture within 4 hours before labour as when they rupture after its onset, suggesting such infection may be a cause of PROM.

Diagnosis of PROM

PROM is normally diagnosed from case history, physical findings and simple laboratory tests. Tests are normally based on determination of vaginal pH (as with **Amnicator[®]**), or the detection of foetal cells in the vagina. Other approaches include biochemical and histochemical tests, and intra-amniotic injection of dyes, but these are not as popular, and the dye-injection method is potentially hazardous.

Basis of Amnicator[®]

The vagina in normal circumstances has a low pH. This is because the mucosa of the vagina contains large amounts of glycogen which upon decomposition produces organic acids. These create an acidic environment whose function is to retard microbial growth. Thus the pH within the vagina in normal women during pregnancy will lie between 5.2 and 6.0.

PROM results in a seepage of fluid which passes from the uterus to the vagina. Since amniotic fluid has a pH of 7.1 – 7.2, this will cause an increase in the pH of fluid present in the vagina.

In the past the indicator bromothymol blue was used to detect this change of pH. It, however, does not have a sharp end point, requiring the pH to change from 6.0 to 7.7 for a complete colour change. This is a poor sensitivity. Nitrazine yellow has an end point between 6.4 and 6.8, which is particularly appropriate for the change in vaginal pH which occurs in the presence of amniotic fluid. The colour change from yellow to deep blue is very visible and definite.

Limitations

As the **Amnicator[®]** is a pH determination test, It is clear that some factor can influence the test:

Treatment with antibiotics may increase vaginal pH.

Some vaginal infection (*Trichomonas vaginalis*, some cocci) can give false positive result.

The membranes should not be touched with the swab, do not introduce the swab in cervix.

It is often stated semen (pH 7.3-7.5) raises the vaginal pH.

The pH of chlorhexidine obstetric cream and lotion were respectively 6.2 and 5.0 to 6.5, but if it's use properly with 5% solution there is not affect the result.

Some other obstetric solution has alkaline pH, a vaginal application of concentrated lotion may give false positive result.

The colour of the blood could create bad condition for reading.

Amnicator®

Amnicator® are sterile, high quality swabs impregnated with nitrazine yellow. The swab is easily inserted into the vagina. Any fluid present is sampled and the **Amnicator®** is withdrawn after about 5 seconds. Normally the bud should remain bright yellow. If amniotic fluid is present, the bud will change to blue-green or deep blue. This indicates that the membranes have ruptured, and the clinicians must decide on the appropriate management of the case.

Features

- **Easy to use**
- **Highly sensitive indicator**
- **Non-invasive (i.e. no needles)**
- **Non-threatening to patient**
- **Visible negative result gives quick reassurance to patients**
- **Safe**
- **Room temperature storage**
- **Long shelf life (2 years)**

Interpretation of Amnicator® colour change	
Intact membranes	Ruptured membranes
pH 5.0 yellow	pH 6.5 blue-green
pH 5.5 yellow	pH 7.0 blue
pH 6.0 yellow	pH 7.5 blue-black

Intact Membranes

Ruptured Membranes



Medical Devices Directive

Amnicator® are Class I (Sterile) devices as defined by the European Medical Devices Directive 93/42 EEC, and are CE-marked.

Safety information for Nitrazine Yellow

<i>Carcinogenicity</i>	<i>No evidence of carcinogenic properties</i>
<i>Mutagenicity</i>	<i>No evidence of mutagenic properties</i>
<i>Stability</i>	<i>Stable</i>
<i>Reaction</i>	<i>None with water</i>

References

1. Abe, T. The detection of the rupture of fetal membranes with the nitrazine indicator. *American Journal of Obstetrics and Gynaecology* 1940, **39**:400-404
2. Drife, J. Preterm rupture of the membranes. *British Medical Journal* 1982; **285**:583
3. Mills, A., Garrioch D., Use of the nitrazine yellow swab test in the diagnosis of ruptured membranes. *British Journal of Obstetrics and Gynaecology* 1977; **84**:138-140
4. Pauersterin, C., Premature rupture of the membranes. in: *Clinical Obstetrics*, Anonymous, ed., John Wiley & Sons and Churchill Livingstone, 1987; 367-381
5. Pritchard, J., Macdonald, P., *Williams Obstetrics* Anonymous, ed., New York: Appleton-Century-Crofts, 1980; 407-408