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The Accuracy of Sanitary Pad of Nitrazine Test in the Diagnosis of Premature Rupture of Membranes

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Abstract

Background: *Sanitary Pad of Nitrazine Test (SPONT) is one of the newest method to diagnosis premature rupture of membranes (PROM) that doesn't need women attending hospital and applying speculum. The aim of this study was to assess the performance of SPONT versus standard clinical assessment.*

Methods: *A prospective diagnostic accuracy study, 140 pregnant women with symptoms of PROM in 22-42 weeks of gestation were involved. The accuracy of SPONT in the diagnosis of PROM was compared with Nitrazine, Fern and Pooling tests that were performed at the same time.*

Results*: The sensitivity, specificity, positive predictive value, and negative predictive value of SPONT, routine Nitrazine, Fern and Pooling tests were 93.2%, 85.7%, 97.3%, 69.2%; 94.1%, 90.5%, 98.2% 73.1%; 80.1%, 95.2%, 98.9%, 46.5%; and 68.1%, 95.2%, 98.9% 46.5%, respectively. The sensitivity of SPONT was the same as routine Nitrazine test (P.V=0.811). SPONT has higher sensitivity than Fern test (P.V=0.008) and Pooling test (P.V<0.001). The accuracy of the applied tests was 92.1%, 93.6%, 82.8% and 72.8% respectively for SPONT, Nitrazine, Fern and Pooling tests. There wasn't significant difference between accuracy of SPONT and standard clinical assessment (92.1% vs. 89.3%).*

Conclusions: *The accuracy of SPONT was the same as routine Nitrazine test in PROM diagnosis that pregnant women can use it if they do not have immediate access to health centers.*

Keywords: Nitrazine, Premature ruptures of membrane, Diagnostic test, Accuracy, PROM.
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Introduction

Disruption of amniotic membranes before the onset of labor, commonly known as premature rupture of membranes (PROM), is one of the most common problems during pregnancy.[1,2] It occurs in 8 - 10% of all pregnancies.[3] PROM could lead to either fetal or maternal morbidity such as prolapse of the umbilical cord, necrotizing enterocolitis, intraventricular hemorrhage,[4] respiratory distress syndrome, sepsis, chorioamnionitis, or postnatal endometritis.[5,6] The early and precise diagnostic method reduces feto-maternal morbidity. Additionally, preterm disruption of amniotic membranes leads to 20–450% of premature births.[7] One of the major problems is PROM in clinical practice, and it absolutely requires accurate and fast methods for its identification. Also, a major challenge in the current obstetric practice is the diagnostic confirmation in equivocal cases, since there is not always enough fluid or visual leakage in the vagina to confirm.[8] Thus, correct diagnosis is vital in order to decide upon the most suitable treatment and ultimately to decrease both maternal and fetal complications.[9,10] There are many tests to recognize PROM. The gold standard methods for diagnosis of PROM include Polling, Ferning, and Nitrazine tests.[11] Previous investigations have examined the performance of these tests. Fern test predicted the PROM correctly in 63% and incorrectly in 29% of pregnant women and the test was more precise after the onset of the labor phase.[6] The results of a meta-analysis study indicated that the Nitrazine test has high sensitivity (73-91%) and specificity (72-83%) for diagnosis of PROM.[12]

These tests need applying speculum which is inconvenient for pregnant women. There have been several efforts on finding easier tests for PROM diagnosis which are comfortable for them.[11] Measurement of vaginal pH assessment by sanitary pad is one of the newest innovations that does not require women to attend the hospital and apply speculum,[13] but we were concerned about the validity of this test, because of its usage and interpretation by pregnant women. Nevertheless, there is also a question whether the insertion of the test inside the sanitary pad alters its accuracy. The aim of this study was to assess the performance of the Sanitary Pad of Nitrazine test (SPONT) versus standard clinical assessment.

Materials and Methods

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional review board of Imam Reza (a.s.) hospital, Ayvan, Ilam, Iran No. 96/44284 on Jan 11, 2018 and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

This study was a prospective observational study. Consecutive pregnant women presenting to the obstetrics block of the Imam Reza hospital with symptoms, signs or complaints suggestive of membrane leakage or rupture between 22 and 42 weeks were eligible for the study. The study was performed from Mar to Oct 2018. The sample size of this study was calculated as 140 pregnant women, using a previous similar study[14,15] while considering a potential loss to follow-up of 20%.

Women with plenty of vaginal bleeding, taking vaginal disinfectants or drugs, signs of chorioamnionitis and placenta Previa were excluded from the study. Patients with a complaint of PROM underwent medical history and clinical examination without using lubrication and disinfectants.

Clinical decisions were made by only the standard clinical assessment (2/3 Ferning, Pooling, Nitrazine) for participants. All women who provided written consent underwent the

clinical assessment (Ferning, Pooling and routine Nitrazine tests) and SPONT in sequence.

Ultimately, PROM diagnosis was made at initial examination using standard clinical assessments criteria (two of the three clinical signs were positive). If initial evaluation tested negative by the standard tests, a repeat test was conducted at least 30 minutes after the first assessment.[7,16]

A sterile swab was used for preparing a thin smear without any antiseptics or lubricants for the Ferning test. The smear was put on the slide and allowed to air dry. The fully-dried slide was also examined microscopically. Branching view of crystals indicates that there is amniotic fluid. The pooling test consisted of seeing amniotic fluid in Posterior Fornix or seeing a clear flow from the uterus cervix spontaneously or after coughing.

We used a strip of pH paper swab for routine Nitrazine test for the study. The color on the strip matched the closest color on the dispenser color chart. The negative test of amniotic fluid was considered when the pH paper color was yellow to olive green (pH from 4.5 to 6.0), but the positive for amniotic fluid was considered when the pH paper color was blue-green to deep blue (pH from 6.5 to 7.5). After doing these three tests, SPONT was given to pregnant women. A midwife trained each pregnant woman how to interpret this test based on the dispenser color chart. Then, the pregnant women were asked to walk for 20 minutes and to interpret the test themselves by observing the sanitary pad. Ultimately, the women interpreted the SPONT. The interpretation of SPONT was also similar to routine Nitrazine test but Routine Nitrazine test was interpreted by midwives while SPONT by pregnant women.

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of SPONT in diagnosis of PROM were compared with those of other tests.

The sensitivity, specificity, PPV, and NPV were calculated for each test. Additionally, the accuracy ([true positive + true negative] / [true positive + true negative + false positive + false negative] × 100%)[17] of each test was also estimated. Data were analysed using the tests of Kruskal-Wallis and Mc Nemar exact tests.

Data were analyzed using the Statistical Package for the Social Science (SPSS version 17). P.V < 0.05 were considered as statistically significant.

Results

A total of 140 women were included in our study, there were no eligible pregnant women at 20–31 weeks of gestation. The mean age of the participants was 29.2 ± 5.1 years (range, 19–40) and average of gestational age was 37.8±6.2 weeks. Also, 68.6% of pregnancies were term, 25% between 34-37 weeks and 6.4% less than 34 weeks. The results of the tests are shown in figure 1.

Initial observations and standard tests confirmed PROM in 108 women and SPONT indicated PROM in 114 women. Finally, 85% (119) of involved women were diagnosed with PROM. Among 12 cases which were negative in at least two standard tests and positive in SPONT, 11 cases had PROM. Among these 11 cases, 8 cases had only positive Nitrazine test and 3 cases had only positive Ferning test, while pooling test was negative in all of them. Of the 119 women who were tested true positive, ultimately, 11 people were initially tested negative on the initial assessment by standard tests, but the result of a repeat evaluation by standard tests indicated positive after 30 min from the first evaluation.

Table 1 reports the overall performance of the SPONT versus standard clinical assessment. The SPONT has 93.2% sensitivity, 85.7% specificity, 97.3% PPV and 69.2% NPV in PROM diagnosis. P.V comparison between the tests is summarized in table 2. The sensitivity of the SPONT did not statistically differ from that of the routine Nitrazine test (93.2% vs. 94.1%, P.V=0.811).

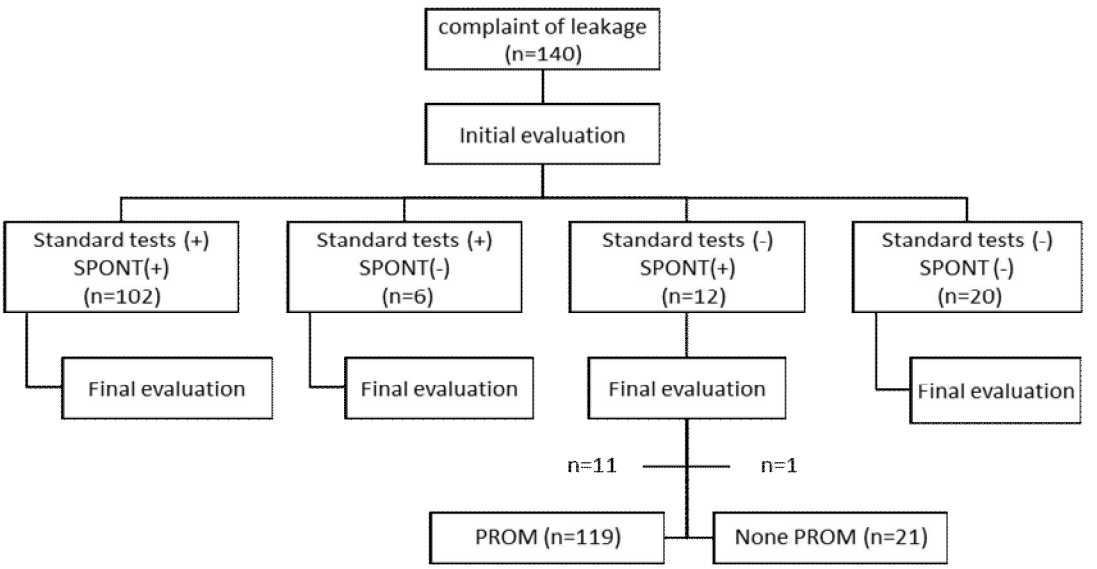

Figure 1. Flowchart of pregnant women with complaints of Premature Rupture of Membranes. Standard tests (+): at least two tests of Ferning, Pooling and routine Nitrazine tests are positive. Standard tests (-): at least two tests of Ferning, Pooling, and routine Nitrazine test are negative. SPONT: Sanitary Pad of Nitrazine Test. PROM: Premature Rupture of Membranes

Table 1. Performance of the Sanitary Pad Nitrazine test (SPONT) compared with the standard clinical assessment in the diagnose of PROM

Classification	Fern	Pooling	Nitrazine	Standard clinical assessment (2/3, Ferning, Pooling, Nitrazine)	SPONT
True positive	96	81	112	106	111
True negative	20	21	19	19	18
False positive	1	0	2	2	3
False negative	23	38	7	13	8
Total	140	140	140	140	140
Sensitivity (%)	80.1	68.1	94.1	89.1	93.2
Specificity (%)	95.2	100	90.5	90.5	85.7
Positive predictive value (%)	98.9	100	98.2	98.1	97.3
Negative predictive value (%)	46.5	35.6	73.1	59.9	69.2
Accuracy (%)	82.8	72.8	93.6	89.3	92.1

Table 2. P.V comparison between tests

	SPONT and Fern	SPONT and Nitrazine	SPONT and Pooling test	SPONT and Standard clinical assessment
SN (P.V)*	0.01	0.81	<0.001	0.08
SP (P.V)**	0.03	0.07	0.01	0.07
Accuracy	0.04	0.79	0.04	0.19

*Mc Nemar Test, **Kruskal-Wallis test

SPONT has higher sensitivity than Fern test (P.V=0.008) and Pooling test (P.V<0.001). In contrast, the specificity of Fern and pooling tests was greater than that of the SPONT (P=0.034) and (P.V<0.009) respectively. The accuracy of the applied tests was 93.6%, 92.1%, 82.8%, and 72.8% for Nitrazine, SPONT, Fern and pooling tests respectively. Overall, there was no significant difference between the accuracy of the SPONT and standard clinical assessment (92.1% vs. 89.3%, P=0.19).

Discussion

Since PROM is known as a common obstetric problem and it has serious consequences, using a sensitive, non-invasive and accessible test for its identification is of importance.[18]

This study found that the SPONT has similar accuracy, sensitivity, specificity, positive predictive value and negative predictive value in the detection of PROM when compared with the routine Nitrazine test. More recently, the sensitivity and specificity of the Nitrazine test were reported as 98.0% and 88.2% in a laboring group, respectively.[6,19]

SPONT is a screening test conducted and interpreted by pregnant women. The important characteristic of a screening test is high sensitivity as it recognizes more people who are healthy (false positive).[8] This is the nature of the screening test.

This study found that the SPONT has greater accuracy, sensitivity, positive predictive value in the detection of PROM when compared with the Ferning (P.V<0.008) and pooling test (P.V<0.001) individually, but it has lower specificity and negative predictive value than them. This finding is in accordance with the results of previous studies regarding the comparison of the routine Nitrazine test with Ferning and Pooling tests.[15,20]

The results of the present study indicated that the performance of Nitrazine test was the same when it was conducted by a clinician or inserted in a sanitary pad and interpreted by pregnant women. There is a belief that examiner`s skill affects the tests and reporting the results.[15] However, the results of another study suggested the patient education lead to better reporting assessment and following outcomes[21] occurring in this study.

This study demonstrated that the accuracy of Sanitary Pad of Nitrazine test was the same as routine Nitrazine test in PROM diagnosis. Note that the SPONT has more benefits than routine Nitrazine test including being applicable by pregnant women without any need to be visited by a clinician or midwife thus eliminating the unnecessary presence of pregnant women in physician's offices or hospitals. It also saves time in detecting PROM; it is more accessible and applicable to pregnant women who live in a suburb or rural areas. Further applying speculum is unpleasant for patients, but this test does not need applying speculum. Further, the overall cost for the SPONT is probably lower compared to standard clinical tests through cost reductions including no physician visit, transfer fee and equipment used for testing such as sterile gloves and speculum.[13] To the only issue to bear in mind is that errors should be avoided in interpretation of the test by pregnant woman. Thus, the key points should be mentioned on the package of the SPONT to reduce false positive cases. The instructions should also be clear regarding the dispenser color chart.

The accuracy of SPONT was the same as routine Nitrazine test in PROM diagnosis. As such, pregnant women can use it if they do not have immediate access to health centers.

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Conflict of Interest

All authors declare that they have no conflict of interest. The manuscript has been read and approved by all the authors. Also, the requirements for authorship as stated earlier in this document have been met, and each author believes that the manuscript represents honest work, and the information has not been provided in any other form.

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