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Research Article

Detection of Amniotic Fluid Leakage in Women with Suspicion of Prelabour Rupture of Membrane or Unexplained Vaginal Wetness by Amniotic Fluid Detection Kit and its Comparison with Fern Test

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Abstract: Prelabour rupture of membranes represents one of the most frequent and most controversial problem obstetricians are faced with. The timely and accurate diagnosis of ruptured fetal membranes during pregnancy is of utmost importance for indicating the appropriate approach towards treatment. The objective was to find out agreement between amniotic fluid detection kit and fern test in detection of prelabor rupture of membrane (PROM) in women with history of suspicion of PROM or unexplained vaginal wetness. One sixty eligible women with history of suspected leaking were subjected to fern test and Amniotic Fluid Detector Panty Liner Kit (AFDK) test, after excluding out obvious leaking by speculum examination. Results were statistically analysed and investigated regarding reliability, sensitivity and specificity of AFDK. Mean age of the women was 23.66 ± 2.75 yrs. Majority of cases (63.13%) was primigravidae and in the 36-40 wks gestational age group (53.75%). The overall agreement between AFDK and fern test was 92.5%. Sensitivity and specificity of AFDK was 90.91% and 93.61% respectively. In our study positive predictive value of AFDK was 90.90% and negative predictive value was 93.61%. In conclusion, this study demonstrates that amniotic fluid detection kit is highly sensitive, non-invasive method and more acceptable than speculum examination to detect the presence of amniotic fluid.
Keywords: Prelabor rupture of membranes, Vaginal wetness, AFDK test, Fern test..

INTRODUCTION

Prelabour rupture of membranes represents one of the most frequent and most controversial problem obstetricians are faced with. Preterm prelabor rupture of membranes is associated with premature birth, respiratory distress syndrome and infection in the neonate. The mother is also at increased risk of developing infection, particularly choroamnionitis [1-3]. Therefore accurate diagnosis is critical to both long-term and short-term health and survival for the baby as it facilitates the commencement of appropriate antibiotic therapy, that reduce both maternal and fetal morbidity [4].

The timely and accurate diagnosis of ruptured fetal membranes during pregnancy is of utmost importance for indicating the appropriate approach towards treatment. In majority of cases diagnosis of PROM is obvious by history and "sudden gush of fluid", confirmed by clinical assessment and documentation of amniotic fluid leakage from the cervical os with visualization of pooling in the posterior vaginal wall fornix [5]. However the diagnosis of PROM is difficult when the classic gush of fluid does not occur or a patient history is suspicious for membrane rupture but clinical examination is inconclusive or negative creating an obstetrical dilemma. The modalities used to diagnose premature rupture of membranes are variable, it begins by history taking and clinical examination with visualization of amniotic fluid pooling in the posterior fornix (speculum examination), use of Nitrazine/ pH based paper, microscopic examination for crystallisation of amniotic fluid (fern test) and Amnisure for placental alpha-

microglobulin-1 (PAMG-1) used alone or in combination. But still there is no reliable standard [6-8].

An ideal diagnostic aid for the detection of amniotic fluid leak should be non-invasive inexpensive, easy to use, easy to read and available for use at home to detect intermittent fluid leakage over a period of time. In addition, it should provide high sensitivity, high specificity and could differentiate amniotic fluid from another source of vaginal discharge or urinary incontinence.

A non invasive pH based AFDK pad embedded with an indicator strip to detect amniotic fluid, is commercially available to detect amniotic fluid leakage, even in small amount. AFDK pad is an absorbent pad (approximately 12 x 4 cm) with a central contact strip that changes colour on contact with small amount of fluid with a pH >5.2. In the presence of liquor, the contact strip changes colour which persists once the strip has dried [9]. So the present study has been done to detect amniotic fluid leakage in pregnant women with a history suspicious for membranes rupture or women complaining an unexplained vaginal discharge or wetness by using amniotic fluid detector liner absorbant pad. The sensitivity and specificity of this test were compared with standard fern test.

METHODOLOGY

This clinical descriptive study was conducted in the Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur during the year 2011-2012. Pregnant women with gestational age >28 weeks with history of suspected amniotic fluid leakage or unexplained vaginal wetness were recruited in the study after obtaining informed written consent. Women with a demonstrable amniotic fluid leakage or with clinically detectable absent membranes, spontaneous or traumatic vaginal bleeding, history of urinary incontinence, had sexual intercourse or vaginal douching within the previous 12 hours, with any evidence of maternal ill health and fetal compromise at the time of admission or in active labor were excluded from study. Sample size was calculated by using Z test for difference between two proportion at 80% study power and 5% alpha error assuming sensitivity of kit 90% and 99% of fern test. The sample size was 160.

All **eligible women subjected to fern test and** AFDK (marketed as Sensitek by German Remedies).

Fern Test

Secretion causing unexplained vaginal wetness was collected from posterior fornix by using a sterile swab and placed on a glass slide and was dried for 20-30 mintues. If slide showed arborisation (ferning) under the microscope at low magnification (x40), it is suggestive of amniotic fluid leakage.

Amniotic Fluid Detector Panty Liner Kit (Sensitek)

Each sensitek contains one amniotic leakage detection kit (absorbent pad), one plastic drying tray and instruction literature. Woman was given the amniotic fluid detector panty liner absorbent pad to wear for upto 12 hrs or until vaginal wetness was noticed. After the allotted time or when the panty liner was wet, the indicator strip was removed by gently pulling the loose tail of the indicator strip. The indicator strip was placed on the white cloth in the open plastic box (drying unit). If the indicator strip turned blue or green, we waited for 30 minutes to recheck the colour of the indicator strip. Sustained blue or green colouration indicates PROM.

A false positive result may be obtained if woman is having bacterial vaginosis.

KOH Test

In cases in which amniotic fluid detector kit show positive result we add a small amount of fluid from the posterior fornix with 10% KOH to see fishy odour to rule out bacterial vaginosis (Whiff Test).

Data were collected and AFDK test was compared with the reference standard (fern test). Prevalence, sensitivity, specificity, positive predictive value and negative predictive value for the test were calculated.

Formulas used in statistical analysis were as follows

$$\text{Prevalence} = \frac{Total\ Positive}{Population} \times 100$$

$$\text{Sensitivity} = \frac{True\ Positive}{True\ Positive + False\ Negative} \times 100$$

$$\text{Specificity} = \frac{True\ Negative}{True\ Negative + False\ Positive} \times 100$$

$$\text{PPV} = \frac{True Positive}{True\ Positive + False\ Positve} \times 100$$

$$\text{NPV} = \frac{True\ Negative}{True\ Negative + False\ Negative} \times 100$$

RESULTS

Mean age of the cases were 23.66 ± 2.75 years. Most of the cases were Hindus (78.12%), from urban area (80.62%) and belonging to middle socio-economic status (76.24%). Majority of the cases were primigravida (63.13%) and mean gravidity was 1.45 ± 0.67. Most of the cases were literate (77.5%) and booked (85.63%). Maximum cases (53.75%) were in the 36-40 weeks gestational age group. Mean gestational age was 37.53 ± 0.806 weeks (Table 1).

41.25% cases were Fern positive which means total positive and 58.75% were negative which means total negative (Table 2).

58.75% cases showed negative results and 41.25% showed positive results after using Amniotic Fluid Detector Kit Test (Table 3).

Fern test was positive in 66 patients, out of whom 60 were AFDK positive (true positive) and 6 were AFDK negative (false negative). Fern test was negative in 94 cases and out of which 88 were AFDK negative (true negative) and 6 were AFDK positive (false positive) (Table 4). Out of 6 false positive cases 3 were KOH test (Whiff test) positive. So it indicates that some of false positive results may be due to bacterial vaginosis which cause elevated pH of vaginal secretion.

Sensitivity and specificity of AFDK in comparison with fern test was 90.90% and 93.61% respectively, positive predictive value was 90.90% and negative predictive value was 93.61%. The results were statistically significant (P<0.01) (Table 5).

Table 1: Distribution of cases according to gestational age

Gestational Age (in weeks)	Number	%
28 - 32	21	13.12
32 - 36	43	26.88
36 - 40	86	53.75
>40	10	6.25
Total	160	100.00

Table 2: Distribution of cases according to result of fern test

Fern Test	Number	%
Positive	66	41.25
Negative	94	58.75
Total	160	100.00

Table 3: Distribution according to result of amniotic fluid detector kit test

Amniotic Fluid Detector Kit Test	Number	%
Positive	66	41.25
Negative	94	58.75
Total	160	100.00

Table 4: Distribution of cases according to result of fern test and amniotic fluid detector kit test *(AFDK)*

	Fern Test Positive		Fern Test Negative	
	Number	%	Number	%
AFDK Positive	60 (TP)	90.91	6 (FP)	6.38
AFDK Negative	6 (FN)	9.09	88 (TN)	93.62
Total	66	100.00	94	100.00

Table 5: Sensitivity and specificity of amnio sense test for detection of spontaneous rupture of membranes

	%
Prevalence	41.25
Sensitivity	90.90
Specificity	93.61
Positive Predictive Value	90.90
Negative Predictive Value	93.61
Statistical Significance	p = <0.01

DISCUSSION

In present study the reliability, sensitivity and specificity of amniotic fluid detector kit test for diagnosis of PROM in comparison with Fern test (Gold standard) were investigated. Mean age of women presented with a history suggestive of PROM was 23.66 ± 2.75 yrs. The result of our study was comparable with the study of Bornstein J *et al*. [10] and Hosseini *et al*. [11] where the mean age of the participants was 25.4 yrs and 24.3 yrs respectively while the mean maternal age was higher (29.1 yrs) in the study done by Vargeni *et al*. [12]. Mean gestational age was 37.53 ± 0.806 yrs (range from >28 wks). These results are comparable with the study of Bornstein J *et al*. [10] in which average gestational age of the participants was 37.2 wks.

Prevalence of true cases of PROM was 41.25%. The overall agreement between the AFDK and Fern test was 92.5%. With a large cohort (n = 160) has provided evidence to suggest that a negative AFDK test result will provide reassurance of intact membrane and both term and preterm gestation. In this study 86 cases were preterm and 74 were term. In preterm cases AFDK was

negative in 55 cases. These cases are also negative for Fern test. Out of these 55 cases 47 were managed conservatively. So accurate and prompt diagnosis of PROM lead to optimize the outcome of pregnancy, eliminate unnecessary obstetric procedure and reduces visits to hospital.

Based on the overall results AFDK test has a 90.90% chance of having ruptured membranes confirmed by Fern examination. Whereas a woman with a negative AFDK result has a 93.61% chance of not having ruptured membranes.

We have shown that the AFDK performs with high sensitivity in an antenatal population when compared with the standard method of assessment by Fern test.

Out of 6 false positive cases 3 were KOH test (Whiff test) positive. So it indicate that some of false positive results may be due to bacterial vaginosis which cause elevated pH of vaginal secretion.

Bornstein J, Geva D *et al*. [8] demonstrated that the diagnostic panty liner had a sensitivity of 100% and a specificity of 75% but when women with bacterial vaginosis or trichomonas vaginalis were excluded from the analysis the specificity increased to 90%. In detecting PROM the overall agreement between the panty liner test result and history of clinical diagnosis was 82.35%. Bornstein *et al*. [10] also evaluated the ability of diagnostic panty liner (DPL) to differentiate between amniotic fluid and urine (i.e. the reliability of test). It (DPL) demonstrated sensitivity of 95.65% and specificity of 84.46%. The results were comparable to our study.

Mulhair *et al*. [13] also demonstrated in their study that the DPL had a sensitivity of 98% and specificity of 65%.

CONCLUSION

In conclusion, this study demonstrates that amniotic fluid detection kit is highly sensitive, non-invasive method and more acceptable than speculum examination to detect the presence of amniotic fluid. All women with the positive test results require gestational age specific management. Sensitivity and specificity of amniotic fluid detector kit (AFDK) suggest that a negative result can provide reassurance of intact membranes. Use of diagnostic AFDK test before considering the speculum examination will reduce the number of speculum examination and unnecessary hospital referral for those women with the negative test.

Hence, AFDK kit helps in prompt and accurate diagnosis of PROM, thus leading to optimise pregnancy outcome. It also eliminates unnecessary obstetric procedures thereby reducing the complications of PROM.

REFERENCES

1. Modena AD, Fieni S; Amniotic fluid dynamics. Acta Biomed Ateneo Parmense, 2004; 75(Suppl 1): 11-13.
2. Mataloun M, Prescinotii EA, Arcas RA, Ramos JL, Leone CR; Prolonged rupture of membranes and neonatal infection. J Pediatr., 1997; 73: 311-316.
3. Von dadelszen P, Kives S, Delisle MF, Wilson RD, Joy R, Ainsworth L *et al*.; The association between early rupture, latency, clinical chorioamnionitis, neonatal infection, and adverse perinatal outcomes pregnancies complicated by preterm prelabour rupture of membranes. Twin Res, 2003; 4: 257-62.
4. Kenyon S, Boulvain M, Neilson J; Antibiotics for preterm rupture of membranes. Cochrane Database Syst Rev., 2003; CD001058.
5. Mercer BM; Preterm rupture of the membranes: diagnosis and management. Clin Perinatol., 2004; 31: 765-782.
6. ACOG Committee on Practice Bulletins-Obstetrics, Obstetrician-Gynecologists. (ACOG Practice Bulletin No.80: premature rupture of membranes). Obstet Gynecol., 2007; 109: 1007-1019.
7. Cousins LM, Smok D, Lovett SM, Poeltler DM; AmniSure placental alpha microglobulin-1 rapid immunoassay versus standard diagnostic methods for detection of rupture of Bornstein J, Geva A, Solt I, Fait A, Shoham HK et al. Nonintrusive diagnosis of premature ruptured amniotic membranes using a novel polymer, Am J Perinatol, 2006; 23: 351-4.
8. Bornstein J, Geva A, Solt I, Fait A, Shoham HK et al.; Nonintrusive diagnosis of premature ruptured amniotic membranes using a novel polymer. Am J Perinatol., 2006; 23: 351-354.
9. Park JS, Lee SE, Norwitz ER; Non-invasive testing for rupture of the fetal membranes. Touch Briefings: US Obstetrics and Gynecology, 2007; 1: 13-16.
10. Bornstein J, Ohel G, Sorokin Y, Reape KZ, Shnaider O, Kessary-Shoham H, Ophir E; Effectiveness of a novel home-based testing device for the detection of rupture of membranes. Am J Perinatol., 2009; 26(1): 45-50.
11. Hosseini MA, Nahidi F, Majdfar Z; Comparison of fern and evaporation tests for detection of ruptured fetal membranes. East Mediterr Health J., 2007; 13(1): 197-200.
12. Vergani P, Chidini A, Locatelli A, Cavallone M, Ciaria S, Capellini A *et al.*; Risk factors for pulmonary hypoplasia in second trimester premature rupture of membranes. Am J Obstet Gynecol., 1994; 170: 1359-1364.
13. Mulhair L, Carter J, Poston L, Seed P, Briley A; Prospective cohort study investigating the reliability of the AmnioSens method for detection of spontaneous rupture of membranes. BJOG, 2009; 116: 313–318.