IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 16, Issue 8 Ver. IX (Aug. 2017), PP 35-39
www.iosrjournals.org

Utilizing Home Pregnancy Test Kits for Diagnosis of Leaking Liquor

Maad Mahdi Shalal[1], *ShaymaaKadhim Jasim[2], Maysoon Sami Khraibet[3]
[1]*Professor,Department of Obstetrics and Gynecology, College of Medicine,University of Baghdad, Iraq.*
[2]*Tutor (lecturer), Department of Obstetrics and Gynecology, College of Medicine,University of Baghdad, Iraq.*
[3]*Doctor (obstetrician),Department of Obstetrics and Gynecology, Baghdad Teaching Hospital, Medical City directorate,Ministry of Health, Iraq*
*Corresponding Author: *ShaymaaKadhimJasim, email: shaimaa79kadhim@yahoo.com*

Abstract:*Before the start of delivery, any membranes rupture could be named as a premature rupture of membranes (PROM), which may need special obstetrical interactions to minimize perinatal complications, it is important topromptly diagnose PROM, the method used should be accurate, cheap, simple, and widely available. This was exactly the idea behind this study to use an ordinary pregnancy test kit aiming to confirm presence of PROM.Over a 6 months' period, 60 pregnant women with a history of leaking liquor and a positive speculum examination for amniotic fluid pooling were collected prospectively and compared with other 60 women (control group) with uneventful pregnancy. Majority of patients with positive leaking liquor signs and symptoms had a positive score ofhome pregnancy test kit (88.3% of PROM had positive B-HCG results, and only 11.7% had negative outcomes) while the test was negative in the majority of uncomplicated control group (95% of them had negative B-HCG test kit findings and, 5% had positive results), p-value touched a significant level of< 0.0001. Accordingly; this home pregnancy test kit was considered as a new, good, delicate, frugal, and dependable tool to confirm diagnosis of PROM.*

Key words:*leaking liquor, pregnancy test kit, and PROM.*

Date of Submission: 15 -08-2017 Date of acceptance: 23-08-2017

I. Introduction

Premature rupture of membranes (PPROM) is defines as "rupture of the fetal membranes prior to the onset of labor irrespective of gestational age. Once the membranes rupture, delivery is recommended when the risk of ascending infection outweighs the risk of prematurity". In case of PROM takes place at term, labor would occur spontaneously or induced within a day or half of it.It happened in about 8% of term pregnancies and only 2-3% of pregnancies that have not caught 37 weeks' gestation.[1-3]Usually this occurs near term, but when membrane rupture occurs before 37 weeks' gestation, it is known as preterm PROM. There may be an increment in the risk of prematurity which leads to other perinatal and neonatal complications, including 1-2 % fetal mortality risk, so it's vital to differentiate between term premature rupture of membranes (PROM) and preterm PROM, they have different causes, risks, and management workout. However; a rapid diagnosis and a planned management are key factors for a favorable result. [3,4]A previous history of PROM is the most dependable risk factor for recurrence, ladies with a PROM previous history had a 13.5% rate of recurrence when matched to 4.1% recurrence in females without a PROM history. [3,5]Genital tract infection, low socioeconomic status, smoking, uterine over distension such as polyhydramnios or multiple pregnancy, cervical weakness, iatrogenic procedures (cervical cerclage), and genetic factors are well-recognized risk factors of PROM. [2-3,6-9]Kits aimed to diagnose pregnancy at home need a urine sample in order to detect specific pregnancy markers, B-HCH (beta-human chorionic gonadotropin) is one of these markers, but unfortunately it is undetected until implantation, a false negative diagnosis of pregnancy is the fate during a very early stage. [10]Detection of PROM could be achieved through HCG measurements in vaginal fluid which is normally present in low levels during pregnancy. Nevertheless; when PROM takes place, vaginal cavity receives amniotic fluid release, and HCG measurements are significantly elevated when evaluated in vaginal fluid. [11,12]

II. Aim of the study

To demonstrate that home pregnancy test kits can be used as a simple and cheap test for detection of PROM.

III. Patients and methods

This prospective case-control study was accomplished in Baghdad teaching hospital, Obstetrics and Gynecology department, started in 15th January 2013, and ended in 14th June of the same year.The statistical test used in this study is Pearson correlation which was calculated for the correlation between two quantitative variables, statistical significance was considered whenever P value was equal or less than 0.05. Our study sample was pregnant women (not in labor) with singleton pregnancy, gestational age 28 - 35 weeks, reassuring fetal heart monitoring, and no history of medical disease that prevent the patient from lying in lithotomy position.The sample was subdivided into two groups: First group (the study group) included women diagnosed as PROM by history and speculum examination.Second group was the control group which includedwomen with uncomplicated healthy pregnancy and no history of leaking liquor. We tried to collect the same number of women in both groups, for each case of PROM, one women was added as a control.Ladies with the following criteria was excluded: vaginal bleeding, active labor, history of cervical abnormal lesion as blood might affect the result of the test, and women who had a recent coitus.Verbal consent was taken from all women included in the study and their gestational age was confirmed by last menstrual period and/ or by early pregnancy ultrasound examination. A full history and examination were performed by a gynecologist present on time.

Under aseptic conditions, when the patient was lying down, a warm speculum was inserted in the vagina, then liquor (in cases of PROM), or vaginal secretion (in the control group), was aspirated by a micro-dropper, 3-4 drops of the collected sample were squeezed into the pregnancy kit, results appeared after 5 minutes (in line with manufacturer`s recommendations). After that; women involved were sent for ultrasonographic assessment of liquor amount.The kit type that was used in this study had a brand of (SD BIO LINE) HCG pregnancy test, which was an in vitro immunochromatographic one step assay kit, designed for qualitative determination of HCG in urine.This test kit used specific antibodies to selectively identify HCG in urine with a high degree of sensitivity,elevated levels of HCG as low as 25 mIU\ml (micro-international units per milliliter) could be detected within 5 minutes.

IV. Results

There were 120 pregnant ladies whom entered into this study, half of them (60 cases) had PROM, while the other half (60 ladies) were normal pregnant women without a diagnosis of PROM and considered as a control group.Looking into ages of our sample patients; a higher percentage for both patients` groups (cases and control) was found within the age group of 20 – 24 years old (40% and 46.7%, respectively). Para 2 pregnancy, and 30 - 31 weeks` gestational age had been the most common between our cases of PROM and controls (31.7%, 23.3%, and 33.3%, 31.7% respectively).All the above general features of cases (PROM patients) and controls (normal healthy pregnant ladies) were not significant from statistical point of view, as seen in Table (1).

Table (1): Distribution of patients according to age in years, parity, and gestational age in the tow studying groups

Variables		PROM		Control		P value
Age (years)		No.	%	No.	%	
	< 20	10	16.7	11	18.3	0.265
	20 -24	24	40	28	46.7	
	25 - 29	17	28.3	10	16.7	
	30 - 34	9	15	8	13.3	
	≥ 35	0	0	3	5	
Parity	Primigravida	8	13.3	15	25	0.417
	Para 1	13	21.7	16	26.7	
	Para 2	19	31.7	14	23.3	
	Para 3	13	21.7	10	16.7	
	≥ Para 4	7	11.7	5	8.3	
Gestational age (weeks)	28 -29	12	20	13	21.7	0.987
	30 - 31	20	33.3	19	31.7	
	32 - 33	14	23.3	13	21.7	
	34 - 35	14	23.3	15	25	

A highly statistically significant value ($p < 0.0001$) through using Pearson Chi square test, was encountered in a pregnancy test kit result, it was positive in 88.3% of PROM cases and negative in 95% of control women, as shown in Table (2).

Table (2): Distribution according to B-HCG result

Kit results	PROM		Control		P value
	No.	%	No.	%	
Negative	7	11.7	57	95	< 0.0001
Positive	53	88.3	3	5	

The majority of patients with PROM came after 6-12 hours (48.3%), while 25% came after 12-18 hours, 16.7% after 18 hours, and 10% came before 6 hours. These are noticed in Table (3).

Table (3): Time of rupture of membranes before diagnosis of PROM

Time of membranes rupture (hours)	PROM	
	No.	%
< 6	6	10
6 - 12	29	48.3
12 - 18	15	25
> 18	10	16.7

Table (4) illustrated a highly significant ($p < 0.0001$ using Pearson Chi square test) ultrasonography (U/S) findings of oligohydramnios in PROM patients (70%), while normal liquor volume was found in (86.7%) of control pregnant ladies.

Table (4): Distribution according to ultrasound finding of liquor volume

U/S Liquor Finding	PROM		Control		P Value
	No.	%	No.	%	
Oligohydramnios	42	70	8	13.3	< 0.0001
Normal Amount	18	30	52	86.7	

Patients of PROM group whom had positive kit results for B-HCG, and ultrasonographic (U/S) oligohydramnios examination constituted (92.9%), while those with normal U/S liquor amount and positive kit findings were (77.8%). Applying a Pearson Chi square test; p value became statistically significant (< 0.0001). All control group members (100%) with negative kit results were having a normal liquor volume measured by U/S. Table (5) had clear details.

Table (5): B-HCG kit result and ultrasound (U/S) findings of liquor volume

U/S liquor finding	PROM, B-HCG kit result				Control, B-HCG kit result			
	Negative		Positive		Negative		Positive	
	No.	%	No.	%	No.	%	No.	%
Oligo.	3	7.1	39	92.9	5	62.5	3	37.5
Normal	4	22.2	14	77.8	52	100	0	0

V. Discussion

The current study tried to evaluate an accurate diagnosis of PROM which is still a challenging and important issue, as an early identification of preterm PROM would give the chance for an appropriate obstetricalapproach to have a good perinatal outcome with the least possible sequelae, while over diagnosis of PROM could pave the way to an unnecessary intervention with presumable unwanted adverse events, so that; a fast, simple, and non-invasive diagnosis of PROM was the aim for all obstetricians. [13,14]The diagnosis of PROM could be very obvious when membranes rupture could be noticed, a patient`s complete history was reliable in (10 – 50%) of cases. [11,15]Inspection of fluid leakage from cervix has been traditionally the only method for confirming diagnosis of PROM, this method was associated with 12-30% false negative results when there was a long time since rupture. [16]

Moreover; different diagnostic approaches such as nitrazin test might lead to false positive (16.2%) or false negative (12.7%) results, also; Fern test had (13-30%) as a false positive result. [11,17]Accordingly; this study had an idea of an easy, rapid, inexpensive, and accurate test thatcould not be hampered by the presence of blood, semen, infected urine, or other contaminants,with accurate biochemical markers for membrane rupture which had a high concentration in the amniotic fluid, a low concentration in maternal blood, and an extremely low background concentration in cervicovaginal discharge with intact membranes were considered by usinghome pregnancy test kit.[10,18]Anai et al. study [19],was one of scanty studieswhere cervicovaginal B-HCG was measured in all trimesters of pregnancy and its values in first, second and third trimesters were 6.3, 9.5, and 37.9 mIU/mL, in a sequence.Standing on the above paper, utilizing a cutoff 50 mIU/ml for cervicovaginal B-HCG in third trimester resulted in sensitivity of 100%, specificity of 96.5%, positive predictive value was 88.9%, negative predictive value was 100%, and accuracy was 97.2%. They demonstrated that cervicovaginal B-HCG levels reached a relatively stable level after the first trimester of pregnancy. They used a high cutoff value in theirstudy while our cut off value was 25 mIU/ml, this might be due to participation of women in all trimesters of pregnancy during their study.

Cooper et al. data [20], performed a comparison between a three-steps B-HCG kit and an ELIZA (enzyme-linked immunosorbent assay) method for detection of PROM, while our data used a one-step B-HCG method (pregnancy home kit) which was easier, cheaper, faster, non-invasive, could be used by midwives also (not limited to obstetricians), and widely available in outpatient and inpatient settings without a need to a complex laboratory equipment, while ELIZA method used for detection of B-HCG in vaginal fluid needed a special laboratory equipment, time consuming, and more expensive.Kariman et al. [21]also compared between ELIZA method and three-steps pregnancy test dipsticks for detection of HCG in cervicovaginal wash in asimilar way to cooper et al. [19], but with higher values of sensitivity and specificity. They stated that HCG measurement in cervicovaginal discharge with ELISA for HCG detection had an acceptable diagnostic value as high as 3 steps pregnancy text dipsticks. In normal pregnancy; cervical glands secrete HCG into cervicovaginal secretions, but its concentration was less than 10 mIU/ml after 20th gestational week,thus, they used a cutoff value of 25 mIU/mlwhich was in agreement with our work.Al-Byati M. et al. [22] studied the use of B-HCG in vaginal washing fluid for the diagnosis of PROM, which concluded that the B-HCG level in vaginal fluid could be used as a simple test for diagnosis of PROM, again they used ELIZA for detection of B-HCG and nitrazin test. The same above justification regarding our data may be applied.Another study done by Maad M. Shalal [23]pointed out that the level of B-HCG in vaginal fluid washing in patients with proved PROM by speculum examination, and in patients with a suspected leaking liquor showed a significant elevated level (30 folds in PROM cases, and 11 folds in suspected leaking liquor patients) when matched to normal pregnant women with intact membranes, but they used B-HCG as a marker for detecting PROM by a radioimmunoassay test, while we used a simple pregnancy test kit.

VI. Conclusion

Pregnancy test kit, was a simple way with a high potential to diagnose premature rupture of membranes or leaking liquor.

References

[1]. Caughey AB, Robinson JN, Norwitz ER. Contemporary diagnosis and management of preterm premature rupture of membranes. Reviews in Obstetrics and Gynecology. 2008;1(1):11.

[2]. Fernando Arias,Shirish N. Daftary,Amarnath G. Bhide"Premature Rupture of Membranes",High –Risk Pregnancy &Delivery,South Asian,2008,240-46.

[3]. David M. LueslyandPhilip N. Baker,"Premature Rupture Of Membranes",Evidence-based,GreatBrtain,2010;309-13.

[4]. Mercer BM. Preterm premature rupture of the membranes. Obstet Gynecol.2003;101:178–93.

[5]. Keith Edmonds,"Preterm Premature Rupture of Membrane",InDewhurst,s Text book of Obstetrics &Gynaecology,8thed,Black Well Puplishing London ,2012;353-54.

[6]. MaymonE.,RomeroR.,andPacraP,"Human Neutrophil Collagens(Matrix Metalo Proteinase 8)in Parturition, Premature Rupture of Membrane,andInfection",AmObstetGyncol,2000;183:94-96.

[7]. Ekin A, Gezer C, Taner CE, Ozeren M, Uyar I, Gulhan I. Risk factors and perinatal outcomes associated with latency in preterm premature rupture of membranes between 24 and 34 weeks of gestation. Archives of gynecology and obstetrics. 2014 Sep 1;290(3):449-55.

[8]. Vadillo-Ortega F.,Gon.Zalez-Avila G.,andFurtu EE..,"92-Kd Type IV Collagens C Matrix Metalo Proteinase-9 Activity in Human Amniochorion increases with Labour"AMJ Pothole 1995;146:148-56.

[9]. Savitz DA, Blackmore CA, Thorp JM. Epidemiologic characteristics of preterm delivery: etiologic heterogeneity. Am J Obstet Gynecol. 1991;164:467–71.

[10]. Butler SA, Khanlian SA, Cole LA. Detection of early pregnancy forms of human chorionic gonadotropin by home pregnancy test devices. Clinical Chemistry. 2001 Dec 1;47(12):2131-6.

[11]. Esim E, Turan C, Unal O, Dansuk R, Cengizglu B. Diagnosis of premature rupture of membranes by identification of β-HCG in vaginal washing fluid. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2003 Mar 26;107(1):37-40.

[12]. Mohamed RS, Rashed RM, Hassanein RA, Oun A, Abdel-Maksoud SM. Vaginal fluid creatinine versus human chorionic gonadotropin for diagnosis of premature rupture of membranes. J Am Sci. 2015;11(01):33-9.

[13]. Cunningham G, Leveno K, Bloom S, Spong CY, Dashe J. William's Obstetrics. 24th Edition. New York: McGraw-Hill Education; 2014.

[14]. Ghasemi M, Jaami R, Alleyassin A, Ansarimoghaddam A. The value of urea, creatinine, prolactin, and beta sub-unit of human chorionic gonadotropin of vaginal fluid in the diagnosis of premature preterm rupture of membranes in pregnancy. Journal of Turkish Society of Obstetrics & Gynecology. 2016 Jun 1;13(2).

[15]. Erdemoglu E, Mungan T. Significance of detecting insulin-like growth factor binding protein-1 in cervicovaginal secretions: comparison with nitrazine test and amniotic fluid volume assessment. ActaObstetGynecol Scand. 2004;83:622–6.

[16]. Sucak A, Moroy P, Çakmak P, Mungan T, Mollamahmutoğlu L, Danişman N. Insulin-like growth factor binding protein-1: a rapid detection of amniotic fluid leakage after amniocentesis. Turk J Med Sci. 2005;35:157– 61.

[17]. Ayala A.R.,SerranoJ.,de la Luna-OsenE.,LeisM.T.,BustosH.,Lopez-Garcia R.,"B-HCG in the amniotic fluid in normal pregnant women" Arch Invest Med (Mex). 1989 ;20:223-7.

[18]. Sanders M, inventor. At-Home Blood Pregnancy Test Kit. United States patent application US 14/615,628. 2015 Feb 6.

[19]. Anai T, Tanaka Y, Hirota Y, Miyakawa I. Vaginal fluid hCG levels for detecting premature rupture of membranes. Obstetrics & Gynecology. 1997 Feb 1;89(2):261-4.

[20]. Cooper AL, Vermillion ST, Soper DE. Qualitative human chorionicgonadotropin testing of cervicovaginal washings for the detection of preterm premature rupture of membranes. American journal of obstetrics and gynecology. 2004 Aug 31;191(2):593-6.

[21]. Kariman NS, Jafari E, Moghadam HR, Majd HA, Mortazavi M. Comparing the diagnostic power of qualitative and quantitative measurements of ß-hCG in cervicovaginal washing-fluid for the diagnosis of PROM. Journal of Reproduction & Infertility. 2007 Apr 1;8(1).
[22]. Al-Bayati M, Al-Kazaly E, Athrab S. Vaginal Washing Fluid β-HCG Levels for Detecting Premature Rupture of Membranes. The Iraqi Postgraduate Medical Journal. 2011;10:61-6.
[23]. Maad M. Shalal," B-HCG level in vaginal wash fluid of suspected leaking liquor patients to prove its rupture", Iraqi J Com Med, 2011;12:38-43.

*Maad Mahdi Shalal. " Utilizing Home Pregnancy Test Kits for Diagnosis of Leaking Liquor." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS) 16.8 (2017): 35-39