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The Efficacy of Placental Alpha Microglobulin-1 Testing in the Diagnosis of Rupture Membranes between 32- and 37-Weeks of Gestation

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Abstract

Background: *Premature or prolabor rupture of membranes (PROM) is a spontaneous rupture of the amniotic membranes before the onset of uterine contractions and it consists for about 10%, while preterm premature rupture of membranes (PPROM) is defined when the membranes rupture occurs before 37 weeks, it is recorded in about 30% of women with PROM.*
Objective: This study was conducted to determine the diagnostic accuracy of placental alpha microglobulin-1 (PAMG-1) assay in comparison to the routine clinical methods (fluid pool in posterior fornix test and ultrasound) for detecting rupture of membranes.
Methods: *A Retrospective cross-sectional study, from February 2018 to February 2020 at Duhok Hospital for obstetrics and gynecology/ Kurdistan/ Iraq was carried out on 400 women whom they have suspicion of having rupture membranes. Clinical evaluation performed to the participants including history, clinical examination which involved the assessment of fluid pool in posterior fornix (FP) test. U/S to detect the Amniotic Fluid Index and placental alpha microglobulin-1 immunoassay (PAMG-1) test. The actual rupture of membranes was diagnosed on review of the medical records after delivery (considered as a final diagnosis). Sensitivity, specificity, negative and positive predictive values were calculated.*
Results: *The age of the recruited patients were between 19 to 41 years old, and Mean±SD was 35.7±6.54, (13%) had previous history of PROM. The results of the performed tests were in the following: PAMG1 sensitivity was (94.8%) and positive predictive value (PV+) was excellent (98.91%), the specificity was (75%) and negative predictive value (PV-) was (37.5%). Regarding fluid pool collection test, the sensitivity (78.1%), PV+ was very good (96.25%) and specificity (25%), but the PV- was very low (4.5%). The U/S showed sensitivity of (48.9%), with excellent of PV+ (97%), specificity (75%), and low PV- (5.7%).*
Conclusions: *The PAMG-1 immunoassay is an accurate test for the detection of premature rupture of amniotic membranes, compared to fluid pool in the posterior fornix test and ultrasound imaging.*

Keywords: *(PAMG-1) Test, premature rupture of amniotic membranes, fluid pool, U/S*

1. Introduction

The approving or conformation of rupture membranes is considered as a dilemma since it is a very important step in which the obstetrician has sometimes to take a step which may affect the fetal out come in the pregnancy as well as maternal complications, especially if the mother have previous operations or medical problem which may end with false preterm delivery dissection (Irogue et al., 2017).

Clinical tools are emerging to detect the presence of placental alpha macroglobulin-1 in the vagina. Rapid testing as an immediate one for detecting amniotic fluid proteins in cervicovaginal fluids are quick in approaching the diagnosis of rupture membranes either preterm or premature one. These tests may indicate disruption in the fetal membranes integrity and raises the risk for preterm birth (Mariona & Cabero, 2016).

AmniSure is a non- invasive test that have been designed to detect rupture of membranes by the presence of PAMG1 which is present in the amniotic fluid at the cervico-vaginal area. It earns the approval of FDA in 2012. The easy technique of using the tool makes it available for the nursing staff to work on it and quick results can be obtained (Lee et al., 2012).

2. Materials And Methods

A cross sectional study was carried out involving 400 women admitted to Duhok Hospital for obstetrics and gynecology, it is a tertiary one with bed occupancy of 120. It receives all high-risk patients referred from all over the city. The selected women have a suspicion of PROM between 32 to 37 weeks gestation. The study started from February 2018 till February 2020. All patients were examined clinically and U/S done to them as well as PAMG-1 testing. The final diagnosis of rupture membranes was achieved and recorded at time of the delivery of the patient.

The inclusion criteria are: Resent gush of watery vaginal discharge within 12 hours, Patient which do not need interventions with well control medical record like Diabetes mellitus or Hypertension, Twin pregnancy, welling to participate,

The Exclusion criteria: Cases need urgent C/S or urgent management, Fever and suspicion of chorioamnitis, Ante-partum hemorrhage, Intra uterine death (IUD) or congenital anomalies.

3. Results and Discussion

The age of the recruited patients was between 19 to 41years old & (40%) were between 20 to 29 years old, (70%) were multiparas, (13%) had previous history of PROM. Those who ended with C/S were only (15%). Table 1.

Table 1: The Study Sample in Terms of Socio-demographic and Obstetrics Features

Variables		Frequency	%	Mean±SD	*P*-value
Age groups	< 20 years	90	22.5	35.7±6.54	0.898*
	20 to 29 years	160	40		
	30 to 39 years	80	20		
	≤40	70	17.5		
Parity	Para 1	120	30	2.4±1.1	0.840*
	Multipara 2- 4	240	60		
	≥5	40	10		
History of PROM	Yes	52	13		
Hx. of preterm labor	Yes	44	11		
No history	No	304	76		
Mode of delivery	Vaginal	340	85		0.099*
	C section	60	15		
Total		**400**	**100**		

* Fisher Exact Test

Table 2. The Accuracy of the Three Methods in the Diagnosis of PROM.

Variables Tests	PAGM 1/ final diagnosis			
		Positive	**Negative**	**Total**
PAMG 1	**Positive**	364	4	368
	Negative	20	12	32
	Total	384	16	400
Fluid pool in the posterior fornix	**Positive**	300	12	312
	Negative	84	4	88
Final diagnosis	Total	384	16	400

U/S	**Positive**	188	4	192
	Negative	196	12	208
	Total	384	16	400

Regarding the validity of the three methods in the diagnosis of PROM in the study sample, the sensitivity ranging from 48.9% to 94.8%, the lowest was with Ultrasound methods and the higher was with PAMG 1 test. While the specificity was the same 75% and higher in PAMG1 and US methods in comparisons with 25% of fluid pool in posterior fornix. In addition, the PAMG1 had the highest PPV 98.9%, on the contrast the fluid pool in posterior fornix had the lowest NPV 4.5%. Table 3.

Table 3: The Validity Indicators in the Final Diagnosis of PROM of the Study Sample

Variables	Sensitivity%	Specificity%	PPV%	NPV%
PAMG 1	94.8	75	98.9	37.5
Fluid pool in posterior fornix	78.1	25	96.2	4.5
Ultrasound (US)	48.9	75	97	5.7

*PPV and NPV calculated at 1% prevalence.

The test is very simple and does not any instruments like speculum. At the same minimal time consuming. The recorded results in our study show the high efficacy of the test in approaching the diagnosis of rupture membranes. In comparison to the classic U/S & fluid collection in the posterior fornix, it was highly sensitivity and positive predictive value. A meta-analysis carried out at 2013 showed that the specificity and positive predictive value were significantly high for detecting PMG1 by AmniSure test (Palacio et al., 2014).

In a comparative prospective study, Abdelazim IA, *et al. 2012*, recorded 150 patients after 37 weeks' gestation (term) he divided them into two groups according to the presence or absence of PROM. He found that sensitivity was (97.33%) which is similar to our finding, whereas the specificity (98.67%) which is higher than ours.

Another study, by Ng BK, *et al*.2013 [6], he compared AmniSure test with other two classical methods for approaching the diagnosis of ROM. Total number of patients were 211, the sensitivity was 95.7% which comparable to our results while the specificity of 100% which is much higher than us.

PAMG 1 test is a noninvasive technique, rapid, and highly accurate in detecting ROM. A very small amount of PAMG 1 if present in the vagina it is very sufficient to approach the diagnosis of broken membranes (Kan an *et al., 2015*).

In spite of the high accuracy of AmniSure in diagnosis of PROM (Mustafa Albayrak, *et al, 2011*), found that there was no significant deference in sensitivity and specificity between AmniSure test and conventional ways. A result which is totally in controversy to our finding.

The AmniSure has a high sensitivity as a first-line nurse-administered screening test for membrane rupture. The test had a sensitivity of 95.7%, specificity of 92.3%, negative predictive value of 98.0% and positive predictive value of 84.9% (Brie Thumm et al., 2020).

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