

**A comparative study between Amniosense and Nitrazine test
in detection of premature rupture of membranes (PROM)**

Thesis
Submitted for fulfilment of
Masters Degree in
OBSTETRICS AND GYNAECOLOGY

Presented By
Ahmed Shahat Abdel Razek Omran
Research Fellow of Obstetrics and Gynaecology
National Research Centre
(M.B.B.CH. Faculty of Medicine-Cairo University, 2005)

Supervised by
Prof. Dr. Magdy Ibrahim Mostafa
Professor of Obstetrics and Gynaecology
Faculty of Medicine
Cairo University

Prof. Dr. Osama Mahmoud Azmy
Professor of Obstetrics and Gynaecology
Reproductive Health and Family Planning Department
National Research Centre

Dr. Mamdouh Abdel Aziz Pepars
Assistant Professor of Obstetrics and Gynaecology
National Research Centre

Dr. Rana Abdel Samie Abdellah
Lecturer of Obstetrics and Gynaecology
Faculty of Medicine
Cairo University

**Faculty of Medicine
Cairo University
2012**



قَالُوا سُبْحَانَكَ لَا عِلْمَ لَنَا
إِلَّا مَا عَلَّمْتَنَا إِنَّكَ أَنْتَ
الْعَلِيمُ الْحَكِيمُ

صدق الله العظيم
الآية (٣٢) سورة البقرة



Thanks are all to **Allah**, our Merciful and Compassionate Lord. He has always helped me and guided me through paths that I eventually knew to be of the best interest to me.

Words can never suffice to reflect my sincere appreciation and gratitude to **Prof.Dr.Magdy Ibrahim Mostafa**, Professor of obstetrics and gynaecology, Faculty of Medicine, Cairo University for suggesting and supervising this work, I do owe him alot.

I'm very thankful for **Prof.Dr.Osama Mahmoud Azmy**, Professor of obstetrics and gynecology and Head of the Reproductive Health Dept., National Research Centre, for his close support and continuous observation and guidance throughout this work, His most kind fatherhood has always been overwhelming.

I'm also grateful to **DR.Mamdouh Abdel Aziz Pepars**, the Assistant Professor of Obstetrics and Gynecology and Reproductive Health, National Research Centre, who gave his experience throughout this work,

I'm greatly indebted to **Dr.Rana abdel samie Abdellah**, the Lecturer of Obstetrics and Gynecology, Faculty of Medicine, Cairo University for her continuous support, meticulous correction, valuable guidance, assistance and encouragement.

Thanks fail to express my deepest gratitude and indebtedness to my family. Their good breeding, and the scientific atmosphere in which I stepped my very first steps, they have the greatest impact on my steps ever since. To Them, I humbly dedicate this work,

AHMED SHAHAT ABDEL RAZEK ALI OMRAN

M.B.,B.Ch.

ABSTRACT

Premature rupture of the fetal membranes (PROM) is defined as the rupture of the fetal membranes with release of the amniotic fluid more than 1 hour prior to the onset of labor.

PROM may be subdivided into term PROM (TPROM, i.e. PROM after 37 weeks of gestation) and preterm PROM (PPROM, i.e. PROM prior to 37 weeks of gestation). PPROM is responsible for a third of all preterm births.

This study was performed on 60 pregnant women recruited from Cairo University (Kasr Al-Aini) Maternity Hospital's outpatient clinic and casualty unit with gestational age more than 28 weeks and gave suspected history of ROM. They were divided into two groups according to the results of the vaginal fluid cytology.

According to the results of this study, Amniosense sensitivity to detect PROM was 96.67%, specificity was 100% and accuracy was 98.33% while nitrazine test sensitivity was 83.33%, specificity was 90% and accuracy was 86.67%.

Key words :-

Amniosense - nitrazine test - vaginal fluid cytology - PROM

Content

• <u>Introduction</u>	1
• <u>Aim of the work</u>	4
• <u>Review of Literature</u>	5
 <u>Chapter 1: Amniotic membranes</u>	5
 <u>Chapter 2: Amniotic fluid</u>	10
 <u>Chapter 3: Physiological rupture of the fetal membranes</u>	17
 <u>Chapter 4: Premature rupture of the fetal membranes</u>	19
 • Patients and Methods	55
• Results	60
• Discussion	72
• Conclusion	80
• References	82
• Arabic summary	

List of figures

Figure no.	List of figures	Page no.
Figure:1	Amniosense pad.	3
Figure:2	Development of the chorion and amniochorionic membrane.	8
Figure:3	Anatomy of the amniotic membrane.	9
Figure:4	Histology of the amniotic membrane.	11
Figure:5	Various Mechanisms that have been proposed to result in PROM or PPRM.	23
Figure:6	Paradigm for membrane weakening and possible re-strengthening in vivo.	27
Figure:7	Nitrazine paper test	37
Figure:8	AmniSure® ROM test for the diagnosis of ruptured fetal membranes.	43
Figure:9	Amniosense pad.	44
Figure:10	Management algorithm for women presenting with preterm PROM remote from term (23 weeks, 0 days–31 weeks, 6 days).	54
Figure:11	Management algorithm for women presenting with preterm PROM near term (32 weeks, 0 days–36 weeks, 6 days).	55
Figure:12	Management algorithm for women presenting with preterm PROM before the current limit of potential viability (23 weeks, 0 days of gestation).	56
Figure:13	Nitrazine paper test	61
Figure:14	Amniosense results	61
Figure:15	Test Panty Liner.	62

List of figures

Figure:16	Test Panty Liner.	62
Figure:17	Test Panty Liner.	62
Figure:18	Bar chart shows differences between both groups as regards the patient age.	65
Figure:19	Bar chart shows differences between both groups as regards the patient's obstetric history.	66
Figure: 20	Bar chart shows differences between both groups as regards the previous history of PROM.	67
Figure:21	Bar chart shows differences between both groups as regards the gestational age on examination and at delivery.	68
Figure:22	Bar chart shows differences between both groups as regards the AFI on ultrasound examination.	69
Figure:23	Bar chart shows differences between both groups as regards the pulse and temperature.	70
Figure:24	Bar chart shows differences between both groups as regards the cusco speculum examination results.	71
Figure:25	Bar chart shows differences between both groups as regards nitrazine paper test results.	72
Figure:26	Bar chart shows differences between both groups as regards Amniosense results	73
Figure:27	Bar chart shows differences between both groups as regards the latent period.	74

List of figures

Figure:28	Bar chart shows differences between both groups as regards the mode of delivery.	75
Figure:29	Bar Chart shows comparison between amniosense and nitrazine test in detection of PROM as regards specificity, sensitivity, positive and negative predictive values and accuracy.	76

List of Tables

Table no.	Contents	Page no.
Table 1	Comparison between both groups as regards the patient age.	65
Table 2	Comparison between both groups as regards the patient's obstetric history.	66
Table 3	Comparison between both groups as regards the previous history of PROM.	67
Table 4	Comparison between both groups as regards the gestational age on examination and at delivery.	68
Table 5	Comparison between both groups as regards the AFI on ultrasound examination.	69
Table 6	Comparison between both groups as regards the pulse and temperature.	70
Table 7	Comparison between both groups as regards the cusco speculum examination results.	71
Table 8	Comparison between both groups as regards nitrazine paper test results.	72
Table 9	Comparison between both groups as regards Amniosense results.	73
Table 10	Comparison between both groups as regards the latent period.	74
Table 11	Comparison between both groups as regards mode of delivery.	75

List of Tables

Table 12	Comparison between amniosense and nitrazine test in detection of PROM as regards specificity, sensitivity, positive and negative predictive values and accuracy.	76

LIST OF ABBREVIATIONS

AF	Amniotic fluid
AFI	Amniotic fluid index
AFP	Alpha feto-protein
AFS	Antenatal fetal surveillance
AFV	Amniotic fluid volume
BPP	biophysical profile
BV	Bacterial vaginosis
C.trachomatis	Chlamydia Trachomatis
CA	Chorioamnion
CD14	Cluster of differentiation 14
CI	Confidence interval
CIN	Cervical intraepithelial neoplasia
CRP	C-reactive protein
CS	Cesarean section
CTG	Cardiotocography
DAO	Diamine-Oxidase
DD	Differential diagnosis
DNA	Deoxyribonucleic acid
ECM	Extracellular matrix
ELISA	Enzyme-Linked Immunosorbant Assay
fFN	Fetal fibronectin
FHS	Fetal heart sound
GBS	group B streptococcus
HCG	Human chorionic gonadotrophin
IGFBP-1	Insulin-like growth factor binding protein-1
IL	Interleukin
IQR	Interquartile range
LEEP	loop electrosurgical excision procedures
LLETZ	large loop excision of the transformation zone
LPS	Lipopolysaccharide

List of abbreviations

LTP	largest transverse pocket
LVP	largest vertical pocket
MAFD	mean amniotic fluid diameter
MBPP	modified BPP
MMP	matrix metalloproteinases
MVP	maximum vertical pool
npIGFBP-1	Non-phosphorylated insulin-like growth factor binding protein-1
NST	non-stress test
OR	Odds ratio
P	Probability
PGE2	Prostaglandin E2
PGF2 alpha	Prostaglandin F2 alpha
PPROM	preterm premature rupture of fetal membranes
PROM	Premature rupture of the fetal membranes
PTD	Preterm delivery
PTL	Preterm labour
RDS	Respiratory distress syndrome
ROM	Rupture of membranes
ROS	Reactive oxygen species
RR	Relative risk
SD	Standard deviation
STD	Sexually Transmitted Disease
T. vaginalis	Trichomonas vaginalis
TIMPs	Tissue inhibitors of matrix metalloproteinases
TPROM	term PROM
TNF alpha	Tumour necrosis factor alpha
vAF	vaginal amniotic fluid
WBC	White blood cells

Introduction

Premature rupture of the fetal membranes (PROM) is defined as the rupture of the fetal membranes with release of the amniotic fluid more than 1 hour prior to the onset of labor (*Canavan et al., 2004a*).

PROM may be subdivided into term PROM (TPROM, i.e. PROM after 37 weeks of gestation) and preterm PROM (PPROM, i.e. PROM prior to 37 weeks of gestation). PPROM is responsible for a third of all preterm births (*Mercer BM., 2003*).

Premature rupture of membranes is a commonly used term, although prelabour rupture of membranes is more precise and less likely to cause confusion regarding gestational age, conveniently, either "prelabour rupture of membranes" or "premature rupture of membranes" can be shortened to PROM (*Marowitz and Jordan, 2007*).

PROM accounts for substantial neonatal morbidity and mortality including preterm birth, respiratory distress syndrome and neonatal infections. The mother is also at risk of developing infections particularly chorioamnionitis that occurs in 15 to 60% of cases and the risk increases with the increasing duration of rupture (*Gaucherand et al., 1995*). Therefore, accurate diagnosis of PROM is critical to both short and long term health and survival for the baby as it facilitates the commencement of appropriately timed management, which has been shown to reduce both maternal and neonatal morbidity and mortality (*Enkin M et al., 2000*).

Accurate diagnosis of PROM is not always easy. The modalities used to diagnose premature rupture of membranes are variable including history taking, clinical examination by sterile vaginal speculum with visualization of the amniotic

Introduction

fluid pooling in the posterior vaginal fornix, measuring the amniotic fluid index (AFI) by ultrasound, testing vaginal pH by nitrazine paper, as well as laboratory investigations like assaying fetal fibronectin in the vagino-cervical fluids or maternal serum, prolactin, alpha fetoprotein and human chorionic gonadotropin (Esim et al., 2003).



Figure (1): Amniosense pad.

A non invasive absorbent pad, brand name Amniosense to detect rupture of membranes, is now commercially available. The manufacturers claim a sensitivity of 100%. Amniosense is a small absorbent pad with a central strip that changes in colour on contact with a pH > 5.2. In the presence of liquor, the contact strip changes in colour and the colour remains the same once the strip has dried. Colour change may also occur on contact with other fluids, e.g. urine but the contact strip reverts to its original colour on drying due to a reaction caused by detachment of the conjugate nitrazine molecules by the urine ammonium ions. This differentiates Amniosense test from nitrazine test. (Bornstein, et al, 2006).

Aim of the work

Measuring the accuracy of the commercially available absorbent pads brand named "AmnioSense™" compared with the nitrazine test in detection of premature rupture of the fetal membranes.