ISSN: 0975-833X

*Available online at http://www.journalcra.com*

*International Journal of Current Research*
*Vol. 12, Issue, 03, pp.10750-10753, March, 2020*

**DOI: https://doi.org/10.24941/ijcr.38303.03.2020**

**INTERNATIONAL JOURNAL OF CURRENT RESEARCH**

**RESEARCH ARTICLE**

# A CROSS SECTIONAL STUDY TO EVALUATE DIAGNOSTIC ROLE OF VAGINAL FLUID CREATININE IN PREMATURE RUPTURE OF MEMBRANES IN THE DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY AT S.M.S. MEDICAL COLLEGE, JAIPUR

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**ARTICLE INFO**

*Article History:*
Received 24th December, 2019
Received in revised form
10th January, 2020
Accepted 28th February, 2020
Published online 30th March, 2020

*Key Words:*
Prom,
Vaginal Fluid,
Creatinine.

**ABSTRACT**

**Aims and Objective:** To evaluate the diagnostic role of vaginal fluid creatinine in PROM (premature rupture of membranes) and find out appropriate cut off value of vaginal fluid creatinine levels to predict PROM. **Materials and Methods:** It was a cross-sectional study including two groups with 50 women in each group. Group I included confirmed PROM and controls were included in Group II. Vaginal fluid sampling was done and creatinine levels were assessed in both groups. Data analysis was done by Student's t-test, Receiving operator characteristic curve and chi square test. **Results:** The mean value of vaginal fluid creatinine (mg/dL) was higher in the PROM group than the control group (0.75±0.16 and 0.19±0.06 respectively). The best cut-off point for vaginal fluid creatinine for diagnosis of PROM was >0.34mg/dL, with 100% sensitivity, 100% specificity, 100% PPV and 96% NPV (P=0.001). **Conclusion:** Vaginal fluid creatinine is a simple, practical, cost-effective and easily accessible test and its incorporation in the low resource setting will be a game changer in the diagnosis of PROM.



**Citation:** ***Dr. Abhilash, E., Dr. Pushpa Nagar, Dr. Mahima Sharma and Dr. Surabhi Arora.*** **2020.** "A cross sectional study to evaluate diagnostic role of vaginal fluid creatinine in premature rupture of membranes in the department of obstetrics and gynaecology at S.M.S. medical college, Jaipur", *International Journal of Current Research*, 12, (03), 10750-10753.

## INTRODUCTION

Premature rupture of membranes (PROM) refers to rupture of the fetal membranes prior to the onset of labor, regardless of gestational age. It is seen in 10% of term pregnancies and 2-4% of preterm pregnancies (DeFranco, 2007). It is an obstetric conundrum which is poorly defined with an obscure aetiology, difficulty in diagnosis, association with significant maternal & neonatal morbidity and mortality, with a diverse and controversial management strategies. A better understanding of the diagnosis and management of PROM allows obstetrician to optimize perinatal outcome and minimize neonatal morbidity. Women with rupture of the membranes typically presents as a large gush of clear vaginal fluid or as a steady trickle. Diagnosis of rupture of membranes depends on clinical ability to document three clinical signs on sterile speculum examination: (1) visual pooling of clear fluid in the posterior fornix of the vagina or leakage of fluid from the cervical os; (2) an alkaline pH of the cervicovaginal discharge, which is typically demonstrated by seeing whether the discharge turns yellow nitrazine paper to blue (nitrazine test); and (3) microscopic ferning pattern of the cervicovaginal discharge on drying (fern test) (Mercer, 2003).

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Over the years in the obstetrical practice, several approaches have been proposed for the diagnosis of PROM. The mere number of such studies signals the importance of making an accurate diagnosis of PROM. However, none of these tests could diagnose or exclude rupture of membranes with certainty and the results have been variable. These tests are mainly focused on the biophysical and biochemical characteristics of amniotic fluid. An accurate biochemical marker for diagnosis of membrane rupture should have a high concentration in the amniotic fluid and a low concentration in maternal blood & cervicovaginal discharge with intact membranes. Amniotic fluid urea and creatinine are one of these biochemical markers that mainly originated from excretion by fetal kidneys and are found to be gradually increasing throughout the pregnancy (Oliviera, 2002; Begum, 2017). The fetus starts excreting urine into the amniotic fluid at around 8th to 11th week of gestation (El-Sabee, 2015). On the other hand, urea and creatinine levels in cervicovaginal secretions are in accordance with maternal serum levels. Therefore, in the presence of PROM the level of these fetal originated markers should be higher in the amniotic fluid than in normal cervicovaginal secretions (Duff, 1996). As there is no need for extra equipment and reagent, considering the technical ease and cost effectiveness of vaginal fluid urea and creatinine measurement, introduction of this method into routine use is feasible and practical.

### Aims and objective

- To find out the diagnostic role of vaginal fluid creatinine in PROM (Premature Rupture of membranes).
- To find out appropriate cut off value of vaginal fluid creatinine levels to predict PROM.

## MATERIALS AND METHODS

It was a cross-sectional study conducted in the Department of Obstetrics and Gynaecology, S.M.S. Medical College and Attached Group of Hospitals, Jaipur. Women with gestational age between 20 and 40 weeks were included in the study after taking written informed consent. The study included two groups with 50 women in each group: a)

**GROUP I** (Confirmed PROM)-Diagnosis of premature rupture of membranes by visualization of amniotic fluid from cervical canal or vaginal pooling of amniotic fluid. b) **GROUP II** (Control)-Without any complaint or complications. All the women who participated in study were subjected to full history taking, general and abdominal examination. Period of gestation in weeks was estimated by last menstrual period or 1st trimester ultrasonography. Sterile speculum examination was done for inspection of Amniotic fluid passing from cervical canal. 5ml sterile normal saline was flushed into the posterior fornix of vagina, then aspirated by the same syringe and sent to the laboratory. Sampling was done before Per Vaginal examination or administration of vaginal drugs. Creatinine in the vaginal fluid sample was estimated by JAFFE'S method. Ultrasonography was done for foetal well-being and AFI (Amniotic Fluid Index).

**Statistical Analysis:** Data collected was entered in MS Excel sheet. Continuous variables were summarized as mean and standard deviation while nominal/categorical variables were expressed as percentages. Unpaired t-test was used for analysis of continuous variables while chi-square test and Fischer Exact test were used for nominal/categorical variable. Sensitivity, Specificity, PPV and NPV was calculated using standard formulae. ROC (Receiving operator characteristic) curve was made to find out optimal cut-off of vaginal fluid creatinine level to get maximum specificity and sensitivity. p value < 0.05 was taken as significant. Medcalc 16.4 version software was used for all statistical calculations.

## RESULTS

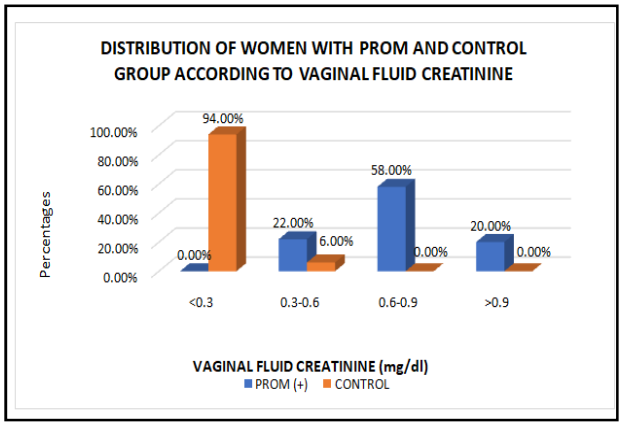
Demographic data for study groups is represented in table 1. There was no statistically significant difference between both groups regarding maternal age, gravida, parity and gestational age. There was a statistically significant difference between the two groups regarding vaginal fluid creatinine. The mean vaginal fluid creatinine (mg/dL) in women with PROM and control were 0.75±0.16 and 0.19±0.06 respectively(p=0.001). The best cut-off point for vaginal fluid creatinine (mg/dL) for diagnosis of PROM was >0.34mg/dl, with 100% sensitivity, 100% specificity, 100% PPV and 96% NPV (P=0.001). Our study observed that women with PROM had a decreased AFI (cms), which was statistically highly significant (p=0.001). The mean AFI (cms) in women with PROM and control group were 5.18±1.96 and 9.58±2.43, respectively. The best cut-off point for AFI (cms) for diagnosis of PROM was ≤6, with 98% sensitivity, 100% specificity, 100% PPV and 98.4% NPV

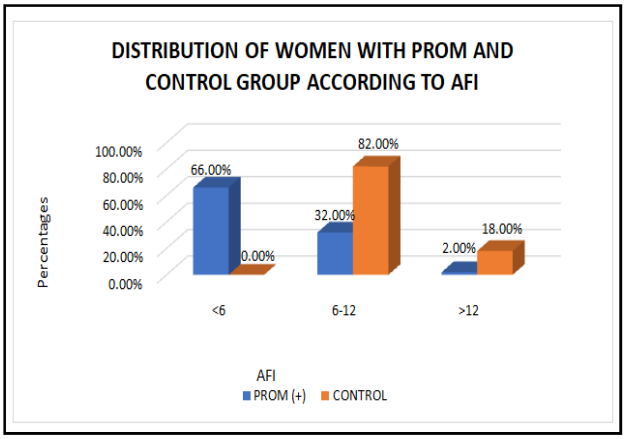
**Table 1. The demographic characteristics of groups**

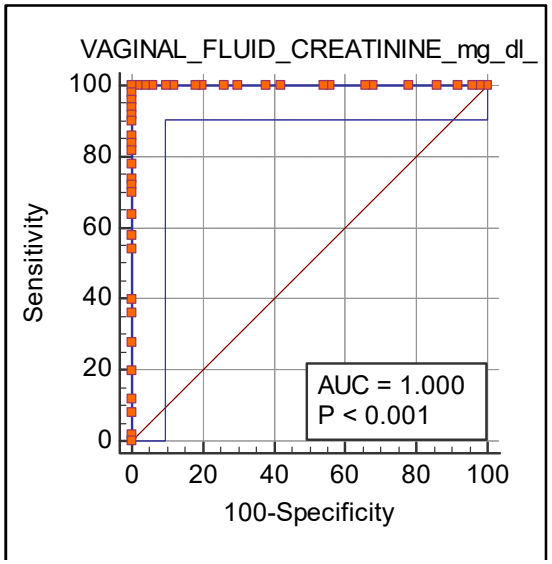
| *PARAMETERS* | *PROM (+)* | *CONTROL* | *p-value* |
|---|---|---|---|
| Age (years) | 25.54±4.04 | 25.04±3.61 | 0.551 |
| Gestational age (weeks) | 34.98±4.26 | 35.08±3.65 | 0.90 |
| Primigravida | 26% | 30% | 0.94 |
| Multigravida | 74% | 70% | 0.94 |

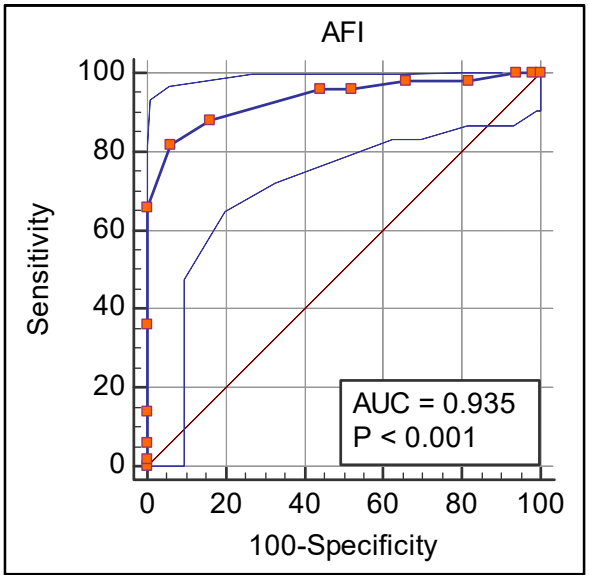
**Table 2: Vaginal fluid creatinine level (mg/dl) and AFI (cm) among groups**

| *PARAMETER* | *PROM (+)* | *CONTROL* | *p-value* |
|---|---|---|---|
| Vaginal fluid creatinine level (mg/dl) | 0.75±0.16 | 0.19±0.06 | 0.001 |
| AFI (cm) | 5.18±1.96 | 9.58±2.43 | 0.001 |






(P=0.001). Receiver operating characteristic (ROC) curve analysis was used to establish the optimal cut-off concentrations for vaginal fluid creatinine and AFI. The areas under the curves for creatinine was 1.00 and for AFI it was 0.94.

CONTROL group, which was statistically significant. In a study by Sekhavat et al. (2012), Amniotic fluid index in definite PROM group was significantly lower than suspected PROM and no PROM group (62.7 ± 18.3, 83.3 ± 27.3 and 98 ± 14.5, respectively, P = 0.001)**.** In our study mean vaginal fluid creatinine (mg/dL) in women with PROM and control were 0.75±0.16 and 0.19±0.06 respectively, which was statistically highly significant (p=0.001). Similar findings were observed in a study done by Begum et al. (2017), where the mean value of vaginal fluid creatinine was higher in the PROM group than in the control group (0.67 ± 0.31 vs. 0.16 ± 0.09), which was statistically significant**.** In a similar study by Kedar et al. (2018), it was observed that the mean concentration of creatinine was 1.22 ± 0.28 mg/dL in the case group and 0.36 ± 0.26 mg/dL in the control group, which was statistically significant. Gezer et al. (2016), also observed a statistically significant association between vaginal fluid creatinine and PROM, where the vaginal fluid creatinine levels were higher in women with PPROM when compared to women of the control group (0.51±0.31 versus 0.09±0.17)**.** In a study by Sekhavat et al. (2012), mean vaginal fluid creatinine (mg/dL) in PROM group was 0.40 ± 0.20, in suspected PROM 0.16 ± 0.04 and 0.08 ± 0.01 in control, which was statistically significant (p=0.001)**.**

**Table 3. ROC Curve Analysis**

| Parameter | Sensitivity | Specificity | PPV | NPV | Cut off Value | p-value | AUC |
|---|---|---|---|---|---|---|---|
| AFI | 98.00% | 100.00% | 100.00% | 98.4% | ≤6 | 0.001 | 0.94 |
| vaginal Fluid Creatinine | 100.00% | 100.00% | 100.00% | 96.00% | >0.34 | 0.001 | 1.00 |

## DISCUSSION

PROM is one of the most troublesome issues in today's obstetrics. The initial management of a woman presenting with PROM should focus on confirmation of diagnosis, validating the gestational age, documenting fetal well-being and deciding the mode of delivery. In a common clinical situation where the obstetrician encounters a woman with possible ruptured membranes, diagnostic accuracy is the key to successful management and improved perinatal outcome. Early and accurate diagnosis of premature rupture of membranes allows for gestational age–specific obstetric interventions, designed to optimize the perinatal outcome and minimize the serious complications. Conversely, a false diagnosis of PROM may lead to unnecessary obstetric intervention including hospitalization, inadvertent administration of antibiotics and corticosteroids, and even induction of labor (Gian Carlo, 2011). The present study was perpetrated to find out the diagnostic value of vaginal fluid creatinine in PROM and timely obstetric intervention to minimise the feto-maternal risk, especially in a low resource setting.

In our study, mean AFI (cms) in women with PROM and control group were 5.18±1.96 and 9.58±2.43, respectively. AFI<6 was seen in 66% women with PROM and none of the control. Our study observed that women with PROM had a decreased AFI, which was statistically highly significant (p=0.001). Similar findings were observed in a study by Osman et al. (2014), where AFI was ≤5 in 38% of PROM group, in 12% of suspected PROM and in 2% of CONTROL group, which was statistically significant (p < 0.05). Effat et al. (2012) also observed similar findings, where AFI was ≤5 in 34% of PROM group, in 14% of suspected PROM and none in

Tigli et al. (2014) in their study observed that the mean concentration of creatinine was 0.58±0.59mg/dL in the case group and 0.25±0.20mg/dL in the control group, which was statistically significant (p<0.001). In a recent study by Kuruoğlu et al (2019), mean creatinine level in vaginal flushing fluid was 0.39 ±0.31 mg/dL in the PROM group, and 0.04± 0.10 mg/dL in the control group. In the present study vaginal fluid creatinine was found to be a reliable marker for diagnosis of PROM. Less time was required to diagnose PROM using vaginal fluid creatinine, which led to timely obstetric intervention minimising the maternal and fetal risk.

### Conclusion

Vaginal fluid creatinine is a simple, practical, cost-effective and easily accessible test and its incorporation in the low resource setting will be a game changer in the diagnosis of PROM. Further studies can be taken up with different gestational age groups for determination of cut-off values of vaginal fluid creatinine for diagnosing PROM.

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