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Review Article

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VALIDITY OF PAP SMEAR IN CORRELATION WITH COLPOSCOPY IN SCREENING OF MALIGNANT AND PREMALIGNANT LESION OF THE CERVIX, IRAQ

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ABSTRACT

Introduction: Papanicolao (Pap) smear remains the most available, feasible, and cost-effective tool for screening of the cervix premalignant and malignant lesions. Via the pap smear, several premalignant lesion of the cervix including the cervical dysplasia and inflammatory lesion could be diagnosed in early stage of the disease. However, the accuracy of the pap smear has been reported to range between 53 and 78% between various studies with the same method of interpretation. The sensitivity and specificity of the pap smear in detecting high-grade lesions of the cervical intraepithelial neoplasia (CINII and CINIII) have been shown to be 55.4 and 96.8%, respectively. The colposcopy is another screening tool for premalignant lesion of the cervix which is not available in all the centers and is expensive. **Objectives:** determine validity of pap smear test related with colposcopy investigation. **Methods:** This cross-sectional descriptive study on 85 married or sexually active reproductive-age women (21–78 years) who they attended in Al Yarmouk Teaching Hospital, in Baghdad, Iraq. Data was collected from the medical records in the cervical cancer unit in the hospital for the period from (1/1/2022 to 1/1/2023). The collected data were coded and entered into SPSS 16.0 (Statistical Package for the Social Sciences (SPSS) 16.0 by IBM) (SPSS for windows, Rel. 16.0.2007, SPSS Inc., Chicago, IL, USA). The categorical data were analyzed by frequency (n) and percentage. **Results:** The pap smear results were positive 46 (54.11%) patients while colposcopy was found to be abnormal in 30 (35.30%) patients. The results of biopsy and histopathology examination revealed 25 (29.41%) positive and 60 (70.58%) negative results. The detailed results of each diagnostic study are summarized in Table2. The diagnostic accuracy of the pap smear was evaluated based on the histopathological results (gold standard). The sensitivity and specificity of pap smear were found to be 66.6% and 96.7%, respectively. In the same way, the PPV and NPV of the pap smear were calculated to be 67.6% and 95.9%, respectively. The overall diagnostic accuracy of the pap smear was found to be 93.9%. **Conclusion:** In conclusion, the results of this study demonstrate that pap smear is a good valid diagnostic accuracy in detecting cervical premalignant lesions when correlated with colposcopy.

KEYWORDS: *Pap Smear, Validity, Correlation, Colposcopy, Cervical Cancer.*

INTRODUCTION

The most cost effective method for the prevention and detection of cervical cancer is the pap smear test, and when the test result is abnormal, colposcopy and endocervical curettage or biopsy may be necessary to perform. However, the definite method to diagnose cervical cancer is biopsy.[1],[2],[3],[4] Cancer of the cervix is considered the second mostly diagnosed cancer in women. According to the 2018 global statistics, 569,847 new cases are diagnosed annually of whom 311,365 die due to the cancer itself.[5] The incidence and mortality are increasing worldwide gradually which is associated with increased social and economic burden along with years of life lost.[6] The cervical cancer most important risk factors have been reported to be the human papilloma virus (HPV) infection which is a very common infection in sexually active women.[7],[8] The cervical cancer can be prevented or diagnosed in early stages via the routine and structured screening programs of the cervical cytology.[9],[10] In addition, introduction and application of HPV vaccination programs have resulted in decreased rate and mortality rates of the cervical cancer in recent year in specific age groups.[11] Papanicolao (Pap) smear

remains the most available, feasible, and cost-effective tool for screening of the cervix premalignant and malignant lesions.[12] Since the results of ASC in pap smear are common in our country and there is no accurate way to evaluation, this causes the need for several visits and invasive procedures such as unnecessary biopsy which themselves cause tremendous cost and unwanted complications for patients. Therefore, if an alternative way than conventional pap smear could be found it would help the patients significantly.[13] Via the pap smear, several premalignant lesion of the cervix including the cervical dysplasia and inflammatory lesion could be diagnosed in early stage of the disease. However, the accuracy of the pap smear has been reported to range between 53 and 78% between various studies with the same method of interpretation.[14],[15] The sensitivity and specificity of the pap smear in detecting high-grade lesions of the cervical intraepithelial neoplasia (CINII and CINIII) have been shown to be 55.4 and 96.8%, respectively[16],[17] The colposcopy is another screening tool for premalignant lesion of the cervix which is not available in all the centers and is expensive.[18] Those with abnormal pap smear results should undergo the colposcopy to confirm the result.[13],[19] But the gold standard for diagnosis of the cervical premalignant lesion remains the biopsy and histopathological examination.[20] The cervical biopsy is an invasive procedure being associated with some complications including the pain, bleeding, and fibrosis.[21] Thus, there is a trend toward developing high accuracy appropriate non-invasive screening tools for early diagnosis of the cervical premalignant lesions. The diagnostic accuracy of the pap smear and the colposcopy depends on the physician expertise as well as the appropriate technical issues.[18],[13] Several studies have evaluated the diagnostic accuracy of these tests in order to determine the best screening modality in these patient groups.[12],[22],[16],[18],[19]

AIM OF THE STUDY

The purpose of the study is to determine validity of pap smear test related with colposcopy investigation.

MATERIAL AND METHODS

This cross-sectional descriptive study on 85 married or sexually active reproductive-age women (21–78 years) who they attended in Al Yarmouk Teaching Hospital, in Baghdad, Iraq, so they were complaining of vaginal discharges, vaginal bleeding, post-menopausal bleeding, Postcoital pain, Postcoital bleeding and Abnormal cervical discharge. Also Pap smear was taken in a medical procedure as it cleared here (Usually the woman is asked to lie on her back on the edge of the examination table, with her legs spread apart in the foot holds. This allows the medical practitioner to access the opening to the vagina, which is needed to conduct the test. A speculum is then inserted into the vagina, which opens up the walls of the vagina and provides access to the cervix, where the cell sample needs to be taken. The medical practitioner commonly uses a spatula to scrape a sample of cells from the outer opening of the cervix wall. Then an endocervical brush is used along the central opening of the cervix to collect cells from this area as well. When the cell sample has been gathered, the speculum can then be removed and the procedure is finished. The same is then sent away to a laboratory to be tested for abnormalities and a follow up appointment is often scheduled to discuss the results.[23] Data was collected from the medical records in the cervical cancer unit in the hospital for the period from (1/1/2022 to 1/1/2023). The collected data were coded and entered into SPSS 16.0 (Statistical Package for the Social Sciences (SPSS) 16.0 by IBM) (SPSS for windows, Rel. 16.0.2007, SPSS Inc., Chicago, IL, USA). The categorical data were analyzed by frequency (n) and percentage.

Data management and Statistical analysis

The histopathology of the cervix was considered as the gold standard for the diagnosis of endometrium abnormalities. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of pap smear and colposcopy were calculated on the basis of pathologic reports. Receiver-operating characteristics (ROC) curve was prepared (plot of sensitivity vs. one specificity) and the areas under the curves (AUC) estimated. $AUC = 1$ indicates a perfect test, $AUC > 0.9$ indicates high accuracy, and AUC between 0.7 and 0.9 indicates moderate accuracy.[24]

RESULTS

Overall, we included a total number of 85 patients with abnormal clinical findings or routine checkup who were referred to our center for pap smear, colposcopy, and biopsy during the study period. table 1 showed the characteristics of the study sample consisting of 85 participants whose ages ranged between 21 and 78 years, as the age range was highest in the 30-39 years' category, amounting to 32.29%, and the age at marriage was 58% in the 14-19 category. As for 68.2%, the parity rate was ≥5. smokers were 5.8% among the participants, but the largest percentage of them had excessive obesity, as the percentage of body mass index was ≥30, 32.94% their waist circumference between (90-99cm), and 62% of them did not have a multiple sexual partner.

Table 1: General characteristics of study sample, n=85.

Characteristics	n= 85	%
Age		
21-29	15	17.64
30-39	30	32.29
40-49	27	31.76
50-59	8	9.41
60-69	3	3.53
70-78	2	2.35
Age at marriage		
14-19	58	68.23
20-29	23	27.05
30-39	3	3.53
40	1	1.17
Parity		
<3	21	24.70
≥3	64	72.30
Smoking		
Current +	5	5.88
Negative	80	94.11
CCP		
<5	41	48.23
≥5	44	51.76
BMI		
<30	37	43.53
≥30	48	56.47
Waist Circumference		
68-69	4	4.70
70-79	14	16.47
80-89	27	31.76
90-99	28	32.94
100-107	12	14.12
Partner multiple relation		
Positive +	23	27.05
Negative -	62	72.94
CCP=(Combine Contraceptive Pills), BMI= Body Mass Index,		

The most common clinical symptom was the postcoital bleeding being reported in 21 (24.70%) of the patients while only 1 (1.17%) patients had postcoital pain. About 10 (11.76%) had Post-menopausal bleeding and 11 (12.94%) had Cervical discharge, 13 (15.29%) had Abnormal cervical discharge, 24 (28.23%) had vaginal bleeding, 2 (2.35%) had abnormal vaginal bleeding, 1 (1.17%) had vaginal discharge, 2 (2.35%) Abnormal vaginal discharge, and 10 (11.76%) Abnormal pap smear Table 2.

Table 2: Clinical findings of the 85 patients included in the current study.

Variable	Value
Postcoital pain (%)	1 (1.17%)
Postcoital bleeding (%)	21 (24.70%)
Post-menopausal bleeding (%)	10 (11.76%)
Cervical discharge (%)	11 (12.94%)
Abnormal cervical discharge	13 (15.29%)
Vaginal bleeding (%)	24 (28.23%)
Abnormal vaginal bleeding (%)	2 (2.35%)
Vaginal discharge (%)	1 (1.17%)
Abnormal vaginal discharge (%)	2 (2.35%)
Abnormal pap smear (%)	10 (11.76%)

The pap smear results were positive 46 (54.11%) patients while colposcopy was found to be abnormal in 30 (35.30%) patients. The results of biopsy and histopathology examination revealed 25 (29.41%)

positive and 60 (70.58%) negative results. The detailed results of each diagnostic study are summarized in Table3.

Table 3: Clinical and laboratory findings of the 85 patients included in the current study.

Variable	Value
Pap smear	
Normal (%)	39 (45.88%)
Abnormal (%)	46 (54.11%)
Colposcopy	
Normal (%)	60 (70.58%)
Abnormal (%)	25 (29.41%)
Pap smear findings	
Normal (%)	39 (45.88%)
ASCUS (%)	32 (37.64%)
LSIL (%)	8 (9.41%)
HSIL (%)	6 (7.1 %)
Colposcopy findings	
Normal (%)	60 (52.94%)
CIN I (%)	15 (17.64%)
CIN II (%)	6 (7.1%)
CIN III (%)	3 (3.53%)
Invasive (%)	1 (1.17%)
NILM = Negative for Intraepithelial Lesion or Malignancy, CIN 1= cervical squamous intraepithelial neoplasia 1, CIN 2= cervical squamous intraepithelial neoplasia 2. CIN 3= cervical squamous intraepithelial neoplasia 3. ASC-US = atypical squamous cells of undetermined significance.	

The diagnostic accuracy of the pap smear was evaluated based on the histopathological results (gold standard). The sensitivity and specificity of pap smear were found to be 66.6% and 96.7%, respectively. In the same way, the PPV and NPV of the pap smear were calculated to be 67.6% and 95.9%, respectively. The overall diagnostic accuracy of the pap smear was found to be 93.9%, as shown in table 4.

Table 4: The diagnostic accuracy of pap smear in diagnosis of premalignant lesion of the cervix in a series of 85 patients with clinical findings or routine check-up.

	Sensitivity	Specificity	PPV	NPV	Accuracy
Pap smear	66.6%	96.7%	67.6%	95.9%	93.9%

DISCUSSION

The diagnostic validity of different methods for diagnosing precancerous and malignant lesions of the cervix has been the subject of many research and controversies.[14],[22],[18] Although many studies have scored the diagnostic validity of these diagnostic methods, the consensus on the best diagnostic method remains a matter of research. In the current study, we determine the validity of Pap smear scored with colposcopy for the diagnosis of precancerous and malignant lesions of the cervix. We found that the diagnostic accuracy of Pap smear which is (93.9%) and that identified with higher Specificity 96.7% and higher NPV 95.9%. Thus, based on the results of the current study, we can indicate that pap smear is a good investigation and valid in detecting the malignant and premalignant lesions of the cervix. We found that atypical squamous cells of undetermined significance (ASCUS) were reported in 32 (37.64%) patients which is in concordance with previous reports.[13],[19],[25] On the other hand, colposcopy demonstrated that CIN1, CIN3 were presented in 15 (17.64%) and 3 (3.53%) patients, respectively. These findings are near of the results from previous studies.[26],[27] Various factors may affect the accuracy of colposcopy in diagnosing premalignant and malignant cervical lesions, including the quality of performing colposcopy and result interpretation, operator skill, and classifications of results. In another study reviewing the ASCUS cases, it was reported that conventional pap smear was 18% accurate and LBC pap smear was 13.7% which shows a reduction in cases of ASCUS in LBC method. This was in agreement with the results of Annie and colleagues in 2003.[4] In a study by Lonky et al[28], in California, only 17% of cases with high grade dysplasia and 38% of patients with invasive malignancy were recognized using Pap smear and the abnormality was found trivial in 77% of Pap smear results. This study emphasized a poor correlation

between Pap smear and cytology findings when a low grade lesion was reported in Pap smear. In contrast, in a study by Moy et al[29], in China, the sensitivity and specificity of Pap smear in detecting non-benign cervical lesions were 85% and 91%, respectively, which were considerably higher than that in relevant reports. Maybe a higher sensitivity of Pap smear in the present work compared to similar reports is the scarcity of menopause cases, because it has been shown that menopause induces atrophic changes in the cervix, reducing the sensitivity of Pap smear testing. Finally, in a general and comprehensive review, the sensitivity, specificity, positive predictive value, negative predictive value, and the compliance of three methods: conventional pap smears, LBC and colposcopy, in diagnosis of any cervical lesions was determined based on biopsy results.[30]

CONCLUSION AND RECOMMENDATIONS

In conclusion, the results of this study demonstrate that pap smear is a good valid diagnostic accuracy in detecting cervical premalignant lesions when correlated with colposcopy. Since cervical cancer is the most common gynecological cancer in developing countries, and high cost of other investigation, pap smear is recommended for screening of the cervical malignant and premalignant lesions in primary health care centers.

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