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Comparison of PAP- Smear and Colposcopy in the Absence of HPV Test for the Diagnosis of Premalignant and Malignant Cervical Lesions

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Abstract: Cervical cancer, the 4th most common cancer in women, is the result of precancerous intraepithelial lesions which are associated with persistent human papillomavirus (HPV) infection. Prevention through vaccination and screening is critical, but access, awareness and care gaps, especially among disadvantaged populations, contribute to high incidence, late diagnosis and higher mortality rates in the world. Aim of the Study to evaluate PAP smear and colposcopy results in comparison with the histopathological results of cervical samples in women with abnormal cytology and/ or abnormal colposcopy results, without the presence of human papillomavirus (HPV) test. This is a cross sectional study, which was carried out at Basrah Maternity and Children Hospital from 1st January 2024 to 1st January 2025 for the comparison of PAP smear and colposcopy with histopathology in the diagnosis of cervical lesions. Eligible women were interviewed, Pap smear, colposcopy and biopsy. Data collected were demographic, gynecological history, and clinical findings. Histopathology was used as a diagnostic gold standard to help with future management. 111 women (mean age 44.12±12.8 years) were included in the study, the majority being married, unemployed and poorly educated. Abnormal vaginal bleeding (75.7%) and genital infections (56.8%) were common. Abnormality detected by PAP smear, colposcopy and histopathology was 50.5%, 52.2% and 54.1% respectively, and confirmed the presence of cervical intraepithelial neoplasia CIN or carcinoma. Important results were that PAP smear had an accuracy of 81.1% (sensitivity 75.0% and specificity 78.4%) and colposcopy was slightly better with an accuracy of 82.0% (sensitivity 81.6% and specificity 82.4%). There was good agreement between both tests and histopathology with colposcopy exhibiting greater predictive values. Therapy included hysterectomy (27.0%) and conization (21.6%) emphasizing the importance of the correct early diagnosis. Colposcopy demonstrated slightly better accuracy as compared with PAP smear but the gold standard was histopathology. The high prevalence of high CIN2/3 and carcinoma calls attention to the need for timely screening, and for that, PAPsmear combined with colposcopy is useful in low resource settings.

Keywords: Pap Smear, Colposcopy, Cervical Cancer Screening, Human Papillomavirus (HPV), Cervical Intraepithelial Neoplasia (CIN)

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Introduction

Cervical cancer is still a huge public health problem and is the fourth largest cancer in women worldwide. Premalignant cervical lesions including abnormal changes in the epithelial cells may go on to develop invasive carcinoma. So it is very important to screen and diagnose the patient as early as possible to minimize the incidence and mortality of cervical cancer [1].

High risk human papillomavirus (HPV) infection, especially HPV types 16 and 18 is the major etiological factor linked to cervical carcinogenesis. Other risk factors include smoking, oral contraceptive use, high parity, multiple sexual partners, early sexual activity and immunosuppression. Even with efforts to improve the screening programs, restricted resources, socio-economic inequalities and poor access to diagnosis services are still significant obstacles to early detection [2].

The Papanicolaou (Pap) smear and the colposcopy are frequently used techniques to detect pre-cancerous and cancerous cervical lesions, especially when HPV testing is not available. Pap smear is a simple, non-invasive, cost-effective cytological screening technique, which can detect abnormal cells in the cervix. However, sampling errors and interpretation of the cytology may affect its diagnostic performance leading to false negative results [3].

On the other hand, colposcopy offers direct magnified visualization of cervix which helps to identify the suspicious area and target the biopsy for a histopathological confirmation. Colposcopy is more sensitive for detection of high grade CIN (CIN2+) but requires skilled practitioners and has less specificity and high costs [4].

In areas where HPV testing is not available, assessment of the performance of these traditional methods is especially relevant. The present study thus seeks to compare the Pap smear and colposcopy results with the histopathology results of cervical sampling in women with abnormal cytology and/or colposcopic findings and evaluate the diagnostic value of Pap smear and colposcopy in the detection of premalignant and malignant cervical lesions in the absence of HPV testing.

Methodology

We designed a cross-sectional diagnostic accuracy study for comparing the diagnostic accuracy of Pap smear and colposcopy for the detection of premalignant and malignant cervical lesions, using histopathology examination as a reference (gold standard) method. This study was conducted at the Cervical Disease Screening Center in Al-Basrah Maternity and Children hospital, Basrah, Iraq, between January 1, 2024, and January 1, 2025.

Women seen at the Cervical Disease Screening Center for routine cervical screening as well as women who presented with symptoms of a gynecologic problem (e.g., postcoital bleeding, pelvic pain, or abnormal vaginal bleeding) were included in the study during the study period. Eligible participants underwent clinical examination, Pap smear, colposcopy and/or histopathological assessment as appropriate.

Cervical cancer and pre-cancerous cervical lesions were the exclusion criteria as well as women who had a history of cervical surgery in the last six months or were pregnant. Participants were also excluded if they had a poor-quality Pap smear or biopsy to ensure a good diagnostic evaluation.

The data were obtained from direct interview using an interview schedule to elicit the relevant information of the respondents in terms of their demographic, obstetric, gynecological and medical information. Demographic factors were age, place of residence, marital status, level of education and smoking status. The obstetric and gynecological data collected were gravidity, parity, contraceptive practices, abnormal vaginal bleeding and genital infection history. Further, the medical and surgery

history of the participants and the family history of cervical cancer was taken.

A clinical examination of the cervix was carried out on all of them to ascertain any abnormality such as contact bleeding, abnormal cervical discharge, chronic cervicitis, cervical erosion, cervical hypertrophy, suspicious cervical masses and ulcerative lesions.

Samples for Pap test were taken with a cervical brush or spatula, smeared on to glass slides and promptly fixed with 95% ethyl alcohol. The results of the cytology were analyzed using the Bethesda System as "normal", "atypical squamous cells of undetermined significance" (ASC-US), "low grade squamous intraepithelial lesion" (LSIL), "high grade squamous intraepithelial lesion" (HSIL) or "invasive carcinoma".

A colposcope was used to see the cervix at a high magnification and look for abnormal epithelial and vascular changes (colposcopic examination). The assessment comprised of the lesion grade, anatomic location, the number of cervical quadrants involved, and staining patterns such as the Schiller's iodine test. The findings on colposcopy were classified as normal, Grade 1, Grade 2, nonspecific findings, leukoplakia (keratosis or hyperkeratosis), abnormal Schiller's staining patterns or erosion, and other findings. Atypical vessels, acetowhite epithelium, punctation and mosaicism were deemed to represent abnormal colposcopic features.

Histopathological assessments by pathologists were performed on cervical biopsies that were taken from areas of suspicious abnormality that were seen during colposcopic examination. The histological results were categorized as normal, cervical intraepithelial neoplasia Grade I (CIN I), Grade II (CIN II), Grade III (CIN III) and invasive carcinoma. Histopathology was used as the reference method for assessment of the diagnostic accuracy of Pap smear and colposcopy for the detection of premalignant and malignant cervical lesions. Finally, the correlation between the results of the cervical smear, colposcopy and histopathology were evaluated.

Other suggested diagnostic and therapeutic procedures were recorded based on the clinical findings. These were: local treatment, endocervical curettage, polypectomy, cervical cauterisation, conisation and total abdominal hysterectomy.

The research was approved by the Iraqi Board for Medical Specializations and Basrah Health Directorate. Informed consent and confidentiality of participants was guaranteed. The data were analyzed based on SPSS 26. Normally distributed continuous variables were expressed as mean ± SD and categorical variables were expressed as number and percentages. Chi-square and independent-samples t-tests were used for statistical comparisons. Pap smear and colposcopy were compared to histopathology as the standard of comparison for the diagnostic performance of the tests. A p value of ≤ 0.05 was considered significant.

Results

The study included 111 women who underwent cervical cancer screening, comparing Pap smear and colposcopy results with the gold-standard histopathology. The study included women with a mean age of 44.1 years, ranging from 25 to 70 years. The majority were married (97.3%), unemployed (81.1%), and had low educational attainments, with 24.3% having no formal education, 45.9% having primary education, 24.3% secondary education, and 5.6% college-level education.These data are presented in Table 1.

Table 1. The baseline Characteristics of Study Participants

Variables		No	%
Age	Mean± SD	44.12± 12.8	
	Range	(25-70)	
Marital status	Single	3	2.7
	Married	108	97.3
Educational level	No formal education	27	24.3
	Primary	51	45.9
	Secondary	27	24.3
	College Education	6	5.6
Occupation	Employed	21	18.9
	Unemployed	90	81.1

Table 2 presents the clinical history and parity distribution. Regarding parity**,** 43.2%had more than 5 children**.** Abnormal vaginal bleeding **(75.7%)** and genital infections (56.8%) were commonly reported. Notably, 62.2% had a history of hormonal contraceptive use**.** Only 16.2% reported a family history of cervical cancer.

Table 2. Clinical History and Parity Distribution

Variables		No.	%
Parity	Nullipara	6	5.4
	1-4	57	51.4
	>5	48	43.2
Abnormal vaginal bleeding		84	75.7
History of genital infection		63	56.8
Family history of cervical cancer		18	16.2
History of contraception	Hormonal	69	62.2
	Non-hormonal	6	5.4
	None	36	32.4

The findings of Pap smear examination are presented in Table 3 Regarding Pap smear results, 49.5% were normal, 22.5% showed atypical squamous cells, 12.6% showed low-grade lesions, 7.2% had high-grade lesions, and 8.1% were diagnosed with invasive carcinoma.

Table 3. Findings of Pap smear Examination

Findings of pap smear	No.	%
Normal	55	49.5
Atypical squamous cells	25	22.5
Low-grade lesion	14	12.6
High-grade lesion	8	7.2
Invasive carcinoma	9	8.1
Total	111	100.0

Colposcopic examination showed normal findings in 47.8% of participants, grade 1 findings in 18.9%, grade 2 in 12.6%, non-specific findings in 9.9%, and invasive carcinoma in 10.8%. (table 4).

Table 4. Findings of Colposcopy Examination

Findings of colposcopy	No.	%
Normal	53	47.8
Grade 1	21	18.9
Grade 2	14	12.6
Non-specific finding	11	9.9
Invasive carcinoma	12	10.8

Histopathological examination revealed normal results in 45.9%, CIN 1 in 24.3%, CIN 2 in 10.8%, CIN 3 in 10.8%, and invasive carcinoma in 8.1% of cases (Table 5).

Table 5. Findings of Histopathology Examination

Findings of histopathology	No.	%
Normal	51	45.9
CIN 1	27	24.3
CIN 2	12	10.8
CIN 3	12	10.8
Invasive carcinoma	9	8.1

Correlation between Pap smear and histopathology showed that out of 56 cases with abnormal Pap smears, 45 had abnormal histopathology and 11 were normal, while among 55 with normal Pap smears, 40 were normal and 15 were abnormal (Table 6).

Table 6. Correlation of Pap Smear Results with Histopathological Findings

Pap smear	Histopathological correlation		Total
	Abnormal	Normal	
Abnormal	45	11	56
Normal	15	40	55
Total	60	51	111

The Correlation between colposcopy and histopathology revealed that among 58 abnormal colposcopy cases, 49 were abnormal and 9 were normal on histopathology, while among 53 normal colposcopy cases, 42 were normal and
11 were abnormal (Table 7).

Table 7. Correlation of Colposcopy Results with Histopathological Findings

Colposcopy	Histopathological correlation		Total
	Abnormal	Normal	
Abnormal	49	9	58
Normal	11	42	53
Total	60	51	111

The diagnostic accuracy of Pap smear compared to histopathology showed an accuracy of 81.1%, sensitivity of 75.0%, specificity of 78.4%, PPV of 80.4%, and NPV of 72.7%. For colposcopy, the accuracy was 82.0%, sensitivity 81.6%, specificity 82.4%, PPV 84.4%, and NPV 82.4%. (Table 3).

Table 8. Diagnostic Accuracy of Pap smear and Colposcopy Compared to Histopathology

Histopathological correlation	Sensitivity	Specificity	PPV	NPV	Accuracy
Pap smear	75.0	78.4	80.4	72.7	81.1
Colposcopy	81.6	82.4	84.4	82.4	82.0

Regarding recommended advanced examinations and treatments, 37.8% were advised local treatment, 5.4% endocervical curettage, 8.1% cervical cauterization, 21.6% conization, and 27.0% total abdominal hysterectomy (Table 9).

Table 9. Recommended Advanced Examinations and Treatments

Item	No.	%
Local treatment	42	37.8
Endocervical curettage	6	5.4
Cervical cauterization	9	8.1
Conization	24	21.6
Total abdominal hysterectomy	30	27.0

Discussion

Despite the fact that the disease burden is high in low and middle-income countries, due to a lack of adequate screening coverage and late stage diagnosis, cervical cancer is still a significant public health problem [5]. Cervical cancer is the fourth leading cause of cancer in women worldwide, and is highly preventable and treatable with early detection through an organized screening programme, according to the World Health Organization (WHO) [6]. Although pap smear cytology and colposcopy have gained widespread acceptance as important means of detecting pre-cancerous and cancerous lesions, the accuracy of these methods in diagnosis varies according to the extent of population characteristics, adequacy of samples and expertise of examiner [7]. Research is important to assess their diagnostic performance with the gold standard of histopathology in a particular population to guide clinical decision making, optimize screening and improve patient outcome in resource-limited environments such as Basrah.

The mean age of the participants in the present study was 44.1 years, and most women were married (97.3 %), had low educational levels (70.2 % had no or only primary education) and were not working (81.1 %). These demographic characteristics align with the typical cervical cancer screening population in similar Middle Eastern and South Asian studies, as described by Anderson et al., (2018) and Djordjecvic et al. (2024) [8, 9] where cultural, social and economic factors play a major role in health-seeking behaviour. Low education level is a known risk factor for delayed screening and higher incidence of cervical cancer because of low awareness of the benefit of screening and poor access to health care services, which is consistent with the findings of Adedimeji et al. (2021) [10].

Regarding the clinical aspects high parity was common with 43.2% having more than five children which

is in line with the findings of Tekalegn et al. (2022) [11] which associated multiparity with the development of cervical cancer, possibly due to hormonal changes, cervical trauma during childbirth and prolonged exposure to high estrogen levels.

The most common presenting symptom was abnormal vaginal bleeding (75.7%) followed by genital infection history (56.8%) and hormonal contraceptive use (62.2%). As reported by Mwaka et al. (2016) and Smith et al. (2013) [12, 13] the latter has been linked to slightly higher risk of cervical cancer in particular when used for extended periods of over 5 years.

Interestingly, 16.2% said that they had a family history of cervical cancer, highlighting that the disease is multifactorial with environmental and infectious factors, especially persistent high-risk HPV infection, contributing most to the disease [14].

In our study, 50.5% of the cases were positive for pap smear, of which 22.5% were ASC, 12.6% were LG, 7.2% were HG and 8.1% were invasive carcinoma. The prevalence of abnormal smear is consistent with the other developing countries, which ranges from 4% to 20% in general population and may be higher in symptomatic populations as reported by Ezzelarab et al (2024) [15].

The accuracy of Pap smear was 81.1%, with sensitivity of 75.0%, specificity of 78.4%, PPV of 80.4%, and NPV of 72.7% when compared with the histopathology. These are similar to the values reported in similar studies of the sensitivity (55% to 80%) and specificity (60% to 85%) of the Pap smear [16]. In our study, Pap smear was relatively less sensitive than colposcopy, which could be explained by sampling errors, subjectivity in the interpretation of the Pap smear, and the fact that the lesions may not be in the areas adequately sampled during smear collection [17].

Colposcopy had slightly higher diagnostic accuracy (82.0%), sensitivity (81.6%), specificity (82.4%), PPV (84.4%) and NPV (82.4%). This aligns with the literature on the detection rates of colposcopy, especially in symptomatic women or women with abnormal cytology as described by Balmagambetova et al. (2020) and Li et al. (2024) [18, 19]. The advantage of colposcopy is that it is able to visualize the lesions in the cervix and direct the biopsy to the area of concern explaining why it is more effective in detecting CIN and invasive carcinoma. However, the method is subjective and false positive may be seen as a result of inflammatory or metaplastic changes which are not malignant [20].

In this study, the diagnostic accuracy of both Pap smear and Colposcopy were comparable to other studies worldwide but were slightly better for Colposcopy, which was also seen in Iran by Najib et al., 2020 [7]. Interestingly, the sensitivity of our pap smear (75%) is higher than some studies in Africa done by Cudjoe et al (2021) (~55%) which may be attributed to improved sample preparation and interpretation in our centre [21].

In contrast, in our data the accuracy of Pap smear versus colposcopy is only slightly different (81.1% vs. 82.0%) although in other meta-analyses, the superiority of colposcopy is well demonstrated. This may indicate that Pap screening is still useful, at least in conjunction with HPV testing as is recommended by many current guidelines [17].

Specifically, 24.3% had histopathology CIN1, 10.8% had CIN2 and 10.8% had CIN3, and 8.1% had invasive carcinoma. This relatively high prevalence of high-grade lesions and carcinoma in our sample was probably due to a group of symptomatic women and women with visible findings on examination being included, as opposed to a purely screening population. The higher abnormality rates may be due to this selection bias compared to populationbased screening studies [22; 23].

The results highlight the need for complementary use of Pap smear and colposcopy. Although Pap smear is a practical, inexpensive, and easily available screening tool, colposcopy is extremely useful for the confirmation and localization of lesions, particularly in women who are symptomatic or have abnormal

cytology [24]. With the sensitivity/specificity findings presented here, there is a possibility that a "screen-and-treat" strategy, based on colposcopy after an abnormal Pap smear, could boost detection rates and decrease progression to invasive disease [25].

Moreover, the prevalence of multiparity, low education and contraceptive use among the participants indicate the need for targeted education and prevention programs. Public health strategies should focus on raising awareness of the risk factors for cervical cancer, HPV vaccination and timely follow up of abnormal screening results.

Conclusion

Diagnostic accuracy of Pap smear and colposcopy were good for the detection of premalignant and malignant lesions in the cervix, with Pap smear having slightly lower diagnostic accuracy. But the definitive diagnosis can only be made by histopathological examination. The relatively high prevalence of CIN II/III and invasive cervical carcinoma in this study indicates that participants in this study were at high risk and it is important that screening and early diagnosis are done in time and appropriate follow up is provided to the patient. Using Pap smear as a primary screening tool, with the aim of using colposcopy to assess any abnormalities, is a reasonable and viable option in resource-constrained health care environments where HPV testing is not available, for the purpose of improving early detection of cervical lesions.

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