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Keywords:

Biopsy, Cervical cancer, Colposcopy,
Histopathology examination, PAP
smear.

Article History:

Received Date: June 13, 2023

Acceptance Date: Aug 10, 2023

Citation:

Rajakeerthana R, Swarnapriya K, Kavitha G. Comparison of Pap Smear and Colposcopy in the Evaluation of Unhealthy Cervix Among Women Visiting a Tertiary Care Center: A Hospital-based Descriptive Observational Study. *Nep J Obstet Gynecol.* 2023;18(1):13-19

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Comparison of Pap Smear and Colposcopy in the Evaluation of Unhealthy Cervix Among Women Visiting a Tertiary Care Center: A Hospital-based Descriptive Observational Study

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Abstract

Aims: Cervical cancer is fourth most common type of cancer in women worldwide. Early identification of unhealthy cervix helps in reducing the disease burden. Hence, aim of this study was to compare diagnostic accuracy of colposcopy and PAP smear in evaluation of unhealthy cervix.

Methods: Observational study was conducted for a period of 2 years from June 2014 to June 2016 at tertiary care institute. After ethical approval, women of age above 21 years with unhealthy cervix were recruited. Baseline characteristics included demographics, obstetrics history and comorbidities were recorded. All women underwent pap smears, colposcopy, and cervical biopsy if required. Correlation of PAP smear and colposcopy histopathology findings as gold standard.

Results: Among 100 study women included finally, 39% were 40-49 years. Among them, only 10% were primigravida. 54% had complaint of white discharge and 10% had intermenstrual bleeding. Inflammatory atypia was reported in 60% and 55% had erosion cervix. Abnormal PAP results was seen in 88.2% of HPE-positive women whereas abnormal colposcopy results was seen in 64.7%. Difference in proportion of PAP smear, Colposcopy findings and histopathological findings were statistically significant. PAP-smear showed sensitivity of 88.2%, specificity of 74.7%, and diagnostic accuracy of 77% in predicting histopathologic findings. While, colposcopy showed better specificity of 97.6% and diagnostic accuracy of 92%.

Conclusion: PAP-smear had higher sensitivity and lower specificity while colposcopy showed better specificity and diagnostic accuracy in predicting histopathological findings.

Introduction

Cervical cancer, second most common cancer among women, is caused by human papillomaviruses (HPV) with global prevalence of 99.7%.¹ 122,844 women are diagnosed with cervical cancer, and 67,477 die in India per annum.² World Health Organization (WHO) had launched an initiative in November 2020, involving 194 countries with the aim to reduce new cases of cervical cancer to less than four per 100,000 women by 2030. To achieve this, full vaccination of 90% young girls with HPV vaccine by age of 15 years and screening 70% of women two times per life with high performance test, and treating 90% of women diagnosed with cervical precancerous or cancerous lesions is required.³

Cervical pre-cancer has very slow progression; there is therefore window of opportunity, even in low-resourced countries to discover and manage it in time. Precancerous stage

is quite long and ranges from 7 to 20 years which enables early diagnosis and treatment at this stage. Visual inspection of the cervix with the application of 5% acetic acid (VIA) and with lugol's iodine (VILI), Papanicolaou's smear test (PAP smear), liquid-based cytology (LBC), human papillomavirus deoxyribonucleic acid test (HPV DNA) and colposcopy are different methods for its screening.⁴

Aims

To compare the diagnostic accuracy of colposcopy and Pap smear in the evaluation of unhealthy cervix at a tertiary care centre in Kanchipuram District, Tamil Nadu, India

Methods

The current Descriptive observational study was carried out in the Department of Obstetrics and Gynecology in a tertiary care teaching hospital in Kanchipuram, Tamil Nadu, India for a period of 2 years from June 2014 to June 2016. The study was approved by the Institutional Human Ethics Committee. Women presenting to the outpatient and inpatient departments with various symptoms suggestive of the pathology of the uterine cervix and diagnosed with unhealthy cervix were included in the study. Married women with age greater than 21 years, presented with symptoms like profuse white discharge, post-coital bleed, intermenstrual bleed, post-menopausal bleeding and diagnosed with clinically unhealthy cervix like cervical erosion, cervicitis, cervix polyp, condyloma, etc by speculum examination were included in the study. Pregnant women, women who underwent total hysterectomy, women presented with vaginal infection at the time of examination along with those of frank invasive carcinoma were excluded from the study.

A total of 100 subjects were selected as sample size recruited sequentially by purposive sampling, till the required sample size was reached. All the women who met our inclusion and exclusion criteria were explained about the study procedure, risks and benefits by participating in the study and were cleared with all doubts. Those who accepted for participation were included after obtaining an informed consent signed.

Data collection: The data was collected in a structured case report form (CRF), which was designed for the purpose of the study. The baseline characteristics including demographics (age), obstetrics history (gravida, parity, abortion, living), and comorbidities were recorded. All the women underwent pap

smears, colposcopy, and cervical biopsy if needed (procedures described below). Final diagnosis of the unhealthy cervix, as per PAP smear, colposcopy, and HPE were documented. HPE was considered as the gold standard for comparison of PAP same and colposcopy. Confidentiality of the study women was maintained throughout the study. All the collected data was analysed as per the statistical plan.

Pap smear: During this test, the patient was placed in the lithotomy position. Cusco's speculum was introduced and the smear was taken with an Ayres spatula or with a moistened brush around the external of making 360-degree rotation with minimal pressure and smeared and fixed in a glass slide with 95% alcohol, and glass slides are transported in complex gear. Staining was done with Papanicolaou's staining procedure. The slides are finally mounted in Canada balsam and were examined and interpreted.

Colposcopy examination: This includes examination of unstained cervix, inspection after 5% acetic acid application, inspection with green filter, Lugol's iodine application which differentiates the normal and abnormal cervical epithelium aiding in diagnosing the unhealthy cervix.

Biopsy: Suspected areas were sampled for biopsy using cervical punch biopsy forceps and sent for histopathological examination (HPE).

PAP smears were interpreted according to the New Bethesda System 2014.⁵ Histopathological slides were interpreted according to the WHO Classification 2003.⁶

Initially descriptive analysis of all the variables was done using frequency and percentages for categorical variables, and mean and standard deviations for continuous variables. The diagnostic accuracy of Pap smear and colposcopy in the evaluation of the unhealthy cervix was assessed by calculating the sensitivity, specificity, and predictive values of each of the methods. IBM SPSS⁷ version 22 was used for statistical analysis.

A total of 100 eligible women were included in the final analysis.

Among them, majority of 39% (n=39) were in the age group of 40- 49 years and 90% (n=90) were multipara women of which 36% women had 3 live children. Most of them were illiterates (47%) or had education up to higher secondary school (40%). Similarly, 38% (n=38) of them were using permanent contraception. (Table 1).

Table 1: Summary of baseline characteristics of the study women (N=100).

Baseline characteristics	Frequency (Percentage) n (%)
Age group (in years)	
20 to 29	15(15%)
30 to 39	30(30%)
40 to 49	39(39%)
50 to 59	16(16%)
Parity	
Primi	10(10%)
Multi	90 (90%)
Number of living children	
1	14(14%)
2	32(32%)
3	36(36%)
4	18(18%)
Education	
Illiterate	47(47%)
Up to higher secondary school	40(40%)
Diploma	4(4%)
Graduate	4(4%)
Post Graduate	5(5%)
Socio Economic status	
<1000 INR	74(74%)
1000 to 1500 INR	19(19%)
Above 1500 INR	7(7%)
Duration of marriage (in years)	
<5	13(13%)
5 to 10	35(35%)
11 to 20	30(30%)
>20	22(22%)
Contraception	
Permanent	38(38%)
IUCD	15(15%)
OCP	11(11%)
Barrier	5(5%)
Nil	31(31%)

Footnotes: INR-Indian rupees, IUCD-Intrauterine contraceptive devices, OCP-Oral contraceptive pills

The majority 54% had complications of white discharge. PAP smear and per speculum examination revealed 60% with inflammatory atypia and 55% with erosion cervix respectively. (Table 2)

Table 2: Summary of the clinical examination and PAP smear findings of the study women (N=100)

Parameter	Summary
Complaints/ presentations	
White Discharge Per Vagina	54(54%)
Inter Menstrual Bleeding	10(10%)
Post Coital Bleeding	8(8%)
Post Menopause Bleeding	5(5%)
Weight loss	5(5%)
Others	18(18%)
PAP smear findings	
Normal	3(3%)
Inflammatory atypia	60(60%)
Low-grade Squamous Intraepithelial Lesion	21(21%)
Atypical Squamous Cells of Undetermined Significance	4(4%)
High-grade Squamous Intraepithelial Lesion	10(10%)
Atypical Squamous cells	2(2%)
Per speculum appearance of the cervix	
Erosion Cervix	55(55%)
Congestion	20(20%)
Hypertrophy + Erosion	11(11%)
Hypertrophy + Congestion	7(7%)
Polyps	5(5%)
Atrophy	2(2%)

While 71% of women were normal for acetic acid inspection, 43% were found with partial positive Lugol's iodine application. Colposcopy examination revealed 34% women with erosive cervix while HPE revealed 42% with chronic cervicitis. (Table 3)

Table 3: Summary of the colposcopic and HPE findings among the study women (N=100).

Parameter	Frequency
Acetic Acid	
Normal	71(71%)
Flat aceto white areas with sharp margins	17(17%)
Mosaic pattern	12(12%)
Lugol's iodine application	
Partial positive	43(43%)
Negative	33(33%)
Positive	24(24%)
Colposcopy appearance	
Erosion	34(34%)
Inflammation	18(18%)
Unsatisfactory	13(13%)
Normal	12(12%)
Polyp	7(7%)
Leukoplakia	3(3%)
CIN I	8(8%)
CIN II	3(3%)
CIN III	2(2%)
HPE	
Chronic cervicitis	42(42%)
Chronic cervicitis + Erosion	32(32%)
CIN I	8(8%)
CIN II	5(5%)
CIN III	4(4%)
Polyps	5(5%)
Erosion	2(2%)
Epithelial hyperplasia	2(2%)

Footnotes: CIN-Cervical Intraepithelial Neoplasia, HPE-Histopathological Examination

Abnormal PAP results was seen in 88.2% of the HPE-positive results whereas abnormal colposcopy results was seen in 64.7% of HPE-positive results. The difference in the proportion of PAP and histopathology report and Colposcopy and histopathology report was statistically significant (P value <0.001)

Table 4: Comparison of PAP smear and colposcopy with HPE as gold standard among the study women (N=100).

Parameter	HPE		Chi-square	P value
	Positive (CIN)	Negative (No CIN)		
Abnormal PAP	15 (88.2%)	21 (25.3%)	24.256	<0.001
Abnormal Colposcopy	11 (64.7%)	2 (2.4%)	48.41	<0.001

Table 5: Predictive values of PAP smear and colposcopy compared to HPE as gold standard (N=100).

Diagnostic tests	PAP smear Value (95% CI)	Colposcopy Value (95% CI)
Sensitivity	88.2% (65%- 96%)	64.7% (41%- 82%)
Specificity	74.7% (64%-82%)	97.6% (91 – 99%)
False positive rate	25.3% (17%- 35%)	2.4% (0%- 08%)
False negative rate	11.8% (3%- 34%)	35.3% (17%- 58%)
Positive predictive value	41.7% (27%- 57%)	84.6% (57%- 95%)
Negative predictive value	96.9% (89%-99%)	93.1% (85%- 96%)
Diagnostic accuracy	77% (67%-84%)	92% (85%- 95%)

The PAP smear test had a sensitivity of 88.2% (65% - 96%), a specificity of 74.7% (64% -82%) and a diagnostic accuracy of 77% (67% -84%) in predicting histopathology examination reports. Similarly, the colposcopy test had a sensitivity of 64.7% (41% - 82%), a specificity of 97.6% (91 – 99%), and a diagnostic accuracy of 92% (85%- 95%) in predicting histopathology examination reports. (Table 5)

Discussion

According to the authors, this is the first study that compared the diagnostic accuracy of PAP Smear and Colposcopy in the evaluation of unhealthy cervix among women visiting their tertiary care centre. PAP smear showed a sensitivity of 88.2%, a specificity of 74.7%, and a diagnostic accuracy of 77% in predicting histopathologic examination findings. The colposcopy showed better specificity of 97.6% and a diagnostic accuracy of 92% in predicting histopathologic examination findings when compared to the PAP smear.

In the present study, the maximum number of women were in the age group of 40-49 years (39%) almost similar to a study by Goyal et al.¹⁵ where the mean age was 39.38 years.⁸ In the present study, white discharge was the most common complaint in 54% of the study women, which is in agreement with the study findings by Chaudhary RD et al.⁹ who reported 39% of rural women in India complained of white discharge. A maximum number of women on histopathological examination had chronic cervicitis (42%) and cervical Intraepithelial neoplasia I(CINI) in 8% of women, CIN II in 4% of women and CIN III in 5% of women. The findings were in comparison to a study by Joshi C et al.¹⁰ where a maximum number of women on histopathological examination had chronic cervicitis (48%) and CIN I in 28% women, and CIN II and CIN III were reported in 15%, and squamous cell carcinoma (SCC) and adenocarcinoma were reported 2% women, respectively.

As per colposcopy appearance in the present study, most of them (88%) had abnormal findings and only 12% showed normal mucosa. Prasad D et al.¹¹ among 150 symptomatic women and women with unhealthy cervix found 30.6% having abnormal

colposcopy findings which was in contrast to the present study. PAP smear showed a sensitivity of 88.2%, and a specificity of 74.7%, in the current study which was similar to the study of S. Amrita et al.¹² that reported sensitivity and specificity of PAP smear as 81.8% and 78.2% respectively. In contrast, T. S. Savitha et al.¹³ reported low sensitivity (50%) and high specificity (90%) of PAP smear.

When compared to PAP, colposcopy showed better specificity of 97.6% and diagnostic accuracy of 92% in predicting histopathologic examination findings in the present study. In contrast, the sensitivity and specificity of colposcopy in the detection of premalignant and malignant cervical lesions were 80.1 % and 72.2 %, respectively in a study by Meybodi NF et al.¹⁴ who compared the diagnostic accuracy of the triple test with that of colposcopy. Previous studies by Dawood R et al.¹⁵ have shown that combinations of tests are associated with higher sensitivity and specificity for the diagnosis of premalignant and malignant cervical lesions.

Given the high incidence of cervical cancer and the importance of prompt diagnosis and treatment, scientists have given substantial attention to the development of accurate and cost-effective methods for screening and diagnosing of this type of cancer.¹⁶ The diagnosis of cervical cancer becomes crucial, as with late diagnosis and treatment, the number of patients who face the long-term consequences of cervical cancer increases.¹⁷ The present study showed the diagnostic accuracy of PAP smear and colposcopy in the detection of the unhealthy cervix and suggested that combined tests (PAP smear + colposcopy) may be more reliable and suitable screening test in low-income countries.

Limitations

The screening test was applied only to a population of symptomatic women visiting a single hospital due to which the results cannot be generalized to the entire community thus compromising external validity. There was no comparative group or controls to further validate the findings of the present study affecting its internal validity. Also, a PAP smear

is a subjective test, and also there may be a sampling error, an error of fixation, error of interpretation. Hence, multicentric randomized controlled trials, with large populations and with the same disease prevalence are recommended to support the findings of the present study.

Conclusion

PAP smear had higher sensitivity and lower specificity, when compared to colposcopy and is ideal as an initial screening tool at the primary level. The colposcopy showed better specificity and diagnostic accuracy in predicting histopathologic examination findings when compared to the PAP smear. Subjecting the abnormal PAP smear- cases to subsequent colposcopy can increase the overall specificity and increases diagnostic accuracy. The simultaneous usage of PAP smear and colposcopy may be reliable and complementary to each other to screen women having unusual symptoms for diagnosing premalignant lesions. Colposcopy, however, surpass the requirement for continued follow-up as in PAP smear. Nevertheless, histopathological examination of the suspected lesion remains the gold standard for the final diagnosis of these precancerous lesions. The best result in early detection of the unhealthy cervix could be obtained by combined use of PAP smear and colposcopy-directed biopsy in low-income countries and should be carried out in all women of reproductive and menopausal age groups at least once in a lifetime.

Acknowledgements

We acknowledge the technical support in data entry, analysis and manuscript editing by "Evidencian Research Associates."

Conflict of Interest: None

Source of Funding: None

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