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Cross Sectional Study to Determine Association Between Abnormal Cervix on Colposcopy and Histopathology

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ABSTRACT

Cervical cancer is the most frequent genital tract cancer among Indian women. Colposcopy has proven to be a much better screening method for premalignant lesions because it yields faster results, directs the site of biopsy and can be completed in one visit.To critically evaluate the role of colposcopy in women with abnormal looking cervix as a screening and diagnostic tool for cervical cancer by comparing it with pap smear and histopathology wherever indicated.Total 132 women with the clinically unhealthy cervix and with abnormal symptoms were included. Detailed clinical examination was done. Pap smear results were interpreted as per Bethesda classification and Colposcopy findings as per the IFCPC criteria. Women with abnormal pap smear and normal pap smear but unhealthy looking cervix, were subjected to colposcopy. In case of abnormal colposcopy, biopsy was taken. Also cases where Pap smear and colposcopy results were incongruent, biopsy was taken. For colposcopy against histopathology the sensitivity was 90% with specificity of 42.86%. The positive and negative predictive values were 69.23-75%, with accuracy of 70.5%.For PAP smear against histopathology the sensitivity was 90.4% with specificity of 33.3%. The positive and negative predictive values were 65.51-71.42%, with accuracy of 66.67%. When findings of PAP smear and colposcopy were compared, there was fair agreement between the findings of PAP smear and histopathology findings, with Kappa value of 0.2 and p value of 0.000538 and chi-square statistics with yates' correction is 10.6819 and p-value is 0.001 (significant). Present study concludes sequential screening is needed for diagnosing cervical precancerous lesions. Sensitivity and specificity of pap smear and colposcopy in our study are at par. They complement each other as specificity is not so high.

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Key Words
Precancerous lesions, cancer cervix, colposcopy, histopathology, pap smear

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INTRODUCTION

Cervical cancer incidence was 6.9 % in 2020. Over 604,127 new cases were identified in the year 2020 and more than 3,41,831 women passed away from it. (Cancer, 2020) This disease disproportionately affects the world's poorest areas[1,2].

WHO considers cervical cancer a preventable disease as it is possible to detect it in precancerous stages due to its protracted pre-invasive disease phase that progresses from cellular atypia to different grades of dysplasia (Cervical Intraepithelial Neoplasia- CIN) and finally into invasive cancer[3].

Effective screening programs can be designed due to factors like easy accessibility of the cervix for clinical examination the propensity of epithelial cells to exfoliate the rapid turnover of epithelial cells the wide spectrum of histopathological changes and the prolonged natural history of the disease[4].

The most commonly used screening tests for cancer cervix are Pap Smear, HPV DNA detection, Visual inspection with acetic acid (VIA), and Visual inspection with Lugol's iodine (VILI). Colposcopy is a screening procedure widely used to assess for vaginal, vulvar and cervical dysplasia as a crucial interim step in cases of abnormal screening tests[5-7] .

In India, these tests are done as opportunistic screening when women present to hospital with complaints of foul-smelling discharge per vaginum, lower abdominal pain, vaginal pruritus, dyspareunia, abnormal bleeding and post-coital and intermenstrual bleeding amongst others. Successful implementation of cervical cancer prevention programs requires good linkages between screening and treatment. For low-resource settings single visit approach is recommended for maximum coverage of the population for screening.

In cytology-based programs, studies have shown that when a low-grade lesion is detected on a Pap smear, if immediate colposcopy is offered there are significantly higher detection rates of CIN3+ as compared to the repeat cytology approach (30.9 vs. 17%, RR: 1.80, (1.11-2.92)[8].

Colposcopy has proven to be a much better screening method for premalignant lesions because it yields faster results and directs the site of biopsy, which can be completed in one visit. At our center, in house HPV testing facility is not available. There is a well-established colposcopy unit and the test is offered at a very low cost. So this study was undertaken to critically evaluate the role of colposcopy in women with abnormal looking cervix as a screening and diagnostic tool for cervical cancer.

MATERIALS AND METHODS

The study was conducted in the department of obstetrics and gynecology at the tertiary care center. It was approved by Institutional Ethics Committee. It is a cross-sectional observational study done during the period from September 2020 to September 2022 after matching the inclusion and exclusion criteria. One hundred thirty two sexually active women between the age of 21-65 years with abnormal Pap smear, or clinically unhealthy cervix were included. Women with frank invasive cancer, those who underwent a hysterectomy or pregnancy were excluded. After obtaining proper informed written consent, a thorough history according to predetermined proforma was taken and detailed clinical evaluation done. Colposcopy was done with BORZE digital colposcope. Targeted biopsies were performed on abnormal areas, and histopathology was used to confirm cytological abnormality. The collected data was coded and entered into Microsoft Excel Sheet and analyzed using SPSS (Statistical Package for Social Sciences) version 20.0 software. The chi-square test was used for the comparison of variables used in the study.

RESULTS

Out of total 132 women, 51.51% were in the age group of 36-50 years. Almost all were symptomatic-95.5% .The most common symptoms seen were pv white discharge (41.7%), vaginal pruritus (40.2%), lower abdominal pain (30.3%) and abnormal pv bleeding (25.8%).The per-speculum findings were congestion (40.9%), cervicitis (18.18%), ectopy (15.9%), ulcer (4.54%) and hypertrophy (4.54%).Pap smear findings were normal i.e. NILM in 83 (62.8%), abnormal i.e. ASCUS 17(12.8%), LSIL 20 (15.15%), HSIL 10(7.57%), Squamous cell carcinoma 1(0.75%), Suspicious for adenocarcinoma 1(0.75%).Colposcopy was normal in 78(59.09%), abnormal i.e. minor lesions seen in 42 (31.81%) and major lesion in 2 (1.5%). 3 (2.27%) colposcopies were inadequate.

Histopathology was normal(benign) i.e. chronic cervicitis in 15 (41.66%), abnormal i.e CIN I-13 (36.1%), CIN II-5 (13.9%), CIN III-1 (2.8%), SCC-2 (5.6%).Thirty six out of 132 underwent histopathology.

For PAP smear when compared with histopathology as gold standard the sensitivity was 90.4% with specificity of 33.33%. The positive and negative predictive values were 65.51 % and 71.42 %, with accuracy of 66.67%. For colposcopy the sensitivity was 90 % with specificity of 42.86 %. The positive and negative predictive values were 69.23-75%, with accuracy of 70.5%. When findings of PAP smear and colposcopy were compared, there was fair agreement between the findings of PAP smear andcolposcopy, with Kappa value of 0.2 and p-value of 0.000538 and chi-square statistics and p>0.001 (significant).

DISCUSSIONS

In this comprehensive study we explored the possibility of using Colposcopy as a screening and diagnostic tool for cervical pre-cancerous lesions in

Table 1: Correlation between pap smear and Histopathological diagnosis

	CC	CIN I	CIN II	CIN III	CIS	SCC	AdenoCA	Total
ASCUS	02	01	01	00	00	00	00	04
NILM	07	02	00	00	00	00	00	09
LSIL	03	07	03	00	00	00	00	13
HSIL	02	03	01	00	00	02	00	06
SCC	00	00	00	01	00	00	00	01
Suspicious for AdenoCA	01	00	00	00	00	00	00	01
Total	15	13	05	01	00	02	00	36

Table 2: Correlation between colposcopy vs Histopathological diagnosis

Colposcopy(IFCPC)	CC	CIN I	CIN II	CIN III	CIS	SCC	AdenoCA	Total
Normal	06	01	00	01	00	00	00	08
Abnormal(Minor lesion)	08	12	04	00	00	00	00	24
Abnormal(Major lesion)	00	00	01	00	00	01	00	02
Abnormal(Nonspecific findings)	00	00	00	00	00	00	00	00
Suspicious for invasion	00	00	00	00	00	00	00	00
Miscellaneous	00	00	00	00	00			

Table 3: Correlation between pap smear and colposcopy

	Normal	Abnormal(Minor)	Abnormal(Major)	Abnormal(Nonspecific)	Suspicious for invasion	Miscellaneous	Inadequate	Total
ASCUS	10	04	01	01	00	00	01	17
NILM	57	19	00	01	00	05	01	83
LSIL	08	12	00	00	00	00	00	20
HSIL	02	06	01	00	00	00	01	10
SCC	01	00	00	00	00	00	00	01
Suspicious for AdenoCA	00	01	00	00	00	00	00	01
Total	78	42	2	2 0	5	3	132	

Table 4: Agreement between PAP smear and colposcopy

	Abnormal Pap smear	Normal pap smear	Total
Abnormal colposcopy	25	19	44
Normal colposcopy	22	63	85
Total	47	82	129

abnormal looking cervix . The currently recommended screening guidelines as per ACOG and Uspstf suggest screening to begin from 21 years till 65 years age Cytology alone, primary HPV testing and CO testing with both modalities are recommended screening methods. The current WHO screening strategy in low resource settings recommends Screen and treat OR Screen, triage and treat strategy. In affordable settings HPV DNA from the age of 30 as a primary screening test is recommended. In Western countries, primary screening with hrHPV(16/18) has become the mode of screening. While these countries have designed screening programs based on self-sampling, we are still struggling to offer population wide screening. In our country cervical cancer screening remains an opportunistic screening.

In our study the mean age of participants was 40.5 years. Majority of these women were married at early age and multiparous. None of these women had undergone any screening test for precancerous cervical lesions previously. The most common symptoms in our study were white discharge, followed by vaginal pruritus and abdominal pain which were in sync with previous studies.

The per speculum findings of our study corresponded to study by Kalyankar *et al*.[5] bulky cervix, erosion, both bulky cervix and erosion, ectopy, congested cervix. The most accessible, practical and economical method for detecting premalignant and malignant cervix lesions remains Pap smear. A variety of studies using the same method of interpretation have reported pap smear accuracy to range from 53-78 percent which was similar to our study-66.67%[11-13]. As Pap smear needs at least two visits to the Hospital and subsequent follow up for abnormal report. Though Colposcopy is considered as costly and scarcely available screening test to confirm abnormal pap smears[14] single visit approach turns out to be cost equalizer hence, we evaluated the role of direct colposcopy in abnormal looking cervix.

In the Prasad *et al*.[9] study, a higher incidence of normal colposcopies was observed among individuals with abnormal pap smears. In our current investigation, colposcopy results indicated normal findings in 78 (59.09%) patients and abnormal findings in 44 out of 132 patients. Among the remaining 10 patients, 3 had inadequate colposcopies, 2 (1.5%) showed nonspecific findings, and 5 (3.78%) exhibited miscellaneous findings. Minor lesions were identified in 42 (31.81%) patients, while 2 (1.5%) had major lesions. Among the 24 patients with abnormal minor lesions on colposcopy, 12 (50%) had CINI, and 4 (16%) had CIN II. The 2 patients with abnormal major lesions on colposcopy included one with CIN III and one with SCC. Histopathology serves as the gold standard for detecting premalignant and malignant cervical lesions. In our study, patients with significant colposcopy-detected lesions and discrepancies between pap smear and colposcopy were advised excisional biopsy via the Loop electrode. A total of 36 patients underwent biopsy, with 21 (58.33%) showing abnormal findings and 15 (41.66%) displaying normal results.

When the results of sequential tests i.e. Pap Smear, Colposcopy and histopathology were correlated

following outcomes were noted Out of 83 patients having normal pap smear findings i.e NILM/NILM with inflammation, colposcopy showed normal finding in 57 patients, Minor lesion in 19 patients, 5 had miscellaneous findings,1 had leukoplakia and one colposcopy was inadequate due to type 3 transformation zone. 4 patients with colposcopy suspected minor lesions underwent biopsy. Though minor lesion does not need immediate biopsy as per guidelines, as these patients were not ready for follow up, biopsy was offered. Amongst them 2 patients had CIN I and the other two were normal showing chronic cervicitis.

There were 49 patients having abnormal pap smear findings ASCUS(17), LSIL(20),HSIL(10), SCC(1), Suspicious of adenocarcinoma[1]. Out the 17 patients with ASCUS, 10 patients had normal colposcopy findings and 4 patients had minor lesion. 1 patient had major lesion ,1 was non specific and 1 was inadequate colposcopy .The patient having ASCUS with inadequate colposcopy underwent biopsy which showed chronic cervicitis. Out of the 20 patients with LSIL, 8 patients had normal colposcopy, 12 patients had minor lesions. Amongst the 10 patients with HSIL, 2 cases had normal colposcopy and 6 had minor lesions. Only 1 patient was reported to have major lesion.

In patient suspected to have SCC on pap smear, there was no visible lesion on colposcopy. In patient with pap smear showing suspicious for adenocarcinoma, Colposcopy showed minor lesion. In both these patients biopsy with ECC was advised. When the findings of PAP smear and colposcopy were compared statistically, there was the fair agreement between the findings of PAP smear and colposcopy, and the agreement was significant (p = 0.001) and there was an agreement of 66.67% between the two methods.

This was in contrast to study by Prasad *et al*.[9] where the two methods had a poor agreement and thus complemented each other. We advised histopathology in patients with abnormal pap smear beyond LSIL and colposcopy with major lesions/inadequate colposcopy. Total 36 patients underwent biopsy.

Out of 15 cases having chronic cervicitis, Pap smear showed low grade lesion (LSIL,ASCUS) in 5 and high grade lesion (HSIL/SCC/Suspicious for adenocarcinoma) in 3 cases, Colposcopy showed normal findings in 6 cases and minor lesions in 9 cases. Out of 13 patients with CIN I, Pap smear showed low grade lesion in 8 cases and high grade in 3 cases, Colposcopy showed normal in 1 case and 12 had minor lesions.

Out of 5 patients with CIN-II , pap smear showed low grade lesion in 4 cases and high grade lesion in 1 case, Colposcopy showed minor lesion in 4 cases and major lesion in 1 patient. In one patient with CIN III, pap smear was reported as SCC colposcopy did not detect any lesion. And out of 2 patients with SCC on histopathology both had high grade lesion(HSIL) in pap smear; corresponding colposcopies were 1 major and 1 was inadequate.

Whenever there is discrepancy between 2 tests pap smear and colposcopy it is advisable to do biopsy from multiple sites on cervix. For the PAP smear the sensitivity was 90.4% with a specificity of 33.3%. The positive and negative predictive values were 65.51% and 71.42%, with an accuracy of 66.67%. The false positive rate for pap smear was 34.4% and false negative were 28.7%.

According to Kalyankar *et al*.[5] the PAP smear's sensitivity and specificity for diagnosing CIN were 26.66 percent and 80 percent, respectively. Its positive predictive value was 85.71 percent, its negative predictive value was 19.51 percent and its accuracy was 36.36 percent. In diagnosing precancerous lesions of cervix, colposcopy has shown 90% sensitivity and 42.86% specificity. The positive and negative predictive values of colposcopy were 69.23-75%, with an accuracy of 70.5%.

While the specificity of our study was lower the sensitivity was comparable to Prasad *et al*.[9] and Kalyankar[5].In contrast ,Vijay *et al*.[10] reported lower sensitivity (40%) and higher specificity (84%) with positive and negative predictive values of 71% and 58%, respectively. Inconsistencies between the severity of premalignant lesions and the visible changes in the cervical epithelium lead to accuracy problems. According to reports, high-grade CIN 2 or worse has a diagnostic sensitivity of between 30 and 70 percent. It has been suggested that increasing the number of biopsies and performing random biopsies on areas devoid of disease-related symptoms will improve the diagnostic accuracy. In high-grade lesions, colposcopic accuracy is strongly correlated with high sensitivity, but in low-grade lesions, this correlation is much weaker[15-17]. A Pap smear test can detect early cervical epithelial changes even though it is less sensitive. At affordable costs, screening with HPV and Pap tests every two years seems to add years to life. In contrast, a colposcopy can occasionally be uncomfortable and painful[18].

Colposcopy is a crucial component of cervical cancer prevention. Over the past 50 years, colposcopy has been instrumental in lowering the incidence and mortality of cervical cancer along with precancer screening and treatment. Colposcopy has a crucial role in the prevention of cervical cancer but its accuracy and reproducibility are limited[19,20]. Although colposcopy has unquestionably aided in the treatment of cervical cancer, there is ongoing debate over its diagnostic efficacy.

CONCLUSION

Our study highlights the need for robust screening program for cancer cervix. Mean age of our patients is 40 years. Most of the patients were married at early age, still had not undergone a single screening test. This calls attention to the need for increasing public awareness about cervical cancer screening. Sequential screening is needed for diagnosing cervical precancerous lesions. Sensitivity and specificity of pap smear and colposcopy in our study are at par. They complement each other as specificity is not so high. In abnormal looking cervix , if follow-up is the issue, we can offer colposcopy and biopsy at the same sitting. Overdiagnosis is an acceptable trade off as the prevalence of cancer cervix is high in our country.

Limitations of our study: Sample size of the study was less. It was a hospital based opportunistic screening. Population based study, with biopsy offered in every case will address these issues.

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