

Colposcopic evaluation of cervix in symptomatic women and its correlation with Pap smear. A prospective study at a tertiary care centre

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ABSTRACT

Introduction: Back in India, cervical cancer is the second most frequent cancer in women (aged 15–45 years) following breast cancer, accounting for nearly 14% of all female cancer cases. The aim of this study is to yell the findings of pap smear with colposcopy and directed biopsy (if needed) and to evaluate the usefulness of colposcopy in discovering the premalignant and malignant lesions of the cervix. **Methods:** This is a prospective observational analysis of 150 symptomatic women attending the gynecology OPD of Indira Gandhi Institute of Medical Sciences, Patna, for a period of one year from 2019 to 2020. Assessment of symptomatic women was completed with a pap smear, colposcopy, and biopsy in selected instances. **Statistical Analysis Used:** MS Excel spreadsheet application, SPSS v23 (IBM Corp.), was used for data analysis. **Results:** The expression age (years) has been 34.68 ± 8.05 . The sensitivity and specificity of pap smear were 91.7% and 45.45%, respectively, whereas the sensitivity and specificity of colposcopy were 83.3% and 72.72%, respectively, in the present study. **Conclusions:** Pap smear had low specificity as compared to colposcopy. Hence simultaneous use of colposcopy has shown to rise in the rate of carcinoma cervix discovery in symptomatic women.

Keywords: Abnormal cervix, cervical biopsy, colposcopy, pap smear

Introduction

In India, cervical cancer is the 2nd most frequent cancer in women (aged 15–44 years) after breast cancer accounting for nearly 14% of female cancer cases.^[1] According to GLOBOCAN, India bears 18% of a load of invasive cancer in the world, and 80–85% of cases are found in phase III/IV.^[2] The initiating cervical dysplasia in the majority of patients regresses back, but within a period of 10 to 20 years, it has got the capacity to convert to cervical cancer. Cervical dysplasia, also called cervical

intraepithelial neoplasia (CIN), frequently arises in a place of metaplasia in the transformation zone in the progressing squamocolumnar junction. Cervical dysplasia is a precursor of cervical cancer, but it's a treatable illness.

Carcinoma cervix is a disease that can be prevented through early detection (because it has a very long pre-invasive stage) along with access to screening tests. The price for HPV testing in the Indian situation is restrictive now, and other screening modalities need to be appropriately used.

Because of the high false-negative rate of pap smear, premalignant lesion of the cervix can be missed in women with inflammatory pap smear findings. The Papanicolaou (Pap) smear is an Easy, secure, non-invasive, and effective way for

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the detection of precancerous, cancerous, and non-cancerous changes in the cervix.

Colposcopy is a globally accepted method for detection of early carcinoma Cervix, because it provides quicker results and guides the site of biopsy, which could be done in one visit, demonstrating itself as a much better screening modality for a premalignant lesion. At a meta-analysis, the diagnostic precision of colposcopy had a sensitivity from 29% to 100% and specificity from 12% to 88%.^[3] The current study was, therefore, done to appraise the function of colposcopy as a diagnostic and screening tool for cervical cancer and other cervical lesions in high-risk women.

Aim and Objective

The aim of the study was to do a colposcopic evaluation of all cervical lesions and the early detection of all cervical precancer and invasive lesions of the cervix in symptomatic women.

The objectives of this study were:

- (1) Screening of all symptomatic women with pap smear test
- (2) Colposcopy findings were compared with cytology and histopathological examination.

Methods

The study was performed on patients attending the gynecological OPD of IGIMS, Patna. A total of 150 married women were recruited within a span of 12 months from 2019 to 2020. Whether an abnormal pap test was found, afterward, it had been followed by colposcopy, and also colposcopy directed biopsy was done once indicated depending on abnormal colposcopy findings.

The study was done after clearance from the Institutional Ethics committee as per the letter No. 1040/IEC/IGIMS/2019.

Inclusion criteria

- Age- >20–60 years.
- Women with symptoms such as white discharge, post-coital bleeding, and intermenstrual bleeding.
- Women with the clinically unhealthy cervix (erosion, bleeding on touch, simple leukoplakia, keratinization)
- Women with Pap smear showing dysplasia.

Exclusion criteria

- Women with bleeding per vaginum.
- Women who had been previously treated for carcinoma cervix.
- Women who underwent a hysterectomy.
- Pregnant women.

Procedure

Informed consent was taken from patients fulfilling the inclusion criteria. Pap smear results were correlated with colposcopy.

A thorough history of the patient was taken, and per speculum examination has been performed in all symptomatic patients. Bethesda classification system of pap-smear was used to analyze the exact results. They were classified as ASCUS, ASC-H, LSIL, HSIL, and invasive carcinoma. Subsequently, the women have been exposed to Colposcopy examination--system details including ASCON version AC3-2000SN having a green filter using ELMOCCD, television camera along with CTV display, focal length 250 mm and magnification 7.5 X - 10 X and also a functional distance of 25 cm.

In the event the complete transformation zone wasn't visualized, colposcopy was named as "Unsatisfactory." The green filter has been utilized to examine vessels. Acetic acid (5%) and Lugol's iodine had been used. Abnormal Colposcopy findings, for example, aceto-white region and abnormal staining regions, were evaluated by Modified Reid's indicator.

A cervical biopsy has been performed from the suspected lesion in women with the disproportionately abnormal-looking cervix and corresponding abnormal colposcopy findings. A tiny part of an abnormal area on the surface of the cervix has been eliminated for histopathology (in 10% formalin solution).

Statistical analysis

Data were coded and listed from the MS Excel spreadsheet application. SPSS v23 (IBM Corp.) was used for data analysis. Group comparisons for continuously distributed data were created using a separate sample 't' evaluation when you compare two groups. A Chi-squared evaluation was employed for group comparisons to categorical data. In an event where the estimated prevalence in the contingency tables has been found to be < 5 for >25% of these cells, then Fisher's Exact Test was used alternatively. The statistical value was retained at $P < 0.05$.

Results

Most of the variables were not significantly associated ($p < 0.05$) with the variable 'Biopsy Impression.'

Pie chart showed 30.6% symptomatic women with abnormal colposcopy finding, 15.3% of women had acetowhite lesion, 6%

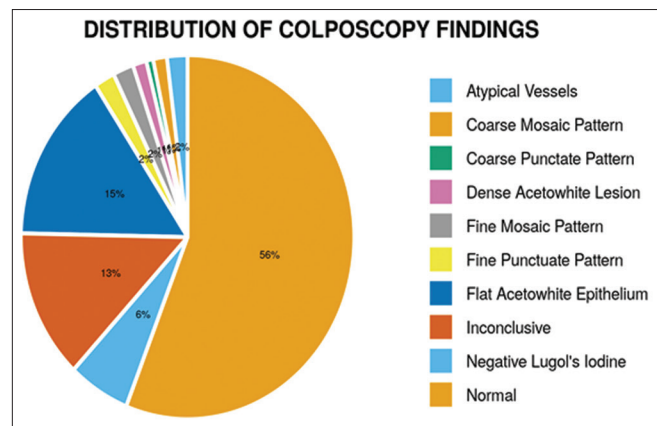


Table 1: Demographic Profile of Study Populations

Parameters	Biopsy Impression		P
	Invasive Lesion Absent (n=11)	Invasive Lesion Present (n=12)	
	Education		
Illiterate	3 (100.0%)	0 (0.0%)*	
Literate	8 (40.0%)	12 (60.0%)	
Residence***			0.0051
Rural	6 (100.0%)	0 (0.0%)*	
Urban	5 (29.4%)	12 (70.6%)	
Presenting Complaint			0.0891
Intermenstrual Bleeding	0 (0.0%)	3 (100.0%)	
Itching Vulva	1 (50.0%)	1 (50.0%)	
Menorrhagia	1 (100.0%)	0 (0.0%)	
Pelvic Pain	5 (83.3%)	1 (16.7%)	
Postcoital Bleeding	0 (0.0%)	2 (100.0%)	
White Discharge	4 (44.4%)	5 (55.6%)	
Age (Years)	40.36±5.03	38.17±6.93	0.5162
Age			1.0001
<20 Years	0 (nan%)	0 (nan%)	
20-29 Years	1 (33.3%)	2 (66.7%)	
30-39 Years	3 (60.0%)	2 (40.0%)	
40-49 Years	7 (46.7%)	8 (53.3%)	
Parity Group			1.0001
P0/P1	0 (0.0%)	1 (100.0%)	
P2	1 (33.3%)	2 (66.7%)	
≥P3	10 (52.6%)	9 (47.4%)	
P/S Examination			0.0701
Cervical Erosion	2 (25.0%)	6 (75.0%)	
Discharge++	5 (45.5%)	6 (54.5%)	
Smooth Cervix	4 (100.0%)	0 (0.0%)	

*Reason for this might be the patients coming to our hospital were mostly literate and belonged to the urban class. ***Significant at P<0.05, 1: Fisher's Exact Test, 2: Wilcoxon Test

Table 2: Comparison of PAP smear impression with colposcopy impression (n=150)

	Colposcopy Impression			Cohen's Kappa	
	Normal	Abnormal	Total	K	P
PAP Smear impression					
Normal	23 (15.3%)	9 (6.0%)	32 (21.3%)	0.018	0.725
Abnormal	81 (54.0%)	37 (24.7%)	118 (78.7%)		
Total	104 (69.3%)	46 (30.7%)	150 (100.0%)		

The green cells on the diagonal represent cases where both the methods agreed. The red shaded cells represent cases where the two methods disagreed

Table 3: Association between biopsy and PAP smear (n=23)

PAP Smear	Biopsy Impression		Total	Fisher's Exact Test	
	Invasive Lesion Absent	Invasive Lesion Present		X ²	P
	Normal	4 (80.0%)		1 (20%)	5 (100.0%)
Abnormal	7 (38.9%)	11 (61.1%)	18 (100.0%)		
Total	11 (47.8%)	12 (52.2%)	23 (100.0%)		

Fisher's exact test was used to explore the association between 'Biopsy Impression' and 'PAP Smear'. There was a significant relationship between the Pap smear and of Biopsy Impression (X²=6.970, P=0.03)

women had negative Lugol's iodine, 2% had atypical vessel, 2% had fine mosaic, 1.3% had coarse mosaic lesion, 2% had subtle punctate lesion, 0.8% had coarse punctate lesion and 1.3% had dense acetowhite lesion:

Table 1 shows that the mean Age in (Years) was 34.68 ± 8.05. The most typical complaint was white discharge (50%) followed by pelvic pain (20%) amongst all symptomatic women. In our study, 60% of women were multiparous.

Table 2 shows comparison of Pap smear impression with Colposcopic impression. In this table we can see that out of total normal, 32 pap smear findings; 23 came out to be normal and 9 abnormal on Colposcopic finding. And out of 118, abnormal pap smear findings; 81 came out to be normal and 37 came out to be abnormal on Colposcopic findings. The two methods agreed in 40.0% of the cases and disagreed in 60.0% of the cases. There was Poor agreement between the two methods, and this agreement was not statistically significant (Cohen's Kappa = 0.018, P = 0.725). Thus, the two tests are complementary.

The two methods agreed in 40.0% of the cases and disagreed in 60.0% of the cases.

There was Poor agreement between the two methods, and this agreement was not statistically significant (Cohen's Kappa = 0.018, P = 0.725). Thus the two tests are complementary.

Table 3 shows association between biopsy impression and pap smear impression. Out of 5 normal pap smear findings, biopsy findings show no invasive lesion in 4 patients and presence of invasive lesion in 1 patient. Out of 18 abnormal pap smear findings, 7 patients had no invasive lesion and 11 patient showed presence of invasive lesion on biopsy. The association was statistically significant P = 0.03%.

Table 4 shows association between biopsy and colposcopy. Out of 10 normal Colposcopic findings, 8 patients had no invasive lesions & 2 patients had presence of invasive lesion on biopsy. Out of 13 abnormal Colposcopic findings, 3 patients had no invasive lesion and 10 patients had invasive lesion on biopsy. The association between these two was statistically insignificant P = .022.

Discussion

Cervical cancer screening was proved to be an essential part of the preventive health care of women. Routine screening with pap smear has a high false-negative rate from 1.8 to 20%. Colposcopy has the ability to localize and determine the extent of all lesions not seen on the naked eye and are detected in a single sitting. Colposcopy helps in selecting the site of biopsy and patients for the conservative treatment of CIN.

In the present study, the most typical complaint was white discharge (50%) followed by pelvic pain (20%) amongst all

Table 4: Association Between Biopsy and Colposcopy (n=23)

Colposcopy	Biopsy		Total	Fisher's Exact Test	
	Invasive Lesion Absent	Invasive Lesion Present		X ²	P
Normal	8 (66.7%)	2 (33.3%)	10 (100.0%)	5.24	0.022
Abnormal	3 (41.2%)	10 (58.8%)	13 (100.0%)		

Fisher's exact test was used to explore the association between 'Biopsy Impression' and colposcopy. There was a significant relation between colposcopy and Biopsy Impression (X²=5.24, P=0.022)

Table 5: Comparison of the sensitivity of Pap smear with different studies

Different studies	Sensitivity	Specificity
Present study	91.7%	45.45%
S. Amrita <i>et al.</i> ^[7]	81.8%	78.2%
Manizheh Sayyah-Melli ^[8]	77.4%	69.7%
T.S Savitha <i>et al.</i> ^[9]	50%	90%

Table 6: Comparison of sensitivity and specificity of colposcopy with different studies

Different studies	Sensitivity	Specificity
Present study	83.3	72.7%
Ramesh G <i>et al.</i> ^[10]	83.33	46.42%
Kalyankar Vijay Y <i>et al.</i>	90%	76.92%
Chaudhary RD <i>et al.</i> ^[11]	79.37%	81.02%
Süleyman Cemil Oğlak1 <i>et al.</i> ^[12]	85.7%	76.2%

symptomatic women, 12.7% had complaints of intermenstrual bleeding, 8.7% had menorrhagia, 04% had post-coital bleeding, and the rest 4.6% had complaint of itching vulva.

Garg R *et al.*, in his study on sequential screening with cytology and colposcopy in the detection of cervical neoplasia on 200 symptomatic women and women with an unhealthy cervix, also observed similar results with white discharge being the most common complaint, i.e., 58.5%.^[4]

The present study on 150 symptomatic women and women with unhealthy cervix sequential screening with cytology and colposcopy shows that 30.6% had abnormal colposcopy findings.

Malur PR *et al.* in his study on sequential screening with cytology and colposcopy in the detection of cervical neoplasia on 190 symptomatic women and women with unhealthy cervix reported positive colposcopy in 37.89% cases.^[5]

In the present study, among 30.6% symptomatic women with abnormal colposcopy finding, (15.3%) women had acetowhite lesions, 6% women had negative Lugol's iodine, 2% had atypical vessels, 2% had fine mosaic, 1.3% had coarse mosaic, 2% had subtle punctate lesions, 0.6% had coarse punctate lesions, 1.3% had dense acetowhite lesions.

Aceto-white staining was the most common finding as it is very non-specific and may also found in flat condyloma, immature squamous metaplasia, the congenital transformation zone, inflammation, and healing and regenerative epithelium. So women with these findings need further follow up. Bhalero *et al.* also reported aceto-whiteness in 42.5% as the most common colposcopy feature in his study.^[6]

A biopsy was performed in 23 cases, which were selected on the basis of clinical or colposcopy findings. The biopsy was not done in women with insignificant colposcopy lesions. Among biopsies performed in 23 such cases, 11 women (47.8% of all biopsies) had chronic non-specific cervicitis, (21.7%) had mild dysplasia, (13.4%) had moderate dysplasia, women (8.6%) had severe dysplasia, and 8.6% had non-keratinizing squamous cell carcinoma.

Correlative study of histopathology and cytology shows that pap smear has significant sensitivity of 91.7%. The possible reason for this might be because it was a hospital-based study and not a community-based study, and the screening test was applied to a population of symptomatic women. Pap smear is a subjective test, and also there may be a sampling error, an error of fixation, error of interpretation. So false positive is more, and thus a fewer case of the disease was missed. All symptomatic women with smear-positive should be further evaluated by colposcopy and histopathology if needed.

Correlative study of histopathology and colposcopy shows that the latter is making the sensitivity of the test as 83.3%, which is less than as compared to cytology. Out of 10 normal Colposcopic findings, 8 patients had no invasive lesions & 2 patients had presence of invasive lesion on biopsy which shows that colposcopy overestimated the cervical lesions, which is a most common drawback of colposcopy as the majority of these lesions regress spontaneously over time and during follow up or after treatment.

This study suggests that colposcopy is sensitive (83.3%) and specific (72.2%). However, a pap smear is more sensitive (91.7%) than colposcopy but lesser specificity (45.5%). Table 5 compares the sensitivity and specificity of pap smear with different studies. S. Amrita *et al.* had sensitivity and specificity of 81.8% and 78.2% respectively; Manizheh Sayyah-Melli *et al.* had sensitivity (77.4%) and specificity (69.7%) while T. S. Savitha *et al.* had low sensitivity (50%) and high specificity (90%). Table 6 compares the sensitivity and specificity of colposcopy with different studies. Present study had sensitivity (83.3%) and specificity (72.2%). Ramesh G *et al.* shows similar sensitivity but lower specificity (46.4%). Kalyankar Vijay *et al.* had sensitivity (90%) and specificity (76.92%); Chaudhary RD *et al.* had sensitivity (79.37%) and specificity (81.02%); Suleyman Cemil Oglak1 *et al.* showed a sensitivity (85.7%) and specificity (76.2%) which was similar to our study. There is a strong correlation between findings of Pap smear and histopathology and between colposcopy and histopathology.

Therefore, Pap smear, colposcopy, and directed cervical biopsy together are useful and complementary in arriving at a correct diagnosis. It is not possible to screen every woman with cytology and colposcopy, so both tests should be performed in women presenting with symptoms. The differences in the sensitivity and specificity of different studies are due to differences in laboratory values and the availability of trained personal.

Real-time use of pap smear and colposcopy enhance the rate of carcinoma cervix detection in symptomatic women by the primary physician.

Conclusion

Colposcopy was found helpful in understanding the morphology of the cervical lesions, be it the neoplastic or the non-neoplastic ones, which was very valuable in planning their management. Cytology can be an acknowledged procedure of screening for cervical neoplasia, and that the worth of colposcopy was known mainly from the evaluation of patients with abnormal cervical smears.

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, removes the requirement for continued follow-up as in pap-smear. Nevertheless, histopathology of the suspected lesion remains the gold standard for the final diagnosis of these precancerous lesions.

Hence utilization of a single-visit way by which cytology, colposcopy, and directed biopsy each is done at one single sitting and treated thus in over-burden tertiary care centre including ours that aids in early identification and treatment of precancerous lesions of the cervix.

Declaration of patient Consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Key Message

Till now Pap smear was thought to detect pre- invasive lesion at early stage but now it is evident that Pap smear and colposcopy are complementary to each other in early detection of Pre-invasive lesion and these helps in reducing morbidity and mortality due to carcinoma cervix.

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Conflicts of interest

There are no conflicts of interest.

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