

ORIGINAL RESEARCH

Colposcopic evaluation and management of unhealthy cervix at tertiary care center

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ABSTRACT

Aims and objectives: The present study was aimed to assess the sensitivity, specificity and predictive value of colposcopy as tool for early detection of premalignant lesions in unhealthy cervix at a tertiary care center, catering to both rural and urban population.

Material and methods: The study is a prospective study comparing Pap smear and colposcopy for early diagnosis of cervical cancer, spans over one and a half year and was carried out in the Department of Obstetrics and gynecology, Mahatma Gandhi Medical College & Hospital, Jaipur.

Results: For PAP, the calculated Sensitivity was 37.93% and the Specificity was 95.04%. The Positive predictive value was 64.71% and Negative predictive value was 86.47%.

For colonoscopy, the calculated Sensitivity was 87.93% and the Specificity was 77.69%. The Positive predictive value was 48.57% and Negative predictive value was 96.41%.

Discussion: Colposcopy was found to be useful in understanding the morphology of the cervical lesions, both of the neoplastic and the non-neo-plastic ones and this was very helpful in planning their management.

Keywords: Colposcopic, Cervix, PAP

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INTRODUCTION

Cervical cancer is the most common cause of death among women in developing countries despite the fact that this has been declared by WHO as a preventable cancer. Cervical cancer is the commonest genital malignancy found amongst Indian women and the 3rd most common cancer in the world. In India, 132,000 new cases diagnosed and 74,000 deaths occur annually¹. The incidence rises at 30-34 year of age and peaks at 55-65 year with a median age of 38 year. Estimates suggest that more than 80% of the sexually active women acquire genital HPV by 50 years of age¹. The high burden of Cervical Cancer in South and Southeast Asian countries is due to a high prevalence of HPV and due to lack of screening. The recent NCRP (National Cancer Registry Program) data shows that between 2009-2011 Aizawl district (Mizoram) in the north eastern part of India had the highest levels of cervical cancer at an age-adjusted rate of 24.3, followed by Barshi (Maharashtra) at 19.5 and Bangalore at 18.9. The annual percentage

decrease ranged from a minimum of 1.3% in Bhopal to 3.5% in Chennai in the years from 1982 to 2010.¹ Among healthy women in a slum in Delhi, the incidence rate for HPV infection (the most common risk factor) was found to be 5 per 1,000 woman-months.² In the southern part of India, the north eastern districts of Tamil Nadu show a distinctive pattern with a high incidence of cervical cancer.³ The exact data on incidence are lacking from western India, but it is seen in equal proportion to breast cancer according to studies. There are numerous risk factor for cervical carcinoma which are young age at first intercourse (<16yr), Human Papilloma virus infection (HPV), HIV, herpes simplex virus, multiple sexual partners, oral contraceptive pills, poor genital hygiene, cigarette smoking, race, high parity and low socio-economic status. Cervical cancer is mainly caused by infection with the oncogenic subtypes (16, 18, 33, 35) of HPV.⁴ Invasive cancer of cervix is considered to be a preventable condition, since it is associated with long preinvasive stage making it

amenable to screening and treatment. Therefore, preventing HPV infection can prevent cervical cancer. This can be achieved by complete abstinence from sexual activity since teenage or by a vaccine. Primary prevention involves a risk reduction approach through behavioral intervention for sexual and health care-seeking behavior or through mass immunization against high-risk HPV.⁵The objective of cervical screening/secondary prevention is to prevent invasive cervical cancer from developing by detecting and treating women with CIN2/3 lesions, and the effectiveness is determined by reduction in incidence, mortality and morbidity.⁶Colposcopy is the technique used for direct visualization of the cervix enabling a view of transformation zone, making it a unique method to study the benign and premalignant lesions. Colposcopy has high sensitivity and can provide immediate results for evaluation of cervical precancerous lesions. It is used to identify the site, severity and extent of the abnormality as well as to aid directed biopsy, plan treatment and to allow use of conservative methods to treat the precursor lesions. Colposcopy is an observer dependent procedure gives faster results and guides the site of biopsy which can be done in a single visit making it probably a better screening modality for premalignant lesions in symptomatic patients. The present study was aimed to assess the sensitivity, specificity and predictive value of colposcopy as tool for early detection of premalignant lesions in unhealthy cervix at a tertiary care center, catering to both rural and urban population.

MATERIAL AND METHODS

The study is a prospective study comparing Pap smear and colposcopy for early diagnosis of cervical cancer, spans over one and a half year and was carried out in the Department of Obstetrics and gynecology, Mahatma Gandhi Medical College & Hospital, Jaipur.

INCLUSION CRITERIA

1. Age: 20-50 years.
2. Patients with abnormal symptoms like profuse white discharge, postcoital bleeding, intermenstrual bleeding and post-menopausal bleeding.
3. Patients with unhealthy cervix diagnosed by speculum examination like, cervical erosion, cervical polyp, cervicovaginitis.
4. Patients with abnormal Pap smear.

EXCLUSION CRITERIA

Women with frank invasive cancer.

METHODS

Ethical approval of the study protocol was obtained from the Institutional Review Board of Mahatma Gandhi Medical College, Jaipur. Subjects were enrolled after taking informed content. Preliminary details in the form of Name, Age, Husband name,

Address, Socioeconomic status and Registration number were noted. Detailed interrogation of the subjects was done regarding first sexual intercourse, marriage before 18 years, first conception at an early age, multiple conception, multiple sexual partners, post coital bleeding, sexually transmitted diseases, leucorrhoea, genital hygiene, cigarette smoking and tobacco intake, family history of cervical cancer. Obstetrics history (deliveries, abortions, MTP, Lactation), menstrual history and contraception history (OC pills), and general examination (weight, pulse, B.P) was done. Pap smear, colposcopy and biopsy were performed on all women of the target population attending Mahatma Gandhi Hospital Gynecology OPD. These findings were recorded on a predesigned proforma. Speculum examination was performed which included direct visual inspection of the cervix (without any magnification), and macroscopic abnormalities such as cervicitis, cervical warts, polyps, erosions, nabothian cysts, bleeding erosions, stippled cervix, irregular edematous elongated cervix, growths and ulcers were identified and noted. Cervical Pap smear using a wooden Ayre's spatula for cytological examination was taken which was immediately fixed in a mixture of (95% ethyl alcohol and 5% ether) because cells lose their differential staining characteristics on drying. The samples were examined at the department of pathology, Mahatma Gandhi Hospital, Jaipur. Pap smear reportings were done according to the Bethesda classification. Subject is kept in dorsal position; Labia are separated and vaginal speculum is inserted for PAP smear. After examination the patients were subjected to colposcopy. All subjects underwent colposcopic evaluation. Reid's score was used to predict the grading of abnormal colposcopic findings. In RCI, colposcopic signs i.e. margins, colour, vascular patterns and iodine-staining are scored and graded into two objective categories; low-grade CIN-1 or high-grade CIN-2 and CIN-3, combined into a weighted index called RCI. Sensitivity, specificity and positive and negative predictive values of various tests described were analysed using colposcopic directed biopsy as the reference standard. Women with abnormal Colposcopic findings were treated as per HPR. Statistical analysis was performed with the SPSS, Trial version 23 for Windows statistical software package (SPSS inc., Chicago, IL, USA) and Primer. The Categorical data were presented as numbers (percent) and were compared among groups using Chi square test. Quantitative data were presented as mean and standard deviation. Analysis of the effectiveness of a diagnostic criterion was done obtaining sensitivity, specificity, positive and negative predictive value. Probability P value <0.05 was considered statistically significant.

RESULTS

A total of 300 patients were included in the study. The maximum number of cases i.e. 78 (26%) were found in

35- 39 years age group. 70 (23.33%) cases were in the age group of 40-44 years. In present study majority of patients were from a rural setting (67.33%) compared to 32.67% from urban areas. In our study majority of cases (64.67%) were from lower socio-economic background and (35.33%) cases were from upper socio-economic class. Out of 300 patients in our study 247 (82.33%) cases were married at age of 18 years or less. In our study highest number of cases were seen in parity 4 (31.6%). Majority of cases were between parity 2 to 4. In our study white discharge was the main complaint of maximum number of cases and represented (62.33%) followed by post coital bleeding (14%). Pain lower abdomen was complaint by 7% of cases and pain during coitus by 6% of cases. In our study maximum number of cases showed Cervical Erosion (34%) which was followed by Hypertrophy with Erosion (28.66%). Out of 300 patients on Pap smear Grade 2 (Inflammatory) findings were observed in 152 (50.67%) cases. Grade 3A (CIN I) was seen in 18 (6%), Grade 3B (CIN II) in 10 (3.33%) and Grade 4 (CIN III) in 4 (1.33%) cases. Frank invasion (Grade 5) was seen in 2 cases. In our study on colposcopy Grade 1 (CIN I) was seen in 22 (7.33%) cases, Grade 2 (CIN II) in 14 (4.67%) cases and Grade 3 (CIN III) in 11 (3.66%) cases. In our study the most common abnormal Colposcopic finding was Ectropion observed in 100 (33.33%) cases, followed by Acetowhite areas seen in 23 (7.6%) cases and Abnormal vasculature was seen in 20 (6.66%) cases. Punctuation and Mosaic was seen in 9 (3%) and 6 (2%) cases respectively. Out of 300 patients Abnormal HPR findings were seen in 104 (34.67%) cases. The most common abnormal HPR finding was chronic

cervicitis (44.23%) followed by CIN I (23.08%) CIN II was observed in 15.38% and CIN III in 11.54% cases. Squamous cell carcinoma was seen in 5.77% cases. In our study out of 300 cases, Caution was done in 7 cases and LEEP was done in 2 cases. They presented with acetowhite and abnormal vascularity on colposcopy. Cryotherapy was done in 19 cases, majority of them presented with white discharge and excessive bleeding followed by one case of post coital bleeding and one with post-menopausal bleeding. On colposcopy, among them 14 cases were of CIN I and rest were CIN II. There were 11 cases of CIN III on colposcopy out of which 4 turn out to be squamous cell carcinoma with breach of basement membrane on HPR and they were advised for Radiotherapy as they were inoperable. And 7 cases underwent Hysterectomy out of which in 4 cases Wertheims with pelvic lymphadenectomy was done. Risk of positive HPR finding were 6.733 (2.035 to 22.271) times significantly more in >30 years of age groups as compared to ≤30 years of age (P<0.001S). Risk of positive HPR finding were 3.427 times more in ≤18 years of age groups as compared to >18 years of age as odd's ratio was 3.427 (95% CI 1.184 to 9.922) (P=0.0285S). Significant association was observed between socioeconomic findings and HPR findings. Risk of positive HPR finding were 2.161 (95% confidence interval: 1.106 to 4.219) times Significantly more in LOWER socioeconomic status as compared to upper (P=0.032S). Significant association was observed between parity and HPR findings. Positive findings with HPR were significantly more in higher parity as compared to Nulliparous (0%) and P1 (0%).

Table1: Major Presenting Complaints and Relationship with Biopsy (HPR) Findings

	Total	Chronic Cervicitis		CIN		normal		SQC		P Value LS
	No	No	%	No	%	No	%	No	%	
Excessive Bleeding	14	0	0.0	6	42.86	8	57.14	0		0.054NS
Intermenstrual Bleeding	8	1	12.5	0	0.00	7	87.5	0		0.71NS
Pain During Coitus	18	0	0.0	4	22.22	12	66.67	2	11.1	0.014S
Pain Lower Abdomen	21	6	28.6	5	23.81	10	47.62	0		0.26NS
Post Coital Bleeding	42	13	31.0	7	16.67	22	52.38	0		0.024S
Post Menopausal Bleeding	10	2	20.0	3	30.00	3	30	2	20	<0.001S
White Discharge	187	24	12.8	27	14.44	134	71.66	2	1.07	0.028S
Total	300	46	15.3	52	17.33	196	65.33	6	2	

Significant association was observed between complaints of white discharge and post coital bleeding. On HPR out of 187 cases with white discharge 27 cases were positive for CIN. And out of 42 cases with post coital bleeding HPR confirmed 7 cases as CIN.

Table 2: Diagnostic Statistics of the Pap

Pap's Report	Cervical biopsy (HPR)		
	Positive	Negative	Grand Total
Positive	22	12	34
Negative	36	230	266
Total	58	242	300

P <0.001S

The calculated Sensitivity was 37.93% and the Specificity was 95.04%. The Positive predictive value was 64.71% and Negative predictive value was 86.47%.

Table 3: Diagnostic Statistics of Colposcopy

Colposcopic Findings	Cervical biopsy (HPR)		
	Positive	Negative	Grand Total
Positive	51	54	105
Negative	7	188	195
Total	58	242	300

P < 0.001S

The calculated Sensitivity was 87.93% and the Specificity was 77.69%. The Positive predictive value was 48.57% and Negative predictive value was 96.41%.

DISCUSSION

Cervical cancer is the second most frequent cancer worldwide, in women after breast carcinoma. However invasive cancer of the cervix was considered to be a preventable condition as it is associated with a long pre-invasive stage i.e. CIN making it amenable to screening and treatment. Screening for early detection of cervical cancer is still the best option available for arresting and curing the disease at an early stage and thus reducing the mortality and morbidity associated with it. Women found positive on screening are usually referred for confirmatory colposcopy and biopsy to obtain a definite diagnosis. Treatment is then offered on the basis of the biopsy results. The “test-and-treat” approach to manage pre-invasive lesions is being investigated as a means to minimize the number of visits and thus increase the compliance to the protocol on screening programs. In our study high incidence of CIN was found among the age group of 35-39 years. 94.82% cases of CIN were from age group above 30 years. Kushtagi P and Fernandez P wherein their study showed the prevalence of CIN was higher in women over 30 years.⁷ Ashmita D et al was showed in her study that CIN was more prevalent in age group of >30 years.⁸ Akhter S et al was showed the mean age patients with cancer cervix was >35.⁹ Socio economic status had always been playing an epidemiological role in genesis of dysplasia. In our study the incidence of CIN was found to be higher among the low socio-economic group. 77.58% cases of CIN were from low socio-economic group. Vaidya Ahad showed that low socioeconomic status had a definite role on the development of dyskaryosis.¹⁰ The present study was supported by the studies done by Bukhari MH et al who concluded that maximum no of cases were from low Socio-Economic status.¹¹ Gopal M et al showed in their study that CIN was higher among the low socio-economic group.¹² Poor personal hygiene poor living conditions, unstable marriages and early age at first intercourse are factors associated with both low socio economic conditions and cervical cancer. Age at marriage and duration of exposure to sexual intercourse had a distinct role in genesis of cervical dysplasia. In our study, the incidence of CIN was 93.10% in women who were married at age of 18 years or less. This observation was also supported by

Sherwani RK et al¹³ and Bal MS et al¹⁴ who demonstrated that the severity of underlying CIN increased with increase in the duration of marital life and hence the increase in the duration of exposure to sexual intercourse. Our study showed increased incidence of CIN among multiparous women. Out of total cases of CIN 8.6% cases were Para 2, 34.48% cases were Para 3 and 50% cases were Para 4. Kushtagi P and Fernandez P showed the prevalence of CIN was significantly higher in parity of more than 2.⁹ Ashmita D et al was showed in her study that CIN was more prevalent in multiparity.¹⁰ Akhter A et al showed more positive cases of CIN were found with parity 4.¹¹ This might be attributed to hormonal and nutritional changes that occur in pregnancy, immune suppression during pregnancy, and cervical trauma during vaginal delivery.¹⁵ Among the complaints, majority of women 62.33% (187/300) complained of excessive white discharge per vaginum. Among them CIN was found in 14.43% (27/187). Excessive vaginal discharge playing a role in contributing to the development of CIN was also proved to be a risk factor in the study conducted by Vaidya A.¹² Post coital bleeding was found in 14% (42/300) of cases. Among them CIN was found in 16.66% (7/42). Shalini R et al,¹⁶ in their study showed the relationship of post coital bleeding and CIN. In their study, among the women who had post coital bleeding, 85.5% had benign findings, 5.6% had HPV and CIN I, 3.6% had CIN II and III, and 5.5% had invasive cancer. There was no correlation between the duration of bleeding and pathology. In our study on Per speculum examination, the most common finding was erosion of cervix where the squamous epithelium of ectocervix was replaced by the columnar epithelium of endocervix. In our study cervical Erosion was seen in 34% (102/300), Cervical hypertrophy in 27.67% (82/300) and hypertrophy with erosion in 28.67% (86/300) among them CIN was found in 18.6% (19/102), 17% (14/82) and 19.76% (17/86) cases respectively. This observation was also found by Bal MS et al¹⁴ who showed 35.7% cases of erosion in CIN and invasive carcinoma which is consistent with the present study. Gopal M et al in their study found CIN in 12.5% of women with erosion, 33.3% in women with hypertrophy and 25% in women with hypertrophy and erosion.¹⁶ Padmini

CP et al in their study found cervical erosion were the most common lesions, followed by hypertrophied cervix.¹⁷ Pap smear diagnosed 34 women out of 300 as positive (CIN). Out of which 22 of them were correctly confirmed on histopathology, giving sensitivity, specificity, positive predictive value and negative predictive value of 37.93%, 95.04%, 64.71%, and 86.47% respectively. Meta-analysis of the Pap smear accuracy by Fahey MT et al¹⁸ found that estimates of sensitivity and specificity ranged from 11 to 99% and 14 to 97%, respectively. Our findings also correspond to the estimated figures. Our findings agree closely with Basu PS et al who got a sensitivity and specificity of 29.5% and 92.3% respectively.¹⁹ Goel A et al,²⁰ and Shastri SS et al²¹ reported sensitivities of 44.3%, 50.0% and 57.4% respectively and specificities of 90.6%, 97.0%, and 98.6% respectively. All three reported a little higher sensitivity but the specificities were corresponding well with our observations. Our present study showed sensitivity, specificity, positive predictive value and negative predictive value of 87.93%, 77.69%, 48.57% and 96.41% respectively. Pimple SA et al found sensitivity of colposcopy was 58.0-74.7% and that of specificity was 57.5-92.9%.²² Our results also fall around the observed range. Ramesh G et al in his study out of the 80 patients, the incidence of CIN I and CIN II, III was found to be 11.25% and 10% respectively.²³ The sensitivity of colposcopy in the study was 83.33%. Gupta V et al a study was undertaken in 300 patients; the sensitivity and specificity of colposcopy was 85.85% and 87.65% respectively.²⁴ Positive predictive value was 75.83% and negative predictive value was 95.38%. Our results also fall around the observed range. Colposcopy had the highest sensitivity (87.93%) in detecting CIN. Pap smear had the highest specificity rate (95.04%) compared to (77.69%) Colposcopy. The comparative PPV rates for Pap smear, Colposcopy were 64.71%, 48.57% respectively. The NPV were 86.47%, 96.41% respectively. Barut MU et al²⁵ carried out a study in which he found Sensitivity, specificity, PPV and NPV of Pap smear were 0.57%, 0.76%, 0.26% and 0.92% respectively. Sensitivity, specificity, PPV and NPV of colposcopy were 0.92%, 0.67%, 0.52% and 0.96% respectively. Akhter S et al,¹¹ in her study Sensitivity and Specificity of Colposcopy findings were 86% and 79% respectively. Sensitivity and Specificity for Pap smear was 38.8% and 71.8%. These figures correspond closely with our findings. Padmini CP et al,²⁶ in study 100 patient were subjected to Pap smear, Colposcopy and biopsy. Colposcopy sensitivity was 80.37%, specificity 81.06%, PPV 66.89%, NPV 90.52% respectively. Pap smear sensitivity was 24.3% specificity 98.3%, PPV 93.12%, NPV 74.36%. These figures correspond closely with our findings.

CONCLUSION

Colposcopy was found to be useful in understanding the morphology of the cervical lesions, both of the neoplastic and the non-neo-plastic ones and this was

very helpful in planning their management. It can identify the site, severity and extent of abnormality as well as aid acid-directed biopsy. Colposcopy offers advantages over more invasive diagnostic tests. Diagnosis can be made and patients treated in an ambulatory setting without general anesthesia. The minimally invasive nature of colposcopy preserves the cervix for future childbirth. This is a particularly important feature in light of the increasing prevalence of young women with pre-invasive forms of cervical disease.

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