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A COMPARISON OF PAP SMEAR, COLPOSCOPY AND COLPOSCOPY DIRECTED BIOPSY IN EVALUATION OF UNHEALTHY CERVIX

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ABSTRACT: OBJECTIVES: To obtain Colposcopic directed biopsy from suspicious and abnormal areas on the cervix, to correlate the findings in women with unhealthy cervix by Papsmear, Colposcopy and Histopathological findings and to assess the utility of Colposcopy in detecting carcinoma of the cervix in its preinvasive stage. **STUDY DESIGN:** Observational study over a period of one and half years. **Setting:** Study was carried out in the Out Patient Department (OPD) at the Kempegowda institute of medical Sciences. Bangalore. **SAMPLE SIZE:** One hundred women. **METHODS:** 100 patients who were aged between 18- 65 yrs and had clinically unhealthy cervix, were subjected to pap smear, colposcopy and colposcopic directed biopsies and the findings were noted. All the patients underwent both the acetic acid and the Schiller's test before they were subjected to colposcopic directed biopsies. The biopsies were taken from the acetowhite areas and the iodine negative areas. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy were calculated for pap smear colposcopy with colpscopic directed biopsy as the gold standard. **RESULTS:** The sensitivity and specificity of Pap smear was found to be 50% and 90% respectively and that of colposcopy 85% and 83.75% respectively. Colposcopy showed higher sensitivity and lower specificity and higher positive predictive value compared to Pap smear. The accuracy of colposcopy was higher than that of Pap smear. **CONCLUSION:** Colposcopy is useful in detecting premalignant and malignant lesions of the cervix. Colposcopy and cytology used together in patients of cervical lesions have a relatively higher chance of detecting squamous intraepithelial lesions/malignancy as compared to either procedure when performed alone.

INTRODUCTION: Carcinoma of the cervix is the most frequent of all the genital tract cancers. It is a very common for the gynaecologists who work in tertiary care institutes in the developing countries to get referrals from practitioners and peripheral health centres for patients with a clinical diagnosis of an "unhealthy cervix".¹ The Papanicolaou's (Pap) smear is the primary screening tool for Cervical Intra-epithelial Neoplasia (CIN) and for invasive cancer of the uterine cervix. Recently, the assumed accuracy of the Pap smear, which was found to be 80% to 95% for detecting CIN and early invasive cancer, was questioned. Conversely, a false negative rate of the Pap smear had been reported under carefully controlled conditions.²

The simultaneous use of cytological studies and screening colposcopy has been shown to increase the rate of the cervical cancer detection. A colposcopic evaluation and a guided biopsy remains a critical diagnostic step for women with squamous intraepithelial lesions, in order to identify the women who require treatment.³ Hence, there is obvious need to subject women with clinically unhealthy cervix to colposcopy and directed biopsy. This study was done to evaluate the role of colposcopy in the detection of unhealthy cervix.

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AIMS AND OBJECTIVES:

1. To obtain colposcopic directed biopsy from suspicious and abnormal areas on the cervix.
2. To detect carcinoma of the cervix in its pre invasive stage.
3. To correlate Pap smear, Colposcopy and Histopathological findings.

MATERIALS AND METHODS: This was an observational clinical study of 100 Women aged between 18-65 years with clinically unhealthy cervix attending gynaecology OPD at KIMS hospital, Bangalore who fulfilled inclusion criteria, study was conducted between Dec. 2012 to June 2014 studied using cytology and colposcopy. Relevant obstetrics and gynaecology history was taken and recorded.

Inclusion Criteria:

1. Age: 18-65 years.
2. Patients with abnormal symptoms like profuse white discharge, postcoital bleeding, intermenstrual bleeding and post-menopausal bleeding.
3. Patients with pap smears showing dysplasia.
4. Patients with unhealthy cervix diagnosed by speculum examination like, cervical erosion, cervical polyp, condylomas.

Exclusion Criteria:

1. Women with frank invasive cancer.
2. Patients with bleeding at the time of examination
3. Pregnant women.

RESULTS: Maximum number of cases were found to be in the age group 31-40 years (86%). The mean age was 36.5 years. {TABLE 1}.

Age in years	No. of patients	%
<30	5	5
31-40	86	86
41-50	9	9
Total	100	100

TABLE 1: Distribution of patients According to Age

In Maximum number of cases, Age of marriage was found to be in the age group of 19-21 years. (62%). {TABLE: 2}.

AOM in years	No. of patients	%
16-20	70	70
21-25	30	30
Total	100	100

TABLE 2: Distribution of patients according to Age of Marriage (AOM)

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Majority of the patients had cervical erosion (74%), in that 44 % had only erosion cervix, 30% hypertrophied cervix with erosion, 21% had hypertrophied cervix which bleeds on touch. {TABLE: 3}.

Clinical Appearance of Cervix	No. of patients	%
Cervix flushed with vagina	3	3
Endocervical polyp	2	2
Erosion	44	44
Hypertrophied cervix with erosion	30	30
Hypertrophied cervix bleeds on touch	21	21
Total	100	100

TABLE 3: Distribution of patients according to clinical appearance of cervix

The commonest symptom was white discharge per vaginum. (86%). {TABLE: 4}.

Symptoms	No. of patients	%
White Discharge	86	86
Intermenstrual bleeding	5	5
Post coital bleeding	5	5
post-menopausal bleeding	4	4
Total	100	100

TABLE 4: Distribution of patients According to Symptoms

Pap smear revealed that 78% had an inflammatory smear and 18% had a positive Pap smear. The result of Pap smear was considered positive if it revealed LSIL, HSIL, carcinoma in situ or invasive cancer. Among 18 positive cases, there were 13 LSIL, 5 HSIL and no case of malignancy.{TABLE: 5}.

PAPSMEAR	No. of patients	%
Normal	4	4
INF	78	78
LSIL	13	13
HSIL	5	5
Total	100	100

TABLE 5: PAP Smear results

On colposcopy, 30% women found to have a positive result, colposcopy was considered positive, if it revealed lesions of LSIL and above. Among the 30 women with abnormal colposcopies there were 15 LSIL, 13 HSIL and 2 case suspicious of malignancy. Colposcopy was unsatisfactory in 7 cases.{TABLE 6}.

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COLPOSCOPY	No. of patients (n=100)	%
Normal	3	3
Abnormal	97	97
Inflammation/squamous metaplasia/erosion	60	60
Hazy/faint acetowhite areas. Fine punctations or mosaicism	15	15
Dense acetowhite areas. Coarse punctations or mosaicism	13	13
Unsatisfactory	7	7
Malignancy (intense acetowhite lesion, coarse irregular punctations, cork screw vessels	2	2
TABLE 6: COLPOSCOPY results		

The positive biopsy includes 20 cases out of 100. Biopsy was considered positive if it revealed Mild Dysplasia and above. It includes 9 mild dysplasias (LSIL), 7 moderate to severe dysplasias (HSIL) and 4 malignancies. Out of 04 malignancies none had visible growth on per speculum examination. {TABLE: 7}.

Biopsy	No. of patients (n=100)	%
Normal	3	3
Abnormal	97	97
A. Cervicitis	75	75
B. Chronic non- specific polypoidal Endocervicitis with Benign Polyp	2	2
C. Mild dysplasia	9	9
D. Moderate/Severe dysplasia	7	7
E. SCC	4	4
TABLE 7: BIOPSY results		

30 out of 100 women were positive on colposcopy. 20 out of 100 women were positive on biopsy. Colposcopy was positive in 16 out of 20 biopsy proven positive cases. Colposcopy was unsatisfactory in 7 cases. 2 cases of mild dysplasia and 1 case of moderate/severe dysplasia were under reported as metaplasia/ erosion on colposcopy. 15 cases of cervicitis/ metaplasia were over reported as LSIL/HSIL on colposcopy. {TABLE 8}.

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Colposcopy	Biopsy					Total
	Normal	Cervicitis/ metaplasia	Mild dysplasia	Moderate/ Severe dysplasia	Malignancy	
Normal	2(66.7%)	0(0%)	1(11.1%)	0(0%)	0(0%)	3(3%)
Inflammatory/Squamous metaplasia/erosion	1(33.3%)	56(72.7%)	2(22.2%)	1(14.3%)	0(0%)	60(60%)
Hazy/Faint acetowhite areas, fine punctations or mosaicism	0(0%)	11(14.3%)	4(44.4%)	0(0%)	0(0%)	15(15%)
Dense acetowhite areas, coarse punctations or mosaicism	0(0%)	4(5.2%)	2(22.2%)	5(71.4%)	2(50%)	13(13%)
Unsatisfactory	0(0%)	6(7.8%)	0(0%)	1(14.3%)	0(0%)	7(7%)
Malignancy	0(0%)	0(0%)	0(0%)	0(0%)	2(50%)	2(2%)

TABLE 8: Correlation between Colposcopy and Biopsy

Colposcopy	Biopsy		Total
	Positive	Negative	
Positive	17(85%)	13(16.2%)	30(30%)
Negative	3(15%)	67(83.7%)	70(70%)
Total	20(100%)	80(100%)	100(100%)

TABLE 9: DIAGNOSTIC EFFICACY OF COLPOSCOPY AND BIOPSY

	Sensitivity	Specificity	PPV	NPV	TP	FP	TN	FN	Accuracy
Pap Smear	50%	90%	55.50%	87.80%	10	8	72	10	82%
Colposcopy	85%	83.75%	56.60%	95.70%	17	13	67	3	84%

TABLE 10: DIAGNOSTIC EFFICACY OF TESTS

TP= True Positive, FP= False Positive, TN=True Negative, FN= False Negative

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Pap Smear	Biopsy					Total
	Normal	Cervicitis	Mild dysplasia	Mod/Severe dysplasia	Malignancy	
Normal	2(66.7%)	2(2.6%)	0(0%)	0(0%)	0(0%)	4(4%)
Inflammatory	1(33.3%)	67(87.01%)	6(66.7%)	4(57.14%)	0(0%)	78(78%)
LSIL	0(0%)	8(10.3%)	2(22.2%)	2(28.57%)	1(25%)	13(13%)
HSIL	0(0%)	0(0%)	1(11.1%)	1(14.2%)	3(75%)	5(5%)
Total	3(100%)	77(100%)	9(100%)	7(100%)	4(100%)	100(100%)

TABLE 11: Correlation between Pap smear and biopsy

20 cases out of 100 were positive on Biopsy. Pap smear was positive in 10 out of 20 biopsy proven positive cases. 8 cases of LSIL were under reported as Cervicitis on Biopsy. 10 cases of Inflammatory Smear were over reported as Mild Dysplasia/Moderate to Severe Dysplasia.

Pap smear	Biopsy		Total
	Positive	Negative	
Positive	10(50%)	8(10%)	18(18%)
Negative	10(50%)	72(90%)	82(82%)
Total	20(100%)	80(100%)	100(100%)

Table 12: Diagnostic efficacy of Pap Smear

The comparison between two categorical variables were analyzed using Chi Square test. The statistical analysis was done by calculating diagnostic efficacy of each test. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy were calculated for Pap smear and colposcopy with colposcopy directed biopsy results as gold standard.

DISCUSSION: The incidence of cervical cancer can be reduced by as much as 80% if the quality, coverage and follow-up of screening methods are of high standard.⁴ Frequently repeated cytology screening programs have led to a large decline in cervical cancer incidence and mortality in developed countries. Cytology based screening programs have achieved very limited success in developing countries like India due to lack of trained personnel, laboratory facilities, equipments, high cost of services and poor follow-up. It has become necessary to find out alternative screening procedure to cytology which has high sensitivity and specificity.

In our study mean age was 36.5 years. Kushtagi and Fernands,⁵ in their study showed the prevalence of CIN was higher in women over 30 years. Vaidya⁶ showed in his study that CIN was more prevalent in the age group of >35 years.

The mean age of marriage was 19.94 years because of high rate of illiteracy and low socioeconomic status. The commonest symptom was white discharge per vagina (86%), among the patients with white discharge per vagina, CIN was found in 15.11% and malignancy in 2 cases. 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 et al. In their study, 24% had CIN with white vaginal discharge. Post coital bleeding was found in 7% (7/100) of cases. Among them CIN was found

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in 28.6% (2/7).

In our study among those with intermenstrual bleeding, 40 % (2/5) had CIN, and 1 case had malignancy. Among those with post-menopausal bleeding 25% (1/4) had CIN. Among those with postcoital bleeding, 1 case had malignancy.

CIN was found in 33.33% (1/3) in women who showed cervix flushed with vagina, 47.6%(10/21) in women who showed hypertrophy cervix which bleeds on touch, 10% in women with erosion and 16.66% in women with hypertrophy + erosion.

In our study, 30 out of 100 women were positive on colposcopy. Colposcopy was considered positive if it revealed lesions of LSIL and above. Among the 30 women with abnormal colposcopies there were 15 LSIL, 13 HSIL and 2 case suspicious of malignancy. Colposcopy was unsatisfactory in 7 cases.

Among those with Hazy/faint acetowhite areas. Fine punctations or mosaicism , 26.66% (4/15) were found to be Mild Dysplasia. Among those with dense acetowhite areas, Coarse punctations or mosaicism 63.3% (7/11) had CIN, in that 18.1% had mild dysplasia and 45.4% had moderate/severe Dysplasia and 2 cases had malignancy. Among those with Inflammation/squamous metaplasia/erosion 5% (3/60) showed CIN, 3.3% were Mild Dysplasia and 1.6% were moderate to severe Dysplasia. Among normal cases 33% (1/3) showed Mild Dysplasia. The sensitivity and specificity of colposcopy in our study was 85% and 83.75% respectively. The positive predictive value was 56.6%. Colposcopy was unsatisfactory in 7 cases of which 6 showed cervicitis/metaplasia and 1 showed moderate/severe dysplasia on histopathology. Colposcopy over reported 15 cases of cervicitis/metaplasia as LSIL in 11 cases and HSIL in 4 cases.

In our study, sensitivity of Pap smear was found to be 50%. As a screening test, the Pap smear has been found to have a low sensitivity, between 44% and 50%, resulting in a high false negative rate of 36-40%.⁷ The sensitivity of Pap smear has been found to be lower in developing countries because of presence of infection and inflammation. The high specificity of Pap smear (90%) found in our study is similar to findings from other studies in which specificity ranges from 91-97%.⁸ The positive predictive value was found to be 55.5%.

The positive biopsy includes 20 out of 100 cases. It includes 9 mild dysplasias (LSIL), 7 moderate to severe dysplasias (HSIL) and 4 malignancies. Out of the 4 malignancies none had visible growth on per speculum examination. Overall correlation is good with sensitivity of 85%, specificity 83.7%, positive predictive value of 56.66%, negative predictive value of 95.7% and accuracy of 84%.

SENSITIVITY AND SPECIFICITY OF PAP SMEAR BY VARIOUS AUTHORS:

Sl.NO.	AUTHORS	SENSITIVITY	SPECIFICITY
1	Shalini R, Amith S, Neera M.A. ⁷	56	90
2	Pete I, Toth V, Bosze P ⁹	47	77
3	PRESENT STUDY	50	90

TABLE 13

SENSITIVITY AND SPECIFICITY OF COLPOSCOPY BY VARIOUS AUTHORS

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Sl. NO.	AUTHORS	SENSITIVITY	SPECIFICITY
1	Olaniyan B Mete Analysis ¹⁰	87-99%	26-87%
2	Massad LS Collins Y C ¹¹	89%	52%
3	Sukhpreet L Singh ¹²	95%	63.50%
4	Present Study	85%	83.75%
TABLE 14			

In our study sensitivity and specificity of pap smear and colposcopy were comparable with other authors as mentioned above in the tables.

CONCLUSION: Cervical cancer is most common cancer in women in India and developing countries. Invasive cervical cancer is preceded by preinvasive disease in most women. There is a lag time of 10-20 years before the disease progresses from pre invasive to invasive disease. Prevention of invasive cancer is by screening, diagnosis and treatment of preinvasive diseases. Thus early diagnosis of CIN in adult women is a desirable goal.

From the results of this study, it is evident that colposcopy and colposcopy guided biopsy is definitely more sensitive and accurate than pap smear. By combining pap smear with colposcopy and colposcopy guided biopsy, we can maximize the sensitivity and specificity of cancer cervix screening.

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