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## Original Research Article

# Colposcopic evaluation and papanicolaou smear in high risk groups and its correlation with histology

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## ABSTRACT

**Background:** Cervical cancer is one of the most common gynaecologic neoplasms. PAP smear and colposcopy are used for its early detection. This study aims to find the correlation of colposcopic evaluation with Pap smear in cervical cancer screening and with histology.

**Methods:** All women attending the OPD with unhealthy cervix and abnormal symptoms, who gave written informed consent were included in the study. Pap smear cytological grading, colposcopic findings were recorded. Pap smear and colposcopy findings was compared with histopathology.

**Results:** The study included 73 patients. Pap smear was negative in more than half of the patients (56.2%), followed by atypical squamous cells of undetermined significance in 12 (16.4%), low-grade squamous intraepithelial lesion in 17 (23.3%), high-grade squamous intraepithelial lesion in 2 (2.7%) and squamous cell carcinoma in 1 patient (1.4%). The histopathology showed normal findings in 46 patients (63%), followed by CIN 1 in 11 (15.1%), CIN 2 in 6 patients (8.2%), CIN 3 and squamous cell carcinoma in 5 patients each (6.8%). Pap smear's predictability of cervical malignancy showed that it had a sensitivity of 48.15, it's specificity for identifying patients without cervical malignancy was 84.78%. Colposcopy's predictability of cervical malignancy showed that it had a sensitivity of 88.89%, it's specificity for identifying patients without cervical malignancy was 95.65%.

**Conclusions:** Colposcopy does seem to be better than Pap smear in diagnosing cervical carcinoma and also identifying patients without it.

**Keywords:** Cervical carcinoma, Colposcopy, Pap smear

## INTRODUCTION

Cervical cancer is the second most common cancer among women worldwide, and it is responsible for 275,000 deaths each year.<sup>1</sup> Among all known types of cancer, the prospects for preventing or curing cervical cancer are among the best because it can be diagnosed early when it is still curable. About 80% of cervical cancer cases occur in developing countries, and it is the most common cause of death in women.<sup>2,3</sup> The Papanicolaou (Pap) test is the most common and cost-effective screening method for detecting cervical cancer, and it has been effective in reducing the prevalence of this cancer and the associated

mortality rates among women.<sup>4</sup> Since 1950, the Pap smear has decreased the rate of cervical cancer by as much as 79%, and it has decreased the mortality rate by 70%.<sup>5</sup> The sensitivity of the conventional Pap smear in detecting lesions before cervical cancer occurs is 51%, which means the false negative value of this method is 49%.<sup>6</sup> The sensitivity and specificity of the Pap test in detecting high-grade lesions of cervical intraepithelial neoplasia (CIN II and CIN III) have been shown to be 55.4 and 96.8%, 87 respectively.<sup>7</sup> In a study performed in Iran, it was found that less than 2% of the patients with cervical cancer had undergone a Pap smear in the previous 10 years.<sup>8,9</sup> Human papilloma virus (HPV) is the main cause of cervical

intraepithelial neoplasia (CIN) and cervical cancer. Some studies have shown that women infected with high-risk HPV have a higher rate of progression from CIN to cancer, with a 300- fold increase in the risk of high-grade disease.<sup>10,11</sup> Usually, HPV infections are not persistent, but those that remain may be latent for many years. Most women who are exposed have no clinical signs, and the infection is finally suppressed or eliminated. In other women, low-grade cervical lesions occur, but, for the most part, they regress spontaneously. In many cases, the infection will clear in 9 to 15 months. In a limited number of women who are exposed to HPV, persistent infection occurs that may progress to CIN.<sup>10,11</sup> The aim of this study was to compare two methods, i.e., Pap smear and colposcopy, for screening patients for cervical cancer. This study helps to evaluate the effectiveness of colposcopic evaluation of unhealthy cervix and its correlation with Pap smear and histology, so that these methods may be used more efficiently. And thus, help to decrease the incidence of invasive carcinoma.

## METHODS

This hospital based cross sectional (Diagnostic evaluation) study, was done at MES Medical College Kerala from 1<sup>st</sup> January, 2019 to 31<sup>st</sup> December, 2019. All women attending the OBGOPD with unhealthy cervix and abnormal symptoms, who gave written informed consent were included in the study. As the specificity of colposcopy directed biopsy was 95% in the study conducted in KIMS hospital, Bangalore 12 is taken as 95%, absolute error as 5% and confidence interval as 95%, sample size is found to be 73 cases, according to the formula  $n = Z^2 pq/d^2$ .

All high-risk women in the age group 20-50 (i.e. with symptoms like discharge p/v, post coital bleeding, intermenstrual bleeding per vaginum, unhealthy cervix on clinical examination showing erosions, bulky cervix, contact bleeding, leucoplakia, ulcer). Women with bleeding per vaginum at the time of examination, has undergone vaginal douching/had sexual intercourse in past 48 hours, with frank invasive carcinoma, pregnant women. The study was conducted after institutional review board approval from 1<sup>st</sup> January, 2019 to 31<sup>st</sup> December, 2019. After obtaining patient's demographic data and detailed history, clinical examination including per speculum examination was recorded. After getting informed consent, Pap smear and colposcopy was then done in patients with abnormal symptoms or unhealthy cervix on naked eye examination. Bethesda system of classification was used for Pap smear cytological grading colposcopy findings was documented on the basis of following criteria: Colour of lesion, sharpness of margin, characteristics of stromal blood vessels and uptake or rejection of iodine. Each criterion was then given a score of 0, 1 or 2 according to severity and the total scores was calculated as Reid's colposcopic index. - Index 0-2: insignificant or low grade; index 3-4: intermediate lesion; and index 5-8: High grade lesion Pap smear and colposcopy findings was compared

with histopathology of colposcopy directed biopsies, taking the histopathology report as gold standard. Data was entered in Microsoft Excel and analysis was done using IBM SPSS 17. Sensitivity, specificity, positive predictive value, negative predictive value was calculated according to the formulas. Correlation of colposcopic evaluation with Pap smear was assessed using chi square test.

## RESULTS

The study included 73 patients. In the study population the majority of the patients were between the age group 41 to 50 years (65.8%), followed by 31 to 40 years at 28.8% and only 2.7% in 26 to 30 years and 51 to 60 years. The mean age among the study population were 43.42±5.9 years. Almost all of the study population were multipara (98.6%) and just patient was nullipara (1.4%). Abnormal uterine bleeding was most common symptoms presented in 31 patients (42.5%), followed by discharge per vagina in 23 (31.5%), asymptomatic in 9 (12.3%), post-menopausal bleeding in 8 (11%) and postcoital bleeding in 2. Pap smear was negative in more than half of the patients (56.2%), followed by atypical squamous cells of undetermined significance in 12 (16.4%), low-grade squamous intraepithelial lesion in 17 (23.3%), high-grade squamous intraepithelial lesion in 2 (2.7%) and squamous cell carcinoma in 1 patient (1.4%). The Reid colposcopic index showed most of patients in score 0 to 2 (64.4%), followed by score 3 to 4 in 19.2% and score 5 to 8 in 16.4%.

**Table 1: Pap smear findings vs histopathology.**

		On histopathology report		Total
		Benign	Malignant	
<b>On Pap smear findings</b>	Benign	39 TN	14 FN	53
	Malignant	07 FP	13 TP	20
<b>Total</b>		46	27	73
X <sup>2</sup> = 9.276 (d.f 1); p 0.002				
<b>Test prediction for Pap smear</b>		<b>%</b>	<b>95% Confidence Interval</b>	
Sensitivity		48.15	28.67 to 68.05	
Specificity		84.78	71.13 to 93.66	
Positive predictive value		65.00	45.82 to 80.31	
Negative predictive value		73.58	65.50 to 80.35	

The histopathology showed normal findings in 46 patients (63%), followed by CIN 1 in 11 (15.1%), CIN 2 in 6 patients (8.2%), CIN 3 and Squamous cell carcinoma in 5 patients each (6.8%). The histopathology was taken as gold standard for analysis. The Pap smear's predictability of cervical malignancy showed that it had a sensitivity of 48.15%; meaning it has 48.15% accuracy in predicting cervical malignancy. The specificity of Pap smear for

identifying patients without cervical malignancy was 84.78%. The positive predictive value was low at 65% and Negative predictive value was 73.58%. The predictions were statistically significant with p value of 0.002. The colposcopy's predictability of cervical malignancy showed that it had a sensitivity of 88.89%; meaning it has

88.89% accuracy in predicting cervical malignancy. The specificity of colposcopy for identifying patients without cervical malignancy was 95.65%. The positive predictive value was low at 92.31% and negative predictive value was 93.62%. The predictions were statistically significant with p value <0.001 (Table 1 and 2).

**Table 2: Colposcopy findings vs histopathology.**

	On histopathology report		Total	
	Benign	Malignant		
<b>On colposcopy findings</b>	Benign	44 TN	03 FN	47
	Malignant	02 FP	24 TP	26
<b>Total</b>		46	27	73
X <sup>2</sup> = 53.028 (d.f 1); p <0.001				
<b>Test prediction for colposcopy</b>	<b>%</b>	<b>95% Confidence Interval</b>		
Sensitivity	88.89	70.84 to 97.65		
Specificity	95.65	85.16 to 99.47		
Positive predictive value	92.31	75.45 to 97.91		
Negative predictive value	93.62	83.44 to 97.71		

**DISCUSSION**

In our study the pap smear was normal in more than half of the patients (56.2%), followed by atypical squamous cells of undetermined significance in 12 (16.4%), low-grade squamous intraepithelial lesion in 17 (23.3%), high-grade squamous intraepithelial lesion in 2 (2.7%) and squamous cell carcinoma in 1 patient (1.4%). Which was similar to the reviewed studies by Denny et al, 84.8% of PAP smears were normal, 7% were ASCUS, 5.3% reports LSIL <2.7% reports HSIL and 0.1% had invasive carcinoma.<sup>13</sup> In study by Shastri et al, 95.4% were normal, 0% had ASCUS, 0.026% reported LSIL, 0.01% as HSIL and 0.0007% had Invasive carcinoma.<sup>14</sup> In study by Durdi et al, 35% were normal, 29.2% had ASCUS, 23.8% reported LSIL, 12% as HSIL and 0.0% had invasive carcinoma.<sup>15</sup> In a study by Vijay et al showed that 85.71% were normal, 0% had ASCUS, 11.22% reported LSIL, 12% as HSIL and 0.0% had invasive carcinoma.<sup>16</sup> Differences in Pap smear reporting in different studies are due to differences in sampling, staining and fixation techniques and observer's errors.

In our study the Reid colposcopic index showed most of patients in score 0 to 2 (64.4%), followed by score 3 to 4 in 19.2% and score 5 to 8 in 16.4%. There were similar findings in the reviewed studies by Vijay et al. Out of 51 women having abnormal colposcopic findings, 25.63% were CIN I, 45.45% were CIN I-CIN II and 5.45% were CIN II-CINII.<sup>16</sup> In Zarchi et al study out of 47 patients having abnormal colposcopic findings, 15% were CIN I, 6.5% CIN II and 4.15% were CIN III.<sup>17</sup> In a study by Pimpale et al out of 1931 patients with abnormal Colposcopy, 35.27% were CIN I, 8.97% were CIN II and CIN III.<sup>18</sup> In a study by Durdi et al out of 254 patients having abnormal colposcopic findings, 29.8% were CIN I,

1.9% CIN II and 7.4% CIN III.<sup>15</sup> The histopathology showed normal findings in 46 patients (63%), followed by CIN 1 in 11 (15.1%), CIN 2 in 6 patients (8.2%), CIN 3 and squamous cell carcinoma in 5 patients each (6.8%). In Durdi et al study, out of 254 cases 51 (20.1%) were CIN I, 4 (1.5%) CIN II and 19 (7.4%) CIN III by both colposcopy and histology.<sup>5</sup> In the present study, out of 55 cases 15 (27.27%) were CIN I, 19 (34.54%) CIN II and 5 (9.09%) were CIN III by both colposcopy and histology respectively.<sup>15</sup>

In our study the Pap smear's predictability of cervical malignancy showed that it had a sensitivity of 48.15, it's specificity for identifying patients without cervical malignancy was 84.78%. The positive predictive value was low at 65% and negative predictive value was 73.58%. In our study the colposcopy's predictability of cervical malignancy showed that it had a sensitivity of 88.89%, it's specificity for identifying patients without cervical malignancy was 95.65%. The positive predictive value was low at 92.31% and negative predictive value was 93.62%. There were similar findings in the reviewed studies by Vijay et al had 90.47% and 76.92% specificity respectively and are comparable to previous studies.<sup>16</sup> Positive predictive value is 92.68% while negative predictive value is 71.42% and accuracy is 82.27%. In a study by Karimi-zarchi et al, sensitivity, specificity, and the positive and negative predictive values test of Pap smear were determined to be 18.2, 98.5, 85.7, and 71.3%, respectively.<sup>19</sup> Sensitivity, specificity, and the positive and negative predictive values of colposcopy were calculated as 66.7, 98.94, 80, and 97.9%, respectively. Which is similar to our own study and several meta-analysis studies have shown that the sensitivity and specificity of cervical cytology is relatively low, since sensitivity is 30-87% and specificity is 100 to 86%.<sup>20</sup> The sensitivity and specificity

for colposcopy was 84.2% and 97.6%. 103 while in study of Durdi et al, these are 88.5 % and 86.2% respectively. Other studies like Karimizarchi et al showed sensitivity for Pap smear as 51% and specificity as 66.6% and colposcopy sensitivity as 70.9% and specificity as 44.4%.<sup>19</sup> Ashmita et al showed lower sensitivity for Pap smear as 19.5% and specificity as 83.33% and colposcopy sensitivity as 90.24% and specificity as 72.73%.<sup>21</sup>

The Pap smear's ability for screening is not justified in our study, which was a limitation. Further the sample size though adequate, a larger study may be able to justify the results in a better manner. Further the pathologist was not blinded to the individual procedures and this may have biased the result, which is also a limitation.

## CONCLUSION

This study shows that colposcopy does seem to be better than Pap smear in diagnosing cervical carcinoma and also identifying patients without it. The Pap smear's ability for screening is not justified in our study, often it needs to be clubbing with colposcopy, histopathology to correctly identify everyone with cervical carcinoma and everyone without cervical carcinoma. Therefore, study helps in identifying the effectiveness of various screening modalities especially colposcopy and pap smear, so that these methods may be used effectively and will help in reducing the incidence of invasive cervical carcinoma.

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