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Research Article

## Correlation of diagnostic efficacy of unhealthy cervix by cytology, colposcopy and histopathology in women of rural areas

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### ABSTRACT

**Background:** The objective was to assess the sensitivity and specificity of pap smear and colposcopy and to study the socio demographic parameters of women with unhealthy cervix.

**Methods:** This was a prospective observational study conducted from August 2011 – August 2013 in the Department of Obstetrics and Gynaecology. Pap smear was performed by the conventional method and colposcopy was done for all 200 sexually active women who came with complaints of discharge per vagina, inter menstrual or post coital bleeding. Colposcopy results were analysed. Final correlation of pap smear and colposcopy were based on histopathology.

**Results:** There were 200 samples that were suitable for statistical analysis. The sensitivity of colposcopy was 79.37%, specificity 81.02%, positive predictive value 65.79%, negative predictive value 89.52% respectively and accuracy was 80.5%. Pap smear had a sensitivity of 25.4%, specificity of 99.27%, positive predictive value of 94.12%, negative predictive value of 74.32%, and accuracy of 76.0% respectively.

**Conclusions:** Pap smear had a poorer sensitivity compared to Colposcopy but a better specificity than colposcopy. Hence it may be better to utilise both tests as they complement each other in screening of premalignant lesions of cervix.

**Keywords:** Pap smear, Colposcopy, Premalignant lesion of cervix, Suspicious looking cervix, Atypical squamous cell of undetermined significance, Negative for intra epithelial lesion or malignancy

### INTRODUCTION

It is 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”.<sup>1</sup> If abnormal growth, ulcer, or vasculature is present, the cervix is clinically diagnosed as unhealthy.<sup>2</sup> an “unhealthy cervix” or grossly abnormal cervix can harbour premalignant cervical lesions or invasive carcinoma.<sup>3</sup> The naked eye evaluation of unhealthy cervix is deceptive sometimes and it so happens that intraepithelial lesions are considered as simple cases of erosion due to inflammation.

The basic purpose of screening is to sort out from a large group of healthy persons those likely to have the disease or at increased risk of the disease under study and to bring those who are ‘apparently abnormal’ under medical supervision and treatment.

The long pre – clinical stage of cervical cancer during which precursor lesions can be treated conservatively and successfully make cervical cancer an ideal target for screening and treatment. Success of screening programmes is limited in the villages of India wherein females are illiterate, health infrastructure is mediocre, and cervical screening is unknown.<sup>4</sup>

Cancer uterine cervix is a serious health problem in India.<sup>5</sup> India which accounts for the world's one sixth of the world's population also bears one fifth of the burden of cervical cancer. There are approximately 1,30,000 new cases of cervical cancer every year and the disease is responsible for 20 % of all the female deaths.<sup>6</sup> In India, every 7<sup>th</sup> minute a woman dies due to cervical cancer. It is predicted that figures are expected to double by 2020 if no action is taken.<sup>7</sup>

Cancer cervix accounts for 7% of all malignancies in developed countries which is in sharp contrast to 24% in developing countries. The disparity is almost attributed to primarily differences in screening and treatment of precancerous lesion.<sup>8</sup>

The diagnostic algorithm of various organized screening programmes consists of cytology & colposcopy (which help in detecting the abnormality) & which can be established by histology (grade of lesion).

Colposcopy is an optical method of visualizing lower female genital tract under bright illumination under stereoscopic vision. It is a simple non invasive OPD procedure which helps in determining the location, size and extent of abnormal cervical lesions and serves for detecting the site for biopsies and for selecting the most appropriate treatment.

Colposcopy is complimentary to cytology. Cytology (pap smear) is the lab method while colposcopy is the clinical method of detection. Colposcopy is more than a simple intermediate link between cytologic screening and histologic diagnosis.<sup>9</sup> Colposcopic guided biopsy of suspicious areas provides the final diagnosis and is taken as the gold standard in diagnosis of intra epithelial lesions.

Pap smear has become a routine method of cervical cancer screening. Also, in a developing country like India, cytology based screening programmes are difficult to organize because of absence of trained manpower, infrastructure, logistics, costs involved and has other limitations like low sensitivity and high false negative rates.<sup>10</sup>

This has led to a search for alternative screening methods that can be more cost-effective for application in low-resources settings. Thus this study was done to evaluate the role of colposcopy in the detecting preinvasive and invasive lesions in clinically unhealthy cervix in our rural setup.

## METHODS

Material of the present study was collected from 200 cases visiting the Department of Obstetrics and Gynaecology Acharya Vinoba Bhave Rural Hospital, Sawangi (Wardha) from August 2011 – August 2013.

## Inclusion Criteria

- Sexually active women with “unhealthy cervix” (clinically suspicious cervix, cervical erosions, hypertrophied cervix) on per speculum examination.

## Exclusion Criteria

- Unmarried women
- Pregnant women
- Diagnosed cases of carcinoma cervix
- Post hysterectomy cases

## Methodology

Written and informed consent was taken from all the patients after brief explanation of the procedure. Ethical clearance was obtained from institute's ethical clearance committee. A careful history including demographic data like age, socioeconomic status, education, parity, age at marriage of the patient was taken.

After preliminary inspection of the cervix, pap smear was taken using Ayre's spatula and the scrapings were fixed by dipping in the jar containing equal parts of 95% ethyl alcohol and ether.

Revised Bethesda system<sup>11</sup> was used for describing pap smear results. Pap smear results were classified as NILM, ASC (US), LSIL, HSIL and Carcinoma. LSIL and above lesions were considered as positive on cytology.

For colposcopic examination Dr Camscope colposcope model 150 FC with magnification between 10X to 12.5X was used. Colposcopic examination included:

- Direct examination of cervix with green filter and saline application.
- Examination of the cervix after test with 3% acetic acid, seeing the junction of squamous cell, erosion, papillary lesions, aceto-white areas and vascular design.
- Examination of the cervix after Lugol test in which normal squamous epithelium, which contains glycogen, turns brown.

Findings were recorded and colposcopy diagnosis was made based on Modified Colposcopic Reid Index.<sup>12,13</sup>

## Reid's Colposcopic Index /Score [RCI].<sup>12,13</sup>

Score	Colposcopic findings
0-2	Benign Inflammation
3-5	Low grade lesion
6-8	High grade lesion
>8	Invasive Lesion

Colposcopy Sign	Score 0	Score 1	Score 2
Margin	Condylomatous or micropapillary contour. Flocculated or feathered, jagged, angular, satellite lesion, AWA beyond original squamo-columnar junction.	Regular lesion with smooth indistinct borders.	Rolled, peeling edges, sharp margins.
Colour	Shiny, snow white, areas of faint (semi transparent) whitening.	intermediate shade (Shiny but grey white)	Dull, oyster grey
Vessels	Uniform, fine caliber non dilated capillary loops fine punctuation or mosaic	Absence of surface vessels	Definite, coarse punctuation or mosaic.
Iodine staining	Any lesion staining Mahogany brown; mustard yellow staining by a minor lesion (by first three criteria).	Partial iodine uptake(mottled pattern)	Mustard Yellow staining of a significant lesion (an acetowhite area scoring 3 or more points by the first three criteria)

Low grade lesions and above were considered as positive on colposcopy. Unsatisfactory smears and unsatisfactory colposcopy were excluded from the study.

#### Colposcopy guided biopsy

Biopsy was taken under colposcopy guidance by punch biopsy forceps or four quadrant biopsy. The specimen was sent for histopathological examination in formalin solution and slides were analysed by consultant pathologists.

Biopsy results were categorized as<sup>14</sup> cervicitis with metaplasia, LSIL (correlating to Mild dysplasia), HSIL (correlating to Moderate to severe dysplasia, carcinoma in situ) and carcinoma.

Final correlation of pap smear and colposcopy were based on histopathology.

## RESULTS

White discharge per vaginum was the most common complaint followed by pelvic pain in 39 % cases (Table 1).

**Table 1: Presenting Complaints of 200 Cases.**

Sr. No	Symptoms	No. of Cases	Percentage
1.	White Discharge Per Vaginam	78	39.0%
2.	Pain in Abdomen	41	20.5%
3.	Menstrual Disorders	35	17.5%
4.	Postmenopausal Bleeding	30	15%
5.	Burning Micturition (UTI)	14	7%
6.	Itching Over Genitals	2	1%
	Total	200	100.0%

On per speculum examination, cervical erosion was the most common clinical presentation in 86.5% cases (Table 2).

**Table 2: Per speculum examination of the cervix of 200 cases.**

Clinical finding	Number	%
Cervical erosion	173	86.5%
Hypertrophied cervix	23	11.5%
Suspicious looking cervix	04	2%

Out of the 200 cases, 124 (62%) cases were having benign inflammatory lesion colposcopically and 76 (38%) were atypical colposcopically. Out of these atypical cases, 19% cases were low grade lesions, 18% cases were high grade lesions and 1% were invasive carcinoma (Table 3).

**Table 3: Distribution of colposcopic lesions.**

Sr. No	Reid Colposcopic Score	No. of Cases	Percentage
1.	0- 2 (Benign Inflammatory)	124	62%
2.	3 – 5 (Low Grade Lesion )	38	19%
3.	6- 8 (High Grade Lesion )	36	18 %
4.	>8 (Carcinoma)	2	1 %
	Total	200	100

NILM was encountered in maximum number of cases (166). 8.5% cases were ASC (US) Atypical Squamous Cells of Undetermined Significance, 5% were LSIL, 2.5% were HSIL and only 1% were carcinoma (Table 4).

**Table 4: Distribution of various grades of cytology.**

Sr. No	Types of Smear	No. of Cases	Percentage
1.	NILM	166	83%
2.	ASC(US)	17	8.50%
3.	LSIL	10	5.0%
4.	HSIL	5	2.5%
5.	Carcinoma	2	1.0%
	Total	200	100.0

Out of 200 cases, 68.5% cases were cervicitis (with metaplasia), 16.5% were LSIL (mild dysplasia), 10% were HSIL (moderate – severe dysplasia) and 5% were invasive carcinoma. None of the histopathological report was suggestive of carcinoma in situ (Table 5).

**Table 5: Distribution of various grades of histopathology.**

Sr. no	Histopathology report	No. of cases	%
1.	Cervicitis with metaplasia	137	68.5%
2.	LSIL (Mild dysplasia)	33	16.5%
3.	HSIL (Moderate - severe dysplasia)	20	10%
4.	Carcinoma	10	5%
	Total	200	100.0

Overall the sensitivity of pap smear for detecting lesions above LSIL (mild dysplasia and above) came out to be 25.40%, specificity 99.27%, positive predictive value 94.12%, negative predictive value 74.32% respectively. Accuracy of pap smear in our study was 76% (Table 6, 7).

**Table 6: Correlation of Pap smear with histopathology.**

Pap smear	Histopathological findings			
	Chronic cervicitis with metaplasia	LSIL (mild dysplasia)	HSIL (moderate - severe dysplasia)	Ca
NILM (166)	132 (66%)	20 (10%)	14 (7%)	0 (0%)
ASC(US) (17)	4 (2%)	12 (6%)	0 (0%)	1 (0.5%)
LSIL (10)	0(0%)	1 (0.5%)	2 (1%)	7 (3.5%)
HSIL (5)	1(0.5%)	0 (0%)	3 (1.5%)	1 (0.5%)
Carcinoma (2)	0(0%)	0 (0%)	1 (0.5%)	1 (0.5%)
Total (200)	137 (68.5%)	33 (16.5%)	20 (10%)	10 (5%)
χ <sup>2</sup> -value	173.4			
p-value	<0.0001, Significant			

**Table 7: Sensitivity and specificity of Pap smear.**

Pap Smear	Histopathology		χ <sup>2</sup> -value	p-value
	Positive	Negative		
Positive	16	1	33.76	P<0.0001 Significant
Negative	47	136		
Total	63	137		

	%	95% CI
Sensitivity	25.40	15.27-37.94
Specificity	99.27	96.00-99.98
PPV	94.12	71.31-99.85
NPV	74.32	67.35-80.46
Accuracy	76.00%	

In our study the sensitivity of colposcopy for detecting low grade lesions and above came out to be 79.37%, specificity 81.02%, positive predictive value 65.79%, negative predictive value 89.52% respectively. Accuracy of colposcopy in our study was 80.50% (Table 8, 9).

**Table 8: Correlation of colposcopy with histopathology.**

Reid Colposcopy score	Histopathology			
	Cervicitis (with metaplasia)	LSIL (Mild dysplasia)	HSIL (Moderate - severe dysplasia)	Ca
0-2 (Benign Inflammatory) 124	111(55.5%)	12(6%)	1 (0.5%)	0(0%)
3-5 (Low grade lesion) 38	18(9%)	15(7.5%)	4 (2%)	1 (0.5%)
6-8 (High grade lesion) 36	8(4%)	6(3%)	15 (7.5%)	7 (3.5%)
>8(Ca)2	0(0%)	0(0%)	0 (0%)	2(1%)
Total (200)	137(68.5%)	33(16.5%)	20 (10%)	10(5%)
χ <sup>2</sup> -value	165.2			
p-value	P<0.0001, Significant			

**Table 9: Sensitivity and specificity of colposcopy.**

Colposcopy	Histopathology		$\kappa^2$ -value	p-value
	Positive	Negative		
Positive	50	26	66.79	P<0.0001 Significant
Negative	13	111		
Total	63	137		

	%	95% CI
Sensitivity	79.37	67.30-88.53
Specificity	81.02	73.44-87.21
PPV	65.79	54.01-76.29
NPV	89.52	82.74-89.30
Accuracy	80.50%	

The incidence of preinvasive lesions – LSIL (mild dysplasia) and HSIL (moderate – severe dysplasia) were 16.5% and 10% respectively while the incidence of invasive lesions was 5% in our study (Table 10).

**Table 10: Incidence (%) of preinvasive and invasive lesions.**

Total no of patients	200
Preinvasive Lesions	53(26.5%)
LSIL	33(16.5%)
HSIL	20(10%)
Invasive lesions	10(5%)

## DISCUSSION

Sensitivity of Pap smear was 25.40%; specificity was 99.27%, positive predictive value 94.12 %, negative predictive value 74.32 % for diagnosing LSIL and above lesions.

On comparison with other studies the following results were obtained.

Study	Sensitivity	Specificity	PPV	NPV
Present study	25.40%	99.27%	94.12%	74.32%
Ashmita & Shakuntala <sup>15</sup> et al	19.51%	83.33%	80.00%	23.26%
Mallur et al <sup>16</sup>	41.66%	81.2%	86.21%	78.26%
Jain et al <sup>17</sup>	78%	91.1%	26.9%	11.3%

The accuracy of pap smear was 76% in our study which is comparable to Bhatla et al<sup>18</sup> (89%), Maziah et al<sup>19</sup> (90%), Jain et al<sup>17</sup> (2010) 73.2%. However Malur PR<sup>16</sup> et al and Ashmita and Shakuntala<sup>15</sup> et al concluded the accuracy of Pap smear to be 40% and 33.96% respectively.

Sensitivity of colposcopy was 79.37%; specificity was 81.02%, positive predictive value 65.79%, negative predictive value 89.52% for diagnosing low grade and above lesions.

On comparison with other studies the following results were obtained.

Study	Sensitivity	Specificity	PPV	NPV
Present study	79.37%	81.02%	65.79%	89.52%
Ashmita & Shakuntala <sup>15</sup> et al	90.24%	72.73%	66.67%	86.54%
Mallur PR <sup>16</sup> et al	80%	81.54%	66.66%	89.83%
Pimple SA et al., in 2010 <sup>20</sup>	74.5%	92.9%		

The accuracy of colposcopy in our study was 80.50% which is in parallel to the findings of Maziah et al<sup>19</sup> (94%), Ashmita and Shakuntala<sup>15</sup> et al (86.54%), Mallur et al<sup>16</sup> (80%) and Ancuța Boicea et al<sup>21</sup> (98.3%). Literature is replete with data pertaining to the sensitivity of Pap smear and colposcopy ranging from 27% to 50% vs 44%-89% respectively. Specificity of Pap smear and colposcopy ranging from 19.5%-98.71% vs 52%-93.4% respectively.<sup>22,23</sup>

Overall Pap smear had a poor sensitivity compared to colposcopy, 25.40% vs 79.37% respectively. Pap had a better specificity though not significantly compared to colposcopy, 99.27% vs 81.02% respectively.

The incidence of preinvasive lesion in our study was 26.5%. The incidence of premalignant lesions of the cervix range in various studies range from 8.15% to 35.2%.<sup>15</sup>

The main goal of cervical screening is to identify women with moderate – severely dysplastic lesions (HSIL) (10% women in our study), which are considered to be the true precursors of invasive cancer and require treatment, thus ultimately decreasing morbidity and mortality due to cervical cancer.

## CONCLUSION

The results from the current study support the claim to perform combination screening tests as part of routine screening for cervical cancer screening rather than pap smear alone in order to detect maximum number of

cases with accuracy and minimal loss of patients to follow up.

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