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Original Research Article

Colposcopic evaluation of unhealthy cervix and it's correlation with Papanicolau smear in cervical cancer screening

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ABSTRACT

Background: In present study colposcopic evaluation of unhealthy cervix was done and it's correlation with Papanicolau smear in screening of Cancer cervix. Objective of present study was to critically evaluate the sensitivity and specificity of PAP smear with that of Colposcopy in screening of Cancer Cervix in women with unhealthy cervix.

Methods: 100 women with clinically unhealthy cervix on naked eye examination and / or abnormal symptoms attending Gynaecology Out patient department in 2 years period were subjected to PAP smear, Colposcopy, biopsies under Colposcopic guidance and findings correlated with Histopathology at Govt. Medical college, Aurangabad, Maharashtra, India. The sensitivity and specificity of PAP smear with that of Colposcopy in screening of Cancer Cervix was evaluated.

Results: Both PAP smear and Colposcopy can be reliably used to screen women with premalignant lesions of Cancer cervix.

Conclusions: Colposcopy is a better tool for diagnosis of precursors of Cancer Cervix than PAP Smear and Histopathology of suspected lesion remains the gold standard for final diagnosis.

Keywords: Abnormal cervix, Cervical cancer screening, Colposcopy, PAP smear

INTRODUCTION

Cervical cancer is the commonest malignancy found amongst Indian women and third most common cancer in world. Over 5, 00,000 new cases of invasive cervical cancer are diagnosed annually worldwide.^{1,2}

Cancer cervix has a long phase of pre-invasive disease progresses from cellular atypia to various grades of dysplasia or Cervical Intraepithelial Neoplasia before progressing to invasive cancer. Factors like easy accessibility of cervix, propensity of cervical epithelial cells to exfoliate, rapid turnover of epithelial cells, wide spectrum of histopathological changes, prolonged natural history of disease provide best potential for control of progression of disease by screening of population. PAP smear is cytological examination of exfoliated or

scrapped cells to detect dysplasia. VIA is visual inspection of cervix using acetic acid, a simple screening method which includes 3-5% acetic acid application to the cervix and looking for abnormal aceto-white areas suggestive of dysplasia or invasive disease. VILI is visual inspection of cervix using Lugol's iodine, to identify Schiller's light areas to screen pre-invasive disease. VIA and VILI are both easy to perform and interpret, even by the paramedical staff after providing sufficient training.

By Colposcopy, the Squamo-columnar junction and Transformation zone is identified, acetic acid is then used to assess the details of any lesion and labeled according to IFCPC. Abnormal areas can be target biopsied; treatment of lesions can be done preserving fertility. Cytological abnormality can be confirmed by histopathology of Colposcopically biopsied lesions.

Objective of present study was to critically evaluate the sensitivity and specificity of PAP smear with Colposcopy in screening of Cancer Cervix by correlating with Histopathology in women with unhealthy cervix and abnormal symptoms

METHODS

This prospective clinical study was done at Govt. medical college, Aurangabad, Maharashtra, India from May 2012 to Nov 2014 on 100 women with unhealthy cervix on naked eye examination and abnormal symptoms.

Inclusion criteria

- Age- 20-60 years.
- Women with symptoms like white discharge, post coital bleeding, and inter-menstrual bleeding.
- Women with clinically unhealthy cervix (erosion, bulky cervix, bleeding on touch, ulcer, simple leukoplakia, keratinisation).
- Women with PAP smear showing dysplasia.

Exclusion criteria

- Women with bleeding per vaginum at the time of examination.
- Women with frank invasive cancer.
- Women underwent hysterectomy.
- Pregnant women.

Patients attending Gynecology OPD with complaints like white discharge, backache, pain in abdomen, menstrual disorders, something coming out of vagina, post coital bleeding, post menopausal bleeding were subjected to detail history, clinical and Gynecological examination and naked eye examination of cervix. Inguinal and general Lymphadenopathy, Vulval infections, vaginal inflammation, discharge- it's characters (color, odor, amount, type), cervical inflammation, any growth or bleeding was looked for. PAP smear and Colposcopy was planned in women with abnormal complaints and abnormal cervix on naked eye examination, after consent. PAP smear was not done during menses, during abnormal vaginal bleeding, vaginal douching / sexual intercourse/ antibiotic taken in immediate past. On PAP smear, the Bethesda classification system was used for cytological grading.

Then the women were subjected to Colposcopy examination—machine details as ASCON model AC-3-2000SN with green filter with ELMOCCD, TV camera and CTV display, focal length 250mm and magnification 7.5 X – 10 X and working distance of 25cm. If complete transformation zone was not visualized, Colposcopy was termed as “Unsatisfactory”. The green filter was also used to study vessels. Acetic acid (5%) and Lugol's iodine were used. Abnormal Colposcopy findings like aceto-white area and abnormal iodine staining areas were analyzed by Modified Reid's index.

Cervix biopsy under intramuscular sedation and para cervical block with 1% Lignocaine injection was done in whom either PAP smear or Colposcopy or both were abnormal. Biopsy was not taken in whom both PAP smear and Colposcopy were normal and women were asked to follow up at 4-6 months interval, till 3 subsequent negative PAP smears were obtained. Histopathology was done by Senior pathologist. Sensitivity, specificity, positive predictive value, negative predictive value of Colposcopy in diagnosing lesions which were likely to be CIN I or CIN II or CIN III was calculated. Modified Reid's index on Colposcopy was validated with histopathology and this validation was compared with previous studies.

Statistical analysis

Formulae used for calculation of efficacy

- Sensitivity= $TP/TP + FN$.
- Specificity= $TN/ TN+FP$.
- Positive predictive value= $TP/TP+FP$.
- Negative predictive value= $TP/TP+FN$.
- Accuracy= $TP+TN/ Total$.

Where, TP is true positive, TN is true negative, FP is false positive and FN is false negative.

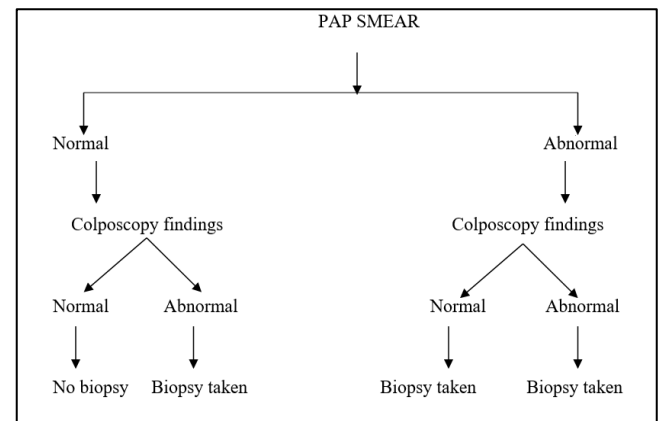


Figure 1: Tree diagram of study protocol.

Unhealthy cervix on naked eye examination.

RESULTS

31-40 age group 39 cases, 42 cases had Kuppaswamy classification stage IV, 51 were Hindus, 64 were from Rural area and only 8 cases were Para 1.

100 Women with abnormal cervix were subjected to PAP smear and Colposcopy. Unsatisfactory Colposcopy in 2 cases were excluded and rest 98 were included in study. Of these 98, biopsy was taken in 55 cases in whom either PAP smear or Colposcopy or both were abnormal and their correlation studied.

Table 1: Sociodemographic profile of cases.

Profile	Class	Number
Age in years	21-30	25
	31-40	39
	41-50	23
	51-60	11
Socio-economic class (Kuppuswamy classification)	I	05
	II	15
	III	17
	IV	42
	V	19
Religion	Hindu	51
	Muslim	34
	Buddhist	13
Residence	Urban	34
	Rural	64
Parity	Para 1	08
	Para 2	45
	Para 3 and above	45

White discharge was the most common (56.12%) symptom followed by pain in Abdomen (16.32%) and Backache (14.28%).

Table 2: Distribution of cases according presenting symptoms.

Presenting symptoms	No. of cases	%
White discharge	55	56.12
Backache	14	14.28
Pain in abdomen	16	16.32
Menstrual disorder	10	10.20
Dyspareunia	07	07.14
Postmenopausal bleeding	06	06.12
Post-coital bleeding	03	03.06

Bulky cervix (34.69%), erosion (30.61%), both bulky cervix with erosion (13.26%), ectropcy (14.28%), congested cervix (6.12%) and 1.02% of simple leukoplakia made an abnormal cervix to naked eye.

Out of 98 PAP smears, 85.71% were normal (also included atypia—with no malignancy) and 11.22% were reported to have LSIL while 3.06% had HSIL reports. According to International Colposcopy terminology (1990), 57% were normal, 41% were abnormal, and 2% were unsatisfactory.

Amongst 41 patients with abnormal colposcopic findings, 13 (23.63%) were likely to be CIN I, 25 (45.45%) were likely to be CIN I-II, 3 (5.45%) were likely to be CIN II-III according to Modified Reid's Index. On histopathological report, CIN I was found in 15 (27.27%), CIN II in 21 (38.18%), CIN III in 5 (9.09%) women. Histopathology was normal in 10 (18.18%), chronic cervicitis in 2 (3.63%), endopapillary cervicitis was found in 1 (1.81%) and squamous cell carcinoma in 1 (1.81%) women.

Table 3: Correlation between PAP smear report and colposcopy finding.

PAP smear	Colposcopic finding				Total
	CIN I	CIN II	CIN III	Normal	
Normal	11	16	0	14	41
ASCUS	0	0	0	0	0
LSIL	2	8	2	0	12
HSIL	0	1	2	0	3
Sq. cell Ca	0	0	0	0	0
Total	13	25	4	14	56

Out of 55, PAP smear reports abnormal were for 14 women, in whom 11 were having LSIL, and 3 were having HSIL, 41 reported normal on PAP smear.

While, colposcopy was abnormal for 41 women and 13 of them were likely to be having CIN-I, 25 were likely to be having CIN-II, and 3 were likely to have CIN-III, and 14 were having normal colposcopic findings, according to Modified Reid's index.

Table 4: Correlation between PAP smear report and histopathological report.

PAP smear report	Histopathological report							Total
	CIN I	CIN II	CIN III	Sq. cell Ca in situ	Endopapillary cervicitis	Chr. Cervicitis	Normal	
Normal	15	14	0	1	1	2	8	41
ASCUS	0	0	0	0	0	0	0	0
LSIL	0	7	2	0	0	0	2	11
HSIL	0	0	3	0	0	0	0	3
Sq. cell Ca	0	0	0	0	0	0	0	0
Total	15	21	5	1	1	2	10	55

Amongst 41 women with normal PAP smear, 15 had CIN I, 14 had CIN II, None of them had ASCUS on PAP smear.

Out of 11 women having LSIL on PAP smear, 7 had CIN II, 2 had CIN III. Out of 3 women having HSIL on PAP smear, all had CIN III on histopathology.

Table 5: Correlation between colposcopic findings and histopathology.

Colposcopic findings	Histopathological report							Total
	CIN I	CIN II	CIN III	Sq. cell Ca	Endopapillary Cervicitis	Chr. Cervicitis	Normal	
Likely to be CIN I (0-2)	13	0	0	0	0	0	0	13
Likely to be CIN II (3-4)	0	19	3	0	1	2	0	25
Likely to be CIN III (5-8)	0	0	2	1	0	0	0	3
Normal	2	2	0	0	0	0	10	14
Total	15	21	5	1	1	2	10	55

Table 6: Evaluating validity of colposcopy using modified Reid's Index with histopathology.

Modified Reid's Index	Over estimation	Accurate estimation	Under estimation	Total
Likely to be CIN I (0-2)	0	13	2	15
Likely to be CIN II (3-4)	3	19	3	25
Likely to be CIN III (5-8)	0	2	3	5
Total	3	34	8	45

Table 7: Sensitivity and specificity of PAP smear in diagnosing CIN.

	Percentage
Sensitivity	26.66
Specificity	80.00
Positive predictive value	85.71
Negative predictive value	19.51
Accuracy of PAP	36.36

Out of 13 women who were likely to be CIN I on colposcopy, all were having CIN I, and in 2 women having normal colposcopic finding were having CIN I on histopathology.

Table 8: Sensitivity and specificity of Colposcopy in diagnosing CIN.

	Percentage
Sensitivity	90.47
Specificity	76.92
Positive predictive value	92.68
Negative predictive value	71.42
Accuracy of colposcopy	82.27

Out of 25 women who were likely to be CIN I-II on colposcopy, none were having CIN I, 19 were having CIN II, 3 of them were having CIN III and 1 was having endopapillary cervicitis and 2 were having chronic cervicitis. Out of 3 women who were likely to be CIN II-III on colposcopy, on histopathology 1 was having squamous cell carcinoma, 2 were having CIN III

Out of 14 women normal on colposcopy, 10 were normal on histopathology. Out of 45 women 34 were estimated accurately, 3 women were overestimated and 8 were underestimated.

DISCUSSION

Routine screening with PAP smear has high false negative rates from 1.8 to 20%. Colposcope, has the ability to localize and determine the extent of all lesions not seen on naked eye are detected in single sitting. Colposcopy helps in selecting the site of biopsy, patients for conservative treatment of CIN, follow up of Intraepithelial neoplasia and early invasive carcinoma, evaluation of Adenosis.

The mean age of women in Our study was 36.5 years. This corresponds to 34.5, 36 and 36 in studies done by Pandey et al, Goel et al, Durdi G et al respectively.³⁻⁵

The mean parity of women in Our study was 3. This corresponds to 2.7, 2 and 3 in studies done by Goel et al, Durdi G et al and Ashmita D et al respectively.⁴⁻⁶

The Indian registries show a significantly lower incidence of cervical cancer in Muslims compared to other religious groups.⁷ Mohanty J et al had zero Muslims.⁸ Swarnakumari et al had 25% Muslims and present study had 34.69% Muslims, 52% Hindus and 13.26% others.⁹ Probably, early marriages, low socio-economic status, poor hygiene offset the advantages of Circumcision. Mohanty et al had 55%, Ashmita D in had 46.11% and

present study had 62.29% women from low socio-economic class.^{6,8} Thus, low income favors increase in cervical cancer. The present study had 56.12% women with white discharge for more than 1 year and 7.14 % with post coital bleeding. Durdi G et al in 66% and 5.1% while Bharani Bharati et al in had 52% and 6.28% respectively for the same.^{5,10}

In study by Denny L 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.¹¹ In study by Shastri SS et al, 95.4% were normal, 0% had ASCUS, 0.026% reported LSIL, 0.01% as HSIL and 0.0007% had Invasive carcinoma.¹² In study by Durdi G et al, 35 % were normal, 29.2% had ASCUS, 23.8 % reported LSIL, 12% as HSIL and 0.0% had Invasive carcinoma.⁵ In the present study, 85.71% were normal, 0% had ASCUS, 11.22% reported LSIL, 12% as HSIL and 0.0% had invasive carcinoma. Differences in PAP

smear reporting in different studies are due to differences in sampling, staining and fixation techniques and observer's errors.

We had "unsatisfactory colposcopy" in present study to 2%. This was 7.4% in Bharani Bharati et al, 5.22% in Durdi G et al, and 2% in Pravin S et al in respectively.^{5,9,10}

Bharati B et al had 22.2%, Sankarnarayan R et al had 16.1%, Sherwani RK et al (12) had 31.1% while Present study had 42%, respectively as "abnormal colposcopic" findings.^{10,3,14} The percentage of Vascular abnormalities were respectively 12.8%, 11.1% and 7.14% in studies done by Arora R et al, Sherwani RK et al and in Present study.^{13,15}

Table 9: Distribution of cases according to histopathological findings.

Name of study	Normal	Benign	CIN I	CIN II	CIN III	Invasive carcinoma
Zarchi M et al ¹⁶	193 (90.6%)	-	16 (6.5%)	2 (0.9%)	-	2 (0.9%)
Pimpale SA et al ¹⁷		1576 (85.14%)	113 (4.32%)	56 (3.02%)	50 (2.7%)	56 (3.02%)
Durdi GS et al ⁵	-	167 (66%)	60 (23.6%)	8 (3%)	19 (7.4%)	
Present study	10 (18.18%)	3 (5.45%)	15 (27.27%)	21 (38.18%)	5 (9.09%)	1 (1.81%)

Table 10: Correlation between PAP smear report and colposcopy finding.

Pap smear	Colposcopic finding by Modified Reid's Index					
	Asmita D et al			Present study		
	0-2	3-6	>6	0-2	3-6	>6
Normal/NLIM	27.9	51.2	20.9	26.82	39.02	0
ASCUS	00	100	00	00	00	00
LSIL	00	66.7	2.3	18.18	72.72	18.18
HSIL	00	66.7	00	00	33.33	66.66
Unsatisfactory smear	00	00	100	Not included in study criteria		

Percentage of LSIL is more in present study.

Table 11: Correlation between PAP smear report and histopathology report.

PAP smear report	Histopathology report								
	Ashmita D				Present study				
	Normal	CIN I	CIN II-III	Benign	Normal	CIN I	CIN II-III	Benign	Sq. cell
Normal	23.3	4.7	0	67	19.51	36	34	7	0.02
ASCUS	0	33	0	67	0	0	0	0	0
LSIL	0	0	0	100	18	81	0	0	0
HSIL	0	0	100	0	0	0	100	0	0
Sq. cell Ca	-	-	-	-	0	0	0	0	0

In Zarchi MK 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.¹⁶ In a study by Pimpale

SA et al out of 1931 patients with abnormal Colposcopy, 35.27% were CIN I, 8.97% were CIN II and CIN III.¹⁷

In a study by Durdi GS et al out of 254 patients having abnormal colposcopic findings, 29.8% were CIN I, 1.9% CIN II and 7.4% CIN III.⁵ In present study 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-CIN III.

Sampling variation and difference in inclusion criteria may produce disparity in Colposcopic findings of different studies.

So, the percentage of LSIL and HSIL that reported CIN on histopathology is more in Present study. The differences in the Observations of two studies is due to differences in cytological reporting of smears and subjective variations in Colposcopy findings in both above tables. In Durdi G 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.⁵

In 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.

Sampling variation may lead to disparity between results of different studies.

Table 12: Incidence of accurate, under and over estimation in different studies.

Estimation		CIN I	CIN II	CIN III
Durdy G et al	Accurate	51 (67.1%)	4 (80%)	19 (100%)
	Over	22 (29%)	--	--
	Under	3 (3.9%)	1 (20%)	--
Present study	Accurate	13 (86.66%)	19 (76%)	3 (60%)
	Over	00	3 (12%)	00
	Under	2 (13.33%)	3 (12%)	2 (40%)

In present study, no case was overestimated by Colposcopy and Results were comparable with other studies.

Statistical parameters for PAP smear in different studies

Basu and Sankarnarayan et al gave 29.5% sensitivity and 92.3% specificity.¹⁸ Goel A gave 50% sensitivity and 97% specificity.⁴ Similarly, Surendra S et al gave 57.4 % Sensitivity and 98.6% Specificity.¹² Sherwani RK et al had 53.7% and 50%, Ghosh P et al had 52.6% and 99.1%, while present study had 26.66% and 80% Specificity respectively.^{13,19} Thus, we found them lower than previous studies. The differences in sensitivity and specificity of different studies is due to differences in

laboratory values and availability of trained personnel. Positive predictive value is 85.71% while negative predictive value is 19.51% and accuracy is 36.36%.

Statistical parameters for colposcopy in different studies

In the study of Ghosh P et al, in sensitivity and specificity for coploscopy was 84.2% and 97.6%.¹⁹ while in study of Durdi G et al, these are 88.5 % and 86.2% respectively.⁵ Present study had 90.47% and 76.92% specificity respectively and are comparable to previous studies. Positive predictive value is 92.68% while negative predictive value is 71.42% and accuracy is 82.27%.

CONCLUSION

Both PAP smear and colposcopy can be used reliably to screen women having abnormal symptoms for diagnosing premalignant lesions. Critical evaluation of the statistical analysis says that colposcopy can be used as a better tool than PAP smear for diagnosis of precursors of carcinoma of cervix. However, the accuracy of colposcopy is dependent on the training, expertise and skill of the Operator with emphasizes proper training, certification and experience of Colposcopist.

Colposcopy eliminates the need for repeated follow up as in PAP smear which has low sensitivity. As the number of cases studied is less, more cases should be studied for better conclusions. Histo-pathology of suspected lesion remains gold standard for final diagnosis of precancerous lesions, in view of the false positive and false negative cases in this study.

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