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Original Research Article

Association of colposcopy with pap smear in evaluation of unhealthy cervix- a prospective study

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ABSTRACT

Background: Unhealthy cervix is a very common finding in our country due to poor genital hygiene, malnutrition and multiparity. The cervix is the commonest site for female genital cancer. 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. An "unhealthy cervix" or grossly abnormal cervix can harbour premalignant cervical lesions or invasive carcinoma. That's why present study was planned to evaluate colposcopy role in relation to PAP smear in symptomatic patients.
Methods: The present study was a prospective, analytical study. After institutional committee approval this study was conducted from January 2021 to January 2022 in department of obstetrics and gynecology at RNT Medical college, Udaipur. Total 140 women were assessed for this study.
Results: Our study results based on combined cytology and colposcopy with histopathology- sensitivity =100%, specificity =87.03%, PPV=84.09%, NPV=100%, accuracy =92.30%. The result of current study supports that, PAP smear demonstrates premalignant and malignant lesions, whereas colposcopy shows the exact site for biopsy for histopathological diagnosis and for further management.
Conclusions: Colposcopy and cytology are complementary to each other. Best result in early detection of pre-invasive carcinomas could be obtained by combined use of cytology, colposcopy and colposcopy guided biopsy. So, use of 'single visit approach' in which cytology, colposcopy and guided biopsy all are done in one setting and treated accordingly in resource poor countries will enable maximum utilization of scarce medical resources.

Keywords: Colposcopy, Pap smear, Unhealthy cervix

INTRODUCTION

Unhealthy cervix is a very common finding in our country due to poor genital hygiene, malnutrition and multiparity. The cervix is the commonest site for female genital cancer. 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".[1] If abnormal growth, ulcer or vasculature is present, the cervix is clinically diagnosed as unhealthy.[2] An "unhealthy cervix" or grossly abnormal cervix can harbour premalignant cervical lesions or invasive carcinoma.[3] 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.

According to Indian Council of Medical Research (ICMR), the incidence of cervical cancer in India varies from 20 to 35 per 100,000 women between the age group

of 35 and 64 years while in developed countries it is as low as 1 to 8 per 100,000 women. In India, 132,000 new cases are reported annually with 74,000 deaths occurring each year hence, every 7th minute a woman dies due to cervical cancer.[4]

Despite the fact that more than 80% of cervical cancer cases are in developing countries, only 5% of women there have ever been screened for cervical abnormalities.[5]

The easy accessibility of the cervix to inspection, palpation and application of cytological and tissue sampling procedures has led to extensive screening programs for early detection and treatment of the disease, thereby contributing to a remarkable lowering of incidence, and mortality from cervical cancer. This screening can be effectively done by cytology (Pap smear), colposcopy and colposcopy directed cervical biopsy.

The Papanicolaou (PAP) smear is a simple, safe, non-invasive, and effective method for detection of precancerous, cancerous and noncancerous changes in the cervix and vagina.[6]

Reporting of PAP smears is done by using The Bethesda System, prior to which many classification systems were developed. To check the sensitivity and specificity of Bethesda system, the cytological findings have to be correlated with histology considering histopathology as gold standard.

International agency of research on cancer (IARC) reported 93% reduction in the incidence of cervical cancer when women aged between 35 and 64 years were screened at 1 to 3 yearly, 84% reduction when screened 5 yearly and 64% reduction when screened 10th yearly.

In 1925, Hinselmann first hypothesized visualization of cervical epithelium under magnification. Colposcopy provides a unique method to study the benign and premalignant lesions.[7] The colposcope is a binocular microscope used for direct visualization of the cervix enabling a view of the transformation zone which is the junction between the squamous and columnar epithelium.

Colposcopy is simple, non-invasive procedure which helps in determining the location, size and extent of abnormal cervical lesions and serves for detecting the site for biopsies, which can be done in a single visit making it probably a better screening modality for premalignant lesions in symptomatic patients.

Colposcopy is complementary to cytology. Cytology (PAP smear) is the lab method while the colposcopy is the clinical method of detection. The final diagnosis must be made on histopathological examination.[8]

Despite the introduction of PAP smear and colposcopy for many years still the mortality and morbidity with cervical cancer is 274,000 and 493,000 respectively each year in India.[9]

To best of our knowledge, no screening test is yet 100% specific. Thus, there is scope for evaluating existing modalities of screening cancer cervix. That is why present study was planned to evaluate the role of colposcopy in relation to PAP smear in symptomatic patients.

METHODS

Source of data

After institutional ethical committee approval this study was conducted at in Department of Obstetrics and Gynaecology of RNT Medical college, Udaipur from January 2021 to January 2022.

Study design

The present study was a prospective, analytical study.

Sample size

Total 140 women were assessed for this study by taking 5% absolute error and 10% prevalence at 95% CI.

$$n = \frac{Z_\alpha^2 P(1-P)}{E^2}$$

Sample size was 140

Where Zα=95% confidence level equals to 1.96. P-prevalence 10%, E- Absolute error 5%

Inclusion criteria

Women of age between 20-65 year, women with symptoms like vaginal discharge, postcoital bleeding, postmenopausal bleeding, intermenstrual bleeding, women with abnormal cervical finding on per speculum examination.

Exclusion criteria

Menstruating women, women with diagnosed cancer, pregnant women, post hysterectomised women.

Methodology

Selection of cases was done according to the inclusion criteria and exclusion criteria. A detailed history regarding presenting complaints e.g., vaginal discharge, post coital bleeding, irregular bleeding, postmenopausal bleeding was taken. A detailed medical, surgical, obstetric and menstrual history was taken. Informed consent was taken from each woman.

All women were examined in post menstrual period. Detailed general examination for pallor, oedema, pulse rate and detailed systemic examination was done. Per speculum and per vaginal examination was done.

PAP smear sample collection

Informed consent was taken. Patient was put in dorsal position, labia aparted and the Cusco's self-retaining speculum gently introduced without the use of lubricant or jelly. Cervix was exposed, the squamo-columnar junction was now scraped with ayre's spatula by rotating the spatula all around. The scrapings were evenly spread onto glass slide, and immediately fixed by dipping the slide in the jar containing equal parts of 95% alcohol and ether.

Smear is classified as per Bethesda system of classification- 1) within normal limits, 2) reactive and reparative changes (NILM in Bethesda classification 2001), 3) ASCUS, 4) LSIL, 5) HSIL, 6) SCC.

Colposcope

The colposcope is a binocular instrument providing a magnification of 10-20 times. The purpose of colposcope is to map the abnormal areas so that selective biopsy can be obtained under magnification. Basically, a colposcope is composed of a single or double main objectives lens, a magnification changer, binocular tubes with prism, eyepieces, dioptre adjustment and a green filter to study blood vessel patterns.

Colposcopy

Informed consent was taken. Patient was examined in dorsal position. Patient was reassured and the procedure explained. Cusco's speculum was inserted after examining vulva and vagina and the colposcope focused on the external os at a distance of about 20 cm. The external os was moistened with normal saline. This increases the transparency of cervix and provides a clearer view of vascular pattern when visualized with green filter. Freshly prepared 3-5% acetic acid was applied on the cervix for 1 minute. After 30 seconds the epithelial changes were noted and recorded. Acetic acid precipitates protein and abnormal epithelium appears white. Finally, the cervix was painted with Schiller's iodine which differentiates the darker glycogen-laden cells from the paler glycogen-free cells. Biopsy was then taken from abnormal areas.

After histological examination, they were finally grouped into: i) normal, ii) changes consistent with repair (chronic cervicitis), iii) CIN- I, II, III, iv) micro-invasive cancer, v) invasive cancer.

RESULTS

A total of 140 women were taken for this study. Majority of the patients were of age group 31-40 years. Mean age was 41.23 years.

For test of significance, here we use "Chi-square distribution (χ^2 test)".

Table 1: Age distribution among the patients.

Age (in years)	No. of population	Percentage
21-30	16	11.42
31-40	52	37.14
41-50	47	33.57
51-60	21	15.0
≥61	4	2.85
Total population	140	100
% Mean±SD	41.23±9.002 years	
Min. and max.	25 and 62 years	

χ^2 cal =38.302 [at 95% confidence limit, with degree of freedom $(n_1 - 1).(n_2 - 1) = 4$, χ^2 tab =9.488] χ^2 cal >χ^2 tab (38.302>9.488) at 5% level of significance Hence, there were statistically significant differences among the patients according to their age, with p value (p<0.0001). In 31 years to 50 years percentage of patients were much more than other age group.

Table 2: Parity distribution among the patients.

Parity	No. of population (n=140)	%
Nullipara (P0)	2	1.42
Primipara (P1)	15	10.71
Multipara (2-4)	101	72.14
Grand multipara (>4)	22	15.71

Majority of the patients were multipara (para 2-4). For test of significance, here we use "Chi-square distribution (χ^2 test)".

χ^2 cal = 105.72 [at 95% confidence limit, with degree of freedom $(n_1 - 1).(n_2 - 1) = 3$, χ^2 tab =7.815] χ^2 cal >χ^2 tab (105.72>7.815) at 5% level of significance

Hence, there were statistically significant differences among the patients according to their parity, with p value (p<0.0001). In multiparaous and grand multiparaous group percentage are much more than other group.

Distribution according to type of residence

Among 140 patients, majority (88) were from rural areas while 52 patients belonged to urban area.

Rate of literacy among the patients

Out of 140 patients only 38 (27.14%) were illiterate while majority of the population was literate.

Socio-economic status

The socio-economic distribution of cases is done according to Kuppuswamy's socio-economic scale.

Majority of the patients in the present study were from the low socio- economic status (70.00%) and very few patients belong to high socio-economic status (5.71%).

Active married life

As evident from the table, majority of the patients had active married life of >10 years which shows that duration of marriage and duration of exposure to sexual intercourse has a distinct role in genesis of cervical dysplasia.

Distribution of cases as per symptoms

Most common presenting complaint among the patients was white discharge per vagina (51.42%) followed by irregular bleeding per vaginum (19.28%). 17.14% patients presented with pain lower abdomen, 8.57% with postmenopausal bleeding and only 3.57% presented with post-coital bleeding.

Table 3: Per speculum examination of the cervix.

Appearance of cervix	Number	Percentage
Erosion	55	39.28
Congestion	31	22.14
Hypertrophied	28	20
Hypertrophied +erosion	16	11.42
Hypertrophied + congestion	5	3.57
Polyp	5	3.57
Total	140	100

Majority of the patients (39.28%) were found to have erosion in the per speculum examination, followed by congestion in (22.14%), hypertrophied cervix in (20%) and hypertrophy + erosion in 11.42%. Hypertrophy + congestion and polyp in the cervix was present in 3.57% patients each type.

Table 4: PAP smear findings among the patients.

PAP smear	No. of population (n=140)	Percentage
Normal	15	10.71
Inflammatory	81	57.85
ASCUS	6	4.28
LSIL	24	17.14
HSIL	14	10.0
SCC	0	00

Pap smear was normal in 10.71%, inflammatory in 57.85%, ASCUS was reported in 4.28%, LSIL in 17.14% and HSIL in 10.0%. No case of SCC was reported in Pap smear.

Table 5 shows that total number of aceto-white areas =93 =66.42%. Total number of punctations =42 =30%. Total mosaic =23 =16.42%.

Table 5: Colposcopic findings among the patients.

Colposcopic findings	No. of population (n=140)	Percentage
Normal	47	33.57
Aceto-white	42	30.0
Aceto-white +punctation	28	20.0
Aceto-white +mosaic	9	6.42
Aceto-white +mosaic +punctation	14	10

Histopathological findings

On histopathological examination 16.42% patients were normal, 45.71% had chronic cervicitis, 22.14% had CIN-1, 9.28% had CIN-2, 4.28% had CIN-3 and 2.14% had SCC.

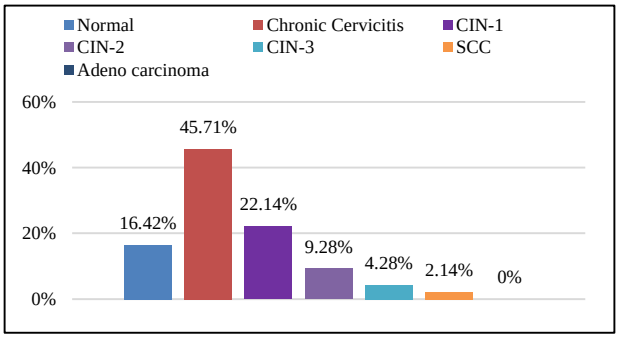

Figure 1: Histopathological findings.

Table 6: Correlation of combined cytology and colposcopy with histopathology.

		Histopathology		Total
		Positive	**Negative**	
Cytology + Colposcopy	Positive	37	7	44
	Negative	0	47	47
Total		37	54	91

True positive= 37, true negative= 47, false positive= 7, false negative= 0.

Sensitivity, specificity, PPV and NPV of combined cytology and colposcopy with histopathology- sensitivity= TP/TP+FN =100%, specificity= TN/TN+FP= 87.03%, PPV= TP/TP+FP = 84.09%, NPV= TN/TN+FN =100%, accuracy= TP+TN/TP+TN+FP+FN=92.30%

DISCUSSION

The present study was conducted to correlate the Pap smear findings and colposcopic findings in relation to histopathological findings and to calculate sensitivity, specificity and accuracy of Pap smear and colposcopy in diagnosis of cervical neoplasia in cases of unhealthy cervix. An attempt has been made to compare the various

parameters in the study with the results obtained by different workers. In the present study, 140 cases were studied.

Age

distribution of cases according to the age. A total of 140 women were enrolled in this study with an age range of 21-65 years.

Table 7: Comparison of mean age in different studies.

Age	Range	Mean age
Kohli et al[13]	30-49 years	39.91
Joshi et al[15]	41-50 years	-
Akhter et al[16]	-	44
Kaveri et al[17]	31-40 years	44.18
Nayani et al[18]	31-50 years	-
Chandru et al[24]	-	50
Present study	31-50 years	41.23

The mean age in the present study was 41.23 years which was comparable with the mean age of other studies.[13,15-18,24] All these studies indicate that carcinoma cervix is common in middle age group.

Parity

It shows that majority of the patients were multipara i.e., para 2-4 which constituted 72.14%. It was comparable with the study done by Kaveri et al (73.4%), Gopal et al (76.3%) and Chandru et al (95.6%).[10,17,24]

Socio-economic status

The socio-economic distribution of cases is done according to Kuppuswamy's socio-economic scale. Majority of the patients in the present study were from the low socio- economic status (70.00%) and very few patients belong to high socio-economic status (5.71%). In a similar study by Kaveri et al 63.34% patients were from the low socio-economic class and 3.33% from the upper socio-economic class, which was comparable with the present study.[17] Gopal et al study also shows majority of the cases from low socio-economic class.[10]

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.

Education

Regarding the literacy, 27.14% of the population in the present study was illiterate, 58.85% population belonged to those studied upto 12th class and 15% of the study population were graduate. Kaveri et al showed illiteracy rate of 29.16% which was comparable to the present study.[17] Rate of illiterate patients was also high in Nayani et al study.[18]

The higher rate of educated people in our study indicates the awareness of screening programs among the people. Education level indicates the awareness of coming to hospital for check up and ready for screening test after counselling.

Active married life

Duration of marriage and duration of exposure to sexual intercourse has a distinct role in genesis of cervical dysplasia. majority of the patients were those who had married life of 16-20 years (32.85%) followed by those having active married life >20 years (24.28%). Least number of patients (5.71%) was having married life less than 5 years. Results of present study was comparable with Nayani et al in which 32.69% patients had married life of 10-20 years.[18] Shrivastava et al also shows the direct relation of CIN with the increasing number of active married life.[19]

Symptoms

Among the complaints, most of the patients complaint of white discharge per vaginum (51.42%), followed by irregular bleeding per vaginum (19.28%), pain lower abdomen was present in 17.14% patients, 8.57% patients presented with post-menopausal bleeding and the least common complaint was of post coital bleeding (3.57%).

Table 8: Symptoms were compared with the other studies.

Studies	Symptoms				
	White discharge per vaginum	**Irregular bleeding per vaginum**	**Pain lower abdomen**	**Post-menopausal bleeding**	**Post-coital bleeding**
Ramesh et al[9]	50%	16.25%	16.25%	3.75%	6.25%
Gopal et al[10]	56%	11%	-	5%	7%
Joshi et al[15]	40%	16%	20%	15%	-
Kaveri et al[17]	68.3%	51.7%	-	14.2%	8.3%
Mohan et al[23]	91%	-	-	-	-
Present study	51.42%	19.28%	17.14%	8.57%	3.57%

As evident from the Table 8, white discharge per vaginum was the most common symptom in all the other studies.[9,10,15,17,23] High number of patients with irregular bleeding per vaginum in Kaveri et al may be explained because in their study majority of the patients had frank growth in the cervix, which may bleed on touch.[17]

Pain lower abdomen was comparable with the other studies.[9,15]

Postmenopausal bleeding per vaginum was also comparable with the other studies except with that of Ramesh et al (3.75%) and Gopal et al (5%).[9,10,15,17]

Correlation between Pap smear and colposcopy

In result section shows that 28.51% of abnormal Pap smears findings correlated with the abnormal colposcopic findings which was comparable with that found in the study of Joshi et al.[15]

Correlation between Pap smear and histopathology

Study results showed the correlation of Pap smear and histopathology. It is evident from both the tables that Pap smear and histopathology are significantly correlated to each other ($p<0.0001$). Studies of Chaudhary et al ($p<0.0001$), Suguna et al ($p<0.01$) and Shashwat et al ($p=0.0001$) also shows similar correlation of Pap smear and histopathology.[12,14,21]

Correlation between colposcopy and histopathology

Statistics reveal that in the present study, colposcopy and histopathology are significantly correlated with a p value of <0.05, which was comparable with the study of Chaudhary et al ($p<0.0001$), Suguna et al ($p<0.01$) and Shashwat et al ($p=0.0001$).[12,14,21]

Sensitivity, specificity, PPV, NPV and accuracy of PAP smear

On applying statistics, it was found that sensitivity, specificity, PPV, NPV and accuracy of Pap smear in the present study was 69.81%, 91.95%, 84.09%, 83.33% and 83.57% respectively.

On comparing it with other studies, as seen in Joshi et al, Kaveri et al, Vidya Rani et al, Gohil et al, Mohan et al studies, sensitivity of Pap smear was less than the specificity.[15,17,20,22,23] All the other parameters in the present study were also comparable with the Joshi et al, Kaveri et al, Vidya Rani et al.[15,17,20]

Sensitivity, specificity, PPV, NPV and accuracy of colposcopy

Statistics show that the sensitivity, specificity, PPV, NPV and accuracy of Colposcopy in the present study was 100%, 54.02%, 56.98%, 100% and 71.42% respectively.

Table 9: Statistics of other studies.

Study	Colposcopy				
	Sensitivity	**Specificity**	**PPV**	**NPV**	**Accuracy**
Kohli et al[13]	100%	57.14%	50%	100%	70%
Suguna et al[14]	95.23%	60.75%	39%	97.95%	68%
Shashwat et al[21]	85.9%	74.3%	59.8%	92.2%	77.9%
Gohil et al[22]	87.87%	72.72%	-	-	-
Chandru et al[24]	97.37%	88.46%	-	-	-
Prasad et al[25]	83.3%	72.72%	-	-	-
present study	100%	54.02%	56.98%	100%	71.42%

From all the above studies it is evident that sensitivity of colposcopy is better than its specificity and also that the sensitivity of colposcopy (100%) is higher than that of Pap smear (69.23%) in the present study.

Sensitivity, specificity, PPV, NPV and accuracy of the present study was comparable with the others except in Suguna et al in which PPV is slightly less as compared to present study which may be due to large sample size of their study.[13,14]

Correlation of combined cytology and colposcopy with histopathology

Sensitivity, specificity, PPV, NPV and accuracy of combined cytology and colposcopy with histopathology was calculated in the present study which was found to be 100%, 87.03%, 84.09%, 100% and 92.30% respectively and that it was more than individual cytology and colposcopy suggesting that both cytology and colposcopy are complementary to each other. Shashwat et al study also concluded the same and emphasized on combined use of cytology and colposcopy.[21]

The study included a small number of populations, so the results of cytology and colposcopy may vary in wider range of population.

CONCLUSION

A detailed colposcopic evaluation of the cervix with a guided biopsy is an important diagnostic method for the detection of preneoplastic and early cervical cancer. The result of current study supports that, PAP smear demonstrates of premalignant and malignant lesions, whereas colposcopy shows the exact site for biopsy for histopathological diagnosis and for further management. Colposcopy and cytology are not competitive method, but complementary to each other. Best result in early detection of pre-invasive carcinomas could be obtained by combined use of cytology, colposcopy and colposcopic directed biopsy.

So, use of 'single visit approach' in which cytology, colposcopy and guided biopsy all are done in one setting and treated accordingly in resource poor countries like ours will enable maximum utilization of scarce medical resources. More research on large cohort is needed to fully categorize the use of colposcopy in symptomatic women.

Recommendations

Since the results of combined cytology and colposcopy are better than the individual cytology and colposcopy, hence patients should be advised to undergo both the tests. Cytology, colposcopy and histopathology should be performed in a single visit only because in our country most of the patients do not turn for the follow up. Larger number of populations should be included in order to further evaluate the results of these tests. Efficacy of screening can be increased by HPV kit + cytobrush in single sitting, Truscan, Digital Colposcopy with automated analysis and tumour markers. Newer HPV vaccine- we must recommend vaccination at early age group to prevent this deadly and preventable disease with advance nonavalent vaccine. "Vaccination and screening are the two keys to lock carcinoma cervix".

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