ORIGINAL ARTICLE

A Study on Screening of Premalignant Conditions of Uterine Cervix Using Pap Smear Test in the Tertiary Care Centre

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Abstract:

Introduction:
Cervical cancer has a high incidence in developing countries like India. It accounts for one- quarter of the worldwide burden.HPV virus is an etiological factor for cervical carcinoma. Pap smear is a gold standard screening tool for early detection of precancerous lesions in the uterine cervix. The aim of the study is to screen precancerous lesions of cervix using Pap smear test in tertiary care setup.

Materials and Methods:
After ethical approval, outpatients attending gynaecology clinic with a variety of complaints were enrolled in the study. Pap smear was taken and sent to pathology laboratory for cytological examination. Report received in due time were plotted in Excel sheet according to the proforma. Statistical analysis was done by IBM SPSS 20.0 version software.

Results:
In our study 269 (38.2%) participants were in the 31-40 years age group. Early age at marriage was noted in 73(10.35%) participants. Two hundred and sixty–three (37.3%) participants complained of white vaginal discharge. Cervical erosion was observed in 238 (33.75%) participants. The epithelial abnormalities ASCUS, LSIL, and HSIL were found in 1.98%, 4.11%, and 0.7% of the participants respectively. The most common clinical lesion seen in patients with LSIL was erosion over cervix followed by cervicitis and cervix bleeding on touch. The most abnormal Pap smear findings of HSIL were found in patients with complains of foul smelling / blood stained discharge.

Conclusion:
Pap smear testing is a simple, economical and safe tool for detecting precancerous cervical epithelial lesions. It should be established as a routine screening procedure to reduce the treatment burden, morbidity, and mortality.

Keywords: Cervical cancer, Pap smear

Introduction:
Worldwide cervical cancer rank second in incidence behind breast cancer. In India, cervical cancer incidence is highest among all the cancers occurring in females. In contrast to developed countries, cervical cancer is a public health problem in developing countries like India, so much so that India alone accounts for one-quarter of the worldwide burden of cervical cancers.[1,2]

It is one of the leading causes of cancer mortality, accounting for 17% of all cancer deaths among women aged between 30 and 69 years. It is estimated that cervical cancer will occur in approximately 1 in 53 Indian women during their lifetime compared with 1 in 100 women in additional developed regions of the world.[2] More than one-fifth of all cervical cancer deaths occur in India.[3] Every year, 122,844 women in India are diagnosed with cervical cancer, and 67,477 women die from the disease.[4] HPV infection is the main etiological factor in majority of the cases.[5,6] The viral infection is mainly contracted after sexual activity. High incidence of infection in Indian women is due to early marriages, lack of hygiene, female illiteracy,

social taboos and lack of knowledge to access health facilities and lack of effective population-based cervical cancer screening programmes.

Cervical cancer is a preventable disease. Significant premalignant changes take place in the uterine cervix long before occurrence of invasive carcinoma. Early detection of these premalignant changes by effective screening methods can lead to timely intervention, high cure rate and higher life expectancy. Cytology is meant to detect cervical premalignant lesions from the cervix also known histologically as cervical intraepithelial neoplasia (CIN). Pap smear by cytology is one of the sensitive tools for cervical screening .The test was invented by and named for, the prominent Greek doctor Papanikolaou. The overall sensitivity of the Pap test in detecting a high-grade squamous intraepithelial lesion (HSIL) is 70.80%.[7] Pap screening done in association with an HPV DNA test increases the sensitivity for early detection of precancerous lesions.[8] Abnormal findings are often followed up by more sensitive diagnostic procedures, and, if warranted, interventions that aim to prevent progression to cervical cancer. There is a need to spread cervical cancer screening awareness programs, educate women regarding the symptoms of cervical cancer, and motivate them to visit the hospital for screening. We have to strengthen our health-care system for effective screening at primary health centers.

The present study aims to screen women attending the tertiary care centre for precancerous lesions using the Pap smear test and investigate its clinical correlation.

Materials and Methods:

The study was conducted at Dr. M. K. Shah Medical College and Research centre, Ahmedabad, Gujarat, India with written approval from Institutional Ethical Committee and Head of the Institute.

Married women attending gynaecology outdoor clinic at department of Obstetrics and Gynaecology, Dr. M. K. Shah Medical College, Ahmedabad, Gujarat with different complaints like vaginal discharge, itching over vulva, blood-mixed discharge, foul-smelling discharge, postcoital bleeding, intermenstrual bleeding, postmenopausal bleeding, abdominal pain, infertility, prolapse were enrolled in the Pap smear examination study after counseling and explanation of procedure in their local vernacular language. Women during menstrual bleeding, antenatal patients and those who presented with visible malignant lesion were excluded from the study.

Seven hundred and five women participated in the study. Written informed consent was obtained from all patients.

Procedure:

The detailed history of all patients was taken and data was recorded in the proforma. Before the examination, patients were asked to assume lithotomy position. Per abdominal examination was done. Per speculum examination was performed by exposure of cervix using sterile speculum and anterior wall retractor or Cusco's bivalve speculum. The Pap smear was taken by collecting cells from the transformation zone and cervical canal by scraping it with an Ayer's spatula by rotating the spatula to 360°. The cells were quickly smeared on a labelled glass slide and fixed with 95% ethyl alcohol. The slides were sent to the pathology department for the cytological examination. After staining the smear was examined by Pathologist and reported according to Bethesda Grading System (2001).

A) Adequacy of sample

- Satisfactory
- Unsatisfactory

B) Negative for intraepithelial lesion or malignancy (NILM)

- Organisms
- Non-neoplastic changes
- Glandular cell status
- Atrophy

C) Epithelial cell abnormalities

a) Squamous cell abnormalities (SIL):

- Atypical squamous cells of undetermined significance (ASC-US)

Results:

Table No.1: Demographic Profile of patients

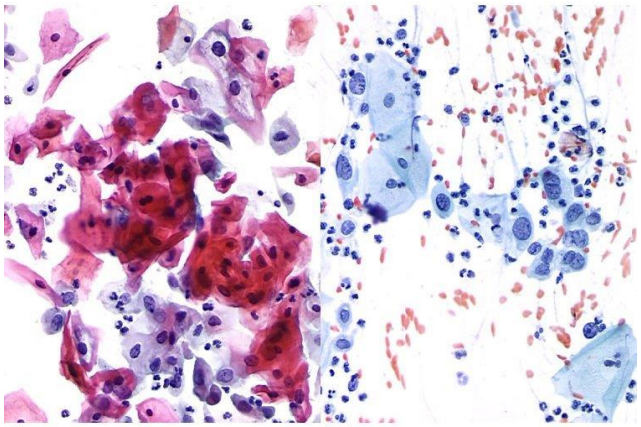
Age group in years	**No of patients (n=705)**	**Percentage (%)**
10-20	5	0.7
21-30	107	15.2
31-40	269	38.2
41-50	252	35.7
51-60	46	6.5
61-70	23	3.3
71-80	3	0.4
Residence	**No of patients (n=705)**	**Percentage (%)**
Urban	530	75.2
Rural	175	24.8
Socioeconomic status	**No of patients (n=705)**	**Percentage (%)**
Upper	27	3.82
Middle	411	58.29
Lower	268	38.01
Literacy	**No of patients (n=705)**	**Percentage (%)**
Literate	615	87.23
Illiterate	90	12.76
Religion	**No of patients (n=705)**	**Percentage (%)**
Hindu	690	97.87
Muslim	10	1.41
Christian	3	0.4
Sikh	2	0.28
No of deliveries	**No of patients(n=705)**	**Percentage (%)**
0	28	3.97
1	110	15.6
2	365	51.77
3	151	21.41
4	40	5.67
5	8	1.13
6	0	0
7	2	0.28
8	0	0
9	1	0.14
Age at marriage	**No of patients(n=705)**	**Percentage (%)**
15-20	73	10.35
21-25	457	64.82
26-30	172	24.39
31-35	3	0.42
Menstrual phase	**No of patients(n=705)**	**Percentage (%)**
Proliferative	422	59.85
Secretory	172	24.39
Menopause	111	15.74

- Atypical squamous cells – cannot exclude HSIL (ASC-H)
- Low-grade squamous intraepithelial lesion (LGSIL or LSIL)
- High-grade squamous intraepithelial lesion (HGSIL or HSIL)
- Squamous Cell Carcinoma

b) Glandular epithelial cell abnormalities:

- Atypical glandular cells not otherwise specified (AGC or AGC-NOS)
- Atypical cell favor neoplastic
- Adenocarcinoma in situ
- Adenocarcinoma

c) Other malignant neoplasm. Treatment was provided to women that had abnormal Pap smear test results.



A B

Figure No 1: A: LSIL. B: HSIL
Cytopathology of the uterine cervix - digital atlas

Table No.2: Frequency of presenting complains of patients attending gynaecological outdoor

Symptoms of Patients	No of patients (n=705)	Percentage (%)
Asymptomatic	264	37.44
White discharge	263	37.3
Foul- smelling/blood- stained discharge	12	1.7
Itching over vulva	51	7.23
Irregular cycles/scanty cycles	25	3.54
Intermittent bleeding	12	1.7
Post- coital bleeding	11	1.56
Postmenopausal bleeding	16	2.26
Pain in abdomen	40	5.67
Something coming out of vagina	16	2.26
Menorrhagia	39	5.53

Table No.3: Per speculum examination findings of gynaecological cases

Per Speculum Findings	No of patients (n=705)	Percentage (%)
Normal cervix	389	55.17
Hypertrophied cervix	40	5.67
Cervical erosion	238	33.75
Cervicitis	41	5.81
Cervix bleeds on touch	26	3.68
Vaginitis	49	6.95
Discharge	389	55.17
Ulcer over prolapsed cervix	12	1.7
Cervical polyp	3	0.42

Table No.4: Pap Smear Report

Cytology Report	No of patients (%) n=705	Percentage (%)
Normal	431	61.13
Inflammation	212	30.07
Atrophic smear	9	1.27
ASCUS	14	1.98
LSIL	29	4.11
HSIL	5	0.7
Inadequate sample	5	0.7

Table No. 5: Cross- tabulation B/W Age Group & Pap Smear Result

Pap Smear Result							
Age Group	**Normal**	**Inflammatory**	**Atrophic**	**ASCUS**	**LSIL**	**HSIL**	**Total**
15-20	3	2	0	0	0	0	5
21-30	71	33	0	1	2	0	107
31-40	163	92	0	5	7	0	267
41-50	156	74	3	4	11	3	251
51-60	27	7	1	2	5	2	44
61-70	11	4	3	2	3	0	23
71-80	0	0	2	0	1	0	3
Total	**431**	**212**	**9**	**14**	**29**	**5**	**700**

The chi-square statistic is 26.2912.The p-value = 0 .000028.The result is significant at $p < 0.05$.

Table No. 6: Cross Tabulation B/W Chief Complaints & Pap Smear Result

Pap Smear Result							
Chief Complaints	**Normal**	**Inflammatory**	**Atrophic**	**ASCUS**	**LSIL**	**HSIL**	**Total**
Asymptomatic	192	59	5	3	4	1	262
White Discharge	142	107	4	7	13	1	274
Foul Smelling/Blood Stained Discharge	1	3	0	2	4	2	12
Itching over vulva	15	32	0	1	3	0	51
Irregular cycles/Scanty Menses	15	7	0	0	2	0	24
Intermittent bleeding	7	4	0	0	1	0	12
Post coital bleeding	6	3	0	0	2	0	11
Postmenopausal bleeding	6	4	1	0	5	0	16
Pain in abdomen	24	12	0	0	3	1	40
Something Coming out of Vagina	10	4	0	2	0	0	16
Menorrhagia	27	10	0	0	1	0	38

chi^2 Value with yate's correction is 45.428(compared normal v/s abnormal results) p value = 0.00000077. The result is significant at $p < 0.05$.

Discussion:

In our study 269 (38.2%) participants were in 31-40 years age group followed by 252(35.7%) participants in 41-50 years age group,107 (15.2%) in 21-30 years,46(6.5%) in 51-60years,23(3.3%)in 61-70 years,5(0.7%) in less than 20 years and3(0.4%) in 70-80 year age group. The participants below 20years and above 65 years were either symptomatic or had erosion. Five hundred thirty participants (75.2 %) were from urban area where as 24.8 %(175) participants were from rural area. Our institute is situated in the outskirts and easily accessible to both urban and rural population. The highest number of participants 411(58.29%) was from middle socioeconomic status followed by 268(38.01%) from lower and 27(3.82%) from upper socioeconomic status. Six hundred and fifteen participants (87.23%) were literate and 90(12.76%) were illiterate. Majority of the participants were Hindu 690(97.87%).The participation rate of Muslims women was only 10(1.41%) in spite of sizable Muslim population in the nearby areas. Their low participation rate may be religious reason, shyness, or lack of awareness of the cervical cancer screening program in our hospital. Christian and Sikh participants constituted 0.4% and 0.28% of the study subject respectively. Maximum participants 365 (51.77%) were para 2, followed by para 3 (21.41%) and para 1(15.6%). Surprisingly very few para 7 and para 9 were enrolled in the study. Four hundred and fifty-seven (64.82%) participants had married between 21-25 years of age followed by 172(24.39%) between 26-30 years of age. Early age of marriage was noted in 73(10.35%) participants. The results may be attributed to middle socioeconomic status of the study population and higher literacy level among urban and rural populations. Four hundred and twenty two (59.85%) participants were in proliferative phase and 172(24.39%) were in secretory phase of menstrual cycle. One hundred eleven participants (15.74%) had achieved menopause.

According to Table-2 asymptomatic participants were 264(37.44%). Two hundred sixty three participants (37.3%) had complained of white vaginal discharge followed by 51(7.23%) reports of itching over vulva, pain in abdomen 40 (5.67%) and, menorrhagia 39(5.53%). Irregular/scanty cycles (3.54%), postmenopausal bleeding and something coming out of vagina(2.26%),intermittent bleeding and foul-smelling/blood-stained discharge(1.7%), post-coital bleeding(1.56%) were low incidence complains.

Table-3 shows that, upon per speculum examination normal cervix was found in 389(55.17%) of participants. Discharge was found in 389 (55.17%) and Erosion over cervix in 238 (33.75%) of participants. Vaginitis was reported in 49(6.95%), cervicitis in 41 (5.81%), hypertrophied cervix in 40 (5.67%), cervix bleeds on touch in 26 (3.68%) and, ulcer over prolapsed cervix in 12 (1.7%) of participants. Patients with chronic cervicitis and cervical bleeding on touch had epithelial abnormalities. The most common clinical lesion seen in patients with LSIL was erosion over cervix 17 (58.6%) followed by cervicitis and cervix bleeding on touch 8(27.5%). Hypertrophied cervix was observed in 4(13.7%) subjects, and 2(6.8%) had healthy cervix. While in patients of HSIL, common findings were erosion, cervix bleeds on touch and hypertrophy of cervix.

Inadequate sample were obtained from 5(0.7%) participants (Table no. 4). This might have been due to dryness of the smear or some technical error. Normal report was found in 431(61.13%) and inflammation was found in 212(30.07%) of participants. Other studies[9,10] have reported 95% and 74.5% incidence of inflammation in Pap smear test, respectively. A few studies[11,12] reported that women with persistent inflammation should be appropriately treated; otherwise, the chance of development of cervical intraepithelial lesions increases. A repeat Pap smear should be taken after proper antibiotic treatment. The epithelial abnormalities ASCUS, LSIL, and HSIL were found in 1.98%, 4.11%, and 0.7% of the participants respectively. Atrophic smear was found in 9(1.27%) cases. Similar results were obtained in study by

Verma et al.[13] who reported ASCUS in 1%, LSIL in 5.5%, and HSIL in 2.5% of screened women.Table-5 shows the cytological results in different age groups. Epithelial abnormality of LSIL was found in 11(37.93%) patients in the 41-50 year age group followed by 7(24.13%) in the 31-40 year age group. HSIL was also observed in 3(60%) in the 41-50 year age group followed by 2 (40%) in the 51-60 year age group. In a study by Pushp Lata Sachan et al[14], 54 women with LSIL belonged to the 41–50-year-old age group, followed by 17 women who belonged to the 51–60-year-old age group. HSIL was found mostly in the women 41–50 years of age group. Ascus was reported in 31-50 years of age group. These results show that a long period is available for screening before the malignant changes takes place. Atrophic smear was common in post-menopausal age group.

The results in Table - 6 shows that majority of the patients with complaint of white discharge had normal pap smear results followed by inflammatory smears. The most abnormal Pap smear findings of HSIL were found in patients with complains of foul- smelling/ blood-stained discharge followed by white vaginal discharge followed by patients with abdominal pain. One Patient was asymptomatic. Pap smear findings of LSIL were found mostly in patients with complains of white vaginal discharge followed by postmenopausal bleeding. Other complains foul smelled / blood stained discharge, itching over vulva, and pain in abdomen, post coital bleeding, and irregular cycles/ scanty menses. LSIL was found in 4 asymptomatic patients. Ascus was found in majority of patients with white vaginal discharge and blood stained/foul smelling discharge whereas 3 participants with similar reports were asymptomatic. This abnormal pap smear results in asymptomatic participants alarms us to screen females irrespective of any complains. High Parity and early age at marriage were common in both LSIL and HSIL group.

The American Cancer Society recently recommended that women should undergo cervical cancer screening at age 25 and primary HPV testing every 5 years till 65 years. If primary HPV testing is not available, individuals aged 25to 65 years should be screened with co-testing (HPV testing in combination with cytology) every 5 years or cytology alone every 3 years.[15]

Conclusion:

The high prevalence of cytological abnormality observed in Indian studies might be due to cultural differences, early age of marriage, high incidence of infections and low levels of awareness about cervical screening programs in different parts of the country. Pap smear testing is a very useful, simple, economical, and safe tool for detecting precancerous cervical epithelial lesions. It should be established as a routine screening procedure to reduce the treatment burden, morbidity, and mortality. When the Pap test is combined with an HPV DNA test, the sensitivity for detection of cervical pathology improves. Thus, there is a need to spread cancer-screening programs to help prevent mortality and morbidity due to cervical cancer.

Conflict of Interest - Nil

Sources of Support - Nil

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