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Original Research Article

A clinical audit of Pap smear test for screening of premalignant and malignant cervical lesions

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ABSTRACT

Background: Cervical cancer, the second most common type of cancer in females, can be easily screened and prevented by Papanicolaou smear test which is a very simple, effective and inexpensive testing modality. The clinical audit aimed to estimate the rate of routine testing as well as the prevalence of various findings of Pap smear tests done at a tertiary level hospital.

Methods: It was an analytical cross-sectional study that utilised results of 100 pap smear tests chosen against a set of exclusion and inclusion criteria out of the total 719 pap smears done at Adesh Medical College and Hospital between the duration of 1 January 2022 to 31 May 2022.

Results: Only 4.29% of total patients that attended gynaecology OPD got a Pap smear done. A mere 22% patients of those under study came for routine testing. 93% of these 100 patients were negative for intraepithelial lesions, of which 42% were normal, 35% showed non-neoplastic changes and infection was seen in 16% of patients. 7% showed epithelial cell abnormality and 0% had malignant changes.

Conclusions: The acceptance of Pap smear for routine screening continues to be low in the Indian setting. There is a massive need to spread awareness among the general public about the importance of Pap smear Test.

Keywords: Pap smear, Cervical cancer, Cancer screening, Clinical audit

INTRODUCTION

Cervical cancer is the second most common cancer in women in India and the fourth most common globally. ^{1,2} In India, the crude cervical cancer incidence was 18.7 per 1,00,000 women in the year 2020. ³

Almost all cervical cancer cases are linked to infection with human papillomaviruses (HPV) commonly transmitted through sexual contact. Most infections with HPV are resolved through natural viral clearance by the body and thus cause no symptoms. However, persistent infection, the exact cause of which is unknown, can cause cervical premalignant lesions and cancer in women.¹

HPV is classified into high-risk and low-risk types, of these HPV types 16 and 18 (high risk) are the most common strains responsible for its pathogenesis. Normally the cervix is made up of two types of epithelia, squamous (ectocervix) and columnar (endocervix). There is a physiological process of metaplasia that occurs at the junction of the two called the cervical transformation zone. Persistence of infection in the zone results in one of the following three: latent infection, active infection with no genomic integration resulting in characteristic cellular changes, for instance, increase in nuclear size, multiple nuclei or perinuclear halo basically, resulting in premalignant lesions detected on pap smear like-low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), atypical squamous

cells of undetermined significance (ASCUS), atypical glandular cells of undetermined significance (AGUS) and atypical squamous cells, histopathological examination cannot rule out HSIL (ASC-H). Lastly the most feared possibility of genomic integration and neoplastic transformation, cancer cervix.^{5,6}

The Papanicolaou smear is a simple and inexpensive test. Although the test may not have great sensitivity, it has high specificity and low false-positive results. This is primarily because the cervix is relatively accessible to investigations and treatment, and early stages of its morphogenesis when diagnosed; it is one of the most successfully treatable forms of cancer. It has a high negative predictive value; this means that a Pap smear can guide the necessity for cervical biopsy in patients with leucoplakia pattern on colposcopy, thus avoiding stern interventions like biopsy. A study by Cabrera et al also claimed to have identified protein biomarkers in the sample that have up to 92% of diagnostic power to even be able to diagnose endometrial cancer in patients, if the sample was subjected to liquid cytology.

These results allow Pap smear to serve as an early and non-invasive screening tool for endometrial cancer. This can change the standards of diagnosis and care even in endometrial cancer. 9

In India, fewer than 1 in 10 women have been screened for cervical cancer between the years 2015-2020.³ Higher a women's knowledge in a particular region about cervical cancer and Pap smear, higher the performance rates of Pap test. Advice by a healthcare professional is perceived to play one of the most pivotal roles in its facilitation.¹⁰ The community should be educated about the Pap smear test, including its objectives and the required frequency of application, by widespread educational and media programs. Most women who visit an outpatient clinic are not aware of cervical cancer screening.¹¹ Thus, there is a need to spread access to cancer screening programs to help prevent mortality and morbidity due to cervical cancer. With a comprehensive screening approach, cervical cancer can be eliminated as a public health problem.

METHODS

Inclusion and exclusion criteria

The pap smear test results of patients that attended the gynaecology OPD and were 21 years of age or older were included in the study. All pregnant females were strictly excluded from the study. Any patient that had had any previous history of treatment of premalignant cervical lesions (LEEP- loop electrosurgical excision procedure, LLETZ- large loop excision of transformation zone, cone biopsy, cryo-cautery) were not considered. Anyone under the age of 21 was not included. The subjects were selected irrespective of sexual activity.

Study design and study sample

This was an analytical cross-sectional study. An arbitrary 100 Pap smears were done at Adesh Medical College and Hospital between 1 January 2022 and 31 May 2022, befitting the above inclusion and exclusion criteria were retrieved from the pathology department. Since more than 100 Pap tests apt for the study were found in the specified time duration, 100 tests were chosen on a random basis keeping in mind the general representation of data.

Data collection tool

This was a retrospective study. Records of Pap tests done in the OPD of obstetrics and gynaecology department, at Adesh Medical College and Hospital were retrieved from the pathology department employing a proforma. This was a well-structured and brief proforma to obtain uniform and relevant information for each result, according to the Bethesda system for reporting cervical cytopathology: 2014. The personal details of each individual were kept strictly confidential. The data collected via the proforma was entered into MS excel sheet and analysed by SPSS version 27. The data was expressed in frequencies and percentages.

RESULTS

Table 1: Demographic distribution of study population.

Parameters		
Age group (years)	<25	9
	26-35	36
	36-45	33
	>45	22
	Nullipara	5
Parity	Primipara	31
	Multipara	64
Marital status	Yes	98
	No	02
Education	Illiterate	5
	10th pass	31
	12th pass	51
	Graduate and above	13
Contraception use	None	33
	Barrier	16
	Natural methods	15
	IUCD	17
	Tubal ligation	11
	Others	8
Smoking/tobacco	Yes	3
use	No	97

A total of 16,723 patients that attended the gynaecology OPD at Adesh Hospital, Mohri from 1 January 2022 to 31 May 2022, 719 patients were tested through Pap smear cervical cytology, which accounts for 4.29% of the total.

Among the patients under study, the majority of these patients belonged to the middle age group i.e., from 26-45 years. A detailed demographic distribution of the study population is given in Table 1.

Only 22% of the total patients under study came for a routine pap smear screening while the rest got tested following the doctor's advice for varying clinical presentations including that of AUB, cervicitis, ectropion, PID, UTI and vaginal discharge among others.

Table 2: Descriptive result distribution of Pap smear tests.

S. no.	Category	N (%)
1.	Negative for intraepithelial lesion or malignancy (NILM)	93
	Non neoplastic changes	35
	Inflammatory	32
	Atrophic	2
	Ectropion	1
	Organisms	16
	Bacterial vaginosis	12
	Candida	3
	Herpes Simplex virus	1
2.	Epithelial cell abnormalities	7
	ASCUS	4
	LSIL	2
	HSIL	1
	Squamous cell carcinoma	0
3.	Other malignant neoplasms	0

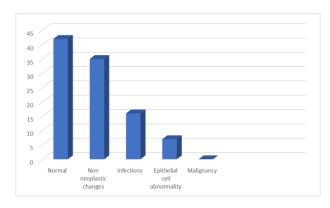


Figure 1: Broad categorisation of Pap smear test results according to Bethesda system of classification 2014.

Results of the selected 100 patients, based on inclusion and exclusion criteria, were classified based on the Bethesda system of classification 2014 and presented in the form of a graph and a descriptive table (Table 2).

While 93% of results were negative for intraepithelial lesions, 7% showed epithelial cell abnormalities (Figure 1).

Among the 16% of patients that showed the presence of infective organisms, a majority, 12% had bacterial vaginosis. Among the others, 3% had vaginal candidiasis and 1% had infection with Herpes Simplex Virus (HSV); helping in extending the use of pap smear tests not only for the timely detection of precancerous lesions but also for detection of sexually transmitted infections (STI) and other genital tract infections (Table 2).

DISCUSSION

The occurrence of cervical cancer is nearly four times higher in low- or middle-income countries like India as compared to developed countries.¹² In our hospital, the cervical cancer screening was offered to all patients above 21 years of age who attend the gynaecology clinic as well as to those who visited for routine screening check-ups. Though it can be observed in our study that only 22% of the total patients under study came for routine screening, thus indicating the need for awareness among the population of India as more than one-fifth of all cervical cancer deaths occur in India.¹³

Many recent research studies had shown that the sensitivity of a single cervical cytology test was relatively low, hence an alternative strategy that seemed quite promising was to screen using HPV DNA testing and therefore, a combination of both cervical smear cytology and HPV genotyping was a relatively better method of screening.14 Cervical cancer had a long preinvasive stage thus making it one of the highly preventable cancers and its early detection and appropriate treatment were possible if a robust screening method was implemented.¹⁵ Our study had clearly shown the effectiveness of cervical cancer screening by detecting a significant number of premalignant lesions much before they could turn malignant with zero rates of malignancy in our test subjects. Pap smear test is quite simple, non-invasive, cost-effective and easy to perform thus making it one of the most important screening methods for pre-malignant and malignant lesions of the cervix but awareness about this test among the community is very low which is evidently visible through our study too.11

Our study results included 32% of inflammatory smear cases and many studies have shown that women with persistent inflammation need to be treated appropriately or the chances of development of cervical intraepithelial lesions increase quite significantly. 16,17

In our study, ASCUS was found in 4% of screened women, LSIL in 2% and HSIL in 1%, the results being seemingly comparable to those in a study done by Narasimha et al. 18 Cervical cancers commonly developed in women between the ages of 40 and 50 years and its precursor lesions usually occur 5-10 years earlier, this age group being comparable to the majority of our study participants' age. Therefore, it was recommended that women should have at least one Pap smear test before the age of 45 years. 19,20

Limitations

The prevalence of gynaecological diseases as documented in several research studies and articles has a very strong dependence on wide range of factors based on geography and population of the area under study. This poses a limitation. The results of the current study may not be extrapolated and generalised to those under different resource settings. Further, this was a single centre study including 100 patients and considering that environment has influence of numerous facets, the results may not be generalizable and hence, the findings must be interpreted carefully bearing in mind these influences.

CONCLUSION

Thus, it can be concluded from our study that even though pap smear is an effective test for screening pre-malignant and malignant lesions of the cervix, the acceptance of this test as routine screening is somewhat low in the Indian setup. Therefore, we need mass education regarding the same in both public and private centres. Creating more and more awareness among the population about cervical cancer will further result in an improvement in the proportion of women visiting hospitals or healthcare setups for routine cervical smear cytology. Furthermore, to obtain a high yield, pap smear testing can be combined with other tests like HPV DNA testing or visual inspection with acetic acid or Lugol's iodine.

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Institutional Ethics Committee

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