

Article

Pap smear: Are we choosing wisely? An observational study of clinicopathologic variables of patients undergoing Pap smear examination

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Abstract: Background: Cervical cancer is a major cause of mortality in women. Pap smear is a screening test used in the screening of cervical cancer. There are well defined guidelines regarding its use. It should be offered to all sexually active women between the ages of 30-65 years, irrespective of whether or not they are symptomatic. Moreover, those women who have undergone hysterectomy for reasons other than cervical cancer or precancerous lesions, do not require this test.

Materials and methods: We undertook an observational study to describe the age, presenting complaint, previous history of hysterectomy and reason for hysterectomy in women undergoing Pap smear testing in a private super speciality hospital in Central India in the past 3 years.

Objectives: The objective of this study was to examine how closely the aforementioned guidelines were being followed, so as to deduce how wisely were we choosing the women to whom the test was being offered.

Results: This study found that a significant proportion of tests were being offered to women who did not need them. And more importantly, we were missing the opportunity to screen women who presented with non gynaecologic complaints in our hospital.

Conclusion: Hence we present the findings of this study to reassert the role of Pap smear as a screening test, the primary goal of which is to identify high grade precancerous lesions of the cervix; and to sensitise specialist physicians other than gynaecologists to offer Pap smear to women presenting with complaints unrelated to the genitourinary tract: so that we can choose wisely as to who should and who should not get the test.

Keywords: Cervical cancer; Choosing wisely; HPV; Pap smear; Patient anxiety; Screening; Screening guidelines; Unnecessary cost; Unnecessary testing.

1. Introduction

As per Globocan 2020, 6,04,100 new cases of cervical cancer were detected globally in 2020 and 3,41,831 deaths were attributed to this malignancy. In India, cervical cancer accounted for 9.4% of all cancers and 18.3%(1,23,907) of new cases in 2020: making it the third most common cancer incidence wise in the Indian population. It was also the second most common cause of cancer death in the Indian population [1] Department of Health Research has released a Health Technology Assessment for early diagnosis of cervical cancer. There is sufficient evidence that suggests that screening leads to a reduction in the occurrence of cervical cancer cases with a decrease in cancer deaths [2].

The Papanicolaou test (abbreviated as Pap test, also known as Pap smear, cervical smear) is a method of cervical cancer screening. The test was independently invented in the 1920s by Georgios Papanicolaou and Aurel Babeş and named after Papanicolaou. The primary goal of cervical cancer screening is to identify precancerous lesions caused by Human Papilloma Virus (HPV) so they can be removed to prevent invasive cancers from developing. A secondary goal is to find cervical cancers at an early stage, when they can usually be treated successfully. Abnormal findings are often followed up by more sensitive diagnostic procedures and, if warranted, interventions that aim to prevent progression to cervical cancer.

Choosing Wisely is an initiative of the ABIM (American Board of Internal Medicine) Foundation that seeks to advance a national dialogue on avoiding unnecessary medical tests, treatments and procedures [3]. The campaign identifies over 500 tests and procedures and encourages doctors and patients to discuss, research, and possibly get second opinions, before proceeding with them.

The Choosing Wisely Pap Test patient resource web page [4] states:

Pap tests usually don't help low-risk women

Many women have a very low risk for cervical cancer.

- Cervical cancer is rare in women younger than 21, even if they are sexually active. Abnormal cells in younger women usually return to normal without treatment.
- Cervical cancer is rare in women over 65 who have had regular Pap tests with normal results.
- Pap tests are not useful for women who have had their cervix removed during a hysterectomy, unless the hysterectomy was done because there were cancer or pre-cancer cells in the cervix.

Pap tests can have risks

A Pap test can be uncomfortable and cause a little bleeding.

The test may show something that does not look normal but would go away on its own. Abnormal results cause anxiety. And they can lead to repeat Pap tests and follow-up treatment that you may not need.

The tests cost money

A Pap test is done during a pelvic exam. Although costs vary across the country and even from practice to practice, any money spent on an unnecessary test is money wasted.

So, when do I need a Pap test

That depends on your age, your medical history, and your risks.

- Ages 21 to 30: You should have a Pap test every three years. Cervical cancer takes 10 to 20 years to develop, so you don't need the test each year. You do not need a Pap test before age 21, even if you are sexually active.
- Ages 30 to 65: The new guidelines from the American Cancer Society and others say that you can have the Pap test every five years as long as you have a test for the human papillomavirus, or HPV, at the same time. HPV is a sexually transmitted infection that can cause cervical cancer.
- Age 65 or older: You do not need Pap tests if your recent ones have been normal. If you have risk factors for cervical cancer, ask your doctor how often you need a Pap test. Risk factors include: pre-cancer cells in your cervix, a history of cervical cancer, or a weak immune system."

The Operational Framework-Common Cancers published by Ministry of Health and Family Welfare(MOHFW), Government of India states that women ages 30-65 years should be screened for cervical cancer using Visual Inspection with Acetic Acid(VIA) once every 5 years [4].

2. Material and methods

Study design: Descriptive Observational study.

Inclusion criteria

I collected data regarding age, presenting complaint, and interpretation of Pap smears of women undergoing Pap smear examination in a private superspeciality hospital in Central India in the past 3 years. I also recorded whether those women undergoing Pap smear had a previous history of hysterectomy, and if yes, then whether hysterectomy was performed because there was invasive cancer or precancerous lesion in the cervix. All the data was collected from the investigation request form sent along with the Pap smear slides.

Exclusion criteria

Those subjects whose investigation request form sent along with the Pap smear slides lacked the details regarding age, presenting complaint, history of hysterectomy, and reason for hysterectomy were not included in this study.

The age of the study participants was recorded in years and subjects were categorized into age groups as follows:

1. <21,
2. 21-29,
3. 30-65,
4. >65.

The presenting complaints of the study participants were grouped under the following categories:

1. Screening: where there was no complaint, Pap smear was done as a screening procedure (in asymptomatic subjects).
2. Abdominal pain (as reported by the patient).
3. AUB(abnormal uterine bleeding): including menorrhagia, irregular bleeding in women of reproductive age group, post coital bleeding, post menopausal bleeding. (as reported by the patient).
4. Leucorrhoea: thick whitish or yellowish colour discharge from the vagina. (as reported by the patient).
5. Prolapse:the uterus slipped down into or protruding out of the vagina(as reported by the gynaecologist).
6. Erosion: red, inflamed patch surrounding the external is(as reported by the gynaecologist).
7. Fibroid: benign neoplasm of smooth muscle in the uterus (as reported by the gynaecologist).
8. Cervicitis: Any redness on cervix, discharge, blood on vagina or cervix.(as reported by the gynaecologist).
9. UTI: urinary tract infection, an infection in any part of urinary system-kidneys, ureters, bladder and urethra.(as reported by the gynaecologist).
10. Other: including polyp, infertility, vaginitis, ovarian cyst, ovarian cancer.

The subjects undergoing Pap smear and having a history of hysterectomy were categorized as:

1. Hysterectomy Not done,
2. Hysterectomy done.

The reasons for hysterectomy in those who had a history of hysterectomy and were undergoing Pap smear testing were categorized as:

1. Invasive cancer/precancerous lesion (including LSIL, HSIL, AGC),
2. other.

All the smears we received were made by conventional method and stained using Biolab Rapid Pap kit. The Bethesda system for reporting cervical Pap smears was used to interpret the Pap smears received. The smears were categorized into the following diagnostic categories;

1. NILM: Negative for Intraepithelial Lesion or Malignancy.
2. Inadequate: A conventional smear broken (shattered) beyond repair; there was deemed to be a poor or scanty squamous epithelial component to the cervical smear (less than 8,000 to 12,000 well preserved, well visualized squamous cells on a conventional smear); blood, inflammatory cells, lubricant, thick clumps of cells, air-drying artefact or poorly fixed cells hindered the accurate interpretation of the sample.
3. ASCUS: Atypical Squamous Cells of Undetermined Significance.
4. LSIL: Low-grade Squamous Intraepithelial Lesion.
5. ASC-H: Atypical Squamous Cells, Cannot Rule Out High Grade Squamous Intra-epithelial Lesion.
6. HSIL: How-grade Squamous Intraepithelial Lesion.
7. SCC: Squamous Cell Carcinoma.
8. AGC: Atypical Glandular Cells.

I then compared the observations of this study with the Choosing Wisely patient resources for Pap smear [4] , and MOHFW guidelines [5].

3. Results

Out of a total of 1878 request forms for Pap smear test received in the past 3 years, only 1005 carried all the required data pertaining to age, presenting complaint, previous history of hysterectomy, and the diagnosis of cancer or precancerous lesion in those who had had a hysterectomy.

The age distribution (Table 1) of subjects undergoing Pap smear examination was as follows:

The frequency of distribution of various presenting complaint (Table 2) of women undergoing Pap smear was as follows:

The number of subjects undergoing Pap smear and having History of hysterectomy (Table 3) was as follows

The reason for hysterectomy in those who had a history of hysterectomy and were undergoing Pap smear testing (Table 4) was as follows:

The frequency of distribution of various interpretations (Table 5) on Pap smear was as follows:

Table 1. Age distribution of subjects undergoing Pap smear examination

Age	Number	Percent
<21	3	0.3
21-29	124	12.3
30-65	859	85.5
>65	19	1.9
Total	1005	100

Table 2. frequency of distribution of various presenting complaint of women undergoing Pap smear

Presenting complaint	Number	Percent
Screening	230	22.9
Abdominal pain	225	22.5
AUB	160	15.9
Leucorrhoea	115	11.5
Prolapse	92	9.2
Erosion	56	5.5
Fibroid	30	2.9
Cervicitis	27	2.7
UTI	26	2.6
Other	44	4.3
Total	1005	100

Table 3. number of subjects undergoing Pap smear and having History of hysterectomy

Hysterectomy	Number	Percent
Not done	992	98.7
done	13	1.3
Total	1005	100

Table 4. Reason for hysterectomy in those who had a history of hysterectomy and were undergoing Pap smear testing

Reason for hysterectomy	Number	Percent
Invasive cancer/precancerous lesion	1	7.7
Other	12	92.3
Total	13	100

Table 5. Frequency of distribution of various interpretations on Pap smear

Interpretation	Number	Percent
NILM	873	86.8
Inadequate	91	9.1
ASCUS	16	1.6
LSIL	14	1.4
HSIL	7	0.7
SCC	3	0.3
AGC	1	0.1
ASC-H	0	0.0
Total	1005	100

4. Discussion

As per the Choosing Wisely patient resources for Pap smear [4], women less than 21 years of age do not need to be screened for cervical cancer, as they are at a very low risk for developing it. In this study only 3 subjects (0.3%) were falling in this age group. The majority (983(97.8%)) were conforming to the age of screening recommended by Choosing Wisely. However, 19 subjects(1.9%) were aged greater than 65 years. In this older age group there was no record of previous Pap smear done, and hence a Pap smear done in them was still justified as per the Choosing Wisely guidelines.

However, the Choosing Wisely guidelines differ from those of MOHFW, Government of India [4], which recommend starting screening every 5 years from the age of 30 years and continuing upto 65 years of age. As per these guidelines 127(12.6%) of the study subjects were less than 30 years of age and did not require screening.

Pap smear is a screening test for cervical cancer.

A screening test is defined as "the search for unrecognized disease or defect by means of rapidly applied tests or examinations or other procedures in apparently healthy individuals" [6]. Opportunistic screening relies on screening patients for common diseases unrelated to their presenting complaint. In this study 230 subjects (22.9%) were apparently healthy(had no presenting complaint), the majority (775(77.1%)) presented with some genitourinary complaint. In a country like India where awareness regarding Pap screening among the population is limited, and social and cultural attitudes are limiting factors, this kind of opportunistic screening might be justified. However, all those subjects who presented with a complaint were primarily managed by a gynaecologist, none of the subjects in this study were primarily managed by a specialist other than a gynaecologist. From this observation it can be deduced that gynaecologists, who are trained in obtaining Pap smear and are also sensitized to the cause of cervical cancer screening are more likely to screen their patients opportunistically for the same as compared to other specialist physicians. This highlights the need to sensitize specialist physicians other than gynaecologists to opportunistically screen their patients for cervical cancer.

Also notable in this study was that 115 subjects (11.5%) presented with leucorrhoea (white discharge from vagina), this figure closely correlating with the proportion of Pap smears interpreted as "Inadequate"(91 smears,9.1%). Out of the 91 smears interpreted as Inadequate in our study, 83 were due to dense inflammatory infiltrate obscuring the nuclear details of the cervical cells on the slide. This highlights the need for treating clinically apparent causes for leucorrhoea prior to taking the Pap smear. The "Inadequate" interpretation leads to repeat testing and patient anxiety. Though an argument can be made against this that a Pap smear might be helpful in finding out the cause of vaginal discharge (sexually transmitted infections such as Trichomoniasis, bacterial vaginosis, gonorrhoea, candida), detecting infectious agents is not the primary goal of Pap smear, the primary goal of Pap smear is to identify precancerous lesions caused by Human Papilloma Virus (HPV) so they can be removed to prevent invasive cancers from developing. Also, not treating the infection prior to Pap smear can lead to a higher rate of false negatives due to obscuring inflammation, as well as higher rate of false positives due to reactive changes induced by the inflammation being misinterpreted as cervical cells suspicious for precancerous lesion. This again leads to unnecessary patient anxiety and extra costs of repeated testing, follow up diagnostic testing or unnecessary therapy.

In this study, 12 subjects had undergone a previous hysterectomy for causes other than invasive cancer or precancerous lesions. This again was not justified as per the Choosing Wisely guidelines [4].

I do acknowledge the fact that this was a small study, involving the experience from a single institute, and that it might not be appropriate to extrapolate these observations to the population at large. Given that this study was conducted at a private institute, where the patients were capable of paying higher costs for healthcare (and thus had access to purportedly better healthcare), and were also more literate than the general population (thus more capable of making informed decisions for themselves), is all the more reason to ponder: Pap smear: are we choosing wisely?

Conflicts of Interest: "The author declares no conflict of interests."

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