

Is It Time to Move Towards Human Papilloma Virus (HPV) Testing in Self-Collected Genito-Urinary Samples for Cervical Cancer Screening? A Survey-Based Study from India

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Abstract

Background: Cervical cancer is one of the most common as well as the most preventable cancer. Screening tests have been developed for decades, but awareness, availability and uptake have not been uniform especially in low-resource countries.

Aim: Gauging the knowledge, awareness and attitude of women towards cervical cancer, willingness to undergo screening and preferred sample collection methods.

Method: Women in an urban region of India were given an online survey regarding cervical cancer, screening and preferred type of sample collection.

Result: 836 women participated in this study, 87.2% were already aware about cervical cancer, 65.7% were aware of screening, 60.4% preferred self-collection of genito-urinary samples for screening.

Conclusion: Despite being aware of cervical cancer and screening protocols, the screening rate was extremely low. Majority of women preferred self-collection of samples for screening. This information can be used to strategize accessible and acceptable screening programs, beginning with promotion of self-collection of genito-urinary samples for HPV DNA testing.

Keywords: Cervical Cancer; Screening; Human Papilloma Virus (HPV); Self-Collection; Genito-Urinary Samples.

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Introduction

Cervical cancer is the fourth most common and fatal cancer among women globally [1]. Almost all cases of cervical cancer are caused due to long term persistence of one/more high-risk human papillomavirus (HPV) strains in the cervical epithelial cells. Since cervical cancer develops over a long span of time, various screening tests have been developed and are aimed at identifying presence of high-risk HPV strains and/or precancerous lesions at early actionable stages [2] (Table 1).

Various cervical cancer screening guidelines exist from different organizations, [World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), American Cancer Society, Australian Department of Health, Indian Society of Colposcopy and Cervical Pathology (ISCCP) and Federation of Obstetrics and Gynecology Society of India (FOGSI)] which overlap or differ over the age of initiation of cancer screening (21 Vs 25 Vs 30 years) and employment of HPV test alone Vs Co-testing by HPV and cytological

tests. Despite the development of these screening guidelines, about 604,000 women were diagnosed with and about 342,000 women succumbed to cervical cancer globally in 2020 [1]. In India the overall population coverage for cervical cancer screening is estimated to be only about 10-20% [9]. Currently certain opportunistic cancer screening programs and guidelines have been formulated in India too, but organised nation-wide implementation needs to be addressed to reach majority of the population and for maximum uptake [10]. To gain a better understanding of where the gap lies, we undertook an online survey for women in Pune city in India. The aim of this survey was to try and assess the knowledge, attitude and awareness about cervical cancer, different screening modalities, their uptake and preference of sample collection methodology.

Methodology

A cross-sectional survey was conducted online for the women



Table 1: The salient features of multiple cervical cancer screening strategies [3-8].

Test	Purpose	Sample type	Sensitivity	Specificity	Limitations	Advantages
Papanicolaou (PAP) test	Check for pre-cancerous alterations in cervical cells that could progress to cervical cancer, if untreated.	Cervical cells are collected using a specialised brush/spatula on a slide, stained and visualised by a trained pathologist in the lab.	55%-80%	75% (CIN-1) 95%-98% (CIN 2+ and CIN 3+)	<ol style="list-style-type: none"> 1. Gynecological speculum examination is required to collect the sample. 2. Cannot be done when woman is experiencing bleeding or discharge per vaginum. 3. Slides need to be sent for examination by the pathologist 4. Inadequate sample collection may affect the test's accuracy [3]. 5. There is a possibility of uncertain results [7]. 	<ol style="list-style-type: none"> 1. Standard practice for more than 50 years 2. Can be done by a trained nurse or health worker in rural settings 3. Can also identify other genital infections
Liquid-based cytology (LBC)	Check for unusual cervical cell changes related to cervical precancer or cancer. It is grossly similar to the Pap test in collection and testing.	The cells are collected in a specialised liquid medium.	52%-98%	73%-97% (CIN 2+ and CIN 3+)	<ol style="list-style-type: none"> 1. More expensive than a Pap test. 2. As with the PAP test 	<ol style="list-style-type: none"> 1. Slides can be prepared at the lab and not at the point of collection 2. HPV testing can also be done from an LBC specimen
Visual Inspection with Acetic acid (VIA)	To visually examine the morphological changes in the cervix after application of acetic acid and grading the lesions.	Application of 3%-5% of acetic acid on the cervix and checking for areas that turn white and opaque.	69%-77%	82%-87%	<ol style="list-style-type: none"> 1. Requires gynecological speculum examination. 2. Subjective interpretation by observer. 3. Higher false positivity as the lesions could be due to other causes of parakeratosis [4]. 	<ol style="list-style-type: none"> 1. Treatment can be offered at the point of testing in a single visit 2. Practical method in low-resource countries as "screen and treat" method
High-risk HPV DNA test	Check for presence of high-risk HPV genetic material strains in cervical cells.	Sample from the cervix is taken using a special brush/swab, cells are transferred to a transport medium and tested for presence of HPV DNA.	84%-97%	64%-95% (CIN 2+ and CIN 3+)	<ol style="list-style-type: none"> 1. Gynecological speculum examination is required to collect the sample. 2. Molecular laboratory setup is needed to process the samples. 3. At least two visits to health clinics are required in case treatment is recommended. 4. Considered to be expensive in a low resource setting. 5. Lower specificity could lead to cases of overtreatment. 	<ol style="list-style-type: none"> 1. High sensitivity and negative predictive values [5] 2. No observer dependent variations 3. Self-collected samples can also be used as specimens for HPV testing [8]

of Pune city for two weeks in December 2018. A google-form based questionnaire was designed in English to understand their awareness about cervical cancer and its etiology, screening options and their preferred method for sample collection. The link to the google form was provided via email/ WhatsApp to all the participants. The questionnaire was divided into two sections. Section one consisted of four questions aimed at collecting the demographic information of the participants like age, education and annual income. Section two, an awareness and opinion section, contained eight questions. First three were designed to gauge the participants' awareness about cervical cancer and screening options. The next two questions were added to identify how many in the cohort had actually undergone cervical cancer screening. The last three questions were opinion-based questions to understand the preferences and views of the participants regarding undergoing screening, the method they would prefer and how much would they be willing to pay for it.

Results

836 women of different ages and financial backgrounds undertook

the online survey. Majority of the women fell between the age group of 30-45 years (60.5%) followed by women older than 45 years (21.1%). 63.4% had a postgraduate/ higher degree whereas 2.8% had completed high school/ standard 12th. The monthly income lay majorly between Rs.50,000-Rs.2,00,000 (39.1%) and more than Rs.2,00,000 (38.6%). Most of the participants [757(90.6%) out of 836] had engaged in sexual activity before taking the survey.

For the questions about awareness regarding cervical cancer and HPV, 756 participants (90.4%) responded out of 836. Most of the women who responded [(87.2%) 659 out of 756] were aware of cervical cancer. However only 45.9% [347 out of 756] were aware of the association of HPV infection with cervical cancer. 65.7% [496 women] were aware of cervical cancer screening prior to taking the survey out of the 755 who answered. Out of 756 women, only 43.4% [328 women] had undergone a cervical cancer screening by a Pap test and 3.2% [24 women] were unsure about having undergone one. Of 755 women, 15.1% [114 women] had undergone HPV testing from a cervical swab and 10.2% [77 women] were not sure. When asked about



willingness to undergo cervical cancer screening, 83.5% [624 women] of the participants responded in affirmative from the 747 women who answered. Out of 770 responses on preference of collection method, about half of the women responded that they would prefer to get the swab collected by a gynaecologist [(54.5%) 365 women], 46.4% [311 women] preferred to collect a urine sample, 14% [94 women] responded towards self-collection of the vaginal swab. Lastly, for the amount they were willing to pay for screening, out of 735 responses, for 35.1% [258 women] cost did not seem to influence their screening decision. For one time screening 27.2% [200 women] were ready to spend up to Rs.1000, 23.3% [171 women] were willing to spend up to Rs.500, 12.2% [90 women] and 2.2% [16 women] were willing to spend up to Rs.2000 and Rs.5000 respectively.

Discussion

The study assesses the knowledge, attitude and awareness about cervical cancer, screening and acceptance for self-collected genito-urinary samples in 836 women residing in Pune city, Maharashtra, India. In our survey, almost all of women had a favourable attitude towards screening and were willing to undergo screening. Our study revealed that 87.2% of women in our cohort were already aware about cervical cancer, which is considerably more than reported in a review by Taneja N, et al. (2021) [11]. They collected data from 19 published studies (between 2012-Mar 2020), mainly conducted in urban India and presented the knowledge, attitude and practices (KAP) data of 7688 Indian women. The studies showed that only 40% women were aware about cervical cancer. This difference may be because literature in their study was published between the 2012-2020 and was highly heterogeneous in terms of study population and methodology. In other KAP studies from India, 65-75% of women were aware about cervical cancer, 5-30% had undergone any form of screening, none of them had heard about the visual inspection with acetic acid (VIA) methodology and 40-75% were keen to opt for screening, provided they were given enough information about it [11].

In our survey, despite being aware about cervical cancer, the knowledge about its etiological association with HPV was present only in half the cohort who answered (even when >90% of the women were graduates and above). In a study conducted in the urban region of North India, out of 1500 women only 10% of women were aware about the causal association of HPV with cervical cancer [12]. The knowledge about causal association of HPV with cervical cancer was much higher (86.2%) among healthcare professionals, as expected [13]. This vast difference in the knowledge about association between HPV and cervical cancer points towards lack and thus need of uniform education and awareness programs in India. If more women can be made aware of this causal relationship, the acceptance of highly sensitive HPV based screening programs will be much higher.

Nearly half of our cohort (43.4%) had already undergone a PAP test, which is higher than 13.5% reported by Taneja N, et al. (2021) [11]. In the study done by Dahiya N, et al. (2019) [14], in an urban region of India, 18% women ever had a PAP smear in their life. 15% of women in our cohort had undertaken an HPV test and 13.2% of women were unsure whether they have undergone PAP smear or HPV testing for cervical cancer. In 2019, CDC released data analysing the percentage of Indian women aged 30-49 years who had ever been screened for cervical cancer, which was less than 30% (29.8%). This screening coverage varied by geographic region, from 10.0% in the Northeast Region (lowest) to 45.2% (highest) in the Western Region of India. High prevalence of screening correlated positively with higher

levels of education, household wealth and urban residents [15]. A study done in an urban South Indian community also revealed that only about 7% women had undergone cervical screening [16]. These data collectively suggest the need for making women aware and offer clinically acceptable method(s) of cervical cancer screening.

In the present study, more than half of the women (60%) were open to self-collected genito-urinary samples for cervical cancer screening. In the study by Madhivanan P, et al. (2021) [17], in rural South India, the acceptability of HPV testing on self-collected samples was much higher than samples collected by healthcare professionals. In a study performed on 3863 women in a low resource setting, 75% reported that sample collection was easy; almost half of them (52%) initially had some concerns about hurting themselves and one fourth (24%) were worried about not getting a good sample [18]. However, 90% women could satisfactorily provide their own samples [18]. Other studies also suggest that incorporation of self-collection of cervico-vaginal samples for screening has been positively accepted and screening coverage has been higher in other countries, especially where efficient health care infrastructure may not be available or easily accessible for cervical cancer screening programs [19,20]. This emphasizes that most women will be willing and able to provide their self-collected samples for screening provided they are guided appropriately and their fears are alleviated. A large study compared the performance of high-risk HPV testing in the self-collected vaginal and urinary samples Vs cervical samples collected by clinician [8]. The absolute sensitivity of HPV testing in vaginal/urinary samples for CIN2+ was 96% and 93% respectively which is similar to HPV testing in clinician collected cervical samples.

Nearly half of the women in our cohort were ready to pay just Rs. 500-1000 for cervical cancer screening. In Dahiya N, et al. (2019) [14] study, 58.0% were ready to undertake cervical cancer screening if offered free of cost [16]. Thus, there is a need for developing affordable screening modalities to reach across various socio-economic groups and eliminate cost as a barrier to screening. A systematic screening program is needed considering the cost of testing per user, cost of infrastructure establishment Vs cost of treatment, loss to overall economy due to cancer related deaths and poor quality of lives in women with cervical cancer.

The major limitation of the present study was that the survey was conducted on a semi-urban demographic with women mostly belonging to middle, upper middle socio-economic status and did not capture the perception of women in the lower economic strata. Another limitation is that the survey did not check on factors which may be barriers to screening, awareness about the risk factors for HPV infection and about the sources through which the women got information about cervical cancer screening.

Conclusion

This study brings forth various aspects of the levels of knowledge, awareness and attitudes of women from a semi-urban, middle and upper-middle section of the society towards HPV and cervical cancer screening to help strategize for development practical and successful screening programs. The favourable attitude towards screening but lack of actual uptake highlights the gap in awareness as well as the availability of the resources. Along with spreading awareness, creative solutions need to be devised to overcome the barriers to screening. This can be done by developing culturally acceptable, low-cost technologies to improve screening coverage, which can be scaled up sustainably to reach the maximum population. It can be started with promotion of



self-collection of genito-urinary samples for HPV DNA testing even in low resource settings via more coordinated actions by the government and the private sector.

Supplementary Section

A. Questionnaire sent to the participants:

Cervical Cancer Survey for Women

Cervical cancer is the most common cancer affecting women in India. Nearly 1 in 50 women are affected by it. Common symptoms include vaginal bleeding and/or foul- smelling vaginal discharge. A definitive diagnosis typically requires testing and examination by qualified medical practitioners. A gynecologist collects a swab sample from the cervix (uppermost part of the vagina), which is then examined by a pathologist for the presence of cancer cells. If diagnosed with cervical cancer, treatment usually involves surgical removal of the uterus, cervix, and both ovaries, followed by radiation therapy in some cases. For advanced cases where surgery is not an option, radiation therapy remains the only mode of treatment.

Early detection of cervical cancer facilitates prompt treatment that leads to significantly better survival rates accompanied by a substantial improvement in overall quality of life. Early detection strategies typically include regular screening by cervical swab once every three years for women over the age of 30 years. Recent studies have clearly demonstrated that almost all cervical cancers are preceded by an infection with pathogenic strains of Human Papillomavirus (HPV). Early detection of high-risk HPV infections has become a powerful method to identify women at an increased risk of developing this cancer. Current options for HPV testing for cervical cancer are performed on cervical swabs collected using the same protocol as described above.

We are carrying out an anonymous survey to understand public awareness about cervical cancer and available testing options. This survey should not take more than 90 seconds. Thank you for your participation.

* Required

1. What is your age? *

Less than 18 years

More than 18 years and less than 30 years

More than 30 yrs and less than 45 years

45 years or more

2. What is your education level? *

Upto Standard 12

Upto Graduation (e.g., BA, BCOM, BE, MBBS)

Post-graduation or more

3. What is your family income per month? *

Less than or equal to Rs. 20000

More than Rs. 20000 but less than or equal to Rs. 50000

More than Rs. 50000 but less than or equal to Rs. 200000

More than Rs. 200000

4. Have you ever had sexual intercourse? *

Yes

No

Awareness and opinion

5. Were you aware of cervical cancer before taking this questionnaire?

Yes

No

6. Were you aware that cervical cancer is caused by an infection from the HPV virus?

Yes

No

7. Were you aware of any screening/ testing options for cervical cancer before taking this questionnaire?

Yes

No

8. Have you ever undergone a PAP Smear test?

Yes

No

I'm not sure

9. Have you ever been tested for HPV infection from a cervical/ vaginal swab?

Yes

No

I'm not sure

10. Would you consider undergoing screening for cervical cancer?

Yes

No

11. If yes, which method would you prefer (assuming all methods were equally effective)?

Check all that apply.

a cervical swab collected by a gynecologist

a cervical swab collected by a gynecologist a self-collected vaginal swab

a self-collected urine sample

12. How much will you be willing to pay for cervical cancer screening once every year?

Upto Rs. 500

Upto Rs. 1000

Upto Rs. 2000

Upto Rs. 5000

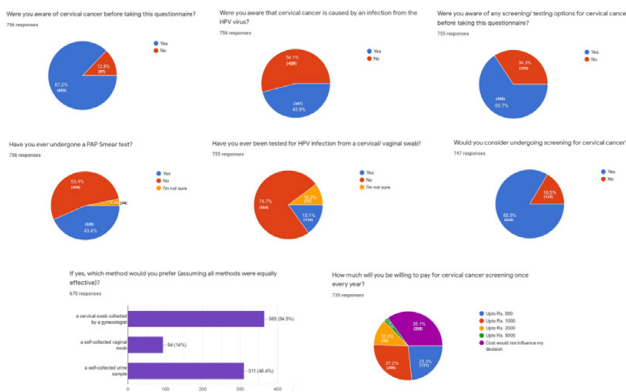
Cost would not influence my decision



B. Demographic details of the cohort

Demographic Parameters	Number of individuals	Prevalence (%)
Age Group		
Less than 18 years	3	0.4
18-30 years	151	18.1
31-45 years	506	60.5
More than 45 years	176	21.1
Education level		
Upto 12th standard	23	2.8
Graduation	283	33.9
Post-graduation or more	530	63.4
Family Income per month		
Less than equal to Rs. 20,000	40	4.8
More than Rs. 20,000 to Rs. 50,000	146	17.5
More than Rs. 50,000 to Rs. 2,00,000	327	39.1
More than Rs. 2,00,000	323	38.6

C. Responses data from the 'Awareness and Opinion' section:



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Data Availability and Materials

Attached in the 'Supplementary Section'.

Authorship

Each author meets criteria for authorship and has made integral contributions in this study.

Funding

Not applicable.

Conflict of Interest

The authors were employed at GenePath Diagnostics India Private Limited when the study was conducted. GenePath Diagnostics is a molecular diagnostic testing laboratory in the private sector in India and has been undertaking human papilloma virus DNA testing on clinical samples commercially.

Informed Consent

Not required as it was an anonymised survey.

Ethical Approval

Not applicable.

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