

The Acceptability and Preference of Vaginal Self-sampling for Human Papillomavirus (HPV) Testing among a Multi-ethnic Asian Female Population



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ABSTRACT

Vaginal self-sampling for human papillomavirus (HPV) testing can potentially increase cervical screening coverage. This study aimed to investigate the acceptability of vaginal self-sampling for HPV testing and factors that might influence a woman's preference for this as a cervical screening method. This was a cross-sectional study that recruited 725 women from the urban and suburban areas of Selangor, Malaysia. All study participants were instructed to self-collect vaginal sample using a dry flocked swab before responding to a detailed questionnaire documenting their experience and preference for self-sampling. Most of the study participants (>80%) perceived vaginal self-sampling as easy, convenient, not embarrassing, comfortable, and were confident in performing the test. This suggests high acceptability toward vaginal self-sampling for HPV testing. Of the 725 women, 83% preferred self-sampling HPV testing over healthcare personnel sampling HPV testing and Pap test. Women with higher household

income and full-time employment status were more likely to prefer self-sampling. Those who had not undergone Pap test also expressed preference for self-sampling HPV testing. Convenience and women's confidence in performing a vaginal self-sampling for HPV testing were the independent key factors that influenced the preference for self-sampling method. Vaginal self-sampling for HPV testing is highly acceptable among Malaysian women. It is the preferred choice as a primary cervical screening method and serves as an alternative to healthcare-acquired sample for Pap test.

Prevention Relevance: Organized cervical cancer screening remains unachievable in many countries. Self-sampling HPV testing is an evidence-based method that can remove barriers to cervical screening. This is particularly important for developing countries in order to achieve the WHO global strategy to accelerate cervical cancer elimination.

Introduction

Cervical cancer remains a global health issue as 570,000 cases have been diagnosed worldwide with a death toll of approximately 311,000 women in 2018 (1). The major cause of cervical cancer is the persistent infection of oncogenic human papillomavirus (HPV) types, notably HPV 16 and 18, that collectively account for 70% of cervical cancer and precancerous lesions (2). In May 2018, World Health Organization made a call for global

efforts in the elimination of cervical cancer emphasizing on three key interventions, which are to achieve 90% of HPV vaccination coverage, 70% of cervical screening for women ages 35–45 using high precision test, and 90% of women diagnosed with cervical disease to receive proper treatment (3).

Cervical cancer is the second most common cancer among Malaysian women ages 15–44 years (4). Several strategies have been implemented in the effort toward cervical cancer elimination. These include the initiation of a national school-based HPV vaccination program for 13-year-old females and the availability of the conventional cervical screening test, Pap test, in most government-run healthcare facilities. The primary HPV vaccination program was successful, with a high coverage of 82.2%, but the uptake of Pap test remains low at 12.8% (5, 6). The main barriers to Pap test uptake were reported to be fear, embarrassment, and lacking awareness and time (7–9). Low screening coverage remains a big challenge in the effort to eliminate cervical cancer. Therefore, HPV testing deployed using a self-collection method could be a more acceptable alternative to overcome common barriers to screening by conventional Pap test. HPV testing detects presence of high-risk HPV types and is proven to be more sensitive than Pap test (10, 11). In addition, high negative predictive value of HPV testing permits a much

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longer screening interval compared with cytology (12). Studies have also shown that a self-sampling vaginal sample and a clinician-acquired cervical sample, both are equally effective in detecting oncogenic HPV types, making self-sampling strategy strongly feasible as a primary screening approach (13, 14).

Emerging evidence indicates that self-sampling for HPV testing has led to not only a rise in cervical screening participation but also diagnosis and follow-up care at healthcare facilities (15–18). Before adopting self-sampling HPV testing for the optimization of cervical screening coverage in the local setting, it is essential to assess the feasibility of vaginal self-sampling HPV testing among our multi-ethnic Asian population. This study aimed to investigate the acceptability of vaginal self-sampling for HPV testing and factors that might potentially influence its preference as a cervical screening method in a lower middle-income country setting.

Materials and Methods

Study participants

This was a cross-sectional study that recruited 725 healthy women from June 2019 to February 2020. Subjects were recruited via convenience sampling as part of an on-going community-based HPV prevalence study (The Malaysian HPV Prevalence Study II) from three primary care public health clinics, one tertiary hospital, two public universities, and one private university situated in urban and suburban areas of Selangor, Malaysia. The subjects were mainly healthy women who visited clinics or hospitals for primary care services such as routine health checks or accompanied family members. Women ages 35–45 who consented to vaginal self-sampling HPV testing and answering questionnaires were recruited to this study. The exclusion criteria were pregnancy, partial/complete hysterectomy, currently menstruating, acute illness, and never been sexually active. This study obtained ethical approval from the Medical Research Ethics Committee (NMRR-13-3229-44851) and the University of Malaya Medical Ethics Committee (Kuala Lumpur, Malaysia, MREC ID 20181219-6935). Written informed consent was obtained from all participants.

Sample and data collection

Trained research staff was placed at the recruitment sites to screen and recruit women into the study. Eligible women who refused to perform vaginal self-sampling HPV testing were interviewed briefly to determine reasons for declining to participate. Eligible women who agreed to perform vaginal self-sampling HPV testing were provided with oral and diagrammatic instructions for sample collection. The self-sampling device for vaginal sample collection was a dry Flocked Swab (Copan Diagnostic Inc, #552C/80 mm) enclosed in a plastic packaging tube. Briefly, participants were instructed to gently insert the swab into the lower vagina and twist for five to ten times before placing it back to its packaging tube. All participants collected their sample in a designated private room or washroom. Immediately after sample collection, a face-to-face interview was conducted by

a trained research staff in a private area to collect sociodemographic data, reproductive history, and cervical screening history. These data were collected using a questionnaire previously used in a study done in the local setting (19). For post self-sampling acceptability assessment, a questionnaire that was previously used in the local setting was used in this study (20). This questionnaire was available in English, Malay, and Chinese versions to suit the multilingual local population. The questionnaire was originally developed and validated by Dzuba and colleagues (21). The domains for acceptability indices were developed on the basis of identified barriers to cervical screening by a qualitative study (22). This questionnaire was first modified by Waller and colleagues and then further modified by Ma'som and colleagues (20, 23) to fit the local setting. The acceptability of vaginal self-sampling was assessed on the basis of six indices related to personal perception of the self-sampling procedure. The six items were overall feeling, ease of procedure, convenience, embarrassment, discomfort/pain, and confidence measured using a five-item Likert scale, where 5 indicated the most positive response and 1 the most negative response. A score point of 4 and above was considered as a positive response implying the self-sampling method was acceptable. Participants were also asked about their preference of cervical screening method: self-sampling HPV testing, healthcare personnel sampling HPV testing (using same device as self-sampling testing), Pap test, or no preference.

Statistical analysis

Reliability analysis using Cronbach- α coefficient was used to measure the internal consistency of the acceptability assessment questionnaire. A value of ≥ 0.7 indicated a good reliability of a construct. Sociodemographic data such as ethnicity, marital status, education level, and household income were recorded and analyzed as categorical data. The acceptability of self-sampling was described using percentages. The association between variables and preference for self-sampling HPV testing was evaluated using a χ^2 test or Fisher exact test when $>20\%$ of cell counts were less than 5. Variables with $P \leq 0.2$ in the univariable analysis were included into multivariable analyses to determine the potential factors that influence the preference for self-sampling HPV testing. The independent factor was estimated with ORs [with 95% confidence interval (CI)] using a binary logistic regression model. A two-tailed $P < 0.05$ was considered as statistically significant. All analyses were performed using Statistical Package for Social Science V.20.

Results

Study participants

A total of 1,083 women who fulfilled the inclusion criteria were invited and 66.9% (725/1,083) agreed to participate in this study. The top three reasons for declining vaginal self-sampling HPV testing were lack of interest (45.5%, 163/358), lack of time (35.7%, 128/358), and had recently performed or planned for cervical screening (13.7%, 49/358; **Table 1**). Of those who declined to participate, only 3.4% indicated that this was due

Table 1. Reasons for rejecting vaginal self-sampling HPV testing (*n* = 358).

Reasons	<i>n</i> (%)
Not interested	163 (45.5)
Busy/no time	128 (35.7)
Have recently done/planned for cervical screening	49 (13.7)
Afraid of self-sampling procedure	6 (1.7)
Not confident with self-sampling testing	6 (1.7)
Partner's refusal	4 (1.1)
Afraid of cervical screening results	1 (0.3)
Others	1 (0.3)

to fear or lack of confidence in performing the vaginal self-sampling test. Majority of the subjects were recruited from the primary care clinics and hospitals (93.5%, 678/725) and the rest were university staff (6.5%, 47/725). The main ethnic group for this study population was Malay (60.7%, 440/725) followed by Chinese (22.9%, 166/725) and Indian (13.1%, 95/725). Most of them were married women (90.8%, 658/725) and had ever done a Pap test (77.9%, 564/725). These data are shown in **Table 2**.

Acceptability of vaginal self-sampling for HPV testing

The reliability analysis for the self-sampling acceptability questions indicated good internal consistency with Cronbach- α coefficient of 0.743. The results for acceptability of self-sampling for HPV testing are shown in **Table 3**. A vast majority of the participants reported that vaginal self-sampling HPV testing was easy to perform (93.8%, 680/725), convenient (95.6%, 693/725), and not embarrassing (96.8%, 702/725). Overall, most of the participants (>80%) provided a positive response (scored 4 points and above in Likert scale) to the six acceptability indices. This indicated that vaginal self-sampling HPV testing was highly acceptable in our study population. The overall feeling toward self-sampling, ease of procedure, convenience, comfort, and confidence in performing the procedure were all associated with an increased preference toward self-sampling (*P* < 0.05). Feelings of embarrassment did not significantly influence the preference for self-sampling procedure (*P* = 0.535). Almost all our study participants (99.9%, 724/725) were willing to repeat vaginal self-sampling HPV testing as a routine cervical screening test.

Preference for vaginal self-sampling for HPV testing and its associated factors

Most of the study participants opted for self-sampling as their preferred mode of cervical screening (83%, 602/725) compared with healthcare personnel sampling HPV testing (3.3%, 24/725) and Pap test (1.7%, 12/725). The remaining participants had no preference (12%, 87/725), as shown in **Fig. 1**. Among the participants that preferred self-sampling, 602/458 (76.1%) have had a previous Pap test for cervical screening. In our study population, 22% (160/724) of women had never undergone a Pap test. The main reasons for not doing a Pap test were inconvenience (77/160, 48.1%), fear of pain (71/160, 44.4%), embarrassed to be examined by a

Table 2. Demographic characteristics associated with preference for vaginal self-sampling HPV testing (*N* = 725).

Variables	<i>n</i> (%)	Preferred self-sampling (%)	<i>P</i>
Overall	725 (100)	83.0	
Ethnicity			0.192 ^a
Malay	440 (60.7)	83.6	
Chinese	166 (22.9)	78.3	
Indian	95 (13.1)	86.3	
Others	24 (3.3)	91.7	
Marital status			0.023 ^b
Single/never been married	14 (1.9)	64.3	
Currently married	658 (90.8)	82.8	
Divorced/separated	47 (6.5)	93.6	
Widowed	6 (0.8)	66.7	
Education			0.133 ^a
Primary	12 (1.7)	91.7	
Secondary	238 (32.8)	84.9	
Tertiary	391 (53.9)	80.3	
Postgraduates	84 (11.6)	89.3	
Employment			0.003 ^b
Full-time	538 (74.2)	82.7	
Part-time	14 (1.9)	50.0	
Temporarily unemployed/ students/retired/disabled	9 (1.2)	66.7	
Work from home/housewives	164 (22.6)	87.8	
Income group (RM)			0.151 ^a
<5,000	285 (39.3)	83.2	
5,000–10,000	292 (40.3)	80.5	
>10,000	148 (20.4)	87.8	
Have ever done Pap test			0.009 ^a
No	160 (22.0)	90.0	
Yes	564 (77.9)	81.2	
Missing	1 (0.1)	0	
Number of pregnancies			0.929 ^a
0	57 (7.9)	80.7	
1–3	383 (52.8)	82.8	
4–6	257 (35.4)	83.7	
>6	28 (3.9)	85.7	

Note: Missing data were not included in the analysis.

^a*P* value generated using χ^2 test.

^b*P* value generated using Fisher exact test.

physician (61/160, 38.1%), and lack of awareness for Pap test (49/160, 30.6%; Supplementary Table S1). In the univariable analysis, divorcees (93.6%; *P* = 0.023) and housewives or those reporting to work from home (87.8%; *P* = 0.003) expressed preference toward self-sampling HPV testing. There was no significant difference in terms of preference toward self-sampling across various ethnic groups (*P* = 0.192), income groups (*P* = 0.151), educational background (*P* = 0.133), and number of pregnancies (*P* = 0.929; **Table 2**).

In the multivariable analysis, women who had prior Pap test experience were less likely to choose self-sampling HPV testing (*P* = 0.037; adjusted OR, 0.533; 95% CI, 0.295–0.963; **Table 4**). Furthermore, women in full-time employment preferred self-sampling HPV testing when compared with those employed part-time (*P* = 0.010; adjusted OR, 0.216; 95% CI, 0.067–0.694). Women with higher income also expressed higher preference for this test compared with those from a

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Table 3. Acceptability of self-sampling HPV testing and its association with preference for vaginal self-sampling procedure ($N = 725$).

Aspect	<i>n</i> (%)	Preferred self-sampling (%)	<i>P</i>
Overall feeling			
Bad	84 (11.6)	69.0	<0.001
Good	641 (88.4)	84.9	
Ease of procedure			
Not easy	45 (6.2)	66.7	0.003
Easy	680 (93.8)	84.1	
Convenience			
Not convenient	32 (4.4)	56.2	<0.001
Convenient	693 (95.6)	84.3	
Embarrassment			
Embarrassing	23 (3.2)	78.3	0.535
Not embarrassing	702 (96.8)	83.2	
Comfort/pain			
Not comfortable/painful	137 (18.9)	74.5	0.003
Comfortable/not painful	588 (81.1)	85.0	
Confidence			
Not confident	135 (18.6)	67.4	<0.001
Confident	589 (81.4)	86.6	
Missing	1 (0.1)	100	

Note: A positive response to each index was defined by a score point of 4 and above measured using Likert Scale. *P* value was generated using χ^2 test.

lower income background (<RM 5,000; $P = 0.012$; adjusted OR, 2.746; 95% CI, 1.246–6.055). The convenient nature of the procedure and confidence in performing self-sampling HPV testing were reported to be the key factors that potentially affected the preference of self-sampling in the multivariable analysis ($P = 0.036$ and $P < 0.001$).

Discussion

To the best of our knowledge, this is the first study in Southeast Asia assessing the acceptability of vaginal self-

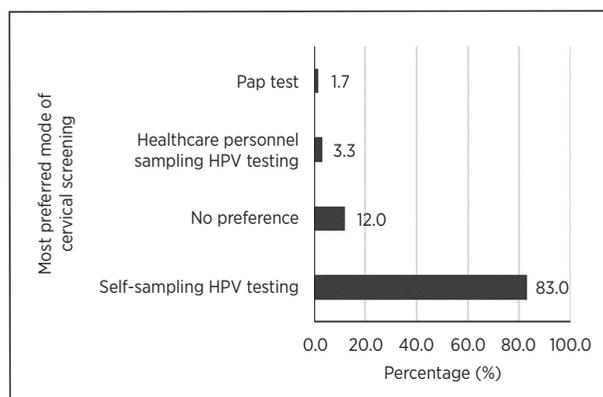


Figure 1. Preference of mode of cervical screening among study participants. The most preferred mode of cervical screening among study participants was vaginal self-sampling for HPV testing (83%), whereas the least preferred cervical screening method was Pap test (1.7%; $n = 725$).

Table 4. Multivariable analysis assessing factors associated with the preference for self-sampling HPV testing ($n = 723$).

Variables	<i>n</i>	Adjusted OR (95% CI)	<i>P</i>
Ethnicity			
Malay	438	1	
Chinese	166	0.713 (0.422–1.204)	0.206
Indian	95	0.962 (0.478–1.934)	0.913
Others	24	2.251 (0.482–10.510)	0.302
Marital status			
Single/never been married	14	1	
Currently married	657	1.466 (0.362–5.926)	0.592
Divorced/separated	47	6.008 (0.946–38.167)	0.057
Widowed	5	1.251 (0.112–13.958)	0.856
Education			
Primary	12	1	
Secondary	236	0.734 (0.088–6.119)	0.775
Tertiary	391	0.554 (0.066–4.682)	0.588
Postgraduates	84	1.171 (0.118–11.612)	0.892
Employment			
Full-time	537	1	
Part-time	14	0.216 (0.067–0.694)	0.010
Temporarily unemployed/ students/retired/disabled	9	0.330 (0.067–1.628)	0.173
Work from home/housewives	163	1.596 (0.882–2.887)	0.122
Income group (RM)			
<5,000	283	1	
5,000–10,000	292	1.243 (0.724–2.135)	0.430
>10,000	148	2.746 (1.246–6.055)	0.012
Have ever done Pap test			
No	159	1	
Yes	564	0.533 (0.295–0.963)	0.037
Overall feeling			
Bad	83	1	
Good	640	1.440 (0.670–3.095)	0.350
Ease of procedure			
Not easy	45	1	
Easy	678	0.888 (0.332–2.375)	0.813
Convenience			
Not convenient	32	1	
Convenient	691	2.902 (1.072–7.857)	0.036
Comfort/pain			
Not comfortable/painful	137	1	
Comfortable/not painful	586	1.456 (0.825–2.570)	0.194
Confidence			
Not confident	135	1	
Confident	588	2.469 (1.501–4.060)	<0.001

Note: *P* value was generated using a binary logistic regression model.

sampling HPV testing using a simple dry flocced swab. The study population was predominantly Malay (60.7%) and married (90.8%). The preference for vaginal self-sampling for HPV testing was reported to be 83%, indicating that self-sampling is highly acceptable in our study population. The main factors influencing a respondent's preference for vaginal self-sampling were not having a prior Pap test, full-time employment status, high household income, the convenient nature of the test, and women's confidence in performing the test.

Of the 1,083 eligible women that were invited to join this study, 33.1% (358/1,083) declined to perform a vaginal self-sampling HPV testing. The main reason for declining this test

was lack of interest (163/358, 45.5%) in having a cervical screening test. The lack of awareness and knowledge to cervical screening remains the main barrier to cervical screening and more attention should be paid to this aspect during the development of cervical cancer prevention program in future (24). The second most common reason for declining self-sampling for HPV testing was the lack of time (128/358, 35.7%) as these women had attended clinic for other purposes such as immunization of their children and medication collection.

The overall high acceptability and preference toward self-sampling for HPV testing in this study were consistent with a recent systematic review by Nelson and colleagues (25). However, the preference recorded in this study (83%) was comparably higher compared with published studies (51%–78%; refs. 15, 20, 26). The effect size relies on the approaches used in the implementation of self-sampling HPV testing (27). Some of the studies provided written explanation and delivery of kits by mail. In this study, our trained research staff allowed examination of the sampling kit before sampling and conducted face-to-face education to resolve any doubts related to the sampling process. Comprehensive education and assistance by staff significantly increased self-sampling acceptability (28). Another possible explanation to the variation of preference to self-sampling testing is the different kits used resulting in different self-sampling experience. The Copan 552C flocked swab is simple and not too different from a Q-tip swab, which women are familiar with.

In our study population, 22% (160/724) of women had never undergone a Pap test. The top four reasons reported for not doing a Pap test were inconvenience, fear of pain, embarrassed to be examined by a physician, and lacking awareness for Pap test. These were similar to factors cited in previous studies (7, 8, 15, 24). In this study, most of the participants felt self-sampling HPV testing was convenient (95.6%), not embarrassing (96.8%), and not painful (81.1%). These responses were encouraging for self-sampling HPV testing in overcoming the common barriers in cervical screening particularly among the nonattendees. In addition, women who had never done a Pap test were twice more likely to choose self-sampling HPV testing compared with those who have ever had a Pap test. This finding matched several similar studies and suggested that self-sampling HPV testing can be a promising option to increase uptake of cervical screening among the underscreened population (20, 29).

Another sociodemographic factor that was associated with preference to self-sampling HPV testing was employment status. Women who were in full-time employment demonstrate lower cervical screening participation compared with unemployed women in Asian population because of difficulties in obtaining time-off and long waiting hours at clinic (30). Self-sampling HPV testing could possibly tackle this issue because it requires less time than conventional cervical screening. Thus, compared with those women who were unemployed/part-timers, women who were in full-time employment were three

times more likely to choose self-sampling HPV testing as their most preferred mode of cervical screening. Another possible reason could be employed women may be more knowledgeable in cervical screening and its linkage to disease compared with unemployed women (31).

Women with higher household income were more likely to opt for self-sampling HPV testing compared with those with lower household income. This might be because women who earn more have a higher commitment to work and therefore, find this test more convenient than Pap test. Income status may also be associated with education levels, and lower education level has been associated with a reduced preference for self-sampling in previous studies and this might be due to lower awareness of the risk of developing cancer and the importance of cervical screening (32, 33). We, however, did not find a significant association between different education levels and the preference of self-sampling HPV testing in this study. This could be possibly because the majority of participants were recruited from health clinics, which likely represented a biased population with an increased health awareness and health-seeking behavior. Besides, it is also worth noting that the high acceptability of self-sampling HPV testing remained consistent across different ethnic groups in our multicultural setting. This finding was consistent with other studies (34, 35).

Generally, most of the participants (>80%) perceived self-sampling HPV testing as easy, not embarrassing, convenient, and comfortable. These results are consistent with other studies (15, 20, 26). The independent factors that influenced the willingness to participate in self-sampling cervical screening were convenience and confidence. These key factors have been reported previously (36, 37). In this study, most of the women addressed their confidence in collecting own samples before they received their test results. This finding was similar to several studies that had conducted self-sampling screening using different approaches, such as kit delivery and home-based screening (15, 38). However, these are also contrary to some reports, which found a lack of confidence for self-sampling HPV testing among Asian women (23, 39). Enhancing women's confidence in performing self-sampling testing should remain a key focus in the effort to expand cervical screening coverage in our population.

To date, only a few studies have assessed the acceptability and preference of self-sampling HPV testing in a multi-ethnic population. Our study considered women's perception toward self-sampling HPV testing together with diverse sociodemographic characters to determine the key factors that could influence the acceptability of self-sampling HPV testing in community-based cervical screening programs. However, these findings might not adequately represent the whole population as these women were recruited mainly from urban and suburban areas. In addition, the opportunistic sampling from healthcare clinics might have caused an undersampling of underscreened population, which are an important target group for the success of any screening program. This includes

women who could not attend clinics due to logistics issue. Therefore, future work should aim to include underscreened population, especially those in the rural areas that have limited healthcare access and education.

This study demonstrates high acceptability toward vaginal self-sampling HPV testing as the primary cervical screening method in a relatively conservative multi-ethnic population in Southeast Asia. Almost all the study participants were willing to adopt this method as a routine cervical screening test. Convenience was the key benefit for self-sampling HPV testing and women's confidence in performing the test is the key factor that can potentially drive the success of a cervical screening program. Future cervical screening programs in Malaysia should take into account these key factors to achieve at least 70% cervical screening coverage in women ages 35–45 using a high precision test. This strategy would certainly complement the national HPV vaccination program that was initiated in 2010 to eliminate cervical cancer.

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Authors' Contributions

S.P. Khoo: Data curation, software, formal analysis, investigation, visualization, methodology, writing-original draft, project administration. **W.T. Lim:** Investigation, project administration. **R. Rajasuriar:** Resources, supervision, investigation, methodology, writing-review and editing. **N.H. Nasir:** Conceptualization, resources, supervision, methodology. **P. Gravitt:** Conceptualization, resources, methodology. **Y.L. Woo:** Conceptualization, resources, supervision, funding acquisition, validation, investigation, visualization, methodology, project administration, writing-review and editing.

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