BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2015-011022
Article Type:	Research
Date Submitted by the Author:	04-Jan-2016
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Primary Subject Heading:	Public health
Secondary Subject Heading:	Obstetrics and gynaecology, Oncology, Patient-centred medicine, Sexual health
Keywords:	human papillomavirus, pap smear, cervical cancer screening, self sampling, cervico-vaginal sampling

Attitudes and factors affecting acceptability of self-administered cervico-vaginal sampling as an alternative to Pap testing among multi-ethnic Malaysian women

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Key words

human papilloma virus (HPV), cervical screening, self-administered cervico-vaginal sampling, Pap smear , acceptability

Word count

2,741 words

ABSTRACT

Objective: The objective of this study is to determine the attitudes and acceptability of self-administered cervico-vaginal sampling compared to conventional physician acquired Papanicolaou (Pap) smear among multi-ethnic Malaysian women.

Method: A cross-sectional study was carried out via interviewer-administered surveys from August 2013 through August 2015 at five government-run, urban health clinics in the state of Selangor. Subjects were participants of an on-going community-based human papillomavirus prevalence study who answered a standard questionnaire before and after self-sampling. The cervico-vaginal self-sampling was performed using a simple brush ("Just for Me", Preventive Oncology International Inc., Hong Kong Ltd.). Data on socio-demographics and previous cervical Pap smear experience was collected and analysed as well as attitudes towards self-administered cervico-vaginal sampling. Acceptability was inferred using a 5-item Likert scale that included 6 different subjective descriptives: experience, difficulty, convenience, embarrassment, discomfort or pain, and confidence at collecting one's own sample.

Results: Of the 839 participants, 47.9% were Malays, followed by 30.8% Indians, 18.8% Chinese, and 2.5% from other ethnicities. Median age of participants was 38 years (interquartile range = 30-48 years old). 68.2% of participants indicated a preference for self-sampling over Pap test, with 95% indicating willingness to follow-up a positive result at the hospital. Age, ethnicity and previous Pap test experience were significant independent factors associated with preference for self-sampling. The older the individual, the less likely they were to prefer self-sampling (adjusted OR=0.94, 95% CI: 0.90 - 0.98). The Chinese were less likely to prefer self-sampling (72.6%) than the Malays (85.1%)

(adjusted OR=0.57, 95% CI: 0.33-0.99). Participants who have never undergone a Pap smear were also more likely to prefer self-sampling (88.5%) than women who had a previous Pap (80.9%) (adjusted OR=0.06, 95% CI: 0.35-0.87).

Conclusion: Overall, urban Malaysian women from multi-ethnic backgrounds found self-sampling to be an acceptable alternative to Pap smear.

299 words

INTRODUCTION

Cervical cancer is the second most common cancer among Malaysian women with an incidence of over 16 per 100,000 and mortality of over 8 per 100,000 (1, 2). While there is no population-based cervical cancer screening program in Malaysia, the government has supported opportunistic screening by providing free Pap smear tests since 1995. The uptake of Pap tests among Malaysian women remains suboptimal with less than half (47.3%) of the population having received it (3). Many reasons have been cited for the lack of cervical cancer screening participation including cost, embarrassment, fear, lack of knowledge and lack of time (4-7). In 2010, the Malaysia government started a national school-based human papillomavirus (HPV) immunisation programme (8). Despite the success of the national HPV vaccine program, with more than 90% of 13 year old school girls being vaccinated (9), more comprehensive coverage and increased uptake of cervical screening remains important for at least another 30-40 years to adequately prevent the development of cervical cancer in the Malaysian population.

In communities where uptake of conventional cervical screening by cytology has been low, self-sampling may offer an attractive alternative. Unlike Pap smear tests, this procedure can be carried out by the individual themselves without the help of a physician or medical staff. This means that other logistical barriers involved with Pap test screenings such as long waiting times in hospitals, inadequate number of and inexperienced cytologists, and unequal distribution of health care resources(10) can be overcome, making it a more efficient and cost-effective option (11, 12). Studies

have shown a rise in participation from non-respondents to screening programs when self-sampling methods are introduced (13-18). However, due to socio-cultural and religious differences, it was important to assess the value of self-sampling in the context a multi-ethnic Asian community such as Malaysia. This study aims to explore the attitudes and perception before and after the process of self-sampling to determine acceptability in comparison to the Pap smear test amongst a multi-ethnic population.

METHOD

Participants

Volunteers for this cross-sectional study were recruited between August 2013 and August 2015 from five government-run general practice clinics; Klinik Kesihatan Pandamaran, Klinik Kesihatan Ampang, Klinik Kesihatan Bandar Botani, Klinik Kesihatan Batu 9, and University Malaya Medical Centre which are located in Selangor, the most developed state in Malaysia with a high level of urbanisation. Subjects were participants of an on-going community-based human papillomavirus prevalence study (The Malaysian HPV Prevalence Study), who were recruited during their visits to the health clinics for primary care services including immunization, routine health checks, and while accompanying family members to these clinics. Participants were aged between 18 and 60 years old. The exclusion criteria included pregnancy, menstruation, acute illnesses, or never having been sexually active. This study received approval from the Medical Research Ethics Committee (NMRR-13-444-14609), and University Malaya Medical Ethics Committee (MREC989.32). Written informed consent was obtained from all participants. All patient responses were treated as confidential.

Cervico-vaginal self-sampling and assessment

Participants were invited to perform self-sampling on their own using a simple brush (“Just for Me” ©, courtesy of Preventive Oncology International. Inc, Hong Kong Ltd.) (POI). See Figure 1. Instructions on how to use the self-sampler were given to the participants. Briefly, participants were

instructed to gently push the brush to the top of the vagina with one leg on a chair. The brush is turned a few times to the left and then the right before being removed completely. After withdrawal, the brush is rubbed onto the POI FTA card provided with the kit and sealed in an envelope. The FTA card is a solid media specimen transport card and therefore, eliminates problems encountered with alcohol-based liquids, temperature exposure and transportation difficulties (19). A questionnaire which has been developed in a previous study (20) was modified and translated into Malay and Mandarin so it could be applied to our multi-lingual population. It was administered before and after the procedure (Supplementary File). Acceptability indices for the self-administered cervico-vaginal sampling included six items: experience, difficulty, convenience, embarrassment, discomfort or pain, and confidence. A 5-item Likert scale was used in the pre- and post-self-sampling questions where the value 5 was the most favourable response and 1 the most disagreeable. In this study, values 4 and 5 were deemed as a positive attitude. Cronbach's alpha coefficient which ranges from 0 to 1 was used to ascertain internal consistency. A low value shows poor reliability or consistency among the items within the construct and a value of at least 0.7 is generally needed to show good reliability. Comprehensive socio-demographical information was collected via interviewer-administered questionnaire.

Statistical Analysis

Data was analysed using IBM Statistical Package for Social Science (SPSS) version 20. Acceptability items in the questionnaire were described in percentages, and compared using the Chi square test. McNemar's test was used for correlated proportions to measure any significance in the change of acceptability. Continuous variables were described using medians, and compared using the Mann Whitney-U test. Multivariable logistic regression analysis was used to investigate factors associated with preference for self-sampling. A *p*-value of <0.05 was considered to be statistically significant.

RESULTS

Participant Characteristics

A total of 839 women were interviewed and the median age of the study participants was 38 years (interquartile range: 30 and 48 years old). 82.7% of the study population were pre-menopausal, aged 50 years old and below. Malay women represented the largest ethnic group (47.9%), followed by Indians (30.8%), Chinese (18.8%) and other races (2.5%) with 86.3% being married. 57% of the participants were employed while 35.2% were fulltime home-makers. 62.1% had completed secondary education. Only 11.8% of women reported a monthly household income of more than RM5000 (USD1100). Out of the 839 women, 76% have heard of the Pap smear before with 63.1% ever undergoing a pap test. Most of the women (81.9%) who had undergone Pap smear tests, received it in the last 5 years preceding the study. Factors positively associated with Pap testing include higher education level ($p<0.05$), older age ($p<0.05$) and higher income ($p<0.05$) of the participants. Of women who have never undergone Pap test, primary barriers that were stated include lack of awareness (13%), lack of time (10%), no existing symptoms (6.6%) and fear (5.1%)(data not shown).

Self-administered cervico-vaginal sampling is acceptable

Both sections of the survey showed a high internal consistency with the pre-questionnaire having a Cronbach's alpha value of 0.796 and the post-questionnaire being 0.862. In the pre-questionnaire, more than half of the participants gave a positive response (score 4 or 5 on the Likert scale) for all the six items that were tested; experience, ease of procedure, convenience, embarrassment, comfort, and confidence (Table 1). Following self-sampling, most women reported the procedure to be easy (67.9%), convenient (77.1%), not painful (50.8%) and expressed confidence (67.6%) about collecting their own samples correctly (Figure 2). The level of education was inversely associated with confidence ($r= -0.14$, $p<0.0005$) whereas ethnicity, age and marital status were not significantly associated with confidence. About 7% of the respondents still found self-sampling to be embarrassing, of which more than half were those who have never undergone a Pap test before. No

factors were found to significantly influence the discomfort or pain felt by the women, and though it was reduced post-self-sampling, 17.4% reported discomfort after performing the self-sample. Ethnicity was significantly associated with the ease ($x^2(3) = 7.817$, $p<0.05$) and agreeableness ($x^2(3) = 9.93$, $p<0.019$) of the experience of self-sampling. Tukey's post hoc tests indicated Malays (95% CI: 0.01-0.19, p = 0.0015) and Indians (95% CI: 0-0.19, p=0.048) found self-sampling to be more positive in experience compared to the Chinese. Education was negatively correlated with convenience (r= -0.083, p=0.018).

Overall, the above findings indicate that there was an increase in all 6 indices of acceptability after self-sampling. In the post-questionnaire, it was also revealed that a vast majority (91.8%) of the participants would be willing to self-sample if it was made to be the only cervical cancer screening option available. Most (95.2%) participants expressed willingness to go for a follow-up should they obtain a positive result. Approximately two thirds (60%) preferred to carry out self-sampling at home and almost half (49.1%) would prefer to pick up the self-sample kit at a near-by clinic.

Self-sampling versus conventional Pap Test

After the procedure, 68.2% of the participants were reported to have a preference towards self-sampling compared to 13.5% who preferred Pap smear tests while 14.1% stated no preference. There were no significant differences in preference for self-sampling based on education level, smoking, and marital status (Table 2). However, ethnicity influenced preference for self-sampling where the Chinese were less likely to prefer self-sampling than the Malays (OR=0.57, 95% CI: 0.33-0.99). Besides that, older individuals were less likely to prefer self-sampling (OR=0.94, 95% CI: 0.90-0.98). As a sensitivity analysis, the group of women were split into those that have and have not undergone Pap tests and further analysed. It was found that prior experience of undergoing Pap test had a significant impact on the preference (p=0.01). For the women with no prior experience of Pap testing, self-administered cervico-vaginal sampling was found to be more favourable than physician-

sampling for approximately 75% of the women. These women were also almost twice as likely to prefer self-sampling compared to participants who have undergone physician-sampled Pap testing, who were less likely to prefer self-sampling (OR=0.06, 95% CI: 0.35-0.87).

DISCUSSION

To our knowledge, this is one of the largest studies where self-sampling acceptability was systematically assessed before and after the procedure was done in a multi-ethnic Southeast Asian population. In this study, 98.3% of the participants were within the screening age population (21-65 years old), where 39.8% of the participants had not done a Pap test in the past three years or more, and 36% of participants have never received a Pap test. Cervical cancer, the second most prevalent cancer amongst Malaysian women is preventable and an estimated reduction of 70% of new cases can be prevented by screening and early detection (21, 22). Unfortunately, the overall uptake of Pap smear in Asian countries including Malaysia is still poor (4-7, 23). Lack of awareness was the main reason cited by the participants in this study for never having done Pap smear tests prior to this. This is also the most commonly cited reason in other countries such as Turkey, Bangladesh, Gabon and Korea (24-27). Therefore, increasing awareness of and education about cervical cancer screening is necessary and independent of the modality of screening. While self-swabs and other self-sampling devices have been examined and reported to be reliable (6) and not inferior to specimens obtained by physicians (28), it is necessary to investigate the perception and acceptability of self-sampling amongst multi-ethnic Malaysian women especially among potential users who have never done Pap testing.

Generally, participants showed a high acceptability towards self-sampling. Negative perceptions regarding the use of self-sampling reported before experience with collection decreased after having experienced the self-collection first-hand. The acceptability scores indicated that the participants were highly confident in collecting their own samples. This is similar to studies undertaken in Sub-

Saharan Africa (29) and Finland (17). Interestingly, in studies where physician-sampling was compared directly to self- sampling, women trusted the physician-sampling more and had lower confidence on their own competency (20, 30). In our study, the level of education was significantly associated with confidence where surprisingly, those with a higher level of education were less confident about self-collection. There could be several explanations for this. It can be postulated that those with higher education tend to overthink and question their abilities more. Education programmes designed to show the validity of self-collection may help to alleviate any concerns raised by doubtful participants. Another reason could be that women with higher education were more comfortable with a professional carrying out the test rather than themselves. This is contradictory to studies showing that education level did not have a significant impact on self-sampling acceptability (31). The majority (68.2%) of the women surveyed preferred self-sampling compared to physician-sampled Pap smear tests after carrying it out. This is not surprising as issues such as embarrassment and inconvenience could be overcome with the use of self-samplers, enabling women to do it independently in the comforts of their own homes. These results are in line with those of previous studies (20, 32-36). However, prior experience with Pap testing or the absence of any previous experience may have influenced this decision. The results indicated that physician-sampling was less likely to be preferred compared to the self-administered cervico-vaginal sampling for women who have never done Pap testing. This result matched a similar study (23) where patients with no history of Pap testing were more inclined to self-sampling. This finding has important implications as one of the target groups aimed to improve cervical screening rates is non-attendees or those that have not done screening in any form.

It is worth noting that the different religions and cultures amongst Malaysian women did not influence the acceptability of self-sampling. This is in agreement with previous findings (37, 38) which also reported that cultural or religious beliefs were not a barrier to screening participation. Though in agreement with these findings, Padela et al. (39) noted that there was a fatalistic attitude

related to negative religious coping whereby individuals felt that health issues were a penance from God which resulted in decreased willingness to undergo Pap testing. Therefore, while religious beliefs did not appear to influence acceptability of self-sampling, problems related to fear of the diagnosis should still be addressed when trying to implement self-administered cervico-vaginal sampling. In this study, self-sampling was found to be a very acceptable tool even before it was carried out. The results also suggest that age and ethnicity are important predictors in this study to determine preference for self-sampling. When planning a community-based model for cervical cancer prevention, the involvement and proper management by the local government administration and community leaders is vital for its success. This was exemplified in the work by 130 communities in China (40). A similar approach should be considered so that the resources, planning and massive screening is carried out efficiently and successfully in Malaysia.

Study Strengths and Limitations

One of the strengths of this study is its large sample size and the diversity of the population surveyed in terms of social and demographic characteristics. However, the findings might not accurately represent the whole Malaysian population because the participants mostly consist of women in urban areas from a developed state and not women in rural areas. Furthermore, the study population was recruited from women who came to the health centres resulting in missing those unable to come due to logistical barriers. Thus, the results represented women who had reasonable health care access. Despite this, nearly 40% had not previously received a Pap test, indicating that access alone does not completely explain the poor screening participation rates in Malaysia. However, because of this design feature, further studies are needed to assess the attitudes and acceptability of the rural Malaysian population towards self-administered cervico-vaginal sampling, as this may represent one of the only feasible alternatives to broad screening in remote areas. It is possible even with our findings in women who have access to healthcare and hospitals, that others

in rural areas might not necessarily find self-sampling acceptable due to different reasons such as traditional mind sets or cultural taboos.

CONCLUSION

This study has examined the acceptability of self-administered cervico-vaginal sampling amongst Malaysian women with encouraging results. Overall, Malaysian women from different backgrounds found the self-sampling method to be an acceptable alternative to traditional Pap smears, increasing the options for expanded cervical cancer prevention strategies in this population.

ACKNOWLEDGMENTS

We thank participants and their families for taking part in this study, the nurses in the clinics for their assistance and Su Pei and “Kak Sya” for assistance with patient recruitment.

AUTHOR’S CONTRIBUTIONS

YLW, NBP, PG and JB contributed to the overall design of the study. MM, NHN, SS, YTM and GPP contributed to patient recruitment. MM, NBP and YLW drafted the manuscript. MM, SHY and NBP performed the data analysis. All authors read, amended and approved the final manuscript.

COMPETING INTERESTS

YLW received a study grant from Merck Sharp and Dohme (Malaysia) Sdn Bhd to support the MyHPV prevalence study.

FUNDING

This study was funded by the Ministry of Higher Education, Malaysia, under the High Impact Research/Ministry of Higher Education Grant (Grant no: UM.0000068/HIR.C1), the University of Malaya’s University of Malaya Research Grant (UMRG RP029A-14HTM) and a research grant from

Merck Sharp and Dohme (Malaysia). The research assistants were from the Clinical Research Centre, Ministry of Health. The 'Just for me' self-samplers were donated by POI.

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Table 1

Percentage of women that found self-sampling acceptable (answered 4 above on the Likert scale)

	Pre-questionnaire (%)	Post-questionnaire (%)	p-value
Good experience	70.1	81.7	0.00397*
Easy to do	67.9	84.5	0.00031*
Very convenient	77.1	86.3	0.02085*
Not embarrassing	85.3	88.2	0.26664
No discomfort	50.8	78.2	0.00025*
Very confident	67.6	79.6	0.00278*
Overall Median Score	4.333	4.833	

Derived using McNemar's test. *P*-values <0.05* were considered statistically significant

Table 2

Factors associated with preference for self-sampling

Participant characteristics	Overall (N)	Preferred self-sampling (%)	*P*-value	OR	95% Confidence Interval (CI)
Age (median)	38	37	0.017*	0.94	0.90 - 0.98
Education level					
Basic	89	86.5	0.714	Ref	
Secondary	436	83.0		0.73	0.36 - 1.45
Tertiary and above	160	83.1		0.67	0.30 - 1.47
Ethnicity					
Malay	335	85.0	0.004*	Ref	
Indian	213	85.9		1.13	0.67 - 1.91
Chinese	117	72.6		0.57	0.33 - 0.99
Other	20	95.0		2.38	0.31 - 18.6
Marital status					
Single	82	80.5	0.433	Ref	
Married	603	83.9		1.28	0.69 - 2.38
Smoking					
Never	642	82.9	0.112	Ref	
Current or former	40	92.5		2.39	0.70 - 8.14
Previous Pap Experience					
No	243	88.5	0.01*	Ref	
Yes	434	80.9		0.551	0.35 - 0.87

Notes: Multivariate logistic regression model was used to analyse whether age, education level, ethnicity, marital status, smoking status and previous pap experience influenced preference for self-sampling. The results were considered as statistically significant when the *p*-value was <0.05*.

Abbreviation: Ref, reference. OR, odds ratio.

Figure 1 The "Just for Me" © self-administered cervico-vaginal sampling brush, courtesy of Preventive Oncology International. Inc, Hong Kong Ltd.

Figure 2. Response frequencies for different acceptability indices among 839 multi-ethnic women before and after self-sampling.

Figure 1
The "Just for Me" © self-
1422x1066mm (72 x 72 DPI)

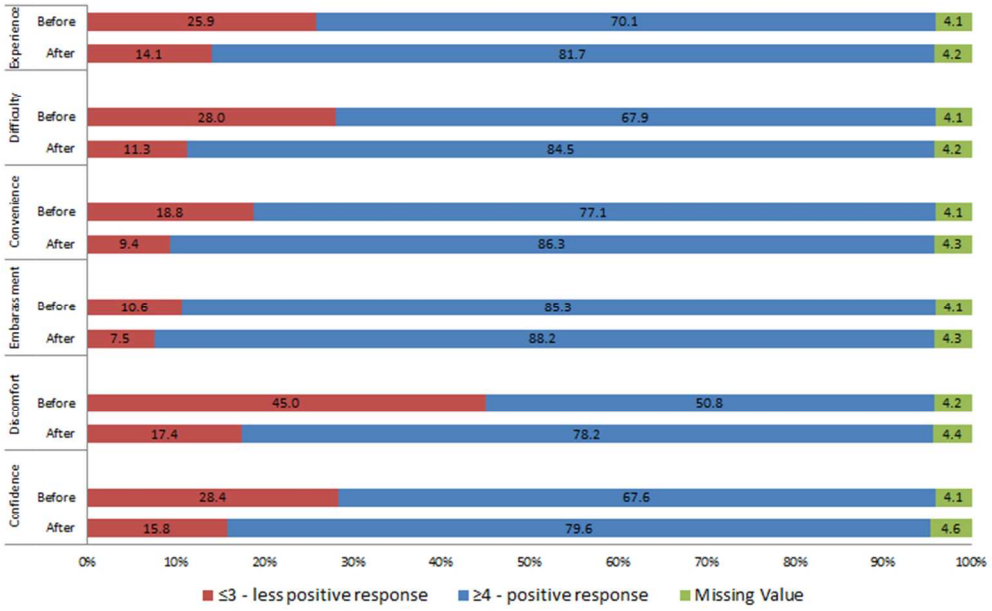

Figure 2
Response frequencies for diffe
203x127mm (96 x 96 DPI)

BMJ Open

Attitudes and factors affecting acceptability of self-administered cervico-vaginal sampling for human papillomavirus (HPV) genotyping as an alternative to Pap testing among multi-ethnic Malaysian women

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2015-011022.R1
Article Type:	Research
Date Submitted by the Author:	26-Apr-2016
Complete List of Authors:	Ma'som, Mahirah ; University of Malaya, Dept of Obstetrics and Gynaecology Bhoo-Pathy, Nirmala; University of Malaya, Dept of Obstetrics and Gynaecology Nasir, Nazrila; Ministry of Health, Selangor State Health Department Bellinson, Jerome; Preventive Oncology International, Inc. Subramaniam, Shridevi; Clinical Research Centre, Clinical Epidemiology Unit Ma, Yuntong; Washington University in Saint Louis Yap, Siew Hwei; University of Malaya, Dept of Obstetrics and Gynaecology Goh, Pik Pin; Clinical Research Centre, Clinical Epidemiology Unit Gravitt, Patti; George Washington University Milken Institute of Public Health Woo, Yin Ling; University of Malaya, Dept of Obstetrics and Gynaecology
Primary Subject Heading:	Public health
Secondary Subject Heading:	Obstetrics and gynaecology, Oncology, Patient-centred medicine, Sexual health, Health policy
Keywords:	human papillomavirus, pap smear, cervical cancer screening, self sampling, cervico-vaginal sampling

Attitudes and factors affecting acceptability of self-administered cervico-vaginal sampling for human papillomavirus (HPV) genotyping as an alternative to Pap testing among multi-ethnic Malaysian women

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Key words

human papilloma virus (HPV), cervical screening, self-administered cervico-vaginal sampling, Pap smear , acceptability

Word count

2,741 words

ABSTRACT

Objective: The objective of this study is to determine the attitudes and acceptability of self-administered cervico-vaginal sampling compared to conventional physician acquired Papanicolaou (Pap) smear among multi-ethnic Malaysian women.

Method: A cross-sectional study was carried out via interviewer-administered surveys from August 2013 through August 2015 at five government-run, urban health clinics in the state of Selangor. Subjects were participants from an on-going community-based human papillomavirus (HPV) prevalence study who answered a standard questionnaire before and after self-sampling. The cervico-vaginal self-sampling for HPV genotyping was performed using a simple brush ("Just for Me", Preventive Oncology International Inc., Hong Kong). Detailed data on socio-demographics, previous Pap smear experience and attitudes towards self-administered cervico-vaginal sampling were collected and analysed. Acceptability was inferred using a 5-item Likert scale that included 6 different subjective descriptives: experience, difficulty, convenience, embarrassment, discomfort or pain, and confidence at collecting one's own sample.

Results: Of the 839 participants, 47.9% were Malays, followed by 30.8% Indians, 18.8% Chinese, and 2.5% from other ethnicities. Median age of participants was 38 years (interquartile range = 30-48 years old). 68.2% of participants indicated a preference for self-sampling over Pap test, with 95% indicating willingness to follow-up a positive result at the hospital. Age, ethnicity and previous Pap test experience were significant independent factors associated with preference for self-sampling. The older the individual, the less likely they were to prefer self-sampling (adjusted OR=0.94, 95% CI:

0.90 - 0.98). The Chinese were less likely to prefer self-sampling (72.6%) than the Malays (85.1%) (adjusted OR=0.57, 95% CI: 0.33-0.99). Participants who have never undergone a Pap smear were also more likely to prefer self-sampling (88.5%) than women who had a previous Pap (80.9%) (adjusted OR=0.06, 95% CI: 0.35-0.87).

Conclusion: Overall, urban Malaysian women from multi-ethnic backgrounds found self-sampling to be an acceptable alternative to Pap smear.

299 words

Strengths and limitations of this study

- This is one of the largest study systematically assessing the acceptability of cervico-vaginal self-sampling as an alternative to pap smear in a population with low screening uptake.
- The study cohort consisted of a convenience sample from health-care clinics, possibly introducing bias as it excluded those who may not attend health-care facilities for a variety of reasons.
- This study could not assess and compare the sensitivity and specificity of the screening methods i.e. HPV genotyping versus pap smear.
- The attitudes of those who declined to join the study may have introduced bias to the results.

INTRODUCTION

Cervical cancer is the second most common cancer among Malaysian women with an incidence of over 16 per 100,000 and mortality of over 8 per 100,000 (1, 2). While there is no population-based cervical cancer screening program in Malaysia, the government has supported opportunistic screening by providing free Pap smear tests since 1995. The uptake of Pap tests among Malaysian women remains suboptimal with less than half (47.3%) of the population having received it (3). Many reasons have been cited for the lack of cervical cancer screening participation including cost, embarrassment, fear, lack of knowledge and lack of time (4-7). In 2010, the Malaysia government started a national school-based human papillomavirus (HPV) immunisation programme (8). Despite

the success of the national HPV vaccine program, with more than 90% of 13 year old school girls being vaccinated (9), more comprehensive coverage and increased uptake of cervical screening remains important for at least another 30-40 years to adequately prevent the development of cervical cancer in the Malaysian population.

In communities where uptake of conventional cervical screening by cytology has been low, self-sampling may offer an attractive alternative. Unlike Pap smear tests, this procedure can be carried out by the individual themselves without the help of a physician or medical staff. This means that other logistical barriers involved with Pap test screenings such as long waiting times in hospitals, inadequate number of and inexperienced cytologists, and unequal distribution of health care resources(10) can be overcome, making it a more efficient and cost-effective option (11, 12). There is a variety of self- samplers available that allows for different methods of screening for cervical cancer. Generally, they are divided into brush-based or lavage-based self-sampling devises most commonly used for HPV genotyping but are also suitable for cervival cytology and detection of biomarkers associated with cervical premalignant or malignant diseases (13, 14) . Studies have shown a rise in participation from non-respondents to screening programs when self-sampling methods are introduced (15-20). However, due to socio-cultural and religious differences, it was important to assess the value of self-sampling in the context a multi-ethnic Asian community such as Malaysia. This study aims to explore the attitudes and perception before and after the process of self-sampling for HPV genotyping to determine acceptability in comparison to the Pap smear test amongst a multi-ethnic population.

METHOD

Participants

Volunteers for this cross-sectional study were recruited via convenience sampling between August 2013 and August 2015 from five government-run general practice clinics; Klinik Kesihatan

Pandamaran, Klinik Kesihatan Ampang, Klinik Kesihatan Bandar Botani, Klinik Kesihatan Batu 9, and University Malaya Medical Centre which are located in Selangor, the most developed state in Malaysia with a high level of urbanisation. Subjects were participants from an on-going community-based human papillomavirus prevalence study (The Malaysian HPV Prevalence Study), who were recruited during their visits to the health clinics for primary care services including immunization, routine health checks, and while accompanying family members to these clinics. Participants aged between 18 and 60 years old who agreed to do self-sampling joined this study. The exclusion criteria included pregnancy, menstruation, acute illnesses, or never been sexually active. This study received approval from the Medical Research Ethics Committee (NMRR-13-444-14609), and University Malaya Medical Ethics Committee (MREC989.32). Written informed consent was obtained from all participants. All patient responses were kept confidential.

Cervico-vaginal self-sampling and assessment

Participants were invited to perform self-sampling on their own using a simple brush ("Just for Me" ©, courtesy of Preventive Oncology International. Inc, Hong Kong Ltd.) (POI). An image of the brush can be seen in Figure 1. Instructions on how to use the self-sampler were given to the participants. Briefly, participants were instructed to gently push the brush to the top of the vagina with one leg on a chair. The brush is turned a few times to the left and then the right before being removed completely. After withdrawal, the brush is rubbed onto the POI FTA card provided with the kit and sealed in an envelope. The FTA card is a solid media specimen transport card and therefore, eliminates problems encountered with alcohol-based liquids, temperature exposure and transportation difficulties (21). A questionnaire which has been developed in a previous study (22) was modified and translated into Malay and Mandarin so it could be applied to our multi-lingual population (Supplementary File). It was administered before and after the procedure. The pre-assessment intended to evaluate the initial response of the participants when they were introduced with the kit and later compared to their actual experience which was recorded in the post-

assessment. Acceptability indices for the self-administered cervico-vaginal sampling included six items: experience, difficulty, convenience, embarrassment, discomfort or pain, and confidence (as shown in Table 1). A 5-item Likert scale was used in the pre- and post-self-sampling questionnaire where value 5 was the most favourable response and 1 the most disagreeable. A positive response towards self-sampling (deemed as acceptable) was defined based on participant responses of 4 or 5 points using the Likert scale. Following self-sampling, we additionally inquired about participants' preference for HPV testing; prefer self-sampling, no preference (agreeable to both), prefer Pap testing. Socio-demographical information was collected via interviewer-administered questionnaire and included information on age, ethnicity, highest attained education, marital status, smoking status and previous Pap testing experience.

Statistical Analysis

Cronbach's alpha coefficient which ranges from 0 to 1 was used to ascertain internal consistency of the questionnaire. A low value shows poor reliability or consistency among the items within the construct and a value of at least 0.7 is generally needed to show good reliability. McNemar's test was used for correlated proportions to measure any significance in the change of acceptability following self-sampling. Categorical variables were compared using Chi-square. Continuous variables were described using medians as most of the variables were assumed to be not normally distributed in the population, and compared using the Mann Whitney-U test. Participants who indicated that they preferred self-sampling as well as those who did not have any preference (agreeable to both methods) were categorised into 'prefer self-sampling' and compared against participants who preferred Pap test. Multivariable logistic regression analysis including age, highest attained education, ethnicity, marital status, smoking status and previous Pap testing experience was conducted to determine independent predictors of preference for self-sampling. A *p*-value of <0.05 was considered to be statistically significant. Data was analysed using IBM Statistical Package for Social Science (SPSS) version 20.

RESULTS

Participant Characteristics

A total of 839 women were interviewed and the median age of the study participants was 38 years (interquartile range: 30 and 48 years old). 82.7% of the study population were pre-menopausal, aged 50 years old and below. Malay women represented the largest ethnic group (47.9%), followed by Indians (30.8%), Chinese (18.8%) and other races (2.5%) with 86.3% being married. 57% of the participants were employed while 35.2% were fulltime home-makers. 62.1% had completed secondary education. Only 11.8% of women reported a monthly household income of more than RM5000 (USD1100). Out of the 839 women, 76% have heard of the Pap smear before with 63.1% ever undergoing a pap test. Most of the women (81.9%) who had undergone Pap smear tests, received it in the last 5 years preceding the study.

Factors positively associated with previous experience of Pap testing include higher education level ($p<0.05$), older age ($p<0.05$) and higher income ($p<0.05$) of the participants. Of women who have never undergone Pap test, primary barriers that were stated include lack of awareness (13%), lack of time (10%), no existing symptoms (6.6%) and fear (5.1%)(data not shown).

Self-administered cervico-vaginal sampling is acceptable

Both pre and post questionnaires showed a high internal consistency with the pre-questionnaire having a Cronbach's alpha value of 0.796 and the post-questionnaire being 0.862. In the pre-questionnaire, more than half of the participants gave a positive response (score 4 or 5 on the Likert scale) for all the six items that were tested; experience, ease of procedure, convenience, embarrassment, comfort, and confidence. Table 2 shows the pre- and post-test proportions of women who found self-sampling acceptable (answered 4 above on the Likert scale). Most women's perceptions changed significantly after experiencing self-sampling in that following self-sampling,

most women reported the procedure to be easy (84.5%), convenient (86.3%),not painful (78.2%) and expressed confidence (79.6%) about collecting their own samples correctly.

Overall, the above findings indicate that there was an increase in all 6 indices of acceptability after self-sampling. In the post-questionnaire, it was also revealed that a vast majority (91.8%) of the participants would be willing to self-sample if it was made to be the only cervical cancer screening option available. Most (95.2%) participants expressed willingness to go for a follow-up should they obtain a positive result. Approximately two thirds (60.0%) preferred to carry out self-sampling at home and almost half (49.1%) would prefer to pick up the self-sample kit at a near-by clinic.

Self-sampling versus conventional Pap Test

After the procedure, 68.2% of the participants reported to have a preference towards self-sampling compared to 13.5% who preferred Pap smear tests while 14.1% stated no preference (agreeable to both methods). There were no significant differences in preference for self-sampling based on education level, smoking, and marital status (Table 3). Women who preferred self-sampling were significantly younger than their counterparts preferring Pap test. Ethnicity also influenced preference for self-sampling where the Chinese were less likely to prefer self-sampling than the Malays (OR=0.57, 95% CI: 0.33-0.98). As a sensitivity analysis, the group of women were split into those that have and have not previously undergone Pap tests. It was found that prior experience of undergoing Pap test had a significant impact on the preference (p=0.01). Among the women with no prior experience of Pap testing, self-administered cervico-vaginal sampling was preferred over physician-sampling in 75% of participants.

DISCUSSION

To our knowledge, this is one of the largest studies where acceptability of self-sampling was systematically assessed before and after the procedure was done in a multi-ethnic Southeast Asian

population. In this study, 98% of the participants were within the screening age population (21-65 years old), where 40% of the participants had not done a Pap test in the past three years or more, and 36% of participants have never received a Pap test. Cervical cancer, the second most prevalent cancer amongst Malaysian women is preventable and an estimated 70% of new cases can be prevented by screening and early detection (23, 24). Unfortunately, the overall uptake of Pap smear in Asian countries including Malaysia is still poor (4-7, 25). Lack of awareness was the main reason cited by the participants in this study for never having done Pap smear tests prior to this. This is also the most commonly cited reason in other countries such as Turkey, Bangladesh, Gabon and Korea (26-29). Therefore, increasing awareness of and education about cervical cancer screening is necessary and independent of the modality of screening. While self-swabs and other self-sampling devices have been examined and reported to be reliable (6) and not inferior to specimens obtained by physicians (30), it is necessary to investigate the perception and acceptability of self-sampling amongst multi-ethnic Malaysian women especially among potential users who have never done Pap testing.

Generally, participants showed a high acceptability towards self-sampling. Negative perceptions regarding the use of self-sampling reported before experience with collection decreased after having experienced the self-collection first-hand. The acceptability scores indicated that the participants were highly confident in collecting their own samples. This is similar to studies undertaken in Sub-Saharan Africa (31) and Finland (19). Interestingly, in studies where physician-sampling was compared directly to self- sampling, women trusted the physician-sampling more and had lower confidence on their own competency (22, 32). In our study, the level of education was significantly associated with confidence where surprisingly, those with a higher level of education were less confident about self-collection. There could be several explanations for this. It can be postulated that those with higher education tend to overthink and question their abilities more. Education programmes designed to show the validity of self-collection may help to alleviate any concerns

raised by doubtful participants. Another reason could be that women with higher education were more comfortable with a professional carrying out the test rather than themselves. This is contradictory to studies showing that education level did not have a significant impact on self-sampling acceptability (33). The majority (68.2%) of the women surveyed preferred self-sampling compared to physician-sampled Pap smear tests after carrying it out. This is not surprising as issues such as embarrassment and inconvenience could be overcome with the use of self-samplers, enabling women to do it independently in the comforts of their own homes. These results are in line with those of previous studies (22, 34-38). However, prior experience with Pap testing or the absence of any previous experience may have influenced this decision. The results indicated that physician-sampling was less likely to be preferred compared to the self-administered cervico-vaginal sampling for women who have never done Pap testing. This result matched a similar study (25) where patients with no history of Pap testing were more inclined to self-sampling. This finding has important implications as one of the target groups aimed to improve cervical screening rates is non-attendees or those that have not done screening in any form.

It is worth noting that the different religions and cultures amongst Malaysian women did not influence the acceptability of self-sampling. This is in agreement with previous findings (39, 40) which also reported that cultural or religious beliefs were not a barrier to screening participation. Though in agreement with these findings, Padela et al. (41) noted that there was a fatalistic attitude related to negative religious coping whereby individuals felt that health issues were a penance from God which resulted in decreased willingness to undergo Pap testing. Therefore, while religious beliefs did not appear to influence acceptability of self-sampling, problems related to fear of the diagnosis should still be addressed when trying to implement self-administered cervico-vaginal sampling. In this study, self-sampling was found to be a very acceptable tool even before it was carried out. The results also suggest that age and ethnicity are important predictors in this study to determine preference for self-sampling. When planning a community-based model for cervical

cancer prevention, the involvement and proper management by the local government administration and community leaders is vital for its success. This was exemplified in the work by 130 communities in China (42). A similar approach should be considered so that the resources, planning and massive screening is carried out efficiently and successfully in Malaysia.

Study Strengths and Limitations

One of the strengths of this study is its large sample size and the diversity of the population surveyed in terms of social and demographic characteristics. However, the findings might not accurately represent the whole Malaysian population because the participants mostly consist of women in urban areas from a developed state and not women in rural areas. Furthermore, the study population was recruited from women who came to the health centres resulting in missing those unable to come due to logistical barriers. Thus, the results represented women who had reasonable health care access. Despite this, nearly 40% had not previously received a Pap test, indicating that access alone does not completely explain the poor screening participation rates in Malaysia. However, because of this design feature, further studies are needed to assess the attitudes and acceptability of the rural Malaysian population towards self-administered cervico-vaginal sampling, as this may represent one of the feasible alternatives to broad screening in remote areas. It is possible even with our findings in women who have access to healthcare and hospitals, that others in rural areas might not necessarily find self-sampling acceptable due to different reasons such as traditional mind sets or cultural taboos.

CONCLUSION

This study, which examined the acceptability of self-administered cervico-vaginal sampling amongst Malaysian women has shown encouraging results. Overall, Malaysian women from different backgrounds found the self-sampling method to be an acceptable alternative to traditional Pap

smears, hence increasing the options for expanded cervical cancer prevention strategies in this population.

ACKNOWLEDGMENTS

We would like to thank the participants of this study, the doctors, nurses, and support staff in Klinik Kesihatan Pandamaran, Klinik Kesihatan Ampang, Klinik Kesihatan Bandar Botani, Klinik Kesihatan Batu 9, and University Malaya Medical Centre for their support, and Khoo Su Pei and Syahirah Binti Shaharudin for assistance with patient recruitment.

AUTHOR'S CONTRIBUTIONS

YLW, NBP, PG and JB contributed to the overall design of the study. MM, NHN, SS, YTM and GPP contributed to patient recruitment. MM, NBP and YLW drafted the manuscript. MM, SHY and NBP performed the data analysis. All authors read, amended and approved the final manuscript.

COMPETING INTERESTS

YLW received a study grant from Merck Sharp and Dohme (Malaysia) Sdn Bhd to support the MyHPV prevalence study.

FUNDING

This study was funded by the Ministry of Higher Education, Malaysia, under the High Impact Research/Ministry of Higher Education Grant (Grant no: UM.0000068/HIR.C1), the University of Malaya's University of Malaya Research Grant (UMRG RP029A-14HTM) and a research grant from Merck Sharp and Dohme (Malaysia). The 'Just for me' self-samplers were donated by POI.

DATA SHARING STATEMENT

No additional data are available

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Table 1

Indices of the 5-item Likert scale for each of the categories.

5-likert scale	1	2	3	4	5
Experience	Very bad	Bad	Neither	Good	Very good
Difficulty	Very hard	Hard	Neither	Easy	Very easy
Convenience	Very inconvenient	Inconvenient	Neither	Convenient	Very convenient
Embarrassment	Very embarrassed	Embarrassed	Neither	Not embarrassed	Not embarrassed at all
Discomfort / Pain	Severe discomfort/ Pain	Some discomfort / Pain	Neither	No Discomfort / Pain	No Discomfort / Pain at all
Confidence	Not at all confident	Unconfident	Neither	Confident	Very confident

Table 2

Percentage of women that found self-sampling acceptable (answered 4 or above on the Likert scale)

	Pre-questionnaire (N,%	Post-questionnaire(N,%)	*p*-value
Good experience	588 (70.1)	686 (81.7)	0.004[1]
Easy to do	570 (67.9)	709 (84.5)	<0.001[1]
Very convenient	647 (77.1)	724 (86.3)	0.021 [1]
Not embarrassing	716 (85.3)	740 (88.2)	0.267
No discomfort	426 (50.8)	656 (78.2)	<0.001[1]
Very confident	567 (67.6)	668 (79.6)	0.003[1]
Overall Median Score	4.333	4.833	

1 Derived using McNemar's test. *P*-values <0.05 were considered statistically significant

Table 3 Factors associated with preference for self-sampling

Participant characteristics	Overall (N)	Preferred self-sampling, N (%)	Preferred Pap test N, (%)	*P*-value[2]	OR[1]	95% Confidence Interval
Age (median,IQR)	38	37 (30-47)	43 (31-52)	0.001[3]	0.98[3]	0.96-1.00
Education level						
Basic	89	77 (86.5)	12 (13.5)	0.714	1.00[4]	
Secondary	436	362 (83.0)	74 (17.0)		0.72	0.35 - 1.48
Tertiary and above	160	133 (83.1)	27 (16.9)		0.67	0.30 - 1.52
Ethnicity						

Malay	335	285 (85.0)	50 (14.9)	0.004[3]	1.00[4]	
Indian	213	183 (85.9)	30 (14.1)		1.09	0.65 - 1.83
Chinese	117	85 (72.6)	32 (27.4)		0.57[3]	0.33 - 0.98
Other	20	19 (95.0)	1 (5.0)		2.24	0.29 – 17.55
Marital status						
Single	82	66 (80.5)	16 (19.5)	0.433	1.00[4]	
Married	603	506 (83.9)	97 (16.1)		1.41	0.76 - 2.60
Smoking						
Never	642	532 (82.9)	110 (17.1)	0.112	1.00[4]	
Current or former	40	37 (92.5)	3 (7.5)		2.38	0.70 - 8.13
Previous Pap Experience						
Yes	434	351 (80.9)	83 (19.1)	0.010[3]	1.00[4]	
No	243	215 (88.5)	28 (11.5)		1.46	0.88-2.41

1 OR: Odds ratio for preference for self-sampling compared to preference for Pap testing, derived using multivariable logistic regression model mutually adjusted for age, highest attained education, ethnicity, marital status, smoking status and previous Pap test experience

2 Chi-square test was used to compare categorical variables whereas Mann-Whitney test was used to compare age

3 Results were considered as statistically significant as the *p*-value was <0.05, or 95%CI for OR did not include 1.00

4 Reference indicator

Figure 1 The "Just for Me" © self-administered cervico-vaginal sampling brush, courtesy of Preventive Oncology International. Inc, Hong Kong Ltd.

Figure 1. The "Just for me" © self-administered cervico-vaginal sampling brush, courtesy of Preventive Oncology International Inc., Hong Kong Ltd.

192x144mm (300 x 300 DPI)

Pre/post questionnaire:

We are conducting this survey to get your feedback on alternative methods of cervical cancer screening. In this study we will be asking you to collect your own vaginal sample with a collection brush that can be tested for HPV as an alternative to Pap testing performed by a physician. We are not collecting any identifying information and so we cannot provide you with any test results. We just want to understand how you feel about this self-collection method as an option for use in the future.

Pre:

1. Have you ever heard of a Pap smear (also called a Pap test)?
   - ☐ Yes
   - ☐ No → The Pap smear is the main screening test for cervical cancer and pre-cancerous changes. The Pap smear is a procedure used to collect cells from the cervix for cervical cytology testing. The health care professional first places a speculum inside the vagina. The speculum is a metal or plastic instrument that keeps the vagina open so that the cervix can be seen clearly. Next, using a small spatula, a sample of cells and mucus is lightly scraped from the exocervix. A small brush or swab is then inserted into the opening of the cervix to take a sample from the endocervix. The cell samples are then prepared so that they can be examined under a microscope in the laboratory.

2. Have you had a Pap smear in the last 5 years?
   - ☐ Yes
   - ☐ No, please indicate reasons and select all that apply:
     - Not aware of the test
     - Not convenient/no time
     - Fear
     - No symptoms, so test is not needed
     - Other, please specify_____

3. How convenient do you think getting a Pap smear is?

	1	2	3	4	5	
Not at all convenient						Very convenient

4. How embarrassed are you or would you be to get a Pap smear?

	1	2	3	4	5	
Very embarrassed						Not at all embarrassed

5. How much discomfort/pain do you experience during a Pap smear or how much discomfort/pain do you think you would experience?

	1	2	3	4	5	
Severe discomfort/pain						No discomfort/pain

6. How confident are you that a physician would perform a Pap smear correctly?

	1	2	3	4	5	
Not at all confident						Very confident

The HPV test is another method used to screen for cervical cancer. It will work on samples that are collected by a woman in her own home, called "self-sampling." In this study, we will ask you to collect your own vaginal sample.

7. Overall, how do you feel about collecting your own vaginal swab?

	1	2	3	4	5	
Very bad						Very good

8. How easy do you think it will be to collect this self-sample?

	1	2	3	4	5	
Very hard						Very easy

9. How convenient do you think collecting this self-sample is (at the clinic or at home)?

	1	2	3	4	5	
Not at all convenient						Very convenient

10. How embarrassed are you to collect this self-sample?

	1	2	3	4	5	
Very embarrassed						Not at all embarrassed

11. How much discomfort/pain do you think you will experience while collecting this self-sample?

	1	2	3	4	5	
Severe discomfort/pain						No discomfort/pain

12. How confident are you that you will be able to collect this self-sample correctly?

	1	2	3	4	5	
Not at all confident						Very confident

Post:

1. Overall, how did you feel about collecting your own vaginal swab?

	1	2	3	4	5	
Very bad						Very good

2. How easy was it to collect this self-sample?

	1	2	3	4	5	
Very hard						Very easy

3. How convenient was it to collect this self-sample (at the clinic or at home)?

	1	2	3	4	5	
Not at all convenient						Very convenient

4. How embarrassed were you to collect this self-sample?

	1	2	3	4	5	
Very embarrassed						Not at all embarrassed

5. How much discomfort/pain did you experience while collecting this self-sample?

	1	2	3	4	5	
Severe discomfort/pain						No discomfort/pain

6. How confident are you that you collected this self-sample correctly?

	1	2	3	4	5	
Not at all confident						Very Confident

7. Did you experience any difficulties in collecting this self-sample?
- ☐ No
- ☐ Yes, please specify_____

8. Where would you prefer to collect this self-sample?
- ☐ At home
- ☐ At the clinic or hospital
- ☐ Other, please specify_____

9. If the government offered self-sampling, how would you prefer to get the test kit?
- ☐ By post
- ☐ Pick up at clinic
- ☐ Pharmacy
- ☐ Other, please specify_____

10. How would you prefer to get your test results?
- ☐ By post
- ☐ By going to the clinic
- ☐ By email
- ☐ By SMS
- ☐ By telephone
- ☐ Other, please specify_____

11. If a positive result were reported to you, would you be willing to come the hospital for a follow-up test?
- ☐ Yes
- ☐ No, please explain why_____

12. If you had a choice, would you prefer to have a Pap smear or self-sampled vaginal swab?
- ☐ Pap smear
- ☐ Self-sample
- ☐ Either one is fine

13. Why do you prefer this method?_____

14. If the only option for cervical cancer screening is a self-sampled vaginal swab, would you be willing to do it regularly as a method of screening?

- ☐ Yes
- ☐ No, explain why not_____

15. Which is more troubling for you to receive: a positive HPV test from a self-sampled swab or an abnormal Pap smear result?

- ☐ Positive HPV test
- ☐ Abnormal Pap test
- ☐ They are equally troubling