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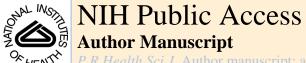
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Acceptability of Cervical and Anal HPV Self-sampling in a Sample of Hispanic Women in Puerto Rico

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Abstract

Self-sampling techniques have been shown to be reliable in determining human papillomavirus (HPV) infection, although the acceptability of this method of sampling has not been studied in Puerto Rico (PR). The objective of this study was to determine the acceptability of cervicovaginal and anal self-sampling for HPV DNA testing among women in PR. One hundred women aged 18-34 years old and undergoing routine Pap smears in an OBGYN clinic in PR were recruited. Interviewer-administered and computer-based questionnaires were used to collect information on relevant risk factors. To assess acceptability, four-item acceptability Likert scales were used that measured comfort, pain, privacy, and embarrassment. Overall acceptability indexes were calculated as the sum of the Likert scores. Clinician-collected and self-collected cervicovaginal and anal samples for HPV-DNA testing were obtained from the participating women. Although the acceptability of both sampling methods was high, it was higher for self- rather than cliniciansampling of the cervix (difference in mean score = -0.71, p<0.05); contrarily, it was higher for clinician-sampling of the anus (difference in mean score = 0.64). When analyzing individual items within the scale, less embarrassment was observed with respect to the self-collection of cervical and anal samples. Nevertheless, most women reported that they preferred having a clinician collect cervical and anal samples (67% and 61%, respectively); and most of these women (86% for cervical samples and 92% for anal samples) felt more confident that this sample would be properly taken. Despite this, in this population, the high level of acceptability with regard to selfcollected samples and the previously documented concordance between self- and cliniciancollected samples support the use of cervical and anal HPV DNA self-sampling techniques in future HPV-related population-based studies and screening programs in PR.

Keywords

acceptability; cervix; anus; self-sampling; HPV

Introduction

Most sexually active individuals will be infected with HPV at some point in their life. HPV is known to be a necessary cause of cervical cancer; in addition, it can be linked to 93% of the cases of anal cancer. The incidence and mortality rates for cervical cancer have decreased in the US, although they continue to increase for anal cancer. Despite racial/ethnic differences in disease burden, declines in cervical cancer rates are related to the wide use of cervical cancer screening methods such as cervical cytology. Conversely, while the reasons for increasing anal cancer incidence rates in the US are unknown, screening for anal cancer precursors is still controversial, although routine screening should be considered for at-risk patients, such as HIV-positive individuals.

HPV testing can be used as primary screening for cervical cancer precursors^{3,7–8} or as an adjunct to primary cervical cytologic screening,^{9–10} and has in fact been incorporated into cervical cancer screening guidelines, where co-testing of cervical cytology and high-risk HPV typing have been recommended for women aged 30 years or older.¹¹ Meanwhile, anal HPV testing also has important implications for HIV patients and for anogenital cancer prevention. In fact, HPV testing has also been incorporated into anal cancer screening approaches.⁶

Clinician-directed pelvic and anal examinations are still unacceptable to many women, represent a challenge in the research setting, involve high operational costs, and require complex infrastructure. 12–17 With the aim of further strengthening cervical and anal cancer screening efforts, self-sampling techniques for the collection of cervical and anal cytology and HPV specimens have been proposed as an appropriate and effective alternative to overcome these limitations. 12,16,18–21 Cervical self-sampling techniques have been shown to be reliable in the detection of HPV infection in the US, 19–21 Puerto Rico (PR), 22 and other regions. 19 Although data for anal samples are very limited, studies in women in PR 22 and in MSM in the US 12 have also shown there to be good agreement between self-sampling and clinician-sampling methods with respect to obtaining anal samples from.

Despite this evidence, the acceptability of self-collection for HPV DNA detection has been less explored. Studies report that cervical self-sampling for HPV is acceptable to women 17,23–26 and has been acknowledged as a way to increase the likelihood of participation in cervical cancer screening programs, particularly among underserved populations. Nonetheless, ethnic/racial disparities in the acceptability of HPV testing and self-sampling have been reported, 25,28–30 with a lower acceptability of self-sampling seen among Hispanic women. Although data on women are limited, self-sampling proved to be a feasible and acceptable method of collecting anal specimens for HPV and other STI detection among MSM. 12,31

To incorporate anogenital HPV self-sampling as the first step to a comprehensive HPV screening strategy in PR and in other areas that have Hispanic populations and thus have a potential impact on cervical and anal cancer prevention, more information is needed on the acceptability or preference of these types of tests among women in these populations. This is of particular significance given the high burden and economic impact of HPV-related cancers in PR³² and other Hispanic populations and given, as well, the documented racial/ethnic disparities in HPV awareness and sampling acceptability. ^{17,32,33} Thus, this study

aimed to determine the acceptability of cervicovaginal and anal self-sampling for HPV testing among a clinic-based sample of women in PR.

Methods

Study design and study population

This cross-sectional study was approved by the Institutional Review Board (IRB) of the University of Puerto Rico, Medical Sciences Campus. One hundred consecutive non-institutionalized women aged from 18 to 34, who had gone to the University of Puerto Rico Gynecology Clinic for routine cervical cytology screening from November 2007 to 2008 and who completed an informed consent, were included. This age group was selected as it represents a population that is at high risk for HPV infection.^{7,34} Women were eligible if they had an intact uterus, no history of cervical cancer, and no recent cervical procedures, and ineligible if they were HIV-positive or cognitively or physically impaired.

Collection of cervicovaginal and anal specimens

Data collection procedures for this study have been described in detail in a previous publication by our group. ²² A trained gynecologist did a pelvic exam of and collected specimens from each participant. Participants underwent a pelvic examination and the collection of specimens by a trained gynecologist. The study gynecologists collected cervicovaginal and anal specimens for HPV-DNA detection using a cytobrush and a Dacron swab, respectively. After the physician collected the specimens, participants were given verbal instructions for self-collection and a sterile collection kit containing written instructions for anal and cervicovaginal self-sampling. The procedures for performing self-sampling are similar to those used in previous studies. ^{18,20}

Data collection instrument

After the collection of samples, participants completed a face-to-face interview that collected information on demographic, lifestyle, and reproductive characteristics. Information on sexual practices was collected through a self-administered questionnaire using an audio computer-assisted self-interview system implemented using Questionnaire Development System (NOVA Research Co., Washington, D.C.). Information detailing the acceptability of self-sampling for HPV testing was also collected. Questions related to the acceptability of the self-collection of anogenital HPV samples were modeled after a 16-item instrument developed for cervical cancer screening in a Mexican population.³⁵ This instrument also included a question that was intended to determine whether a given patient preferred the clinician- or self-sampling method for retrieving cervical samples ("Which of the following methods for retrieving cervical samples did you prefer?"), followed by a question on the reasons for this preference, the answer to which included all the reasons that applied (Why did you prefer this method?: "Because you...1) felt less embarrassment, 2) felt more comfortable, 3) felt more confident that the sample would be done properly, and 4) spouse/partner would prefer that method). Two similar questions were included for the anal sample-collection method.

Statistical analysis

Four-item acceptability Likert scales were used to measure comfort (1 = very uncomfortable, 4 = very comfortable), pain (1 = a lot of pain, 4 = no pain), privacy (1 = lacked privacy, 4 = completely private), and embarrassment (1 = a lot of embarrassment, 4 = no embarrassment) for each of the collection methods (anal self-sampling, anal clinician-sampling, cervical self-sampling, cervical clinician-sampling). For both cervical and anal

sampling, overall acceptability indices were calculated as the sum of individual Likert scores (minimum score 4, maximum score 16).

Differences between clinician- and self-collected anal and cervical samples in the total acceptability score and individual item acceptability scores were evaluated using paired Student's *t*-tests or Wilcoxon signed-rank tests, when appropriate. Differences were calculated as the clinician-sampling scores minus the self-sampling scores. The reasons for sampling method preference were compared among women who preferred self-sampling versus those who preferred clinician-sampling using using Fisher's exact test. Following the analytical approach of Dzuba,³⁵ acceptability ratios for both cervical and anal sampling were calculated by dividing the clinician-sampling acceptability index by the self-sampling acceptability index. Women with a higher score on the self-sampling acceptability index than on the clinician-sampling acceptability index had acceptability ratios below 1, while women who scored higher on the clinician-sampling acceptability index had ratios above 1. Similar ratios were calculated for the individual items of pain, discomfort, embarrassment, and privacy based on each woman's Likert scores.

Results

Characteristics of participants

The mean age of the participants was 26.4 years (SD = 0.4); most had been born in PR (87%) and had at least a high school education (65%), while 35.4% were married or cohabitating. Most women (81.9%) had had more than two sexual partners, and 67% had never been pregnant; 21% reported their age at first sexual intercourse as 15 years, 12.1% had had 10 lifetime sexual partners, and 71% reported undergoing annual cervical cytology testing (Table 1).

Acceptability of collection methods

The reliability of the scales was tested with the Cronbach's alpha coefficient; cervical physician-collected samples were 0.44, cervical self-collected samples were 0.48, anal physician-collected samples were 0.65, and anal self-collected samples were 0.47.

An analysis of the overall scale revealed that the acceptability of the self-sampling method for the cervix was greater than that of the clinician-sampling method for the same organ (difference in mean score = -0.71, p<0.05). Nonetheless, higher acceptability was observed for the clinician sampling of the anus (difference in mean score = 0.64). An analysis of the individual items within the scale showed that the magnitude of the difference between cervical clinician-sampling and self-sampling was the greatest for embarrassment and pain (mean difference of -0.36 and -0.23, respectively), indicating that participants felt less embarrassment and pain when self-collecting samples; however, for self-collected anal samples, the mean difference was significantly greater for embarrassment (mean difference of -0.49) (Table 2).

Overall, 28% of the women found both cervical sampling methods to be equally acceptable, 22% found the clinician collection method to be more acceptable, and 50% found the self-sampling method to be more acceptable (Figure 1). For anal sampling, 35% of women found both methods equally acceptable, 22% found the clinician-sampling method to be more acceptable, and 43% found the self-sampling method more acceptable (Figure 2). For individual items, the results showed that a greater proportion of women felt that the techniques were equally acceptable in terms of pain (58%), embarrassment (71%), discomfort (47%), and privacy (94%). Similar results were seen with anal sampling methods. Nonetheless, for both cervical and anal sampling, a higher proportion of women

reported a higher acceptability of all of the individual items of the scale (less pain and embarrassment, more comfort and privacy) that used self-collection methods. This was true for all of the items except for pain during anal sampling: 16% of the women reported experiencing less pain when this sample was collected by a physician, while only 11% reported experiencing less pain when this sample was self-collected (Figures 1 and 2).

Preference of collection methods

Despite finding self-collection to be more acceptable than clinician collection in the areas evaluated, a larger proportion of women ended up preferring clinical collection. More women reported a preference for clinician collection of cervical (67%) and anal (61%) samples, while a smaller proportion preferred cervical and anal self-sampling (33% and 39%, respectively). Although results were not statistically significant, additional bivariate analyses showed that a larger proportion of women from the younger age groups (71% in the 18–24 and 72% in the 25–29 years age groups vs. 57% in the 30–34 years age group), those with 12 years of education (69% vs. 58% in those with <12 years of education) and with health care insurance (70% vs. 45% in those with no health care insurance), preferred cervical HPV clinician-collection methods. Meanwhile, a slightly larger proportion of women from the younger age-groups (76% in the 18–24 years and 61% in the 25–29 years age groups vs. 57% in the 30–34 years age group), with 12 years of education (62% vs. 58% in those with <12 years of education), and with health care coverage (63% vs. 55% in those with no health care coverage), preferred anal HPV clinician-collection methods (data not shown).

A comparison of women who preferred self-sampling with those who preferred clinician sampling showed that the reasons for their preference differed (p<0.001). A higher proportion of women who preferred the cervical clinician-collection method felt more confident that the sample would be more properly taken (85.6%) compared with the women who preferred the self-sampling technique (6.1%). Nonetheless, the percentage of participants who preferred cervical self-sampling to clinician sampling was greater in terms of feeling both greater comfort (72.7% and 20.9%, respectively [p<0.001]) and less embarrassment (27.3% and 1.5%, respectively [p<0.001]) (Table 3). Similar results were seen among women who preferred clinician-collected anal samples: 91.8% preferred this method because they thought it was more properly taken (Table 3). However, a higher proportion of those who preferred the anal self-sampling felt more comfortable (69.2% vs. 21.3%) and less embarrassment (28.2% vs. 1.6%) when compared with those who preferred clinician-sampling (Table 3). The method that would be preferred by the patient's partner did not seem to influence women's preference. Meanwhile, 68% of the women said that they would like to perform the cervical self-sampling if a health professional gave them the test at home, and 71% of them said that they would like to do the self-sampling at home if the test was sent to them through the mail. The same proportion of women said the same for anal self-sampling (data not shown). Meanwhile, 92% and 88% of women, respectively, said that they understood the instructions received for cervicovaginal and anal self-sampling.

Discussion

With the accuracy of HPV DNA self-testing established by different studies, ^{15,19–20,36} it has become more important than ever to understand the preferences of women with regard to self-sampling techniques as well as determining these women's willingness, regardless of preference, to practice said techniques. Our results show that overall acceptability indices measuring comfort, pain, privacy, and embarrassment were high for both self-sampling and clinician collection methods, although there was higher overall acceptability for self-collection with regard to the cervix.

Our analysis of individual scale items revealed that significantly less embarrassment and pain were observed in the self-collection of cervical samples. Despite these results, when women were asked specifically which method of cervical sampling they preferred, more than half (67%) opted for the clinician-collected sampling method; and of these, 86% reported that they felt more confident that this sample would be properly taken, and this was the most common reason reported. Our results are not exclusive to PR as they are consistent with those found in a study of a Mexican population that described the high acceptability of cervical HPV DNA self-sampling.³⁵ In the members of this population, according to the study, the clinician-sampling associated with Pap tests consistently provoked more discomfort, pain, and embarrassment than did self-sampling. However, contrary to our results, in this Mexican population, more women (68%) preferred self-collection overall because they considered it to be more comfortable and to cause less embarrassment. Our results are also consistent with those found in a study by Kahn et al.³⁷ that looked at women aged 14-21 years in the US; in this study, a higher proportion of participants reported a preference for clinician sampling (73%). As in our study, a given woman's preference for one cervical sampling method over another was related to that woman's concern over whether or not the sample could be collected correctly. Nevertheless, although the acceptability indices of the Likert scales were high for both methods (which is contrary to our results), in the Mexico study, acceptability indices for cervical sampling were also higher for clinician-collected specimens. The preference for clinician-sampling among young women may be related to the idea that younger women might rely more on health providers regarding their health and may not have as much confidence as adult women have regarding specimen collection. Although the results were not statistically significant, a similar pattern was observed in our study: A higher proportion of women in the youngest age-groups preferred clinician-testing (72%). This finding should be further evaluated in future research studies that have adequate power to study this and other potential sociodemographic correlates of HPV sampling preferences.

Similar to our study, other authors have seen that despite high acceptability for selfsampling, the predominant reason for preferring clinician-collected HPV cervical samples was the perceived likelihood of the samples so collected yielding more reliable test results. Waller et al.²⁵ found that more women (56%) were more confident that the cliniciancollected samples had been properly done as compared to self-sampling, while 39% of women rated both tests the same. Meanwhile, 70% of participants in a study by Forrest et al.³⁰ also expressed concern about doing the self-sampling properly. In an adult low-income population in the US, Anhang et al. ¹⁷ found that although 57% of the participating women did not find anything wrong with the self-sampling, they still preferred that a clinician collect their HPV cervical samples; 31% were not sure they had done the sampling correctly. The preference for clinician-collected sampling, which has been seen across studies, has been explained by concerns among women regarding efficacy of self-sampling, and as such warrants attention. One of the challenges is to improve public awareness and show that HPV self-sampling compares favorably with clinician-sampling, as has been demonstrated in multiple randomized studies^{15,20} as well as in a previous study in PR.²² A preference for clinician-collected samples could also be linked to the idea that the annual physician/ OBGYN visit is only for cervical cancer screening, and the concern that such visits might not occur if self-sampling is instituted. 15 This idea could lead expert groups to oppose this screening method. However, in these times, when reducing health costs may assume more importance than do the health that those costs are attempting to protect or improve, it is advisable to find less resource-intensive methods that nevertheless do not compromise the quality of established screening programs. Thus, although cervical cytology testing is the gold standard for cervical cancer screening, the fact that a large proportion of women are still not participating in screening programs makes the evaluation of self-sampling very important. In PR, an estimated 25% of women do not participate in routine cervical cancer

screening,³⁸ a proportion that is higher than the US median (19%),³⁸ although similar to the US, according to PR-Behavioral Risk Factor Surveillance Survey (BRFSS) data; lack of cervical cancer screening in PR has been associated with decreased income, older age, and the lack of routine medical check-ups.³⁹ Those women who are not participating in screening programs should be the target population for new screening methods. Screening alternatives in PR could include not only self-sampling but also sampling at home or through the mail, two alternatives highly accepted in our study population and supported in other studies.^{20,36}

Regarding anal HPV sampling, to our knowledge, there are no published data about its acceptability among women. Nonetheless, anal self-sampling was shown to be generally acceptable in a study of B streptococcus infection in US women. 40 In our study, higher acceptability for clinician sampling of the anus was observed through the scale, and a greater proportion of women reported preferring clinician-directed HPV anal sampling (61%); the main reason for this preference was that they felt more confident that the sample would be properly taken. Nonetheless, no significant differences in individual scale items were observed, except for the fact that less embarrassment was observed in the case of selfsampling than it was in clinician-sampling. Our results in women are contrary to the high acceptability of anal HPV self-sampling observed in studies among MSM. 12,31 A study on STI anal self-sampling among MSM in the US showed that the majority of participants preferred self-sampling rather than clinician-sampling, citing reasons of comfort and privacy as well as autonomy. ³¹ Nonetheless, consistent with our results, those MSM who preferred the clinician-collection method had a concern regarding their ability to accurately collect the samples. Although routine anal HPV testing is not currently part of any screening program, the women in our study had similar concerns for both anal and cervicovaginal self-sampling in terms of sample accuracy. However, even though more research is warranted, anal selftesting may be a cost-effective method of evaluating women at risk of anal lesions, such as women with cervical dysplasia. 41–42

Limitations of this study include of the fact that the sample pool was limited to a group of women who were visiting a gynecology clinic for a routine cervical cytology screening. Thus, the results may not be generalizable to the entire population of women in PR. Taking into consideration the notion that the greatest impact of HPV self-testing may be felt by individuals not currently participating in routine screening, ^{43,44,45} the high level of acceptability of self-sampling seen in this group of women (who were participating in cervical cancer screening) may encourage the offering of self-sampling to the general population. Also, given the small sample size, the power of our study to detect significant differences in the parameters evaluated may be limited; in addition, we could not fully assess the sociodemographic correlates of HPV sampling acceptability and preference. Future studies should assess the preference for self-collection methods among women not participating in screening programs and determine how the social determinants of health—including having a rural vs. urban residence—influence sampling preference.

Conclusion

This is the first study to assess the acceptability of anogenital HPV self-sampling collection methods in PR, and is, to our knowledge, the first report in the literature to assess women's acceptability for anal HPV sampling. Despite the preference of the study subjects for clinician sampling, the high acceptability and previously documented good concordance between the two methods (self-collecting and clinician-collecting) support the use of cervical and anal HPV self-sampling techniques in future HPV-related population-based studies and screening programs in PR.²² For the most part, women not only accept these methods but also find them understandable and less embarrassing. Given the observed

discrepancy between acceptability and preference, particularly for cervical sampling, patients need better education on the efficacy of self-collected samples in order to increase their preference for self-collection in both anatomical sites. Utilizing self-collection methods for obtaining anogenital samples could result in decreased costs for HPV-related population-based studies. Also, HPV self-sampling has the potential to promote cervical and anal cancer screening as it could facilitate the development of new screening programs and could attract women who do not participate in currently available screening initiatives. Thus, self-testing could contribute to the prevention and early detection of these cancers by making screening more accessible.

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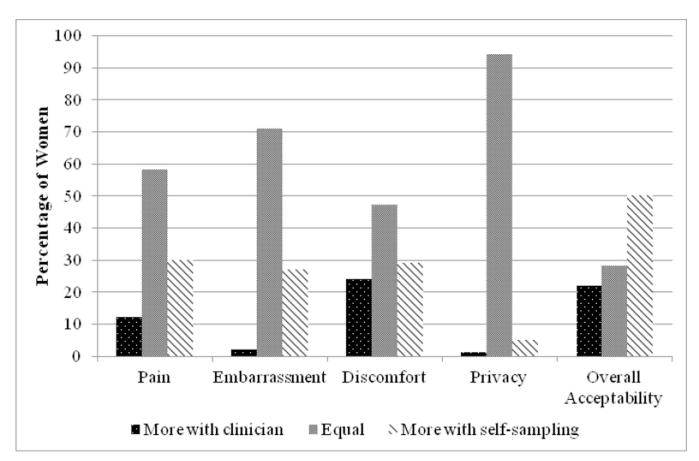


Figure 1. Comparison of women's HPV cervical sampling experiences (self-sampling vs. clinician-sampling) based on the acceptability ratios.

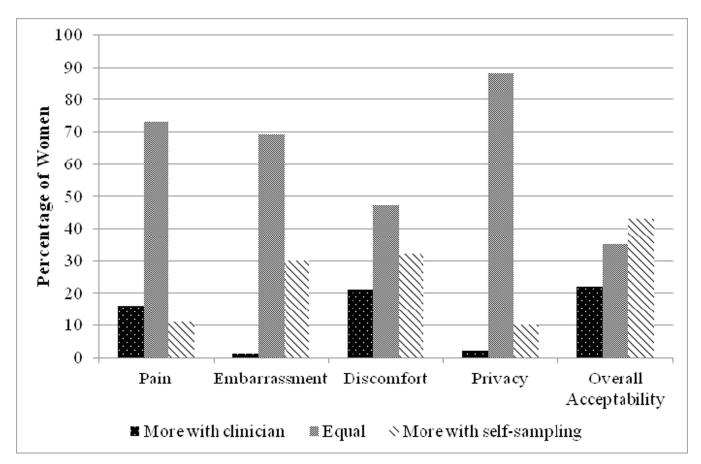


Figure 2. Comparison of women's HPV anal sampling experiences (self-sampling vs. clinician-sampling) based on the acceptability ratios.

Table 1

Characteristics of the study population (n = 100).

Characteristic	n (%)
Age (years)	
18–24	35 (35.0)
25–29	37 (37.0)
30–34	28 (28.0)
Place of birth	
Puerto Rico	87 (87.0)
United States	6 (6.0)
Dominican Republic	7 (7.0)
Education	
Less than high school	35 (35.0)
High school	65 (65.0)
Marital status*	
No couple (divorced, separated, widowed)	64 (64.7)
Current couple (married, living together)	35 (35.3)
Age at first sexual intercourse	
15 years	21 (21.0)
16 years	79 (79.0)
Number of lifetime sexual partners*	
0 - 1	18 (18.2)
2 – 9	69 (69.7)
10 or more	12 (12.1)
Health care coverage	
Yes	89 (89.0)
No	11 (11.0)
Number of live births	
0	67 (67.0)
1 - 2	23 (23.0)
3 or more	10 (10.0)
Annual cervical cytology test screening	
Yes	71 (71.0)
No	29 (29.0)

^{*} Missing n = 1

 Table 2

 Differences between acceptability scores: clinician-sampling versus self-sampling

	Physician- sampling	Self- sampling				
Scale item	Mean±SD	Mean±SD	Difference in mean score*	95% CI [†]		
Cervix						
Comfort	3.3±0.8	3.4±0.9	-0.06	-0.27 to 0.15		
Pain	3.3±0.9	3.6±0.8	-0.23	$-0.42 \text{ to } -0.04^{\dagger}$		
Privacy	3.9±0.4	4.0±0.2	-0.06	-0.13 to 0.01		
Embarrassment	3.6±0.8	3.9±0.3	-0.36	$-0.52 \text{ to } -0.20^{\dagger}$		
Total scale	14.1±1.8	14.8±1.5	-0.71	$-1.11 \text{ to } -0.30^{\dagger}$		
Anus						
Comfort	3.0±1.0	3.1±1.1	-0.14	-0.37 to 0.09		
Pain	3.5±0.8	3.4±0.9	0.08	-0.08 to 0.24		
Privacy	3.9±0.4	4.0±0.4	-0.09	-0.20 to 0.02		
Embarrassment	3.4±1.0	3.9±0.5	-0.49	-0.67 to -0.31^{\dagger}		
Total scale	14.3±1.9	13.7±2.3	0.64	0.18 to 1.10^{\dagger}		

 $^{^{\}ast}$ Differences were calculated as physician-sampling score minus self-sampling score.

 $^{^{\}dagger}{}_{P<0.05}$

 $\label{eq:Table 3} \textbf{Reasons for preference according to sampling method preference } (n=100).$

	Preferred Clinician sampling	Preferred self-sampling	P-value*	
Cervix	(n = 67)	(n = 33)		
Felt less embarrassment				
Yes	1 (1.5%)	9 (27.3%)	< 0.001	
No	66 (98.5%)	24 (72.7%)		
Felt more comfortable				
Yes	14 (20.9%)	24 (72.7%)	< 0.001	
No	53 (79.1%)	9 (27.3%)		
Felt more confident sample would be properly taken				
Yes	58 (85.6%)	2 (6.1%)	< 0.001	
No	9 (13.4%)	31 (93.9%)		
Spouse/partner would prefer that method				
Yes	0 (0.0%)	0 (0.0%)		
No	67 (100.0%)	33 (100.0%)		
Anus	(n = 61)	(n = 39)		
Felt less embarrassment				
Yes	1 (1.6%)	11 (28.2%)	< 0.001	
No	60 (98.4%)	28 (71.8%)		
Felt more comfortable				
Yes	13 (21.3%)	27 (69.2%)	< 0.001	
No	48 (78.7%)	12 (30.8%)		
Felt more confident sample would be properly taken				
Yes	56 (91.8%)	0 (0.0%)	-0.001	
No	5 (8.2%)	39 (100.0%)	< 0.001	
Spouse/partner would prefer that method				
Yes	0 (0.0%)	0 (0.0%)		
No	61 (100.0%)	39 (100.0%)		

^{*}Fisher's exact test p-value