International Journal of Gynecology and Obstetrics 126 (2014) 156–160

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

CLINICAL ARTICLE

Acceptability of self-collected versus provider-collected sampling for HPV DNA testing among women in rural El Salvador

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ARTICLE INFO

Article history:
Received 13 August 2013
Received in revised form 19 February 2014
Accepted 27 April 2014

Keywords:
Acceptability
Cervical cancer
HPV
Latin America
Self-sampling

ABSTRACT

Objective: To determine the acceptability of self-collected versus provider-collected sampling among women participating in public sector HPV-based cervical cancer screening in El Salvador. *Methods:* Two thousand women aged 30–49 years underwent self-collected and provider-collected sampling with careHPV between October 2012 and March 2013 (Qiagen, Gaithersburg, MD, USA). After sample collection, a random sample of women (n = 518) were asked about their experience. Participants were questioned regarding sampling method preference, previous cervical cancer screening, HPV and cervical cancer knowledge, HPV risk factors, and demographic information. *Results:* All 518 women approached to participate in this questionnaire study agreed and were enrolled, 27.8% (142 of 511 responding) of whom had not received cervical cancer screening within the past 3 years and were considered under-screened. Overall, 38.8% (n = 201) preferred self-collection and 31.9% (n = 165) preferred provider collection. Self-collection preference was associated with prior tubal ligation, HPV knowledge, future self-sampling preference, and future home-screening preference ($P < 0.05$). Reasons for self-collection preference included privacy/embarrassment, ease, and less pain; reasons cited for provider-collection preference were result accuracy and provider knowledge/experience. *Conclusion:* Self-sampling was found to be acceptable, therefore screening programs could consider offering this option either in the clinic or at home. Self-sampling at home may increase coverage in low-resource countries and reduce the burden that screening places upon clinical infrastructure.

1. Introduction

More than 85% of cervical cancer-related deaths occur in low- and middle-income countries, making it a leading cause of cancer-related mortality among women in these nations [1]. Cervical cancer incidence and mortality among women in El Salvador are among the highest in the Latin American and Caribbean region (37.2 and 18.2 per 100 000 women, respectively), and cervical cancer is the most frequent cause of cancer-related deaths [2,3].

Lack of infrastructure and facilities, the requirement of specialized training, and the need for multiple visits for follow-up and treatment after a positive screening result have all contributed to high cervical cancer mortality rates in Latin America [4,5]. Current cytology-based programs in Latin America have suffered from poor laboratory performance, lack of systematic quality control, low coverage rates, and inadequate follow-up from positive screening results [6,7].

High-risk HPV testing is being considered for primary screening in low-resource settings because it has greater sensitivity and reliability than cytology for detecting pre-cancer and early cancer, and may potentially reduce cervical cancer rates when combined with adequate follow-up [8,9]. The introduction of self-sampling as a method to obtain cervico-vaginal samples has demonstrated promise in improving access among under-screened populations, including those in low-income

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http://dx.doi.org/10.1016/j.ijgo.2014.02.026
0020-7292/

nations [10–12]. Despite decreased sensitivity and specificity compared with provider-collected sampling, self-sampling has been shown to be at least as sensitive as cytology and more sensitive than visual inspection with acetic acid [12,13].

To date, studies that have investigated the acceptability of self-sampling compared with provider-collected sampling in low- and middle-income countries have found varying results. Some studies, albeit among populations with high screening rates, have disagreed whether women prefer self-collection or provider collection [11,14–16]. Interestingly, studies have generally found a preference for provider-collected sampling to be associated with women with a lower level of education because they viewed it as more reliable [14,15].

The primary objective of the present study was to assess the acceptability of self-collection and provider collection of samples for HPV testing and to identify factors associated with either preference as well as with no preference. In El Salvador, self-sampling and HPV testing have the potential to improve participation in cervical cancer screening. Investigating the acceptability of the procedure among women is an important first step toward developing effective educational programs, communicating with patients, increasing the number of patients undergoing HPV testing in the future, and better direction of screening efforts toward women who are not covered by current screening programs.

2. Materials and methods

The present study was nested within the first phase of the Cervical Cancer Prevention in El Salvador (CAPE) initiative, the aim of which was to provide HPV DNA screening to 2000 women. The first phase of CAPE recruited women between October 2012 and March 2013. The study took place at four rural health units (San Pedro Perulapan, San Rafael Cedros, Apastepeque, and San Sebastián) in the Paracentral region of El Salvador, which are responsible for providing primary preventive care. Health promoters are local employees of the Ministry of Health (MOH) who reside in the communities in which they work and promote preventive health initiatives by providing education and counseling. The health promoters and MOH administration used the 2010 census to identify all women aged 30–49 years (the recommended ages for screening by the World Health Organization [17]) and therefore potentially eligible for HPV testing in their catchment areas (n = 11 421). The study was approved by the University of Pittsburgh Institutional Review Board and the National Ethical Review Board of El Salvador.

All women enrolled in the study attended government-run community education sessions to learn about the opportunity to receive HPV DNA testing through the CAPE initiative. The study used a HPV DNA testing system that was designed specifically for lower-resource areas: careHPV (QIAGEN Gaithersburg, Gaithersburg, MD, USA).

Health promoters used health unit cytology registries to identify women who had not been screened within the past 3 years and visited them in their home. Upon visiting them, many women reported that they had recently been screened in a screening campaign or on another occasion. Women deemed eligible in the home (n = 2649) were invited to attend an educational session in their community covering cervical cancer prevention. Women were eligible if they were aged 30–49 years, not pregnant, able to provide informed consent, and without history of cryotherapy, loop electrosurgical excision procedure, or hysterectomy. Some women arrived at the educational session without having been seen at their home by a healthcare promoter, so eligibility was confirmed at that time. A total of 1896 women were deemed eligible and scheduled for a screening appointment to take place at their local health clinic.

To obtain a random sample of women for this study of self-sampling acceptability, upon arrival at the health clinic, the first 24 women were given a card that was one of three colors, distributed in an alternating fashion. After all women had arrived, one color was chosen at random to select one-third of the women. Selected women were invited to participate in the self-sampling acceptability study and informed consent was obtained. Up to eight women were enrolled at each screening day. No incentive to participate was provided. Recruitment for the self-sampling study ceased when 387 women had completed the self-sampling acceptability questionnaire. A target sample size of 387 women was selected to provide a 95% confidence interval width of 10% when estimating the percentage of women who would prefer self-sampling or have no preference.

An initial analysis of these 387 women showed that fewer under-screened women (previous screen 3 or more years previously) had participated than expected (20% vs 40%). In order to obtain a larger sample size of under-screened women, the same recruitment scheme was used to seek enrollment of an additional 175 women for the study who were under-screened. Phase 1 ended before 175 additional women were enrolled; only 131 additional women were interviewed. All women (100%) recruited for this self-sampling study consented to participate during first and second enrollment periods.

Women were shown the self-sampling device and a provider gave verbal instructions on how to perform the self-sampling procedure; the women were then individually called into the examination room to be seen by a provider. First, the provider performed a speculum exam and collected a cervical sample. Then the patient was instructed to go to a private area to self-collect a cervico-vaginal sample. Samples were collected and then immediately placed in labeled containers.

Following the sampling, research assistants administered the questionnaire to women in a private location. Women were asked which sampling method (self-sampling or provider-collected sampling), if any, they preferred during their screening that day, were prompted to provide justification for the choice in an open-ended format, and were asked which method they would prefer during a future screening visit. Women were also asked for their preferred location of screening (home vs clinic). The questionnaire asked for demographic information (age, education, marital status, household size, and number of children), sexual history (age of first intercourse, lifetime sexual partners, and current birth control method), smoking history, previous cervical cancer screening history, and knowledge of HPV and cervical cancer. Univariate analysis was used to describe women in the cohort including their demographic characteristics, sexual history, smoking history, screening history, knowledge of HPV and cervical cancer, and preference for current and future sampling method and location of screening. These factors were then evaluated for their association with preference using χ^2 tests of significance. An association was considered to be statistically significant if the P value was less than or equal to 0.05. Stata version 12.1 (StataCorp LP, College Station, TX, USA) was used for data analysis.

3. Results

The participating population is described in Fig. 1; enrollment in the CAPE study ended before 175 additional under-screened women could be enrolled for this questionnaire study; only 131 additional women were enrolled. All 518 women who were randomly selected and invited to participate in this self-sampling acceptability study agreed and participated in both methods of sample collection. Demographic characteristics of the participants are presented in Table 1. Most women (n = 307, 59.3%) were between the ages of 30 and 39 years, and had not achieved greater than an elementary school education (n = 297, 57.3%). The majority were married (n = 265, 51.2%) or lived with a significant other (n = 145, 28.0%), a significant proportion had five or more children (n = 146, 28.2%), and most women lived in households of six or more people (n = 325, 62.7%). Very few participants had ever smoked (n = 21, 4.1%). Most participants had initiated sex before the age of 20 years (n = 376, 72.9%) and 97 (18.8%) of those before the age of 16 years. Approximately half (n = 274, 52.9%) reported one sexual partner in their lifetime. Approximately half (n = 264, 51.0%) of the women reported never having used contraceptives, while 117 (22.6%) reported having had a tubal ligation.

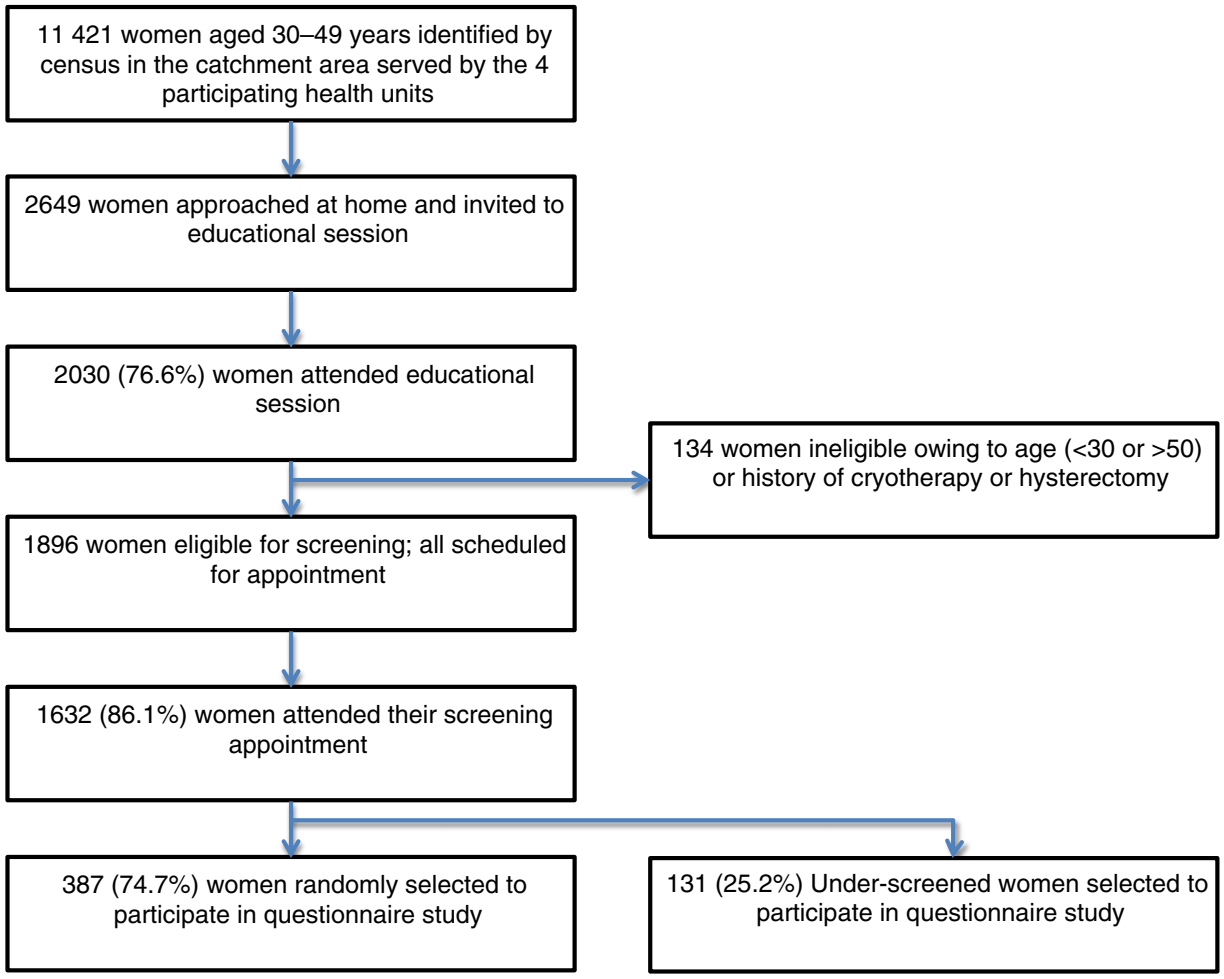

Fig. 1. Enrollment flow chart.

A minority of women had previous knowledge of HPV before their screening appointment (n = 196, 37.8%; Table 2) and believed they could get cervical cancer (n = 207, 40.0%). Few patients were naive to screening (n = 18, 3.5%), although a larger proportion (n = 124, 24.3%) had previously been screened but were under-screened (not screened within the past 3 years). Of women with a previous cervical cancer screening, 450 (90%) had received screening during a routine visit.

More women preferred self-collection (n = 201, 38.8%; 95% confidence interval [CI], 34.6–43.2) than provider-collected sampling (n = 165, 31.9%; 95% CI, 27.9–36.1) and those with no preference (n = 152, 29.3%; 95% CI, 29.3–33.5). Preference for self-collection was associated with prior tubal ligation ($P = 0.002$). Preference for provider-collected sampling versus self-collected or no preference was associated with a low level of education (elementary school or below vs. middle school or higher, 107 [64.9%] vs 58 [35.2%]; $P = 0.02$).

Interestingly, approximately 85% (n = 152) of women who expressed a screening method preference during the present screening stated they would prefer sampling with that method in the future. Overall, 37.5% (n = 194) expressed a preference to have a future screening at home, 42.1% (n = 218) at the health center, and 20.4% (n = 106) had no location preference. Among those who preferred provider-collected sampling at the current visit, 63% (n = 104) had a preference for future screening at the health center, with 24.2% (n = 40) preferring a future sampling at home. Within the group who preferred self-sampling, 56.7% (n = 114) would prefer a future screening at home and 27.4% (n = 55) at the health center.

Preference for self-collection during the present visit was associated with knowledge of HPV ($P = 0.003$), a preference for future self-sample collection ($P < 0.001$), and a preference for future screening to take place at home ($P < 0.001$). Preference for self-collection among under-screened women was not statistically significant ($P = 0.1$) compared with the overall population, although the trend was similar as to that for the whole population.

The most frequently cited reasons among the women who preferred self-sampling were privacy/embarrassment (n = 60, 29.9%), ease (n = 40, 19.9%), pain (n = 38, 18.9%), comfort (n = 30, 14.9%), and time/convenience (n = 17, 8.5%). The most commonly mentioned justifications among those who preferred provider-collected sampling were result accuracy (n = 55, 33.3%), the provider's knowledge (n = 40, 24.2%), the practice or experience the provider has had performing the procedure (n = 27, 16.4%), fear of improper sampling (n = 22, 13.3%), and comfort (n = 13, 7.9%). Among women preferring self-collection, those with elementary or no education were less likely to report time and convenience (5 [4.7%] vs 12 [12.6%], $P = 0.04$) as the reason for their preference.

Among those who reported a preference for future screening to occur in the health center, the most frequently cited reasons were comfort (n = 72, 33.0%), the availability of assistance/equipment (n = 55, 25.2%), the sanitation of the facilities (n = 27, 12.4%), and privacy (n = 24, 11.0%). Women who preferred a future screening in their home cited privacy (n = 49, 25.3%), comfort (n = 47, 24.2%), time (n = 41, 21.1%), travel (n = 29, 15.0%), ease (n = 16, 8.3%), and financial costs (n = 11, 5.7%) as justification.

Table 1
Sociodemographic characteristics of participants and collection method preference.

	Total		Provider-collected		Self-collected		No preference		*P* value [a]
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	
Total	518	(100.0)	165	(31.9)	201	(38.8)	152	(29.3)	
Age, years									
30–39	307	(59.3)	102	(61.8)	117	(58.2)	88	(57.9)	
40–49	211	(40.7)	63	(38.2)	84	(41.8)	64	(42.1)	0.72
Highest education									
Elementary/none	297	(57.3)	107	(64.9)	106	(52.7)	84	(55.3)	
Middle school or higher	221	(42.7)	58	(35.2)	95	(47.3)	68	(44.7)	0.06
Marital status									
Married	265	(51.2)	80	(48.5)	106	(52.7)	79	(52.0)	
Living together	145	(28.0)	48	(29.1)	53	(26.4)	44	(29.0)	
Single/widowed/ separated	108	(20.9)	37	(22.4)	42	(20.9)	29	(19.1)	0.90
Smoked >100 cigarettes in life	21	(4.1)	7	(4.2)	11	(4.5)	3	(2.0)	0.25
Number of children									
0–2	145	(28.0)	50	(30.3)	50	(24.9)	45	(29.6)	
3–4	227	(43.8)	76	(46.1)	92	(45.8)	59	(38.8)	
≥5	146	(28.2)	39	(23.6)	59	(29.4)	48	(31.6)	0.37
Size of household									
1–3	33	(6.4)	15	(9.1)	11	(5.5)	7	(4.6)	
4–5	160	(30.9)	50	(30.3)	67	(33.3)	43	(28.3)	
≥6	325	(62.7)	100	(60.6)	123	(61.2)	102	(67.1)	0.37
Age of first intercourse, years									
<16	97	(18.8)	32	(19.4)	34	(17.1)	31	(20.4)	
16–19	279	(54.1)	88	(53.3)	113	(56.8)	78	(51.3)	
≥20	140	(27.1)	45	(27.3)	52	(26.1)	43	(28.3)	0.88
Lifetime sexual partners									
1	274	(52.9)	86	(52.1)	108	(53.7)	80	(52.6)	
2–3	210	(40.5)	67	(40.6)	77	(38.3)	66	(43.4)	
≥4	34	(6.6)	12	(7.3)	16	(8.0)	6	(4.0)	0.57
Current birth control method									
Tubal ligation	117	(22.6)	24	(14.6)	45	(22.4)	48	(31.6)	
Other	137	(26.5)	51	(30.9)	44	(21.9)	42	(27.6)	
None	264	(51.0)	90	(54.6)	112	(55.7)	62	(40.8)	0.002

[a] χ^2 or Fisher exact test.

4. Discussion

The present study compared the acceptability of self-sampling versus provider-collected sampling for careHPV testing in El Salvador. Compared with previous studies examining sampling preference, women were given the option of answering "no preference" in regard to sampling method preference (n = 152, 29.3%) and location (n = 106, 20.4%) [14–16]. This indicates that these women are equally likely to participate in a cervical cancer screening program regardless of that particular aspect of the screening program design. By isolating these responses, it reduces the possibility that these responses may artificially skew the overall preference results and allows for analysis of preferences among the remaining women who may be inclined to act upon those preferences.

Table 2
Knowledge, risk perception, and screening history of participants and collection method preference.

	Total		Provider-collected		Self-Collected		No preference		*P* value [a]
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	
Total	518	(100.0)	165	(31.9)	201	(38.8)	152	(29.3)	
Heard about HPV before today									
Yes	196	(37.8)	48	(24.5)	93	(47.5)	55	(28.1)	
No/not sure	322	(62.2)	117	(36.3)	108	(33.5)	97	(30.1)	0.003
Could get cervical cancer									
Yes	207	(40.0)	55	(33.3)	88	(43.8)	64	(42.1)	
No	137	(26.4)	48	(29.1)	57	(28.4)	32	(21.1)	
Don't know/not sure	174	(33.6)	62	(37.6)	56	(27.9)	56	(36.8)	0.08
Last screen for cervical cancer									
Never	18	(3.5)	9	(5.5)	3	(1.5)	6	(4.0)	
≥3 years ago	124	(24.3)	34	(20.7)	57	(29.1)	33	(21.9)	
≤3 years ago	369	(72.2)	121	(73.8)	136	(69.4)	112	(74.2)	0.11
Previous screen was routine	450	(90.0)	144	(92.3)	174	(87.9)	132	(90.4)	0.21
Preferred location of future screen									
Home	194	(37.5)	40	(24.2)	114	(56.7)	40	(26.3)	
Health center	218	(42.1)	104	(63.0)	55	(27.4)	59	(38.8)	
No preference	106	(20.4)	21	(12.7)	32	(15.9)	53	(34.9)	<0.001
Preferred future sampling method									
Provider-collected	156	(31.9)	111	(71.2)	10	(5.0)	35	(23.0)	
Self-collected	269	(51.9)	41	(6.4)	178	(88.6)	50	(32.9)	
No preference	93	(18.0)	13	(22.4)	13	(6.5)	67	(44.1)	<0.001

[a] χ^2 or Fisher exact test.

The results support previously reported findings that self-sampling is at least as acceptable as provider-collected sampling for HPV or cytology in other areas of the world [18–20]. Furthermore, a significant percentage of those who prefer self-sampling would prefer to have future sampling offered in their home, in agreement with a previous study conducted in a low-resource setting [21]. A trend for a preference for self-sampling was found among under-screened women, although the present study lacked the power to show significance in this key subgroup.

A large percentage of women in the study stated that they would prefer sampling at home. Accordingly, providing women with this option may increase screening coverage among the under-screened population; a comprehensive program offering both options to the patients may lead to an increase in overall coverage. Such a program would address sociocultural factors that have been cited as barriers to improving screening in previous studies, including the unavailability of female providers, insensitive staff, and poor counseling [5,22]. A large proportion of women in the current study agreed, as 60 (29.9%) women who preferred self-sampling associated it with greater privacy or less embarrassment.

The strengths of the study included an assessment of women's cervical cancer screening preferences—an important factor in healthcare utilization that empowers women by providing them with suitable choices. By identifying characteristics associated with women's preferences, programs can serve their communities better and increase screening coverage. The study also randomly sampled the target population to describe many of these associations. Another strength of the study is that the administration of the device, laboratory testing, and programmatic organization and logistics were performed in collaboration with the Salvadoran Ministry of Health, whose input and dedication will be critical for any national, sustainable programming involving HPV testing.

The greatest limitation of the present study is that a significant proportion of women who participated in the study were already participating in the current screening program. This subpopulation would be expected to feel comfortable with provider-collected sampling, and may also have the means and availability to travel to the health clinic for care. Furthermore, these women had participated in a cytology program, which may not present them with the same burden of responsibility that self-sampling imposes; perhaps the results would be different among women naive to screening because that responsibility would be viewed as an understood component of the screening from the outset and not perceived as a new challenge. While the current study was ultimately underpowered to demonstrate statistical significance with respect to sampling method preference, the trend found in the study highlights an important area for future investigation.

In conclusion, women living in Paracentral El Salvador found self-sampling to be an acceptable collection method, and future cervical cancer screening programs could consider offering this option to women either in the clinic or in their own homes. A program allowing women to self-sample at home may increase screening coverage among women in low-resource countries who are not participating in current cervical cancer screening programs and may reduce the burden that screening places upon clinical infrastructure in these settings.

Acknowledgments

The Einhorn Family Charitable Trust and the Fulbright US Student Program provided financial support.

Conflict of interest

The authors have no conflicts of interest.

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