Acceptability of self-taken vaginal for early detection of HPV DNA in women with limited access to health services: An alternative to increase the coverage in a state of the Mexican Republic

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ABSTRACT

Objective: To determine the acceptability of self-taken vaginal to detect HPV DNA in women living in marginalized areas as an alternative to increase the coverage of health services. Methods: A cross-sectional study from March 2009 to April 2011 in 20 municipalities with the highest marginalization in the Huasteca Region of the State of San Luis Potosi, México. We applied a non-probabilistic quota sampling, which was composed of 608 women aged 25 years and more. The recruitment of women was performed through loudspeakers, leaflets and community meetings. A survey consisted of two sections: socio-demographic data and risk factors, which was validated by construct. We checked the reliability by Cronbach's Alpha (0.90). Acceptability was determined by considering three indicators: perceived comfort, acceptability of the test and the reasons of acceptability. Results: 41.4% of this woman had 31 - 40 years. 70.5% were married. 35.3% finished high school and 6.7% had not education experience. 67.4% began their sexual life at 18 years or younger. 85.5% preferred self-collection and 14.5% Pap. These results show a clear acceptability of self-making on the other screening method. Regarding the reason for the preference is that 99.4% of women prefer self-take because they feel more comfortable compared to 0.6% who prefer the Papanicolaou. On the perception of comfort 91% mentioned feel very comfortable with self-making compared with 9% of Pap. There was a statisti-cally significant correlation between preference reasons that women have to choose the screening test and the perception of comfort (X^2p = 0.000). Conclusions: The self-taken vaginal HPV DNA detection is a well accepted method in women who live in marginalized areas; therefore, it is an alternative that can be considered in the uterine cancer detection testing program.

Keywords: Self-Taken Vaginal HPV; Cervical Cancer; Acceptability of Self-Making

1. INTRODUCTION

Cervical cancer (CC) remains one of the most frequent causes of death in women [1] and a public health problem worldwide especially in underdeveloped countries, with an annual report of 510,000 cases [2,3], an estimated 274,883 deaths in 2008. In México the disease ranks second in incidence and is a major cause of cancer death in women older than 25 years [4]. The cause of cervical cancer deaths that occur in México each year mostly affects women living in marginalized areas. For 2007, México recorded that a mortality rate of 14.2 per 100,000 women and specifically in the state of San Luis Potosi (SLP), which has indigenous settlements, was between 17 and 17.5 [5]. Prevention efforts worldwide have focused on the screening of patients at risk using Pap test (Pap) and treatment of precancerous lesions. In México the early detection of cervical cancer program has more than 20 years in operation and avoided less than 13% of preventable cases [6].

The conventional Pap smear is the most used tech-

nique for early detection of cervical cancer and precancerous lesions. Based on the fact that cells of the cervical epithelium layers are shed continuously. To remove cells requires professional or technical staff. For obtaining cells women must be in the gynecological position, the speculum of metal or plastic is inserted into the vagina in order to observe the cervix. Once located proceed to collect the cells by special instruments such as Ayre spatula and cytobrush. The cellular material extends in a glass slide, fixed with alcohol and sent to the laboratory for analysis and interpretation. For this study the woman must expose their private parts so that the doctor or nursing staff take the sample. In México, one of the main factors limiting the success of cervical cancer prevention in addition to those related to the organization of health systems is the socio-cultural aspect that hinders proper implementation of preventive measures.

One explanation for the low coverage is the limited use and poor accessibility of women to the Papanicolaou (PAP) due to cultural and institutional barriers such as: discomfort with the pelvic exam, their husbands or sexual partners are not allowed to take Pap, previous negative experiences with service providers, ignorance of the Pap, perception and the long waiting time for delivery of results [7]. The limited success of this programs has been the estimating testing for DNA Human Papillomavirus (HVP). Several studies have evaluated the clinical utility of the Hybrid Capture (CH2) in cervical cancer screening. The sensitivity was 86% for any type of HLG (low grade lesions) and 93% for LAG (High Grade Lesions), compared with 60% and 73% of Pap [8]. Screening of High-Risk HPV has been shown to be a highly sensitive tool in the early detection, and it has been successfully used in clinical and epidemiological studies showing that it is suitable for population programs obtaining the sample that is much easier, and the interpretation of the result. Recent large-scale studies in women, who do not participate in conventional screening program, have shown that the supply of self-take for HPV detection, and an effective alternative to attract up to 30% of these patients [9-12] have increased the coverage. San Luis Potosi in 2010 began to implement HPV testing [13]. However, the accessibility of the service and the cultural aspect has not been resolved, like time constraints, discomfort, this is how the idea of promoting the patient's own take of the sample (self-making) represents an option that involves social and economic benefits, which together with other actions would lead to a decrease in the incidence of cervical cancer. The objective of this study was to determine the acceptability of self-taken vaginal to detect HPV DNA in women living in marginalized areas as a possible alternative to increase the coverage of health services.

2. PATIENTS AND METHODS

2.1. Data Source

Cross-sectional study conducted in the period March 2009 to April 2011 in the 20 municipalities with the highest marginalized rating in the Huasteca region of the State of San Luis Potosi, México. The level of poverty data were obtained from CONAPO (National Council of Population), which considers five units: Very Low, Low, Medium, High and Very High level of poverty, based on the indicators: private homes inhabited, percentage of population 15 years or more without complete primary illiterate, percentage of occupied private housing inhabited with no toilet and no electricity, percentage of occupied private housing without piped water availability, average occupants per room in occupied private housing with floor and have no refrigerator. The universe of women in municipalities is 79.946. Due to the difficulty in locating women given the characteristics of the geographic area we applied a non-probabilistic sampling fee, which was composed of 608 women aged 25 years and over, distributed as follows: Aquismón 38, Axtla de Terrazas 36, Ciudad Valles 92 Coxcatlán 18, Ébano 45, El Naranjo 14, Huehuetlán 10, Matlapa 35, San Antonio 5, San Martin Chalchicuautla 29, San Vicente Tancuayalab 13, Tamasopo 16, Tamazunchale 88, Tampacán 16, Tampamolón Corona, 15, Tamuín 35, Tancanhuitz 13, Tanlajás 20, Tanquián of Escobedo 16 and Xilitla 48. The recruitment of women was carried out through loudspeakers, leaflets and community meetings. A group of promoters gave a talk about HPV and vaginal self-take to build awareness. The women took the samples in the bathrooms of the health centers. To collect the data, a survey consisting of two sections: socio-demographic data and risk factors which was validated by construct, and the reliability was verified through Cronbach's Alpha (0.90).

2.2. Materials

The samples were obtained as described in the manual collected vaginal National Institute of Public Health (INSP) of México [14]. Briefly, the user is prompted: 1) how to open the collection kit which consists of a cytobrush and specimen transport tube, 2) how to get the brush and 3) how to open and close the tube. Later was taught how to take the sample taking the following order: washing hands, naked from the waist down, pull the cytobrush and transport tube case, take the brush with the dominant hand, raise one leg on the bed, chair or toilet and non dominant hand to separate the labia (genitals), insert the brush vagina and once inside, turn three times to the right and three times to the left, remove and place immediately in the tube, recharging on the wall of the tube and close the pressure, deliver to the trainers. At all

times we used appropriate language for understanding according to the characteristics of the population in each community. When necessary, they requested support from translators in order to communicate with women who only speak a native dialect (Tenek or Nahuatl).

2.3. Sample Processing

Each sample was labeled using a bar code and stored at 4°C. The HR-HPV infection was determined by Hybrid Capture (Digene Hybrid Capture ® 2). Samples were processed in the Laboratory of Molecular Biology Diagnostics on the device INSP Rapid Capture System™ Digene DML 2000.

2.4. Map Production

It was used ILWIS 3.3 software which is an acronym for the integrated management of land and water in a Geographic Information System (GIS) with image processing capabilities developed by the International Institute for Aerospace Survey and Earth Sciences Enschede, Netherlands, which allows you to view different areas at one time. To create the map were obtained databases of geographic coordinates of the locations of the Huasteca, which were converted to Universal Transverse Marker (UTM). He placed the Digital Terrain Model (DTM), and polygon map to identify the boundaries of each municipality.

2.5. Data Analysis

We used SPSS (Statistical Program Social Science) v. 15.0. For the interpretation of the data descriptive statistics were used. To verify whether there was a relationship between the variables: "preference reasons" of self-making as a screening with the "comfort women perceived" to be tested (self-making) was applied Pearson X^2.

2.6. Ethical Considerations

All participants gave their consent to participate in the study. The project was evaluated and accepted by the H. Research Ethics Committee of the Faculty of Nursing UASLP, 0028HCEI key.

3. RESULTS

In México there are 84,769 localities, of which 26.4% (22,443) are classified as highly marginalized degree, while 73.5% (62,326) are highly marginalized (National Institute of Statistics, Geography and Informatics INEGI, 2010). Specifically in the State of San Luis Potosi, 2.2% of the population (781 seats) has a very high level of poverty and 32.9% (3001 seats) are highly marginalized (INEGI, 2010) (**Figure 1**, panel A and B respectively).

On the other hand, in the region where this study was done, it appears that women of all municipalities participants living in high to very high levels of marginalization. This is an indigenous settlement area (**Figure 1**, panel C).

Socio-demographics characteristics were studied. 41.4% were located in the age group of 31 to 40 years, followed by the group of 41 to 50 years with 31.5%. Most women are married (70.5%). The highest level of schooling was to complete high school (35.3%). It is important to show that 6.7% does not have any study. Most women (76.8%) are housewives. 67.4% began their sexual life at 18 years or younger (**Table 1**).

In relation to Acceptability of self-collected vaginal test, 85.5% prefer the self-collected and 14.5% Papanicolaou (**Figure 2**).

With regard to the reasons for preference of each method 99.4% prefer self-take because they feel more comfortable compared to 0.6% who prefer the Pap. The 92.9% reported other reasons for preferring self-taken as the following "easy", "simple", "feel more confident", "is faster", "comfortable", "do not bother or do not hurt", "making it yourself", "practice", "safe", "is more personal", "painless", "no scrape or hurt instruments", "is material unique", "instruments are used only once", "is toilet", "not embarrassed or ashamed", "the instrument is personal", "on-irritating", "does not open from the vagina" With regard to the perception of comfort 91% mentioned feeling very comfortable with self-taken compared with 9% of Pap. It was considered desirable to check whether there was a relationship between the reasons for preference for self-collected vaginal test with the perception of comfort in women who participated in the study. The result was that the perception of comfort influencing the choice of technique (X^2p = 0.000) (**Table 2**).

4. DISCUSSION

The social substrate determined by poverty, gender inequity, and poor access to information, among other factors kept large segments of the female population of this region under conditions of high vulnerability and risk of illness and death from cervical cancer. According to INEGI (2000) in México, 30.6% of all women who died were illiterate, 21.9% attended less than three years of elementary school and 13.8% only three to five years of elementary school, indicating that 66.3% of all deaths from this cause were illiterate or with incomplete elementary school. It has been shown that low socioeconomic status is a significant development in the CC risk factor because of the effect it has on educational and medical resources. Results of several epidemiological studies indicate that Hispanic and African-American women have a higher risk of developing invasive cervi-
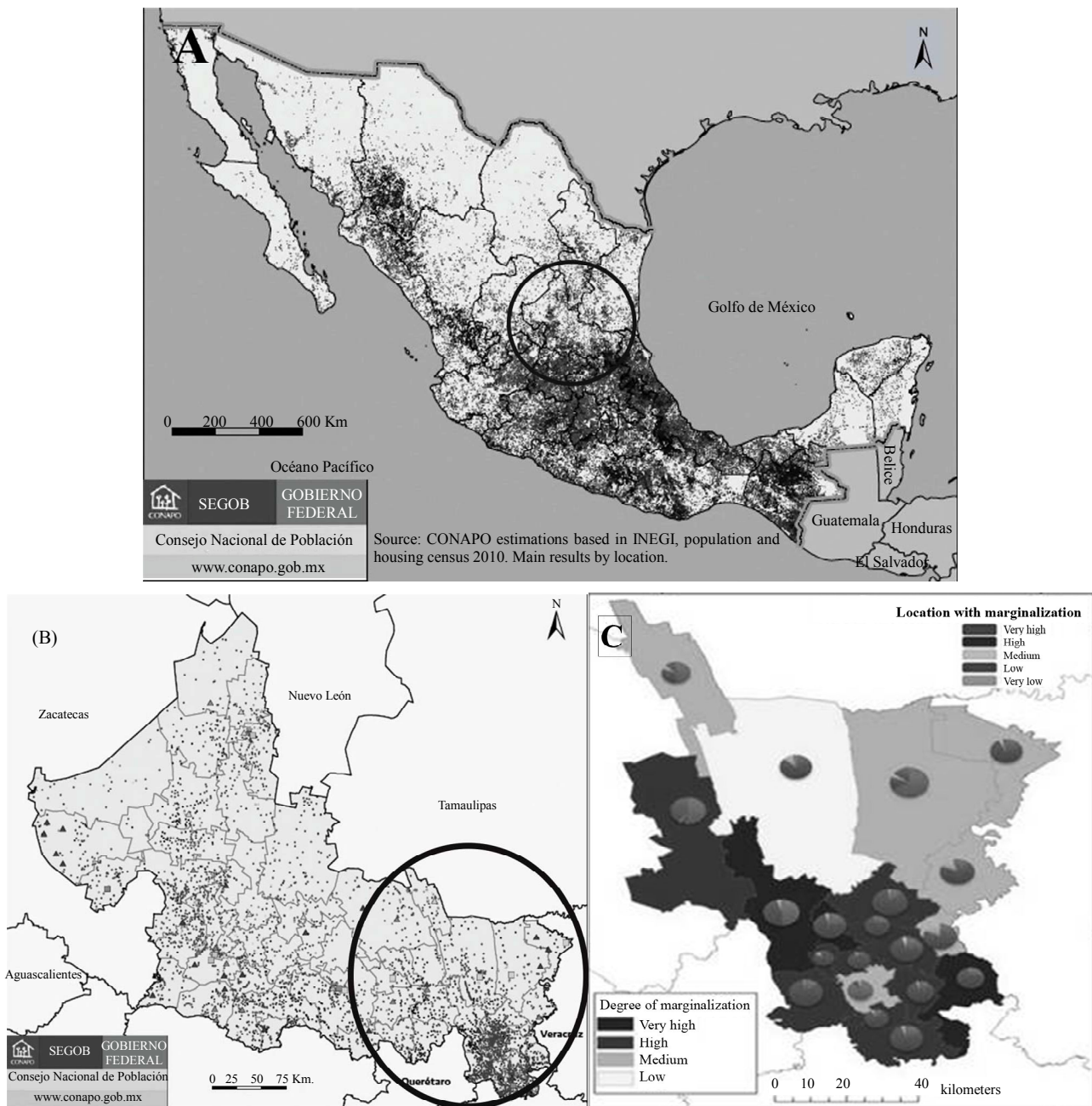
Figure 1. Degree of marginalization in which women who participated in all municipalities live. (A) Map of México in which points light and dark are shown locations with very high and high marginalized respectively (circulated San Luis Potosi region). (B) Map of San Luis Potosi shown circulated the Huasteca Potosina region. The light and dark spots indicate the various degrees of marginalization (Etimations based in INEGI population and housing census 2010). (C) Map of Huasteca Potosina region. Dark areas show very high and high marginalization locations. Graphics show percentage of marginalization location. Maps were obtained from CONAPO, México.

cal cancer compared to Caucasians [15]; a decreased risk of developing this disease is associated with more advanced education. The increased risk associated with low socioeconomic status is attributed to the lack of testing, a failure in the treatment of precancerous conditions, and lack of knowledge about the prevention of HPV infection [16]. Women who participated in this study are in this

poverty. Therefore, it is possible that if access to screening tests such as vaginal self-making, and other measures of health were improved, the race of the person would not be proved to be a significant risk factor.

HPV testing has become increasingly important. In countries that do not have an infrastructure cyto-pathological or have organized health programs, programs are

Table 1. Socio-demographic data and first intercourse of women who live in the Huasteca region of San Luis Potosi, México.

Variable	No.	%
Age group		
30 or less	101	16.6
31 - 40	252	41.4
41 - 50	192	31.5
51 - 60	55	9.0
61 or over	7	1.1
Not answered	1	0.0
Marital status		
Married	429	70.5
Free unión	118	19.4
Single	37	6.0
Widow	14	2.3
Divorced	9	1.4
Not answered	1	0.0
Schooling		
None	41	6.7
Incomplete elementary	92	15.1
Completed elementary	179	29.4
Incomplete secondary	38	6.2
Completed high	215	35.3
Incomplete bachelor	7	1.1
Completed bachelor	31	5.0
Technical career	1	0.1
Unfinished degree	1	0.1
Degree completed	2	0.3
Not answered	1	0.0
Ocupation		
Housewives.	467	76.8
Self-employment	69	11.3
Employee	59	9.7
Business	6	0.9
Cooperative member	5	0.8
Laborer	1	0.1
Not answered	1	0.0
Age of first intercourse		
18 or less	410	67.4
19 or over	197	32.4
Not answered	1	0.0

n = 608.
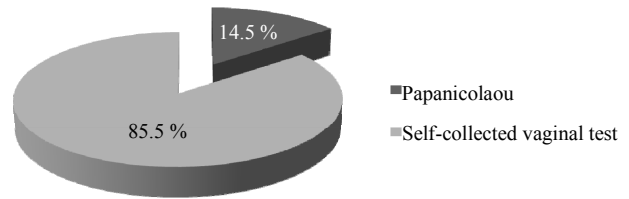
Figure 2. Acceptability of self-collected vaginal test in women who live in marginalized areas of the Huasteca Potosina region.

considering HPV detection as a surrogate marker of abnormal cytology. A study in the USA showed that the timing of self-sampling does not affect HPV detection (intercourse menstrual cycle or pre-shot), plus the number of days since the last sampling does not affect reproducibility of viral detection, which enables the test be repeated at short intervals (days or weeks), important for the practical aspects of screening programs for the possibility of loss, as they cannot be processed or have be repeated rapidly [17].

The acceptability of self-making depends largely on cultural factors. The results of this research in women living in marginalized regions of the Huasteca region indicate that the perception of comfort is related to the acceptability of the test and that the reasons are related to the preferred screening method, so that you can evidence that the comfort of the test is what leads to their acceptance as well. Women do not feel embarrassed and feel more confident in the result. A study by Torres-Poveda in 2008 mentions that in programs for indigenous people whose cultural barriers can be an obstacle to the acceptance of common gynecological, procedures and access of women to them obtaining samples for their own features suitable for use in the HPV DNA test can be a satisfying and culturally acceptable procedure [18]. Heideman in 2012 mentioned that the women report preferring self-takes to the sample by a professional. The reasons women gave are very similar to those presented in this study as follows: the point of sampling, privacy and the simplification of the technique compared to the Pap that causes pain and shame [19]. Given this preference is not surprising that the supply of self-taken for HPV DNA detection attracts up to 30% of women not participating or unwilling to make use of regular screening program [20]. This is encouraging to be implemented in our environment, thereby increasing the coverage and thus achieving the goal of reducing mortality rates in México.

Papers published in US and European populations indicate that acceptance of self-making is almost universal and this technique is preferred to annual review specula. The authors emphatically mention that it is important to perform studies to determine the acceptability of self-take between the target populations before embarking on larger projects [21]. In the cluster randomized controlled trial done in rural India by Sankaranarayanan, found that

Table 2. Reason of preference and perception of comfort with self-taken vaginal and Pap.

	Technique				Overall	
	Self-colleted		Pap test			
Criterion	Frequency	%	Frequency	%	Frequency	%
Preferably reason						
Another	118	92.9	9	7.1	127	100.0
Feel more confident	75	50.7	73	49.3	148	100.0
Se siente más cómoda	324	99.4	2	0.6	326	100.0
Felt ashamed	2	40.0	3	60.0	5	100.0
Not answered	1	50.0	1	50.0	2	100.0
Overall	520	85.5	88	14.5	608	100.0
Comfort perception						
Nothing comfortable	0	0.0	1	100.0	1	100.0
Shortly comfortable	29	46.0	34	54.0	63	100.0
Comfortable	298	89.8	34	10.2	332	100.0
Very comfortable	193	91.0	19	9.0	212	100.0
Overall	520	85.5	88	14.5	608	100.0

a single round of screening with HPV testing substantially reduced the risk of death from cervical cancer in a follow-up of eight years compared to women who were not offered the test, indicating that the former were half as likely to develop or die from this disease [22]. Women with DNA positive for high risk HPV in samples obtained by self-making, currently were advised to do the Pap with a significant risk of loss to follow-up. In the future, this step can probably be avoided by direct application of molecular markers. It is therefore considered that the time has come to introduce self-sampling as an alternative screening by testing for viral DNA [17].

These results are important for the management of public services. The health programs should have special characteristics according to the population it is intended. In this particular case of indigenous communities, health personnel should be trained on the new technologies for cervical cancer screening in order to offer to clients and a safe and reliable screening, guidance on the importance of self-care, because the poorer women are those that generally require treatment for advanced forms of CC, due to the fact that they are those who have had limited access to early detection services likely cultural reasons. This situation of inequality in health in sexual and reproductive health of the indigenous population is sociologically determined and in different cultural contexts is difficult to interpret the epidemiological risk for developing cervical cancer. Increase coverage has been a concern of all countries that implement a public health program for early detection of cervical cancer, even in developed countries. For those who have not achieved 100% coverage, for example in the Netherlands, the program has been since the 70s, and has a participation rate of 67% and together with opportunistic smears and diagnostic coverage of 75% [9], therefore, implement self-making is an opportunity for decision makers, mainly in countries where the magnitude of this problem is still very large.

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