BRIEF REPORT

# CONCORDANCE BETWEEN SELF-SAMPLING AND STANDAR ENDOCERVICAL SAMPLE COLLECTION TO IDENTIFY SEXUAL TRANSMISSION INFECTIONS IN AN URBAN-RURAL AREA OF PERU

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## ABSTRACT

With the objective of evaluating the concordance between the self-sampling of vaginal samples and the standard collection of endocervical samples for the identification of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Candida spp*. carried out by health personnel in women from an urban-rural area of Peru, a prospective and cross-sectional study was carried out in 206 women of childbearing age, we identified some sexually transmitted infections such as *Chlamydia trachomatis* or *Trichomonas vaginalis* in 9/206 (4.4%). We obtained a high degree of agreement in the identification of *Candida* spp. (k = 0.97), *Chlamydia trachomatis* (k=0.92) and *Trichomonas vaginalis* by microscopy (k=1.00), and a considerable agreement for the identification of *Trichomonas vaginalis* by culture (k=0.66). The self-sampling technique can be used to identify some sexually transmitted infections in urban-rural populations.

**Keywords:** Sexually Transmitted Diseases; Specimen Handling; Diagnosis (Source: MeSH NLM).

## INTRODUCTION

Curable sexually transmitted infections (STIs) caused by *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV), have reached 376 million new cases by 2016 worldwide [(1)]. These STIs increase the risk of acquiring human immunodeficiency virus (HIV) [(2)]. However, they lack etiologic diagnosis for reporting, thus reports are limited to at-risk populations. Curable STIs are treated as a syndrome based on signs and symptoms, which is cost-effective because it can start at the patients first visit. However, syndromic management may be unnecessary in 91-95% of women because of the lack of etiologic identification [(3,4)]. Furthermore, considering that *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections may be asymptomatic in a higher proportion of women, under syndromic management, women may not have access to any evaluation to reduce negative outcomes such as pelvic inflammatory disease, ectopic pregnancy, miscarriage or infertility [(1)].

According to the Demographic and Family Health Survey (ENDES) 2018; in Peru, women of childbearing age with reportable STIs (HIV and syphilis), represent 1.1% of the urban

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population and 0.6% of the rural population [5]. These data do not include curable STIs, even though the World Health Organization (WHO) has recommended their etiological identification. It is well known that laboratory diagnosis is limited in urban-rural populations in low- and middle-income countries. One strategy for mass screening for these infections is the use of auto collection (AC) of samples for laboratory diagnosis, which has been used in health care centers [6], clinics [7], at home [8] or in medical campaign tents [9]. The self-sampling technique for STI identification is acceptable and preferred compared to standard collection by health personnel, mainly in urban populations but also in rural populations [10,11].

Our study focuses on evaluating the concordance between the technique of self-sampling of vaginal samples and the standard collection of endocervical samples by health personnel for the identification of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Candida spp*. in an urban-rural population of Peru.

### KEY MESSAGES

**Motivation for the study:** The difficulty for etiological identification limits the syndromic treatment of curable sexually transmitted infections.

**Main findings:** There is a high degree of concordance in the identification by self-sampling of vaginal specimens of *Candida spp*, *Chlamydia trachomatis* and *Trichomonas vaginalis* diagnosed by microscopy, and considerable concordance for the identification of Trichomonas vaginalis by culture.

**Implications:** Vaginal self-sampling could be used for the identification of some sexually transmitted infections in urban-rural population and a wider scope of screening.

## THE STUDY

Between September and November 2014, we made a prospective cross-sectional study on women between 18-50 years of age from an urban-rural population in the province of Morropón in Piura, northern Peru. The population was invited to participate in the study through: a) preventive-promotional talks in health center waiting rooms, b) information during regular visits to sexual and reproductive health (SRH) services, c) local radio or megaphones, d) home visits, e) information flyers, and f) health campaigns. The participants came from the SRH services of three first level health facilities, two of category I-1, "Franco" and "La Huaquilla", and one of category I-4 "Morropón".

Inclusion criteria for the study included being a sexually active woman over 18 years of age; while exclusion criteria included the report of vaginal bleeding at the time of participation, treatment for vaginal infections in the last 15 days and/or sexual intercourse in the last 24 hours.

All participants understood and accepted their participation in the study by signing the informed consent form. Then, an approximately 10-minute questionnaire was administered to assess the sociodemographic, health and sexual behavior characteristics of the participants.

To evaluate the presence of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Candida spp*. two sample collection techniques were used for each participant: 1) Self-sampling of vaginal samples at the SRH services or at the participants home, where an infographic indicated that the swabs should be introduced into the vaginal canal and rotated for 15 seconds, and then placed in aluminum foil; 2) Standard collection of endocervical samples by an obstetric professional with experience in this procedure, in the SRH services (pelvic examination on a gynecological couch with the use of a speculum) or at the participant's home (pelvic examination on a bed with the use of a disposable speculum).

For each collection technique, three swabs were obtained: a) one swab was collected and immediately placed in Aptima Combo2 CT/NG transport medium (Gen Probe Incorporated, San Diego, California, USA) and kept at room temperature until processing, b) two swabs were placed inside aluminum foil and transported at room temperature until processing (maximum 15 minutes for samples collected at the same health center or 2 hours for samples collected at other health centers or at the participant's home).

The study procedures were performed at the diagnostic laboratory of the Morropón Health Center and only the molecular tests were analyzed at the Sexual Health Laboratory of the Interdisciplinary Research Center on Sexuality, AIDS and Society of the Universidad Peruana Cayetano Heredia. The three swabs collected by each collection technique were used for the following procedures: a) molecular test for nucleic acid amplification (NAAT) of *C. trachomatis* and *N. gonorrhoeae* using the Aptima Combo2 CT/NG test (Gen Probe Incorporated, San Diego, California, USA); b) direct examination for microscopic search of *T. vaginalis* and yeasts suggestive of *Candida spp*; c) simultaneous culture of *T. vaginalis* and *Candida spp*. (Trichomonas Medium Oxoid,


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CM0161, Thermo Scientific™), with incubation at 37 °C and reading between days 1, 3 and 5 post-inoculation in the culture medium for the microscopic search of trichomonas or yeasts. The results of the tests performed were delivered to the SRH services of the Morropón Health Center, where, independently of the study, the patients received counseling and treatment when required.

We used absolute and relative frequencies of the study variables to describe the population. The variable age was categorized into young (18-29 years) and adult (30-59 years). The variables marital status, educational level and occupation were collapsed for better interpretation. Finally, we evaluated the concordance between sample collection techniques with Cohen's kappa coefficient considering a 95% confidence interval. Statistical analyses were performed using Stata 12.0 (StataCorp, College Station, TX).

The study was approved by the Ethics Committee of the Faculty of Human Medicine of the Universidad Nacional Mayor de San Marcos (Resolution code N°0174).

## FINDINGS

A total of 209 women were included, of whom 206 completed the survey and both sample collection techniques. The participants' ages ranged from 18 to 49 years (mean: 34.6; standard deviation: 7.8), the sociodemographic characteristics are shown in Table 1. Of the 206 participants, 95.2% reported having had a steady partner in the last year and 92.6% did not use a condom or only sometimes during sexual intercourse. 90.3% had some genital symptom at the time of participation; including vaginal discharge (74.2%), lower abdominal pain (72.6%), itching (47.9%), painful urination (37.1%), foul odor (19.9%) or dyspareunia (19.4%). Of the participants, 59.9% preferred self-sampling over standard sample collection, while 5.9% had no difference in preference for either technique.

We were able to identify the presence of an STI in 4.4% (9/206) of the participants (Table 1). In addition, yeasts were identified in the direct examination of 17.5% (36/206) of the participants and *Candida spp*. in 22.8% (47/206). We identified the presence of *C. trachomatis* in 3.4% (7/206), no cases of *N. gonorrhoeae* were found, *T. vaginalis* was found in 0.5% (1/206) of the women by direct examination and 1.0% (2/206) by culture (Table 2).

Between both specimen collection techniques, standard sample collection identified three more cases of yeasts by microscopy (36/206 versus 33/206; p=0.703) and one more case of *C. trachomatis* by NAAT (7/206 versus 6/206; p=0.771)

**Table 1.** Sociodemographic, health and sexual behavior characteristics of women in an urban-rural population in Peru.

| Characteristics | n (%) |
|---|---|
| Age (years) | |
| 18-29 | 56 (27.2) |
| 30-60 | 150 (72.8) |
| Marital status | |
| Married/cohabitating | 196 (95.2) |
| Single/divorced/separated/widowed | 10 (4.8) |
| Education level | |
| Primary school | 106 (51.4) |
| Secondary school | 83 (40.3) |
| Higher education | 17 (8.3) |
| Employment | |
| Housewife | 167 (81.1) |
| Other | 39 (18.9) |
| Number of sexual partners in the last year | |
| 0 | 2 (0.97) |
| 1 | 186 (90.3) |
| >1 | 18 (8.7) |
| Condom use during sexual intercourse * | |
| Always | 15 (7,4) |
| Sometimes | 86 (42.8) |
| No | 100 (49.8) |
| Use of alcohol during sexual intercourse | |
| Always | 0 (0) |
| Sometimes | 45 (21.8) |
| No | 161 (78.2) |
| Use of drugs during sexual intercourse * | |
| Always | 0 (0) |
| Sometimes | 0 (0) |
| No | 205 (100) |
| Parity [a] | |
| Nulliparous | 6 (2.9) |
| One child | 29 (14.1) |
| Two or more children | 171 (83) |
| Previous abortion | |
| Yes | 75 (36.4) |
| No | 131 (63.6) |
| Any genital symptoms [b] | |
| Yes | 186 (90.3) |
| No | 20 (1.0) |
| Previous pelvic examination | |
| Yes | 195 (94.7) |
| No | 11 (5.3) |
| Self-sampling as a preferred method for the diagnosis of STIs * | |
| Yes | 121 (59.9) |
| No | 69 (34.2) |
| Equal preference with standard collection | 12 (5.9) |
| Any STI [c] | |
| Yes | 9 (4.4) |
| No | 197 (95.6) |

* Due to missing data, some variables do not add up to the total.
[a] Parity: Number of births at the time of participation.
[b] Current genital symptom: vaginal discharge, lower abdominal pain, itching, painful urination, foul odor, or dyspareunia.
[c] Consider any positive results for Chlamydia trachomatis, Neisseria gonorrhoeae and/or Trichomonas vaginalis.
STI: sexually transmitted infection.

than self-sampling. While self-sampling identified one more case of *T. vaginalis* (2/206 versus 1/206; p=0.558) per culture than standard sample collection. However, these differences were not significant.

The concordance between both collection techniques for the identification of yeasts by microscopy, *Candida spp*. by culture, *T. vaginalis* by microscopy and *C. trachomatis* by NAAT showed almost perfect match (k=0.92); while *T. vaginalis* by culture had considerable concordance (k=0.66) (Table 3).

## DISCUSSION

Self-sampling of vaginal samples and standard collection of endocervical samples collected by health personnel in an urban-rural population had a high concordance for the identification of *Chlamydia trachomatis*, *Trichomonas vaginalis* and *Candida spp*.

Self-sampling for the diagnosis of vaginal infections and STIs facilitates screening [9,12], reduces underreporting of cases and contributes in breaking the chain of transmission of STIs [13,14]. The preference for self-sampling has been evaluated mainly in urban populations; in health centers [6], clinics [7], homes [8] and in mobile screening programs [9]; being remarkably easy and comfortable [6,7]. These findings have been observed in the general population [7-11] and in populations at risk of acquiring an STI [15,16]. In rural populations, the preference for self-sampling has been evaluated, emphasizing privacy and comfort, for the diagnosis of *T. vaginalis* (76%) and *C. trachomatis* (98.3%); in contrast to what we found (60.3%) [10,11].

A curable STI (*C. trachomatis* or *T. vaginalis*) was found in 4.4% of the participants. The prevalence of *C. trachomatis* infection in our study (3.4%) was similar to that of Rocha *et al.* (3.7%; p=0.313) [11] but lower than that found in 18 rural districts of Peru (6.8%; p=0.070); as well as *N. gonorrhoeae* in 1.2% (p=0.114) of their participants compared to the absence of cases in our study [17]. *C. trachomatis* and *N. gonorrhoeae* cause mainly asymptomatic infections in women, suggesting that our mostly symptomatic study population may have underreporting of these STIs.

**Table 2.** Results of laboratory tests for *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis* and *Candida* spp. by specimen collection technique in women from an urban-rural population in Peru.

| Microorganism and laboratory test | Self-sampling [a] n (%) | Standard collection [b] n (%) |
|---|---|---|
| Yeasts by microscopy | | |
| Positive | 33 (16) | 36 (17.5) |
| Negative | 173 (84) | 170 (82.5) |
| *Candida spp*. by culture | | |
| Positive | 47 (22.8) | 47 (22.8) |
| Negative | 159 (77.2) | 159 (77.2) |
| *Trichomonas vaginalis* by microscopy | | |
| Positive | 1 (0.5) | 1 (0.5) |
| Negative | 205 (99.5) | 205 (99.5) |
| *Trichomonas vaginalis* by culture | | |
| Positive | 2 (1.0) | 1 (0.5) |
| Negative | 204 (99.0) | 205 (99.5) |
| *Chlamydia trachomatis* by NAAT | | |
| Positive | 6 (2.9) | 7 (3.4) |
| Negative | 200 (97.1) | 199 (96.6) |
| *Neisseria gonorrhoeae* by NAAT | | |
| Positive | 0 (0.0) | 0 (0.0) |
| Negative | 206 (100) | 206 (100) |

[a] Self-sampling: Vaginal specimen collection technique carried out by the participant herself.
[b] Standard collection: Endocervical specimen collection technique carried out by a professional obstetrician.
NAAT: Nucleic acid amplification technique.


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**Table 3.** Concordance between the self-sampling technique and standard sample collection for the diagnosis of curable STIs and vaginal infections in women in an urban-rural population in Peru.

| Vaginal self-sampling | Standard collection by health personnel | | Concordance (%) | Kappa (95% CI) |
|---|---|---|---|---|
| | Positive | Negative | | |
| Yeasts by microscopy | | | | |
| Positive | 33 | 0 | 98.6 | 0.95 (0.89-1.00) |
| Negative | 3 | 170 | | |
| *Candida* spp. by culture | | | | |
| Positive | 46 | 1 | 99.0 | 0.97 (0.93-1.00) |
| Negative | 1 | 158 | | |
| *Trichomonas vaginalis* by microscopy | | | | |
| Positive | 1 | 0 | 99.0 | 1.00 (1.00-1.00) |
| Negative | 0 | 205 | | |
| Trichomonas vaginalis by culture | | | | |
| Positive | 1 | 1 | 98.6 | 0.66 (0.05-1.00) |
| Negative | 0 | 204 | | |
| *Chlamydia trachomatis* by NAAT | | | | |
| Positive | 6 | 0 | 93.9 | 0.92 (0.77-1.00) |
| Negative | 1 | 199 | | |
| *Neisseria gonorrhoeae* by NAAT | | | | |
| Positive | 0 | 0 | -- | -- |
| Negative | 0 | 206 | | |

When comparing with other studies in urban-rural populations, the identification of *T. vaginalis* (0.9%) was not significantly different from that found by Khan *et al.* in India (0.5%, p=0.441) [18]; but it was significantly different from those found in Brazil (5.6%, p=0.007) [10] and Peru (15.3%, p<0.001) [17]. This difference may be due to the method used; molecular tests identified more cases than culture, which has a higher risk of contamination between sample collection and the procedure itself. As for the presence of yeasts by direct examination (17.5%) or *Candida spp*. by culture (22.8%); it was similar to the 26.2% found by Khan *et al* [18].

The concordance between the self-sampling technique and the standard collection was high; similar results were found by Khan *et al*. for the diagnosis by culture of both *Candida spp*. (k=0.99) and *T. vaginalis* (k=1.00) (18), Lockhart *et al*. with NAAT for C. *trachomatis* (k=0.77), *N. gonorrhoeae* (k=0.85) and *T. vaginalis* (k=0.85) [15]; and Arias *et al.* when diagnoses were made in therapeutic abortion clinics and indigent youth with NAAT for *C. trachomatis* (k=0.64) and *N. gonorrhoeae* (k=0.56) [7].

The limitations of the study include the non-probabilistic type of sampling, which could generate selection bias, and the difficulty of accessing potential participants due to the stigma that usually surrounds STIs. Regarding the procedures, the culture medium used for *T. vaginalis* did not allow its development in the presence of *Candida spp*. and variability in the standard sample collection could also occur despite previous training and specific recommendations.

In conclusion, we found adequate concordance between vaginal self-sampling and sampling by a health professional. These results can be used in the evaluation of strategies to bring the diagnosis of some STIs closer to populations with less access to healthcare personnel, such as urban-rural populations, which would allow the massification of STI screening.

**Author contributions:** TMG, SRL and CG participated in the conception, design of the study and interpretation of data for the writing of the article. TMG and MH participated in data collection and field work. JAF participated in the analysis and interpretation of the data, in advising on the execution of the study, as well as in the critical revision of the article. DGP participated in advising on the execution of the study and critical review of the article.

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