BRIEF REPORT

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

Tatiana Marlene Galvez1,a, Juan A. Flores1,2,b, Danny Giancarlo Pérez1,c, César Gutiérrez4,d, Marleny Huertas5,e, Segundo León-Sandoval1,3,f

1 Escuela Profesional de Tecnología Médica, Universidad Privada San Juan Bautista, Lima, Perú.
2 Dirección de Investigación, Universidad Privada San Juan Bautista, Lima, Perú.
3 Facultad de Medicina, Universidad Nacional Mayor de San Marcos, Lima, Perú.
4 Centro de Salud Morropón, Morropón, Piura, Perú.
5 Universidad Peruana Cayetano Heredia, Lima, Perú.

a Medical Technologist, Master in Tropical Medicine and Public Health; b Medical Technologist, Master in Biochemistry and Molecular Biology; c Medical Technologist; d Physician, Master in Epidemiology; e Bachelor in Obstetrics; f Medical Technologist, Master in Infectious and Tropical Diseases

* The study is part of the thesis: Galvez, Tatiana M. Comparación entre la auto-colección de muestras y la toma de muestras por un personal de salud para el diagnóstico de laboratorio de infección por Chlamydia trachomatis, Neisseria gonorrhoeae y Trichomonas vaginalis en mujeres de una población urbano-rural, Morropón, 2014. [Bachelor’s Thesis]. Lima: Facultad de Medicina, E.A.P, Tecnología Médica, Universidad Nacional Mayor de San Marcos; 2015.

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...
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.

**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, https://doi.org/10.17843/rpmesp.2021.381.6571
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)
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 (13,14). 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.
When comparing with other studies in urban-rural populations, the identification of \textit{T. vaginalis} (0.9\%) was not significantly different from that found by Khan \textit{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 \textit{Candida spp.} by culture (22.8\%); it was similar to the 26.2\% found by Khan \textit{et al.}\(^{(18)}\).

The concordance between the self-sampling technique and the standard collection was high; similar results were found by Khan \textit{et al.} for the diagnosis by culture of both \textit{Candida spp.} (k=0.99) and \textit{T. vaginalis} (k=1.00)\(^{(18)}\), Lockhart \textit{et al.} with NAAT for \textit{C. trachomatis} (k=0.77), \textit{N. gonorrhoeae} (k=0.85) and \textit{T. vaginalis} (k=0.85)\(^{(15)}\); and Arias \textit{et al.} when diagnoses were made in therapeutic abortion clinics and indigent youth with NAAT for \textit{C. trachomatis} (k=0.64) and \textit{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 \textit{T. vaginalis} did not allow its development in the presence of \textit{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.

**Funding:** Self-funded.

**Conflicts of interest:** The authors declare that they have no conflicts of interest.

---

**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   | 33            | 0        | 98.6            | 0.95 (0.89-1.00) |
|                       | 3             | 170      |                 |                |
| \textit{Candida spp.} by culture | 46          | 1        | 99.0            | 0.97 (0.93-1.00) |
|                       | 1             | 158      |                 |                |
| \textit{Trichomonas vaginalis} by microscopy | 1           | 0        | 99.0            | 1.00 (1.00-1.00) |
|                       | 0             | 205      |                 |                |
| \textit{Trichomonas vaginalis} by culture | 1           | 1        | 98.6            | 0.66 (0.05-1.00) |
|                       | 0             | 204      |                 |                |
| \textit{Chlamydia trachomatis} by NAAT | 6            | 0        | 93.9            | 0.92 (0.77-1.00) |
|                       | 1             | 199      |                 |                |
| \textit{Neisseria gonorrhoeae} by NAAT | 0            | 0        | --              | --              |
|                       | 0             | 206      |                 |                |
REFERENCES

1. World Health Organization Department of Reproductive Health and Research. Report on global sexually transmitted infection surveillance, 2018 [Internet]. Geneva: World Health Organization;2018 [cited on September 15, 2020]. Available at: https://apps.who.int/iris/bitstream/handle/10665/277258/9798241565691-eng.pdf?ua=1.

2. Ward H, Rönn M. The contribution of STIs to the sexual transmission of HIV. Curr Opin HIV AIDS. 2016;5(4):305–10. doi:10.1097/COH.0b013e32833a8844.

3. Barry MS, Diallo A, Diadihou M, Mall I, Gassama O, Ndiaye Guèye MD, et al. Accuracy of syndromic management in targeting vaginal and cervical infections among symptomatic women of reproductive age attending primary care clinics in Dakar, Senegal. Trop Med Int Heal. 2018;23(5):541–8. doi:10.1111/tmi.13046.

4. Sonkar S, Wasnik K, Kumar A, Mittal P, Saluja D. Comparative analysis of syndromic and PCR-based diagnostic assay reveals misdiagnosis/overtreatment for trichomoniasis based on subjective judgment in symptomatic patients. Infect Dis Poverty. 2016;5(2):1-10. doi:10.1186/s40249-016-0133-x.

5. Instituto Nacional de Estadística e Informática. Encuesta Demográfica y de Salud Familiar (Endes) 2018 [Internet]. Lima: INEI; 2019 [cited on September 15, 2020]. Available at: https://www.inei.gob.pe/media/MenuRecursivo/publicaciones_digitales/Est/Lib1656/index1.html.

6. Huneeus A, Fernández MI, Schilling A, Parra P, Zakharova A. Adolescentes encuentran fácil tomar sus propias muestras para estudio de infecciones de transmisión sexual. Rev Chil Infectol. 2017;34(2):116–9. doi:10.4067/S0716-10182017000200003.

7. Arias M, Jang D, Gilchrist J, Luinstra K, Li J, Smieja M, et al. Ease, Comfort, and Performance of the HerSwab Vaginal Self-Sampling Device for the Detection of Chlamydia trachomatis and Neisseria gonorrhoeae. Sex Transm Dis. 2016;43(2):125–9. doi:10.1097/OLQ.0000000000000406.

8. Van-Rooijen MS, Koekenhier RH, Hendriks A, De-Vries HJ, Van Leeuwen P, Van Veen MG. Young Low-Risk Heterosexual Clients Prefer a Chlamydia Home Collection Test to a Sexually Transmitted Infection Clinic Visit in Amsterdam, the Netherlands, A Cross-Sectional Study. Sex Transm Dis. 2016;43(11):710–6. doi:10.1097/OLQ.0000000000000517.

9. Pittman E, Purcell H, Dize L, Gaydos C, Patterson-Rose S, Biro F, et al. Acceptability and Feasibility of Self-Sampling for Sexually Transmitted Infection Screening in Cabana Privacy Shelters HHS Public Access. Int J STD AIDS. 2018;29(5):461–5. doi:10.1177/0956462417733352.

10. Rocha DA, Azvedo MJ, Batista SJ, Beltrão ÉS, Moraes CO, Araújo AF, et al. T. vaginalis in riverside women in Amazonia, Brazil: An experience using the EVALYN BRUSH vaginal self-collection device. J Infect Dev Ctries. 2019;13(11):1029–37. doi: 10.3855/jidc.11385.

11. Rocha DA, Moraes C, Araújo AF, Beltrão É, Castelo L, Menezes L, et al. Chlamydia trachomatis infection in women living in remote areas in Amazonas, Brazil—a self-collection screening experience. Int J STD AIDS. 2018; 30(4):336–43. doi:10.1177/0956462418809297.

12. Hesse EA, Widdice LE, Patterson-Rose SA, Cyr S, Dize L, Gaydos CA. Feasibility and acceptability of point-of-care testing for sexually transmissible infections among men and women in mobile van settings. Sex Heal. 2015;12(1):71-73. doi:10.1071/SH14132.

13. World Health Organization. Global Health Sector Strategy on STI 2016-2021 [Internet]. Geneva, Switzerland: WHO Document production services;2016 [cited on September 15, 2019]. Available at: https://apps.who.int/iris/bitstream/handle/10665/246296/WHO-RHR-16-09-eng.pdf?sequence=1.

14. Oqale Y, Yeh PT, Kennedy CE, Toskin I, Narasimhan M. Self-collection of samples as an additional approach to deliver testing services for sexually transmitted infections: A systematic review and meta-Analysis. BMJ Glob Heal. 2019;4(2):1-16. doi:10.1136/bmjgh-2018-001349.

15. Lockhart A, Psioda M, Ting J, Campbell S, Mugo N, Kwatompora J, et al. Prospective Evaluation of Cervicovaginal Self- and Cervical Physician Collection for the Detection of Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, and Mycoplasma genitalium Infections. Sex Transm Dis. 2018;45(7):488-93. doi:10.1097/OLQ.0000000000000778.

16. Bustamante MJ, Konda KA, Davey DJ, León SR, Calvo GM, Salvaterra J, et al. HIV self-testing in Peru: questionable availability, high acceptability but potential low linkage to care among men who have sex with men and transgender women. Int J STD AIDS. 2017;28(2):133-137. doi:10.1177/0956462416630674.

17. García PJ, Chavez S, Feringa B, Chiappe M, Li W, Jansen KU, et al. Reproductive tract infections among symptomatic women of reproductive age attending primary care clinics in Dakar, Senegal. Trop Med Int Heal. 2015;20(8):927-33. doi:10.1111/tmi.12845.

18. Khan Z, Bhargava A, Mittal P, Bharti R, Puri P, Khunger N, et al. HIV self-testing in Peru: questionable availability, high acceptability but potential low linkage to care among men who have sex with men and transgender women. Int J STD AIDS. 2017;28(2):133-137. doi:10.1177/0956462416630674.

19. Lockhart A, Psioda M, Ting J, Campbell S, Mugo N, Kwatompora J, et al. Prospective Evaluation of Cervicovaginal Self- and Cervical Physician Collection for the Detection of Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, and Mycoplasma genitalium Infections. Sex Transm Dis. 2018;45(7):488-93. doi:10.1097/OLQ.0000000000000778.

20. Bustamante MJ, Konda KA, Davey DJ, León SR, Calvo GM, Salvaterra J, et al. HIV self-testing in Peru: questionable availability, high acceptability but potential low linkage to care among men who have sex with men and transgender women. Int J STD AIDS. 2017;28(2):133-137. doi:10.1177/0956462416630674.

21. Garcia PJ, Chavez S, Feringa B, Chiappe M, Li W, Jansen KU, et al. Reproductive tract infections among symptomatic women of reproductive age attending primary care clinics in Dakar, Senegal. Trop Med Int Heal. 2015;20(8):927-33. doi:10.1111/tmi.12845.