Self-Obtained Vaginal Swabs for the Detection of STIs

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Abstract

Background: The incidence of sexually transmitted infections (STIs) continues to rise and is a significant public health concern. Gonorrhea and chlamydia are two of the most common but the traditional detection method of a physician-obtained endocervical swab during a speculum exam has become a barrier to diagnosis and treatment.

Methods: In order to explore alternative methods, a literature review was performed using the PICO and PubMed databases with terms such as "self", "chlamydia", "gonorrhea", and "vaginal". A 2015 meta-analysis was identified which included 21 studies but only four studies evaluating chlamydia (N=994) and one study evaluating gonorrhea (N=309) were selected because they compared the use of self-collected vaginal swabs (SOVS) versus the gold standard of clinician-collected cervical specimens. The average age of participants ranged from 21-32.

Results: The chlamydia cross-sectional observational studies (prevalence 6.8-12.6%) resulted in a pooled sensitivity of 0.89 (95% CI, 0.82-0.94) and specificity of 0.98 (95% CI, 0.97-0.99). For gonorrhea, the cross-sectional observational study comparing SOVS versus clinician-collected cervical swabs (prevalence 14.2%) showed a sensitivity of 0.98 (95% CI, 0.88-1.00) and specificity of 0.97 (95% CI 0.94-0.99).

Conclusions: After determining the sensitivity and specificity of SOVS are equivalent to clinician-obtained cervical specimens, the CDC has concluded that they are adequate for the detection of chlamydia and gonorrhea. In fact, vaginal swabs are now the CDC's preferred collection method even when compared against all other current methods. All of these studies were performed in the clinic so additional research is needed to determine how to utilize this method in other community-based settings.

Key Question

Are self-obtained vaginal swabs (SOVS) as effective for screening for vaginal STIs as swabs collected during a speculum exam?

Objective

The incidence of sexually transmitted infections (STIs) continues to increased despite screening guidelines and public education campaigns.

Chlamydia and gonorrhea can both cause pelvic inflammatory disorder and therefore are a significant public health concern.

The gold standard of diagnosis for both of these infections has been a clinician-obtained endocervical swab which requires a speculum exam.

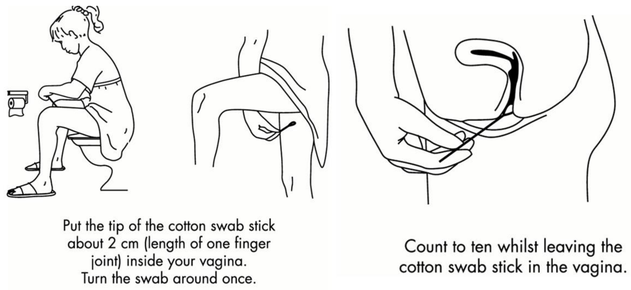
This method of detection is a potential barrier to proper diagnosis and treatment especially for women in remote or international settings with reduced access to a clinic and those with transportation limitations. It also involves an office copay in addition to the lab test which can be a significant burden for women without insurance. Lastly, many women (especially adolescents) are fearful and want to avoid a pelvic exam.

This study seeks to explore a different detection method that could eliminate or reduce some of these barriers.

Methods

A literature review was performed utilizing the PICO and PubMed databases and using combinations of the search terms: *self, Chlamydia, gonorrhea, testing, self, self-obtained,* and *vaginal.* A 2015 meta-analysis was identified which compared cervical specimen to various self-obtained specimens and included 21 composite studies Twenty of the studies evaluated chlamydia and seven studies evaluated gonorrhea with six trials evaluating both in the same study. Studies were excluded that did not involve vaginal specimens as well as those that did not utilize swabs but instead used tampons or other methods to sample the vagina. This resulted in the inclusion of four cross-sectional chlamydia studies and one cross-sectional gonorrhea study.

All of the studies were performed in the clinic setting in various countries including the United States, Lithuania, and the United Kingdom. Some women were symptomatic at the time of testing but others were in the clinic for other reasons and agreed to participate in the study even though asymptomatic. The age of participants varied from 14-56 years. Some of the studies provided the women with specific instructions in order to standardize the collection process. A separate study included a diagram in the instructions which has been included to the right. At least some of the studies randomized the order in which the two types of collection methods were attempted. After the specimens were collected, both the SOVS and the encocervical samples were analyzed using polymerase chain reaction (PCR) although they did not all use the same assay brand.



Results

Chlamydia: The prevalence ranged from 6.8-12.6%. The pooled sensitivity was 0.89 (95% confidence interval, 0.82-0.94). The pooled specificity was 0.98 (95% confidence interval, 0.97-0.99).

Gonorrhea: The prevalence was 14.2%. The sensitivity was 0.98 (95% confidence interval 0.88-1.00). The specificity was 0.97 (95% confidence interval 0.94-0.99)

Table 1: Chlamydia Results

Published Study	No. of Participants	Sensitivity	Specificity
Berwald 2009	162	0.91	0.99
Domeika 1999	283	0.80	0.98
Hook 1997	309	0.91	0.98
Skidmore 2008	240	1.00	1.00

Table 2: Gonorrhea Results

Published Study	No. of Participants	Sensitivity	Specificity
Hook 2007	309	0.98	0.97

Conclusions

Self-obtained vaginal swabs (SOVS) have been found to be equivalent to clinician-collected cervical specimens in the diagnosis of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhea* (GC) (SOR: **A**, based on a meta-analysis).

Discussion

The Centers for Disease Control and Prevention (CDC) performed their own database review and has concluded that the sensitivity and specificity of SOVS is equivalent to endocervical specimens and has even stated that they are the preferred method of collection even above urine and cervical specimens.

Some health systems have now implemented the use of SOVS. There are still questions, however, regarding the best utilization of this collection within the clinic-setting but might include females who are resistant to a pelvic exam.

This same technology can be applied to home-based settings as a separate study showed that women are two times more likely to complete STI screening when a home option is offered. More studies are needed, however, to determine guidelines on how to handle and process these specimens obtained out of the clinic setting.

References

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Disclosures

None

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