Copan Self Vaginal FLOQSwabs®: Agreement between clinician and self-collected samples for HPV detection. Evidence from the scientific literature

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ABSTRACT

In the last years cervical cancer prevention is progressively shifting from cytology-based diagnostics (PAP test) to more efficient, cost-effective, and unbiased molecular based diagnostics (HPV DNA testing). In this context, vaginal self-sampling has risen as a promising approach to increase cervical cancer screening participation, especially for under screened women. Cervical cancer screening programs have been keen to implement self-sampling, but a necessary steppingstone to reach this goal is to establish that vaginal self-sampling is as accurate as clinician-collected samples for HPV detection, without affecting clinical sensitivity and specificity. Here we present evidence from independent published scientific literature on how vaginal self-collected samples with Copan Self Vaginal FLOQSwabs® provide accurate results compared to clinician-collected cervical samples, including performance comparison to other self-sampling devices.

ACCURACY OF SELF VS CLINICIAN-COLLECTED SAMPLES FOR HPV DETECTION

In a meta-analysis published in 2014, Arbyn and colleagues[1] assessed the clinical accuracy of HPV testing on self-samples to detect underlying high-grade CIN or cancer. In their analysis, researchers compared the accuracy of HPV testing in self-samples with HPV DNA and cytology testing on clinician-collected cervical samples (Fig. 1).

The metanalysis (data from 36 studies and more than 150 thousand women enrolled) demonstrated that PCR-based HPV tests generally showed similar sensitivity on both self-samples and clinician-based samples, suggesting HPV testing on vaginal self-sample as an additional strategy to reach women not participating in regular screening programs[1]. An updated meta-analysis including more recent studies, as well as studies performed with Copan Self Vaginal FLOQSwabs, confirmed these findings[2].

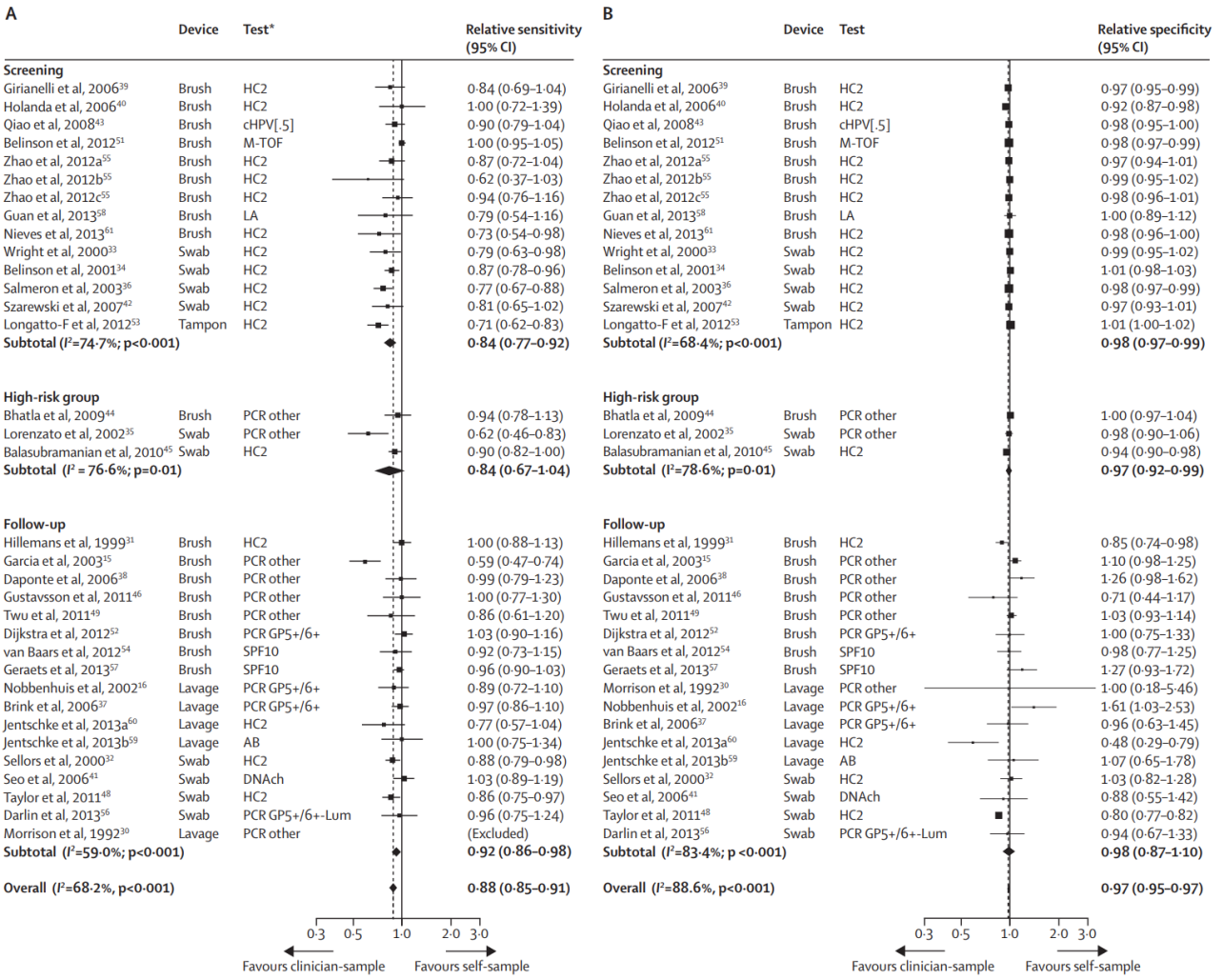

Figure 1: *Relative sensitivity (A) and specificity (B) of human papillomavirus on self-samples versus clinician-taken samples, by clinical setting, for outcome CIN2 or worse*

COPAN SELF VAGINAL FLOQSWABS® PERFORMANCE COMPARED TO CLINICIAN-COLLECTED SAMPLES

Saville and colleagues[3] evaluated the relative sensitivity for HPV detection of self-collected samples compared with practitioner-collected cervical specimens during the National Cervical Screening Program in Australia. 303 enrolled women (age ≥18 years) took a self-collected a vaginal sample using a Copan FLOQSwabs®, while the clinician-collected sample was taken during colposcopy visit. Both samples were tested in the laboratory on six PCR-based HPV assays:

- Roche cobas 4800 HPV test
- Roche cobas HPV test, on Roche cobas 6800 system
- Abbott HPV test
- BD Onclarity HPV test
- Cepheid Xpert HPV test
- Seegene Anyplex II HPV HR detection

Results from the study showed a high observed agreement for HPV16/18 between self- and practitioner-collected samples on all assays (range: 0.94-0.99), with good agreement for non-HPV16/18 oncogenic HPV types (range: 0.64-0.73).

In a study published in 2022 by Ilardo and collegues[4], authors analyzed the performance of self-collected samples versus clinician cervical samples for the detection of HPV genotypes on the Roche Cobas 8800 System. For the study, self-sampling was performed using the self-FLOQSwabs® (product code 5E089N), while the clinician-collected sample was taken by a cervical brush. One hundred and fifty-seven women (median age was 40 years, range 20-73 and IQR 31-49 years) were enrolled in the study. Polymerase chain reaction was used to detect the presence of HPV16, HPV18 and a pool of 12 other HPV types on the Roche Cobas 8800 System. The overall HPV prevalence on the population studied was 27%. The agreement between clinician cervical samples and self-collected vaginal presented good agreement (Kappa =0.90) and high sensitivity (0.91) and specificity (0.98). For swabs stored for 7 days at room temperature, the HPV results presented substantial agreement (Kappa =0.89) and high sensitivity (0.97) and specificity (0.96). The outcome of the study, as defined by researchers, is that the HPV assay performed in the self-collected vaginal samples have high consistency of results with the clinician cervical samples.

COPAN SELF VAGINAL FLOQSWABS® PERFORMANCE COMPARISON TO OTHER VAGINAL SELF-SAMPLING DEVICES

In 2021, Ertik and collegues[5] compared results obtained with a PCR-based high-risk HPV test from a dry vaginal self-collected samples collected with 3 different devices, including FLOQSwabs®, with those obtained from a cervical smear taken by a clinician during colposcopy. They showed that all invasive cancer cases and over 90% of the CIN 3 lesions were found to be hr-HPV positive with the self-collection devices, demonstrating comparable performance. Hr-HPV testing of dry vaginal self-samples showed a high sensitivity for CIN 3+ comparable to that of a clinician-taken smear.

The Predictor 5.1 study, published by Cadman and colleagues in 20216, compared high-risk HPV positivity rates and sensitivity of self-collected vaginal samples using four different collection devices and a urine sample. Samples were collected from 600 women prior colposcopic examination and analyzed on BD Onclarity assay. 71.7% of samples collected with Copan Self Vaginal FLOQSwabs® resulted HPV+. Sensitivity for CIN 2+ after adjusting for a Ct cut off of 38.3 was 92.9, while specificity for CIN 3+ was 94.1. This study showed that Copan Self Vaginal FLOQSwabs® gave the highest rate of HPV+ samples among dry collection devices[6].

CONCLUSIONS

Given the importance of ensuring the best testing accuracy in cervical cancer screening prevention programs, several studies have been performed to evaluate the agreement between both clinician and self-taken samples in detecting HPV DNA.

As described in this scientific literature overview, a high level of HPV detection agreement is achieved in self-collected and clinician collected specimens in women enrolled in the included studies. Vaginal samples collected with Copan Self Vaginal FLOQSwabs® demonstrated high degree of accuracy, comparable or superior to other vaginal self-sampling devices.

In conclusion, introducing vaginal self-collection in cervical cancer screening programs would facilitate participation for women with difficult access to healthcare because of geographical, financial, religious or cultural obstacles without compromising the accuracy of HPV infection detection. In addition, adopting Copan Self Vaginal FLOQSwabs® would ensure a high-quality performance, while being a convenient tool for both women and laboratory workflows.

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