FPIN's Clinical Inquiries

Screening for Cervical Intraepithelial Neoplasia with Patient-Collected HPV Samples

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Clinical Question

How useful are patient-collected human papillomavirus (HPV) vaginal swabs as a screening test for cervical intraepithelial neoplasia (CIN)?

Evidence-Based Answer

Self-collected vaginal swabs using polymerase chain reaction (PCR) for HPV are equal to clinician-collected cytology and HPV swabs for detection of CIN2 or greater (99% sensitive and 98% specific). Signal amplification testing is less sensitive (85%) for diagnosis of CIN2 or CIN3 by self-collection, although similarly specific (96% to 97%). (Strength of Recommendation [SOR]: A, based on a large meta-analysis of accuracy tests performed in Africa, China, India, and Nicaragua, and a large randomized controlled trial in the Netherlands.) Mailing self-collection kits to women produces twice the participation rate compared with clinic visits, is well-accepted, and is preferred by 59% of patients. (SOR: A, based on meta-analyses.)

Evidence Summary

A 2014 meta-analysis of 36 accuracy studies (N = 154,556 women) with a recent 2018 update of 20 additional studies (additional total N not reported) comparing self-collected HPV samples to clinician-collected samples (HPV and cytology) for the diagnosis of CIN2/3 found equal sensitivity with PCR testing.[1,2] The authors collected accuracy studies with a minimum of 400 women and evaluated the sensitivity of diagnosis of HPV infection and CIN, comparing point-of-care HPV DNA tests with self-collected cervical swabs against a diagnostic standard of clinician-collected HPV testing and cytology. The authors included studies with the following criteria: high-risk HPV testing performed on both self-collected and clinician-collected samples, or microscopic examination of the clinician-collected sample. Researchers verified the presence or absence of CIN2+ (or CIN3+) by colposcopy and biopsy in all enrolled women or in women with at least one positive initial test. Trials included patients in five African countries, regions of China and India, and Nicaragua. PCR testing was equally sensitive for the diagnosis of CIN2+ and CIN3+ by self-collected swabs compared with clinician-collected swabs (pooled ratio = 0.99; 95% CI, 0.97 to 1.02), and almost as specific (pooled ratio = 0.98; 95% CI, 0.97 to 0.99). Point-of-care signal amplification testing for high-risk HPV was less sensitive with self-collected swabs (pooled ratio = 0.85; 95% CI, 0.80 to 0.89) and less specific (pooled ratio for CIN2+ = 0.96; 95% CI, 0.93 to 0.98; pooled ratio for CIN3+ = 0.97; 95% CI, 0.95 to 0.99). The

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This series is coordinated by John E. Delzell Jr., MD, MSPH, associate medical editor.

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Author disclosure: No relevant financial affiliations.

authors rated the quality of most included studies as moderate to high, with 2% to 4% rated as "problematic."

A 2017 meta-analysis of accuracy studies contained one study (n = 946 women) that was not included in the above meta-analyses. That study found similar sensitivity and specificity for self-collected specimens that used a hybrid capture HPV assay for the detection of CIN2+ (sensitivity = 0.75; 95% CI, 0.48 to 0.93; specificity = 0.82; 95% CI, 0.79 to 0.84).[3]

A 2019 randomized noninferiority trial (n = 8,212 women) conducted in the Netherlands found no difference in accuracy between self-collected and clinician-collected samples for detection of CIN2+ or CIN3+ lesions.[4] Researchers randomized women 29 to 61 years of age to self-collection of HPV samples or collection by a clinician. Researchers retested all patients with positive results with the other collection method and cytology according to Dutch screening guidelines. Detection of HPV by self-sampling was noninferior to clinician sampling (relative risk [RR] = 1.04; 95% CI, 0.92 to 1.17) for the two primary end points: detection of CIN2+ (relative sensitivity = 0.96; 95% CI, 0.90 to 1.03; relative specificity = 1.00; 95% CI, 0.99 to 1.01) and detection of CIN3+ (relative sensitivity = 0.99; 95% CI, 0.91 to 1.08; relative specificity = 1.00; 95% CI, 0.99 to 1.01).

The same 2018 meta-analysis included 25 randomized controlled trials that found higher participation rates (greater than 75%) when women were mailed self-collection kits compared with requiring women to schedule clinic visits (RR = 2.33; 95% CI, 1.86 to 2.91).[2] Strategies that required women to request a self-collection kit produced results equal to those requiring clinic visits (RR = 1.22; 95% CI, 0.93 to 1.61).

A 2017 meta-analysis of seven studies (N = 1,470) evaluating the acceptability of self-collection vs. clinician collection of swabs found that most women rated self-collection acceptable (87%; 95% CI, 73% to 95%).[5] The studies defined acceptability as willingness to self-sample again in the future. There was large heterogeneity (I^2 = 98%). Twenty-three studies (N = 12,610) found that 59% (95% CI, 48% to 69%) of women preferred self-sampling to clinician sampling.

Recommendations from Others

A 2018 evidence-based review of global screening for cervical cancer states that self-collection HPV testing produces comparable diagnostic accuracy, is highly acceptable among women, and may help reduce nonattendance to cervical screening.[6]

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