

Evidence Base: Cervicography in the detection of CIN

Cervicography has been experimentally validated as a powerful co-test to primary cervical cancer screening with HPV testing, PAP and VIA to improve both the sensitivity and specificity of detecting CINII+ lesions.¹² It has not, however, enjoyed widespread adoption due to technical limitations to scaling including barriers to efficient expert image review, consistent image quality and appropriate mechanisms for feeding expert review results into the patient follow up and disease management workflow.

MobileODT's EVA System has brought digital cervicography into the 21st century by creating a seamless integration of high quality cervical images captured with an intuitive mobile phone based device into the overall clinical workflow to specifically address many of the limitations previously experienced with digital cervicography.

VIA: With the EVA System, quality assurance programs for VIA can be quickly and cost effectively implemented using digital cervicography as the modality of comprehensive oversight³ and continued training of the frontline workforce.⁴ The authors of a well-designed and executed study in South Africa even state that "Quality assurance [using cervicography] should form a cornerstone of any VIA program to improve sensitivity in detecting CIN 2+ lesions."⁵

PAP: A number of large studies validate that the sensitivity of PAP smear is improved by adding cervicography, especially when follow up is poor.⁶⁷ Additionally, one such paper notes that "increased screening costs could be offset by not recalling patients with minor lesions with no apparent potential for progression" using digital cervicography as the measure of lesion severity.⁸

Due to the advances in technology enabled workflow enhancement being leveraged by MobileODT, it is now possible to integrate this well validated method of cervical cancer screening as an adjunct to the favored screening methodologies of today including HPV testing, VIA and PAP.

¹ Ferris, Daron G., et al. "Cervicography: adjunctive cervical cancer screening by primary care clinicians." *Journal of family practice* 37.2 (1993): 158-165.

² Bae, Seog-Nyeon, et al. "Correlation between the digital cervicography and pathological diagnosis performed at private clinics in Korea." *International journal of medical sciences* 9.8 (2012): 698.

³ Firnhaber, Cynthia, et al. "Evaluation of a cervicography-based program to ensure quality of visual inspection of the cervix in HIV-infected women in Johannesburg, South Africa." *Journal of lower genital tract disease* 19.1 (2015): 7-11.

⁴ Soutter, W. P., et al. "Cervicography in a colposcopy clinic." *Journal of Obstetrics and Gynaecology* 11.3 (1991): 218-220.

⁵ Firnhaber, Cynthia, et al. "Evaluation of a cervicography-based program to ensure quality of visual inspection of the cervix in HIV-infected women in Johannesburg, South Africa." *Journal of lower genital tract disease* 19.1 (2015): 7-11.

⁶ Schneider, Achim, et al. "Screening for cervical intraepithelial neoplasia grade 2/3: validity of cytologic study, cervicography, and human papillomavirus detection." *American journal of obstetrics and gynecology* 174.5 (1996): 1534-1541.

⁷ Spitzer, Mark, et al. "Comparative utility of repeat Papanicolaou smears, cervicography, and colposcopy in the evaluation of atypical Papanicolaou smears." *Obstetrics & Gynecology* 69.5 (1987): 731-735.

⁸ Reid, Richard, et al. "Should cervical cytologic testing be augmented by cervicography or human papillomavirus deoxyribonucleic acid detection?." *American journal of obstetrics and gynecology* 164.6 (1991): 1461-1471.

Annotated Bibliography

Denny, Lynette, et al. "Evaluation of alternative methods of cervical cancer screening for resource-poor settings." *Cancer* 89.4 (2000): 826-833.

A large cohort of patients in Cape Town, South Africa participated in this comparison investigation of four cervical cancer screening techniques, specifically Pap, VIA, HPV DNA, and cervicography, in an effort to explore the efficacy of these techniques in regions with limited access to care. Patients underwent all four screening techniques with subsequent cervical biopsy obtained when one or more screening indicated precancerous or cancerous lesions. Findings suggest similar identification rates of CIN2+ and of invasive carcinoma among these methods in biopsy confirmed cases. Notably Denny et al utilized digital cervicography primarily as a quality assurance measure augmenting VIA.

Parham, Groesbeck P., et al. "eC₃ – A modern telecommunications matrix for cervical cancer prevention in Zambia." *Journal of lower genital tract disease* 14.3 (2010): 167-173.

Parham et al demonstrate the effectiveness of an electronic cervical cancer control model serving resource-limited populations thereby increasing access to care. The model facilitates remote gynecological consultation by utilizing local non-physician healthcare providers, widely accessible communication technologies, and low-cost screening comprised of VIA and digital cervicography. This screening and prevention program offers an efficient, cost effective, quality controlled solution for resource-poor populations while simultaneously educating patients, establishing a medical record, and improving the education of local physician extenders.

Ferris, Daron G., et al. "Cervicography: adjunctive cervical cancer screening by primary care clinicians." *Journal of family practice* 37.2 (1993): 158-165.

Ferris et al conducted a prospective study on a large cohort of women to investigate the effectiveness of cervicography and Pap smear as a co-test for routine cervical cancer screening. Findings strongly demonstrate the utility and increased sensitivity of this co-test technique: Approximately two times as many patients were correctly identified with cervical disease compared to the use of Pap alone. This study demonstrates enhanced sensitivity of cytology screening when augmented by cervicography.

Bae, Seog-Nyeon, et al. "Correlation between the digital cervicography and pathological diagnosis performed at private clinics in Korea." *International journal of medical sciences* 9.8 (2012): 698.

Bae et al sought to explore the consistency and accuracy of digital cervicography in detecting cervical disease. A retrospective evaluation of a large collection of patient data gathered over a two year period correlated abnormal findings identified in an abnormal cervigram to a subsequent diagnosis of cervical disease. Findings reveal a strong correlation between the two, demonstrating the accuracy and effectiveness of cervicography as a co-test to primary cervical cancer screening.

Firnhaber, Cynthia, et al. "Evaluation of a cervicography-based program to ensure quality of visual inspection of the cervix in HIV-infected women in Johannesburg, South Africa." *Journal of lower genital tract disease* 19.1 (2015): 7-11.

Firnhaber et al conducted a large investigation on the application of digital cervicography as a quality assurance measure in detecting cancerous lesions when implemented in conjunction with VIA. After extensive training on the technique and interpretation, nurses performed VIA and digital cervicography with findings

subsequently reviewed by expert gynecologists. The addition of specialist-reviewed digital cervicography improved the sensitivity of detection by ten percent, demonstrating the clear benefit of digital cervicography as the cornerstone of a quality assurance program.

Soutter, W. P., et al. "Cervicography in a colposcopy clinic." *Journal of Obstetrics and Gynaecology* 11.3 (1991): 218-220.

Soutter et al explored the use of cervicography during a colposcopy procedure in this pilot study. Using tissue biopsy or smear cytology as diagnostic, the sensitivity and specificity of cervicography were encouraging.

Schneider, Achim, et al. "Screening for cervical intraepithelial neoplasia grade 2/3: validity of cytologic study, cervicography, and human papillomavirus detection." *American journal of obstetrics and gynecology* 174.5 (1996): 1534-1541.

This large study aimed to directly compare cervical cancer detection techniques. The use of Pap smear alone correctly identified approximately one-third of women diagnosed with cervical cancer, while HPV testing and cervicography both resulted in correct identification of approximately half of the diagnosed women. Importantly this study demonstrates the inconsistencies of Pap alone, as well as the improved detection sensitivity of Pap when used in conjunction with HPV testing or with cervicography.

Spitzer, Mark, et al. "Comparative utility of repeat Papanicolaou smears, cervicography, and colposcopy in the evaluation of atypical Papanicolaou smears." *Obstetrics & Gynecology* 69.5 (1987): 731-735.

Spitzer et al investigated the outcomes and cost effectiveness of cervical cancer detection techniques in follow up after an atypical Pap. Patients who had an abnormal Pap were reevaluated for lesions via colposcopy, cervicography, and repeat Pap. Both colposcopy and cervicography detected lesions at higher accuracy than a repeat Pap, with the cost per patient of a repeat Pap equal to cost of cervicography. Use of cervicography as a triage system offers providers serving vulnerable populations with limited follow up access increased accuracy, thereby reducing unnecessary expenditures on repeat or additional testing.

Reid, Richard, et al. "Should cervical cytologic testing be augmented by cervicography or human papillomavirus deoxyribonucleic acid detection?." *American journal of obstetrics and gynecology* 164.6 (1991):1461-1471.

Reid et al performed a direct comparison of three screening techniques used alone and in combination. Individual use of Pap smear, cervicography, or HPV testing resulted in approximately equal detection rates of minor lesions, yet lesion detection and specificity dramatically increased when Pap smear was used in conjunction with either cervicography or HPV testing. The increased accuracy of Pap when augmented by a secondary technique limits unnecessary and costly follow up.