

Cervicography: Adjunctive Cervical Cancer Screening by Primary Care Clinicians

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Background. Cervicography is an adjunct method of cervical cancer screening intended to complement cervical cytologic sampling, ie, Papanicolaou (Pap) smear. Cervicography involves obtaining and evaluating a photographic image of the cervix. The purpose of this investigation was to evaluate the screening use of cervicography as an adjunct to clinical cytologic screening.

Methods. Women presenting at four clinical sites for annual cervical cytologic screening or for follow-up evaluation after receiving an abnormal Pap smear result were enrolled in the study. Each patient received a Pap smear and a cervigram. Those women in whom abnormalities were detected by either test subsequently underwent colposcopy, and when appropriate, histologic specimens were obtained.

Results. Pap smear and cervigram data were obtained for 1449 women. When premalignant or malignant histologic test results were considered as a true positive,

the Pap smear correctly identified 25.6% of subjects with dysplasia and 37.5% with severe dysplasia. The Pap smear failed to identify the one patient with invasive cancer. The cervigram detected 50.5% of the subjects with dysplasia and 77.8% of the subjects with severe dysplasia, and it identified the one patient with invasive cancer when a positive cervigram was considered a true positive. When the results were combined, the two tests identified 62.9% of subjects with histologically confirmed dysplasia, 81.3% of subjects with severe dysplasia, and 100% (one patient) with cancer.

Conclusions. The cervigram detected twice the number of patients with premalignant disease as the Pap smear alone, and correctly identified the invasive cancer. Cervicography improved the detection of cervical disease.

Key words. Cervix disease; Papanicolaou smear; photography; mass screening; disease prevention.
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The incidence of cervical cancer mortality has decreased 70% since the implementation of the Papanicolaou (Pap) smear.¹ However, the Pap smear is unable to accurately and consistently identify premalignant and malignant disease of the cervix.² Consequently, annual cytologic screening is necessary to minimize inherent method failures.³ Interval screening is most efficient when the treatable phase of a disease is prolonged. Yet, data indicate

that cervical premalignant disease may progress quickly, particularly when associated with human papillomavirus types 16 and 18.⁴ Although recent epidemiologic data indicate a leveling off of cervical cancer incidence and mortality rates,⁵ premalignant cervical disease in young women may be increasing in incidence.⁶

Various screening strategies or devices may improve cervical disease detection. Universal screening by the traditional cytologic technique would increase disease detection ability. More frequent screening is impractical both for the patient and the health care system, and less frequent screening has been suggested for many women.⁷ Newer cytologic collection devices with improved sampling and transference characteristics, innovative pre-screening equipment, and greater cytologic scrutiny have contributed to modest reductions in the number of false

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negative cytologic reports. Yet, from very small ectocervical low-grade lesions to advanced cancer, cervical disease is still frequently undetected because of lesion size, location, and obscuring inflammation, blood, or exudate. Thus, an adjunct test to cytologic screening may be needed.⁸ A highly sensitive screening combination for cervical cancer would be cytologic and colposcopic evaluation,^{2,9} but because of costs, time, and expertise limitations, screening colposcopy¹⁰ has proved to be impractical.¹¹

Cervicography (National Testing Laboratories, Fenton, Mo) is a relatively new adjunct method of cervical cancer screening intended to complement cervical cytologic sampling. Cervicography may be described as the process of producing and interpreting a simple static ectocervical photographic image of the cervix, the evaluation of which is based on colposcopic principles. Cervicography is not colposcopic screening¹⁰ or colpophotography.¹² Cervicography combines features of these two items with a laboratory-based system of procedural and equipment standardization, results reporting, consultation, documentation, and quality control that is not unlike that for the Pap smear process. Whereas the Pap smear detects disease at a cellular level, cervicography

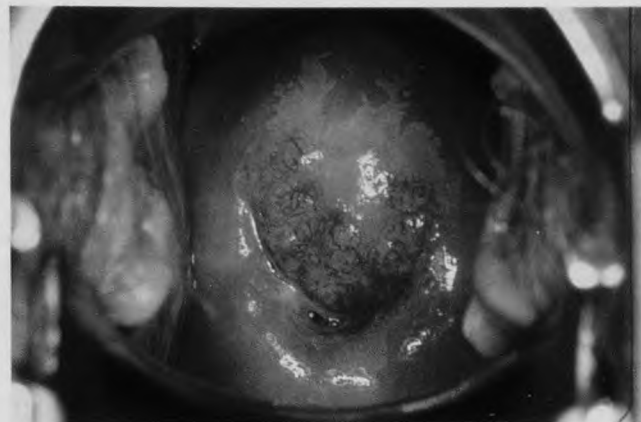


Figure 2. A cervigram depicts a large, complex acetowhite lesion with a coarse, mosaic vascular pattern on the anterior cervical lip. The cervigram was interpreted as positive. Although a low-grade lesion with geographic margins and satellite lesions is noted peripherally, the histologic report of the centrally located, more severe lesion demonstrated high-grade disease.

detects disease at an enhanced macroscopic level. Therefore, cervicography identifies disease expression, and cytologic testing detects cellular level alterations (inflammation, atypia, minimally expressed viral infection, etc).

Cervicography is performed using a cerviscope (Figure 1) or a specially designed hand-held 35-mm camera with a telephoto macrolens and an illumination and flash system. The lens enables a panoramic photograph or cervigram (Figure 2) to be taken of the cervix and proximal vagina. Following cervical cytologic sampling, acetic acid is applied to the cervix, and two cervigrams are taken with the cerviscope. After processing the film into 2×2 slides at a central laboratory, the cervigrams are projected onto a screen and interpreted by trained expert evaluators. A descriptive report is returned to the clinician for management purposes.

The utility of cervicography has been examined by skilled gynecologists.^{9,13-22} Available data on the use of cervicography in traditional primary care settings are limited, however.²² The purpose of this multisite study was to evaluate the use of cervicography by primary care specialists in typical clinical sites and to determine whether its use would enhance and complement the Pap smear.

Methods

Patient Population

Women between the ages of 12 and 90 years of age were prospectively recruited from several sites, which included



Figure 1. The cerviscope, or special 35-mm camera and power unit designed for cervicography.

the Medical College of Georgia Family Practice Center and Student Health Service, the University of Georgia Student Health Clinic, and Humboldt State University Student Health Clinic.

The inclusion criteria were that the subject be a woman who was 12 years of age or older and who presented for a routine annual cervical cytologic screening examination or for evaluation following the receipt of an abnormal Pap smear report. The exclusion criteria included recent douching, severe cervicitis, menses, acetic acid (5%) hypersensitivity, and history of hysterectomy.

Screening Methods

Cervical cytologic specimens were obtained with a Cytobrush (MedScand [USA], Inc, Hollywood, Fla) and spatula or with a Cervex-Brush (Unimar, Inc, Wilton, Conn). Pap smears were collected before cervicography. Pap smears were processed and interpreted independently at the cytology laboratories used by each clinic. Colposcopic examinations were performed by traditional methods at each clinic or, when requested by subjects, occasionally by private clinicians. Cervical histologic specimens obtained from colposcopically directed biopsies were evaluated at each respective site.

Cervicography was performed by trained physicians (family physicians, obstetrician-gynecologists, and a pediatrician) or trained nurses. After the Pap smear had been obtained, the cervix was gently swabbed for a minimum of 30 seconds with 5% acetic acid. A second 30-second application of 5% acetic acid followed, and the cervix was completely visualized through the cerviscope. Focus was obtained by moving the externally located cerviscope to the proper focal length along the cervicovaginal axis. Two cervigrams were taken of each cervix. The film was sent to the central laboratory for processing. Certified expert evaluators interpreted the cervigrams as negative, atypical, positive, or technically defective. The evaluation report, along with a photographic print of the cervigram, was returned to the investigators. Cytologic and histologic evaluators and cervigram evaluators were mutually blinded to results.

Study Design

All eligible subjects initially received a Pap smear followed by a cervigram. Subjects for whom either or both test results were abnormal were further evaluated by colposcopic examination. Colposcopically directed biopsies were obtained only from subjects in whom transformation zone abnormalities were detected.²³

Statistical Analysis

Simple frequency measures were used to analyze demographic and test data. Confidence limits were calculated for test performance data. For the convenience of data analysis, Pap smear results were categorized as follows: within normal limits, "negative"; atypical squamous cells of undetermined significance, "atypia"; and low-grade and high-grade squamous intraepithelial lesions, "positive." Cervigrams were categorized according to interpretation: "negative" if normal; "atypical" if evidence of an acetowhite lesion was found outside the transformation zone or inside the transformation zone but of doubtful significance, or if atypical immature squamous metaplasia was found; and "positive" if evidence of a minor or major grade lesion or cancer was found. Data analysis was complicated by the fact that cytologic atypia and an atypical cervigram are not equivalent.

Results

One thousand six hundred seven cervigrams were taken of 1449 subjects from the collective study sites. The mean age of the subjects was 24.4 years, and the range was 12 to 89 years. One percent of subjects were pregnant, and 89.3% were nulliparous. Twenty-one percent of subjects had a prior history of human papillomavirus infection. A history of previous cervical cryotherapy and laser therapy was reported by 7.5% and 1% of subjects, respectively.

A comparison of Pap smear results with cervigram results is given in Table 1. More than twice as many cervigrams as Pap smears were interpreted as positive (272 vs 118). The two tests demonstrated an overall agreement in 43.3% of the subjects.

Cervical biopsy specimens were obtained from 440 subjects, and complete data (cervigram, Pap smear, and biopsy) were available for 410 subjects. Histologic interpretations were recorded for subjects as negative (20), atypia (79), mild dysplasia (254), moderate dysplasia (40), severe dysplasia (16), and cancer (1).

Pap smear results were compared with histologic interpretations (Table 2). When atypical or premalignant Pap smears were considered as positive test results, the Pap smear detected 79.2% of subjects with dysplasia. When cytologic atypia was not considered as positive, the Pap smear detected only 25.6% (95% CI 20.8% to 30.8%) of subjects with histologically confirmed dysplasia. Using the same restrictive criteria, the positive Pap smear result correctly identified 21.6% of subjects with mild dysplasia, 43.9% with moderate dysplasia, and 37.5% (95% CI 15.2% to 64.6%) with severe dysplasia; it failed to identify the one patient with cervical cancer.

Table 1. Comparison of Pap Smear Results with Cervigram Results (N = 1449)

| Cervigram Results† | Pap Smear Results* | | | Totals |
|--------------------|--------------------|--------|----------|--------|
| | Negative | Atypia | Positive | |
| Negative | 389 | 358 | 48 | 795 |
| Atypical | 167 | 192 | 23 | 382 |
| Positive | 87 | 138 | 47 | 272 |
| Totals | 643 | 688 | 118 | 1449 |

*The following definitions for Pap smear results were used: negative indicated cervical cytologic test results reported as being within normal limits or normal; atypia, cytologic atypia or atypical squamous cells of undetermined significance; and positive, cytologic premalignant (low-grade or high-grade squamous intraepithelial lesion) or malignant characteristics.

†The following definitions for cervigram results were used: negative indicated normal cervigram; atypia, acetowhite lesion inside or outside the transformation zone or atypical immature squamous metaplasia; and positive, minor- or major-grade lesion or cancer.

Cervicography results were then compared with histologic interpretations (Table 3). When atypical or positive cervigrams were considered as positive, 80.4% of subjects with dysplasia were correctly identified. When only positive cervigrams were considered true positives, cervicography detected 50.5% (95% CI 44.9% to 56.0%) of subjects with histologically confirmed dysplasia. A positive cervigram appropriately identified 46.0% of subjects with mild dysplasia, 66.7% of subjects with moderate dysplasia, 77.8% (95% CI 52.4% to 93.6%) with severe dysplasia, and the one patient with cervical carcinoma.

Cervicography is an adjunct test.²⁴ Consequently, the combined Pap smear and cervicography data were compared with histologic results (Table 4). When only premalignant cytologic findings and positive cervigram test results were considered as positive (ie, excluding atypical results), the collective screening tests identified 62.9% (95% CI 57.3% to 68.3%) of subjects with dysplasia or neoplasia, 81.3% (95% CI 54.4% to 96.0%) of subjects with severe dysplasia, and the one subject with cancer. The remainder of patients with dysplasia were identified histologically by prior evidence of cytologic atypia or an atypical cervigram report. A positive cervigram in conjunction with a negative Pap smear result enabled detection of premalignant histologic disease in 44 of 311 women with dysplasia, or an additional 14%. Traditional test performance measures of sensitivity,

specificity, and predictive values could not be determined because, as clinically appropriate, subjects whose cytologic and cervicographic findings were negative were not colposcopically examined, nor were histologic samples obtained.

Discussion

The rationale of effective cervical cancer screening is to maximize the detection of true premalignant precursor lesions in order to prevent progression to cervical cancer while limiting referrals of women with negative or benign diagnoses. The results from this study indicate that cervicography detected twice the number of patients with premalignant cervical disease as did the Pap smear. More women with premalignant cervical disease were identified by both cytologic and cervicographic tests together than with either test individually. These findings are similar to those reported by skilled gynecologists. Tawa et al²¹ similarly evaluated 3271 gynecology patients with cytologic and cervicographic testing. Eighty-one women had cervical intraepithelial neoplasia as detected by colposcopically directed biopsy. Cervicography detected 88.9% of patients with cervical intraepithelial neoplasia, whereas the Pap smear detected only 17.3% of patients with cervical intraepithelial neoplasia. Gunderson et al¹⁹ evaluated 250 patients by means of cervicography and

Table 2. Comparison of Pap Smear Results with Histologic Findings

| Histologic Findings | Pap Smear Results* | | | Totals |
|---------------------|--------------------|--------|----------|--------|
| | Negative | Atypia | Positive | |
| Negative | 7 | 12 | 1 | 20 |
| Atypia | 28 | 45 | 7 | 80 |
| Mild dysplasia | 53 | 150 | 56 | 259 |
| Moderate dysplasia | 7 | 16 | 18 | 41 |
| Severe dysplasia | 6 | 4 | 6 | 16 |
| Cancer | 0 | 1 | 0 | 1 |
| Totals | 101 | 228 | 88 | 417 |

*The following definitions for Pap smear results were used: negative indicated cervical cytologic test results reported as being within normal limits or normal; atypia, cytologic atypia or atypical squamous cells of undetermined significance; and positive, cytologic premalignant (low-grade or high-grade squamous intraepithelial lesion) or malignant characteristics.

Table 3. Comparison of Cervigram with Histologic Findings

| Histologic Findings | Cervigram Results* | | | Totals |
|---------------------|--------------------|--------|----------|--------|
| | Negative | Atypia | Positive | |
| Negative | 3 | 9 | 9 | 21 |
| Atypia | 17 | 30 | 38 | 85 |
| Mild dysplasia | 56 | 87 | 122 | 265 |
| Moderate dysplasia | 7 | 7 | 28 | 42 |
| Severe dysplasia | 1 | 3 | 14 | 18 |
| Cancer | 0 | 0 | 1 | 1 |
| Totals | 84 | 136 | 212 | 432 |

*The following definitions for cervigram results were used: negative indicated normal cervigram; atypia, acetowhite lesion inside or outside the transformation zone or atypical immature squamous metaplasia; positive, minor- or major-grade lesion or cancer.

cytologic testing. Twenty women had cervical intraepithelial neoplasia. Cervicography detected 90% of women with cervical dysplasia while the Pap smear detected only 20%. However, a significant number of positive cervigrams were found to be false-positive interpretations.

As cervicography is intended to be an adjunct to cervical cytologic evaluation, cytologic testing alone should be compared with the combination of cytologic testing and cervicography. In this investigation, the combination of cervicography and cytologic testing detected 62.9% of dysplasia, whereas cytologic testing alone detected only 25.6% of dysplasia. Some may argue that cervical cytologic screening and a second method of screening with cervicography may be no more efficacious than two cytologic samples taken within several months of each other. In a study of 236 women with atypical Pap smears, Jones et al¹⁶ demonstrated that a repeat Pap smear identified only 17% of patients with cervical intraepithelial neoplasia, whereas cervicography identified 81% of patients with cervical intraepithelial neoplasia. Hence, repeat cytologic sampling detected few patients with premalignant disease but cervicography detected nearly five times the number of women with premalignant changes.

The previously cited studies found cervicography to be more sensitive and less specific than the Pap smear. Cervicography false-negative failures may represent dis-

ease located in the endocervical canal and not visible to the evaluator. Failures may also occur with cytologic sampling when smears do not contain cellular material or when cellular material is present but obscured by blood, inflammatory cells, or exudate. Early cellular changes may be detected by cytologic testing and missed by cervicography. False-positive cervigrams typically result from overinterpretation of the significance of acetowhite epithelium. Cervicography may detect mildly atypical or low-grade epithelial changes that may be underreported by histologic evaluators or reported as chronic cervicitis or inflammatory changes. These changes may actually represent minor viral cytopathic alterations.^{7,22} Yet, as shown in this study, both cervicography and cytologic tests are complementary. The higher percentage of disease detected when cervicography is used in conjunction with the Pap smear is of critical importance.

The failures of the current cervical cytologic screening system are well documented.² It has been suggested that "an optimal cancer detection system should probably consist of a cervical smear and a colposcopy" examination.² This complementary screening approach has been advocated by some as "colposcopic screening."¹⁰ However, many national guidelines state that colposcopy should be used only in a diagnostic capacity.²⁵ In principle, cervical cytologic testing along with enhanced visualization of the cervix is superior to a single method.

Table 4. Comparison of Combined Screening of Pap Smear and Cervigram Results with Histologic Findings

| Histologic Findings | Pap Smear and Cervigram Results | | | Totals |
|---------------------|---------------------------------|---------|-----------|--------|
| | Negative* | Atypia† | Positive‡ | |
| Negative | 0 | 10 | 10 | 20 |
| Atypia | 0 | 37 | 42 | 79 |
| Mild dysplasia | 0 | 104 | 150 | 254 |
| Moderate dysplasia | 0 | 8 | 32 | 40 |
| Severe dysplasia | 0 | 3 | 13 | 16 |
| Cancer | 0 | 0 | 1 | 1 |
| Totals | 0 | 162 | 248 | 410 |

*The results of both the Pap smear and the cervigram were negative or normal.

†Neither the Pap smear nor the cervigram result was positive, but at least one of the two test results was atypical.

‡Either the Pap smear or the cervigram result or both were positive.

Cervicography is more suitable for clinicians who may be unfamiliar with colposcopy techniques and abnormal transformation zone characteristics. Most clinicians are familiar with 35-mm camera use but not necessarily as it applies to colposcope operations or use for detection of disease. Simplified and standardized technology provides greater utility and expands access to available screening procedures and preventive health care. Cervicography is a system similar in design to other laboratory testing, including cytologic testing. The analogy encompasses patient preparation, specimen collection, transport, laboratory specimen processing, and specimen interpretation and reporting. Both cervicography and cytologic screening feature quality-control programs and include expert evaluations. Cervicography quality control is maintained by peer review and histologic correlation. Expert evaluators receive extensive training and must qualify by passing a rigid examination conducted by the Medical College of Wisconsin.

The clinical utility of screening cervicography as a Pap smear adjunct is apparent and documented by this study. A significant number of women with premalignant cervical disease not detected by cytologic screening were identified by cervicography. Cervicography, like colposcopy, is most useful in young women in whom the full squamocolumnar junction and transformation zone can be visualized, in women considered at higher risk of cervical neoplasia, and in conjunction with the Pap smear. Cervicography should be considered for women who have been noncompliant with serial Pap smear screening for several years or more. The economic cost and risk of waiting three successive years for cytologic testing in an already defined noncompliant patient may exceed the cost for a single cytologic smear with cervicography. This is especially true considering a shortening spectrum of disease being reported for high-risk viral-associated premalignant diseases.⁴

As in the case of screening mammography, the most efficacious use of screening cervicography, considering cost and maximization of disease detection, is still not clearly defined.^{15,21,25} The use of interval cervicography in conjunction with the Pap smear may be the most efficacious screening strategy. That critical interval, however, has yet to be determined, and further research is necessary. It is conceivable that less frequent screening with the more accurate combination of cytologic testing and cervicography may be equivalent to more frequent but less accurate screening by cytology alone. Such a strategy would reduce patient inconvenience and office visit expenses while maintaining efficacy. Other screening adjuncts, such as human papillomavirus testing, may further enhance this lengthened-interval screening strategy.

Skeptics of cervicography exist.^{26,27} Criticism has centered on the lack of specificity, the cost, and the rate of technically defective cervigrams. Many of these concerns were appropriately raised on the basis of preliminary studies and the early cervicography terminology and classification system, which has since been modified and improved. Cervicography may be of limited value for women whose squamocolumnar junction is located within the endocervical canal (elderly or post-treatment women). Yet, a single cervigram to assess the ectocervical transformation zone in these women would be appropriate based on the capability of cervicography to identify additional women with premalignant disease.

The investigation reported here was limited potentially by two factors. First, most subjects were young nulliparous women in whom the squamocolumnar junction is usually located on the ectocervix and therefore easily visualized. However, both cervicography and cytologic sampling would perform better in this circumstance than in postmenopausal women in whom the squamocolumnar junction, within the endocervical canal, is not readily visualized by cervicography or easily sampled by cytologic techniques. Second, colposcopy was not performed on subjects with negative screening tests. As a result, sensitivity and specificity of the tests could not be determined. Nevertheless, in actual clinical practice women with normal cytologic results and a negative cervigram would not receive a colposcopic examination either.

In summary, cervicography detected twice as many subjects with premalignant cervical disease when compared with the Pap smear alone. Cervicography detected more cases of high-grade premalignant lesions and did not miss the invasive cancer. When used collectively, cervicography and the Pap smear identified nearly 2½ times the number of women with dysplasia as the Pap smear alone. Cervicography performed by primary care physicians effectively enhances cervical cytologic screening.

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