Is Cervicography a Useful Diagnostic Test? A Systematic Overview of the Literature

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Background: **The appropriate approach to women with mild dyskaryotic changes on Papanicolaou smear is subject to controversy. Our aim was to assess the usefulness of cervicography as a diagnostic test in detecting cervical cancer or its precursors.**

Methods: **We undertook an extensive literature search looking for pertinent studies of cervicography published between 1966 and 1996. Eligible studies included those in which the reference standard (colposcopy) was done on all patients. The following information was calculated: sensitivity, specificity, positive predictive value, negative predictive value, disease prevalence, and likelihood ratios.**

Results: **Cervicography has a high false-positive rate. This rate ranged from 8.2 to 61.0 percent (median 42.1 percent) for any dysplasia and 9.8 to 63.4 percent (median 50.6 percent) for high-grade cervical lesions. Likelihood ratios for a positive test result ranged from 1.0 to 10.6. Likelihood ratios for a negative result ranged from 0.02 to 1.0.**

Conclusions: **The usefulness of cervicography is heavily dependent on the approach used to evaluate abnormal findings on a Papanicolaou smear. If a provider typically offers colposcopy to all patients with low-grade cytologic findings on a Papanicolaou smear, cervicography will decrease colposcopy use and allow for detection of cases of high-grade dysplasia missed by the index Papanicolaou smear. If a provider typically uses watchful waiting with repeat Papanicolaou smears for all patients who have low-grade cytologic findings, cervicography will substantially increase the use of colposcopy. Many of these colposcopies will be done as a result of false-positive cervigrams. (J Am Board Fam Pract 1997;10:390-7.)**

The goal of cervical cytology screening is to detect cervical cancer and its precursors. During the last 40 years regular screening with a Papanicolaou smear has proved to be effective in reducing the morbidity and mortality from this disease.[1] Yet despite the success of the Papanicolaou smear, there are concerns about its limitations, the most notable of which is the false-negative rate. Although there is a wide range of reported values for the false-negative rate of Papanicolaou smears, even with optimal conditions the false-negative rate can be as high as 29 percent.[2]

New techniques and devices are being investigated to address this problem, and cervicography is one such method.[3,4] The technique of cervicography involves a photograph of the cervix taken after application of acetic acid. The resulting cervigram is then examined by an expert who looks for evidence of pathologic changes consistent with a dysplastic process. If the changes are found, the patient is referred for colposcopy and directed biopsies.[3,4] When compared with colposcopy, the advantages of cervicography are that it is simple to perform, less expensive, and noninvasive.

Development of a new diagnostic test has particular relevance for detection of cervical cancer and its precursors. Recently the debate has intensified over the appropriate management for women with atypical or low-grade cytologic abnormalities. Management can range from immediate colposcopy to watchful waiting with repeat Papanicolaou smears.[5-7] A new diagnostic test such as cervicography can have an impact on both of these strategies.

Before adoption and diffusion of cervicography become widespread, it is important to review the existing evidence on the performance characteristics of this test. Our study reviewed the published research on cervicography and addressed the following question: Is cervicography useful as a pri-

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Table 1. Summary of Baseline Data and Methods of Eligible Studies.

Author	Year	Number of Subjects	Study Site	Methods
Cecchini et al[27]	1992	606	Colposcopy clinic, Italy	606 consecutive women referred to District of Florence Colposcopy Clinic. Atypical Papanicolaou smear (57.6%), CIN I (7.6%), CIN II-III (5.0%), self-referred (29.9%). All women had cervicography at time of colposcopy
Jones et al[28]	1987	236	2 university obstetric-gynecology clinics, USA	236 consecutive referred nonpregnant women with class II atypia evaluated by colposcopy and cervicography
Kesic et al[29]	1993	418	University obstetric-gynecology clinic, Yugoslavia	One-year study of 418 asymptomatic women as part of a screening program. Most had never been screened before. Class II atypia or greater (8.6%). All had cytology testing, colposcopy, and cervicography
Schauberger et al[30] (a)	1991	100	Colposcopy clinic, USA	Retrospective chart review of 100 women with class II atypia who had undergone colposcopy and cervicography
Schauberger et al[31] (b)	1991	105	Colposcopy clinic, USA	Retrospective chart review of 105 women with active condyloma, history of condyloma, or partner with condyloma, who had undergone colposcopy and cervicography
Soutter et al[32]	1991	211	Colposcopy clinic, England	211 women undergoing colposcopy had simultaneous cervigram. Baseline cytologic abnormalities not recorded
Spitzer et al[33]	1987	97	Obstetrics-gynecology clinic, USA	97 women with an atypical Papanicolaou smear were evaluated by colposcopy and cervicography

CIN - cervical intraepithelial neoplasia.

mary screening test, as an adjunct to a screening Papanicolaou smear, or as a secondary triage tool in the detection of cervical cancer and its precursors? When done concomitantly with a screening Papanicolaou smear, cervicography could serve one of two clinical policy objectives: (1) address the false-negative rate problem currently encountered with cytology screening; or (2) help distinguish those women who have abnormal findings on Papanicolaou smear who should be referred for immediate colposcopy from those for whom follow-up with repeat Papanicolaou smears is appropriate. As a secondary triage tool, the objective of cervicography is to determine which women have atypical or low-grade cytologic abnormalities that can be safely managed with repeat Papanicolaou smears.

Methods

A MEDLINE search of studies published in English from 1966 through 1996 was conducted using the following key words: "cervicography" and "colpophotography." Articles were selected that reported data from studies in which cervicography was used for cervical cancer screening. The reference list of each retrieved report was scanned for potential additional studies. A manual search of the *Index Medicus* was performed as well. We contacted the first authors of selected studies and requested information on any studies that were not included in our list of relevant reports.

Baseline data were obtained from each report retrieved (Table 1). For Papanicolaou smear findings, synonymous terminology for borderline abnormalities included atypia and atypical squamous cells of undetermined significance. For low-grade lesions, equivalent terminology included mild dyskaryosis, mild dysplasia, class II atypia, low-grade dysplasia, cervical intraepithelial neoplasia (CIN) grade I, changes consistent with human papillomavirus (HPV) infection, and low-grade squamous intraepithelial lesion (SIL). For high-grade lesions, equivalent terminology included moderate or severe dyskaryosis, class III

Table 2. Quality Scoring Criteria and Results for Eligible Studies (n = 7).

Criterion	Studies Meeting Criterion
Did patient sample include appropriate spectrum of mild and severe, treated and untreated disease in addition to patients with different but commonly confused disorders?	4
Was study setting, as well as the filter through which study patients passed, adequately described?	1
Was reproducibility and interpretation (observer variation) of test results determined?	1
Was the term "normal" defined sensibly?	2
If test is advocated as part of a cluster or sequence of tests, was its contribution to overall validity of the cluster or sequence determined?	0
Were tactics for carrying out the test described in sufficient detail to permit their exact replication?	0
Was utility of the test determined? (Are patients better off as result of test?)	1
Are results applicable to primary care patients?	0
Will results lead to change in management?	1

From Reid et al,[9] Jaeschke et al,[10] and Irwig et al.[11]

or IV Papanicolaou findings, moderate or high-grade dysplasia, CIN II or III, carcinoma in situ, and high-grade SIL.[2,8] Studies in which all patients received the reference standard test (colposcopy with or without directed biopsies), as well as cervicography, were selected for further analysis.

Each eligible report was reviewed using a quality assessment instrument. The quality assessment criteria, adapted from previous works on assessment of diagnostic test research, are listed in Table 2.[9-11] Two of the authors (JN, JM) independently reviewed each article for quality assessment criteria. Disagreements were discussed, and the final scoring was assigned by consensus.

For each eligible report the percentage of unsatisfactory or technically defective cervigrams and the results of colposcopy (normal, any dysplasia, low-grade dysplasia, high-grade dysplasia, and cancer) were extracted. Sensitivity, specificity, positive predictive value, negative predictive value, disease prevalence, and likelihood ratios for a positive test result (true-positive rate/false-positive rate) and for a negative result (false-negative rate/true-negative rate) were calculated. True-positive cervigrams were defined as those that had histologic findings on colposcopy of either any dysplasia or of only high-grade dysplasia. The test calculations included and then excluded unsatisfactory or technically defective cervigrams in all denominators.

Results

Baseline Data

Twenty-three reports on cervicography were retrieved using the search strategy described above.[3,12-33] After eliminating those studies in which the reference standard (colposcopy) was not performed on all participants, seven studies remained. Baseline data and methodologies are summarized in Table 1.[27-33] The studies, published from 1987 to 1993, had a variety of study populations, and the entry criteria for the study varied widely. In three of the studies eligible women had atypical Papanicolaou smear findings[28,30,33]; in two, the women were those who were scheduled to be seen in a referral colposcopy clinic.[27,32] The study by Cecchini et al[27] included patients seen in a referral colposcopy clinic for abnormal Papanicolaou smear findings (including atypia and dysplasia) and self-referred patients with normal Papanicolaou smear findings. No information is provided on the breakdown of cytologic findings that precipitated colposcopy in the study by Soutter et al.[32] In the study by Kesic et al,[29] eligible participants were from a "screening population," most of whom had never had a previous Papanicolaou smear. In a study by Schauberger et al,[31] those who had an active condyloma, a history of condyloma, or a partner with condyloma were eligible. The wide differences in entry criteria and study participants made meta-analytic techniques inappropriate.[11]

Cervigrams described as unsatisfactory or technically defective ranged from 2.0 to 15.5 percent (median = 7.7 percent) among the eligible studies.

Quality Assessment

Results of the quality assessment scoring are presented in Table 2. No study received a score of greater than 3 (with a maximum possible score of 7).

Test Parameters

The results of the sensitivity, specificity, positive predictive values, negative predictive values, disease prevalence and likelihood ratios are presented in Table 3. The values incorporate technically defective or unsatisfactory cervigrams in all

Table 3. Summary of Cervicography Test Characteristics from Seven Eligible Studies.

Authors	Dysplasia Found on Colposcopy	Sensitivity	Specificity	False-Positive Rate*	Likelihood Ratio, Positive Test	Likelihood Ratio, Negative Test	Prevalence of Dysplasia†	Positive Predictive Value‡	Negative Predictive Value§
Atypia on index Papanicolaou smear									
Jones et al[28]	Any	90.4	60.4	39.6	2.3	0.44	25.8	44.3	94.7
	High grade	100.0	49.4	50.6	2.0	0.02	4.5	8.5	100.0
Schauberger et al[30]	Any	19.4	82.3	17.7	1.1	0.97	36.7	38.9	63.8
	High grade	18.2	81.6	18.4	1.0	1.0	11.2	11.1	88.8
Spitzer et al[33]	Any	93.3	39.0	61.0	1.5	0.18	15.5	21.9	96.9
	High grade	100.0	36.6	63.4	1.6	0.03	7.2	10.9	100
Colposcopy clinic patients									
Cecchini et al[27]	Any (a)‖	81.8	57.7	42.3	1.9	0.31	28.8	43.9	88.5
	(b)‖	82.1	43.3	56.4	1.5	0.42	29.2	37.6	85.4
	High grade (a)‖	95.5	48.1	51.9	1.8	0.08	3.9	6.9	99.6
	(b)‖	90.5	37.0	63.0	1.4	0.24	3.8	5.4	99.0
Soutter et al[32]	Any	73.0	64.0	36.0	2.0	0.42	29.9	45.5	84.8
Screening population									
Kesic et al[29]	Any	88.9	81.8	8.2	10.6	0.12	5.8	44.4	99.1
	High grade	89.5	90.2	9.8	9.1	0.11	4.8	31.5	99.4
Patients with condyloma									
Schauberger et al[31]	Any	89.5	58.1	41.9	2.1	0.17	18.1	32.1	96.2
	High grade	100.0	53.1	48.9	2.1	0.02	6.7	13.2	100.0

*1– specificity.
†Pretest likelihood of dysplasia.
‡Posttest likelihood of dysplasia if test positive.
§Posttest likelihood of no dysplasia if test negative.
‖In the study by Cecchini et al,[27] a and b represent the results of two different cervicography readers.

denominators. There was no substantive difference in the analysis by inclusion or exclusion of these cervigrams.

There is a considerable difference in positive predictive value within each of the studies when comparing the detection of any dysplasia with high-grade dysplasia. The positive predictive values for detection of any dysplasia (median 41.1 percent, range 21.9 to 45.5 percent) were greater than the positive predictive values for detection of high-grade dysplasia (median 10.9 percent, range 5.4 to 31.5 percent).

The difference between the positive predictive value (ie, the posttest likelihood of disease if the test results are positive) and disease prevalence (ie, the pretest likelihood of disease) was small for high-grade lesions. The false-positive rate was generally high. It ranged from 8.2 to 61.0 percent (median 42.1 percent) for the histologic finding of any dysplasia and 9.8 to 63.4 percent (median 50.6 percent) for high-grade lesions. Likelihood ratios for a positive result ranged from 1.0 to 2.3 for six of the seven studies. The study by Kesic et al[29] represents an outlier, as it had relatively higher values for most of the test parameters evaluated. This study was the only one using cervicography as a primary screening test. The negative predictive values for most of the studies were high, particularly for high-grade dysplasias (range 88.8 to 100 percent). The calculated likelihood ratios for a negative test result ranged from 0.12 to 0.97 for any dysplasia and from 0.02 to 1.0 for high-grade dysplasias. In four of the six studies reporting both any dysplasia and high-grade dysplasia,[27,28,31,33] the likelihood ratio for a negative result was substantially lower for high-grade lesions (0.02 to 0.24) than for any lesion (0.18 to 0.44).

Only one study examined interobserver variability of cervigrams. Cecchini et al[27] found good interobserver agreement beyond chance using two independent reviewers of cervigrams (kappa = 0.62).

Discussion

Quality of Research on Cervicography

The quality of research on cervicography is generally poor. Sixteen of the 23 retrieved reports did not apply the reference standard of colposcopy to all test participants. The most common methodologic error was to perform colposcopy only on those participants with positive findings on either Papanicolaou smear or cervigram. It has been well-documented that the properties of a diagnostic test will be distorted if its results influence whether patients undergo confirmation by a reference standard.[34] This problem has been described as ascertainment, verification, or workup bias. This bias will falsely increase the sensitivity of the test being evaluated, because the number of false-negative results is unknown if patients with a negative test result do not receive the reference standard test.[34]

The findings also indicate that the seven eligible studies did not adequately address nine accepted methodologic standards for the evaluation of diagnostic tests. Inadequate appraisal of diagnostic tests in the medical literature has been previously reported.[9]

Cervicography Test Characteristics

Cervicography has a high false-positive rate. Our analysis documents a false-positive rate that ranged from 8.2 to 61.0 percent (median 42.1 percent) for any dysplasia and 9.8 to 63.4 percent (median 50.6 percent) for high-grade lesions. Similar ranges of false-positive rates are reported in the studies excluded from the overview. This problem is not surprising and not without precedent. During colposcopic examination of the cervix, many different processes in the transformation zone can mask the underlying blood vessels by focally increasing the cell density. Overlap between the acetowhite changes occurs not only as a result of dysplasia but also as a result of inflammation and squamous metaplasia and condyloma without dysplasia. It is predictable that differentiation on cervicography of low-grade dysplasias from these other processes is not reliable.[35] The relatively high frequency of nondiagnostic histologic findings after colposcopy, ie, 29.0 to 45.4 percent of colposcopy-directed biopsies, is also consistent with this range of false-positive findings.[36-38]

When cervicography is used as an adjunct to a Papanicolaou smear, the impact of a high false-positive rate would be a high-recall rate for repeat examinations or excessive referrals for colposcopic examination. Although only women with precancerous changes or cancer of the cervix are at risk for a false-negative test result, all women without disease who are screened are at risk for a false-positive result.[34]

Cervicography has a high sensitivity (low false-negative rate) for high-grade dysplasia. In six of the seven studies cervicography had a high sensitivity (89.5 to 100 percent) for high-grade dysplasia. In three of these studies, the sensitivity was 100 percent. The likelihood ratio for a negative test result ranged from 0.02 to 0.24 for high-grade dysplasia in six of the seven eligible studies.

The percentage of defective or unsatisfactory cervigrams poses a problem for general applicability of cervicography. There was a wide range in defective or unsatisfactory cervigrams; from 2.0 to 15.5 percent. A defective cervigram results from either improper technique or the inability to visualize the transformation zone adequately, a common problem in postmenopausal women. The study by Spitzer et al[33] was the only one to address the issue of cervicography in this group. They found that "cervicography for women over age 45 is probably not useful as 8 of 13 cervigrams were uninterpretable." If cervicography is recommended as a screening test or triage tool for patients with minor cytologic abnormalities, the procedure will be performed by many providers. It is likely that providers will have a rate of unsatisfactory cervigrams approaching the upper level of what has been reported (15.5 percent). A substantial number of repeat examinations will have an impact on the cost effectiveness of this test.

Cervicography as a Secondary Triage Tool

The impact of cervicography as a secondary triage tool depends heavily on the comparison strategy used for evaluating atypical or low-grade cytologic findings. It is critical to evaluate diagnostic test characteristics in the context of how the test will influence current practice. The test

characteristics delineated in this study show that cervicography can be useful in ruling out disease. The relatively high negative predictive value and low likelihood ratio for a negative result are desirable characteristics of a triage test. With the exception of one study, Schauberger et al,[30] the prevalence of high-grade lesions (pretest likelihood of disease) ranges from 3.8 to 7.2 percent, whereas the posttest likelihood of a high-grade lesion after a negative cervigram ranges from 0.0 to 1.0 percent.

Recently published practice guidelines allow for different management strategies to be applied to women with atypical or low-grade cytologic findings, that is, immediate colposcopy or watchful waiting with repeat Papanicolaou smears.[5] These guidelines seem to reflect practice variation in the community. The posttest likelihoods of high-grade lesions associated with a negative cervigram might be sufficiently low that clinicians who currently recommend immediate colposcopy for women with low-grade abnormal cytologic findings might want to consider a policy of repeat Papanicolaou smears instead of immediate colposcopy if the cervigram is negative. For these providers, cervicography could be useful as a secondary triage tool. Offering colposcopy only to patients with positive findings on a cervigram will decrease the number of colposcopies performed, and additional cases of high-grade dysplasia missed by the index Papanicolaou smear might be detected.

For providers who follow up with serial Papanicolaou smears to evaluate low-grade abnormalities, cervicography will result in many false-positive referrals for colposcopy. Although additional dysplastic lesions will be detected, whether there is a clinically meaningful advantage to earlier detection of such lesions is unclear. Thirty to 50 percent of low-grade lesions will regress, and it is unlikely that early detection will have an impact on outcome.[39-41] For high-grade lesions it is less clear whether more immediate detection directed by a positive cervigram will result in improved outcomes.

Cervicography as an Initial Screening Test

Only one study addressed cervicography as an initial screening test.[29] Cervicography had a higher sensitivity than cervical cytology (0.89 and 0.52, respectively) in this study. The specificity of the two techniques was similar (0.92 and 0.94). The study included many patients who had never been screened for cervical cancer by any method. It is likely that inclusion of these patients led to a higher rate of detected high-grade lesions. It will be important for future studies to address cervicography in previously screened populations.

These results suggest that it would be appropriate to undertake further studies comparing the clinical and economic efficiency of cervicography with that of cervical cytology as an initial screening test. Such a study is currently in progress.

Need for Rigorous Assessment of New Technology

This report highlights the importance of rigorously evaluating new technology before its dissemination. As noted by Reid et al,[9] "all new diagnostic technologies, before being 'released,' (should) receive a standardized assessment, using accepted methodological criteria." Improved "methodological standards could raise the quality of diagnostic test information, and the careful predissemination evaluation of diagnostic tests could eliminate useless tests before they receive widespread application."

The results of our analysis support these recommendations. Given the growing interest in alternative strategies for management of low-grade cytologic abnormalities and the increasing number of providers using cervicography, future studies on cervicography must employ rigorous methodologic standards.

Conclusions

Is cervicography a useful test in the evaluation of patients for cervical dysplasia? The claims made on behalf of cervicography are best summarized by Spitzer et al[33]: "Because patients are so unlikely to return for follow-up, we should optimize our opportunities for early cancer detection by using multiple screening techniques where possible rather than relying on follow-up smears at a later date." The available evidence indicates that the potential usefulness of cervicography is heavily dependent on the management strategy chosen by the provider. Whether patients with minor cytologic abnormalities should undergo immediate colposcopy or repeat Papanicolaou smears is not resolved by a cervigram. Additional, well-designed studies are needed to evaluate this new technology as both a screening test and a sec-

ondary triage test before its appropriate use can be defined. Such studies must address the deficiencies of previous research, including verification bias, appropriate selection and description of the population to be studied, the impact of interobserver variability, technical problems with cervigram interpretation, applicability in different age and risk groups, and impact on the costs of cervical cancer screening.

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