Women's Responses to Cervical Interrogation by Fluorescent and Reflective Spectroscopy

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■ **Abstract**

Objective. To determine women's responses to cervical interrogation by fluorescent and reflective spectroscopy (FRS).

Materials and Methods. A convenience sample of women scheduled for a colposcopic examination was interrogated by a cervical FRS system. Thereafter, women completed a 24-item questionnaire that assessed their responses to the spectroscopic test. Likert-scale responses were compared among subgroups using the χ^2 test for trend.

Results. Most women favored FRS used for locating (97.7%; 170/174) and selectively sampling (96.6%; 168/174) cervical neoplasia. Fewer women (81.0%; 141/174) wanted FRS to replace the Pap smear. Most women were neither nervous (73.6%; 128/174) nor bothered (89.1%; 155/174) by the extra time for the FRS assessment. Women's acceptance was substantiated by 84.9% (146/174) and 90.8% (157/173) wanting their doctor to have and insurance company to pay for FRS, respectively.

Conclusions. Use of FRS as a colposcopic adjunct was supported very favorably by women. Fewer women supported FRS replacing Pap smears. These high rates of approval by women should help the implementation of FRS technology. ■

Key Words: fluorescent and reflective spectroscopy, patient preferences, cervical neoplasia, cancer diagnosis

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Journal of Lower Genital Tract Disease, Volume 7, Number 3, 2003, 299–303

Many scientific engineering entities are developing sophisticated tests designed to assess for cervical neoplasia. These tests use various wavelengths of energy to accentuate tissue autofluorescence within the epithelium [1–4]. Distinct differences in the amplitude and mean wavelength of certain light emitted from or reflected by the interrogated tissue help to discriminate normal epithelium from cervical neoplasia. Researchers have measured the performance of these tests in comparison with cervical cytologic and histologic diagnoses. Preliminary results suggest several potential clinical roles for these novel, noninvasive, rapid, point-of-care diagnostic instruments.

Because colposcopic skills vary considerably and colposcopic diagnoses are not always in agreement with corresponding histologic interpretations, fluorescent and reflective spectroscopy (FRS) of the cervix may have usefulness by assisting colposcopists in locating cervical neoplasia and selectively sampling the most severe epithelium. Moreover, cervical spectroscopy may help to improve the sensitivity of cervical cytologic analysis if used simultaneously as a Pap smear adjunct test [1]. This new technology may also be used as an intermediate triage test conducted on women after a minimally abnormal Pap smear result (i.e., atypical squamous cells). Although currently unlikely, FRS eventually may replace the Pap smear, provided certain technical difficulties can be resolved.

Although the current developmental focus of FRS has been centered appropriately on the technical character-

istics of these tests, the human aspects should not be overlooked. How will women respond to assessment of cervical neoplasia by what appears to be a special flashlight connected to a computer? In what ways may women accept this technology in the evaluation of cervical neoplasia? We believe the answers to these questions and other pertinent issues are of concern to health care providers who eventually may use these tests in practice. The purpose of this study was to determine women's responses to fluorescent and reflective spectroscopic interrogation of their cervix. Further, we assessed how women may accept this technology when used for different diagnostic and management purposes.

MATERIALS AND METHODS

A convenience sample of 176 women who had completed an FRS examination of the cervix and a colposcopic examination at the Medical College of Georgia Gynecologic Cancer Prevention Center from May 2001 through October 2002 were invited to enroll in the trial. No women declined to participate. The FRS examination involved gently placing a small, hollow cylinder, attached to the spectroscopic device and computer (SpectRx Inc., Norcross, GA), on the ectocervix for approximately 5 minutes of interrogation. The exclusion criteria included age younger than 18 years, inability to read English, and unwillingness to complete a short questionnaire. Each woman was required to read and sign the institutional review board-approved informed consent document before participating.

After being evaluated with FRS, each subject completed a 24-item questionnaire that consisted of demographic information, personal and family medical history, and a series of questions pertaining to the FRS examination. The latter questions were answered using a 5-point Likert scale of agreement (5 = strongly agree, 3 = neutral, and 1 = strongly disagree). These questions assessed subject's responses to the duration and comfort associated with the examination, their preference for how FRS should be used (Pap smear and biopsy replacements, Pap smear adjunct, and aids to locate or selectively to sample potential cervical lesions), and their approval of the test. Subjects independently completed the questionnaire.

Statistical Analyses

Comparison groups were defined by women's history of Pap smear frequency and abnormal results, cervical biopsy, treatment, cancer and death of a family member or friend of cancer. Likert scale responses were compared between groups using the Mantel-Haenszel χ^2 test for trend.

RESULTS

Demographic and historical data of the 176 women enrolled in the study are seen in Table 1. In summary, this group also represents young, single, educated, and employed, but poor, women with an average of one child. Because all subjects were scheduled for a colposcopic examination, most (76.2%; 131/172) had a history of an abnormal Pap smear and 94.3% (149/158) had a Pap smear within the past year.

Many uses of FRS have been proposed. We assessed women's preferences for some of these uses (Table 2). A high level of agreement was noted for all potential uses. Colposcopic assistance in locating (97.7%; 170/174) and selectively sampling (96.6%; 168/174) cervical neoplasia achieved high rates of approval. Fewer women (81.0%; 141/174) supported FRS replacing the Pap smear.

We also assessed women's reactions to specific aspects of FRS (Table 3). The test made 26.4% (46/174)

Table 1. Demographic and Historical Data

Characteristic	Number (%)
Age (yrs)	
Range	29.8 (11.0)
Mean (SD)	15–69
Marital status	
Single or live-in	121 (62.7)
Married	33 (19.2)
Separated or divorced	26 (13.5)
Widowed	9 (4.7)
Number of children	
Range	1
Median	0–7
Employed	117 (60.3)
Mean household income	
<$10,000	86 (46.2)
$10,000–$24,999	64 (34.4)
$25,000–$49,999	25 (13.4)
>$50,000	11 (5.9)
Education	
Grade school	17 (8.9)
High school or GED	120 (62.5)
College	55 (28.7)
History of	
Last Pap smear ≤1 year	149 (94.3)
Abnormal Pap smear results	131 (76.1)
Cervical biopsy	97 (57.1)
Cervical surgery	70 (40.9)
Cancer	10 (5.9)
Family or friend history	
Abnormal Pap smear results	112 (67.1)
Death of cancer	93 (54.7)

Portions of this table replicated with permission [5].

Table 2. Subject's Preferences for Ways in Which Fluorescent and Reflective Spectroscopy Be Used

	Preferences, number (%)[f]				
		Strongly disagree		Strongly agree	
Use of spectroscopy	1	2	3	4	5
Pap smear replacement[a]	0 (0)	2 (1.1)	31 (17.8)	35 (20.1)	106 (60.9)
Biopsy replacement[b]	1 (0.6)	1 (0.6)	15 (8.6)	28 (16.1)	129 (74.1)
Locate cervical neoplasia[c]	1 (0.6)	0 (0)	3 (1.7)	12 (6.9)	158 (90.8)
Selective histologic sampling[d]	1 (0.6)	1 (0.6)	4 (2.3)	18 (10.3)	150 (86.2)
Pap smear adjunct[e]	5 (2.9)	2 (1.2)	15 (8.6)	22 (12.6)	130 (74.7)

[a]Next time, I would rather have the new light test instead of a Pap smear.
[b]If the new light test was as accurate as a cervical biopsy, I would rather just have the light test done.
[c]If the new light test helps doctors find the location of cervical disease (abnormal cells), I would want the test.
[d] If the new light test were able to help reduce the number of cervical biopsies (samples of tissue) taken from my cervix, I would want the new test.
[e]If the new light test and Pap smear used together were more accurate than the Pap smear alone, I would like to have both.
[f]Answered using a 5-point Likert scale of agreement (5 = strongly agree and 1 = strongly disagree). Number and percentage of strongly agree and agree responses.

of subjects feel nervous. The extra time required for the spectroscopic portion of their visit bothered 10.9% (19/174) of subjects. Nearly one third of subjects (30.9%; 54/174) indicated the spectroscopic examination was less comfortable than a Pap smear.

Given these specific responses to FRS, we assessed several other measures of acceptance. A vast majority of women (84.9%; 146/172) wanted their doctor to have this new test. Further, 90.8% (157/173) of subjects would want their medical insurance company to pay for FRS. Most importantly, 87.4% (153/175) of subjects would recommend FRS to a friend.

We compared women's responses to questions regarding proposed uses for FRS between groups defined by history of Pap smear frequency and abnormal results, cervical biopsy, treatment, cancer and death of a family member or friend of cancer. Several significant findings were noted. A greater percentage of women who had a Pap smear collected within the past year were more favorable toward FRS as an adjunct to the Pap smear (79.2%; 118/149, strongly favor) compared with women who had a Pap smear more than 1 year ago (55.6%; 5/9, strongly favor; Mantel Haenszel $\chi^2 = 4.44$; $p = .04$). Women with a history of an abnormal Pap smear result were more in favor of FRS being used as a colposcopic adjunct compared with women without a history of an abnormal Pap smear result (88.6% vs. 80.5% strongly agree; Mantel Haenszel $\chi^2 = 4.27$; $p = .04$). More women with a history of cancer compared with those without, 90.0% (9/10) and 59.5% (94/158), respectively, strongly supported FRS replacing the Pap smear (Mantel Haenszel $\chi^2 = 3.80$; $p = .05$). Similarly, a greater percentage of women with a family member or friend who had died of cancer compared with those who had none wanted FRS to replace the Pap smear (69.9% [65/93] and 53.3% [41/77], respectively; Mantel Haenszel $\chi^2 = 4.33$; $p = .04$).

CONCLUSIONS

Fluorescent and reflective spectroscopic equipment vary substantially in design and operation. Some prototypes require instrument contact with the cervix, whereas others do not. Interrogation times range from less than 1 minute to considerably longer. Several systems provide visual images of the cervix that can be

Table 3. Women's Responses to Fluorescent and Reflective Spectroscopy

	Agreement[a]				
		Strongly disagree		Strongly agree	
Reactions	1	2	3	4	5
Spectroscopy less comfortable than Pap smear	55 (31.4)	21 (12.0)	45 (25.7)	19 (10.9)	35 (20.0)
Bothered by extra time for spectroscopy	87 (50.0)	36 (20.7)	32 (18.4)	11 (6.3)	8 (4.6)
Spectroscopy made me nervous	68 (39.1)	21 (12.1)	39 (22.4)	29 (16.7)	17 (9.8)

[a]Answered using a 5-point Likert scale of agreement (5 = strongly agree and 1 = strongly disagree). Reported as number and percentage (%) of responses.

shared with patients. These characteristics may be altered somewhat if prototype design is significantly modified for commercial units. The potential variations of FRS systems should be realized in context with our study. Nonetheless, the general principles of this technology will remain constant.

Our study results suggest that women may respond favorably to FRS. Nearly three of four women believed the spectroscopic examination was at least as comfortable as a Pap smear. This response was better than expected because the spectroscopic instrument used required contact with the ectocervix. Discomfort from a Pap smear is usually attributed to obtaining an endocervical specimen. Comfort likely would decrease if a probe were used also to interrogate the endocervical canal. Presently, endocervical interrogation is unlikely because of technical design difficulties.

Total interrogation time is determined mainly by how many wavelengths of energy are used for tissue fluorescent and reflective measurements. In general, the greater the number of wavelengths incorporated in the instrument, the greater the potential accuracy of the instrument. However, there are time limits that both women and clinicians reasonably would be willing to tolerate. Ninety percent of subjects were not bothered by the extra time FRS added to their examination. The perceptions of added value and novelty probably influenced women's responses. Although not formally assessed, clinicians performing the spectroscopic examination seemed less tolerant of the additional time involved.

Pap smears are known to create anxiety for many women. However, only one quarter of women in our study reported being nervous with the spectroscopic examination. We were unable to determine the source for this nervousness. Many of these women had a cervical biopsy or cervical surgery in the past. Consequently, they may be less likely to be intimidated by the noninvasive test. However, most of these women sought treatment at the clinic because of an abnormal Pap smear result. Given this circumstance, we would expect some mild anxiety from many of the subjects [6].

The ideal role for FRS in the screening, diagnosis, and management of women with cervical neoplasia is unknown. Several uses have been proposed, ranging from a colposcopic adjunct to a primary screening instrument. Women in our study were very supportive of any spectroscopic application. The greatest approval was for colposcopic adjuncts and for assistance with locating and selectively sampling cervical neoplasia. Finding the source of abnormal cytologic results can be problematic at times even for experienced colposcopists. Novice colposcopists have the tendency to biopsy excessively, which causes unnecessary discomfort and increased cost. Thus, a colposcopic adjunct may be beneficial for women and clinicians. Replacing the Pap smear was viewed least favorably by subjects. Fortunately, this usefulness may be the least promising for health care providers, also. Regardless, 81% of women were receptive to this prospect, much more than we had anticipated.

Personal history influenced women's support of FRS used in different capacities. Women compliant with annual Pap smears were more likely to want FRS used as a Pap smear adjunct. Noncompliant women probably are more indifferent with respect to their health. More women with a history of an abnormal Pap smear wanted FRS used as a colposcopic adjunct compared with women without a previous abnormal Pap smear. Naturally, the former group had more interest in assuring their well being. It was surprising that more women with a history of cancer favored FRS as a replacement for cervical cytologic analysis. Women's acceptance of a novel, unproven cancer screening technology may be explained by their knowledge of the inaccuracy of cervical cytologic analysis. This also may be the explanation for why women with relatives or acquaintances who had cancer were more supportive of FRS used as a replacement for the Pap smear.

In general, women seemed to accept this technology at unexpectedly high levels. This was evidenced by wanting their physician to use the test. Further, they wanted insurance companies to pay for it. Of particular significance, most would recommend FRS to a friend. New technology is not always as warmly embraced. The next hurdle will be to gain Food and Drug Administration approval and acceptance by health plan directors. However, we do not know whether health care practitioners will accept FRS readily. We suspect most well-trained and experienced colposcopists will shun FRS used as a colposcopic adjunct. Novice colposcopists may find FRS useful as a temporary training aid. Yet, these beginning colposcopists must understand that a normal FRS evaluation should not necessarily imply absence of cervical neoplasia. Similarly, an abnormal FRS result at the time of a normal colposcopic examination may indicate occult neoplasia and may merit cervical biopsy. Proper inspection of the entire transformation zone is of paramount importance. One of the greatest challenges confronting colposcopists is inspection of the endocervical canal. Presently, FRS equipment is incapable of offering endocervical assessment assistance or

determination of adequate transformation zone evaluation. Hence, these simple systems will not replace colposcopy in the near future. However, based on our study results, it seems that implementation will not confront major obstacles from our patients.

Acknowledgments

SpectRx Inc., Norcross, GA, provided the fluorescent and reflective spectroscopy equipment for this trial, but did not provide any financial assistance for this independent study. The authors thank Ms. Balasubha Dhandapani for the assisting with data entry and Mrs. Tecia German for helping with manuscript preparation.

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