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Distress after an abnormal Pap smear result: scale development and psychometric validation

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Abstract

Background. Psychological distress is severe in women who receive a report of abnormal findings on Pap smear, and may be one reason 10–61% of such women fail to undergo follow-up testing.

Methods. Using the 14-question Psychosocial Effects of Abnormal Pap Smears Questionnaire (PEAPS-Q) as a basis, we developed the 23-question Cervical Dysplasia Distress Questionnaire (CDDQ), testing its internal consistency and validity with 661 women undergoing colposcopy after an abnormal Pap smear finding in a three-phase analysis.

Results. Items were divided into two sets and factor analyzed separately: one addressed distress during medical procedures, and the other concerned perceived consequences of an abnormal Pap smear. The medical procedures items yielded two factors: embarrassment regarding the procedures and discomfort/tension with the procedures. Factor analysis of the second set also resulted in two factors: concern about sexual and reproductive issues and concern about health consequences. Subscales created from items loading highly on each factor had high internal consistency (α ranged from 0.76 to 0.90) and demonstrated good concurrent validity with other psychometrically validated measures of distress.

Conclusions. The CDDQ is a reliable and valid questionnaire for measuring multiple domains of distress unique to women who test positive on a cervical cancer screening test.

Keywords: Cervical intraepithelial neoplasia; Cervical cancer; Cervical smears; Cervix dysplasia; Distress; Papanicolaou smear; Psychometrics; Questionnaires

Introduction

Although rates for cervical cancer screening among healthy women are high, failure to present for follow-up evaluation after abnormal Papanicolaou (Pap) smear findings is a serious problem [1,2], particularly in women who are low SES [3], inadequately insured, younger than 30 [4], and African-American [5]. Recent reviews indicate that nonadherence to initial colposcopy and subsequent treatment range from 10% to more than 40% [6,7]. One inner city intervention study found even higher nonadherence rates to follow-up colposcopy, ranging from 39% to 61% [8]. Although overall rates of cervical cancer deaths have declined dramatically since the introduction of the Papanicolaou smear test, undergoing Pap smear tests is useless if further diagnostic testing and treatment do not follow abnormal screening results. Up to 15% of invasive cervical cancer cases had not received proper follow-up for abnormal Pap smear [9].

Three reasons for nonadherence to follow-up recommendations after an abnormal Pap test result are delays among appointments, healthcare providers' inadequate communication of the importance of follow-up care, and psychological distress. Multiple visits and delays of up to 6 months between appointments are built into the standard evaluation and treatment process after an abnormal test result. As a result, many women report that forgetting their appointment

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is an influential factor in nonadherence [8]. Second, communication about the importance of follow-up care and the meaning of the abnormal Pap test result is often inadequate [6,10]. Third, psychological distress resulting from receiving an abnormal Pap result may act as a barrier to follow-up care [11,12]. Several studies have documented high levels of distress, intrusive thoughts, and avoidant coping after an abnormal Pap smear result [13–16]. The majority of women interpret the abnormal result as a report of invasive cancer [12,17]. Younger women report that the fear of loss of reproductive functioning is as distressing as the prospect of cancer [15,17]. Other feelings of distress may include a sense of shame or guilt concerning their positive test result. Increased public awareness about the role of the sexually transmitted human papillomavirus (HPV) in cervical cancer also negatively impacts patients' feelings about their bodies and their perceived feelings of responsibility in developing cervical dysplasia [14]. For example, one study of 20 CIN patients who completed semistructured interviews reported that 60% of women reported a change in their sexual activity; their most prevalent underlying reason was a sense of contamination [14].

Research has indicated that psychological distress may increase nonadherence to follow-up colposcopy by undermining coping strategies. Women with abnormal Pap smear result report that anxiety and fear of the procedure as well as fear of cancer and possible loss of reproductive functioning are potential barriers to adherence for follow-up colposcopy [12]. Women with high distress after an abnormal Pap were more likely to exhibit avoidant rather than adaptive coping strategies [15], making it more likely that nonadherence would occur [14]. The distress associated with an abnormal Pap smear result occurs among a wide range of specific domains (cancer worries, reproductive worries, fears of the medical follow-up procedures, and negative impact on sexual self-schema), [15,17] making it more difficult for women to cope effectively with the distress.

The first generation of descriptive studies used open-ended and semistructured interviews to reveal a complex picture of high levels of distress in women related to several specific domains after an abnormal Pap result [14,15,18]. Such research has been key in establishing the importance of psychosocial functioning in these women. The next step in the field is to measure not only the intensity of general distress, but also to measure distress related to the areas of concern specific to positive screenings for cervical cancer. There is a need for a validated measure that can assess domains such as fear of cancer and dying, fears of loss of reproductive functioning, sexual concerns, and fear of diagnostic and treatment procedures for cervical cancer. Previous research in this area has tended to rely on such general measures of psychological distress as the General Health Questionnaire (GHQ) [16]. Other studies have investigated behavioral factors in nonadherence to follow-up colposcopy using non-validated instruments [12]. One analytically derived measure that was specifically developed for women who tested positive on cervical cancer screening, the Abnormal Smears Questionnaire [13], provides subscale scores on procedural distress, smear result distress, and negative cognitions. However, the items were generated during a single development phase (40 colposcopy and laser excision patients participating in semistructured interviews during their appointments) and did not benefit from expert review [19]. Others have criticized the study's small validation sample size ($n = 80$) [20].

Another measure, the Psychosocial Effects of Abnormal Pap Smears Questionnaire (PEAPS-Q), was developed in Australia to measure distress in women undergoing follow-up testing after an abnormal Pap test result [20]. The final version of the scale, which was derived from factor analysis, contains 14 items and four subscales: experience of medical procedures, feelings about cervical abnormality/changes in self, worry about infectivity (infecting others sexually), and effect on sexual relationships. The PEAPS-Q was initially drawn from a pool of more than 200 items generated from individual interviews and from four focus groups of women representing varying levels of age, education, and history of ever having a Pap smear who were attending their first colposcopy or attending follow-up colposcopy. Five independent expert researchers then culled out ambiguous or repetitious items, resulting in 41 core items and five identified domains of concern. The final version of the scale was validated with the GHQ on a sample of 350 women who had either received notification of an abnormal Pap result and were attending their first colposcopy ($n = 93$), or women who were attending follow-up colposcopy ($n = 257$). Test–retest reliability over the overall scale was high ($r = 0.88$) and internal consistency was good ($\alpha = 0.84$).

Interested in evaluating specific distress domains in women with abnormal Pap smears, we identified the PEAPS-Q [20] as a potential method for measuring their distress during optical spectroscopy, which is an experimental technology used in screening and diagnosing cervical cancer. In this study, women were assessed for distress while undergoing follow-up procedures after abnormal Pap, including optical spectroscopy, colposcopy, and biopsy. Because the PEAPS-Q was developed in Australia, we anticipated that some revisions would be necessary to make it more understandable for a sample of U.S. and Canadian women. Therefore, we undertook an effort to modify the PEAPS questionnaire; after significant modifications, it was renamed the Cervical Dysplasia Distress Questionnaire (CDDQ). Here, we present information on the steps taken to modify the PEAPS-Q as well as psychometric data on the CDDQ's internal consistency and validity.

Materials and methods

Background study

Data were collected as part of an NCI-funded program project evaluating optical spectroscopy as a screening and

diagnostic tool for the diagnosis of cervical dysplasia. One of the studies on the program project compared pain and distress ratings for patients with abnormal Pap result during each of the following procedures: optical spectroscopy, Pap smear, and colposcopically directed biopsy.

Study design and sample

Participants ($n = 661$) were eligible for the present study if they were (1) 18 years or older, (2) not pregnant, and (3) referred for colposcopy because of an abnormal Pap smear, or had received an abnormal Pap smear result in the last 12 months. The sample had the following ethnic breakdown: 46% were non-Hispanic White, 22% were African-American, and 28% classified themselves as Hispanic. The sample was recruited from six clinical sites: the Gynecologic Oncology Clinic at The University of Texas M.D. Anderson Cancer Center (UTMDACC), the Harris County Hospital District Lyndon B. Johnson Hospital Clinic (LBJ), the Cancer Prevention Clinic at UTMDACC, Vancouver General Hospital Colposcopy Clinic, the Houston Medical Center (HMC), and the Hermann Professional Building (HPB). HMC and the UTMDACC clinics see primarily white, insured patients, whereas HPB and LBJ Hospital see a triethnic group of patients (white, African-American, and Hispanic) who are typically uninsured or have Medicaid.

The CDDQ was developed in three phases with three separate samples. In the first phase, the original 14-item PEAPS-Q was administered to assess distress in a sample of 253 colposcopy patients. Of these, 52 women who were attending the colposcopy clinic for follow-up colposcopy also completed a cognitive interview about the PEAPS-Q to elucidate problems in interpretation of its questions or response options. The actual cognitive interview process is described in more detail in the next section, Data collection procedures. Feedback from the participants' cognitive interviews were then used to modify the original PEAPS-Q and to generate 20 new items for the next phase of development. The remaining 201 participants in phase 1 were participants in the background spectroscopy study. As part of this background study, these women completed additional pain, anxiety, and distress questionnaires in addition to the PEAPS-Q. Of these 201 women, 37% of the patients were newly referred for colposcopy following an abnormal Pap smear and 63% were women who had volunteered for the background study and who had a history of abnormal Pap smear within the past year. Unlike the referral patients, women who volunteered for the study came to the clinic voluntarily based on their response to media ads advertising the study's free diagnostic and follow-up care, and based on the eligibility requirement of having a history of an abnormal Pap smear within the past year.

For phase 2, the PEAPS-Q was modified based on results from phase 1's initial factor analysis and feedback from the cognitive interviews. The modified PEAPS-Q was then administered to a new sample of 89 colposcopy patients. Of these, 60 women completed a cognitive interview about the modified PEAPS-Q. These 60 women who completed the cognitive interviews were patients who were attending colposcopy clinic for follow-up colposcopy. The remaining 29 patients in phase 2 were enrolled into the background spectroscopy study and thus completed the same pain, anxiety, and distress questionnaires as in the previous phase. Of these 29 women, 31% were newly referred colposcopy patients and 69% were women with a history of abnormal Pap attending colposcopy clinic for the background study.

For phase 3, the questionnaire items were modified again based on the results from phase 2's cognitive interviews, and two of the new items were dropped since they were not easily understood by patients in phase 2. The modified items were administered to a new sample of 319 patients undergoing colposcopy. Of these, 143 women completed cognitive interviews about the modified items to assess further concerns about the interpretability of the items. As with phases 1 and 2, all women who completed the cognitive interview were patients who were attending colposcopy clinic for follow-up colposcopy. Of the 143 women completing cognitive interviews, 12 women who spoke Spanish as a first language were given a Spanish translation of the questionnaire. The cognitive interviews were conducted in Spanish by two Spanish-speaking members of our research team, resulting in minor changes in the Spanish wording of the items. The remaining 176 patients in phase 3 were enrolled into the background spectroscopy study and completed the pain, anxiety, and distress questionnaires in addition to the modified questionnaire items. Of these 176 women, 70% were newly referred colposcopy patients and 30% were women with a history of abnormal Pap attending colposcopy clinic for the background study.

Data collection procedures

After consenting to participation, all patients completed an interview with a female interviewer to assess demographic variables. Immediately following her colposcopy, the participant completed the questionnaire (either the PEAPS-Q or modified versions of the PEAPS-Q, depending on the phase of development for the CDDQ). It was at this time that she also completed a cognitive interview, if applicable (i.e. she was a follow-up colposcopy patient as opposed to a newly diagnosed referral patient or a volunteer for the background study). For the cognitive interviews, the participant was asked to repeat each question of the questionnaire in her own words, report any difficulties she experienced in responding, identify words that were difficult to understand, provide specific examples of actions implied by the responses, report how difficult it was to generate a response, report alternatives that would facilitate a clearer or easier response, and report any other information that might elucidate understanding of the question or the response process [21].

If the participant was enrolled in the background spectroscopy trial, the participant completed the state anxiety and depression measures before the procedures. Then a

female interviewer accompanied the patient into the exam room to assess the patient's pain and anxiety ratings during the Pap smear, colposcopy, spectroscopy, and biopsy procedures. Immediately following the examination, the participant completed measures of state anxiety, cancer worry, and the PEAPS-Q (or CDDQ, depending on the phase of development of the CDDQ).

Measures

For patients who completed the pain and distress procedures, pre- and postexam state anxiety was measured with the Spielberger State-Anxiety Scale [22]. The pain and anxiety ratings taken during the medical procedures were rated on a 0- to 10-point scale. Such single-item scales have been used in studies of distress during gynecologic exams and they have been found to differentiate between experimental conditions designed to influence pain and anxiety and are sensitive to changes in pain and anxiety over the course of a colposcopic examination [23–25]. After the procedures, widely used questionnaires with tested validity and reliability were used to assess distress, including the Spielberger State-Trait Anxiety Inventory [22] and Center for Epidemiological Studies Depression Scale [26], and Cancer Worry [27]. While other measures of Cancer Worry exist, this particular measure represented the state of the science at the time. Its brevity also ensured that it could be easily integrated into the interview.

Measurement and analysis procedures

By the third phase of development, results from the cognitive interviews indicated no further concerns about the interpretability of the CDDQ items. Therefore, it was decided that no additional changes to the items themselves were needed. The factor analysis on this final set of questionnaire items yielded the CDDQ and is presented in the Results section.

For the two sets of CDDQ items, distress and medical procedures, the following procedures occurred. First, the distributions of the items were examined, and items with skewness values above 3.0 or kurtosis values greater than 10 were dropped. The items were then divided into two groups, depending on whether they referred to distress resulting from the colposcopy and related medical procedures, or from concerns about the consequences of having an abnormal Pap smear. These two sets of items were factor analyzed separately because we anticipated that they might be used separately in different situations. Because the maximum likelihood method produced a Heywood case (items with communality greater than 1.0), alpha factoring extraction was used instead, with oblique rotation. Items that had factor loadings above 0.40 onto the factors were retained in the final solution.

In the factor analysis process, items with low communality (<0.30) were dropped, as were items that loaded heavily on more than one factor. Such items were dropped one at a time, until a solution was reached in which all communalities were above 0.30 and all items loaded at least 0.40 on only one factor. The number of factors chosen for the final solution was based on the criteria that all factors should account for at least 10% of the variance and that the percentage of residuals above 0.10 in absolute value would be 10% or less.

To assess the concurrent validity of the CDDQ, Pearson correlation coefficients were calculated between the subscales generated by the factor analysis in phase 3 and the CES-D, Spielberger State Anxiety Scale, Cancer Worry Scale, and the one-item Pain and Anxiety ratings. Cronbach's alpha was used to assess the internal consistency of the CDDQ subscales.

Results

Item and factor analyses

Phase 1

Results from the initial factor analysis of the original 14-item PEAPS-Q did not replicate the four-factor structure of Bennetts et al. [20] (experience of medical procedures, beliefs/feelings about cervical abnormality and changes in the perception of self, worry about infectivity, and effects on sexual relationships). Instead, a three-factor solution was found to be the best fit to the data (experience of medical procedures, distress about health consequences, and distress about sexual consequences). The reliability of these subscales had moderate to high internal consistency (Cronbach's $\alpha = 0.73–0.87$), but the results of the cognitive interviews indicated problems with the interpretation of certain questions, particularly those from the experience of medical procedures subscales. For example, when asked, "Did you find the procedures uncomfortable?" some participants interpreted "uncomfortable" to mean emotionally uncomfortable, while others interpreted it to mean painful or in a physically uncomfortable position.

Phase 2

To remedy the problems with question interpretation, we composed 20 additional questions for each of the three factors. The questions were developed based on the phase 1 participants' rewording of the original questions and additional concerns they identified, such as issues of being emotionally upset by the medical procedures (as opposed to physical discomfort), attractiveness to sexual partners, and specific worry about the test results, cancer, and the possibility of dying from cervical cancer. These were administered to 89 patients undergoing colposcopy, with 60 completing a cognitive interview as well. The main issue identified in this phase was that some patients did not understand the use of the term *test* to refer to parts of the examination, and so the word exam, which they did under-

stand, was substituted. In addition, two of the new questions were not easily understood by patients and so were dropped.

Phase 3

The third phase of the pilot test enrolled 319 colposcopy patients and demographics of this sample are presented in Table 1. Although we did not collect data on the socioeconomic status of the sample, we did collect information on educational level as a proxy measure, and approximately half (48%) of the sample had 12 years of formal education or less. Twenty percent of the sample did not attain a GED level of education: 12% women completed at least some high school and 8% dropped out before the ninth grade. Women who volunteered for the screening and diagnostic trial were more likely to be college educated (79%) compared to the women who were referred to the colposcopy clinic (47%). However, the ethnic breakdown of the volunteer and referred samples was similar. One hundred and forty-three colposcopy patients completed the questionnaire items and a cognitive interview, and 176 colposcopy patients completed the questionnaire items in addition to an interview about the optical spectroscopy procedure. No major concerns about the interpretation of the questions arose in phase 3.

In the analysis of the resulting pool of questionnaire items, we decided to do separate factor analyses on items relating to distress regarding the colposcopy examination procedures (*medical procedures*) and worry about the consequences of having an abnormal Pap smear (*distress*) because the two sets of items might be used at different times for different purposes.

Table 1
Demographic profile of sample

Characteristic	Frequency	%
Age (years)		
18–29	125	39.2
30–39	78	24.5
40–49	76	23.8
50–59	27	8.5
60–69	6	1.9
70–79	5	1.6
80–89	1	0.3
Ethnicity		
White	147	46.2
African-American	70	21.9
Asian/Pacific Islander	7	2.2
American Indian	1	0.3
White Hispanic	88	27.7
Black Hispanic	2	0.6
Other	2	0.6
Education		
Elementary school (grades 1–8)	24	7.5
Some high school (grades 9–11)	38	11.9
Grade 12 or GED	90	28.3
Some college (1–3 years)	89	28.0
College and above (4 years or more)	77	24.2
Marital status		
Never married	71	22.3
Married or living with partner	163	51.1
Divorced or separated	71	22.3
Widowed	13	4.1

Medical procedures

Of 15 questions about the patient's experience of the medical procedures, four were dropped because of their distributions being highly skewed (skewness > 3.0), making them inappropriate for factor analysis. The remaining 11 items were factor analyzed using the alpha factoring extraction method with oblique rotation. Three additional questions (''Did you feel you had control over the things that were done to you during the exam?'' ''Was your body relaxed?'' and ''Did you feel you were in a helpless or vulnerable condition?'') were dropped one at a time from the factor analytic model because of low correlation with the overall solution (communalities for all three items were below 0.30).

A final solution of two correlated factors was selected as the most parsimonious and best fit to the data. The two-factor solution resulted in just 10.7% of the fitted residuals with values greater than 0.10. All items had loadings above 0.40 on either factor 1 or factor 2. The two factors were a six-item ''discomfort and tension'' factor (factor 1) and a two-item ''embarrassment'' factor (factor 2). Factor 1 accounted for 42.9% of the variance and factor 2 accounted for an additional 11.5% of the variance. Table 2 presents the results of the two-factor solution for the medical procedures items. Both the factor pattern, which includes the item loadings, and the factor structure are presented. The structure matrix takes into account the interrelatedness of the two factors, which resulted from the oblique rotation. The two factors had a substantial intercorrelation coefficient of 0.46.

Distress items

None of the 17 questions about distress due to an abnormal Pap smear were dropped from the analysis for reasons of skewness, as all items' distributions had skew values below 3. The 17 items related to distress about the consequences of having abnormal Pap smear findings were also factor analyzed using the alpha factoring extraction method with oblique rotation. One of the questions (''Do you feel your health keeps getting worse?'') had to be dropped because of its low communality. In the analysis of the remaining 16 questions, a solution with two correlated factors was selected as the most parsimonious and best fit to the data. Each factor accounted for >10% of the variance, and only 7.6% of the residuals were greater than 0.10. An additional item, ''Have you had the feeling that you are not as healthy as you thought you were?'' was dropped from the model because of low, equal loadings on both factors, resulting in 15 remaining questions.

In the final two-factor solution, nine items loaded onto the first factor (factor 1) describing concerns about sexual

Table 2
Factor loadings and communality estimates for the medical procedures items

Questions	Factor pattern		Factor structure		Communality estimates
	Factor 1, tension and discomfort	Factor 2, embarrassment	Factor 1, tension and discomfort	Factor 2, embarrassment	
Tension and discomfort					
Did you find the exams uncomfortable?	0.66	0.07	0.70	0.38	0.50
Did you find the exams emotionally upsetting?	0.57	0.03	0.58	0.30	0.34
Did the exams make you nervous?	0.82	−0.04	0.80	0.33	0.63
Did the exam hurt?	0.68	−0.03	0.66	0.28	0.44
Did you feel tense?	0.79	0.01	0.80	0.38	0.64
Were you nervous?	0.73	0.03	0.72	0.38	0.51
Embarrassment					
Were you uncomfortable being partly undressed?	−0.06	0.92	0.36	0.89	0.80
Were you embarrassed having your private parts touched by the doctor or nurse?	0.07	0.67	0.38	0.70	0.50

and reproductive consequences, which accounted for 36.7% of the variance. One item, "How worried are you that you will lose your chance to have a baby?" had low loadings on the two factors (0.29 and 0.20, respectively), but was kept in the analysis since it was the only item in the sample pool which addressed reproductive concerns. Furthermore, it would not necessarily be expected that this item would load highly onto either of the two factors since the sexual items addressed concerns about decline in sexual functioning and attractiveness, and the health concerns were cancer-related. The remaining six items had high loadings on a second factor (factor 2) about concerns with health consequences and accounted for an additional 11.4% of the variance. Table 3 presents the results of the two-factor solution for the distress items. Both the factor pattern, which includes the item loadings, and the factor structure are presented. The structure matrix takes into account the interrelatedness of the two factors, which resulted from the oblique rotation. The correlation between the two factors was 0.49.

Table 3
Factor loadings and communality estimates for the distress items

Question	Factor pattern		Structure pattern		Communality estimates
	Factor 1, sexual consequences	Factor 2, health consequences	Factor 1, sexual consequences	Factor 2, health consequences	
Sexual and reproductive consequences					
How worried are you that you would lose your chance to have a baby?	0.29	0.20	0.39	0.35	0.19
Have you been worried that you could give the problem to a sexual partner?	0.74	−0.04	0.72	0.32	0.52
Have you been worried whether a sexual partner will think they can catch the problems from you?	0.70	−0.07	0.66	0.27	0.45
Have you been worried whether you should continue having sex?	0.75	−0.02	0.74	0.35	0.55
Have you been worried that this problem might affect how attractive you are to your sexual partner?	0.56	0.14	0.63	0.41	0.41
Have you been worried whether having sex will make the problem worse?	0.67	0.09	0.72	0.42	0.52
Have you been worried whether others think you have had more sexual partners than you should?	0.46	0.08	0.50	0.31	0.26
Have you been worried about sex being more painful now?	0.63	−0.06	0.60	0.25	0.36
Have you been worried that this problem might affect how much you enjoy sex?	0.69	−0.05	0.67	0.30	0.45
Health consequences					
How worried are you that cancer will appear in your body?	−0.13	0.81	0.30	0.73	0.54
Have you worried about the test results?	0.11	0.64	0.40	0.70	0.49
Have you worried that you may have cancer?	0.02	0.83	0.41	0.85	0.72
How worried are you that you might die?	0.02	0.76	0.37	0.76	0.57
Have you been worried that your problem may turn into cancer?	0.06	0.85	0.47	0.88	0.78
How worried are you that you might die from cervical cancer?	0.07	0.74	0.41	0.75	0.57

Table 4
Descriptive statistics, reliability, and validity of the CDDQ

Scale	Mean	SD	Reliability	Correlation with					
				Pain during colposcopy	Anxiety during colposcopy	Preexam anxiety	Postexam anxiety	Cancer worry	Depression
Discomfort and tension during medical procedures	2.14	0.74	0.86	0.38***	0.55***	0.36***	0.54***	0.27**	0.30**
Embarrassment due to medical procedures	1.54	0.82	0.76	0.14	0.19*	0.26***	0.32***	0.29***	0.23**
Concerns related to sexual consequences	1.52	0.63	0.85	0.22*	0.19*	0.27***	0.22**	0.38***	0.23**
Concerns related to health consequences	2.26	0.87	0.90	0.11	0.30***	0.48***	0.43***	0.68***	0.38***

* $P < 0.05$.
** $P < 0.01$.
*** $P < 0.001$.

Formation of subscale scores, internal consistency, and concurrent validity of scales

Medical procedures subscales

When the six items on the discomfort and tension factor (factor 1) were combined, the resulting scale had a high internal consistency (Cronbach's $\alpha = 0.86$). As shown in Table 4, the discomfort and tension factor correlated most highly with conceptually related variables, namely, pain and anxiety ratings during colposcopy ($r = 0.38$ and 0.55, respectively), and with pre- and postexam state anxiety ($r = 0.36$ and 0.54). Other significant but smaller correlations were with cancer worry ($r = 0.27$) and depression ($r = 0.30$). The two items that loaded heavily on factor 2 were related to embarrassment during the exam. The resulting embarrassment subscale had an internal consistency of 0.76. Correlations of the embarrassment factor with conceptually related variables are also presented in Table 4. The embarrassment factor showed significant but small correlations with anxiety ratings taken during the colposcopy procedure ($r = 0.19$) as well as state anxiety assessments taken before ($r = 0.26$ and after the exam ($r = 0.32$). The embarrassment factor also showed significant but small correlations with cancer worry ($r = 0.29$) and with depression ($r = 0.23$).

Distress items subscales

The sexual consequences subscale had high internal consistency (Cronbach's $\alpha = 0.85$) and the health consequences subscale had good internal consistency as well ($\alpha = 0.90$). As with the two medical procedures distress subscales, we examined correlations with conceptually related variables to evaluate the validity of the distress subscales (Table 4). The sexual consequences factor correlated most highly with cancer worry ($r = 0.38$). Other significant but small correlations were with preexam anxiety ($r = 0.27$), depression ($r = 0.23$), anxiety during colposcopy ($r = 0.19$), and with postexam assessments of state anxiety ($r = 0.27$). As would be expected, the health consequences factor

Table 5
Mean subscale scores and standard deviations by demographic group

		Discomfort		Embarrassment		Sexual consequences		Health consequences	
		Means	SD	Means	SD	Mean	SD	Mean	SD
Marital status	Never Married ($n = 71$)	2.36[a]	0.75	1.51	0.80	1.75[b]	0.74	2.42	0.71
	Married ($n = 163$)	2.05[a]	0.68	1.50	0.73	1.48[b]	0.61	2.23	0.88
	Divorced or Separated ($n = 69$)	2.12	0.80	1.58	0.94	1.43[b]	0.49	2.17	0.86
	Widowed ($n = 13$)	2.10	0.76	1.92	1.20	1.21	0.38	2.26	0.93
Education	Grades 1–8 ($n = 23$)	2.03	0.53	1.63	0.98	1.52	0.58	2.78[c]	1.03
	Grades 9–11 ($n = 38$)	2.27	0.76	1.67	0.94	1.70	0.72	2.57[c]	1.01
	Grade 12 or GED ($n = 90$)	2.09	0.80	1.63	0.89	1.48	0.64	2.18[c]	0.84
	College 1–3 years ($n = 88$)	2.23	0.74	1.45	0.72	1.47	0.54	2.24[c]	0.85
	College ≥ 4 years ($n = 77$)	2.05	0.69	1.44	0.73	1.55	0.66	2.07[c]	0.72
Age	≤median age of 33 ($n = 161$)	2.24[d]	0.75	1.50	0.70	1.71[e]	0.69	2.29	0.81
	>median age of 33 ($n = 155$)	2.02[d]	0.71	1.58	0.93	1.32[e]	0.48	2.22	0.93
Ethnic group	White ($n = 146$)	2.12	0.73	1.43	0.72	1.48	0.58	2.19	0.77
	Black ($n = 70$)	2.08	0.71	1.66	0.93	1.52	0.61	2.15	0.87
	White Hispanic ($n = 87$)	2.22	0.78	1.68	0.91	1.61	0.16	2.51	1.01

[a] Women who were never married reported more discomfort with the medical procedures compared to women who were married, $P < 0.05$.
[b] Women who were never married were more likely to report concerns about sexual and reproductive consequences than women who were married, divorced, or widowed, $P < 0.05$.
[c] Women with a high school education and above were less likely to report concerns about health consequences, compared to women who did not complete high school, $P < 0.05$.
[d] Women aged 33 and below reported more discomfort with the medical procedures compared to women above the median age of 33 $P < 0.01$.
[e] Women aged 33 and below were more likely to report concerns about sexual and reproductive consequences than women who were above age 33, $P < 0.001$.

correlated highest with cancer worry (r = 0.68) and was highly correlated with state anxiety ratings taken before (r = 0.48) and after the exam (r = 0.43). It showed smaller but significant correlations with anxiety during colposcopy (r = 0.30) and with depression (r = 0.38).

In Table 5, the four mean subscale scores and standard deviations are presented by demographic group. Differences in subscale scores were tested with ANOVA, and significant differences were analyzed post hoc with a Tukey's HSD correction. Women above the median age of 33 were less likely to report discomfort with the medical procedures compared to younger women ($P < 0.01$), and they were also less likely to report distress about sexual and reproductive concerns ($P < 0.05$). Women who had never married were more likely to report concerns about sexual and reproductive issues compared to married, divorced, or widowed women (all comparisons, $P < 0.05$), and more discomfort with the medical procedures compared to married women ($P < 0.05$).

Discussion

The CDDQ is a 23-item questionnaire that was factor-analytically developed in three consecutive phases with 661 women referred for colposcopy after an abnormal finding on a Pap test. The CDDQ can be used to measure the participant's perception of diagnostic procedures themselves, the participant's distress concerning the consequences of testing positive on a screen for cervical dysplasia, or both. Furthermore, as we study the psychosocial and behavioral consequences of providing women with results on HPV testing, optical spectroscopy, and other diagnostic procedures, the CDDQ's distress regarding sexual consequences subscale may be a useful assessment tool since there is no other comparable instrument to measure this domain. The need for a validated instrument is underscored by studies which investigated behavioral factors for nonadherence to colposcopy with a nonstandardized instrument [12]. Furthermore, careful and objective assessment of specific domains of distress can guide targeted intervention to address potential sources of nonadherence to follow-up procedures following abnormal Pap smear result.

All four subscales generated by the factor analysis demonstrated good internal consistency. The two subscales associated with the medical procedures items, embarrassment and discomfort/tension, demonstrated overall good concurrent validity with conceptually related constructs. The embarrassment subscale was expected to be correlated with anxiety, but not pain. This was supported for pain during colposcopy, and modestly so with anxiety (for which there were significant but moderate correlations ranging from 0.26 to 0.32). The relatively small correlation between anxiety and embarrassment may be because the two concepts are related but not similar. The discomfort and tension subscale was expected to be related to pain and anxiety during colposcopy, and pre- and postexam anxiety. This was confirmed, and this subscale was moderately correlated with depression and cancer worry as well. We expected both of the distress subscales related to sexual consequences and health consequences to have high correlations with cancer worry and general psychological distress, but lower correlations with pain and anxiety measured during the exam. In general, these hypotheses were verified, as shown in Table 4 supporting the convergent validity of the subscales.

The 23-item CDDQ is a reliable and valid questionnaire for measuring multiple domains of distress that are unique to women who have tested positive for a screening for cervical cancer. Consistent with past research, our study demonstrated that women's distress after receiving an abnormal Pap test result can be assessed with four specific domains (although in our study, the domains were discomfort and embarrassment about medical procedures, and worries about sexual and health consequences). The CDDQ evolved according to extensive feedback provided by cognitive interviewing, which asks research participants to state their interpretation of each item's meaning, and any difficulties in understanding the wording of the item. Based on the identification of additional specific concerns uncovered in the cognitive interviews, more items were added assessing participants' emotional reaction to medical procedures, and with their concerns about sexual attractiveness to partners, worries about developing cancer and its consequences. In addition, the CDDQ was developed with a diverse sociodemographic group, with sizable representation of African-American and Hispanic ethnic groups.

Limitations

Future research is needed to distinguish the CDDQ's ability to distinguish between psychological distress and other unrelated constructs in women undergoing diagnostic testing for cervical cancer. The CDDQ's subscales would also benefit from further reliability testing. The design of the current study did not allow us to assess test–retest reliability. Furthermore, the factor analysis was exploratory, and further replications in different samples are necessary to confirm the factor structure found in our analysis. Finally, it would be interesting to see how the CDDQ would perform in analyzing differences in adherence to follow-up diagnostic testing in women with abnormal Pap tests results.

Conclusion

The CDDQ is a reliable and valid questionnaire for measuring multiple domains of distress that are unique to women who have tested positive for a screening for cervical cancer. There is a need for a validated measure of the specific domains of distress that many women experience after receiving a positive screening result for cervical cancer. Careful and objective assessment of these separate domains can provide useful information in the development of

targeted intervention programs to increase adherence to follow-up procedures after abnormal Pap smear result.

The four subscales had good internal consistency (α ranged from 0.75 to 0.86) and demonstrated good concurrent validity with other well-known psychometrically validated measures of distress. By providing a measure which presents specific types of distress both about follow-up procedures and about consequences related to an abnormal Pap, the CDDQ can be used in future research to provide further investigation into how specific domains of distress may influence nonadherence to follow-up after abnormal Pap smear result.

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