Psychological Improvements Associated With Behavioral and Drug Treatment of Urge Incontinence in Older Women

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The purpose of this study was to explore changes in psychological distress associated with behavioral treatment and drug treatment for urge incontinence in community-dwelling older women. Participants were 197 ambulatory, nondemented women (aged 55 years or older) with persistent urge urinary incontinence. Participants were patients in a randomized clinical trial comparing biofeedback-assisted behavioral treatment, drug treatment with oxybutynin chloride, and a placebo-control condition. Psychological distress was measured before and after treatment using the Hopkins Symptom Checklist (SCL-90-R). Multivariate and univariate analyses of variance showed that the two treatment groups and the control group had similar significant improvements on the nine subscales and the global severity index. Analysis of individual SCL-90-R subscale scores revealed trends suggesting that behavioral treatment tended to produce the largest improvements. The reductions of distress were not correlated consistently with reduction of incontinence. The results of this study showed that psychological distress was significantly reduced after treatment, regardless of the type of treatment.

Most studies of the treatment of urinary incontinence have evaluated effectiveness in terms of urodynamic change or reduction in the frequency or severity of incontinent episodes. Less is known about the impact of treatments on the quality of the patient’s life, particularly in the realm of psychological distress.

It is widely held that urinary incontinence has a significant negative impact on quality of life (Dowd, 1991; Grimby, Milsom, Molander, Wiklund, & Ekelund, 1993; Herzog, Fultz, Brock, Brown, & Diokno, 1988; Hunskaar & Vinsnes, 1991; Lam, Foldspang, Elving, & Mommersen, 1992; Macaulay, Stern, Holmes, & Stanton, 1987; Macaulay, Stern, & Stanton, 1991; Norton, 1982; Norton, MacDonald, Sedgewick, & Stanton, 1988; Vinsnes & Hunskaar, 1992; Wyman, Harkins, Choi, Taylor, & Fantl, 1987). Using interviews and various instruments to assess impact, previous studies have reported that incontinence contributes to social isolation (Grimby et al., 1993), restriction of activities (Norton et al., 1988; Wyman et al., 1987), embarrassment, loss of self-esteem (Dowd, 1991), fear of institutionalization, worry, emotional disturbance (Grimby et al., 1993), relational problems (Lam et al., 1992), and low life satisfaction (Herzog et al., 1988). In addition, psychological morbidity associated with incontinence is reflected in measures of anxiety (Macaulay et al., 1987; Macaulay et al., 1991), depression (Herzog et al., 1988; Macaulay et al., 1987; Macaulay et al., 1991), hysteria (Macaulay et al., 1991), phobia (Herzog et al., 1988; Macaulay et al., 1987; Macaulay et al., 1991), distress (Vinsnes & Hunskaar, 1992), and somatic complaints (Macaulay et al., 1991). Thus, several studies document the negative impact of incontinence on quality of life.

Urinary incontinence can be caused by a number of factors that affect the nervous system, the bladder itself, or the muscles and tissues that support the bladder and pelvic organs. Likewise, there are a number of different treatment modalities that are effective for treating incontinence, including behavioral interventions, medications, surgery, electrical stimulation, and intrarethral injection. With the array of treatments available today, most cases of incontinence can be cured or significantly improved. Behavioral interventions, in particular, are a group of therapies that include bladder training, habit training, pelvic muscle training, and biofeedback-assisted behavioral training. These treatments have been shown to improve bladder control significantly by teaching patients to adopt new skills or to change old habits (Baigis-Smith, Smith, Rose, & Newman, 1989; Burgio, Stutzman, & Engel, 1989; Burgio, Whitehead, & Engel, 1985; Burns et al., 1993; Burton, Pearce, Burgio, et al., 1988; Cardozo, Stanton, Hafner, et al., 1978; Fantl, Wyman, McClish et al., 1991; Fantl et al., 1996; Jarvis & Millar, 1980; Kegel, 1948; Kegel, 1956; McDowell, Burgio, Dombrowski, Locher, & Rodriguez, 1992; Pengelly & Booth, 1980; Wells, Brink, Diokno, Wolfe, Gillis, 1991).

Although many studies have shown that various treatments reduce or cure urinary incontinence, little research has examined whether treatment for incontinence can ameliorate the negative impact of incontinence on the psychological aspects of life quality. In one study of treatment for urge incontinence, there was a reduction in the frequency of incontinent episodes. In addition, there was also an improvement in the negative psychosocial impact of the problem as measured by the Incontinence Impact Questionnaire and the Urogenital Distress Inventory (Shumaker, Wyman, Uebersax, McClish, & Fantl, 1994).
Another study evaluated how surgery for stress incontinence affected subjective psychological status. Results indicated that women who were treated successfully had significant improvements in psychological symptoms, whereas those whose treatment was not successful did not have psychological improvement as measured by a 10-item symptom questionnaire including questions on depression, nervousness, and sleep (Rosenweig, Hischen, Thomas, Nelson, & Bhatia, 1991).

Thus, the literature provides little information on whether treatment for incontinence can reverse the detrimental effects of the condition. More specifically, very little is known about whether psychological symptoms, one aspect of life quality, can be improved by treatment. This study helps to fill this gap.

The present study examines psychological distress in patients enrolled in a randomized clinical trial that compared the effectiveness of biofeedback-assisted behavioral treatment to a standard drug treatment (oxybutynin chloride) and a placebo-control condition for the treatment of urge incontinence in 197 women. Results of intervention on the primary outcome measure, frequency of incontinence, are reported elsewhere (Burgio et al., 1998). In this study, behavioral treatment resulted in a mean 80.7% reduction of incontinence episodes and was significantly more effective than drug treatment, which yielded a mean 68.5% reduction. Both were more effective than the placebo-control condition, which itself yielded an average 39.4% average reduction in frequency of incontinence. Several secondary outcome measures indicate that the behavioral group had the highest levels of perceived improvement, comfort, and satisfaction with treatment progress.

This article is a secondary article reporting the impact of behavioral and drug treatment on psychological symptoms in these older women with persistent urge incontinence. Although it has been established that behavioral treatment and drug treatment are both effective for reducing the frequency and severity of urinary incontinence, little is known about the effect of these interventions on quality of life as reflected in psychological symptoms. Other studies in the literature have explored quality of life using various measures, including general quality of life instruments, such as the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36; Ware & Sherbourne, 1992); health-related quality of life; and disease-specific quality of life indicators, such as the Incontinence Impact Questionnaire (Shumaker et al., 1994). This study differs from others in that it focuses on psychological distress as a specific aspect of life quality.

**METHODS**

**Participants**

Participants in this study were older, community-dwelling women with urge incontinence. They were recruited through local advertisements and professional referrals and then screened by telephone for eligibility. To qualify, participants had to be at least 55 years of age, ambulatory, and describe urge incontinence occurring at least twice per week and persisting for at least 3 months. Informed consent procedures were approved by the University Institutional Review Board.

**Clinical Evaluation**

Potential participants who met initial criteria were scheduled for a clinical evaluation to identify those who were not appropriate for treatment with oxybutynin chloride or behavioral methods. The evaluation consisted of a history and physical examination, postvoid catheterization for residual urine, urodynamic evaluation, and urinalysis. In addition, the Mini-Mental State Exam (MMSE; Folstein, Folstein, & McHugh, 1975) was used to screen for dementia.

**Bladder Diary**

Participants were provided with bladder diary booklets to document the time of every continent void and incontinent episode, the volume of urine loss (large or small), and the circumstances of each episode in baseline, during treatment, and for two weeks immediately after treatment.

**Inclusion and Exclusion Criteria**

To be included, participants had to average at least two urge accidents per week documented in a 2-week bladder diary, and urge incontinence had to be the predominant pattern (the number of urge accidents had to exceed the number of stress and other accidents). The circumstances of the accident as documented in the bladder diary were used to indicate urge incontinence. For example, “had a big urge” or “running to the bathroom” or “couldn’t make it to the bathroom in time” were coded as urge accidents. Also, there had to be urodynamic evidence of bladder dysfunction (detrusor instability during filling or provocation or maximal cystometric capacity of 350 ml or less).

Participants were excluded if they had continual leakage, postvoid residual urine volume greater than 200 ml, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina, uncompensated congestive heart failure, history of malignant arrhythmias, or impaired mental status (MMSE score below 20).

**Psychological Assessment**

To evaluate psychological symptoms, participants were asked to complete the SCL-90-R (Hopkins Symptom Checklist; Derogatis, 1983) in the baseline evaluation period prior to randomization and to repeat it after treatment was completed. For all groups, the instrument was given to the participants at their first clinic visit when they had their initial evaluation. They also were given the SCL-90-R at their final clinic visit for completion before they returned for the posttreatment assessment two weeks later.

The SCL-90-R is a 90-item self-administered questionnaire (Derogatis, 1983). Participants were asked to rate how distressed they had been feeling by each of 90 symptoms. Distress was rated on 5-point scales ranging from 0 (not at all distressed) to 5 (extremely distressed). This instrument was chosen because it has been validated (Derogatis, Rickels, & Rock, 1976), is relatively brief and time-efficient, and has been used extensively in medical settings.

The SCL-90-R yields nine clinical subscales: somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. In addition, it yields a total score, the Global Severity Index (GSI). A score of 50 on any scale.
is defined as normal. A score of 63 or greater on any scale is considered extreme enough to be a case.

**Design**

The study was a randomized, placebo-controlled clinical trial. Following enrollment, participants were stratified on type and severity of incontinence. Within each stratum, they were randomly assigned to behavioral treatment, drug treatment, or a placebo-control condition.

**Treatment**

For all participants, intervention consisted of four clinic visits at 2-week intervals over an 8-week period. Participants completed a daily bladder diary throughout treatment. At each visit, bladder diaries were reviewed by clinic staff to assure that entries were clear and interpretable. Vital signs were recorded, a urine specimen was collected, and a side-effects checklist was completed. Interventions were implemented by nurse practitioners. The control group was intended to control not only for the placebo effect but also for the effects of clinic visits, self-monitoring (bladder diary), and therapist contact.

*Behavioral training.*—During clinic visits, patients in the behavioral treatment group were taught skills and strategies for preventing incontinence and provided with instructions for daily home practice. In visit #1, anorectal biofeedback was used to help patients identify pelvic muscles and teach them how to contract and relax these muscles selectively while keeping abdominal muscles relaxed (Burgio et al., 1998). Visit #2 was devoted to teaching patients how to respond adaptively to the sensation of urgency (“urge strategies”; Burgio, Pearce, & Lucco, 1989). In visit #3 pelvic muscle biofeedback was repeated for participants who had not achieved at least 50% improvement. Combined bladder–sphincter biofeedback was used to teach patients to contract pelvic muscles against increasing volumes of fluid, in the presence of increasing urgency, and during detrusor contraction. Visit #4 was used to review progress, “fine-tune” home practice, and encourage persistence. Details of treatment and the home program are presented elsewhere (Burgio et al., 1998).

*Drug treatment and control condition.*—Assignment to drug treatment or the placebo-control condition was double-blinded, so all patients in these groups were managed as if they were taking oxybutynin. The protocol was initiated at 2.5 mg of oxybutynin chloride three times a day, half the usual recommended adult dosage. Oxybutynin and placebo were dispensed in identical capsules. Clinic visits were used to review bladder diaries, monitor progress, manage side-effects, and make dose adjustments using a minimum dose of 2.5 mg per day and a maximum of 5.0 mg three times a day. The goal over the following 8 weeks was to stabilize the patient on the most effective dose she could tolerate long term while controlling side effects and avoiding dropout from the study.

**Data Management and Analysis**

A research assistant, blinded to treatment group, scored the SCL-90-R and the bladder diaries. Pretreatment–post- treatment (pre-post) changes on the SCL-90-R subscales and GSI were analyzed separately for each treatment group using dependent t tests. Multivariate repeated measures analysis of variance (ANOVA) was used to examine treatment-related changes in psychological distress based on the nine subscales and univariate repeated measures ANOVA was used to test changes on the GSI.

To explore whether reduction of incontinence might mediate reduction of psychological distress, correlations were calculated between outcome (reduction in frequency of incontinence) and change in each of the SCL-90-R subscale scores. The outcome variable was based upon bladder diary documentation of accidents. The pretreatment and posttreatment frequency of incontinence as recorded in the diaries were used to calculate a reduction percentage for each subject (0% = no improvement, 100% = totally dry). Negative values indicated regression (increased number of accidents compared with baseline diaries).

**Results**

**Participants**

Of 468 women who were evaluated clinically, 271 (57.9%) were ineligible (including 41 for medical reasons and 8 for impaired mental status) or did not participate, and 197 (42.1%) were randomized. For a variety of reasons, 28 did not complete treatment and an additional 14 did not complete the psychological assessment (9.0%). This left 155 women who completed both treatment and pre- and posttreatment psychological assessment included in this analysis. Participants ranged in age from 55 to 91 years with a mean age of 67.5 (SD = 7.2). Ninety-seven percent were White and 3% were African American. The majority of participants (91%) completed at least a high school education, and 23.9% worked outside the home. Fifty-three percent (52.9%) were married, 27.7% widowed, 11.6% divorced, and 7.7% single.

**Pretreatment Characteristics**

Participants in this analysis were compared with those who did not complete both intervention and psychological assessment (i.e., 155 vs. 42). Analysis of their baseline psychological symptom scores indicated that dropouts had higher scores (indicating greater distress) on 6 of the 10 SCL-90-R scales including somatization, obsessive-compulsive, depression, hostility, paranoid ideation, and the global severity index (all p values < .05). Among the 155 patients who completed the study, no differences were found among the three groups on any of the pretreatment SCL-90-R measures.

Patients who scored below 63 on any given scale were deemed as having scores within the normal range, and more than 75% of all patients (including dropouts) were within the normal range on 9 of the 10 SCL-90-R scales. The highest impairment rate was observed on the obsessive–compulsive subscale, with only 67% of all patients scoring within the normal range at pretreatment. Whereas frequency analyses suggested a trend for those who completed the trial to be more likely to have scores within the normal range than those who dropped out, the associated chi-square tests failed
to reach conventional levels of statistical significance. This was due to the relatively small number of significantly elevated cases across the board. Also, the three groups did not differ in terms of the proportion of patients within the normal range at pretreatment on any SCL-90-R measure. Thus the patients who completed this clinical trial were somewhat less distressed than the dropouts, but no differences were found on measures of pretreatment psychological distress or impairment rate among the three groups.

Changes in Psychological Symptoms

The mean and standard deviation scores for the nine subscales of the SCL-90-R and for the GSI before and after treatment are displayed in Table 1. All change scores, with the exception of two, were in the positive direction indicating reduction of distress. The behavioral group showed the largest absolute reductions of psychological distress. The dependent t tests indicated that the pre-post changes were significant for 7 of the 9 subscales as well as the global severity index. The drug group displayed a consistent pattern of change over baseline suggesting a general reduction of distress, and change reached significance on one scale (obsessive–compulsive). In the control group, there was an overall pattern of mild improvement, and significant pre-post change was seen on two scales (obsessive–compulsive and somatization).

The nine subscale scores were subjected to a multivariate repeated measures ANOVA to examine changes in psychological symptoms due to treatment. The independent variables were intervention group and assessment phase (pretreatment vs. posttreatment). The multivariate tests revealed a significant main effect for assessment phase, Wilks’s Lambda = .844, F(9,144) = 2.96, p = .003. Significant univariate effects (p < .05) for assessment phase were found on all subscales except paranoia and phobia. These effects showed a general tendency for psychological symptoms to be reduced at posttreatment regardless of treatment group.

The multivariate test of the difference among the two treatment groups and the control group was not statistically significant: Intervention Group X Assessment Phase Interaction Effect, Wilks’s Lambda = .854, F(18,286) = 1.317, p = .175. Several of the individual SCL-90-R subscales showed trends such that the behavioral treatment group enjoyed the greatest improvement, but these differences were not consistent enough to achieve conventional levels of statistical significance (i.e., all p values > .05).

Similar results were achieved when the GSI score was examined in a univariate repeated measures analysis. A main effect for assessment phase was found, F(1,152) = 12.628, p < .001, indicating general decreases in psychological distress from pretreatment to posttreatment across all three groups. The three groups were not found to differ from each other on the amount of GSI change observed, F(2,152) = 1.375, p = .26.

Changes in Continence

The effects of the three conditions on the continence status of the entire sample are described in detail in a separate article (Burgio et al., 1998). For the subgroup of 155 participants described in the present article, behavioral training resulted in a mean 83.3% reduction in frequency of accidents. Drug treatment yielded a mean 74.4% improvement, and the control condition resulted in a mean 41.4% improvement (p < .001).

Relationship Between Distress and Incontinence

Small positive correlations (all r values < .16) were found for the total sample between the frequency of incontinent accidents and the SCL-90-R scores at baseline. These correlations were statistically significant for the GSI (r = .14, p < .05) and for the psychotism scale (r = .15, p = .04) and paranoid ideation scale (r = .15, p = .04). Correlations were also examined between improvement in incontinence due to treatment and changes on the SCL-90-R scores. Improvement in incontinence was significantly correlated with the GSI only and not the subscales (r = .24, p = .003). These correlations were also examined within each intervention group separately. As displayed in Table 2, correlations between change in psychological symptoms and improvement in incontinence were generally small and not statistically significant.

One correlation was significant in the behavioral group (somatization, r = .28, p < .05), and none was significant in the drug group. However, a stronger relationship was found between outcome and relief of psychological symptoms in

Table 1. SCL-90-R Scores Before (Pre) and After (Post) Treatment, Mean (SD)

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Behavior n = 57</th>
<th>Drug n = 52</th>
<th>Control n = 46</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
</tr>
<tr>
<td>Somatization</td>
<td>56.0 (10.6)</td>
<td>51.8 (11.4)**</td>
<td>51.4 (10.8)</td>
</tr>
<tr>
<td>Obsessive–Compulsive</td>
<td>56.5 (10.7)</td>
<td>53.8 (13.9)**</td>
<td>56.6 (11.4)</td>
</tr>
<tr>
<td>Interpersonal Sensitivity</td>
<td>53.8 (11.0)</td>
<td>49.5 (12.0)**</td>
<td>51.4 (11.9)</td>
</tr>
<tr>
<td>Depression</td>
<td>54.7 (10.0)</td>
<td>51.5 (11.5)**</td>
<td>52.5 (9.7)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>48.7 (13.9)</td>
<td>46.1 (14.6)</td>
<td>46.8 (12.0)</td>
</tr>
<tr>
<td>Hostility</td>
<td>49.3 (10.7)</td>
<td>44.9 (10.8)**</td>
<td>45.9 (10.1)</td>
</tr>
<tr>
<td>Phobia</td>
<td>47.5 (10.2)</td>
<td>47.1 (11.2)</td>
<td>46.7 (10.3)</td>
</tr>
<tr>
<td>Paranoid Ideation</td>
<td>48.6 (12.4)</td>
<td>45.8 (10.9)*</td>
<td>49.3 (11.1)</td>
</tr>
<tr>
<td>Psychoticism</td>
<td>54.1 (10.7)</td>
<td>49.2 (11.7)**</td>
<td>52.1 (10.3)</td>
</tr>
<tr>
<td>Global Severity</td>
<td>54.2 (11.1)</td>
<td>50.8 (12.8)**</td>
<td>52.5 (10.3)</td>
</tr>
</tbody>
</table>

*p < .05; **p < .01; ***p ≤ .001.
the control group as indicated by the anxiety subscale ($r = .34$, $p < .01$) and the GSI ($r = .45$, $p = .001$).

**DISCUSSION**

Both behavioral treatment and drug treatment are highly effective for reducing involuntary urine loss in older adults with urge incontinence. The results of this study showed that psychological distress was also reduced after treatment regardless of the type of treatment. Multivariate and univariate analyses of variance showed that all three groups, including the placebo-control condition, had similar improvements on the subscales and the global severity index.

The results of this study indicate that changes in psychological symptoms were largely independent of improvement in incontinence. Although a significant correlation was found between reduction of incontinence and reduction of distress for the total sample, this correlation was mostly due to changes in the control condition. Behavioral treatment reduced incontinence the most and also tended to have the largest impact on psychological distress. However, the reductions of distress were mild and generally not correlated with reductions in frequency of accidents. Even in the behavioral group where psychological symptoms were reduced significantly on 8 of the 10 scales, there was essentially no correlation between the magnitude of change in continence and these changes in psychological symptoms. Thus, it can be concluded that changes in psychological symptoms were largely unrelated to reductions in incontinence, and, therefore, not dependent on degree of improvement in incontinence.

One possible explanation for the findings is that reduction of incontinence was not the primary mediator of psychological improvement and that amelioration of psychological distress may result from some other features of treatment. For example, an alternative explanation may be that patients were comforted by the nonspecific qualities common to the two treatments and the control condition including the care and attention provided to them by the clinicians, the expectations of benefit, mobilization of patient effort, and validation of an embarrassing problem as a treatable medical condition rather than a hopeless stigma. All of these factors could have contributed to therapeutic outcome and reductions in psychological distress.

One potential limitation to this study is the reliance on the bladder diary for an outcome measure. The accuracy of diary data is always a matter of concern; however, the bladder diary has been shown to be a reliable method of assessing the frequency of incontinent episodes and voluntary urination (Wyman, Choi, Harkins, Wilson, & Fantl, 1988). To improve accuracy, we strongly encouraged patients to make their entries in a timely fashion to avoid any distortions due to inadequate recall. The diaries were designed to fit in a purse so that they could be taken everywhere. To discourage any tendencies to please the research staff by falsely recording improvements in frequency or volume of incontinence, care was taken not to respond negatively or express disappointment to recorded episodes of urine loss. Instead they were to take an interest in the circumstances surrounding each episode and to reward detail in record keeping.

Another limitation to this study is the fact that those with higher levels of distress were more likely to drop out of the study leaving predominantly women who were less distressed and restricting the range of scores. Also, the majority of participants had psychological distress scores that fell within normal range, limiting the degree to which they could potentially improve with therapy. This could partially explain the small changes in psychological distress and limit our ability to detect differences between the intervention groups. It should also be noted that the SCL-90-R does not simply measure psychological distress, but symptoms indicative of various types of psychological disorders as reflected in the subscales. It is reasonable to expect significant changes on only some of these scales such as depression, anxiety, somatization, and interpersonal sensitivity, whereas others would not necessarily be expected to reflect changes (e.g., psychoticism). Nevertheless, the results of this study show clearly that treating people for incontinence by whatever means can reduce psychological distress associated with this disturbing condition.

As described in the introduction, the purpose of this study was to assess impact of treatment on psychological distress as one specific aspect of quality of life. There are many other aspects of life quality such as social withdrawal, relationships, and restriction of activities that may or may not be affected positively by intervention and need to be further investigated. Certainly, the Incontinence Impact Questionnaire and Urogenital Distress Inventory (Shumaker et al., 1994) have emerged as important condition-specific instruments for assessing the broader aspects of life quality for incontinent people. More recently other instruments have been developed that are more targeted to subtypes of incontinence or subpopulations of incontinent people. For example, the Urge-IIQ and Urge-UDI (Brown, Posner, & Stewart, 1999) were developed to measure quality of life for women with urge incontinence specifically; and the Urge Impact Scale (URIS; DuBeau, Kiely & Resnick, 1999) was introduced to measure the impact of urge incontinence on the quality of life of older people. Other instruments are currently being developed. Together these tools will provide a more comprehensive picture of how incontinence affects quality of life and how various interventions may or may not ameliorate the negative sequelae of incontinence.

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**Table 2. Correlations Between Reduction of Incontinence and Changes in Psychological Symptoms**

<table>
<thead>
<tr>
<th>Subscale</th>
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<td>.01</td>
<td>-.14</td>
<td>.02</td>
</tr>
<tr>
<td>Interpersonal Sensitivity</td>
<td>-.09</td>
<td>.04</td>
<td>.13</td>
</tr>
<tr>
<td>Depression</td>
<td>-.04</td>
<td>.03</td>
<td>.07</td>
</tr>
<tr>
<td>Anxiety</td>
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<td>-.01</td>
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<td>-.01</td>
<td>-.01</td>
<td>.13</td>
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<tr>
<td>Global Severity Index</td>
<td>.01</td>
<td>.06</td>
<td>.45***</td>
</tr>
</tbody>
</table>

*$p < .05$; **$p = .001$. 
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