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Psychological and Interpersonal Correlates in Men with Erectile Dysfunction and their Partners: A Pilot Study of Treatment Outcome with Sildenafil

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The role of psychological and interpersonal factors in the treatment of erectile dysfunction (ED) with sildenafil or other oral therapies has not been sufficiently investigated. We conducted a pilot study

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*of psychosocial predictors of pharmacotherapy treatment outcome and satisfaction in men with ED and their partners. Sixty-nine men with mild to moderate ED and their partners were enrolled in a multicenter, open-label, treatment trial with sildenafil. Treatment measures included a battery of validated self-report measures and questionnaires. Subjects also were interviewed according to a semistructured interview protocol. Partner assessments included self-report measures of sexual function, mood, and relationship satisfaction. Results indicated that, prior to treatment, patients had erectile function scores in the range of mild to moderate ED, with relatively low levels of concomitant depression, anxiety, and psychological stress and high overall levels of relationship adjustment. Partner sexual function was in the normal range of total Brief Index of Sexual Functioning for Women (BISF-W; Taylor, Rosen, Leiblum, 1994) scores, although more than one third of female partners had specific sexual complaints or problems. Among couples who completed one or both follow-up visits (*N = *34), sildenafil treatment resulted in significant improvements in all aspects of sexual function in men, including sexual desire, orgasmic function, erectile function and overall sexual satisfaction. Significant improvements also were noted in partners' ratings of sexual function in most domains, including arousal, pleasure, and orgasm. Higher baseline levels of sex-specific anxiety were negatively associated with improvement in erections following treatment. Relationship adjustment at baseline, contrary to expectations, did not predict erectile or sexual satisfaction following treatment in the men or their partners but was significantly correlated with changes in sexual desire. Baseline levels of depression, anxiety, and stress generally were unrelated to efficacy or treatment satisfaction. However, we observed a curvilinear relationship in the men between baseline levels of stress and treatment discontinuation (i.e., subjects with moderate levels of stress were less likely to discontinue treatment). Because of a high number of dropouts, results of this pilot study await confirmation in a larger and more adequately powered clinical trial.*

Erectile dysfunction (ED) is a prevalent, aging-related disorder in men that has been associated with multiple medical and psychosocial risk factors (Bacon et al., 2003; Feldman, Goldstein, Hatzichristou, Krane, & McKinlay, 1994; Laumann, Paik, & Rosen, 1999; Litwin, Nied, & Dhanani, 1998). Because of the approval of sildenafil (Viagra) and other new PDE-5 inhibitors, the number of men seeking medical therapy for the disorder has increased dramatically since the late 1990s. Despite the efficacy and overall safety of these drugs (Padma-Nathan, 2003; Rosen & McKenna, 2002), increasing evidence

suggests that a substantial proportion of men with ED discontinue treatment or fail to seek help. A recent large-scale, multinational study of more than 25,000 men in 8 countries (The Multinational Men's Attitudes to Life Events and Sexuality, [MALES] Study; Rosen et al., 2004), found that 58% of men with erection problems had discussed their problem with a health professional, although fewer than half of these men received a prescription for sildenafil or other medication and only 16% were continuing to use the drug at the time of the study. Multiple reasons were cited for the high rate of discontinuation, including lack of education or counseling from physicians, fear of side effects, partner concerns, cost, and distrust of medications. Despite these concerns, few studies have assessed the psychological or relationship characteristics of couples seeking treatment for ED, nor has the role of psychosocial and interpersonal factors as potential mediators of treatment outcome been evaluated. Accordingly, we designed the present study to assess, a broad range of psychological and interpersonal variables in couples seeking sildenafil treatment for erectile dysfunction, and to evaluate how psychosocial variables might predict or influence treatment outcome. We describe the psychosocial and interpersonal characteristics of men with ED and their partners at baseline.

On the basis of epidemiological data, we know that psychological and interpersonal factors affect the prevalence and severity of ED, both independently and in conjunction with organic factors. Specifically, dysthymia and depression, stress and abuse, sedentary lifestyle, alcohol consumption, and loss of household income in recent years all have been associated in various studies with increased rates of ED (Araujo, Durante, Feldman, Goldstein, & McKinlay, 1998; Bacon et al., 2003; Feldman et al., 1994; Laumann et al., 1999; Rosen et al., 2004). In contrast to the traditional focus of sex therapy on psychological and relationship factors (Leiblum & Rosen, 1989, 2000), studies of pharmacotherapy for ED in the past five years have not investigated the role of psychosocial or partner variables, either prior to or following treatment. Partner concerns are a potentially relevant factor in motivating men with ED to seek treatment and may be a critical factor in the decision whether to initiate or to maintain therapy. It is surprising that little is known, about the short-term or long-term consequences of pharmacotherapy on the couple's relationship or on the sexual and psychological functioning of the partner.

The impact of relationship variables on treatment outcome in ED has been evaluated traditionally in nonpharmacological studies. For example, Hawton, Catalan, and Fagg (1992) examined couples' relationship satisfaction and the outcome of therapy in the context of psychogenic ED. We assessed a total of 36 couples in this study prior to and following treatment. It is interesting that the major determinant of treatment outcome was couples' ratings of marital communication prior to treatment. Couples with higher ratings of agreement responded more rapidly and with markedly better outcomes to the sex therapy treatment.

More recently, studies have begun to examine the influence of psychological factors in predicting outcomes of pharmacotherapy. For example, van Lankveld, van den Hout, Spigt, and van Koeveringe (2003) assessed the role of cognitive factors (e.g., increased self-confidence, partner sexual desire) in maintaining sildenafil-related treatment gains after discontinuation in men with mild or predominantly psychogenic ED. A sample of 65 men and their partners was followed for 6 weeks with and 6 weeks without oral medication (sildenafil). It is of interest that approximately one third (37%) withdrew from the study prior to the follow-up assessment. Of those who returned for posttreatment assessment, 89% reported a positive result. At the 6-week posttreatment follow-up, 66% reported that they had maintained their treatment gains without medication. When we examined specific predictors of this effect, we noted that increased sexual self-confidence was the most important predictor in the men; increased sexual desire in the female partners had the same effect (van Lankveld et al., 2003).

Which psychosocial and relationship variables are most likely to impede or facilitate compliance, treatment outcome, and long-term satisfaction? In the recent multinational, MALES study (Rosen et al., 2004) attitudes toward medications, fear of side effects, and partner concerns were cited as primary reasons for discontinuation of pharmacotherapy for ED. According to the model of sexual avoidance first proposed by Barlow and associates (Barlow, 1986; Cranston-Cuebas & Barlow, 1990; Wiegel, Scepkowski, & Barlow, in press), behavioral avoidance is typical in both men and women with sexual dysfunctions. According to the model, negative expectancies, biased attributions, and self-focused attention not only interfere with erectile functioning but also result in a pattern of avoiding any potential sexual situations. As seen in the findings of the study above by van Lankveld et al. (2003), success expectancies may also impact positively and significantly affect treatment outcome.

More recently, Bancroft and Janssen (2000) have proposed a "dual control" model for sexual dysfunction. According to this model, individuals vary in their psychological propensity for sexual excitation or inhibition. Sexual dysfunction is conceptualized, according to this model, as due to either excessive inhibition or inadequate excitation. The authors hypothesize that men whose ED is predominantly due to inadequate excitation will evidence the greatest improvement from pharmacotherapy for their ED. Partner and relationship factors also are predicted to impact on treatment outcome and compliance. For example, a man whose sexual partner suffers from chronic low sexual desire or does not wish to engage in sexual activity because of relationship conflicts or mood disturbance is more likely to discontinue pharmacotherapy.

The aim of the present study was to assess the potential relevance of psychological and interpersonal factors in predicting efficacy and outcome of pharmacotherapy (sildenafil) treatment, as well as to determine

the effects of treatment on relationship functioning and partner variables. We selected 69 men with ED and their partners to participate in a 24-week, open-label, drug-treatment (sildenafil) study. Both the men with ED and their partners completed a battery of psychological, sexual, and relationship measures at baseline and subsequent study visits. We conceptualized treatment outcome as multidimensional in nature, with at least four major domains of outcome: (a) improvement in erectile function, (b) sexual desire and satisfaction outcomes, (c) treatment discontinuation (last completed study visit), and (d) treatment satisfaction. Potential psychosocial predictors were conceptualized in four broad categories: (a) demographic and socioeconomic characteristics, (b) mood and psychological adjustment variables, (c) sexual performance variables, and (d) relationship factors.

Specific predictions were as follows:

1. Variables predicted to reduce treatment efficacy included higher age, longer duration of ED, higher baseline levels of stress and depression, higher baseline levels of sex-specific anxiety, lower expectancies about treatment efficacy, and low sexual excitation.
2. Predictors of sexual satisfaction and desire were hypothesized to include increases in erectile functioning, lower levels of baseline depression and anxiety, and better baseline relationship quality.
3. We hypothesized also that individuals with lower baseline relationship quality, higher stress levels, or decreased baseline levels of sexual desire would be more likely to discontinue treatment prematurely. In addition, less improvement in erectile dysfunction would also predict earlier dropout.
4. We hypothesized that overall treatment satisfaction would be related to improvements in erectile function, treatment expectancies, and other aspects of the couple's relationship.

A second major aim of the study was to assess the impact of ED therapy with sildenafil on sexual functioning in partners and on selected aspects of the couple's relationship. Improvements in erectile function (EF domain) were predicted to positively affect the partner's sexual function. Specifically, we hypothesized that the domains of partner arousal and orgasm would improve as a result of effective pharmacotherapy for the male's ED. We expected that changes in the partner's sexual desire would be effected by the quality of the couple's relationship and possibly by improvements in erectile function. However, we anticipated that complaints of painful sexual intercourse might intensify in women experiencing these problems at pretreatment. Women with sexual arousal disorder in the absence of pain, however, were predicted to show positive improvements following treatment.

METHODS

Participants

Sixty-nine men with erectile dysfunction and their partners were enrolled in an open-label, prospective study. Demographic characteristics of the sample are shown in Table 1 below. The median age was 55 years (Mean = 54.2 ± 9.3). The subjects were moderately well educated and predominantly Caucasian (93.3 %). A majority of the participants were married, and most of the relationships were long standing (mean yrs = 19.5 ± 14.7). All but one of the participants self-identified as primarily or exclusively heterosexual.

On the basis of clinical history, we determined that most subjects had a mixed pattern of organic and psychogenic etiology. Of the 69 couples recruited for the study, six were excluded from the current analyses because the primary sexual complaint was not ED or their IIEF erectile function score was 26 or above, the recommended cut-off for normal erectile functioning (Rosen et al., 1997). Seven couples discontinued the study prior to beginning treatment, and a further nine couples failed to return for the first posttreatment study appointment. Baseline data was available for these 16 couples and were included in the pretreatment assessment but not the efficacy or outcome analyses. This decision was based on our observation that pretreatment dropouts did not differ significantly from those couples who underwent treatment in terms of age, education, ED severity, depression or anxiety scores, or relationship adjustment. Thus, they were included in the pretreatment analyses.

TABLE 1. Demographic Characteristics of Sample

Category	Percent (*n*)
Age (Mean = 54.2 ± 9.3 yrs.)	(60)
Ethnic background	
Caucasian	93.3% (56)
African American	3.4% (2)
Hispanic	1.7% (1)
Asian	1.7% (1)
Relationship status	
Mean duration = 19.51 (14.73)	
Dating relationship	6.3% (4)
Cohabitating	11.1% (7)
Married	76.2% (48)
Separated/divorced	4.8% (3)
Widowed	1.6% (1)
Religion	
Protestant	50.0% (30)
Catholic	33.3% (20)
Jewish	6.7% (4)
Other	3.3% (2)
None	6.7% (4)
Education (Mean = 14.6 ± 3.6 yrs.)	(60)

The treated sample available for any follow-up assessment consisted of 47 couples, with data available for 34 couples at the 8-week evaluation.

Screening and Recruitment

Participants were recruited at 5 clinical centers through patient lists and recruitment advertisements. Potential subjects were provided with detailed information about the study and screened for eligibility during an initial screening contact. The inclusion criteria included male patients between the ages of 21 and 70 years, presence of ED of at least 6 months' duration, evidence of (partial) erections during sleep or waking during the past 3 months, involvement in a stable, heterosexual relationship for at least 6 months, and the presence of a sexual partner willing to participate in the study. Study participants were medically evaluated and received a physical examination prior to the study to ensure there were no contraindications for treatment with sildenafil. We excluded from the study participants who had used sildenafil on more than four occasions prior to the study or who were unwilling to discontinue other treatments for ED. We had originally planned to include only treatment-naïve individuals in this study but elected to compromise by including those who had used the drug on fewer than four occasions.

Study Design

The design for the study was a prospective, repeated measures open-label study of sildenafil for the treatment of ED. The drug dosages and directions for administration were based on instructions in the approved package insert. In return for free drug supply during the study, couples agreed to be evaluated at baseline and at monthly intervals throughout the study. The schedule of visits is summarized in Table2. During the initial study visit (baseline), we interviewed prospective subjects and their partners to verify eligibility and to further assess the participant's sexual-dysfunction history. In addition, participants and partners completed a battery of self-administered questionnaires. We collected questionnaire measures at baseline and again following a 4-week, no-treatment run-in period. Subsequently, subjects began a 24-week sildenafil treatment phase. We instructed participants to attempt intercourse at least twice per week and to take the medication at least 1 hr before each attempt. Each participant began treatment at a dose of 50 mg, which was titrated to 25 mg or 100 mg, as needed. Additional assessments were conducted at 4, 8 (mid-treatment), 16, and 24 weeks of treatment. During these visits, participants completed questionnaires that assessed sexual function, quality of life, relationship adjustment, depression and anxiety, and treatment expectations (see below). Partner responses were assessed at weeks 8 and 24 of treatment. Subjects and partners also completed brief diary

TABLE 2. Study Procedures by Visit

Visit # (Week #)	Patient questionnaires	Partner questionnaires
Visit 1 (screening) begin 4 week no drug run-in	Sexual History Interview Demographics; Health Form; DAS; DASS; IIEF; SIS, SVSS; Start Sexual Event Log (SEP)	Sexual History Interview DAS; DASS; BSFI, SVSS-F
Visit 2 (week 0) begin sildenafil	IIEF, SVSS; Dosing Log (at home); SEP (at home)	Partner not present
Visit 3 (week 4)	IIEF, SVSS; Dosing Log (at home); SEP (at home)	Partner not present
Visit 4 (week 8) mid-treatment evaluation	IEFF; DAS; DASS; EDITS; SVSS; Dosing Log (at home); SEP (at home)	BSFI; DAS; DASS; EDITS; SVSS-F
Visit 5 (week 16)	IEFF; DAS; DASS; EDITS; SVSS; Dosing Log (at home); SEP (at home)	Partner not present (unless partner missed visit 4)
Visit 6 (week 24) end-treatment evaluation	IEFF; DAS; DASS; EDITS; SVSS; Debriefing form	BSFI; DAS; DASS; EDITS; SVSS-F; debriefing form

Note. BSFI = Brief Index of Sexual Function (Taylor, Rosen, & Leiblum, 1994); DAS = Dyadic Adjustment Scale (Spanier, 1976); DASS = Depression, Anxiety, and Stres Scale (Lovibond & Lovibond, 1995); EDITS = Erectile Dysfunction Inventory of Treatment Satisfaction (Althof et al., 1999); IIEF = International Index of Erectile Function (Rosen et al., 1997); Sexual Inhibition Scale (Janssen, Vorst, Finn, & Bancroft, 2002a), SVSS = Subjective Variable Specific to Sex.

forms regarding each sexual encounter, which recorded the use of sildenafil and the presence or absence of satisfactory erections. Couples were required to complete an informed-consent statement and were free to withdraw from treatment at any time. Treatment discontinuation was monitored and assessed as an outcome measure in the study.

Assessment Measures

The following self-report questionnaires was completed by subjects and their partners.

Baseline Demographic and Sexual Relationship Questionnaire: A study-specific instrument that assesses race, education, relationship status, and duration of ED.

Medical History Form: A study-specific form to assess current allergies, medications, family medical history (e.g., cancer), and past medical and surgical history.

Dyadic Adjustment Scale (DAS; Spanier, 1976): A validated measure of relationship satisfaction and the quality of the partner relationship. Completed by both subjects and partners.

Depression, Anxiety, Stress Scale (DASS; Lovibond & Lovibond, 1995): A validated measure of depression, anxiety, and stress covering the past four weeks. Completed by both subjects and partners.

International Index of Erectile Function (IIEF; Rosen et al., 1997): A validated measure of male sexual function. Specific domains include erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall sexual satisfaction.

Sexual Inhibition Scale/Sexual Excitation Scale (SIS/SES; Janssen, Vorst, Finn, & Bancroft, 2002a, 2002b): A validated measure of sexual excitation and inhibition. Completed by men only.

The Subjective Variables Specific to Sex (SVSS): This study-specific questionnaire assessed participant's expectations about the quality of erections with and without medication, as well as anxiety and worry regarding sexual activity and erections. Partners completed a partner version of this questionnaire.

Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS; Althof et al., 1999): A validated measure of treatment satisfaction. Partners completed an alternate version of this questionnaire.

Brief Index of Sexual Function for Women (BISF-W; Taylor, Rosen, & Leiblum, 1994): A validated measure of female sexual function. This measure assessed domains of partners' sexual desire and performance and was completed by partners only.

RESULTS

The results are presented in two sections. The first section describes the results of analyses for predictors of efficacy and outcomes, whereas the second section focuses on the changes in partner's sexual and psychosocial function following treatment. Because the primary goal of the study was to identify predictors of change (e.g., in erectile function score), a brief note on the statistical properties of difference scores and ratio scores in regards to correlational analyses (e.g., multiple regression) is warranted. Questionnaires designed to measure underlying constructs include a degree of measurement error, which is reflected in the variable's reliability coefficient (e.g., internal reliability or test-retest reliability). Difference scores, which are calculated for variables that are intrinsically correlated, such as posttreatment scores minus pretreatment scores, are intrinsically less valid measures of change. As the correlation between the two scores approaches their average reliability, the reliability of the difference score approaches zero. As a result, difference scores frequently do not correlate sufficiently with other dependent variables, because they are composed largely of measurement error (Cohen & Cohen, 1983, pp. 67–70). Similarly, ratio scores (obtained by dividing two scores) are vulnerable to spurious correlations, because these

correlations are dependent in turn on other correlations among components of the numerator and denominator domains. (Cohen & Cohen, 1983, pp. 73–76). Accordingly, Cohen and Cohen (1983) recommend using hierarchical regression and statistically controlling for the effect of pretreatment scores on posttreatment scores by entering the pretreatment scores into the regression analyses prior to other predictor variables of interest. We followed this approach in assessing predictors of outcome and therapeutic change.

For most analyses, we conducted separate regression analyses for each predictor variable rather than including all of the predictor variables in a single regression analysis. Because this was a pilot study, we adopted a strategy favoring increased statistical power per analysis, at the cost of increased likelihood of experiment-wise type II errors.

Section I: Patient Predictors of Treatment Efficacy and Outcomes

As in previous studies with sildenafil, we used changes in the EF domain score as the primary efficacy measure. Participants' EF scores at week 0 (following 4-week no drug run in period; see Table 2) were compared with their EF scores after 8 weeks of treatment (mid-treatment) and after 24 weeks of treatment with sildenafil. We observed a substantial treatment dropout, resulting in markedly different sample sizes at baseline ($n = 56$), 8 weeks ($n = 34$), and 24 weeks of treatment ($n = 24$). As a result, we used individual repeated measures *t*-tests to evaluate differences between baseline and 8 weeks and between baseline and 24 weeks of treatment. Repeated-measures *t*-tests revealed that erectile function scores were significantly higher at both 8 weeks ($t(33) = -5.23$, $p < .001$) and 24 weeks of treatment ($t(22) = -5.35$, $p < .001$; see Table 3). Given that sildenafil's efficacy is well established and has been evaluated in more than 50 clinical trials to date (e.g., Padma-Nathan et al., 2003; Rosen & McKenna, 2002), subsequent analyses have focused solely on the role of psychological and

TABLE 3. International Index of Erectile Function (IIEF; Rosen et al., 19997) Domain Scores at Baseline and Posttreatment

IIEF domain	Baseline (end of 4-weeks) ($n = 56$)		8 weeks of treatment ($n = 34$)		Study end (24 weeks treatment) ($n = 24$)	
	Mean	(*SD*)	Mean	(*SD*)	Mean	(*SD*)
Erectile function	15.76	(5.84)	23.09*	(7.53)	23.78*	(6.40)
Orgasm function	7.11	(2.55)	8.35*	(2.37)	8.71*	(2.31)
Sexual desire	7.24	(1.54)	7.74*	(1.44)	7.67	(1.58)
Intercourse satisfaction	8.27	(3.34)	10.79*	(3.94)	10.92*	(4.03)
Overall satisfaction	6.15	(2.11)	8.35*	(1.79)	8.54*	(1.72)

*Significantly different from baseline score.

interpersonal predictors of treatment efficacy and broader psychosocial outcomes associated with pharmacological treatment of ED. Because of the small number of participants who completed 24 weeks of treatment ($n = 24$), analyses focused on treatment outcomes at 8 weeks (mid-treatment evaluation). Four types of treatment outcome variables were examined: improvement in EF, changes in sexual desire and satisfaction in patients and partners, treatment discontinuation, and treatment satisfaction.

Predictors of changes in erectile function

To evaluate potential mediating effects of baseline psychological and interpersonal function on treatment efficacy, we conducted a series of hierarchical regression analyses. In the first analysis, we defined EF domain scores at 8 weeks (mid-treatment) as the dependent variable. Pretreatment EF domain scores were entered during the initial step in the regression analysis, thus controlling for the effect of baseline ED severity (adjusted $R^2 = .07$, R^2 change $= .10$, $p = .07$). During the second step, we entered selected demographic, psychological, sexual, and relationship variables into the regression equations. We conducted separate regression analyses for baseline measures of (a) age and duration, (b) depression and stress levels (DASS; Lovibond & Lovibond, 1995), (c) sexual excitation (SIS/SES; Janssen et al., 2002a, 2002b), (d) treatment expectancies (SVSS), and (e) sex specific anxiety (SVSS). Results indicated that only sex-specific anxiety, as measured by the SVSS, accounted for a significant portion of variance in 8-week EF domain scores (Adjusted $R^2 = .19$, R^2 change $= .14$, $\beta = -.46$, $p < .05$). The regression equations for age and ED duration (R^2 change $= .15$, $p = .08$), stress and depression (R^2 change $= .01$, $p = .84$), sexual excitation score (R^2 change $= .00$, $p = .95$), and treatment expectations (R^2 change $= .01$, $p = .51$) were not significant. Because only 34 couples attended the 8-week treatment outcome evaluation, statistical power was insufficient to include all of the predictor variables in a single regression equation.

Predictors of desire and overall sexual satisfaction

We examined the relationship between psychosocial predictors and other measures of sexual function in a similar fashion. We hypothesized that improvement in erectile function, relationship adjustment, baseline depression, and stress levels would impact on sexual desire and overall sexual satisfaction at 8 weeks of treatment. We conducted hierarchical regression analyses with sexual desire levels (IIEF SD) at 8 weeks of treatment as the dependent variable. We entered pretreatment sexual desire scores during the first step in the regression analysis and entered other predictor variables of interest during subsequent steps (adjusted $R^2 = .38$, R^2 change $= .40$, $p < .001$).

To examine the effects of improved erectile function on sexual desire, we entered baseline values for sexual desire and erectile function during step one

and entered IIEF EF scores at 8 weeks of treatment during the second step. We found improvement in erectile function significantly predicted sexual desire at 8 weeks, controlling for baseline levels of sexual desire and erectile function (adjusted $R^2 = .56$, R^2 change = .18, $p < .01$). Most of the variance was accounted for by baseline sexual desire (IIEF SD $\beta = .63$, $p < .001$) and mid-treatment erectile function (IIEF EF $\beta = .45$, $p < .01$) but not baseline levels of ED (IIEF EF $\beta = .04$, $p = .77$).

We found that baseline levels of relationship adjustment (DAS total score) similarly predicted sexual desire at 8 weeks, controlling for baseline levels of sexual desire (adjusted $R^2 = .44$, R^2 change = .09, $p < .05$; DAS total score $\beta = .31$, $p < .05$). Neither depression (R^2 change = .00, $p = .74$) nor anxiety (R^2 change = .02, $p = .36$) scores at baseline predicted sexual desire at 8 weeks of treatment.

To predict overall sexual satisfaction, we conducted hierarchical regression analyses with overall sexual satisfaction domain scores (IIEF OS) at 8 weeks of treatment as the dependent variable and entered baseline sexual satisfaction scores during step one (adjusted $R^2 = .23$, R^2 change = .26, $p < .01$), and other variables of interest during subsequent steps. Changes in sexual satisfaction were predicted by erectile function changes (adjusted $R^2 = .62$, R^2 change = .32, $p < .01$). It is interesting, but not unexpected, that baseline erectile function score had a negative standardized coefficient ($\beta = -.53$, $p < .01$), whereas mid-treatment erectile function had a positive standardized coefficient ($\beta = .60$, $p < .001$), indicating that greatest increases in overall sexual satisfaction occurred in patients with more severe baseline erectile problems who showed greater improvement as a result of treatment. None of the other predictor variables accounted for a significant proportion of the variance in sexual satisfaction at 8 weeks.

Predictors of treatment discontinuation

An additional outcome measure in the current study was treatment discontinuation (last visit attended). Contrary to expectations, lack of improvement in erectile function, using the last observation carried forward, was not a significant predictor of treatment discontinuation (adjusted $R^2 = -.01$, R^2 change = .00, $p < .94$). We hypothesized that in addition to those with lack of ED improvement, individuals with lower baseline relationship quality, higher stress levels, and decreased sexual desire would be more likely to discontinue treatment prematurely. Inspection of the data suggested that baseline relationship adjustment and psychological stress levels appeared to have a curvilinear relationship to dropout rates. We evaluated this trend using a between-groups analysis of variance (ANOVA) with treatment discontinuation as the between-subjects variable, and baseline stress (DASS Stress), sexual desire (IIEF SD), erectile function (IIEF EF), and relationship adjustment (DAS total score) as dependent variables. None of the linear

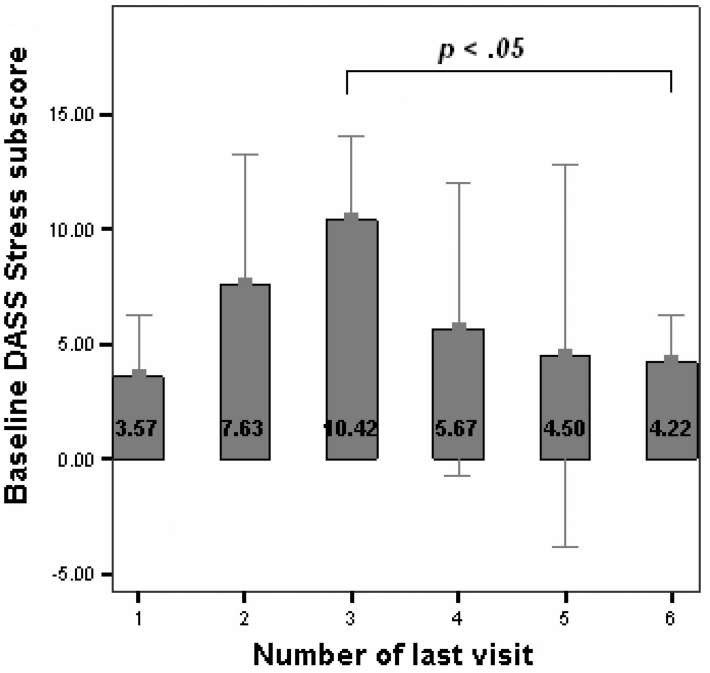

FIGURE 1. Mean Depression, Anxiety, and Stress Scale (Lovibond & Lovibond, 1995) stress scores at baseline by treatment discontinuation DASS stress subscore assessed at baseline (Visit 1). Higher DASS scores reflect a greater amount of stress; Visit 2 = end of baseline and sildenafil treatment start; Visit 4 = 8-week midtreatment evaluation; Visit 6 = 24-week end of study evaluation visit.

terms were significant; however, the quadratic term for stress was significant, $F(5, 59) = 5.63$, $p < .05$, and the quadratic term for sexual desire showed a trend toward significance, $F(5, 60) = 3.98$, $p = .051$. Post hoc follow-up tests with Bonferroni adjustment showed that patients who discontinued treatment at visit three (after 4 weeks of treatment) differed significantly from those who completed all 24 weeks of treatment. The relationship between dropout and baseline stress levels is shown in Figure 1. Individuals with lower levels of stress either discontinued prematurely or completed treatment, whereas those with the highest levels of stress discontinued soon after the onset of treatment. Unfortunately, our study was not designed to evaluate reasons for dropout, and no systematic assessment of this variable was conducted.

Predictors of treatment satisfaction

After 8 weeks of treatment, patients in the study ($n = 32$) completed the EDITS Althof et al., 1999, a measure of ED treatment satisfaction. The mean EDITS score was 84.45 ± 13.58 (45.45–100), indicating a moderate to high degree of overall treatment satisfaction (Lewis et al., 2001). We used hierarchical

regression analyses to evaluate the relationship between treatment satisfaction and changes in erectile function, sexual desire, sexual satisfaction, and relationship quality, with baseline values entered first and mid-treatment values entered during the second step. Not surprisingly we found that EF scores at mid-treatment predicted EDITS mid-treatment scores, controlling for baseline values of EF domain scores (Adjusted $R^2 = .55$; R^2 change = .56, $p < .001$; baseline EF $\beta = -.35$, $p < .05$; mid-treatment EF $\beta = .88$, $p < .001$). Similarly, mid-treatment scores for sexual desire (IIEF SD; Adjusted $R^2 = .26$; R^2 change = .29, $p < .01$; baseline SD $\beta = -.35$, $p = .11$; mid-treatment sexual desire $\beta = .73$, $p < .01$) and overall satisfaction (IIEF OS; Adjusted $R^2 = .34$; R^2 change = .38, $p < .001$; baseline OS $\beta = -.61$, $p < .01$; mid-treatment OS $\beta = .83$, $p < .001$) were significant predictors of treatment satisfaction at mid-treatment. Treatment satisfaction scores also were significantly related to subjects' mid-treatment expectations of treatment efficacy with sildenafil (Pearson $r = .66$, $p < .001$) but not to expectations of being able to achieve an erection without sildenafil ($r = .26$, $p = .16$). Mid-treatment depression scores were negatively correlated with overall treatment satisfaction ($r = -.47$, $p < .01$). In contrast, DAS (Spanier, 1976) scores were not significantly related to treatment satisfaction (Adjusted $R^2 = .04$; R^2 change = .02, $p = .54$).

Section II: Predictors of Partner Treatment Effects and Outcomes

A second aim of the study was to examine the impact of sildenafil treatment on the partner's sexual functioning. Between baseline and the mid-treatment evaluation, female sexual function scores increased significantly, including BISF-W (Taylor et al., 1994) total score ($t(35) = -2.04$, $p < .05$), arousal domain ($t(35) = -2.69$, $p < .05$), frequency domain ($t(35) = -3.31$, $p < .01$), pleasure/orgasm domain ($t(35) = -2.38$, $p < .05$), and relationship satisfaction domain ($t(35) = -2.91$, $p < .01$). The partners' pre- and posttreatment scores can be found in Table 4. The sexual desire and receptivity/initiation domains as well as the sexual problem domain did not improve significantly over the course of pharmacotherapy. A detailed description of the relationship between male and female scores in the respective sexual functioning domains will be presented in detail in a subsequent paper.

Predictors of changes in partner sexual function

We hypothesised that improved erectile capacity in the male would have direct positive effects on the partner's sexual functioning. To explore the relationship between improvements in female sexual function as a result of improved erectile function, we conducted a hierarchical regression analysis with 8-week evaluation BISF-W (Taylor et al., 1994) total score (mid-treatment evaluation) as the dependent variable, baseline BISF-W total score

TABLE 4. Pre- and Midtreatment Brief Index of Sexual Function Women (BISF-W; Taylor, Rosen, Leiblum, 1994) Scores

BISF-W	Intent to treat ($n = 59$) (Baseline Mean (*SD*)	Treated sample $n = 34$		
		Baseline Mean (*SD*)	1st evaluation point Mean (*SD*)	ETA^2 (η^2)
Total score[a]	31.85 (13.16)	33.74 (12.82)	38.42 (9.88)*	.11
Thoughts/desire	5.19 (2.44)	5.37 (2.48)	5.87 (2.22)	.07
Arousal	5.92 (2.81)	6.06 (2.67)	6.98 (2.21)*	.17
Frequency	3.67 (1.90)	3.82 (1.90)	4.66 (1.63)**	.24
Receptivity/initiation	8.85 (3.13)	9.14 (3.03)	8.89 (2.85)	.01
Pleasure/orgasm	4.21 (2.51)	4.83 (2.41)	5.76 (1.92)*	.14
Relationship satisfaction	7.67 (2.98)	7.75 (3.07)	9.11 (2.90)**	.19
Problems affecting sexual functioning	3.76 (2.26)	3.33 (1.48)	2.85 (1.48)	.10

[a]Higher scores correspond to better function, except in the sexual problems domain, where higher scores correspond to more-severe problems.
*$p < .05$, **$p < .01$.

and baseline IIEF (Rosen et al., 1997) erectile function score entered in the first step, and 8-week evaluation IIEF erectile function scored entered during the final step. The results indicated that EF domain scores significantly predicted female sexual functioning, both assessed at midpoint (Model Adjusted $R^2 = .50$; R^2 change $= .13$, $p < .05$; midpoint IIEF EF domain $\beta = .41$, $p < .05$), and controlling for baseline values of erectile functioning ($\beta = -.30$, $p < .05$) and female sexual functioning ($\beta = .52$, $p < .01$).

A second possibility is that the partner's sexual functioning improved indirectly because of improvements in other domains—such as relationship quality, or anxiety, depression, and stress—which may be a result of ED treatment. Improved erectile capacity would then also have indirectly improved the partner's sexual function. Repeated measures *t*-test revealed that levels of depression, anxiety, stress, or relationship quality of the partners differed significantly from baseline to mid-treatment evaluation. A hierarchical regression equation with mid-treatment BISF-W (Taylor et al., 1994) total score as the dependent variable and mid treatment anxiety (DASS Anx) as the predictor variable, and baseline BISF-W total and anxiety scores controlled for by entering them into the equation during step one showed that partner anxiety significantly predicted partner sexual function (Model Adjusted $R^2 = .45$; R^2 change $= .13$, $p < .01$, mid-treatment partner anxiety score $\beta = -.42$). We conducted similar hierarchical regression analyses for depression, stress, and relationship quality. However, none of these variables significantly predicted improvements in partner sexual functioning.

In addition, we hypothesized that relationship quality would predict changes in the partners' level of sexual desire, independent of the effects of

improved erection (EF) scores. However, because neither the BISF-W sexual desire domain nor the partners' relationship quality differed significantly from baseline to mid-treatment evaluation, we conducted no regression analyses to test this hypothesis.

We also hypothesized that women with complaints of sexual pain would experience an increase in pain-related symptoms as a result of their partner's improved erectile function. We examined the pain-related items from the BISF-W sexual problems domain to test this hypothesis. The mean BISF-W sexual complaints domain score did not differ significantly from pre- to mid-treatment evaluations. However, for several of the sexual complaints, the percentage of women who endorsed them decreased notably between baseline and mid-treatment. Table 5 shows the frequency of sexual complaints at baseline and following treatment (mid-treatment evaluation) for the sample that completed at least 8 weeks of treatment ($n = 36$). Because of the small sample size and the use of single-item assessments of sexual complaints, we made no formal statistical comparisons. However, it is interesting to note that, following treatment, the percentage of women complaining of lack of lubrication was reduced by almost 50%. In addition, after 8 weeks of sildenfil treatment for the male's erectile dysfunction, the number of women who

TABLE 5. Percent of Women Endorsing Sexual Complaint at least 50%

	Intent to treat ($n = 60$)	Completed at least 1st eval. point ($n = 34$)	
Sexual complaint	Baseline	Baseline	1st eval. point
Experienced bleeding or irritation after vaginal penetration/intercourse	3.3%	2.8%	0.0%
Experienced lack of vaginal lubrication	21.7%	25.0%	13.9%
Experienced painful penetration or intercourse	10.0%	11.7%	8.3%
Difficulty reaching orgasm	28.3%	16.7%	16.7%
Vaginal tightness	18.3%	16.7%	16.7%
Involuntary urination	6.7%	2.8%	5.6%
Headaches after sexual activity?	3.3%	0.0%	0.0%
Vaginal infection	6.7%	2.8%	0.0%
Own (female) health problems influencing sexual activity	15.0%	11.7%	8.3%
Partner's (male) health problems influencing sexual activity	20.0%	13.9%	2.8%
Conflict in relationship influenced sexual relationship	8.3%	5.6%	0.0%
Women somewhat or very dissatisfied with overall appearance of body	35.0%	27.8%	27.8%
Women who cannot or seldom communicate sexual desires/preferences to partner	21.7%	16.7%	5.6%
Women who are somewhat or very dissatisfied overall with the sexual relationship	43.3%	33.3%	16.7%

endorsed being somewhat or very dissatisfied with their sexual relationship was also reduced by half. These findings are consistent with the significantly increased BISF-W arousal and satisfaction domain scores. Finally, it is noteworthy that the percentage of women who complained specifically about painful penetration or intercourse, vaginal tightness, or bleeding and irritation with intercourse did not increase as expected but decreased slightly with improvements in the male's erectile function.

DISCUSSION

In this prospective study of pharmacotherapy in men with mild-to-moderate ED, we investigated a broad range of psychological and interpersonal variables as baseline correlates of ED and as potential predictors of treatment efficacy and satisfaction. Overall, study participants showed a relatively high level of psychological and relationship adjustment prior to treatment. In particular, baseline scores for depression and anxiety were in the normal range, as were the scores for relationship adjustment. Sildenafil treatment caused significant improvements in erectile function, in addition to improvements in orgasmic function, sexual desire, intercourse satisfaction, and overall sexual satisfaction. Of the psychosocial and relationship variables assessed, sexual performance anxiety at baseline predicted treatment efficacy with sildenafil. Subjects with higher levels of performance anxiety and more negative expectations regarding treatment at baseline showed a lesser degree of response to sildenafil therapy. In contrast, sexual excitation or inhibition, as measured by the SIS/SES (Janssen et al., 2002a, 2002b) scale, was not a specific predictor of treatment efficacy. Effects of this measure and other baseline variables may have been obscured because of the small number of subjects who completed the study, predominant effects of pharmacotherapy in this study, and potential mediating effects of other variables (e.g., partner relationship).

Positive treatment changes were associated with improvements in sexual desire and overall sexual satisfaction. In contrast, relationship adjustment at baseline did not predict erectile function or sexual satisfaction following treatment but was a significant predictor of changes in sexual activity and desire. The relatively high levels of psychological and relationship adjustment prior to treatment may have diminished or obscured effects of these variables on treatment efficacy; alternatively, the high degree of efficacy of sildenafil likely overshadowed the effects of other variables on treatment outcome. On the other hand, relationship adjustment was seen to be a significant predictor of changes in sexual desire and activity. We observed a similar pattern of effects in relation to treatment satisfaction as erectile function. These two measures (IIEF [Rosen et al., 1997], EDITS [Althof et al., 1999]) have previously been shown to be highly correlated.

The present study showed a different overall pattern of predictors of pharmacotherapy outcome compared with van Lankveld et al. (2003). The study designs were different, however; the present study did not include an assessment beyond the discontinuation of sildenafil treatment. However, both studies assessed changes in expectancies regarding erections (SVSS in the present study and sexual self-confidence in van Lankveld et al.). Although sexual self-confidence predicted erectile functioning at follow-up 6 weeks after sildenafil discontinuation in the van Lankveld et al. (2003) study, expectancy ratings regarding the ability to attain erections sufficient for intercourse without using sildenafil were not significant predictors of treatment response in the present study. This may be because the effect of expectancies were overshadowed by the effect of sildenafil and would have been an important predictor of erectile functioning after termination of treatment. However, a related variable, sex-specific anxiety, was the main psychosocial predictor of changes in erectile functioning in our study.

The high rate of treatment discontinuation observed in our study may have been due to a number of factors. Surprisingly, it did not appear to be associated with a lack of efficacy of treatment. Because it was not possible for us to evaluate subjects or their partners following treatment discontinuation, we can only speculate about specific reasons for dropout. In some instances, the burdensomeness of the psychological evaluations or need for partner involvement throughout the study may have led to discontinuation. In other cases, subjects may have chosen to enter clinical trials with other drugs or may have obtained medication through other sources. Among the study variables examined as predictors of dropout, we observed a curvilinear relationship between stress and treatment discontinuation; subjects with moderate stress levels at baseline were more likely to continue treatment. This finding suggests that motivation levels may have been optimal for subjects with moderate levels of stress at baseline. None of the other baseline or treatment variables were significant predictors of treatment discontinuation.

Limitations of the present study are worth noting. First, the study requirements for active partner participation and absence of a history of psychiatric problems in either partner may have biased selection toward couples with better psychological and relationship adjustment at baseline. In addition, the high discontinuation rate is another important limitation of the study, although this appears to be mirrored by survey results of current users of PDE-5 therapies (Rosen et al., 2004). Finally, the lack of randomization or a placebo-blind control may have influenced some variables. Because our study was not designed to evaluate the efficacy of sildenafil per se, we did not include a placebo-control condition. Subject or partner expectations could have influenced ratings of treatment efficacy and outcome in addition to or beyond the specific effects of treatment. On the other hand, these same factors are likely to effect ratings of treatment satisfaction or outcome in naturalistic settings.

Taken together, these findings indicate the need for further studies of psychosocial variables in treatment outcome with oral therapy for ED. This is needed for better understanding of treatment satisfaction and factors that may contribute to premature treatment dropouts. Notwithstanding the high level of efficacy observed with sidenafil treatment in our study, subjective anxiety about sex was associated with significant differences in treatment effects on erectile function. Posttreatment sexual desire and activity levels were strongly associated with relationship adjustment at baseline, independent of the effects of ED severity. Partner function was improved overall following treatment, although changes in erectile function alone did not adequately predict the responses of partners to treatment. Overall, these findings support the potential value and significance of further assessment of the role of psychosocial variables in responses to pharmacotherapy for ED.

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