Impact of Erectile Dysfunction on Confidence, Self-Esteem and Relationship Satisfaction After 9 Months of Sildenafil Citrate Treatment

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Purpose: The first double-blind, placebo controlled trial in the United States of the Self-Esteem And Relationship questionnaire revealed that treatment with sildenafil citrate improves erectile function and measures of quality of life in men with erectile dysfunction. We investigated long-term improvement, and correlations between improved erectile function and confidence, self-esteem and sexual relationship satisfaction in men with erectile dysfunction.

Materials and Methods: This was a 36-week open label extension of the double-blind, placebo controlled trial. The blind was not broken. Patients were 18 years or older with clinically diagnosed erectile dysfunction. Erectile function was assessed using the International Index of Erectile Function. Self-esteem, confidence and relationship satisfaction were assessed using the Self-Esteem And Relationship questionnaire. Correlations were determined using Pearson's product moment coefficients.

Results: A total of 204 participants were enrolled in the open label extension, including 108 on placebo and 96 on sildenafil. In men who received placebo in the double-blind, placebo controlled phase mean erectile function scores and self-esteem, confidence and relationship satisfaction scores were increased significantly at week 36 of the open label extension ($p < 0.0001$). Men who received sildenafil in the double-blind, placebo controlled phase maintained high scores in the open label extension. Correlations between improved erectile function, and self-esteem, confidence and relationship satisfaction were strong and positive ($p < 0.0001$).

Conclusions: Open label extension sildenafil after double-blind, placebo controlled placebo significantly improved erectile function, self-esteem, confidence and relationship satisfaction. Following an initial 12 weeks of double-blind, placebo controlled sildenafil therapy for erectile dysfunction improvements were sustained an additional 9 months. Positive correlations between erectile function, and self-esteem, confidence and relationship satisfaction suggest that improved erectile quality can improve long-term psychosocial quality of life.

Key Words: penis, impotence, sildenafil, quality of life, psychometrics

In men with ED the inability to maintain normal EF can significantly impact psychosocial measures of quality of life. The negative psychological impact of ED is characterized by men feeling emasculated, old and concerned about the romantic relationship with their partner,[1] resulting in anxiety, relationship strain, and loss of self-esteem and self-confidence.[2,3] At the onset of ED men avoid intimacy and lovemaking,[4] have increased feelings of sadness and worry that they are not fulfilling the needs of their partner.[1,5] Furthermore, the loss of self-esteem and confidence imparted by ED can affect interpersonal relationships with friends and others, and it can be distressing to men and their partners.

SEAR is a newly validated, patient reported outcome measure designed to evaluate the ED specific impact on psychosocial factors related to quality of life, particularly confidence and self-esteem.[6,7] In the 10-week open label trial that was used to validate SEAR 93 men with ED demonstrated responsiveness to beneficial treatment for ED with significant improvement in self-esteem, confidence and relationship scores. Improvement in SEAR scores correlated well with improvements in EF domain scores in IIEF.[7] Because proper EF is considered an important component of physiological and psychological health in men,[8] it is important to evaluate these end points when assessing the efficacy of treatment for ED.

The first DBPC study using SEAR was done in the United States.[9] It revealed that improvements in EF with sildenafil were associated with improvements in confidence, self-esteem, sexual relationship satisfaction and sexual relations.

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To our knowledge what has not yet been studied is whether the changes in self-esteem and sexual relationship satisfaction are longer lasting, that is whether they extend beyond the traditional 12-week clinical trial period. Improvement in self-esteem and sexual relationship satisfaction with successful ED treatment may enhance ED treatment satisfaction and long-term treatment compliance. We assessed the OLE of the DBPC trial as well as long-term effectiveness, and changes in confidence, self-esteem and sexual relationship satisfaction after treatment with sildenafil for ED.

MATERIALS AND METHODS

Study Design

This was a 36-week OLE of the first DBPC trial of SEAR in men with ED in the United States.[9] The blind was not broken in this OLE study. The study was performed between August 5, 2002 and September 10, 2003 at 25 investigational sites in the United States. All patients enrolled in the OLE completed the DBPC trial. The final visit of the DBPC trial served as the first visit of the OLE. All patients started the OLE with a 50 mg dose of sildenafil regardless of the dose or treatment that they received at the end of the DBPC trial. They were instructed to ingest it 30 to 60 minutes before sexual activity. The sildenafil dose could be adjusted to 25 mg to enhance tolerability or to 100 mg to boost efficacy.

This study was performed in compliance with the Institutional Review Board/Independent Ethics Committee of the investigators, and with the International Conference on Harmonization and Good Clinical Practice Guidelines, as consistent with the most current version of the Declaration of Helsinki (revised Edinburgh, October 2000). All patients provided informed consent and all local regulatory requirements were adhered to, in particular those that provide greater subject protection and safety.

Patients were enrolled in the DBPC trial if they were 18 years or older, had a clinical diagnosis of ED (Sexual Health Inventory for Men score 21 or less)[10,11] and demonstrated decreased self-esteem (SEAR self-esteem subscale score 75 or less). Patients were excluded from the DBPC trial if they had resting hypotension (blood pressure less than 90/50 mm Hg), hypertension (blood pressure greater than 170/110 mm Hg) or significant cardiovascular disease (cardiac failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or symptomatic or clinically significant cardiac arrhythmia) in the last 3 months. Patients were excluded if they were on nitrates, which can precipitate hypotension, or the CYP3A4 inhibitor ritonavir, they had previously used more than 6 tablets of sildenafil or they had a history of retinitis pigmentosa.

Two populations were used for analyses. The safety population was defined a priori as patients who received at least 1 dose of study medication in the OLE. The intent to treat population was defined as patients who received at least 1 dose of study medication and who provided sufficient efficacy data for at least 1 efficacy analysis.

Study Outcomes

The primary study measure was the change in self-esteem and confidence in men with ED after sildenafil treatment. The effect of sildenafil on confidence, self-esteem and relationship satisfaction was assessed using SEAR. SEAR consists of 14 items divided into 2 domains, including sexual relationship (8 items, questions 1 to 8) and confidence (6 items, questions 9 to 14). The confidence domain is subdivided into the self-esteem (4 items, questions 9 to 12) and overall relationship (2 items, questions 13 and 14) subscales. Responses range from 1—never/almost never to 5—almost always/always. A higher SEAR score is more favorable. Domain, subscale and total SEAR scores are standardized to a 0 to 100-point scale using the transformation, transformed score = 100 × (actual raw score − lowest possible raw score)/possible raw score range.

A secondary study measure was the change in EF. The effect of sildenafil on erection hardness and EF was determined using the EF domain of the IIEF.[12] The EF domain score is the sum of scores on questions 1 to 5 and 15, and ED severity is categorized based on the EF domain score as no ED (normal EF)—26 or greater, mild ED—22 to 25, mild to moderate ED—17 to 21, moderate ED—11 to 16 and severe ED—10 or less.[13]

SEAR and IIEF scores were assessed at baseline in the DBPC trial, at baseline in the OLE study (end point of the DBPC trial), at week 14 of the OLE and at EOT (week 36 of the OLE). Other study measures were changes in scores in the other SEAR components, including overall relationship subscale, sexual relationship domain and overall SEAR score, and in the other IIEF domains, including orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction.

Correlations

We assessed correlations of changes in self-esteem, confidence and relationship satisfaction with changes in IIEF domain scores using Pearson's product moment correlation analysis. Correlations were determined for change in scores from the end of the DBCP trial (OLE study baseline). Thus, further improvements in scores were restricted to previous sildenafil patients and correlations between changes in scores were expected to be higher in previous placebo patients.

Safety

All patients who received at least 1 dose of study medication in the OLE (safety population) were monitored for changes in blood pressure and heart rate. All observed or volunteered adverse events were recorded.

Statistics

Mean scores and the 95% CI are reported for SEAR components and the EF domain of the IIEF. Differences between the OLE baseline score, and scores at week 14 and at EOT (week 36) in previous placebo and previous sildenafil patients were determined using the t test within and between groups. Correlations between changes in IIEF domain and SEAR component scores were determined at week 36 using Pearson's correlations with statistical significance considered at the 5% level.

RESULTS

Demographics

A total of 204 patients completed the DBPC phase and were enrolled in the OLE, including 108 randomized to placebo (previous placebo) and 96 randomized to sildenafil (previous

sildenafil). Of the 108 previous placebo patients 95 (88%) and 75 of the 96 previous sildenafil patients (78%) completed the 36-week OLE study. At week 36, 105 previous placebo patients and 91 previous sildenafil patients were included in intent to treat group analysis. The groups were well balanced for patient age, and ED duration and etiology (table 1).

Self-Esteem and Confidence

Patients randomized to receive placebo in the DBPC phase did not achieve improved self-esteem or confidence scores at the end of the DBPC phase (OLE baseline) but they achieved significant improvements at weeks 14 and 36 in the OLE study (fig. 1). Mean self-esteem subscale scores were 40 (95% CI 36 to 44) at DBPC baseline and 49 (95% CI 44 to 54) at the end of the DBPC phase (OLE baseline). Scores improved significantly vs OLE baseline to 72 (95% CI 66 to 77) and 76 (95% CI 71 to 81) after 14 and 36 weeks of open label sildenafil, respectively ($p < 0.0001$). Mean confidence domain scores in previous placebo patients were similar to self-esteem subscale scores at DBPC baseline, at the end of the DBPC phase (OLE baseline), and at OLE weeks 14 and 36. Previous sildenafil patients maintained the improvements that they had achieved in self-esteem and confidence during the DBPC phase after receiving sildenafil in the OLE for an additional 36 weeks. The maximum self-esteem subscale and confidence domain score is 100. Previous placebo and previous sildenafil patients achieved self-esteem scores that were close to those reported in men without ED (83.5),[6] indicating that self-esteem and confidence improved to almost normal values in each group after sildenafil treatment. At EOT self-esteem subscale and confidence domain scores in previous placebo patients were not different from those in previous sildenafil patients.

EF

Patients randomized to receive placebo in the DBPC phase did not achieve significant improvements in EF domain scores at the end of the DBPC trial (OLE baseline) but they did so at weeks 14 and 36 in the OLE study (fig. 2). Mean EF domain scores at baseline in the DBPC trial were 13 (95% CI 12 to 14) and 16 (95% CI 15 to 18) at the end of the DBPC trial (OLE baseline). Mean scores on the EF domain improved significantly vs the OLE baseline to 25 (95% CI 23 to 26) after 14 weeks of open label sildenafil ($p < 0.0001$). They remained high at 25 (95% CI 24 to 27) after 36 weeks of open label sildenafil. Previous sildenafil patients maintained EF improvements at weeks 14 and 36 of open label sildenafil. The maximum score on the EF domain is 30. Previous placebo and previous sildenafil patients achieved EF domain scores that were close to those reported in men without ED (25.8),[14] indicating that previous placebo and previous sildenafil patients achieved almost normal EF (26 or greater).[13] At EOT EF domain scores in previous placebo patients were not different from those in previous sildenafil patients.

TABLE 1. *Baseline characteristics in OLE intent to treat study group*

	Previous Placebo	Previous Sildenafil
No. pts	105	91
Age:		
Mean ± SD	56.1 ± 12.5	56.8 ± 11.7
Range	23–81	30–84
No. 18–44 (%)	20 (19)	15 (17)
No. 45–64 (%)	57 (54)	56 (62)
No. 65 or older (%)	28 (27)	20 (22)
No. race (%):		
White	70 (67)	53 (58)
Black	25 (24)	22 (24)
Asian	2 (2)	2 (2)
Other	8 (8)	14 (15)
Wt (kg):		
Mean ± SD	177 ± 10	177 ± 9
Range	150–201	147–193
ED duration since first diagnosis (yrs):		
Mean	3.5	4.7
Range	0.4–19.4	0.3–25.7
No. ED etiology (%):		
Mixed	43 (40)	39 (41)
Organic	56 (52)	42 (44)
Psychogenic	9 (8)	15 (16)

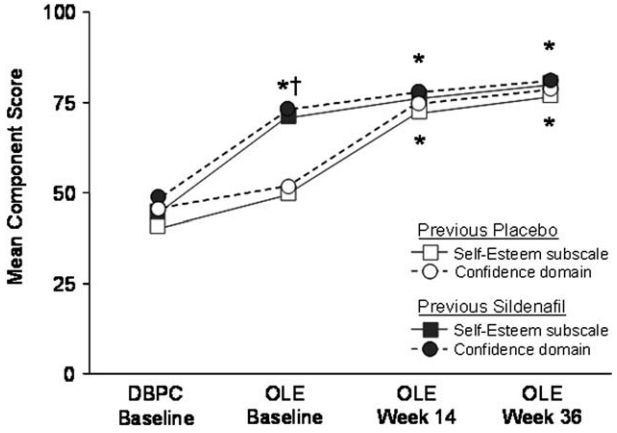

FIG. 1. Mean scores on SEAR confidence domain and self-esteem subscale were determined at baseline in DBPC trial, at end of DBPC trial (OLE baseline), and at weeks 14 and 36 in OLE in patients previously randomized to placebo or sildenafil in DBPC trial. Maximal self-esteem subscale score is 100. Asterisk indicates $p < 0.0001$ vs DBPC baseline scores. Dagger indicates $p < 0.0001$ vs placebo.

Other SEAR Components and IIEF Domains

Changes in other SEAR component scores in previous placebo and previous sildenafil patients mirrored those ob-

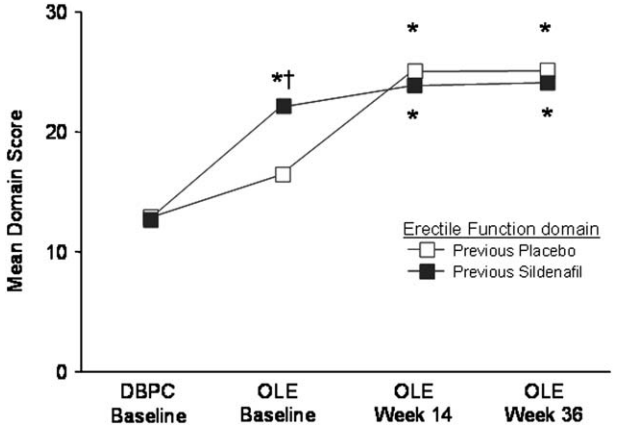

FIG. 2. Mean scores on IIEF EF domain determined at baseline in DBPC trial, at end of DBPC trial (OLE baseline), and at weeks 14 and 36 in OLE in patients previously randomized to placebo or sildenafil in DBPC trial. Maximal EF domain score is 30. Asterisk indicates $p < 0.0001$ vs DBPC baseline scores. Dagger indicates $p < 0.0001$ vs placebo.

TABLE 2. *Baseline, week 14 and EOT week 36 scores in OLE patients*

	No. Pts	Mean Self-Esteem ± SD	Mean Sexual Relationship ± SD	Mean Overall Relationship ± SD	Mean Confidence ± SD	Mean Overall SEAR ± SD
Of OLE baseline:						
Previous placebo	115	49.4 ± 29.8	44.0 ± 25.6	52.6 ± 30.5	50.1 ± 28.9	46.6 ± 26.1
Previous sildenafil*	113	74.7 ± 24.4	67.4 ± 26.5	75.0 ± 28.0	74.6 ± 24.0	70.4 ± 24.3
Wk 14:*						
Previous placebo	100	72.4 ± 25.9	70.9 ± 22.1	75.6 ± 25.8	73.8 ± 25.2	72.1 ± 23.0
Previous sildenafil	91	77.2 ± 25.1	70.7 ± 24.4	78.0 ± 25.8	77.2 ± 23.9	73.5 ± 23.2
Wk 36:*						
Previous placebo	103	76.9 ± 25.0	73.0 ± 21.4	78.9 ± 25.1	77.7 ± 24.1	75.1 ± 22.0
Previous sildenafil	91	80.6 ± 25.2	72.9 ± 27.2	80.8 ± 27.8	80.3 ± 25.1	76.1 ± 25.6

* Vs previous placebo at OLE baseline $p < 0.0001$.

served for self-esteem subscale, confidence domain and EF domain scores (table 2). Previous placebo patients did not achieve significant gains in sexual relationship domain scores or overall relationship subscale scores at the end of the DBPC phase, whereas previous sildenafil patients achieved significant gains in these aspects of psychosocial functioning and well-being at the end of the DBPC trial. During the OLE study mean scores in previous placebo patients improved rapidly and significantly vs OLE baseline from OLE baseline to week 14 ($p < 0.0001$). They continued to improve at week 36. Mean scores in previous placebo patients were not different from scores in previous sildenafil patients at week 14 and at the end of the OLE study (week 36). All scores at week 36 were significantly higher than scores in previous placebo patients at OLE study baseline.

Correlations

Correlations of changes in EF with changes in confidence, self-esteem and overall relationship satisfaction were positive, moderate and statistically significant. Correlations of the EF domain with the confidence domain, the self-esteem subscale and the overall relationship subscale were lower in the previous sildenafil vs previous placebo group (0.33 vs 0.68, 0.30 vs 0.68 and 0.19 vs 0.55, respectively), as expected, because further improvement in scores from OLE study baseline were more restricted in the previous sildenafil group (table 3). Correlations between all other SEAR components and all other IIEF domains were positive and statistically significant in the previous placebo group and higher in the previous placebo group than in the previous sildenafil group, as expected.

Safety

Treatment related adverse events that occurred in greater than 5% of patients who had previously been randomized to placebo included headache in 6%, rhinitis in 6% and flushing in 7%. The rate of these adverse events in patients randomized to sildenafil in the DBPC phase was headache in 7%, rhinitis in 2% and flushing in 2%. Only 1 patient in the previous sildenafil group and none in the previous placebo group withdrew prematurely from the study as a result of a treatment emergent adverse event. That single patient experienced atrial fibrillation, which was not considered to be related to having received sildenafil.

DISCUSSION

Erectile dysfunction adversely affects relationships, self-esteem, confidence and quality of life. Positive correlations in the expected direction between SEAR components and IIEF domains in the current study demonstrate that improvements in EF are associated with tangible long-term improvements in self-esteem, confidence and relationship satisfaction. Patients in the 2 previous DBPC treatment groups demonstrated comparable improvements in EF, self-esteem, confidence and relationship satisfaction at the end of the OLE study, representing significant improvements from baseline in the parent DBPC trial. Moreover, improvements in EF correlated positively with improvements in psychosocial measures of quality of life, which may suggest a high level of satisfaction with treatment in men successfully treated with sildenafil for ED.

TABLE 3. *Changes from OLE baseline in SEAR vs IIEF*

	SEAR Self-Esteem		SEAR Confidence		SEAR Overall Relationship	
IIEF Domain	Previous Placebo	Previous Sildenafil	Previous Placebo	Previous Sildenafil	Previous Placebo	Previous Sildenafil
No. pts	103	89	105	90	105	90
EF	0.68	0.33	0.68	0.30	0.55	0.19
p Value	<0.0001	0.0016	<0.0001	0.0036	<0.0001	0.0735
Orgasmic function	0.59	0.27	0.62	0.29	0.53	0.27
p Value	<0.0001	0.01	<0.0001	0.0048	<0.0001	0.0096
Sexual desire	0.34	0.37	0.33	0.36	0.34	0.24
p Value	<0.0001	0.0003	0.0005	0.0005	0.0004	0.0242
Intercourse satisfaction	0.65	0.40	0.67	0.37	0.56	0.23
p Value	<0.0001	<0.0001	<0.0001	0.0003	<0.0001	0.0266
Overall satisfaction	0.77	0.54	0.79	0.50	0.69	0.33
p Value	<0.0001	<0.0001	<0.0001	<0.0016	<0.0001	0.0016

It is important to understand the impact of ED on male confidence, self-esteem and relationships because, when a man experiences erectile difficulties, his sexual partner may also suffer. In this way ED is the problem of the couple.[15] The psychosocial reaction to ED often begins with feelings of failure or inadequacy and may lead to fear of initiating sexual contact and physical distancing between partners.[16] Long-term avoidance of sexual intimacy can result in the partner feeling guilty and rejected, relationship dissatisfaction, fear of intimacy and lack of sexual desire.[15] However, partners of men with ED who are treated with sildenafil reported significant improvements in relationship satisfaction and satisfaction with treatment.[17–19] A large pooled analysis of 26 DBPC trials revealed that improved EF in men with ED is associated with similar improvements in these satisfaction measures.[20] In addition, an open label study in men treated with sildenafil for ED revealed an increased desire for basic intimacy,[4] which may facilitate greater sexual intimacy and lead to improved sexual and relationship satisfaction.

Measuring the psychosocial impact of ED is important for evaluating ED treatments and long-term treatment success. SEAR extends existing psychosocial instruments of quality of life by adding a self-esteem subscale. Improvements in self-esteem, confidence and relationship satisfaction after successful treatment for ED may increase the desire for long-term treatment and enhance treatment adherence. Positive correlations between improvements in SEAR and IIEF scores, and continued improvements in self-esteem scores up to 48 weeks suggest a psychosocial benefit from successful ED treatment with sildenafil that can be maintained in the long term.

There are limitations to this study. 1) Although the overall relationship subscale score, which correlated well with IIEF domain scores, can be a useful measure of improved relationship satisfaction, it contains only 2 broad questions and neither directly assesses partner satisfaction. A more complete measure of overall relationship satisfaction in which satisfaction scores of each partner are incorporated would have more completely conveyed the intricate and complex nature of relationship satisfaction. 2) In this OLE study only the effect of sildenafil on EF was measured using the IIEF. Any effect of sildenafil on the impact of other measures of sexual function, eg premature ejaculation, was not measured. 3) Patients in this OLE study were primarily white men with ED in the United States. It is possible that the cultural, religious and socioeconomic factors of other countries may affect changes in self-esteem, confidence, and sexual and relationship satisfaction. However, the Global Study of Sexual Attitudes and Behaviors revealed that these factors are similar across many cultures.[21] Thus, we expect improvement in psychosocial function and quality of life in men across cultures after successful treatment for ED.

CONCLUSIONS

These data suggest sustained improvements in confidence and self-esteem, and almost normal EF when sildenafil use was continued for 9 months following a 12-week DBPC trial. Previous placebo patients who used sildenafil for 9 months attained self-esteem, confidence and EF scores that were similar to those in previous sildenafil patients and they were almost normal scores. Significant correlations with expected magnitudes were observed between changes in self-esteem and changes in EF after 9 months of sildenafil treatment.

APPENDIX

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Abbreviations and Acronyms

DBPC	=	double-blind, placebo controlled
ED	=	erectile dysfunction
EF	=	erectile function
EOT	=	end of treatment
IIEF	=	International Index of EF
OLE	=	open label extension
SEAR	=	Self-Esteem And Relationship questionnaire

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