

ORIGINAL RESEARCH—ERECTILE DYSFUNCTION

In Men with Erectile Dysfunction, Satisfaction with Quality of Erections Correlates with Erection Hardness, Treatment Satisfaction, and Emotional Well-Being

Jed C. Kaminetsky, MD,* Andrzej J. Depko, MD,† Peter Ströberg, MD, PhD,‡ Jacques Buvat, MD,§ Li-Jung Tseng, PhD,[¶] and Vera J. Stecher, PhD^{||}

*University Urology Associates, New York, NY, USA; †Sexological Outpatients Clinic, Warsaw, Poland; ‡Urohälsan/ED-kliniken, Skövde, Sweden; §Centre d'Etudes et de Traitement de la Pathologie de l'Appareil Reproducteur et de la Psychosomatique, Lille, France; ¶Pfizer Inc., New York, NY, USA

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ABSTRACT

Introduction. The validated Quality of Erection Questionnaire (QEQ) evaluates satisfaction with erection quality. **Aim.** To collate QEQ data, including correlations between QEQ outcomes and outcomes assessing emotional well-being, treatment satisfaction, and erection hardness after sildenafil citrate treatment.

Methods. In four trials, men older than 18 years and with erectile dysfunction, a stable sexual partner, and no recent phosphodiesterase type 5 inhibitor use were randomized to double-blind flexible-dose sildenafil or placebo (1:1 ratio) for 6 or 10 weeks (two trials), fixed-dose 50 mg, 100 mg, and placebo (1:1:1 ratio) for 8 weeks (one trial), and 50 mg and 100 mg (1:1 ratio) for 4 weeks after 4 weeks of single-blind sildenafil 50 mg. Exclusion criteria included recent significant cardiovascular disease, use of nitrates, nitric oxide donors, cytochrome P450 3A4 inhibitors, or other erectile dysfunction treatment, and sildenafil hypersensitivity or previous severe or serious treatment-related adverse event.

Main Outcomes Measures. Scores on the QEQ, QEQ Question 5 (satisfaction with erection hardness), the Self-Esteem and Relationship Questionnaire, and the Erectile Dysfunction Inventory of Treatment Satisfaction; the percentage of occasions with Erection Hardness Score 3 (EHS 3, hard enough for penetration but not completely hard) and/or EHS 4 (completely hard and fully rigid); and Pearson correlation coefficients.

Results. 1,296 men (18–80 years) were randomized. Except for the percentage of occasions with EHS 3, all outcomes improved in men treated with sildenafil and correlated positively with the change in QEQ scores in all trials.

Conclusions. Satisfaction with the quality of erections, which is easily monitored with the QEQ, correlated positively with measures of emotional well-being and treatment satisfaction and with the change in percentage of erections that were completely hard and fully rigid, but not with the change in percentage of erections that were hard enough for penetration but not completely hard. **Kaminetsky JC, Depko AJ, Ströberg P, Buvat J, Tseng L-J, and Stecher VJ. In men with erectile dysfunction, satisfaction with quality of erections correlates with erection hardness, treatment satisfaction, and emotional well-being. J Sex Med 2009;6:800–808.**

Key Words. Erectile Dysfunction; Quality of Life; Questionnaires; Sexual Satisfaction; Sildenafil

Introduction

The Quality of Erection Questionnaire (QEQ) is a validated, six-item, patient-reported outcome questionnaire for evaluating satisfaction with the quality of erections in terms

of hardness, onset, and duration, as well as for assessing changes in erection quality with successful treatment of erectile dysfunction (ED) [1]. It demonstrated excellent convergent and known-groups validity, high internal consistency, and a unidimensional structure [1]. The QEQ was

developed to be a brief, easy-to-administer, patient-friendly tool to identify men who are dissatisfied with the quality of their erections, and therefore motivated to treat their ED.

The QEQ allows treatment goals to be individualized based on the psychosocial element of “satisfaction with quality of erection” rather than on the clinical element of “quality of erection.” Because it evaluates satisfaction with the quality of erection from the patient’s perspective, it identifies a perceived need of the patient, making it a potentially useful measure for both clinical trials research and the clinical practice setting. The psychosocial patient perspective of the QEQ enables physicians and patients to develop and monitor individualized treatment plans aimed at satisfying the perceived need of the man with ED. Detailed psychometric analyses of the QEQ items and factor structure suggest that hardness is the key driver for overall satisfaction with the quality of erections [1].

Interpreting QEQ scores and establishing criteria for meaningful improvement in scores are important to understanding the relevance of outcomes on this validated health status measure. Convergence of anchor-based and distribution-based criteria supports a minimum clinically important difference in QEQ scores of 12 points between treatments [2].

The QEQ has been administered in four prospective, parallel-group, randomized, double-blind trials in men treated with sildenafil citrate for ED [3–6]. These trials showed that the QEQ is responsive to the benefits of sildenafil treatment in men with ED. To obtain a deeper understanding of relationships between satisfaction with erection quality, specifically hardness, and other outcomes, this report collated data from these four trials, including correlations between the change in QEQ scores and scores on validated measures that assess erection hardness, satisfaction with ED treatment, and emotional well-being after treatment with sildenafil citrate.

Methods

Detailed methods of the trials were reported previously [3–6]. In summary, these were prospective, multicenter, parallel-group, randomized, double-blind trials of men with ED, a stable sexual partner, and no recent phosphodiesterase type 5 inhibitor use, which were conducted in the European Union plus various other locales (Asia, Canada, Israel, Russian Federation, and South

America) [3,5,6] or in the United States [4]. Exclusion criteria included significant hypotension, hypertension, or recent cardiovascular disease, or concomitant ED treatments, nitrates or nitric oxide donors, or cytochrome P450 3A4 inhibitors. In two of the trials, the men were randomized (1:1 ratio) to flexible-dose sildenafil or placebo, initiating treatment at 50 mg and adjusting the dose to 25 mg (trial 1 only) [5] or 100 mg over the 6-week [5] or 10-week [4] double-blind phases. The other trials assessed fixed-dose sildenafil. In one fixed-dose trial, the men were randomized to sildenafil 50 mg, sildenafil 100 mg, or placebo (1:1:1 ratio) for 8 weeks [6]. In the other fixed-dose trial, men who tolerated single-blind sildenafil 50 mg for 4 weeks were randomized to double-blind sildenafil 50 mg or sildenafil 100 mg (1:1 ratio) for 4 more weeks [3]. Thus, there were three trials with parallel placebo control [4–6] and one dose comparison trial [3]. In all of the trials, medication was to be taken as needed, but not more than once daily.

Patients

Major inclusion criteria were a clinical diagnosis of ED confirmed by a score ≤ 25 (out of 30) on the erectile function domain of the International Index of Erectile Function (IIEF), a stable sexual partner, and age ≥ 18 years (two trials had an upper age limit: 55 [5] and 65 [6] years, respectively). Three of the trials excluded men who had taken >6 doses of sildenafil or another phosphodiesterase type 5 inhibitor in total or any dose recently (within 4 weeks [5,6] or 6 months [4]). Other major exclusion criteria included recent significant cardiovascular disease (within 3 or 6 months); use of nitrates or nitric oxide donors in any form on either a regular or intermittent basis; concomitant treatment with a cytochrome P450 3A4 inhibitor, such as ritonavir, saquinavir, ketoconazole, itraconazole, erythromycin, or cimetidine; known hypersensitivity to sildenafil; previous severe or serious treatment-related adverse event to sildenafil; and current use of any other commercially available drug or nondrug treatment for ED. Written informed consent was obtained from all participants. The final protocol was reviewed and approved by an Institutional Review Board and/or Independent Ethics Committee.

Assessments

The QEQ [1] was administered at baseline and at the end of the treatment phase (or at discontinuation). In addition to the QEQ total score, results are reported for Question 5 (QEQ Q5, “Over the

past 4 weeks, the hardness of your erection was . . . ,” scored from 1 [very unsatisfactory] to 5 [very satisfactory]).

The Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) [7], which assesses satisfaction with ED treatment, was administered at the end of the treatment phase (or at discontinuation). The EDITS is a validated 11-item instrument for which responses are reported as the EDITS Index (by transforming the average EDITS score onto a 0–100 scale; higher is better).

In the three trials with parallel placebo control [4–6], the Self-Esteem and Relationship (SEAR) questionnaire [8] was administered at baseline and at the end of the treatment phase (or at discontinuation). The SEAR is a validated 14-item instrument that assesses general and sexually specific emotional well-being in the domains of Confidence (with subscales of Self-Esteem and Overall Relationship) and Sexual Relationship; scores are transformed onto a 0–100 scale (higher is better).

In the three trials with parallel placebo control [4–6], the Erection Hardness Score (EHS) was used to rate erection hardness at every occasion of sexual stimulation as: increase in size but not hard (EHS 1), hard but not hard enough for penetration (EHS 2), hard enough for penetration but not completely hard (EHS 3), and completely hard and fully rigid (EHS 4) [9].

Analyses

Analyses were conducted on data from the intent-to-treat population for each study, which was defined as men who took at least one dose of study medication and who provided sufficient efficacy data for at least one efficacy analysis. Treatment effects were estimated using least squares (LS) means from an analysis of covariance model with terms of baseline value, treatment group, investigator site, and prognostic factors (age, ED duration, ED etiology). *P* values were calculated (at the 5% significance level) for the test of treatment group differences in change from baseline. For EHS occasions, estimated percentage values were derived from logistic regression.

For the QEQ total score and QEQ Q5 (satisfaction with erection hardness), Pearson correlation coefficients (95% confidence interval [CI]) were calculated between the mean change in scores and the EDITS Index score, the SEAR mean change in scores (using data from the three trials that reported SEAR [4–6]), and the percentage of occasions with EHS 3, EHS 4, and EHS 3 or EHS 4 (using data from the three trials that reported EHS [4–6]). *P*

values were calculated under the null hypothesis that the correlation was zero.

Results

Population

Across the four trials, 1,296 men were randomized and received treatment (Table 1). Age ranged from 18 to 80 years, with the means across all groups ranging from the mid-40s to early 50s. More than a third of the men in the fixed-dose comparison of sildenafil 50 mg and 100 mg vs. placebo [6] were Asian, with the remainder being predominantly Caucasian.

Efficacy Outcomes

Because of the design differences between the dose comparison trial [3] and the three trials with parallel placebo control [4–6], the results of the dose comparison trial are reported in the text rather than the tables.

The improvement from baseline in QEQ total scores was four to six times greater in the sildenafil groups (range of improvement, 30–45 points) compared with their respective placebo groups (range of improvement, 5–8 points) in the three trials with parallel placebo control (Table 2). Similar results were seen for the improvement in QEQ Q5 scores from baseline (Table 2). During the single-blind phase of the dose comparison trial (fixed-dose sildenafil 50 mg for 4 weeks), the baseline mean \pm standard deviation QEQ total score improved by 43 ± 31 points in the group subsequently randomized to double-blind sildenafil 50 mg for 4 more weeks, and by 42 ± 27 points in the group subsequently randomized to double-blind sildenafil 100 mg for 4 more weeks [3]. In this trial, the LS mean \pm standard error QEQ total score continued to improve after randomization by 7 ± 1 points and 10 ± 1 points, respectively [3].

Improvement also occurred in the other outcomes. The EDITS Index scores were 67–78 across the sildenafil groups compared with 48–52 across the placebo groups [3–6]. A large improvement favoring sildenafil over placebo was seen in the EHS 4, EHS 3 plus EHS 4, and SEAR outcomes (Table 2). In most of the sildenafil treatment groups, the percentage of occasions with EHS 3 declined with sildenafil treatment, in part because many patients experienced an improvement to more frequent occasions with EHS 4.

Most correlations between the different tests were positive. In the three trials with parallel

Table 1 Baseline characteristics

	Flexible-dose trials [4,5]			Fixed-dose trials [3,6]				
	Placebo (n = 153) [†]	Sildenafil 25, 50, and 100 mg (n = 154) [†]	Placebo (n = 105) [†]	Sildenafil 100 mg (n = 104) [†]	Placebo (n = 95) [†]	Sildenafil 50 mg (n = 94) [†]	Sildenafil 100 mg (n = 99) [†]	Sildenafil 50 or 100 mg* (n = 492) [†]
Age, mean ± SD (range), years	45 ± 9 (18–55)	45 ± 8 (21–55)	51 ± 12 (25–73)	53 ± 12 (20–76)	50 ± 10 (20–65)	52 ± 10 (28–65)	51 ± 10 (22–65)	53 ± 11 (22–80)
Race, n (%)								
White	140 (92)	141 (92)	78 (74)	86 (83)	62 (65)	59 (63)	63 (64)	479 (97)
Black	4 (3)	4 (3)	14 (13)	8 (8)	0	0	0	4 (1)
Asian	0	0	0	2 (2)	33 (35)	35 (37)	35 (35)	3 (1)
Other	9 (6)	9 (6)	13 (12)	8 (8)	0	0	1 (1)	6 (1)
Weight, mean ± SD (range), kg	83 ± 14 (50–162)	80 ± 13 (46–123)	95 ± 22 (62–191)	93 ± 18 (55–138)	81 ± 12 (54–117)	79 ± 12 (56–112)	80 ± 13 (56–120)	86 ± 15 (50–143)
Height, mean ± SD (range), cm	175 ± 8 (158–195)	174 ± 7 (158–197)	178 ± 9 (145–196)	179 ± 7 (163–193)	175 ± 7 (150–195)	174 ± 7 (160–190)	174 ± 7 (156–189)	175 ± 8 (146–197)
ED duration, mean (range), year	2 (<1–21)	2 (<1–18)	3.8 (<1–13)	4.6 (<1–41)	3.2 (<1–29)	3.2 (<1–26)	3.3 (<1–19)	Not available
ED etiology, organic/ mixed/psychogenic, n	24/69/60	19/61/74	61/25/19	60/27/17	27/53/15	27/55/12	24/62/13	Not available
Comorbidities, n (%)								
Hypertension	24 (16)	26 (17)	43 (41)	39 (38)	20 (21)	21 (22)	19 (19)	164 (33)
Diabetes	16 (11)	18 (12)	18 (17)	16 (15)	8 (8)	9 (10)	13 (13)	95 (19)
Hyperlipidemia	4 (3)	1 (1)	10 (10)	9 (9)	6 (6)	7 (7)	2 (2)	114 (23)
Hypercholesterolemia	7 (5)	7 (5)	22 (21)	25 (24)	7 (7)	7 (7)	2 (2)	4 (1)
BPH	4 (3)	7 (5)	18 (17)	17 (16)	9 (9)	15 (16)	12 (12)	36 (7)
Depression	1 (1)	1 (1)	9 (9)	10 (10)	1 (1)	2 (2)	1 (1)	27 (6)

*Men who tolerated 4 weeks of single-blind sildenafil 50 mg were randomized to 4 weeks of double-blind sildenafil 50 mg or sildenafil 100 mg.

[†]Safety population: men who took at least one dose of study medication.

SD = standard deviation; ED = erectile dysfunction; BPH = benign prostatic hyperplasia.

Table 2 Efficacy outcomes

	Flexible-dose trials											
	25, 50, and 100 mg				50 and 100 mg				8-weeks fixed-dose trial [6]			
	6 weeks		6 weeks (interim)		6 weeks		10 weeks		50 mg		100 mg	
	PL	SIL	PL	SIL	PL	SIL	PL	SIL	PL	SIL	PL	SIL
QEQ change [†] in score, LS mean ± SE												
Total (range 0–100)	7 ± 2	41 ± 3**	5 ± 4	30 ± 4**	8 ± 4	34 ± 4**	8 ± 3	40 ± 3**	45 ± 3**			
Q5 (range 1–5)	0.3 ± 0.1	1.7 ± 0.1**	0.2 ± 0.2	1.3 ± 0.2**	0.2 ± 0.2	1.4 ± 0.2**	0.4 ± 0.1	1.6 ± 0.1**	1.9 ± 0.1**			
EDITS Index (range 0–100), LS mean ± SE	52 ± 2	76 ± 2**	48 ± 3	67 ± 3**	50 ± 3	67 ± 3**	50 ± 2	73 ± 2**	78 ± 2**			
EHS occasions, % at baseline/estimated % with treatment												
EHS 3	41/42	40/28*	42/42	41/31*	41/40	41/33	34/39	25/47	42/41			
EHS 4	5/14	5/58**	7/10	4/44**	7/9	4/39**	2/7	1/25**	2/35**			
EHS 3 and EHS 4	46/57	45/88**	49/55	45/84**	48/52	44/79**	35/47	26/77**	45/81**			
SEAR change [†] in score (range 0–100), LS mean ± SE												
Sexual relationship	6 ± 2	31 ± 2**	5 ± 3	20 ± 3**	7 ± 3	24 ± 3**	4 ± 3	27 ± 2**	34 ± 2**			
Confidence	5 ± 2	26 ± 2**	3 ± 3	13 ± 3*	6 ± 3	17 ± 3*	0.3 ± 3	22 ± 3**	28 ± 2**			
Self-esteem	6 ± 2	28 ± 2**	3 ± 3	13 ± 3*	8 ± 3	20 ± 3*	1 ± 2	23 ± 3**	28 ± 3**			
Overall relationship	2 ± 2	23 ± 2**	2 ± 3	12 ± 3*	3 ± 4	12 ± 4*	-1 ± 3	19 ± 3**	28 ± 3**			
Overall	5 ± 2	29 ± 2**	4 ± 3	17 ± 3**	6 ± 3	21 ± 3**	3 ± 2	25 ± 2**	32 ± 2**			

* $P < 0.05$ vs. placebo; ** $P < 0.0001$ vs. placebo.[†]Change from baseline.

PL = placebo; SIL = sildenafil; QEQ = Quality of Erection Questionnaire; LS = least squares; SE = **; Q5 = satisfaction with erection hardness; EDITS = Erectile Dysfunction Inventory of Treatment Satisfaction; EHS = Erection Hardness Score; SEAR = Self-Esteem and Relationship Questionnaire.

Table 3 Correlations with the change in score from baseline on the QEQ total score

	Pearson correlation coefficient (95% CI), overall population			
	Flexible-dose trials [4,5]			Fixed-dose trial [6]
	SIL 25, 50, and 100 mg vs. PL for 6 weeks	SIL 50 and 100 mg vs. PL		SIL 100 or 50 mg vs. PL for 8 weeks
		6 week (interim)	10 weeks	
EDITS Index [†]	0.70 (0.64–0.76)*	0.66 (0.58–0.74)*	0.70 (0.62–0.77)*	0.70 (0.63–0.75)*
EHS change [†] in percentage occasions				
EHS 3	–0.03 (–0.15–0.09)	–0.07 (–0.22–0.07)	0.05 (–0.10–0.19)	0.24 (0.12–0.35)*
EHS 4	0.64 (0.57–0.71)*	0.58 (0.48–0.67)*	0.60 (0.50–0.69)*	0.46 (0.36–0.55)*
EHS 3 and EHS 4	0.57 (0.48–0.65)*	0.54 (0.43–0.64)*	0.60 (0.50–0.68)*	0.62 (0.53–0.68)*
SEAR change [†] in score				
Sexual relationship	0.77 (0.72–0.81)*	0.76 (0.69–0.81)*	0.80 (0.74–0.84)*	0.82 (0.77–0.85)*
Confidence	0.74 (0.68–0.79)*	0.56 (0.46–0.65)*	0.54 (0.44–0.64)*	0.70 (0.64–0.76)*
Self-esteem	0.73 (0.67–0.78)*	0.55 (0.45–0.64)*	0.52 (0.40–0.61)*	0.64 (0.56–0.70)*
Overall relationship	0.54 (0.46–0.62)*	0.39 (0.27–0.51)*	0.41 (0.29–0.52)*	0.66 (0.59–0.72)*
Overall	0.79 (0.74–0.83)*	0.74 (0.67–0.80)*	0.75 (0.68–0.81)*	0.80 (0.76–0.84)*

* $P < 0.0001$.[†]EDITS Index outcome was from the end of treatment, whereas EHS and SEAR outcomes were changes from baseline.

QEQ = Quality of Erection Questionnaire; CI = confidence interval; PL = placebo; SIL = sildenafil; EDITS = Erectile Dysfunction Inventory of Treatment Satisfaction; EHS = Erection Hardness Score; SEAR = Self-Esteem and Relationship Questionnaire.

placebo control, the outcomes on the EHS 4, EHS 3 plus 4, EDITS Index, and SEAR correlated positively with the change in QEQ total score from baseline (Table 3) and with the change in QEQ Q5 score from baseline (Table 4). All except three of the correlations with the change in QEQ total score exceeded 0.50, and two-thirds of the correlations were greater than or equal to 0.60 (r range 0.39–0.82). More than half of the correlations with the change in QEQ Q5 score were greater than or equal to 0.60 (r range 0.36–0.74). The change in percentage occasions of EHS 3 erections did not correlate positively with the change in QEQ scores except in the 8-week fixed-

dose trial of sildenafil 50 mg, sildenafil 100 mg, and placebo {QEQ total score, $r = 0.24$ [95% CI, 0.12–0.35]; QEQ Q5, $r = 0.22$ [95% CI, 0.11–0.33]} (Tables 3 and 4).

In the dose comparison trial [3], the EDITS Index score at the end of the double-blind phase correlated positively with the change in QEQ total score ($r = 0.29$; 95% CI, 0.21–0.37; $P < 0.0001$) and with the change in QEQ Q5 score ($r = 0.28$; 95% CI, 0.19–0.36; $P < 0.0001$). The changes in the scores occurred between the end of 4-weeks' treatment with sildenafil 50 mg (single-blind phase) and the end of 4-weeks' treatment with sildenafil 50 mg or 100 mg (double-blind phase).

Table 4 Correlations with the change in score from baseline on QEQ Question 5 (Satisfaction with Erection Hardness)

	Pearson correlation coefficient (95% CI), overall population			
	Flexible-dose trials [4,5]			Fixed-dose trial [6]
	SIL 25, 50, and 100 mg vs. PL for 6 weeks	SIL 50 and 100 mg vs. PL		SIL 100 or 50 mg vs. PL for 8 weeks
		6 weeks (interim)	10 weeks	
EDITS Index [†]	0.60 (0.52–0.67)*	0.57 (0.46–0.66)*	0.62 (0.52–0.70)*	0.61 (0.53–0.68)*
EHS change [†] in percentage occasions				
EHS 3	–0.05 (–0.17–0.07)	–0.16 (–0.30–0.01)	–0.06 (–0.21–0.08)	0.22 (0.11–0.33)**
EHS 4	0.58 (0.49–0.65)*	0.61 (0.51–0.69)*	0.60 (0.50–0.69) [†]	0.41 (0.31–0.51)*
EHS 3 and EHS 4	0.49 (0.39–0.57)*	0.47 (0.34–0.58)*	0.48 (0.36–0.58) [†]	0.57 (0.48–0.64)*
SEAR change [†] in score				
Sexual relationship	0.65 (0.58–0.71)*	0.67 (0.58–0.74)*	0.70 (0.63–0.77) [†]	0.74 (0.68–0.79)*
Confidence	0.66 (0.59–0.72)*	0.54 (0.44–0.64)*	0.48 (0.36–0.58) [†]	0.61 (0.53–0.68)*
Self-esteem	0.65 (0.57–0.71)*	0.53 (0.42–0.63)*	0.46 (0.34–0.56) [†]	0.53 (0.44–0.61)*
Overall relationship	0.50 (0.41–0.58)*	0.38 (0.25–0.49)*	0.36 (0.23–0.47) [†]	0.61 (0.53–0.68)*
Overall	0.68 (0.62–0.74)*	0.67 (0.59–0.74)*	0.66 (0.57–0.73) [†]	0.71 (0.65–0.77)*

* $P < 0.0001$; ** $P < 0.001$.[†]EDITS Index outcome was from the end of treatment, whereas EHS and SEAR outcomes were changes from baseline.

QEQ = Quality of Erection Questionnaire; CI = confidence interval; PL = placebo; SIL = sildenafil; EDITS = Erectile Dysfunction Inventory of Treatment Satisfaction; EHS = Erection Hardness Score; SEAR = Self-Esteem and Relationship Questionnaire.

Discussion

Sildenafil treatment of men with ED increased satisfaction with the quality of erections in terms of hardness (QEQ total score) and satisfaction with erection hardness (QEQ Q5). In the sildenafil groups, relative to their respective placebo groups, the improvement in satisfaction with the quality of erections in terms of hardness was two to three times the minimum clinically important difference of 12 points [2]. Furthermore, the change from baseline in satisfaction with erection quality and satisfaction with erection hardness correlated positively with the increase in percentage of occasions with completely hard and fully rigid erections (EHS 4), ED treatment satisfaction (EDITS), and the improvement in emotional well-being (SEAR).

The fact that the erection satisfaction outcomes correlated positively with the change in percentage occasions of EHS 4 across all of the trials suggests that a treatment goal of EHS 4 is clinically important. The importance of a treatment goal of EHS 4 is also supported by previous results. For example, a shift in most frequent erection from EHS 3 at baseline to EHS 4 at the end of treatment was accompanied by significant improvements in intercourse and relationship satisfaction (IIEF), emotional well-being (SEAR), and satisfaction with ED treatment (EDITS) ($P < 0.01$) [10]. Also, the odds of successful sexual intercourse for EHS 4 were 23.7 times (95% CI, 19.5–28.9; $P < 0.0001$) than for EHS 3 [11].

The positive correlations between the erection satisfaction outcomes and the EDITS demonstrate the relationship between satisfaction with erections and satisfaction with ED treatment. This is important because treatment satisfaction is a driver of treatment adherence [12]. The positive correlations between the erection satisfaction outcomes and the SEAR demonstrate the relationship between satisfaction with erections and emotional well-being, including both general and sexually specific emotional well-being both from the individual perspective of the man with ED and from his perspective of his relationship with his partner. Further support for the importance of satisfaction with erection hardness on emotional well-being comes from a survey of >12,000 men and women in 27 countries worldwide, which found an association between satisfaction with erection hardness and satisfaction with sex life, love, and romance, as well as with overall health [13].

The current article reports the results of sildenafil treatment on health-related quality of life out-

comes on three validated instruments (QEQ, EDITS, and SEAR). Several other validated ED-specific instruments have also shown improvement on health-related quality of life outcomes in men treated with a phosphodiesterase type 5 inhibitor or other accepted ED therapy, including the Erectile Dysfunction Effect on Quality of Life Measure [14], the Erection Quality Scale [15], the Impact of Erectile Problems Questionnaire [16], the Psychological and Interpersonal Relationship Scales [17,18], the Psychological Impact of Erectile Dysfunction Scores [19], and the Treatment Satisfaction Scale [20]. In contrast to other ED-specific questionnaires, the QEQ focuses on satisfaction with erections “. . . because lack of satisfaction is a prerequisite to concern or bother, the drivers of treatment-seeking behavior.” [1]

The results of the current report are generalizable to the population of men with ED. A limitation of the analysis is the inability to pool data across the trials because the doses and trial designs were not identical. However, the collated (rather than pooled) design allows comparison of different doses and titration strategies. The results of the current report demonstrate that outcomes assessing a broad range of concepts (EHS, EDITS, and SEAR) correlate positively with satisfaction with erections. These positive correlations suggest that satisfaction with erection hardness is a pivotal outcome in the treatment of ED, and are consistent across many cultural groups.

Conclusions

Across several trials involving men with ED from different cultural backgrounds, sildenafil treatment of men with ED increased satisfaction with the quality of erections in terms of hardness, which correlated positively with measures of emotional well-being and treatment satisfaction, and also correlated positively with the change in percentage of erections that were completely hard and fully rigid but not with the change in percentage of erections that were hard enough for penetration but not completely hard.

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Corresponding Author: Jed C. Kaminetsky, MD, University Urology Associates, 215 Lexington Avenue, 20th

floor, New York, NY, USA. Tel: (212) 686-9015; Fax: (212) 686-8607; E-mail: jckammd@att.net

Conflict of Interest: J. Kaminetsky is a consultant/advisor, meeting participant/lecturer, and trial investigator for Pfizer Inc., A. Depko is a meeting participant/lecturer and trial investigator for Pfizer Poland, P. Ströberg is a trial investigator for Pfizer Inc, J. Buvat is a meeting participant/lecturer and trial investigator for Pfizer Inc, L.-J. Tseng and V. J. Stecher are employees of Pfizer Inc.

Statement of Authorship

Category 1

(a) Conception and Design

Jed C. Kaminetsky; Andrzej J. Depko; Peter Ströberg; Jacques Buvat; Li-Jung Tseng; Vera J. Stecher

(b) Acquisition of Data

Jed C. Kaminetsky; Andrzej J. Depko; Peter Ströberg; Jacques Buvat; Li-Jung Tseng; Vera J. Stecher

(c) Analysis and Interpretation of Data

Jed C. Kaminetsky; Andrzej J. Depko; Peter Ströberg; Jacques Buvat; Li-Jung Tseng; Vera J. Stecher

Category 2

(a) Drafting the Article

Jed C. Kaminetsky; Andrzej J. Depko; Peter Ströberg; Jacques Buvat; Li-Jung Tseng; Vera J. Stecher

(b) Revising It for Intellectual Content

Jed C. Kaminetsky; Andrzej J. Depko; Peter Ströberg; Jacques Buvat; Li-Jung Tseng; Vera J. Stecher

Category 3

(a) Final Approval of the Completed Article

Jed C. Kaminetsky; Andrzej J. Depko; Peter Ströberg; Jacques Buvat; Li-Jung Tseng; Vera J. Stecher

References

- 1 Porst H, Gilbert C, Collins S, Huang X, Symonds T, Stecher V, Hvidsten K. Development and validation of the quality of erection questionnaire. *J Sex Med* 2007;4:372–81.
- 2 Stecher VJ, Hvidsten K, Carlsson M, Levinson IP. Clinically meaningful improvement on the Quality of Erection Questionnaire for erectile dysfunction. *J Sex Med* 2008;5(2 suppl):111.
- 3 Buvat J, Hatzichristou D, Maggi M, Farmer I, Martinez-Jabaloyas JM, Miller PJ, Schnetzler G. Efficacy, tolerability, and satisfaction with sildenafil citrate 100-mg titration compared with continued 50-mg dose treatment in men with erectile dysfunction. *BJU Int* 2008;102:1645–50.
- 4 Jones LA, Klimberg IW, McMurray JG, Padula R, Tseng L-J, Stecher VJ, for the Multicenter Study Group. Effect of sildenafil citrate on the male sexual experience assessed with the Sexual Experience Questionnaire; a multicenter, double-blind, placebo-controlled trial with open-label extension. *J Sex Med* 2008;5:1955–64.
- 5 Kadioglu A, Grohmann W, Depko A, Levinson IP, Sun F, Collins S, for the Multicenter Study Group. Quality of erections in men treated with flexible-dose sildenafil for erectile dysfunction: Multicenter trial with a double-blind, randomized, placebo-controlled phase and an open-label phase. *J Sex Med* 2008;5:726–34.
- 6 Loran OB, Ströberg P, Lee S-W, Park NC, Kim S-W, Tseng L-J, Collins S, Stecher VJ. Efficacy of fixed dose sildenafil citrate to provide a better sexual experience in men with erectile dysfunction: A multicenter, double-blind placebo controlled study. *J Sex Med* 2008.
- 7 Althof SE, Corty EW, Levine SB, Levine F, Burnett AL, McVary K, Stecher V, Seftel AD. EDITS: Development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. *Urology* 1999;53:793–9.
- 8 Cappelleri JC, Althof SE, Siegel RL, Shpilsky A, Bell SS, Dutttagupta S. Development and validation of the Self-Esteem And Relationship (SEAR) questionnaire in erectile dysfunction. *Int J Impot Res* 2004;16:30–8.
- 9 Mulhall JP, Goldstein I, Bushmakin AG, Cappelleri JC, Hvidsten K. Validation of the Erection Hardness Score (EHS). *J Sex Med* 2007;4:1626–34.
- 10 Mulhall JP, Althof SE, Brock GB, Goldstein I, Jünemann K-P, Kirby M. Erectile dysfunction: Monitoring response to treatment in clinical practice—Recommendations of an international consensus panel. *J Sex Med* 2007;4:448–64.
- 11 Goldstein I, Mulhall J, Bushmakin A, Cappelleri J, Hvidsten K, Symonds T. The Erection Hardness Score and its relationship to successful sexual intercourse. *J Sex Med* 2008;5:2374–80.
- 12 Barfod TS, Gerstoft J, Rodkjaer L, Pedersen C, Nielsen H, Møller A, Kristensen LH, Sørensen HT, Obel N. Patients' answers to simple questions about treatment satisfaction and adherence and depression are associated with failure of HAART: A cross-sectional survey. *AIDS Patient Care STDS* 2005;19:317–25.
- 13 Mulhall J, King R, Glina S, Hvidsten K. Importance of and satisfaction with sex among men and women worldwide: Results of the Global Better Sex Survey. *J Sex Med* 2008;5:788–95.
- 14 MacDonagh R, Ewings P, Porter T. The effect of erectile dysfunction on quality of life: Psychometric testing of a new quality of life measure for patients with erectile dysfunction. *J Urol* 2002;167:212–7.

- 15 Fisher WA, Brock G, Karlin G, Pommerville P, Huang XY, Bangerter K, Herman-Gnjidic Z, Derogatis L, Group VS, Rosen RC. Vardenafil improves erection quality assessed by the novel Erection Quality Scale in the broad population of men with erectile dysfunction. *J Sex Med* 2006;3(3 suppl): 251–2.
- 16 Giuliano F, Peña BM, Mishra A, Smith MD. Efficacy results and quality-of-life measures in men receiving sildenafil citrate for the treatment of erectile dysfunction. *Qual Life Res* 2001;10:359–69.
- 17 Swindle RW, Cameron AE, Lockhart DC, Rosen RC. The psychological and interpersonal relationship scales: Assessing psychological and relationship outcomes associated with erectile dysfunction and its treatment. *Arch Sex Behav* 2004;33:19–30.
- 18 Swindle R, Cameron A, Rosen R. A 15-item short form of the psychological and interpersonal relationship scales. *Int J Impot Res* 2006;18:82–8.
- 19 Zhang K. From better erection to better sex: Viagra updates 2005. *Zhonghua Nan Ke Xue* 2005;11: 796–9.
- 20 DiBenedetti DB, Gondek K, Sagnier PP, Kubin M, Marquis P, Keininger D, Fugl-Meyer AR. The treatment satisfaction scale: A multidimensional instrument for the assessment of treatment satisfaction for erectile dysfunction patients and their partners. *Eur Urol* 2005;48:503–11.