ORIGINAL RESEARCH—ED PHARMACOTHERAPY

Sildenafil Citrate 100 mg Starting Dose in Men with Erectile Dysfunction in an International, Double-Blind, Placebo-Controlled Study: Effect on the Sexual Experience and Reducing Feelings of Anxiety About the Next Intercourse Attempt

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ABSTRACT

Introduction. Sildenafil citrate 50 mg is the recommended starting dose for men with erectile dysfunction (ED); however, most men are later titrated to sildenafil 100 mg for improved efficacy.

Aim. Assess the tolerability and efficacy of sildenafil initiated at the 100-mg dose in men with ED.

Methods. Men with ED (score ≤25 on the Erectile Function domain of the International Index of Erectile Function) who had received ≤6 total doses of a phosphodiesterase type 5 inhibitor and none within 4 weeks were randomized to 8 weeks of double-blind, placebo-controlled (DBPC), fixed-dose treatment (50 or 100 mg sildenafil or placebo) followed by 4 weeks of open-label flexible-dose sildenafil (50 or 100 mg).

Main Outcome Measures. Efficacy, tolerability, treatment satisfaction, and other end points were measured at baseline and/or the end of the double-blind and open-label phases and compared between placebo and sildenafil initiated at doses of 50 and 100 mg.

Results. Improvements in DBPC patient-reported outcomes from baseline were statistically significant for both sildenafil 50 and 100 mg compared with placebo. At the end of DBPC treatment, 56% of men on the 100-mg dose felt no anxiety about the next intercourse attempt compared with 39% in the 50-mg group (odds ratio 2.03; \( P = 0.0197 \)). Changes in functional scores from baseline were not statistically significant with the 100-mg dose compared with the 50-mg dose in the DBPC. Measures of treatment satisfaction and sexual experience significantly favored the 100-mg dose compared with the 50-mg dose in the DBPC. There was no increase in adverse events with the higher dose.

Conclusions. Sildenafil at 50 mg or 100 mg significantly improved erection quality, treatment satisfaction, anxiety levels, and the sexual experience compared with placebo during DBPC. Sildenafil 100 mg improved the sexual experience and treatment satisfaction, and reduced feelings of anxiety compared with the 50-mg dose. Loran OB, Ströberg P, Lee SW, Park NC, Kim SW, Tseng LJ, Collins S, and Stecher VJ. Sildenafil citrate 100 mg starting dose in men with erectile dysfunction in an international, double-blind, placebo-controlled study: Effect on the sexual experience and reducing feelings of anxiety about the next intercourse attempt. J Sex Med 2009;6:2826–2835.

Key Words. Erectile Dysfunction; Sildenafil; Sexual Experience; Health-Related Quality of Life; Russia; Spain; Sweden; Korea; Brazil
Introduction

The inability to have or complete intercourse successfully can affect a man’s quality of life by causing loss of self-esteem and confidence, leading to sexual dissatisfaction [1]. The loss of self-esteem can affect behavior, causing a man to avoid intimacy, which can consequently affect his partner’s sexual quality of life and self-esteem [2]. Performance anxiety may always be present at some level in men with erectile dysfunction (ED). Anxiety over the failure to respond sexually may further aggravate impaired sexual responsiveness, and can lead to escalating anxiety after a succession of intercourse failures [2,3]. Successful treatment of the functional aspects of ED is one of the key steps necessary to overcome performance anxiety and to improve men’s sexual experience and relationship quality.

Sildenafil citrate has proven efficacy in the treatment of ED [4]. Sildenafil 50 mg is the recommended starting dose for men with ED; however, most men are later titrated to sildenafil 100 mg for improved efficacy [5].

The objective of this randomized, double-blind, placebo-controlled trial was to prospectively assess several ED-specific outcomes in patients initially treated with the higher sildenafil 100-mg dose, rather than first treating with sildenafil 50 mg and later titrating the dose to 100 mg. A broad range of functional, satisfaction (treatment specific and disease specific), and emotional outcomes are compared with those in men treated with the standard initial 50-mg dose of sildenafil. The double-blind phase was followed by an open-label extension with flexible dosing.

Materials and Methods

Study Design

This was a multicenter, parallel-group, randomized (1:1:1 to sildenafil 50 mg: sildenafil 100 mg: placebo) trial conducted in Brazil, Korea, Russia, Spain, and Sweden. The final protocol was reviewed and approved by the Institutional Review Board and/or Independent Ethics Committee at each participating center. The 14-week trial included a 2-week screening phase, an 8-week double-blind, placebo-controlled, fixed-dose treatment phase, and a 4-week open-label, flexible-dose treatment extension.

Inclusion and Exclusion Criteria

Men 18–65 years of age with ED (score of ≤25 on the International Index of Erectile Function [IEF] erectile function [EF] domain) who had taken ≤6 doses of sildenafil or any other phosphodiesterase type 5 (PDE5) inhibitor in total, and no dose within the previous 4 weeks, and who were in a stable sexual relationship for the duration of the study were eligible. The exclusion criteria included resting, sitting, and/or standing hypotension (blood pressure <90/50 mm Hg) or hypertension (blood pressure >170/110 mm Hg); hepatic impairment or severe renal impairment; a history of retinitis pigmentosa or hereditary galactose intolerance problems; Lapp lactase deficiency or glucose-galactose malabsorption; or significant cardiovascular disease in the last 3 months. Patients taking nitrates or nitric oxide donors in any form regularly or intermittently, or those who took alpha blockers were excluded. Concomitant treatment with a CYP3A4 inhibitor or a known hypersensitivity to sildenafil, a previous severe or serious treatment-related adverse event to sildenafil, or the current use of any other commercially available drug or nondrug treatment for ED was also cause for exclusion. All participants provided written informed consent.

Treatment Administration

Participants received fixed-dose (50 or 100 mg) sildenafil or placebo as needed for sexual activity, but medication was not to be taken more than once daily. The men were encouraged to attempt sexual activity at least twice a week.

During the open-label phase (beginning at week 8), all patients started with a sildenafil 50-mg dose. Patients unable to tolerate the 50-mg dose after 2 weeks in the open-label phase were to be discontinued from the study. The sildenafil dose could be increased to 100 mg to improve efficacy, and men taking sildenafil 100 mg were allowed dose adjustments to 50 mg for safety and tolerability between visits.

Efficacy Assessments

At the baseline and at the end of the double-blind and open-label treatment phases or time of discontinuation, the following outcome measures were administered: the Sexual Experience Questionnaire [6,7] (SEX-Q; a 12-item questionnaire in three domains of Erection, Couples Satisfaction, and Individual Satisfaction; transformed score range 0–100); the Quality of Erection Questionnaire (QEQ; transformed score range 0–100) [8]; the IIEF [9], including EF domain (score range, 1–30), Intercourse Satisfaction domain (score range 0–15), Orgasmic Function domain (score range 0–25), and Sexual Desire domain (score range 0–25).
range, 0–10), and Sexual Desire and Overall Satisfaction domains (score range, 2–10); and the Self-Esteem and Relationship questionnaire (SEAR) [10] (transformed score range, 0–100). At the end of double-blind and open-label phases or at time of discontinuation, the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) [11] was administered. The EDITS Index, defined as the average EDITS question score \(\times 25\), ranges from 0 (extremely low treatment satisfaction) to 100 (extremely high treatment satisfaction).

Also, at the end of the double-blind and open-label phases, the men answered a global efficacy question (GEQ), which asked, “Compared to having no treatment at all for your erection problem, has the medication you have been taking over the past 4 weeks allowed you to have better sex?” with seven answer choices that ranged from “Yes, very much better” to “No, very much worse.”

At each occasion of sexual activity, an event log was completed that included questions on study medication use and whether sexual stimulation occurred, an erection was achieved, sexual intercourse was attempted, or the erection lasted long enough for successful sexual intercourse. A question regarding anxiety (“Do you feel anxious about your next attempt at sexual intercourse?”) and the Erection Hardness Score (EHS; “How would you rate the quality [hardness] of your erection?”), which rates erections on a scale of 0 (no erection at all) to 4 (completely hard), were also included [12].

**Outcomes**
The primary outcome of the study was the difference in the change in IIEF-EF domain score from baseline to end point in the EF domain score between sildenafil 50 mg and placebo was 7.52 \(\pm\) 11.96 and between sildenafil 100 mg and placebo was 9.46 \(\pm\) 11.92. A sample size of 70 completed patients per group would be required to detect each of these differences for a two-sided test at a 5% significance level with an overall power of at least 86% for the two comparisons. No \(P\) value adjustment was needed as the overall efficacy claim only applied when both comparisons were statistically significant in favor of sildenafil. Assuming a 20% screen failure with 85% of the randomized men contributing data to the full analysis set for efficacy end-point analyses, a final sample size of 312 men was to be screened.

**Efficacy Analyses**
The two co-primary end points comparisons, 50- or 100-mg dose vs. placebo, were tested at 5%. A step-down procedure was followed to compare the 50- vs. 100-mg dose (tested only when both groups were statistically superior to placebo). An analysis of covariance model, including terms for baseline (when applicable), center, treatment group, age, ED etiology, and ED duration, was used to analyze the changes in IIEF-EF domain change scores (primary end point) and the secondary end points (SEAR, SEX-Q, QEQ, EDITS) during the double-blind, fixed-dose phase. Event log variables were analyzed using a multivariate logistic regression with a scale adjustment for over dispersion and terms for baseline percent, treatment group, age, ED etiology, and ED duration. Treatment effects (percent of successes) were estimated using predicted percents from the model weighted by each patient’s number of attempts at sexual intercourse.

Open-label data for each of the previously randomized treatment groups in the double-blind, placebo-controlled phase were summarized using descriptive statistics.

Correlation was assessed using Pearson product–moment (controlling for treatment group) correlation coefficients.

**Safety Analyses**
All adverse events that were observed, reported by the patients, or elicited by direct questioning of the patients were recorded as to severity, seriousness, and causality, and those attributed to study medication were followed to assess duration and outcome. Adverse event data for all treated patients were summarized.
Results

Patient Population
The disposition of patients is shown in Figure 1. Three hundred-nineteen men were screened, and 288 were assigned to double-blind treatment.

Participants entering the double-blind phase had a mean age of 50–52 years; 63–65% of the participants were white and 35–37% were Asian. The ED etiology in each arm ranged from 56% to 63% for mixed, 24% to 29% for organic, and 13% to 16% for psychogenic. The average duration of ED was just over 3 years. Patient characteristics are summarized in Table 1. Most men had mild-to-moderate to moderate ED. The patient population in this study was diverse, including men from Russia, Korea, Brazil, Sweden, and Spain.

Efficacy Outcomes
Double-Blind, Placebo-Controlled Phase
On all patient-reported outcomes assigned, sildenafil at 50 mg or 100 mg as needed resulted in statistically significant, better outcomes compared with placebo. When starting doses of sildenafil were compared, the 100-mg dose showed statistically significant improvement over the 50-mg dose in the IIEF Overall Satisfaction domain, the overall SEAR score and the SEAR Sexual Relationship domain and Overall Relationship sub-scale, all SEX-Q domain and total scores, and the EDITS Index (Figures 2 and 3).

Event Log Summaries
Before treatment, most men felt at least moderate feelings of anxiety, defined as subjective anxiety or concern, about their next attempt at intercourse. After treatment with sildenafil 50 mg or 100 mg, men felt less anxiety, and 56.3% of men initiating treated with 100 mg sildenafil felt no anxiety about the next intercourse attempt compared with 38.8% of men initiating treatment at sildenafil 50 mg (odds ratio 2.03, \( P = 0.0197 \)) (Figure 4).

The estimated mean percentage of EHS 3 erections was not significantly different between the
placebo (38.7%; 95% confidence interval [CI] 31.7–46.2%) and the sildenafil groups (46.8%; 95% CI 39.4–54.2% in the 50-mg group and 41.4%; 95% CI 34.5–48.7% in the 100-mg group). The estimated mean percentage of EHS 4 erections was significantly improved in both dose groups vs. placebo; 6.9% in the placebo group (95% CI 3.7–12.4%) compared with 25.3% in the 50-mg group (95% CI 18.5–33.4%) and 34.6% in the 100-mg group (95% CI 27.1–42.9%).

Both the 50-mg and 100-mg sildenafil groups had a significantly greater LS mean ± SD scores (5.9 ± 0.13 and 6.3 ± 0.12, respectively) on the GEQ compared with placebo (4.6 ± 0.13; both P < 0.0001), and the difference between the 50-mg and 100-mg groups was also statistically significant (P = 0.0103).

**Correlation Data**

The correlation analyses used the change from baseline to end-of-treatment value for the IIEF, QEQ, and SEAR, and used the end-of-treatment value for all other outcomes. The SEX-Q total and domain scores correlated positively with the IIEF domain scores, QEQ, EDITS, and SEAR scores. The QEQ also correlated positively with event log summaries of successful intercourse attempts and EHS 3 and EHS 4 erections.

**Open-Label Phase**

During the 4-week open-label phase, 90, 91, and 98 patients who were previously on placebo, 50-mg sildenafil, and 100-mg sildenafil, respectively, were treated with sildenafil 50 mg for 2 weeks after completing the double-blind phase. By week 12, 86, 88, and 93 patients formerly in the placebo, 50-, and 100-mg groups, respectively, had been titrated to the 100-mg dose of sildenafil.

Differences in patient-reported outcomes from the end of the double-blind and open-label phases show that patients previously treated with placebo, 50-, and 100 mg sildenafil achieved similar scores at the end of the open-label treatment on the patient-reported outcomes. The greatest change in score occurred in those previously in the placebo group, some further improvement occurred in those previously in the 50-mg group, and the response was maintained in those previously in the 100-mg group between week 8 (end of double-blind treatment) and week 12 (end of open-label treatment) (Figure 5).
On the dichotomized EDITS score, 94%, 96%, and 98% of men previously assigned to placebo, sildenafil 50 mg, and sildenafil 100 mg, respectively, were satisfied with treatment at the end of the open-label phase.

**Safety**

**Double-Blind, Placebo-Controlled Phase**

Most adverse events were mild or moderate in severity, and occurred at similar frequencies in the sildenafil 50 mg and sildenafil 100 mg groups. The

Figure 2 Change from baseline to the end of the double-blind, placebo-controlled phase by treatment. (A) International Index of Erectile Function (IIEF) domains (EF = Erectile Function; IS = Intercourse Satisfaction; OS = Overall Satisfaction; OF = Orgasmic Function; SD = Sexual Desire); (B) the Sexual Experience Questionnaire (SEX-Q) domains (CS = Couples Satisfaction; E = Erectile; and IS = Individual Satisfaction); and (C) in the Self-Esteem and Relationship Questionnaire (SEAR) components (SR = Sexual Relationship domain; C = Confidence domain; SE = Self-Esteem subscale; OR = Overall Relationship subscale). All differences between either dose of sildenafil and placebo were statistically significant (all P < 0.0001). *Statistically significant difference between sildenafil 50 mg and 100 mg. SE = standard error.

Figure 3 A comparison of outcomes of the change from baseline to end of the double-blind, placebo-controlled phase in Quality of Erection Questionnaire (QEQ) score and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) Index at the end of the double-blind, placebo-controlled phase by treatment. All differences between either dose of sildenafil and placebo were statistically significant (all P < 0.0001). *Statistically significant difference between sildenafil 50 mg and 100 mg. SE = standard error.

Figure 4 Feelings of anxiety toward the next attempt at intercourse decreased in men treated with sildenafil 50 mg or 100 mg compared with baseline levels. Anxiety was graded as extreme, high, moderate, slight, or none at baseline and was reassessed at the end of double-blind treatment. No men reported being extremely anxious.
most frequently reported adverse events were flushing, dyspepsia, headache, and nasal congestion (Table 3).

There was one adverse event (chest pain) in 1 patient in the placebo group during the double-blind, placebo-controlled phase that was considered to be both serious and severe. No serious or severe events were reported in the sildenafil arms. One patient in the 100-mg group (treatment-related dyspepsia and heartburn) and one in the placebo group (sprained right wrist) discontinued treatment because of adverse events. No patient had a dose reduction or temporary discontinuation.

Open-Label Phase
The most commonly reported adverse events during the open-label phase were dyspepsia, feeling hot, headache, nasal congestion, and flushing. Of the 49 all-causality adverse events, 22 occurred in patients previously enrolled in the placebo group. All but four of the adverse events were mild in intensity, with two adverse events in the previous sildenafil 100-mg (feeling hot, nasal congestion) and two in the previous placebo (dyspepsia and back pain) groups being of moderate intensity. Forty five of the adverse events were treatment related, with 21 of these occurring in patients who had previously received placebo.

Discussion
To improve response, men are often titrated to a dose of 100 mg sildenafil after beginning treatment at the 50-mg dose [5, but whether the 100-mg dose is an optimal starting dose for most men was an unanswered question. Improvements in relationship, treatment, and sexual satisfaction were observed in previous flexible dose trials in men who were titrated from 50 to 100 mg. However, as all men started sildenafil treatment at a dose of 50 mg in the flexible dose trials, the initial 50-mg dosing before titration to 100 mg may have led to better tolerability. This trial compared the initiation of treatment with sildenafil 50 mg and 100 mg to more clearly assess the effect of a 100-mg starting dose on both functional and psychosocial parameters. Another interesting aspect of this study was the inclusion of a diverse group of men from Asia, South America, and Europe.

Table 2 Correlations with change in QEQ or SEX-Q scores

<table>
<thead>
<tr>
<th>Pearson coefficient (95% CI)*</th>
<th>QEQ</th>
<th>SEX-Q domains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total score</td>
<td>Erection</td>
</tr>
<tr>
<td>IIEF domains*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erectile Function</td>
<td>0.80 (0.76–0.84)</td>
<td>0.82 (0.78–0.86)</td>
</tr>
<tr>
<td>Orgasmic Function</td>
<td>0.57 (0.48–0.64)</td>
<td>0.54 (0.45–0.62)</td>
</tr>
<tr>
<td>Sexual Desire</td>
<td>0.34 (0.23–0.44)</td>
<td>0.30 (0.19–0.41)</td>
</tr>
<tr>
<td>Intercourse Satisfaction</td>
<td>0.69 (0.63–0.75)</td>
<td>0.69 (0.62–0.74)</td>
</tr>
<tr>
<td>Overall Satisfaction</td>
<td>0.68 (0.62–0.74)</td>
<td>0.72 (0.66–0.77)</td>
</tr>
<tr>
<td>QEQ total score</td>
<td>—</td>
<td>0.88 (0.85–0.91)</td>
</tr>
<tr>
<td>SEAR Overall score</td>
<td>0.80 (0.76–0.84)</td>
<td>0.83 (0.79–0.86)</td>
</tr>
<tr>
<td>EDITS Index</td>
<td>0.85 (0.81–0.88)</td>
<td>0.85 (0.81–0.88)</td>
</tr>
<tr>
<td>GEQ3</td>
<td>0.82 (0.78–0.86)</td>
<td>0.84 (0.80–0.87)</td>
</tr>
<tr>
<td>Successful intercourse attempts (event log), %</td>
<td>0.41 (0.31–0.51)</td>
<td>0.44 (0.34–0.53)</td>
</tr>
</tbody>
</table>

*The correlation analyses used the change from baseline to end-of-treatment value for the IIEF, QEQ, and SEAR, and used the end-of-treatment value for all other outcomes. $P < 0.0001$ for all correlations.

CI = confidence interval; EDITS = Erectile Dysfunction Inventory of Treatment Satisfaction; EHS = Erection Hardness Score (3 = hard enough for penetration but not completely hard, 4 = completely hard); GEQ = global efficacy question; IIEF = International Index of Erectile Function; QEQ = Quality of Erection Questionnaire; SEAR = Self-Esteem and Relationship questionnaire; SEX-Q = Sexual Experience Questionnaire.

Table 3 Most frequently (>2% of patients) reported all causality adverse events* during the double-blind, placebo-controlled phase

<table>
<thead>
<tr>
<th>Adverse event, n</th>
<th>Placebo (n = 95)</th>
<th>Sildenafil 50 mg (n = 94)</th>
<th>Sildenafil 100 mg (n = 99)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flushing</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Headache</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Nasal congestion</td>
<td>0</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

*All events were mild to moderate.
Treatment at either sildenafil dose during the double-blind, placebo-controlled phase significantly improved scores on all patient-reported outcomes vs. placebo without increasing adverse events. Significant differences favoring the 100-mg dose during the double-blind, placebo-controlled phase were observed for measures assessing satisfaction with treatment (EDITS, GEQ question 3) and relationship factors (SEAR, SEX-Q, IIEF Overall Satisfaction). Improvements in functional ability after successful treatment of ED were previously associated with improvements in IIEF psychosocial domains, the SEAR questionnaire, and EDITS[13].

Although improvements in functional measures (e.g., QEQ, IIEF–EF, EHS) were observed in the 100-mg group during the double-blind phase, the improvements were not statistically significant compared with the 50-mg group. Interestingly, significant improvements in psychosocial parameters occurred without significant differences in functional parameters. Also of importance, the 100-mg dose significantly increased the number of men who experienced no feelings of anxiety about the next intercourse attempt compared with the 50-mg group. One interpretation of the overall results is that small improvements in erectile function may lead to much larger improvements in psychosocial measures and a better sexual experience in men with ED.

In many men, initiating sildenafil at the 100-mg dose may be beneficial, even if dose reductions to 50 mg are possible later on. In clinical practice, the 50-mg dose may not produce optimal erectile rigidity in some men compared with the 100-mg dose, leading to initial disappointment and discouraging men from seeking additional help. This should be taken into consideration in clinical practice. This result is illustrated by previous studies that followed men treated in the clinical setting who discontinued treatment because of the lack of efficacy. With proper instruction on the use of sildenafil and dose optimization, many of these men were later successfully treated [5,14]. ED affects self-esteem and quality of life [1]. The adverse event profile of the 50- and 100-mg doses
is similar. Consequently, it may be better to prescribe sildenafil 100 mg to ensure immediate efficacy, rather than risk causing the patient further discouragement, and restore his confidence in his erectile ability sooner.

Men who enrolled in the study were motivated to treat their ED, and were willing to attempt intercourse at least twice weekly. Therefore, the concomitant improvement in psychosocial factors may be partly caused by patient selection. Additionally, the trial included men with little or no previous experience with PDE5 inhibitor treatment for their ED, and most men had mild to moderate ED. Therefore, the results may not completely extrapolate to men who have prior experience with PDE5 inhibitors or severe ED.

Conclusions

Treatment with sildenafil 50 or 100 mg as needed during the double-blind phase improved all patient reported outcomes tested. Treatment initiated at the higher dose during double-blind treatment led to greater treatment satisfaction, less feeling of anxiety concerning the next attempt at sexual intercourse, and improved the sexual experience in men with ED without increasing the frequency of adverse events. Initial treatment with sildenafil 100 mg could be considered for men with ED for whom such treatment is not contraindicated, to ensure earlier treatment success.

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Conflict of Interest: Drs. Stecher and Tseng, and Ms. Collins were employees at Pfizer Inc, New York, NY at the time of this research. Drs. Lee, Park, and Kim have nothing to declare. Drs. Loran and Ströberg are both principal investigators of Pfizer-sponsored clinical trials, and Dr. Ströberg is an advisory board member for Pfizer Sweden.

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References


