

Do Impotent Men With Diabetes Have More Severe Erectile Dysfunction and Worse Quality of Life Than the General Population of Impotent Patients?

Results from the Exploratory Comprehensive Evaluation of Erectile Dysfunction (ExCEED) database

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OBJECTIVE — Little is known regarding how diabetic men with erectile dysfunction (ED) differ from the general population of impotent men. The primary objective of this study was to compare disease-specific health-related quality of life (HRQOL) and severity of ED in impotent men with and without diabetes.

RESEARCH DESIGN AND METHODS — Validated functional and HRQOL questionnaires (including the International Index of Erectile Function, the Sexual Self-Efficacy Scale, and the Psychological Impact of Erectile Dysfunction scales) were administered to patients in an ED disease registry. Men with ED and a history of diabetes ($n = 20$) were compared with men with ED and no history of diabetes ($n = 90$) at baseline and at the 12-month follow-up.

RESULTS — Diabetic impotent men reported worse erectile function and intercourse satisfaction at baseline, and ED had a greater impact on their emotional life. Diabetic men with ED had significantly different trends over time in the Erectile Function ($P < 0.001$), Intercourse Satisfaction ($P < 0.013$), Sexual Desire ($P < 0.016$), Overall Satisfaction ($P < 0.023$), and the Sexual Experience—Psychological Impact domains ($P < 0.002$). In addition, there was a trend toward a difference over time in the Emotional Life—Psychological Impact domain ($P < 0.067$).

CONCLUSIONS — Impotent men with diabetes present with worse ED than nondiabetic men with ED, resulting in worse disease-specific HRQOL in the diabetic men. Although diabetic patients initially respond well to ED treatment, responses do not appear to be durable over time. Therefore, clinicians must provide longer-term follow-up when treating ED in diabetic patients.

Diabetes Care 26:1093–1099, 2003

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Received for publication 5 October 2002 and accepted in revised form 16 December 2002.

D.M.L. and D.P.L. have received grant funding from TAP Pharmaceutical Products, Inc.

Abbreviations: ED, erectile dysfunction; ExCEED, Exploratory Comprehensive Evaluation of Erectile Dysfunction; HRQOL, health-related quality of life; IIEF, International Index of Erectile Function; PIED, Psychological Impact of Erectile Dysfunction; VA, Veterans Administration.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Erectile dysfunction (ED) is a common complication of diabetes, with prevalence ranging between 27 and 75% (1–3). Despite the high prevalence of this condition in patients with diabetes, little is known regarding how diabetic subjects with ED differ from the general population of impotent men. Comparison of randomized clinical trials assessing the efficacy of sildenafil show that diabetic men with ED differ from the general population of impotent men in their response to oral therapy (4,5). However, it is not known whether diabetic men present with worse sexual dysfunction than impotent patients from the general population or whether ED has a different impact on quality of life in diabetic men when compared with nondiabetic patients.

In fact, little is known regarding the impact ED has on quality of life in diabetic subjects. To date, there has been a single study that specifically examined health-related quality of life (HRQOL) in impotent men with diabetes. De Berardis et al. (6) used the Short Form 36 (SF-36) to study general HRQOL in 1,460 men with diabetes. Of these patients, 34% reported frequent erectile problems. Impotent diabetic subjects were more likely to report depressive symptoms, have lower scores in the mental domains of the SF-36, and report a less satisfactory sex life. Although this cross-sectional study demonstrates that ED has a deleterious effect on quality of life in diabetic men, it does not address how ED treatment affects HRQOL in diabetic subjects. Furthermore, it does not assess whether the impact of ED on quality of life differs in diabetic subjects when compared with the general population of impotent men.

The primary objective of the current study was to compare disease-specific

HRQOL and severity of ED in impotent men with and without a history of diabetes. In addition, the longitudinal effect of ED treatment on sexual function and HRQOL was compared in the two groups. To accomplish these goals, data from the Exploratory Comprehensive Evaluation of Erectile Dysfunction (ExCEED) database, a multicenter longitudinal observational disease registry of men with ED, were used. Importantly, HRQOL was measured using the Psychological Impact of Erectile Dysfunction (PIED) scale, one of the few ED-specific HRQOL instruments that has been appropriately tested and found to be psychometrically valid and reliable (7).

RESEARCH DESIGN AND METHODS

ExCEED database

The ExCEED database is an observational longitudinal disease registry designed to study ED in the general population of patients who seek care for this condition. Six urologic practices participated in the study: five were located in the U.S. and one in Canada. In addition, one site enrolled patients exclusively from a Veterans Administration (VA) hospital, whereas the remaining practices were located in university settings. Before initiation of the project, approval was obtained from all six local institutional review boards.

To be included in the ExCEED database, patients had to speak English, be >18 years of age, be mentally competent to give informed consent, and present to one of the participating physicians with a primary complaint of ED. If a patient met these inclusion criteria, he was offered entry into the study and informed consent was obtained. Baseline clinical evaluation including physical examination, ED history, medical and surgical history, body systems review, and relevant laboratory testing was conducted by a study physician. Additional sociodemographic data were also collected at this time. Depending on their ED and medical history, participants either received treatment for their ED or were scheduled for further assessment after completing the baseline clinical information with their physician. Before initiating any treatment, subjects were asked to complete a number of validated functional scales and HRQOL instruments including 1) the Ejaculation

domain of the Brief Male Sexual Function Inventory (8), 2) the Sexual Self-Efficacy Scale (9), 3) the International Index of Erectile Function (IIEF) (10), and 4) the PIED scales (7).

Follow-up HRQOL information was collected using patient-centered mail-in surveys at 3, 6, and 12 months after baseline. Participants received a \$100 stipend for taking part in the study, given in three separate increments: \$25 at baseline, \$25 at 3 months, and \$50 after receiving the 6- and 12-month HRQOL questionnaires.

Study cohort

To be included in the study, subjects had to meet four inclusion criteria: 1) patients had to be enrolled in the ExCEED dataset from February 2000 through March 2001, 2) information must have been present delineating whether or not the patient had a history of diabetes (including information regarding medication for this condition), 3) the patient had to have completed the baseline HRQOL survey, and 4) the patient had to have reported receiving treatment for their ED while enrolled in the ExCEED study. A total of 207 men were enrolled in the ExCEED database from February 2000 through March 2001. All patients had information regarding history of diabetes, including medications. Of these 207, 110 (53%) had HRQOL information available at all four time points.

Statistical analysis

The study cohort was divided into two groups on the basis of presence or absence of a history of diabetes. Univariate analyses comparing baseline clinical and sociodemographic factors were completed using the Student's *t* test for comparing means or the χ^2 test for comparing proportions where appropriate. Baseline erectile function and HRQOL outcomes were compared between men with ED reporting a history of diabetes and men without a history of diabetes using the Student's *t* test for comparing means. Higher scores indicated better function or HRQOL for all instruments except the PIED scales, in which lower scores were indicative of better quality of life. To assess differences over time between diabetic men with ED and nondiabetic men with ED, functional and HRQOL scores (adjusted for baseline) were compared between the two groups using a multivariate mixed model to test the group (dia-

betic vs. nondiabetic men), time, and group by time effects.

RESULTS— The initial study cohort consisted of 110 men, 20 of whom reported a history of diabetes. Of the 20 diabetic men in the cohort, 3 (15%) were insulin dependent, whereas the remaining 17 (85%) had non-insulin-dependent diabetes. The average age was 58.6 years (SD 8.5) in the diabetic group and 57.2 years (SD 11.9) in the nondiabetic group ($P = 0.608$). As shown in Table 1, the two study groups were similar in terms of race, education, relationship status, and number of sexual partners. Diabetic men with ED reported lower household income in our study than men with ED because of other causes, with 35% reporting an annual income of \$30,000 or less compared with 13% in the nondiabetic group ($P = 0.021$).

The two groups were similar in terms of patient report of ED severity, with diabetic men reporting severe ED 70% of the time and nondiabetic men reporting severe ED 63% of the time. They were also similar in terms of onset of ED and current or previous use of ED therapies. Although not statistically significant, there was a trend toward more frequent ED in the diabetic cohort, with 100% of the diabetic men reporting that their dysfunction always occurred as opposed to only 80% of nondiabetic subjects ($P = 0.089$). Finally, the two groups were similar in terms of the frequency and number of ED treatments received (Table 2). The only type of treatment in which there was a difference in the frequency of use was urethral alprostadil suppositories, which were used in 20% of diabetic men and only 3% of nondiabetic men ($P < 0.01$).

In contrast to patient-reported impotence severity (Table 1), when ED was assessed using validated functional scales, such as the Sexual Self-Efficacy Scale or the IIEF, diabetic men with ED had more severe dysfunction at presentation than nondiabetic men with ED (Table 3). Although the degree of ED was considerable in both groups, diabetic men with ED had significantly lower scores in both the Erectile Function (6.5 vs. 12.5, $P = 0.004$) and Intercourse Satisfaction (3.9 vs. 6.1, $P = 0.049$) domains of the IIEF when compared with nondiabetic men with ED. In addition, the diabetic men reported lower scores on the Sexual Self-Efficacy Scales, although this did not

Table 1—Baseline clinical and sociodemographic characteristics of 110 men with ED participating in the ExCEED database

Characteristic	Overall	Diabetic	Nondiabetic	P
<i>n</i>	110	20	90	—
Ethnic origin				0.665
White	102 (93)	19 (95)	83 (92)	
African-American	8 (7)	1 (5)	7 (8)	
Educational level				0.472
High school diploma/GED or less	22 (20)	6 (30)	16 (18)	
Four-year degree or some college	49 (45)	9 (45)	40 (44)	
Graduate degree/some post-college	29 (26)	4 (20)	25 (28)	
Household income				0.021
\$0–30,000	19 (17)	7 (35)	12 (13)	
\$30,001–75,000	51 (46)	10 (50)	41 (45)	
More than \$75,000	33 (30)	2 (10)	31 (34)	
Relationship status				0.362
Married	85 (77)	17 (85)	68 (76)	
Not married	25 (23)	3 (15)	22 (24)	
Number of sex partners				0.768
No partners	5 (5)	1 (5)	4 (4)	
Single partner	103 (94)	19 (95)	84 (93)	
Multiple partners	1 (1)	0 (0)	1 (1)	
Patient evaluation of ED severity				0.433
Mild	7 (6)	0 (0)	7 (8)	
Moderate	32 (29)	6 (30)	26 (29)	
Severe	71 (65)	14 (70)	57 (63)	
Onset of ED				0.247
Within past 3 months	8 (7)	0 (0)	8 (9)	
3–12 months	26 (24)	3 (15)	23 (26)	
More than 12 months	74 (67)	17 (85)	57 (63)	
Problematic since first sexually active	2 (2)	0 (0)	2 (2)	
Frequency of ED				0.092
Episodic	4 (4)	0 (0)	4 (4)	
Intermittent	14 (13)	0 (0)	14 (16)	
Always	92 (84)	20 (100)	72 (80)	
Currently or previously used ED therapy	33 (30)	6 (30)	27 (30)	0.999

Data are *n* (%) unless otherwise indicated.

quite reach statistical significance (38 vs. 48, *P* = 0.063). The two groups had similar scores on the Ejaculation domain of the Brief Sexual Inventory and the Orgasmic Function, Sexual Desire, and Overall Satisfaction domains of the IIEF.

In addition to having more severe ED, as measured by various functional scales, diabetic men with ED appeared to have worse disease-specific HRQOL than nondiabetic men with ED, at least in the Psychological Impact of Erectile Dysfunction on Emotional Life domain of the PIED scales (54 vs. 48, *P* = 0.012) (higher scores are indicative of worse quality of life on this questionnaire). Although diabetic men with ED had higher mean scores on the Psychological Impact of Erectile Dysfunction on Sexual Experi-

ence domain of the PIED scales, this did not reach statistical significance (51 vs. 48, *P* = 0.275).

Longitudinal changes in functional status and disease-specific HRQOL were measured at 3, 6, and 12 months after baseline in both groups of patients. Using a multivariate mixed model to test the impact of time, group, and their interaction on HRQOL outcomes, diabetic men with ED had significantly different trends over time than nondiabetic men with ED in the Erectile Function (*P* < 0.001), Intercourse Satisfaction (*P* = 0.013), Sexual Desire (*P* = 0.016), and Overall Satisfaction (*P* = 0.023) domains of the IIEF and the Sexual Experience domain of the PIED scales (*P* = 0.002). In addition, there was a trend toward a difference over time in the Emotional Life domain of the PIED scales (*P* = 0.067).

In all of these domains, the general trend over time was similar. There was some improvement during the first 6 months, and in certain domains, 6-month mean scores in diabetic men approached those of nondiabetic patients. By 12 months, however, mean scores in diabetic men returned to near baseline, whereas mean scores in the nondiabetic patients remained close to 6-month levels and improved from baseline (Figs. 1–4). For example, in the Erectile Function domain of the IIEF, considerable improvement was noted in both groups 3 months after baseline (mean change from baseline scores: 3.6 for diabetic men and 4.1 for nondiabetic men, *P* = 0.86). At 6 months, there was further improvement in the diabetic group, whereas the nondiabetic men re-

Table 2—Frequency and number of ED treatments received

Type of treatment	Total	Diabetic men	Nondiabetic men	P
<i>n</i>	110	20	90	—
Hormone replacement	9 (8)	0 (0)	9 (10)	0.14
Intracavernosal injection therapy	38 (35)	5 (25)	33 (37)	0.32
Oral herbal therapy (i.e., yohimbine)	2 (2)	1 (5)	1 (1)	0.24
Sildenafil	75 (68)	11 (55)	64 (71)	0.16
Urethral alprostadil suppository	7 (6)	4 (20)	3 (3)	<0.01
Vacuum erection device	21 (19)	6 (30)	15 (17)	0.17
Penile prosthesis placement	4 (4)	0 (0)	4 (4)	0.37
Number of different treatments received during study period				0.12
1–2	78 (71)	17 (85)	61 (68)	—
≥3	32 (29)	3 (15)	29 (32)	—

Data are *n* (%) unless otherwise indicated.

Table 3—Baseline domain scores on the Sexual Self-Efficacy Scale, the IIEF the Ejaculation domain of the Brief Sexual Inventory, and the PIED scales in 110 men with ED participating in the ExCEED database

Characteristic	Range of possible scores	Overall (n = 110)	Diabetic (n = 20)	Nondiabetic (n = 90)	P
IIEF					
Erectile Function	1–30	11.3 (8.42)	6.5 (5.54)	12.5 (8.60)	0.004
Intercourse Satisfaction	0–15	5.7 (4.70)	3.9 (4.16)	6.1 (4.74)	0.049
Orgasmic Function	0–10	5.3 (3.25)	4.5 (3.49)	5.5 (3.19)	0.237
Sexual Desire	2–10	7.0 (1.99)	6.8 (1.86)	7.1 (2.03)	0.502
Overall Satisfaction	2–10	5.2 (2.82)	4.6 (2.70)	5.4 (2.84)	0.287
Sexual Self-Efficacy Scale	0–100	45.7 (20.09)	38.2 (17.75)	47.5 (20.30)	0.063
Ejaculation domain of the Brief Sexual Inventory	0–10	4.5 (2.67)	4.3 (3.02)	4.5 (2.58)	0.697
PIED scales					
On the Sexual Experience	0–100	48.8 (9.93)	51.0 (11.90)	48.3 (9.41)	0.275
On Emotional Life	0–100	49.3 (9.41)	54.2 (11.48)	48.2 (8.55)	0.012

Data are means (SD). Higher scores are indicative of better outcomes, except in the PIED scales, where lower scores are indicative of better HRQOL.

mained relatively stable (mean change from baseline scores: 7.7 vs. 2.8, $P = 0.03$). However, 1 year after baseline, the two groups once again had similar change scores (2.3 vs. 4.1, $P = 0.41$). Similar results were noted in the Intercourse Satisfaction domain of the IIEF and both the Emotional Life and Sexual Experience domains of the PIED scales. In fact, paired t test analyses revealed no significant differences between baseline and 12-month scores in any of the domains examined in the diabetic group.

CONCLUSIONS— Results from the ExCEED database, an international multicenter longitudinal observational disease registry of men with ED, indicate that there are significant differences both at initial presentation and over time between diabetic and nondiabetic men with ED. In particular, diabetic men with ED appear to have more severe dysfunction (as measured by the Erectile Function and Intercourse Satisfaction domains of the IIEF) at presentation than nondiabetic men with ED. Although diabetes-related ED is thought to be multifactorial in etiology and to include an endocrinologic component (11,12), no differences were noted in the Sexual Desire domain of the IIEF. Because diabetic men with ED appear to have greater dysfunction than nondiabetic men, it is not surprising that they also present with worse disease-specific HRQOL, as measured by the Emotional Life domain of the PIED scales.

After evaluation for their ED, diabetic men appear to respond differently over time than nondiabetic men. Over the first 6 months after baseline, marked improvement is noted in the diabetic group. In fact, in certain functional and HRQOL domains, it appears that diabetic men with ED have similar outcomes as nondiabetic

men with ED. However, this trend does not appear to be durable, because 1 year after baseline, the diabetic patients again appear to have significantly worse ED and disease-specific HRQOL than the nondiabetic men with ED. The exact reasons for this initial improvement in erectile function and HRQOL followed by a decline to baseline are unclear. It is possible that diabetic men may have different expectations with regard to the overall effectiveness of ED therapy. Given the chronic nature of their condition and the numerous other complications associated with diabetes, these patients may initially consider even a minimal response to therapy to be satisfactory. With time, however, they may become unhappy with the limited effectiveness of therapy, resulting in worse patient-reported ED and quality of life. Obviously, another explanation for the initial improvement and then worsening in the group of diabetic men may lie in the continued physical effects of diabetes on the normal physiology of erection. As mentioned above, ED in diabetic men is multifactorial in nature, affecting the normal vascular, neurologic, and endocrinologic mechanism of erections. Simply put, the diabetic men may have experienced continued diminution of their erectile

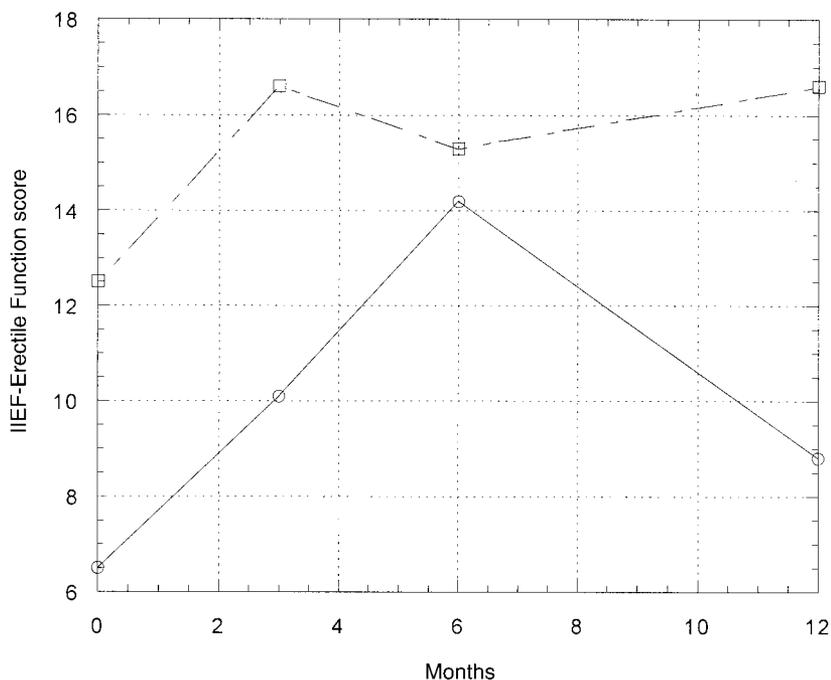


Figure 1—Longitudinal changes in mean scores of the Erectile Function domain of the IIEF in 110 impotent men in the ExCEED database. Higher scores indicate better function. The full range of possible scores for this domain is 0–30. ○, Diabetic subjects; □, nondiabetic subjects.

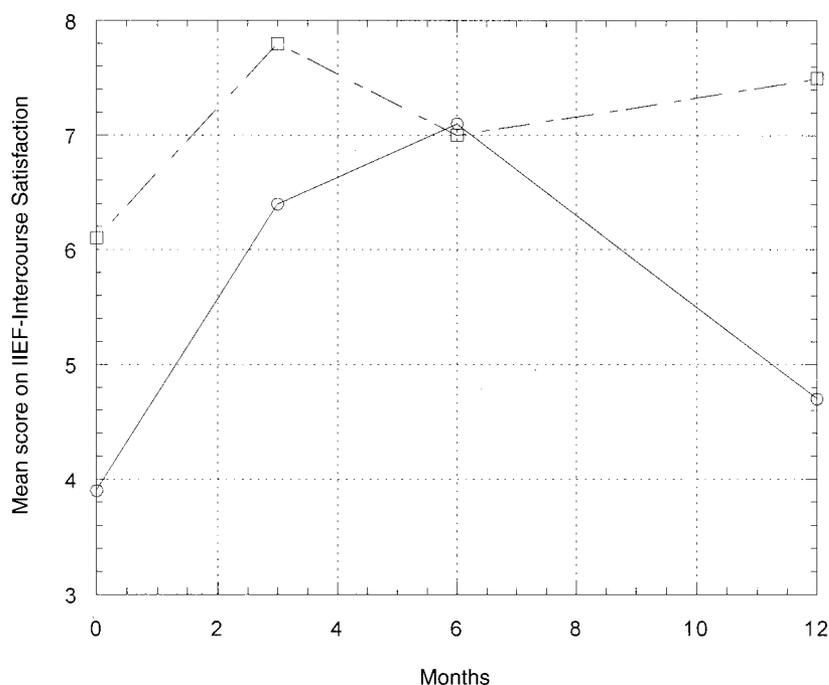


Figure 2—Longitudinal changes in mean scores of the Intercourse Satisfaction domain of the IIEF in 110 impotent men in the ExCEED database. Higher scores indicate better function. The full range of possible scores for this domain is 0–15. ○, Diabetic subjects; □, nondiabetic subjects.

function as part of the natural history of the condition. Further research is needed to determine which of these, or other, hypotheses is true.

These findings have important ramifications for both providers who treat diabetic men with ED as well as patients who suffer from this condition. For providers, this is the first report that documents the commonly held clinical notion that diabetes-related ED tends to be more severe, on average, than ED due to other causes. It also demonstrates the impact this condition has on the quality of life in diabetic men and underscores the specific need to address sexual function when treating these patients. The data regarding long-term outcomes in diabetic men with ED highlight the importance of following these patients for an extended period of time, because patients who initially respond to therapy may ultimately find that this response is not durable over time. These data should be used to help diabetic men set reasonable expectations when initiating ED therapy and to improve communication between the clinician and the patient.

Interestingly, many of the patients in the nondiabetic “control” group suffer from organic conditions that can cause metabolic syndromes similar to diabetes.

These, in turn, may affect erectile function and disease-specific HRQOL in a manner similar to men with diabetes. For example, prostate cancer and its treatment can

cause metabolic changes that can be neurogenic, vasculogenic, or endocrinologic in nature and affect erectile function in a manner similar to diabetes. In the same vein, peripheral vascular disease can cause endothelial dysfunction much like diabetes, resulting in ED (13). If there are metabolic similarities between the two study groups, it makes the findings even more striking because one would expect the two populations to be similar in terms of erectile function and HRQOL, which they are not. These observations further underscore the unique nature of diabetic men with ED when compared with the general population and imply that there may be a psychological burden associated with this condition that is underappreciated.

Prior reports regarding the effectiveness of therapy in diabetic men with ED must be reconsidered in light of the current report. For example, Rendell et al. (4) completed a randomized clinical trial comparing 136 diabetic men with ED treated with sildenafil to 132 diabetic patients treated with placebo. Whereas this report clearly documents that the sildenafil group had superior outcomes at the conclusion of the 12-week trial (56% of subjects in the active treatment arm reported improved erections compared

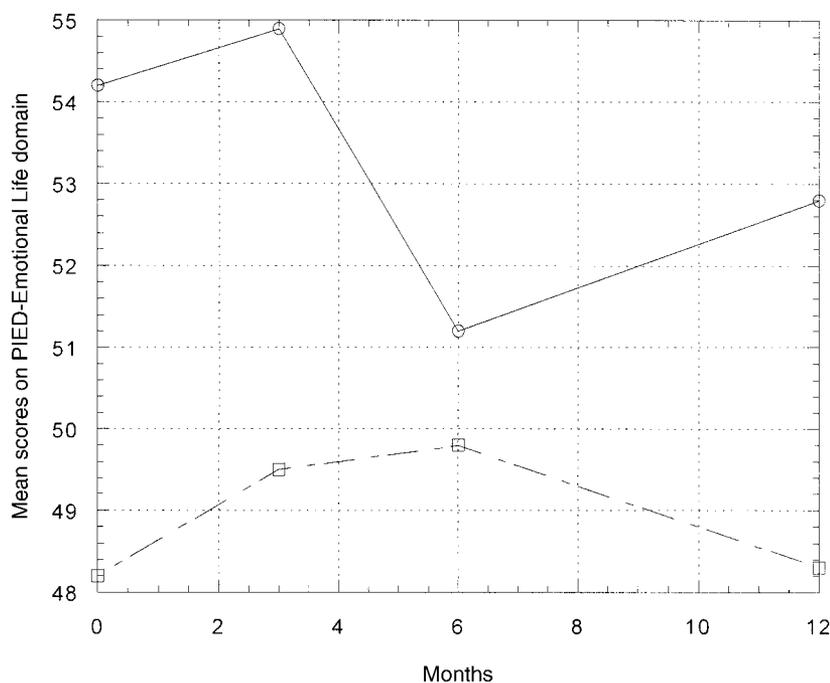


Figure 3—Longitudinal changes in mean scores of the Emotional Life domain of the PIED scales in 110 impotent men in the ExCEED database. Lower scores indicate better quality of life. The full range of possible scores for this domain is 0–100. ○, Diabetic subjects; □, nondiabetic subjects.

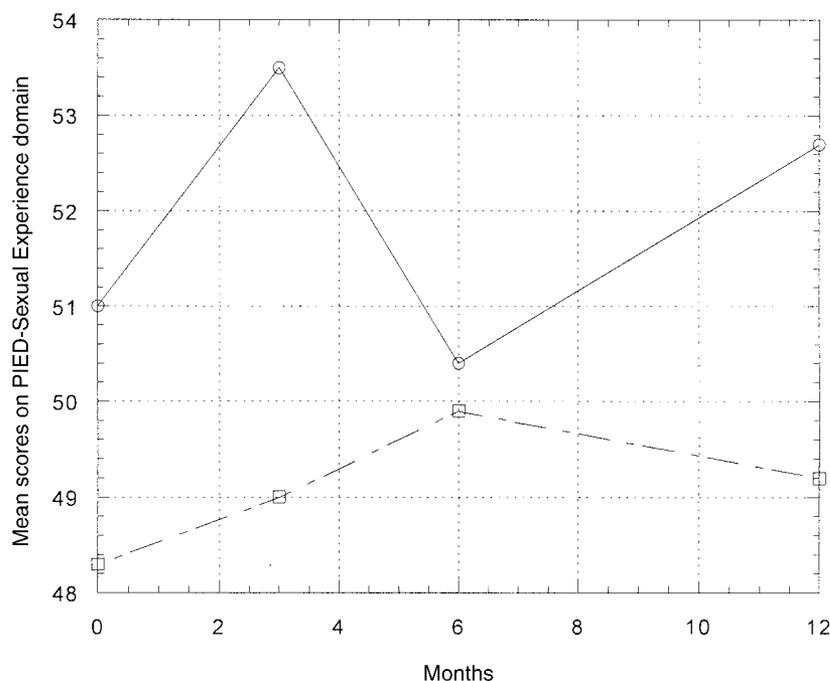


Figure 4—Longitudinal changes in mean scores of the Sexual Experience domain of the PIED scales in 110 impotent men in the ExCEED database. Lower scores indicate better quality of life. The full range of possible scores for this domain is 0–100. ○, Diabetic subjects; □, nondiabetic subjects.

with 10% in the placebo group), the results of the current study question how durable this response is. Similarly, Heaton et al. (14) reported favorable 6-month outcomes in a cohort of 336 diabetic men with ED treated with intracavernosal alprostadil injection therapy. Although these results are encouraging, the current study documents that diabetic men can expect favorable results at 6 months after baseline but that the response to therapy may not be durable. Future studies of therapy for ED in diabetic patients should be designed with longer follow-up so that a better understanding of effectiveness is obtained.

There is little information on the effect of ED on general or disease-specific HRQOL. Litwin et al. (15) used the SF-36 to assess general HRQOL in 57 impotent men who sought treatment at either a university or VA urology clinic. They found that the emotional domains of the SF-36 were associated with more profound impairment than the physical domains in this general population of impotent men. Importantly, they concluded that ED and the bother it causes are discrete domains of HRQOL and distinct from each other in this condition. The current study measured function using the IIEF and as-

essed bother with the PIED scales, which specifically examine the psychological impact (bother) of ED and was among the first to specifically examine HRQOL changes in response to therapy in diabetic men with ED. De Berardis et al. (6) compared general HRQOL in 961 impotent and 499 sexually functional diabetic patients and found that diabetic men with ED had worse general HRQOL. The current study used a condition-specific instrument, the PIED scales, and noted similar findings. Diabetic men with ED reported worse HRQOL in the PIED Sexual Experience domain (51 vs. 48, $P = 0.275$) and significantly worse HRQOL in the PIED Emotional Life domain (54 vs. 48, $P = 0.012$). Even though the difference in the PIED Sexual Experience domain was not statistically significant, both of these differences were >0.3 SDs, indicating that the effect is clinically meaningful to a mild to moderate clinical degree (16). Not surprisingly, the change in HRQOL scores over time mirrors functional response in both domains, although the change is significant only in the Sexual Experience domain. This result may be because of the small sample size but also may be related to better coping mechanisms in the diabetic group and

possibly related to their increased interactions with health care providers primarily responsible for their diabetic care or other comorbid conditions that affect the HRQOL impact of ED. Importantly, the current study documents that diabetic men with ED who respond functionally to therapy can expect improvements in HRQOL, although these improvements disappear if the functional response is not durable.

Like all research, the current study has its limitations. The relatively small sample size of the diabetic cohort may have affected the power of the statistical analysis, causing certain observations to show a trend while not quite achieving statistical significance. In addition, five of the six participating sites were tertiary referral centers, which may have affected the generalizability of these findings, as might the small sample size of diabetic men in the cohort. However, these shortcomings are offset by the strengths of the study, which include, for the first time, the use of a validated condition-specific HRQOL instrument to measure the effects of ED in the cohort, the prospective nature of the study, the long-term follow-up, and the reasonable adherence rates in the population. Although there is no doubt that further research is needed to confirm these findings in other larger and more generalizable populations, the current study furthers our understanding of the unique nature of ED in diabetic men and verifies the clinical impression that men with diabetes have more severe ED than impotent patients without diabetes.

In conclusion, diabetic men with ED present with more severe dysfunction than men with ED due to other causes. The result is worse quality of life in these diabetic patients. Providers need to be aware of this and specifically address these issues in their diabetic patients. Diabetic men with ED can initially expect to have improvements in both erectile function and condition-specific HRQOL. However, this improvement does not appear to be durable in many patients and, by 1 year, diabetic men with ED can expect to have significantly worse erectile function and HRQOL than nondiabetic men with ED. Therefore, clinicians must provide longer-term follow-up when treating ED in diabetic patients and must be prepared to try alternative therapies in their patients who wish additional treatment. Future research also needs to exam-

ine longer-term outcomes in diabetic men with ED and needs to specifically address the impact of ED on HRQOL in this population.

Acknowledgments—ExCEED was sponsored by TAP Pharmaceutical Products, Inc., and managed by the Urology Outcomes Research Group at the University of California San Francisco. This material is the result of work supported in part with resources and the use of facilities at the VA Puget Sound Health Care System, Seattle, WA. Dr. Penson was a Level I VA Health Services Research and Development Career Development Awardee while working on this study.

The authors acknowledge the efforts of William Lenderking and Chris Pashos, who assisted in the development of the PIED scales.

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