

Effects of 12-Month Tadalafil Therapy for Erectile Dysfunction on Couple Relationships: Results from the DETECT Study

Benny Verheyden, MD,* Thierry Roumeguère, MD,[†] Alain Bitton, MD,[‡] Mark Belger, BS,[§] and Henry Schmitt, MD[¶] for the DETECT study investigators

*Andrology Unit, Department of Urology, Antwerp University Hospital, Edegem, Antwerp, Belgium; [†]Erasmus Hospital, Brussels, Belgium; [‡]Private urological practice, Geneva, Switzerland; [§]Eli Lilly, Erl Wood, UK; [¶]Eli Lilly, Brussels, Belgium

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ABSTRACT

Introduction. Erectile dysfunction (ED) is distressing and can affect a couple's relationship.

Aim. To investigate partner awareness of ED, relationship problems, and the effects of tadalafil treatment over 12 months.

Methods. The Determinants of Continued Use of Tadalafil study is a prospective 12-month European observational study in patients with ED initiating or changing treatment to on-demand tadalafil. A total of 1,900 patients were enrolled in eight countries. Assessments were made on predefined treatment outcomes in a routine clinical setting.

Main Outcome Measures. At baseline, 1, 6, and 12 months, patients were asked about relationship problems (unspecified), partner awareness and support of consultation, and partner sexual problems. Data were analyzed for patients continuing tadalafil at 12 months.

Results. At baseline, 96% of patients had a partner, 80% of partners supported an ED consult, and 73% were aware of the consultation. Relationship problems were reported by 17% of patients at baseline. At 12 months, 84% of patients were still taking tadalafil. Of these, 19% reported relationship problems at baseline. After 12 months of treatment with tadalafil, 4% of patients still reported perceived problems. Factors associated with no relationship problems at 12 months were: at baseline, no previous ED treatment, partner in poor health; and at 12 months a lower ED severity. If the partner was felt to have a sexual problem at 12 months, relationship improvement was less likely. Further, 3% of patients developed relationship problems during treatment. Factors associated with developing a relationship problem were: a history of pelvic surgery at baseline, a different partner at 12 months than at baseline, and a partner with a sexual problem at 12 months.

Conclusions. Improvement of ED with tadalafil was associated with reduced relationship problems, suggesting that problems were associated with ED and resolved with treatment. Verheyden B, Roumeguère T, Bitton A, Belger M, and Schmitt H. Effects of 12-month tadalafil therapy for erectile dysfunction on couple relationships: Results from the DETECT study. *J Sex Med* **;***-**.

Key Words. Couple; Erectile Dysfunction; Phosphodiesterase Type 5 Inhibitor; Tadalafil; Sexual Relationship

Introduction

Despite the high prevalence of erectile dysfunction (ED), most men do not seek treatment [1–9]. Among men who initiate treatment with a phosphodiesterase type 5 (PDE5) inhibitor, compliance to therapy decreases over time [5]. Partner support of the patient with ED has been associated with the patient seeking treatment, and partner satisfaction is also important for continuation of therapy [9–16].

ED can impact a man's quality of life by decreasing self-esteem, sexual confidence, and psychological well-being [17–20]. Additionally, ED may also affect sexual functioning of the female partner [21–26]. Consequently, ED may not only cause emotional distress to many couples, but also may weaken the relationship and cause withdrawal of intimacy and affection with the partner [27–29]. These problems likely influence the outcomes of ED treatment [5,28,30–32].

Research concerning ED treatment has primarily focused on improving male sexual function [1,33,34]. It is, however, also important to consider parameters related to the sexuality of the female partner. Although men are more likely to emphasize the importance of sexual intercourse within a sexual relationship [32], restoration of erectile function (EF) is not the only factor involved in successful ED treatment. A more holistic view of treatment effectiveness and satisfaction is needed in routine clinical practice that incorporates, not only erectile capacity, but also satisfaction of the patient and his partner [15].

Previous studies have evaluated partner awareness of ED therapy, but, to our knowledge, the impact of partner awareness on the outcomes of ED treatment has not been evaluated [7,13]. A few studies have investigated the effect of treatment of ED with PDE5 inhibitors on couples' relationships [35–37]. The Determinants of Continued Use of Tadalafil (DETECT) is a prospective observational study designed to evaluate, over 12 months, predefined treatment outcomes associated with tadalafil therapy in men with ED in a natural, clinical practice setting. The effectiveness of, and satisfaction with, tadalafil treatment continuation has previously been reported [15,38]. We report here the views of the patient with ED on his partner's awareness and support of treatment, and his perception of problems in his relationship before and after 12 months of treatment with tadalafil, as well as those factors identified as being associated with relationship changes.

Patients and Methods

Study Design

A detailed description of the study methods has been reported previously [15,38]. Briefly, the DETECT study was a prospective, noninterventional, one-year, observational study conducted at 236 centers in eight European countries and was designed to evaluate treatment outcomes, including continuation, effectiveness, and patient satisfaction. The aim of this analysis is to evaluate the impact of treatment on perceived problems in relationships. Subjects were men with ED who were planning to be sexually active with a female partner and were initiating or changing treatment to tadalafil. Data were collected from participants at four time points (initial baseline visit, 1, 6, and 12 months). Treatment with tadalafil 10 or 20 mg was prescribed at the discretion of the physician and patient according to the usual practice of standard

care. Local institutional review boards approved the protocol, and written informed consent was obtained from all patients.

At the initial visit, responses to items of the EF domain of the International Index of Erectile Function (IIEF) questionnaire [39] were collected. Additional patient information was collected regarding treatment history, demographics, concomitant disease, duration and etiology of ED (investigator assessment), relationship history, perceived problems in relationship, partner age, awareness and support of consultation ("Is your partner aware of consultation?": yes/no; "Does your partner support your consultation?": yes/no), partner perceived health ("How would you describe the health of your partner": good/bad), partner sexual problems ("Does your partner have a sexual problem?": yes/no), and patient treatment expectations (Patient Expectation Questionnaire [15]). Problems in relationships were assessed with a simple question: "Do you consider there are problems in your relationship with your partner?" (yes/no).

At 1, 6, and 12 months, patients were asked to complete the IIEF-EF questionnaire, the Erectile Dysfunction Index of Treatment Satisfaction questionnaire [40], and provide information on number of sexual attempts, tadalafil use and tolerability during the previous 4 weeks, partner awareness and support of consultation, perceived partner health and sexual problems, as well as answer the question on problems in the relationship.

Study Population

A total of 1,900 patients with ED were included. Participants were from Greece (N = 710), followed by the Netherlands (N = 278), Belgium (N = 276), Austria (N = 225), Sweden (N = 192), Denmark (N = 139), Norway (N = 65), and Iceland (N = 15). Of the 1,900 participants, 90% returned a completed data collection form after 1 month, 85% after 6 months, and 81% after 12 months. There was no difference in baseline characteristics between patients who did or did not return data collection forms. Twelve-month follow-up information was obtained from 1,567 patients. Of these, 1,319 (84%) were still using tadalafil at 12 months, 197 (13%) had discontinued treatment, and 51 (3%) reported no longer having ED. While there was a slightly higher proportion of patients with reported relationship problems at baseline who received the 20 mg dose as compared with those with no relationship problems (76% vs.

70%), there were no significant differences in the proportion of patients initially receiving the 20 mg dose according to the degree of severity of ED [38]. At 12 months, 77% of patients were using the 20 mg dose [38]. This amount was similar between those patients reporting or not reporting relationship problems at 12 months.

Statistical Analysis

Baseline data are based on all 1,900 patients with nonmissing information; patients without a current partner ($N = 79$) were not included in the analysis of relationship questions. The longitudinal analysis is based on all nonmissing information from the cohort of patients who continued to use tadalafil at 12 months and reported that they were in a current relationship. Estimates of continuous variables are reported as mean and 95% confidence intervals. For categorical data, the number and percentage of the total are reported.

Multivariate logistic regression models were used to identify patient and treatment factors associated with the dichotomous outcomes, which included: (i) partner's support of consultation (yes/no); (ii) perceived relationship problems at baseline (yes/no); (iii) resolution of relationship problem at 12 months (yes/no); and (iv) development of relationship problem at 12 months (yes/no).

All relevant patient and treatment characteristics were included in the full model (see list of covariates next); the effect of removing variables was investigated using backward elimination methods until a reduced model containing only statistically significant ($P \leq 0.05$) independent variables was obtained. All multivariate models included country to adjust for any underlying country effect.

Multivariate logistic regression models were used to identify which baseline factors were significantly associated with reporting (i) partners support of the consultation; and (ii) perceived relationship problem. All multivariate models considered the following factors for inclusion: baseline patient characteristics (etiology, previous ED treatment, severity of ED, duration of ED, age, patient health); concomitant disease (diabetes mellitus, hypertension, neurological disease, coronary artery disease, depression, obesity, smoking, alcohol abuse/dependency, lower urinary tract symptoms, spinal cord injury, pelvic surgery, prostatectomy); patient's responses to the partner questionnaire at baseline (partner aware of consultation, partner supports consultation, partner's

health, age, duration of relationship, problems in relationship, partner perceived with a sexual problem); and baseline treatment expectations. For models examining 12-month relationship problems, the outcomes at 12 months (IIEF-EF severity, number of sexual attempts, tolerance to treatment, relationship outcomes) were also included in the models. For dichotomous outcomes, odds ratios and associated 95% confidence intervals are reported; the Wald chi-square statistic was used to measure the strength of association. The results from these models were illustrated through univariate summaries of the factors on the outcome measure.

Results

Patient baseline characteristics are summarized in Table 1 by whether patients did or did not consider there to have relationship problems with their partner at baseline. Of the 1,780 men with information on relationship problems, 302 (17%) reported such problems. The prevalence of self-reported relationship problems was higher in some countries (Greece and Belgium, 26%, and 19% respectively) vs. others (Austria, Denmark, Netherlands, Norway, Sweden 8% to 10% each; data not shown). At baseline, 96% (1,791/1,866) of the men reported having a partner with whom they aspired to be sexually active with, and approximately two-thirds of these men indicated the relationship as long-standing (>10 years). A total of 5% of participants felt that their partner had a sexual problem, and 80% of partners were felt to be supportive of the consultation at baseline.

Perceived Partner Support

At baseline, 1,721 patients reported responses to the question on partner support, 80% (1,375/1,721) of patients reported that their partner supported their consultation. A multivariate regression analysis identified the following factors to be significantly associated with the partner being supportive: longer duration of relationship ($P < 0.0001$), no problems in relationship ($P = 0.0002$), and the patient feeling that it was important that his partner was satisfied with treatment ($P < 0.0001$). The proportion of partners who were supportive of patients' ED consultations tended to be higher in Denmark, the Netherlands, Norway, and Sweden (86–94%) compared with Greece (74%) and Belgium (66%).

Table 1 Baseline characteristics in patients with erectile dysfunction (ED)

Characteristics	All patients (N = 1,900)	Relationship problems reported at baseline*	
		No problems (N = 1,478)	Problems (N = 302)
Mean (SD) patient age, year	56.7 (11.1)	57.5 (11.0)	54.4 (10.4)
Mean (SD) partner age, year	50.7 (11.8)	51.4 (11.9)	47.6 (10.8)
No. (%) with ED duration >1 year	1,209 (66)	1,006 (68)	197 (65)
Mean (SD) number of sexual attempts	4.7 (4.5)	4.7 (4.7)	5.2 (3.7)
Mean (SD) IIEF-EF baseline score	13.7 (7.5)	13.8 (7.6)	13.3 (6.9)
ED etiology, No. (%)			
Organic	522 (28)	454 (31)	50 (17)
Psychogenic	401 (21)	277 (19)	76 (25)
Mixed	972 (51)	744 (50)	174 (58)
Previous ED treatment, No. (%)			
Treatment naïve	1,226 (65)	967 (65)	182 (60)
ED treatment in previous 4 weeks	191 (10)	147 (10)	34 (11)
No ED treatment in the last 4 weeks	482 (25)	363 (25)	86 (28)
ED severity, No. (%)			
Normal rated	99 (5)	88 (6)	8 (3)
Mild	612 (33)	492 (33)	92 (31)
Moderate	455 (24)	344 (23)	88 (29)
Severe	695 (37)	545 (37)	113 (38)
Patients with comorbid, No. (%)			
Hypertension	799 (42)	622 (42)	138 (46)
Coronary artery disease	186 (10)	124 (8)	54 (18)
Diabetes mellitus	440 (23)	327 (22)	89 (30)
Depression	251 (13)	143 (10)	80 (27)
Pelvic surgery	68 (4)	60 (4)	5 (2)
LUTS	312 (16)	234 (16)	56 (19)
Currently has partner [†] , No. (%)	1,791 (96)		
Duration of relationship, No. (%)			
<1 year	237 (13)	185 (13)	50 (17)
1–10 years	354 (20)	273 (19)	79 (26)
>10 years	1,179 (67)	1,000 (69)	173 (57)
No. (%) having partner with health problems	104 (6)	65 (4)	39 (13)
No. (%) reporting partner has a sexual problem	89 (5)	52 (4)	37 (12)
No. (%) with partner support of consultation	1,375 (80)	1,162 (82)	208 (72)
No. (%) with partner aware of consultation	1,301 (73)	1,112 (75)	183 (61)
No. (%) reporting relationship problems	302 (17)		

All summaries and their corresponding percentages are based on nonmissing responses to each of the questions.

*1,780 patients answered the question on relationship problems.

[†]All patients answering the question on relationships had a partner.

EF = erectile function; IIEF = International Index of Erectile Function; LUTS = lower urinary tract symptoms; SD = standard deviation.

Perceived Relationship Problems

At baseline, 17% (302/1,780) of patients reported relationship problems. The factors identified from the multivariate model as being statistically associated ($P \leq 0.05$) with self-reported relationship problems at baseline are illustrated through univariate analysis in Figure 1. Such problems were about twice as likely in men with psychogenic compared with organic etiology of ED ($P < 0.0001$), in those aged <60 years ($P < 0.0001$), and in patients with mild, moderate, or severe ED compared with normal EF ($P = 0.05$ for trend) according to the IIEF-EF score. Patients with comorbidities, including depression ($P = 0.0001$), diabetes mellitus ($P = 0.05$), as well as coronary artery disease ($P < 0.0001$) and alcohol abuse/dependency ($P = 0.01$) were also significantly more likely to self-

report relationship problems than their counterparts without comorbidities. Treatment-naïve patients were less likely to have reported perceived relationship problems at baseline ($P = 0.003$).

Certain partner factors were also associated with significantly higher rates of patients self-reporting relationship problems, including partners being perceived in poor general health ($P < 0.0001$) or with a sexual problem ($P < 0.0001$). On the other hand, men were less likely to report a relationship problem if their partner was felt to be aware of the consultation ($P = 0.001$) and if the relationship was of >10 years' duration ($P = 0.01$). In general, patients who had lower expectations of the treatment, as previously reported [15], were more likely to report relationship problems (data not shown).

Of the 302 patients reporting relationship problems at baseline, 243 (80%) were using tadalafil at

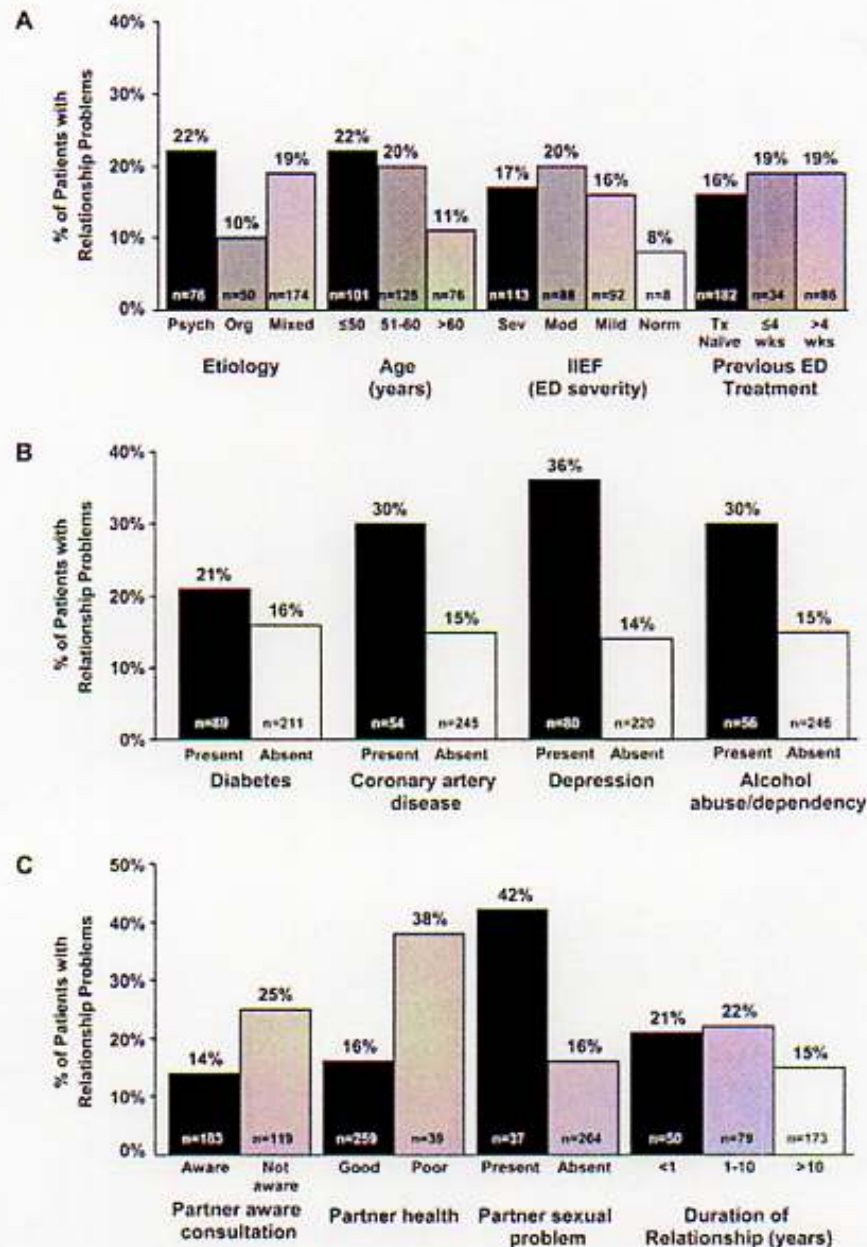


Figure 1 The percentage of patients reporting perceived relationship problems at baseline, stratified by the factors identified to be significantly associated ($P \leq 0.05$) with perceived relationship problems (multivariate logistic regression model). N = number of patients reporting a perceived relationship problem at baseline, per cohort. Analyses within each cohort included only those patients who answered the "problem in relationship" question at 12 months. (A) Demographic characteristics and erectile dysfunction (ED) severity according to the International Index of Erectile Function (IIEF). (B) Comorbidities. (C) Partner and other relationship variables.

12 months, 33 (11%) were lost to follow-up, 19 (6%) were not using tadalafil, and 7 (2%) reported no longer having ED. In the cohort of patients remaining on tadalafil, the proportion of patients reporting relationship problems decreased significantly from baseline (19%) to each postbaseline visit (4% at 12 months) (Figure 2).

To help identify factors at baseline and at 12 months that were associated with improvement

in relationships, a multivariate logistic regression model was used on the cohort of men who indicated they had a problem at baseline, reported using tadalafil at 12 months, and had completed the relationship problem question at the 12-month visit ($N = 243$) (Table 2). Significant factors, as assessed at 12 months, associated with improved relationship problems included lower ED severity (IIEF-EF); the patients' belief that their partners

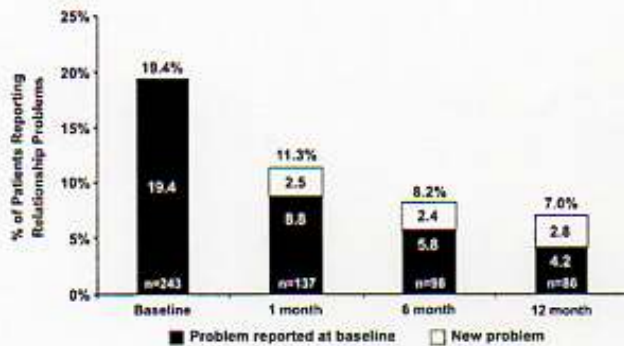


Figure 2 Evolution of relationship problems in patients using tadalafil for 12 months. The percentage of patients whose problems were first reported at baseline (solid bars) and the percentage who reported new problems during the course of the study (open bars). N = total number of patients reporting perceived relationship problems at each time point. Analyses within each cohort included only those patients who answered the "problem in relationship" question at 12 months.

do not have a sexual problem; as well as the patients not having received previous ED treatment at baseline. Figure 3 illustrates the factors associated with improvement in relationship problems using a univariate analysis.

At baseline, 16–20% of men had relationship problems, regardless of the degree of severity of their ED (Figure 1). The majority of patients for each ED severity category at baseline were assessed as having mild or no ED at 12 months [38]. As shown in Figure 3, the majority of patients with mild or no ED at 12 months did not perceive relationship problems any longer. A total of 3% of patients with available data developed new relationship problems during 12-month treatment (Figure 2). Factors significantly associated with development of an incident relationship problem included a history of pelvic surgery at baseline

($P = 0.007$); being with a different sexual partner at 12 months compared with baseline ($P = 0.03$); and having a partner felt to have an incident sexual problem at 12 months ($P < 0.0001$) (Figure 4). The proportion of patients with relationship problems at 12 months was the same (7–8%) whether the patient was prescribed the 20 mg or 10 mg dose at baseline.

In the cohort of patients not using tadalafil at 12 months ($N = 197$), information on relationships was available for 70%, respectively (138/197). Of these men, 12% reported relationship problems at baseline, of which 6% remained at 12 months, while 9% developed new relationship problems.

Perceived Sexual and Health Problems in the Partner

In the cohort of patients using tadalafil at 12 months ($N = 1,319$), information on partner health and sexual problems was available for 1,220 and 1,231 patients, respectively. Of these, 5% (57/1,231) of partners were perceived by patients to have a sexual problem at baseline. This proportion decreased to 3% (33/1,231) after 12 months. A further 2% (28/1,231) of patients reported that they felt their partner had developed a sexual problem during treatment. Likewise, in this cohort, 6% (75/1,220) of patients felt their partner to be in poor health at baseline. This proportion decreased to 1% (10/1,220) during treatment. A further 2% (23/1,220) of patients felt their partner to have poor health after treatment.

In the cohort of patients not using tadalafil at 12 months ($N = 197$), information on partner health and sexual problems was available for 137 and 138 patients, respectively. Of these, 7% (10/137) of patients felt their partner to be in poor health and 9% (13/138) felt their partner had sexual problems, at baseline. These proportions decreased respectively to 6% (8/137) and 5% (7/138) at 12

Table 2 Factors associated with improvement in relationship problems*

Variable	Odds ratio	95% Confidence interval		P value	Wald chi-square†
Previous ED treatment (referent: no previous ED treatment in the last 4 weeks)				0.001	13.7
ED treatment naive	4.01	1.88	8.59	0.0003	
ED treatment in the 4 weeks prior to study enrolment	1.26	0.4	3.96	0.69	
Partner does not have a sexual problem at 12 months (reference partner has a sexual problem)	6.02	2.02	17.97	0.001	10.38
Partner in good health at baseline (reference patient in poor health)	0.17	0.04	0.80	0.025	5.02
IIEF-EF at 12 months (reference each additional point increase)	1.08	1.01	1.15	0.026	4.98

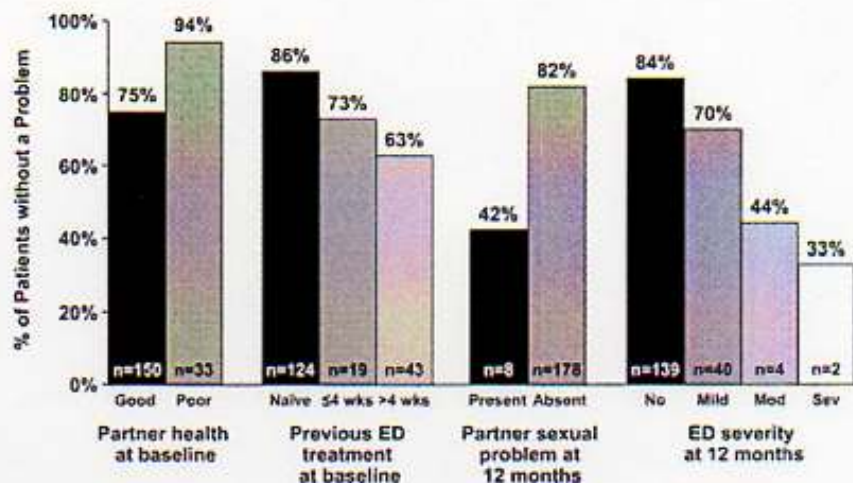
N = 243 patients.

*Baseline problems not persisting at treatment month 12 (based on multivariate analysis on the likelihood of the 243 patients who reported relationship problems at baseline, reporting these problems, and were no longer perceived to exist after 12 months of treatment).

†Factors are listed in descending order of strength of association, as determined by Wald chi-square.

ED = erectile dysfunction; EF = erectile function; IIEF = International Index of Erectile Function.

Figure 3 Factors associated with improvement of relationship problems after 12 months of tadalafil treatment. The bars depict the proportions of patients receiving tadalafil treatment who did not report relationship problems at 12 months, but who had reported perceived relationship problems at baseline. Analyses within each cohort included only those patients who answered the "problem in relationship" question at 12 months. (N = 243). N = number of patients with no perceived problems at 12 months, per cohort. ED = erectile dysfunction.



months, while 6% (8/137) and 7% (10/138) felt their partner had developed new health and sexual problems, respectively, over 12 months.

Concerning other partner parameters in this cohort of patients, the proportion of partners supporting ED consultation increased from 77% at baseline, to 82% after 1 year of tadalafil treatment, and partner awareness of consultation increased from 70% to 82%.

Discussion

Relationship issues can both precipitate and maintain ED [31]; they can be the cause or consequence of ED [36]. In this study, 17% of men with ED reported having relationship problems prior to beginning treatment with tadalafil. While this value

may appear relatively low given the broad impact of ED on couple relationships [30,36], it has been shown that men with ED tend to underestimate marital dissatisfaction, as compared with their partner [28]. This phenomenon could indicate that the number of couples with relationship problems may be higher than observed in this study.

In the present subgroup analysis of the DETECT study, the following baseline factors were found to be associated with increased relationship problems: younger age; a relationship of ≤ 10 years duration; mild to severe or psychogenic ED; and the presence of comorbidities (particularly depression). Partners of patients who reported relationship problems were less likely to be aware of the patient's medical consultation to treat ED, than those who did not report these problems. These findings underscore the fact that the impact of disease on relationships is also dependent on the capacity and confidence of the patient to have a dialog with his partner. Younger men, even with comparatively better EF compared with older men, have been reported to have less relationship satisfaction [41], possibly related to experiencing more difficulties in adjusting to their life with ED [42]. Men with psychogenic ED have been reported to be less self-confident, while their partner may be more likely to take personal responsibility for ED [27]. In addition, depression has been shown to be associated with marital conflict [43–45], and is also frequently associated with ED and lower levels of self-confidence [18–20,46,47].

In the present study, patients reporting that they perceived their partner to be in poor health, or having a sexual problem of their own, had an increased likelihood of self-reported relationship

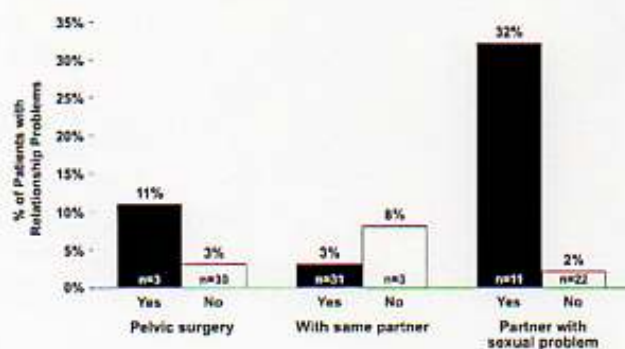


Figure 4 Factors associated with the development of perceived relationship problems at 12 months in the cohort of patients who were using tadalafil at 12 months and had reported no perceived relationship problems at baseline (N = 1,009). N = number of patients reporting a newly perceived relationship problem at 12 months, in each cohort. Analyses within each cohort included only those patients who answered the "problem in relationship" question at 12 months.

problems. It is unclear why men in Greece and Belgium were more likely to report relationship problems than those in other countries. One explanation might derive from the observation that a lower proportion of partners in these countries were reported to be supportive of consultation for ED, a factor associated in this study with less relationship problems. It is, however, unlikely that these observations reflect true cultural, rather than subject sample, differences. Overall, 80% of partners were perceived as supportive of the ED consultation at baseline, a result that is consistent with data from the Men's Attitudes to Life Events and Sexuality (MALES) study, which indicated that partner support was strongly associated with patients seeking PDE5 treatment [1]. Factors associated with the partner being supportive included the following: longer relationship duration, no perceived relationship problems, and the importance to the patient of partner satisfaction with treatment, which further reinforces the value of good communication between the couple in addressing ED treatment. Although a previous study has shown that patients with more severe ED were more likely to have discussed their ED with their partner [48], such an association was not observed in the present study. The proportion of partners perceived to be aware, and in support, of the ED consultation increased on tadalafil treatment, possibly indicating that improvement in self-confidence and satisfaction with treatment facilitated communication between the couple.

Treatment of ED can improve relationships or, alternatively, elicit new problems with dissatisfaction of the partner and treatment discontinuation [32]. In the present study, the proportion of men perceiving relationship problems after 12 months of tadalafil treatment was reduced from 19% to 7%. Improvement in relationships was associated with improved EF, suggesting that the main relationship problem perceived by men in this study was of a sexual nature. This interpretation is reinforced by a lesser decrease of relationship problems in the cohort of patients who were not on tadalafil treatment at 12 months. Likewise, the proportion of men perceiving problems in their partner's health decreased more in patients continuing tadalafil at 12 months, compared with those having stopped treatment, suggesting that the patient perception of partner's health problems might have had a certain component of a sexual nature. These observations are supported by the general perception that, compared with women, men are more likely to emphasize the

importance of sexual intercourse in a mutually satisfying sexual relationship [32].

In a previous analysis of this study, partner satisfaction with ED treatment was viewed as a high expectation by patients [15]; further, partner support, satisfaction, and good relationships were factors associated with treatment satisfaction. Restoration of EF is thus not the only factor involved in a successful treatment. Indeed, in the MALES study, men, with or without ED, placed greater value on couple relationships over purely sexual pleasure as components of their quality of life, across cultures and ages [49]. Additionally, several other studies have shown improvements in patient and partner sexual function and satisfaction with PDE5 inhibitor therapy [14,25,37,50–57].

Cappelleri et al. published data indicating that higher satisfaction with sildenafil citrate treatment correlated to a higher score in the sexual relationship domain of the SEAR questionnaire and, to a lesser degree, also in the overall relationship domain [37]. This supports findings in the current study suggesting a link between lower ED severity at end point and a higher proportion of patients without relationship problems; furthermore, we have previously observed that ED severity is the main parameter influencing patient satisfaction [15]. Importantly, satisfaction with sexual life has been found to be a powerful predictor of satisfaction with life as a whole [58].

Higher patient and partner satisfaction as well as treatment preference have been previously observed with tadalafil, when compared with sildenafil (or upon switching treatment from sildenafil to tadalafil rather than vice versa) [10,11]. These findings may be consistent with tadalafil users and their partners being afforded more time to rebuild emotional intimacy, a critical parameter, in addition to sexual intimacy, that is related to marital satisfaction [29]. Muller et al. have also shown qualitative improvements in other aspects of partnerships (quarreling, tenderness, and togetherness) upon treatment with sildenafil citrate [35].

Potential limitations of our study include the fact that relationship problems were not precisely defined or analyzed in depth. Problems in relationships and their improvement may express, to a varying degree, different aspects of partnership, including sexual relationships. Restoration of sexual function after a long period of asexual equilibrium because of ED, may precipitate relationship problems that had remained dormant during the period of sexual abstinence secondary to ED

[31]. In the present study, however, only 3% of patients perceived new relationship problems after 12 months of tadalafil treatment. The risk was higher if the patient felt his partner had a sexual problem, or if the patient had a new partner at 12 months. Likewise, the proportion of men who perceived a sexual or health problem in their partner decreased with treatment and only 2% felt that their partner had developed a new problem with treatment. The prevalence of 5% of partners perceived to have sexual problems by men in this study population, at baseline, compares with the prevalence of sexual problems viewed as frequent in a global survey [31]. A limitation of the interpretation of our results was that sexual and health problems were not precisely defined in this study. Finally, our study relied on patient self-report to evaluate relationship and sexual problems in their partner; this may result in an underestimation of the problems between the couple. Future studies should seek to assess the partner's perceptions more effectively.

Conclusions

Approximately 17% of men with ED initiating tadalafil treatment in this study perceived that they had relationship problems with their partner. Improvement of ED with tadalafil therapy was associated with a significant reduction in perceived relationship problems. Conversely, treatment with tadalafil was infrequently associated with newly perceived relationship problems and newly perceived sexual problems in the partner. Taken together, these findings suggest that relationship problems before treatment were associated with ED and were resolved in tadalafil responders.

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Corresponding Author: Benny Verheyden, MD, University Hospital Antwerp, Wilrijkstraat 10, 2650 Edegem, Belgium. Tel: +32 3 8213047; Fax: +32 3 8214479; E-mail: benny.verheyden@uza.be

Conflict of Interest: Drs. Verheyden, Roumeguère, and Bitton were investigators and members of the advisory board of this sponsor-funded study. Mr. Belger and Dr. Schmitt are employees of Eli Lilly.

Statement of Authorship

Category 1

- (a) **Conception and Design**
Henry Schmitt; Benny Verheyden; Thierry Roumeguère; Mark Belger; Alain Bitton
- (b) **Acquisition of Data**
Henry Schmitt; Alain Bitton; Mark Belger; Thierry Roumeguère; Benny Verheyden
- (c) **Analysis and Interpretation of Data**
Mark Belger; Henry Schmitt; Benny Verheyden; Thierry Roumeguère; Alain Bitton

Category 2

- (a) **Drafting the Article**
Henry Schmitt; Benny Verheyden
- (b) **Revising It for Intellectual Content**
Thierry Roumeguère; Alain Bitton; Mark Belger

Category 3

- (a) **Final Approval of the Completed Article**
Benny Verheyden; Thierry Roumeguère; Alain Bitton; Mark Belger; Henry Schmitt

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