ORIGINAL RESEARCH—EJACULATORY DISORDERS

Premature Ejaculation: An Observational Study of Men and Their Partners

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ABSTRACT

Introduction. Premature ejaculation (PE) is the most common male sexual dysfunction affecting men and their partners. Lack of community-based data describing this condition limits understanding of PE and its outcomes.

Aim. To characterize PE in a large population of men with and without PE using patient-reported outcome (PRO) measures elicited from men and their partners.

Methods. 4-week, multicenter, observational study of males (≥18 years) and their female partners in monogamous relationships (≥6 months). Screening, baseline, and follow-up visits scheduled at 2-week intervals. Clinicians diagnosed PE utilizing DSM-IV-TR criteria. Intravaginal ejaculatory latency time (IELT), measured by a stopwatch held by the partner, was recorded for each sexual intercourse experience. Subject and partner independently assessed PROs: *control over ejaculation* and *satisfaction with sexual intercourse* (0 = very poor to 4 = very good), *personal distress* and *interpersonal difficulty* (0 = not at all to 4 = extremely), and *severity of PE* (0 = none to 3 = severe).

Results. Of the total study population (N = 1,587), 207 subjects were diagnosed with PE and 1,380 were assigned to the non-PE group. Median IELT (min) was 1.8 (range, 0–41) for PE and 7.3 (range, 0–53) for non-PE subjects (*P* < 0.0001). More PE vs. non-PE subjects gave ratings of "very poor" or "poor" for *control over ejaculation* (72% vs. 5%; *P* < 0.0001) and *satisfaction with sexual intercourse* (31% vs. 1%; *P* < 0.0001). More subjects in the PE vs. non-PE group gave ratings of "quite a bit" or "extremely" for *personal distress* (64% vs. 4%; *P* < 0.0001) and *interpersonal difficulty* (31% vs. 1%; *P* < 0.0001). Subject and partner assessments showed similar patterns and correlated moderately (0.36–0.57).

Conclusions. PE subjects reported significantly shorter IELT. Overlap in IELT distributions was observed between the PE and non-PE groups, indicating the need for additional PRO measures to characterize PE. Shorter IELT was significantly associated with reduced ejaculatory control and sexual satisfaction and increased distress and interpersonal difficulty.

Key Words. Male Orgasmic Disorder; Male Premature Ejaculation; Both Genders Design Methodology of Clinical Trials

Introduction

Premature ejaculation (PE) is the most common male sexual dysfunction, affecting approximately 20–30% of the male population at any one time [1–3]. Currently, available data suggest that only 1–12% of males self-reporting PE receive treatment for their dysfunction [1,4]. This may be attributed in part to the very personal nature of the condition, the hesitancy of both men and physicians to approach and discuss the topic [5], and the lack of awareness of treatment options for PE. In addition, several factors surrounding this condition limit clinicians from having an in-depth understanding of and sophisticated means for assessing it, including the lack of a commonly accepted definition of PE, lack of validated measures for evaluating PE, and limited population-based data to characterize PE [6,7].

The existing definitions of PE take into consideration different aspects of this condition, including distress [6,8,9], interpersonal difficulty [8], sexual satisfaction [10], lack of control over ejaculation [10], persistency [8], and latency time [10]. Some definitions emphasize the importance of these effects on the partner as well as the patient, although effects on partners have been less studied [6,9,10].

Ejaculatory latency, most commonly quantified using intravaginal ejaculatory latency time (IELT), is a dominant component of PE assessment in clinical studies [7]. IELT is defined as the time between vaginal intromission and intravaginal ejaculation [11]. Although it has been suggested that an IELT of 2 minutes or less may serve as an adequately sensitive criterion for defining PE [7], a standard cut-off for ejaculatory latency does not exist, and studies have used latency values ranging from 1 to 7 minutes for defining PE [2,7,9,12–18].

Results of previous studies have indicated that additional patient-reported outcome (PRO) measures are important and noninterchangeable measures of PE that assess distinct aspects of the condition, including perception of ejaculatory control, satisfaction with ejaculatory control, and satisfaction with sexual intercourse [19–21]. These studies further suggested that a multidimensional approach to the assessment of PE would allow for a more in-depth analysis of the condition. Conclusions were limited by the small sample size in each study (N = 57, N = 260, and N = 152, respectively) and by the lack of a comprehensive set of assessment tools for evaluating PE.

As the importance of improving IELT and other treatment outcomes depends on the perceptions of the patient, PRO measures are needed to evaluate both observable and subjective aspects of the condition. Premature ejaculation has been associated with significant distress [1,2,12], interpersonal difficulty [22], and dissatisfaction with sexual intercourse [23] for both the male and his partner. However, these potentially important parameters (together with IELT) have not yet been used to characterize PE in a large population of men and their partners. In addition, although partner distress is a common reason for men to consult a clinician about PE, limited information exists regarding the effects of this condition on the partner.

Aims

The main goal of this study was to characterize men with and without PE in a large, community-based sample. Both observable measures (IELT recorded using a stopwatch) and subjective measures (PROs reported by men and their partners) provided comparative population data. This study sought to better understand PE by investigating how latency time is related to the PRO measures of *control over ejaculation*, *satisfaction with sexual intercourse*, *personal distress*, *interpersonal difficulty*, and *severity* of PE.

Methods

Study Design

This 4-week, multicenter, observational study was conducted at 42 U.S. centers from April 14, 2004 to August 9, 2004. No treatment was administered to participants. Subjects were recruited using radio and newspaper advertisements, as well as brochures posted in the clinic of each participating center. Compensation for study participation varied slightly by site, but payment was approximately $400 per couple. During the 4-week study, three study visits were scheduled at approximately 2-week intervals: visit 1 (screening—week 0), visit 2 (initial assessment—week 2), and visit 3 (reassessment—week 4).

Subjects

Subjects were required to be ≥18 years of age, heterosexual, and in an ongoing, stable, monogamous, sexual relationship (≥6 months). This 6-month requirement was incorporated to avoid any potential effects of a new sexual partner on IELT

and other PROs. Subjects and their female partners were required to provide written informed consent prior to study enrollment.

Screening procedures were conducted following informed consent and no more than 7 days prior to the start of the study, and included a review of medical history, collection of demographic information, and clinician assessment of PE status. Clinicians evaluated all subjects and used the following DSM-IV-TR criteria to determine PE status: (i) persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the person wishes it, taking into account factors that affect duration of the excitement phase, such as age, novelty of the sexual partner or situation, and recent frequency of sexual activity; (ii) marked distress or interpersonal difficulty; and (iii) PE not exclusively due to the direct effects of a substance, for example, alcohol, opioids, and other drugs [8]. Most clinicians were experienced in the diagnosis and treatment of PE. Those who were not received special training by an experienced clinician in using the DSM-IV-TR criteria to diagnose PE.

Eligible subjects and partners were in good general health and able to speak and read English. During the study, subjects and their partners agreed to engage in sexual intercourse at least twice weekly, measure and record the IELT of each episode, and complete several PRO measures at weeks 2 and 4 of the study period.

Subjects were ineligible if they had a history of pelvic surgery or trauma, spinal cord injury or surgery, chronic prostatitis, urethritis, or other medical abnormality considered clinically meaningful by the study physician, a history of drug or alcohol abuse within a year of study enrollment, or a history of major psychiatric disorder (e.g., major depression, bipolar disorder, or schizophrenia). In addition, subjects were excluded who reported decreased sexual interest or other forms of sexual dysfunction (as determined by clinician judgment), including erectile dysfunction, as well as those whose partners indicated decreased sexual interest, painful intercourse, or other forms of female sexual dysfunction that affected the sexual relationship with the subject. Disallowed medications (administered within 30 days before screening) included antipsychotics, selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants, sildenafil, vardenafil, tadalafil, yohimbine, intracorporeal/intraurethral alprostadil, intracorporeal phentolamine or papaverine, and any topical penile treatment for the prolongation of latency time. Subjects having used investigational medication within 30 days (or five half-lives) prior to screening were ineligible for study enrollment.

Main Outcome Measures

At visit 1, subject and partner were given a calibrated stopwatch and event log and instructed on the use of the stopwatch to record IELT. For IELT measurements, the female partner was asked to operate the stopwatch and was given instructions to activate the stopwatch upon vaginal penetration and to stop it upon intravaginal ejaculation or withdrawal without ejaculation at the end of intercourse. Partners were instructed to record the measured IELT in the event log. During the study, couples were also instructed to avoid implementing new sexual techniques to avoid potential effects on IELT or other measures. At visits 2 and 3, the subject was asked to complete single-item PRO measures to assess *control over ejaculation*, *satisfaction with sexual intercourse*, *personal distress*, *interpersonal difficulty*, and *severity* of PE. The partner was not required to return for visits 2 and 3, but was given a packet containing instructions and PRO questionnaires to be completed independently at the end of each 2-week period. Only subjects and their partners assigned to the PE group completed responses for the PRO measure *severity* of PE. The subject and partner questions for the PRO measures are listed in Table 1. The PRO questions for subject and partner were similar.

This study protocol was reviewed and approved by the Institutional Review Boards (IRBs) of the participating study centers in accordance with the United States Code of Federal Regulations and IRB policies, and the study was conducted according to the guidelines of Good Clinical Practice (GCP).

Statistical Analysis

Intravaginal ejaculatory latency time was defined as the average duration of intercourse events attempted since the last clinic visit (past 2 weeks) for which ejaculation was recorded as occurring intravaginally or prior to penetration. For statistical purposes, ejaculation prior to penetration was assigned an IELT value of 0 minutes. All analyses were conducted based on data obtained at visit 2, except for the evaluation of test–retest reliability, which included data from visit 3. A two-sided *t*-test was used for between-group comparisons of IELT and other PRO measures. Test–retest

Table 1 Patient-reported outcome (PRO) questions

Concept	Question	Scores and response options
Control over ejaculation	Subject: *Over the past month, was your control over ejaculation during sexual intercourse:* Partner: *Over the past month, was your partner's control over ejaculation during sexual intercourse:*	0: Very poor 1: Poor 2: Fair 3: Good 4: Very good
Satisfaction with sexual intercourse	Subject and partner: *Over the past month, was your satisfaction with sexual intercourse:*	0: Very poor 1: Poor 2: Fair 3: Good 4: Very good
Severity of PE	Subject: *Over the past month, the severity of my premature ejaculation problem was:* Partner: *Over the past month, the severity of my partner's premature ejaculation problem was:*	3: Severe 2: Moderate 1: Mild 0: None
Personal distress	Subject: *How distressed are you by how fast you ejaculate (come) during sexual (vaginal) intercourse?* Partner: *How distressed are you by how fast your partner ejaculates (comes) during sexual (vaginal) intercourse?*	4: Extremely 3: Quite a bit 2: Moderately 1: A little bit 0: Not at all
Interpersonal difficulty	Subject: *To what extent does how fast you ejaculate (come) during sexual (vaginal) intercourse cause difficulty in your relationship with your partner?* Partner: *To what extent does how fast your partner ejaculates (comes) during sexual (vaginal) intercourse cause difficulty in your relationship with your partner?*	4: Extremely 3: Quite a bit 2: Moderately 1: A little bit 0: Not at all

reliability was assessed by comparing measures reported at visits 2 and 3 using the Intraclass Correlation Coefficient (ICC). Comparison of the distribution of subject and partner responses for each PRO measure between the PE and non-PE groups was accomplished using the Chi-squared test. The relationship between IELT and other PRO measures collected at visit 2 was assessed using the Spearman–Rank Correlation Coefficient. Within the PE group, mean PRO scores were analyzed for differences between lifelong and acquired PE using a two-sided t-test.

Results

This noninterventional observational study enrolled 1,587 men and their partners. Clinicians diagnosed 207 subjects with PE; the 1,380 subjects who did not meet the DSM-IV-TR criteria were assigned to the non-PE group. All aspects of the study were completed by 93.7% (194) of PE subjects and 97.2% (1,342) of non-PE subjects. Subjects (N = 13) in the PE group discontinued the study for the following reasons: "lost to follow-up" (5), "nonadherence" (3), "withdrawal of consent" (3), and "other" (2). The reasons for study discontinuation of subjects (N = 38) in the non-PE group were "personal reasons" (12), "lost to follow-up" (10), "nonadherence" (7), "withdrawal of consent" (5), "other" (3), and "protocol violation" (1).

Demographic characteristics were similar between PE and non-PE groups and are summarized in Table 2. The mean age of the men in the study was 35.4 years, and the majority were Caucasian (75.0%) and living with their partner or spouse (85.6%).

Subjects in the PE group had significantly shorter IELT than subjects in the non-PE group (median, 1.8 minutes for PE vs. 7.3 minutes for non-PE subjects). Mean values observed were 3.0 minutes vs. 9.2 minutes for PE and non-PE subjects, respectively ($P < 0.0001$; Table 3). Considerable overlap existed in the distribution of IELT values between PE and non-PE groups (Figure 1). Ninety-five percent of subjects in the non-PE group had IELT values of at least 1.88 minutes, while 49% of subjects in the PE group met that threshold.

Subjects in the PE group vs. the non-PE group reported significantly lower mean ratings of *control over ejaculation* and *satisfaction with sexual intercourse*, and higher mean ratings of *interpersonal difficulty* and *distress* ($P < 0.0001$ for all). The majority of subjects in the PE group rated their *severity* of PE to be either moderate (47%) or severe (33%). Similar ratings were observed for partners, with significant differences between the PE and non-PE groups observed for *control over ejaculation*, *satisfaction with sexual intercourse*, *interpersonal difficulty*, and *distress* ($P < 0.0001$ for all). Mean

Table 2 Demographics of enrolled subjects

	PE (N = 207)	Non-PE (N = 1,380)	Total	*P* value
Mean age, years (SD)	36.1 (11.0)	35.3 (10.7)	35.4 (10.7)	0.2827
Race (%)				
Caucasian	64.3%	76.6%	75.0%	0.0008
Black	23.7%	13.3%	14.7%	
Hispanic	9.7%	8.2%	8.4%	
Asian	0.5%	0.9%	0.8%	
Other	1.9%	1.0%	1.1%	
Highest education (%)				
Elementary/primary school	0.0%	0.7%	0.6%	0.0179
Secondary/high school	61.2%	49.5%	51.0%	
College degree	26.7%	37.0%	35.7%	
Postgraduate degree	5.8%	7.0%	6.9%	
Other	6.3%	5.8%	5.9%	
Living situation (%)				
Living with partner/spouse	86.0%	85.6%	85.6%	0.7510
Living alone	6.3%	7.5%	7.4%	
Other	7.7%	6.9%	7.0%	
Circumcision status (%)				
Yes	83.0%	84.5%	84.3%	0.5852
No	17.0%	15.5%	15.7%	
Monthly frequency of sexual intercourse in past 6 months				
Mean (SD)	9.9 (9.5)	11.3 (8.8)	11.1 (8.9)	0.0341
Median	8.0	10.0	10.0	
Range	1–85	0–99	0–99	

P values were obtained from a *t*-test for numerical variables or a Chi-square test of independence for categorical variables.
PE = premature ejaculation.

partner ratings suggested less dysfunction than ratings reported by subjects for all measures. Subject and partner responses to PRO measures are shown in Table 3.

The distribution of subject responses to PRO items across response option by PE status highlights the differences between subjects with and without PE, particularly for the PRO measures *control over ejaculation*, *satisfaction with sexual intercourse*, and *personal distress* (Table 3). More subjects in the PE group vs. the non-PE group gave worse ratings ("very poor" or "poor") for *control over ejaculation* (72% vs. 5%, respectively) and *satisfaction*

with sexual intercourse (31% vs. 1%, respectively). In addition, more subjects in the PE vs. non-PE group gave worse ratings ("quite a bit" or "extremely") for *personal distress* (64% vs. 4%, respectively) and *interpersonal difficulty* (31% vs. 1%, respectively) (*P* < 0.0001 for all; Table 3).

The distribution of partner responses to the PRO questions for *control over ejaculation*, *satisfaction with sexual intercourse*, and *personal distress* were also descriptive of subject PE status (Table 3). More partners of PE subjects vs. partners of non-PE subjects gave ratings of "poor" or "very poor" for measures of *control over ejaculation* (53% vs. 3%,
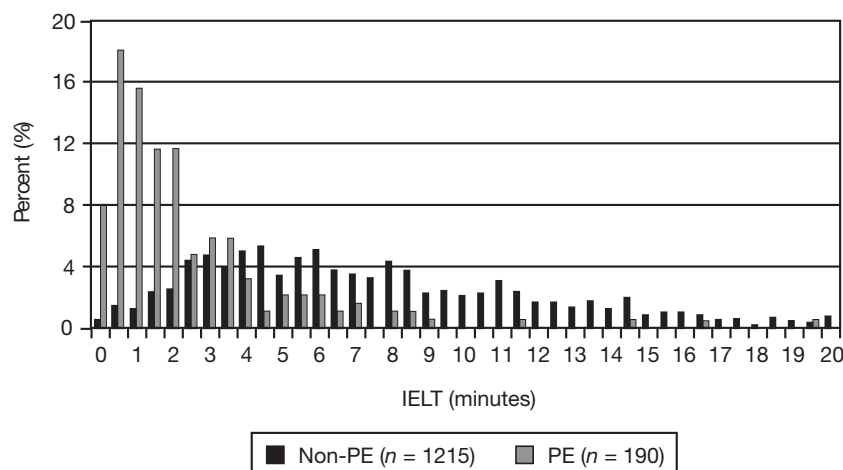

Figure 1 Distribution of subjects across the range of intravaginal ejaculatory latency time (IELT) reported for the PE and non-PE groups.

Table 3 Summary of subject and partner responses to patient-reported outcome (PRO) measures

| | Descriptive statistics | | | | % Response | | | | | | | | | |
| | Mean (SD) | | Median | | 0 | | 1 | | 2 | | 3 | | 4 | |
Measure	PE	Non-PE	PE	Non-PE	PE	Non-PE	PE	Non-PE	PE	Non-PE	PE	Non-PE	PE	Non-PE
IELT	3.0 (4.32)	9.15 (7.17)	1.8	7.3										
5-point scale: 0 = very poor, 1 = poor, 2 = fair, 3 = good, 4 = very good														
Control														
Subject	1.14 (0.86)	2.97 (0.81)	1.0	3.0	22.2	0.2	49.5	4.3	21.7	20.3	5.6	48.9	1.0	26.3
Partner	1.45 (1.02)	3.28 (0.81)	1.0	3.0	18.4	0.5	34.7	2.5	34.2	11.9	8.7	38.2	4.1	46.9
Satisfaction														
Subject	1.98 (1.04)	3.32 (0.69)	2.0	3.0	8.1	0.1	23.2	1.1	37.9	8.8	23.7	46.4	7.1	43.6
Partner	2.10 (1.07)	3.36 (0.72)	2.0	3.0	8.2	0.4	19.9	1.3	33.7	8.4	30.1	42.4	8.2	47.6
5-point scale: 0 = not at all, 1 = a little bit, 2 = moderately, 3 = quite a bit, 4 = extremely														
Distress														
Subject	2.69 (0.92)	0.69 (0.85)	3.0	0.0	1.0	51.1	10.6	33.7	24.2	11.4	46.5	3.2	17.7	0.7
Partner	2.19 (1.15)	0.41 (0.77)	2.0	0.0	9.6	72.3	17.2	17.5	29.3	7.0	32.3	2.7	11.6	0.4
Difficulty														
Subject	1.83 (1.16)	0.28 (0.62)	2.0	0.0	12.1	80.0	31.8	13.9	25.3	4.6	22.2	1.3	8.6	0.1
Partner	1.52 (1.23)	0.22 (0.60)	1.0	0.0	26.3	85.1	26.3	9.8	22.2	3.5	19.7	1.1	5.6	0.4
4-point scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe														
Severity*														
Subject	2.10 (0.79)	N/A*	2.0	N/A*	3.0	N/A*	17.3	N/A*	46.7	N/A*	33.0	N/A*	N/A	
Partner	1.98 (0.92)	N/A*	2.0	N/A*	9.1	N/A*	15.7	N/A*	43.1	N/A*	32.0	N/A*	(4-point scale)	

* Includes subject and partner responses from the PE group only.
SD = standard deviation; PE = premature ejaculation; IELT = intravaginal ejaculatory latency time; N/A = not applicable.

respectively) and *satisfaction with sexual intercourse* (28% vs. 2%, respectively). In addition, a higher proportion of partners of subjects in the PE vs. non-PE group gave worse ratings ("quite a bit" or "extremely") for *personal distress* (44% vs. 3%, respectively) and *interpersonal difficulty* (25% vs. 2%, respectively) ($P < 0.0001$ for all).

Analyses from the data collected at visit 3 revealed statistically significant group differences in IELT and other PRO measures that were comparable to the between-group differences observed with data collected at visit 2. In addition, comparisons of IELT and the other PRO measures from visit 2 with those from visit 3 indicated acceptable test–retest reliability of each outcome measure in PE subjects and their partners over the 2-week period. Intraclass Correlation Coefficients from comparisons of data from visits 2 and 3 for PE subjects or their partners ranged from 0.63 to 0.87.

Control over ejaculation as reported by subjects and partners was most highly correlated with the other PRO measures in this study, including IELT (Table 4). Intravaginal ejaculatory latency time was more strongly correlated with *control over ejaculation* for subjects (0.51) and partners (0.46) than with other PRO measures.

Partner ratings generally indicated less dysfunction than those of subjects. PRO measures for partner and subject were moderately correlated (Table 4). The strongest correlation between subject and partner measures was observed between the measure of *control over ejaculation* (0.57). Other partner measures also correlated moderately with subject *control over ejaculation*, including *satisfaction with sexual intercourse* (0.43), *personal distress* (–0.49), and *severity* of PE (–0.43). In addition, partner measures of *satisfaction with sexual intercourse* correlated moderately with subject measures of *satisfaction with sexual intercourse* (0.46). The two subject and partner measures that most strongly correlated with IELT were *control over ejaculation* and *personal distress* (Table 4).

Table 4 Correlation between outcome measures (PE and non-PE combined)

	Subject PRO					
	IELT	Control	Satisfaction	Severity*	Distress	Difficulty
Subject PRO						
IELT	1.0	0.51	0.36	−0.36	−0.45	−0.37
Control	0.51	1.0	0.59	−0.60	−0.66	−0.52
Satisfaction	0.36	0.59	1.0	−0.45	−0.48	−0.47
Severity*	−0.36	−0.60	−0.45	1.0	0.61	0.33
Distress	−0.45	−0.66	−0.48	0.61	1.0	0.63
Difficulty	−0.37	−0.52	−0.47	0.33	0.63	1.0
Partner PRO						
Control	0.46	0.57	0.41	−0.46	−0.52	−0.49
Satisfaction	0.36	0.43	0.46	−0.33	−0.39	−0.40
Severity*	−0.35	−0.43	−0.37	0.36	0.33	0.28
Distress	−0.39	−0.49	−0.38	0.27	0.50	0.50
Difficulty	−0.25	−0.41	−0.36	0.26	0.45	0.52

* Includes subject and partner responses from the PE group only.
PE = premature ejaculation; PRO = patient-reported outcome; IELT = intravaginal ejaculatory latency time.

The distribution of each PRO measure tabulated by IELT (PE and non-PE subjects combined) indicated a positive relationship between these measures. Better ratings for all PRO measures were associated with longer IELT. This relationship is illustrated for the subject measures of *control over ejaculation* and *satisfaction with sexual intercourse* in Figure 2a and b, respectively.

Figure 2 Distribution by intravaginal ejaculatory latency time (IELT) of subject perception of (A) *control over ejaculation* and (B) *satisfaction with sexual intercourse* (PE and non-PE subjects).

Significant differences in mean IELT and other PRO measures between the lifelong and acquired PE subgroups were evident only for subject and partner measures of *satisfaction with sexual intercourse* and *interpersonal difficulty*. The lifelong PE population and their partners reported better *satisfaction with sexual intercourse* and less *interpersonal difficulty* than the acquired PE population (data not shown).
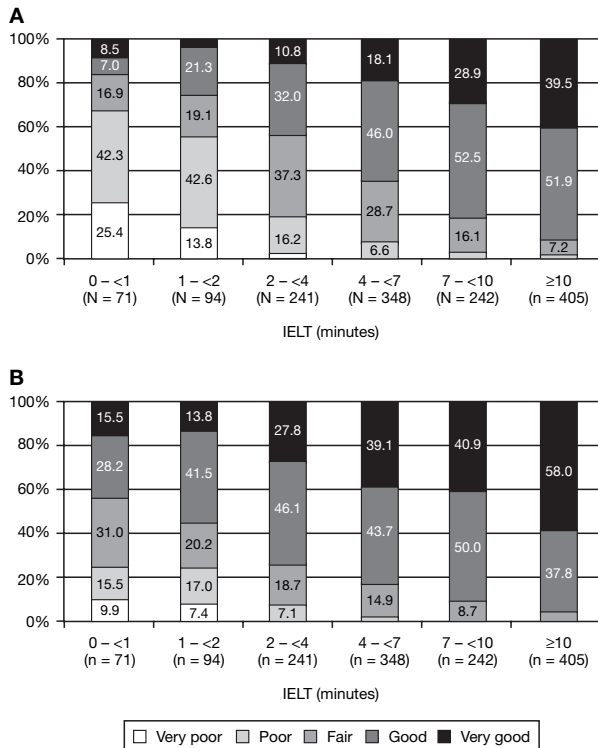
Discussion

This noninterventional, observational study is the first to characterize PE in a large community-based population of men and their partners. This study provides comparative data on IELT measured using a stopwatch and other self-reported outcomes. It is also the first to investigate a comprehensive set of self-reported outcomes considered to be important in currently accepted definitions of PE.

The results of this study demonstrate that IELT, measured and recorded by the female partner using a stopwatch, is able to distinguish between PE and non-PE populations. Subjects diagnosed with PE reported significantly shorter IELT than subjects without PE. The median IELT value observed for males diagnosed with PE (1.8 minutes) fell below 2–3 minutes, commonly used criteria for PE in many clinical studies [24–26]. The median IELT value observed for non-PE subjects (7.3 minutes) was similar to that reported from other smaller, observational studies [20,21].

Use of the DSM-IV-TR diagnostic criteria to identify PE status yielded overlapping IELT values in the PE and non-PE subjects. Overlap could be attributed, in part, to variation in which the

criteria were applied by different clinicians at the clinic sites. IELT alone, however, cannot be used to define PE, as it assesses only one characteristic of the condition. Multiple aspects of PE are included in the DSM-IV diagnostic system, such as timing of ejaculatory response, control, distress, persistence, and interpersonal difficulty. No weighting is implied giving greater emphasis to any one of these aspects. Additional study is needed to address how clinicians use the different criteria in arriving at a diagnosis.

The observed overlap in IELT values between PE and non-PE groups, however, indicates the need for additional measures to be used in conjunction with IELT to provide a more comprehensive description of the condition. To encompass the multifaceted nature of PE, a number of PRO measures were developed to assess concepts previously identified to be associated with this male sexual dysfunction [1,2,12,22,23,26,27]. These PRO measures included *control over ejaculation*, *satisfaction with sexual intercourse*, *personal distress*, *interpersonal difficulty*, and *severity* of PE. In this study, subjects with PE reported significantly worse scores on these measures compared to subjects without PE. Analysis of the distribution of subject responses for each PRO measure provided a more detailed description of men with and without PE compared to IELT alone.

Even though PRO ratings improved with increased duration of IELT, some subjects expressed high levels of *control over ejaculation* and *satisfaction with sexual intercourse* with lower levels of latency time. Conversely, some subjects with longer latency times reported lower levels of *control over ejaculation* and *satisfaction with sexual intercourse*. The measures of *control over ejaculation* and *satisfaction with sexual intercourse* have previously been identified as important measures for assessing treatment efficacy in clinical trials [28]. These discrepancies suggest the importance of multidimensional patient-reported assessment of PE to improve the understanding and treatment of this condition.

Numerous studies have indicated that the effects of PE on the female partner are integral to understanding the effects of PE on the male and on the sexual relationship as a whole [12,21,29]. The results of this study indicate that PE similarly and adversely affects the female partner and the male with PE. Although partner perceptions of PE generally indicated less dysfunction than those of subjects, partner PRO measures play an important part in the assessment of PE. Partner PRO measures correlated moderately with measures of IELT, as well as with other subject PRO measures. In addition, differences between males with and without PE were highlighted by the distribution of partner responses to PRO measures by PE status.

Few differences in outcome measures were observed between the lifelong and acquired PE groups. The better ratings of *satisfaction with sexual intercourse* and lower ratings of *interpersonal difficulty* observed in the lifelong PE group suggest that different aspects of PE may be of greater importance at different times in the natural history of the dysfunction.

Because the recruitment process was not based upon a random sampling of the general U.S. population, these results should not be construed as providing population normative values for the measures collected in this study. These large, community-based samples do, however, capture important differences between men with and without PE based upon these measures.

The PRO measures included in this study were designed to assess those aspects of PE that patients and their partners thought to be relevant to men experiencing this condition. Because they also reflect the criteria for making a diagnosis of PE, it is expected that differences between men with and without PE would be observed on some of these measures. It is also possible that the requirement for partner participation may have had an impact on the sample recruited and the PRO responses observed in this study. However, having sufficient data surrounding the effects of PE on partners was integral to achieving the objectives of this study.

Stopwatch measurement of IELT is impractical in clinical practice. Most clinical trials, however, use IELT as the primary quantifiable measure for evaluating PE. The varied latency cut-off times used as an inclusion criterion for PE groups in clinical studies limit the interpretation and cross-comparison of results. The current study did not include a specific IELT value as a criterion for assigning subjects to the PE group, but instead used the criteria established by the DSM-IV-TR, as implemented by experienced clinicians highly orientated to the study design. This provided the means for investigating how IELT related to clinician diagnosis.

Conclusions

The results of this observational study characterize the condition of PE by IELT and single-item

PROs in a large population of men and their partners. The results indicate that IELT alone does not fully capture the effects of PE, as evidenced by the considerable overlap in the distribution of IELT between PE and non-PE populations. Single-item PRO measures elicited from men and their partners provided a more complete description of PE and its correlates. Partner PRO measures were also important for describing PE. These data suggest that the PRO measures used in this study will be useful in assessing the benefit of treatments for PE in clinical studies. Analyses are currently underway to determine further the reliability and validity of these measures in assessing PE, and their ability to predict a clinician diagnosis of PE in the community.

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