EPIDEMIOLOGY

Real-World Assessment of the Impact of Erectile Dysfunction on Sexual Planning Behavior and Health- and Treatment-Related Outcomes Among Men in 8 Countries



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ABSTRACT

Introduction: The effect of erectile dysfunction (ED) on sexual planning behaviors and outcomes in men taking phosphodiesterase type 5 inhibitors (PDE5Is) is not well studied.

Aims: To assess sexual habits, behaviors, and treatment-related outcomes of PDE5I-treated men with ED.

Methods: This cross-sectional observational study recruited men aged 30 to 70 years with mild-to-severe ED from 8 diverse countries (the United States, the United Kingdom, Italy, Russia, Turkey, Israel, China, and Japan) to complete an approximately 15-minute survey. Differences were evaluated using bivariate analyses, and data were summarized using descriptive statistics.

Main Outcome Measures: Self-reported data were collected for demographics, health characteristics, treatment, sexual habits, ED severity, ED-specific quality of life, and treatment satisfaction.

Results: The survey was completed by 1,575 men. Mean frequency of sexual intercourse was 5.7 times/month. Overall, 87.1% of men always, often, or sometimes planned for sexual activity. Of those planning in advance, 32.8% and 40.6% agreed or strongly agreed that they plan for specific days of the week and times of day, respectively. Sexual planning habits were similar for patients taking short-acting vs long-acting PDE5Is. The most commonly cited reasons for planning sexual activity were needing time to take medication (48.4%), needing to make sure medication has taken effect (43.4%), convenient time for sexual activity (34.9%), and needing the partner's agreement (33.4%). Mean Self-Esteem and Relationship Questionnaire total score was 56.4.

Conclusions: The differences in ED burden and sexual planning behavior observed across countries were not influenced by the type of PDE5I being taken, suggesting that cultural differences are an important factor when considering types of ED treatment. These findings provide a better understanding of burden, sexual habits, planning behaviors, quality of life, and treatment-related outcomes among PDE5I-treated men with ED in 8 Western and non-Western countries and may aid healthcare providers in selecting optimal treatments. Goldstein I, Giraldi A, Maculaitis MC, Real-World Assessment of the Impact of Erectile Dysfunction on Sexual Planning Behavior and Health- and Treatment-Related Outcomes Among Men in 8 Countries. J Sex Med 2020;8:338—349.

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Data Sharing Statement: Upon request and subject to certain criteria, conditions, and exceptions (see https://www.pfizer.com/science/clinical-trials/trial-data-and-results for more information), Pfizer will provide access to individual deidentified participant data from Pfizer-sponsored global interventional clinical studies conducted for medicines, vaccines, and medical devices (i) for indications that have been approved in the US

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Key Words: Erectile Dysfunction; Phosphodiesterase 5 Inhibitors; Sexual Activity Planning; Quality of Life; Global Male Sexual Habits Survey

INTRODUCTION

Erectile dysfunction (ED), defined as the inability to attain or maintain an erection sufficient for satisfactory sexual activity, ¹ affects millions of men worldwide. ² Global ED prevalence is expected to increase to 322 million by 2025. ED prevalence increases with age, being reported in approximately 1–10% of men aged <40 years, compared with 20–40% of men in their sixties. ³ Compared with men without ED, those with ED are more likely to have comorbidities including hypertension, hypercholesterolemia, depression/anxiety, cardiovascular diseases, or diabetes. ^{4–7} Moreover, ED is associated with a negative impact on health-related quality of life (QoL) and on psychological well-being, in addition to economic considerations with impairments in work productivity and non-work activities. ^{8,9}

Phosphodiesterase type 5 inhibitors (PDE5Is) are a mainstay of ED treatment. PDE5Is increase cyclic guanosine monophosphate levels and enhance the effect of nitric oxide to relax smooth muscle in the corpus cavernosum. Currently available PDE5Is differ by onset or duration of action (~ 4 hours vs ~ 17.5 hours for short- and long-acting, respectively) and specific adverse events. However, clinical studies and clinical experience have consistently demonstrated the efficacy and tolerability of PDE5Is. 14,15

While the efficacy of PDE5Is for the treatment of ED is well established, studies focusing on sexual planning behavior remain limited, particularly within non-Western countries where different cultural norms and expectations may exist. One study of men receiving PDE5Is in 7 countries, including Western and non-Western countries, previously indicated that sexual activity is typically planned several hours in advance. ¹⁶ Overall, 83% of men taking ED medication reported sometimes or always planning for sexual intercourse in advance; of these respondents, 60% planned for specific times of day. ¹⁶ Despite these observations focused on planning behaviors, the reasons underlying this planning and any impact of the use of short- or long-acting PDE5Is were not investigated.

The present study sought to determine the impact of ED on sexual activity planning behaviors and to investigate reasons why PDE5I-treated men plan sexual activity, using real-world data. Participants completed a survey in which they self-reported ED medication(s), ED severity, QoL, planning behavior, satisfaction with sexual intercourse frequency, and treatment satisfaction. The impact of short- and long-acting PDE5Is on sexual activity and planning behaviors was also investigated.

MATERIALS AND METHODS

Study Design

This cross-sectional observational study recruited men from 8 countries (the United States [US], the United Kingdom [UK],

Italy, Russia, Turkey, Israel, China, and Japan) via opt-in online Web panels or research databases. Recruitment was through an existing, general-purpose, Web-based consumer panel that recruits members via opt-in emails, panel partner coregistration, banner placements, e-newsletters, and affiliate networks. Potentially eligible panelists were emailed invitations. The survey included screening questions followed by the main survey, which took ~ 15 minutes to complete.

Participant Population

Men aged 30 to 70 years who self-reported a healthcare provider diagnosis of mild-to-severe ED were eligible. Participants must have been taking ≥1 ED medication at least once monthly in the past 3 months. To reduce bias, participants selected the ED medication(s) they were currently taking using a list presented in alphabetical order that included brand and generic medication names; recruitment was not based on ED medication(s). Men using injectable, penile implant/pump, or testosterone therapy were excluded. All participants provided informed consent electronically before survey completion. This study was approved by appropriate institutional review boards as per applicable requirements in each country.

Outcomes

Demographics, health characteristics, treatment, sexual habits, ED severity, ED-specific QoL, satisfaction with sexual intercourse frequency, and treatment satisfaction data were collected. To assess sexual habits, men indicated how often they plan for sexual activity in advance based on the following responses: always, often, sometimes, hardly ever, or never. Respondents reported the number of times they engaged in sexual activity during a typical month. All data were self-reported.

Erection hardness was determined before and after receiving medication using the Erection Hardness Score (EHS), a single-item, patient-reported measure of erection hardness on a scale from 0 (penis does not enlarge) to 4 (penis is completely hard and fully rigid). ¹⁷ Scores of 0 to 1 are associated with severe ED, 2 with moderate ED, 3 with mild ED, and 4 with normal erection. Those reporting a score of 4 without taking ED medication were excluded. ED-specific QoL was calculated using the Self-Esteem and Relationship Questionnaire (SEAR), a 14-item measure that evaluates the impact of ED on psychological functioning and well-being. ¹⁸ Scores are transformed to a 0 to 100 scale, with higher scores corresponding with better QoL. ED treatment satisfaction was assessed using 2 items from the validated Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS). ^{19,20}

Table 1. Demographics and health characteristics

	Total (N = 1,575)	United States (n = 200)	United Kingdom (n = 200)	Italy (n = 200)	Russia (n = 200)	China (n = 200)	Japan (n = 200)	Turkey (n = 175)	Israel (n = 200)
Age, mean (SD), y	50.2 (11.5)	60.5 (7.5)	55.5 (10.6)	51.6 (10.2)	46.7 (9.2)	39.3 (6.2)	54.6 (9.4)	40.3 (8.4)	52.0 (11.5)
Education level, n (%)									
Elementary/no qualification	9 (0.6)	0 (0)	7 (3.5)	1 (0.5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.5)
Middle school/O level/GCSE/ CSE	75 (4.8)	0 (0)	51 (25.5)	12 (6.0)	2 (1.0)	0 (0)	2 (1.0)	6 (3.4)	2 (1.0)
Some high school or high school graduate/A level/ sixth form studies	338 (21.5)	33 (16.5)	27 (13.5)	96 (48.0)	31 (15.5)	5 (2.5)	51 (25.5)	47 (26.9)	48 (24.0)
Some college or college graduate/university/college degree	857 (54.4)	120 (60.0)	81 (40.5)	56 (28.0)	120 (60.0)	153 (76.5)	125 (62.5)	99 (56.6)	103 (51.5)
Graduate school/professional/ postgraduate qualification	294 (18.7)	47 (23.5)	34 (17.0)	34 (17.0)	47 (23.5)	42 (21.0)	22 (11.0)	23 (13.1)	45 (22.5)
Prefer not to answer	2 (0.1)	0	0	1 (0.5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.5)
Relationship status, n (%)									
In a relationship, and living with partner(s)	1,138 (72.3)	141 (70.5)	151 (75.5)	142 (71.0)	153 (76.5)	180 (90.0)	110 (55.0)	137 (78.3)	124 (62.0)
In a relationship, and not living with partner	209 (13.3)	27 (13.5)	19 (9.5)	37 (18.5)	29 (14.5)	10 (5.0)	32 (16.0)	19 (10.9)	36 (18.0)
Not in a relationship, but have ≥1 consistent sexual partner	106 (6.7)	18 (9.0)	7 (3.5)	8 (4.0)	11 (5.5)	7 (3.5)	30 (15.0)	10 (5.7)	15 (7.5)
Not in a relationship, but have random sexual partners	97 (6.2)	12 (6.0)	21 (10.5)	7 (3.5)	6 (3.0)	3 (1.5)	21 (10.5)	8 (4.6)	19 (9.5)
Prefer not to answer	25 (1.6)	2 (1.0)	2 (1.0)	6 (3.0)	1 (0.5)	0 (0)	7 (3.5)	1 (0.6)	6 (3.0)
Length of current relationship, n (%)									
<1 y	69 (5.1)	5 (3.0)	3 (1.8)	4 (2.2)	8 (4.4)	2 (1.1)	12 (8.5)	27 (17.3)	8 (5.0)
1–5 y	243 (18.0)	31 (18.5)	16 (9.4)	43 (24.0)	41 (22.5)	31 (16.3)	18 (12.7)	40 (25.6)	23 (14.4)
≥5 y	1,035 (76.8)	132 (78.6)	151 (88.8)	132 (73.7)	133 (73.1)	157 (82.6)	112 (78.9)	89 (57.1)	129 (80.6)
Employment status, n (%)									
Employed	1,259 (79.9)	100 (50.0)	117 (58.5)	155 (77.5)	179 (89.5)	199 (99.5)	183 (91.5)	162 (92.6)	164 (82.0)
Unemployed	76 (4.8)	13 (6.5)	27 (13.5)	14 (7.0)	5 (2.5)	0 (0)	6 (3.0)	1 (0.6)	10 (5.0)
Retired	240 (15.2)	87 (43.5)	56 (28.0)	31 (15.5)	16 (8.0)	1 (0.5)	11 (5.5)	12 (6.9)	26 (13.0)

(continued)

Table 1. Continued									
	Total	United States		Italy	Russia	China	Japan	Turkey	Israel
	(N = 1,575) $(n = 200)$	(n = 200)	(n = 200)	(n = 200)	(n = 200)	(n = 200)	(n = 200)	(n = 175)	(n = 200)
Diagnosed by healthcare provider, n (%)									
Hypertension	582 (37.0)	112 (56.0)	71 (35.5)	98 (49.0)	96 (48.0)	36 (18.0)	69 (34.5)	39 (22.3)	61 (30.5)
Prostate symptoms	321 (20.4)	31 (15.5)	28 (14.0)	48 (24.0)	87 (43.5)	51 (25.5)	19 (9.5)	32 (18.3)	25 (12.5)
Anxiety	305 (19.4)	39 (19.5)	42 (21.0)	55 (27.5)	60 (30.0)	21 (10.5)	16 (8.0)	34 (19.4)	38 (19.0)
Diabetes	300 (19.0)	39 (19.5)	49 (24.5)	27 (13.5)	25 (12.5)	20 (10.0)	33 (16.5)	43 (24.6)	64 (32.0)
Depression	275 (17.5)	33 (16.5)	40 (20.0)	29 (14.5)	48 (24.0)	10 (5.0)	22 (11.0)	64 (36.6)	29 (14.5)
Bladder control issues	179 (11.4)	24 (12.0)	21 (10.5)	41 (20.5)	31 (15.5)	16 (8.0)	13 (6.5)	11 (6.3)	22 (11.0)
Heart disease	149 (9.5)	13 (6.5)	13 (6.5)	10 (5.0)	42 (21.0)	6 (3.0)	14 (7.0)	19 (10.9)	32 (16.0)
Hypotension	34 (2.2)	1 (0.5)	1 (0.5)	2 (1.0)	9 (4.5)	1 (0.5)	5 (2.5)	8 (4.6)	7 (3.5)

= certificate of secondary education; GCSE = general certificate of secondary education

Statistical Analyses

The sample size targeted approximately 200 men/country, which assumed adequate power to detect small effect size differences (Cohen's f=0.09) between the US and other countries on the study variables. Data analyses used Statistical Package for the Social Sciences, version 23.0. Descriptive statistics were reported to summarize patient characteristics and outcomes.

Bivariate analyses evaluated differences in sexual planning behavior, satisfaction, and ED-specific QoL across countries and by treatment type (short-acting vs long-acting PDE5Is). Bivariate comparisons were analyzed using one-way analysis of variance for continuous variables and chi-square tests for categorical variables. For comparisons between the US and other countries, a Bonferroni-adjusted P-value < .007 was considered statistically significant, whereas for comparisons between short-acting (sildenafil and/or vardenafil without tadalafil use; n = 908) and long-acting (tadalafil with or without sildenafil and/or vardenafil; n = 667) PDE5Is, two-sided P-values < .05 were considered statistically significant.

RESULTS

Survey Respondents

Overall, 1,575 men completed the survey, including 175 from Turkey and 200 each from the remaining countries. The mean (standard deviation [SD]) age for the full survey cohort was 50.2 (11.5) years (Table 1). Common healthcare provider—diagnosed comorbidities included hypertension (37.0%), prostate symptoms (20.4%), anxiety (19.4%), diabetes mellitus (19.0%), depression (17.5%), bladder control issues (11.4%), heart disease (9.5%), and hypotension (2.2%). Overall, 56.3% reported taking branded sildenafil, 40.0% branded tadalafil, and 15.6% branded vardenafil at least once monthly, within the past 3 months (Supplementary Table S1).

Sexual Habits

Mean (SD) frequency of sexual intercourse was 5.7 (5.2) times per month overall, and 5.4 (6.1) times for the US, 5.1 (4.4) for the UK, 5.9 (4.8) for Italy, 6.8 (6.5) for Russia, 6.7 (3.9) for China, 3.1 (3.4) for Japan, 7.7 (6.5) for Turkey, and 5.0 (3.8) for Israel. Compared with the US, mean sexual intercourse frequency was significantly lower in Japan and significantly higher in Turkey (both, P < .001).

Overall, 87.1% of men always, often, or sometimes planned for sexual activity (Figure 1A). There were significant differences between the US and some of the other countries on the frequency of planning for sexual intercourse (P < .001); US men were more likely than men in other countries, apart from Japan, to report always planning for sexual intercourse (21.5% in US vs 25.0% in Japan vs 6.5–19.5% in other countries). Of 1,519 men who always, often, sometimes, or hardly ever planned for sexual intercourse, 29.1% planned up to 1 hour and 43.4% several hours in advance (Figure 2A). These results varied by

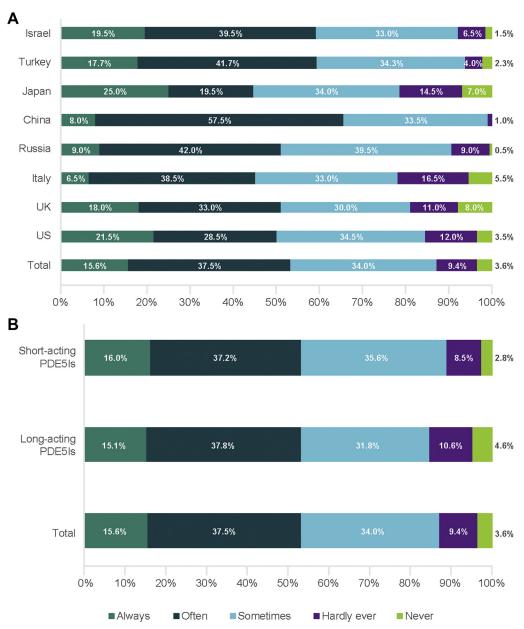


Figure 1. Frequency of planning for sexual intercourse (A) by country and (B) by short-acting vs long-acting PDE5I. Totals may not sum to 100% due to rounding. PDE5I = phosphodiesterase type 5 inhibitor.

country, from 9.7% of Japanese men to 47.3% of UK men who reported planning for sexual intercourse up to 1 hour in advance. Respondents who planned several hours in advance ranged from 24.7% in Japan to 51.3% in Israel. Unlike men in other countries, a high percentage of Japanese men planned up to a week (24.7%) or more than a week in advance (18.8%), which was significantly different from US men (P < .001).

Of 1,519 men who reported planning in advance, 32.8% agreed or strongly agreed that they plan sexual activity for specific days of the week (Supplementary Figure S1A). Overall, 40.6% agreed or strongly agreed that they plan sexual activity for specific times of day (Supplementary Figure S1B). However, these results varied by country; most men in the US, the UK, Italy, Turkey,

and Israel agreed and most men in Russia, China, and Japan disagreed that they plan sexual activity for specific times of day; findings differed significantly between US men and Russian, Chinese, Japanese, and Israeli men (P < .007).

The most commonly cited reasons for planning sexual activity were needing time to take medication (48.4%), to make sure medication has taken effect (43.4%), convenient time for sexual activity (34.9%), needing the partner's agreement (33.4%), and needing time for foreplay (27.6%) (Table 2). Reasons for planning sexual intercourse that were most often rated as somewhat to extremely important included needing to make sure medication has taken effect (96.3%), needing the partner's agreement (95.4%), needing time for foreplay (93.7%), needing time to

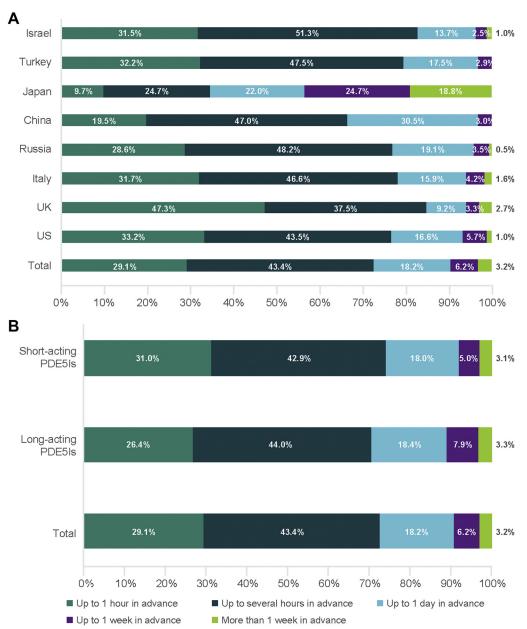


Figure 2. Advance planning for sexual intercourse (A) by country and (B) by short-acting vs long-acting PDE5I. Totals may not sum to 100% due to rounding. PDE5I = phosphodiesterase type 5 inhibitor.

take medication (93.4%), and ensuring convenient time for sexual activity (89.9%). Among the 56 (3.6%) men who never planned sexual activity, the reasons cited were preferring spontaneous sexual activity (51.8%), not liking to plan for sexual activity (32.1%), not needing to plan (28.6%), and planning takes too much energy (7.1%; Supplementary Table S2).

Sexual habits were generally similar between patients taking short- and long-acting PDE5Is. Mean (SD) frequency of sexual intercourse was 5.7 (5.3) times monthly for patients taking short-acting PDE5Is and 5.6 (5.0) times monthly for those taking long-acting PDE5Is. Most men taking PDE5Is sometimes, often, or always planned for sexual activity, with no significant differences between those taking short- (n = 908) or long-acting

(n = 667) PDE5Is (Figure 1B). Among men taking short-acting PDE5Is who planned for sexual intercourse, 31.0% planned up to 1 hour and 42.9% up to several hours in advance (Figure 2B). Similarly, 26.4% of men taking long-acting PDE5Is reported planning up to 1 hour and 44.0% reported planning several hours in advance. The percentages of men who reported planning for sexual activity for specific days of the week and specific times of day were similar between those taking short- and long-acting PDE5Is (Supplementary Figure S2).

ED Severity and QoL

Without medication, 69.6% of men across all countries had moderate-to-severe ED (EHS score: 0-2; Figure 3). During the

Table 2. Reasons for planning sexual intercourse cited by $\geq 20\%$ of men overall who reported planning in advance	sexual intercours	ie cited by $\geq 20\%$	of men overall who re	ported planning	g in advance				
Reasons, n (%)	Total $(N = 1,519)$	United States $(n = 193)$	United Kingdom $(n = 184)$	taly (n = 189)	Russia (n = 199)	China $(n = 200)$	Japan $(n=186)$	Turkey $(n = 171)$	Israel (n = 197)
Needing time to take medication	735 (48.4)	139 (72.0)	95 (51.6)	72 (38.1)	72 (36.2)	80 (40.0)	101 (54.3)	90 (52.6)	86 (43.7)
Needing to make sure medication has taken effect	660 (43.4)	112 (58.0)	90 (48.9)	71 (37.6)	83 (41.7)	96 (48.0)	37 (19.9)	93 (54.4)	78 (39.6)
Convenient time for sexual activity	530 (34.9)	81 (42.0)	54 (29.3)	63 (33.3)	94 (47.2)	56 (28.0)	57 (30.6)	53 (31.0)	72 (36.5)
Needing agreement from partner	508 (33.4)	61 (31.6)	(7.72) 13	51 (27.0)	72 (36.2)	59 (29.5)	84 (45.2)	58 (33.9)	72 (36.5)
Needing time for foreplay	419 (27.6)	61 (31.6)	67 (36.4)	44 (23.3)	61 (30.7)	65 (32.5)	42 (22.6)	39 (22.8)	40 (20.3)
Wanting to ensure a time when partner and respondent both feel a strong sexual desire	320 (21.1)	50 (25.9)	39 (21.2)	27 (14.3)	57 (28.6)	43 (21.5)	53 (7.71)	39 (22.8)	32 (16.2)
Needing to ensure both partner and respondent have energy to engage in sexual activity	304 (20.0)	48 (24.9)	21 (11.4)	(1.11) 12	65 (32.7)	39 (19.5)	32 (17.2)	28 (16.4)	50 (25.4)

past 4 weeks (while taking PDE5I medication), 33.1% had moderate-to-severe ED, with most reporting mild ED or normal erection (EHS score 3 or 4) across all countries, except Japan. Notably, the percentage of Japanese men reporting mild ED or normal EHS was more than 2.5 times higher when taking (vs not taking) a PDE5I (46.0% vs 18.0%).

The mean (SD) SEAR total score was 56.4 (21.7), and the mean overall relationship domain score was 60.9 (27.2) (Figure 4A). Compared with US men, SEAR total scores and domain scores (except for the sexual relationship domain score in Japanese men) were significantly lower in Russian and Japanese men (P < .001).

Satisfaction

Overall, 37.4% of men were somewhat-to-extremely satisfied with their current sexual intercourse frequency (Figure 4B). The proportion of men who were somewhat-to-extremely satisfied ranged from 28.5% in Russia to 47.0% in Israel. Conversely, the proportion of men somewhat-to-extremely dissatisfied ranged from 31.0% in China to 48.5% in Japan.

Overall, 83.9%, 81.0%, and 81.7% of men taking branded sildenafil, tadalafil, or vardenafil, respectively, were somewhat-to-very satisfied with their ED treatment; 74.4%, 75.6%, and 87.5% of men receiving another type of sildenafil, tadalafil, or vardenafil, respectively, were somewhat-to-very satisfied with their treatment. The proportions of respondents reporting that their partner was somewhat-to-very satisfied with ED treatment were 80.0%, 75.2%, and 75.6% for branded sildenafil, tadalafil, or vardenafil, respectively, and 65.8%, 71.1%, and 56.3% for another type of sildenafil, tadalafil, or vardenafil, respectively.

DISCUSSION

The efficacy and tolerability of both short- and long-acting PDE5Is are well established¹¹; however, most men still plan for sexual intercourse several hours in advance. 16 This international, real-world survey was conducted to investigate the reasons behind these planning behaviors in men taking shortor long-acting PDE5Is. We found that the majority of men surveyed (87%) reported planning for sexual intercourse in advance at least sometimes, with many men planning several hours in advance, a finding consistent with results reported previously. 16,21-23 In particular, a study conducted by Mulhall et al¹⁶ also used a survey methodology to examine the sexual habits of PDE5I-treated men across 7 countries, including Italy, Russia, China, Turkey, and Japan (as included in the present study). Mulhall et al¹⁶ reported a similar proportion of men (83%) who take PDE5Is for ED sometimes or always planned for sexual intercourse in advance. However, they also reported a higher percentage of men planning for specific days of the week (55%) or times of day (60%) for sexual intercourse, 16 compared with 33% and 41% of men, respectively, in our study. Although Mulhall et al¹⁶ included data for men



Figure 3. Erectile dysfunction severity assessed using the Erection Hardness Score (A) without medication and (B) with medication, in the past 4 weeks. Erection Hardness Score: 0 = penis does not enlarge; 1 = penis is larger, but not hard; 2 = penis is hard, but not hard enough for penetration; 3 = penis is hard enough for penetration, but not completely hard; 4 = penis is completely hard and fully rigid. Totals may not sum to 100% due to rounding.

taking short- and long-acting PDE5Is, the planning behaviors are not discussed by drug type.

Although Mulhall et al¹⁶ provided key information on the planning activities for men internationally, including non-Western countries, they did not report the reasons behind planning behaviors and the impact on real-world outcomes.¹⁶ The present study provides valuable data detailing the reasons

why men with ED plan for sexual activity. The most common reasons for advance planning captured included needing time to take medication, ensuring the medication has taken effect, convenience, and needing partner agreement; men often cited these reasons as being somewhat-to-extremely important. Approximately one-third of men were somewhat-to-extremely satisfied with their current intercourse frequency, and most were at least

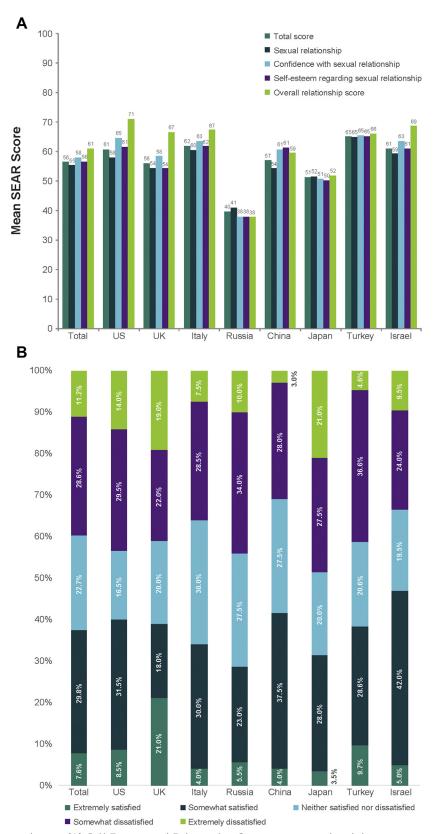


Figure 4. Outcomes assessed using (A) Self-Esteem and Relationship Questionnaire total and domain scores and (B) satisfaction with sexual intercourse frequency. Totals may not sum to 100% due to rounding. SEAR = Self-Esteem and Relationship Questionnaire.

somewhat satisfied with their ED medication. We also found that sexual habits were similar between patients taking short- and long-acting PDE5Is, suggesting that onset and/or duration of action is not an influencing factor in planning behaviors for these men. Collectively, our observations can raise awareness among healthcare professionals about the reasoning behind sexual planning behaviors in men with ED, and help guide treatment discussions with patients to ascertain their individual needs and better align ED treatment, including the preference for short- or long-acting medications, with their sexual planning behaviors.

Our study also suggests that cross-cultural differences in ED burden and sexual planning behavior exist. For example, Japanese men were more likely to plan for sexual activity more than a week in advance, compared with men from other countries surveyed, consistent with other data. 16 We also observed significant differences between men from the US and Japan for advanced planning of sexual intercourse for specific times of day. Furthermore, Japanese men reported significantly lower SEAR scores than US men, highlighting cultural differences in the psychological impact of ED. Cultural differences may affect whether patients consider certain symptoms to be a disorder and influence their likelihood of seeking treatment. 24,25 Moreover, cultural beliefs may affect how patients describe symptoms to healthcare providers, how couples negotiate timing and frequency of sexual intercourse, and how interested in sexual activity a man's partner is. 24,25 As a result, healthcare providers should recognize these cultural differences to ensure the type of PDE5I prescribed meets patient's needs, preferences, and expectations. Findings from our study may help inform healthcare providers of the complexities and experiences of their patients with ED and aid in the normalization of the planning process for PDE5I treatment.

One limitation of our study is the exclusion of men receiving testosterone therapy, which contrasts with previous sildenafil and tadalafil studies. 26,27 A strength of the present study is the use of validated instruments (ie, EHS, SEAR, EDITS). 17-19 However, each instrument has its own inherent limitations. For example, with the EDITS, the respondent and not their partner provided partner-satisfaction ratings. Satisfaction may differ between the respondent and partner, but our study did not assess this possibility. Evidence suggests that men with severe ED may benefit from combining short- and long-acting PDE5Is, such as tadalafil with sildenafil.²⁸ Frequency and planning results may represent conservative estimates as we did not distinguish those taking long-acting PDE5Is alone or in combination with short-acting agents. In addition, sensitivity analyses were not performed between long- and short-acting PDE5I users owing to the sample size. Participants were not asked to report their sexual orientation or the sex of their partners. Not collecting these data precluded the ability to examine whether sexual planning behaviors differ accordingly. Future studies would be needed to specifically examine how sexuality, relationship status, and different types of sexual activity (eg, penetrative, receptive anal, and/or performative oral sex) may influence sexual planning behaviors in patients taking medication for ED.

Using an anonymous online survey allowed large numbers of participants in diverse geographic regions to be reached quickly and conveniently, and sensitive questions can be asked to elicit candid responses across a wide range of topics from populations that might be difficult to survey otherwise. Online data collection allows for checking of validity and skip patterns, which can be automated; specifically, the quality control procedures implemented to minimize intentionally false reporting included programming logic to ensure answers were within range and that all skip logic was applied by the computer program. However, there are limitations inherent to online data collection methods. Data were self-reported, and respondents' answers could not be independently confirmed. Owing to the study's quantitative nature, information on the lived experience of respondents was not collected, thereby potentially influencing differences observed among countries. Moreover, the study's cross-sectional nature did not allow establishment of causal conclusions, and temporal changes in planning behavior could not be examined. Because of selection bias, the study sample may underrepresent those without internet access or elderly men. Furthermore, convenience sampling was used, and our results may not reflect the entire population of men with ED in each country. However, by establishing clear and defined eligibility criteria and a sampling frame before conducting the survey, we sought to minimize risk of selection bias.²⁹ Our study question was specific to men with ED on PDE5Is and was not designed to investigate any other group of men with or without ED. We suggest specifically designed studies would be needed to assess how sexual planning behaviors in men with ED may differ to men with ED who do not take medication, and furthermore to planning behaviors in men who do not have ED.

Despite these limitations, this is the first such study providing data on reasons for planning or not planning for sexual activity using respondents from several countries, including countries where little-to-no research has been conducted on the impact of ED on sexual planning behaviors and outcomes among PDE5I-treated men.

CONCLUSIONS

This large international, online survey demonstrates the sexual habits, preferences, and planning behaviors of men with ED from countries of different cultures and customs. Most men with ED, taking either long- or short-acting PDE5I, plan for sexual intercourse up to several hours in advance and for specific times of the day or week. Forward planning ensures men have time to take their ED medication, so that the medication has taken effect, and they can coordinate with their partner. These observations give healthcare providers a better understanding of the sexual habits, behaviors, and treatment-related outcomes of men with ED in culturally diverse countries. This information can aid

healthcare providers in selecting optimal treatment options for their patients.

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SUPPLEMENTARY DATA

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