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Sexual life of Japanese patients with erectile dysfunction taking phosphodiesterase type 5 inhibitors: An Internet survey using the Psychological and Interpersonal Relationship Scales-Short Form questionnaire

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Abbreviations & Acronyms
ED = erectile dysfunction
IIEF = International Index of Erectile Function
PAIRS-SF = Psychological and Interpersonal Relationship Scales-Short Form
PDE5 = phosphodiesterase type 5
PDE5-I = phosphodiesterase type 5 inhibitors
SEP = Sexual Encounter Profile

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Objectives: To investigate details of sexual function of erectile dysfunction in Japanese patients taking phosphodiesterase type 5 inhibitors.

Methods: A Japanese version of the Psychological and Interpersonal Relationship Scales-Short Form was used to carry out a nationwide survey using the Internet. A total of 556 erectile dysfunction patients (age 30–70 years) who had been prescribed a phosphodiesterase type 5 inhibitor and had attempted sexual intercourse within the past 6 months were included in this survey. Scores were compared in relation to the phosphodiesterase type 5 inhibitors most frequently taken within the past 6 months.

Results: In the subdomains of self-confidence and spontaneity of the Psychological and Interpersonal Relationship Scales-Short Form, scores for vardenafil and tadalafil were significantly higher than those for sildenafil. In the subdomain of time concern of the Psychological and Interpersonal Relationship Scales-Short Form, the score for tadalafil was significantly lower than that for others.

Conclusions: Our findings support the hypothesis that Japanese patients with erectile dysfunction have high sexual self-confidence, spontaneity and low time concerns when taking tadalafil. These characteristics of tadalafil could be associated with high patient satisfaction and high preference.

Key words: erectile dysfunction, inhibitors of phosphodiesterase type 5 inhibitors, internet survey, Psychological and Interpersonal Relationship Scales-Short Form.

Introduction

A selective inhibitor of PDE5 that inhibits the degradation of cyclic guanosine monophosphate in the corpus cavernosum of the penis has been widely used as the first-line treatment for ED.[1] In Japan, three PDE5-I, sildenafil, vardenafil and tadalafil, have been approved and used clinically in recent years. Efficacy among these three drugs as assessed by specific questionnaires, such as the IIEF[2] and the SEP has been reported to be similar in Japanese patients with ED.[3–5] Although the IIEF has contributed to research and clinical practice in the area of ED including the assessment of PDE5-I, the questionnaire provides limited assessment of erection quality beyond the ability to achieve or maintain an erection sufficient for penetration. The SEP also focuses on the success rate of penetration and maintenance of erection. In general, ED is associated with complex psychological and interpersonal issues. However, clinical studies typically assess sexual function with less attention paid to other treatment outcomes than the efficacy of ED therapies, which might be important to men and their partners. With this aspect in mind, a new self-reported questionnaire, the PAIRS,[6] has been developed to evaluate broader outcomes associated with ED, and current treatments for ED that are not assessed in existing measures, such as the IIEF and SEP. PAIRS measures three conceptual domains: sexual self-confidence, spontaneity, and time concerns leading up to and during sexual encounters. An analysis of PAIRS in a community sample suggested that PAIRS domains are independent predictors of both sexual satisfaction and relationship satisfaction.[7] Recently, the PAIRS-SF with 15 items was also developed, because it might not be possible to administer an instrument with the length of the 23-item PAIRS for many studies (Table 1).[8] It was already reported that the PAIRS-SF generally maintains the psychometric integrity of the full-length PAIRS, and that it offers brevity for clinical use and in research application when there is not enough time for the full 23-item PAIRS.

Table 1 PAIRS-SF

How much do you agree or disagree with each of the statements?†

1. The dating experience feels rushed when we are planning to have sex later
2. I feel very comfortable about my sexual abilities
3. I am very aware that if I wait too long after taking my medication, it may not work‡
4. Before we have sex, our time together can be spontaneous
5. Once I take my medication, I want to have sex as soon as it takes effect‡
6. Dates feel programmed in order to have sex on schedule
7. We are able to be easygoing when we are out together
8. I find myself feeling hurried when I think we will have sex later on
9. I am confident I can achieve an erection when the mood is right
10. When we are alone before having sex, we can talk freely without feeling rushed
11. Sometimes I ruin the mood by having to worry about the time
12. We are able to have a good time together without worrying about the time
13. I feel fantastic about my sex life
14. I find myself worrying whether my medication will wear off before I can use it‡
15. My partner sometimes feels some pressure to have sex with me

†Response scale: 1 = Strongly disagree; 2 = Disagree; 3 = Agree; 4 = Strongly agree. Subdomains: Self-confidence; items 2, 9, 13; Spontaneity; items 4, 7, 10, 12; Time concerns; items 1, 3, 5, 6, 8, 11, 14, 15. ‡Medication-related items. The time concerns are computed without these items if no ED medication is used.

Because the Japanese version of this questionnaire is not available, confidence, spontaneity and time concerns for sexual life have not been assessed in Japanese patients with ED.

In the present study, we developed the first Japanese version of the PAIRS-SF, and then carried out a nationwide questionnaire survey using the Internet to investigate details of sexual function with this questionnaire for Japanese patients with ED who are currently prescribed a PDE5-I.

Methods

Internet survey

The survey was carried out nationwide using the Internet, and was carried out for 1 week during 19–26 July 2011. Screening for ED was carried out by a survey panel from the Internet research agency, Macromill (Tokyo, Japan). Included in the present study were 546 ED patients between the ages of 30–70 years who had been prescribed any kind of PDE5-I and had attempted sexual intercourse within the past 6 months. Of the participating patients, 13% were aged in their 30s, 35% in their 40s, 35% in their 50s and 17% in their 60s. Among them, 24% were unmarried. The PDE5-I that patients had taken most frequently in the past 6 months was sildenafil in 201 patients, vardenafil in 177 patients and tadalafil in 168 patients. Hypertension, hyperlipidemia, diabetes, depression, and lower urinary tract symptom were found in 21%, 18%, 15%, 10% and 6% of patients, respectively. The PAIRS-SF was translated into Japanese, which was back-translated by native speakers with proficiency in both languages. Then after comparison between original and back-translated versions, necessary corrections

were made. Finally, the research coordinator (A.) checked it and made corrections according to the medical considerations. Participating patients answered all questions of the PAIRS-SF via the Internet, and the scores of the questionnaire were compared in relation to the three PDE5-I most frequently used in the past 6 months. All questions of the PAIRS-SF are measured on a scale of 1–4 (1, strongly disagree; 2, disagree; 3, agree; 4, strongly agree). Thus, higher scores show greater confidence in the subdomain of self-confidence and more natural sexual behavior in the subdomain of spontaneity, and lower scores show less bother in the subdomain of time concern. The PAIRS-SF consists of three questions in the self-confidence subdomain, four questions in the spontaneity subdomain and eight questions in the time concern subdomain.
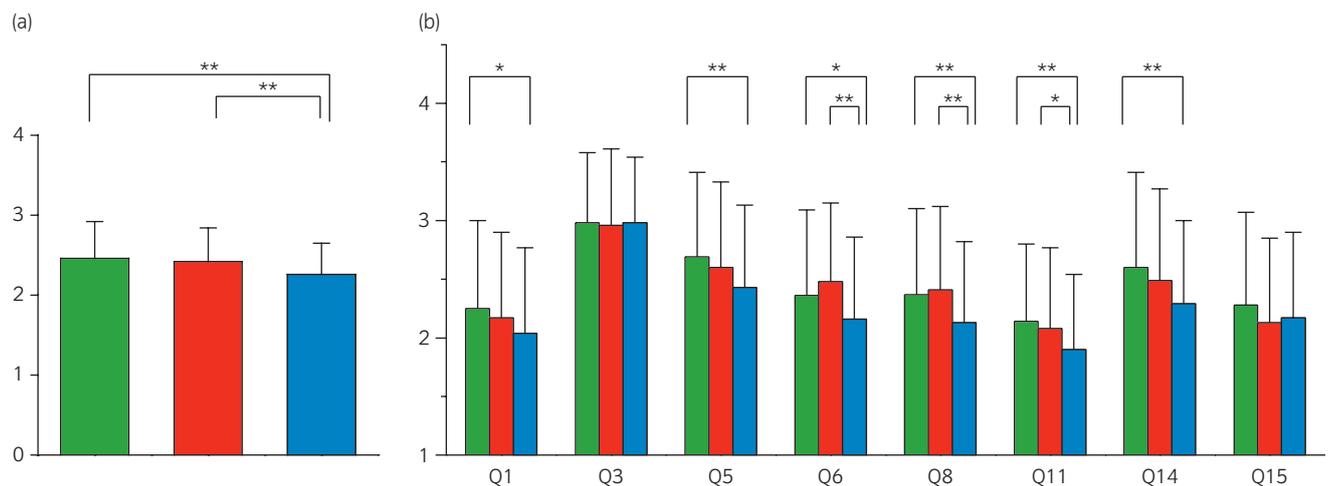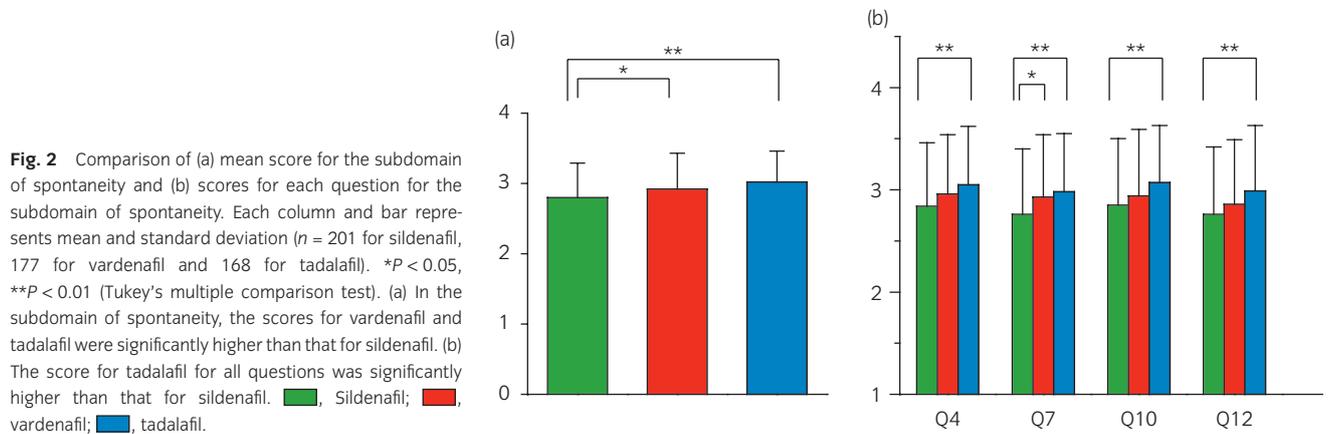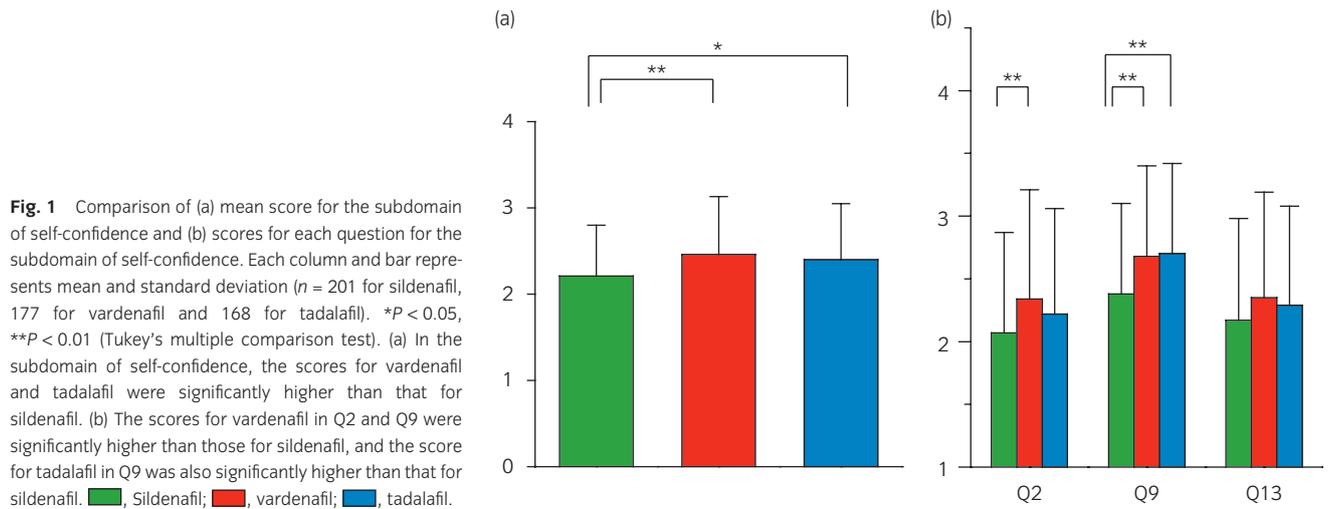
Statistical analysis

All comparisons were carried out by Tukey's multiple comparison test. Statistical significance was set at $P < 0.05$.

Results

The scores of the PAIRS-SF are shown in Figures 1 and 2. In the mean scores for the subdomains of self-confidence, scores for vardenafil and tadalafil were significantly higher than those for sildenafil (Fig. 1a). In the comparison of each score for the subdomains of self-confidence, the score for vardenafil in Q2 and Q9 was significantly higher than that for sildenafil, and the score for tadalafil in Q9 was also significantly higher than that for sildenafil (Fig. 1b). In the mean scores for the subdomains of spontaneity, scores for vardenafil and tadalafil were also significantly higher than those for sildenafil (Fig. 2a). Remarkably, the score for tadalafil for all questions in the subdomain of spontaneity was significantly higher than that for sildenafil (Fig. 2b). In the mean scores for the subdomains of time concern, the score for tadalafil was significantly lower than those for sildenafil and vardenafil (Fig. 3a). In the comparison of each score, the score for tadalafil for six (Q1, 5, 6, 8, 11 and 14) of eight questions was significantly lower than that for sildenafil (Fig. 3b). The score for tadalafil for three questions (Q6, 8 and 11) was also significantly lower than that for vardenafil (Fig. 3b).

Discussion

We already reported that vardenafil and tadalafil appeared to be better than sildenafil according to the evaluation with the IIEF-5, which assesses erectile status, such as rigidity and maintenance, by an Internet survey.[9] In the current study, we investigated details of sexual function through the new questionnaire, the PAIRS-SF, accessed by the responses of patients taking PDE5-I via the Internet. Several studies with sildenafil and tadalafil have been reported in regard to the PAIRS-SF. For the subdomain of self-confidence, it was previously reported that the score for patients taking tadalafil was higher than that for patients taking sildenafil.[10] The present study also showed that the scores for patients taking vardenafil and tadalafil were significantly higher than that for patients taking sildenafil (Fig. 1a). Among three questions regarding the subdomain of self-confidence, this was most apparent in relation to Q9, "I am confident I can achieve an erection when the mood is right"

(a)

(b)

Fig. 1 Comparison of (a) mean score for the subdomain of self-confidence and (b) scores for each question for the subdomain of self-confidence. Each column and bar represents mean and standard deviation ($n = 201$ for sildenafil, 177 for vardenafil and 168 for tadalafil). $*P < 0.05$, $**P < 0.01$ (Tukey's multiple comparison test). (a) In the subdomain of self-confidence, the scores for vardenafil and tadalafil were significantly higher than that for sildenafil. (b) The scores for vardenafil in Q2 and Q9 were significantly higher than those for sildenafil, and the score for tadalafil in Q9 was also significantly higher than that for sildenafil. ▮, Sildenafil; ▮, vardenafil; ▮, tadalafil.

(a)

(b)

Fig. 2 Comparison of (a) mean score for the subdomain of spontaneity and (b) scores for each question for the subdomain of spontaneity. Each column and bar represents mean and standard deviation ($n = 201$ for sildenafil, 177 for vardenafil and 168 for tadalafil). $*P < 0.05$, $**P < 0.01$ (Tukey's multiple comparison test). (a) In the subdomain of spontaneity, the scores for vardenafil and tadalafil were significantly higher than that for sildenafil. (b) The score for tadalafil for all questions was significantly higher than that for sildenafil. ▮, Sildenafil; ▮, vardenafil; ▮, tadalafil.

(a)

(b)

Fig. 3 Comparison of (a) mean score for the subdomain of time concern and (b) scores for each question for the subdomain of time concern. Each column and bar represents mean and standard deviation ($n = 201$ for sildenafil, 177 for vardenafil and 168 for tadalafil). $*P < 0.05$, $**P < 0.01$ (Tukey's multiple comparison test). (a) In the subdomain of time concern, the score for tadalafil was significantly lower than that for sildenafil and vardenafil. (b) The scores for tadalafil were significantly lower than those for sildenafil in six questions and for vardenafil in three questions. ▮, Sildenafil; ▮, vardenafil; ▮, tadalafil.

(Fig. 1b). This question more directly addresses confidence of erection than do questions Q2, "I feel very comfortable about my sexual abilities" and Q13, "I feel fantastic about my sex life." This finding indicates that improved confidence is mainly related with erection quality. For the subdomain of spontaneity, several previous studies have shown significantly higher sexual spontaneity in patients receiving tadalafil treatment compared with sildenafil treatment.[10,11] We also showed that the scores for

patients taking vardenafil and tadalafil were significantly higher than that for patients taking sildenafil, similar to the findings for the subdomain of self-confidence (Fig. 2a). Furthermore, the score for tadalafil was significantly higher than that for sildenafil for all questions related to the subdomain of sexual spontaneity (Fig. 2b). We suggest that in regard to sexual spontaneity, tadalafil is more favorably accepted by Japanese patients with ED than is sildenafil. Interestingly, for the subdomain of time concern, the score for patients taking tadalafil was lower than that for patients taking sildenafil or vardenafil (Fig. 3a). When we analyzed the score of each question for time concern, we found superiority of tadalafil to sildenafil for most questions (Q1, 5, 6, 8, 11 and 14; Fig. 3b). This result was consistent with that of previous studies showing that the score for time concern was statistically significantly lower after treatment with tadalafil when compared with sildenafil post-treatment.[10,12] Furthermore, we also found superiority of tadalafil to vardenafil in the subdomain of time concern. The questions with significant difference between vardenafil and tadalafil seemed to be related to patient emotion during dates with sexual partners; for example, Q6, "Dates feel programmed in order to have sex on schedule"; Q8, "I find myself feeling hurried when I think we will have sex later on"; and Q11, "Sometimes I ruin the mood by having to worry about the time." The present findings are also consistent with a recent study of 8047 patients in nine European countries reporting that the three subdomains of the PAIRS-SF showed statistically significant changes from baseline, and there were significant differences in favor of tadalafil among the subdomain of time concern.[13]

Regarding patient preference for PDE5-I, a previous study comparing sildenafil with vardenafil showed a similar preference rate: 34.5% of patients preferred sildenafil and 38.9% of patients preferred vardenafil.[14] In a comparison between sildenafil and tadalafil, a double-blind study showed that 73% of patients preferred tadalafil to sildenafil.[15] Outcomes of other studies with particular populations and lack of blinding have also confirmed the results that most patients prefer tadalafil to sildenafil.[16–18] Interestingly, only one patient preference study to compare tadalafil directly with vardenafil as well as sildenafil has been carried out.[19] In that study, 20.0% of patients preferred vardenafil and 27.8% preferred sildenafil, whereas 52.2% of patients preferred tadalafil, although the sample was too small to provide adequate power. It was speculated that this result was caused by the more flexible instructions for use and tolerance associated with adverse events. Indeed, in a study asking the reasons for the patient preference, the main reasons for preferring tadalafil were the ability to obtain an erection with sexual stimulation for a long period after taking the drug and the firmness of the erection.[11] Furthermore, it was reported that greater changes in the PAIRS score were significantly associated with patient preference.[20] Our finding in the PAIRS-SF that the score for tadalafil was significantly higher than that for sildenafil, particularly in the subdomain of time concern, might support the advantage of long action. Furthermore, these advantages could have resulted in our previous findings that both patient and partner satisfaction and patient inclination for continuity of dosing by the treatment with tadalafil was significantly higher than that with sildenafil.[9]

The present study included several limitations. One was the methodology of the study; the participants were recruited via the Internet, and the survey was anonymous. Thus, there is a risk that the participants might answer without considered thought, indicating less reliability of the results. However, we believe that our findings are not unrealistic and are relatively reliable, because the subdomain scores of the PAIRS-SF in the present study were extremely similar to those of a longitudinal, prospective, observational study across Europe with a large and diverse population.[13]

The other limitation was lack of information on PDE5-I dosage. In Japan, high dosage of sildenafil (100 mg) is not approved by the government, whereas high doses of vardenafil and tadalafil (20 mg) are approved. Thus, there is no denying that the inferiority of sildenafil to the other two drugs in several questionnaires might be associated with differences in dosage, because we did not compare medications on this basis. Although these limitations should have been carefully considered in the study protocol, we believe that the present findings are still valuable and informative to perceive and understand the actual status of Japanese patients with ED who were prescribed any kind of PDE5-I and attempted sexual intercourse.

In conclusion, the present findings support the hypothesis that Japanese patients with ED have great sexual self-confidence, spontaneity and few time concerns when taking tadalafil.

Conflict of interest

None declared.

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