

EFFICACY OF SILDENAFIL FOR JAPANESE PATIENTS WITH AUDIO-VISUAL SEXUAL STIMULATION (AVSS) TEST BY THE RIGISCAN PLUS

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□ *Sildenafil is most effective in men with mild-to-moderate ED, but not severe ED in Japan. In order to evaluate the efficacy of sildenafil, we conducted the present study using the AVSS test by the RigiScan Plus. The subjects were 56 patients (age: 34–82 years, mean: 60.5 years) with ED. The IIEF5 questionnaire and the AVSS test were conducted before and after administration of sildenafil. The penile rigidity could not be measured in 19 patients. Of these 19, sildenafil was effective in 7 and not effective in 12. The 7 cases in whom sildenafil was effective were all false-negatives. The sensitivity of sildenafil was 84%, and its specificity was 100%. This study suggests that the AVSS test by RigiScan Plus can objectively evaluate the efficacy of sildenafil, and shows potential for predicting that efficacy.*

Keywords audio-visual sexual stimulation test (AVSS Test), erectile dysfunction (ED), RigiScan Plus, sildenafil citrate

INTRODUCTION

Erectile dysfunction (ED) is a very common but frequently unrecognized or ignored condition. It reportedly occurs to some degree in as many as 50% of men older than 40 years [5]. The prevalence of ED increased with age from 39% in the 40-year-old men to 67% in the 70-year-olds. Sildenafil is one of the most commonly investigated first-line therapies, with clinical trials documenting its efficacy in patients of all ages and ED of

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various etiologies and degrees of severity [6]. Overall, sildenafil has been reported to be clinically effective in 70% to 80% of patients [3].

The drug is most effective in men with mild-to-moderate ED, but a significant improvement may not be achieved in many patients with severe ED. Now, it is very difficult to predict the efficacy of sildenafil in patients with severe ED. Although the international index of erectile function (IIEF) [9, 10] is widely used to evaluate the efficacy of sildenafil citrate, its objectivity is questionable, given its self-administered nature. Moreover, it is difficult to estimate the sildenafil efficacy only on the basis of IIEF5 questionnaire score. In order to predict the efficacy of sildenafil, we conducted the present study using the audio-visual sexual stimulation (AVSS) test and the RigiScan Plus (DACOMED CO., U.S.A.) [2] software.

MATERIALS AND METHODS

The study involved 56 men 34–82 yrs old with ED requesting treatment with sildenafil who attended the sexual function clinics. The underlying diseases of ED in 35 patients were diabetes mellitus (12 cases), hypertension (8 cases), trans-urethral resection of the prostate (TUR-P, 4 cases), cardiovascular diseases (4 cases), psychiatric disorders (3 cases), total cystectomy (1 case), spinal cord injury (1 case), alcoholism (1 case), and Behcet's disease (1 case). No evidence of underlying disease could be identified in the other 21 patients. Before sildenafil administration, the IIEF5 questionnaire and the AVSS test were conducted. The patients were assessed as appropriate on the bases of history, blood tests and exercise electrocardiography, and were given 5 tablets of sildenafil (50 mg). They then revisited the clinics 2 to 8 weeks after using the prescribed drug. At the time of revisit, the IIEF5 questionnaire was given again. One hour after administration of sildenafil (50 mg), the AVSS test was conducted. For that test, the RigiScan Plus software was used, and the maximum rigidity (%), the average rigidity (%), and the penile tumescence (cm) at the penile tip and base were measured for 15 minutes from the non-erectile state after providing AVSS via video tape for 20 minutes. Moreover, to eliminate the patients' anxiety as much as possible, quiet private rooms in the affiliated institutions, free from contact with other persons, were used. Data obtained before and after sildenafil administration, was evaluated by Macintosh computer, StatView software (version 5.0J), and the Wilcoxon rank test. A p value of less than 0.05 was considered significant.

RESULTS

A 44-year-old patient complained mainly of difficulty in maintaining penile erection, and the underlying cause was Behcet's disease (Figure 1).

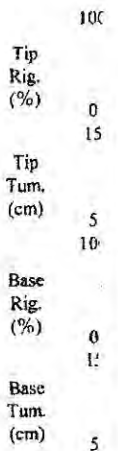


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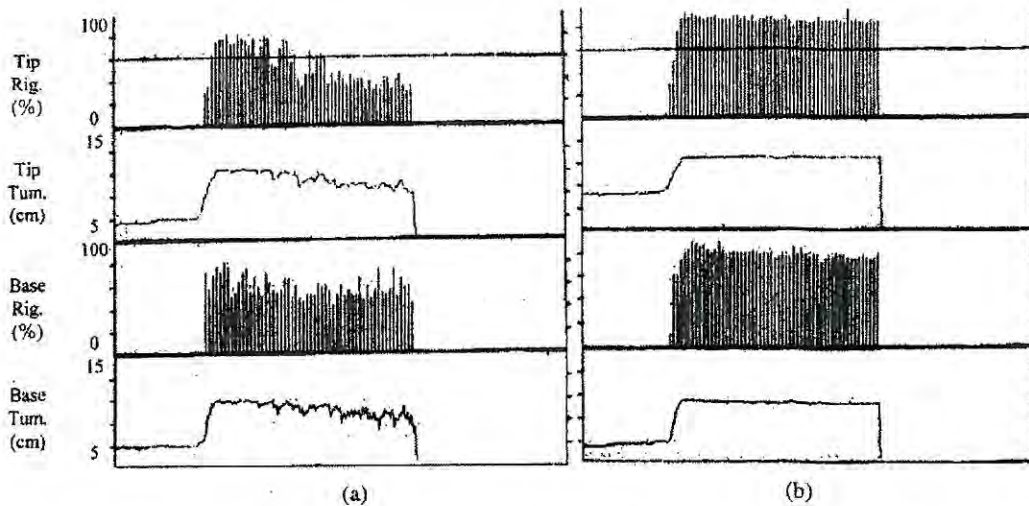


FIGURE 1 Case 1, a 44-year-old patient, complained mainly of difficulty in maintaining penile erection. The AVSS test were conducted (a) before and (b) after administration of sildenafil. After sildenafil administration, the mean rigidity (%) improved remarkably from (a) 51 to (b) 83 at the penile tip and from (a) 57 to (b) 77 at the penile base. The improvement in the mean rigidity, a significant factor in maintaining erection, was especially remarkable in this case.

Transient visual impairment was observed as an adverse reaction. After sildenafil administration, the IIEF5 score (maximum score 25) improved remarkably from 10 to 24, and the maximum rigidity (%) improved from 80 to 94 at the penile tip and from 80 to 89 at the penile base. The mean rigidity (%) improved from 51 to 83 at the penile tip and from 57 to 77 at the penile base. The penile tumescence (cm) increased at the penile tip from 3.5 to 4.3 and from 3.1 to 4.0 at the penile base. The improvement in the mean rigidity, a significant factor in maintaining erection, was especially remarkable in this case. Indeed, after sildenafil administration, the patient was able to maintain erection and reach ejaculation.

A 56-year-old patient, complained mainly of ED, and the underlying cause was myocardial infarction (Figure 2). Adverse reactions were not observed. After sildenafil administration, the IIEF 5 score improved from 5 to 22, the maximum rigidity (%) improved from 26 to 55 at the penile tip and from 5 to 73 at the penile base. The mean rigidity (%) improved from 0 to 47 at the penile tip and from 0 to 53 at the penile base. The penile tumescence (cm) at the penile tip increased from 1.5 to 2.7 and from 1.4 to 2.6 at the penile base. In this case, the maximum rigidity, the mean rigidity, and the penile tumescence were all remarkably improved after sildenafil administration, indicating the drug's efficacy.

Regarding the IIEF 5 score before sildenafil administration in the effective cases and the ineffective cases of sildenafil, the mean score of the 44 effective cases was 6.4 ± 7.3 and the mean score of the 12 ineffective cases

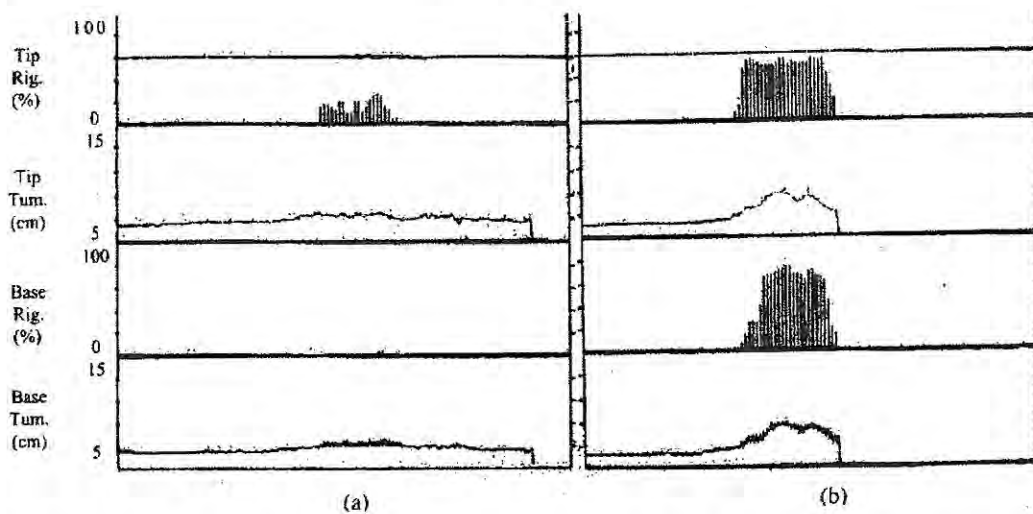


FIGURE 2 Case 2, a 56-year-old patient, complained mainly of ED. The AVSS test were conducted (a) before and (b) after administration of sildenafil. After sildenafil administration, the maximum rigidity (%) improved from (a) 26 to (b) 55 at the penile tip and from (a) 5 to (b) 73 at the penile base. The mean rigidity (%) improved from (a) 0 to (b) 47 at the penile tip and from (a) 0 to (b) 53 at the penile base. The penile tumescence (cm) at the penile tip increased from (a) 1.5 to (b) 2.7 and from (a) 1.4 to (b) 2.6 at the penile base. In this case, the maximum rigidity, the mean rigidity, and the penile tumescence were all remarkably improved after sildenafil administration, indicating the drug's efficacy.

was 3.5 ± 2.1 . There was no significant difference between the effective cases and the ineffective cases. However, the mean score of the 44 effective cases improved from 6.4 ± 3.7 to 21.1 ± 2.8 after sildenafil administration. In the 12 ineffective cases, however, no changes were observed, and the mean score remained at 3.5 ± 2.1 . There was a significant difference between the mean score of the effective cases and that of the ineffective cases ($p < 0.0001$).

Concerning the maximum rigidity (%) before sildenafil administration in the effective cases and the ineffective cases of sildenafil, the maximum rigidity of the 44 effective cases was 31 ± 28 at the penile tip and 40.3 ± 35 at the penile base. The rigidity could not be measured in the 12 ineffective cases before sildenafil administration at either the penile tip or base (0 ± 0).

Regarding the mean rigidity (%) before sildenafil administration in the effective cases and the ineffective cases of sildenafil, the mean rigidity of the 44 effective cases was 13.2 ± 17.9 at the penile tip and 20.2 ± 24.3 at the penile base. The rigidity could not be measured in the 12 ineffective cases before and after sildenafil administration at either the penile tip or base. There were significant differences between the mean rigidity of the effective cases and that of the ineffective cases at both the penile tip and base ($p < 0.0001$).

Regarding the penile tumescence (cm) before sildenafil administration in the effective cases and the ineffective cases of sildenafil, the penile

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tumescence of the 44 effective cases was 1.5 ± 1.0 at the penile tip and 1.7 ± 1.2 at the penile base. The penile tumescence of the 12 ineffective cases was 0.4 ± 0.4 at the penile tip and 0.4 ± 0.3 at the penile base. There were significant differences between the penile tumescence of the effective cases and that of the ineffective cases at both the penile tip and base ($p < 0.0001$).

The penile rigidity could be measured in 37 patients, and in all of them, sildenafil proved effective. The rigidity could not be measured in 19 patients. Of these 19, sildenafil was effective in 7 and not effective in 12.

DISCUSSION

Sildenafil's efficacy has been evaluated in the U.S.A. [3], and in Japan [11]. Our authors used "frequency of successful sexual intercourse" and "frequency of maintaining erection after successful sexual intercourse" in the IIEF 15-item questionnaire as primary endpoints, and they found that these frequencies improved from 1.65 to 3.82 and from 1.30 to 3.53, respectively, in a group receiving 50 mg of sildenafil. Shirai et al. [12] studied the pertinence and credibility of the Japanese version of the IIEF, and reported that it can be used as a questionnaire for evaluating the Japanese patients with ED. The RigiScan Plus, a modified model of the RigiScan [1], is enhanced to easily interpret the mean penile rigidity. The AVSS test was conducted to objectively measure the ED [4, 7, 8]. Measurement of such parameters as the maximum rigidity and penile tumescence using the RigiScan is useful in evaluating ED. Although the mean rigidity (%) may serve as a criterion for whether erection can be maintained or not, no definite decisive criterion has yet been posited. However, Yamanaka et al. [13] reported that patients showing a mean rigidity of more than 30% on the AVSS test and the RigiScan Plus readings were all patients with functional ED.

It would appear that the AVSS test by the RigiScan Plus can objectively evaluate the efficacy of sildenafil, and shows a potential for a predicting that efficacy. The AVSS test by the RigiScan Plus may therefore be useful in predicting the efficacy of sildenafil before sildenafil administration.

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