Efficacy of sildenafil citrate in the treatment of female sexual dysfunction

Original Article

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ABSTRACT

Introduction: Female sexual dysfunction (FSD) defines as disturbances in the female sexual response cycle resulting in marked distress and interpersonal difficulties. Sildenafil citrate was effective in treatment of FSD through increasing blood flow to corpus cavernosum of clitoris, vagina and labia minor.

Aim: To evaluate the effect of sildenafil citrate in treatment of female sexual dysfunction.

Patients and Methods: An observational study had been done on 43 females complaining of FSD who were fulfilling the inclusion criteria. They were taken oral sildenafil citrate 25mg daily for 6 weeks and were evaluated by 19–items Female Sexual Function Index (FSFI) questionnaire before and after treatment.

Results: Our results showed that 34.4% became normal with score of FSFI>26.5; while 65.6% showed some improvement but still have FSD (FSFI<26.5). There was significant improvement in all female sexual domains in FSFI ranged from 21% to 69%. There was significant improvement of total score in both 1st degree circumcision more than 2nd degree circumcisions with 41%- 35%, respectively.

Conclusion: We concluded that the treatment of patients with FSD by sildenafil citrate 25mg daily for 6 weeks had significant improvement effect on all domains of FSD with no improvement in pain score and effective in1st degree circumcised female more than 2nd degree according to FSFI questionnaire.

Key Words: Efficacy, female sexual dysfunction, sildenafil citrate

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INTRODUCTION

Female sexual dysfunction (FSD) includes a wide range of common disorders such as hypoactive sexual desire, poor sensation, vasocongestion, lubrication, sexual pain, and inability to achieve orgasm/satisfaction^[1]. Sexual dysfunction occurs in 40-45% of women and 20-30% of men at least once in their lifetime^[2].

FSD can be treated by hormonal therapy such as estrogen, progesterone, and testosterone and others like the phosphodiesterase type 5 inhibitors, dopaminergic agonists, and prostaglandins^[3].

Sildenafil citrate is among the phosphodiesterase type 5 inhibitors that improve FSD through increasing blood flow to corpus cavernosum of clitoris, vagina, and labia minor^[4].

Because there is a controversy about treatment of FSD, we aim in this study to evaluate the effect of sildenafil citrate in the treatment of FSD.

MATERIALS AND METHODS

A quasi-experimental pre–post-test single group design of 43 women complaining of sexual dysfunction was established from November 2015 till June 2017. Patients in a stable, heterosexual relationship with normal hormonal profile and normal sexual function of male partner by using the international index of erectile function-5 were included.

Women with a history of hypertension and on antihypertensive treatment, those with coronary heart disease or on treatment with vasodilator such as nitrates and α -blocker, those with impaired hepatic function, and those who were taking any medication such as antidepressant and antipsychotic drugs were excluded.

Each patient completed the 19-item FSFI questionnaire at the beginning of the study and at the end of study after 6 weeks of taking sildenafile citrate 25 mg daily on empty stomach. A score up to 26.5 is classified as FSD.

Ethical approval:

Approval from the Institutional Ethics and Research Committee of Faculty of Medicine, South Valley University, Egypt, was obtained. Moreover, informed written consent was obtained from each woman before enrollment in the study.

Analysis of data was done by IBM computer using statistical program for social sciences (SPSS Inc., Chicago, ILUSA, version 20) as follows: description of quantitative variables as mean, SD, and range, and description of qualitative variables as number and percentage. Paired t-test was used to compare the difference in means between the two groups, and correlation coefficient test (r) was used to rank variables against each other either positively or inversely. Correlation is significant at the 0.05 level (two tailed) based on normal approximation.

RESULTS

Our study was performed on 43 women complaining of sexual dysfunction with a mean of age 30.5 ± 6.4 years old. Overall, 37.2% of the women in our study had first-degree circumcision and 62.8% were had second-degree circumcision.

At the start of this study, 100% of participants had been complaining of FSD with score less than 26.5 of FSFI questionnaire, whereas after completing 6 weeks of treatment, 34.4% of women became normal and had a score more than 26.5 on FSFI questionnaire, but 65.6% of the women still had FSD, as they had scores less than 26.5 on FSFI. At the end of the study, 11 woman not able to complete the study and missed the follow-up.

The six female sexual domains and the total FSFI score were compared before and after treatment with sildenafil 25 mg daily for 6 weeks. There was a statistically significant improvement in all female sexual domains in FSFI and in total FSFI score (P<0.001). Improvement in the domains ranged as follow: orgasm 69% is the best followed by desire 68%, lubrication 64%, arousal 48%, satisfaction 42% and pain 21%, whereas the total score improvement by 41% (Table 1).

We also found that there was a statistically significant (P < 0.001) improvement of percentage after treatment of first-versus second-degree circumcision in desire, lubrication, orgasm domains, and total score (Table 2).

Table 1: Comparative analysis of the studied groups (before vs. after treatment)

FSFI item	Baseline	After treatment	P valueª	Percent change	Absolute change (%)
Desire	2.49±1.3	4.18±1.1	<0.001	1.69	68
Arousal	2.80±0.9	4.13±1.3	<0.001	1.33	48
Lubrication	2.81±0.9	4.61±1.4	<0.001	1.80	64
Orgasm	1.80±0.7	3.04±1.4	<0.001	1.24	69
Satisfaction	3.29±0.7	4.67±1.4	<0.001	1.38	42
Pain	3.81±0.7	3.15±0.9	<0.001	0.66	21
Total	16.98±3.0	23.80±5.6	< 0.001	6.82	41

^{*}Paired T-test was used to compare the difference in means between the two groups Significance level is considered when $p \le 0.05$

Table 2: Improvement percentage after treatment(1st vs. 2nd Degree Circumcision)

FSFI item		Baseline	After treatment	P value ^a	Percent change	Absolute change (%)
Desire	1st degree	2.40 ± 1.1	4.38 ± 0.7	< 0.001	1.98	83%
	2 nd degree	2.78 ± 1.4	4.06 ± 1.1	< 0.001	1.28	46%
Arousal	1 st degree	3.00 ± 1.1	4.58 ± 1.1	< 0.001	1.58	53%
	2 nd degree	2.48 ± 0.9	3.86 ± 1.1	< 0.001	1.38	56%
Lubrication	1st degree	3.26 ± 1.4	5.03 ± 1.2	< 0.001	1.77	54%
	2 nd degree	2.90 ± 0.9	4.36 ± 1.2	< 0.001	1.46	50%
Orgasm	1st degree	2.10 ± 0.9	3.46 ± 1.1	< 0.001	1.36	65%
	2 nd degree	1.76 ± 1.1	2.79 ± 1.3	< 0.001	1.03	59%
Satisfaction	1st degree	3.80 ± 0.9	5.08 ± 1.1	< 0.001	1.28	34%
	2 nd degree	3.17 ± 0.9	4.43 ± 1.2	< 0.001	1.26	40%
Pain	1st degree	3.85 ± 0.6	3.70 ± 0.8	< 0.001	0.15	4%
	2 nd degree	3.31 ± 0.9	3.05 ± 0.7	< 0.001	0.26	9%
Total	1 st degree	18.41 ± 3.9	25.88 ± 4.4	< 0.001	7.47	41%
	2 nd degree	16.76 ± 3.3	22.57 ± 4.7	< 0.001	5.81	35%

^{*}Paired T-test was used to compare the difference in means between the two groups Significance level is considered when $p \le 0.05$

DISCUSSION

In the current study, we found that the treatment of patients with FSD by sildenafil citrate 25 mg daily for 6 weeks had significant improvement effect on all domains of FSD, with no improvement in pain score, and was more effective in the first-degree circumcised women than second-degree circumcised women according to FSFI questionnaire.

Nurnberg *et al.*^[5] showed an improvement in orgasmic functioning and sexual arousal with sildenafil in female patients on selective serotonin re-uptake inhibitors.

Nurnberg *et al.*^[6] found that the women receiving sildenafil had significantly greater improvements in sexual function than those who had taken placebo.

Berman *et al.*^[7]had demonstrated significant increases in satisfaction, subjective desire, arousal, and lubrication

after 6 weeks of sildenafil 100 mg administration as assessed by questionnaire.

Caruso *et al.*^[8-10] showed a significant improvement in all aspects of FSD, including desire, arousal, lubrication, satisfaction, orgasm, and dyspareunia when use sildenafil 25 mg.

On contrary, Kaplan *et al.*^[11] found that sildenafil citrate was safe but less effective in FSD, although there were changes in vaginal lubrication and clitoral sensitivity.

Basson *et al.*^[12] showed that there was no improvement in sexual response with multiple doses of sildenafil in a large randomized, placebo controlled, double-blind study in 781 estrogenized and estrogen-deficient postmenopausal women with female sexual arousal disorder who had received 10, 50, or 100 mg of sildenafil or placebo.

Basson and Brotto^[13] conducted a randomized, doubleblind and placebo-controlled study on 34 estrogenized

postmenopausal women with acquired genital female sexual arousal disorder and impaired orgasm. Sildenafil did not improve either orgasm or arousal in those patients.

Alexander *et al.*^[14] found a nonsignificant difference between sildenafil versus placebo in successful sexual activities at the end of treatment versus baseline.

Therefore, further studies are needed to evaluate the effects of sildenafil citrate on FSD.

CONCLUSION

Sildenafil may improve all domains of FSD, mainly affecting desire, orgasm, and lubrication. However, further studies on a bigger sample of patients is needed to confirm our findings.

CONFLICT OF INTEREST

There are no conflicts of interest.

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