A Prospective Duplex Doppler Ultrasonographic Study in Women with Sexual Arousal Disorder to Objectively Assess Genital Engorgement Following Therapeutic Use with the Eros Therapy

Munarriz-Talakoub-Goldstein Study: Presented at the Female Sexual Function Forum, October 2001, Boston, MA

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Introduction

The Eros Therapy is an FDA-approved device for the treatment of women with sexual dysfunction. The device provides three levels of gentle vacuum suction (low, medium and high) during application to the glans clitoris. In women with sexual arousal disorder, use of Eros Therapy has been shown to improve sexual function and satisfaction.

Purpose

The aim of this prospective, IRB-approved study was to obtain objective information regarding the effectiveness of the Eros Therapy to increase genital blood flow to the clitoris following therapeutic use in women with sexual arousal disorder.

Methods

Seven patients with sexual arousal disorder completed questionnaires (Female Sexual Function Index) and were instructed as to the use of the Eros Therapy device. Instructions included correct placement of the device over the clitoris, using the device at the lowest vacuum setting for approximately 10 seconds, and, if there was no discomfort, using the device at different vacuum settings. Subjects then completed a diary recording a minimum of 4 home use therapies and until they felt comfortable with the device. During the second office visit, subjects underwent a baseline duplex Doppler ultrasound, similar to the one they underwent during the initial office visit for assessment of sexual dysfunction. The following ultrasound variables were recorded: clitoral shaft diameter in the region of the suspensory ligament, right cavernosal artery peak systolic, end diastolic velocity and resistive index values, right corpus spongiosum diameter, right corpus spongiosum artery peak systolic, end diastolic velocity and resistive index values. Subjects then privately utilized the Eros Therapy for approximately 10 minutes of therapeutic use. Following the post-Eros Therapy ultrasound study, a brief physical examination was then performed.

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Results

All seven subjects (mean age 45, range 25–63 years; mean height 1.65 ± 6.3 (1.57–1.72) meters, mean weight of 69.1 ± 12.2 (63–69) kg) met inclusion and exclusion criteria including having normal hormonal values at the time of the study (mean total testosterone 42.4 ng/dl (normal 15–70 ng/dl); bioavailable testosterone 2.61 ng/dl (normal 0.6–5.0 ng/dl); mean estradiol 82.8 pg/ml; mean estrone 60 pg/ml). All subjects were receiving androgen replacement therapy. A total of 4 subjects were pre-menopausal and three were post-menopausal. The mean duration of clinical symptoms of sexual dysfunction until presentation was 7 ± 10 years. Varying degrees of clitoral phimosis were present in 29%. The mean FSFI scores were 57 ± 16.4 /95. All seven subjects were able to comfortably operate the device and 6/7 used only 4 home sessions until comfort with the device was reached. All seven reported either slight–moderate pleasure or orgasm at home with the device. Pleasure from the therapy lasted seconds, 1–10 minutes, and 10 minutes to 1 hours following release of the vacuum in 2, 3 and 2 subjects, respectively. There were no adverse events observed including clitoral or labial pain, discomfort, irritation, or increased sensitivity. The pre and post Eros Therapy ultrasound values are presented in table 1. There were no differences in the hemodynamic increases of those with and without clitoral phimosis. The increase in pre- and post-arousal corpus spongiosum diameter directly correlated ($p = 0.04$) with an increase in both the pre- and post-arousal corpus spongiosum end diastolic velocity values.

	Baseline	Post Eros Therapy	P-value
Clitoral diameter (cm)	0.9 ± 0.2 (0.8–1.3)	1.2 ± 0.2 (1–1.5)	0.005
R Clitoral Art PSV (cm/sec)	7.1 ± 6 (0–13.8)	26.2 ± 16 (15–60.9)	0.01
R Clitoral Art EDV (cm/sec)	2.1 ± 1.5 (0–3.4)	8.4 ± 8.4 (2.8–26.3)	0.05
R Clitoral Art RI	0.48 ± 0.34 (0–0.84)	0.71 ± 0.11 (0.57–0.87)	0.23
R Corp. Spong. diameter (cm)	1.2 ± 0.3 (0.9–1.7)	1.6 ± 0.3 (0.8–1.3)	0.003
R Corp. Spong. Art PSV (cm/sec)	9.4 ± 9.3 (0–27.7)	21.0 ± 15 (10–50.8)	0.02
R Corp. Spong. Art EDV (cm/sec)	4.1 ± 3.8 (0–10.9)	7.1 ± 5.7 (2.1–19.1)	0.04
R Corp. Spong. RI	0.4 ± 0.28 (0–0.62)	0.66 ± 0.11 (0.51–0.80)	0.1

Conclusions

A prospective Duplex Doppler ultrasound study in women with sexual arousal disorder has shown that Eros Therapy is associated with significant increases in clitoral and corpus spongiosum diameter as well as clitoral and corpus spongiosum peak systolic and end-diastolic velocity values.