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File: ■ Ashwagandha (*Withania somnifera*, Solanaceae)
■ Sexual Function
■ Female Sexual Dysfunction

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RE: Ashwagandha Improves Sexual Function in Premenopausal Women

Dongre S, Langade D, Bhattacharyya S. Efficacy and safety of ashwagandha (*Withania somnifera*) root extract in improving sexual function in women: a pilot study. *Biomed Res Int*. October 4, 2015;2015:284154. doi: 10.1155/2015/284154.

Many factors can lead to a lack of sexual function and desire in women, including stress or physical problems. Botanicals may be useful to alleviate these. Ashwagandha (*Withania somnifera*, Solanaceae) is used as an adaptogen, and the root extract has been shown to be efficacious in treating sexual problems. This randomized, double-blind, placebo-controlled study investigated whether a high-concentration ashwagandha root water extract (HCARE) (KSM-66®; Ixoreal Biomed; Los Angeles, California) would alleviate stress or modulate hormones to affect female sexual dysfunction (FSD).

This study took place in India and enrolled women diagnosed with FSD and meeting criteria for hypoactive sexual desire disorder (HSDD), female sexual arousal disorder (FSAD), female orgasmic disorder (FOD), or "combined genital and subjective arousal disorder." Patients enrolled scored <26 on the Female Sexual Function Index (FSFI, an index of function items, where an elevated score is indicative of better sexual function) and >11 on the Female Sexual Distress Scale (FSDS, a scale addressing worry and distress about sex, where a lower score shows lower distress). Patients were 21-50 years old, in a heterosexual partnership for a year or more, and had a history of sexual activity. Additional inclusion criteria were the agreement to have sex twice per week with attempts at orgasm, the use of condoms, and ability to speak, read, and write fluent English. Those who had underlying untreated endocrine disease; had experienced painful sex within the past year; appeared to be experiencing sexual distress or exploitation; were pregnant, lactating, infertile, or in menopause; suffered from psychiatric conditions or drug abuse; used hormonal contraceptives or had taken other drugs or supplements for sexual function within the past year; or had an allergy to ashwagandha were excluded.

In total, 50 patients were enrolled, with 25 each randomly assigned to the treatment and placebo groups. The HCARE product used was selected for its high content of >5% withanolides, which was confirmed by high-performance liquid chromatography (HPLC). For placebo, starch was used. Treatment and placebo were placed in capsules of 300 mg each, with 2 doses of 1 capsule taken per day (after meals with water) for 8 weeks. Along with the treatment or placebo, patients underwent counseling to address FSD.

The primary outcome was the FSFI score, which measures aspects of sexuality such as desire, arousal, lubrication, pain, orgasm, and satisfaction. Secondary outcomes included the FSDS, the Sexual Activity Record (SAR, a gauge of the frequency of sex), the Patients' Global Assessment of Response to Therapy (PGART, a 5-point scale rating sexual activity and satisfaction), and the Patients' Global Assessment of Tolerability to Therapy (PGATT, an assessment of adverse side effects on a 5-point scale). Assessments were conducted at baseline and 4 and 8 weeks. Returned capsules were used to gauge compliance, with ≥80% consumption considered to be compliant.

Patients' mean age was 28.12 ± 5.12 in the treatment group and 29.44 ± 6.14 in the placebo group. It is mentioned that the enrollment criteria and study demands resulted in a homogeneous patient population consisting mostly of highly stressed, married, affluent stay-at-home mothers. No patients dropped out or were excluded after enrollment. At baseline, patients' FSFI scores were within the range associated with FSD. At weeks 4 and 8, total FSFI scores for the treatment group had improved significantly more than in the placebo group ($P<0.001$). At 8 weeks, the FSFI score was significantly greater in the HCARE group as compared with the placebo group (23.86 vs. 20.06, $P<0.001$), compared to values at week 0 of 13.63 vs. 13.57. The treatment group had significantly greater improvements in the arousal, lubrication, orgasm, and satisfaction domains of the FSFI (at 8 weeks, $P<0.001$ for all comparisons). The "desire" domain did not improve more in the treatment group; the authors note that this means it would be inappropriate to describe HCARE as an "aphrodisiac."

Additionally, FSDS scores in those taking HCARE decreased significantly more (indicating improvement) as compared to the placebo group at both 4 and 8 weeks ($P<0.001$ for both). No significant differences were seen in overall SAR scores, though at 8 weeks the number of "successful" sexual encounters was greater in the treatment group ($P<0.001$). On the 5-point PGART scale, 15 in the treatment group rated the response as "excellent," 9 as "good," and 1 as "moderate." [Note: The authors failed to provide comparable data for the placebo group.] For those taking HCARE, no adverse effects were observed, and compliance was considered "excellent" for both groups.

This study suggests the efficacy of ashwagandha water extract in treating FSD. Suggested mechanisms may include ashwagandha's previously reported antistress bioactivity, as well as modulating hormones such as testosterone. The authors mention that cultural attitudes about sex may have affected the survey scores and note that significant, though lesser, improvements in the placebo group may reflect efficacy of counseling. A discussed limitation is the small sample size, and further research would be necessary to determine the mechanism of action behind the observed results. The diagnostic labels applied in this study have been the subject of some controversy.

Ixoreal Biomed provided the study product and some financial assistance for this study.

—Amy C. Keller, PhD

Referenced article can be accessed at http://www.hindawi.com/journals/bmri/2015/284154/.