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AMERICAN
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File: ■ ArginMax®
■ Sexual Dysfunction
■ Breast and Gynecological Cancers

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RE: Herbal Supplement ArginMax® Improves Quality of Life but Not Sexual Function in Female Cancer Survivors

Greven KM, Case LD, Nycum LR, et al. Effect of ArginMax on sexual functioning and quality of life among female cancer survivors: results of the WFU CCOP Research Base Protocol 97106. *J Community Support Oncol.* March 2015;13(3):87-94.

Those that have experienced breast or gynecological cancer are often left with sexual dysfunction, such as limited desire and satisfaction. Targeting blood flow and hemodynamics is a popular approach to this problem. ArginMax® (The Daily Wellness Company; Honolulu, Hawaii) is a mixture of L-arginine, Korean ginseng (Asian ginseng; *Panax ginseng*, Araliaceae) aerial parts and root, ginkgo (*Ginkgo biloba*, Ginkgoaceae) leaf, and damiana (*Turnera diffusa* var. *aphrodisiaca* syn. *T. aphrodisiaca*, Passifloraceae) leaf, along with vitamins and minerals. L-arginine supports vascular function, and ginseng and ginkgo have been investigated for effects on various aspects of the vascular system.¹ This randomized, placebo-controlled trial investigated the potential effects of ArginMax on sexual function in female cancer survivors.

The study took place between May 10, 2007, and March 24, 2010, and patients were recruited from Wake Forest University Community Clinical Oncology Program (Winston-Salem, North Carolina) member sites. Female cancer survivors who were 6 months post-treatment with no evidence of cancer, had not been in another clinical trial within 30 days of the study's start, and had sexual dysfunction not caused by other reasons were enrolled. Patients were allowed hormonal therapy and trastuzumab (a chemotherapy drug). Those who were pregnant, allergic to any component of ArginMax, on other medications such as anticoagulants or antidepressants, or had other illness, planned surgery, or planned pregnancy were excluded.

Prior to the study, patients were asked about their sexual function. If they answered that they had dissatisfaction with their sex life, had sexual problems, and a desire for improvement, they were considered. Patients were categorized based on pelvic or non-pelvic cancer and ovarian function and were randomly assigned to receive ArginMax or placebo. ArginMax and matched placebo were supplied by The Daily Wellness Company. Neither the exact dosage of L-arginine and botanicals per caplet of ArginMax

nor contents of placebo were described. Note: The Arginmax website lists the amount per serving size as 6 caplets, which was the amount the patients received. The amounts for 6 caplets are as follows: L-arginine, 2500 mg; Korean ginseng, 100 mg; ginkgo, 50 mg; damiana, 50 mg. <http://www.arginmax.com/sexual-enhancement-for-women/ingredients.php>. Patients took 3 caplets twice per day for 12 weeks and took note of the total caplets consumed for compliance. At baseline and at 4, 8, and 12 weeks, assessment was made of sexual function, quality of life, and toxicity.

The primary outcome was the score of the Female Sexual Function Index (FSFI). This assessment addresses sexual desire, arousal, lubrication, orgasm, satisfaction, and pain, with higher scores meaning better sexual function. The secondary outcome was health-related quality of life as measured by the Functional Assessment of Cancer Therapy-General (FACT-G). This assessment consists of physical, social, emotional, and functional well-being, with higher scores meaning better quality of life.

Overall, 186 patients were randomly assigned, with 92 in the placebo group and 94 in the ArginMax group. Of these patients, 163 (74%) completed the study, with reasons for dropout including refusal of treatment, loss to follow up, cancer progression, physician advice, surgery, and other reasons. The number of patients who completed the study per group was not given. Based on returned caplets, 92.6% of the dosage was taken by the placebo group, and 92.9% by the ArginMax group. Baseline characteristics were not significantly different between groups, with a median age of 50 years; 78% had breast cancer, 12% had gynecologic cancer, and 10% had other types of cancer. Patients were an average of 41 months past their cancer diagnosis. Prior to treatment, the majority of patients in both groups had sex <1 time per month, with 22% of the ArginMax group and 25% of the placebo group never climaxing. Also, the majority of patients mentioned being unsatisfied with their sex lives, but categorized their relationships as "very good" or "excellent."

Patients' FSFI average score at baseline was 14.15 ± 0.62 , and scores were significantly greater after 4 weeks of treatment in both groups (17.40 ± 0.80 for the placebo group and 16.66 ± 0.80 for the treatment group, $P < 0.001$ for both) but were not significantly different between groups. Even after 12 weeks, scores were improved (17.15 ± 0.91 for the placebo group and 17.81 ± 0.90 for the treatment group) but remained under 26, the cutoff considered indicative of sexual dysfunction. It was determined that ArginMax did not affect FSFI scores, and changes in scores were generally linked to younger patients, patients that had more interest in sex, and those having sex more often.

The mean FACT-G score at baseline for patients was 87.03 ± 1.01 (the scale ranges from 29-106). The scores were significantly greater for the treatment group as compared to the placebo group after 4 and 12 weeks ($P = 0.017$ and 0.010 , respectively). Further statistical analysis revealed that patient age was significantly correlated with change in the physical score ($P = 0.001$), length of time from diagnosis was significantly correlated with change in social score ($P = 0.028$), sexual interest at baseline was correlated with change in emotional score ($P = 0.011$), and amount of sex was correlated with change in the functional score ($P = 0.009$).

In total, 5 serious adverse side effects were observed in this study, with 3 in the ArginMax group and 2 in the placebo group. Stomach pain, diarrhea, night sweats, insomnia, vulvar abscess, hyperglycemia, and infection were reported. Hot flashes and headaches were reported for 66% and 29% of patients, respectively. Neuropathy was

reported in 19%, along with nausea and vomiting in 9% and 3%, respectively. The authors determined that the stomach pain and diarrhea were related to treatment, with other effects thought to be unrelated.

Overall, ArginMax did not improve sexual function in female cancer survivors as measured by the FSFI score; however, it did improve certain quality of life metrics in patients as compared to placebo. Discussed mechanisms for this result include improved blood flow and/or psychological benefits of taking part in the study and addressing sexual problems even if the desired outcome was not reached. The authors mention that study limitations include a high dropout rate, missing metrics that may have helped to further assess sexual function, and no comparisons with sexual function prior to cancer. Additionally, the lack of information about the exact dosage of the ArginMax components confounds results and is problematic regarding adverse side effects. Regardless, the improvements in quality of life of cancer survivors warrants further research into these botanicals.

The Daily Wellness Company provided funding for this study.

—Amy C. Keller, PhD

Reference

¹Blumenthal M, Goldberg A, Brinckmann J, eds. *Herbal Medicine: Expanded Commission E Monographs*. Austin, TX: American Botanical Council; Newton, MA: Integrative Medicine Communications; 2000.

Referenced article can be accessed at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4544777/>.

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