

**Provide your patients with
the relief they deserve.**



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clinical information here](#)**

Ristela®

**This arousal enhancer provides
stimulating support for increased
sexual satisfaction.***

- Increases orgasm and physical arousal*
- Plant-based & hormone and steroid-free
- Effective, high quality ingredients



**“Game Changer! Back to having even
better orgasms and feeling aroused again.”**

- Tina

*These statements have not been evaluated by the Food and Drug Administration.
These products are not intended to diagnose, treat, cure, or prevent any disease.



Ristela™

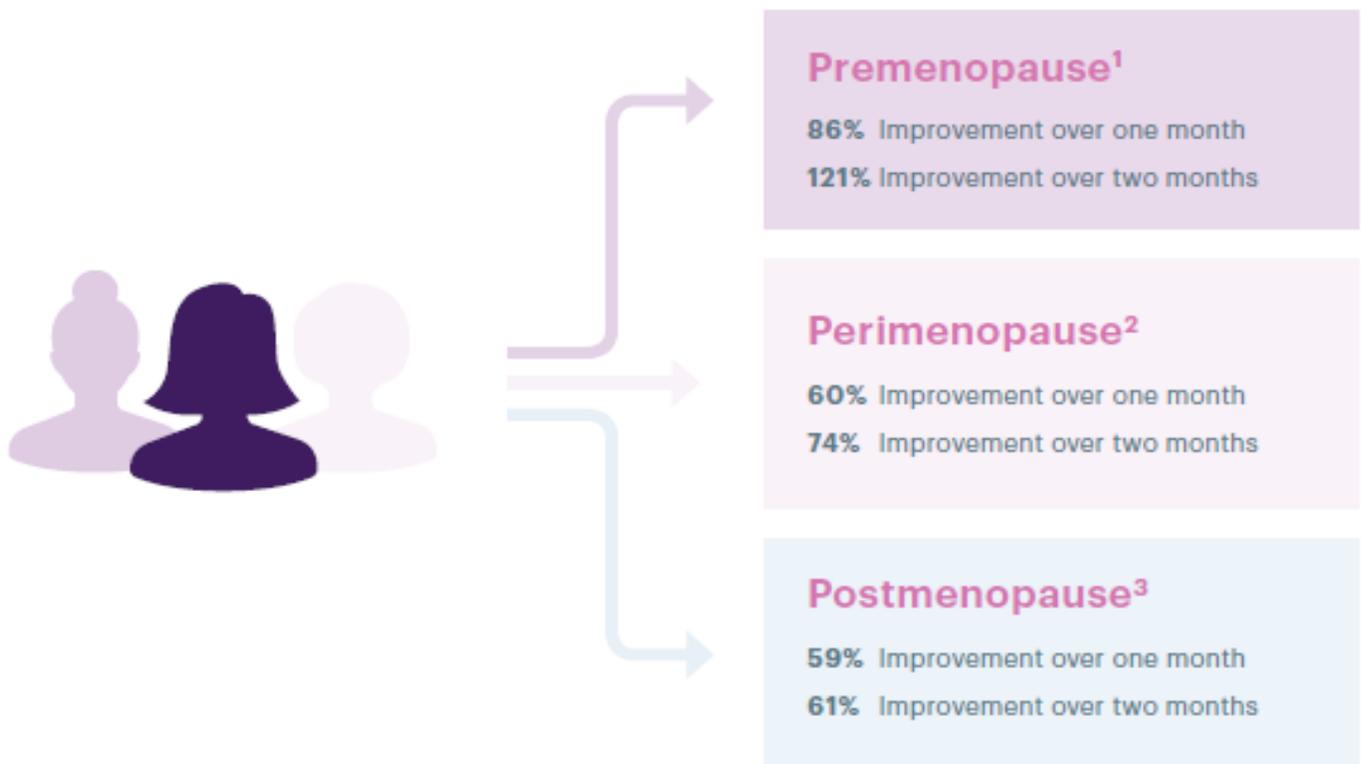
Presented at the 2019 meeting of the International Society for the Study of Women's Sexual Health (ISSWSH).

A Review of Clinical Study Data on Ristela, a Supplement Blend for Improved Sexual Function in Women.

Sharon Parish, MD¹, Susan Kellogg-Spadt, CRNP, PhD² 1: Weill Cornell Medical College, New York, NY; 2: Drexel University College of Medicine, Philadelphia, PA/Center for Pelvic Medicine, Bryn Mawr, PA

IN THREE RANDOMIZED CONTROLLED TRIALS ACROSS A TOTAL OF 263 WOMEN:

Ristela significantly improved patients' overall Female Sexual Function Index* scores at 4 weeks and 8 weeks. ($P < 0.05$ vs. placebo/control)



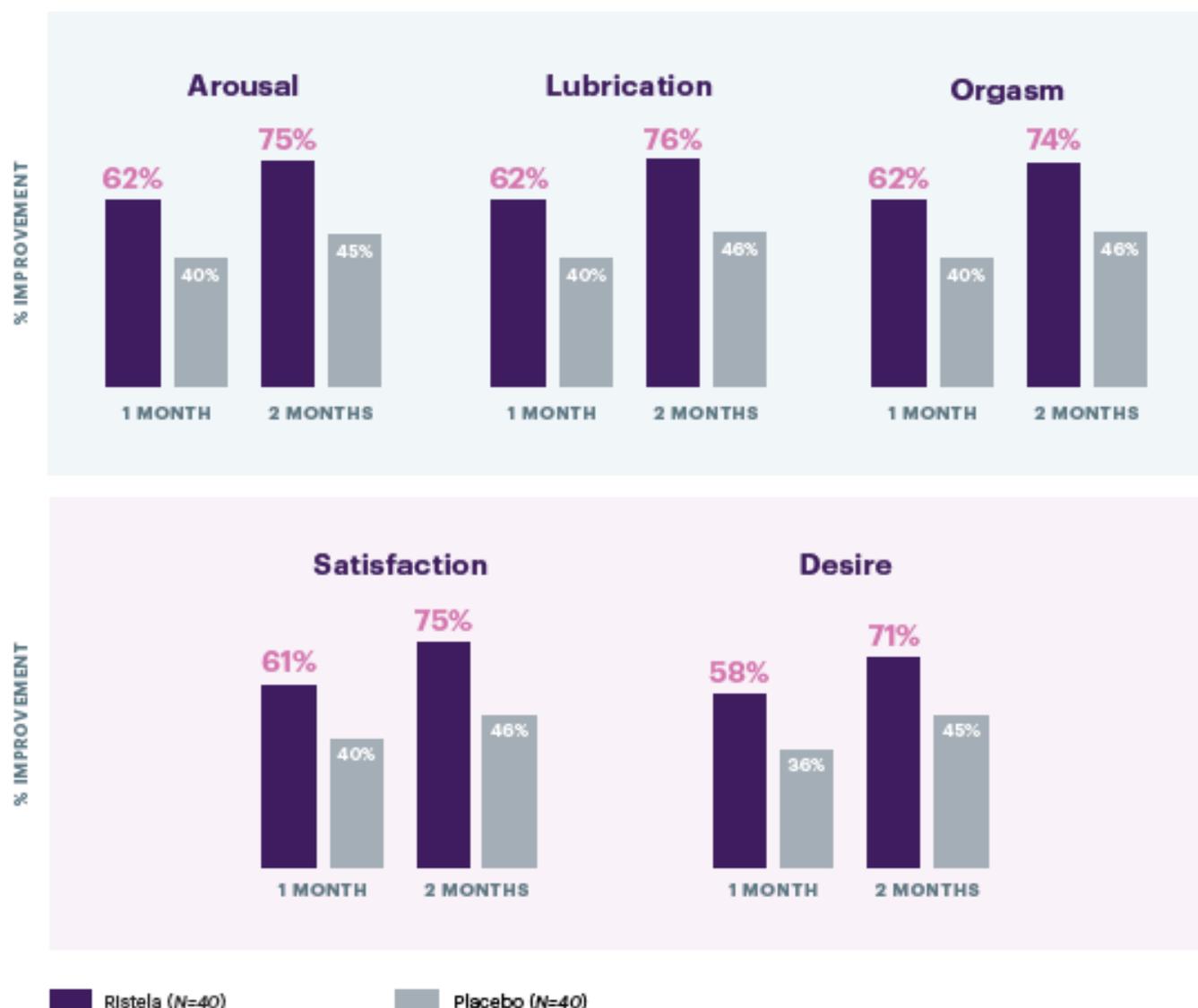
*The FSFI is a validated questionnaire with multidimensional scales for assessment of female sexual function and represents the standard tool for assessment of women's sexual function. It measures six separate domains: arousal, desire, satisfaction, orgasm, pain, and lubrication.

Ristela significantly improves all key domains of sexual function.

IN A TWO-MONTH, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY IN 80 PERIMENOPAUSAL WOMEN:

Ristela significantly improves all FSFI domains as early as month 1.²

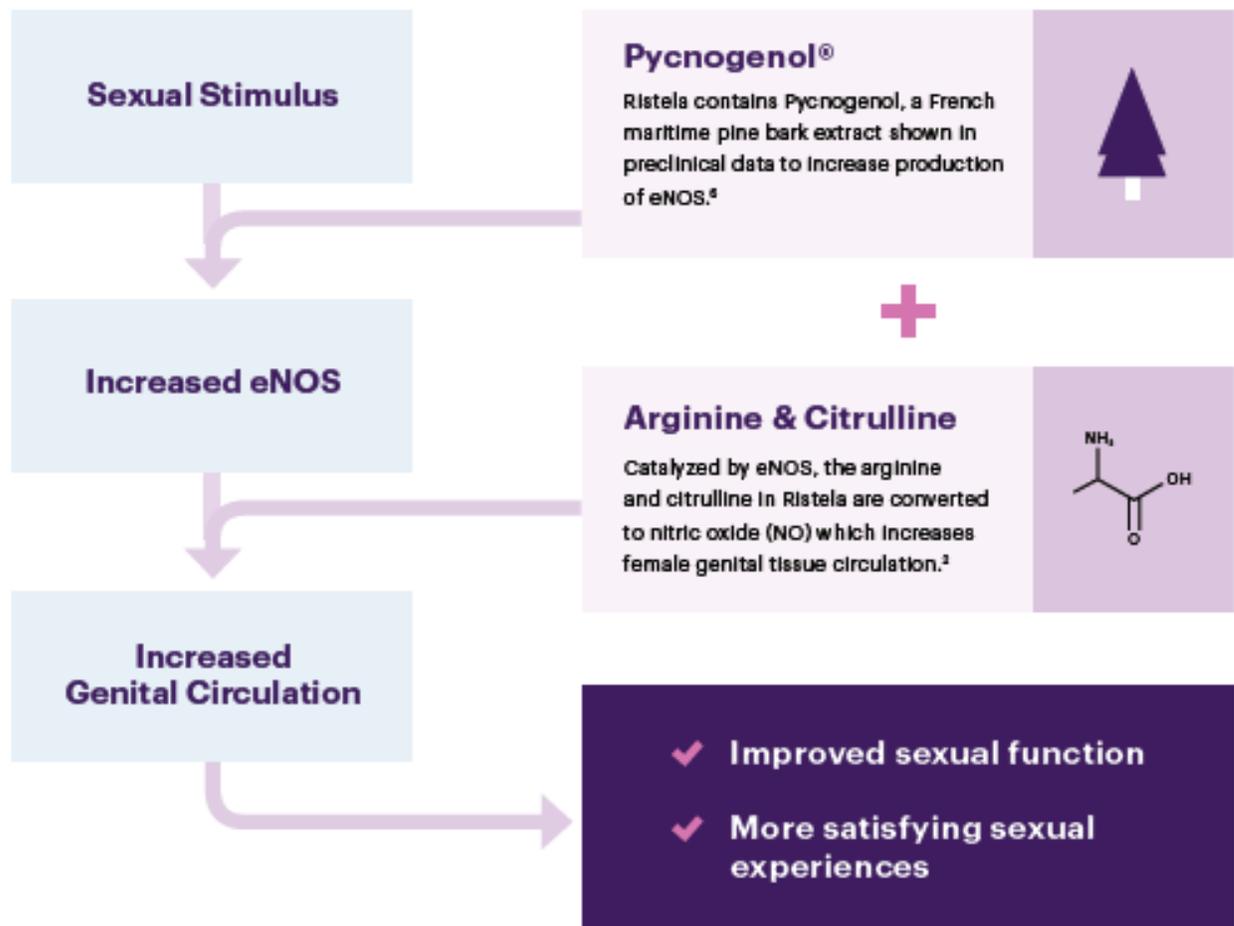
($P < 0.001$ vs placebo)



Ristela demonstrated similar improvements in individual FSFI domains in premenopausal ($P < 0.001$ vs. control) and postmenopausal women ($P < 0.05$ vs. placebo) in two separate 8 week controlled trials.^{1,3}

Ristela is formulated to enhance female genital circulation, making it easier for women to become aroused and experience orgasm.²

- During the female sexual response, the body produces Endothelial Nitric Oxide Synthase (eNOS), an enzyme that converts arginine and citrulline into nitric oxide.²
- eNOS activity is important for healthy sexual function, but can decrease with age and hormonal changes.^{4, 5}



Ristela also contains rose hips extract, a potent antioxidant, and has been shown to significantly reduce free radicals and improve oxidative stress after 8 weeks, supporting overall sexual function.^{1, 2}

Discussion and Conclusions

Efficacy

In three separate clinical studies, Ristela significantly improved overall sexual function as measured by the FSFI, and specifically improved arousal, lubrication, orgasm, satisfaction, pain, and desire. Improvements were seen as early as four weeks, with continued improvement at eight weeks.

Mechanism

Ristela is formulated to increase eNOS and genital circulation, leading to improved female sexual function and more satisfying sexual experiences. Ristela has also been shown to significantly improve oxidative stress, supporting overall sexual function.

Safety

No side effects due to treatment were observed in any study.

Ristela is a safe, effective, hormone-free treatment for improving sexual response in pre, peri, and postmenopausal women.

Help your patients have sex the way they want it to be.

Talk to your patients about Ristela today.

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Presented at the International Society for the Study of Women's Sexual Health Annual Meeting 2019

Poster presentation

A Review of Clinical Study Data on Ristela™, a Supplement Blend for Improved Sexual Function in Women

Sharon Parish, MD, Susan Kellogg-Spadt, CRNP, PhD

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The Journal of Sexual Medicine 2019

Abstract

Introduction: Sexual dysfunction is a prevalent condition among adult females of various age groups including postmenopausal women. Ristela™, a patented formula of scientifically established nutritional ingredients, has been used for years in European countries to improve female sexual function. The formulation is composed of Pycnogenol® (French Maritime Pine Bark extract), amino acids L-Arginine and L-Citrulline, and a proprietary rose hip extract. Pycnogenol is a powerful antioxidant that has been studied in more than 160 clinical trials. It works synergistically with the other ingredients to enhance nitric oxide production, enhance blood flow, and allow for increased nutrients and oxygen to reach sensitive tissues in the body, including the reproductive organs and brain. Research suggests that Ristela improves vaginal dryness and overall sexual function.

Objective: Review of published randomized controlled trials (RCTs) that investigated the safety and efficacy of Ristela on female sexual function.

Methods: Three RCTs, evaluating a total of 263 women on Ristela were reviewed. All studies were 60 days in length and used the total score on the Female Sexual Function Index (FSFI), a validated questionnaire that assesses sexual functioning in women, specifically the domains of sexual desire, arousal, orgasm, satisfaction, and pain. All women had moderate sexual dysfunction, as determined by baseline FSFI scores. Total antioxidant capacity (TAC) and plasma free radicals (PFR) were assessed by measuring oxidative inhibition, reactive oxygen metabolites, and antioxidant potential in the plasma. Distress was not assessed in these trials.

RCT1: The first trial was conducted in 83 healthy postmenopausal women (45-55 years) using a single-blind, placebo-controlled design. After one month, total FSFI score improved by 59.0% in the Ristela group vs. 2.0% in the control group. After two months, total FSFI score improved by 60.8% in the Ristela group vs. 7.5% in the control group.

RCT2: The second trial was conducted in 80 healthy perimenopausal women (40-50 years) using a randomized, double-blind, placebo-controlled, parallel group design. After one month, total FSFI score improved by 60% in the Ristela group vs. 40% in the control group ($p < 0.001$). After two months, total FSFI score improved by 73% in the Ristela group vs. 46% in the control group ($p < 0.001$). Ristela significantly improved climacteric symptoms evaluated by the Kupperman's index and TAC ($p < 0.05$).

RCT3: The third trial was conducted in 100 healthy premenopausal women (37-45 years) using an open label, active-controlled design. Women participated in a healthy lifestyle program with or without Ristela. After one month, total median FSFI score increased by 85.5% in the Ristela group vs. 35.3% in the control group ($p < 0.05$). After two months, total median FSFI score increased by 121.4% in the Ristela group vs. 31.5% in the control group ($p < 0.0001$). Ristela significantly decreased PFR ($p < 0.05$). There were no adverse events associated with Ristela use.

Conclusions: The results of this review suggest that Ristela use significantly improves sexual function, as well as menopausal symptoms and oxidative stress, in as early as one month, with continued improvement after two months.

Introduction

Sexual dysfunction is prevalent among adult females of various age groups. Ristela™, a patented formula of scientifically established nutritional ingredients, has been marketed for years across Europe to improve female sexual function. Ristela is an oral supplement composed of Pycnogenol® (French Maritime Pine Bark extract), amino acids L-Arginine and L-Citrulline, and a proprietary rose hip extract. Pycnogenol is a powerful antioxidant that has been studied in more than 160 clinical trials. It works synergistically with the other ingredients to enhance nitric oxide production and increase blood flow to the genital organs, thereby increasing arousal, orgasm, lubrication and overall sexual function.

Aim

This study was conducted to review published randomized controlled trials (RCTs) that investigated the safety and efficacy of Ristela for female sexual function.

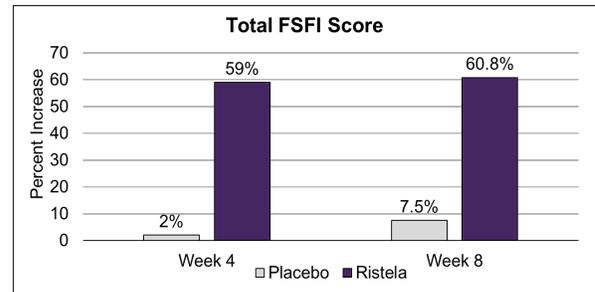
Methods

Three RCTs, evaluating a total of 263 women on Ristela were reviewed. RCT1 was conducted in 83 healthy postmenopausal women (45-55 years) using a single-blind, placebo-controlled, parallel group design. RCT2 was conducted in 80 healthy perimenopausal women (40-50 years) using a double-blind, placebo-controlled, parallel group design. RCT3 was conducted in 100 healthy premenopausal women (37-45 years) using an open label, active-controlled, parallel group design. Women participated in a healthy lifestyle program with or without Ristela. All studies were eight weeks long and used the total score on the Female Sexual Function Index (FSFI) as the primary endpoint. The FSFI is a 19-item, validated questionnaire that assesses the key domains of female sexual function (desire, arousal, lubrication, orgasm, satisfaction, and pain). RCT3 used a 9-item version of the questionnaire, which includes all domains. Subjects had moderate sexual dysfunction (determined by baseline FSFI scores). Plasma free radicals (PFR) were evaluated by measuring reactive oxygen metabolites (using the d-ROMS test) and biological antioxidant potential (using the PAT test) in whole plasma samples. Total antioxidant capacity (TAC) of plasma was measured with ABTs cation radical decolorization, an assay that measures oxidative inhibition. Distress was not assessed in these trials.

Results

RCT1 (Postmenopausal Women)

Total FSFI Score



Increases in mean total FSFI scores (absolute values) were significantly greater in the Ristela group compared to placebo after 4 and 8 weeks ($p < 0.05$).

Figure 1. Percent increases in mean total FSFI scores in postmenopausal women from baseline to Week 4 and 8. Total FSFI scores were not calculated using the established computational formula.

RCT2 (Perimenopausal Women)

Total FSFI Score

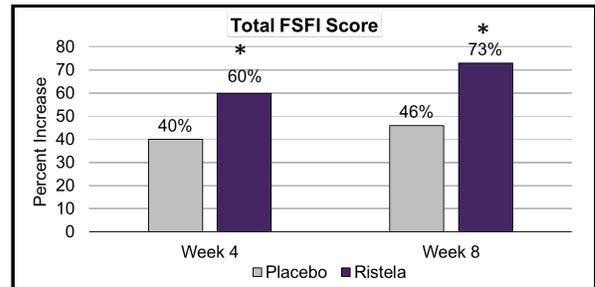


Figure 2. Percent increases in total FSFI scores in perimenopausal women from baseline to Week 4 and 8. Percent increases in total FSFI scores were significantly greater in the Ristela group compared to placebo after 4 and 8 weeks. (* $p < 0.001$)

FSFI Domain Scores

	Baseline		Week 8	
	Placebo	Ristela	Placebo	Ristela
Desire	2.13 (0.51)	2.58 (0.43)	2.67 (0.51)	4.23 (0.66)
Arousal	2.13 (0.51)	2.85 (0.59)	2.67 (0.51)	4.47 (0.62)
Lubrication	2.13 (0.51)	2.85 (0.59)	2.76 (0.56)	4.53 (0.62)
Orgasm	2.13 (0.51)	2.85 (0.59)	2.73 (0.54)	4.46 (0.64)
Satisfaction	2.13 (0.51)	2.85 (0.59)	2.73 (0.54)	4.47 (0.61)
Pain	1.77 (0.61)	2.52 (0.53)	3.06 (0.60)	4.32 (0.65)

Table 1. FSFI domain scores (SD). Differences between groups were highly significant ($p < 0.001$) for each parameter.

Blood Measurements

	Baseline		Week 8	
	Placebo	Ristela	Placebo	Ristela
SBP	124.0 (3.95)	128.13 (3.87)*	119.88 (1.79)*	114.00 (3.24)
DBP	80.25 (1.10)	81.63 (3.28)*	79.50 (1.52)*	75.00 (1.60)
TAC	1.23 (0.03)	1.25 (0.05)	1.23 (0.04)	1.48 (0.07)*

Table 2. Mean (SD) systolic and diastolic blood pressure (SBP and DBP, mmHg) and total antioxidant capacity (TAC, $\mu\text{mol Trolox}$). After 8 weeks, the Ristela group had higher TAC and lower BP compared to placebo. (* $p < 0.05$)

RCT3 (Premenopausal Women)

Total FSFI Score

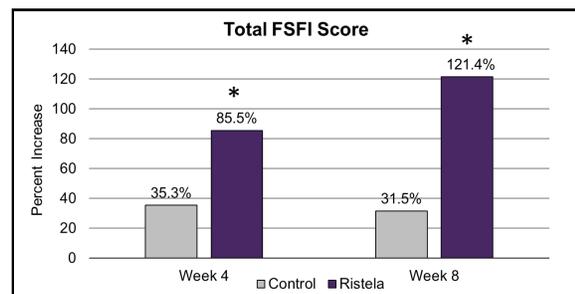


Figure 3. Percent increases in median total FSFI scores in premenopausal women from baseline to Week 4 and 8. Percent increases in total FSFI scores were significantly greater in the Ristela group compared to control after 4 and 8 weeks. (* $p < 0.05$)

Plasma Free Radicals (Carratelli Units)

	Baseline	Week 4	Week 8
Control	389 (33)	377 (32)	365 (33)
Ristela	398 (29)	344* (28)	332* (31)

Table 3. Plasma free radicals (PFR (SD)). All women had high PFR at baseline. Women on Ristela had lower levels of PFR at Week 4 and 8 compared to control. (* $p < 0.05$)

Discussion and Conclusions

This study reviewed three published clinical studies on Ristela (a blend of antioxidants and amino acids that increase blood flow to female genital organs) to evaluate its effects on female sexual function. In all studies, subjects on Ristela reported improvements in overall sexual function in as early as four weeks, with continued improvement up to eight weeks. After eight weeks of treatment with Ristela, women in all three studies reported improvements across all FSFI domains. No side effects due to treatment were observed in any study. These results suggest that Ristela is a safe, effective treatment option for improving sexual response in pre, peri, and postmenopausal women.

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1. Bottari A. et al. Lady Prelox[®] improves sexual function in post-menopausal women. *Panminerva Med.* 2012;54.
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Ristela is sold in other countries under the registered trade name Lady Prelox[®]
 This reprint has been slightly edited from the original abstract

Presented at the International Society for the Study of Women's Sexual Health Annual Meeting 2020

Poster presentation

The effect of Ristela supplementation on female sexual function in women taking antidepressants: an open-label trial

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Abstract

Introduction: Impaired sexual desire, arousal, and orgasm are common in women taking antidepressants. Ristela® is a hormone-free supplement that has been shown to improve female sexual function in three randomized controlled trials. Comprised of Pycnogenol® (French Maritime Pine Bark extract), L-Arginine, L-Citrulline, and a proprietary rose hip extract, Ristela is formulated to increase nitric oxide production, blood flow, and delivery of nutrients and oxygen to tissues including the reproductive organs and brain. A recent experience trial confirmed data from previous clinical trials, showing that Ristela improves female sexual function and satisfaction, decreases distress, and enhances women's relationship satisfaction and quality of life. However, Ristela has not been specifically studied in women taking antidepressants, a medication class associated with impairment in female sexual function.

Objective: An open-label experience trial was conducted to determine the effects of Ristela on sexual function and satisfaction in women taking antidepressants.

Methods: Thirty peri and postmenopausal women (37-74 years) taking antidepressants were recruited from a sexual medicine practice in the U.S and provided with eight weeks of free study product. Women were taking selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and atypical antidepressants. Participants were required, at baseline, to self-report any aspect of their sexual function (desire, arousal, orgasm) as "low" or "very low or none at all." Participants were allowed to remain on preexisting medications and not precluded from social alcohol intake.

Participants were instructed to take Ristela, two tablets daily, for eight weeks and provide feedback on their experience via online questionnaires after two, four, and eight weeks. Questionnaires consisted of the 9-item version of the validated Female Sexual Function Index (FSFI) and additional questions related to relationship quality and distress related to sexual function. FSFI scores were not adjusted. After completion of each questionnaire, subjects were compensated with a \$25 gift card.

Results: Scores of each FSFI question improved in as early as two weeks, with continued improvements over eight weeks. At eight weeks, Ristela improved scores of individual questions (over baseline levels) on arousal, orgasm, and desire in 65%, 61%, and 55% of women, respectively. In addition, 73% of women reported that their sexual relationships improved since taking Ristela and 55% reported that Ristela improved their quality of life. Sixty-three percent (63%) of women reported greater emotional closeness with their partners and 82% reported lower distress about their sex lives. Eighty-six (86%) percent of respondents indicated that they would continue taking Ristela on a daily basis. The total score of the 9-item FSFI questionnaire improved by 44%.

Conclusions: Ristela improved overall sexual function and satisfaction in women taking antidepressants. While arousal and orgasm were greatly improved by Ristela, the effects on desire were not as pronounced. These effects are consistent with the primary vasoactive mechanism of action of the product. Overall, these data suggest that Ristela can be considered a possible therapy to ameliorate the negative effects of antidepressants on female sexual arousal and orgasm and improve women's overall sexual experiences and quality of life.

Introduction

Impaired sexual desire, arousal, and orgasm are common in women taking specific antidepressants. Ristela® is a hormone-free supplement that has been shown to improve female sexual function in three randomized controlled trials¹⁻⁴. Comprised of Pycnogenol® (French Maritime Pine Bark extract), L-Arginine, L-Citrulline, and a proprietary rose hip extract, Ristela is formulated to increase nitric oxide production, blood flow, and delivery of nutrients and oxygen to tissues during the female sexual arousal response, including the reproductive organs and brain. A recent experience trial confirmed data from previous clinical trials, showing that Ristela improves female sexual function and satisfaction, decreases distress, and enhances women's relationship satisfaction and quality of life⁵. However, Ristela has not been specifically studied in women taking certain antidepressants, a medication class associated with impairment in female sexual function.

Aim

An open-label experience trial was conducted to determine the effects of Ristela on sexual function and satisfaction in women taking antidepressants.

Methods

Thirty peri and postmenopausal women taking antidepressants were recruited from a sexual medicine practice in the U.S. Antidepressant classes included selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and atypical antidepressants. Participants had to report their desire, arousal, or orgasm as "low" or "very low or none at all" at baseline. Participants could remain on preexisting medications and were not precluded from social alcohol intake. Participants took Ristela, two tablets daily, for eight weeks. Each tablet of Ristela contains Pycnogenol (40 mg), L-Arginine (400 mg), L-Citrulline (400 mg), and rose hip extract (100 mg). At two, four, and eight weeks, subjects filled out an online questionnaire that consisted of the 9-item Female Sexual Function Index (FSFI) and additional questions related to relationship quality and distress related to sexual function. Responses to FSFI questions were calculated as non-adjusted mean scores. Subjects were provided with free study product and were compensated with a \$25 gift card for each questionnaire that was completed.

Results

Mean FSFI Scores

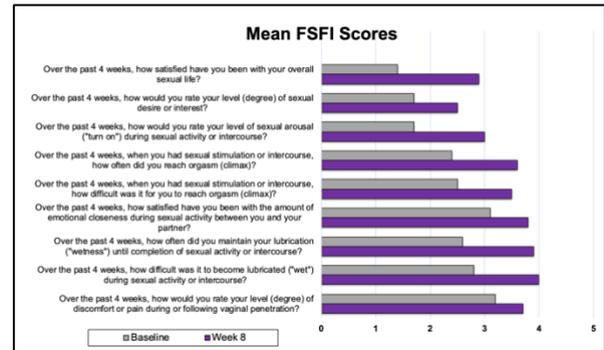


Figure 1. Mean baseline and week eight scores for the 9-item FSFI, as seen in Carpenter et al., 2016⁶. Questions were scored from 1 to 5 points, with an increase in score indicating improvement.

Response Rates

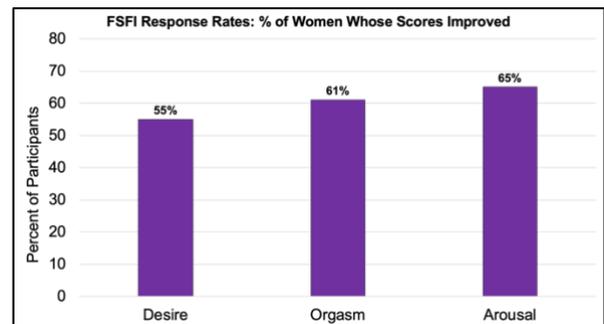


Figure 2. The percentage of women whose scores improved by ≥ 1 point, over baseline, on individual questions related to arousal, desire, and orgasm after eight weeks. At eight weeks, Ristela improved arousal in 65% of women, orgasm in 61% of women, and desire in 55% of women.

Total FSFI Score

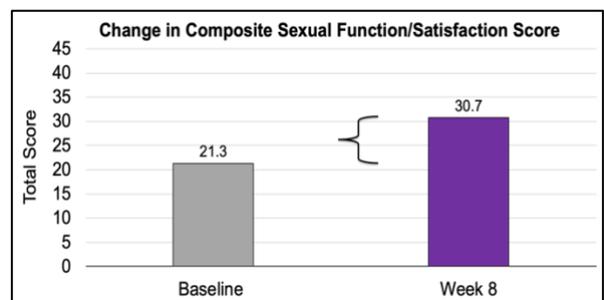


Figure 3. Change in the composite score of the 9-item FSFI. The composite score was recorded at baseline and after eight weeks of supplementation. Maximum possible score was 45. This change showed that overall sexual function/satisfaction improved by 44%

Sexual Distress, Sexual Relationship, and Quality of life

Question Focus	Percent of Women Who Showed Improvement
Distress	82%
Sexual Relationship	73%
Quality of Life	55%

Table 1. Percentage of women who showed improvements in questions focusing on distress related to sexual function, their sexual relationship, and their quality of life after eight weeks.

Discussion and Conclusions

In women, antidepressants often cause problems with arousal, orgasm, and desire. The most common adverse sexual effect reported by women taking antidepressants is problems with arousal, affecting 83% of women⁷. Ristela is a dietary supplement formulated with ingredients that can improve blood flow and enhance the female sexual arousal response. Ristela had not previously been studied specifically in women taking antidepressants. Results from the present study show that in as early as two weeks, with continued improvement up to eight weeks, Ristela improves female sexual function with no significant adverse effects in women taking various classes of antidepressants. Ristela had the greatest effect on sexual arousal and orgasm, which corresponds to its vasoactive mechanism of action. These results suggest that Ristela may ameliorate some of the sexual side effects of antidepressants and improve women's overall sexual function, satisfaction, and quality of life when taking antidepressants.

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1. Bottari A. et al. Lady Prelox[®] improves sexual function in post-menopausal women. *Panminerva Med.* 2012;54.
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Ristela is sold in other countries under the registered trade name Lady Prelox[®]