

CHARACTERIZATION OF WOMEN ACCORDING TO THEIR SEXUAL SATISFACTION AFTER TREATMENT WITH THE NOVEL VAGINAL PH MODULATOR DURING THE AMPOWER STUDY

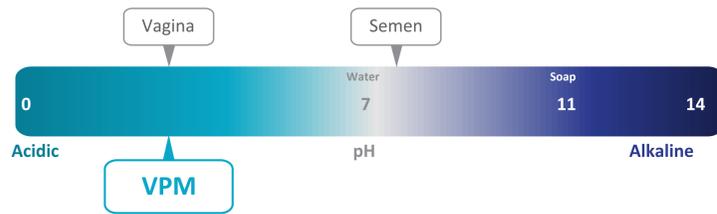
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INTRODUCTION

- The novel vaginal pH modulator (VPM; Phexxi™) is a non-hormonal, woman-controlled contraceptive vaginal gel
- VPM contains 3 active ingredients (L-lactic acid, citric acid, and potassium bitartrate) and is designed to maintain the acidic vaginal environment even in the presence of alkaline semen (Figure 1)^{1,2}

Figure 1. Acid-buffering Properties of VPM



- The phase 3 AMPOWER study assessed the efficacy and safety of VPM in 1384 healthy women; primary results have been previously reported and demonstrated that VPM was safe and met the primary endpoint for the 7-cycle cumulative pregnancy percentage³

OBJECTIVE

- Describe the characteristics of women in the phase 3 AMPOWER trial who reported better sexual satisfaction after 1 cycle of VPM use compared to those who did not

METHODS

- AMPOWER was a single-arm, open-label, multi-center trial based in the United States (NCT03243305)
- Women aged 18-35 years administered one prefilled applicator of VPM intravaginally ≤1 hour before each act of sexual intercourse
- The primary study objective was the cumulative pregnancy percentage over 7 cycles as determined by the Kaplan Meier method
- Sexual satisfaction was an exploratory endpoint, assessed via questionnaires administered at baseline and after approximately the first, fifth, and seventh cycle of VPM use
- Women assessed how VPM use impacted their sex lives using the following scale: "lot better than before"=1, "little better"=2, "no different"=3, "little worse"=4, "lot worse"=5
- Sensitivity analyses for sexual satisfaction were conducted with respect to women's demographic, obstetric, and contraceptive histories

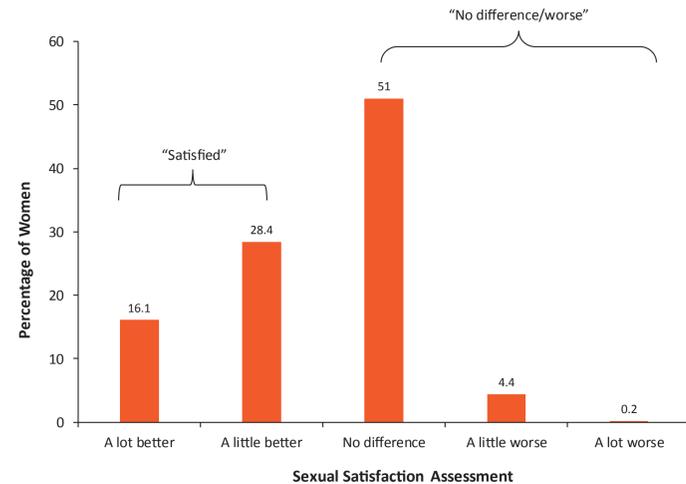
RESULTS

Overall Sexual Satisfaction Results After One Cycle of VPM

- Sexual satisfaction data were available for 1118 women enrolled in AMPOWER
- After 1 cycle of VPM use, 180 (16.1%) women reported their sex life as a lot better than before and 317 (28.4%) reported it as a little better (Figure 2)

- For this post-hoc analysis, women who reported their sex life as a lot better or a little better after 1 cycle of VPM were grouped as "satisfied," representing 497 (44.5%) women
- Women who reported no difference in their sex life or who reported that their sex life became a little or a lot worse after 1 cycle of VPM were grouped as "no difference/worse", representing 621 (55.5%) women

Figure 2. Sexual Satisfaction with VPM Compared to Baseline



- After 1 cycle of VPM, the mean sexual satisfaction score was 2.4 (standard deviation [SD], 0.8)
- A mean sexual satisfaction score improvement of 0.5 was observed after 1 cycle of VPM (P<0.0001)

Baseline Characteristics by Sexual Satisfaction Results

- Baseline characteristics, including age, ethnicity, race, and body mass index, were generally similar in women who responded after 1 cycle of VPM that they had a better sex life compared to women who responded that they had no difference or worse sex life (Table 1)

Table 1. Baseline Characteristics by Sexual Satisfaction Results

	Satisfied ^a n=497	No difference/worse ^b n=621
Age at Enrollment, yrs. (SD)	27.5 (4.64)	28.0 (4.32)
Ethnicity, n (%)		
Hispanic or Latino origin	248 (49.9)	237 (38.2)
Not Hispanic or Latino origin	247 (49.7)	379 (61.0)
Not Reported	2 (0.4)	5 (0.8)
Race, n (%)		
White	349 (70.2)	446 (71.8)
Black or African American	125 (25.2)	132 (21.3)
Asian	6 (1.2)	21 (3.4)
Other	17 (3.4)	22 (3.5)
BMI at Screening, kg/m ² (SD)	28.3 (7.6)	29.1 (8.0)

BMI, body mass index; SD, standard definition. Values are means unless otherwise indicated.

^aWomen who responded after 1 cycle of VPM use that they had a better sex life (a lot/a little better).

^bWomen who responded after 1 cycle of VPM use that they had no difference in, or a worse, sex life (a little/a lot worse).

Prior Contraceptive Use by Sexual Satisfaction Results

- The most common recently-used (last 6 months) contraceptive methods were male condom, oral contraceptive, and withdrawal (Table 2)
- Among women recently using male condoms, 48.7% reported satisfaction, 51.3% reported no difference/worse
- Among women recently using oral contraceptives, 37.6% were satisfied, 62.4% were no difference/worse
- Among women recently using withdrawal method, 40.5% experienced improvement, 59.5% reported no difference/worse
- Among women reporting satisfaction, 19.1% had recently used male condoms, 7.0% used oral contraceptives, and 3.0% used withdrawal method
- Among women reporting no difference/worse satisfaction, 16.1% had recently used male condoms, 9.3% used oral contraceptives, and 3.5% used withdrawal method

Table 2. Recent Contraceptive Use by Sexual Satisfaction Results^a

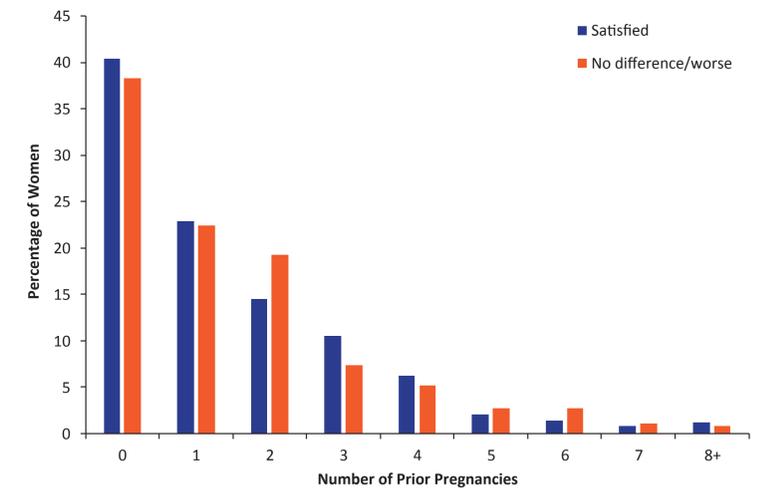
	Satisfied n=497 n (%)	No difference/worse n=621 n (%)
Male Condom	95 (19.1)	100 (16.1)
Oral Contraceptive	35 (7.0)	58 (9.3)
Withdrawal Method	15 (3.0)	22 (3.5)
Emergency Contraception	7 (1.4)	14 (2.3)
Vaginal Ring	6 (1.2)	9 (1.4)
Rhythm Method (Fertility Awareness)	6 (1.2)	7 (1.1)
Progestin IUD	5 (1.0)	8 (1.3)
Female Condom	5 (1.0)	8 (1.3)
Abstinence	4 (0.8)	2 (0.3)
Contraceptive Patch	3 (0.6)	3 (0.5)
Contraceptive Implant	3 (0.6)	6 (1.0)
Spermicide	3 (0.6)	4 (0.6)
Non-Hormonal IUD	2 (0.4)	4 (0.6)
Diaphragm, Cervical Cap, or Sponge	2 (0.4)	0
Injectable Contraceptive	0	1 (0.2)
Other	0	1 (0.2)

^aUsed within last 6 months.

Obstetric History by Sexual Satisfaction Results

- Mean (±SD) number of past pregnancies was similar between groups (1.4±1.9 satisfied; 1.5±1.8 no difference/worse)
- Among women reporting sexual satisfaction, 40.4% had no past pregnancies, 54.1% had 1-4, and 5.4% had ≥5; among women reporting no difference/worse satisfaction, 38.3% had no past pregnancies, 54.3% had 1-4, and 7.4% had ≥5 (Figure 3)
- Mean (±SD) number of full-term deliveries was also similar between groups (0.9±1.3 satisfied; 0.9±1.2 no difference/worse)

Figure 3. Number of Prior Pregnancies by Sexual Satisfaction Results



CONCLUSIONS

- Demographic characteristics, recent contraceptive methods, and obstetric history were comparable between women who reported better sexual satisfaction with VPM and those who reported no difference or worse sexual satisfaction

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DISCLOSURES

MAT: Research, Evoform Biosciences, Inc.

KC, BH: Employees, Evoform Biosciences, Inc.

CD: Employee, Health Decisions, which received funding from Evoform Biosciences, Inc., to help conduct this study.