SEXUAL SATISFACTION WITH PHEXXI®, A HORMONE-FREE VAGINAL CONTRACEPTIVE: RESULTS FROM THE AMPOWER CLINICAL TRIAL

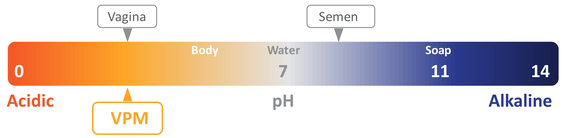
Michael A. Thomas, MD[1]; Kelly Culwell, MD, MPH[2]; Clint Dart, MS[3]; Brandon Howard, PhD[2]

[1]University of Cincinnati, Cincinnati, OH, USA; [2]Evofem Biosciences, Inc., San Diego, CA, USA; [3]Health Decisions Inc., Durham, NC, USA.

INTRODUCTION

- Current guidelines recommend women who have been diagnosed with or are receiving treatment for cancer to avoid hormonal contraceptive methods due to the possibility of hormone-related risks and sensitivities, and to seek reversible and/or hormone-free methods[1]
- The vaginal pH modulator (VPM; Phexxi®) was developed as a novel, woman-controlled, vaginal gel for the prevention of pregnancy and sexually transmitted infections[2,3]
  - Compared with other vaginally administered products such as spermicides and vaginal rings that may contain surfactants, VPM is a surfactant-free, water-based, non-hormonal, non-systemic vaginal gel[4]
  - VPM has acid-buffering properties and is able to maintain the acidic vaginal environment (pH 3.5-4.5) even in the presence of alkaline semen
  - VPM has bioadhesive and viscosity-retaining properties designed to contribute to the effectiveness of the gel[2] (**Figure 1**)

Figure 1. VPM Has Unique Acid-buffering Properties and Can Maintain the Acidic Vaginal Environment



VPM, vaginal pH modulator.

- AMPOWER was a phase 3 contraceptive trial that evaluated the efficacy, safety, and acceptability of VPM[4]
  - Sexual satisfaction was examined as an exploratory outcome
- AMPOWER is the first large-scale trial to evaluate sexual satisfaction with a contraceptive method
  - Water-based vaginal lubricants such as VPM are associated with increased sexual pleasure and satisfaction[3,5]

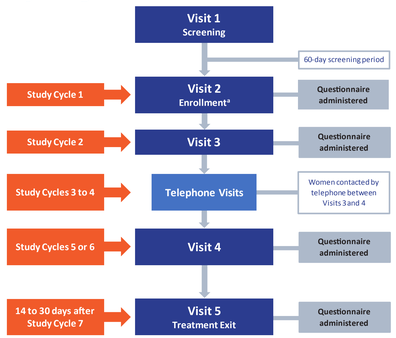
AIM

- Given the lubricating properties of VPM, the objective of the current analysis is to report on sexual satisfaction and function in women participating in the AMPOWER trial

METHODS

- AMPOWER (NCT03243305) was a phase 3, single-arm, open-label, IRB-approved trial in women aged 18-35 years and conducted at 112 US sites (**Figure 2**)
  - The primary efficacy endpoint was 7-cycle cumulative pregnancy rate and the secondary objectives included safety of VPM over 7 cycles of use
  - Sexual satisfaction and function with VPM were exploratory endpoints
- Women were instructed to administer VPM intravaginally immediately before or up to 1 hour before each episode of vaginal intercourse

Figure 2. AMPOWER Study Design



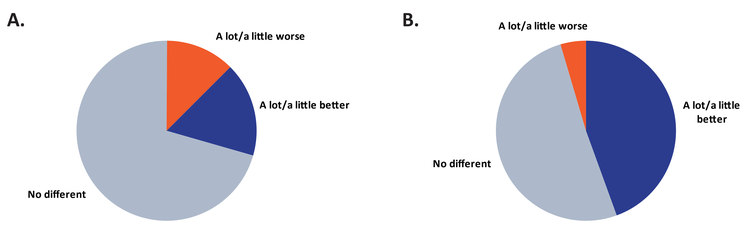
[a]The cycle during which enrollment occurred was considered cycle 0. The woman's 7 study cycle was cycles 0 to 6 if the time from enrollment to the woman's next menstrual period was ≥21 days. If the time from enrollment to the woman's next menstrual period was <21 days, the woman's 7 study cycles were cycles 1 to 7.

- To assess sexual satisfaction and function, 3 questionnaires (sexual satisfaction, Female Sexual Function Index [FSFI], and sexual function) were administered at baseline (Visit 2) and at Visits 3-5
- The **sexual satisfaction** questionnaire evaluated:
  - The impact that the woman's prior contraceptive and VPM had on her sex life
- The **FSFI** provides scores on six domains of sexual function. Results were summarized only for the lubrication question:
  - How difficult was it to maintain lubrication until completion of sexual activity or intercourse with VPM?
- The **sexual function** questionnaire assessed if VPM impacted:
  - Vaginal dryness during sexual activity
  - Lack of sexual interest or desire
  - Vaginal tightness
  - Pain during penetration or intercourse
  - Anxiety about your sexual performance
  - Unable to orgasm
  - Vaginal bleeding or irritation from penetration or intercourse
  - Increased sensitivity of your skin to intimate touching
  - Sharp pain inside or outside your vagina
  - Other problem with sexuality

RESULTS

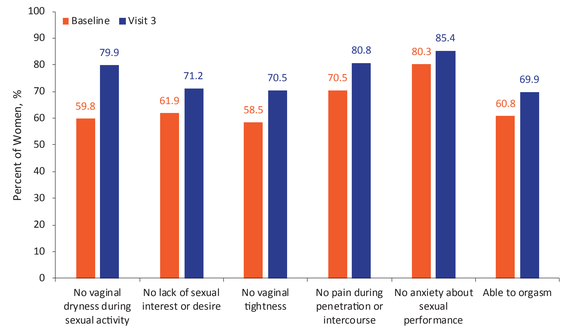
- Of the 1,384 women enrolled in AMPOWER, 1,330 used at least 1 application of the study drug and were included in the sexual satisfaction/function questionnaire analyses
- At baseline, most women (70.7%, 934/1,322) reported that sexual satisfaction with their most recent contraceptive method in the 4 weeks prior to study enrollment was "no different" than before (**Figure 3A**)
- Over twice as many women reported positive impacts on sexual satisfaction after 1 cycle of VPM use at Visit 3, with 44.5% (497/1,118) reporting their sex life "a lot" or "a little" better than before, compared with how women reported their previous contraceptive method impacted their sexual satisfaction at baseline (16.9%, 224/1,322) (**Figure 3B**)
- Positive impacts to women's sexual satisfaction with VPM were maintained throughout study, with approximately half of women surveyed reporting improvements at Visits 4 and 5

Figure 3. Women's Sexual Satisfaction With A) Their Prior Contraceptive Method in the 4 Weeks Prior to Enrollment (n=1,322) and With B) VPM at Visit 3 (n=1,118)



- With VPM, more women reported no difficulty in maintaining lubrication at Visit 3 (82.5%, 923/1,119) compared with baseline (73.9%, 980/1,326)
  - Similarly, there was a decrease in the proportion of women reporting difficulty maintaining lubrication at Visit 3 (17.5%, 196/1,119) compared with baseline (26.1%, 346/1,326)
  - The proportion of women who reported vaginal dryness also decreased from baseline to Visit 3, and throughout study
- Most women surveyed at Visit 3 reported improvements in sexual function measures compared with baseline, and reported **not** experiencing vaginal dryness (79.9% vs 59.8%); lack of sexual desire/interest (71.2% vs 61.9%); vaginal tightness (70.5% vs 58.5%); pain during intercourse (80.8% vs 70.5%); anxiety about sexual performance (85.4% vs 80.3%); and inability to orgasm (69.9% vs 60.8%) (**Figure 4**)
  - Most women reported "seldom" or "not at all" at baseline and showed little changes at any visit for the following issues: vaginal bleeding or irritation from penetration or intercourse, increased sensitivity of skin to intimate touching, sharp pain inside or outside vagina, and other problems with sexuality

Figure 4. Improvements in Sexual Function Measures with VPM at Visit 3



CONCLUSIONS

- In AMPOWER, approximately half (44.5%) of women surveyed reported "a lot" or "a little" improvement in their sexual satisfaction with VPM compared with 16.9% reporting these levels of improvement at baseline with their previous contraceptive method
- After 1 cycle of use, most women reported improvements in many sexual function measures, which were maintained throughout the study
- VPM has the potential of fulfilling an unmet need in women's sexual and reproductive health as a non-hormonal, woman-controlled, contraceptive option that offers a high level of sexual satisfaction

REFERENCES

1. Patel A, et al. *Contraception*. 2012;86:191-198.
2. Garg S, et al. *Contraception*. 2001;64:67-75.
3. Bayer LL, et al. *Contraception*. 2014;90:11-18.
4. Thomas MA, et al. *Contraception X*. 2020;2:100031.
5. Herbenick D, et al. *J Sex Med*. 2011;8:202-212.

ACKNOWLEDGEMENTS

The study was sponsored by Evofem Biosciences, Inc. Medical writing assistance was provided by PharmaWrite, LLC (Princeton, NJ, USA) and funded by Evofem Biosciences, Inc. (San Diego, CA, USA).

DISCLOSURE

MAT: *Research, Evofem Biosciences, Inc.*
KC: *Employee, Evofem Biosciences, Inc.*
CD: *Employee, Health Decisions, which received funding from Evofem Biosciences, Inc. to help conduct this study.*
BH: *Employee, Evofem Biosciences, Inc.*

For questions, please contact the corresponding author:
Brandon Howard, PhD, Head of Medical Affairs, Evofem Biosciences, Inc.
bhoward@evofem.com

Presented at the National Community Oncology Dispensing Association (NCODA) International 2021 Spring Forum Virtual E-Meeting; April 28-30, 2021.