COMPLIANCE WITH VAGINAL PH MODULATOR IN THE PHASE 3 AMPOWER CONTRACEPTIVE TRIAL

#224

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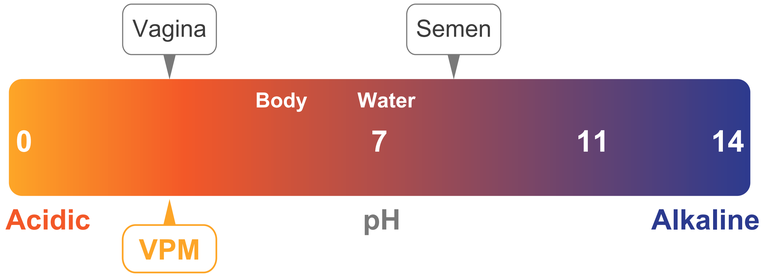
INTRODUCTION

- Phexxi®, the novel vaginal pH modulator (VPM) was developed as a non-hormonal, bioadhesive woman-controlled contraceptive vaginal gel for the prevention of pregnancy[1,2]
  - 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[1] (**Figure 1**)
  - VPM has bioadhesive and viscosity-retaining properties designed to form a barrier layer over the vaginal and cervical surfaces[1]

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



AIM

- The objective of the current analysis is to report on compliance with VPM use in women participating in the AMPOWER trial
  - Compliance with VPM use and the treatment protocol were exploratory outcomes

METHODS

- AMPOWER (NCT03243305) was a phase 3, single-arm, open-label, IRB-approved study in women aged 18–35 years conducted at 112 US sites[3]
  - The primary efficacy endpoint was 7-cycle cumulative pregnancy rate and the secondary objectives included safety of VPM over 7 cycles of use
- In AMPOWER, compliance with VPM use was defined as:
  - Administration of VPM intravaginally ≤1 hour before each episode of intercourse
  - Re-application with additional acts of intercourse
  - No use of an additional contraceptive method
- To calculate treatment compliance, the proportion of the following among all acts of intercourse were calculated from eDiary entries:
  - 1) only VPM and used as directed
  - 2) VPM only but not used as directed
  - 3) VPM and other contraceptive used
  - 4) other contraceptive only used
  - 5) no VPM or other contraceptive used

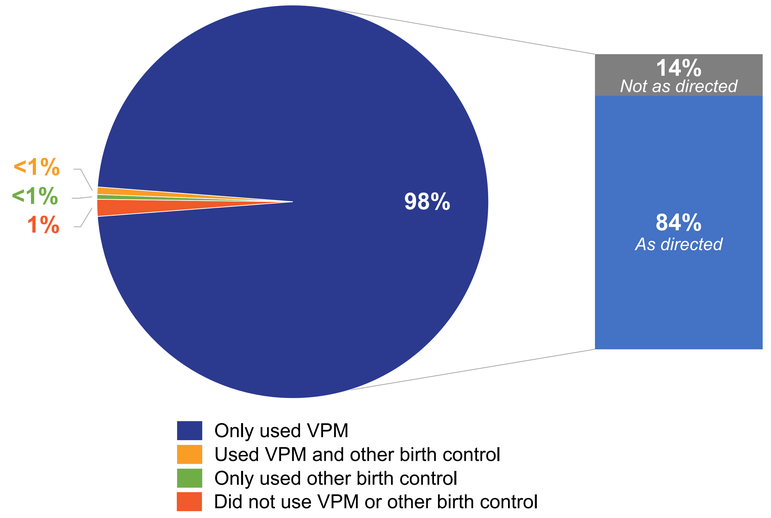
METHODS (CONT.)

- Daily electronic diaries were used to record coital information, VPM use, use of other birth control methods, and any symptoms that she or her partner may have experienced
- Compliance was calculated based on the percentage of total coital acts reported by each woman throughout the duration of her enrollment in the study

RESULTS

- AMPOWER enrolled a total of 1384 women[3]
  - VPM demonstrated 86.3% contraceptive effectiveness with typical use and 93.3% with perfect use, and was well-tolerated and highly acceptable[3,4]
- Of 1384 women enrolled in AMPOWER, 1330 women reported ≥1 use of VPM and 1255 women recorded ≥1 coital act
- Of 32,680 total acts of intercourse, VPM was used as the only contraceptive method in 98% of coital acts (**Figure 2**)
  - VPM was used correctly and as the only contraceptive method 84% of the time
  - Fewer than 3% of total acts of intercourse recorded were with VPM and another method, with another method alone, or with no contraceptive method at all

Figure 2. Summary of Compliance by Contraceptive Method in AMPOWER

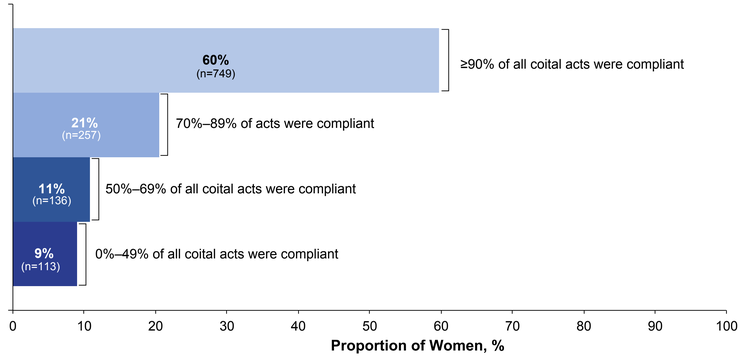


VPM, vaginal pH modulator.

- Among the 1255 women who recorded at least one coital act, 60% of women were compliant with the proper use of VPM for ≥90% of all coital acts (**Figure 3**)

RESULTS (CONT.)

Figure 3. Proportion of Women Who Were Compliant With VPM Use by Frequency of Coital Acts



VPM, vaginal pH modulator.

- Among the 1255 women who recorded at least one coital act, 51% of women were compliant with study instructions for 100% of their coital acts during the study
- There were 49% of women who reported intercourse occurring more than 1 hour after VPM application, but these departures occurred in 0%–5% of total coital acts with reported VPM use

CONCLUSIONS/IMPLICATIONS

- **Overall, most women enrolled in AMPOWER used VPM correctly and as the only contraceptive method for most coital acts throughout the study**

REFERENCES

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DISCLOSURES

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

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