CHARACTERIZATION OF WOMEN WHO EXPERIENCED URINARY TRACT INFECTIONS IN THE PHASE 3 AMPOWER TRIAL

Bassem Maximos, MD, MPH[1]; Clint Dart, MS[2]; Brandon Howard, PhD[3]

[1]Maximos Obstetrics and Gynecology, League City, TX, USA; [2]Health Decisions, Inc., Durham, NC, USA; [3]Evofem Biosciences, Inc., San Diego, CA, USA.

2009233

INTRODUCTION

- Vaginal pH modulator (VPM; Phexxi®) is a non-hormonal, on-demand, woman-controlled gel for the prevention of pregnancy
- VPM is available by prescription-only in the US
- When VPM is inserted intravaginally, its active ingredients (lactic acid, citric acid, and potassium bitartrate) act as a buffer to maintain the acidic vaginal environment even in the presence of alkaline semen, resulting in immobilization of sperm[1-3]
- In the single-arm, open-label, phase 3 AMPOWER study, VPM resulted in a seven-cycle cumulative pregnancy percentage of 13.7% with typical use and 9.99% with perfect use[4,5]
- The most common adverse events (≥2%; N=1330) included vulvovaginal burning sensation (20.0%), vulvovaginal pruritus (11.2%), urinary tract infection (5.7%), vulvovaginal pain (3.8%), vulvovaginal mycotic infection (2.9%), bacterial vaginosis (2.8%), and nasopharyngitis (2.6%)[4]
- Overall, less than 1% of women discontinued from AMPOWER due to genitourinary symptoms[4]

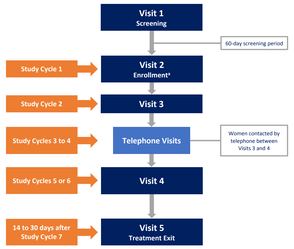
OBJECTIVE

- The objective of this post hoc analysis was to characterize women who experienced urinary tract infections (UTIs) while using VPM in the AMPOWER trial

METHODS

- AMPOWER was a phase 3, single-arm, multicenter (112 sites) study that evaluated the contraceptive efficacy/safety of VPM over 7 cycles of use in sexually active women aged 18-35 years (**Figure 1**; NCT03243305)

Figure 1. AMPOWER Study Design

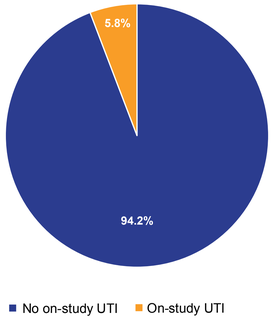


- Exclusion criteria included ≥3 UTIs in the past year or an active UTI at screening
- In this post hoc analysis, women who experienced an on-study UTI were assessed by demographic characteristics and by reports of product use and sexual intercourse
- Any of the following Medical Dictionary for Regulatory Activities (MedDRA; version 21.0) preferred terms were counted as UTIs:
  - *Escherichia* urinary tract infection
  - *Streptococcal* urinary tract infection
  - Urinary tract infection
  - Urinary tract infection bacterial

RESULTS

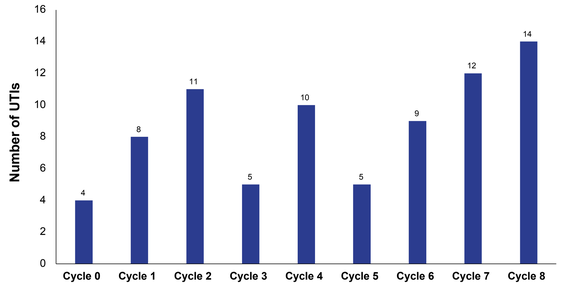
- Of the 1339 women who self-administered at least one dose of VPM and were included in the safety population (including duplicate enrollers), 77 (5.8%) experienced an on-study UTI (**Figure 2**)
  - Of the 77 women who experienced UTIs, one woman experienced an event that was classified as "urinary tract infection bacterial"; the remaining 76 women had events classified as "urinary tract infection"

Figure 2. Percentage of Women Experiencing an On-Study UTI in AMPOWER (N=1339)



- The number of on-study UTIs by cycle ranged from 4 to 14 (**Figure 3**)

Figure 3. Number of On-Study UTIs by Cycle[a]



[a]In total, 77 subjects had 81 UTIs, 3 of which could not be assigned due to lack of diary data.

- Demographic characteristics of women who experienced an on-study UTI were similar to those of the overall AMPOWER safety population (**Table 1**)

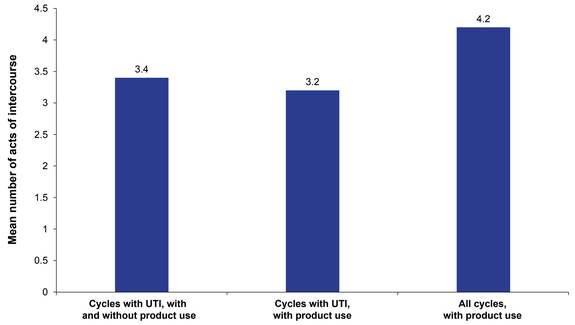
Table 1. Demographic Characteristics of Women who Experienced an On-Study UTI Compared to the Overall Safety Population

Characteristic	Population With On-Study UTI (n=77)	Overall Safety Population (N=1339)
Age at enrollment, years, mean (SD)	28.1 (4.6)	27.6 (4.5)
Ethnicity, n (%)		
Hispanic or Latino origin	33 (42.9)	555 (41.4)
Not Hispanic or Latino origin	44 (57.1)	775 (57.9)
Not reported	0	9 (0.7)
Race, n (%)		
Asian	0	34 (2.5)
Black or African American	16 (20.8)	330 (24.6)
American Indian or Alaska Native	0	6 (0.4)
Native Hawaiian or Pacific Islander	1 (1.3)	2 (0.1)
White	58 (75.3)	931 (69.5)
Other	2 (2.6)	36 (2.7)
Weight at screening, lbs., mean (SD)	170.4 (45.4)	169.9 (49.5)
Height, inches, mean (SD)	64.8 (2.6)[a]	64.3 (3.0)[b]
Body mass index at screening, kg/m^2, mean (SD)	28.3 (7.1)[a]	28.8 (8.2)[b]

[a]n=76. [b]n=1338.

- Prior to the study, the majority of women who participated in AMPOWER had never had a UTI (59.8%, based on intent-to-treat population), and of those who had, almost a third (29.6%) had not had a UTI in the year prior to study participation
- In the cycles in which a UTI was diagnosed/reported, the mean number of all acts of intercourse per cycle (standard deviation [SD]) was 3.4 (3.8), and the mean number of acts of intercourse with product use per cycle (SD) was 3.2 (3.7) (**Figure 4**).
- By comparison, the mean number of product uses per cycle in the overall population (SD) was 4.2 (3.2)

Figure 4. Number of Acts of Vaginal Intercourse With and Without Product Use Per Cycle



CONCLUSIONS/IMPLICATIONS

- Compared to the overall AMPOWER safety population, women who experienced on-study UTIs had similar baseline characteristics and slightly lower product use
- The percentage of women who experienced an on-study UTI (5.8%) in AMPOWER was lower than the prevalence of UTIs in the general population of the US (11.0%)[6]

Disclosures

BM: Research support and consultant, Evofem Biosciences, Inc.

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

BH: Employee, Evofem Biosciences, Inc.

Acknowledgements

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

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

medicalinformation@evofem.com

References

1. Garg S, et al. *Contraception*. 2001;64(1):67-75.
2. Bayer LL, Jensen JT. *Contraception*. 2014;90(1):11-8.
3. Amaral E, et al. *Contraception*. 2004;70(6):492-7.
4. Thomas MA, et al. *Contracept X*. 2020;2:100031.
5. Chappell BT, et al. *Obstet Gynecol*. 2020;135:995.
6. Medina M, Castillo-Pino E. *Ther Adv Urol*. 2019;11:3-7.

Presented at the 2022 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical & Scientific Meeting, May 6-8, 2022, San Diego, CA, USA.