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GENITOURINARY SIDE EFFECTS WITH VAGINAL PH REGULATOR: RESULTS FROM AMPOWER

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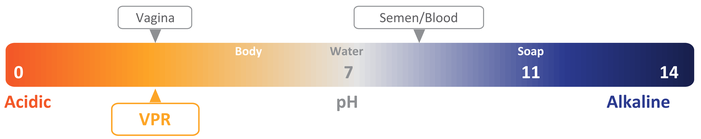
INTRODUCTION

- The investigational vaginal pH regulator (VPR™) is a novel, non-hormonal, woman-controlled, water-based, surfactant-free vaginal gel being studied for prevention of pregnancy and sexually transmitted infections
  - Provides acidic pH buffering, thereby maintaining the acidic vaginal environment to immobilize sperm, even in the presence of alkaline semen[1,2] (**Figure 1**)
  - Has bioadhesive and viscosity-retaining properties designed to contribute to the effectiveness of the gel

Figure 1. Acid-buffering Properties of VPR



VPR, vaginal pH-regulator.

AIM

- The objectives of the current analysis are to report on genitourinary (GU) side effects with VPR based on the phase 3 AMPOWER trial

METHODS

- AMPOWER was a single-arm, open-label, IRB-approved, multi-center trial based in the United States (NCT03243305)
- Women, aged 18-35 years, administered VPR intravaginally immediately before or up to 1 hour before each episode of vaginal intercourse
- The primary study objective was to measure contraceptive efficacy over 7 cycles of use
- Safety was assessed through adverse event reporting
- Incidents of GU symptoms, including vaginal burning, itching, or pain were reported by women via their eDiary at the time they recorded product use and intercourse; women were proactively asked whether they experienced any GU symptoms and, if so, when the symptoms occurred in relation to product use, the severity of the symptoms, and how long the symptoms persisted

RESULTS

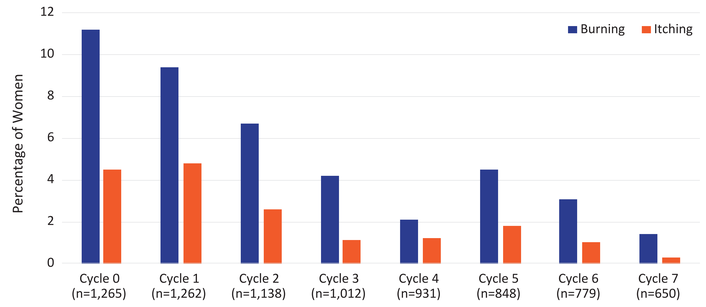
- In total, 1,384 women were included in the intent-to-treat population and 1,330 used at least 1 application of study drug and were included in the safety population
- In the safety analysis, the two most common adverse events were vulvovaginal burning sensation (burning; 20.0%) and vulvovaginal pruritus (itching; 11.2%) (**Table 1**)

Table 1. Incidence of Adverse Events Occurring in ≥2% of Women

Adverse Event (Preferred Term)	VPR (N=1,330) n (%)
Vulvovaginal burning sensation	266 (20.0)
Vulvovaginal pruritus	149 (11.2)
Urinary tract infection	76 (5.7)
Vulvovaginal pain	51 (3.8)
Vulvovaginal mycotic infection	38 (2.9)
Bacterial vaginosis	37 (2.8)
Nasopharyngitis	35 (2.6)

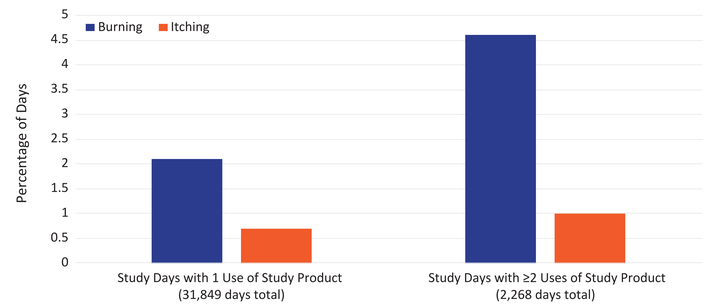
- Rates of vaginal burning and itching decreased over time (burning: Cycle 0=11.2%, Cycle 3=4.2%, Cycle 7=1.4%; itching: 4.5%, 1.1%, and 0.3%, respectively) (**Figure 2**)

Figure 2. Incidence of Genitourinary Symptoms by Cycle



- Rates of burning and itching by act of intercourse were lower when VPR was used once/day (2.1% and 0.7%, respectively) compared to 2 or more times/day (4.6% and 1.0%, respectively) (**Figure 3**)

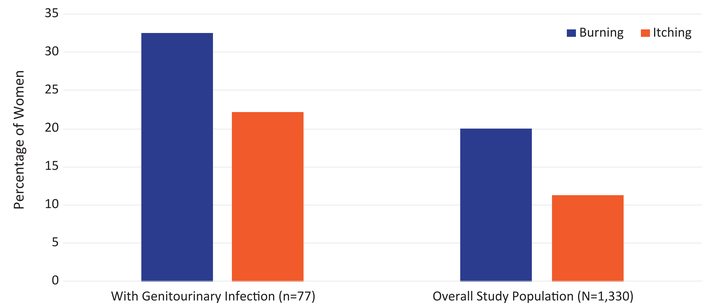
Figure 3. Incidence of Genitourinary Symptoms by Subgroups of Frequency of Product Use*



*Included duplicate enrollers (N=1,339).

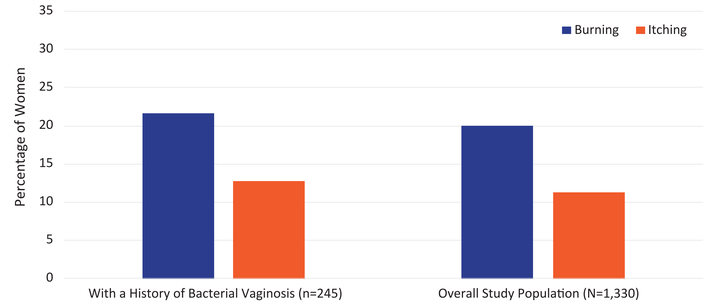
- In women who had GU infections on-study (n=77), rates of burning (32.5%) and itching (22.1%) were higher than in the overall study population (**Figure 4**)

Figure 4. Incidence of Genitourinary Symptoms in Women With Genitourinary Infections On-Study



- Women with a history of bacterial vaginosis (n=245) had similar rates of burning (21.6%) and itching (12.7%) compared to the overall study population (**Figure 5**)

Figure 5. Incidence of Genitourinary Symptoms in Women With a History of Bacterial Vaginosis



- Overall, only 1% [13/1,330] of women discontinued due to GU symptoms

CONCLUSIONS/IMPLICATIONS

- In the phase 3 AMPOWER trial, rates of the GU symptoms of burning and itching with VPR decreased substantially over time, with higher rates reported in women with existing GU infections compared to the general study population
- The rates of burning (20.0%) and itching (11.2%) with VPR were similar to those reported in a randomized crossover trial evaluating female and male condom acceptability in which 30% and 17% of women using the female and male condom, respectively, experienced burning/itching/irritation[3]
  - These rates should be considered in the context of symptoms women experience with sexual intercourse generally
- Overall, only 1% of women discontinued due to GU symptoms

REFERENCES

1. Garg S, et al. *Contraception*. 2001;64:67-75.
2. Bayer LL, et al. *Contraception*. 2014;90:11-8.
3. Kulczycki A, et al. *Perspect Sex Reprod Health*. 2004;36:114-9.

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

***BM:** A principal investigator on the pharmaceutical clinical trial, AMPOWER, sponsored by Evofem Biosciences, Inc.; **KC, BH:** Employee, Evofem Inc. **CD:** Employee, Health Decisions, which received funding from Evofem Biosciences to help conduct this study.*

Presented at the Virtual Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecology (ACOG); April 24-27, 2020.