WOMEN'S SATISFACTION WITH THE VAGINAL pH-REGULATOR (VPR™): RESULTS FROM THE PHASE 3 AMPOWER TRIAL

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P-497

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INTRODUCTION

- Research suggests that some women have concerns with hormone-based contraceptive options and that some would prefer a short-term, nondaily contraceptive option[1]
- Current contraceptive options may not be meeting individual women's needs and preferences
- The investigational vaginal pH regulator (VPR™) is a novel, non-hormonal, woman-controlled contraceptive vaginal gel that can be used "in the moment"
- VPR provides acidic pH buffering to immobilize sperm even in the presence of alkaline semen[2,3]
- VPR is being investigated for prevention of pregnancy and sexually transmitted diseases

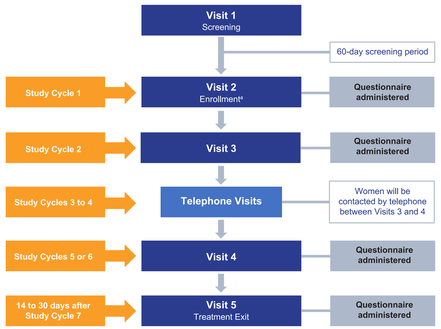
OBJECTIVE

- To better understand the treatment experience with VPR from the woman's perspective

METHODS

- The phase 3 AMPOWER trial (clinicaltrials.gov NCT03243305) was a multicenter, single-arm, open-label study of the contraceptive efficacy and safety of VPR (**Figure 1**)
- The primary endpoint was contraceptive efficacy over 7 cycles of use
- Secondary objectives included safety over 7 cycles of use
- Women's satisfaction with VPR was an exploratory endpoint
- Inclusion criteria:
  - Sexually active, healthy women at risk of pregnancy desiring contraception
  - Age range of 18 to 35 years at enrollment
  - Normal cyclic menses with a usual length of 21-35 days over the last 2 cycles OR ≥2 consecutive spontaneous menses (21-35 days in length) since delivery, abortion, or after discontinuing hormonal contraception or hormonal therapy prior to the date of consent
  - Willing to engage in ≥3 acts of heterosexual vaginal intercourse per cycle
- A satisfaction questionnaire was administered at enrollment (Visit 2) and at study Visits 3-5 and assessed the following 4 categories:
  - Satisfaction with previous birth control method and study birth control method
  - Likelihood of recommending this method to others considering a vaginal contraceptive gel
  - Likelihood of recommending this method to others considering another birth control option
  - Likelihood of continuing this method after study termination
- Responses were given on a 5-point scale (1, very satisfied/very likely; 5, dissatisfied/unlikely)

Figure 1. AMPOWER Study Design



AMPOWER, clinicaltrials.gov NCT03243305.
[a]The cycle during which enrollment occurred was considered cycle 0. The woman's 7 Study Cycles were 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.

RESULTS

- Of the 1384 women enrolled in AMPOWER, 1330 used at least 1 application of the study drug and were included in the satisfaction questionnaire analysis
- VPR was found to be safe and effective in preventing pregnancy
  - The 7-cycle cumulative pregnancy percentage with typical-use was 13.7% (upper bound 95% CI; 17.4)
  - Fewer than 2% of study participants discontinued due to adverse events (AEs) (1.7%, 23/1384), and the most common treatment-emergent AEs were vaginal burning sensation (20.0%, 266/1330) and vaginal itching (11.2%, 149/1330)
- At enrollment, 46.5% (616/1325) of women were "very satisfied" or "satisfied" with their birth control method (**Figure 2**)
- Compared with satisfaction levels at enrollment, women's satisfaction nearly doubled at Visits 3 and 4:
  - At Visits 3 and 4, 85.3% (954/1118) and 89.5% (734/820) of women, respectively, reported being "very satisfied" or "satisfied" with the study drug (**Figure 3A** and **3B**)
- At enrollment, approximately 15% (194/1325) of women were dissatisfied with their contraceptive method (**Figure 2**)
  - At Visits 3 and 4, 0.4% (5/1118) and 0.6% (5/820), respectively, reported being "dissatisfied" with the study drug (**Figure 3A** and **3B**)

Figure 2. Women's Satisfaction With Their Prior Contraceptive Method at Enrollment (n=1325)

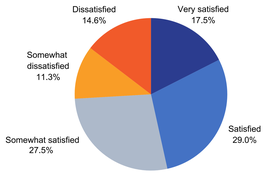
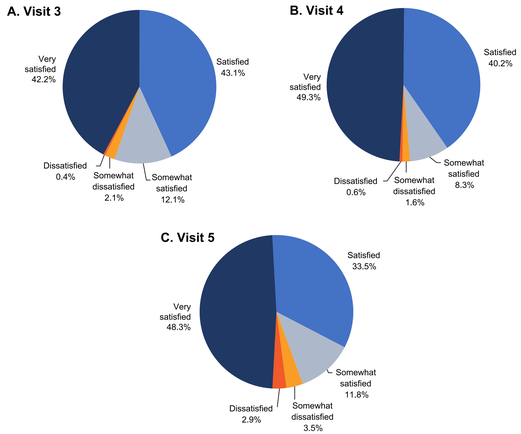


Figure 3. Women's Satisfaction With Study Drug at A) Visit 3 (n=1118), B) Visit 4 (n=820), and C) Visit 5 (n=942)



- Almost all women were in favor of recommending VPR to a friend either as a vaginal contraceptive gel method (**Figure 4**) or as an alternative contraceptive method (**Figure 5**)
  - At Visits 3 and 4, 86.6% (968/1118) and 89.8% (736/820) of women, respectively, were "very likely" or "likely" to recommend the study drug as a contraceptive vaginal gel to a friend (**Figure 4**)
  - Women surveyed at Visits 3 and 4 were "very likely" or "likely" to recommend the study drug as an alternative birth control option (85.7% [958/1118] and 88.2% [723/820], respectively) to a friend (**Figure 5**)

Figure 4. Likelihood of Recommending Study Drug as Vaginal Contraceptive Gel Method to a Friend

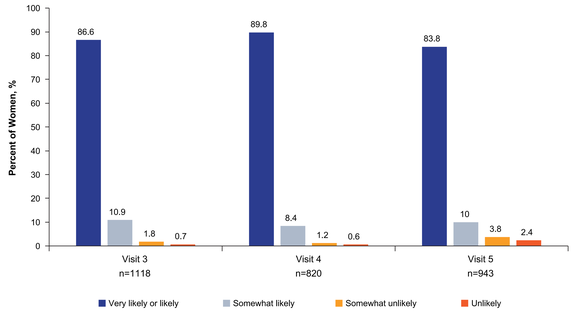
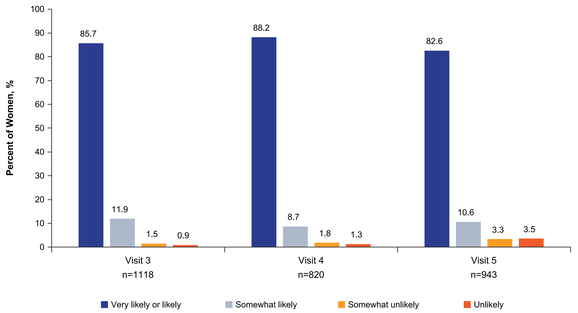
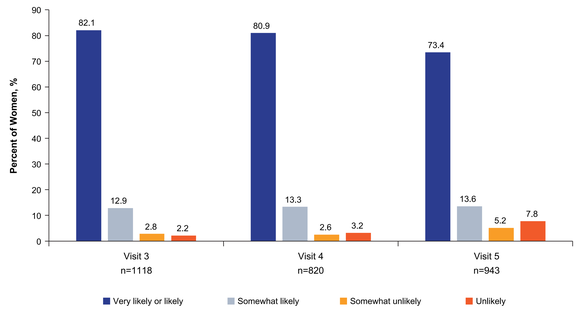


Figure 5. Likelihood of Recommending Study Drug as an Alternative Contraceptive Method to a Friend



- Most women surveyed at Visit 3 (82.1%, 918/1118) and at Visit 4 (80.9%, 664/820) were "very likely" or "likely" to continue with VPR if it were to be available, compared with 2.2% (25/1118) and 3.2% (26/820), respectively, of women who were "unlikely" to continue (**Figure 6**)

Figure 6. Likelihood of Continuing With Study Drug After Study Termination, If Available



CONCLUSIONS

- Data from the phase 3 AMPOWER trial indicate a very high level of satisfaction in women on VPR compared with their previous birth control method
- ≥85% of women on VPR would recommend the study drug to others
- ≥80% of women were in favor of continuing with VPR after study termination
- VPR 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 satisfaction

REFERENCES

1. Mansour D, et al. *Int J Women's Health*. 2014;6:367-375.
2. Garg S, et al. *Contraception*. 2001;64:67-75.
3. Amaral E, et al. *Contraception*. 2004;70:492-7.

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DISCLOSURE

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KC: Employee, Evofem Inc.
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