A Comparison of Women Who Completed or Discontinued the AMPOWER Study, a Phase 3 Contraceptive Trial for Vaginal pH Modulator

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Objective: To describe differences in patient characteristics between completers, early completers, and non-completers in women enrolled in AMPOWER, a phase 3 contraceptive trial investigating vaginal pH modulator.

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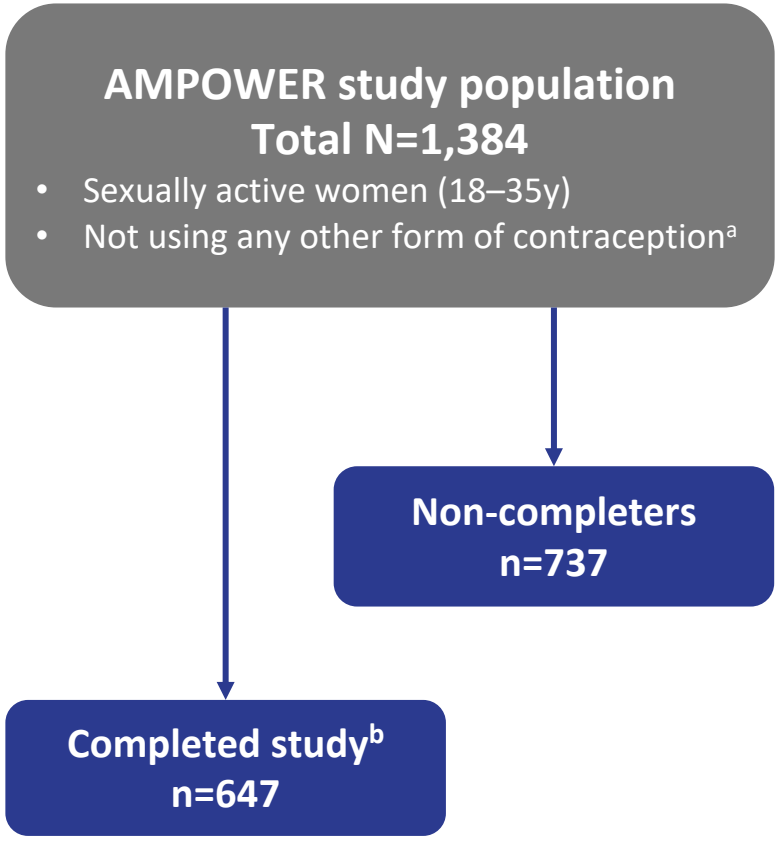
Comparison of Characteristics by Study Completion Status of Women Enrolled in AMPOWER

Potential differences were examined with respect to the following factors:

- Baseline demographics
- Prior contraceptive history
- Adverse events
- Overall satisfaction

AMPOWER (NCT03243305).

Characteristics of Women Enrolled in AMPOWER Were Analyzed for Any Differences Related to Study Completion Status



- AMPOWER was an open-label phase 3 trial evaluating the contraceptive efficacy and safety of Phexxi™ gel, a novel vaginal pH modulator (VPM) over 7 cycles of use[1]
- Among 647 women who completed the study, 449 completed 7 cycles (completers) and 198 completed ≥6 cycles (early completers) due to sites inadvertently bringing some women in early for their last visit

	Completers n=449	Early completers n=198	Non-completers n=737
Demographics			
Age, years, mean (SD)	28.2 (4.5)	28.0 (4.6)	27.2 (4.4)
BMI, kg/m^2, mean (SD)	28.4 (8.1)	28.4 (7.2)	29.1 (8.3)

- No significant differences in baseline demographics (eg, age, ethnicity, race, and BMI) among completers, early completers, and non-completers were found
- Women's contraceptive history was not related to study completion status

AMPOWER (NCT03243305). Phexxi™ is an FDA-approved, hormone-free contraceptive vaginal gel. [a]Except for use of emergency contraception, as indicated. [b]Includes 449 women who completed 7 cycles ("completers") and 198 "early completers" who had completed ≥6 study cycles but were inadvertently scheduled for their final study visit before study end. BMI, body mass index.

1. Thomas MA et al. *Contraception X.* 2000;2:100031.

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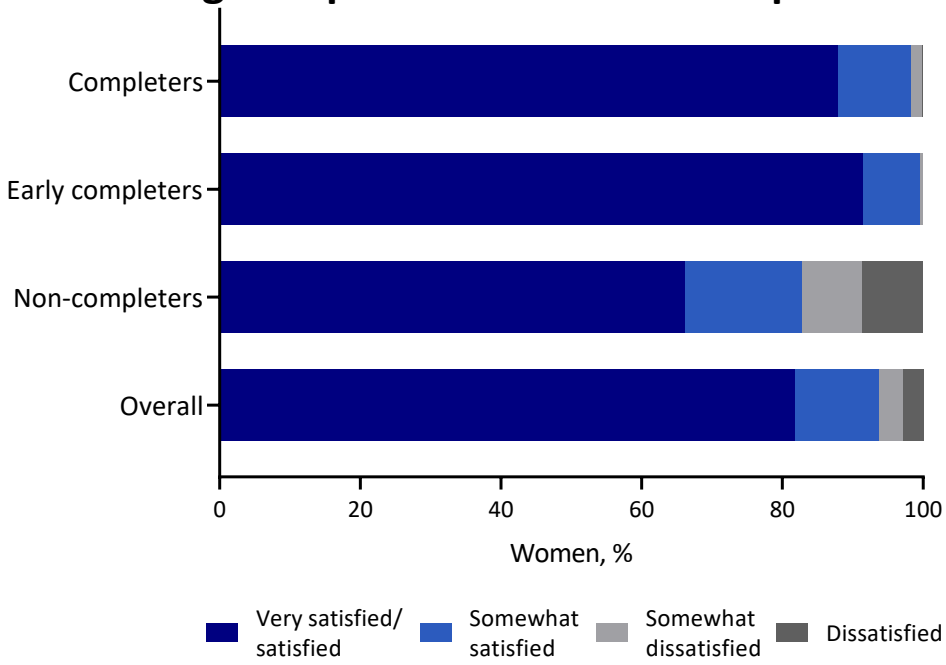
Adverse Events and Patient Satisfaction Not Associated With Study Completion Status of Women Enrolled in AMPOWER

	Completers[a] n=449	Early completers[b] n=198	Non-completers n=683
Safety, n (%)			
Vaginal burning sensation	97 (21.6)	43 (21.7)	126 (18.4)
Vaginal pruritus	55 (12.2)	26 (13.1)	68 (10.0)
Urinary tract infection	43 (9.6)	10 (5.1)	23 (3.4)
Vaginal pain	19 (4.2)	9 (4.5)	23 (3.4)
Vaginal mycotic infection	9 (2.0)	7 (3.5)	22 (3.2)

Women's Satisfaction With VPM was Higher Among Completers Than Non-Completers



Conclusions

- There were no differences in baseline characteristics, contraceptive history, and safety among completers, early-completers, and non-completers
- Non-completers experienced fewer AEs, consistent with <2% of women in the study discontinuing due to AEs
- Completers and early-completers reported similarly high levels of satisfaction, which were higher than those reported by non-completers

AMPOWER (NCT03243305). [a]Women who completed 7 cycles. [b]Women who had completed ≥6 study cycles but were inadvertently scheduled for their final study visit before study end. AE, adverse event; VPM, vaginal pH modulator.

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