

Tenofovir Gel as PrEP for African Women
CAPRISA-004

Tenofovir Gel as PrEP for African Women

CAPRISA-004: Study Design

- **Background:** Randomized, phase 2b, double-blind, placebo-controlled trial to examine the efficacy and safety of tenofovir gel as preexposure prophylaxis in sexually-active heterosexual women in South Africa
- **Inclusion Criteria** (889 enrolled)
 - Cisgender women 18-40 years of age
 - HIV-negative
 - Sexually active (vaginal sex >2x in prior 30 days)
 - Using non-barrier form of contraceptive
 - Excluded if had genital deep epithelial disruption
 - Excluded if pregnant
 - Excluded if CrCl <50 mL/min
- **Treatment Arms**
 - Placebo: per gel application schedule
 - Tenofovir gel: per gel application schedule*

Placebo Gel
(n = 444)

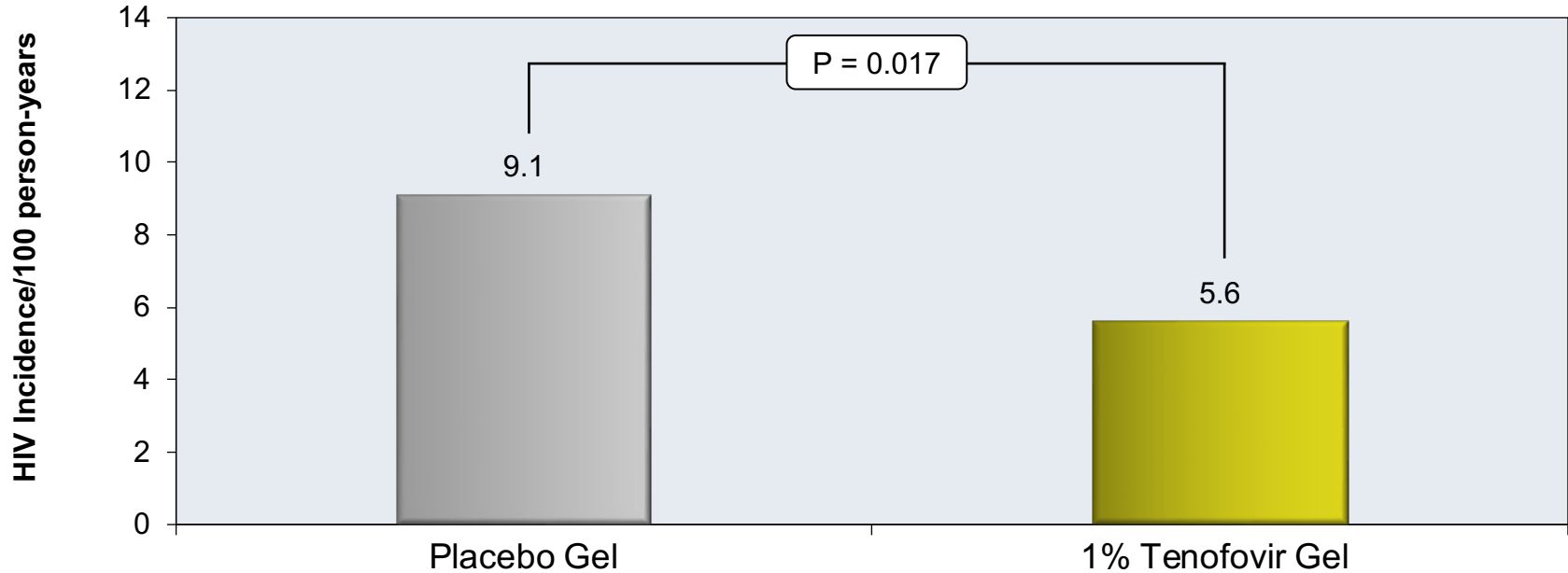
1% Tenofovir Gel
(n = 445)

*Gel Application Schedule: apply before sex and again as soon as possible after sex dose (within 12 hours). Maximum: 2 doses of gel per 24 hours

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CAPRISA-004: Results

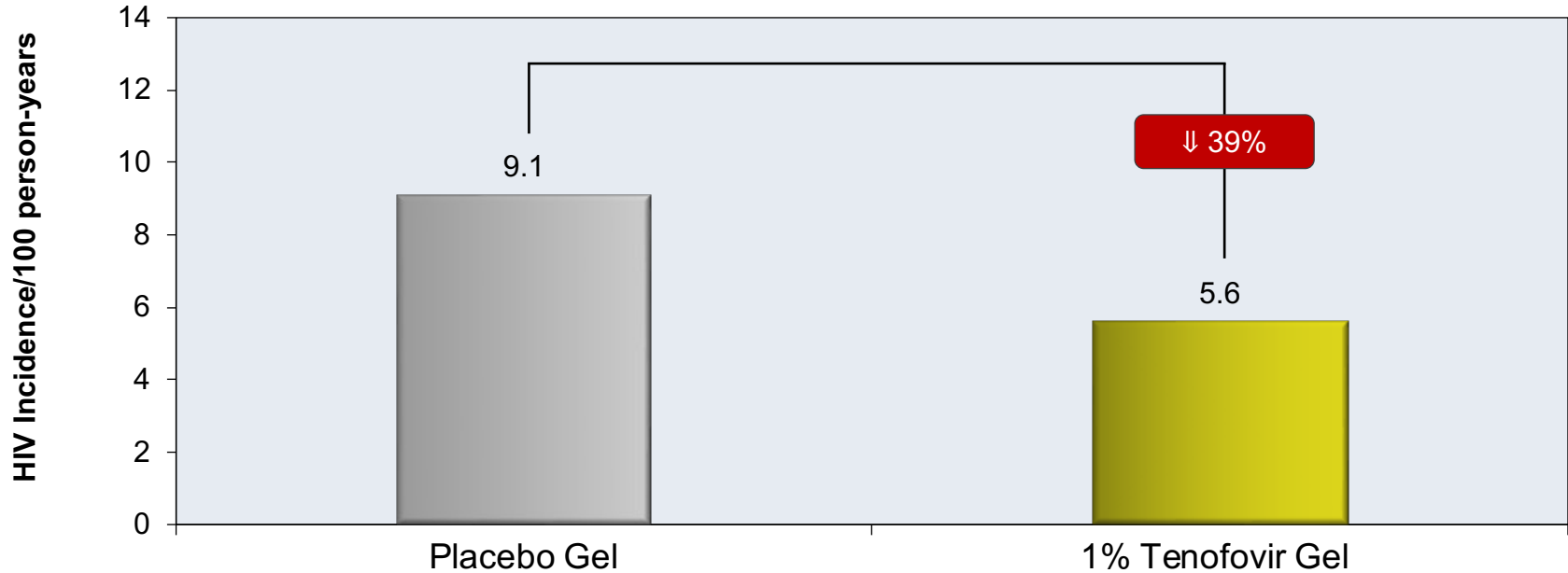
HIV Incidence



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CAPRISA-004: Results

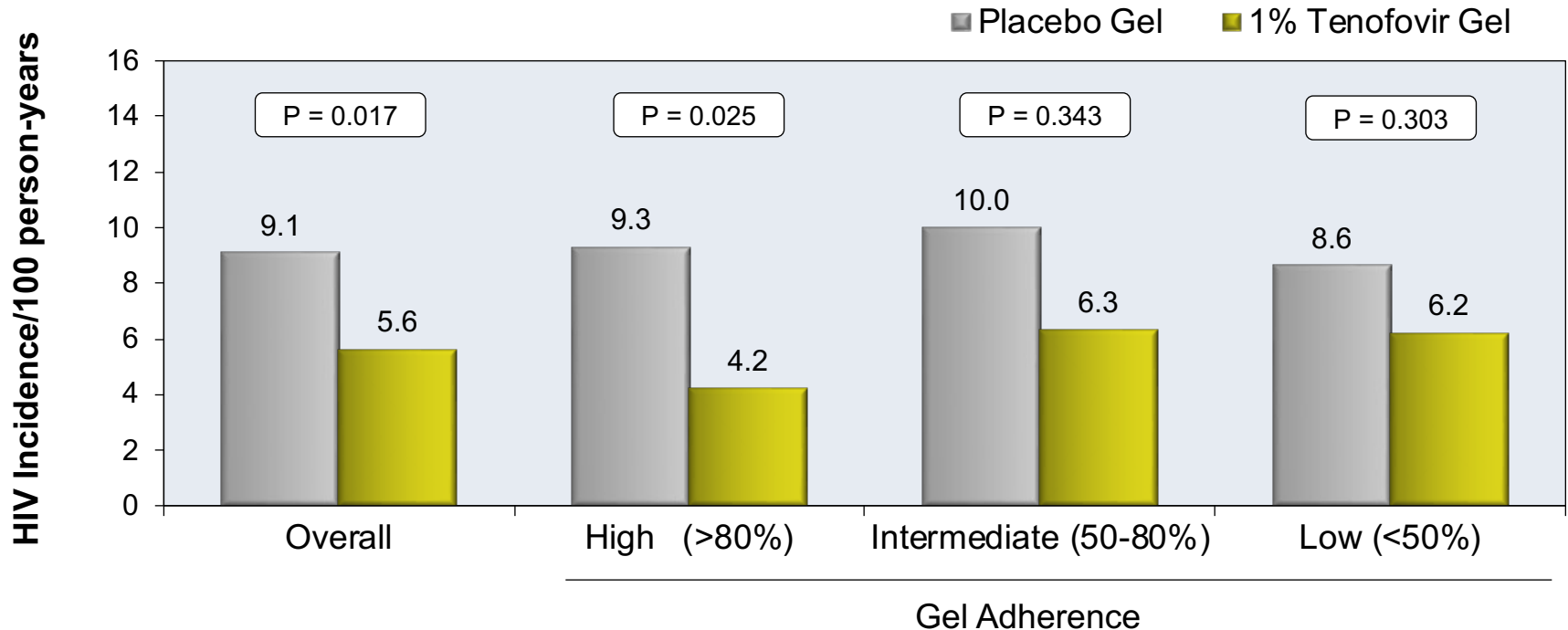
HIV Incidence and Risk Reduction



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CAPRISA-004: Results

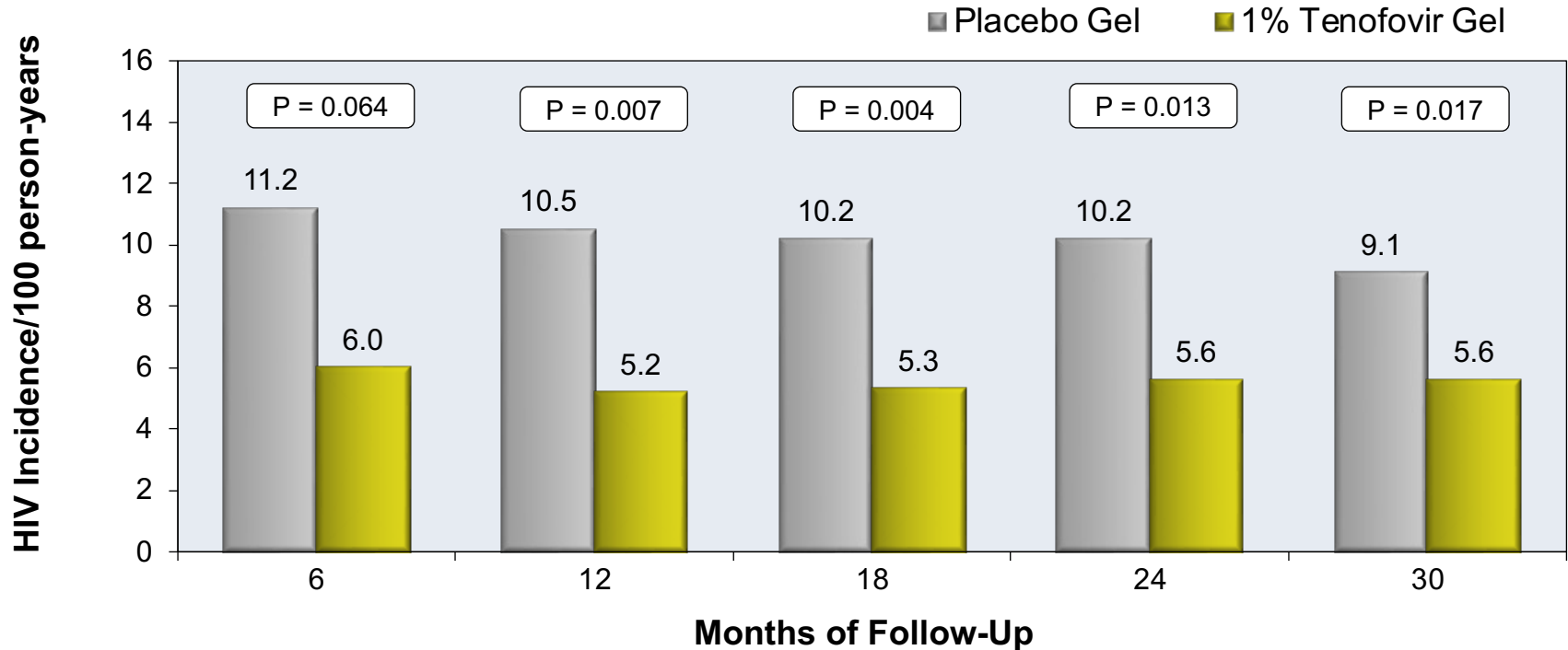
HIV Incidence Based on Adherence



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CAPRISA-004: Results (

HIV Incidence, by Months of Follow-Up



Source: Abdool Karim Q, et al. Science 2010;329:1168-74.

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CAPRISA-004: Conclusions

Conclusions: “Tenofovir gel reduced HIV acquisition by an estimated 39% overall, and by 54% in women with high gel adherence. Tenofovir gel could potentially fill an important HIV prevention gap, especially for women unable to successfully negotiate mutual monogamy or condom use.”

Acknowledgments

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