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Efficacy of a *Coriolus versicolor*-based vaginal gel on HR-HPV clearance: Final Results from the PALOMA 2 Clinical Trial.

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Introduction

The PALOMA 2 randomized clinical trial assessed the efficacy of a *Coriolus versicolor*-based vaginal gel in promoting high-risk HPV (HR-HPV) clearance among women with low-grade cervical lesions under watchful waiting.

Methods

This randomized, multicenter, prospective, open-label, parallel-group, watchful-waiting-controlled trial included unvaccinated HR-HPV-positive women aged 30–65 years with ASCUS/LSIL cytology and concordant colposcopy. Participants were randomized (1:1:1:1) to: A) Standard regimen: once daily for 1 month, then every other day for 5 months; B) Intensive regimen: once daily for 3 months, then every other day for 3 months; C) Very Intensive regimen: once daily for 6 months; D) Control group.

HR-HPV clearance was assessed at 6 and 12 months and defined as total (no detectable baseline genotypes) or partial (loss of ≥ 1 genotype with normal cytology and concordant colposcopy). Ethical approval and informed consent were obtained. Chi-square test was used.

Results

A total of 124 women (mean age 41.1 years) were included, with homogeneous baseline characteristics. Among 109 completing the 6-month visit, HR-HPV clearance rates were 57.7% (A), 88.5% (B), and 75.9% (C) versus 53.6% (D) ($p < 0.01$ for B vs D) (Figure 1). In women positive for HPV 16/18/31 ($n = 56$), clearance was 57.7% (A), 93.3% (B), and 64.3% (C) versus 30.8% (D) ($p = 0.0011$ for B vs D). At 12 months, regimen B maintained sustained clearance in 77.3% of women compared with 50.0% in controls ($p = 0.05$) (Figure 2).

Figure 1. Clearance at 6 months in HR-HPV population

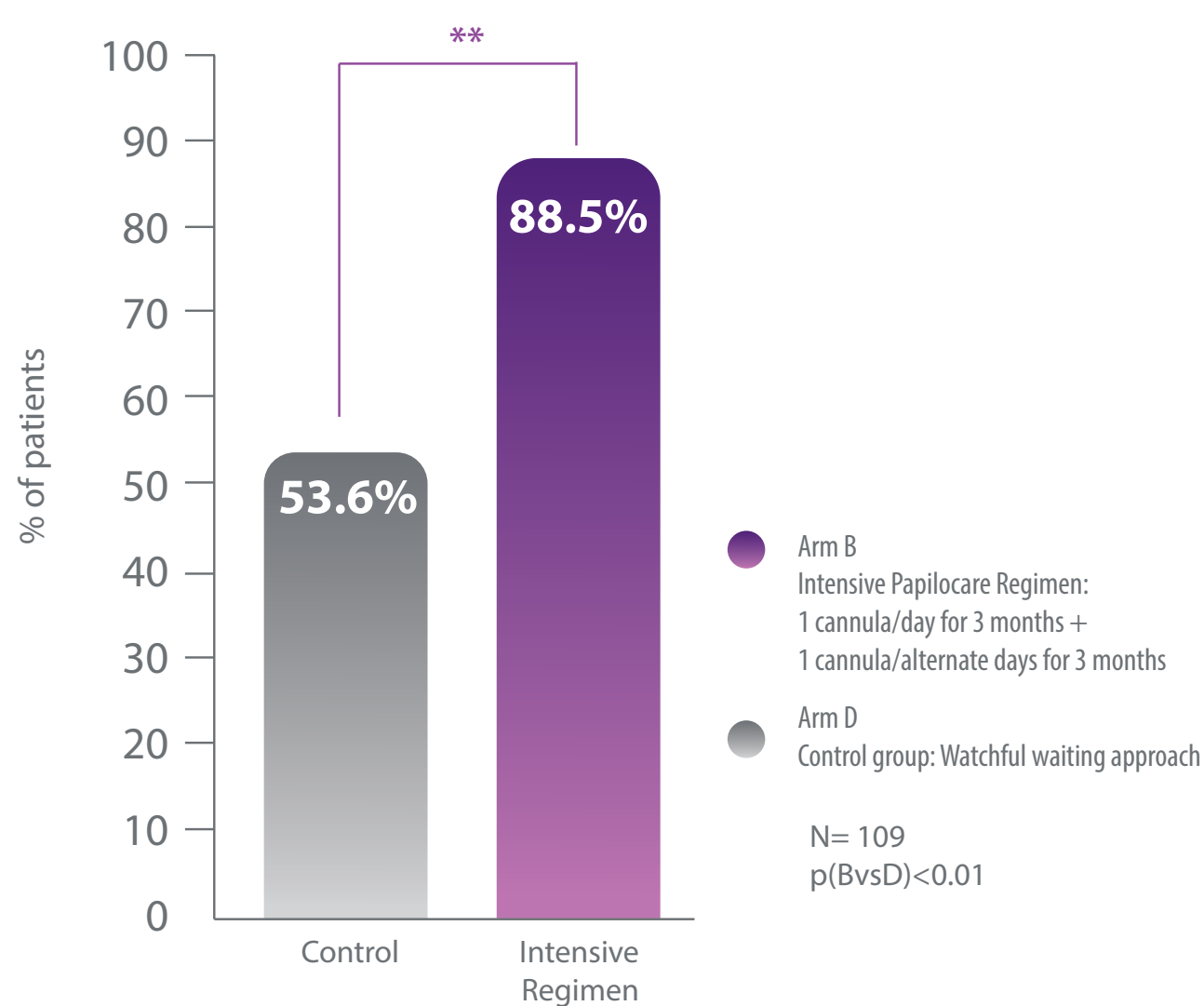
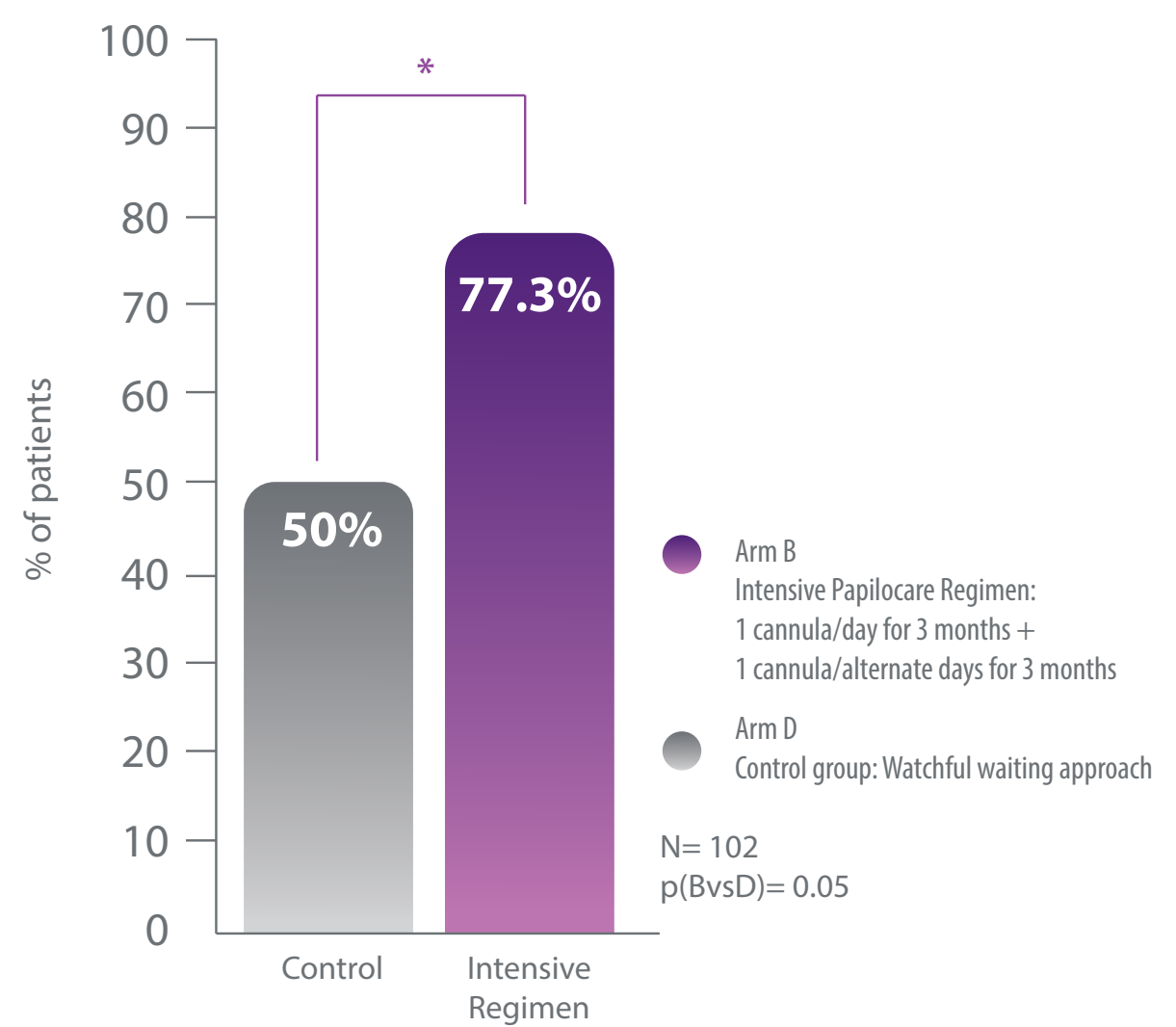


Figure 2. Clearance at 12 months in HR-HPV population



Conclusions

The intensive regimen of *Coriolus versicolor*-based vaginal gel demonstrated significant efficacy in promoting HR-HPV clearance, supporting its role as a non-invasive, evidence-based option during the watchful waiting approach.