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; 46.8% were current or former smokers. Baseline characteristics were homogeneous across groups, with no significant differences in variables such as HPV genotype distribution; HPV16, 18 and 31 were evenly distributed. Among the 109 women completing the 6-month visit, HR-HPV clearance rates were 57.7% (A), 88.5% (B), and 75.9% (C) and 53.6% (D) ($p<0.01$ for B vs. D) (Figure 1). In the subgroup of women positive for HPV-16/18/31 (n=56), clearance was 57.7% (A), 93.3% (B), and 64.3% (C) and 30.8% (D) ($p<0.01$ 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).

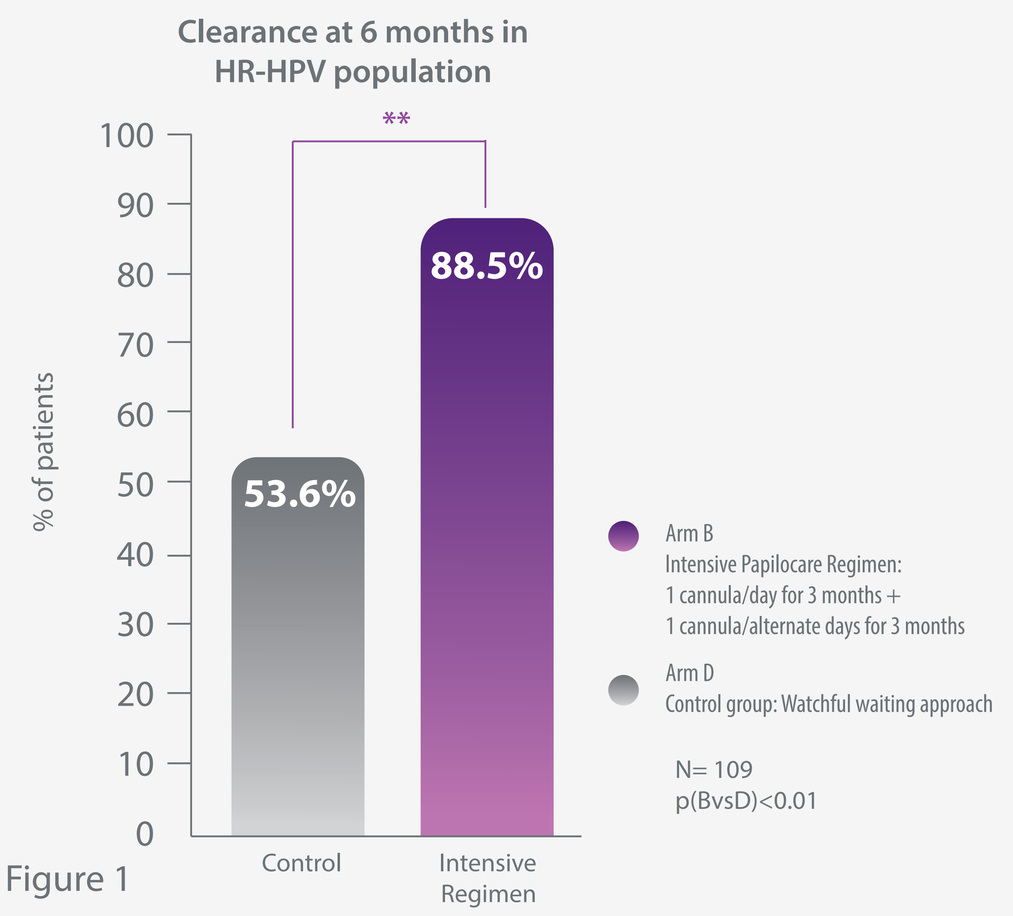

Figure 1

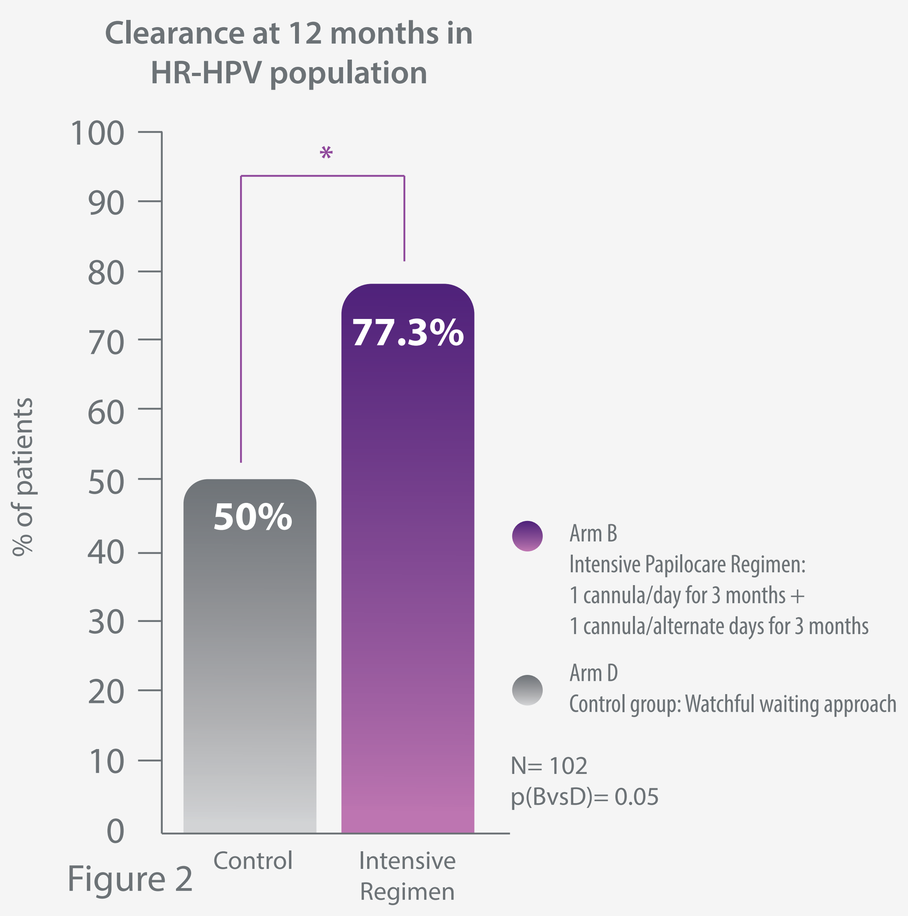

Figure 2

Conclusions:

The intensive regimen of the *Coriolus versicolor*-based vaginal gel demonstrated both statistically and clinically significant HR-HPV clearance after 6 months of treatment and at the 12-month follow-up, supporting its role as a non-invasive, evidence-based option within the watchful waiting approach.