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# Efficacy of a *Coriolus versicolor*-based vaginal gel on HR-HPV clearance and low-grade cervical lesions repair: final pooled results from the PALOMA 1 and PALOMA 2 randomized clinical trials.

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## Introduction

PALOMA 1 RCT demonstrated the efficacy of a *Coriolus versicolor*-based vaginal gel in low-grade cervical lesions and HR-HPV clearance. PALOMA 2 confirmed these findings, showing consistent and reproducible results, enabling a pooled analysis to strengthen evidence on HR-HPV clearance and lesion repair at 6 months.

## Methods

Randomized, multicenter, prospective, open-label, parallel-group, watchful-waiting-controlled clinical trials. Unvaccinated HR-HPV positive women (30-65 years) with ASCUS/LSIL cytology and concordant colposcopy were randomized (1:1:1:1): A) Standard regimen: once daily for one month, followed by every other day for five months; B) Intensive regimen: once daily for three months, followed by every other day for three months; C) Very Intensive regimen: once daily for six months; D) Control group. Cervical lesion repair (cytology normalization and concordant colposcopy) and HR-HPV clearance (total or partial) were assessed after the 6 months. IRC approval and informed consents were obtained. Chi-square test was used.

## Results

Data from 101 patients were analyzed: 48 in the treatment group and 53 in the control group. A significantly higher rate of HR-HPV clearance and lesion repair was observed in the treatment group compared with controls (77.1% vs 45.3%;  $p=0.0011$ ) (Figure 1). The subgroup of patients positive for HPV/16/18/31 also showed significantly higher clearance and lesion repair rates in the treatment group (69.6% vs 33.3%;  $p=0.0107$ ) (Figure 2).

Figure 1. HR-HPV clearance and lesion regression in general population at 6 months

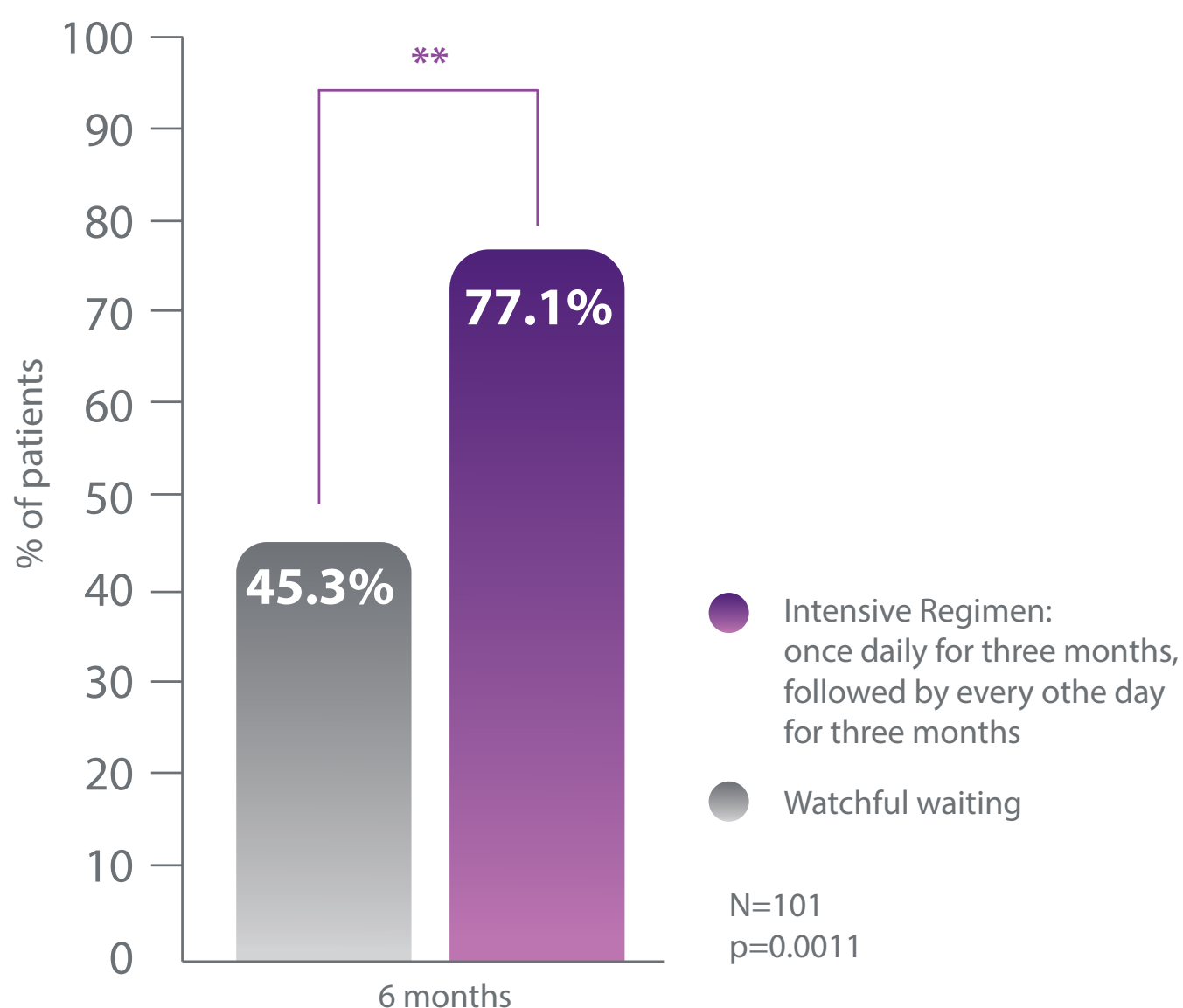
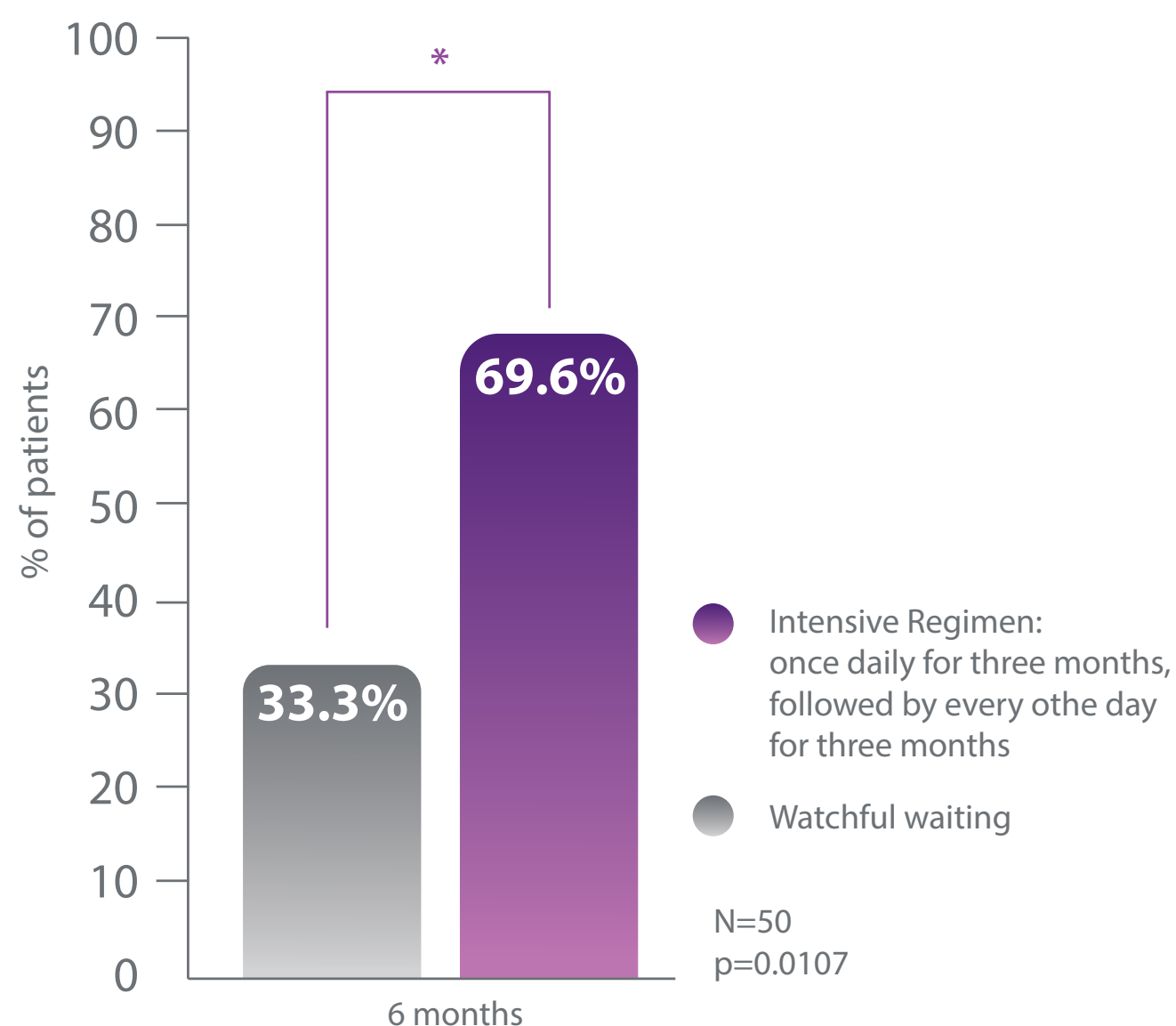


Figure 2. HR-HPV clearance and lesion regression in HPV 16/18 and/or 31 at 6 months



## Conclusions

These findings suggest that after a 6-month treatment period, the intensive regimen of a *Coriolus versicolor*-based vaginal gel significantly enhances HR-HPV clearance, highlighting it as a valuable clinical tool for managing HR-HPV infections compared to watchful waiting approach.