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# EFFICACY OF A MULTI-INGREDIENT *CORIOLUS VERSICOLOR*-BASED VAGINAL GEL IN HR-HPV CLEARANCE: FINAL POOLED RESULTS FROM THE PALOMA 1 AND PALOMA 2 CLINICAL TRIALS.

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## Introduction:

Following PALOMA 1's demonstration of *Coriolus versicolor*-based vaginal gel efficacy in HPV-dependent low-grade cervical lesions, PALOMA 2 incorporated HR-HPV clearance as a secondary endpoint. We present the pooled results on HR-HPV clearance at 6 months from both trials.

## Methods:

Randomised, multi-centre, prospective, open-label, parallel-group, watchful waiting-controlled clinical trial. Unvaccinated HR-HPV positive women aged between 30 to 65 years, with Atypical Squamous Cells of Undetermined Significance (ASCUS) or low-grade squamous intraepithelial lesions (LSIL) cytology and concordant colposcopy were randomised (1:1:1) into: 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) Control group. This analysis presents pooled results on HR-HPV clearance at six months for the

intensive regimen versus control group. HPV clearance was considered as total (negative HPV test or the disappearance of all species detected at baseline) or partial clearance (disappearance of at least one HPV genotype present at baseline, along with normal cytology and concordant colposcopy observations). All patients signed informed consent, and studies were approved by centralized IRBs.

## Results:

Data from 101 patients were analyzed: 48 in the treatment group (PALOMA 1, n=22; PALOMA 2, n=26) and 53 in the control group (PALOMA 1, n=25; PALOMA 2, n=28). A significantly higher rate of HR-HPV clearance was observed in the treatment group compared with controls (85.4% vs 47.2%;  $p<0.0001$ ; RR=1.81) (Figure 1). In the subgroup of patients positive for HPV 16, 18, and/or 31 at baseline, clearance rates were also significantly higher in the treatment group (82.6% vs 37.0%;  $p=0.0011$ ; RR=2.23) (Figure 2).

Clearance at 6 months in HR-HPV population

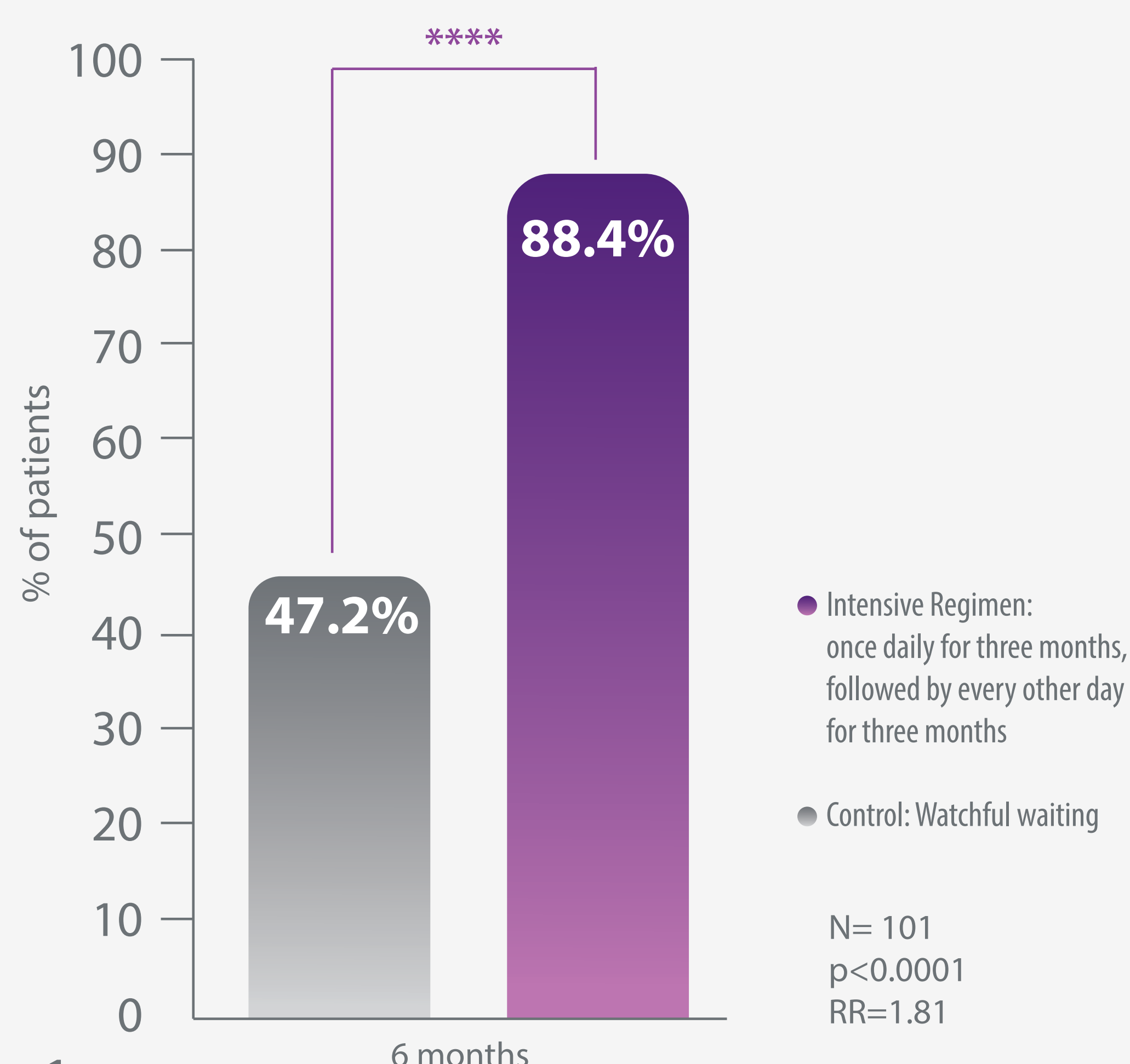


Figure 1

Clearance at 6 months in patients positive for HPV 16, 18 and/or 31

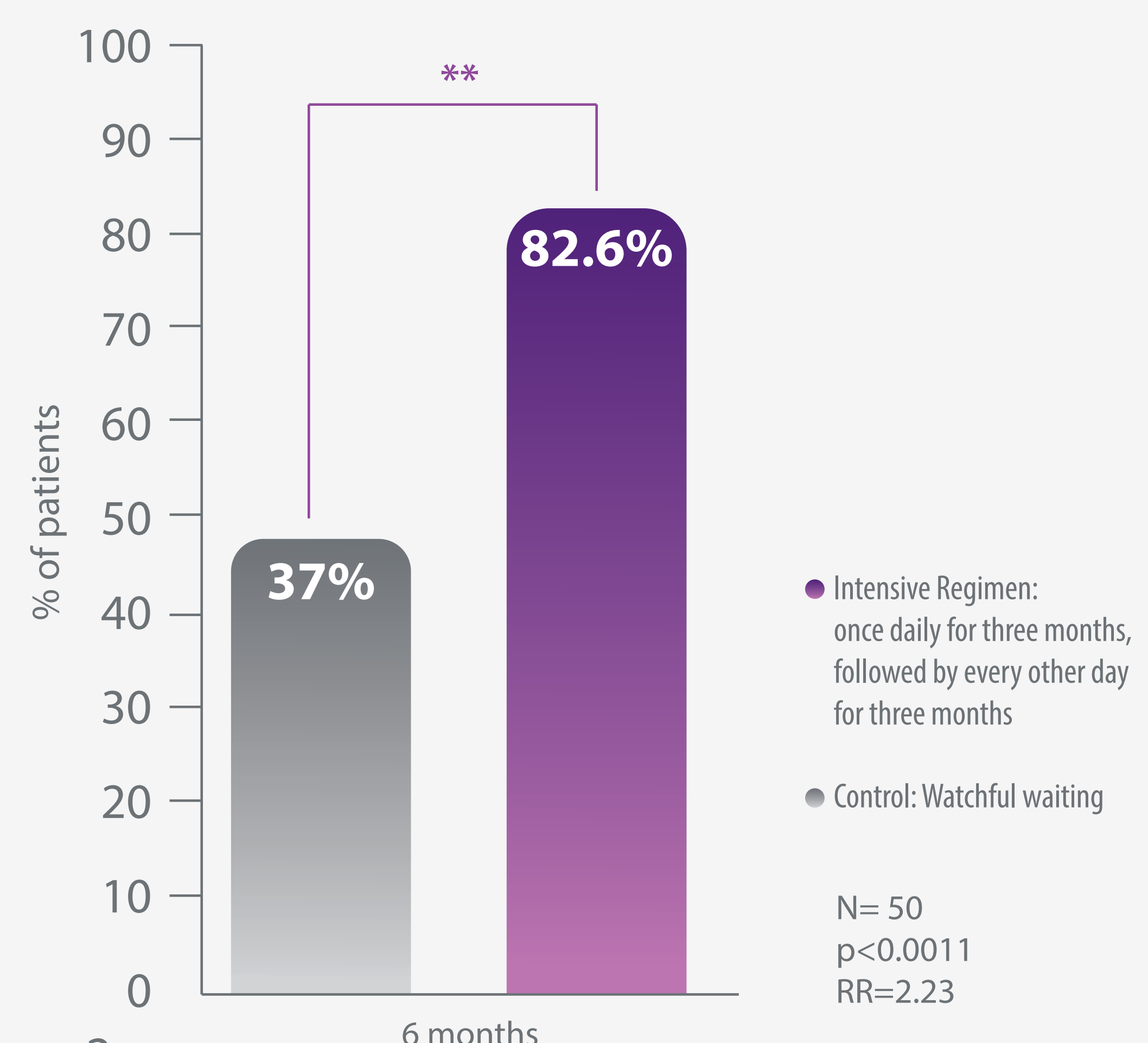


Figure 2

## Conclusions:

These findings suggest that 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.