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EFFICACY OF A MULTI-INGREDIENT *CORIOLUS VERSICOLOR*-BASED VAGINAL GEL IN HIGH-RISK HPV WOMEN OVER 40 : SUB-ANALYSIS OF THE PALOMA CLINICAL TRIAL & PAPILOBS REAL-LIFE STUDY

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BACKGROUND

HPV clearance and resolution of cervical HPV-dependent lesions become especially difficult in peri and postmenopausal women. Papilocare®, a *Coriolus versicolor*-based vaginal gel has proven to be effective and safe to repair the low-grade cervical lesions and enhance the HR HPV clearance.

AIMS

The objective of this sub-analysis was to evaluate the effect of the Papilocare®, a multi-ingredient *Coriolus versicolor*-based vaginal gel in repairing the high-risk (HR) HPV-dependent low-grade cervical lesions in women over 40 years old in two studies, the Paloma clinical trial and the Papilobs real-life study.

METHODOLOGY

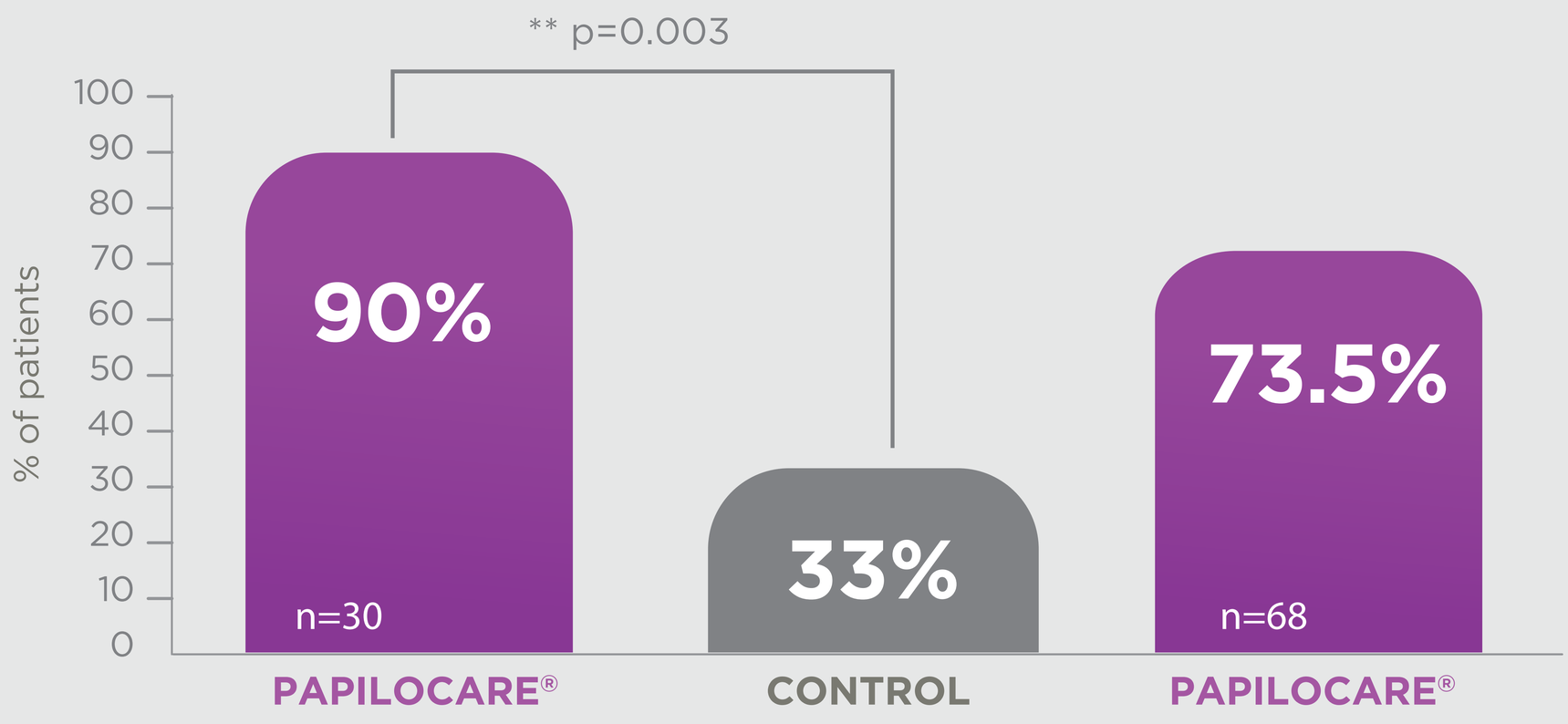
Paloma study (NCT04002154) was a multicenter, randomized, open-label, parallel-group, watchful waiting approach-controlled clinical trial. Unvaccinated HPV-positive women aged between 30-65 with cytology of ASCUS/LSIL and concordant colposcopy image were randomized into: A) Papilocare® 1 cannula/day (1 month) + 1 cannula/alternate days (5 months); B) Papilocare® 1 cannula/day (3 months) + 1 cannula/alternate days (3 months); C) Control group: watchful waiting approach. Papilobs study (NCT04199260), was an observational, multicenter, prospective, one-cohort study. HPV-positive women aged > 25yo with cytology of ASCUS/LSIL and concordant colposcopy were included. Patients were treated with Papilocare® 1 cannula/day (1 month) + 1 cannula/alternate days (5 months). Percentages of HR-HPV patients with normal cytology and concordant colposcopy after treatment in over 40yo subpopulation are presented.

RESULTS:

A total of 30 and 68 HR-HPV patients were evaluated in Paloma and Papilobs studies, respectively. In the Paloma trial, normal cytology and concordant colposcopy was observed in 90% vs 33% patients in A+B Papilocare® arms and control groups, respectively, (p=0.003, Fisher test). In the Papilobs study, normal cytology and concordant colposcopy was achieved in 73.5% of patients.

CLINICAL TRIAL
PALOMA
ClinicalTrials.gov NCT 04002154

PAPILOBS
ClinicalTrials.gov NCT 04199260



CONCLUSIONS:

After a 6-month treatment period, Papilocare® showed a clinically robust and statistically significant efficacy in repairing cervical HR-HPV lesions in women over 40yo with HR-HPV vs watchful waiting approach. This efficacy was corroborated in real-life conditions.