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EFFICACY OF A CORIOLUS VERSICOLOR-BASED MULTI-INGREDIENT VAGINAL GEL IN HPV+ WOMEN OLDER THAN 40 YEARS: SUB-ANALYSIS OF PALOMA CLINICAL TRIAL

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OBJECTIVES:

HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri and postmenopausal women. The objective of this sub-analysis was to evaluate the effect of the Papilocare®, a multi-ingredient *Coriolus versicolor*-based vaginal gel, on the normalization of cervical HPV-dependent atypia (ASCUS and LSIL) and associated colposcopic alterations in women older than 40 years.

METHODS:

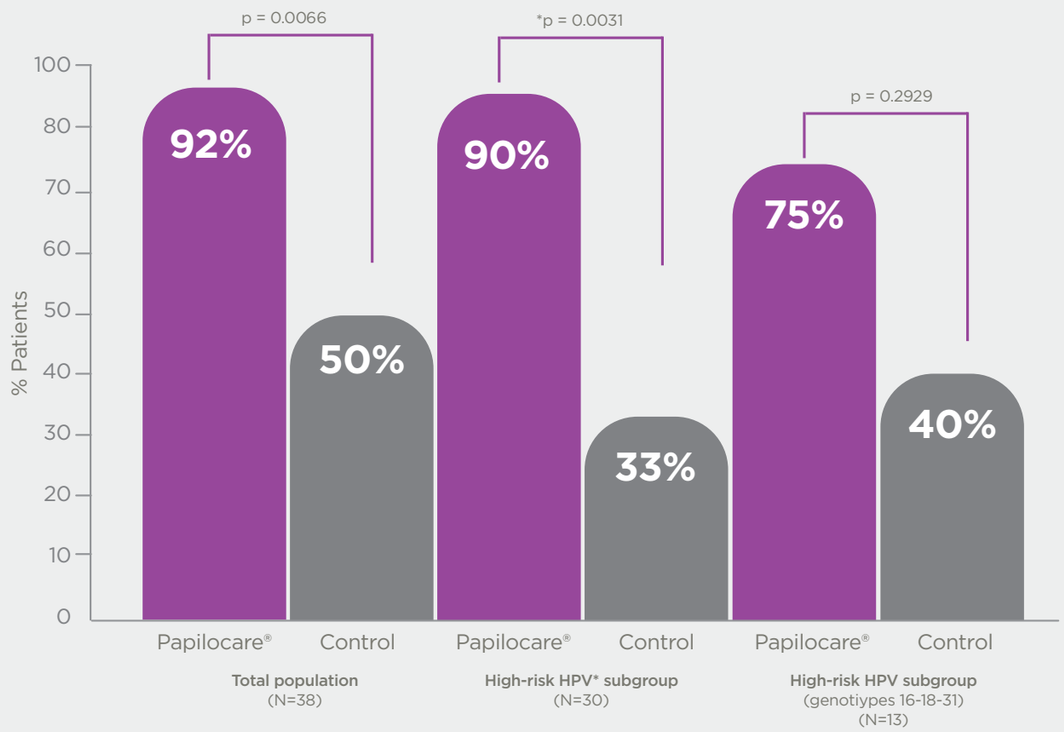
Paloma clinical trial (ClinicalTrials.gov NCT04002154) was a multicenter, randomized, open-label, parallel-group, usual practice-controlled clinical trial. Unvaccinated HPV positive women aged between 30-65 with cytology of ASCUS or LSIL and concordant colposcopy were randomized into 3 groups:
A) Papilocare® 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months;
B) Papilocare® 1 cannula/day for 3 months + 1 cannula/alternate days for 3 months;
C) Control group: no treatment (usual clinical practice). Primary endpoint: % of patients with normal cytology and concordant colposcopy after 6 months of treatment in the total population, high-risk HPV (16,18,31,33,35,39,45,51,52,56,58,59,68) and very high-risk HPV (patients infected by any combination of 16, 18 and 31) subpopulations. Pap smear evaluations were blind and centrally conducted by an independent researcher at the IECM laboratory (Lugo, Spain). Papilocare® arms (A+B) were combined as treatment group.

RESULTS:

A total of 38 out of 84 evaluated patients included in Paloma trial were older than 40y [mean (SD) age: 47.71 (5.56)], of which 30 and 13 were high-risk HPV and 16-18-31 HPV patients, respectively. At 6 months, normal cytology and concordant colposcopy was observed in 92%, 90% and 75% of patients treated with Papilocare® vs 50%, 33% and 40% of patients in control group, in the total population, and high-risk and 16-18-31 subpopulations (p=0.0066; p=0.0031; p=0.2929, Fisher test) respectively.

REPAIRMENT OF LOW-GRADE CERVICAL HPV-INDUCED LESIONS

Cytological normalization + concordant colposcopy



CONCLUSION:

Papilocare® showed a robust efficacy in repairing cervical HPV lesions in women older than 40 years old, with a statistically significant difference vs control group in the total and high-risk populations.

DISCLOSURES:
Gaslain Y: CEO at Procare Health Iberia and shareholder of the Company. **Seydoux G:** Consultant for Procare Health Iberia and shareholder of the Company. **Palacios S:** Consultant for Procare Health Iberia. **Serrano L:** Consultant for Procare Health Iberia. **Cortés J:** Consultant for Procare Health Iberia