

Authors:

Palacios S¹, Serrano L², Gaslain Y³, Seydoux G⁴, Cortés J⁵

¹Instituto Palacios, Salud y Medicina de la Mujer, Madrid, Spain, ²Centro Médico Gabinete Velázquez, Madrid, Spain, ^{3,4}Procare Health Iberia, Barcelona, Spain, ⁵Private Practice, Palma, Spain

OBJECTIVE:

To evaluate the efficacy of the PAPILOCARE®, a *Coriolus versicolor*-based vaginal gel, on the repairing of low-degree HPV-dependent cervical lesions 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 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).

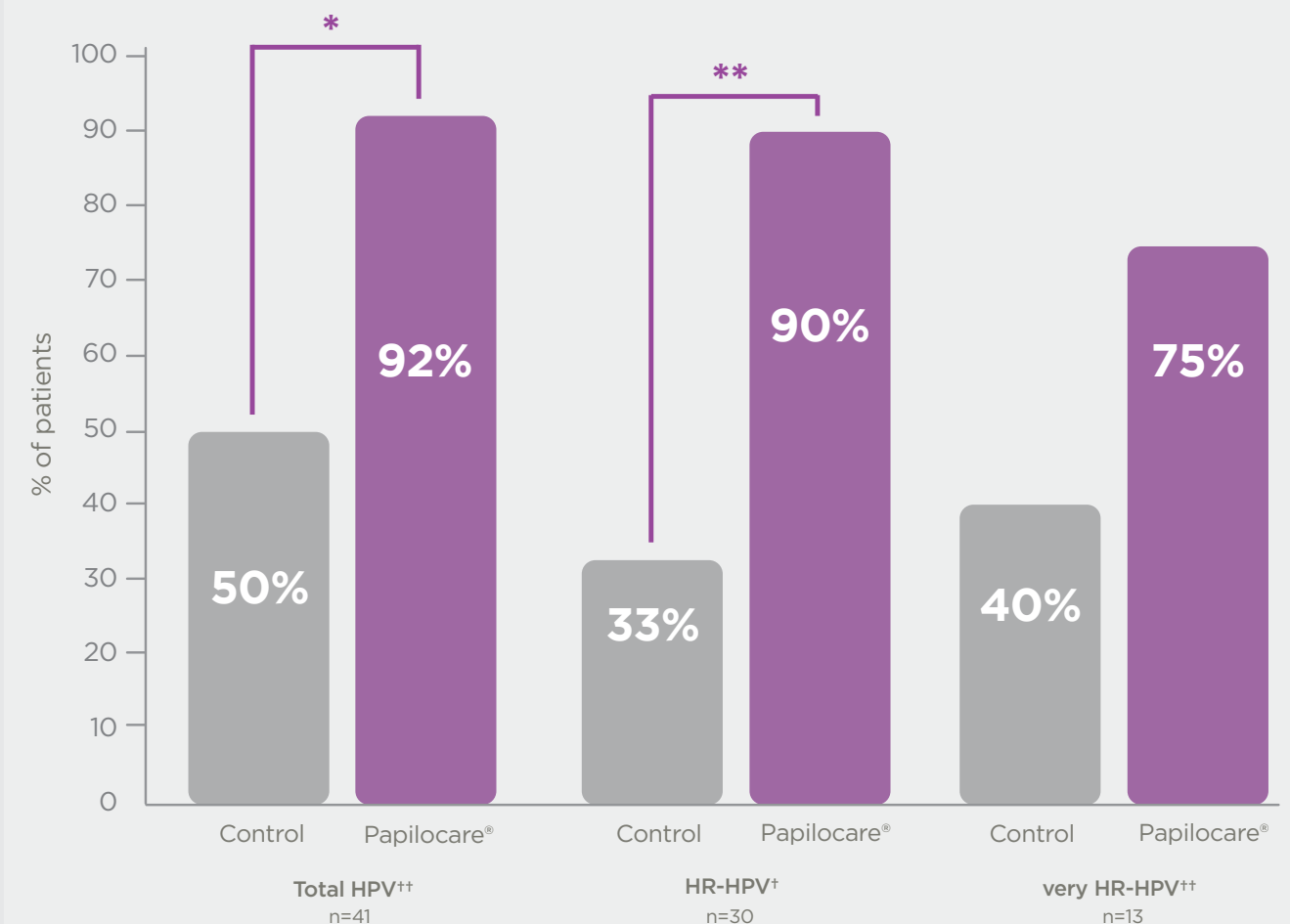
Primary endpoint: % of patients with normal cytology and concordant colposcopy after 6 months of treatment in the total population, high-risk HPV and very high-risk HPV (any combination of 16, 18 and 31) subpopulations. Cytology evaluations were blind and centrally conducted. PAPILOCARE® arms were combined as treatment group.

RESULTS:

41 out of 84 patients included in the clinical trial were older than 40 yo, of which 30 and 13 were high-risk HPV and 16-18-31 HPV patients, respectively. At 6 months, normal cytology and concordant colposcopy were 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, high-risk and 16-18-31 subpopulations respectively (p=0.0066; p=0.0031; p=0.2929, Fisher test).

ASC-US/LSIL Normalisation lesions with concordant colposcopy at 6 months

Average age 47.7 yr (DE 5,56)



*p=0,0066; **p=0,0031; p=0,2929 very HR-HPV. Fisher Test

[†]HR-HPV: 16,18,31,33,35,39,45,51,52,56,58,59, 68

^{††}very HR-HPV: 16, 18, 31

CONCLUSIONS:

Papilocare® has shown a consistent and significant efficacy in repairing low-grade HPV-dependent cervical 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