626 EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV INFECTED PATIENTS: RESULTS OF 7 DIFFERENT STUDIES

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Introduction/Background* To evaluate the consistency of the efficacy of a multi-ingredient Coriolus versicolor-based vaginal gel, Papilocare®, on high-risk HPV (HR-HPV) clearance in 7 different studies.

Methodology Results of the 6 month-treatment period of Papilocare ® from 5 independent observational (3 Spanish and 2 Italian hospitals) were compared to results from a randomized, open, parallel, controlled trial (Paloma: ClinicalTrials.gov NCT04002154) and an observational, multicenter, prospective, one-cohort study (PapilOBS: ClinicalTrial.gov NCT04199260). Two prospective one-cohort (Vigo and Bari), 2 retrospective one-cohort (Coruña and Hospitalet) and 1 retrospective controlled (Roma) studies have been performed.

Vigo study. Secondary endpoint (SE): HPV clearance in 25 patients infected by HPV 16 and/or 18.

Bari study. Primary endpoint (PE): HPV clearance in 98 HR-HPV patients.

Coruña study: PE; HPV clearance assessed in 57 medical patients' records.

Hospitalet study. PE: composite efficacy variable (patients with normal cytology and/or HPV clearance) in 91 HR-HPV patients.

Roma study. PE: HPV clearance in 183 HR-HPV patients.

PapilOBS study. SE: HR-HPV clearance in 178 patients.

Paloma trial. SE: HR-HPV clearance in 66 patients.

Result(s)* After the 6-month treatment period, 48% and 57% of patients cleared HPV 16-18 and HR-HPV in Vigo and Bari studies, respectively. 58% of reduction was observed in the number of HR-HPV patients (Coruña) and 72.5% of patients negativized cytology and/or cleared HR-HPV (Hospitalet). 67% HR-HPV clearance was observed (treated group) vs 37.2% (control group), p<0,0001 in the Roma study. In the Paloma trial, HR-HPV clearance reached 63% (treated group) vs 40% (control group). Similar rate of 57.4% HR-HPV clearance was observed in the PapilOBS study.

Conclusion* Papilocare® has shown clinically significant consistent rates of HR-HPV clearance ranging from 50% to 70% in 7 different studies and 827 patients. These results reinforce the evidence of its beneficial effect for HR-HPV patients.

641 EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HPV+ WOMEN OVER 40 YEARS OLD : A SUB-ANALYSIS OF THE PALOMA CLINICAL TRIAL

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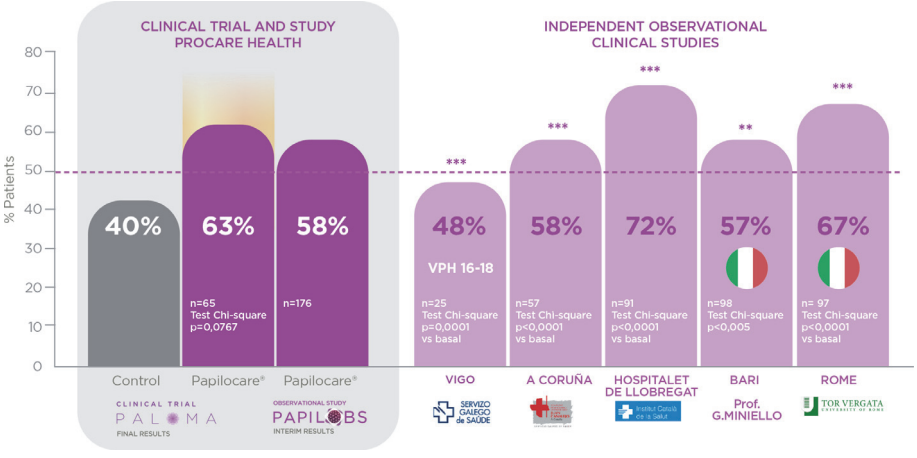
Introduction/Background* HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri and postmenopausal women. The objective of this sub-analysis was to evaluate the effect of the Papilocare®, a multi-ingredient Coriolus versicolor-based vaginal gel in repairing the HPV-dependent low-grade cervical lesions in women over 40 years.

Methodology

Paloma study (ClinicalTrials gov 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 or LSIL and concordant colposcopy image 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: watchful waiting approach (usual clinical practice). Primary endpoint:% of patients with normal cytology and concordant colposcopy after 6 months of treatment in the total population, high-risk (HR) HPV (16,18,31,33,35,39,45,51,52,56,58,59,68) and very HR 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.



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