The British Society for Colposcopy and Cervical Pathology

bsccp | Annual Scientific Meeting
ICC Belfast
4-6th May 2022

EFFICACY OF A MULTI-INGREDIENT *CORIOLUS VERSICOLOR*-BASED VAGINAL GEL IN HIGH-RISK HPV INFECTED PATIENTS: RESULTS OF 6 DIFFERENT STUDIES

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BACKGROUND:

Papilocare® is a patented multi-ingredient vaginal gel which includes *Coriolus versicolor* and other active ingredients. It is approved in Europe with the indication of re-epitelization for the cervical transformation zone for the prevention and co-adjuvant treatment of HPV-induced lesions.

AIMS:

The main objective is to evaluate the consistency of the efficacy of a multi-ingredient *Coriolus versicolor*-based vaginal gel on high-risk HPV (HR-HPV) clearance in 6 different studies.

METHODOLOGY:

Results from 4 independent observational studies (6 month-treatment period with Papilocare®) were compared to results from a randomized, open, parallel, controlled trial (Paloma: NCT04002154) and an observational, multicenter, prospective, one-cohort study (PapilOBS: NCT04199260).

• **Vigo study:** Prospective one-cohort. Secondary endpoint (SE), HPV clearance in 86 patients infected by HPV 16 and/or 18.

• **Coruña study:** Retrospective one-cohort. Primary endpoint (PE), HR-HPV clearance assessed in 86 medical patients' records.

• **Hospitalet study:** Retrospective one-cohort. PE, Composite efficacy variable (patients with normal cytology and/or HPV clearance) in 91 HR-HPV patients.

• **Roma study**: Retrospective controlled. PE, HR-HPV clearance in 183 patients.

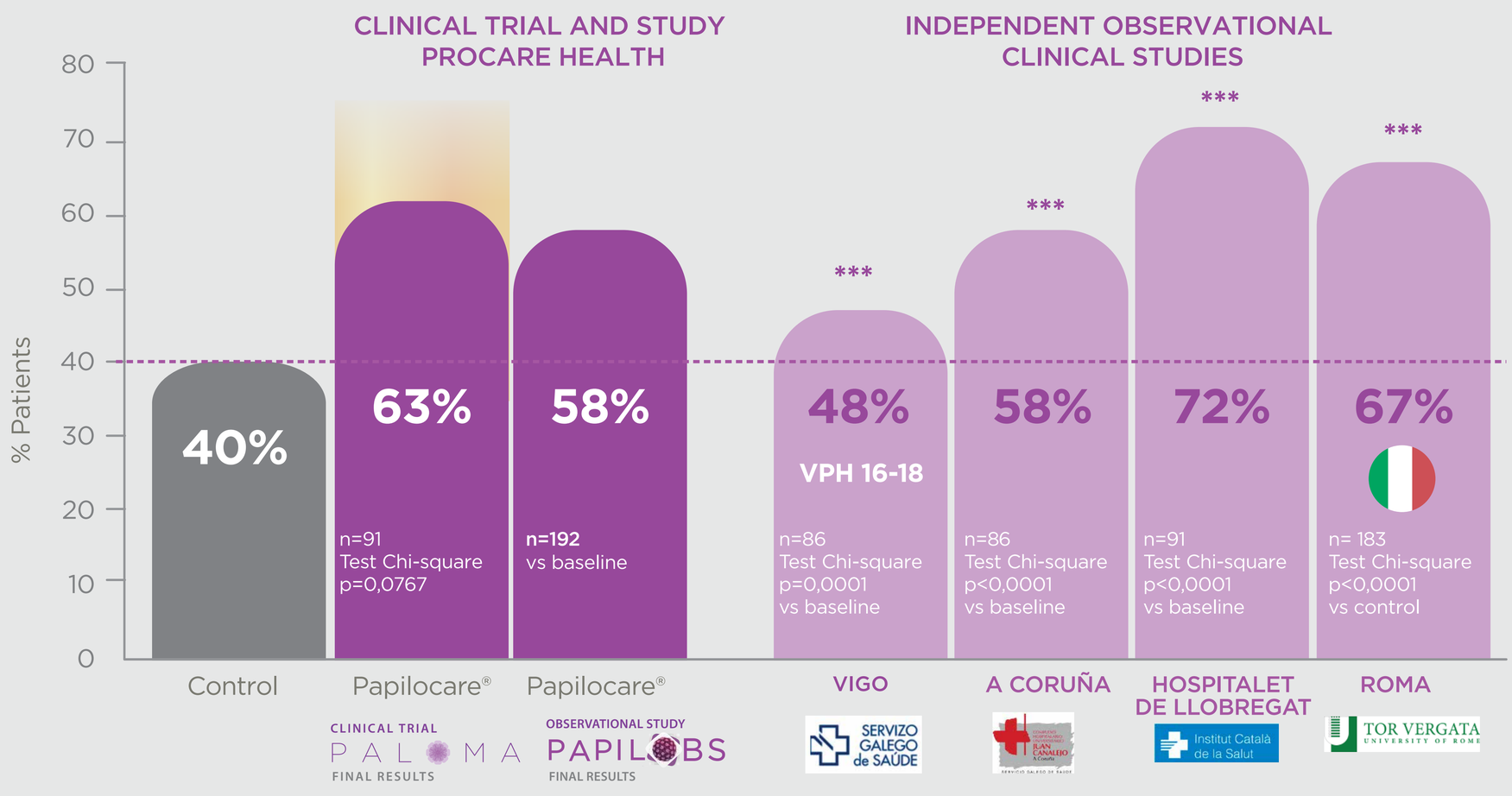
• **Paloma trial:** SE, HR-HPV clearance in 91 patients.

PapilOBS study: SE, HR-HPV clearance in 192 patients.

RESULTS:

After the 6-month treatment period 48% of patients cleared 16-/18 -HPV in the Vigo study. A reduction of 58% was observed in the number of HR-HPV patients in the Coruña study and 72.5% normalized cytology and/or cleared HR-HPV in the Hospitalet study. 67% of HPV clearance was observed in the treatment group vs 37.2% (control group), in the Roma study. In the Paloma trial, HR-HPV clearance reached 63% (treated group) vs 40% (control group). 57.4% HR-HPV clearance was observed in the PapilOBS study.

HR-HPV CLEARANCE AT 6 MONTHS RESULTS IN DIFFERENTS STUDIES



CONCLUSION:

Papilocare® has shown significant consistent rates of efficacy with a 64% of HR-HPV clearance in weighted average in 6 different studies involving more than 700 patients. These data reinforce the beneficial effect observed in HR-HPV patients.