Abstract #903 Efficacy of a multi-ingredient Coriolus versicolor-based vaginal gel in high-risk HPV women over 40: a sub-analysis of the Paloma clinical trial & Papilobs real-life study

Introduction/Background HPV clearance and resolution of HPV-dependent cervical lesions become difficult in menopausal women. The aim of this sub-analysis was to evaluate the effect of a multi-ingredient Coriolus versicolor-based vaginal gel (Papilocare®) in repairing high-risk (HR) HPV-dependent low-grade cervical lesions in women over 40-years-old.

Methodology The 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 or LSIL and concordant colposcopy image were randomized into 3 groups: A) treatment with the Coriolus versicolor-based vaginal gel 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months; B) treatment with the Coriolus versicolor-based vaginal gel 1 cannula/day for 3 months + 1 cannula/alternate days for 3 months; C) control group: watchful waiting approach. The Papilobs study (NCT04199260) was an observational, multicenter, prospective, one-cohort study. Vaccinated or unvaccinated HPV-positive women over 25-years-old with cytology of ASCUS or LSIL and concordant colposcopy were included. Patients were treated with the Coriolus versicolor-based vaginal gel 1 cannula/day for 21 days during the first month + 1 cannula/alternate days for 5 months. A sub-analysis involving patients from both studies, over 40-years-old with HR-HPV was performed.

Results 30 and 68 HR-HPV patients above 40-years-old were evaluated in the Paloma and Papilobs studies, respectively. In the Paloma trial, normal cytology and concordant colposcopy was observed in 90% vs 33% patients in A+B vs. control groups, respectively (p=0.003, Fisher test). In the Papilobs study, normal cytology and concordant colposcopy was achieved in 73.5% of patients.

Conclusion After a 6-month treatment, the Coriolus versicolor-based vaginal gel has shown clinically robust and statistically significant efficacy in repairing cervical HR-HPV lesions in women over 40-years-old vs watchful waiting approach. This efficacy was corroborated in the real-life study.

Disclosures.

Abstract #907 Real life efficacy of a multi-ingredient Coriolus versicolor-based vaginal gel in women with HPV dependent cervical lesions: a sub-analysis of the Papilobs study in women over 40

Introduction/Background HPV clearance and resolution of cervical lesions become difficult in postmenopausal women. Therefore, therapies that are effective at dealing with this condition in this population are essential. Papilocare®, a Coriolus versicolor-based vaginal gel has proven to be effective and safe in repairing low-grade cervical lesions and enhancing HPV clearance in various studies. However, no multicentric prospective studies had been performed in a real-world setting.

Methodology The Papilobs study (NCT04199260) was an observational, multicentric, prospective, non-comparative clinical study conducted on HPV-positive women with ASCUS or LSIL cervical cytology and concordant colposcopy images, to evaluate the effectiveness of Papilocare® in repairing low-grade cervical lesions and clearing HPV in routine clinical practice. This study was approved by the Ethics Committee of Puerta de Hierro Majadahonda Hospital (Madrid) and all patients signed the Informed Consent Form. Patients received one cannula/day for 21 days (first month) + one cannula/alternate days (five months). Results of a sub-analysis in patients over 40 are presented.

Results The Papilobs study included 201 patients. When solely looking at patients over 40, and patients over 40 with high-risk (HR) HPV, 74 and 69 patients accounted for the analysis, respectively. 82.4% of patients over 40 and 81.2% of patients over 40 with HR-HPV, repaired their cervical lesions after treatment with Papilocare®. Additionally, a total of 73.3% and 73.5% of patients over 40; and patients over 40 with HR-HPV, respectively, were observed to clear HPV.

Conclusion The Coriolus versicolor-based vaginal gel was shown to successfully repair HPV-dependent low-grade cervical lesions and lead to HPV clearance in those patients over 40, and over 40 with HR-HPV in real life conditions. These results are in line with those observed in the PALOMA trial and in other observational studies, which strengthens the role of Papilocare® as a beneficial alternative to the watchful waiting approach in HPV-related low-grade cervical lesions.

Disclosures.