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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

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INTRODUCTION:

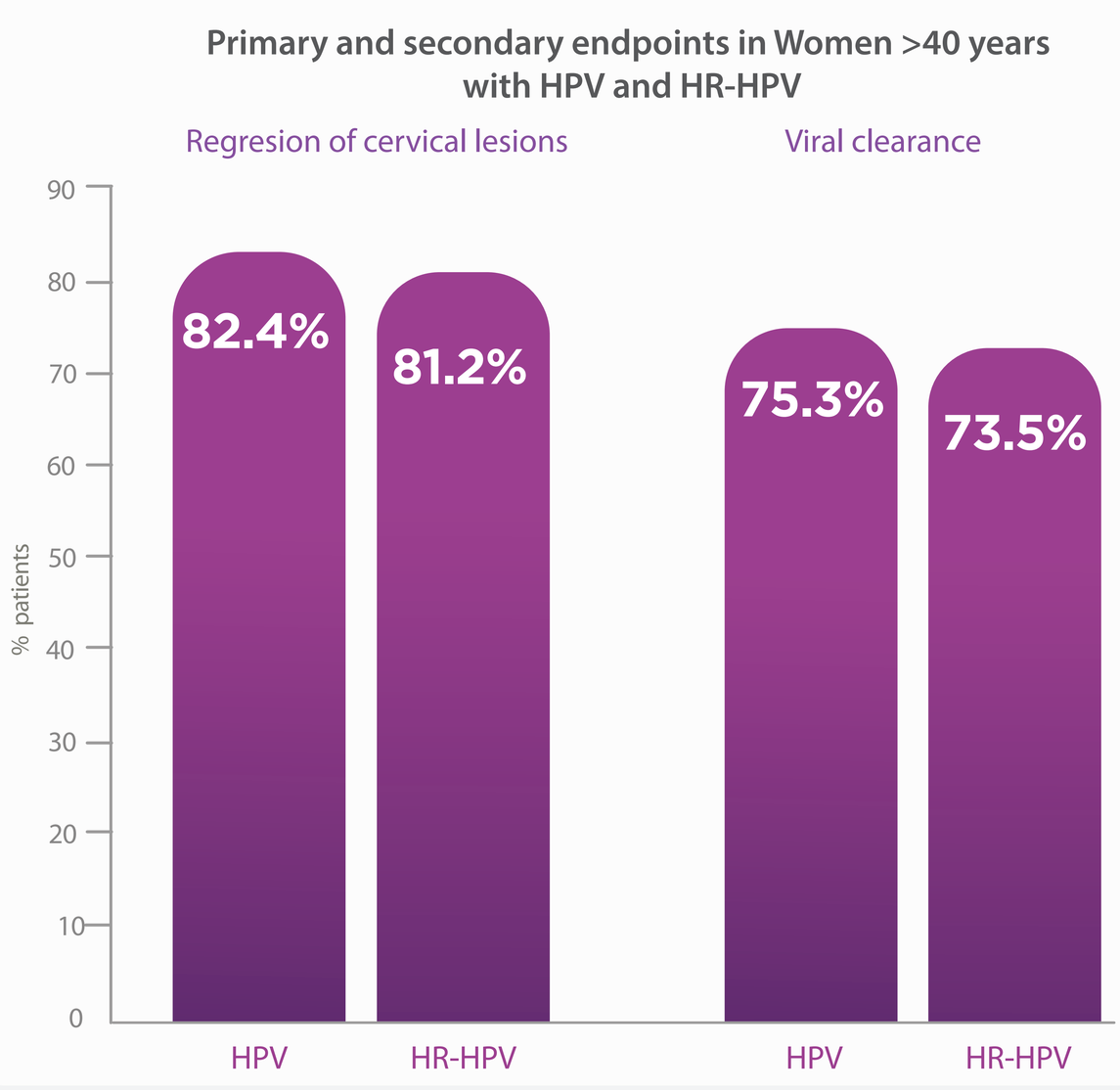
HPV clearance and resolution of cervical lesions become difficult in peri and postmenopausal women. Therefore, therapies that are effective at dealing with this condition in this population are essential. A *Coriolus versicolor*-based vaginal gel has proven to be effective and safe in repairing low-grade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

METHODS:

This was an observational, national, multicentric, prospective, non-comparative clinical study (PAPILOBS trial, #NCT04199260). Inclusion criteria included: women over 25 years old, vaccinated or not against HPV; an HPV-positive test; ASCUS or LSIL cytology results together with concordant colposcopy images. Participants were treated with Papilocare® one cannula/day for 21 days during the first month followed by one cannula/alternate days during the subsequent five months. Those who continued with altered cytology/colposcopy and/or HPV persistency were offered an additional 6-month treatment period with the same dosage, making their total treatment time 12 months. The primary endpoint was the repair of the cervical low-grade lesions and secondary objective included the HPV clearance. This study was approved by the Ethics Committee of Puerta de Hierro Majadahonda University Hospital and all patients signed the Informed Consent form. Results of a sub-analysis in patients over 40 years old are presented.

RESULTS:

The Papilobs study included 201 patients. When solely looking at patients over 40, and patients over 40 with high-risk HPV (HR-HPV), 74 and 69 patients accounted for the sub-analysis, respectively. Of the patients over 40, 82.4% repaired their cervical lesions after treatment with a *Coriolus versicolor*-based vaginal gel, of which 88% of them achieved this normalization within 6 months of treatment. Of the patients over 40 with HR-HPV, 81.2% repaired their cervical lesions, of which 89% achieved this normalization within 6 months of treatment. Additionally, 75.3% and 73.5% of patients over 40, and patients over 40 with HR-HPV, were observed to clear HPV respectively (of which 80% achieved this clearance within 6 months of treatment in both groups).



CONCLUSIONS:

The *Coriolus versicolor*-based vaginal gel has been shown to successfully repair HPV-dependent low-grade cervical lesions and increase HPV clearance rates in those patients over 40, and over 40 with HR-HPV after a 6-month treatment period. These results are in line with those observed in the PALOMA clinical trial and other studies. This shows that these results are robust and reproducible, which strengthens the *Coriolus versicolor*-based vaginal gel as a valuable alternative to the watchful and waiting approach within the recommended management of thoses HPV+ patients.