ASCCP 2023
SCIENTIFIC MEETING ON ANOGENITAL & HPV-RELATED DISEASES

# EFFECTIVENESS OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HPV+ AND HIV+ PATIENTS: A PILOT OBSERVATIONAL STUDY.

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#### OBJECTIVE:

Immunosuppressed, human immunodeficiency virus (HIV)-positive, patients have an increased risk of incident, persistent, or recurrent human papillomavirus (HPV) infection. They also have lower clearance rates, higher viral load, and a marked predisposition for being colonized by several serotypes: all leading to more frequent and severe HPV-dependent lesions<sup>1,2</sup>. In fact, HIV-positive women are six times more at risk of developing cervical cancer, and it is estimated that up to 5% of all cervical cancer cases can be attributed to HIV-derived immunosuppression<sup>1,2</sup>. Following HPV infection confirmation among HIV-positive patients, the clinical approach focuses on diagnosing and treating potential cytological alterations that may appear in the anogenital tract<sup>1,3</sup>. A *Coriolus versicolor*-based vaginal gel has been shown to repair HPV-dependent low-grade cervical lesions and to increase high-risk HPV clearance in immunocompetent HPV-positive patients<sup>4</sup>.

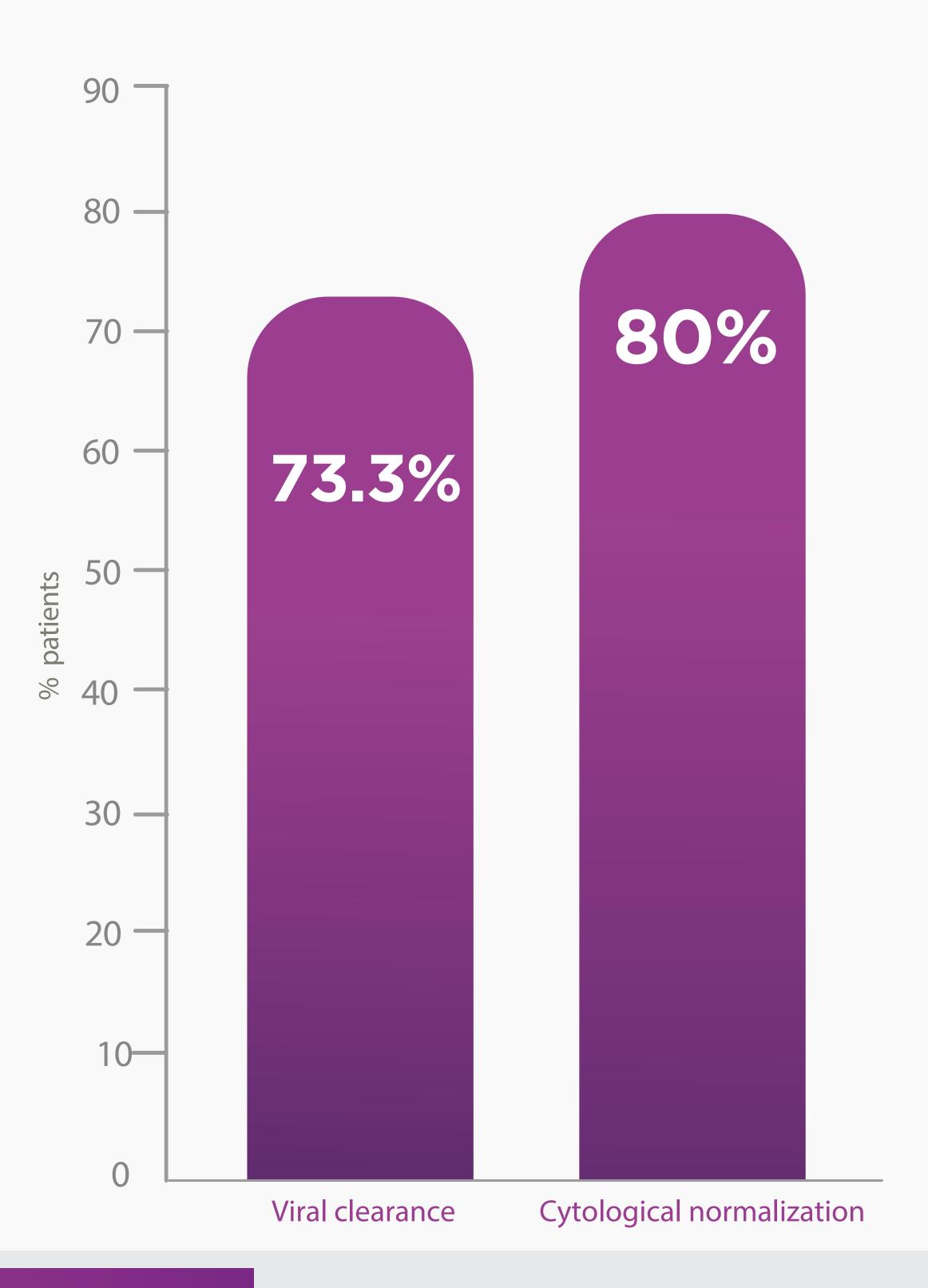
The aim of this study is to provide evidence about the effectiveness of a *Coriolus versicolor*-based vaginal gel on HPV-dependent cervical alterations and HPV clearance in HIV+ patients.

### METHODS:

In this pilot, prospective, one-cohort, observational study, 15 HIV-positive patients with HPV endocervical colonization and anomalous cervicovaginal cytology, received a *Coriolus versicolor*-based vaginal gel 1 cannula/day for 21 days during the first month + 1 cannula/alternate days for 5 months. Analysis of normalization (by cytology and concordant colposcopy) and HPV clearance (measured using hybrid capture test) are presented.

## RESULTS:

A total of 15 patients were included with an average age of 41 years old and with 67% of them being smokers. Six subjects fulfilled the criteria for Acquired Immune Deficiency Syndrome (AIDS). The overall HPV clearance and cytological normalization rates were 73.33% and 80%, respectively. Endocervical colonization by HPV also partially cleared in 13.33% of the cases. At the end of the study, the normalization of the colposcopy was achieved in 55.56%.



#### CONCLUSION:

Our results suggest that a 6-month treatment period with a *Coriolus versicolor*-based vaginal gel could be an effective therapy in the management of endocervical HPV infection in HIV+ patients. These promising results obtained from a small cohort of patients with especially poor prognosis due to their smoking habits, age above 50, and HIV infection, are in agreement with data previously reported in other studies in immunocompetent HPV infected patients.

<sup>1.</sup> Liu G, Sharma M, Tan N. HIV-positive women have higher risk of human papilloma virus infection, precancerous lesions, and cervical cancer. AIDS. 2018;32:795-808. 2. Looker KJ, Rönn MM, Brock PM, et al. Evidence of synergistic relationships between HIV and human papillomavirus (HPV): systematic reviews and meta-analyses of longitudinal studies of HPV acquisition and clearance by HIV status, and of HIV acquisition by HPV status. J Int AIDS Soc. 2018;21:e25110. 3. Rositch A, Koshiol J, Hudgens MG, et al. Patterns of persistent genital human papillomavirus infection among women worldwide: a literature review and meta-analysis. Int J Cancer. 2013; 1336:1271-1285.) 4. Serrano L, López AC, González SP, et al. Efficacy of a Coriolus versicolor-based vaginal gel in women with human papillomavirus-dependent cervical lesions: The PALOMA Study. Low Genit Tract Dis. 2021;25:130-136.