12° CONGRESS of the EUROPEAN SOCIETY of Gynecology
BARCELONA 18/21 OCTOBER 2017

P100. EFFECT OF A NON-HORMONAL CORIOLUS VERSICOLOR VAGINAL GEL AMONG POSITIVE-HPV WOMEN WITH NO COLPOSCOPY CERVICAL LESIONS. A PILOT STUDY.

Gonzalez S (ES) [1], Serrano L (ES) [2], Gaslain Y (ES) [3]

Context: Lack of cervical epithelium integrity is one of factors for HPV anchoring. Well epithelized cervix with squamous epithelium, and limited or non-existent transformation areas do not provide a suitable environment for inclusive colonization of HPV. PapilocareÂ® is a non-hormonal Coriolus versicolor-based vaginal gel. In a pilot study, application of PapilocareÂ® for 12 consecutive days showed positive effects toward improving vaginal microbiota, cervical epithelization and vaginal health among asymptomatic women.

Objective: To evaluate the effect of PapilocareÂ® on cervical epithelialization in positive-HPV women with no colposcopy lesions.

Methods: An exploratory, prospective, non-comparative observational study.

Patients: Sexually active positive-HPV women aged > 25y with negative pap and no colposcopy cervical lesions were included during routine clinical visits.

Interventions: PapilocareÂ® once daily for 21 consecutive days.

Main outcome measures: Primary endpoint: change vs baseline in epithelialization degree of the cervix mucosa evaluated by standard colposcopy and rated by investigator from 5 = No ectopy o 1= severe ectopy and bleeding. Secondary endpoints: 1) changes in vaginal signs and symptoms evaluated by likert-type scale from 7= severity to 28= absence, 2) changes in vaginal microbiota evaluated by pyrosequencing and 3) patient satisfaction.

Results: 21 patients were included. PapilocareÂ® showed a positive trend to improve the re-epithelialization of the cervix: mean score improved 20% (3.79 vs 4.47 baseline vs final; T-test p<0.006). 52.6% of patients improved cervix epithelialization and a score of 5 was observed in 63% of women. A trend to improve symptoms was observed despite of few symptoms at baseline: 71% of patients reached maximum symptoms score at the end of treatment period. Eight patients improved the

[1] Gabinete Medico Velazque, [2] Gabinete Medico Velazquez, [3] Procare Health, Barcelona

symptoms score and 3 worsened. A "moderate/complete satisfaction" and some degree of Â«positive impact on wellnessÂ» were reported by 84% and 90% of evaluated patients, respectively. Vaginal microbiota analysis is currently ongoing.

Conclusion: In this pilot study, PapilocareÂ® shows promising benefits in the variables analyzed; these findings need to be confirmed in a larger study.