ASCCP 2023

SCIENTIFIC MEETING ON ANOGENITAL & HPV-RELATED DISEASES

A CONSERVATIVE TREATMENT OF CIN 2 USING A *CORIOLUS VERSICOLOR*-BASED VAGINAL GEL: AN OBSERVATIONAL STUDY

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OBJECTIVE:

Cervical cancer (CC) is the fourth most common malignant neoplasm among women worldwide[1]. As women with CIN2-3/HSIL have an elevated likelihood of developing CC, this diagnosis has often been considered the threshold for indicating excisional treatments, such as conization. However, this has led to some overtreatment. Additionally, studies have shown that excisional treatment is associated with a significantly increased risk of preterm birth[2]. Due to the risks associated with this type of procedure, there are some instances in which a conservative management can be taken.

According to the Spanish Association of Cervical Pathology and Colposcopy´s guidelines[3] for cervical cancer screening, a conservative management is only acceptable for a maximum of two years in the following cases: 1) HSIL/CIN 2 in women with gestational desire or lesion smaller than two quadrants, or 2) HSIL/CIN 3 in women under 30 years of age and lesion of less than one quadrant. The aim of this study was to evaluate the effect of a *Coriolus versicolor*-based vaginal gel in the conservative management of CIN 2 lesions.

METHODS:

A one-cohort, prospective, single-centre, observational study including ≥ 18 years-old women, with CIN 2 diagnosis were treated with 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months of a *Coriolus versicolor*-based vaginal gel.

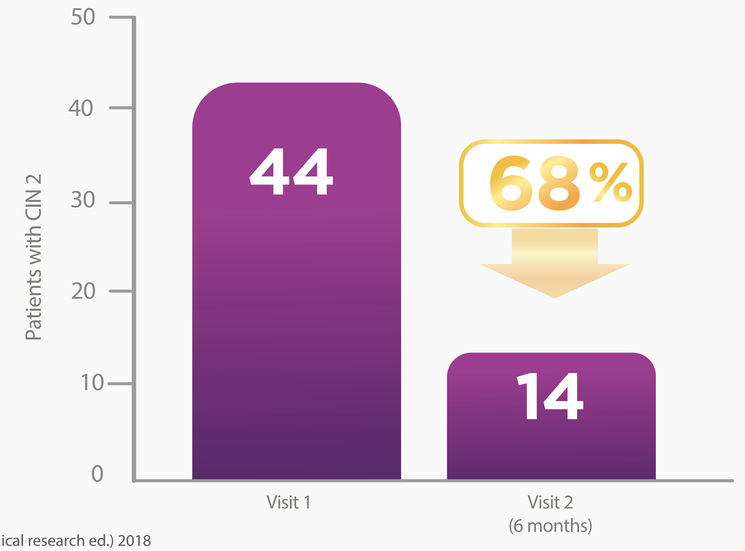
Inclusion criteria have been based on the Spanish Society of Colposcopy and Cervical Pathology (AEPCC) guidelines for CIN 2 conservative treatment[3]: colposcopy image with visible transition zone, completely visible lesion affecting less than 2 quadrants, non-affected endocervix and accepting cytology/colposcopy after 6 months. Baseline and 6-month biopsies were performed.

1. Cohen, P. A., Jhingran, A., Oaknin, A., & Denny, L. (2019). Cervical cancer. Lancet (London, England), 393(10167), 169–182. https://doi.org/10.1016/S0140-6736(18)32470-X 2. Bruinsma FJ, Quinn MA. The risk of preterm birth following treatment for precancerous changes in the cervix: a systematic review and meta-analysis. BJOG. 2011;118:1031–1041. doi: 10.1111/j.1471-0528.2011.02944.x. 3. Torné A. et al. (2022). Prevención Secundaria del Cáncer de Cuello del Útero, 2022. Conducta Clínica Ante Resultados Anormales del Las Pruebas de Cribado. AEPCC-Guía. https://www.aepcc.org/wp-content/uploads/2022/05/AEPCC-Guia_Prevencion-cancer-cervix_2022_v05.pdf 4. Tainio, Karoliina et al. "Clinical course of untreated cervical intraepithelial neoplasia grade 2 under active surveillance: systematic review and meta-analysis." BMJ (Clinical research ed.) vol. 360 k499. 27 Feb. 2018, doi:10.1136/bmj.k499

RESULTS:

A total of 44 women 35.5 years-old on average were included. After a 6-month treatment period, 68.2% of them showed a regression by biopsy, 11.4% persisted on CIN 2 and 18.2% progressed to CIN 3.

Three patients were considered null and not included in the data analysis because they did not have a biopsy taken after 6 months.



1.Tainio, Karoliina *et al*., BMJ (Clinical research ed.) 2018

CONCLUSION:

The *Coriolus versicolor*-based vaginal gel 6 month treatment seems to increase the regression of lesions (68.2% at 6 months) compared to spontaneous resolution. According to a systemic review and meta-analysis of 36 studies that included 3160 women, 46% of untreated CIN 2 lesions regress spontaneously at 12 months, with that rate being higher (51%) in women under 30 years old[4]. Therefore, in light of the results of this study which achieve higher regression rates in less time, treatment with a *Coriolus versicolor* based vaginal gel could represent a clinical advantage compared to the "wait and see" approach in patients meeting the conservative treatment criteria for CIN 2 lesions.