

Evaluation of the Efficacy of *Coriolus Versicolor** Supplementation in HPV Lesions (LSIL)

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Introduction

The use of mushroom nutrition with an immunomodulator effect is a common and ancient practice in Asian cultures. The significant amounts in free polysaccharides, proteoglycans, enzymes, and secondary metabolites (e.g. terpenes, alkaloids, steroids) constitute the main compounds responsible for their immunomodulating activity.

The *Coriolus versicolor* biomass, is a non-specific immunomodulator which can be very useful as an adjunct to nutrition in support of the immune system in common patients undergoing chemotherapy or radiotherapy during oncological treatment.

Objectives

With the aim of evaluating the supplementation effects in patients with cervix lesions (LSIL) by HPV, a group of 43 LSIL patients (confirmed by cytology, colposcopy and biopsy) was randomly divided into 2 sub-groups:

The first group received supplementation with *Coriolus versicolor* (biomass) for 1 year-3g/day (6 tablets: 3 tablets at breakfast and 3 tablets at dinner). The control group did not receive any supplementation.

In neither group was any therapeutic procedure performed (cryotherapy, electrocoagulation or laser vaporization) thus performing an evaluation of the *Coriolus versicolor* effects in patients not submitted to routine surgical treatment.

Material and methods

Study Design

The 43 patients, selected randomly, were divided into two groups:

The first group (21) was not submitted to any conventional treatment: the Control group.

The second group (22) was submitted to *Coriolus versicolor* supplementation for a period of one year (6 tablets/day i.e. 3g/day).

Protocol

All patients were submitted to colposcopy, biopsy and HPV tipification (hybrid capture) at the first observation.

Cervical cytology exams (Pap smear tests) determined the LSIL patients. The colposcopy and biopsy tests reconfirmed LSIL status.

Four months after the first observation, all patients were once again evaluated performing colposcopy and cervical cytology. At the same time, there was an evaluation of possible side effects from *Coriolus* supplementation.

After one year, (at the end of the supplementation with *Coriolus*), all patients were examined for the third time (colposcopy, cervical cytology and HPV tipification).

The efficacy of *Coriolus* supplementation in LSIL patients was evaluated considering the evolution of HPV tipification (from HPV+ to a HPV- status) as well as the persistence of the cervical lesions (persistence measured by colposcopy and cytology LSIL) both over the course of the study period.

Success Parameters

The efficacy of the administration of *Coriolus versicolor* as a food supplement was evaluated in the LSIL group by:

- reverting the HPV positive stage (HPV+) to a HPV negative stage (HPV-);
- establishing cervical cytology normalization after 1 year.

Study Population

Of the 43 patients who started the experiment, 39 completed the trial. Of the four (4) who did not complete the trial, 1 patient left the country and 3 discontinued supplementation due to minor side-effects (See side effects).

The age distribution of the two groups was very similar. Patients submitted to *Coriolus* presented an average age of 31.7 years, with a minimum age of 19 and a maximum age of 49 years. The control group had an average age of 33.4 years, with a minimum age of 19 and a maximum of 51 years.



Results

Thirty-nine (39) patients already concluded one year of follow-up. The first time they were controlled, 22 patients had HPV+ High Risk.

Eighteen (18) patients took *Coriolus* supplementation, while the other twenty-one (21) patients had no therapy (control), all being under clinical observation for 365 days.

Of the 22 patients who showed HPV+ High Risk tipification, 10 patients took *Coriolus* supplementation and 12 patients did not.

Of the 18 patients who took *Coriolus* supplementation over one year, 13 (72,5%) still showed normal cervical cytology, after one year of follow up.

Of the 21 patients who did not take any supplementation, 10 (47,5%) still showed normal cervical cytology after one year of follow-up.

Regarding HPV tipification, from 10 patients who had HPV+ High Risk and took *Coriolus* supplementation, 9 (90%) reverted to HPV- status after one year. On the other hand, of the 12 HPV+ High Risk status patients who did not take *Coriolus* supplementation, only 1 (8,5%) reverted to HPV- status.

Table 1. Results of the treatment of LSIL lesions

	With <i>Coriolus versicolor</i>		Without supplementation		Total
	Negative after 1 year	Positive after 1 year	Negative after 1 year	Positive after 1 year	
Citology	13 (72,5%)	5 (27,5%)	10 (47,5%)	11 (52,5%)	39
HPV	9 (90%)	1 (10%)	1 (8,5%)	11 (91,5%)	22

LSIL-% of regression (1 year)

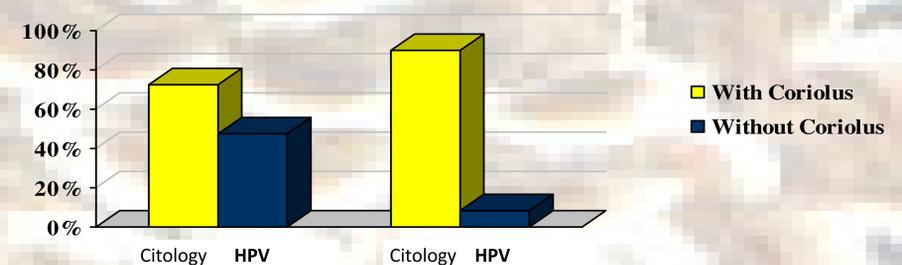


Fig.1 - Percentage of regression of cytologies LSIL and HPV + in LSIL patients

Side effects

Three patients stopped taking *Coriolus* supplementation as they showed minor side effects:

- 1 patient had gastric pain
- 1 patient had diarrhoea
- 1 patient had nausea

The side effects were not serious in any of the cases, and it was not necessary to take any kind of therapeutic action in response to these side effects. After stopping the *Coriolus* supplementation the symptoms did not remain.

Conclusions

The use of *CORIOLUS VERSICOLOR* for 1 year revealed a great efficacy, whether in the regression of the displasia (LSIL), or in the disappearance of the High Risk HPV. It seems therefore, to be a very useful food supplementation with positive therapeutic impact, either in the reversion of LSIL (with High Risk HPV+), or in those HSIL patients, who have undergone surgery but experience continued High Risk HPV viral count.