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 (performed 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:

a) reverting the HPV positive stage (HPV+ to a HPV negative stage (HPV-);

b) 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%) reverted to HPV-status.

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

<table>
<thead>
<tr>
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<th>With Coriolus versicolor</th>
<th>Without supplementation</th>
<th>Total</th>
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<tbody>
<tr>
<td>Citology</td>
<td>Negative after 1 year</td>
<td>Positive after 1 year</td>
<td>Negative after 1 year</td>
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<tr>
<td>HPV</td>
<td>12 (92,3%)</td>
<td>5 (27,3%)</td>
<td>10 (47,5%)</td>
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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.

*Coriolus MRL – Mycology Research Laboratories Ltd