

## **Clinical Results in Use of *Coriolus versicolor* as Immunonutrition in HPV Patients with Cervical Lesions (LSIL)**

On Friday, March 7<sup>th</sup>, at the 20<sup>th</sup> European Congress of Obstetrics and Gynaecology, in Lisbon Portugal, Dr. Jose Silva Couto and Dr. Daniel Pereira da Silva of the Cervical Pathology Unit of the Portuguese Institute of Oncology in Coimbra, Portugal presented a poster on their results of a year long study on *Coriolus versicolor* supplementation in HPV patients with low-grade squamous intraepithelial lesions (LSIL).\*

Dr. Couto and Dr. Pereira da Silva found that *Coriolus versicolor* supplementation over a period of one year significantly increased regression of the dysplasia (LSIL) and clearance of the high risk sub-types of the HPV virus responsible for cervical cancer.

- a) *Coriolus versicolor* supplementation demonstrated a 72% regression rate in LSIL lesions compared to 47.5% without supplementation.
- b) *Coriolus versicolor* supplementation demonstrated a 90% regression rate in the high risk HPV virus sub-types compared to 8.5% without supplementation.

### **What is the link between HPV and Cervical Cancer?**

Cervical cancer rates are high in women between the ages of 35 and 55. Risk for cervical cancer seems to increase the earlier a woman first has sexual intercourse and as the number of sexual partners increases. Failure to have a regular Pap test also increases risk.

Once diagnosed with HPV there may a change in cervical epithelial (skin wall) cells from normal (CIN-0) to one of two squamous cell types: high-grade squamous intraepithelial lesions (HSIL) or low-grade squamous intraepithelial lesions (LSIL).

The degree of cervical dysplasia is categorized accordingly:

CIN Status	Epithelial Status	Category
CIN-0		Normal
CIN-1	LSIL	Minimal or mild cervical dysplasia
CIN-2	HSIL	Moderate cervical dysplasia
CIN-3	HSIL	Severe cervical dysplasia
CIS	HSIL	Carcinoma in situ
	HSIL	Invasive Carcinoma

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\**Coriolus versicolor* supplied by Mycology Research Laboratories Ltd.

## **CIN-2/ CIN-3 Treatment (HSIL)**

Usual treatment for HSIL patients involves removing lesions with a scalpel, laser therapy, or loop electrosurgical excision procedure. These surgical treatments preserve a women's ability to have children. As HSIL lesions can recur after surgery, medical practitioners advise women to return for examinations and Pap smear tests every 3 months for the first year after surgery and every 6 months subsequently.

If the cancer is more advanced (CIS), then hysterectomy plus removal of adjacent structures and lymph nodes (radical hysterectomy) is usually necessary. Radiation therapy is also highly effective for treating advanced cervical cancer that has not spread beyond the pelvic region.

## **CIN-1 Treatment (LSIL)**

The usual treatment for CIN-1 patients is one of "wait and see". The prognosis of this situation is not as dangerous as with HSIL. In some cases, especially among women below the age of 35, their immune system is capable of "clearing" or keeping the virus under control.

However, in women (and their sexual partners) over the age of 35, especially those who take oral contraceptives and smoke, their immune system is often too compromised to clear the virus. Consequently, when diagnosed with CIN-1 (LSIL-HPV) infection, such patients may need adjunct supplementation to support their immune system against progressive HPV infection.

## **Study Design**

The year long study was funded by Mycology Research Laboratories Ltd., and the study design included forty-three (43) patients with HPV Lesions (LSIL) who were divided into two groups:

-The first group (21) did not receive any treatment (Control Group).

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

## **Protocol Design**

The patients were examined with colposcopy, biopsy and HPV tipification (hybrid capture) at the first observation. Cervical cytology exams (Pap smear tests) determined the patients' LSIL status and this was confirmed through colposcopy and biopsy.

Four months after the first observations, colposcopy and cervical cytology was again carried out on all patients. At the same time, there was an evaluation of the possible side effects from *Coriolus* supplementation.

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

### **Success Parameters**

The efficacy of *Coriolus* supplementation in LSIL patients was evaluated in terms of the evolution of HPV tipification from High Risk HPV+ to High Risk HPV- status as well as the persistence of cervical lesions as measured by colposcopy and cytology.

### **Study Population**

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

The age distribution of the two groups was very similar. Patients receiving *Coriolus versicolor* supplementation had 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**

Of the 39 patients who completed one year of follow-up 18 took *Coriolus* supplementation, while the other 21 patients received no therapy (Control group). After 1 year 13 of the 18 patients in the *Coriolus* group showed normal cervical cytology (72.5%) while only 10 of the patients in the control group did (47.5%).

Of the 39 patients, 22 were positive for high risk HPV subtypes. 10 of these patients were in the *Coriolus* group and 12 in the control group. After 1 year 9 of the 10 in the *Coriolus* group had reverted to HPV- status (90%) while only 1 of the 12 in the control group had (8.5%).

### **Conclusion**

While the study sample is limited in number, the results strongly suggest that *Coriolus versicolor* supplementation offers gynaecologists a useful nutritional tool when treating HPV (LSIL) patients.

It is also likely that *Coriolus versicolor* could be beneficial in HSIL patients who have undergone surgery but who experience recurrent lesions in order to reduce the viral load.

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