

Available online at [www.sciencedirect.com](http://www.sciencedirect.com)**ScienceDirect**

Procedia in Vaccinology 9 (2015) 35 – 37

**Procedia in  
Vaccinology**[www.elsevier.com/locate/procedia](http://www.elsevier.com/locate/procedia)

8th Vaccine &amp; ISV Congress, Philadelphia, USA, 2015

## Use of yeast lysate in women with recurrent vulvovaginal candidiasis.

Vrzal, V.<sup>a</sup>, Bittner, L.<sup>a</sup>, Nepereny, J.<sup>a</sup><sup>a</sup> *Bioveta, a. s., Komenskeho 212, 683 23 Ivanovice na Hane, Czech Republic*

---

### Abstract

Vulvovaginal candidiasis (VVC) affects a significant number of women, especially in working age. In an estimated 75% of women an episode of acute vulvovaginal candidiasis occurs during lifetime and another 5 – 10% of women develop recurrent vulvovaginal candidiasis (RVVC). This is mainly characterized by intense burning, itching, pain, abnormal discharge, dyspareunia. Immune response to candidiasis is both cellular (CMI) (natural protection mechanisms) and humoral (antibody production). Understanding the principles of immunity in candidiasis is also important for development of candida vaccines.

CANDIVAC contains lyophilized *Candida* lysate (*C. albicans*, *C. krusei*, *C. glabrata*) together with immunostimulatory bacterial strain of *Propionibacterium acnes*. The product is taken orally in capsules for 10 days followed by a 20-day pause. It is administered for 3 to 6 months. The product has been tested in a total of 75 women at the age of 18 – 45 years. In these women at least 4 episodes of vulvovaginal candidiasis have been microscopically or laboratory diagnosed during the last 12 months. Following CANDIVAC administration, statistically significant changes occurred in the evaluation of subjective and some objective criteria. The most important marker of product efficiency is a significant reduction in recurrence compared to the recent state. This criterion has a fundamental importance in patient satisfaction. Before medication the patients suffered from at least 4 attacks, while after medication an attack occurred in only 31% of women and more than 2 attacks in only 3% of treated women. Compromised balance of immune system plays a major role in recurrent vulvovaginal candidiasis. Specific oral product CANDIVAC, prepared from the most common strains of yeast infections, supports immune mechanisms, ensuring resistance of the human organism against yeasts. Its administration significantly prolongs remission, leads to a reduction in application of antimycotics and also changes properties of cellular and humoral immunity in medicated patients.

© 2015 Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Selection and peer-review under responsibility of the 8th Vaccine Conference Organizing Committee.

**Keywords:** vulvovaginal candidiasis, candida, vaccine, antibody

---

### Introduction

Vulvovaginal candidiasis (VVC) and recurrent vulvovaginal candidiasis caused by *Candida* type of bacteria are a significant public health problem affecting a large number of otherwise healthy women. That is why the

immunotherapy and vaccines are subject to medical research<sup>1, 2</sup>. CANDIVAC medication is a lysate of *Candida albicans*, *C. krusei*, *C. glabrata* and *Propionibacterium acnes*. This product is patented in the EU and in the USA<sup>3</sup>. A clinical study verified its effects in female patients. This study is subject to further analysis in this paper<sup>4</sup>.

### Methodology

The study included 75 women aged 18 - 45 (mean age 31.2) from 5 gynaecology outpatient clinics who had experienced at least 4 episodes of mycotic vulvovaginitis in the last 12 months and received microscopy-based or laboratory-based diagnosis. At the moment of inclusion a participant had to be free of acute inflammation of internal genitalia, and of bacterial vaginosis.

After meeting all the inclusion criteria the female participants started using CANDIVAC®. CANDIVAC® contains lyophilized inactivated strain of *Candida albicans*, *Candida glabrata* and *Candida krusei* and the immunostimulating strain of *Propionibacterium acnes*. Total volume of the lyophilized bacterial lysate is 5 mg, vehiculum volume is 195 mg in 1 capsule. One package contains 30 capsules of 200 mg. CANDIVAC® was administered orally 1x daily on empty stomach for 10 days followed by a 20-day pause period. This dosage model was followed for 6 months.

Assessments were performed just before inclusion of the female participants into the study and repeated after 6 months (cessation of planned medication) and after 9 and 12 months since the study initiation. The study was completed by 68 women (7 were excluded).

### Results

#### a) Subjective criteria

There were some statistically significant changes during evaluation of subjective criteria (Tab. 1).

#### b) Lactobacilliary gradient (LG) values and number of leukocytes in the visual field

Lactobacilliary gradient (LG) values and number of leukocytes in the visual field remained without any changes (Tab. 2).

#### c) Vaginal yeast colonisation

The number of vaginal yeast colonisations declined (cultivation and microscopy). (Tab. 3).

#### d) The progress of relapsing vulvovaginal candidiasis during the study

During the study there was a decline in vulvovaginal candidiasis (Tab. 4).

Tab. 1, Evaluation of subjective complications in patients using Total Symptom Score (TSS)

#### A - Inclusion criteria

Type of complication	None	Mild	Medium	Severe
Discharge	0	1	2	3
Itching	0	1	2	3
Burning	0	1	2	3

Total number above 5 indicates acute inflammation and patient cannot be included into the study

#### B - Progress of subjective complications index in patients (TSS) during the study

Assessments	Total Symptom Score
Initial	2.4
After 6 months	0.7
After 9 months	0.9
After 12 months	1.4

Tab. 2, Evaluation of lactobacilliary gradient (LG) and number of leukocytes (LEU) in the visual field during the study

	Study lasted (months)			
	0	6	9	12
LG I	41.2 %	44.1 %	39.7 %	39.7 %
LG II	51.1 %	51.4 %	57.4 %	52.9 %
LG III	7.4 %	4.4 %	2.9 %	7.4 %
LEU ≤ 10	92.6 %	94.1 %	95.6 %	94.1 %
LEU >	7.4 %	5.9 %	4.4 %	5.9 %

Tab. 3, Progress of vaginal yeast colonisation during the study

	Study lasted (months)			
	0	6	9	12
Cultivation	55.9%	36.8%	36.8%	39.7%
Microscopy	39.7%	25.0%	20.6%	22.1%

Tab. 4, Progress of relapsing vulvovaginal candidiasis during the study (prior to study at least 4 episodes in each patient per year!)

Assessment	Total	Frequency of relapses		
		1 times	2 times	Multiple times
After 6 months	10 (15 %)	9	1	0
After 9 months	16 (24 %)	11	4	1
After 12 months	21 (31 %)	12	6	3

## Discussion

Recurrent vulvovaginal candidiasis presents a transient secondary immunodeficiency or reduction of non-specific natural immunity. Immunomodulation may help; it aims to put the immunocompetent cells in a state of emergency. The most natural and safest immunomodulators are lysates that contain mixture of required specific antigens. The best way to attain optimal immunomodulatory effect is to administer lysates in order to reach the epithelial cells of mucosa. Body mucosa is accompanied by immunocompetent tissue. In the lymphoid tissue, there are essential immune processes taking place and the immune reactions then spread to the whole body. Therefore, oral administration of yeast lysates is irreplaceable.

## Conclusion

During relapsing vulvovaginal candidiasis the balance of immunity system is impaired. Patented, specific, oral and immunostimulating product CANDIVAC enhances immunity mechanisms that ensure resilience to yeast, and it has been prepared from the most common strains of yeast infections affecting vulvovaginal system. Its administration was proved to prolong the relapse period of vulvovaginal conditions, it leads to reduction of antimycotic agents and it has a positive effect on qualities of cellular immunity.

## References

1. Fidel PL, Cutler J E. Prospects for Development of a Vaccine to Prevent and Control Vaginal Candidiasis. *Curr Infect Dis Rep* 2011 February;13(1): 102-7.
2. Vecchiarelli A, Pericolini E, Gabrielli E, Pietrella D. New approaches in the development of a vaccine for mucosal candidiasis: progress and challenges. *Front Microbiol* 2012 Aug 13;3:294
3. Patent EP 1791601B1, patent US 7,648,698,B2 „Vaccine for veterinary and human medicine prophylaxis and therapy“.
4. Unzeitig V, Stará A, Dvořák J, Nový, J. Využití kvasinkového lyofilizátu CANDIVAC cps. u žen s rekurentní vulvovaginální kandidózou: Results of clinical study. *Prakt Gyn* 2012; 16 (2-4): 71-74.