

Clinical efficacy of peroral autogenous microbial vaccines in the treatment of chronic and recurrent vulvovaginitis

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INTRODUCTION AND PURPOSE

Autogenous microbial vaccines are medicinal products with immunomodulatory effect prepared from autologous isolates of microorganisms causing chronic or recurrent infections of the patient. Nowadays, in the so-called post-antibiotic era, the treatment of chronic and recurrent infections represents a serious problem. Even though the accurate mechanism of action of autogenous microbial vaccines is not known, recent studies indicate their dominant effect on the innate immunity by stimulating the production of proinflammatory cytokines by peripheral monocytes, macrophages and dendritic cells. The aim of our study was to monitor the clinical efficacy of peroral autogenous vaccines in the treatment of chronic and recurrent vulvovaginal infections.

METHODS

Autogenous vaccines were prepared from bacteria or yeasts repeatedly isolated from the patient's vaginal or cervical swabs. The microorganisms were multiplied by cultivation on the surface of cellophane placed on a non-selective nutrient agar. Subsequently, the cellophane was rinsed by sterile saline and the microbial suspension was inactivated by 3,6% formaldehyde. The inactivated suspension was diluted to the final density $10^7 - 10^8$ CFU/ml depending on the microbial strain. The concentrated vaccine was diluted 1:10, 1:100, 1:1000 and 1:10 000. Preparation of autogenous vaccines was carried out in a laminary flow cabinet class A placed in a cleanroom class B according to the requirements of GMP.

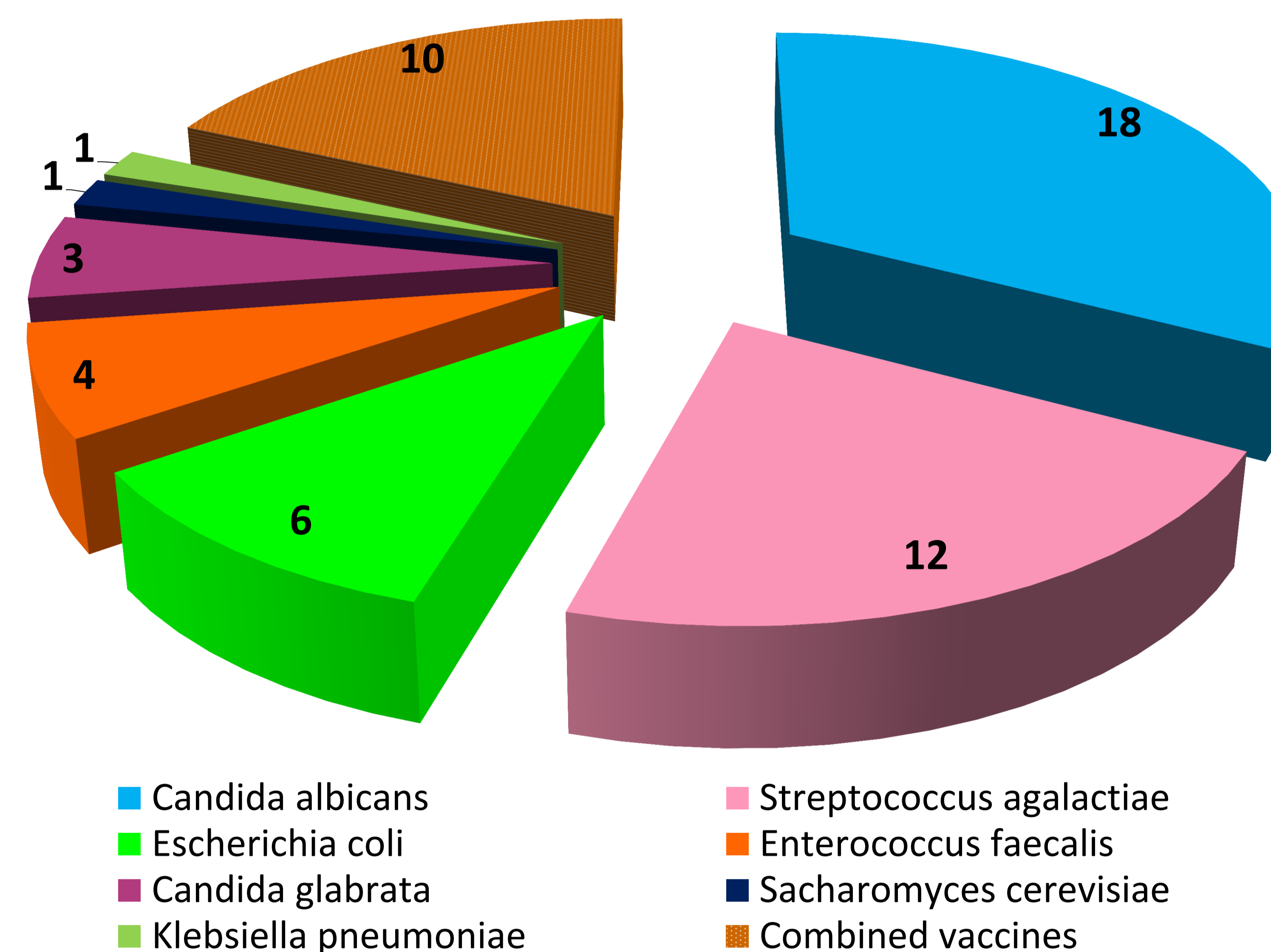
RESULTS

Clinical efficacy of autogenous vaccines was studied on a group of 55 women treated during the years 2011 and 2012. Before the treatment they had chronic and recurrent vulvovaginitis with 4-8 relapses/year. The patients were using the vaccines for 10 months according to the standard hyposensibilisation schedule. 20 (36,36%) of them had no relapse during the treatment (I), 16 (29,09%) of them had 1 relapse at the beginning of the treatment (II), 12 (21,82%) of them had 2 relapses during the treatment (III) and in 7 (12,73%) cases the treatment had no effect (IV). 18 (32,73%) of the 55 treated women has been hitherto (i.e. 1-1,5 year after the treatment) asymptomatic (a), 2 (3,63%) of them had the first relapse 1 year after the completion of the treatment (b), 6 (10,9%) of them had the first relapse 6 months after the completion of the vaccine treatment (c), 5 (9,09%) of them were asymptomatic up to 3 months after the treatment (d), 17 (30,90%) women had a relapse right after the completion of the treatment (e). Among the most efficient vaccines belong those which contained the antigen complex of microorganisms *Candida albicans* or *Escherichia coli*, the least effective were the ones containing antigen complex of *Streptococcus agalactiae*.

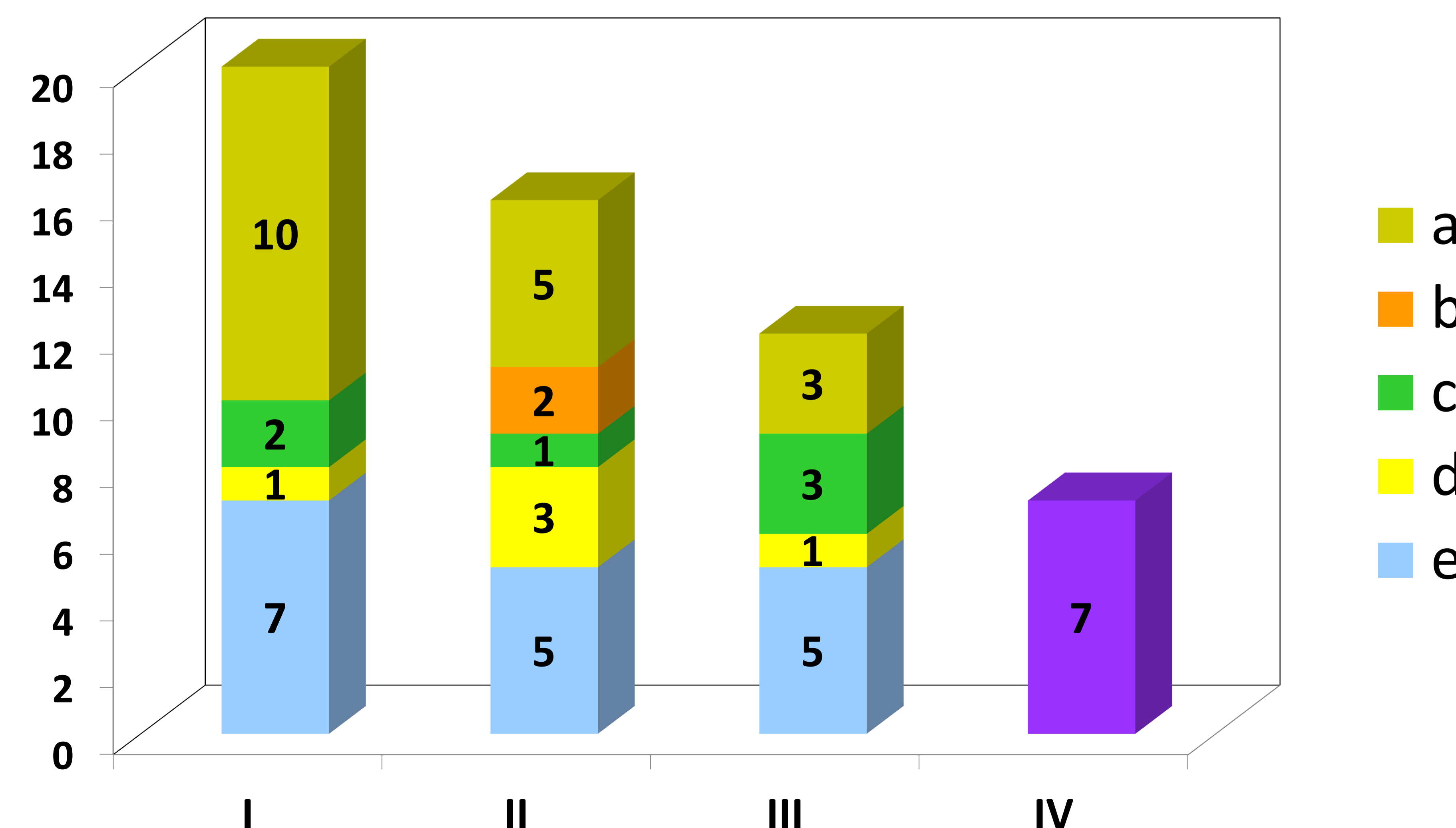
CONCLUSIONS

Our results show that treatment with peroral autogenous microbial vaccines effectively reduces the number of relapses of chronic and recurrent vulvovaginitis and also helps to suppress the usage of antibacterials and antimycotic drugs.

Composition of prepared autogenous vaccines



Clinical efficacy of prepared autogenous vaccines



Single-base autogenous vaccines

Microorganisms	Antigen concentration	Amount of vaccines
<i>Candida albicans</i>	1x10 ⁸ CFU/ml	18
<i>Streptococcus agalactiae</i>	1,5x10 ⁸ CFU/ml	12
<i>Escherichia coli</i>	6x10 ⁸ CFU/ml	6
<i>Enterococcus faecalis</i>	4x10 ⁸ CFU/ml	4
<i>Candida glabrata</i>	1x10 ⁸ CFU/ml	3
<i>Sacharomyces cerevisiae</i>	1x10 ⁸ CFU/ml	1
<i>Klebsiella pneumoniae</i>	6x10 ⁸ CFU/ml	1

Combined autogenous vaccines

Microorganisms	Antigen concentration	Amount of vaccines
<i>Enterococcus faecalis</i>	8x10 ⁷ CFU/ml	1
<i>Klebsiella pneumoniae</i>	2x10 ⁸ CFU/ml	
<i>Streptococcus agalactiae</i>	6x10 ⁷ CFU/ml	1
<i>Sacharomyces cerevisiae</i>	3x10 ⁷ CFU/ml	
<i>Enterococcus faecalis</i>	8x10 ⁷ CFU/ml	1
<i>Escherichia coli</i>	2x10 ⁸ CFU/ml	
<i>Enterococcus faecalis</i>	8x10 ⁷ CFU/ml	1
<i>Candida albicans</i>	3x10 ⁷ CFU/ml	
<i>Streptococcus agalactiae</i>	6x10 ⁷ CFU/ml	3
<i>Candida albicans</i>	3x10 ⁷ CFU/ml	
<i>Streptococcus agalactiae</i>	6x10 ⁷ CFU/ml	1
<i>Enterococcus faecalis</i>	8x10 ⁷ CFU/ml	
<i>Streptococcus agalactiae</i>	6x10 ⁷ CFU/ml	2
<i>Escherichia coli</i>	2x10 ⁸ CFU/ml	