Molecular Analysis of the Vaginal Microbiome applying the Femoflor16 Test System in Women with Non-specific Colpitis

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Introduction

The physiological vaginal microbiome contributes essentially to the health of women preventing urogenital diseases such as aerobic and anaerobic vaginitis, urinary tract infections and sexual transmitted diseases. Dysbiotic changes affecting the balance in the vaginal ecosystem may result in a loss of the protective effect of the vaginal microbiome. In order to detect pathological alterations of the vaginal microbiome the results of conventional microbiology were directly compared to the molecular based test system Femoflor16 (DNA-Technology LLC, Russia).

Material & Methods

Our pilot study included 100 vaginal swabs to characterize the vaginal flora of women with non-specific colpitis after conventional culture. Criteria for exclusion were the growth of specific pathogenic microorganisms (e.g. *Candida spp.*) as well as the presence of pathogens causing sexual transmitted diseases. Total DNA extraction was performed by the automated system QIASymphony SP (Qiagen GmbH, Germany). Subsequently, isolated DNA was analyzed applying the molecular-based Femoflor16 test system. These results were directly compared to the microbiological findings in order to determine the correlation of both procedures.

Figure 1: Workflow – DNA-extraction > real-time PCR > data analysis

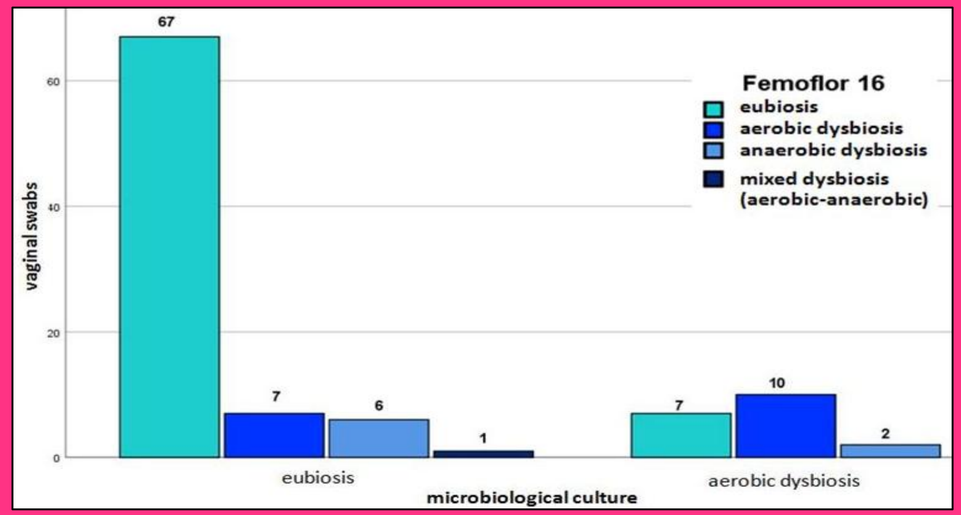

Figure 2: Comparison of Microbiology and Molecular Biology based on the Assessment of the Vaginal Flora State

Results

67/100 (67%) of the samples showed eubiosis of the vaginal flora using both methods. 10/100 (10%) specimens were identified as showing aerobic dysbiosis by both methods. Comparing microbiology and the Femoflor16 test a highly statistically significant correlation was observed ($p < 0.001$). However, in 14/100 (14%) samples a dysbiosis was detected by the Femoflor assay alone but not by conventional microbiology. 9/100 (9%) specimens showed aerobic dysbiosis in culture and were classified as eubiosis or anaerobic dysbiosis with the molecular methode. Additionally, the molecular test system was capable to detect *Lactobacillus spp.* 16/18, 88.9%) and *Candida spp.* (82/100, 82%), which were not detected by culture.

Conclusion

In summary, it could be confirmed that the real-time PCR-based Femoflor16 system provides results corresponding to those of conventional microbiology regarding the assessment of the vaginal flora state. In order to obtain reliable results the pre-analytics (e.g. quality and collection of sample, appropriate conditions of storage/transport, along with careful handling) play an essential role. In conclusion, the molecular procedure is a more sensitive method for the analysis of the vaginal microbiome than the microbiological culture and seems to be a useful tool to support microbiological analysis.