Synbiotic vaginal insert containing *Lactobacillus crispatus*, fructo-oligosaccharides and ascorbic acid: technological and microbiological characterization

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Reproductive-aged women are frequently subjected to disturbances in the vaginal environment due to vaginal infections and abnormal vaginal flora. The most common vaginal infections are candidiasis and aerobic vaginitis in which the normally present *Lactobacillus* spp. are replaced by *Candida albicans* or aerobic organisms, predominantly enteric commensals or pathogens, respectively [1, 2]. The use of lactobacilli of human origin as probiotics against the infections of urogenital tract can represent an alternative approach to help restore and maintain the natural healthy balance of the vaginal microbiota.

PURPOSE

The aim of this work was to develop a synbiotic vaginal insert containing high number of viable cells of *Lactobacillus crispatus* BC5, a probiotic strain recently isolated from healthy women [3], the prebiotic substrate fructo-oligosaccharide (FOS) and the antioxidant agent ascorbic acid (AA).

METHODS

L. crispatus BC5 loaded vaginal inserts were prepared through freeze-drying by associating hydroxypropylmethylcellulose (HPMC) and different amounts of FOS, AA and skimmed milk. Inserts were stored at +2-4°C for 90 days and characterized in terms of morphology and mucoadhesion properties. *In vitro* water-uptake and release studies were performed in order to investigate insert ability to hydrate and release *L. crispatus* BC5. Microbiological tests were carried out to investigate lactobacilli viability during freeze-drying and the subsequent storage period, and to evaluate antimicrobial activity toward *C. albicans* and representative bacteria responsible for aerobic vaginitis.

RESULTS

Inserts showed a different morphology based on their composition and good mucoadhesion properties [4]. Moreover, insert hydration over time gave rise to a gel system able to modulate lactobacilli release in virtue of the different FOS amounts. Complete survival of *L. crispatus* BC5 was found immediately after insert preparation as well as after 90 days in the vaginal inserts containing FOS, AA and skimmed milk. Finally, antimicrobial activity exerted by *L. crispatus* BC5 released from the vaginal formulation is not affected by the technological process and/or storage conditions.

CONCLUSIONS

The inclusion of suitable FOS and AA amounts into the formulation was found to be a key factor affecting insert technological and functional properties. In particular, vaginal inserts made from HPMC, FOS and AA loading *L. crispatus* BC5 are applicable and promising for the treatment and prevention of genito-urinary infections.

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