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Properties of a new, long-lasting vaginal delivery system (LASRS) for contraceptive and antimicrobial agents

L. J. Zaneveld, D. P. Waller, N. Ahmad, J. Quigg, J. Kaminski, A. Nikurs and C. De Jonge

Department of Obstetrics and Gynecology, College of Medicine, Rush University, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois 60612, USA.

lzanevel@rush.edu

In view of the need for improved vaginal formulations that are contraceptive, that may prevent transmission of sexually transmitted infections, or both, a new delivery system (base formulation; called Long Acting, Sustained Release of Spermicide, or LASRS) was developed that contains bioadhesive and other ingredients with a long history of safety, and was designed to provide long-lasting vaginal retention of the formulation and to minimize possible vaginal irritation caused by incorporated active ingredients. Nonoxynol-9 (N-9) was added as an active ingredient to study the vaginal irritating properties of the formulation and to assess its long-term effectiveness by postcoital spermicidal tests. In the first series of experiments, *in vitro* studies showed that the formulation spreads rapidly over a cellulose membrane, forming a bioadhesive layer that remained for at least 12 hours. The second series of experiments addressed the safety of the LASRS suppository in rabbits and primates. Even with a very high concentration of N-9 (20.5%), LASRS caused only mild/moderate but acceptable irritation in the rabbit. No vaginal irritation occurred in the primate at an even higher concentration (22.5%). During the third series of experiments, the long-lasting vaginal retention properties were evaluated by postcoital spermicidal tests in the primate. LASRS with N-9 was highly spermicidal even when mating was delayed for 12 hours after placement of the formulation. Spermicidal activity was also observed when 1) mating was delayed for 24 hours after insertion of the formulation, and 2) if the females were mated 2 or even 3 times without reinsertion of the suppository before collection of the vaginal contents. In the final series of tests, the postcoital spermicidal properties of menfegol, another cytotoxic spermicide, were evaluated as were several modifications in the base formulation. Menfegol produced essentially the same results as N-9. Altering the base formulation proved to be nonbeneficial because a decrease in the long-term spermicidal effectiveness was obtained. These results suggest that the LASRS suppository has good vehicle properties for the delivery of active ingredients to the vagina.

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