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Nanoparticles-in-vaginal films for combined delivery of anti-HIV microbicide drugs

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Statement of the Problem: There is an urgent need to reinforce battle against HIV/AIDS, namely by investing more in preventing new infections. Scientific and medical evidence produced over recent years supports that both oral and topical Pre-Exposure Prophylaxis (PrEP) are promising approaches that can reduce sexual transmission of the virus. Still, anti-retroviral with different physicochemical properties may be challenging to combine in one single microbicide product.

Methodology & Theoretical Orientation: We propose a new system comprising the incorporation of Nano Particles (NPs) into films for the combined vaginal delivery of hydrophobic/hydrophilic molecules. EFV-loaded poly (lactic-co-glycolic acid) NPs were incorporated alongside free TFV into fast disintegrating films during film manufacturing. The delivery system was characterized for physicochemical properties, as well as for genital distribution, local and systemic 24 h pharmacokinetics, and safety upon intra vaginal administration to mice.

Results: EFV NPs with diameter of 145 nm were incorporated into a film with TFV. The film was soft and flexible. Disintegration time in simulated vaginal fluid was 9 min, resulting in dispersions with osmolality values near physiologic and pH of 4.24±0.02. The film presented low toxicity to CaSki, HEC-1-A and HeLa cells. NPs were evenly distributed and retained upon vaginal administration to mice. Mild epithelial penetration of NPs was observed. Drug concentrations in vaginal lavages and tissues peaked rapidly after film administration but slowly decreased up to 24 h. Still, drug concentrations were maintained at potentially protective levels. Films were found safe after daily 14 days administration as assessed by histological observation and analysis of IL-1b, IL-6, KC and TNFα levels.

Conclusion & Significance: The proposed NPs-in-vaginal film is a promising new system that can adequately combine microbicide drugs with different solubility profiles. Results support that the system may be safe and able to provide sustained and potentially effective drug levels for preventing vaginal HIV transmission.

Biography

Bruno Sarmento completed his PhD in Pharmaceutical Technology and Degree in Pharmaceutical Sciences at University of Porto, Portugal. He is an Affiliated Researcher at Institute of Investigation and Innovation in Health (i3S) and Institute of Biomedical Engineering (INEB), University of Porto, Portugal. He is an Assistant Professor of Pharmaceutical and Biopharmaceutical Technology at IUCS, Portugal. His current research is focused on "The development of functionalized nanomedicines and their application in the pharmaceutical and biomedical fields; in particular, nano-formulations of biopharmaceutical drugs with interest in diabetes, cancer and infectious diseases". He has also specialization in "Mucosal tissue engineering models to validate functionalized nanomedicines and to perform *in vitro/in vivo* correlation". He has published more than 160 papers in international peer reviewed (ISI) journals, 34 book chapters and more than 180 proceedings. He edited four books, participated in more than 50 invited/selected talks in national and international meetings and was awarded several distinctions. He is a member of Editorial Advisory Board of 10 international journals and has acted as referee for top-ranked journals in his area of expertise and for international funding agencies.

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