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Testing Candidate Topical Microbicides – Distinguishing Toxicity from Efficacy in Preclinical Testing

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from 2005 International Meeting of The Institute of Human Virology
Baltimore, USA, 29 August – 2 September 2005

Published: 8 December 2005

Retrovirology 2005, 2(Suppl 1):S92 doi:10.1186/1742-4690-2-S1-S92

Topical microbicides are considered an affordable choice for the prevention of sexually transmitted diseases in women. We have developed a comprehensive testing program for preclinical microbicide development. Over the years, we have tested several thousand compounds for use as topical microbicides in a series of cell-based assays addressing HIV-1 efficacy and toxicity. Recently, we compared historical data of the spermicide nonoxonyl-9 (N-9) in a multi-center study and found that the HIV-1 efficacy paralleled its toxicity. Intra-assay, inter-assay, and inter-laboratory variability for toxicity were remarkably consistent. In a recent clinical trial, N-9 was found to enhance HIV-1 infection, thus confirming the preclinical toxicity data. In addition to N-9, lemon and lime juices have been proposed and used as contraceptives and were recently shown to exhibit *in vitro* activity against HIV-1. Therefore, we tested freshly prepared lemon juice, lime juice, and household vinegar (concentration = 100%) for HIV-1 efficacy and toxicity and for effect on beneficial *Lactobacillus* species. In all assays, the therapeutic index was <10, due to toxicity of the juices and vinegar to cells (mean TC₅₀ of lemon juice = 5.6%, mean TC₅₀ of lime juice = 4.9%, and mean TC₅₀ of vinegar 0.1%). Ten percent lemon or lime juice were not toxic to beneficial *Lactobacillus* species, in contrast to 10% vinegar which was highly toxic. Our pre-clinical data indicate that candidate topical microbicides should be moved forward into clinical trials with caution.