Retrovirology

Poster presentation

P11-12. A novel vaginal ring device for the sustained delivery of recombinant C-clade HIV-1 CN54gp140

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Background

Cervicovaginal (CV) tissue is the primary site for HIV transmission and a major reservoir for viral replication. Therefore, a successful vaccine strategy should induce potent immune responses at this mucosal surface. One potential method for achieving a localised immune response is to administer the antigen directly to the CV tissue (Marx et al., 1993, Wassen et al., 1996). The aim of the study was to evaluate the in vitro release characteristics of lyophilised hydroxypropylmethylcellulose (HPMC) gel inserts containing HIV envelope protein CN54gp140 either as stand-alone formulations or located within a novel rod-insert vaginal ring device (RIVR).

Methods

Vaginal gel formulations comprising either low or high molecular weight (MW) HPMC and CN54gp140 (0.25% w/w) were prepared. The gels were injected into silicone elastomer tubing, cut to 40 mm lengths, and then lyophilised to produce solid rod inserts. *In vitro* release testing was performed on rod inserts alone and rod insert vaginal rings (RIVRs) containing two CN54gp140-loaded rod inserts. Release of gp140 was quantified by ELISA.

Results

Release of CN54gp140 from rods prepared from low MW HPMC was similar for both inserts alone and rings containing inserts (99% cf. 90% over two hr). Release from the high MW inserts was significantly slower and more sustained than the low MW formulations. Also, CN54gp140 release from high MW rod inserts rings (68% of theoretical over 48 hr) was significantly more sustained than high MW inserts alone (86% over 24 hr).

Conclusion

The study demonstrates that CN54gp140 (i) maintains its antigenicity during the preparation of HPMC lyophilised rod inserts, and (ii) may be administered in a sustained manner when the inserts are placed into an RIVR device. This stable, sustained-release formulation strategy has the potential to induce stronger immune responses and immune memory upon vaginal administration (Zhao and Leong, 1996; Lofthouse, 2002).