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Preclinical evaluation of an innovative RSV virus like particulate vaccines for RSV infection

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Purpose: The respiratory syncytial virus (RSV) is one of the major causes of bronchiolitis and pneumonia in infants and immunocompromised adults. As a result, there is a need for a safe and effective vaccine for RSV. One of the major proteins present on the surface of the virus is the fusion protein F, which can be integrated into a virus-like particle (VLP), yielding a highly immunogenic F-VLP antigen. This study also aims at using a intradermal route of administration to exploit the rich population of Langerhans cells present in the epidermis and dermis.

Methods: In this study, the F-VLP antigen was incorporated into a biodegradable polymer matrix and spray dried to form microparticles. The in vitro immunogenicity was evaluated to evaluate surface co-stimulatory expression, wherein antigen presenting cells were stimulated with the vaccine-adjuvant combinations. Further, vaccine-adjuvant combination was administered to C57BL/6 mice via the intradermal route using microneedles (AdminPatch®) to evaluate the immunogenicity of the vaccine in vivo. The mice were challenged with RSV A2 (1 x 106 PFU per mouse) and body weight changes were monitored 5 days after challenge. Lung histopathology was performed using hematoxylin and eosin (H&E) staining to assess lung inflammation and necrosis post-challenge.

Results: Enhanced cell-surface expression of MHC I and MHCII as well as their costimulatory molecules CD80/86 and CD40 respectively on dendritic cells was observed. The immune sera of mice treated with a prime dose of microparticulate F-VLP with MPL (intradermal) showed significantly higher levels of IgG titers compared to FI-RSV immunized (intramuscular), F-VLP solution and microparticulate F-VLP treated mice. The intradermally administered microparticles with adjuvant (TD MP+A) group elicited a higher CD4 T cell count from lymph node and spleen cell populations when compared with the control and other test groups. The lung histopathology showed gross inflammation in lungs of mice intramuscular FI-RSV as a vaccine as compared to intradermal F-VLP MP + MPL. The other groups showed show overt inflammation, which indicates that the F-VLP antigen proved to be a safe vaccine.

Conclusion: The ability of the RSV F-VLP to induce an innate immune response provides a great foundation for the potential of microparticulate vaccines due to their robust nature and efficient immunogenic properties. Adjuvants such as MF59 and MPL A help in potentiating the immune response. Also, intradermal route of administration augments the efficacy of the microparticle vaccine. In the absence of a licensed RSV vaccine, intradermal microparticulate vaccines have immense potential and offer an alternative approach in the development of a vaccine against RSV.

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