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Formulation and preclinical testing of novel particulate vaccines loaded into Oral Dissolving Films (ODF) for measles

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Indroduction: Measles is a highly contagious infection that is caused by the measles virus. It mainly affects children and can be fatal. The disease causes about 100,000 deaths every year worldwide, although it is completely preventable by vaccines. Since the primary targets of this disease are children, we aimed at formulating an oral vaccine that would prevent the use of needles, making the vaccine more patient-compliant. The oral cavity of the mouth is covered by a lining that is rich in immune cells. These immune cells help the body to distinguish between harmful and harmless foreign material entering the body through the mouth. On dissolution, the microencapsulated vaccine antigen are recognized by the immune cells in the mouth and further processed to produce protective antibodies against measles virus. Later, whenever the body is exposed to the virus, the protective antibodies present will be capable of combating the measles infection. The goal of this study was to explore the potential of oral disintegrating films (ODF) loaded with measles vaccine nanoparticles as a viable immunization strategy.

Methods: A 1% w/v solution of sterile BSA in sterile water was prepared and cross-linked overnight with glutaraldehyde. Excess glutaraldehyde was neutralized with sodium bisulphite the following day. Live attenuated measles virus (antigen) and Aluminium Hydroxide (adjuvant) were added to the solution and spray dried using a Buchi Spray Dryer B-290. These nanoparticles were then incorporated in the ODF. The film solution was prepared at room temperature by incorporating the film forming polymer (Lycoat RS720) in an aqueous plasticizer solution under continuous mixing for 10-15 minutes until the suspension was monodisperse. The measles vaccine nanoparticle powder was then added to this suspension. The film formulation was cast using a BYK- Gardner, mechanical drive Resource I equipment and dried air dried. The measles ODF vaccine was tested *in-vivo* in pigs by delivery via the buccal route. Blood serum samples were collected every 2 weeks and a specific ELISA was performed to quantify the amount of specific antibody present.

Results: The size of the vaccine nanoparticles was in the range of 400 to 1200 nm. Using the pre-gelatinized hydroxypropyl pea starch, Lycoat RS720, we obtained the desired film strength and disintegration properties. There was a significant increase in the specific antibody against measles virus as seen after 4 weeks of dosing and remained elevated until the end of the 6 week study period.

Conclusion: The buccal delivery of ODF loaded with vaccine nanoparticles is a promising immunization delivery system. These encouraging preliminary results, will lead the way for further research in this area.

Translational Relevance: Oral disintegrating films (ODF) are a practical method of vaccination due to the stability of the vaccine in the dry film which dissolves when placed in the mouth. These films are inexpensive and an effective means to deliver drugs/vaccines orally without the use of needles.

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