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Maternal vaccination with DNA encoding the respiratory syncytial virus fusion protein leads to neutralizing antibody and virus load reduction

Damian C Odimegwu[1,2], Charles C Esimone[3], Klaus Uberla[2] and **Thomas Grunwald[2]**
[1]University of Nigeria, Nigeria
[2]Ruhr University, Germany
[3]Nnamdi Azikiwe University, Nigeria

Introduction: Respiratory syncytial virus (RSV) is the most important cause of viral lower respiratory tract illness (LRI) in infants and children worldwide. Unfortunately, development of vaccines against this virus has been fraught with many obstacles. Moreover, there are only limited options for treatment of the disease, hence there is a need to search for novel therapeutic and vaccine prophylactic options against the RSV. Maternal vaccination approach employing DNA vaccine encoding the RSV fusion F-protein was analyzed for possible protection against RSV infection and disease.

Methods: To distinguish between placental and breast-milk transfer, native mice pups one week after birth were roomed together with unrelated vaccinated mothers immediately. After RSV challenge, broncho-alveolar lavages (BALs) and lung homogenates (LHs) were collected from both mothers and pups. Samples were analyzed for IgG1, IgG2a and IgA by ELISA. Virus neutralization employing cell culture infectivity and viral load in BALs and LHs was analyzed by RTqPCR

Results: The outcome of immunization using genetic constructs encoding the fusion F-protein reveal high neutralization antibodies observed in sera taken from pups of immunized mothers in comparison to control pups from untreated or control treated mothers. Significant reduction of viral load of young offspring from immunized mothers was over 10-120 fold relative to the control offspring after viral challenge. Thus, continued effort towards RSV vaccine development should be pursued utilizing maternal vaccination as a proof-of-concept to protect the infant babies against this severe virus infection.

barb.namax@gmail.com

Development of novel therapeutic hepatitis B vaccine

Gerardo Guillén
Centro de Ingeniería Genética y Biotecnología, Cuba

Despite the existence of effective prophylactic vaccines, Hepatitis B Virus (HBV) infections remain a major public health problem. About 370 million people are chronically infected worldwide. Chronic Hepatitis B (CHB) infection also increases the risk of liver diseases such as cirrhosis and hepato-cellular carcinoma. Current antiviral therapies fail to control viral replication in the long term in most patients. As HBV persistence has been associated with a defect in the development of HBV-specific cellular immunity, therapeutic vaccination has been extensively studied in CHB. HBsAg-based vaccines, including prophylactic vaccines and HBsAg-based formulations with novel adjuvants have been used with unclear or negative results. The development of therapeutic vaccines against CHB requires proofing the capacity of the formulation to subvert a tolerated immune response. NASVAC as a new generation vaccine include the use of a novel immunization route (intranasal-IN) and a novel antigen (HBcAg) expressed in *E. coli*, used in a combined formulation with HBsAg. The evaluation in mouse support the rationality of the therapeutic vaccine candidate targeting the stimulation of CD4(+) and CD8(+) T-cell responses and the induction of pro-inflammatory cytokines capable of controlling viral replication. NASVAC proved to be immunogenic in mouse models and then in phase I, II and III, randomized, double blinded and placebo controlled clinical trials developed in healthy volunteers and CHB patients.

gerardo.guillen@cigb.edu.cu