Enhancement of efficacy of *Haemophilus influenzae* type B (Hib) vaccine by formulation strategy: Liposomal systems

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Current immunization preparation for *Haemophilus influenzae* type B (Hib) infections is based on Hib polysaccharide – tetanus toxoid (TT) conjugate, which is administered to children by i.m. and s.c. injection. The conjugate preparation process involves several cumbersome and complex steps and harsh reagents, resulting in antigen losses. As an alternative, particulate carriers can be developed to co-entrap the antigen and TT, which are reported to ensure good adjuvant effect, to potentiate T-cell dependent immune response.

In the present study, Hib capsular polysaccharide (Hib-CPS) and Tetanus toxoid (TT) co-entrapped liposomes were prepared by dehydration-rehydration of vesicles method and characterized. Comparative in vivo efficacy evaluation of the liposomal systems with conventional Hib-TT conjugate vaccine, was carried out in Wistar rats, wherein the antibody titres (IgG and IgA) in serum, nasal lavage and BAL were compared. In addition, lymphocyte proliferation assay was carried out on blood samples of the immunized animals to assess T cell response (in vitro CD4+ T cell response).

Small unilamellar vesicles (540-570 nm), with good antigen entrapment (60-70%) were obtained. In vivo efficacy study has revealed increased IgG and IgA titres with liposomal system, and good and comparable lymphocyte proliferation index values, indicating T-cell response. In conclusion, Hib polysaccharide co-entrapped with TT in liposomal systems can be an effective alternative to conventional Hib-TT conjugate vaccine.

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