

V8. PROPOSAL OF AN INTRANASAL FORMULATION FOR MENINGOCOCCAL GROUP C CONJUGATE VACCINE.

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INTRODUCTION *Neisseria meningitidis* group C is the main responsible for meningitis outbreaks in Brazil. This is a public great concern due to the high mortality rates and sequelae in survivors. The Immunobiological Technology Institute (Bio-Manguinhos), an Oswaldo Cruz Foundation's unit, developed a conjugate vaccine for *N. meningitidis* group C from the conjugation of polysaccharide with tetanus toxoid using the modified reductive amination method. The common application of this vaccine is by injection. Mucosal immunization (intranasal) for *N. meningitidis* is the most indicated administration route, due to the microorganism feature to cause infection through the respiratory tract. Mucosal vaccines offer a better immune response, because they can stimulate the systemic and local responses. However, despite the high mucosal immune system efficiency, only a reduced number of vaccines use this administration route, due to difficulties in developing appropriate formulations. One of the strategies adopted to deliver the antigen to the mucosa is using biodegradable polymers.

OBJECTIVE This study describes an intranasal formulation strategy for a meningococcal group C conjugate vaccine using the polymer chitosan for encapsulation. Thus, the encapsulation efficiency of the vaccine antigen must be evaluated with different chitosan concentrations, the formulation's characterization, and the generated immunological activity.

METHODOLOGY The meningococcal group C conjugate vaccine was provided by the Bacterial Technology Laboratory (LATEB), located in Bio-Manguinhos. The formulation preparation was performed by a precipitation process. Sodium sulfate salt was added to the chitosan solution with the vaccine antigen. Moreover, different concentrations of chitosan (0,25%, 0,5%, 0,75% e 1%) were used to select the most appropriate formulation. After the preparations were made, the encapsulation efficiency

of each formulation was investigated by protein measurement using the bicinchoninic acid method (BCA).

RESULTS Until this moment, the developed formulation showed good encapsulation results at different evaluated chitosan concentrations. In the chitosan formulation concentration of 0,5% were obtained an average of 46,48% for 15 µg doses and 52,04% for 20 µg doses; in the case of 0,75% of chitosan were obtained an average of 55,36% e 70,10% for 15 µg and 20 µg doses respectively.

CONCLUSION Despite the need to finish the immunological evaluation testing and characterization of particles, data showed that the proposed formulation methodology is promising for mucosal immunization against *N. meningitidis* group C.

KEYWORDS meningococcal group C conjugate vaccine, intranasal, chitosan.