32nd International Conference on
VACCINES AND IMMUNIZATION &
4th Annual Summit on
INFANCY, CHILD NUTRITION & DEVELOPMENT
November 09-10, 2018 | Atlanta, USA

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Novel particulate vaccine against Gonorrhea

Introduction: Gonorrhea is one of the most common sexually transmitted infections caused by Gram-negative *Diplococcus* bacteria, *Neisseria* gonorrhea. In 2009, 301,174 cases of gonorrhea were reported in the US, which accounts for 99.1 cases per 100,000 people. Patients suffer from symptomatic urethritis and cervicitis, pelvic inflammation, pus discharge, abdominal pain and dyspareunia. The treatment for gonorrhea involves use of antimicrobials but development of drug resistance is a great threat to public health and therefore novel methods for prevention of gonorrhea infection are needed.

Methods: In the present study, we formulated microparticles with pre-crosslinked BSA to deliver and evaluate efficacy of formalin fixed whole cell of gonorrhea bacteria as vaccine through subcutaneous route. *N. gonorrhoeae* were grown in GC broth and formalin fixed bacterial suspension was used to prepare vaccine microparticles by spray drying method. The microparticles were characterized for size, charge and poly dispersity index (PDI). To assess the *in-vivo* efficacy of the whole-cell particulate vaccine, 10mg of spray dried particles powder containing 500µg of the antigen was administered subcutaneously to 3 groups of 4-6 weeks old Balb/c mice. One group received subcutaneous gonorrhoea microparticulate vaccine (GnH MP), one group received subcutaneous gonorrhea vaccine in suspension (GnH Susp – 500ug) and a negative control group received the blank BSA microparticles (N=6). The vaccine dosing study comprised one prime dose, followed by two booster doses at weeks 2 and 4. Blood samples were collected prior to prime dose and every 2 weeks after dosing. The antibody levels in the blood were measured using indirect ELISA for IgG antibodies.

Results: The percent yield for vaccine particles was 89 % w/w. Vaccine particles were 4.5 um and PDI was 0.447 with a charge of -25.1±5.79 mV. In the pre-clinical studies in mice, an increase in specific antibody levels was observed beginning at week 4 in groups that received the vaccine compared to the group receiving blank particles.

Conclusion: Vaccine particles were successfully prepared and characterized for yield, size, PDI and charge and *in-vivo* studies demonstrated significant antibody levels in mice.

Translational Impact: At the present time there are no vaccines for gonorrhea. This vaccine shows promise since the whole cell vaccine can be used without modifications in humans after appropriate scale up. By using the whole cell bacteria, all the antigens are preserved.

Biography

Martin D'Souza has obtained his PhD degree from the University of Pittsburgh, PA, USA. He is a Professor and Director of Graduate Programs in the College of Pharmacy at Mercer University in Atlanta, Georgia. He also serves as the Director of the Clinical Laboratory and Co-Director of the Center for Drug Delivery Research. He has graduated over 50 PhD students and has published over 100 manuscripts. He has been the recipient of several research grants from the National Institutes of Health (NIH), the American Diabetes Association, the Georgia Cancer Coalition, and Georgia Research Alliance. He serves on several Editorial Boards and is a journal reviewer for over 10 scientific journals and has several patents issued in the area of Nanotechnology.

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