

Insight on Hepatitis B Vaccine
Adjuvanticity “Future Perspectives”SM Sivakumar*, Mohammed M Safhi, Mohammad Firoz Alam, Tarique Anwer,
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Editorial

Globally, hepatitis B viral infection is a significant health problem leading to one million deaths annually from liver failure, cirrhosis and hepatocellular carcinoma. It has been estimated that 400 million people worldwide are carriers of Hepatitis B Virus (HBV), which is an important cause of morbidity and mortality after kidney transplantation [1]. Progressive liver diseases affect more than 80% of Hepatitis B Surface Antigen (HBsAg) positive renal transplant recipients. The natural history of HBV infection is complex, which is influenced by many factors including age at infection, viral factors such as HBV genome type, viral mutations, level of HBV replication and host factors such as gender, age and immune status. Due to various drawbacks of therapeutic approach to cure hepatitis B, vaccination is the only way to alter disease prevalence. The ultimate aim of vaccination is to augment the immune response therefore traditionally adjuvants have been used in vaccine formulation. In 1982, the first hepatitis B vaccine was licensed in the USA [2], which was plasma derived containing inactivated virus HBsAg derived from chronic hepatitis B carrier. In this formulation aluminum hydroxide was used as an adjuvant and thiomersal as preservative. However, some of the reports explained that the plasma derived HBsAg failed to induce adequate immune response [3-5]. A safe and effective yeast derived recombinant vaccine expressed against hepatitis B virus infection has been made available for past two decades [6,7]. However, it requires at least three doses to elicit an optimum immune response. For many decades alum was the only adjuvants approved by US FDA, Alum vaccine but it is not suitable for recombinant proteins and small peptides [8].

The historic concept of alum adjuvanticity was altered during last decade by health care companies Novartis vaccine and GSK biologics [9]. MF 59 is an O/W emulsion developed by researcher of Chirion corporation in 1990s which was acquired by Novartis in 2006. This vaccine comprises of 4.3% squalene oil as dispersed phase and citrate buffer as continuous phase. Earlier studies proved that MF 59 with HBV vaccine elicits good immune response [10,11]. Adjuvant System 04 (AS04) that have been developed by GSK biologics containing 3-O-desacyl- 4'-Monophosphoryl Lipid A (MPL) adsorbed on either aluminum hydroxide or aluminum phosphate has proved the induction of strong immune response [9]. Though MF 59 and AS04 were considered as better adjuvant than Alum type adjuvant but they also have some disadvantages such as reactogenicity and cost effectiveness [8].

The state of art of adjuvant development for hepatitis B vaccine is still under study and slowly progressing towards biodegradable polymeric particle technology. Studies have proved that PLGA, PLA and chitosan polymeric particles have shown good immune response. Among these polymeric particulate systems chitosan was reported as better polymeric adjuvant system for recombinant hepatitis B vaccine adjuvanticity [12,13]. Though the vaccine entrapped biodegradable polymeric micro particle system elicit good immune response, the size of particle dictates the immune response. Therefore, the concept of particle delivery system has been recently evaluated as nanoparticle delivery technology since the size is in nanoscale, easily transports through extra cellular and intra cellular biological barriers and is easily processed by dendritic cells, which in turn stimulate both Th1 and Th2 responses [14]. Several Studies have proved that polymeric nano particle systems are promising vaccine adjuvants as they regulate both humoral as well as cell mediated immunity and are capable of presenting antigens in sustained manner to elicit CD4+ and CD8+ T cells responses [14,15]. However, the toxicity profile is highly challenging, and should be established. Based on the pros and cons, nanoparticle delivery system as vaccine adjuvants was established by various researchers across the world. On aiming to develop better adjuvants, it is hoped that the polymeric nanoparticle delivery system would aid as better adjuvant for successful development of hepatitis B vaccine there by serving the human society.

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