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Topical imiquimod before intradermal hepatitis B vaccination overcome hypo-responsiveness in chronic renal failure patients on dialysis, a double blind randomised controlled trial

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Background: Hepatitis B virus infection remains an important clinical issue among patients on renal replacement therapy. Seroprotection rate after intramuscular hepatitis B vaccination (HBVv) remains poor in this cohort. Imiquimod, a synthetic Toll-like receptor 7 agonist useful for the treatment of DNA virus infection, has been shown to expedite and improve vaccine immunogenicity against influenza virus. We therefore performed a prospective double-blind randomized controlled trial to evaluate the effect and safety of topical treatment with imiquimod before intradermal HBVv in patients on renal replacement therapy.

Material/methods: We enrolled adult patients on renal replacement therapy [continuous ambulatory peritoneal dialysis (CAPD) or hemodialysis patients (HD)] in this prospective double blind randomized placebo controlled trial between November 2015 and February 2017. All recruited patients had negative HBsAg and anti-HBs at baseline. The HBVv used in this study is Sci-B-Vac™. All intradermal vaccination was delivered by the MicronJet600™ needle (Nanopass).

Enrolled patients were randomized into 3 groups. All patients received 3 doses Sci-B-Vac™ regime at 0, 1 and 6 months. Group 1 received 10µg intradermal HBVv with topical imiquimod ointment

pretreatment applied to the deltoid of injection site 5 minutes before vaccination. Group 2 received 10µg intradermal HBVv with topical placebo aqueous cream pretreatment before vaccination; Group 3 received 10µg intramuscular HBVv with topical placebo aqueous cream pretreatment. All enrolled patients were blinded to the topical treatment they received. Anti-HBs titre was measured at baseline and at 1, 3 and 6 months after the last dose of vaccination. The primary outcome was the seroprotection rate at 1 month defined by the percentage of recruited subjects with anti-HBs antibody titre ≥ 10 IU/L.

Results: This is an interim analysis of the study. Between November 2015 and February 2017, 69 patients were recruited, in which 41 patients were male. 51 patients were on CAPD and 18 patients on HD. The median age was 65.5 years. 24, 22 and 23 patients were randomized to group 1, 2 and 3 respectively. The seroprotection rate at 1 month was 62.5% in group 1, 50% in group 2 and 39% in group 3. There was no difference among the three groups in seroprotection rate. Nevertheless, the overall anti-HBs titre was significantly different among the three groups. The median anti-HBs was significantly higher for group 1 at one-month: 50.5 IU/L, three-month 201.5 IU/L and six-month 431.5 IU/L, comparing to group 2 at one-month: 5.5 IU/L, three-month 142 IU/L and six-month 246.8 IU/L; and group 3 at one-month: 0 IU/L, three-month 8 IU/L and six-month 6.5 IU/L ($p= 0.06$; 0.006 and 0.13 respectively). Overall side effects are few and self-limiting.

Conclusions: Topical imiquimod before intradermal HBVv was highly effective and significantly overcome hyporesponsiveness in chronic renal failure patients on dialysis