Long term protective level of hepatitis B antibody after revaccination in liver transplanted children: an open-label randomized control trial study

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Background: High prevalence of hepatitis B (HB)-antibody loss after liver transplantation (LT) was documented and reimmunization is merit. This study aims to evaluate the long-term protective level of HB surface antibody (anti-HBs) after HB revaccination in liver transplanted children.

Methods: Liver-transplanted children with previously immunization but anti-HBs after LT ≤ 100 mIU/mL were recruited and randomized to reimmunization with standard-3-dose (SD) and double-3-dose (DD) HB vaccine intramuscularly at 0-1-6 months. Participants with anti-HBs < 100 mIU/mL after reimmunization was defined as antibody loss. Antibody loss rate was estimated using Kaplan-Meier method and the difference between antibody loss from SD and DD was compared using log-rank test. To assess the variable associated with antibody loss over time, multivariable Cox proportional hazard regression analysis was performed.

Results: From 2016 to 2020, 68 children were recruited. The rate of anti-HBs ≥ 100 mIU/mL after complete vaccination was 87.1% and 80% in SD and DD. After the median follow-up period of 2.21 years (1.34, 2.96) from enrollment, geometric mean titer of anti-HBs was 199.32 mIU/mL (101.37–391.93) and 129.80 mIU/mL (60.59–278.08) in SD and DD ($P=0.419$). There were 64.5% and 56.7% of participants with anti-HBs > 100 mIU/mL in SD and DD ($P=0.530$). The median for antibody loss over time were 3.01 (95% confidence interval [CI], 2.865–3.155) and 2.69 (95% CI, 2.341–3.049) years for SD and DD. There was no significant antibody loss over time between both groups ($P=0.156$). On the univariate analysis, low anti-HBs level at the enrollment was the only factor associated with increased risk of antibody loss over time (median anti-HBs of 2.2 mIU/mL; hazard ratio, 3.403; 1.631–7.099; $P<0.001$).

Conclusions: SD and DD for HB reimmunization were highly effective to maintain the protective level of anti-HBs in liver-transplanted children after long-term follow-up. Moreover, early HB reimmunization should be scheduled for liver-transplanted children at the time that anti-HBs level is not too low.

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