Introduction

• HIV-infected adults have decreased serological response to HBV vaccination with faster decline of antibody titer
• In those with isolated anti-HBc Ab, the role of vaccination remains controversial

Objectives

Primary objective:
• Percentage of responders (anti-HBs Ab ≥ 10 mIU/mL) at month 7

Secondary objectives:
• Anamnestic response at month 1
• Percentage of high-level responders (anti-HBs Ab ≥ 100 mIU/mL) at month 7
• Geometric mean titers (GMT) of anti-HBs Ab at month 1 and 7
• Predictive factors associated with anamnestic response and vaccine response at month 7

Materials and Methods

• An open-label randomized controlled trial was conducted among HIV-infected adults attending the Infectious Diseases clinic of the Maharaj Nakorn Chiang Mai Hospital, Chiang Mai, Thailand, between July 2017 and March 2018.
• Inclusion criteria: Aged ≥ 18 years, isolated anti-HBc Ab, anti-HCV negative, CD4 ≥ 200 cells/mm³, HIV VL < 20 copies/mL, on cART between July 2017 and March 2018.
• Exclusion criteria: Aged < 18 years, isolated anti-HBc Ab, anti-HCV negative, CD4 ≥ 200 cells/mm³, HIV VL < 20 copies/mL, on cART, unable to participate at month 1 and 7

Methods

Participants were randomized to receive HBV vaccination with either:
1. Standard doses (20 mcg IM) at month 0, 1, 6, or 2 and 6
2. 3-standard-doses (20 mcg IM) at month 0, 1, 2, and 6
3. 4-standard-doses (20 mcg IM) at month 0, 1, 2, 3, and 6

Primary outcome measures:
1. Percentage of responders (anti-HBs Ab ≥ 10 mIU/mL) at month 7
2. Anamnestic response at month 1
3. Percentage of high-level responders (anti-HBs Ab ≥ 100 mIU/mL) at month 7
4. Geometric mean titers (GMT) of anti-HBs Ab at month 1 and 7
5. Predictive factors associated with anamnestic response and vaccine response at month 7

Results

Table 1. Baseline characteristics (n=54)

Baseline Characteristics (n=54) 3-doses (n=27) 4-doses (n=27) P-value
Age (years ± SD) 45.8 ± 13.5 46.6 ± 11.0 0.826
Male 16 (59.3%) 16 (59.3%) 1.000
Time since HIV diagnosis, years (mean ± SD) 12.4 ± 6.2 11.3 ± 6.4 0.534
Duration of cART, years (mean ± SD) 10.0 ± 4.8 9.4 ± 4.7 0.691
CD4 cell count, cells/mm³ (median IQR) 611 (429, 853) 534 (392, 829) 0.697
Nadir CD4 count, cells/mm³ (median IQR) 148 (52, 323) 110 (52, 228) 0.392
Nadir CD4 count >200 cells/mm³ (n=54) 19 (70.4%) 18 (66.7%) 0.770

Table 2. Comparison of outcomes between the 2 regimens

Outcomes 3-doses (n=27) 4-doses (n=27) P-value
Responders at month 7 23 (85.2%) 24 (88.9%) 1.000
Anamnestic response 7 (25.9%) 9 (33.3%) 0.551
High-level responders at month 7 12 (44.4%) 17 (63.0%) 0.172
GMT of anti-HBs Ab at month 1 (95% CI) 4.4 (2.1 – 8.4) 5.29 (2.4 – 10.8) 0.714
GMT of anti-HBs Ab at month 7 (95% CI) 63.8 (20.9) 20.8 (90.0 – 487.4) 0.030

Figure 1. Percentages of responders at month 7

Figure 2. Percentages of high-level responders at month 7

Conclusions

• Among Thai HIV-infected adults with isolated anti-HBc Ab, HBV vaccination with 3- and 4-standard-doses regimen produced high and comparable immunological response.
• However, the GMT of anti-HBs antibody level was higher in the 4-doses regimen.

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