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Randomized Controlled Trial of Hepatitis B Virus (HBV) Revaccination among Men Who Have Sex with Men and Were Born in the Era of Universal Neonatal HBV Immunization

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Background

- The HBV seroprevalence has declined among the individuals born in Taiwan in the era of the universal neonatal HBV vaccination program that was implemented in 1986. Individuals who had lost adequate anti-HBsAg antibody in their adulthood are at risk of acquiring HBV.
- The optimal revaccination strategy remains unknown, however.
- We aimed to compare the efficacy of revaccination with standard-dose (20-μg) vs double-dose (40-μg) of HBV vaccine among men who have sex with men (MSM).

Methods

- MSM aged ≥20 years who had undergone HBV vaccination at birth and tested negative for HBsAg and anti-HBc with anti-HBs titer <10 mIU/ml were randomized to receive standard-dose or double-dose HBV vaccine (1:1 ratio with a block size of 4) at weeks 0, 4, and 24.
- Plasma HIV RNA <50 copies/ml for ≥6 months was required for HIV-positive MSM.
- The primary endpoint was the proportion of participants achieving anti-HBs ≥10 mIU/ml at week 28. The secondary endpoints were high-titer response (≥100 mIU/ml) at weeks 28 and 48, serological response at week 48, and adverse events (AE).

Results

- From 2017 to 2020, 175 HIV-positive and 81 HIV-negative MSM were enrolled. The serological response at week 28 was 87.4% for the standard-dose group and 93.8% for the double-dose group (p=0.151) (Figure 1). The proportion of high-titer response was higher for the double-dose group than the standard-dose group at 28 weeks (83.3% vs 71.8%, p=0.053) (Figure 2).
- The respective serological response and high-titer response at week 48 were 81.6% and 58.4% for the standard-dose group vs 94.8% and 77.9% for the double-dose group (p=0.015 and p=0.012, respectively) (Figure 2).
- In generalized estimating equations model, double-dose HBV revaccination was associated with serological and high-titer response. HIV infection was not associated with serological response and high-titer response (Table2).
- The double-dose group had a higher rate of local AEs (22.9% vs 33.0%, p=0.131). One (0.8%) severe AE occurred in the double-dose group, which resolved without sequelae.

Conclusion

- Double-dose HBV revaccination results in sustained serological and high-titer responses among MSM who were born in the era of universal neonatal vaccination.

Table 1. Baseline characteristics of participants

Baseline characteristics	Standard dose (n=130)	Double dose (n=126)	p-value
Age, mean (SD), years	27.5 (3.1)	27.5 (3.3)	0.957
Anti-HBs titer at baseline, <2.5 mIU/ml, n (%)	84 (64.6)	81 (64.3)	0.956
HIV infection, n (%) Median CD4 of HIV patient (cell/mm³) (IQR)	88 (67.7) 614 (480-747)	87 (69.0) 605 (477-726)	0.816
Syphilis, n (%)	30 (23.1)	49 (38.9)	0.006
HCV, n (%)	5 (3.8)	10 (7.9)	0.159

Figure 1. Serological response

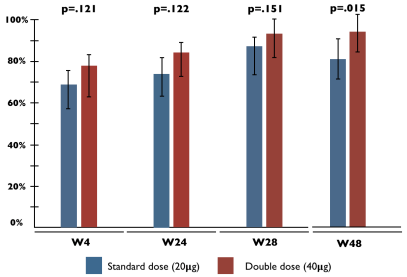

Figure 2. High-titer response

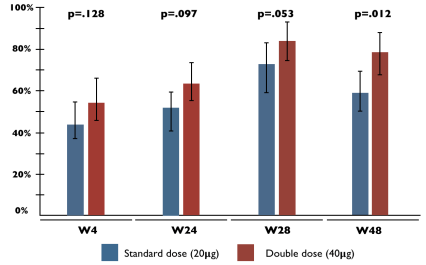

Table 2. GEE model of vaccine efficacy and associated factors

	Serological response (anti-HBs≥10 mIU/ml)		High-titer response (anti-HBs≥100 mIU/ml)	
	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value
Dose (double-dose vs single-dose)	2.08 (1.15-3.76)	**0.015**	1.89 (1.17-3.03)	**0.008**
Age , per 1-year increase	0.91 (0.84-1.01)	0.076	0.96 (1.13-1.03)	0.251
HIV infection	0.93 (0.48-1.82)	0.833	1.00 (0.58-1.70)	0.995
Anti-HBs titer ≥2.5 mIU/ml at screening	15.64 (5.23-47.23)	**<0.001**	7.65 (4.36-13.45)	**<0.001**
HCV coinfection	0.68 (0.31-1.48)	0.336	1.55 (0.50-2.20)	0.908
Syphilis	0.84 (0.47-1.52)	0.570	0.72 (0.44-1.18)	0.194