Hepatitis A and B vaccine uptake and immunisation among men who have sex with men seeking PrEP: a substudy of the ANRS IPERGAY trial

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ABSTRACT

Vaccination against hepatitis A virus (HAV) and hepatitis B virus (HBV) is recommended in men who have sex with men (MSM). We assessed HAV and HBV vaccine uptake in the non-immune participants and their immunisation during follow-up of the ANRS IPERGAY (Intervention Préventive de l'Exposition aux Risques avec et pour les Gays) pre-exposure prophylaxis (PrEP) trial.

During the ANRS IPERGAY trial among MSM (NCT 01473472), vaccination against HAV and HBV was offered free of charge to all non-immune participants at baseline. We assessed anti-HAV IgGs and anti-hepatitis B surface (HBs) antibodies (Abs) at baseline, 1–3 months after each vaccine dose and on the last follow-up visit. Vaccination uptake and immunisation were analysed in non-immune participants with at least 6 months of follow-up after the 1st vaccine dose.

A total of 427 MSM with a median age of 34.8 years were analysed. Median follow-up was 2.2 years (Q1–Q3, 1.6–2.9). Absence of anti-HAV IgG at baseline (50.4%, 215/427) was associated with younger age (p=0.0001). Among HAV non-immune participants, 96.1% (197/205) received one or more vaccine doses and 91.0% (172/189) received two vaccine doses. Among HBV non-immune participants, 97.6 % (81/83) received one or more vaccine doses and 78.4% (58/74) received three doses. On the last-visit sample, anti-HAV IgG and anti-HBs Abs were respectively detected in 94.8% (95% CI 90.0% to 97.7%) and 79.6% (95% CI 66.5% to 89.4%) of participants with complete vaccination and in 80.0% (95% CI 51.9% to 95.7%) and 40.0% (95% CI 16.3% to 67.7%) of participants with incomplete vaccination.

Vaccine acceptability against HAV and HBV infections was very high in MSM starting PrEP. Immunisation was high in participants with a full vaccination scheme. Physicians must consider PrEP visits as major opportunities to propose and complete HAV and HBV vaccination in at-risk non-immune subjects.

Pre-exposure prophylaxis (PrEP) is offered to subjects who are highly exposed to HIV infection and therefore to other STIs, including hepatitis A virus (HAV) and hepatitis B virus (HBV) infections. We assessed HAV and HBV vaccine uptake in non-immune participants of the ANRS IPERGAY PrEP trial and their immunisation during follow-up.

ANRS IPERGAY was a placebo randomised blinded trial of HIV-1 PrEP among men who have unprotected anal sex with men[1] followed by an open-label phase.[2] HAV and HBV immune status were assessed at baseline, and free-of-charge vaccination against hepatitis A and B was offered. All participants of blinded and open-label phases were included in this substudy. Patients with ongoing vaccination at enrolment were excluded. Vaccination uptake was defined by the

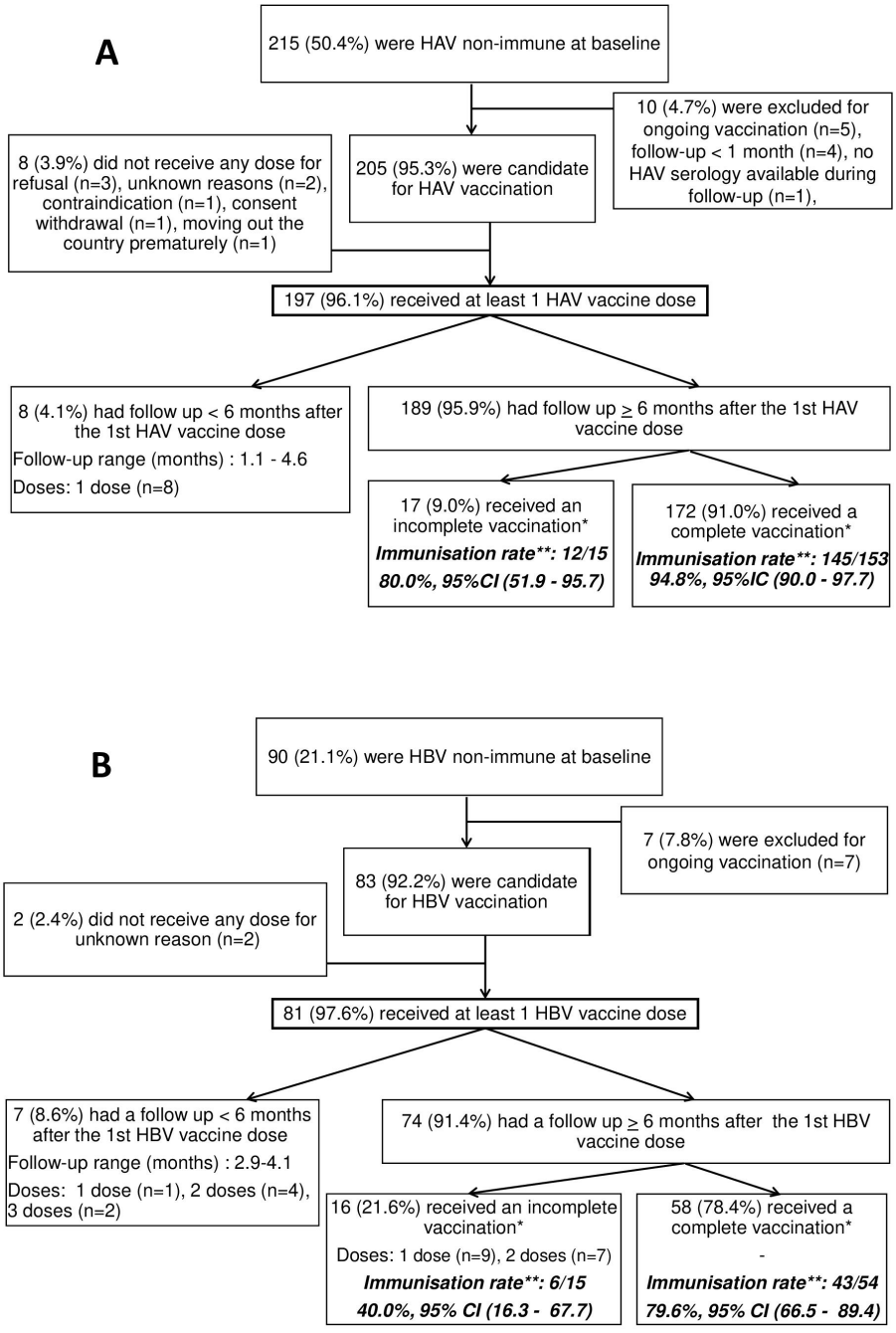

Figure 1 Flowchart of HAV (A) and HBV (B) vaccination uptake in study population and immunisation rate on the last-visit sample in vaccinated participants. *Incomplete vaccination scheme was defined as the receipt of less than two doses of vaccine for HAV and less than three doses of vaccine for HBV. ** Immunisation was defined as the detection of anti-HAV IgG or anti-HBs Ab. Immunisation rate is reported for participants with a follow-up of >6 months after receiving the first vaccine dose and a last-visit serum sample. Ab, antibody; HAV, hepatitis A virus; Hbs, hepatitis B surface; HBV, hepatitis B virus.

receipt of at least one dose of HAV or HBV vaccine. Completeness of the vaccination schedule and immunisation were analysed in participants with a follow-up of >6 months after the first vaccine dose. Vaccination was incomplete when all scheduled doses were not administered during follow-up. Vaccine-induced immunisation was ascertained by detecting anti-HAV IgG and antihepatitis B surface (HBs) antibody (Ab) on serum samples collected 1–3 months after each vaccine dose and at the last follow-up.

Baseline factors (age, level of education, number of partners and intercourse, alcohol consumption and recreational drugs use) were compared according to baseline HAV and HBV immune status and according to vaccination uptake with univariate and multivariate logistic regression models with the use of SAS software V.9.4. All p values and CIs are two-sided.

After excluding two participants with isolated anti-HBC Abs, 427 participants were analysed with a median follow-up of 2.2 years (Q1–Q3, 1.6–2.9).

Absence of HAV immunity at baseline was documented in 215 participants (50.4%) and was associated with a younger age (p=0.0001). Anti-HBs Abs were detected in 337 participants (78.9%), among whom 85.2% (287/337) were vaccinated. No factor was associated with HBV baseline immune status.

The flowcharts of HAV and HBV vaccination uptake are presented in figure 1. No factor was associated with HAV nor HBV vaccination uptake. Regardless of the vaccination completeness, anti-HAV IgGs were detected in 35.8% (95% CI 28.7% to 43.2%), 98.0% (95% CI 94.3% to 99.6%) and 93.5% (95% CI 88.6% to 96.7%) of participants in serum samples collected after one dose, two doses and on the last visit, respectively. On the last visit, HAV immunisation rate after complete (94.8%, 95%CI 90.0% to 97.7%) or incomplete vaccination (80.0%, 95%CI 51.9% to 95.7%) was not significantly different (p=0.062) (see figure 1A). Regardless of the vaccination completeness, anti-HBs Abs were detected in 63.8% (95% CI 50.1% to 76.0%), 71.7% (95% CI 58.6% to 82.5%), 84.6% (95% CI 71.9% to 93.1%) and 71.0% (95% CI 58.8% to 81.3%) of participants in serum samples collected after one dose, two doses, three doses and on the last visit, respectively. On the last-visit sample, HBV immunisation rate was twice higher after complete (79.6%, 95%CI 66.5% to 89.4%) than incomplete vaccination (40.0%, 95%CI 16.3% to 67.7%; p=0.008) (see figure 1B). During follow-up, no HAV or HBV infection case occured.

Among people consulting for PrEP initiation, up to 65% of HAV vaccine candidates are not vaccinated during follow-up.[3] The high vaccination uptake observed here in eligible participants (>95% of at least one vaccine dose) may be explained by several factors. First, baseline vaccine awareness and acceptability were probably high, considering the baseline HBV vaccination level was higher than expected in general population.[4] Second, the free-of-charge vaccination solved the potential affordability issue.[5 6] Third, the repeated visits with trained professionals specialised in management and counselling of patients at high risk of STIs surely helped to promote acceptability and access to vaccination. Immunisation rate post vaccination was up to 95% (HAV) and 80% (HBV). The significantly lower rate of HBV immunisation on late samples in participants with incomplete vaccination reminds the need to complete immunisation schedule to obtain satisfying long-term HBV immunisation.

Our study is limited by (1) the restricted analysis of participants of a preventive trial and not real-life people seeking PrEP, (2) the limited size of the population and the high level of vaccine uptake and immunisation, which limited the analysis of their respective associated factors.

In conclusion, during the ANRS IPERGAY PrEP trial, HAV and HBV vaccination uptake was very high among non-immune participants. Immunisation was satisfactory especially after receiving complete vaccination. Physicians must consider PrEP visits as major opportunities to propose HAV and HBV vaccinations in at-risk non-immune subjects and to complete vaccine schedules as needed.

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