HAV AND HBV VACCINATION COVERAGE AND ACCEPTABILITY AMONG MSM ON PREP

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BACKGROUND

- Sexually transmitted viral hepatitis have a rising incidence in MSM as revealed by recent large hepatitis A outbreaks.
- Preexposure prophylaxis (PrEP) is proposed in subjects with a high risk of HIV who have also a high risk of STI including viral hepatitis. During the ANRS IPERGAY PrEP trial (NCT 01473472), vaccination against HAV and HBV was offered free of charge to non-immune participants.
- The objective was to evaluate the HAV and HBV vaccine acceptability in this population and its determinants at baseline.
- The secondary objective was to assess the vaccine antibody response rate after each injection and at the end of follow-up in vaccinated subjects.

METHODS

- All subjects included in the IPERGAY blind (Feb 2012-Oct 2014) and/or open phases (Nov 2014-Jan 2015) were studied.
- MSM with unprotected anal sex were randomly assigned to tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) or placebo (blind phase), TDF/FTC (open-label phase) before and after sexual activity.
- HAV and HBV immune status were assessed at baseline and after vaccination.
- Anti-HAV IgG and anti-HBs antibodies were assessed on available samples taken 1 to 3 months after each vaccine dose and on the latest available sample.
- The vaccination scheme was analyzed in subjects with a follow-up >6 months after receiving the 1st vaccine dose and was considered incomplete when the last injection was not given (3rd if HBV, 2nd if HAV).
- Subjects who started vaccination before trial start were excluded.
- Sociodemographic factors associated with baseline immune status were explored by univariate analysis.

RESULTS

- A total of 429 subjects were studied.
- Two subjects were excluded because of isolated anti-HBc antibodies at baseline.
- The median follow-up was 2.2 ~~2~~ 1 years (IQR 1.6-2.9).
- Absence of anti-HAV IgG at baseline (50%, 215/427) was associated with younger age (p=0.0001) and tobacco use (p=0.02).
- HBV immunization after infection and vaccination was noted at baseline for 12% (50/427) and 67% (287/427) of subjects, respectively. Absence of prior HBV immunization (21%, 90/427) was associated with tobacco use (p=0.05).
- The vaccine acceptability is represented in figure 1 (HAV) and figure 2 (HBV). No factor was associated with vaccine acceptability in the analysis.

Figure 1 *– HAV vaccination acceptability*

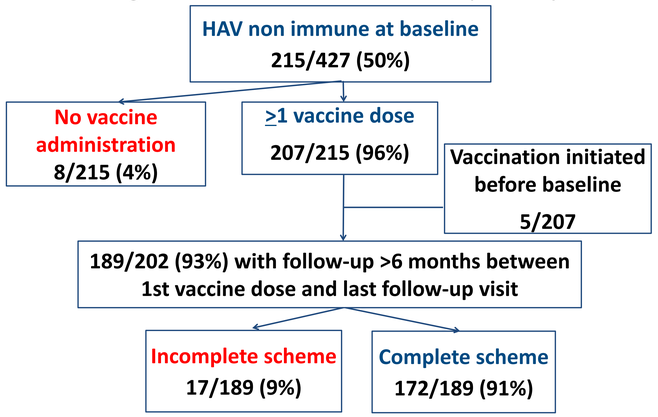
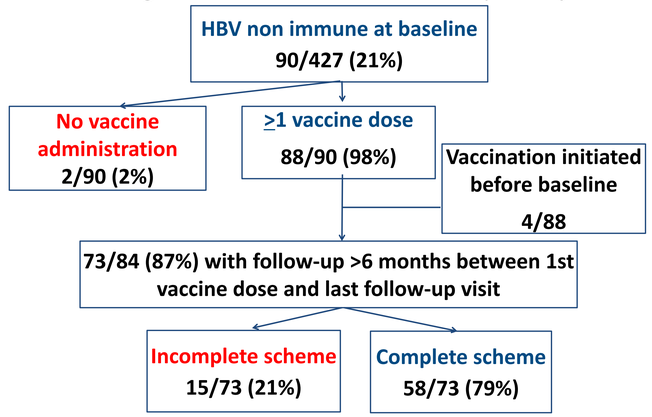


Figure 2 *– HBV vaccination acceptabilty*



RESULTS – VACCINE COMPLETION

- Among HAV non-immune subjects, 96% (207/215) received ≥1 dose of HAV vaccine and among subjects with follow-up >6 months, 91% (172/189) received a complete scheme.
- Among HBV non-immune subjects, 98% (88/90) received ≥1 dose of HBV vaccine and among subjects with follow-up >6 months 79% (58/73) received a complete scheme.

RESULTS – POST-VACCINATION SEROCONVERSION

- Among subjects with complete scheme, anti-HAV IgG and anti-HBs antibodies were detected on last available sample in 93% (148/159) and 80% (44/55) respectively.
- Among subjects with incomplete scheme, anti-HAV IgG and anti-HBs antibodies were detected on last available sample in 80% (12/15) and 36% (5/14) respectively.
- Among subjects with complete or incomplete scheme , 63% (37/59) of subjects developed anti-HBs antibodies after the 1st dose of HBV vaccine .

Table. *Seroconversion rates after doses of hepatitis A and B vaccination*

	HAV (n=189)**		HBV (n=73)**	
	Incomplete scheme (n=17)	Complete scheme (n=172)	Incomplete scheme (n=15)	Complete scheme (n=58)
Seroconversion rates* after 1st dose, % (n/N)	50 (8/16)	35 (56/162)	50 (3/6)	64 (34/53)
Time between 1st dose and sample, days (median [IQR])	36 [30-64]	42 [29-58]	30 [28-56]	32 [28-53]
Seroconversion rates* on last available sample, % (n/N)	80 (12/15)	93 (148/159)	36 (5/14)	80 (44/55)
Time between last dose and sample, days (median [IQR])	504 [334-721]	519 [319-853]	692 [365-823]	651 [388-997]

* Anti-HAV IgG antibodies (HAV) and anti-HBs antibodies (HBV)
** Data only for subjects who initiated vaccination after enrollment with follow-up >6 months are presented.

In IPERGAY trial population (MSM with high HIV risk)

- **Vaccination was indicated for 50% (HAV) and 21% (HBV) of subjects**
- **Among subjects followed more than 6 months**
  - **. >90% of HAV non immune subjects received a complete vaccination scheme of whom 93% seroconverted during follow-up.**
  - **. 79% of HBV non immune subjects received a complete vaccination scheme of whom 80% seroconverted during follow-up.**

DISCUSSION / CONCLUSION

- **HAV and HBV vaccine acceptability and immunogenicity were high in the ANRS IPERGAY trial population.**
- **No factors were statistically associated with acceptability. However vaccine acceptability may have been favored by some intrinsic factors of the study population (high receptivity to prevention messages), high implication of the care team and a free of charge vaccination.**
- **Physicians must consider PrEP initiation visits as major opportunities to initiate HAV and HBV vaccination in this at-risk population.**

ADDITIONAL INFORMATION

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