

BACKGROUND

- High incidence of HCV infection has been reported among high risk MSM [1, 2].
- Current guidelines recommend that these individuals should be screened at least once a year with ALT and anti-HCV antibody [3].
- **Our aim was to assess the sensitivity of different tests for early diagnosis of acute hepatitis C in high risk MSM.**

METHODS

Population and samples

- **High risk MSM** enrolled in the ANRS IPERGAY PreP trial blinded and open phases
- Follow-up visits : screening, M1, M2 and every 2 months
- Stored sera at each visit

Screening for Hepatitis C

- **ALT at each visit**
- **3rd Generation (3thG) HCV antibody immunoassay (EIA 3thG)**
 - ✓ At the **screening visit** and **every 6 months**
 - ✓ If ALT > 2.5 times the upper limit of normal (ULN)

POSITIVE 3thG EIA

→ **Diagnosis of acute hepatitis C**

Evaluation of the sensitivity of HCV diagnostic tests

- At the **visit of diagnosis**
- At the **previous visit (using stored sera)**

INDIRECT tests Anti-HCV antibody

- EIA 3thG ARCHITECT HCV Ab® (Abbott)
- **OraQuick®** HCV test (Orasure)
- **TOYO®** HCV test (Nephrotek)



DIRECT tests HCV antigen & RNA

- EIA ARCHITECT HCV Ag® (Abbott) : reactive > 3,00 fmol/L
- **Cobas®** HCV test (Roche)
- **Xpert HCV Viral Load** (Cepheid)

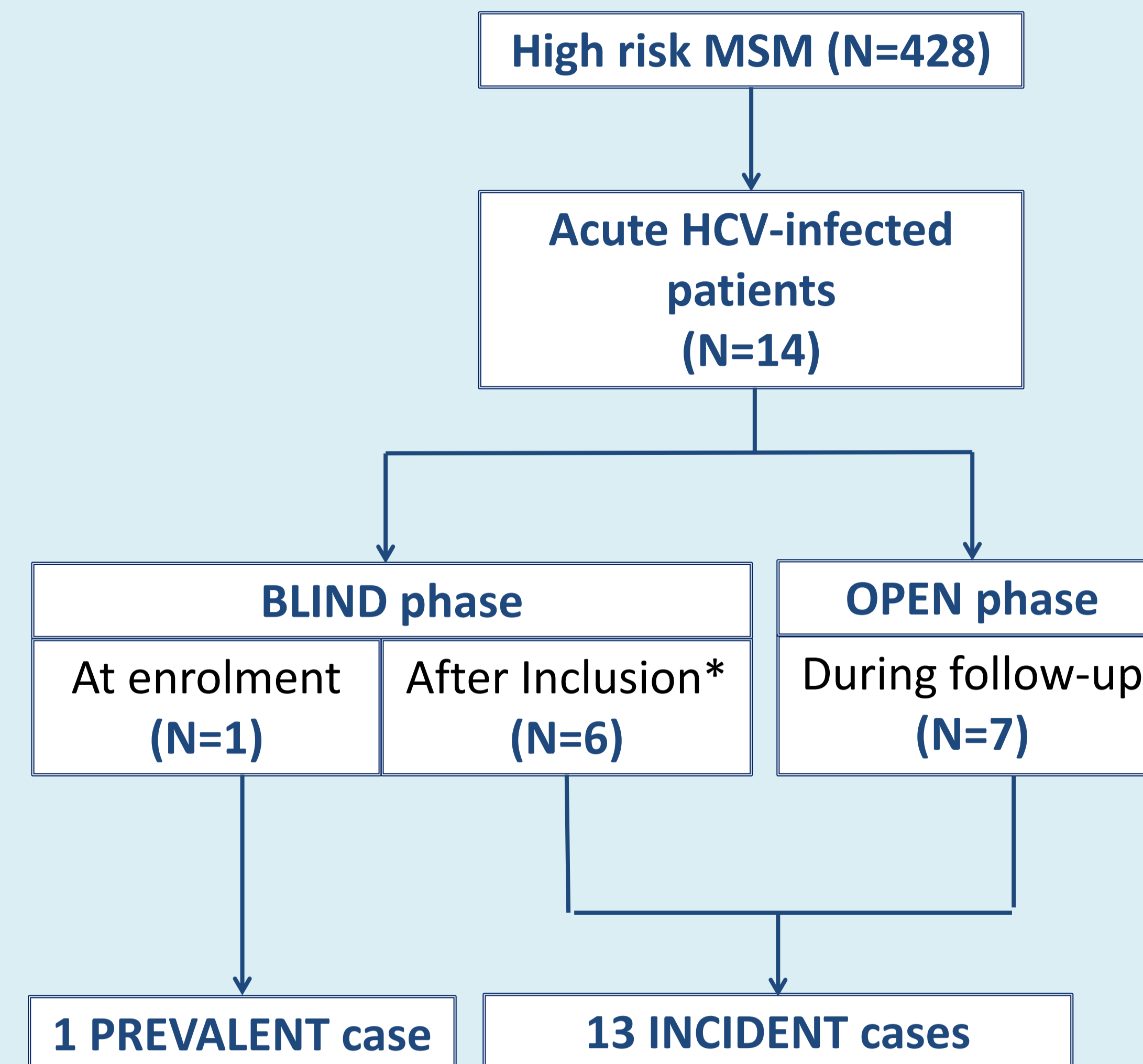


FIGURE 1. Flow-chart. Description of the number of HCV-infected patients diagnosed (based on trial HCV serology) during the ANRS IPERGAY PreP trial. * One patient was HIV-HCV co-infected

- During the study period (from March 5, 2012 to June 30, 2016), 428 participants were enrolled with a **median follow-up of 2.1 years (IQR: 1.5-2.8)**
- **14 patients were diagnosed with HCV infection including one co-infected with HIV**
- One case was diagnosed at enrollment and 13 during follow-up
- **HCV incidence was 1.40 per 100 person-years (95%CI: 0.74-2.39).**
- **Genomic analysis** at diagnosis identified the following genotypes
 - **Type 1 : N=6 patients (43%)**
 - **Type 3 : N=1 patients (7%)**
 - **Type 4 : N=7 patients (50%)**

RESULTS

Patients characteristics at HCV diagnosis	N=13†
Partners in last two months	25 [16; 40]
Sexual acts in the past 4 weeks (NA = 2)	15 [8; 20]
Condomless receptive anal sex (last sexual act / past 4 weeks) (NA = 1)	11/12
CHEMSEX* (during last sexual act)	7/13
Bleeding (after last sexual act) (NA = 3)	1/10
Fisting (during last sexual act) (NA = 3)	2/10
Sexually transmitted infections**	5/13

TABLE 1. Characteristics of patients at hepatitis C diagnosis (N=13).

Risk factors for hepatitis C were collected during the last two months or the last four weeks before hepatitis C diagnosis visit (data are presented as median or n/N evaluated)

† 1 participant with no data at HCV diagnosis

* CHEMSEX: use of ecstasy / cocaïn / GHB.GBL / ketamine / crack / heroin / speed / LSD / mephedrone or slam;

** Anal Chlamydia (N=4), syphilis (N=1).

IQR=interquartile range; NA: not available.

Test	Visit of diagnosis (N=14)		Prior visit (N=13*)		
	Number of positive tests / number of sera tested	Sensitivity (95% CI)	Number of positive tests /number of sera tested	Sensitivity (95% CI)	
EIA 3thG HCV Ab®	14/14	100% (77-100)	0/13		
Anti-HCV antibody rapid tests	OraQuick®	13/14	93% (66-99)	0/9	0% (0-34)
	TOYO®	11/14	79% (49-95)	0/9	0% (0-34)
EIA HCV Ag® (UI/ml)	13/13 (median[IQR]: 938 [12-5 274])	100% (75-100)	8/9 (median[IQR]: 13 475 [2 936-33 351])	89% (52-100)	
HCV RNA Tests (cp/mL)	Cobas® HCV test	14/14 (median[IQR]: 1 539 693 [10 414-3 415 663])	100% (77-100)	11/13 (median[IQR]: 1 935 372 [71 036-10 900 000])	85% (55-98)
	Xpert HCV viral load	13/13 (median[IQR]: 903 500 [115 643-4 600 000])	100% (75-100)	8/8 (median [IQR]: 1 545 000 [28 475-3 712 000])	100% (63-100)
Increased ALT (UI/mL)	13/13 (median[IQR]: 451 [103-597])	100% (75-100)	3/12 (median[IQR]: 291 [83-381])	25% (2-57)	

TABLE 2 : Sensitivity of the different tests available for acute HCV infection diagnosis at the visit of diagnosis and during the prior visit. Prior visit occurred within a median delay of 2 months earlier (IQR: 1.5-2). Among 12 patients who were tested during prior visit with both HCV RNA (Roche) and ALT, 7 had an HCV RNA detectable and no increased ALT (p=0.008, McNemar's test)

* 1 participant with no previous visit data

CONCLUSION

- **The HCV antigen immunoassay and plasma HCV RNA test were positive within a median of 2 months before the detection of antibodies and ALT elevation,** when patients were asymptomatic and had no increased ALT in the majority of cases
- These tests **should be used in high risk MSM for early diagnosis of acute HCV infection** and prevention of transmission.

Acknowledgments

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