Usefulness of Rapid Tests for HIV Diagnosis in the ANRS IPERGAY Trial

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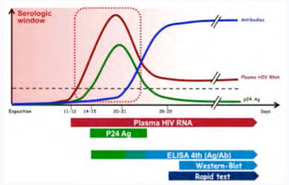
Background

- Pre-exposure prophylaxis (PrEP) implementation will lead to more frequent HIV testing. Rapid tests are likely to be used especially in resource limited countries.
- HIV diagnostic tests could be challenged at the time of primary infection due to the kinetic of virological and serological markers.

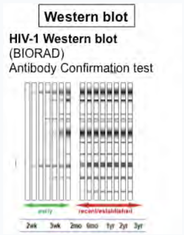


Objective

- **Our aim was to assess the usefulness of rapid tests for HIV diagnostic in the setting of the ANRS IPERGAY PrEP trial**

Methods

- The 4th generation (4thG) antigen/antibody immunoassay (ARCHITECT HIV Ag/Ab Combo®, Abbott) and/or plasma Viral Load (pVL) (AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0) were used for HIV diagnosis at screening and during the follow up
- The date of HIV diagnosis correspond to the first date with a positive test
- We used stored sera to perform the following tests at the date of diagnosis: pVL, 4thG, rapid test (VIKIA® HIV1/2, Biomérieux) and HIV-1 western blot (WB, GS HIV-1 Western Blot®, Biorad)



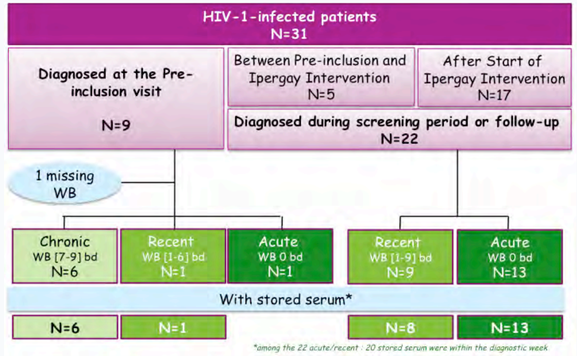
- HIV-1 subtype was determined after phylogenetic analysis of the RT sequence

- Three stages were defined according to the number of WB antibodies (Ab) and the time of diagnosis

		Time of HIV Infection diagnosis	
		At pre-inclusion visit	Negative at pre-inclusion visit. Diagnosed during screening period or follow-up visit
WB (Ab)	0	Acute	Acute
	[1-6]	Recent	Recent
	>= 7	Chronic	

Results

- Overall, **31 HIV-1-infected patients** were diagnosed during the ANRS IPERGAY trial



- Stored sera were available for 28 cases of HIV infection. In the 22 recent/acute infection, the stored serum was available within the diagnosis week for 20.

- Overall, the median pVL is 5.22 log10 copies/ml, the 4thG was positive in 26 (93%) (median index 40), positive WB (≥ 1 Ab) in 15 (54%) patients and rapid test in 15 (54%).

- HIV-1 subtype B was identified in 16/26 (62%) cases, CRF02 in 7 (27%) and non B-non CRF02 in 3 (11%).

	Log10 HIV-1 RNA median [IQR]	Nb Antibodies median [IQR]	POSITIVE 4th G ELISA Architect N (%)	Index 4th G ELISA Architect median [IQR]	POSITIVE RAPID TEST Biomérieux N Se (95%CI)
Chronic N=6	5.16 [5.15-5.23] (1 missing)	8.5 [7-9]	6 (100%)	424 [186-440]	6 Se=100% (54%-100%)
Recent N=9	4.59 [3.74-5.54] (2 missing)	5 [3-5]	9 (100%)	11.1 [4.7-27.1]	7 Se=78% (40%-97%)
Acute N=13	6.81 [5.13-6.99] (1 missing)	0 [0-0]	11 (85%)	52.2 [1.25-107]	2 Se=15% (2%-45%)
Total N=28	5.22 [4.45-6.81] (4 missing)	1 [0-6.5]	26 (93%)	40.4 [4.7-161]	15 Se=54% (34%-72%)

Results (follow)

• ELISA 4thG failed to diagnose two patients during acute infection with pVL 110 and 450 copies/ml, respectively.

• Sensitivity of rapid test was 100% (95%CI: 54-100) for chronic infection, 78% (95%CI: 40-97) for recent infection and only 15% (95%CI: 2-45) for acute infection ($p < 0.002$).

• Among the 13 positive sera with the 4thG assay but negative with rapid test (11 acute and 2 recent), 8 were retested at the follow-up visit (median [IQR]: 5 [3-26 days]) :

→ 4 became positive after 4, 6, 30 and 31 days

→ 4 remained negative after 3, 3, 3 and 22 days

• We tested the relationship between the sensitivity of rapid test and pVL, index of ELISA 4thG and viral subtype (B or non B) for the 28 patients. A significant relationship was only found for the 4thG index with a median index of 135 [19 – 416] in positive rapid test samples and 8.4 [1.3 – 56] in negative rapid test samples ($p = 0.017$).

Conclusions

Rapid test was able to adequately detect chronic infection at screening but largely failed to diagnose acute HIV infection in people at high risk enrolled in a PrEP trial.

4th G assays should be used in settings where PrEP is implemented to avoid missing acute HIV infection, with the risk of selecting drug resistance and of ongoing HIV transmission.

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