Low performance of the OraQuick HCV rapid antibody test in HIV/HCV-infected people

ID 2582

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Background

There is a global need to expand HCV diagnostic testing and saliva sampling may provide an easier access to HCV screening test[1,2]. An estimated 2.3 million people living with HIV are coinfected with HCV globally[3]. Despite this high numbers, the performance of HCV rapid test has not been extensively studied in HIV population.

Methods

We enrolled consecutive patients (pts) attending the Outpatient Infectious Disease Clinic of S. M. Goretti in Latina from Oct 2017 to Jan 2018 and 30 healthy donors (HD) with a known plasma test for HCV and HIV infection.

We performed the OraQuick HCV Rapid Antibody Test (OraSure Techn, Inc.). We collected personal, clinical and laboratory data. The OraQuick HCV Rapid Antibody Test was used according to kit instruction.





Reactive *Not Reactive* *Not valid*

Statistical analysis was performed using Kruskall-Wallis, Mann-Whitney and $\chi 2$ test. The 95% confidence interval (CI) was estimated for sensitivity, specificity, and positive and negative predictive values.

References

[1] Hepatitis C Virus Diagnosis and the Holy Grail. Applegate TL, Fajardo E, Sacks JA. Infect Dis Clin North Am. 2018
[2] Hepatitis C eradication: A long way to go.Waheed Y. World J Gastroenterol. 2015
[3] Prevalence and burden of HCV co-infection in people living with HIV: a global systematic review and meta-analysis. Platt L, Easterbrook P, Gower E, et al. Lancet Infec.Dises. 2016

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Results

A total of 227 persons were recruited into the study, characteristics of population are shown in table 1.

	HCV+/HIV- (n=83)	HCV+/HIV+ (n=84)	HCV-/HIV+ (n=30)	HCV-/HIV- (n=30)
Male sex n(%)	53(64%)	68(81%)	18(60%)	12(40%)
Median Age (min-max)	61 (18-89)	55 (34-71)	45 (23-65)	26 (20-71)

Table 1. Age and sex of the study population

In all the study population a sensivity of 53% (95% CI, 45%–60%) and specificity of 100% was found. The positive predictive value (PPV) was 1 (95% CI 0.96-1), while the negative predictive value (NPV) was 0.43 (95% CI 0.35-0.52). The results of OraQuick in the 4 groups are showed in table 2.

The PPV and NPV of the two group HCV+/HIV- and HCV+/HIV+ are shown in table 3.

	HCV+/HIV- (n=83)	HCV+/HIV+ (n=84)	HCV-/HIV- (n=30)	HCV-/HIV+ (n=30)
OraQuick POS	83	5	0	0
OraQuick NEG	0	79	30	30
Sensitivity	100%	6%	100%	100%
Specificity	100%	100%	100%	100%

Table 2. Results of OraQuicK Test

	HCV+/HIV-	HCV+/HIV+
Negative Predictive Value (95% CI)	1 (0.88-1)	0.28 (0.19-0.37)
Positive Predictive Value (95% CI)	1 (0.96-1)	1 (0.48-1)

Table 3. Predictive value of HCV monoinfected and coinfected pts.

Conclusions

In the context of HCV eradication goal the development of easy and quick tests may offer relevant opportunities to facilitate HCV screening. However, in our study the OralQuick test performance is strongly impaired in the HIV-infected people showing a very low sensitivity thus it should be discouraged in known HIV pts where serology can not be replaced.

No differences in the group of HCV+/HIV- and HCV+/HIV+ in terms of HCV-RNA level, year living with HCV, fibrosis. A differences in terms of treatment with DAA was found.

	HCV+/HIV- (n=83)	HCV+/HIV+ (n=84)	HCV-/HIV+ (n=30)	*P*
HCV-RNA UI/ml median (min-max)	0 (0-8.210.980)	0 (0-9.779.991)	-	NS
Years living with HCV, median (min-max)	16 (1-55)	21 (2-32)	-	NS
F3/F4 n, (%)	36 (43.4%)	34 (41.3%)	-	NS
DAA treatment finished/under DAA/waiting for DAA	39/13/31	62/10/12	-	0.0009
HIV-RNA UI/ml, median (min-max)	-	0 (0-542.251)	0 (0-412.553)	NS
Years living with HIV, median (min-max)	-	26 (2-36)	28 (4-38)	NS
CD4 mm^3, median (min-max)	-	605 (54-2085)	635 (45-1998)	NS

Table 4. Charcarteristics and differences between groups

Despite the low number of true positive compare to false negative patients, no associations were found between false positive results and CD4 count, HCV-RNA, liver fibrosis, DAA use, sex.

	True HCV+/HIV+ (n=5)	False HCV-/HIV+ (n=79)
HCV-RNA UI/ml median (min-max)	0 (0-325.282)	112.737 (0-9.779.991)
Years living with HCV, median (min-max)	13 (9-26)	21 (2-32)
F3/F4 n, (%)	2	28
Genotypes (1a/1b/3b/3b/4)	2/2/1	39/14/10/2/4
DAA treatment finished/under DAA/waiting for DAA	3/1/1	62/10/12
HIV-RNA UI/ml, median (min-max)	0 (0-542.251)	0 (0-508.251)
Years living with HIV, median (min-max)	26 (11-27)	25 (2-36)
CD4 mm^3, median (min-max)	950 (325-1458)	682 (54-2085)

Table 5. Characteristics of true and false HCV pts.