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A real-life study in HIV-infected patients on NNRTI-regimen undergoing therapeutic optimization

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Introduction/Summary

- The new antiretroviral therapies for HIV infection available today have made it possible to overcome obstacles linked to old co-formulations, such as pharmacological interactions with widely used over-the-counter drugs, or even the need to take therapies together with food, up to the crucial aspect such as that of forgiveness.

Study Design

- In this retrospective observational study conducted at the Infectious Diseases Operating Unit of the University Hospital of Palermo we analyzed a cohort of 78 patients with HIV infection already on antiretroviral therapy (Table 1). A first group of patients (n=48) suspended RPV/TAF/FTC by carrying out a pharmacological switch (switch group), while a second group of patients maintained antiretroviral therapy with RPV/TAF/FTC (RPV-regimen group). A viro-immunological evaluation was carried out, anthropometric parameters were collected, laboratory parameters and reasons for switch were evaluated.

Results

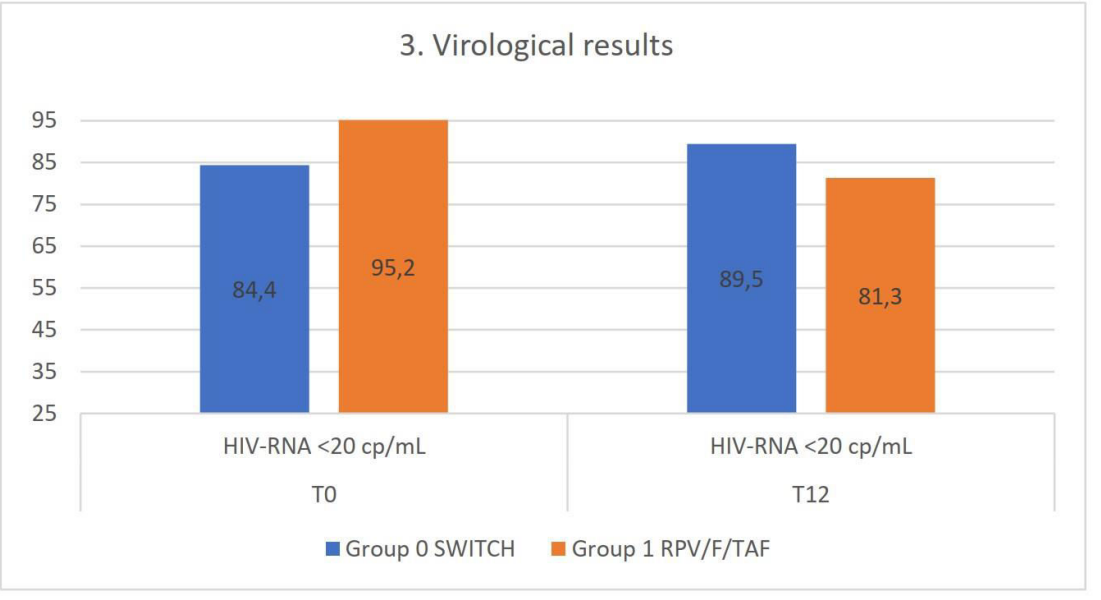
- The characteristics of the two groups are summarized in Tab.1. At the beginning of the analysis period, the percentage of viro-suppressed patients with HIV-RNA <20 cp/mL in switch group and RPV-regimen group were 84.4% and 95.2%, respectively. In the switch group, the main motivation was simplification (56.7%), followed by reduction of metabolic/CV risk (22.2%), toxicity (10%), patient's choice (7,8%), DDIs (3.3%). At 12 months from the start of the analysis, the percentage of viro-suppressed patients with HIV-RNA <20 cp/mL in switch group and RPV-regimen group were 89.5% and 81.3%, respectively (Tab.2). In the switch group, a single-tablet-regimen INI regimen was mainly started (43.8%), a 2DR regimen (20.8%) or a single-tablet-regimen NNRTI (20.8%), and finally the new long-acting regimens (12.5%). At the beginning of the analysis period and at 12 months, no differences emerged regarding body weight or the laboratory parameters analyzed. No adverse events occurred in both groups, and all patients continued therapy without interruption.

	Group 0 (stop RPV/TAF/FTC), n=48	Group 1 (continue RPV/TAF/FTC), n=30
Age, mean (min-max)	51 (28-77)	48 (25-66)
Male, %	39 (81,3%)	24 (80%)
Female, %	9 (18,8%)	6 (20%)
Years of HIV Infection, mean (min-max)	16,98 (4-33)	16,87 (6-32)
Risk factor for HIV infection		
Heterosexual contact	29,2%	13,3%
Homosexual/Bisexual	31,3%	50%
Drug user/Ex drug user	6,3%	---
Unknown	33%	36,7%
History of AIDS events	2,1%	16,7%
History of virological failure	0%	0%
Reason for drug switch		
Drug-drug-interactions	3,3%	
Simplification	56,7%	
Toxicity	10%	
Cardiovascular/metabolic risk	22,2%	
New antiretroviral therapy		
2DR	10 (20,8%)	
INI STR	21 (43,8%)	
Long-Acting	6 (12,5%)	
NNRTI STR	10 (20,8%)	
Comorbidities		
Dyslipidemia	45,7%	36,7%
Hypertension	36,2%	20%
Osteoporosis	13%	10%
Obesity	11,1%	10,3%
Diabetes	6,4%	10%
COPD	---	
Ischemic heart disease	4,2%	---
CKD, eGFR < 60 ml/min	6,3%	---
Neurologic diseases	4,2%	---
Psychiatric pathologies	14,6%	10%
Other cardiovascular diseases	6,4%	---
Cancer	8,3%	6,7%
Smoke	41,7%	50%

Tab.1 Patient characteristics.

	Group 0 Switch, n= 48	Group 1 RPV/TAF/FTC, n= 30	p
Virologic outcome			
HIV-RNA T0 < 20 cp/mL	38/45 (84,4%)	20/21 (95,2%)	,203
HIV-RNA 12 months < 20 cp/mL	17/19 (89,5%)	13/16 (81,3%)	,415
Immunologic outcome			
CD4 T0	694	840	,076
CD4 12 months	818	844	,625
Anthropometric parameters			
Weight T0	78,97	76,19	,216
Weight 12 months	77,0	80,14	,262
Metabolic outcome			
Total Cholesterol T0	174,55	170,60	,727
Total Cholesterol 12 months	168,79	173,65	,663
HDL Cholesterol T0	51,32	44,08	,028
HDL Cholesterol 12 months	47,16	46,80	,663
LDL Cholesterol T0	100,48	104,00	,434
LDL Cholesterol 12 months	102,24	108,15	,626
Triglycerides T0	107,61	111,52	,613
Triglycerides 12 months	111,89	107,90	,482
Glycemia T0	92,62	90,40	,509
Glycemia 12 months	87,21	95,29	,892
Serum creatinine T0	,98	,85	,068
Serum creatinine 12 months	1,01	,95	,695
eGFR T0	91,81	101,48	,022
eGFR 12 months	86,32	95,14	,250
AST T0	23,24	18,88	,037
AST 12 months	23,53	20,00	,378
ALT T0	26,62	21,04	,197
ALT 12 months	24,16	20,67	,357
Platelet count T0	228	272	,020
Platelet count 12 months	234	254	,438
kPa T0	6,7	6,0	,848
kPa T1 > 12 months	5,5	4,3	,881
CAP	254	251	,683
CAP T1 > 12 months	208	250	,180

Tab.2 Viro-immunological and chemistry outcome.



Conclusion

- Despite the effectiveness of RPV-based regimens, it is important for the clinician to maintain high attention towards drugs taken by the patient but which are often not communicated, first of all proton pump inhibitors which rank first in terms of expense healthcare and in second place in terms of consumption in Italy. Likewise, the clinician must implement every measure aimed at optimizing the patient's compliance with therapy, such as the possibility of taking drugs outside of meals.

The availability of antiretroviral drugs that combine several characteristics such as a high genetic barrier, excellent tolerability, consolidated experience in clinical trials and real-world studies, allows the doctor to make a therapeutic change not only by keeping the viremia undetectable, but also by strengthening retention-in-care. The future is also represented by regimens with fewer drugs and the new long-acting formulation, and clinicians must be aware of this.