Mini-Oral Abstract Presentations 3

#22 Short-Cycle Therapy in HIV-Infected Adults: 4 days on / 3 days off with Combinations Containing Rilpivirine

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Short-Cycle Therapy in HIV-infected adults:

4 days on / 3 days off with combinations containing rilpivirine

presented by: dr. Dora Luise

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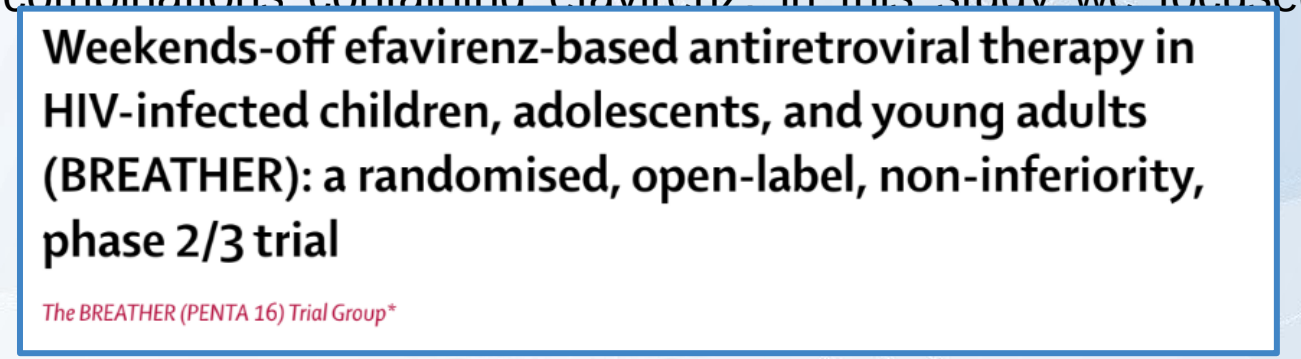
Background

- Short-cycle therapy (SCT) is a safe and effective alternative to the standard every-day regimen for HIV-1 infected patients, both in high- and in low-income countries
- By reducing the number of doses taken by the patient, SCT improves and quality of life, and reduces the cost of antiretroviral therapy (ART)
- Previous studies on SCTs focused on combinations containing efavirenz, in this study we focused on combinations containing rilpivirine



- **Primary aim** of the study: monitor virological suppression (viral load <50 copies) 24 weeks after the implementation of SCT of four consecutive days on/three consecutive days off therapy
- **Secondary aims:** observe the modifications in CD4+ cell counts and CD4+/CD8+ ratio and the occurrence of potential adverse events and virological resistance

Materials and Methods

- A single-centre retrospective observational study, conducted in the HIV outpatient clinic of Verona University Hospital from March 2019 to November 2019
- Inclusion criteria:

  - adults with HIV-1 infection;

  - in ART for more than 12 months with a three-drug standard-dosage combination containing rilpivirine;

  - at least 12 months of virological suppression <50 copies/ml;

  - CD4+ cells count >200/ul for more than 6 months;

  - no evidence of drug resistances or failures with their regimens before the beginning of SCT.
- Included patients started taking their treatment in a SCT scheme of **4 consecutive days on-therapy (Monday to Thursday) and 3 days off treatment (Friday to Sunday)**
- Routine tests including HIV viral load and CD4+ cell count were performed at week 4, 8, 12 and 24. After 24 weeks of SCT, data were collected and retrospectively analyzed for all the patients

Results: baseline characteristics (n=33)

Age (years): median (range)	48 (28-68)
Sex: Male, n(%)	28 (84.8%)
Risk category, n(%): - Homosexual (men) - Bisexual - Eterosexual - Intravenous drug user	 23 (69.7%) 3 (9.1%) 6 (18.2%) 1 (3%)
Ethnic group, n(%): - Caucasian - African	 32 (96,9%) 1 (3,1%)
Years since HIV diagnosis: median, (range)	4 (1-26)
Number of ART regimens before switch to RPV containing AR: median (range).	1 (0-6)
Years of HIV suppressed viraemia (<50 copies/ml): median, range	3 (1-6)
ART at screening n(%): - TAF/FTC + RPV - ABC/3TC + RPV	 29 (87.9%) 4 (12.1%)
CD4+ cells count: mean (range)	770 (311-1163)
CD4+, % on total lymphocytes count: mean (range)	33.92% (21.2%-56.6%)
Baseline CD4+/CD8+ ratio: mean (range)	0.94 (0.4-2.9)

Results (2)

- 33 patients included in the study
- At week 24 **no virological failure was observed**
- **One viral blip was observed at week 24**
- Both CD4+ cells count and CD4+/CD8+ ratio showed no significant variations in the period of observation
- No adverse events were reported by the patients, and no significant alterations were found in the blood analyses
- Most of the patients reported to prefer the SCT over the standard treatment regimen
- **two patients decided to switch back to seven-days-a-week** regimens, for their own convenience, even if the virological suppression was maintained

Further results

- Follow up period extended to 48 weeks after implementation of SCT
- **At week 48 after the implementation of SCT, no virological failures occurred**
- **Three patients switched back to continuous ART**: two left at week 4 for their own convenience, while one had a viral blip with HIV RNA 136 copies/ml that was attributed to poor adherence at week 36, and we decided to switch back to continuous ART, with the same drug combination with prompt viral re-suppression after 4 weeks
- **Other three viral blips were reported in three different patients**, one with VL=50 copies/ml, at week 24, one with VL=55 copies/ml at week 48, one with VL=58 copies/ml at week 48. **All patients returned to VL<50 copies/ml after 4 weeks of SCT without therapy changes**
- **The virological success rate is 100%, while the overall success rate of the SCT scheme is 91%**
- No severe adverse events and no resistance mutations were observed
- Mean CD4+ cells count and mean CD4+/CD8+ ratio increased in the study period but without statistical significance

Conclusion

Short Cycle Therapy with three-drugs ART containing rilpivirine could be a feasible option for optimization of ART in selected HIV patients, especially in low-resource settings

Thank you for your attention!
Please, feel free to contact me for any information!