SWITCHING TO DOLUTEGRAVIR/LAMIVUDINE IS CLINICALLY NON-INFERIOR TO CONTINUING DOLUTEGRAVIR-BASED TRIPLE DRUG ANTIRETROVIRAL THERAPY: 1 YEAR RESULTS OF THE DUALING PROSPECTIVE MATCHED REAL-WORLD COHORT STUDY

Vasylyev, Marta 1; Wit, Ferdinand 2; Jordans, Carlijn 1; Soetekouw, Robert 1; van Lelyveld, Steven 1; Kootstra, Gert-Jan 1; Delsing Corine 1; Ammerlaan, Heidi 1; van Kal, Hendrik 1; van Kuijk, Birgit 1; Krouwer, Elisabeth 1; Leyten, Elaine 1; Claassen, Mark 1; Hassing, Robert-Jan 1; den Hollander, Jan 1; van den Berge, Marcel 1; Roukens, Anna 1; Bierman, Wouter 1; Groeneveld, Paul 1; Lowe, Selwyn 1; van Welzen, Berend 1; Richel, Olivier 1; Neelen, Jeannine 1; van den Berk, Guido 1; van der Valk, Marc 1; Rijnders, Bart 1; Rokx, Casper 1

1 Erasmus MC Universitair Medisch Centrum, Internal Medicine, Rotterdam, Netherlands; 2 SHM, HIV Monitoring Foundation, Amsterdam, Netherlands; 3 Amsterdam University Medical Centers, Internal Medicine, Amsterdam, Netherlands; 4 Academic Medical Center, Internal Medicine, Amsterdam, Netherlands; 5 Catharina Ziekenhuis Eindhoven, Internal Medicine, Eindhoven, Netherlands; 6 Zuyderland Medical Center, Internal Medicine, Heerlen, Netherlands; 7 Maastro Institut, Internal Medicine, Maastricht, Netherlands; 8 Leiden University Medical Center, Internal Medicine, Leiden, Netherlands; 9 University Medical Center Utrecht, Internal Medicine, Utrecht, Netherlands; 10 Maastricht Universitair Medisch Centrum, Internal Medicine, Maastricht, Netherlands; 11 Zuyderland Medical Center, Internal Medicine, Heerlen, Netherlands; 12 Amsterdam University Medical Centers, Internal Medicine, Amsterdam, Netherlands; 13 Onze Lieve Vrouwe Gasthuis, Internal Medicine, Amsterdam, Netherlands; on behalf of the ATHENA observational HIV cohort study.

BACKGROUND

• Dolutegravir/lamivudine (DTG/3TC) is a recommended treatment option for treatment-naïve and experienced people with HIV (PWH).

• Real-world clinical efficacy data in PWH switching to DTG/3TC compared to well-matched controls continuing triple drug DTG-based regimens is scarce.

METHODS

• Prospective cohort study embedded within the Dutch ATHENA cohort.
• Comparison treatment outcomes of switching from DTG-based triple antiretroviral therapy (ART) to DTG/3TC in well-suppressed PWH without prior virological failure (cases) with matched controls continuing DTG-based triple ART.

• Cases - selected from 9 HIV treatment centers that in 2019 had implemented a policy to actively recommend all eligible PWH to switch to DTG/3TC.

• Controls - recruited from the other 15 HIV treatment centers in the Netherlands.

• A formal sample size calculation, assuming a viral suppression rate of 95%, a control-to-intervention ratio of 2:1, and a non-inferiority margin δ = 0.05, resulted in a required sample size for the active arm of 390 cases in order to have 90% power to detect non-inferiority of the intervention arm.

• We matched the first 390 consecutive cases 1:2 to 780 controls by age, sex, HIV acquisition category, absent prior virological failure, pre-ART CD4 count (< or ≥ 200 cells/mm3), and pre-ART viral load (< or ≥100,000 cps/mL).

• Follow-up for controls started at their clinic visit date closest to the start date of DTG/3TC of the matched case. The protocol-defined primary endpoint of the study was the 1-year virological outcome in the ‘on-treatment’ population with virological treatment failure defined as:
  - 2 consecutive viral loads >50 cps/mL, or
  - 1 viral load >50cps/mL directly followed by ART switch, death, or lost-to-follow-up.

• In the ‘on treatment’ analysis, individuals switching ART or becoming lost-to-follow-up while their viral load at the moment of switching was <50 cps/mL were censored.

Table 1

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<tbody>
<tr>
<td>Cases (n=390)</td>
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<tr>
<td>Age, years</td>
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<tr>
<td>Male sex</td>
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<tr>
<td>HIV acquisition category</td>
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<tr>
<td>- Sexual transmission</td>
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<td>- Intravenous drug use</td>
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<td>- Other</td>
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<td>NRTI backbone</td>
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<td>- 3TC</td>
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<td>- ABC/3TC</td>
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<td>- Tenofovir/FTC</td>
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<tr>
<td>CD4 prior to ART</td>
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<td>Viral zenith, log10 cps/ml</td>
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<td>Prior use of ART, years</td>
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A sensitivity analysis, ignoring all ART switches with a last viral load <50 cps/mL in the control group only, showed virological treatment failure in 8 of 762 (1.05%) controls.

CONCLUSIONS

In a real-world setting, switching well-suppressed PWH from DTG-based ART to DTG/3TC was highly efficacious and non-inferior after 1 year compared to matched controls who continued DTG-based triple ART.