

Real world data of using Triumeq (dolutegravir/abacavir/lamivudine; DTG/ABC/3TC): final outcomes of the 3-year German TRIUMPH cohort show good virologic effectiveness and safety in routine clinical practice

Postel Nils¹, Heuchel Thomas², Malfertheiner Peter³, Brust Jürgen⁴, Scholten Stefan⁵, Stephan Christoph⁶, Bohr Ulrich⁷, Hillenbrand Heribert⁸, Lutz Thomas⁹, Glaunsinger Tobias¹⁰, Westermayer Bernd¹¹, Lüftenegger Daniel¹², Walli Ravi-K¹² on behalf of the TRIUMPH study team

¹prinzmed, Munich; ²Medcenter, Chemnitz; ³Universitätsklinikum Magdeburg, Magdeburg; ⁴Mannheimer Onkologie Praxis, Mannheim; ⁵Praxis Hohenstaufenring, Cologne; ⁶Universitätsklinikum-HIVcenter, Frankfurt am Main; ⁷Praxiszentrum Kaiserdamm, Berlin; ⁸Praxis City Ost, Berlin; ⁹Infektiologikum, Frankfurt; ¹⁰Praxis Prenzlauer Berg, Berlin; ¹¹GlaxoSmithKline, Munich; ¹²ViiV Healthcare, Munich

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Background

- TRIUMPH was a prospective, 3-year observational German cohort study in ART-naïve and pre-treated adult HIV-infected patients with negative HLA-B*5701 receiving Triumeq, an onepill-regimen consisting of dolutegravir/abacavir/lamivudine (DTG/ABC/3TC).
- Primary and secondary outcomes include health care resource utilization, effectiveness and safety of DTG/ABC/3TC use in routine clinical care.

Objectives

- Frequency and type of monitoring measures while on DTG/ABC/3TC
- Virological effectiveness using an on-treatment (OT) analysis and a modified ITT (mITT) snapshot approach (HIV-RNA<50 cp/mL [visit window ≥month 33], discontinuation=failure, missing/loss-to-follow-up=excluded)
- 3-year persistence in the study and reasons for discontinuation
- Incidence of adverse drug reactions (ADRs) (coded with MedDRA preferred terms (PTs) and classified by system organ classes [SOCs])
- Time to study discontinuation due to ADRs (Kaplan-Meier analysis; discontinuations for other reasons than ADRs are censored)

Results

Study population

- The analysis population consisted of N=387 patients (40.1% ART-naïve).
- Of 232 pre-treated patients, 19.4% had ≥3 prior regimens and 47.8% were switched from a protease inhibitor (PI)-based regimen.

Table 1. Baseline characteristics	Overall (N=387)	ART-naïve (N=155, 40.1%)	Pre-treated (N=232, 59.9%)
Sex, male, n (%)	348 (89.9)	147 (94.8)	201 (86.6)
Age, years, median (IQR*)	42 (33 – 50)	38 (29 – 48)	45 (35 – 52)
CDC stage C, n (%)	60 (15.5)	8 (5.2)	52 (22.4)
HIV-RNA level, median (IQR*)	1.7 (1.7 – 4.3)	4.4 (3.9 – 4.9)	1.7 (1.7 – 1.7)
<50 cp/mL, n (%)		---	197 (84.9)
≥100,000 cp/mL, n (%)		28 (18.1)	---
CD4 cell count, median (IQR*)	533 (368 – 760)	450 (282 – 613)	600 (434 – 834)
<200 cells/μL, n (%)		20 (12.9)	---
Presence of comorbidities, N (%)	171 (44.2)	45 (29.0)	126 (54.3)
Comorbidities in >10% of patients			
Depression**, n (%)	76 (19.6)	18 (11.6)	58 (25.0)
Hypertension**, n (%)	43 (11.1)	14 (9.0)	29 (12.5)

*IQR, interquartile range; **8.5% of the cohort received antidepressants, 11.6% antihypertensives;

Monitoring measures

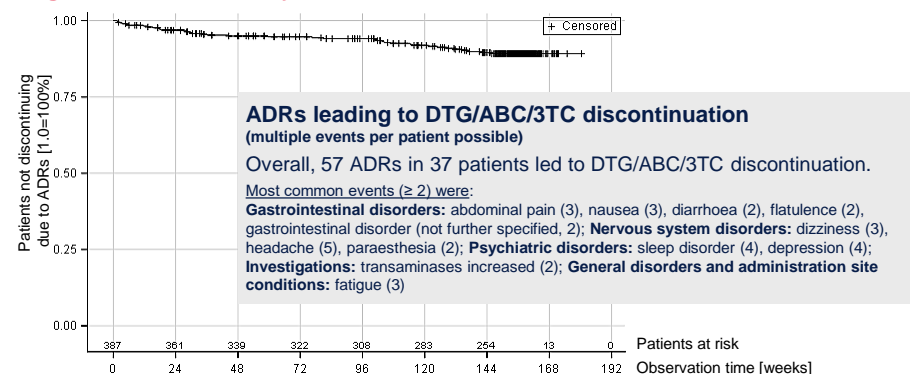
- The median number of documented visits to HIV specialists was 4.6 (IQR, 4.1 – 5.4) per patient year (PPY). The median number of referrals to specialists (excluding infectiologists) was 1.0 (IQR, 0.5 – 1.7).
- The median rates of monitoring measures such as HIV-RNA/CD4 cell controls or blood count/serum chemistry controls were 4.0 PPY (IQR, 3.5 – 4.3) and 4.1 PPY (IQR, 3.6 – 4.5), respectively. Urine tests or microbiological tests (including one or multiple tests) were performed 1.8 (IQR, 0.0 – 3.8) and 1.0 (IQR, 0.0 – 2.3) times PPY, respectively.

Patients disposition after 3 years and reasons for study discontinuation (multiple responses permitted)

- In 36.2% of patients (n=140) premature study discontinuation was reported.
- Most common reasons were stopping DTG/ABC/3TC (18.3%; reasons see Table 2), loss to follow-up (13.4%) and patient decision/withdrawal of consent (5.7%).

Table 2. Study or DTG/ABC/3TC discontinuations and most common reasons (multiple responses permitted)	Overall (N=387)	ART-naïve (N=155)	Pre-treated (N=232)
Patients with study discontinuation, n (%)	140 (36.2)	53 (34.2)	87 (37.5)
Reasons for study disc. (>5%)			
Loss to follow-up, n (%)	52 (13.4)	18 (11.6)	34 (14.7)
Patient decision/withdr. consent, n (%)	22 (5.7)	6 (3.9)	16 (6.9)
Patients stopping DTG/ABC/3TC, n (%)	71 (18.3)	24 (15.5)	47 (20.3)
Reasons for stopping DTG/ABC/3TC			
ADRs, n (%)	37 (9.6)	15 (9.7)	22 (9.5)
Patient wish, n (%)	33 (8.5)	8 (5.2)	25 (10.8)
Virologic failure, n (%)	3 (0.8)	2 (1.3)	1 (0.4)
Comorbidity/comedication, n (%)	2 (0.5)	1 (0.6)	1 (0.4)
Other, n (%)	9 (2.3)	1 (0.6)	8 (3.4)

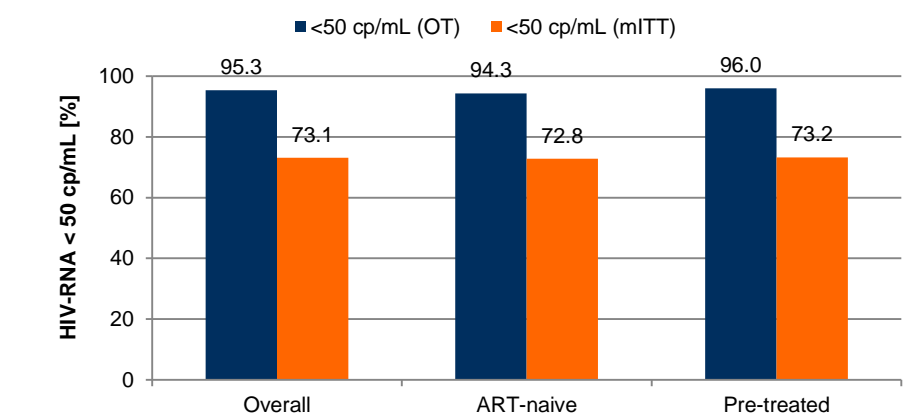
Figure 1. Time to study discontinuation due to ADR



Virological effectiveness after 3-year follow-up

- Virologic effectiveness was 73.1% (mITT; 244/334) [ART-naïve 72.8 (99/136), pre-treated 73.2% (145/198)].
- In OT analysis, HIV-RNA was <50 cp/mL in 95.3% (244/256) [ART-naïve 94.3% (99/105), pre-treated 96.0% (145/151), see Figure 2].

Figure 2. Virologic effectiveness of DTG/ABC/3TC use in routine care



Adverse drug reactions (ADRs)

- Overall, 92 ADRs (81 non-serious ADRs in 59 patients, 11 SADR in 6 patients) were reported resulting in an event rate of 0.097 PPY.
 - SADR (N=11): sleep disorder, depression, hyperlipidaemia, headache, psychiatric decompensation (6 events in 1 patient), acute myocardial infarction
- 77.2%, 12.0% and 10.9% of ADRs occurred in years 1, 2 and 3.

Conclusions

- During the course of the 3-year TRIUMPH cohort, the good safety profile and high virological effectiveness of the onepill-regimen DTG/ABC/3TC in clinical trials was confirmed in real-life with discontinuation rates for intolerance or virologic failure of 9.6% and 0.8%, respectively.
- Moreover, ADR rates decreased over time.
- Monitoring measures were mainly related to routine quarterly controls of HIV-disease, reflecting local HIV treatment guidelines.

Acknowledgments

Special thanks to the participating patients and investigators. of TRIUMPH. Support in medical writing was provided by MUC Research. The study is sponsored by ViiV Healthcare, Germany.