Effectiveness and tolerability of Triumeq (DTG/ABC/3TC) in routine clinical care in Germany: First interim analysis of the TRIUMPH cohort

PE 9/50

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Background

- TRIUMPH is a prospective, 3-year observational German cohort study in adult HIV-1 infected patients receiving Triumeq, a onepill-Regimen consisting of DTG/ABC/3TC, in routine clinical care.
- Primary and secondary objectives include health care resource utilization, effectiveness and safety in patients receiving Triumeq.
- Here we present the results of the first interim analysis (data-cut 31 December 2016), i.e. 15 months after last patient in.

Methods

Study population/Eligibility criteria

- Adult HIV-1 infected patients with negative HLA-B*5701 status initiating Triumeq

Outcome measures

- Frequency and type of monitoring measures (including laboratory tests and referrals to specialists) while on Triumeq (primary endpoint)
- Virological effectiveness of Triumeq, using on-treatment analysis (LOCF, last observation carried forward, between month 9 and 15)
- Discontinuations of Triumeq and respective reasons
- Time to Triumeq discontinuation due to adverse drug reactions (ADRs) applying Kaplan-Meier statistics

Results

Study population

For this first interim analysis, 392 patients from 32 centers were included.

Table 1. Baseline characteristics

		Overall (N=392*)	ART-naïve (N=158)	Pre-treated (N=234)
Sex, male, N (%)		353 (90.1)	150 (94.9)	203 (86.8)
Age, years, median (Range)		42 (33 - 50)	38 (29 - 48)	45 (35 - 52)
CDC stage C, N (%)		61 (15.6)	8 (5.1)	53 (22.6)
BL HIV-RNA, log c/mL, median (IQR**)		1.7 (1.7 - 4.3)	4.4 (3.9 - 4.9)	1.7 (1.7 - 1.7)
BL HIV-1 RNA ≥100.000 c/mL, N (%)			28 (17.7)	---
BL HIV-1 RNA ≥500.000 c/mL, N (%)			6 (3.8)	---
BL HIV-1 RNA <50 c/mL, N (%)			---	198 (84.6)
Presence of comorbidities, N (%)		175 (44.6)	47 (29.7)	128 (54.7)
(>10.0%)	Depression, N (%)	79 (20.2)	20 (12.7)	59 (25.2)
	Hypertension, N (%)	43 (11.0)	13 (8.2)	30 (12.8)

*392/394 patients; 2 patients were excluded from analysis due to incomplete baseline documentation ; **IQR, interquartile range

Previous ART in pre-treated patients

Of 234 pre-treated patients, 113 (48.3%) were exposed to a protease inhibitor (PI) prior to switching to Triumeq. The main reasons for switching from PI-based ART were (multiple responses permitted): treatment simplification (76/113; 67.3%), patient wish (34/113; 30.1%) and intolerability of PI-based regimen (29/113; 25.7%).

Observation time

Median observation time until data cut was 18.7 months (IQR 16.5-20.8), with 84.4% of patients remaining under follow-up.

Monitoring measures

- The median number of documented visits to the HIV specialist was 4.8 (IQR: 4.0-5.5) per patient year (PPY).
- The median number of monitoring measures PPY was 15.7 (IQR 11.9-19.4), most common among them serum chemistry (4.0; 3.3-4.6), blood count (4.0; 3.2-4.6), and HIV-RNA/CD4 cell checks (3.8; 3.2-4.3).
- Referrals to other medical specialists were documented in 56.6% of patients (n=222/392). In patients referred to specialists, the median number of visits was 1.2 PPY (IQR 0.7-2.1).

Virologic response

- HIV-RNA was <50 c/mL in 92.3% of patients (n=322/349) under follow-up at the first data-cut (LOCF between month 9 and 15), i.e. in 95.0% of ART-naïve (n=133/140) and in 90.4% of pre-treated patients (n=189/209; Figure 1).

Acknowledgments

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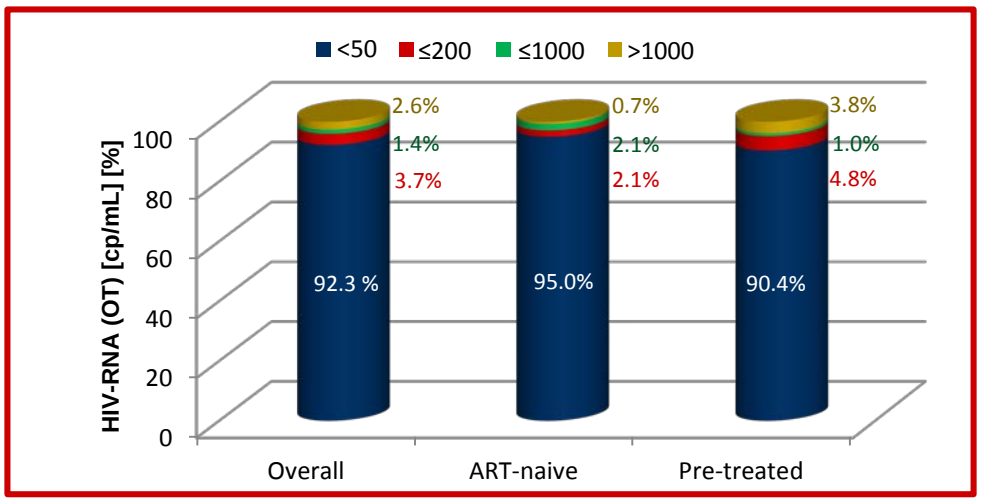
Figure 1. Distribution of HIV-1 RNA levels (LOCF between month 9 and 15): overall and stratified by treatment status (on-treatment analysis)



Adverse drug reactions (ADRs)

ADRs were reported in 11% of patients (n=43/392), in 4.6% leading to discontinuation of Triumeq (see Table 2) after a median time of 4.0 months (IQR 1.1-6.9). Most common ADRs included gastrointestinal disorders (n=12), psychiatric disorders (n=11, without any depression) and nervous system disorders (n=10).

Reasons for study discontinuation until data cut

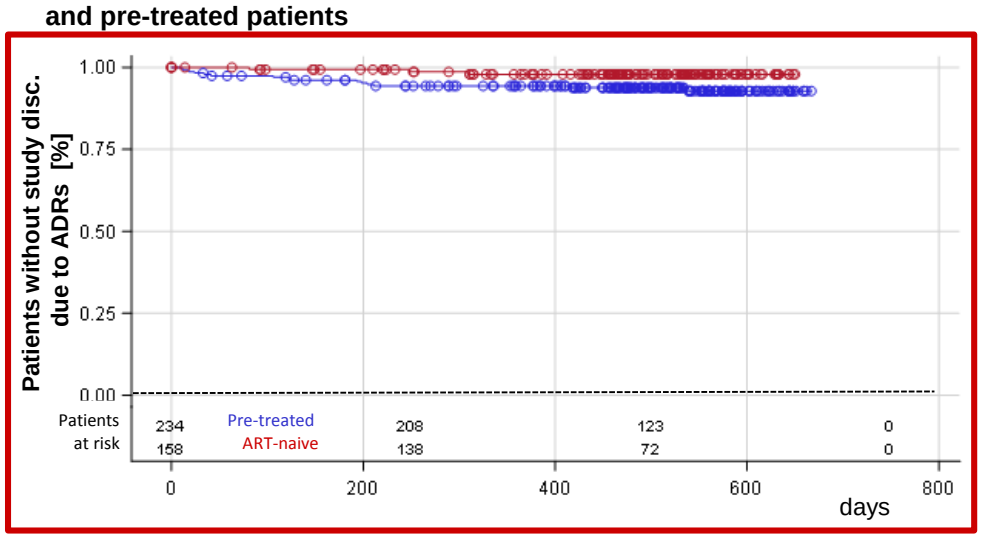
- N=57/392 patients (14.5%) discontinued from the study.
- Reasons for study discontinuation were (multiple responses permitted):
  - Discontinuation of Triumeq (n=35/392; 8.9%; multiple response permitted) attributed to
    - ADRs (n=18/392; 4.6%; see Table 2)
    - patient wish to stop Triumeq (n=15/392; 3.8%)
    - comorbidities/comedication (n=2/392; 0.5%)
    - virological failure (n=1/392; 0.3%)
    - other reasons (n=6/392, 1.5%)
  - Patient decision/withdrawal of consent (n=11/392; 2.8%)
  - Loss to follow-up (n=18/392; 4.6%)
  - Death (n=1/392; 0.3%; unrelated to Triumeq)
  - Other reasons/missing (n=2/392; 0.5%)
- Of patients previously on PI-based ART, 15.9% (18/113) discontinued from the study.
  - Main reason for study discontinuation was discontinuation of Triumeq (13/113; 11.5%) involving intolerance (6/113; 5.3%) and patient wish (5/113; 4.4%).

Table 2. ADRs leading to discontinuation of Triumeq until data-cut (≥ 1 event per patient)

ADR	n	%
Gastrointestinal	6	1.5
Sleeping disorders/ Fatigue	5	1.3
Headache	4	1.0
CNS*	3	0.8
Paraestesia	2	0.5
Liver-related	1	0.3
Other**	8	2.0

*dizziness (3x) **alopecia, anxiety disorder, breaking into a sweat, mastodynia, mentally stressed, ostealgia, palpitation, psycholgical instability

Figure 2. Time to Triumeq discontinuation due to ADR for ART-naïve and pre-treated patients



Conclusions

- The first interim analysis of the TRIUMPH cohort reveals high virological effectiveness in real-life with low discontinuation rates for intolerance (4.6%) or virologic failure (0.3%). There was no discontinuation due to depressive disorders despite a high baseline prevalence of depression.
- The average annual number of documented visits reflects current guidelines concerning monitoring of HIV infection with at least quarterly visits.

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