Incidence and outcomes of AIDS-defining illnesses after dolutegravir/lamivudine initiation in advanced HIV in the DOLCE study

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BACKGROUND

AIDS-defining illnesses (ADIs) remain a major cause of morbidity among people with advanced HIV disease.

Data on incident ADIs following initiation of dual antiretroviral therapy (DT) remain limited.

We evaluated the cumulative incidence, timing, and outcomes of ADIs through 48 weeks in the DOLCE study.

METHODS

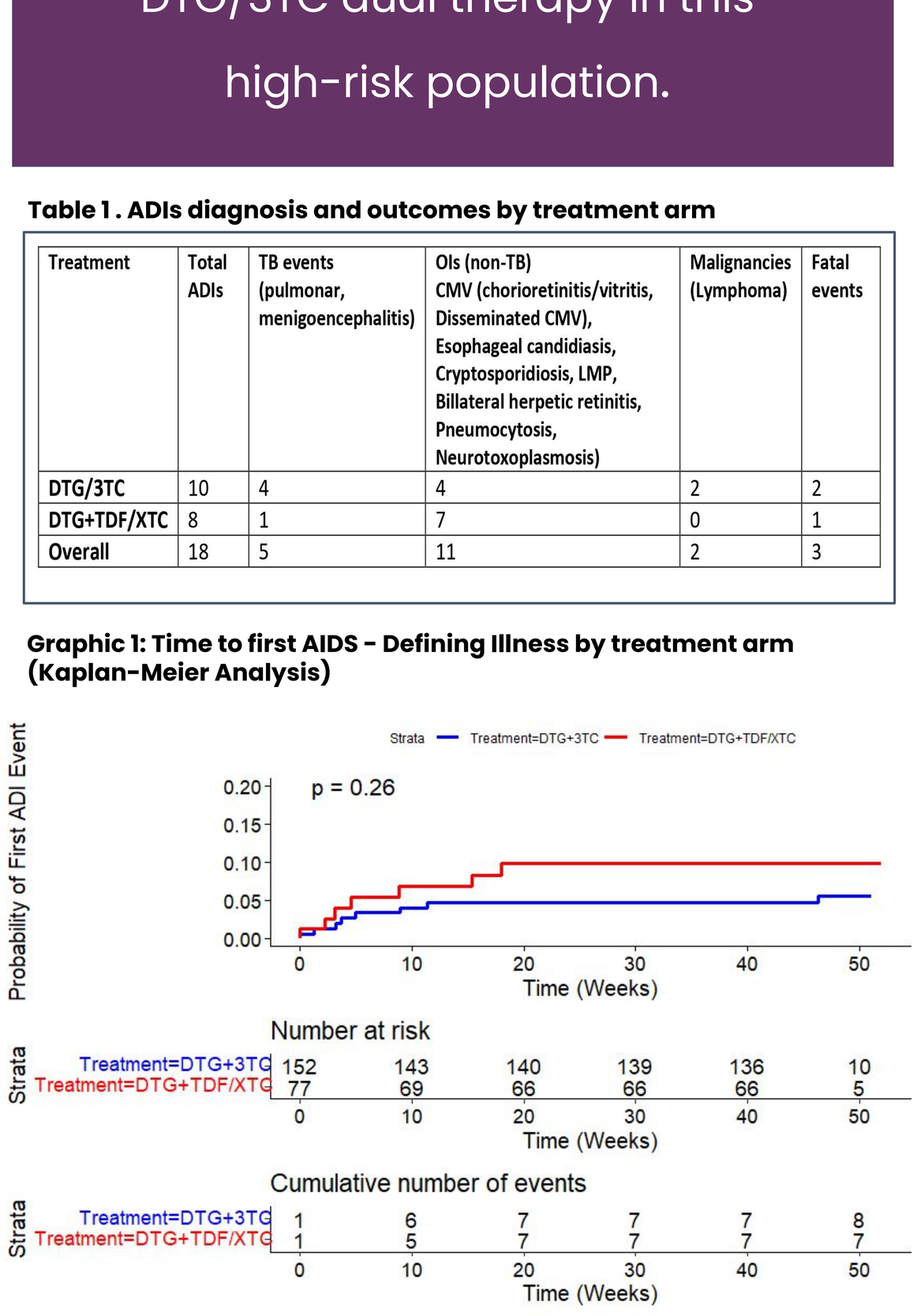
- The DOLCE study enrolled ART-naïve adults with HIV and CD4 ≤200 cells/mm³, randomized 2:1 to dual therapy (DT: dolutegravir/lamivudine) or triple therapy (TT: dolutegravir plus TDF/XTC).
- Incident ADIs were defined as new CDC stage C conditions diagnosed after study entry, using standardized clinical criteria with microbiological, histopathological, or radiological confirmation when available.
- We assessed the 48-week cumulative incidence, type, timing,outcomes, and treatment arm distribution.
- Categorical variables are presented as frequencies and percentages, and continuous variables as medians (IQR), comparisons used chi-square or Wilcoxon tests.
- Time to first ADI event was analyzed using Kaplan–Meier method and Cox regression model comparing between treatment arms.

Among ART-naïve adults with advanced HIV disease (CD4 ≤200 cells/mm³), the **incidence of AIDS-defining illnesses was low and comparable between dolutegravir/lamivudine dual therapy and dolutegravir-based triple therapy**, with no significant differences in time to first ADI or clinical outcomes, providing further evidence supporting the safety of DTG/3TC dual therapy in this high-risk population.

Table 1 . ADIs diagnosis and outcomes by treatment arm

Treatment	Total ADIs	TB events (pulmonar, menigoencephalitis)	OIs (non-TB) CMV (chorioretinitis/vitritis, Disseminated CMV), Esophageal candidiasis, Cryptosporidiosis, LMP, Billateral herpetic retinitis, Pneumocytosis, Neurotoxoplasmosis)	Malignancies (Lymphoma)	Fatal events
DTG/3TC	10	4	4	2	2
DTG+TDF/XTC	8	1	7	0	1
Overall	18	5	11	2	3

Graphic 1: Time to first AIDS - Defining Illness by treatment arm (Kaplan-Meier Analysis)



RESULTS

- Eighteen ADI events occurred in 15 of 229 participants : **48-week cumulative incidence of 6.6%.**
  (5.3%) [CI95%: 2.5%-10%] (8/152) in **the DT** arm and **9.1%** [CI95%: 4%-18%] (7/77) in the **TT arm** (p=0.30).
  Three participants experienced more than one ADI.
- The **most frequent ADIs** was tuberculosis.Event distribution by treatment arm is shown in **Table 1**.
- **Median time to ADI** occurrence was **34 days** (IQR 22–80), with no difference between DT (31 days; IQR 23–68) and TT (47 days; IQR 19–117; p=0.90).
- **No statistically significant differences in time to first ADI** event were observed between treatment arms (TT arm HR=1.78; CI95% 0.65–4.91, p=0.26) **(Graphic 1).**
- **Outcome:** By week 48, 9 events (50%) resolved and 6 (33%) were improving. Three fatal events occurred (DT n=2; TT n=1). Four events led to treatment discontinuation (DT n=3; TT n=1).

CONCLUSIONS

Incident ADI rates were comparable between treatment arms. These findings add further evidence regarding the safety of DTG/3TC-based dual therapy, even in individuals initiating ART with advanced immunodeficiency.

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