The Impact of Immune Reconstitution Inflammatory Syndrome (IRIS) in HIV-Positive People with CD4 <200 Cells/mm³ Initiating Dolutegravir/Lamivudine Dual Therapy: Findings from Dolce Study

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BACKGROUND

- IRIS is a complication of ART with significant morbidity and mortality.
- Occurs in up to one-third of patients starting treatment.
- Risk factors: CD4 <100, male sex, young age, rapid viral suppression, and latent infections.
- Limited data in dual therapy.

OBJECTIVE

To report the incidence of IRIS identified within the DOLCE study

METHODS

DOLCE, a randomized study conducted in Argentina and Brazil, reported comparable rates of virologic suppression between dual therapy (DT) based on Dolutegravir/3TC or Dolutegravir plus TDF and 3TC or FTC (TT) in naïve PLWH with CD4 counts below 200 cells/mL.

Participants were monitored for the development of IRIS through 48 weeks of treatment.

The diagnosis of IRIS was based on clinical criteria (French, 2004), excluding other causes of the symptoms. Baseline data, including CD4 counts, HIV RNA viral load, and prior opportunistic infections, were collected to identify potential risk factors.

ACKNOWLEDGMENTS

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FUNDING

ViiV Healthcare provided the study drugs and funded the study

Severely immuno deficient treatment-naive PWH initiating **dual or triple ARV therapy developed IRIS at a similar incidence rate** of 5,9% and 7.8% respectively (p:0.6).

Table: IRIS List

IRIS Diagnosis	ART	CD4 at ART initiation	VL at ART initiation	Days to iris	VL at Iris	CD4 at Iris
Tuberculosis meningoencephalitis	DT: DTG+3TC	141	586.460	23	586460	141
Burkitt's lymphoma (non-Hodgkin's lymphoma)	DT: DTG+3TC	222	201.210	321	65	680
Bilateral herpetic retinitis	TT: DTG+TDF/XTC	138	147.673	284	39	279
Possible lymphoma	DT: DTG+3TC	328	47.306	324	39	176
Bilateral Pneumonia	TT: DTG+TDF/XTC	16	1.363.421	5	109	505
Disseminated TB with meningeal involvement	DT: DTG+3TC	145	66.454	26	39	123
Cytomegalovirus chorioretinitis and vitritis	DT: DTG+3TC	31	222.923	80	32	250
Probable pulmonary tuberculosis	TT: DTG+TDF/XTC	234	1.075.000	126	39	313
Neurotoxoplasmosis	TT: DTG+TDF/XTC	102	40.594	108		78
Cryptosporidiosis	DT: DTG+3TC	102	826	9	349	207
Artrite reativa	TT: DTG+TDF/XTC	8	278.494	11	39	249
Prurigo strophilus	DT: DTG+3TC	7	44.468	Date of the event not available	Date of the event not available	Date of the event not available
Neurotoxoplasmosis	TT: DTG+TDF/XTC	17	136.963	32	39	182
Herpes zoster	DT: DTG+3TC	108	113.548	223	23	312
Hepatotoxicity event	DT: DTG+3TC	177	81.139	3675	96	304

RESULTS

Among the 229 participants who received treatment**, 15 IRIS events were reported,** resulting in an overall incidence of 7% (15/229) trough 48 weeks (Figure 1).

The median time from ARV treatment initiation to IRIS presentation was 80 days in the DT arm (IQR range: 26-321) and 70 days in the TT arm (IQR range: 16-122),(p=0.5).

The median baseline CD4 count was 116 cells/mL (IQR: 53.3-188), and at the time of IRIS presentation, it was 249 cells/mL (IQR: 159-308). In the DT arm, the median CD4 count at IRIS presentation was 207 cells/mL (IQR: 141-304), and in the TT arm, it was 264 cells/mL (IQR: 199-305)(p=0.7).Figure 2

The IRIS events are included in Table 1 being lymphoma diagnosis the most frequent. Ten IRIS events (66,6%) were classified as serious adverse events (SAEs). Out of the 15 IRIS events, five were treated with corticosteroids (33%). Two IRIS events were fatal.

CONCLUSIONS

- The IRIS incidence reported in this study is within the expected range and reflects the typical early presentation of IRIS, as seen in patients with low CD4 counts initiating antiretroviral therapy.
- No significant differences were observed between the DT and TT regimens. These results underscore the importance of early monitoring for IRIS, especially in individuals with low baseline CD4 counts and pre-existing opportunistic infections.

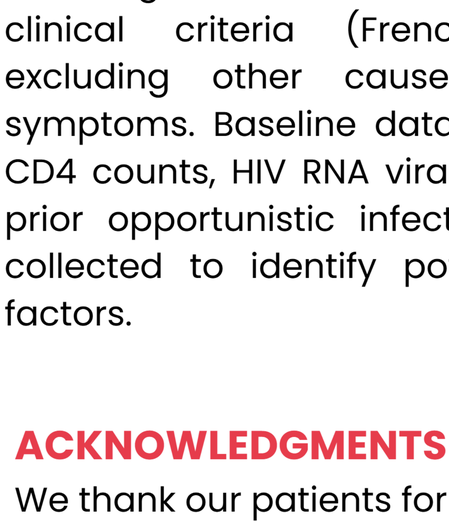

Figure 1. IRIS incidence

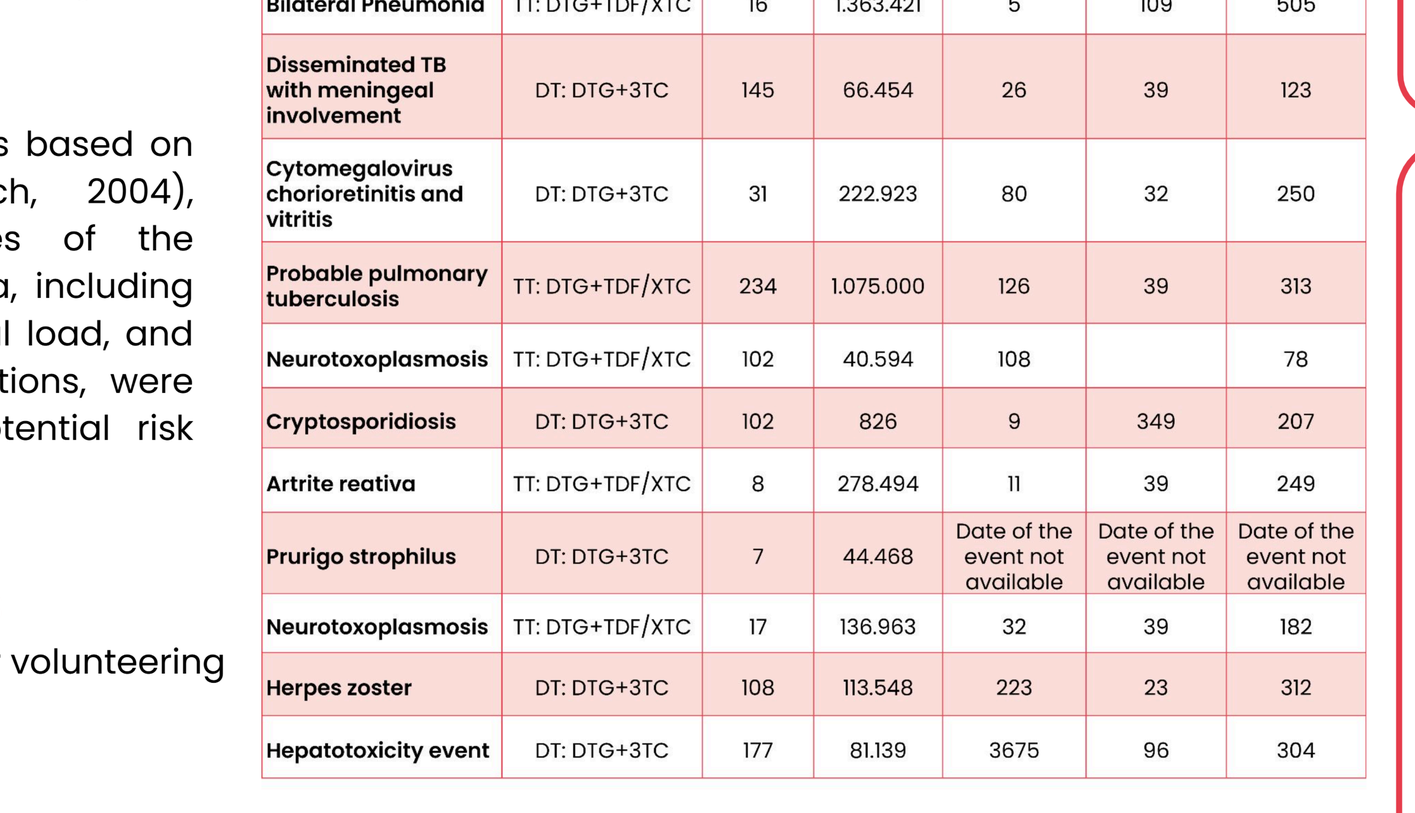

Figure 2. Cd4 absolute value ,cell count at baseline and Iris events in 15 participants

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