Real-World Effectiveness of Dolutegravir + Lamivudine (DTG + 3TC) in Treatment-Naive People With HIV-1 and Low CD4+ Cell Count or High Viral Load at Baseline: A Systematic Literature Review

Emilio Letang,1 Tristan J. Barber,1 Clotilde Allavera,1 Laurent Hocqueleurs,2 José Casado,2 Simona Di Giambenedetto,3 Alfonso Cabello-Ubeda,4 Antonella d’Arminio Monforte,5 Madhusudan Kabra,6 Julie Prince,7 Ana Milinkovic,8 Bryan Jones9

1VIIH Healthcare, Madrid, Spain; 2Van Charleroi Day Centre, Royal Free London NHS Foundation Trust, London, UK; 3Institute for Global Health, University College London, London, UK; 4CNR-Nenit-Dixie, Nantes, France; 5Centre Hospitalier Universitaire de Dijon, Dijon, France; 6Hospital Universitario Ramón y Cajal, Madrid, Spain; 7Université Paris-Sud; 8Virology Department, National Institute for Health Research Biomedical Research Centre, London, UK; 9VIIH Healthcare, Durham, NC, USA

Key Takeaway

Results from a systematic literature review (SLR) of real-world studies of treatment-naive people with HIV-1 initiating DTG + 3TC demonstrated high rates of virologic suppression (HIV-1 RNA <50 copies/mL) among individuals with high baseline viral load or baseline CD4+ cell count <200 cells/mm² at Weeks 48 and 96.

Introduction

• Treatment-naive people with HIV-1 who initiate antiretroviral therapy (ART) with high viral load or low CD4+ cell count <200 cells/mm² suffer higher rates of treatment failure, morbidity, and mortality.

• In the GEMINI-1/2 and STAT clinical trials, DTG + 3TC was effective for achieving virologic suppression among treatment-naive participants with baseline viral load >100,000 copies/mL. At Week 24, 79% (95% CI 76%–81%) of participants in the GEMINI-1/2 study (n=424; 12% experience higher rates of treatment failure, morbidity, and mortality)

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• The original SLR excluded from January 2013 to November 2014, to supplement the original SLR, additional 990 studies were included.

• Reports identified in the search were subsequently screened and only those with baseline or outcome data on treatment-naive individuals with high baseline viral load or low baseline CD4+ cell count were further reviewed for analysis.

Methods

The SLR was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Figure 1). A search of Embase, PubMed, and Google Scholar (January 2013 to November 2014) was performed.

Results

Who are the participants in the SLR? The SLR identified 187 publications, including 67 related to cohorts and including 363,913 people with HIV-1 using DTG + 3TC.

Virologic Outcomes in Treatment-Naive Populations With Low Baseline CD4+ Cell Count

7 and 4 studies reported the virologic effectiveness of DTG + 3TC for 10 treatment-naive individuals with high baseline viral load in low baseline CD4+ cell count, respectively (Table)

Conclusions

Conclusions

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Acknowledgments

References

Figure 1. PRISMA Diagram

Figure 3. Proportion of Individuals With Baseline Viral Load ≥100,000 Copies/mL, Achieving Virologic Suppression at Weeks 24, 48, and 96

Figure 4. Proportion of Individuals With Baseline CD4+ Cell Count <200 Cells/mm²

Figure 2. Breakdown of Real-World Publications Reporting Data on People With HIV-1 Initiating DTG + 3TC With (A) Viral Load ≥100,000 Copies/mL and (B) CD4+ Cell Count <200 Cells/mm²

Table. Studies With Virologic Effectiveness Data for Individuals With HIV-1 and Baseline Viral Load >100,000 Copies/mL, or CD4+ Cell Count <200 Cells/mm²

Achieving Virologic Suppression at Weeks 24, 48, and 96

Virologic Outcomes in Treatment-Naive Populations With Low Baseline CD4+ Cell Count

Overall, 85% (78/90) of people with baseline CD4+ cell count <200 cells/mm² were virologically suppressed at Week 24, 69% (51/75) at Week 48, and 71% (70/97) at Week 96.

Detailed data and real-world evidence from treatment-naive people with HIV-1 (initiating DTG + 3TC) shows high rates of virologic suppression regardless of viral load or CD4+ cell count at baseline.

The DOLLCE clinical trial (ClinicalTrials.gov; NCT00888353) is an ongoing study that will provide additional efficacy data on DTG + 3TC in these subpopulations.
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