Impact of Dolutegravir-based regimens on patient satisfaction and quality of life among people living with HIV: A systematic review and meta-analysis protocol

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KEYWORDS: HIV, Dolutegravir, DTG, Quality of Life, Patient Satisfaction, Treatment Satisfaction, Patient Preferences, Systematic Review, Meta-analysis

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RECEIVED
23/04/2025

ACCEPTED
07/08/2025

PUBLISHED
07/08/2025

LINK

https://afenet-journal.org/impact-of-dolutegravir-based-regimens-on-patient-satisfaction-and-quality-of-life-among-people-living-with-hiv-a-systematic-review-and-meta-analysis-protocol/

CITATION
Mustapha Muhammed Abubakar et al., Impact of Dolutegravir-based regimens on patient satisfaction and quality of life among people living with HIV: A systematic review and meta-analysis protocol. Journal of Interventional Epidemiology and Public Health. 2025;8(3):61.
DOI: https://doi.org/10.37432/jieph-d-25-00099

ABSTRACT

Introduction: The use of antiretroviral therapy (ART) in HIV management has closed the gap in life expectancies between Persons Living with HIV (PLHIV) and the general populace, leading to longevity among PLHIVs. However, increased life expectancies or longevity do not translate to better treatment satisfaction and Quality of Life (QoL). Available literature indicates a divergence in findings with regards the effect of ART on patient satisfaction levels and QoL. With dolutegravir (DTG)-based regimens currently the mainstay of HIV management, there is the need to ascertain effects of DTG on patient satisfaction and QoL among PLHIV. Thus, the aim of this study is to review the existing literature and pool the patient satisfaction levels and QoL among PLHIV exposed to DTG. **Methods**: This is a systematic review and meta-analysis. Study outcomes will be the mean values of the QoL, as well as the proportions, odds ratios and risk ratios of patient satisfaction with DTG. Searches will be conducted on PubMed and Scopus databases, with search period limited to the last 10 years. Studies that reported on the effect of DTG on our outcomes of interest will be included. For studies where the study population was exposed to other integrase strand transfer inhibitors or other ART classes, we will collect data separately for the outcomes of those exposed to DTG and those of the comparator. Also, included studies will be peer-reviewed articles that utilized standardized assessment tools to evaluate QoL among PLHIV exposed to DTG. Conversely, this review will exclude case studies, commentaries, editorials, and all forms of reviews. The study will employ the Preferred Reporting Items for Systematic Review and Meta-analysis checklist. Data extraction and screening will be conducted by 4 independent reviewers. Quality assessment will be conducted using the Newcastle Ottawa Scale. Further, narrative synthesis will be conducted as well as a random effect meta-analysis to pool estimates of patient satisfaction and QoL among PLHIV. All statistical analysis will be performed using the R Studio v 4.2.1. **Results**: Findings from this study will be presented at relevant theme-specific conferences and published in a peer-reviewed journal. **Conclusion:** Given the global adoption of DTG-based regimens as the mainstay of current treatment guidelines, a comprehensive systematic review focusing on the effects of DTG on patient satisfaction and QoL is required. This study will represent the first study to present the estimates of patient satisfaction levels and QoL among PLHIVs exposed to DTG. Our review will provide a background for clinical decision-making and patient-centred policies. **Protocol Registration**: This systematic review and meta-analysis protocol was registered on 6 February 2025 on PROSPERO with the identification number, CRD42025643301.

Introduction

The introduction of antiretroviral therapy (ART) in the management of the Human Immunodeficiency Virus (HIV) has over the years reduced the mortality and morbidity associated with the disease [1]. Currently, there are an estimated 29 million out of 37 million persons on ART, with evidence showing that Persons Living with HIV (PLHIV) on long term ART have almost similar life expectancy to that of the general populace [2]. ART typically comprise the backbone of two nucleoside reverse transcriptase inhibitors and either a non-nucleoside reverse transcriptase (NNRTI), a protease inhibitor or integrase strand transfer inhibitor (INSTI). In recent years, HIV treatment guidelines have incorporated INSTI because of their relatively few adverse effects and minimal drug interactions [3].

Raltegravir, the first approved INSTI, though well-tolerated has the shortcomings of twice-daily dosing, with potential consequences for medication adherence. Another recently approved INSTI, elvitegravir, though available as a single-tablet regimen, is associated with significant drug-drug interactions as well as a low genetic barrier to the development of resistance [4]. In 2018, the World Health Organization (WHO) recommended the combination of the INSTI, dolutegravir (DTG) with two NNRTIs as the preferred first-line regimen for PLHIV initiating ART. Additionally, the WHO recommended DTG as second-line regimen for individuals who had failed on a NNRTI-based ART [5]. As of 2021, more than 22 million PLHIV had transitioned to DTG-based ART [6]. This recommendation was enabled by overwhelming evidence that DTG-based combinations led to higher viral suppression as well as improved adherence because of the convenience of its single-tablet regimen, suggesting improved patient satisfaction.
Patient satisfaction is defined as "an individual's cognitive evaluation of and emotional reaction to, his or her health-care experience" [7]. Essentially, patients who experience or perceive improvement in their condition tend to be satisfied with therapy or care and vice versa [8]. Therefore, it forms a critical component in the management of chronic conditions as it influences health outcomes [9,10]. For instance, high levels of satisfaction with ART are associated with improved medication adherence, which could in turn lead to improved virological suppression [11]. Hence, indications are that determining the level of patient satisfaction with DTG-based regimens as well as factors associated with patient satisfaction are essential for optimizing treatment strategies. Importantly, there are suggestions that there exists a solid relationship between patient satisfaction and quality of life (QoL), with dissatisfied patients often having poor QoL [12].

The WHO refers to QoL as a broad ranging concept that comprehensively evaluates a person's physical health, psychological state, and other aspects of life [13]. Being a self-reported assessment, QoL is subjective and reflects on the perceived effects of a disease or health intervention on an individual and is a predictor of treatment success [13,14]. The effect of health interventions such as ART on the QoL of PLHIV has become pertinent as longevity due to ART might not translate to QoL. Available literature suggests diverse findings with regards the effect of ART on the QoL of PLHIV. While there are settings where ART-exposed PLHIV have shown improved QoL, some studies on the impact of ART on QoL have found no differences in outcomes between ART-naïve and ART-exposed persons or any long-term improvement on QoL [15–17] Notably, a scoping review established the debilitating effect of HIV on the QoL of PLHIV despite exposure to ART [18].

Given the adoption of DTG-based regimens by most countries and its use recommended by current treatment guidelines, a comprehensive systematic review focusing on the effects of DTG on patient satisfaction and QoL is required. Such a review could present the factors influencing patient satisfaction and QoL, further providing a solid background for clinical decision-making and patient-centred policies. Also, there is no existing attempt to estimate the effects of DTG on patient satisfaction and QoL on a global scale. Hence, quantifying the level of patient satisfaction and QoL per DTG would present the overall impact of DTG on both outcomes. Further, this would allow policymakers note the global disparities of the effect of DTG on patient satisfaction and QoL among PLHIV. Thus, we aim to systematically review the exiting literature that presents estimates of the impact of DTG on patient satisfaction and QoL among PLHIV. Additionally, we would conduct a meta-analysis to present estimates of the effects of DTG on our outcomes as well as perform a subgroup analysis to ascertain the factors influencing patient satisfaction and QoL among PLHIV.

Review questions The conduct of this systematic review and meta-analysis is premised on the following questions:

1. What is the aggregate level of patient satisfaction and QoL among PLHIV exposed to DTG?
2. What are the factors influencing patient satisfaction and QoL among PLHIV exposed to DTG?

Methods

Search Strategy

The Search would be conducted on PubMed and Scopus databases to cover for the period of 1 January 2015 to 1 January 2025. Keywords identified will be: *Dolutegravir, quality of life and patient satisfaction*. MMA and HI would independently develop and implement all search strategies. For *quality of life* and *patient satisfaction,* we would search for peer-reviewed, published systematic review and operationalise the key words [19–21]. The complete search strategy is detailed at Annex 1. MMA, HI, SM and CN would screen the articles on Microsoft Excel by removing all duplicates as well as reading the title and abstracts of the papers. For the articles that meet our inclusion criteria, the screening team would read the full text to determine whether to finally include it. Where there is a disagreement, another reviewer, RJ would break the tie. This systematic review and meta-analysis protocol is registered on PROSPERO with the identification number CRD42025643301.

Eligibility Criteria

This review would include peer-reviewed original studies that used assessment tools to evaluate QoL and patient treatment preferences among patients exposed to DTG. For studies where the study population was exposed to other INSTIs or other ART classes, we will collect data separately for the outcomes of those exposed to DTG and those of the comparator. Where comparisons were done between DTG-exposed and DTG-naïve populations, we would report both. Conversely, we would exclude the following types of publications: case studies, commentaries, editorials, and all forms of reviews. Further, articles lacking assessment tools to evaluate QoL will be excluded. The study will employ the Preferred Reporting Items for Systematic Review and Meta-analysis checklist (Page et al., 2021).

Data Extraction and Quality Assessment

The following data would be extracted from each of the included studies: first author and publication year, country, study design, sample size, mean age of participants, and percentage of females. Further, period of DTG exposure, the assessment tools used for QoL, and patient satisfaction would be extracted. Reported outcomes of the study would also be collected. The Newcastle-Ottawa Scale would be used to assess for quality of the included studies. The Scale assigns a maximum of 9 points based on the selection, comparability, and outcome parameters. Quality assessment would be performed by two independent authors (MMA and IKI). Any uncertainty would be resolved by contacting a third reviewer, AI.

Data Synthesis and Analysis

Outcomes considered would be the mean values of the QoL validated tools as well as proportions, odds ratios and risk ratios of patients' satisfaction with DTG use. Results for QoL and patient satisfaction would be pooled in a meta-analysis if at least two studies reported the outcomes, and if data were reported consistently enough for analysis to be feasible. Otherwise, results would be synthesised narratively. Where meta-analyses will be performed, we will utilize the standard random-effects DerSimonian-Laird meta-analyses. Subgroup analysis will be performed for the different geographic regions, age, sex and DTG exposure period. Statistical heterogeneity will be assessed using the I2 statistic. We will visualise the funnel plots to ascertain publication bias. All analyses will be conducted on the statistical environment RStudio, version 4.2.1 (RStudio, 2024).

Ethics statement

No ethics review was required as the study involved an analysis of published studies. However, we have registered the protocol in PROSPERO

Discussion

This systematic review and meta-analysis protocol will provide a detailed summary of the levels of patient satisfaction and QoL among PLHIV exposed to DTG and DTG-based regimens. Findings from this review will be discussed in the context of the existing literature on effects of ART on patient satisfaction and QoL. We will also present the implication of our findings for clinical practice by

comparing our results with that of similar studies that focused on other ART regimens. By including high-quality studies, we will make robust recommendations to support policy promulgations for enhanced patient care. Through the identification of factors influencing patient satisfaction and QoL, findings from this study will have the potentials to update recommendations for clinical practice. We also aim to present significant findings that are reported in the included studies to identify future research and practice directions.

Potential Strength and Limitations

This systematic review and meta-analysis would represent the first study to synthesise evidence on the impact of DTG on the level of patient satisfaction and QoL globally, providing broader implications for clinical practice and patient care for PLHIV. Our study would not apply restrictions to language, providing a wider and comprehensive search of the literature. Further, we have registered this review work on PROSPERO, to curtail any chance of researcher bias. Also, by including only high-quality studies, we would be providing robust evidence on the effect of DTG on our outcomes. Nevertheless, we anticipate some limitations in this study. First, due to variations in the use of QoL and patient satisfaction instruments, there could be a high level of heterogeneity across the studies which may pose a challenge to definitive conclusions. However, we will conduct subgroup analysis to identify potential sources of heterogenicity as well as present findings as a narrative synthesis to support our statistical analysis. Second, the search of literature on only two databases presents the potential of missing out on some studies, leading to publication bias. However, we would ascertain this with the test for publication bias via visualization of the funnel plot. We would aim to report all potential limitations at the end of this study.

Conclusion

The use of ART in the management of HIV has reduced mortality and morbidity among PLHIV as well as closed the gap in life expectancies between the general populace and PLHIV. To optimise the management of PLHIV on ART, there is a need to generate evidence on the effect of current treatment regimens on self-reported health metrics such as patient satisfaction and QoL.

Competing Interest

The authors of this work declare no competing interest

Funding

The authors did not receive any specific funding for this work

Acknowledgements

The authors thank the University of Nottingham, UK, for their support.

Authors´ contributions

MMA, AI, and BOU-K conceived the study idea, designed the review protocol, and led the drafting of the manuscript. All authors contributed to the development of the search strategy, inclusion criteria, and methodological framework. MMA and BOU-K provided critical revisions to the protocol and assisted in the design of the data extraction and quality assessment tools. All authors reviewed and approved the final manuscript and agreed to be accountable for all aspects of the work.

References

1. Fauci AS, Lane HC. Four decades of HIV/AIDS — much accomplished, much to do. N Engl J Med. 2020;383(1):1-4. Available from: http://www.nejm.org/doi/10.1056/NEJMp1916753. doi:10.1056/NEJMp1916753.
2. Joint United Nations Programme on HIV/AIDS. The path that ends AIDS: UNAIDS Global AIDS Update 2023 [Internet]. Geneva: Joint United Nations Programme on HIV/AIDS; 2023 Jul 13 [cited 2025 Aug 7]. Available from: https://www.unaids.org/sites/default/files/media_asset/2023-unaids-global-aids-update_en.pdf.
3. Miller M, Liedtke MD, Rathbun RC, Lockhart SM. The role of dolutegravir in the management of HIV infections. Infect Drug Resist. 2015;8:19-31. Available from: http://www.dovepress.com/the-role-of-dolutegravir-in-the-management-of-hiv-infections-peer-reviewed-article-IDR. doi:10.2147/IDR.S58706.
4. Fantauzzi A, Mezzaroma I. Dolutegravir: clinical efficacy and role in HIV therapy. Ther Adv Chronic Dis. 2014;5(4):164-77.

Available from: https://journals.sagepub.com/doi/10.1177/2040622314530461. doi:10.1177/2040622314530461.
5. World Health Organization. Update of recommendations on first- and second-line antiretroviral regimens [Internet]. Geneva: World Health Organization; 2019 Jul 17 [cited 2025 Aug 7]. Available from: https://iris.who.int/bitstream/handle/10665/360836/9789240053335-eng.pdf?sequence=1.
6. World Health Organization. Update on the transition to dolutegravir-based antiretroviral therapy: report of a WHO meeting, 29–30 March 2022 [Internet]. Geneva: World Health Organization; 2022 Mar [cited 2025 Aug 7]. Available from: https://www.who.int/publications/i/item/WHO-CDS-HIV-19.
7. Shirley ED, Sanders JO. Patient satisfaction: implications and predictors of success. J Bone Joint Surg Am. 2013;95(10):e69. Available from: http://journals.lww.com/00004623-201305150-00020. doi:10.2106/JBJS.L.01048.
8. Batbaatar E, Dorjdagva J, Luvsannyam A, Savino MM, Amenta P. Determinants of patient satisfaction: a systematic review. Perspect Public Health. 2017;137(2):89-101. Available from: https://journals.sagepub.com/doi/10.1177/1757913916634136. doi:10.1177/1757913916634136.
9. Ofei-Dodoo S. Patients satisfaction and treatment outcomes of primary care practice in Ghana. Ghana Med J. 2019;53(1):63-70. Available from: https://www.ajol.info/index.php/gmj/article/view/185461. doi:10.4314/gmj.v53i1.10.
10. Chen Q, Beal EW, Okunrintemi V, Cerier E, Paredes A, Sun S, Olsen G, Pawlik TM. The association between patient satisfaction and patient-reported health outcomes. J Patient Exp. 2019;6(3):201-9. Available from: https://journals.sagepub.com/doi/10.1177/2374373518795414. doi:10.1177/2374373518795414.
11. Somi N, Dear N, Reed D, Parikh A, Lwilla A, Bahemana E, Khamadi S, Iroezindu M, Kibuuka H, Maswai J, et al. Perceived satisfaction with HIV care and its association with adherence to antiretroviral therapy: a prospective cohort study. Int J Infect Dis. 2020;93:168-74. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1201971220300390. doi:10.1016/j.ijid.2020.01.047.
12. Dubina MI, O'Neill JL, Feldman SR. Effect of patient satisfaction on outcomes of care. Expert Rev Pharmacoecon Outcomes Res. 2009;9(5):393-5. Available from: https://www.tandfonline.com/doi/full/10.1586/erp.09.45. doi:10.1586/erp.09.45.
13. World Health Organization. Programme on mental health: WHOQOL user manual, 2012 revision [Internet]. Geneva: World Health Organization; 2012 [cited 2025 Aug 7]. Available from: https://iris.who.int/bitstream/handle/10665/77932/WHO_HIS_HSI_Rev.2012.03_eng.pdf?sequence=1.
14. Haraldstad K, Wahl A, Andenæs R, Andersen JR, Andersen MH, Beisland E, Borge CR, Engebretsen E, Eisemann M, Halvorsrud L, et al. A systematic review of quality of life research in medicine and health sciences. Qual Life Res. 2019;28(10):2641-50. Available from: http://link.springer.com/10.1007/s11136-019-02214-9. doi:10.1007/s11136-019-02214-9.
15. Bunupuradah T, Kosalaraksa P, Vibol U, Hansudewechakul R, Sophonphan J, Kanjanavanit S, Ngampiyaskul C, Wongsawat J, Luesomboon W, Vonthanak S, et al. Impact of antiretroviral therapy on quality of life in HIV-infected Southeast Asian children in the PREDICT study. AIDS Patient Care STDS. 2013;27(11):596-603. Available from: http://www.liebertpub.com/doi/10.1089/apc.2013.0203. doi:10.1089/apc.2013.0203.
16. Desta A, Biru TT, Kefale AT. Health related quality of life of people receiving highly active antiretroviral therapy in Southwest Ethiopia. PLoS One. 2020;15(8):e0237013. Available from: https://dx.plos.org/10.1371/journal.

pone.0237013. doi:10.1371/journal.pone.0237013.
17. Mohammed SA, Yitafr MG, Workneh BD, Hailu AD. Health-related quality of life and associated factors among people living with human immunodeficiency virus on highly active antiretroviral therapy in North East Ethiopia: cross-sectional study. PLoS One. 2021;16(3):e0247777. Available from: https://dx.plos.org/10.1371/journal.pone.0247777. doi:10.1371/journal.pone.0247777.
18. Dickson Shey N, Dzemo KO, Siysi VV, Ekobo AS, Jelil NA. Quality of life of HIV patients on highly active antiretroviral therapy: a scoping review. J Public Health Epidemiol. 2020;12(1):63-73. Available from: https://academicjournals.org/journal/JPHE/article-full-text/0B245FD63143. doi:10.5897/JPHE2019.1148.
19. Florek AG, Wang CJ, Armstrong AW. Treatment preferences and treatment satisfaction among psoriasis patients: a systematic review. Arch Dermatol Res. 2018;310(4):271-319. Available from: http://link.springer.com/10.1007/s00403-018-1808-x. doi:10.1007/s00403-018-1808-x.
20. Pizzol D, Demurtas J, Celotto S, Maggi S, Smith L, Angiolelli G, Trott M, Yang L, Veronese N. Urinary incontinence and quality of life: a systematic review and meta-analysis. Aging Clin Exp Res. 2021;33(1):25-35. Available from: https://link.springer.com/10.1007/s40520-020-01712-y. doi:10.1007/s40520-020-01712-y.
21. Pogorzelska K, Chlabicz S. Patient satisfaction with telemedicine during the COVID-19 pandemic—a systematic review. Int J Environ Res Public Health. 2022;19(10):6113. Available from: https://www.mdpi.com/1660-4601/19/10/6113. doi:10.3390/ijerph19106113.