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Original Research Article

Hepatotoxicity in Dolutegravir vs Non - Dolutegravir Antiretroviral Regimen: Narrative Review

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Abstract: ***Background*:** Dolutegravir (DTG) is recommended by the WHO as a first-line antiretroviral. While its efficacy and tolerability are well established, hepatotoxicity concerns persist due to inconsistent findings, underscoring the need for a comprehensive synthesis of global data. ***Methods*:** We performed a systematic narrative review analyzing 19 eligible studies (2015-2025) from PubMed, Mendeley, Cochrane, and Google Scholar using keywords related to dolutegravir and hepatotoxicity alongside comparator antiretroviral agents. Inclusion criteria encompassed adult and pregnant populations with reported hepatic outcomes, while exclusions applied to low-quality studies, non-English publications, and participants under 15 years. Bias was assessed using the Newcastle-Ottawa scale, with one randomized trial showing low bias and most observational studies demonstrating moderate bias. ***Results*:** Across cohorts, DTG therapy was associated with hepatotoxicity in 20–30% of patients. Comparative analyses often favored DTG, with lower rates of liver enzyme abnormalities than efavirenz and reduced bilirubin compared to protease inhibitors. Predictors of hepatotoxicity included prior ART exposure and elevated baseline liver enzymes. ***Conclusion*:** Dolutegravir demonstrates an acceptable hepatic safety profile, comparing favorably with other antiretroviral regimens. These findings support its continued role as a WHO-endorsed first-line therapy. Further randomized studies are warranted to refine risk estimates and guide monitoring strategies.

Keywords: ARV Drugs, Dolutegravir, Hepatoxicity, Tenofovir, Lamivudine.

INTRODUCTION

Dolutegravir, a second generation integrase strand transfer inhibitor that is used as a core component of antiretroviral therapy. It works by selectively inhibiting the HIV integrase enzyme, preventing the strand transfer step that allows viral DNA to integrate into the host genome which is essential for the viral replication. It has rapidly become the backbone of antiretroviral therapy worldwide due to its potent viral suppression, high genetic barrier to resistance, favourable tolerability profile and once daily dosing convenience. In 2019, the World Health Organisation, (WHO) recommended DTG based regimens as the preferred first line therapy for people living with HIV, accelerating the adoption across high, middle and low income countries. Early safety concerns such as neural tube defects in pregnant women have been largely mitigated by accumulating evidence, further reinforcing DTG global dominance in ART guidelines. (Scott *et al*., 2020)

Despite its strong safety reputation, emerging reports have increasingly documented cases of DTG associated hepatotoxicity. Hepatic adverse effects linked to DTG range from asymptomatic elevations of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) to clinically apparent hepatitis and, in rare cases, severe drug induced liver injury (DILI). (Cottrell *et al*., 2013) These events may be influenced by factors such as underlying viral hepatitis coinfection, alcohol use, metabolic comorbidities, and concomitant hepatotoxic medications. Furthermore, comparative studies evaluating DTG against efavirenz, nevirapine, or protease inhibitor based regimens have produced heterogeneous findings with some reporting increased hepatotoxicity risks and others finding no significant difference (Otto *et al*., 2021) Such variability emphasizes the need to quantify the true burden of DTG related hepatic events.

Given the global scale of DTG use, accurate estimates of hepatotoxicity prevalence are crucial for

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clinical decision making, pharmacovigilance, and guideline refinement. However, the current evidence is fragmented across different study designs, populations, settings and definitions of hepatotoxicity, making it difficult to derive a clear consensus. No comprehensive synthesis exists that pools hepatotoxicity outcomes - including ALT/AST elevation, DILI, any grade hepatotoxicity, and clinical hepatitis - among adults on DTG regimen worldwide nor one that systematically compares DTG to non DTG regimens (apart from efavirenz)

To address this gap, we conducted a global narrative systematic analysis to estimate the pooled prevalence of dolutegravir associated hepatotoxicity among adults living with HIV. Additionally, we compared hepatotoxicity outcomes between DTG based and other ART regimens to determine whether DTG confers a differential hepatic safety profile. This work aims to provide an updated, evidence based assessment to inform clinicians, researchers and policy makers on hepatic safety of one of the world's widely used antiretroviral regimens.

Research Question

How does the use of dolutegravir as a first-line regimen compared with non-dolutegravir antiretroviral regimens influence the prevalence of hepatotoxicity among HIV patients?

METHODOLOGY

Search Strategy

The search was conducted in the databases: pubmed, Mendeley, Cochrane and Google Scholar using the following keywords: *Hepatotoxicity, Dolutegravir, Abacavir, Atazanavir, Zidovudine, Ritonavir, Lamivudine, Efavirenz, Lopinavir, Tenofovir, Raltegravir and Tenofovir Disoproxil Fumarate* in the format: Drug AND Dolutegravir AND Hepatotoxicity within the timeline of 2015 - 2025 from inception to December 14th 2025.

Inclusion Criteria:

- Studies published between 2015 - 2025
- Studies involving patients diagnosed with Human immunodeficiency virus.
- Assessment of liver injury
  - measuring AST/ALT elevation
  - other biomarkers like ALP, GGT, Albumin
  - Grades of hepatotoxicity
  - Discontinuation following hepatotoxicity
  - Clinical features

Exclusion Criteria:

- Studies not meeting the Newcastle-Ottawa quality assessment criteria for the involved cohort studies, Risk of bias (ROB 2) assessment for the included randomized trials studies and ROBINS for individual non-randomized studies included.
- Studies with insufficient methodological details
- Non-english language publications
- People below the age of 15 years
- Studies done on non-human subjects.

Risk of Bias Assessment

We ran a Risk of Bias assessment for the 19 studies used in this narrative review and the result was noted to be as follows:

- The low risk of bias identified in studies such as PACTR Trial as it was a randomised trial
- Moderate risk seen in Wadesango *et al*., Joshi *et al*., Odegbemi *et al*., Okech *et al*., Mengistu *et al*., Yang *et al*., Gan *et al.*, Negedu *et al*., Ebrahim *et al*., Johnson *et al*., Shepherd *et al*., Deshwal and Arora *et al*., Abraham *et al*., Namulindwa *et al*., Ejike *et al*., Pelchen Matthew's *et al*., which comprised of observational, cross-sectional, cohort, retrospective studies etc
- High risk - Benedicto *et al*., Mengistu *et al*., Gill *et al*., which were reviews

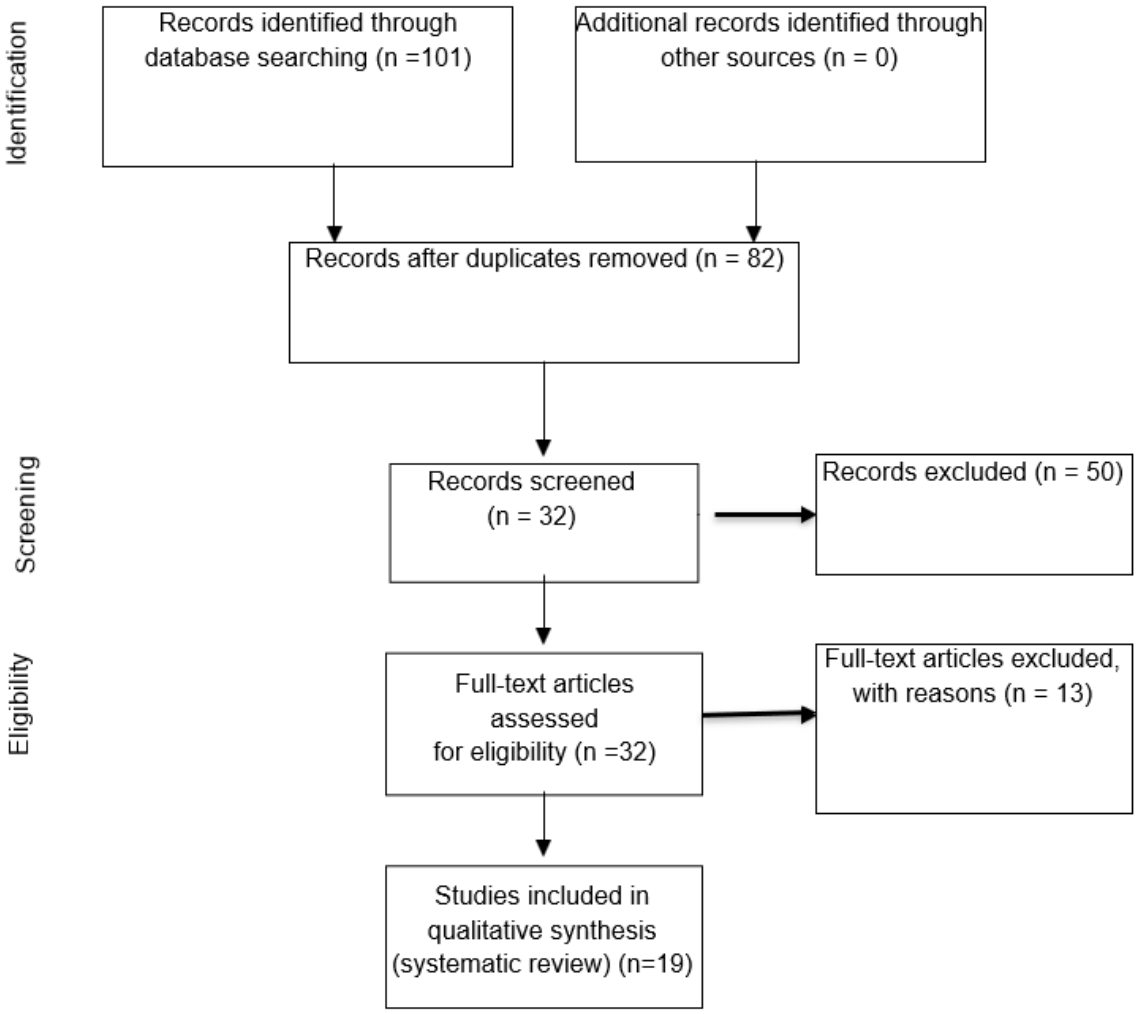
There was noted a high level of publication bias in the studies due to varying potential reasons e.g. larger studies tended to note less hepatotoxicity while the vice versa occurred in smaller studies. Dolutegravir is a relatively recent drug and considering the donor driven setting, it necessitates the need for more unbiased research with more randomized controlled trials and quantitative data collection.

Table 1: Table of Characteristics

Study	Year	Country	Design	Intervention	Participants	Sample size	Parameters	Key findings
Obegdemi *et al*.,	2024	Southern Nigeria	Cross sectional	TLD regimen	Patients diagnosed with HIV	170	ALT/AST / GST/TP/ ALB	TLD minimal alt impact but changes in ast, tb, gst, and alb
Lesley Wadesango	2022	Johannesburg, South Africa	Systematic review	Safety of DTG alone or in combination with other ARVs	DTG related ADRs	138,466 participants 33 studies	ALT elevation	ALT less frequent

Study	Year	Country	Design	Intervention	Participants	Sample size	Parameters	Key findings
Joshi *et al*.,	2024	Western India	Prospective Observational Study	TLD regimen	Patients diagnosed with HIV	319	SGOT, SGPT	6% hepatotoxicity in DTG vs 14% in raltegravir
Awere	2020	Kenya	Mixed cross sectional and historical cohort	DTG(TDF/3TC/DTG) Vs NVP(TDF/3TC/NVP) regimen	Patients diagnosed with HIV	111	Grades of hepatotoxicity	DTG superior in viral suppression and safety profile
Junyang Yang *et al*.,	2025	Shanghai China	Single centre Retrospective study	3TC + DTG Vs B/FTC/TAF	ART naive in patients diagnosed with HIV	380	ALT/AST	ALT and AST remained stable throughout follow-up in both groups. No significant hepatotoxicity observed; no associated treatment discontinuations
Gan *et al*.,	2023	Guiyang, China	Retrospective cohort analysis	3TC + DTG Vs B/FTC/TAF	ART naive with HIV	276	Grades of hepatotoxicity AST/ALT levels	No statistically significant differences in liver enzyme elevations No grade ≥3 hepatic adverse events reported, and no ART discontinuations due to liver-related toxicity.
Otto *et al*.,	2021	USA	Systematic review	NNRTIs, NRTIs, INSTIs (including dolutegravir, bictegravir), protease inhibitors, and entry inhibitors.	ARV drugs on cases	Around 41 studies analyzed	Grades of Hepatotoxicity Elevated Liver Enzymes-ALT, AST, GGT, ALP, Alb,TP Drug-Induced Liver Injury (DILI)	Integrase inhibitors (e.g., dolutegravir, bictegravir): associated with low incidence of hepatic adverse events Rare serious hepatotoxicity cases reported (e.g., sub-acute liver failure with dolutegravir, liver toxicity on DTG/3TC combo
Mengistu *et al*.,	2024	Northwest Ethiopia	Comparative cross sectional study	DTG Vs EFV based	Patients diagnosed with HIV	106	AST/ALT abnormalities	DTG is not associated with increased hepatic toxicity compared to efavirenz
Negedu *et al*.,	2017	UK	Retrospective Review	DTG based ART	Patients diagnosed with HIV	129	LFT abnormalities and discontinuations	Very low hepatotoxicity

Study	Year	Country	Design	Intervention	Participants	Sample size	Parameters	Key findings
Gill *et al*.,	2019	UK	Narrative review	DTG based regimen	Patients diagnosed with HIV	118 records	LFT trends	Multiple causes of ALT elevation including ART
PACTR	2019	Ethiopia & Uganda	Randomized Non inferiority trial	DTG vs EFV400 vs EFV600	Pregnant vs lactating women with HIV	156	Efficacy of DTG vs EFV400	DTG efficacious, safe and tolerable in pregnant women, slightly more serious adverse effects, EFV400 safe alternative
Johnson *et al*.,	2019		Safety analysis	B/FTC/TAF	PLWH	634	Hepatic safety	Generally safe low hepatotoxicity
Shepherd *et al*.,	2017	Europe	Prospective cohort (EuroSIDA)	INSTI regimens(DTG,RAL, EVG)	PLWH	4366	Hypersensitivity reactions, hepatotoxicity discontinuations	1 DTG related discontuniation, very rare
Deshwal & Arora	2019	India	Observational	NNRTI based ART	Patients diagnosed with HIV	320	ALT over 1 year	16.9%, ALT peaked at 24 weeks
Abraham *et al*.,	2025	Ethiopia	Retrospective cohort	DTG based ART	ART-naive in patients diagnosed with HIV	234	Incidence of DILi, ALT, AST, ALP levels	29.1% developed DILI: cholestatic injury more
Namulindwa *et al*.,	2022	Uganda	Mixed-methods	DTG based ART	Adults on DTG>= 12 weeks	375	ADE prevalence, liver toxicity	33.1% ADE; 3 casesof liver toxicity discontinuations
Ejike *et al*.,	2025	Nigeria	Cross sectional comparative	DTG vs PI based ART	Patients diagnosed with HIV	60 plus 30 control	Liver biomarkers	
Benedicto *et al*.,	2021	Spain	Review	NNRTIs (1st &2nd gen)	Patients diagnosed with HIV	-	Mechanisms of liver damage	High risk with NVP/EFV;low with newer NNRTIs
Pelchen-Matthew *et al*.,	2021	Europe	EuroSIDA	INSTIs (DTG<RAL <EVG)	Patients diagnosed with HIV	4366	Hypersensitivity reactions, hepatotoxicity discontinuations	1 DTG related discontuniation, very rare



RESULTS

Across multiple studies, dolutegravir-based antiretroviral therapy was associated with measurable hepatotoxicity, though severe liver injury was uncommon. In a cohort from Wolaita Sodo, 29.1% of patients on dolutegravir experienced drug induced liver injury (DILI) during follow-up, with most cases showing a cholestatic pattern; increases in ALT, AST, and alkaline phosphatase were all statistically significant post-therapy ($p<0.001$) (Abraham *et al*., 2025). Predictors of DILI in multivariable analysis included elevated baseline alkaline phosphatase and prior ART exposure ($p<0.001$ and $p<0.026$, respectively).

Comparative analyses indicated relatively lower rates of liver enzyme abnormalities with dolutegravir versus efavirenz. In one cross-sectional study, 22.4% of patients on dolutegravir had elevated AST/ALT compared to 30.2% on efavirenz, though differences in absolute liver enzyme values did not reach statistical significance (Mengistu *et al*., 2024). Additionally, dolutegravir recipients demonstrated higher mean CD4+ counts and lower viral loads than efavirenz recipients ($p<0.05$), suggesting better overall treatment response without proportionally increased hepatic toxicity.

In a Southern Nigerian cohort, comparisons of TLD (tenofovir lamivudine dolutegravir) recipients to HIV-negative controls revealed significant differences in liver function markers: AST and albumin levels were significantly lower in the TLD group ($p<0.05$), while total protein and GST concentrations were significantly higher ($p<0.05$), though ALT differences were non-significant (Odegbemi *et al*., 2024). Another study found that dolutegravir-based regimens had lower mean direct and total bilirubin than protease inhibitor regimens ($p<0.01$), despite higher mean ALT ($p<0.05$) (Ejike *et al*., 2025).

In summary, dolutegravir-associated hepatotoxicity occurred in approximately 20 to 30% of patients, typically as mild to moderate enzyme elevations, with severe clinical liver injury being rare. These data support an acceptable hepatic safety profile for dolutegravir, though routine liver monitoring remains recommended.

DISCUSSION

The findings from included studies indicate that dolutegravir is associated with hepatotoxicity in a notable minority of patients, with reported DILI frequencies in the range of approximately 20 to 30%, but that the **MAJORITY** of these abnormalities are biochemical rather than clinically severe. The 29.1% DILI rate reported by Abraham *et al*., underscores that liver enzyme derangements after dolutegravir initiation are not rare and must be anticipated in clinical practice. Importantly, the predominant pattern was cholestatic or mixed injury, which may reflect interference with bile acid transport pathway and metabolic pathways rather than direct hepatocellular necrosis.

The introduction of Integrase Strand Transfer Inhibitors (INSTIs) such as dolutegravir (DTG) has altered the landscape of HIV management over the past few years. Previously, the first-line regimens included Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) such as nevirapine, while Protease Inhibitors (PIs) such as ritonavir were reserved for second-line treatment (Sigaloff, 2013, p.14). However, due to dolutegravir's fewer side effects and higher genetic barrier to developing drug resistance it has been recommended as a first-line regimen by the World Health Organisation (WHO, 2019). Subsequently, countries in Sub-saharan Africa such as Ethiopia, Nigeria and Kenya have transitioned to Tenofovir/Lamivudine/Dolutegravir (TLD) as a first-line regimen. Despite this transition, concerns regarding adverse drug reactions, specifically hepatotoxicity, remain.

Hepatotoxicity is liver injury due to toxic substances leading to an abnormal elevation of liver enzymes such as ALT and AST. The mechanism of hepatotoxicity from dolutegravir based regimens is unknown. However, recent reviews indicate that dolutegravir has been implicated in acute liver injury (Ejike *et al*., 2025; Annegret *et al*., 2021). This could be as a result of metabolic changes such as weight gain and hyperglycemia which may contribute to hepatic steatosis and subsequent liver injury, or due to Immune Reconstitution Inflammatory Syndrome (IRIS) (Wadesango *et al*., 2022; National Institute of Diabetes and Kidney Diseases, 2018). Hepatotoxicity in non-dolutegravir based regimens is mainly attributed to hypersensitivity reactions, mitochondrial toxicity, inhibition of liver enzymes or to extensive accumulation of the drug inside the liver (Ana *et al*., 2021).

Global studies show a significant variance in hepatotoxicity rates between DTG-based regimens (<1%) and non DTG-based regimens (5%) (Annegret *et al*., 2021; Sharon *et al*., 2013). However, regional studies from East and West Africa challenge the assumption that DTG is devoid of hepatic risk. DTG-based regimens were found to have a hepatotoxicity rate of 22.4% compared to 30.2% in non DTG-based regimens. This conflicting data highlights the possible influence of regional, genetic and environmental factors. Currently, there is insufficient prevalence data within the Kenyan population. This narrative review aimed to bridge this gap by synthesizing available regional data to estimate the comparative prevalence of hepatotoxicity, thereby informing national monitoring guidelines.

However, when dolutegravir is compared with older regimens, a more refined picture emerges. Across comparative cohorts, the rates of liver enzyme elevation were similar to or lower than efavirenz based therapy, and protease inhibitor regimens were associated with higher bilirubin abnormalities. These findings support current guideline positioning of dolutegravir as a preferred first line agent, since its hepatotoxicity risk does not exceed that of alternatives and is coupled with superior virologic suppression and immune recovery. This favourable benefit-risk balance likely explains why discontinuation due to hepatotoxicity remains uncommon despite frequent biochemical abnormalities.

The identification of risk factors including elevated baseline liver enzymes, previous ART exposure, higher BMI and concomitant medications suggest that dolutegravir does not act in isolation but interacts with host susceptibility and metabolic status. The observation that severe clinical outcomes were rare aligns with the hypothesis that much of the observed hepatotoxicity is idiosyncratic or adaptive, rather than progressive liver injury. Nonetheless immune reconstitution, metabolic effects and hypersensitivity mechanisms described in the literature provide plausible biological explanations for the abnormalities observed.

Implications for Practice and Future Research

This review supports a pragmatic approach, where dolutegravir should remain a cornerstone of antiretroviral therapy while ensuring active screening and management of drug induced liver injury (DILI). This targeted vigilance can be achieved via baseline and periodic liver function monitoring, particularly in those with pre-existing liver disease, with viral hepatitis co-infection, undergoing tuberculosis treatment, with prior ART exposure, or obese; enhanced clinician training to identify suspicious clinical symptoms (jaundice, nausea, vomiting), and differentiate DILI from IRIS; and strengthening pharmacovigilance reporting at the facility level.

Future research could look into the development of low-cost clinical algorithms for the early detection of DILI in primary healthcare centres where diagnostic testing may not be readily available. Additionally, future research can aim to incorporate pharmacodynamics/kinetic counters to the liver damage and evaluate outcomes in resource limited settings where monitoring capacity is variable.

Overall, the evidence suggests that while dolutegravir is not fully free from hepatic risk, its effects are manageable or rare in the absence of other liver damaging factors. It also maintains its safety and efficacy profile in comparison to other ARTs in line with the current WHO recommendations.

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