Survey Report

Perception Mapping of Clinicians on Understanding the Place of Integrase Inhibitors in HIV-1 Treatment

Version No.: 1.1

The study was conducted according to the approved protocol and in compliance with the protocol, Good Clinical Practice (GCP), and other applicable local regulatory requirements.

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1. INTRODUCTION

Human Immunodeficiency Virus (HIV) continues to be a significant global health challenge, with approximately 39.9 million people living with HIV worldwide in 2023, and estimates ranging from 36.1 million to 44.6 million [1]. The advent of antiretroviral therapy (ART) has transformed HIV from a fatal illness to a manageable chronic condition, dramatically improving life expectancy and quality of life for people living with HIV [2]. Among the various classes of antiretroviral drugs, integrase strand transfer inhibitors (INSTIs) have emerged as a cornerstone of modern HIV treatment regimens due to their high efficacy, favorable safety profile, and high genetic barrier to resistance [3].

Integrase inhibitors, particularly second-generation agents like dolutegravir (DTG) and bictegravir (BIC), have become preferred options in many treatment guidelines worldwide [4]. These drugs are often combined with nucleoside reverse transcriptase inhibitors (NRTIs) such as tenofovir (in its various formulations) and emtricitabine or lamivudine to create potent single-tablet regimens [5]. The use of fixed-dose combinations (FDCs) has been associated with improved adherence and better virologic outcomes, contributing to their widespread adoption in clinical practice [6].

However, the optimal use of integrase inhibitors in various clinical scenarios, including treatment-naïve patients, virologically suppressed individuals, and special populations like pediatric patients or those with comorbidities, remains an area of ongoing research and clinical decision-making [7]. Factors such as drug-drug interactions, potential side effects, and long-term safety considerations play crucial roles in treatment selection and management [8].

Moreover, the frequency of viral load monitoring, choice of NRTI backbone, and management of potential adverse effects are important aspects of patient care that may vary based on clinician experience and local guidelines [9]. Understanding how these factors influence clinicians' perceptions and practices regarding the use of

integrase inhibitors is crucial for optimizing HIV care and identifying areas for further education or research.

This survey study aimed to map clinicians' perceptions and practices regarding the use of integrase inhibitors, particularly dolutegravir and bictegravir, in combination with various NRTI backbones for HIV-1 treatment.

2. RATIONALE OF THE STUDY

The rationale for this survey on clinicians' perceptions of integrase inhibitors in HIV-1 treatment was to explore the real-world application of these medications, despite their proven efficacy and status in treatment guidelines. As HIV treatment evolves with newer integrase inhibitors and fixed-dose combinations, understanding physicians' perceptions, preferences, and experiences is crucial for bridging the gap between clinical trial data and actual practice.

This study aimed to identify factors influencing treatment decisions, including long-term tolerability, comorbidity management, and patient quality of life. By examining monitoring practices, side effects, and patient adherence, the survey will provide insights into the effectiveness and challenges of integrase inhibitor-based regimens.

Focusing on specific options like dolutegravir and bictegravir, the survey will help reveal prescribing patterns and unmet needs in HIV care. Ultimately, the findings will contribute to optimizing HIV treatment by aligning clinical practice with evidence-based recommendations and improving patient outcomes.

3. OBJECTIVES

The primary objective of this study was to assess clinicians' perceptions, preferences, and experiences regarding the use of integrase inhibitors in HIV-1 treatment in real-world clinical settings.

4. METHODS

This study was designed as a cross-sectional, questionnaire-based survey to assess clinicians' perceptions and practices regarding the use of integrase inhibitors in HIV-1 treatment in India. The survey consisted of 15 questions focused on testing practices, preferred NRTIs for combination therapy, adherence to FDCs, common side effects, potential drug interactions, and laboratory monitoring in HIV care.

Clinicians, including infectious disease specialists, general practitioners, and HIV specialists who regularly prescribe antiretroviral therapy, were identified and invited to participate through professional networks, medical associations, and HIV care centers across India. Prior to participation, all potential participants received detailed information about the study and provided informed consent. The 15-question survey was administered electronically to ensure ease of access and convenience for respondents.

Responses were securely collected and stored to ensure confidentiality. After data collection, statistical analysis was performed to summarize the findings, identify trends, and draw conclusions regarding the real-world application of integrase inhibitors in HIV-1 treatment. Results were compiled into a comprehensive report, which will be shared through scientific publications and presentations at conferences, where appropriate.

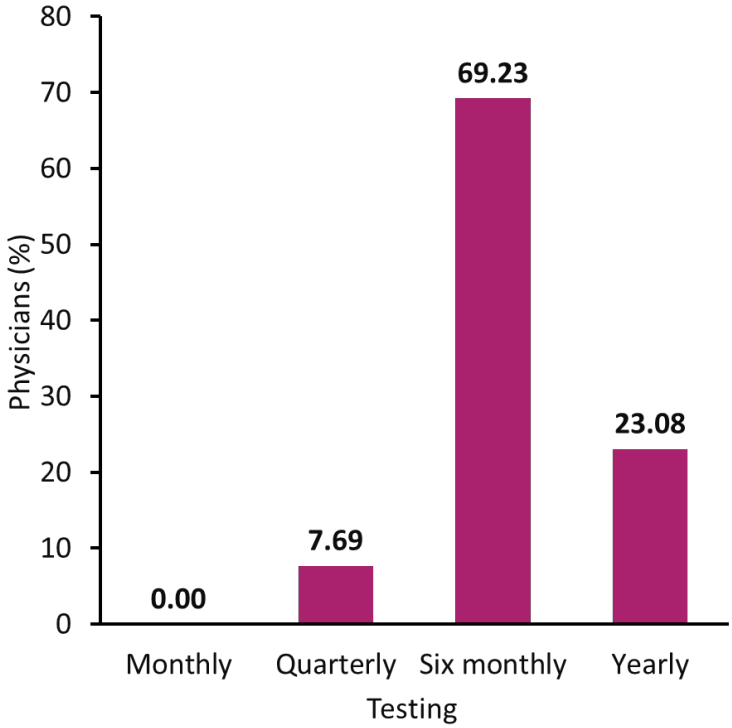
The target sample size for the study was set at 100 clinicians to ensure a diverse and representative sample. The study adhered to ethical guidelines outlined in the Declaration of Helsinki, with approval sought from an independent ethics committee. Participants were assured of their right to withdraw at any time, and all responses were anonymized to protect their privacy.

5. RESULTS

A total of 91 HCPs participated in the survey. Below is the summary of the responses.

[1] In routine clinical practice, how frequent testing for viral load would you recommend after initiation of ART?

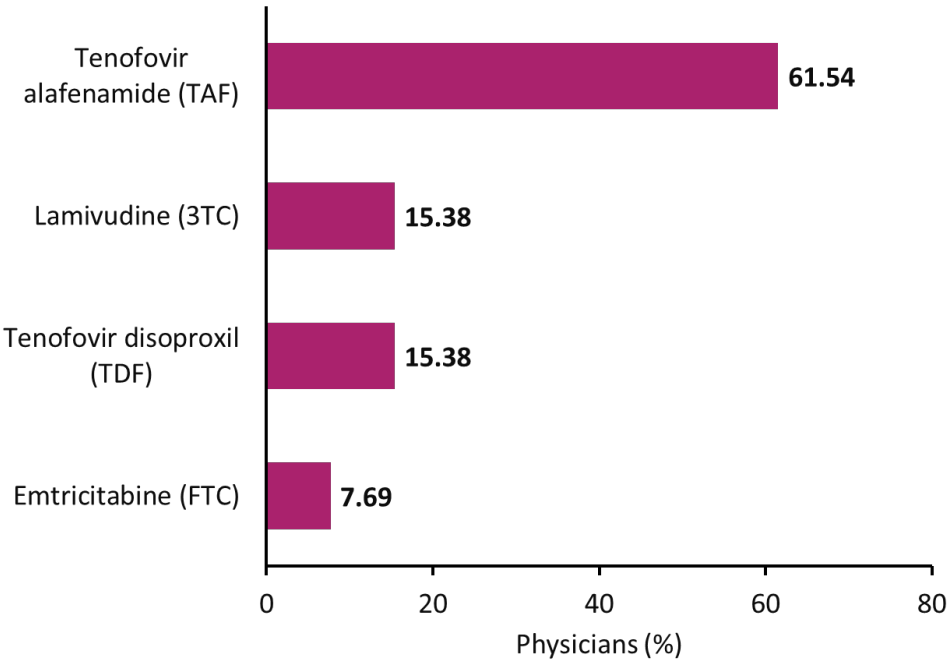
a. Monthly
b. Quarterly
c. Six monthly
d. Yearly



- The majority (69.23%) of physicians recommended testing for viral load every six months after initiation of ART in their routine clinical practice.
- Around 23.08% of physicians preferred testing for viral load yearly after initiation of ART in routine their clinical practice.
- A small portion (7.69%) of physicians recommended testing for viral load quarterly.
- None of the physicians recommended viral load testing monthly.

[2] In your clinical practice, which NRTIs do you prefer in combination with integrase inhibitors for HIV patients?

a. Tenofovir disoproxil (TDF)
b. Tenofovir alafenamide (TAF)
c. Lamivudine (3TC)
d. Emtricitabine (FTC)



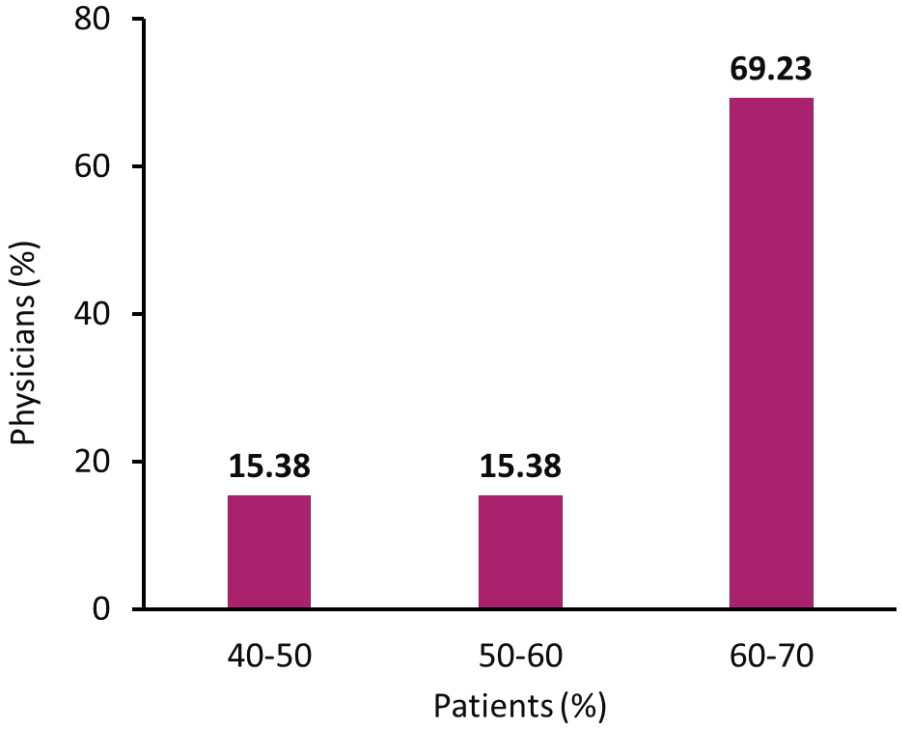
- The majority (61.54%) of physicians preferred a combination of tenofovir alafenamide (TAF) with integrase inhibitors in their clinical practice.
- A significant portion (15.38%) of physicians preferred tenofovir disoproxil (TDF) in combination with integrase inhibitors.
- A similar portion (15.38%) of physicians opted for lamivudine (3TC) with integrase inhibitors.
- A smaller portion (7.69%) of physicians prescribed emtricitabine (FTC) with integrase inhibitors.

[3] In your clinical practice approximately how many percentage of patients are put on fixed dose combination of dolutegravir (DTG), tenofovir alafenamide (TAF) and emtricitabine (FTC) in 1 month?

a. 40-50%

b. 50-60%

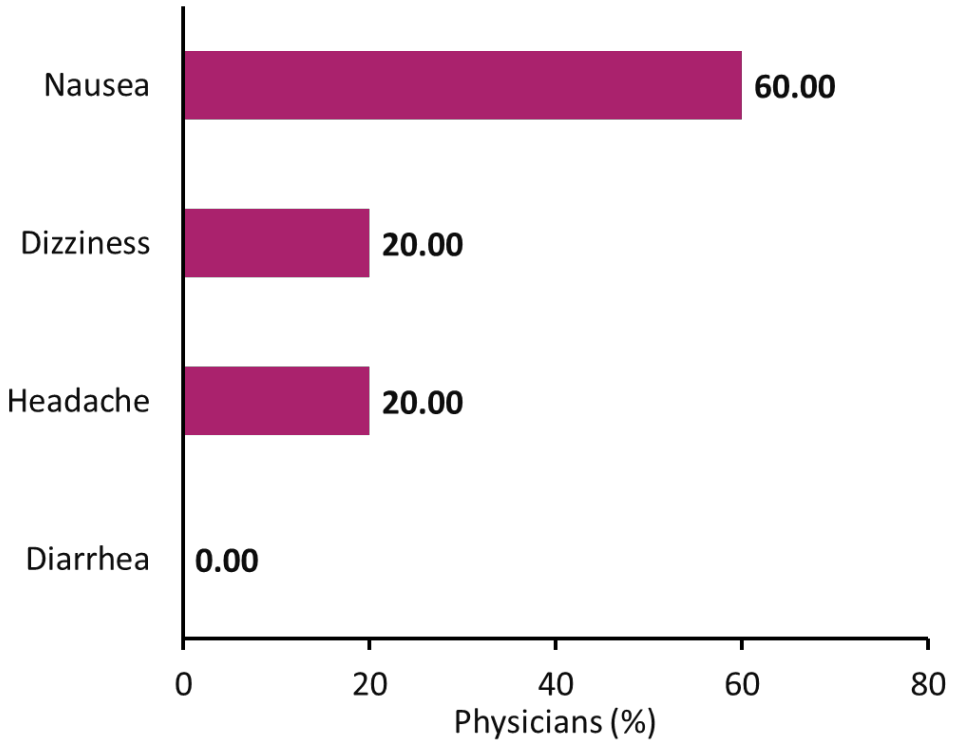
c. 60-70%



- The majority (69.23%) of physicians reported that approximately 60-70% of their patients were prescribed the fixed-dose combination of dolutegravir (DTG), tenofovir alafenamide (TAF), and emtricitabine (FTC) in 1 month.
- A smaller portion (15.38%) of physicians stated that 40-50% of their patients were prescribed this combination of dolutegravir (DTG), tenofovir alafenamide (TAF), and emtricitabine (FTC) in 1 month.
- Approximately 15.38% of physicians indicated that 50-60% of their patients were put on this fixed-dose combination.

[4] In your clinical practice, which is the most common side effect reported with DTG, TDF and 3TC fixed-dose combination?

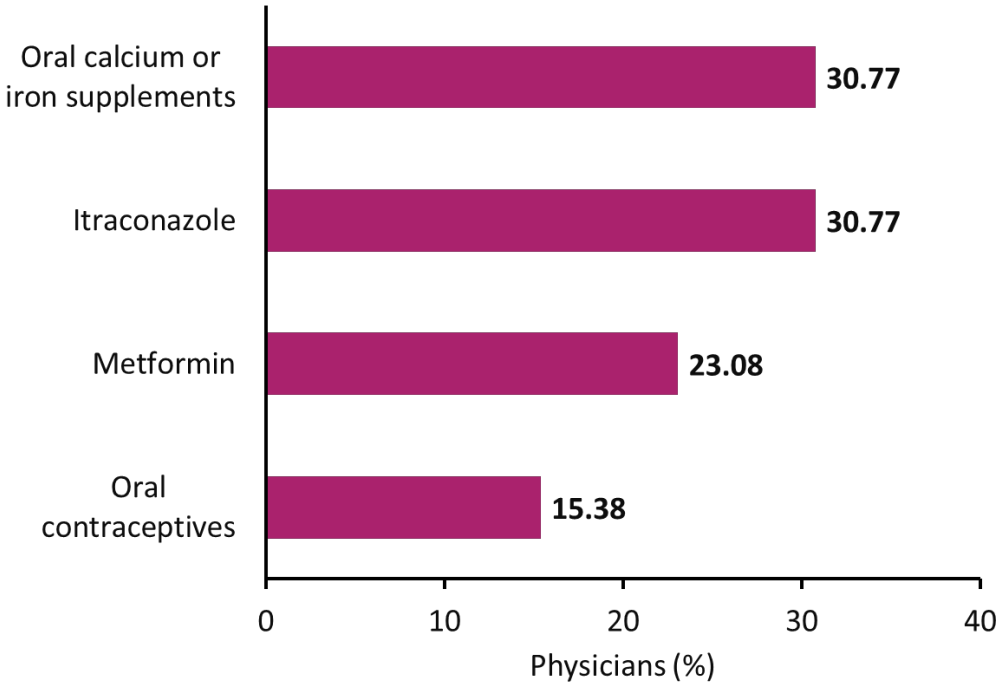
a. Diarrhea
b. Headache
c. Nausea
d. Dizziness



- The majority (60.00) of physicians reported nausea as the most common side effect of DTG, TDF and 3TC fixed-dose combination.
- Around 20.00% of physicians observed both dizziness and headache as the most common side effect of DTG, TDF and 3TC fixed-dose combination.
- None of the physicians noted diarrhea as the side effect of this combination.

[5] In your clinical experience, which of the following can have a potential drug interaction with DTG, TAF and FTC FDC?

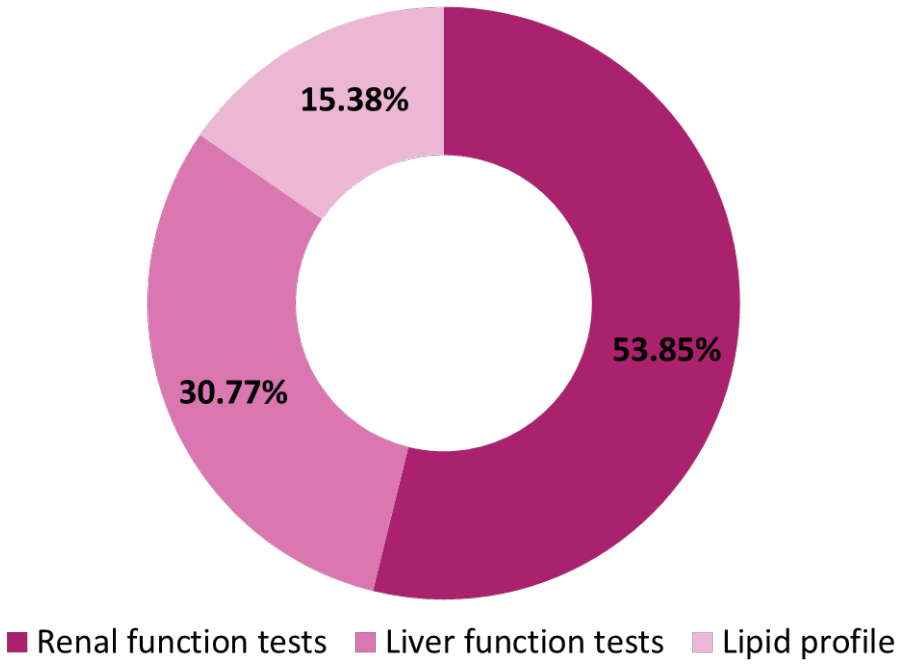
a. Itraconazole
b. Metformin
c. Oral calcium or iron supplements
d. Oral contraceptives



- Around 30.77% of physicians identified itraconazole as having a potential drug interaction with the fixed-dose combination of dolutegravir (DTG), tenofovir alafenamide (TAF), and emtricitabine (FTC).
- A similar portion (30.77%) of physicians also highlighted oral calcium or iron supplements as potentially interacting with this FDC.
- Approximately 23.08% of physicians reported that metformin could have a potential drug interaction with DTG, TAF, and FTC.
- A smaller portion (15.38%) of physicians noted that oral contraceptives might have a potential drug interaction with this FDC.

[6] In your clinical practice, which of the following laboratory investigations is essential for monitoring patients on FDC of DTG, TAF and FTC?

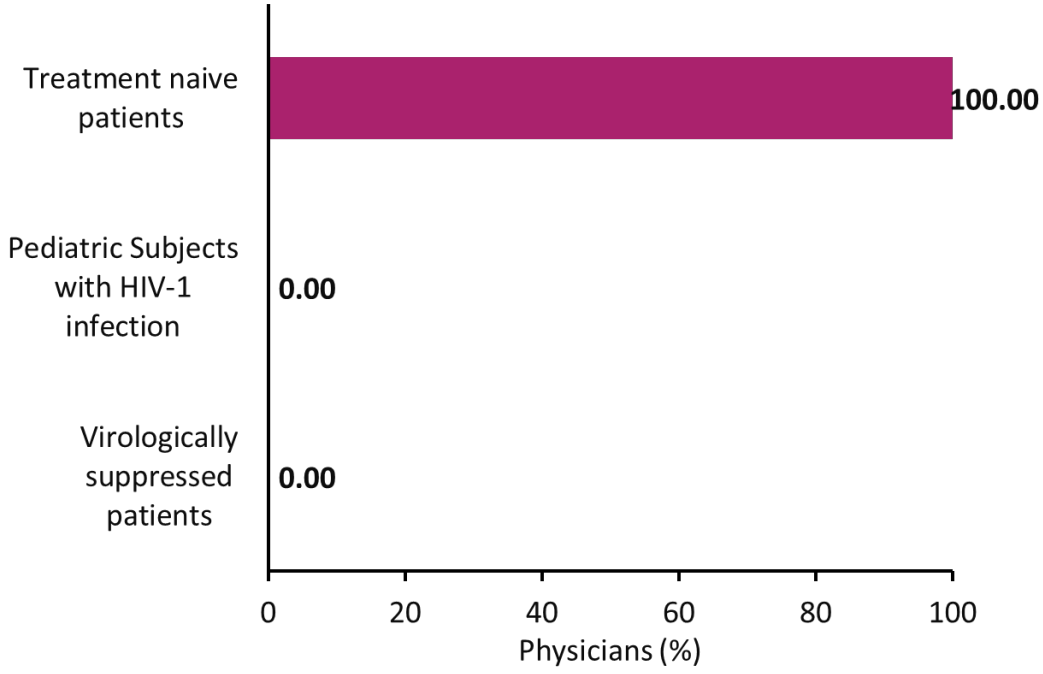
a. Liver function tests
b. Renal function tests
c. Potassium levels
d. Lipid profile



- The majority (53.85%) of physicians reported that renal function tests are essential for monitoring patients on the FDC of DTG, TAF, and FTC.
- Around 30.77% of physicians considered liver function tests to be important for monitoring this fixed-dose combination.
- A small portion (15.38%) of physicians noted that lipid profile is an essential monitoring parameter for patients on the FDC of DTG, TAF, and FTC.
- None of the physicians mentioned potassium levels as an essential investigation for monitoring of this combination.

[7] In your clinical practice, in which category of HIV patient would you prefer the ART containing FDC of DTG, TDF and 3TC?

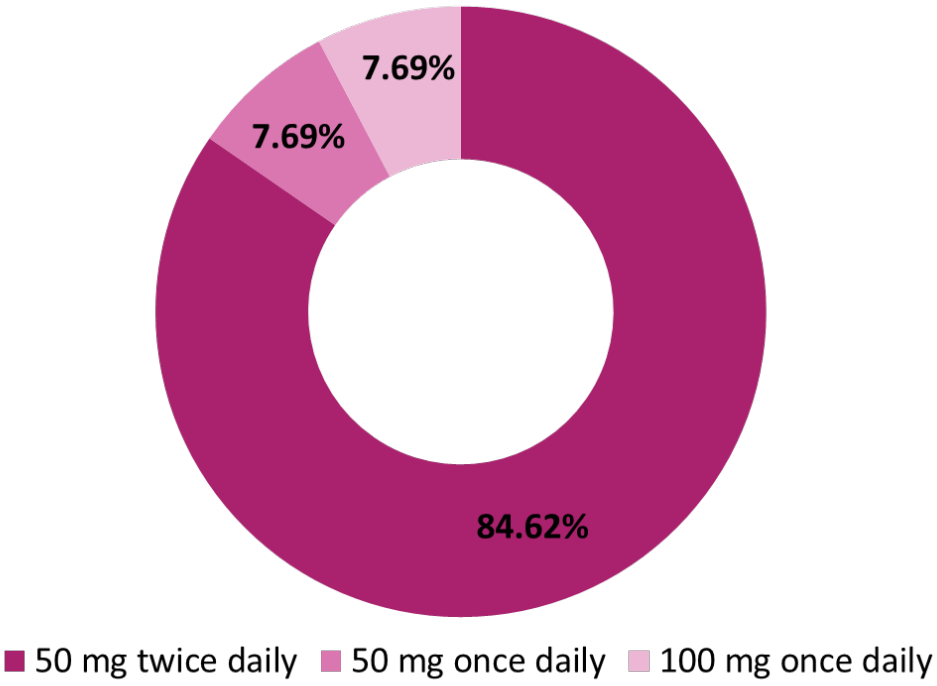
a. Treatment naïve patients
b. Virologically suppressed patients
c. Pediatric Subjects with HIV-1 infection



- The majority (100%) of physicians reported that they prefer the ART containing the FDC of DTG, TDF, and 3TC for treatment-naive patients.
- None of the physicians selected virologically suppressed patients or pediatric subjects with HIV-1 infection as the preferred category for this fixed-dose combination.

[8] What dose of DTG you use in your routine practice when you want to co-prescribe with Rifampicin?

a. 50 mg twice daily
b. 50 mg once daily
c. 100 mg once daily



- The majority (84.62%) of physicians reported using 50 mg of DTG twice daily when co-prescribing with rifampicin.
- A small portion (7.69%) of physicians preferred using 50 mg of DTG once daily in combination with rifampicin.
- A similar portion (7.69%) of physicians opted for 100 mg of DTG once daily when co-prescribing with rifampicin.

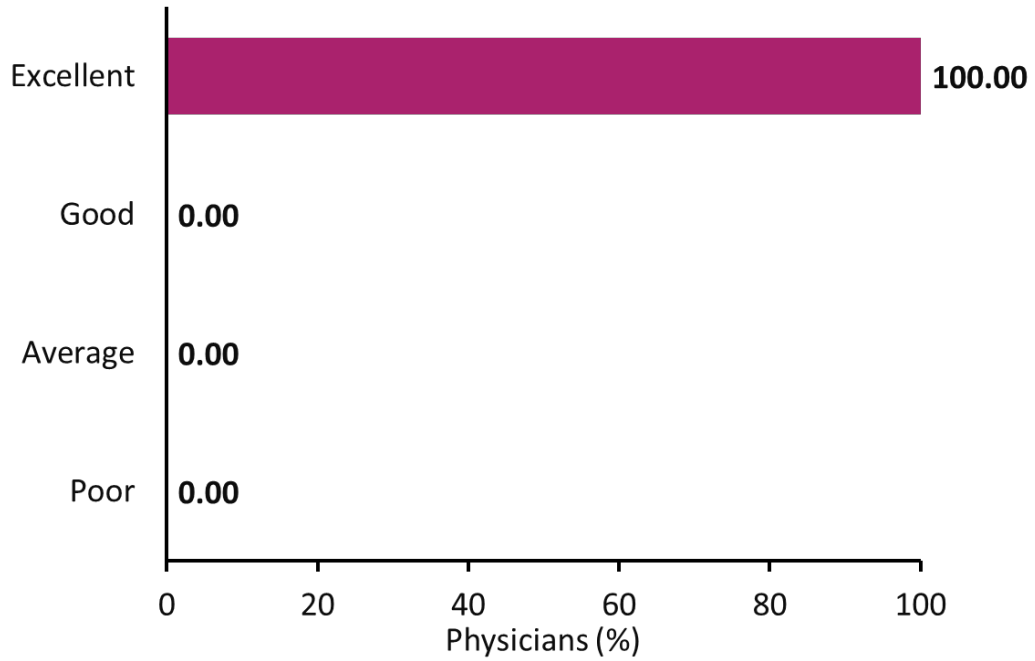
[9] In your opinion, how do you rate the adherence of FDC of dolutegravir, tenofovir alafenamide, emtricitabine tablets FDC for the patients with HIV as ART treatment?

a. Excellent

b. Good

c. Average

d. Poor



- The majority (100%) of physicians reported the adherence to the FDC of dolutegravir, tenofovir alafenamide, and emtricitabine as excellent for HIV patients on ART treatment.
- None of the physicians rated adherence to the FDC as good, average and poor.

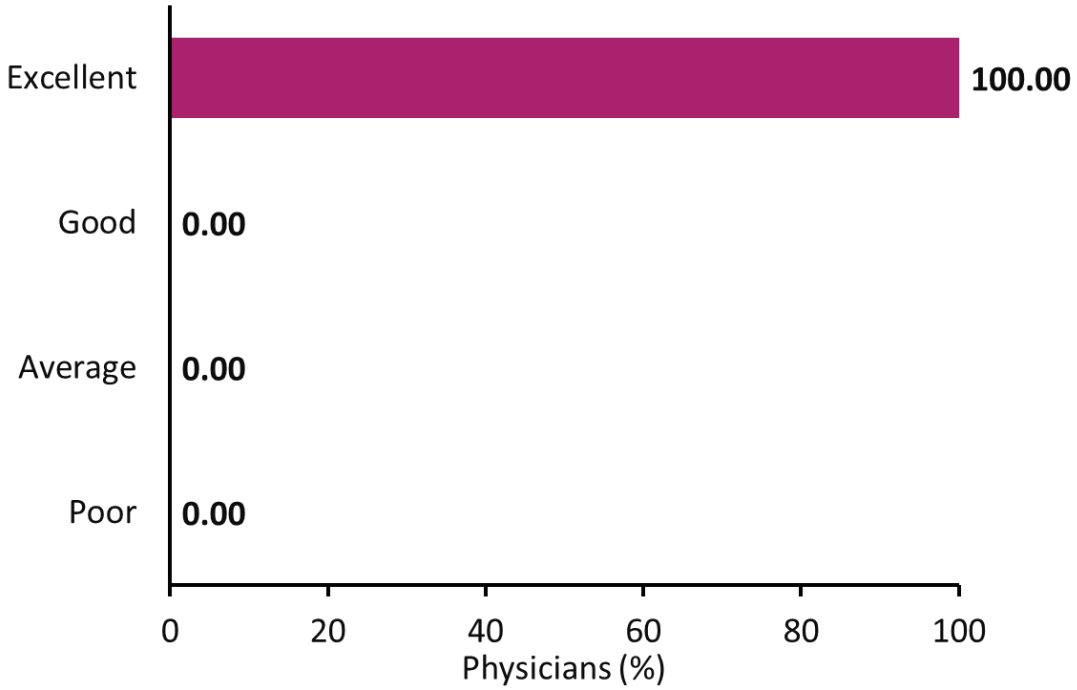
[10] In your opinion, please rate the efficacy of FDC of dolutegravir, tenofovir alafenamide, emtricitabine tablets for the patients with HIV as ART treatment?

a. Excellent

b. Good

c. Average

d. Poor



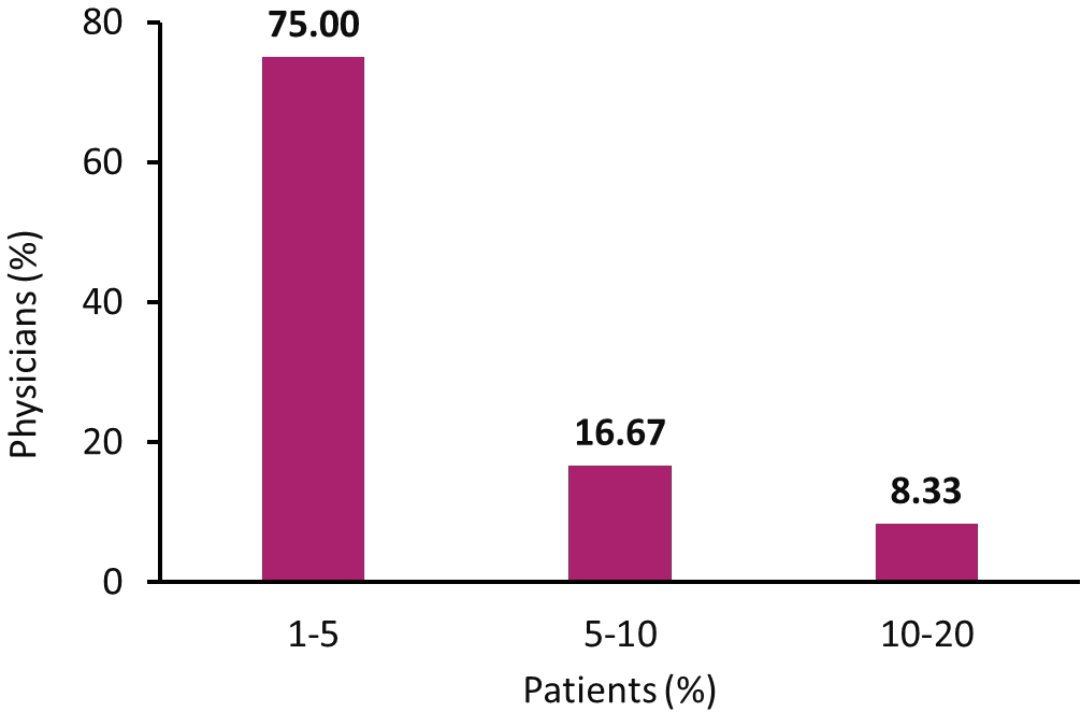
- The majority (100%) of physicians reported the efficacy to the FDC of dolutegravir, tenofovir alafenamide, and emtricitabine as excellent for HIV patients on ART treatment.
- None of the physicians rated efficacy to the FDC as good, average and poor.

[11] In your clinical practice how many percentage of patients are put on fixed dose combination (FDC) of bictegravir (BIC), tenofovir alafenamide (TAF) and emtricitabine (FTC)?

a. 1-5%

b. 5-10%

c. 10-20%



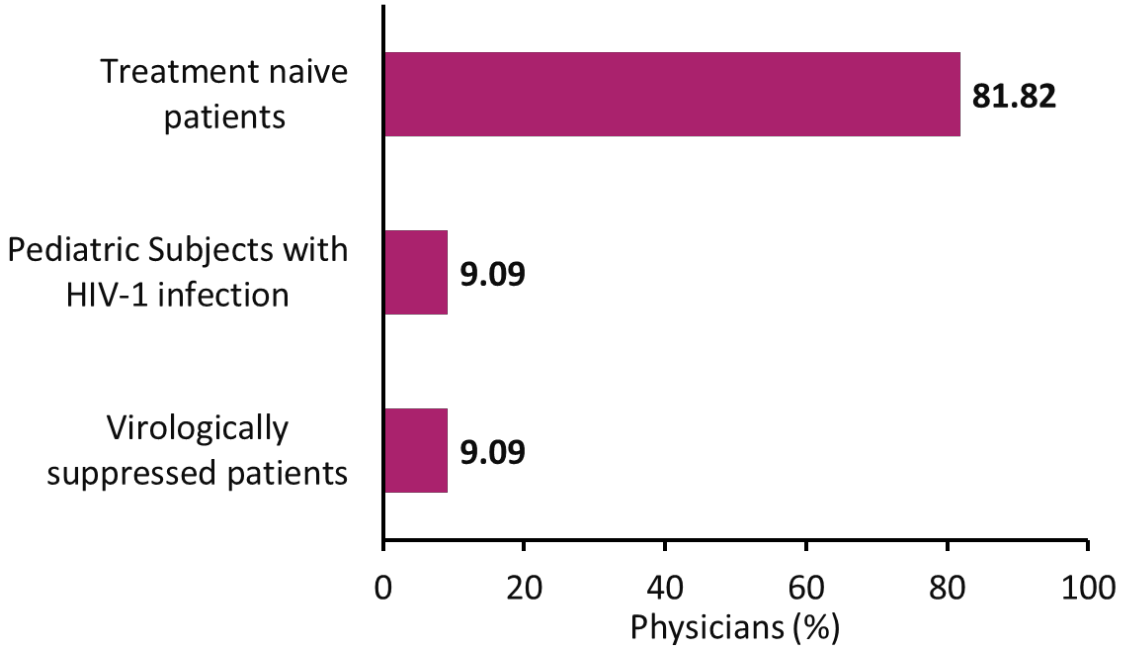
- The majority (75.00%) of physicians reported that 1-5% of their patients are put on the fixed-dose combination (FDC) of bictegravir (BIC), tenofovir alafenamide (TAF), and emtricitabine (FTC).
- Around 16.67% of physicians noted that 5-10% of their patients are on the fixed-dose combination (FDC) of bictegravir (BIC), tenofovir alafenamide (TAF), and emtricitabine (FTC).
- A small portion (8.33%) of physicians reported that 10-20% of their patients are on this combination.

[12] In your clinical practice, in which category of HIV patients would you prefer the ART containing FDC of BIC, TAF and 3TC?

a. Treatment naïve patients

b. Virologically suppressed patients

c. Pediatric Subjects with HIV-1 infection



- The majority (81.82%) of physicians reported that they prefer the ART containing the FDC of bictegravir (BIC), tenofovir alafenamide (TAF), and emtricitabine (3TC) for treatment-naive patients.
- Around 9.09% of physicians preferred this ART combination for virologically suppressed patients.
- A similar portion (9.09%) of physicians indicated that they would prescribe this combination to pediatric subjects with HIV-1 infection.

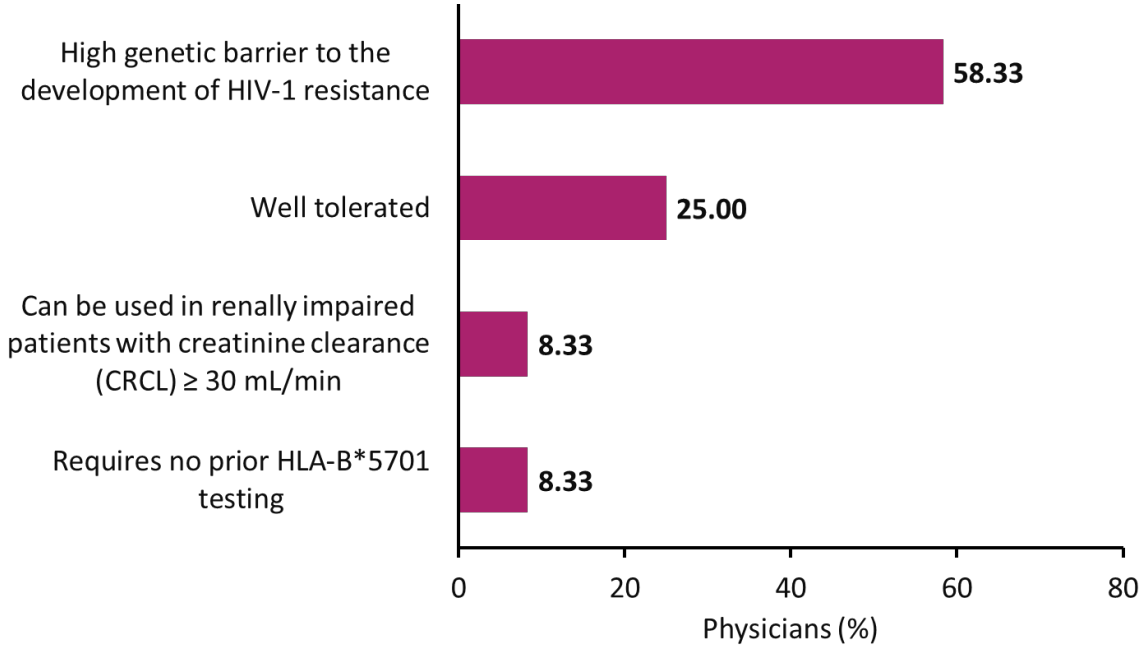
[13] According to your expert opinion, what are the advantages of bictegravir (BIC), tenofovir alafenamide (TAF) and emtricitabine (FTC) fixed dose combination in your clinical practice?

a. High genetic barrier to the development of HIV-1 resistance.

b. Requires no prior HLA-B*5701 testing

c. Can be used in renally impaired patients with creatinine clearance (CRCL) ≥ 30 mL/min

d. Well tolerated



- The majority (58.33%) of physicians reported that the main advantage of the bictegravir (BIC), tenofovir alafenamide (TAF), and emtricitabine (FTC) fixed-dose combination is its high genetic barrier to the development of HIV-1 resistance.
- Approximately 25.00% of physicians cited that this combination is well tolerated as an advantage.
- A small portion (8.33%) of physicians highlighted that it can be used in renally impaired patients with creatinine clearance (CRCL) ≥ 30 mL/min.
- A similar portion (8.33%) of physicians mentioned that no prior HLA-B*5701 testing is required before prescribing this combination.

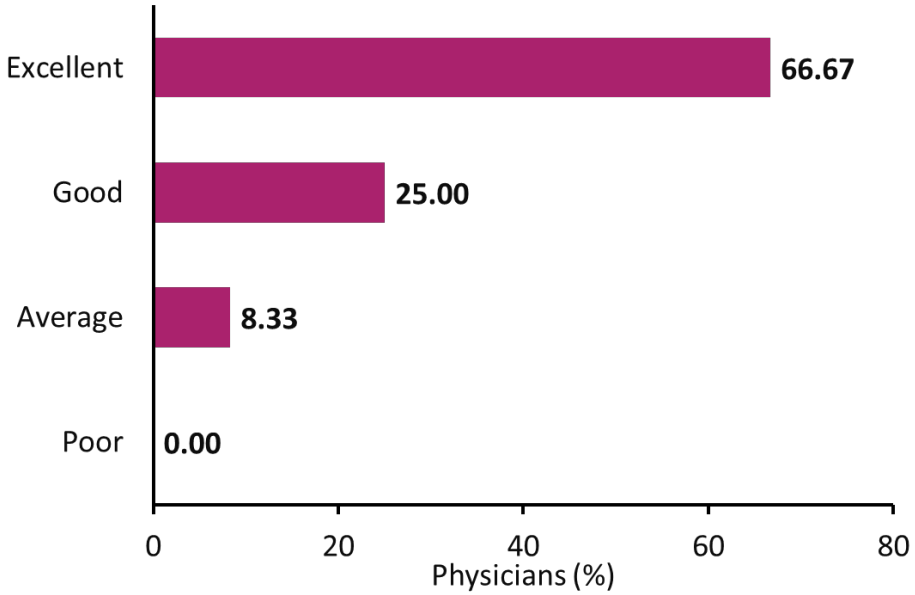
[14] In your opinion, how do you rate the treatment adherence of FDC of bictegravir (BIC), tenofovir alafenamide (TAF) and emtricitabine (FTC) in your clinical practice?

a. Excellent

b. Good

c. Average

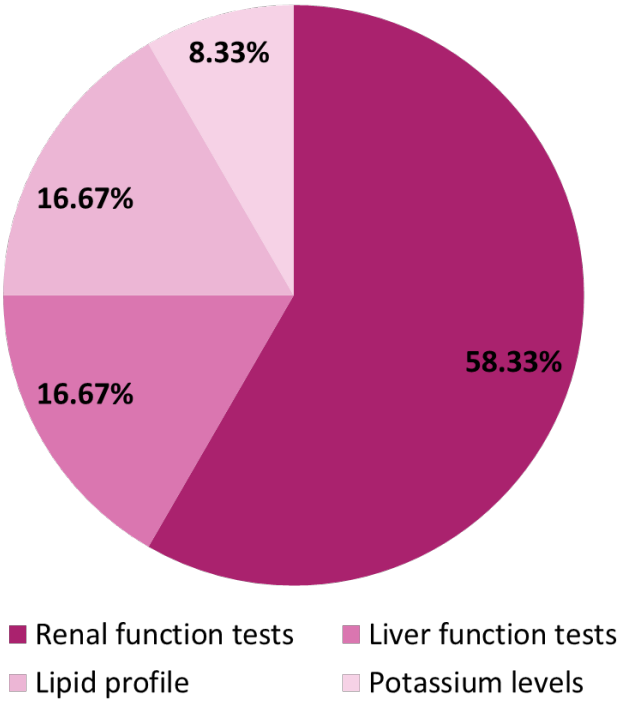
d. Poor



- The majority (66.67%) of physicians reported the treatment adherence to the FDC of bictegravir (BIC), tenofovir alafenamide (TAF), and emtricitabine (FTC) as excellent.
- Around 25.00% of physicians rated the treatment adherence to the FDC of bictegravir (BIC), tenofovir alafenamide (TAF), and emtricitabine (FTC) as good.
- A small portion (8.33%) of physicians rated treatment adherence as average to this combination.
- None of the physicians rated treatment adherence as poor to this combination.

[15] In your clinical practice, which of the following laboratory investigations is essential for monitoring patients on FDC of BIC, TAF and FTC?

a. Liver function tests
b. Renal function tests
c. Potassium levels
d. Lipid profile



- The majority (58.33%) of physicians reported that renal function tests are essential for monitoring patients on the FDC of BIC, TAF, and FTC.
- Around 16.67% of physicians considered liver function tests essential for monitoring patients on this combination of BIC, TAF, and FTC.
- A similar portion (16.67%) of physicians also noted that potassium levels are important to monitor in these patients.
- A small portion (8.33%) of physicians reported that a lipid profile is essential for routine monitoring.

6. SUMMARY

This survey investigated the clinical practices of 91 physicians regarding HIV treatment, focusing on FDC, viral load testing, and monitoring strategies. The majority of physicians (69.23%) recommend viral load testing every six months after initiating ART, while 23.08% prefer yearly testing, and 7.69% suggest quarterly testing. No physicians favored monthly testing.

When it comes to NRTIs used in combination with integrase inhibitors, tenofovir alafenamide (TAF) was the most preferred option (61.54%), followed by tenofovir disoproxil (TDF) and lamivudine (3TC) (15.38% each), and emtricitabine (FTC) (7.69%). This reflects a clear preference for TAF-based regimens.For fixed-dose combinations like dolutegravir (DTG), TAF, and FTC, 69.23% of physicians reported prescribing it to 60-70% of their patients, with nausea being the most common side effect (60%). Drug interactions with itraconazole and calcium/iron supplements were noted by 30.77%, while interactions with metformin (23.08%) and oral contraceptives (15.38%) were also highlighted. Monitoring practices for patients on this regimen emphasize renal function (53.85%), followed by liver function (30.77%) and potassium levels (15.38%).

Regarding bictegravir (BIC), TAF, and FTC, 75.00% of physicians prescribe it to 1-5% of their patients, mainly for treatment-naive individuals (81.82%). The combination is valued for its high genetic barrier to resistance (58.33%) and good tolerability (25.00%). Adherence to this regimen was rated as excellent by 66.67% of physicians.

In conclusion, TAF-based FDCs are preferred for their efficacy, tolerability, and strong genetic barrier to resistance. Physicians also emphasized the importance of regular renal function monitoring, with drug interactions and consistent adherence being key considerations in HIV treatment.

7. DISCUSSION

The results of this survey provide valuable insights into the prescribing practices and perceptions of physicians regarding the use of FDCs for HIV treatment. The findings highlight several key trends that reflect current preferences in ART regimens, patient monitoring, and the management of potential drug interactions. A notable trend from the survey is the strong preference for tenofovir alafenamide (TAF) in combination with integrase inhibitors, with 61.54% of physicians favoring this combination. This aligns with existing clinical guidelines that emphasize the use of TAF for its improved safety profile and reduced renal and bone toxicity compared to tenofovir disoproxil (TDF). The preference for TAF-based regimens underscores the growing confidence in these newer formulations, which are better tolerated by patients, particularly those with pre-existing renal conditions.

The high adoption rate of the dolutegravir (DTG), TAF, and emtricitabine (FTC) FDC regimen among physicians, with 69.23% reporting its use for 60-70% of their patients, reflects its efficacy, simplicity, and ease of adherence. This FDC's excellent tolerance profile, particularly with nausea being the most common side effect, highlights its position as a first-line treatment in many clinical settings. The fact that no physicians reported diarrhea as a common side effect further supports the favorable gastrointestinal tolerability of this combination.

However, the survey also reveals a concern regarding drug interactions, with itraconazole and calcium/iron supplements identified as potential interactions with the DTG/TAF/FTC FDC. This is consistent with known pharmacokinetic considerations in HIV treatment, where co-administration of certain medications can impact drug absorption and efficacy. The presence of such interactions underscores the need for careful monitoring and patient education, particularly for those on polypharmacy regimens.

Regarding monitoring practices, the emphasis on renal function tests by more than half of physicians (53.85%) aligns with the renal concerns associated with TAF-based regimens. Regular monitoring of renal function is crucial, especially in the

long-term management of HIV, to mitigate potential adverse effects. The importance of liver function and potassium levels was also acknowledged by a smaller proportion of physicians, reinforcing the necessity of comprehensive patient monitoring.

The survey also highlights a growing interest in the bictegravir (BIC), TAF, and FTC FDC, with 75.00% of physicians prescribing it to a small proportion (1-5%) of their patients. This regimen's high genetic barrier to resistance (58.33%) and good tolerability (25.00%) make it an attractive option, particularly in treatment-naive patients. The fact that this combination is perceived as suitable for renally impaired patients (8.33%) further broadens its applicability in diverse patient populations.

In conclusion, this survey reflects a positive shift towards the use of TAF-based FDCs, which are favored for their efficacy, safety, and ease of use. However, the findings also emphasize the need for continued vigilance regarding drug interactions and the importance of regular monitoring, particularly of renal function. As these regimens continue to dominate HIV treatment, their role in improving patient outcomes remains promising, while careful management of potential side effects and interactions will be essential for optimizing long-term treatment success.

8. CLINICAL RECOMMENDATIONS

The results of this survey provide valuable insights into the prescribing patterns, preferences, and clinical practices surrounding the use of FDCs in HIV treatment. Based on these findings, several clinical recommendations can be made to optimize the management of HIV patients, particularly in the context of ART regimens, patient monitoring, and management of potential drug interactions.

First, it is clear from the survey that tenofovir alafenamide (TAF)-based FDCs, especially combinations like dolutegravir (DTG), TAF, and emtricitabine (FTC), are highly favored by physicians. Over 60% of surveyed clinicians preferred TAF-based regimens due to their superior safety profile compared to tenofovir disoproxil fumarate (TDF), particularly regarding renal and bone health. TAF is less nephrotoxic than TDF, which makes it a more suitable choice for many HIV patients.

Therefore, clinicians should prioritize TAF-based combinations as a first-line treatment for HIV, particularly for treatment-naive patients. Given the widespread adoption of this regimen, it is essential for physicians to incorporate renal function monitoring as part of the routine care for these patients. Baseline and periodic tests for serum creatinine, creatinine clearance, and glomerular filtration rate (GFR) should be performed to detect any signs of renal impairment early and adjust treatment if necessary.

The survey also underscores the importance of monitoring for potential drug interactions with ART regimens. A significant number of physicians identified itraconazole, calcium/iron supplements, and metformin as drugs that may interact with the DTG/TAF/FTC FDC. This highlights the need for clinicians to conduct thorough medication reviews and educate patients on the timing and possible interactions of their prescribed ART with other medications. For example, physicians should advise patients to take calcium or iron supplements at different times from their ART regimen to avoid reduced drug efficacy. Similarly, alternative therapies or dose adjustments may be needed for patients who require both ART and interacting medications, like metformin.

Another key recommendation is to address side effects proactively, particularly nausea, which was the most commonly reported side effect of the DTG/TAF/FTC FDC (reported by 60% of physicians). Patients should be informed about potential side effects before starting ART, and clinicians should closely monitor them, especially in the early stages of therapy. If side effects such as nausea or dizziness are severe, clinicians may consider adjusting the dose or switching to an alternative ART regimen. The proactive management of side effects will help ensure better adherence and improve the overall quality of life for HIV patients.

The adherence rates for both DTG/TAF/FTC and bictegravir (BIC)/TAF/FTC FDCs were reported to be excellent, suggesting that these regimens are well-tolerated and convenient for patients. Since FDCs reduce pill burden and simplify dosing, they should be considered a first-line option for treatment-naive patients. Encouraging patients to adhere to their prescribed regimen and emphasizing the benefits of fixed-

dose combinations will help improve viral suppression rates and reduce the risk of resistance.

Finally, the survey results suggest that regular monitoring of renal function is critical, particularly for patients on TAF-based ART. Although TAF is less nephrotoxic than TDF, renal function should still be closely monitored, with physicians conducting creatinine clearance and serum creatinine tests periodically. Additionally, clinicians should stay informed about new developments in HIV treatment, including the latest evidence on FDCs and emerging ART options. Continuing education and the integration of updated clinical guidelines into practice will ensure that healthcare providers are equipped to offer the most effective and personalized care for HIV patients.

9. CONSULTING OPINION

The survey findings reveal a strong preference among Indian physicians for TAF-based FDCs like DTG/TAF/FTC and BIC/TAF/FTC, which are increasingly becoming the go-to choices for HIV treatment. With 69.23% of physicians favoring TAF-based FDCs, these regimens are gaining traction due to their efficacy, simplified dosing, and improved safety profile, especially in addressing renal and bone health concerns—a key issue in long-term HIV care.

TAF's unique advantages, such as its better renal and bone safety compared to older tenofovir formulations, position these FDCs as crucial options for patients with comorbidities or those at risk of treatment-related toxicity. The survey also indicates that 75% of physicians prescribe BIC/TAF/FTC for patients with complex needs, such as resistance issues, highlighting its versatility.

Despite these preferences, the survey also shows a moderate uptake of TAF-based FDCs in clinical practice, indicating a gap in broader adoption. To address this, pharmaceutical companies should consider targeted marketing strategies that emphasize the safety, efficacy, and patient convenience of these therapies. Furthermore, educational initiatives for healthcare providers could help increase

awareness of the unique benefits of these FDCs, particularly in managing patients with renal concerns or those seeking a simplified treatment regimen.

Additionally, exploring dosage-specific formulations or combination products tailored to the needs of specific patient populations—such as those with resistance concerns or renal impairments—could further enhance patient outcomes and compliance. Ongoing real-world evidence will also play a crucial role in solidifying TAF-based FDCs as a cornerstone in HIV treatment. In conclusion, the growing physician confidence in TAF-based FDCs presents significant market opportunities. By leveraging educational outreach, targeted marketing, and continued research, stakeholders can expand the adoption of these therapies and improve HIV care outcomes in India.

10. MARKET OPPORTUNITIES

The rising prevalence of HIV, coupled with the limitations of existing treatments, presents significant market opportunities for TAF-based FDCs such as DTG/TAF/FTC and BIC/TAF/FTC in the Indian healthcare landscape. With India being home to one of the largest HIV-positive populations globally, there is an increasing demand for effective, safe, and accessible ART. TAF-based FDCs offer a promising solution due to their efficacy, tolerability, and relatively low incidence of side effects. These combinations, particularly DTG/TAF/FTC, are positioned as first-line treatments, making them an attractive option for both treatment-naive and virologically suppressed patients.

Survey results indicate a strong preference among Indian physicians for DTG/TAF/FTC as the regimen of choice, with 69.23% of physicians prescribing this FDC to 60-70% of their patients. The combination’s high efficacy and excellent adherence rates make it particularly appealing, suggesting significant potential for expanding its market share. Moreover, physicians favor these combinations for their

ease of use and safety profile, which includes lower risks of renal and liver toxicity compared to older treatments.

The BIC/TAF/FTC combination, although prescribed to a smaller proportion of patients (75% of physicians reporting 1-5%), also shows promise due to its high genetic barrier to resistance and suitability for patients with renal impairments. These features align with the growing demand for personalized HIV treatment options. As healthcare providers increasingly prioritize tailored therapies for individual patients, BIC/TAF/FTC could carve out a strong niche within specific patient groups, particularly those at risk for resistance or renal complications.

Furthermore, TAF-based FDCs have a clear competitive advantage in terms of tolerability. The low incidence of side effects reported by physicians, particularly nausea as the most common adverse event, reinforces their attractiveness to patients who may otherwise face challenges with older regimens. This safety profile could be a key selling point in marketing campaigns targeting physicians and patients, emphasizing the importance of long-term adherence without significant discomfort.

The current healthcare landscape in India, which is increasingly shifting toward patient-centered care and non-invasive treatment options, provides an ideal environment for TAF-based FDCs. The growing focus on HIV care and the expansion of access to healthcare services across urban and rural areas create significant market potential. Strategic educational initiatives aimed at healthcare professionals and patients can further enhance the adoption of these FDCs, particularly by emphasizing their ease of use, minimal side effects, and proven efficacy.

11. MARKET POSITIONING

TAF-based fixed-dose combinations (FDCs), such as DTG/TAF/FTC and BIC/TAF/FTC, have become key players in the HIV treatment landscape, addressing the growing demand for efficacy, safety, and patient adherence. These regimens leverage the advantages of tenofovir alafenamide (TAF), which offers improved renal and bone safety compared to older tenofovir formulations, positioning them as a preferred option in clinical practice. This is particularly important in India, where comorbidities and concerns over long-term toxicity are common in HIV care.

Survey results reveal that 69.23% of Indian physicians prefer TAF-based FDCs, with DTG/TAF/FTC being the most favored regimen for both treatment-naive and virologically suppressed patients. The high efficacy in viral suppression and the simplified one-pill-per-day dosing make this regimen highly appealing. The favorable safety profile, characterized by low rates of side effects like nausea and dizziness, further strengthens its positioning as a first-line treatment, especially for patients at risk of renal complications or other comorbidities.

TAF-based FDCs are also well-suited for the growing trend toward personalized medicine in HIV treatment. These regimens offer flexibility for managing patients with different clinical profiles, such as those with renal impairments or those at risk of resistance. Survey findings indicate that 75% of physicians prescribe BIC/TAF/FTC for 1-5% of their patients, reflecting its role in managing complex patient profiles, including those with resistance concerns.

The rapid onset of action, excellent adherence rates, and lower pill burden of TAF-based FDCs are critical factors that contribute to their market appeal, especially in India, where treatment adherence is a significant challenge. These features make them an attractive option for patients who prioritize simplicity and convenience in managing their condition. Moreover, the low incidence of side effects strengthens the overall market positioning of both DTG/TAF/FTC and BIC/TAF/FTC.

The strong preference among Indian physicians for TAF-based regimens underscores their growing recognition as a new standard of care in HIV treatment.

Continued education and awareness efforts targeting both healthcare providers and patients will be essential to maximize the adoption of these FDCs and ensure that their benefits are fully realized. The integration of TAF-based FDCs into clinical practice is expected to expand, with real-world evidence further solidifying their role in HIV management.

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