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Switching to Dolutegravir + Lamivudine in a Highly Treatment-Experienced Patient Living with Human Immunodeficiency Virus Infection

İnsan İmmün Yetmezlik Virüsü ile Yaşayan ve Yoğun Tedavi Deneyimi Olan Bir Kişide Dolutegravir + Lamivudin İkili Tedavi Rejimine Geçiş

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Abstract

Dolutegravir (DTG) + lamivudine (3TC) dual therapy regimen has entered the guidelines as a preferred first-line treatment regimen in antiretroviral treatment naïve individuals and as a switch regimen in cases with virologic suppression. Although clinical studies and real-life data suggest that virologic suppression could be achieved or maintained in patients with baseline or acquired M184V/I mutation, doubts exists about its use. This report presents a patient living with human immunodeficiency virus infection who had no resistance test results available, had heavy treatment experience, and maintained viral suppression following switching to DTG + 3TC dual therapy.
Keywords: Dolutegravir, lamivudine, dual antiretroviral treatment

Öz

Dolutegravir (DTG) + lamivudin (3TC) ikili tedavi rejimi, daha önce antiretroviral tedavi almamış bireylerde birinci basamak tedavi rejimi ve virolojik baskılanma elde edilmiş olgularda geçiş rejimi olarak kılavuzlarda yer almıştır. Klinik çalışmalar ve gerçek yaşam verileri, başlangıçta veya edinilmiş M184V/I mutasyonu olan hastalarda virolojik baskılanmanın sağlanabileceğini veya sürdürülebileceğini öne sürse de, ikili rejimin bu tür olgularda kullanımı hakkında hala şüpheler vardır. Bu olgu sunumunda, direnç testi sonuçları bulunmayan, yoğun tedavi deneyimi olan ve DTG + 3TC ikili tedavisine geçtikten sonra viral baskılanması devam eden insan immün yetmezlik virüsü ile yaşayan bir birey ele alınmıştır.
Anahtar Kelimeler: Dolutegravir, lamivudin, ikili antiretroviral tedavi

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Introduction

Antiretroviral treatment (ART) has multiple benefits for people living with human immunodeficiency virus (HIV) such as improving life expectancy and quality of life and public health benefits such as reducing onward transmission by viral suppression[1]. However, adherence to the regimen is the key in achieving viral suppression, and suboptimal adherence may result in resistance mutations to one or multiple drugs or drug classes, which critically limits future treatment options. Compared with earlier molecules, novel antiretroviral drugs with better tolerability, milder side effects, and fewer doses allow much better adherence to the regimen. In addition, especially potent integrase strand transfer inhibitors (INSTIs) with a high genetic barrier such as dolutegravir (DTG) and bictegravir (BIC) are highly forgiving in cases with suboptimal adherence[2,3].

Combination ART, including three or more drugs from different classes, has been the mainstay of treatment since 1996. However, compared with three-drug regimens, two-drug regimens recently proved to be non-inferior in terms of virologic suppression and allowed patients to take all the advantages of ART with a much-reduced lifelong pill burden[4,5]. Dolutegravir combined with lamivudine (3TC) has proved to be one of the most promising two-drug combinations in two large-scale randomized controlled studies, i.e., Gemini-1 and Gemini-2, which analyzed the efficacy and tolerability of the combination in treatment-naïve individuals[6]. Subsequent studies by Tango and Salsa reported that it could be safely used as a switch regimen for the simplification of ART in treatment-experienced patients with virologic suppression, no baseline resistance mutations, and no history of virologic failure[7,8]. However, the exclusion of individuals with baseline resistance from clinical studies created doubts about the potency and efficacy of DTG + 3TC in patients with baseline M184V/I mutation, which confers full resistance to 3TC, who had achieved virologic suppression with a three-drug regimen. Current guidelines do not recommend DTG + 3TC in patients with no baseline resistance test results and those with M184V/I mutation[9,10]. This paper presents a patient who was diagnosed in the early years, had a heavy treatment experience, had a history of using multiple drugs from many different classes in various combinations, had no drug resistance result, and switched to DTG + 3TC maintaining virologic suppression.

Case Report

A 65-year-old man was diagnosed with HIV infection in Belgium in 1986. He had no complaints for the following 10 years and did not use ART. He reported a history of recurring herpes and zoster attacks and several lower respiratory tract infections. Antiretroviral treatment was initiated in 1996. He reported using various combinations of zidovudine, stavudine, didanosine, indinavir, and atazanavir since then up to 2008 when he individually decided to stop ART. He was restarted with tenofovir disoproksil fumarate (TDF)/3TC + lopinavir/ritonavir (LPV/r) in 2009. His previous laboratory monitoring results for HIV RNA, CD4+ T cell count, and resistance tests were not available. In 2012, he returned to Turkey, and his treatment was switched to TDF/emtricitabine (FTC) + LPV/r. He reported being adherent to his visits between 2012 and 2015 and having negative viral load measurements. In 2015, he was diagnosed with renal artery stenosis and underwent surgery for stent placement. He was also diagnosed with femoral artery stenosis in another healthcare center at the same period, reported placement of a stent to the femoral artery, and initiated clopidogrel.

Six months later, he presented to our clinic with diarrhea, abdominal pain, bloody stools, frequent urination, and forgetfulness. Physical examination revealed muscle weakness. He reported very infrequent smoking and alcohol consumption, and he has been using marijuana for the last 30 years regularly. He had a family history of cardiovascular disease and diabetes mellitus. His body mass index was low (21.6), and he reported living a healthy lifestyle. He was diagnosed with anxiety and has been using escitalopram for the last 15 years. Urinalysis and prostate-specific antigen levels were normal. He was referred to the urology department for a prostate examination. Gastroscopy revealed pangastritis, and colonoscopy revealed no active pathology. Symptomatic treatment was given, and gastrointestinal symptoms subsided. He was also referred to the psychiatry department to be assessed for anxiety and forgetfulness. His blood tests revealed that HIV RNA levels were negative, CD4+ T lymphocyte count was 770 cells/mm3, serum creatinine 1.47 mg/dl, estimated glomerular filtration rate (eGFR) 51.48 ml/min, serum total cholesterol 258 mg/dl, triglyceride 246 mg/dl, high-density lipoprotein cholesterol 44 mg/dl and low-density lipoprotein cholesterol 165 mg/dl. The results of the remaining biochemistry tests were within the normal range. He has been using atorvastatin for the last 10 years. He was immune to hepatitis A and B. Anti-HCV, Venereal Disease Research Laboratory (VDRL), Rapid Plasma Reagin (RPR), and *Treponema pallidum* IgM + IgG tests were negative. His 10-year Framingham score was 20%. His dual X-ray absorptiometry scan values for bone mineral density were within the normal range.

Three months later, the patient was switched to DTG + darunavir/ritonavir and rosuvastatin 20 mg because of the increasing creatinine levels and high cardiac risk score. Lipid levels were steadily high despite lipid-lowering agents. He also developed hypertension and proteinuria in 2018. His antiretroviral regimen was switched to DTG + 3TC because of high lipid levels, high cardiovascular risk, and renal impairment. The dose of

rosuvastatin was escalated to 40 mg, and amlodipine 5 mg/day was initiated. He was also referred to the nephrology department for renal monitoring. There has been no viral rebound or blips since his presentation to the clinic, CD4+ T lymphocyte counts remained stable at high levels (>900 cells/mm^3), creatinine and lipid levels returned to normal, hypertension was controlled, and the Framingham risk score was reduced to 10% in 2019. Rosuvastatin therapy was re-initiated in March 2019 because of increasing and fluctuating lipid levels (Table 1).

Discussion

This is a complex case that requires a multidimensional approach given the long duration (>30 years) of HIV infection, history of ART interruption, advanced age, heavy ART experience, and several comorbidities (renal artery stenosis, progressively decreasing eGFR, hyperlipidemia, hypertension, and high cardiovascular disease risk). The ART regimen that the patient has been using was switched upon initial presentation for several reasons. First was the potential renal toxicity of TDF and LPV/r in this patient with a history of renal artery stenosis and increasing creatinine levels[11,12]. The second reason was the potential negative effects of protease inhibitors and specifically LPV/r on lipid levels in this patient with an already high cardiovascular risk and severe dyslipidemia[13]. The ART options for this case were very limited at the time of presentation. Besides, the heavy treatment history and the lack of an antiretroviral resistance assay result made it even more challenging to find the optimal treatment option. Having no history of non-nucleoside reverse-transcriptase inhibitor (NNRTI) use suggested a very low likelihood of having resistance to this class. One option would be to use nevirapine or efavirenz from the NNRTI group in combination with a TDF/FTC or ABC/3TC backbone. However, using an NNRTI drug with a low genetic barrier without any resistance result would be too risky for a patient with heavy treatment experience[14]. In addition, the renal toxicity risk of TDF and the increased cardiovascular risk with ABC made it difficult to use these options in a patient with an already high cardiovascular and renal risk[9,10]. Combinations including raltegravir (RAL), an INSTI that was available at that date, held a similar drawback in terms of the backbones[15]. Another issue to consider was the likelihood of suboptimal adherence to twice-a-day dosing of RAL in this patient already using multiple drugs for chronic conditions. The best option appeared to be the DTG + DRV/r regimen accommodating two drugs with high genetic barrier despite several disadvantages such as high tablet number and the likelihood of DRV/r-induced dyslipidemia. Although being a member of the protease inhibitor class, the negative effect of DRV/r on lipid levels is much lower than that of LPV/r[16,17].

Following the regimen switch, creatinine levels returned to normal; however, as expected, the lipid levels and the Framingham score continued to increase. Clearly, the patient would not benefit from any lifestyle changes as he is a non-smoker, exercises regularly, eats a healthy diet, and has a low body mass index. In this case, the only option left was to switch to a dual regimen with DTG + 3TC. This was a very difficult decision owing to the lack of any information on resistance and the scarcity of data on the efficacy of this regimen in those with M184V/I mutations or any other mutations at that date. The reasons for and the pros and cons of switching to DTG + 3TC were discussed with the patient, and the high risk of a cardiovascular event was specifically emphasized if he opted for staying on the same regimen; upon receiving consent, the patient was switched to DTG + 3TC dual regimen. Lipid levels dropped significantly after the switch and the Framingham risk score was reduced without compromise from viral suppression.

If newer INSTI drugs such as TDF/FTC/elvitegravir (EVG)/cobicistat (c) or tenofovir alafenamide (TAF)/FTC/EVG/c had been available at that date, similar drawbacks such as lack of resistance assay results for TDF and FTC, low genetic barrier of EVG, and the likelihood of drug-drug interactions with cobicistat would

Table 1. Antiretroviral treatment regimens used, serum creatinine and lipid levels, CD4+ T lymphocyte count, and HIV RNA levels

	At presentation (TDF/FTC + LPV/r)	One month after switching to DTG + DRV/r	One month after switching to DTG + 3TC	Last visit on DTG + 3TC
Creatinine	1.47 mg/dl	1.18 mg/dl	1.09 mg/dl	1.01 mg/dl
eGFR	51.48 ml/min/1.73 m^2	>60 ml/min/1.73 m^2	>60 ml/min/1.73 m^2	>60 ml/min/1.73 m^2
CD4+ T lymphocyte count	770 (37%) cells/mm^3	585 (34%) cells/mm^3	NA	1134 (29%) cells/mm^3
HIV RNA level	Negative	Negative	Negative	Negative
Total cholesterol	285 mg/dl	313 mg/dl	162 mg/dl	176 mg/dl
Triglyceride	246 mg/dl	392 mg/dl	137 mg/dl	126 mg/dl
HDL	44 mg/dl	35 mg/dl	47 mg/dl	49 mg/dl
LDL	165 mg/dl	200 mg/dl	88 mg/dl	105 mg/dl

3TC: Lamivudine, DTG: Dolutegravir, eGFR: Estimated glomerular filtration rate, FTC: Emtricitabine, LPV/r: Lopinavir/ritonavir, NA: Not available, TDF: Tenofovir disoproxil fumarate, HIV: Human immunodeficiency virus, HDL: High-density lipoprotein, LDL: Low-density lipoprotein

be also valid for these combinations[18,19]. On the contrary, a more recent INSTI-based regimen TAF/FTC/BIC may be a good alternative for similar cases, considering the high genetic barrier of BIC and the milder effect of TAF on the kidneys[20,21].

Randomized clinical trials have suggested that patients switching from three- or four-drug regimens to DTG + 3TC usually maintain virologic suppression and tolerate the regimen well and that blips and virologic failure rates are similar to those with three-drug regimens. This was also confirmed in real-life settings where the most common reason for switching to DTG + 3TC was toxicity caused by the previous regimen and patient-initiated simplification of the ART regimen[22-24], with >90% maintaining virologic suppression[23,25-28] and very low rates of discontinuation[23-29]. The dual regimen was well-tolerated by the majority of the patient populations[23,27-29]. The most commonly questioned issue and the major concern for this dual regimen was its efficacy in patients with heavy treatment experience and those with a history of virologic failure. However, real-life data revealed similar efficacy to that with three- or four-drug regimens[24,29].

Another major concern about the DTG + 3TC regimen was whether it could maintain virologic suppression in cases with previous M184V/I mutations, and real-life data suggested that virologic suppression rates in those with M184V/I mutation were similar to those without it[24,27,29]. This was attributed to the specific effect of M184V/I mutation on reducing the replicative capacity of the virus enabling 3TC to maintain its antiviral effect, resulting in effective virologic suppression when coupled with the potent antiviral effect of DTG[30]. In addition, M184V/I mutation was suggested to prevent the development of mutations against DTG[31]. The lack of resistance mutations in cases with no virologic suppression is another major advantage of this regimen[23,24].

Conclusion

In conclusion, DTG + 3TC dual regimen may be a potent ART option as a switch regimen in cases with virologic suppression that have limited options because of heavy treatment history and lack of resistance test results. Dolutegravir + 3TC has recently become a preferred antiretroviral regimen with high clinical efficacy, no renal and bone toxicities, and a high genetic barrier, and is an inexpensive alternative to three- or four-drug regimens[26]. Close monitoring is critical for patients with a heavy treatment history or those with baseline or acquired mutations.

Ethics

Informed Consent: Consent form was filled out by all participants.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: D.G., Concept: D.G., Design: D.G., Data Collection or Processing: D.G., O.A., Analysis or Interpretation: D.G., O.A., Literature Search: D.G., O.A., Writing: D.G., O.A.

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