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Impact of Antiretroviral Therapy (ART) Regimen Initiation or Switch in Virologically Suppressed People With Human Immunodeficiency Virus-1 (HIV-1) on Lipid Profile at 48 weeks: A Systematic Literature Review

J. Olalla[1], I. Ollà[2], A. Calvache[2] and P. González-Rodríguez[3]
1 Hospital Costa del Sol, Marbella, Spain; 2 Gilead Sciences, Madrid, Spain; 3 Outcomes'10, S. L., Castellón de la Plana, Spain

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PURPOSE

Antiretroviral treatment (ART) has transformed human immunodeficiency virus 1 (HIV) into a manageable chronic condition[1,2]. While data suggest that certain ART initiation or switching may impact lipid profiles, evidence is limited, and clinical significance remains uncertain[3,4].

This study evaluates the impact of initiating or switching ART with second-generation integrase inhibitor-based regimen on lipid profiles in people with HIV (PWH).

METHODS

A **systematic literature review** was conducted across PubMed, ClinicalTrials.gov, EU Clinical Trials Register, Cochrane and Embase (April 2015-April 2025), and major HIV conferences (April 2023-April 2025). Eligible studies included **Phase III/IV trials and real-world data with 48 weeks of follow-up in PWH initiating treatment or virologically suppressed (vsPWH) switching regimens** recommended by the 2023 GESIDA guidelines[5].

CONCLUSIONS

- **In treatment-naïve patients at 48 weeks, the impact of different ARTs on lipid profile is similar, which may be an indication of a 'return to health' effect**
- **In the switching population, this ratio generally remained stable across switch strategies, indicating a limited impact on lipid profile.**

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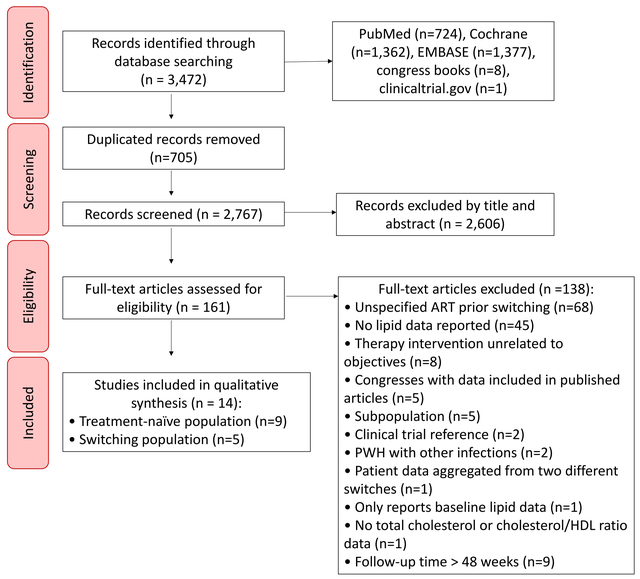
RESULTS

- 14 articles met the inclusion criteria (**Figure 1**).
- 8 were clinical trials, and 6 were observational studies.
- 9 involved naïve PWH; 5 referred to vsPWH after switching.
- The study population sizes ranged from 44 to 483 patients.
- All the publications had the same follow-up time of 48 weeks (DOLAVI[1], BIC-NOW[6], GS-US-380-1489[7,8], GS-US-380-1490[9,10], BICTARG[11], BICSTaR[12], BICSTaR 2[13,14], Study 15[15], Study 16[16], GS-US-380-1489/1490 (OLE)[17,18], GS-US-380-1844[16], Study 18[20], DYAD[21], SOLAR[22]).
- Randomized trials presented a low risk of bias, while non-randomized studies presented a moderate-to-serious risk of bias.

Figure 1. PRISMA flow diagram



Changes from baseline in lipid parameters on PWH at 48 weeks

In the naïve population, B/F/TAF and DTG/ABC/3TC initiation were associated with reductions in the total cholesterol/HDL ratio (up to -0.5 and -0.3 mg/dl, respectively), suggesting a potentially favorable impact on lipid metabolism. In contrast, DTG/3TC and DTG+F/TAF showed a minimal change (0.1 and -0.1 mg/dl, respectively), indicating a limited benefit (**Table 1**).

Table 1. Median Change from baseline in lipid profile in ART-naïve PWH

Regimen	Study	n	Total cholesterol mg/dl (median)	HDL mg/dl (median)	LDL mg/dl (median)	Tryglicerides mg/dl (median)	Total cholesterol/HDL ratio (median)
B/F/TAF	BIC-NOW[5]	208	15.2 (mean)*	6.3 (mean)*	3.9 (mean)*	15.6 (mean)*	-0.5 (mean)*
	GS-US-380-1489[6,7]	314	13	5	7	9	-0.1
	GS-US-380-1490[8,9]	320	12	5	9	3	-0.1
	BICTARG[10]	87	11.5*	3*	10*	14*	-
	BICSTaR 1[11]	179	13.9#	3.9#	8.1#	7.1#	-0.1#
	BICSTaR 2[12,13]	180	9.3#	3.5#	5.8#	7.1#	-0.1#
	Study 15[14]	408	10	3	5	9	-
DTG/ABC/3TC	Study 16[15]	44	7*	8*	4*	2.5*	-0.3*
	GS-US-380-1489[6,7]	315	11	5	4	3	-0.2
DTG + F/TAF	GS-US-380-1490[8,9]	325	15	5	12	7	-0.1
DTG/3TC	DOLAVI[1]	88	18.4 (mean)*	-2 (mean)*	9.4 (mean)*	10.6 (mean)*	0.1 (mean)*

*Change from baseline was calculated (value at week 48 - value at BL), as the original publication only reported basal and final levels. #Values originally reported in mmol/L were converted to mg/dL for consistency using the corresponding conversion (cholesterol molecular weight: 386.65 g/mol; HDL: 1 mmol/l = 38.61 mg/dl; LDL: 1 mmol/L = 38.61 mg/dL; and tryglicerides: 1 mmol/L = 88.57 mg/dL). B/F/TAF: Bictegravir, Emtricitabine, Tenofovir Alafenamide; BL: Baseline; DTG + F/TAF: Dolutegravir, Emtricitabine, Tenofovir Alafenamide; DTG/ABC/3TC: Dolutegravir, Abacavir, Lamivudine; HDL: high-density lipoprotein; LDL: low-density lipoprotein; NS: Not specified.

Changes from baseline in lipid parameters on vsPWH switching to preferred ART regimens at 48 weeks

In the switching populations, ART regimens showed minimal impact on the total cholesterol/HDL ratio, since only slight variations were observed. Most of vsPWH continuing B/F/TAF showed improvement (-0.1 mg/dl) or no change (0 mg/dl) in the ratio, as well as those vsPWH switching from B/F/TAF to DTG/3TC (-0.2 mg/dl). No changes in this ratio were observed in those switching from DTG/ABC/3TC to B/F/TAF or from B/F/TAF to CAB/RPV, indicating a neutral effect (**Table2**).

Table 2. Change from baseline in lipid profile in virologically suppressed people with HIV-1 switching to preferred ART regimens

Regimen	Total cholesterol mg/dl (median)	HDL mg/dl (median)	LDL mg/dl (median)	Tryglicerides mg/dl (median)	Total cholesterol/HDL ratio (median)
Continued DTG/ABC/3TC	2	0	2	3	0
Switch from DTG/ABC/3TC to B/F/TAF	0	-1	1	-5	0
Continued B/F/TAF	20	7	22	10	-0.1
Switch from DTG/ABC/3TC to B/F/TAF	9.7	-1.9	-16.2	5.3	0.3
Continued B/F/TAF	17	5	21	2	0
Switch from DTG+F/TAF to B/F/TAF	10.1	0.8	-1.9	1.8	0.1
Continued B/F/TAF	3.3	0.6	1.4	9.3	-0.1
Switch from B/F/TAF to DTG/3TC	-2.3	0	-0.3	3.8	-0.2
*Continued B/F/TAF**	*4.8*	*-1*	*1.9*	*3.4*	*2.2*
*Switch from B/F/TAF to CAB/RPV**	*4.6*	*0.4*	*4.3*	*0.4*	*0*

* Median % change from baseline. B/F/TAF: Bictegravir/ Emtricitabine /Tenofovir Alafenamide; CAB/RPV: Cabotegravir/Rilpivirine; DTG/ABC/3TC: Dolutegravir/Abacavir/Lamivudine; DTG + F/TAF: Dolutegravir + Emtricitabine/Tenofovir Alafenamide; HDL: High-Density Lipoprotein; LDL: Low-Density Lipoprotein.

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CONTACT INFORMATION

Julián Olalla Sierra , Department of Internal Medicine, Hospital Universitario Costa del Sol, Marbella, Málaga, Spain.

E-mail: julio.olalla@gmail.com