HIV Drug Therapy GLASGOW 2022 HYBRID | 30 YEARS

P091

RIS Red Española de Investigación en Sida | CoRIS Cohort of the Spanish HIV Research Network

Real-world Effectiveness And Tolerability Of Dolutegravir- Based Two-drug Regimens

Belen Alejos, Inés Suárez-García, Luz Martín-Carbonero, Ana María Moreno-Zamora, Rebeca Font, Joaquín Portilla, Onofre Juan Martínez, Mohamed Omar, David Vinuesa, Santiago Moreno, Inma Jarrín, for CoRIS cohort

Introduction

The evidence from clinical trials provides strong support for the efficacy and safety of both RPV/DTG and 3TC/DTG. However, the evidence from cohort studies is still limited, particularly in treatment-naïve subjects.

Objective

We assessed the use, effectiveness and tolerability of dolutegravir-based two-drug regimens in both antiretroviral (ART)-naïve and virologically suppressed treatment-experienced individuals.

Methods

CoRIS

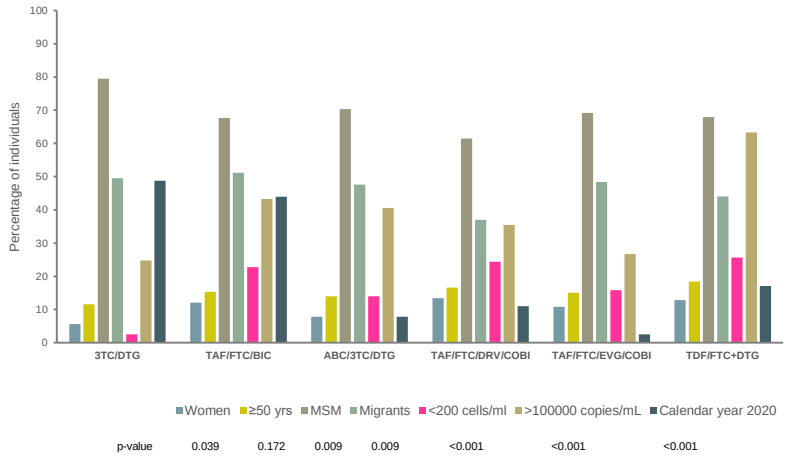
- CoRIS is an open, prospective, multicentric cohort of treatment-naïve HIV+ adults. Enrolment started in 2004 and is still ongoing.
- For analyses in treatment-naïve individuals, we included antiretroviral-naïve individuals who started ART between Aug-18 and Nov-20. Only regimens accounting for >5% of individuals were considered.
- For analyses in treatment-experienced individuals, we included virologically suppressed individuals (defined as viral load (VL) ≤50 copies/ml) switching to RPV/DTG or 3TC/DTG between Jan-18 and Nov-20.

Statistical Analyses

- We calculated odds ratios (OR) for viral suppression (VS) (HIV-RNA<50 copies/mL) and mean differences in CD4 count increases at 24 and 48 weeks from ART initiation comparing initial ART regimens.
- We also calculated the proportion of virologically suppressed individuals who maintained VS at 24 and 48 weeks after switching to RPV/DTG and 3TC/DTG.

Results

Figure 1: Sociodemographic and clinical characteristics at ART initiation according to first-line antiretroviral regimens



During the study period 2,056 individuals older than 18 years initiated treatment; among these, 108 (5.3%) with no follow-up after ART initiation, 220 (10.7%) who initiated ART in a clinical trial and 220 (10.7%) who initiated a treatment prescribed in <5% of patients were excluded. Finally, 1,524 individuals were included **(Figure 1)**.

The most frequent first-line regimens among the 1,524 ART-naïve individuals analyzed are shown in **Table 1**. The preferred starting regimen changed over time: while ABC/3TC/DTG (34.8%), TDF/FTC+DTG (27.2%) and TAF/FTC/EVG/COBI (24.5%) were the preferred options in 2018, TAF/FTC/BIC (57.4%) and 3TC/DTG (25.7%) were the most frequent in 2020.

At 24 and 48 weeks from treatment initiation, 82.4% and 88.8% of individuals achieved VS, and mean (95% CI) CD4 count increase was 192 (181; 204) and 253 (239; 267) cells/microL, respectively. No significant differences by first-line regimen were found except for a lower chance of VS with TAF/FTC/DRV/COBI compared to 3TC/DTG at 24 weeks (Table 1). During the first 48 weeks after initiation of ART the proportion of discontinuations due to AE was higher with TDF/FTC+DTG (8.1%) and TAF/FTC/EVG/COBI (5.8%).

Table 1: Effectiveness of initial antiretroviral therapy and treatment discontinuations due to AEs in the first 48 weeks among treatment naïve individuals from the CoRIS cohort

	Treatment discontinuations due to AEs	Viral Suppression		CD4 count increase from ART initiation	
		Adjusted OR (95% CI)*		Adjusted mean difference (95% CI)*	
		24 weeks (n = 1040)	48 weeks (n = 715)	24 weeks (n = 1288)	48 weeks (n = 951)
3TC/DTG (n=234, 15.3%)	1 (0.4%)	1.0	1.0	Ref.	Ref.
TAF/FTC/BIC (n=580, 38.1%)	9 (1.5%)	1.23 (0.80; 1.88)	0.73 (0.23; 2.30)	30 (-4; 64)	21 (-18; 61)
ABC/3TC/DTG (n=229, 15.0%)	7 (3.1%)	1.08 (0.56; 2.11)	0.78 (0.26; 2.37)	27 (-10; 63)	26 (-23; 74)
TAF/FTC /DRV/COBI (n=127, 8.3%)	3 (2.4%)	0.55 (0.34; 0.89)	0.63 (0.17; 2.25)	4 (-43; 51)	3 (-59; 66)
TAF/FTC/EVG/COBI (n=120, 7.9%)	7 (5.8%)	1.11 (0.53; 2.34)	1.97 (0.48; 8.04)	15 (-29; 58)	41 (-5; 88)
TDF/FTC+DTG (n=234, 15.4%)	19 (8.1%)	1.27 (0.61; 2.63)	0.95 (0.26; 3.50)	43 (-10; 96)	35 (-29; 99)
Overall p-value	<0.001	0.006	0.424	0.381	0.213

* Adjusted by sex, age at ART initiation, transmission category, educational level, country of origin, CD4 T-cell count and viral load within 6 months prior to ART initiation, presence of hepatitis C virus antibodies, presence of hepatitis B virus surface antigen and AIDS diagnosis at start of ART

Among **virologically suppressed individuals**, the proportion of switches to RPV/DTG and 3TC/DTG increased from 1% and 7.3% in 2018, to 3.8% and 41.9% in 2020. At 24 and 48 weeks, 96.1% (74/77) and 90% (45/50) of individuals who switched to RPV/DTG and 97.0% (487/502) and 93.5% (300/321) of those who switched to 3TC/DTG maintained VS.

Conclusions

- In treatment-naïve individuals, the effectiveness and tolerability of 3TC/DTG was similar to other first-line ART regimens.
- Switching to RPV/DTG or 3TC/DTG in virologically suppressed individuals did not seem to impair treatment effectiveness.

Executive committee: Santiago Moreno, Julia del Amo, David Dalmau, María Luisa Navarro, María Isabel González, José Luis Blanco, Federico García, Rafael Rubio, Jose Antonio Iribarren, Félix Gutiérrez, Francesc Vidal, Juan Berenguer, Juan González. Fieldwork, data management and analysis: Paz Sobrino, Victoria Hernando, Belén Alejos, Débora Álvarez, Inma Jarrín, Nieves Sanz, Cristina Moreno. Participating centres: Hospital General Universitario de Alicante (Alicante): Joaquín Portilla, Esperanza Merino, Sergio Reus, Vicente Boix, Lluis Giner, Carmen Gadea, Irene Portilla, María Pamplega, Marcos Díez, Juan Carlos Rodríguez, Jose Sánchez-Payá. Hospital Universitario de Canarias (San Cristóbal de la Laguna): Juan Luis Gómez, Jehovara Hernández, María Remedios Alemán, María del Mar Alonso, María Inmaculada Hernández, Felicitas Díaz-Flores, Dácil García, Ricardo Pelazas. , Ana López Lirola. Hospital Universitario Central de Asturias (Oviedo): Víctor Asensi, Eulalia Valle, José-Antonio Cuello, María Eugenia Rivas Carmenado. Hospital Universitario 12 de Octubre (Madrid): Rafael Rubio, Federico Pulido, Otilia Bisbal, Asunción Hernando, María Lagarde, Mariano Matarranz, Lourdes Domínguez, Laura Bermejo, Mireia Santacreu. Hospital Universitario de Donostia (Donostia-San Sebastián): José Antonio Iribarren, Julio Arrizabalaga, María José Aramburu, Xabier Camino, Francisco Rodríguez-Arrondo, Miguel Ángel von Wichmann, Lidia Pascual Tomé, Miguel Ángel Goenaga, Mª Jesús Bustinduy, Harkaitz Azkune Galparsoro, , Maialen Ibarguren, Maitane Umerez. Hospital General Universitario De Elche (Elche): Félix Gutiérrez, Mar Masiá, Sergio Padilla, Andrés Navarro, Fernando Montolío, Catalina Robledano, Joan Gregori Colomé, Araceli Adsuar, Rafael Pascual, Marta Fernández, Elena García, Jose Alberto García , Xavier Barber. Hospital Universitari Germans Trias i Pujol (Can Ruti) (Badalona): Roberto Muga, Jordi Tor, Arantza Sanvisens. Hospital General Universitario Gregorio Marañón (Madrid): Juan Berenguer, Juan Carlos López Bernaldo de Quirós, Pilar Miralles, Isabel Gutiérrez, Margarita Ramírez, Belén Padilla, Paloma Gijón, Ana Carrero, Teresa Aldamiz-Echevarría, Francisco Tejerina, Francisco José Parras, Pascual Balsalobre, Cristina Díez. Hospital Universitari de Tarragona Joan XXIII (Tarragona): Francesc Vidal, Joaquín Peraire, Consuelo Viladés, Sergio Veloso, Montserrat Vargas, Miguel López-Dupla, Montserrat Olona, Anna Rull. Esther Rodríguez-Gallego, Verónica Alba. Hospital Universitario y Politécnico de La Fe (Valencia): Marta Montero Alonso, José-López Aldeguer, Marino Blanes Juliá, Mariona Tasias Pitarch, Iván Castro Hernández, Eva Calabuig Muñoz, Sandra Cuéllar Tovar, Miguel Salavert Lletí, Juan Fernández Navarro. Hospital Universitario La Paz-Carlos III-Cantoblanco: Juan González-García, F Arnalich, José Ramón Arribas, José Ignacio Bernardino, Juan Miguel Castro, Luis Escosa, Pedro Herranz, Víctor Hontañón, Silvia García-Bujalance, Milagros García Lopez-Hortelano, Alicia González-Baeza, María Luz Martín-Carbonero, Mario Mayoral, María José Mellado, Rafael Micán, Rocío Montejano, María Luisa Montes, Victoria Moreno, Ignacio Pérez-Valero, Berta Rodés, Talia Sainz, Elena Sendagorta, Natalia C Stella y Eulalia Valencia. Hospital San Pedro Centro de Investigación Biomédica de La Rioja (CIBIR) (Logroño): José-Ramón Blanco, José-Antonio Oteo, Valvanera Ibarra, Luis Metola, Mercedes Sanz, Laura Pérez-Martínez. Hospital Universitario Miguel Servet (Zaragoza): Ascensión Pascual, Carlos Ramos, Piedad Arazo, Desirè Gil. Hospital Universitari MutuaTerrassa (Terrasa): David Dalmau, Angels Jaén, Montse Sanmartí, Mireia Carió, Javier Martínez-Lacasa, Pablo Velli, Roser Font, Mariona Xercavins, Noemí Alonso. Complejo Hospitalario de Navarra (Pamplona): María Rivero, Jesús Repáraz, María Gracia Ruiz de Alda, Carmen Iñigoyen, María Jesús Arraiza. Corporació Sanitària Parc Taulí (Sabadell): Fernán Segura, María José Amengual, Gemma Navarro, Montserrat Sala, Manuel Cervantes, Valentín Pineda, Víctor Segura, Marta Navarro, Esperanza Antón, Mª Merce Niguarda. Hospital Universitario de La Princesa (Madrid): Ignacio de los Santos, Jesús Sanz Sanz, Ana Salas Aparicio, Cristina Sarriá Cepeda, Lucio García-Fraile Fraile. Hospital Universitario Ramón y Cajal (Madrid): Santiago Moreno, José Luis Casado, Fernando Dronda, Ana Moreno, María Jesús Pérez Elías, Cristina Gómez Ayerbe, Carolina Gutiérrez, Nadia Madrid, Santos del Campo Tomón, Paloma Martí, Lissa Arca, Sergio Serrano, María Jesús Vivancos. Hospital General Universitario Reina Sofía (Murcia): Alfredo Cano, Enrique Bernal, Ángeles Muñoz. Hospital Nuevo San Cecilio (Granada): Federico García, José Hernández, Alejandro Peña, Leopoldo Muñoz. Ana Belén Pérez, Marta Álvarez, Natalia Chueca, David Vinuesa, Jose Angel Fernández. Centro Sanitario Sandoval (Madrid): Jorge Del Romero, Carmen Rodríguez, Teresa Puerta, Juan Carlos Carrió, Mar Vera, Juan Ballesteros. Hospital Clínico Universitario de Santiago (Santiago de Compostela): Antonio Antela, Elena Losada. Hospital Universitario Son Espases (Palma de Mallorca): Melchor Riera, María Peñaranda, María Leyes, Mª Angels Ribas, Antoni A Campins, Carmen Vidal, Francisco Fanjul, Javier Murillas, Francisco Homar. Hospital Universitario Virgen de la Victoria (Málaga): Jesús Santos, Manuel Márquez, Isabel Viciana, Rosario Palacios, Isabel Pérez, Carmen María González. Hospital Universitario Virgen del Rocío (Sevilla): Pompeyo Viciana, Nuria Espinosa, Luis Fernando López-Cortés. Hospital Universitario de Bellvitge (Hospitalet de Llobregat): Daniel Podzamczer, Elena Ferrer, Ariadna Imaz, Juan Tiraboschi, Ana Silva, María Saumoy. Hospital Universitario Valle de Hebrón (Barcelona): Esteban Ribera. Hospital Costa del Sol (Marbella): Julián Olalla, Alfonso del Arco, Javier de la Torre, José Luis Prada, José María García de Lomas Guerrero. Hospital General Universitario Santa Lucía (Cartagena): Onofre Juan Martínez, Francisco Jesús Vera, Lorena Martínez, Josefina García, Begoña Alcaraz, Amaya Jimeno. Complejo Hospitalario Universitario a Coruña (Chuac) (A Coruña): Eva Poveda, Berta Pernas, Álvaro Mena, Marta Grandal, Ángeles Castro, José D. Pedreira. Hospital Universitario Basurto (Bilbao): Josefa Muñoz, Miren Zuñiga Zubero, Josu Mirena Baraia-Etxaburu, Sofía Ibarra, Oscar Ferrero, Josefina López de Munain, Mª Mar Cámara. Iñigo López, Mireia de la Peña. Hospital Universitario Virgen de la Arrixaca (El Palmar): Carlos Galera, Helena Albendín, Aurora Pérez, Asunción Iborra, Antonio Moreno, María Ángeles Campillo, Asunción Vidal. Hospital de la Marina Baixa (La Vila Joiosa): Concha Amador, Francisco Pasquau, Javier Ena, Concha Bonilo, Vicenta Fenoll. Hospital Universitario Infanta Sofía (San Sebastian de los Reyes): Inés Suárez-García, Eduardo Malmierca, Patricia González-Ruano, Dolores Martín Rodrigo. Complejo Hospitalario de Jaén (Jaen): Mohamed Omar Mohamed-Balghala, Maria Amparo Gómez Vidal. Hospital San Agustín (Avilés): Miguel Alberto de Zarraga. Hospital Clínico San Carlos (Madrid): Vicente Estrada Pérez, María Jesús Téllez Molina, Jorge Vergas García, Elisa Pérez-Cecilia Carrera. Hospital Universitario Fundación Jiménez Díaz (Madrid): Miguel Górgolas., Alfonso Cabello., Beatriz Álvarez., Laura Prieto.

Red de Investigación en Sida
ViiV Healthcare