Baseline characteristics in JUNGLE, a German observational cohort study of Juluca as 2-Drug Regimen in virologically suppressed patients, compared to the phase-3 SWORD 1 & 2 study populations

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Background

- Juluca, the combination of Dolutegravir (DTG) and Rilpivirine (RPV) was approved by the EMA in 2018 as the first single-tablet 2-drug regimen (2DR) for maintenance therapy in HIV-1 infected patients
- The JUNGLE cohort will provide prospective real-world data regarding effectiveness and tolerability of using DTG/RPV
- Here we describe the characteristics of the study population and reasons for switch to DTG/RPV

Methods

JUNGLE is an ongoing non-interventional, 3-year, prospective, multi-center cohort study in Germany

Main inclusion criteria

- Adult HIV-1 infected patients on suppressive ART for ≥6 months switched to DTG/RPV
- No prior virologic failure
- No INSTI or NNRTI resistance mutations
- No hepatitis B coinfection
- No contraindication based on the SmPC (summary of product characteristics)

Results

Study population

- Between June 2018 and July 2019, 201 patients were enrolled across 24 study centers

Table 1. Baseline characteristics	Total	Observed data
Sex, male, n (%)	181 (90.0)	201
Age, years, median (interquartile range; IQR)	49 (40 – 57)	201
Age ≥50 years, n (%)	97 (48.3)	201
BMI, kg/m², median (IQR)	25 (22 – 27)	173
CD4 T-cell count, cells/µL, median (IQR)	709 (573 – 934)	199
History of AIDS (CDC C), n (%)	37 (18.4)	201
Time since HIV diagnosis, years (median, IQR)	11 (6 – 16)	198
Time on ART, years (median, IQR)	8.0 (5.0 – 14.0)	180
Treatment switches prior to DTG/RPV, n (%)		201
no modifications	20 (10.0)	
1-2 modifications	81 (40.3)	
≥3 modifications	87 (43.3)	
unknown	13 (6.5)	

Antiretroviral treatment (ART) prior to switch to DTG/RPV

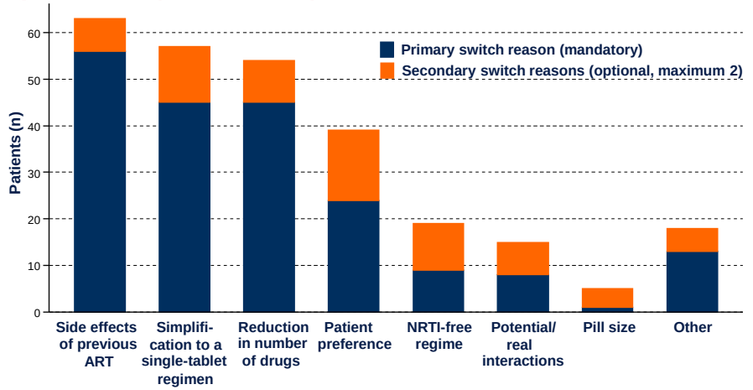
- The median duration of the previous ART before DTG/RPV was 2.6 years (IQR: 1.5 – 5.1)
- Of 201 patients, 10.0% switched from first-line ART, 43.3% had a history of ≥3 ART changes (Table 1)
- 86.6% of patients were switched from triple ART and 46.8% had been on a multi-tablet regimen

Table 2. Previous ART prior to switch to DTG/RPV (>5%)	n (%); N=201
RPV/FTC/TAF	28 (13.9)
DTG/3TC/ABC	25 (12.4)
EVG/COBI/FTC/TAF	16 (8.0)
EFV/FTC/TDF	15 (7.5)
DTG + RPV	14 (7.0)
RPV/FTC/TDF	12 (6.0)
DTG + FTC/TAF	11 (5.5)

Reasons for switch

- Primary reasons for switch to DTG/RPV were side effects of previous ART (25.9%), switch to a single-tablet regimen (22.4%) and reduction in number of drugs (20.4%)

Figure 1. Primary and secondary reasons for switch to DTG/RPV



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Relevant comorbidities und co-medication at baseline

- Relevant comorbidities and concomitant medication have been documented In 58.2% and 50.7% of patients, respectively (see Tables 3 and 4)

Table 3. Comorbidities at baseline (>5%)	n (%); N=201
Hypertension	58 (28.9)
Depression	34 (16.9)
Lipid disorders	31 (15.4)
Chronic kidney disease	26 (12.9)
Insomnia	23 (11.4)
Pulmonary disease	19 (9.5)
Osteopenia/osteoporosis	17 (8.5)
Coronary heart disease	13 (6.5)
Diabetes mellitus	13 (6.5)

Table 4. Concomitant Medication at baseline (>5%)	n (%); N=201
Antihypertensives	58 (28.9)
Statins	31 (15.4)
Antidepressants	19 (9.5)
Drugs for cardiovascular disease other than antihypertensives or antiarrhythmics	18 (9.0)
Calcium and iron supplements or multivitamins	16 (8.0)
Sleeping drugs	14 (7.0)
Antidiabetics (metformin [n=7])	11 (5.5)

Conclusions

- In the JUNGLE cohort, 87% of patients were on triple ART prior to switching to the 2DR Juluca
- Main reasons for switch were side effects of previous ART, simplification to a single-tablet regimen and reduction in number of drugs
- Compared to the SWORD 1 & 2 study population[1] switched to DTG+RPV, the JUNGLE cohort is
  - Older in age (48% vs 29% ≥50 years)
  - More extensively pre-treated (43% with ≥3 ART changes vs 100% on first- or second-line ART in SWORD studies, median pre-treatment time 8.0 vs 4.3 years)
  - Clinically more advanced in HIV disease (18% vs 11% with history of AIDS)

References

[1] Llibre JM, Hung CC, Brinson C, et al. Lancet. 2018 Mar 3;391(10123):839-849.