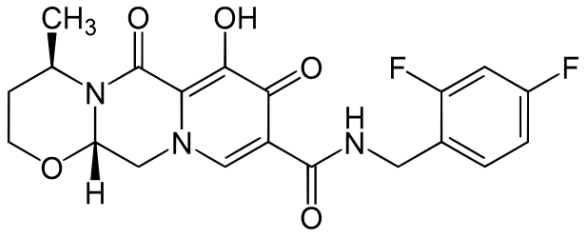

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A belgian multicenter non-interventional, observational, retrospective study of daily practice use of Dolutegravir in the treatment of HIV positive patients

BREACH Symposium

November 30th 2018

UZ LEUVEN

INSTITUTE OF TROPICAL MEDICINE ANTWERP

Hôpital Erasme

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Un hôpital pour la Vie

Introduction

- **Dolutegravir** (DTG), a second generation integrase strand transfer inhibitor, is being increasingly used as part of combined anti-retroviral treatment (CART), both in naive and experienced patients with HIV-1 infection.

- **Real world data** are needed to characterize the population currently being treated:
  - outcome in terms of viral suppression,
  - rate of DTG discontinuation,
  - emerging side effects which were not or rarely described in clinical trials

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Objectives

- Describe treatment **outcomes** for DTG based regimen in HIV-1 infected patients in daily clinical practice in Belgium
- Study specific **subpopulations** outcomes
- Describe the **profile and characteristics** of HIV infected patients receiving treatment with DTG in daily clinical practice in Belgium

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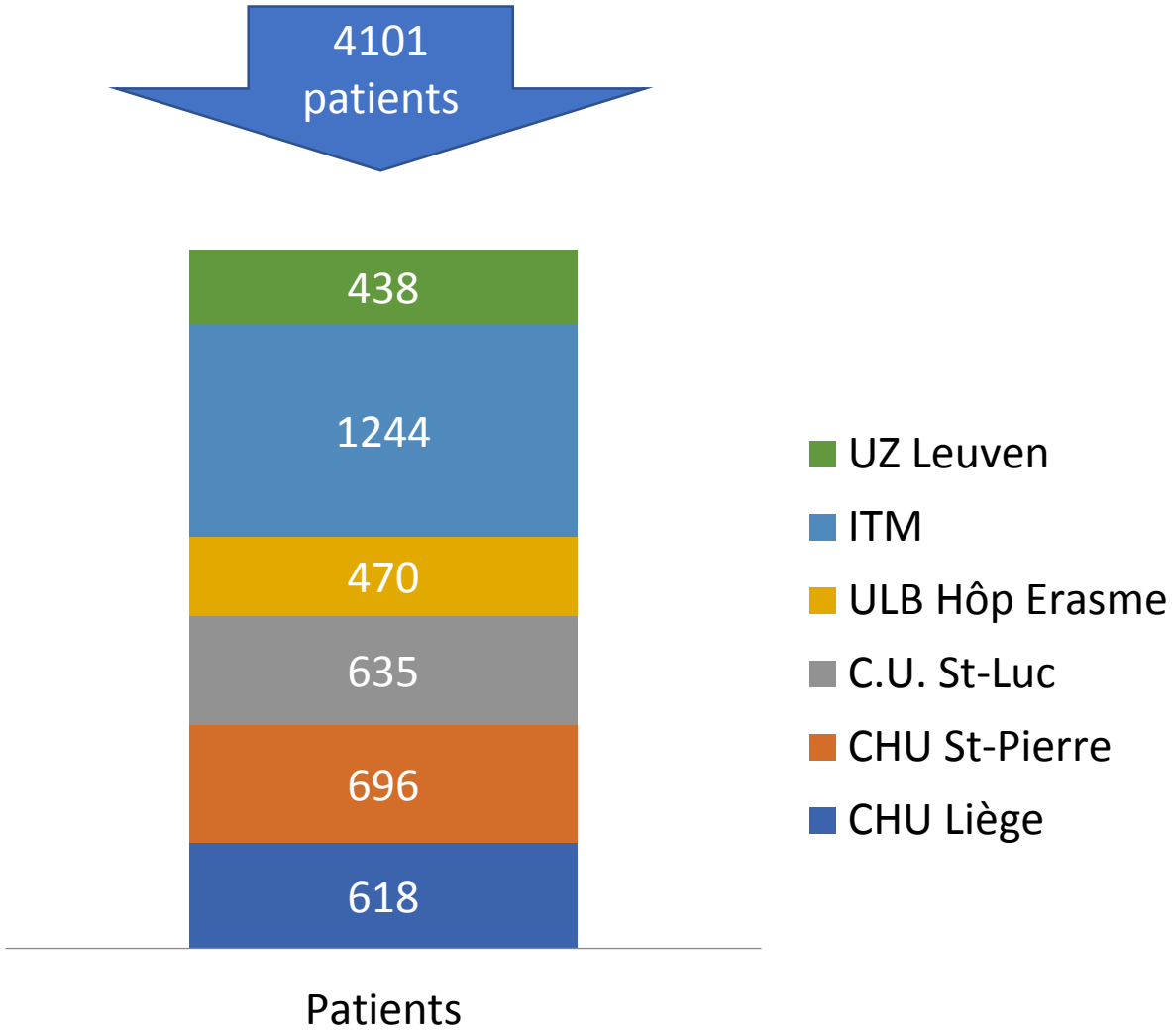
Methods

- An observational, non-interventional, non-comparative, retrospective, multicenter cohort study
- Data were collected from **six Belgian AIDS Reference Centers**
- All patients who received at least one dose of DTG with a minimum follow-up of 6 months were **included**



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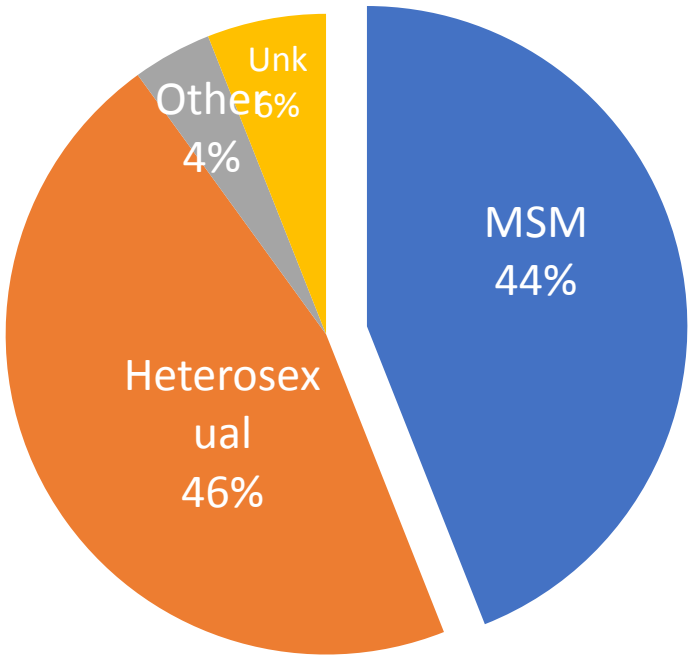
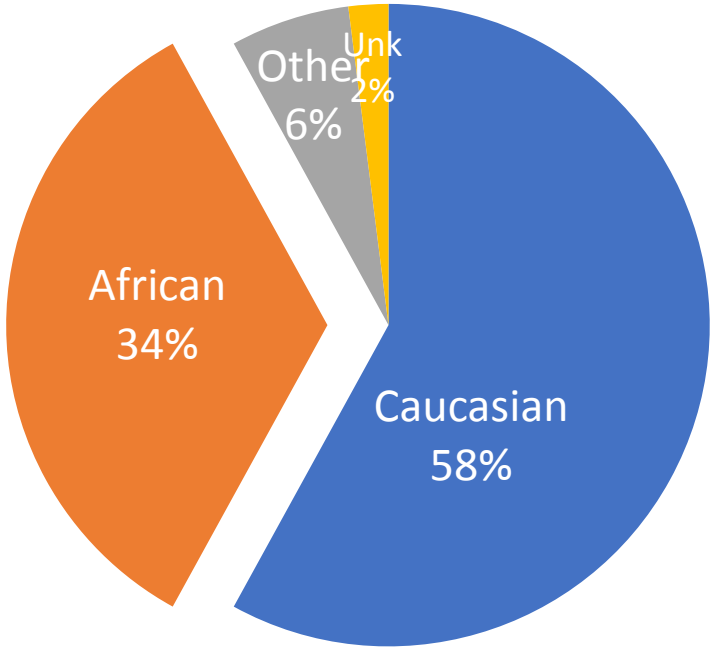
Results

- Median age 46 yo
- 20% Naive of ARV
- 67% Male – 33% Female





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Results

- Baseline **characteristics**

CD4	Median nadir: 240 cells/µL [IQR*: 114;391] Median current: 555 cells/µL [IQR: 377;763]
VL	62 % of patients below 50 copies/mL
AIDS	21 % of patients had a history of AIDS
Co-infection	3,6 % HBV 6,3 % HCV

*(Inter Quartile Range: P25;P75)

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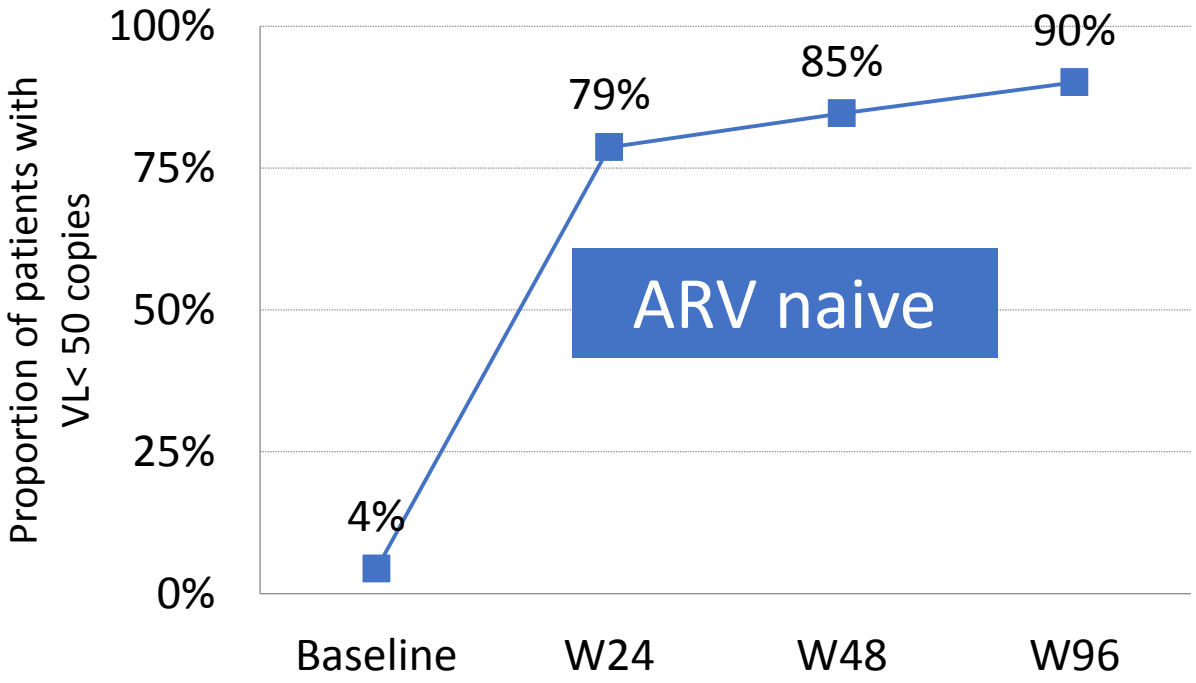
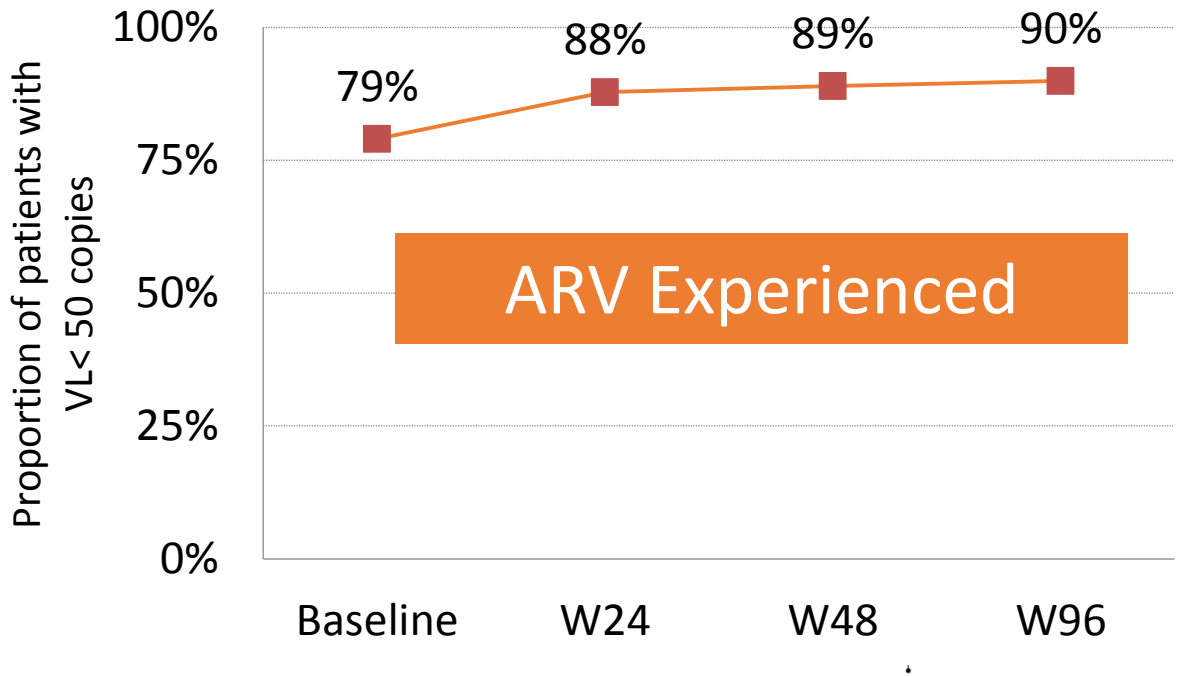
Results

- **Primary Endpoint -** Virologic suppression
  - Viral load < 50 copies/mL at W24, W48 and W96. (This allows for blips during the follow up period)





Results

- **Primary Endpoint -** Virologic suppression
  - VL response was similar across subpopulations

	Baseline	W24	W48	W96
Highly treatment experimenced*	79%	87%	88%	87%
Migrants sub-saharian Africa	66%	86%	87%	87%
Women	66%	87%	88%	89%
Men	63%	85%	88%	91%

* (defined as patients with a treatment history of at least 3 core agents switches from at least 3 separate classes (PI, NNTRI or INSTI), i.e. being on their 4th or higher line of treatment)

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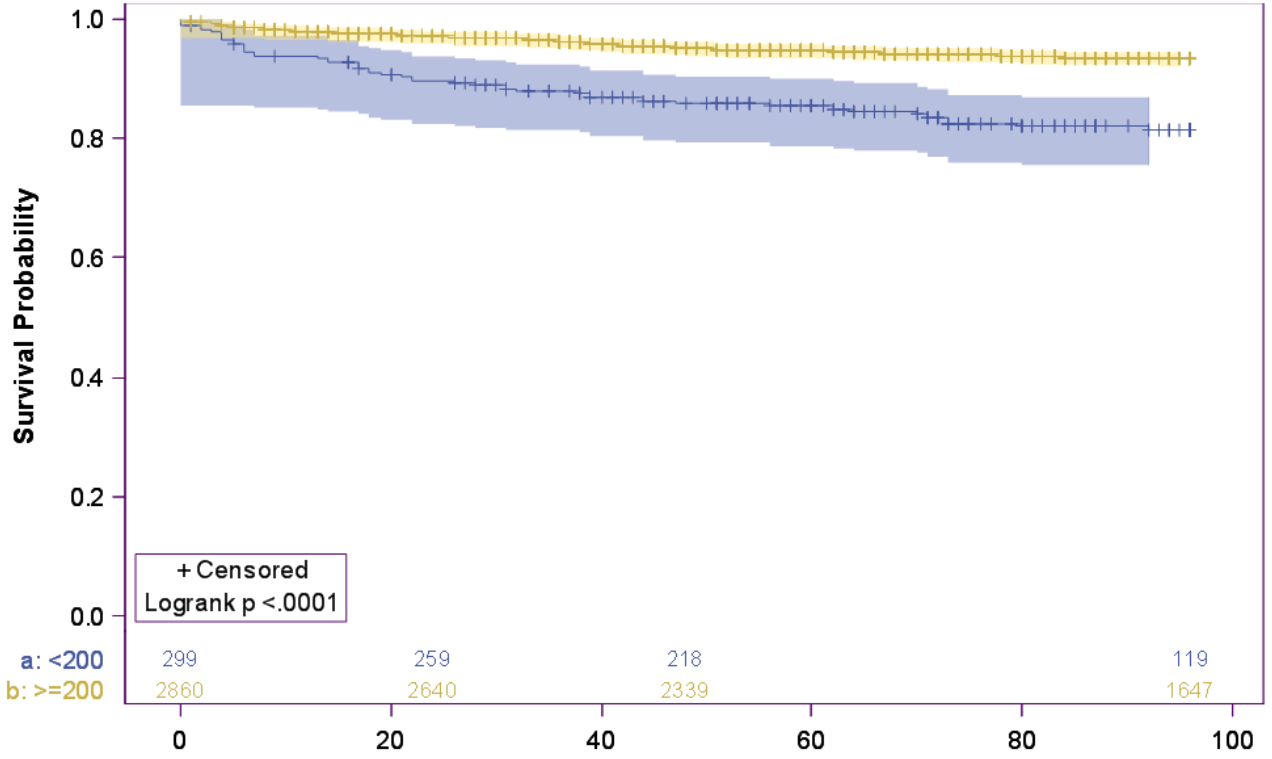
Results

- **Secondary Endpoint - Durability** of the DTG-based HAART regimen by time to virological failure
  - Viral load response at W96 was lower in patients with CD4 below 200 cells/µL when starting DTG (83% vs 94%).



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Results

- **Discontinuation**
  - Median exposure to DTG was 120.6 weeks [IRQ: 72;155]
  - DTG was stopped in 785 patients (19%)
  - Main reasons
    - CNS side effects (215 patients, 27%)
    - GI tract side effects (56 patients, 7%)
    - Pregnancy-related (49 patients, 6%)
  - Death occurs in 16 patients (2%).

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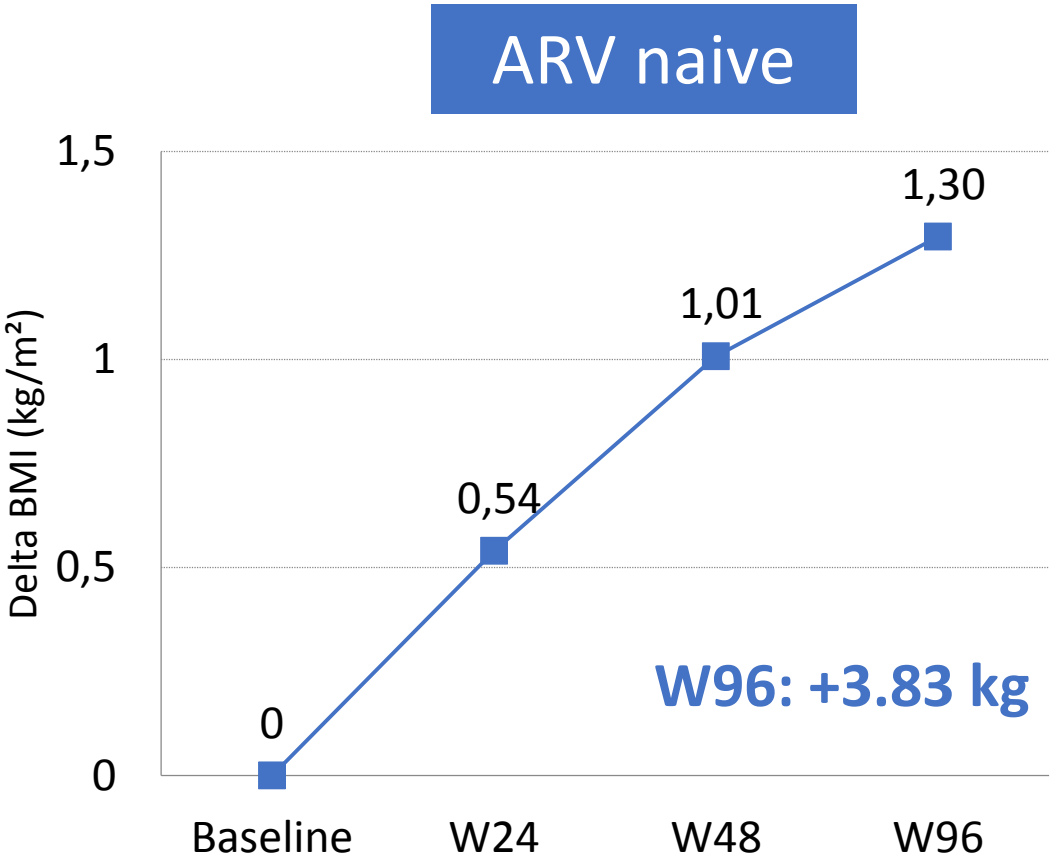
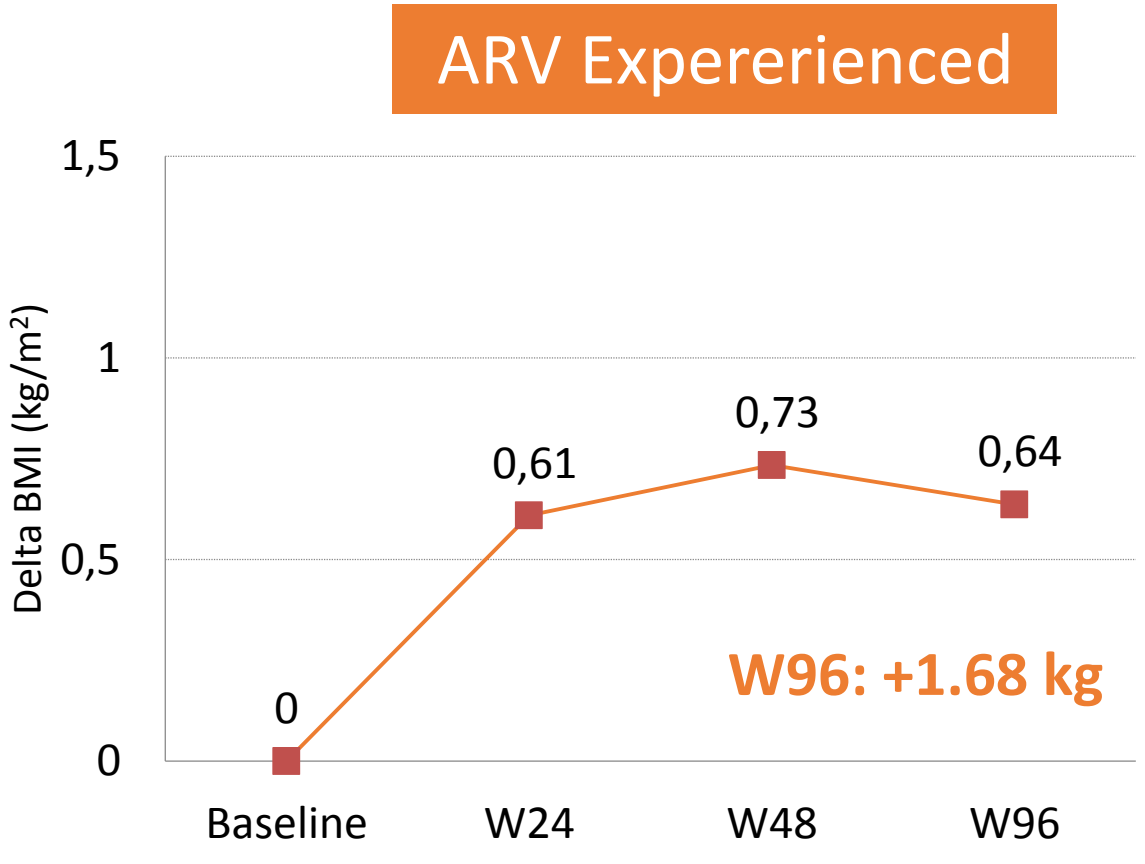
Results

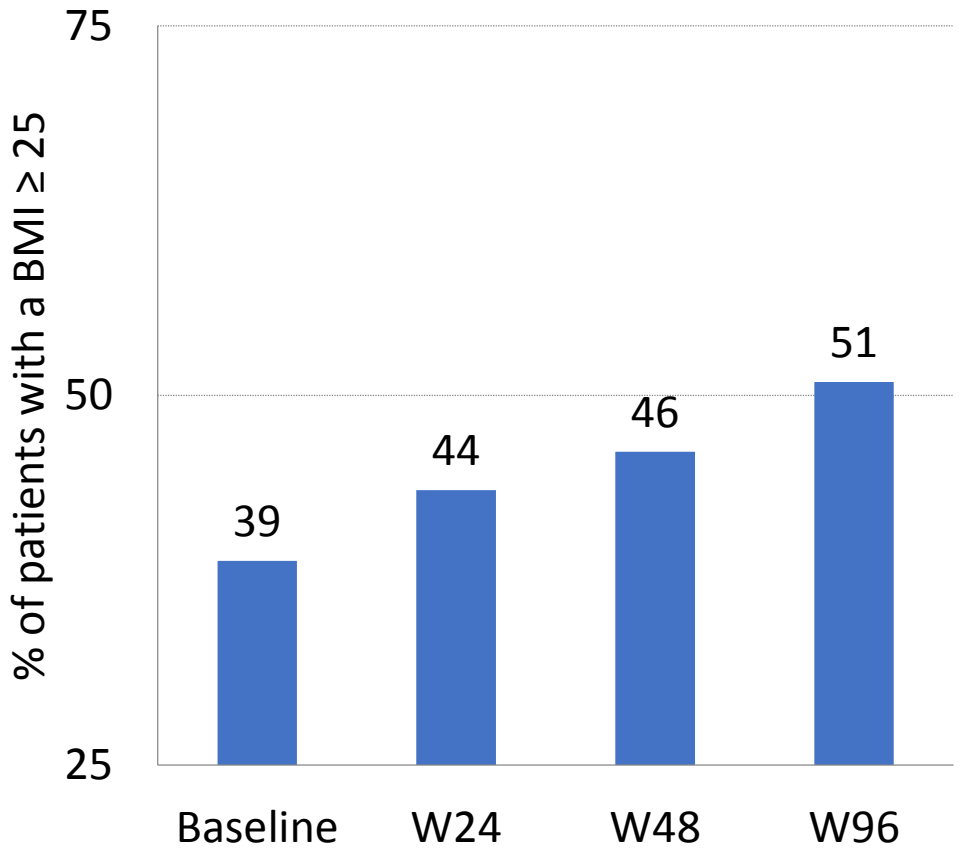
- **BMI increased** mainly seen in ARV naïve patients

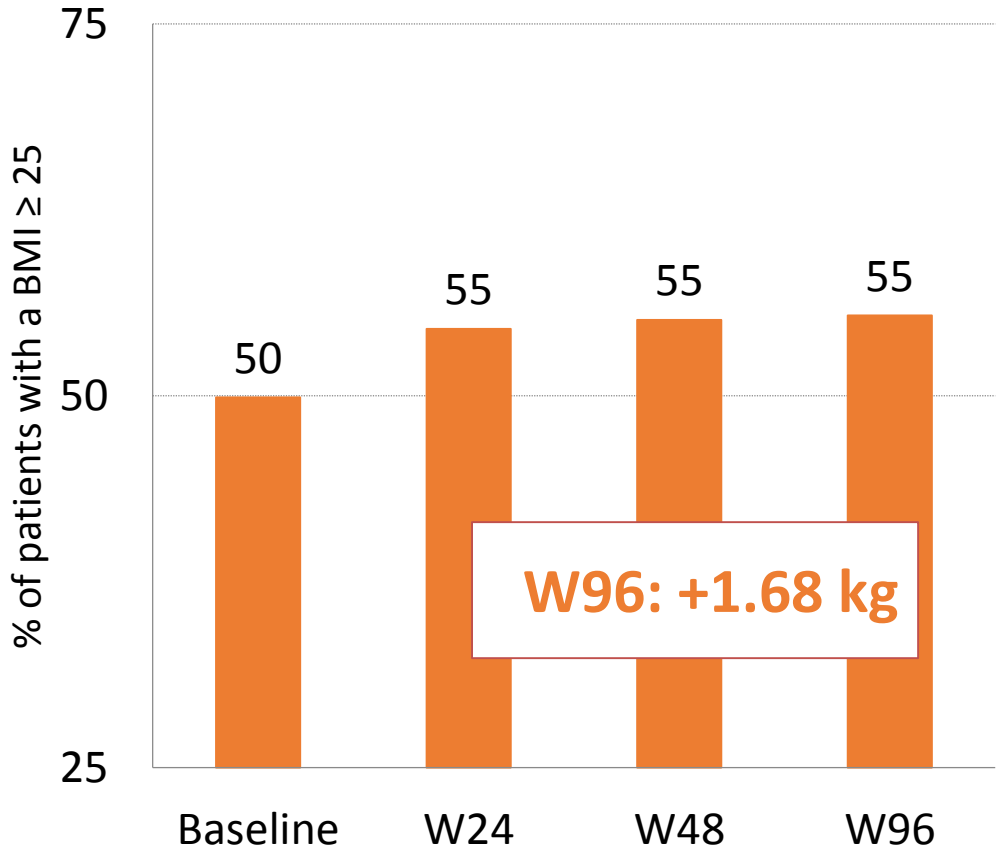




Results

	Baseline	W24	W48	W96
% of patients with a BMI ≥ 25	48.2	52.9	53.7	54.8

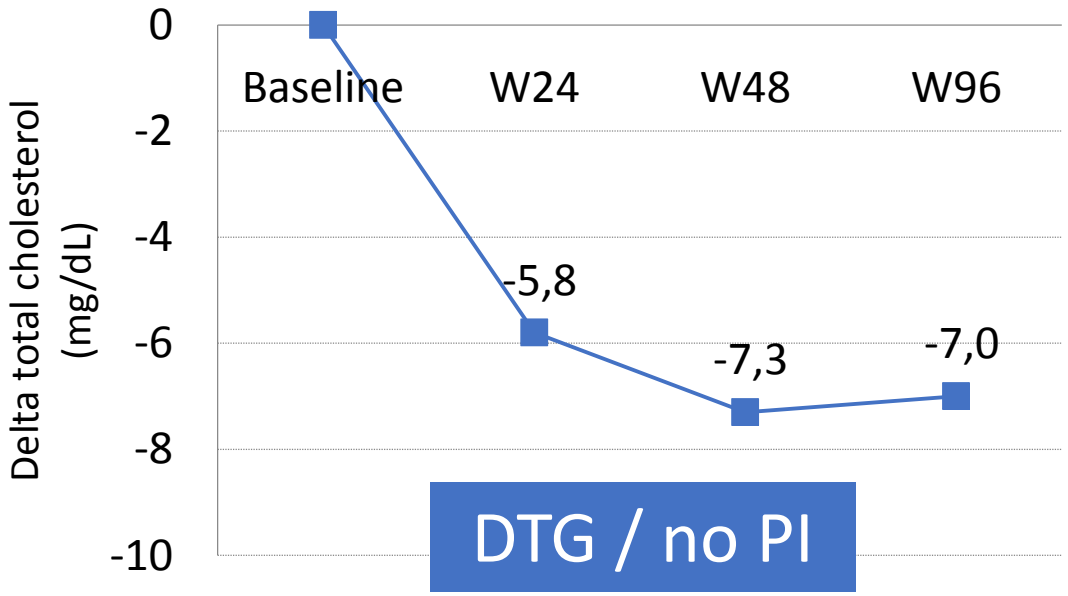


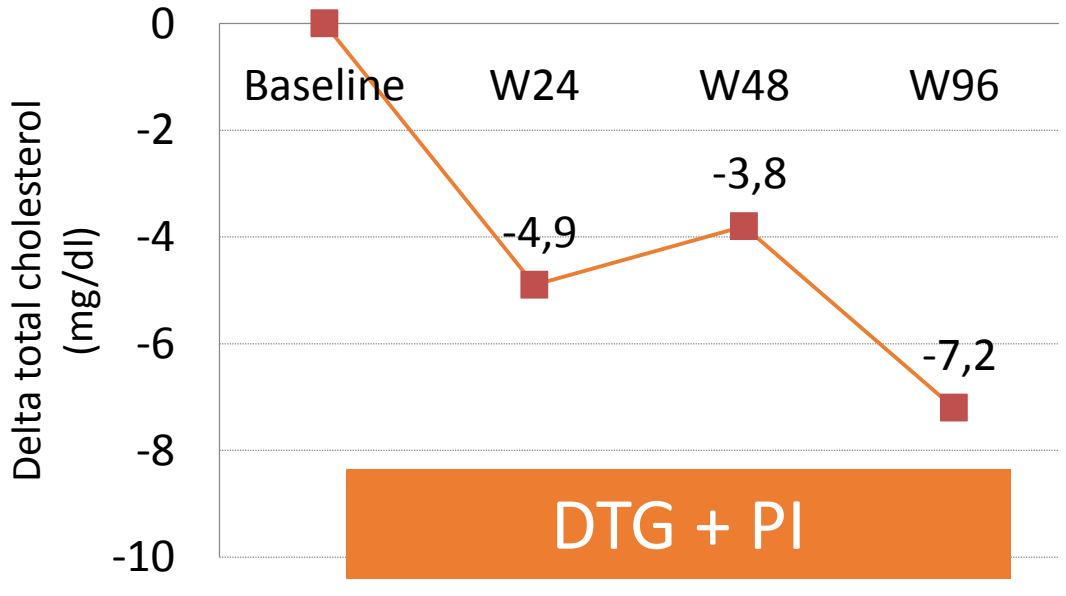


Results

- Mean **decline** of **total cholesterol**

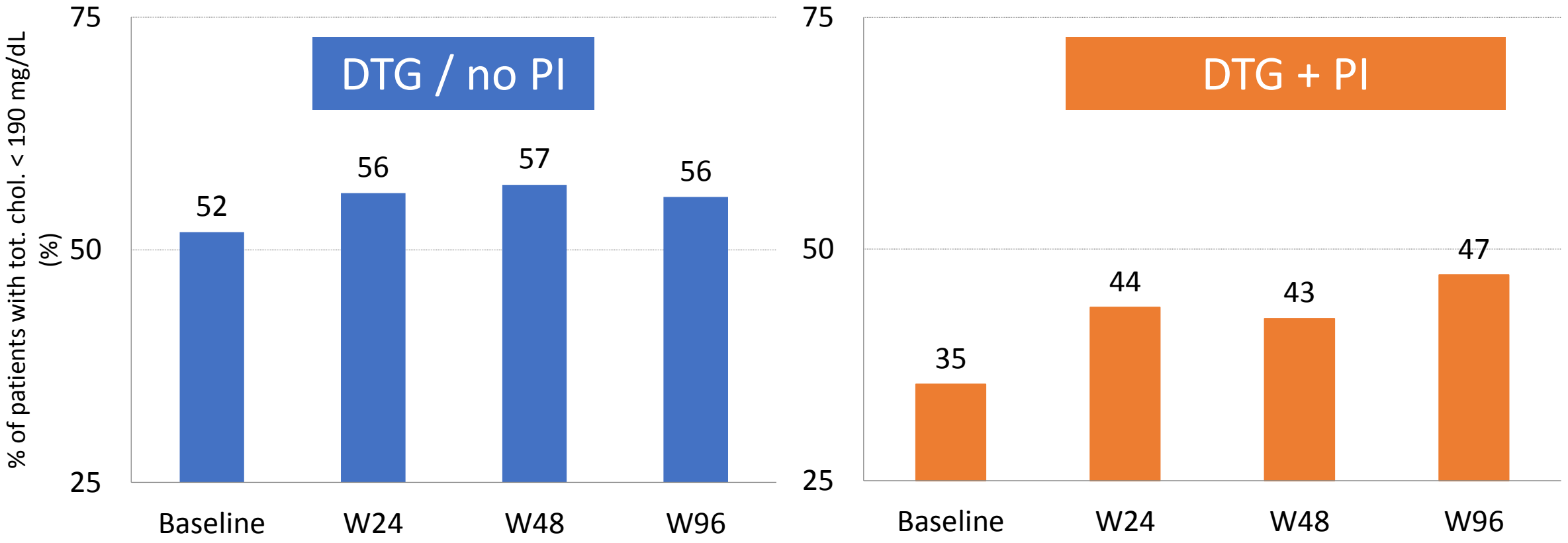
	Baseline	W24	W48	W96
Delta total cholesterol	0	-5.7	-6.8	-7





Results

	Baseline	W24	W48	W96
% of patients with tot. chol. < 190 mg/dL	49.4	54.3	55	54.5



Conclusion

- This large **real world cohort** of patients confirms the **high efficacy of DTG**, including in highly experienced patients and in specific populations such as women and migrants

- The rate of DTG **discontinuation** was 785/4101, 19 % and was mainly related to CNS side effects, GI tract or pregnancy

- DTG led to an increase of BMI, in both naive and experienced and a small decrease of cholesterol. The clinical relevance of these findings is unknown.

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Acknowledgements

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