A FULLY INTEGRATED CLINICAL TRIAL-LIKE SYSTEM TO MANAGE AND MONITOR PERSISTENCE IN PLANNED HEPATITIS C TREATMENT

Gomes I[1], Figueira A[1], Sequeira C[1], Ferreira da Silva S[1], Machado F[1], Figueiredo P[1], Rabadão E[3], Andreozzi V[4], Félix J[4], Feio J[1]

1. Centro Hospitalar e Universitário de Coimbra, Hospital Pharmacy, Coimbra, Portugal; 2. Centro Hospitalar e Universitário de Coimbra, Gastroenterology Department, Coimbra, Portugal; 3. Centro Hospitalar e Universitário de Coimbra, Infectious Disease Department, Coimbra, Portugal; 4. Exigo Consultores, Lisbon, Portugal

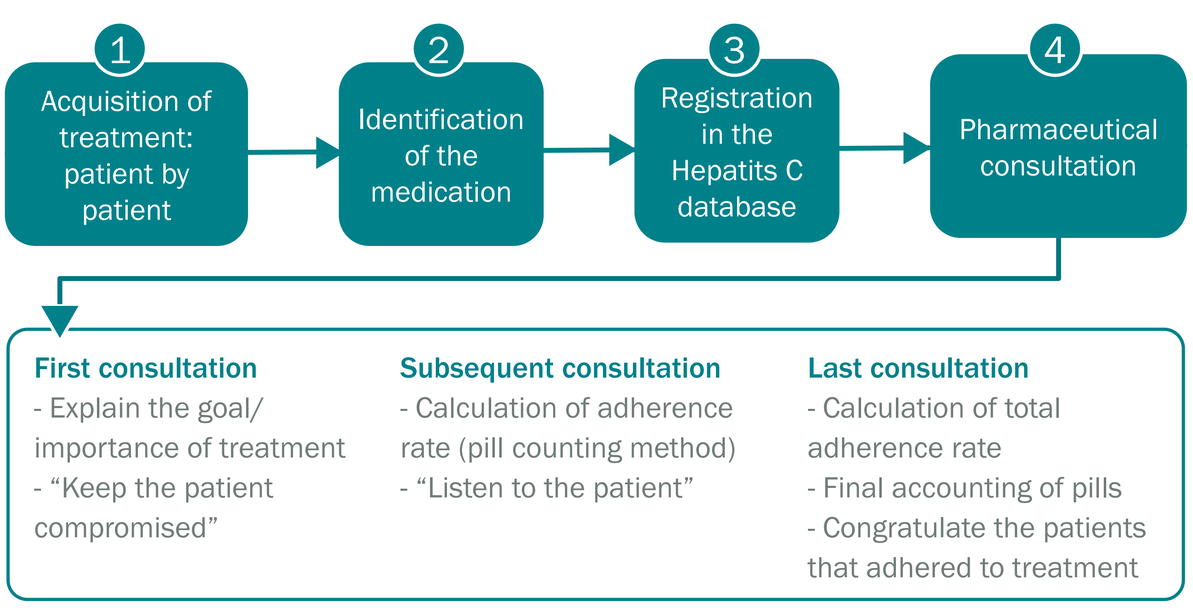
INTRODUCTION / OBJECTIVES

Portugal was one of the first countries in the world to have a universal access programme to new direct-acting antivirals (DAA) therapy for hepatitis C. The implementation of such a policy in our university hospital was managed by the hospital pharmacy based on a new and specific system designated fully integrated clinical trials-like system (CTLIKE), allowing full traceability of hepatitis C therapy and patient outcomes.

Our aim was to assess CTLIKE system efficiency in terms of patients' persistence on DAA therapy for hepatitis C in our hospital. Adherence by the pill count method was a second exploratory objective.

METHODS

CTLIKE is based on a set of day-to-day routines and protocols, supported by a dedicated software with the aim of controlling DAA dispensing and refiling, and also therapy and patient outcomes monitoring, with the ultimate goal of capturing full benefits from hepatitis C treatment for all stakeholders involved. CTLIKE, illustrated below, is managed by the hospital pharmacy in our university hospital.



The efficiency of CTLIKE was assessed by measuring persistence, defined as remaining in therapy and not discontinuing (end of treatment). The Kaplan–Meier method was used for crude survival calculations. The risk of DAA treatment discontinuation was estimated by Cox proportional hazard models. Adherence was a secondary exploratory endpoint calculated by the pill count method.

RESULTS

Data supporting this research was retrospectively collected and refers to 721 patients initiating DAA therapy since January 2015. Mean (SD) age at therapy initiation was 49.9 (10.8) years and 76.0% were male.

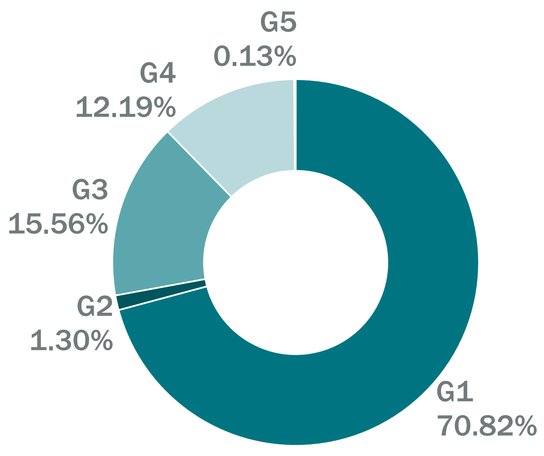


Figure 1 Genotype distribution

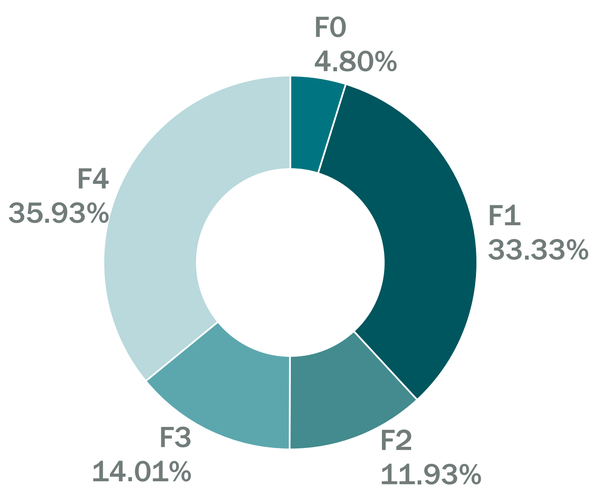


Figure 2 Metavir stage distribution

RESULTS (CONT.)

Majority of the population were treatment naïve (69.5%). Sofosbuvir based regimens accounted for 94.7% of treatments. Planned treatment duration was: 12 weeks (73.6%); 24 weeks (26.4%) (Figure 3).

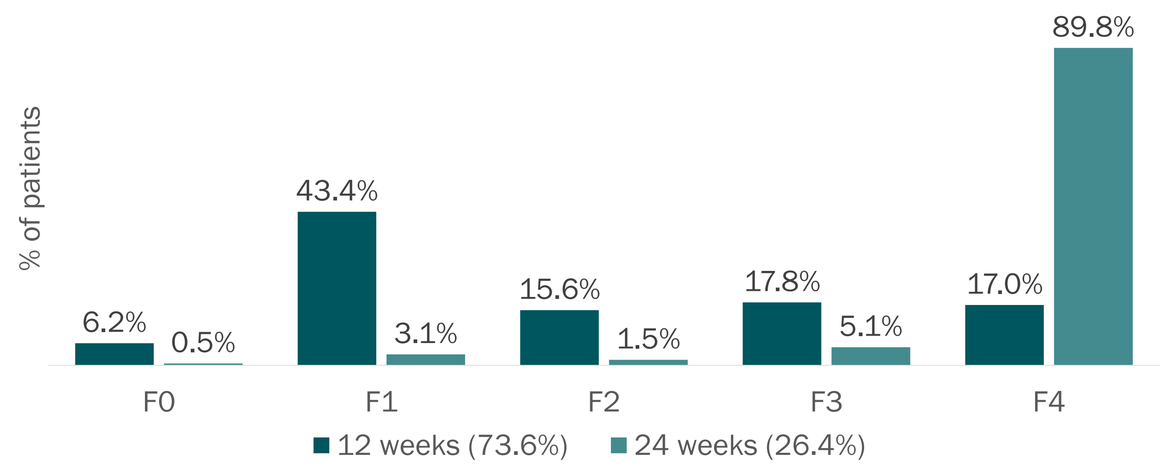


Figure 3 Patient´s distribution according to planned treatment duration and metavir stage

CTLIKE system culminate in very high persistence on hepatitis C therapy.

Premature treatment discontinuation before planned 12 and 24 weeks was estimated at 9.5% (95%CI: 6.9%-12.1%) and 20.4% (95%CI: 14.4%-26.0%), respectively.

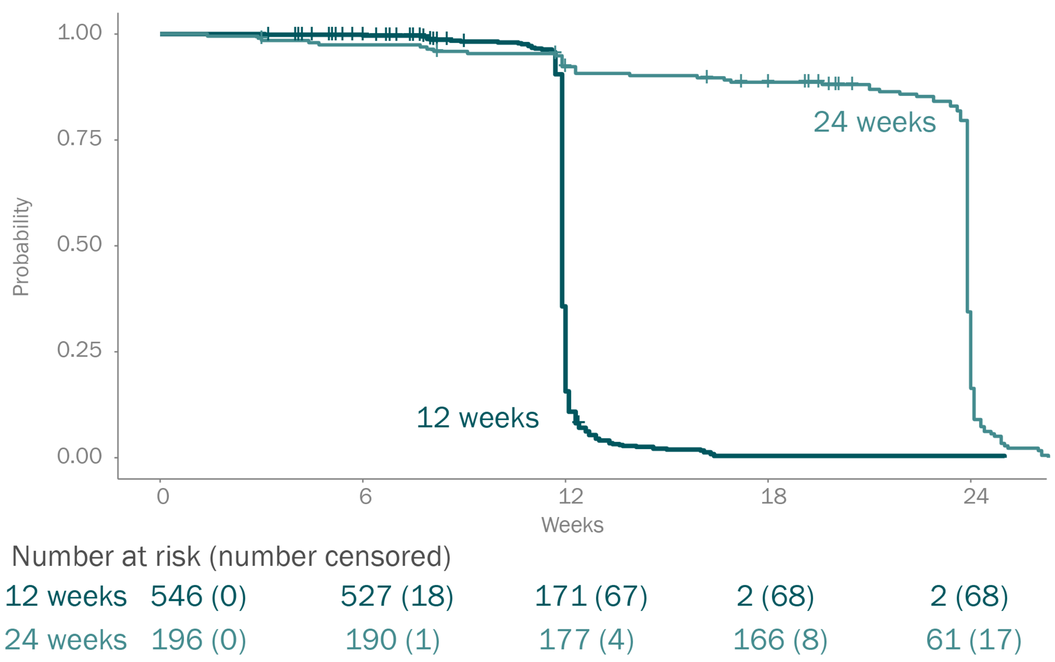


Figure 4 Persistence on hepatitis C planned treatment

The risk of discontinuation among males was 15% less than females (HR of discontinuation=0.85, 95%CI: 0.69-1.04).

Non-cirrhotic patients were more likely to persist on treatment when compared with cirrhotic patients (HR of discontinuation = 0.73, 95%CI: 0.57-0.95).

Adherence (pill count) level ≥95% to DAA was:

- 97.8% in 12 weeks treatment duration;
- 98.9% in 24 weeks treatment duration.

http://www.eahp.eu/24-4CPS-086

CONCLUSION

The CTLIKE system revealed full efficacy in DAA dispensing and hepatitis C treatment outcomes monitoring, guaranteeing very high persistence and adherence rates in hepatitis C therapy in this real-world setting.