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

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 refilling, 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 at 9.5% (95%CI: 6.9%-12.1%) and 20.4% (95%CI: 14.4%-26.0%), respectively.

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).

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.

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.