Real-World (RW) Use of Cladribine Tablets in Portugal: A Two-Year Update of a Cohort Database

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OBJECTIVES

To present a two-year update on RW data available from a patient registry of patients with multiple sclerosis (MS) being treated with cladribine tablets in Portugal.

INTRODUCTION

Multiple sclerosis (MS) is an inflammatory disease of the central nervous system, with an annual incidence ranging from 2 to 10 cases per 100.000 persons per year.[1]

In Portugal the estimated incidence of MS is 4,48 cases per 100.000, or 450 new cases per year[2], while the prevalence has been estimated as being 56,2 cases per 100.000, for a total of 6.000 cases in Portugal.[3]

Cladribine tablets was launched in Portugal in May 2018, for the treatment of adult patients with highly active relapsing MS.[4] Cladribine tablets has a unique mechanism of action permitting long-term efficacy over a 4-year time period, associated to two short treatment courses in year 1 and 2.[5]

Cladribine tablets was funded for its complete label indication on the assumption that it will considerably lower the overall cost of treatment per patient by eliminating the costs of therapeutic treatment in years 3 and 4.[5,6] For this reason, it is of the upmost importance to confirm the real-world effectiveness of cladribine tablets when compared with the efficacy seen in clinical trials.

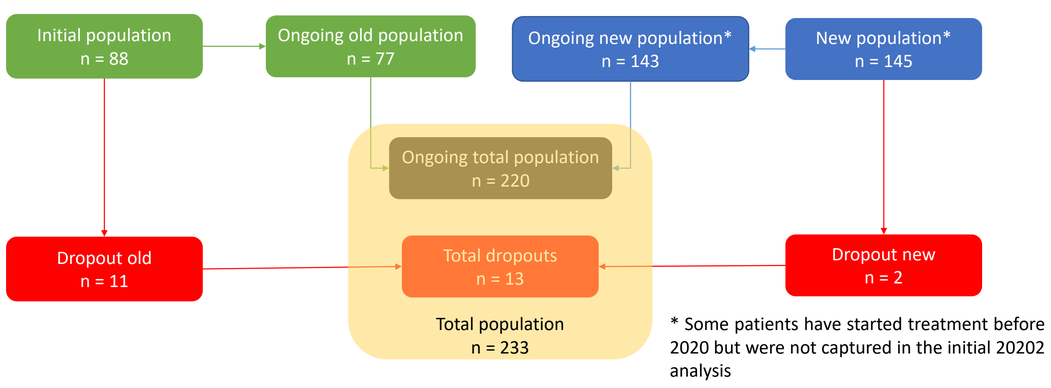
METHODS

Anonymized data was retrieved from a patient registry database of MS patients currently being treated with cladribine tablets in Portugal. Data was checked for missing values and descriptive analysis was run for the available information using STATA17. For all parameters missing data was censured, with number of samples being mentioned. Information was available from a total of 28 hospitals. Cut-off date for the analysis was May 20th, 2022.

RESULTS

Since last cut-off in May 2020, 145 new patients were enrolled for a total of 233 patients. On the same period 13 patients dropped out of treatment, having switched to other treatments. The full flow of patients is presented in Figure 1.

Figure 1: Patient flow in the study (2020 – 2022)



Overall, five different populations were considered in the analysis, total population, total ongoing population, ongoing old population, ongoing new population and dropout population.

For each population, gender, age at time of analysis and time on treatment (ToT) were captured and are presented in Table 1.

Figure 2 presents the patients distribution per hospital, with 5 hospitals representing half of the population under analysis.

Figure 3 presents the Kaplan-Meier estimate for the whole population on treatment.

Subsequent treatments in case of dropout were ocrelizumab (46%), natalizumab (23%) and Interferon beta-1a (15%), with 15% being unknown.

Table 1: Main parameters for analyzed populations

Population	Total population n = 233	Total ongoing n = 220	Ongoing old n = 77	Ongoing new n = 143	Total Dropouts n = 13
Gender					
% female	75,11%	75,91 %	74,03 %	76,92%	61,54%
Age (years)					
Average ± SD	42,20 ± 11,90	42,40 ± 11,89	43,43 ± 11,22	41,84 ± 12,23	38,67 ± 12,09
Median	41	41	43	40	39,5
Min – Max	22 – 77	22 - 77	22 – 65	22 – 77	22 – 60
ToT (days)					
Average ± SD	587,8 ± 382,9	582,3 ± 389,3	1016,1 ± 183,6	348,6 ± 242,1	682,4 ± 244,5
Median	540	521	956	319	729
Min – Max	3 - 1423	3 - 1423	739 - 1423	3 – 1173	347 - 1117

Figure 2: Population distribution per hospital in the sample (n=233)

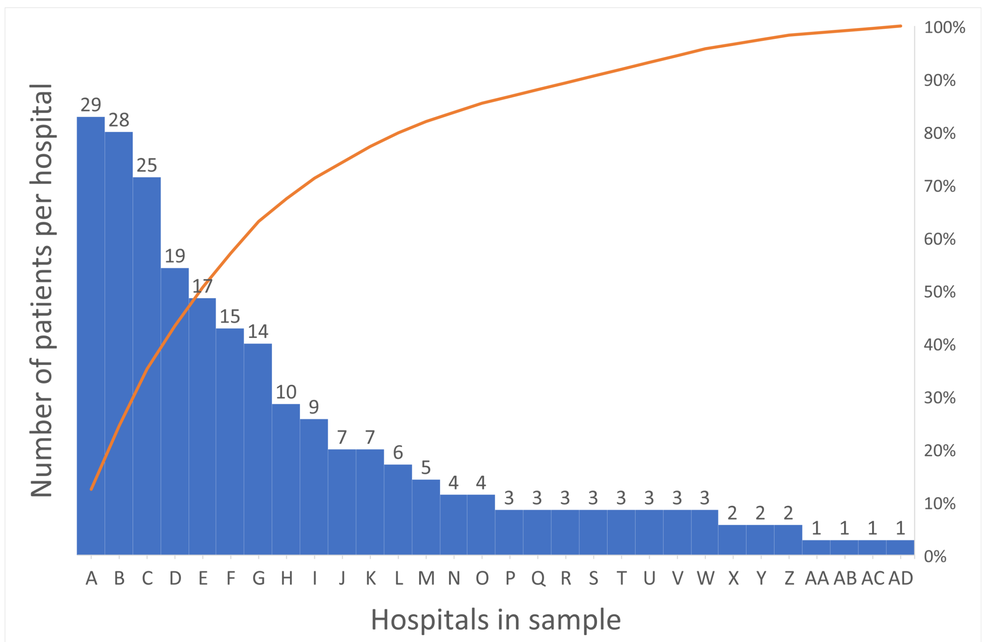
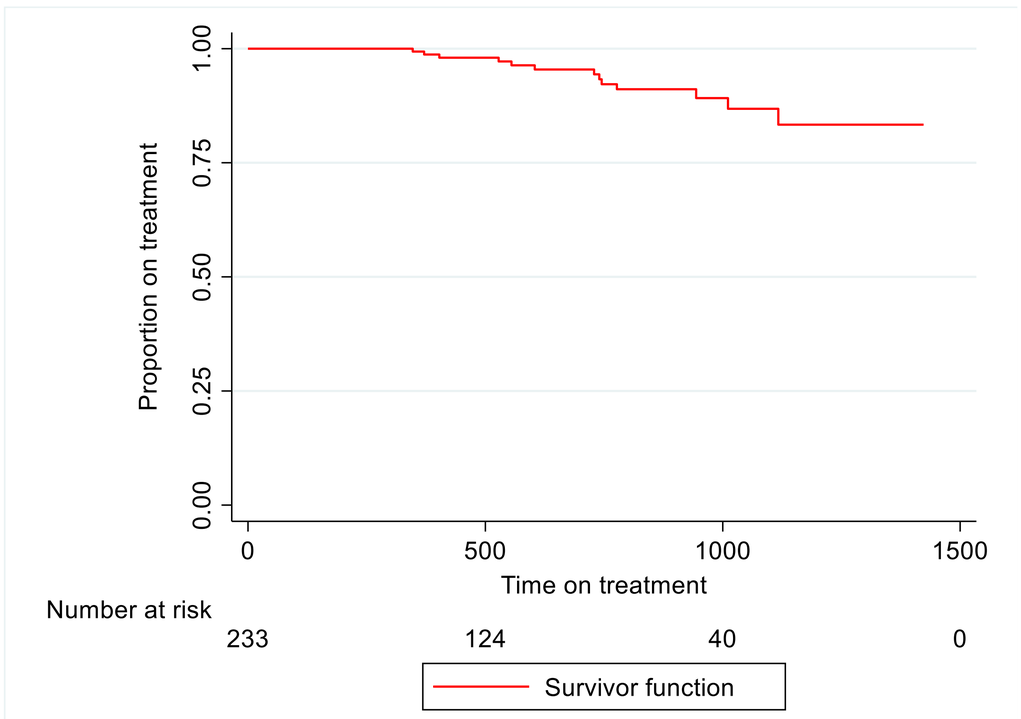


Figure 3: Kaplan-Meier of time on treatment for the whole population



CONCLUSIONS

Data observed seems to validate the long-term ToT for cladribine tablets, in line with what has been observed in randomized-controlled trials and also in other RW studies.

References:

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