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Real-world experience with Cladribine Tablets in the MSBase Registry

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MSBase
Neuro-Immunology Registry

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MSBase
Neuro-Immunology Registry

Background

Introduction

Cladribine tablets are approved for treatment of multiple sclerosis (MS) in many jurisdictions. Real-world outcomes data is very limited.

Objectives

To analyse the Cladribine treatment experience in a real-world setting, to describe 1) baseline characteristics of MS patients treated with Cladribine tablets, 2) treatment pathways, and 3) relapse and discontinuation outcomes in patients with at least 6 months follow-up data from Cladribine initiation.

Methods

Secondary data analysis using MSBase Registry data of patients with a confirmed diagnosis of MS and newly treated with Cladribine tablets after regulatory approval.

Descriptive statistics were used to analyse baseline patient characteristics recorded within 3 months prior to Cladribine table initiation, including demographics, disease course and duration, prior disease modifying drugs (DMD), and Expanded Disability Status Scale (EDSS).

MSBase Neuro-Immunology Registry

Results - Demographics

MSBase included 576 patients treated with Cladribine from 9 countries, mainly from Australia and Europe. Average age of MS patients was 46.33 years. Baseline characteristics for RRMS, SPMS and PPMS patients are shown in Table 1 and Table 2.

Table 1. Demographics for Cladribine treated patients in the MSBase Registry

Characteristic	RRMS (n=496)	SPMS (n=60)	PPMS (n=3)
Age (years) – mean (SD)	45.06 (11.73)	57.56 (9.80)	60.39 (12.17)
Gender, n (%)			
Female	378 (86.7)	45 (75)	0 (0.0)
Male	118 (23.8)	15 (25)	3 (100)
Country, n (%)			
Australia	314 (63.3)	49 (91.7)	3 (100)
Belgium	22 (4.4)	1 (1.7)	0 (0.0)
Canada	80 (16.1)	9 (15.0)	0 (0.0)
Spain	58 (11.7)	1 (1.7)	0 (0.0)
Italy	6 (1.2)	0 (0.0)	0 (0.0)
Kuwait	4 (0.8)	0 (0.0)	0 (0.0)
Other	12 (2.4)	0 (0.0)	0 (0.0)

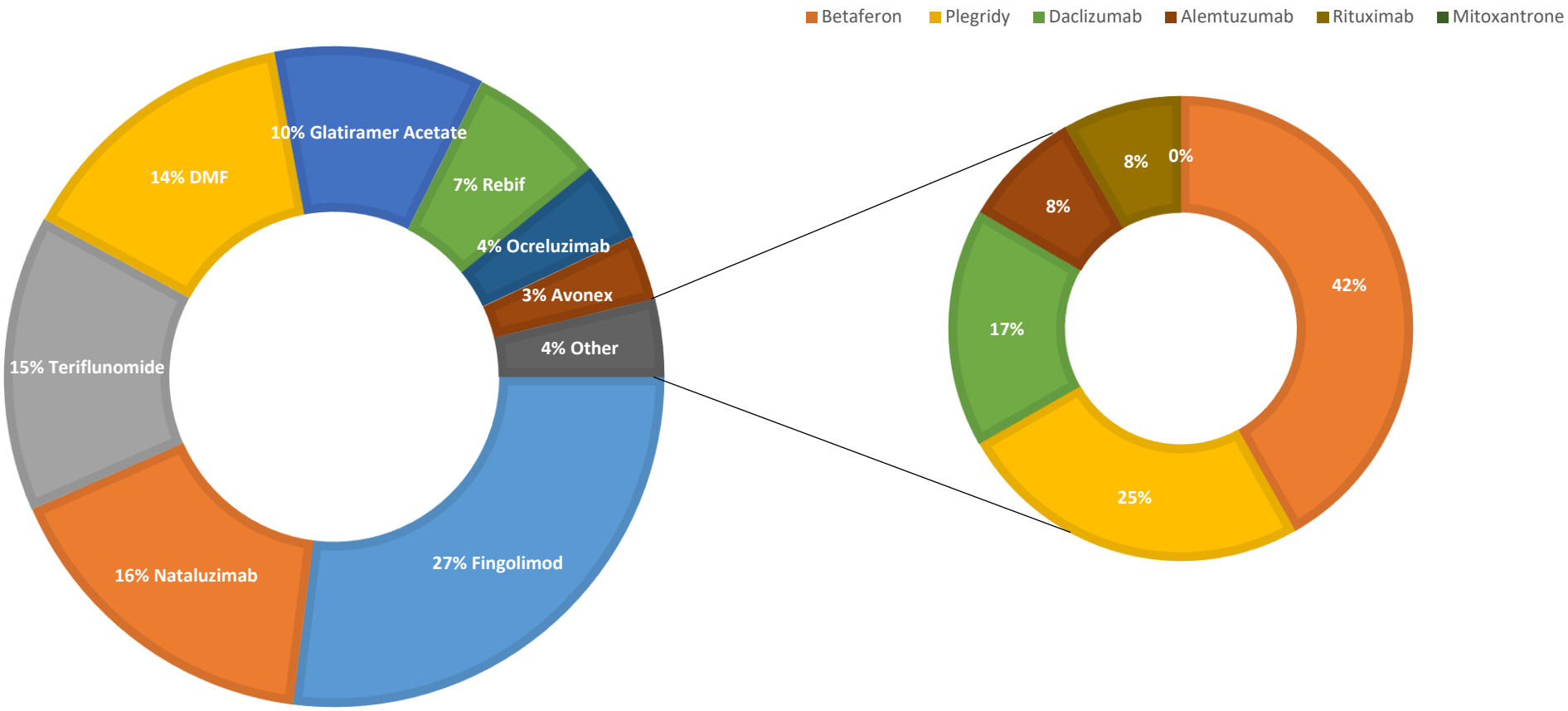
Results - Characteristics

Table 2: Disease characteristics and Treatment history of Cladribine treated MS patients in the MSBase Registry

Characteristic	RRMS (n=496)	SPMS (n=60)	PPMS (n=3)
Disease duration, mean (SD), years			
Since diagnosis	9.64 (7.71)	20.19 (7.17)	12.39 (2.73)
Baseline EDSS score, median (IQR)	2.5 (1.5, 4.5)	6.5 (5.5, 7)	6.5 (6.5, 6.5)
Relapse Rate, mean (SD)			
Past 12 months	0.38 (0.61)	0.30 (0.79)	0 (0.0)
Past 24 months	0.56 (0.82)	0.45 (1.11)	0 (0.0)
MS Therapy history prior to Cladribine initiation, n(%)			
Treatment naïve	64 (12.9)	4 (6.7)	1 (33.3)
Previously treated with DMTs	432 (77.1)	56 (93.3)	2 (66.6)

Results - DMT Switch Group

Figure 1. RRMS patients switching from a DMT to Cladribine (by drug name and/or class such as oral, IV, platform therapy, other)*



*Switch was defined as a treatment gap of < 6 months (n=311)

Results - Relapse events

Figure 2. Time to first relapse event in RRMS patients using Cladribine

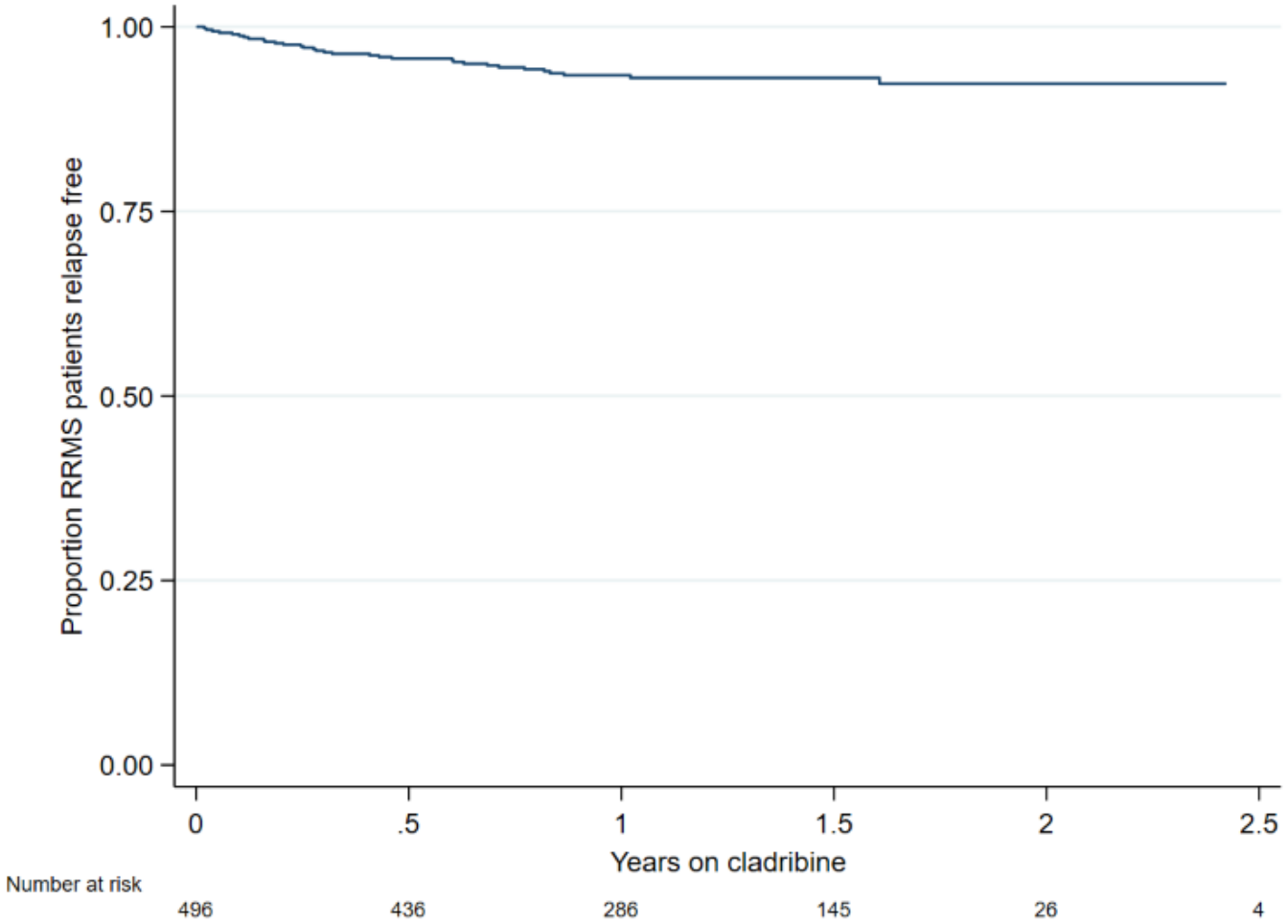
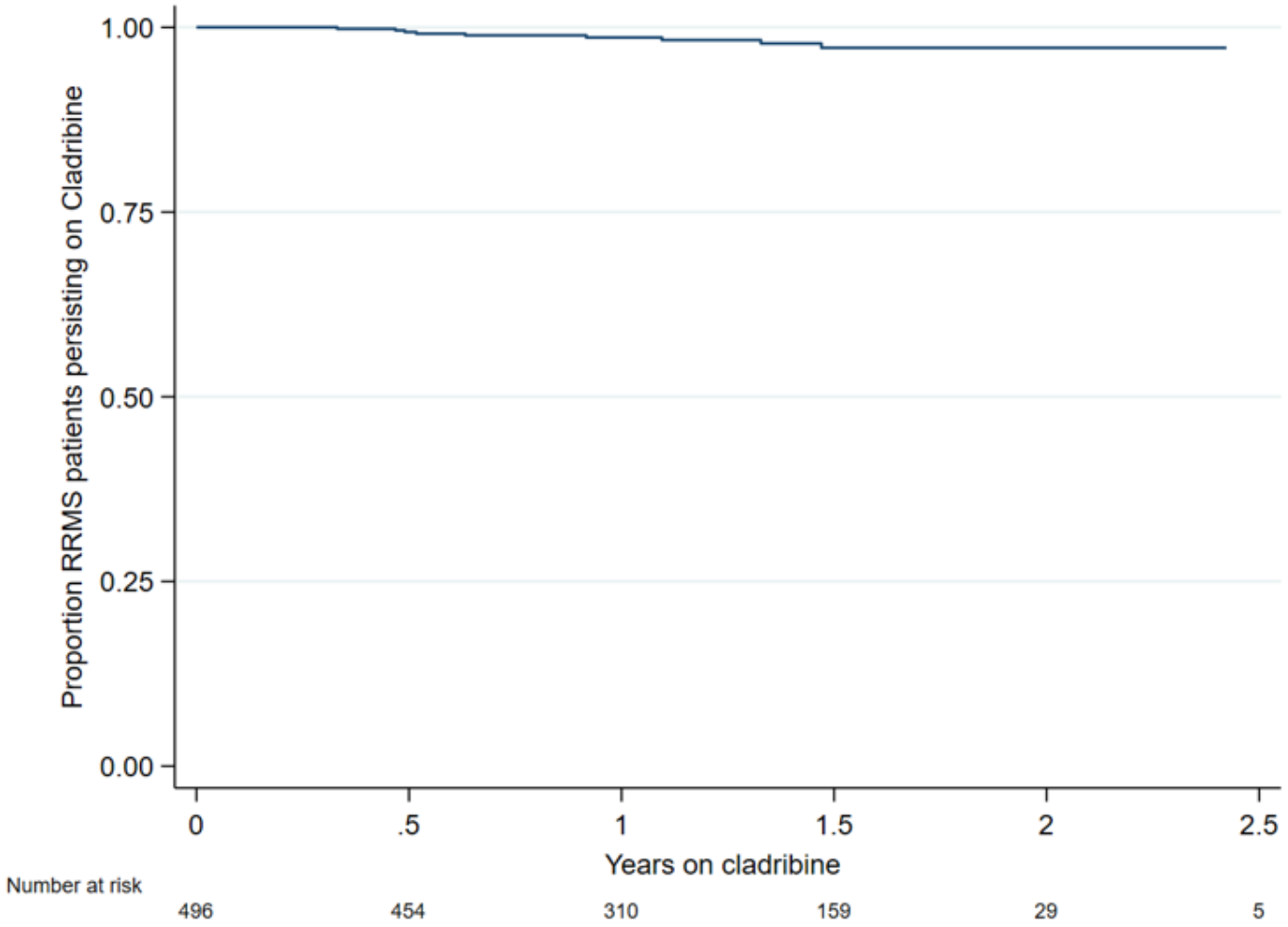


Table 3. Annualised relapse rate (ARR): RRMS patients

n	ARR	95% CI
496	0.13	(0.09, 0.19)

Results - Discontinuation Rates

Figure 3. Persistence of RRMS patients using Cladribine



Discontinuation rate for **RRMS** patients:

3.27 per 100 person-years
(95% CI 1.50, 6.21)

Conclusion

This study demonstrates very favourable outcomes for patients treated with Cladribine tablets in the MSBase registry.

First-line use was uncommon (13%).

Annualised relapse rate in RRMS patients was low (0.13) and consistent with clinical trial data.

Treatment persistence rate in the first year was 95%.

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