Valentina Perrone, valentina.perrone@clicon.it

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The Epidemiology and Economic Burden of Different Phenotypes of Multiple Sclerosis (MS) in Italy: Relapsing-Remitting Multiple Sclerosis (RRMS) and Secondary Progressive Multiple Sclerosis (SPMS)

Valentina Perrone[1], Chiara Veronesi[1], Elisa Giacomini[1], Daniela Paoli[1], Rita Citraro[2], Stefania Dell'Orco[3], Fabio Lena[4], Arrigo Paciello[5], Anna Maria Resta[6], Mihaela Nica[7], Daniela Ritrovato[7], Luca Degli Esposti[1]

1 CliCon, Health Economics & Outcomes Research, Bologna, Italy; 2 Dipartimento di Scienze della Salute, Università Magna Grecia di Catanzaro, UNITA' OPERATIVA DI FARMACOLOGIA CLINICA E FARMACOVIGILANZA, AZIENDA OSPEDALIERO-UNIVERSITARIA "Mater Domini, Catanzaro, Italy; 3 ASL Roma 6, Albano Laziale, Roma, Italy; 4 USL Toscana Sud Est , Grosseto, Italy; 5 ATS Bergamo, Bergamo, Italy; 6 Struttura Complessa di Farmacia Territoriale Area Vasta 1, Fano, Italy; 7 Novartis Farma, Origgio, VA, Italy

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KEY FINDINGS & CONCLUSIONS

- By using administrative databases, we provided insights into the **epidemiology of MS in Italy** and the **economic burden** associated with the disease management. We analyzed three cohorts of MS patients: the overall MS, the relapsing-remitting (RRMS), and the secondary-progressive (SPMS).
- The estimated prevalence of MS, RRMS and SPMS was in line with the published literature [1].
- A **high economic burden** was associated with the management of MS patients, mainly derived from **DMTs costs**.
- A bigger healthcare resource consumption was associated with the **secondary progressive MS phenotype**, SPMS, suggesting that the **diagnosis in an early phase** of switch from RRMS to SPMS and **the appropriate treatment** could be effective in modifying the **clinical course of MS**, **reduce disability, improve the quality of life and avoid costly consequences**.

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OBJECTIVES

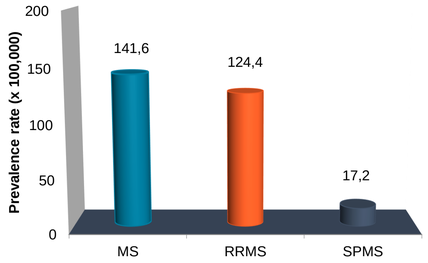
A retrospective analysis of real-world data was performed to assess the epidemiology and economic burden of MS, RRMS and SPMS in Italy.

METHODS

- **Observational study** based on secondary-use data from administrative databases of 3 Italian Local Health Units and 2 Regions, was carried out.
- Patients were included in the study from **01/01/2010 to 31/12/2017** by ≥1 **MS diagnosis code** (ICD-9-CM code 340 and/or **active exemption code** 046) and/or ≥1 **disease-modifying therapies** (DMT).
- In the cohort, **SPMS patients** were identified by presence of ≥2 symptoms of MS progression or ≥2 drug prescriptions to treat these symptoms.
- MS patients not fulfilling SPMS criteria were included in the **RRMS cohort**.
- **Mean annual healthcare costs** (drugs, hospitalizations, outpatient specialist services) were reported during follow-up stratified by treatment/untreatment condition. A focused analysis on the mean cost of **first- and second-line DMTs** (defined by the Agenzia Italiana del Farmaco (AIFA) reimbursement criteria) during all available follow-up, was performed.

RESULTS

Figure 1. Prevalence of MS, RRMS and SPMS.



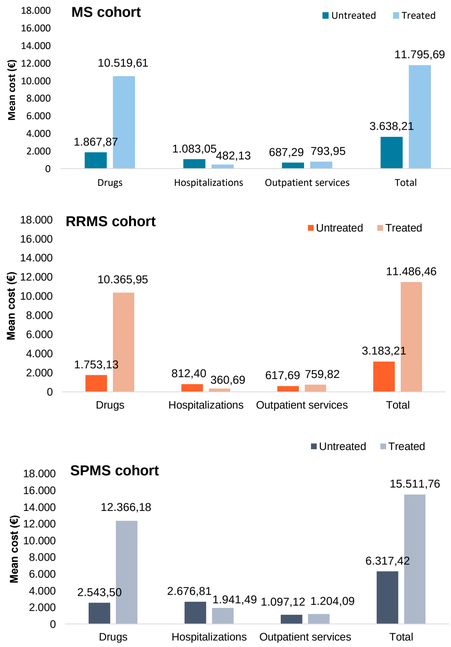
The **estimated prevalence** of MS was 141.6/100,000 inhabitants, precisely 124.4/100,000 for RRMS and 17.2/100,000 for SPMS, in line with published data [1].

Table 1. Clinical and Demographic Characteristics.

	MS	RRMS	SPMS
n	9,543	8,397	1,146
Age (mean, SD)	47.8 ± 14.9	47.1 ± 15.1	53.1 ± 11.2
Male, n (%)	3,304 (34.6)	2,864 (34.1)	440 (38.4)
Charlson comorbidity index (mean, SD)	0.9 ± 1.7	0.9 ± 1.8	0.8 ± 1.0
Previuos MS hospitalization , n (%)	2,579 (27.0)	2,105 (25.1)	474 (41.4)
Previuos hospitalization (any), n (%)	3,605 (37.8)	3,061 (36.5)	544 (47.5)
Previuos MS treatment, n (%)	5,538 (58.0)	5,055 (60.2)	483 (42.1)

A total of **9,543 MS patients** were included: **8,397** were classified as **RRMS** and **1,146** were classified as **SPMS**. **27% of MS and 25,1% of RRMS** patients had previous **MS-related hospitalizations** as opposed to **41.4% of the SPMS** patients. On the contrary, a higher extent of MS and RRMS patients (**58% and 60.2% respectively**) had a **previous MS specific treatment prescription**, as opposed to **42.1% of the SPMS** patients.

Figure 2. Resource consumption on alive patients during follow up period by presence/absence of treatment.



MS cohort: patients' management was associated with a mean annual cost/patient of **€ 11,795.69** (for treated patients) and **€ 3,638.21** (for untreated patients)

RRMS cohort: the total annual cost/patient averaged **€ 11,486.46** (for treated patients) and **€ 3,183.21** (for untreated patients)

SPMS cohort: patients' management was associated with a higher cost both for treated (**15,511.76 €**) and for untreated patients (**6,317.42 €**).

During the follow-up, we performed an update of cost analysis on patients who had a first -line DMT followed by a second-line DMT course. The duration of the first-line treatment averaged 27.4±22.8 months and the mean cost was **19,004€** for the whole period. The second-line DMT treatment lasted on average 31.1±24.5 months and the mean cost was **47,293€** for the whole period. The mean annual cost estimated was **€ 8,322.93 for the first- and €18,248.04 for the second-line treatment**.

Disclosures

All authors declare no conflict of interest. MN and DR are Novartis Farma employees.

References

1. Battaglia MA, Bezzini D. Neurol Sci 38:473–479 (2017).

Data privacy statement

The present study has been approved by the Ethics Committee of each Region/Local Health Units involved in the analysis. The integration of administrative datasets makes it possible to represent the patient's entire clinical history and not just individual prescriptions. The analyses were conducted on exclusively anonymous data in full compliance with privacy regulations. Clicon s.r.l. has obtained the approval as per legislation by all the Ethics Committees to analyse these data. The results are exclusively in aggregated form and never attributable to a single institution, department, doctor, individual, or individual prescribing behaviours. The study was conducted in full compliance with current legislation for retrospective studies.