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The incidence of the multiple sclerosis in Italy: 2011-2015

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Abstract

Introduction. There are very few scientific papers (and only on delimited areas) about incidence and prevalence of the multiple sclerosis (MS) in Italy. We analysed 2011-2015 national data by correlating INPS database with ISTAT data. Materials: we assessed 10,725 MS invalids. We compared geographical distribution of MS patients with the Italian census.

Results. We found a MS mean incidence equal to 3.54 patients every 100,000 Italian residents. The female MS mean incidence was 4.52 versus the male mean incidence of 2.52 ($p<0.001$). MS incidence is growing up from 2011 to 2015. Incidence values, for 100,000 inhabitants, become from 2.8 to 4.0 (female from 3.6 to 5.2 and male from 1.9 to 2.7). During 2011-2015 period, the MS patients median age decreases of two years ($p<0.01$).

Conclusions. We couldn't calculate the MS prevalence because we do not have an official database managed by a national authority. This work wishes to be a stimulus to investigate more deeply and to promote public health in the care of the multiple sclerosis patients. We propose our work to realize a base more appropriate health planning on the national and regional territories for MS patients care. ***Clin Ter 2022; 173 (5):453-457 doi: 10.7417/CT.2022.2462***

Key words: *Multiple sclerosis, Italian incidence, epidemiology*

Introduction

If we analyse papers from scientific literature, we can find only estimate values about Italian national incidence of multiple sclerosis (MS). We searched the PubMed, SCOPUS, EMBASE and Web of Knowledge databases, conference proceedings, and reference lists of retrieved articles by key words "Italy – Italian - incidence – multiple sclerosis". There is some article about restricted areas, but we have not information about large part of Italian territory and their inhabitants (1-15). The article of Battaglia (13) reported "Applying these media to the Italian population in 2015, we obtained an estimate of more than 109,000 MS patients in Italy. Our estimates were higher than the latest published rates but consistent with the annual increase of prevalence due to incidence that exceeds mortality, with the increase of survival and, maybe, with the probable increase of incidence".

In Italy, we have only one official regional registry for multiple sclerosis in Sardinia (Regional Law 21/2012, article 1/c), but we do not have a governmental national registry for multiple sclerosis. There are only some private registers of association that collect data from a part of the Italian multiple sclerosis patients. These private databases have not requirements and officially decreed by Italian law (Decreto del Presidente del Consiglio dei Ministri. DPCM 3 marzo 2017 – published on the Gazzetta Ufficiale n.109/2017) (16).

In Italy, after an official diagnosis by a medical committee, all MS patients are classified "invalid people" by Italian "Servizio Sanitario Nazionale" (SSN - National Health System). All MS patients have free medical care.

The Italian "Istituto Nazionale di Previdenza Sociale" (INPS – National Social Security and Welfare Institution) provides social assistance and monthly allowance to MS patients without salary.

INPS is the only governmental institution that has a database with all Italian MS patients that had an official diagnosis by a medical committee. In our study, a legal medical commission, with neurologists and medical experts, valuated each patient and give each one a specific diagnosis based on ICD IX and ICD X.

Primary objective

The primary objective is to assess at a national level the variation in the incidence of MS patients recognized as invalid in the investigated period of 5 years

Secondary objectives

The secondary objectives of the study are the topographical distribution and incidence in the Italian regions of these patients and the assessment of medium age variation of this sample MS patients.

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Rationale

We used INPS database and official census tables by Italian Istituto Nazionale di Statistica (ISTAT - Italian National Institute of Statistics) to measure the Italian incidence of MS on years 2011-2015.

Materials

From 2011 to 2015 INPS databases we obtained data about patients with diagnosis of MS with ICD-9 equal to "340". We compared geographical distribution of MS patients with the Italian distribution of population extracted from official ISTAT census (17).

Results show tables of MS incidence stratified by years and Italian geographical regions. After that, we analysed changes in the five years and compared MS incidences with Italian (national, regional) areas using higher value as measure unit.

We have no INPS data about MS patients from Valle d'Aosta and Trentino Alto Adige.

Statistical analysis

General frequencies were evaluated on variables and ratios. Analysis of variance were performed for continuous variables. The value of $p < 0.05$ was used as statistically significant level. Wilcoxon rank test was used to display MS incidences.

Results

INPS 2011-2015 database shows 10725 Italian MS invalids (Law 102/2009). ICD-9 code "340" was used for selecting MS patients from all INPS invalids. MS patients were 7060 females (F) plus 3665 males (M) with a mean age of 51 ± 12 years (Table 1).

Data from present work show:

- Italian MS incidence is growing up from 2011 to 2015 (see Table 2 for details). Incidence values, for 100,000 inhabitants, become from 2.8 to 4.0 (female from 3.6 to 5.2 and male from 1.9 to 2.7) (Table 3).
- Sardinia has higher MS incidence. If we use data from Sardinia measure unit (100%), we can list a decrescent percentage of incidence in other Italian regions. We can also calculate a mean Italian incidence (Table 4). In this way we may indicate the regions that show an MS incidence higher than national mean value (Piemonte, Liguria, Sardegna, Lazio, Marche, Abruzzo e Molise) (Fig. 1).
- On 2011-2015 period, the median age of MS patients decreases two years. The difference is statistically significant (Fig. 2).

Table 1. Number of multiple sclerosis patients in Italy stratified by year and sex.

YEAR/SEX			
	FEMALE	**MALE**	**F + M**
2011	1133	564	1697
Row %	66.8	33.2	100.0
% Column	16.0	15.4	15.8
2012	1435	804	2239
Row %	64.1	35.9	100.0
% Column	20.3	21.9	20.9
2013	1477	754	2231
Row %	66.2	33.8	100.0
% Column	20.9	20.6	20.8
2014	1399	747	2146
Row %	65.2	34.8	100.0
% Column	19.8	20.4	20.0
2015	1616	796	2412
Row %	67.0	33.0	100.0
% Column	22.9	21.7	22.5
TOTAL	7060	3665	10725
Row %	65.8	34.2	100.0
% Column	100.0	100.0	100.0

Table 2. Italian regional distribution of MS patients on period 2011-2015

PERIOD 2011-2015			
	F	**M**	**F+M**
ABR = Abruzzo	229	95	324
BAS = Basilicata	66	34	100
CAL = Calabria	288	145	433
CAM = Campania	513	284	797
EMI = Emilia Romagna	454	248	702
FVG = Friuli Venezia Giulia	144	67	211
LAZ = Lazio	836	413	1249
LIG = Liguria	237	117	354
LOM = Lombardia	864	445	1309
MAR = Marche	234	106	340
MOL = Molise	77	32	109
PIE = Piemonte	638	341	979
PUG = Puglia	364	197	561
SAR = Sardegna	490	257	747
SIC = Sicilia	616	337	953
TOS = Toscana	352	177	529
UMB = Umbria	168	72	240
VEN = Veneto	490	298	788
TOTAL	7060	3665	10725

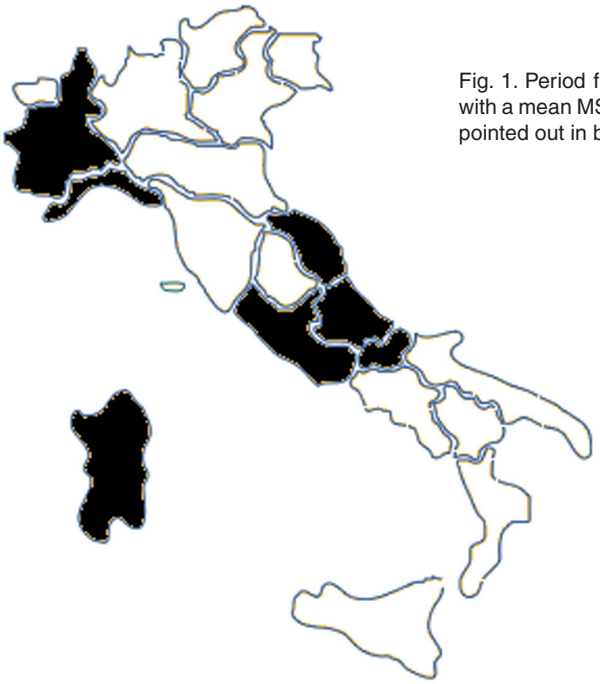

Fig. 1. Period from 2011 to 2015. On the map, the Italian regions with a mean MS incidence higher than national mean incidence are pointed out in black. (see table 2 for details)

Table 3. Incidence of MS patients stratified by year and sex

YEAR	FEMALE	MALE	F + M
2011	5.2	2.7	2.8
2012	4.6	4.0	3.7
2013	4.7	2.6	3.7
2014	4.5	2.6	3.5
2015	5.2	2.7	4.0

Table 4. Sardinia is the Italian region with highest incidence of MS patients. If we use data about Sardinian MS incidence as measure unit, we may classify the other regions and evaluate a list with a rank score of gravity of health situation. In bold the mean Italian MS incidence.

2011	2012	2013	2014	2015		total
SAR	SAR	SAR	MOL	SAR		SAR
MOL	LIG	MOL	SAR	MOL		MOL
BAS	PIE	MAR	ABR	ABR		ABR
UMB	MAR	LIG	CAL	UMB		PIE
SIC	UMB	LAZ	LIG	CAL		LAZ
LAZ	MOL	CAL	**ITALY**	**ITALY**		MAR
FVG	LAZ	PIE	LAZ	PIE		LIG
ITALY	CAL	ABR	PIE	MAR		**ITALY**
PIE	ABR	UMB	VEN	FVG		UMB
ABR	**ITALY**	**ITALY**	MAR	LIG		SIC
MAR	EMI	FVG	SIC	LAZ		FVG
EMI	SIC	SIC	CAM	SIC		BAS
CAL	TOS	EMI	LOM	BAS		VEN
VEN	BAS	VEN	PUG	PUG		EMI
PUG	VEN	TOS	FVG	VEN		PUG
CAM	FVG	LOM	EMI	CAM		TOS
LIG	LOM	BAS	TOS	TOS		CAM
TOS	PUG	CAM	UMB	TEMI		LOM
LOM	CAM	PUG	BAS	LOM		CAL

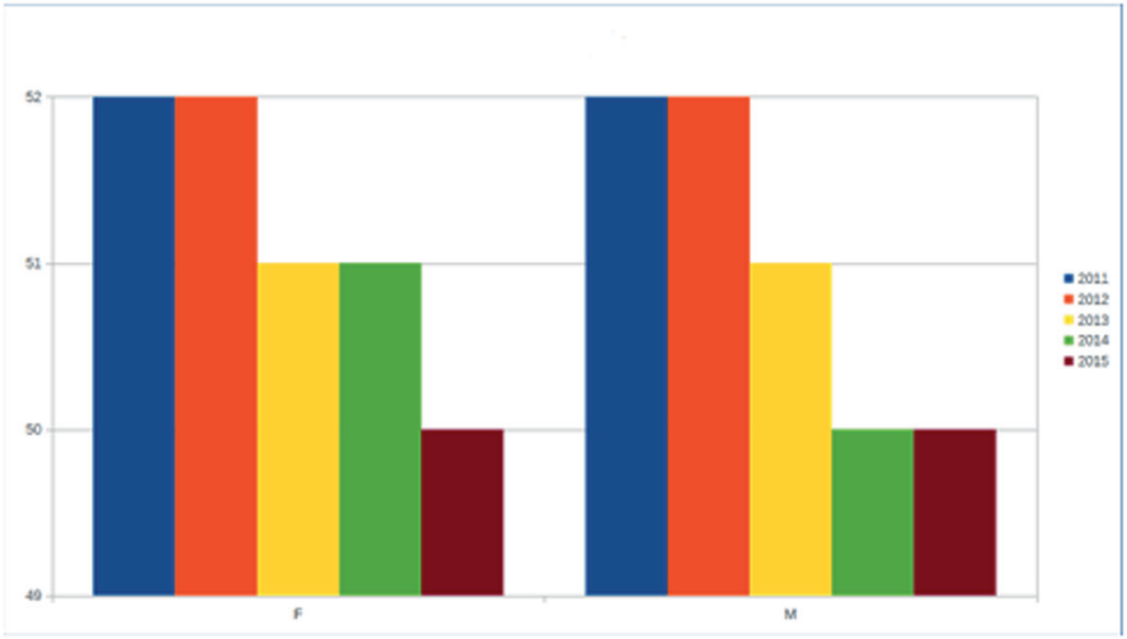

Fig. 2.- On period 2011-2015, difference in female median age (F) is statistically significant with p<0.001 (H di Kruskal-Wallis = 24,9046 with 4 df) On period 2011-2015, difference in male median age (M) is statistically significant with p<0.01 (H di Kruskal-Wallis = 16,3801 with 4 df)

Discussion

There are very few scientific papers about incidence and prevalence of the multiple sclerosis in Italy. We can find only data from specific and delimited areas.

Bargagli AM et al. (1) estimated MS prevalence in the Lazio region between 130.5 (for 100,000 male) and 167.9 (for 100,000 female). They have not data about incidence.

Dell'Avvento S et al. (2) estimated the incidence and prevalence of paediatric MS (patients aged 0-18) in northern Sardinia. They found respectively an incidence of 2.85 and a prevalence of 26.92 for 100,000 resident people.

Solaro C et al. (3) studied 1312 MS patients were residing in the province of Genoa. The overall crude MS prevalence rate was 148.5/100,000; 103.1/100,000 in men and 189.1/100,000 in women. The crude mean annual MS incidence rate was 6.6 cases/100,000 (4.4/100,000 men; 8.6/100,000 women).

Lucenti A et al. (4) reviewed 4987 patients from Sardinia (2007) and Sicilia (2002) in comparison with European and worldwide MS patients.

Nicoletti A et al. (5) reported MS incidence in Sicilia: 4-5 (Etna area) and 7 (Catania province) for 100,000 inhabitants on period 2000-2004.

Bellantonio P et al. (7) studied 47 MS patients from Campobasso province. Total MS prevalence was 91.02 for 100,000 (male 68.62 and female 111.68). MS incidence rates were: 10.84/100,000 (1996–2000) and 4.26/100,000 (2001–2005).

Gajofatto A et al. (8) showed, in 270 MS patients from Verona province, a prevalence of 106.6/100,000 (female 140.8/100,000 and 68.5/100,000 male).

Puthenparampil M et al. (9) observed MS patients in Padova province on decade 2000-2009. MS incidence rate for 100,000 inhabitants was 5.5±0.5 (7.4±0.8 for female and 3.5±0.6 for male). On 31 December 2009, the MS prevalence was 139.5/100,000 (192.0±9.5 for female and 83.9±6.3 for male).

Grimaldi LM et al. (10) estimated MS prevalence in Caltanissetta province on period 1970-2000. They valuated a MS prevalence from 69.2 (retrospective prevalence rate) to 165.8/100,000 population with incidence increasing from 2.3 to 9.2/100,000/year.

Ranzato F, et al. observed "The actual prevalence (80.5/100,000) and incidence (4.2/100,000) of MS in the province of Padova but these findings probably do not support a real increase in the frequency of MS in northeast Italy (14).

Sotgiu S, et al. reported "So far, our results indicate that variations at the level of territorial distribution and HLA-association are present which render MS heterogeneous even in this ethnically homogeneous population" of Sardinia, insular Italy. Eur J Neurol. 2002 (15).

Trojano M, The Italian multiple sclerosis register. Neurol Sci. 2019 (18) "The aim of this article is to present the current framework and network of the Italian MS register, including the methodology used to improve the quality of data collection and to facilitate the exchange of data and the collaboration among national and international groups." It is not an official Italian register. It is a MS patients' list of 140 centers associated to a private organization operating in Italy, but not on entire land.

All these works (and other papers cited in bibliography) demonstrate a very lack and insufficient data to determinate

Italian national MS incidence before our data on period 2011-2015.

On the other hand, our study analyses all MS patients from an official and governmental INPS database out from all Italian regions.

Results are showed by tables illustrating:

– Annual incidence of the MS patients on 100,000 Italian resident people stratified by sex.
– Analysis of frequency and geographical distribution of Italian MS patients.
– Ranking of incidence by year and by region with higher Italian regional MS incidence used as reference unit.
– On 2011-2015 period, the median age of MS patients decreases two years. The difference is statistically significant and shows the necessity of a rapid national project for the prevention of this disease.

Conclusions

In Italy, every region must prepare a three-years health planning to assess health budget and that for patient's care. About MS, the planning is prepared on a speculative assumption based on previous years financial reports. The analysis of real data would more useful than a hypothetical consensus.

Our results on annual incidence of the MS patients on 100,000 Italian resident people stratified by sex, the analysis of frequency and geographical distribution of Italian MS patients, on the ranking of incidence by year and by region with higher Italian regional MS incidence used as reference unit and on the decreases of two years median age of MS patients on 2011-2015 period show very interesting data.

We propose our work to realize a base more appropriate health planning on the national and regional territories for MS patients care.

To perform these goals, it will be useful a national governmental MS patients' database (see Decreto del Presidente del Consiglio dei Ministri. DPCM 3 marzo 2017 – published on the Gazzetta Ufficiale n.109/2017) to continue to the monitoring health aspects of these patients to planning for enhancing health care and social assistance in MS patients.

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