



Epidemiological characteristics of treated multiple sclerosis patients – Lublin experience (South-Eastern Poland)

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Abstract

Introduction and Objective. Multiple sclerosis (MS) is one of the most common neurological diseases affecting about 2.8 million people worldwide. The aim of this study is to analyze the current MS patient population in Lublin, south-east Poland, to enhance understanding of disease risk and treatment options.

Materials and Method. The study was conducted in 2023–2024 in the hospitals and neurological MS centres in the city of Lublin. Demographic and clinical data of adult patients with MS were collected from registries. The obtained results were compared with the results of previous studies, including a study conducted in Lublin in 2004.

Results. In Lublin, there are 1034 patients treated because of MS, approximately 70% are women. The mean age of patients is 46.25 ± 12.11 years. About 79.2% have a relapsing-remitting (RR) type of MS, 8.0% – secondary progressive (SP) type, 11.4% – primary progressive (PP) type, and 1.4% – rapidly evolving or severe type (RES). About 28% of RRMS patients are treated with modestly effective drugs (i.e. platform therapy), with mean disability assessed by the Expanded Disability Status Scale, EDSS=2.11, about 40% of these patients – with moderately effective drugs, with mean EDSS=1.99, and about 28% of RRMS patients with highly effective drugs (HED), with mean EDSS=2.53.

Conclusions. Compared to 2004, when 204 patients were recorded, the number of MS patients in Lublin has increased fivefold due to improved diagnosis, treatment, and rising MS incidence. Mean EDSS is higher in RRMS patients treated with HED compared to patients treated with moderately effective drugs, probably due to higher activity of MS and more rapid progression of disability in patients requiring more effective therapy. Further research is needed to deepen understanding of MS and its treatment.

Key words

risk factors, epidemiology, incidence, morbidity, prevalence rate, multiple sclerosis, MS treatment, modestly effective drugs, moderately effective drugs, highly effective drugs

INTRODUCTION

Multiple sclerosis (MS) is a chronic autoimmune disease during which multifocal demyelination of nerve fibres in the central nervous system occurs. This results in inflammation with subsequent neurodegeneration in the brain and spinal cord, manifesting clinically as a disability, classified according to the Expanded Disability Status Scale (EDSS). The disease occurs more commonly in women [1]. There are three main phenotypes of the clinical course of the disease: relapsing remitting (RRMS), secondary progressive (SPMS) and primary progressive (PPMS) [2]. A subtype of RRMS – rapidly evolving or severe MS (RES) – is also distinguished, which concerns treatment-naïve patients with at least two relapses in the first year, and at least one gadolinium-enhancing lesion on magnetic resonance imaging (MRI) at baseline [3].

The development of MS is influenced by a complex interaction between genetic and environmental risk factors;

however, the specific factor responsible for the onset of the disease remains unknown, although it is thought that genetic factors may increase the risk of developing the disease by up to 30% [1]. Nearly 100 regions in the genome associated with MS have been identified, most notably the HLA variant HLA-DRB1*15:01, HLA-A02:01 and genes encoding the α chains of IL-2 and IL-7 receptors [1]. Nevertheless, environmental factors, such as smoking, obesity, viral infections, vitamin D₃ deficiency and diurnal rhythm disorders, play important roles [1, 4].

Recently, the Epstein-Barr virus (EBV) infection has proved to be a triggering factor of MS development [5]. The involvement of EBV is reinforced by the heightened risk of MS following infectious mononucleosis, elevated levels of serum antibodies against EBV nuclear antigens, and the identification of EBV within demyelinated lesions. One of the most commonly used and efficacious therapies for MS involving anti-CD20 monoclonal antibodies, acts by reducing the population of memory B cells, which are the main location where EBV persists in the latent state [5].

Populations living north or south of the 40-degree parallel, are prone to vitamin D deficiency. This is the region where the

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highest prevalence of MS occurs, and among other countries, Poland belongs to the area of high MS prevalence [6]. Moreover, low vitamin D levels have been associated with an increased risk of MS [1, 6]. There is also substantial evidence indicating that cigarette smoking, both active and passive, poses a risk factor for the onset of MS. A 2022 study showed that the incidence of MS in people who had ever smoked increased by 41% compared to never smokers [7]. Elevated body mass index (BMI) and obesity are also significant factors. BMIs exceeding 30 kg/m² during adolescence not only elevate the risk of MS, but also correlate with heightened disability levels [8].

Disease-modifying therapies (DMTs) alter the course of MS by suppressing or modulating immune function. They mainly provide anti-inflammatory benefits during the relapsing phase, stabilize neurological condition, and delay the development of disability [9]. In Poland, there are currently two drug lines: the first-line treatment is indicated for patients with RRMS as an escalation therapy. The second-line treatment targets patients who have been treated with medications available in the first-line and have had an exacerbation of disease or have RES [10, 11]. Siponimod and interferon β -1b are approved in Poland for active SPMS, and ocrelizumab – the only approved DMT for the treatment of PPMS [9–12].

The Atlas of MS demonstrated that the prevalence of MS worldwide increased to 2.8 million (from 2.1 million in 2008) with an incidence rate of 35.9 per 100,000 people [13], while in Poland, in a study conducted by the Ministry of Health at the end of 2023, the prevalence was 58 878 and the incidence rate was 15.6 per 10,000 inhabitants [14].

OBJECTIVE

The aim of the study is to present the current state of the population of patients treated because of MS in the city of Lublin, south-east Poland, in order to increase understanding of the risk and possibilities of treatment of the disease. Factors that may have altered the morbidity rate and number of patients treated because of MS are also taken into consideration. In 2004, the results of an epidemiological study on MS in Lublin by dr Alicja Łobińska and prof. Zbigniew Stelmasiak [15] was compared with the results of the current study. This, in turn, made it possible to draw conclusions about the current treatment of MS in Lublin.

MATERIALS AND METHOD

The study was conducted in Lublin, south-east Poland, a city with a population of 329.4 thousand residents (data from the Statistical Office in Lublin). Data collection was carried out in 2023–2024 in neurological departments of University Clinical Hospital No. 4 and the Provincial Specialist Hospital in Lublin, where the Programme of Treatment of MS, refunded by the National Health System is available, as well as from other MS clinical research centres in Lublin. The patients were not only residents of the city, but also inhabitants of other cities, towns or villages in Poland, although the majority were from the Lublin province.

Demographic and clinical data of the patients were collected from medical registries, and the diagnosis of

MS based on McDonald criteria from 2005, 2010 or 2017, depending on the time of disease onset [16]. Duration of MS was calculated from the onset of each patient's disease; disability was assessed according to EDSS. The obtained results were subjected to epidemiological analysis.

The study was approved by the Ethics Committee of the Faculty of Medicine at the University of Lublin (Approval No. KE-0254/10/01/2022). All participants provided written informed consent in accordance with the Declaration of Helsinki.

Statistica v.13.3 (StatSoft) was used for the statistical analyses. In order to present the results obtained in a quantitative scale, descriptive statistical methods were used, i.e.: mean, median, standard deviation, interquartile range (IQR), minimum (Min), maximum (Max). In order to assess the consistency of the distribution of the studied variables with the normal distribution, the Shapiro-Wilk test was used, and the Mann-Whitney test used to assess the difference between the two groups. The Kruskal-Wallis ANOVA rank test and Dunn's test, as a *post-hoc* test, were used to assess statistically significant differences between multiple groups. Assessment of the relationship between variables was performed using Spearman's rank correlation. Results with $p < 0.05$ were considered statistically significant.

PubMed, Embase, and Google Scholar databases were utilized for systematic literature retrieval, using the following key words: multiple sclerosis, risk factors, epidemiology, prevalence rate, morbidity, incidence, MS treatment, modestly effective drugs, moderately effective drugs, highly effective drugs.

RESULTS

As the present time, there are 1,034 adult patients in the city of Lublin under care because of MS: 719 (69.54%) women and 315 (30.46%) men, with a female-to-male ratio of 2.28:1. Mean age of patients is 46.25 years, standard deviation (SD) – 12.11. The youngest patient is 19 years-old, while the oldest – 81.

The first symptoms of MS typically appeared in patients at the mean age of 33.68 years. For women, the mean age of disease onset was 33.54 years, and for men – 34.01 years. The earliest age at which first symptoms occurred was 11 years, while the oldest – 77. Individuals, on average, were 35.42 years old at the time of MS diagnosis; mean duration of the disease – 12.58 years.

Among the 1,034 diagnosed with MS, 819 patients (79.21%) have RRMS, 118 patients (11.41%) – PPMS, 83 patients (8.03%) – SPMS, and 14 patients (1.35%) – RES (Tab. 1 and 2).

Table 1. Characteristic of patients with multiple sclerosis (MS) treated in Lublin, results expressed in years (\pm standard deviation, SD), F-females, M-males

Mean age	46.25 (\pm 12.11)	F: 46.36 (\pm 12.19) M: 46.00 (\pm 11.96)
Mean age of MS onset	33.68 (\pm 11.20)	F: 33.54 (\pm 11.25) M: 34.01 (\pm 11.10)
Mean age at the diagnosis	35.42 (\pm 11.48)	F: 35.21 (\pm 11.57) M: 35.70 (\pm 11.29)
Mean duration of the disease	12.58 (\pm 8.14)	F: 12.82 (\pm 8.35) M: 12.02 (\pm 7.64)

Table 2. Numerical and percentage distribution of patients by multiple sclerosis (MS) phenotype (RRMS-relapsing-remitting MS, PPMS-primary progressive MS, SPMS-secondary progressive MS, RES-rapidly evolving severe MS)

Type of MS	Number of patients	Percentage of patients
RRMS	819	79.21 %
PPMS	118	11.41 %
SPMS	83	8.03 %
RES	14	1.35 %

The mean EDSS score for the entire population was 2.82, in women – 2.74 and in men – 3.01. When divided by MS phenotypes, the highest mean EDSS was 5.76 for SPMS patients, followed by 5.07 for PPMS patients, 3.18 for RES patients, and the lowest at 2.19 – for RRMS patients. Patients with the highest EDSS of 8.5 among those studied had either SPMS or PPMS, while patients with the lowest EDSS of 0 had the RRMS subtype (Tab. 3).

Table 3. Description of patients' disability according to the Expanded Disability Status Scale (EDSS) depending on the multiple sclerosis (MS) phenotype

EDSS						
	Type	Mean	Median	Minimum	Maximum	Standard deviation
RRMS		2.19	2	0	7	1.17
SPMS		5.76	6	2	8.5	1.19
RES		3.18	2.5	1	6.5	1.91
PPMS		5.07	5	1.5	8.5	1.56

RRMS-relapsing-remitting MS, PPMS-primary progressive MS, SPMS-secondary progressive MS, RES-rapidly evolving severe MS

Regarding age, the lowest mean EDSS of 1.70 was observed in the group aged under 30, while the highest mean EDSS was 4.93 in the 71–80 age group and 6.0 in the group aged over 81. The lowest EDSS of 0 was found in patients under 30 and those aged 41–50. The highest EDSS of 8.5 was recorded in patients aged 41–50 and 51–60 (Tab. 4).

Upon establishing diagnosis of MS, oligoclonal bands in the cerebrospinal fluid (CSF) were assessed in 48.16% patients: present in 445 patients (89.36% of all assessed samples of CSF) and absent in 53 patients (10.64% of all assessed samples of CSF) [17].

Currently, a range of drugs are used worldwide in the treatment of MS, which are also used for treating patients in Lublin (Tab. 5) [10].

Table 5. Distribution of treatment in RRMS patients under the care of MS centres in Lublin [9]

Treatment	Number of all patients	Percentage of patients
Modestly effective drugs: interferon β , pegylated interferon β , glatiramer acetate, teriflunomide	231	28.20 %
Moderately effective drugs: dimethyl fumarate, cladribine in tabl., fingolimod, ozanimod, ponesimod	332	40.53 %
Highly effective drugs: ocrelizumab, ofatumumab, natalizumab	231	28.20 %
No treatment	25	3.05 %

Disease modifying drugs in RRMS can be divided in three main groups: modestly effective drugs – drugs belonging to platform therapy, moderately effective drugs – dimethyl fumarate (DMF), cladribine in tablet form, and sphingosine receptor modulators, and highly effective drugs – HED (monoclonal antibodies) (Tab. 5) [9]. In Lublin, most patients are treated with moderately effective drugs (40.17%), and a comparable number of patients are treated with modestly effective and HED (28.20% each). The most commonly used drug for RRMS is DMF. Among the diagnosed patients, 25 are not receiving any treatment (3.05%). The most commonly used drug in Lublin for the treatment of the SPMS type is siponimod (40 of 83 SPMS patients, 48.19%) and for the RES type – natalizumab (nine of 14 RES patients, 64.29%).

Disability assessed by EDSS was statistically higher in the group of RRMS patients treated with HED, compared to those treated with modestly effective drugs ($p=0.0478$) and in compared to the group of patients treated with moderately effective drugs ($p<0.0001$). There was no statistically significant difference in EDSS between patients treated with modestly effective and moderately effective drugs (Tab. 6).

The age of patients was statistically higher in the group of RRMS patients treated with modestly effective drugs, compared to those treated with moderately effective drugs ($p<0.0001$) and in comparison to the group of patients treated with HED ($p<0.0001$) (Tab. 6). There was no statistically significant difference in age between patients treated with moderately effective drugs and HED (Fig. 1).

Duration of treatment was statistically longer in the group of RRMS patients treated with modestly effective drugs, compared with those treated with moderately effective drugs ($p<0.0001$), and in comparison to the group of patients treated with HED ($p<0.0001$) (Tab. 6). There was a statistically

Table 4. Distribution of patients by disease type, age-group, gender and disease activity across the Expanded Disability Status Scale (EDSS)

Age-group (years)	Patients under the care of Lublin MS centres												EDSS				
	Type of MS												Mean	Median	Minimum	Maximum	SD
	RR			SP			PP			RES							
F	M	Total	F	M	Total	F	M	Total	F	M	Total						
18–30	74	27	101	0	0	0	1	2	3	2	4	6	1.70	1.5	0	6.5	0.99
31–40	135	65	200	4	1	5	5	7	12	4	1	5	2.12	1.5	0	8.0	1.31
41–50	191	70	261	10	0	10	17	17	34	0	1	1	2.58	2.0	0.5	8.5	1.62
51–60	145	53	198	26	4	30	25	23	48	1	1	2	3.39	3.0	1.0	8.5	1.78
61–70	40	11	51	19	7	26	8	10	18	0	0	0	4.36	4.5	1.0	7.0	1.77
71–80	7	1	8	8	3	11	1	2	3	0	0	0	4.93	4.5	2.0	8.0	1.72
81–100	0	0	0	1	0	1	0	0	0	0	0	0	6.00	6.0	6.0	6.0	-

RRMS-relapsing-remitting MS, PPMS-primary progressive MS, SPMS-secondary progressive MS, RES-rapidly evolving severe MS, F-females, M-males

Table 6. Comparison of mean EDSS, mean age and duration of treatment between RRMS patients treated with modestly, moderately and high-efficacy drugs. Kruskal-Wallis test was used for statistical analysis

Group of drugs	n	Mean EDSS	Median	Min	Max	IQR	SD	p
Modestly effective drugs	231	2.11	2.00	1.00	6.50	1.00	0.98	0.0001
Moderately effective drugs	332	1.99	2.00	0.00	5.50	1.50	1.00	
Highly effective drugs	231	2.53	2.00	0.00	7.00	2.00	1.43	
Group of drugs	n	Mean patients' age	Median	Min	Max	IQR	SD	p
Modestly effective drugs	231	47.84	48.00	19.00	75.00	15.00	11.10	<0.0001
Moderately effective drugs	332	42.97	43.00	19.00	77.00	16.00	11.07	
Highly effective drugs	231	42.07	41.00	19.00	73.00	17.00	11.37	
Group of drugs	n	Mean duration of treatment	Median	Min	Max	IQR	SD	p
Modestly effective drugs	231	7.45	8.00	0.00	18.00	7.00	4.03	<0.0001
Moderately effective drugs	332	5.11	5.00	0.00	15.00	7.00	3.81	
Highly effective drugs	231	3.90	3.00	0.00	16.00	4.00	3.34	
Post-hoc Dunn comparison			Mean EDSS	Mean patients' age	Mean duration of treatment	p		
Modestly effective drugs	Moderately effective drugs	0.3212	<0.0001	<0.0001				
Modestly effective drugs	Highly effective drugs	0.0478	<0.0001	<0.0001				
Moderately effective drugs	Highly effective drugs	< 0.0001	0.9390	0.0012				

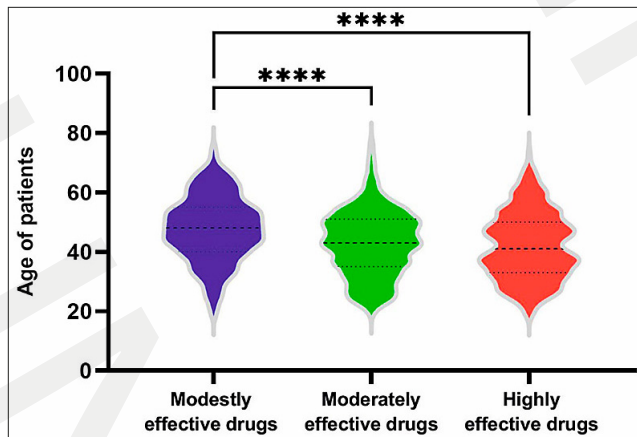


Figure 1. Comparison of mean age between RRMS patients treated with modestly, moderately and highly effective drugs. ****p <0.0001

significant difference in duration of treatment between patients treated with moderately effective drugs, compared to patients treated with HED (p=0.0012) (Fig. 2).

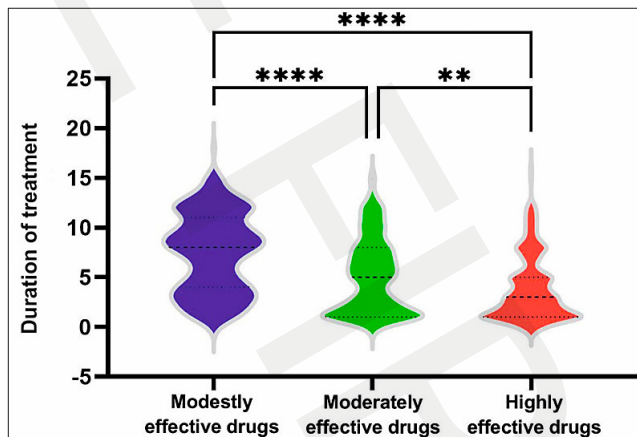


Figure 2. Comparison of duration of treatment between RRMS patients treated with modestly, moderately and highly effective drugs. ****p <0.0001, **p < 0.01

DISCUSSION

A 2004 study based on data from 1996–2000 indicated that only 204 people were diagnosed with MS at that time in Lublin, with an incidence rate of 1.7 and prevalence – 57.3 per 100,000 inhabitants [15]. The current study found 1,034 MS patients under the care of MS centres in Lublin. In a Polish study, according to the algorithm that required at least three administrative health claims from the National Health Fund with G35 ICD-10 diagnosis, age-adjusted European standardized MS incidence and prevalence in Poland in 2019, estimated 6.6 and 131.2/100,000 inhabitants, respectively, and in Lublin – 6.13 and 156.37/100,000 inhabitants. From 2014 – 2019, a significant trend in an increasing prevalence and decreasing incidence of MS was observed, although compared to the results from 2004, the incidence has increased a few times during 15 years [18]. Today, as 20 years ago, females suffer from MS approximately twice as often as males. Comparing two cohorts from 2004 and 2024, there is no significant difference between the percentage of each gender and female-to-male ratio [15]. Based on these results, a trend can be perceived in the population of Lublin of an increasing MS treatment exposure through two decades. During that time, the number of patients under the care of MS centers in Lublin has increased about five times [15]. This increasing trend has been observed not only in Poland, but also worldwide [13]. Based on the Atlas of MS, three main potential reasons for this change were identified from the respondents: improvement in MS diagnosis (60%), improved MS treatment and support (56%), and improved ability in counting the number of people with MS (53%) [13].

The new McDonald criteria, updated in 2005, 2010 and 2017, with revisions, allow a definitive diagnosis of MS to be made more quickly than in the past. A diagnosis of MS can be established in patients previously experiencing a clinically isolated syndrome – a single episode of neurologic symptoms, if their brain MRI reveals demyelinating lesions, and the patient fulfills the criteria of dissemination in space (DIS) and time (DIT), and the other alternative diagnoses are excluded. Since the 2017 revision of the McDonald criteria,

the presence of oligoclonal bands in the CSF has been used as a substitute for the DIT [16].

The scientific investigation of MS has significantly advanced due to the utilization of MRI and clinical management, which have resulted in better detection of the disease and its increased prevalence [16]. Additionally, since the publication of the 2004 study [15], a greater number of medications have become available.

In Poland, MS centres are localized in big cities which means that many patients have to travel to MS centers in order to obtain refunded immunomodulating drugs. This study shows that most patients are treated with various medications (17 different types of medications are available). In 2004, only interferon β and glatiramer acetate were available. In 2024, the drugs used in Poland in the treatment of RRMS patients included so-called 'platform' therapy with low-to-moderate efficacy, the same as injected drugs: interferons β and glatiramer acetate, and oral drugs: DMF and teriflunomide. These therapies have a well known and relatively safe risk profile and in a so-called escalation strategy are chosen as an initial treatment [19]. If activity of disease persists despite the regular use of the mentioned drugs, the therapy is escalated to the higher efficacy drugs – monoclonal antibodies, sphingosine-1-phosphate-receptor modulators, and cladribine in tablets [10, 19].

The drugs used in Lublin include platform therapy and HED almost equally. Newly-diagnosed patients are treated according to recommendations, with first-line drugs. If negative prognostic factors exist in a patient, neurologists usually begin therapy with HED or switch former therapy to administration of these drugs [9,10]. This could explain the large number of patients treated with HED. When a patient fulfills criteria for the diagnosis of RES, natalizumab, fingolimod, cladribine in tablets or alemtuzumab can be used [10]. In Lublin, most patients with RES are treated with natalizumab. According to the results of studies, this drug exerts its action more quickly than other HED [9]. In Lublin, many RRMS patients are treated with DMF, which is a good option that enables the treatment of young females until conception, without suspending the treatment before a planned pregnancy. As young women constitute an important group of MS patients, this could explain the high percentage of patients treated with this drug [20].

Mean EDSS of RRMS patients treated with HED is significantly higher than EDSS of patients treated with modestly effective drugs. Patients treated with HED are also younger and the duration of their treatment is shorter, which could be associated with a more severe activity of MS and more rapid progression of disability in these patients. On the other hand, the worst neurological condition, associated with the highest EDSS, are experienced by patients with SPMS and PPMS, with a usually long duration of the disease in the case of SPMS patients. Additionally, in the case of PPMS patients, the mean EDSS is higher compared to the other patients, as the progression of disability is more rapid in this type of clinical course of MS [2, 9, 12].

Today, new drugs are available for patients as well as some new therapies appearing on the horizon. In Lublin, patients are treated both with platform therapy and HED. Since November 2022, some high and moderate efficacy drugs have been refunded for Polish RRMS patients – ofatumumab, ozanimod and ponesimod, and July 2023 – cladribine in tablets in first line treatment [11, 21].

Compared to the results of a study published in 2020 in the United States [22], glatiramer acetate and DMF were the most commonly used first-line treatments, representing almost 62% of patients on DMTs. Treatment diversity increases after the first therapy, with DMF, teriflunomide, ocrelizumab, fingolimod, and natalizumab each being prescribed to over 10% of patients as the second drugs. Among patients who progressed to at least three distinct DMTs, ocrelizumab emerged as the most frequently chosen treatment. According to a 2022 publication in Germany [23], also the most commonly used DMT was DMF with a prescription rate of 97.5 per 1,000 MS patients, followed by glatiramer acetate. In comparison to the above data, in another study published in 2021 in Taiwan [24], the majority of patients (64.9%) received interferon β -1a as the first-line treatment. Interferon β -1b was the second most commonly used treatment, although there was a declining trend in its prescription as an initial therapy during the study period. Among those patients who were prescribed the second-line treatment, 63.4% received fingolimod [24].

As the world has become a global village with access to the internet and therefore, to knowledge, patients are more aware of the treatments available and want to be treated, and more persistent in their therapy. As a consequence of more common and earlier diagnosis, the survival of patients has lengthened, resulting in an increase in prevalence [13]. In the current study, RRMS patients in the group aged 41–50 years, and SPMS and PPMS patients in the group aged 51–60 years, constituted the biggest group. This means that the population of MS patients is increasing in age and the issue of appropriate treatment of older MS patients is becoming a matter of urgency [25].

A decreasing vitamin D₃ level in the Polish population [6] may also have an impact on the increasing prevalence of MS [1, 6]. The extensive integration of motorization and automation in both daily activities and occupational tasks have led to a reduction in energy expenditure, which has resulted in excessive fat accumulation and rising obesity in Poland [8], which, as mentioned earlier, is a risk factor for MS [1, 8]. All these factors are responsible for the increase in the population of MS patients under the care of MS centres in Lublin.

Limitations of the study. The patients were not assessed prospectively, i.e. the disability of patients treated with different drug groups over time was not evaluated. To date, the data obtained have not been compared with those from other MS centres in Poland, which is another limitation. Other parameters related to treatment efficacy, such as MRI, relapse or cognitive function, were not evaluated. This will be rectified in future studies. However, the focus was mainly on the epidemiological aspects of the study, assessing a large cohort of MS patients treated in Lublin. Such comparisons could provide valuable insights into regional variations in patient characteristics, treatment approaches, and clinical outcomes. Addressing this gap will require future investigations, ideally conducted within the framework of a multicentre study, to ensure broader generalizability and enhance the external validity of the findings.

CONCLUSIONS

Compared to data from 2004, the rate of patients under the care of MS centres in Lublin has increased about five times. Factors that are responsible for this include an improvement in MS diagnosis and treatment, improved ability to count patients, as well as the increased incidence of the disease. Patients in the age group 41–50 years (RRMS patients) and 51–60 years (SP and PPMS) constitute the biggest group of all. Most RRMS patients in Lublin are treated with moderately effective drugs. This reflects the degree of disease activity in RRMS patients as disability assessed by EDSS is the highest in patients treated with HED. This could be explained by tailored treatment, adjusted to the rate of disease activity in MS patients. Further studies are necessary to increase awareness and understanding of MS and its treatment among medical practitioners and the general public.

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