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ABSTRACT

of the dissertation for the degree of Doctor of Philosophy

EPIDEMIOLOGICAL AND CLINICAL FEATURES OF MULTIPLE SCLEROSIS IN THE CITY OF BAKU

Speciality: 3223.01 – Nervous diseases

Field of science: Medicine

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The dissertation work was performed at the Department of Neurology and Clinical Neurophysiology, Azerbaijan State Advanced Training Institute for Doctors named after. A. Aliyeva

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GENERAL DESCRIPTION OF WORK

Relevance and degree of development of the topic. Multiple sclerosis (MS) is a chronic autoimmune, demyelinating disease of the central nervous system, usually characterized by a progressive course and multiple lesions of the brain and spinal cord¹. The disease affects the able-bodied, often young population, seriously reducing their quality of life, alienating them from social activities, and therefore becomes not only a medical, but also a socio-economic problem, the solution of which requires significant economic resources^{2;3}. Common clinical and neurological manifestations of MS include visual disturbances, loss of coordination and balance, motor and sensory disturbances, fatigue, pain, bladder dysfunction, cognitive dysfunction and mood changes. Most often, patients with MS enter the progressive phase of the disease one to two decades after the onset of the disease. The pathophysiology of MS is complex and is considered an autoimmune disease caused by autoreactive CD4 and helper T cells causing demyelination.

Genetic and infectious factors, vitamin D deficiency, obesity, smoking, and some other modifiable factors associated with an increased risk of developing MS have been described in many studies. According to various medical sources, early clinical signs of MS are first detected between the ages of 20 and 40 years^{4:5}.

¹Stephen,L.H., Bruce,A.C.C. Treatment of Multiple Sclerosis: A Review // The American Journal of Medicine, - 2020. 133(12), - p.1380-1390.

 $^{^2}$ Thomson., A. New insights into the burden and costs of multiple sclerosis in Europe: Results for the United Kingdom /A.Thompson, G.Kobelt, J.Berg [et al.] // Multiple Sclerosis Journal, - 2017. 23,3. – p. 204-216.

³ Vermersch, P. The patient's perspective: How to create awareness for improving access to care and treatment of MS patients / P.Vermersch, A.Faller, D.Czarnota-Szalkowska [et al.] // Multiple Sclerosis Journal, - 2016. 22,2, -p. 9-17.

⁴Yamout, B.I. Epidemiology and phenotypes of multiple sclerosis in the Middle East North Africa (MENA) region / B.I.Yamout, W.Assaad, H.Tamim [et al.] // Multiple Sclerosis Journal – Experimental, Translation and Clinical, - 2020. 6 (1), -p.1-6.

Recent decades have been characterized by the development and introduction into practice of a large number of drugs that modify the course of multiple sclerosis, which has led to a significant improvement in the possibility of treating this disease and, accordingly, to a decrease in the degree of disability and long-term ability to work in patients⁶;⁷

Over the past 20 years, throughout the world, an increase in the prevalence of MS has been recorded, characterized by changes in both epidemiological indicators and clinical features of the disease. However, along with a true increase in incidence, according to many authors, the reason for the increase in the prevalence of MS is associated with improved diagnostic capabilities, identification of cases of "mild course" of the disease and improved treatment methods⁸.

Scientific research conducted in Azerbaijan was devoted to the study of individual parts of the genetics, pathogenesis, diagnosis, clinical picture and neurophysiological features of MS 9;10;11;12

⁵ Romero-Pinel,L. The age at onset of relapsing-remitting multiple sclerosis has increased over the last five decades / L.Romero-Pinel, L.Bau, E.Matas [et al.] // Mult Scler Relat Disord, - 2022. 68:104103

⁶Cohan, S.L. Interferons and Multiple Sclerosis: Lessons from 25 Years of Clinical and Real-World Experience with Intramuscular Interferon Beta-1a (Avonex) / S.L.Cohan, B.A.Hendin, A.T.Reder [et al.] // CNS Drugs, - 2021. 35(7), - p. 743-767.

⁷Reder,A.T., Feng,X. How type I interferons work in multiple sclerosis and other diseases: some unexpected mechanisms // Journal of Interferon & Cytokine Research, - 2014. 34(8), - p. 589-599.

⁸ Jia, D., Zhang, Y., Yang, C. The incidence and prevalence, diagnosis, and treatment of multiple sclerosis in China: a narrative review // - Neurological Sciences, - 2022, 43(8), -p.4695-4700.

⁹ Байрамова, Р.А. Клиническая характеристика рассеянного склероза в Азербайджане: /автореферат диссертации на соискание ученой степени кандидата медицинских наук./ - Баку, 1973. - 16 с.

To date, large-scale epidemiological studies on MS have not been conducted, and there are still no data on the prevalence and incidence of MS in Azerbaijan, including the city of Baku.

Due to the special medical and social importance of this disease, in 2012 the President of the Republic of Azerbaijan issued a decree approving the "State Program for the treatment, prevention and control of Multiple Sclerosis," which made it possible to study both the epidemiological and clinical features of the disease in Azerbaijan.

Considering the above, the importance of studying the epidemiology of MS, clinical, neurological and therapeutic aspects ensure the relevance of the study.

Object and subject of research. The object of the study were residents of the city of Baku with a confirmed diagnosis of multiple sclerosis. The subject of the study was to study epidemiological indicators, clinical aspects and radiological features of multiple sclerosis in residents of the city of Baku, as well as the results of specific treatment with a drug that changes the course of multiple sclerosis.

Purpose of the study. Study of the epidemiological and clinical features of multiple sclerosis among the adult population of the city of Baku.

¹⁰Ширалиева, Р.К. Диагностика и патогенетические механизмы рассеянного склероза (клиническое, компьютерно-томографическое, иммуногенетическое, иммунологическое и биохимическое исследование): /автореферат диссертации на соискание ученой степени доктора медицинских наук./ - Москва, 1995. – 34 с.

¹¹ Несруллаева, Н.А. Клинико-нейрофизиологическое исследование аксональной дегенерации и ремиелинизации у больных рассеянным склерозом с оптическим невритом в дебюте: / автореферат диссертации на соискание ученой степени доктора философии по медицине./ - Баку, 2015. – 22 с.

¹² Mirzəyev, A.H. Dağınıq skleroz zamanı baş beyinin maqnit-rezonans tomoqrafik morfometriyasının diaqnostik və proqnostik əhəmiyyəti: / tibb üzrə fəlsəfə doktoru dis.avtoreferatı./ - Bakı, 2023.- 30 s.

Research objectives:

1. To determine the prevalence of MS among the adult population of Baku city.

2. To assess the incidence of MS among the adult population of the city of Baku.

3. To determine the age specificity of the manifestation and development of MS depending on the medical and social characteristics of patients.

4. To study the clinical features and MRI characteristics of MS depending on the forms of the clinical course of the disease.

5. To evaluate the results of specific treatment of patients with multiple sclerosis.

Research methods.

- Epidemiological research methods.
- Clinical and neurological research methods using a standard neurological examination and the EDSS scale.
- Neuroimaging research methods: MRI (magnetic resonance imaging).
- Statistical research methods.

The main provisions of the dissertation submitted for defense. The conducted research allowed us to put forward the following provisions for defense.

- 1. The prevalence of MS in the city of Baku increases from 2013 to 2020, mainly due to the increase in this indicator among women.
- 2. The incidence of MS in the city of Baku in the period 2013-2019 was relatively stable, while this indicator among women had a progressive increase, while among men it steadily decreased.
- 3. In women and men, the disease manifests itself at approximately the same age. Patients born in the city of Baku fall ill at an earlier age than patients born in the regions of Azerbaijan.
- 4. The majority of patients with multiple sclerosis are patients with relapsing multiple sclerosis who are under the age of

40 years. Over 40 years of age, patients with progressive multiple sclerosis predominate.

5. Beta interferon 1a delays the development of the disease during the first 2 years of treatment.

Scientific novelty of the research. For the first time, epidemiological indicators of multiple sclerosis among the adult population of the city of Baku have been studied. The age specificity of the manifestation and development of MS was assessed depending on the medical and social characteristics of the patients. The clinical and neuroimaging features of MS in various disease phenotypes were studied. The effectiveness of specific treatment for various disease phenotypes was assessed.

The theoretical significance of the study lies in the study of the epidemiological and clinical features of multiple sclerosis in the city of Baku, which will allow us to assess the prevalence of the disease and the annual dynamics of growth in the number of patients, and determine the clinical specificity of multiple sclerosis depending on the medical and social characteristics of patients.

The practical significance lies in the fact that the epidemiological data obtained as a result of the study will make it possible to update the role of primary health care structures in the early detection of patients with multiple sclerosis, the organization of medical care (advisory, medicinal, rehabilitation) and optimization of patient treatment issues.

Research testing and application. The initial discussion of the dissertation was held at an inter departmental meeting (department of Neurology and clinical neurophysiology, department of Organization and management of healthcare with pedagogy, psychology, and foreign language courses, department of Radiation therapy courses and radiation diagnostics) (10.07.2024, protocol Nº 12) of the State Advanced Training Institute named after A. Aliyeva. Approbation of the work was carried out at the Approbation Seminar of the Dissertation Council ED 2.05 (17.01.2025, protocol N°5), Azerbaijan Medical University.

The main provisions of the dissertation were presented and discussed at: VI Conference of Azerbaijani Neurologists (2017);

scientific and practical conference dedicated to the birthday of National Leader Heydar Aliyev (2017); scientific-practical conference of young scientists and residents dedicated to the birthday of National Leader Heydar Aliyev (2019); 4th International Neurological Congress of Turkic-Speaking Countries (2019); online conference dedicated to World Multiple Sclerosis Day (2021); scientific and practical conference dedicated to the birthday of Aziz Mammadkerim ogly Aliyev (2022); international scientific and practical conference dedicated to the 100th anniversary of National Leader Heydar Aliyev (2023); 5th International Turkic World Congress on Multiple Sclerosis (2023); scientific and practical conference dedicated to the birthday of Aziz Mammadkerim oglu Aliyev (2024); 5th International Neurological Congress of Turkic-Speaking Countries (2024).

Publications. Nineteen scientific papers have been published on the topic of the dissertation, including six abroad.

Implementation of results. The results of the research are being applied in the Departments of Neurology and Clinical Neurophysiology, as well as in the Healthcare Organization and Management courses with Pedagogy, Psychology, and Foreign Language courses at the Azerbaijan State Institute for Advanced Training of Doctors named after. A. Aliyev, in the Department of Neurology at Azerbaijan Medical University, at the M. Mirqasımov Republic Clinical Hospital, and also at the City Polyclinic No. 1 named after A. Kazımov.

Structure and scope of the dissertation. The dissertation work is presented on 163 pages of computer text, illustrated with 42 tables, 22 diagrams. Consists of an introduction (8291 character), literature review (49338 character), materials and methods (14315 character), results of own research (Chapter III - 20490 character, Chapter IV - 40121 character, Chapter V – 10580 character, Chapter VI - 6677 character) discussion of the results Chapter VII – 55858 character), conclusions (2543 character), practical recommendations (880 character) and bibliographic index. The bibliographic index includes 10 domestic, 19 Russian-language and 106 English-language sources of literature. The total number of characters (not

including spaces, tables, figures, diagrams and references) is 209013 characters.

MATERIAL AND METHODS OF RESEARCH

The research work was carried out on the basis of the Department of Neurology and Clinical Neurophysiology of the Azerbaijan State Institute for Advanced Training of Physicians (ASIATP) named after. A. Aliyev in two neurological departments of the Republican Clinical Hospital (RCH) named after Academician M. Mirgasymov. During the period from July 1, 2013 to June 30, 2020, 559 patients aged 15 to 65 years were examined and dynamically observed, of which 167 (29.9%) were men, 392 (70.1%) women. The average age of patients at initial visit to the RCH was 34.36±0.4 years, and the median was 33.0 (27.0-41.0) years; among men, the average age was 33.3±0.8 (Me=32.0 (26.0-41.0)) years, and for women 34.8±0.5 (Me=33.0(27.0-41.5)) years. Of the total number of studied patients living in the capital, 318 (56.9%) people were born in the city of Baku (Rv.B), and 241 (43.1%) were born in other cities and regions of Azerbaijan (Rv.R). Among Rv.B patients, the number of women was 215 (67.7%), men 103 (32.4%), and among Rv.R, respectively, 177 (73.4%) and 64 (26.6%), respectively. Married (family) patients accounted for 343 (61.4%), and 216 (38.6%) were unmarried (non-family). The number of family patients predominated among both men and women. Among those examined, 229 (41.0%) patients with MS were employed, 287 (51.3%) did not work, and 43 (7.7%) had varying degrees of disability. In the group of nonworking MS patients there were more men and women (47.9% and 52.8%, respectively), compared to the groups of workers and those with disabilities (43.1% and 40.1%; 9.0% and 7.1%). McDonald's MS diagnostic criteria (2010 modification) were used to confirm the diagnosis of MS¹³. According to the criteria, confirmation of the

¹³Polman, C.H. Diagnostic criteria for multiple sclerosis: 2010 revisions to the McDonald criteria / C.H.Polman, S.C.Reingold, B.Banwell [et al.] // Annals of Neurology, - 2011. 69(2), -p.292-302.

diagnosis was based on the following: dissemination in space and dissemination in time. All patients were given registration forms, including information about the patient: social characteristics gender, age, marital status, social status (education, profession, work); medical characteristics - date of onset of the disease, diagnosis and initial treatment, duration of remissions, clinical nature of the onset and course of the disease, data from additional examination methods (MRI of the brain and spinal cord, spinal puncture, laboratory examinations, ophthalmological examination data). treatment adopted. Anamnestic data were taken into account and recorded exclusively based on information obtained from previous medical documents (outpatient medical record, inpatient medical record, discharge summary). A neurological examination was carried out both during the initial visit of patients to the center and in all subsequent cases of exacerbation. In addition to the standard neurological examination, a special expanded scale for assessing the degree of disability EDSS (Expanded Disability Status Scale) was used, intended specifically for the examination of MS patients. This scale makes it possible to determine the clinical effectiveness of the therapy. The EDSS scale scores from 0 to 10. Scores from 0 to 4.5 refer to people who can move and care for themselves independently. More than 7 points – a deep degree of disability.

The radiological examination was carried out according to the protocol for examining MS patients in the appropriate modes of a magnetic resonance imaging installation with an electromagnetic induction of at least 1.5 Tesla. The study of the conduction status of the visual pathways was based on the results of visual evoked potentials. Interpretation of responses was accomplished by assessing response amplitude and peak time-latency. If it was necessary to clarify the diagnosis of MS, a lumbar puncture was performed to determine oligoclonal antibodies that destroy the myelin sheath of nerve fibers of the central nervous system¹⁴.

¹⁴Solomon,A.J., Naismith,R.T., Cross,A.H. Misdiagnosis of multiple sclerosis: Impact of the 2017 McDonald criteria on clinical practice // Neurology, - 2019. 92(1), - p.26-33.

In this work, when studying epidemiology, the following statistical indicators were used: Prevalence is an indicator that determines the prevalence of registered diseases, both newly emerging and pre-existing, for which there were initial complaints in the calendar year. Incidence is an indicator that determines the number of diseases registered for the first time in a calendar year (new cases). The visibility indicator is used to analyze the degree of the phenomenon being studied over time, which shows how many times or how many times this indicator has increased or decreased over a certain period of time. Direct risk is the difference in morbidity rates between individuals exposed and not exposed to a risk factor. Relative risk is the ratio of incidence rates in one group of people to another group of people.

Statistical processing of all data was performed on a personal computer, using the statistical data analysis package Statistica 10,0 for Windows, graphic drawings on Microsoft office Excel 2007. Depending on the distribution of data, parametric and non-parametric research methods were used. In particular, for independent samples with identical scales from nominal factors and responses, the Chisquare test was used; for quantitative non-normal distribution. Spearman's correlation; for unequal scales with non-normal distribution, analysis was carried out using the Mann-Whitney U test and the Kruskal-Wallis test, and if the distribution was normal, Student's T test for independent samples and ANOVA were used. For dependent samples, the Wilcoxon test was used for quantitative scales, and for nominal scales, the Cochran test was used. Quantitative indicators were assessed by calculating average values with an error of the mean (M±m) and median with quartiles (Me (Q1-Q3)). The reliability of the obtained data was accepted at p < p0.05.

RESEARCH RESULTS AND DISCUSSION

According to our study, from July 1, 2013 to June 30, 2020, 559 patients diagnosed with multiple sclerosis were registered in the city of Baku. Considering that since the end of 2019 the whole world has been engulfed by the COVID-19 pandemic, due to which a

number of restrictions on movement within the city have been established in Azerbaijan, starting in March 2020, an analysis of the prevalence rate in the city of Baku was carried out from 2013 to 2020. According to the State Statistics Committee of Azerbaijan, by January 1, 2020, 2,293,047 residents lived in Baku and, accordingly, in 2019, the prevalence of MS was 23.3 patients per 100,000 population. The medical literature on the epidemiology of MS indicates a certain increase in the prevalence of MS around the world¹⁵. To determine the dynamics of MS prevalence, we analyzed this indicator for each year of the study. It was found that in 2013 the prevalence corresponded to 10.2 patients per 100,000 population. In subsequent years, 2014 to 2019, there was an increase in prevalence from 12.3 to 23.3patients per 100,000 population (Table 1).

Currently, the high-risk zone for MS corresponds to more than 50 cases, the medium-risk zone - from 10 to 50 cases, and the low-risk zone - less than 10 cases per 100,000 population.

Taking into account the results of our study, we can classify the city of Baku as an area of medium risk for developing MS.

There was an increase in the prevalence of the disease among both women and men in the study years we studied. If, by 2019, the prevalence of MS among women was 32.5 (CI: 29.2-35.9) patients per 100,000 population, then the same figure for men corresponded to 14.0 (CI: 11.8-16.24) patients (p<0.05).

Moreover, if in 2013 the ratio of women to men was 1.7:1, then by the last year of the study this figure reached 2.3:1 (Picture 1).

The prevalence rate prevailed in the age group of 30-39 years and corresponded to 46.2 cases per 100,000 population. In the group of 20-29 and 40-49 years old, the prevalence corresponded to 35.8 and 38.9 patients per 100,000 population. The prevalence curve of MS by age group tended to increase, starting from 20 years of age,

¹⁵Walton, C. Rising prevalence of multiple sclerosis worldwide: Insights from the Atlas of MS, third edition / C.Walton, R.Kong, L.Rechtman [et al.] // Multiple Sclerosis Journal, - 2020. 26(14), -p. 1816-1821.

reaching a maximum at 30-39 years of age, with a further decrease in this indicator by 60 or more years of age.

Year	Number of patients	Population	Prevalence DS per 100,000 population, ^{0/0000} (CI)
2013	222	2181854	10,2 (8,84-11,56)
2014	271	2204230	12,3 (10,82-13,78)
2015	335	2225838	15,1 (13,46-16,74)
2016	386	2245790	17,2 (15,46-18,94)
2017	433	2262560	19,1 (17,28-20,92)
2018	483	2277500	21,2 (19,28-23,12)
2019	535	2293047	23,3 (21,3-25,3)

Table 1. Prevalence of MS in the Baku city (2013-2019)

Similar dynamics in the prevalence of MS depending on age are observed in almost all epidemiological studies conducted around the world ¹⁶. At the same time, the data obtained for 2019 show that in the age group under 19 years of age the ratio of women: men correspond to 0.9:1 with a slight predominance of men, but from 20 to 50 years of age there is an increase in this indicator in favor of women from 1.9:1 to 2.9:1.

A study of the prevalence in two groups of districts of the city of Baku (central and embankments) revealed that the prevalence of MS, in 2019, in the central districts of Baku city was statistically significantly higher than in the embankments (26.1 and 19.3 per 100,000 population, respectively).

¹⁶ Correa-Diaz, E.P. Prevalence of multiple sclerosis in Cuenca, Ecuador / Edqar Patricio Correa-Diaz, Maria Angelica Ortiz, Ana Maria Toral [et al.] // Multiple Sclerosis Journal – Experimental, Translational and Clinical, - 2019 Oct-Dec; 5(4): 2055217319884952. – p. 1-9.



*- statistically significant difference (p < 0.05) between women and men

Picture 1. Prevalence of multiple sclerosis in the city of Baku, among women and men, and their ratio.

This trend has been maintained throughout the entire time continuum since 2013, which is most clearly revealed in the central: embankment ratio. So, from 2013 to 2019, this figure remained in the range from 1.3:1 to 1.5:1.

We analyzed the incidence of MS over time, for each calendar year from 2013 to 2020. The incidence rate of MS in the city of Baku for 7 years (2013-2019) remained relatively stable within the range of 2.1 - 2.9 per 100,000 population (Table 2).

Morbidity rates for men and women in the city of Baku show different dynamics. If, in men, starting from 2013, the incidence decreased from 2.1 to 0.9 cases per 100,000 population, then in women this figure increased over the years from 2.7 to 3.7 cases per 100,000 population. Accordingly, the ratio of women to men increased from 1.3:1.0 to 4.1:1.0. Thus, according to our data, the average incidence during the study period for men was 1.3 ± 0.4 , for women 3.4 ± 0.6 , and the ratio of women to men was 2.6:1.0.

The presence of a varied clinical picture during the manifestati-

on of multiple sclerosis, spontaneous remissions, the absence in some cases of MRI signs confirming MS, a huge number of other diseases simulating MS and the so-called human factor, such as insufficient awareness of doctors about the nature of the clinical course of the disease, as well as the inattention of most patients to the condition their health in the presence of minimal complaints leads to a delay in diagnosis.

(2013-2019)						
Year	Number of	Population	Incedece			
	patients		DS per 100,000			
			population ⁰ / ₀₀₀₀ (CI)			
2013	53	2181854	2,4 (1,8-3,0)			
2014	49	2204230	2,2 (1,6-2,8)			
2015	65	2225838	2,9 (2,1-3,7)			
2016	55	2245790	2,4 (1,8-3,0)			
2017	48	2262560	2,1 (1,5-2,7)			
2018	50	2277500	2,2 (1,6-2,8)			
2019	53	2293047	2,3 (1,7-2,9)			
Averag	ge annual incidence	over 7 years	2,4 (1,8-3,0)			

 Table 2. Incidence of multiple sclerosis in the city of Baku

 (2013-2019)

The results of our study showed that the patients we studied at the time of the first symptoms of the disease represented a heterogeneous group. Thus, about 41.0% of patients, at the first symptoms of the disease, went to medical institutions, of which 33.6% were diagnosed with MS and began appropriate treatment, while 7.0% of patients were not suspected of MS and, accordingly, were treated other diagnoses were made. 59.4% of patients, despite existing complaints, for various reasons, did not go to medical institutions. By the second attack of the disease (2.5 years later), the representation of patients diagnosed with MS increased to 64.3%, while at the same time the percentage of patients with an incorrect diagnosis decreased slightly, to 5.4%. The presence of repeated neurological symptoms reduced the number of patients, the delay in diagnosis was 3.0 years, which is not a very informative indicator, since this group also included patients with a correctly diagnosed MS already at manifestation, so we calculated the time from manifestation to correct diagnosis in patients with an incorrect diagnosis and not going to medical institutions. It was revealed that in this group of patients the correct diagnosis of MS was made with a delay of 5 years for those who did not go to medical institutions and by 3 years for patients with an incorrect diagnosis.

The age of patients at the manifestation of MS is widely discussed in many scientific studies, so according to various sources, early clinical signs of MS are first detected within 20-40 years, and the average age of manifestation in many studies ranges from 27 to 34 years. In our study, patients were studied in a time continuum, where the age of patients was determined at the onset of the first symptoms of the disease (manifestation), subsequent exacerbation (second attack) and upon admission to the RCH. It was revealed that the manifestation of MS in our patients occurred at the age of 28 years, the second attack was at 30.5 years. The duration of remission between manifestation and the second attack was 2.5 years (24.0 months). Patients were admitted to the RCH at the age of 33.0 years (Table 3).

Analyzing the age specificity of MS patients by gender at the manifestation of the disease, we did not find a statistically significant difference in the age of onset of the first symptoms, so men and women get sick at approximately the same age (men - 27.0 years, women - 28.0 years) (Table 3).

However, the subsequent exacerbation of MS in women occurred significantly later (2.0 years) than in men (31.0 years and 29.0 years, respectively) and this is consistent with the generally accepted point of view that men reach disability indicators faster due to a more severe course of the disease and demonstrate poorer recovery after the initial relapse¹⁷.

¹⁷ Ysrraelit, M.C., Correale, J. Impact of sex hormones on immune function and multiple sclerosis development // Immunology, - 2019 Jan, 156(1), - p. 9-22.

Table 3. MS patients at the manifestation of the disease, the second attack and at the time of contacting the Republican Clinical Hospital (years) (Me (Q1-Q3))

	manifestation	II attack	RCH
General group	28,0	30,5	33,0
	(23,0-35,0)*	(25,0-38,0)**	(27,0-41,0)
Women	28,0	31,0	33,0
	(23,0-35,0)*	(26,0-39,0)**,+	(27,0-41,5)
Men	27,0	29,0	32,0
	(22,0-34,0)*	(24,0-36,0)**	(26,0-41,0)

* - statistically significant difference (p=0.001) between manifestation and 2nd attack; ** - statistically significant difference (p=0.001) between the 2nd attack and RCH; + - statistically significant difference (p=0.001) between women and men.

The age of admission to the RCH between the sexes did not have a statistically significant difference and was equal to 33.0 years and 32.0 years, respectively.

Table 4. Representation of patients with MS by age group at manifestation, second attack and when contacting the RCH

Age group	manifestation		II attack		RCH	
	n	%	n	%	N	%
<19	76	13,6	38	6,8	31	5,5
20-29	248	44,4	196	35,1	185	33,1
30-39	155	27,7	170	30,4	176	31,5
40-49	75	13,4	88	15,7	106	19,0
50-59	5	0,9	18	3,2	60	10,7
>60	-	-	-	-	1	0,2

The distribution of patients by age category in our study, at the manifestation of the disease, revealed a predominance of patients in the age group of 20-29 years. Of the total number of patients, 44.4% were in this age group (Table 4). The same trend of predominance of this age group was observed both during the second attack and during the visit to the RCH (35.1% and 33.1%, respectively). The

second most common age group in terms of the number of patients was 30-39 years old, where the percentage of representation corresponded to 27.7%, 30.4% and 31.5% (Table 4).

The age of patients with multiple sclerosis of residents of the city of Baku in the group of patients living in the central areas (28.0 (23.0-35.0) years) at the manifestation of the disease did not differ from the group of patients living in embankment areas (28.0 (22.0-35.0) years) city. We also studied the age of disease manifestation in patients born in the city of Baku (RvB) and those born in the regions of Azerbaijan (RvR). In our study, the age of MS patients in the RvB group at manifestation (27.0 (22.0-34.0) years) of the disease was statistically significantly less than in the RvR group (29.0 (24.0-37.0) years). The same age-related features are found during the second attack and upon admission to the RCH. (Table 5)

Table 5. Age of MS patients at manifestation, second attack and referral to the RCH, depending on place of birth (years),

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	manifestation	II attack	RCH
RvB	27 (22,0-34,0)***	29,5 (24,0-36,5) *,+	32 (26,0-39,0) *
RvR.	29 (24,0-37,0) **	32 (27,0-40,0) +	34 (28,0-44,0)

*- statistically significant difference (p<0.001) between the RvB and RvR groups, **- statistically significant difference (p<0.001) between manifestation and 2nd attack, +- statistically significant difference (p<0.001) between 2nd attack and RCH.

When studying the clinical phenotypes of MS, it was revealed that the majority of patients had a relapsing (RRS - 69.8%), and to a lesser extent a progressive type of course (PRS - 19.5%), and 10.7% of all patients were diagnosed with CIS. Data on the type of course similar to this distribution were recorded in many clinical and epidemiological studies. It is generally accepted that RMS is the most common type of course, which occurs in 60 - 95% of cases, while PRS ranges from 3.0% to 19.0% ¹⁸. As in the general group,

¹⁸Sa, M.J. State of the Art and Future Challenges in Multiple Sclerosis Research and Medical Management: An Insight into the 5th International Porto Congress of

the RMS phenotype prevailed in both women and men (Table 6). There were no statistically significant differences between the sexes in any of the MS phenotypes.

Gender	RMS	PMS	CIS	Total
Total	390	109	60 (10,7%)	559
	(69,8%)	(19,5%)		(100%)
Women	270	77	45	392
	(68,9%)	(19,6%)	(11,5%)	(100%)
Men	120	32 (19,2%)	15	167
	(71,9%)		(9,0%)	(100%)

	Table 6.	Clinical	phenotypes	of MS	(diagnosis	of RCH).	(N	(%))
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We determined that the age of patients with the RMS type of course was 31.0 years, in the CIS group – 28.0 years and in the PRS group – 44.0 years (Table 7), which was confirmed when patients were distributed by age category. Thus, the number of patients with the RMS type of course prevailed in the age groups 20-29 years (36.2%) and 30-39 years (35.1%), CIS in the group 20-29 years (56.7%) and PRS in groups 40-49 years old (33.9%) and 50-59 years old (32.1%).

Table 7. Age and clinical type of MS in patients upon admissionto the Republican Clinical Hospital (years) (Me (Q1-Q3)).

	CIS	RMS	PMS
Age	28,0 (24,0-36,5) *'**	31,0 (26,0-38,0) ***	44,0 (37,0-50,0)

*- statistically significant difference (p < 0.05) between CIS and RMS;

** - statistically significant difference (p < 0.0001) between CIS and PMS;

*** - statistically significant difference (p<0.0001) between RMS and PMS.

The symptoms of MS manifestation in the patients we studied

Multiple Sclerosis / M.J.Sa, R.Soares Dos Reis, A.Altintas [et al.] // Neurology and Terapy, - 2020. 9(2), -p.281-300.

were characterized by clinical diversity. Therefore, at the first stage of analysis in the general group of patients, we divided patients into groups with mono - (Ms) and polysystem (Ps) manifestations. The concept of multisystem manifestations meant the presence of symptoms indicating damage to two or more central nervous system systems. The results of our study showed that in 61.7% of patients, MS clinically manifests itself with damage to one part and in 38.3% of cases, a combination of two or more parts of the nervous system. The next exacerbation (second attack) was characterized by a change in the ratio of Ms and Ps, which changed towards an increase in the percentage of Ps patients. The number of Ms patients decreases to 23.1%, and Ps patients increases to 68.2%. Of the 345 patients with Ms manifestations during manifestation, 38.3% had visual disorders, 28.7% had sensory disorders and motor disorders occurred in 16.5% of patients. Other parts of the nervous system (cerebellar, pelvic, speech and others) were affected in small percentages. By the second attack there was a slight increase in sensory and motor disorders. (Table 8).

Symptoms	manifestation	2 attack				
	N=345	N=129				
Visual	132 (38,3 %)	34 (26,4 %)				
Pelvic	5 (1,4 %)	1 (0,8 %)				
Sensitive	99 (28,7 %)	50 (38,8 %)				
Motor	57 (16,5 %)	25 (19,4 %)				
Cerebellar	25 (7,2 %)	6 (4,7 %)				
Speech	-	1 (0,8 %)				
other	27 (7,8 %)	12 (9,3 %)				

 Table 8. Distribution of monosystemic manifestations in patients with MS at manifestation and second attack (N - %)

The study of the above indicators did not reveal differences by gender.

Separately, in patients diagnosed with MS at the time of manifestation, Ms and Ps manifestations were represented in approximately the same percentage. At the same time, visual disorders in this group of patients occurred in 51.6% of cases, which was a good reason forcing the doctor to take the complaints more seriously and thoroughly examine the patient to make an accurate diagnosis. However, among patients with Ms who did not go to medical institutions, the manifestations were significantly higher (69.3%) compared to Ps (30.7%), which most likely could be the reason for them ignoring their complaints and neglecting to go to the doctor.

We found that in patients with CIS and RMS types of course, the disease manifests mainly with Ms, while at the same time in RMS Ps manifestations predominate (p < 0.05) (Pict. 2).



* - statistically significant difference (p = 0.009) between CIS and PRS * * - statistical difference (p = 0.002) between RRS and PRS

Picture 2. Involvement of functional parts of the central nervous system during manifestation depending on the type of MS.

Upon admission to the RCH, patients had a wide variety of clinical symptoms, including damage to individual cranial nerves. At the same time, the cranial nerves had varying degrees of involvement in the demyelinating process. Thus, if the optic (44.5%) and facial (48.7%) nerves were the most frequently affected, then other cranial nerves were rarely involved in the pathological process (Table 9).

When studying motor disorders, 55.3% of varying degrees of muscle weakness were recorded, with lower spastic paraparesis most often found (in 22.7% of cases). In 21.1% of cases, an increase in tone was detected, in 17.4% of cases, clonus of the feet and in 65.3% of cases, pathological reflexes, both flexion and extension. At the same time, in 18.1% of patients there was a decrease in tone in the muscles of the lower limb in the supine position. At the same time, purely spastic gait was observed only in 5.0% of patients.

Half (47.9%) of the patients had disorders of superficial types of sensitivity, of which 9.1% had a decrease or absence of pain sensitivity in the lower extremities, 21.3% had hypoesthesia on one half of the body and 9.5% in one limb. At the same time, disorders of deep types of sensitivity were found in 8.9% of patients, and only 1.4% of them had anamnestic and clinical diagnosis of Lhermitte syndrome.

Manifestations of disturbances in the coordination area were in the form of gait disturbances, dyssynergia, dysmetria, intentional and postural tremor, which occurred in 71% of cases. Moreover, in 40.1% of patients, ataxia was of both static and dynamic nature. Purely ataxic gait upon admission to the Republican Clinical Hospital occurred in 22.5%, spastic-atactic gait in 11.8% of cases.

44.7% of patients had a urination disorder, of which difficulty urinating in 27.5%, and frequent urination in 15.2% of patients. In 1.6% of patients there was a combined disorder of urination and defecation.

Of the patients we examined, 7 (1.25%) had convulsive syndrome. Of these, 6 are women and 1 is a man. All patients had pathological changes on the EEG. None of the patients had other risk factors for epilepsy, such as cranial trauma, cerebral ischemia, drug abuse, etc. None of the patients had status epilepticus.

In this scientific study, to assess the neurological status of patients with MS, in addition to clinical assessment of the state of cranial nerves and various functional systems of the body, the scale of integrative assessment of the functional capacity of patients with MS - EDSS.

Table 9.	Damage	to	the	nervous	system	in	patients	with	multiple
sclerosis									

Divisions of the nervous system	Number of patients	(%)
Olfactory nerve		-
Optic nerve	249	44,5
Oculomotor nerves:	58	10,4
oculomotor, trochlear, abducens		
nerves		
Trigeminal nerve	26	4,7
Facial nerve:		
1.peripheral lesion	1.11	1. 2,0
2. central lesion	2.272	2.48,7
Vestibulocochlear nerve:		
1.hearing loss	1.28	1. 5,0
2. vestibular disorder	2.171	2.30,6
Bulbar nerves:	31	5,5
glossopharyngeal, vagus nerves		
Hypoglossal nerve	101	18,1
Movement disorders	310	55,5
Sensory disorders	268	47,9
Pelvic disorders	250	44,7
Cerebellar disorders	317	56,7

In our study, the overall EDSS corresponded to moderate MS (3.5 (2.0-4.5) points), and no statistically significant difference was found between genders (women and men were 3.5 (2.0-4.5)) points and 3.0 (2.0-4.5) points, respectively). When examining EDSS by age group, the same trend was found as presented in the literature: in younger age groups, EDSS was lower and as age increased it increased from 2.0 to 7.0 points. This also confirms that as the duration of the disease increases, the level of disability increases. A correct diagnosis of MS during the manifestation of the disease and timely initiation of treatment delays the development of the disease and the onset of disability, which was confirmed in our study. Thus,

the group of patients who were diagnosed with MS at presentation had an EDSS score of 2.0 (2.0-3.0), and upon admission to the Republican Clinical Hospital there was a slight increase in EDSS, which reached 2.5 (2.0- 4.0) points. At the same time, in the group where MS was not diagnosed upon manifestation, EDSS in patients increased from 2.0 (1.5-3.5) points (mild MS) to 4.0 (3.0-6.0) points (moderate MS). An interesting point is that the group of patients who did not go to medical institutions during the manifestation of the disease, and accordingly did not receive treatment, had an intermediate EDSS level between the first and second groups upon admission to the Republican Clinical Hospital (4.0 (2.5-5.0) points). The reason for this slight increase in the level of disability, in the absence of treatment, could be the initial minimal neurological symptoms at the onset of the disease or perhaps a favorable course of MS.

We have found that the features of the clinical manifestation of the disease have a certain connection with the subsequent dynamics of MS. If the disease began with Ms symptoms, patients had a lower EDSS upon admission to the RCH (3.0 points) than patients with Ps phenomena, whose EDSS corresponded to 4.0 points. At the same time, within the group of patients with Ms manifestations, there were also some peculiarities. Thus, the manifestation of MS with exclusively movement disorders led to a higher EDSS (4.5 points moderate MS) upon admission to the RCH, while the onset of the disease exclusively with pelvic disorders had a relatively favorable outcome of the disease and at the time of admission to the RCH the EDSS corresponded to 2. 0 points (mild MS).

Along with the clinical picture of the disease, neuroimaging research methods are decisive in the diagnosis of MS. Therefore, in our study, the results of MRI data from 559 MS patients were analyzed. In the 178 patients we examined with MRI studies during the manifestation of the disease, in more than half (56.7%) the foci of demyelination were located exclusively supratentorially, slightly less (42.1%) both supra- and subtentorially, and only in one patient (0 .6%) the lesion was located exclusively subtentorial. As can be seen, according to the results of our study, at the manifestation of MS, 1/3

(32.0%) of patients had a combined lesion of the brain and spinal cord, and in subsequent exacerbations (MRI 3) more than half of the patients (54.4%) had such combined defeat.

When dividing patients into groups according to the number of foci of demyelination on MRI1 examination, it was found that 14.6% of patients had three or fewer lesions, and 84.8% of patients had more than three foci of demyelination.

It is known that brain atrophy in MS begins at an early stage of the disease and tends to progress, regardless of the clinical type of course. In our study, 7.9% of patients already had moderate, diffuse brain atrophy when they were diagnosed with MS. Subsequent examinations revealed an increase in the percentage of this indicator, so on MRI 2 - 13.6% and on MRI 3 - 21.1% (p < 0.05). It is significant that the percentage of brain atrophy varies depending on the type of disease. The PRS type of course is characterized by a greater prevalence of atrophy than RMS and CIS. It was revealed that on MRI3 in the group of patients with PRS, brain atrophy increases to 57.4% (Pic. 3). Our data are consistent with the view that atrophy is caused to a greater extent by neurodegenerative changes characteristic of the progressive type of MS than by inflammatory lesions that occur in RRMS and CIS ¹⁹.

Of the 559 patients involved in the study, 284 patients received DMT. In the group of patients who received beta-interferon 1a (Avonex) upon admission to the Republican Clinical Hospital, EDSS corresponded to 3.0 points. Assessment of the clinical condition of patients after 6 months, one year, and then two years from the start of treatment showed an improvement in the functional state of patients, manifested by a consistent statistically significant decrease in EDSS (2.0 points, 2.0 points and 2.5 points, respectively).

However, in the future (more than 2 years) there was an increase in EDSS with a slight increase from the initial level (3.5

¹⁹Moccia,M., de Stefano,N., Barkhof,F. Imaging outcome measures for progressive multiple sclerosis trials // Multiple Sclerosis, -2017. 23(12), - p.1614-1626.

points). When distributing patients receiving beta-interferon, depending on the type of disease, mixed results were revealed.



*- p<0.05, statistically significant difference between PRS and RRS, between PRS and CIS

Picture 3. Atrophic changes on MRI of the brain in various types of MS

In patients with the relapsing type of multiple sclerosis, the use of interferon beta led to a stable and long-term remission for two or more years (3.0 points). At the same time, in patients with a progressive type of course, despite some stabilization and improvement in the functional state in the first year of using the drug, there was a subsequent increase in EDSS to 6.0 points, which corresponds to severe disability. In the CIS group, against the background of the use of PMTRS, the EDSS results ranged from 3.0 to 4.0 points, without a statistically significant difference. The data we obtained on the use of the drug Avonex are similar to the results of previous studies. Beta interferons are believed to be one of the most widely prescribed disease-modifying drugs used worldwide and its early use reduces the progression of EDSS in patients with MS, maintaining the effect for two to three years.

CONCLUSIONS

- The prevalence of multiple sclerosis in the city of Baku in the period 2013-2019 tended to increase (from 10.2 ⁰/₀₀₀₀ to 23.3⁰/₀₀₀₀) and according to the level of prevalence of the disease, the city of Baku can be classified as a zone of "medium risk of prevalence" of multiple sclerosis. The highest prevalence of multiple sclerosis among residents of the city of Baku occurred in women (12.7-32.5⁰/₀₀₀₀), people living in centrally located areas of the city (11.7-26.1⁰/₀₀₀₀) and in the age group 30-39 (46,2⁰/₀₀₀₀) years [9,s.114; 13,s.110; 17,s.169; 16, c.23; 11,p.88].
- The incidence rate of multiple sclerosis in the city of Baku during the period 2013-2019 remained relatively stable, ranging from 2,1⁰/₀₀₀₀ to 2,9⁰/₀₀₀₀. In women, this indicator tended to increase (2,7-3,7^{0/0000}), while in men it decreased (2,1-0,9⁰/₀₀₀₀), which was manifested in an increase in the ratio of women to men, from 1.3:1.0 to 4.1:1.0. The highest incidence of multiple sclerosis was in the age groups 20-29 and 30-39 years (5,5⁰/₀₀₀₀ x 4,4⁰/₀₀₀₀) [17,s.170; 16, c.25-26; 11,p.88].
- 3. The average age of patients with multiple sclerosis at the onset of the disease was 29.1±0.37 years, and the median was 28 years, and there was no difference in age between women and men (mean age 29.5±0.4 and 28.3± 0.7 years and median 28 and 27 years, respectively). The duration of remissions between subsequent attacks tended to decrease their duration (24.0 and 15.0 months, respectively), mainly due to female patients (34.0 and 12.0 months, respectively). In patients born in the city of Baku, multiple sclerosis manifested itself at an earlier age than in patients born in the regions of Azerbaijan (27.0 and 29.0 years, respectively) [13, s.109; 17, s.170].
- In terms of percentage representation, relapsing multiple sclerosis prevailed over other types of course (RRS 69.8%; PRS 19.5%, CIS 10.7%), and mainly occurred under the age of 40 years (20-29 years 36 .2%; 30-39 years 35.1%), while over 40 years the progressive type of course prevailed (40-49 years 33.9%; 50-59

years - 32.1%). The clinical manifestation of RMS was characterized by monosystem manifestations and minor neurodegenerative changes in MRI results, while at the same time, RMS manifested itself with the involvement of several neurological functional systems and more pronounced neuroimaging manifestations in the form of brain atrophy [18,s.85; 17,s.171; 6,c.10; 14,c.66; 15, p.153-154].

5. The use of drugs that modify the course of MS (beta interferon 1 a) for more than two years, according to EDSS, led to stabilization of the functional state of patients (3.0 points; after 6 months - 2.0 points; after 12 months - 2.0 points; after 18 months - 2.5 points; after 24 months - 3.5 points). RMS was characterized by a better response to the use of the drug compared to other MS phenotypes [17,s.171; 15,p.153].

PRACTICAL RECOMMENDATIONS

- 1. Due to the increasing prevalence of multiple sclerosis among residents of the city of Baku, it is necessary to continue the functioning of the program for treatment, prevention and measures to combat multiple sclerosis, which will provide the necessary level of medical services and social assistance to patients.
- 2. Considering the poor awareness of the population about the features of multiple sclerosis and the lack of alertness of primary care physicians (local doctors and family doctors), which leads to delayed diagnosis of this disease, it is necessary to strengthen sanitary educational work both among the population and among medical personnel.
- 3. Satisfactory results of using beta interferon 1a in multiple sclerosis allow us to recommend this drug for all phenotypes of MS, especially in relapsing-remitting multiple sclerosis.

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LIST OF CONVENTIONAL ABBREVIATIONS

- CI - Confidence Interval - Clinically Isolated Syndrome CİS CNS - Central Nervous System MS - Multiple Sclerosis EEQ - Electroencephalography EDSS - Expanded Disability Status Scale MRI - Magnetic Resonance Imaging - Monosystemic Manifestations Ms PMS - Progressive Multiple Sclerosis - Polysystemic Manifestations Ps RCH - Republic Clinical Hospital RMS - Relapsing Multiple Sclerosis RvB – Patients born in Baku RvR - Patients born in the regions of Azerbaijan and
- RvR Patients born in the regions of Azerbaijan and living in Baku

The defense will be held on <u>June</u> 18 2025 at 2.05 of Supreme Attestation Commission under the President of the Republic of Azerbaijan at the Azerbaijan Medical University

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