CHARACTERISTICS OF TRANSITIONS BETWEEN CLINICAL COURSES OF MULTIPLE SCLEROSIS

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Introduction. Multiple sclerosis (MS) phenotype transition, is a clinically important milestone with implications for prognosis and treatment. **The objective of this study** was to examine MS phenotype transitions and associated factors in Azerbaijan. **Material and methods.** A longitudinal analysis (2013–2022) included patients diagnosed with clinically isolated syndrome (CIS) and relapsing-remitting MS (RRMS) in Azerbaijan (67 and 1397 patients accordingly). Phenotype transition was defined as CIS→RRMS or RRMS→secondary progressive MS (SPMS). Statistical analyses were performed using the Pearson chi-square test and the Mann–Whitney U test. Associations were evaluated using univariable and multivariable binary logistic regression in a cohort with complete baseline and follow-up data (n=408). **Results.** During follow-up, 378 patients (25.8%) changed phenotype. CIS→RRMS occurred in 70.1% of CIS cases (47) and RRMS→SPMS in 23.7% of RRMS cases (331). Phenotype change was more common after CIS than after RRMS ($p<0.001$). Median time was shorter in CIS than RRMS ($p<0.001$). Overall, univariable analyses identified candidate predictors of phenotype transition for inclusion in the multivariable logistic regression model. In the multivariable model, 24-month disease-modifying therapy (DMT) adherence and disease duration ≤10 years were associated with lower odds of phenotype change ($p<0.001$). No relapse in the first year and absence of sensory symptoms were associated with higher odds ($p<0.001$ and $p=0.010$), whereas absence of speech disturbance was associated with lower odds ($p=0.019$). **Conclusion.** One quarter of patients transitioned between MS phenotypes, earlier after CIS. DMT adherence and selected baseline clinical features were independently associated with phenotype change, supporting risk-stratified follow-up and treatment optimization.

Keywords: multiple sclerosis, clinically isolated syndrome, relapsing-remitting multiple sclerosis, secondary progressive multiple sclerosis, phenotype transition, Azerbaijan

Introduction. Multiple sclerosis (MS) is a chronic immune-mediated demyelinating disease of the central nervous system and a leading cause of non-traumatic neurological disability in young and middle-aged adults. According to the third edition of the Atlas of MS, approximately 2.8 million people worldwide were living with MS in 2020, underscoring its substantial public health and socioeconomic burden [1]. Most patients are initially diagnosed with a relapsing-remitting course, and a considerable proportion first present with clinically isolated syndrome (CIS), which may later evolve into definite MS [1, 2]. Over time, many patients with relapsing-remitting MS (RRMS) accumulate disability and transition to secondary progressive MS (SPMS), a stage associated with irreversible neurological worsening, greater functional impairment, and reduced therapeutic opportunities [2, 3]. For this reason, phenotype transition represents a clinically meaningful milestone in the natural history of MS and has important implications for prognosis, follow-up intensity, and treatment optimization [2, 3].

Existing evidence indicates that phenotype transition in MS is heterogeneous and influenced by demographic, clinical, and treatment-related factors. Previous longitudinal and registry-based studies have shown that conversion from CIS to MS and from RRMS to SPMS may be associated with age, baseline disability, relapse activity, symptom profile, and disease-modifying therapy (DMT) exposure [3-5]. Moreover, early and more effective DMT use has been associated with a reduced or delayed risk of progression to SPMS, highlighting the practical importance of identifying patients at higher risk of phenotype change [4, 5]. However, most available data originate from Western Europe and other registry-rich settings, whereas evidence from low-data and underrepresented countries remains limited [3-5].

In Azerbaijan, published MS research has primarily addressed epidemiological and clinical characteristics, while national longitudinal data on phenotype transitions remain lacking. Recent studies from Azerbaijan have contributed important regional and national data on the epidemiology and risk factors of MS; however, to our knowledge, no published nationwide study has specifically investigated transitions from CIS to RRMS and from RRMS to SPMS, or the factors associated with these transitions [6-8]. This knowledge gap is also consistent with the Atlas of MS, which indicates that data on MS type at initial diagnosis are not available for Azerbaijan [1, 9]. Therefore, a longitudinal evalu-

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ation of MS phenotype transitions in Azerbaijan is needed to improve risk stratification, support timely therapeutic decision-making, and inform long-term clinical management [6, 7].

The objective of this study was to examine the frequency and timing of phenotype transitions in multiple sclerosis in Azerbaijan, specifically CIS to RRMS and RRMS to SPMS, and to identify demographic, clinical, and treatment-related factors associated with phenotype change.

Material and methods. This longitudinal observational study was conducted in Azerbaijan and included patients diagnosed with clinically isolated syndrome (CIS) or relapsing-remitting multiple sclerosis (RRMS) during 2013–2022. The study aimed to examine transitions between MS phenotypes over time. All eligible patients were included, yielding a total sample of 1464 cases, of whom 67 had CIS and 1397 had RRMS at baseline. Patients with other baseline MS phenotypes or insufficient data on diagnosis or follow-up phenotype were excluded from the relevant analyses. For regression analysis, a complete-case cohort of 408 patients with available baseline and follow-up data was used.

Phenotype transition was defined as conversion from CIS to RRMS or from RRMS to secondary progressive multiple sclerosis (SPMS). Time to transition was calculated in years from the initial diagnosis to the first documented phenotype change. Demographic and clinical variables included sex, place of residence, disease duration, age at diagnosis, 24-month disease-modifying therapy (DMT) adherence, relapse activity during the first and second years, and symptoms at first attack.

Data were obtained from clinical records and entered into the study dataset in a standardized manner. Descriptive analysis was performed for the full cohort, whereas associated factors were assessed in the complete-case cohort. Categorical variables were presented as number and percentage, and continuous variables as mean±standard deviation or median with interquartile range, as appropriate. The Pearson chi-square test was used to compare proportions, and the Mann-Whitney U test was used to compare time to transition between groups; Student's t-test was also applied as a supplementary parametric test. Factors associated with phenotype transition were evaluated using univariable and multivariable binary logistic regression. Odds ratios (ORs) with 95% confidence intervals (CIs) were reported, and $p<0.05$ was considered statistically significant [10].

Results and discussion. During the study period, 67 patients were diagnosed with clinically isolated syndrome (CIS) and 1397 with relapsing-remitting multiple sclerosis (RRMS). Overall, 378 of 1464 patients (25.8%) experienced a phenotype transition during follow-up, mainly CIS→RRMS and RRMS→SPMS (Table 1). Transition occurred in 70.1% of patients with CIS and in 23.7% of those with RRMS; thus, phenotype change was significantly more frequent after CIS than after RRMS ($\chi^2(1)=72.039$; $p<0.001$). The mean time to phenotype transition was 5.9±2.91 years (range 1–16 years). Time to transition was significantly shorter in the CIS group than in the RRMS group (median 3 vs. 6 years; $U=1641.0$; $p<0.001$; $t(376)=-8.814$; $p<0.001$). These findings are consistent with previous reports showing that conversion after CIS is common but varies across cohorts and follow-up duration, whereas RRMS-to-SPMS conversion is usually slower and more gradual rather than a sharply defined event [2, 11, 12].

Table 1

Characteristics of transitions between multiple sclerosis clinical phenotypes

Indicator		CIS	RRMS	Total
MS clinical course transitions, n (%)		47 (70.1)	331 (23.7)	378 (25.8)
Test statistics		$\chi^2(1)=72.039$; $p<0.001$*		
Time to transitions (years)	Me [Q_1-Q_3]	3 [2-3]	6 [4-8]	6 [4-8]
Test statistics		$U=1641.0$; $p<0.001$*		

Note: CIS – clinically isolated syndrome, RRMS – relapsing–remitting multiple sclerosis, n –number of patients, Me – median; Min. – minimum value; Max. – maximum value. Q1, Q3 – 25th and 75th percentiles. Test statistics: χ^2 – Pearson chi-square test; t – Student's t-test; U – Mann–Whitney U test; P – level of statistical significance; * – the null hypothesis is rejected.

In univariable logistic regression (n=408), 24-month disease-modifying therapy (DMT) adherence was associated with lower odds of phenotype transition (OR=0.442; p<0.001), whereas no relapse during the first year (OR=1.790; p=0.028), rural residence (OR=1.677; p=0.030), disease duration >10 years, age at diagnosis >30 years, absence of sensory symptoms at onset (OR=1.946; p=0.006; Table 2), and absence of "other symptoms" (OR=2.184; p=0.005) were associated with higher odds of transition. These results indicated that phenotype change was influenced by multiple demographic and clinical factors rather than by a single variable, which is in line with current concepts of the heterogeneous evolution of multiple sclerosis [2, 12].

Table 2

Univariable logistic regression of factors associated with phenotype change

Indicator (category)	Reference category	OR (95% CI: LL-UL)	P
Received DMT	Did not receive DMT	0.442 (0.281-0.696)	<0.001*
No relapse in the first year	≥1 relapse in the first year	1.790 (1.064-3.010)	0.028*
No relapse in the first two years	≥1 relapse in the first two years	1.363 (0.779-2.386)	0.278
Sex (male)	Sex (female)	1.071 (0.663-1.731)	0.779
Residence (rural)	Residence (urban)	1.677 (1.052-2.673)	0.030*
Disease duration (≤10 years)	Disease duration (>10 years)	0.283 (0.177-0.454)	<0.001*
Age at diagnosis (≤30 years)	Age at diagnosis (>30 years)	0.593 (0.376-0.934)	0.024*
Visual impairment at first relapse (absent)	Visual impairment at first relapse (present)	0.712 (0.452-1.121)	0.143
Bladder/bowel dysfunction at first relapse (absent)	Bladder/bowel dysfunction at first relapse (present)	1.867 (0.937-3.722)	0.076
Sensory symptoms at first relapse (absent)	Sensory symptoms at first relapse (present)	1.946 (1.212-3.125)	0.006*
Motor symptoms at first relapse (absent)	Motor symptoms at first relapse (present)	1.091 (0.697-1.707)	0.704
Cerebellar symptoms at first relapse (absent)	Cerebellar symptoms at first relapse (present)	1.055 (0.657-1.694)	0.825
Speech disturbance at first relapse (absent)	Speech disturbance at first relapse (present)	0.514 (0.264-1.003)	0.051
Brainstem symptoms at first relapse (absent)	Brainstem symptoms at first relapse (present)	1.268 (0.808-1.989)	0.302
Other symptoms at first relapse (absent)	Other symptoms at first relapse (present)	2.184 (1.270-3.756)	0.005*

Note: OR – odds ratio; CI – confidence interval; LL – lower limit; UL – upper limit; DMT – disease-modifying therapy; P – level of statistical significance; * – the null hypothesis is rejected.

In the multivariable model, 24-month DMT adherence remained independently associated with lower odds of phenotype transition (OR=0.408; p<0.001), as did disease duration ≤10 years (OR=0.286; p<0.001), whereas no relapse in the first year was associated with higher odds of transition (OR=2.968; p<0.001; Table 3). The protective association of sustained DMT use agrees with previous studies showing that DMT exposure may delay conversion to SPMS [5, 13]. By contrast, the seemingly paradoxical association between absence of first-year relapse and higher odds of phenotype change may reflect progression independent of relapse activity (PIRA), since disability accumulation in multiple sclerosis may occur even in the absence of overt relapses [14]. The model was statistically significant overall (Omnibus $\chi^2(9)=70.653$; p<0.001), but its explanatory power was moderate

(Nagelkerke R^2=0.234), and sensitivity for identifying phenotype transition remained low (23.1%), suggesting that clinical variables alone may be insufficient for accurate prediction [2, 15].

Table 3

Multivariable logistic regression of factors associated with clinical course change

Indicator (category)	Reference category	OR (95% CI)	P
Received DMT	Did not receive DMT	0.408 (0.243-0.684)	<0.001*
No relapse in the first year	≥1 relapse in the first year	2.968 (1.605-5.487)	<0.001*
Sex (male)	Sex (female)	1.218 (0.705-2.104)	0.479
Residence (rural)	Residence (urban)	1.550 (0.923-2.604)	0.098
Disease duration (≤10 years)	Disease duration (>10 years)	0.286 (0.171-0.478)	<0.001*
Age at diagnosis (≤30 years)	Age at diagnosis (>30 years)	0.748 (0.444-1.259)	0.274
Bladder/bowel dysfunction at first relapse (absent)	Bladder/bowel dysfunction at first relapse (present)	2.095 (0.978-4.487)	0.057
Sensory symptoms at first relapse (absent)	Sensory symptoms at first relapse (present)	2.035 (1.188-3.487)	0.010*
Speech disturbance at first relapse (absent)	Speech disturbance at first relapse (present)	0.405 (0.190-0.864)	0.019*

Note: OR - odds ratio; CI - confidence interval; LL - lower limit; UL - upper limit; DMT - disease-modifying therapy; P – level of statistical significance; * – the null hypothesis is rejected.

Among baseline symptoms, absence of sensory symptoms was independently associated with higher odds of phenotype transition (OR=2.035; p=0.010), whereas absence of speech disturbance was associated with lower odds (OR=0.405; p=0.019). The finding regarding sensory symptoms is consistent with earlier studies indicating that sensory and visual onset is generally linked to a more favorable course, while more disabling presentations tend to predict faster progression [16, 17]. In contrast, sex and age at diagnosis were not independently associated with phenotype transition after adjustment. Overall, these findings suggest that phenotype transition in Azerbaijani patients with multiple sclerosis is shaped by treatment exposure, disease duration, and initial clinical presentation, and they support risk-stratified follow-up with particular attention to early treatment adherence and patients without apparently "active" early relapses [5, 14-17].

Conclusion. In this longitudinal study from Azerbaijan, approximately one quarter of patients with multiple sclerosis experienced a transition between clinical phenotypes during follow-up. Phenotype change was markedly more frequent and occurred earlier in patients with clinically isolated syndrome than in those with relapsing-remitting multiple sclerosis, indicating that the earliest disease stage is a particularly dynamic period in the clinical course of multiple sclerosis. Sustained 24-month disease-modifying therapy adherence and disease duration ≤10 years were independently associated with lower odds of phenotype transition, whereas no relapse during the first year and absence of sensory symptoms at onset were associated with higher odds; absence of speech disturbance was associated with lower odds.

These findings suggest that phenotype transition in multiple sclerosis is influenced not only by treatment exposure, but also by disease stage and initial clinical presentation. From a practical perspective, the results support closer risk-stratified follow-up, early optimization of disease-modifying therapy, and careful monitoring even in patients without apparently active early relapses. As one of the first nationwide longitudinal analyses of phenotype transition in Azerbaijan, this study adds locally relevant evidence to support clinical decision-making and long-term management of multiple sclerosis.

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XÜLASƏ

DAĞINIQ SKLEROZUN KLİNİK GEDİŞ TİPLƏRİ ARASINDA KEÇİDLƏRİN XÜSUSİYYƏTLƏRİ

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Giriş. Dağınıq sklerozun (DS) fenotipləri arasında keçid proqnoz və müalicə baxımından klinik cəhətdən mühüm mərhələdir. **Tədqiqatın məqsədi** Azərbaycanda DS fenotipləri arasında keçidləri və onlarla əlaqəli amilləri öyrənmək olmuşdur. **Material və metodlar.** 2013–2022-ci illəri əhatə edən longitudinal analizə Azərbaycanda klinik izolə olunmuş sindrom (KİS) və residivverən DS (RDS) diaqnozu qoyulmuş xəstələr daxil edilmişdir (müvafiq olaraq 67 və 1397 xəstə). Fenotip keçidi KİS→RDS və ya RDS→ikincili proqressiv DS (İPDS) kimi müəyyən edilmişdir. Statistik analizlər Pearson-un xi-kvadrat testi və Mann–Whitney U testi ilə aparılmışdır. Assosiasiyalar başlanğıc və izləmə məlumatları tam olan kohortda (n=408) təkdəyişənli və çoxdəyişənli binar logistik reqressiya ilə qiymətləndirilmişdir. **Nəticələr.** İzləmə dövründə 378 xəstədə (25,8%) fenotip dəyişmişdir. KİS→RDS keçidi KİS hallarının 70,1%-ində (47), RDS→İPDS keçidi isə RDS hallarının 23,7%-ində (331) baş vermişdir. Fenotip dəyişikliyi KİS-dən sonra RDS-lə müqayisədə daha çox müşahidə olunmuşdur (p<0,001). Median keçid müddəti KİS-də RDS-lə müqayisədə daha qısa olmuşdur (p<0,001). Ümumilikdə, təkdəyişənli analizlər çoxdəyişənli logistik reqressiya modelinə daxil ediləcək fenotip keçidinin potensial prediktorlarını müəyyən etmişdir. Çoxdəyişənli modeldə 24 aylıq xəstəliyin gedişini dəyişən müalicəyə (XGDM) əməl etmə və xəstəlik müddətinin ≤10 il olması fenotip dəyişmə ehtimalının azalması ilə əlaqəli olmuşdur (p<0,001). Birinci ildə həmlənin olmaması və hissi simptomların olmaması daha yüksək fenotip dəyişmə ehtimalı ilə əlaqəli olmuşdur (müvafiq olaraq p<0,001 və p=0,010), nitq pozuntusunun olmaması isə daha aşağı ehtimalla əlaqələnmişdir (p=0,019). **Yekun.** Xəstələrin dörddə birində DS fenotipləri arasında keçid baş vermiş, bu keçid KİS-dən sonra daha erkən müşahidə olunmuşdur. XGDM-ə əməl etmə və seçilmiş başlanğıc klinik xüsusiyyətlər fenotip dəyişikliyi ilə müstəqil əlaqəli olmuşdur ki, bu da riskə görə diferensial izləmə və müalicənin optimallaşdırılmasını dəstəkləyir.

Açar sözlər: dağınıq skleroz, klinik izolə olunmuş sindrom, residivverən dağınıq skleroz, ikincili proqressiv dağınıq skleroz, fenotip keçidi, Azərbaycan

РЕЗЮМЕ

ХАРАКТЕРИСТИКА ПЕРЕХОДОВ МЕЖДУ КЛИНИЧЕСКИМИ ТИПАМИ ТЕЧЕНИЯ РАССЕЯННОГО СКЛЕРОЗА

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Введение. Переход фенотипов рассеянного склероза (РС) представляет собой клинически важную веху, имеющую значение для прогноза и лечения. **Целью данного исследования** было изучить переходы между фенотипами РС и связанные с ними факторы в Азербайджане. **Материал и методы.** В продольный анализ (2013–2022 гг.) были включены пациенты, у которых в Азербайджане был установлен диагноз клинически изолированного синдрома (КИС) и рецидивирующе-ремиттирующего РС (РРРС) (67 и 1397 пациентов соответственно). Переход фенотипа определяли как КИС→РРРС или РРРС→вторично-прогрессирующий РС (ВПРС). Статистический анализ проводили с использованием критерия хи-квадрат Пирсона и U-критерия Манна–Уитни. Ассоциации оценивали с помощью однофакторной и многофакторной бинарной логистической регрессии в когорте с полными исходными данными и данными последующего наблюдения (n=408). **Результаты.** В период наблюдения у 378 пациентов (25,8%) произошла смена фенотипа. Переход КИС→РРРС наблюдался в 70,1% случаев КИС (47), а РРРС→ВПРС — в 23,7% случаев РРРС (331). Смена фенотипа чаще отмечалась после КИС, чем после РРРС ($p<0,001$). Медианное время перехода было короче при КИС, чем при РРРС ($p<0,001$). В целом однофакторный анализ позволил выявить потенциальные предикторы перехода фенотипа для включения в многофакторную модель логистической регрессии. В многофакторной модели приверженность к терапии препаратами, изменяющими течение заболевания (ПИТРС), в течение 24 месяцев и длительность заболевания ≤10 лет ассоциировались с более низкой вероятностью смены фенотипа ($p<0,001$). Отсутствие обострения в первый год и отсутствие чувствительных симптомов ассоциировались с более высокой вероятностью смены фенотипа ($p<0,001$ и $p=0,010$), тогда как отсутствие нарушений речи ассоциировалось с более низкой вероятностью ($p=0,019$). **Заключение.** У четверти пациентов произошёл переход между фенотипами РС, при этом он возникал раньше после КИС. Приверженность ПИТРС и отдельные исходные клинические характеристики были независимо связаны со сменой фенотипа, что подтверждает необходимость риск-стратифицированного наблюдения и оптимизации лечения.

Ключевые слова: рассеянный склероз, клинически изолированный синдром, рецидивирующе-ремиттирующий рассеянный склероз, вторично-прогрессирующий рассеянный склероз, переход фенотипа, Азербайджан

Redaksiyaya daxil olub: 07.04.2025
Çapa tövsiyə olunub: 02.05.2025
Rəyçi: Professor A.K.Məmmədbəyli