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ORIGINAL ARTICLE

Nationwide prescription big data: An evaluation of injectable, oral, and monoclonal antibody disease-modifying therapies in multiple sclerosis

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ABSTRACT

Objectives: This study aimed to assess changes over time in the use of disease-modifying therapies among patients with multiple sclerosis in Türkiye.

Patients and methods: This retrospective observational study used data obtained from national health information systems between January 2, 2015, and December 31, 2022. Patients diagnosed with multiple sclerosis (ICD-10 [International Classification of Diseases, 10th Revision]: G35) who received disease-modifying therapies on at least three occasions during the study period were included. Therapies were classified as injectable, oral, or monoclonal antibody treatments. Annual utilization frequencies and proportional distributions were analyzed. All data were anonymized, and ethical approval was obtained.

Results: Data from 54,795 patients (37,574 females, 17,221 males; mean age: 43.4 ± 11.8 years; range, 11 to 93 years), comprising 562,899 treatment records, were analyzed. Over the study period, the use of injectable therapies gradually decreased, while the use of oral therapies and monoclonal antibody-based treatments markedly increased. Similar patterns were observed in both sexes.

Conclusion: Multiple sclerosis treatment practices in Türkiye have changed substantially in recent years. The increasing use of oral agents and monoclonal antibody therapies likely reflects expanding availability, reimbursement policies, and evolving prescribing practices. These findings provide valuable descriptive insights for clinical practice, healthcare planning, and policy development.

Keywords: Disease-modifying therapies, injectable treatments, multiple sclerosis, national data.

Multiple sclerosis (MS) is a chronic, inflammatory, and neurodegenerative disease of the central nervous system and represents one of the most common causes of nontraumatic neurological disability among young adults worldwide.[1,2] The heterogeneous clinical course of the disease, its variable rate of progression, and the complexity of its immunopathogenesis have led to substantial changes in therapeutic strategies over time.[3,4] In particular, over the past 15 years, a clear paradigm shift has occurred in MS management, moving away from low-efficacy therapies primarily aimed at reducing relapse rates toward more effective treatments that suppress inflammatory activity and may influence long-term outcomes.[5,6]

As observed globally, MS treatment practices in Türkiye have undergone a marked transformation. The broad portfolio of disease-modifying therapies (DMTs) reimbursed by the Ministry of Health, together with nationwide digital recording of prescription data, enabled large-scale national analyses based on real-world evidence.[6] The robustness of Türkiye's health informatics infrastructure provides a unique advantage for

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generating real-world data in the management of chronic diseases.[7,8] In this context, evaluating the temporal distribution of DMTs used in patients with MS is of critical importance not only from an epidemiological perspective but also for understanding national treatment trends, clinical decision-making processes, and healthcare policies.[9]

Agents used in the treatment of MS are generally classified into three main categories: injectable therapies, oral therapies, and monoclonal antibody-based treatments.[10] First-generation agents, including interferon beta formulations and glatiramer acetate, constituted the cornerstone of MS treatment for many years.[11] These injectable therapies continue to be used in a substantial proportion of patients owing to their favorable safety profiles and extensive clinical experience. However, their relatively limited efficacy and the negative impact of parenteral administration on patients' quality of life have increased the demand for alternative therapeutic options.[12]

The introduction of oral therapies into clinical practice during the 2010s marked a major turning point in MS pharmacotherapy.[13] This process, initiated with fingolimod, was subsequently expanded by dimethyl fumarate, teriflunomide, and other oral agents introduced in later years.[14,15] Oral therapies have been increasingly favored by clinicians due to improved treatment adherence, accessibility, and favorable benefit-risk profiles.[16]

In parallel, the advent of monoclonal antibody-based therapies have enabled more selective suppression of inflammatory disease activity in MS.[17] Natalizumab, alemtuzumab, and anti-CD20–targeting agents demonstrate substantial disease-modifying capacity owing to their high efficacy profiles.[18] The availability of these agents has contributed to evolving treatment strategies and broader therapeutic options in clinical practice.[19] Nevertheless, given their potency, potential adverse effects, and immunological consequences, careful patient selection remains essential in clinical decision-making.[20]

In Türkiye, patterns of DMT utilization have exhibited a dynamic evolution over time, influenced by both regulatory frameworks governing access to novel therapies and changes in clinician preferences.[21] Importantly, several high-efficacy therapies became available in Türkiye during the study period, including the licensing and clinical introduction of agents such as alemtuzumab and ocrelizumab after 2018. Such timing of drug availability may have contributed to observed temporal trends in prescribing patterns.

The present study aimed to analyze all MS prescriptions in Türkiye using a nationwide large-scale dataset covering the years 2015-2022. The originality of this study lies in both the magnitude of the dataset and the evaluation of treatment categories (injectable, oral, and monoclonal antibody therapies). Quantitatively characterizing temporal changes in treatment preferences has the potential to generate valuable insights that may inform future healthcare planning and reimbursement policies.

Accordingly, the objectives of this study are to determine the annual distribution of DMTs used in patients with MS in Türkiye between 2015 and 2022, to compare utilization rates across the three therapeutic categories, and to evaluate temporal trends and delineate the transformation of MS treatment practices over time.

PATIENTS AND METHODS

This study is a nationwide, database-based retrospective cohort analysis evaluating DMT prescriptions among patients diagnosed with MS in Türkiye January 2, 2015, and December 31, 2022. The study population comprised all patients who received an MS diagnosis on at least three separate occasions and were prescribed at least one DMT during the study period. Data were obtained from centralized national health informatics systems, in which all prescriptions issued across Türkiye are digitally recorded. The dataset was filtered based on ICD-10 (International Classification of Diseases, 10th Revision) codes compatible with MS (G35), and only prescriptions containing DMTs were included in the analysis. Written informed consent was obtained from all participants. The study protocol was approved by the Health Sciences University Gülhane Scientific Research Ethics Committee (Date: 10.09.2024, No: 2024-433). The study was conducted in accordance with the principles of the Declaration of Helsinki.

All prescriptions included in the database were initially subjected to preprocessing with respect to diagnosis codes, medication name, dosage, prescription date, and prescribing physician or healthcare institution. During the data cleaning process, prescriptions with incomplete information or those identified as being prescribed for indications other than MS were excluded.

Duplicate prescriptions belonging to the same patient were reviewed based on prescription date and medication content and were deduplicated where appropriate. To ensure accurate assessment of temporal trends, the dataset was analyzed not only at the individual prescription level but also stratified by annual time periods.

Disease-modifying therapies were categorized into three therapeutic groups: injectable, oral, and monoclonal antibody therapies. Injectable therapies included interferon beta-1a, interferon beta-1b, pegylated interferon beta-1a, and glatiramer acetate. Oral therapies included fingolimod, dimethyl fumarate, teriflunomide, and cladribine. Monoclonal antibody therapies included natalizumab, alemtuzumab, and ocrelizumab.

Each medication was evaluated within its respective categories. Annual prescription proportions were calculated for each treatment group, and temporal trends in category utilization were assessed over the eight-year study period. Both absolute annual prescription counts and relative percentage distributions were calculated and analyzed separately.

Statistical analysis

Statistical analyses were primarily descriptive in nature. Annual absolute prescription counts and proportional distributions of injectable, oral, and monoclonal antibody therapies were calculated for each calendar year between 2015 and 2022. Treatment category utilization was evaluated longitudinally by examining year-by-year percentage distributions. Sex-stratified proportional analyses were also performed to assess the consistency of temporal trends across male and female patients. No inferential statistical testing was applied, and findings are presented descriptively to characterize national prescribing patterns over time.

RESULTS

A total of 562,899 DMT prescriptions belonging to 54,795 patients (37,574 females, 17,221 males; mean age: 43.4 ± 11.8 years; range, 11 to 93 years) with MS were included in the analysis during the study period. The annual distribution of DMT categories over the study period is presented in Figure 1.

Temporal distribution of treatment categories

Evaluation of DMT prescriptions over time demonstrated a clear change in treatment preferences throughout the study period. Injectable therapies constituted a substantial proportion of prescriptions in earlier years, while oral therapies and monoclonal antibody treatments became increasingly prominent in later years. The longitudinal changes in the distribution of these three therapeutic categories highlight a progressive transition in national MS prescribing patterns (Figure 1).

Year-specific proportional distribution

The proportional distribution of treatment categories within each calendar year was also assessed to better characterize changes in prescribing patterns over time. This analysis demonstrated a gradual shift in the relative contribution of each treatment category across the study period. The year-by-year proportional distribution of injectable, oral, and monoclonal antibody therapies is illustrated in Figure 2.

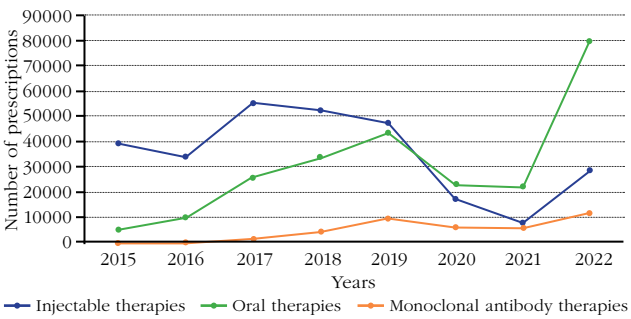

Figure 1. Annual prescription counts of injectable therapies, oral therapies, and monoclonal antibody therapies in patients with MS in Türkiye between 2015 and 2022.
MS, multiple sclerosis.

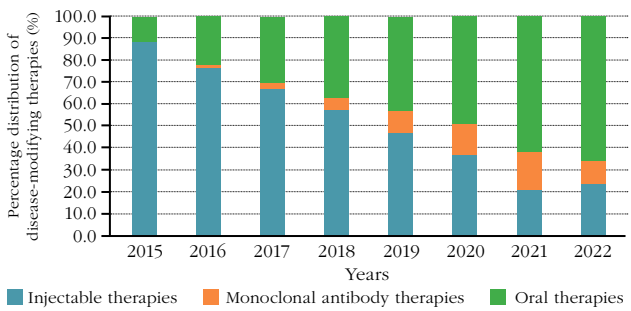

Figure 2. Annual percentage distribution of injectable, oral, and monoclonal antibody therapies within total MS prescriptions in Türkiye between 2015 and 2022.
MS, multiple sclerosis.

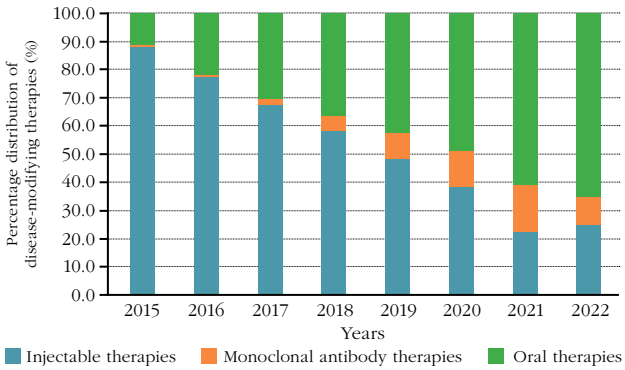

Figure 3. Annual percentage distribution of injectable, oral, and monoclonal antibody therapy groups among female patients with MS in Türkiye between 2015 and 2022.
MS, multiple sclerosis.

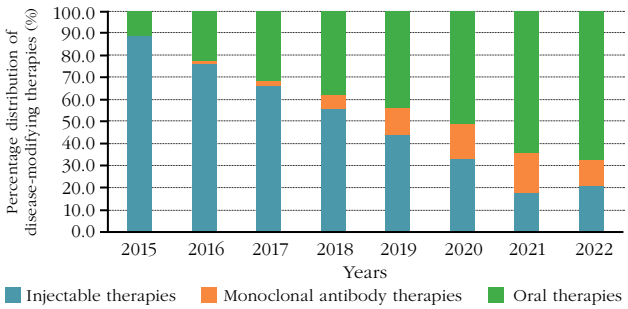

Figure 4. Annual percentage distribution of injectable, oral, and monoclonal antibody therapy groups among male patients with MS in Türkiye between 2015 and 2022.
MS, multiple sclerosis.

Sex-specific analyses

Sex-stratified analyses were performed to evaluate potential differences in treatment patterns between male and female patients. The annual proportional distribution of treatment categories among female patients is shown in Figure 3, while the corresponding distribution among male patients is presented in Figure 4. No statistically interpretable divergence between sexes was observed, and therefore, the sex-stratified figures are presented primarily to demonstrate the consistency of national prescribing trends across demographic groups.

Across both sexes, similar temporal trends were observed, with changes in treatment category utilization occurring in parallel over time. Although female patients accounted for a higher absolute number of prescriptions, the overall pattern of treatment category distribution and its evolution over the study period were comparable between sexes.

DISCUSSION

In this nationwide analysis of DMT prescriptions among patients with MS in Türkiye between 2015 and 2022, we demonstrate a substantial transformation in prescribing patterns over time. Consistent with global trends, our findings indicate a progressive shift from injectable agents toward oral therapies and monoclonal antibody–based treatments.[22]

One of the most prominent findings is the marked decline in the proportion of injectable therapies over the study period. First-generation agents, including interferon beta formulations and glatiramer acetate, long served as the foundation of MS treatment owing to their established safety profiles and extensive clinical experience.[23] However, administration-related challenges, injection-site adverse effects, and declining long-term adherence have limited their sustained use. In parallel, the increasing availability of alternative therapies after 2015 has naturally reduced reliance on injectable treatments.[24]

The pronounced increase in oral therapy use cannot be attributed solely to their efficacy and ease of administration. In Türkiye, the growing availability of generic formulations has substantially improved access to agents such as dimethyl fumarate and teriflunomide. The entry of generics has reduced treatment costs and alleviated pressure on reimbursement systems, facilitating broader clinical adoption. This economic dimension underscores that treatment trends are shaped not only by clinical considerations but also by pharmacoeconomic dynamics.[25]

The increasing utilization of monoclonal antibody therapies represents another indicator of the evolving treatment landscape. In particular, the introduction and reimbursement of anti-CD20 agents after 2018, together with licensing of additional high-efficacy therapies, likely contributed to the observed increase in their use. Accumulating evidence and international guideline recommendations have supported broader use of these agents in appropriate patients.[26] Nevertheless, their relatively high costs compared to other DMT classes have influenced reimbursement policies. In Türkiye, regulatory frameworks linking their use to predefined clinical criteria have acted as a moderating factor. Over time, revisions of these criteria and increasing clinician experience appear to have facilitated broader use of monoclonal antibody therapies.[27]

An important external factor influencing prescribing patterns during the study period was the COVID-19 (coronavirus disease 2019) pandemic (2020-2021). This period exerted substantial pressure on healthcare delivery and clinical decision-making.[28] Reduced hospital visits, limitations in face-to-face follow-up, and concerns regarding immunosuppressive therapies may have influenced treatment continuation and prescribing choices. Some patients postponed treatments, and clinicians occasionally extended dosing intervals of certain therapies. Conversely, the need to maintain continuity of care under constrained conditions may have favored therapies requiring less intensive monitoring, particularly oral agents.[29] In addition, during the pandemic period in Türkiye, patients with valid chronic disease medication reports were permitted to obtain ongoing treatments directly from pharmacies without new prescriptions. As a result, prescription counts during this interval may appear artificially reduced. However, because treatment switching required new documentation, this policy is unlikely to have substantially affected category-level distribution. Accordingly, percentage-based analyses provide a more reliable indicator of prescribing trends during this period.[30]

Healthcare policies and cost-containment measures also played a decisive role in shaping treatment preferences. Reimbursement strategies guided by cost-effectiveness considerations have influenced access to various DMTs. Increased availability of generics, pricing regulations, and structured reimbursement pathways have facilitated the use of certain agents, whereas controlled access criteria for higher-cost therapies have moderated their uptake.

A major strength of this study lies in the use of a comprehensive nationwide dataset encompassing all MS prescriptions in Türkiye, ensuring a high level of real-world representativeness. The large sample size, long observation period, and complete national coverage provide a robust overview of temporal prescribing trends and enable evaluation of treatment distribution patterns at the population level. Such large-scale real-world data are valuable for understanding healthcare utilization and policy-driven changes in treatment access.

However, several limitations must be acknowledged. The prescription-based nature of the dataset precluded assessment of important clinical variables such as disease duration, disease subtype, disability level, imaging findings, treatment response, or relapse activity. Information regarding treatment line, switching sequence, and specific clinical indications was not available, preventing evaluation of escalation versus early high-efficacy strategies. In addition, classification of therapies according to route of administration does not directly reflect disease severity, therapeutic intent, or patient selection, which may introduce indication bias. Furthermore, temporal trends may have been influenced by external factors such as drug launch dates, reimbursement regulations, and pandemic-related healthcare policies in Türkiye. Therefore, the findings should be interpreted as describing national prescribing patterns rather than individualized treatment strategies or clinical decision pathways.

In conclusion, the period from 2015 to 2022 represents a phase of substantial evolution in MS treatment practice in Türkiye. A clear shift from injectable therapies toward oral agents has occurred, accompanied by increasing use of monoclonal antibody therapies. Drug availability, reimbursement policies, and external factors such as the COVID-19 pandemic have collectively shaped these trends. By leveraging national-level data, this study provides robust descriptive insights into real-world treatment patterns with important implications for healthcare planning and policy development.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: E.T., B.Ö.: Idea/concept, design, writing the article, critical review; N.A., Ş.B.: Control/supervision; E.T., B.Ö., Ş.B., N.A.: Data collection and/or processing; B.Ö.: Analysis and/or interpretation; E.T.: Literature review, funding materials.

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