Paper RE01

Annualized Relapse Rate and Clinical Profiles in South Korean Multiple Sclerosis Patients: A Sample Cohort Study Using Korean National Health Insurance Data

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ABSTRACT

Background:

Multiple Sclerosis (MS) is a chronic, immune-mediated disorder of the central nervous system, with a globally increasing prevalence. This study aimed to explore the potential of Annualized Relapse Rate (ARR) as a predictor of disease course in Korean MS patients, using the National Health Insurance Service (NHIS) sample cohort data (2007-2019). Given the sample size, this study serves as an exploratory analysis to characterize relapse patterns in a Korean MS cohort. Additionally, we sought to generate Real-World Evidence (RWE) by analyzing the clinical characteristics and relapse risk factors among Korean MS patients.

Methods:

To ensure diagnostic accuracy, we included patients newly diagnosed with MS between 2009 and 2019 who had at least two MS diagnoses (ICD-10: G35) and at least one record of the rare/intractable disease code (V-code: V022), excluding those with any MS diagnosis in 2007–2008. We assessed demographic data, medication use (vitamin D, corticosteroids), comorbidities, and healthcare utilization. MS relapse was defined as hospitalization due to MS-related complications that occurred ≥ 30 days after the most recent MS diagnosis, based on claims data. This definition captures severe relapses requiring hospitalization but may underestimate overall relapse rates by excluding outpatient-managed relapses. ARR was calculated as the total number of relapses divided by the total person-years (PY) at risk. Follow-up time was calculated in days and converted to PY by dividing by 365.25. ARR was summarized descriptively across increasing follow-up cut-offs since diagnosis (up to 1, 2, …, 7 years), and time to first relapse was analyzed using the Kaplan–Meier method.

Results:

Among included MS patients, women accounted for 69.09% and most were aged 20-59. Patterns of vitamin D and corticosteroid use, frequency of autoimmune comorbidities, and healthcare utilization were thoroughly analyzed. Among hospitalization-requiring relapses, cumulative ARR estimates up to increasing follow-up cut-offs since diagnosis (up to 1, 2, …, 7 years) ranged from 0.12 to 0.16, and 38% of patients experienced at least one hospitalization-requiring relapse. The observed ARR (0.12-0.16) is lower than Western reports, likely reflecting our restrictive definition rather than biological differences.

Conclusion:

This real-world study of a Korean MS cohort showed that ARR estimates were highest in the early disease period and tended to decline over time. Given the claims-based, hospitalization-defined relapse outcome and limited sample size, early ARR should be interpreted as a descriptive indicator that may approximate longer-term relapse activity, rather than a validated surrogate. Longer-term follow-up in larger cohorts with standardized relapse assessment is warranted.

Keywords: Multiple sclerosis (MS), Annualized Relapse Rate (ARR), Real-World Evidence (RWE), National Health Insurance Service (NHIS), Ethnic Differences

INTRODUCTION

Multiple sclerosis (MS) is a chronic, immune-mediated disease of the central nervous system (CNS), with a global prevalence that has recently increased. The prevalence of MS varies markedly by race, with the highest prevalence in Western white populations and relatively lower prevalence in Asian and Hispanic populations[1]. Furthermore, MS is characterized by demyelination and axonal damage that disrupts neural transmission[2]. While its pathogenesis is not fully understood, it is believed to involve a process in which damage to the myelin sheath surrounding nerves disrupts the transmission of nerve impulses from the brain to various parts of the body[3].

Relapses, acute episodes of neurological dysfunction, are a primary clinical feature of MS, with the relapsing-remitting type affecting around 85% of patients diagnosed with MS[4]. The relapses have been shown to correlate with inflammation and demyelination, leading to irreversible disability, with each event conferring a 1.5- to twofold increased risk of irreversible axonal loss over 15 years[5].

Since the mid-1990s, numerous drugs have been approved by large clinical trials to reduce the number and severity of MS relapse. The majority of these trials have been funded and led by industry. However, designing and conducting MS clinical trials remains challenging due to the unpredictable nature of the disease, which necessitates a large number of patients studied over extended periods of time[6].

In Phase III placebo-controlled clinical trials for relapsing MS, ARR has been widely used as a primary or secondary efficacy endpoint, owing to its ability to quantitatively capture relapse activity over the observation period[7]. However, ARR can fluctuate throughout the disease process, significantly impacting the interpretation of results and clinical trial design. According to clinical trials registered on ClinicalTrials.gov, observation periods for ARR measurement vary from 48 weeks to 8 years[8]. While some studies suggested that a one-year observation period may be sufficient for detecting changes in relapse rates, many clinical trials still involve long-term follow-up to ensure robust estimation of ARR in patients with MS.

The aim of this study is to estimate ARR across increasing follow-up cut-offs since diagnosis (e.g., up to 1, 2, …, 7 years) and to explore whether ARR measured over an early observation window descriptively aligns with ARR estimates observed over longer follow-up in South Korean MS patients.

MATERIALS AND METHODS

DATA SOURCE

We used South Korea's National Health Insurance Service-National Sample Cohort (NHIS-NSC) database. The National Health Insurance (NHI) is a single-insurer system with complete universal healthcare coverage in South Korea since 2000. The NHIS uses a systematic stratified sampling approach to randomly select a representative database of approximately 1 million people who maintained health insurance and were beneficiaries of medical benefits in South Korea for 1 year in 2006 and were followed up from 2002 to 2019. This database contains sociodemographic data, medical diagnoses, and prescription information for both inpatients and outpatients. Disease diagnosis codes are recorded according to *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)* coding system, and drugs are documented using domestic National Health Insurance coding systems[9]. The present study was approved by the Institutional Review Board (IRB) of the Korea National Institute for Bioethics Policy (IRB No. P01-202210-01-031).

STUDY DESIGN AND POPULATION

We included patients diagnosed with MS from 2009 to 2019. Eligible participants were those diagnosed with MS at least twice during the observation period (2009-2019), identified using International Classification of Disease-Tenth Revision (ICD-10) codes for MS (G35). To ensure the accuracy of MS diagnoses, we included patients with a V-code (V022), which is designated for tracking patients with rare, intractable diseases (RID).

We excluded patients who did not have a record of the V-code (V022) or those diagnosed with MS fewer than twice with the ICD-10 code (G35) during the observation period. Additionally, to focus on newly diagnosed patients, we excluded MS patients diagnosed with MS in 2007 or 2008.

The RID registration program, introduced in Korea in 2009, provides a special copayment reduction to support the diagnosis and treatment of certain diseases. Physicians submit the diagnoses for applicable conditions, after which the NHI committee certifies the patient's registration into the program.

Detailed information regarding the selection of eligible patients is illustrated in Figure 1.

The first date of MS diagnosis was designated as the index date, and patients were followed from the index date until the end of the last claim date or until death occurred, whichever came first.

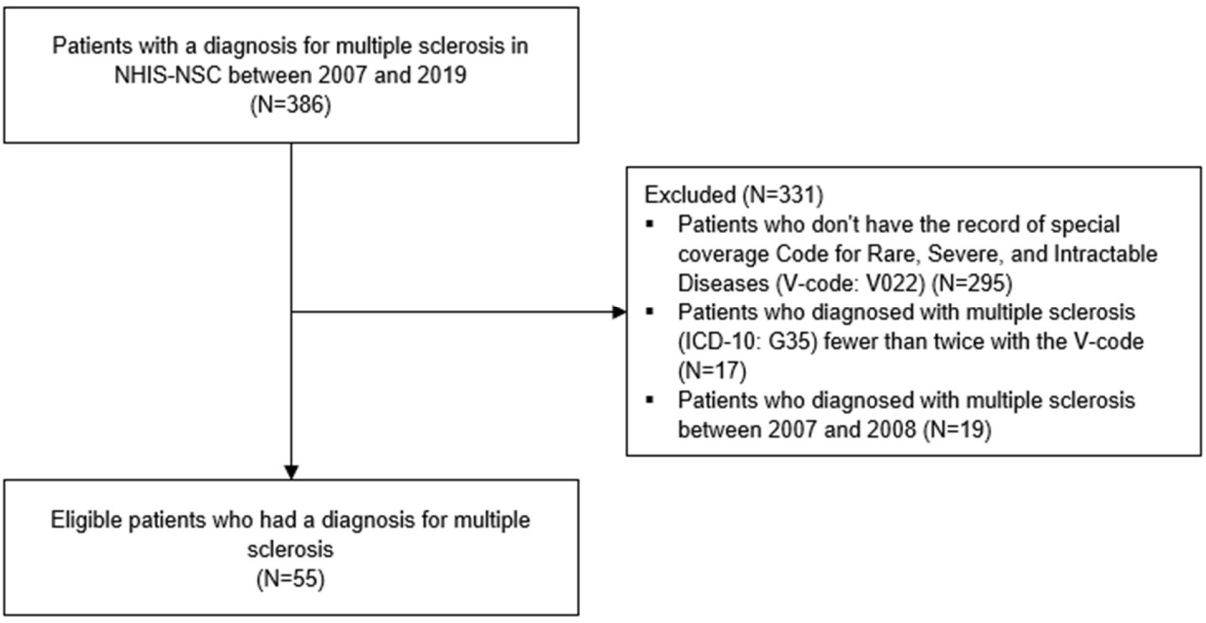

Figure 1. Flow Chart of the Study Population

PATIENT CHARACTERISTICS

Baseline characteristics, including age, sex, BMI and medication were examined in the study population. In addition, the history of autoimmune diseases, aside from MS, and diseases related to MS symptoms were assessed within 3 years prior to the index date.

Furthermore, we evaluated the survival probability of MS patients, and examined proxies for overall health status related to MS, such as the number of hospital visits for MS, the duration of hospitalization for MS were also evaluated for the follow-up period.

RELAPSE OF MULTIPLE SCLEROSIS

In this study, relapses in MS patients were identified using hospitalization records. To avoid double-counting clustered claims, multiple hospitalization claims occurring within a 30-day window were considered part of the same relapse episode; hospitalizations separated by ≥30 days were counted as distinct relapse events. The general formula is expressed as follows:

$$ARR = \sum_i \left(\frac{r_i}{t_i} \times \frac{t_i}{T}\right) = \frac{\sum_i r_i}{\sum_i t_i}$$

, where the subscript i represents each individual, ri is the number of relapses during follow-up in each individual, ti is the length of follow-up in each individual, and T is the total sum of follow-up periods within the cohort.[10]

To provide a standardized measure of relapse frequency, we calculated the Crude ARR. The standard method for calculating the crude ARR in a study cohort is the person-years method as follows:

$$ARR = \frac{Total\ number\ of\ relapses}{Total\ person\ time\ (in\ years)\ at\ risk\ of\ relapse}$$

, where Total number of relapses is the sum of all confirmed relapse events across all participants, and Total person years (PY) is the combined follow-up time for all participants. If individual follow-up periods vary, each participant's time at risk is summed to find the total. For each patient, follow-up time was calculated in days from the index date to the last observed claim date or death, whichever came first, and converted to PY by dividing by 365.25.[10]

ARR was summarized descriptively across increasing follow-up cut-offs since diagnosis (up to 1, 2, …, 7 years), as presented in Tables 4 and 5.

Additionally, to investigate the clinical characteristics of relapse, the number of relapses per patient, time to first relapse from the initial diagnosis of MS and time to second relapse following the first relapse were estimated for patients who experienced a relapse.

STATISTICAL ANALYSIS

We reported baseline characteristics of MS patients as frequencies with proportions for categorical variables and means with standard deviations (SD) or median with Q1, Q3 for continuous variables. The survival probability of study population was plotted using the Kaplan-Meier model.

For statistical estimates, 95% Confidence Intervals (CIs) were calculated. The 95% CI of the ARR was estimated Poisson distribution.[10] Two-sided p-values < 0.05 were considered statistically significant.

All statistical analyses were performed using Statistical Analysis Software (SAS) version 9.4 (SAS Institute Inc., Cary, North Carolina, USA).

RESULTS

BASELINE CHARACTERISTICS OF STUDY POPULATION

Table1. Baseline Characteristics of MS Patients in South Korea between 2009 and 2019

	MS patients (n=55)
Age, mean ± SD (year)	45.20 ± 16.17
Age group, n (%)	
< 20 years	2 (3.64%)
20 ~ 39 years	20 (36.36%)
40 ~ 59 years	24 (43.64%)
≥ 60 years	9 (16.36%)
Sex, n (%)	
Male	17 (30.91%)
Female	38 (69.09%)
BMI, n (%)	
Underweight (< 18.5)	3 (5.45%)
Normal bodyweight (18.5 to < 23)	8 (14.55%)
Overweight (≥23)	10 (18.18%)
Missing/Unknown	34 (61.82%)

	MS patients (n=55)
Medication, n (%)	
Vitamin D	4 (7.27%)
Corticosteroid	40 (72.73%)
Overall health status	
No. of outpatient visits, mean ± SD	7.71 ± 6.23
No. of Emergency room (ER) visits, mean ± SD	1.07 ± 1.49
No. of prescription of steroids, mean ± SD	2.04 ± 2.29
No. of hospitalization, mean ± SD	2.20 ± 3.45
Duration of hospitalization, median (Q1 - Q3)	21 (8 – 119)

The baseline characteristics of the study population are presented in Table 1. A total of 55 eligible MS patients were identified from a nationwide database. The mean age of the study population was 45.2 years (SD: 16.17 years). The highest proportion of patients was observed in the 40-59 years age group, while the lower proportions were found in the < 20 years and ≥ 60 years age groups. The majority of the MS patients were female (69.09%) and some were classified as overweight (18.18%). Most of the patients (72.73%) were treated on corticosteroids.

Table 2. History of Other Autoimmune Disease of MS Patients

	MS patients (n=55)
Autoimmune Disease (n, %)	11 (20.00%)
Rheumatoid Arthritis	6 (10.71%)
Narcolepsy	3 (5.45%)
Systemic sclerosis	3 (5.45%)
Myasthenia Gravis	2 (3.57%)
Antiphospholipid Syndrome	1 (1.82%)
Chronic Inflammatory Demyelinating Polyneuropathy	1 (1.82%)

Note: Subcategories are not mutually exclusive; a patient may be counted in more than one condition.

Table 3. History of Disease Related to Symptoms of MS Patients

	MS patients (n=55)
Myelitis	11 (20.00%)
Neuromyelitis Optica Spectrum Disorder (NMOSD)	5 (9.09%)
Sensory syndrome	3 (5.45%)
Visual syndrome	3 (5.45%)
Motor syndrome	1 (1.82%)

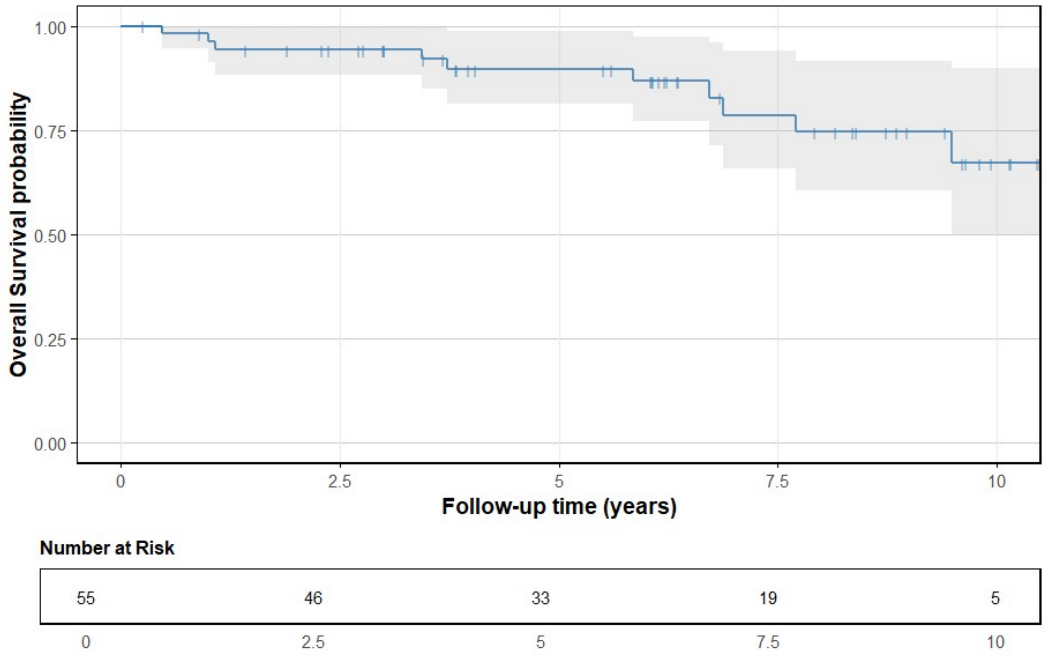

Figure 2. Kaplan-Meier Curve of Overall Survival in MS Patients

Additionally, 20% of the patients had a history of other autoimmune diseases aside from MS. Autoimmune diseases were evaluated within 3 years before the index date, as first diagnosis date of MS. Specifically, 10.71% of MS patients had been diagnosed with rheumatoid arthritis prior to their MS diagnosis, while 5.45% had narcolepsy and systemic sclerosis, as shown in Table 2. Regarding conditions related to MS symptoms, 20% of patients were diagnosed with myelitis before the index date (Table 3). Disease related to symptoms were evaluated within 3 years before the index date, as first diagnosis date of MS. Sensor syndrome includes paresthesia; motor syndrome includes unsteadiness on feet, paraplegia, hemiplegia, spasmodic torticollis, and myoclonus; visual syndrome includes visual disturbances.

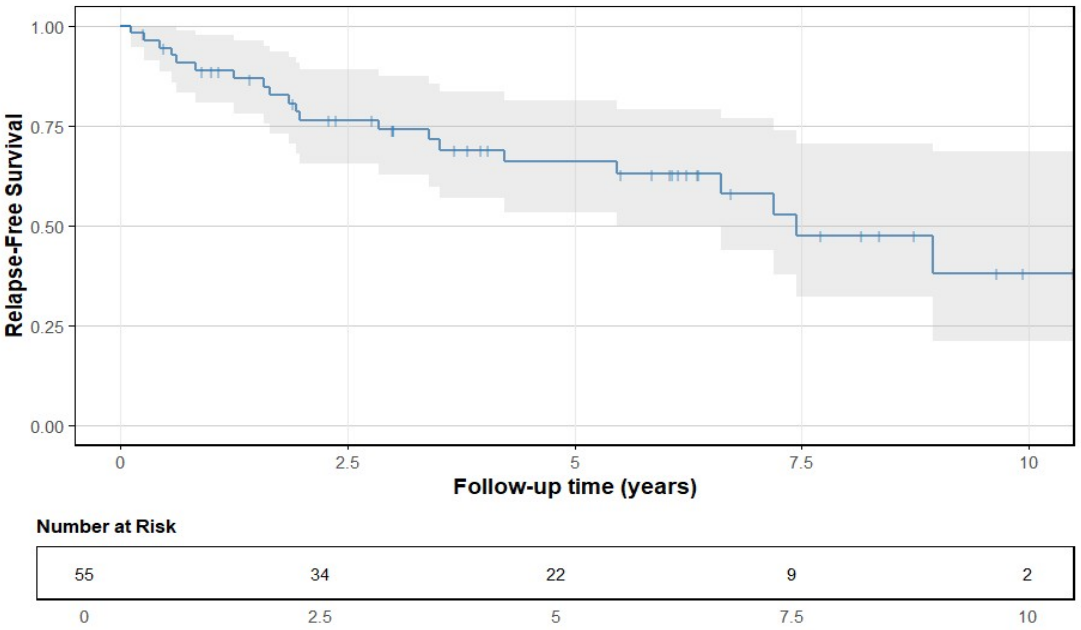

Figure 3. Kaplan-Meier Curve of Relapse-Free Survival in MS Patients

Figure 2 is a graphical representation of the survival rates of patients newly diagnosed with MS in Korea from 2009 to 2019, using a Kaplan-Meier curve. A total of 55 patients with MS were included in the analysis, and the Kaplan-Meier survival analysis estimated the 10-year overall survival rate to be approximately 70%.

Figure 3 is a graphical representation of the relapse-free survival (RFS) of patients newly diagnosed with MS in Korea from 2009 to 2019, using a Kaplan-Meier curve. A total of 55 patients with MS were included in this analysis, and survival analysis using the Kaplan-Meier method estimated the median RFS to be approximately 7 years.

RELAPSE OF MULTIPLE SCLEROSIS

Of the 55 MS patients, 21 patients (38.18%) experienced at least one hospitalization-requiring relapse, with a mean of 1.86 hospitalization-requiring relapse events per patient among those with relapses. Table 4 presents the ARR of MS in our study population, summarized by follow-up duration categories after the index date. The overall Crude ARR during the entire study period was 0.12 (95% CI; 0.09, 0.17), 95% CI for the ARR was calculated using the Poisson distribution method, which likely represents an underestimate of the true relapse rate as it excludes outpatient-managed relapses.

Table 4. Annualized Relapse Rate of MS Patients according to Follow-up duration after Diagnosis

Follow-up duration category (since diagnosis)	No. of relapse	No. of patients	Sum of PYs (years)	Crude ARR (95% CI)
≤1 year since first diagnosis	7	6	53.62	0.13 (0.05, 0.27)
≤2 years since first diagnosis	16	12	103.04	0.16 (0.09, 0.25)
≤3 years since first diagnosis	23	13	149.20	0.15 (0.10, 0.23)
≤4 years since first diagnosis	28	15	188.16	0.15 (0.10, 0.22)
≤5 years since first diagnosis	30	16	221.22	0.14 (0.09, 0.19)
≤6 years since first diagnosis	33	17	253.18	0.13 (0.09, 0.18)
≤7 years since first diagnosis	35	18	276.12	0.13 (0.09, 0.18)
Total	39	21	320.08	0.12 (0.09, 0.17)

Table 5. ARR of MS according to Follow-up duration after Diagnosis (Sensitivity Analysis: Redefined Cohort)

Follow-up duration category (since diagnosis)	No. of relapse	No. of patients	Sum of PYs (years)	Crude ARR (95% CI)
≤1 year since first diagnosis	14	10	158.09	0.09 (0.05, 0.15)
≤2 years since first diagnosis	25	17	305.17	0.08 (0.05, 0.12)
≤3 years since first diagnosis	32	18	436.13	0.07 (0.05, 0.10)
≤4 years since first diagnosis	38	21	549.02	0.07 (0.05, 0.10)
≤5 years since first diagnosis	40	22	642.54	0.06 (0.04, 0.08)
≤6 years since first diagnosis	43	23	723.26	0.06 (0.04, 0.08)
≤7 years since first diagnosis	46	24	778.13	0.06 (0.04, 0.08)
Total	50	27	862.68	0.06 (0.04, 0.08)

When the MS cohort was redefined (Figure 4), ARR estimates were generally lower than those in the main analysis across follow-up cut-offs (Table 5). These findings should be interpreted descriptively given the claims-based relapse definition and limited sample size.

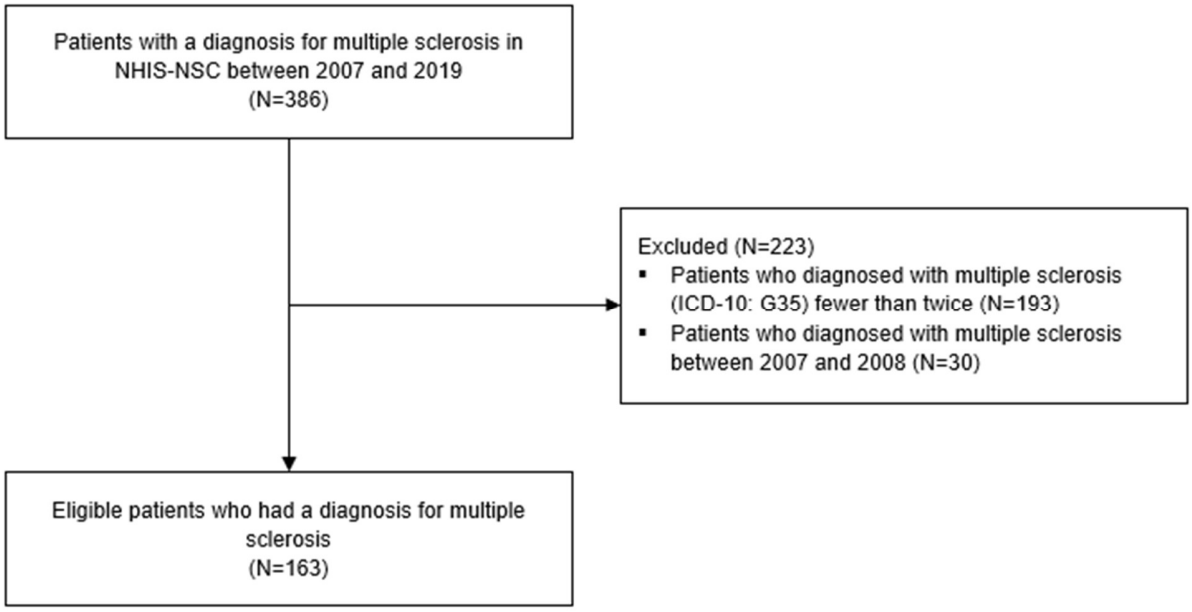

Figure 4. Flow Chart of the Study Population (Sensitivity Analysis)

DISCUSSION

This study used NHIS cohort data to describe the relapse patterns of Korean MS patients using real-world data. Furthermore, we assessed ARR across follow-up periods in Korean MS patients and examined temporal patterns and the predictability of early ARR for long-term prognosis. Our findings revealed that the overall Crude ARR was 0.12, with the highest ARR of 0.16 observed within the first two years after diagnosis, followed by gradual decline. This temporal pattern is consistent with previous studies, such as Tremlett et al., which demonstrated that relapse rates in MS are both age- and time-dependent, with a natural decline in ARR as the disease progresses[11]. While the observed ARR (0.12-0.16) is lower than typically reported in Western populations (typically 0.5-1.5 for untreated patients), this likely reflects our restrictive definition capturing only severe, hospitalization-requiring relapses rather than fundamental differences in disease biology. The early peak in ARR followed by a reduction aligns with the established understanding that inflammatory activity is highest during the initial years of MS and diminishes as the disease transitions to a more progressive phase[12,13]. Additionally, the relatively small sample size and retrospective nature of our study may have influenced the observed trends.

These findings have important clinical implications for the design of MS clinical trials. ARR is a key indicator for evaluating treatment efficacy and calculating sample sizes in clinical trials. As ARR is a commonly used endpoint for evaluating treatment efficacy and calculating sample sizes, understanding the temporal dynamics of ARR is crucial. Our results suggest that ARR measured within 1–2 years post-diagnosis provides a reasonable approximation of long-term relapse patterns.

Similarly, previous studies have found that ARR in clinical trials is 25–40% higher in months 1-12 compared to months 13-24, suggesting that ARR is not constant and tends to decrease over time. Focusing on early ARR may therefore help optimize both the duration and design of follow-up in MS studies[14]. Furthermore, Sormani et al. suggested that ARR measured one year after diagnosis provides sufficient power to detect clinically meaningful changes in recurrence[15].

These observations highlight the need to consider the timing of ARR measurement when designing trials and interpreting treatment effects. Early ARR, particularly within 1–2 years after diagnosis, may provide a pragmatic descriptive signal for longer-term hospitalization-requiring relapse activity in claims-based studies. However, it should not be interpreted as a validated surrogate endpoint, and the applicability to clinical trial design requires confirmation in larger cohorts with standardized relapse ascertainment.

Patient characteristics in our cohort, such as the predominance of females and the presence of comorbid autoimmune diseases, are consistent with the known epidemiology of MS[16-18]. The relatively high proportion of patients treated with corticosteroids reflects current clinical practice[19,20]. Interestingly, 20% of patients had a history of other autoimmune diseases, which may influence disease activity and relapse risk[21]. Further studies are warranted to explore the impact of comorbidities on relapse rate in MS.

This study has several strengths. To our knowledge, this is the first real-world study exploring MS relapse using a large-scale, nationwide health insurance database in Korea. By leveraging comprehensive claims data, our study provides valuable epidemiologic insights into relapse pattern in the Korean MS population, complementing findings from Western populations.

However, there are several limitations to consider. First, relapse was defined according to hospitalization records rather than comprehensive clinical criteria (e.g., new or worsening neurological symptoms lasting >24 hours, occurring $\geq$30 days after a previous episode, and not attributable to infection or fever). Although our operational definition is suitable for claims data analysis, it may not capture milder, atypical, or subclinical relapses, potentially resulting in underestimation or misclassification of relapse events. Because claims data may contain diagnostic code overlap during the early diagnostic work-up, misclassification between MS and related demyelinating disorders (e.g., NMOSD) cannot be fully excluded. Although we required RID registration (V022) to increase diagnostic specificity, residual misclassification may remain. Second, detailed information on disease-modifying therapy (DMT) use, treatment adherence, and expanded disability status scale (EDSS), and other relevant clinical variables was not available in our database, which limits the ability to assess the impact of these factors on relapse risk and may affect the generalizability of our results. Third, the small sample size (n=55) represents a major limitation that significantly restricts the statistical power and generalizability of our findings. With only 21 patients experiencing relapses and even smaller numbers in subgroup analyses, our ability to detect meaningful associations and draw definitive conclusions is substantially limited. The wide CIs observed (e.g., 95% CI: 0.05-0.27 for 1-year ARR) reflect this limited precision. Therefore, our findings should be considered hypothesis-generating and require validation in larger cohorts before clinical application. The retrospective design may also introduce selection and information bias.

Despite these limitations, our study provides a valuable foundation for understanding relapse epidemiology in Korean MS patients and highlights the need for future studies incorporating richer clinical detail and standardized relapse definitions.

CONCLUSION

In conclusion, this exploratory study of a Korean MS sample cohort suggests that hospitalization-requiring relapses are most frequent within the first two years after diagnosis and decline thereafter. While the observed ARR (0.12-0.16) is lower than typically reported in Western populations, this likely reflects our restrictive definition capturing only severe, hospitalization-requiring relapses rather than fundamental differences in disease biology.

Given the significant limitations of this study, particularly the small sample size (n=55) and restrictive relapse definition, our findings should be interpreted as preliminary and hypothesis-generating. Validation in larger, prospectively followed cohorts with comprehensive relapse assessment is essential before these results can be applied to clinical trial design or prognosis assessment.

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