Characteristics of a population exposed to a disease-modifying drug for multiple sclerosis in the real-world setting (1996-2017)

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Background

- The efficacy of a disease-modifying drug (DMD) is typically established via short, 2-3 year clinical trials in highly select and motivated groups of people with multiple sclerosis (MS).
- In clinical practice, DMDs are used for many years in a more diverse population of persons with MS.

Objective

To describe the **characteristics of a population with MS** who were **exposed to their first DMD in the real-world setting.**

Methods

- Linked, population-based health administrative data in the province of British Columbia, Canada (see **Data sources**).
- ***Population***: All persons with MS aged ≥ 18 years who filled **a prescription for a MS DMD** between 1996 and 2017.
- ***Study follow-up***: from the most recent of their first MS or demyelinating event or 01/January/1996 (study entry), to the earliest of death, emigration, or 31/December/2017 (study end) .
- **Characteristics** captured:
  - **Sex, age and DMD class:** at **date of 1st prescription filled**
  - **Socioeconomic status** (based on neighbourhood income)
  - **Comorbidity burden** (using the Charlson Comorbidity Index, applied to one-year prior to study entry date)
  - **Calendar period** 1996-2012 and 2013-2017 (differentiating the time periods when <5 and ≥5 individual DMD classes were available)

Data sources: administrative data, facilitated by Population Data BC

Prescription | Hospital | Physician | Vital Statistics | Provincial Insurance

Photo source: https://www2.gov.bc.ca/gov/content/health/health-drug-coverage

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Results

Table 1. Characteristics of the multiple sclerosis cohort

Characteristics	Total N=4,732 n (%)
Sex	
Women	3,469 (73.3)
Men	1,263 (26.7)
Age group at first DMD	
< 30 years	815 (17.2)
30 to 39 years	1,547 (32.7)
40 to 49 years	1,560 (33.0)
50 to 59 years	686 (14.5)
≥ 60 years	124 (2.6)
Calendar period at first DMD	
1996-2012	3,477 (73.5)
2013-2017	1,255 (26.5)
Socioeconomic status[a]	
1 (lowest income quintile)	914 (19.3)
2	870 (18.4)
3	992 (21.0)
4	1,006 (21.3)
5 (highest income quintile)	938 (19.8)
Unavailable	12 (0.3)
Comorbidity score[b]	
0	3,960 (83.7)
1	584 (12.3)
2	146 (3.1)
≥ 3	42 (0.9)

[a]**Socioeconomic status** is represented by neighborhood income quintiles, based on the closest available measurement to the study entry date.
[b]**Comorbidity** is measured using the Charlson Comorbidity Index (modified to exclude hemiplegia/paraplegia to avoid misclassifying MS complications as comorbidity) during the one-year period prior to the study entry date.

Table 2. Sex and age of the MS population by individual DMD class

Characteristics	Sex [female] n/Total N[a] (%)	Age at first DMD Mean (SD)
Overall cohort	3,469/4,732 (73.3)	39.7 (10.1)
By individual DMD class		
Beta-interferon	2,169/2,955 (73.4)	39.7 (10.0)
Glatiramer acetate	869/1,128 (77.0)	39.2 (10.1)
Natalizumab	45/68 (66.2)	40.0 (12.3)
Fingolimod	27/33 (81.8)	39.0 (11.5)
Dimethyl fumarate	202/313 (64.5)	39.7 (10.2)
Teriflunomide	132/196 (67.4)	43.1 (10.8)
Alemtuzumab	24/37 (64.9)	35.9 (10.3)

[a]**Total N** is the total number of people with that type (class) of first DMD. Key: SD, standard deviation.

Table 3. Disease-modifying drug use in the MS population, by calendar period

First DMD (drug class)	First DMD filled 1996-2012 n (%) of adults with MS	First DMD filled 2013-2017 n (%) of adults with MS
Beta-interferon	2,740 (78.8)	215 (17.1)
Glatiramer acetate	697 (20.1)	431 (34.3)
Natalizumab	31 (0.9)	37 (3.0)
Fingolimod	9 (0.3)	24 (1.9)
Dimethyl fumarate	*NA*	313 (24.9)
Teriflunomide	*NA*	196 (15.6)
Alemtuzumab	*NA*	37 (3.0)
Total	***3,477 (100)***	***1,253 (100)***

Key: NA, not applicable (as those individual DMDs were marketed in Canada after 2012).

Summary points

Overall, 4,732 with MS filled a DMD prescription during the 22-year study period.

- **Most were women**:
  - Variations in sex distribution observed.
  - Ranged from 65% for alemtuzumab and dimethyl fumarate to 82% for fingolimod.
- **Mean (SD) age at first DMD:**
  - Variations in the average age at first prescription fill across the different DMDs observed.
  - Ranged from 35.9 (SD 10.3) years for alemtuzumab to 43.1 (SD 10.8) years for teriflunomide.
- **Socioeconomic status:**
  - The cohort was distributed evenly across the income-based quintiles (neighborhood-level).
- **Patterns of treatment:**
  - Changed considerably between 1996-2012 vs. 2013-2017
  - Increased uptake of the oral DMDs.
  - Likely reflects increased availability (choice) of DMDs to treat MS.
- **Overall study population and implications:**

people with MS had at least **some comorbidity**.

≥50 years old at the **time of their first DMD**.

Implications

Older individuals or individuals with comorbidity are **typically excluded from clinical trials**.

Findings illustrate the need to **understand the harms and benefits** of DMD use in **these understudied groups**.

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