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

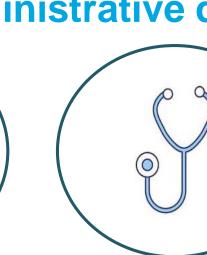
- ➤ Linked, population-based health administrative data in the province of British Columbia, Canada (see Data sources).
- Population: All persons with MS aged ≥ 18 years who filled a prescription for a MS DMD between 1996 and 2017.
- > Study follow-up: from the most recent of their first MS or demyelinating 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

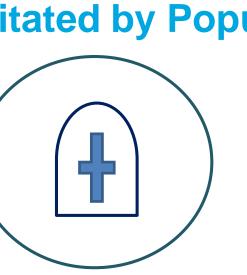




Hospital







Vital Statistics



Provincial Insurance

Acknowledgement

Prescription

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Access to, and use of, BC data was facilitated by Population Data BC and approved by: the BC Ministry of Health; BC PharmaNet; and the BC Vital Statistics Agency. All inferences, opinions, and conclusions drawn in this manuscript are those of the authors, and do not reflect the opinions or policies of the British Columbia Data Steward(s).

Physician

Disclosures

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Results

Table 1. Characteristics of the multiple sclerosis cohort

Characteristics	Total N=4,732 n (%)	C
Sex Women Men	3,469 (73.3) 1,263 (26.7)	St St 1
Age group at first DMD < 30 years 30 to 39 years 40 to 49 years	815 (17.2) 1,547 (32.7) 1,560 (33.0)	2 3 4 5 U
50 to 59 years ≥ 60 years	686 (14.5) 124 (2.6)	C 0
Calendar period at first DMD 1996-2012	3,477 (73.5)	1 2 ≥
2013-2017	1,255 (26.5)	a Soc base

Characteristics	Total N=4,732 n (%)
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)

^aSocioeconomic status is represented by neighborhood income quintiles, based on the closest available measurement to the study entry date.

^bComorbidity 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)

^aTotal 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

coverage	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.









