ECTRIMS 2022
38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis
27th Annual RIMS Conference
26 – 28 October 2022
Amsterdam, The Netherlands

P102

Existing claims-based algorithm may overestimate relapses in multiple sclerosis (MS) patients using infusible disease modifying therapies (DMTs) that require steroid premedication

C. Hersh[1], D. Conway[2], W. Chow[3], Q. Shao[3], F. Yang[3], M. Wang[4], C. Deshpande[3]
[1]Cleveland Clinic, Lou Ruvo Center for Brain Health, Las Vegas, United States, [2]Cleveland Clinic, Mellen Center, Cleveland, United States, [3]Novartis, Health Economics and Outcomes Research, East Hanover, United States, [4]KMK Consulting, Morristown, United States

Introduction: Claim databases lack information on clinical outcomes such as relapses, thus algorithms to estimate MS relapse events were developed. [1,2] These algorithms use MS-related hospitalizations and outpatient steroid prescriptions to identify relapses, which may lead to overestimation, particularly in patients on DMTs that require steroid premedication.[3]
Objective: Assess the strength of a published algorithm [1] and a revised algorithm for correctly identifying relapses in MS patients on intravenous (IV) DMTs requiring steroid premedication: ocrelizumab (OCR) and alemtuzumab (ALM) vs. common therapies that do not: glatiramer acetate, interferon beta, and dimethyl fumarate (BRACE&DMF). Natalizumab (NTZ), an IV monoclonal antibody (mAb) that does not require steroid premedication, was included as a reference.
Methods: This retrospective study used the Truven MarketScan® Commercial & Encounters database with adult MS patients who started OCR, ALM, NTZ, or BRACE&DMF (4/2014-6/2020) with continuous enrollment ≥24 months before and ≥12 months after treatment initiation (index date). Relapse was identified via a published algorithm[1] and a revised algorithm that excluded steroid use from the relapse count when given within ±5 days of the infusible DMT. Inverse probability treatment weighting (IPTW) was used to adjust for confounding.
Results: 2,791 patients were included (OCR n=495, ALM n=22, NTZ n=346, BRACE&DMF n=2,274). After IPTW, the observed characteristics (age, sex, region, comorbidities, MS disability level, and pre-index relapses) were balanced across groups. During 12-month post-treatment, using the published algorithm, the proportion of patients with a relapse was 82.4% OCR, 63.4% ALM, and 20.1% NTZ vs. 20.3% BRACE&DMF. With the revised algorithm, the proportion of patients with relapses decreased to 21.7% OCR, 19.0% ALM, and 18.0% NTZ vs. 18.6% BRACE&DMF; resulting in annualized relapse rates (ARR) of 0.34 OCR, 0.24 ALM, and 0.24 NTZ vs. 0.26 BRACE&DMF. Change in relapse rate from the traditional to revised algorithm was most obvious for IV mAbs requiring steroid premedication.
Conclusion: Despite adjusting for steroid use in the revised algorithm, we unexpectedly found similar relapse rates in IV mAbs and BRACE&DMF. This is contrary to clinical trial and practice, suggesting continued overestimation of relapses in IV mAbs due to unmeasured confounding. This algorithm warrants further revision to accurately estimate relapses in the age of mAbs.
Disclosure: Wing Chow, Qiujun (Samantha) Shao, Fei Yang, and Chinmay Deshpande are employees of Novartis Pharmaceuticals Corporation. Mengru Wang is an employee of KMK Consulting, Inc. and works as a consultant to Novartis Pharmaceutical Corporation. Dr. Hersh has received speaking, consulting, and advisory board fees from Genentech, Genzyme, Biogen, Novartis, EMD-Serono, Bristol Myers Squibb, and TG Therapeutics. She has received research support paid to her institution by Biogen, Novartis, Genentech, Patient-Centered Outcomes Research Institute (PCORI) and NIH - NINDS 1U01NS111678-01A1 sub-award. Dr. Conway has received consulting fees from Novartis Pharmaceuticals. He has received speaking fees from Biogen and NeuroLive. He has received research support paid to his institution by Novartis Pharmaceuticals and EMD Serono.