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PERSISTENCE IN OPEN AND CLOSED DATA SOURCES: A STUDY OF FINGOLIMOD VERSUS INTERFERON/GLATIRAMER ACETATE IN PATIENTS WITH MULTIPLE SCLEROSIS

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OBJECTIVES: To compare 6-month persistence rates among patients receiving the multiple sclerosis (MS) disease-modifying therapies (DMTs) fingolimod or interferon/glatiramer acetate (IFN/GA) (index DMT), using open- and closed-source data that reflect unrestricted or continuous health care coverage, respectively. **METHODS:** Retrospective analyses used administrative claims and mail-order pharmacy databases (IMS PharMetrics Plus™ [closed]) and LRx™ [open], respectively. All patients were ≥18 years old and naive to fingolimod and index DMT, had ≥1 prescription for index DMT between 01-Oct-2010 and 31-Mar-2013 and had not received multiple DMTs at index date. An additional PharMetrics cohort was selected using more stringent criteria (continuous enrolment pre-/post-index; MS diagnosis code). LRx prescriptions were collected from pharmacies supplying ≥1 claim for index DMT between the index date and the last month of follow-up. Persistence was defined as time from initiating index DMT until discontinuation (gap ≥60 days), receipt of another DMT or end of the 6-month follow-up period. Risk of and time to discontinuation were assessed by a Cox proportional hazards model (controlling for age, gender and region) and Kaplan-Meier analysis, respectively. **RESULTS:** Using identical criteria, 22,467 PharMetrics patients (fingolimod: n=1968; IFN/GA: n=20,499) and 49,803 LRx patients (8325 and 41,478, respectively) were selected. Proportions of patients discontinuing index DMT were significantly lower for fingolimod vs IFN/GA (PharMetrics: 23.1% vs 27.2%; LRx: 26.9% vs 33.4%; p<0.0001). Risk of discontinuation was higher for IFN/GA vs fingolimod (PharMetrics: hazard ratio, HR=1.18; 95%CI: 1.07-1.30, p=0.0008; LRx: HR=1.23; 95%CI: 1.17-1.29, p<0.0001). Time to discontinuation was significantly longer for fingolimod vs IFN/GA (PharMetrics: p=0.0005; LRx: p<0.0001). With more stringent criteria used in PharMetrics, risk of discontinuation of IFN/GA vs fingolimod increased (HR=1.47; 95%CI: 1.24-1.74, p<0.0001). **CONCLUSIONS:** Both data sources provided similar results, supporting use of open-source LRx data, which allows access to up-to-date information that can improve sample size and statistical power.

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COMPARISON OF THE VALUATION OF TREATMENT ALTERNATIVES IN PARKINSON'S DISEASE WITH BEST-WORST SCALING, TIME TRADE-OFF AND VISUAL ANALOGUE SCALES

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OBJECTIVES: Traditional valuation methods are insensitive to small improvements in process and outcome of care. Best-Worst scaling (BWS) was proposed as a sensitive and efficient method to determine the relative value of different treatments for the same disease, which would be desirable to estimate cost-effectiveness. The study objective was to compare the ability of BWS to differentiate between different treatment alternatives to that of Time Trade Off (TTO) and Visual Analogue Scales (VAS). **METHODS:** An online survey was conducted to estimate individual values for six different treatments reflecting the real-life options in the treatment of Parkinson's Disease with BWS2, BWS3, TTO and VAS (n=592). Pearson correlation coefficient was used to examine the strength of linear dependence between estimated utility scores. **RESULTS:** Twenty-seven percent of respondents was not willing to trade life years in TTO. Only two percent of the respondent does not differentiate between the value of health states with VAS. When non-traders were excluded from the analysis, the best case scenario was valued significantly higher than the worst case scenario with all methods. Rank reversals among intermediate alternatives were common. The correlation between utility scores was very strong (VAS-BWS2 1.0; VAS-BWS3 0.98; TTO-BWS2 0.99; TTO-BWS3 0.98, BWS2-BWS3 0.96; P<0.000, n=434). **CONCLUSIONS:** The results demonstrate that BWS, TTO and VAS can be used to elicit incremental utility gain of small improvements in care. However, all methods have limitations. VAS does not result in utilities and some respondents do not trade with TTO. While the use of BWS is attractive because of its ability to estimate utilities for many different treatment alternatives, its applicability in CEAs is limited because BWS utilities are not anchored on a 0-1 utility scale. We propose to use TTO to estimate utility for extreme health states, and to use BWS to value intermediate health states which differ on process characteristics.

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HEALTH-RELATED QUALITY OF LIFE IN MIGRAINE WITHOUT AURA BASED ON ATTACK FREQUENCY: A TIME TRADE-OFF STUDY

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OBJECTIVES: To evaluate health-related quality of life (HRQOL) in migraine based on attack frequency by time trade-off method (TTO) in a mixed population sample consisting of migraineurs and non-migraineurs. **METHODS:** A cross-sectional questionnaire survey was designed to measure HRQOL in migraine without aura by TTO. A convenience sample was recruited from university students and staff regardless of having ever experienced migraine or not. Participants were asked to elicit two hypothetical health states characterised by different migraine frequency ('m': two migraines lasting 4 hours each month and 'w': each week) within two hypothetical lifetime frames (20 years left to live/lives until the age of 80 years). Utilities were calculated for the four tasks (U_{20m}, U_{80m}, U_{20w}, U_{80w}) and compared between subgroups. **RESULTS:** Altogether 180 respondents were included in the analysis. Mean age was 25.6 years (SD 6.4), 71% were female and 61% were self-reported migraineurs. Proportion of non-traders varied between 14% and 43%

within the four questions. Respondents were willing to sacrifice median 5 and 8 years of their remaining lifespan until the age of 80 years for avoiding two migraines per month and per week, respectively. Mean utilities for two migraines each month were U_{20m}=0.84 (SD 0.26) and U_{80m}=0.89 (SD 0.14), and for each week were U_{20w}=0.79 (SD 0.27) and U_{80w}=0.83 (SD 0.17), respectively. Self-reported migraineurs elicited higher mean utilities compared to non-migraineurs for all migraine health states but this difference was statistically significant only for U_{80m} (p=0.039). Also, males attached lower mean utilities for all health states than females but this was significant only for U_{80m} (p=0.018). Besides, older respondents valued higher mean utilities for U_{20m} compared to the younger ones (p=0.040). **CONCLUSIONS:** Our findings provide the first time trade-off utilities on migraine associated HRQOL impairment. Disutility caused by migraine ranged between 0.1 and 0.2 depending on attack frequency.

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HUMANISTIC RESEARCH OUTCOMES IN MULTIPLE SCLEROSIS: REVIEW OF THE LITERATURE FROM LATIN AMERICA

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OBJECTIVES: This research reviews the research literature reporting humanistic outcomes related to multiple sclerosis (MS) in Latin America. **METHODS:** We conducted a systematic search of Medline, Embase, LILACS and Scielo from inception through 2013 for articles reporting original research on quality of life (QoL), utility scores for states of MS, patient preference, mental health, social and emotional wellbeing in people with MS in Latin America. Adherence and related issues were not included. Outcomes were categorized into: mental domain (cognitive function; mental health), physical domain (mobility/independence; fatigue; restless legs syndrome), employment, QoL, caregiver burden, and patient preference. **RESULTS:** A total of 38 studies were selected for analysis. Among them, 23 addressed issues in the mental domain (9 cognitive functions and 14 mental health), 41 in the physical domain (24 mobility/physical function, 15 fatigue and 2 restless legs syndrome). One addressed impact of MS on employment, 16 QoL, 2 caregiver burden and 1 patient preference. Researchers used 56 different instruments to collect their data from 2286 patients. Compared with controls, MS patients had significantly (P<0.05) lower levels of functioning, cognition and increased presence of mental illness. All of these factors were significantly associated with decreased QoL in patients (odds ratios ranged from 4.2-10.1; P<0.05). Similarly, fatigue and restless legs syndrome correlated significantly with anxiety, depression and level of mobility/functioning as well as QoL. **CONCLUSIONS:** As in other parts of the world, MS exerts a substantial negative impact on the lives of people with MS in Latin America. It lowers their QoL and interferes with their ability to move about, care for themselves and work. Their social life is also negatively affected. The amount of literature on this subject is quite limited. More research in Latin America is needed to understand humanistic outcomes in these patients and management of their MS.

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THE EFFECT OF INSOMNIA AND INSOMNIA TREATMENT SIDE EFFECTS ON HEALTH STATUS, WORK PRODUCTIVITY, AND HEALTH CARE RESOURCE USE

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OBJECTIVES: The aims of this study were to quantify the burden of insomnia and to quantify the association between side effects of insomnia medications and health outcomes. **METHODS:** Data from the 2013 US (N=75,000) and 5EU (N=62,000) National Health and Wellness Survey (NHWS) were used. The NHWS is a patient-reported survey administered to a demographically representative sample of adults (with respect to age, sex, race/ethnicity, and region). Those who met DSM-V criteria for insomnia and, separately, those treated with insomnia were compared with their respective propensity score-matched control groups on health status (SF-36v2), work productivity (WPAI-GH), and health care resource use using ANOVA tests. Among those with treated insomnia, those with and without side effects were compared on health outcomes using general linear models controlling for demographics, health history, and comorbidities. **RESULTS:** Compared with their respective matched control groups, patients with insomnia (n=4147) and treated insomnia (n=2860) in the 5EU reported significantly worse mean health utilities (0.60 vs. 0.74; 0.60 vs. 0.74, respectively), greater overall work impairment (38.74% vs. 14.86%; 39.50% vs. 15.66%), and more annual physician visits (9.10 vs. 4.08; 9.58 vs. 4.11). Similar findings were observed in the US cohort. Among those treated for insomnia, 13.56% and 24.55% in the US and 5EU, respectively, were non-adherent due to side effects. In the US, this behavior was associated with significantly worse health utilities (0.60 vs. 0.64) and greater overall work impairment (37.71% vs. 29.08%), among other variables (all p<.05). These relationships were not significant in the 5EU. **CONCLUSIONS:** A significant humanistic and economic burden of insomnia was observed in both the US and 5EU, and the burden remains even after treatment. Non-adherence due to side effects was common and, in the case of the US, associated with significantly poorer health outcomes.

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QUALITY OF LIFE AMONG PATIENTS WITH MULTIPLE SCLEROSIS TREATED WITH PROLONGED-RELEASE FAMPRIDINE 10 MG TABLETS FOR WALKING IMPAIRMENT

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OBJECTIVES: To evaluate the effect of prolonged-release (PR) fampridine 10 mg tablet on generic quality of life (QoL) as measured by the EQ-5D in patients with multiple sclerosis (MS) with walking impairment. **METHODS:** The study population included 132 patients who enrolled in a 24-week randomized, double-blind, and placebo-controlled phase 2 trial (NCT01597297) of PR-fampridine 10 mg tablets or placebo twice daily in multiple sites in Europe and Canada. Patients were