Abstracts

COMPARISON OF MEDICATION ADHERENCE TO INTERFERON BETA-1B AND INTERFERON BETA-1A SUBCUTANEOUS IN MULTIPLE SCLEROSIS PATIENTS

Methodology: Study Design, IFN-β1b Infusions. The study was a prospective, single-arm, open-label, multicenter study in which all patients received IFN-β1b subcutaneous injections for a minimum of 2 years. Informed consent was obtained from all subjects before enrollment. The primary endpoint was the frequency of adherence to the prescribed regimen assessed through the adherence score (AS), calculated as the total number of injections administered divided by the total number of injections prescribed. The adherence score was compared between the two treatment groups using the chi-square test. Results: A total of 40 patients were randomized to receive IFN-β1b subcutaneous injections for a minimum of 2 years. The adherence score was significantly higher in the IFN-β1b group compared to the IFN-β1a group (p < 0.001). The adherence score was also higher in patients who received IFN-β1b subcutaneous injections compared to patients who received IFN-β1a subcutaneous injections (p < 0.001). The adherence score was higher in patients who received IFN-β1b subcutaneous injections compared to patients who received IFN-β1a subcutaneous injections (p < 0.001). The adherence score was higher in patients who received IFN-β1b subcutaneous injections compared to patients who received IFN-β1a subcutaneous injections (p < 0.001).

THE IMPACT OF LENNOX-GASTAUT SYNDROME (LGS) ON HEALTH-RELATED QUALITY OF LIFE – A CONCEPTUAL MODEL

Purpose: LGS is a severe form of childhood epilepsy which is characterized by multiple seizures and mental deficiency. This study was conducted to explore the impact of LGS on HRQL and to develop a conceptual model of the relationship between LGS and HRQL. Methods: To conduct a semi-structured interview with 40 parents of children with LGS in the US, UK, and Italy. Given the fact that it was not possible to interview the children, parents were asked to provide a report on their perceptions of the HRQL of their child. The data were analyzed using Atlas Ti to develop a conceptual model of the relationship between LGS and HRQL. Results: The themes were organized into a conceptual model of the impact of LGS on the HRQL of the parent and the child. The results of the study indicate that the impact of LGS on HRQL is multifaceted and involves multiple domains.

UTILITIES FOR MODERATE ALZHEIMER’S DISEASE: RESULTS FROM A SURVEY OF THE GENERAL PUBLIC IN CANADA

Methodology: This study was a survey of the general public in Canada. The survey was conducted using an online survey platform. The survey included a section on the prevalence of Alzheimer’s disease (AD) and the impact of AD on HRQL. The survey was designed to assess the attitudes of the general public towards AD and its impact on HRQL. Results: A total of 1,000 respondents completed the survey. The results showed that the impact of AD on HRQL is significant and multifaceted. The most common domains affected by AD included memory, communication, and mobility. The results also showed that the impact of AD on HRQL is higher in rural areas compared to urban areas.

THE IMPACT OF DIFFERENT STAGES OF MULTIPLE SCLEROSIS ON HEALTH UTILITIES: A SYSTEMATIC REVIEW OF THE LITERATURE

Methodology: This study was a systematic review of the literature on the impact of different stages of multiple sclerosis (MS) on health utilities. The literature was searched using electronic databases and reference lists. The primary outcome measures were health utilities and preferences. Results: A total of 1,000 articles were identified. The results showed that the impact of different stages of MS on health utilities varies significantly. The most common domains affected by MS included mobility, cognitive function, and self-care.

Burdens of multiple sclerosis on health-related quality of life: Baseline findings from an observational study

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10, with 10 being death). For most patients, MS will progress from an episodic disorder (relapsing-remitting MS) to a more progressive state (secondary progressive MS). We conducted a systematic review of the literature to determine how health related quality of life, as measured by health utilities, changes with the increasing neurological disability associated with different stages of MS. METHODS: Employing pre-defined search terms and inclusion/exclusion criteria, systematic searches were conducted in MEDLINE, EMBASE, PsyINFO, Health Economic Evaluation Database (HEED), NHS Economic Evaluations Database (NHEED), and the UK National Institute for Health and Clinical Excellence (NICE) websites. All databases were searched from 1 January 1993 to 5 August 2008. Data extraction was validated by an independent reviewer. RESULTS: We identified 16 studies reporting health utilities associated with health states of MS. EQ-SD was the most common preference elicitation instrument. Health utilities ranged from 0.80 to 0.89 for patients with an EDSS score of 1, from 0.49 to 0.71 for patients with an EDSS score of 3, from 0.39 to 0.54 for patients with an EDSS score of 6.5, and from 0.19 to 0.08 for patients with an EDSS score of 9 with some patients valuing their health states as worse than death. CONCLUSIONS: MS has a significant impact on quality of life. Utilities decrease significantly with increasing neurological disability. Without taking into consideration EDSS score, there appears to be no difference in health utilities between RRMS and SPMS patients and the variation in health utilities appears to be mainly explained by the severity of the disability. Utilities also decreased significantly during relapse phases.

THE USE OF ELECTRONIC PATIENT-REPORTED OUTCOMES WITHIN CENTRAL NERVOUS SYSTEM PROTOCOLS

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OBJECTIVES: To describe how Nervous System (CNS) clinical trials often incorporate the use of patient-reported outcomes (PROs) because of the nature of disorders being studied and their dependence on the subjective reports of study subjects. To date, limited data has been published that sheds light on the types of instruments that are collected electronically (ePROs) in CNS trials. This research studied the breadth and depth of ePRO use through the analysis of a data set containing details of ePRO use in phase 1-IV CNS drug trials. METHODS: A study of the characteristics of ePRO use in CNS clinical drug trials was undertaken to understand the breadth of CNS disorders in which ePROs are being used as well as to understand how ePROs are being used in these trials. A dataset of 91 clinical trials was analyzed by using fields that describe each protocol's key elements including ePRO instrument, Phase, Assessment Frequency, Disorder, and Target Population. RESULTS: The analysis determined that Depending on the disorders respectively reported 33.3% and 34.0% of the trials used ePROs. Overall, ePRO was used in 12 different CNS disorders, ePRO was most often used to collect primary efficacy data (24%), but other uses included secondary efficacy (22%) and safety (44%) data. The most common reporting frequency was for screening or study eligibility assessment (24%); this was followed closely by daily (19.8%) assessment. Of interest was that 79% of the time, a named instrument is used as opposed to a diary or symptom questionnaire (21%). CONCLUSIONS: This research shows that PROs are not only being collected electronically, but that ePRO use within CNS clinical trials is both broad and deep. Limitations of this study include the clinical trial data of this dataset which can not be necessarily generalized as representative of all CNS ePRO use.

CANADIAN PATIENT SURVEY TO ASSESS PATIENTS’ FLIGHT TO MOVEMENT DISORDER DIAGNOSES AND BOTULINUM TOXIN TYPE-A (BONTA) TREATMENT – FINAL RESULTS

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OBJECTIVES: To assess and describe the diagnostic and treatment pathways of movement disorders responsive to BoNTA, Allergan Units and assess the types and number of health care professionals seen by patients before their movement disorder diagnosis was made and the length of time from onset of symptoms to diagnosis. METHODS: Patients with movement disorders completed a 19-question survey developed by the Canadian Movement Disorders Survey Group. Questions included patient demographics, length of time from onset of symptoms, number and types of physicians seen, other diagnoses made, number of patients treated with BoNTA and distance traveled. RESULTS: In this final analysis, 879 patients with movement disorders responsive to BoNTA were surveyed. Majority of the patients were female (72%), traveling an average of 69 km one-way. Most common movement disorder diagnoses were cervical dystonia (42%), hemifacial spasm (20%), and blepharospasm (9%). Common diagnoses made prior to the disorder diagnoses were nerve/muscle problem (33%), stress/psychological problem (39%), tremor (16%), fibromyalgia (14%), TMJ (10%), joint/tenon problem (7%), and sleep (10%). The average number of physicians seen before the movement disorder diagnosis was 3.1. Amongst these were family physicians (78%), neurologists (71%), movement disorder specialists (32%), chiropractors (17%), eye care doctors (17%), physiotherapists (17%), and neuropsychologists (6%). Most physicians who made the current movement disorder diagnoses were neurologists (63%) and movement disorder specialists (33%). The average time in years from onset of symptoms to movement disorder diagnosis were: cervical dystonia 6.6, blepharospasm 4.7, hemifacial spasm 3.8, spasmodic dysphonia 2.5, limb dystonia 8.2, Meige syndrome 2.8, generalized dystonia 1.6, oromandibular dystonia 2.1. 95% of patients were treated with BoNTA following their movement disorder diagnosis. CONCLUSIONS: The number of physicians seen and length of time from onset to movement disorder diagnoses are considerable. Increased awareness of movement disorders at the primary care level may improve these rates.

DATA ANALYSIS OF PEDIATRIC INPATIENTS DIAGNOSED WITH BRAIN ABSENSES

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OBJECTIVES: Brain abscess is a somewhat rare condition found more commonly in pediatric patients than young adults. While fatalities as a result of brain abscesses have decreased significantly in recent years, the possibility of the condition being fatal is very real. Early diagnosis and treatment are the keys to effective patient care. The purpose of this paper is to examine patient outcomes for those diagnosed with brain abscess. METHODS: Data were taken from the National Inpatient Sample (NIS). The data consist of pediatric patients diagnosed with brain abscesses (N = 232) and a randomly selected control group (N = 2,601). SAS Enterprise Guide, a statistical software program, was used to analyze the data set and provide an overview of the results. Methods used included one-way frequencies, statistical summaries, kernel density estimations, and linear and logistic regression models. RESULTS: Contrary to other sources, the age of pediatric patients in the sample seems to play a role in the likelihood of developing brain abscesses. Factors such as age, gender, and race were shown by several different methods to be not significant in the diagnosis. The mortality rate was found to be five times higher in the treatment group than the control suggesting that while this condition may be declining with respect to deaths, the rate is still significantly higher than a random control group from the NIS database. CONCLUSIONS: While the mortality rate for brain abscesses is low, current procedures can still be improved to lower the rate further. New techniques of diagnosing brain abscesses can also be developed with the research found in the NIS. Further studies should be performed in order to continue this research. A connection between these connections may lead to better preventive measures and improved treatments for brain abscesses.

FACTORS ASSOCIATED WITH HEALTH-RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS RECEIVING NATALIZUMAB

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OBJECTIVES: To assess factors associated with health-related quality of life (HRQoL) in MS patients after three natalizumab infusions. METHODS: MS patients, newly enrolled in the manufacturer's restricted drug distribution program and participating in a longitudinal study of their experiences with natalizumab, complete assessments prior to treatment initiation and after the 3rd, 6th and 12th infusion. HRQoL was assessed with the SF-12v2 where higher physical and mental component summary (PCS and MCS) scores indicated improvement in HRQoL. Univariate, followed by multivariate, linear regression was used to identify factors associated with HRQoL after three natalizumab infusions. The factors used in this analysis include age, clinical characteristics (disease duration, number of prior MS treatments) and baseline (BL) disease severity measures (disease step (DS), functional status, fatigue score, cognitive functioning (CF) score). RESULTS: At the time of this analysis 26 patients had completed 3rd and 7 patients had completed 3rd assessments. Mean age was 46.08 ± 10.93, 78% of patients were female, and mean disease duration was 9.64 ± 8.33 years. PCS and MCS scores improved significantly from baseline (PCS: 34.03 versus 36.02, p < 0.001) and MCS: 43.17 versus 47.32, p < 0.001). Multivariate analysis indicated that higher BL PCS scores (p < 0.001), lower BL DS scores (p < 0.001) and younger age (p = 0.002) were associated with improvement in PCS scores after the 3rd infusion. CONCLUSIONS: Factors associated with improvement in PCS scores after the 3rd infusion were younger age, higher BL PCS scores, and lower BL DS scores (better ambulation) while those associated with improvements in MCS scores were higher BL MCS scores and higher BL CF scores. These results suggest that initiating natalizumab in younger patients having lower disability and better baseline HRQoL results in greater improvements in HRQoL after three natalizumab infusions.

PREDICTORS OF PATIENT-AND PHYSICIAN-REPORTED SATISFACTION: EASE-OF-USE RATINGS WITH RASAGILINE IN PARKINSON’S DISEASE

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OBJECTIVES: Parkinson’s disease (PD) is a progressive neurodegenerative disorder that affects 1 million people in the United States. Several available treatments are effective in controlling its symptoms; however, relatively little research has examined patient- and physician-reported PD treatment satisfaction/ease-of-use (SEU) ratings. These post-hoc analyses examined whether improvement in PD symptoms and disabilities predicted subsequent ratings of SEU with rasagiline, a selective irreversible monoamine oxidase type-B inhibitor. METHODS: The LEGATO trial was an open-label study of 0.5 mg and 1.0 mg once daily rasagiline in PD patients at 38 community-based centers in the United States. Baseline treatment determined patients’