

# Platform Presentations



## COGNITION AND DEPRESSION

1:15 pm – 1:35 pm	<b>P01</b>	Recognition and Treatment of Co-morbid Mental Health Problems in People with MS: An 18 Month Evaluation of a Nurse-led Mental Health Service for People with MS
1:35 pm – 1:55 pm	<b>P02</b>	Assessment of Depression in MS: Validity of Including Somatic Items on BDI-II
1:55 pm – 2:15 pm	<b>P03</b>	Comparison of NPT Findings and Driving Evaluation Performance in MS Patients
2:15 pm – 2:35 pm	<b>P04</b>	Validation of the NARCOMS Depression Scale
2:35 pm – 2:55 pm	<b>P05</b>	Cognitive Impairments in Relapsing Remitting Multiple Sclerosis: A Quantitative Investigation
2:55 pm – 3:15 pm	<b>P06</b>	Cognitive Concerns as Predictors of Later Functioning in Persons with MS

## DISEASE MEASUREMENT, MECHANISMS, AND TREATMENT

1:15 pm – 1:35 pm	<b>P07</b>	Avonex® Long-Term Follow Up of Patients With Relapsing Multiple Sclerosis: The 15-Year ASSURANCE Study
1:35 pm – 1:55 pm	<b>P08</b>	Clinical Characteristics of Neuromyelitis Optica Spectrum Disorders
1:55 pm – 2:15 pm	<b>P09</b>	Plasma Exchange Accelerates Natalizumab Clearance and Restores Leukocyte Function
2:15 pm – 2:35 pm	<b>P10</b>	BG00012 Reduces Accumulation of Gd+ Lesions in Subgroups of MS Patients
2:35 pm – 2:55 pm	<b>P11</b>	Efficacy with Early Use of Alemtuzumab in MS is Independent of Baseline Disease Status
2:55 pm – 3:15 pm	<b>P12</b>	The Importance of Clinically-Defined Spatial Dissemination for Prediction of MS Risk

## PSYCHOSOCIAL ISSUES

1:15 pm – 1:35 pm	<b>P13</b>	Telephone-based Exercise Promotion for Major Depression in People with MS
1:35 pm – 1:55 pm	<b>P14</b>	MS Patients Pace Their Activities During Day-and-a-Half Testing
1:55 pm – 2:15 pm	<b>P15</b>	CRISP: Community Reintegration for Socially Isolated Patients
2:15 pm – 2:35 pm	<b>P16</b>	Factors Related to Nursing Home Versus Home-Based Care in Patients with MS
2:35 pm – 2:55 pm	<b>P17</b>	Multiple Sclerosis (MS) Literacy: The Gap Between ‘Need to Know’ and ‘Know the Need’
2:55 pm – 3:15 pm	<b>P18</b>	Factors that Influence Adherence with Disease-Modifying Therapy in Multiple Sclerosis: A Multivariate Analysis

## SYMPTOMS AND REHABILITATION

1:15 pm – 1:35 pm	<b>P19</b>	Comparing Sleep Problems in MS using the WHI Insomnia Rating Scale and MOS Sleep Scale
1:35 pm – 1:55 pm	<b>P20</b>	Exaggerated Startle Response (Hyperreflexia) in Multiple Sclerosis: Review of 20 Patient-Reported Cases
1:55 pm – 2:15 pm	<b>P21</b>	Validation of an Ambulation-Specific Visual Analog Scale (VAS) Using the Lifeware System
2:15 pm – 2:35 pm	<b>P22</b>	Effect of Exercise Training on Walking Mobility in Multiple Sclerosis: A Meta-Analysis
2:35 pm – 2:55 pm	<b>P23</b>	Observations on Use of Nitrofurazone- Impregnated Urinary Catheters in Patients with Neurogenic Bladder and Multiple Sclerosis
2:55 pm – 3:15 pm	<b>P24</b>	Discrepancies in Subjective and Objective Outcomes with ITB Therapy

**(P01) RECOGNITION AND TREATMENT OF CO-MORBID MENTAL HEALTH PROBLEMS IN PEOPLE WITH MS: AN 18 MONTH EVALUATION OF A NURSE-LED MENTAL HEALTH SERVICE FOR PEOPLE WITH MS**

Recognition and treatment of co-morbid mental health problems in people with MS: An 18 month evaluation of a nurse-led mental health service for people with MS

**Background:** Mental health and emotional problems are widespread within the MS population. These needs are often undiagnosed and often lead to a reduction in quality of life.

**Objectives:** In order to meet this unmet need, a Mental Health Nurse was appointed to a local MS Service. The aim of this appointment was to assess and treat mental health issues within the local MS population, to work collaboratively between mental health, neurology and MS Nurse Services and to provide education to local MS Nurses with a view to improving detection and treatment of mental health issues.

**Methods:** MS Professionals provided initial screening of MS patients using their clinical skills and Hospital and Anxiety and Depression Scale (HADS) and those with identified mental health difficulties were referred through to the mental health nurse. All details of those referred, diagnoses and treatment pathways were recorded.

**Results:** At eighteen months, 115 people were referred into the project. 81 received assessment and 32 declined input. Mean number of received sessions with the Mental Health Nurse was 4.79.

68.7% of referrals were female; mean age of patient was 42.5.

Of the patients referred, 63.2% had relapsing remitting MS, with 16.7% experiencing secondary MS and 15.8% having primary progressive MS.

82.5% were referred with depression, 48.5% were referred with anxiety, and 43.8% presented with depression co-morbid with anxiety. 34.5% were experiencing difficulties with cognition and 5.3% were diagnosed with frontal lobe syndrome. Psychosis was present in 4.1% of this population whereas bipolar disorder presented in 5.2%.

Suicidal ideation was also common in 33.7% of patients, of these 12.4% (N=11) had formulated plans and 2%(N=1) had made an attempt on their life.

Patients were offered a variety of treatments including medication (52.6%) and 40% were offered Cognitive Behaviour Therapy (CBT). Of those receiving CBT, HADS Scores indicate a reduction in mood scores over the treatment period.

**Conclusions:** Mental health and emotional problems are common in people with MS. Detection and treatment of mental health problems are vital to improving the quality of life of people with MS. Mental health nurses can assess and treat a spectrum of problems and can provide a beneficial service to patients with MS working collaboratively between neurology and psychiatric services to provide multi-disciplinary provision to patients.

*Study Supported by: UK MS Society and TEVA Pharmaceuticals Ltd*

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(P02) ASSESSMENT OF DEPRESSION IN MS: VALIDITY OF INCLUDING SOMATIC ITEMS ON BDI-II

**Background/Objective:** Signs and symptoms of MS including fatigue may overlap with those of depression, a common co-morbidity in MS, and falsely elevate depression scores. However, few studies have documented this problem in the clinical assessment of depression in MS.

**Design/Methods:** 557 adults with a diagnosis of MS were seen by Health Psychology for consecutive evaluations including chart review, interview, and completion of the Beck Depression Inventory-II (BDI-II). Patients had a mean age of 42.6 years, were predominately female (76.8%), Caucasian (81.1%), married (57%), educated (66.7% with at least some college), not employed (50.7%), with Relapsing-Remitting MS (76.4%), and mean of 5.7 years since diagnosis. Exploratory Factor Analyses (EFA) were conducted to test the validity of Beck's 2-factor (Cognitive-Affective and Somatic) model. Then, we compared overall depression scores; the percentage contribution of specific items: energy, tiredness or fatigue and sleep to the total BDI-II score; and the sum contribution of the somatic factor between patients who identified fatigue as their worst MS symptom and all other patients.

**Results:** The BDI-II mean total score was 20.8 with 29.8% endorsing minimal, 19.2% mild, 27.3% moderate, and 23.7% endorsing severe depression. The EFA revealed two factors (Cognitive-Affective and Somatic) consistent with Beck's model and previous work with non-MS populations. The 20.3% who identified fatigue as their worst MS symptom had comparable BDI-II scores, depression severity, and percentage contribution of the somatic factor. In the fatigue group, the only item with a significantly higher percentage contribution was loss of energy ( $p < .05$ , 9.5% vs 7.6%).

**Conclusion/Discussion:** We conclude that somatic items do not necessarily confound depression scores for individuals with MS and should be retained in the BDI-II. Additional implications and recommendations for clinical assessment of depression in MS will be discussed.

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**(P03) COMPARISON OF NPT FINDINGS AND DRIVING EVALUATION PERFORMANCE IN MS PATIENTS**

**Background:** With the comprehensive decline in physical, cognitive, and behavioral functions that is often associated with the disease progression of MS, a patient's ability to operate a motor vehicle may be adversely affected, impacting their level of independence or potential employment.

**Objective:** Identify the cognitive and physical characteristics of MS patients who received clinical Neuropsychological Testing (NPT) and community-based, Behind-the-Wheel (BTW) driving evaluations within one year and then compare the driving recommendations from both disciplines.

**Method:** A chart review of MS patients referred for BTW driving evaluations between 2001 and 2005. Of the 73 patients who received driving evaluations through two Occupational Therapists at this time, 9 patients also participated in NPT within one year. These 9 patients served the basis of our chart review.

**Results:** All 9 patients reviewed were ambulatory. Two patients had relapses between their NPT and BTW driving evaluations. For these 9 patients, the neuropsychologist concluded one had mild to moderate cognitive impairment, six had moderate cognitive impairment, and two had moderate to moderately severe impairment. The neuropsychologist (NP) and driving evaluators (DE) were in complete agreement for only 1 patient (recommended driving with hand controls). For the other 8 patients, there were disagreements between the NP and DE recommendations. The NP always recommended more severe restrictions than the DE.

**Conclusion:** Due to the subjective nature and interrater variability between clinical NPT and community-based BTW driving evaluations, as demonstrated with the NP and DE only in complete agreement for 1 out of 9 MS patients, a more valid, reliable, and objective measurable assessment tool to assess driving skills is needed. One such possibility is Virtual Reality computer technology that can simulate more potential "real-life" driving hazards in a 3-dimensional format in a clinical setting.

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#### (P04) VALIDATION OF THE NARCOMS DEPRESSION SCALE

**Background:** The North American Research Committee on Multiple Sclerosis (NARCOMS) Registry is a self-report registry for patients with multiple sclerosis (MS). NARCOMS participants report depression using one question, which has not been validated.

**Objective:** We assessed the criterion validity of the NARCOMS depression scale against the Clinical Epidemiology Depression Scale (CESD) and self-reported diagnoses of depression.

**Methods:** In 2006 8983 NARCOMS participants reported lifetime diagnoses of depression. Participants completed the Clinical Epidemiology Depression Scale (CESD), where a score  $\geq 21$  was considered to indicate probable major depression; and the NARCOMS depression scale which is scored from 0 (no depression) to 5 (total depression). We assessed the criterion validity of the depression scale in two ways. First, we compared the depression scale to the CESD using Spearman rank correlations with casewise deletion. Second, we determined the sensitivity and specificity of a NARCOMS depression scale score  $\geq 2$  for a CESD score  $\geq 21$ , and for a lifetime diagnosis of depression. To assess construct validity we correlated the depression scale with pain (NARCOMS pain question), fatigue (Performance Scales subscale), age, and body mass index.

**Results:** The median (IQR) CESD score was 17 (13-23), and the median NARCOMS depression score was 1 (0-2). The depression scale correlated with the CESD ( $r = 0.73$ ; 95% CI: 0.72-0.74). For a CESD score  $\geq 21$ , a depression scale score  $\geq 2$  had a sensitivity of 78.5% and specificity of 81.9%. A depression score  $\geq 2$  had a sensitivity of 87% and specificity of 92% for a lifetime diagnosis of depression and current CESD score  $\geq 21$ . Correlations between the depression scale and age ( $r = -0.03$ ), BMI ( $r = 0.10$ ) were low indicating divergent validity, while correlations with pain ( $r = 0.39$ ), and fatigue ( $r = 0.45$ ) were moderate indicating convergent validity.

**Conclusion:** The NARCOMS depression scale has adequate criterion and construct validity in MS.

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**(P05) COGNITIVE IMPAIRMENTS IN RELAPSING REMITTING MULTIPLE SCLEROSIS: A QUANTITATIVE INVESTIGATION**

**Background:** Researchers in the last few decades, employing tests developed in cognitive psychology and neuropsychology, have attempted to understand the specific cognitive deficits associated with MS. Though there is consensus regarding the presence of cognitive impairment in these domains, studies differ as to the nature of these cognitive impairments and the specific tasks that are used in the assessment of cognitive deficits.

**Objective:** In this meta-analytic review of 57 studies with 3891 participants, the primary goal was to investigate the nature and pattern of cognitive impairments seen in patients with relapsing remitting multiple sclerosis (RRMS) relative to healthy controls. There is debate in the literature on the impact of disease subtype on cognition, with recent studies suggesting differences in cognitive abilities as a function of disease subtype. For this review, we were primarily interested in studies that specifically examined the cognitive performance of RRMS patients.

**Design/Methods:** Studies from 1983 to July, 2007 were included in the current review yielding a total of 769 effect sizes. The aggregated or mean effect size was computed using a random effects model and adjusted for sample size (Hedges adjusted g) using Comprehensive Meta-Analysis, Version 2.0. (Borenstein, 2005).

**Results:** Results suggest that there is moderate decline in cognitive functioning in patients relative to healthy controls. Largest effect sizes were found for domains of motor functioning, mood and psychological status and memory and learning. In addition, we found that several demographic and clinical variables influenced cognitive performance within the MS sample. Of these age and gender were found to influence all cognitive domains, whereas neurological disability and disease duration were primarily associated with deficits on tasks assessing memory and learning.

**Conclusion/Discussion:** This meta-analysis suggests that MS is associated with a global decline in cognitive functioning. Deficits were seen across tasks and across cognitive domains.

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**(P06) COGNITIVE CONCERNS AS PREDICTORS OF LATER FUNCTIONING IN PERSONS WITH MS**

**Background:** Cognitive difficulties in MS may affect social and role-related functioning as well as basic and instrumental activities of daily living. Memory impairment is the most common cognitive difficulty, affecting 40-60% of persons with MS. While the incidence and types of memory problems have been frequently studied, few studies have examined metamemory (self-report of memory ability and skills) in persons with MS or examined how perceptions of memory problems may predict later disability.

**Objective:** The purpose of this study was to explore the relationships between perceived feelings about memory (e.g. confidence, embarrassment), perceived memory ability/failures and social and role-related functioning 3 years later. Specifically, we explored what contextual factors (age, length of diagnosis, depressive symptoms) and cognitive concerns (feelings about memory and memory ability/failures) predict later social and role functioning and whether the use of internal and external memory strategies might moderate relationships between cognitive concerns and social, role-emotional and role-physical functioning.

**Design/Methods:** A sample of 412 persons with MS (344 females, 68 males; mean age 54, mean time since diagnosis 16.9 years) completed a survey including measures of demographic and disease-related variables, the Multifactorial Memory Questionnaire and the Medical Outcomes Study SF-36 in 2003 and 2007. Correlational and hierarchical regression analyses were used to explore predictors of later functioning.

**Results:** All components of the metamemory scale were significantly related to functioning four years later. Years since diagnosis ( $b=-.13$ ), depressive symptoms ( $b=-.39$ ) and cognitive failures/mistakes ( $b=-.26$ ) explained 24% of the variance in later social functioning. Depressive symptoms and cognitive mistakes explained 21% and 17% of the variance respectively in role-emotional and role-physical functioning.

**Conclusion:** Metamemory related to failures/mistakes was the strongest predictor of future functioning after the impact of contextual factors. Use of memory strategies did not moderate the impact of cognitive concerns on future functioning.

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**(P07) AVONEX® LONG-TERM FOLLOW UP OF PATIENTS WITH RELAPSING MULTIPLE SCLEROSIS: THE 15-YEAR ASSURANCE STUDY**

Intramuscular interferon beta-1a (IFN $\beta$ -1a; Avonex<sup>®</sup>) significantly reduced the accumulation of physical disability and relapse rate in patients with relapsing multiple sclerosis (RMS) compared with placebo in the pivotal phase 3 clinical trial (MSCRG study). In the safety extension of the MSCRG study, during which all patients received open-label IFN $\beta$ -1a, significant treatment effects were observed in the original IFN $\beta$ -1a group compared with the placebo group on mean Expanded Disability Status Scale (EDSS) score, EDSS change over time, and percentage of patients reaching EDSS milestones over a total of 8 years. These results suggest a significant benefit of early versus delayed initiation of therapy in RMS. The objective of the ASSURANCE study was to evaluate the longer-term impact of early versus delayed initiation of treatment on disability. ASSURANCE is an open-label, multicenter, 15-year follow-up study that includes patients who received  $\geq 2$  years of treatment in the MSCRG study. As of December 5, 2007, 93 of 172 eligible patients had been located and enrolled (completed questionnaires or noted as deceased). Forty-two patients are pending consent or return of information, 35 patients are still being located and 2 patients declined to enroll. Of the 93 patients, 50 (54%) were originally randomized to IFN $\beta$ -1a and 43 to placebo. Of 81 patients still living, 74% are women with a mean age of 51.8 years, a mean time since initial MSCRG study enrollment of 16.1 years, and a mean disease duration of 22 years. Eighty-two percent of patients live independently and 91% of patients completed the questionnaire by themselves. Since entry into MSCRG, patients have used a mean of two disease-modifying therapies for MS. Fifty-four percent of patients have been taking IM IFN $\beta$ -1a for a median duration of  $\geq 5$  years. Enrollment in ASSURANCE is expected to be completed soon. Final analyses of clinical outcomes will be presented.

*Study Supported by: Biogen Idec, Inc.*

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(P08) CLINICAL CHARACTERISTICS OF NEUROMYELITIS OPTICA SPECTRUM DISORDERS

**Background:** The observation of cases of neuromyelitis optica (NMO) spectrum disorders has made possible to study these disorders.

**Objective:** To assess the clinical characteristics of relapsing-NMO (R-NMO), monophasic NMO (m-NMO), recurrent optic neuritis (r-ON), recurrent longitudinally extensive transverse myelitis (r-LETM) and associated with symptoms of Central Nervous System (r-LETM-CNS).

**Methods:** 62 patients NMO spectrum disorders were studied. Results of CSF/MRI/somato-sensory (SSEP)/visual (VEP)/ brainstem (BAEP) evoked potentials were registered.

**Results:** Clinical forms were: R-NMO (65.6%), r-LETM/ r-LETM-SNC (21%), (6.6%) m-NMO and (6.6%) r-ON. Black patients had a longer disease duration ( $16.4 \pm 6.5$  years) ( $p = 0.009$ ), more relapses ( $8.2 \pm 3.9$ ) ( $p = 0.0008$ ) and 90% had brain MRI abnormalities, while they were present in only 11(42.3%) of Caucasians and 6(40%) of Mulattoes ( $\chi^2 = 7.600$ ,  $p = 0.022$ ). These results suggest that there is possibly a higher “resistance and tolerance” in blacks for R-NMO. Recurrent- LETM, have a more delayed age at onset, attain a higher physical disability and lower number of relapses in a short period of time. Coexisted diseases 6 (9.6%), associated factors 12 (19.3%), cases with familiar forms 5 (8.1%) and aggressive course were observed. Abnormalities of SSEP/VEP were in correspondence with the clinical localization. The possible utility of VEP and SSEP seeking for optic nerve or spinal cord subclinical abnormalities could also be evaluated. The clinical form was relapsing-remitting type 1b and progressive forms were not found. A cooperative study is in progress to know the course and prognosis of NMO spectrum disorders in the Caribbean area.

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**(P09) PLASMA EXCHANGE ACCELERATES NATALIZUMAB CLEARANCE AND RESTORES LEUKOCYTE FUNCTION**

**Background:** Natalizumab (TYSABRI®) is an anti- $\alpha$ 4-integrin monoclonal antibody that demonstrated significant efficacy in pivotal studies of relapsing multiple sclerosis (MS) patients. However, progressive multifocal leukoencephalopathy (PML) is a rare complication of natalizumab treatment. Currently, immune reconstitution is the only intervention shown to be effective in improving outcomes in patients with PML. Plasma exchange (PLEX) may accelerate clearance of natalizumab, and therefore may increase leukocyte migration into the central nervous system and improve the clinical outcome in the event of PML.

**Methods:** Three 1.5-volume exchanges were performed over 5 or 8 days in 12 patients with MS 10-14 days after  $\geq 3$  monthly infusions with natalizumab 300 mg. Serum natalizumab concentrations and mononuclear cell  $\alpha$ 4-integrin receptor saturation were evaluated daily throughout the PLEX course and 3 times over the subsequent two weeks. Peripheral blood mononuclear cells (PBMCs) from a subset of 6 patients were assessed for chemokine CCL2-induced migration across an in vitro blood brain barrier (ivBBB) during natalizumab treatment and after PLEX. Pharmacokinetic modeling was performed based on concentration and saturation data from all 12 patients undergoing PLEX in the present study, and 245 patients who participated in a phase 3 study of natalizumab.

**Results:** Immediately following PLEX, mean serum natalizumab concentrations were reduced by  $\geq 95\%$  vs. baseline. Decreases in serum natalizumab concentrations to  $< 2$  mcg/ml resulted in subsequent decrease in  $\alpha$ 4-integrin receptor saturation. PLEX resulted in a 2.2-fold increase in PBMC migration across the ivBBB ( $P < 0.006$ ). Measures for optimizing the efficiency of PLEX as suggested by pharmacokinetic modeling will be presented.

**Conclusions:** Based on its ability to accelerate the clearance of natalizumab and restore the migratory capacity of leukocytes, PLEX holds potential for immune reconstitution in the setting of suspected or confirmed cases of PML associated with natalizumab administration.

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**(P10) BG00012 REDUCES ACCUMULATION OF GD+ LESIONS IN SUBGROUPS OF MS PATIENTS**

**Background:** BG00012 is an oral formulation of dimethyl fumarate that has a distinct dual mechanism of action, targeting an important neuroprotective and anti-inflammatory pathway. During the phase 2b study in relapsing-remitting multiple sclerosis (RRMS) patients, BG00012 240 mg by mouth (PO) three times daily (tid) significantly reduced the number of new gadolinium-enhancing (Gd+) lesions from Weeks 12 to 24 by 69% vs. placebo ( $p < 0.001$ ). Analyses were conducted to determine whether the primary efficacy results from the BG00012 phase 2b study were consistent among patients with different baseline characteristics.

**Methods:** The phase 2b study was a placebo-controlled trial. Two hundred fifty-seven RRMS patients were randomized to receive one of four treatments during a double-blind, 24-week treatment period: BG00012 capsules 120 mg PO once daily, 120 mg PO tid, 240 mg PO tid, or placebo. The primary endpoint was the total number of new Gd+ lesions over cranial MRI scans at Weeks 12, 16, 20, and 24. Data on the primary endpoint were analyzed in the following subgroups: Expanded Disability Status Scale (EDSS) score ( $\leq 2.5$ ,  $> 2.5$ ) at baseline, presence of Gd+ lesions (0,  $\geq 1$ ) at baseline, age ( $< 40$ ,  $\geq 40$ ), and gender.

**Results:** Results from subgroup analyses were consistent with the overall results. BG00012 720 mg/day reduced the number of new Gd+ lesions from Weeks 12 to 24 compared with placebo: EDSS  $\leq 2.5$ , 1.2 vs. 4.6 (76%,  $p = 0.006$ ); EDSS  $> 2.5$ , 1.6 vs. 4.3 (63%,  $p = 0.002$ ); 0 Gd+ lesions, 0.6 vs. 3.0 (80%,  $p = 0.005$ );  $\geq 1$  Gd+ lesion, 3.0 vs. 6.7 (55%,  $p = 0.003$ ); age  $< 40$ , 2.0 vs. 3.9 (49%,  $p = 0.009$ ); age  $\geq 40$ , 0.6 vs. 5.7 (89%,  $p = 0.002$ ); male, 1.8 vs. 2.9 (38%,  $p = 0.063$ ); female, 1.1 vs. 5.7 (81%,  $p < 0.001$ ).

**Conclusions:** BG00012 reduced the accumulation of new Gd+ lesions across subgroups of RRMS patients defined by age, gender, disability, and baseline MRI activity.

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**(P11) EFFICACY WITH EARLY USE OF ALEMTUZUMAB IN MS IS INDEPENDENT OF BASELINE DISEASE STATUS**

**Background:** Preliminary studies suggest the lymphocyte targeting monoclonal antibody, alemtuzumab, markedly suppresses disease activity when administered during early stages of relapsing-remitting multiple sclerosis (RRMS). The randomized, multi-center, rater-blinded, Phase 2 study, CAMMS223, compares alemtuzumab with high dose interferon beta-1a (IFNB-1a) in treatment naïve RRMS. A subgroup analysis of the Year 3 data evaluates the role of baseline disease status in efficacy.

**Design/Methods:** Participating patients were treatment naïve with onset of symptoms within 3 years of screening, Expanded Disability Status Scale (EDSS) scores of 0 to 3.0 inclusive,  $\geq 2$  attacks in the prior 2 years, and  $\geq 1$  enhancing lesion on a screening cranial MRI. 334 patients were randomized 1:1:1 to 44  $\mu\text{g}$  IFNB-1a 3 times/week or annual cycles of low-(12 mg/day) or high-dose (24 mg/day) IV alemtuzumab. Alemtuzumab was administered for 5 days at Month 0, 3 days at Month 12, and in some patients, 3 days at Month 24. Co-primary efficacy endpoints were time to 6-month sustained accumulation of disability (SAD) and relapse rate.

**Results:** Compared to patients treated with IFNB-1a, alemtuzumab-treated patients overall demonstrated a 73% reduction in risk for relapse ( $p < 0.0001$ ) and a 70% reduction in risk for SAD ( $p < 0.0001$ ) after 3 years of treatment. Subgroup analyses of the co-primary endpoints indicate alemtuzumab's treatment effects are largely independent of disease duration ( $< 2 / \geq 2$  years), baseline EDSS ( $\leq 1.5 / \geq 2.0$ ), relapse rate ( $\leq 2 / > 2$  relapses in prior 2 years), cerebral volume on MRI-T1 ( $< 320 / \geq 320$  ml), or MRI-T2 lesion volume ( $< 10 / \geq 10$  ml).

**Conclusions/Relevance:** Alemtuzumab is significantly more effective than IFNB-1a at suppressing relapses and disability progression in patients with RRMS through 3 years of follow-up regardless of pretreatment relapse rate or baseline disease duration, disability, cerebral volume or lesion load. A comprehensive safety monitoring program has effectively minimized morbidity due to side effects of alemtuzumab such as thyroid disorders, infection, and immune thrombocytopenic purpura.

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**On behalf of the CAMMS 223 International Study Group**

## (P12) THE IMPORTANCE OF CLINICALLY-DEFINED SPATIAL DISSEMINATION FOR PREDICTION OF MS RISK

**Objective:** To investigate the value of clinically-defined dissemination in space for predicting time to clinically definite multiple sclerosis (CDMS) and the added prognostic value of magnetic resonance imaging (MRI) parameters.

**Background:** A diagnosis of MS requires evidence for spatial dissemination of central nervous system lesions. There are clear guidelines on how to derive this evidence from MRI findings, but no definition of how a patient's symptoms and signs can indicate disease dissemination. To provide a uniform approach, a clinical system has recently been described for the classification of patients with a first event as having monofocal presentation (symptoms being explained by a single lesion) or multifocal (symptoms only explained by the presence of more than 1 lesion).

**Methods:** As part of the ongoing BENEFIT studies, 468 patients with a first event suggestive of MS were classified centrally by two neurologists blinded to MRI results and followed for up to 2 years. Two hundred and ninety-two patients were randomized to IFNB-1b and 176 to placebo. The risk for CDMS was studied using Kaplan-Meier statistics in placebo-treated patients with mono- and multifocal disease, both with and without the presence of MRI parameters of potential prognostic relevance.

**Results:** There was no difference between patients with monofocal and multifocal presentation in terms of "time to CDMS". In monofocal patients, the risk for CDMS over 2 years was significantly higher in those who had  $\geq 9$  T2 lesions at the first event or  $\geq 1$  Gadolinium-enhancing lesion at the first event or 3 or 6 months later. These MRI parameters had no significant predictive value for time to CDMS in patients with a multifocal presentation.

**Conclusion:** These data indicate that a carefully-performed neurological assessment of symptoms and signs is important for determining the risk of conversion to CDMS.

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(P13) TELEPHONE-BASED EXERCISE PROMOTION FOR MAJOR DEPRESSION IN PEOPLE WITH MS

**Background:** Major depression (MD) is prevalent and disabling among persons with MS. Epidemiologic and experimental studies suggest that exercise is a promising treatment for MD. We chose a telephone based approach because it can be effective and overcomes barriers to treatment.

**Method:** Subjects were 101 community residing persons with a confirmed diagnosis of MS and MD who were ambulatory and not exercising regularly. Participants underwent a baseline assessment and were randomized to a 12 week treatment condition (n=50) or a wait-list control group (n=51). Treatment consisted of a single face-to-face motivational interview to negotiate a home exercise plan plus 8 scheduled telephone counseling sessions to promote adherence to the plan.

**Primary outcome:** Hamilton Rating Scale for Depression (HAM-D). Secondary outcomes: Hopkins Symptom Checklist (SCL-20), metabolic equivalent units (MET) as estimated by the 7-Day Physical Activity Recall, minutes of exercise and the Modified Fatigue Impact Scale (MFIS).

**Analyses:** Intent-to-treat analysis of post-test outcomes, controlling for pre-test.

**Results:** 85% of the sample were female, 92% were Caucasian, and 75% had relapsing MS. Randomization was effective, though the treatment group had higher HAM-D scores at baseline. Efficacy analyses demonstrated that at 12 weeks there was significant improvement on the HAM-D in the treatment group (17.7 to 11.4) but not among controls (15.8 to 14.2;  $p=.0005$ ). Similar results emerged on the SCL-20 ( $p=.002$ ) and MFIS ( $p<.0001$ ). There was a non-significant trend for exercise, as measured by METs, to improve more in the treatment versus control group ( $p=.08$ ).

**Conclusion:** This intervention is a promising approach for treating MD in people with MS who can walk but are not exercising regularly. Mechanisms other than exercise dose may account for the antidepressant effect. Future research should include an attention control group and methods to identify potential biopsychosocial mediators of the antidepressant effect of this intervention.

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(P14) MS PATIENTS PACE THEIR ACTIVITIES DURING DAY AND A HALF TESTING

**Background:** People with Multiple Sclerosis (MS) suffer from overwhelming fatigue and reduced function that limits their ability to sustain normal daily activities.

**Objective:** This study determined the effects of a simulated workday on physiologic and functional performance and fatigue during the day and the next morning, after a normal night's rest, for individuals with MS.

**Design/Methods:** Sixty-nine MS patients with EDSS scores  $\leq 6.5$  (age= $47.1 \pm 7.5$  yrs) and 17 controls (C: age= $46.0 \pm 10.8$  yrs) participated in three test batteries (morning, end of day and next morning) over a day and a half. Testing included maximal neuromuscular (strength, endurance, velocity) and maximal cardiorespiratory (VO<sub>2</sub>, heart rate, blood pressure, lactate) function, functional performance (walking, stair climbing, reaction time), cognitive function (PASAT), and fatigue (Buffalo Fatigue Scale). During the remainder of the day, the subjects performed sedentary (1MET) to slightly active (3METs) activities (i.e. reading, computer work, low level arm/leg pedaling) to simulate the energy expenditure during a typical workday.

**Results:** There were significant differences ( $p < 0.05$ ) between MS and C on all functional variables and most neuromuscular and cardiorespiratory variables. MS reported higher levels of fatigue for lower levels of physiologic work than C. There were no significant differences within MS or C for the three test periods, except for physical and cognitive fatigue. MS did not have a complete recovery in physical or cognitive ( $p < 0.05$ ) fatigue by the next morning. Even with increased perceived fatigue by the MS subjects, they were able to perform to the same level at the end of the day and the next morning, as they did at the beginning of the first day.

**Conclusions/Discussion:** It appears that the MS group paced their activities over the day, thereby sustaining physiological and functional performance over time; however, they had increased fatigue and time to recovery from fatigue.

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**(P15) CRISP: COMMUNITY REINTEGRATION FOR SOCIALLY ISOLATED PATIENTS**

Multiple sclerosis (MS) has a profound impact on social well-being. For individuals with advanced disease, every daily activity becomes increasingly difficult, especially when leaving home. From transportation to accessibility, every step of a trip must be thoroughly planned. In addition to physical barriers, clients are afraid of being stigmatized because of their MS symptoms or fear becoming disoriented due to cognitive impairments. Many MS clients avoid social outings leading to isolation and depression which directly affect psychosocial well-being and quality of life (QOL).

Community ReIntegration for Socially isolated Patients (CRISP) is a program addressing isolation in MS by combining educational treatment with recreational therapeutic activities to help tackle impediments of living with a disability. Groups of 10-15 clients are taken to Broadway shows, museums, concerts, operas, sporting games and other exciting events. Clients are educated concerning community resources, accessibility, transportation, safety, and independence. For subsequent outings clients are required to actively participate in the planning and execution of the event. The program also serves as a setting for clients to develop social networks and support systems for one another.

Efficacy of the program was assessed by administering a self-rated QOL questionnaire we developed to a sample of 50 clients (from over 200) who participated in the CRISP program during the past year. 96% of clients rated the program positively. Most of them had not left their homes for a social event in months. Examples of topics included inspiration to socialize more often and having a sense of feeling less isolated. Clients have begun making plans with others they met at events (i.e. dinner plans or shows) and overall report feeling less isolated. Over the next six months, durability of the program will be assessed.

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**(P16) FACTORS RELATED TO NURSING HOME VERSUS HOME-BASED CARE IN PATIENTS WITH MS**

**Background:** MS is a progressive disease and many patients ultimately develop severe disability requiring extensive, long-term care. Patients with MS who are nursing home (NH) residents are often distinctly younger than the typical NH population.

**Objective:** To investigate the extent and characteristics of MS patients with severe, sustained disability followed at a specialized MS Center and to identify factors that may predict admission to a NH compared to home-based care (HBC).

**Methods:** Baird MS Center database, constituent of the New York State Multiple Sclerosis Consortium, was queried for patients with an advanced sustained disability defined as an EDSS  $\geq 7.0$ . Demographic characteristics, education, marital and insurance status, and ever-use disease modifying therapies were considered in the analysis.

**Results:** Of data extracted from 1,850 registered MS patients, 369 had an EDSS  $\geq 7.0$  (74% female, 92% Caucasian). Twenty-one percent were NH residents. No difference in age of MS onset, mean (SD) 31.4 (9.1) vs. 32.5 (9.9) and no significant difference in sex, race, education, disease type, family history, and ever-use of disease modifying drugs were found between NH residents compared to HBC patients, respectively. Significant variables that appear to predict NH vs. HBC found in adjusted logistical regression models (odds ratio with 95% CI) were marital status: single/divorced/widowed vs. married (OR 4.1 (2.0, 8.5)  $p=.000$ ), insurance status: private vs. public insurance (OR 4.7 (1.4, 16.5)  $p=.017$ ), bowel/bladder (OR 1.5 (1.2, 1.8)  $p=.000$ ) and cerebral dysfunction (OR 1.7 (1.3, 2.1)  $p=.000$ ).

**Conclusion:** Twenty-one percent of MS patients with comparable disability are NH residents vs. living alone or with a family member in HBC. Marital status, insurance provider, bowel/bladder dysfunction and cognitive impairment are the strongest predictors for need of NH care. Models of constructive interventions to keep these young individuals in a home-based care environment are essential.

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(P17) MULTIPLE SCLEROSIS (MS) LITERACY: THE GAP BETWEEN 'NEED TO KNOW' AND 'KNOW THE NEED'

**OBJECTIVE:** To evaluate MS specific health literacy of a sample of MS patients seen at the Mellen Center and to survey MS clinician expectations for health literacy.

**BACKGROUND:** A core aspect of self-management of chronic disease is a working knowledge of key terms used to describe that disease and its management. In MS there are many medical terms that are used by health care professionals. We evaluated the MS specific literacy of a sampling of our MS population and compared this with our team's expectations. We also evaluated whether other measures of general health literacy correlated with MS specific literacy.

**DESIGN/METHODS:** Pilot Project, Survey sample, using a convenience sample of patients currently cared for at the Mellen Center for MS, Cleveland Clinic. Patients asked to define twelve MS related terms (e.g. demyelination, axon, white matter, etc.). Duration of MS, education, general health literacy questions also reviewed. Responses scored as not known, wrong, partially right, correct (ARG, DM).

**RESULTS:** 24 patients surveyed using two sets of 12 MS related terms. Age  $45 \pm 10$  years, Time from diagnosis  $7.7 \pm 7$  years, Gender F 71% M 29%. Ethnicity African American 8%, Caucasian non-Hispanic 92%. Education High school 21%, Some College 50%, Bachelor Degree 21%, Graduate degree 8%. Perception about general health literacy correlated moderately with MS specific literacy (Spearman correlation 0.55182,  $P=0.0052$ ). No significant correlation with gender, education, ethnicity. Twelve Mellen Center Clinicians felt that patients should understand  $17.2 \pm 2.8$  out of 24 terms related to MS (range 11-23 terms). Patients gave 'correct' definitions for MS related terms 17% of the time.

**CONCLUSIONS/RELEVANCE:** There is a gap between 'need to know' MS related terms and the pilot sample's demonstrated knowledge. We conclude that further sampling of larger populations will help us 'know the need' in terms of literacy for MS specific terms.

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**(P18) FACTORS THAT INFLUENCE ADHERENCE WITH DISEASE-MODIFYING THERAPY IN MULTIPLE SCLEROSIS: A MULTIVARIATE ANALYSIS**

**Background:** Long-term adherence to disease-modifying therapy (DMT) for multiple sclerosis (MS) is affected by many factors. Knowledge of the factors associated with decreased adherence may allow health care providers to intervene with patients at the greatest risk of poor adherence and encourage them to remain on therapy long term.

**Objective:** A multivariate analysis of data from this multicenter, retrospective, observational (three-wave) study using Internet-delivered patient surveys was conducted to identify factors associated with adherence to DMTs in 798 patients with MS. Adherence was defined as not missing a DMT injection in the 4 weeks prior to survey completion.

**Methods:** Univariate analyses of all questionnaire responses were conducted and then questions univariately related to adherence ( $p \leq 0.10$ ) were included in the multivariate analysis. Two complementary analyses, stepwise regression (SWR) and all possible regression (APR), were performed and the results of both analyses were combined (CAS [combining results of APR and SWR]) to select variables associated with adherence.

**Results:** An older age at diagnosis (OR=1.032,  $p=0.0004$ ), satisfaction with treatment (OR=2.085,  $p=0.0003$ ), and self-reported excellent or very good general health (OR=1.425,  $p=0.0284$ ) were associated with better adherence. Patients taking prescription medicine for fatigue were less likely to adhere (OR=0.642,  $p=0.0067$ ). After adjusting for potential confounders, significant differences in adherence among the DMTs were observed. Patients on interferon beta (IFN $\beta$ )-1b (OR=0.362,  $p<0.0001$ ) or glatiramer acetate (OR=0.322,  $p<0.0001$ ) had significantly lower odds of adherence than patients on either subcutaneous or intramuscular IFN $\beta$ -1a.

**Discussion:** Patients who are diagnosed with multiple sclerosis at a younger age, who perceive their health as fair or poor, or who are taking medication for fatigue may need more counseling on the importance of adherence. Focusing on factors associated with decreased adherence may enable health care providers to effect a favorable change in adherence.

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**(P19) COMPARING SLEEP PROBLEMS IN MS USING  
THE WHI INSOMNIA RATING SCALE AND MOS SLEEP SCALE**

**Background:** Research studies suggest that that up to 50% of individuals with multiple sclerosis (MS) complain of sleep-related problems. However, sleep difficulties have received comparatively little research attention in MS and few large scale sleep studies have been completed to date. Because sleep is known to have a substantial impact on quality of life, it is important to examine the prevalence of sleep disorders and functioning of sleep instruments in individuals with MS. The purpose of this study was to estimate the prevalence of sleep difficulties in MS using two sleep scales and evaluate the psychometric functioning of both measures in an MS population.

**Methods:** A large cross sectional sample (n=1,063) of community dwelling individuals with MS completed a self report mail survey. Sleep was assessed using the Medical Outcomes Study Sleep Scale (MOSSS) and the Women's Health Initiative Insomnia Rating Scale (WHIIRS). Both measures were scored based on recommendations of scale developers and summary statistics calculated. Item Response Theory (IRT) with a graded response model was used to evaluate the psychometric functioning of the scales.

**Results:** Mean scores on the WHIIRS and MOSSS Sleep Index II were 9.8 (SD: 5.3) on a scale from 0-20 and 38.9 (SD: 19.7) on a scale from 1-100 respectively. These scores indicate individuals with MS have significantly more sleep problems than the general population and other chronically ill populations. IRT analysis found that both scales have significant numbers of misfitting items and response categories did not perform as expected. Both scales measured individuals with more sleep difficulties more accurately than those below the mean of this sample.

**Conclusions:** Sleep difficulties appear to be a significant problem for a large percentage of individuals with MS. Further research on sleep difficulties in MS and development of better measurement tools for evaluating sleep difficulties is needed.

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**(P20) EXAGGERATED STARTLE RESPONSE (HYPEREKPLEXIA) IN MULTIPLE SCLEROSIS:  
REVIEW OF 20 PATIENT-REPORTED CASES**

Exaggerated startle response or hyperkplexia (also known as hyperreflexia) is not recognized to be associated with multiple sclerosis (MS). It is not mentioned in MS reviews or textbooks. Only one MS case report was found in the literature review.

The purpose of this report is to increase the awareness of this symptom in MS. Thirty-seven patients self-reported “startle response” after an inquiry in the Multiple Sclerosis Association of America’s (MSAA) “Ask the Doctor” column in their magazine, *The Motivator*. This unexpected high response prompted a literature review on hyperkplexia. Most cases of hyperkplexia in the medical literature are related to hereditary neonatal hyperkplexia and post-traumatic stress disorder (PTSD). Hyperkplexia involves an overactive autonomic arousal, which creates difficulty discriminating and interpreting stimuli. The primary treatment reported in the literature has been clonazepam. No MS patients received clonazepam.

Thirty of the 37 respondents completed the survey. Startle was usually precipitated by auditory (82%), visual (17%), tactile (6%), or a combination of stimuli. The average age of onset of MS symptoms was 26 and the onset of startle was 35. Less than 20% of MS patients had startle before their MS, which suggests previous trauma (PTSD) is not related. Other data include: 67% have the relapsing–remitting form of MS; 93% reported multiple episodes per day; 90% have an exaggerated startle response at least once a week and half of these experience startling at least daily. Hyperkplexia was variously described as frightening, embarrassing, painful, dangerous (falling), and disruptive to personal and professional relationships. A total of 73% had not had discussions with any healthcare professional, and 17% reported that their doctors stated that startle might be related to MS, but had no therapeutic suggestions.

In conclusion, hyperkplexia is an underrecognized but potentially treatable symptom of multiple sclerosis. Increased recognition and understanding will promote treatment options.

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(P21) VALIDATION OF AN AMBULATION-SPECIFIC VISUAL ANALOG SCALE (VAS)  
USING THE LIFEWARE SYSTEM

**Background:** When defining a clinically meaningful change in ambulation in multiple sclerosis (MS), consideration of the patient's perspective is crucial. Subjective visual analog scales (VASs) represent potentially promising complements to objective clinical measures. The LIFEware System (LIFEware) has been widely embraced as a valid, reliable patient-oriented measure of functional status.

**Objective:** To validate the VAS as a measure of patient-perceived change in ambulation using the MSPhysical component of LIFEware.

**Design/Methods:** Data from 90 MS patients (mean age: 47.8+/-10.5yrs; mean EDSS: 2.9+/-1.7) were studied. Patients reported change in ambulation by marking a horizontal 10cm line anchored by word descriptors (ie. "much worse"). Scored on a scale of 0-100, VAS scores  $\leq 25$  were arbitrarily selected to represent meaningful worsening. Patient-perceived problems rising from a low seat (GETUP), stair climbing (STAIRS), standing (STAND), fatiguability (FTG) and using right (RLL) and left (LLL) lower limbs were assessed and compared to data available from previous evaluations (med. 442.5 days). Functional changes detected by VAS and MSPhysical item scores were dichotomized (ie. 'worse' or 'no change/better').

**Results:** Patient-perceived worsening was reported by 27.8% of patients via the VAS. Worsening functional status was detected in 14.4-31.1% of patients according to changes in MSPhysical item scores. Statistically significant correlations between VAS and the following MSPhysical item scores were observed: GETUP ( $r=.46$ ,  $p<.05$ ), STAIRS ( $r=.40$ ,  $p<.05$ ), STAND ( $r=.42$ ,  $p<.05$ ), FTG ( $r=-.23$ ,  $p<.05$ ), RLL ( $r=-.44$ ,  $p<.05$ ) and LLL ( $r=-.34$ ,  $p<.05$ ). Chi square analyses of independence demonstrated no statistically significant differences between VAS and any MSPhysical item scores ( $p>.05$ ).

**Conclusion/Discussion:** Patient-perceived changes in ambulation detected by the VAS appear to reflect patient-reported functional status captured by the MSPhysical items of LIFEware. While further validation is warranted, incorporating complementary patient-oriented measures when attempting to define clinically meaningful changes may provide valuable insight into the diverse impact of MS.

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(P22) EFFECT OF EXERCISE TRAINING ON WALKING MOBILITY IN MULTIPLE SCLEROSIS: A META-ANALYSIS

**Background:** Exercise training is a promising behavioral strategy for mitigating reductions in walking mobility among people with MS. To date, the existing research has not uniformly provided evidence for a beneficial effect of exercise on walking mobility in MS, and the magnitude of the influence of exercise training on walking mobility has varied considerably. Such issues underscore the importance of conducting a quantitative synthesis of the magnitude of the overall effect of exercise training on walking mobility in MS.

**Objective:** This study examined the overall effect of exercise training interventions on walking mobility among individuals with MS using meta-analytic procedures.

**Methods:** We conducted a search for published exercise training studies across the period of 1960 to November, 2007 using MEDLINE, PsychINFO, CINAHL, and CURRENT CONTENTS PLUS. Studies were selected if they measured walking mobility, using instruments identified as acceptable walking mobility constructs and outcome measures for individuals with neurological disorders, before and after an intervention that included exercise training.

**Results:** 43 papers were located and reviewed, and 22 provided enough data to compute effect sizes. 66 effect sizes were retrieved from the 22 publications with 600 MS participants. The distribution of the effects had slight negative skewness ( $g_1 = -.07$ ) and leptokurtosis ( $g_2 = 0.89$ ). 54 of the 66 effect sizes were greater than zero. The weighted mean effect size ( $g = 0.19$ ) was significantly different from zero (95% CI = 0.09 – 0.28). The Fail-safe  $k$  was 285. The funnel plot suggested against publication bias. The moderator analysis indicated that there were larger effects associated with supervised exercise training, exercise programs that were less than 3-months in duration, and mixed samples of relapsing-remitting and progressive MS.

**Conclusions:** The cumulative evidence supports that exercise training is associated with a small, but meaningful improvement in walking mobility among individuals with MS.

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**(P23) OBSERVATIONS ON USE OF NITROFURANZONE- IMPREGNATED URINARY CATHETERS IN PATIENTS WITH NEUROGENIC BLADDER AND MULTIPLE SCLEROSIS**

**Introduction:** Asymptomatic bacteriuria is a common problem in patients with multiple sclerosis (MS). They are associated with use of intermittent catheterization and indwelling catheters, both urethral and suprapubic. Symptomatic urinary tract infections (UTIs) in persons with MS include fever, hematuria, fatigue, urinary urgency, frequency, and incontinence, which result in hospitalizations, pseudo-exacerbations, and loss of productivity. Long term risks of recurrent UTIs can include the development of resistant organisms within urine, stone formation, and renal failure.

**Methods:** A total of 7 patients with MS and 1 patient with transverse myelitis, all with a history of recurrent symptomatic UTIs, were managed with nitrofurazone- impregnated urinary catheters. Indwelling catheters were routinely changed every three to four weeks. Urine analysis and cultures were performed at the time of the catheter change and when the patient reported feeling ill. With the patients who performed clean intermittent catheterization (CIC) only when the patient reported feeling ill were urine tests ordered. Rates of symptomatic infections were monitored over a 6 month period. Patients were assessed by phone and during routine clinical visits.

**Results:** The data in the poster documents the symptomatic infection rates before and during the observation period. The primary outcome symptomatic UTI was reduced overall in 4 of 8 patients over a 4 month period. No skin irritations or allergic responses were noted or observed.

**Conclusions:** Our results suggest that use of nitrofurazone- impregnated urinary catheters may reduce the risk of symptomatic urinary tract infections in neurogenic patients. However, due to the limited number of patients, further large prospective studies with longer follow-up are needed to confirm these observations. Until these studies are completed, use of this type of catheter may be considered as a treatment option for MS patients with recurrent UTIs who require intermittent catheterization, or use chronic urethral or suprapubic catheters for bladder management. In our experience, to date this catheter has not resulted in any additional cost to the patient.

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**(P24) DISCREPANCIES IN SUBJECTIVE AND OBJECTIVE OUTCOMES WITH ITB THERAPY**

**Background/Objective:** The intrathecal baclofen (ITB) pump has been effective managing spasticity in patients with MS, but little is known about what influences patient perceptions of treatment effects or how their definition of success compares with objective assessments.

**Design/Methods:** Ten ambulatory MS patients with severe spasticity aged 31 to 52 (90% female, 100% Caucasian, 40% married, and 50% employed) referred to the Mellen Center Spasticity Clinic, underwent implantation of a baclofen pump. At baseline, 1, 3 and 6 month follow-ups, measures included 25-foot walk, SF-36, and MOS Pain Effects Scale as well as patient ratings of change in symptoms and function, satisfaction, and likelihood of repeating the procedure at 1, 3 and 6 months.

**Results:** No patients showed consistency between the subjective (likelihood of repeating) and objective (timed walk) outcome (i.e., both positive or negative) at all 3 follow-ups. Three patients were consistent at 2 points, with the remainder consistent at no more than 1 point. At any one follow-up, at least half the sample had consistent outcomes. Patients with consistency between the subjective and objective outcome at any follow-up also reported at the same follow-up stable or positive change in symptoms, and were neutral, satisfied or very satisfied with ability to control symptoms, function, and quality of life related to the pump. Patients with inconsistency between the subjective and objective outcome at any follow-up, specifically those with greater likelihood of repeating the procedure who also experienced no improvement in gait speed, reported stable or improved physical health, and worsening effects of pain.

**Conclusion/Discussion:** The findings illustrate considerable inconsistency between how patients subjectively and clinicians objectively define success with ITB therapy. This emphasizes the need to identify specific and meaningful patient goals at baseline and follow them throughout treatment. Potential application of this model to additional MS treatments will be discussed.

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