



Platforms





Abstracts - Platform



MS DISEASE MECHANISMS AND MODIFYING THERAPY

1:00 - 1:20 pm	P01	Brain MRI Findings in Relapsing-Neuromyelitis Optica Using the Protocol of the Consortium of Multiple Sclerosis Centers.
1:20 - 1:40 pm	P02	Clinical Utility of Neutralizing Antibody Testing in Multiple Sclerosis Patients
1:40 - 2:00 pm	P03	Autologous Trivalent T Cell Therapy in Multiple Sclerosis: A Study of Patients Previously Treated with Monovalent T Cell Therapy
2:00 - 2:20 pm	P04	Multiple Sclerosis Patients' Willingness to Accept a Risk of Treatment-Related Serious Adverse Events in Exchange for Clinical Benefits
2:20 - 2:40 pm	P05	Quality of Life and Disability in Relapsing MS with Natalizumab Treatment
2:40 - 3:00 pm	P06	Three Year Changes in MS Symptoms and Quality of Life Following Mitoxantrone Treatment

REHABILITATION AND SYMPTOM MANAGEMENT IN MS

1:00 - 1:20 pm	P07	Balance-Based Torso-Weighting Improves Balance and Mobility in MS
1:20 - 1:40 pm	P08	Use and Availability of Assistive Technology in MS
1:40 - 2:00 pm	P09	Effects of Cognitive Demand on Functional Mobility in Multiple Sclerosis
2:00 - 2:20 pm	P10	Use of a Hip Flexion Assist Orthosis in Ambulatory Patients with Multiple Sclerosis: Functional Outcomes and Patient Satisfaction.
2:20 - 2:40 pm	P11	Adherence to CDC/ACSM Physical Activity Guidelines in a Community Sample of Persons with Multiple Sclerosis
2:40 - 3:00 pm	P12	Safety of AVP-923 in the Treatment of Multiple Sclerosis Patients with Involuntary Emotional Expression Disorder

PSYCHOSOCIAL ISSUES IN MS

1:00 - 1:20 pm	P13	What are the Needs of Patients Severely Affected by Multiple Sclerosis Referred to a New Palliative Care Service?
1:20 - 1:40 pm	P14	Dietary Practices of Persons with Multiple Sclerosis
1:40 - 2:00 pm	P15	MS Care Partner Stress: A Narcoms Study
2:00 - 2:20 pm	P16	Quality of Mental Health Care in MS: Four Models of Care
2:20 - 2:40 pm	P17	The Family Caregiver Pilot Projects and a Strategy for Supporting Caregivers in the MS Society of Canada
2:40 - 3:00 pm	P18	Factors Associated with Health-Related Quality of Life: What We Know and What We Don't





(P01) BRAIN MRI FINDINGS IN RELAPSING- NEUROMYELITIS OPTICA USING THE PROTOCOL OF THE CONSORTIUM OF MULTIPLE SCLEROSIS CENTERS.

BACKGROUND: Some studies showed abnormalities in brain magnetic resonance imaging (MRI) as to relapsing-Neuromyelitis Optica (R-NMO) from 12-46%. These abnormalities are described as compatible/non-compatible with Multiple Sclerosis (MS). The aim of this study was to describe the abnormal brain MRI lesions in R-NMO with imaging studies conducted with more sensitive white matter changes than with those techniques used in the original papers.

METHODS: 30 patients with R-NMO (Wingerchuck et al) from the Cuban prevalence study were selected. All MRI brain studies were performed with a 1.5 Tesla superconducting Siemens MRI system according to the protocol of the Consortium of Multiple Sclerosis Centers (CMSC).

RESULTS: Data of the 30 patients were: 27 (90%) females; age at onset 32.1 ± 8.89 years; whites 16 (53.3%), negroes 9 (30%), mulattoes 5 (16.6%); 10.43 ± 7.17 year duration of disease and mean of relapses 4.16 ± 2.2 . Brain MRI images were evaluated in 29 R-NMO cases because in one case the MRI images were not appropriate for the study. Of these 29 brain MRI studies, 19 cases (65.51%) had at least one or more lesions (1-57) and 10 were negative (34.48%). Brain MRI findings in 19 cases, were characterized in T2/ Fluid-attenuated inversion-recovery by the presence of subcortical/ deep white matter lesions in 16 (84.2%) cases (1-50), most of them < 3 mm; periventricular lesions in 13 (68.4%) cases without oval, ovoid or perpendicular orientation in morphology, and infratentorial lesions, all > 3 mm, in 4 (21.05%) cases. No cases had cerebellar involvement. T1 studies demonstrated absence of black holes. Optic nerve enhancement was observed in 6/19 patients (31.5%). All MRI abnormalities observed were not compatible with acute disseminated encephalomyelitis or MS (Barkhof et al).

CONCLUSIONS: Brain MRI findings in R-NMO patients with protocol of the CMSC were characterized by subcortical/ deep white matter lesions, most of them < 3 mm, periventricular lesions without oval, ovoid or perpendicular orientation, infratentorial lesions, all > 3 mm, optic nerve enhancement and absence of black holes.

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(P02) CLINICAL UTILITY OF NEURTRALIZING ANTIBODY TESTING IN MULTIPLE SCLEROSIS PATIENTS

BACKGROUND: Recent evidence suggests that neutralizing antibodies (NABs) in patients who receive interferon beta for Multiple Sclerosis (MS) are associated with relapse and MRI activity.^{1,2} There has been no critical analysis as to whether NAb testing is sufficiently predictive to be used in routine clinical practice.

OBJECTIVE: To evaluate NAb testing as a prediction of disability progression in MS.

METHODS: Summary statistics from two recent clinical studies^{1,2} were used to compute the following values for NAb testing in order to evaluate clinical predictability: sensitivity (percent of patients with a positive outcome correctly detected), specificity (percent of patients with a negative outcome correctly detected), positive and negative predictive value, overall (% of patients for whom NAb status agreed with patient outcome) and chance agreement, and Phi correlation coefficient. The three efficacy values that were used were: percent relapse-free patients, mean relapse rate, and percent patients with 1 point confirmed disability progression over the course of the studies.

RESULTS: The overall percentage of patients with negative outcomes at 48 months (58%¹ and 50%²) correctly detected by NABs testing was nominally greater than chance (54%¹ and 45%²) in both studies. The calculated positive and negative predictive values indicated 39%-58% of patients who tested NAb+ had negative outcomes, and 48%-73% of patients who tested NAb- had positive outcomes. There was a weak correlation (Phi coefficient=0.12-0.19) between NAb status and all 3 efficacy values for both studies. The negative (sensitivity) outcome was 30%-38%, and the positive (specificity) outcome was 70%-74%.

CONCLUSION: This analysis indicates that a positive NAb test is not significantly correlated with relapse or disability progression to support clinical decision-making. At the current time, treatment decisions should not be based solely on a positive NAb test.

Study supported by: Serono Inc. Pfizer Inc. PCoyle: consultant, speaker bureau, honoraria (Serono, Pfizer) Grant (Serono)

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**(P03) AUTOLOGOUS TRIVALENT T CELL THERAPY IN MULTIPLE SCLEROSIS:
A STUDY OF PATIENTS PREVIOUSLY TREATED
WITH MONOVALENT T CELL THERAPY**

OBJECTIVE: To evaluate the safety of a trivalent autologous T cell therapy (TovaxinT) in patients who had previously received a monovalent autologous T cell therapy (TCT) for treatment of multiple sclerosis. Background: Myelin peptide-reactive T cells (MRTCs) play a critical role in the pathogenesis of MS. Previous T cell therapy pilot studies used a monovalent formulation of attenuated MRTCs to deplete myelin basic protein (MBP) reactive T cells. Because several myelin antigens are described as potential autoantigens for MS, depletion of MRTCs using a trivalent formulation may have enhanced therapeutic effects.

DESIGN/METHODS: Patients with RRMS or SPMS who had received monovalent TCT and either progressed or relapsed donated blood from which T cells reactive to two peptides each of three proteins [MBP, proteolipid protein (PLP) and myelin oligodendrocyte glycoprotein (MOG)] were expanded ex vivo and prepared as a TCT formulated as CD4+ and CD8+ MRTCs. The MRTCs were attenuated by Cesium 137 irradiation prior to patients receiving subcutaneous injections of 30-45 million cells at weeks 0 and week 8. MRTC frequency was analyzed at months 0, 3, 6, 12. EDSS was determined at months 0, 1, 3, 6, 9, 12.

RESULTS: MRTCs in the peripheral blood were depleted in all 3 types of MRTCs at all follow up visits. 4 of 10 patients had clinically significant improvements in EDSS to date. No patient had clinically significant worsening in EDSS to date. There were no serious adverse events attributable to TCT.

CONCLUSION: MRTCs in patients with worsening MS following monovalent TCT can be depleted by Tovaxin treatment. At 6months, EDSS improved in 40% of patients and none worsened. The treatment appears safe and well tolerated as a retreatment vaccination therapy. A Phase IIb double-blind placebo-controlled trial to study the effects of Tovaxin in CIS or early RRMS is planned.

Study supported by: PharmaFrontiers Corp (formerly Opexa Pharmaceuticals). I am the principal investigator and receive only research funding. Jim Williams, PhD, is their Chief Operating Officer and receives salary and has an equity position and stock options. Mitzi Montgomery, DVM is a former employee (received salary within the last 5 years), a current consultant, and has an equity position and stock options.

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(P04) MULTIPLE SCLEROSIS PATIENTS' WILLINGNESS TO ACCEPT A RISK OF TREATMENT-RELATED SERIOUS ADVERSE EVENTS IN EXCHANGE FOR CLINICAL BENEFITS

BACKGROUND: Medical interventions carry risks of adverse outcomes that must be evaluated against their clinical benefits. This study calculated the maximum acceptable 10-year risk (10-year MAR) of serious adverse events (SAEs) in exchange for specified levels of treatment benefit in MS patients.

METHODS: A patient questionnaire containing stated preference benefit-risk trade-off items was developed and pre-tested. Treatment attributes included time to disability progression, number of relapses, risk of death/disability from progressive multifocal encephalopathy (PML) and risk of death from liver failure or leukemia. The questionnaire also contained items regarding demographics, disease and treatment history, and the Patient Determined Disease Steps (PDDS). Patients were recruited from a panel of commercial and clinical trial natalizumab patients and an internet MS patient panel.

RESULTS: The survey was completed by 563 patients (natalizumab panel=190, internet panel=373). The two panels were demographically similar, however the natalizumab panel reported a greater mean number of relapses in the past 2 years (3.2 vs. 2.2, $p < 0.01$) and had slightly higher disability. Overall, lower disability levels were more heavily represented within the sample (>60% did not require ambulatory aid). Patients were primarily focused on clinical efficacy in making their treatment decisions. The estimate of patients' 10-year MAR of death/disability due to PML in exchange for a clinically relevant increase in time to progression from 3 to 5 years was 1.6% (CI=0.3%-3.9%) for the natalizumab panel and 1.0% (CI=0.3%-2.6%) for the internet panel. The MARs for the three studied SAEs is well above the observed rates of SAE occurrence with natalizumab or any of the commonly used MS medications.

CONCLUSIONS: MS patients are willing to accept a defined risk of treatment-related death or severe disability in exchange for specified levels of clinical efficacy. The patient perspective on balancing potential benefits and risks can assist in making treatment decisions.

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(P05) **QUALITY OF LIFE AND DISABILITY IN RELAPSING MS
WITH NATALIZUMAB TREATMENT**

OBJECTIVE: To determine the effect of natalizumab (TYSABRI®) on health-related quality of life (QoL) and its relationship to disability in patients with MS.

BACKGROUND: MS has a substantial negative impact on health-related QoL; however, currently available therapies have not demonstrated Class I evidence of a significant effect on QoL. AFFIRM and SENTINEL were randomized, double-blind, placebo-controlled, 2-year phase 3 clinical trials that evaluated the efficacy and safety of natalizumab monotherapy and natalizumab added to interferon beta-1a (AVONEX®), respectively, in relapsing MS.

STUDY DESIGN/METHODS: In AFFIRM and SENTINEL, the effects of natalizumab (as monotherapy and as add-on therapy, respectively) on disability progression was measured using the Expanded Disability Status Scale (EDSS) and the Multiple Sclerosis Functional Composite (MSFC). QoL was assessed using the Medical Outcomes Study Short Form-36 Health Survey (SF-36). A Spearman correlation coefficient was used to assess the relationship between QoL (SF-36) and disability (EDSS and MSFC) at 2 years.

RESULTS: Over 2 years in AFFIRM, natalizumab significantly reduced disability progression as measured by EDSS ($P < 0.001$) and the MSFC ($P < 0.001$), and improved QoL scores on the physical ($P = 0.003$) and mental ($P = 0.011$) subscales of the SF-36 compared with placebo. Significant favorable correlations were observed between SF-36 and EDSS scores; stronger correlations were observed with the SF-36 physical subscale (natalizumab $r = -0.543$, $P < 0.001$; placebo $r = -0.545$, $P < 0.001$) than the mental subscale (natalizumab $r = -0.136$, $P = 0.001$; placebo $r = -0.289$, $P < 0.001$). There were significant favorable correlations between SF-36 and MSFC scores; similar to EDSS, stronger correlations were observed with the SF-36 physical subscale (natalizumab $r = 0.404$, $P < 0.001$; placebo $r = 0.410$, $P < 0.001$) than the mental subscale (natalizumab $r = 0.145$, $P < 0.001$; placebo $r = 0.268$, $P < 0.001$). Results from SENTINEL will also be presented.

CONCLUSIONS: Natalizumab significantly improves health-related QoL in relapsing MS patients. There is a significant relationship between QoL and disability as measured by both the EDSS and MSFC.

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(P06) **THREE YEAR CHANGES IN MS SYMPTOMS AND QUALITY OF LIFE
FOLLOWING MITOXANTRONE TREATMENT**

BACKGROUND: Mitoxantrone (Novantrone) is an immunosuppressive agent approved for treatment of secondary progressive (SP) or worsening relapsing-remitting (WRR) MS. Data collection continues in an open-label study evaluating the safety of mitoxantrone (Registry to Evaluate Novantrone Effects in Worsening MS, RENEW).

OBJECTIVES: We conducted a prospective companion study of RENEW participants to examine the relationship between disease activity, disease progression, quality of life (QOL) and disease-related costs. We report outcome data related to symptom control and quality of life.

METHODS: 254 of the 500 RENEW patients with WRR or SP disease consented to participate in this companion study. Of these, 113 (44%) completed both the baseline and closing questionnaires. Changes over time were analyzed with a Wilcoxon matched pairs signed rank test.

RESULTS: The 113 participants were predominantly female (66.4%), with mean age of 49.7 (SD 8.1) years, mean disease duration of 14.6 (SD 8.4) years, and mean duration of participation of 35.1 (SD 4.4) months. Participants received an average of 8.5 (SD 3.6) mitoxantrone infusions. There was no meaningful change in the group's general health perception as measured by the first item of SF12 (baseline $x = 3.15$ SD = .9 vs. closing $x = 3.09$ SD = .9). Only patient determined disease step (PDDS) scale ($p=.045$) and mobility ($p=.002$) and bladder/bowel ($p=.022$) out of the 11 performance scale sub-scores worsened statistically significantly. Mean score for fatigue improved statistically significantly ($p=.030$) with standardized effect size calculation revealing a minimum clinical improvement (-.211).

CONCLUSIONS: On average, these WRR and SPMS patients demonstrated stability in 8 out of 11 performance scale domains and QOL over a mean period of 35 months following their enrollment in RENEW. Further analysis will be presented evaluating SF12 physical and mental component summary scores and Health Utilities Index scores obtained at 0, 12, 24 and 36 months.

Study supported by: Serono Inc.

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(P07) BALANCE-BASED TORSO-WEIGHTING IMPROVES BALANCE AND MOBILITY IN MS

BACKGROUND: Balance-Based Torso-Weighting (BBTW) is an intervention technique involving strategic weight placement on the torso of an individual to offset balance dysfunction. Previously, a patient with MS demonstrated improvement in posture and function: walked faster with decreased knee hyperextension, turned with less balance loss, demonstrated decreased visual dependence, and performed a more challenging home exercise program while weighted. We have taken this original observation a step further by testing the hypothesis that BBTW improves balance and mobility immediately and long term.

METHOD: Sixteen ambulatory subjects, mean age 44.5 years with MS were evaluated in baseline (BL), vest no weight (NW), and BBTW to determine immediate effects of BBTW on static and dynamic balance. In addition, a single subject case study using a 12 week, ABA design (B = 4 week intervention) was used to demonstrate long-term effects of BBTW versus baseline. Subjects were evaluated for balance dysfunction by perturbing trunk and resisted trunk rotation. Small amounts of weight (less than two percent body weight) were strategically placed on the torso to counteract the dysfunction. Standardized tests were used to measure the effects of BBTW.

RESULTS: The 16 subject study BBTW versus BL and NW demonstrated statistical differences in balance using the Computerized Dynamic Posturography in the eyes open condition ($p < .03$, $p < .02$), Sharpened Romberg Eyes Open NW versus BBTW ($p < 0.02$), and Timed Up and Go (TUG) BL versus both NW and BBTW ($p < 0.02$). No differences were seen between variables in the 25-foot walk ($p = 0.49$). The long-term case study subject demonstrated immediate and continued improvement in TUG, BERG balance scale, and during complete 360 degrees turns. The subject maintained the improvement post intervention.

CONCLUSION: Balance-Based Torso-Weighting is an effective treatment for ambulatory people with MS and may facilitate rehabilitation and enhance balance and mobility.

Study supported by: California PT Fund and Samuel Merritt Faculty Grant. I will be developing an evaluation vest for clinicians at some point and will want to teach the technique.

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(P08) USE AND AVAILABILITY OF ASSISTIVE TECHNOLOGY IN MS

Individuals living with multiple sclerosis (MS) face many barriers to participation in activities they value because of difficulties with mobility, pain, fatigue, and other complications of the disease. Assistive technology (AT) can often help facilitate independence and participation in employment, education, and recreation, but little is known about the prevalence of AT use or unmet AT needs. A 2005 self-administered mail survey asked participants with MS about AT they (a) currently used and (b) needed, but didn't have. Of the responders (N=110), the highest use of assistive technology was seen with use of memory aids (68%) or strategies (45%). High use of assistive technology was also seen with walking aids (42%), mobility aids (34%), bathroom aids (41%), and home modifications (36%). Use of vehicle modifications (15%), cooking/eating aids (17%), computer aids (10%), and communication aids (3%) was less prevalent. Importantly, this study found that individuals who needed assistive devices did not always have them available. Overall, 35% of individuals claimed that they needed assistive devices in at least one category but did not have the device available. The highest need for devices that were not available was for aiding with memory (19%). The next highest categories in which people needed devices but did not have them available were personal/home aids (16%), vehicle aids (11%), and mobility aids (7%). The results suggest that cognitive aids and strategies that enhance memory are two areas of considerable need for this population. More research and effort is needed to develop efficient devices and strategies that address cognitive issues experienced by individuals living with MS.

Study supported by: This project was supported by the Multiple Sclerosis Rehabilitation Research and Training Center (NIDRR grant #H133B031129).

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(P09) EFFECTS OF COGNITIVE DEMAND ON FUNCTIONAL MOBILITY IN MULTIPLE SCLEROSIS

BACKGROUND: Multiple sclerosis (MS) is an unpredictable and disabling condition that has been associated with decreased mobility, balance problems, and cognitive dysfunction. It has been speculated that persons with MS also have more difficulty multi-tasking compared to age-matched adults. We hypothesize that ambulation in people with multiple sclerosis (MS) is adversely affected by cognitive distractions more than in the control group.

RESEARCH DESIGN: A prospective case-control study conducted at The University of Washington.

METHODS: Sixty ambulatory (EDSS=6.0) community-dwelling adults (30 with MS, 30 age and sex-matched controls) are being enrolled. Two ambulation measures are being used: the Timed Up and Go Test (TUG) and a 100-foot walking test. These measures are performed under three conditions: no cognitive task; a simple cognitive task: reciting the alphabet; a more difficult cognitive task: counting backwards by three. In addition, subjects will count backwards by three while seated and complete the Paced Auditory Serial Addition Test.

Results: In MS subjects (n=7) and controls (n=2) studied to date, both simple and complex cognitive tasks adversely affect motor performance. MS subjects showed trends towards greater differences in speed between the TUG alone and the TUG with a cognitive task. The control group was 9% slower when performing the TUG with a cognitive task; MS subjects were 30% slower. Similar results were seen in the 100-foot walking tests while performing the more difficult cognitive task.

CONCLUSIONS: This study is highly relevant to multiple sclerosis as it addresses the interplay between two areas that are commonly affected by MS: cognition and motor function. The results allow us to better understand the impact of distraction on common motor functions. By better understanding the conditions under which falls occur, the treating physician will be able to employ rehabilitation strategies more effectively, thus minimizing morbidity in this population.

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(P10) USE OF A HIP FLEXION ASSIST ORTHOSIS IN AMBULATORY PATIENTS WITH MULTIPLE SCLEROSIS: FUNCTIONAL OUTCOMES AND PATIENT SATISFACTION

OBJECTIVE: to evaluate the efficacy and safety of a hip flexion assist orthosis (HFAO)

DESIGN: pre-post intervention study with prospective data collection up to 12 +/- 2 weeks.

SETTING: neurorehabilitation clinic within an outpatient multiple sclerosis (MS) center.

PARTICIPANTS: ambulatory patients with MS and severe hip flexor weakness.

INTERVENTION: fitting of a customized HFAO, and training prior to use in routine activities

MAIN OUTCOME MEASURE(S): lower extremity (LE) Manual Muscle Testing (MMT) and Modified Ashworth Scale (MAS), 25 ft Walk (25 FW), Six Minute Walk (6MW), Mellen Center Gait Test (MCGT), patient satisfaction questionnaire.

RESULTS: Mean age was 52 +/- 8.3 years, 67% of patients were women. Mean disease duration was 16 +/- 7.7 years, 50% had RRMS, 17% SPMS, 17% PPMS, 16% PRMS. Comparison between baseline and 12 weeks showed a statistically significant improvement in MMT (effect size 0.28; $p=0.0002$), 25FW (effect size 0.28; $p=0.05$), 6MW (effect size 0.33; $p=0.00002$), MCGT (effect size 0.32; $p=0.007$), and Pain (effect size 0.64; $p=0.004$). There was no statistically significant change in MAS. Mean satisfaction score at 12 weeks was 38.8 +/- 7.2 (maximum 45).

CONCLUSIONS: the use of a HFAO was associated with significant improvement of walking performance. There was also significant improvement of LE strength, which may be related to increased walking activity with brace use in daily life. There was also significant improvement of pain, suggesting that improved gait pattern decreased pain level. There was no worsening of spasticity. Patients reported a high level of satisfaction. A few patients experienced increased low back pain and mild skin irritation. There were no severe complications associated with the use of the HFAO.

Keywords: multiple sclerosis, rehabilitation, gait, orthosis

Study supported by: National MS Society. Dr. Bethoux has received honoraria for speaking for NMSS functions in the past.

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(P11) ADHERENCE TO CDC/ACSM PHYSICAL ACTIVITY GUIDELINES IN A COMMUNITY SAMPLE OF PERSONS WITH MULTIPLE SCLEROSIS

BACKGROUND: Physical inactivity has increasingly been reported as a risk factor associated with an array of morbidities. Despite this evidence, nearly 70% of adults in the US remain sedentary by the Centers for Disease Control (CDC) and the American College of Sports Medicine's (ACSM) standards for physical activity. This study sought to determine the proportion of persons with multiple sclerosis (MS) who meet the CDC/ACSM guidelines for physical activity and examine variables that may be related to meeting these guidelines.

METHODS: Subjects were 236 persons with MS living in the Seattle area. A research assistant asked subjects over the telephone for the frequency, duration, and type of exercise performed in the last month and basic demographic and medical history data. Respondents were classified as adherent to the CDC/ACSM guidelines if they engaged in moderate-intensity physical activity at least five days per week for 30 minutes or vigorous activity at least three days per week for 20 minutes.

RESULTS: Eighty-seven percent of the sample did not meet the CDC/ACSM guidelines for exercise and 29% had not exercised at all in the preceding month. Chi-square analysis did not reveal any significant relationships between meeting the exercise guidelines and 1) gender, 2) type of MS, 3) being ambulatory, 4) extreme heat sensitivity, or 5) balance problems. Body Mass Index values were significantly greater for those who met the exercise guidelines (mean=26.7, SD=5.9) versus those who did not (mean=24.3, SD=2.9) (Student's t-test $p=.038$).

CONCLUSIONS: These findings highlight the clinical importance of encouraging increased participation in physical activity for persons with MS and developing exercise interventions that are feasible for persons in this population.

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(P12) SAFETY OF AVP-923 IN THE TREATMENT OF MULTIPLE SCLEROSIS PATIENTS WITH INVOLUNTARY EMOTIONAL EXPRESSION DISORDER

OBJECTIVE: Evaluate common adverse event rates of investigational therapy AVP-923 (capsules containing dextromethorphan hydrobromide [DM; 30 mg] and quinidine sulfate [Q; 30 mg]) in Multiple Sclerosis patients with involuntary emotional expression disorder (IEED).

BACKGROUND: IEED is a condition characterized by the disinhibition of emotional expression secondary to neurological disease or injury. Episodes typically involve involuntary emotional expressions such as laughing, crying, or related facial features that are incongruent or exaggerated in relation to underlying mood. IEED is associated with neurological diseases such as MS, amyotrophic lateral sclerosis (ALS), Parkinson's disease, dementia, and neurological injuries, such as stroke and traumatic brain injury. IEED is also commonly known as emotional lability, pathological laughing and crying, and pseudobulbar affect. Q is included in the formulation of AVP-923 as a CYP2D6 inhibitor to block the rapid first-pass metabolism of DM and to increase its pharmacological potential.

METHODS: IEED patients from a phase III study (n=76) in MS patients and a large open label safety study (n=294) were included in the analysis. Common adverse event rates of AVP-923 treatment in MS patients were analyzed and compared to IEED patients with differing diagnoses such as ALS, Parkinson's disease, dementia, stroke, and traumatic brain injury.

RESULTS: Common AE's (occurring >10%) in MS patients included fatigue (24%), nausea (21%), dizziness (19%), diarrhea (16%), weakness (16%), and fall (15%). Common adverse events reported in MS patients were similar to those reported by patients with other underlying conditions. The majority of common AE's were reported during the first week of therapy and dissipated throughout the remainder of the trial.

CONCLUSIONS: Investigational therapy AVP-923 appears to be safe and well-tolerated in the treatment of MS patients with IEED. Most of the common adverse events were reported in the first week of treatment and decreased in frequency over time.

Study supported by: Avanir Pharmaceuticals. Laura Pope, Ryan Arnold, and James Berg are employees of Avanir Pharmaceuticals

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(P13) WHAT ARE THE NEEDS OF PATIENTS SEVERELY AFFECTED BY MULTIPLE SCLEROSIS REFERRED TO A NEW PALLIATIVE CARE SERVICE?

AIM: To determine the characteristics of patients referred to a new palliative care service for people severely affected by multiple sclerosis (PwMS) in southeast London.

METHODS: PwMS were referred to the new service by health and social care providers. Those patients consenting to participate in the evaluation of the service were randomised to one of two groups (fast track (FI) and standard intervention (SI)) then underwent baseline and follow up interviews. The outcome measures used were: UNDS, AMTS, MSIS, POS, POS-MS-S1, health and social services questionnaire. The data was entered into SPSS and analysed using descriptive statistics.

RESULTS: 52 PwMS were included in the study. The demographics of the two groups were equally matched - mean age 53; 36 females & 16 males; year of diagnosis 1987; total UNDS score 29 in the FT group and 30 in the SI group. 50% of PwMS had secondary progressive MS, 44% had primary progressive, 6% had other MS types or MS-related diseases. 48 PwMS (92%) used a wheelchair to get around most or all of the time. 44 PwMS reported problems with their legs, of which 33 had either severe or overwhelming problems. 39 PwMS mentioned problems with their arm function - 11 had very limited arm function and a further 6 PwMS displayed virtually no arm function. On the POS-MS questionnaire, 40 PwMS (80%) experienced fatigue, 37 (75%) reported feeling sleepy, 36 experienced spasms (69%), with 8 PwMS reporting severe or overwhelming spasms. 34 (65%) were affected by pain; 13 PwMS (26%) had pain they considered severe or worse. 23 (47%) PwMS reported constipation, 22 (45%) incontinence, 18 (34%) difficulty sleeping, 16 (31%) poor appetite and 13 (26%) nausea.

CONCLUSION: This is the first study to describe the needs of people severely affected by MS. These people experience significant disability and symptom burden.

Study supported by: Multiple Sclerosis Society (UK).

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(P14) DIETARY PRACTICES OF PERSONS WITH MULTIPLE SCLEROSIS

BACKGROUND: Good nutrition is important for good health which maximizes functioning and quality of life. Little is known about current dietary practices of persons with multiple sclerosis (MS), including sources of food and nutrition information, food consumption patterns, frequency of meals and snacks and intake of dietary supplements.

OBJECTIVE: To determine the current dietary practices of persons with MS and to see how these practices relate to disability level, dietary adequacy, and Body Mass Index (BMI).

METHOD: This descriptive comparative study used a sample of 123 persons with MS grouped according to disability level: mild to moderate and cane and/or wheelchair users. Participants completed a self-report mailed instrument regarding dietary practices and sources of nutrition information.

RESULTS: Both groups reported food labels as their primary source of nutrition information; only 20% received information from a registered dietitian. Fruit, vegetable, dairy and grain consumption for both groups was below 2005 United States Department of Agriculture (USDA) Dietary Guidelines. Most respondents reported at least one supplement daily, especially multivitamins. Both groups reported being too tired to cook at least once a week. Dining away was most likely to occur for the evening meal, at a sit-down restaurant. More than 50% of both groups reported a height and weight consistent with a BMI greater than 25.5, indicating overweight or obesity.

CONCLUSIONS: Findings show that fiber and calcium intakes are suboptimal. The incidence of overweight and obesity are significant. Determining currently utilized sources of nutrition information by persons with MS will help identify untapped resources. Registered dietitians can educate the entire MS care team to screen for dietary problems, provide appropriate nutritional guidance, and know when to refer to a registered dietitian for more specialized medical nutrition therapy. Education to promote accurate use of food labels is essential. Nutrition pamphlets should be made available in healthcare offices.

Study supported by: MS Family affiliated with Rutgers, The State University.

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(P15) MS CARE PARTNER STRESS: A NARCOMS STUDY

In 2005, the MS Center of the Neurology Center of Fairfax and the North American Research Committee on Multiple Sclerosis (NARCOMS) partnered together to empirically address the level and extent of Carepartner stress-related issues within the MS community.

Approximately 12,000 registrants in the NARCOMS database were electronically contacted. Permission for participation and referral to a secure website (separate from the NARCOMS database) to complete a specific CarePartner survey was requested. Electronic informed consent was collected. CarePartner responses were anonymous and confidential.

Basic demographic information was collected, and the Zarit Caregiver Burden Interview was electronically administered. The Zarit Burden Interview has been specially designed to reflect the stresses experienced by caregivers by asking 22 questions about the impact of the patient's abilities and disabilities on their life.

1,461 MS CarePartners (554 women and 907 men; mean age 50.44 years, SD 10.02 years, range 18-83 years) responded to the survey. The following health issues emerged from the group: 28% of CarePartners reported high blood pressure, 26% reported high cholesterol, 13% reported chronic headache, 13% reported persistent sleep disturbance and 17% reported Mood Disorder. Hypertension rates tended to be higher for CarePartners of patients with Secondary Progressive MS than for CarePartners of patients with Relapsing-Remitting MS. Although the literature often refers to caregivers as the "hidden patient" and stresses the importance of letting their physicians know they are caring for someone (Parks, & Novielli, 2000), 23% of the respondents indicated that their Primary Care Physician was not aware of their role as a CarePartner.

The present data reveals that MS CarePartners tend to experience the impact of caregiving stress differently based on MS-type, among other factors. It is hoped that these findings help to inform early intervention programs targeting the identification and treatment of CarePartner stress within the MS community.

Study supported by: Serono.

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(P16) QUALITY OF MENTAL HEALTH CARE IN MS: FOUR MODELS OF CARE

BACKGROUND: In spite of the high frequency of affective changes among persons with MS, little is known about the models and quality of mental health care in MS and there is no standardized method for assessing the quality of this care.

OBJECTIVES: This NMSS-funded study was designed to identify what constitutes quality mental health care in MS and how quality can be measured and improved.

METHODS: Focus groups and in-depth interviews were conducted at four MS Centers as part of larger study in which persons with MS responded to a survey about their experiences with mental health care. Focus groups illuminated the characteristics associated with high and low quality mental health care and shed light on experiences of individuals with MS with mental health services. In-depth interviews with MS Center staff provided information about the challenges of providing mental health care and the strengths and weaknesses of various models of care.

RESULTS: Seven focus groups (50 participants) and 21 in-depth interviews at four sites were conducted. 3,325 questionnaires were completed (of 8,700 mailed).

CONCLUSIONS: This presentation, based on the qualitative data (focus groups and in-depth interviews) obtained in the context of a larger questionnaire-based study, describes the experiences of individuals with MS from four MS Centers in accessing and utilizing mental health services and their opinions about the quality of care they received. It presents providers' perspectives on the challenges of providing mental health care to their patients and the impact of the system of MS care on the quality of mental health services.

Study supported by: National Multiple Sclerosis Society.

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(P17) THE FAMILY CAREGIVER PILOT PROJECTS AND A STRATEGY FOR SUPPORTING CAREGIVERS IN THE MS SOCIETY OF CANADA

From 2000-2005, the National Client Services department of the MS Society of Canada developed and evaluated an innovative caregiver program through a two-phase pilot project. Central to this was a Caregiver Wellness Funding Pilot Project which provided funding to a maximum of \$300/caregiver. This afforded many opportunities to hear directly from caregivers of people with MS regarding their needs and valued supports.

Three foundational principles guided the projects:

- Caregiver Voice — Caregivers should be involved in the assessment of their needs, have opportunities to express their needs and identify how they feel their needs can best be met.
- Caregiver Choice — Caregivers should have an opportunity to identify and choose individualized service options instead of having to fit into a narrowly or rigidly defined service.
- Respite as an outcome — A caregiver's relief or renewal, whether emotional, psychological, spiritual, physical and/or social, which results from services and strategies intended to help them maintain their own health and achieve greater balance in their lives. This in turn enables caregivers to secure better quality of life for themselves and the family members or friends for whom they provide care and support.

To conclude the project, stakeholders from across Canada reviewed the project findings and related implications for the MS Society's role in supporting caregivers. This resulted in a draft Strategy for Supporting Caregivers of People with MS, that includes a series of fundamental beliefs regarding caregivers arising out of project findings, and recommended actions in support of caregivers.

Broader caregiver engagement on this strategy was then sought to ensure that it accurately reflected caregiver beliefs, values and needs. Over 500 additional caregivers responded to a survey on the Strategy. Of these:

- 96% reported that the Fundamental Beliefs capture the important aspects of caregiving
- 97% felt that the Society's Recommended Actions in support of caregivers will benefit them

The Strategy was approved by the Society's National Board of Directors in November, 2005 and additional multi-year funding was secured to facilitate its implementation at all levels of the Society from coast-to-coast.

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(P18) FACTORS ASSOCIATED WITH HEALTH-RELATED QUALITY OF LIFE:
WHAT WE KNOW AND WHAT WE DON'T

BACKGROUND: Health-related quality of life (HRQoL) is an important factor in chronic diseases. Researchers have found that HRQoL decreases substantially in the early stages of MS.

OBJECTIVE: The purpose of this study was to review the existing literature to determine the factors which have been well established as having an association with HRQoL in the MS population, and which factors merit further investigation.

METHODS: We performed a systematic search and critical review of the literature on HRQoL in persons with MS. We included literature indexed in Medline and published between January 1, 1990 and August 31, 2005. We found 66 articles, which we critically reviewed and the findings were summarized into evidence tables, which formed the basis for our best-evidence synthesis.

RESULTS: Studies examining demographic/socio-economic factors are inconsistent, but there are suggestions that younger persons with MS have better physical, but poorer mental HRQoL. Being employed is associated with better HRQoL, although the causal direction of this association is unclear. Health and MS-specific factors that are strongly and consistently associated with poor HRQoL include fatigue, depression, and number of relapses. Disability had a very strong negative association with the physical component of HRQoL, but the association with the mental component is unclear. Further research into the association between disability and mental HRQoL is needed. The synthesis also highlighted the importance of psychosocial factors such as feelings of loss of control in the HRQoL of persons with MS.

CONCLUSIONS: The synthesis provides a unique understanding of what factors have been identified in the literature to be associated with the HRQoL in MS, and what factors require further investigation. This knowledge may assist health care providers in identifying patients who may be at risk for decline in their HRQoL, as well as serving as a springboard for future research.

Study supported by: Saskatchewan Health

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