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(S01) THE PHYSICAL AND OCCUPATIONAL THERAPY MS REHABILITATION PROGRAM

Introduction: In the Brazilian MS Society, ABEM, a multi-disciplinary team provides assessment and treatment to clients with M.S. An Occupational Therapist (O.T.) and Physical Therapist (P.T.) have worked together to create a rehabilitation program. The patients were separated in groups by their mobility level (walks unaided, walks with an aid, uses a wheel chair). Enjoyable activities were used to improve independence, autonomy, social life, self-esteem, physical condition, cognitive function and coping with MS. Each group attended one hour, once a month for a six months period. Unfortunately the sample was small owing problems with the schedules and transportation difficulties.

Objective: The goal of this study is to develop an interdisciplinary work between O.T and P.T to add knowledge of each area, making the therapy pleasant and give priority to quality of life issues.

Sample: 10 individuals with MS, average (\pm SD) age 44, $10 \pm 7,36$, 60% male, 40% female, the mean EDSS $5,75 \pm 2,15$

Methods: 2 self evaluations in a six months period, using the Multiple Sclerosis Impact Scale (MSIS-29) to gauge Quality of Life.

Results: Statistic Analyses (Wilcoxon test) showed a significant increase ($p < 5$) in quality of life. In the first evaluation the median was $76,7 \pm 18,73$ and in the second evaluation was $63,3 \pm 15,9$.

Conclusion: The P.T. and O.T treatment was advantageous as quality of life was improved for people with MS in this project. The success of this program was responsible for creation of a new sector of rehabilitation in ABEM, where O.Ts and P.Ts work together in the same therapy session.

Study supported by: Brazilian MS Society

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(S02) A NEW PERSPECTIVE ON LOCUS OF CONTROL AS A PREDICTOR OF MS OUTCOMES

Studies on a broad range of acute and chronic illnesses including multiple sclerosis have shown a significant positive relationship between internal health locus of control and more effective coping styles, reduced severity of symptoms, and higher scores on Quality of Life measures. Using the Multidimensional Locus of Control Instrument (MHLC) as part of an assessment protocol for the outpatient clinic at the Hospital for Joint Diseases MS Care Center, we noted two distinctive patterns of response to the items loading on the internal locus of control dimension. One showed a consistent response pattern across all items relevant to this dimension, as would be expected. However, 45% of the patients tested showed a striking dichotomy in their responses. Items relating to control of health, e.g., "I am in control of my health" were given the higher ratings of agreement whereas items relating to the control of sickness, e.g. "When I get sick, I am to blame" were given the lower ratings of agreement. Thus, a strong bias in the one direction concerning perceived control of health was cancelled by a strong bias in the opposite direction concerning the perceived control of illness. These results have direct implications for the validity of the MHLC as a general measure of internal locus of control and also its reliability since different forms of the instrument are not equated for health and sickness items. These results also indicate that for a substantial number of patients, there may be a fundamental difference in the perception of factors that control health and those that control sickness. We are currently investigating the parameters of this difference to better understand how locus of control moderates the psychological and physical sequelae of MS. Implications for developing more effective interventions that target perceived control, goal-oriented behavior, and particularly, adherence to injectable immunomodulating therapy, are also be explored.

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**(S03) TOLERABILITY OF MINOCYCLINE AND IM IFN BETA-1A IN
RELAPSING-REMITTING MULTIPLE SCLEROSIS**

Lymphocytes play an important role in the pathogenesis of relapsing-remitting multiple sclerosis (RRMS) and enter the central nervous system (CNS) across the blood brain barrier through the action of metalloproteinases (MMP). Minocycline, an antibiotic used to treat acne and rheumatoid arthritis reduces T cell proliferation, inhibits production of MMP-9, IL-2, and TNF-alpha and reduces the severity of experimental allergic encephalomyelitis. Given these effects, minocycline may be a useful agent for RRMS but the tolerability of the combination of intramuscular (IM) IFN beta and minocycline has not been established. This study examined the tolerability of this combination. Twenty patients (19 females) with RRMS and naive to IFN beta and minocycline (EDSS scores 0-5) with at least 1 relapse in the past 12 months were enrolled. MRI scans, blood work, EDSS and MSFC were performed at baseline and one year. Blood work was repeated at three, six and nine months. Patients received IM IFN beta-1a, 30 mcg per week and oral minocycline 100 mg bid, for one year, and then minocycline was discontinued. Primary endpoints were adverse events, laboratory abnormalities, and physical and neurological exam results. EDSS, MSFC, and number and volume of enhancing lesions were secondary endpoints. Median EDSS at entry was 1 and mean pre-study relapse rate was 1.36 relapses per year. Eight patients had one enhancing brain lesion, one had three and one had six. The most frequent side effect was vaginal candidiasis (nine). Nausea (eight), dizziness (six), headache (six) and depression (four) were mild and transient. Eleven patients completed 1 year on study and 2 patients dropped out (reversible hair loss [one]; depression [one]). Six patients had increased hepatic enzymes (minimal and transient in four, two requiring IFN beta-1a dose adjustment). None of the five patients completing the study had enhancing brain lesions on MRI.

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**(S04) FROM EMPIRICAL CAREGIVER TO NEURO –ASSISTANT:
THE NEED OF A QUALIFIED CAREGIVER TO OPTIMISE THE ACHIEVEMENT OF
NEUROREHABILITATION GOALS IN PEOPLE WITH MULTIPLE SCLEROSIS (PWMS)**

BACKGROUND AND GOALS:

Patients who suffer from moderate to severe neurological disease require specialized care. In our daily environment this labour is performed by a relative or domestic service (both not properly qualified). People with Multiple Sclerosis (PwMS) have special needs regarding neurorehabilitation, given the complexity of the clinical course of this disease.

This work aims to present a education program for the empirical caregiver (from now on the Neuro-assistant) which implies knowledge and training in critical matters such as daily living activities and community-based rehabilitation skills, among others, based on the study of a situation involving assistance to PwMS.

METHOD AND PROCEDURE: are based on an integral analysis of 32 evaluations for admission of PwMSs into neurological rehabilitation programs at an specialized institution. Taken into consideration will be: 1) existence of a caretaker at the time of the evaluation, 2) professional background of the caretaker (nurse, familiar caretaker, or rented caretaker not described, also denominated empirical caretaker).

OUTCOMES: 32 integral evaluations of PwMS admissions were analysed: Women 69 %; mean age 45,88 years (35-74); mean disease evolution time 11,79 years (2-33); Types PP= 21.9%, SP= 31.25%, RR= 46.9%; EDSS 5.5= 15.62%, 6.0 = 31.25%, 6.5 = 31.25%; 7= 15.62%, 7.5= 6.25%; Mean F.I.M. 102,92/126 points (56-123). Findings have shown that out of the total number of cases: 1) 69 % indeed had a caretaker at the time of admission, and 2) Only 1% of those caretakers had formal qualifications. Based on the findings of this analysis, a special training program has been developed with the aim to provide caretakers of PwMS the necessary qualifications.

CONCLUSIONS: if a greater specific rehabilitation translates into a better fulfilment of the objectives of neurorehabilitation, then the training of caretakers will extend the reaches of the institutional rehabilitation to the household and the to community. It is expected that a specialized PwMS caretaker favours and optimises the fulfilment of those objectives (extending therefore the boundaries of institutional rehabilitation).

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**(S05) A STUDY OF THE EFFECT OF GENDER ON
INTERFERON BETA-1A (AVONEX® 30 MCG) TREATMENT IN MS PATIENTS**

The effect of gender on the safety and efficacy of Avonex was examined by pooling data from five clinical studies to compare the treatment response of male and female MS patients to Avonex. Four efficacy endpoints were examined: time to first relapse, annualized relapse rate, time to 1-point sustained EDSS progression, and Gd-enhancing lesions. Safety data were also pooled and analyzed. A total of 1406 subjects were included in the analyses; 1027 (73%) female subjects and 379 (27%) male subjects. The results of the analyses on the four pre-specified efficacy endpoints indicated that the effect of Avonex was favorable for both genders, and was not different between female and male patients. The safety profile was also similar for female and male patients, indicating that for both genders, Avonex was safe and well tolerated.

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**(S06) A SURVEY OF DIETARY SUPPLEMENT USE AMONG
A LARGE GROUP OF PEOPLE WITH MULTIPLE SCLEROSIS**

Objective: To collect data regarding dietary supplement use among a large group of people with multiple sclerosis (MS) by self report.

Background: Although previous surveys have suggested supplements are widely used by people with MS, detailed information related to such practices is lacking.

Design/Methods: Using email, an MS disease registry (www.ms-cam.org), and a web-based survey, we collected self-reported data related to supplement use from over 500 people with MS by self report. Data collection will continue through October 2005.

Results: At this writing, of 519 respondents, 93% reported having used supplements since being diagnosed with MS and 84% described current supplement use (used in the last four weeks). Current use was highest for caffeine/coffee (36%), calcium (36%), vitamin C (35%), vitamin B12 (32%), vitamin D (31%), and vitamin E (31%). The supplements listed above were each used most frequently to obtain general health benefits, rather than MS specific benefits. The supplement that was used most often primarily "to control the disease course" was fish oil, for which current use was 23%. Information regarding the perceived efficacy and side effects of selected supplements will be presented. Supplementation practices in relation to selected disease characteristics and demographic information will also be presented.

Conclusion: Among our respondents, current supplement use, which was broadly defined, was high (84%). The results of this survey, when data collection and analysis are completed, will provide additional insight into supplementation practices and may generate new hypotheses about supplement use in MS. Quality of care may be improved if MS healthcare professionals become knowledgeable about supplements frequently used by people with MS.

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**(S07) THE COST OF MS?:
VHA AND PRIVATE SECTOR HOSPITAL USE AND EXPENDITURES 1999-2001**

PURPOSE:

This study compared both hospital use and expenditures for MS in veterans using Veteran Healthcare Administration (VHA) facilities against patients using non-VHA hospitals, from 1999 through 2001.

DATA SOURCES:

VHA administrative, research and expenditure data were integrated for a cohort of veterans. Non-VHA users are represented in the Health Care Utilization Project (HCUP) data of AHRQ. This Nationwide Inpatient Sample is a 20% stratified sample of US community hospital stays - representing 85% of all discharges. Both sources provide lengths of stay (LOS) and expenses, adjusted for gender and age.

METHODS:

VHA and HCUP admissions, with any diagnostic code of 340 (MS in ICD-9) appeared, identified MS care. 25,712 unique veterans who had been given a diagnostic code for MS generated from 5,700 to 6,000 VHA admissions. From HCUP, non-VHA events include from 19,000 to 21,000 admissions. VHA expenditures were derived from total VHA expenditures and Medicare DRG rates. HCUP uses "charges" in national weighted estimates.

FINDINGS:

- A VHA and Non-VHA MS-related admissions are compared along demographic, insurance and other descriptive categories.
- B VHA Hospital Resource Use (1999, 200, 2001):
 - 1 An average expense of \$11,804, \$12,673 and \$13,484 per admission.
 - 2 Average LOS were 13.9, 13.7 and 15.0 days.
- C Non-VHA Hospital Resource Use (1999, 200, 2001):
 - 1 An average charge of \$9,605, \$11,300 and \$11,802 per admission.
 - 2 Average LOS were 5.1, 5.0 and 4.9 days.

LIMITATIONS:

Using extant data from administrative and research sources is an economical alternative to a national survey; although limited to coded evidence of MS, without opportunity to validate cases. Neither data source included MS subtype or disability measures to adjust for severity.

CONCLUSION:

VHA hospital care for suspected or probable MS requires twice the length of stay, but at 37% to 45% of the daily economic expenditures in the private sector.

Study supported by: VHA MS Center of Excellence – EAST (All authors are associated with the VHA MS CoE; a few actually received salary support from this VHA-funded Center)

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**(S08) FLU-LIKE SYMPTOMS IN MS PATIENTS ON IM IFN β -1A THERAPY:
MANAGEMENT STRATEGIES**

Treatment of relapsing (RMS) patients with intramuscular (IM) interferon beta-1a (IFN beta-1a) delays the progression of sustained disability, reduces the frequency of exacerbations, and reduces accumulation of MS lesions seen on MRI. Flu-like symptoms (FLS) including muscle aches, fever, and asthenia are associated with IFN treatment in multiple sclerosis. Procedures to manage FLS would be beneficial to patients who might otherwise discontinue use of IFN therapy. A multicenter, randomized, open-label study was conducted to evaluate dosage titration and choice of analgesic in the management of FLS in relapsing multiple sclerosis (RMS) patients beginning weekly IM IFN beta-1a 30 mcg. Less frequent dosing of IFN beta-1a is generally associated with fewer FLS, but the goal of this study was to further improve tolerability. Subjects were randomized into one of five groups: no dosage escalation + acetaminophen (Group 1), quarter dose escalation + acetaminophen (Group 2), quarter dose escalation + ibuprofen (Group 3), half dose escalation + acetaminophen (group 4), and half dose escalation + ibuprofen (Group 5). Quarter dose escalation groups used the lyophilized powder form of IFN beta-1a, and half dose escalation groups used the pre-filled syringe formulation (PFS) of IFN beta-1a. Subjects were assessed over 12 weeks for the presence and intensity of FLS. Prior interim analysis suggested that patients who started on IM IFN beta-1a therapy with no dosage escalation (Group 1) experienced significantly more frequent and severe FLS than those patients started on IM IFN beta-1a therapy using quarter dose escalation (Groups 2 and 3). These results indicate that quarter dose escalation of IFN beta-1a at initiation of therapy results in significantly fewer and less severe FLS in RMS patients while acetaminophen and ibuprofen are equally effective in managing FLS. The second part of this study examines half dose escalation of IM IFN beta-1a using the PFS. Results of both parts of this study will be presented.

Study supported by: A grant from Biogen Idec. (Dr Brandes has received honoraria, speaking fees, and educational grants from Biogen Idec, Berlex, Serono/Pfizer, and Teva Neurosciences. Dr Warth is an employee of Biogen Idec.)

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**(S09) EVALUATION OF MULTIPLE SCLEROSIS THERAPY ADHERENCE
AT A SPECIALTY PHARMACY**

Introduction:

The purpose of this pilot study is to observe therapy adherence and tolerance in Multiple Sclerosis patients that are managed by clinicians at a Specialty Pharmacy.

Methods:

Prospective, naive Multiple Sclerosis patients starting on one of four self-injectable disease-modifying drugs: interferon beta-1a agents, interferon beta-1b, and glatiramer acetate, were being monitored in the first twelve months of therapy. All patients were provided Multiple Sclerosis education at start of therapy. Patients were contacted via phone at end of month one, three, six and twelve by clinicians per clinical protocol. Clinical assessment was conducted at each phone interview to evaluate therapy tolerance and adherence. Adherence rate is calculated based on number of injections administered during the observed months.

Results:

A total of 264 patients were screened, 220 patients were enrolled in an 18-month period, of which 108 patients received interferon-beta and 112 patients received glatiramer acetate. Preliminary results indicate 96% adherence rate in the first 12 months of therapy. Patients generally tolerated medications well. There was 26% patients experienced side effects, of which 21% are therapy unrelated and 17% had severe adverse events that resulted in therapy discontinuation. The reported severe adverse events were flu-like symptoms, injection site reaction, depression, anxiety and post injection reaction.

Conclusions:

Based on the patient population sampled, multiple sclerosis patients who were provided initial education and were managed by clinicians by specialty pharmacy had good adherence rate while the national adherence rate indicates X%. Evaluation of the correlation between providing patient education and adherence is necessary.

Learning Objectives: Audience participants will:

- Learn the clinical intervention strategy through Specialty Pharmacy
- Understand the disease management program at Specialty Pharmacy
- Evaluate clinical interventions and patient education impact on therapy adherence
- Recognize the important role of clinical nurses in the treatment of multiple sclerosis
- Understand the advantage of pharmacy service through Specialty Pharmacy

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**(S10) RELAPSING NEUROMYELITIS OPTICA SYNDROME
IS A PREVALENT DISEASE IN CUBA. AN EPIDEMIOLOGICAL STUDY.**

OBJECTIVE: The aim of this study is to estimate the prevalence of Neuromyelitis Optica Syndrome (NMO) in the Cuban population by performing a complete island-wide case ascertainment.

BACKGROUND: Neuromyelitis optica syndrome is a rare form of inflammatory demyelinating disease in western countries in comparison with Asian. Cases of NMO have been reported worldwide but the prevalence of the disease is unknown.

DESIGN/METHODS: Members of the Cuban Committee for Treatment and Research on Multiple Sclerosis participated in this study. The entire island (population 11,122,308) was surveyed from October 2003- November 2004. Neurologists completed a Case Report Form for 89 cases of possible NMO. These cases were re-confirmed by two neurologists trained to diagnose NMO according to Wingerchuck et al criteria. All of these cases were prospectively examined and all should have had complementary tests performed (blood, cerebrospinal fluid, evoked potentials, magnetic resonance imaging). Cases were considered to be prevalent if the patients were alive and residents in Cuba on November 30 th 2004.

RESULTS: Fifty- four patients, 51 (94.4%) females and 3 (5.5%) males, were identified with NMO by the Wingerchuck et al criteria. The prevalence for all Cuban patients in November 30th 2004, was 0.49/105 ,95% CI 0.4; 0.6 Classic (C), 95% CI 0.4; 0.6 Bayesian (B). The prevalence in the various provinces will be presented. Age at onset was 32.35 ± 8.96 with a range of 11-51 years. Demographic data were: Caucasians 34 (62.9%), mulattoes 16 (29.6%) and negroes 4 (7.4%) with an advanced educational level in 40 (74.07%). Genetic data showed European ancestry in 24 (44.4%), African 13 (24.07%), Euro-African-Asian 9 (16.6 %) and 8 (14.8%) unknown origin. Familial NMO was observed in one family (mother-daughter) and conjugal NMO and MS in another. The clinical form in all NMO cases was relapsing-remitting 1b with an EDSS 5.21 ± 2.86 .

CONCLUSIONS: Relapsing NMO syndrome is a prevalent disease in Cuba.

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**(S11) BRAIN MRI FINDINGS IN RELAPSING NEUROMYELITIS OPTICA SYNDROME.
A PROSPECTIVE STUDY IN 30 CUBAN PATIENTS.**

BACKGROUND: Magnetic Resonance Imaging (MRI) studies showed that relapsing Neuromyelitis Optica Syndrome (NMO) patients have abnormal spinal cord MRI findings with extensive lesions during acute episodes, swelling from single to diffuse involvement at cervical, thoracic and usually multiple levels involved. Conversely, brain MRI in relapsing NMO did not show any specific changes. For the current diagnostic criteria for NMO, a patient must have a normal brain MRI.

OBJECTIVE: To present a cohort of 30 Cuban patients with relapsing-NMO and brain MRI findings.

DESIGN/METHODS: We studied prospectively 30 relapsing- NMO syndrome cases according to Wingerchuck et al criteria. We recorded the history of each patient as to personal, demographic and clinical data. A standard neurological examination, impairment, disability scales and lab tests were obtained. All brain MRI and cervical-thoracic spinal cord studies were performed on a high-field-strength (1.5 Tesla) Siemens MRI system according to the protocol of the Consortium of Multiple Sclerosis Centers (Traboulsee et al). Statistical analysis for different variables were according to χ^2 and Fisher tests.

RESULTS: 30 relapsing-NMO patients: 28 (93.3%) females; age 40.7 ± 10.5 (median \pm SD) (11; 56); time of evolution 12.3 ± 8.9 (1; 39); Caucasians 14 (43.3%), Mulattoes 11 (33.3%) and Negroes 5 (16.7%) from different provinces of Cuba were studied. EDSS score was 4.6 ± 2.2 (1; 8.5) and Visual Functional System showed a score of 6-6x in 9 (30.04%); 1-1x in 6 (20%), 5-5x in 4 (13.3%); 3x in 3 (10%); 2-2x and 4-4x in 2 (6.6%) respectively. Analyses of 29 brain and spinal cord MRI studies showed spinal cord abnormalities in 20 (66.7%), whereas brain MRI was abnormal in 13 (43.3%). All Brain MRIs did not fulfill the diagnostic criteria of Multiple Sclerosis according to Barkhoff et al. The relations of demographic and clinical variables of patients among abnormal/normal brain MRIs were as follows: females 12 (44.4%)/ 15 (55.6%); males 1 (50%) /1 (50%) Fisher tests 1.000 NS; age < 42 years in 5 (35.7%)/9 (64.3%); age > 42 years 7 (53.8%) P (χ^2) 0.342 NS; time of evolution < 9.5 years in 8 (53.3%)/7 (46.7%) 0.339 P (χ^2) NS; > 9.5 years in 5 (35.7%) / 9 (64.3%) P (χ^2) 0.339 NS; Caucasians 3 (25%)/9 (75%) P (χ^2) 0.065 and Mulattoes-Negroes 9 (60%)/6 (40%) P (χ^2) 0.065. Brain MRI protocol of Consortium of Multiple Sclerosis Centers demonstrated brain abnormalities, not fulfilling MS criteria, in 43.3% of relapsing-NMO cases. Brain MRI abnormalities were not related to demographic, gender and time of evolution with the exception of an increase in abnormal brain MRI studies with marginal statistical significance in mulattoes and blacks.

CONCLUSIONS: The results of this brain MRI study demonstrated a more widespread extension of relapsing-NMO, not restricted only to optic nerves and spinal cord but with more brain MRI lesions in mulattoes and blacks.

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**(S12) NEUROMYELITIS OPTICA SYNDROME IN CUBA.
A PROSPECTIVE CLINICAL STUDY OF 54 CASES.**

BACKGROUND: An epidemiologic study of neuromyelitis optica syndrome (NMO) in Cuban population demonstrated 54 patients at the prevalence day.

OBJECTIVE: To present a cohort of 54 Cuban patients with Neuromyelitis Optica Syndrome (NMO).

DESIGN/METHODS: Neurologists participated filled-up a case report NMO form according to Wingerchuck et al criteria. They record the history of each patient as to personal, demographic and clinical data. A neurological examination and laboratory tests (blood, CSF, evoked potentials (EP) and MRI) were obtained. All the cases were examined prospectively by two neurologists trained to diagnose of NMO. They selected 54 NMO cases and checked the disability scales.

RESULTS: Fifty- four patients, 50 (92.5%) females, age at onset 20-49 years in 45 (83.3%) were identified with NMO. Caucasians 26 (48.1%) and mulattoes 22 (40.7%). Familial diseases were observed in 29.6%; psychiatric diseases in 40.8% and other diseases coexisted with NMO in 21.9%. The first symptoms at the onset of NMO were: diminished vision 32 (59.2%), loss of strength 26 (48.1%), amaurosis 18 (33.3%). Triggered factors, at onset, were observed in 77.5%. Time to diagnose was less than 3 years in 25 (46.2 %). Analysis of impairment of the FS: pyramidal 52 (96.2%), visual 50 (92.5%), sensorial 30(55.5 %) and sphincter 29 (53.7%). The disability scales showed: EDSS 1-2.5 in 6 (11.1%); 3.0-4.5 in 19 (35.1%); 5.0-6.5 in 10 (18.5%); 7.0-8.5 in 8 (14.8%) and 9.0-9.5 in 9 (16.6%). Abnormalities in the complementary tests: motor EP 100%, visual EP 95%, MRI spinal cord 90% and brain 26.9%, somatosensory EP 90%, CSF 30%. Neuropsychological tests (14 patients) showed cognitive dysfunction in 10 (71.43%). Fifty-one (94.4%) patients had relapsing-remitting form, type 1b (70%) and type 1a (25%) and two (3.7%) monophasic.

CONCLUSIONS: Relapsing NMO syndrome in Cuba is a prevalent disease in young women with trigger factors at onset, visual and pyramidal impairment and moderate disability. Cognitive dysfunction and brain abnormalities deserves further studies.

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**(S13) 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 October 15, 2003. We found 51 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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**(S14) FATIGUE REPORTED BY MS PATIENTS AND RESPONSE TO MODAFINIL:
ASSESSMENT FROM A MS CENTER DISEASE MANAGEMENT DATABASE**

OBJECTIVE: Fatigue is the worst symptom in more than 40% of individuals diagnosed with Multiple Sclerosis. The purpose of this study is to analyze the effect of Modafinil in alleviating the fatigue associated with MS over a prolonged treatment period.

BACKGROUND: No therapy is approved for the treatment of MS Fatigue. Modafinil has been studied in short-term use and shown to be effective. The need exists to demonstrate long-term benefit of Modafinil on MS Related Fatigue

DESIGN/METHODS: The study was conducted as a retrospective chart review. Eligibility criteria included being a patient at the Baptist Hospital East MS Center, a diagnosis of definite MS, and having been prescribed Modafinil. Sixty-four subjects fulfilled these inclusion criteria and their performances on seven assessment tools were analyzed. Data was obtained at three-month intervals and analyzed to determine changes in performance and the number of significant improvements from the initial date of Modafinil prescription followed up to 57 months.

RESULTS: At the 4-6 month mark, 53.33% of patients showed a significant improvement on the Modified Fatigue Impact Scale (MFIS). This percentage increased to 80% at the 10-12 month point. The mean values for all data showed a significant improvement in total MFIS score, as well as significant improvement in the physical and cognitive subsections. No other assessment tool showed a significant improvement over the treatment period in any large percentage of patients.

CONCLUSIONS: Modafinil seems to have a positive long term effect on MS related fatigue and this effect seems to be specific for MS Related Fatigue. The benefit is not reflected as a response to resolution of depression. Resolution of MS Fatigue also does not appear dependent on or result in improvement in functional abilities as measured by upper extremity or ambulation assessments.

Study supported by: University of Louisville Medical School 2004 Summer Research Scholars Program

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**(S15) A DESCRIPTION OF THE STATUS OF MULTIPLE SCLEROSIS IN PUERTO RICO:
A PRELIMINARY REPORT**

The number of newly diagnosed MS cases in Puerto Rico is higher than expected. The Puerto Rican MS foundation (PRMSF) patients' membership is near 1,100. The Puerto Rico Continuous Health Survey in 1992 estimated 1,308 MS patients. Rivera & Cabrera (2,000) estimated a prevalence rate of 40/100,000.

The purpose of this study is to describe the status of multiple sclerosis (MS) in Puerto Rico. The data analyzed is part of an on going prevalence study being conducted. A Cross-sectional design was used. Patients were contacted through the PRMSF. Also, the media were used to invite persons with MS to identify themselves or others with the condition. A questionnaire and an informed consent form were mailed to all patients registered by the PRMSF. The questionnaire asked the patients regarding patients' general information, date of multiple sclerosis onset, date of diagnosis, symptoms, relapse/remission episodes, MS family history, medications, and utilization of assistive equipment. For the purpose of this preliminary report 345 questionnaires were analyzed. Descriptive statistics were calculated for all variables.

267 of the patients were female and 78 men. The mean age of patients was 43 years; females 44 and males 41. The mean age at onset was 31 years; females 32 and males 28. The mean interval between symptoms and diagnosis was 3 years. The mean duration of disease was 9 years. The most common symptom at onset was numbness (72%) followed by weakness of extremities (63%). 17% of the patients had relatives with MS, most of them cousins. 60% use interferon and 21% do not use any medication. The characteristics of MS patients in Puerto Rico do not differ significantly from those found in patients from other Latin American countries and the United States. However, the proportion of patients who do not use MS medications is still significant.

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(S16) CASE VALIDATION OF MULTIPLE SCLEROSIS FROM VHA EXTANT DATABASES

PURPOSE: A mandate for the VHA MS Center of Excellence was to establish a surveillance registry (MSSR) consisting of only veterans confirmed to have MS. The initial query of the VHA extant databases identified 25,712 patients that had an encounter with a MS ICD-9-CM code and/or prescribed a MS-specific medication for the period of FY1998 through FY2002. This MS user cohort was much larger than expected; in large part due to the ICD-9-CM coding that provides only a single, three-digit code (340). This single code is used to account for suspected MS, rule-out MS as well as clinically definite MS. Thus, a method was needed to validate the cases in the MS user cohort prior to implementation of the MSSR.

METHOD: Chart review validation was conducted for the VISN 5 cases from the MS user cohort and served as the "gold standard" for evaluation of the case validation algorithm derived from the extant databases. Cases were dichotomized as not MS (0) or possible/definite MS (1). Chart review followed the McDonald criteria. The extant database algorithm classified cases as possible/definite MS (1) if they had a service connected disability for MS and/or prescribed an MS-specific medication and/or had one or more encounters per year of enrollment where an MS ICD-9-CM code appeared. Otherwise, cases classified as not MS (0) if not meeting the above criteria.

RESULTS: Based on 600 cases for whom complete data were available, the Kappa coefficient was .807 ($p < .001$). Further analysis revealed a sensitivity of .89, specificity of .92, positive predictive value of .92 and negative predictive value of .89.

CONCLUSIONS: These findings suggest that the extant database algorithm for case validation provides a reliable method for validation of MS cases. The generalizability of the VISN 5 findings to the rest of the VHA requires further evaluation.

Study supported by: VHA MS Center of Excellence, Baltimore VAMC

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**(S17) INITIAL ANALYSIS OF STANDARDIZED ASSESSMENTS OF
SENSORY-MOTOR SKILLS IN PATIENTS WITH MS**

Cortical and subcortical sensory and motor disturbances in patients with Multiple Sclerosis (MS) are among the most common, and first reported, symptoms. However, despite the prevalence of these signs and symptoms, a review of the literature reveals a paucity of studies investigating a standardized approach to the analysis of sensory and motor skills. This may be due to the overall lack of objective neuropsychological testing that is used in MS clinics (Benedict et al., 2002) or to the poor psychometric qualities of most neuropsychological measures of sensory-motor functioning. The importance of quality standardized and normative-based measures of sensory-motor functioning are critical in the early diagnosis and subsequent tracking of MS, since even one error on a sensory-motor task may be pathognomic of cerebral dysfunction. This current study is investigating sensory-motor skills in a large sample of patients with MS using a new measure, the Dean-Woodcock Sensory Motor Battery (DWSMB, Dean & Woodcock, 2003). The DWSMB provides a large normative sample of 1,000 individuals, and early investigations have demonstrated high reliability and validity (i.e., Davis, Finch, Dean, & Woodcock, 2004; Woodward, Ridenour, Dean, & Woodcock, 2002). Multivariate Analysis of Variance (MANOVA) has revealed significant differences between the sensory-motor skills in a sample of 12 patients with MS and a demographically matched sample of 207 normals (Wilks' Lambda = .357, $F(36, 182) = 9.113, p = .000$). Subsequent univariate tests revealed a number of subtest differences, including subcortical motor differences, cortical motor differences, and sensory skills. This poster will present the results of subsequent analyses on larger samples of patients with MS, as well as discuss the implications for the standardized assessment of sensory-motor skills in patients with MS. Additionally, correlational analyses will be presented relating DWSMB subtest and index scores to clinical EDSS scores.

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**(S18) THE SPECTRUM OF CLINICAL AND RADIOLOGICAL CHARACTERISTICS
OF ACUTE DISEMINATED ENCEFALOMYELITIS**

Acute disseminated encephalomyelitis (ADEM) is a clinical diagnosis of an inflammatory demyelinating disease. Multiple sclerosis is the most common idiopathic demyelinating diseases observed in clinical practice. The clinical course is usually monophasic but relapses occur. Hemorrhagic forms are less frequent. It has been described following viral infections, immunizations, and rabies vaccination prepared in embryo brain tissue. There are no clinical based evidence guidelines or biological markers for the diagnosis.

We describe the wide spectrum of clinical and radiological features of three patients with ADEM.

Methods: 3 patients with clinical diagnosis of ADEM evaluated with spinal fluid examination (CSF), viral serology, magnetic resonance image (MRI) in all cases and magnetic resonance spectroscopy (MRS) in one of them.

(CASE 1) 6 y boy , rapid onset ataxia, generalized weakness, vomit, urinary incontinence, somnolence and stupor, 5 days after an upper respiratory tract infection. Admitted in coma, with unresponsive bilateral midriasis and bilateral Babinski sign. CT scan showed brain stem and internal capsule hypodensities consistent with symmetric demyelinating disease. Normal CSF; negative HVS 1, 2, varicella, CMV.

(CASE 2). 29 y female: 8 weeks after receiving weight reduction injections (containing suine embryo tissue and organ extracts). Presented with malaise, sleepiness, generalized weakness, ataxia, blur vision, nausea, vomit, intense headache and tonic-clonic seizures, bilateral papiledema and epileptic status; Mechanical ventilation was required. She progressed to brain death. MRIs and spectroscopy were consistent with demyelinating pathology ; CSF negative for oligoclonal bands.

(Case 3). 12 y boy, 4 weeks after airway tract infection presented with high grade fever , delirium, malaise, sleepiness, progressive symmetrical weakness of both legs. At admission, he was dehydrated, partially orientated, with decreased short term memory, and bidirectional horizontal nystagmus. Diminished motor strength and sensory sensations on left side, dismetría, intentional tremor and ataxia. CSF negative oligoclonal bands.

CONCLUSION:

1. ADEM has a wide spectrum of clinical and radiological characteristics. Discrimination between the first presentation of MS can be difficult, the diagnosis remains clinical.
2. Except for the use of embryo brain tissue in the preparation of rabies vaccine, there are no descriptions of allergic encephalitis in humans, and this hypothesis has to be considered in the etiology in one of our cases.

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**(S19) CONTRIBUTING FACTORS TO RESILIENCE
IN RELAPSING-REMITTING MULTIPLE SCLEROSIS.**

This study examined the relationship between spirituality, medical access and support, social support and involvement, perceived severity of illness, illness status and resilience (i.e., self-reliance, equanimity and meaningfulness) in multiple sclerosis (MS).

The sample consisted of 152 individuals diagnosed with relapsing-remitting MS who were either attending a neurology clinic, members of the National MS Society or members of a support group in the Northern Virginia, Washington DC area. Participants completed the Contributing Factors Questionnaire (CFQ), the Resilience Scale (RS), and the Spiritual Perspective Scale (SPS).

The results indicated that individuals who had attributed higher rates of importance to medical access and support from doctors and nurses had an increased awareness that their lives had purpose and meaning. Furthermore, perceived severity of illness was significantly negatively related to self-reliance; those individuals who had a more severe perception of illness had a decreased belief in themselves and their capabilities. There was also a significant interaction effect between perceived severity of illness and spirituality on self-reliance and meaningfulness. That is, individuals with a more severe perception of illness who had higher levels of spirituality reported increased belief in themselves and their capabilities and an increased awareness that their lives had purpose and meaning. In addition, there was a significant interaction effect between illness status and spirituality on self-reliance and meaningfulness. That is, those individuals experiencing a relapse with higher levels of spirituality reported an increased belief in themselves and their capabilities and an increased awareness that their lives had purpose and meaning.

There was neither a statistically significant relationship between spirituality, illness status and self-reliance, equanimity and meaningfulness nor between social support and involvement and self-reliance, equanimity and meaningfulness. There was not a significant relationship between medical access and support and self-reliance and equanimity. There was not a significant relationship between perceived severity of illness and equanimity and meaningfulness. There was not a significant relationship between spirituality and self-reliance, equanimity and meaningfulness after controlling for other contributing factors. There was not a significant interaction effect between perceived severity of illness and spirituality and between illness status and spirituality on equanimity.

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**(S20) SOLUBLE FAS LIGAND (SFASL) LEVELS IN SERA
FROM MULTIPLE SCLEROSIS PATIENTS**

Multiple Sclerosis (MS) is an autoimmune, demyelinating disease of the Central Nervous System whose cause is unknown. Programmed cell death (apoptosis) of inflammatory cells may be an important immunopathogenic mechanism of this disease. Several studies have demonstrated defective apoptosis pathways in MS patients. However, the role of soluble Fas ligand (sFasL) and other apoptosis-related molecules is not well understood. To look for a relationship between sFasL and the clinical course of MS, we determined the levels of sFasL in sera from different sub-populations of MS patients.

We obtained serum samples from MS patients with relapsing-remitting (RR) course during relapse (n=5), or remission (n=10), with secondary progressive (SP) course (n=4), or with primary progressive (PP) course (n=3). Healthy individuals served as the control group (n=5). MS patients had not been treated with any immunomodulating agents nor steroid treatment for 1 month before sample collection. Serum sFasL levels were determined by ELISA (R&D Systems, Inc., catalog # DFL00). We compared these results to disease activity, progression, disability score (EDSS) and serum TNF-A levels. Serum sFasL levels were significantly depressed in RR-MS patients during relapse (62 ± 19.3 pg/ml; $p < 0.01$), in SP-MS (75 ± 18 pg/ml; $p < 0.05$), and in PP-MS (91 ± 6.4 pg/ml; $p = 0.0527$) compared with the levels in RR-MS during remission (116 ± 28.9 pg/ml) and controls. Serum sFasL levels in RR-MS patients in remission did not differ significantly from control levels (126 ± 24 pg/ml). Among all MS patients, there was a tendency to negative correlation of sFasL values with EDSS, but this was not statistically significant.

Preliminary results showed increased TNF-A levels in progressive MS compared with relapse activity. These findings suggest a possible defective Fas/ FasL -mediated pathway associated with acute or progressive MS activity. It could be related to neurological disability. Other apoptotic mechanisms could be involved as well.

Study supported by: Berlex

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(S21) TISSUE BANK COLLABORATION: BENEFITS TO THE RESEARCH COMMUNITY

GOAL: Through collaboration between two multiple sclerosis (MS) tissue banks we hope to increase the quality and quantity of brain tissue available for research.

BACKGROUND: Researchers studying MS have been hampered by limited amounts of available tissue and lack of consistent methods for tissue acquisition. The two brain banks have formed a collaboration to acquire, process, and distribute tissue in a uniform manner. It is expected that this will increase the quantity and quality of tissue available to researchers.

METHODS: The National MS Society continues to support the Rocky Mountain MS Center (RMMSC) in Englewood, Colorado and the Human Brain and Spinal Fluid Resource Center (HBSFRC) in Los Angeles, California, to collaborate on acquiring, processing and distributing tissues for research. Based on our experience, we have concluded that MS caregivers (MDs, PhDs, RNs and family members) as well as patients are not fully aware of the existence of these banks. The banks collect tissues to best preserve the morphological details and cellular characteristics optimal for research. Neuropathology reports and images of dissections showing the locations accompany each sample shipment. Easy Internet access to the banks allows tissue donors to enroll and investigators to choose suitable tissue for their research.

RESULTS: Availability of larger amounts of the highest possible quality specimens will help enhance the research efforts of MS investigators. With the combined resources of both banks, larger number of specimens can be made available for research.

CONCLUSION: MS researchers need to utilize human tissue for their investigations. Collaboration of efforts of the RMMSC and the HBSFRC will aid in the effort to find a cause and a cure of MS. Patient flyers should be presented by MS caregivers to every potential donor to allow them to contribute to MS research.

Study supported by: The Rocky Mountain MS Center Tissue Bank is supported by a grant from the National Multiple Sclerosis Society, award no. RG 2859-C-9 and the Rocky Mountain MS Center. The Human Brain and Spinal Fluid Resource Center is supported by a grant from the National Multiple Sclerosis Society, award no. 829-M-39 and the NIMH, NINDS Consortium.

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**(S22) A BRIEF COMPREHENSIVE NEUROPSYCHOLOGICAL BATTERY
FOR COGNITIVE ASSESSMENT IN MS**

Background: Cognitive deficits occur in 45 to 65% of MS patients. Typical deficits include attention, processing speed, word retrieval, short-term memory, multi-tasking, depression, and adjustment difficulties. Cognitive assessments can range from narrow assessment of processing speed using the Paced Auditory Serial Addition Test (PASAT) to lengthy, time-consuming neuropsychological evaluation. Due to costs and time constraints, many cognitive and emotional conditions may not be diagnosed or treated.

Methods: We developed a comprehensive battery of psychometrically sound instruments capturing the neuropsychological strengths and weakness of MS patients, completed under one hour and validated against established norms. Tests include: Digit Span and Letter-Number Sequencing of the Wechsler Adult Intelligence Scale-III (WAIS-III), California Verbal Learning Test -Revised(CVLT-R), Controlled Oral Word Association Test (COWA), Stroop Color-Word Test, Wechsler Memory Scale Logical Memory Test I & II, PASAT 3 & 2 second versions, North American Adult Reading Test, Beck Depression Inventory-II(BDI-II), Neurobehavioral Functioning Inventory (NFI).

Results: Forty-one females and 9 males with a mean age of 51, 32 with RRMS and 18 with SPMS, completed the battery. There was no gender effect with age. Average estimated pre-morbid IQ was 106. Scores differed significantly from established norms on all but two tests: Digit Span and the Delayed Logical Memory. Remaining standardized measures were significant utilizing two-tailed z-tests: Logical Memory ($p=0.0001$), Letter-Number ($p=0.022$), Stroop ($p=0.001$), COWA ($p=0.002$), PASAT 3 & 2 ($p=0.001$). Mean BDI-II score was 14.1 or mild to moderate depression. The NPI mean was 172.8 and mean CVLT-II T-score was 46.5.

Conclusions: This brief, replicable neuropsychological battery reflects the common cognitive complaints of MS patients often found in more lengthy batteries, revealing significant neuropsychological weaknesses in new learning/recall, information processing speed, word retrieval/fluency, depression, and functional deficits. This is an efficient battery, well tolerated by MS patients.

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(S23) THE POTENTIAL USE OF TELEHEALTH IN VETERANS WITH MULTIPLE SCLEROSIS

Research Objective:

To determine access to personal computers (PC) and Internet resources in veterans with multiple sclerosis (MS) to determine the potential of telehealth monitoring for management of MS symptoms. A secondary aim was to determine primary symptoms, need for assistance, and availability of a caregiver.

Study Design:

This is an in-person interview survey of a convenience sample of veterans (n=25) attending the Baltimore Veterans Administration Medical Center (BVAMC) MS Clinic during a 5-month period in 2004. Survey questions about PC and Internet access and use were developed by the investigators based on previous general population surveys. Questions about MS symptoms and ADLs were identified from previous literature. Interviews took approximately 15 minutes to complete. Proxy responses were also recorded.

Principal Findings:

The majority of patients had MS for greater than 10 years (56%). Most individuals lived within 30 miles of the BVAMC; 24% lived greater than 30 miles. 36% of the patients reported that traveling prevented them from visiting the VA hospital for their MS care. Most subjects (92%) lived with someone; the majority lived with a spouse (68%). Most (88%) had a PC at home but fewer had access to the Internet (68%). When asked which symptoms affect work, sleep, activities of daily living (i.e., dressing, bathing) and independent activities of daily living (i.e., shopping, driving), most patients complained of fatigue and difficulty with mobility.

Conclusions:

This study demonstrates that patients with MS in the VHA have difficulty accessing care either due to distance or difficulty with mobility. Telehealth is a method for patients to have regular access to specialty healthcare services. Individuals with mobility limitations, need for continuous monitoring, or live too far from a specialty center, may benefit from this technology. Therefore, telehealth is a potential way for individuals with MS to receive specialty care.

Study supported by: Baltimore Veteran's Affairs Medical Center, MS Center of Excellence-East

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(S24) SELF CARE TO MULTIPLE SCLEROSIS HOLDERS – CATEM

Keyword: multiple sclerosis, nursery, self-care

Introduction: The progress of degenerative and chronic diseases around the world, like MS, lead us to the need of reviewing the assistance procedures. In this context, CATEM -Centro de Atendimento e Tratamento da Esclerose Múltipla – from the Santa Casa in São Paulo-Brazil, developed a proposal to use professional team of nurses to guide MS patients to self-care using imunomodulatory injectable MS treatments.

Objective: characterize the MS patient from CATEM who use imunomodulators linked by the process of home self-care orientation.

Methodology: descriptive, quantitative study, including 230 patients from CATEM, during 1997-2004, who completed a Nursing Consult in the process of home self-care orientation.

Results: the study showed that 75,2 % of the population was female, with 59,1% from 25-39 years old and 56,5% finished college. 75% patients were considered independent. Visual deficits were present in 38.7% of the patients. Fatigue, referred as most common symptom, received 27% of complaints. The symptoms from parental injections included fever/ shivering / shaking/, in 34% of the cases. Local reaction including hyperemia occurred in 12,6% in these cases. After the orientation process made by the Nurse 94% of helpers/family members learned the parental injection technique. Education beyond the initial orientation included hygiene, self injection skills (medicine preparation, local application, disposal of materials, and general side effect management). The Nurse Consultant was used for the first 3 injections with each of the patients.

Conclusion: The nurse's job as a guide in the learning process about parenteral self-injection at home improved self-care of these MS patients.

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**(S25) "INJECTION ANXIETY" IN MULTIPLE SCLEROSIS PATIENTS
ON AN INJECTABLE AGENT**

Currently, disease modifying agents for Multiple Sclerosis (MS) are only available in the injectable form. Injection anxiety or needle phobia is a real phenomenon for MS patients. As health care professionals, one must recognize these fears, examine the multiple factors involved, and provide intervention to decrease injection anxiety. A patient survey was sent to gather information about this issue. Surveys were mailed to 800 MS patients seen at the West County MS Center in St. Louis, MO. Data from 300 patients with MS on an injectable agent will be presented (n=300). This data will identify the prevalence of injection anxiety. Additional data will look at such factors as intramuscular vs. subcutaneous injections, auto injector vs. manual injections, self injecting vs. others injecting and gender. Potential interventions will be outlined. It is believed that adherence to the prescribed injectable therapy will be enhanced if injection anxiety is identified and addressed.

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(S26) HEALTH-RELATED SERVICE NEEDS OF PEOPLE AGING WITH MS

In the USA, there are approximately 400,000 people who have MS. Estimates suggest that forty-five percent of these individuals are over 55 years of age. Currently, very little is documented in the MS literature about aging with MS. This presentation summarizes a 3-year study funded by the National Multiple Sclerosis Society that investigated the unmet health related services needs of people who are aging with MS in the Great Lakes Region of the USA.

Since 2002, 1282 people aged 45 to 90 have been interviewed by telephone about their current use of and satisfaction with a range of medical and social services, as well as their unmet need for services. Descriptive findings indicate differences in extent of service use, satisfaction with services received, and unmet need across age groups (45-54, 55-64, 65-74, 75+). Depending on the service being examined, some of these differences disappear in multivariate regression models after accounting for disability level, co-morbid conditions, and social situation. In general, findings indicate that older participants (65+) express more unmet need for social services (e.g., meals, transportation). Younger participants (45-64) have the greatest unmet need for health insurance. Differences in unmet need are also observed across participants living in different geographical locations (rural, suburban, urban), particularly for social services.

The presentation will highlight the key differences in service use, service satisfaction and unmet need uncovered in the analyses. Recommendations for medical and social service providers, as well as for organization advocacy will be presented based on the findings.

Study supported by: National Multiple Sclerosis Society, Health Care Delivery and Policy Research Contract, #HC049

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**(S27) THE BENEFIT STUDY:
'BETASERON IN NEWLY EMERGING MS FOR INITIAL TREATMENT'**

We present data on baseline findings and treatment adherence in the BENEFIT study evaluating the value of high-dose/high-frequency interferon-beta treatment in patients with a first event suggestive of multiple sclerosis (MS). BENEFIT is a double-blind, placebo-controlled, randomized, parallel-group, multi-center study running in Europe, Israel, and Canada. 487 patients were randomized to interferon beta-1b (250 mcg every other day [eod]) or placebo (5:3 ratio). After 2 years, or development of clinical definite MS (CDMS), patients are offered open-label interferon beta-1b for at least 3 years within a follow-up study. BENEFIT contains a representative population of patients at risk for MS by also including patients with 'polysymptomatic' onset.

At baseline, 60% of patients were locally classified as 'monosymptomatic' and 40% as 'polysymptomatic' (ratio similar to ETOMS). Because of the importance of a uniform assessment for 'dissemination in space' as required by the McDonald criteria, the number of clinical lesions was reassessed centrally based on reported signs and symptoms (judged as monofocal versus multifocal). Using this procedure, 52% of patients were classified as 'monofocal', whereas 48% were judged as 'multifocal'. These and other baseline parameters will be presented, in order to better understand the characteristics of patients with possible MS at the time of the first event.

During the first year of the study, only 4.7% of the BENEFIT patients withdrew from the study before CDMS was reached. This low drop-out rate in BENEFIT indicates that high-dose/high-frequency treatment is well tolerated by possible MS patients in the earliest phase of the disease.

Study supported by: Schering AG, Berlin, Germany and Berlex Laboratories Inc., Montville, USA (Drs Bauer, Ghazi and Sandbrink are salaried employees of the Schering Germany Group of companies. Drs Freedman, Polman, Kappos, Edan, Hartung, Miller, Montalban and Uitdehaag have received honoraria from Schering/Berlex.)

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**(S28) PREDICTION OF BALANCE CONFIDENCE, BALANCE, AND FALLS
IN ONE YEAR IN PEOPLE WITH MS**

Impaired balance and increased risk of falls are related to several factors in people with MS. Purpose: To develop a prediction model for balance confidence, static balance and number of falls in one year in ambulatory persons with MS. Subjects: Forty-six ambulatory people [male (8) & female (38)] with clinically diagnosed MS participated in this study. Age ranged from 23-69 years old, mean (X)=47.96. Expanded Disability Status Scale scores ranged from 2.0-6.5 with X=3.60; MS Type: relapsing remitting (n=26), secondary progressive (n=7), primary progressive (n=5), progressive relapsing (n=3), unknown (n=5). Methods: Design: Pilot cross-sectional descriptive study. Balance Confidence was measured by the Activities-specific Balance Confidence Scale (ABC). Static standing balance (BAL) was measured as total time to balance on one leg. Subjects unable to maintain single-limb stance for > 3 seconds were tested using tandem stance. Physical performance tests (sit-to-stand, stair test, walk test) were administered. One subject was eliminated due to inability to complete BAL testing. 39 subjects completed the ABC and fall number collected on a separate day. Data Analysis: Descriptive statistics and Pearson Product-Moment Correlations to examine relationships between variables for inclusion in the multiple stepwise regression analysis ($p < 0.05$). Results revealed 73% of ABC variance is predicted by number of falls and walk test. ABC is an important predictor of number of falls.

Study supported by: University of Michigan-Flint Research Initiatives Grant and Partnership, Flint, Michigan.

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**(S29) FALLS, BALANCE AND SELF-REPORTED BALANCE CONFIDENCE
IN PEOPLE WITH MS**

Purpose: To describe the relationship between static standing balance, number of falls per year, and balance confidence in ambulatory persons with Multiple Sclerosis (MS).

Subjects: Forty-six ambulatory individuals (8 male & 38 female) with clinically diagnosed MS participated in this study. Age ranged from 23-69 years old, mean (X)=47.96. Expanded Disability Status Scale scores ranged from 2.0-6.5 with X= 3.60. Type of MS as reported by subjects was: relapsing remitting (n=26), secondary progressive (n=7), primary progressive (n=5), progressive relapsing (n=3), unknown (n=5). One subject was eliminated due to inability to complete balance testing. Thirty-nine subjects completed the balance confidence test and fall number on a separate day.

Methods: Design: A cross-sectional descriptive study. Static standing balance (BAL) was measured by total time to balance on one leg (up to 30 seconds). Subjects unable to maintain single-limb stance for more than 3 seconds were tested using tandem stance. Balance confidence, measured by the Activities-specific Balance Confidence (ABC) Scale, and physical performance tests (sit-to-stand, stair test, walk test) were administered.

Data Analysis: Descriptive statistics and Pearson correlations are reported.

Results: Twenty-seven of 39 subjects reported falling in the past year. Mean (s.d.) single-limb stance time (n=28) was 15.83 (9.15) sec, with a range of 1.15-30.00. Mean tandem stance time (n=17) was 13.92 (11.17) sec, with a range of 1.67-30.00. Mean (s.d.) ABC total score was 65.64 (21.32), with a range of 27.50-98.13. Number of falls was moderately correlated with total number of medications (r=0.50). BAL is poorly correlated with all variables of interest. ABC was significantly correlated with the walk test (r=0.82), stair test (r=-0.72) and moderately correlated with EDSS scores (r=-0.67) and sit-to-stand (r=-0.59).

Conclusion and Clinical Relevance: Community ambulating persons with MS experience a high rate of falls which is not significantly correlated with static balance tests or their balance confidence.

Study supported by: University of Michigan-Flint Research Initiatives Grant and Partnership, Flint, Michigan.

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(S30) WALKING AIDS IN PEOPLE WITH MULTIPLE SCLEROSIS

Introduction: Walking restriction is the most frequent disability and the most important problem, according to patient's reference, of the set of functional alterations in multiple sclerosis (MS). Neurological physiotherapy proposes to make it safe, independent, that it fulfills a useful distance without producing fatigue. A problem solving approach includes walking aids (WA) indication, devices whose function is to increase the stability.

Objectives: To analyze prescription's sources, demographic characteristics associated to WA use, relative importance of each WA.

Method: 104 physiotherapist evaluations during 1998-2003. Inclusion's criteria : MS defined diagnosis (Poser), Relapse-Remission type, EDSS up to 6.5 inclusively, patients clinically stable (30 days). An assistant used to be able to make the walk is interpreted like a WA.

Results: Women 68 %; mean age 41,54 years; mean disease evolution time 7,4 years; EDSS 5.5= 42,31%, 6.0 = 29,81%, 6.5 = 25,88%; mean of kinematics deviations 7.

Statistical analysis: t, z, X2 tests, alpha: 0,05

WA are used for 57,69% of patients, reason use/not use: 1,47. Only 6,6% cases had professional indication.

Respect this WA use: 71.4% were women (P=0.02); mean age 44.6 years (P = 0.0006); mean disease evolution time 9.7 years (P = 0.000009); amount of kinematics deviations using WA was minor who without ones (6.6 versus 7.5, P = 0.23).

WA most used: one point stick 31,71%; assistant 25,4%, walking frame 20,73%.

Conclusions: Professional WA prescription was exceptional in deed, patients or his near persons select the same one.

Predominance in women of the WA use.

WA use was directly proportional at the age of the patients and the years of pathology evolution.

A high and real disability level and dependency was found, due to use of assistant.

The less biomechanically efficient WA, the one point stick, was the prevalent WA.

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(S31) COST ANALYSIS, TOLERANCE AND EFFECTIVENESS OF HIGH DOSE ORAL PREDNISONE FOR MS RELAPSES

Background: Oral prednisone (OP) 1250 mg does not increase gastric damage more than intravenous methylprednisolone (IVMP) 1000 mg (Metz et al, 1999) and has approximately equal bioavailability (Morrow et al, 2004). Our patients prefer oral therapy (Metz et al, 2000). OP has been first line treatment at our clinic for MS exacerbations since 1999. In this study we evaluated the financial benefit of OP and will evaluate effectiveness.

Methods: The cost of IV treatment was derived from analysis of reported treatment costs (Robson et al, CJNS 1998). The reported cost of \$714.64 (CAN, 1996 dollars) for four outpatient doses was multiplied by 1.25 to arrive at a five dose cost of \$893.30 per patient. We multiplied the number of oral treatments since 1999 by this treatment cost and subtracted the cost of OP (\$35.00 per treatment), and thus determined the amount saved over the past 6 years. Patient reported tolerance and effectiveness will be determined by prospective nurse telehealth data using a follow up questionnaire. Data will be collected at 3 predetermined time points for all patients receiving steroid treatment between January 1st and April 30th 2005.

Results: Over six years 610 patients received OP. The cost of treatment was \$21,350.00 (\$35.00 x 610). The cost of treatment with IVMP would have been \$544,913.00 (\$893.30 x 610). Thus, \$523,563.00 was saved by the use of OP. Both tolerance and effectiveness will be reported.

Conclusion: Even based on 1996 costs, use of OP rather than IVMP saved at least \$523,563.00 over the past 6 years. Our clinical impression is that OP is safe and effective. We will demonstrate if patient-reported outcomes support this impression.

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**(S32) A PILOT STUDY FOR THE EARLY DETECTION OF DEPRESSION
IN MULTIPLE SCLEROSIS**

The accurate and early detection of depressive symptoms in Multiple Sclerosis (MS) is difficult due to the overlap of the neurovegetative symptoms of Major Depression and MS. Debate continues as to the construct validity of commonly used depression screening instruments in determining the rate and severity of depressive symptoms in the MS population. The primary objective of this pilot study is to compare the efficacy of standardized, psychological self-report measures of depression, the Beck Depression Inventory II (BDI-II) and the Geriatric Depression Scale (GDS) in identifying early depressive symptoms in patients with MS. The secondary objective is to establish the prevalence of Major Depression in this sample using the Structured Clinical Interview for DSM-IV: Clinical Version Module A (SCID-CV Module A).

Preliminary review of baseline data reveals that no participants met DSM-IV diagnostic criteria for Major Depression, as measured by the SCID-CV (Module A). Twenty percent reported moderate depressive symptoms on two self-report measures. These individuals also reported negative health perception and more physical limitations on the MSQOL. There was no correlation between disability status (as measured by the EDSS at day one) and depressive symptoms.

To date, 90% of participants enrolled in this study have completed 3 month follow up visits. Interim analysis of the three month data revealed no statistical or clinically significant change in the rate or severity of depressive symptoms. Interestingly, there was no consistent relationship between depression and neurovegetative symptoms (such as fatigue, loss of energy, and/or sleep disturbance) in this MS population. The study is ongoing and further data will be included in the presentation.

Study supported by: Research grant to Neurology Center of Fairfax from Serono, Inc.

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(S33) CAREPARTNER STRESS AND MULTIPLE SCLEROSIS: A FOLLOW-UP REPORT

Caring for a physically-challenged loved one can be both a rewarding, as well as a physically and emotionally demanding experience for the MS CarePartner. Indeed, the National Alliance for CareGiving estimates that caregiving spouses between the ages of 66 and 96 who are experiencing mental or emotional strain have a 63% higher risk of dying than people the same age who are not caregivers.

To empirically address Carepartner issues within the MS community, a Carepartner Support Group was initiated in June 2003. There is an expected range of attendance (between 8 and 28 participants, both male and female) who attend the two hour meeting every other month. Objective health questionnaires (CSAQ) and subjective quality of life measures (SF-36) were re-administered in October 2004 to a sub-set of the original group members. The follow-up data reveals that 71% of CarePartners who participated in follow-up testing described increased levels of stress and anxiety this year compared with last year. 43% of CarePartners described their current medical health as "worse" compared to what it was this time last year. Importantly, 57% of CarePartners self-reported increased sleep difficulties. Several of the group members specifically characterized sleep maintenance difficulties (as opposed to sleep onset issues).

Preliminary follow-up data suggests that MS CarePartners would benefit from increased mental health and behavioral medical services. The impact of sustained caregiving stress appears to be negatively impacting sleep hygiene in a majority of MS CarePartners. As increased fatigue has been demonstrated to exacerbate both concentration deficits as well as mood disorders, further evaluation of the role of interrupted sleep in the MS CarePartner appears warranted. As a minimal change, we have decided to meet once a month as a CarePartner Group to address these issues. Increased behavioral medical services (such as increased cardio-vascular exercise and stress management techniques) will be incorporated in future group meetings.

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**(S34) MULTIPLE SCLEROSIS CARE DELIVERY IN THE CAPITAL REGION OF ALBERTA, CANADA:
STRENGTHS, GAPS AND RECOMMENDATIONS FOR CHANGE.**

Objective:

When persons with Multiple Sclerosis (MS), from the Capital region of Alberta (Canada), reported that there was inequality of service in MS care delivery across publicly funded health regions in the province, a project aimed at determining the validity of these expressed concerns was proposed. A comprehensive list of the care needs of persons with MS, derived from an in-depth review of the literature, was used as the starting point in discussions with health care providers to determine whether the health care delivery was currently meeting these needs.

Method:

Interviews were conducted with a convenience sample of ten health care professionals, including one person living with MS. At the time of the interviews, these participants held greater than 40 years of cumulative experience in MS care delivery, acquired in the Capital region of Alberta. This presentation is a report of a content analysis of these interviews.

Results:

Care design was found to be an overarching theme in the content analysis. Participants did identify several strengths and made recommendations for change to fill the identified gaps. In addition, comparisons between two MS care delivery systems found in the Capital region and the systems found in other regions of Alberta and Canada were made. Recommended MS care delivery models are outlined.

Conclusion and implications:

Inequality of service for persons and families living with MS exists within the Capital region of Alberta and across regions in Alberta. Collaborative action may be necessary to influence change.

Study supported by: Teva Neurosciences

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**(S35) HYPNOTIC ANALGESIA FOR CHRONIC PAIN IN PERSONS WITH MS:
A CASE SERIES**

Chronic pain is a serious problem for many persons with MS, yet there are limited treatment options for MS-related pain. Previous case reports suggest that hypnotic analgesia has the potential to benefit at least some of these individuals, but there are no published data to indicate the number of individuals who might benefit from this intervention. To address this gap, 13 adults with MS and chronic pain were given 10 sessions of hypnotic analgesia treatment. Six (46%) of the participants reported a clinically meaningful (30% decrease or greater) change in average pain intensity during the week after treatment compared with the week immediately before treatment. This decrease in average pain was maintained at three-month follow-up for three participants. The findings support the potential benefit of hypnotic analgesia for the treatment of pain in persons with MS for some patients, and indicate that a controlled clinical trial is warranted.

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(S36) ANTIDEPRESSANT USE AMONG INDIVIDUALS WITH MS

Depression is a common symptom among individuals with MS and is often associated with fatigue, cognitive changes and greater disability. We wanted to determine the prevalence of antidepressant use among individuals living with MS. We hypothesized that those using antidepressants might differ in terms of their demographic, symptom, functional status, and immunomodulating therapy use compared to those not using antidepressants. We examined survey data collected from individuals with multiple sclerosis (MS) living in Eastern Washington State (N=548, 55% response rate). The survey included instruments measuring demographic characteristics, disease history, symptoms, health care and health status, depression, coping, and use of immunomodulating therapies. Similar to other studies, 47% (N = 250) of our respondents scored in the range of people with depressive symptoms on the CESD (CESD>16). We found that 35% (N=189) of our sample reported currently taking antidepressants, while 43% (N=108) of those endorsing depression reported currently taking an antidepressant. Those taking antidepressants were more likely to have moderate-severe functional limitations ($\chi^2=6.76$, $p<0.05$), and report fatigue as being a problem ($\chi^2=14.1$, $p<0.000$), but less likely to endorse pain ($\chi^2=13.1$, $p<0.000$). Those taking antidepressants were also more likely to be currently taking one of the immunomodulating therapies (avonex, betaseron, or copaxone) ($\chi^2=15.1$, $p<0.000$). Use of antidepressants within this population was not associated with age, duration of MS, or measures of life satisfaction and coping. 57% (N=142) of those endorsing depression are not currently being treated with antidepressants. Many explanations exist: past antidepressant use was unsuccessful (35% took antidepressants in the past); they are undiagnosed or haven't reported depressive symptoms to their health care provider; they didn't report use of antidepressants on the survey; may prefer not using medication, or prefer using alternative therapies. More research is needed to answer research questions about use of antidepressants by individuals with MS.

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**(S37) EDSS RATINGS DERIVED REMOTELY AND FROM HANDS-ON EXAMINATION:
TELENEUROLOGY IN VETERANS WITH MS**

The use of telemedicine within the Veterans Health Administration (VHA) has grown substantially over the past decade. Telemedicine is an efficient way to serve a growing population of aging veterans with chronic disease and limited resources. It is also a method for improving access to specialty care for individuals with multiple sclerosis without easy access to specialized centers. The present study was designed to assess the efficacy of telemedicine for performing neurological examinations when the MS specialist is at a different location than the patient. To date seventeen patients with MS were examined by a nurse practitioner or physician assistant at the Baltimore or Washington DC VA Medical Centers. At the completion of this study, a total of 20 patients will be examined, 10 from each site. The examination was directed by a remote MS specialist observing the neurological exam over a videoconferencing linkage. In addition, an MS specialist in the room with the patient observed the exam. All three clinicians independently completed the Kappos rating scale: a scored neurological examination based on the Kurtzke EDSS producing scores within 8 neurological systems along with a total score. Analyses from the first 17 patients demonstrated high agreement between all three raters (Spearman correlation coefficients between .978 and .998; $p=.000$) with respect to the EDSS total score. However, variation was noted depending upon which domain was assessed and the location of the rater. The most consistent ratings between examiners were seen for optic, pyramidal, bowel/bladder and cerebral functions. Substantial, but somewhat lower correlations were seen with regards to scores for brain stem, cerebellar, and sensory functions. Generally, agreements were higher between the hands-on examiner and the MS specialist in the room with the patient. Data were encouraging for further development of neurological services using telemedicine.

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**(S38) PHYSICAL THERAPY TREATMENT OF A 49 YEAR OLD FEMALE WITH
MULTIPLE SCLEROSIS, LEUKEMIA, AND BILATERAL PERIPHERAL VESTIBULAR LOSS.**

This case describes the physical therapy management of a woman with Multiple Sclerosis (MS) who developed Acute Promyelocytic Leukemia (APL) as a complication of treatment with Novantrone. Over the course of her treatment for the APL she experienced bilateral peripheral vestibular loss (BPVL) as a complication of treatment with Gentamycin. At the time that she began physical therapy, she was experiencing weakness as a result of the chemotherapy, primary neurologic impairment as a result of the Multiple Sclerosis, and severe vertigo and imbalance as a result of the vestibular loss. Treatment of the patient involved the use of vestibular rehabilitation, emphasizing principles of habituation, adaptation, and compensation. Vestibular Ocular Reflex (VOR) training, as well as exercises to enhance proprioceptive inputs and to improve the use of visual cues were utilized. Overall conditioning exercises were also included. A progressive treatment approach was used which emphasized exercising to the patient's tolerance in the setting of weekly outpatient visits and a home program. Over a 6 month period, the patient progressed from being entirely bed bound due to vertigo and weakness to ambulating independently with a forearm crutch. Berg Balance Scale (BBS) scores improved from 38 to 52 and Dizziness Handicap Inventory (DHI) scores improved from 90 to 46. The combination of MS, bilateral vestibular hypofunction, and Leukemia might suggest a poor rehabilitation prognosis; however, this case demonstrates a successful rehabilitation program in a patient not normally considered appropriate for such an approach.

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(S39) FATIGUE ASSESSMENT IN THE USUAL CARE OF PATIENTS WITH MS

Background:

Fatigue is a common occurrence in individuals with multiple sclerosis (MS), with as many as 40% describing it as their worst symptom. MS Fatigue can be divided into three principal types: physical, mental and social. Self-report scales such as the Modified Fatigue Impact Scale (MFIS) can be used to assess patients' experiences.

Purpose of Study:

-To determine if there are correlations between MFIS-reported fatigue and Beck Inventory (BI) depression scores.
-To determine if patients on glatiramer acetate experience less fatigue than patients on other immunomodulators, as measured by the MFIS scale at 12 months.

Methods:

Patients followed at the Baptist Hospital East Multiple Sclerosis Center, Louisville, Kentucky, completed the MFIS and BI at visits beginning in January 2000. Consent was obtained allowing health assessment scores to be abstracted. The MFIS, BI and EDSS scores were recorded. Patients on twelve months or more of immunomodulatory therapy in addition to those not on therapies were analyzed. Only patients who completed one or more MFIS and BI at the same visit were included.

Results:

There was a strong correlation ($r = 0.91$) between fatigue and depression scores among the 53 patients completing both measures at baseline. Likewise, for 37 patients with both measures at 12 months, the scores were strongly correlated ($r = 0.72$). Twenty-four patients completed fatigue and depression scales at both baseline and 12 months. Over the twelve months fatigue and depression remained stable for those treated with interferon beta-1a, fatigue declined somewhat while depression remained stable for those treated with interferon beta-1b, while those treated with glatiramer acetate showed decline in fatigue and depression despite their higher level of disability at baseline.

Conclusions:

Despite the small sample size, this exploratory analysis shows that patients treated with glatiramer acetate may experience improvement in the symptoms of fatigue and depression over 12 months.

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(S40) ASKING FOR HELP: THE EXPERIENCE OF INDIVIDUALS WITH MS

While the course of multiple sclerosis (MS) is variable, many individuals will require care and assistance with a variety of activities. The literature suggests that most people with MS receive care from family members. Studies have been conducted to examine issues that caregivers frequently face, such as stress, burden and poor health. Only a few studies have examined the experience of care giving from the perspective of the person who is receiving the care or asking for help. The purpose of this study was to understand the experience of receiving care from the perspective of the person with MS. One man and five women with moderate to severe MS participated in semi-structured interviews. Participants were asked: "What is it like to ask for help from your care giver, i.e. spouse, friends, other family members?" A phenomenological analysis was conducted and three major themes emerged. The themes were preservation of family roles, not being a burden, and changing personal expectations. The individuals with MS felt that it was difficult to maintain his/her position in the family when he/she required help with personal care. Participants indicated that family members viewed them differently and his/her role in the family became compromised. Those interviewed also felt great concern about becoming a burden to the family. They reported monitoring the amount of help they asked for and always being aware of not asking too much. The individuals interviewed also discussed the need to change personal expectations. Since he/she required assistance he/she had to adjust to things being done differently, and felt they had lost a sense of control when personal expectations had to be changed. Awareness and understanding of both perspectives (caregiver and person with MS) can help to establish and maintain a partnership between caregiver and the person with MS.

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(S41) IMPACT OF IMMUNOMODULATING THERAPY ON QUALITY OF LIFE IN WOMEN NEWLY DIAGNOSED WITH RELAPSING REMITTING MULTIPLE SCLEROSIS

Background: Monitoring clinical outcomes following treatment with disease modifying therapy (DMT) and, assessment of quality of life (QOL) are critical and integral part of MS disease management. Both impact the patient's health perception, relationship with healthcare providers and understanding of the disease process and treatment, and each of these factors are necessary to develop appropriate interventions at the time of diagnosis that will promote therapy adherence and, ultimately, effective disease management.

Purpose of Study:

- To assess over time the QOL in women newly diagnosed with Relapsing-Remitting Multiple Sclerosis (RRMS) who are starting DMT.
- To identify factors that impact DMT selection and adherence.

Methods:

Sample: Women newly diagnosed with RRMS were recruited by general neurologists in private practice in the Louisville, KY metro area.

Measures: The MS Quality of Life Inventory (MSQLI), a validated measure of QOL, was administered at the time of diagnosis and every three months for a year in the physician's office. In addition, subjects completed a demographic characteristics sheet to ensure compatibility with eligibility criteria:

- EDSS score less than 2.5
- Not pregnant or planning to become pregnant; and
- No cognitive, psychiatric or other health problems which would compromise the subject's ability to complete the surveys.

Factors influencing DMT selection were collected at the baseline visit by the investigator using subject interview. Adherence issues were also identified by subject interview at subsequent study visits.

Summary of Findings: Seventeen women newly diagnosed with RRMS were recruited; 82.4% were Caucasian; 11.8% were African American and 5.8% were of other ethnic background, reflecting local demography. The age range of the sample was 26 to 54 years, with a mean of 36 years. Some women with RRMS reported anxiety and depression at the time of diagnosis and initiation of treatment as measured with the MSQLI. The healthcare providers for these women observed that psychological factors influenced:

- Ability to select an appropriate DMT in partnership with their healthcare provider;
- Comprehension of injection training and side effect management.
- Experience of injection site pain; and
- Experience of MS symptoms.

There were markedly different perceptions of the healthcare providers' involvement versus the patients' involvement in the DMT selection. Although not statistically significant, anxiety and depression decreased over the course of twelve months, as did fear of recurrent relapse.

Conclusion: Although this study involved only a small sample size, the implications for healthcare delivery for RRMS are important. Healthcare providers need to be mindful of the anxiety and depression that are present at the time of diagnosis and initiation of therapy and the ways that it may be influence their patients' decisions and responses.

Study supported by: Teva Neuroscience, Inc.

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(S42) EFFECTIVENESS OF URINARY REHABILITATION IN MS PATIENTS.

Over 80% of MS patients have symptoms of lower urinary dysfunction during the disease course. Urinary dysfunction can have a significant impact on patient quality of life. Comprehensive evaluation is essential for MS specialists to effectively manage these potentially life-disrupting symptoms. This study evaluated the effectiveness of a rehabilitation programme for MS patients with urinary dysfunction being followed in a specialised rehabilitation centre and the impact of this problem on their quality of life.

Thirty female MS patients with urinary symptoms consecutively referred for the first time to the rehabilitation centre were enrolled in the study. Data collected at Time 0 (pre-treatment) included: age, EDSS, course and duration of disease, mobility status, symptoms (urgency, retention, hesitation, incontinence, frequency), Post Void Residual (PVR) with bladder ultrasound, Multiple Sclerosis Quality of Life-54 (MSQOL-54), Wagner Test, Visual Analogue Scale (VAS), uro-dynamic investigation, pelvic floor muscle evaluation (Grading Test and muscle coordination evaluation), current pharmacological therapies. Patients also completed a 5-day bladder diary. Based on the information collected an individualised urinary rehabilitation programme was developed. Components of the urinary rehabilitation programme included: hydration and nutrition counselling, self-catheterisation training, pelvic floor muscle re-education, biofeedback, pelvic floor muscle electro-stimulation, Stoller Afferent Nerve Stimulation (SANS), Intra Vescical Electro Stimulation (IVES).

At the end of the rehabilitation programme (mean duration:12 sessions) all patients repeated the same evaluation as was conducted at Time 0 without the uro-dynamic investigation. During the rehabilitation treatment period, pharmacological therapies were not modified.

Primary outcomes include urinary incontinence (Wagner Test), mean number of episodes of leakage (bladder diary), mean number of episodes of urinary frequency in 5 days (bladder diary) and urinary retention (PVR). Secondary outcomes include change in MSQOL-54, VAS and Grading Test. Results will be presented.

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(S43) HANDWRITING ANALYSIS IN MULTIPLE SCLEROSIS POPULATION

Purpose:

Handwriting analysis is a convenient and effective way to evaluate physiological and neurological changes through changes in an individual's handwriting. Multiple sclerosis (MS) is a widespread neurological disorder with a variety of symptoms, some of which are noticeable changes in handwriting. The purpose of this handwriting analysis study was to explore the relationship between physiological aspects in one's handwriting pattern and disease status in MS population.

Methods:

The handwriting samples and a short questionnaire were collected through a mailing survey. A self addressed and postage pre-paid envelope was provided to increase response rate. The handwriting sample was to be written in ink by each subject on an 8 1/2" x 11" sheet of unlined paper. Writing samples from people with any other neurological disorders (e.g., Parkinson disease, Alzheimer disease) were excluded from this study. To avoid rater bias, the handwriting analyses were performed "blindly" by the certified handwriting analyst (i.e., the analyst was unaware of whether the writing samples were from case or control group).

Six domains of an individual's handwriting are believed to be affected when physiological changes occur to an individual. These six domains (tremor, rhythm, legibility, stroke quality, irregularity, and form) of each handwriting sample were analyzed, using the Kahlowsky Scale (2002). Multivariate correlations (Spearman's Rho correlation coefficient) were used to explore the relationship between the handwriting variables and physical condition.

Results:

To date, a total of 89 writing samples were analyzed. 44 indicators were recorded for the six domains. Only in MS population, tremor was found statistically significantly associated with rhythm ($r=0.76$, $p<.0001$), legibility ($r=0.71$, $p<.0001$), stroke quality ($r=0.58$, $p<.0001$), irregularity ($r=0.71$, $p<.0001$), and form ($r=0.74$, $p<.0001$).

Conclusions:

These results suggest that neurological damage is reflected in handwriting and can be measured in MS population. Possible reasons for variance and future research directions are discussed.

Study supported by: A grant from Multiple Sclerosis Foundation

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(S44) VITAMIN D SERUM LEVELS AND MULTIPLE SCLEROSIS: A CASE CONTROL STUDY**Introduction:**

Multiple sclerosis (MS), the most common demyelinating disease of the central nervous system (CNS), affects over 2.5 million people. There are limited data suggest a role for micronutrients and MS. Defective CNS myelin production and maintenance characterize MS pathophysiology and clinical manifestation. Evidence suggests that cell-mediated autoimmunity is important in MS disease pathogenesis, specifically cytokine production. Experimental data suggest the active form of vitamin D can prevent or suppress MS progression, by impacting on cytokine production. MS patients may be genetically predisposed to developing abnormal vitamin D metabolism. Vitamin D must first be metabolized in the liver to 25-hydroxy D3 and then in the kidney to the final active, hormonal form 1,25-dihydroxy D3. There are no reported data on vitamin D profiles in the MS population. The objective of this study was compare the levels of active Vitamin D in MS patients to the control group, therefore exploring the importance of Vitamin D in this autoimmune disorder.

Methods: 60 adult MS patients and 40 adult non-MS controls are eligible. Dietary intake is based on the food frequency questionnaire (FFQ) and laboratory serum vitamin D metabolites are assayed by high performance liquid chromatography (HPLC).

Results: To date, serum vitamin D results are available for 27 cases and 27 controls. FFQ data are not yet available. For cases and controls the mean level of 1,25 dihydroxy D, the final active form, was 44 versus 66.5 pg/ml respectively and for 25 hydroxy D, the major liver metabolite, 41 and 34.5 ng/l respectively.

Discussion: Compared to the controls, MS patients have less active, hormonal vitamin D, the form metabolized in the kidney. These data support a possible metabolic alteration for vitamin D in the MS populations. Future research direction

Study supported by: A grant from Nova Southeastern University President Faculty Scholarship Award

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(S45) VALIDATION OF THE NARCOMS REGISTRY: FATIGUE ASSESSMENT

Background: The North American Research Committee on Multiple Sclerosis (NARCOMS) Registry is a multiple sclerosis (MS) self-report registry with more than 24,000 participants. Participants report disability status upon enrollment, and semi-annually using Performance Scales (PS) and Patient Determined Disease Steps (PDDS). PS is a self-report measure that assesses disability in eight domains, mobility, hand function, vision, spasticity, cognition, bladder/bowel, sensory and fatigue. In the November 2002 semiannual update questionnaire we collected the Fatigue Severity Scale (FSS) and the Modified Fatigue Impact Scale (MFIS).

Objective: Our aim was to validate the PS fatigue question using the FSS and MFIS as our criterion measures.

Methods: We measured Spearman correlations between the fatigue scales to assess criterion validity. We measured Spearman correlations between the PS fatigue question and age, disease duration, various PS subscales, and PDDS to assess construct validity.

Results: 9324 participants completed the update questionnaire out of 19297 mailed (48.3%). Only 97 (1.0%) participants did not answer the PS fatigue question. Fatigue data was complete for all three fatigue scales in 8119 (87.1%) participants. The correlation between the PS fatigue scale and the MFIS was $r=0.72$ ($p<0.0001$). The correlation between the Performance Scale fatigue question and the FSS was $r=0.75$ ($p<0.0001$). Correlations between the fatigue question and age, disease duration were low indicating divergent validity. Correlations between the fatigue question and spasticity, sensory, mobility PS subscales and PDSS were moderate, indicating convergent validity. Although the study was not designed to test reliability, 100 participants also completed a questionnaire in November 2001, and reported no change in PDDS or the PS between November 2001 and November 2002. The correlation between the PS fatigue scores was $r=0.72$ ($p<0.0001$).

Conclusion: The PS fatigue question has adequate criterion and construct validity in MS. Reliability of the fatigue question remains to be assessed.

Study supported by: The NARCOMS Registry receives support from the Consortium of Multiple Sclerosis Centers.

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(S46) EMPOWERING CAREGIVERS FOR INDIVIDUALS WITH MULTIPLE SCLEROSIS

One of the foremost responsibilities of Multiple Sclerosis (MS) caregivers is the necessity of becoming the conduit for communication between patient and provider. Many caregivers express a myriad of feelings regarding their interaction with health care professionals ranging from helplessness to intimidation. The National Family Caregivers Association (NFCA) recognized the need for increased communication skills and empowerment training for all family caregivers and developed an extensive training program in that regard called the "The NFCA Family Caregiver Self-Advocacy Training Project". The project 1) emphasizes family caregiver self-empowerment, utilizing a diversified network of professionals and family caregivers to convey the philosophy and needed skills, and 2) focuses specifically on improving understanding of medical terminology and communicating effectively with professionals in the health and social service system. The Multiple Sclerosis Center of Excellence-East (MSCoE) adapted this workshop to meet the needs of our MS Caregivers in two ways: 1) we introduced vocabulary and common scenarios regarding symptoms and treatments specific to MS and 2) we developed a pre-post questionnaire to analyze the effectiveness of the training with regard to variables of self efficacy, comfort/confidence levels, and knowledge/skill improvement.

Significance was found in 26 out of 28 variables. Of notable interest was improvement in managing power in a caregiving relationship ($p < 0.000$) and confidence in using key principles of effective communication ($p < 0.000$). Self efficacy change in skills regarding empowerment and communication pre and post was significant ($p < 0.000$). Caregivers felt significant improvement in self-efficacy regarding their place in the health care team following completion of the training ($p = 0.001$). There was also significant improvement ($p = .021$) in self-efficacy beliefs regarding the ability to communicate well with health care professionals and organizational skills needed to provide information and records regarding their care recipients ($p = 0.012$).

Study supported by: Veterans Health Administration MS Center of Excellence - East

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(S47) NEEDS ASSESSMENT IN MULTIPLE SCLEROSIS: A SYSTEMATIC REVIEW

In order to better understand the needs of persons with MS, a systematic review was conducted. The purpose of this review is to: 1) synthesize research on assessment of needs in MS; 2) identify trends in needs; and 3) explore strategies for meeting identified needs. The parameters of this review involved searching Medline, PSYCHInfo and EBSCO for all articles published after January 1, 1990 with the terms 'multiple sclerosis' and 'quality of life' or 'needs' as a keyword. The search produced over 325 hits, with 34 articles identified as being highly relevant, as they addressed needs assessments in MS. The systematic review revealed eleven areas of needs: depression, adaptive coping skills, multi-disciplinary approach to managing MS, self-empowerment and self-esteem, fatigue, mobility issues, employment issues, alternative forms of therapy, sexuality issues, gender-specific needs, and the needs of care partners of MS patients. The most frequent were related to depression as well as programs dealing with adaptive coping strategies and the multi-disciplinary approach. Depression was consistently identified in the research, but accurate diagnoses and treatment were suboptimal. The development and implementation of adaptive coping strategies increased the quality of life and reduced depression among MS patients. The research suggests that teaching adaptive coping strategies may provide the tools necessary for MS patients to deal more effectively with the unpredictable nature of the disease and the many diverse daily issues faced. The research identified the need for an integrated multi-disciplinary approach that focuses on the psychosocial and emotional needs of MS patients in addition to their physical well-being. Implications of this systematic review and recommendations for future needs assessment research in MS will be presented.

Study supported by: Multiple Sclerosis Association of America

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(S48) EXTENDING THE CASE MANAGER'S ROLE TO INCLUDE DOULA TO SUPPORT DISABLED WOMEN DURING PREGNANCY, CHILDBIRTH AND THE FIRST YEAR FOLLOWING BIRTH

Objective

This program was developed by Every Child Inc., a social service agency, to assist women with disabilities prepare for birth and transition successfully into motherhood.

Background

Women with physical and cognitive disabilities have unique needs pre and postpartum. Barriers in health care settings can be physical or attitudinal. Disabled women often report negative birth experiences with traditional care. Parents with disabilities state that the same opportunities to parent do not exist for them in a community.

Methods

The idea was to use a doula as the main support person in this project as the role is clearly defined. Rather than hire a doula, the agency extended the staff's role and staff became certified as doulas. The additional activities of the case managers involved in this project are: assisting the woman with preparation for childbirth, advocating for special needs during labor and delivery, preparing the home for the baby, and assisting and supporting the mother (and father) in the year following the birth. Woman can self refer or are referred to the program through other health professionals or community programs.

Results

To date all pregnancies were healthy, few medical interventions were required during labor, healthy full term infants were born, and infants and mothers were discharged together. Overall women state they felt empowered due to the support received and their success in the delivery process. They feel confident in their ability to be a parent, and mothers appear more assertive according to staff.

Conclusions

Women with MS in Allegheny County have a unique program that assists them through a time in life that can be filled with stress, confusion, fatigue, and uncertainty. Programs like this can be replicated to support and nurture women with any disability who wish to become a parent.

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(S49) MANAGEMENT OF INFUSION-RELATED HYPERSENSITIVITY REACTIONS DURING NATALIZUMAB TREATMENT

Objective: To describe the management of hypersensitivity reactions following natalizumab (Tysabri) treatment.

Background: The potential for hypersensitivity reactions exists with all biological therapeutics. Such reactions can be acute or delayed, local or systemic, and can range from mild to severe. Natalizumab demonstrated efficacy in relapsing MS patients in two phase III studies. Although hypersensitivity reactions were uncommon (serious reactions occurred in approximately 1%), it is essential healthcare professionals become familiar with the management of drug-related reactions.

Study Design: AFFIRM and SENTINEL are randomized, placebo-controlled phase III trials of natalizumab (300 mg IV once monthly) as monotherapy and as add-on therapy to IFN β -1a (Avonex). Infusion reactions were defined as any event occurring within 2 hours of the start of infusion. Hypersensitivity reactions were defined as urticaria with or without systemic symptoms, as well as any additional event the investigator felt was allergic in origin. Per protocol, patients who experienced hypersensitivity reactions were required to discontinue study drug.

Results: After a median follow-up of 20 months in AFFIRM, infusion reactions were experienced by 22% of natalizumab patients vs. 17% of placebo patients. Similarly, after a median follow-up of 19 months in SENTINEL, infusion reactions were experienced by 22% on add-on therapy vs. 18% on IFN β -1a alone. Overall, 24 of 627 (3.8%) patients in AFFIRM and 10 of 589 (1.7%) in SENTINEL experienced a hypersensitivity reaction. Hypersensitivity reactions were associated with persistent antibody positivity. Treatment was determined by on-site health care personnel and generally consisted of combinations of antihistamines, corticosteroids, and rarely subcutaneous epinephrine. All patients recovered fully without sequelae once appropriate treatment was initiated. Details of symptoms and management of hypersensitivity reactions will be described.

Conclusions: Natalizumab is a significant advancement in the treatment of MS. Although hypersensitivity reactions can occur, their impact can be minimized by timely and appropriate medical management.

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**(S50) CHARACTERISTICS OF VETERANS WITH MULTIPLE SCLEROSIS WHO DIE:
A PRELIMINARY ANALYSIS**

OBJECTIVES: To identify demographic and disease characteristics of veterans who die compared to those who do not in a large sample of veterans with multiple sclerosis (MS).

METHODS: A cohort of all veterans who received health services for multiple sclerosis between Jan. 1, 1995 and Dec. 31, 2000 was identified via a computer database. After excluding individuals who were incorrectly identified as having MS, redundant identifiers, and those who had died during the study interval, a sample of 1024 veterans with MS was surveyed to assess health care needs and 451 responded. The Consumer Health Information Performance Sets (CHIPS) was then used to assess characteristics of veterans who died from 1999-2000, those responded to the survey and were alive at Dec. 31, 2002, and those who responded to the survey but died between Jan. 1, 2001 and Dec. 31, 2002.

RESULTS: Increasing age, male gender, and white race, and never receiving a prescription for a MS disease modifying therapy (interferon beta-1b, interferon beta-1a, or glatiramer acetate) were independently associated with death in both 1995-2000 and 1995-2002. When comparing survey respondents who were alive from 2001-2002 with those who died during that time period, survey respondents who died reported higher levels of NARCOMS disability on the mobility scale than those who were alive. Self-reported disease subtype was not significantly different between the two groups.

CONCLUSIONS: These data will be used in a multivariate model to predict risk factors for death in this VA population. Underlying causes of death will be determined from the National Death Index.

Study supported by: The Multiple Sclerosis Center of Excellence has accepted unrestricted educational funds from Biogen, Inc. All authors and co-authors are members of the Multiple Sclerosis Center of Excellence. (Biogen Idec have given small, unrestricted educational grants to the MS Center of Excellence over the past few years.)

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**(S51) QUALITY OF LIFE (QOL) IN MULTIPLE SCLEROSIS (MS) IN MEXICO
(PRELIMINARY REPORT)**

MS affects QOL importantly. QOL is a subjective individual term adjoining several components. QOL are commonly assessed by standardized surveys.

We evaluate the Expanded Disability Status Scale (EDSS) by physical examination and self-reported QOL (SF-36) validated for México, depression (Hamilton), fatigue (Kurpp) and Pain questionnaires in multiple sclerosis remittent recurrent (MSRR) patients and were correlate with the scores obtained by the EDSS.

We recruited 220 patients from tertiary care centers living at different Mexican states of the North and Central-West regions. All the patients were diagnosed as MSRR clinically definite patients, according with Poser criteria, without relapses or steroid therapy in the last 30 days.

The general profile of the group was: median age of 31 years old (16-56 range), EDSS 2.9 ± 1.5 ; median scores for QOL (SF-36) subscales were: 49 for physical functioning, 32 for physic role and 62 for social functioning; all of them with significant correlation with EDSS. Hamilton, Fatigue and Pain questionnaires gave respectively: means of 11, 56 and 41, without statistical correlation.

Our study showed an important decrease in the QOL of patients with MS of the north and central western regions from Mexico, compared with normal population. Social and Physical roles are the most affected areas. Fatigue and Depression do not correlated with EDSS. The low impact of Fatigue in the QOL of our MS patients deserves a more profound study. This is the first Mexican study of the QOL in MS patients.

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(S52) ANALYSIS OF A MULTIPLE SCLEROSIS POPULATION OF A SPECIALIZED OUTPATIENT NEUROREHABILITATION CENTER

Background: Multiple Sclerosis (MS) is the second leading cause of disability in young adults. The use of neurorehabilitation (NR) in MS is high, but fragmented and not comprehensive. Specific features of the disease condition its approach by a specialized team.

Objectives: 1 Analyze the clinical and demographic features of an MS outpatient population of a NR center, 2 Assess clinical course pattern, 3 Compare disability assessment measured by disease-specific and general scales, 4 Analyze the outcomes in terms of impairment, disability and handicap.

Material and methods: 32 comprehensive NR assessments were performed between January and December 2004. MS patients (McDonald criteria) were included. Disability scales (EDSS, Barthel index and Functional Independence measure (FIM)) were performed.

Results: Women: 70% . Average age: 47.4 years, Mean duration of disease: 11.2 years, Clinical patterns: RR: 50 %, SP: 26.6 % and PP: 23.3 %, Average EDSS:6.2, The level of disability measured by EDSS was different ($p < 0.05$) compared to FIM and Barthel; otherwise we did not find differences between FIM and Barthel themselves ($p > 0.05$), Fatigue: 96.6 %. Comorbidity: 47.6 %, Immunological treatment: 73 %, Symptomatic treatment: 70 %, Mean time to reach EDSS 6.0: 8.2 years, 6.5:10 years and 7.0: 7.5 years, Impairment: pyramidal tract signs: 100%, Sphincter and cerebellar tract signs: 86.6%, Gait disability: 100 %. Only a 48 % of patients were working, Mood disorders: 69 % (depression 70), Cognitive impairment suspicion: 56.6 %

Conclusions: This was a moderately disabled, chronic but young population. The clinical course was similar to regional previous cohort studies. There was no adequate correlation between disease-specific and general scales. Gait disturbance was the most frequent impairment and disability.

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(S53) SEP TESTING TO CATEGORIZE MULTIPLE SCLEROSIS SUBTYPES

There are currently no laboratory methods available to categorize Multiple Sclerosis (MS) patients into primary progressive (PP) vs. secondary progressive (SP) subtypes. Somatosensory evoked potential (SEP) testing has been used as an adjunctive aid in diagnosing multiple sclerosis. Histological studies indicate that patients with SP MS exhibit demyelination changes. Conversely, PP MS patients show more axonal degeneration and relatively less demyelination. We hypothesize that SEP testing can assist in the differentiation between SP and PP subtypes. We performed a cross-sectional, two group comparison study within a university hospital setting comparing SEP results in 50 patients representing these two subtypes. All subjects carried a confirmed diagnosis of MS. Standardized multi-channel median and tibial nerve SEP testing was performed on all patients. SEP tests were performed; latencies, amplitudes and central conduction times were evaluated. Initial analysis of the data support the hypothesis that SP MS exhibits relatively more central conduction slowing and PP MS exhibits relatively more amplitude attenuation. We propose that SEP testing may be a useful adjunct in the differentiation between SP and PP multiple sclerosis.

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(S54) RESEARCH OF THE QUALITY OF MS PATIENTS' LIFE IN RUSSIA, NOVOSIBIRSK

MS is a disease with a pronounced clinical variability with an unpredictable course and prognosis. Research on the quality of life helps to estimate the disease influence on the most important aspect of a person's life.

The aim of our research was to study the influence of MS on the quality of patients' life. We used the International questionnaire SF-36. We questioned 338 MS patients (280 females (83%), 58 males (17%). The average age was 41 years and the average duration of a disease was 11.6 years; the average level of disability was 5 EDSS. These patients with MS were compared with 144 healthy controls. The analyses of the results showed decreased quality for MS patient's. All of the indexes of the life quality were different: PF (MS-49.26, control-85.41, $p < 0.05$), RP (MS-28.61, control- 61.95, $p < 0.05$), RE (MS-38.66, control-63.31, $p < 0.05$). We will review the results about the decreased quality of life for people with MS, especially connected with the increased disability, gender, age at disease onset, and duration of disease.

Conclusion: 1. The quality of MS patients' life has decreased compared to the control group. The questionnaire SF-36 is high sensitive for this estimation. 2. The analysis of the quality of MS patients showed the changes in all areas (PF, RP, RE) 3. Quality of life variables include gender, age at disease onset, disease duration, and the level of disability (Scale EDSS) 4. Indexes of the quality of life are sensitive to changes in MS patient's state and can be used for planning treatment and dynamic monitoring.

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(S55) VALIDITY OF THE 6-MINUTE WALK IN PATIENTS WITH MULTIPLE SCLEROSIS.

Objective: The 6-minute walk was first validated in 1985 in patients with chronic heart failure. It has been widely used since then in various populations, but to our knowledge its properties have never been formally tested in multiple sclerosis (MS). The goal of this study was to evaluate the validity and usefulness of the 6-minute walk in patients with MS.

Design: Cross-sectional evaluation of MS patients during a routine office visit. Longitudinal evaluation of ambulatory MS patients before and up to 24 weeks after implantation of a baclofen pump.

Setting: large outpatient comprehensive care center for persons with MS.

Participants: patients with definite MS, able to walk at least 25 feet with or without a walking aid, either coming for a routine follow-up visit for MS management (FU group, one-time evaluation), or participating in a longitudinal outcomes study of intrathecal baclofen therapy (ITB group, baseline and 6-month post-surgery evaluation).

Methods: Patients were asked to walk up and down a 60 meter hallway as many times as they could within a 6-minute time period. They were instructed to walk safely at a comfortable speed, with their usual walking aid if appropriate, and were allowed to take rest periods. The examiner timing the patient provided verbal encouragement, and verified the tolerance and safety of the test. The total distance walked over 6 minutes was recorded for all patients. In addition, the distance walked at each minute was measured in the FU group only. Demographic and disease-related data were recorded. A timed-25 foot walk (T25FW) was also performed (before the 6-minute walk), and EDSS scores were obtained.

Results:

39 patients completed the assessments (29 FU patients, 10 ITB patients). ITB patients were significantly more likely to have a progressive course and to walk with support; EDSS scores were significantly higher, T25FW and total distance walked during 6 minutes (TD6) were significantly lower in this group. Neither T25FW nor TD6 changed significantly after baclofen pump implantation. The feasibility and tolerability of the 6-minute walk were excellent in both groups. Eleven patients (28%) took at least 1 rest period (none in the ITB group). In the entire sample, TD6 was significantly correlated with disease duration, EDSS, and T25FW. T25FW values were skewed towards the lower end of range, suggesting a ceiling effect, while TD6 values exhibited a bimodal distribution.

Conclusions:

The 6-minute walk was overall well tolerated in our sample of ambulatory MS patients, across a wide range of disability. Our results suggest that this test exhibits good discriminant validity, and concurrent validity with the 25-foot walk. Due to the absence of ceiling effect, the 6-minute walk may allow to detect physical fatigability in patients with mild to moderate disability, who are otherwise able to walk at high speed on a short distance. However, its sensitivity to change needs to be further explored.

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(S56) COMBINATION THERAPY IN RELAPSING MULTIPLE SCLEROSIS (RMS)

Currently approved disease-modifying therapies (DMTs) for RMS are only partially effective. While the heterogeneous nature of RMS suggests the best treatment approach may be to use a combination of agents, no comprehensive analysis of the safety and efficacy of various combination therapies exists. This was a retrospective chart review of all patients from the MS Center of Atlanta (n~1300). Eligible patients had a diagnosis of clinically definite RMS, had been treated with IM IFN beta-1a for at least 12 months prior to initiation of combination therapy, and were on combination therapy for breakthrough disease. In addition, patient records must have contained data on relapses, Expanded Disability Status Scale (EDSS) scores, MRI scans, laboratory values, and adverse events (AEs) for at least 12 months prior to and 12 months after initiation of combination therapy. Of the 46 patients who met the criteria, the mean age was 47.2 years, 87% were female, and the duration of disease ranged from 3 to 9 years. Data were available for the following combinations with IM IFN beta-1a: pulse steroids only (n=25; 26.6 months), pulse steroids plus cyclophosphamide (n=13; 23.8 months), and pulse steroids plus mycophenolate (n=8; 18.1 months). Relapse rate was significantly reduced by all 3 combination therapies compared with monotherapy (0.3 vs. 1.2, p=0.001, 0.5 vs. 1.5, p=0.006, and 0.3 vs. 1.9, p=0.003, respectively). Neither EDSS nor MRI was significantly improved by any treatment; however, stable EDSS scores and MRI scans were observed after combination therapy for all 3 groups. A total of 3 serious AEs were noted, with 2 judged as related to study medication: 1 with cyclophosphamide (WBC decrease resolved by holding one dose), and 1 with mycophenolate (increased liver function tests resolved with discontinuation of drug). These results suggest that combination therapy is useful for treatment of breakthrough disease in MS.

Study supported by: A grant from Biogen Idec. (Dr Stuart has received honoraria and financial support for research from Biogen Idec. Drs Warth and Yawn are employees of Biogen Idec.)

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**(S57) ANALYSIS OF THE EPISODIC MEMORY IN A MULTIPLE SCLEROSIS POPULATION.
ITS IMPACT IN DAILY LIFE.**

Background: Cognitive dysfunction is common in patients with Multiple Sclerosis (MS), through the Reconem survey, performed in Argentina in the year 2002, a prevalence of 46% of Cognitive impairment (CI) in MS patients has been confirmed. Memory is the first subjective complain in our patients.

Objective:

- 1) To analyze the performance of the Episodic memory through the Amount and Speed of learning in MS patients with and without cognitive impairment.
- 2) To obtain the results of memory in the SRT in MS patients.

Method: 111 (92 female and 19 male) patients with clinically definite MS (Relapsing Remitting n=83% Secondary progressive n=8%, Primary progressive n=9%) and 222 age and education matched normal controls were consented in this study.

Of the 111 patients with MS, 46% had cognitive impairment.

The Selective Reminding Test (SRT) was administered in a specially adapted Spanish version. The Neuropsychological Screening Battery for MS, EDSS, MSFC and the Beck Depression Inventory were other outcome measures.

Results:

Long Term Retrieval: MS with CI=35.53 ±17.6; MS without CI=49.70 ±8.99; Healthy controls=51.52 ±11.51

Control Long Term Retrieval: MS with CI=23.63 ±17.78; MS without CI=38.16 ±11.1; Healthy controls = 42.63 ±13.95

Delay recall: MS with CI=6.82 ±2.76; MS without with MS=9.53 ±1.96; Healthy controls=9.82 ±1.90

All the subtests studied show a statistically significant difference between MS patients and the Control Group of $p < 0.001$.

There was a statistically significant difference in the amount and the speed of learning between the MS groups with and without CI ($p < 0.01$) both in the LTR and CLTR. Within the MS group without CI and the control group, there was a statistically significant difference in the speed of learning, but not in other outcome measures.

Conclusion: The amount and speed of learning in the episodic memory gives clinically useful information because it allows distinguish patients with slow learning curves from those with absence of learning. And it is useful to know the way how people with MS have to receive the information, number of repetitions, kind and amount of information.

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**(S58) SERIAL CASTING FOLLOWING BOTULINUM TOXIN A
INJECTION IN 3 M.S. PATIENTS**

Purpose: Serial casting is used to increase range of motion (ROM) in individuals with spasticity and decreased ROM due to stroke. This intervention has not been fully explored in individuals with similar impairments secondary to M.S.

Subjects: Three patients with chronic M.S. were referred to PT for gait evaluation secondary to gait dysfunction. All patients presented with: decreased ankle ROM, increased spasticity, and compensatory gait secondary to tight gastroc/soleus muscles. All patients were modified independent in ambulation with an assistive device. One patient presented with back pain, severe enough to limit the amount of walking she was able to do.

Methods: Patients received Botulinum toxin A (Botox) injections to calf muscles and underwent serial casting. Passive ROM (PROM) was measured prior to casting. Patients were casted in prone, with the knee flexed. Walking casts were used, and were changed weekly on average. Instructions were given for care of the casts.

Results: Two out of three patients improved ankle ROM and were fitted with a custom articulating ankle-foot orthosis. Gait improved in both, with more toe clearance and less compensation during gait. The third patient was referred to an orthopedic MD for an Achilles lengthening procedure, as her ROM did not improve.

Conclusion: Serial casting following Botox injection to the calf muscles is beneficial for patients with decreased ankle ROM and spasticity secondary to M.S. Serial casting may increase ankle ROM, and lead to improvements in gait. Furthermore, serial casting allowed the therapist to quickly determine an alternative intervention (surgical release) was required. Further research is required to determine the extent to which serial casting after Botox is useful in individuals with M.S. Finally, it is important to determine if Botox injection is required prior to casting, or if serial casting alone is a beneficial intervention for individuals with M.S.

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**(S59) SYMPTOM CONTROL AND QUALITY OF LIFE FOLLOWING
MITOXANTRONE TREATMENT**

Background: Mitoxantrone (Novantrone) is an immunosuppressive agent approved for treatment of secondary (SP) progressive or aggressive relapsing remitting (RR) MS. An open-label study evaluating the safety of mitoxantrone (RENEW) was completed in August 2004.

Objectives: We conducted a companion study of these RENEW participants to examine the relationship between disease activity, disease progression, quality of life (QOL) and disease related costs. We present the preliminary data related to symptom control and quality of life of RENEW participants.

Methods: 254 MS patients with aggressive RR and SP disease consented to take part in this companion study. Of these, 114 (45%) completed both the baseline and closing questionnaires.

Results: The mean age of the 114 participants is 49.6 (SD =8.0). Mean duration of participation was 35.1 months (SD =4.4). There were 36 males and 79 females. They received an average of 8.4 (SD=3.6) mitoxantrone infusions. Fifteen of the patients were receiving mitoxantrone at the time of the closing survey. For the 99 who were not, the mean length of time since their last infusion was 19.1 months (SD=23.7). The group's general health perception as measured by the first item of SF 12 was good (mean of 3.0, SD=0.9). Thirteen percent reported that their MS had not changed, 41% reported improvement, and 51% reported improvement in their QOL and 23 (20%) were working at least part time at the time of the closing survey. Side effect rates were comparable to those reported in the product insert. Forty-three patients (38%) reported relapses within the past 12 months, with a mean of 2.0 (SD=1.5) during that period.

Conclusions: Most of these aggressive RR and SP MS patients reported improvement in QOL and 41% reported symptom improvement following their participation in RENEW. Further analysis will be presented evaluating effects over time and non-respondent patient characteristics.

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**(S60) A COMBINATION TRIAL OF INTERFERON AND GLATIRAMER ACETATE
IN RR MS(COMBIRX)**

Objective: To determine whether combining interferon -1a (IFN) and glatiramer acetate (GA) is superior to either agent alone.

Background: We have previously shown that combining IFN and GA is safe. The efficacy of combining these two agents, which have different mechanisms of action, has not been tested.

Design/Methods: We now enrolling patients in an investigator-initiated, independent NINDS/NIH sponsored phase III randomized, controlled clinical trial of combining IFN and GA in early relapsing-remitting MS. We are recruiting 1,000 patients from 80 clinical sites across North America. Patients must have RR MS, EDSS 0-5.5, 2 attacks in the prior three years and be between 18-60 years old. Subjects should be treatment naive for IFN and GA. There are 3 treatment arms: GA daily and placebo weekly (25% of subjects), IFN weekly and placebo daily (25%) and GA daily and IFN weekly (50%). All patients will receive at least one active agent. The primary outcome measure will be relapse rate reduction. Measures of disability and MRI change will be assessed. The treatment period will be 3 years. The study is powered to show an additive effect of the study drugs and thus, if successful, should provide a relapse reduction greater than any available agent. An ancillary study, BioMS, directed by Dr. Roland Martin (NINDS) and supported by NINDS/NIH will study the baseline and on-treatment gene and protein expression profiles of subjects participating in CombiRx. This will provide valuable baseline demographic information and, in concert with the clinical and MRI measures, provide identifying patterns of IFN and GA responders and non-responders.

Results: Recruitment is underway and will continue until early 2006. Study participant sites will be listed for those interested in referring subjects. The trial is supported by NIH/NINDS and is the first major MS therapeutic trial to be supported by NIH in over a decade. The IFN is provided gratis by Biogen Idec and GA is provided gratis by Teva Neuroscience.

Conclusions: CombiRx is the first large scale study of combining IFN and GA in treatment naive patients. In addition to, hopefully, providing a significant improvement over current treatment strategies, this study will serve as a proof-of-concept for combination trials in MS and, in concert with the NINDS BioMS study, will provide baseline and treatment responsive profiling information on patients with RR MS.

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**(S61) THE EFFECT OF COMBINATION THERAPY (PROVIGIL + AVONEX)
ON QUALITY OF LIFE: 4 MONTH FOLLOW-UP**

Objective: Prior research indicated that at 2 months, combination therapy (modafinil plus interferon β -1a, Avonex®) is safe and improves quality of life (QOL) in MS patients with breakthrough cognitive deficits. The goal of the current follow-up study is to demonstrate the persistence of these findings over time.

Background: Interferon treatment can slow the progression of MS-related cognitive dysfunction. Studies have recently demonstrated the benefits of using adjunctive modafinil to treat MS-related fatigue and improve QOL. Prior preliminary research also indicated that, early in treatment (i.e., at two months), combination therapy (modafinil plus interferon β -1a) was helpful in addressing breakthrough cognitive symptoms. Recent data indicate that the cognitive efficacy of this combination persists over time. There are currently no data as to whether the associated improvements in (QOL) also persist.

Design/Methods: The current pilot study is a multi-center, randomized, parallel-group design intended to provide preliminary data on safety, efficacy, and QOL for MS patients on adjunctive treatment with modafinil. MS patients on (Avonex®) who demonstrated significant attention problems at screening were randomized to receive modafinil (200 mg/day) or no additional treatment. Evaluators were blind to medication status. Subjects underwent a complete neuropsychological battery (including QOL measures) at baseline, two months (reported elsewhere), and four months.

Results: 40 MS patients were enrolled in the study, 20 in each group. 35 patients completed the four-month evaluation. There were no significant differences between groups on demographic variables. Two-month and four-month cognitive data were presented elsewhere. At 4 months, compared to the interferon-alone group, patients taking adjunctive modafinil reported significant improvement in QOL. Modafinil side effects were mild and no different from those described in the package insert.

Conclusions: In this pilot study, modafinil in addition to interferon β -1a (Avonex®) is safe and has significant positive impact on patients' QOL.

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(S62) THE ETIOLOGY AND INCIDENCE OF DEPRESSION IN PATIENTS WITH MS

The rate of depression in multiple sclerosis (MS) is greater than in other chronic medical conditions. The increased rate of depression in patients with MS may be due to one or more factors, including: the biological impact of brain lesions, immune dysfunction, neuro-endocrine (HPA axis) dysfunction, or the psychosocial impact of the disease. Results from early studies of interferons (IFN) raised concerns that treatment with IFN caused or increased the severity of depression in patients with MS. However systematic reviews of the evidence regarding the link between IFN beta and depression in MS are lacking. There is a need for increased awareness of the potential for depression among patients with MS, its relationship to IFN therapy, and the likelihood of a positive response to antidepressant therapy among patients receiving IFN therapy. A retrospective literature review of the possible etiologies of depression in patients with MS and clinical trials of IFN beta-1a and -1b was performed to evaluate causes of depression in patients with MS. Evidence linking depression in MS with biological and psychosocial factors will be presented along with evidence demonstrating that depression and IFN therapy are not linked. An analysis of the evidence indicates that IFN is not associated with an elevated incidence of depression and that patients with MS respond favorably to antidepressant therapy. It is important to recognize that patient expectations, therapeutic outcomes, and psychosocial factors have an impact on patients with MS and to ensure that disease modifying therapy is not interrupted as a result of mood disorders. Clinicians will be provided with updated information relevant to the management of patients with MS presenting with symptoms of depression. This information will assist physicians in providing optimal care for patients with MS.

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(S63) BOTULINUM NEUROTOXIN TYPE A (BONT-A) IN THE MANAGEMENT OF PERSISTENT TRIGEMINAL NEURALGIA (TN) IN MULTIPLE SCLEROSIS (MS)

Background: TN stands out as one of the craniofacial pain syndromes. 2-8 % of patients with MS have TN. BoNT-A is used to treat various neurological disorders and pain syndromes. In addition to reduction in muscle tone, BoNT-A tends to reduce pain. In an open label pilot study for the treatment of chronic facial pain, 8 of 11 patients with idiopathic TN responded favorably (1).

Design: Three MS patients with persistent TN, who had failed routine medical management (carbamazepine, gabapentin, amitriptyline, narcotics, non-steroidal anti-inflammatory agents, divalproex sodium, and topiramate) were given BoNT-A. Each one of the three patients received 50 units of BoNT-A (100 units diluted in 1cc of preservative-free sodium chloride) using #30 needle: 5 units of BoNT-A was injected at 3 sites of the masseter, 7.5 units at 3 sites of the temporalis, 2.5 units at 2 sites of the nasalis, and 2.5 units each following the pain distribution path.

Results: The response started within 5 days and lasted 2-3 months. Two of the patients received only 2 injections (3 months interval) and were able to control the pain thereafter. The third patient is getting the BoNT-A treatment with excellent result every 4-5 months. One of the patients had recovered Bell's palsy and hemifacial spasm and the BoNT-A helped in improving the hemifacial spasm. Side effects were mild erythema at the injection site.

Conclusion: In the three MS patients with persistent TN, BoNT-A injection was very effective to control pain. Results from this report suggest that BoNT-A injection is a safe and effective therapy for TN. We propose that before subjecting patients with persistent TN to invasive procedures, a trial of BoNT-A be recommended. Additional studies are indicated to better elucidate the therapeutic effectiveness of BoNT-A in the management of persistent TN.

Study supported by: Bay Pines Foundation

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(S64) CORRELATION OF EXPANDED DISABILITY STATUS SCALE (EDSS) TO FUNCTIONAL AMBULATION PROFILE (FAP) SCORE IN INDIVIDUALS WITH MULTIPLE SCLEROSIS (MS).

Background: Gait dysfunction is a major source of disability in people with MS. The EDSS is commonly used to determine level of disability and neurological function in MS. The EDSS is non-linear, heavily weighted towards gait dysfunction and can be subjective due to the examiner's interpretation of the physical exam. The FAP score is a quantitative means of assessing gait based on specific spatial and temporal gait parameters that can be applied to the performance of persons with neuromuscular disorders, such as MS.

Purpose: To determine if a correlation existed between the EDSS and the FAP. Subjects: Fourteen ambulatory (with or without an assistive device) people with MS, (3 males, 11 females, ages 20-65 years). The University of Tennessee Health Science Center IRB approved the study and informed consent was obtained.

Methods: Demographics were collected for all participants. A neurologist who was blinded to the results of the FAP determined EDSS. Temporo-spatial gait parameters were measured with the GAITRite™ system; and a FAP score was calculated using GAITRite™ software. Statistical Methods: Pearson product-moment correlation was used to correlate the two tests. $P < 0.05$ level of confidence.

Results: Good to excellent correlations were found when comparing the EDSS with FAP ($r = 0.87$), and when comparing the EDSS with walking velocity ($r = 0.81$). Moderate to good correlations were found when comparing onset of symptoms with FAP ($r = 0.75$), onset of symptoms with EDSS ($r = 0.71$), and walking velocity with onset of symptoms ($r = 0.56$).

Discussion/Conclusion: The FAP correlates with the EDSS indicating it can be used to measure gait function in individuals with MS. The FAP gives more quantitative data than the EDSS. Further study is needed to determine if the FAP is more sensitive for measuring subtle changes in disease progression in people with MS.

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