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Multiple Sclerosis

CLINICAL AND LABORATORY RESEARCH

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WORLD CONGRESS ON TREATMENT AND RESEARCH IN MULTIPLE SCLEROSIS
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13th Annual Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis

24th Congress of the European Committee for Treatment and Research in Multiple Sclerosis

5th Congress of the Latin American Committee for Treatment and Research in Multiple Sclerosis

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understand that MS is not the only stressor in their lives. Participants reported positive results when mental health services were available at the MS Center. They believed that communication and collaboration between neurologists and mental health providers was an essential aspect of quality care. Participants whose family members were included in their treatment reported that it had been very helpful. Community referrals by Center staff led to good results for many participants. **Conclusions:** Patients indicated quality mental health care for MS patients includes early screening at MS Centers, care availability soon after diagnosis and beyond, by providers familiar with the issues faced by people with MS and their families, and collaboration between health care and mental health providers.
Supported by: National Multiple Sclerosis Society (USA).

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Employment discrimination experiences of adults with multiple sclerosis
Rick Roessler[1], Phil D. Rumrill[2]

[1]RHRC Department, University of Arkansas, Fayetteville, Arkansas, USA; [2]Kent State University, Kent, Ohio, USA

Background: This presentation reviews results of research on discrimination allegations and resolutions pertaining to employees with multiple sclerosis (MS) in the American workforce. The research was conducted with the support of the National Multiple Sclerosis Society and the United States Equal Employment Opportunity Commission (EEOC). **Objective:** Presenters will discuss the results of investigations a) comparing the employment discrimination encountered by workers with MS and workers with other types of disabilities; b) comparing the discrimination allegations and resolutions of women and men with MS; c) describing the predictors and patterns of perceived employment discrimination encountered by employees with MS; and d) analyzing the rate, type, and predictors of merit resolutions (i.e., allegations verified by the EEOC). **Methods:** With permission of the EEOC, the research team analyzed data that included all charges of employment discrimination resolved by the EEOC since implementation of the ADA in 1992 through 2003. **Results:** Selected conclusions from the research include: a) adults with MS were more likely than the comparison disability group to allege discrimination related to reasonable accommodations, terms of employment, constructive discharge, and demotion; b) women and men with MS reported similar background characteristics and patterns of employment discrimination, although some evidence suggested that women were more likely to file allegations of intimidation and harassment; c) the EEOC found no cause for discrimination in the majority of allegations filed by women and men with MS, although both groups had higher rates of merit closure than the comparison group; and d) merit closures were more likely to occur for reinstatement, reasonable accommodation, and terms of employment than for discharge. **Conclusions:** Findings support the need for early workplace intervention to help employees with MS identify and respond to instances of discrimination. Similarly both women and men with MS require additional information clarifying how to document allegations of discrimination and file such allegations with the EEOC.
Supported by: Healthcare Delivery and Policy Research Contract from the National Multiple Sclerosis Society (USA).

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A prospective study on clinical outcome of inpatient versus outpatient rehabilitation in subjects with multiple sclerosis
Biagio Ciccone[2], Filippo Martinelli Boneschi[1], Elda Judica[1], Paolo Rossi[1], Pasquale Vivo[3], Mauro Comola[1], Giovanna Griso[2], Claudio Crisci[2], Giancarlo Comi[1]

[1]Neurorehabilitation Unit, Neurological Dept. University 'Vita Salute' - Ospedale San Raffaele, Milano, Italy; [2]Multiple Sclerosis Rehabilitation Unit. Centro 'Salus', Centro 'Buonincontro', Marigliano-Casalnuovo, Napoli, Italy; [3]Multiple Sclerosis Center, Ospedale 'G. Moscati', Aversa, Caserta, Italy

Background: Several data support the utility of rehabilitation to improve clinical and functional performance of patients with multiple sclerosis (MS). It is still debatable whether intensive inpatient treatment results in a more evident benefit than outpatient treatment. **Objective:** In this study we evaluate the clinical and functional outcome of inpatient and outpatient rehabilitation in two different cohorts of patients with MS. **Methods:** We considered a group of 21 consecutive patients with both relapsing-remitting (RRMS) and secondary-progressive (SPMS) course of disease in two different region of Italy. All patients had worsening of neurological condition of at least 1.0 point on the Expanded Disability Status Scale (EDSS) in the last 12 months without superimposed relapses in the previous 3 months, and had an EDSS score of 3.5 to 6.5. Nine subjects (3 RRMS, 9 SPMS) underwent an intensive inpatient rehabilitation program in a Neurorehabilitation Department in Northern Italy and 12 patients (6 RRMS, 6 SPMS) followed the same program in a outpatient clinic in Southern Italy. As outcome measures we evaluated EDSS, Barthel Index (BI), time to walk.15 feet (t15F) and 9-Hole-Peg-Test (9HPT). Both groups are similar in basal data such as age, sex, duration of disease, EDSS, BI, and 9HPT. **Results:** We found that inpatient and outpatient rehabilitation gave a significant improvement in EDSS score ($p<0.0001$), 9HPT, BI ($p<0.02$), while there seemed to be no effective in t15F ($p=0.09$). Comparing inpatient vs outpatient outcome, we found that first group had significantly more improvement in EDSS, 9HPT and BI with respect to the outpatient group. We did not find any differences in outcome measures with respect to course of disease. **Conclusions:** Our data demonstrate that both inpatient and outpatient rehabilitation gave significant results in terms of clinical and functional improvement in MS patients regardless of their clinical course. Moreover, intensive inpatient rehabilitation provided greater benefit than outpatient rehabilitation.

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The relationship between baseline clinical measures and quality of life in patients with relapsing multiple sclerosis: analyses from the phase 3 trial of intramuscular interferon beta-1a
Richard Rudick[1], Deborah M. Miller[1], Bianca Weinstock-Guttman[2], Dennis N. Bourdette[3], Pamela Foulds[4], X. You[4]

[1]Mellon Center for Multiple Sclerosis Treatment and Research, Cleveland Clinic Foundation, Cleveland, Ohio, USA; [2]Baird Multiple Sclerosis Center, Buffalo, New York, USA; [3]Oregon Health and Science University, Portland, Oregon, USA; [4]Biogen Idec, Inc., Cambridge, Massachusetts, USA

Background: There is evidence that multiple sclerosis (MS) patients' quality of life (QoL) correlates with clinical measures such as the Expanded Disability Status Scale (EDSS) and relapse rate. **Objective:** To further evaluate the relationship between baseline QoL and clinical measures as well as the impact of intramuscular (IM) IFNβ-1a on QoL in relapsing-remitting MS (RRMS). **Methods:** In the pivotal phase 3 clinical trial, it was hypothesized that IM IFNβ-1a would improve QoL as measured by the Sickness Impact Profile (SIP) in patients with poorer baseline QoL. Hence, patients were stratified based on their baseline SIP score: intact QoL (SIP <10) or poorer QoL (SIP ≥10); SIP of 10 is ≥2 standard deviations away from values observed in healthy controls. The SIP, consisting of Total, Physical, and Psychosocial scores, was administered at baseline and every 6 months over 2 years. Correlation between baseline SIP and clinical measures (EDSS, relapse rate) was assessed using t-test and Pearson correlation analysis. **Results:** SIP data from 158 patients (Total <10, n=94; Total ≥10, n=64; Physical <10, n=117; Physical ≥10, n=41; Psychosocial <10, n=82; Psychosocial ≥10, n=76) were analyzed. Patients with higher Total ($P=0.017$) and Physical ($P<0.0001$) SIP scores had significantly higher baseline EDSS scores. Total SIP correlated with Cerebellar ($P=0.005$) and Bowel/Bladder ($P=0.003$) functional systems (FS). Physical SIP correlated with Pyramidal ($P=0.008$), Cerebellar ($P<0.0001$), Sensory ($P=0.0009$), and Bowel/Bladder ($P=0.0006$) FS. Psychosocial SIP correlated with Bowel/Bladder ($P=0.01$) FS only. In contrast, prestudy relapse rate did not correlate with SIP scores. EDSS progression (worsening by ≥1 point, sustained for 6 months) was associated with significant worsening in Physical scores over 2 years ($P=0.031$) compared with non-progression. Over 2 years, IM IFNβ-1a therapy significantly improved Physical scores in patients with poorer baseline QoL ($P=0.045$) compared with placebo. **Conclusions:** MS patients with greater disability and FS impairment had lower baseline QoL. Treatment with IM IFNβ-1a significantly improved QoL in these patients.
Supported by: Biogen Idec, Inc.

A PROSPECTIVE STUDY ON CLINICAL OUTCOME OF INPATIENT VERSUS OUTPATIENT REHABILITATION IN SUBJECTS WITH M.S.

Biagio Ciccone[2], Elda Judica[1], Filippo Martinelli Boneschi[1], Paolo Rossi[1], Pasquale Vivo[3], Mauro Comola[1], Giovanna Griso[2], Claudio Crisci[2], Giancarlo Comi[1]

Poster n. 414

Background and Objective

Several data support the utility of rehabilitation to improve clinical and functional performance of patients with MS. It is still debatable whether intensive inpatient treatment gives a more evident benefit than the outpatient treatment. In this study we evaluate clinical and functional outcome in two different cohorts of patients with M.S., comparing an intensive rehabilitation program versus an ambulatory one (inpatient vs outpatient).

METHODS

INPATIENT: 9 subj 4 M and 5 F - 3 RRMS and 6 SPMS
mean age 47.9 (28.5-58.9)

OUTPATIENT 12 subj 4 M and 8 F - 6 RRMS and 6 SPMS
mean age 45.2 (21-68)

We have evaluated 21 patients affected with MS both Relapsing-Remitting (RR) and Secondary-Progressive (SP) in two different rehabilitation centres in Italy. All patients have had worsening of neurological condition of at least 1.0 point at EDSS in the previous 12 months without superimposed relapses in the last 3 months. Moreover they had an EDSS score from 3.5 to 6.5. The first group of 9 subjects (3 RRMS and 6 SPMS) underwent an intensive daily rehabilitation program, twice a day, for three weeks in an inpatient neurorehabilitation clinic in northern Italy (inpatient - HSR). The other group of 12 patients (6 RRMS and 6 SPMS) followed a 6 month rehabilitation program,3 times a week, in a local outpatient centre in southern Italy (outpatient - Centro Salus). The following indicators have been used to evaluate outcome measures: EDSS, Barthel Index (BI), test of 15 feet (t15f) and 9-hole-peg test (9HPT). Outcome measures have been considered with the following time progression:

Baseline: evaluation of both groups at the beginning of the treatment.

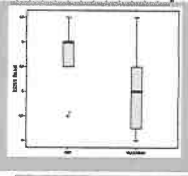
Time 1: Follow-up after 3 weeks of intensive rehabilitation for the inpatient group and after 3 months of ambulatory rehab program for the outpatient group

Time 2: Follow-up of 3 months after hospitalization without any rehabilitation treatment for the inpatient group and after adjunctive 3 months of ambulatory rehabilitation for the outpatient group.

BASAL — Test Statistics[a]

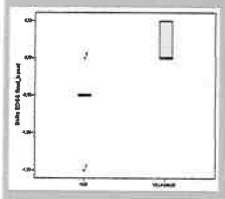
	Durata malattia	Età	Deviat12	dEDSS6	EDSS Basal	15 foot Basal	9HPT dx Basal	9 HPT sn Basal	Barthel Basal
Mann-Whitney U	46,000	43,000	37,000	45,000	24,000	41,000	45,000	45,000	50,000
Wilcoxon W	124,000	121,000	115,000	88,000	102,000	119,000	123,000	123,000	96,000
Z	-,570	-,783	-1,269	-,421	-2,173	-,629	-,040	-,040	-,252
Asymp. Sig. (2-tailed)	,569	,434	,205	,674	,030	,530	,968	,968	,801
Exact Sig. [2*(1-tailed Sig.)]	,602[b]	,494[b]	,247[b]	,854[b]	,034[b]	,582[b]	,954[b]	,954[b]	,808[b]

a. Not corrected for ties.
b. Grouping Variable: CENTRO



TIME 1 — Group Statistics

		N	Mean	Std. Deviation	Std. Error Mean
Delta EDSS final_basal	HSR	9	-,6667	,50000	,16667
	Centro SALUS	12	,1667	,24618	,07107
Delta 15 foot finAL_basal	HSR	9	-4,5700	5,52257	1,84086
	Centro SALUS	12	-1,2083	4,03089	1,16362
Delta 9 HPT dx final_ basal	HSR	9	-2,9222	24,60172	8,20057
	Centro SALUS	12	2,8333	9,02354	2,60487
Delta 9HPT sn final_ basal	HSR	9	-8,7056	8,63235	2,87745
	Centro SALUS	12	1,5833	3,23218	,93305
Delta Barthel final_basal	HSR	9	2,7778	2,68225	,89408
	Centro SALUS	12	,3333	1,96946	,56854



TIME 2 — Group Statistics

		N	Mean	Std. Deviation	Std. Error Mean
Delta EDSS fup_basal	HSR	9	-,2222	,97183	,32394
	Centro SALUS	12	,2083	,65017	,12995
Delta 15 foot fup_basal	HSR	9	2,4378	14,56019	4,85340
	Centro SALUS	12	-,8750	3,47832	1,00402
Delta 9 HPT dx fup_basal	HSR	9	6,0244	12,81792	4,27264
	Centro SALUS	12	,0833	7,25457	2,09421
Delta 9HPT sn fup_basal	HSR	9	-,6822	4,88647	1,62882
	Centro SALUS	12	,2500	5,42030	1,56720
Delta Barthel fup_basal	HSR	9	-1,6667	6,63325	2,21108
	Centro SALUS	12	1,3333	4,58959	1,41064

RESULTS

At the baseline there weren't significant statistical differences between both groups considering age, sex, length and course of the disease (RR vs SP) and the outcome measures used: BI, t15t, 9hpt, with the exception of the EDSS that scored 1 point more in inpatient group (EDSS 6) compared to the outpatient group (EDSS 5).

At time 1 there was a significant statistical difference. The HSR inpatient group had an improvement of all outcome measures compared to the Centro Salus outpatient group. The amount of improvement was of 0.5 on the EDSS scale.

At time 2 there weren't a significant statistical difference between the two groups. The inpatient group lost the initial improvement at time 2, while the outpatient group maintained with stability the score it had at baseline.

CONCLUSION

These data demonstrate the effectiveness of both in-patient and out-patient rehabilitative treatment with a more significant evidence for the in-patient intensive treatment at time 1. However this important gain decreases during the following 3 months in absence of a continuative rehabilitation program.
Outpatient continuative rehabilitation program seems instead to be able to preserve patient from progression of clinical disability as demonstrated by the slight improvement of EDSS score during the whole treatment period.

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3. Multiple Sclerosis Center, Ospedale "S. Maugeri", Avenza, Caserta, Italy.

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STUDIO PROSPETTICO SU RISULTATI CLINICI RIABILITATIVI IN PAZIENTI RICOVERATI RISPETTO A PAZIENTI AMBULATORIALI CON SM

Biagio Ciccone2, Elda Judica1, Filippo Martinelli Boneschi1, Paolo Rossi1, Pasquale Vivo3, Mauro Comola1, Giovanna Griso2, Claudio Crisci2, Giancarlo Comi1

Premessa e obiettivo

Diversi dati confermano l'utilità della riabilitazione nel miglioramento clinico e funzionale delle performance in pazienti con SM. E' ancora oggetto di dibattito se il trattamento intensivo di pazienti ricoverati dia un beneficio maggiore rispetto ai pazienti ambulatoriali. In questo studio abbiamo valutato i risultati funzionali e clinici tra due diversi gruppi di pazienti con SM, confrontando un programma riabilitativo intensivo rispetto ad uno ambulatoriale (inpatient vs outpatient).

Metodi:

Abbiamo valutato 21 pazienti con forma RR e SP di SM in due differenti regioni e centri di riabilitazione italiani. Tutti i pazienti erano peggiorati di almeno 1 punto all'EDSS negli ultimi 12 mesi ed erano liberi da ricadute negli ultimi tre mesi. Inoltre, i pazienti avevano un EDSS compreso tra 3.5 e 6.5.
Il primo gruppo di 9 soggetti (3 RRMS e 6 SPMS) sono stati sottoposti ad un programma intensivo di riabilitazione quotidiano con due sedute al giorno, per tre settimane, con ricovero presso un dipartimento ospedaliero di neuroriabilitazione nel Nord Italia (inpatients HSR). L'altro gruppo di 12 pazienti (6 RRSM e 6 SPSM) ha seguito un programma di neuroriabilitazione ambulatoriale di sei mesi, con una seduta tre volte a settimana, presso un centro territoriale di riabilitazione del Sud Italia (outpatient Centro Salus). Gli outcome sono stati valutati attraverso i seguenti indicatori: EDSS, Bartel Index (BI), test dei 15 piedi (t15f) e test dei nove pioli (9HPT). I tempi di valutazione degli outcome sono stati così divisi :

- tempo basale: valutazione dei due gruppi all'inizio del trattamento;
- tempo 1: follow-up dopo tre settimane di riabilitazione intensiva per il gruppo inpatient e dopo 3 mesi di programma riabilitativo ambulatoriale per il gruppo di outpatient;
- tempo 2: follow-up di 3 mesi dopo l'ospedalizzazione senza nessun trattamento riabilitativo per il gruppo inpatient e dopo aggiuntivi 3 mesi di riabilitazione ambulatoriale per il gruppo di outpatient.

Risultati

A tempo basale non c'erano differenze statisticamente significative fra i due gruppi di pazienti relativamente al sesso, all'età, alla durata e alla storia di malattia (RR verso SP) e agli indicatori di outcome scelti Bartel Index, test dei 15 piedi e test dei 9 pioli, tranne l'EDSS che era maggiore di 1 punto nel gruppo di inpatient (EDSS 6) rispetto a quella dei outpatient (EDSS 5).

A tempo 1 c'era una differenza statisticamente significativa. Il gruppo degli inpatient HSR aveva un miglioramento in tutti gli indicatori di risultato, rispetto al gruppo degli outpatient del Centro Salus. L'ammontare del miglioramento era di 0.5 sulla scala EDSS

A tempo 2 non c'erano differenze statisticamente significative fra i due gruppi. Il gruppo degli inpatient perdeva il miglioramento iniziale che aveva al tempo 2, mentre il gruppo ambulatoriale manteneva stabilmente il punteggio che aveva a tempo basale.

Conclusioni

Questi dati dimostrano l'efficacia di entrambi i trattamenti riabilitativi inpatient ed outpatient, con una maggiore significativa evidenza per il trattamento intensivo inpatient a tempo uno. Tuttavia questo importante guadagno diminuisce durante i successivi tre mesi in assenza di un programma riabilitativo continuo.
Il programma riabilitativo continuo outpatient sembra invece poter preservare il paziente dalla progressione della disabilità clinica come dimostrato dal leggero miglioramento del punteggio EDSS durante tutto il periodo di trattamento.

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A PROSPECTIVE STUDY ON CLINICAL OUTCOME OF INPATIENT VERSUS OUTPATIENT REHABILITATION IN SUBJECTS WITH MULTIPLE SCLEROSIS.

Background and Objective:

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