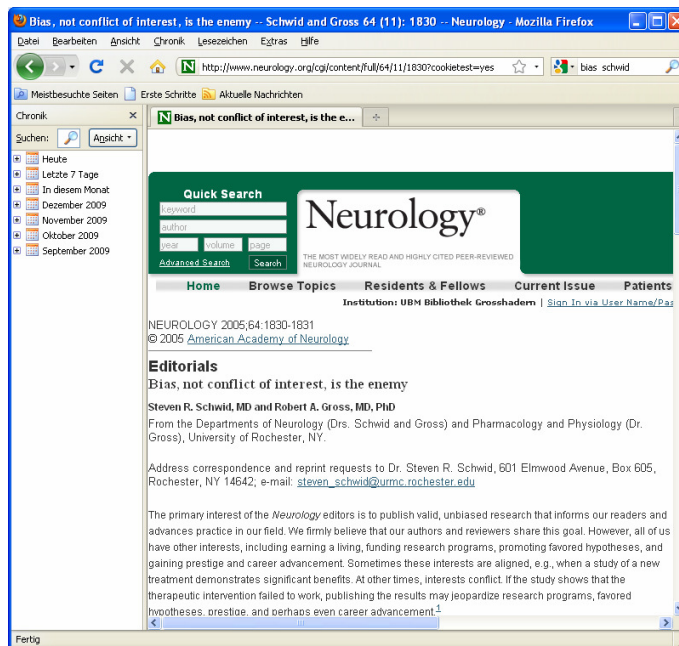




Evidence-Based Public Health
International Workshop
Munich, Germany, 17th and 18th November 2010
Martin Daumer



ARTICLES

Disability as an outcome in MS clinical trials

G.C. Ebers, MD
L. Hägenhauser, MSc
M. Daumer, PhD
C. Lakerer, PhD
J.H. Noseworthy, MD

ABSTRACT

Background: Inferences about long-term effects of therapies in multiple sclerosis (MS) have been based on surrogate markers studied in short-term trials. Preventing progressive disability is a key therapeutic goal but there remains no validated definition for its measurement in clinical trials. Meanwhile, MS trials continue to shorten and to depend on unvalidated surrogates. There have been no treatment claims for improving unremitting disability, worsening in the placebo/control arm must occur for effectiveness on this outcome to be shown.

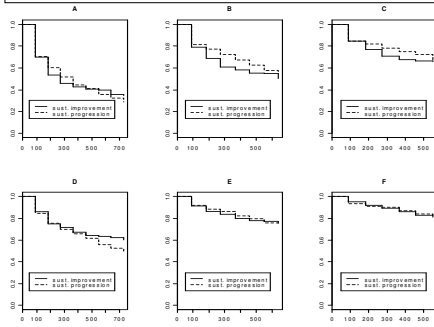
EDITORIAL

You get what you measure

Evaluating endpoints in MS clinical trials

Ruth Ann Maritz, MD, PhD

Since the emergence of the modern therapeutic era in multiple sclerosis (MS), the field has focused on preventing disability. However, improvement in physical health may occur without demonstrable benefit on vascular



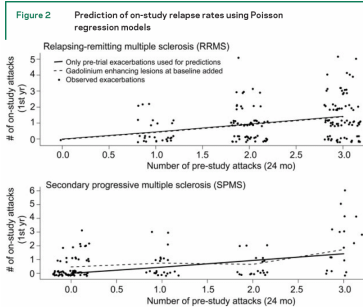
EBDiMS
Evidence-Based Decision Support
in MS

MRI as an outcome in multiple sclerosis clinical trials

M. Daumer, PhD
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R. Hintzen, MD
G.C. Ebers, MD

ABSTRACT

Introduction: T2-weighted and gadolinium enhanced T1-weighted MRI scans measure plaque burden and breakdown of the blood-brain barrier, respectively, in multiple sclerosis (MS) lesions. These have become widely used outcome measures for monitoring disease activity in clinical trials and clinical practice. However, their use as surrogates or biomarkers for disability and relapses, key clinical outcome measures, has remained incompletely validated.



Commentary: Outcome measures were flawed -- Ebers 340 -- bmj.com - Mozilla Firefox

http://www.bmj.com/content/340/bmj.c2693.full

Home > Archive > BMJ 2010; 340:c2693 doi:10.1136/bmj.c2693 (Published 3 June 2010)

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BMJ 2010;340:c2693 doi:10.1136/bmj.c2693 (Published 3 June 2010)
Cite this as: BMJ 2010;340:c2693

Analysis

Commentary: Outcome measures were flawed

G C Ebers, Action Research professor of clinical neurology

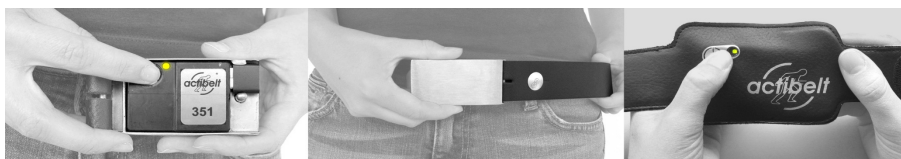
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 George.Ebers@cineuro.ox.ac.uk

Interferons were introduced for multiple sclerosis in the early 1990s, after US-Canadian trials showed effects on clinical relapse rate and magnetic resonance imaging (MRI) spots, which were taken as surrogate outcomes for disability.¹ The drug companies who marketed the interferons, and later glatiramer acetate, were given extended patent protection under the Orphan Drug Act. Under the terms of this act surrogate markers of response to treatment can

What's new
 ▪ Last 7 days
 ▪ Past weeks
 ▪ Current
 ▪ Rapid responses

Blogs
 ▪ Hamish white paper
 ▪ Richard Schloss
 ▪ David Pelearn
 ▪ Domhnall journals, Nov 2010
 ▪ Richard review – Nov 2010

Mobile accelerometry - actibelt®

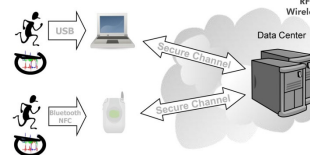


- What is actibelt®?
- The actibelt is a three-dimensional accelerometer integrated in a belt buckle.
- It can be used for the long term monitoring of a person's activity, and also for gait quality and postural stability assessment in clinical trials.
- Discrete, non-invasive, portable
- Placed near the COM

Hardware & Communications

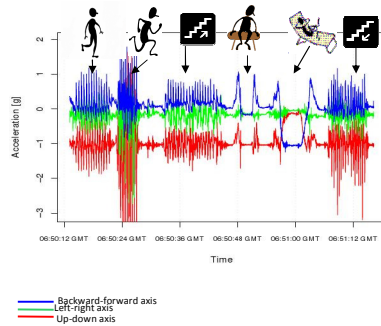
512 MB memory
 100 Hz sampling frequency
 operating time in full precision mode = 10 days
 battery life = 1 month

New prototypes include:
 temperature sensor
 barometric pressure sensor
 LED display
 Bluetooth
 RFID
 Wireless



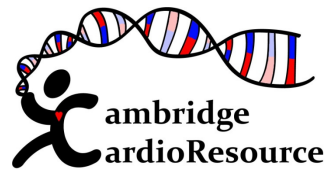
Mobile accelerometry - actibelt®

- Pattern of the acceleration signal near the body's COM while performing different activities



- Towards the standardization of a gait and balance quality assessment tool using mobile accelerometry.

"Black box" in RCT's



TOWARD A BIOBANK IN UK BLOOD DONORS



ACCELEROMICS MEETS GENOMICS – Physical activity and genes for personalized medicine

Results from an international expert panel meeting – Schloss Höhenried, Oct. 2010

- “Mobile accelerometry has great potential for improving human health by contributing to the diagnosis of gait and balance disorders in daily life and clinical practice, improving outcome measures in chronic disabling diseases as well as a tool for prescribing and monitoring exercise therapy.”



Selection of Projects

BEGIN study with Bayer Schering: Betaferon treatment and Exercise data Gathering IN early **MS**

PerCoMed: Case study “**MS** Nurses” in the “Rhön -Klinik” in Bad Neustadt

Clinical study with the Masku Neurological Rehabilitation Centre in Finland: Physical activity of patients with early multiple sclerosis (**MS**) as monitored with a new measure – ActiBelt

Clinical trials with **Lupus, Osteoporosis & MS**

PhD together with the Technical University Munich: actibelt and **Depression/Schizophrenia**

BWiiMi - Advanced Body Motion Analysis ABMA – **Sport Science**

FP7: VPHOP: Application of the actibelt within **osteoporosis** – fall risk prediction

FP7 Marie Curie ITN: Netsim: **CVD**

Parabola flights in Bordeaux in November 2006, in Houston in June 2007 and Cologne in September 2007

BMBF – German Competence Network **MS**: IPAT integrated platform for measuring physical activity as outcome and treatment option

Physical activity assessment in **osteoarthritis** using actibelt®, Mayo Clinic

CardioResource – **healthy blood donors**

