DOI: 10.1002/alz.075674

CLINICAL MANIFESTATIONS

POSTER PRESENTATION

Alzheimer's & Dementia®
THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION

NEUROPSYCHOLOGY

ALZHEIMER'S DEMENTIA EARLY DIAGNOSIS, CHARACTERIZATION, PROGNOSIS AND TREATMENT DECISION VIA A SOFTWARE-AS-MEDICAL DEVICE WITH AN ARTIFICIAL INTELLIGENT AGENT

Petronilla Battista[1,2] | Raffaello Nemni[3] | Paolo Vitali[4] | Marco Alì[5] | Moreno Zanardo[6] | Christian Salvatore[7,8] | Graziella Sirabian[9] | Dario Capelli[9] | Luciano Bet[6] | Edward Callus[6] | Enrico Giuseppe Bertoldo[10] | Valentina Fiolo[10] | Brigida Minafra[11] | Cira Fundarò[12] | Giuseppe Scotti[13] | Francesco Sardanelli[14] | Sergio Papa[3] | Isabella Castiglioni[7,15]

[1]Maugeri Clinical Inistitute IRCCS, Bari, Italy

[2]Global Brain Health Institute (GBHI) - UCSF, San Francisco, CA, USA

[3]Bracco Imaging - Centro Diagnostico Italiano – Milano, Milan, Italy

[4]Unit of Radiology, IRCCS Policlinico San Donato & Department of Biomedical Sciences for Health - Universita' degli Studi di Milano, Milan, Italy

[5]Centro Diagnostico Italiano - Bracco Imaging, Milan, Italy

[6]Department of Biomedical Sciences for Health - Università degli Studi di Milano, Milan, Italy

[7]DeepTrace Technologies S.r.l., Milan, Italy

[8]IUSS, Pavia, Italy

[9]Clinical Psychology Service - Centro Diagnostico Italiano, Milan, Italy

[10]Clinical Psychology Service - IRCCS Policlinico San Donato Milan San Donato Milanese, Milan, Italy

[11]Istituti Clinici Scientifici Maugeri IRCCS, Bari, Italy

[12]Istituti Clinici Scientifici Maugeri IRCCS, Pavia, Italy

[13]Bracco Imaging - Centro Diagnostico Italiano, Milan, Italy

[14]IRCCS Policlinico San Donato, San Donato Milanese, Italy

Abstract

Background: TRACE4AD (DeepTrace Technologies s.r.l, Italy) is a machine learning-based software-as-medical device able to predict the conversion to Alzheimer's disease (AD) dementia of subjects at risk within 24-months exploiting automatic processing of T1-weighted MPRAGE brain MRI study and neuropsychological tests. TRACE4AD provides a report with the predicted individual risk of conversion to AD dementia, specific cognitive deficits, and suggestions supporting neurologists in diagnosis and characterization, prognosis, and decision-making. We tested TRACE4AD in the clinical setting in its ability, at baseline, to: a) predict amnestic Mild Cognitive Impairment (MCI) conversion to AD dementia within 24-months; b) characterize cognitive deficits; c) support neurologists' decision-making.

Method: We retrospectively included 92 subjects (mean age 73.12±7.6, 46% female): 32 patients from two Italian centers where TRACE4AD was implemented after user training; and 60 subjects from the ADNI dataset. All patients had a brain MPRAGE study at baseline, 77/92 patients (83.7%) also performed a neuropsychological assessment at baseline, 75/92 patients (81.5%) had a stable clinical diagnosis at 24-month. TRACE4AD extracted the gray matter map from MPRAGE and used it (combined with cognitive measures when available) to make inferences. Reference standards were: a) the neurologist's clinical diagnosis at 24-months, b) the neuropsychological assessment at the baseline, c) the agreement with the neuro exam and intervention decision time and type defined by neurologists at the baseline.

Result: TRACE4AD accurately predicted conversion to AD dementia in 93.3% of patients based on the MRI, and in 96.6% based on MRI and cognitive measures. Cog-

[15]Università Milano Bicocca, Milan, Italy

Correspondence
Petronilla Battista, Maugeri Clinical Inistitute IRCCS, Bari, Italy.
Email: petronilla.battista@gbhi.org

nitive deficits were found in agreement with the neuropsychological assessment for all patients except one who presented with major depression. We found disagreement between the neurologist's decision at baseline and the tool in only two patients, defined with normal cognition by the neurologist and predicted at high risk of AD dementia conversion by the tool. TRACE4AD supported neurologists' decision by 12 months in 15/17 patients for the prompt decision at baseline.

Conclusion: TRACE4AD is promising, safe, and effective in supporting neurologists in the clinical practice of MCI across different centers.