Introducing BrainSee: A Novel, MRI-Based Virtual Microscope Technology for Non-invasive Prognosis of Amnestic MCI in Clinics and Clinical Trials

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ABSTRACT

Purpose

Prediction of progression from amnestic mild cognitive impairment (aMCI) to Alzheimer's dementia (AD) is a critical need in the evaluation and management of cognitive impairments. Darmiyan Inc. has developed a novel virtual microscope technology, *BrainSee*, for accurate and reliable prediction of progression from aMCI to AD (Alzheimer's Dementia) based on standard clinical brain MRI and basic cognitive screening. The purpose of this study was to evaluate:

1. The performance accuracy of *BrainSee* for 5-year prognosis of aMCI
2. The robustness of *BrainSee* to standard routine clinical-grade data
3. Test-retest reliability of *BrainSee*
4. The clinical utility and usability of *BrainSee's* quantitative whole brain maps

Materials and Methods

Data for third party validation were provided by the Knight ADRC (Washington University), Huntington medical research institutes (HMRI), Baycrest Institute, University Health Network (UHN), and GERAS Hamilton Health Sciences (HHS). De-identified data including basic patient demographics (age, sex, education), MMSE, CDRSB, and brain MRI (T1, T2, DWI or DTI) were provided for analysis. *BrainSee*'s algorithm was blind to the distribution and clinical outcomes of all patients. *BrainSee* generated a prognostic prediction of conversion to dementia within 5 years. Clinician's diagnosis at 5-year follow-up was considered the ground truth.

Prognosis analysis sample: 95 subjects, 101 independent clinical time points, age range 51 to 95 years, male to female ratio 1.18.

Test-retest reliability sample: 60 subjects, 78 scan sessions, age range 53 to 88 years, male to female ratio 1.21.

Results

Balanced accuracy of prognostic prediction = 91.0 %
Sensitivity = 89.2 %, Specificity = 92.9 %
PPV_pc = 92.6 %, NPV_pc = 89.6 % (prevalence corrected)
Test-retest coefficient of variation = 4.6%

BrainSee's report, grading system, and quantitative whole-brain maps were easy for clinicians to understand and interpret.

Conclusion

Darmiyan's novel virtual microscope technology (*BrainSee*) had a 91% prognostic performance accuracy on blind, clinical-grade brain MRI data from amnestic MCI patients and showed high test-retest reliability confirmed by third-party investigators. Darmiyan's *BrainSee* technology is therefore an accurate, non-invasive, and reliable tool to be used for prognostication of cognitive impairments in clinics and clinical trials.

References

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