Title
The incremental diagnostic value of 18F-Florbetapir imaging in naturalistic patients with cognitive impairment: the INDIA-FBP study.

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Background
Amyloid PET imaging enables the in vivo estimation of brain β-amyloid neuritic plaque density and can be used to support an Alzheimer’s Disease (AD) diagnosis in research settings (Albert et al., 2011). The added value of amyloid PET imaging in clinical settings is less known. Data are starting to emerge but still limited (Vandenberghe et al., 2013; Grundman et al., 2012).

Aim
We report preliminary findings about the incremental diagnostic value of 18F-Florbetapir amyloid PET on top of routine assessment in an Italian naturalistic setting.

Methods
The study started in Sept 2013 and plans to enroll 250 patients coming to observation of 21 Alzheimer’s Evaluation Unit in Eastern Lombardy, Italy, until Dec-2014. 30 healthy elderly controls (HC) will also be enrolled. Patients will undergo a diagnostic work-up according to usual local practice. Physicians will formulate a clinical diagnosis and rate their diagnostic confidence (range between 15% and 85%). Patients will undergo 18F-Florbetapir PET. Diagnosis, diagnostic confidence and treatment plan will be revised based on 18F–Florbetapir scan results.

Preliminary results
During the first 5 months, 73 patients and 9 HC were enrolled. Of these, 57 patients completed their diagnostic work-up. Clinical diagnosis were as follows n=15 MCI due to AD; n= 23 AD; n=3 FTD; n=7 MCI not due to AD; n=9 had other dementias (PDD, DBL, CBS). 56 patients and 8 HC underwent 18F-Florbetapir PET. Negative scans occurred in 18% of AD, 33% of MCI due to AD, 29% of MCI not due to AD, 33% of FTD, 33% of patients with other dementias. Two HC had a positive amyloid-PET scan. To date, the diagnosis was re-evaluated post-amyloid imaging in 40 patients, and 18F-florbetapir results led to a change in diagnosis in 42% of these patients. The diagnostic
confidence increased significantly after amyloid imaging for both confirmed and changed clinical diagnoses (15% and 17% increase in confidence respectively, p<0.0005). Amyloid PET positivity had a significant impact on the therapeutic plans of patients with an initial diagnosis of AD, MCI due to AD or DLB, with an increase of 29% in the prescription of AChE (p=0.01).

**Conclusion**
18F-Florbetapir PET has a significant impact on diagnosis, diagnostic confidence and treatment plan of dementia experts.