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Amyloid positron emission tomography candidates may focus more on benefits than risks of results disclosure

Jennifer H. Lingler[a,b,*], J. Scott Roberts[c], Hyejin Kim[a], Jonna Morris[a], Lu Hu[d], Meghan Mattos[e], Eric McDade[f], Oscar Lopez[b,g]

[a]Department of Health and Community Systems, School of Nursing, University of Pittsburgh, Pittsburgh, PA, USA
[b]Alzheimer Disease Research Center, School of Medicine, University of Pittsburgh, Pittsburgh, PA, USA
[c]Department of Health Behavior and Health Education, University of Michigan School of Public Health, Ann Arbor, MI, USA
[d]New York University Medical Center, New York, NY, USA
[e]School of Nursing, University of Virginia, Charlottesville, VA, USA
[f]Department of Neurology, School of Medicine, Washington University, St. Louis, MI, USA
[g]Department of Neurology, School of Medicine, University of Pittsburgh, Pittsburgh, PA, USA

Abstract

Introduction: Given mounting calls to disclose amyloid positron emission tomography (PET) research results to participants, we explored factors underlying decisions by patients with mild cognitive impairment to receive amyloid imaging results.

Methods: Prospective, qualitative interviews were conducted with 59 participants (30 = mild cognitive impairment patients, 29 = care partners) from the scan arm of an RCT on the effects of amyloid PET results disclosure in an Alzheimer Disease Research Center setting.

Results: Sixty-three percent of the participants were female, with an average age of 72.9 years, and most had greater than a high school level of education (80%). Motivations included the following: (1) better understanding one's mild cognitive impairment etiology and prognosis to plan ahead, and (2) learning one's brain amyloid status for knowledge's sake, regardless of whether the information is actionable. Most participants demonstrated an adequate understanding of the scan's limitations, yet instances of characterizing amyloid PET as a definitive test for Alzheimer's disease occurred. Mention of potential drawbacks, such as negative psychological outcomes, was minimal, even among care partners.

Discussion: Findings demonstrate a risk of disproportionate focus on possible benefits of testing among amyloid scan candidates and suggest a need to clearly emphasize the limitations of amyloid PET when counseling cognitively impaired patients and their families before testing. Future research should examine whether minimizing drawbacks at the pre-imaging stage has adverse consequences on results disclosure.

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1. Introduction

Despite the rapid proliferation of imaging-based and other biomarkers for Alzheimer's disease (AD) in research and practice, investigations into how patients and families view undergoing predictive or diagnostic testing for AD are limited. Understanding the motivations for, and perceived drawbacks of, pursuing such testing will be critical to developing best practices for providing information and support to candidates for AD biomarker testing. The need for such data is underscored, on the one hand, by advocates for early detection of AD who are working to minimize barriers to diagnostic testing [1], and on the other hand, by commentators who caution against indiscriminately screening for AD pathology in the absence of a preventative or curative intervention for those who test positive [2,3].

Regarding positron emission tomography (PET) amyloid imaging, there is growing consensus that patients and research participants who will receive their scan results should be adequately counseled before imaging [4–7]. Efforts to develop such pretest counseling (PTC) protocols have focused on considerations unique to cognitively healthy individuals [8] and those with mild cognitive impairment (MCI) [7]. Early evaluations of protocols to inform MCI patients of the benefits, risks, and limitations of amyloid PET have shown PTC to be well received and comprehensible to patients [7]. Yet, prospective studies of factors influencing real-time decisions to pursue amyloid imaging are limited. One recent study documented that the ability to better understand one's brain heath and make future decisions to be the main reasons MCI research participants seek amyloid PET results [9]. Extending this line of inquiry, we examined factors influencing decisions to pursue amyloid PET among both scan candidates with MCI and their family members, focusing on a critical 2-week window following PTC, but before scheduling a scan.

2. Methods

2.1. Study design, sample, and setting

We conducted a prospective, interview-based qualitative study as part of a larger, ongoing investigation of how amyloid PET disclosure impacts the understanding of and ability to cope with a diagnosis of MCI. Patients with MCI and their care partners (typically family members) were recruited into the ongoing parent study from the University of Pittsburgh Alzheimer Disease Research Center (ADRC; NIA grant P50 AG005133) beginning in October of 2015. Of the 113 ADRC participants invited by the ADRC staff, 75 (66%) agreed to be referred to the parent study; to date, 72 of those have enrolled. Primary reasons for declining to participate in the parent study included health problems on the part of either the patient or the care partner and concerns that the study was very time consuming. Inclusion criteria for the parent study were as follows: (1) a current ADRC consensus diagnosis of MCI (isolated impairment in memory, isolated deficit in non-memory domain, or mild deficits in multiple cognitive domains) [10]; (2) the capacity to provide informed consent based as verified by the University of San Diego Brief Assessment of Capacity to Consent [11,12]; (3) residence within 100 miles from the university (to facilitate home study visits); and (4) having a care partner who also consented to participate. Exclusion criteria were as follows: (1) familial AD genetic mutation carriers (this group already has biomarker-based AD risk information); and (2) active, untreated mood, or anxiety disorders defined as a Hamilton Depression Rating Scale [13] score of >17 or a Spielberger State Anxiety [14] score of >40. Care partner participants had to be 18 years of age or older. The sample for the sub study reported herein consists of the first 30 dyads (participant + care partner) to undergo a qualitative interview as described below.

2.2. Procedures

This research was approved by the University of Pittsburgh Institutional Review Board. All patients with MCI and their care partners provided informed consent, but one care partner later declined the qualitative interview. Baseline interviews for the parent study included a 10-point self-rating of interest in pursuing amyloid PET and receiving the scan results. Higher ratings indicated greater interest in obtaining a scan. Participants completed this scale at baseline and following the qualitative interview that is the focus of this report. After baseline data collection, all parent study participants were randomized to a scan with results disclosure group or to a comparison group with an MCI education session. All participants were informed of their group assignment at the completion of the baseline visit. An exception was made for individuals who had previously undergone a research PET amyloid scan under a protocol that precluded results disclosure. The randomization process was overridden in these cases, and these individuals were placed in the scan group, with the opportunity to undergo a new amyloid PET scan and results disclosure.

Scan group participants underwent formal PTC. Based on a protocol described previously, PTC sessions were conducted by master's prepared clinicians and included an overview of MCI and AD, followed by a presentation of the purpose of amyloid imaging and its potential pros, cons, and limitations in the context of MCI [7]. At the end of PTC, dyads were encouraged to carefully consider whether or not they wanted to pursue amyloid imaging. During a 2-week interim between PTC and the scheduling of the scan (if decided upon), a qualitative interview was conducted to capture participants' perspectives on the decision-making process in real time. The interview guide contained five semi-structured questions (e.g., "Tell me about your experience with deciding whether or not to get the scan.") and 15 follow-up probes (e.g., "What kinds of factors did you consider when making your decision?"). Questions were open-ended and neutrally worded (See Table 1). Interviewers were trained in qualitative data collection and instructed to probe for clarification when ambiguous or conflicting statements were made. Interviews were completed in participants' homes by two study staff members, one who interviewed the patient and another who simultaneously interviewed the care partner. Interviews were audio-recorded and transcribed verbatim.

2.3. Data analysis

The current report describes findings from qualitative analysis of the first 30 dyads in the scan group to undergo a qualitative interview after PTC. Descriptive analysis of this subsample was conducted using IBM SPSS Statistics for Windows, version 24.0. Interview data were managed in ATLAS.ti 7.0 and analyzed using the qualitative method of constant comparison [15]. This method centers the analysis on comparing and contrasting data between and within interview transcripts