Decisional capacity in cognitively impaired patients with Parkinson disease

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Decline in complex abilities is a crucial early clinical dimension of neurodegenerative diseases such as Alzheimer dementia (AD)[1–3] and Parkinson disease (PD),[4,5] and of their prodromal states such as mild cognitive impairment (MCI).[6,7] As memory and executive cognitive abilities decline, these patients demonstrate initially subtle but increasingly salient changes in important decisional capacities such as treatment consent, research consent, and financial decision-making. These progressive decisional impairments raise critically important ethical issues concerning patients' personal autonomy and competency, with implications for patients and families, and for physicians, scientists, bioethicists, and legal professionals.[1,4] For example, meaningful consent to participate in research is possible only when the person giving it has the capacity to understand and use disclosed information to decide whether to enroll in a proposed research protocol.[8] Such decisional capacity assessments are particularly relevant, but have not always been conducted, in aggressive surgical trials such as deep brain stimulation.[9]

The great majority of decisional capacity research in dementia has been conducted in patients with AD and amnestic MCI.[1–3,6] In contrast, relatively little is known about the trajectory of decisional impairments that occur in PD dementia (PDD) and its prodrome (PD-MCI). The prominent motor symptoms in PD may have obscured cognitive and neuropsychiatric contributions to patients' functional decline. Only a few studies have empirically examined impaired decision-making in prodromal and clinical PDD.[4,5,7] This represents an unfortunate knowledge gap in clinical PD research. From a scientific standpoint, the neuropathologic, neuropsychiatric, and motor aspects of PDD differ notably from AD, so the natural history of decisional impairment in PDD is also likely to differ. Until the nonmotor effects of PD on decision-making capacity are better understood, clinical assessment of decisional impairment and functional disability in patients with PD is likely to remain confounded.

For these reasons, the study conducted by Karlawish et al.[10] in the current issue of *Neurology*® is a welcome and timely scientific contribution to the field of PD clinical research. The authors focused on research consent capacity (RCC) in a sample of patients with PD representing a broad spectrum of cognition. While earlier studies addressed treatment consent capacity in PD,[4,5,7] the topic of RCC is of major import to the PD scientific field. The continuing search for effective medications and ultimately a cure depends heavily on the volunteerism of patients with PD and their families participating in research and in particular clinical trials. Accurate assessment of these patients' capacity to participate in research is thus of vital importance to the PD scientific enterprise.

In their study, Karlawish et al. investigated RCC in a sample of cognitively normal elderly subjects, cognitively normal patients with PD, and patients with PD with borderline impaired cognition or impaired cognition (n = 30 per group, total n = 120).[10] Key outcome measures were the 4 consent abilities of the MacArthur Competence Assessment Tool for Clinical Research (McCAT-CR) and the independent capacity judgment outcomes of 3 expert physician raters. The authors found that patients with PD with both borderline impaired and impaired cognition had impairments in RCC, whereas cognitively normal patients with PD did not. The authors also found that the Montreal Cognitive Assessment (MoCA), a simple cognitive screen, showed more sensitivity than the Mini-Mental State Examination in detecting impaired RCC in patients with PD at risk for impaired decisional capacity. Strengths of the study included the relatively large sample of patients with PD stratified into 3 cognitive groups, the use of a modified McCAT-CR and the Appelbaum/Grisso consent ability model, the use of 2 different research consent scenarios that presented differential risk scenarios for evaluating RCC, and the use of expert raters as an alternative assessment modality to the McCAT-CR.

The article's most important and interesting finding was that patients with PD with "borderline cognitive impairment" (i.e., patients without frank dementia) demonstrated impairments in research consent abilities and represented a "clearly vulnerable" group.[10] This finding echoes closely that of the earlier PD treatment consent

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studies, which found that, in relation to older controls, patients with PD-MCI demonstrated deficits across a range of medical consent abilities, in particular understanding.[7] Taken collectively, the message from these studies is clear: impairment in decisional capacity is already present in cognitively impaired patients with PD without dementia, and increases as these patients develop dementia. Thus research coordinators need to carefully screen for decisional capacity in all cognitively impaired participants with PD and, as Karlawish et al. point out (in perhaps an abundance of caution), even in "cognitively normal" participants with PD.

A final kudo is related to Karlawish and colleagues' care in qualifying their findings regarding the power of simple mental status screens to predict RCC outcomes in PD. For researchers and clinicians alike, it is tempting but specious to conflate cognitive screening and capacity assessment outcomes. Karlawish et al. properly resist this temptation, stating emphatically that "measuring cognition with the MoCA is not a substitute for capacity assessment."[10] Capacity assessments, which ultimately concern an individual's personal autonomy and freedom to make a defined set of decisions, must never be relegated to outcomes on a capacity-remote mental status test. The authors should be commended on a valuable new contribution to the emerging capacity literature in PD.

AUTHOR CONTRIBUTIONS

Daniel Marson: drafting/revising the manuscript, study concept or design, analysis or interpretation of data. Linda Hershey: drafting/revising the manuscript, study concept or design, analysis or interpretation of data.

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DISCLOSURE

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