



Published in final edited form as:

*JAMA Intern Med.* 2014 September ; 174(9): 1514–1516. doi:10.1001/jamainternmed.2014.3450.

## Use of Cardiac Implantable Electronic Devices in Older Adults With Cognitive Impairment

**Nicole R. Fowler, PhD, MHSA, Kim G. Johnson, MD, Jie Li, MS, Charity G. Moore, PhD, Samir Saba, MD, Oscar L. Lopez, MD, and Amber E. Barnato, MD, MPH, MS**

Division of General Internal Medicine, Department of Medicine, School of Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania (Fowler, Moore, Barnato); Department of Psychiatry, Duke University Medical Center, Durham, North Carolina (Johnson); Center for Research on Health Care, University of Pittsburgh, Pittsburgh, Pennsylvania (Li, Moore); Division of Cardiology, Department of Medicine, School of Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania (Saba); Department of Neurology, School of Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania (Lopez).

Older adults with mild cognitive impairment (MCI) and dementia have cardiac comorbidities, making them eligible for device-based therapy for cardiac rhythm abnormalities.<sup>1-3</sup> The risks and benefits of device implantation should be weighed carefully by patients with cognitive impairment, family members, and clinicians given the potential of these devices to have an impact on the quantity and quality of life. This study describes the epidemiology of cardiac implantable electronic devices among a population-based sample of older adults with and without cognitive impairment.

### Methods

We conducted a retrospective cohort study of de-identified data from the National Alzheimer Coordinating Center Uniform Data Set<sup>4</sup> gathered prospectively from 33 Alzheimer Disease Centers (ADCs) from September 2005 through December 2011. The

Copyright 2014 American Medical Association. All rights reserved.

**Corresponding Author:** Nicole R. Fowler, PhD, MHSA, Division of General Internal Medicine, Department of Medicine, School of Medicine, University of Pittsburgh, 200 Meyran Ave, Ste 300, Pittsburgh, PA 15213 (fowlernr@upmc.edu).

**Author Contributions:** Drs Fowler and Barnato had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Fowler, Johnson, Saba, Lopez, Barnato. **Acquisition, analysis, or interpretation of data:** Fowler, Li, Moore, Lopez, Barnato.

**Drafting of the manuscript:** Fowler, Johnson, Lopez, Barnato.

**Critical revision of the manuscript for important intellectual content:** Fowler, Li, Moore, Saba, Lopez, Barnato.

**Statistical analysis:** Fowler, Li, Moore.

**Obtained funding:** Fowler.

**Administrative, technical, or material support:** Fowler.

**Study supervision:** Fowler, Saba, Lopez, Barnato.

**Conflict of Interest Disclosures:** None reported.

**Previous Presentations:** This work was previously presented as a poster at the American Geriatrics Society Meeting; May 3, 2013; Grapevine, Texas; and at the Annual Meeting of the Society for Medical Decision Making; October 21, 2013; Baltimore, Maryland.

**Additional Contributions:** Sarah Monsell, MS, from the University of Washington and the National Alzheimer's Coordinating Center, assisted with obtaining and interpreting the data and reviewed the manuscript. Greg Sachs, MD, from Indiana University School of Medicine, reviewed a final draft of this manuscript prior to submission. They were not compensated for their participation.

institutional review board of the University of Pittsburgh approved the study. The sample included participants with a baseline ADC visit and at least 1 follow-up visit during the study period. Participants without cognitive impairment included ADC normal controls and participants who had minor deficits on cognitive testing but did not meet criteria for MCI or dementia. The dependent variable was incident (new) device, assessed at each ADC visit as determined by the clinician's best judgment based on informant report, medical records, and observation. The independent variable was cognitive status, measured by ADC diagnosis and Clinical Dementia Rating (CDR) Scale.<sup>5</sup>

We fitted generalized estimating equation models with a binomial distribution and logit link function accounting for cognitive status and CDR the visit before the device was implanted and for multiple pairs of consecutive visits for each participant allowing for time-varying cognitive status. We used a multiple comparison Bonferroni correction to compare each level of the independent variable to the group without cognitive impairment and adjusted for age, sex, race, intensity of pacemaker use in the ADC hospital referral region,<sup>6</sup> as well as time-varying health status, cardiac comorbidity burden, functional status, and Hachinski Ischemic Score.

## Results

There were 16 245 participants with a baseline visit and at least 1 follow-up visit in the study period. At baseline 7446 (45.8%) had no cognitive impairment, 3460 (21.3%) had MCI, and 5339 (32.9%) had dementia. Participants with cognitive impairment were significantly older and more likely to be male and to have ischemic heart disease and stroke. However, they had similar rates of atrial fibrillation and congestive heart failure (**Table 1**). Over the 7-year study period, rates of incident pacemakers were 4 per 1000 person-years for participants without cognitive impairment, 4.7 per 1000 person-years for participants with MCI, and 6.5 per 1000 person-years for participants with dementia ( $P = .001$ ) (**Table 2**). Incidence of implantable cardioverter-defibrillators in all cognitive groups was low ( 0.5 per 1000 person-years) and prohibited multivariable modeling.

In adjusted models, participants with dementia the visit before assessment for an incident pacemaker were 1.6 (95% CI, 1.1-2.5) times more likely to receive a pacemaker compared with participants without cognitive impairment ( $P = .02$ ) (Table 2). In the model that accounted for cognitive status over consecutive visits, participants with stable dementia were 1.8 (95% CI, 1.2-2.8) times more likely ( $P < .01$ ) to receive a pacemaker compared with those without cognitive impairment (Table 2). In a separate model for severity of cognitive impairment, participants with a CDR of 3 (severe dementia) were 2.9 (95% CI, 1.2-7.4) more likely to receive a pacemaker than those with a CDR of 0 (no cognitive impairment) ( $P = .02$ ) (Table 2).

## Discussion

Patients with dementia were more likely to receive a pacemaker than patients without cognitive impairment, even after adjusting for clinical risk factors. This runs counter to the normative expectation that patients with a serious life-limiting and cognitively disabling

illness might be treated less aggressively. While it is possible that unmeasured confounding by indication explains this observation, future research should explore the patient, caregiver, and clinician influences on decision making regarding cardiac devices in this population.

## Acknowledgments

**Funding/Support:** This study was supported by the Agency for Healthcare Research and Quality (AHRQ), grant K12HS019461, and National Institutes of Health (NIH), National Institute on Aging, grant P50 AG05133. The National Alzheimer Coordinating Center database is funded by the NIH, National Institute on Aging, grant U01 AG016976.

**Role of the Sponsor:** The AHRQ and NIH had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

## References

1. Launer LJ. Demonstrating the case that AD is a vascular disease: epidemiologic evidence. *Ageing Res Rev.* 2002; 1(1):61–77. [PubMed: 12039449]
2. DeCarli C. The role of cerebrovascular disease in dementia. *Neurologist.* 2003; 9(3):123–136. [PubMed: 12808409]
3. Vermeer SE, Prins ND, den Heijer T, Hofman A, Koudstaal PJ, Breteler MMB. Silent brain infarcts and the risk of dementia and cognitive decline. *N Engl J Med.* 2003; 348(13):1215–1222. [PubMed: 12660385]
4. National Alzheimer Coordinating Center Uniform Data Set (UDS) Coding Guidebook. [October 18, 2013] <https://www.alz.washington.edu/NONMEMBER/UDS/DOCS/VER2/ivpguide.pdf>.
5. Morris JC. The Clinical Dementia Rating (CDR): current version and scoring rules. *Neurology.* 1993; 43(11):2412–2414. [PubMed: 8232972]
6. [April 23, 2012] Dartmouth Atlas of Health Care. <http://www.dartmouthatlas.org/tools/downloads.aspx>.

Table 1

## Baseline Demographics by Cognitive Status

Characteristic	Baseline Cognition, No. (%)			P Value
	No Cognitive Impairment (n = 7446)	MCI (n = 3460)	Dementia (n = 5339)	
Age, mean (SD), y	72.4 (10.08)	74.05 (9.25)	73.63 (10.20)	<.001 <sup>a</sup>
Sex male	2637 (35.4)	1704 (49.2)	2623 (49.1)	<.001
White race	6047 (81.2)	2810 (81.2)	4456 (83.5)	<.001
Follow-up visits, mean, No.	3.72 (1.39)	3.39 (1.30)	3.12 (1.21)	<.001 <sup>a</sup>
Years from first pacemaker or ICD implant to death, mean (SD)	2.58 (1.21)	2.75 (1.41)	2.48 (1.46)	.33 <sup>a</sup>
Clinical dementia rating, mean (SD)	0.08 (0.19)	0.45 (0.18)	1.10 (0.69)	<.001 <sup>a</sup>
MMSE, mean (SD)	28.79 (1.58)	27.15 (2.46)	20.56 (6.46)	<.001 <sup>a</sup>
Hachinski ischemic score	0.74 (1.10)	1.05 (1.50)	1.09 (1.61)	<.001 <sup>a</sup>
Functional status				
Independent	7143 (95.9)	2596 (75.0)	1060 (19.9)	<.001
Requires some assistance with complex activities	223 (3.0)	755 (21.8)	2592 (48.6)	
Requires some assistance with basic activities	63 (0.9)	88 (2.5)	1213 (22.7)	
Completely dependent	8 (0.11)	6 (0.2)	436 (8.2)	
Unknown	9 (0.12)	15 (0.4)	38 (0.7)	
Pacemaker status, baseline	157 (2.1)	96 (2.8)	167 (3.1)	.001
ICD, baseline	3 (0.0)	3 (0.1)	5 (0.1)	.46
Ischemic heart disease	796 (10.7)	511 (14.8)	664 (12.4)	<.001
Atrial fibrillation	369 (5.0)	192 (5.6)	239 (4.5)	.09
Congestive heart failure	120 (1.6)	67 (1.9)	91 (1.7)	.07
Stroke or TIA	58 (0.8)	42 (1.2)	75 (1.4)	<.001
Diabetes mellitus	818 (11.0)	458 (13.2)	613 (11.5)	<.001
Comorbidity burden <sup>b</sup>				
None	5527 (74.2)	2309 (66.7)	3732 (69.9)	<.001
1	1447 (19.4)	829 (24.0)	1198 (22.4)	
2	380 (5.1)	241 (7.0)	315 (5.9)	
3	79 (1.1)	72 (2.1)	80 (1.5)	
4	11 (0.2)	7 (0.2)	10 (0.2)	
5	0	0	0	
Hypertension	3929 (52.8)	1967 (56.9)	2811 (52.7)	<.001
Hypercholesterolemia	3742 (50.3)	2000 (57.8)	2854 (53.5)	<.001
Cholinesterase inhibitor use	129 (1.7)	630 (18.2)	2395 (44.9)	<.001
Cardiac drug use <sup>c</sup>	3567 (47.9)	1978 (57.2)	2747 (51.5)	<.001

Abbreviations: ICD, implantable cardioverter-defibrillators; MMSE, Mini-Mental State Examination; TIA, transient ischemic attack.

<sup>a</sup>P value of analysis of variance tests.

<sup>b</sup>Includes a count of ischemic heart disease, atrial fibrillation, congestive heart failure, stroke/TIA, diabetes mellitus.

<sup>c</sup>Includes any use of angiotensin-converting enzyme inhibitor, anti-adrenergic,  $\beta$ -blocker, anticoagulant, antiplatelet, or angiotensin.

**Table 2**

## Impact of Cognitive Status on Receipt of Incident Pacemaker

Cognitive Status	Adjusted OR (95% CI) <sup>a</sup>
Cognitive status the visit before assessed for incident pacemaker	
MCI <sup>b</sup>	1.2 (0.9-1.7)
Dementia <sup>c</sup>	1.6 (1.1-2.5)
No cognitive impairment <sup>d</sup>	1 [Reference]
CDR the visit before assessed for incident pacemaker	
0.5, MCI	1.5 (1.1-2.1)
1, Mild dementia	1.6 (1.0-2.5)
2, Moderate dementia	1.5 (0.7-3.1)
3, Severe impairment	2.9 (1.2-7.4)
0, No cognitive impairment	1 [Reference]
Cognitive status the visit before and the visit assessed for incident pacemaker	
Stable MCI at both visits	1.1 (0.7-1.7)
Stable dementia at both visits	1.8 (1.2-2.8)
No cognitive impairment with decline to MCI or dementia	1.3 (0.8-2.3)
MCI with decline to dementia	1.7 (1.0-3.1)
Dementia or MCI with an improvement to MCI or no impairment	1.2 (0.6-2.3)
Stable; no cognitive impairment at both visits	1 [Reference]

Abbreviations: CDR, clinical dementia rating; MCI, mild cognitive impairment; OR, odds ratio.

<sup>a</sup>Analyses were adjusted for sex; age; race; pacemakers per 1000 Medicare beneficiaries in the Alzheimer Disease Centers hospital referral region; and time-varying variables for functional status, cardiac comorbidity status, hypertension, and Hachinski Ischemic Score.

<sup>b</sup>Unadjusted rates of incident pacemaker device, 4.7 per 1000 person-years.

<sup>c</sup>Unadjusted rates of incident pacemaker device, 6.5 per 1000 person-years.

<sup>d</sup>Unadjusted rates of incident pacemaker device, 4.0 per 1000 person-years.