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Cluster Enrollment: A Screening Tool for Stroke Risk Factors in Minority Women Caregivers

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Abstract

BACKGROUND AND PURPOSE: Women minorities have an overall increased lifetime incidence of cerebrovascular disease. The provision of risk factor modification in this group can prove difficult. In a population-based study, we used cluster enrollment to identify vascular risk factors in the female caregivers of stroke survivor study participants.

METHODS: Obese women caregivers were identified as part of Swipe out Stroke, a Phase I PROBE study assessing the use of SmartPhone based intervention for dietary modification in minority stroke survivors. After written informed consent was obtained, both patients and caregivers were screened for vascular risk factors at study enrollment. Descriptive statistics were used to depict the study population. Continuous baseline variables were compared using 2 sample *t*-test or Wilcoxon rank-sum test by caregivers and patients. Categorical baseline variables were compared using Fisher's exact test.

RESULTS: Thirty-six stroke patients (63.9% African-American, 36.1% Hispanic) and thirteen female caregivers (69.2% African-American, 30.8% Hispanic) were enrolled. Mean age, patients – 54.1 (SD 9.4), caregivers - 51.3 (SD 15.6) years, education, employment status and family history of stroke or obesity did not differ significantly. Compared to stroke patients, female caregivers

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were significantly less likely to self-report hypertension (69.2 versus 97.2%; $P=0.01$) and hyperlipidemia (16.7 versus 60%; $P=0.02$).

Female caregivers were more likely to have elevated systolic blood pressure (147.6 vs 127.7 mmHg; $P=0.05$), total cholesterol (207.5 versus 167 mg/dL; $P=0.01$) and low density lipoprotein values (119.5 versus 88 mg/dL; $P=0.03$) compared to stroke patients.

CONCLUSIONS: Using cluster enrollment, we discovered minority female caregivers were more likely to have unknown or poorly controlled vascular risk factors compared to stroke patients. Innovative health screening tools may benefit the extended family of minority patients participating in clinical trials.

Keywords

race; ethnicity; women; primary prevention; obesity; clinical trial; caregiver; risk factor; disparities

Introduction:

Stroke in Women & Minorities

Disparities in the diagnosis and treatment of stroke risk factors in women are a major public health concern. Compared to men, women have greater stroke related disability, higher mortality and an overall increased lifetime risk [1,2]. Women accounted for 58% of stroke-related death in the U.S. in 2014, and non-Hispanic black women showed a higher incidence of age-adjusted death compared to other races [2].

One way to reach this at-risk female population is through their role as caregivers. Caregivers and stroke survivors have significant similarities, such as education level and socioeconomic status, which have been shown to increase stroke risk [3]. Unfortunately, most stroke related caregiver interventions focus on assessing burnout, depression and health related quality of life [4], not the assessment or modification of stroke risk factors. Innovative protocols to screen minority women caregivers for vascular risk factors are needed to engage this high-risk group. Swipe out Stroke (SOS) explored the feasibility of using a SmartPhone application to engage stroke caregivers in risk factor modification through weight monitoring. The focus of the present study was to evaluate the baseline stroke risk factors of female caregivers enrolled in SOS.

Methods:

Swipe out Stroke, a Phase I, prospective, randomized controlled trial with open-blinded endpoint (PROBE), served as a unique opportunity to engage stroke caregivers through cluster enrollment (NCT 02531074) [5]. After Institutional Review Board (IRB) approval, a total of 36 obese [body mass index (BMI) of 30 to 45 kg/m²], minority stroke survivors were randomized to the use of a SmartPhone based mobile application or a food journal for weight loss. Each participant's caregiver was asked to voluntarily participate in SOS prior to randomization, a total of 18 caregivers agreed, 13 were women. The remaining 18 caregivers chose not to participate due to lack of interest (10), one personal SmartPhone per household (6) and work responsibilities (2). Written informed consent was obtained from all

participants, who were either African-American or Hispanic, and lived within a 200-mile radius of Houston, Texas.

Demographics and cardiovascular risk factors such as BMI, systolic blood pressure (SBP), total cholesterol, high-density lipoprotein (HDL) and low-density lipoprotein (LDL) were collected in both patients and female caregivers, with normative ranges derived from American Heart Association (AHA) guidelines [6,7]. In both groups, all study measurements were collected within two weeks of the index stroke. Descriptive statistics were used - mean $\pm$ standard deviation for BMI and SBP; median and interquartile range were used for Montreal Cognitive Assessment (MOCA) and cholesterol measures. Two sample *t*-test or Wilcoxon rank-sum test were used to compare continuous baseline variables; Fisher's exact test was used to compare categorical baseline variables. All analyses were performed using SAS 9.4 (Cary, NC); $P < 0.05$ was considered significant.

Results:

The majority of female caregivers were married, employed, high school graduates with a mean age of 51.3 years (Table 1). Median MOCA score of 26 among caregivers fell in normative range compared to patient MOCA score of 23.5 ($P = 0.02$; Table 1). A larger proportion of patients self-reported hypertension (97.2 vs. 69.2%; $P = 0.01$) and hyperlipidemia (60 vs. 16.7%; $P = 0.02$; Table 1).

Mean caregiver SBP exceeded patient SBP by 19.9 mmHg (147.6 vs. 127.7, $P = 0.05$; Table 2). Caregiver total cholesterol (207.5 mg/dL, $P = 0.01$) and LDL cholesterol (119.5 mg/dL; $P = 0.03$; Table 2) were significantly elevated compared to patient values. HDL cholesterol was significantly elevated in the patient group, both groups were within normative range (57 vs. 44 mg/dL; $P = 0.04$; Table 2).

Discussion:

The engagement of minority stroke caregivers during the acute stroke period identified a new, majority female population with limited knowledge or attenuated treatment of existing vascular risk factors. In Swipe out Stroke, female caregivers had three of the seven American Heart Association components of intermediate to poor cardiovascular health – total cholesterol > 200 mg/dL, SBP ≥ 140 mm Hg and BMI > 30 kg/m² [8]. Furthermore, the female caregiver mean BMI of 40.8 is indicative of Class 3, or high risk obesity [9], which further amplifies cerebrovascular disease risk.

Stroke statistics for minority women are foreboding. Age adjusted hypertension-attributable mortality rates per 1000 persons for non-Hispanic white, non-Hispanic black and Hispanic-American women were 15.8, 35.6 and 14.6 respectively [10]. Our study findings highlight the opportunity to use innovative engagement strategies, such as SmartPhone applications, to promote recognition of stroke risk factors in high-risk groups.

The majority of Swipe out Stroke caregiver participants were married employed women. Although the psychological and social consequences of caregiving and its economic benefit to society are well recognized, caregivers' medical needs, particularly women caregivers, are

often given a low priority [11]. Singh-Manoux et al showed among midlife women, clinical risk factors, such as hypertension, obesity and hyperlipidemia, were important predictors of first metabolic disease, however, socioeconomic and behavioral factors determined progression to multimorbidity [12]. Therefore, changes in familial roles, coupled with increased financial pressures, can potentially serve as a nidus for cardiovascular disease progression in the caregiver population.

Time spent on caregiver activities are an additional barrier to self-care. Haley et al found caregiving strain was significantly associated with higher estimated stroke risk compared with caregivers reporting no strain [3]. Male caregivers have been found to have more assistance, either through extended family or paid services, than female caregivers, which can decrease caregiving strain [13]. In this study, the five male caregivers had secondary support from female siblings, spouses or children.

In summary, innovations such as cluster enrollment could potentially be used to screen for undiagnosed, treatable vascular risk factors in the caregivers of stroke research participants. The most relevant future clinical trials could concomitantly focus on primary stroke prevention in caregivers, and secondary stroke prevention in stroke survivors. Community engagement networks, such as stroke support groups and community advisory panels, could be used to screen caregivers for hypertension and hyperlipidemia treatment studies. By using creative means to reach minority populations, we have opportunities to further bridge the disability gap in cerebrovascular disease.

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REFERENCES:

1. Bushnell C, McCullough LD, Awad IA, Chireau MV, Fedder WN, Furie KL et al. Guidelines for the prevention of stroke in women: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2014;45: 1545–158. [PubMed: 24503673]
2. Benjamin EJ, Blaha MJ, Chiuve SE, et al. Heart disease and stroke statistics–2017 update: a report from the American Heart Association. *Circulation*. 2017;135:e146–603. [PubMed: 28122885]
3. Haley WE, Roth DL, Howard G, Safford MM. Caregiving strain and estimated risk for stroke and coronary heart disease among spouse caregivers: differential effects by race and sex. *Stroke*. 2010;41:331–6. [PubMed: 20075357]
4. Bakas T, McCarthy M, Miller ET. Update on the State of the Evidence for Stroke Family Caregiver and Dyad Interventions. *Stroke*, 2017; 48, e122–5. [PubMed: 28351961]
5. Ifejika NL, Noser EA, Grotta JC, Savitz SI. Swipe Out Stroke (SOS): Feasibility and Efficacy of Using a SmartPhone Based Electronic Application to Improve Compliance with Weight Loss in

Obese Minority Stroke Patients and their Carers. *Int J Stroke* 2016;11:593–603. [PubMed: 26956032]

6. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for the management of dyslipidemia and prevention of cardiovascular disease. *Endocr Pract* 2017;23:1–87.
7. Fox CS, Golden SH, Anderson C, Bray GA, Burke LE, de Boer IH et al. Update on prevention of cardiovascular disease in adults with type 2 diabetes mellitus in light of recent evidence: a scientific statement from the American Heart Association and the American Diabetes Association. *Circulation*. 2015;132:691–718. [PubMed: 26246173]
8. Lloyd-Jones DM, Hong Y, Labarthe D, Mozaffarian D, Appel LJ, Van Horn L et al. American Heart Association Strategic Planning Task F, Statistics C. Defining and setting national goals for cardiovascular health promotion and disease reduction: The American heart association's strategic impact goal through 2020 and beyond. *Circulation*. 2010;121:586–613. [PubMed: 20089546]
9. Blackburn GL, Wollner S, Heymsfield SB. Lifestyle interventions for the treatment of class III obesity: a primary target for nutrition medicine in the obesity epidemic. *The American Journal of Clinical Nutrition*. 2010;91(1):289S–292S. doi:10.3945/ajcn.2009.28473D. [PubMed: 19906805]
10. Centers for Disease Control and Prevention. Compressed Mortality File: Underlying Cause of Death 1999–2013. 2014 Available at: <https://wonder.cdc.gov/mortsql.html>.
11. Anderson CS, Linto J, Stewart-Wynne EG. A population based assessment of the impact and burden of care-giving for long-term stroke survivors. *Stroke*. 1995;26:843–849. [PubMed: 7740578]
12. Singh-Manoux A, Fayosse A, Sabia S, Tabak A, Shipley M, Dugravot A, Kivimäki M. Clinical, socioeconomic, and behavioural factors at age 50 years and risk of cardiometabolic multimorbidity and mortality: A cohort study. *PLoS Med*. 2018;21;15(5):e1002571. doi: 10.1371/journal.pmed.1002571
13. Pinquart M, Sörensen S. Gender differences in caregiver stressors, social resources, and health: an updated meta-analysis. *J Gerontol B Psychol Sci Soc Sci*. 2006;61B:P33–P45.

Table 1:**Demographics & Self-Reported Stroke Risk Factors**

	Patients (n=36)	Female Caregivers (n=13)	P
Age, mean±SD	54.1 ± 9.4	51.3 ± 15.6	0.56 ^t
Race, n(%)			
Black	23 (63.9)	9 (69.2)	1.00 ^f
Hispanic	13 (36.1)	4 (30.8)	
Marital Status, n(%)			
Married/Domestic Partner	21 (58.3)	11 (84.6)	0.11 ^f
Not Married	15 (41.7)	2 (15.4)	
Employment status, n(%)			
Employed	20 (55.6)	9 (69.2)	0.58 ^f
Not Employed	2 (5.6)	1 (7.7)	
Retired/Receiving Disability	14 (38.9)	3 (23.1)	
Education, n(%)			
Associate's Degree/Other	5 (13.9)	1 (7.7)	0.58 ^f
Bachelor's Degree	3 (8.3)	1 (7.7)	
High School/Some College/GED	21 (58.3)	11 (84.6)	
Less than High School	5 (13.9)	0 (0)	
Montreal Cognitive Assessment, median(IQR)	23.5 (21 – 26)	26 (24 – 28)	0.02 ^w
Hypertension, n(%)	35 (97.2)	9 (69.2)	0.01 ^f
Hyperlipidemia, n(%)	21 (60)	2 (16.7)	0.02 ^f
Family History of obesity, n(%)	33 (94.3)	12 (92.3)	1.00 ^f
Family History of stroke, n(%)	24 (68.6)	11 (84.6)	0.47 ^f

^fP values by Fisher's exact test

^tP values by two sample *t*-test

^wP values by Wilcoxon rank sum test

Table 2:

Objective Health Measures

	Patients (n=36)	Female Caregivers (n=13)	P
Body Mass Index, kg/m ² , mean±SD	35.7 ± 5.7	40.8 ± 9.3	0.08 ^t
Systolic Blood Pressure, mmHg, mean±SD	127.7 ± 17.0	147.6 ± 32.7	0.05 ^t
Total Cholesterol *, median(IQR)	167 (140 – 187)	207.5 (157.5 – 229.5)	0.01 ^w
Low Density Lipoprotein *, median(IQR)	88 (73 – 116.5)	119.5 (85.5 – 146)	0.03 ^w
High Density Lipoprotein *, median(IQR)	44 (36– 48)	57 (42.5 – 64.5)	0.04 ^w

^t P values by two sample t-test

^w P values by Wilcoxon rank sum test

* units equal mg/dL