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The Relevance of Living Supports on Antiplatelet Adherence and Trial Participation: The SPS3 Trial

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Abstract

Background—While living with others has been associated with improved functional outcome after acute stroke, it is unclear if this affects adherence to stroke prevention measures. We examined the relationship between living arrangement and adherence to antiplatelet therapy (AP) assignment and participation status in an international randomized trial for secondary stroke prevention.

Methods—AP therapy adherence, trial retention outcomes, and baseline characteristics for participants enrolled in the Secondary Prevention of Small Subcortical Strokes Study (SPS3) were compared between those who lived alone vs. with others (n=2374). Participant status at end-of-trial was categorized into (1)on assigned antiplatelet, (2)off assigned antiplatelet by participant request, or (3)participant withdrew consent/lost to follow-up. Multivariable multivariate logistic regression was used to identify patient features at entry predictive of participant status at trial end.

Results—Living arrangement, alone vs. with other(s), was not significantly associated with participant status. Participants enrolled in the US/Canada (OR 3.1, CI 2.0-5.0, vs. Latin America), taking more (7+) prescription medications (OR 1.7, CI 1.1-2.7, vs. 0-2 medications), and scoring lower on the Stroke Specific Quality of Life (SSQoL) scale (OR 1.3, CI 1.1-1.5, per 10 points) were more likely to withdraw or become lost-to-follow-up in the study versus completing the study on assigned AP. Participants enrolled in the US/Canada (OR 5.0, CI 2.4-10.0, vs. Latin America) and taking fewer (0-2) medications (OR 1.9, CI 1.2-3.1 vs. 3-6 medications) were more likely to request discontinuation of assigned antiplatelet medication vs. completing the study.

Conclusions—Living with others was not independently predictive of protocol adherence in this cohort. Number of medications and Stroke Specific Quality of Life (SSQoL) scale score may be more indicative of likelihood of trial participation and acceptance of long-term antiplatelet regimen.

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Keywords

Living support; trial participation; adherence; antiplatelet therapy; retention; clinical trial; stroke

Introduction

Living with a spouse or family member has been associated with improved overall health outcomes, including reduced cardiovascular risk factors, increased likelihood of seeking general medical care, and reduced mortality. [1,2] In the aftermath of stroke, the leading cause of adult-acquired disability in North America, living alone is likewise associated with adverse outcomes, including increased length of hospital stay and decreased medication compliance following discharge. [3-7] However, this has not been universally observed; a study investigating stroke scale validity in a European population found that living conditions prior to stroke did not predict independent survival at three and six months within the six simple variable (SSV) model. [8]

Little is known about the relationship between living arrangement and adherence to study protocols in the context of secondary stroke prevention trials, though poor medication adherence affects efficacy and safety of pharmacotherapeutic interventions and may reduce preventative benefits of antiplatelet therapy. [9] A previous analysis of antiplatelet adherence for secondary stroke prevention in a clinical trial found 18% of patients prematurely ceased assigned AP treatment for no clear medical reason. Older age and higher aspirin dosage were associated with poor antiplatelet adherence. [10]

Aims

Available data investigating structural social support in the general adult population suggests a weak association between adults living with another person and increased medication adherence. [11] While pre-stroke living status has been used to predict functional outcome after acute stroke, [12] to our knowledge living status has not been investigated as a characteristic in secondary stroke prevention trials to predict completion of trial on assigned AP treatment.

We investigated the association between living status, as an indicator of functional and structural support, and antiplatelet therapy adherence and trial participation measures in participants enrolled in the Secondary Prevention of Small Subcortical Strokes study.

Methods

The SPS3 study rationale, design, participant characteristics, and results have been published elsewhere. [13-15] Briefly, persons with a recent (within 180 days) small subcortical stroke were randomized simultaneously in a 2×2 factorial design to an antiplatelet therapy (double-blind, aspirin + placebo vs. aspirin + clopidogrel) and a target level of systolic blood pressure. Ineligible patients included those with significant cognitive impairment (MMSE ≥ 2 SD below the mean for age and education) or moderate-severe disability (modified Rankin

scale > 3). Living arrangement status was collected at study entry for all patients randomized from the year 2005 onwards. The 646 patients (21%) randomized prior to this time were excluded from our analyses. SPS3 participants enrolled in 2005 onwards were followed for up to 6 years. [14]

Post-stroke disability in terms of functionality and independence in activities of daily living (ADL) was measured at study entry by the modified Rankin scale and the Barthel Index. [16] Mild cognitive impairment was defined psychometrically; neuropsychological test scores were adjusted for region, age, and education. [17] The Stroke Specific Quality of Life (SSQoL) scale, [18] a self-reported measure of quality of life across 12 domains, was administered 3 months following randomization. The modified frailty index was also calculated for this analysis from baseline data as a summary measure of participant mortality and morbidity risk. [19] Data was gathered in SPS3 for all 11 items scored in the index, with one point given for each of: non-independent functional status (defined in this analysis as Barthel Index score < 95), diabetes, chronic obstructive pulmonary disease, congestive heart failure, myocardial infarction, prior cardiac surgery/PCI/angina, hypertension, peripheral vascular disease, impaired sensorium (defined in this analysis as adjusted MMSE <25th percentile for age and education), stroke or TIA without deficit, and stroke with neurologic deficit. Minimum score in SPS3 participants was one due to inclusion criteria requiring prior subcortical stroke.

Participants were required to attend quarterly in-clinic follow-up visits following randomization. At each visit, participants underwent blood pressure measurement, received study medications, and responded to questionnaires assessing quality of life, concomitant medications, side effects, endpoint detection, and adverse events.

Antiplatelet adherence, determined by pill count, was computed as an average across all follow-ups for each patient. At each quarterly followup visit, compliance for each of the antiplatelet bottles was computed, and the minimum compliance of the two included in the computation of the average compliance for each patient. Pill counts were not performed when the participant temporarily or permanently discontinued assigned antiplatelet study medication.

Status for each participant at the end of antiplatelet trial was categorized as: (1) on assigned antiplatelet, (2) off assigned antiplatelet by participant request, or (3) participant withdrew consent/was lost-to-follow-up. The “on assigned AP” group included participants who permanently discontinued their assigned antiplatelet medication for a medical reason (i.e. experienced an endpoint or adverse event, required another antithrombotic, could not tolerate the study medication, etc) and did not withdraw or were lost to followup. Participants could withdraw consent at any time.

Participant characteristics and protocol adherence measures were compared between groups using Student's t-test or ANOVA for continuous variables and a chi-square test (or Fishers' exact test if expected cell count < 5) for categorical variables. Multivariable binomial and multinomial logistic regression were used to identify patient features independently associated with patient status at end of the antiplatelet trial. All statistical tests were two-

sided, and significance was accepted at the 0.05 level. All analyses were done using SPSS Statistics for Windows, Version 20 (Armonk, NY).

Results

Living arrangement at study entry was collected for the 2374 participants enrolled in SPS3 from 2005 onwards: 424 participants lived alone, 1932 lived with a spouse, relative, or other person(s), and 18 lived in a nursing home. The 18 participants living in nursing homes were excluded from subsequent analyses due to insufficient numbers.

Compared to those living with other(s), participants living alone were more likely to be female, white, more educated, not currently married, and living in the US or Canada. (Table 1) Eight percent of participants from Latin America lived alone, compared with 17% in Spain, and 23% in the US/Canada ($p < 0.001$). Those living alone were more independent with respect to basic activities of daily living and mobility (Barthel Index score ≥ 95), and were less frail.

Participant compliance was generally high overall with 91% of included participants attending at least 80% of their follow-up appointments, and with only 4% of patients requesting to discontinue study medication and 9% withdrawn or lost-to-follow-up. Those living with others attended more follow-up appointments and were more adherent to their assigned antiplatelet regimen as measured both by pill counts and self-report. More participants living with others “completed” the study, as opposed to requesting to discontinue assigned antiplatelet or withdrawing consent/being lost-to-follow-up. (Table 2)

Participants who requested discontinuation of study medication or who withdrew or were lost to follow-up more often lived in the US/Canada, had lower SSQoL scores, were more frail, and were prescribed more medications. (Table 3) In a multivariable model considering all significant ($p < 0.05$) study entry covariates from Table 3, each of site location ($p < 0.001$), SSQoL score ($p = 0.002$), and number of concomitant medications ($p = 0.02$) was independently associated with end of study status. (Table 4) Participants enrolled in the US/Canada, taking more prescription medications, and scoring lower on the SSQoL (at 3 mo) were more likely to withdraw or become lost-to-follow-up in the study. Participants enrolled in the US/Canada and taking fewer (0-2) medications were more likely to request discontinuation of assigned antiplatelet medication. Living arrangement was not independently predictive of end of trial status.

As few participants enrolled in Latin America and Spain requested to discontinue assigned antiplatelet (n=9 and n=16 respectively) or withdrew consent/lost-to-followup (n=24 and n=24 respectively), or were living alone (Latin America 8%; Spain 17%) compared with the US/Canada (23%), we also examined the US/Canada cohort (n = 1315) separately. (Supplementary Tables e-1 and e-2) Participant characteristics at entry independently associated with end of study status were SSQoL score ($p = 0.02$) and number of concomitant medications ($p = 0.008$). (Table 4) As in the full cohort model, participants taking fewer (0-2) medications at study entry were more likely to request permanent discontinuation of assigned antiplatelet therapy but less likely to withdraw consent or be lost to followup.

Participants scoring lower on the SSQoL were again more likely to withdraw consent or become lost to followup.

Discussion

In this large, well-defined cohort of patients with symptomatic lacunar infarcts, we found that living alone was not independently associated with overall trial retention or adherence to assigned antiplatelet therapy over the duration of the trial. Strengths of our analysis include its size and representation of participants from a number of countries and minority groups, as well as its prospective nature in the context of a large, randomized trial. Our study is the first, to our knowledge, to examine study medication compliance and participation as related to living arrangements within a cohort of patients with small vessel disease and minimal physical disability.

Few participants in Latin America lived alone, and few requested to discontinue assigned antiplatelet or withdrew consent/lost-to-follow-up. Whether this result represents a strong association between living supports and participation in this context, or whether patients living alone were proportionally underrepresented in the trial participants as compared to in a real-world clinical context, is unclear from our available data. Factors contributing to medication adherence and follow-up visit participation are complex, and our analysis is limited by an incomplete characterization of other factors that could be of potential importance, including changes in living arrangements or cognition over time, alcohol abuse, socioeconomic status, or diagnosed depression. Assessing adherence by pill count also requires the assumption that missing pills have been taken, and validity is debated and possibly context-specific, [20,21] though pill count has demonstrated similar adherence estimates to blood pressure medication when compared to electronic monitoring in a hypertensive population. [22] The external generalizability of our study may also be limited by the inclusion and exclusion criteria of the SPS3 trial.

Lacunar stroke may be associated with better short-term clinical and functional outcomes than other stroke subtypes, [23] though over the longer term patients may face an increased burden of disability due to recurrent ischemic infarcts, intracranial hemorrhage, white matter disease and dementia. [24] In our cohort, quality of life as measured by the SSQoL scale captured participants with greater residual deficits post-stroke who were more likely to discontinue participation in the trial; this instrument consists of 12 most commonly affected domains following stroke. [18] As participants in our study who lived alone were more independent in activities of daily living and less frail, overall well-being captured in the SSQoL, including social roles and self-care components, may more aptly reflect the impact of social and home support than living arrangement considerations alone in stroke trial participation.

However, despite the relatively low mean age (63 years) of our patients, our results are consistent with other studies demonstrating an association between complexity of therapy, number of medications and adherence, especially in those with cognitive impairment. [25] In our study, taking very few medications was associated with antiplatelet discontinuation by request, while the participants taking the most medications more often withdrew or were lost

to follow up. Applied within the Health Beliefs Model, the participants taking the least medications at study entry may have had fewer coexisting conditions or deficits, possibly contributing to perceived lack of severity of their condition and therefore did not believe consequences for non-adherence to be serious. [26] Conversely participants taking more medications are less medically well, resulting in increased complexity of treatment and possibly lower quality of life, and possibly less able to manage a strict clinical trial protocol and withdraw completely or become lost to follow-up over the course of the trial.

While stroke trial investigators need to stress the benefits of remaining on assigned treatments and attending follow-up visits as scheduled to all participants, comprehensive domain-specific quality of life and functionality scale scores, rather than living arrangement status, are likely of greater utility to investigators for identifying trial participants at higher risk for lost-to-follow up and/or poor study medication adherence. Integration of quality of life score algorithms into trial protocols for the purpose of identifying participants in need of additional contacts or referral to other health care providers to optimally manage comorbidities and post-stroke rehabilitation may increase adherence and completion of study protocol.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Table 1
Demographic and clinical characteristics of SPS3 participants by living arrangements

	Living alone; own home (n = 424)	With spouse/relatives/others (n = 1932)	p-value
Age, mean (sd)	63 (11)	63 (11)	0.3
Male gender, %	58	65	0.02
Ethnicity, %			< 0.001
White, not Hispanic	60	47	
Hispanic	16	39	
Black	22	12	
Other or multiracial	2	2	
Region, %			< 0.001
United States	57	43	
Canada	16	9	
Mexico/Latin America	12	32	
Spain	15	15	
Education, %			< 0.001
0-4 yrs	7	14	
5-8 yrs	15	18	
9-12 yrs	39	37	
any college	40	31	
Marital status, %			< 0.001
never married	23	5	
married/common law	16	76	
separated/divorced	37	10	
widowed	25	9	
Mild cognitive impairment, %	44	44	1.0
Barthel Index ≥ 95, %	85	78	0.001
Modified Rankin Score, %			0.2
0	17	15	
1	55	52	
2	23	25	
3+	6	9	
Stroke-specific Quality of Life score at 3 mo, mean (sd) (n = 2213)	49 (9)	48 (10)	0.09
Prior symptomatic small subcortical stroke or TIA, %	14	15	0.9
Frailty index			

	Living alone; own home (n = 424)	With spouse/relatives/others (n = 1932)	p-value
mean (sd)	3.2 (1.2)	3.4 (1.2)	0.003
1-2	27	23	0.01
3	37	32	
4	23	27	
5+	13	18	
# Prescription medications, mean (sd)	4.1 (2.3)	4.0 (2.6)	0.4
0-2	28	28	0.4
3-6	56	59	
7+	16	13	

Table 2
Various adherence measures by living arrangements

Outcomes by living situation	Living alone; own home (n = 424)	With spouse/relatives/others (n = 1932)	p-value
Median (IQR) follow-up in years	2.6 (2.6)	2.9 (2.9)	0.08
Follow up appointment attendance, %			< 0.001
≥ 80%	86	92	
< 80%	14	8	
Status at end of AP trial*, %			0.04
On assigned AP	84	88	
Off assigned AP per patient request	5	4	
Withdrew consent or lost to-follow-up	11	8	
Mean pill count compliance while on assigned AP, %			0.003
80-110%	90	94	
< 80% or > 110%	10	6	
Reports taking assigned AP as directed, %			0.003
≥ 80% of follow-ups	90	94	
< 80% of follow-ups	10	6	

* On assigned AP group includes participants who permanently discontinued study medication during trial due to endpoint, other medical reason, or medication intolerance.

Table 3
Baseline demographic and clinical characteristics by trial participation status

	On Assigned AP (n = 2060)	Off assigned AP per patient request (n = 94)	Withdrew consent or lost to-follow-up (n = 202)	p-value
Age, mean (sd)	63 (11)	64 (12)	62 (11)	0.4
Male gender, %	64	66	56	0.08
Ethnicity, %				< 0.001
White, not Hispanic	48	55	55	
Hispanic	37	20	20	
Black	13	20	23	
Other or multiracial	2	4	2	
Region, %				< 0.001
United States/Canada	53	73	76	
Mexico/Latin America	31	10	12	
Spain	16	17	12	
Education, %				0.3
0-4 yrs	13	12	9	
5-8 yrs	18	12	16	
9-12 yrs	38	35	39	
any college	32	41	35	
Marital status, %				0.07
never married	8	9	11	
married/common law	66	55	57	
separated/divorced	14	21	18	
widowed	12	15	14	
Living arrangement, %				0.04
alone in own home or apt	17	22	24	
with others in home or apt	83	78	76	
Mild cognitive impairment, %	43	50	50	0.1
Barthel Index ≥ 95, %	79	82	81	0.6
Modified Rankin Score, %				0.4
0	15	19	17	
1	53	47	50	
2	24	24	28	
3	8	10	5	
Stroke-specific Quality of Life score at 3 mo, mean (sd) (n = 2213)	48 (9)	47 (10)	46 (10)	0.002

	On Assigned AP (n = 2060)	Off assigned AP per patient request (n = 94)	Withdrew consent or lost to-follow-up (n = 202)	p-value
Prior symptomatic small subcortical stroke or TIA, %	14	10	19	0.09
Frailty index				
mean (sd)	3.3 (1.2)	3.3 (1.1)	3.6 (1.3)	0.008
1-2	25	21	20	0.02
3	33	41	29	
4	26	26	27	
5+	16	12	25	
# Prescription medications, mean (sd)	3.9 (2.2)	4.1 (2.6)	4.7 (2.6)	< 0.001
0-2	29	24	28	
3-6	60	56	51	
7+	12	20	28	< 0.001

Table 4
Independent participant characteristics associated with trial status

All Sites	Off assigned AP per patient request*	Withdrew consent or lost to-follow-up*
Site location		
US/Canada	ref group	ref group
Latin America	0.20 (0.10, 0.41)	0.32 (0.20, 0.51)
Spain	0.54 (0.27, 1.1)	0.69 (0.43, 1.1)
# of prescription medications		
0-2	ref group	ref group
3-6	0.52 (0.32, 0.86)	1.2 (0.80, 1.7)
7+	0.63 (0.32, 1.3)	1.7 (1.1, 2.7)
Stroke-specific Quality of Life score at 3 months per 10 point decrease	1.2 (0.93, 1.5)	1.3 (1.1, 1.5)

US-Canada only	Off assigned AP per patient request*	Withdrew consent or lost to-follow-up*
# of prescription medications		
0-2	ref group	ref group
3-6	0.50 (0.29, 0.88)	1.3 (0.75, 2.2)
7+	0.41 (0.17, 0.94)	2.1 (1.1, 3.8)
Stroke-specific Quality of Life score at 3 months per 10 point decrease	1.2 (0.91, 1.5)	1.3 (1.1, 1.6)

* compared to patients who continued on assigned antiplatelet (see methods)