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Risk of all-cause mortality and its association with health status in a cohort of community-dwelling older people: FIBRA study

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Abstract *This article aims to estimate the risk of death according to sociodemographic characteristics, chronic diseases, frailty, functional capacity, and social participation in older people as well as determine the median time of death in relation to health status and social participation. A retrospective longitudinal study was conducted with older people (≥65 years) in 2008-09 and 2016-17 in the city of Campinas and the subdistrict of Ermelino Matarazzo in the city of São Paulo. Face-to-face interviews were conducted at community centers and the participants' homes. The cumulative incidence of death was estimated and associations with the predictor variables were analyzed using Poisson multiple regression. The Kaplan-Meier method and the log-rank test were also used. Among the 741 individuals located at follow-up, 192 had deceased. The incidence of death was higher among those who reported having heart disease and those who were dependent on others regarding the performance of instrumental activities of daily living. The incidence of death was lower among women, individuals in the highest income stratum, and those who performed three or more activities related to social inclusion. No differences in median survival times were found. Predictors of mortality can contribute to broadening knowledge on the singularities of the aging process.*

Key words *Mortality, Aged, Frailty, Activities of daily living, Social participation*

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Introduction

Population aging in Brazil and the world stems from demographic and epidemiological changes, scientific-technological advances, and improvements in quality of life, which have resulted in an increase in both longevity[1,2] and the prevalence of chronic noncommunicable diseases[2,3].

Like other age groups of the population, older Brazilians have a broad range socioeconomic characteristics[2,4] and considerable disparities in social support, psychosocial aspects, lifestyle, functional capacity[5], and access to healthcare services for the diagnosis, treatment, and control of chronic diseases[6]. Thus, there is a need for new care-related concepts, technologies, policies, and models focused on health promotion and the prevention of disease[7] that can enable healthy aging.

Data from the Mortality Information System on the distribution of deaths in the Brazilian population reveal that approximately 60% of all deaths occurs among individuals aged ≥65 years, with a higher prevalence among older women (68.5%) compared to older men (52.4%), particularly in the 65-to-74-year-old range. Records for the year 2018 on specific causes indicate that 65% of deaths among Brazilians 65 years of age or older were caused by diseases of the circulatory system, followed by neoplasms (tumors), and diseases of the respiratory system[8], which is similar to findings reported for other countries[9]. Accounting for more than 30% of deaths in this population group, cardiovascular diseases[8,10], especially ischemic heart disease and cerebrovascular disease, are the main cause of death and are associated with risk factors such as hypertension and diabetes *mellitus*[11], which occur with greater frequency and severity with the increase in age[12]. In 2007, 72% of all deaths in Brazil were attributed to noncommunicable diseases, with heterogeneous distribution in the population[13].

In this study, we test the hypothesis that frequent conditions among older people, such as frailty, functional limitations, and social isolation, increase the risk of all-cause mortality independently of sociodemographic characteristics and the presence of chronic diseases (such as cardiovascular disease), which are associated with death in all age groups.

Data from a systematic review of population-based studies published between 1990 and 2010 indicate the frail older people (based on the frailty phenotype) have lower survival rates and a 50% greater risk of death in comparison to non-frail older people[14]. A comparative study on measures of frailty in terms of the accuracy in predicting mortality revealed greater risk among frail older people (classified by the frailty phenotype)[15].

With the aging of the population and greater burden of chronic diseases, there has been an increase in functional loss and premature death[16]. The Epidoso Study, which followed up older people for 10 years in four home-based surveys, detected a 17.8% incidence of functional disability[17]. The loss of autonomy regarding the performance of instrumental activities of daily living, which reflect tasks of social independence[18], and its association with mortality has been described little in the literature.

Cross-sectional data from the English Longitudinal Study of Ageing (ELSA) show that social isolation, which is characterized by not having a spouse, having little face-to-face or telephone contact with family and friends, and non-participation in social organizations (clubs, religious groups, etc.), was associated with a greater risk of all-cause mortality (hazard ratio=1.28)[19]. Analyzing an aged cohort from the Bambuí Project (2004 to 2011), Gontijo et al.[20] found that social participation was independently associated with mortality, with a twofold higher risk among older people who did not participate in social groups or community associations.

The occurrence of conditions stemming from past and current exposures that vary according to sociodemographic characteristics underscores the need to estimate the magnitude of the independent risk of death among older people and identify modifiable factors that could be the target of interventions to assist in actions and strategies that can minimize predictive conditions of death. Using data from the *Fragilidade em Idosos Brasileiros* (Frailty in Brazilian Older People - FIBRA) study[21], the aim of the present study was to estimate the risk of death and associations with sociodemographic characteristics, chronic diseases, frailty, functional capacity, and social participation in community-dwelling older people as well as determine the median time of death in relation to health status and social participation.

Methods

A retrospective longitudinal study was conducted with individuals aged 65 years or older. The data were from the baseline (2008-2009) and follow-up (2016-2017) surveys of the FIBRA study

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conducted in the city of Campinas (state of São Paulo, Brazil) and the subdistrict of Ermelino Matarazzo in the city of São Paulo (state of São Paulo, Brazil).

At baseline, census sectors were selected and the groups were stratified by sex and age according to the census distribution of men and women aged ≥65 in these locations. The locations were selected by convenience[21] with final samples of 900 older people in Campinas and 384 in Ermelino Matarazzo. For the follow-up survey (2016-2017), recruitment was based on the lists of home addresses in the baseline databanks. The recruiters visited the addresses to locate participants and performed the data collection in the homes. Up to three attempts were made to locate each participant. In both municipalities, the confirmation of deaths and information on the deceased individuals were obtained from a family member and/or acquaintance. The interviewers also collected information on the informant. Data were obtained from 741 older people (523 in Campinas and 218 in Ermelino Matarazzo), 192 of whom had decreased (129 from Campinas and 63 from Ermelino Matarazzo) before the 2016-2017 follow-up of the FIBRA study (Figure 1).

Variables and measures

The variable of interest in the present study was the occurrence of death in the period (yes or no). In the occurrence of death, the date was verified by a family member (informant) in the follow-up study (2016-2017). For the analysis of risk factors (sociodemographic and health-related characteristics), the following variables from the baseline databank were considered:

▪ *Sociodemographic*: sex (female and male), age group (65 to 69, 70 to 74, and 75 years or older), schooling (none, one to four, and five or more years of study), and monthly family income *per capita* (in quartiles: up to R$ 830, R$ 831 to 1,200, R$ 1,201 to 2,000, and more than R$ 2,000).

▪ *Chronic diseases*: Morbidities were evaluated using nine dichotomous items based on self-reported information investigating whether a physician had ever performed a diagnosis of heart disease, systemic arterial hypertension, stroke, diabetes *mellitus*, cancer, arthritis/rheumatism, depression, lung disease, or osteoporosis (yes or no).

▪ *Functional capacity:* evaluated considering the self-reported the need for assistance for the execution of seven instrumental activities of

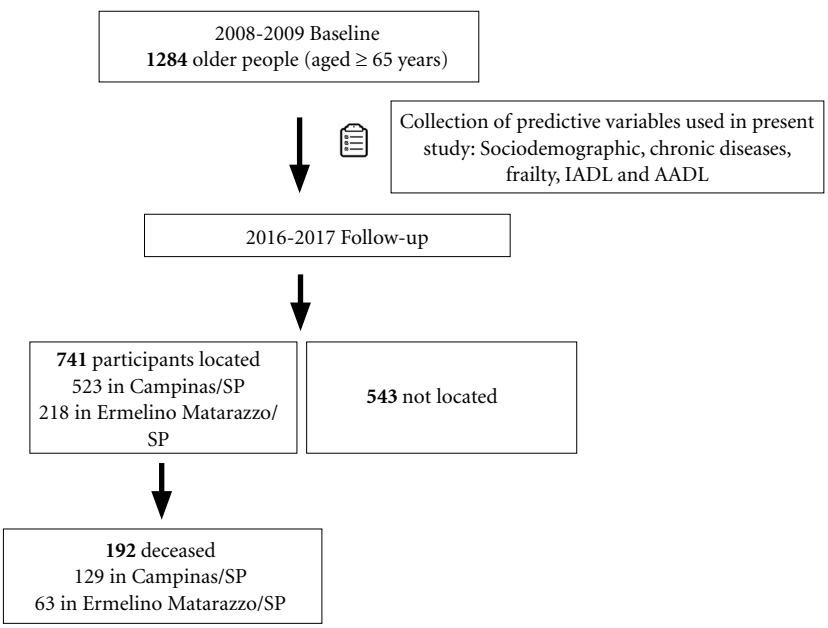

Figure 1. Flowchart of steps of 2008/09 and 2016/17 FIBRA Study.

Source: Elaborated by the authors.

daily living (IADL): using a telephone and transportation, self-management of medications, managing finances, shopping, meal preparation, and housekeeping activities. Individuals who reported needed partial or complete assistance for the performance of one or more activities were considered dependent[22,23].

▪ *Frailty*: investigated using the five criteria proposed by Fried et al.[24]. Individuals exhibiting three or more criteria were classified as frail, those with one or two criteria were classified as pre-frail, and those who did not meet any of the following five criteria were classified as non-frail:

1. Unintentional weight loss in the previous year (yes or no). If affirmative, the participant was asked how much weight (in kilograms) was lost; those who reported weight loss greater than 4.5 kg or 5% of body weight were considered to have met this criterion.

2. Fatigue, measured using two self-reported items from the Center for Epidemiologic Studies Depression Scale, with four response options (always, most of the time, sometimes, and rarely/never). Individuals with responses of "always" or "most of the time" for either of the two questions were considered to have met this criterion.

3. Grip strength, measured using the Jamar dynamometer (Lafayette Instruments, Lafayette, Indiana, USA) placed in the dominant hand of the participant for three trials with a one-minute rest between trials. Individuals whose mean of the three readings was among the lowest 20% of the values in the distribution [adjusted for sex and body mass index (kg/m²) according to the ranges suggested by the World Health Organization and described by Marucci and Barbosa[25] were considered to have met this criterion.

4. Slowness (gait speed), indicated by the mean time (in seconds) required to walk three times at the usual pace on a flat surface for a distance of 4.6 meters, following the recommendations of Guralnik et al.[26] and Nakano et al.[27]. Individuals whose mean (adjusted by the median of height for men and women) of the three trials was among the lowest in the distribution of time were considered to have met this criterion.

5. Low physical activity: weekly frequency and daily duration of physical exercise, active sports, and household tasks based on the items of the Minnesota Leisure Time Activity Questionnaire[24,28,29]. For the calculation of the weekly caloric expenditure in leisure and household activities, the number of items was considered for which the participant answered affirmatively, multiplied by the number of days in the week and the number of minutes per day in which the activities were practiced. Next, quintiles of the distribution of this variable were calculated for men and women, separately. Individuals who scored among the lowest 20% of the distribution of weekly calorie expenditure per respective sex were considered to have met this criterion.

▪ *Variables indicative of social involvement:* four advanced activities of daily living (AADL) were considered: visits to the homes of friends or family members, visits to church/religious temple for religious rituals or social activities linked to religion, participation in social meetings, parties, or balls, and meetings with others in public places, such as restaurants, movie houses, theaters, clubs, etc. All these variables were categorized as never performed, stopped performing, or still performs and classified as yes or no (performs or does not perform).

Data analysis

Descriptive analysis was performed of the sociodemographic characteristics and the conditions investigated considering absolute and relative frequencies of the categorical variables and comparisons between proportions using Pearson's chi-square test with a 5% significance level for the overall sample of older people located or not located (losses) in the follow-up study. Next, participants for whom it was possible to obtain data at follow-up were classified according to the occurrence of death (yes or no) in the period. The absolute number of accumulated incidence (%) was determined according to the variables selected. Raw and adjusted (sex, age, and schooling) incidence ratios (relative risk) and respective 95% confidence intervals were also calculated.

Poisson multiple regression analysis was performed using a hierarchical model. The sociodemographic characteristics associated with mortality were included in the first step. The second step involved those variables in the first block that maintained significance after adjusting for the other variables on the same hierarchical level plus the variables of the second block (chronic diseases, frailty, functional capacity, and indicator of social involvement). Variables with a significant association with mortality in the simple analysis ($p<0.20$) were included in the models. Only those with a p-value<0.05 after being adjusted by the variables on the higher and same hierarchical levels remained in the final model.

For the analysis of time until the occurrence of death considering the variables independently

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associated with mortality in the period, the *time* (in months) variable was created based on the dates of the first interview and death. Using the Kaplan-Meier method, the median survival times were estimated and the curves for each variable were created. Equalness in the survival distributions was determined for the different levels of the variables considered using the log-rank (Mantel-Cox) test, with a 5% significance level. All analyses were performed with the aid of the Stata 15.1 and SPSS (version 21) programs.

Ethical aspects

The projects received approval from the Human Research Ethics Committee of Campinas State University. All participants received clarifications regarding the objectives of the study, the procedures, and their rights and signed a statement of informed consent.

Results

This study involved the analysis of information from 741 older people who participated in the 2008-2009 baseline survey, 67.3% of whom were women and mean age was 72.6±5.8 years. Table 1 shows that only age group and the indicator of social involvement exhibited differences between proportions ($p<0.05$) for the sample of older people located and those not located for the follow-up study. Regarding the comparison of the located individuals (n=549) and those not located due to the occurrence of death (n=192), nearly all variables presented significant differences, except cancer, stroke, lung disease, diabetes *mellitus*, and hypertension (data not presented in table).

A greater risk of death was found among older people with a more advanced age (RR=1.85; 95%CI: 1.30-2.63), those with heart disease (RR=1.58; 95%CI: 1.11-2.26), those classified as pre-frail (RR=1.53; 95%CI: 1.06-2.20), those classified as frail (RR=1.74; 95%CI: 1.09-2.79), and those who reported being dependent regarding the performance of IADL (RR=1.61; 95%CI: 1.13-2.29). Among the women, the risk was 28% lower. The risk was also lower among individuals with more schooling (RR=0.64; 95%CI: 0.41-0.98) and those who reported three or more AADL (Table 2).

The results of the hierarchical regression analysis are displayed in Table 3. The incidence of death was significantly lower among women (RR=0.64; 95%CI: 0.43-0.95), those with a higher family income (RR=0.51; 95%CI: 0.27-0.96), and those who reported performing three or more activities related to social participation (RR=0.53; 95%CI: 0.32-0.87). Among the oldest participants, the incidence of death was higher among those who reported having heart disease and those who were dependent on others for the performance of IADL ($p<0.05$).

The general median time until the occurrence of death among the participants who reported having heart disease was 62 months (95%CI: 54.5-69.5). For those with limitations regarding the performance of IADL and those who reported performing less than three AADL, the median time until death was 60 months (Figure 2).

Discussion

The main findings of the present study were that the male sex, an older age, a lower income, difficulty performing IADL, less social involvement, and heart disease independently increased the risk of death in older people. The living context of the majority of older Brazilians, who are subject to the cumulative effects of a low economic level, low schooling, and the absence of social support, requires a care approach that considers several dimensions[4,5,7,21].

The greater mortality rate among men has been observed in all ages and groups of causes in Brazil[30]. The greater life expectancy among women results largely from differences in work activities, lifestyle, and health-related behaviors[30-32]. Despite variations in different regions of the world, women proportionally surpass half the older population[33].

Associations between mortality and both socioeconomic inequalities and the increase in the concentration of wealth are widely described in the literature[34,35]. Brazil occupies 10th position in the world ranking regarding the concentration of wealth and the first in terms of the degree of wealth concentrated in the richest one percent of the population[36], which has negative impacts on health, especially among older people[37].

Advanced activities of daily living encompass recreational, productive, and social activities of greater complexity in the functional evaluation of older people[38]. In the present study, the risk of death was lower among individuals who reported greater social involvement (measured by the number of advanced activities performed). Beyond the prevention of disease, the limitations

Table 1. Characteristics of older people (≥65 years) who remained in study and those lost to follow-up. FIBRA Study, 2008/09 and 2016/17.

Variables	Follow-up		Lost to follow-up		p-value*
	n=751	%	n=543	%	
Sex					
Male	242	32.7	160	29.5	0.223
Female	499	67.3	383	70.5	
Age group (years)					
65 to 69	241	32.5	214	39.4	**0.011**
70 to 74	234	31.6	173	31.9	
75 or more	266	35.9	156	28.7	
Schooling (years)					
0	140	18.9	93	17.2	0.069
1 to 4	430	58.1	293	54.2	
5 or more	170	23.0	155	28.6	
Family income (quartiles)#					
1st quartile	188	29.6	121	25.8	0.208
2nd quartile	138	21.7	119	25.4	
3rd quartile	177	27.9	118	25.2	
4th quartile	132	20.8	110	23.5	
Medical diagnosis of disease					
Hypertension	381	64.7	257	63.9	0.807
Arthritis/arthrosis/rheumatism	237	40.2	170	42.3	0.519
Heart disease	149	25.3	101	25.1	0.921
Diabetes mellitus	135	22.9	90	22.4	0.844
Lung disease	68	11.6	37	9.2	0.236
Cancer	57	9.7	28	7.0	0.134
Stroke	52	8.8	28	6.9	0.285
Frailty					
Non-frail	223	30.1	163	30.0	0.857
Pre-frail	429	57.9	320	58.9	
Frail	89	12.0	60	11.1	
Performance on activities of daily living					
Dependent on IADL (partial/total)	176	30.2	120	29.7	0.856
Indicator of social involvement (number of AADL)					
0 to 1	140	24.1	79	19.7	**0.005**
2	196	33,7	111	27,7	
3 ou mais	245	42,2	211	52,6	

*p-value of Pearson's chi-square test: p<0.05 in bold. #Family income values: 1st quartile (up to R$ 830), 2nd quartile (R$ 831-1,200), 3rd quartile (R$ 1,201-2,000), 4th quartile (>R$ 2,000). AIDL: instrumental activities of daily living. AADL: advanced activities of daily living.

Source: Elaborated by the authors.

imposed by diseases, and other determinants directly related to the living conditions and health of older people, conceptual benchmarks in the field of aging have sought strategies that can ensure the continued participation of this population in diverse activities[4]. Thus, the multidimensional concept of active aging involves not only the economic participation of older people, but also other non-paid forms, such as involvement in social, cultural, intellectual, physical, and political activities[39,40]. Besides age and schooling, mobility, sociability, material support, and emotional support are associated with perceived quality of life among older Brazilians[41].

The idea that old age is dominated by disease is not always the real situation; even with the occurrence of losses in the biological as well as the economic, social, and psychological realms, the main-

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Table 2. Accumulated incidence and adjusted relative risk of mortality among older people (≥ 65 years) according to sociodemographic characteristics, chronic diseases, frailty, and performance on instrumental activities of daily living. FIBRA Study, 2008/09 and 2016/17.

Variáveis	Number of deaths	Incidence of mortality %	Crude RR (95%CI)	Adjusted RR** (95%CI)
Sex		**0.011***		
Male	77	31.8	1	1
Female	115	23.0	0.72 (0.54-0.96)	0.72 (0.54-0.96)
Age group (years)		**<0.001***		
65 to 69	46	19.1	1	1
70 to 74	45	19.2	1.00 (0.67-1.52)	0.96 (0.63-1.44)
75 or more	101	38.0	1.99 (1.40-2.82)	1.85 (1.30-2.63)
Schooling (years)		**0.002***		
0	52	37.1	1	1
1 to 4	105	24.4	0.66 (0.47-0.92)	0.72 (0.52-1.01)
5 or more	35	20.6	0.55 (0.36-0.85)	0.64 (0.41-0.98)
Family income (quartiles)#		**0.020***		
1st quartile	57	30.3	1	1
2nd quartile	32	23.2	0.76 (0.50-1.18)	0.81 (0.52-1.25)
3rd quartile	44	24.9	0.82 (0.55-1.21)	0.93 (0.62-1.40)
4th quartile	20	15.1	0.50 (0.30-0.83)	0.60 (0.35-1.04)
Medical diagnosis of disease				
Hypertension		0.996*		
	88	23.1	1.00 (0.70-1.42)	1.07 (0.75-1.52)
Arthritis/arthrosis/rheumatism		**0.006***		
	41	17.3	0.64 (0.44-0.92)	0.71 (0.49-1.04)
Heart disease		**0.008***		
	46	30.9	1.52 (1.07-2.17)	1.58 (1.11-2.26)
Diabetes mellitus		0.373*		
	35	25.9	1.16 (0.79-1.71)	1.16 (0.79-1.71)
Lung disease		0.099*		
	21	30.9	1.41 (0.88-2.24)	1.37 (0.86-2.19)
Cancer		0.957*		
	13	22.8	0.99 (0.56-1.75)	1.00 (0.56-1.78)
Stroke		0.998*		
		23.1	1.00 (0.55-1.81)	0.95 (0.52-1.72)
Frailty		**<0.001***		
Non-frail	39	17.5	1	1
Pre-frail	119	27.7	1.59 (1.10-2.28)	1.53 (1.06-2.20)
Frail	34	38.2	2.18 (1.38-3.46)	1.74 (1.09-2.79)
Instrumental activities of daily living		**<0.001***		
Independent	74	18.2	1	1
Dependent (partial or total)	60	34.1	1.87 (1.33-2.63)	1.61 (1.13-2.29)
Indicator of social involvement		**<0.001***		
0 to 1	45	33.8	1	1
2	52	39.1	0.82 (0.55-1.23)	0.83 (0.56-1.24)
3 or 4	36	27.1	0.46 (0.29-0.71)	0.51 (0.33-0.79)

*p-value of Pearson's chi-square test: p<0.05 in bold. RR: relative risk, **RR adjusted by sex, age, and schooling, #Family income values: 1st quartile (up to R$ 830), 2nd quartile (R$ 831-1,200), 3rd quartile (R$ 1,201-2,000), 4th quartile (>R$ 2,000).

Source: Elaborated by the authors.

tenance of activities and both social and family engagement favors healthy aging[42](p.1765).

The independent risk of death by heart disease (angina, myocardial infarction, etc.) con-

Table 3. Poisson hierarchical multiple regression model and variables associated with mortality in older people (≥65 years). FIBRA Study, 2008/09 and 2016/17.

Variables	1st step*		2nd step*	
	Adjusted RR (95%CI)	p-value	Adjusted RR (95%CI)	p-value
Sex				
Male	1		1	
Female	0.69 (0.50-0.96)	0.028	0.64 (0.43-0.95)	0.027
Age group (years)				
65 to 69	1		1	
70 to 74	1.08 (0.69-1.70)	0.729	1.01 (0.59-1.74)	0.958
75 or more	2.06 (1.39-3.06)	< 0.001	1.94 (1.20-3.12)	0.007
Family income (quartiles)#				
1st quartile	1		1	
2nd quartile	0.76 (0.49-1.18)	0.222	0.88 (0.53-1.46)	0.620
3rd quartile	0.84 (0.57-1.26)	0.411	0.87 (0.52-1.45)	0.598
4th quartile	0.50 (0.30-0.83)	0.007	0.51 (0.27-0.96)	0.037
Heart disease				
No			1	
Yes			1.55 (1.03-2.34)	0.036
Instrumental activities of daily living				
Independent			1	
Dependent (partial or total)			1.66 (1.11-2.47)	0.013
Indicator of social involvement (number of AADL)				
0 to 1			1	
2			0.91 (0.58-1.43)	0.690
3 or more			0.53 (0.32-0.87)	0.013

*Variables incorporated in 1st step of model: sex, age group, schooling, and income. **Variables incorporated in 2nd step: arthritis/arthrosis/rheumatism, heart disease, lung disease, frailty, IADL, and indicator of social involvement. 1st step: relative risk (RR) adjusted by sociodemographic variables. 2nd step: RR adjusted by all variables in table. #Family income values: 1st quartile (up to R$ 830), 2nd quartile (R$ 831-1,200), 3rd quartile (R$ 1,201-2,000), 4th quartile (>R$ 2,000).

Source: Elaborated by the authors.

firms the considerable impact of cardiovascular disease on the morbidity and mortality of the population, represented mainly by ischemic heart disease and cerebrovascular disease[13,43]. Besides the high costs of hospitalization and outpatient follow-up, these diseases continue to be the major cause of death among older people[43,44].

Risk factors for cardiovascular disease include hypertension and diabetes *mellitus*, which are highly prevalent among older people[45-47], dyslipidemia, physical inactivity, overweight/obesity, an inadequate diet, smoking, and abusive alcohol use, among other factors[48] that are less frequent in this age group. Part of deaths due to heart disease among older people may be characterized as avoidable[49] if we consider that this event results from effects that could be controlled through early diagnosis and treatment, strategies targeting the prevention of complications of preexisting base conditions, and the more timely use of technologies, especially for the economically less privileged[34,35,50].

Regarding time until the incidence of death, no statistically significant difference was found for the variables associated with the risk of death. The median time until death among the older people was approximately 60 months (five years). It should be pointed out that the participants in the FIBRA study were a sample of older people with no evident signs of dementia at baseline and who appeared at public places for the collection of the data, which may have led to selection bias, enabling the participation of individuals with a better physical, emotional, and cognitive status[21]. Particularly for the outcome studied (death), both better conditions at baseline and the fol-

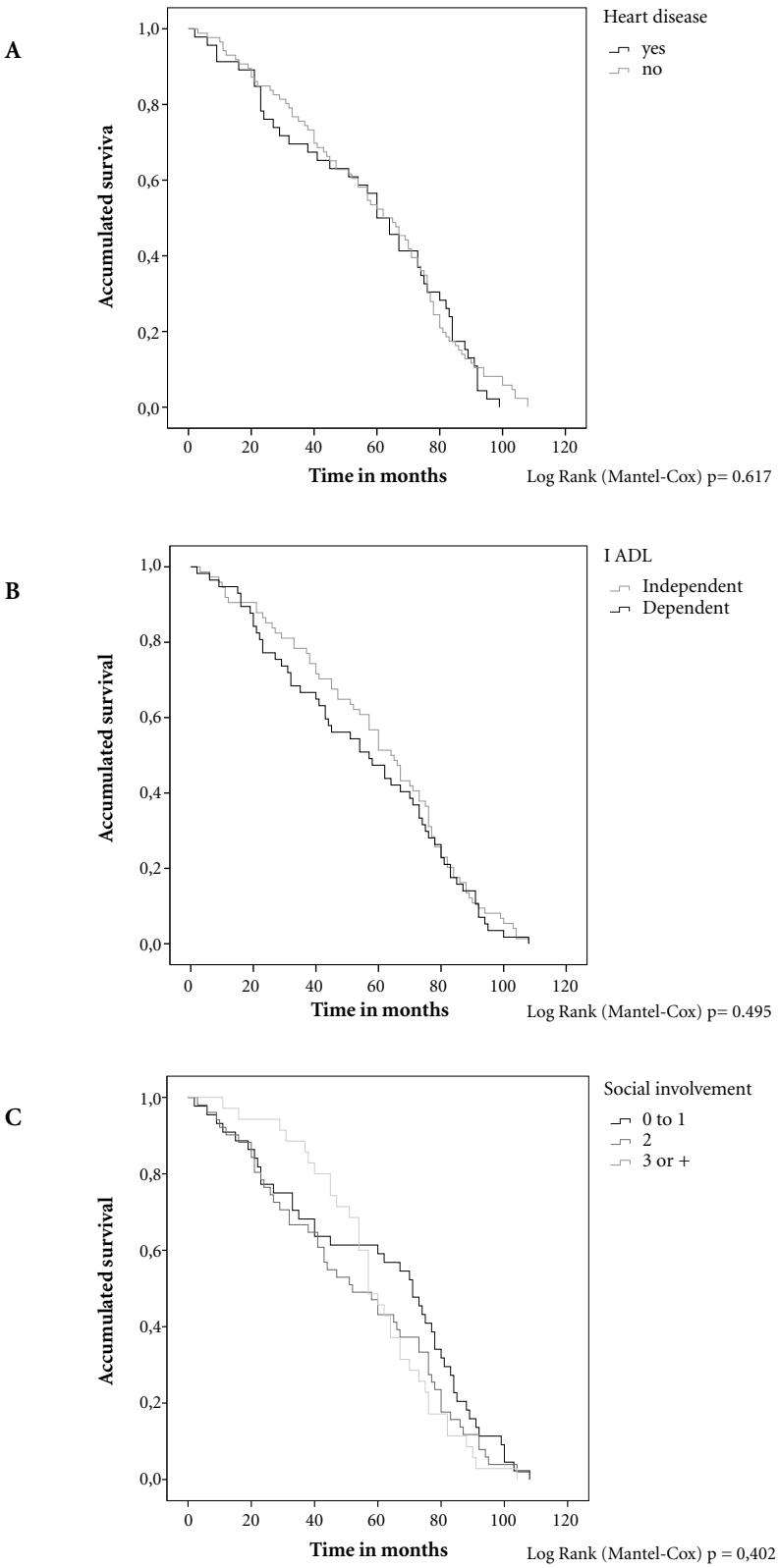

Figure 2. Survival curves Kaplan-Meier according to heart disease (A), IADL (B) and social involvement (C).

Source: Elaborated by the authors.

low-up time (about eight years) may have exerted an influence on the magnitude of the risk and the differences found in the median time until the occurrence of death.

Regarding all variables considered in the cohort of older people, the only difference in those lost to follow-up and those located was age, which is associated with the performance of activities related to active aging[51]. The percentage of age 75 years or older was significantly higher among the individuals located, which could partially compensate for the selection bias, as age is known to be an independent predictor of death, especially among older people. Although aging and disease do not constitute closely dependent factors, there is a greater risk of becoming ill in this phase of life.

In the present study, besides age and the male sex, a worse socioeconomic status and poorer mobility increased the risk of death among the older people in the period analyzed. Among the health conditions investigated, only heart disease was associated with death after adjusting for the other variables. Sociability was inversely associated with the occurrence of death. These findings enable us to reflect upon the complexity of the health-disease-care process in the older population. The findings also point to singularities inherent to individuals with regards to the social dimension, which exerts diverse effects on morbidity and mortality that cannot be measured directly.

Collaborations

PMSB Francisco guided the study proposal, analysis, data interpretation, text writing and final critical review. D Assumpção performed the analysis, data interpretation, text writing and final critical review. FSA Borim contributed to the literature review and critical review of the final version of the article. MS Yassuda participated in the data collection and critical review of the final version of the article. AL Neri carried out the conception of the FIBRA Study, data collection and critical review of the final version.

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