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Falls Risk and Mortality among Chronic Complex Outpatients: Results of Community-Based Prospective Study

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Abstract

Introduction: In the developed countries around 3-4% of the people could be identified as *chronic complex patient* and they are increasingly at risk of falling. The main objective of this study was to evaluate the association of fall risk and mortality risk.

Materials and Methods: We carried out a multicenter and prospective cohort study of mortality incidence from 01.01.2013 to 30.09.2016 among 825 adult patients registered in the electronic health record of Primary Care as *Chronic Complex Outpatient* (CCP). To predict hazard ratios, mean survival time, and survival probabilities used a multivariate Cox regression.

Results: Patients with falls were more likely to be women, be older age (85.46±SD7.39 vs 81.94±SD10.21, p <0.001), have more CCP criteria (4.22±SD1.26 vs 3.75±SD1.17, p<0.001); score higher in Pfeiffer test (3.75±SD3.35 vs 2.86±SD73.23, p <0.001) and had lower score in Barthel index (53.38±SD33.24 vs 68.82±SD31.33, p<0.001). The global mortality was 32, 5% (n= 257). This study confirms that cognitive deficits detected on clinical assessment among people on fall risk are associated with an increased mortality risk in community and the Barthel score remained a significant factor in reduction in mortality [HR 0.984 CI95% 0.976-0.993, p <0.001].

Conclusion: This study confirms that the cognitive impairment and the score Barthel <60 are associated with an increased mortality risk in community and they are a useful indicator to identify subjects eligible for preventive measures in public health strategies.

Keywords: Falls; Chronicity; Aged; Risk factors; Mortality; Cognitive function; Disability

Abbreviations

CCP: Chronic and Complex Patient; HR: Hazard Risk; IDIAP: Primary Care Research Institute *Jordi Gol I Gurina;* NOACs: Novel Oral Anticoagulants; SD: Standart Deviation; SSRI: Serotonin Reuptake Inhibitor; TTR: Time in Therapeutic Range.

Introduction

We face an epidemic of multi-morbidity and rising complexity of health needs [1,2] resulting from changing demographics and global circumstances. In the developed countries around 3-4% of the people could be identified as *chronic complex patient* and they are increasingly at risk of falling. Falls can be markers of poor health and declining function, and they are often associated with. Falls and their subsequent outcomes are likely to remain a major health care cost for all European countries for the foreseeable future. The prevention of falls is of major importance because they engender significant morbidity and mortality. Nowadays the falls among older people are major issues for health and social care providers [3-6].

The objectives of this study were: (i) to evaluate the association of fall risk and mortality risk among people registered as chronic *complex outpatients and* (ii) to explore differences in the association of outcome factors on mortality. We hypothesized that, given the high burden of multimorbidity in Chronic Complex Patients (CCP), falls risk would be associated with a higher risk of death.

Materials and Methods

We carried out a multicenter and prospective cohort study of mortality incidence from 01.01.2013 to 30.09.2016 among out-of-hospital patients over 65 years old attending primary care teams in the *Terres de l'Ebre* health area in Catalonia (Spain). All people included were managed by the Public Health System in Catalonia. The overall number of CCP registered was 3,490 people. We included a randomized sample of 825 adult patients registered in the electronic health record of Primary Care as *Chronic Complex Outpatient* (CCP) in the period 01/01/2013-31/12/2014. Patients were excluded if they resided in a long-term institutional setting. Alpha Risk = 5%; Beta Risk = 20%; Power = 80, 0%.

Patient outcome was followed until death or study end (30.09.2016) since date of report as CCP in the electronic health record. Data included demographics, functional, comorbidity, cognitive and social assessment, and were collected directly from the

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Table 1: Basal characteristics Complex and Chronic Pacients Group with and without fall risk.

CCP People With Falls Risk N 143	Without Cognitive Impairment	With Cognitive Impairment	P
N (%)	78 (54.5%)	65 (45.5%)	
Age (average ±SD)	83.65±8.20	87.63±5.61	0.001
Percentage >80 year-old n (%)	54 (47.8%)	59 (52.2%)	0.001
Women n (%)	42 (48.8%)	44 (51.2%)	
CCP criteria number (average±SD)	3.82±1.25	4.71±1.10	< 0.001
Charlson score (average±SD)	2.23±1.23	2.83±1.34	0.006
Daily medications number (average±SD)	9.45± 4.01	8.08±2.77	0.021
Antidepressants and/or sedating or similars n (%)	41 (52.6%)	51 (78.5%)	0.002
Statines treatment n (%)	24 (30.8%)	23 (35.4%)	0.342
Pfeiffer Test Score (average±SD)	1.08±1.23	6.95±2.00	< 0.001
Barthel score (average±SD)	68.4±30.9	35.31±26.24	<0.001
Gijón score (average±SD)	11.50±4.12	11.45±2.42	0.979
Stroke after CCP report n (%)	8 (10.3%)	12 (18.5%)	0.226
Oral Anticoagulant treatment n (%)	16 (20.5%)	12 (18.5%)	0.99
Hypertension no controlled n (%)	21 (26.9%)	12 (18.5%)	0.16
Alcoholism n (%)	4 (5.1%)	0 (0%)	0.085
Death n (%)	21 (26.9%)	34 (52.3%)	0,.002
Average survival time (days) (average±SD)	972.3±295.6	770.41±395.23	0.001

Shared Individual Intervention Plan [Pla d'Intervenció Individualitzat Compartit (PIIC)] written and managed by nursing service in Primary care. In the PIIC, determinants related to the personal factors, social and physical environment are described as well a tailored personal approach according the patient's preferences in case of hospital readmission o emergency use, and main caregiver. The report is updated automatically to ensure that relevant information is shared across the electronic health record. Currently 82% of people registered as CCP have this basic information in their PIIC.

Definitions

Chronic Complex Patient (CCP) definition: *Those who meet at least four of the next criteria*: Age (≥65 year-old). Chronic comorbidities (≥4). Psychosocial disorders (cognitive impairment or psychological disorder with functional disability). Geriatric conditions such as functional disability (Barthel score <55, living to assisted living, nursing home, or in-home caregivers) or recurrent falls or fall risk. Previous high health care utilization (two hospitalizations no programmed for exacerbation of chronic pathologies or three emergency department visits in last year). Number of active medications last six months (≥4 active medications). Living alone or with caregiver ≥75 year-old. "They defined the "Chronic Complex Patient" [6] as those who have chronic illness and also complex clinical situations which make their management significantly far more difficult.

There are problems in defining falls risk as many studies fail to specify an operational definition, leaving room for interpretation. A fall is an unintentional event that results in the person coming to rest on the ground or another lower level (W19.9 code in the electronic health record). A fall was defined as the result of any event that caused the patient to end up on the ground against their will, according to the WHO definition [7,8]. We used "the report clinical in the electronic health record *that a person had falls risk or previous recurrent falls with or without any serious injury*". If a patient is thought to be high by medical or nursing staff, allied health or careers such patients will be identified as "fall risk" in the PIIC. This might include mention of the patient's level of orientation and cognition, gait and balance, continence status, and number and types of prescribed medications, as well as number of diagnosis.

The independent variables were:

Sex: woman (0) man (1).

Age: <80 year-old (1), ≥80 year-old (2).

Number CCP criteria: <4 (0) ≥4 (1).

Charlson comorbidity index [7]. Short version.

Polypharmacy (defined as four or more daily medications) [8]: <5 (0), entre 5-9 (1), and ≥10 (2). Oral anticoagulants (acenocumarol or warfarina) con TTR ≥60% (1), si TRT <60% (2) or New Oral Anticoagulants NOACs (0). Antidepressants and/or, sedating or other drugs affecting the neurologic system: man (1), woman (2).

Recurrent falls or fall risk: no (0), yes (1).

Hypertension not controlled by therapy (≥ 160/90 mmHg): no (0), yes (1).

Alcoholism abuse vs dependence: no (0), yes (1).

Presence de cognitive impairment [9]: a disease-specific diagnosis of cognitive impairment, without specification of sub-type or severity, was used and measured by Pfeiffer test [2]: [0-2 errors] = Intact Intellectual Functioning (1); [≥3 errors] = Mild to severe Intellectual Impairment (2)].

Presence de disability: score in [Barthel ≥60 (1) <60 (2)] or in [Rankin <4 (1) 5(2)].

Sociofamiliar risk: score in Gijon [10] scale 10-14 (1) ≥15 (2)].

Demographic data were summarized using mean and SD or median and quartiles for continuous variables and percentages for categorical data. Data analysis information extracted was the adjusted risk estimates and 95% Confidence Intervals (CI). Statistical tests of homogeneity were performed using Cochran's Chi-squared test for homogeneity (Q) and the percentage of total variation across studies attributable to heterogeneity (I^2).

To predict hazard ratios, mean survival time, and survival probabilities used a multivariate Cox regression. The variables were included in a multivariable model Cox to identify their influence on the mortality. In the survival analyses of risk factors for death, follow-up began at the start of the study, and patients were censored when follow-up ended for reasons other than death. A graphical presentation of the survival of fallers versus non fall risk was made using an adaptation of the Kaplan–Meier product-limit estimator.

Ethics approval was granted by Ethics Commitee Research Institut Primary Care Jordi Gol i Gurina (IDIAP), Health Department, Generalitat de Cataluña.

Results

825 CCP cases were included (52.3% women). The basal characteristics are showed in Table 1. Average age was 82.5 yr (CI95% 81.8-83.2). Average number of CCP criteria was 3.83 (CI 95% 3.75–3.92). The global mortality was 32, 5 % (n= 257). The average survival time was 1,032.13 days (DS 2022.0; IC95% [890.86-1173.40]). In the survival analyses of risk for death, the outcome independent factors were: age [HR 1.04 CI95% 1.02-1.05, p <0.001], the genre [HR 0.61 CI95% 0.48-0.78, p <0.001], the Charlson score [HR 1.19 CI95% 1.09-1.29, p <0.001], the Barthel score [HR 0.98 CI95% 0.98-0.99, p <0.001].

143 (17.3%) cases were registered as "fall risk" (60.1% women). The basal characteristics are showed in Table 1. Patients with falls were more likely to be women, be older age (85.46±SD7.39 vs 81.94±SD10.21, p<0.001), have more CCP criteria (4.22±SD1.26 vs 3.75±SD1.17, p<0.001); score higher in Pfeiffer test (3.75±SD3.35 vs 2.86±SD73.23, p<0.001) and had lower score in Barthel index (53.38±SD33.24 vs 68.82±SD31.33, p<0.001) with higher baseline burden of functional dependence in one or more daily activities compared with non fallers. Other interesting points were: higher stroke incidence (69 events/1000 people/year vs 24events/1000people/year, p<0.001) after diagnosis CCP; more percentage with high blood pressure not controlled (23.1% vs 9.4%, p<0,001), cognitive impairment (45.5% vs 32.7%, p<0.005), and treatment with Central Nervous System medications (antidepressants, sedating and others I) (64.3% vs 52.9, p 0.008), but less treatment with statins (32.9% vs 48.5%, p 0.001) and oral anticoagulants (28.6% vs 19.6%, p 0.044).

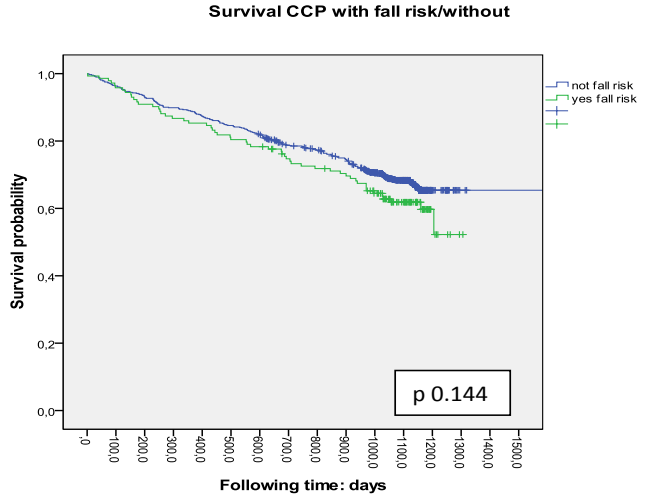

Figure 1: Complex and Chronic Pacients Survival: fallers versus non fall risk.

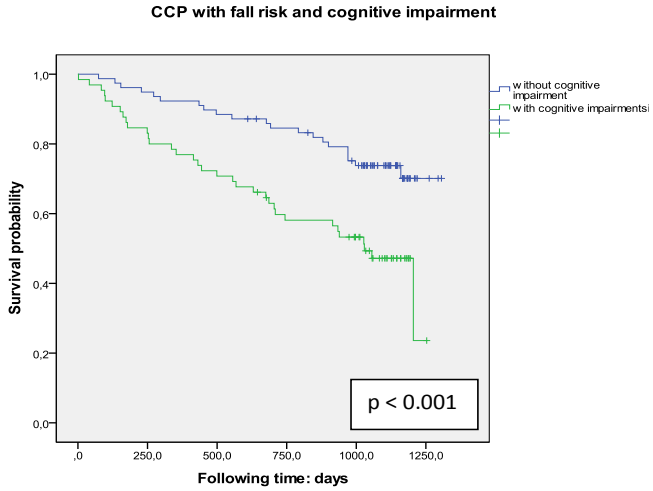

Figure 2: Complex and Chronic Pacients Survival: fall risk and cognitive impairment.

While falls are more common among older women than men risk fall-related mortality is not different. The difference in fall risk in older age may stem from the gender-related factors, such as women being inclined to make greater use of multiple medications and living alone [11]. In addition, biological difference also contributes to greater risk. If the women are more likely than men to fall it will result in more hospitalizations and emergency department visits than men [9].

The overall mortality among the CCP people *with fall risk* was 38.5%. The WHO reported falls account for 40% of all injury deaths [8]. The average survival time was 880.5±357.7 days. The long term survival was not different (Figure 1) between the group of CCP with fall risk and without fall risk (logs Rank 2.133, p 0.144). In unadjusted analysis, patients who had fall risk were at a significantly higher risk of death if were older ≥80 year-old (42.5% vs 23.3%, p 0.042), ≥4 active medications (52.0% vs 25.0%, p 0.002), cognitive impairment (52.3% vs 26.9%, p 0.002), or Barthel score <60 (53.2% vs 20.4%, p <0.001).

The CCP people with fall risk have shorter survival (Figure 2) when they have cognitive impairment (Log Rank 11.43, p <0.001)

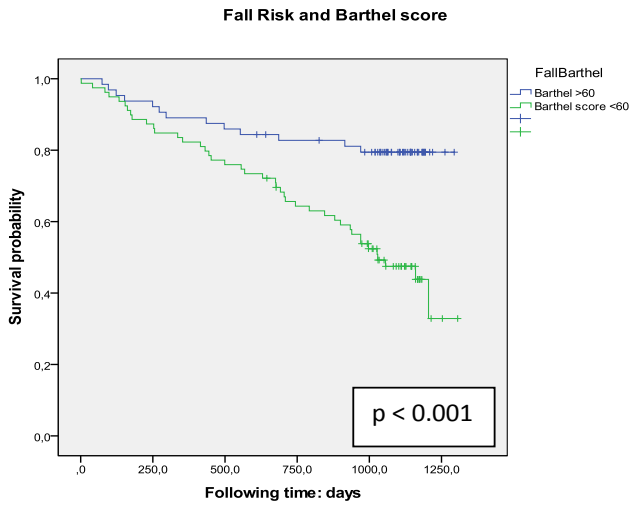

Figure 3: Complex and Chronic Pacients Survival: fall risk and Barthel score <60.

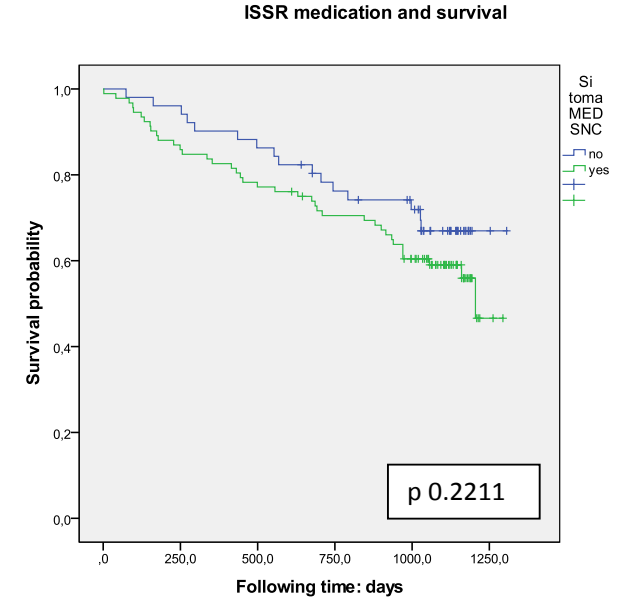

Figure 4: Complex and Chronic Pacients Survival: fall risk and SSRI medication.

and when (Figure 3) the score Barthel <60 (Log Rank 13.96, p <0.001). The basal characteristics of CCP with [fall risk and cognitive impairment] and [fall risk and moderate dependence (Barthel score <60)] are showed respectively in Table 2 & 3. Using a reduced model and adjusting for the strongest known predictors of mortality (age at the register CCP, sex and Charlson score), the Barthel score remained a significant factor in reduction in mortality [HR 0.984 CI95% 0.976-0.993, p<0.001]. We observed a strong association between cognitive impairment and higher mortality that persisted even after adjustment for known mortality risk factors, such as age. Routine clinical questioning about previous falls may, thus, be a key strategy to identify at-risk individuals, and therefore, preventive interventions can be introduced.

We have found higher percentage of CCP with selective serotonin reuptake inhibitor along with fall risk, but without differences (p 0.2211) in mortality risk (Figure 4).

Discussion

The clinical status of older individuals with multimorbidity can be further complicated by concomitant geriatric syndromes. The coexistence of chronic diseases and geriatric syndromes has been extensively described in the literature [12] and makes difficult considering one condition at a time. There are a lot of related definitions: *"Geriatric syndromes, the frail elderly, frailty and dependence in aging population, Complex chronic syndromes, multiple chronic conditions, complex individuals with chronic disease, complex multiple chronic conditions, etc…"* and beyond the meaning of the words, the comprehensive biopsychosocial assessment of needs and resources has become the most important part of the intervention process to halting the frailty cascade. Care guidelines and quality indicators should be designed to provide comprehensive and coordinated management of chronic conditions and geriatric syndromes.

This study is one of the few prospective studies to examine the significance of fall risk and their association with mortality among elderly individuals identified as CCP. Given there is not differences in the long term survival between CCP with fall risk and without fall risk, the outcome factors associated would be the same. Falling, at least among CCP, appears to result from the accumulated effect of multiple factors associated with changes due to ageing such as the decline of physical, cognitive and affective capacities, and the co-morbidity associated with chronic illnesses.

This study confirms that cognitive deficits detected on clinical assessment among people on fall risk are associated with an increased mortality risk in community. A diagnosis of fall risk in people with cognitive impairment confers a high risk for mortality and suggests that the recurrent falls could be a predictor of cognitive impairment [4]. Taken together, these findings support the idea that gait impairment antedates cognitive dysfunction and may even represent a reliable risk factor for cognitive decline. The presence and severity of functional disability is a useful indicator of the risk of falling and mortality. It has been described [13] that these patients are older, suffer more chronic diseases and have poorer functional status at baseline and functional deterioration which could explain the higher mortality. It would appear as a worsening factor in any CCP condition. The Isolation and loneliness has been shown to be a risk factor for falls. The percentage in our study was 22.3% among people ≥75 year-old.

Several studies demonstrated the effectiveness of physical activity for preventing cognitive decline. A recent large meta-analysis concluded that physical activity is inversely associated with dementia risk [14]. Walking Programs for Reducing Dementia Risk may be effective. The Barthel score may be useful clinically because it provides a dynamic, integrated assessment of mobility. However, some studies suggest a U-shaped association, that is, the most inactive and the most active people are at the highest risk of falls [15]. 55.2% of CCP with fall risk scored Barthel <60 (moderate dependence). Unfortunately, longitudinal data on functional changes were not measured as part of this study. This reveals a complex relationship between falls, activity and risk. The disability may precipitate a reduced activity level and

Table 2: Basal characteristics Complex and Chronic Pacients with fall risk and cognitive impairment.

	Without Falls Risk	With Falls Risk	All	P
N (%)	682(82, 7%)	143(17, 3%)	825	
Age (average ±SD)	82.55±9.86	85.46±7.39	83.7±8.80	< 0.001
Percentage >80 year-old n (%)	466(68.3%)	113(79%)	579(70.2%)	0.012
Women n (%)	337(49.4%)	86(60.1%)	423(51.3%)	
CCP criteria number (average±SD)	3-83±1.20	4.22±1.26	3.80±1.21	< 0.001
Charlson score (average±SD)	2.47±1.39	2.50±1.31	2.43±1.38	0.752
Daily medications number (average±SD)	8.94±3.57	8.83±3.55	8.87±3.58	0.141
Antidepressants and/or sedating or similars n (%)	361 (52.9%)	92 (64.3%)	453 (54.9%)	0.008
Statines treatment n (%)	331 (48.5%)	47 (32.9%)	378 (45.8%)	0.013
Pfeiffer Test Score (average±SD)	3.01±3.26	3.75±3.35	3.02±3.29	0.003
Cognitive Impairment n (%)	223 (32.7%)	65 (45.5%)	288 (34.9%)	0.003
Barthel score (average±SD)	66.14±31.62	53.38±33.24	66.20±31.33	< 0.001
Gijón score (average±SD)	9.58±5.13	11.47±2.80	9.58±4.80	0.021
Stroke after CCP report n (%)	39(5,7%)	20(14%)	59(7.2%)	0.001
Oral Anticoagulant treatment n (%)	195 (28.6%)	28 (19.6%)	223 (27.0%)	0.044
Hypertension no controlled n (%)	64(7.8%)	33(4.0%)	97(11.8%)	< 0.001
Alcoholism n (%)	14(1.7%)	4(0.5%)	18(2.2%)	0.534
Death n (%)	217(31.8%)	55(38.5%)	272(33.0%)	0,142
Average survival time (days) (average±SD)	1047.23±2172	880.53±357	1018.33±1981	0.361

fewer falls: probabily they are aided or don't move, which in turn, increases the risk of dependence and death. Our results showed higher stroke incidence, but less treatment with oral anticoagulants mainly among those with Barthel score <60 ($p < 0.001$). One trial found [16] that increased physical activity was associated with a decreased risk of falls, but an increased risk of suffering a serious injury. Those who cannot be aided but have many fall risk factors constitute the highest priority group for fall interventions.

The method used to define "fall risk" can be little clear. Epidemiological research into falls and fall-related injuries has been affected by a series of conceptual and methodological problems. Clinicians are often unaware of the many existing scales for identifying fall risk and are uncertain about how to select an appropriate one. But to know fall and fall-related injury rates, we need to know who fell, when the fall occurred and what the degree of injury was, if any. The fall may simply be an isolated event and most non-injurious falls (75%-80%) are never reported to health professionals [17]. Given that the majority of falls do not come to the attention of any medical service, the use of the evaluation of the fall risk in the community could improve knowledge translation of into clinical practice. Unfortunately, there are no national bench marks with which we can compare our fall rates. Eventually for risk factor assessment to make a difference, all risk factors identified on the risk assessment need to be addressed in the care plans, and the care plans need to be acted on.

The STRATIFY risk assessment tool [18] is simple to complete and allows for the identification of inpatients at highest risk of falling, but has been validated for hospital inpatients only. Lately, the FROP-Com screen has a relatively good capacity to predict falls [19] by observation of the person's balance and whether the person required assistance to perform domestic ADLs. Again the diagnosis of functional disability appears as a useful indicator of the risk of falling and mortality. Measures of increased fall risk are not sufficient to identify [20] and Advice alone about fall risk factor modification without measures to implement recommended changes appears ineffective at reducing falls [21].

The use of four or more medications is associated with a nine-fold increased risk of cognitive impairment and risk of falling. The 91.6% CCP had ≥4 active medications, 52.4% between 4-9, and 32.9% ≥10. Antidepressants have long been associated with an increased risk for falls. The selective serotonin reuptake inhibitor (SSRI) antidepressants have been presumed to be safer for use in persons at high risk for falling. In our study there was not difference in mortality between patients receiving and those not receiving SSRIs [11], but reducing the number of medications, particularly those that contribute to postural hypotension or sedation, is most often reported as target area for fall reduction.

Conclusion

In summary, we report an independent positive association between fall risk and mortality risk. The long term survival was not different between the group of CCP with fall risk and without fall risk, but was significativaly different when introduce the cognitive

Table 3: Basal characteristics Complex and Chronic Pacients with fall risk and Barthel score <60.

CCP People With Falls Risk (N 143)	With Barthel Score ≥60	With Barthel Score <60	P
N (%)	64 (44.8%)	79 (55.2%)	
Age (average ±SD)	83.68±8.33	86.9±6.21	0.009
Percentage >80 year-old n (%)	45 (39.9%)	68 (60.2%)	0.018
Women n (%)	34 (53.1%)	52 (65.8%)	0.085
CCP criteria number (average±SD)	3.52±1.0	4.80±1.15	< 0.001
Charlson score (average±SD)	2.61±1.38	2.42±1.25	0.388
Daily medications number (average±SD)	9.91±3.95	7.95±2.94	0.001
Antidepressants and/or sedating or similars n (%)	34 (53.1%)	58 (73.4%)	0.01
Statines treatment n (%)	28 (43.8%)	19 (24.1%)	0.01
Pfeiffer Test Score (average±SD)	1.98±2.21	5.18±3.45	< 0.001
Cognitive Impairment n (%)	14 (21.9%)	51 (64.6%)	< 0.001
Barthel score (average±SD)	85.5±13.0	27.3±18	< 0.001
Gijón score (average±SD)	9±2.82	11.85±2.70	0.191
Stroke after CCP report n (%)	7 (10.9%)	13 (16.5%)	0.242
Oral Anticoagulant treatment n (%)	19 (29.7%)	9 (11.4%)	0.022
Hypertension no controlled n (%)	15 (23.4%)	18 (22.8%)	0.541
Alcoholism n (%)	3 (4.7%)	1 (1.3%)	0.325
Estado vital (muertos)	13 (20.3%)	51 (64.6%)	< 0.001
Average survival time (days) (average±SD)	957.84±328.2	817.9±370.27	0.019

impairment and the score Barthel<60. This study confirms that all both conditions detected on clinical assessment among people on fall risk are associated with an increased mortality risk in community and they are a useful indicator to identify subjects eligible for preventive measures in public health strategies.

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