

## ORIGINAL RESEARCH

# A NOVEL TOOL FOR THE EARLY IDENTIFICATION OF FRAILTY IN ELDERLY PEOPLE: THE APPLICATION IN PRIMARY CARE SETTINGS

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**Abstract:** *Objectives:* Frailty is a pre-disability condition in older persons providing a challenge to Health-Care Systems. Systematic reviews highlight the absence of a gold-standard for its identification. However, an approach based on initial screening by the General Practitioner (GP) seems particularly useful. On these premises, a 9-item Sunfrail Checklist (SC), was developed by a multidisciplinary group, in the context of European Sunfrail Project, and tested in the Community. *Objectives:* - to measure the concordance between the judgments of frailty (criterion-validity): the one formulated by the GP, using the SC, and the one subsequently expressed by a Comprehensive Geriatric Assessment Team (CGA-Team); - to determine the construct-validity through the correspondence between some checklist items related to the 3 domains (physical, cognitive and social) and the three tools used by the CGA-Team; - to measure the instrument's performance in terms of positive predictive value (PPV) and negative predictive value (NPV). *Design:* Cross-sectional study, with a final sample-size of 95 subjects. *Setting:* Two Community-Health Centers of Parma, Italy. *Participants:* Subjects aged 75 years old or more, with no disability and living in the community. *Measurements:* We compared the screening capacity of the GP using the SC to that one of CGA-Team based on three tests: 4-meter Gait-Speed, Mini-Mental State Examination and Loneliness Scale. *Results:* 95 subjects (51 women), with a mean age of 81±4 years were enrolled. According to GPs 34 subjects were frail; the CGA-Team expressed a frailty judgment on 26 subjects. The criterion-validity presented a Cohen's  $k$  of 0.353. Construct-validity was also low, with a maximum contingency-coefficient of 0.19. The analysis showed a PPV of 58.1% and a NPV equal to 84.6%. *Conclusions:* Our data showed a low agreement between the judgements of GP performed by SC and CGA-Team. However, the good NPV suggests the applicability of SC for screening activities in primary-care.

**Key words:** Ageing, frailty, multimorbidity, integrated care, sunfrail.

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## Introduction

### *Bio-psycho-social model of frailty*

Frailty is a condition of vulnerability to adverse events (1), traditionally considered a clinical entity; given its multidimensional nature (2), authors have proposed the bio-psycho-social model of frailty (2, 3). According to this approach, the assessment of frailty requires a comprehensive analysis of physical-functional, socio-environmental-economic, educational and psychological contributors (3). Studies underline the reversible nature of frailty and suggest the need for interventions able to slow down the progression towards disability (4).

### *Identification of frailty*

Although numerous tools are already available, there is no recognized gold-standard in the literature (3). Most of the instruments are also targeting one-dimension/domain, are difficult to be administered with numerous items and scores calculation and are often targeting advanced-frailty and

disability. All these factors explain why none is currently and widely used in the daily practice.

An approach based on initial screening by the General Practitioner (GP) seems useful [4], especially if followed by Comprehensive Geriatric Assessment (CGA) which is the key step for the implementation of an integrated management (5, 6).

However, the tools currently available are not suitable for satisfying the needs of the GPs and most of them haven't been validated for use in primary care (5).

An exception is the EASY-Care-TOS tool (5, 6), designed to be used in a complex two-phase model, where the GP makes a judgment following a 14 item checklist. However, in case of «uncertain» patients, the instrument requires the application of a second part composed of 49 items to make possible the final judgment of frailty (6).

### *Sunfrail checklist*

The Sunfrail checklist (SC) was developed following the standard methodology used for creating questionnaires (7-9), as part of a project funded by the third Health Program 2014-2020

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of the European Commission. It was built by an international group, composed of geriatricians, sociologists, and public health experts.

This study aimed at validating the SC in primary care, in order to verify its discriminating capacity of identifying patients requiring CGA. We hypothesize that the GP, by using Sunfrail, will be able to identify individuals at risk of frailty.

### Methods

#### Objectives

The primary objective was to measure the concordance between the two judgments of frailty (criterion validity), the one formulated by the GP, using the SC, and the one expressed by a Comprehensive Geriatric Assessment Team (CGA-T) using three tools (4m-Walking Test, Mini-Mental State Examination, Loneliness-Scale). These tests were chosen because considered as gold standard in the physical, neuropsychological and socio-economic domain, respectively.

The secondary objectives were:

- to determine the construct validity through the correspondence between some SC items related to the 3 domains and the outcomes of 3 tools (1 per domain) used by the CGA-T.
- to measure the predictive ability of SC in terms of positive predictive value (PPV) and negative predictive value (NPV).

#### Study design

Descriptive observational study, with transversal enrollment and prospective method on data collection.

#### Target population

Community-dwelling older persons with no disability evaluated by GP's. Since patients who benefit most from screening for frailty in primary care are usually very old people (3), those aged 75 or over, a category at greatest risk of frailty, were enrolled in the Study.

#### Sunfrail Checklist development

A literature review was performed during the time period 2015-2016, focusing on manuscripts concerning community-dwelling older persons. The group identified a set of items selected from existing tools, especially the Edmonton Frailty Scale (10), the Tilburg Frailty Indicator (11), and the Gerontopole Frailty Screening Tool (12) all inspired to the biopsychosocial model of frailty. Items were discussed with experts of Frailty, in particular with European Working Group on Frailty of the European Union Geriatric Medical Society. After that, SC was translated from English into Italian, French, Polish, Spanish and backtranslated. The verification of the understandability and comprehensibility of the tool was performed with professionals, community actors, caregivers and beneficiaries. Finally, nine items were selected: 5 in the physical domain, 2 in the neuropsychological domain and 2 in the socio-economic one.

#### Comprehensive Geriatric Assessment as the comparator

Given the lack of an unanimous gold-standard screening tool adopting the bio-psycho-social-model (3), it was decided to compare the GP judgement with the one formulated by the CGA-T, and based on the administration of three tests, selected for their role as gold standard as referenced in the literature (6).

The 4m-walking test to address the physical frailty, with a 5-second cut-off score (13); the Mini-Mental State Examination (MMSE) for the evaluation of the cognitive status, with a cut-off of  $\leq 24$  points suggesting cognitive impairment (14); the UCLA-Loneliness Scale (UCLA-LS), which uses a cut-off of  $\geq 25$  to indicate a greater perceived sense of loneliness (15).

The CGA-T was composed by a geriatrician, a nurse and a social assistant (16).

#### Setting and procedures

The study was carried out in two Community Health Centers of two rural areas in Parma, preceded by 3-hour education training.

Subjects who met eligibility criteria were offered to participate. Disability was assessed by GPs, verifying the presence of any social-assistance paths activated. After the inclusion, the GP using the SC and the CGA-T produced their judgment, independently.

#### Sample-size

Assuming a degree of agreement, measured with the Cohen's  $\kappa$  index, higher than 0.70, a type I error of 0.05 and a test power of 80%, the minimum size was 88 patients. Estimating a 10% drop-out rate, we planned to recruit 97 subjects.

#### Statistical analysis

Cohen's kappa was used to evaluate the agreement between the two judgments, assessed with the categorization proposed by Altman (17).

To measure the construct validity, the Pearson  $\chi^2$  test was used and the strength of the relation was interpreted according to the following Cohen's criterion (18).

Furthermore, the predictive capacity was evaluated using the Positive-Predictive-Value (PPV) and the Negative-Predictive-Value (NPV).

### Results

#### Characteristics of the participants

GPs enrolled 122 subjects, but due to a 22% drop-out, we had complete data for the analysis for 95 patients: these subjects had characteristics superimposable to those of the total sample (table 1).

Table 2 and Figure 1 indicate the distribution of affirmative answers to the questions in the SC, divided by the GP's judgment.

**Table 1**  
Characteristics of the study population

Characteristics	Participants (N=122)		Analyzed (N=95)	
		Missing		Missing
Age, Mean± SD	81 ± 4	1	81 ± 4	1
Sex (Female), n (%)	65 (53%)	0	51 (54%)	0
Married, n (%)	83 (71%)	5	65 (71%)	4
Living alone (Yes), n (%)	27 (24%)	8	18 (20%)	7
Educational level, n (%)				
Low	101 (88%)	7	76 (85%)	6
Middle	13 (11%)		12 (14%)	
High	1 (1%)		1 (1%)	
Memory				
MMSE, Mean± SD			26.4 ± 2.9	2
Mobility				
Walking speed (sec), Mean± SD			4.8 ± 1.3	2
Social context				
Loneliness (≥ 25pt), n (%)			68 (72%)	0
Frailty measures				
GP judgement, n (%):				
Yes, I suspect the patient is frail	37 (31%)	3	34 (36%)	0
No, I don't suspect the patient is frail	78 (66%)		59 (62%)	
I'm uncertain	4 (3%)		2 (2%)	
CGA judgement, n (%):				
Yes, the patient is frail		26 (27%)	0	
No, the patient is not frail		58 (61%)		
We are uncertain		11 (12%)		

### **Criterion validity (Primary Endpoint)**

GPs suspected a frailty condition in 31,1% of subjects, CGA identified 27% of subjects as frail (table 1).

The degree of agreement between GP and CGA is 66.3%, with a Cohen k of 0.353 [95% CI: 0.19-0.52, p <0.001], indicating a low agreement.

### **Construct validity**

The 4m-walking test showed a contingency coefficient of 0.12 with the question 3, and 0.18 with the question 5; MMSE displayed a coefficient of 0.17 with the question 6, while UCLA-LS had a coefficient of 0.19 with the question 7 and 0.14 with the question 8 (table 3).

### **Instrument performance**

The analysis of the instrument's performance, determined by excluding the cases for which the CGA did not provide a certain suspicion, showed NPV equal to 84.6% (table 4).

### **Discussion**

GPs suspected a frailty condition in 31.1% of subjects. These data are consistent with EASY-Care TOS that estimated in Nimega, a similar area in terms of population sample and rural areas, a frailty prevalence of 39.4% (6).

The concordance (k=0.35) was lower compared to instruments like the EASY-Care TOS (k=0.63).

This can be due to many factors: firstly, an exhaustive CGA cannot be the administration of 3 simple tests, but it must be customized to the patient's needs (4). This can also explain the uncertain judgments formulated by CGA-T.

The SC is more an alert questionnaire rather than a screening tool and is more oriented towards an earlier state of frailty than EASY-Care TOS, which is more devoted to address the condition of mobility-disability.

Although the education training was carried out at the GPs, the concept of frailty has become just recent matter of education in the Medicine Courses and the overlapping and

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**Table 2**

Distribution of affirmative answers to the questions in the SUNFRAIL checklist divided by the GP’s judgment (% of column)

ITEM	Yes, I suspect the patient is frail (N=37)	No, I don’t suspect the patient is frail (N=78)	I’m uncertain (N=4)
8. If necessary, can’t you count on someone close to you?	8%	3%	0%
4. Weren’t you visited by your family doctor during the past year?	0%	11%	1%
1. Do you regularly take 5 or more medications per day?	78%	53%	75%
3. Your physical state made you walking less during the last year?	70%	53%	50%
6. Have you experienced memory decline during the last year?	51%	19%	75%
5. Have you fallen one or more times over the past year?	54%	12%	25%
7. Do you feel lonely most of the time?	32%	6%	50%
2. Have you recently lost weight such that your clothes has become looser?	22%	9%	50%
9. Have you had any financial difficulties in facing dental care and health care costs during the last year?	14%	4%	0%

\*Question 8 and 4, were «turned»

**Table 3**  
Construct validity

SUNFRAIL CHECK LIST (administered by GP)	OB 2: Construct validity	Contingency coefficient	Strength of the relationship (Cohen 1992)	Chi-square	p-value
3. Your physical state made you walking less during the last year?	4-m walking test	0.12	WEAK	0.14	0.713
5. Have you fallen 1 or more times during the last year?	4-m walking test	0.18	WEAK	3.43	0.064
6. Have you experienced memory decline during the last year?	Adjusted MMSE Score	0.17	WEAK	1.69	0.193
7. Do you feel lonely most of the time?	Loneliness Scale	0.19	WEAK	2.59	0.107
8. In case of need, can you count on someone close to you?	Loneliness Scale	0.14	WEAK	0.60	0.440

interchangeability with multimorbidity in the GP perspective cannot be excluded (19). Furthermore, the Sunfrail was not designed to be specifically used by the GP and just for clinical purpose, but also by other “actors” in settings closer to the user’s life context.

The percentages of subjects identified as frail during screening activities can be greater in social-health rather than specifically clinical settings (20). Future studies should focus on the applicability of SC in these settings, with the potential administration by non-medical personnel. The low agreement between the judgements suggests that frailty assessment by GP using SC is far to replace the CGA, which remains the best method to assess and confirm the frailty status (4).

Construct validity shows a small relationship between the 5 items of the SC and the tests used for the CGA (18). This may be due to a discrepancy between these tests and the meaning of some SC’s questions.

Regarding the question 3, recent studies have linked the 0.8 m/s cut-off to a condition of mobility-disability, and not of frailty (21).

Moreover, although MMSE is the most widely used screening tool, it isn’t sensitive for mild cognitive impairments. This may have affected the agreement between this test and question 6 (22).

The question 8 cannot also completely be captured by the UCLA-LS: family support, which offers instrumental support, can be less important than peers support (23).

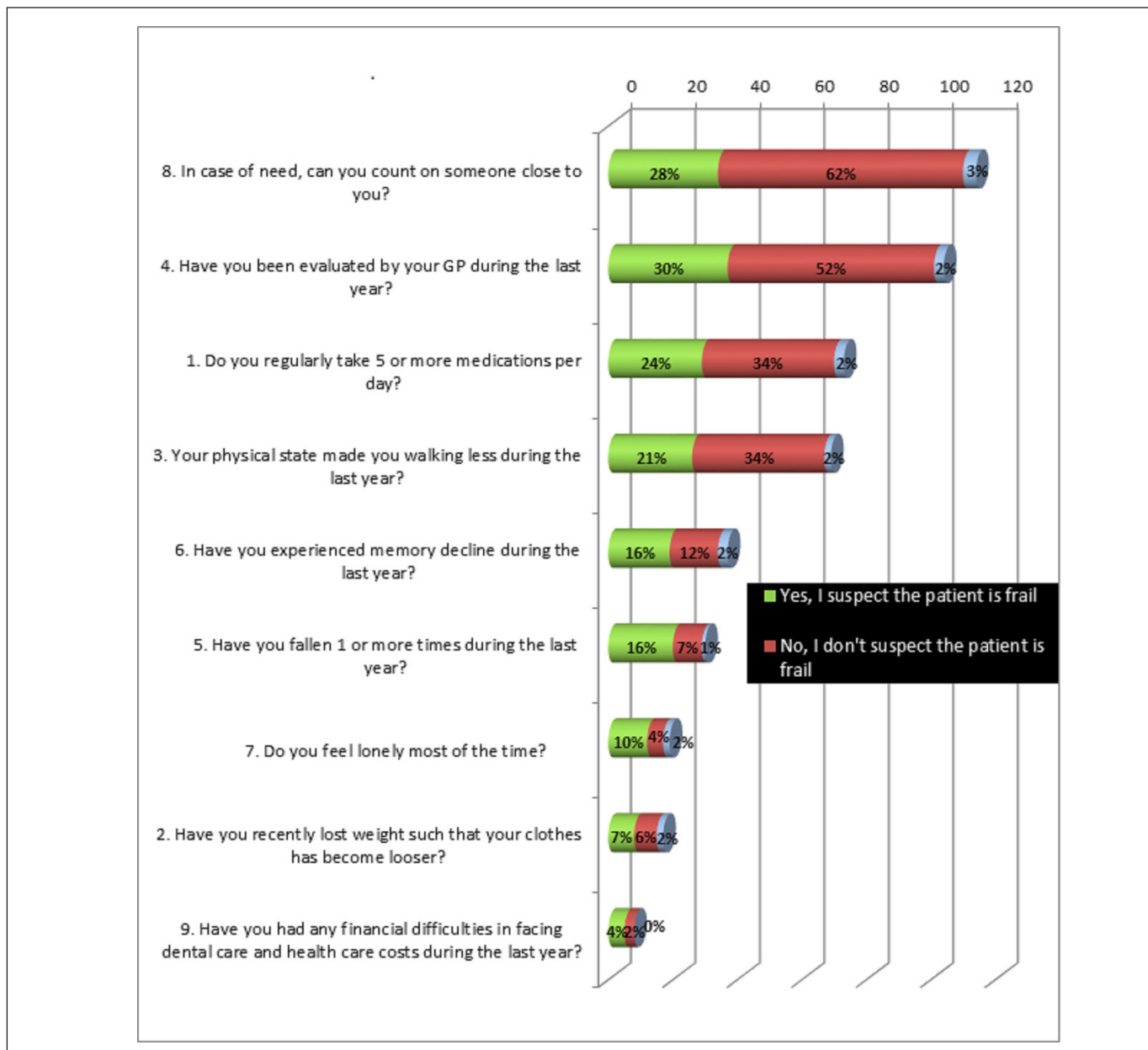
The exclusion of non-frail subjects (NPV) with correct exclusion of CGA, is crucial for assessing the performance of the instrument. Any screening of elderly subjects by the GP, must have a high NPV (>75%). The analysis here presented showed a NPV equal to 84.6%, confirming the goodness of SC (24).

Despite similar performance in terms of NPV, the SC offers advantages in comparison with other tools such as care assessment need (CAN) (24). In fact SC requires less time for the administration, is one-phase model, it’s validated for use in primary and it’s more devoted to address the risk of early-frailty condition than advanced-frailty and disability. Other tools, including GSFT, as reported in recent systematic reviews,

**Table 4**  
Instrument performance measurements

GP judgement	CGA Judgement			
	Yes, the patient is frail	No, the patient is not frail	We are uncertain	
Yes, I suspect the patient is frail	18 (Se=69,2%; PPV=58,1%)	13 (FalsePos=22,8%)	3	34 (35,8%)
No, I don't suspect the patient is frail	8 (FalseNeg =30,8%)	44 (Sp=77,2%; NPV=84,6%)	7	59 (62,1%)
I'm uncertain	0	1	1	2 (2,1%)
	26 (27,4%)	58 (61,1%)	11 (11,6%)	95

**Figure 1**  
Positive and negative answers to single checklist items allowing the final judgement of frailty by GP (N=122)



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have not been considered gold standard at least in the specific setting of primary care.

This study has some limitations.

The pre-set sample size was not reached due to a high percentage of drop-out. This inconvenience was caused by the presence of two clinics in one center, with subjects who didn't reach the CGA-T.

The education carried out at the GPs of the 2 recruiting centers was inhomogeneous, and this may have caused differences in the approach of frailty concept.

Disability was not assessed by ADLs and IADLs, but only by GPs judgement.

Given also the specific rural nature of the setting, the complete translation of our findings in different areas cannot be guaranteed.

In conclusion, the concordance between GP and CGA-T judgement of frailty was very low. This suggests that the SC cannot replace the CGA. However, due to the high NPV the SC seems to be an excellent screening tool of frailty, thanks to its high discriminating power of false negatives. Its wide use by the GP could improve the appropriateness in the request of CGA.

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*Conflicts of Interest:* All the authors have nothing to disclose.

*Ethical standards:* The project was approved by the local ethics committee on 12 december 2017, protocol number 44605.

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