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Research

Psychometric Properties of the Self Care Oral Anticancer Agents Index (SCOAAI)

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ABSTRACT

Objective: To test the Self-Care Oral Anticancer Agents Index (SCOAAI)'s psychometric properties (structural validity, convergent validity, predictive validity, and internal consistency) in a sample of patients with solid tumour on Oral anticancer agents (OAA).
Methods: A methodological research in five in- or out-patient Italian facilities. Structural validity was tested by confirmatory factor analysis, and internal consistency was assessed through Cronbach's alpha and composite reliability. The Mann–Whitney U-test was used to test associations between SCOAAI scores and patient's emergency room admission, re-hospitalization, mortality, and quality of life measured three months after baseline.
Results: We enrolled 356 patients; mostly were male (52.24%), and mean age was 59.10 years. Analyses demonstrated the SCOAAI's factorial validity and internal consistency. Moreover, patients that experienced emergency room admissions (U = 3484.5; $P = .002$) and re-hospitalization (U = 2446.0; $P = .001$) showed lower self-care maintenance scores; those who experienced emergency room admission (U = 3263.5; $P = .019$) and died at follow-up (U = 700.5; $P = .025$) had lower self-care monitoring scores; while patients that experienced re-hospitalisation (U = 2931.5; $P = .040$) and emergency room admission (U = 3285.0; $P = .012$) had lower self-care management scores. Patients with adequate self-care (≥ 70) reported significantly higher quality of life (self-care maintenance U = 1228.500, $P < .001$; self-care monitoring U = 3512.500, $P < .001$; self-care management U = 3287.500, $P < .001$).
Conclusion: According to our findings the SCOAAI is a valid and reliable tool. Patients with inadequate self-care can experience more emergency room accesses, re-hospitalization, death, and lower quality of life.
Implications for Nursing Practice: Adequate self-care behaviors can improve patient's outcomes and should be assessed by healthcare providers during the disease pathway.

According to the International Agency for Research on Cancer, there were an estimated 18.1 million new cases of cancer recorded globally in 2020. The International Agency for Research on Cancer reports that by 2040 there will be a 54.9% increase in new cancer case from 2020, proving that cancer is among the leading causes of death in the world.[1] The most frequent types of cancer diagnosed for men were: pancreas, testis, kidney and renal pelvis, while for women: lung and bronchus, breast, colon and rectum, pancreas, ovarian.[2]

In the last 10 years there has been a continuous development of new treatment modalities for cancer, in particular oral anticancer agents (OAAs) has increased exponentially.[3] These medicines can offer patients greater comfort and convenience, allowing for more self-management and fewer hospital visits compared to intravenous therapy. The use of OAAs due to multiple advantages, including better tolerability given the safety profiles of these medicines, greater

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Plain English Summary / Layperson Summary

Although the use of oral anticancer agents is increasing, self-care behaviours in patients with cancer using oral anticancer agents has not been studied yet. We enrolled 356 patients in 5 Italian centres to whom we administered the Self-Care Oral Anticancer Agents Index questionnaire, a newly developed questionnaire that measures self-care behaviours in these patients, to assess its validity and reliability. Additionally, we explored if adequate self-care behaviours could lead to better patients' outcomes, namely emergency room admission, re-hospitalization, mortality, and quality of life, all measured three months after baseline enrolment. Our results showed that the Self-Care Oral Anticancer Agents Index is a valid and reliable tool that can be used to measure self-care behaviours. Patients with adequate self-care reported significantly higher quality of life and less emergency room accesses, rehospitalisation, and mortality. Implementing targeted educational interventions for patients with cancer taking oral anticancer agents can enable them to acquire disease maintenance, monitoring and management behaviours that ensure an adequate level of self-care. Adequate self-care behaviours can improve patients' quality of life, but they could also reduce the costs related to use of healthcare service (through rehospitalisation and emergency room access).

comfort and adaptability to activities of daily living, less stress associated with intravenous administration, and lower cost compared to intravenous medications administered in inpatient settings. Moreover, OAAs are generally preferred by patients because, with these medications, they can manage therapy at home and avoid hospitalisation.[4]

However, patients taking OAAs are exposed to lower adherence to treatment due to their beliefs in medicines,[5] psychological disorders (eg, depression),[6,7] drug interactions[8] and side effects,[9] especially if they take more medications and have comorbidities.[10,11] Cancer is increasingly regarded as a chronic condition;[12] therefore, all cancer patients taking OAAs require ongoing health support and self-care management. Patients taking OAAs need good education on treatment from healthcare professionals or need to develop behaviours that help them manage these drugs properly and avoid complications. These behaviours have been defined as 'self-care'.

Self-care was defined as a process by which the patient seeks to ensure physiological and emotional stability in the presence of an illness (self-care maintenance), monitors the possible appearance of signs and symptoms related to the illness (self-care monitoring), and acts if he/she recognizes elements of relapse or worsening (self-care management).[13] Self-care has been extensively studied in chronic conditions (eg, heart failure, diabetes, chronic pulmonary diseases), and several instruments have been developed for its assessment (https://self-care-measures.com/).[14-16]

Self-care is also being studied in patients with cancer treated with OAAs,[17,18] but currently there are no studies that described in-depth the role of self-care in improving patient outcomes. Few studies focused only on adherence behaviours, reporting that nonadherence can be associated with worse symptom burden[19] and quality of life (QoL).[20] This issue can also be more significant, as patients manage their treatment at home and side effects that influence QoL and adherence could not be always reported during routine visits with the oncology team.[21] Supporting this evidence, a recent study published by Howell and colleagues [22] emphasized that it is necessary to integrate self-care of cancer patients into the care process, through high-quality, person-centred support, to foster better health outcomes of patients. Numerous studies have found that self-care improves the management of chronic illnesses (eg, type 2 diabetes mellitus[23] and heart failure[24]). According to this research, self-care can lower hospitalization rates and death rates,[24,25] and it can also improve patients' quality of life.[24,26] Similarly, a number of studies have demonstrated that poor self-care behaviours can result in worse outcomes for cancer patients (eg, worse quality of life,[27] cancer-related symptoms,[20] higher overall healthcare costs,[28] and a lower disease-free survival[29]).

To assess the level of self-care (and its dimensions, eg, self-care maintenance, self-care monitoring, self-care management) in patients affected by a solid tumour taking OAAs, the Self Care Oral Anticancer Agents Index (SCOAAI) instrument was developed.[30] This instrument was developed in the attempt to fill the gap in the literature regarding the concept of self-care in the oncology setting, as to date no studies assess self-care behaviours in this population. It is commonly acknowledged that effective self-care is essential to maintain good health and manage sickness, as demonstrated by the several tools validated for measuring self-care in different chronic conditions.[31] The content validity was carried out following the Consensus-based Standards for selecting health Measurement Instruments (COSMIN) criteria.[32] However, the psychometric properties of this instrument and its predictive validity in recognizing potential negative outcomes still need to be evaluated.

Thus, this study aimed to test the SCOAAI's psychometric properties (structural validity, convergent validity, predictive validity, and internal consistency) of the in a sample of patients affected by solid tumour on treatment with OAAs.

Methods

Design

This paper present the results of a methodological research that tested the psychometric properties and validation of the SCOAAI. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) reporting guidelines were used for the study reporting.[33]

Setting and Sample

A convenience sample of 356 patients undergoing OAAs was enrolled in five Italian in- and outpatient settings from November 2022 to July 2023. The patient's inclusion criteria were: 1) adult patients ($\geq$ 18 years); 2) who gave consent to participate in the study; 3) diagnosis of metastasized or locally advanced solid tumour; 4) space-temporal orientation; 5) understanding of the Italian language; and 6) active treatment with oral anticancer agents (cytotoxic chemotherapy, molecular targeted therapy, hormone therapy) for at least 3 months. Patients with haematological malignancies were excluded.

Instruments

Socio-demographic (eg, age, gender) and clinical characteristics (eg, primary tumour site, isotype, stage, etc.) of cancer patients were collected using an ad hoc questionnaire.

The SCOAAI is a theory-based instrument composed by 32 items: 15 on self-care maintenance; 11 on self-care monitoring and 6 on self-care management. The SCOAAI was developed and tested for its content validity in the Italian population and it showed good content validity (the average Scale Content Validity Index was 0.95).[30] All items were rated on a 5-point Likert scale format. The self-care maintenance and monitoring scales ranged from 1 (Never) to 5 (Always), while the self-care management scale ranged from 1 (not at all likely) to 5 (Totally likely). Each scale score was obtained in a standardized

manner: 1) sum of the items 1-10; 2) the lowest possible score (ie, 10) was subtracted from the sum obtained; 3) the result obtained in the second step was then divided by the range of the minimum and maximum score possible (ie, 40); 4) lastly, the score obtained in the third step was multiplied by 100.[34] A higher final score indicates a higher self-care level.

The Self-Care Self-Efficacy Scale was used to test convergent validity, as previous showed that self-care self-efficacy have an influence on the self-care in patients with chronic illnesses.[35,36] This is a widely used scale validated in several countries, including Italy and it consists of 10 items and investigates the patient's self-care efficacy, ie, the level of self-confidence in performing specific self-care activities.[37] All items are rated on a 5-point Likert scale format. The scale ranges from 1 (Not Confident) to 5 (Extremely Confident). This scale has a standardised score ranging from 0 to 100, with a higher score indicating better self-efficacy. In our sample, the Self-Care Self-Efficacy Scale showed excellent internal consistency reliability (Cronbach's alpha = 0.99).

The EORTC-QLC C30 scale was used to assess the association between an adequate level of self-care and quality of life (QoL). This scale consists of 30 self-reported items assessing different aspects of patient functioning, global health status, and cancer-related symptoms. It includes nine multi-item scales: five functional scales (physical, role, cognitive, emotional, and social); three symptom scales (fatigue, pain, nausea, and vomiting) and one global health and quality of life scale. Two single-item symptom measures are also included. The score for each scale ranges from 0 to 100. A higher score for the global health status indicates a higher level of QoL; a higher score for the functional scales indicate an healthier level of functionality; while an higher score for the symptom scales indicate an higher level of symptoms (insufficient control). This scale has been validated in several countries, including Italy.[38] In our sample, the internal consistency reliability for the global health status was excellent (Cronbach's alpha = 0.93).

Data Collection

The study participants were recruited according to the inclusion and exclusion criteria by trained research assistants who identified eligible inpatients and outpatients from the different healthcare Italian institutions participating in this study. Eligible participants were provided with detailed study information and invited to participate. Data collection started after the patient signed the informed consent form. Patients were invited to participate at follow-up at the first routine outpatient visit three months after enrolment.

Ethical Considerations

The Good Clinical Practice Standards of the European Union and the Declaration of Helsinki were followed in developing this study's protocol. Participants were required to give written informed consent. They were made aware of the study's objectives and that there were no hazards in participating in the study. Participants were made aware that they were free to leave the study at any moment and without justification. Information about the participants will be safely maintained on dedicated premises accessible to the principal investigator only. The study was approved by the Ethics Committee of the *[Blinded for peer review]* with reference number #188.22.

Data Analysis

The clinical and sociodemographic characteristics of the individuals were described using descriptive statistics (mean, frequency, percentage, and standard deviation [SD]). Additionally, skewness and kurtosis were calculated to determine the distribution of the SCOAAI items. We looked at missing data at the item and variable levels. Missing data were less than 5%, so only complete cases are analysed as this does not compromise the result.[39] A *P* value of equal to or less than .05 was considered statistically significant. All analyses were performed using JASP© (version 0.18.3)[40] and R® (version 4.3.1) [41] with the "lavaan," "semPlot" and "semTools" packages.

Structural Validity

Confirmatory Factor Analysis (CFA) was used to test the dimensionality of the SCOAAI, according to the theoretical reference model of Middle-Range Theory of Self-Care of Chronic Illness.[13] CFA was conducted using the unweighted least square (ULS) estimator. This estimator was chosen as it was found to produce more accurate and precise factor loadings than other estimators used for ordinal data.[42] The following fit indices were considered while evaluating the efficacy of the tested model:[43] comparative fit index (CFI) and the Tucker-Lewis index[44], which values of equal to or greater than 0.95 indicate an excellent fit; standardized root mean square residual (SRMR), which values of equal to or less than 0.08 indicate a good fit; root mean square error of approximation (RMSEA), which values of less than 0.05 indicate a well-fitting model, 0.05 to 0.08 moderate fit and values higher than 0.10 a poor fit;[45] and chi-square statistics. Since the *P*-value of the $\chi 2$ statistic tends to be significant when the sample size is large, it was not used to evaluate the model fit.[45] Moreover, *P*-value is not available in R for ULS estimator. We considered a sample size of 200 patients as appropriate for an effective CFA.[43] We used a CFA approach to determine the number of dimensions in each scale because the instrument is theory-based. We performed four separate confirmatory factor analyses (CFA), one for each scale of the SCOAAI (Self-Care Maintenance, Monitoring and Management Scale and one considering all items of the instrument), in line with previous validation studies conducted with other self-care tools[36,46] based on the self-care theory of chronic diseases. Moreover, a second-order CFA was conducted to confirm the overall factor model.

Convergent Validity

In accordance with previous studies[14,36] the construct validity of the SCOAAI was tested by comparing the self-care maintenance, monitoring, management with the Self-Care Self-Efficacy instrument via Pearson's correlation coefficient "r." Correlations ranging from 0.10 to 0.29 were categorized as weak, those from 0.30 to 0.49 as moderate, and values equal to or greater than 0.50 were considered strong.

Predictive Validity

Predictive validity was tested comparing the SCOAAI scores obtained for each SCOAAI scale (ie, self-care maintenance, self-care monitoring and self-care management) with emergency room admissions, re-hospitalisation, death, and quality of life (QoL) measured at three months after the patient's enrolment. The Mann–Whitney U test was used to conduct these analyses. Specifically, for measuring QoL the cut-off of 70 for SCOAAI measured at baseline (higher values indicate adequate self-care) was used, in accordance with previous research.[47] Consistently with the EORTC QLQ-C30 reference manual,[48] quality of life was calculated considering items Q29 and Q30.

Internal Consistency

The internal consistency of unidimensional scales (self-care monitoring) was analysed by means of Cronbach's alpha, while reliability of multidimensional scales (self-care maintenance and self-care management) was assessed with composite reliability.[49] A coefficient of 0.70 or higher indicates a satisfactory level of internal consistency,

while a coefficient of 0.80 or higher suggests a high level of internal consistency.

Results

Clinical and Sociodemographic Characteristics of the Participants

A total of 356 patients were enrolled in the study. The mean age was 59.10 (± 12.24) years. The sample's 47.75% (n = 170) were females; 75.56% (n = 269) were married; 44.10% (n = 157) had high school education; and 35.39% (n = 126) were employees. Breast cancer was the most frequent malignancy (37%, n = 134). The mean duration of OAAs' treatment was 16.95 (± 24.10) months. Approximately half of patients enrolled (n = 166; 46.62%) were using a tyrosine kinase inhibitor (eg, erlotinib, sorafenib and sunitinib, etc.) (Table 1).

The Skewness, Kurtosis, Mean, Standard Deviation of the items' scores are reported in Table 2. Skewness and Kurtosis indices had all values > |1| so items were non-normally distributed. Item #2, "Take the cancer medication as prescribed," reported the highest score (4.88) while item #30, "Use stress reduction practices (eg, yoga, outdoor activities etc.)," reported the lowest score (3.61).

Self-Care Maintenance Scale

Dimensionality

A two factors model confirmatory analysis was conducted. The two factors were: "Prevention and healthy lifestyle behaviours" and "adherence behaviours." The initial CFA model revealed a negative variance for self1, indicating a potential issue with model specification. Modification indices suggested that item #1 might fit better with the prevention and healthy lifestyle behaviours. However, a simple reassignment did not fully resolve the issue. Given the conceptual overlap of item #1 with both prevention and healthy lifestyle behaviours and adherence behaviours, a cross-loading was introduced. This adjustment resulted in significant loadings for item #1 on both factors. Fit indices for this model were: $\chi 2\,(88) = 235.142$, CFI = 0.990 and TLI = 0.987, RMSEA = 0.069 (90% CI = 0.058-0.079, $P = .002$) SRMR = 0.074 demonstrating a good fit (Table 3). The factor loadings were all statistically significant, only the item #1 had a factor loading < 0.40 (0.31) in the Prevention and healthy lifestyle behaviours, the other values were all greater than 0.70 (Table 2). Items correlated with the first factor "Prevention and healthy lifestyle behaviours" were: #1, #4, #6-15 and for the second one "adherence behaviours" were items #1-3, #5. Correlation between the two factors was strong (.77), thus a second-order model was tested (Fig. 1). The second-order model yielded to the same fit indices as the first-order model.

TABLE 1
Sociodemographic Characteristics of Patients on OAA

Patients (N=356)	N	%	Mean
Gender			
Male	186	52.24	
Female	170	47.75	
Age (years)			59.10 (12.24)
Marital status			
Single	33	9.27	
Married/ partnered	269	75.56	
Divorced	17	4.77	
Widowed	37	10.39	
Level of education			
None	2	0.56	
Primary school	41	11.51	
Secondary school	78	21.91	
High school	157	44.10	
Graduation	78	21.91	
Employment status			
Unemployed/retired	12	3.37	
Employee	126	35.39	
Freelance	61	17.13	
Household	38	10.67	
Retired	116	32.58	
Primary tumour site			
Lung	52	14.61	
Genitourinary	104	29.21	
Breast	134	37.64	
Bones, Brain, Ovarian	35	9.83	
Gastrointestinal	31	8.71	
OAA			
Cytotoxic agents	84	23.59	
TKIs	166	46.62	
Hormonal therapy	104	29.21	
Time since treatment started (months)			16.95 (24.10)

OAA, oral anticancer agent; TKIs, tyrosine kinase inhibitors.

Reliability and Item Analysis

The composite reliability was 0.857 for "Prevention and healthy lifestyle behaviours" and 0.691 for "adherence behaviours." The first value indicated a high reliability, while the second one indicated a slightly poor reliability. The items of the self-care maintenance had a high item total corrected correlation with values >0.30. For the factor "Prevention and healthy lifestyle behaviours" item total correlation coefficients ranged from 0.60 (item #10) and 0.81 (item #7) and for the factor "adherence behaviours," ranged from 0.64 (item #2) to 0.83 (item #3).

Self-Care Monitoring Scale

Dimensionality

For the self-care monitoring scale, a one factor model confirmatory factor analysis was tested (Fig. 2). The indices of the goodness of fit were as follows: $\chi 2\,(44) = 77.696$; CFI = 0.997 and TLI = 0.996, RMSEA = 0.046 (90% CI = 0.029 - 0.063, $P = .615$), SRMR = 0.058 demonstrating a good fit of the model tested (Table 3). Factor loadings were all > 0.7, with a mean value of 0.86 indicating a significant portion of shared variance among the items.

Reliability and Item Analysis

The internal consistency was tested with Cronbach's alpha coefficient, which was 0.955. The items of the self-care monitoring had a higher item total corrected correlation with values >0.30. Item total correlation coefficients ranged from 0.71 (item #19) and 0.83 (item #16).

Self-Care Management Scale

Dimensionality

Self-care management was tested with a two-factor model, "problem solving behaviours" and "consulting behaviours," including items #27-30 and items #31-32, respectively. Factor analysis demonstrated excellent fit indices: $\chi^2\,(8) = 6.012$; CFI = 1.000 and TLI = 1.002, RMSEA = 0.000 (90% CI = 0.000-0.051, $P = .945$), SRMR = 0.028 (Table 3). All factor loadings were significant and >.80. The two factors had a correlation of 0.71. Thus, a second-order hierarchical model including the first-order factors was tested, obtaining the same fit indices as the first-order model (Fig. 3).

Reliability and Item Analysis

We calculated the composite reliability for this scale, which was 0.904 for "problem solving behaviours" and 0.861 for "consulting behaviours." The items of the self-care management scale had a high item total corrected correlation with values >0.30. Item total correlation coefficients ranged from 0.68 (item 31 e item 32) and 0.84 (item 28).

TABLE 2
Descriptive Statistics of the Items Composing the Self-Care of Oral Anticancer Agents Index (SCOAAI) with Their Respective Factor Loadings

	Items	N	Mean	SD	Skew	Kurtosis	Factors Loading
	Self-Care Maintenance In reference to the cancer medication that you take, how often do you do the following? (tick the corresponding number)						
1	Follow the recommendations of healthcare providers	356	4.77	0.59	−2.68	7.35	0.308 (phb) 0.708 (ab)
2	Take the cancer medication as prescribed	356	4.88	0.42	−4.41	25.65	0.706
3	Attend all medical visits as scheduled	356	4.86	0.42	−4.00	22.94	0.988
4	Use a system/method that helps you to remember to take your medications (eg, calendar, writing on medication boxes, etc.)	356	4.24	1.33	−1.62	1.15	0.778
5	Only take medication recommended by your healthcare providers	356	4.76	0.52	−2.68	9.99	0.932
6	Do physical activity (eg, walking, cycling, etc.) within the limits of your possibilities	356	3.90	1.35	−0.82	−0.72	0.738
7	Eat sufficiently and with healthy food	356	4.35	0.90	−1.22	0.45	0.896
8	Take liquids adequately (eg, 1-1.5 litres of water per day)	356	4.33	0.83	−1.01	0.23	0.805
9	Get enough sleep to feel rested	356	4.08	1.09	−0.93	−0.23	0.796
10	Refrain from tobacco	356	4.42	1.11	−1.80	1.98	0.728
11	Limit drinking alcohol	356	4.49	0.86	−1.50	1.33	0.766
12	Asking healthcare providers about your cancer medications	356	4.29	1.11	−1.38	0.67	0.795
13	Maintain good oral hygiene	356	4.39	1.03	−1.85	2.81	0.858
14	Preventing infections (eg, by washing your hands often, getting vaccinated against the flu, etc.)	356	4.42	1.01	−2.14	4.17	0.733
15	Limit situations that can bring to physical and / or emotional stress	356	4.12	1.01	−0.87	−0.29	0.739
	Self-Care Monitoring Regarding the cancer medications you take, how often do you monitor the following? (tick the corresponding number)						
16	Cancer medication side effects	356	4.07	1.26	−1.28	0.41	0.897
17	New symptoms	356	4.15	1.20	−1.39	0.84	0.866
18	Decrease or increase in appetite	356	4.15	1.14	−1.18	0.42	0.900
19	If you have constipation or diarrhoea	356	4.22	1.09	−1.36	1.16	0.818
20	Whether you tire more than usual doing normal activities	356	4.21	0.96	−1.05	0.44	0.853
21	Skin and nail changes	356	3.88	1.24	−1.00	0.04	0.896
22	Your pain level	356	4.02	1.11	−0.94	−0.08	0.856
23	The colour and the quantity of your urine	356	3.79	1.29	−0.87	−0.32	0.794
24	Your mouth, teeth, and eyes	356	3.94	1.21	−1.03	0.10	0.887
25	Any measurements your healthcare provider recommends (eg, blood pressure, heart rate, etc.)	356	4.03	1.21	−0.99	−0.07	0.831
26	Your weight	356	3.99	1.35	−1.14	0.02	0.870
	Self-Care Management When you have symptoms attributable to the cancer medication(s) (eg, nausea, vomit, constipation, diarrhoea, fatigue, etc.), how likely are you to do the followings? (tick the corresponding number)						
27	Modify your daily routine (eg, modifying the diet, the time of daily life activities, etc.)	356	3.90	1.25	−0.76	−0.74	0.880
28	Implement home remedies that help you reduce symptoms (eg, hot/cold packs, drink cola, etc)	356	3.78	1.36	−0.64	−1.01	0.911
29	Take prescribed medications to reduce symptoms	356	3.94	1.35	−0.98	−0.41	0.914
30	Use stress reduction practices (eg, yoga, outdoor activities etc.)	356	3.65	1.46	−0.61	−1.09	0.831
31	Contact your doctor or nurse to ask what to do if you have symptoms that you are unable to manage	356	4.31	1.04	−1.46	1.40	0.970
32	Tell your healthcare provider about the symptom at the next oncological visit	356	4.57	0.77	−2.07	4.66	0.840

Phb, prevention and healthy lifestyle behaviours; ab, adherence behaviours.

Simultaneous Confirmatory Factor Analysis

To demonstrate that the factors underlying the SCOAAI scale emerged clearly, we performed a simultaneous CFA with all 32 items combined. This analysis reported the following indices: χ^2 (453) = 848.211; CFI = 0.994 and TLI = 0.993, RMSEA = 0.050 (90% CI = 0.044- 0.055, *P* = .547), SRMR = 0.067. Factor loadings ranged from 0.27 (item #1 in the Prevention and healthy lifestyle behaviours) to 0.98 (item #3).

Predictive Validity

We performed a Mann−Whitney U test to assess the association of the SCOAAI scales with emergency room admission, re-hospitalisation, death and QoL. Patients that were re-hospitalised (U = 2446.000; *P*-value = .001) and had emergency room admission (U = 3484.500; *P*-value = .002) had significantly lower self-care maintenance scores. No differences emerged regarding mortality (U = 806.500; *P*-value = .068). Patients that had emergency room (U = 3263.50;

TABLE 3
Fit Indices from Confirmatory Factor Analysis for the Self-Care of Oral Anticancer Agents Index (SCOAAI)

SCALE	χ2	CFI	TLI	SRMR	RMSEA (90% CI)	*P*-value
Self-Care Maintenance Scale	235.142 (88)	0.990	0.987	0.074	0.069 (0.058- 0.079)	.002
Self-Care Monitoring Scale	77.696 (44)	0.997	0.996	0.058	0.046 (0.029- 0.063)	.615
Self-Care Management Scale	6.012 (8)	1.000	1.002	0.028	0.000 (0.000- 0.051)	.945

CFI, comparative fit index; CI, confidence interval; DF, degree of freedom; *P*, probability; RMSEA, root mean square error of approximation; SRMR, standardized root mean square residual; TLI, Tucker and Lewis index; χ2, Chi-square.

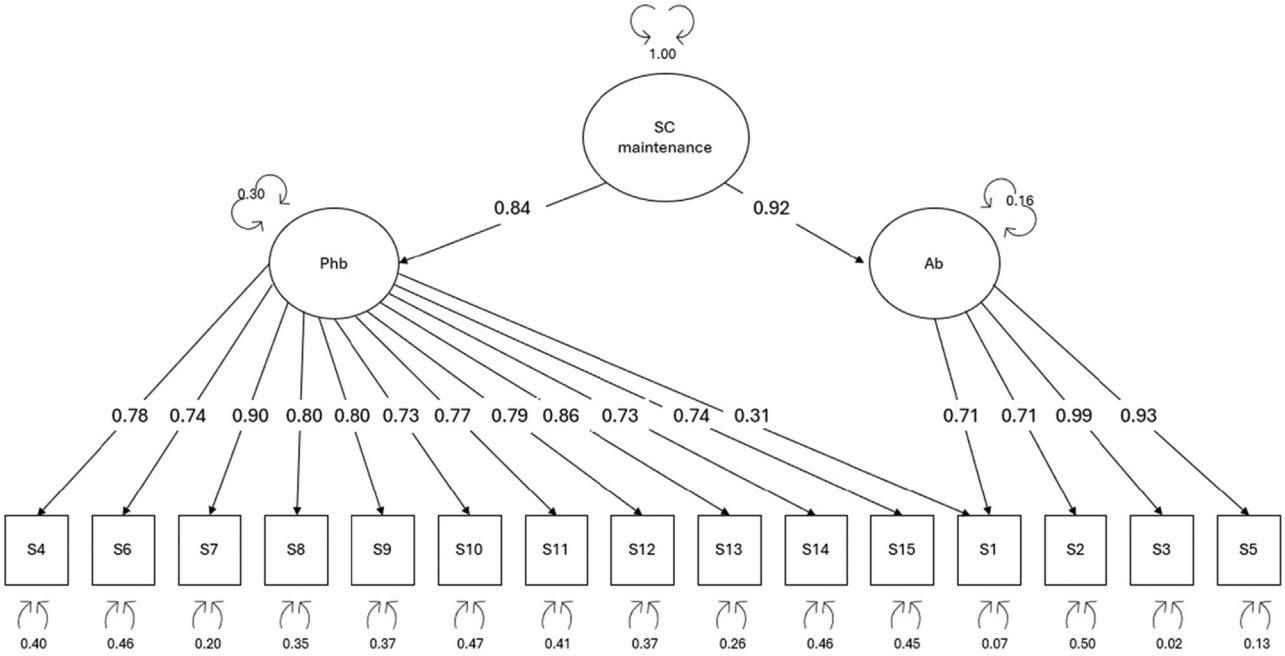

FIG 1. Confirmatory factor analysis of the self-care maintenance scale. Ab, Adherence behaviors; I, item; Phb, Prevention and Healthy lifestyle behaviors; SC maintenance, Self-care maintenance.

P-value = .019) and died (U = 700.5; *P*-value = .025) at follow-up had significantly lower self-care monitoring scores. No significant differences were found in re-hospitalisations (U = 3132.000; *P*-value = .139). Finally, patients that were re-hospitalised (U = 2931.5; *P*-value = .040) and had emergency room admission (U = 3285.0; *P*-value = .012) had significantly lower self-care management scores. No differences emerged regarding mortality (U = 828.500; *P*-value = .075).

An adequate self-care ($\geq$ 70) in all self-care scales was associated with QoL (self-care maintenance: U = 1228.500, $P < .001$; self-care monitoring: U = 3512.500, $P < .001$; self-care management U = 3287.500, $P < .001$). Mann–Whitney U test along with descriptive statistics were reported in (Table 4).

Convergent Validity

The SE score exhibited significant strong correlations with SCOAAI self-care maintenance (r = 0.71; $P < .001$), self-care monitoring (r = 0.69; $P < .001$) and self-care management (r = 0.66; $P < .001$) scales.

Discussion

This study aimed to test the psychometric properties of the SCOAAI scales which measures the level of self-care of patients on treatment with OAAs. We found evidence of good structural and construct validity, and internal consistency reliability for SCOAAI scales.

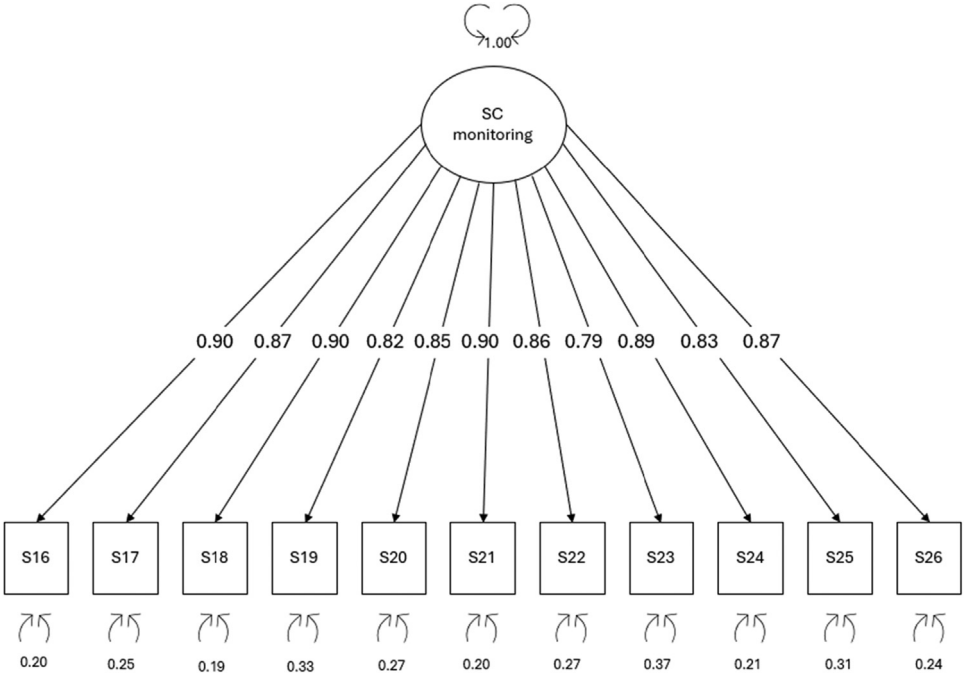

FIG 2. Confirmatory factor analysis of the self-care monitoring scale. I, item; SC monitoring, Self-care monitoring.

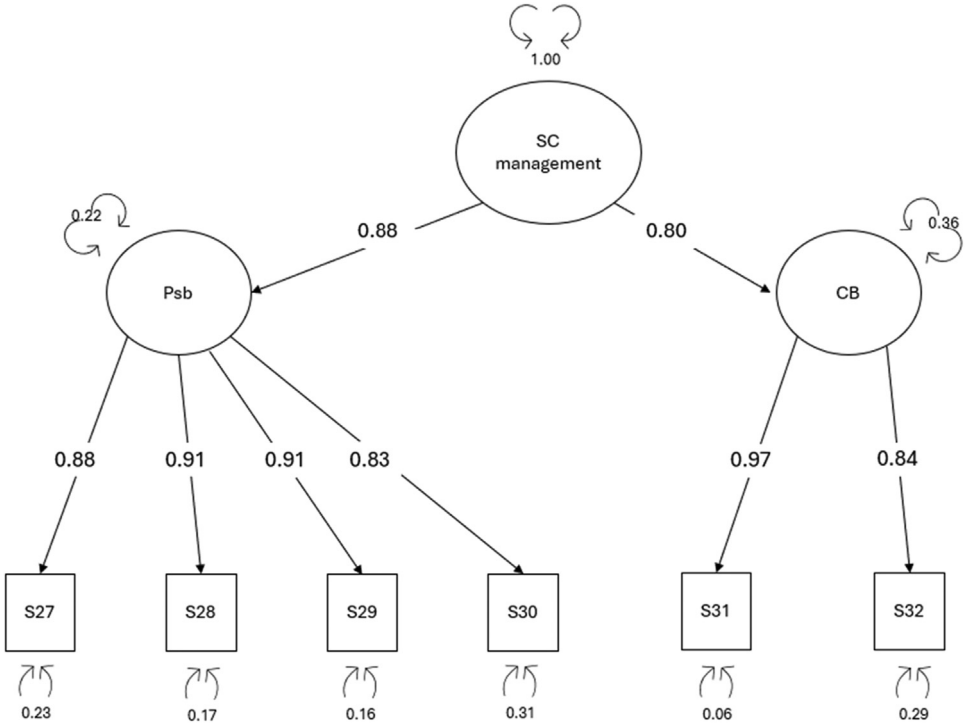

FIG 3. Confirmatory factor analysis of the second-order model self-care management. CB, Consulting behaviors; I, item; Psb, Problem solving behaviors; SC management, Self-care management.

Our results are in line with previous studies that validated instruments assessing patients' self-care in chronic diseases,[14,36,46,50] demonstrating the importance of self-care behaviours.

Regarding the self-care maintenance scale, we tested a two-factor model, obtaining a good fit. The psychometric findings were consistent with the existing model, which identifies two dimensions: health promotion and disease-related behaviour.[46] In this study, the two-factor model was confirmed, namely "Prevention and healthy lifestyle behaviours" and "Adherence behaviours" factors. The items of "prevention and healthy lifestyle behaviours" involve similar behaviours considered in chronic disease self-care scales. In contrast, the items in the "adherence behaviours" factor represent behaviours that are specific to this population. The only exception was item #1 which loaded on both factors. This can be explained by the nature of the item, as following the recommendations of healthcare providers can reflect a preventative behaviour performed in daily life to maintain health and a behaviour indicative of adhering to therapy to manage a health condition.

Items falling under the dimensions of "adherence behaviours" are consistent with the idea that adherence is a crucial aspect of the therapeutic process and determines the success of any therapeutic intervention. The lack of adherence is a common, complex, and multidimensional healthcare problem, and it may negatively affect treatment efficacy and increased costs related to ineffective disease management.[51,52] Predictive factors of OAA adherence have been extensively studied.[53-55] However, adherence is only one part of the self-care process, so the SCOAAI can provide a more complete view of factors interfering with the self-care of patients taking OAAs.

For the self-care monitoring scale, a one-factor solution resulted in excellent fit indices, and the psychometric findings were consistent

TABLE 4
SCOOAI Scores and Their Association with Emergency Room Admissions, Re-Hospitalization, Death, and Quality of Life

	SC Maintenance Scale				SC Monitoring Scale				SC Management Scale			
	U (p)		N	Mean (SD)	U (p)		N	Mean (SD)	U (p)		N	Mean (SD)
Mortality	806.5 (.06)	**Yes**	9	82.77 (8.07)	700.5 (**.02**)	**Yes**	9	61.36 (23.75)	828.5 (.07)	**Yes**	9	64.44 (23.24)
		No	276	86.37 (17.30)		**No**	276	77.58 (25.35)		**No**	276	76.41 (26.85)
Re-hospitalization	2446.0 (**.001**)	**Yes**	30	82.33 (11.61)	3293.5 (.20)	**Yes**	30	75.45 (21.39)	2931.5 (**.04**)	**Yes**	30	72.83 (15.18)
		No	250	86.87 (17.72)		**No**	250	77.61 (25.76)		**No**	250	76.76 (27.78)
Emergency Room Admission	3484.5 (**.002**)	**Yes**	19	80.96 (10.64)	3263.5 (**.02**)	**Yes**	19	71.17 (19.56)	3285.0 (**.01**)	**Yes**	19	64.73 (20.71)
		No	260	86.79 (17.57)		**No**	260	77.81 (25.68)		**No**	260	77.26 (26.96)

	Quality of life			
	U (p)		**N**	**Mean**
SC Maintenance Scale	1228.5 (< **.001**)	< **70**	38	26.75 (21.50)
		≥ **70**	257	63.19 (22.29)
SC Monitoring Scale	3512.5 (< **.001**)	<**70**	97	38.48 (27.17)
		≥ **70**	198	68.30 (17.38)
SC Management Scale	3287.5 (< **.001**)	< **70**	114	39.18 (26.92)
		≥ **70**	181	70.67 (14.34)

P, probability; SC, self-care; SD, standard deviation; U, Mann–Whitney U-test.

with previous studies.[34,46] The self-care monitoring scale measures patients' observation of signs and symptoms of their disease.[56] The 11-items of this scale refer to how often the patients check or monitor their condition. The actions may be objective (eg, checking vital signs) or subjective (eg, patients get more tired than usual in doing normal activities). Recognition of cancer-related symptoms is essential for symptom management and the ability to manage the disease properly. One of the item with the highest loading (0.90) was monitoring side effects of OAAs in general. This is not surprising, as several studies reported that side effects are often associated with nonadherence to OAA,[7,57,58] remarking on the necessity to adequately monitor side effects. Thus, monitoring behaviours may increase awareness of change in health status and influence patient decisions regarding his/her own health, with the possibility to impact on the cancer care continuum.

For the self-care management scale, we tested a two factor model with an excellent goodness-of-fit, and the two factors were named "Problem-solving behaviours" and "Consulting behaviours" as tested in a similar study.[50] The four problem-solving behaviours refer to actions that the patient could undertake alone (eg, change lifestyle habits), while the consulting behaviours refer to actions that involve the consultation with healthcare providers. The increasing use of OAAs necessarily leads to a transformation in the clinical care management of patients with cancer. Therefore, with the increasing number of patients taking OAAs, understanding the factors that play a key role in self-care is crucial. Indeed, a previous study remarked the self-management of OAA-induced side effects and the patient-provider communication as attributes of an adequate OAA self-management, highlighting that effective self-care management can be associated with better patient outcomes.[59] The Mann–Whitney test was performed to assess if patients who had access to the emergency room, had re-hospitalization or died at follow-up, showed lower self-care scores at baseline. To the best of our knowledge, this is the first study highlighting that patient on OAAs with those outcomes had lower self-care scores. As hypothesized, we found that all self-care scales were associated with at least one of the outcomes considered. Self-care maintenance was associated with emergency room admission and re-hospitalisation. This is not surprising, as a previous study highlighted how individuals with adequate self-care maintenance behaviours (for maintaining the disease) are more likely to report outcome improvements in other chronic conditions.[60] Self-care monitoring was associated with emergency room admission and mortality. This is a noteworthy result, as an adequate control of symptoms related to OAAs use can potentially prevent unnecessary emergency room admission and improve survival.

Lastly, self-care management was associated with emergency room admission and re-hospitalisation. This seemed to be related either on one hand to the fact that most patients on OAAs experiencing side effects rely on the support from general practitioners or oncology teams, or on the fact that they prefer waiting for the side effect disappear without intervening.[17] Therefore, not providing patients on OAAs with adequate therapeutical education on how to manage side effects could lead to more emergency room visits and re-hospitalisation.

An adequate level of self-care (a score $\geq$ 70 on each scale) was associated with improved quality of life at three months after the first assessment. This result is linked to the association between lower self-care scores and rehospitalisation and emergency room visits. Indeed, as lower self-care levels can be associated with more emergency room visits and re-hospitalizations, they can also impact the social and psychological sphere of patients and their caregivers.[61]

To improve the self-care levels of patients taking OAAs, it is certainly necessary to improve the communication skills of the oncology team, which is responsible for educating patients about the management of their therapy at home. Boons and colleagues have shown that patients perceive that they need more information from healthcare professionals regarding the management of OAAs.[62] These aspects are confirmed in a recent review[17] emphasizing the requirement for multidisciplinary and cross-healthcare settings to provide self-care education and assistance.

Finally, OAAs better use is of interest also for oncological scientific societies. For instance, the Italian Association of Medical Oncology (AIOM) indicated among its priorities the need to implement a pathway to decentralisation of care that has the potential to improve the outcome and quality of life of cancer patients and to reduce costs.[63] They also suggested modifying anticancer treatment in favour of oral medications when applicable. This suggests that OAA use will further increase soon, and thus the importance of studying and improving self-care in cancer patients. Furthermore, symptom management was identified as a priority for oncology nurses,[64] specifically through the implementation of telecare, another approach that could improve the self-care behaviours of patients under OAAs.

Limitations and Strengths

A limitation of this study is the relatively small sample size, which prevents the results from the broadest generalizability. Moreover, patients who needed an emergency room admission, re-hospitalization, or died were few compared to the total number of patients included in the study (n = 19, n = 30, n = 9, respectively). This is again a potential limit to the generalizability of the findings; therefore, they should be interpreted cautiously. Nevertheless, our findings are significant because they emphasize the leading role of self-care in patients on OAAs in preventing the related adverse outcomes.

Implications for Clinical Practice and Research

The SCOAAI is a reliable and valid instrument for measuring the level of self-care in patients undergoing treatment with OAAs. Information collected through this instrument can be used to design personalized educational programs that address individual needs, enhance understanding of cancer- or OAA-related symptoms, and promote adherence to healthy lifestyles or anticancer therapy. Future studies should evaluate the feasibility of implementing this tool for clinical practice in order to confirm its role in daily nursing practice.

Conclusion

The Self Care Oral Anticancer Agents Index (SCOAAI) is a theory-based, valid, and reliable instrument to measure self-care behaviours in the adult population with cancer under OAAs. The psychometric characteristic tested in this study supported the validity and internal consistency of the SCOAAI. The results of the SCOAAI associated with re-hospitalisations, emergency room admissions and mortality provide a first insight into the need to ensure an adequate level of self-care in these patients in order to reduce adverse outcomes.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Marco Di Nitto: Writing – original draft, Software, Project administration, Investigation, Formal analysis, Data curation, Conceptualization. **Silvia Ucciero:** Writing – original draft, Methodology. **Tatiana Bolgeo:** Writing – review & editing. **Vincenzo Damico:** Writing – review & editing. **Greta Ghizzardi:** Writing – review & editing. **Sipontina Rita Zerulo:** Writing – review & editing. **Mario Roselli:** Writing – review & editing. **Rosaria Alvaro:** Writing –

review & editing, Supervision, Funding acquisition. **Francesco Torino:** Writing – review & editing, Supervision, Conceptualization. **Ercole Vellone:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Funding acquisition, Conceptualization.

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