

RESEARCH PAPER

Two new tools for self-care in ostomy patients and their informal caregivers: Psychosocial, clinical, and operative aspects

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Stoma patients and their caregivers need to be autonomous in stoma care, but there are few instruments for measuring the level of self-care. This study aims to develop and test the psychometric properties of the Ostomy Self-Care Index (OSCI) and the Caregiver Contribution to Self-Care in Ostomy Patient Index (CC-OSCI), from a clinical, operative and psychosocial perspective. A multicentre validation study was conducted on a convenience sample of 468 ostomy patients and 227 caregivers. The signed informed consent forms were obtained before data collection. Tool validation was performed by testing content validity, construct validity, criterion and internal consistency. Two indexes were developed, building on the self-care theory of chronic illness. For the OSCI, 32 items were developed and grouped into four 5-point Likert scales: maintenance, monitoring, management and confidence. For the CC-OSCI, 22 items were developed and grouped into three 5-point Likert scales: maintenance, monitoring and management. The content validity indexes for the OSCI and CC-OSCI were 95% and 93%, respectively. Exploratory factor analysis showed appropriate factor loadings (OSCI: min 0.395 to max 0.852; CC-OSCI: min 0.442 to max 0.841). Criterion validity was established through significant correlation between levels of quality of life, complications, readmissions and self-care in patients and caregivers. Strong internal consistency was found for the overall index, and within the scales (OSCI: $\alpha = 0.975$; CC-OSCI: $\alpha = 0.972$). The OSCI and CC-OSCI are valid and reliable indexes. Further studies specifically aimed at predicting the level of self-care are especially recommended.

KEYWORDS

applied social psychology, cancer, caregiver, clinical aspects, instrument development, ostomy, psychosocial functioning, psychometric testing, self-care

1 | BACKGROUND FOR THE STUDY

In Europe, approximately 700 000 people are living with a stoma, and survey results have indicated that in Italy the number of people with a stoma is more than 70 000.¹⁻³ This number includes patients with an ileostomy, colostomy and urostomy. Some reports have found a steady increase in the number of people surviving colorectal and bladder cancer for at least 5 years following diagnosis; these data suggest that patients with cancer-related ostomies are living longer, and they

must cope not only with the daily maintenance of the stoma, but also with the associated changes in body image and physical, sexual, emotional, cognitive, work-related and psycho-social functionality.⁴⁻⁹ Many studies have indicated that successful adjustment to a permanent ostomy is related to self-care ability.^{8,10-14}

A variety of theories offer good explanations of self-care. None of them, however, is explicitly focused on ostomy care, even though ostomy patients have some of the same characteristics as patients with other chronic illnesses. Over the years, advances in surgical

techniques and ostomy care have reduced ostomy complications and improved the rate of positive outcomes (eg, survival) in ostomy patients as well as other chronically ill patients.^{4,8,12,15} For this reason, the theoretical framework of this research proposal will centre on a broad psychosocial perspective, as instantiated by Riegel's theory of the self-care of chronic illness.¹⁶

From a broad integrative psychosocial perspective, self-care has been defined as a process of naturalistic decision-making, which influences actions that maintain physiological stability, facilitates the perception of symptoms and directs the management of those symptoms.¹⁶ Key self-care concepts include self-care maintenance, self-care monitoring and self-care management.¹⁶ *Self-care maintenance* consists of those behaviours enacted by patients with a chronic illness to maintain physical and emotional stability. Such behaviours may be entirely self-determined or may reflect recommendations that, within a broader social context, are mutually agreed upon by patients and their health care providers. *Self-care monitoring* refers to the process of observing oneself for changes in signs and symptoms. *Self-care management* is reflected in patients' responses to signs and symptoms when they occur.¹⁶

Factors influencing self-care include skills and experience, motivation, cultural beliefs and values, self-confidence, well-established habits, functional and cognitive abilities, social support from others and access to care.¹⁶ Self-care is strongly influenced by *attitudes* and *beliefs* (eg, self-efficacy). Self-efficacy is defined as the confidence one has in the ability to perform a specific action and to persist in performing that action despite barriers.¹⁷ Confidence in the ability to perform self-care moderates the relationship between self-care and clinical outcomes, and it is important in each stage of the self-care process.¹⁶

Although self-care is, by definition, performed by the individual who has the illness, most chronically ill individuals would acknowledge the essential contributions of family and friends (eg, in terms of communication, decision-making, reciprocity, social and emotional support).^{16,18-21} Several studies have focused on concepts other than sheer self-care in ostomy patients, such as quality of life (QoL),²²⁻²⁴ adjustment^{9,25} and stoma-care abilities.²⁶ Although tools for measuring self-care in chronically ill patients are available (eg, diabetes, heart failure), they do not cover all facets of ostomy patient self-care.^{27,28}

To our best knowledge, a valid and reliable stoma-specific self-care tool for patients and their caregivers still does not exist. It may be extremely important, however, for stoma nurses to screen and identify patients in greatest need of support, and to subsequently assess the manifestations of such a need—including self-care tools—in the relationship with their patients.^{9,29}

1.1 | Aim

The main aim of this study was to develop and validate two tools: the Ostomy Self-Care Index (OSCI) and the Caregiver Contribution to Self-Care in Ostomy Patient Index (CC-OSCI). In developing the instruments, our study paid special attention to the clinical, operative and psychosocial facets assessed by the instruments. The research question is: How to measure self-care in ostomy patients and their caregivers?

WHAT IS KNOWN ABOUT THIS TOPIC

- Self-care is mandatory for patients with an ostomy, and the caregiver contribution to self-care is essential.
- Until now, there has been no valid and reliable way to measure self-care in ostomy patients and their caregivers.

WHAT THIS PAPER ADDS

- The OSCI and CC-OSCI scales have been shown to be valid and reliable tools for measuring self-care in ostomy patients and their caregivers, from a clinical, operational, and broad psychosocial perspective.

2 | METHODS

A multistep process was implemented, articulated along the following phases: instruments' development, content validity, construct validity, criterion validity and internal consistency.³⁰⁻³³

2.1 | Development phase

We conducted the operationalization phase of the index development in accordance with the guidelines set out in the methodological literature.³¹ To this end, we followed four steps in accordance with a detailed literature review of self-care in ostomy patients and their caregivers, Riegel's theory of self-care and self-care in ostomy patients. In the first two steps, we defined the construct of self-care and created the tools, respectively. In the third step, we defined and selected the pertinent indicators; in the last step we performed a back-translation into English.

2.2 | Validation phase

We examined content validity by referring to three sources: (a) the literature, by checking the correspondence of items to theory and literature, (b) the representativeness of the relevant populations, by asking people with stoma and their caregivers to read the scale and (c) expert analysis, to evaluate the clarity and relevance of the items with respect to the concept (dichotomous yes/no), and also to calculate the Content Validity Index (CVI). We used the CVI, as described by Lynn,³² to ensure that the OSCI and CC-OSCI conceptualizations were consistent with the measurement content domain. We obtained the CVI from a panel of 11 experts, including 2 nurses with expertise in self-care research, 5 expert stomatherapist nurses and 4 surgical nurses from surgical and urology departments. We asked these experts to rate each item's relevance to the conceptual definition, to critique the clarity of each item in terms of content and style, and to evaluate the comprehensiveness of items on both a dichotomous and 4-point scales ranging from 1 (not relevant) to 4 (highly relevant).³²

We evaluated construct validity in factor analysis, by using both principal axis factoring and Promax rotation procedures to confirm the structure of the scales.

We assessed criterion validity by comparing the patients' and caregivers' index scores with those of the stoma care quality of life (stoma-QoL) scale, a specific instrument that is commonly used to assess QoL in ostomy patients and that is validated in the Italian context. The stoma-QoL consists of 20 items based on four domains: sleep, sexual activity, relations to family and close friends and social relations outside family and close friends. Every item uses a 4-point Likert scale ranging from "always" to "not at all." The total score ranges from 20 to 80, with higher scores signalling comparatively higher levels of reported QoL.²² To our knowledge, in the Italian context there are no validated indexes for the measurement of self-care. For this reason, we chose the stoma-QoL scale because it is specific to ostomy patients, and QoL is a construct influenced by self-care. Because of such a lack of a proper self-care scale, and for all of the reasons outlined above, we decided also to investigate the correlation between self-care levels and the presence of complications or readmissions.

The internal consistency of the indexes was assessed using the Cronbach's alpha coefficient. A Cronbach's alpha of 0.80 is considered good, and greater than 0.90 excellent.³⁴

2.3 | Sample

Patients' inclusion criteria were (a) having an elective or urgent ostomy of any type (ie, ileostomy, colostomy, urostomy) for more than 1 month (b) being older than 18 years, (c) ability to speak Italian and (d) providing written consent to participate in the study. Patients were excluded if they had severe psychiatric deficits or severe cognitive impairments.

Caregivers' inclusion criteria were (a) being identified as the main informal (ie, not salaried) caregiver by the patient, (b) having the ostomy patient's agreement to participate in the study and (c) providing written consent to participate.

2.4 | Data collection methods

We collected data from adult ostomy patients and their caregivers in eight stoma outpatient clinics. Data collection took place from May 2017 to May 2018. The patient questionnaire was composed of a socio-demographic-clinical data form, which was used to collect information about demographics, living conditions, family and work conditions and clinical information about ostomy type; the OSCI and the Stoma-QoL. The caregiver questionnaire was composed by a socio-demographic-clinical data form, administered to collect information about demographics, living conditions and family and work conditions and the CC-OSCI.

For participants' answers to be relevant, both patients and caregivers had to be able to complete the questionnaire independently. A trained nurse approached patients and their caregivers in a private and quiet place and asked them to participate in the study while they waited for their appointments in the ostomy outpatient centre. After receiving informed consent, the nurse informed each potential participant about how to answer the questionnaire. The questionnaire took approximately 10 minutes to complete.

2.5 | Data analysis

Analyses were conducted using SAS (Sas Institute, Cary, NY, USA) and SPSS (IBM Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.) software. Continuous variables were summarized as median and interquartile range values. The scales and the Stoma-QoL scores were calculated according to the instructions provided by the original authors.²²

Correlations among patients'/caregivers' scales and the Stoma-QoL scores were assessed by Pearson's product-moment correlation coefficient, after data transformation according to Blom's method, and a normality check. Data transformation was necessary because scores were derived from Likert scales, and were not normally distributed. Next, either *t* tests or Mann-Whitney *U* tests were used to investigate the differences in the number of complications and readmissions among patients in relation to each scale of the patient and caregiver questionnaires, depending on whether the data fitted the assumptions for parametric vs non-parametric statistic calculations.

Further, all analyses were conducted by strictly abiding by the instructions provided by authors who have previously developed and tested self-care instruments based on Riegel's theory.^{20,35,36}

2.6 | Ethical considerations

The study complies with the Declaration of Helsinki, and it was approved by the Ethics Committee of the Hospital. Patients and caregivers were enrolled on a voluntary basis. Before data collection, all study participants were informed about the aims of the studies. Further, they were reassured that their data and all sensitive information were confidential and, as such, stored in a safe place. We obtained the signed informed consent forms before data collection. We also reassured participants that the study results were to be published only in aggregated form, preventing the identification of individual participants. Finally, once again, we told patients they had the right to withdraw from the study at any time. Trained research assistants were instructed to adapt to patients' time constraints and needs during data collection (eg, if research assistants noticed that patients were becoming tired during data collection, they would propose a brief rest).

3 | RESULTS

3.1 | Description of stoma patients and caregivers

Out of 703 questionnaires, 695 were returned and analysed (98.86%). The sample considered was composed of 468 patients and 227 caregivers, for a total of 695 people. Patients were 68 years old on average and mostly male, the majority were married (70.90%). In almost 82% of the cases, patients did not live alone, and most of the patients were retired (68.80%). Regarding clinical data, 189 people (40.38%) had a colostomy. The predominant causes of stoma creation were oncological (84.40%). Almost half of the patients declared they were autonomous in stoma management (49.97%). The average age of caregivers was about 59 years. The sample consisted of 78.41% women; the recruited caregivers were mainly husbands/wives/partners (64.32%),

and in 78.41% of the cases they lived with the patient. Finally, the average time spent on caregiving was about 43 hours per week.

3.2 | Development phase

We conducted the operationalization phase of index development in accordance with guidelines previously established in the methodological literature.³¹ In the first step, we defined self-care. More precisely, we defined *ostomy self-care* as a naturalistic decision-making process that influences actions related to maintaining the physiological stability of the stoma and peristomal skin, facilitates the perception of problems and complications, and directs the management of those problems and complications. In the second step, we defined the indexes. The patient index was composed of four scales: (a) self-care maintenance (daily routine behaviours), (b) self-care monitoring (stoma and peristomal skin recognition), (c) self-care management (problem recognition and response behaviours) and (d) self-care confidence (confidence in the ability to engage effectively in self-care). The caregiver index was composed of three scales: (a) caregiver contribution to self-care maintenance (contribution to daily routine behaviours), (b) caregiver contribution to self-care monitoring (contribution to stoma and peristomal skin recognition), (c) caregiver contribution to self-care management (contribution to problem recognition and response behaviours). The third step in operationalization was the definition and selection of indicators, and the last step was the back translation into English. We constructed the items according to a detailed review of the literature; the preliminary procedures of OSCI and CC-OSCI development consisted of the generation of an initial pool of 35 and 25 items, respectively. The OSCI and the CC-OSCI are self-reported tools that use a 5-point Likert scale (1 = never, 2/3/4 = sometimes, 5 = always). Item construction resulted in a summative score for each scale. The higher the score, the higher the reported self-care behaviour. A back translation from Italian into English, which was supervised by B. Riegel, was necessary to guarantee congruence of the translation with the original theory.

3.3 | Validation phase

We examined content validity by referring to three sources. The first included checking the congruence of the items with Riegel's theory of self-care and with the literature on self-care in ostomy patients and their caregivers. The second included asking people with stomas and their caregivers to read the index and mark all sentences that they could not—for any reason—understand or answer. No sentences were deleted; however, three items were rated as difficult to understand, and they were rewritten. The last source was an expert analysis, which was performed to evaluate the clarity and relevance of the items with respect to self-care. The results of the CVI evaluation indicated that the OSCI and CC-OSCI items had the highest rate of agreement among experts (95% and 93%, respectively).³² After the analysis, the current versions of the OSCI and CC-OSCI contained 32 items and 22 items, respectively, obtained through selection on the basis of the content validity.

We conducted an exploratory factor analysis to assess the structure of the two indexes through principal axis factoring and Promax

rotation. The same analysis was conducted for each of the OSCI and CC-OSCI scales. In order to allocate a factor relating to factor loading, we used Stevens' cut off, which was found to be 0.24 for the OSCI and 0.34 for the CC-OSCI. The analysis for each OSCI scale, except for self-care maintenance and self-care management, revealed one factor. All items exhibited high factor loadings, minimum 0.395 (OSCI.16) and maximum 0.852 (OSCI.31) (Table 1). The self-care maintenance scale exhibited a two-factor solution, labelled as appropriate stoma appliances maintenance (Factor 1) and stoma-care behaviour (Factor 2). The self-care management scale yielded a three-factor solution; however, one factor had low factor loading, and it was considered additional and not strictly relevant (OSCI.18). The other two factors were labelled as autonomous self-care management behaviours (Factor 1) and consultative self-care management behaviours (Factor 2). The same results were found for the CC-OSCI scales: the factor analysis revealed two factors for the self-care maintenance scale: stoma applied maintenance (Factor 1) and stoma-care behaviour (Factor 2). The self-care monitoring scale yielded one factor, and the self-care management scale yielded two factors: autonomous self-care management behaviours (Factor 1) and consultative self-care management behaviours (Factor 2). One factor was considered additional and not strictly relevant because of low factor loading (CC-OSCI.18). All other items exhibited high factor loadings, minimum 0.442 (CC-OSCI.17) and maximum 0.841 (CC-OSCI.5) for the CC-OSCI (Table 2). For both indexes, the analysis revealed good structure.

To assess the relationship between self-care behaviour and QoL, each scale of the OSCI and CC-OSCI was correlated with the Stoma-QoL scale.²² Table 3 shows the correlations between the Stoma-QoL scores and each scale of the OSCI and CC-OSCI.

Overall, the correlations were moderate and statistically significant for all scales, except for the confidence scale, for which we observed a comparatively weaker correlation. Overall, this pattern of results indicates that self-care behaviour and QoL are systematically related to one another.

Out of 468 patients, 71 (15.17%) had one or more complications and 62 (13.25%) had readmissions. We examined the differences in self-care scores between patients experiencing complications or readmissions and those who had no adverse events. The aim of these calculations was to assess whether the scales could detect the difference in incidence rates of complications or readmissions according to self-care behaviours, which is an important characteristic of the clinical situation of these patients. All scales showed statistically significant differences in the presence or absence of complications or readmissions ($P < 0.0001$ in all scales). The Mann-Whitney U test was used for these calculations.

Internal consistency was evaluated by using Cronbach's alpha coefficient. Very high internal consistency was revealed for the total OSCI ($\alpha = 0.975$). For the maintenance, monitoring, management and confidence scales, the Cronbach's alpha values were 0.965, 0.953, 0.930 and 0.962, respectively. The CC-OSCI also exhibited very high internal consistency. The Cronbach's alpha was 0.972 for the overall index and 0.972, 0.928 and 0.912 for the maintenance, monitoring and management scales, respectively.

Each of the OSCI and CC-OSCI scales' scores were calculated. We used median, interquartile range, minimum and maximum

TABLE 1 OSCI factor loadings after rotation of the pattern

	Factor 1	Factor 2	Factor 3
Self-care maintenance			
OSCI.1 Check that the stoma appliance and the collecting bags are appropriate to your needs	0.538		
OSCI.2 Check that the stoma appliance and the collecting bags are in good conditions before use	0.520		
OSCI.3 During substitution, remove the stoma appliance and the collecting bags from up to down		0.796	
OSCI.4 Clean the skin around the stoma and stoma		0.744	
OSCI.5 Dry dabbing the skin around the stoma		0.842	
OSCI.6 Adjust the size of the stoma in a new stoma appliance		0.831	
OSCI.7 Fit a new stoma appliance from down to up by joining the lower edge of the stoma appliance to the lower edge of the stoma		0.654	
OSCI.8 Change the stoma appliance according to information received		0.811	
OSCI.9 Eating and drinking according to information received		0.705	
Self-care monitoring			
OSCI.10 Monitor for leaks (faeces or urine) from the stoma appliance	0.812		
OSCI.11 Monitor the condition of filling of the collecting bag	0.826		
OSCI.12 Monitor the stoma state	0.547		
OSCI.13 Monitor the skin around the stoma	0.405		
OSCI.14 Monitor the amount and the changes in faeces and urine	0.497		
OSCI.15 Monitor the effects of eat and drinking on the faeces and urine (faeces too liquid/solid, concentrated urine)	0.578		
OSCI.16 Monitor your weight	0.395		
OSCI.17 Monitor your stoma appliance provision	0.747		
Self-care management			
OSCI.18 If you had stoma and/or the skin around the stoma problems during the last month, how quickly did you recognize it as a stoma problem?			0.240
OSCI.19 Change your diet or fluid intake to decrease or to stop the problem	0.836		
OSCI.20 Change the way you manage the stoma and the skin around the stoma	0.625		
OSCI.21 Call your stomatherapist/nurse/doctor for guidance		0.850	
OSCI.22 Talk about the problem to your stomatherapist/nurse/doctor to the next visit		0.843	
Self-care confidence			
OSCI.23 Maintain the stoma and the skin around the stoma in good conditions without problem?	0.793		
OSCI.24 Follow the treatment advice you have been given for stoma management	0.808		
OSCI.25 Persist to follow the treatment advice you have been given for stoma management even if it is hard	0.848		
OSCI.26 Monitoring the stoma and the skin around the stoma condition	0.809		
OSCI.27 Persist to monitor the stoma and the skin around the stoma condition	0.827		
OSCI.28 When they happen, recognize changes in your stoma and the skin around the stoma?	0.752		
OSCI.29 Evaluate the importance of stoma and the skin around the stoma problems	0.663		
OSCI.30 Do something that will relieve your stoma and the skin around the stoma problems	0.819		
OSCI.31 Persist to find a remedy for a stoma and the skin around the stoma problems even if it is difficult/hard	0.852		
OSCI.32 Evaluate how well a remedy works for stoma and the skin around the stoma problems	0.596		

Abbreviation: OSCI, Ostomy Self-Care Index.

descriptives, because the data were not normally distributed. Table 4 presents the scores of the scales.

Overall, the scores indicated a good level of self-care. For QoL, the mean of the Stoma-QoL score was 63.14 ± 15.35 . Such values indicate average level of QoL, because the score has a theoretical range between 20 (worst possible QoL) and 80 (optimal QoL).

4 | DISCUSSION

This study developed and tested the psychometric properties of two new instruments for measuring the self-care of ostomy patients and their caregivers, from a broad integrative psychosocial perspective.

Within a socio-psychological relational context, we used Riegel's middle range theory of chronic illness,¹⁶ and developed two instruments for measuring self-care maintenance, self-care monitoring, self-care management and self-care confidence for patients and their caregivers. We also showed that the OSCI and CC-OSCI had high content, construct, and criterion validity, and very high internal consistency, and thus be useful to other scholars and/or professionals wishing to measure self-care in people with an ostomy and their caregivers. To our knowledge, these tools are the first to measure self-care in the ostomy patient and caregiver populations.

Content validity tests revealed a high rate of agreement among experts. The dimensionality of the OSCI and CC-OSCI was analysed using exploratory factor analysis. The analysis was conducted on the

TABLE 2 CC-OSCI factor loadings after rotation of the pattern

	Factor 1	Factor 2	Factor 3
Caregiver contribution to self-care maintenance			
CC-OSCI.1 Check that the stoma appliance and the collecting bags are appropriate to your needs.	0.590		
CC-OSCI.2 Check that the stoma appliance and the collecting bags are in good condition before use.	0.630		
CC-OSCI.3 During substitution, remove the stoma appliance and the collecting bags from up to down.		0.743	
CC-OSCI.4 Clean the skin around the stoma and stoma.		0.808	
CC-OSCI.5 Perform dry dabbing of the skin around the stoma.		0.841	
CC-OSCI.6 Adjust the size of the stoma in a new stoma appliance		0.815	
CC-OSCI.7 Fit a new stoma appliance from down to up by joining the lower edge of the stoma appliance to the lower edge of the stoma.		0.732	
CC-OSCI.8 Change the stoma appliance according to information received.		0.718	
CC-OSCI.9 Eat and drink according to information received.		0.553	
Caregiver contribution to self-care monitoring			
CC-OSCI.10 Monitor for leaks (faeces or urine) from the stoma appliance.	0.669		
CC-OSCI.11 Monitor the condition of filling of the collecting bag.	0.677		
CC-OSCI.12 Monitor the stoma state.	0.783		
CC-OSCI.13 Monitor the skin around the stoma.	0.748		
CC-OSCI.14 Monitor the amount of and the changes in faeces and urine.	0.646		
CC-OSCI.15 Monitor the effects of eating and drinking on the faeces and urine (faeces too liquid/solid, concentrated urine).	0.478		
CC-OSCI.16 Monitor your weight.	0.535		
CC-OSCI.17 Monitor your stoma appliance provision.	0.442		
Caregiver contribution to self-care management			
CC-OSCI.18 If the patient had problems with the stoma and/or the skin around the stoma during the last month, how quickly did you recognize it as a stoma problem?			0.268
CC-OSCI.19 Change your diet or fluid intake to decrease or to stop the problem.	0.630		
CC-OSCI.20 Change the way you manage the stoma and the skin around the stoma.	0.726		
CC-OSCI.21 Call your stomatherapist / nurse / doctor for guidance.		0.683	
CC-OSCI.22 Talk about the problem with your stomatherapist / nurse / doctor during the next visit.		0.678	

Abbreviation: CC-OSCI, Caregiver Contribution to Self-Care in Ostomy Patient Index.

items defining each of the scales (four scales for the OSCI and three for the CC-OSCI). The structure was good for both tools, with high factor loadings, and therefore supported the hypothesized models. The analyses showed an interesting structure of the index. The analysis showed a hierarchical structure for two scales composed by two factors for each scale: the self-care maintenance for patient and caregiver and the self-care management for patient and caregiver. As in some previous Italian studies, factor analysis revealed similar results.^{20,35}

Criterion validity tests showed the correlations between self-care and QoL. The strength of correlation was moderate for both indexes,

except for self-care confidence, showing a comparatively weaker correlation ($r = 0.27$). Pearson correlation coefficients ranged from 0.27 to 0.48. In relation to complications and readmissions, all scales showed statistically significant differences in the presence or absence of complications or readmissions. This result confirmed the literature review, underlining that patient QoL can be influenced by several factors, such as the presence and severity of ostomy complications, hospital readmissions and self-care abilities.^{8,23,27}

Internal consistency in both indexes was very high in both the overall indexes and their individual scales too, with Cronbach's alphas

TABLE 3 Pearson's correlation coefficients between stoma-QoL and OSCI and CC-OSCI scores

Score	Pearson's <i>r</i>	<i>P</i> -value
OSCI maintenance	0.44	<0.0001
OSCI monitoring	0.43	<0.0001
OSCI management	0.44	<0.0001
OSCI confidence	0.27	<0.0001
CC-OSCI maintenance	0.46	<0.0001
CC-OSCI monitoring	0.45	<0.0001
CC-OSCI management	0.48	<0.0001

Abbreviations: CC-OSCI, Caregiver Contribution to Self-Care in Ostomy Patient Index; OSCI, Ostomy Self-Care Index; QoL, quality of life.

TABLE 4 Scores of the scales

Scale	Median [IQR]	Min-Max
OSCI maintenance	41.0 [34.5; 44.0]	4.0-45.0
OSCI monitoring	36.0 [29.0; 39.0]	6.0-40.0
OSCI management	18.0 [16.0; 20.0]	8.0-21.0
OSCI confidence	38.0 [30.0; 46.0]	10.0-50.0
CC-OSCI maintenance	40.0 [30.0; 44.0]	3.0-45.0
CC-OSCI monitoring	31.0 [24.0; 36.0]	5.0-40.0
CC-OSCI management	16.0 [12.0; 18.0]	7.0-23.0

Abbreviation: CC-OSCI, Caregiver Contribution to Self-Care in Ostomy Patient Index; IQR, interquartile range; OSCI, Ostomy Self-Care Index.

ranging from 0.930 to 0.965 for the OSCI and from 0.912 to 0.972 for the CC-OSCI.

Unlike other studies conducted in Italy on chronic populations with different clinical conditions, the level of self-care of the ostomy patients and their caregivers was good.^{20,35} This result probably reflects the high support to self-care performed by stomatherapist nurses. In fact, the study participants were enrolled in several outpatient clinics where patients and caregivers received education in stoma care. It would be interesting to study in depth the level of self-care in populations who do not have access to outpatient clinics.

4.1 | Limitations of the study

Along with strengths, this study also has limitations. First, although we enrolled patients and caregivers from multiple locations, we used convenience sampling at each location. Second, the tools were developed in an Italian population; because self-care and the role of caregivers are influenced by culture and local health care systems, it would be advisable to test the content validity of the OSCI and CC-OSCI scales also in different cultural context. Third, further analysis is needed to assess advanced psychometric properties of the instruments. For example, we could have conducted factor analysis using the exploratory structural equation modelling approach, as in research on the Self-Care of Diabetes Inventory,^{35,37} and we could have used a more appropriate reliability coefficient that takes into account the multidimensionality of the scale as the global reliability index for multidimensional scales.³⁷ Also, psychometric testing could show differences and peculiarity in the subgroups (kind of ostomy). Thus, future research could profitably include confirmatory factor analysis focusing on ileostomy, colostomy and urostomy samples.

5 | CONCLUSIONS

The new self-administered instruments can be used easily and scored quickly in clinical and research environments. Clinicians could, for instance, use the indexes to better understand patients' self-care, and to tailor subsequent specific interventions aimed at improving one or more of the self-care processes. They could also involve informal caregivers in the education process, because caregivers play a key role in providing care to ostomy patients. Furthermore, clinicians could profitably use the theory-based language to measure, document and communicate where and in which domain the patient is having a specific problem.

In the literature, the three processes of self-care (maintenance, monitoring, management) and self-care confidence have never been described in ostomy patients and their caregivers. Beyond the results brought about by our study, further research is needed to describe such processes, to identify their determinants, to shed light on the various outcomes associated with the processes, and to study the effect of specific, tailored health care interventions. Furthermore, the OSCI and CC-OSCI scales were developed based on a theory of chronic illness already used to study other diseases (heart failure, diabetes, stroke), and—as such—they could profitably contribute to a broader understanding of living with chronic conditions. On a more

abstract level, these and analogous empirical data, that is, data derived from the two instruments we proposed in the present article, could as well be helpful, in the future, in guiding scholars to corroborate, support, refine or revise, if necessary, the middle range theory itself—that is, the theoretical guide we chose to follow in this work.

6 | RELEVANCE TO CLINICAL PRACTICE AND RESEARCH

Further studies specifically aimed at predicting the level of self-care are especially recommended. Such studies should specifically focus, for instance, on the role of caregivers in order to determine if the contribution of caregivers to stoma patients' self-care has an effect on patient outcomes. It would be important to demonstrate whether caregivers are even more important than patients in terms of checking problems, facilitating patient adherence to stoma care, or managing problems. Understanding the contributions of caregivers to stoma patient self-care may provide another path of intervention for this problematic condition. Because the CC-OSCI is equivalent in its contents to the OSCI, future studies could include a dyadic analysis of the psychosocial patients-caregivers mutual interactions and perspectives to account for dependency in the dyadic data as well.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest

Author contribution

GV, EV, SS, GP conceived and implemented the study design. GV, EV, SS, GP performed data collection and analysis. GV, EV, SS, AS, MGP, DFM, EM, GP wrote the manuscript.

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