

Assessing the Validity and Reliability of the Peristomal Skin Lesion Assessment Instrument Adapted for Use in Turkey

Ali Ay, MsN, RN; and Hülya Bulut, PhD, RN

Abstract

Many ostomy patients experience peristomal skin lesions. A descriptive study was conducted to assess the validity, usability, and reliability of the Peristomal Skin Lesions Assessment instrument (SACS instrument) adapted to Turkish from English. The SACS Instrument consists of 2 main assessments: lesion type (utilizing definitions and photographs) and lesion area by location around the ostomy. The study was performed in 2 stages: 1) the SACS language was changed and its content validity established; and 2) the instrument's content validity and inter-observer agreement (consistency) were determined among pairs of nurses who used the tool to assess peristomal skin lesions. Patients (included if they were >18 years old and receiving treatment/observation at 1 of the 4 participating stomatherapy units) and 8 stomatherapy nurses also completed appropriate sociodemographic questionnaires. Of the 393 patients screened during the 7-month study, 100 (average age 56.74 ± 14.03 years, 55 men) participated; most (79) had a planned operation. A little more than half (59) of the patients had colorectal cancer and 28 had their stoma site marked preoperatively by a stomatherapy nurse. The most common peristomal skin lesion risk factors were having an ileostomy and unplanned surgery. The content validity index of the entire Turkish SACS instrument was 1, and the inter-observer agreement Kappa statistic was very good ($K = 0.90$, 95% CI 0.80- 0.99). Individual SACS item K values ranged from $K = 0.84$ (95% CI 0.63-1) to $K = 1$ (95% CI 1). Most (62.5%) nurses found the terms and pictures used in the SACS classification adequate and suitable, and 50% believed the Turkish version of the SACS instrument was a valid and suitable assessment tool for use by Turkish stomatherapy nurses. Validity and reliability studies involving larger and more diverse patient and nurse samples are warranted.

Keywords: validity, reliability, stoma, complications, skin

Index: *Ostomy Wound Management* 2015;61(8):26-34

Potential Conflicts of Interest: none disclosed

A stoma (from the Greek meaning opening or mouth) is a surgical intervention that may be used to manage cancer related to the urinary system, colorectal cancers, ulcerative colitis, Crohn's disease, diverticular diseases, imperforate anus, traumas, intestinal obstruction, familial polyposis, and congenital abnormalities.^{1,2} One of the most common stoma types is the intestinal stoma.⁴ The creation of a stoma for the purpose of evacuation, a fundamental human need, may lead to physiological, social, and psychological problems for the individual. Gas and odor, fecal leakage, skin problems, fatigue, loss of appetite, indigestion, nausea, diarrhea, constipation, and pain are among the physiological problems.^{3,4} According to a descriptive study by Baykara et al,² odor and fecal leakage are the most discomforting problems. In a multicenter prospective observational study by Bosio et al,⁵

surgical technique and experience, procedure type (planned or emergency), patient health problems such as obesity and diabetes, and the ability of the individual to perform self-care have been shown to have an impact on the prevalence of complications.

Stoma complications can develop instantly (ie, within 12 hours of ostomy creation) and include hemorrhage and ischemia.^{1,6} Early stage complications (those that develop within 1 month of stoma surgery) include hemorrhage, ischemia, excessive output, obstruction, retraction, peristomal skin irritation, peristomal infection/abscess/fistula, acute peristomal herniation, and early postoperative intestinal perforation.⁶ Later-stage complications can occur months after the operation; these include peristomal skin problems, stenosis, retraction, hernia, prolapse, fistula,

Mr. Ay is a research assistant and Dr. Bulut is an Associate Professor, Gazi University, Faculty of Health Sciences, Nursing Department, Ankara, Turkey, Please address correspondence to: Ali Ay, MsN, RN, Gazi Üniversitesi, Emniyet Mahallesi, Muammer Yaşar Bostancı Caddesi, Number: 16, Ankara, Cankaya 6500 Turkey; email: sabune_63@hotmail.com.

perforation, fluid/electrolyte loss, renal calculus, and gallstones.^{1,7} Peristomal skin problems can occur at any stage of living with a stoma.

Stoma complication prevalence varies in the literature⁸ from 10% to 70%. In a retrospective extensive study of 20 years of ileostomy and colostomy data by Park et al,⁹ the most frequently observed early stage complication was peristomal skin irritation (12%). In a retrospective study conducted on 128 individuals regularly observed at a stomatherapy clinic, Karadağ¹⁰ found 32.8% experienced stoma complications and the most frequently encountered complication was peristomal skin irritation (17.9%).¹⁰ Akçam et al¹¹ obtained data from the records of 120 patients with a stoma; 24.1% experienced stoma complications and the most frequent complication was dermatitis (5.8%). Reasons for the discrepancies in data could be inconsistencies in the terminology, as well as the absence of a standard observation (data collection, assessment) instrument.^{12,13}

Even though peristomal skin complications are not life-threatening, they make the placement of the ostomy appliance difficult and may cause leakage, odor, fear of appliance nonadherence, and difficulty choosing clothing, which can lead to social isolation, anxiety, and depression.^{1,3,5,14,15} Observational prospective, cross-sectional, and quantitative studies have shown peristomal skin complications and the accompanying symptoms also lengthen the course of treatment, increase of the cost of care, and cause loss of labor.^{14,16,17} All of these outcomes lead to an adverse impact on activities of daily living and reduce individual quality of life. In prospective, observational, and systematic review studies, prevention of peristomal skin complications has been shown to be easier and cheaper than treatment,^{12,18,19} making assessment of the peristomal area important in diagnosis and treatment decisions.^{14,17,20} Using a stomal complication assessment instrument with proven validity has been shown in prospective observational and cross-sectional quantitative studies^{5,16} to help establish the prevalence and incidence of peristomal complications, be a factor in the comfort and life quality of the patient, and decrease care costs and frequency of use of many products.

Ostomy Care and Ostomy Nurses in Turkey

The first stoma care unit was opened in the Turkish capital of Ankara in Gazi University Hospital in 2000; by 2013, there were 22 stoma care units with 376 certified stoma care nurses. Most of these nurses are employed in university and public hospitals and involved in ostomy and wound care. Stoma care nurses in these units provide stoma care and counseling; teach patients, their families, and health care professionals; and conduct research. The stoma care units provide service free of charge based on an appointment system.²³ If a decision has been made to create a stoma, the patient will be referred to a stoma care nurse for an appointment at the polyclinic for the patient and his/her family. During the appointment,

Ostomy Wound Management 2015;61(8):26–34

Key Points

- Assessment variables and instruments should be valid and reliable.
- The authors of this study translated, adapted, and tested a previously validated peristomal skin assessment instrument for use in Turkey.
- The Turkish version of the Peristomal Skin Lesions Assessment (SACS) instrument had good validity and reliability scores when tested by 8 stomatherapy nurses who assessed 100 patients.

stoma care nurses provide information about the stoma and stoma care, answer questions, and mark the stoma site. After the surgery, stoma nurses visit the patient in the intensive care unit or ward, assess the stoma and peristomal area, change the pouch, and show the patient and his/her relatives how to empty the pouch. Finally, the stoma nurse provides a booklet that includes information about stoma and stoma care to the patient and his/her relatives and makes an appointment to change the pouch with the patient or his/her relative for the purpose of correcting their mistakes. These services are designed to decrease the length of hospitalization; improve quality of life by addressing physiological, psychological, and social problems; and perform scientific studies. The Turkish Wound Ostomy Incontinence Nurses Society (TWOINS) has 136 members; 111 are certified stoma care nurses.²²

Peristomal Skin Assessment Instruments

Although the literature discusses instruments utilized in the assessment of peristomal skin lesions,^{18,24} these instruments have undergone only limited validity-reliability studies. Salvadalena¹⁸ conducted a meta-analysis of 21 studies assessing stomal or peristomal complications to determine their incidence. The author concluded differences in study designs, absence of standard definitions, and variation in assessment times thwarted determination of the incidence of stomal or peristomal complications.

Ostomy Skin Tool (OST). The validity and reliability of 3 instruments/scales that assess stomal and peristomal skin complications have been tested, including the OST,^{14,16,24} the Ostomy Algorithm,^{14,16} and the Studio Alterazioni Cutanee Stomali (SACS Instrument).^{5,24} The OST is a standardized assessment tool developed by a team of 12 ostomy nurses for assessing peristomal skin. The OST consists of standardized descriptions of the abnormal peristomal skin: discoloration (D), erosion (E) and tissue overgrowth (T). Each domain facilitates assessment of the affected area (scored between 0 and 3) and the severity of the problem (scored between 0 and 2); therefore, for each domain the score is between 0 and 5, and the resultant total DET value is between 0 and 15.^{24,31}

Jemec et al's¹⁴ OST validation study in Denmark and Spain among 20 ostomy nurses demonstrated a high inter-nurse assessment agreement of this scale according to Kappa analysis ($K = 0.84$).

Ostomy Algorithm. The Ostomy Algorithm is comprised of 11 assessments: type of ostomy, type and volume of output, stoma type, stoma profile, stoma shape, abdominal contour, level pouching surface, presence/absence of devices, presence/absence of stoma complications, SACS score, and presence/absence of peristomal skin complications. Preliminary face validity of the Ostomy Algorithm was established by 9 wound ostomy continence (WOC) nurses in the United States with extensive ostomy experience (7 WOC nursing consultants and 2 WOC nurse employees of ConvaTec [Skillman, NJ], the company that supported development of the algorithm). When used properly, it allows for the selection of a suitable pouching system, maintenance of intact peristomal skin, and effective prevention, identification, and management of commonly identified stomal and peristomal complications. The section that includes the SACS instrument allows clinicians to assess and classify peristomal skin lesions.¹⁶

Beitz et al¹⁶ conducted a content validation of the Ostomy Algorithm in which validity-reliability studies were performed on real patients. As part of this study, the SACS instrument's content validity index (CVI) was determined to be 0.94. Based on the content validation assessment results (the overall content validity score was 0.95), the Ostomy Algorithm was well received by expert WOC nurses, and the number of persons willing to participate in the survey ($n = 166$) suggests a clear need for this instrument.¹⁶

SACS instrument. The SACS instrument was developed in Italy between 2003 and 2006 and a validity study was performed. The instrument consists of 3 main parts: assessment of lesion types (5 options with definitions and photographs), assessment of lesion areas (5 options using a clockwise orientation), and documentation examples. Lesion types include hyperemic (L1: peristomal redness with intact skin), erosive (L2: open lesion not extending into subcutaneous tissue; partial-thickness skin loss), ulcerative (L3: open lesion extending into subcutaneous tissue and below; full-thickness skin loss), ulcerative (L4: full-thickness skin loss with nonviable, dead tissue), and proliferative (L5: abnormal growths present; ie, hyperplasia, granulomas, neoplasms). The peristomal lesion areas are determined according to a topographic (T) location scale: TI: left upper peristomal quadrant, 12–3 o'clock; TII: left lower peristomal quadrant, 3–6 o'clock; TIII: right lower peristomal quadrant, 6–9 o'clock; TIV: right upper peristomal quadrant, 9–12 o'clock; and TV: all peristomal quadrants.

The first reliability study of the SACS instrument was performed by Bosio et al⁵ in 2007. Researchers sent 20 lesion photographs to clinicians who assessed them using the SACS instrument. Inter-observer agreement percentage according to kappa analysis was $K = 0.91$. A reliability study of the SACS instrument was performed through indepen-

dent inter-observer agreement and also analyzed using the Kappa statistic. Inter-observer agreement percentage was determined to be very good ($K = 0.90$). The confidence interval (CI) of the instrument was determined to be between 0.80 and 0.99.

Validated in Italy and the United States, the SACS instrument is currently the only content-validated peristomal skin assessment and classification instrument. As previously noted, the SACS instrument was assessed as part of the Ostomy Algorithm, with a content validity index of 0.94 out of 1.0 ($N = 166$).^{16,25}

The current descriptive study was conducted for the purpose of assessing the validity, usability, and reliability of the SACS instrument adapted for Turkish patients.

Materials and Methods

Patient sample. The study involved a convenience sample of 100 patients with a peristomal skin lesion. This number was chosen in accordance with Kappa statistic and Number Cruncher Statistical System (NCSS, Kaysville, UT) statistical programs for ample sample size to power statistical analyses. Inclusion criteria stipulated participants must agree to participate in the study, be >18 years old, and receiving treatment/observation at one of the stomatherapy units at a university hospital, located in 4 different regions. The study was conducted between December 2012 and June 2013.

Nurse sample. The study involved 8 certified stoma and wound care nurses working in the stomatherapy units. To determine inter-observer agreement, 2 nurses in each unit assessed all the patients using the SACS instrument and recorded the results. Nurses provided and recorded the care of all patients with existing or newly developed peristomal skin lesions.

Ethical aspects of the study. Written consent to translate and adapt the SACS for use in Turkey was obtained from the ConvaTec (Skillman, NJ), which holds the right to commercial use of the instrument. The Clinical Research Ethics Board approved use of the data collection forms, and written permission to conduct the study was obtained from the hospitals where the study was performed. Patient participation was voluntary, and written informed consent was obtained from patients included in the study. The nurses used the forms with the patients who agreed to participate in the study.

Data collection instruments. Peristomal skin variables were collected using the SACS instrument record form, which consists of 3 columns in which nurses can mark the lesion type (L1-L5), lesion area (TI-TV), and record the obtained assessment result for each patient. Skin lesion severity is assessed on a scale from 1 to 5; for instance, L1 is used for low severity skin complications and L5-LX is used for very severe skin complications (see Figure 1).

Demographic data were collected using a Patient Characteristics Form. The form contains 26 questions about so-

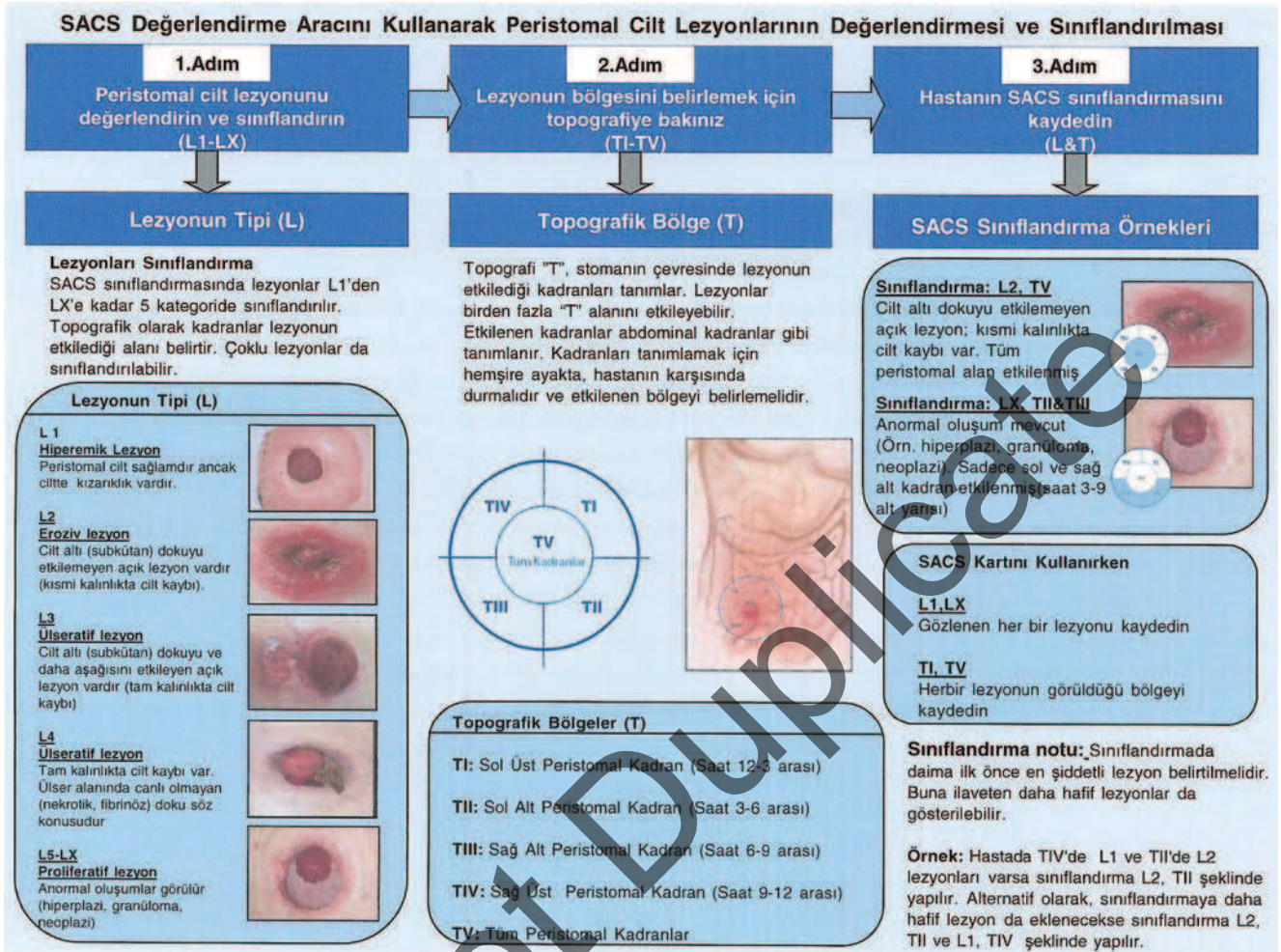


Figure 1. Peristomal Skin Lesions Assessment (SACS) instrument. Used with permission.

ciodemographic characteristics, health conditions, and risk factors associated with peristomal lesions, including medical diagnosis (eg, diabetes, obesity), stoma type (eg, ileostomy, urostomy), form of feeding (eg, no oral intake, total parenteral nutrition), material allergy (eg, hydrocolloid, adhesive), presence of creases, stoma level (eg, flat), stool amount (eg, excessive), and form of stool (eg, liquid, semisolid). Treatment was determined exclusively from the information on the SACS instrument.

Participating nurses also completed the Nurse Characteristics Form, which contains 9 questions including age, time as a stoma nurse, and 2 questions regarding the prevention of peristomal skin lesions. Nurses also completed a Nurse SACS instrument evaluation form consisting of 20 questions on the practical characteristics of the instrument (including time to complete, practicality, comprehensibility, whether the instrument addresses all peristomal skin lesions and determines peristomal skin lesions correctly, and the relevance of terms and pictures used).

The data were collected using multichoice data collection paper forms during patient visits at wards or when the patients visited the stomatherapy unit and stored at these units by nurses who completed the forms.

Study process. The study was performed in 2 stages. First, the instrument was adapted from English to Turkish and its content validity established. Then, nurses used the instrument to assess peristomal skin lesions on real patients and inter-observer agreement (consistency) of the nurses' assessment was measured.

Language adaption of the SACS instrument. Before assessing the content validity of the SACS instrument, language validity studies of the instrument were performed. For language adaptation, the SACS instrument was first translated to Turkish from English by a faculty member from the Faculty of Medicine and 2 faculty members from the Nursing Department of the Faculty of Health Sciences, all competent in English. The SACS instrument was translated back to English from Turkish by a faculty member competent in English

Table 1. Inter-observer consistency of individual Peristomal Skin Lesion Assessment (SACS) instrument lesion type variables (N = 100)

L1: Hyperemic lesion		Second nurse			Kappa value
		Yes n (%)	No n (%)	Total N (%)	0.89 (95% CI, 0.80–0.98)
First Nurse	Yes	38 (95.0%)	2 (5.0%)	40 (100.0%)	
	No	3 (5.0%)	57 (95.0%)	60 (100.0%)	
	Total	41 (41.0%)	59 (59.0%)	100 (100.0%)	
L2: Erosive lesion		Second nurse			Kappa value
		Yes n (%)	No n (%)	Total N (%)	0.85 (95% CI, 0.75–0.95)
First Nurse	Yes	39 (95.1%)	2 (4.9%)	41 (100.0%)	
	No	5 (8.5%)	54 (91.5%)	59 (100.0%)	
	Total	44 (44.0%)	56 (56.0%)	100 (100.0%)	
L3: Ulcerative lesion		Second nurse			Kappa value
		Yes n (%)	No n (%)	Total N (%)	0.84 (95% CI, 0.70–0.97)
First Nurse	Yes	17 (81.0%)	4 (19.0%)	21 (100.0%)	
	No	1 (1.3%)	78 (98.7%)	7 (100.0%)	
	Total	18 (18.0%)	82 (82.0%)	100 (100.0%)	
L4: Ulcerative lesion		Second nurse			Kappa value
		Yes n (%)	No n (%)	Total N (%)	0.84 (95% CI, 0.63–1)
First Nurse	Yes	6 (85.7%)	1 (14.3%)	7 (100.0%)	
	No	1 (1.1%)	92 (98.9%)	93 (100.0%)	
	Total	7 (7.0%)	93 (93.0%)	100 (100.0%)	
L5: Proliferative lesion		Second Nurse			Kappa value
		Yes n (%)	No n (%)	Total N (%)	1 (95% CI 1)
First Nurse	Yes	7 (100.0%)	0 (0.0%)	7 (100.0%)	
	No	0 (0.0%)	93 (100.0%)	93 (100.0%)	
	Total	7 (7.0%)	93 (93.0%)	100 (100.0%)	

from the Faculty of Nursing. The instrument translated to Turkish from English and retranslated back to English from Turkish was compared by the researchers and necessary corrections were performed. The revised instrument was evaluated to determine its suitability in terms of Turkish language grammar and sentence structure and finalized by a Turkish language expert.

Determining SACS instrument content validity. Content validity refers to the degree an instrument covers the content it is supposed to measure and determined using the CVI developed by Waltz and Bausse.²⁷ Items are rated 1 (irrelevant), 2 (needs to be made relevant), 3 (relevant but needs minor changes), or 4 (very relevant); space also is allocated for comments regarding each item.²⁷ This type of assessment can help ensure construct validity and ensure confidence for the users and researchers. Two judgments are necessary: the measurable extent of each item for defining the traits and the set of items that represents all aspects of the traits.²⁶

The content validity of the translated SACS instrument relied on the opinion of 7 experts: 4 faculty members from the Nursing Department, 2 stomatherapy nurses, and 1 faculty

member from the Faculty of Medicine. The CVI for each item was calculated by dividing the number of experts grading the items with 3 and 4 points and the total number of experts.

Nurse implementation of the SACS instrument. In this stage of the study, 2 nurses used the SACS instrument to assess the peristomal skin lesions on a real patient and then inter-observer agreement between nurses was measured. The authors sent all data collection forms to nurses who agreed to participate in the study through post. At the same time, a written directive was sent to the nurses about how to apply the forms, collect the data, and keep the forms confidential. According to this directive, nurses completed nurse characteristics forms first and then completed patient characteristic forms and used the SACS instrument to assess patients. Nurses working in the stomatherapy units were asked to use the SACS to assess skin lesions and classify and record data independently of each other at every patient visit when they changed the ostomy bag/system, each recording data on a separate data collection form. Every patient visited at least once up to 3 times until discharged, but every patient was assessed 1 time by 2 nurses independently at the same time. At

Do Not Duplicate

Table 2. Inter-observer consistency of individual Peristomal Skin Lesion Assessment (SACS) instrument lesion area variables (N=100)

TI: Area 1 (left upper quadrant, 12–3 o'clock)		Second nurse	Kappa value		
		Yes n (%)	No n (%)	Total N (%)	0.92 (95% CI 0.83–1)
First Nurse	Yes	25 (96.2%)	1 (3.8%)	26 (100.0%)	
	No	2 (2.7%)	72 (97.3%)	74 (100.0%)	
	Total	27 (27.0%)	73 (73.0%)	100 (100.0%)	
TII: Area 2 (left lower quadrant, 3–6 o'clock)		Second nurse	0.88 (95% CI 0.78–0.98)		
		Yes n (%)	No n (%)	Total N (%)	
First Nurse	Yes	28 (93.3%)	2 (6.7%)	30 (100.0%)	
	No	3 (4.3%)	67 (95.7%)	70 (100.0%)	
	Total	31 (31.0%)	69 (69.0%)	100 (100.0%)	
TIII: Area 3 (right lower quadrant, 6–9 o'clock)		Second nurse	0.89 (95% CI 0.79–0.98)		
		Yes n (%)	No n (%)	Total N (%)	
First Nurse	Yes	33 (97.1%)	1 (2.9%)	34 (100.0%)	
	No	4 (6.1%)	62 (93.9%)	66 (100.0%)	
	Total	37 (37.0%)	63 (63.0%)	100 (100.0%)	
TIV: Area 4 (right upper quadrant, 9–12 o'clock)		Second nurse	0.93 (95% CI 0.85–1)		
		Yes n (%)	No n (%)	Total N (%)	
First Nurse	Yes	30 (96.8%)	1 (3.2%)	31 (100.0%)	
	No	2 (2.9%)	67 (97.1%)	69 (100.0%)	
	Total	32 (32.0%)	68 (68.0%)	100 (100.0%)	
TV: Area 5 (all quadrants)		Second Nurse	0.94 (95% CI 0.87–1)		
		Yes n (%)	No n (%)	Total N (%)	
First Nurse	Yes	46 (97.9%)	1 (2.1%)	47 (100.0%)	
	No	2 (3.8%)	51 (96.2%)	53 (100.0%)	
	Total	48 (48.0%)	52 (52.0%)	100 (100.0%)	

the end of the study, all nurses sent the data forms through post to the authors and the authors recorded data in statistical analysis programs databases.

After implementation of the instrument, nurses were asked to complete the Nurse SACS instrument evaluation form.

Data assessment. Nurse characteristics, patient characteristics, and nurse SACS instrument evaluation data were assessed using descriptive analyses (percentage, frequency), hypothesis tests, and consistency analyses using the SPSS 15 (IBM, New York, USA) program.

Items such as physical exam findings, radiographic interpretations, or other diagnostic tests often rely on some degree of subjective interpretation by observers. The Kappa statistic (or Kappa coefficient) is the most commonly used statistic for this purpose.²⁹ Inter-observer agreement among the nurses was assessed using the Kap-

pa statistic. The Kappa statistic was designed to provide a numeric value for the size of the consistency between observers.³⁰ A Kappa coefficient of <0 is construed as having no agreement, 0.0–0.20 implies agreement at an insignificant level, 0.21–0.40 implies having agreement at a medium level, 0.41–0.60 implies good agreement, 0.61–0.80 implies significant agreement, and 0.80–1.00 means agreement at a nearly perfect level.³⁰ The understandability of the SACS instrument also was assessed using the CVI statistic as previously described; space also was allocated for comments regarding each item.²⁸ For the purpose of assessing usability of the SACS instrument, the Kappa statistic was applied. Inter-observer variation between 2 or more independent observers evaluating the same thing is calculated based on agreement between the observations (see Table 1 and Table 2).

Results

Content validity. All experts scored each item 3 or 4; thus, the CVI was determined to be 1. For this study, the minimum value from the table created by Veneziano and Hooper²⁸ for content validity at a significance level of $\alpha = 0.05$ was determined to be 0.99. As a result, the content validity of the Turkish SACS instrument was determined suitable for use. Once expert suggestions from their comments were incorporated, the SACS instrument was finalized. No major changes were necessary before the instrument's content validation except minimal word changes according to expert suggestions. After these changes, the Turkish language expert assessed the instrument to ensure suitability regarding Turkish language grammar and sentence structure.

Usability of the SACS instrument. Inter-observer agreement for the entire instrument was very good ($K = 0.90$). The confidence interval of the instrument ranged from 0.80 (lower limit) to 0.99 (upper limit).

Patient population. During the study period, 171 (Gazi University), 108 (Çukurova University), 58 (İstanbul University), and 56 (Uludağ University) patients received care at the 4 stomatherapy units; the 100 patients with peristomal complications participating in the study comprised 25.44% of the total population. Of these patients, 33 were observed at Gazi University, 32 at Çukurova University, 24 at İstanbul University, and 11 at Uludağ University. Ostomy types included ileostomy (67), colostomy (25), and urostomy (8); coincidentally, all of the patients were using a 2-piece bag/adaptor system. More than half of the patients (52) were 40–64 years old, average age was 56.74 ± 14.03 , 55 were men, 55 had completed primary school or lower, 32 were diagnosed with rectal cancer, and 27 with colon cancer. Twenty-six (26) had a chronic disease. Six (6) had an allergy (although not to hydrocolloids), which affected the development of peristomal skin lesions. The majority of patients (96) performed normal oral feeding, and 86 had no problem performing their stoma care.

Among the 100 participating patients, 79 had planned operations, 28 had their stoma area marked preoperatively by the stomatherapy nurse, and the average period of living with a stoma was 6.49 ± 1.69 years (range 1 day to 12 years). The majority (77) had later-developing complications. Among these complications, 34 had a stoma at the same level as their skin, 23 had an improperly shaped stoma (ie, not circular/smooth edged), 93 had soft peristomal skin, 8 had a supporting rod, 50 had a liquid stool, 15 had excessive output, 14 had mucocutaneous separation, 2 had a peristomal hernia, and 35 had a crease in the peristomal area.

The nurse participants included 8 women, 6 with Bachelor's and 2 with graduate degrees in nursing. All were certified stomatherapy nurses and had been working in that capacity for an average of 5.5 ± 3.17 years; 62.5% said they provided care to 10 individuals with a stoma per week, and 37.5% said they provided care to more than 20 individuals. The nurses stated they had not previously used a peristomal

skin lesion assessment instrument. A large majority (87.5%) had received information on basic stoma and wound care nursing with regard to the prevention/treatment of peristomal skin lesions. Despite her certification, one of the nurses stated she did not have enough knowledge on prevention/treatment of peristomal skin lesions.

Inter-observer comparisons. The inter-observer agreement for the individual lesion types in the SACS instrument was very good (see Table 1). For hyperemic lesions (L1), agreement was $K = 0.89$ (95% CI, 0.80–0.98); for erosive lesions (L2) $K = 0.85$ (95% CI, 0.75–0.95); for ulcerative lesions (L3) $K = 0.84$ (95% CI, 0.70–0.97); ulcerative lesions (L4) $K = 0.84$ (95% CI, 0.63–1); and proliferative lesions (L5) $K = 1$ (95% CI 1).

The inter-observer agreement percentage of the SACS instrument by lesion areas was also very good and ranged from TII $K = 0.88$ (95% CI 0.78–0.98) to TV $K = 0.94$ (95% CI 0.87–1) (see Table 2).

Nurse opinion of the SACS instrument. All nurses stated the use of instruments with validity-reliability studies performed was necessary for the assessment of peristomal skin lesions. All nurses believed validity-reliability testing is needed before an instrument is used. Half of the nurses did not agree that SACS classification addressed all lesions; 62.5% found the terms and pictures used in the SACS classification adequate and suitable and that the SACS instrument determined lesions correctly, but they did not believe nonostomy care experts/clinicians would be able to correctly assess peristomal skin lesions using the SACS instrument. Most nurses (87.5%) said the instrument was practical and facilitated the provision of care to patients with peristomal skin lesions; that same percentage did not experience difficulties using the SACS instrument and thought use of the SACS instrument is important in terms of determining and documenting skin lesions, that it would contribute to the exact measurement of the prevalence and incidence of skin lesions, and that it would provide assistance in clinical decision making. In addition, 75% of the nurses found using the SACS instrument helped them determine correct care management and reduced costs by reducing the use of excessive products.

Discussion

In the 7-month study period, 100 of 393 patients (25.4%) had peristomal skin lesions, between the rates that mentioned in the literature both in Turkey and in the world.^{8–13} Among participants, 65% of the patients had an ileostomy, 72% of the stoma sites had not been marked before the operation, 49% of the patient's had a flat or retracted stoma, 35% of the patients had a stoma in the abdominal contour, 50% of the patients had liquid stool, and 15% had an excessive output — all risk factors for peristomal skin lesions as reported in the literature.^{1,5–7,9,12,18}

The SACS instrument was developed and accepted by a consensus of health care professionals in Italy and subsequently

content-validated in both Italy and the United States (CVI of latter = 0.94^{16,18}). In the current study, validity, usability, and understandability were assessed for use of the SACS instrument in Turkey. Content validity was found to be 1, higher than defined minimum values (Confidence coefficient: $1 - \alpha = 1 - 0.05 = 0.95$, although half of the nurses thought the SACS instrument did not include all possible lesions.

According to the literature,^{5,14} use of an assessment instrument with proven validity will reduce costs and enable clinicians to accurately measure the prevalence and incidence of stomal and peristomal complications. In this study, 75% of participating nurses agree the use of the SACS instrument would assist them determining the correct method of care and will decrease costs by decreasing the use of excessive products. Using valid and reliable instruments will assist caregivers in identifying the skin lesion type, location, and characteristics more expediently and more accurately to help clinicians avoid providing care by trial and error.

In the planning stage of the study, no other instrument with proven validity and reliability was found in Turkey. The results of this study suggest the Turkish version of the SACS instrument is valid and suitable for the assessment of peristomal skin lesions.

Study Limitations

Only stoma nurses participated in the study; in addition, the nurses performing the peristomal skin lesion assessment both worked at the same stomatherapy unit, and although the nurses were instructed to perform the assessment independently of each other, it was not observed whether this occurred. A larger reliability study with a larger sample and additional advanced statistical methods (as well as kappa) is recommended.

Conclusion

A descriptive study conducted among 8 stomatherapy nurses assessing 100 patients in Turkey found the use of the SACS instrument for peristomal skin lesion assessment to have a CVI of 1, as well as adequate independent inter-observer agreement regarding suitability and practical use (CI 0.80–0.99). The Turkish version demonstrated validity and usability for persons speaking this language. The SACS instrument is recommended for use in clinics as a peristomal skin lesion assessment instrument. Repetition of the validity and reliability study with a larger sample group of nurses and patients and the use of the SACS instrument in studies regarding cost of care, prevalence, and incidence of peristomal complications is warranted. ■

References

- Korkut H, Karadağ A. Peristomal skin complications: prevention, treatment, and care. *National Surg J*. 2010;26(3):175–179.
- Baykara ZG, Leventoğlu S, Menteş B. A pilot study on the feelings and thoughts of individuals with closed stomas on evacuation. *Colon Rectum Dis*. 2007;17(2):76–81.
- Karadağ A, Menteş B, Ayaz S, İrkörücü O, Alabaz Ö. *Guidebook on the Care of Patients with Colostomy and Ileostomy*, 1st ed. Ankara, Turkey: Ayhun Ofset;2003.
- Karadağ A, Baykara ZG, Korkut H, Çelik B. Adaptation of the ostomy adjustment inventory into Turkish Language. *National J Surg*. 2011;27(4):206–211.
- Bosio G, Pisani F, Lucibello L, Fonti A, Scrocca A, Morandell C, et al. A proposal for classifying peristomal skin disorders: results of a multicenter observational study. *Ostomy Wound Manage*. 2007;53(9):38–43.
- Kann BR. Early stomal complications. *Clin Colon Rectal Surg*. 2008;21(1):23–30.
- Husain SG, Cataldo TE. Late stomal complications. *Clin Colon Rectal Surg*. 2008;21(1):31–40.
- Colwell JC, Beitz J. Survey of wound, ostomy and continence (WOC) nurse clinicians on stoma and peristomal complications: a content validation study. *J Wound Ostomy Continence Nurs*. 2007;34(1):57–69.
- Park JJ, Del Pino A, Orsay CP, Nelson RL, Pearl RK, Cintron JR, et al. Stoma complications: the Cook County Hospital experience. *Dis Colon Rectum*. 1999;42(12):1575–1580.
- Karadağ A. Frequency of stomal complications. *WCET J*. 2004;24(2):41–43.
- Akçam AT, Alabaz Ö, Parsak CK, Sakman G, Erkoçak EU. Ostomy complications. *Ostomy J*. 2005;1:7–9.
- Ratliff CR. Early peristomal skin complications reported by WOC nurses. *J Wound Ostomy Continence Nurs*. 2010;37(5):505–510.
- Kalashnikova I, Achkasov S, Fadeva S, Vorobiev G. The development and use of algorithms for diagnosing and choosing treatment of ostomy complications: results of a prospective evaluation. *Ostomy Wound Manage*. 2011;57(1):20–27.
- Jemec GB, Martins L, Claessens I, Ayello EA, Hansen AS, Poulsen LH, et al. Assessing peristomal skin changes in ostomy patients: validation of the Ostomy Skin Tool. *Br J Dermatol*. 2011;164(2):330–335.
- Ayaz S. Role of the nurse in patients with stoma. *Clinics of Turkey J Med Sci*. 2007;27(1):86–90.
- Beitz J, Gerlach M, Ginsburg P, Ho M, McCann E, Schafer V, et al. Content validation of a standardized algorithm for ostomy care. *Ostomy Wound Manage*. 2010;56(10):22–38.
- Woo KY, Sibbald RG, Ayello EA, Coutts PM, Garde DE. Peristomal skin complications and management. *Adv Skin Wound Care*. 2009;22(11):522–532.
- Salvadalena G. Incidence of complications of the stoma and peristomal skin among individuals with colostomy, ileostomy, and urostomy: a systematic review. *J Wound Ostomy Continence Nurs*. 2008;35(6):596–607.
- Robertson I, Leung E, Hughes D, Spiers M, Donnelly L, Mackenzie I, et al. Prospective analysis of stoma-related complications. *Colorect Dis*. 2005;7(3):279–285.
- Karadağ A. Assessment of the stoma and parastomal area. *Colon Rectum Dis*. 2008;18(2):63–70.
- Karadağ A, Addis G. Nurse perspectives on stoma care in Turkey. *WCET J*. 2005;25(1):14–20.
- Karadağ A. World Council of Enterostomal Therapists (WCET) International Delegates Country Reports-Turkey. Unpublished report.
- Karadağ A. *WCET Reports -Turkey*. 2003:57–58.
- Haugen V, Ratliff CR. Tools for assessing peristomal skin complications. *J Wound Ostomy Continence Nurs*. 2013;40(2):131–134.
- McCann E. A content-validated tool to effectively document peristomal skin lesions. *Ostomy Wound Manage*. 2010;56(10):14.
- Yaghmaie F. Content validity and its estimation. *J Med Educ*. 2003;3(1):25–27.
- Erefe İ. Quality of data collection instruments. In: Erefe İ (ed). *Research, Principle, Process, and Methods in Nursing*, 4th ed. Ankara, Turkey: Odak Ofset Matbaacılık;2012:169–188.
- Yurdugül H. Use of content validity indices for content validity in scale development studies. XIV National Educational Sciences Congress. 2005:1–6.
- McCann EM. Common ostomy problems. In: Milne CT, Corbett LQ, Dubuc DL. *Wound Ostomy and Continence Nursing Secrets*. Philadelphia, PA: Hanley & Belfus Inc. US; 2003:319–325.
- Viera AJ, Garrett JM. Understanding interobserver agreement: the Kappa statistic. *Fam Med*. 2005;37(5):360–363.
- Martins L, Ayello EA, Claessens I, Hansen AS, Poulsen LH, Sibbald RG et al. The Ostomy Skin Tool: tracking peristomal skin changes. *Br J Nurs*. 2010;19(15):960–964.