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Validation and Clinical Experience With a Turkish Language Version of the Pittman Ostomy Complication and Severity Index

Serap Sayar ♦ Fatma Vural

ABSTRACT

PURPOSE: The purpose of this study was to evaluate the content validity and interrater reliability of a Turkish language version of the Pittman Ostomy Complication and Severity Index (OCSI).

DESIGN: Psychometric evaluation of instrument.

SUBJECTS AND SETTING: The sample comprised 90 individuals living with an ostomy for 2 to 6 months. Their mean age was 59.48 years (SD 13.292); 52.2% were female. Almost two-thirds (73.3%, $n = 66$) had experienced at least 1 ostomy complication. The study was conducted in the Wound and Stoma Therapy Unit of the Dokuz Eylül University Hospital General Surgery Clinic and Polyclinic in Izmir, Turkey.

METHODS: A Turkish language version of the OCSI was created using a translation, back-translation technique. The instrument's content validity was analyzed by 26 experts. Interrater reliability test was evaluated using Cohen's κ and intraclass correlation coefficients. Data were collected between January 15, 2017 and July 30, 2017 through face-to-face interviews conducted in our Wound and Stoma Therapy Unit.

RESULTS: The overall content validity index was 0.95. Cohen's κ coefficient varied from 0.70 and 1.0 for all items. The Pearson correlation coefficient and intraclass correlation coefficient were 0.982 ($P = .000$) and 0.986 ($P = .000$), respectively, indicating good internal consistency. The most prevalent complications were leakage (41.1%), peristomal moisture-associated skin damage (42.2%), and stomal retraction (27.7%).

CONCLUSIONS: Findings indicate that the Turkish language version of the Pittman OCSI is a reliable and valid instrument for assessment of presence and severity of early postoperative complications in individuals with an ostomy. We found the instrument parsimonious, easy-to-use, and clinically practical. It can be used to determine appropriate interventions to prevent or treat complications and evaluate the effects of nursing interventions designed to improve outcomes for patients with ostomies.

KEY WORDS: Complications, Ostomy, Pittman OCSI, Reliability, Stoma, Validity.

INTRODUCTION

Stoma-related complications may negatively affect the quality of life of stoma patients.¹ Multiple factors influence the likelihood of stomal and peristomal complications, including type of ostomy and effluent, surgical technique used to create the ostomy, body mass index, comorbid conditions such as cancer requiring additional radiation or chemotherapy, cigarette smoking, formation of an urgent ostomy, and preoperative stoma site marking.²⁻⁶ Complications are often divided into 2 categories—stomal and peristomal. Stomal complications include prolapse, necrosis, mucocutaneous separation, stomal

retraction, stenosis, fistula, and trauma. Peristomal complications are defined as skin inflammation, injury, or damage that occurs within the skin immediately surrounding an abdominal stoma or covered by the adhesive portion of the pouching system.⁷⁻¹¹ Peristomal complications include moisture-associated skin damage, hernia, allergic contact dermatitis, and trauma. In addition, complications may be divided based on timing of their occurrence—early complications occur within 30 days of ostomy surgery and late complications occur after this timeframe.^{12,13}

Reported incidence rates of stomal and peristomal complications vary widely; Salvadalena¹⁴ reviewed the literature in 2008 and reported incidence rates varying 15% to 43%.¹¹ In a subsequent study, Salvadalena¹⁴ examined the incidence of stoma and peristomal complications and related variables in 43 adults with ostomies; she reported and found that peristomal skin complications developed in 63% of the sample. Park and colleagues¹⁵ evaluated 1616 persons with ostomies and found that 34% experienced a stomal or peristomal complication; 28% were classified as early versus 6% classified as late. Both authors reported that peristomal complications were more prevalent than stomal complications. Özaydın and coworkers² conducted a retrospective study and reported an overall complication rate of 48% in 96 persons with ostomies; the most

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The authors declare no conflicts of interest.

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common was peristomal moisture-associated skin damage and peristomal infection (25%).² Uddin and associates¹⁶ reported an overall complication rate of 25% in a group of 152 participants; the most common was inflammation and erythema of the peristomal skin (peristomal moisture-associated skin damage).

Stomal or peristomal complications make daily life activities and adaptation to life with a stoma more difficult.¹⁷ A WOCN Society guideline for management of patients with an ostomy recommends use of a validated tool for accurate identification of stoma and peristomal complication problems and classification of prevalence and incidence.¹⁸ The Pittman Ostomy Complication and Severity Index (OCSI) was designed to measure the incidence and severity of common ostomy-related complications. The main purpose of this study was to evaluate the content validity, interrater reliability, incidence, and severity of a Turkish language version of the Pittman OCSI. Specific study aims were to: (1) translate the Pittman OCSI into Turkish, (2) evaluate its content validity and interrater reliability, and (3) measure the incidence and severity of ostomy complications using the OCSI.

METHODS

The OCSI was developed by Pittman and colleagues¹⁹; it was designed to measure the incidence and severity of prevalent ostomy complications. The instrument comprises 9 items that query presence and severity of leakage, peristomal moisture-associated skin damage (irritant dermatitis), pain, bleeding, stomal necrosis, stenosis or retraction, mucocutaneous separation, and hyperplasia. Each item is ranked using a score of 0 to

3, where a score of 0 indicates absence of a particular complication and 3 indicates greater severity of the complication. The minimum cumulative score is 0 (indicating no complications) and the maximum cumulative score is 27 (indicating presence of 9 severe complications). We gained permission from Dr Pittman before development and validation of a Turkish language version of the OCSI.

Initially 2 researchers (S.S. and F.V.) translated the original (English language) version of the OCSI into Turkish. This draft translation was then reviewed by 2 linguists with extensive knowledge of both languages and cultures; both speak Turkish as their first language. The instrument was then back-translated into English and compared with the expressions of the original instrument (Figure). Psycholinguistic characteristics of the scale were analyzed within a framework of language and content validity. Guidance for cultural adaptation of scale studies was used to inform the linguists' psycholinguistic analysis.²⁰⁻²¹

Content Validity and Interrater Reliability Measurement

After completing the translation, we evaluated the instrument's content validity. The validation panel comprised 2 ostomy nurse specialists who practice at our university hospital; both are master's-prepared advanced practice nurses and both are certified in WOC nursing. Additional panel members included a colorectal surgeon and professor of the university's school of medicine. We also empaneled 23 faculty members from a different nursing school in Turkey (all hold a PhD in nursing) and all have at least basic knowledge of ostomy care. The panel evaluated the clarity, comprehensiveness, and appropriateness of each item. Evaluations were based on a 4-point scale, where a score of 1 indicated no need to further review or alter the

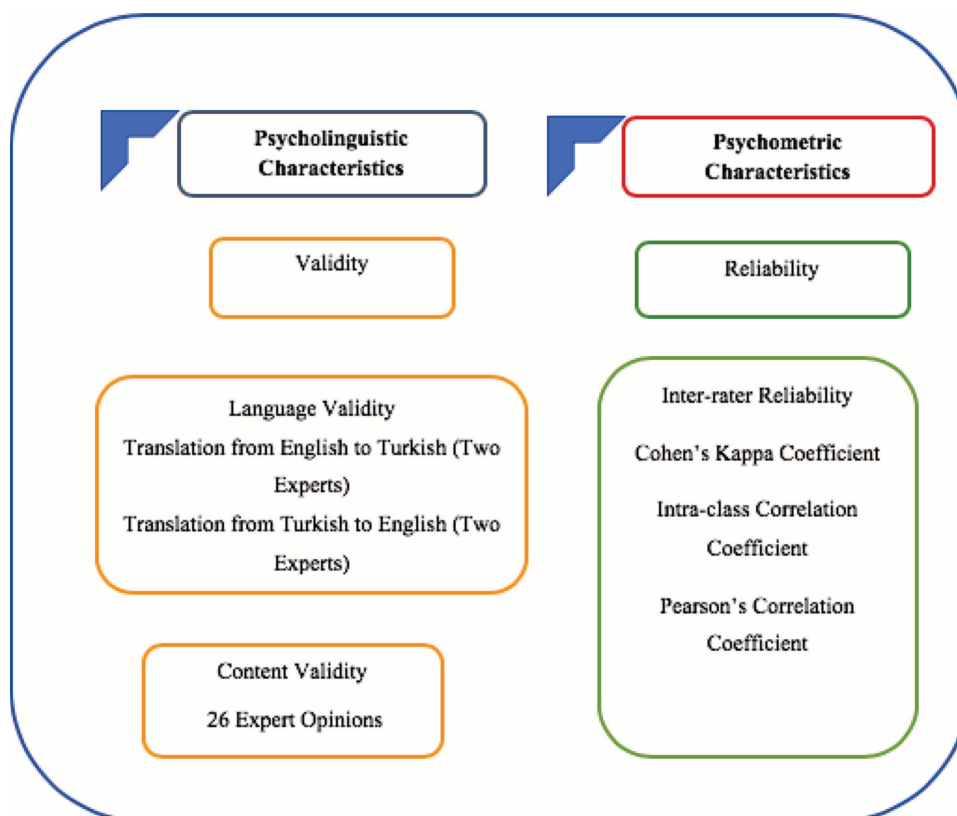


Figure. Steps followed in the Turkish adaptation of the Pittman OCSI. OCSI indicates Ostomy Complication and Severity Index.

item, 2 indicated a need for review and minor revisions for clarity, 3 indicated major review and revisions enhancing clarity, and a score of 4 indicated no relevance of the item to the presence or severity of stomal or peristomal complications.

Interrater reliability was evaluated by the principal investigator (SS) and 1 ostomy nurse specialist at the hospital; all scoring was completed independently in 10 study participants selected randomly. Both raters were advised by Dr Pittman on use of the instrument prior to its use in study participants.

Clinical Application

We evaluated use of the OCSI in a group of patients cared for in the Wound and Stoma Therapy Unit of the Dokuz Eylül University General Surgery Clinic and Polyclinic. Data were collected between January 15 and July 30, 2017. Inclusion criteria were individuals 18 years and older with a new ostomy (created 2-6 months prior to data collection), able to speak and understand Turkish, and free of a psychiatric illness or neurological disease negatively affecting their cognitive function.

Verbal and written consent was obtained from all study participants. Study procedures were reviewed and approved by the Non-Invasive Research Ethical Committee of Dokuz Eylül University Medical School on June 2, 2016, with 2016/15-32 decision number.

Data Collection Form

Data concerning participant characteristics, occurrences and severity of stomal and peristomal complications, and OCSI scores were collected using a standardized form designed for purposes of this study. Demographic data collected included age, sex, marital status, and education completed. We also collected clinical data regarding type of stoma, reason for ostomy surgery, time since ostomy surgery, stoma care, adjunctive chemotherapy or radiotherapy, provision of preoperational information regarding the ostomy, and preoperative stoma site marking. Demographic and pertinent clinical data were collected via face-to-face interviews and medical records.

Data Analysis

We used the Statistical Package for Social Sciences software (version 24.0, SSS, Chicago, Illinois) for data analysis. Content validity was examined by calculating a cumulative and individual content validity index (CVI). We used the technique recommended by Lynn for calculating cumulative and individual item CVI; values 0.80 or more were deemed acceptable.^{22,23} Interrater reliability was analyzed based on independent scoring of participants by the principal investigator (S.S.) and a trained WOC nurse using Cohen’s κ coefficient, and intraclass coefficients. The incidence and severity of each ostomy complication were examined by frequency analyses.

RESULTS

Content validation was based on 2 outcomes—cumulative and individual item indices. The overall mean CVI score was 0.95, supporting acceptable content validity of the overall instrument. Individual item CVI scores ranged from 0.88 to 1.0 (Table 1). These findings indicate content validity of the Turkish language OCSI.

Interrater reliability was based on scores provided by the 2 independent raters (Table 2). Cohen’s κ coefficient between items on the OCSI varied from 0.70 to 1.0. Comparison of the total OCSI score yielded a Pearson coefficient of 0.982

TABLE 1. Cumulative and Individual Item Content Validity Indices

Individual Items	Individual Item Content Validity Index	Cumulative Content Validity Index
Leakage	0.88	0.95
Peristomal irritant dermatitis	1	
Pain	1	
Bleeding	0.96	
Stomal necrosis	0.88	
Stomal stenosis	0.92	
Retraction	0.96	
Mucocutaneous separation	1	
Hyperplasia	1	

($P = 0.000$) and an intraclass correlation coefficient of 0.986 ($P = 0.000$).

Clinical Application

The OCSI was used in a sample of 90 individuals living with an ostomy for 2 to 6 months; their mean age was 59.48 years (SD 13.292 years). Slightly more than half were female ($n = 47, 52.2\%$), 87.8% ($n = 79$) were married, 56.6% ($n = 51$) were primary school graduates, 35.6% ($n = 32$) were not employed, and 37.8% ($n = 34$) were retired. The vast majority of participants (93.3%, $n = 84$) underwent planned ostomy surgery and underwent stoma site marking prior to surgery. Slightly more than half of participants (52.2%, $n = 47$) had a colostomy and the remaining 43 (47.8%) had an ileostomy. Almost 3 quarters of the 73.3% ($n = 66$) of the stomas were deemed temporary and 76.7% ($n = 69$) underwent surgery for management of colorectal cancer. Fifty-three participants (58.9%) received chemotherapy and 44.4% ($n = 40$) were managed with radiotherapy. The vast majority of participants ($n = 72, 80.0\%$) indicated they were independent in their ostomy care, but 63.3% felt that they had not received sufficient information regarding stoma self-care.

Table 3 summarizes the occurrence rates and severity of stomal and peristomal complications in a group of 90 patients living with an ostomy for 2-6 months. Nearly 3 quarters of participants ($n = 66, 73.3\%$) experienced at least 1 stomal

TABLE 2. Interrater Reliability ($n = 10$)

Items	Cohen’s κ
Leakage	1.0
Peristomal irritant dermatitis	1.0
Pain	1.0
Bleeding	1.0
Stomal necrosis	1.0
Stomal stenosis	1.0
Retraction	1.0
Mucocutaneous separation	1.0
Hyperplasia	0.70

TABLE 3.
Incidence and Severity of Ostomy Complications^a (n = 90)

Ostomy Complications	Participants n (%)	OCSI Item Score Mean (SD)
Leakage		0.61 (0.81)
None	53 (58.9)	
1-2 ×/mo	20 (22.2)	
1-2 ×/wk	16 (17.8)	
1-2 ×/d	1 (1.1)	
Peristomal moisture-associated skin damage (irritant dermatitis)		0.61 (0.81)
None	52 (57.8)	
Mild	23 (25.6)	
Moderate	13 (14.4)	
Severe	1 (2.2)	
Pain		0.18 (0.55)
None	79 (87.8)	
1-3	8 (8.9)	
4-6	1 (1.1)	
7-10	2 (2.2)	
Bleeding		0.10 (0.33)
None	82 (91.1)	
Superficial	7 (7.8)	
Moderate	1 (1.1)	
Severe	0 (0)	
Stomal stenosis		0.05 (0.38)
None	88 (97.8)	
<5th digit diameter, no discomfort	1 (1.1)	
<5th digit diameter, occasional discomfort	1 (1.1)	
Unable to insert 5th digit, no output	0 (0)	
Stomal retraction		0.32 (0.55)
Stoma above skin	65 (72.2)	
Stoma skin level	21 (23.3)	
Stoma below skin level	4 (4.4)	
Stoma >2 cm below skin level	0 (0)	
Mucocutaneous separation		0.16 (0.58)
None	82 (91.1)	
1%-49%	3 (3.3)	
50%-74%	3 (3.3)	
75%-100%	2 (2.2)	
Hyperplasia		0.24 (0.64)
None	76 (84.4)	
1%-49%	8 (8.9)	
50%-74%	4 (4.4)	
75%-100%	2 (2.2)	

Abbreviations: OCSI, Ostomy Complication and Severity Index; SD, standard deviation.

^aThere were no cases of stomal necrosis; this item was not included in the table.

or peristomal complication after surgery. Thirty-seven participants (41.1%) reported leakage, 38 participants (42.2%) experienced peristomal moisture-associated dermatitis, 25 participants (27.8%) experienced retraction, 14 participants (15.5%) experienced hyperplasia, and 11 participants (12.3%) reported pain. Eight participants (8.9%) had bleeding and mucocutaneous separation and 2 (2.2%) had stomal stenosis. The only complication not seen in our patient participants was stomal necrosis.

Leakage (41.1%) and peristomal moisture-associated skin damage (irritant dermatitis) (42.2%) were both prevalent and most likely to be moderate to severe; 16 participants (17.8%) experienced leakage more than once weekly and 14 (16.6%)

experienced moderate to severe peristomal moisture-associated dermatitis. Hyperplasia and mucocutaneous separation and hyperplasia were moderate to severe in 5.4% and 6.6%, respectively. The proportion of patients with all other complication varied from 0% to less than 5%.

DISCUSSION

We translated the Pittman OCSI into Turkish and evaluated its content validity and interrater reliability. The cumulative CVI was 0.95 and the individual item CVI varied from 0.88 to 1.00. The instrument also achieved acceptable interrater reliability with Cohen's κ varying from 0.7 to 1.00. In addition, a comparison of cumulative OCSI score yielded a Pearson coefficient of 0.982 ($P = .000$) and an intraclass correlation coefficient of 0.986 ($P = .000$).

We then used the OCSI to evaluate frequency and severity of stomal and peristomal complications in a group of 90 adults living with an ostomy for 2 to 6 months. Slightly less than 3 quarters of participants (73.3%) experienced at least 1 complication. Our prevalence is higher than prior reports that vary from 15% to 50%.^{2,14-16,24,25} As Salvadaleña¹⁴ noted in her systematic review of incidence rates in persons with ostomies, multiple factors lead to variability in measurement of stomal and peristomal complications including variability in ostomy, type, time since surgery, and criteria for what comprises a stomal or peristomal ostomy. The OCSI includes both leakage from the ostomy pouching system and peristomal skin irritation (moisture-associated skin damage) as complications, whereas others count only skin irritation or damage as a complication. In addition, the OCSI lists pain as a complication. Leakage and peristomal moisture-associated dermatitis were the most prevalent complications; this finding is similar to prior work in this area.^{2,3,6,10,18}

Limitations of the Study

Several limitations exist that may influence the generalizability of our findings. We assessed only content validity, and reliability testing was limited to interrater reliability between 2 raters in a subsample of 10 patients. In addition, our report of the rate and severity of complications is based on a relatively small sample of 90 adults from a single site. We recommend additional evaluation of the OCSI in other types of health care setting, in patients with various types of ostomies, and in patients who have lived with an ostomy for more than 6 months.

CONCLUSIONS

We developed a Turkish language version of the Pittman OCSI and found its content validity and interrater reliability to be acceptable. Using of the instrument in a group of 90 adults with colostomies or ileostomies, we found the instrument to be parsimonious and clinically practical for both identification of stomal and peristomal complications and ranking their severity.

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- Case studies, case series or original research reports focusing on stomal or peristomal complications.
- Case studies, case series or original research reports focusing on other potential sequelae of ostomy surgery including physical manifestations such as low back pain or psychosocial manifestations such as depression, altered sexual function or embarrassment.
- Original research reports confirming or challenging the assertions of the ongoing WOCN Ostomy Consensus Session including ostomy pouch wear time and minimum standards for immediate postoperative education of patient and family.