Validity and Reliability of the Turkish Version of Pittman Ostomy Complication Severity Index

Pittman Ostomi Komplikasyon Şiddet İndeksi'nin Türkçe Geçerlilik ve Güvenilirliği

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ABSTRACT

Aim: This study aimed to investigate the reliability and validity of the Turkish version of the Pittman Ostomy Complication Severity index. **Method:** This methodological research was carried out between January 1, 2017, and January 1, 2018, at the Stomatherapy Unit of a Health Practice and Research Center in the Western Black Sea Region. The sample of the study consisted of 90 patients with an ostomy who had colostomy and ileostomy for at least one month. Stoma Individual Follow-up Form and Pittman Ostomy Complication Severity Index form were used in the study. Preoperative demographic characteristics, stoma-related characteristics within the first 24 hours after surgery, and 30 days postoperatively were evaluated according to the Pittman Ostomy Complication Severity Index. SPSS 19.0 and Excel 2016 software were used for statistical analysis.

Results: The mean age of patients was 60.22±13.23 years. It was determined that 44.4% of the patients were women, and 55.6% were men. Of all patients, 90% were married, 71.1% were primary school graduates, and 41.1% were housewives. Translation-back translation was performed for the language validity of the index. Content validity was taken from 11 experts, and Content Validity Index was determined to be 0.95. Complication-related parameters for the construct validity of the index were calculated from the significance of the total score of the Pittman Ostomy Complication Severity index. The reliability of the Pittman Ostomy Complication Severity index was evaluated with the compliance between independent observers. The linguistic compliance, which was evaluated with the compliance between observers in expert opinions, was significant (p<0.001; Kendall's W=0.132; chi-square: 67.529).

Conclusion: We showed that the Turkish version of the Ostomy Complication Severity index is a valid and reliable tool for evaluating the severity of complications in individuals with an ostomy. This index can also be used to identify and measure the severity of early complications in patients with an ostomy.

Keywords: Colostomy, ileostomy, complication, nursing care

ÖZ I

Amaç: Bu çalışma Pittman Ostomi Komplikasyon Şiddet indeksinin Türkçe geçerliliğini ve güvenilirliğinin incelenmesi amacı ile yapıldı.

Yöntem: Metodolojik tipte olan bu araştırma, Batı Karadeniz Bölgesi'nde yer alan bir sağlık uygulama ve araştırma merkezinin stomaterapi ünitesinde 1 Ocak 2017-1 Ocak 2018 tarihleri arasında yürütüldü. Araştırmanın örneklemini en az bir aydır kolostomi ve ileostomiye sahip olan 90 ostomili birey oluşturdu. Araştırmada Stomalı Birey İzlem Formu ve Pittman Ostomi Komplikasyon Şiddet indeksi formu kullanıldı. Ameliyat öncesinde hastaların demografik özellikleri, ameliyattan sonraki ilk 24 saat içerisinde stoma ile ilgili özellikleri, ameliyattan 30 gün sonra ostomi bölgesi "Pittman Ostomi Komplikasyon Şiddet indeksi'ne" göre değerlendirildi. İstatistiksel analizlerinde SPSS 19,0 ve Excel 2016 paket programları kullanıldı.

Bulgular: Ostomili bireylerin yaş ortalamasının 60,22±13,23; %44,4'ü kadın, %55,6'sı erkek, %90'ının evli, %71,1'inin ilkokul mezunu, %41,1'inin ev hanımı olduğu belirlendi. İndeksin dil geçerliliği için çeviri-geri çevirisi yapıldı. Kapsam geçerliliği için 11 uzmandan görüş alındı ve kapsam geçerlilik indeksinin 0,95 olduğu belirlendi. İndeksin yapı geçerliliği için komplikasyonla ilişkili parametreler Pittman Ostomi Komplikasyon Şiddet indeksi toplam puan arasındaki anlamlılık hesaplandı. Pittman Ostomi Komplikasyon Şiddet indeksinin güvenilirliği bağımsız gözlemciler arası uyum ile değerlendirildi. Uzman görüşlerinde gözlemciler arasındaki uyum incelendiğinde dil bakımından uyum olduğu görüldü (p<0,001; Kendall's



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©Copyright 2020 by Turkish Society of Colon and Rectal Surgery Turkish Journal of Colorectal Disease published by Galenos Publishing House. W=0,131; ki-kare=66,668). Uzman görüşlerinde gözlemciler arasındaki uyum değerlendirilmiş olup içerik bakımından uyum olduğu görüldü (p<0,001; Kendall's W=0,132; ki-kare=67,529).

Sonuç: Pittman Ostomi Komplikasyon Şiddet indeksinin Türkçe versiyonunun ostomili bireylerin komplikasyon şiddetini değerlendirmede geçerli ve güvenilir bir araç olduğunu göstermektedir. Ostomili bireyler de erken dönemde oluşan komplikasyonları tanımlamak ve şiddetini ölçmek için bu indeks kullanılabilir.

Anahtar Kelimeler: İleostomi, hemşirelik bakımı, kolostomi, komplikasyon

Introduction

The stoma that has been created to eliminate the underlying pathology and improve the patient's condition affects the whole life of the individuals. The stoma causes a variety of physiological, psychological, and social problems to the individual from the first time to the post-discharge period and thus adversely affects the adaptation process to life.¹ Despite the development of surgical methods and precautions taken, it is observed that the rate of complication development after stoma is high. Complications of the stoma may occur due to surgical intervention, underlying pathology, insufficient preoperative, and postoperative treatment and care.^{2,3,4}

Complications related to stoma can be a dull discomfort or a severe life-threatening problem. Complications are classified as early and late complications depending on the time of occurrence. It has been reported that early stoma complications are seen mainly in cases where the stoma region cannot be marked in emergency conditions or in case of technical errors. Ischemia and stoma necrosis, peristomal skin problems, and mucocutaneous separation develop in the early period. Late complications are usually seen in permanent stomas and can be listed as parastomal hernia, stomal prolapse, stenosis, and peristomal dermatitis.^{2,5,6} The incidence of stoma complications varies, and the rate is reported to be between 10% and 70%.7,8,9,10 It is stated that complication rates increase in emergency surgical procedures, and these rates are higher in individuals who do not have stoma sites marked than those who are marked.^{2,8,9} The incidence of stoma complications is related to the followup frequency of patients with a stoma, and the incidence of stoma complications decreases as the frequency of followup increases. Studies have reported a 6-fold reduction in the risk of complications associated with the care provided by the stoma team.^{11,12,13} The main goal of stoma care should be to support individuals with a stoma to adapt to the new lifestyle, to accept the image change in their body, and to be able to continue their life independently. Stoma and wound care nurses are responsible for the prevention and early recognition of complications and differentiating factors causing complications.14 Therefore, monitoring of complications is essential in terms of nursing care outcomes.

The tools with proven validity and reliability for the monitoring of stoma complications are limited in Turkey.³ The Pittman Ostomy Complicity Severity index (OCSI) was developed by Joyce Pittman to identify and assess the severity of complications during the follow-up period (30 days postoperatively) of patients with a stoma.⁴

This study aimed to evaluate the validity and reliability of the Turkish version of OCSI, which was prepared originally in English for patients with a stoma.

Materials and Methods

Type of research: Methodological research.

Time and Place of the Study: The research was conducted between January 1, 2017, and January 2018 at the Stomatherapy Unit of an Application and Research Center in the Western Black Sea Region. In the stomatherapy unit, training, counseling, and care services are provided to the individual with a stoma and his family by the researcher who has stomaterapy nursing certificate.

Population and Sample of the Study: The study population consisted of individuals who had colostomy and ileostomy for at least one month and who applied for treatment to the study centre during the study period. Inclusion criteria included being 18 years of age or older, having no hearing and speech problems, not having any cognitive problems preventing him/her from expressing himself/herself, having a stoma (colostomy, ileostomy) for one month (30 days), not having a psychiatric diagnosis and volunteering to participate in the study. One of the methods recommended in the determination of sample size in validity and reliability studies is the presence of at least 10 participants per item.¹⁵ In this research, this method was adopted, and 90 individuals with stoma were recruited.

Data Collection Tools

Stoma Follow-up Form and Turkish version of OCSI were used to collect data. This index is a tool used by the doctor or nurse to assess the individual with an ostomy.

Stoma Follow-up Form: This form, which was formed in accordance with the related literature¹⁶, included following data: The socio-demographic characteristics of the

individuals with stoma, being informed about stoma and surgery, and stoma site marking status in the preoperative period, chemotherapy/radiotherapy status and whether the surgery was urgent or planned, and surgery, type of stoma, duration of stoma, stoma region, stoma color, stoma moisture, stoma height, stoma shape, peristomal skin, stoma diameter, presence of baguette, presence of bleeding, mucocutaneous separation status in the postoperative period (within the first 24 hours), and whether there were stoma care-related impeding conditions.

Pittman Ostomy Complication Severity Index: OCSI was developed by Joyce Pittman in 2014 to assess the frequency and severity of early postoperative complications during follow-up (30 days postoperatively) in individuals with a stoma. The OCSI demonstrated acceptable evidence of content validity index [(CVI)=0.9)], interrater reliability for individual items (k=0.71-1.0), and almost perfect agreement for total scores among raters (ICC=0.991, p≤.001).⁴ This index evaluates leakage, peristomal irritant dermatitis, pain, bleeding in or around the stoma, stomal necrosis, stenosis, retraction, mucocutaneous separation, and hyperplasia. All complications are scored 0 to 3 (0=none, 1=mild, 2=moderate, 3=severe) with a Likert-like scale. The total score ranges between 0 and 27. Higher scores indicate more severe ostomy complications.⁴

Study Process

The original version of the index was obtained from Dr. Joyce Pittman by establishing communication via e-mail, and we gained permission for using a Turkish version of OSCI for a validity and reliability study. The following steps were taken in order to conduct the validity and reliability study of the scale with the patients in the study cohort:

· Language and content validity of the index were examined,

• For language validity, the index was translated from English to Turkish by two medical experts with extensive knowledge of English, and then translated from Turkish to English by one medical expert with extensive knowledge of English without seeing the original English version,

- 11 experts were consulted for content validity,
- · The Turkish version of the index was finalized,

• Following finalizing the index after expert opinions, it was applied as pre-application to five individuals included in the study,

• Data were collected by face-to-face interview method and physical evaluation before and 30 days postoperatively from individuals who met the inclusion criteria.

Evaluation of Data

SPSS 19.0 and Excel 2016 software were used for statistical analysis. Descriptive data were shown with numbers,

percentage, mean, standard deviation, median, minimum, and maximum values. The suitability of continuous variables to normal distribution was examined by the Shapiro-Wilk test. Mann-Whitney U test and Kruskal-Wallis test were used for comparison of variables that did not meet normal distribution. The relationships between quantitative variables were analyzed by the Spearman correlation coefficient. Pearson chi-square test was used to compare qualitative variables between groups. The agreement between the expert opinions was examined by the Kendall W coefficient. P<0.05 was considered statistically significant.

Ethical Aspects of Study

Permission was granted from Joyce Pittman to use OCSI in the study. Permission was obtained from the Non-Interventional Clinical Research Ethics Committee of a University in the Western Black Sea Region (Date: 30.11.2016 No: 5/14). Written permission was obtained from the institution for the implementation of the study. The purpose of the study was explained by the researcher, and informed consent was obtained from the individuals willing to participate in the study.

Results

Evaluation of Descriptive Characteristics of Individuals with Stoma

The mean age of the participants was 60.22±13.23 years, and the mean body mass index was 25.42±7.5. Of all participants, 55.6% were male, 71.1% were primary school graduates, 50% were retired, 90% were married, 93.3% had social insurance coverage, and 94.4% were living with their families. The medical diagnosis of patients was colon cancer in 35.6%, rectal cancer in 26.7%, and other malignancies and diseases in 37.8%. It was determined that 53.3% had a chronic disease, 74.4% had previous surgical operation, and 16.7% had a regular smoking habit (Table 1). It was determined that 58.9% of the stoma sites were marked before the surgery and that patients were informed about surgery. There were no impeding conditions to stoma care in all patients, and 15.6% of the patients received neoadjuvant therapy before surgery. It was found that 41.1% of the individuals in the study were operated urgently, and 58.9% of them were scheduled for surgery (Table 2).

In the evaluation results of individuals within the first 24 hours after surgery, it was found that 36.7% underwent colostomy, 37.8% underwent loop colostomy, 68.9% had a temporary stoma, and 58.9% had stoma in the left lower quadrant. It was determined that stoma color was pale pink in 63.3%, the stoma was moist in 96.7%, stoma height was

individuals with a stoma Variables Mean SD 60.22 13.23 Age Body mass index 25.42 7.5 Gender % n Female 40 44.4 Male 50 55.6 **Education Level** Not literate 7 7.8 Primary school 64 71.1 Middle School 12 13.3 High school and university 7 7.8 Profession Working 8 8.9 Retired 45 50 Housewife 37 41.1 Marital status 90 Married 81 Single 9 10 Social insurance coverage Yes 84 93.3 No 6 6.7 Lives with 5.6 Alone 5 Family 85 94.4 Diagnosis Colon cancer 32 35.6 Rectum cancer 24 26.6 Other malignancies and diseases (stomach 34 37.8 cancer, Fournier gangrene, etc.) Allergy Yes 4 4.4 No 86 95.6 Chronic disease status Yes 48 53.3 No 42 46.7 History of previous surgery Yes 74.4 67 23 No 25.6 Habits Smoking 15 16.7 Alcohol 2 2.2 73 81.1 No

Table 1. Sociodemographic and clinical characteristics of

SD: Standard deviation

Fable 2 . Preoperative evalu	uation of stoma
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Conditions related to stoma	n	%	
Informed about stoma			
Yes	53	58.9	
No	37	41.1	
Stoma marking			
Yes	53	58.9	
No	37	41.1	
Impeding factors to stoma care			
None	90	100	
Chemotherapy status			
Neoadjuvant	14	15.6	
Adjuvant	7	7.8	
None	69	76.6	
Type of surgery			
Urgent	37	41.1	
Elective	53	58.9	

prolapsed in 87.8%, the stoma was round in 73.3%, and peristomal skin was soft in 70%. The mean stoma diameter of the subjects was 43.93±5.33 mm. In the first 24 hours postoperatively, all individuals in the study group were found to have no bleeding and mucocutaneous separation of the stoma (Table 3).

Language Validity of Pittman Ostomy Complication Severity Index

In order to determine the validity and reliability of OCSI, firstly, language validity studies were conducted. First, the index was translated from English to Turkish by two experts in the field of medicine. In the last step, the backtranslation (Turkish to English) was performed by an expert in the field of medicine. The index was compared with the statements in the original form and presented to the expert opinion of 11 faculty members in the nursing and medical departments. Experts were asked to evaluate each item from 1 to 4 using a Likert-like scale for clarity of items [1= Major revision required (as suggested), 2= Minor revision required (as suggested), 3= Relevant, 4= Very relevant]. Following the recommendations of the experts, the scale items with a value of 1 and 2 were reviewed, and corrections were made, and the scale was finalized. When the analyzes of the scores given by the experts for OCSI language validity were evaluated, content validity ratio (CVR) was 0.59, and CVI was 0.954.

Content Validity of Pittman Ostomy Complication Severity Index In the content validity study of the index, it was aimed to determine whether the items in the index were appropriate

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Evaluation parameters	n	%
Surgery performed		
Low anterior resection	21	23.3
Ileostomy	13	14.4
Colostomy	33	36.7
Other	23	25.6
Stoma type		
End colostomy	22	24.4
Loop colostomy	34	37.8
End ileostomy	9	10.0
Loop ileostomy	25	27.8
Stoma duration		
Permanent	28	31.1
Temporary	62	68.9
Stoma site		
Left lower quadrant	53	58.9
Left upper quadrant	1	1.1
Right lower quadrant	36	40.0
Stoma color		
Pale pink	57	63.3
Reddish pink	33	36.7
Stoma moisture		
Moist	87	96.7
Dry	3	3.3
Stoma height		
Prolapsed	79	87.8
At the same level with skin	10	11.1
Retracted	1	1.1
Stoma shape		
Round	66	73.3
Oval	24	26.7
Parastomal skin		
Hard	27	30.0
Soft	63	70.0
Baguette		
Yes	14	15.6
No	76	84.4
Bleeding		
No	90	100
Mucocutaneous separation		
No	90	100
	Mean	± SD
Stoma radius	43.93	±5.33
SD: Standard deviation		

Table 3. Evaluation results within the first 24 hours after surgery

for their purpose, whether they represented the content to be evaluated, whether they were related to the problem adopted and whether they contained different concepts outside the content. As for language validity, the same experts were asked to score by using a 4-point Likert-like scale. When the scores of experts given for OCSI content validity were analyzed, CVR was 0.59, and CVI was 0.971 (Table 4).

Reliability Analysis of Pittman Ostomy Complication Severity Index

The reliability of the index was evaluated by the agreement between the independent observers, and there was agreement in terms of language (p<0.001; Kendall's W=0.131; chi-square=66.668) and content (p<0.001; Kendall's W=0.132; chi-square=67.529).

Comparison of Socio-demographic and Clinical Characteristics of Patients with Total Score of Pittman Ostomy Complication Severity Index

When OCSI total score and sociodemographic and clinical characteristics of subjects were compared, the total OCSI score was significantly higher in the case of female gender (p = 0.046), stoma in the right lower quadrant (p=0.038) and baguette (p=0.011). It was found that the difference was not significant regarding the type of surgery, information about stoma, stoma marking, surgery performed, type of stoma, and duration of the stoma (Table 5).

Discussion

A stoma is opened in order to ensure the continuity of the system and improve the quality of life of individuals with problems related to the gastrointestinal system. It is a condition that both changes the lifestyles of individuals and affects the quality of their lives. It is essential to prevent complications in temporary or permanent stomas and to ensure that they do not adversely affect the quality of life. Although colon cancers are the most common cause of stoma, they can be created because of colon obstructions and diseases such as Fournier gangrene.^{6,17,18,19,20} In this study, the stoma was created due to colon and rectal cancer in the majority of patients. This is in parallel with the literature.

The validity and reliability of some tools have been made for the problems that patients with a stoma may experience in the long term. Often, these tools are intended to measure the quality of life of patients.^{17,21,22,23} However, valid tools for evaluating patient outcomes in the early postoperative period are very limited. In this study, it was evaluated whether or not the Turkish version of OCSI is a valid and reliable tool to follow up on the complications 30 days after stoma surgery.

Items of Pittman Ostomy Complication Severity Index	Minimum, maximum item scores	Mean item score	Content validity ratio	Content validity index
Pittman Ostomy Complication Severity Index	3-4	3.91±0.30		
Complication	4-4	4.00±0.00		
0. None	4-4	4.00±0.00		
1. Mild	4-4	4.00±0.00	0.50	0.071
2. Moderate	4-4	4.00±0.00	0.39	0.971
3. Severe	4-4	4.00±0.00		
Leakage	4-4	4.00±0.00		
0. None	4-4	4.00±0.00		
1. Approximately 1-2X / months	2-4	3.82±0.60		
2. Approximately 1-2X / weeks	2-4	3.82±0.60		
3. Approximately 1-2X / days	2-4	3.82±0.60		
Peristomal irritant dermatitis	4-4	4.00±0.00		
0. None	4-4	4.00±0.00		
1. Erythema or rash, but no skin loss. Skin intact.	3-4	3.82±0.40		
2. Rash with less than 50% peristomal skin loss	2-4	3.64±0.67		
3. More than 50% peristomal skin loss	2-4	3.55±0.69		
Pain	4-4	4.00±0.00		
0.0	4-4	4.00±0.00		
1. 1,2,3	4-4	4.00±0.00		
2. 4,5,6 🔫	3-4	3.91±0.30		
3. 7,8,9,10	3-4	3.91±0.30		
Bleeding	2-4	3.55±0.66		
0. None	4-4	4.00±0.00		
1. Superficial; easily stopped	3-4	3.91 ± 0.30		
2. Persistent bleeding requiring ten minutes or more pressure, silver nitrate, cauterization or hemostatic agent	3-4	3.64±0.50		
3. Bleeding requiring further medical intervention (sutures, transfusion)	3-4	3.73±0.47		
Stoma necrosis	3-4	3.91±0.30		
0. None	4-4	4.00±0.00		
1. Stoma Dusky	1-4	3.55±0.93		
2. Stoma ≤ 50% black	2-4	3.55±0.82		
3. Stoma >50% black/dry	3-4	3.91± 0.30		
Stoma stenosis	3-4	3.91±0.30		
0. None	4 - 4	4.00±0.00		
1. <5th digit diameter, No pain or discomfort, output normal	3-4	3.73±0.47		
2. <5th digit diameter, Ribbon-like output,	3-4	3.64±0.50		

Table 4. Content validity of Pittman Ostomy Complication Severity index

Table 4. contiuned

3. Unable to insert 5th digit, no output. Abdominal pain and distention.	3-4	3.82±0.40
Retraction	4-4	4.00±0.00
0. Stoma above skin	4-4	4.00±0.00
1. Stoma at skin level	4-4	4.00±0.00
2. Stoma below skin level	4-4	4.00±0.00
3. Stoma >2 cm below skin level or unable to see the stoma	4-4	4.00±0.00
Mucocutaneous separation	4-4	4.00±0.00
0. None	4-4	4.00±0.00
1. 1-49%	4-4	4.00±0.00
2. 50-74%	4-4	4.00±0.00
3. 75-100%	4-4	4.00±0.00
Hyperplasia	4-4	4.00±0.00
0. None	4-4	4.00±0.00
1.1-49%	4-4	4.00±0.00
2. 50-74%	4-4	4.00±0.00
3. 75-100%	4-4	4.00±0.00

Table 5. Comparison of Sociodemographic and ClinicalCharacteristics of Patients with Ostomy with Total Score ofPittman Ostomy Complication Severity index

OCSI	n	Mean ± SD	р
Gender			
Female	40	1.65±1.87	0.046
Male	50	0.96±1.53	0.046
Type of surgery			
Urgent	37	0.97±1.51	0.120
Elective	53	1.47±1.83	0.139
Informed about stoma			
Yes	53	1.47±1.83	0.120
No	37	0.97±1.51	0.139
Stoma marking			
Yes	53	1.47±1.83	0.120
No	37	0.97±1.51	0.139
Surgery performed			
Low anterior resection	21	1.14±1.55	
Ileostomy	13	1.46±1.45	0.006
Colostomy	33	1.33±2.08	0.800
Other	23	1.17±1.49	
Stoma type			
End colostomy	22	0.81±1.62	
Loop colostomy	34	1.38±2.00	0.100
End ileostomy	9	0.88±1.16	0.109
Loop ileostomy	25	1.64±1.52	

Table 5. contiuned

Stoma duration			
Permanent	28	1.35±1.78	0 744
Temporary	62	1.22±1.70	0.744
Stoma site			
Left lower quadrant	53	1.07±1.83	
Left upper quadrant	1	-	0.038
Right lower quadrant	36	1.44±1.42	
Baguette status			
No	14	2.28±1.93	0.011
Yes	76	1.07±1.62	0.011

OCSI: Pittman Ostomy Complication Severity Index, SD: Standard deviation

While adapting a scale, it is necessary to investigate whether that scale is necessary for that society. The most important basic features sought in scales are validity and reliability. Reducing errors in both features can improve both the validity and reliability of the scale.²⁴ Validity is the ability of the scale to accurately measure the property it aims to measure without confusing it with other features. Since validity is the degree to which a scale serves the purpose for which it is used, the measurement validity will vary depending on the purpose for which the measurements to be obtained are used. The validity of a scale cannot be determined solely by itself. It also depends on the purpose

of use of the scale, the group to which it is applied, the way it is applied, and scoring. The validity of a scale is calculated by calculating the validity coefficient of that scale. This coefficient is the relationship between the values obtained from the scale and the values determined in accordance with the purpose of use of the scale. This value is between "-1.00" and "+1.00. The increased coefficient means that the scale serves the purpose more.²⁵ Content validity indicates whether the items of the scale are sufficient in terms of quality and quantity of the characteristics or behaviors that they want to measure. The agreement or disagreement between expert opinions, such as the comprehensibility of the items and their suitability to the intended audience, are used as a prediction for the validity of the content or construct.²⁶ Expert opinion is consulted to test face validity and content validity. The expert is asked to evaluate the items of the test in terms of content validity. Different methods can be used to evaluate expert opinion. The Lawshe technique is used to obtain opinions from a minimum of 5 and a maximum of 40 experts. The CVR is obtained by gathering expert opinions. The formula of CVR is CVR=(Ne/N/2)-1, in which the Ne is the number of experts indicating "essential" to an item, and N is the total number of experts who have expressed an opinion about an item.²⁷ The other method is the Davis technique. With this technique, expert opinions for each item are graded as a) very relevant, b) relevant but need minor revision, c) item need major revision, d) not relevant. With this technique, the number of experts choosing options (a) and (b) is divided by the total number of experts to CVI. CVI is obtained over the means of the items' total CVR (26). In this study, the opinions of 11 experts were taken in terms of language and content. CVRs were calculated as a result of expert opinions. In terms of language and content validity, CVR was found to be 0.59. CVI was calculated as a result of expert opinions. CVI was 0.954 in language validity analysis and 0.971 in content validity analysis. In this sense, the index was found to be valid in terms of Turkish language and content.

Reliability is the ability of a scale to measure (error-free measurement) close to the actual size of the particular feature. In other words, reliability is the level of consistency between different measurement results of a scale. It is necessary to be confident that the data provided by the scale is stable and that the same results will be obtained in a second measurement for the same purpose. The unreliable scale is useless.²⁵ The Kendall's W test, which is used to evaluate the similarity of the evaluation results of multiple observers evaluating the same subject, was used in the reliability analysis of the index. In order to see the agreement between the opinions of the experts, it was evaluated whether there is an agreement in terms of language and content. Kendall's

W value of 0.131 in terms of language and 0.132 in terms of content confirmed that expert opinions were consistent and reliable.

A stoma can be created for any reason, either urgently or planned, and postoperative complications may occur, no matter how much precautions have been taken. Creating a stoma in an emergency setting increases the risk of peristomal complications, and the risk of complications increases by up to 18%.28 In a prospective single-center study, including 192 patients, Parmar et al.¹¹ reported that 22% of patients developed complications after elective surgery and 46% after emergency surgery. Stoma site marking in the preoperative period facilitates compliance, improves quality of life, and reduces complication rates.8 The stoma site should be marked even in an emergency setting. The common recommendations of the American Society of Colon and Rectal Surgeons and Wound, Ostomy, and Continence Nurses Society are to mark the stoma site by the surgeon or stoma nurse before the surgical procedure in all individuals who will undergo bowel operation.^{29,30} If preoperative stoma site marking is not possible and the patient is obese, the stoma should be placed high above the abdomen from the subcostal region. This helps the patient to see the stoma more clearly.¹¹ In a study including 593 patients, Ratliff et al.³¹ reported that 95 of 292 individuals who were evaluated by the stoma nurse before surgery had postoperative complications, and 131 of 301 patients who had no preoperative evaluation were reported to have complications. Kozan and Gültekin³² found that the only factor that can be controlled in reducing the risk of parastomal hernia was the marking of the stoma site in the preoperative period. In this study, it was seen that all patients who underwent elective surgery (58.9%) were evaluated by the surgeon or stoma nurse, and the marking was performed, but that marking was not performed in emergency patients. Also, there was no significant difference in the severity of complications according to the type of surgery, information about stoma, stoma marking, surgery performed, type of stoma, and duration of the stoma. Risk factors for stoma complications include gender, body mass index, short mesentery, type of stoma, and abdominal features in the stoma site.^{8,9,10,11} In this study, it was found that the severity of complications was significantly higher in the female gender, stoma created in the right lower quadrant, and in the case of baguette. Although studies on gender are limited in the literature, the female gender is the predisposing factor in the parastomal hernia.^{32,33,34} The intestinal segment to be used for the stoma, age of the patient, the reason for the stoma, comorbid diseases, habits of the patient, and body structure are essential in determining the stoma site.35 The type and location of the stoma directly affect the

complications, and the highest complication is seen in loop ileostomy.^{35,36,37} Another complication is retraction with a 6-10% incidence due to early removal of baguette used in loop stoma and intestinal dysfunction.⁷ A stoma is a very important condition that affects the life of individuals in physiological, psychological, and social aspects, so it is essential to pay attention to risk factors in order to avoid complications.

Conclusion

This study concluded that OCSI is a valid and reliable tool for assessing the severity of early complications of a stoma. As it is easy and practical to use, it guides health professionals in diagnosing and treating early complications. Accordingly, we recommend using this index in the followup of individuals with an ostomy.

Ethics

Ethics Committee Approval: Permission was obtained from the Non-Interventional Clinical Research Ethics Committee of a University in the Western Black Sea Region (Date: 30.11.2016 No: 5/14).

Informed Consent: The purpose of the study was explained by the researcher, and informed consent was obtained from the individuals willing to participate in the study.

Peer-review: Externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: A.U.A., Concept: A.U.A., E.K, M.Ç.B., Design: A.U.A., E.K., M.Ç.B., Data Collection or Processing: A.U.A., Analysis or Interpretation: E.K., M.Ç.B., Literature Search: A.U.A., E.K., Writing: A.U.A, E.K., M.Ç.B.

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Appendix F: Pittman Ostomy Complication Severity Index (OCSI)

Time 2: 30 Days post surgery Subject

PITTMAN OSTOMY COMPLICATION SEVERITY INDEX					
For each item mark the score that corresponds to the description and mark in the Total column on the right. Then total all items for total					for total
Complication:	0-None	1-Mild	2-Moderate	3-Severe	Total
	▼	▼	▼	▼	
Leakage	None	Approx. 1-2x/mo	Approx. 1-2x/wk	Approx. 1-2x/day	
Peristomal Irritant Dermatitis	None	Mild- <u>erythema</u> or rash but no skin loss. Skin intact	Moderate- Rash with skin loss <50% peri-stoma	Severe- Skin loss >50% <u>peri</u> -stoma	
Pain		1, 2, 3	4, 5, 6	7, 8, 9, 10	
Bleeding-stoma or <u>peristoma</u>	None	Superficial; Stopped easily	Moderate-persistent bleeding requiring prolonged pressure ≥10 min, AgNO3, cauterization, or <u>hemostatic</u> agent	Severe-requiring advanced medical intervention (sutures, transfusion)	
Stomal Necrosis	None	Stoma dusky	Stoma black ≤ 50 % or greater	Stoma black/dry > 50%	
Stomal Stenosis	None	Stoma Os <5 th digit diameter, No pain or discomfort, Output normal	Stoma Os < 5 th digit diameter, Ribbon-like output, Occasional discomfort.	Unable to insert any digit into stoma os, No output x ≥6 hrs, Abd pain and distention.	
Retraction	Stoma above skin level	Stoma level with skin	Stoma below level of skin	Unable to see stoma Or Stoma >2cm below skin	
Mucocutaneous Separation	None	1%-49%	50%-74%	75 %- 100%	
Hyperplasia	None	1%-49%	50%-74%	75%-100%	
Total	•				