Title: Turkish Reliability and Validity of The Ostomy Skin Tool

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Abstract

**Background:** Peristomal skin disorders are common problem. In respect of studies related to incidence of peristomal skin complication 12 to 76% of ostomy patients experience some type of peristomal skin problems.

**Objective:** The aim of this study is to explore Turkish validity and reliability of Ostomy Skin Tool (OST).

**Methods:** This is a methodological study planned to evaluate Turkish reliability and validity of OST. The OST consists of two parts. The first part of this tool is DET (Discolouration, Erosion, Tissue overgrowth) score tool, and second part is AIM (Assessment, Intervention and Monitoring) guide. For the DET Score tool reliability and validity, thirty peristomal skin photographs obtained from a stoma care unit archives were presented twice to two ostomy care nurses to determine intra and inter nurse assessment variability. For the AIM guide validity, content validity index calculated according to Lawshe’s content validity ratio.

**Results:** The inter nurse agreement and the intra nurse agreement evaluated with Linear Weighting Kappa. According to the inter nurse assessment, there was a moderate to a substantial agreement (0.51-0.77). According to intra nurse assessment there was a perfect agreement (0.83-1). AIM Guide content validity index was found 0.99. According to this ratio, there is an agreement between experts and all the items were found essential.

**Conclusions:** The Ostomy Skin Tool is valid and reliable tool.

**Implications for Practice:** Turkish version of OST could provide a richer contribition to the assessment and intervention of peristomal skin condition in all settings to the ostomy care nurses.

Keywords: Peristomal complications, ostomy, nurses

Introduction

Ostomy creation is a frequently performed surgical procedure [1]. The most common underlying conditions resulting in the need for stoma surgery are colo-rectal (bowel) cancer, bladder cancer, ulcerative colitis and Crohn’s disease [2]. Whether the ostomy is the result of an emergent or elective procedure, the WOC (Wound Ostomy Continence) nurses and staff nurses are responsible for monitoring and ensuring quality healthcare for the patient. Nevertheless, many patients undergoing ostomy surgery experience a complication during the postoperative period [3]. Peristomal skin disorders are common problem of ostomy patients. Reported rates of stomal complications in the literature vary widely [4]. A prospective study by Cottam et al. reported a peristomal skin complication rate of 34% in a series of 3970 consecutive patients undergoing stoma creation [5]. The other retrospective study carried out by Sung et al. reported a peristomal skin complication rate is 28% in a series of 1170 ostomy patients [6]. According to the other study results interested in incidence of peristomal skin disorders carried out by Richbourg et al., the incidence of peristomal skin disorders was found 76% in a series of 34 ostomy patients [7]. In respect of studies related to incidence of peristomal skin complication, 12 to 76% of ostomy patients experience some type of peristomal skin problems [5-10]. And many ostomy patients have a negative impact on quality of life because of peristomal skin complications. In fact, it has been suggested that how well a person comes to terms with living with an ostomy depends to a large extent on the health of peristomal skin. Major challenges can include; a poorly created or sited ostomy, skin breakdown from contact with ostomy output, lack of knowledge about peristomal skin disorders and ostomy management, delay in obtaining intervention from an ostomy care nurse or other healthcare professionals [11].

Ostomy care nurses have a crucial role in the assessment and management of peristomal skin disorders, and spend a significant proportion of their time preventing and managing them [10]. Ostomy care nurses are responsible for educating individuals with
ostomy and their caregivers about the care of ostomy. Individuals with ostomy are taught about maintaining healthy peristomal skin, the signs and symptoms of skin irritation, and when to consult an ostomy care nurse [11].

Assessment of disease severity is an integral part of any diagnostic and therapeutic decision. This process is highly individualized among healthcare professionals, but standardized assessment schemes may help to describe the clinical reality and reduce inter-observer variation. Such tools are therefore useful in routine clinical assessments, research and in communication between healthcare professionals [12]. In the literature, two instruments found to assess peristomal skin complications. First one is SACS™. The SACS™ (Studio Alterazioni Cutanee Stomali or Study on Peristomal Skin Disorders) Instrument was developed by seven enterostomal nurses and four surgeons from eight facilities in Italy. This instrument presented at the 2010 WOCN/WCET Conference, and it validated in Italy and the US. The SACS™ Instrument is content-validated peristomal skin assessment and classification instrument, with a content validity index of 0.94. The instrument reduces the subjective assessment of peristomal skin lesions and promotes a universal language for communicating peristomal skin disorders. However, the SACS™ Instrument only addresses one component of ostomy clinical decision-making and a broader instrument, such as an algorithm, is needed to address all aspects of the management of stomal and peristomal complications [13].

In another effort to provide clinicians with a classification system for peristomal skin complications is the Ostomy Skin Tool (OST) was developed by a group of 12 ostomy care nurses from around the world in collaboration with an ostomy products manufacturer [14]. The Ostomy Skin Tool is comprised of two sections. Part one which name is DET (Discolouration, Erosion and Tissue overgrowth) Score tool is used to calculate a score that describes the peristomal skin condition and incorporates both the area affected and severity of the problem. Part two which called AIM (Assessment, Intervention and Monitoring) guide is a diagnostic tool that allows categorisation of the peristomal skin disorder according to its cause and offers guidance on care [15]. The OST has international acceptance and use and it has multicultural terminology, availability in not only one language. At the same time, it is suitable for varying health services and practices. Therefore, the OST was chosen to use in our study to assess and diagnos our ostomy patients. The aim of this methodological study to evaluate Turkish validity and reliability of OST [14].

**Methods**

**Sample and Setting**

Interobserver variation can be measured in any situation in which two or more independent observers are evaluating the same thing [16]. Therefore, two experienced and certified ostomy care nurses from Turkey participated to the study for the validity and reliability of DET Score tool. One of the nurses attended national certification program to be an ostomy care nurse and the other nurse who is also one of the researcher of this study attended both national and international certification program to be an ostomy care nurse. At the same time, one of the nurses who is one of the researchers of this study attended Coloplast Ostomy Days 2012 in Hamburg, Germany to learn and increase informations about OST. After researchers learned using of OST, the other nurse was trained to use of the OST. The 30 photographs were used to evaluate DET Score tool’s validity and reliability. The photographs obtained from a stoma care unit archives carefully selected in different levels of peristomal skin disorders by the researchers. Those photographs presented to the two ostomy care nurses, in two separate sessions in a university hospital’s stoma care unit.

In order to evaluate AIM guide validity, Turkish version of guide were sent to 10 experts via e-mail. The experts group was consisted of two general surgeons, five nursing academicians, and three stoma care nurses. According to experts views, the guide was revised and calculated content validity by the researchers.

**Instrument**

**Ostomy Skin Tool (OST)**

The OST was developed by an international group of 12 expert ostomy care nurses working in collaboration with Coloplast A/S (Humblebaek, Denmark), and with advice from a dermatologist in 2009 [15].

The OST provides a common language to describe the severity, extent and likely cause of a peristomal skin disorder. The OST consists of two parts. First part of this tool is DET (Discolouration, Erosion, Tissue overgrowth) score tool, and the second part is AIM (Assessment, Intervention and Monitoring) guide. The scoring component which is DET score tool is a standardised way of evaluating the severity and extent of the disorder. The diagnostic guide which is AIM guide provides a set of standard terms that were agreed upon by an international consensus process. These two elements of the OST enable clinical comparisons of the peristomal skin between different healthcare professionals and different settings [15].

**DET Score Calculation:** The peristomal skin is examined and evaluated based on the descriptions in each of the three domains (discolouration, erosion and tissue overgrowth). Maximum point of size of affected area in terms of every domains is 3 and, for the severity maximum point is 2. Firstly, the affected area (area is defined as the peristomal skin area that is covered by the adhesive) size is assessed in each of the three domains and scored based on the key (below).

<table>
<thead>
<tr>
<th>Affected area</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unaffected</td>
<td>0</td>
</tr>
<tr>
<td>&lt;25 %</td>
<td>1</td>
</tr>
<tr>
<td>25-50 %</td>
<td>2</td>
</tr>
<tr>
<td>&gt;50 %</td>
<td>3</td>
</tr>
</tbody>
</table>

Then, the severity in each of the three domains is assessed by using the definitions and photographs and scored according to (Table 1). The total score is calculated by adding all of the subscores from each domain together [14].

The Validity of DET score tool was calculated by Jemec at al. Thirty photographs of peristomal skin were presented twice to 20 ostomy care nurses - 10 from Denmark (DK) and 10 from Spain (ES) - to determine intra- and inter nurse assessment variability. A high intra-nurse assessment agreement, (K= 0,84), was found with no differences in the intra-nurse assessments from the two groups of nurses (DK and ES). The inter-nurse assessment agreement was ‘moderate to good’ (K= 0,54) [12].
The second section of the Ostomy Skin Tool is the AIM (Assessment, Intervention and Monitoring) Guide for Peristomal Skin Care - allows categorisation of the peristomal skin disorder according to its cause and offers guidance on care. Clinical observations are matched with standard descriptions, which are grouped according to the probable cause. For each cause there is a set of questions to be considered [15]. There are 5 categorised peristomal skin disorders, 22 causes and 78 interventions, and 26 sentences for the visual changes in the AIM guide. Categorised peristomal skin disorders are as follows:

- **Irritant contact dermatitis** (6 causes, 19 intervention, 7 visual changes sentences).
- **Alergic Dermatitis** (3 causes, 10 interventions, 1 visual changes sentence).
- **Mechanical Trauma** (5 causes, 13 interventions, 6 visual changes sentences).
- **Disease Releated** (5 causes, 21 interventions, 7 visual changes sentences).
- **Infection Related** (3 causes, 15 interventions, 5 visual changes sentences).

### Table 1: Severity Score Guide

<table>
<thead>
<tr>
<th>Severity</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain 1: Discolouration</strong></td>
<td></td>
</tr>
<tr>
<td>Slight redness and other discolouration of the peristomal skin</td>
<td></td>
</tr>
<tr>
<td>Deep or high-acyosed skin potentially causing further complications</td>
<td>2</td>
</tr>
<tr>
<td><strong>Domain 2: Erosion</strong></td>
<td></td>
</tr>
<tr>
<td>Damaged top layer of the skin (epidermis)</td>
<td>1</td>
</tr>
<tr>
<td>Damaged lower layers (dermis) of the skin with complications (mixture, bleeding, ulceration)</td>
<td>2</td>
</tr>
<tr>
<td><strong>Domain 3: Tissue overgrowth</strong></td>
<td></td>
</tr>
<tr>
<td>Tissue overgrowth that interferes with application of the adhesive</td>
<td>1</td>
</tr>
<tr>
<td>Tissue overgrowth that interferes with application of the adhesive and causes bleeding and/or pain</td>
<td>2</td>
</tr>
</tbody>
</table>

Reliability and Validity Studies

For the validity and reliability studies, translation procedures, content validity, intra observer agreement and inter observer agreement were performed.

**Translation procedures**

In order to translate and use of Ostomy Skin Tool, firstly, the permission was taken from Lis Hentze Poulsen and Coloplast A/S via e-mail. Then, the tool was translated using back-translation technique. The original tool was translated from English to Turkish by one bilingual people with Turkish as a mother tongue. Then, Turkish version was back-translated to English by the English language specialist. The first preliminary Turkish version and the back-translated version were compared and found to be compatible with each other. After that, a Turkish language specialist from Ege University checked the sentence structure of Turkish version of tool and according to his advices sentence sentence structures were revised by the researchers. A pilot study of the first preliminary Turkish version of the tool was conducted with 10 participants. Results showed that the items were understandable and the results of this pilot study were not included in the larger study.

**Content Validity**

After language validation, the Turkish guide was sent to ten experts via e-mail. All the experts were asked “Is the skill or knowledge measured by this item?” The experts scored 1 to 4 point for every item of AIM guide. One point means “the item is not necessary”, 2 point means “the item needs more differences”, 3 point means “the item needs little differences”, and 4 point means “the item is essential”. At the same time, the experts wrote their suggestions for every items when they scored 2 or 3. According to experts views, the guide was revised. Because of one expert’s view, photographs were added to the AIM guide for every peristomal skin disorders.

**Intra Observer and Inter Observer Agreement**

For the DET score tool validity and reliability, intra and inter observer agreement were calculated. In order to reduce examiner bias, and ensure that the nurses were unable to recall the measurements, the 30 photographs were fixed in two different orders and presented to the two ostomy care nurses, in two separate sessions. The nurses were blinded to each other’s assessments. To further reduce recall bias the two sessions were separated by a 1 hour break during which the nurses were asked not to discuss the photographs. In both sessions the nurses were asked to assign a DET score to each photograph using the OST.

**Data Analysis**

Intra observer agreement was calculated for the DET score tool validity and inter observer agreement was calculated for its reliability with the Linear Weighting Kappa test. In order to calculate the validity of AIM guide, Lawshe’s Content Validity Index was used. Calculation of Lawshe’s content validity ratio contains 6 steps; 1) Constitute of expert group, 2) Preparing of sample tool, 3) Obtaining of experts view, 4) Calculation of content validity ratio for every items, 5) Calculation of content validity index, 6) Constitute of the final tool according to content validity index [17]. In order to calculate content validity index, these steps were followed.

**Ethical Considerations**

In order to translate and use of the Ostomy Skin Tool, the permission was obtained from Lis Hentze Poulsen and Coloplast A/S via e-mail. Before begining the research, permission obtained from Dokuz Eylül University Ethical Committee. At the same time, a permission was obtained from Dokuz Eylül University Hospital management to use stoma care unit’s archive photographs.

**Results**

**Turkish Reliability and Validity of The DET Score Tool**

Relative to observers as data consistency has been assessed through two approaches: between-observer for the validity (interobserver agreement) and within-observer for the reliability (intraobserver reliability). The interobserver agreement and the intraobserver reliability were evaluated with Linear Weighting Kappa. The interpretation of kappa was followed the guideline of Viera and Garrett: k<0.20, slight agreement; 0.21<k<0.40, fair agreement, 0.41<k<0.60, moderate agreement; 0.61<k<0.80, substantial agreement; 0.81<k<0.99, almost perfect agreement [16].

Every domains’ inter and intra nurse agreements were calculated separately. According to the inter nurse assessment reliabilities, there was a moderate to a substantial agreement (0.51-0.77). According to intra nurse assessment there was a perfect agreement (0.83-1) (Table 2).
Table 2: Kappa (K) Values of Inter and Intra Nurse Agreements

<table>
<thead>
<tr>
<th>Domains</th>
<th>Inter Nurse Agreement (K value)</th>
<th>Intra Nurse Agreement (K value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area of Discoloration</td>
<td>0.52</td>
<td>0.91</td>
</tr>
<tr>
<td>Severity of Discolouration</td>
<td>0.77</td>
<td>0.92</td>
</tr>
<tr>
<td>Area of Erosion</td>
<td>0.51</td>
<td>0.91</td>
</tr>
<tr>
<td>Severity of Erosion</td>
<td>0.55</td>
<td>1.0</td>
</tr>
<tr>
<td>Area Of Tissue Over growth</td>
<td>0.62</td>
<td>0.83</td>
</tr>
<tr>
<td>Severity Of Tissue Over growth</td>
<td>0.62</td>
<td>0.87</td>
</tr>
</tbody>
</table>

Turkish Validity of AIM guide
The ten experts’ mean score for every item was between 3.4 to 4 (min=1, max= 4). Content validity ratio of every item was calculated by the content validity ratio formula (CVR (content validity ratio) = (count of experts who say ‘essential’ to the item/ the count of all the experts)/2)-1).

When an expert group is composed of ten members, a minimum CVR of 0.62 is required to satisfy the five percent level. Only those items with CVR values meeting this minimum are retained in the final form of the test [17]. Content validity index was found 0.99. According to this ratio, there is an agreement between experts and all the items were found essential.

Discussion
Ostomy care nurses have a crucial role in the assessment and management of peristomal skin disorders, and use a significant proportion of their time preventing and managing them [18]. Several other assessment schemes for peristomal skin have been developed and introduced over the years [10]; however none has achieved widespread international acceptance or use. Reasons for this have included lack of validation, lack of international compatibility (e.g. development by healthcare professionals from a single country without international input), lack of multicultural terminology, availability in only one language and unsuitability for varying health services and practices, and usefulness in only one type of ostomy [15]. Several of these shortcomings have been addressed by the systematic development of the OST. Jemec et al was evaluated intra- and inter nurse assessment reliability and validity of DET score tool. An ‘excellent’ intra nurse assessment agreement, K= 0.84, was found whereas the inter nurse assessment agreement was ‘moderate’, K = 0.54 [12]. In our study, there was a moderate to a substantial agreement (0.51-0.77) in the inter nurse assessment and there was a perfect agreement (0.83-1) for intra nurse assessment. These results could suggest that while the tool may be good for the monitoring of an individual patient by the same nurse, comparison between different assessors is less reliable.

The highest inter nurse assessment agreement was seen in Domain 1(Severity of discoloration, K= 0.77), and the lowest was seen for domain 2 (Area of erosion, K = 0.51). In the Jemee’s study there were the similar results. In their study, the highest inter nurse assessment agreement was seen in domain 1 (Discoloration, K = 0.59), and the lowest was seen for domain 2 (Erosion, K = 0.35) [12]. It is speculated that the use of photographs may have influenced this as erosions are three-dimensional and hence difficult to assess reliably in photographs.

Content validity is the extent to which a test adequately samples the universe or domain of items which it is supposed to measure. It is of importance in the field of achievement testing [19]. Therefore, content validity was calculated for the AIM guide in our study. Firstly, the guide was translated to Turkish language by the English language specialist. After language validation, Turkish guide was sent to ten experts via e-mail. According to experts views, the guide revised. Content validity measured with Lawshe’s content validity ratio [17]. Content validity index was found 0.99. According to this ratio, there is an agreement between experts and all the items were found essential.

Limitations of study
In this study, we assessed all the cases with photographs. Therefore, assessing especially erosion is difficult and it could cause decreasing of inter observer agreement. Assessing only photgraphes is a limitation of this study. At the same time, only two nurses assessed the cases so this is the other limitation of this study.

Conclusion and recommendations
The Ostomy Skin Tool has two parts and every part’s reliability and validity was assessed with different ways. DET score tool validity and reliability results suggest that the tool is good for the monitoring of patients by the same nurse. According to AIM guide content validity results, this guide is valid. Turkish version of OST can provide a rich contribution to the assessment and intervention of peristomal skin condition in all settings to the ostomy care nurses.

A recommendation that this tool should be further evaluated; with the more than two nurses and the nurses may observe peristomal skin complications on patients not only photographs.

Acknowledgments
We would like to thank Ceylanım Üçer who is ostomy care nurse for the help of assessment of our cases with the DET score tool. At he same time, thanks all the experts who scored AIM guide items. And, thanks all the nurses who is working in Céleleveland Clinic Stomasteraphy Unit because we introduced the OST with their help.

References

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