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VALIDITY AND RELIABILITY OF PERISTOMAL SKIN ASSESSMENT INSTRUMENTS: INTEGRATIVE REVIEW

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ABSTRACT
The incidence of early complications such as skin irritation, erosion, and peristomal ulceration is reported to be quite high. It is important to assess the peristomal skin in order to prevent complications. Valid and reliable instruments are needed to collect assessment data. This integrative review aims to summarize and identify the current literature related to valid and reliable peristomal assessment instruments. An integrative review was carried out using published literature during the search period March 9, 2007-9 March 2022. Database using PubMed, Science Direct, EBSCO, ProQuest, Cochrane Library, and Wiley Online Library. Study selection (both on title/abstract screening and full-text screening) was carried out by two independently experienced reviewers. disagreements were resolved by the decision of the third reviewer. A total of 7 peristomal skin assessment instruments were found from 10 articles passed as the main study. Among the peristomal skin assessment instruments that have good value and process validation and reliability are Ostomi Skin Tools dan Studio Alterazioni Cutanee Stomali. Peristomal skin assessment as an effort to prevent early stoma complications can be carried out by conducting an assessment using a valid and reliable measuring instrument, and practically easy to introduce.

Keywords : peristomal skin; reliability; instrument; validity

INTRODUCTION

One of the early complications that can occur at ostomate is in the area around the stoma (peristomal) (Shabbir & Britton, 2010). Peristomal skin irritation (36%) was the most consistent complication followed by laparotomy wound infection (13%)(Ahmad et al., 2013). Normally, the skin color of the abdomen should match the color of the skin around the stoma and the peristomal skin should also be clear of any lesions(Wise, 2019). Skin disorders in the peristomal area are reported by two thirds of stoma patients, which can lead to leakage of the pouch and reduce its stickiness(Hellman & Lago, 1990). Most (70%) of the ostomates experienced peristomal complications with skin damage being the most common, and healthy peristomal skin greatly contributes to the effectiveness of bag attachment and prevention of faecal leakage(Kelly, 2019).

Prevention of peristomal skin pain is the goal of good stoma management (Kelly, 2019). Maintaining the integrity of the peristomal skin and preventing leakage of the stoma bag are the main goals of peristomal skin care(Jones, 2016). Therefore, it is necessary to conduct an assessment to determine the condition of the peristomal area in order to obtain accurate data about it so that prevention and treatment of the peristomal area can be carried out. In peristomal skin care, it is effectively carried out by nurses, improves quality of life, prevents and treats postoperative peristomal complications (Harputlu & Özsoy, 2018). Knowing the causes of skin wounds and how to deal with them is the reason why nurses need to assess ostomates thoroughly (Burch, 2010).

There are no instruments to assess peristomal skin complications that have been widely accepted internationally(Haugen & Ratliff, 2013). Using consistent parameters and the same method is important for health professionals to assess and communicate the condition of the peristomal skin (Martins, Ayello, Claessens, Steen, et al., 2010). An Integrative Review (IR) conducted by (Nunes and Santos, 2018) regarding instruments for assessing peristomal skin complications and reports on instruments that can be used but the IR has not discussed the validity and reliability of each instrument(Nunes & Santos, 2018). The research question is from existing studies, which peristomal skin assessment is valid and reliable?.

METHOD

This study uses an Integrative Review (IR) design. IR is a specialized review method that summarizes past empirical or theoretical literature to provide a more comprehensive understanding of a particular phenomenon or health problem(Torraco, 2016).IR as a comprehensive research methodology that allows the study, criticism, and synthesis of literature that represents a topic or issue, and which is able to generate new approaches and perspectives on the issue (Soares et al., 2014). Data extraction templates were used to extract relevant data from the included studies, Data extraction was carried out independently by two experienced reviewers to minimize errors. Differences of opinion from the two reviewers are resolved by consensus or by the decision of the third reviewer(Aromataris E; Munn Z, 2020).

Researchers used inclusion and exclusion criteria to get articles that match the research theme. Inclusion criteria, (a.) Research developing and testing peristoma skin assessments; (b.) All articles except Review articles, (c.) Published in English, (d.) Published in the last 15 years (March 2007-March 2022). Exclusion Criteria: Articles that are not available full text. The search was conducted on the PubMed database using the keywords “peristomal skin AND assessing OR assessment AND validity and reliability OR valid and reliable”. Science Direct uses the keyword “peristomal skin assessment tools”. EBSCO uses the keyword “peristomal skin AND assessing OR assessment AND validity and reliability OR valid and reliable”. ProQuest uses the keyword “peristomal skin assessment”. Cochrane Library uses the keyword “peristomal skin AND assessing OR assessment AND validity and reliability OR valid and reliable”. Wiley Online Library uses the keyword “peristomal skin AND assessment AND validity and reliability”. And secondary search.

The data analysis process started from selecting and determining 10 articles to be included in the main study which were verified by two reviewers. The initial phase of the data extraction table is created and modified according to the needs of the review. Another table made is a table of the types of instruments and indicators that are assessed as well as a table of validity and reliability tests for each instrument. The first and second reviewers analyzed separately, then the data entered in the data extraction table, types of assessment instruments and indicators as well as the validity and reliability test tables were read back by the two reviewers to reach consensus in selecting the relevant items. The next phase of the differences and similarities between the reviews related to the method across the data in the analysis. The final step is drawing conclusions and verification is carried out by the third reviewer to ensure that all articles are thoroughly reviewed in terms of the type of instrument and the validity and reliability test methods used and the results are in accordance with the research questions you want to assess(Hopia et al., 2016).

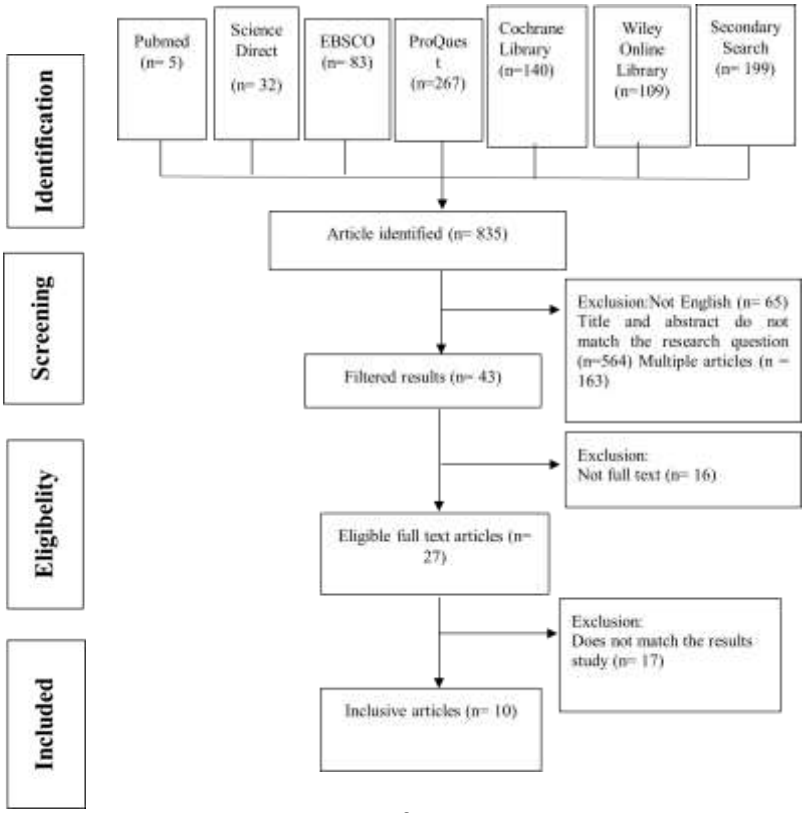
Contains relevant and detailed information based on the methodology and related evidence. Various methodologies that are included in IR can lead to lack of accuracy, imprecision and bias, so it is necessary to establish bias control. Studies are divided into subgroups based on pre-determined classifications, for example categorization based on the type of instrument,

methodology or sample characteristics. Furthermore, data is extracted from primary sources using prepared instruments to simplify, summarize, and organize the findings, so that each study is reduced to a single page with relevant content. The next step is data visualization in the form of graphs or tables. Any statement regarding a relationship or conclusion requires verification of the primary sources to avoid premature conclusions or exclusion of relevant evidence during the process (M. T. de Souza et al., 2010).

RESULT

Literature search

We identified 835 articles from the database that were relevant to the health sector. Pubmed, science direct, EBSCO, ProQuest, Cohcrane library, Wiley Online Library and secondary search (google scholar) were selected as the search data base. After reading the title and abstract, 564 articles were excluded because they did not match the research question, 65 articles were excluded because they were not available in English, and 163 articles were double-identified. The next stage is full text access and 16 articles are issued because full text is not available. After reading the research results, 17 articles were issued because the research results did not match the research questions. Finally, as many as 10 articles were entered into the next stage, namely data extraction.



Gambar 1 : Diagram flow article selection PRISMA

Main Study

There were 10 articles included in the main study. By country of origin, 5 articles are from the UK, 1 in Japan, 2 in Italy, and 2 more in Turkey. All articles are in English. The main author's background, 5 authors are nurses in nursing practice, general hospitals and teaching hospitals, and 5 authors have educational backgrounds in educational institutions. The year of publication in order from 2010 was 2 articles, 2011, 214, 2015, 2016, 2018 and 2019 each with 1 article, the last 2020 there were 2 articles.

Types of Assessment Instruments and Indicators

Seven instruments were found to assess peristomal skin including severity, including:

1. The Ostomy Skin Tool (OST) in this case assesses discolouration (D), erosion (E), and tissue overgrowth (T) which is abbreviated as DET.
2. Studio Alterazioni Cutanee Stomali (SACS) is a peristomal assessment that assesses the type and area of the lesion. the type of lesion denoted (L) consists of L1: hyperemic L2: erosive L3: L4: ulcerative, and the revised version adds L5: Ulcerative involving areas outside the muscle fascia and LX: Proliferative lesion (neoplasia, granuloma, oxalate deposit). The area/topography denoted (T) consists of T1: left upper quadrant T2 : Left lower quadrant T3: lower right quadrant T4: right upper quadrant).
3. Peristomal Lesion Scale (PLS) assesses the wound bed including: Erythema, papules, pustules, vesicles and bubbles >0.5mm, ulcerative overgrowth including: erosions, wound healing, mixed wounds and worsening wounds.
4. ABCD-stoma assesses the area close to the stoma: adjacent(A), obstruction(B), border(C) and discoloration(D).
5. Peristomal Skin Discoloration (PDS) in the form of image analysis automatically PSD assesses color changes, peritomal area, ostomy, background, leaks, ostomy product, center hole, back hole.
6. Pittman Ostomy Complication Severity Index (OCSI). This index evaluates: (1) Complications (2) Leakage (3) Peristomal irritant dermatitis (4) Pain, (5) Bleeding in or around the stoma, (6) Stoma necrosis,(7) Stenosis,(8) Retraction,(9) Mucocutaneous separation, (10) Hyperplasia.
7. Color indicator digital photo of peristomal skin that assesses erythema index (EI), melanin index (IM), and Hypopigmentation index (HI).

Instrument validity and reliability

Assessing the completeness of the validity and reliability tests of each instrument (1.) The OST DET instrument has been carried out a valid test using face validity and a reliability test using a retest test with moderate to very good agreement results (kappa values ranging from = 0.54-0.84). (2.) SACS has been tested for content validity with a CVI result of 0.94, and an interrater reliability test with a very good agreement between observers (κ=0.90.90%CI 0.80-0.99), the SACS revision has also been tested for face validity, 15 panels experts received the revised version of SACS results. (3.) PLS has been tested for construct validity where PLS is better at distinguishing lesions based on severity because of the level of detail, using standard terminology, and completeness than SACS. (4.) Instrument Indicator color digital photo of peristomal skin has been tested for criterion validity where all indicators EI, MI, HI are significantly correlated with the DET color change severity score and total score ($p < 0.05$), for reliability testing using a retest test with the results the interclass correlation coefficient (ICC) for EI, MI, and HI was >0.7, indicating substantial or near-perfect agreement between baseline and end. (5.) The color indicator of the peristomal skin digital photo of the Face validity test gives an accuracy of 95.0%, a precision and a recall score of 79.6 and 75.0%, respectively for the color change criteria. Peristomal area detection showed an accuracy score of 93.3% with a precision and recall score of 80.2, respectively. (6.) Ostomy Complication Severity Index (OCSI), content and language validity test, Language validity ratio (CVR) 0.59, and CVI 0.954. CVR content validity 0.59, and CVI 0.971. Interterrater reliability test with results: agreement between independent observers, and 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; chikuadrat = 67.529). (7) ABCD-stoma in the main article of validity and reliability test is not available.

DISCUSSION

Demographic Data

The expert sample used in the main study were stoma care specialists with at least >2 years experience, and international dermatologists. This is commonly found in almost all research methods that involve experts to determine inclusion criteria, including experience and expertise in certain fields (Andersen et al., 2020; J. Beitz et al., 2010; J. M. Beitz & Colwell, 2014; Jemec et al., 2011; Martins et al., 2022b). Involving international experts is intended so that the validation is universal and not limited to one particular country. Respondent characteristics of stoma patients were defined as age ≥18 years, the average age of patients with stomas was 56 to >80 years. In line with Jane's research, age inclusion >18 years and patient demographic data results are 7% of patients in the age range 18-39 years(Fellows et al., 2021). Although it was reported in the study Shiraisi, Nishizawa, Nakajima, Kado, Ikeda, Tsukada, Sasaki and Ito (2020) that age was not statistically significant correlated with the presence or absence of peristomal skin disorders and risk factors for severity(Shiraishi et al., 2020), the peristomal assessment instrument seems to focus on adults. This is in line with Janice's and Colwell (2014) research which prioritized approaches to managing stoma and peristomal complications in adults(J. M. Beitz & Colwell, 2014). Almost all studies used inclusion criteria that were relatively the same in terms of age, length of time having had a stoma, not limited to the type of stoma, all were included, had peristomal skin complications/peristomal lesions.

Peritomal assessment instrument

There are 2 instruments that have been widely used for many years and are not limited to their country of origin, namely SACS and OST-DET. SACS was developed in 2007 as the first validated classification attempt not based on the assessment of lesions caused by etiopathogenetic factors, the resulting instrument facilitates the interpretation and detection of lesions (L), including topography (T)(Bosio et al., 2007) Instrument revisions have been experienced by SACS, which was originally developed to only classify 4 types of lesions (L1, L2, L3, L4+LX) to the latest version of SACS 2.0 with the addition of a classification of lesion types (L5) (Antonini et al., 2016)). In 2019 Menin et al developed a reliable peristomal skin assessment tool PLS to classify lesions according to their severity and compare their validity with the most widely used peristomal tool in Italy (SACS). Menin stated that PLS was better at differentiating lesions based on their severity because of the level of detail, using standard terminology, and completeness compared to SACS(Menin et al., 2019). However, no other studies have supported this statement.

The OST developed in 2008 focuses on changes in three domains: discoloration (D), erosion (E), and tissue overgrowth (T)(Jordan Rosalyn et al., 2013). There are limitations to the identified OST, namely there must be a change in color peristomal skin to be assessed. If there is no discoloration, the DET score will be zero, and the peristomal skin will be graded as normal skin without complications (Jemec et al., 2011). From a multinational survey on living with an ostomy, the prevalence and impact of peristomal skin complications it was reported that 75% of participants without peristomal discoloration still experienced at least one other Peristomal Skin Complication (PSC) symptom (such as pain, itching and burning, bleeding and sores)(Fellows et al., 2021). Therefore, persons with ostomy who present with PSC symptoms without any discoloration are at risk of being wrongly categorized as having healthy and unaffected skin when using the DET score as a measuring tool. A qualitative consensus on patients with ostomy, health professionals and a panel of experts was undertaken to make changes to the OST instrument by adding patient-reported PSC items so that the resulting OST with the name OST 2.0 includes a patient-reported outcome questionnaire on symptoms and an

objective assessment of color change. with a combined score that can define the severity of skin peristoma(Martins et al., 2022a).

Of the seven instruments, the closest to these parameters are the OST-DET and SACS because they meet several criteria. The use of peristomal skin assessment instruments in Indonesia has not been widely used. From several hospitals and independent practices that the authors contacted, some have not used it. Those who use it use more SACS for the reason that they are more socialized.

Validity test

Our main objective was to look at the validity of the peristomal skin assessment instrument. The experts assessed the face validity and content validity for most of the peristomal skin assessment instruments in our review and showed good validity results with a CVI value close to 1 (0.95 – 0.97) and a CVR 0.59, and the face validity test using a panel of experts showed a good correlation between instruments and between raters. Validity describes how accurately the measuring instrument should be measured (Ahmed & Ishtiaq, 2021). Face validity assesses subjectively the operational constructs and content validity ensures that the instrument includes all important items and eliminates items that are considered irrelevant(Taherdoost, 2016). Assessment of content validity qualitatively through the opinion of a committee of experts(A. C. de Souza et al., 2017) and quantitatively based on CVI and CVR ratios where the value is based on the number of expert panels(Ayre & Scally, 2014). The minimum value of CVR according to Lawshe's based on the number of expert panels for 5 expert panels is 0.99(Ayre & Scally, 2014). Content validity is highly recommended for newly developed instruments(Tah erdoost, 2016).

Based on the objectivity for the assessment of the content validity of the SACS instrument, it meets very good validity criteria with a CVI value close to 1, while the face validity of the OST instrument presents a good correlation between assessors and is compared with the golden standard, but the name of the golden standard is not mentioned. The reliability and reliability of OST has been described and tested by several studies(Harputlu et al., 2017; Jemec et al., 2011; Martins, Ayello, Claessens, Steen, et al., 2010). OST has been used for many years as an instrument validated standard for health professionals to evaluate and treat PSC(Martins et al., 2022b). Reliable results that meet the research objectives were obtained when the SACS instrument was translated into Portuguese in(Invernizzi Silveira & Boghossiam Lanza, 2019).

Reliability test

The second major objective of our review looked at reliability tests of peristomal scoring instruments. Generally using test retes and interaters which show high consistency results on repeated measurements and moderate to very good agreement seen from the kappa values presented. In the OST-DET and SACS instruments, apart from using the test-retest test, the interrater was also used, with good results. The objectivity for the test retest is consistency between the first and second measurements, while the interrater is measured based on the kappa value (κ) which ranges from 0.50 (low) to ≥0.90 (very good)(Taherdoost, 2016).

From instrument studies, OST and SACS provide excellent reliability results(Ay & Bulut, 2015; Jemec et al., 2011). The reliability for each assessment indicator of the instrument seen in the SACS ranges from high to very good (Ay & Bulut, 2015). Instrument reliability is important for research but is insufficient if it is not valid, in other words good reliability is supported by good validity(Taherdoost, 2016). However, other instruments, such as the use of photographs, are relatively new in Indonesia, although there has been no reliability test and only a face validity test, it seems to use objective indicators. For its use in Indonesia it has not been

carried out widely because of limited tools and in terms of price it is not yet affordable in general. Along with current technological advances, it is certainly a promising thing.

CONCLUSION

SACS and OST-DET are the most widely adopted instruments in assessing peristoma skin and its severity. the validity and reliability of SACS and OST-DET including revised versions of both have been carried out with acceptable results. To be recommended, the instrument must be easy to understand in terms of language and supported by acceptable validity and reliability

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