

Risk factors for peristomal skin complications in elimination stomas: a systematic review and meta-synthesis protocol*

Fatores de risco para lesões periestomais em estomas de eliminação: um protocolo de revisão sistemática e metassíntese

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ABSTRACT

Objective: To analyze risk factors for peristomal skin complications in elimination stomas. **Method:** A systematic review and meta-synthesis protocol will be conducted using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and the methodological guidelines and recommendations of the Joanna Briggs Institute (JBI). Two independent researchers will search the following databases: Web of Science, Scopus, Embase, PubMed via CAPES, and LILACS. Eligible studies will include observational, experimental, and quasi-experimental studies published in English, Spanish, and Portuguese, focusing on risk factors for peristomal skin complications in elimination stomas. A software will be used to aid in the study selection process. The risk of bias will be presented using weighted bar graphs and traffic light plots to display the results for each assessed domain in each included study. The meta-synthesis will be conducted using qualitative analysis software, employing textual similarity analysis.

Descriptors: Risk Factors; Wounds and Injuries; Ostomy; Enterostomal Therapy.

RESUMO

Objetivo: Analisar os fatores de risco para complicações de lesão periestomal em estomas de eliminação. **Método:** Uma revisão sistemática e um protocolo de meta-síntese serão conduzidos de acordo com o *checklist* Principais Itens para Relatar Revisões Sistemáticas e Metanálises (PRISMA) e as diretrizes e recomendações metodológicas do *Joanna Briggs Institute* (JBI). Dois pesquisadores independentes realizarão buscas nas seguintes bases de dados: Web of Science, Scopus, Embase, PubMed via CAPES e LILACS. Os estudos elegíveis incluirão estudos observacionais, estudos experimentais e estudos quase-experimentais publicados em inglês, espanhol e português, com foco em fatores de risco para complicações da pele periestomal em estomas de eliminação. Será utilizado o *software Rayyan Intelligent* para auxiliar no processo de seleção dos estudos. O risco de viés será apresentado usando gráficos de barras ponderadas e gráficos de semáforos para exibir os resultados para cada domínio avaliado em cada estudo incluído. A metassíntese será realizada em software de análise qualitativa, empregando análise de similaridade textual.

Descritores: Fatores de risco; Ferimentos e lesões; Estomia; Estomaterapia.

INTRODUCTION

Ostomy is a Greek term that refers to a surgically created opening in the hollow organs of the body. The creation of an ostomy allows communication between the body's internal and external environment and is important for maintaining the physiological functions of the body and the individual's quality of life⁽¹⁻³⁾.

In adults, ostomies are commonly performed for major causes such as colorectal cancer, gunshot or sharp weapon injuries, motor vehicle accidents, and inflammatory bowel diseases such as ulcerative colitis and Crohn's disease⁽⁴⁾. On the other hand, ostomies resulting from congenital malformations of the gastrointestinal tract are usually performed

in children, typically before the age of one year, with more than half performed within the first month of life⁽⁵⁾.

Regarding the name and type of ostomy, they differ depending on the part of the body involved. There is the tracheostomy, which involves the opening of the trachea; the gastric stoma, known as gastrostomy; urinary stomas, called urostomies, which can be classified as nephrostomy, ureterostomy, and cystostomy; and intestinal stomas, including jejunostomy, ileostomy, and colostomy^(1,3,6,7).

Elimination stomas are classified as either intestinal or urinary. Intestinal stomas are characterized by the protrusion of the colon (colostomy) or a segment of the ileum (ileostomy), which allows the elimination of stool and secretions into a collection device attached to the abdominal wall. They can be permanent, involving amputation of the affected segment, or temporary, used to protect the bowel⁽⁴⁾. On the other hand, urinary stomas or urostomies involve the creation of an opening in the urinary tract through the abdomen to eliminate urine⁽⁶⁾.

As a result, these stomas can lead to complications, with rates exceeding 70%. It is estimated that a person with an ostomy will experience some form of complication within two years of surgery. The most common complication is damage to the peristomal skin where the collection device adheres. When the integrity of the skin is compromised, the device may lose adhesion, leading to the development of wounds and injuries^(7,8).

Among the skin conditions affecting the peristomal area, the most common is dermatitis, which can be classified as allergic contact dermatitis caused by the device or the products used or chemical dermatitis resulting from leakage and irritation of the skin by the enzymes present in the effluent⁽²⁾. However, other types of conditions may also occur, such as pyoderma gangrenosum, erythema, ulceration, candidiasis, folliculitis, varicose veins, pseudoverrucous lesions, psoriasis, and granulomas⁽⁸⁻¹⁰⁾.

It should be noted that several factors contribute to the occurrence of peristomal skin complications, such as inadequate removal and repeated application of the collection device, moisture, improper or absent marking of the implantation site, exposure of the skin to corrosive effluents, infection, allergic reaction, misuse of inappropriate topical products, excessive hygiene, and improper handling and cutting of the collection device^(4,11). These factors disrupt the homeostatic balance of the skin and affect

the quality of life, well-being, and rehabilitation of ostomy patients⁽²⁾.

In addition, these complications can interfere with activities of daily living (ADLs), cause difficulties with self-care, discomfort, pain, reduced social interaction, mood changes, additional use of appliances and devices, specific stoma care, and increased healthcare costs^(10,12,13).

This study is justified by the opportunity to gain a deeper understanding of the risk factors associated with peristomal skin complications in ostomy patients, as these complications directly impact a patient's quality of life. Identifying complications and associated factors will allow the direction of care toward prevention, thereby reducing the occurrence of such cases. Therefore, this systematic review analyzes the risk factors for peristomal skin complications in ostomy patients.

It should be noted that no previous studies systematically summarize the risk factors for peristomal skin complications in elimination stomas and then perform textual similarity analysis between the studies.

METHOD

Type of study

Meta-synthesis refers to systematic approaches to reviewing qualitative research. Therefore, this is a protocol for a qualitative systematic review conducted per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines⁽¹⁴⁾ and the methodological guidelines and recommendations of the Joanna Briggs Institute (JBI)⁽¹⁵⁾. It has been submitted to the International Prospective Register of Systematic Reviews (PROSPERO) and assessed and approved under registration number CRD42023404487.

Research question

The PICO format will be followed to guide the research question and subsequent data extraction and descriptive synthesis (P, population; I, intervention; C, control; O, outcome). The structure is as follows: P, Individuals with elimination stomas; I, Peristomal skin complications; C, Not applicable to this review; O, Risk factors.

The guiding research question is: "What are the risk factors for peristomal skin complications in elimination stomas?"

Categorization of studies

Eligible study designs will include observational studies (cross-sectional, prospective, cohort,

and case series), experimental studies, and quasi-experimental studies (randomized, controlled trials and non-randomized, controlled ones). Studies published in English, Spanish, and Portuguese will be considered, focusing on risk factors for peristomal skin complications in elimination stomas. Studies involving animals or in vitro research and reviews, reflections, letters to the editor, and editorials will be excluded. There will be no specific time frame, and data collection is expected to begin in April 2023.

Article search strategy

Article searches are conducted by two independent researchers in the following databa-

ses: Web of Science, Scopus, Excerpta Medica Database (Embase), National Library of Medicine (PubMed) via CAPES (*Coordenação de Aperfeiçoamento de Pessoal de Nível Superior*), and Latin American and Caribbean Health Sciences Literature (LILACS).

The Medical Subject Headings (MeSH), Health Sciences Descriptors (DeCS), and Embase Subject Headings (Emtree) terms are structured using the Boolean operators AND and OR to enhance the search strategy through various combinations that will subsequently guide the searches (Figure 1).

Database	Search string
MEDLINE/PubMed	<i>(((((((Ostomy) OR (Colostomy)) AND (Wounds and Injuries)) AND (Risk Factors))</i>
SCOPUS	<i>(TITLE-ABS-KEY (ostomy) OR TITLE-ABS-KEY (colostomy) OR TITLE-ABS-KEY (ileostomy) OR TITLE-ABS-KEY (jejunostomy) OR TITLE-ABS-KEY (Urinary Diversions) OR TITLE-ABS-KEY (Ileal Conduit) AND TITLE-ABS-KEY (wounds AND injuries) AND TITLE-ABS-KEY (risk AND factors) OR TITLE-ABS-KEY (risk AND index) OR TITLE-ABS-KEY (risk))</i>
Embase	<i>(ostomy:ab,ti OR colostomy:ab,ti) AND wounds:ab,ti AND injuries:ab,ti AND 'risk factors':ab,ti</i>
Web of Science	<i>Ostomy (Title) OR Colostomy (Title) AND Wounds and Injuries (Title) AND Risk Factors (Title)</i>
LILACS	<i>(Ostomy) OR (Colostomy) OR (Ileostomy) OR (Jejunostomy) OR (Urinary Diversions) OR (Ileal Conduit) AND (Wounds and Injuries) AND (Risk Factors) OR (Risk Index) OR (Risk)</i>

Figure 1 - Search string for article searches. Crato, CE, Brazil, 2023

The studies will be directly searched in the databases using the adapted strategies for each database. They will be extracted and saved in RIS format for selection and then exported to the Rayyan Intelligent software⁽¹⁶⁾, which will serve as a tool for title and abstract screening. This approach helps minimize the risk of potential information loss and increases the reliability of the systematic review development. The researchers, independently and in a double-anonymized manner, will systematically analyze the eligibility of all titles and abstracts assigned to them in the software for extraction without knowledge of the authors' names and journal details of the evaluated articles. In this stage, the excluded studies will be

separated and justified for future discussion among the researchers, aligning the reasons for exclusion. Regarding disagreements in the evaluation process of titles and abstracts, they will be resolved through consensus in subsequent meetings. However, if there is no agreement between the two researchers, a third researcher will be involved in the selection process to assess the disagreements and make the final decision. The two reviewers will download and assess the eligible preliminary research studies in full-text format, independently and in a double-anonymized manner, aiming to fulfill the eligibility criteria. Any disagreements between the two reviewers that cannot be resolved will be

decided by the third reviewer, who will make the final decision. The excluded studies will be justified and included in a separate database,

indicating the reasons for exclusion. Figure 2 shows the article search and selection flow-chart described in this protocol.

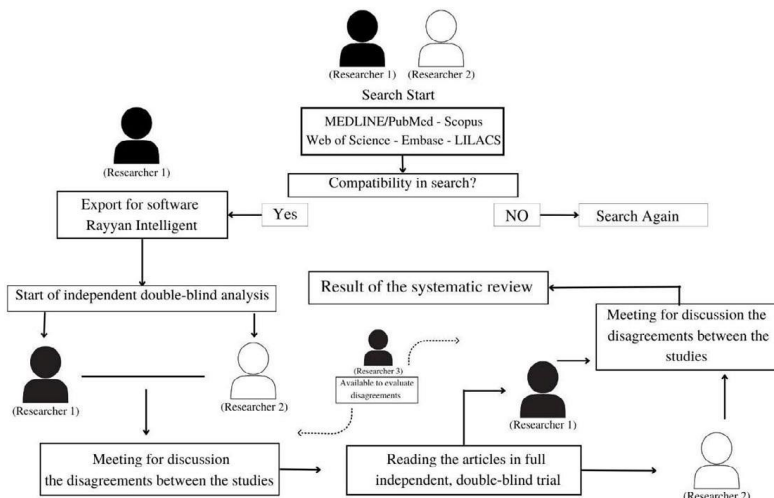


Figure 2 - Illustrative flowchart of the search and selection process. Crato, CE, Brazil, 2023

Assessment of risk of bias

The included studies' methodological quality and risk of bias will be assessed using the Joanna Briggs Institute standardized critical appraisal tool⁽¹⁵⁾ for experimental, quasi-experimental, and observational studies. The assessment will be performed by two researchers and then reviewed by a third researcher. Studies will be classified as "low risk of bias", "high risk of bias", or "unclear risk of bias".

The bias analysis will be performed using the RoB 2.0 tool⁽¹⁷⁾ and presented using figures such as weighted bar graphs indicating bias ratings for each domain. In addition, traffic light plots will display the results for each domain assessed in each included study.

Data extraction

Data will be collected by two independent researchers and thoroughly reviewed by a third researcher. Information about the study population, study method, intervention, and significant findings related to the research question will be extracted and synthesized. The data will then be structured and presented in tables for clarity.

Qualitative analysis of studies/metanalysis

The risk factors for peristomal skin complications in elimination stomas will be compiled into

a textual corpus for further lexicographic analysis using IRaMuTeQ software⁽¹⁸⁾. This software is a free, open-source tool that allows for qualitative statistical analysis of textual data. The resulting data from the analysis will be interpreted and discussed by the researchers of this study. In terms of data processing, Hierarchical Descendant Classification (HDC) and similarity analysis will be used. To perform the lexical analysis of the textual corpus, the software will divide the text into segments of approximately 40 characters each for analysis purposes.

Ethical considerations

As this is a literature review, submitting this protocol to the research ethics committee was unnecessary. It was only registered in the PROSPERO database.

CONFLICT OF INTERESTS

The authors have declared that there is no conflict of interests.

*Paper extracted from the master's dissertation "Construction and validation of a scale to predict peristomal lesions in elimination stomas", presented to the Universidade Federal de São Paulo, SP, Brasil.

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