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STOMA SITE MARKING: SYSTEMATIC REVIEW WITH META-ANALYSIS

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ABSTRACT

The marking of the stoma is the determination of the ideal place to besiege the stoma, aiming at self-care, resumption of normal activities and quality of life. **Objective:** To systematically analyze the relationship between marking of the ostomy site and post-surgical complications related to the stoma. **Methods:** A search was performed in the databases (Medline, Embase, Scopus, Web of Science, SciELO, Lilacs, Cochrane via pubmed, Proquest and Cinahl). Cohort, case-control, and cross-sectional studies were eligible. Article selection and data extraction were performed by three independent reviewers. Random effects meta-analyses for crude and adjusted measures of association. **Results:** 13,703 articles were found, of which 1,709 were excluded. 11,994 titles and abstracts were read and, after analysis, only 13 studies met the eligibility criteria and three were included in the meta-analysis. There was no statistically significant difference between the practice of previous and post-smarkingsurgical complications related to the stoma. **Conclusions:** Studies have shown the existence of postoperative complications even in patients who have been marking as the location of the stoma. However, they emphasized the importance of preoperative information, marking and adaptation to the devices, in addition to patient education for care and self-care, ratifying the WOCN guideline.

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INTRODUCTION

Stoma marking is the determination of boundaries through marks that adopt specific criteria in the anatomical planes. The critical points must be respected when marking the stoma on the abdominal wall, obeying a minimum distance of 5 cm from the waistline, iliac crest, costal margin, umbilical region and surgical scar (Meirelles, 2001, Santos, 1993, Watt, 1982 and Scarpa et al, 2010). The marking of the stoma site helps the patient to self-care and return to activities of daily living. Hence the need to previously marking the stoma site to reduce the possibility of the patient experiencing future problems related to the stoma, negatively compromising their quality of life (Gok et al, 2019). The absence of demarcation or even inadequate marking has been studied as a risk factor in the lives of patients with ostomies (Cakir & Ozbayir, 2018, Ambe, et al, 2018, and Arolfo et al, 2018). Another determinant is the education about care, provided by the ostomy wound and continence nurse even in the preoperative

period and during the postoperative follow-up. Thus, preoperative marking is essential to facilitate care, increase the acceptance of the ostomy and reduce complications related to the stoma (Gok et al, 2019), Ambe et al, 2018, and Arolfo et al, 2018). Some researchers [Sabbagh et al, 2018] confirm that, in the absence of identification of previous stoma marks, we expose the patient to a risk of a "avoidable" complication. Among the possible barriers that make it difficult for health professionals to carry out the marking are the lack of institutional protocols about the procedure for potential patients to make a stoma; the lack of involvement, interest and communication between nurses and doctors who work with the clientele; the realization of projects to better serve them in the perioperative scope, covering all work shifts, in addition to the lack of permanent health education with the interprofessional team. In emergency surgeries, in which it is impossible for the patient to adopt the three positions for demarcation, the identification of the anatomical points must be carried out, at a minimum, in the lying position. And, finally, a barrier related to the patient's physical constitution, such as obesity, orthopedic devices and wheelchair

users who need some expertise given their body specificities. In 2018, the Wound, Ostomy and Continence Nurses Society (WOCN Society) published a guideline, which was intended to provide information to help health professionals. It included evidence on the following topics: stoma site marking, stoma construction, preoperative education, selection the feces collection bag system, postoperative education, postoperative management issues, follow-up and care after hospital discharge, health-related quality of life and stomach and peristomal complications (WOCN, 2018). The study on the care and management of intestinal ostomy revealed that demarcation serves as a protective factor and, as it is a simple practice, it can drastically reduce complication rates, being recommended for all patients with a consistent probability of creating an ostomy (Ambe, *et al.*, 2018). Mahjoubi *et al.* (2005) found that patients with colostomy had a relatively high 69.4% (n=330) rate of stoma complications. In this sense, Ozaydin *et al.* (2013) reported that 48% of patients had complications, with skin irritation (63%) being the most frequent. In the literature, in a comprehensive way, the rates of complications related to the stoma range from 10% to 70%. Considering the context of studies on the subject, it is believed that the prior marking of the ostomy site is an essential factor to avoid post-surgical complications. Thus, this study aims to systematically analyze the relationship between the marking of the ostomy site and post-surgical complications related to the stoma.

METHODS

The search for systematic reviews on the subject was performed in the database of the International Prospectus of Systematic Reviews (PROSPERO) and no records were found. The systematic review was registered in PROSPERO under protocol number CRD42019124063.

The PICO strategy was used based on the guiding question “What are the unfavorable outcomes related to the marking of the stoma site?”

P	corresponds to adult and elderly patients with ostomy
I	is equivalent to previous demarcation of the ostomy site in relation to surgery
C	absence of previous demarcation of the ostomy site in relation to surgery
O	adverse effects related to demarcation or absence of prior appointment

This review did not have randomized clinical trials. Observational cohort, case-control, and cross-sectional studies were included. Eligibility criteria were studies that evaluated any adult and elderly patient with ostomy who had the location of the stoma demarcated or not, with or without complications. There were no restrictions on publication date, type of study or language. The search for information was carried out from October 10, 2018 to January 5, 2019. The electronic databases used were Medline, Embase, Scopus, Web of Science, SciELO, Lilacs, Cochrane (via pubmed), Proquest and Cinahal. Previously, the Peer Review of Electronic Search Strategies (PRESS) was applied to validate the search strategies. The descriptors used and their synonyms were identified in Medical SubjectHeadings (MeSH) and Embase SubjectHeadings (Emtree). The keywords and Boolean operators in English used in the search strategies were (adults OR elderly) AND (Colostomy OR Ileostomy OR Ostomy OR Enterostomy OR Surgical Stomas OR Peritoneal Stomatous OR Cistostomy OR Nephrotomy OR Ureterostomy OR Post-Stomach Complications OR Stomach Effects OR Local complications OR -surgical. First, through the State of the Artthrough Systematic Review (Start) program, version 3.4, duplicate studies were identified. Three independent reviewers selected eligible titles and abstracts. During the article selection process, researchers were not aware of the decisions made by others. After this phase, three researchers independently read the full text of the previously selected articles. Studies that met the eligibility criteria were included in the systematic review. At any previous stage, in cases where there was disagreement among researchers, the inclusion or exclusion of articles was decided by consensus.

Data were extracted from the articles included by three independent researchers and later compared. Data were entered into the Start software version 3.4 database, containing the following fields: author's name, year of publication, place and year of study, objective, study design, sample size, place of data collection, source of data, demarcation as exposure, stoma demarcation technique, complications as outcome, measure of association and confidence interval, and methodological quality. When data were not available in the articles, study authors were contacted. The quality of selected studies was assessed using the Newcastle-Ottawa instrument (Wells *et al.*, 2014), recommended by the Cochrane Collaboration for observational cohort, case-control, and cross-sectional studies. It consists of eight questions comprising three axes: study selection, comparability and verification of exposure and investigated outcome. This instrument has a rating system in which an article receives stars for each criteria found. The quality rating categories for studies are: (1) low quality - when the article receives up to 3 stars, (2) moderate quality - from 4 to 6 stars - and (3) high quality - from 7 to 9 stars. At first, the description of the studies included in the research was performed. After compiling the results, the meta-analytic summary measure was estimated using the crude and adjusted OddsRatio and the respective 95% confidence intervals. For dichotomous data, random effects meta-analysis was adopted using the technique of Der Simonian & Laird. Statistical heterogeneity was assessed using I², with the following classification: not very important (I²: 0% to 40%); moderate (I²: 30% to 60%); important (I²: 50% to 90%); and very important (I²: 75% to 100%). Data analysis and calculation of the summary measure of the meta-analysis were performed using the statistical package STATA®, version 15, serial number: 301506206729. The period of publication of the investigations evaluated was from 2001 to 2018.

RESULTS

From the database searches, 13,703 records were identified. Of this total, 1,709 were removed, 1,566 of which were duplicates and, in 143, there were no title, authorship and year of publication. Then, 11,994 titles and abstracts were read, and after analysis, 35 articles were selected for full reading, which resulted in the exclusion of 22 articles - 19 for not reporting results of interest and three for being review articles. Thus, only 13 studies met the eligibility criteria of this systematic review (Figure 1).

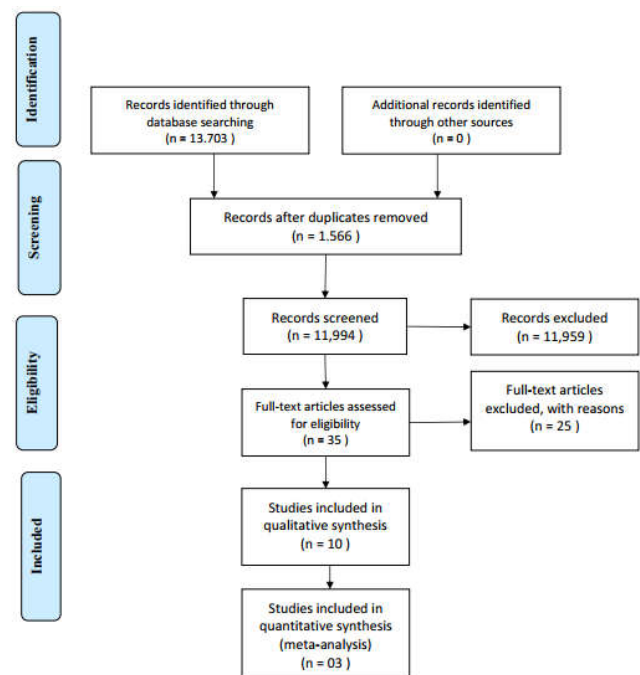


Figure 1. Flowchart on search, selection and inclusion of studies according to *Prism*

Thirteen studies were selected, being six retrospective cohort, four prospective, two cross-sectional and one case-control. All manuscripts were published in journals in the specialties of coloproctology, gastrointestinal and stomatherapy, having as authors physicians and nurses working in the respective areas. Most of the researches were carried out between 1994 and 2013, in Asian countries with a high Human Development Index (HDI), developed in a surgical clinic and outpatient hospital sector for post-surgical follow-up. The population of the studies included in this review consisted of 8,758 patients with a mean age of 64 years, with a slight predominance of males (56%). The studies demonstrated that the follow-up of patients in periodic assessments had different intervals and aimed to investigate the adaptations/confrontations with the ostomy and collecting equipment. In addition, the follow-up aimed to provide post-surgical guidance on care, hygiene, cleaning, food, clothing, among others, and intervene to minimize the worsening of the clinical condition in case of complications.

and Parmar *et al*, 2011). The demarcation or site of the ostomy site was performed by a nurse/physician in the preoperative period after clarification, guidance as to the best location for making the stoma, adopting some criteria, such as critical reference point, distance, folds and accidents. Most studies emphasized the importance of demarcation. However, some authors have reported that, even with demarcation, some problems may appear, due, for example, to stoma protrusion, the surgeon's experience and preexisting diseases such as diverticulitis. Among the risk factors, emergency surgery, high or low body mass index (BMI), age, obesity and non-demarcation were highlighted (Arolo *et al*, 2018, Baykara *et al*, 2014, Pitmam *et al*, 2008, Formijne *et al*, 2012 and Parmar *et al*, 2011 and Sarkut *et al*, 2015). Post-surgical complications as an outcome were identified in 76.9% of the studies. Thus, the incidence of stomach and parastomal complications ranged from 26% to 82%, with an emphasis on the poor location of the stoma in 38.4% of cases [1,8,17,18,24]. In four prospective studies [14,17,18,21], complications related to the ostomy

Quadro 1. Characterization of studies regarding country, study type, sample, ostomy type, nature of ostomy, research periods, site marking and outcome Brasilia-DF, March 2019

1st Author and year	Country	Study type	Sample	Type		Nature		Period	Site Marking	Complications
				Colostomy	Ileostomy	Elective	Emergency			
Andersen, 2017 [14]	Denmark	Prospective	5019	2752	2267	2927	2090	2007 2013	Yes	Yes
Baykara, 2014 [15]	Turkey	Retrospective	748	354	363 +30	55	89	2012 2012	Yes	Yes
Chaudhary 2015 [17]	India	Prospective	630	-	630	-	630	2008 2013	Yes	Yes
Formijne, 2012 [18]	Netherlands	Prospective	100	81	19	59	41	2007 2008	Yes	Yes
McKenna, 2016 [19]	United States	Case-control	59	29	30	527	221	2008 2010	Yes	No
Meirelles, 2001 [1]	Brazil	Retrospective	50	38	12	50	-	1994 1998	Yes	Yes
Oliphant, 2015 [20]	United Kingdom	Retrospective	222	96	126	189	33	1999 2011	No	No
Parmar, 2011 [21]	United Kingdom	Prospective	192	101	91	150	42	2007 2007	Yes	Yes
Pittman, 2008 [16]	United States	Cross-sectional	239	158	81	239	-	NI	Yes	Yes
Pittman, 2011 [22]	United States	Cross-sectional	144	72	53 +19	54	90	2007 2009	Yes	No
Sarkut, 2015 [23]	Turkey	Retrospective	141	-	141	72	69	2003 2006	Yes	Yes
Scarpa, 2010 [4]	Italy	Retrospective	44	-	44	30	14	1996 2007	Yes	Yes
Sung, 2010 [24]	South Korea	Retrospective	1170	1051	119	837	333	1994 2005	Yes	Yes

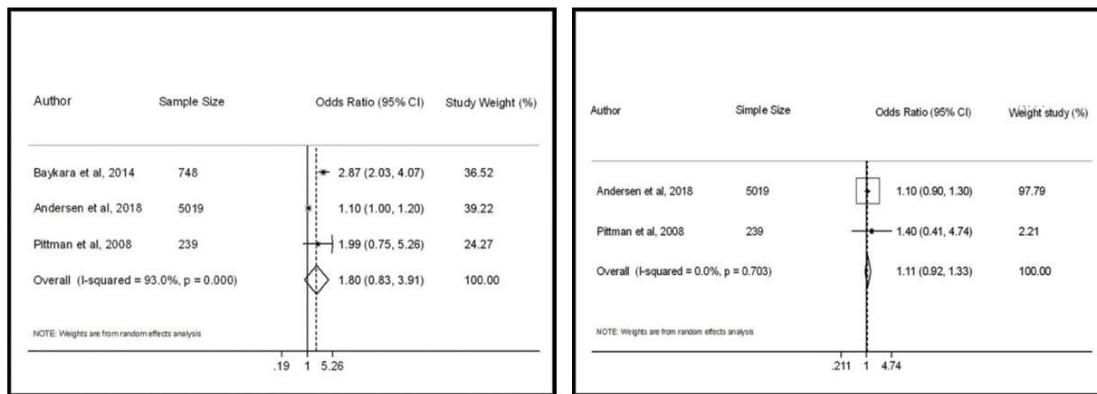


Figure 2. Meta-analysis with crude effect measures for the evaluated studies and 95% confidence intervals

The methodological quality of the studies was considered moderate (61.5%) and three selected articles were considered insufficient (Oliphant *et al*, 2015, Sarkut *et al*, 2015 and McKenna *et al*, 2016). In most studies, the cause that led to intestinal ostomy was colorectal cancer (77%), followed by benign diseases of the gastrointestinal tract (23%), such as complicated diverticulitis, intestinal obstruction, inflammatory disease, ulcerative colitis, polymorphism Familial adenomatous (FAP), Crohn's disease, and intestinal peritonitis due to perforation due to typhoid fever (Chaudhary *et al*, 2015). In the selected studies, a total of 8,758 surgeries that generated ostomies were performed, with loop or terminal colostomy having the highest prevalence (55%) on an elective basis (59%), but emergency surgery was performed in 3,652 patients, which, therefore, were not demarcated (41.3%). The creation of loop and terminal colostomy was the most common surgical procedure performed in patients with colorectal cancer (55%). It is noteworthy that the choice of making ileum or colostomy as a surgical technique varied according to the academic current advocated by each surgeon (Andersen *et al*, 2018, Baykara *et al*, 2014, Pitmam *et al*, 2008, Formijne *et al*, 2012

had high rates 82%, 27.1%, 58% and 52.8% respectively (Table 1). In the present review, only two studies (McKenna *et al*, 2016 and Pitmam, 2011) did not mention complications related to the ostomy, as the methodological focus was quality of life related to demarcation. And another (Oliphant *et al*, 2015) correlated complications with the adjuvant chemotherapy treatment experienced by patients with ileostomy. The methodological quality of the studies was considered moderate (61.5%) and three selected articles were considered insufficient, according to the Grading the Quality of Evidence and the Strength of Recommendations (GRADE) system, which includes assessment of the quality of evidence, with subsequent definition of direction and strength of the recommendations (Brasil, 2014). For the meta-analysis of demarcation effects related to post-surgical complications, only three studies were included (Andersen *et al*, 2018, Baykara *et al*, 2014, Pitmam *et al*, 2008). It was possible to observe that there was no statistically significant difference between the practice of previous demarcation and post-surgical complications in patients who underwent ostomy, both for crude and adjusted measurements.

Heterogeneity was considered high for the crude measure meta-analysis, however, it was low for the adjusted Odds Ratio (Figure 2). This finding points to the need for more work to be carried out on this theme to give consistency to the reviews.

DISCUSSION

This systematic review summarized data from thirteen observational studies related to prior marking of the stoma site and the incidence of complications. The methodological quality of the longitudinal studies used in this systematic review, which included prospective/retrospective cohort designs, was considered moderate, and the studies were conducted in different countries on all continents. The studies in this review reveal a slight prevalence of male participants, with an average age of 64 years, who underwent surgery for colorectal cancer. However, in a study that evaluated patients with peritonitis due to bowel perforation due to typhoid fever, the mean age was 34 years (Chaudhary *et al*, 2015). Colorectal disease is among the five most diagnosed cancers worldwide, ranking 3rd in the incidence of new cases and reaching the mark of 1.8 million people of both sexes. In terms of mortality, it ranks 2nd among all cancer deaths (881,000) (WHO, 2018). The results regarding complications corroborate other studies (Gok *et al*, 2019, Cakir, 2018, Ambe *et al*, 2018, Arolfo *et al*, 2018, Sabbagh *et al*, 2018, Malik *et al*, 2018, Stoffels *et al*, 2018, Koc *et al*, 2017, and Hsu *et al*, 2020). The main findings of this systematic review show that most perform the demarcation of the ostomy site, however there were postoperative complications. WOCN strongly supports that the site be demarcated in the preoperative phase to select the ideal point of the stoma, in order to promote the patient's independence for self-care in the resumption of normal activities of daily living, in addition to predicting the time of use of the bag systems and minimize possible postoperative complications (Meirelles, 2001, Santos, 1993, WOCN 2018, Bass *et al*, 1997, Hocevar & Gray, 2008, Person *et al*, 2012). In most of the analyzed studies, a total of 5,189 patients undergoing elective surgery were demarcated and received counseling regarding pre- and post-surgical procedures. The importance of the procedure in the patients' lives was recognized. Similar results are reported in other studies (Ambe *et al*, 2018, Arolfo *et al*, 2018).

The demarcation of the ostomy site was seen as a positive predictive factor in the quality of life of people with an ostomy (Scarpa *et al*, 2010 and McKenna *et al*, 2016), as well as a protective factor (Ambe *et al*, 2018). Unmarked stoma in emergency surgeries was considered a contributing risk factor to increase the rate of complications. The authors recognized the importance of marking and justified that, in urgent situations, it is difficult to have a ostomy wound and continence nurse in the service, but they advocate that it is still necessary to consider the presence of the professional to locate the stoma in the abdominal wall before surgery (Scarpa *et al*, 2010, Chaudhary *et al*, 2015, Baykara *et al*, 2014, Pitmam *et al*, 2008, Formijne *et al*, 2012, Pitmam, 2011 and Sung *et al*, 2010). Braumann *et al* (2019) conducted a multicenter cross-sectional study (Berlin Ostomy Study) using a nine-field grid to specify the exact location of the ostomy. Over 24 months, 2,344 patients responded to the questionnaire, of which 1,344 had some complication related to the ostomy. Although studies have shown that demarcation of the preoperative ostomy site by a trained stomal nurse or surgeon helps to improve quality of life and reduce the rates of ostomy-related complications (Gok *et al*, 2019 and Andersen *et al*, 2018), it is estimated that about 20% of patients operated on in an emergency situation do not undergo any preoperative marking (WOCN, 2018).

Although the study by Braumann *et al* (2019) is robust, it points out that "there were no significant differences between the different abdominal locations of the stoma in cases of complications" related to the stoma. At the same time, it states "the lack of differences between locations and complications are important for preoperative demarcation" due to positioning the ostomy respecting the abdominal configuration. Furthermore, the statement that marking ostomy sites preoperatively is advantageous in relation to complication rates can

be confirmed in the literature. Patients demarcated preoperatively had a lower risk of developing stoma problems, that is, a lower rate of post-surgical complications (Scarpa *et al*, 2010, Formijne *et al*, 2012 and Parmar *et al*, 2011). As the marking performed by the stomy wound and continence nurse, delimited within the rectus abdominis muscle (Sarkut *et al*, 2015 and sung *et al*, 2010), determining folds, spaces and, in all orthostatic directions (Meirelles, 2001, Baykara *et al*, 2014, Formijne *et al*, 2012, McKenna *et al*, 2016 and Sarkut *et al*, 2015), it is considered the first stage of adaptation to the stoma. Patients with ostomy have their life perspective changed, mainly related to negative body image, not only due to the use of the collection bag, but also, in many cases, due to the consequences of incorrect demarcation or non-demarcation of the stoma (Freitas *et al*, 2018). Marking was accepted as a proven benefit (WOCN, 2018 and Baykara *et al*, 2014). The study by Kocet *et al* (2017) confirms that the location of the stoma is an isolated risk factor for the development of complications. This corroborates the retrospective studies analyzed (Bass *et al*, 1997, Hocevar & Gray, 2008, Person *et al*, 2012). It was seen that individuals with stoma problems were more likely to be discharged late, with a tendency to be unable to participate in the care of their stoma in the first three postoperative weeks, in addition to requiring additional visits to care for the stoma (Parmar *et al*, 2011). Another factor that was strongly mentioned in the studies was that patients were not marking in emergency surgery situations. Such findings corroborate results of other researches (Gavriilidis *et al*, 2019 and Hendren *et al*, 2015).

In a meta-analysis (Hsu *et al*, 2020), patients undergoing stoma site marking was associated with a reduction in stomach and peristomal complications (Odds Ratio [OR] = 0.52; 95% CI, P < 0.001). These people also had fewer hernias and peristomal cutaneous complications (OR=0.25 and 0.30; 95% CI, 0.09-0.71 and 0.20-0.44, respectively; both P<0.001). The results revealed that the marking of the stoma site was associated with early and late reduction of complications (OR = 0.76 and 0.38; 95% CI, 0.61-0.94 and 0.32-0.46; P = 0.010 and P < 0.001, respectively). Another important issue is the high heterogeneity found among the studies, which is justified by the lack of research on the subject. Furthermore, there are few studies with the objective of evaluating the hypothesis of this review, that is, evaluating the unfavorable outcomes related to the marking of the ostomy site. Thus, the quality of evidence was considered very low, according to the GRADE System parameters. The meta-analysis of our study was carried out, at first, with three articles (Andersen *et al*, 2018, Baykara *et al*, 2014 and Pitmam *et al*, 2008), through crude measures, however, it was not possible to include the study by Baykara (2014) in the adjusted association measure, therefore, only two (Andersen *et al*, 2018 and Pitmam *et al*, 2008) were part of this measure. As for the results, no significant differences were found in relation to the marking associated with the outcome. This finding demonstrates the need for more studies related to the theme, preferably with longitudinal designs for monitoring patients and large samples, aiming to give greater consistency to the results. The strengths of this review include the high number of databases employed, the use of research techniques and validated instruments, and the meta-analysis of observational studies in epidemiology to assess the studies and write the systematic review (Stroup *et al*, 2000). Despite the extensive search in several databases, as limitations of this review, the small number of studies used in the meta-analysis stands out, as well as the type of study. No randomized clinical trials were found for this review. Thus, it was necessary to use prospective, retrospective and cross-sectional studies, greatly increasing the heterogeneity in the review.

CONCLUSION

Marking is a simple technique considered the gold standard for the prevention of surgical complications in emergency and elective situations, to be implemented in health services. This systematic review summarized available evidence regarding the marking of the ostomy site and its relationship to complications. In most of the analyzed studies, there was only demarcation of the site in elective

surgeries. It was also found that non-marking patients undergoing emergency surgery had a significant percentage of complications. Three studies included in the meta-analysis did not have significant results between the practice of prior marking and post-surgical complications in patients who underwent an ostomy, as they are observational studies with high heterogeneity. In this sense, the development of multicenter and prospective studies on the subject is suggested. Studies have shown the existence of postoperative complications even in patients whose stoma site was marking. However, they emphasized the importance of preoperative information, prior demarcation and adaptation to the devices, in addition to patient education for care and self-care management, ratifying the WOCN guideline. In this context, it is necessary to consider the presence of a stomy wound and continence nurse to demarcate the stoma on the abdominal wall before surgery. It is believed that the previous marking of the ostomy site is an essential factor to avoid postoperative complications.

Supplementary Materials

- 1: Search strategy (Appendix 1).
2. PRESS registration (Appendix 2).

Author contributions

SNCM, AIAL, KRO, ABDV and ALS: study concept, manuscript writing, critical review and final manuscript approval. All authors are responsible for all aspects of this work and for ensuring that issues relating to the accuracy or integrity of the work are properly investigated and resolved.

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