Original article

The incidence of stomal and peristomal complications: preliminary results three months after stoma creation

ABSTRACT

Background The creation of an intestinal and/or urinary ostomy is often associated with a wide variety of complications, whose incidence and risk factors reported in the literature are often discordant.

Aims A prospective longitudinal repeated-measures observational study was conducted aimed at investigating the incidence of complex stomal complications and ascertaining the determinants of their occurrence. The ultimate goal is to improve the available data for the development of new knowledge in this area.

Methods A total of 181 adult subjects were recruited and followed for a period of three months at set intervals (T0 to T5), surveying the occurrence of any complications. Fisher's Test and Chi-square Test were used to study the relationship between the various variables and the occurrence of complications.

Results Complications occur most frequently in the immediate postoperative period (iT0= 54.14%). The incidence rate of stomal and peristomal complications demonstrated a different distribution in the various follow-ups. Complications show a different character depending on the type of ostomy, with a higher incidence in intestinal ostomies; they also appear to be statistically correlated with the presence of general preoperative comorbidities.

Conclusions The purpose of this study was to implement the available data regarding complex stomal complications for the future development of new knowledge through two objectives: 1) to determine the incidence of complex stomal complications in new ostomate patients residing in the Empolese-Val d'Elsa and Lower Valdarno area of Italy, 2) to verify what the factors determining the occurrence of these complications are.

Keywords ostomy, stoma complications, peristomal complications, incidence, risk factors

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INTRODUCTION

Ostomy surgery can cause several complications, including surgical, stoma, and peristomal skin problems, as well as inherent difficulties with stoma care. In addition, the new stoma may have an adverse effect on the person's mental and physical state affecting their ability to adjust to the presence of the stoma. These complications have a negative impact on ostomy management and are considered a health problem for ostomy patients.[1]

Researchers have studied the different types of complications associated with ostomies and peristomal skin, as well as associated incidence rates and risk factors. The most commonly reported complications are divided into early complications (ischemia and necrosis, stomal retraction, mucocutaneous detachment, inadequate positioning, parastomal ulceration, early skin excoriation) and late complications (parastomal hernia, prolapse, stenosis, peristomal dermatitis, varices, peristomal Pyoderma Gangrenosum).[2-3] However, the literature shows varying levels of occurrence, with the incidence of these conditions ranging from 20% to 70%.[4-8] A systematic review conducted by Malik et al (2018) identified the incidence of various types of stomal complications, defining peristomal skin complications and parastomal hernia as "the most common adverse events across all types of ostomies".[9] During the literature review for this study, the authors reviewed a wide variety of studies regarding the incidence rate of ostomy

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complications.[8-12] For example, regarding parastomal hernias, Krishnamurty (2017) in his study of a total of 345 patients reports an incidence rate ranging from 0 to 48% depending on the type of ostomy (between terminal and loop ostomies)[8]; Malik (2018) in his study of a total of 864 patients reports a rate ranging from 0 to 88.2%, but excluding terminal ostomies.[9] Nybaek (2010) reported a parastomal hernia incidence rate of 12 % in a total of 67 patients.[10] This inconsistency in results may be due to differences in study design. Similarly, Salvadalena in 2010 highlighted the limitations of the studies reviewed at that time. Those limitations included: inconsistent definitions and measurements of complications, making it difficult to reliably and validly determine their incidence.[11] In addition, there are differences in the study designs and the timing of the assessment of the subjects postoperatively. Many studies are retrospective in nature. This leads to limitations such as inconsistencies in data collection and possible differences between the actual condition of participants and what is reported in clinical reports.[13–17] These factors make the incidence rate of ostomy-related surgical and peristomal skin complications reported in retrospective studies less reliable and less usable as strong evidence. Generally, these limitations require more attention and standardisation in stomal and peristomal skin complication research.[9]

What seems to be less clear today are the risk factors that influence and/or may influence the occurrence of these complications. This is the subject of several studies. One such study, by Pittman et al (2008), listed demographic and clinical factors that could contribute to ostomy complications, which would then affect quality of life (QoL).[18] Their study was used to support an investigation of factors contributing to reduced QoL and focused primarily on factors associated with QoL.[19] In 2010, Nybaek et al. investigated the relationship between the occurrence of complications like irritant contact dermatitis, peristomal medical adhesive-related skin injury (PMARSI), folliculitis, psoriasis and other uncommon diseases and specific risk factors. Their conclusion was that repetitive tape stripping and sodium lauryl sulfate testing may have a role as predictive tests to identify patients at risk of peristomal skin problems but "a model describing the relationship between the occurrence of stomal and peristomal complications and possible risk factors would be necessary for future studies".[10] Based on this, Salvadalena (2010) developed a model to represent the possible relationship between variables previously reported in the literature to correlate with the development of stomal/peristomal morbidity. This model involved the identification of four groups of variables: patient variables (such as age, gender, body mass index or BMI, health condition); surgical variables (such as stoma type and construction, suture type); preoperative care variables (such as stoma site marking, patient education); stoma-care variables (such as development of stoma complications and/or peristomal complications that could impact QoL). This has been developed to represent the underlying understanding of the physiological and anatomical complications of the stoma and peristomal skin and therefore provides a framework for future studies aimed at investigating the incidence of stoma and peristomal complications and the relationships that may exist between these complications and other variables.[11]

Based on these parameters, the aims of this study were to determine the incidence of stoma and peristomal complications in patients with a newly constructed stoma during three months of follow-up of those patients living in the Empolese-Val d'Elsa and Valdarno Inferiore areas of Italy, and to define risk factors for their occurrence.

METHODS

Overall study design: An observational, prospective, longitudinal, repeated measures study was conducted.

Sample and Setting: The study was carried out at the Stoma Rehabilitation Centre (CE.RI.STOM) in Empoli (Local Health Authority Toscana Centro, Florence, Italy). The study commenced on 19 May 2021 and ended on 31 Decmber 2021, and lasted seven months. The study included observation and recording of stomal and peristomal complications, as well as review of the personal and medical history of each subject. Inclusion criteria for participation were: patients who underwent ostomy creation for the first time between May and September 2021; in an emergency or elective setting; with an intestinal or urinary ostomy; with or without peristomal skin lesions according to SACS scale 2.0[20] and/or stomal complications (Table 1). Patients were excluded from the study if they were under 18 years of age and/or unable to give valid informed written consent. Withdrawal criteria included: patients who changed treatment or follow-up center for strictly personal reasons; patients who received surgery to restore normal intestinal continuity before the end of the three month period; and patients who died during the same period.

Instrument: To conduct the study, the research team created double-entry tables in Excel files with acceptable inter-rater reliability. These tables were separated by observation time: T0 at the time of enrollment; T1 at one week; T2 at two weeks; T3 at one month; T4 at two months; and T5 at three months. At the time of enrollment, the student, after obtaining appropriate consent, subjected each participant to a face-to-face interview to learn about the patient's medical history. Questions included: How old are you? How tall are you and how much do you weigh? Does you have any pathology unrelated to the ostomy? If so, is it medical (such as heart disease, respiratory disease, diabetes) or neoplastic in nature? When was the stoma created? Is the stoma permanent or temporary? Did you have any immediate postoperative complications? Except for the first two questions, the other answers were dichotomous. This interview allowed identification of the risk factors considered in the study. These data are reported only in times T0, as they were not necessary for the later conduct of the study. In times T1, T2, T3, T4, T5, the data collected concerned the presence/absence of stomal and peristomal complications, their type and classification, and the need for medical or surgical treatment. These complications were observed, defined and

Table 1. Definitions of complications. Chirco G, Antonini M. Stoma and peristomal complications: a rapid overview of the literature. Infermieristica Journal 2023;2(1):13–25. doi: 10.36253/if-2075

Definitions of complications			
Stomal complications		**Malpositioning or inappropriate location**	Defined as a condition in which the stoma is packed in such a location that proper management of effluent collection is not possible, or even impossible.
		Malpacking or miscreation	Represented by improper execution of surgical technique during the act of ostomy packing.
		Edema	Occurs as a result of an obstruction to venous outflow that causes an increase in the interstitial water component of the stoma. The most common causes are: excessive traction and/or manipulation of the bowel loops; insufficient diameter of the opening on the abdominal wall; fluid stagnation; plaque hole of a smaller diameter than the stoma itself. If the causes that induced it continue to persist over time, it may result in momentary stenosis and/or paracellular necrosis of the stomal mucosa, with consequent risk of the onset of mucocutaneous detachment.
		Ischemia and necrosis	Insufficient arterial blood supply at the stomal site. It can be partial, if it affects only the emerging portion of the stoma, or total involves the entire intestinal loop.
		Retraction	Can be defined by the presence of one or more conditions, among them: the leveling of the stoma below the skin plane; the underlying viscera applies excessive tension on the stoma, which, drawing inward, carries the surrounding skin with it; the stoma lies within a skin fold.
		Stenosis	Defined as the reduction of the stomal lumen such that normal outflow of effluent is not assured.
		Hernia	Defined as the dislocation of the stomal loop by collapse of the abdominal wall due to complete or partial detachment of the aponeurotic fascia, which may collect in the subcutis surrounding the ostomy, so it will be referred to as a peristomal hernia, or occupying a lateral space, a parastomal hernia.
		Bleeding/ hemorrhage	It can be an early or late stomal complication; blood loss can come from the peristomal suture, so it will be referred to as peristomal bleeding, or from the viscera itself, referred to as intra-stomal bleeding. The occurrence of this complication may depend on factors intrisecal to the surgical procedure, prior pathology of the patient, intrinsic factors of the complex stoma.
		Fistula	Clinically defined as the formation of a neo-route that connects two cavities or a cavity with the outside. With regard to the stomal complex, two types of fistulas can be distinguished: viscero-cutaneous fistula, connects the lumen of the stomal loop with the skin; transtomal fistula, connects the visceral lumen with the outside, disgorged from the everted mucosa above the skin plane. They can occur as a result of repeated transtomal trauma or be the result of a parastomal abscess, excessively deep seromuscular sutures, or suppuration of a suture point.
		Prolapse	Referred to as the excessive protrusion of the stomal loop beyond the abdominal skin plane. It can be partial, defined as mucosal prolapse, in the case where there is exclusively slippage of the mucosal tonaca over the muscular tonaca, by a maximum of 3–4cm, or be total, in the case where there is evagination of the entire intestinal loop.
Peristomal complications		**Irritative contact dermatitis (ICD)**	Defined as skin damage caused by prolonged contact between abdominal skin and feces, urine, or gastric juice, confined to the area of exposure, the lesion of which will be erythematous-edematous with superficial areas of erosion.
		Allergic contact dermatitis	Characterised by inflammation of the skin related to sensitisation against one or more components of products used for stoma-cere, with lesions of erythematous-vesicular, papular or bullous type with undefined margins.
		Mucocutaneous detachment	Defined as the separation of the peristomal skin from the intestinal loop that constitutes the stoma; it may be partial if it affects only part of the peristomal suture, or total if it affects the entire circumference of the stoma.

Definitions of complications			
Peristomal complications	Loss-of-substance lesions	Pyoderma gangrenosum peristomale	This is a noninfectious neutrophilic dermatosis that has onset with the appearance of sterile pustules, which progress rapidly and evolve into painful ulcerations of variable depth and diameter, the edge of which is irregular and characterised by a purplish or bluish color. This complication is often associated with the presence of recurrent skin ulcerations with muco-purulent or hemorrhagic exudate. It generally occurs in patients with chronic inflammatory bowel disease, chronic rheumatologic diseases, and hematologic malignancies.
		Decubitus injury or pressure ulcer	Defined in 2016 by the EPUAP/NPUAP as a "localised injury to the skin and/or underlying tissue, usually located on a bony prominence, as a direct result of high or prolonged compression, or shear or stretching forces, resulting in mechanical stress to the tissues and constriction of blood vessels." In this specific case, decubitus injuries affecting the peristomal skin are more likely to be related to the use of convex plates compressing on the abdominal wall, the use of support belts, or the presence of rigid ostomy rods.
		Trauma injuries or PMARSI	Defined by the presence of lesions caused by traumatic events on the peristomal skin, such as adhesives to keep the garment in place for a longer time. The resulting injury may have an erosive character until it evolves into true ulceration.
		Artifact dermatitis	Defined by the presence of a self-induced traumatic lesion presenting atypical distribution and shape and chronic course over time.
	Proliferative lesions	Foreign-body granulomas	Also called stitch granulomas, form mainly at the muco-cutaneous junction as a result of a chronic inflammatory reaction.
		Hypergranulation tissue	Represents an outgrowth of red, friable, shiny and easily bleeding tissue that extends beyond the margins of the lesion, above the surrounding skin tissue.
		Neoplasia	True neoplastic masses that form at the base of the stoma or in the peristomal region, subsequent to inadequate resections of the primary tumor or following recurrence of the disease, or the outcome of nonmalignant disease, such as a chronic peristomal inflammatory process.
		Oxalate deposits or hyperkeratosis	Defined by the presence of whitish crystals, on the peristomal skin and stoma, the formation of which is facilitated by the excretion of alkaline, concentrated urine or the presence of urinary tract infection.
	Peristomal skin infections	Candidiasis	Defined by the presence of lush vegetation of microorganisms belonging to the Candida family, resulting in erythematous itchy lesions with irregular borders associated with satellite pustulosis.
		Folliculitis	The etiology of this is related to Staphylococcus Aureus infection of one or more follicles resulting in inflammation and the onset of erythematous-pustular lesions.
	Pre-existing skin disorders	Psoriasis	A hyperproliferative, benign skin disorder characterised by well-defined, silvery-white erythematous-squamous plaques. The patient with this pathology, will present below and around the collecting garment, what is called "Koebner's phenomenon".
		Eczema	Related to an underlying inflammatory process that is likely to be established as a result of contact with a specific agent, presents as a dermatitis characterised by abundant exudate and vesicle formation, accompanied by itching and redness, which may scab or form crusts on their surface.
		Seborrheic dermatitis	It is an eczematous process that follows a characteristic pattern of body distribution. The resulting lesion is characterised by a typical erythematous rash, accompanied by yellowish, greasy scales.

photographed by the experienced nurse. Specifically, the SACS 2.0 Classification[20] was used to classify peristomal skin changes, and the literature review by Chirco et al (2023)[21] was used to classify stomal complications.

At the end of the observation period, XLSTAT Software (version2021.3.1) was used to study risk factors, considering a p-value <0.05 as significant, and Pivot Tables were used to study the incidence of complications.

Study procedure: The study included an initial phase of research protocol writing and literature search. This was primarily done by the nursing student under the supervision of the expert nurse and the surgeon who sponsored the study. The criteria for the literature search included: studies published in international indexed journals, in English, conducted within the last 20 years, investigating risk factors associated with the development of stoma and peristomal complications, and investigating individual complications.

Following approval by the local ethics committee, the study team was able to begin the second phase of observation and data collection. Specifically, the 181 patients were enrolled from May to September 2021. Each patient was enrolled in the immediate post-operative period and within 48–72 hours of surgery. Surgery was performed by specialist ostomy surgeons who were part of the surgical team. Patients were seen by an ET/Wound Care nurse who assessed them for the presence or absence of ostomy complications at both the initial and subsequent follow-up visits. The student nurse was responsible for interviewing participants and collecting data. For the purpose of the study, participant data were collected in the immediate postoperative period, within 48–72 hours after surgery in the inpatient ward of the hospital (T0), and then within the special outpatient clinic as follows: one week after the first assessment (T1), two weeks after (T2), one month after the first access (T3), two months after (T4) and three months after (T5). The interview was conducted during the first visit, and stoma and peristomal skin data were collected for the next three months until December 2021. Demographic data collected included: sex; age; BMI (≤18 underweight; 18≤BMI≤24.5 standard; ≥24.5 overweight); previous comorbidity and type of comorbidity (cardiac, respiratory, gastrointestinal, diabetes, previous neoplasm and systemic disease); type of ostomy surgery and whether emergency or elective; date of surgery; type of stoma created or formed and if it's temporary or permanent; postoperative complications; type of complication, whether stomal or peristomal; type of treatment for complication, whether medical or surgical. At the end of the observation period, in January and February 2022, data analysis was performed by the student nurse under the supervision of the study sponsor surgeon.

All patients and their caregivers received regular training on stoma self-management as outlined by the Association for Technical-Scientific Stomatherapy and Pelvic Floor Rehabilitation (AIOSS)[22] in the first two weeks after surgery and, if necessary, in the months following.

Outcomes Measures: As this was a prospective observational study, no outcome measures were defined, but two objectives were included in the research protocol: (i) to determine the incidence of stomal and peristomal complications and (ii) to verify independent risk factors for the complications found using Fisher's exact test and chi-square.

Ethical approval: The research protocol of the study was reviewed by the Regional Zonal Ethics Committee of the Azienda USL Toscana Centro and was approved by Measure No. 1325 dated 18.05.2021. Patients who voluntarily participated in the study from May to December 2021 were enrolled in accordance with the current regulations regarding data confidentiality and ethical requirements. The patients were informed of the objectives and methods of the study and signed the informed consent and release form for the collection of iconographic material.

DATA ANALYSIS

At the end of the observation period, both incidence and cummulative rates were studied, with respect to the total number of complications that occurred during the three months of observation, and individually over the different observation periods, using Pivot Tables generated from data processed in the Excel database. In each of the six observation periods, the incidence was calculated: over the total number of complications that occurred; by differentiating between stomal from peristomal complications: and by individual type of ostomy, between urinary (Nephrostomies, Cutaneous Ureterostomies and Ileocutaneous Ureterostomies) and intestinal (Caecostomies, Ascending Transverse Colostomies, Descending Transverse Colostomies and Sigmoid Colostomies, and Ileostomies).

To study the correlation between the different variables found in this study and the occurrence of complications, Fisher's Test and the Chi-square Test were used, performed with XLSTAT Software (version 2021.3.1) (By Addinsoft PARIS, France, Europe), considering a p-value <0.05 for each variable to be significant. The presence/absence of complications was defined as the dependent variable, while the independent variables included: age, sex, BMI, type of surgery (urgent vs elective), previous comorbidities, type of comorbidities (medical vs neoplastic).

After careful situational analysis, we agreed to follow the protocol proposed in the study by Antonini et al (2018) published in the WCET Journal[23] for the proposed secondary goal of defining a universally accepted treatment for individual complications.

RESULTS

A total of 181 subjects were recruited, 66 women and 115 men, with a mean age of 73 years (range 32–97 years). Of these, 130 had a BMI >24.5, only three had a BMI ≤18, and 48 were normal weight. In addition, 168 of 181 subjects reported at least one comorbidity among cardiac, respiratory, chronic gastrointestinal, urologic, previous neoplastic, and systemic diseases such as hypo-/hyperthyroidism. Regarding surgical variables, 87 subjects underwent emergency surgery, while the remaining 94 subjects underwent elective surgery (Table 2). Of the latter, only one participant received preoperative planning for proper ostomy placement; therefore, this variable was excluded from the statistical analysis performed for the risk factor identification study. 51.9% had a intestinal ostomy; the remaining 48.1% had a urinary ostomy.

During each observation period, the number of patients decreased from time to time according to the various withdrawal criteria described above. Of the 181 patients enrolled at T0, only 98 (54.1%) manifested complications. At the end T5 (three months), 129 patients remained and of these, only 18 (13.9%) had complications. Furthermore, the number of patients with complications at each observation time point ranged from 1 to a maximum of 4 (Table 3).

Incidence analysis

Data analysis shows the incidence rate of stomal complications decreases progressively over time: from 54.1% in T0 to 13.9% in T5, with a slight increase at two weeks (T2=17.8%) and one month after recruitment (T3=20.5%).

A total of 356 complications were recorded during the three months of observation; in order, from T0 to T5, the most representative incidence rates were: irritant contact dermatitis (ICD) 18.5% (66/356) and evenly distributed among the different follow-ups; ostomy malposition in the abdominal plane with 13. 2% (47/356), observed at T0; stomal edema 10.9% (39/356), mainly observed at T0; mucocutaneous detachment 8.1% (29/356), mainly observed at T2 (Table 4).

Furthermore, the data collected shows that the incidence rate of the different complications, stomal and peristomal, is distributed differently at the different observation times (Table 5). At T0, the predominance of stomal complications over peristomal complications can be observed in relation

Table 2. Distribution of the demographic and surgical variables in the population of the study

Demographic variables			Surgical variables	
Sex	66 **women**, 115 **men**		**Surgery**	94 **elective**
				87 **emergency**
Median age	73 (range 32–97 years)		**Bowel ostomies**	**51.9%**
Body Mass Index or BMI	**<18** =3 patients			Caecostomy 1 Ascending transverse colostomies 1 Descending transverse colostomies 3 Sigmoid colostomies 45 Ileostomies 24
	18<x<24.5 =60 patients			
	>24.5 =118 patients			
Comorbidities	**NOT Present** 13 patients		**Urinary ostomies**	**48.1%**
	PRESENT 168 patients			Cystostomies 3 Nephrostomies 46 Cutaneous ureterostomies 36 Ileocutaneous ureterostomies 2
	1 comorbidity 58 patients **2 comorbidities** 79 patients **3 comorbidities** 31 patients			

Table 3. Summary table of the complications recorded during the six observation times.

Time	%	Stomal complications (%)	Peristomal complications (%)	Distribution of complications (c) by patient (from 1c to 4c)
T0 98 of 181 patients	**54.1%**	**75.7%**	**24.2%**	55 patients= 1c 29 patients= 2c 8 patients= 3c 6 patients= 4c
T1 18 of 176 patients	**10.2%**	**24.1%**	**75.8%**	9 patients= 1c 7 patients= 2c 2 patients= 3c
T2 31 of 174 patients	**17.8%**	**21.3%**	**78.7%**	17 patients= 1c 12 patients= 2c 2 patients= 3c
T3 34 of 166 patients	**20.5%**	**21.7%**	**78.3%**	16 patients= 1c 10 patients= 2c 8 patients= 3c
T4 24 of 146 patients	**16.4%**	**6.4%**	**93.5%**	15 patients= 1c 8 patients= 2c
T5 18 of 129 patients	**13.9%**	**32.14%**	**67.8%**	12 patients= 1c 2 patients= 2c 4 patients= 3c

to the number of total complications recorded, with ostomy malposition (*i*= 29.1%) and stomal edema (*i*= 21.7%) showing a higher incidence. However, it increases again three months after enrollment, when a higher incidence of late stomal complications were shown, such as retraction (iT1=29%; iT2=40%; iT3=38%) and parastomal hernia (iT4=100%; iT5=67%). In the subsequent observation periods from T1 to T5, peristomal complications occurred more frequently. The most common complications were:

- ICD, recorded almost consistently at all observation times (iT1=31%; iT2= 19.2%; iT3= 23.3%; iT4= 38.7%; iT5= 32.1%)
- Mucocutaneous detachment, predominantly seen two weeks after enrollment (iT2= 35%)
- Proliferative lesions of different types were an almost constant presence, (i= 16-21%), classified according to the SACS 2.0 scale;
- Peristomal skin infections (i=10-11%)

Data obtained from analysing the incidence of ostomy complications, differentiated according to the type of ostomy, then revealed that 77.5% (276/356) of the total number of complications recorded during the six different follow-ups occurred in intestinal ostomies. Those with the highest incidence were:

- ICD, *i*=19.5% (54/276), more common in ileostomies (i=30.2%) and caecostomies (i=2.5%)

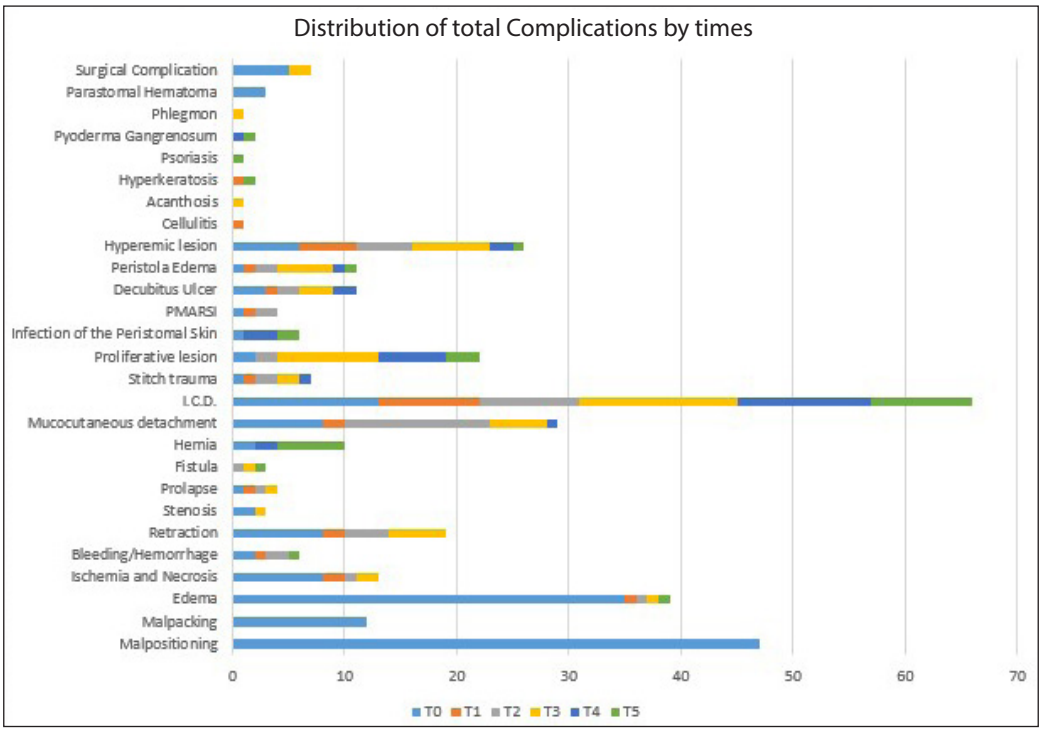


Table 4. Distribution of total complications in the various follow-ups in relation to the number of observed complications.

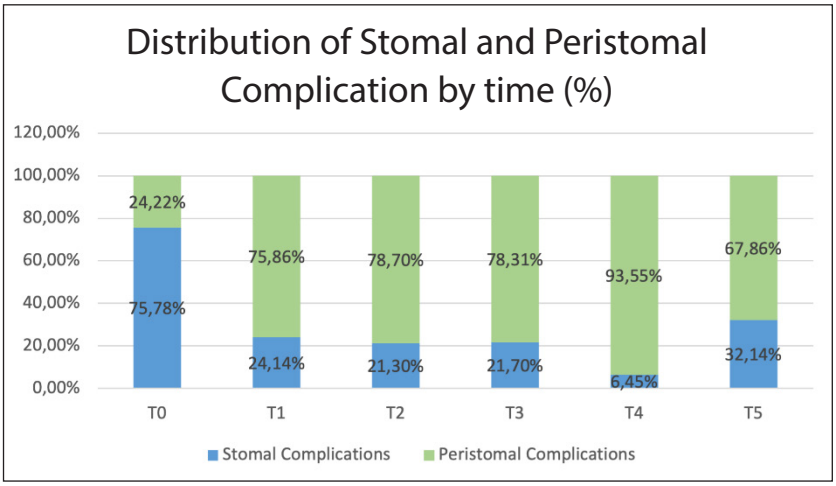


Table 5. Distribution of the incidence of stomal and peristomal complications at different observation times (T0–T5).

- Stomal edema, *i*=13.4% (37/276), most frequent in colostomies (Table 6)
- Ostomy malposition, *i*=9.7% (27/276), also most frequent in colostomies
- Mucocutaneous detachment, *i*=8.7% (24/276), also mainly in colostomies.

In addition 22.4% (80/356) of the total complications recorded occurred in urinary ostomies. The most representative ones were:

- Ostomy malposition, *i*=25% (20/80), mainly in cutaneous ureterostomies (i=50%)
- ICD, *i*=15% (12/80), mainly in ileocutaneous ureterostomies (i=33.3%)
- Proliferative injury, *i*=12.5% (10/80), and hyperemic injury due to inflammatory process, *i*=11.2% (9/80), both more common in nephrostomies (Table 7).

Risk Factor Analysis

The highest incidence rate of stomal complications was observed in the period immediately after surgery (T0). Therefore, a static analysis

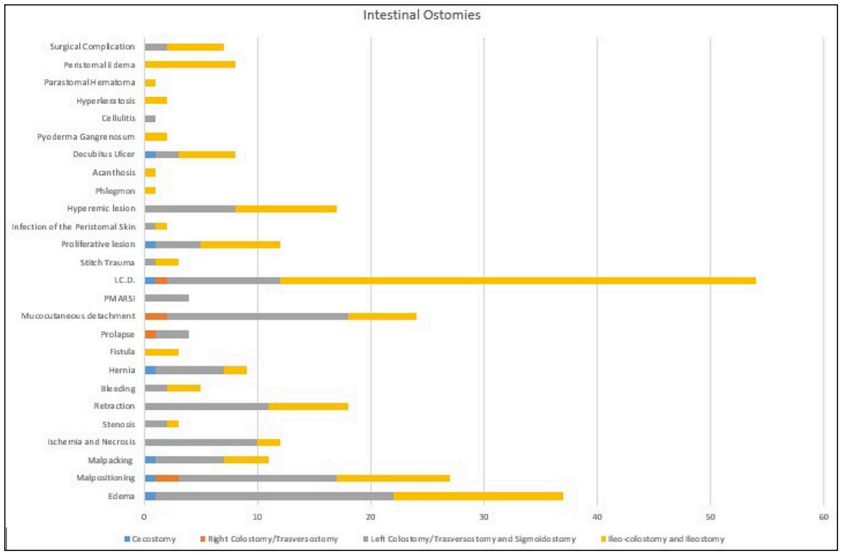


Table 6. Distribution of Total Stomal Complications (T0 to T5) in Intestinal Stomies in comparison to the number of complications.

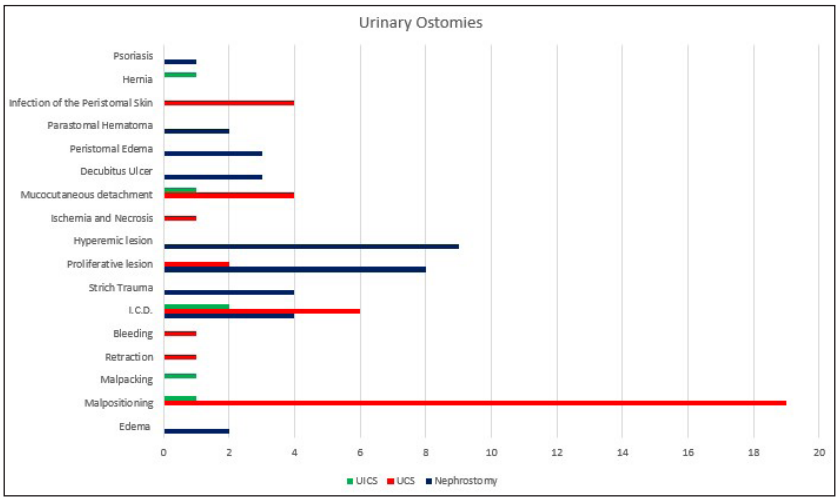


Table 7. Distribution of Total Stomal Complications (T0 to T5) in Urinary Stomies with respect to the number of complications.

nonparametric inferential statistical analysis was performed in this period to evaluate the correlation between the different variables and the occurrence of complications. To perform this analysis, the Fisher's Test, significance test used with nonparametric statistics for hypothesis testing, and a Chi-square Test, was used to test the statistically significant association between two qualitative variables. We considered a p-value<0.05 as significant.

The analysis showed that the presence of a general preoperative comorbidity was a determinant factor for the development of stomal/peristomal complications (*p-value* =0.005) (Table 8). However, there was no statistically significant correlation (*p-value* =0.013) when stratified by type of preoperative comorbidity (medical vs neoplastic). Similarly, sex (*p-value* =0.097), age (*p-value* =0.789), BMI (*p-value* =0.188), and type of surgery (urgent vs elective) (*p-value* =0.010) were not associated with the occurrence of complications.

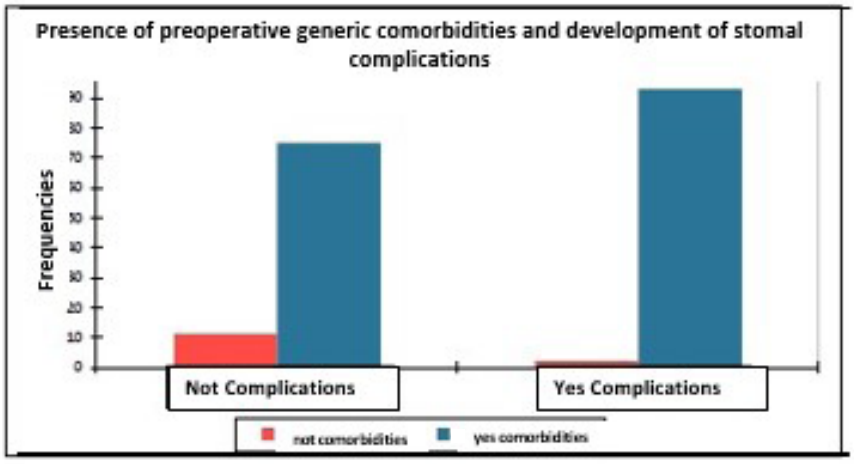
DISCUSSION

A careful review of the international literature published in the last two decades shows that there is still great heterogeneity in the available data, both regarding the incidence and prevalence of stomal and peristomal complications and the risk factors for developing these complications. According to a recent systematic review by D'Ambrosio et al (2022), the causes of these discrepancies can be attributed to several factors: small and heterogeneous sample sizes, differences in the type of ostomy, differences in the type of complications considered and in the way cases were identified, and variability in the assessment/classification of the skin problem.[24] In addition, most of the studies conducted are retrospective in nature. Based on these assumptions, there is a need to study: the incidence of individual complications in the first three months after ostomy creation; the variables influencing their occurrence; and possible risk factors using a standardised study design.

Our study concludes that stomal complications are more frequent than peristomal complications, especially regarding early complications. This predominance seems to be reversed in the other five observation times, where the ratio of stomal to peristomal complications is almost always 1:3. As the observation time increases, the probability of developing stomal complications seems to decrease.

Among the most common early stomal complications we report: ostomy malposition (i=29.1%), stomal edema (i=21.7%) predominantly present at T0, and stoma retraction (iT1=29%; iT2=40%). Two factors may explain the higher incidence of ostomy complications at T0 in this sample: firstly, in the center where the study was conducted, it is not common practice to perform preoperative stoma positioning; second, among the studies in the literature and analysed, none of them considers ostomy malposition and stomal edema among the stomal complications. The latter is considered a pathological process, the causes of which need to be carefully studied, and not a physiological manifestation of the stress to which the bowel is subjected during surgery.[25] Failure to adopt the practice of preoperative ostomy placement in the institution has a negative impact on study outcomes and patient well-being. It also exposes the patient to an increased risk of developing stomal and peristomal complications, as demonstrated by previous studies.[26-28] Millan et al in 2010 showed in their study that the sample who benefited from preoperative stoma education and stoma placement by stomatherapists had fewer peristomal skin complications than the control group in both emergency and elective surgery patients.[29] Pinto et al (2017), through their review of 22 articles, also defined four categories of risk factors; stoma position is among the treatment-related risk factors.[30] This undoubtedly explains the high rate of malpositioned or poorly positioned ostomies recorded in the data collection. In our opinion, the study of such a single complication allows the surgical team to improve their approach and, as a goal for a future study, to evaluate the correlation between the presence of malposition at T0 and the occurrence of complications at subsequent follow-ups, defining which of these are the most common.

The analysis of the incidence of complications also showed that the type of complications differed according to the type of ostomy, intestinal or urinary. The cause of this difference may be attributed to the different type of harmful input of stomal effluent with which the skin comes into contact. We can state that, in agreement with the literature, especially the review by Steinhagen et al published in (2017), peristomal



Comorbidities Vs Complications	Not complications	Yes complications
Not Present Comorbidities	11	2
Present Comorbidities	75	93

Chi-square test (observed value)	7,731
Chi-square test (critical value)	3,841
GDL	1
p-value	*0,005*
alfa	0,050

Table 8: Correlation between dependent variable "presence/absence of complications" and independent variable "presence/absence of general pre-operative comorbidity".

skin complications occur mainly in ileostomies,[31] with a high incidence of ICD (i= 30.2%); in colostomies, however, stomal complications are more common. In our study, the highest incidence rate of colostomy-related complications was attributed to mucocutaneous detachment (i= 33.3%), which mainly occurred two weeks after enrollment (T2) presumably due to the removal/loosening of sutures at the muco-cutaneous junction. The aforementioned study by Steinhagen et al. reported that the incidence rates of mucocutaneous detachment are underestimated in the literature and that it is predominantly a complication of the early postoperative period.[31] Therefore, we can say that the complications are different depending on the type of stoma.

Finally, the statistical analysis performed showed that the stomal and peristomal complications identified in this study of the ostomies were statistically related to the presence of one or more common preoperative comorbidities, although with important limitations due to the partial heterogeneity of the sample and the difficulty of stratification. In contrast, Koc et al (2017), in their retrospective analysis conducted to study risk factors for the development of early complications, define stoma siting as an independent risk factor for the development of stomal complications.[2] Guerra et al (2023) suggest that proper stoma care and maintenance, including the use of protective films and careful monitoring of weight and comorbidities, are key to minimising the risk of stoma-related complications.[3]

Strengths

The design of this study, through the use of clear operational definitions, standardised assessment methods, and the prospective, longitudinal, repeated-measures nature of the study, is an improvement over previous studies in the literature. In addition to describing the cumulative incidence of complications and to define the significance of the possible risk factors, the data provide a detailed description of the type of complications that occur at each follow-up and the types of ostomy in which they occur. Few previous studies of this type have been found in the literature,[24;32-33] and only one researcher[11] has reported longitudinal data on the incidence rate of stomal complications, both cumulatively and individually over the periods of observation.

Limitations

The partial heterogeneity of the data obtained was due to the small sample size, therefore study results should be viewed with caution. Moreover, of the 181 subjects enrolled in the immediate postoperative period, only 129 reached the end of observation (three months), and of this loss, logistic regression analysis would be useful.

It is the authors' opinion that, in order to have a complete view of late stoma complications, the observation period should be extended to at least one year and that it would be more appropriate to have the involvement of other stoma rehabilitation centers in order to have a broader view of the phenomenon.

CONCLUSION

The results of this study are believed to have implications for colorectal and general surgeons performing ostomy surgery, ET/Stomal Therapy Nurses and ward nurses in providing ostomy education and practice. However, there is a clear need for continuation of the study, expansion of the study in terms of length of follow-up, and research into the relationships between the variables that have the greatest impact on the development of individual complications. The research and current study is ongoing and its primary goal is to define a standardised approach to ostomy complications for use in the various hospital and non-hospital settings. The ultimate goal is to improve the QoL for all ostomy patients.

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