# Early peristomal complications: detailed analysis, classification and predictive risk factors



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## Early peristomal complications: detailed analysis, classification and predictive risk factors.

INTRODUCTION: Peristomal complications are frequently neglected by surgeons. Our aim was to assess peristomal complications occurring within 30 days after surgery and identify predictive risk factors.

METHODS: All patients who underwent stoma creation from January 2014 to June 2016 in our institution were included unless patients who died, had their stoma reversed or were lost to follow-up. Peristomal complications were retrospectively analysed using a photography database, a validated scale for peristomal skin lesions and the Clavien-Dindo score. Peristomal complications were categorized as absent, mild or relevant. Univariate and multivariate analysis were performed to identify risk factors for a) incidence of and b) persistence of relevant peristomal complications at 30 postoperative days.

Results: 111 patients were included, 16 (14%) patients had mild and 65 (59%) patients had relevant complications. The most common event was mucocutaneous separation in 57 (51%) patients. Complications were still present at 30 days in 36 (32%) patients. Double-barrel (vs end stoma) was an independent risk factor for significant morbidity (OR=2.394 (95%CI=1.082-5.293), p=0.030). Persistence of relevant complications at 30 days was more likely associated to urgent surgery (OR=4.239 (95%CI=1.105-16.257), p=0.035) and to ASA score III/IV (OR=5.963 (95%CI=1.447-24.569), p=0.013). Male sex (OR=0.246 (95%CI=0.069-0.874), p=0.030) and age over 70 years (OR=0.121 (95%CI=0.029-0.515), p=0.004) appeared to be protective.

CONCLUSIONS: Early peristomal complications are common, usually mild. They are most likely to persist beyond 30 days in patients operated as emergencies and with an ASA score of III-IV.

KEY WORDS: Complications, Complications, Stoma, Mucocutaneous separation,

# Introduction

Stoma formation is a commonly performed procedure after colorectal surgery. The presence of a stoma is associated with its own morbidity and psychologic distress for the patient <sup>1-3</sup>. Peristomal complications are frequent and further increase patients' distress, however, they are frequently neglected by surgeons.

The reported rate of stoma complications varies widely from 6 to 96% <sup>3-6</sup> this mainly because of variable definitions and different inclusion criteria. Some studies report on all stoma complications combining early and late complications, such as fluid and electrolyte imbalance, inappropriate positioning, parastomal ulceration, stoma necrosis or retraction, stoma prolapse, or parastomal hernia <sup>4,7</sup>. Others have focused on stoma care problems defined as the need of one or more accessories

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to keep the patient clean and dry for a minimum period of 24h <sup>6</sup>, day and night-time leakage, soiling and night-time emptying<sup>3</sup> and few focused on skin complications<sup>8-10</sup>.

The aim of this study was to perform a detailed and standardized analysis of the incidence and type of early peristomal complications that could serve as a benchmark, to identify predictive risk factors and to evaluate the persistence or resolution of complications after thirty postoperative days.

## Materials and Methods

#### STUDY POPULATION

We performed a retrospective analysis of all consecutive patients undergoing stoma formation in our institution from January 2014 to June 2016. Patients were identified through billing and surgical intervention codes. The criteria of exclusion were reversal of stoma or death within thirty postoperative days, lack of photographic documentation, and loss of follow-up at 30 days (Fig. 1).

Methods to Recognise and Define Peristomal Complications

Complications were analysed using clinical notes and a photography database performed by a single dedicated enterostomal therapy nurse (ET nurse). As no consensus exists on defining peristomal complications, we used the validated scale SACS (Studio Alterazioni Cutanee Stomali) <sup>8</sup>. The SACS scale proposes a detailed classification of skin complications according to recurrent clinical manifestations (L) and topographical location (T) <sup>2</sup>. We added to this scale clinical findings observed in our centre such as suture fissure (SF), muco-cutaneous separation (D), abscess (A), retraction (R) and necrosis (N). In addition, we used the Clavien-Dindo score to classify the severity of complications. However, as the vast



Fig. 1: Flow-chart.

majority of complications were Clavien-Dindo class I, we additionally and deliberately classified the complications in two categories: mild (L1, L2, SF) or significant (all other and any Clavien-Dindo >I), based on the time and efforts needed to resolve them (Fig. 2).

### ETHICS AND REGISTRATION STATEMENT

This study was reviewed and approved by the local ethics committee. The present study has been registered in the ResearchRegistry.com with the identifying number researchregistry 4605.

This study has been reported in line with the STROCSS statement <sup>12</sup>.

TABLE I - Patient demographics and analysed risk factors.

Gender	
Male	64 (58%)
Female	47 (42%)
Age	67.61 ± 15
Risk factors	
Smoking	25 (23%)
Non smoking	61 (54%)
Unknown	25 (23%)
Diabetes	17 (15%)
No diabetes	94 (85%)
Systemic steroids	7 (6%)
No steroids	104 (94%)
ASA I - II	58 (52%)
ASA III - IV	53 (48%)
BMI<30 kg/m <sup>2</sup>	91 (82%)
BMI>30kg/m <sup>2</sup>	20 (18%)

TABLE II - Surgery settings and stoma characteristics

Related disease	
Malignant disease	72 (65%)
Benign disease	39 (35%)
Surgery intent	
Curative oncologic surgery	56 (50%)
Palliative surgery	55 (50%)
Surgery setting	
Elective surgery	61 (55%)
Emergency surgery	50 (45%)
Stoma site	
Ileostomy	71 (64%)
Colostomy	40 (36%)
Stoma type	
Loop	71 (64%)
End	40 (36%)
Mucocutaneous suture	
Intradermic	76 (68%)
Donati	35 (32%)
Stoma duration intent	
Temporary	95 (86%)
Permanent	16 (14%)
Pre-operative site location marking	
Marked by ET nurse	73 (66%)
Not marked by ET nurse	38 (34%)

#### **S**TATISTICS

Preliminary univariate analyses were performed using chisquare test (asymptotic significance was computed). The factors resulting with a p<0.1 at this analysis were further analysed including them into the following multivariate analysis. Forward conditional binary logistic regression was applied to identify the risk factors for relevant complications after 30 days at the net of multicollinearity. Coefficient beta, its standard error (S.E.), its exponential (coinciding with the odds ratio, OR), significance level (p) and 95% confidence intervals of OR (95% CI), and the variance explained by the model were computed.

#### Results

A total of 127 patients underwent stoma formation during the study period. After exclusion of 16 patients a total of 111 patients, 64 males and 47 females, were included (Fig. 1). Patients demographics and analysed risk factors (smoke, diabetes mellitus, use of corticosteroids, ASA score and BMI) are shown in Table I.

Approximately two thirds of the 111 stomas were temporary loop ileostomies made after an elective low anterior resection surgery. Surgery settings and stoma characteristics are showed in Table II.

The peristomal complication rate was 73%, and 59% were considered as relevant using our predefined criteria. Superficial mucocutaneous separation was the most frequent complication 57(51%) patients, followed by superficial skin erosion 25(22%) patients. Several patients presented more than one lesion\* (Table III).

Only 2 (2%) patients required surgery for peristomal complications (Clavien-Dindo score IIIa and IIIb). All other complications were Clavien-Dindo grade I.

At thirty postoperative days 75 (68%) patients had a complete resolution of the complications reported, with persistence of relevant complications in 18 patients (16%) (Table IV).

TABLE III - Detailed analysis of peristomal complications.

6 (5%)
25 (23%)
9 (8%)
6 (5%)
0 (0%)
57 (51%)
3 (3%)
5 (5%)
2 (2%)

\*Each patient can present more than one lesion

TABLE IV - Analysis of peristomal complications and persistent complications beyond thirty post-operative days.

Peristomal complications	
Absent	30 (27%)
Any kind	81 (73%)
Mild	16 (14%)
Relevant	65 (59%)
Persistent complication beyond thirty post-operative days	
Absent	75 (68%)
Any kind	36 (32%)
Mild	18 (16%)
Relevant	18 (16%)
Surgery for stoma complications	2 (2%)

\*in case of synchronous complications, the most relevant complication was reported.

TABLE V - Univariate analysis performed using  $\chi^2$ -test for the two endpoints. In bold the statistically significant values (p<0.05). § included into the multivariate analysis.

Factors	Sign comp wit post χ <sup>2</sup>	nificant blications hin 30 -op days p-value	Persistence of significant complications at 30 post-op days $\chi^2$ p-value	
Male	0.042	0.839	3.100	0.078§
Age > 70 years	0.112	0.738	2.855	0.091§
Malignant disease	0.114	0.735	3.931	<b>0.0</b> 47§
Oncological surgery	0.723	0.395	6.848	0.009\$
Emergency surgery	0.444	0.505	9.299	0.002\$
Loop stoma	4.747	0.030§	0.076	0.783
Small bowel stoma	3.151	0.076§	1.817	0.178
Permanent stoma	2.462	0.117	1.164	0.281
Not marked by ET nurse	0.504	0.478	2.372	0.124
Prominence of stoma < 10mm	2.082	0.149	3.110	0.078§
Smoking	0.497	0.481	0.021	0.884
Diabetes	0.313	0.576	0.030	0.862
Steroids	0.006	0.937	0.020	0.886
ASA III - IV	0.574	0.449	7.765	0.005§
BMI < 30	0.015	0.903	3.357	0.067§
BMI >30	0.021	0.884	2.501	0.114
Donati's suture	2.101	0.147	3.394	0.065§

Loop stoma was the only statistically significant factor for developing relevant peristomal complication within 30 days from the surgery (OR=2.394 (95%CI=1.082– 5.293), p=0.030) (Table V).

Emergency surgery (OR=4.239 (95%CI= 1.105-16.257), p=0.035) and ASA III/IV (OR=5.963 (95%CI= 1.447-24.569), p=0.013) independently predicted the persistence of relevant complications at 30 postoperative days. Male (OR=0.246 (95% CI=0.069-0.874), p=0.030) and patients older than 70 years (OR=0.121 (95%CI=0.029-0.515),p=0.004) were less likely to have persistent relevant complications at 30 postoperative days (Table VI).

Final Step of forward logistic regression analysis						
	Entered step	beta	S.E.	p-value	OR	lower – upper 95% CI
Male	4th	-1.403	0.648	0.030	0.246	0.069 - 0.874
Age > 70 years	2nd	-2.109	0.738	0.004	0.121	0.029 - 0.515
Emergency surgery	1st	1.444	0.686	0.035	4.239	1.105 - 16.257
ASA III-IV	3rd	1.786	0.722	0.013	5.963	1.447 - 24.569

TABLE VI - Results of logistic regression analysis for the persistence of significant complications at 30 post-operative days (endpoint2).

# Discussion

In our study we found a high rate of early peristomal complications. Other prospective studies demonstrated a high incidence of early complications, ranging from 27 to 82% <sup>12-14</sup>. The high rate of peristomal complications observed in our centre was related to the use of strict definition criteria (considering also mild lesions as complications) and a very detailed photography database. As shown in this study most complications are mild and can be solved with conservative treatment and adequate follow-up.

We categorized complications using a validated scale of peristomal skin lesions that we modified, and classified the severity of complications to mild or relevant using clinical common sense, to reflect patients' discomfort and quality of life impairment and efforts needed to cure the complication. Integrating systemic and bowel related stoma complications, we propose a classification system that, if validated in future prospective studies, could be used to report stoma complications in a more simple and standardized fashion (Table VII).

Mucocutaneous separation was the most common lesion reported as showed in another study <sup>15</sup>. Superficial skin erosion was the second complication most frequently reported, similar to previous studies <sup>13,16,17</sup>.

In the current analysis it was the double-barrel conformation of a stoma that was the only factor associated with early significant complications, independently whether it was a colostomy or an ileostomy. This may be explained by more frequent muco-cutaneous separation on the sides of a loop stoma because of higher tension at this point as compared to the lower and upper part. Ileostomy has been found to be a predictive factor for higher peristomal morbidity in several studies <sup>3,6,17</sup>. In our study we found a trend (p=0.076) for more complications for small bowel stoma, which in our study were mostly loop ileostomies.

Obesity and diabetes are frequently found to be predictive of stoma complications <sup>7,12</sup> but not in our study. This may be due to the small size of the study with very few diabetic patients included.

We also searched for predictive risk factors for persistence of complications at thirty postoperative days, as we thought that this may have had an impact on patients' quality of life. Such analysis could also identify patients more at risk, for whom a close follow-up

TABLE VII - Classification proposal of stoma related complications

Mild	Relevant
Systemic complications	
5 1	Dehydration
	Electrolyte imbalance
	Psychological distress
Bowel complications	
*	Necrosis
	Retraction
	Stricture
	Peristomal hernia
	Stoma prolapse
Peristomal skin complications	1 1
Hyperemic lesion	Abscess
Erosive lesion	Fistula
Suture fissure	Ulcerative lesion
	Proliferative lesion
	Muco-cutaneous separation

could help to decrease the rate of persistent complications. In line with other studies, we found that emergency surgery <sup>6,7,12,17</sup>, ASA III-IV <sup>16,18</sup>, female gender <sup>6,15</sup> and age <70 years <sup>6</sup>, were significant predictors for persistence of peristomal complications at thirty postoperative days. In particular, subjects with ASA III-IV showed a risk 6 times higher of significant complications, those with emergency surgery or female gender about 4 times higher. These are unfortunately all factors that cannot be influenced, but we suggest that such patients should be followed by a specialized therapist more closely.

The main limit of our study is that it was retrospective, but it was performed with a very detailed clinical and photographic database. The small number of patients were all followed by the same ET nurse, improving the quality of data recorded. Stoma creation was performed by different surgeons of variable experience. Surgical technique (mucocutaneous fixation with Donati sutures versus intradermic) and type of suture used were a choice of the individual surgeon. However, we did not find any statistically significant difference between the two surgical techniques. No analysis of economic impact was made in this study. We did not consider elements as number of bag changes, number of products and procedures used to treat the peristomal complication as used in other studies <sup>10</sup>. Due to the retrospective nature of the study, we were unable to analyse the direct impact of the complications on the patients' quality of life.

In conclusion, we found that early peristomal complications are common, usually mild and most likely to persist beyond 30 days in patients with a higher ASA score of III-IV, operated in emergency. More prospective studies, possibly using the classification we used in this study, with a clear definition of stoma complications and standardized surgical technique are needed.

#### Riassunto

Le complicanze peristomali sono spesso trascurate dai chirurghi. Il nostro obiettivo era valutare le complicanze peristomali che si verificano entro 30 giorni dall'intervento chirurgico e identificare i fattori di rischio predittivi.

Nello studio sono stati inseriti tutti i pazienti che tra gennaio 2014 e giugno 2016 hanno ricevuto la creazione di una stomia nel nostro istituto, a meno che non siano deceduti oppure che siano stati persi al follow-up. Le complicanze peristomali sono state analizzate retrospettivamente utilizzando un database fotografico, una scala validata per lesioni cutanee peristomali e il punteggio Clavien-Dindo e dunque classificate come assenti, lievi o rilevanti.

Sono state eseguite analisi univariate e multivariate per identificare i fattori di rischio per a) incidenza di b) persistenza di rilevanti complicanze peristomali a 30 giorni postoperatori. I pazienti inclusi nello studio sono stati 111: 16 pazienti (14%) avevano complicanze lievi e 65 pazienti (59%) complicanze rilevanti.

L'evento più comune è stata la separazione mucocutanea in 57 (51%) pazienti.

Complicanze erano ancora presenti a 30 giorni in 36 (32%) pazienti. La stomia a doppia canna (vs stoma terminale) è risultato un fattore di rischio indipendente per morbilità significativa (OR = 2.394 (IC 95% = 1.082-5.293), p = 0.030). La persistenza di complicanze rilevanti a 30 giorni era più probabilmente associata a un intervento chirurgico urgente (OR = 4.239 (IC 95% = 1.105-16.257), p = 0.035) e al punteggio ASA III / IV (OR = 5.963 (IC 95% = 1.447 - 24.569), p = 0.013).Il sesso maschile (OR = 0,246 (IC 95% = 0,069-0,874), p = 0,030) e l'età superiore ai 70 anni (OR = 0,121 (IC 95% = 0,029-0,515), p = 0,004) sembrano essere protettivi. In conclusion, le complicanze peristomiche precoci sono comuni, generalmente lievi. È più probabile che persistano oltre i 30 giorni nei pazienti operati in emergenza e con un punteggio ASA di III-IV.

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