Original Article

Risk Factors for Development of Peri-stomal Skin Complications: A Single-center Retrospective Cohort Study

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Key Words
Peristomal skin complications;
PSCs;
Ileostomy;
Colostomy;
Ostomy surgery

Purpose. Stoma creation surgeries alleviate various gastrointestinal conditions but may lead to complications, notably peri-stomal skin complications, impacting patients' well-being. This retrospective study aimed to identify risk factors of peri-stomal skin complications for patients undergoing stoma creation surgery in a single center.
Method. A retrospective cohort study at Chimei Medical Center, Taiwan, analyzed 359 patients' demographics, stoma characteristics, and peri-stomal skin complication incidence.
Results. We discovered a 4.7% peri-stomal skin complication incidence, with female sex and emergency surgery significantly associated with higher risk. Although stoma height and pre-operative site marking showed potential protective effects, they did not reach statistical significance.
Conclusion. Based on our study, female patients and those undergoing emergency surgery require special attention during stoma care. Pre-operative stoma site marking and increasing the height of the stoma during surgery may benefit in reducing the incidence of peri-stomal skin complications.

[*J Soc Colon Rectal Surgeon* (*Taiwan*) *2025;36:1-6*]

Stoma creation surgeries are commonly performed procedures for managing a variety of gastrointestinal conditions, serving purposes such as decompression and protecting intestinal anastomoses. Despite their therapeutic benefits, these surgeries can lead to complications, including parastomal hernia, stomal stenosis, and peri-stomal skin complications, all of which significantly impact patients' quality of life. Among these complications, peristomal skin complications (PSCs), in particular, can cause prolonged discomfort and distress.

Internationally, extensive literature has highlighted several factors influencing the occurrence rate of peri-stomal skin complications. These factors include sex, BMI, stoma location, choice of stoma barrier, preoperative stoma marking, and the urgency of the operation. However, there is a notable absence of local data from Taiwan to confirm the applicability of these risk factors to the Taiwanese population. For example, some studies suggest that the fitting of the stoma barrier to the skin plays a role in complication rates, with variables such as patient physique, skin condition, and preoperative stoma marking potentially affecting the fitting, where these factors could vary due to differences in race, geography, or healthcare practices. Thus, this article aims to identify the risk factors associated

Received: May 4, 2024. Accepted: May 22, 2024.
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with PSCs through a single-center retrospective cohort study.

Materials and Methods

A retrospective cohort study was conducted, encompassing patients who underwent stoma creation surgery between January 2018 and February 2021 (Fig. 1). Demographic data, including sex, age, BMI, serum albumin level, post-operative length of stay, diagnosis (malignant or benign disease), were documented. Stoma characteristics were also recorded, including stoma sites further classified as loop, end, or double barrel, stoma dimensions, pre-operative stoma site marking, choice of stoma barrier, and urgency of the surgery. Pre-operative stoma site marking was performed by experienced enterostomal therapists based on their specialization. Stoma dimensions and the occurrence of PSCs were measured and evaluated by these experienced colleagues.

Central to the study design was the comparison of two groups: those with PSCs just before discharge and those without PSCs. The primary endpoint, the incidence of PSCs (including irritant dermatitis, pressure ulceration, and infection), was assessed just before discharge using the standardized SACS^{TM} instrument (ConvaTec, U.K.). This systematic approach ensured uniform classification and evaluation of skin alterations, facilitating data analysis.

Patient characteristics were examined using the chi-square test and Fisher's exact test for categorical variables, and Student's t-test for continuous variables. Continuous variables were presented as mean ± standard deviation to ensure clarity and precision in data reporting. All reported p-values adhered to a two-sided conventional 5% significance level, maintaining robustness and reliability in statistical inference.

Statistical analyses were performed using IBM SPSS Statistics ver. 29.0.1, employing univariate logistic regression to evaluate risk factors with 95% confidence intervals. Factors with a p-value ≤ 0.200 were included in a multivariate logistic regression analysis, enhancing the depth and accuracy of the study findings.

Results

A total of 372 patients were initially included in the study. After screening, 13 patients were excluded due to undergoing procedures other than ileostomy or colostomy, as well as incomplete data, resulting in a final cohort of 359 patients. Among all patients, 16 patients developed peri-stomal skin complications (PSCs), resulting in an incidence rate of 4.7%. Demographic data of the patients are summarized in Table 1. In the group with PSCs, there were more female patients than male patients (87.5% vs. 35.3% in the group without PSCs, $p < 0.001$), more patients with benign disease (50.0% vs. 23.6%, $p = 0.032$), and more patients who underwent emergent surgery (68.8% vs. 31.8%, $p = 0.002$). Additionally, the mean stoma height in patients with PSCs was lower (1.0 ± 0.8 vs. 1.5 ± 0.6, $p = 0.004$). Furthermore, there was no significant statistical difference between the two groups in mean age, mean BMI, stratified BMI by quartile, stoma site, stoma type, mean stoma length and width, pre-operative stoma site marking, and choice of stoma barrier.

Upon univariate analysis (Table 2), several variables were examined to reveal their relationship with PSCs. Notably, female sex exhibited a significantly higher odds ratio (OR) of 12.843 (95% CI: 2.871-57.446; $p < 0.001$) for developing PSCs compared to male sex. Patients with benign disease also had an OR of 3.235 (95% CI: 1.177-8.891; $p = 0.023$). Moreover, emergency surgery played a role in the higher inci-

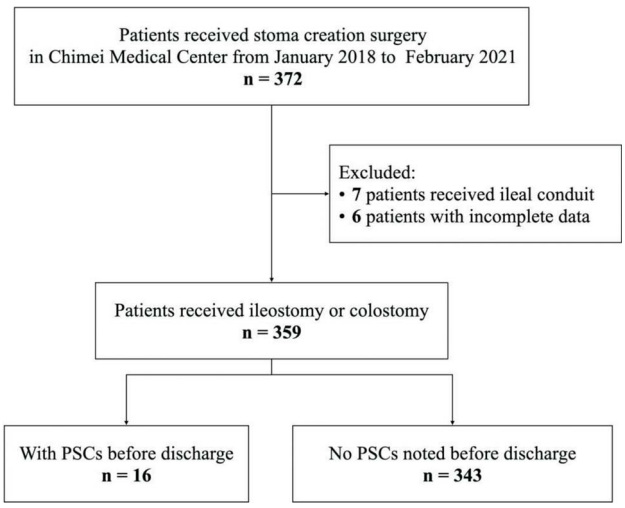

Fig. 1. Flow chart for patient enrollment.

Table 1. Demographic data

	With PSCs (n = 16) n (%)	No PSCs (n = 343) n (%)	p-value
Sex			< 0.001
Male	2 (12.5)	222 (64.7)	
Female	14 (87.5)	121 (35.3)	
Age (mean ± SD)	60.9 ± 14.4	62.5 ± 12.6	0.638
BMI (mean ± SD)	22.6 ± 3.5	23.3 ± 4.1	0.498
BMI (quartile)			0.914
≤ Q1	4 (25)	86 (25.1)	
Q1-Q2	5 (31.3)	85 (24.8)	
Q2-Q3	3 (18.8)	87 (25.4)	
> Q3	4 (25)	85 (24.8)	
ECOG			0.935
0	9 (56.3)	227 (66.2)	
1	5 (31.3)	81 (23.6)	
2	2 (12.5)	33 (9.6)	
3	0 (0)	1 (0.3)	
4	0 (0)	01 (0.3)	
Albumin level (g/dL) (mean ± SD)	3.2 ± 0.8	3.3 ± 0.7	0.771
Post-operative length of stay (day) (mean ± SD)	23.0 ± 13.5	18.9 ± 14.2	0.257
Diagnosis			0.032
Malignant	8 (50)	262 (76.4)	
Benign	8 (50)	81 (23.6)	
Stoma site			0.064
Ileostomy	6 (37.5)	214 (62.4)	
Colostomy	10 (62.5)	129 (37.6)	
Stoma type			0.350
Loop	12 (75)	295 (86)	
End	4 (25)	44 (12.8)	
Double barrel	0 (0)	4 (1.2)	
Urgency of surgery			0.002
Elective	5 (31.3)	234 (68.2)	
Emergency	11 (68.8)	109 (31.8)	
Stoma length (cm) (mean ± SD)	4.1 ± 1.1	4.0 ± 1.3	0.685
Stoma width (cm) (mean ± SD)	2.8 ± 1.1	2.9 ± 1.1	0.533
Stoma height (cm) (mean ± SD)	1.0 ± 0.8	1.5 ± 0.6	0.004
Stoma site marking			0.080
No	1 (6.3)	250 (72.9)	
Yes	15 (93.8)	93 (27.1)	
Stoma barrier			0.270
Conventional	9 (56.3)	145 (42.3)	
Moldable	7 (43.8)	198 (57.7)	

PSCs, peri-stomal skin complications; BMI, body mass index; Q1, first quartile; Q2, second quartile; Q3, third quartile.

dence of PSCs, with an OR of 4.723 (95% CI: 1.602-13.925; p = 0.005). However, colostomy did not indicate a lower incidence of PSCs, with an OR of 2.765 (95% CI: 0.982-7.787; p = 0.054), despite lacking statistical significance. In contrast, stoma height exhibited a noteworthy association, with an OR of 0.295 (95% CI: 0.126-0.691; p = 0.005), indicating it as a protective factor against the development of PSCs. Additionally, pre-operative stoma site marking also demonstrated an OR of 0.179 (95% CI: 0.023-1.376; p = 0.098), revealing it as a potential protective factor even without statistical significance.

Table 2. Univariate analysis of factors associated with PSCs

	OR	95% CI	*p*-value
Female sex	12.843	2.871-57.446	< 0.001
Age	0.991	0.953-1.030	0.637
BMI	0.956	0.839-1.089	0.497
ECOG	1.233	0.643-2.361	0.529
Albumin level	0.900	0.441-1.833	0.771
Post-operative length of stay	1.016	0.988-1.044	0.262
Benign disease	3.235	1.177-8.891	0.023
Colostomy	2.765	0.982-7.787	0.054
Stoma type	1.670	0.591-4.722	0.333
Emergency surgery	4.723	1.602-13.925	0.005
Stoma length (cm)	0.907	0.567-1.451	0.684
Stoma width (cm)	0.849	0.509-1.418	0.533
Stoma height (cm)	0.295	0.126-0.691	0.005
Pre-operative marking	0.179	0.023-1.376	0.098
Moldable stoma barrier	0.570	0.207-1.565	0.275

Moreover, the multivariate analysis (Table 3) confirmed the significant impact of female sex and emergent surgery on PSCs, with an OR of 12.489 (95% CI: 1.486-11.157; $p = 0.001$) and 3.754 (95% CI: 1.154-12.209; $p = 0.028$), respectively. The benign diagnosis and stoma height did not achieve statistical significance in the multivariate analysis.

Discussion

When we focused on the factors that cause PSCs, all the factors we talked about are linked to the leakage of the pouching system.[1] Leakage from stomas stands out as a primary risk factor for PSCs. If the ill-fitting between stoma barrier and the skin occurs, stoma output may accumulate in the dead space midway. The direct contact of the stoma output to the skin contribute to significantly higher risk of PSCs, as the effluent causes irritation to the skin. Factors such as BMI, emergency surgery, pre-operative stoma site marking and stoma height could affect the rate of stoma leakage.

The protective effect of preoperative stoma site marking lies in its ability to determine the optimal location on the abdominal wall. This optimal placement ensures a better fit of the stoma barrier with the skin, thereby reducing the risk of stoma effluent leakage and preventing further skin damage. Millan M. et al. revealed that the absence of preoperative stoma site marking, whether in elective or emergent surgeries, increases the likelihood of developing PSCs.[2] This finding aligns with our own results, which showed that the risk of PSCs was over three times higher in patients undergoing emergency surgery compared to those undergoing elective surgery. Although emergency surgery emerges as an independent risk factor for causing PSCs,[2,3] and this finding was further validated in our study, the etiology behind the higher incidence of PSCs in patients undergoing emergency surgery remains unclear. Notably, only 36.4% of patients undergoing elective surgery received preoperative stoma site marking in our study, whereas this figure was merely 5.8% among patients undergoing emergency surgery. Preoperative stoma site marking may still play a significant role in influencing the outcomes of emergency surgery, and further research is needed to explore the relationship and underlying mechanisms.

Persson et al. found that a low stomal height has a significant association with PSCs. Higher stoma height could avoid dislocation of the stoma barrier, thus facilitates firm attachment with the skin and keep the skin way from effluent leakage. An ileostomy with height lower than 20 mm and a colostomy lower than 5 mm could make skin problems take place easier.[4]

In our study, female patients present a twelve times higher risk than male patients to develop PSCs. However, the association between sex and PSCs remains a topic of debate. Ratliff et al. observed a four-fold increase in leakage among females compared to males.[5] Additionally, certain studies have reported a higher incidence of irritant contact dermatitis, hyperplasia, and peristomal hernias among female patients.[6] Despite these significant findings, there has been no study to date that definitively explains why women are more susceptible to leakage. Conversely, some studies have suggested that male patients are more

Table 3. Multivariate analysis of factors associated with PSCs

	OR	95% CI	*p*-value
Female sex	12.489	2.722-57.313	0.001
Benign disease	1.765	0.565-5.511	0.328
Emergency surgery	3.754	1.154-12.209	0.028
Stoma height (cm)	0.428	0.173-1.060	0.196

vulnerable to PSCs[7] and some studies also disclosed negative relationship between sex and PSCs.[8]

For obese patients, two factors may contribute to the increased incidence of PSCs. Firstly, the creasing of the abdominal wall in these patients can lead to poor fitting of the stoma barrier with the skin, creating dead space as previously mentioned. This facilitates the occurrence of PSCs. Secondly, obese patients tend to have thicker and shorter mesentery. Once the stoma is formed, there is a higher chance of poor stomal perfusion, resulting in ischemic changes and stoma retraction.[9,10] This may also lead to leakage and subsequent PSCs. However, our study did not reveal a significant association between BMI and the incidence of PSCs, even when stratifying BMI into quartiles. One possible reason for this could be that the BMI of our patients mostly did not meet the criteria for obesity in Taiwan (BMI ≥ 27.0 kg/m^2), leading to this discrepancy.

Several limitations should be acknowledged in our study. First, the sample size was relatively small, which may affect the generalizability of our findings. Second, the study design was observational, limiting our ability to establish causality. Third, we did not account for all potential confounding variables, such as the specific techniques used by different surgeons, which could influence outcomes.

Future studies should aim to confirm our findings in larger, more diverse patient populations and explore additional factors that may influence PSCs. Randomized controlled trials could provide more definitive evidence regarding the efficacy of stoma height adjustment and other preventive measures. Additionally, investigating the underlying mechanisms contributing to the higher risk in female patients and those undergoing emergency surgery would further enhance our understanding and management of these complications.

Conclusion

Our study identified two significant risk factors for developing PSCs: female sex and emergency surgery. Additionally, factors such as stoma height and preoperative stoma site marking may serve as protective factors against these complications. In other words, female patients and those undergoing emergency surgery require special attention during stoma care. Furthermore, we strongly suggest making preoperative stoma site marking a routine procedure, regardless of whether the surgery is elective or emergency. Increasing the height of the stoma during surgery may also help reduce the incidence of peristomal skin complications.

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原　著

造口周圍皮膚併發症之風險因子：單一中心回溯性世代研究

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目的　對於一些腸胃道疾病的患者而言，腸造口手術是治療的必要手段，但不可避免的也會導致相關併發症。其中，造口周圍皮膚併發症更是會顯著的影響患者的生活品質。本研究旨在找出有哪些危險因子和造口周圍皮膚併發症有相關性。

方法　我們以奇美醫療財團法人奇美醫院的數據進行了一項回溯性世代研究，分析了 359 名患者的人口特徵、造口相關參數和造口周圍皮膚併發症的發生率。

結果　結果顯示，造口周圍皮膚併發症發生率為 4.7%，女性和接受緊急手術的患者都具有更高的相關風險。在研究中也發現，雖然造口高度和術前皮膚定位皆可能是保護因子，但並未達到統計學上的顯著意義。

結論　對於接受造口手術的女性及緊急手術患者，我們應該加強其造口手術術後的皮膚照護。我們也建議無論是常規或緊急手術，皆應幫患者進行術前皮膚定位，若情況允許，在術中也應盡量加高造口高度，來降低皮膚併發症的發生率。

關鍵詞　造口周圍皮膚併發症、造口手術、迴腸造口、結腸造口。