

THE RISK FACTORS FOR PARASTOMAL HERNIA DEVELOPMENT: A 8-YEAR RETROSPECTIVE STUDY IN COLORECTAL SURGERY

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Received: 26.12.2022; **Accepted:** 29.03.2023; **Available Online Date:** 31.05.2023

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Cite this article as: Bisgin T, Ayik C, Cenan D, Manoglu B, Sokmen S, The Risk Factors for Parastomal Hernia Development: A 8-year Retrospective Study in Colorectal Surgery. J Basic Clin Health Sci 2023; 7: 773-781.

ABSTRACT

Purpose: Although parastomal hernia is a common complication of ostomy surgery, the exact risk factors for its development remain unclear. The aim of this study was to determine the incidence and risk factors of parastomal hernia in ostomy patients.

Material and Methods: A retrospective study was conducted. The data from a cohort of 952 ostomy patients' hospital records between 2013 and 2020 were extracted and analyzed. Patients' ostomy-related characteristics, complication notes, and the occurrence of parastomal hernia were retrieved.

Results: The patients' mean age was 59.6 years (± 14.4 years), and 524 (55%) of them were male. Colorectal cancer (476 patients, 50%) was the most common etiology for surgery. Parastomal hernia developed in 100 (10.5%) of patients. Age >65 (OR=1.753; 95%CI=1.071-2.869), BMI >24.9 (OR=2.009; 95%CI=1.201-3.362), co-morbidity (OR=1.773; 95%CI=1.021-3.080), laparoscopic surgery (OR=5.643; 95%CI=3.113-10.230), height of ostomy (OR=1.906; 95%CI=1.122-3.236), left lower quadrant ostomy location (OR=2.252; 95%CI=1.319-3.845), prolapse (OR=7.876; 95%CI=3.571-17.372), and other ostomy-related complications (OR=2.888; 95%CI=1.179-7.074) were risk factors based on logistic regression analysis.

Conclusion: The incidence of parastomal hernia was nearly one in ten patients after colorectal surgery with an ostomy. Advanced age, co-morbidity, laparoscopic surgery, the height of the ostomy, the left lower quadrant ostomy location, prolapse, and other ostomy-related complications were independent risk factors.

Keywords: Parastomal hernia, ostomy, stoma, colorectal surgery

INTRODUCTION

Parastomal hernia (PSH), defined as an incisional hernia at the site of an intestinal ostomy, is a common complication that occurs in 4–48% of ostomy

surgeries (1-3). Even though PSHs can be asymptomatic, a substantial proportion of patients with PSHs report a low quality of life (4). Peristomal dermatitis, pain, and problems with ostomy

appliances that result in leakage are common symptoms associated with PSH. Additionally, it can result in life-threatening consequences such as obstruction, perforation, and strangulation (1, 5, 6). These surgical emergencies are associated with higher morbidity and mortality as well as a decline in quality of life (4, 7).

The repair methods for PSH include a primary suture of the defect, stoma relocation, and mesh repair (1). The risk of recurrence of PSH is approximately 70% after a primary suture repair and 20% after a mesh repair (8-10). Unfortunately, stoma relocation is also associated with the risk of PSH in the new location and the risk of incisional hernia in the area of the closed ostomy, with reported recurrence rates between 24 and 86% (11). PSH repair is technically challenging and is associated with increased morbidity. Some authors have suggested that placing a "preventive" parastomal mesh during ostomy formation reduces the risk of PSH occurrence (12-14). However, mesh insertion can lead to severe complications such as wound infection, dense adhesions, difficult-to-treat fistulas, and obstruction. Besides, a multicenter randomised trial did not support the use of a reinforcing mesh for preventive or prophylactic purposes because it had no impact on the incidence of PSH (15). Since preventing PSHs is preferable to treating them, it is crucial to identify their risk factors.

Age, female gender, obesity, diabetes, wound infection, aperture size, laparoscopic procedure, and transperitoneal route have been considered to increase the risk of PSH, but their precise roles remain controversial (1, 16-19). Verifying the risk factors for the development of PSH can help avoid hernia/mesh repair-related complications, enhance the quality of life, and reduce medical costs. The aim of this study was to determine the incidence and risk factors of PSHs in colorectal surgery..

MATERIAL AND METHODS

The Study Design and Patients

This was a retrospective cohort study examining the hospital archival records of ostomy patients followed in the stoma therapy unit of Dokuz Eylul University between January 2013 and December 2020. This research was reported using the STROBE checklist (20). All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committees and

with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the Dokuz Eylul University, Non-Invasive Research Ethics Committee (Approval Date: 10.11.2021, Number: 2021/32-12). All patients gave their written consent both for the surgery and to participate in the study.

A chart review was created to include hospital records in the study. The eligibility of consecutive patient hospital records (n=1714) was initially evaluated using the sample inclusion criteria. The inclusion criteria were to be older than 18 years of age, to have an ostomy after colorectal surgery, and to be followed up in the outpatient clinic at least three times after discharge. The forms of patients who did not follow up after ostomy creation and had missing information were excluded from the study. The final study sample consisted of 952 patient records after the exclusion of 61 forms with missing information and patients lost to follow-up.

Sample Size

From a preliminary analysis of the patient records, it was estimated that there were approximately 200 patient records per year. All patient files were reviewed in order to determine the incidence more accurately and to reach the maximum number of patients who were diagnosed with PSH. Therefore, a prior power analysis was not performed. G-Power version 3.0.10 was used to determine the post-power analysis of this study. The power of the study was revealed to be 99% based on the results of the regression analysis with an alpha of 0.05 and a two-tailed test.

Surgical Technique for Ostomy Creation

All ostomies were created in the middle of the rectus abdominis muscle via a transperitoneal route. Initially, a circular incision was made in the area of skin defined for the ostomy. The anterior rectal sheath was cut in a cruciform manner. The rectus abdominis muscle was split in the middle to reveal the posterior rectal sheath. This structure, along with the peritoneum, was longitudinally cut. The intestine stump was then grasped with Babcock forceps and pulled through the skin incision. The ostomies were then fixed with Vicryl 3-0 (Ethicon, Inc., Somerville, NJ) sutures after being matured by mucocutaneous eversion.

Outcome Measures and Data Acquisition

After the creation of ostomy surgery, patients were trained in ostomy care and scheduled for outpatient follow-up by three wound, ostomy, and continence (WOC) nurses and physicians. WOC nurses evaluated patients in terms of the condition of the ostomy and complications during follow-up outpatient visits, and they recorded physical examination findings and ostomy complications on hospital record forms.

Hospital records, including patients' characteristics, outpatient follow-up, and complication notes, were extracted, anonymized, and recorded in a secure database. The primary outcome variable was PSH's presence or absence. PSH was defined as a defect in the abdominal fascia that allowed the intestine to bulge or herniate into the parastomal area. PSH was initially evaluated by physical examination (while supine or erect and performing the Valsalva manoeuvre) and confirmed by a computed tomography (CT) scan. Factors such as gender, body mass index, co-morbidities, smoking status, preoperative neo-adjuvant chemo-radiotherapy, type of ostomy (end/loop colostomy, end/loop ileostomy), the reason for ostomy creation, marking of the stoma site in the preoperative period, type of surgery (emergency or elective), approach type (laparoscopy or open), the height of ostomy, the aperture size of ostomy, other ostomy-related complications, and stomal prolapse were examined to determine the factors causing PSH. The height of the ostomy, the aperture size of the ostomy, and complications were assessed by WOC nurses. The height of the ostomy was determined by measuring its maximum height from the surface of the skin. Using a special instrument frequently used by WOC nurses, the aperture size of all ostomies was measured in millimetres. The instrument consists of a ring with a central hole. The aperture size of the ostomy was determined by placing the instrument on the mucocutaneous line and reading the measurement in millimetres on the device. The height and aperture size of the ostomy were assessed and recorded on the first postoperative day during the initial patient encounter. Valid and reliable definitions were used to identify complications (21). Prolapse was defined as the term for the intestine telescoping through the stoma. Peristomal skin complications were defined as disruptions of skin integrity such as redness, epidermis loss, warmth, itchiness, or pain. Other

ostomy-related complications were classified as stenosis, fistula, and retraction.

Validity and Reliability

The PSH diagnosis in the patient records should have been accurate. Thus, PSH was determined both on paper (physical examination notes) and digitally (CT scan). In addition, a protocol for data extraction using graph review was developed prior to data collection based on previous research (16, 19, 21, 22). Two researchers (CA and DC) meticulously checked and reviewed all the data to ensure its validity and dependability. The analysis did not include missing data. Confounding factors were also taken into account using advanced statistical analysis. The assumptions of observations being dependent and independent variables being linearly related to logic were verified and met before analyzing logistic regression.

Statistical Analysis

The data were analyzed using the SPSS 22.0 program. Absolute values and percentages were used to represent categorical data. Chi-squared and t-tests were utilized to determine the relationship between each independent variable and PSH. The variables' ability to predict the development of PSH was evaluated using a logistic regression model. According to the literature and taking univariate analyses into consideration, the predictor variables for the logistic regression model were chosen.

RESULTS

Among the 1714 potential ostomy patient records screened for eligibility, 952 (55.5%) were recruited. The mean age of the patients was 59.6 years (\pm 14.4 years), and 524 (55%) of them were male. The mean BMI was 26.50 ± 10.4 kg/m². Colorectal cancer (476 patients, 50%) was the most common etiology for surgery. Six hundred twenty-two (65.3%) patients underwent elective surgery. The most common type of ostomy was an end colostomy, which was performed on 415 (43.6%) patients. The right lower quadrant was the most frequently used location for ostomies in 483 patients (50.7%), followed by the left lower quadrant in 435 patients (45.7%).

PSHs were identified in 100 (10.5%) of the patients. Age ($p=0.002$), BMI > 24.9 kg/m² ($p=0.003$), laparoscopic surgery ($p<0.001$), the aperture size of the ostomy ($p=0.003$, $p=0.002$), end colostomy ($p<0.001$), ostomy location in the left lower quadrant

Table 1. Patient characteristics and risk factors for parastomal hernia formation (univariate analysis)

	Parastomal Hernia -	Parastomal Hernia+	Total	P value
Age (yr)				
<65	529 (92.0)	46 (46.0)	575 (60.4)	.002
>65	323 (85.7)	54 (54.0)	377 (39.6)	
Gender				
Female	390 (45.8)	38 (38.0)	428 (45.0)	.139
Male	462 (54.2)	62 (62.0)	524 (55)	
BMI				
<24.9 kg/m ²	371 (43.5)	28 (28.0)	399 (41.9)	.003
>24.9 kg/m ²	481 (56.5)	72 (72.0)	553 (58.1)	
Comorbidity				
No	321 (37.7)	28 (28.0)	349 (36.7)	.057
Yes	531 (62.3)	72 (72.0)	603 (63.3)	
Smoking				
No	400 (46.9)	51 (51.0)	451 (47.4)	.443
Yes	452 (53.1)	49 (49.0)	501 (52.6)	
Preoperative CT&RT				
No	426 (50.0)	52 (52.0)	478 (50.2)	.705
Yes	426 (50.0)	48 (48.0)	474 (49.8)	
Preoperative stoma site marking				
No	535 (62.8)	62 (62.0)	597 (62.7)	.877
Yes	317 (37.2)	38 (38.0)	355 (37.3)	
Aetiology of disease				
Benign	330 (38.7)	42 (42.0)	372 (39.1)	.526
Malign	522 (61.3)	58 (58.0)	580 (60.9)	
Indication of surgery				
Colorectal cancer	431 (50.6)	45 (45.0)	476 (50.0)	.290
Other	421 (49.4)	55 (55.0)	476 (50.0)	
Type of the surgery				
Elective	560 (65.7)	62 (62.0)	622 (65.3)	.459
Emergency	292 (34.3)	38 (38.0)	330 (34.7)	
Type of approach				
Laparoscopic	59 (6.9)	29 (29.0)	88 (9.2)	< .001
Open	793 (93.1)	71 (71.0)	864 (90.8)	
Type of the ostomy				
End colostomy	349 (41)	66 (66)	415 (43.6)	< .001
Loop colostomy	50 (5.9)	5 (5)	55 (5.8)	
End ileostomy	241 (28.3)	13 (13)	254 (26.7)	
Loop ileostomy	212 (24.9)	16 (16)	228 (23.9)	
Ostomy location				
Left lower	368 (43.2)	67 (67)	435 (45.7)	< .001
Right lower	453 (53.2)	30 (30)	483 (50.7)	
Left upper	15 (1.8)	3 (3)	18 (1.9)	
Right upper	16 (1.9)	0 (0)	16 (1.7)	
Aperture size of ostomy (mm)				
Horizontal (mm)	37.01 ± 6.89	39.23 ± 7.75	37.24 ± 7.02	.003
Vertical (mm)	42.65 ± 7.62	45.23 ± 8.02	42.92 ± 7.70	.002
Height of ostomy				
< 10 mm	344 (40.4)	56 (56.0)	400 (42.0)	.003
> 10 mm	508 (59.6)	44 (44.0)	552 (58.0)	
Peristomal skin complications				
No	632 (74.2)	67 (67.0)	699 (73.4)	.124
Yes	220 (25.8)	33 (33.0)	253 (26.6)	
Stomal prolapse				
No	829 (97.3)	83 (83.0)	912 (95.8)	< .001
Yes	23 (2.7)	17 (17.0)	40 (4.2)	
Other ostomy-related complications*				
No	818 (96.0)	90 (90.0)	908 (95.4)	.019
Yes	34 (4.0)	10 (10.0)	44 (4.6)	
Total	852 (100)	100 (100)	952 (100)	

BMI: Body Mass Index, CT Chemotherapy, RT: Radiotherapy) *Fisher exact test was used.

Table 2. The complications associated with ostomy.

	Total	
	(n)	%
Participants evaluated (n)	952	100
No complication	573	60.2
Peristomal skin complications	253	26.6
Parastomal hernia	100	10.5
Prolapse	40	4.2
Other complications	44	4.6

ostomy-related complications ($p=0.019$), and prolapse ($p<0.001$) were associated with PSH based on univariate analysis. Table 1 presents the demographic and ostomy characteristics of patients according to the development of PSH.

In the late period, 39.2% of patients experienced one or more complications. Among the participants, 4.2% had a prolapse, 10.5% had PSH, and 4.6% had other complications. The complications associated with an ostomy are listed in Table 2.

Logistic regression analysis was conducted to assess whether the seventeen index variables significantly predicted the development of PSH. When seventeen predictor variables are considered together, they significantly predict whether or not PSH is developed ($X^2 = 125.188$, $df=17$, $p<0.001$). Table 3 presents the odd ratios, which suggest that the odds of PSH were increasingly greater as age > 65 (OR=1.753; 95%CI=1.071-2.869), BMI>24.9 (OR=2.009; 95%CI=1.201-3.362), co-morbidity (OR=1.773; 95%CI=1.021-3.080), laparoscopic surgery (OR=5.643; 95%CI=3.113-10.230), the height of ostomy (OR=1.906; 95%CI=1.122-3.236), left lower quadrant ostomy location (OR=2.252; 95%CI=1.319-3.845), prolapse (OR=7.876; 95%CI=3.571-17.372), and other ostomy-related complications (OR=2.888; 95%CI=1.179-7.074).

DISCUSSION

This study determined the incidence of parastomal hernia and identified risk factors associated with its development. Understanding the risk factors for PSH is crucial because the surgical team can potentially reduce the incidence of related complications, improve quality of life, and reduce medical costs. In this study, the incidence of PSH was 10.5%; however, the actual incidence may have been higher, as only symptomatic patients were included. We

demonstrated that age > 65 years old, BMI > 24.9, co-morbidity, laparoscopic approach, the height of ostomy < 10 mm, ostomy location in the left lower quadrant, stomal prolapse, and other ostomy-related complications were all significantly associated with PSH formation.

PSH formation may be influenced by both patient-related and technical factors. In numerous studies, a correlation between PSH and patient-related factors such as age (3, 14, 17, 18, 23, 24), obesity (16–18, 25–27, 28), and female gender (17, 18) has been well documented. However, a recent meta-analysis demonstrated that smoking, end colostomies, emergency surgery, no preoperative stoma site marking, diabetes, hypertension, peristomal infection, severe cough, operation time, and surgical techniques were risk factors for PSH in individual studies. It also suggested that more research is required to approve these risk factors (17). Therefore, it is thought that the results of this study will shed light on the literature.

A recent meta-analysis showed that older age is a risk factor for PSH (17). The authors suggested that this may be due to the thinning of the abdominal muscles, weakening of muscle strength, and increased thickness of subcutaneous fat with the increasing age of the patient. However, only three studies (7,14,18) identified the age threshold as a risk factor for PSH (≥ 60 years, ≥ 65 years, or ≥ 75 years). We reported that the risk of developing PSH increases with age over 65. Considering the lack of evidence that age stratification is a risk factor for PSH, our study may contribute to the literature.

Obesity has been proven to influence PSH formation. This may be because obese patients have thicker abdominal subcutaneous fat, thinner abdominal wall muscles, and higher intra-abdominal pressure (17, 30). Consistent with previous research, this study defined obesity as having a BMI ≥ 25 kg/m², which is considered a significant risk factor for the development of PSH (7, 31). Co-morbidities such as diabetes (18) and chronic obstructive pulmonary disease (1, 29) have been shown to be factors in the development of PSH. This study did not examine co-morbidities under subheadings, which may be considered one of its limitations. Despite this fact, the results of this study demonstrated that the presence of any co-morbid disease significantly increased the risk of developing PSH.

Some studies had reported an increased risk of PSH following laparoscopic surgery (16, 19, 23, 32, 33),

Table 3. Independent significant factors predicting parastomal hernia formation (multivariate analysis)

Variable	Peristomal Hernia		
	Odds ratio	Confidence Interval	P value
Age >65	1.753	1.071-2.869	.025
Gender	1.530	.943-2.482	<i>.085</i>
BMI >24.9 kg/m ²	2.009	1.201-3.362	.008
Comorbidity	1.773	1.021-3.080	.042
Smoking	1.182	.735-1.901	<i>.490</i>
Benign/malign	1.089	.629-1.886	<i>.761</i>
Stoma site marking	1.157	.663-2.017	<i>.608</i>
Elective/emergency	.793	.435-1.443	<i>.447</i>
Laparoscopic approach	5.643	3.113-10.230	< .001
Height of ostomy < 10mm	1.906	1.122-3.236	.017
Left lower ostomy location	2.252	1.319-3.845	.003
Type of ostomy (end/loop)	.782	.417-1.465	<i>.443</i>
Aperture size of ostomy-horizontal (mm)	1.025	.980-1.072	<i>.276</i>
Aperture size of ostomy-vertical (mm)	1.029	.979-1.081	<i>.263</i>
Prolapse	7.876	3.571-17.372	< .001
Peristomal skin complications	1.251	.735-2.127	<i>.409</i>
Other ostomy-related complications	2.888	1.179-7.074	.020
Constant	.004		< .001
Hosmer and Lemeshow Test: .747 Nagelkerke R Square: .252 p: < .001 X ² = 125.1888 df= 17			

(BMI: Body Mass Index)

whereas others had found no association (5). This study revealed a statistically significant association between PSH and the laparoscopic approach. Shiraishi et al. reported in a retrospective study that the laparoscopic approach was associated with the formation of ostomies that did not pass through the middle of the rectus abdominis muscle (19). In the laparoscopic approach, in creating an ostomy, the operating table is usually not flat, but in an upside-down and right-lateral position, pneumoperitoneum may persist. Dislocation of the stoma site and difficulty passing the ostomy through the middle of the rectus abdominis muscle may occur due to the position of the muscle and the pneumoperitoneum. Before creating an ostomy during laparoscopic

surgery at our institution, the patient was not routinely replaced. Regardless of the required time, before creating the site for the passage of the ostomy, it is essential to lay the patient flat and release the pneumoperitoneum. This is the direction in which we intend to modify our routine procedures.

There are many surgical factors that increase the risk of PSH. We found a significant correlation between an ostomy height of less than 10 mm or an ostomy location in the lower left quadrant and the development of PSH. A recent meta-analysis revealed that aperture size was a risk factor for PSH (17). In a different study, the authors hypothesized that an aperture greater than 43 mm was a risk factor for PSH (29). However, current recommendations

state that there is no ideal data on aperture size and recommend minimizing aperture size to ensure adequate blood flow to the intestine (3). Our study revealed that aperture size was not associated with PSH development. Kozan et al. reported that not marking the stoma site preoperatively was a risk factor for PSH. This may be due to the fact that preoperative stoma marking ensures that the ostomy is correctly positioned within the abdominal rectus muscle (27). In addition, the relationship between peristomal skin complications and PSH has been demonstrated in other studies (19, 34). This could be due to frequent pouch leakage caused by PSH, which can cause peristomal skin damage. However, we found no association between preoperative stoma site marking or peristomal skin complications and the development of PSH. Moreover, this study found a significant association between PSH and ostomy-related complications, including stenosis, fistula, and retraction. These complications are often related to improper ostomy placement or construction, which may account for the increased incidence of PSH. The association between PSH and stomal prolapse has been previously demonstrated (19, 35), and the incidence of stomal prolapse was found to be significantly higher in patients with PSH than in patients without PSH in this study.

Our study has some limitations that need to be acknowledged. This study was designed to be a single-institution retrospective trial. Secondly, it only disclosed the results of a specific period. Due to the fact that not every patient was visited after surgery, the PSH rate may be lower than the actual rate. Our findings, on the other hand, demonstrated a clear review of PSH in a relatively large consecutive series.

CONCLUSION

In conclusion, PSH is a common and problematic complication of gastrointestinal surgery, and prevention is preferable to treatment. The prevalence of PSH increases with advancing age, obesity, and the presence of co-morbid conditions. Stomal prolapse and other ostomy-related complications were also significantly associated with PSH. During laparoscopic surgery, the creation of an ostomy requires special consideration. Positioning the operating table flat and releasing the pneumoperitoneum may decrease the incidence of PSH following laparoscopic surgery. Creating an ostomy with proper surgical technique can reduce stoma-related complications and PSH development.

Acknowledgement: None.

Author contributions: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by TB, CA, DC, BM. The first draft of the manuscript was written by TB, CA, DC, BM, DÖ, SS and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Conflict of interests: The authors declare no conflict of interest.

Ethical approval: The study was approved by the Dokuz Eylül University, Non-Invasive Research Ethics Committee (Approval Date: 10.11.2021, Number: 2021/32-12).

Funding The authors received no specific funding for this work.

Peer-review: Externally peer-reviewed.

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