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ORIGINAL PAPER

Parastomal hernia after radical cystectomy. Incidence, natural history and predictive factors – A single center study

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Summary ***Purpose: Parastomal hernia (PH) is one of the most frequent complications after stoma creation. Our objective was to analyze the incidence, evolution and predictive factors of PH in Bricker-type urinary diversion.***
Patients and methods: Case series analysis of 125 patients submitted to radical cystectomy and ileal conduit diversion for cancer in a single center during 2006-2021. Patient's record and imaging tests were reviewed to identify those suffering PH. Moreno-Matías classification was used to define radiological PH (rPH). Demographic and preoperative characteristics of the patients, surgical details and postoperative complications were recorded. Univariate and multivariate analyses were conducted to determine the effect of each predictive variable on the development and progression of PH.
Results: 21.6% of patients developed PH (median follow-up 37 months). Incidence increased with follow-up time (15.2% at 1 year, 20.8% at 2 years). BMI ≥ 25 (Expβ 8.31, 95% CI 1.06-65.18, p = 0.04), previous midline laparotomy (Expβ 6.74, 95% CI 1.14-39.66, p = 0.04) and wound infection (Expβ 3.87, 95% CI 1.21-12.33, p = 0.02) were significantly associated with PH. Half of the patients with hernia had symptoms, 25.9% requiring surgical correction. 46% of type 1 hernias and 40% of type 2 hernias progressed to grade 3 with a median of 11 months. No variable was associated with radiological progression.
Conclusions: This study proved 3 independent factors (overweight, laparotomy and wound infection) that increase the risk of developing PH.

KEY WORDS: *Parastomal hernia; Radical cystectomy; Ileal conduit; Risk factors; Natural history.*

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INTRODUCTION

Bricker ileal conduit is one of the most commonly used urinary diversions in radical cystectomy. Stoma-related complications, with a reported incidence of up to 60% (1), are a major problem because of their negative impact on patients' quality of life (2).

Parastomal hernia (PH), defined as an incisional hernia associated with a stoma in the abdominal wall, is one of the most frequent complications following Bricker urinary diversion (3). Its incidence varies widely depending on the series (4-65%) (4, 5), as a consequence of the heterogeneity of the definitions applied, the follow-up time and the way it is diagnosed.

Clinical parastomal hernia (cPH) is defined as peristomal protrusion through a wall defect detected by physical examination, with the patient in the supine or standing position. One of the most frequently used classifications to define *radiological PH* (rHP) is the one proposed by *Moreno-Matías* and *Serra-Aracil et al*. in 2009 (Figure 1), creating three different categories according to the relationship between the hernia sac and the bowel forming the stoma.

Although most patients remain asymptomatic, up to one third may require surgical repair (4), in most cases due to pain, skin irritation, leakage and, in a small percentage, bowel obstruction.

Most of the information dedicated to PH research comes from the colorectal literature, and there is little data about the natural history and risk factors associated with the development of PH in Bricker-type urinary diversions.

The aim of our study was to analyze the incidence of PH after radical cystectomy with ileal conduit and to describe the evolution and predictive factors.

PATIENTS AND METHODS

Patients

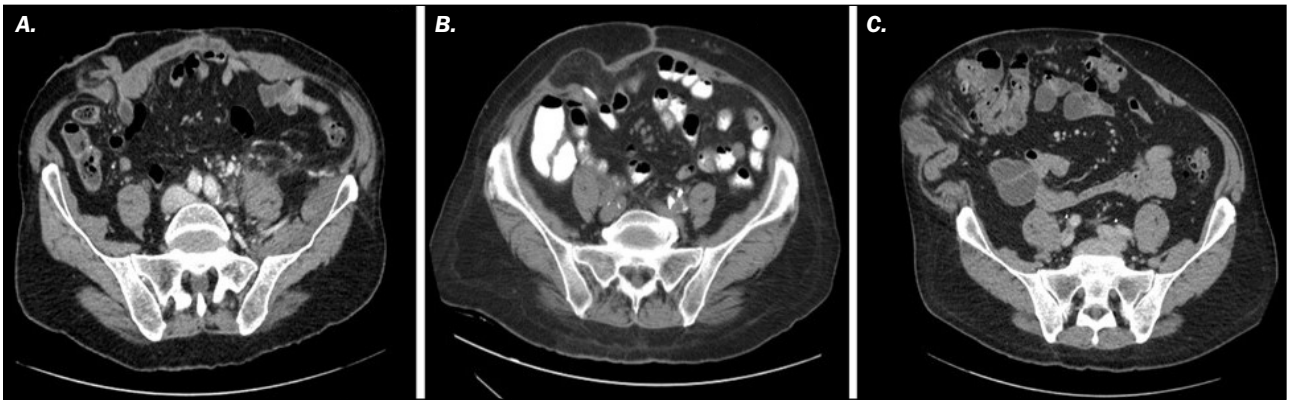
The files of 125 consecutive patients undergoing open or lap radical cystectomy and Bricker urinary diversion at our institution (January 2006-January 2021) were retrospectively reviewed.

Patient records were reviewed to gather any information suggesting the development of PH. Time since the cystectomy, presence of symptoms, and the requirement for surgery and surgical outcome were also gathered.

Demographic data were collected, including age, gender, BMI, HT, DM, COPD, chronic kidney disease, smoking, preoperative hemoglobin and albumin, and history of previous pelvic radiotherapy, abdominal surgery and neoadjuvant chemotherapy.

We also documented the approach (open or laparoscopic), stoma fixation to the rectus aponeurosis, surgical time, days of hospitalization and the application of Fast-track protocol.

Figure 1.
Radiological classification of PH. A) Type 1: hernia sac contains prolapsed bowel forming the stoma.
B) Type 2: PH contains abdominal fat or omentum herniating through the abdominal wall defect created by the stoma.
C) Type 3: hernial sac contains bowel loops.



Additionally, we analyzed the effect of the following complications on the development of PH: evisceration, paralytic ileus, wound infection, transfusion, intestinal and urinary fistula, pelvic abscess and *intensive care unit* (ICU) admission.

Statistical analysis

Uni- and multivariate logistic regression analyses were performed to determine the effect of each predictive variable on the development and progression of PH. Patients with radiological follow-up shorter than 12 months and those with incomplete clinical data were excluded. Statistical analysis was performed using the IBM SPSS Statistics version 20.

Results

Patient characteristics

125 patients undergoing radical cystectomy and Bricker urinary diversion were included in the study. Average age (84.8% male) was 66.2 years (SD 9.4). Table 1 shows the main patients characteristics and univariate and multivariate analyses.

Multivariate analysis detected a significant association between PH and BMI ≥ 25 (Expβ 8.31, 95% CI 1.06-5.18, p = 0.04) and previous abdominal surgery with previous midline laparotomy (Expβ 6.74, 95% CI 1.14-39.66, p = 0.04).

Variable	Overall (n = 125)	Univariate analysis HR (95% CI)	p	Multivariate analysis HR (95% CI)	p
Age, years	66.2 (DE 9.4)	0.97 (0.95-1.05)	0.34		
Gender, n (%)					
Male	106 (84.8)	Reference			
Female	19 (15.2)	0.72 (0.21-2.99)	0.78		
BMI, n (%)					
Normal (BMI < 25)	32 (25.6)	Reference			
Overweight and obesity (BMI ≥ 25)	93 (74.4)	**10.18 (1.31-78.98)**	**0.026**	**8.31 (1.06-65.18)**	**0.04**
Diabetes, n (%)	29 (23.2)	1.18 (0.42-3.41)	0.75		
Hypertension, n (%)	72 (57.6)	1.14 (0.46-2.83)	0.77		
Smoking, n (%)	53 (42.4)	1.59 (0.66-3.86)	0.30		
COPD, n (%)	27 (21.6)	0.45 (0.12-1.72)	0.23		
Chronic kidney disease, n (%)	23 (18.4)	0.58 (016-2.15)	0.42		
Previous midline laparotomy, n (%)	8 (6.4)	**9.30 (1.60-54.34)**	**0.023**	**6.74 (1.14-39.66)**	**0.04**
Previous hernioplasty, n (%)	17 (13.6)	2.10 (0.65-6.92)	0.21		
Pelvic radiotherapy, n (%)	8 (6.4)	0.75 (0.10-6.71)	0.97		
Anemia (Female Hb < 12. Male Hb < 13.8), n (%)	70 (56)	0.59 (0.24-1.44)	0.25		
Hypoalbuminemia (< 3.5 g/dL), n (%)	27 (21.6)	0.65 (0.19-2.15)	0.48		
Pathological stage, n (%)					
≤ T2. N0	50 (40)				
> T2. N0	50 (40)				
Any T, N+	25 (20)				

BMI Body mass index, COPD Chronic obstructive pulmonary disease. Values in bold indicate a p-value < 0.05.

Table 1.
Univariate and multivariate Cox regression analyses of the predictive factors for the development of PH (patient characteristics).

Variable	Overall (n = 125)	Univariate analysis HR (95% CI)	p	Multivariate analysis HR (95% CI)	p
Neoadjuvant chemotherapy, n (%)	49 (39.2)	0.67 (0.26-1.72)	0.41		
Fast-track protocol, n (%)	48 (38.4)	1.41 (0.57-3.44)	0.45		
Approach, n (%)					
Open	103 (82.4)	Reference			
Laparoscopy	22 (17.6)	1.33 (0.43-4.11)	0.61		
Aponeurosis attachment, n (%)	97 (77.6)	0.63 (0.15-3.52)	0.60		
Operating time (> 6h), n (%)	36 (28.8)	**2.57 (1.02-6.47)**	**0.04**	2.38 (0.92-6.17)	0.07
Long length of stay (> 15 days), n (%)	43 (34.4)	1.26 (0.49-3.18)	0.62		
Postoperative complications (first 90 days)					
Evisceration, n (%)	26 (20.8)	1.92 (0.68-5.35)	0.21		
Paralytic ileus, n (%)	58 (46.4)	0.48 (0.19-1.22)	0.12		
Wound infection, n (%)	18 (14.4)	**3.72 (1.22-11.28)**	**0.02**	**3.87 (1.21-12.33)**	**0.02**
Intestinal fistula, n (%)	11 (8.8)	2.00 (0.46-8.63)	0.35		
Urinary fistula, n (%)	22 (17.6)	0.94 (0.28-3.11)	0.92		
Pelvic abscess, n (%)	34 (27.2)	1.15 (0.43-3.09)	0.78		
ICU admission, n (%)	30 (24)	0.56 (0.18-1.81)	0.33		
Polytransfusión (> 5 RBC Concentrates), n (%)	23 (18.4)	0.77 (0.23-2.55)	0.67		
Parenteral nutrition, n (%)	62 (49.6)	0.41 (0.16-1.03)	0.06		
Clavien complication ≥ 3, n (%)	54 (43.2)	1.62 (0.67-3.93)	0.28		

ICU Intensive care unit, RBC red blood cells. Values in bold indicate a p-value < 0.05.

Table 2.
Univariate and multivariate Cox regression analyses of the predictive factors for the development of PH (surgery-related characteristics).

Surgery-related characteristics and postoperative complications

Open approach was the technique of choice (82.4% of the patients). Mean operative time was 322 min (SD 60). Mean hospital stay was 15.9 days [SD 16.7, R (5-122)]. 43.2% (54/125) of the patients presented severe postoperative complications (score 3 or higher on the Clavien-Dindo scale), the most frequent being paralytic ileus.

The main postoperative complications and their effect on the development of PH are described in Table 2.

Univariate analysis showed a significant association between PH and two different variables: prolonged surgical time and surgical wound infection, but only wound infection was confirmed in the multivariate analysis (Expβ 3.87, 95% CI 1.21-12.33, p = 0.02).

PH: diagnosis, symptoms and natural history

21.6 % (27/125) of patients developed PH, with a median follow-up of 37 months (SD 37). Median time to diagnosis was 7 months (SD 6.4). The incidence increased with follow-up time, with an incidence of 15.2% one year after surgery, and 20.8% at two years.

Radiological detection rate was more frequent than the detection after clinical examination (21.6% *vs.* 11.2%, respectively) (Figure 2). Approximately half of the patients with PH (48.2%, 13/27) presented symptoms (Table 3). 76.8% (10/13) of these symptomatic patients, corresponded to grade 2 and 3 hernias, while only 23.2% (3/13) of grade 1 hernias caused symptoms.

7 patients (25.9%) underwent PH correction, surgical repair being significantly higher in patients with grade 3 rPH (HR 4.4, 95% CI 1.06-18.33, p = 0.04). Pain was the main indication for surgery, except in one patient who required emergent surgical intervention due to bowel obstruction. Open approaches were the rule. In 85.7% (6/7) of the patients, a mesh was placed during the repair, while in one case primary closure was performed, with early recurrence at 2 months. One patient required stoma relocation.

Regarding natural history, 46% (5/11) of type 1 hernias and 40% of type 2 (4/10) progressed to type 3 at a median time of 11 months (SD 9.4) (Figure 3). None of the previously described variables were significantly associated with PH progression.

Table 3.
Reported symptoms in 27 patients with clinical or radiological PH.

Patients with PH	n = 27 (%)
Asymptomatic patients	14 (51.8)
Symptomatic patients	13 (48.2)
Pain	10 (37)
Device-related problems (leak, poor adjustment)	4 (14.8)
Skin irritation	3 (11.1)
Aesthetic problems	4 (14.8)
Bowel obstruction	1 (3.7)

Discussion

The *European Hernia Society* (EHS) defines PH as an abnormal protrusion of the contents of the abdominal cavity through an abdominal wall defect created during placement of a colostomy, ileostomy, or ileal conduit stoma (6). This term does not include protrusions caused by atony or paresis of the abdominal wall muscles, but rather true peritoneal sac hernias (3).

PH is the most frequent complication after stoma placement, to the point that many authors consider it an evolutionary consequence and part of the natural history of the stoma (3). Its incidence is difficult to estimate and varies widely in the series [incidence described as 4-65% (4, 5)], due to the heterogeneity in the definition used, the

Figure 2.
PH detected by physical examination.

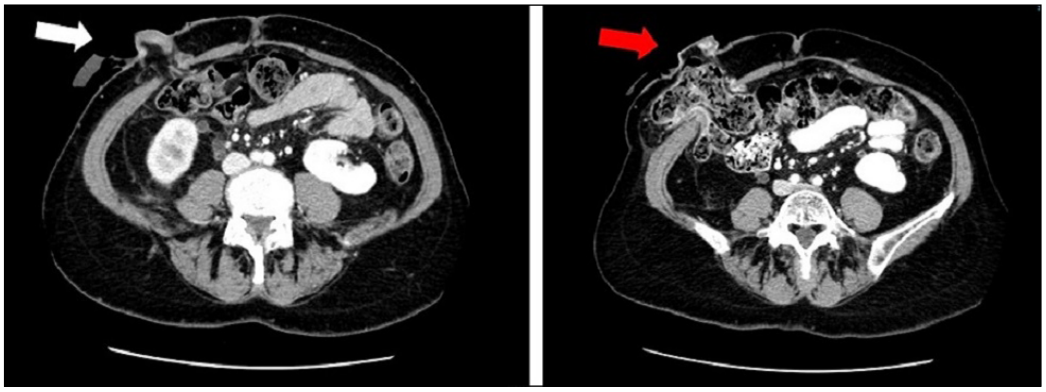


Figure 3.
PH type 2 with radiological progression to type 3 during follow-up.

follow-up time and the way of diagnosis. The type of ostomy also has an important impact on the incidence of PH. Thus, terminal colostomy is the one with the highest rates of hernia, while bowel-dependent ostomies, whether terminal ileostomies, loop ostomies or Bricker-type urinary diversions, are those with the lowest incidence of PH (7). Most of them develop in the first two years following surgery (4, 8-9), but presentation can be delayed up to 20 or 30 years (10).

Diagnosis of PH can be clinical or radiological. Most clinical definitions are based on the finding of a protrusion close to the stoma, but studies differ considerably as how the clinical examination is performed: supine vs. standing, and with or without Valsalva maneuvers. The use of physical examination as a diagnostic tool, especially in retrospective studies underestimates the number of PH, mainly at the expense of low-grade hernia.

Radiological evaluation of the stoma aids the clinical examination improving the detection rate of PH. Radiographic criteria have the advantage of being more objective and less influenced by the patient's body habitus (4). In addition, imaging allows measurement of the size of stoma and hernia sac over time, which is essential in the study of the natural history of PH.

Cingi et al. (11) described a radiographic PH rate (rPH) of 78% and a *clinical PH* rate (cPH) of 52% in a series of 23 patients evaluated by *computed tomography* (CT) and physical examination, supporting the hypothesis that imaging is superior to clinical examination in detecting PH. *Dechao Feng et al.* (12) performed a meta-analysis involving a total of 1878 patients with PH. In this case, the radiological incidence of PH was 23%, while the incidence of clinical PH was 15%. These data agree with those obtained in our series, where radiological detection of PH with CT was higher than those obtained by physical examination (21.6% *vs.* 11.2% respectively).

A frequent concern arising from the increased use of imaging tests is the detection of a higher number of clinically insignificant hernias. Although data are limited, there appears to be good correlation between radiologic diagnosis and symptoms resulting from PH (4).

Seo et al. (13) described the rates of cPH and rPH in 83 patients with terminal colostomy. All patients with type 3 PH had PH on clinical examination and all of them were symptomatic; 80% of type 2 PH were clinically detectable and 75% were symptomatic; and 60% of type 1 PH were detectable on physical examination, with 63% showing symptoms.

In our experience, more than one third (76.8%) of the 13 patients developing symptoms corresponded to grade 2-3 hernias, while only 23.2% of grade 1 hernias were symptomatic. Also, surgical repair, motivated in most cases by pain, was significantly higher in patients with radiological grade 3 PH (HR 4.4, 95% CI 1.06-18.33, p = 0.04).

The etiology of PH is multifactorial, and determined by factors related to the patient and the surgical technique (4-7, 14-15).

Donahue et al. performed a retrospective study of 386 patients undergoing radical cystectomy and ileal diversion (15), with female gender (HR 2.25), BMI (1.08) and preoperative hypoalbuminemia (HR 0.4) accounting for a significant association with the development of PH. In another study involving 58 patients with PH after cystectomy, previous median laparotomy (HR 1.98) and severe obesity BMI > 40 (HR 4) were identified as independent risk factors for PH (5). DM (HR 1.81), *Chronic Obstructive Pulmonary Disease* (HR 1.78) (16) and long operative time (17) have also been shown to predispose to the development of this complication.

The most important modifiable risk factor for PH is obesity, contributing to the weakening of the abdominal wall and thus to the formation of hernias through several mechanisms such as increased intra-abdominal pressure, seroma development, necrosis and wound infection (5, 16).

Regarding technical factors, size and location of the stoma and preoperative stoma site marking by certified ostomy nurse, have been described in the literature as factors that may influence the development of PH after stoma creation (3-5, 15).

The size of the cutaneous and aponeurotic orifice should be wide enough to allow passage of the bowel, but not too large, to avoid the risk of herniation. Several studies have described the correlation between larger stoma diameter and the risk of developing symptomatic PH. For instance, *Seo et al.* (13) reported significant differences in the diameter of the stoma fascial defect in symptomatic versus asymptomatic patients (76.45 mm *vs.* 49.41 mm, p = 0.00) and, furthermore, they observed a significant correlation between the size of the opening and the type of rHP (rHP type 2, 62.69 mm, rHP type 3, 81.01; p = 0.003). Despite this, there is insufficient evidence to define an ideal size preventing the development of hernias. Traditionally, it is estimated that the orifice should not exceed 3 cm in colostomies and 2.5 cm in ileostomies (18), since fascial defects larger than this size can multiply the risk of developing a PH by up to five times (17).

The use of fascial support sutures is a procedure routinely performed in clinical practice despite the lack of evidence of any effect in reducing PH rates. *Pisters et al.* (19) described the impact of anterior fascial fixation sutures in 496 patients undergoing radical cystectomy with ileal conduit at the *MD Anderson Cancer Center*, with a median follow-up of 16 months. Sixty-one patients (12.2%) developed PH. The rate of cPH was significantly higher in patients who had anterior fascial sutures placed compared to those who did not (15.3% *vs.* 7.3%, p = 0.02). Furthermore, they observed that the use of these sutures was an independent risk factor in multivariate analysis for the development of PH (OR 2.3 CI95%, 1.03-5.14; p = 0.04), so they discouraged their use in radical cystectomy with ileal diversion. Moreover, multiple studies in the colorectal literature also advise against facial support sutures, since they have not been shown to reduce PH rates in this type of stoma (15, 20, 21).

Our series confirmed the association between PH and obesity, and previous midline laparotomy, two factors that contribute to weakening the abdominal wall and promote herniation. The other factors previously mentioned as predisposing the development of PH (female sex, DM, hypoalbuminemia, prolonged surgical time, etc. [4-7, 14-17)] did not show a significant association in our series, probably as a consequence of the limited number of cases.

We also observed that PH was significantly more frequent in patients with postoperative surgical wound infection. Although studies in the colorectal literature have previously described this association (20, 21), to our knowledge, this is the first study in the field of urology to link surgical wound infection with PH. This could be explained by the tissue damage and necrosis produced by the infection, which contributes to the weakening of the abdominal wall and therefore to the development of PH.

The pathophysiology and natural history of PH is a poorly studied subject, and most of the available data is derived from the colorectal literature. Radiographic classifications are indispensable, as they provide insight into its evolution, especially regarding changes in size and time to progression to a higher grade in the classification. In our series, radiological progression occurred in 46% of type 1 and 40% of type 2 hernias, with a median time of 11 months (SD 9.4). As in other previously reported studies (16), we found no predictive factors for progression, although the small number of events could also affect the results.

Despite this, only 25.9% of our patients with PH required surgical repair, and only one patient underwent emergency surgery due to intestinal obstruction, a figure similar to the previously reported (9-30%) (4, 5, 15-17). In general, PH surgical correction tends to be postponed due to its extreme complexity and high recurrence rate.

Primary repair and stoma relocation have traditionally been associated with unacceptably high hernia recurrence rates (up to 76%) (10, 20, 21). This figure drops to 10% (21) when a mesh is placed during the surgery, making this procedure the preferred choice. The two main techniques described so far are the Sugarbaker technique (reduction of the contents of the hernial sac and placement of intraperitoneal mesh covering the aponeurotic orifice and the bowel forming the stoma) and the *Keyhole technique* (creation of a hole in the mesh through which the stoma passes). In the colorectal literature, the first one has shown lower recurrence rates (18), although data are limited in patients with ileal diversion.

The high prevalence of PH along with the negative impact on patients' quality of life, morbidity of surgical repair, and high recurrence rates have encouraged urologists to attempt to prevent its development by prophylactic mesh placement at the time of stoma creation. Recently, three prospective randomized trials have demonstrated a significant reduction in the rate of PH by more than 50% with no differences in postoperative complications or mesh-related complications (infection) (22-24). The only difference between the two groups lies in surgical time (median 50

min more in patients with mesh placement). Prospective trials with longer follow-up time are needed, as well as cost-effectiveness studies to evaluate the role of prophylactic mesh in cystectomy and to determine if it should be placed systematically in all patients or only in those with a higher risk of PH (obese patients, female sex, COPD...).
The main limitation of our study lies in its retrospective nature, which may lead to underdiagnosis of clinical PH, mainly low-grade PH (I and II).

Conclusions

Parastomal hernia is a common complication following radical cystectomy and Bricker-type urinary diversion, and can be considered as part of natural evolution after stoma creation. Consideration of the predictive factors can help for patient preoperative optimization and in the planning of surgery. Obesity, wound infection and a history of midline laparotomy represent independent risk factors.

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