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ORIGINAL ARTICLE

Clinical outcomes after parastomal hernia repair with a polyester monofilament composite mesh: a cohort study of 79 consecutive patients

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Abstract

Purpose Different techniques and mesh materials are used in parastomal hernia repair with recently reported recurrence rates ranging from 10 to 28%. The aim of this cohort study was to examine the risk of recurrence and chronic pain after Sugarbaker or keyhole parastomal hernia repair with intraperitoneal placement of a polyester monofilament macroporous composite mesh.

Methods Data on all patients undergoing parastomal hernia repair with Parietex™ Composite Parastomal Mesh at our institution during a 4-year period were examined. Patients with urostomy were excluded. A team of three experienced surgeons performed all repairs. Follow-up including physical examination was done after 10 days, 6 and 12 months, and hereafter as annual structured telephone interviews. Patients suspected of hernia recurrence were offered computed tomography scan. Chronic pain was defined as pain requiring out-patient visit(s) and/or regular use of analgesics.

Results 79 patients (Sugarbaker, $n = 69$; keyhole, $n = 10$) were included. Of those, 72 procedures were performed laparoscopically and seven by open technique. Two patients were reoperated within 30 days with removal of the mesh. In total, seven (9%) patients had parastomal hernia recurrence (reoperation, $n = 3$; conservative management, $n = 4$) during follow-up of median 12 months (range 0–49 months). In univariable logistic analyses, type of stoma was associated with recurrence (ileostomy 28% vs colostomy 3%, $p = 0.007$). Three patients (4%) reported chronic pain.

Conclusion In this study, we found low rates of recurrence and chronic pain following parastomal hernia repair using intraperitoneal reinforcement with a polyester monofilament composite mesh.

Keywords Parastomal hernia repair · Parietex parastomal mesh · Recurrence · Chronic pain

Introduction

Parastomal herniation is the most common complication related to ostomy, occurring in up to 30 and 50% of patients with an ileostomy and colostomy, respectively [1, 2]. In Denmark, around 4000 (0.07%) stomas are created every year with an estimated prevalence of 11,000 (0.2%) [3]. In the USA, a yearly incidence of 120,000 (0.04%) and prevalence of 800,000 (0.25%) has been estimated [4]. Some surgeons have stated that parastomal herniation is unavoidable, given that the ostomy in itself includes a permanent fascial defect [2]. Herniation may negatively affect the patient's quality of life due to stoma care problems, pain, impaired cosmetics or life-threatening events such as strangulation and incarceration [5].

Parastomal hernia repair faces the surgeon with a demanding challenge as to balance the restoration of the parastomal abdominal wall against stoma malfunction. Different repair techniques have been developed over the years, with laparoscopically performed keyhole and Sugarbaker techniques being the most cited in recent years [6].

The aim of this study was to examine the risk of recurrence and chronic pain after Sugarbaker or keyhole parastomal hernia repair with Parietex™ Composite Parastomal Mesh in a series of consecutive patients during a 4-year period.

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Materials and methods

This was a retrospective cohort study with a prospective follow-up including all patients who underwent Sugarbaker or keyhole parastomal hernia repair with intraperitoneal placement of a polyester monofilament macroporous composite mesh between April 2012 and June 2016 at the Digestive Disease Center, Bispebjerg Hospital. This institution serves as a referral center for repair of parastomal hernias in the Capital Region of Copenhagen with about two million inhabitants.

Patient selection

A computed tomography scan is offered all patients who are referred with a clinical suspicion of parastomal herniation. Patients with a radiologically confirmed parastomal hernia are scheduled for an out-patient consultation. The indication for repair may be any parastomal hernia-related symptom, such as pain, soiling or cosmetic issues. The surgeon evaluates the medical comorbidities and physical appearance of the patient, and offers surgical management only to patients assessed sufficiently fit to tolerate the surgical procedure and potential complications. There are no strict exclusion criteria such as an upper body mass index limit, number of previous surgical procedures or episodes of peritonitis. The present hernia-related symptom load is discussed with the patient and compared to the surgical procedure, expected outcome and risk of complications, and hence an informed consent is obtained prior to surgery.

Patient identification

Potentially eligible patients for inclusion were identified through a search in the administrative data of the department for the occurrence of procedure codes KJFG40 (open revision of enterostomy or colostomy) and KJFG41 (laparoscopic revision of enterostomy or colostomy) including all sub-classifications. The procedure notes of the identified patients' medical records were read. All patients who underwent parastomal hernia repair with insertion of a monofilament polyester composite mesh were included. Furthermore, to identify potentially misclassified procedures, a search was performed in the Danish Hernia Database. According to Danish law, the operating surgeon is obligated to prospectively register perioperative data for all ventral hernia repairs including parastomal hernia repairs through an online registration form [7]. Patients not identified through the administrative data of the department were assessed for inclusion eligibility by reading the procedure note. Patient characteristics and data related to the surgical procedure were recorded.

Modified laparoscopic Sugarbaker technique

The operations were performed as described by Hansson et al. [8]. With the patient in the supine position, pneumoperitoneum was established, after which three trocars were introduced. Adhesiolysis was performed as necessary. Any hernia sac content was reduced, followed by sharp mobilization and lateralization of the stoma bowel. A polyester monofilament macroporous composite mesh (Parietex™ Composite Parastomal Mesh, Medtronic, Trevoux, France) with a diameter of 20 cm was introduced to cover the stoma bowel and fascial defect with a minimum overlap of 5 cm in all directions. The visceral side of the implant is covered with collagen to minimize visceral attachment, and a central translucent band in the mesh facilitates identification of the bowel and hernia defect before fixation [9]. The mesh was fixed using 5 mm titanium helical tacks (ProTack™ Fixation Device, Medtronic, North Haven, CT, USA) The tacks were fastened 1 cm apart around the border of the mesh, in addition to adjacent to the course of the stoma bowel, creating a lateral tunnel. If deemed necessary, additional anchoring sutures were likewise placed along the mesh border.

Laparoscopic keyhole technique

After reduction of any hernia sac content, the stoma bowel was encircled with a mesh with a central hole, the "keyhole". A 15 cm Parietex™ Composite Parastomal Mesh with a central hole of 35 mm was used. First, the mesh was given a radial incision, to place the mesh around the stoma bowel. Next, the mesh was fixed with 5 mm titanium helical tacks (ProTack™ Fixation Device) along the outer border, the border of the fascial defect, and the slit. Finally, a stitch (monofilament non-absorbable suture 3-0) was placed centrally to tighten the "keyhole" around the stoma bowel.

Open approach

When laparoscopic surgery was deemed inappropriate, an open approach through a midline incision was performed. The mesh material was placed and fixed as described for the laparoscopic approaches.

Follow-up

Patients who underwent parastomal hernia repair at our department were offered routine clinical examination by specialized stoma care nurses at 10 days, 6 and 12 months postoperatively. Patients were then followed up via a telephone

interview once a year, which was documented in the patient's medical record. The clinical examination and the semi-structured telephone interview uncovered complications related to the stoma, including parastomal hernia recurrence. If a recurrence was suspected, the patient was offered a visit in the office of a colorectal surgeon. Diagnosis of a recurrence was confirmed by a computed tomography scan.

The primary outcome of the study was parastomal hernia recurrence. The secondary outcome was chronic pain, defined as pain requiring out-patient visit(s) and/or regular use of analgesics later than 3 months from index surgery. The follow-up consisted of a manual read of the patients' medical records from the day of surgery until reoperation with removal of the mesh, parastomal hernia recurrence, death or end of study period. It was noted if the patient had any complications within 30 days of surgery. In addition, long-term complications including subcutaneous prolapse, chronic pain or parastomal hernia recurrence were noted.

Statistics

Categorical variables were reported as number (%). Gaussian- and non-Gaussian-distributed continuous variables were reported as mean (sd) and median (range), respectively based on Shapiro–Wilks test of normality. Univariable logistic analyses were performed to compare baseline characteristics and outcomes for keyhole vs. Sugarbaker repair and to determine factors associated with recurrence. Imputation of missing data was not performed. Data management and analyses were made with the statistical software R version 3.1.1 (R Foundation for Statistical Computing, Vienna, Austria). The reporting of the study conforms to the STROBE statement [10]. The Danish Data Protection Agency (ref. BFH-2016-071) and the Danish Patient Safety Authority (ref. 3-3013-1848/1) approved the study.

Results

In total, 79 consecutive patients who underwent parastomal hernia repair with insertion of Parietex™ Composite Parastomal Mesh during a 4-year period were included. A team of three experienced surgeons in an elective setting performed all procedures. The median follow-up was 12 months (range 0–49 months).

The patient characteristics and procedural data are presented in Table 1. 5 of the 10 keyhole procedures (50%) were performed on patients with a colostomy. Preoperatively, these patients were counselled on the increased risk of recurrence associated with the keyhole procedure compared with the Sugarbaker, however, all opted for the former as they wished to continue colostomy irrigation postoperatively. Five of the 19 patients (26%) with an ileostomy underwent the keyhole procedure. In these cases, the Sugarbaker was the planned technique, however, the mesentery was deemed too short to lateralize the stoma bowel satisfactorily. One laparoscopic procedure on a patient with a colostomy was converted to open Sugarbaker repair due to extensive adhesions. In one multi-operated patient with a colostomy, an open Sugarbaker repair was performed due to anticipated gross adhesions. An open Sugarbaker repair was chosen in four other patients with colostomies as concomitant incisional hernia repair was performed. Of these, one patient underwent concomitant incisional hernia repair for a 2 cm fascial defect that was reinforced with an intraperitoneal mesh, and three patients underwent repair for 7 cm fascial defects that were reinforced with a retromuscular mesh (two after unilateral endoscopic component separation). One patient with an ileostomy underwent an open keyhole repair with a concomitant incisional hernia repair with open bilateral component separation reinforced with a retromuscular mesh for a 12 cm fascial defect. Five patients underwent laparoscopic modified Sugarbaker repair with concomitant laparoscopic incisional hernia repair with intraperitoneal mesh reinforcement for fascial defects ranging 2–4 cm. In total, ten (13%) patients underwent parastomal hernia repair with concomitant incisional hernia repair.

Readmission within 30 days occurred for six patients of whom two underwent reoperation (Table 2). One patient with a colostomy undergoing laparoscopic modified Sugarbaker repair underwent reoperation due to subcutaneous abscess formation with a fistula complex from the stoma. The mesh material was removed, the stoma relocated and a Vypro II® mesh was inserted in the retromuscular position. One patient with an ileostomy undergoing laparoscopic Sugarbaker repair experienced stoma obstruction and underwent stoma relocation and removal of the mesh. Follow-up was discontinued at the time of reoperation for these two patients. All other patients who underwent reoperation did not undergo relocation of the stoma or removal of the Parietex™ Composite Parastomal Mesh.

In total, 7 of 77 patients (9%) patients developed recurrence during follow-up. There was no significant difference in the risk of recurrence after keyhole compared to Sugarbaker repair (1/10 = 10% vs. 6/67 = 9%, $p = 1.000$). In explorative univariable logistic analyses for factors associated with recurrence, parastomal hernia repair performed on patients with an ileostomy was associated with an increased risk of recurrence compared with colostomy (5/18 = 28% vs. 2/59 = 3%, $p = 0.007$). We did not identify any other factor associated with an increased risk of recurrence. In a subgroup analysis of patients undergoing laparoscopic modified Sugarbaker repair, type of stoma was likewise the only factor associated with recurrence, ileostomy (4/13 = 31%) vs. colostomy (2/48 = 4%), $p = 0.020$. There was no difference in length of follow-up ($p = 0.936$) or any baseline characteristic for patients

Table 1 Characteristics of 79 consecutive patients undergoing parastomal hernia repair with a polyester monofilament composite mesh according to repair technique

Characteristics	Keyhole $n = 10$	Sugarbaker $n = 69$	Total $n = 79$	p
Male gender	4 (40)	38 (55)	42 (53)	0.580
Age (years)	62.0 (42.6, 79.0)	70.9 (25.0, 89.6)	70.3 (25.0, 89.6)	0.077
BMI, kg/m^2, mean (SD)	27.4 (5.3)	28.3 (5.3)	28.2 (5.3)	0.635
Missing	1	19	20	
Comorbidities				
Diabetes	1 (10)	5 (7)	6 (8)	1.000
Hypertension	3 (30)	25 (36)	28 (35)	0.975
Tobacco use	3 (30)	13 (19)	16 (20)	0.689
Chronic bronchitis	0 (0)	6 (9)	6 (8)	0.740
Indication for stoma formation				0.439
Colonic malignancy	0 (0)	2 (3)	2 (3)	
Rectal malignancy	3 (30)	38 (55)	41 (52)	
Anal malignancy	0 (0)	1 (1)	1 (1)	
Diverticular disease	0 (0)	3 (4)	3 (4)	
Anal fistula	1 (10)	2 (3)	3 (4)	
Inflammatory bowel disease	3 (30)	13 (19)	16 (20)	
Adhesive small bowel obstruction	0 (0)	1 (1)	1 (1)	
Obstructed defecation	2 (20)	2 (3)	4 (5)	
Fecal incontinence	1 (10)	6 (9)	7 (9)	
Congenital anomaly	0 (0)	1 (1)	1 (1)	
Previous abdominal surgery				0.372
One	4 (40)	30 (44)	34 (43)	
Two	1 (10)	18 (26)	19 (24)	
Three or more	5 (50)	21 (30)	26 (33)	
Type of stoma				0.097
Colostomy	5 (50)	55 (80)	60 (76)	
Ileostomy	5 (50)	14 (20)	19 (24)	
Re-repair of parastomal hernia	1 (10)	4 (6)	5 (6)	1.000
Approach				1.000
Laparoscopic	9 (90)	63 (91)	72 (91)	
Open[a]	1 (10)	6 (9)	7 (9)	
Anchoring sutures	4 (40)	39 (57)	43 (54)	0.522
Operative time (min)	90.0 (81.0, 327.0)	77.0 (27.0, 214.0)	82.0 (27.0, 327.0)	0.016
Hospitalization (days)	3.5 (2.0, 8.0)	4.0 (1.0, 36.0)	4.0 (1.0, 36.0)	0.869

The values given are *n* (%) or median (range) unless otherwise stated

BMI body mass index

[a] One procedure converted from laparoscopic approach

with an ileostomy compared with a colostomy. Three (4%) patients reported chronic pain. Six (8%) patients died during follow-up after median 17 months (range 4–24 months), all unrelated to the parastomal hernia repair. The 1-year cumulative mortality incidence was 4% (95% confidence interval 0–9%).

Discussion

Parastomal herniation is a common complication after ostomy creation with potentially invalidating consequences [2]. It is estimated that the prevalence of patients with an ostomy will increase 3% each year [4], which may lead to a growing demand for safe and effective treatment of stoma-related complications in the future. In this study, we found a low risk of complications after parastomal hernia repair with Parietex™ Composite Parastomal Mesh.

Table 2 Short- and long-term complications (before and after 30 days) after parastomal hernia repair with a polyester monofilament composite mesh according to repair technique

Characteristics	Keyhole $n = 10$	Sugarbaker $n = 69$	Total $n = 79$	p
Short-term complications				
Readmission[a]	1 (10)	5 (7)	6 (8)	1.000
Pain	1	3	4	
Abscess	0	2	2	
Reoperation[a]	0 (0)	5 (7)	5 (6)	1.000
Stoma obstruction due to mesh	0	3	3	
Abscess	0	1	1	
Adhesions	0	1	1	
Other complications	1 (10)	4 (6)	5 (6)	1.000
Pneumonia	0	2	2 (3)	
Urinary retention	1	2	3 (4)	
	$n = 10$	$n = 67$	$n = 77$	
Long-term complications[b]				
Subcutaneous prolapse	1 (10)	19 (28)	20 (26)	0.396
Chronic pain	0 (0)	3 (5)	3 (4)	1.000
Recurrence	1 (10)	6 (9)	7 (9)	1.000
Surgically treated	0	3	3	
Conservatively treated	1	3	4	

The values given are n (%)

[a] Two patients were reoperated during readmission and thus appear in both variables

[b] Two patients underwent reoperation with removal of the mesh within 30 days and follow-up was discontinued at the time of reoperation

The laparoscopic approach is usually preferred for parastomal hernia repair, as it is associated with shorter hospital stay and lower risk of overall morbidity [11], however, consensus lacks on mesh type and placement [4]. In the beginning of the century, the keyhole approach was introduced as an appealing and promising new technique [12], but long-term follow-up revealed high recurrence rates, thus giving favor to the laparoscopic Sugarbaker technique whenever suitable [8, 13]. In a recent systematic review and meta-analysis, recurrence rates of 10 and 28% for the modified laparoscopic Sugarbaker and keyhole technique were reported [6]. In this study, we report a favorable recurrence rate of 9 and 10% for the Sugarbaker and keyhole technique, respectively, which demonstrates an excellent outcome compared with the available literature. In our opinion, the low rates relate to centralization, where our department serves as a referral center for this disease, covering a background population of almost two million individuals. Moreover, the small group of consultant surgeons who carried out the procedures had several years of experience before this series of patients were operated on.

In our institution, we have chosen the Parietex™ Composite Parastomal Mesh for this procedure, as the semi-translucency of the mesh gives the surgeon added overview that alleviates mesh placement and fixation to reinforce the abdominal wall without kinking the stoma loop, which potentially may lead to obstruction. Furthermore, the mesh is collagen-coated on the visceral side, which reduces the risk of intraperitoneal adhesions compared with uncoated mesh material [14].

Within 30 days after the hernia repair, five (7%) patients were reoperated on, of whom three (4%) had stoma obstruction. This was slightly less than the 8.5% rate reported in nationwide Danish data [5]. The risk of other short- and long-term complications in our series are comparable to those reported elsewhere, but low incidence rates preclude definite conclusions, and the risk of chronic pain has not been reported previously [6, 15, 16].

Several studies have reported an increased risk of parastomal hernia in relation to a colostomy compared with an ileostomy [1, 4, 17]. It has been hypothesized that the larger fascial aperture size needed for a colostomy could be a causative factor. However, the increased risk could also be due to an effect of time, as a colostomy is less often reversed compared with an ileostomy [18]. Interestingly, we found an increased risk of recurrence for patients with an ileostomy compared with a colostomy, with no difference in length of follow-up. To our knowledge, no studies

have considered stoma type as a potential risk factor for recurrence and reported recurrence rates for non-pooled data [6, 16]. However, further studies are warranted before conclusions are drawn, as our finding might be spurious owing to the explorative nature of the analysis.

This study has some limitations. The insignificant higher recurrence risk after keyhole compared with Sugarbaker repair are prone to type II error due to, in particular, the few keyhole procedures included. Furthermore, the number of recurrences did not allow for multivariable confounder-adjusted analyses [19]. Although the study material was gathered retrospectively, the study is strengthened by a standardized prospective follow-up protocol. To our knowledge, this study represents the largest consecutive series of patients undergoing parastomal hernia repair to date [6].

In this study, data on 79 parastomal hernia repairs with insertion of a polyester monofilament composite mesh was presented. An overall low recurrence rate and acceptable rates of short- and long-term complications were identified. Therefore, this study demonstrated that this mesh material was an excellent choice for parastomal hernia repair performed by experienced surgeons in a high-volume referral center.

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Compliance with ethical standards

Sources of funding None.

Conflict of interest EO has received a travel Grant from Medtronic. LNJ has received fees for educational activities and oral presentations from Medtronic, BARD and Acelity, and received funding for data collection and expert report drafting from Medtronic of the present material. BP has nothing to disclose.

Ethical statement According to Danish law, approval from a local ethics committee was not required.

Statement on human rights For this type of study, formal consent is not required.

Statement on the welfare of animals This article does not contain any studies with animals performed by any of the authors.

Statement on informed consent According to Danish law, informed consent from included individuals are not required for this type of study.

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