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Trangbæk, Rune Munch; Mynster, Tommie

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Prevention of parastomal hernia using mesh in patients undergoing rectum extirpation

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ABSTRACT

INTRODUCTION: Developing a parastomal hernia can lead to emergency surgery and cause discomfort. Placing a prophylactic mesh around the ostomy may potentially prevent hernias from developing. Randomised clinical trials and reviews have reported contradictory results from this prophylactic procedure with different rates of hernias and success. This descriptive cohort study aimed to investigate the rate of parastomal hernia after applying prophylactic mesh in patients undergoing surgery for rectal cancer.

METHODS: In the period from 2010 to 2016, we included 133 patients who had a permanent colostomy with prophylactic mesh placement due to rectal cancer. The patients were seen in the ostomy ambulatory at least three times annually, and bulges and hernias were registered by a trained nurse. Computed tomography was used for verification of parastomal hernia. Data were registered retrospectively from patient files.

RESULTS: After a median follow-up of 22 months, 24% of patients developed a parastomal hernia. Development of parastomal bulge without a subsequent hernia diagnosis was seen in 21%. The one-year rate of parastomal hernia was 9.7%.

CONCLUSIONS: This cohort study supports the thesis of a low short-time rate of parastomal hernia in patients who had a prophylactic mesh placed during the ostomy formation and indicates that the rate of hernia increases over time after the first post-operative year.

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TRIAL REGISTRATION: not relevant.

In 2012, colorectal cancer was the second-most common type of cancer in women and the third-most common type in men [1]. In 2016, 4,896 cases of new colorectal cancer were registered in Denmark, among which 1,461 were rectal cancers [2]. Patients undergoing surgery for low rectal cancer frequently acquire a permanent ostomy. After ostomy surgery, the risk of developing a parastomal hernia (PSH) is 5-78% [3-6]. The presence of a PSH can lead to ostomy leaks, abdominal discomfort, pain and - in the most serious cases - an incarceration requiring emergency surgery. In recent years, surgeons have been applying a prophylactic mesh around the ostomy to prevent the development of PSH. The results are promising, and the procedure has been found safe to use without complications related to the mesh placement [7, 8]. However, contradictory results have been reported, and in 2017 results from three noteworthy studies were published; the PRESTO study, the STOMAMESH study and the PREVENT trial. The PRESTO study was a systematic review of mesh application including eight randomised controlled trials (RCT) and three non-RTCs. The authors found that RCTs showed positive results following the use of a prophylactic mesh with a PSH rate of 0-59% compared with 20-94% in patients without a mesh [9]. The STOMAMESH study, an RCT including 211 patients with follow-up after one year, showed no difference in the rate of PSH between the prophylactic mesh group (30%) and a no-mesh group (33%) [10]. The PREVENT trial was a RCT showing a 4.5% PSH rate in mesh cases compared with a 24.2% PSH rate in no-mesh cases [11]. In the abdominal center at Bispebjerg Hospital, Copenhagen, we have been using prophylactic mesh since 2010 in eligible patients undergoing rectal extirpation due to rectal cancer. The primary outcome of this study was to examine the PSH rate in patients operated for rectal cancer at Bispebjerg Hospital.

METHODS

This is a descriptive retrospective cohort study on elective consecutive patients operated due to low rectal cancer at Bispebjerg Hospital from 2010 to 2016. The patients were identified in the surgery booking system. They were included if they had surgery with permanent ostomy due to rectal cancer and were able to complete at least one year of follow-up in the outpatient clinic. A prophylactic mesh was placed around the ostomy formation. The mesh was placed as a sublay between the posterior sheath of the peritoneum and the rectus abdominis muscle. The size of the mesh was adjusted to fit within the free space of the rectus sheath, allowing for a minimum 3 cm margin from the aperture of the stoma hole. The mesh used was Vypro II fixated with two Vicryl sutures to the sheath. The procedures were all performed by two of the five surgeon consultants affiliated with rectum cancer treatment in our department. All surgery descriptions were examined, and patients who did not have a mesh placement were ex-

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Digestive Disease Center, Bispebjerg Hospital, Denmark

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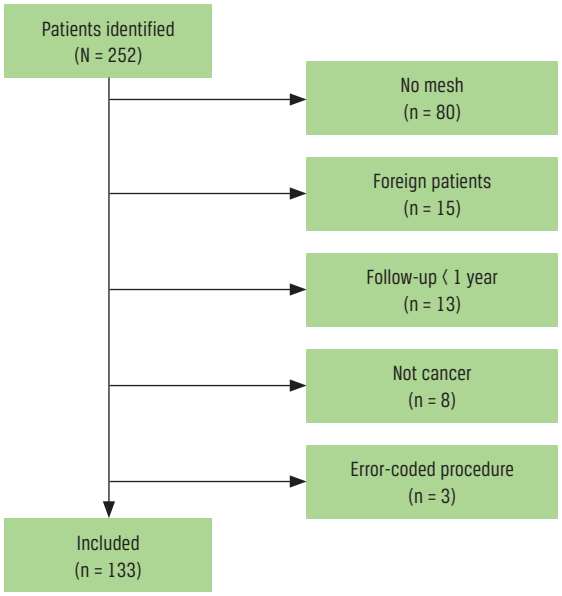
FIGURE 1

Inclusion[a].



a) There was no significant difference between the included and excluded patients in terms of age or gender.

cluded. Patients who did not undergo follow-up in the outpatient clinic for at least one year were excluded. Patient charts were examined for demographic data, comorbidity and downstaging chemotherapy and/or radiation. The Union for International Cancer Control (UICC) staging was extracted from the pathology database in each case. All included patients had three annual follow-up visits in the outpatient ostomy clinic in the course of at least one year, and from the charts we noted whether the patient had developed a parastomal bulge (PSB) or a PSH. A PSH was defined as herniation of intra-abdominal contents (not the ostomy bowel) intimately connected to the ostomy. A PSB was defined as an elevation around the ostomy that was either claimed to have been observed by the patient or suspected by a trained nurse in the stoma outpatient clinic. A PSB could be due to seroma, scar tissue or a subcutaneous prolapse of the ostomy bowel, which is not defined as a hernia [12]. All patients were undergoing annual CT's for three years as part of their cancer control; in case of uncertainty about a bulge, a specific scan for hernia was performed. A radiologist not affiliated with the project was consulted to state the fact of herniation in case of doubt about the classification. In order to investigate a potential surgical learning curve, we compared the PSH rate in the three periods 2010-2012, 2013-2014 and 2015-2016.

Statistics

SPSS 22.0 was used for all statistical analyses. Percentage, range and median values were calculated to describe demographic data and were used as appropriate. For further analysis, age and BMI were dichotomised. To determine and evaluate risk factors for hernia development, we used chi-squared (and Fisher's exact test, as appropriate) for univariate analysis. A p-value < 0.05 was considered significant. As this was a descriptive study, we see no risk of type I or II error.

Trial registration: not relevant.

RESULTS

A total of 133 patients were included over a period of six years (**Figure 1**). Patients were excluded due to a short follow-up, either dropped out of follow-up by choice, died from non-mesh-related causes or moved from the hospital's uptake area. The 80 patients without prophylactic mesh had no mesh placed due to prior surgery with abdominal scaring or because existing hernia or surgery made difficult by intra-abdominal factors did not allow for a safe placement of the mesh. There was no statistical difference in terms of age or gender between the excluded and included patients. In the period from 2010 to 2016, 24% (32 patients) developed a PSH after a median of 22 months of follow-up. The one-year rate for PSH was 9.7% (13 patients). This means that 41% of the developed PSH were diagnosed within the first post-operative year. Of the 13 patients who developed PSH within the first year, 38% had parastomal repair surgery. Demographic data for all included patients are shown in **Table 1**. UICC staged as zero was constructed due to complete downstaging. In the univariate analysis, a BMI ≥ 30 kg/m^2 as well as UICC stage showed a statistically significant difference in patients developing a PSH (Table 1). In the follow-up period, 52 patients (39%) were suspected of having a PSB, and 24 (46%) hereof were diagnosed with PSH after a CT, leaving 28 patients (21%) diagnosed solely with PSB. Univariate analysis of patient-related factors for PSB showed no significant difference (Table 1). In the course of the study period, the one-year rate of PSH did not change significantly over the inclusion period, meaning that we found no learning curve (**Figure 2**). In the follow-up period, 11 patients died, but none of these deaths were related to the prophylactic mesh.

DISCUSSION

The overall hernia rate in this cohort more than doubled from 12 months to a median of 22 months. The increase in PSH over time is supported by prior research and raises the question whether a one-year rate should be the benchmark for comparison [13]. The one-year rate of PSH in this study is lower than the rate found in the STOMAMESH study, but higher than the one reported in the PREVENT trial. Furthermore, we found

that the surgeons' potential learning curve had no impact on the development of PSH in this cohort. PSH may lead to emergency surgery for mechanical obstruction and necrotic intestines. This is an important reason for preventing PSH. In the present cohort, the one-year rate for PSH was 9.7%. The study from Sweden (STOMAMESH) is currently the largest RCT on the use of prophylactic mesh [10]. They found a high one-year rate of PSH of just over 30%, regardless of mesh or no mesh. The cohort in this study is comparable to the STOMAMESH cohort apart from American Society of Anesthetists (ASA) score and smoking status. The Swedish study had a higher ASA score, but fewer smokers. In the present study, we included only patients with surgery due to rectal cancer, whereas the STOMAMESH study included patients with benign conditions of the rectum and colon. This might account for some of the difference in rates that cannot necessarily be explained by the use of mesh. For example; patients with Crohn's disease and diverticulitis might be more prone to the development of PSH after prolonged illness with a higher physiological stress and a poorer wound healing potential. However, we find it hard to imagine that this accounts for the total difference from a 30% to a 10% PSH rate. The PREVENT trial found a lower PSH rate of 4.5% in the group with mesh placement. The patients in the PREVENT trial were almost ten years younger than the patients in our cohort, and that may potentially explain some of the difference. Both the STOMAMESH and the PREVENT trial had sublay positioning of the mesh as did the patients in the present cohort. Other studies have focused on an onlay approach with the mesh placed on the external rectus fascia, or an intraperitoneal approach where the mesh is placed on the inside of the peritoneum in direct contact with the bowel. No larger studies on the prevention of PSH comparing sublay, onlay and intraperitoneal placement have been conducted; however, a study from 2017 suggested that onlay mesh is a better option for the prevention of incisional hernias [14]. We investigated the development of PSB and found that 46% of patients with a PSB in fact did have a PSH, suggesting that all patients diagnosed with a PSB should have radiological assessment to rule out PSH. With respect to PSB only (without PSH), we found no significant differences due to risk factors. Unfortunately, we were unable to subcategorise the different types of PSB as these were not recorded.

Limitations

Overall, a larger study population would have been preferable to gain more statistical power. This study lacks comparison with a control group of patients undergoing the same type of surgery but without receiving a prophylactic mesh. Such a group may have an equal or lower rate of PSH as the mesh group, as was previously shown in an emergency setting in the same hospital [15]. We did not investigate how different sur-

TABLE 1

Demography and hernia and bulge development within median 22 months.

		Developed PSH		Developed solely PSB[a]	
	n (%)	n (%)	p-value	n (%)	p-value
Age[b]			0.38		0.75
≤ 70 yrs	63	13 (21)		14 (22)	
> 70 yrs	70	19 (27)		14 (20)	
BMI[c]			0.03		0.41
< 30 kg/m^2	112	23 (21)		25 (22%)	
≥ 30 kg/m^2	21	9 (43)		3 (14%)	
Sex			0.40		0.08
Male	71 (53)	15 (21)		9 (13)	
Female	62 (47)	17 (27)		19 (31)	
ASA score			0.49		0.82
I	24 (19)	8 (32)		4 (17)	
II	89 (66)	20 (22)		20 (22)	
III	20 (15)	4 (20%)		4 (20)	
Alcohol overuse			0.09		0.55
Yes	24 (18)	9 (38)		4 (17)	
No	109 (82)	23 (21)		24 (22)	
Smoker			0.63		0.65
Yes	29 (22)	6 (21)		7 (24)	
No	104 (77)	26 (25)		21 (20%)	
Diabetes			0.17		0.17
Yes	18 (14)	2 (11)		6 (33)	
No	115 (86)	30 (26)		22 (19)	
Hypertension			0.57		0.52
Yes	64 (48)	14 (22)		15 (23)	
No	69 (52)	18 (26)		13 (19)	
Former hernia			0.81		0.51
Yes	14 (11)	3 (21)		2 (14)	
No	119 (89)	29 (24)		26 (22)	
UICC stage			0.04		0.27
0	6 (5)	1 (17)		1 (17)	
I	36 (27)	15 (42)		6 (17)	
II	33 (25)	7 (21)		10 (30)	
III	40 (30)	3 (8)		10 (25)	
IV	18 (14)	3 (16)		1 (6)	
Downstaging			0.18		0.32
Yes	42 (32)	7 (17)		11 (26)	
No	91 (68)	25 (27)		17 (19)	
Adjuvant chemo			0.85		0.76
Yes	35 (26)	8 (23)		8 (23)	
No	98 (74)	24 (24)		20 (20)	
Laparoscopy			0.34		0.35
Yes	95 (71)	25 (26)		22 (23)	
No	38 (29)	7 (18)		6 (16)	

ASA = American Society of Anesthetists; PSB = parastomal bulge; PSH = parastomal hernia; UICC = Union for International Cancer Control.

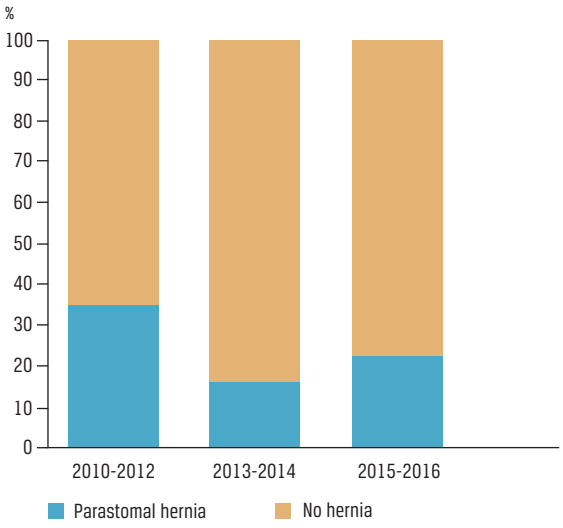
a) Patients who developed PSB without a later development of hernia.

b) Median (range): 71 (32-92) yrs.

c) Median (range): 25 (14-43) kg/m^2

FIGURE 2

Rate of parastomal hernia development during the observation period, p = 0.12.



geons performed the procedures, as the team in our institution has developed a uniform procedure together (always two rectal surgeons). As is evident from the results of the learning curve, it also seemed that placing and securing the mesh was done with uniform effectiveness over time. We were only able to investigate patients who attended the follow-up programme in the out-patient clinic. A total of 15 patients were foreign and were excluded since they did not have documented follow-up visits available for study. The relatively low number of patients in this study makes it difficult to draw conclusions about what places a patient at risk for developing PSH; to avoid type II errors, we did not conclude on the findings from the univariate analysis. Before collecting the data, we had a notion that the PSH rate at our facility was low, which does place us at risk of confirmation bias. However, we do not believe that this has influenced the final results of this study as the statement of hernia needed to be confirmed by an (unbiased) radiological diagnosis in the CT description, or by consultation.

In future studies, it would be interesting to investigate a longer follow-up period since the hernia rate after 22 months was more than twice as high as the one-year rate. Looking at the five-to-ten- year hernia rate, preferably in the context of an RCT, would produce a better understanding of PSH development. It would also be beneficial to compare different placements of the mesh in a larger study to determine which placement is associated with the lowest rate of PSH. Another aspect to consider is whether developing a PSH despite of a prophylactic mesh yields more complications than arise in patients who develop PSH and do not have a mesh. One might hypothesise that surgery to repair the PSH would be harder to perform due to the placed mesh – but also that it could be more effective due to the fibrosis it causes.

CONCLUSIONS

The rate of parastomal hernias develops over time and after almost two years, it was more than doubled compared with the one-year rate. The one-year rate for developing a parastomal hernia after surgical application of prophylactic mesh for rectal cancer is 10% at Bispebjerg Hospital, Copenhagen, Denmark. Patients diagnosed with a parastomal bulge should always receive radiological assessment to rule out hernia. Increased BMI may be a risk factor for developing parastomal hernias, also in patients receiving prophylactic treatment with sublay mesh.

CORRESPONDENCE: *Rune Munch Trangbæk*. E-mail: Runemt@gmail.com
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