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ORIGINAL ARTICLE

Use of a prosthetic mesh to prevent parastomal hernia during laparoscopic abdominoperineal resection: a randomized controlled trial

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Abstract
Purpose Prevention of parastomal hernia represents an important aim when a permanent stoma is necessary. The objective of this work is to assess whether implantation of a prophylactic prosthetic mesh during laparoscopic abdominoperineal resection contributed to reduce the incidence of parastomal hernia.
Methods Rectal cancer patients undergoing elective laparoscopic abdominoperineal resection with permanent colostomy were randomized to placement of a large-pore lightweight mesh in the intraperitoneal/onlay position by the laparoscopic approach (study group) or to the control group (no mesh). Parastomal hernia was defined radiologically by a CT scan performed after 12 months of surgery. The usefulness of subcutaneous fat thickness measured by CT to discriminate patients at risk of parastomal hernia was assessed by ROC curve analysis.
Results Thirty-six patients were randomized, 19 to the mesh group and 17 to the control group. Parastomal hernia was detected in 50 % of patients in the mesh group and in 93.8 % of patients in the control group ($P = 0.008$). The AUC for thickness of the subcutaneous abdominal was 0.819 ($P = 0.004$) and the optimal threshold 23 mm. Subcutaneous fat thickness $\geq$23 mm was a significant predictor of parastomal hernia (odds ratio 15.7, $P = 0.010$), whereas insertion of a mesh was a protective factor (odds ratio 0.06, $P = 0.031$).
Conclusions Use of prophylactic large-pore lightweight mesh in the intraperitoneal/onlay position by a purely laparoscopic approach reduced the incidence of parastomal hernia formation. Subcutaneous fat thickness $\geq$23 mm measured by CT was an independent predictor of parastomal hernia.

Keywords Parastomal · Hernia · Mesh · Prevention · Laparoscopy

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Introduction

Parastomal hernia is a major clinical problem after stoma formation with a reported incidence of up to 50 % when assessed by clinical findings [1] and 78 % with physical examination and computerized tomography (CT) evaluation together [2]. About 11–70 % of patients will require surgical repair of the hernia due to pain, obstruction, bleeding, a growing protrusion, a poorly fitting appliance, fecal leakage, or incarceration [1]. Nowadays, parastomal hernia repair by insertion of a mesh appears to be the most efficacious procedure either by open or by laparoscopic surgery. However, surgical repair of parastomal hernia is still associated with significant recurrence rates and remains controversial [3, 4].

Due to the frequency of parastomal hernia and disappointing results of parastomal hernia repair, attention has

been focused on preventing parastomal herniation. A recent systematic review [5] and a meta-analysis [6] concluded that mesh reinforcement of stomas in the preperitoneal/sublay position at the time of stoma formation is a safe procedure and reduces the risk of parastomal hernia. However, evidence from randomized studies (level 1) is scarce, and the only three randomized controlled clinical trials published in the literature were performed in patients undergoing open surgery using different types of mesh placed in a preperitoneal or sublay position [7–11]. Moreover, even when a stoma is constructed by minimally invasive surgery using a laparoscopic approach, the development of parastomal hernias is still a problem [12, 13]. Recently, Janson et al. [14] described the use of a prophylactic mesh in a sublay position as an easy and safe procedure associated with a low rate of parastomal hernia in patients undergoing laparoscopic stoma formation. In their experience, parastomal hernia developed in 15 % of patients with a sigmoidostomy created by a laparoscopic technique and followed after 11–31 months.

To our knowledge, the effectiveness of prophylactic placement of a mesh during laparoscopic abdominoperineal resection for rectal cancer to prevent parastomal herniation has not been previously assessed in a randomized controlled study. We hypothesized that in a sample of patients randomly distributed undergoing permanent end colostomy after laparoscopic Miles operation, the insertion of a prophylactic large-pore lightweight composite mesh in the intraperitoneal/onlay position by a purely laparoscopic approach would reduce the incidence of parastomal hernia. The objective of this study was to assess the reduction in the incidence of parastomal hernia after this approach.

Materials and methods

Design

A prospective, open, randomized, parallel-group, and single-blind clinical trial was conducted at the Department of Surgery of Hospital Universitari Vall d'Hebron in Barcelona, Spain. The purpose of the study was to determine whether a mesh was effective in the prevention of a parastomal hernia when a permanent ostomy is performed through a laparoscopic approach. The study protocol was approved by the ethics committee of the hospital, and all patients signed an informed consent before operation. The study was officially registered under NCT00908661 on clinicaltrials.gov providing additional study information.

Patients

Between November 2007 and January 2010, all consecutive patients scheduled for permanent end sigmoid colostomy to treat cancer of the lower third of the rectum, aged over 18 years, and with a life expectancy of more than 1 year were included in the study. Exclusion criteria were allergy to the compounds of the mesh, patient's refusal, emergency surgery, life expectancy of less than 1 year, and prior meshes in the surgical site. All surgical procedures were performed by six surgeons with experience in laparoscopic surgery from the Abdominal Wall and Colorectal Surgery Units of the hospital. The duration of the recruitment period was defined as the time interval between the dates of the first and last surgical procedures.

Study protocol

The control group (without mesh) consisted of patients receiving conventional sigmoid end colostomy. The study group (with mesh) consisted of patients receiving conventional sigmoid end colostomy plus a lightweight mesh in the intraperitoneal/onlay position. All patients underwent an abdominoperineal resection through the laparoscopic route. Patients were randomly assigned to one or other group using a computer-generated list of random numbers generated by an independent statistician. All possible patients who fulfilled the inclusion criteria during the recruitment period were randomized independently of whether or not the required sample size was reached.

A fine-thread, large-pore lightweight mesh (PROCEED^{TM} Surgical Mesh, ETHICON Inc., a Johnson & Johnson company) measuring 12 × 12 cm made of polypropylene encapsulated with polydioxanone (PDS). One of the surfaces of the mesh is covered by a surface composed of oxidized regenerated cellulose (absorbable), which allows placement in direct contact with abdominal viscera.

Before surgery, a stomatherapy nurse marked the ideal site for the colostomy. All patients underwent mechanical preparation of the colon and received antibiotic prophylaxis with a single dose of amoxicillin–clavulanic acid administered intravenously at induction of anesthesia.

The surgical technique was laparoscopic total mesorectal excision, in both groups. Once the resection was completed and the perineal wound was closed, patients randomly assigned to the mesh group had a mesh placed in an intraperitoneal/onlay fashion by a pure laparoscopic approach using a technique previously described by our group [15]. Briefly, a 12 × 12 cm mesh was used. A suture was tied to the center of the mesh surface that will be in contact with the abdominal wall. This suture will be used to make traction over the mesh with the help of a grasper introduced through the trocar that is placed at the site of the future stoma and will help to ensure a correct placement of the mesh. Once the mesh was totally fixed with tackers (Pro Tack^{TM}, Covidien Surgical), a circular skin incision on the premarked site was made and the skin and subcutaneous

tissue excised. Then, a cruciate incision over the anterior rectus sheath was made, the rectus muscle split, and a cruciate incision was performed on the mesh over the previous mark done with the stitch. The colon was brought to the outside through mesh opening.

All patients underwent CT scanning at 12 months after surgery, which is the minimum length of follow-up to assess the development of a parastomal hernia [1]. Because no consistent radiological definition of parastomal hernia has been used in previous studies, we applied a wide definition to describe a loop of intestine or any abdominal organ, as well as preperitoneal fat, protruding through the defect alongside the ostomy was considered as parastomal hernia. Abdominal CT was performed by a radiologist who was blind to the technique used. Subcutaneous abdominal fat thickness was measured at the level of the stoma and on the contralateral site.

Preoperative and postoperative variables were recorded, including age, sex, body mass index (BMI), comorbidities frequently associated with parastomal hernia [16] (obesity defined as BMI > 25 kg/m^2, smoking habit, American Society of Anesthesiologists (ASA) physical status classification, diabetes mellitus, history of other hernias, prostatism, constipation, chronic obstructive pulmonary disease), mesh infection (defined as a collection in contact with the mesh yielding a positive culture), ostomy-related complications (e.g., necrosis, prolapse, eczemas). and other complications unrelated to the mesh or the ostomy. The operative mortality was defined as death within 30 days of operation.

Sample size and statistical analysis

The sample size was calculated with parastomal hernia as the main variable and according to the prevalence of parastomal hernia reported in the literature before and after placement of the lightweight mesh [9, 11]. For a chi-square test, accepting an alpha error of 0.05 and a beta error of 0.20 in a two-sided test, 17 subjects in the control group and 17 subjects in the mesh group were required for an expected difference between groups equal or greater than 45 % units (60 % for the control group and 15 % for the mesh group).

Analysis was performed in the per-protocol data set that included all patients receiving surgery in the control group and in the mesh group who underwent control CT scan 12 months after operation. The description of the variables and the statistical analysis were performed using the statistical package for the social sciences (SPSS) program, version 12.0 for Windows. Quantitative variables are expressed as mean and standard deviation (SD) and categorical variables as absolute numbers and percentages. The Student's t test was used for the analysis of continuous variables and the chi-square (χ^2) test or the Fisher's exact test for the analysis of categorical variables. The interrelationship between the main outcome variable (parastomal hernia) and the remaining variables was assessed with a binary logistic regression analysis. Tentatively, the diagnostic performance of the subcutaneous abdominal fat thickness to discriminate patients at risk for a parastomal hernia was explored by a receiver operating characteristics (ROC) curve analysis. The area under the ROC curve (AUC) and the best cutoff (highest Youden index value) for predicting parastomal hernia formation were calculated. Statistical significance was set at $P < 0.05$.

Results

During a 26-month recruitment period, 78 patients with cancer of the lower third of the rectum underwent an abdominoperineal resection (Miles procedure) with a permanent end colostomy at our hospital. Laparoscopic approach with total mesorectal excision was performed in 44 of them. Eight patients were excluded from the study because of lack of fulfillment of the inclusion criteria. Therefore, 36 patients were randomized, 19 to the mesh group and 17 to the control group. The study ended in November 2010 (date of the last CT examination). Two patients were excluded from the final analysis, one assigned to the mesh group died in the immediate postoperative period due to pulmonary thromboembolism, the diagnosis of which was confirmed at the postmortem examination. The other patient assigned to the control group was lost to follow-up. Figure 1 shows the distribution of the study population. Clinical follow-up lasted a median of 317 days.

Baseline characteristics of the patients assigned to the control group and the mesh group were similar (Table 1). In all patients, abdominoperineal resection was successfully completed by the laparoscopic route and conversion to open surgery was not necessary.

Perioperative complications are shown in Table 2. Ostomy-related complications included partial cutaneous dehiscence of the stoma in 3 patients (2 in the mesh group and 1 in the control group) and partial necrosis of the stomal margin in 1 patient (control group). Complications other than those related to the ostomy were significantly more frequent in the mesh group than in the control group (57.9 vs. 17.6 %, $P = 0.013$).

Parastomal hernia was detected by CT scan in 9 (50 %) out of 18 patients in the mesh group and in 15 (93.8 %) out of 16 patients in the control group ($P = 0.008$). Four patients, 3 in the control group and 1 in the mesh group necessitated redo surgery to correct symptomatic parastomal hernias.

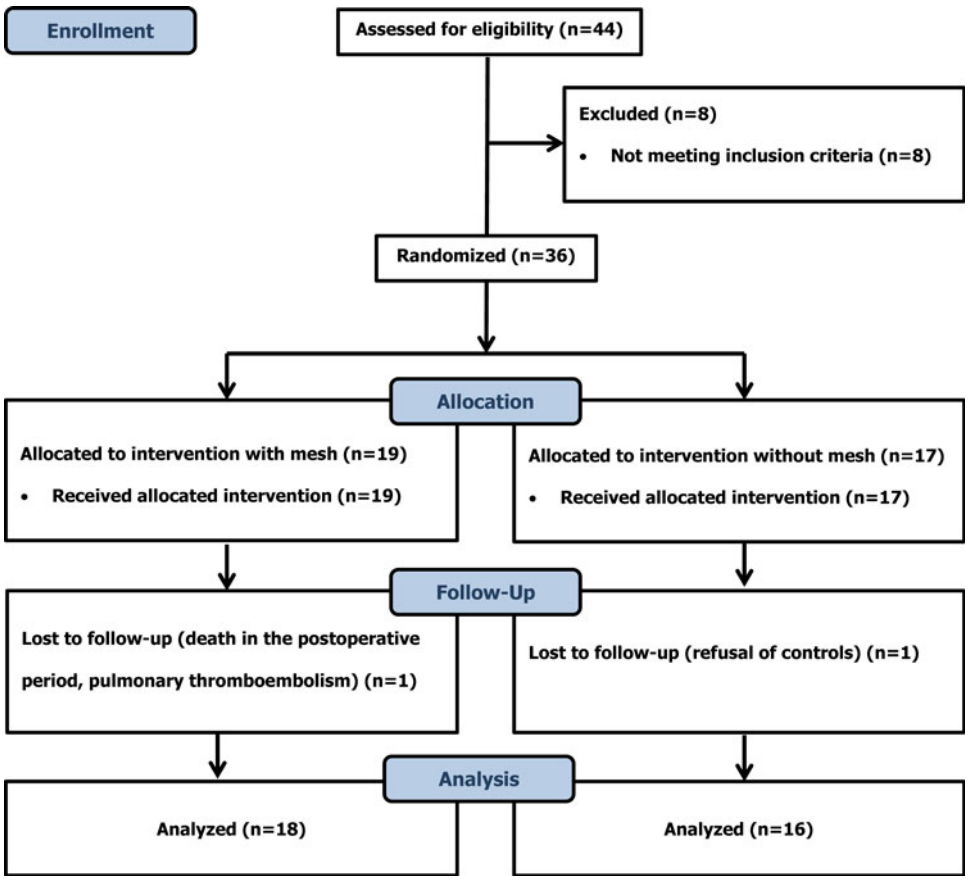

Fig. 1 Flow chart of the study participants

Table 1 Baseline characteristics of patients in the two study groups

	Patients with mesh ($n = 19$)	Patients without mesh ($n = 17$)	P value
Sex (M:F)	11:8	7:10	0.317
Age, years, mean (SD)	72.2 (7.6)	65.9 (13.9)	0.113
BMI, kg/m^2, mean (SD)	26.3 (3.2)	27.5 (4.7)	0.382
Current smoker, no. (%)	8 (42.1)	7 (41.2)	0.955
ASA classification			0.554
1		1 (5.9)	
2	10 (52.3)	9 (52.9)	
3	9 (47.4)	6 (35.3)	
4		1 (5.9)	
Diabetes mellitus	16 (84.2)	13 (76.5)	0.684
History of other hernias	3 (15.8)	2 (11.8)	1
Prostatism	8 (42.1)	5 (29.4)	0.429
Constipation	3 (15.8)	6 (35.3)	0.255
Chronic obstructive pulmonary disease (COPD)	6 (31.6)	4 (23.5)	0.717

Percentages in parenthesis unless otherwise stated

The mean (SD) thickness of the subcutaneous abdominal fat was 23.1 (11.4) mm for patients in the mesh group and 28.1 (12.5) mm for patients in the control group ($P = 0.232$). However, there were statistically significant differences in the mean (SD) thickness of the subcutaneous abdominal fat between patients with and without parastomal hernia (29.2 [10.7] vs. 16.2 [10.1], $P = 0.003$). Other differences in baseline data and perioperative complications were not found.

The AUC for thickness of the subcutaneous abdominal fat to discriminate patients at an increased risk for developing a parastomal hernia was 0.819 (95 % confidence interval [CI] 0.65 to 0.98, $P = 0.004$). After calculation of the Youden index, the optimal threshold of subcutaneous abdominal fat thickness was 23 mm. In other words, for patients with a subcutaneous fat thickness $\geq$23 mm, the probability to develop a parastomal hernia was 80 %. In the binary logistic regression analysis, subcutaneous abdominal fat thickness $\geq$23 mm was independently associated with parastomal hernia (odds ratio [OR] 15.7, 95 % CI 1.92 to 129.34, $P = 0.010$), whereas insertion of a mesh was a protective factor (OR 0.06, 95 % CI 0.005 to 0.78, $P = 0.031$). Finally, BMI showed a significant relationship with thickness of the subcutaneous abdominal fat ($r = 0.475, P = 0.005$) (Fig. 2).

Discussion

The present study shows that in permanent sigmoid colostomy performed after laparoscopic abdominoperineal

Table 2 Perioperative complications in the two study groups

	Patients with mesh ($n = 19$)	Patients without mesh ($n = 17$)	P value
Ostomy-related complications			1.0
Partial cutaneous dehiscence	2	1	
Partial necrosis of the colostomy border		1	
Other complications	11	3	0.013
Pelvic abscess	3	2	
Perineal wound infection	5	1	
Trocar site evisceration	1		
Heart failure	1		
Lower respiratory tract infection	1		

resection, the insertion of a large-pore lightweight mesh in the intraperitoneal onlay position by the laparoscopic approach had a statistically significant preventive effect on parastomal hernia formation, with 94 % of patients presenting parastomal hernia in the control group as compared with 50 % in the mesh group after a follow-up of 1 year. The high percentage of parastomal hernia found in the control group is consistent with the classical assumption that some degree of parastomal hernia may even be considered an almost inevitable complication of colostomy formation [17]. Moreover, this high percentage is also related to the use of CT scan as an objective technique to detect parastomal hernia formation as well as the wide definition of parastomal hernia accepted in our study. It has been shown that evaluation of the ostomy site using CT has significantly increased the hernia incidences by demonstrating clinically undetectable cases [1, 2, 16].

Interestingly, parastomal hernia developed in 50 % of patients in the mesh group. This is a higher incidence than that previously reported in the three clinical trials in which a mesh was inserted by open surgery [7–11]. Because no relationship was found between hernia formation and comorbidities most frequently reported as risk factors for parastomal hernia, it is possible that this high incidence among patients in the mesh group may be related to the laparoscopic technique and the need to perform a central incision on the mesh to allow the bowel to pass through the abdominal wall, although mesh shrinkage at follow-up may result in a widening of the central opening. It has been shown that laparoscopic parastomal hernia repair using a keyhole technique in which a mesh with a central keyhole is fashioned around the bowel to close the hernia has a high recurrence rate [18]. Moreover, in patients in the mesh group who necessitated redo surgery also performed by the laparoscopic approach, at reoperation, the mesh appeared smaller and central opening wider, which resembled the hernial orifice found in reoperated patients from the control group. The effectiveness of a preventive mesh of the same characteristics (large-pore lightweight) without a central opening using a modified Sugarbaker technique similar to that described for parastomal hernia repair [19] should be assessed in future studies.

Mesh infection was not observed. This finding is also consistent with studies of prophylactic mesh insertion using open surgery, in which absence of infection was attributed to a lower inflammatory reaction and better defense against infection with large-pore lightweight mesh [7–11]. On the other hand, the laparoscopic approach and placing the mesh intraperitoneally may also contribute to host defense

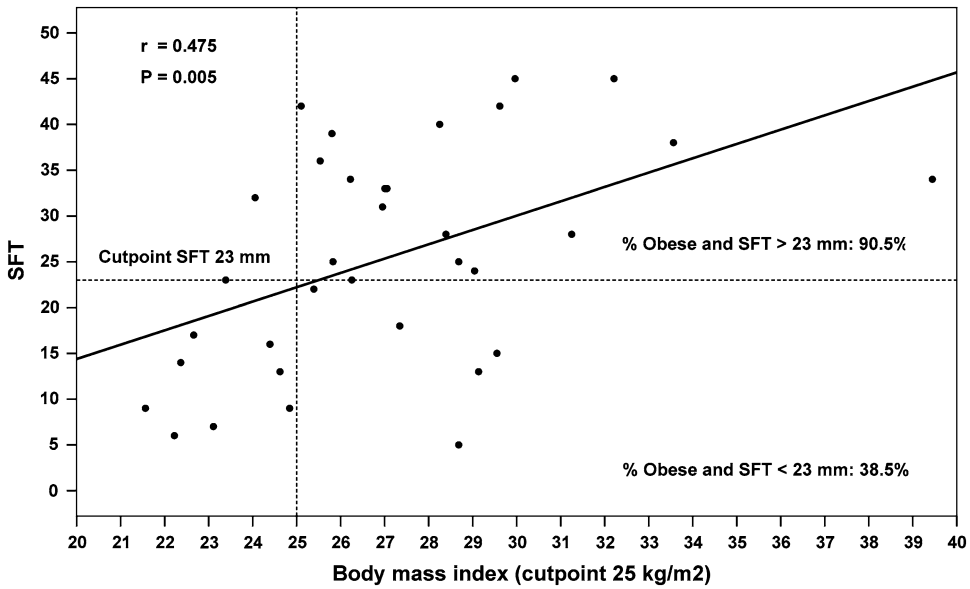

Fig. 2 Relationship between body mass index (BMI) (cutpoint 25 kg/m^2) and subcutaneous abdominal fat thickness (SFT) (cutoff 23 mm)

against infection as reported for laparoscopic surgery of incisional hernia [20]. However, patients in the mesh group showed a significantly higher number of complications unrelated to the ostomy, particularly pelvic abscess and perineal wound infection, which are probably more related to the abdominoperineal resection [13, 21] than to the presence of the mesh.

A novel aspect of the study was the measurement of subcutaneous abdominal fat thickness and its relationship with parastomal hernia formation. As may be expected, thickness of the subcutaneous fat was significantly greater among patients with parastomal hernia. On the other hand, a cutoff value of ≥23 mm was an independent predictor of parastomal hernia, whereas insertion of a mesh was inversely associated with hernia. It has been reported that patients with a waist circumference >100 cm have a 75 % risk of developing a parastomal hernia [22]. The present study shows that the risk of parastomal hernia formation was 80 % in the presence of a subcutaneous abdominal fat thickness ≥23 mm. Technical difficulties in creating an end colostomy in obese patients have been extensively recognized [23] and, by necessity, the defect created in the fascial layer in obese patients has to be larger than in others, presumably increasing the risk and rate of parastomal hernia formation [24]. In our study, obesity (BMI > 25 kg/m^2) was unrelated to parastomal hernia, although most patients with abdominal fat thickness ≥23 mm were obese. However, obese patients with predominantly extra-abdominal fat distribution may have an abdominal fat thickness <23 mm (38.5 % of patients in our series). In our opinion, given that thickness of the fat layer was the only predictor of parastomal hernia formation, it seems that patients with an abdominal fat thickness <23 mm would be those with the greatest benefit from prophylactic mesh insertion. This simple CT measurement may be easily incorporated into the preoperative studies of patients with low rectal cancer scheduled for elective abdominoperineal resection by the laparoscopic approach.

Limitations of this study include the small number of patients, the relatively short follow-up period (although a minimum of 12 months is recommended) [1], the lack of comparison of different mesh types, and the fact that CT studies were not performed in the prone position, the proportion of parastomal hernias may be underestimated [25]. The randomized design of the study and the use of radiologic criterion to determine the presence of parastomal hernia increase the strength of the results obtained. It should be noted that the contribution of abdominal wall thickness measured by CT scan as a risk factor for parastomal hernia formation was tentatively examined using a ROC curve analysis. Although a threshold of ≥23 mm was found to be an independent predictor of parastomal hernia, this finding should be interpreted taking into account the small sample size but may serve to stimulate further studies in this direction.

In summary, in patients undergoing permanent colostomy after laparoscopic surgery, the addition of a prophylactic large-pore lightweight composite mesh in the intraperitoneal onlay position by a purely laparoscopic approach reduced the incidence of parastomal hernia but the overall rate of parastomal hernia was in both groups (mesh and controls) surprisingly high.

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Conflict of interest The authors declare that they have no conflict of interest.

Ethical standards The study comply with the current laws of the country. The study protocol was approved by the Ethics Committee of the hospital and all patients signed an informed consent before operation. The study was officially registered under NCT00908661 on clinicaltrials.gov.

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