Bioprosthetic mesh reinforcement during temporary stoma closure decreases the rate of incisional hernia: A blinded, case-matched study in 94 patients with rectal cancer

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Background. *This case-matched study aimed to assess the feasibility and the potential benefits of placement of a prophylactic bioprosthetic collagen porcine mesh during closure of the temporary ileostomy after total mesorectal excision (TME) for rectal cancer.*

Methods. *From September 2012 to March 2013, 30 consecutive patients underwent placement of a retromuscular bioprosthetic mesh in the abdominal wall during closure of a diverting ileostomy after sphincter-saving laparoscopic TME for rectal cancer (mesh group). These 30 patients were matched individually to all identical patients who underwent a closure of the ileostomy without mesh after laparoscopic TME extracted from our prospective database (control group). The matching process was performed according to sex, age, body mass index, medically treated diabetes mellitus, neoadjuvant radiotherapy, and the delay between TME and closure of the ileostomy. The primary endpoint was stoma site incisional hernia, assessed in a blinded fashion by CT 1 year later.*

Results. *Mesh placement was feasible in all mesh group patients. There was no postoperative mortality. Overall postoperative morbidity rates were similar between mesh and control groups (n = 5 [17%] vs n = 7 [11%], respectively; P = .512). On the 1-year CT, incisional hernia at the site of stomal closure was less in the mesh group (n = 1) compared with the control group (n = 12; P = .043). Reoperation for incisional hernia at the site of stomal closure was performed in 8 patients (13%) in the control group, whereas no patient from the mesh group required repair of the hernia (P = .052).*

Conclusion. *Placement of a bioprosthetic collagen porcine mesh during closure of the temporary ileostomy after laparoscopic TME for rectal cancer seems to decrease the chance of hernia formation at the stoma site, at least at the 1-year follow-up. (Surgery 2015;■:■-■.)*

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PROCTECTOMY WITH TOTAL MESORECTAL EXCISION (TME) is the gold standard treatment for rectal cancer management.[1] Over the last decade, advances in

neoadjuvant radiochemotherapy and operative techniques, including a decrease in the required distal margin and intersphincteric resection, has led to an increased rate of sphincter-saving procedures for rectal cancer.[2] Despite its excellent oncologic results, sphincter-saving TME is associated with a substantial rate of postoperative complications, even if a laparoscopic approach is performed.[3,4] More specifically, anastomotic leakage remains among the most feared and frequent complications after sphincter-saving TME with a reported incidence varying from 3 to 27%.[5-8] This high risk has led an increasing number of surgeons to perform routinely a diverting stoma after sphincter-saving TME, which decreases the risk of symptomatic anastomotic leakage in a large randomized, controlled trial[5] and a metaanalysis.[9]

Reversal of a diverting stoma after TME is regarded generally as a minor and safe procedure. Indeed, a recent metaanalysis highlighted very low rates of short-term postoperative mortality and morbidity.[10] Nevertheless, reversal of the stoma is associated with a substantial risk of abdominal wall hernia. In 2012, Bhangu et al[11] performed a systematic review and metaanalysis on this topic and reported a 30% pooled rate of postoperative hernia formation among studies designed specifically to assess this complication. The occurrence of these hernias lead to abdominal pain, discomfort, impaired quality of life, unplanned hospitalization, and the need for additional operative procedures in ≤51% of patients.[11]

Although several risk factors for postoperative hernia have been identified, such as obesity, diabetes mellitus, chronic obstructive pulmonary disease, and surgical site infection,[12-14] none of these risk factors are controllable preoperatively. Therefore, operative technique might be the cornerstone of preventing hernia formation after stomal reversal. In this setting, prophylactic placement of mesh in the abdominal wall during the procedure may help to decrease the rate of long-term hernias. The use of nonabsorbable synthetic prosthetic mesh, as validated for standard incisional hernia repair,[15-17] is associated with a risk of local infectious complications in contaminated surgical site,[18] although the rate is surprisingly low for placement of mesh at the time of creation of a permanent stoma.[19] In contrast, bioprosthetic collagen-based meshes can be used in grossly contaminated wounds, such as parastomal hernia, with limited infectious complications.[20,21]

The aim of this study was to assess the feasibility and the potential benefits of an incisional hernia-prophylactic bioprosthetic mesh placement during stoma reversal after TME for rectal cancer.

PATIENTS AND METHODS

Patients. From September 2012 to March 2013, 30 consecutive patients underwent placement of a bioprosthetic mesh in the abdominal wall during their reversal of a temporary diverting ileostomy after sphincter-saving laparoscopic TME for rectal cancer (mesh group). Each of these 30 patients were matched individually to all identical patients from our prospective, institutional review-board approved database who underwent a stomal reversal without mesh placement after sphincter-saving laparoscopic optimal mesorectal excision or TME for rectal cancer with diverting ileostomy since 2005. Matching process was blinded to the study outcomes and performed according to sex, age (±10%), body mass index (BMI; ±10%), medically treated diabetes mellitus, neoadjuvant radiotherapy, and the delay between TME and stomal reversal. These latter patients constituted the control group.

Operative procedures. All patients underwent preoperative mechanical bowel preparation before rectal cancer surgery, as suggested by a randomized control trial from our group.[22] TME was performed as described previously,[23] according to a totally laparoscopic technique with only a 5-cm incision in the right lower quadrant for both specimen extraction and the formation of a temporary loop diverting ileostomy. The operative procedure involved routinely a high ligation of the inferior mesenteric vessels, complete mobilization of the splenic flexure, and optimal mesorectal excision or TME, according to the tumor distance from the dentate line.

Stomal reversal was performed at 6–8 weeks after TME if a CT with contrast enema control did not show any evidence of anastomotic leakage. Stomal reversal was delayed in cases of anastomotic leakage. Patients who underwent adjuvant chemotherapy also had their stomal reversal performed at 6–8 weeks after TME. The reversal procedure was performed according to a standardized technique in all patients. Briefly, patients received prophylactic intravenous antibiotics (cefoxitin, 2 g), and a peristomal incision was always performed. Careful dissection into the peritoneal cavity and mobilization of the bowel segments were then performed. A short bowel resection was performed when necessary. A circular, end-to-end manual anastomosis was always performed using 5-0 polydioxanone (PDS, Ethicon, Somerville, NJ). Patients who required a midline incision or a stapled anastomosis during stomal reversal were excluded from the present study. In all patients, the abdominal wall was closed in 2 layers using continuous sutures of polyglactin 1 (Vicryl; Ethicon) on the posterior and anterior layers of the rectus sheath. In the mesh group, a 10 × 10-cm bioprosthetic, non–cross-linked collagen, porcine dermal matrix with 1.4 mm thickness (Meccellis BioTech, France) was placed in retromuscular position and fixed with four 2-0 polypropylene stitches (Prolene, Ethicon). Skin was sutured with a purse-string approximation technique using a 4.0 poliglecaprone suture (Monocryl, Ethicon) in all patients, according to the results a recent randomized trial.[24] No wound drains were inserted.

Follow-up and study endpoints. All patients underwent routine oncologic follow-up after TME for rectal cancer every 3 months during the first 2 years after TME, then every 6 months for 3 years, and annually thereafter. During follow-up, they

underwent clinical examination, thoracoabdomi-nopelvic CT, and blood sample for tumor markers (carcinoembryonic antigen and carbohydrate anti-gen 19.9). Colonoscopy was performed 1 year after surgery, then every 3 years.

The primary endpoint of the present study was radiologic parastomal hernia at 1 year after stomal reversal. Radiologic hernia was defined as any protrusion of abdominal contents including the anterior parietal peritoneum through a disconti-nuity of the fascial layers on CT performed during follow-up without Valsalva maneuver. All CT exam-inations were performed by an expert GI radiolo-gist (M.Z.), blinded to the study group. Biologic mesh is not visible on postoperative CT, leading to effective blinded analysis. Secondary endpoints included wound infection (defined as a suppura-tive discharge at wound incision), postoperative morbidity (defined as any postoperative 30-day or in-hospital complication), clinical incisional her-nia at 1 year (defined as a palpable fascial defect or visible protrusions at or near the surgical incision at rest or with Valsalva maneuver, and assessed in a blinded fashion), and a radiologic parastomal hernia at the end of follow-up.

Statistical analysis. Descriptive analyses are pre-sented as mean values ± standard deviation (ranges) for quantitative data and as number of cases (per-centage of cases) for categorical variables. Compar-isons were made using Student's t or Mann–Whitney U tests for quantitative data (depending on their dis-tribution) and Pearson's χ^2 or Fisher exact tests for categorical variables (depending on the sample size). All tests were 2 sided. All analyses were per-formed using the Statistical Package for the Social Sciences (SPSS) software (SPSS Inc, version 22.0, Chicago, IL).

This study was conducted according to the ethical standards of the Committee on Human Experimentation of our institution and reported according to the guidelines of the Strengthening the Reporting of Observational Studies in Epide-miology (STROBE).[25]

RESULTS

Patients. Baseline characteristics of the study patients are presented in Table I. The 30 patients from the mesh group were matched with 64 patients who constituted the control group. The 2 groups did not present any difference regarding matching criteria (sex, age, BMI, diabetes mellitus, preopera-tive radiotherapy, and delay between TME and sto-mal reversal) or other demographic characteristics including chronic pulmonary disease (3 in the

mesh group vs 8 in the control group; P = .725). No patient in the 2 groups developed a surgical site infection at the ileostomy site after rectal cancer surgery.

Feasibility of mesh placement. The placement of mesh was possible in all 30 patients. All meshes were placed in a retromuscular position. Mean operative time, from skin incision to skin closure, was 100 ± 27 minutes (range, 60–150), including a mean operative time devoted to placement of the mesh of 7 ± 1 minutes (range, 5–10). Perioper-atively or during long-term follow-up, no mesh-related allergic reactions were observed.

Short-term outcomes. Short-term outcomes of the 2 groups are detailed in Table II. There was no postoperative mortality. Overall postoperative morbidity showed no difference comparing Mesh and Control groups (n = 5 [17%] vs n = 7 [11%], respectively; P = .512). More specifically, there were no differences regarding the rate of wound abscess (n = 2 [7%] vs n = 3 [5%], respectively; P = .238) or wound hematoma (n = 1 [3%] vs n = 0; P = .319). All wound abscesses were treated medically and did not require additional operative intervention. No seroma was observed during follow-up.

Long-term outcomes. At 1 year, CT was available for all patients at 12.1 ± 0.7 months (range, 10.7–13.7) in the mesh group versus 12.1 ± 0.9 (range, 10.1–15) in the control group (P = .563). On this 1-year CT, the incidence of parastomal hernia was less in the mesh group (n = 1 [3%] vs n = 12 [19%]; P = .043). The presence of a clinically evident parastomal hernia was also less frequent in the mesh group (n = 1 [3%] vs n = 10 [16%]; P < .17).

During follow-up (16.8 ± 3.3 months [range, 11.4–23.9] in the mesh group vs 39.2 ± 16.9 [range, 14.9–79.7] in the control group), a radiologic parastomal hernia was diagnosed less frequently in the mesh group (n = 1 [3%] vs n = 15 [24%]; P = .016). Operative repair of the stoma site hernia was performed in 8 patients (13%) in the control group but none in the mesh group. No cases of incarcerated parastomal hernia were observed.

DISCUSSION

This study aimed to assess the feasibility and the potential benefits of prophylactic placement of a non–cross-linked bioprosthetic during stomal reversal after TME for rectal cancer. Comparing the results of 30 patients with the bioprosthetic mesh to those of 64 matched patients without mesh, the rate of development of a parasternal hernia was

Table I. Demographic characteristics of 94 patients who underwent diverting ileostomy reversal after TME for rectal cancer, with or without bioprosthetic mesh placement

Characteristic	Mesh group (n = 30)	Control group (n = 64)	P value
Sex			.824*
Male	18 (60)†	40 (62)	
Female	12 (40)	24 (38)	
Age (y)	61 ± 13 (25–79)‡	61 ± 13 (28–84)	.903*
BMI (kg/m^2)	26 ± 4 (19–36)	25 ± 4 (18–38)	.801*
ASA score			.653
1/2	28 (93)	61 (95)	
3/4	2 (7)	3 (5)	
Diabetes mellitus	6 (20)	8 (13)	.363*
Chronic obstructive pulmonary disease	3 (10)	8 (13)	.725
Preoperative radiotherapy	19 (63)	43 (67)	.816*
Delay TME—stomal reversal (wk)	11 ± 5 (5–26)	11 ± 5 (5–27)	.826*

*Matching variables.
†Number of cases (percentage of cases).
‡Mean ± standard deviation (range).
ASA, American Society of Anesthesiologists; *BMI*, body mass index; *TME*, total mesorectal excision.

Table II. Short-term postoperative outcome of 94 patients who underwent diverting ileostomy reversal after TME for rectal cancer, with or without bioprosthetic mesh placement

Outcome	Mesh group (n = 30)	Control group (n = 64)	P value
Postoperative mortality	0	0	–
Postoperative morbidity			
Anastomotic leakage	0	2 (3)*	.328
Small bowel obstruction	1 (3)	4 (6)	.557
Wound hematoma	1 (3)	0	.319
Wound abscess	2 (7)	1 (2)	.238
Medical complication	2 (7)	3 (5)	.653
Patients with ≥1 complication	5 (17)	7 (11)	.512
Duration of postoperative hospital stay (d)	6 ± 2 (4–10)†	6 ± 1 (4–16)	.134

*Number of cases (percentage of cases).
†Mean ± standard deviation (range).

markedly less (3% vs 19%; *P* < .5) at 1 year, without any increase in postoperative morbidity.

Stomal reversal is usually regarded as a minor and safe procedure, associated with low short-term postoperative morbidity. The results of a metaanalysis published in 2009 by Chow et al, which analyzed the results of >6,000 stomal reversals, support this idea, with reported mortality and morbidity rates as low as 0.4 and 17%.[10] The most important risk of stomal reversal other than anastomotic leaks is long-term complications related to development of a parasternal hernia, although the rate of parasternal hernias is to determine from the literature. Bhangu et al[11] in 2012 published a systematic review on this topic, including 34 studies. The authors reported very heterogeneous reported rates of hernia, ranging from 0 to 48%, and pointed out that the majority of the studies based their results of retrospective clinical

findings and that very few were designed specifically to assess such complication. Selecting only studies that assessed meticulously the stoma site, the authors reported a 30% pooled rate of hernias, suggesting that this complication might be more common that thought previously.[11] The results of this metaanalysis were in line with our experience as a tertiary care center in colorectal surgery and prompted the present study.

Prophylactic placement of some form of prosthetic material has been suggested to be effective in preventing parastomal hernias[19,26-29] or during abdominal surgery in high-risk patients,[30,31] but its use during stomal reversal has been mostly precluded because of the fear of bacterial contamination at the stomal site. Indeed, many surgeons, including the authors of the present study, regard the use of a nonabsorbable synthetic prosthetic

material (as validated for standard incisional hernia repair[15-17]) in this indication as exposing the patient to a high risk of septic complications. In contrast, bioprosthetic, collagen-based prostheses can be used in grossly contaminated wounds, such as parastomal hernia, with limited infectious complications.[20] This is why we choose a bioprosthetic collagen porcine prostheses (not a true "mesh" with "pores" as occurs with true mesh prosthetics) as the reinforcement method during in the present study. Fixation of this bioprosthetic "mesh" was performed using polypropylene to obtain a reliable and durable fixation, thus limiting the risk of mesh migration. Although absorbable sutures might help to decrease the inflammatory response induced by the sutures, no data to our knowledge have been reported supporting improved outcomes of fixation of biologic mesh using absorbable material. The mesh placement required dissection of the retromuscular space, which might lead to differences with the control group; however, we regard this difference as minimal because we perform routinely a retromuscular space dissection in all patients, irrespective of a mesh use, to perform a satisfactory and tension-free closure of the abdominal wall defect during stomal reversal. Finally, short-term degradable sutures have been shown in 1 study to be associated with a greater rate of postoperative hernia compared with long-term degradable materials.[32] Several points should be taken into account. First, all available studies have focused primarily on the midline laparotomy closure, and no good quality study has focused on materials for stoma site or laparoscopic port closure.[33] Second, the same techniques were used in the 2 groups in the present study, thus adjusting on this point during the comparative analysis. The benefit of prophylactic mesh suggested in the present study should be compared with other alternatives such as nonabsorbable sutures or alloplastic mesh.

We used CT as a surrogate marker for a parasternal hernia in the present study. Several points prompted this decision. First, in their metaanalysis, Bhangu et al[11] showed that imaging allowed a greater detection rate of stoma hernia than clinical examination only. Second, Cingi et al[34,35] showed that, among imaging modalities, CT was associated with a greater detection rate for stoma site hernia than ultrasonography. Third, although not detectable clinically, a stoma site hernia detected on CT might be responsible for pain and incarceration, especially in obese patients in whom clinical examination is difficult. Fourth, CTs were readily available and performed every 3 months, because all our included patients were operated on for rectal cancer

and therefore required oncological follow-up. Finally, CT limits the risk of a potential observational bias and might therefore be used in multicentric randomized trials. To limit the bias in the present study, CT examinations were performed by an expert radiologist blinded to the study group.

To assess the impact of the technique of bioprosthetic mesh reinforcement, we designed the present study as a case-matched study. The control group patients were chosen from our prospective database to obtain a group of patients with similar risk of postoperative hernia compared with the mesh group. This approach explains is we chose to include only ileostomy reversals after TME as a way to maintain homogeneity of the studied population. Furthermore, we chose sex, age, BMI, medically treated diabetes mellitus, neoadjuvant radiotherapy, and the delay between TME and stomal reversal as matching criteria. BMI and diabetes mellitus have been suggested to be risk factors for postoperative hernia in several studies.[12-14] We chose to add the occurrence of a neoadjuvant radiotherapy, because such irradiation might have an impact on postoperative healing and functional results, which might have an impact on the risk of wound hernia. Furthermore, the delay between TME and stomal reversal was considered as a matching criterion, because these reflect directly the occurrence of post-TME complications and especially anastomotic leakage in our routine practice. Indeed, although stomal reversal is usually performed 6–8 weeks after TME in our institution (even in patients with adjuvant chemotherapy), we always delay the stomal reversal in case of clinical or asymptomatic anastomotic leakage. Finally, although it was not selected as a matching criterion, patients from both groups did not present significant discrepancies regarding the rate of chronic obstructive pulmonary disease or associated comorbidities (reflected by their similar American Society of Anesthesiologists scores), which are also risk factors for postoperative hernias.[12-14,36]

Patients in the mesh group were consecutive. To perform a case-matched study, we had to select patients from a greater duration time period in our prospective database. Obviously, this difference led to different mean final follow-ups in the 2 groups, because patients from the control group were operated on before patients from the mesh group. To limit the bias related to such comparison, we chose the 1-year radiologic hernia rate as the primary outcome in this study. Furthermore, all included patients (irrespective of their group) were operated on by senior consulting surgeons, according to the same standardized surgical technique.

To date, only 2 studies to have assessed the results of wound reinforcement designed to decrease the rate of stoma site incisional hernia.[37,38] In a study published in 2014, van Barneveld et al[37] reported the results of 10 patients in whom reinforcement was performed at the time of the stoma creation using a double-sided, lightweight, keyhole intraperitoneal mesh to allow the passage of the bowel loops. During stomal reversal, the wound was closed with the mesh left in place, thus allowing a satisfactory reinforcement. After a median follow-up of 26 months, the authors did not report any incisional hernias. Unfortunately, this study had no comparison group, limiting its conclusions. In 2013, Liu et al[38] published the results of a polypropylene mesh placement during stomal reversal, according to a technique very similar to the present study and reported a decreased rate of stoma site hernia without significant rates of mesh infection. Although this study suggested the potential safety of a nonabsorbable mesh placement in this indication, this technique failed to achieve a wide adoption, probably mainly because the majority of the surgeons are worried about mesh infection. Furthermore, this study was limited by the heterogeneity of its population (which included cancers, inflammatory bowel disease, diverticular disease, and small bowel obstructions) and by the absence of a satisfactory matching process limiting the risk of bias regarding its retrospective design.

One of the main concerns regarding bioprosthetic mesh is related to its cost. The cost of such device is decreasing rapidly with the progress of bioengineering. The mesh used in the present study is available at a relatively acceptable price of a 550€ in France. Although a formal cost analysis was not conducted in the present study, this price has to be considered with the cost of the 8 patients who required a hernia repair in the control group. Furthermore, other considerations of course include social cost for patients, costs associated with failed hernia repairs, and emotional and physical stress for patients who undergo a second operation.

Although we tried to limit the potential biases of the present study, our results should be confirmed in a prospective, randomized, controlled trial to validate fully the strategy of mesh reinforcement during stomal reversal after TME for rectal cancer. We used the present results as a basis for such a randomized, controlled trial, which will start as a national, multicenter trial in France in September 2015.

In conclusion, this case-matched study suggested that prophylactic bioprosthetic collagen porcine mesh placement during stomal reversal after laparoscopic TME for rectal cancer significantly reduces stoma site incisional hernia rate.

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