End Colostomy With or Without Mesh to Prevent a Parastomal Hernia (GRECCAR 7)

A Prospective, Randomized, Double Blinded, Multicentre Trial

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Objective: To evaluate whether systematic mesh implantation upon primary colostomy creation was effective to prevent PSH.

Summary of Background Data: Previous randomized trials on prevention of PSH by mesh placement have shown contradictory results.

Methods: This was a prospective, randomized controlled trial in 18 hospitals in France on patients aged ≥18 receiving a first colostomy for an indication other than infection. Participants were randomized by blocks of random size, stratified by center in a 1:1 ratio to colostomy with or without a synthetic, lightweight monofilament mesh. Patients and outcome assessors were blinded to patient group. The primary endpoint was clinically diagnosed PSH rate at 24 months of the intention-to-treat population. This trial was registered at ClinicalTrials.gov, number NCT01380860.

Results: From November 2012 to October 2016, 200 patients were enrolled. Finally, 65 patients remained in the no mesh group (Group A) and 70 in the mesh group (Group B) at 24 months with the most common reason for drop-out being death (n = 41). At 24 months, PSH was clinically detected in 28 patients (28%) in Group A and 30 (31%) in Group B [$P = 0.77$, odds ratio = 1.15 95% confidence interval = (0.62;2.13)]. Stoma-related complications were reported in 32 Group A patients and 37 Group B patients, but no mesh infections. There were no deaths related to mesh insertion.

Conclusion: We failed to show efficiency of a prophylactic mesh on PSH rate. Placement of a mesh in a retro-muscular position with a central incision to allow colon passage cannot be recommended to prevent PSH. Optimization of mesh location and reinforcement material should be performed.

Keywords: hernia, mesh, parastomal, prevention

(*Ann Surg* 2021;274:928–934)

Nearly 45,000 patients in the UK have an end colostomy.[1] Parastomal hernias (PSH) occur in 4% to 50% of end colostomy patients,[2] with a median interval until PSH of around 18 months.[3] PSH is the most frequently reported complication for stoma patients, severely diminishing quality of life (QOL).[3] PSH can cause difficulties in fitting the pouching system, peristomal pain, stoma leakage, and compromises stoma irrigation. PSH may also lead to life-threatening complications such as incarceration or strangulation of the hernia.

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.[4] Treatment of PSH is often complex, and the various techniques have not been extensively compared.[2] The morbidity of these procedures varies from 10% to 30%, and recurrence rates up to 75% have been reported if no mesh is used.[2] The most effective technique is certainly the Sugarbaker technique,[5] but it requires insertion of a mesh in an underlay position (intraperitoneally) that may induce bowel adhesion or erosion.[6]

Considering the high PSH rate, the difficulties of treatment, and high morbidity, preventive treatment of PSH is compelling. The European Hernia society claims that fitting prophylactic mesh results in fewer PSH than any other technique.[5] Several randomized studies have been conducted on the prevention of PSH by the use of a mesh

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MP conceived the idea, designed the study, interpreted data, and drafted the manuscript.

CD did the statistical analysis. PFP contributed to study design. ER and MB helped to draft the manuscript. ER, EC, ZL, YP, BM, PR, JJT, MJ, GPo, DP, IS, YP, JLF, GM, BL, GPi, MK, and AD enrolled patients and collected data. All authors approved the final version of the manuscript.

This research was funded using a National Hospital Clinical Research Program (PHRC-N 2011) grant.

The authors report no conflicts of interest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.annalsofsurgery.com).

ISSN: 0003-4932/20/27406-0928

DOI: 10.1097/SLA.0000000000004371

during stoma formation. These trials revealed significantly less PSH in the mesh group compared with the non-mesh group,[7–11] although sample sizes were small and methodologies lacked robustness. Although meta-analyses assuage the bias posed by the small numbers of patient included in these studies, there is still a considerable risk of bias due to non-uniform reporting of clinical parameters.[12–15] The European recommendations[5] based on these meta-analyses propose insertion of a synthetic mesh when constructing an elective permanent end colostomy. However, this recommendation is not followed in everyday practice.[16]

Strikingly, 2 of the largest series with comparable methodology, using a retro-muscular prosthesis, had opposite results. In the Stomamesh study[17] (n = 211) after 1 year of follow-up, the rates of clinically diagnosed PSH were similar in control group and mesh group: 30% versus 29%, respectively. In the Dutch Prevent-trial[18] (n = 150), inserting a mesh in a sublay position significantly decreased the incidence of PSH (4.5% vs 24.2%, $P = 0.0011$) after 1 year of follow-up. Therefore, the contradictory results of previous studies, which have informed the European recommendations, warrant an additional large randomized controlled trial with a longer follow-up to definitively determine the efficiency of retro-muscular mesh placement to prevent PSH, improve QOL of these patients and to evaluate long-term adverse events of this technique.

The main objective of this study was to evaluate the efficiency of a prophylactic mesh on the occurrence of PSH after 2 years of follow-up between patients with a mesh inserted in a sublay position compared to those without mesh. Secondary objectives were to compare stoma-related complications: septic complications, pain, and QOL between groups.

METHODS

Study Design and Patients

This was a prospective, randomized, double-blind, multicenter, parallel, controlled trial in patients undergoing a permanent colostomy by laparotomy or laparoscopy. The protocol has been previously published.[19] The study was approved by the institutional review board (Comite de Protection des Personnes, Sud Mediterranee III) and all patients provided written informed consent.

Subjects were recruited from 18 French hospitals. Patients were eligible for inclusion if they were undergoing elective surgery for a definitive colostomy, were older than 18 years, and had no previous stoma. Terminal colostomy was indicated for the following criteria: anal, rectal or colon cancer preventing anastomosis; chronic inflammatory bowel disease; failure or poor functional result after colorectal surgery; or fecal incontinence. The procedure might be performed by laparoscopy or by laparotomy. The exclusion criteria were: peritonitis; stoma creation for sepsis; and a non-signed informed consent.

Randomization and Masking

Patients were randomized 1:1 into 2 groups immediately before the procedure: Group A undergoing classical stoma creation and Group B receiving a mesh inserted in a sublay position. Patients were randomized by blocks of random size stratified by center by the methodologist (BESPIM, CHU Nimes) using a program developed specifically for the study (SAS, Cary, NC, USA). Participants were assigned a unique identification code. The surgeon could not be blinded, but patients and outcomes assessors were blinded to patient group. The imaging exam was not performed until after the final follow-up visit (24 months).

Procedures

The surgical technique has been described previously.[19] Briefly, a circular cutaneous incision was made at the preoperatively marked ostomy site. After exposing the anterior rectus sheath, a cross-shaped (2.5 cm × 2.5 cm) incision was made in the fascia. In the mesh group (Group B), a retromuscular space was created by finger dissection and a 10 × 10 cm synthetic mesh was inserted on the posterior rectus sheath. For both groups, a cross-shaped incision was made in the peritoneum (and the mesh for Group B) and the stapled colon was brought through the reinforced abdominal wall and sutured to the skin.

The surgeons were all colorectal surgeons of the GRECCAR (Groupe de REcherche Chirurgicale sur le CAncer du Rectum) group, specialized in rectal cancer surgery but not specifically in hernia procedures. Standardization of the surgical procedure was ensured by 4 recorded group meetings with the video subsequently diffused to all the participants (Supplementary Video, http://links.lww.com/SLA/C518). The choice of peritoneal (intra or extra) and the muscular (trans- or pararectal) routes of the stoma was left to the discretion of the surgeon. Group B patients received a synthetic, lightweight (<50 g/m^2) monofilament mesh. The choice was dependent on surgeon preferences; 1 proposal being Parietex (Sofradim Production, France). The mesh was inserted by a stomal approach allowing a laparoscopic or an open procedure to perform the stoma. Patients were followed-up every 3 months for 2 years.

Outcomes

The primary endpoint was the clinically diagnosed PSH rate at 24 months. Clinical PSH was defined as any detectable bulge in the vicinity of the colostomy with the patient erect or supine or during a Valsalva maneuver and was diagnosed by a blinded surgeon or enterostomal therapy nurse and confirmed by another physician.

The secondary endpoints were: (a) technical criteria (duration of hospitalization, duration of operation, re-intervention rate, loss of blood, postoperative temperature); (b) clinically detected PSH at 12 months and radiologically detected PSH at 24 months; (c) PSH repair acts (number of repairs, repositioning of stoma); (d) stoma related-complications (mucocutaneous separation, prolapse, retraction, stenosis, necrosis, abscess, occlusion, strangulation, perforation, necrosis, eczema, irritation dermatitis, localized erythema, ulceration, peristomal pyoderma gangrenosum, and pain); (e) difficulties for fitting the appliance; (f) QOL; and (g) for patients in Group B, mesh characteristics (infection rate, exposure rate).

PSH was radiologically defined as any intra-peritoneal structure or organ outside the parietal peritoneum and was blindly determined by an abdominal computed tomography (CT)-scan if this exam was necessary for the patient's cancer surveillance, or by an magnetic resonance imaging exam for this study, as required by the ANSM (Agence National de Sécurité du Médicament), to avoid excessive radiation. A symptomatic PSH was defined as a PSH associated with pain, stoma appliance dysfunction and leakage, peristomal skin injury (severe irritation dermatitis, ulceration or peristomal pyoderma gangrenosum), and recurrent partial bowel obstruction. Pain was evaluated by a 10-point visual analog scale and by analgesics consumption. Ease of pouch fitting was measured by 10-point visual analog scale, leakage frequency, and number of pouches used daily. Finally, QOL was evaluated by the stoma-QOL after surgery at 1, 12, and 24 months. This 20-item questionnaire explores 4 domains: sleep, sexual activity, relations to family and friends, and wider social relations, with a score ranging from 20 to 80.[20]

Statistical Analysis

This was a superiority trial. Based on available literature at the time of the study conception and on our own experience, it was hypothesized that 25% of patients would develop a PSH[3] with 5% in the study group receiving the prophylactic mesh.[7,8] To see a 20%

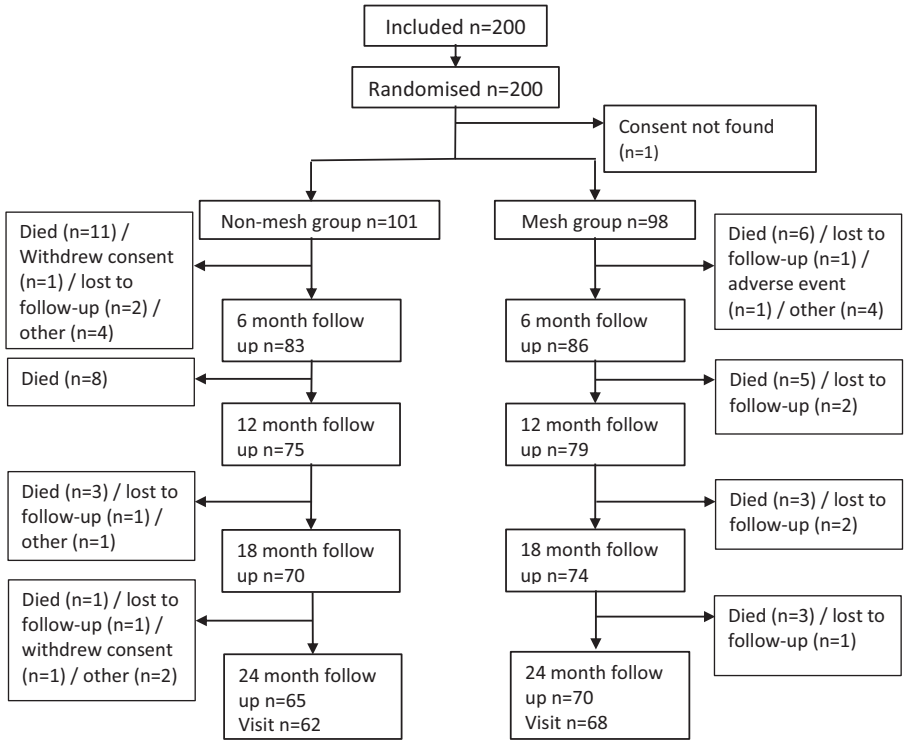

FIGURE 1. Flowchart.

difference between the 2 groups, with a power of 80% and a 5% alpha risk, 177 patients were required considering an adjustment on the number of centers. Thus a conservative sample size of 200 patients was chosen, to be randomly allocated in both groups to allow for a potential 10% loss to follow-up.

Quantitative data were expressed as mean and standard deviation or median and interquartile range, according to their distribution. Qualitative data were expressed as absolute number and frequency (%). Comparison between groups used, when appropriate, Student *T*, Wilcoxon, Chi-square, or Fisher tests.

The appearance of PSH at follow-up was analyzed with the Kaplan-Meier estimation method and the 2 groups were compared with the log-rank test. A multivariate cox-model was adjusted on the following confounders (defined a priori): center, type of mesh, surgeon, body-mass index, obesity, age, sex, indication for colostomy, previous abdominal surgery, immunology treatments (immunosuppressive treatments), surgeon experience, position of colostomy, chronic obstructive pulmonary disease, and size of incision. The final model included confounders with no more than 10 missing values and respecting the proportional hazards hypothesis. The adjusted hazard ratio (HR) was given with its 95% confidence interval (CI). The intention-to-treat analysis included all randomized patients. An as-treated analysis was also performed, transferring the patients from the mesh group who did not receive the mesh to the no mesh group, and excluding nonoperated or patients who did not receive a colostomy.

A P-value < 0.05 was considered as statistically significant. Statistical analysis was performed with R 3.5.1 software (R Development Core Team, (2018). R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

A total of 200 patients were included from November 19th, 2012 to October 20th, 2016 and randomized to no mesh (Group A) or mesh (Group B). One patient was excluded after randomization as the consent form was missing, thus 101 patients were included in Group A and 98 in Group B. Patient flow is shown in Figure 1. Four centers included 53% of the patients, with each including more than 20 patients (20–35 patients). Five patients did not have a colostomy: 4 patients were not operated (Group B) and 1 patient had an anastomosis without colostomy Group A). Nine patients in Group B did not receive the mesh for various reasons: inability to dissect the retro-muscular plane due to previous surgery (n = 3), inoculation of the surgical field (n = 3), pelvic sepsis diagnosed during surgery (n = 1), intraoperative cardiac complication (n = 1), and forgetting to place mesh (n = 1). These 9 patients were included in the mesh arm in the intention-to-treat analysis (Table 1). At 24 months, 65 patients were analyzed in Group A and 70 in Group B. Patients dropped out largely due to death (23 in Group A, 17 in Group B), lost to follow-up (4 in Group A, 6 in Group B), withdrawal of consent (2 in Group A), adverse events (1 in Group B), and other reasons (7 in Group A, 4 in

TABLE 1. Baseline Characteristics of the Intention-to-treat Population

	Group A (n = 101)	Group B (n = 98)
Sex ratio (Female)	44 (43.6%)	41 (41.8%)
Age (yr)	70.5 (11.1)	67.2 (12.4)
BMI (kg/m^2)	24.8 (4.7)	25.6 (4.6)
Smoker	14 (13.9%)	30 (30.6%)
COPD	5 (5.0%)	7 (7.1%)
Cancer	90 (89.1%)	82 (83.7%)
Fecal incontinence (%)	22 (21.8%)	22 (22.4%)
IBD	0	3 (3.1%)
Failure of rectal surgery	9 (8.9%)	7 (7.1%)

Data are n (%), mean (SD) or median (IQR).

BMI indicates body-mass index; COPD, chronic obstructive pulmonary disease; IBD, inflammatory bowel disease.

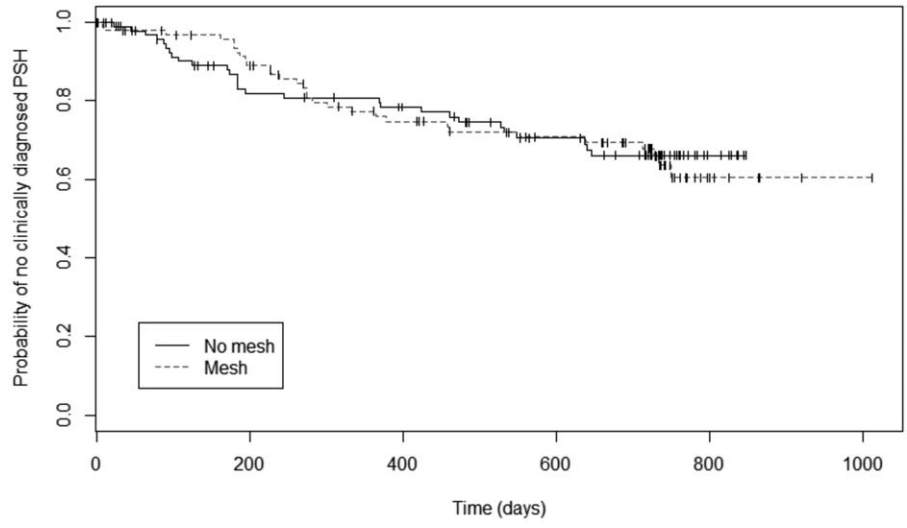

FIGURE 2. Kaplan-Meier representation for clinically diagnosed PSH. PSH indicates parastomal hernia.

Group B). Patient and operative characteristics are described in Table 1. There was no difference between the 2 groups in terms of sex, body-mass index, and chronic obstructive pulmonary disease. In the mesh group, patients were younger (67 vs 70 years) and more frequently smokers (31% vs 14%). Characteristics of patients analyzed at 24 months (n = 135) and patients excluded from analysis (n = 64) did not differ (Supplementary Table 1, http://links.lww.com/SLA/C537).

At 24 months follow-up, the rate of clinically detected PSH did not differ significantly between groups: 28% in Group A (n = 28) and 31% in Group B (n = 30) [odds ratio (OR) = 0.87 (0.47; 1.60)] Figure 2. We observed similar results in as-treated analysis, with no significant difference between groups [28% in Group A and 33% in Group B, OR = 0.77 (0.42; 1.44)]. Similarly, there was no difference in the median time until the first PSH [184 (97; 463) days for Group A vs 272 (189; 438) days for Group B, $P = 0.19$] Figure 2. The rate of symptomatic PSH was 13% in Group A versus 12% in Group B ($P = 1$).

In the multivariate analysis (Table 2), a center effect for higher PSH rate was found for centers including more than 20 patients (HR = 2.835; $P < 0.001$. There was more PSH in groups A and B for centers with 20 patients or more included. The difference between groups was not significantly different (41% vs 40%, respectively, $P = 0.84$). However, in groups with fewer than 20 patients included, the PSH rate was lower in groups A and B (12.5 vs 20; $P = 0.32$) without significant difference between groups. Placement of a mesh was not an independent factor for PSH rate (HR = 0.884; $P = 0.65$). Similarly, there was no surgeon experience effect, with comparable rates of PSH between the 2 groups for surgeons performing <2, 2 to 7, or >7 procedures (29% vs 35%, $P = 0.37$, 31% vs 29%, $P = 0.84$, 25% vs 33%, $P = 0.51$ in Groups A and B, respectively). PSH at 12 months did not differ between groups. Nineteen (18.8%) patients in Group A and 22 (22.4%) in Group B experienced at least 1 PSH at 12 months ($P = 0.64$).

In the patients remaining at 24 months, 64/65 patients in group A (98%) underwent a radiological exam versus 67/70 (96%) remaining in group B. Magnetic resonance imaging was performed in 64% (n = 41) and in 67% (n = 45) of patients in group A and B, respectively ($P = 0.7$), with CT scan for the remainder (36%, n = 23 in group A and 33%, n = 22 in group B; $P = 0.7$).

The rate of PSH determined by imagery was 34% in Group A and 22% in Group B ($P = 0.17$).

Surgical data and operative outcomes are presented in Table 3. Duration of hospitalization, loss of blood, and postoperative temperature did not differ significantly between groups (Table 3). The operative time was 12 minutes longer in the mesh group: 222 minutes

TABLE 2. Multivariate Analysis

Variables	Adjusted HR	95% CI Lower Limit	95% CI Upper Limit	*P*-value
Arm (with mesh)	0.884	0.517	1.512	0.65
Center >20 patients	2.835	1.538	5.228	0.00084
BMI >30	1.674	0.865	3.236	0.13
Age	1.022	0.999	1.044	0.060
Indication for colostomy				
Cancer (colon, rectum or anal canal)	0.779	0.295	2.059	0.61
Failure of rectal surgery	0.42	0.146	1.215	0.11
Anal incontinence	1.197	0.558	2.569	0.64
Previous abdominal surgery	1.203	0.677	2.135	0.53
Immune deficiency, immunosuppressant medication, or corticosteroids	1.726	0.525	5.675	0.37
History of COPD	0.84	0.259	2.727	0.77

CI indicates confidence interval; COPD, chronic obstructive pulmonary disease; HR, hazard ratio.

TABLE 3. Surgery Characteristics of the Intention-to-treat Population

	Group A (n = 101)	Group B (n = 98)	*P*-value
Surgery duration (h)	3.7 (2.9–4.9)	3.9 (3.1–5.3)	0.43
Preoperative stoma location	84 (96.8%)	71 (95.6%)	0.71
Extraperitoneal course	20 (21.5%)	14 (16.1%)	0.45
Transrectal course	84 (90.3%)	71 (80.7%)	0.09
Colon injuries during intervention	4 (36.4%)	5 (33.3%)	1
Hospital stay (d)	15 (11–27.5)	15 (9–21)	0.24
Blood loss (mL)	406.8 (544.7)	336.1 (422.1)	0.35
Number of compresses used	47.0 (41.3)	52.8 (42.6)	0.42
Temperature >37.2°C postoperatively	11 (11.7%)	4 (4.4%)	0.11
At least 1 surgical re-intervention	10 (9.9%)	6 (6.1%)	0.47
Stoma repositioning	0	1	0.49

Data are n (%), mean (SD) or median (IQR).

versus 234 minutes, in Group A and B, respectively ($P = 0.43$). Re-intervention for a complication was noted in 3 patients in Group A (polyp excision, parastomal hematoma, stenosis) and in 3 patients in Group B (colonic stenosis, bowel obstruction, and stoma dysfunction). At 2 years, the rate of reintervention for both hernia repair and repositioning colostomy did not differ between groups. Surgical treatment of a PSH was required in 5/28 (18%) patients in Group A and in 2/30 (7%) patients in Group B ($P = 0.62$). The stoma was not relocated in any patient in Group A and in 1 patient in Group B ($P = 0.49$).

No complications associated with mesh infections were reported. At discharge, median stoma diameters were equivalent: 35 ± 7.6 versus 33.9 ± 8.5 in Group A versus B, respectively ($P = 0.38$). In total, 32 and 37 stoma-related complications were observed in Group A and B, respectively (Table 4). The number of abscesses,

TABLE 4. Stoma-related Complications

	Group A (n = 32)	Group B (n = 37)	*P*-value
Stoma complications			
MC separation	9	10	0.81
Prolapse	9	6	0.59
Retraction	5	8	0.40
Stenosis	4	5	0.75
Necrosis	0	3	0.12
Stoma infections			
Abscess	5	5	1
Intestinal complications			
Occlusion	8	14	0.18
Strangulation	0	0	
Perforation	0	0	
Necrosis	0	1	0.49
Cutaneous complications			
Eczema	1	1	1
Irritation dermatitis	20	16	0.58
Localized erythema	11	19	0.11
Ulceration	5	11	0.12
Peristomal pyoderma gangrenosum	0	0	

MC separation indicates mucocutaneous separation.

TABLE 5. Stoma-QOL Total Scores

Stoma-QOL	Group A	Group B	*P*-value
M1	60.4 (11.3)	60.3 (10.2)	0.98
M12	63.2 (11.6)	62.1 (11.6)	0.59
M24	62.1 (14.2)	63 (11.4)	0.71

Data are presented as mean (standard deviation).
QOL indicates quality of life.

stenoses, and stoma prolapses were not significantly different between the groups. Maximum pain at the vicinity of the stoma was reported on Day 1, but with no between-group difference (2.3 ± 2.9 Group A vs 2.2 ± 2.8 Group B, $P = 0.89$) (Supplementary Table 2, http://links.lww.com/SLA/C537). No pain was described after 3 months in either group. A similar result was found for abdominal pain, with no pain reported after month 3 and no differences between the groups (Supplementary Table 3, http://links.lww.com/SLA/C537). Likewise, analgesic consumption did not differ according to treatment over the duration of the study (Supplementary Table 4, http://links.lww.com/SLA/C537).

Neither group struggled to fit the pouches, and at the end of the follow-up the fitting was considered to be easy to perform in each group [10 (10–10) vs 10 (10–10), $P = 0.93$] (Supplementary Table 5, http://links.lww.com/SLA/C537). The percentage of patients experiencing leakage around the stoma was low at each time point (range: 8%–17%) with no difference between groups (Supplementary Table 6, http://links.lww.com/SLA/C537). A median of 1 pouch was used per day at each time point and in each group. Stoma-QOL scores increased over time but were not significantly different between the 2 groups at any time point (Table 5). Mean scores at month 24 were 62.1 in Group A and 63 in Group B ($P = 0.71$).

DISCUSSION

The aim of this study was to evaluate whether systematic mesh implantation during primary colostomy creation was effective to prevent PSH. We found no difference in PSH rate between the mesh and the control groups. This study is one of the largest multicenter studies with a double-blinded clinical evaluation and a systematic radiological assessment of PSH with a 2 year-follow-up and a QOL evaluation.

In our study, after a 2-year follow-up, the rate of clinically detected PSH was 28% in the control group and 31% in the mesh group, without statistical difference. Several meta-analyses of randomized studies have reported the efficiency of these meshes to significantly reduce the rate of PSH.[12–15,21,22] The rate of clinically detected PSH ranged from 32% without mesh to 11% with a mesh according to the Chapman et al meta-analysis.[12] The PSH rate in the mesh group in our study is higher than in a recent meta-analysis (31% vs 22%),[14] due to the different methodologies; the other results come from smaller studies performed at single institutions with a special interest in PSH. The results of these other studies are difficult to extrapolate to routine clinical practice for the non-specialized surgeons investigated in our study due to non-uniform reporting of clinical parameters.[23] Furthermore, unlike in other studies,[4,7,8,18] the clinical diagnosis of PSH, blinded to patient group might have generated a higher PSH rate here. Clinical definitions of PSH vary considerably across studies.[12,21] The definition used in our study "any detectable bulge in the vicinity of the colostomy" was chosen to be most relevant for the patient, and this wider interpretation will have contributed to the higher rate. More surprisingly, the PSH rate in the control group was very different to other studies: 28% in our

study versus 41% in the meta-analysis for a follow-up from 6 months to 1 year.[14] This high rate of PSH in the control groups may explain many significant differences in favor of meshes in other studies.

Despite European recommendations to systematically implant meshes, ours is not the only study to conclude that the use of a mesh does not modify the rate of PSH.[9,17,24] The Stomamesh study had a similar methodology to ours and studied 211 patients.[17] After 1 year of follow-up, the rate of clinically diagnosed PSH was similar: 30% versus 29% in control group versus mesh group, respectively. The radiologically-diagnosed PSH rate was 26% versus 24% in control group vs mesh group, respectively. In contrast to the Dutch Prevent-trial[18] (n = 150), which was similar in design to ours and to the Stomamesh study, although using open surgery, inserting a mesh in a sublay position significantly decreased the incidence of PSH (5% vs 24%, $P = 0.0011$). The rate of PSH in the mesh group was very low and could be explained by the short follow-up of 1 year and perhaps because of a non-blinded evaluation. The clinical definition of PSH was similar to ours. CT scan confirmed clinically-detected PSH but not all patients had a radiological exam to define a rate of radiological PSH.

No negative side-effects of prophylactic mesh were detected despite the large trial population. No septic complications requiring removal of the mesh were reported. The number of peristomal abscesses was identical (n = 5) in both arms. Complication and reoperation rates did not differ between groups. Although not statistically significant, there was more re-intervention for PSH in the no-mesh group (18% vs 7%). It is possible that the risk of re-intervention to repair PSH, often complex to achieve, may be limited by the insertion of a mesh, which would be clinically relevant.

QOL was also similar in the 2 arms. In the literature, postoperative morbidity has been shown to be extremely low after the placement of meshes, with a prosthetic infection rate around 2%,[1,12,22] using synthetic meshes positioned in contact with the colon. However, the limited follow-up of all the studies should encourage vigilance and warrants long-term monitoring of these devices.

Placement of mesh in the retro-muscular position was a relatively new technique for many of the study surgeons and may require additional experience. However, regardless of the number of procedures performed, the rates of PSH were comparable between the groups. It could be argued that our results are due to mesh design. However, the size and cruciform incision of the prosthesis are similar to other studies when a sublay technique has been performed, and especially in studies in favor of the mesh.[4,7,8,10,18] The cruciform incision can be enlarged over time by a shrinkage effect of the surrounding mesh[6,25] and may favor PSH through the mesh keyhole. In a porcine ventral hernia model, a light-weight mesh (45 g/cm^2) shrank by 33% of its initial surface area within 5 months.[26] This significant decrease in size leads to an insufficient parietal coverage and may induce PSH. Intraperitoneal location is not always simple and requires training, although the Sugarbaker technique is largely performed for PSH repair.[5,6] However, this technique, without mesh opening, should theoretically reduce the risk of shrinkage and PSH. Yet implanting an intra-peritoneal prosthesis for prevention is questionable because of the risk of adhesions or erosion into the viscera.[6,8]

This study had certain limitations. Despite randomization, there appeared to be differences between groups in terms of age and smoking, with more smokers in the mesh group (31% vs 14%). However, PSH levels were comparable among smokers and non-smokers, irrespective of mesh (PSH in smokers: 21% in Group A and 27% in Group B; PSH in non-smokers: 29% in Group A and 33% in Group B). This study included 200 patients, followed quarterly, of whom only 135 patients completed the 2-year follow-up, yet the calculated number of patients required to obtain 80% power was 177. However, all the patients were included for analysis of the primary endpoint, taking into account all events until the loss of follow-up, using the censure mechanism to allow for the shorter follow-up for these patients (Fig. 2).

Despite this censored survival analysis there is still a possibility of a type II error in this negative study in which complete follow-up of the intended number of patients was not possible.

In conclusion, placement of a mesh in a retro-muscular position with a central incision to allow colon passage is clearly not the best option to prevent PSH. According to our results and the Stomamesh study, the European Recommendations on the use of a non-absorbable synthetic mesh for the prevention of PSH should be revisited. Moreover, the monitoring of these synthetic meshes implanted around the colon must continue, and a 5-year surveillance of this cohort will soon be available to allow better understanding of the long-term merits and risks of these approaches.

ACKNOWLEDGMENTS

The authors thank the patients who participated in the trial, Noëmie Coneau (data manager) Lyamin Bendjedou (research assistant) and Sarah Kabani (medical writer) and all at the Nîmes University Hospital.

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