

Effect of Sublay Preventive Mesh for Terminal Colostomy on Symptoms and Quality of Life in Patients With Parastomal Hernia: A Post Hoc Analysis of the GRECCAR 7 Cohort

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BACKGROUND: Recent randomized clinical trials and meta-analyses confirm that the use of a prophylactic mesh does not significantly reduce the parastomal hernia rate. Data about the benefits of these meshes concerning the symptoms of parastomal hernia are lacking in the existing literature.

OBJECTIVE: The aim of this study was to perform a post hoc analysis of the patients presenting parastomal hernia from the GRECCAR 7 (Groupe de recherche sur la chirurgie du cancer du rectum) randomized clinical trials cohort on whether the presence or the absence of the mesh influenced the symptoms, the quality of life, and complications of patients with parastomal hernias.

DESIGN: We studied the parastomal hernia-related symptoms among the 2 groups of the GRECCAR 7 randomized clinical trial, with or without prophylactic mesh at the time of the index surgery.

SETTINGS: Data were retrospectively extracted and analyzed from the GRECCAR 7 database.

PATIENTS: Patients diagnosed with a parastomal hernia during the 2 years of the GRECCAR 7 study.

MAIN OUTCOME MEASURES: Several prospectively collected data about the symptoms were studied among this population. We also studied the average interval between parastomal hernia repair surgery and both index surgery and diagnosis of parastomal hernia.

RESULTS: Among the 199 patients included in the GRECCAR study, 36 patients (35.6%) in the nonmesh group and 33 patients (33.7%) in the mesh group were diagnosed with clinical and/or radiological parastomal hernia at 2-year follow-up, without a statistically significant difference ($p = 0.89$). None of the studied symptoms showed any statistically significant difference between the groups.

LIMITATIONS: This study relies on a relatively small number of patients, and although data were prospectively collected, we lacked some details about the categorization of parastomal hernias.

CONCLUSIONS: We believe that the use of a prosthetic mesh in a sublay position to prevent parastomal hernia in terminal end colostomy patients should no longer be recommended. See **Video Abstract**.



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EFFECTO DE LA MALLA PREVENTIVA RETROMUSCULAR PARA COLOSTOMÍA TERMINAL CON RESPECTO A LOS SÍNTOMAS Y LA CALIDAD DE VIDA EN PACIENTES CON HERNIA PARAESTOMAL: UN ANÁLISIS POST-HOC DE LA COHORTE GRECCAR 7

ANTECEDENTES: Los recientes metaanálisis y ensayos clínicos aleatorizados confirman que el uso de una malla profiláctica no reduce significativamente la tasa de hernia paraestomal. En la literatura existente faltan datos sobre

los beneficios de estas mallas en relación con los síntomas de la hernia paraestomal.

OBJETIVO: El objetivo de este estudio fue realizar un análisis post-hoc de los pacientes que presentaron hernia paraestomal de la cohorte de 7 ensayos clínicos aleatorizados GRECCAR sobre si la presencia o ausencia de la malla influyó en los síntomas, la calidad de vida y las complicaciones de los pacientes con hernias paraestomales.

DISEÑO: Estudiamos los síntomas relacionados con la hernia paraestomal entre los dos grupos del ensayo clínico aleatorizado GRECCAR 7, con o sin malla profiláctica en el momento de la cirugía índice.

AJUSTES: Los datos fueron extraídos y analizados de manera retrospectiva de la base de datos GRECCAR 7.

PACIENTES: Pacientes diagnosticados con hernia paraestomal durante los dos años del estudio GRECCAR 7.

PRINCIPALES MEDIDAS DE RESULTADO: Se estudiaron varios datos recopilados de manera prospectiva sobre los síntomas en esta población. También estudiamos el intervalo promedio entre la cirugía reparadora de la hernia paraestomal así como también la cirugía índice como el diagnóstico de la hernia paraestomal.

RESULTADOS: De entre los 199 pacientes incluidos en el estudio GRECCAR, 36 pacientes (35,6%) fueron diagnosticados con hernia paraestomal de manera clínica y/o radiológica en el grupo sin malla a los 2 años de seguimiento y 33 (33,7%) en el grupo con malla, sin diferencia estadísticamente significativa ($p = 0,89$). Ninguno de los síntomas estudiados mostró diferencias estadísticamente significativas entre los grupos.

LIMITACIONES: Este estudio se basa en un número relativamente pequeño de pacientes y, aunque los datos fueron recopilados de forma prospectiva, nos faltaron algunos detalles sobre la categorización de las hernias paraestomales.

CONCLUSIONES: Creemos que ya no se debe recomendar el uso de una malla protésica en posición retromuscular para prevenir la hernia paraestomal en pacientes con colostomía terminal. (*Traducción—Dr. Osvaldo Gauto*)

KEY WORDS: Hernia-related symptoms; Mesh; Parastomal hernia; Prevention; Quality of life.

Parastomal hernia (PSH) is an incisional hernia in the site of an abdominal wall stoma.¹ The incidence and prevalence are difficult to evaluate because of the absence of a standard definition, and therefore, the prevalence of the symptoms related to a PSH is also uncertain. Nearly half of patients undergoing rectal cancer surgery will receive a stoma,² in half of whom the stoma becomes

permanent. PSH is one of the most frequent complications of a permanent stoma (up to 50%),³ with a detrimental impact on quality of life (QoL).⁴ Indeed, PSH can cause difficulties in fitting the pouching system, pain, and stoma leakage. Furthermore, PSH compromises stoma irrigation and may induce occlusion episodes.⁵

In 2017, the European Hernia Society recommended the use of nonabsorbable synthetic prostheses for the prevention of PSH when terminal end colostomy is being performed.⁶ Later, other groups also made recommendations concerning the utility of a synthetic mesh placed at the time of the colostomy, varying from strong advocacy to more cautious recommendations.^{7,8} However, colorectal surgeons rarely followed these recommendations.⁹

In 2021 and 2022, our team published a randomized controlled trial (RCT) and a meta-analysis on this subject. Our RCT,¹⁰ in line with the STOMAMESH RCT,¹¹ showed no benefit of using a mesh in a sublay position on the occurrence of a PSH. Our meta-analysis¹² showed that the benefits found in earlier and smaller studies^{13–19} were outweighed by the absence of benefit found in the larger and more recent studies, resulting in no benefit as a prevention strategy. Another interesting finding was that, despite the absence of a significant difference between the mesh and nonmesh groups in terms of PSH, we found a statistically significant effect of the mesh on the need for surgical repair of any arising PSH. Other studies have found similar results.²⁰ The authors believe that 2 interpretations can be made: the presence of a mesh is responsible for a smaller/less clinically symptomatic PSH or conversely, the presence of the mesh makes the surgeon or patient reluctant for repair surgery.

As recently noted by Rajaretnam and Smart,²¹ a more in-depth analysis of the results of prophylactic meshes is required before we determine the proper role of these meshes in prophylaxis. As they state, a binary end point of PSH versus no PSH, particularly when diagnosed radiologically, is not necessarily clinically relevant. Indeed, a reduction of the symptoms related to the PSH or a smaller impact on QoL, as shown in the STOMAMESH study, would provide more pertinent outcomes.¹¹

The present study aimed to perform a post hoc analysis of patients presenting with a PSH from the GRECCAR 7 (Groupe de recherche sur la chirurgie du cancer du rectum) study cohort to determine whether the presence or the absence of the mesh influenced the symptoms, QoL, and complications related to PSH.

MATERIALS AND METHODS

Study Design and Patients

Data were retrospectively extracted and analyzed from the GRECCAR 7 database. The methodology of the GRECCAR 7 RCT has been previously described.^{10,22} In

brief, it was a prospective, randomized, double-blind, multicenter, parallel, controlled trial in patients undergoing a permanent colostomy by laparotomy or laparoscopy. The group of patients receiving the mesh all underwent the same technique for the placement of the mesh as described in the following paragraphs.

The study was approved by the institutional review board (comité de protection des personnes, Sud Mediterranee III) and registered on clinicaltrials.org (NCT01380860).

Treatment Techniques

First, a circular cutaneous incision at the preoperatively marked ostomy site is made. No subcutaneous tissue is excised. After exposing the anterior rectus sheath, a cross-shaped (2.5 cm × 2.5 cm) incision is made in the fascia (Figs. 1A and B). The rectus abdominis muscle is split in the direction of the fibers. In the mesh group, a retromuscular space is created by finger dissection (Fig. 1B). The posterior fascia/peritoneum is left undisturbed. A lightweight (<50 g/m²) polypropylene mesh (10 × 10 cm) is placed on the posterior rectus sheath (Figs. 1C and D). A cross-shaped incision is made in the peritoneum and the mesh, and the stapled closed colon is passed through the reinforced abdominal wall and sutured to the skin (Fig. 1E).

In the control group, the steps remain the same except that no preperitoneal dissection is made and no mesh is placed. A stapled closed colon is passed through the abdominal wall and sutured to the skin.

Outcome Measures

The primary end point was the clinically diagnosed PSH rate at 24 months. In the GRECCAR 7 study, 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; this was meant to limit diagnostic errors because of a confused definition that could lead to an intuitive diagnostic.

PSH was radiologically defined as any intraperitoneal structure or organ projected over the parietal peritoneum, and it was blindly determined by a CT scan or MRI, depending on the imaging technique recommended in the follow-up of the patient.

Secondary end points included the PSH repair acts (number of repairs, repositioning of stoma); stoma-related complications (hernia, infectious, intestinal, cutaneous, and pain); difficulties for fitting the appliance; QoL; and, for patients in the mesh group, the evolution of the mesh (infection rate, exposure rate) and the rate of symptomatic PSH.

QoL was evaluated by the Stoma-QoL after surgery at 1, 12, and 24 months. The 20 items of the questionnaire explore 4 domains: sleep, sexual activity, relations to family and friends, and wider social relations, with a score ranging from 20 to 80.²³

Groups

In this article, we considered only the patients experiencing a PSH (both clinically and radiologically diagnosed PSH)

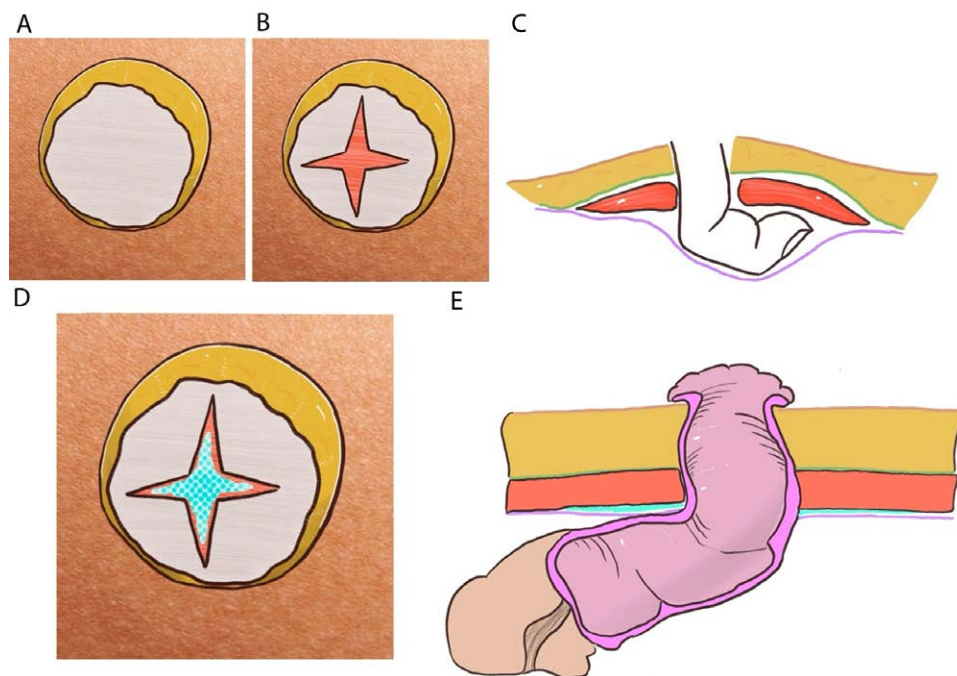


FIGURE 1. Subway mesh placement technique in the GRECCAR 7 trial. A, Circular cutaneous incision. B, Exposition of the anterior rectus sheath and cross-shaped incision. C, Creation of the retromuscular space. D and E, Final position of the mesh. GRECCAR 7 = Groupe de recherche sur la chirurgie du cancer du rectum.

during the 2 years of the GRECCAR 7 study, comparing the group receiving a prophylactic mesh at the time of the index surgery versus the control group without mesh.

We looked for any statistically significant difference between the 2 groups concerning: patient characteristics, QoL evaluated by the Stoma-QoL score, abdominal and parastomal pain evaluated by visual analog scale (VAS), prevalence of occlusion, stoma-related complications (retraction, stenosis, prolapse, necrosis), fitting difficulties, peristomal leakage, average pouch replacement per 24 hours, peristomal cutaneous complications (eczema, dermatitis, ulceration, localized erythema), and PSH-related symptoms. We also studied the average interval between PSH repair surgery and both index surgery and diagnosis of PSH.

Statistical Analysis

Quantitative data were expressed as mean and SD or median and interquartile range, according to their distribution. Qualitative data were expressed as absolute number and frequency (%). Comparison between groups used either Student *t* test, Wilcoxon test, χ^2 test, or Fisher exact probability test as appropriate.

A *p* value of <0.05 was considered statistically significant. Statistical analysis was performed with R version 4.1.1 software (R Development Core Team [2021]. R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Patient Characteristics

Among the 199 patients included in the GRECCAR study, 36 patients (35.6%) were diagnosed with clinical and/or radiological PSH in the nonmesh group at 2 years follow-up and 33 (33.7%) in the mesh group, with no statistically significant difference (*p* = 0.89). In the mesh group, 30 patients (30.6%) had a clinically diagnosed PSH versus 28 (27.7%) in the nonmesh group (*p* = 0.77).

As shown in Table 1, there were no significant baseline differences between the 2 groups of patients diagnosed with a PSH.

Quality of Life

As evaluated by the Stoma-QoL score, QoL showed no significant difference between groups at any time point (Table 2).

PSH-Related Symptoms

Peristomal pain evaluated by VAS was not significantly different between the 2 groups at any of the time points. It was highest on day 1 (average 2.2 ± 2.6 in the nonmesh group vs 2.5 ± 3.1 in the mesh group; *p* = 0.7). Median peristomal pain dropped to 0 in both groups after 6 months and no difference was found between groups. Similar findings were made for more diffuse abdominal pain. The average was highest on day 1 (3.4 ± 2.9 in the nonmesh group

versus 3.6 ± 3.2 in the mesh group) with no statistically significant difference (*p* = 0.77). Median VAS abdominal pain dropped to 0 at 6 months in both groups.

Table 3 shows the PSH-related symptoms. None reached significance, and apart from erythema, the overall prevalence of these complications is low. No reoperation was necessary because of stoma complications. Intestinal occlusion occurred in 2 patients (5.6%) in the nonmesh group versus 6 patients (18.2%) in the mesh group (*p* = 0.14). Fitting difficulties, stomal leakages, and average number of pouch changes per 24 hours were also not significantly different between the 2 groups.

Five patients (13.9%) in the nonmesh group versus 2 patients (6.1%) in the mesh group were operated on (*p* = 0.43). Neither the interval between PSH repair and index surgery (449 days [353–482] in the nonmesh group vs 357 days [330–384] in the mesh group; *p* = 0.38) nor the interval between PSH repair and diagnosis of PSH (56 days [51–58] in the nonmesh group versus 36 days [32.5–39.5] in the mesh group; *p* = 0.095) were clinically relevant.

DISCUSSION

Primary Outcome

In this study, we conducted a post hoc analysis of the impact of a prophylactic mesh on stoma- and PSH-related symptoms. It showed that around 36% of patients with

TABLE 1. Patients characteristics

Characteristics at the time of inclusion	Without mesh (N = 36)	Mesh (N = 33)	<i>p</i>
Sex, women	12 (33.3%)	16 (48.8%)	0.30
Age, y	72.5 ± 11.4	68.8 ± 12.3	0.21
BMI	25.6 ± 4.3	27.6 ± 5.0	0.064
Indication for colostomy			
Anal canal, rectal, or colon cancer	32 (88.9%)	27 (81.8%)	0.50
Anal incontinence	10 (27.8%)	8 (24.2%)	0.95
Rectal surgery failure	4 (11.1%)	2 (6.1%)	0.68
Past medical history			
COPD	1 (2.8%)	3 (9.1%)	0.34
Active smoking	4 (11.1%)	8 (24.2%)	0.26
History of abdominal surgery	21 (58.3%)	20 (60.6%)	1
Immunosuppressant medications	2 (5.6%)	0	0.49

Data presented as n (%) or mean ± SD.

COPD = chronic obstructive pulmonary disease.

TABLE 2. QoL evaluated by Stoma-QoL score

Time point	Without mesh (N = 36), mean ± SD	Mesh (N = 33), mean ± SD	<i>p</i>
M1	60.2 ± 14.0	59.2 ± 11.5	0.76
M12	62.7 ± 10.1	57.9 ± 11.0	0.12
M24	60.3 ± 8.9	60.1 ± 9.8	0.93

QoL = quality of life.

TABLE 3. PSH-related symptoms

At least 1 episode of PSH-related symptom during follow-up	Without mesh (N = 36), n (%)	Mesh (N = 33), n (%)	p
Retraction	1 (2.8%)	3 (9.1%)	0.34
Stenosis	1 (2.8%)	4 (12.1%)	0.19
Prolapse	5 (13.9%)	5 (15.2%)	>0.99
Suture dehiscence	3 (8.3%)	5 (15.2%)	0.47
Necrosis	0	2 (6.1%)	0.23
Peristomal eczema	1 (2.7%)	0 (0%)	>0.99
Dermatitis	12 (33.3%)	6 (18.2%)	0.18
Localized erythema	4 (11.1%)	6 (18.2%)	0.50
Ulceration	1 (2.8%)	4 (12.1%)	0.19
At least 1 eventration symptom during follow-up (increasing protrusion, occlusion, pain, or incarceration)	13 (36.1%)	12 (36.4%)	>0.99

PSH = parastomal hernia.

a PSH developed some level of complications related to the stoma, compared with the 63% overall complications reported in the Stoma-Const study.²⁴ The Stoma-Const study did not use the same classification of complications, which may explain this difference. Similarly, our study did not show any statistically significant difference between the 2 groups for these symptoms. It is important to note that both studies used a prosthetic mesh in a sublay position.^{10,25} In the overall GRECCAR 7 study population, no difference was found concerning the stoma-related complications between groups.¹⁰ This new analysis confirms those findings in the population of patients diagnosed with PSH.

Another interesting result in this subgroup of patients diagnosed with PSH was that no difference was found concerning patients' QoL. Indeed, the overall QoL scores were high when compared against a population of colostomy patients (from 53.8 to 62.6),²³ meaning that the impact of PSH on QoL was low.

In the 1-year follow-up of the STOMAMESH study, the authors found no significant differences between the groups regarding the occurrence of PSH, bulging only, stenosis, prolapse, or stoma dressing problems.²⁶ Using the QLQ C-30 questionnaire, the authors found a non-significant difference in the QoL between groups. Some of the differences in the subscores reached significance for "emotional functioning" and "cognitive functioning," as outlined by Rajaretnam and Smart,²¹ although the clinical significance and relevance of that finding are unclear, and these factors have no reasons to be influenced by the presence or absence of mesh. No other significant difference in the other domains (fatigue and pain) was found.

It seems that there is now abundant data that the use of a prosthetic mesh in a sublay position does not provide any benefit either on the occurrence of a PSH or on related symptoms. The question now remains: Should this matter now be considered resolved, and should the preventive use of meshes be abandoned?

We believe several aspects need to be discussed, as outlined in the following paragraphs.

Technical Aspects

The different studies applied different techniques. Several studies used a sublay position of the mesh with 1 edge included in the continuous suture of the midline incision.^{11,14,17,27} The surgical technique itself limits the significance of these results, as most colorectal surgery nowadays is performed laparoscopically. All these studies, except the study by Odensten et al,¹¹ found a benefit in favor of the mesh. All the studies using intraperitoneal meshes found a benefit in the mesh group either with a modified Sugarbaker technique in only 1 study¹⁶ or with a keyhole-like technique.^{15,19,28} Finally, in 2 cases, the mesh was inserted through the stomal incision in a sublay position^{10,13}; one study found a benefit, but the other one did not. The high heterogeneity of the results urges caution about drawing hasty conclusions.

From a technical aspect, the conclusion is that the sublay position of the mesh should now be abandoned, colostomy should be performed with an extraperitoneal route according to the meta-analysis of Luo et al,²⁹ and the intraperitoneal position of the mesh cannot yet be ruled out. The ongoing Chimney trial³⁰ will hopefully provide answers to these questions.

General Question of PSH Prevention Versus Treatment

Although almost 50% of patients will experience PSH after undergoing terminal end colostomy, only a few of them will experience symptoms and even fewer will require repair surgery. In the meantime, the development of new materials³¹ makes the treatment of PSH relatively easy and effective, and the laparoscopic Sugarbaker technique is now the standard for this kind of procedure. This raises the question of the clinical interest of prevention versus the better standardization of the techniques and indications for repair surgery.

Definition and Diagnostic Method

The definition of PSH varies considerably from one study to another,³² as does the diagnostic method to assess PSH, from clinical alone,¹⁷ to radiological,^{18,27} or both.¹⁰ Yes, the relevance of all these methods could be questioned; clinical definition should be blinded as it is highly subjective,¹⁴ whereas the radiological method is of questionable clinical interest. As outlined by Rajaretnam and Smart,²¹ the current binary presence/absence definition of the PSH, which requires radiological confirmation because the clinical examination is subject to interindividual variation, results in a nonclinically relevant definition. A definition taking into account the gravity of the PSH, the impact on the QoL, or the related symptoms would be more useful and would enable more relevant conclusions from the studies. We suggest a Clavien-Dindo-like definition of PSH based on the therapeutic consequence. This would be both more clinically relevant and reproducible among teams. We propose the following classification:

Grade 1: Infraclinic PSH: no symptoms, radiological diagnosis.

Grade 2: Clinical PSH: no or few symptoms, clinically diagnosed, no treatment.

Grade 3: Pauci-symptomatic PSH: medical treatment (such as support abdominal belt).

Grade 4: Symptomatic treatment requiring surgical treatment.

The purpose of such a classification is not meant to be used in clinical practice or to replace clinical or radiological diagnostic methods but rather to be used in clinical trials so that the severity of the PSH can be compared a posteriori.

Limitations

This study relies on a relatively small number of patients, and although data were prospectively collected, we lacked some details about the categorization of the PSH.

Implications for Further Research

Further research on the subject should focus on the intraperitoneal position of the mesh, and sublay position should be abandoned. More studies on the risks of adhesions or erosion of a prophylactic mesh are also needed.³³ There is an urgent need for a better definition and more granular categorization of PSH. The ongoing PROPER trial will also provide interesting results about the patient-reported outcomes of the treatment of PSH and will guide further studies on the subject.³⁴

Implication for Clinical Practice

The most direct implication for clinical practice is that the use of a prosthetic mesh in a sublay position for systematic prevention of PSH after terminal end colostomy should

no longer be recommended. If effective, one benefit of the prevention strategy would have been eliminating the debate about diagnosis, categorization, and optimal treatment strategy.

CONCLUSION

Based on the GRECCAR 7 database, this study compared the symptoms of patients diagnosed with PSH between the mesh and nonmesh groups. No statistically significant difference was found between these groups in terms of symptoms or QoL. We believe that the use of a prosthetic mesh in a sublay position to prevent PSH in patients who underwent terminal end colostomy should no longer be recommended. We also believe that a more clinically relevant definition of PSH should be adopted, and we suggest a Clavien-Dindo-like definition.

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