JAMA Surgery | Original Investigation

Parastomal Hernia Prevention Using Funnel-Shaped Intra-Abdominal Mesh Compared to No Mesh
The Chimney Randomized Clinical Trial

Elisa Mäkäräinen, MD, PhD; Heikki Wiik, MD, PhD; Maziar Nikberg, MD, PhD; Jyrki Kössi, MD, PhD; Monika Carpelan-Holmström, MD, PhD; Tarja Pinta, MD, PhD; Kirsi Lehto, MD, PhD; Marko Nikki, MD, PhD; Jyri Järvinen, MD, PhD; Pasi Ohtonen, MSc; Tero Rautio, MD, PhD

IMPORTANCE Prophylactic placement of a mesh has been suggested to prevent parastomal hernia. Evidence to support this practice is contradictory.

OBJECTIVE To determine whether funnel-shaped permanent synthetic parastomal mesh is effective and safe in parastomal hernia prevention.

DESIGN, SETTING, AND PARTICIPANTS The Chimney Trial was a randomized single-blinded multicenter trial conducted in 4 hospitals in Finland and 1 in Sweden from February 2019 and September 2021. Of 439 patients with rectal adenocarcinoma undergoing either laparoscopic or robotic-assisted abdominoperineal resection or the Hartmann procedure, 143 were enrolled in the trial, 135 received their allocated intervention, and 121 were analyzed at 12-month follow-up. Data were analyzed from December 2023 to May 2024.

INTERVENTION In the intervention group, a permanent colostomy was created with a funnel-shaped intraperitoneal mesh and compared to a control group with a stoma without the mesh.

MAIN OUTCOME AND MEASURE The primary end point was the incidence of computed tomography (CT)–confirmed parastomal hernia 12 months after surgery.

RESULTS There were 68 patients (mean [SD] age, 68.7 [11.6] years; 36 [53% male and 32 [47%] female) who received the intended allocation in the mesh group and 67 (mean [SD] age, 66.4 [11.7] years; 48 [72%] male and 19 [28%] female) who received the intended allocation in the control group. CT scans were available for 58 patients in the mesh group and 59 patients in the control group at the 12-month follow-up. CT scans confirmed parastomal hernia in 6 of 58 patients (10%) in the mesh group compared to 22 of 59 patients (37%) in the control group (difference, 27%; 95% CI, 12-41; $P < .001$). Clinical parastomal hernia as a secondary outcome was recorded in 1 of 60 patients (2%) in the mesh group compared to 27 of 61 (43%) in the control group (difference, 41%; 95% CI, 29-55; $P < .001$). The number of patients with Clavien-Dindo class II ileus was 23 (35%) in the mesh group compared to 11 (17%) in the control group (difference, 18%; 95% CI, 3-32; $P = .006$). Only slight differences between the groups were detected in other stoma-related complications, readmissions, operative time, surgical site infections, reoperations, and quality of life.

CONCLUSIONS AND RELEVANCE In this study, funnel-shaped parastomal mesh prevented a significant number of parastomal hernias without predisposing patients to mesh- or stoma-related complications during 12-month follow-up. The results of this study suggest the funnel-shaped mesh is a feasible option to prevent parastomal hernia.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT03799939

Visual Abstract
Invited Commentary
Supplemental content

Author Affiliations: Oulu University Hospital, Medical Research Center Oulu, Oulu, Finland (Mäkäräinen, Wiik, Nikki, Järvinen, Ohtonen, Rautio); Department of Surgery Västmanland's Hospital Västerås and Centre for Clinical Research Region Västmanland, Uppsala University, Uppsala, Sweden (Nikberg); Päijät-Häme Central Hospital, Lahti, Finland (Kössi); Helsinki University Hospital, Helsinki, Finland (Carpelan-Holmström); Seinäjoki Central Hospital, Seinäjoki, Finland (Pinta); Tampere University Hospital, Tampere, Finland (Lehto).

Corresponding Author: Elisa Mäkäräinen, MD, PhD, Oulu University Hospital, Medical Research Center Oulu, PL29, 90029 OYS, Oulu, Finland (elisa.makarainen@pohde.fi).

JAMA Surg. doi:10.1001/jamasurg.2024.3260
Published online August 28, 2024.

The recommendation from the European Hernia Society (EHS) to use mesh for parastomal hernia (PSH) prevention was questioned after conflicting results of randomized clinical trials involving the use of keyhole mesh were published.[1-4] All the trials showed that retrorectus keyhole mesh did not decrease the PSH rate compared to the nonmesh control group.[2-4] Consequently, the recommendation on PSH prevention was recently updated. However, the recommendation still concluded that prophylactic synthetic mesh placement is likely associated with a reduced risk of PSH.[5]

In contrast, retrospective case series and cohort studies assessing the effectiveness and safety of a specially designed parastomal mesh, made of polyvinylidene fluoride with a funnel-shaped configuration, have consistently shown positive outcomes since Berger[6] first described the technique. Subsequent retrospective case series have reported a significant reduction in PSH rates of 3.8% to 13% with use of the funnel-shaped mesh, with no increased risk of complications.[7-11]

Considering the high risk of a PSH in a colostomy without preventive measurements and suboptimal outcomes of repairs in real-life scenarios,[12-14] there is a justifiable demand to explore more effective approaches to prevent PSH. The Chimney Trial was designed to evaluate the efficacy and safety of intra-abdominal funnel-shaped permanent synthetic mesh in PSH prevention comparing the mesh group to a nonmesh control group after either minimally invasive abdominoperineal resection (APR) or the Hartmann procedure due to rectal adenocarcinoma. The hypothesis is that the funnel-shaped design of the mesh may prevent a significant number of PSHs compared to no mesh.

Key Points

Question Is funnel-shaped intra-abdominal mesh effective and safe in parastomal hernia prevention in permanent colostomy?

Findings In a 12-month follow-up of a randomized clinical trial including 143 patients, the computed tomography–confirmed parastomal hernia rate and clinical parastomal hernia were lower in the mesh group than in the control group. Mesh did not predispose patients to complications.

Meaning The results of the 12-month follow-up suggest that the funnel-shaped parastomal hernia mesh is both effective and safe in parastomal hernia prevention.

Methods

Trial Design

The Chimney Trial was a randomized, multicenter, single-blinded trial conducted across 4 hospitals in Finland (Oulu University Hospital, Helsinki University Hospital, Tampere University Hospital, and Seinäjoki Central Hospital) and Västmanland's Hospital, Västerås, in Sweden between February 2019 and September 2021.[15] The trial was registered in Clinical Trials prior to patient enrollment. All eligible patients received oral and written information about the trial, including the potential risks as well as benefits of prophylactic mesh placement or absence of mesh prevention. All enrolled patients provided written informed consent for participation. The trial protocol (Supplement 1) received approval from the ethics committee at Oulu University Hospital and the Swedish Ethical Review Authority before initiation. Institutional approvals were obtained by each participating hospital. The trial adhered to the principles of the Declaration of Helsinki. The objective of the Chimney Trial was to determine the effectiveness and safety of the funnel-shaped parastomal mesh in PSH prevention compared to nonmesh among patients undergoing minimally invasive abdominoperineal resection or the Hartmann procedure.

Participants

Patients who underwent laparoscopic or robotic-assisted APR or the Hartmann procedure for rectal adenocarcinoma in each attending hospital were considered for enrollment. Patient inclusion took place in the outpatient department during a presurgery visit. Inclusion criteria were laparoscopic or robotic-assisted abdominoperineal resection with curative intent or the Hartmann procedure with permanent end colostomy, age 18 years or older, life expectancy of at least 12 months, and signed informed consent. Exclusion criteria included open surgery or conversion to laparotomy, complications necessitating laparotomy during postoperative hospitalization, American Society of Anesthesiologists score of 4 or 5, concurrent or previous malignant tumors within 5 years of study enrollment, T4b tumors requiring multiorgan resection, rectal malignancy other than adenocarcinoma, emergency procedures, planned rectal surgery with major concomitant procedures, metastatic disease without the possibility of curative surgery, pregnancy or suspected pregnancy, geographically distant residency or unwillingness to comply with the study requirements, active abdominal infection at the time of surgery, previous surgery at the colostomy site, and no informed consent.

Intervention

Polyvinylidene fluoride (PVDF) mesh (DynaMesh-IPST; FEG Textiltechnik) (eFigure 1 in Supplement 2) was placed in the intra-abdominal space following the technique described by Berger et al[6] (eFigures 2-6 in Supplement 2). The bowel forming the colostomy was closed with a linear stapling device. The trephine was formed by excising the premarked skin area aiming to the transrectus ostomy. A cross-shaped incision was made in the anterior rectus sheath followed by a blunt split of the rectus abdominis muscle. The posterior rectus sheath was opened longitudinally to fit the bowel. A 15 × 15-cm mesh with a tube length of 4 cm and a width of 2 cm was used. The mesh tube was manually stretched to match the bowel diameter. The bowel was brought through the abdominal wall opening and then through the saline-lubricated tube in the PVDF mesh. The mesh was translocated into the intra-abdominal space with a funnel oriented posteriorly and fixed on the abdominal wall with absorbable tackers (Securestrap; Ethicon) using the double crown technique as described by Köhler et al.[7] The stoma was fixed and everted with monofilament sutures to the skin. In

the control group, the colostomy was formed using the identical method described above, excluding the use of the mesh. The specimen was removed through the perineal opening in all patients undergoing APR. Patients who underwent the Hartmann procedure had specimen removal through the Pfannenstiel incision.

Outcomes

The primary end point of the Chimney trial was the computed tomography (CT) scan–detected PSH rate 12 months postsurgery. Secondary outcomes were clinical PSH at 12 months, 3 years, and 5 years; PSH in the CT scan at 3-year follow-up; PSH operations during follow-up; surgical-site infection rate and Clavien-Dindo classification I to V complications during a 30-day follow-up; stoma-related complications during follow-up until 5 years; stoma-related readmissions; reoperation rate; operative time; length of stay; quality of life during follow-up (RAND-36, colostomy impact score), direct hospital costs and indirect costs by sick leave; and radiological substudy, including definition of abdominal wall measurements and location of stoma. PSH was defined according to the EHS classification of PSH for CT as a protrusion of abdominal cavity contents through the abdominal wall through the stoma site.[15] Clinical parastomal hernia was defined the same, as a suspicion of PSH at the stoma site. Surgical site infection was defined as per the US Centers for Disease Control and Prevention.[16]

Randomization

Random allocation in a 1:1 ratio was carried out through a computer-generated list, compiled by a biostatistician uninvolved in patient care. Randomization was performed in blocks, with block size varying randomly between 2, 4, and 6 patients. Separate randomization lists were created for each study center. Both the randomization and data collection were done using software designed for the study.

Blinding

Patients were blinded to the randomization group during their primary stay at the hospital. For safety reasons, their group designation was stated in medical records for immediate access in case of complications. Patients had access to their medical records after hospitalization, and as a result maintaining blinding during follow-up was not possible. Both the radiologists analyzing the CT scans were blinded to the randomization group by pseudo-anonymizing the CT scans.

Statistical Analysis

To determine the required sample size for comparing the 2 groups, we based our estimation on a 6.4% PSH rate for the PVDF mesh group and a 34% PSH rate for the control group during a 12-month follow-up.[2,8,17] Assuming α of .05 and power of 90%, a sample size of 51 patients per group was necessary. Accounting for a 5-year dropout rate of 50%, a total of 102 patients per group was required to achieve statistically significant results during long-term follow-up.[18] As published studies on funnel-shaped mesh were scarce in 2018 when the Chimney Trial was designed,[6,7] we decided to set a per-protocol safety analysis once 30 patients had completed a 30-day follow-up in both groups. According to previously published results and our hypothesis, the predetermined number of 30 patients in both groups was assessed to prove both safety and preventive efficacy of the mesh placement. If 10% or more serious complications occurred as defined by Clavien-Dindo classification 3B in either group, continuation of the trial would be regarded as unethical. For the same safety concerns, another similar per-protocol analysis was conducted at the 12-month follow-up with trial termination if the PSH rate was more than 35% in the control group compared with the PVDF mesh group, or complications exceeded 10% as defined by Clavien-Dindo classification 3B in either group. The unblinded data were reviewed only at these predefined points. No statistical analysis was conducted when assessing the safety of the trial.

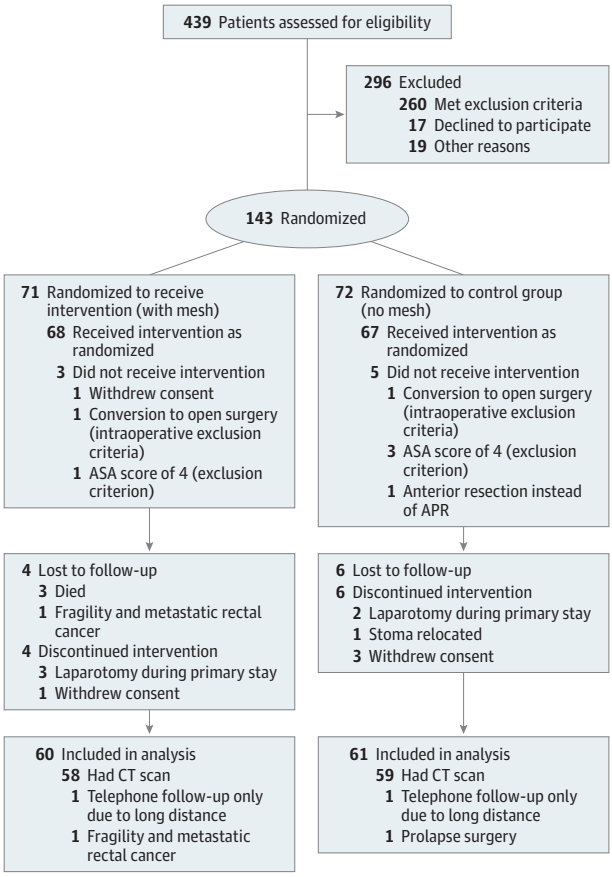
After analyzing 30 patients at the 12-month follow-up visit in both groups, the clinical PSH rate in the control group exceeded the difference of 35% compared to the mesh group. Thus, the trial was prematurely terminated as it was deemed unethical. All analyses were performed by or under the guidance of professional statisticians (P.O.) and following the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.

Summary measurements are presented as means with SDs unless otherwise stated. The primary end point was PSH rate detected by CT scan with 95% CIs for both study groups at 12-month follow-up. Analyses were based on modified intention-to-treat principles (**Figure**). Categorical data including the primary endpoint were analyzed using the χ^2 test or Fisher exact test, the latter with tables with sparse cell counts. The *t* test or Welch test was used for continuous variables, the latter if the equality of variances assumption failed. The linear mixed model was used for repeatedly measured continuous data. In the linear mixed model, time, group, and time × group interaction were used as fixed factors and patient was used as a random factor. We present between-group differences with 95% CIs and *P* values for 30 days and 12 months as the result of the linear mixed model. Multiple imputation data were created for the sensitivity analyses. Fifty different datasets were created assuming fully conditional specifications. The result according to multiple imputation analysis is presented in the eMethods in Supplement 2 and is calculated only for the primary outcome. IBM SPSS Statistics for Windows version 28.0 (IBM Corp) and SAS version 9.4 (SAS Institute) were used for all analyses. Two-sided *P* values less than .05 were considered statistically significant. Data were analyzed from December 2023 to May 2024.

Results

From February 2019 to September 2021 a total of 439 patients with rectal cancer undergoing either laparoscopic or robotic-assisted APR or the Hartmann procedure were screened, and 143 patients were enrolled before terminating the randomization (Figure). After randomization, 8 patients (6%) were excluded from analysis because of randomization

Figure. CONSORT Diagram



APR indicates abdominoperineal resection; ASA, American Society of Anesthesiologists.

Table 1. Baseline Characteristics of Patients in the Chimney Trial

Characteristic	No. (%)	
	Mesh group (n = 68)	Control group (n = 67)
Sex		
Male	36 (53)	48 (72)
Female	32 (47)	19 (28)
Age, mean (SD), y	68.7 (11.6)	66.4 (11.7)
BMI, mean (SD)	25.9 (3.8)	26.0 (3.8)
ASA score, mean (SD)	2.3 (0.5)	2.4 (0.5)
Smoking status		
Active	8 (12)	7 (10)
Previous	4 (6)	15 (22)
Previous hernia	5 (7)	7 (10)
Hypertension	31 (46)	28 (41)
COPD	1 (2)	0
Asthma	4 (6)	6 (9)
Diabetes	5 (7)	13 (19)
Impaired kidney function	5 (7)	1 (2)
Cirrhosis	0	0
Rheumatoid arthritis	2 (3)	3 (4)
Corticosteroids	1 (2)	2 (3)
Immunomodulatory medication	1 (2)	1 (2)
Neoadjuvant therapy		
Short-course radiotherapy, operation within 1-2 wk	15 (22)	14 (21)
Short-course radiotherapy, operation within 8-12 wk	5 (7)	3 (4)
Long-course chemoradiotherapy	24 (35)	34 (51)
No neoadjuvant therapy	24 (35)	16 (24)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); COPD, chronic obstructive pulmonary disease.

protocol violations (conversion to open surgery (n = 2), changed surgical technique to anterior resection instead of APR (n = 1), American Society of Anesthesiologists score of 4 (n = 4), and early patient withdrawal of consent (n = 1)), leaving 68 patients (mean [SD] age, 68.7 [11.6] years; 36 [53% male and 32 [47%] female) assigned to the mesh group and 67 (mean [SD] age, 66.4 [11.7] years; 48 [72%] male and 19 [28%] female) to the control group who received the intended intervention. Baseline demographic characteristics for both groups are presented in **Table 1**. At the 12-month follow-up, clinical data for 60 patients in the mesh group and 62 patients in the nonmesh group were analyzed, along with CT scan data for 58 and 59 patients, respectively. Details on loss to follow-up are stated in the Figure. All reported deaths during follow-up (3 patients in the intervention group) were unrelated to intervention and surgery. Operative details are presented in **Table 2**. Only 2 operations (1%) were Hartmann procedures, both in the mesh group. The operative technique was laparoscopy in 64% of patients, with the remaining procedures being robotic assisted.

As the primary outcome, CT confirmed PSH in 6 patients (10%) in the mesh group compared to 21 (37%) in the nonmesh group (difference, 27%; 95% CI, 12-41; $P < .001$) (**Table 3**). According to multiple imputation analysis, the result was comparable (data not shown). As the secondary outcome, one patient (2%) had clinical PSH in the mesh group compared to 27 patients (43%) in the nonmesh group (difference, 41%; 95% CI, 29-55; $P < .001$) (**Table 4**).

The number of patients with Clavien-Dindo class II ileus was 23 (35%) in the mesh group compared to 11 (17%) in the control group (difference, 18%; 95% CI, 3-32; $P = .006$). Reoperation by laparotomy during the hospital stay led to exclusions per protocol, with 3 patients in the mesh group and 2 in the control group undergoing laparotomy. Reasons for laparotomies included small bowel obstruction in 2 patients in the mesh group and 1 in the control group, while stoma necrosis required laparotomy in 1 patient in each group. Additionally, 1 laparoscopic repair and 1 local repair for stoma necrosis were performed on patients in the control group. Intra-abdominal abscess occurred in 7 patients in the mesh group compared to 5 patients in the control group (difference, 3%; 95% CI, −8 to 14; $P = .39$). No other surgical site infections were reported during the hospital stay. Length of hospital stay was not shown to be different between the groups (mean [SD], 10.1 [4.7] days in the mesh group compared to 9.1 [8.6] days in the control group; $P = .58$). Similarly, length of prescribed sick leave was

Table 2. Operative Details

Variable	No. (%) Mesh group (n = 68)	Control group (n = 67)	*P* value
Operation			
APR	66 (97)	67 (100)	.25
Hartmann	2 (3)	0	
Operative technique			
Robotic assisted	25 (37)	27 (40)	.43
Laparoscopic	43 (63)	40 (59)	
Operation room time, mean (SD), min	416 (110)	412 (108)	.78
Operation time, mean (SD), min	299 (89)	308 (93)	.66
Blood loss, mean (SD), mL	150 (128)	175 (159)	.33
Tackers used to attach the mesh, mean (SD) No.	26.7 (5.6)	NA	
Omentoplasty	5 (7)	1 (1)	.11
Abdominal drain	57 (84)	57 (85)	.50

Abbreviations: APR, abdominoperineal resection; NA, not applicable.

Table 3. Results of Computed Tomography Follow-Up

Result	No. (%) Mesh group (n = 58)	Control group (n = 59)	*P* value
PSH	6 (10)	22 (37)	<.001
PSH content			
Bowel	2 (3)	12 (22)	.32
Omentum	4 (7)	10 (17)	
EHS parastomal hernia classification			
Type I[a]	1 (2)	3 (5)	.64
Type II[b]	0	0	
Type III[c]	5 (9)	19 (32)	
Type IV[d]	0	0	
Subcutaneous fat (cm) on the contralateral side (mm), mean (SD)	22.8 (9.3)	23.3 (9.9)	.89
Distance of stoma to midline, mean (SD), mm	67.4 (16.4)	66.2 (16.8)	.42
Area of stoma aperture, mean (SD), cm^2	5.1 (2.9)	8.4 (6.5)	.23

Abbreviations: EHS, European Hernia Society; PSH, parastomal hernia.

[a] Type I ≤ 5-cm PSH without concomitant incisional hernia.

[b] Type II ≤ 5-cm PSH with concomitant incisional hernia.

[c] Type III > 5-cm PSH without concomitant incisional hernia.

[d] Type IV > 5-cm PSH with concomitant incisional hernia.

not shown to be different between the groups (mean [SD], 37 [22] days in the mesh group compared to 47 [35] days in the control group; *P* = .63).

During 30-day follow-up, 1 patient (2%) in the mesh group experienced stoma stricture, and 1 (2%) in the control group had the stoma relocated due to necrosis. Quality of life measured by RAND-36 and Colostomy Impact Score did not significantly differ between the groups at 30-day or 12-month follow-up (eTable in Supplement 2). Readmission within 30 days after surgery occurred for 11 patients (17%) in the control group and 9 (14%) in the mesh group (*P* = .51). Most readmissions was due to perineal wound complications (11 patients). Other indications for readmissions were pelvic abscess (2 patients), small bowel obstruction (1 patient), stoma necrosis (1 patient), heart failure (1 patient), large bowel obstipation (1 patient), superficial skin infection (1 patient), urinary retention (1 patient), and hematuria (1 patient).

The results of the 12-month follow-up are presented in Table 4. Four patients in the control group had a stoma prolapse, 1 of which required surgery. There were no prolapses in the mesh group. Overall, reoperation was needed for 4 patients (7%) in the control group and 5 (8%) in the mesh group (Table 4) (difference, 2%; 95% CI, −9 to 12; *P* = .49). The patient in the mesh group with a stricture underwent a local repair saving the mesh about 3 months after the primary operation. The results of the CT scan are stated in detail in Table 3. The EHS classification of PSH did not differ between groups.

Discussion

In this randomized clinical trial, the use of funnel-shaped mesh significantly reduced both the CT-confirmed and clinically detected PSHs at 12-month follow-up, which is in line with previously published retrospective case series.[7-11] The mesh did not predispose patients to complications, although the number of patients with Clavien-Dindo II ileus was higher in the mesh group. However, the PSHs did not affect the quality of life measured with RAND-36 or Colostomy Impact Score.

The number of clinically detected PSHs (43%) was higher in the nonmesh group compared to the PSHs detected on CT scans in the nonmesh group (37%). The conflict between clinical assessment and the CT scan results is in line with a previous study.[2] The most likely reason for this is that parastomal

Table 4. Results of 12-Month Clinical Follow-Up

Result	No. (%)		*P* value
	Mesh group (n = 60)	Control group (n = 61)	
Clinical parastomal hernia	1 (2)	27 (43)	<.001
Retraction	0	0	NA
Stricture	0	0	NA
Skin irritation	1 (2)	3 (5)	.32
Prolapse	0	4 (7)	.06
Leakage	3 (5)	0	.12
Bleeding granuloma of the stoma	0	1 (2)	.89
Skin hair around the stoma causing problems	0	1 (2)	.89
Reoperation	5 (8)	4 (7)	
Small bowel obstruction	3 (5)	2 (3)	
Stoma stricture, local repair	1 (2)	0	
Stoma prolapse	0	1 (2)	.49
Stoma necrosis, laparotomy	0	1 (2)	
Perineal revision	0	1 (2)	
Perineal hernia	0	1 (2)	

Abbreviation: NA, not applicable.

bulging has in some contexts been defined as PSH. The CT scan was supposed to be conducted using the Valsalva Maneuver per protocol to reach better sensitivity for detecting hernias. However, only 3 patients had a scan using Valsalva, which may have led to underestimation of CT-detected PSHs. The 2 radiologists who analyzed the CT scans were blinded to the randomization group by pseudo-anonymizing the CT scans. Conversely, the clinical assessment was unblinded.

By the time the trial was designed in 2018, the EHS had released a statement strongly recommending the use of prophylactic mesh in permanent colostomy.[1] Despite the recommendation, the Chimney Trial had a control group without mesh to determine the true effect of the mesh compared to the nonmesh group. The results in the interim analysis were 15 of 30 (50%) clinical PSHs in the control group compared to 1 of 30 (3%) in the mesh group. Therefore, study enrollment was terminated.

Laparotomy during the primary hospital stay was designed as an exclusion criterion in the protocol. As the Chimney trial was designed to establish the efficacy and safety of the mesh, and as previous research stated that both PSH and incisional hernia affect the likelihood of the other,[19] we tried to keep the study groups as homogenous as possible regarding the risk of PSH.

Concerns of mesh-related complications with this funnel-shaped intra-abdominal mesh may limit its use. The results of the 12-month follow-up do not suggest the mesh predisposes patients to complications. Additionally, the long-term results of using the same mesh material in the intra-abdominal space were published earlier, reporting no long-term mesh-related complications.[18]

The cost of the mesh at the time of this study was €713 (US$ equivalent, $774), and the cost of the mesh fixation device was 261€ (US$ equivalent, $283). Mesh application did not increase the operation time, the operative room time or length of stay. The length of prescribed sick leave was similar between the groups. Therefore, the only easily measurable extra costs between the groups are the mesh price and mesh fixation device.

Limitations

The study is limited by a smaller number of patients than intended in sample size calculation and by short follow-up time. The long-term risk of mesh-related complications remain to be seen during the remainder of follow-up. Additionally, the clinical evaluation was not blinded, potentially leading to an increased number of suspected PSHs in the control group. The sensitivity of the CT scan analysis was limited by the small number of CT scans done applying the Valsalva maneuver. Additionally, although mesh is not visible on a CT scan, the radiologists may have been able to conjecture whether or not the patients had mesh.

Conclusions

The prophylactic laparoscopic placement of funnel-shaped mesh in this study significantly reduced the overall risk of parastomal hernia following minimally invasive surgery for rectal adenocarcinoma. These results suggest the funnel-shaped mesh is a feasible option to prevent parastomal hernia.

ARTICLE INFORMATION

Accepted for Publication: June 20, 2024.

Published Online: August 28, 2024. doi:10.1001/jamasurg.2024.3260

Author Contributions: Dr Mäkäräinen had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Mäkäräinen, Wiik, Kössi, Ohtonen, Rautio.
Acquisition, analysis, or interpretation of data: Mäkäräinen, Wiik, Nikberg, Carpelan-Holmström, Pinta, Lehto, Nikki, Järvinen, Ohtonen, Rautio.
Drafting of the manuscript: Mäkäräinen, Wiik, Nikberg, Pinta, Ohtonen, Rautio.

Critical review of the manuscript for important intellectual content: Mäkäräinen, Wiik, Kössi, Carpelan-Holmström, Lehto, Nikki, Järvinen, Ohtonen, Rautio.
Statistical analysis: Mäkäräinen, Ohtonen, Rautio.
Obtained funding: Mäkäräinen, Rautio.
Administrative, technical, or material support: Mäkäräinen, Wiik, Nikberg, Carpelan-Holmström, Pinta, Lehto, Järvinen.
Supervision: Mäkäräinen, Wiik, Kössi, Rautio.

Conflict of Interest Disclosures: Dr Mäkäräinen reported grants from the European Hernia Society and grants from Ella and Georg Ehrnrooth Foundation outside the submitted work. Dr Nikberg reported grants from Västmanlands forskningsfond mot cancer during the conduct of the study. Rautio reported a host/proctor contract with Intuitive. No other disclosures were reported.

Funding/Support: The trial was funded by the European Hernia Society.

Role of the Funder/Sponsor: The European Hernia Society had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Data Sharing Statement: See Supplement 3.

Additional Contributions: We thank Malin Engdahl, Surgical Department, Region Västmanland, for assistance. No compensation was provided.

REFERENCES

1. Antoniou SA, Agresta F, Garcia Alamino JM, et al. European Hernia Society guidelines on prevention and treatment of parastomal hernias. *Hernia*. 2018;22(1):183-198. doi:10.1007/s10029-017-1697-5

2. Odensten C, Strigård K, Rutegård J, et al. Use of prophylactic mesh when creating a colostomy does not prevent parastomal hernia: a randomized controlled trial—STOMAMESH. *Ann Surg*. 2019;269(3):427-431. doi:10.1097/SLA.0000000000002542

3. Prudhomme M, Rullier E, Lakkis Z, et al; GRECCAR research group. End colostomy with or without mesh to prevent a parastomal hernia (GRECCAR 7): a prospective, randomized, double blinded, multicentre trial. *Ann Surg*. 2021;274(6):928-934. doi:10.1097/SLA.0000000000004371

4. Correa Marinez A, Bock D, Erestam S, et al. Methods of colostomy construction: no effect on parastomal hernia rate: results from stoma-const-a randomized controlled trial. *Ann Surg*. 2021;273(4):640-647. doi:10.1097/SLA.0000000000003843

5. Stabilini C, Muysoms FE, Tzanis AA, et al. EHS rapid guideline: evidence-informed European recommendations on parastomal hernia prevention-with ESCP and EAES participation. *J Abdom Wall Surg*. 2023;2:11549. doi:10.3389/jaws.2023.11549

6. Berger D. Prevention of parastomal hernias by prophylactic use of a specially designed intraperitoneal onlay mesh (Dynamesh IPST). *Hernia*. 2008;12(3):243-246. doi:10.1007/s10029-007-0318-0

7. Köhler G, Hofmann A, Lechner M, et al. Prevention of parastomal hernias with 3D funnel meshes in intraperitoneal onlay position by placement during initial stoma formation. *Hernia*. 2016;20(1):151-159. doi:10.1007/s10029-015-1380-7

8. Conde-Muíño R, Díez JL, Martínez A, Huertas F, Segura I, Palma P. Preventing parastomal hernias with systematic intraperitoneal specifically designed mesh. *BMC Surg*. 2017;17(1):41. doi:10.1186/s12893-017-0237-7

9. Ammann Y, Widmann B, Sparn M, Warschkow R, Weitzendorfer M, Brunner W. Prophylactic funnel mesh to prevent parastomal hernia in permanent end colostomy: a retrospective cohort study. *Colorectal Dis*. 2021;23(10):2627-2636. doi:10.1111/codi.15817

10. López-Borao J, Madrazo-González Z, Kreisler E, Biondo S. Prevention of parastomal hernia after abdominoperineal excision with a prophylactic three-dimensional funnel mesh. *Colorectal Dis*. 2019;21(11):1326-1334. doi:10.1111/codi.14738

11. Bertoglio CL, Maspero M, Morini L, et al. Permanent end-colostomy parastomal hernia prevention using a novel three-dimensional mesh. *Hernia*. 2021;25(3):655-663. doi:10.1007/s10029-020-02326-z

12. Mäkäräinen-Uhlbäck E, Vironen J, Falenius V, et al. Parastomal hernia: a retrospective nationwide cohort study comparing different techniques with long-term follow-up. *World J Surg*. 2021;45(6):1742-1749. doi:10.1007/s00268-021-05990-z

13. López-Cano M, Pereira JA, Rodrigues-Gonçalves V, Verdaguer-Tremolosa M, Hernández-Granados P, Bravo-Salvá A; EVEREG registry. Parestomal hernia repair. prospective observational study based on the Spanish Registry of Incisional Hernia (EVEREG). *Cir Esp (Engl Ed)*. 2021;99(7):527-534. doi:10.1016/j.ciresp.2020.07.017

14. Odensten C, Strigård K, Dahlberg M, Gunnarsson U, Näsvall P. Parastomal hernia repair; seldom performed and seldom reported: results from a nationwide survey. *Scand J Surg*. 2020;109(2):96-101. doi:10.1177/1457496918818984

15. Śmietański M, Szczepkowski M, Alexandre JA, et al. European Hernia Society classification of parastomal hernias. *Hernia*. 2014;18(1):1-6. doi:10.1007/s10029-013-1162-z

16. US Centers for Disease Control and Prevention. Definition of surgical site infection. Accessed July 26, 2024. https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf

17. Mäkäräinen-Uhlbäck E, Wiik H, Kössi J, Nikberg M, Ohtonen P, Rautio T. Chimney Trial: study protocol for a randomized controlled trial. *Trials*. 2019;20(1):652. doi:10.1186/s13063-019-3764-y

18. Mäkäräinen-Uhlbäck EJ, Klintrup KHB, Vierimaa MT, et al. Prospective, randomized study on the use of prosthetic mesh to prevent a parastomal hernia in a permanent colostomy: results of a long-term follow-up. *Dis Colon Rectum*. 2020;63(5):678-684. doi:10.1097/DCR.0000000000001599

19. Timmermans L, Deerenberg EB, Lamme B, Jeekel J, Lange JF. Parastomal hernia is an independent risk factor for incisional hernia in patients with end colostomy. *Surgery*. 2014;155(1):178-183. doi:10.1016/j.surg.2013.06.014