

Prophylactic mesh at end-colostomy construction reduces parastomal hernia rate: a randomized trial

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Abstract

Aim Parastomal hernia (PSH) is the most common complication of an end-colostomy and about one-quarter of patients need operative repair, which is often unsuccessful. A randomized trial was carried out to compare the results of using mesh or no mesh at the time of formation of a colostomy with the clinical identification of PSH as the primary outcome.

Method In this two-centre randomized trial (Oslo University Hospital and Sykehuset Innlandet Hospital Trust, Norway), patients with rectal cancer undergoing open pelvic surgery were randomized to receive a retro-muscular synthetic mesh (study group, $n = 32$) or no mesh (control group, $n = 26$) at the time of end-colostomy formation. Postoperative follow up was not blinded and included clinical examination and routine CT.

Results The median period of follow up was 40 (range: 84) months. There were no differences in demographic variables or complications between the study and control groups. PSH developed in two patients of the study group and in 12 of the control group [OR = 0.04 (95%

CI: 0.01–0.30) and hazard ratio 0.134 (95% CI: 0.030–0.603); $P < 0.001$]. The number needed to treat to avoid one PSH was 2.5 patients. CT demonstrated an increase over time in the size of the fascial orifice in patients with PSH without mesh prophylaxis, in contrast to a stable size in patients with mesh and in the control patients who did not develop PSH.

Conclusion The retromuscular insertion of synthetic mesh at the time of formation of an end-colostomy reduced the risk of PSH.

Keywords Parastomal hernia, mesh prophylaxis, randomized controlled trial, end-colostomy

What does this paper add to the literature?

The study confirms that the incidence of parastomal hernia at the site of an end-colostomy is reduced by the implantation of synthetic mesh at the time of construction. It has added substantially to the accumulated evidence of the value of mesh insertion in the prevention of PSH and thus enhances the knowledge base of the surgical community.

Introduction

The incidence of stoma creation in a general population is 4–6/10 000 and the prevalence is 15–20/10 000 [1–3]. Most permanent stomas are created in an elective setting. Complication rates after creation of end-colostomy are reported to range from 21% to 70% [4,5]. Commonly they include stomal prolapse, stenosis and skin problems around the stoma. Fistula formation and

stoma retraction are less frequent. The most common delayed complication is development of a parastomal hernia (PSH), which is observed clinically in up to 48% of patients with an end-colostomy [6] and in up to 78% when assessed by CT [7]. More than 25% of patients with clinical PSH require surgical repair [8]. This has a high recurrence rate and the best strategy is therefore prevention. There is no agreement on whether it is better to bring the colon directly through the rectus abdominis muscle or lateral to it, or whether the terminal colonic segment should be sited retroperitoneally [9,10]. Use of a prophylactic mesh in stoma creation

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has been reported to reduce the incidence of PSH without increase in complications [11–14]. The data available regarding long-term outcome are, however, insufficient to determine the benefit of mesh insertion and its impact on clinical practice.

The aim of the present study was to compare the use of mesh with no mesh insertion at the time of formation of an end-colostomy. A randomized clinical trial (RCT) was designed, with PSH determined by clinical assessment as the primary outcome. Secondary outcomes included stoma complications and re-operation rates. In addition, the size of the stoma orifice in the anterior abdominal wall and the radiological diagnosis of PSH were determined retrospectively by CT.

Method

Study design

The study was a multicentre design with blinded randomization of patients to two groups, namely mesh prophylaxis (study group) and no mesh prophylaxis (control group), in the creation of an end-colostomy. A 90% power estimation with $\alpha = 0.05$, based on a published study [15], suggested a sample size of 50 patients. After adjustment for expected mortality, a sample size of 60 was planned. Before the start of the study, the computerized randomization process was carried out by the project leader in blocks of six and sealed in numbered envelopes. The patients were consigned to the next sequential envelope after inclusion by the indiscriminately allocated operating surgeons. Patients having abdominoperineal excision (APE) with curative intent for low rectal cancer and those having surgery with curative intent for recurrent rectal cancer or other pelvic cancer resulting in an end-colostomy were included. Patients having palliative resections were excluded. Two surgical centres in Norway participated, including a specialized research centre (Oslo University Hospital, Norwegian Radium Hospital) and a district teaching hospital (Sykehuset Innlandet Hospital Trust, Gjøvik). Written informed consent was mandatory. The trial was approved by the Regional Committee for Medical and Research Ethics South East Norway (REK number: S-07203a). Data handling was approved by the Norwegian Data Inspectorate (NSD number: 07/4222), and the study was reported to ClinicalTrials.gov before inclusion was initiated (ClinicalTrials.gov number: NTC00496418).

Patients and surgical procedures

Sixty patients were included from September 2007 to September 2011. All were White people and 25% were

female. The mean age was 64 years. Three patients underwent pelvic exenteration, nine Hartmann's operation and 48 APE. Thirty-two patients were randomly allocated to the study group and 28 were randomly allocated to the control group, but two patients in the control group were excluded from the trial as palliative status was identified during surgery. The remaining 26 patients in the control group underwent an APE. The stoma trephine was made through the rectus abdominis muscle. A large-pore, low-weight polypropylene mesh, measuring 10 × 10 cm (Prolite Ultra; Atrium/Maquet Getinge Group, Göteborg, Sweden), was used in 28 patients and a Parietene Light (Covidien/Medtronic, Minneapolis, Minnesota, USA) was used in four patients. The mesh was trimmed to fit in the space between the rectus muscle and the posterior rectus sheath, most often 7 or 8 cm wide. A cruciform incision, 2 × 2 cm was made in the centre of the mesh to allow passage of the colon. The lateral corners of the mesh were sutured to the rectus sheath with a single stitch (Polysorb 2-0 (Covidien/Medtronic) and medially included in the continuous Maxon 0 (Covidien/Medtronic) or PDS 0 (Ethicon, Somerville, New Jersey, USA) main wound fascial closure [16]. In the control group, no mesh was used.

Follow up

Patients underwent clinical assessment and CT scan of the chest, abdomen and pelvis as part of the cancer follow up at 6-month intervals for the first 2 years and thereafter annually for 4 years. This regime was interrupted in the event of incurable cancer recurrence or death. The stoma was assessed by inspection and palpation with the patient in the supine and erect positions and during a Valsalva manoeuvre. A bulge associated with the stoma was defined as a clinical PSH and was graded similarly to the classification of the European Hernia Society (EHS) [17], as follows: Type I, PSH ≤ 5 cm without concomitant main wound incisional hernia (cIH); Type II, PSH ≤ 5 cm with cIH; Type III, PSH > 5 cm without cIH; and Type IV, PSH > 5 cm with cIH. CT assessment of PSH was not part of the original protocol, but the size of the orifice in the anterior abdominal wall was measured from the last CT examination. The orifice was measured in transverse and sagittal planes and its area was calculated using the formula for an ellipse. The CT scans were evaluated for PSH by an experienced radiologist (LJ) who was unaware of the randomization category. CT-assessed PSH was categorized according to the classification of Moreno–Matias [18], as follows: Grade Ia, bowel forming the stoma with a peritoneal sac < 5 cm; Grade Ib,

bowel forming the stoma with a peritoneal sac > 5 cm; Grade II, the presence of omentum alongside the stoma in the dorsal rectus sheath; or Grade III, a protruding bowel loop other than forming the stoma.

Statistical analysis

Fisher's exact test was used for binomial data, and parametric or nonparametric tests were used for continuous variables and in multiple logistic regression models. The adjusted odds of PSH were estimated for mesh prophylaxis and adjusted for body mass index (BMI) (≤ 25 kg/m²; > 25 and ≤ 30 kg/m²; or > 30 kg/m²), age (≤ 60 years, > 60 and ≤ 70 years; or > 70 years), the size of the stoma aperture at the time of the first postoperative CT examination (≤ 500 , > 500 and ≤ 750 mm²; or > 750 mm²), acquired other incisional hernia (IH), chronic obstructive pulmonary disease (COPD) and gender. The cumulative occurrence of PSH was determined by Kaplan–Meier and Cox regression analysis. The significance level was set at five per cent in all tests. ORs with 95% CI were determined, with the control group as reference.

Results

Clinical parameters

There were no differences in the patient characteristics between the 32 patients in the study group and the 26 in the control group (Table 1). One patient in the study group received steroid therapy and did not develop PSH or complications. The median follow-up was 36 (range: 81) months in the study group and 48 (range: 71) months in the control group (Table 2). Twelve and six patients in the study and control groups, respectively, developed recurrence of cancer and subsequently died.

Stoma-related complications

There were no stoma-site infections, stoma retraction or fistula formation. Two patients in the study group had a stomal stenosis in the immediate postoperative period. Both needed intervention; this involved digital distention of the stoma orifice in one patient and enlargement of the aperture of the mesh in the other. One patient without mesh had stomal necrosis and needed surgical revision (Table 1).

Clinical detection of PSH

Two (6%) patients with mesh developed PSH compared with 12 (46%) in the control group ($P < 0.001$,

Table 2). The adjusted OR for PSH with mesh *vs* no mesh was 0.032 (95% CI: 0.003–0.333, Table 3). Adjustment for hernia in previous history and COPD was omitted in the analysis because of the low prevalence and even distribution of these between the groups. The presence of an IH of the main abdominal wound did not influence the results and without this adjustment a more precise estimate was revealed (OR = 0.043; 95% CI: 0.006–0.304). In contingency table analysis the relative risk for PSH with mesh was 0.14 (95% CI: 0.02–0.55) and the number of mesh implants needed to avoid one PSH was 2.5 (95% CI: 1.9–6.9).

The two patients with PSH in the study group died shortly after 3 years of follow-up. They both had a BMI in the normal range (23 and 24 kg/m²) and were in their early 60s. They developed no other complications and did not have hernia in their previous history. In adjusted analysis of the patients who were alive at 3 years, the reduction of the risk of PSH was maintained (OR = 0.019; 95% CI: 0.001–0.352). The survival analysis demonstrated a significant difference between the groups (Kaplan–Meier analysis, log-rank test: $P = 0.001$). In adjusted Cox regression analysis the hazard ratio for PSH with mesh prophylaxis was 0.134 (95% CI: 0.030–0.603, $P = 0.009$) (Fig. 1). The risk of developing PSH continued over time in the control group, whereas this was not the case in the study group: in the study group, both instances of PSH occurred after 3 and 12 months; in contrast, eight of the 12 instances of PSH in the control group occurred later than 18 months after surgery.

Factors associated with PSH and clinical detection of PSH

Eleven of the 12 patients with PSH in the control group and the two patients with PSH in the study group were men ($P = 0.330$), but the estimate for gender as an adjustment factor was imprecise. In multinomial regression analysis of male patients, the OR for developing PSH with mesh in comparison with no mesh was 0.036 (95% CI: 0.003–0.390). A postoperative IH of the main abdominal wound occurred in eight (31%) patients in the control group, concurrently with PSH in seven. In contrast, five (16%) patients in the study group developed an IH without PSH ($P = 0.213$). Development of IH was associated with PSH (OR = 10.11; 95% CI: 1.22–83.55; $P = 0.032$) and is a complicating factor in stoma care and PSH repair, as exemplified by the EHS classification [17]. BMI was associated with development of PSH in the control group (OR = 1.31; 95% CI: 1.00–1.72; $P = 0.050$). Applying the CT measurements of the aperture in the anterior abdominal wall, the clinical distribution corre-

Table 1 Characteristics of patients having (study group) and not having (control group) mesh prophylaxis against parastomal herniation during the formation of an end-colostomy.

Variable	Mesh (<i>n</i> = 32)	No mesh (<i>n</i> = 26)	<i>P</i>
Patient data			
Age (years)	64 ± 4.0	63 ± 4.1	0.729*
ASA (0–E)	1.7 ± 13	1.8 ± 10	0.603*
BMI (kg/m ²)	24.6 ± 0.6	25.5 ± 0.8	0.531*
Female	10 (31)	5 (19)	0.374 [†]
Pulmonary disease	3 (9)	2 (8)	1.000 [†]
Heart disease	12 (38)	9 (35)	1.000 [†]
Previous hernia	2 (6)	3 (12)	0.648 [†]
Colostomy complications			
Stenosis	2 (6)	0	0.497 [†]
Necrosis	0	1 (4)	0.448 [†]
Prolapse	0	1 (4)	0.448 [†]
Dehiscence	0	1 (4)	0.448 [†]
Skin problem	1 (3)	2 (8)	0.582 [†]
Total complications	3 (9)	5 (21)	0.446 [†]
Reoperations	2 (6)	1 (4)	1.000 [†]

Values are given as mean ± SD or *n* (%).

*Independent variables *t*-test.

[†]Fisher's exact test.

ASA, American Association of Anaesthesiologists' physical score; BMI, body mass index.

sponding to the EHS classification was as follows: Type I (*n* = 3), Type II (*n* = 6), Type III (*n* = 2) and Type IV (*n* = 1) in the control group; and Type I (*n* = 2) in the study group.

CT evaluation of the stomal aperture

The mean interval from stoma creation to the first post-operative CT scan was 4 months in both groups and at this time the median size of the stoma aperture was similar in the groups (Table 2). After controlling for age, a large aperture size at the first CT scan was associated with a higher BMI in the study group (*P* = 0.038) but not in the control group (*P* = 0.495). At the last CT examination, the median aperture size was 688 mm² in the control group and unaltered, at 494 mm², in the study group (*P* = 0.024), at a mean respective interval of 33 ± 23 months and 28 ± 18 months between CT studies. This significant increase of aperture size in the control group was highly associated with the development of PSH. BMI was associated with a change in the area of the aperture in the control group (increase of 37 mm² per BMI point increase, *P* = 0.011) and was correlated with the size of

the stoma orifice at the last CT scan in both groups (*P* = 0.015, study group and 0.024, control group).

Association between the CT scan and clinical detection of PSH

In the control group, CT failed to detect four clinical PSHs, one of which was in need of surgical repair, and three patients in the control group with a PSH diagnosed by CT did not have clinical evidence of PSH. PSH was detected in eight patients by both methods. In the study group, six patients with a nonclinical PSH were diagnosed by CT. One of these had abdominal surgery 2 years after creation of the colostomy and no PSH was found. The two clinically detected PSHs in the study group were both also diagnosed by CT. There was therefore poor agreement between the clinical and CT diagnosis of PSH, but when these methods of diagnosis were combined, there was a difference in the rate of PSH (25% vs 58%; *P* = 0.016, Fisher's exact test).

Discussion

This randomized trial suggests that a synthetic mesh placed in the retromuscular space at the time of fashioning an end-colostomy protects against PSH. The risk of mesh-related complications was low and in keeping with previously published results originally described by Bayer *et al.* [19], but now confirmed with the use of a modern large-pore mesh. The significant difference in the development of PSH in this study is in accordance with previously reported results from four RCTs [12,13,20,21] and five observational studies [14,22–25]. Two of the RCTs, with 27 patients in each arm, employed a partially degradable synthetic mesh placed in the retromuscular space [13,21]. One of the other RCTs used a similar technique with a biological mesh but it included only 10 patients in each arm [20], and in the fourth RCT, with 18 and 16 patients in the experimental and control groups, respectively, the mesh was placed intraperitoneally [12]. Three systematic reviews [26–28] and one meta-analysis [29] evaluating the first three RCTs concluded that retromuscular mesh prophylaxis has short-term efficacy without increased morbidity, but further studies were needed before a recommendation could be made. The results of the present study substantiate the conclusion regarding efficacy and further suggest that this strategy also provides longer-term protection against PSH, in agreement with another report of the long-term outcome [30].

Although recently described techniques of laparoscopic repair of PSH appear to be promising [25,31], secondary repair still has a failure rate of up to 46% and

Table 2 Prophylaxis against parastomal hernia formation by insertion of a mesh during fashioning of an end-colostomy.

Characteristic	Mesh (study group) (n = 32)	No mesh (control group) (n = 26)	P	OR (95% CI)
Developed PSH	2 (6)	12 (46)	< 0.001*	0.08 (0.01–0.45)
Developed IH	5 (16)	8 (31)	0.213a*	0.42 (0.10–1.72)
Developed cIH	0/32	7/26 (30)	0.002*	0.00 (0.00–0.53)
Developed cIH, PSH patients	0/2	7/12 (58)	0.462*	0.00 (0.00–4.49)
Died during follow up	12 (38)	6 (23)	0.268*	2.00 (0.55–7.51)
Follow up (months)	36 (6–87)	48 (3–74)	0.254†	
Stoma orifice size				
At first CT (mm ²)	511 (236–1018)	499 (283–1244)	0.896‡	
At last CT (mm ²)	494 (198–1144)	688 (207–1824)	0.024‡	
Change (mm ²)	–18 (–452 to 320) (P = 0.644§)	114 (–189 to 899) (P = 0.003§)	0.001‡	

Values are given as n (%), n/n total (%) or median (minimum–maximum).

*Fisher’s exact test/contingency table analysis.

†Mann–Whitney U-test.

‡Independent-samples t-test on log₁₀ transformation of the variables.

§Related-samples sign test.

cIH, concomitant incisional hernia; IH, incisional hernia, main abdominal wound; PSH, parastomal hernia.

carries a risk of infection in up to 17% of cases [32]. A reduction in the incidence of PSH by mesh prophylaxis will thus have an important impact on the quality of life of stoma patients. The number needed to treat (NNT) to prevent one PSH repair within the study period was 13 (P = 0.24, CI: 7, ∞), approaching results that can be derived from an analogous study [13]. As survival after treatment for rectal cancer is increasing, PSH will also increase [6,33] and this will lead to an even lower stoma NNT with mesh to avert PSH repair. In summary, prevention of PSH by mesh insertion should reduce the complications resulting from development of PSH and the need for a PSH repair (which has a high chance of failing), demonstrating that this is an advance in the treatment of patients who require a permanent colostomy.

With laparoscopic procedures becoming more common, alternative techniques to open retromuscular mesh placement will be required. For these situations, the intraperitoneal slit [25] or modified Sugarbaker [12] methods for prophylactic mesh placement have been proposed. A simpler procedure resembling the open retromuscular mesh insertion technique has been described, in which a retromuscular mesh insertion is made through the stoma site before bringing the colon through the orifice in the abdominal wall [34]. An evaluation of synthetic and biological mesh was made by Fleshman *et al.* [35]. They found no difference in the rate of PSH between the groups, but almost 40% of stomas were ileostomies, PSH rates for separate stoma types were not reported and the PSH rate in the control group was exceptionally low, at just 13% at 24 months.

Table 3 Multinomial logistic regression of mesh prophylaxis against parastomal hernia after the formation of an end-colostomy

Variable	Parastomal hernia	
	All patients	3-year survivors
Mesh prophylaxis*	0.032 (0.003–0.333)	0.018 (0.001–0.452)
Mesh prophylaxis†	0.043 (0.006–0.304)	0.019 (0.001–0.352)
Mesh prophylaxis* (male patients)	0.034 (0.003–0.433)	0.036 (0.002–0.732)
Mesh prophylaxis† (male patients)	0.036 (0.003–0.390)	0.040 (0.002–0.683)

Values are adjusted ORs (with 95% Wald CIs) for clinical parastomal hernia formation compared with no mesh insertion.

*Adjusted for age, body mass index (BMI), stoma aperture size at first CT and development of other incisional herniation.

†Adjusted for age, BMI and stoma aperture size at first CT (control).

Poor correlation between the clinical and CT detection of PSH was found in the present study. If clinically diagnosed PSH were to be the reference, CT detected nine false positives and four false negatives, suggesting that detection of a hernia sac without a Grade III PSH category is difficult and that a CT aimed mainly to detect recurrence is unreliable in distinguishing omentum from mesocolic or epiploic fat, whereas a dedicated CT scan,

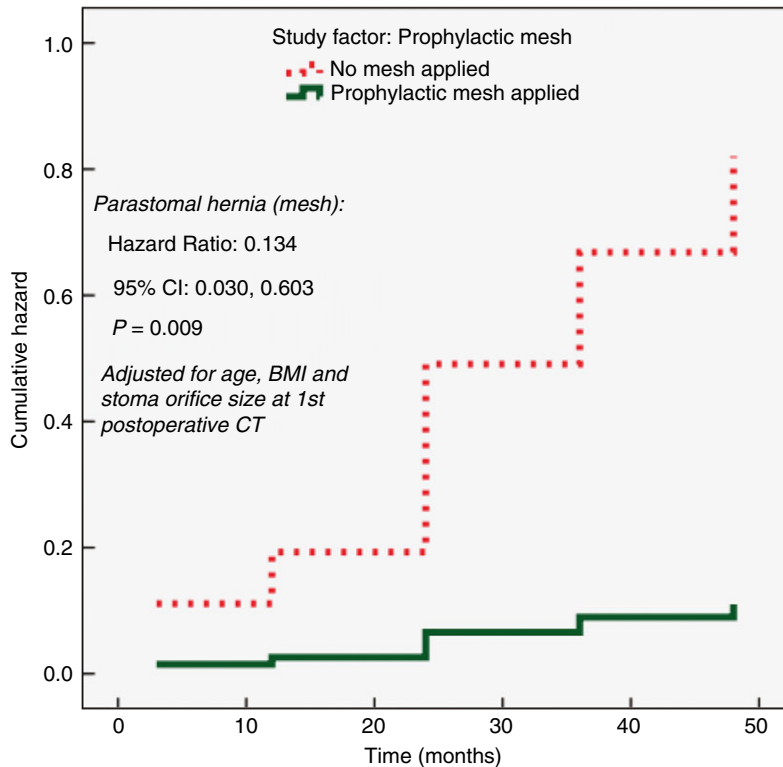


Figure 1 Cumulative incidence of clinical parastomal hernia (PSH) formation. Cox regression analysis on randomization between mesh or no mesh during the formation of an end-colostomy.

namely one that is focussed on detecting PSH, has previously been shown to correspond well with the clinical findings [36]. Furthermore, the clinical significance of a diagnosis by a nondedicated CT scan is indeterminate [7] and clinical evaluation and patient-reported symptoms seem more relevant. Interestingly, the median size of the fascial orifice increased over time in patients without a mesh, but mostly in patients who developed PSH. Stabilization of the fascial opening possibly explains the prophylactic effect of the mesh against PSH.

In accordance with previously published studies, the present randomized trial dramatically reduced the rate of PSH formation without increasing complications. CT-assessed fascial orifice size was markedly associated with PSH, and stabilization by the mesh is possibly a crucial factor for the prevention of PSH. Patients scheduled for a permanent colostomy should be considered for a prophylactic mesh procedure to reduce the incidence of PSH.

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Author contributions

Jan Roland Lambrecht: Study design and execution, data collection, analysis and interpretation, manuscript preparation. Stein Gunnar Larsen: Study design, data collection, manuscript revision. Ola Reiertsen: Data interpretation, manuscript revision. Arild Vaktskjold: Data analysis, manuscript revision. Lars Julsrud: Data collection, manuscript revision. Kjersti Flatmark: Study design, data collection, manuscript revision.

Conflicts of interest

None of the authors or authors' spouses are employed or in any other manner economically involved in the medical industry. All authors are employees of the Kingdom of Norway.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1 Mesh prophylaxis against parastomal hernia (PSH) formation during the formation of an end-colostomy.