Methods of Colostomy Construction: No Effect on Parastomal Hernia Rate

Results from Stoma-const—A Randomized Controlled Trial

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Objective: The primary objective of this trial was to compare the parastomal hernia rates 1 year after the construction of an end colostomy by 3 surgical techniques: cruciate incision, circular incision in the fascia and using prophylactic mesh. Secondary objectives were evaluation of postoperative complications, readmissions/reoperations, and risk factors for parastomal hernia.

Summary of Background Data: Colostomy construction techniques have been explored with the aim to improve function and reduce stoma complications, but parastomal herniation is frequent with an incidence of approximately 50%.

Methods: A randomized, multicenter trial was performed in 3 hospitals in Sweden and Denmark; all patients scheduled to receive an end colostomy were asked to participate. Parastomal hernia within 12 months was determined by computed tomography of the abdomen in prone position and by clinical assessment. Complications, readmissions, reoperations, and risk factors were also assessed.

Results: Two hundred nine patients were randomized to 1 of the 3 arms of the study. Patient demographics were similar in all 3 groups. Assessment of parastomal hernia was possible in 185 patients. The risk ratio (95% confidence interval) for parastomal hernia was 1.25 (0.83; 1.88), and 1.22 (0.81; 1.84) between cruciate versus circular and cruciate versus mesh groups, respectively. There were no statistically significant differences between the groups with regard to parastomal hernia rate. Age and body mass index were found to be associated with development of a parastomal hernia.

Conclusion: We found no significant differences in the rates of parastomal hernia within 12 months of index surgery between the 3 surgical techniques of colostomy construction.

Keywords: parastomal hernia, randomized controlled trial, stoma, surgical technique

Parastomal herniation is the most common complication related to colostomies, with an incidence of approximately 50%. Previously described risk factors include age, high body mass index (BMI), cancer, diabetes, and waist circumference of more than 100 cm. Prophylactic mesh and Valsalva maneuver have over the last few years been shown to reduce complications. The relationship between the technique of colostomy construction and the risk of postoperative parastomal hernia formation is still unclear. The management of modifiable risk factors, for example, surgical technique, may be a key to reduce complications.

The traditional technique to construct a colostomy has been to make a cruciate incision in the rectus fascia during the construction of the stoma. A circular incision instead of a cruciate incision has been suggested as an option, but this alternative has not been studied in randomized trials. A third approach is to use a prophylactic mesh at the time of colostomy construction. This is a controversial issue; a large number of prospective studies, have reported reduced rates of parastomal hernias when using a prophylactic mesh at the time of stoma construction, and the technique has been strongly recommended. In other studies, it has not been possible to confirm these results, and the use of a prophylactic mesh has not been universally accepted. A recent Swedish trial found that no advantage resulted from the use of prophylactic mesh, but the details of the stoma construction in the control arm were scarce. No recent trials have tried to develop the stoma construction technique without a mesh.

The primary objective of this trial was to compare the rate of parastomal hernia 1 year after end colostomy construction using 3 surgical techniques: cruciate incision (control group), circular incision in the fascia or reinforcement of abdominal wall with a mesh.

METHODS

The Stoma-const trial is a randomized, multicenter trial of 3 different surgical techniques of stoma construction: cruciate incision
(control group), circular incision in the fascia, and reinforcement of abdominal wall with a mesh around the stoma (prophylactic mesh), and comparing the resulting rates of parastomal hernia.

Participants
Included in the study were all patients, who were electively scheduled to receive an end colostomy regardless of the underlying indication for surgery, who had no prior history of abdominal hernia, who could be operated on with regard to concomitant disease, and who gave informed consent. All patients, who fulfilled the inclusion criteria, were asked to participate in the study. The inclusion started in June 2013 and the study reached full accrual in September 2017. The reasons for noninclusion or exclusion of patients were recorded in a screening log. The trial was stopped when the number of randomized patients met the required sample size.

Randomization
Randomization was stratified by hospital with a block size of 6. The sequence was computer-generated by a statistician. Allocation was concealed by sequentially numbered, opaque, sealed envelopes. Blinding of the groups was not possible, as the operative chart was available for surgeons and patients to read. The majority of surgeons performing the procedures were colorectal surgeons, who had performed more than 50 colostomy constructions before joining the trial. They received instructions about how to perform all 3 stoma construction techniques both laparoscopically and by open approach.

The surgical approach for the primary procedure (laparoscopic or open) was at the surgeon’s discretion. The size of the incision was related to the patient’s bowel; the length of the cruciate incision was calculated using 50% of the bowel width. This measurement was chosen after a pilot study indicating that it could be an appropriate measurement. If, however, this seemed inappropriate, the incisional length was shortened or lengthened as required and the deviation was noted in the clinical record form.

The circular incision in the fascia was performed with diathermy and no sharp device or circular stapler was used. The size of the circular incision was calculated using a diameter that was 50% of the width of the bowel. Again, this was adjusted if the operating surgeon deemed it necessary and noted in the clinical record form. Patients receiving a mesh also had a cruciate incision. The mesh was a 10 × 10 cm lightweight partially absorbable mesh (Ultrapro, ETHICON, Johnson & Johnson). It was placed in a sublay position and anchored with absorbable sutures 2-0 to the posterior rectus sheath. The size of the aperture in the mesh was calculated in a similar fashion as the cruciate incision. The diameter of the bowel and its mesentery, the diameter of the fascia, the subcutaneous depth, and the diameter and length of the stoma were measured during the operation and recorded in the clinical record form.

Follow Up
Postoperative complications were recorded in the clinical record forms at the time of discharge from the hospital, at 6 months and at the 1-year postoperative follow-up. A clinical assessment to diagnose parastomal hernia was made by a surgeon (not the operating surgeon) at 6 (range 5–7) and 12 (range 11–13) months postoperatively. The clinical examination of the stoma was performed with the patient in both the supine and erect position and with the Valsalva maneuver. At the same time points, patients were also evaluated by stoma care nurses to identify stoma related complications and parastomal herniation.

Complications and Reoperations
Postoperative readmissions, reoperations, and complications within 90 days were recorded. Complications were classified according to the Clavien-Dindo classification of surgical complications and the comprehensive complications index (CCI) was calculated for each patient.

CT
All patients were scheduled to undergo a CT examination of the abdomen 12 months postoperatively. The CT of the abdomen was performed in the supine position, and a supplementary series of the stoma in the prone position was performed on most of the patients with an inflatable ring around the stoma to get a standardized abdominal pressure around the colostomy for a more accurate assessment of parastomal hernia. Any herniation of intraabdominal content beyond the abdominal wall or a hernia sac identified in the prone or supine position (if only the latter was available) was defined as parastomal hernia. A bulging bowel only at prone position was registered but not considered a hernia. All CT images were reviewed by 1 experienced radiologist (PK).

Sample Size
With 62 evaluable patients per group, a true difference of 20% would be detected with 80% power with a 2-sided test using normal approximation of binomial distribution, with 5% significance level, assuming true annual incidences of parastomal hernia incidence of 30% after cruciate incision and 10% after circular incision or reinforcement with mesh. Assuming a dropout rate of 20%, the aim was to randomize up to a total of 240 patients. The dropout rate was; however, lower than anticipated, and the trial was stopped when it was estimated that the required number of evaluable patients was reached; 62 in each group.

Statistical Analysis
A statistical analysis plan was written and finalized before the database was accessed. The analyses were performed according to an intention to treat principle. A per protocol analysis was also performed.

The primary and secondary objectives, evaluation of parastomal hernia and the complications and readmissions/reoperations, respectively, involved 2 comparisons (cruciate vs circular and cruciate vs mesh), rendering 6 statistical hypotheses. Adjustment for influential background variables was made by including the covariates age, BMI, sex, and comorbidity in the statistical models. For the primary endpoint, the modified Poisson regression approach of Zou was used. Results were presented as risk ratios (RR) between the intervention groups (circle and mesh respectively) and the control group (cruciate incision), 95% confidence intervals and adjusted P-values. The secondary endpoints were evaluated by the same model but with a negative binomial distribution. To manage over-dispersion, the results are presented as geometric mean ratios, 95% confidence intervals and adjusted P-values.
To prevent inflation of the family wise error rate induced by the 6 hypotheses, a parallel Bonferroni gatekeeping procedure was used to account for multiple comparisons.42 The 2 $P$-values for the primary endpoint were first adjusted using a Bonferroni correction. If none of the adjusted $P$-values were below 0.05, the procedure was stopped. If at least 1 $P$-value was below 0.05, the same procedure was performed for complications. Likewise, if at least 1 of the null hypotheses was rejected, the hypotheses for readmissions/reoperations were tested. Sensitivity analyses involved unadjusted analyses and analyses after imputations of missing data in the covariates. Multiple imputations with chained equations were used to generate 50 data sets with imputed data.43 Results were obtained by pooling the estimates from the 50 analyzed data sets. The modified Poisson regression approach was also used in the analysis of risk factors. The SAS procedures GENMOD, MI, and MIANALYZE were used for the statistical analyses SAS 9.4 (SAS Institute, Cary, NC), and R package Mediana was used for calculation of adjusted $P$-values.44 Clinical data were collected prospectively at the different centers and sent to the coordinating center, where all analyses were performed.

Endpoints

The primary endpoint was the rate of parastomal hernia, determined by CT scan, within 12 months of the colostomy construction. Clinical assessment by surgeon and stoma nurse was used when CT was absent. Secondary endpoints were postoperative complications according to Clavien-Dindo classification,45 CCI,46 readmissions and reoperations. The secondary outcome quality of life and a health economic evaluation will be analyzed separately.

Ethical Approvals

The trial has been approved by the Swedish Ethical Committee (EPN/Göteborg Dnr 547-12) and the Swedish Radiotherapy Protection Committee (Dnr 12-38). It has been approved by the Danish Regional Ethics Committee (Protocol H-4-2013-061) and by the Danish Data Protection Agency (no. HEH-2013-049, I-Suite no:02418).

Trial Registration

Clinicaltrials.gov, NCT01694238.

RESULTS

A total of 563 patients were assessed for inclusion. Reasons for exclusion, in accordance with the trial protocol, are shown in Fig. 1. A total of 209 patients, who received an end colostomy, were randomized intraoperatively to 1 arm of the study. Two patients were randomized to the mesh group, but due to technical difficulties and the surgeon’s decision, a mesh was not placed, and cruciate incision was performed instead.

Preoperative patient demographic and operative data are shown in Table 1. The characteristics were similar in all 3 groups; a majority of the patients in the study were men, and 85% underwent the operation due to cancer. Other indications for surgery were diverticulitis (n = 6), Crohn disease (n = 3), fecal incontinence (n = 8), obstruction (n = 3), and complicated anal fistula (n = 3). Three patients had undergone rectal resection and anastomosis due to rectal cancer and had developed problems with the anastomosis, and for another 8 patients the reasons were diverse.

The patients were followed clinically up to 12 months after index surgery and a CT was performed (n = 185). At 12 months, 24 patients did not undergo clinical or radiological follow-up. Fifteen patients died due to their cancer during the follow-up period. Six patients declined further participation in the study, and 3 patients were lost to follow-up (1 moved to another area and 2, who had been re-operated due to stoma complications, were not referred for the 12 months follow-up).

Parastomal Hernia

Thirty-two (50.8%), twenty-four (37.5%), and twenty-three (39.7%) patients in the cruciate, circular, and mesh group, respectively, developed a parastomal hernia (identified with radiology or clinical assessment if radiology was absent) within 12 months. One patient in the cruciate group underwent surgery for a parastomal hernia during the 1-year follow-up. There were no significant differences in parastomal hernia rate between cruciate and circular groups (RR 1.25 [95% confidence interval (CI): 0.83; 1.88], $P = 0.571$) or between the cruciate and mesh groups (RR 1.22 [95% CI: 0.81; 1.84], $P = 0.701$) in either the unadjusted or the adjusted analyses (Table 2).

Complications

Postoperative complications up to 90 days (Table 3) were recorded and classified according to the Clavien-Dindo classification of surgical complications.43 Most complications were classified as CD I (postoperative pain more than the usual, bowel paralyzis with the use of nasogastric tube), CD II (pneumonia, urinary infection, blood transfusion, parenteral nutrition), and CD III (an abscess that required percutaneous drainage or suprapubic urinary catheter). Most complications were associated with the index cancer operation performed at the same time as the stoma formation. Stoma related complications were not included in the Clavien-Dindo classification unless they required an intervention.

The mean number of complications per patient within 90 days were 1.18 (95% CI: 0.90; 1.54), 1.43 (95% CI: 1.12; 1.82), and 1.04 (95% CI: 0.78; 1.39) in the cruciate, circular, and mesh groups, respectively.

Readmissions and Reoperations

Mean number of readmissions and reoperations within 90 days were 0.38 (95% CI: 0.25; 0.59), 0.46 (95% CI: 0.30; 0.71), and 0.32 (95% CI: 0.18; 0.58) of the patients in the cruciate, circular, and mesh groups, respectively. 17/74 (23%) patients in the cruciate group, 18/72 (25%) in the circular group, and 12/63 (19%) in the mesh group were re-operated within 90 days. Some were re-operated more than once. The reasons for re-operation were drainage of a pelvic or perineal abscess under general anesthesia and perineal wound revision, which was not primarily related to the stoma. All reoperations within 90 days, including reoperations due to stoma complications, are shown in Table 3.

Risk Factors for Development of Parastomal Hernia

Age and BMI were found to be associated with the development of a parastomal hernia. The strength of association between subcutaneous depth, perioperative bleeding, CCI and fascia diameter, and parastomal hernia formation varied across different types of analyses (simple and multiple regression and with multiple imputations) but was not statistically significant at the 5% level (Table 4).

DISCUSSION

We found no statistically significant differences within 12 months after index surgery in the rates of parastomal hernia between cruciate incision, circular incision, and cruciate incision with prophylactic mesh. Our results; therefore, imply that the 3 techniques for creating a stoma can be considered equal in the clinical perspective regarding parastomal hernia.

A recently published multicenter randomized trial, STOMA-MESH trial, also with a large sample size, compared the use of prophylactic mesh with no mesh.36 Participating hospitals and...
surgeons in the STOMAMESH trial were different from those in
the Stoma-const trial, though both trials were Swedish. The tech-
nique for mesh placement was similar in both studies. An instruc-
tion video from Sundsvall’s Hospital, which showed implantation
of the prophylactic mesh in open surgery, was send to participant
surgeons to standardize the surgical technique. In our study;
however, the surgical technique in the control group and in the
circular incisional group was detailed in the trial protocol,40 which
was not the case in the STOMAMESH trial. STOMAMESH and 1
other observational study in Sweden37 did not find a reduced
incidence of parastomal hernia rate when prophylactic mesh was
used. STOMAMESH was a multicenter trial in 8 Swedish hospitals
of different types. No details of the surgeons’ competence were
reported. STOMAMESH and Stoma-const were both multicenter
studies that included different types of hospitals (University and
county hospitals); they reflect general clinical practice in contrast
to the single-center studies with a special interest in parastomal
hernia surgery that have reported a benefit from mesh place-
ment.15,27,30,31 The results from multicenter randomized trials
generally have higher external validity.

FIGURE 1. Flow-chart of included patients.

* Not elective surgery or no end colostomy (n=87), concomitant disease (n=17);
† Failed to include (n=20), unclear (n=26);
‡ Missing follow up at 12 months
§ Died (n=8), declined participation (n=2), re-operated and not referred to 12 months follow up (n=1);
¶ Died (n=2), declined participation (n=1), re-operated and not referred to 12 months follow up (n=1), moved to another area (n=1).
### TABLE 1. Patient Demographics

| Randomization Groups | Cruciate n = 74 (%) | Circular n = 72 (%) | Mesh n = 63 (%) | Missing |
|----------------------|---------------------|---------------------|----------------|---------|
| **Age, yr, median (min-max)** | 72 (34–94) | 68 (34–87) | 68 (33–91) | 0 |
| **Sex** | | | | 0 |
| Female | 31 (42) | 35 (49) | 21 (33) | |
| Male | 43 (58) | 37 (51) | 42 (67) | |
| **BMI, median (min-max)** | | | 26.3 (17.3–40.4) | 1 |
| **ASA** | | | | 12 |
| 1 | 9 (13) | 5 (7) | 9 (14) | |
| 2 | 30 (42) | 35 (52) | 35 (56) | |
| 3 | 27 (40) | 26 (39) | 18 (29) | |
| 4 | 1 (2) | 1 (2) | 1 (2) | |
| **Comorbidity** | | | | |
| Coronary disease | 3 (4) | 7 (10) | 9 (14) | |
| Pulmonary disease | 5 (7) | 9 (13) | 0 (0) | |
| Diabetes | 9 (12) | 10 (14) | 6 (10) | |
| **Previous abdominal surgery** | | | | 6 |
| Yes | 36 (50) | 38 (54) | 24 (39) | |
| No | 36 (50) | 32 (46) | 37 (61) | |
| **Previous stoma** | | | | 1 |
| Yes | 3 (4) | 10 (14) | 2 (3) | |
| No | 70 (96) | 62 (86) | 61 (97) | |
| **Preoperative stoma marking** | | | | 5 |
| Yes | 70 (99) | 70 (100) | 63 (100) | |
| No | 1 (1) | 0 | 0 | |
| **Diagnosis** | | | | 6 |
| Cancer | 61 (85) | 55 (81) | 54 (86) | |
| No cancer | 11 (15) | 13 (19) | 9 (14) | |
| **Operative data** | | | | 5 |
| Surgeon’s competence | | | | |
| Resident | 5 (7) | 2 (3) | 1 (2) | |
| Specialist | 15 (21) | 15 (21) | 21 (33) | |
| Consultant | 51 (72) | 53 (76) | 41 (65) | |
| **Surgical approach** | | | | 7 |
| Laparoscopic surgery | 37 (53) | 24 (35) | 21 (33) | |
| Open surgery | 33 (47) | 45 (65) | 42 (67) | |
| **Type of operation** | | | | 11 |
| Colostomy only | 16 (23) | 11 (17) | 6 (10) | |
| Hartman operation | 12 (17) | 16 (24) | 12 (19) | |
| APE | 41 (60) | 39 (59) | 45 (71) | |
| **Intraoperative bleeding mL, median (min-max)** | 175 (0–3900) | 300 (0–6000) | 500 (0–3900) | 34 |
| **Intraoperative stoma measurements, cm, median (min–max)** | | | | |
| Bowel diameter | 5.0 (3–13) | 6.0 (3–11) | 6.0 (1.8–11) | 20 |
| Diameter of the fascia incision | 2.5 (2–5) | 2.5 (1.5–5.5) | 3.0 (2–4) | 15 |
| Subcutaneous depth | 2.5 (0.7–5.0) | 2.8 (0.5–7.5) | 3.0 (0.5–8.0) | 12 |
| Hospital stay, d (min-max) | 9 (3–79) | 10 (3–105) | 10 (4–52) | 1 |

| **Assessment** | | | |
| No cancer: diverticulitis (n = 6), Crohn disease (n = 3), fecal incontinence (n = 8), obstipation (n = 3), and complicated anal fistula (n = 3) | | | |
| Problems with anastomosis (n = 8), and for another 8 patients the reasons were diverse (n = 8). | | | |
| Specialist: qualified specialist in surgery. | | | |
| Consultant: qualified specialist in surgery with more than 5 yr post specialist experience. | | | |
| Thickness of subcutaneous abdominal fat. | | | |
| APE indicates abdominoperineal excision; ASA, American Society of Anesthesiologists classification; BMI, body mass index. | | | |

### TABLE 2. Parastomal Hernia Rate Within 1 Yr

| Group | Parastomal Hernia Rate Within 1 Yr | Missing | Comparison | Risk Ratio (95% CI) | Adjusted P-value |
|-------|-----------------------------------|---------|------------|---------------------|-----------------|
| Cruciate incision | 32/63 (50.8) | 11 | Cruciate versus circular | 1.25 (0.83;1.88) | 0.571 |
| Circular incision | 24/64 (37.5) | 8 | Cruciate versus prophylactic mesh | 1.22 (0.81;1.84) | 0.701 |
| Prophylactic mesh | 23/58 (39.6) | 5 | Circular versus prophylactic mesh | 0.97 (0.62;1.53) | N/A |

| **Assessment** | | | |
| Adjusted for age, sex, BMI, and comorbidity. | | | |
| CI indicates confidence interval. | | | |
Most studies have used the same technique initially described for insertion of the mesh in a sublay position\(^2\)\(^5\),\(^3\)\(^3\) with clinical and radiological assessment with CT in supine position, with or without Valsalva maneuver and show different results. We have not found any studies using a circular incision in the fascia during the stoma construction, but it has been described as an option. Circular incision has been suggested with the use of circular stapling to perform the incision in the fascia instead of cruciate incision, but it was a small study and the lack of randomization impairs final conclusions regarding parastomal hernia.\(^2\)\(^4\)

| TABLE 3. Complications According to Clavien-Dindo Classification and Reoperations Within 90 d of Index Operation |
|--------------------------------------------------|
| Randomization Group                              | Cruciate Incision | Circular Incision | Prophylactic Mesh |
|                                                   | n = 74 Patients   | n = 72 Patients   | n = 63            |
| Complications according to Clavien-Dindo classification\(\superscript{*}\) (%) |                  |                  |                  |
| Grade I                                          | 15 (20.8)         | 17 (21.8)        | 10 (18.2)         |
| Grade II                                         | 20 (27.6)         | 27 (34.6)        | 22 (40.0)         |
| Grade IIIa                                       | 17 (23.7)         | 10 (12.8)        | 9 (16.4)          |
| Grade IIIb                                       | 13 (18.0)         | 18 (23.1)        | 12 (21.8)         |
| Grade IVa                                        | 4 (5.5)           | 3 (3.8)          | 2 (3.6)           |
| Grade IVb                                        | 0 (0)             | 0 (0)            | 0 (0)             |
| Grade V                                          | 3 (4.2)           | 3 (3.8)          | 0 (0)             |
| Total number of complications                    | 72                | 78               | 55               |

| Comprehensive complications                      | 1 |
| Index (CCI) median (min-max)                     | 20.9 (0–33.7)     | 16.6 (0–33.7)    | 20.9 (0–33.7)     |
| Number of complications per patient              |                  |                  |
| 0                                                | 30 (41.1)         | 27 (37.5)        | 24 (38.1)         |
| 1                                                | 17 (23.5)         | 17 (23.6)        | 18 (28.5)         |
| 2                                                | 12 (16.4)         | 10 (13.9)        | 10 (15.9)         |
| 3                                                | 7 (9.6)           | 10 (13.9)        | 6 (9.5)           |
| 4                                                | 3 (4.1)           | 5 (6.9)          | 3 (4.8)           |
| >5                                               | 4 (5.5)           | 3 (4.2)          | 2 (3.2)           |

| Reoperations within 90 d                         |                  |                  |
| Total number of patients with at least 1 reoperation | 13/74       | 18/72            | 12/63             |
| Total number of reoperations                     | 27                | 28               | 21                |
| Reason for reoperation                           |                  |
| Perineal abscess                                 | 18                | 15               | 13                |
| Bleeding                                         | 0                 | 1                | 1                 |
| Small bowel obstruction                          | 2                 | 2                | 2                 |
| Abdominal Fascia dehiscence                      | 2                 | 0                | 1                 |
| Stoma related complication\(^1\)                | 2                 | 3                | 3                 |
| Laparotomy\(^y\)                                | 1                 | 4                | 0                 |
| Others\(^z\)                                     | 2                 | 3                | 1                 |
| Mortality within 90 d                            | 3                 | 3                | 0                 |

\(^*\)A patient can have more than 1 complication, % from total of number of complications.
\(^1\)One patient pulled out stoma, 6 patients operated due to necrosis of the stoma, 1 patient ischemia of the colon, and colectomy was performed.
\(^y\)Laparotomy: 5 patients operated due to suspected bowel perforation.
\(^z\)Others: 1 patient operated due to appendicitis, 3 patients had urine leakage, 1 patient operated due to inguinal hernia, and 1 patient operated due to forgotten towel.

**TABLE 4. Analysis of Risk Factors for Development of Parastomal Hernia**

| Bivariate regression\(^*\) | Multiple regression\(^1\) |
|----------------------------|--------------------------|
| Risk Ratio (95% CI)        | P-value                  |
| Sex; female versus male    | 1.10 (0.79–1.54)         | 0.560                     |
| Comorbidty; yes versus no  | 1.18 (0.80–1.74)         | 0.397                     |
| Surgery; laparoscopy versus open | 0.94 (0.66–1.34) | 0.729                     |
| Age (increase by 10 yr)    | 1.22 (1.05–1.42)         | 0.011                     |
| Body mass index (increase by 5 units)\(^3\) | 1.16 (1.01–1.32) | 0.030                     |
| Bleeding (increased by 100 mL) | 1.01 (0.99–1.03) | 0.490                     |
| Comprehensive complications index (increased by 5 units) | 1.07 (1.02–1.13) | 0.009                     |
| Diameter of fascia incision (increase by 5 mm) | 1.04 (1.01–1.07) | 0.009                     |
| Subcutaneous depth (increase by 5 mm each) | 1.23 (1.10–1.37) | <0.001                     |

\(^*\)Group included as fixed effect in the model.
\(^1\)Missing values of the factors imputed by multiple imputations by chained equations (46). Group included as fixed effect in the model.
\(^3\)Subcutaneous depth and diameter of fascia incision were not included in the multiple regressions due to its correlation with BMI.

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In the present study, we found a parastomal hernia rate of approximately 50% with cruciate incision, which could be considered high; nevertheless, previous studies have reported rates up to 81% within 5 years after stoma formation. One reason for the high parastomal hernia rate could be that we had few exclusion criteria compared to some other studies, and that we considered both a radiological and a clinical diagnosis. However, prophylactic mesh has been compared with “non-mesh” techniques in several studies, reporting hernia rates varying from 5% to 51.4%. It is possible that due to our efforts to assess patients both with CT in prone position and to clinically come close to the real incidence of parastomal hernia, the high rate found here reflects the true number of patients with a hernia, but it is questionable whether it reflects the number of patients with a symptomatic parastomal hernia at the time. It is probable that some patients outside of studies do not find a hernia cumbersome and do not seek healthcare due to parastomal herniation. This could partly explain the difference in reported rates of parastomal hernia between clinical data and studies.

We considered a difference in hernia rate of 20% to be clinically relevant but only observed a difference of approximately 10% between the groups. As we have previously reported that only 10%–15% of all patients with a colostomy had a symptomatic parastomal hernia, it seemed reasonable to have a fairly large difference to ascertain that the results were clinically relevant. On the other hand, this might be something to evaluate further, because a parastomal hernia may be problematic for the patient even though they do not seek medical attention.

In the analyses of risk factors, higher age and BMI were found to be risk factors for the development of parastomal hernia, as suggested in previous studies. Regarding other possible risk factors, the results of these analyses varied somewhat. One risk factor that appeared not to influence the outcome was whether the surgical procedure was performed with laparoscopic or open technique, which is in agreement with the results of a recent study, although others have had opposite findings.

The postoperative complications seen in the present study were primarily due to the main surgical procedure, for example, abdominoperineal excision, rather than to the stoma formation alone. This is not surprising as extensive surgical procedures such as abdominoperineal excision are associated with considerable risk of complications. Still, it is important to note that we found no real disadvantage related to complications with any of the techniques, though this has been a fear when using mesh.

The strengths of this trial include the randomized design and relatively large sample size compared to several of the previous studies. Furthermore, the controlled surgical technique in the control group, in terms of standardized measurements of fascia incision related to the individual patient, gives a standardized control group and this is considered a strength. The radiology was assessed by 1 radiologist who was blinded to group assignment. CT was standardized by a prone technique with abdominal pressure without further interaction from the patient to increase sensitivity and obtain an accurate diagnosis.

The fact that both open and laparoscopic surgeries were included reflects clinical reality. We believe that our results reflect the clinical situation as we have included all types of patients rendering high external validity, and the experience of the surgeon was not solely limited to colocolorectal surgery. Limitations of the trial included incomplete data regarding the primary end-point, where about 10% of patients were unavailable for assessment. The lack of systematic blinding of patient, surgeon or stoma nurse at clinical follow-up may be another limitation. The design of randomization was pragmatic in the sense that participating centers were allowed to randomize between control and one of the experimental arms, if requested. The radiology assessment was not according to a classification described in the literature; however, no classification has so far been validated. It is also possible that a longer follow-up could have revealed a larger number of parastomal hernias, but we chose to use the same follow-up as several other trials to enable comparison. It could be considered a limitation to stop the trial before the inclusion of the 240 patients, but this was done as the dropout rate was lower than the anticipated 20%.

CONCLUSIONS

There was no significant difference in rate of parastomal hernia between the 3 surgical techniques for stoma construction: cruciate incision, circular incision, or cruciate incision with prophylactic mesh, within 12 months after index surgery. Thus, we cannot suggest that there is a clear advantage in using either of the tested techniques. Considering our results together with the results from another large study in Sweden, the recent guidelines from the European Hernia Society, suggesting a prophylactic mesh as routine, may need to be reconsidered.

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