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Work in Progress

Primary prevention of peristomial hernias via parietal prostheses: A randomized, multicentric study (GRECCAR 7 trial)

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ABSTRACT

Background: Peristomal hernia (PH) is a common complication of colostomy. It often leads to a decrease in the patient's quality of life. Surgical procedures for PH are difficult and present high failure and morbidity rates. This randomized, double blind, multicentre trial was conducted to determine the benefits and risks of mesh reinforcement vs conventional stoma formation in preventing PH.
Methods: 200 patients undergoing a permanent end colostomy are randomized into two groups. In the mesh group an end-colostomy is created inserting a lightweight (<50 g/m^2) monofilament mesh in a sublay location, and compared to a group with traditional stoma creation. The presence or absence of a PH is determined by another practitioner by clinical exam and by a CT scan or MRI after 24 months of follow-up. 19 university hospitals participate during a 3-year inclusion period. The primary endpoint is the comparison of the PH incidence. To find a difference of 20% with a power of 80% a total number of 174 patients must be included.
Conclusion: This GRECCAR study is a multicentre, double blind, and randomized trial conducted to determine whether a preventive insertion of a prosthetic mesh decreases the incidence of a PH with an acceptable morbidity.
Trial registration: ClinicalTrials.gov Identifier: NCT01380860.

1. Introduction

Peristomal hernia (PH) is one of the most common complications following stoma creation and its prevalence is only expected to increase [1]. Its incidence varies from 4% to 48% for colostomies and from 1.8% to 28.3% for terminal ileostomies [2]. These important variations of incidence are due to different diagnosis methods and durations of follow-up. In a previous study including 782 patients [3], the authors had found a rate of clinically significant PH of 25.6%. Systematic radiological evaluation would certainly increase this rate as well as the rate of asymptomatic hernias diagnosed. Ten to 56% of patients with a PH will be operated on. Difficulties in fitting the pouching system, peristomal pain, an associated prolapse or occlusion episodes are the main indications leading to surgery. Recurrence rate after mesh-free surgery is around 50%. Median time before occurrence is 18 months [3].

Patient-related risk factors for PH comprise obesity, malnutrition, causes of increased abdominal pressure, use of corticoids, aging and postoperative abdominal wall infection.

Surgery-related risk factors comprise, trephine size, location on the abdominal wall, fixation of the stoma to the fascia or muscles, scheduled or emergency surgery. Six studies [4–9] have focused on the relation between the occurrence of a PH and the position relative to the rectus abdominis muscle. Only one study found a decrease of the PH rate when the stoma was made through the rectus abdominis muscle [6] while the review by the Cochrane collaboration found no robust conclusion regarding this aspect [10]. Trephine size is certainly one of the major risk factors of PH. Pilgrim et al. demonstrated that PH rate was proportional to aperture [11] size.

Several surgical techniques have been described to treat a PH. Mesh repair gives a lower rate of recurrence (0–33.3%) than direct tissue repair (46–100%) or stoma relocation (0–76.2%) [2].

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Among mesh-free techniques, stoma transposition seems to have less recurrence rate than direct tissue repair [3], but theoretically leads to the same rate of PH as after the stoma creation. Recurrence rate is lower when a mesh is used but surgeons often hesitate to use such material during a contaminated or clean-contaminated surgery because of the risk of prosthesis infection. However, the rate of prosthesis removal and re-intervention for sceptical reasons is low in literature [12,13].

Low-weighted or partially absorbable or even bio-meshes could be used to prevent such a risk. Because of the high incidence, inconsistent results of parastomal repair and lack of sufficient treatment options, surgeons started focusing on primary prevention of PH [14]. Since the number of patients requiring a stoma will undoubtedly increase owing to longer survival of patients and increased numbers of patients identified by screening, prevention of parastomal hernia formation is of the utmost importance.

Primary prevention of PH using a low-weighted mesh when confectioning the stoma would enable to lower the PH risk with a restricted number of mesh infections as shown by several recent studies [15–17]. Two randomized studies compared the use of retro-muscular peristomal meshes vs classical colostomy technique [18–20]. Janes's study has been criticized because of the important number of PH in the control group and of lost of follow-up at 5 years. Serra-Aracil's study included 54 patients with a median follow-up of 19 months. PH rate was significantly reduced in mesh group in both studies (13% vs 81%; $p < 0.001$ [20] and 15% vs 41%; $p < 0.03$ [18]). One multicentre randomized controlled trial evaluated the use of a bio-prosthesis in this preventive indication [21]. Surprisingly, the authors found no difference between the two groups. Another non-randomized study found no impact of the use of a prophylactic synthetic mesh, but its methodology was questionable [22]. One cost-effectiveness study found that in patients undergoing abdominoperineal resection with permanent colostomy for rectal cancer, mesh prophylaxis might be the least costly and most effective strategy compared with no mesh to prevent PH [23]. Several systematic reviews have been published on the subject [24–26] and found that reinforcement of a stoma with a synthetic mesh at the time of its formation significantly reduced the incidence of PH formation with no increase in morbidity. These studies also stressed the need for an additional large RCT with long-term follow-up to obtain detailed information regarding the type and location of the mesh and any resulting long-term serious adverse effects.

These preliminary studies need to be confirmed by a multicentric randomized study before new guidelines for stoma creation can be edited and change our everyday practice. This is the aim of the GRECCAR 7 study presented here.

2. Aims

The main objective of this study is to evaluate in a randomized trial the impact of a prophylactic prosthetic mesh on the incidence of PH after 2 years of follow up. Secondary objectives include technical intra-operative data, need for repair surgery, comparison of other stoma-related complications (infectious complication in particular) between both groups, comparison of pouching difficulties and quality of life (Table 1).

3. Method and design

It is a double-blinded comparative randomized and multicentric controlled trial.

Table 1
Data recorded during follow up.

- A – Technical evaluation
  - a. Hospital stay
  - b. Total duration of the surgery depending on surgeons' experience
  - c. Re-intervention rate
  - d. Estimated intraoperative blood loss
  - e. Postoperative body temperature
- B – Evaluation and comparison of clinical PH after 12 months of follow-up and of clinical and radiological (CT/MRI) PH after 24 months of follow-up
- C – Evaluation and comparison of need for repair surgery
  - a. Repair surgery (1st, 2nd, . . ., episode)
  - b. Stoma relocation (1st, 2nd, . . ., episode)
- D – Evaluation and comparison of other complications during the 24 month follow-up period
  - a. Stoma characteristics
    - i. Retraction
    - ii. Stenosis
    - iii. Prolapse
    - iv. Wound dehiscence
    - v. Necrosis
  - b. Stomal infections
    - i. Stomal/peristomal abscess
    - ii. Erysipelas
    - iii. Cellulitis
  - c. Intestinal complications
    - i. Occlusion
    - ii. Strangulation
    - iii. Perforation
    - iv. Necrosis
  - d. Cutaneous complications
    - i. Eczema
    - ii. Irritation dermatitis
    - iii. Localized erythema
    - iv. Ulceration
    - v. Pyoderma gangrenosum
  - e. Pain
    - i. Peristomal pain (pain visual analogue scale)
    - ii. Abdominal pain (pain visual analogue scale)
    - iii. Analgesic consumption
- E – Evaluation and comparison of pouching difficulties
- F – Evaluation and comparison of quality of life at 1, 12 and 24 month after surgery
- G – Evolution of the mesh during 24 months (patients included in the mesh group)
  - a. Mesh infection
  - b. Mesh exposure

After the patient's inclusion, randomization is made to determine whether or not the patient will receive the mesh during the surgery for stoma creation.

3.1. Participants

3.1.1. Inclusion criteria

Patients fitting the following criteria were eligible for inclusion in this study:

A. Indication for terminal colostomy
   a. Anal, rectal or colon cancer with impossibility to perform an anastomosis
   b. Chronic inflammatory bowel disease
   c. Failure or poor functional result of colorectal surgery
   d. Faecal incontinence

   Patients were recruited during surgical consultation for one of the previous indications.
B. Inclusion criteria:
   a. Free and prior informed consent
   b. Affiliation to social security
   c. Availability for a 25-month follow-up
   d. Minimum age 18 years old
C. Only patients operated on during scheduled surgery were eligible for this study