PROJECT INFORMATION/file content:

Study protocol

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Project title:

LAPAROSCOPIC REPAIR OF OSTOMY HERNIA WITH MESH OUTSIDE OF THE ABDOMINAL CAVITY

NCT number:

NCT04440514

Project description – ePauli

1. Project title:
Endoscopic preperitoneal parastomal hernia repair (ePauli repair)
Short title: ePauli

2. Introduction

The near-invincible parastomal herniation (PSH) problem has been met with stoicism but is addressed more often with repair in recent years (1). Historically, low efficiency rendered repairs to back-against-the-wall emergency situations. Recent mesh technology and technique has optimized recurrence rates and adverse outcomes and a more aggressive attitude towards repair is exerted – both from a patient and a surgeon perspective. A local repair with synthetic non-absorbable mesh has better outcomes than relocation. A laparoscopic intraperitoneal repair (IPOM) has lower infection rate compared to open repair. However, the one-year recurrence rate still seems to be considerable (2-4). Key-hole techniques have worse outcome than the modified Sugarbaker technique: the most popular endoscopic procedure today with a recurrence rate around 15%.

E. Pauli has described a modification of the Sugarbaker technique, the "Pauli repair", employing a transversus abdominis release (TAR) and placement of mesh in the preperitoneal/pretransversalis fascia plane (5). Previous reports of TAR for incisional hernia involved reinforced relocation or a key-hole repair with reconstruction of the stoma (6). A series of open Pauli procedures have been published, with concerns about mesh complications and recurrence rate of 11% after median 13 months follow up (7).

Intraperitoneal mesh increases risk of adhesion and fistula formation. In a quest for endoscopic repair with inherent less infection risk, but extraperitoneal mesh application to avoid adhesion and pain from mesh fixation, we adopted the principles of the Pauli repair to endoscopic surgery in a prospective series, that we termed ePauli repair. The aim was to assess feasibility, adverse reactions, and monitor recurrence rate.

Objectives

Feasibility, adverse reaction and effect assessment with a procedure modification.

4. Project methodologies
Patients with PSH selected for and operated with ePauli repair are enrolled in a prospective observational study. The study is registered as a local quality control study at Sykehuset Innlandet Hospital Trust with oral and written patient information and subscribed consent to participation and publication. The study and patient information are approved by the Institutional Review Board and the Data Protection Officer at Sykehuset Innlandet Hospital Trust.

4.1 Project design, method selection and analyses

Design

Primary aims: feasibility of preperitoneal endoscopic repair of parastomal hernia
Secondary aims: adverse reactions and hernia recurrence

Intervention

Laparoscopy with three ports in the opposite flank, contralateral to the stoma/PSH. Robotic assistance employed when available, however, in the beginning patients with concomitant midline hernia are selected for a laparoscopic procedure. After adhesiolysis in the abdominal cavity and freeing of the intestinal stoma in the hernia cavity, the rectus sheath is incised medially and a Rives dissection towards the semilunar line is performed. The parastomal hernia sack is incised in its circumference. Next step is TAR, with incision of the rectus sheath medial to neurovascular bundles and medial release of the fibers of the transversus abdominis muscle. An up-to-down approach is preferred as it is perceived easier to stay in the pretransversalis fascia plane and avoid making holes in the peritoneum during lateral development of the plane. The dissection is continued at least 10 cm lateral to the ostomy, and longitudinally to accommodate a 20-centimeter mesh. Previously placed meshes are left in situ. The posterior ostomy is moved by incision of the transversalis fascia, the bowel lateralized, and the fascia sutured medially. The stoma bowel is fixated to the flank with absorbable V-Loc and mesh is not fixated. The anterior ostomy is adapted to accommodate the stoma bowel with non-absorbable V-Loc placing the bowel against the lateral edge of the opening. A mesh, typically 18x18 centimeters in size, is placed in the developed pocket – in front of the posterior fascia but behind the intestine and the anterior abdominal wall. Mesh choice is preferably a uncoated synthetic midweight non-absorbable mesh with Bio-A synthetic absorbable mesh placed as barrier between the mesh and the bowel, laterally overlapping the non-absorbable mesh with 1 cm in order to avoid mesh ingrowth in the intestine. Ultimately the posterior rectus sheath is re-adapted to the linea alba with absorbable V-Loc. In patients with concomitant midline hernia the procedure is extended with an enhanced-view Rives-Stoppa (eRS) with port insertion in the ipsilateral flank and contralateral retromuscular dissection to the semilunar line. The linea alba is reconstructed with non-absorbable V-Loc and the posterior fascia/peritoneum closed with absorbable V-Loc. A mesh reaching from the contralateral semilunar line to the ipsilateral flank with stoma is placed without fixation. Drains are used selectively.

4.2 Participants, organization and collaborations

SI Hamar and Gjøvik. Project leader and executer is Jan Lambrecht, MD PhD.

4.3 Budget

No cost

4.4 Plan for activities, visibility and dissemination

Assemble journal data, interviews and submit publication in June 2020.

5. User involvement

Patient have an active role in choice of treatment and have chosen the investigated method with verbal informed consent.

6. Ethical considerations

The method is a modification from the “traditional” endoscopic method (Sugarbaker) with intraperitoneal mesh. The modification involves a component separation with medial release of the inner of the three lateral muscles in the abdominal wall (transversus abdominis) to avoid damage to motoric nerves and blood vessels to the rectus muscle and in order to create a pocket for extraperitoneal mesh placement. This is a very advanced procedure and in untrained hands possible calamities with break-down of abdominal wall function and structure can occur. The advantage with the procedure is that the problems with pain from mesh fixation and adhesion and fistula to a mesh placed intraperitoneally is vastly decimated. The quest to get meshes out of the abdominal cavity again, after being introduced for the masses with the influx of laparoscopic abdominal wall hernia repair around year 2000, has just begun and we increasingly use endoscopic preperitoneal techniques for abdominal wall hernia. We expect better outcomes regarding recurrence of hernia and definitively less pain and adhesion/fistula formation with the mesh outside the abdominal cavity as we know it from open surgery. However, we maintain the advantage of minimal infection risk and pain with laparo-endoscopic operations. We also have the experience, skill, and anatomic knowledge to perform excellently. Patients are made fully aware of the described modification and are actively choosing this treatment and referred from outside regions to receive this specific treatment. We believe it is an advancement in parastomal hernia repair and we are obliged to document effect and monitor adverse events in a quality database – as is prudent even with minor but advanced modifications to standard treatment. However, we do expect significant ramifications for future parastomal hernia treatment and focus on specialization with this evolving solution.

7. References

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