Sublay vs onlay mesh in incisional hernia: A randomized control study

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Incisional hernias in the midline is among the most common conditions requiring surgery. There are several factors which can increase the risk of incisional hernias, e.g. surgical technique, truncal obesity and other co-morbidities. Truncal obesity increases the intraabdominal pressure, thereby forcing the abdominal contents to protrude through the umbilical hernia defect. The obesity also increases the symptoms from the hernia, since the intraabdominal pressure increases the tension in the tissue. Furthermore, abundance of intraabdominal and subcutaneous fat renders the repair more complicated and increases the risk for postoperative complications, including seroma, bleeding and surgical site infection(SSI).

Some surgeons advise elective repair of primary incisional hernias after diagnosis while others advise expectance. The treatment decision is usually based on the size of the hernia, symptoms and an estimation of the risk for incarceration. Mesh-reinforced is mostly used for the treatment of incisional hernias. Onlay and sublay mesh placements are the most usual methods. There are many different types of mesh available to use. Despite the widely use of composite ventral-patch (Ventralex®), there are few studies with small numbers of patients showing the advantage and disadvantage of ventral-patch [2]. Some studies show that the onlay mesh-reinforcement remains a good alternative to the sublay mesh technique [1,4]. While others showing fewer

recurrences with the sublay mesh technique. The Ventralex® mesh is usually placed on the peritoneum as a IPOM (Intra peritoneum onlay mesh). In this study intend to compare pre peritoneal Ventralex® mesh in sublay position with ProGrip™ self-fixating onlay mesh.

Methods

Trial design

Single-blind parallel randomized controlled trial.

Primary outcome measures:

Recurrence rate one year after surgery

Secondary outcome measures:

Intra- and postoperative complications

Recurrence

Hematoma

Seroma

Chronic pain assessed with Ventral Hernia Pain Questionnaire

Sick leave

Inclusions criteria:

Hernia defect 1-4 cm

Incisional hernia

Recurrent ventral hernia

BMI <35

Age 18-100

Exclusion criteria:

Defect size >4cm

Pregnancy

MI >35

Primary hernia

Minor

Randomization

Sequence generation: Simple randomization

Allocation concealment mechanism: The surgeon retrieves the allocation through the online randomization system (Smart-trail) prior to surgery without notifying the patient. The procedure is performed under general anesthesia.

Implementation

Information about the study will be provided to all patients who meet the criteria for the study. Oral and written consent will be obtained from patients that agree to participate. Current illnesses (ICD codes) and ongoing medication are recorded. Waist width is also registered.
Shortly after the patient has been anesthetized on the operation table, randomization is done online. The patient will be allocated to one of the following:

Sample size estimation

Number of patients: 200 The cumulative incidence of recurrences one year after surgery may be assumed to be 15 with onlay mesh. In a previous study [5], the cumulative incidence was found to be 3% when Ventralex® patch

was used. Based on these assumptions, a total of 176 patients would be needed to reach 80% of showing a difference between the groups at the $p<0.05$ level. In order to compensate for drop-outs, we aim on including 200 patients.

Sublay mesh group

A round composite mesh in diameter (Ventralex® ™ patch, BARD) is placed in the pre-peritoneal space (sublay) with open technique. If the fascia defect is 1-2cm the mesh with 6.4cm in diameter will be used, if the defect size is 2-4cm in diameter the mesh will be 8cm in diameter. The mesh-straps are then fixed to the facial defect edges with non-absorbable monofilament suture as recommended and then suturing of facial defect with continues 0-Prolen suture horizontally.

Onlay mesh group

After the reposition or resection of hernia sac, suturing the facial defect with the 0-prolen horizontally. If the fascia defect is 1-2cm the mesh with 6.4cm in diameter will be used, if the defect size is 2-4cm in diameter the mesh will be 8cm in diameter. The subcutaneous fate then dissected from the external fascia and a light weight polypropylene mesh (ProGrip™, Medtronic) applies on the fascia over the sutured defect. The mesh then sutures to the fascia with 2/0 prolen suture.

The patient and staff responsible for the care of the patient postoperatively are blinded to the allocation.

Four hours after the procedure has been finished, the patient is requested to rate the pain from the abdomen on a VAS scale.

Patient follow up:

The first follow up begins 4 hours after the surgery before the is discharged from the hospital. The patients are then invited to follow-up one week, one month and one year after surgery. At each visit, the patients will undergo a clinical investigation by a physician blinded to the allocation. Any wound complication or other symptoms will be registered directly digitally.

Sublay mesh group and onlay mesh group

Complications that may be assumed to be related to the hernia repair are recorded in both groups. In case an obvious recurrence is found, this is registered. In case a suspicion of a recurrence is raised, but not definitely confirmed, the patient is referred to a computer tomography. The patients will also be requested to fill in the VHPQ [9] at each follow-up.

Importance

The study may provide unique data on the outcome after incisional hernia patch repair, since there are very few studies evaluating this technique. Ventral patch has been questioned since it could cause fistulas to the intestines or adhesions if placed incorrectly. The present study will therefore focus on the safety of the technique based on the outcome when it is used with a standardized routine. If there will be intraabdominal complications in the Ventral Patch group, this may indicate that the technique should be abandoned. On the other hand, if it turns out that the patch is safe and reduces the risk for recurrences, this suggests that further studies should be undertaken to evaluate the technique.

Onlay mesh technique on the other hand is easier and quicker approach with less risk for bowel complication, deeper infection end hematoma.

In separate analyses, we will explore the impact of waist width on the outcome. A hypothesis that will be tested is that truncal obesity has greater impact on the outcome than BMI.

studies comparing ventral patch with the onlay mesh technique. We intend to compare the use of sublay composite mesh (ventral-patch) with onlay mesh repair and observe recurrence rate and other short and long-term postoperative complications in these two methods.

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