Barbed suture vs ventral patch in small ventral hernia: A randomized control study

A Katawazai, F Ali, G Sandblom, G Wallin

Background

Primary hernias in the midline, including umbilical hernias and epigastric hernias, are among the most common conditions requiring surgery. The pathogenesis of umbilical hernias is closely associated with truncal obesity. 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 ventral hernias after diagnosis while others advise expectance. Mesh-reinforced as well as suture repair are used for the treatment of primary hernias, but for smaller umbilical hernias (diameter 1–3cm), there is little evidence for the superiority of mesh repair [1]. In a meta-analysis, the recurrence rate in mesh patients found to be slightly better than prolen-suture repair without mesh in small hernias. However, the mesh may cause persisting pain or other mesh-related complications [2, 3]. Despite the widely use of composite ventral-patch, there are few studies showing the advantage and disadvantage of ventral-patch [4]. In recent years, the barbed-PDS suture has been widely used in umbilical and incisional hernias, in laparoscopic as well as in open surgery. However, there are no

studies comparing ventral patch with slowly absorbable barbed suture in open surgery. A prospective laparoscopic hernia repair study on non-absorbable barbed suture versus mesh repair showed similar results regarding recurrence [5]. We intend to compare the use of sublay composite mesh (ventral-patch) with non-resorbable barbed-PDS suture repair only and investigate recurrence rate and other short and long-term postoperative complications in these two methods.

Trial design: Single-blind parallel randomized controlled trial.

Inclusion criteria:

Hernia defect 1-4 cm

Primary hernia

BMI <35

Age 18-100 years

Exclusion criteria:

Defect >4cm

BMI >35

Recurrent hernia

Pregnancy

Minors

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

Randomization

Sequence generation: Simple randomization

Allocation concealment mechanism: The surgeon retrieves the allocation through the online system (Smart-trail) randomly prior to surgery without notifying the patient. As the procedure is performed under general anesthesia, the patient will not be aware of the allocation

Implementation of randomization: The surgeon responsible for the repair retrieves the allocation through the online system and completes the repair according to the allocation.

Implementation

Information about the study should be provided to all patients who meet the criteria for the study. Oral and written consent will be obtained from the patient. Current illnesses (ICD codes) and ongoing medication are recorded. Waist width is also registered.

Sample size estimation

Number of patients: 200

The cumulative incidence of recurrences one year after surgery may be assumed to be 20% without mesh. In a previous study [6], 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.

Methods

Shortly after the patient has been anesthetized on the operation table, randomization is done online (Smart-trail). The patient will be allocated to one of the following:

Ventralex groupe

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.

Stratafix groupe

Suturing of hernia defect with the non-absorbable barbed unidirectional 2-0 stratafix suture only (Stratafix® 2-0 polypropylene spiral, Ethicon). The defect will be sutured horizontally.

Follow-up

The patients are invited to follow-up 4 hours, 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 complications that may be related to the hernia repair are recorded. 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 [7] at each follow-up.

Sublay mesh groupe and stratafix groupe

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 ventral 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.

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.

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