Defect closure in laparoscopic ventral hernia repair

Randomized control study

Background

Midline ventral hernia is a hernia protruding through the vertical line anywhere from the xiphoid process to the pubic tubercle. Ventral hernias may develop due to weakness of the rectus muscles on either side of the linea alba in case ofprimary ventral hernia or after previous abdominal surgery in case of secondary ventral hernias.

Incisional hernia is a common problem that may occure as consequence of previous abdominal surgery. Previous studies have shown that the cumulative incidence of incisional hernias may be up to 20% in patients that undergo abdominal surgery (Mudge M, Hughes LE (1985) Incisional hernia: a 10-year prospective study of incidence and attitudes. Br J Surg 72:70–71.) According to the National Centre for Health, more than 100,000 ventral hernia repairs are performed annually in USA. Although the recurrence rate after incisional hernia repair used to be high, the introduction of tension-free techniques with the use of mesh has resulted in a dramatic decrease of the rate of hernia recurrence. Meanwhile post-operative seroma remained as common problem, which is not resolved yet.

Laparoscopic ventral hernia repair (LVHR) is now widely accepted as well established as a minimal invasive procedure for managing ventral hernias. Intra peritoneal onlay mesh (IPOM) or closure of the hernia defect prior to applying a mesh (IPOM-plus) are two alternative laparoscopic techniques for repairing ventral hernias .Previous studies have showed lower recurrence rates in IPOM-plus, but seroma formation remains an unsolved problem.

In accordance to the principle of tension free suture in closing the hernia defects, using peritoneal bridging in a previous pilot stud gave less seroma formation when using peritoneal bridging instead of primary closure of hernia defect prior to applying a mesh. This technique also gave less post operative pain, but due to small size including in the study.

This study is intended to resolve the potential benefit of peritoneal bridging and includes a large enough sample to reach 80% power to verify the previous study result.

Aims

The aim of this study is to test whether peritoneal bridging may improve the post operative outcome in terms of seroma formation and pain for patients undergoing laparoscopic ventral hernia repair.

Material

Patient's	procedure	phase
Primary and secondary ventral hernia	laparoscopic ventral hernia repair	2

Summary:

One hundred patients were planned for Laparosopic Ventral Hernia Repair (LVHR) for midline ventral hernia (primary and secondary hernia) will be included.

The patients will be divided into 2 equal groups by randomization. The patients will be blinded to the allocation . Patients in G1 undergo LVHR without closure of the hernia defect prior to applying a mesh (IPOM). Patients in G2 undergo LVHR with closure of hernia defect (peritoneal bridging) prior to applying the mesh,

Primary outcome

Postoperative seroma (site, volume, character, morphology, type)

Secondary outcome

Recurrence, postoperative pain, local symptoms and quality of life.

Study design

Randomized control study for evaluation LVHR with or without defect closure. The same mesh and same fixation technique will be applied in both groups.

Clinical trial with 100 patients randomly divided into 2 equal groups. The observer, i.e. the physician performing the postoperative clinical examination, and patients will be blinded to the allocation.

The purpose of the study is to find ways of improving the LVHR technique to reduce the seromaformation postoperatively and improve quality of life.

Eligibility criteria

Age ≥ 18 years

Gender: male and female

Patients planned for elective laparoscopic ventral hernia repair, primary and secondary hernia

Defect size 3-10 cm diameter

BMI <40

Exclusion criteria

Defect size >10 cm (W3 according to EHS classification (Muysoms)

Ventral hernia with other localization than the midline

Emergency surgery and incarcerated hernias

Multiple abdominal operation, loss of abdomen domain

Pregnancy or intended pregnancy

Serious comorbidity, ASA score > 3

Primary outcome measure

Seroma assessed with ultrasonography performed by the same radiologist and same equipment.

Secondary parameters measures

Seroma found at clinical examination according Morale's Conde score 1month, 3 months, 6 months and 12 months postoperatively.

Post-operative complication registered 0-12 months postoperatively

Symptom rated with the Ventral Hernia Pain Questionnaire (VHPQ) and VAS scale

Duration until return to normal daily activity

Sick leave duration (patients not retired)

Hernia recurrence within one year after surgery

Methods divided to phases

1- Allocation

Patients with ventral midline hernia referred to our surgical department, regardless of residence. The patients will be given information about the study orally and by a written form. Those who give oral and written consent to the study will be included.

Randomization will be performed by the surgeon performing the procedure through a sealed envelope system.

2- Operative phase

All procedures are performed by the same surgeon. At the day of surgery the surgeon opens the envelope in order to determine allocation group.

Positioning

Patients are positioned so that the hernia defect may be easily accessed, not causing ergonomic problem for the surgery crew. Supine position, with the arms along the side of the patients is the usual position for midline ventral hernia. This enables adhesion lysis and fixation of the mesh .in case needed, the patient tilted or tipped in either direction in order to achieve optimal exposure.

Urinary catheter

The decision whether an indwelling catheter is required depends on the site of the hernia. In the lower midline, especially if close to the symphysis, an indwelling catheter is usually needed. Applying a mesh .usually requires fixation to the inferior pubic ramus away from urinary bladder. An indwelling

catheter also make it possible continuous monitoring the patient, by emptying urinary bladder ,more space in the abdominal cavity I provide .if three ways catheter is used ,saline may be installed which is help to visualize the bladder to avoid injury during dissection.

Prophylactic antibiotic

Cefazolin iv is given within 60 minutes before the procedure. Patients with multi resistant staphylococcus aureus (MRSA), iv Vancomycin is given within 120 minutes before the procedure.

Clindamycin or Vancomycin is given to patients with allergy against Beta-lactam antibiotic.

Trocar placement

A 12 mm trocar is introduced under visual control in order to get access to the abdominal cavity. The trocar should ideally be as far as possible from the hernia defect. CO_2 gas under 12 mm mercury pressure is connected a 30-degree vision camera introduced through a trocar placed in the upper right or left quadrant. The position chosen by taking the patient history and anatomy into account. Two 5 mm trocars are introduces as laterally as possible from the defect in order to enable good ergonomics during lysis of the adhesion and mesh applying.

Adhesiolysis

Adhesiolysis is undertaken with careful technique with minimum of electrocautery to avoid bowel injury visualizing the whole field is important. The falciform ligament is dissected to enable applying the mesh. The intestine inspected through all the procedure to avoid unfavorable injuries

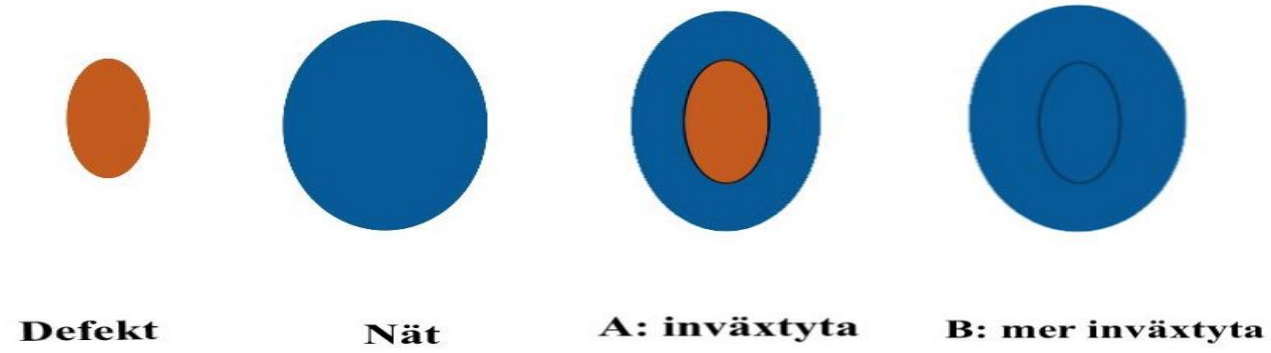
Defect measuring

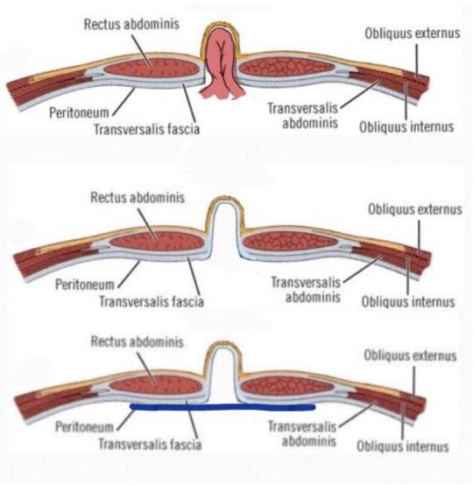
The defect is measured intracorporally to ensure sufficient mesh coverage, with at least 4 cm overlap from the defect edge to minimize hernia recurrence. The length as well as the width is measured.

Peritoneal bridging

In case, the patient is allocated to peritoneal bridging group the peritoneum is dissected 2-3 cm from the defects edge. The hernia sac dissected all the way to the opposite edge of the defect and the peritoneum used as flap to cover the defect by suturing with 2-0 knotless strati fix (PDS) Fig 2B. The aims of the bridging are to increase the surface in contact with the mesh Fig (1), and to close the defect with tension-free principle.

Fig 1





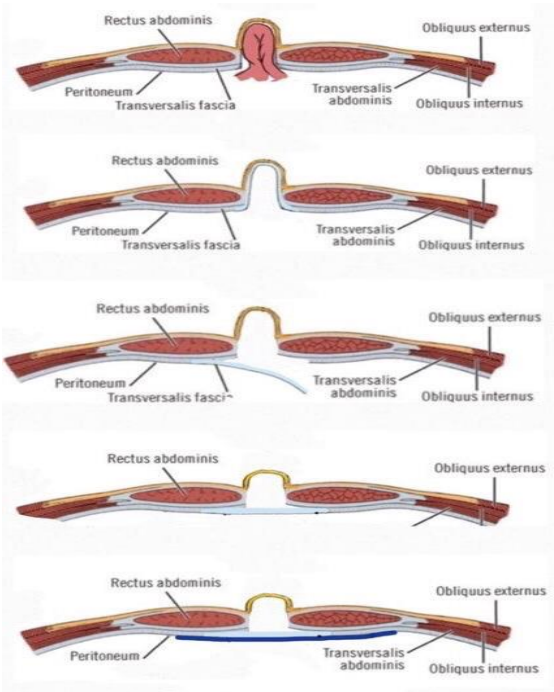


Fig 2 A

F2 B

IPOM without defect closure

IPOM with peritoneal bridging

Mesh and fixation

The Bard mesh is positioned to cover the defect if the patient is allocated to IPOM without closure of the defect prior applying a mesh. In case the patient is allocated to peritoneal bridging the defect is covered by the peritoneal flap prior to applying the mesh.in both groups the mesh fixing with

absorbable tacks double crows technique. The same type of mesh and same technique is used.to reduce bias effect.

Local anesthesia

Ropivacain 7,5 mg/ml 20 ml is injected intraoperatively. An elastic girdle is used for two weeks by all patients.

Postoperative analgesia

Ipren 200 mg + paracetamol 500 mg.

Variables registered postoperatively

Operation time

complication s

Discharge

All patients meet the surgeon at discharge.

3-Follow up phase

All patients are followed up with clinical examination by another surgeon one months, 3 months, 6 months, 12 months. The surgeon performing the examination registers the variables in a standardised protocol.

The presence of seroma found at clinical examination is done according Morales Conde Score:

- Type 0a. No detectable seroma
- Type 0b. Seroma seen with imaging but not at clinical examination.
- Type 1. Postoperative seroma persisting one month.
- Type 2a. Seroma persisting 1-3 months.
- Type 2b. Seroma persisting 3-6 months.
- Type 3. Symptomatic postoperative seroma.
- Type 4 Seroma with local secondary complications.

Symptoms are rated with the Ventral Hernia Pain Questionnaire (VHPQ) and VAS scale.

Ultrasonography control

Ultrasound examination is performed on all patients 1,3,6, and 12 months postoperatively by an ultrasonographist with the same ultrasound equipment. Based on the parameters (site, morphology, character and volume) the seromas are divided into 3 groups, each group subdivided to further 5 classes to precise the score is assigned .the value between (3-15) represent prognostic index (PI).Low PI asymptomatic seroma no need for management;. High PI requires intervention.

Volume measures. V= L x W x D.

Localisation: anterior or posterior to the rectus sheath

Shape: oval, spherical or flat.

Character: turbid or clear.

Sample size estimation

The sample size based on assumption of superiority. Mean seroma volume is 300 ml in plain IPOM group. Standard deviation 100 ml that is reduced by 20% in the IPOM –peritoneal bridging group. We need 88 patients in order to reach a chance of 80% to obtain a statistic significant. Difference at the p <0, 05 level. Excluding that, in order to compensate for dropouts, we plan to include 100 patients.

Importance

The study is intended as 2 phase with the aim of evaluating if a peritoneal bridging is appropriate alternative procedure for patients with ventral hernia. The hypothesis is that peritoneal bridging will cause less seroma formation, less post-operative pain and better quality of life for patient post-operative.

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