CLINICAL GUIDELINES DANISH MEDICAL BULLETIN

Danish Hernia Database recommendations for the management of inguinal and femoral hernia in adults

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SUMMARY

The nationwide Danish Hernia Database, recording more than 10.000 inguinal and 400 femoral hernia repairs annually, provides a unique opportunity to present valid recommendations in the management of Danish patients with groin hernia. The cumulated data have been discussed at biannual meetings and guidelines have been approved by the Danish Surgical Society. Diagnosis of groin hernia is based on clinical examination. Ultrasonography, CT or MRI are rarely needed, while herniography is not recommended. In patients with indicative symptoms of hernia, but no detectable hernia, diagnostic laparoscopy may be an option. Once diagnosed, hernia repair is recommended in the presence of symptoms affecting daily life. In male patients with minimal or absent symptoms watchful waiting is recommended. In females, however, repair is recommended also in asymptomatic patients. In male patients with primary unilateral or bilateral groin hernia the preferred method is mesh repair, either at open surgery (Lichtenstein) or laparoscopically, irrespective of age. Conventional tension-producing methods like Bassini, McVay or Shouldice are no longer recommended in a routine elective setting. Whether repair should be done by open or laparoscopic technique, depends on local expertise, economical considerations and patient preference. Compared to the Lichtenstein operation

laparoscopic repair is associated with less acute pain and faster recovery. Furthermore, available data suggest less chronic longterm pain after laparoscopic repair. In female patients laparoscopic repair is the recommended method. In patients with recurrent hernia laparoscopic repair is preferred in patients with a previous open repair, while patients with recurrence after laparoscopic repair should undergo open mesh repair. In open repair it is recommended to use a mesh secured with a non-absorbable monofilament suture. In laparoscopic repair a mesh without a slit and with a minimum size of 15 x 10 cm is used. For mesh fixation absorbable or non-absorbable tacks or glue can be used. Elective surgery for groin hernia should be performed in an out-patient setting, using cost-effective local anaesthesia in open mesh repair and general anaesthesia for laparoscopic repair. Spinal anaesthesia is not recommended. Routine prophylactic antibiotics are not indicated. In the early convalescence period there are no physical restrictions. These guidelines will also be available at the website for the Danish Hernia Database (www.herniedatabasen.dk). The guidelines will be updated when new substantial evidence becomes available.

INTRODUCTION

The purpose of national guidelines within hernia repair is to seek unification of the treatment algorithms on a national basis in order to be able to improve clinical outcome in a large number of patients. This can not be obtained in a randomized clinical trial and instead a national clinical database is required.

Based on the work from European hernia experts recent guidelines from the European Hernia Society (EHS) suggested an evidence-based approach to treatment of inguinal hernia in adults (1). However, not all of these European recommendations are related to the treatment of Danish patients. In Denmark, groin hernia surgery has gone through a continuous development through the last 20 years with monitoring through the Danish Hernia Database of more than 130,000 inguinal hernia procedures over the last 11 years (2). Thus, the Danish Hernia Database has provided substantial evidence for the international community regarding recurrence and chronic pain after groin hernia repair, outcome after the Lichtenstein procedure as well as laparoscopic inguinal hernia repair (3,4,5). However, no recommendations from the database regarding Danish patients have so far been given.

Recently, the Danish National Database has published its current proposal for the treatment of ventral hernia (6). The aim of

the present paper is therefore to provide recommendations for the treatment of inguinal hernia with special reference to Danish conditions. The paper should therefore be regarded as the official guidelines for elective inguinal and femoral hernia repair in adults from The Danish Hernia Database.

Table 1

Summary of guidelines for diagnosis and elective treatment of inguinal and femoral hernia in adults.

DIAGNOSIS

The diagnosis is mainly based on clinical examination

WHO

Surgical treatment should be restricted to male patients with symptoms or in case of complications and femoral hernia, and to all females with an inguinal or femoral hernia irrespective of symptoms or complications

MFN

Men with unilateral primary hernia should be treated by laparoscopic or Lichtenstein's repair depending on local expertise, economical considerations and patients preferences Men with bilateral hernia should be treated by laparoscopic or Lichtenstein's repair depending on local expertise, economical considerations and patients preferences

WOMEN

Women with primary hernia should be treated by laparoscopic

Women with bilateral hernia should be treated by laparoscopic repair

Groin hernia repair in adults should always include a mesh regardless of surgical technique (open or laparoscopic)

RECURRENT HERNIA

A recurrent hernia after previous open repair should be operated by laparoscopic technique

A recurrent hernia after previous laparoscopic repair should be operated by open technique

AMBULATORY SURGERY

Groin hernia repair should primarily be performed in an outpatient setting

ANESTHESIA

Local anaesthesia is a cost effective method for open repair but general anaesthesia is the choice for laparoscopic repair. Regional anaesthesia (spinal or epidural) should be abandoned

SICK LEAVE AND CONVALESCENCE

Immediate resumption of normal activity and work is possible and without increased risk of recurrence unless pain is a hindrance

LEGAL IMPLICATIONS

Practice guidelines are not legal requirements that should be followed in all situations. They are meant as recommendations based on the available evidence as well as consensus agreements between peers in the clinical area. Thus, the guidelines are based on the average patient and can be deviated when necessary. In such cases the reasons for not following the guidelines should be explained in the patients file.

METHODS

Based on the EHS evidence-based guidelines (1) we have specifically addressed relevant material for Danish conditions in combination with consensus decisions from our national database meetings. The outline of these recommendations has been discussed between the authors of the present paper constituting the steering committee of The Danish Inguinal Hernia Database. Recommendations were subsequently discussed and approved at the biannual meeting (Copenhagen, spring 2010) representing most of the surgical departments in the country. Subsequently, the guidelines were approved by the Danish Surgical Society before publication. These guidelines will also be available at the website for the Danish Hernia Database

(www.herniedatabasen.dk). The guidelines (Table 1) will be updated when new substantial evidence becomes available.

DIAGNOSIS

The diagnosis of a groin hernia is based on clinical examination. An inguinal or femoral hernia is a protrusion in the groin and not necessarily associated with localized pain or discomfort during palpation. If in doubt, the clinical examination may be supplemented by ultrasonography, CT-scan or MRI depending on local expertise. Herniography has currently no place in the diagnosis of hernia in Denmark. Diagnostic laparoscopy is indicated if the patient has persistent symptoms but no positive diagnosis on clinical examination or ultrasound, CT, or MRI. If, by laparoscopy, a hernia is not apparent on inspection and still suspected clinically (this counts especially for femoral hernia), the peritoneum should be incised and the area of the internal ring and femoral orifice dissected. If a hernia is found during this procedure it should be repaired laparoscopically. If there is no hernia, it is not indicated to place a mesh in the groin area (7).

CLASSIFICATION

In order to standardize description of inguinal hernias, the EHS classification (8) should be used in the operative notes (Table 2). Furthermore, it will be integrated in the recording of the operative findings in the Danish Hernia Database. The EHS classification is simple and reliable and will secure posthoc analyses if needed.

INDICATIONS FOR TREATMENT

In male patients without symptoms or with only minimal complaints surgical repair should not be offered as a routine (Figure 1). This strategy is based on data supporting watchful waiting if only minimal symptoms are present (9). Due to increased risk of strangulation it is advisable to offer laparoscopic repair (see below) in all women with a hernia in the inguinal region (Figure 1).

SURGICAL TREATMENT

In the general surgical population the risk of recurrence can be reduced by inserting a flat mesh in the inguinal region, either by open repair or laparoscopically (10,11). Thus, suture based methods without a mesh such as Shouldice, Bassini or McVay are not recommended. Also, the use of a plug for an inguinal hernia is not recommended.

Since young age may be a risk factor for chronic pain after inguinal hernia repair (12) the use of mesh repair in young male patients (e.g. 18-30 years) is controversial but so far data does not support any disadvantages but rather the contrary (13, 14). The use of a mesh is therefore recommended in all adult patients (>18 years) with indication of inguinal hernia repair.

MEN

Men with inguinal hernia can be treated by Lichtenstein's repair or by laparoscopic repair (Figure 1). The choice of surgical technique in primary unilateral hernia in men depends on local expertise, economical considerations and patient preferences. The available data suggest less pain and faster recovery after laparoscopic compared with open repair. Furthermore, the incidence of chronic postoperative pain may be less after laparoscopic compared with Lichtenstein repair although data are not uniform (15). In Denmark, the preferred method for laparoscopic repair is the transabdominal preperitoneal approach (TAPP) (3) but the total extraperitoneal approach (TEP) is equally safe and effective in skilled hands. In case of severe comorbidity, previous extensive pelvic surgery or radiation therapy it may be advisable to perform the operation as an open procedure, depending on local expertise.

WOMEN

Data from the Danish Hernia Database have previously shown that the risk of recurrence in women is higher when performing an open repair compared with a laparoscopic repair for a primary hernia (4). Furthermore, due to excellent exposure of the myopectineal orifice including the femoral canal during the laparoscopic dissection it is recommended that all women with a groin hernia (inguinal or femoral) should be offered a laparoscopic repair (Figure 1). In case of severe comorbidity, previous extensive pelvic surgery or radiation therapy it may be advisable to perform the operation as an open procedure, depending on local expertise.

BILATERAL HERNIA

There are no conclusive data to support a laparoscopic approach to treat bilateral inguinal hernia repair compared with open repair (4). In fact, initial data from The Danish Hernia Database suggested a higher risk of recurrence after bilateral laparoscopic repair of inguinal hernia compared with results after a laparoscopic unilateral repair (4). These findings may be due to a learning curve effect during the early years of laparoscopic inguinal hernia repair and have not been confirmed in recent analyses in the database or by others (16). Thus, the choice of surgical technique in bilateral hernia depends on local expertise, economical considerations and patient preferences.

RECURRENCE

Large-scale national data from Denmark support the recommendation of a laparoscopic repair after a previous open repair independently of using a mesh or sutured repair for the primary operation. An open repair for recurrence is recommended after a primary laparoscopic repair (5) (Figure 1).

INGUINOSCROTAL HERNIA

Large or incarcerated inguinoscrotal hernia may preferably be treated by open repair, although international expert centers have shown good results after laparoscopic repair (17).

AMBULATORY SURGERY

Inguinal hernia surgery as day surgery is as safe and effective as inpatient treatment and more cost effective (18). This applies for all patients including selected elderly and ASA-III-patients, but may depend on local factors such as social backup etc. It is therefore recommended that inguinal hernia repair is performed in an outpatient setting unless argued otherwise from specific factors.

ANAESTHESIA

The use of regional anaesthesia (spinal and epidural anaesthesia) is followed by increased urological complications and even increased mortality risk in patients undergoing inguinal hernia repair (19) and should be avoided. Local anaesthesia for open inguinal hernia repair is the most cost effective method.

CONVALESCENCE AND RESTRICTIONS

The duration of the convalescence period after uncomplicated inguinal hernia repair depends mainly on the recommendations for duration of convalescence given to the patients. Other factors of importance may be postoperative pain and perhaps operative technique (open versus laparoscopic surgery) (20). There is no evidence supporting prolonged convalescence periods to avoid recurrence (21), and patients can therefore be active immediately after surgery when pain is not a hindrance.

ANTIBIOTICS

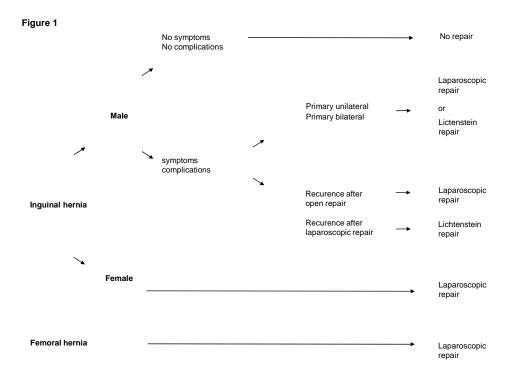
Because of the very low risk of wound infections the routine use of antibiotics is not recommended (1). In patients with increased risk of infections antibiotics may be indicated, although the evidence for this is lacking.

THROMBOEMBOLIC PROPHYLAXIS

There is controversy regarding the use of thrombosis prophylaxis in hernia surgery (22). There are no guidelines available for open inguinal hernia repair, and for this operation we do not recommend routine prophylaxis.

For laparoscopic routine thrombosis prophylaxis is recommended by the Society of American Gastrointestinal and Endoscopic Surgeons depending on patient risk factors (23). According to these guidelines a patient undergoing laparoscopic inguinal hernia repair should receive prophylaxis if ≥ 2 of the following risk factors are present: Duration of surgery > 1 hour, history of venous thromboembolism, congestive heart failure, age >40, previous myocardial infarction, immobility, hormone replacement therapy, varicose veins, oral contraceptive use, cancer, multiparity, chronic renal failure, inflammatory bowel disease, obesity, severe infection, or peri-partum. In general, the prophylaxis in laparoscopic outpatient repair should be as a single perioperative dose.

At present, the Danish Hernia Database does not endorse the SAGES guidelines because of the lack of data to support it.



Flow-chart of suggested treatment algorithm for elective inguinal and femoral hernia repair in adults.

OPERATIVE TECHNIQUE

LICHTENSTEIN REPAIR

The skin is incised from 1-2 cm above the pubic tubercle, with the incision extending laterally. The fascia of the external oblique is cleaved and the spermatic cord is mobilized. The hernia is dissected free from the spermatic cord. In a direct hernia, creating a flat posterior wall by closure of the defect may facilitate subsequent mesh placement. In an indirect hernia, the hernia sack may be transected, excised or inverted.

A mesh (standard size 7 x 14 cm) is trimmed to size (allowing for covering of the entire posterior wall, with a 2 cm overlap at the pubic tubercle) and is sutured along the edge with continuous stitches of polypropylene, starting at the pubic tubercle, extending laterally along the posterior shelve of the inguinal ligament at least to the level of the internal ring. The spermatic cord is passed through a slit extending from the lateral edge of the mesh, to the level of the internal ring. Superiorly/medially the mesh is sutured with a number of polypropylene stitches. Approximately 1 cm lateral to the internal ring, the lower edges of the upper and lower flaps of the mesh are sutured to the posterior shelve of the inguinal ligament.

If a femoral hernia is found, after opening and dissection of the inguinal canal, a mesh-modified version of the McVay-repair may be performed, with anchoring of the mesh as described above, but instead of fixating the mesh solely along the posterior border of the inguinal ligament, the mesh is sutured to the Coopers ligament, until closure of the femoral canal is obtained. The mesh is then advanced to the inguinal ligament where it is sutured to the posterior shelve, as described above.

In applying and suturing the mesh, care should be taken, to identify the nerves and to avoid damage to the nerves, especially at the medial edge of the mesh and when opening and mobilising the spermatic cord (ilioinguinal nerve and the genital branch of

the genitofemoral nerve) and when suturing the upper edge of the mesh (iliohypogastric nerve). If a nerve location hinders sufficient placement of the mesh it may be transected at a proximal site of the mesh.

LAPAROSCOPIC REPAIR

A 5 or 10 mm lens is used. When using a 5 mm lens, the operation can be performed by use of only 5 mm ports. The first entry is placed at the upper edge or bottom of the umbilicus and then a port is placed at each side by the lateral edge of the musculus rectus abdominis. Prepare an intra-abdominal transverse incision of peritoneum, and the peritoneum is detached from the groin area using primarily blunt dissection and electrocautery when outside the area containing the nerves (triangle of pain). For all laparoscopic repairs a mesh of at least 10 x 15 cm size is used. The mesh is fixed to the underlying tissue with tacks or glue. When using tacks for fixation it is common practice to fixate the mesh at the Cooper's ligament, and along the top border of the mesh, sparing the inferior epigastric vessels and no fixation is used at the triangle of doom or triangle of pain. When using glue for fixation the mesh can also be fixated in these danger areas. The peritoneum is then closed using tacks, glue or suture. A more detailed description in Danish is available at the website (www.herniedatabasen.dk).

MESH

There is no clear evidence as to what type of mesh and weight of mesh to be used for inguinal hernia repair (open and laparoscopic). However, recent data suggest that light weight meshes may be followed by less complaints after surgery although the risk of recurrence may be slightly elevated (1).

The size of the mesh for laparoscopic repair should be at least 10 x 15 cm (24,25,26,27). In case of large hernia defects (direct > 3-4 cm, indirect >4-5 cm) the use of a larger mesh is advisable (e.g. 12 x 17 cm), or if this is not available 2 meshes with adequate overlapping may be used. It should be emphasized that the dissection space has to be adequate to accommodate the size of mesh in order to leave the mesh largely unfolded against the abdominal wall (28,29,30).

Cutting a slit in the mesh to allow the structures of the funicle to pass through the mesh may be a risk factor for recurrence after laparoscopic inguinal hernia repair although data are sparse (31,32). It is therefore in general recommended not to cut a slit in the mesh in laparoscopic inguinal hernia repair.

Fixation

For open sutured repair (without mesh) it has been shown that the use of absorbable sutures for mesh fixation is followed by an increased recurrence rate compared with non-absorbable suture material (33). We don't have similar data for the Lichtenstein method, but have agreed in the database at a national meeting to use non-absorbable monofilament suture material for mesh fixation.

Theoretically, the use of sutures may be a contributing factor in the development of chronic pain after operation due to nerve entrapment. We are currently awaiting results of several ongoing clinical trials before general recommendations can be given regarding the use of fibrin sealants or self-gripping meshes for open inguinal hernia repair.

Mesh fixation in laparoscopic inguinal hernia repair is controversial. Current evidence suggests that fixation of the mesh with tacks may be followed by increased risk of acute and chronic pain and recent reports have suggested that laparoscopic repair can be performed without fixation or with glue fixation without increased risk of recurrence. However, because of the limited amount of data we recommend mesh fixation for laparoscopic repair, and this can be performed by non-absorbable tacks, absorbable tacks or by glue fixation. There is not yet sufficient data to support one method for another.

TREATMENT OF CHRONIC PAIN

In case of chronic pain (pain for more than 3 months after repair) it is advisable to postpone the decision for surgical exploration until 12 months after hernia repair since several patients may return to low pain levels with prolonged observation (34). However, in case of high intensity immediate postoperative 'neuropathic' pain presenting as new sensory abnormalities to the scrotum or femur a subacute reexploration for nerve entrapment should be considered (sutures, tacks, etc.). Medical treatment of chronic pain can be performed at local centers (surgical departments and/or local pain clinics) whereas surgical treatment with e.g. mesh removal, neurectomy etc. (35) should be done in only 1-2 places in Denmark (currently only Rigshospitalet) (36). Referral of patients for surgical treatment of chronic pain should include a detailed description of the primary operation (copy of patient file), a detailed anamnesis of the pain pattern etc. according to the form given at the Danish Hernia Database website (www.herniedatabasen.dk).

CONCLUSION

Based on the data available both from The Danish Hernia Database and internationally, we have given national guidelines regarding inguinal and femoral hernia repair in adults. The present guidelines are recommendations based on the available evidence but should of course be individualized when necessary.

<u>Disclosure forms</u> provided by the authors are available with the full text of this guideline at danmedbul.dk.

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