

Inguinal Hernia: Follow or Repair?

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Keywords

• Inguinal hernia • Watchful waiting • Herniorrhaphy

Key points

- Inguinal herniorrhaphy is one of the most common surgeries performed in general surgery practice.
- Recent evidence suggests that routine repair of all inguinal hernias at diagnosis is not necessary.
- Patients with symptoms caused by their hernias benefit from operative therapy to eliminate pain.
- A strategy of watchful waiting for patients with minimally symptomatic hernias has been shown to be safe. However, patients should be counseled that the crossover rate to surgery approaches 75% by 10 years.

INTRODUCTION

Abdominal wall hernias have been a subject of interest since the beginning of surgical history, and the evolution of hernia repair parallels closely the advances in anatomic understanding and development of the techniques that made modern surgery possible [1]. Inguinal herniorrhaphies are now routinely performed with low morbidity and a recurrence rate that approaches 0% and are effective in preventing the life-threatening complications of bowel obstruction or strangulation (a *hernia accident* for the purposes of this article) [2]. These factors have led surgeons to recommend routine repair of inguinal hernias at

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diagnosis for most of the twentieth century. Recent results from 2 large randomized controlled trials (RCTs) challenged this concept by clearly showing that a watchful waiting (WW) approach to patients with minimally symptomatic inguinal hernias is safe [3,4]. Patients from these 2 randomized trials have now been followed for nearly a decade providing valuable insight into the natural history and progression of untreated inguinal hernias [5,6]. The purpose of this article is to review the available evidence that deals with observation versus routine repair for asymptomatic inguinal hernias.

INCIDENCE

Inguinal hernias are one of the most common afflictions in adults, especially men [2]; inguinal herniorrhaphy is one of the most common procedures performed by surgeons. More than 20 million inguinal herniorrhaphies are performed yearly around the world [5,7]. In the past, it has generally been taught that there is a higher risk of hernia accident with increased age and an increased mortality rate associated with emergency hernia surgeries [8–10]. However, modern studies are now providing evidence that the incidence of emergent inguinal hernia repair is low and seems to be decreasing, which is important when considering a strategy of WW. This finding was shown in a population-based study in Olmsted County from the Mayo Clinic in which the incidence of emergent hernia surgery over the last 2 decades decreased from 18.2 to 12.4 per 100,000 person-years in men and from 6.4 to 2.4 per 100,000 person-years in women [11]. This finding has been confirmed by the results of the long-term follow-up of the 2 RCTs referred to frequently in this article, which have provided information on natural history. Older studies in the literature that purport a higher incidence of hernia accident in the elderly and a higher mortality for emergency surgery can no longer be considered relevant [5].

CAUSE AND NATURAL HISTORY

The cause of an inguinal hernia is thought to be multifactorial. For those with a direct inguinal hernia, increased intra-abdominal pressure and relative weakness of the posterior inguinal wall are the 2 important causative factors. In those with indirect inguinal hernias, elevations in intra-abdominal pressure secondary to coughing and strenuous activity might make an asymptomatic patent processus vaginalis symptomatic [12]. The literature dealing with the role of strenuous activity and the development of inguinal hernias is contradictory, with some retrospective data showing a correlation with acute indirect inguinal hernias in patients who recalled strenuous activity before the identification of the hernia [12]. There is also an abundance of literature contradicting this [13]. Variations in the attachment of the iliopubic tract, increased intra-abdominal pressure, and size and shape of the femoral ring contribute to the development of femoral hernias. Familial predisposition, prostatism, connective tissue diseases, and disease processes that cause an increase in intra-abdominal pressure are thought to increase an individual's chance of developing an inguinal hernia [14]. Metabolic

disorders, such as osteogenesis imperfecta, Marfan syndrome, Ehlers-Danlos syndrome, and congenital elastolysis, that result in decreased hydroxyproline and collagen type I/III ratio are thought to be predisposing factors to the development of direct inguinal hernias [15]. The systemic effect of tobacco usage has been well documented. Smoking causes uninhibited proteolytic activity, activation of large numbers of neutrophils and macrophages, and uncontrolled neutrophil elastase activity. These changes inhibit repair and alter the collagen framework of the musculofascial elements of the abdominal wall, playing a role in the pathogenesis of inguinal hernias [15].

Fruchaud proposed a model whereby the failure of the transversalis fascia to retain the contents of the abdomen in the region of the myopectineal orifice was the final common denominator for all groin hernias, direct, indirect, and femoral. His model was the basis for operations (eg, the Stoppa procedure or the laparoscopic inguinal herniorrhaphies) that use a prosthesis placed between the fascia and peritoneum (the preperitoneal space) providing the reinforcement needed to retain the contents of the abdomen [14].

The natural progression of an untreated inguinal hernia is not easy to determine because of the difficulty in finding whole groups of patients who have not had their hernias repaired. This difficulty is because of a prevailing attitude that inguinal hernias should be repaired routinely at diagnosis to prevent a hernia accident [8].

Important revelations concerning the natural history have come from recent publications of the long-term outcomes of the 2 RCTs mentioned in the introduction and described in more detail later. In the North American hernia trial, only 2.4% of patients in the WW group suffered a hernia accident over a period of 10 years. The calculated incidence rate of hernia accident was 0.2 per 100 person-years in this trial for the overall patient cohort and was lower at 0.11 per 100 person-years in patients older than 65 years [5]. This finding is similar to the 2.5% incidence of hernia accident over an average period of 7.5 years in the WW group in the UK trial [6]. There was no mortality associated with emergency repair of inguinal hernias in both trials. The fact that the risk of hernia accident and its associated mortality and morbidity is much lower than previously appreciated has been the basis of recent changes in recommendations for inguinal hernia management. The reasons for improved postoperative outcomes of emergency hernia surgeries are thought to be related to better access to emergent care, surgical care by a trained surgeon (as opposed to a junior resident or a general practitioner), and improvement in postoperative management [2].

CLINICAL PRESENTATION AND DIAGNOSIS

The review of the prevalence of groin hernia repair shows a bimodal distribution with spikes in hernia repair rates in patients less than 5 years of age or older than 75 years [16]. Patients with inguinal hernias can present with a wide range of symptoms from none at all to the life-threatening complication of strangulation of incarcerated intra-abdominal contents [14]. The most common symptom is usually mild to moderate pain, which does not generally affect

work or leisure activity [3]. Up to one-third of patients are asymptomatic from their hernia [17]. Femoral hernias only represent 10% or less of all groin hernias, but 40% present with incarceration or strangulation [18].

An asymptomatic inguinal hernia is usually identified during a routine examination as a painless bulge in the inguinal region. A symptomatic hernia is typically described by patients as a sensation of a heavy feeling or dragging within the inguinal region that increases as the day goes on. Oftentimes patients will complain of radiation of pain to the testicle, which is intermittent, whereas others will complain of sharp pain that is either localized or diffuse. Because the pain is typically elicited after activity, it is often initially confused with groin strain.

Inguinal hernias are diagnosed by physical examination. Although an inguinal hernia may be visible, many are appreciated only on digital examination. Classically, on examination, an indirect inguinal hernia will push against the fingertip of an examiner, whereas a direct inguinal hernia will push against the pad of the finger of the examiner. Many authorities question the reliability of this method to accurately distinguish between the two.

Diagnostic investigations are only needed in cases of obscure pain and/or doubtful swelling in the groin. The European Hernia Society recommends the following flow chart in these cases [19]:

- Ultrasound (if expertise is available)
- If ultrasound negative → magnetic resonance imaging (MRI) (with Valsalva)
- If MRI negative → consider herniography

ECONOMIC IMPACT

In the United States, surgical repair of inguinal hernias accounted for more than \$48 billion in 2005 health care expenditure dollars [20]. Stroupe and colleagues [20] looked at the cost-effectiveness of the strategy of WW on patients involved in the North American hernia trial. To measure the effectiveness of the procedure, they used quality-adjusted life-years (QALY), which incorporates health-related quality of life and medical outcomes into a single measure. Using a variety of statistical methods, their cost-effectiveness analysis found that at 2 years the estimate of the average cost per QALY gained from tension-free repair (TFR) of inguinal hernia was \$59,065 (95% confidence interval [CI], \$1358–\$322,765); the investigators concluded that both WW and immediate surgery for inguinal hernias are reasonable approaches from the viewpoint of cost-effectiveness.

MANAGEMENT

Women

Groin hernia repair is much less likely in women compared with men, with a ratio of roughly 1 to 9 [16]. Although femoral hernias are more common in women than men, inguinal hernia repairs (mainly indirect) still outnumber femoral repairs by a ratio of 5 to 1. The natural history of an untreated groin hernia in woman is clearly different than men; thus, recommendations for

treatment must be different. Indeed, in the 2 large randomized trials discussed in this article, women were excluded because it was thought that it was unethical to include them. The variations in pelvic anatomy and Hesselbach triangle in women and men decreases a woman's overall chance of having a groin hernia but ultimately increases a woman's chance of developing femoral hernias. The current recommendation for women is that all should have their hernias repaired at diagnosis because the incidence of hernia accident is much higher than in men. Koch and colleagues [18] analyzed data from the Swedish Hernia Register between 1992 and 2003 for women undergoing surgery for groin hernias and identified 6895 patients aged 15 years or older. The investigators compared their outcomes with 83,753 men in the same registry. Analysis of their data found that women were more likely to undergo an emergency operation and were more likely to develop a recurrent femoral hernia when compared with men with groin hernias. Because femoral hernias are more dangerous than inguinal with a much higher incidence of a hernia accident thought to be related to the rigid nature of the femoral canal, it is not surprising that there is an increased incidence of emergent surgery in women. The higher incidence of femoral recurrence in women can be explained by the fact that the most common herniorrhaphy for all groin hernias is the Lichtenstein tension-free hernia repair. In this procedure, the inferior edge of the prosthesis is sewn to the inguinal ligament; thus, the femoral space is not addressed. Because it is not always possible to differentiate inguinal from femoral hernias by physical examination and the fact that concomitant femoral hernias occur, an operation that corrects defects in the direct, indirect, and femoral spaces (the myopectineal orifice) is preferred. It is not surprising that preperitoneal herniorrhaphies, such as the laparoscopic hernia repairs, yield better results in women than the open Lichtenstein repair used commonly in men. However, the Lichtenstein operation can be modified by suturing the inferior edge of the prosthesis to the Cooper ligament instead of the inguinal ligament medially with a transition stitch just medial to the femoral vein, which closes the femoral canal.

The European Hernia Society recommends the following for women patients [19]:

- In women patients, the existence of a femoral hernia should be excluded in all cases of a hernia in the groin.
- A preperitoneal (endoscopic) approach should be considered in women hernia repair.

Men

Symptomatic inguinal hernias

The European Hernia Society has issued the following guidelines for symptomatic inguinal hernias in 2009 [19]. These guidelines have gained acceptance, with only the last one questioned by some authorities:

- All male adult (>30 years) patients with a symptomatic inguinal hernia should be operated on using a mesh technique.

- When considering a nonmesh repair, the Shouldice technique should be used.
- The open Lichtenstein and endoscopic inguinal hernia techniques are recommended as the best evidence-based options for the repair of a primary unilateral hernia provided the surgeon is sufficiently experienced in the specific procedure.
- For the repair of recurrent hernias after conventional open repair, endoscopic inguinal hernia techniques are recommended.
- When only considering chronic pain, endoscopic surgery is superior to open mesh.

Asymptomatic/Minimally symptomatic inguinal hernias

The management of minimally symptomatic inguinal hernias is controversial. Historically, all inguinal hernias have been treated surgically at diagnosis to avoid a hernia accident. Inguinal herniorrhaphies can be performed in an outpatient setting under local anesthesia and are associated with an uneventful recovery in most patients. However, it has become increasingly clear that the operation may not be as benign as surgeons have thought. In addition to the usual surgical complications of hemorrhage, infection, and recurrence, the alarming incidence of postherniorrhaphy pain syndromes caused by neuroma, suture ligation of vital structures, or nociceptive nerve damage has only recently been generally appreciated (Fig. 1). In 2012, Mizrahi and Parker [21] systematically reviewed the available literature on the management of asymptomatic inguinal hernias. They could only find 5 articles suitable to include in the review; all articles were from 2 large prospective RCTs, which are discussed later.

The North American trial

Participants in the North American trial, conducted by Fitzgibbons and colleagues [4], were randomized to WW or conventional Lichtenstein

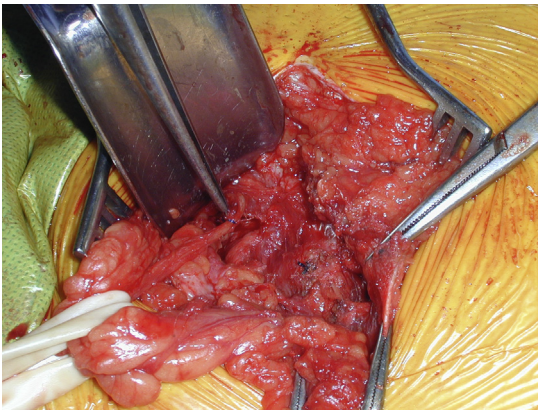


Fig. 1. Polypropylene suture around vas deferens.

herniorrhaphy. After informed consent, 720 men aged 18 years and older with inguinal hernias that were asymptomatic or minimally symptomatic were recruited. The trial was coordinated at 5 locations across North America, and the initial results were published with a minimum follow-up of 2 years. Pain interfering with normal activities and physical function as measured by the physical component score of the 36-Item Short Form Health Survey (SF-36) was similar between the 2 groups. The rate of crossover (CO) to surgery at 2 years was 23% with increased pain associated with the hernia as the most common reason for CO. The 2 groups were similar at baseline with respect to age, American Society of Anesthesiology classification, preexisting conditions, hernia type, and hernia characteristics. No statistically significant differences were found between the patients in operative time, complications, recurrence rates, and satisfaction with the results of the operation. Patients who reported higher baseline pain during activity and pain unpleasantness at the start of the trial were more likely to CO from WW to surgery. These characteristics of individuals may help clinicians identify those that may be more likely to elect to have repair of their hernias. Patients who crossed over from WW to surgery reported an increase in pain after the operation; but by the 2-year follow up, the pain was not significantly higher than that in the group managed conservatively. At 2 years, only one patient (0.3%) experienced an acute hernia incarceration that was without strangulation. By the end of the trial, with a maximum follow up of 4.5 years, another patient had an acute incarceration with obstruction of the bowel resulting in a hernia accident rate of 1.8 per 1000 patient-years. The conclusion from the trial was that observation was an acceptable treatment option for men with minimally symptomatic inguinal hernias.

UK trial

Another RCT conducted in a single center in Glasgow in the United Kingdom also investigated WW for minimally symptomatic men with inguinal hernias [3]. The study recruited 160 men older than 55 years, with 80 men in each arm, and followed them at 6 months, a year, and then annually afterward. Pain was assessed using the visual analogue scale score, and the SF-36 was used to measure the general health status.

The 2 groups had a similar baseline health status. At 1 year, no significant differences were found between the groups for pain at rest or with movement and use of analgesia. The surgical repair group had significant improvement in their perceived quality of life. Twenty-three patients (29%) in the WW group crossed over to surgery with increasing pain and hernia enlargement as the most common reasons. Three patients had an acute presentation: one patient with hernia incarceration and 2 patients with cardiovascular events after CO to surgery from the WW group. The degree of hernia protrusion was the only variable identified on the Cox proportional hazards regression model that predicted CO to surgery.

The 2 RCTs are compared in Table 1 [5].

Table 1

Comparison of 2 RCTs on WW for inguinal hernia

Variable	North American hernia trial	UK trial
Number of patients	720	160
Age (y)	>18 (mean = 58)	>55 (mean = 70)
Size	Any	Visible bulge
Reducibility	Not required	Required
Incarceration (%)	0.3	1.0
CO	23% (24 mo)	26% (15 mo)

LONG-TERM RESULTS OF THE RANDOMIZED CONTROLLED TRIALS

The North American hernia trial

Two hundred fifty-four (69.4%) men randomized to the WW group from the original North American hernia trial agreed to participate in a long-term follow-up registry and were contacted annually by mail questionnaire for an additional 7 years (maximum follow-up of 11.5 years) [5].

One hundred forty-one patients crossed over at the end of the registry study. At baseline, patients who remained in the WW group were younger and more likely to have chronic cough and alcohol intake before randomization compared with the CO group. A Cox proportional hazards regression analysis revealed that age of more than 65 years, prostatism, and higher education level were associated with CO to surgery. Kaplan-Meier analysis estimated a CO rate of 68% at 10 years from randomization. The most common reason for CO was pain (54.1%). By the end of the study period, only 3 patients (2.4%) required emergency surgery for a hernia accident with no mortality.

On completion of the long-term follow-up, the investigators concluded that most men who present to their physician because of a minimally symptomatic inguinal hernia are likely to have progression of symptoms that will eventually require them to request surgical repair. The incidence of hernia accident is very low, and observation is a safe and reasonable management strategy if desired by patients [5].

UK trial

Of the 160 patients who participated in the original UK trial, 42 men died during a median follow-up of 7.5 years (range 6.3–8.3) [6]. Forty-six of the 80 men in the WW group crossed-over to surgery during this period. The Kaplan-Meier estimated conversion rate from WW to surgery was found to be 16% at 1 year, 54% at 5 years, and 72% at 7.5 years. Pain was the most common reason for CO to surgery. The estimated median time from randomization to CO to surgery was 1678 days. Two patients in the WW group had acute hernia presentations. The investigators concluded that surgical repair should be recommended for medically fit patients with a painless inguinal hernia, as most patients will require one in their near future.

COMPARISON BETWEEN THE 2 TRIALS AND THEIR LONG-TERM FOLLOW-UP STUDIES

There are some important differences between the 2 RCTs (see Table 1) and their subsequent long-term follow-up studies (Table 2). The North American hernia trial was a multicenter trial that included both academic and community medical centers, whereas the UK trial was conducted in a single academic center. The inclusion criterion for age was broader in the North American hernia trial compared with the UK trial. The median ages and age span between the trials varied greatly as well as the framework of the medical system, as a large portion of those in the North American study had private insurance and were predominantly white. The definition of an asymptomatic hernia was different in the 2 trials. In the UK trial, only patients with a visible swelling on standing were included, whereas 40% of the North American hernia trial patients had only a cough impulse. There was no difference between the WW and TFR groups for pain at 1 year in the UK trial or at 2 years for the North American hernia trial. On long-term follow up, the number of patients who died in the UK hernia trial WW group was higher (23%) than the North American hernia trial WW group (3.5%). This finding was caused by the fact that only older patients were included in the UK hernia trial. Patients in the UK trial were seen at 6 months, 12 months, and 5 years in a research clinic or were sent mail questionnaires. The patients in the North American hernia trial were followed yearly by mail questionnaire or by e-mail and telephone encounters if they did not respond to the mail questionnaire. The difference in the

Table 2

Comparison of long-term follow-up of WW in men with minimally symptomatic inguinal hernias in 2 RCTs

Variable	North American hernia trial	UK trial
Number of patients	254	80
Follow-up period (y)	7 (maximum = 11.5)	Median = 7.5 (range = 6.2–8.2)
Method of follow-up	Mail questionnaire, e-mail, telephone contact	Research clinic visit at 6 and 12 mo, 5 y after randomization or mail questionnaire
Incarceration (%)	2.4	2.5
CO rate by Kaplan-Meier analysis (%)	At 10 y = 67.97	At 7.5 y = 72.0
Median time to CO from randomization (the point at which 50% of the observation group had crossed over)	7.3 y (95% CI = 5.3–8.4 y)	4.6 y (95% CI: 3.5–5.6 y)
Main reason for CO (%)	Pain (54.1)	Pain (41.2)
Contralateral hernia (%)	2.7	0.1

follow-up methods could be caused by the wide geographic distribution of patients in the North American hernia trial, which made it more difficult for the investigators to physically examine patients in a clinic. The method of follow-up could have an impact on the outcome of the studies, as there was only 65.7% complete follow-up data available in the North American hernia trial. The hernia accident rate was very low and comparable in both long-term follow-up studies. These trials show that the risk of a hernia accident should not be considered an indication for surgery. Pain was the main reason for CO on long-term follow-up in both studies. The median time to CO was longer in the North American hernia trial patients (7.3 years). The reason for this could be due to a large number of patients having only a cough impulse initially at the time of randomization while the UK trial patients already had a visible bulge and had symptoms for several years before presentation.

The rate of CO to surgery was high in both studies. The patients in the UK trial had a 72% CO rate at 7.5 years, whereas the patients in the North American hernia trial had a 68% CO rate at 10 years. The UK trial group concluded that there was little point in waiting because most patients will require an operation in the near future. The North American hernia trial investigators, however, were more cautious and thought that the results may not necessarily imply routine surgery for all asymptomatic inguinal hernias. The recruitment process of the studies was considered an important factor, as patients in both trials presented to the clinic because of concern about the hernia and the investigators thought that it may not be valid to apply the conclusions based on these patients to the general population. The results of both long-term follow-up studies show that if patients present to a physician with concern about a hernia, they will almost certainly undergo surgery over the next decade.

SUMMARY

Observation is an acceptable management strategy for asymptomatic and minimally symptomatic inguinal hernias because it is safe. The rate of hernia accident is very low and is not an indication for surgery. However, patients who present to their physician with a hernia will almost certainly undergo a hernia repair if they live long enough.

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