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Watchful Waiting for Inguinal Hernia

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Keywords

• Inguinal hernia • Watchful waiting • Routine repair • Herniorrhaphy

Key points

- Inguinal herniorrhaphy is one of the most common surgeries performed worldwide.
- Recent evidence from 3 randomized controlled trials suggests that routine repair of all inguinal hernias at diagnosis is not necessary in asymptomatic or minimally symptomatic men.
- 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.
- These data should not be extrapolated to women, as the natural history is different from men, and watchful waiting should not be routinely recommended.

INTRODUCTION

Inguinal hernia is one of the most common afflictions known to humans. The lifetime risk of developing an inguinal hernia is estimated at 27% for men and 3% for woman [1]. In the United States, the annual incidence of an inguinal hernia is 315 per 100,000, and the annual incidence of an inguinal herniorrhaphy is

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217 per 100,000 [2,3]. As many as 20 million inguinal herniorrhaphies are performed annually worldwide [4]. These numbers make the socioeconomic consequences of the most appropriate treatment strategy important to health policy makers. Given this high incidence, the most cost-effective strategy that provides a maximum risk-benefit ratio for patients is essential.

Until recently, standard surgical dictum has been to repair all inguinal hernias at diagnosis to prevent the serious complications of bowel obstruction and strangulation, usually referred to as hernia accidents. This is because of the large difference in mortality and morbidity rates between emergent versus elective inguinal hernia repairs. Based on a meta-analysis of multiple studies, a hernia accident results in a mean mortality of 4.0% (range 0% to 22.2%) compared with 0.2% (range 0% to 1.8%) with elective hernia repair [5]. Because modern inguinal herniorrhaphy techniques are safe, effective, and can be performed under local anesthesia for high-risk patients, the logical recommendation is routine repair at diagnosis; but these studies for the most part did not stratify patients according to symptoms.

Recent randomized controlled trails that did stratify for symptoms have challenged this concept for asymptomatic or minimally symptomatic patients with inguinal hernias showing that a strategy of planned nonoperation or ''watchful waiting'' is safe for this subgroup of patients with a low incidence of hernia accident. With approximately one-third of men with inguinal hernias being either asymptomatic or minimally symptomatic, a very large number of hernia repairs may be unnecessary [6]. Another consideration is that complication rates may not be as favorable as previously believed by many surgeons. The long-term complication of post herniorrhaphy groin pain occurs in 6% to 8% of patients, and has now emerged as the single most pressing issue facing inguinal hernia surgeons [7]. It is an obvious disservice to successfully repair a minimally symptomatic hernia, only to leave a patient with chronic pain; and although recurrence is less with modern techniques of repair, it is still a relevant consideration. Short-term complications are possible, including hematoma or seroma (8%–22%), urinary dysfunction, and early pain [8]. Surgical site infections occur in 1% to 3% of patients [9]. Laparoscopic accidents, such as enterotomies, are rare, but potentially catastrophic.

In this article, the authors examine the available evidence regarding nonoperative treatment or ''watchful waiting'' of inguinal hernias. The goal is to develop evidence-based recommendations to provide patients with inguinal hernia the treatment strategy that will maximize benefit while minimizing potential risks.

NATURAL HISTORY OF AN INGUINAL HERNIA

The natural history of an untreated inguinal hernia is surprisingly difficult to determine for a condition with such a large prevalence. The problem is the difficulty in finding whole populations in which hernia repairs are not routinely performed. Two studies have reported a yearly risk of a hernia accident at 0.0037 and 0.0038, and have historically been used as a basis to justify repair [10]. The first was from a truss clinic in Paris in the late eighteenth century.

This was at a time before Bassini's operation had become widely accepted and therefore routine repair was rarely performed. The second group came from Cali, Colombia, and was the result of an aggressive 1-year (1965–1966) government initiative, the purpose of which was to accurately examine a stratified, randomized sample of its civilian population, looking at common conditions such as inguinal hernia. Using the formula (1 – [1 – p]e), where *p* is the probability of an accident per hernia patient per year which is the average of the 2 studies (0.00375) and *e* from actuarial life tables from the respective years, one can calculate the probability of a hernia accident. Table 1 shows the lifetime probability of a hernia accident for an 18-year-old and a 72-year-old. The difference in the 1980 and 2001 data reflects the fact that the 2001 patients are living longer and thus have more years at risk [11]. The desire to obtain prospective, up-to-date data was the incentive for the development of 3 randomized controlled trials that have served to substantially change the way surgeons approach their patients with inguinal hernia (see Table 1).

THE NORTH AMERICAN TRIAL (2006)

Participants in the North American trial, conducted by Fitzgibbons and colleagues [12], were randomized to "watchful waiting" or conventional Lichtenstein 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. The physical component score (a 36-item Short Form survey) measured pain that interfered with normal activities and physical function and showed similar results between the 2 groups. The rate of crossover to surgery at 2 years was 23%, with "increased pain" as the most common reason for crossover. 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 groups regarding operative time, complications, recurrence rates, and satisfaction with the results of the operation. Patients who reported higher baseline pain during activity or "unpleasantness" at the start of the trial were more likely to cross over from the watchful waiting group to the surgery group. These characteristics have helped clinicians council patients who are more likely to require an inguinal herniorrhaphy eventually. Patients who crossed over did report an increase in pain after the operation, but by the 2-year follow-up, it was not

Table 1
Lifetime risk of a hernia accident for an untreated inguinal hernia

	Overall		Male patients	
Age, y	1980	2001	1980	2001
18	1 in 5.18	1 in 4.95	1 in 5.49	1 in 5.15
72	1 in 22.72	1 in 20.41	1 in 27.03	1 in 22.73

significantly higher than that in the group managed conservatively. At 2 years, only 1 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 bowel obstruction, 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. A long-term follow-up Kaplan-Meier analysis demonstrated a total crossover rate of 68%, mainly due to pain at 10 years [4]. There were only a total of 3 acute hernias requiring operation.

UNITED KINGDOM TRIAL (2006)

Another randomized controlled trial conducted in a single center in Glasgow, United Kingdom, also investigated watchful waiting for minimally symptomatic men with inguinal hernias [13]. The study recruited 160 men older than 55 years, with 80 men in each arm, and followed them at 6 months, 1 year, and then annually afterward. Pain was assessed using the visual analogue scale score, and the Short Form-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, pain with movement, or the use of analgesia. The surgical repair group did have significant improvement in their perceived quality of life. Twenty-three patients (29%) in the watchful waiting group crossed over to surgery, with "increasing pain" and "hernia enlargement" as the most common reasons. Three patients had an acute presentation: 1 with hernia incarceration and 2 with cardiovascular events after crossover to surgery from the watchful waiting group. The degree of hernia protrusion was the only variable identified on the Cox proportional hazards regression model that predicted crossover to surgery. Long-term follow-up at 7.5 years showed a total crossover rate of 72% [14]. Reasons for patients seeking surgical repair of their hernia were pain (72%), quality of life (13%), and an increase in hernia size (11%).

NETHERLANDS TRIAL (2018)

Most recently, results from another randomized controlled trial were published in January 2018 that again sought to shed more light on this controversy [15]. This was a noninferiority trial designed to determine the noninferiority of watchful waiting to elective repair in men aged 50 years and older with mildly symptomatic or asymptomatic inguinal hernias. Recruits were men older than 50 years with asymptomatic or minimally symptomatic inguinal hernias. The same pain scale scoring system was used as in the North American trial. After randomization and final exclusions, 234 patients were assigned to the elective repair group and 262 into the watchful waiting group. Of the 262 patients assigned to watchful waiting, 99 crossed over to elective hernia repair and 163 were treated without surgery. Follow-up physical examinations were performed at 3, 12, 24, and 36 months. The primary endpoint was the difference between the 2 groups in pain/discomfort scores, calculated as a mean of the 4

follow-up visits. Secondary endpoints included health-related change in quality-of-life measures from baseline; 3, 12, 24, and 36-month intervals; overall crossover rate; and event-free survival between the 2 groups. The result of the primary endpoint (mean of the pain/discomfort scores measured at follow-up visits over a 24-month period) was 0.35 (95% confidence interval [CI] 0.28–0.41) in the elective group and 0.58 (95% CI 0.52–0.64) in the watchful waiting group for a difference of 0.23 (95% CI 0.32–0.14). In this noninferiority trial, the widths of these 95% CIs indicated that a difference of means greater than 0.20 in favor of elective repair cannot be excluded. Thus, the data could not rule out a relevant difference in favor of elective repair. Secondary endpoints, such as measures of quality of life and mean changes over time compared with baseline, were not found to reach clinical significance, although there was a slight statistically significant favor for the elective repair group. Of the 262 patients assigned to watchful waiting, 99 (37.8%) crossed over to surgery by 3 years, most often because of worsening hernia-related pain. Of these crossover patients, 2.3% underwent urgent operation, and 1 patient had bowel strangulation. No patients required a bowel resection. The 3-year event-free survival in the elective repair and watching waiting groups were 80.9% and 77.2%, respectively. The 3-year cumulative incidence of patients with 1 or more events was 17.5% (41 of 234) in the elective repair and 20.6% (54 of 262) in the watchful waiting group. In the elective repair group, these events consisted of 25 cases of moderate-severe pain, 1 hernia complication, 1 ischemic orchitis, and 20 recurrent hernias. In the watchful waiting group, 69 patients reported moderate-severe pain, 7 hernia complications in 6 patients, and 7 recurrent hernias. The 3-year cumulative death rates were 3.0% and 3.1% in the repair and watchful waiting group, respectively, with none of these deaths related to hernias. There was no difference in perioperative complication rates between the elective repair group and the crossover patients who underwent surgery. The investigators concluded that although the results of the primary endpoint could not rule out a relevant difference in favor of elective repair, "in view of all other findings" their results justified watchful waiting as a reasonable alternative to surgery in male patients aged 50 years and older.

COMPARISON AMONG THE 3 TRIALS

There are some important differences among the 3 randomized controlled trials (Table 2) and the subsequent long-term follow-up studies from the first 2 studies (Table 3). The North American and Netherlands hernia trials were multicenter trials that included both academic and community medical centers [12,15], whereas the UK trial was conducted in a single academic center [13]. The inclusion criterion for age was broader in the North American hernia trial compared with both the UK and Netherlands trials. The median ages and age span among 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 3 trials. In the UK trial, only patients with a visible

Table 2
Comparison of 3 watchful waiting randomized controlled trials

Variable	North American trial	UK trial	Netherlands trial
Patient number	720	160	496
Age	>18 (mean 58)	>55 (mean 70)	>50 (mean 65)
Size	Any	Visible bulge	Any
Reducibility	Not required	Required	Not required

swelling on standing were included, whereas 40% of the patients in the North American hernia trial had only a cough impulse. The Netherlands trial used only physical examination with optional ultrasonography confirmation. There was no difference in pain between the 2 groups at 1 year in the UK trial or at

Table 3
Comparison of crossover rates and long-term follow-up

	North American trial, short-term	North American trial, long-term	UK trial, short-term	UK trial, long-term	Netherlands trial, short-term
Follow-up, y	Mean 3.2 (range 2–4.5)	Maximum 11.5	Median 1.6	Median 7.5 (range 6.2–8.2)	3
Crossover rate	23% at 2 y 32% at 4.5 y	68% at 10 y	29%	54% at 5 y 72% at 7.5 y	38%
Hernia accident rate in watchful waiting group	0.6% (n = 2)	1.2% (n = 3)	1.3% (n = 1)	2.5% (n = 2)	2.3% (n = 6)
Reasons for crossover	Pain (47.1%) Some degree of pain and discomfort (86%)	Pain (54%) Tired of having the hernia (3.3%) Incarceration (2.4%) Advised by doctor to have it repaired (4.1) Employer wanted hernia repaired (0.8%) Other (8.1) Combination of reasons (30.9%)	Pain (48%) Increase in size (35%) Affecting work or leisure activities (13%)	Pain (72%) Quality of life (13%) Increase in size (11%)	Pain (91%) Cosmetic reasons (1%) Unknown (2%)

2 years for the North American hernia trial. The Netherlands trial showed patients had less pain at 3 months in the watchful waiting group; however, at 12 months and afterward, the patients in the elective hernia group had less pain. The Netherlands trial has yet to produce long-term follow-up results and offers only 3-year cumulative data. On long-term follow-up, the number of patients who died in the UK hernia trial watchful waiting group was higher (23%) than in the North American hernia trial watchful waiting group (3.5%). This finding was presumed to be related to the fact that only older patients were included in the UK hernia trial. However, in the Netherlands trial, which also enrolled only older patients, the death rate was much lower at 3.1% (all unrelated to hernias). Patients in the UK trial were seen at 6 months, 12 months, and 5 years in a research clinic or were sent mail questionnaires. Patients in the Netherlands trial had physical examinations at 3, 12, 24, and 36 months. The patients in the North American hernia trial were personally followed by study nurses and examined by independent surgeons at prescribed intervals to ensure objectivity during the 5 years of the original study. Long-term follow-up was yearly by mail questionnaire or by e-mail and telephone encounters if they did not respond to the mail questionnaire. A criticism of the long-term follow-up data from the North American trial was that it was only 65.7% complete. This was caused in part by the inability to obtain institutional review board approval at one of the sites (McGill) for a secondary follow-up study. Also contributing to this might have been 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. There are some relevant findings that are consistent in all 3 trials. The hernia accident rate was very low and comparable in all 3 studies. These trials all support that the potential future risk of a hernia accident should not be considered an indication for surgery. Pain was the main reason for crossover in all 3 studies. The median time to crossover was longest in the North American hernia trial (7.3 years). The reason for this could be because a large number of patients had only a cough impulse initially at the time of randomization, whereas patients in the UK trial were required to have a visible bulge. The rate of crossover to surgery was high in all 3 studies. Kaplan-Meyer estimates disclosed a 72% crossover rate in the UK trial at 7.5 years, and in the North American hernia trial, 68% at 10 years. The Netherlands trial crossover rate of 37.8% at 3 years can be assumed to be following a similar trendline. The UK trial group concluded that there was little point in waiting because most patients will require an operation in the 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 Netherlands trial investigators concluded that although they could not rule out a relevant difference in favor of elective repair based on their primary endpoint analyses of the mean pain score over a 24-month period, the overall results including secondary endpoints justified waiting as a reasonable alternative. Investigators

from all 3 studies cited the recruitment process as a limiting factor, as patients in all 3 trials presented to the surgery clinic after referral, mostly from primary care physicians (PCPs). The investigators speculated that applying conclusions based on referred patients to the general population may not be appropriate, assuming the PCP had enough concern to refer them.

A meta-analysis published in 2018 by Gong and Li [16], compares the results of 8 watchful waiting randomized controlled trials, including the 3 trials discussed previously, encompassing a total of 1303 patients. The study found significantly less pain with movement in the operation group ($P<.01$) at a minimum follow-up of 12 months; however, there was no significant differences in the physical component score (as measured by the Short Form-36 Version 2 health-related quality-of-life survey), mortality, surgical complications, or postoperative hernia recurrence. Crossover from watchful waiting to operation was consistent across all studies and confirmed that most patients will have had an operation by 10 years. Pain was the most common reason for the crossover. Because of the overall low rate of acute hernia–related adverse events, the investigators concluded that for asymptomatic or minimally symptomatic inguinal hernias, watchful waiting is a relatively safe and acceptable option in the short-term; however, watchful waiting would rather delay, than avoid a surgical repair in most patients (see Tables 2 and 3).

ECONOMIC IMPACT

In the United States, surgical repair of inguinal hernias accounted for more than $48 billion in 2005 health care expenditures. Stroupe and colleagues [17] looked at the cost-effectiveness of the strategy of watchful waiting 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. By 2 years, the average cost for patients with tension-free repair (TFR) was approximately $1800 higher than for the watchful waiting group. When looked at in terms of QALYs, the average cost per additional QALY unit per patient for TFR patients was $59,065. It is generally agreed that for a procedure to qualify for public funding, a cost per QALY should be $50,000 or greater. The investigators concluded that at 2 years, both watchful waiting and immediate surgery for inguinal hernias are reasonable approaches from the viewpoint of cost-effectiveness. Of significance, this cost analysis was done at 2 years follow-up, by which time 23% of the watchful waiting patients had decided to cross over to receive surgery for various reasons, mostly pain. By 10 years of observation, however, the crossover rate nearly triples. As such, the conclusion/results cannot be considered valid at 10 years. Although the initial data are insightful, additional work must be done to evaluate a more long-term cost analysis. Currently, there are insufficient data to say whether watchful waiting or surgical management strategies are more cost-effective.

INGUINAL HERNIA IN WOMEN

Groin hernia repair is much less likely in women compared with men, with a ratio of roughly 1 to 9 [18]. Although femoral hernias are more common in women than men, inguinal hernia repairs (mainly indirect) still outnumber femoral hernia repairs by a ratio of 5 to 1. The natural history of an untreated groin hernia in women is clearly different from men; thus, recommendations for treatment must be different. Indeed, in the 3 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 [19] 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 because 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 stich just medial to the femoral vein, which closes the femoral canal.

GUIDELINES FOR TREATMENT OF INGUINAL HERNIA IN MEN

The European Hernia Society (EHS) guidelines were updated with Level 1 studies in 2014 [20] and include the following statement and recommendation:

> Watchful waiting is safe and an acceptable option for men with minimally symptomatic or asymptomatic inguinal hernias. It is very likely (70% chance) that, in time, the symptoms will increase leading to surgical intervention. (Level 1B)

> It is recommended in minimally symptomatic or asymptomatic inguinal hernia in men to consider a watchful waiting strategy, especially when older or in the presence of major comorbidity. (Grade B)

More recently, the HerniaSurge Group (made up of the EHS plus international experts) published international guidelines for the management of inguinal hernias [18]. This includes the following statement:

> Although most patients will develop symptoms and need surgery, watchful waiting for minimal or asymptomatic inguinal hernias is safe since the risk of hernia complications is low. Management decision is made between the surgeon and patient. (High grade)

SUMMARY

Traditionally it has been recommended to repair all inguinal hernias at diagnosis to prevent the complications of strangulation or bowel obstruction. Three randomized controlled trials comparing a strategy of watchful waiting versus routine repair for asymptomatic or minimally symptomatic men have questioned this, because the chance of one of these complications in this subgroup of patients is extremely low, and the morbidity and mortality for the rare emergently needed repair is not excessive. There appears to be no penalty for delaying surgery, as the surgical complication rates in the long-term crossover patients was the same as those randomized to surgery initially. However, in long-term follow-up, most of the patients were found to have crossed over to surgery, usually because of increasing symptoms. Men older than 65 years cross over at a considerably higher rate than younger men. Although watchful waiting for an asymptomatic or minimally symptomatic inguinal hernia is a safe strategy for men, patients should be counseled that they are probably just delaying surgery rather than avoiding it.

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