

# Watchful Waiting vs Repair of Inguinal Hernia in Minimally Symptomatic Men

## A Randomized Clinical Trial

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**M**ANY MEN WITH AN INGUINAL hernia are asymptomatic or minimally symptomatic. They and their physicians sometimes delay hernia repair until emergence of pain or discomfort. Surgical repair, while generally safe and effective, carries long-term risks of hernia recurrence, pain, and discomfort.<sup>1-4</sup>

The natural history of an untreated inguinal hernia is not known. For minimally symptomatic men, the usual basis for recommending surgical repair is to prevent a hernia accident (ie, acute hernia incarceration with bowel obstruction, strangulation of intra-

**Context** Many men with inguinal hernia have minimal symptoms. Whether deferring surgical repair is a safe and acceptable option has not been assessed.

**Objective** To compare pain and the physical component score (PCS) of the Short Form-36 Version 2 survey at 2 years in men with minimally symptomatic inguinal hernias treated with watchful waiting or surgical repair.

**Design, Setting, and Participants** Randomized trial conducted January 1, 1999, through December 31, 2004, at 5 North American centers and enrolling 720 men (364 watchful waiting, 356 surgical repair) followed up for 2 to 4.5 years.

**Interventions** Watchful-waiting patients were followed up at 6 months and annually and watched for hernia symptoms; repair patients received standard open tension-free repair and were followed up at 3 and 6 months and annually.

**Main Outcome Measures** Pain and discomfort interfering with usual activities at 2 years and change in PCS from baseline to 2 years. Secondary outcomes were complications, patient-reported pain, functional status, activity levels, and satisfaction with care.

**Results** Primary intention-to-treat outcomes were similar at 2 years for watchful waiting vs surgical repair: pain limiting activities (5.1% vs 2.2%, respectively;  $P = .52$ ); PCS (improvement over baseline, 0.29 points vs 0.13 points;  $P = .79$ ). Twenty-three percent of patients assigned to watchful waiting crossed over to receive surgical repair (increase in hernia-related pain was the most common reason offered); 17% assigned to receive repair crossed over to watchful waiting. Self-reported pain in watchful-waiting patients crossing over improved after repair. Occurrence of postoperative hernia-related complications was similar in patients who received repair as assigned and in watchful-waiting patients who crossed over. One watchful-waiting patient (0.3%) experienced acute hernia incarceration without strangulation within 2 years; a second had acute incarceration with bowel obstruction at 4 years, with a frequency of 1.8/1000 patient-years inclusive of patients followed up for as long as 4.5 years.

**Conclusions** Watchful waiting is an acceptable option for men with minimally symptomatic inguinal hernias. Delaying surgical repair until symptoms increase is safe because acute hernia incarcerations occur rarely.

**Clinical Trials Registration** ClinicalTrials.gov Identifier: NCT00263250

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**For editorial comment see p 328.**

abdominal contents, or both), but this is a rare event. Only an 1896 report from Berger's Paris truss clinic<sup>5</sup> and a 1981 report from Colombia<sup>6</sup> are avail-

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