Long-term Results of a Randomized Controlled Trial of a Nonoperative Strategy (Watchful Waiting) for Men With Minimally Symptomatic Inguinal Hernias

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Objective: To assess the long-term crossover (CO) rate in men undergoing watchful waiting (WW) as a primary treatment strategy for their asymptomatic or minimally symptomatic inguinal hernias.

Background: With an average follow-up of 3.2 years, a randomized controlled trial comparing WW with routine repair for male patients with minimally symptomatic inguinal hernias led investigators to conclude that WW was an acceptable option [JAMA. 2006;295(3):285–292]. We now analyze patients in the WW group after an additional 7 years of follow-up.

Methods: At the conclusion of the original study, 254 men who had been assigned to WW consented to longer-term follow-up. These patients were contacted yearly by mail questionnaire. Nonresponders were contacted by phone or e-mail for additional data collection.

Results: Eighty-one of the 254 men (31.9%) crossed over to surgical repair before the end of the original study, December 31, 2004, with a median follow-up of 3.2 (range: 2–4.5) years. The patients have now been followed for an additional 7 years with a maximum follow-up of 11.5 years. The estimated cumulative CO rates using Kaplan-Meier analysis was 68%. Men older than 65 years crossed over at a considerably higher rate than younger men (79% vs 62%). The most common reason for CO was pain (54.1%). A total of 3 patients have required an emergency operation, but there has been no mortality.

Conclusions: Men who present to their physicians because of an inguinal hernia even when minimally symptomatic should be counseled that although WW is a reasonable and safe strategy, symptoms will likely progress and an operation will be needed eventually.

Keywords: inguinal hernia, hernia accident, minimally symptomatic, randomized controlled trial, watchful waiting

Annually, more than 20 million inguinal herniorrhaphies are performed worldwide, and it is one of the most common operations performed by general surgeons. Up to one third of patients with inguinal hernias are asymptomatic or minimally symptomatic at the time of presentation. Historically, surgeons have recommended repair of an inguinal hernia at diagnosis even if minimally symptomatic to avoid a hernia accident, which is defined as a bowel obstruction caused by the hernia or strangulation of the contents of the hernia, or both. However, on the basis of the results of 2 recent randomized clinical trials (RCTs), one conducted in the United Kingdom and the other in North America, watchful waiting (WW) has now become an accepted alternative to routine repair. In 2011, the longer-term results of the United Kingdom trial were published. Using Kaplan-Meier analysis, 72% of patients were predicted to crossover (CO) from WW to surgery by 7.5 years causing the authors to conclude that routine repair should be recommended for minimally symptomatic patients without medical contraindications to surgery. We now report the long-term results of the WW arm of the North American Trial.