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

Robert J. Fitzgibbons, Jr, MD, FACS, Bala Ramanan, MBBS,* Shipra Arya, MD,* Scott A. Turner, MD,* Xue Li, MA, PhD,† James O. Gibbs, PhD,* and Domenic J. Reda, PhD†; Investigators of the Original Trial*

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

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Annually, more than 20 million inguinal herniorrhaphies are performed worldwide,[1] and it is one of the most common operations performed by general surgeons.[2] Up to one third of patients with inguinal hernias are asymptomatic or minimally symptomatic at the time of presentation.[3] 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.[2] However, on the basis of the results of 2 recent randomized clinical trials (RCTs),[4,5] 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.

METHODS

Data

The methods and study design used for the American College of Surgeons (ACS) hernia trial have been previously reported in detail.[5,6] In brief, after informed consent, men who were 18 years or older and had an asymptomatic or minimally symptomatic inguinal hernia were recruited from 5 different geographical locations in North America including both community and academic centers (Table 1). These patients were randomized to WW or a standard Lichtenstein open tension-free repair. Patients with female gender, undetectable hernias, symptomatic hernias, acute hernia complications, and local or systemic infection; those in ASA (American Society of Anesthesiologists) class IV; or those participating in another clinical trial were excluded from the trial. The outcomes of the trial have been published previously.[5] After completion of the trial on December 31, 2004, study participants were invited to voluntarily enroll in a registry for long-term follow-up after approval from the institutional review board (IRB) of each participant center. Because of inability to obtain IRB approval for one site (McGill University, Montreal, Quebec, Canada), this center was excluded from the registry. After informed consent, men who agreed to participate in the study were contacted by mail questionnaire in mid 2005, mid 2006, early 2008, early 2009, and late 2010. Nonresponders were contacted by phone or e-mail for additional data collection. Patients initially randomized to WW either underwent surgery during follow-up (CO group) or continued to remain in the WW group. For the CO group, the questionnaire collected information about reason for CO and details of surgery including date, side, type of surgery, whether mesh was used for the hernia repair, postoperative pain, and hernia recurrence. For those who remained in the WW group, details about their hernia including size, descent into scrotum, use of truss, and pain associated with hernia were collected. Patient satisfaction was recorded for both the groups. The questionnaire was purposely kept very short and simple and did not contain items related to quality of life or standardized instruments for pain and activity assessment to maximize compliance.

Patients

Patients assigned to the WW group in the initial RCT were divided into the CO group and WW group for this study. Baseline medical comorbidities and demographic and lifestyle variables that

From the *Department of Surgery, Creighton University, Omaha, NE; and †Hines VA Hospital, Cooperative Study Program Coordinator Center, Hines, IL.

#The list of investigators of the original trial is given in Table 1.

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Reprints: Robert J. Fitzgibbons, Jr, MD, FACS, Division of General Surgery, Department of Surgery, Creighton University, Omaha, NE 68131; E-mail: fitzjr@creighton.edu.

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