

IN THE LITERATURE

Is watchful waiting a reasonable approach for men with minimally symptomatic inguinal hernia?

Fitzgibbons RJ Jr, Giobbie-Hurder A, Gibbs JO, et al. Watchful waiting vs repair of inguinal hernia in minimally symptomatic men: a randomized clinical trial. *JAMA* 2006;295:285-92.

Background: Men presenting with inguinal hernia often have minimal symptoms, if any. Although elective surgery is often recommended to prevent complications, it carries the risk of hernia recurrence, pain and discomfort as well as the risks associated with anesthesia and surgery, such as hematoma and infection.

Design: Men over 18 years of age with palpable asymptomatic or minimally symptomatic inguinal hernias were randomly assigned to watchful waiting or surgical repair. Patients were excluded if they had local or systemic infection or were at high risk of complications from anesthesia. Patients with minimally symptomatic chronically incarcerated hernias were included. At 2-year follow-up, pain and discomfort interfering with usual activities was assessed, along with change in the physical component score (PCS) of the Short Form-36 Version 2 survey, which measures health-related quality of life. Postoperative and long-term complications, chronic pain, functional status, activity levels and satisfaction with care were also measured.

Results: Intention-to-treat analysis at 2-year follow-up showed that pain interfering with activities and the mean change in PCS from baseline were similar in the 2 groups (Table 1).

Since 85 (23%) of men assigned to watchful waiting went on to receive surgical repair within 2 years, mostly because of increasing discomfort, and 62 (17%) of patients assigned to receive surgical repair elected not to undergo surgery, an as-treated analysis was also performed. The mean time to crossover was 27 months, and beyond 2 years the crossover rate was 4% each year (Fig. 1). At 2 years, the proportion of patients

with pain interfering with activity was similar among those who had crossed over from waiting to surgical repair and those assigned to repair. However, patients who crossed over to surgical repair reported significantly greater improvement in PCS from baseline than those receiving surgery as assigned (difference 2.50; 95% confidence interval [CI] 0.01–5.0, $p = 0.01$).

Results at 2 years for other outcomes were similar in both intention-to-treat and as-treated analyses, including patient satisfaction and pain reduction at rest and during normal activity, work and exercise. The reduction in perception of pain was greater for those receiving surgical repair (dif-

ference 3.9 mm, 95% CI 0.8–7.0 mm, $p = 0.01$).

Adjustment for imbalance in baseline characteristics (e.g., patients assigned to surgery had greater body mass indexes and engaged in fewer ambulatory activities) did not change primary outcomes.

Almost one-third of patients who received surgical repair experienced short-term complications such as hematomas and infections, and 3 had life-threatening complications. One acute incarceration occurred in the watchful waiting group within 2 years and another at 4 years of follow-up, for a hernia accident rate of 1.8 events per 1000 patient-years.

Commentary: These findings suggest that men with minimally symptomatic hernias can be safely watched rather than undergo surgical repair. Some men will, however, seek surgical intervention for painful symptoms; almost

Table 1: Intention-to-treat analyses of outcomes following watchful waiting and surgical repair at 2-year follow-up

Outcome	Surgical repair	Watchful waiting	Difference, % (95% CI)*
Pain interfering with activities, %	2.21	5.07	2.86 (-0.04 to 5.77)
Physical component score, mean change from baseline (SD)†	0.13 (0.42)	0.29 (0.41)	0.16 (-1.19 to 1.50)

Note: CI = confidence interval, SD = standard deviation.

*The reference group is surgical repair.

†Represents group differences in 2-year change from baseline.

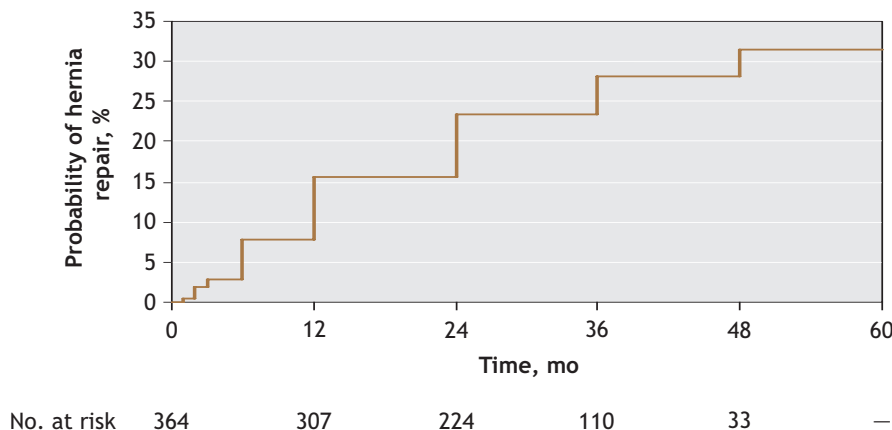


Fig. 1: Probability of crossover from watchful waiting to surgery. Reprinted, with permission, from *JAMA* 2006;295(3):290.

one-quarter of men in this study crossed over for surgical repair. Before surgery these men reported high levels of sensory and affective pain during their normal activities and commonly had impaired physical function and prostatism. Their improvement post-surgery was greater than that of the patients who had originally been assigned to surgery. Knowledge of these factors may influence which patients are more likely to benefit from surgical intervention than watchful waiting.

Otherwise, outcomes for both groups of men were similar, and thus

watchful waiting may offer an opportunity to avoid potential complications related to surgery. Because the study was designed to follow patients for only 2 years, longer-term risk of hernia accidents and progression of symptoms in those choosing watchful waiting are unknown.

Practice implications: Men with minimally symptomatic inguinal hernia should be advised that watchful waiting is a safe therapeutic option, although almost one-quarter of patients in this study went on to have elective surgical

repair within 2 years. Patients and health care providers should weigh the risks of hernia incarceration with those of surgical repair on a case-by-case basis.

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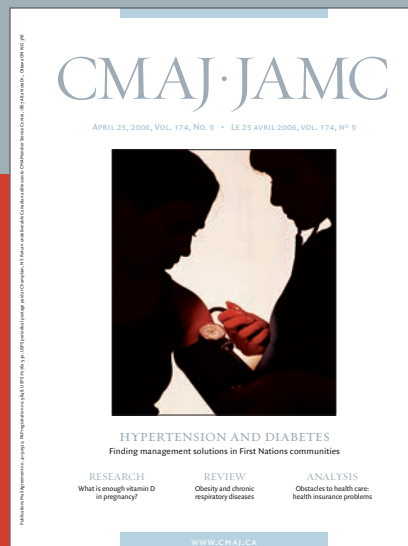
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