Inguinal Hernia: Repair is preferred

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Surgical Grand Rounds

2/13/12

Inguinal Hernia

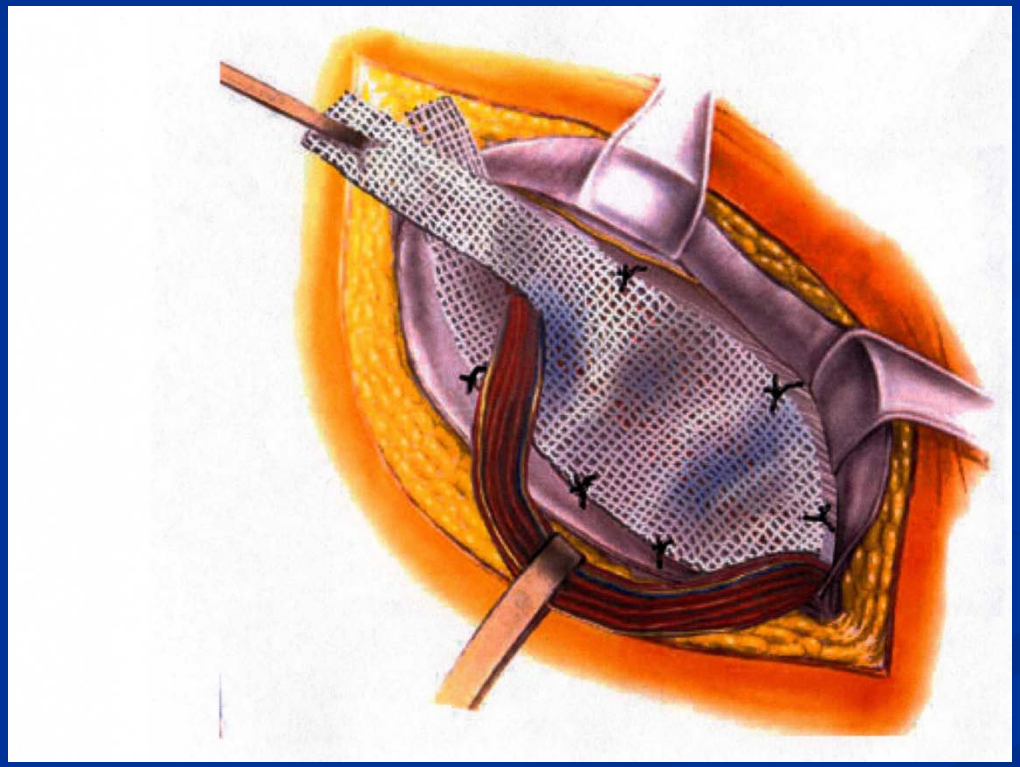
- A sac formed from the peritoneum and containing a portion of the intestine or omentum, or both, pushes either directly outward through the weakest point in the abdominal wall (direct hernia) or downward at an angle into the inguinal canal (indirect hernia)

Inguinal Hernia

- Lifetime risk 27% men, 3% women
- Up to 1/3 present with minimal symptoms
- 30% indicate interference with leisure
- 13% take time off work

How do you fix it?

- Lichtenstein tension free repair most common



Why wait?

- Cost?
- Risks of operation

Risks

- Complications in 20% of repairs (generally minor such as hematoma or SSI)
- Chronic (>3m) postop groin pain
  - As much as 30%
  - Affects everyday activities in 3-10%
- Recurrence 5-10%
- Cord or testicular dysfunction, testicular atrophy, osteitis pubis, problems with mesh

Why not wait?

- Symptoms worsen over time?
- Concern that a herniorrhaphy becomes more difficult the longer the repair is delayed?
- Cost? Time lost from work, then same expensive operation
- Incarceration in 4/1000/yr
  - Strangulation, 1 in 400 require bowel resection

Observation or Operation for Patients With an Asymptomatic Inguinal Hernia

A Randomized Clinical Trial

Annals of Surgery • Volume 244, Number 2, August 2006

- 160 males, randomly assigned, 12 months f/u
- Visual pain score (rest and movement) and general health status questionnaire
- Op reported improved general health
- Conclusions: Repair of an asymptomatic inguinal hernia does not affect the rate of long-term chronic pain and may be beneficial to patients in improving overall health and reducing potentially serious morbidity

TABLE 2. Pain Scores at Rest and at Movement at Baseline, 6 Months, and 12 Months

Pain Measure	Observation n	Observation Mean (SD)	Operation n	Operation Mean (SD)	Model	Mean Difference [Operation − Observation (95% CI)]	*P*
At rest							
Baseline	80	2.0 (3.0)	80	2.0 (2.9)	—	—	—
6 mo	78	8.0 (14.0)	79	4.8 (10.7)	A	−3.2 (−0.7, 7.1)	0.11
					B	−3.3 (−0.2, 6.8)	0.062
12 mo	75	3.7 (8.2)	79	5.2 (12.3)	A	1.6 (−1.6, 4.8)	0.34
					B	1.4 (−1.7, 4.5)	0.38
At movement							
Baseline	80	2.3 (3.0)	80	2.4 (3.1)	—	—	—
6 mo	78	10.9 (16.0)	79	6.1 (11.9)	A	−4.8 (−9.2, −0.3)	0.036
					B	−5.0 (−9.1, −0.9)	0.018
12 mo	75	7.6 (15.0)	79	5.7 (11.5)	A	−1.9 (−6.1, 2.4)	0.39
					B	−2.4 (−6.6, 1.7)	0.25

Models: A, adjusting for relevant baseline pain measurement; B, additional adjustment for analgesia and other baseline covariates.

TABLE 3. SF-36 at 6 Months and 12 Months

Dimension	Observation (n = 78)	Operation (n = 79)	Mean Difference [Operation − Observation (95% CI)]	P
6 mo				
General health	−10.3 (18.9)	−3.4 (17.6)	5.8 (0.1, 11.5)	0.046
Physical functioning	−11.7 (20.4)	−4.7 (22.3)	4.8 (−1.7, 11.4)	0.15
Physical role	−12.7 (21.9)	−3.3 (22.5)	6.2 (−0.5, 12.8)	0.069
Emotional role	−8.5 (45.7)	−3.4 (40.2)	0.8 (−11.2, 12.9)	0.89
Social functioning	−11.4 (23.3)	−4.4 (23.5)	5.4 (−1.7, 12.5)	0.14
Bodily pain	−10.1 (22.5)	−1.6 (25.2)	5.3 (−1.7, 12.3)	0.14
Vitality	−9.9 (17.3)	−3.3 (21.0)	5.0 (−0.8, 10.9)	0.093
Mental health	−8.5 (15.9)	−2.6 (17.9)	4.9 (−0.3, 10.0)	0.063
Change in 12 mo	−3.5 (22.0) (n = 75)	7.3 (20.5) (n = 79)	9.4 (3.6, 15.1)*	0.0016
12 mo				
General health	−10.1 (18.3)	−5.3 (16.7)	3.7 (−1.8, 9.2)	0.097
Physical function	−12.9 (17.7)	−7.2 (22.5)	4.5 (−2.0, 11.0)	0.17
Physical role	−12.8 (22.0)	−6.8 (23.3)	3.3 (−3.7, 10.2)	0.36
Emotional role	−5.8 (45.3)	−4.2 (46.9)	3.3 (−9.3, 15.9)	0.60
Social functioning	−9.0 (21.4)	−4.2 (21.8)	3.3 (−3.3, 9.9)	0.33
Bodily pain	−11.1 (23.8)	−3.0 (24.8)	5.2 (−2.1, 12.5)	0.16
Vitality	−6.6 (16.4)	−4.7 (18.2)	0.1 (−5.1, 5.2)	0.98
Mental health	−5.0 (14.4)	−2.4 (17.2)	1.6 (−3.2, 6.4)	0.51
Change in 12 mo	−0.3 (23.4)	8.5 (25.6)	7.0 (0.2, 13.7)*	0.045

Data shown are mean (SD) for the change over baseline, and the estimated difference between operation and observation, with a 95% confidence interval and associated *P* value, from a linear model that adjusts for the baseline level of the relevant SF-36 component.

*For overall change in health status in the preceding 12 mo, from a linear model that adjusts for other baseline covariates, the difference between operation and observation groups was 8.0 (95% confidence interval, 2.1–13.8, $P = 0.0079$) at 6 mo, and 7.3 (0.4–14.3, $P = 0.039$) at 12 mo.

Crossover

- By 1 year 8 participants randomized to surgery were reclassified to observation and 15 observation to surgery
- At a median of 574 days 23 in obs group had operation (Fig. 2) for pain (11), increase in size (8), affecting work or leisure activities (3), and acute presentation (1).

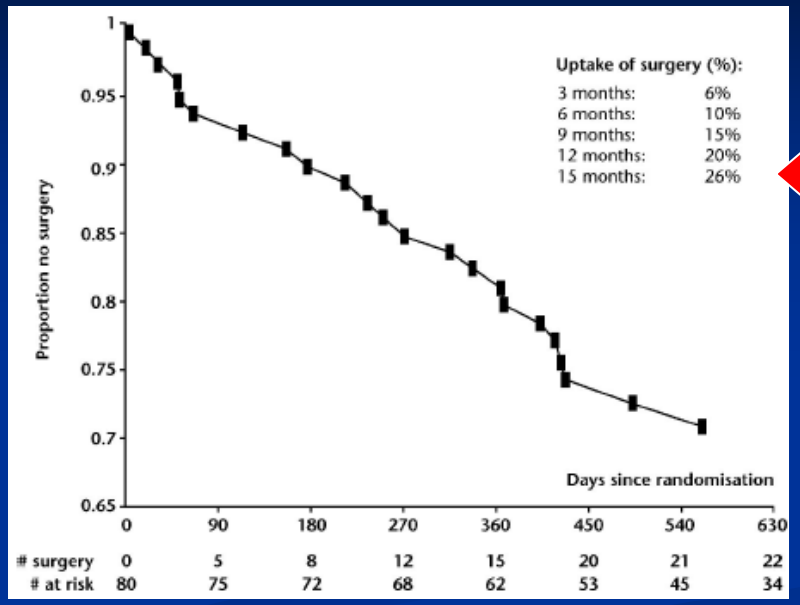


TABLE 4. Univariate and Multivariate Cox Proportional Hazards Model for Baseline Predictors of Crossover From Observation to Surgery

	Univariate		Multivariate	
Baseline Covariate	**HR (95% CI)**	***P***	**HR (95% CI)**	***P***
Direct	1.54 (0.63, 3.79)	0.34	1.80 (0.71, 4.60)	0.22
Duration (1 yr)	1.02 (0.87, 1.19)	0.80	1.05 (0.89, 1.24)	0.56
Left only	0.80 (0.35, 1.85)	0.60	0.84 (0.35, 2.01)	0.69
Protrusion (1 cm)	1.29 (0.98, 1.69)	0.073	1.35 (1.00, 1.83)	0.053
Vertical (1 cm)	1.35 (0.65, 2.80)	0.42	Not fitted*	
Transverse (1 cm)	1.14 (0.57, 2.29)	0.72	Not fitted*	
Age (10 yr)	1.03 (0.60, 1.77)	0.92	0.97 (0.55, 1.71)	0.91

Data shown are hazard ratio (HR) for the given increment (eg, 1 yr of age) with a 95% confidence interval and associated *P* value.

*Not fitted in the multivariate model (Spearman correlations: vertical size and protrusion 0.68, transverse and protrusion 0.48, vertical and transverse 0.46).

Cost

- Cost to Health Service was £401.9 per patient greater for the operation group at the median follow-up of 574 days.
- Took into account clinic and operative costs and the cost of complications
- Some subjective improvement in general health

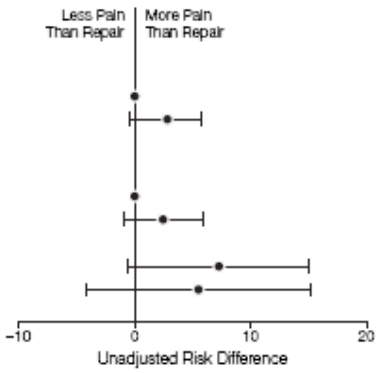
Watchful Waiting vs Repair of Inguinal Hernia in Minimally Symptomatic Men

A Randomized Clinical Trial

JAMA, January 18, 2006—Vol 295, No. 3 285

Figure 2. Pain Interfering With Activities: Group Differences at 2 Years

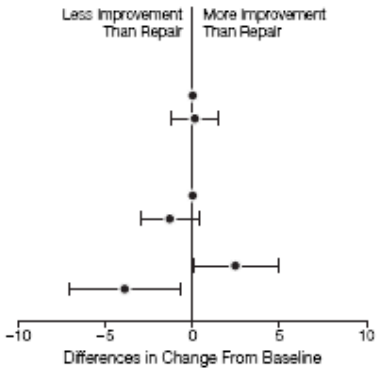
Intention-to-Treat	Pain Interfering With Activities, No. (%)	Risk Difference (95% CI), %
Repair	7 (2.21)	Reference
Watchful Waiting	17 (5.07)	2.86 (−0.04 to 5.77)
As-Treated		
As Assigned		
Repair	4 (1.46)	Reference
Watchful Waiting	10 (3.94)	2.86 (−0.98 to 5.94)
Crossed Over		
To Repair	7 (8.64)	7.18 (−0.63 to 14.99)
To Watchful Waiting	3 (6.98)	5.52 (−4.12 to 15.15)



Reference group for intention-to-treat is tension-free repair (score=0); reference group for as-treated is patients randomized to and received tension-free repair (score=0).

Figure 3. Physical Component Score: Group Differences in 2-Year Change From Baseline

Intention-to-Treat	Change From Baseline, Mean (SD)	Difference (95% CI)
Repair	0.13 (0.42)	Reference
Watchful Waiting	0.29 (0.41)	0.16 (−1.19 to 1.50)
As-Treated		
As Assigned		
Repair	0.66 (0.44)	Reference
Watchful Waiting	−0.62 (0.46)	−1.27 (−2.96 to 0.44)
Crossed Over		
To Repair	3.16 (0.81)	2.50 (0.01 to 4.99)
To Watchful Waiting	−3.22 (1.10)	−3.87 (−7.10 to −0.65)



Reference group for intention-to-treat is tension-free repair (score=0); reference group for as-treated is patients randomized to and received tension-free repair (score=0).

- 724 pts (25% of those initially screened) randomly assigned to watchful waiting group or surgical repair
  - representative of intended target population?

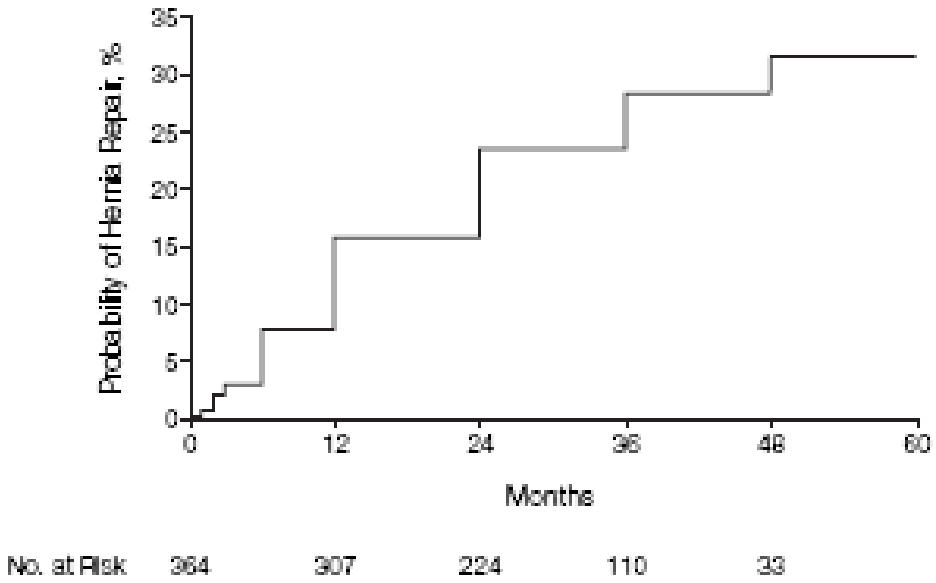
- **Conclusions** "Watchful waiting is an acceptable option for men with minimally symptomatic inguinal hernias. Delaying surgical repair until symptoms increase is safe because acute hernia incarcerations occur rarely"

Problems

- SS differences between groups
  - BMI (1.2 m/kg2 higher in repair group)
  - 3 of the Activity Assessment Scale (AAS) scores
  - Proportion of patients with enlarging hernia (higher in watchful waiting group)
- The study population also included patients recruited by radio advertising

Crossover

Figure 4. Probability of Crossover From Watchful Waiting to Surgery



"A considerably high crossover rate was observed in this trial and, as such, one must evaluate whether the crossover rate represents a threat to the internal validity of the study."

Crossover

- "Delayed operation"
- Operative complication rate 21.7% in repair group, 27.9% in crossovers, not SS
- Recurrence rate at 2 years 1% in op, 2.3% in crossovers. Not SS (although the trial design was not powered to detect this difference)

Crossover

- Assuming that crossing-over=failure in the ITT analysis
  - Immediate repair has superior primary outcome of pain-limiting activities vs crossovers
    - (50/317 [15.8%] vs 97/336 [28.9%])
  - % of pts with pain interfering with activities at 2 years was lower among assigned repair than crossovers
    - (4/274 [1.5%] vs 7/80 [8.8%])

Tension-Free Repair Versus Watchful Waiting for Men with Asymptomatic or Minimally Symptomatic Inguinal Hernias: A Cost-Effectiveness Analysis

J Am Coll Surg Vol. 203, No. 4, October 2006

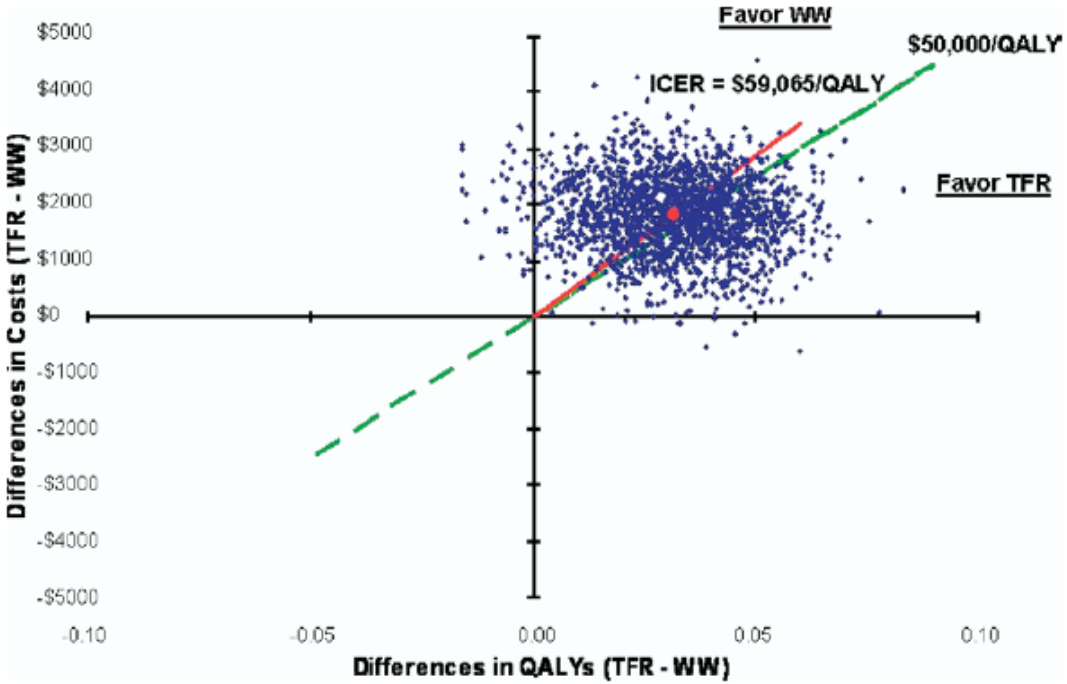


Figure 3. Cost-effectiveness plane for tension-free repair versus watchful waiting at 2 years followup. ICER, incremental cost-effectiveness ratio (ΔCost/ΔQALY); QALY, quality-adjusted life-years; TFR, tension-free repair; WW, watchful waiting.

Conclusion: At 2 years, WW was a cost-effective treatment option for men with minimal or no hernia symptoms.

The American Journal of Surgery 195 (2008) 89–93
Clinical surgery–American

Does delaying repair of an asymptomatic hernia have a penalty?

Table 1
Timing of surgery

Mo. between randomization and surgery	Frequency (%)	Cumulative frequency (%)
≤1	104 (29.5)	104 (29.5)
>1 to 2	81 (23.0)	185 (52.4)
>2 to 3	48 (13.6)	233 (66.0)
>3 to 6	55 (15.6)	288 (81.6)
>6 to 12	40 (11.3)	328 (92.9)
>12 to 24	20 (5.7)	348 (98.6)
>24	5 (1.4)	353 (100.0)

Perioperative complications

Complications	Mo. between randomization and surgery		*P*	Total (N = 353)
	≤6 (N = 288)	>6 (N = 65)		
Intraoperative (%)	3 (1.0)	0 (.0)	1.00	3 (.9)
Postoperative				
Hernia site infection	5 (1.7)	1 (1.5)	1.000	6 (1.7)
Wound hematoma	15 (5.2)	6 (9.2)	.243	21 (6.0)
Scrotum hematoma	11 (3.8)	3 (4.6)	.728	14 (4.0)
Orchitis	5 (1.7)	0 (.0)	.589	5 (1.4)
Seroma	2 (0.7)	1 (1.5)	.458	3 (0.9)
Groin neuralgia	2 (0.7)	0 (.0)	1.000	2 (0.6)
Leg neuralgia	1 (0.4)	0 (.0)	.184	1 (0.3)
Urinary retention	7 (2.4)	0 (.0)	.357	7 (2.0)
Urinary infection	0 (.0)	1 (1.5)	.184	1 (0.3)
Other	12 (4.2)	2 (3.1)	1.000	14 (4.0)
Total	49 (17.0)	14 (21.5)	.375	63 (17.9)

More conversions as time passed

No SS differences, but trend toward higher comp % with later op

Does Delay of Hernia Repair in Minimally Symptomatic Men Burden the Patient's Family?

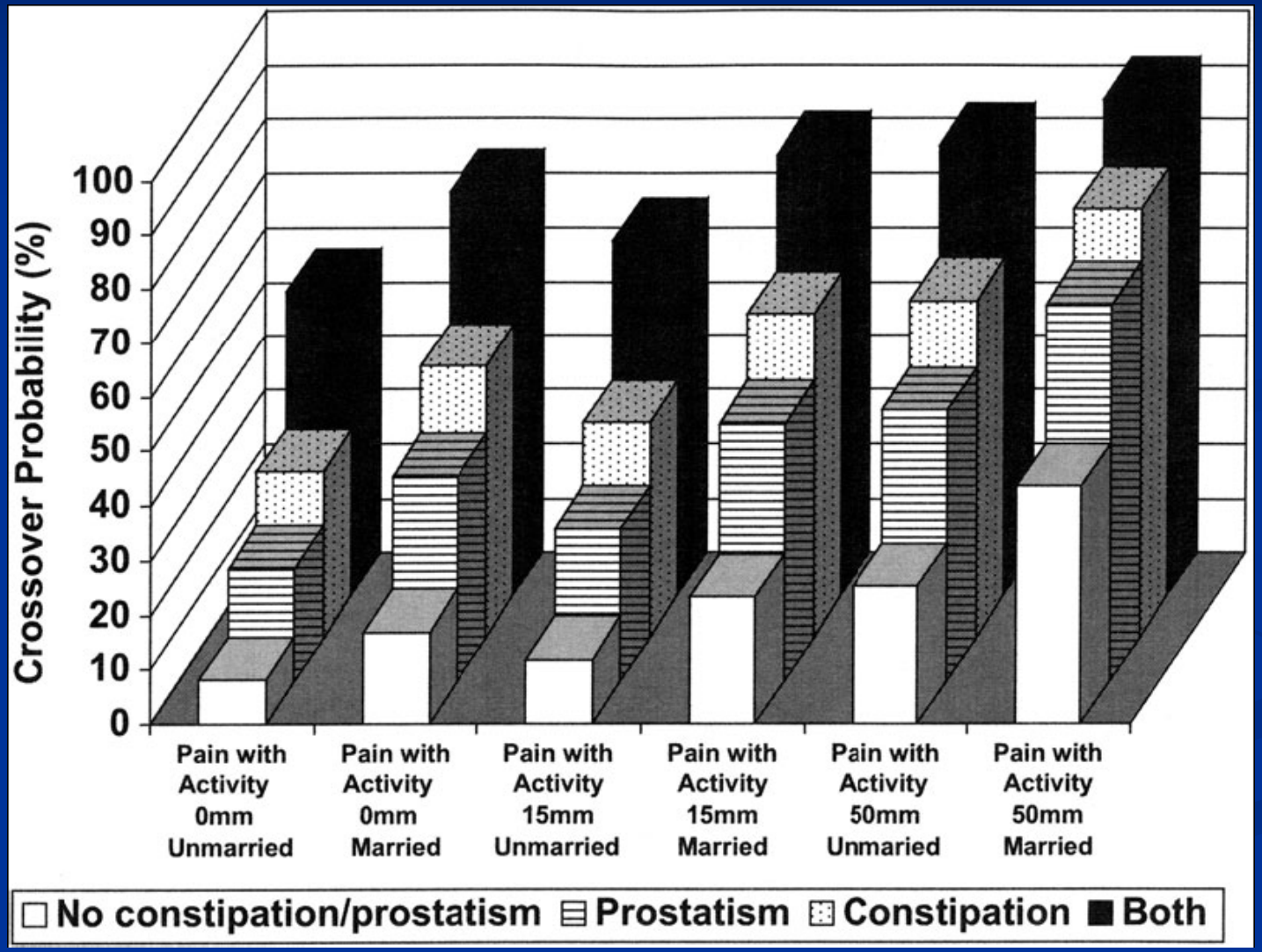
J Am Coll Surg Vol. 205, No. 3, September 2007

- **Results:** In both intention-to-treat and as-treated analyses, at 2 years after enrollment, family members of patients assigned to WW were more likely to report concern about the patient's ability to perform the four types of activities.
  - In the as-treated analysis, family members of patients assigned to TFR who did not receive repair reported more time assisting the patient than those of TFR patients who received the assigned treatment

- **Conclusions:** The results favor repair, but the low level of concern about the patient's functioning reported for both TFR and WW patients suggests that this is not a major issue in delaying repair of inguinal hernias in minimally symptomatic men

A Clinician's Guide to Patient Selection for Watchful Waiting Management of Inguinal Hernia

Annals of Surgery • Volume 253, Number 3, March 2011



"In summary, it is apparent that a watchful waiting approach to hernia management is not optimal for all patients with a minimally symptomatic inguinal hernia."

Is surgical repair of an asymptomatic groin hernia appropriate? A review

Hernia (2011) 15:251–259

- Systematic review of literature
  - More than 10,000 pts
- Emergency repair
  - Average morbidity 32%
  - Average mortality rate is 5.8%
- Elective Repair
  - Average morbidity 8%
  - Average mortality 0.5%

Proposed Algorithm (Netherlands)

- "Elective repair rec. to pts with an increased risk of incarceration and strangulation and to pts at risk for increased morbidity and mortality after emergency repair"
- Pts must understand f/u recs and be able to perform
- Live close to hospital

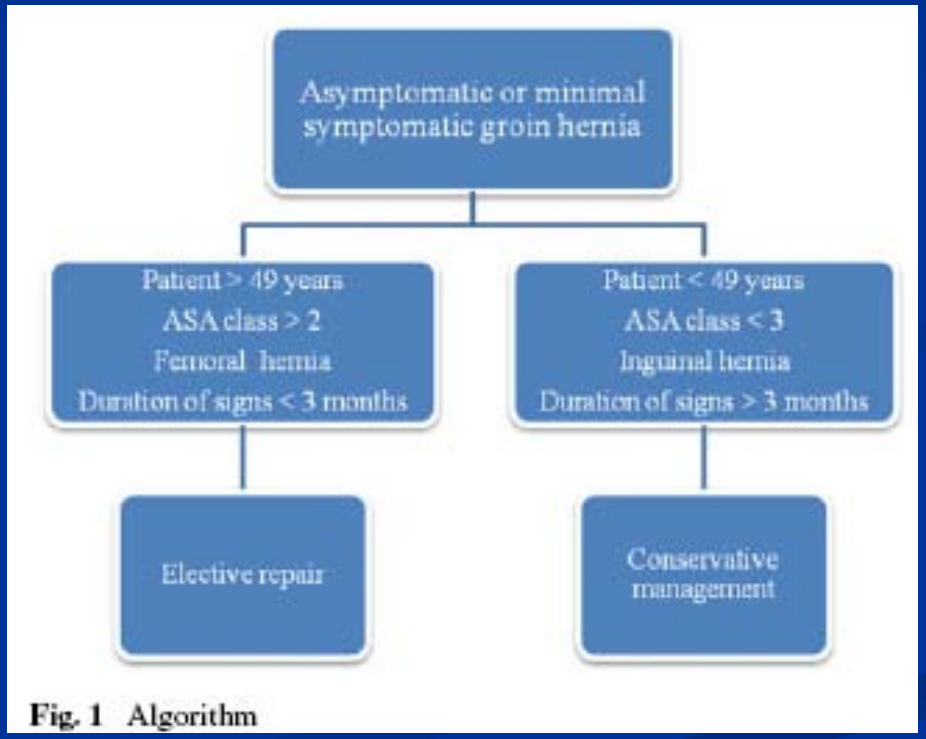


Fig. 1 Algorithm

Long-term follow-up of patients with a painless inguinal hernia from a randomized clinical trial

British Journal of Surgery 2011; **98**: 596–599

- "Conclusion: Most patients with a painless inguinal hernia develop symptoms over time. Surgical repair is recommended for medically fit patients with a painless inguinal hernia."

Fig. 1 Study profile

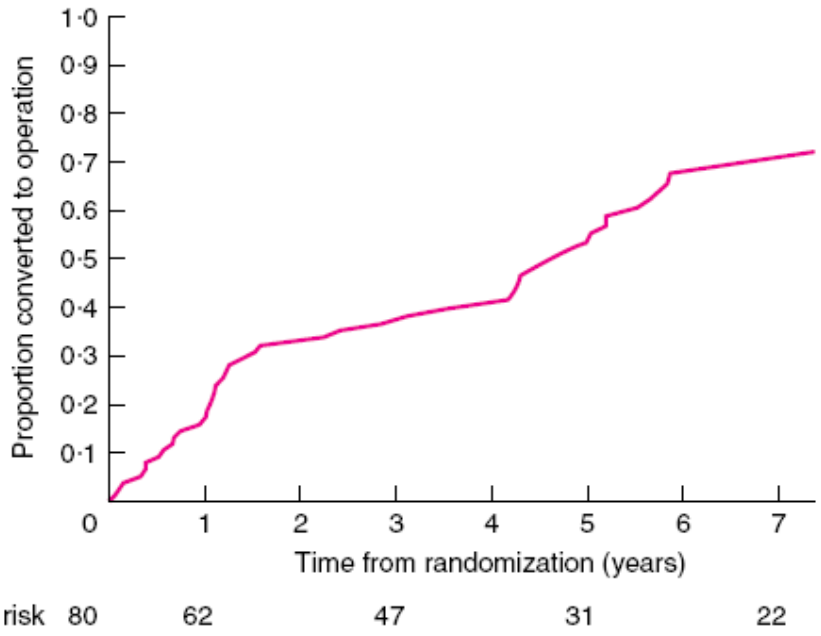


Fig. 2 Time from randomization to operation in the observation group of patients with a painless inguinal hernia

Repair

- "Safe to wait" does not mean "best"
- In long term f/u become symptomatic and repaired anyway
- When symptomatic have unnecessary distress and many cannot work ($)
- Different pt populations
- In the USA it is ultimately the pts decision
  - Our job is to inform and advise…REPAIR