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Original Article

Reoperation Rates after Inguinal Herniorrhaphy: A 10-year Review at a Tertiary Care Hospital

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Abstract ***Objective:*** **To estimate the reoperation rates for various inguinal hernia repairs using appropriate statistical methods, and to assess the effects of losses to follow up on these rates.**

Methods: **Medical charts of patients who underwent elective herniorrhaphy during January 1998 to December 2007 were reviewed. Cumulative reoperation rates were estimated using the Nelson-Aalen method.**

Results: **There were 1,852 hernia operations on 1,533 patients. There were 1,697 (92%) primary and 155 (8%) secondary hernias. Of these, 1,207 (65%) were tissue-based repairs and 645 (35%) were mesh-based repairs, of which 152 (8%) were laparoscopic repairs. There were 94 reoperations and 57% (981/1,727) loss to follow-up. The estimated overall reoperation rates were 17.4%, 27.8%, and 60.9% at 3, 5, and 10 years, respectively. Assuming complete 10 year follow-up for those lost to follow-up yielded reoperation rates of 4.9%, 6.1% and 7.1% at 3, 5, and 10 years respectively. Mesh-based repairs had slightly fewer reoperations than tissue-based repairs for primary hernias. Laparoscopic repairs had a slightly higher reoperation rate than open mesh repairs.**

Conclusion: **The reoperation rates in the present study were overestimated due to a high proportion of losses to follow-up. Mesh-based repairs including laparoscopic repairs did not differ significantly from tissue based repairs in terms of reoperations.**

Key words: **Inguinal hernia, herniorrhaphy, reoperation rate, mesh repair, tissue repair, loss to follow-up**

INTRODUCTION

Although inguinal herniorrhaphy is one of the most commonly performed operations anywhere in the world, there is a relative lack of carefully analyzed, long-term follow-up data for this group of operations.[1-3] The objectives of the present review of our institution's experience in the past 10 years were to determine the long-term reoperation rates of various elective inguinal hernia repair methods, and to compare these rates with those of previous studies. We aimed to estimate the reoperation rates with the most valid statistical methodology currently available and to examine the effects of a large number of losses to follow-up on these estimates. We also examined the complication rates of various hernia operations. In addition, we wished to examine how the introduction of mesh-based repairs influenced the reoperation rates, specifically whether the laparoscopic mesh-based repairs, which were first introduced during the study period, would affect these rates in any appreciable way.

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Patients and Methods

Medical records of patients who underwent elective inguinal herniorrhaphy during the period between January 1998 and December 2007 were reviewed. Hernia operations were excluded if the operative records were not available, if they were emergency operations or if they were for femoral or other hernias. The Hospital's Research Ethics Committee approved the study. The primary unit of analysis was the individual hernia, which could be located on the left or right side, or classified as primary or secondary and could occur several times in the same patient.

Secondary or recurrent inguinal hernias were diagnosed by the finding of a new, reducible bulge at the site of a previous inguinal hernia repair. This diagnosis was definite if a hernia was found on subsequent operation. Each hernia operation included in the analysis was documented in sufficient detail in the operative notes such that the type of repair could be reliably classified. Other clinical data were collected if they were readily available in the medical records: these included demographic data, type of inguinal hernia, predisposing conditions, defect size, type of anesthesia, experience of the surgeon, operative time, and length of hospital stay. The outcome measures included the time to reoperation, operative complications, and loss to follow-up.

The Nelson-Aalen method was used for estimating the cumulative reoperation rates. Statistical significance of the differences in the reoperation rates between groups were determined using either the log-rank test or the Cox proportional hazards regression analysis. Non-independence between observations on the same patient was ignored in calculating the Nelson-Aalen estimates, but was taken into account in all regression analyses by clustering on each patient and calculating standard errors using the Lin-Wei sandwich estimators.[4] All statistical analyses were performed using Stata version 9 (Stata Corp, College Station, TX, USA).

Results

There were 1,533 patients who underwent 1,852 hernia operations during the period under study. There were 1,697 primary hernias (92%) and 155 secondary hernias (8%). Baseline and clinical characteristics of patients and their hernias including treatment and follow-up times are presented in Table 1, in which primary and secondary hernia groups are separately shown and compared.

According to Table 1, secondary hernias were likely to be direct, associated with older age, and were likely to be treated with mesh-based methods. These hernias were also followed for a shorter period of time. "Other tissue repairs" mentioned in Table 1 included mainly the McVay Cooper ligament repair, the Shouldice repair and the darning repair.

There was a large number of losses to follow-up in the present study. Loss to follow-up was defined as the absence of follow-up information for at least two years after any given hernia repair. The two-year cutoff was chosen because most technical failures should occur within this time,[1,3,6] and if a patient did not seek further consultation within this time period, or he or she was not likely to return. By this criteria, for all operations performed at least two years prior to last follow-up date in the data set (29th November 2008), 981 of 1,727 operations (57%) were lost to follow-up. There was a significantly higher proportion of losses to follow-up for the secondary hernia group compared with the primary hernia group.

The overall, the primary hernia, and secondary hernia cumulative reoperation rates at 3, 5 and 10 years are presented in Table 2, along with their 95% confidence interval (95% CI) values. There were insufficient data for calculating the reoperation rate for secondary hernias at 10 years. The Nelson-Aalen plots of the cumulative reoperation rates for primary and secondary hernias are shown in Figure 1. Although the reoperation rates for the secondary hernia group were slightly higher, this difference was not statistically significant (p-value = 0.303, by log-rank test).

To show the possible effect of the loss to follow-up on the cumulative reoperation rates more clearly, we performed an analysis in which patients lost to follow-up were assumed to have completed the 10-year follow-up, with no further reoperations beyond those observed. The Nelson-Aalen plots of this extreme hypothetical scenario are shown in Figure 2. The reoperation rates are now much lower (Table 2, last column), and the differences between primary and secondary hernias are much more discernable, as well as being statistically significant.

A univariable Cox regression analysis of factors potentially affecting the reoperation rates, for primary

Table 1 Baseline characteristics of patients, hernias and their repairs

Characteristics	Primary hernias[a] N = 1,697	Secondary hernias[a] N = 155	p-value[b]
Male gender[c]	1,347 (91)	55 (98)	0.065
Age (years) at time of repair			
Mean (SD)	57.6 (16.5)	65.5 (13.6)	<0.001
Predisposing conditions[d]	327 (19)	29 (19)	0.866
Right-sided hernia	924 (54)	93 (60)	0.186
Inguinal Hernia			
Indirect (Nyhus Types 1 & 2)	1,251 (74)	97 (63)	0.003
Direct only or with indirect type	445 (26)	58 (37)	
Defect size, largest diameter (cm.)			
Mean (SD)	4.6 (2.9)	4.6 (2.8)	0.988
Hernia operation			
Bassini repair	1,104 (65)	41 (26)	<0.001
Other tissue repair	59 (4)	3 (2)	
Open mesh repair	425 (25)	68 (44)	
Laparoscopic mesh repair	109 (6)	43 (28)	
Anesthesia			
Local or regional	902 (54)	58 (38)	<0.001
General	779 (46)	96 (62)	
Surgeon experience			
Trainee	881 (52)	31 (20)	<0.001
Staff	813 (48)	123 (80)	
Operative time (minutes)			
Mean (SD)	97.9 (40.0)	112 (52.2)	<0.001
Hospital stay (days)			
Mean (SD)	4.2 (2.3)	4.9 (2.7)	<0.001
Follow-up time			
Median (range)1.5 mo (2 days to 11 yrs)	4 mo (3 days to 9 yrs)	<0.001	
Loss to follow-up[e]	924/1596 (58)	57/131 (44)	0.001
Number of reoperations	81	13	NA

[a] All summaries are number (%) unless stated otherwise; [b]p-values according to chi-square, unpaired t-test and ranksum test as appropriate; [c]Total number of individual subjects is 1,533; [d]Predisposing conditions included: benign prostatic hyperplasia, chronic obstructive pulmonary disease, chronic renal failure, cirrhosis, chronic asthma, and pulmonary tuberculosis. [e]For operations done at least two years prior to the last follow-up, 29th Nov 2008; NA: not applicable; mo: months.

Table 2 Cumulative reoperation rates and 95% CI for primary, secondary, and all hernias

Reoperation rate	All hernias N = 1,852	Primary hernia N = 1,697	Secondary hernia N = 155	No loss to F/U[a] N = 1,852
3 years	17.4 (13.5 to 22.5)	16.9 (12.8 to 22.3)	21.3 (10.4 to 21.3)	4.9 (3.8 to 6.2)
5 years	27.8 (21.5 to 36.0)	26.1 (19.8 to 34.6)	39.1 (20.3 to 75.1)	6.1 (4.9 to 7.6)
10 years	60.9 (39.7 to 93.3)	62.2 (39.4 to 98.3)	NA	7.1 (5.8 to 8.7)

[a]Assuming all losses to have completed the 10-year follow-up with no further reoperations; F/U: follow-up; 95% CI: 95% confidence interval

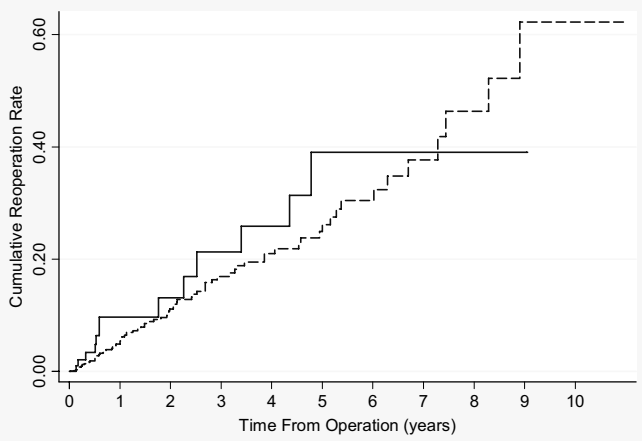

Figure 1 The Nelson-Aalen cumulative reoperation rates for primary herniorrhaphy (dashed line) and secondary herniorrhaphy (solid line): actual data with 57% loss to follow-up.

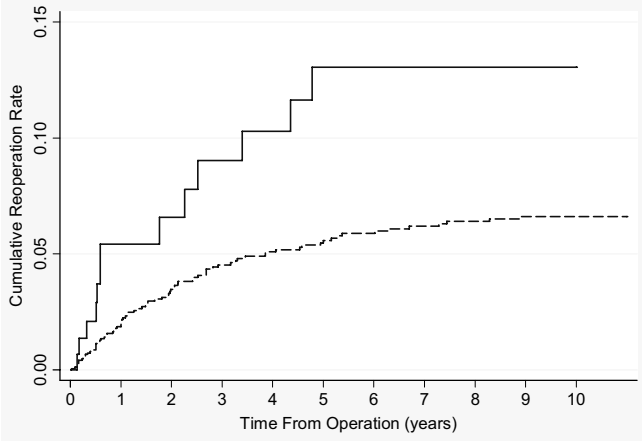

Figure 2 The Nelson-Aalen cumulative reoperation rates for primary herniorrhaphy (dashed line) and secondary herniorrhaphy (solid line): imputed data assuming no loss to follow-up.

Table 3 Univariable Cox-regression analysis of factors influencing hernia reoperation

Factors	Primary hernias (N = 1,697)		Secondary hernias (N = 155)	
	Hazard ratio (95% CI)	p-value	Hazard ratio (95% CI)	p-value
Age, per year increase	1.01 (1.00 to 1.03)	0.125	1.09 (1.03 to 1.16)	0.002
Sex, male vs. female	1.36 (0.57 to 3.22)	0.488	Not estimable	NA
Predisposing factors, yes vs. no	1.25 (0.80 to 1.93)	0.328	3.40 (1.06 to 10.83)	0.039
Side of hernia, right vs. left	1.16 (0.77 to 1.77)	0.479	1.10 (0.37 to 3.32)	0.860
Direct hernia vs indirect hernia	1.95 (1.22 to 3.10)	0.005	2.37 (0.85 to 6.60)	0.097
Defect size, per cm. increase	1.00 (0.91 to 1.08)	0.846	1.47 (1.09 to 1.98)	0.012
Anesthesia, general vs. regional	1.20 (0.76 to 1.88)	0.435	0.74 (0.22 to 2.44)	0.617
Surgeon, trainee vs. staff	0.88 (0.55 to 1.42)	0.598	1.00 (0.30 to 3.36)	0.996
Operative time, per half hour increase	1.25 (1.05 to 1.48)	0.011	1.03 (0.85 to 1.25)	0.744
Mesh repair vs. tissue repair	0.88 (0.49 to 1.59)	0.674	1.17 (0.25 to 5.58)	0.845
Postoperative complications	1.24 (0.56 to 2.74)	0.596	0.52 (0.06 to 4.36)	0.547

95% CI: 95% confidence interval; NA: not applicable

hernia patients, are presented in Table 3, columns 2 and 3. A similar analysis was done for secondary hernias, presented in Table 3, columns 4 and 5. There seemed to be no significant differences in the reoperation rates between mesh-based (open and laparoscopic) and tissue-based repairs whether for primary or secondary hernias.

On multivariable Cox regression analysis (not shown), only direct hernia and longer operative time were significantly associated with reoperation for primary hernias, while for secondary hernias older age and presence of predisposing factors were significantly associated with reoperation.

Looking at the differences between the various herniorrhaphy methods in greater detail, the high reoperation rate for the mesh-based repairs seemed to be associated with laparoscopic herniorrhaphy (Table 4, second column, and Figure 3), although this association was not statistically significant. However, this association was significant in the hypothetical extreme scenario in which patients lost to follow-up were assumed to have complete follow-up at 10 years (Table 4, fourth column, and Figure 4).

Acute or early operative complications of hernia repairs are shown in Table 5. The overall rates of complications were 8% (138/1,697) for the primary hernia group, and 10% (16/155) for the secondary hernia group. These two rates were not statistically

Table 4 Cox proportional hazard regression analysis comparing various techniques of hernia repair (N = 1,852)

Herniorrhaphy method	Actual, observed data		Imputed data[a]	
	Hazard ratio (95% CI)	p-value	Hazard ratio (95% CI)	p-value
Bassini repair (reference)	1	NA	1	NA
Other tissue repair	0.45 (0.13 to 1.49)	0.192	0.61 (0.16 to 2.36)	0.474
Open mesh repair	0.79 (0.41 to 1.52)	0.475	0.77 (0.40 to 1.46)	0.415
Lap mesh repair	1.41 (0.68 to 2.92)	0.350	2.08 (1.02 to 4.23)	0.043

[a]Imputed data for those lost to follow-up, by assuming complete follow-up at 10 years without further reoperations; lap: laparoscopic; 95% CI: 95% confidence interval

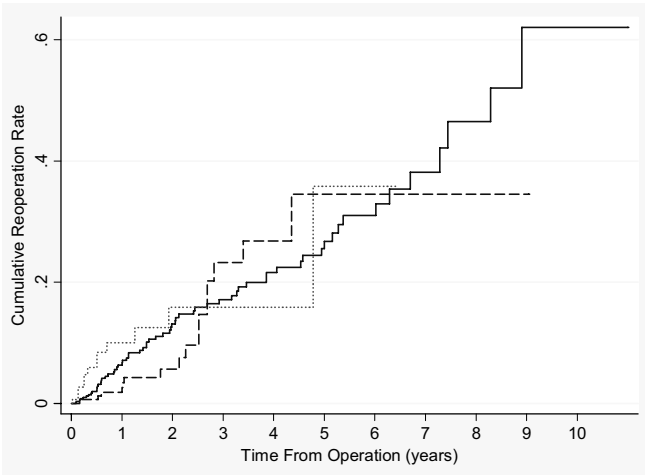

Figure 3 The Nelson-Aalen cumulative reoperation rates for Bassini and other tissue-based herniorrhaphy (solid line), open mesh herniorrhaphy (dashed line), and laparoscopic mesh herniorrhaphy (dotted line): actual data with 57% loss to follow-up.

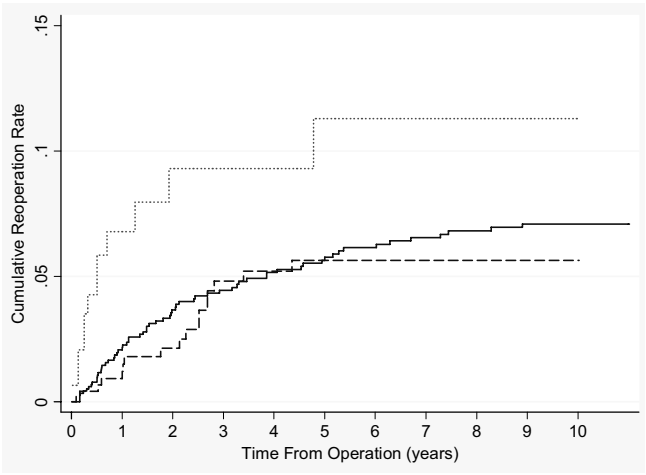

Figure 4 The Nelson-Aalen cumulative reoperation rates for Bassini and other tissue-based herniorrhaphy (solid line), open mesh herniorrhaphy (dashed line), and laparoscopic mesh herniorrhaphy (dotted line): imputed data with no loss to follow-up.

Table 5 Complications of the various types of hernia repair

Complications	Bassini	Other tissue	Open mesh	Lap mesh	p-value[a]
Primary hernia	N = 1,104	N = 59	N = 425	N = 109	
All complications	92 (8%)	5 (8%)	32 (8%)	9 (8%)	0.964
Hematoma, seroma, infection & pain	59 (5%)	4 (7%)	25 (6%)	5 (5%)	0.912
Visceral, vascular & bowel complications	26 (2%)	0	5 (1%)	2 (2%)	0.325
Secondary hernia	N = 41	N = 3	N = 68	N = 43	
All complications	3 (7%)	1 (33%)	5 (7%)	7 (16%)	0.173
Hematoma, seroma, infection & pain	1 (2%)	1 (33%)	5 (7%)	5 (12%)	0.120
Visceral, vascular & bowel complications	1 (2%)	0	0	1 (2%)	0.331

[a]p-values by chi-square test (primary hernia) and Fisher's exact test (secondary hernia); lap: laparoscopic

different. In addition, there were no significant differences in the occurrence of complications between the four repair groups, whether for primary hernias or secondary hernias. Long-term complications, such as persistent groin pain (lasting longer than 3 months), were not reliably recorded and were not obtained for analysis in the present study.

Discussion

Reports of hernia recurrence or reoperation rates in many studies in the past were usually misleading or incomplete.[5] Although it is well known that the appropriate statistical methodology to deal with the timing and occurrence of events, even in the presence

of losses to follow-up, is the time-to-event analysis methodology ("survival analysis"),[2,3,6] many authors ignored these methods entirely. The resulting misleading statistics have been quoted and re-quoted extensively leading to the myth of the "typical hernia recurrence rates" that by themselves have no meaning and cannot be used as standards for comparison. A good example is the often-quoted 10% recurrence rate for the Bassini repair.[7] Without further information, this number is meaningless. For example, does 10% refer to the cumulative recurrence rate, and if so, at what year after operation? Is it the life-time recurrence rate? Is it the recurrence rate per year, i.e., the hazard of recurrence, and if so, at what year after operation? Is it the average hazard, but averaged over how many years? With so much ambiguity involved in interpretation, it is a wonder that surgeons can attach so much meaning to these numbers without question.

Further, many authors used different measures for estimating the "recurrence rates". For example, the well-known recurrence rate for the Shouldice repair, approximately 1% for a 35-year experience as reported by the Shouldice Clinic,[8] was defined by the authors as a "cumulative recurrence rate". However, this cumulative recurrence rate was different from the accepted definition as used by statisticians. In fact, the Shouldice Clinic's measure was biased towards a lower estimate of the true recurrence rate and could not be compared with that of other institutions unless these institutions were also using the same non-standard definition. Another method of estimating the recurrence rate was to use the "crude" recurrence or reoperation rate.[1,5] For example, in the present study the crude reoperation rate was 94 of 1,852 operations or 5.1%, over a 10-year follow-up period. This number is an obvious underestimate of the true cumulative reoperation rate. Such estimates do not take into account the variation in follow-up times and the importance of censoring, and should never be quoted or used for comparison.

In the present study, we used the time-to-event methods extensively to estimate the various reoperation rates. We compared our estimates with those of other studies, obtained via similar analytical methods.[2,6,9,10] In the Danish Hernia Registry study of 23,695 hernia operations,[2] the 30-month reoperation rate was 2 to 3% for primary hernias and 4 to 12% for secondary hernias. In the Swedish registry study of 12,542 repairs,[6] the 3-year reoperation rates for primary and secondary hernias were 2.5% and slightly over 8%, respectively, and the 5-year reoperation rates were 6 and 14 %. In comparison, our numbers appeared to be high (table 2) mainly because over half of our patients (57%) were lost to follow-up early on, according to the available medical records. When we imputed the follow-times for these patients to be 10 years without any further occurrence of reoperations, the reoperation rates were much lower and conformed to those of other studies (figure 2). In particular, the 10-year, secondary hernia reoperation rate of almost 15 % for the imputed data set was similar to that of the updated Swedish registry study.[9]

The reoperation rate is a more objective and less labor-intensive, but indirect, measure of the recurrence rate.[2] Some authors have estimated that the true recurrence rate is roughly 1.5 to 2 times the reoperation rate.[2,11] Although this ratio is likely to vary between institutions, it is probably true that the reoperation rate underestimates the true recurrence rate. Therefore the results of the present study must be considered in this light.

We found that the reoperation rate for tissue repairs was not significantly different from that of mesh-based repairs. Early postoperative complications were also similar among the repair methods (Table 5), with an acceptable rate of 8 to 10 %.[12,13] This was true for both primary and secondary hernias. However, mesh-based repairs required slightly fewer reoperations than tissue-based repairs. Some reports also found that tissue and mesh-based repairs had similar recurrence rates,[3,13] but it is more likely that mesh-based repairs should have a much lower reoperation or recurrence rates.[14,15] The explanation for the apparently poor results of the mesh repair in the present study was probably technical, i.e., due to poor surgical techniques or the failure to adequately cover all defects.[1,11] Although, according to the present data, mesh repairs were performed on older patients with direct hernias, who were more likely to have predisposing conditions and to undergo prolonged operations, all of which were factors related to higher reoperation rates (Table 3), these factors might not be sufficient to explain the observed (high) reoperation rates. Looking at Figure 3, for example, there was an initial low reoperation rate for the open mesh repair group; but at 2 years, there was a rapid rise in

reoperations, suggesting the onset of technical failure just before that time.[1] In addition, according to Table 1, most primary hernia operations, whether mesh or tissue-based, were performed by surgical trainees. These findings underscored the need for proper training and performance of mesh-based herniorrhaphy procedures.[1,11,16]

Laparoscopic mesh repair had a slightly higher reoperation rate than that of the open mesh repair, a difference which was not statistically significant (Figure 3 and Table 4). This difference was much more pronounced for the imputed data set (Figure 4). Although a recent large multicenter trial found similar results,[17] the explanation for the present findings was, again, probably technique-related. Most of the reoperations following laparoscopic repairs occurred during the introduction of the laparoscopic technique to our hospital and could reflect the learning curve experience.[1,3] Several authors have noted that the learning curve for laparoscopic herniorrhaphy is long and requires much more than the typical 20 or 30 operations before the recurrence rate will drop to a low and steady level.[1,11,16] Thus, it seemed that the learning curve experience had an appreciable, adverse effect on the reoperation rate of the mesh-based hernia repair in the present study.

The major weakness of the present study was a consequence of the retrospective research design, i.e., the large number of losses to follow-up. It was likely that these losses were informative, that is, those lost to follow-up were prognostically different from those who were followed regularly, and hence probably had a different rate of reoperation. From an analysis, not shown, of patients lost to follow-up as compared with those who were followed for a longer period, there were certain characteristics which pointed to those lost to follow-up as being both more and less likely to have a reoperation. That is, patients lost to follow-up tended to be younger but with recurrent, indirect inguinal hernias which were repaired using tissue-based methods, and had fewer postoperative complications. So it was not clear how these patients would systematically differ in terms of reoperations from those not lost to follow-up.

Nonetheless, as illustrated by the hypothetical, imputed data set, it is likely that with a more complete follow-up, the reoperation rates would be much lower than those obtained from incompletely observed data.

Conclusion

We performed a retrospective analysis of 1,533 hernia patients with 1,852 hernia repairs. There were 94 reoperations within a 10 year follow-up period, but with 57% loss to follow-up. The estimated reoperation rates were 17% and 28% at 3 and 5-year follow-up, respectively. These rates were much lower when we assumed that patients lost to follow-up completed their follow-up at 10 years without further reoperations. We found no clear differences in the rates of reoperations between tissue-based and mesh-based repairs, and virtually no differences in the rates of early postoperative complications. Laparoscopic mesh repair had the highest overall reoperation rate, probably reflecting the learning curve experience. A more complete follow-up could resolve most of these uncertainties.

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