Reoperation Rates for Laparoscopic vs Open Repair of Femoral Hernias in Denmark
A Nationwide Analysis

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IMPORTANCE In Denmark approximately 10,000 groin hernias are repaired annually, of which 2% to 4% are femoral hernias. Several methods for repair of femoral hernias are used including sutured repair and different types of mesh repair with either open or laparoscopic techniques. The use of many different approaches reflects a rather low level of evidence for the best method of repair. Randomized clinical trials are lacking. Large, prospective cohort studies are an alternative way of acquiring improved evidence regarding the best type of repair.

OBJECTIVE To investigate the reoperation rate after laparoscopic vs open femoral hernia repair, analyzing data from a nationwide database.

DESIGN, SETTING, AND PARTICIPANTS A prospective cohort study was conducted. Data on femoral hernia repairs registered in the Danish Hernia Database from January 1998 until February 2012 were extracted and analyzed. All repairs were followed in the database and analyzed for reports of reoperation, which were used as a proxy for recurrence. Femoral hernia recurrence and inguinal hernia occurrence after the index repair were analyzed.

EXPOSURE Repair of a femoral hernia.

MAIN OUTCOMES AND MEASURES Reoperation for a femoral hernia.

RESULTS A total of 3970 primary femoral hernia repairs were analyzed; 27.3% occurred in men. There were 2413 elective repairs (60.8%) and 1557 emergency procedures (39.2%). In a multivariate analysis, laparoscopic repair was found to result in reduced risk of reoperation (hazard ratio, 0.33; 95% CI, 0.09-0.95) compared with open repair. The risk of reoperation was higher in women (hazard ratio, 1.95; 95% CI, 1.10-3.45). Furthermore, the laparoscopic approach seemed to reduce the risk of subsequent occurrence of an inguinal hernia in the same groin.

CONCLUSIONS AND RELEVANCE Laparoscopic repair of a femoral hernia reduces the risk of reoperation for a recurrence compared with open repair. The results from this study support the guidelines recommending the use of the laparoscopic approach for repair of femoral hernias.

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Femoral hernias may pose a special risk for the patient because they often present as emergencies with suspected intestinal obstruction. Several methods for repair of femoral hernias are used including sutured repair and different types of mesh repair with either open or laparoscopic techniques. The fact that many approaches are currently in use reflects a rather low level of evidence for the best method of repair. Randomized clinical trials are lacking. Large, prospective cohort studies are an alternative way of acquiring improved evidence regarding the best type of repair.

The Danish Hernia Database has prospectively recorded hernia repairs for the past 15 years and has national coverage. The aim of the present study was to investigate the reoperation rate after laparoscopic and open repair of a femoral hernia on a nationwide basis.

### Methods

The study was approved by the Danish Data Protection Agency (Journal No. 2011-41-6856). Approval from the regional ethics committee was not required, according to Danish law. Data for this study were extracted from the Danish Hernia Database. The database prospectively records information on adults undergoing femoral and inguinal hernia repairs in Denmark. The repairs are registered by the operating surgeon, who completes an online form after every procedure. Patients are identified on later entries to the database by their unique social security number, which means that a reoperation is registered even if the patient attends a different center. The characteristics and functioning of the database have been described in detail elsewhere.

From January 1, 1998, until February 22, 2012, a total of 148,277 groin hernia repairs were registered in the Danish Hernia Database. In the present study, only primary repair of femoral hernias was analyzed. If patients underwent an operation for a femoral hernia in both the left and the right groins, they were analyzed separately (ie, 2 separate entries).

Reoperation was defined as a subsequent hernia repair in the groin but subsequent occurrence of an inguinal or combined (femoral and inguinal) hernia was also analyzed. A femoral or inguinal hernia found at a third or later procedure in the groin was not included in the analysis. Observation time was defined as the time from first repair in the groin until either a second surgery in the groin or until February 22, 2012 (closing of the analysis), whichever came first.

Statistical analyses were performed using SPSS, version 20 (SPSS Inc). The Mann-Whitney test was used to compare age between groups, and the χ2 test was used to compare unadjusted reoperation rates. Cumulative reoperation rates were illustrated using Kaplan-Meier plots. The log-rank test was used for comparing the cumulative incidence of reoperation rates between groups. A Cox regression model was fitted to perform multivariate analysis. The following covariates were entered simultaneously into the model: age and sex of the patients, emergent or elective repair, and open or laparoscopic repair. Covariates of P > .20 were removed using a backward stepwise approach. Hazard ratios (HRs) and 95% CIs were calculated. Statistical significance was considered at P < .05.

### Results

A total of 3,970 primary femoral hernia repairs were registered including operations in 2,888 women (72.7%) and 1,082 men (27.3%). The median (range) age was 63 (18-106) years for women and 67 (18-100) years for men (P = .02). There were 2,413 elective repairs (60.8%) and 1,557 emergency repairs (39.2%). The median (range) follow-up was 82 (0-169) months for elective femoral hernia repairs and 97 (0-169) months for acute repairs. The intraoperative findings at a second procedure after acute and elective repair are reported in the Table. The distribution of findings at a secondary procedure after elective repair was significant. For example, following open repair, inguinal hernias were found in 4.1% of the cases, and following laparoscopic repair, inguinal hernias were found in 1.8% of the cases (overall for elective repair: Fisher exact test, P < .001).

The most frequently used method of repair was the plug repair, constituting 894 procedures. The highest rate of any subsequent repair following open elective repair was found with the McVay repair (n = 186) (unadjusted rate of subsequent repair, 12.4%), with 16 of the 23 subsequent repairs being for an inguinal hernia.

The overall rate of any reoperation in the groin after elective repair was 152 operations after 2,413 primary repairs (unadjusted rate of subsequent repair, 6.3%). The lowest rate of any subsequent hernia repair in the groin was found after laparoscopic repair (unadjusted rate of subsequent repair, 2.4%).
Reoperation Comparing Elective and Emergency Open and Laparoscopic Repairs

When comparing elective and emergency repair of femoral hernias, no significant difference in cumulated reoperation rates (finding of a femoral hernia at a second procedure) was found (3.1% vs 2.5%; \(P = .51\)). However, elective laparoscopic repair (n = 454) had a significantly lower cumulative incidence of reoperations compared with elective open repair (n = 1959) (0.62% vs 3.4%; \(P = .04\)), as shown in Figure 1. Overall, women (n = 2888) had a significantly higher cumulative incidence of reoperation compared with men (n = 1082) (3.3% vs 1.5%; \(P = .01\)).

No statistically significant difference was found on overall comparison of the cumulative reoperation rate after different open repairs using the log rank (other repair, 5.15%; other open, 4.0%; McVay, 3.9%; modified McVay with mesh, 3.6%; other supraligament repair, 2.9%; plug, 2.8%; open repair with mesh, 2.4%; and other infraligament repair, 0%; \(P = .86\)). Figure 1 shows the cumulative incidence of reoperation after elective open repair compared with elective laparoscopic repair. The result of the Cox regression analysis showed that older age of the patient at the initial repair was a protective factor for reoperation (HR, 0.98; 95% CI, 0.97-0.99), laparoscopic repair compared with open repair was a protective factor for reoperation (HR, 0.33; 95% CI, 0.09-0.95), and women had an increased risk of reoperation (HR, 1.95; 95% CI, 1.10-3.45).

Figure 2 shows the distribution of method of repair for elective femoral hernias from 1998 to 2011. From 2003 to 2011, laparoscopic repair was increasingly used and from 1998 to 2011 there has been a decrease in the use of the classic McVay repair and fewer repairs have been categorized as other. In 2011, 70.3% of femoral hernias were repaired using a laparoscopic approach, 17.0% were repaired with a plug, and 5.5% were repaired using a modified McVay technique with mesh.

Discussion

The main finding of this nationwide study was that laparoscopic repair of hernias reduced the risk for reoperation compared with open repair. Furthermore, female sex was a risk factor for reoperation. The timing of repair (emergent vs elective) did not have a significant effect on the risk of reoperation.

In addition to the risk of developing a true recurrence of a femoral hernia, there is a risk for other types of groin hernias. As reported in the Table, 3.1% of the patients initially receiving a repair for a femoral hernia later developed an inguinal hernia. Because the best method of repair for a femoral hernia would ideally prevent any hernia to occur afterward in the same groin, this could include a routine exploration of both the femoral and the inguinal canal during open repair. In a laparoscopic repair the entire myopectineal orifice (including potential medial, lateral, and femoral defects) is routinely covered by the mesh, aiming to prevent the occurrence of any hernia in the same groin, and should therefore minimize the risk of developing any groin hernia. This hypothesis is supported by our study because laparoscopic repair had the lowest recurrence rate of any hernia in the groin (Table). The elective McVay repairs resulted in a high number of subsequent occurrences of inguinal hernias. Therefore, the use of McVay repair should be minimized. A correct preoperative diagnosis in terms of inguinal or femoral hernia can be difficult. However, the
The finding that 39.2% of femoral hernia repairs were emergency procedures imposes a risk for patients with femoral hernia. That percentage could reflect that diagnosis of a femoral hernia is made too late. Furthermore, it could be the result of hernias developing in a narrow channel, but it could also indicate that patients and physicians are not reacting properly to the suspicion of a femoral hernia. The diagnosis, especially the distinction between inguinal and femoral hernia, may be difficult even in an elective setting. In the present study it could not be shown that emergency procedures had a worse outcome in terms of recurrence, but a study based on data from the Danish Hernia Database and the Danish National Hospital Registry showed that emergent repair and femoral hernias were overrepresented among patients who died within 30 days following a groin hernia repair.

In addition to recurrence, other patient-centered outcomes must be taken into account when selecting the type of repair. Patients receiving a groin hernia repair have a risk for developing chronic pain. It has been shown that the surgical technique for femoral hernia repair does not affect this risk. Therefore, it seems reasonable to make the choice of repair based on the observed reoperation rates and surgeon’s expertise. In this aspect the most appropriate method may be laparoscopic repair, which is also in accordance with current guidelines. The increased use of laparoscopic repair, as shown in Figure 2, is reflecting these recommendations. Thus, in 2003 the members of the Danish Hernia Database recommended use of the plug repair as standard, with consideration of laparoscopic repair. In 2008, the members of the Danish Hernia Database recommended use of a laparoscopic approach can be used to identify and repair both femoral and inguinal defects.

In a Cochrane review the authors failed to draw firm conclusions with regard to any superior methods of femoral hernia repair, basically because randomized clinical trials are lacking. However, it would be a challenge to conduct randomized trials, primarily because of the low incidence of femoral hernias. We therefore have to rely on data from large cohort studies such as the Danish Hernia Database. Because the data have been prospectively recorded and retrospectively analyzed, this provides a valid alternative to randomized clinical trials. The Swedish hernia database also provides a cohort of patients with groin hernias. In a 1999 study, 588 femoral hernia repairs were analyzed, but no conclusion could be made regarding the optimal type of repair, although a tendency toward lower reoperation rates following mesh-repair was shown. Another study, published in 2009, found that laparoscopic repair mitigated recurrence in the elective setting. However, multivariate analysis in that study did not include emergent/elective repair as a covariate, as opposed to the present study, where HRs were estimated for the whole population rather than for subgroups. Therefore, our finding that laparoscopic repair minimizes the risk of recurrence is valid for both emergent and elective procedures.

Female sex was found to be a risk factor for reoperation. This could be the result of differences in the anatomy of the pelvis between men and women. Because of those differences women are more likely to develop femoral hernias; therefore, female sex may be a risk factor for recurrence and reoperation, regardless of the type of repair.
approach if a preoperative diagnosis of a femoral hernia had been made. If a femoral hernia was diagnosed intraoperatively using the anterior approach, a plug repair or a modified McVay repair with mesh was recommended. Figure 2 shows that these recommendations were instituted, with most femoral hernias in 2011 repaired using the laparoscopic technique (70.3%), plug repair (17%), or modified McVay repair with mesh (5.5%).

Our study investigated the reoperation rate, which is correlated with the true recurrence rate and therefore can be used for evaluating the quality of repair. However, the reoperation rate will undoubtedly underestimate the true rate of recurrence. The true recurrence rate in direct, indirect, and femoral hernia has been shown to be approximately 40% higher than the reoperation rate 3 years after initial repair, but without evidence to suggest that some procedures had a true recurrence rate that was higher or lower than others. Our conclusion is limited to which method had the lowest reoperation rate and not necessarily which method should be implemented, because this decision also needs to take into account factors such as anesthesia, costs, patient’s preferences, and surgeon’s expertise. The European guidelines state that 50 to 100 procedures are needed for surgeons to gain proficiency in laparoscopic hernia repair. This should be considered when choosing the method of repair. In Denmark there is no standardized curriculum for surgeons performing laparoscopic groin hernia surgery, nor has the Danish Surgical Society set a minimum requirement for the number of procedures that should be performed under supervision. Despite this lack of guidelines, we found lower reoperation rates when comparing laparoscopic with open repair. This could indicate that the training and supervision performed on a locally planned basis is sufficient, but this issue needs further investigation.

Conclusions
Open repair and female sex were independent risk factors for reoperation after femoral hernia repair. Furthermore, a laparoscopic repair was protective for later operation for inguinal hernias. These nationwide data add important results to the body of evidence supporting the use of the laparoscopic approach for repair of femoral hernias.