

# Nationwide quality improvement of groin hernia repair from the Danish Hernia Database of 87,840 patients from 1998 to 2005

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for the Danish Hernia Database Collaboration

Received: 13 July 2007 / Accepted: 7 September 2007 / Published online: 16 October 2007  
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## Abstract

**Background** Increased focus and research on surgical technique and anaesthesia in groin hernia repair have improved outcomes from centres of interest in hernia surgery, but little information is available from nationwide data to document the incorporation of scientific evidence into general clinical practice.

**Aim** To review outcomes after groin hernia repair in Denmark from the Danish Hernia Database 1998–2005 in 87,840 patients.

**Results** The nationwide Danish hernia collaboration with two annual meetings discussing own results and those of others has led to >50% reduction in reoperation rates, increased use of the Lichtenstein hernia technique, higher rate of outpatient surgery, near elimination of regional anaesthesia, and documentation and focus on incidence and mechanisms of chronic pain.

**Conclusion** Establishment of nationwide groin hernia databases leads to general improvement in outcomes and, due to the large number of patients, allows analyses of specific sub-groups or complications which otherwise could not be obtained from single centres. Nationwide collaboration is important for multi-centre research and further improvement of outcomes, especially in chronic pain.

**Keywords** Hernia · Recurrence · Anaesthesia · Pain

## Introduction

Groin hernia repair is one of the most common operations in which significant scientific improvements have been made in recent years in technical aspects, anaesthesia and pain. These improvements have been expected to improve the overall quality of groin hernia repair and lead to more cost-effective treatment. However, most information comes from specialist centres or from surgeons with a special interest in hernia surgery, and nationwide data to document effectiveness in the general population have only been available from Denmark [1] and from regional populations from England [2], Sweden [3], Germany [4], Holland [5] and Scotland [6].

This report represents the cumulated results from the nationwide Danish Hernia Database for the 8-year period from 1998 to 2005 covering 87,840 groin hernia repairs.

## Methods

### Aim of database

Before the collection of data, a steering committee elected by the Danish Surgical Society decided on the main topics for quality improvement: reoperation rates, type of anaesthesia, ambulatory set-up, convalescence, role of laparoscopic surgery, and chronic pain (Table 1).

### Data collection

The database started registration on January 1, 1998. Immediately after an operation, the surgeon records data from any patient over 18 years, including details on anaesthesia, surgical technique, primary or recurrent repair, type of

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**Table 1** Primary aims of the Danish Hernia Database collaboration

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To reduce reoperation rates by >50%
To eliminate conventional, non-mesh repair techniques
To eliminate the use of regional anaesthesia (spinal and epidural)
To increase the use of an ambulatory set-up
To outline rational convalescence recommendations
To monitor and validate the laparoscopic approach
To assess the incidence and pathogenic mechanisms of persistent post-herniorrhaphy pain and outline strategies for prevention

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hernia and whether it was performed on an ambulatory basis [7]. The forms are mailed to a central secretariat where data are scanned optically. Due to the unique social security number of all citizens in Denmark, which allows each operation to be matched to a specific patient, the calculation of reoperation rates, independently of treatment site in the country, can be made. Operations recorded are compared with those recorded in the Danish hospital administrative system to assess completeness of data collection, and mortality rate is obtained from the Danish central civil registration register. The system allows for collection of discharge notes, information on readmissions, surgical notes for the operation, etc., where required for specific projects.

#### Database management

The steering committee is responsible for the content and use of data. Participation of the nationwide institutions is voluntary and free of charge, but feedback is provided to participants twice annually, and results for each participant compared with the nationwide data are returned twice annually. From 2005, institution-specific data have also been available on the database Web site (<http://www.herni-databasen.dk>). As a key function of the database, the participants meet twice annually to discuss results, make use of their own and other data from the hernia literature, and develop and implement supplementary protocols. The database includes more than 98% of Danish groin hernia repairs, including data from the few private hernia surgeons and private hospitals.

#### Data analysis

Reoperation is defined as a hernia repair in the same groin as the previous repair done after January 1, 1998, and recorded in the database, irrespective of hernia type. Groin hernia is any hernia (inguinal or femoral) in the groin, but specific analyses are done for the type of hernia. Types of repair are categorised in the following groups: sutured posterior wall repair (Bassini, McVay, Shouldice,

annulorrhaphy, and other anterior sutured repairs); Lichtenstein procedure, other anterior mesh repair (plug, plug and patch, and others); and laparoscopic procedures.

Crude reoperation rates are calculated as the number of reoperations in every group divided by the number of operations followed up in the same group. Reoperation rates adjusted for observation time are calculated as Kaplan–Meier estimates and are based on patient-specific observations. Patients not reoperated on by the end of the observation time, and patients who died before the end of the observation time, are right-censored.

#### Details

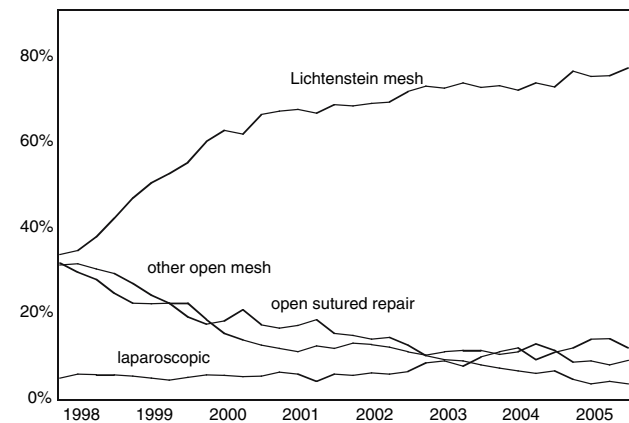
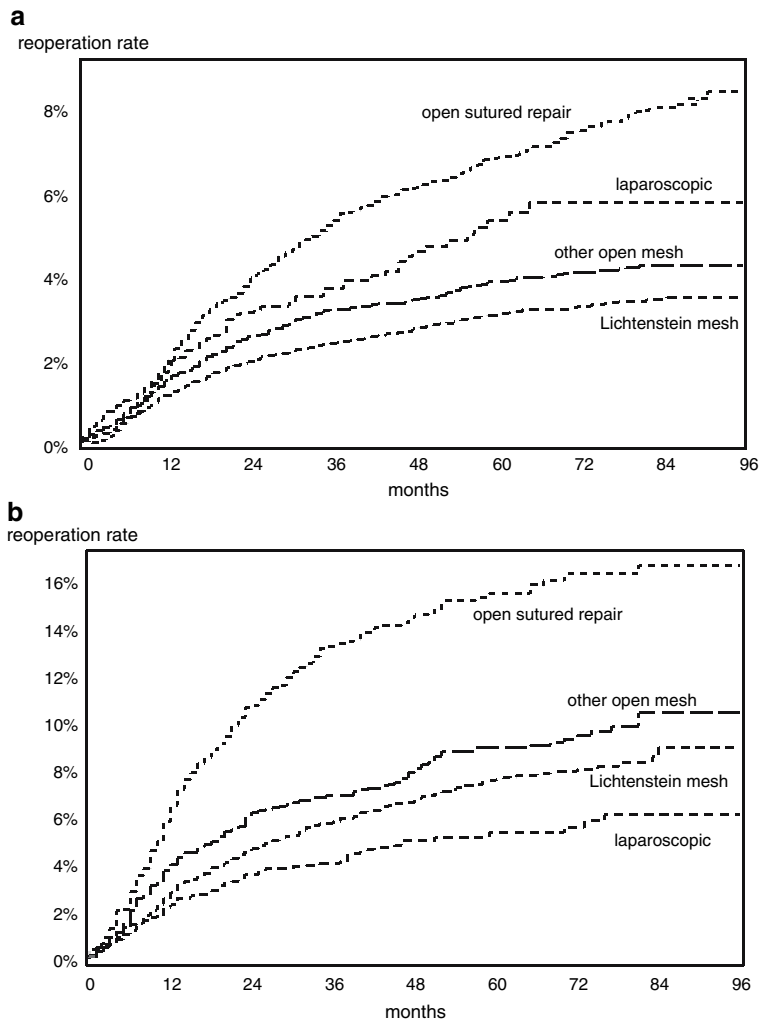
Between January 1, 1998, and December 31, 2005, 87,840 operations were recorded in the database, thus including about 11,000 patients per year. In the following, the main results of the database collaboration are presented, excluding data from the 3,698 acute operations and the 3,086 femoral hernia repairs, where a detailed analysis is in progress. Thus, the results primarily focus on repair of a primary or recurrent inguinal hernia, in addition to the specific projects performed within the database collaboration.

#### Reoperations

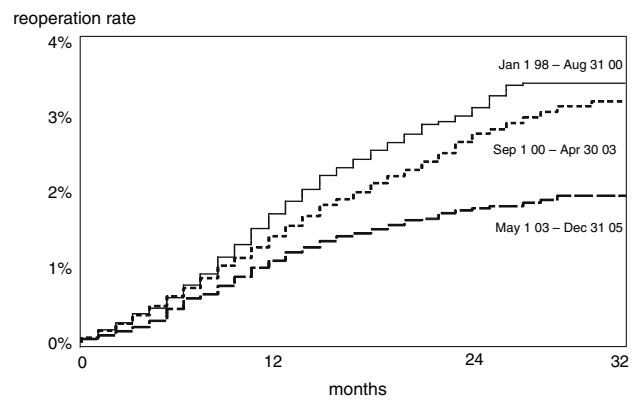
The reoperation rates (Fig. 1) after a primary or recurrent elective inguinal hernia are high after conventional sutured repairs (Bassini, Shouldice, McVay) and low after Lichtenstein mesh repair and laparoscopic repair, except in primary inguinal hernia, where a surprisingly higher reoperation rate was found after laparoscopic repair [8]. The explanation is most probably an insufficient surgical technique, since most of the reoperations were observed after a laparoscopic bilateral inguinal hernia repair, calling for an increased focus on learning and organisation of the technique, which only amounts to about 8% of repairs (Fig. 2). Reoperation rates after a recurrent inguinal hernia are generally 50% higher than after a primary repair (Fig. 1), calling for improvement of technique and probably centralisation to fewer centres. A major ( $n = 500$ ) randomised study to compare the Lichtenstein mesh repair versus laparoscopic repair for recurrent inguinal hernias has finished inclusion and awaits follow-up.

As seen in Fig. 2, the database collaboration has succeeded in increasing the use of the Lichtenstein mesh repair and almost eliminating the conventional sutured repairs that had documented very high reoperation rates (Fig. 1). The time course of the quality improvement obtained by decreasing reoperation rates is shown in Fig. 3, where a continuous reduction has been obtained, most probably explained by the increased nationwide use of the Lichten-

**Fig. 1** Reoperation rate.  
**a** Primary inguinal hernias,  
**b** recurrent inguinal hernias



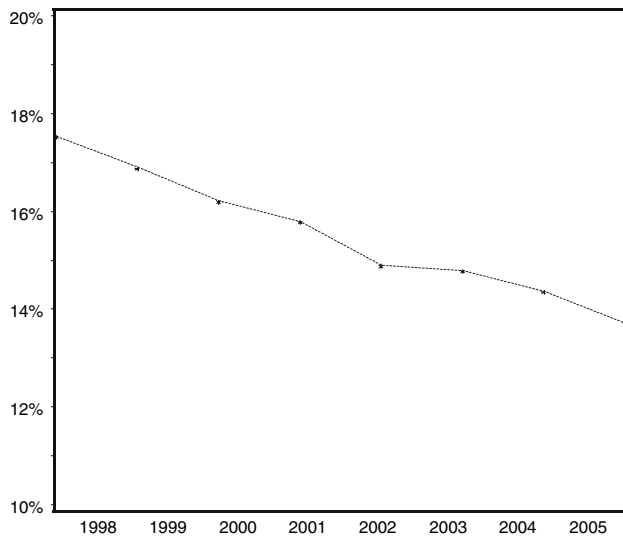
**Fig. 2** Type of surgical technique for inguinal hernia repairs in Denmark, 1998–2005 (combined primary and recurrent hernia repairs)



**Fig. 3** Nationwide reoperation rates in Denmark for three periods with a similar post-operative observation time (32 months)

stein mesh repair. In contrast, the nationwide percentage of operations performed for a recurrent hernia is only slowly decreasing from about 17.5% in 1998 to about 13.5% at the end of 2005 (Fig. 4). The slow decrease in the total number of reoperations, despite the improvements made between

1998 and 2005 (Figs. 1, 2, 3, 4), is explained by a continuous inflow of recurrent hernias from operations performed with sutured, non-mesh techniques before 1998. Thus, a recent nationwide survey with an observation time of 5–8 years has demonstrated that reoperation rates are low



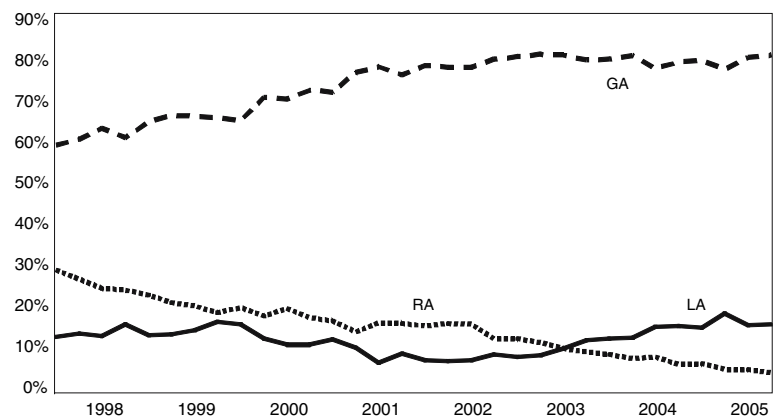
**Fig. 4** Proportion of inguinal hernia repairs done for a recurrent hernia in Denmark 1998–2005

and almost steady after 5 years of observation after a Lichtenstein mesh repair compared to a continuous inflow of reoperations after sutured non-mesh repairs, even after more than 5 years of observation time [9].

In collaboration with the Swedish hernia database, the database has collected a large series of reoperations after Lichtenstein mesh repair ( $n = 87$ ) and analysed the operative findings during reoperation to document that most recurrences are due to insufficient mesh fixation near the pubic tubercle [10].

A specific problem with female inguinal hernia repairs has been addressed and made possible due to the large number ( $n = 3,696$ ) of these relatively infrequent operations. Surprisingly, reoperations were about 30% higher than in males and occurred earlier, probably due to overlooked concomitant femoral hernias at the time of primary inguinal hernia repair [11]. The same results have been found in the Swedish hernia database [12] and argue for a laparoscopic approach for female inguinal hernia repair.

**Fig. 5** Anaesthetic techniques used for groin hernia repairs in Denmark, 1998–2005. GA General anaesthesia, RA regional anaesthesia, LA local infiltration anaesthesia



The importance of looking for a concomitant femoral hernia during inguinal hernia repair has also been demonstrated in a nationwide study in males where early reoperation for a “recurrence” was more often due to a femoral hernia than a recurrent inguinal hernia [13].

#### Anaesthesia

Three types of anaesthesia are used for groin hernia repairs: local infiltration anaesthesia, regional anaesthesia (spinal/epidural), and general anaesthesia. Many data from large consecutive series and randomised trials have demonstrated local infiltration anaesthesia to be the most cost-effective technique, allowing less use of anaesthesia personnel, discharge within 2 h and similar patient satisfaction compared to the other techniques [14–18]. Although one of the main aims of the database collaboration was to eliminate the use of regional anaesthesia due to its well-documented higher risk of morbidity, including urinary retention, the use of this technique has only been slowly decreasing over the 8-year period (Fig. 5), despite a continuous discussion of the unfavourable results with spinal anaesthesia, especially in elderly patients, including prolonged hospitalisation [19]. Hopefully, the institution-specific public data presentation on the Web site and recent nationwide documentation of a higher early mortality and risk of prostatectomy following spinal anaesthesia [20], which currently accounts for about 5% of cases, will lead to its elimination within a few years. The database collaboration has been unsuccessful in increasing the use of the more cost-effective local infiltration technique (Fig. 5), which is predominantly used by hernia surgeons in private practice.

#### Ambulatory set-up

The otherwise well-established ambulatory set-up for elective groin hernia repairs [15–17] has only been slowly implemented nationwide, but increased from about 55% in 1998 to about 70% in 2005 (Fig. 6). A large variability in

the implementation of an ambulatory set-up has been demonstrated, reflecting the difficulties in changing traditional-care practice based on available scientific evidence [15–17].

### Convalescence

Before the start of the database, Danish hernia surgeons usually recommended 3–4 weeks of convalescence. A multi-centre study within the database collaboration with a recommendation for only 2 days of convalescence (unless pain argued for longer), resulted in a convalescence time (sick leave) of 7 days in patients at work and 5 days in patients without work (mostly elderly patients) [21]. Despite earlier resumption of normal activities, reoperation rates assessed in the database were slightly lower in centres with the short convalescence recommendations ( $n = 1,007$ ) compared to the rest of the country [21], indicating that early resumption of activity does not increase the risk of recurrence.

### Chronic pain

The database presented the first nationwide data in 2001 of a 9% risk of chronic pain influencing daily activities [22]. Subsequently, the problem of chronic pain following groin hernia has become the most important outcome in hernia surgery [23], since reoperation rates are sufficiently low after the introduction of the mesh repair techniques. A collaboration between the Danish and Swedish hernia databases in 2,612 younger males undergoing open inguinal hernia repairs with either Lichtenstein mesh, annulorrhaphy or a Shouldice technique could not demonstrate differences in the risk of chronic pain [24]. The few laparoscopic repairs in Denmark have not allowed a sufficient analysis of a potentially lower risk of chronic post-herniotomy pain as suggested from available randomised studies [23, 25].

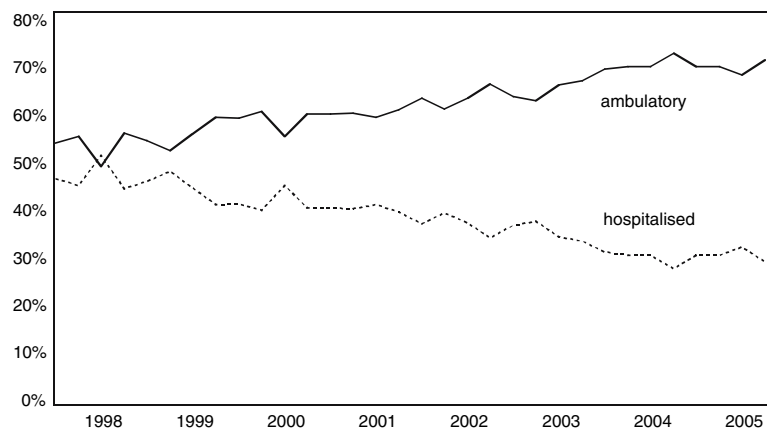
Due to the unique complete follow-up in the database, a detailed questionnaire follow-up study 1 year [22] and 6 years postoperatively [26] compared the incidence of chronic pain influencing daily activities. These results showed an about 50% reduction in chronic pain from about 9 to 4.5% after 6 years and indicated that a reoperation was a significant risk factor for persistent pain [26]. More recently a specific focus has been placed on pain-related sexual dysfunction, especially dysejaculation, in younger males [27, 28]. This nationwide survey found a surprisingly high incidence (2.7%) of pain-related sexual dysfunction [27]. Presently, a nationwide group of these patients together with other severe chronic pain patients are undergoing neurophysiological and psycho-social evaluation [28, 29], together with imaging techniques (MR) to evaluate the potential for reoperation (neurectomy/mesh removal). These studies with detailed pre- and postoperative characterisation hopefully will help to further clarify and define indications for reoperation for chronic pain since the results in the literature are difficult to interpret, mostly due to sub-optimal study designs [30].

### Other topics

Due to the large number of operations collected, more rare occurrences, such as femoral hernias and acute hernias, are currently being analysed, and represent the largest available number of patients (3,086 and 3,698 patients, respectively). These reports will support similar large regional surveys from the Swedish Hernia Database [31, 32] to help improve outcomes and facilitate future treatment strategies in these conditions.

As an example, the rare event of finding no hernia intra-operatively has been assessed in 317 patients. These nationwide data indicated that it is recommended not to do a repair if no hernia is found, since a reoperation for an overlooked hernia could not be demonstrated [33], and since a repair would probably increase the risk of chronic pain.

**Fig. 6** Proportion of patients operated in an ambulatory set-up versus hospitalisation for elective groin hernia repairs in Denmark 1998–2005 (hospitals only)



## Discussion

The results from the first 8 years of the nationwide Danish Hernia Database collaboration of 87,840 patients have demonstrated that such a collaboration is able to improve the treatment effectiveness based on recent scientific progress within several areas of groin hernia repair and to encourage the implementation of these improved techniques. Thus, it has been possible to document increased effectiveness by implementing mesh repairs and thereby decreasing reoperation rates, decreasing the use of spinal anaesthesia, increasing ambulatory set-ups, decreasing convalescence without an increased risk of reoperation by use of short convalescence recommendations and finally allowing the chronic pain problem to be addressed.

However, despite these improvements, a few areas of concern have also appeared. The incorporation of scientific evidence into clinical practice regarding elimination of spinal anaesthesia has been slow, despite overwhelming data in the literature [14] documenting a higher risk of urinary retention, as well as prolonged stays and increased morbidity in the country with this technique [19, 20]. During this educational process, data from the literature and the Danish data have been presented to the Danish Societies of Anaesthesiology and Surgery to promote change of practice but apparently with little impact. Another area for concern is the inability to change surgical practice in hospitals (but not in the private clinics) regarding the use of the more cost-effective local infiltration anaesthesia, despite continuous discussion in the database collaboration and Danish Surgical Society. Finally, it was a surprise to find that the reoperation rates with the laparoscopic technique were higher than with the open technique for bilateral hernias [8]. Subsequently, a debate in the database collaboration with presentation of educational videos on the laparoscopic technique as well as efforts to centralize these operations to fewer specialized centres have been made, since the number the laparoscopic hernia operations only amounts to about 8–10% of all operations, and they are performed in many low volume centres [8].

From the beginning, a high priority has been made in the database collaboration to present and discuss data and to use this as a basis for multi-centre/nationwide collaboration for future studies. Current projects are large randomised trials ( $n = 1,000$ ) to compare different mesh types in terms of chronic pain as well as a large study ( $n = 500$ ) to compare reoperation rates after recurrent inguinal hernia repair done laparoscopically or with an open Lichtenstein mesh technique. During this process, discussions have also been held with representatives of the Swedish Hernia Database, resulting in collaborations to solve more rare problems such as chronic pain after different open procedures in young males [24] and detailed analyses of operative findings in recurrent

hernia repair after a previous Lichtenstein procedure [10]. Hopefully, this positive collaboration can be extended to other national/regional hernia databases to answer more rare questions in hernia surgery (e.g. mortality, the asymptomatic hernia, specific chronic pain problems, the role of newer mesh types, and nerve-sparing techniques).

The database collaboration has an increased focus on chronic pain [22–24, 26–29], and currently patients with severe pain problems are referred to two centres for detailed characterisation including neurophysiological examinations, MR imaging, and psycho-social interviews, and a project has been started to evaluate the indication and results for reoperation with neurectomy and/or mesh removal and pharmacological pain treatment.

Establishment of the Danish Hernia Database was approved by the Danish Surgical Society, which may have helped with the early success of including more than 95% of hernias. The database collaboration has been funded by the Danish government with an annual budget ~EUR 50,000, covering salary for part-time secretarial assistance and physician support for data management and analysis. These small annual expenses therefore confirm the value and cost-effectiveness of establishing a national surgical database, based upon the documented improvements in several areas of care.

At the beginning of 2005, the Danish government made it mandatory to report to recognised databases, which supports the inclusion of patients and work within the collaboration. Biannual reports of nationwide and individual results are presented on the database Web site (<http://www.herniedatabasen.dk>) in a non-anonymous fashion. From June 2006, the data collection system has been Internet-based and, based upon the positive experiences with inguinal hernias, the database has been expanded to also include nationwide data on incisional hernias.

In summary, the Danish Hernia Database Collaboration has proven to be an effective and cheap instrument to serve as a basis for monitoring and to stimulate nationwide collaboration and studies to improve quality of care in groin hernia repair. The collected results and data from more rare entities within groin hernia repair should stimulate a more widespread international collaboration between regional and nationwide groin hernia databases in order to enhance progress and knowledge.

Members of the Steering Committee for the Danish Hernia Database:

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Niels Christian Hjortsø, Glostrup Hospital  
Torsten Asmussen, Øresund Hospital  
Finn Heidemann Andersen, Charlottenlund Private Service

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