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Outcomes After Lumbar Disk Herniation Surgery in the Dutch Population

Maike H. J. Schepens, PharmD, MBA[1], Miranda L. van Hooff, PhD[2,3], Judith A. van Erkelens, MSc[4], Ronald Bartels, MD, PhD[5], Eric Hoebink, MD[6], Margot Smits, MD[7], Johannes L. P. Kuijpens, MD, PhD[8], and Jacques van Limbeek, MD, PhD[7]

Abstract

Study Design: Retrospective cohort study.

Objective: There is only limited data on the outcome of primary surgery of lumbar disk herniation (LDH) in Dutch patients. The objective of this study is to describe undesirable outcomes after primary LDH.

Methods: The National Claims Database (Vektis) was searched for primary LDH operations performed from July 2015 until June 2016, for reoperations within 18 months, prescription of opioids between 6 to 12 months and nerve root block within 1 year. A combined outcome measure was also made. Group comparisons were analyzed with the Student's t-test.

Results: Primary LDH surgery was performed in 6895 patients in 70 hospitals. Weighted mean of reoperations was 7.3%, nerve root block 6.7% and opioid use 15.6%. In total, 23.0% of patients had one or more undesirable outcomes after surgery. The 95% CI interval exceeded the 50% incidence line for 14 out of 26 hospitals with less than 50 surgical interventions per year. Although the data suggested a volume effect on undesired outcomes, the t-tests between hospitals with volume thresholds of 100, 150 and 200 interventions per year did not support this (*P* values 0.078, 0.129, 0.114).

Conclusion: This unique nationwide claims-based study provides insight into patient-relevant undesirable outcomes such as reoperation, nerve root block and opioid use after LDH surgery. About a quarter of the patients had a serious complication in the first follow up year that prompted further medical treatment. There is a wide variation in complication rates between hospitals with a trend that supports concentration of LDH care.

Keywords

lumbar, spine surgery, lumbar disk herniation, outcomes, surgical complications, reoperations, opioids, nationwide study, claims data

[1] Department Strategy and Quality of Care, Dutch Association of Health Insurers (ZN), Zeist, Netherlands
[2] Department Research, Sint Maartenskliniek, Ubbergen, Netherlands
[3] Department Orthopedics, Radboud University Medical Center, Nijmegen, Netherlands
[4] Department Research, Vektis, Zeist, Netherlands
[5] Department Neurosurgery, Radboud University Medical Center, Nijmegen, Netherlands
[6] Department Orthopedics, Amphia Hospital, Breda, Netherlands
[7] Department Medical Advice, Zilveren Kruis Health Insurance Company, Leusden, Netherlands
[8] Department Medical Advice, VGZ Health Insurance Company, Eindhoven, Netherlands

Corresponding Author:
Miranda L. van Hooff, Department Research, Sint Maartenskliniek, Ubbergen, Netherlands; Department Orthopedics, Radboud University Medical Center, Nijmegen, Netherlands.
Email: m.vanhooff@maartenskliniek.nl

Introduction

Lumbar disk herniation (LDH) is in most cases located in the lower lumbar levels of the spine.[1] Often this does not lead to clinical symptoms, but in some cases irritation of a lumbar or sacral nerve root can lead to radiating pain in the area of the buttock or leg, possibly in combination with loss of strength in peripheral muscle groups.[1]

In 2017, 260,800 Dutch patients visited the general practitioner (GP) with complaints of low back pain with radiating pain.[2] Lumbar disk hernia usually has a favorable natural course; spontaneous recovery occurs in 3 quarters of patients with radiating pain from LDH.[1] A Dutch study with a follow up of 1 year by Peul et al. showed that a surgical intervention, measured 1 year after the procedure, has no advantages over conservative treatment. However, surgical intervention did provide a faster functional recovery in leg pain.[3] Since the first successful LDH operation in 1934,[4] the international consensus is that surgery only makes sense if symptoms persist after a period of conservative management and progressive failure or caudal syndrome.[5] There is no consensus yet on the optimal duration of conservative treatment. In the first 3 months, conservative treatment is preferred.[6]

There is evidence that pain is relieved more quickly in patients who receive surgical treatment. However, there is limited insight in the adverse i.e. undesirable outcomes. Outcomes after LDH surgery are defined by the International Consortium for Healthcare Outcomes (ICHOM) and consist of outcomes such as complications, re-operations, mortality, pain, quality of life etc.[7] For shared-decision making in the choice for surgery or conservative treatment it is important to have information on probability of complications and (un)desirable outcomes.

So far, there is limited insight in outcomes after primary surgery on LDH in Dutch patients. This study aims to determine the occurrence of undesirable outcomes relevant for patients after primary LDH surgery based on claims data. We analyzed the possible undesirable outcomes (based on the ICHOM outcomes set) that could be analyzed using claims data.

Methods

Approval for the Study

Using claims data of Health Insurance Companies is covered by the Code of Conduct for the Processing of Personal Data by Health Insurance Companies (in Dutch: Gedragscode Verwerking Persoonsgegevens Verzekeraars). This Code of Conduct is applicable in this case. The researchers had a mandate from the Board Committee of Health Insurance Companies in the Netherlands to process the data for this specific study. The mandate complies with the General Data Protection Regulation (GDPR), the European Union's data protection law. Working with claims data covered by this mandate exempts authors from the requirement of patient informed consents.

Population

Claims data was extracted from the Vektis data bases of specialist medical care and pharmaceutical care for all Dutch persons who underwent primary LDH surgery in the period from July 1, 2015 to June 30, 2016. Vektis has a nationwide almost complete coverage of all medical care claims that are reimbursed by insurance companies. Each patient in the database is unique, based on the social security number and the delivered healthcare can be tracked over years using an encrypted ID.

Each patient who underwent LDH surgery in this period and had no previous hernia surgery up to 24 months earlier was defined as a primary LDH patient and included in the study. All diagnostic descriptions in which LDH and lumbosacral discotomy occur, were included. No distinction was made between open procedures and percutaneous transforaminal endoscopic discectomies (PTED).

Patients were followed up until 18 months after surgery. An opioid-using patient is defined as a patient for whom a prescription for an opioid substance has been claimed at least once during the relevant postoperative period. An opioid prescription is defined as a prescription with Anatomic Therapeutic Chemical Classification (ATC) codes from the therapeutic subgroup N02A (opioids). All opioid users are included regardless of whether or not they used the opioids for primary LDH surgery.

Outcome Measures

Based on the international ICHOM set of Low Back Pain, a selection of undesirable patient outcomes could be determined on the basis of claims data.[7,8] Three relevant outcomes were investigated: (1) Re-operations within 18 months, (2) Nerve root blocks within 12 months and (3) Opioid use in the timeframe 6-12 months after surgery.

In order to get one overall measure per hospital a combined outcome measure was composed of these 3 separate outcome measures. Each patient with at least one of these outcome measures counts for the combined outcome measure.

Statistical Analysis

For each of the 3 outcome measures and the combined outcome measure the percentage per hospital was calculated with corresponding 95% confidence interval (95% CI) according to the Agresti-Coull method and depicted in the figures.[9] Hospitals with less than 5 LDH operations in the study period were included in the analyses, but not shown in the graphs. To determine whether there was a volume effect in the combined outcome measure, unpaired t-tests were performed in which hospitals were divided into a high- or a low-volume group. In total, 3 t-tests were performed, each at a different volume threshold. Threshold-values 100,150 and 200 patients per year were used to distinguish between the high and low volume hospitals.

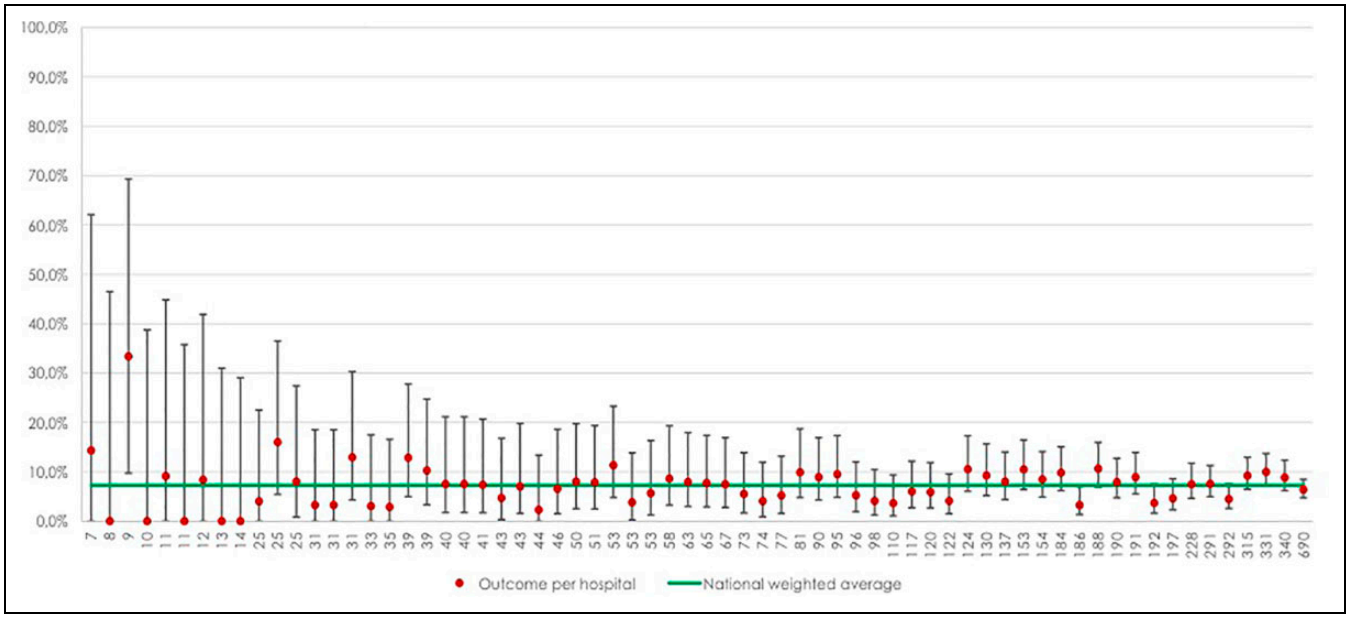

Figure 1. Percentage of patients with reoperation within 18 months after primary lumbar disk herniation surgery per hospital. The number of yearly surgical procedures in the hospitals are shown on the x-axis. The percentage of patients with reoperations is shown on the y-axis. The bars represent the 95% confidence interval. The horizontal line represents the national weighted average of patients with reoperations.

Results

In total, 7,067 HNP patients were found in the database. For 172 (2.4%) patients the intervention was not the initial LDH operation; these patients were excluded. Therefore, the study population included 6,895 primary LDH patients (52.8% men and 47.2% women; mean age 47.3 years (SD 13.6)). In total 70 hospitals performed primary LDH surgery; 47 of the 70 hospitals performed less than 100 primary LDH operations and 30 institutions performed less than 50, and 4 less than 5. Twenty-eight patients (0.4%) died during the study period; these patients were not excluded from the study.

Reoperation

The weighted mean reoperation percentage after 12 months was 5.6% and after 18 months 7.3%, varying from 0 to 33% (see Figure 1). In one hospital the 95% CI was above this weighted average. In that hospital 3 out of 9 (33.3%) operated patients underwent reoperation. For one hospital the 95% CI was below the weighted average. In this hospital only 6 out of 186 (3.2%) patients underwent reoperation. A total of 63 hospitals (90%) performed reoperations during the study period. About 80% of the reoperations was performed in the hospital of primary operation.

Nerve Root Blocks

The percentage of patients with nerve root block intervention within 12 months after primary LDH was 6.7% (range between hospitals 0-23%; see Figure 2). For 5 hospitals, the 95% CI around the point estimate was above this weighted average. In these hospitals nerve root blocks were performed in 12.3% of patients in the first year after LDH surgery. In 4 out of these 5 hospitals 25 to 43 primary LDH surgeries per year only were performed.

Four other hospitals had a 95% CI below the weighted average. These hospitals had a yearly volume of more than 130 primary LDH surgeries and nerve root blocks were performed in 2.5% of their patients.

Opioid Use

Within 6-12 months after surgery, the weighted grand mean of all opioid use was 15.6% (see Figure 3; range between hospitals 0-38%). For 6 hospitals, the 95%CI was above the weighted average, 25.1% of patients from these 6 hospitals used opioids 6-12 months after surgery. Five of these 6 hospitals had a volume lower than 100 and one had a volume 228 primary LDH surgeries. For 4 hospitals (all performing more than 120 primary LDH surgeries), the 95% CI was below the weighted average. The opioid use within 6-12 months after primary LDH surgery for all patients in these hospitals was 9.9%.

Combined Outcome Measure

After surgery 23% of the patients had at least one of the 3 outcomes mentioned (see Figure 4; range between hospitals 0-50%). For 5 hospitals, the 95% CI was above the weighted average; volumes of these 5 hospitals varied between 25 and 154 surgeries per year, and 33.6% had at least one of the 3 undesirable outcomes. Four other hospitals showed a 95% CI below the weighted average. Of these, 17.5% of the patients had at least one of the 3 undesirable outcomes. These hospitals performed more than 120 primary LDH operations per year.

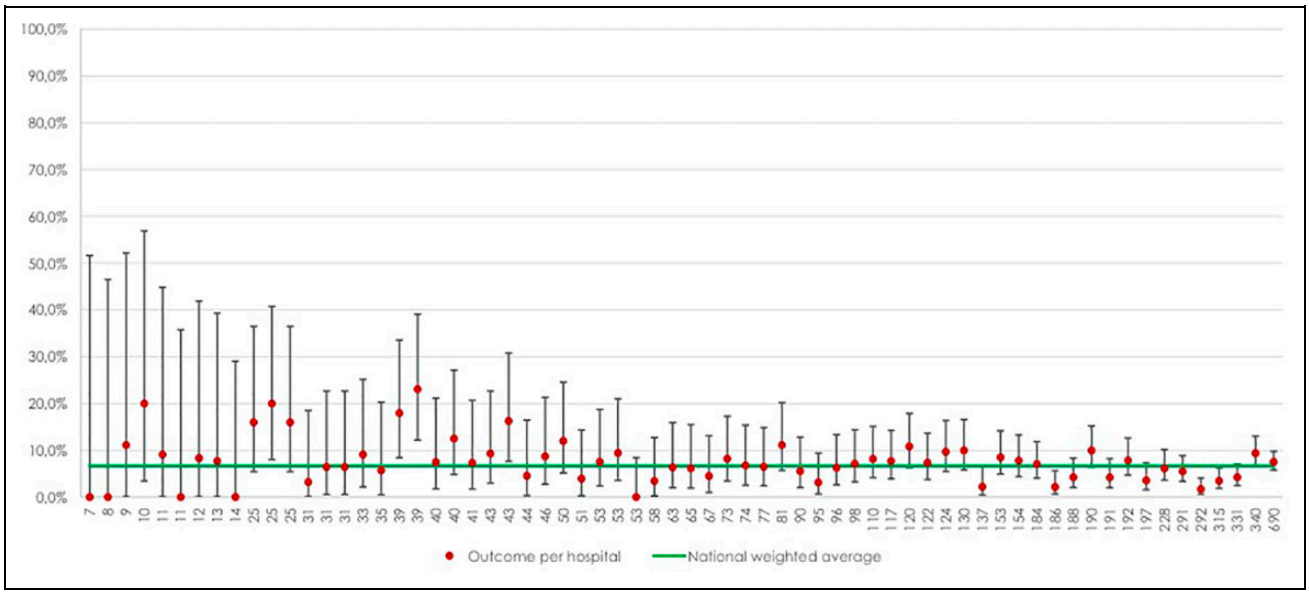

Figure 2. Percentage of patients with nerve root block within 12 months after primary lumbar disk herniation surgery per hospital. The number of yearly surgical procedures in the hospitals are shown on the x-axis. The percentage of patients with nerve root block is shown on the y-axis. The bars represent the 95% confidence interval. The horizontal line represents the national weighted average of patients with nerve root block procedures.

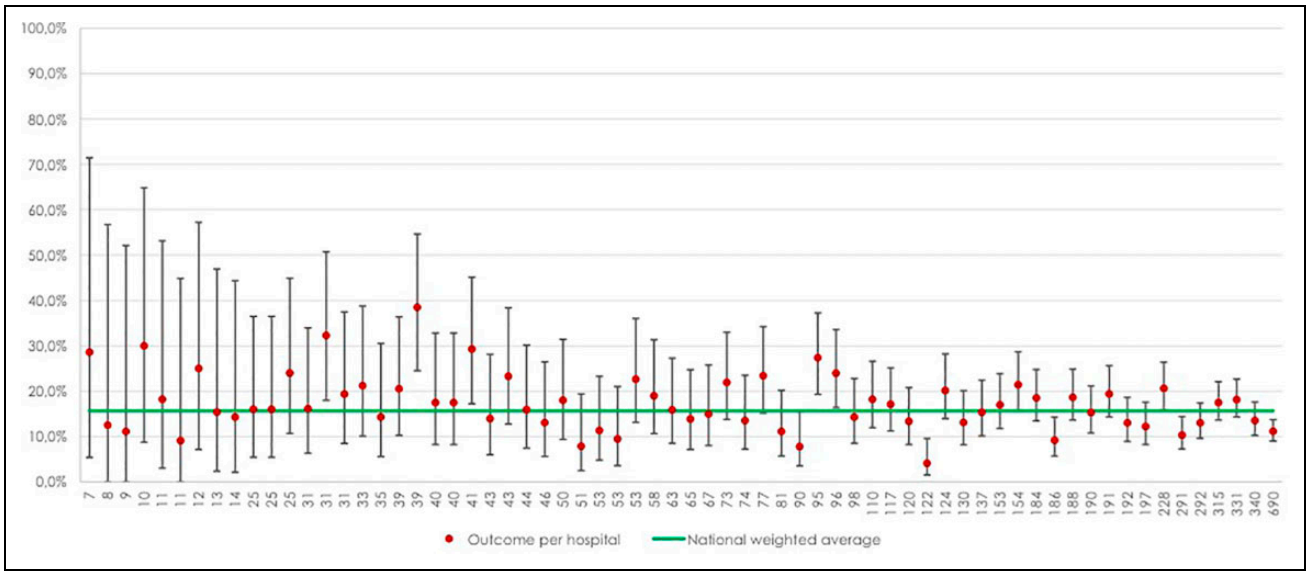

Figure 3. Percentage of patients with opioid use within 6-12 months after primary lumbar disk herniation surgery per hospital. The number of yearly surgical procedures in the hospitals are shown on the x-axis. On the y-axis the percentage of patients using opioids and its 95% confidence interval are shown. The horizontal line represents the national weighted average of patients with opioids.

The results indicate a trend of a volume effect on this undesired outcome, however no statistically significant volume effect (volume of primary operated patients) was found. The *P*-values at the volume thresholds of 100,150 and 200 were: 0.078, 0.129, and 0.114, respectively.

Discussion

This is to our knowledge the first study describing undesirable outcomes in terms of reoperation, nerve root blocks, opioid use and a combined outcome measure after primary LDH surgery based on national registration of claims data from all Dutch health insurance companies. Nearly a quarter of all patients had an undesirable outcome. This means that they underwent at least one of the following: a subsequent operation for LDH, needed prolonged opioid use and/or received invasive pain treatment through nerve root block. It is also remarkable that a large variation exists between the different hospitals for all outcome measures.

The results of this study are consistent with those from other studies that report reoperation percentages ranging from

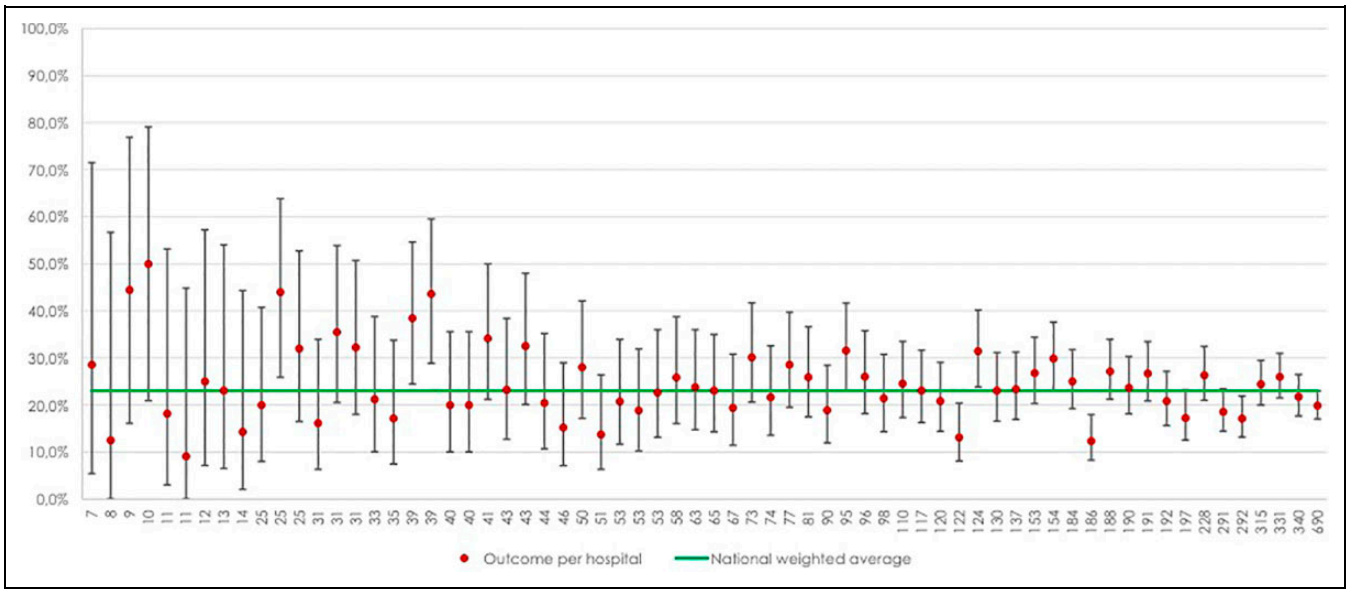

Figure 4. Percentage of patients with reoperation within 18 months and/or nerve root block within 12 months and/or opioid use within 6-12 months after primary lumbar disk herniation surgery per hospital. The number of yearly surgical procedures in the hospitals are shown on the x-axis. On the y-axis the percentage of patients with one or more undesirable outcome(s) and its 95% confidence interval are shown. The horizontal line represents the national weighted average of the combined outcome measure.

0.6-24%.[10-12] The broad ranges of registered reoperations may be due to definition and registration differences, different follow up periods or even differences in hospital care. The percentage of reoperations increases within the years after surgery. The current study also confirms these literature data. In a large Finnish study with 25,366 patients, 12% had at least one reoperation within 4 years after LDH surgery.[13] Another study showed that 71% of reoperations are performed on the same side and at the same level as the primary LDH surgery.[12] It is also known that a recurring HNP at the exact same position has a shorter period of time from primary surgery to reoperation than an HNP arising at a different location.[10]

Prolonged or even chronic pain can develop after diverse surgical procedures.[14] Although evidence is available for chronic pain development after lumbar spine surgery in general, there is to our knowledge currently no evidence available on chronic pain development after LDH surgery. Pain is a very common complaint and most patients experience less pain improvement than was anticipated pre-operatively. It is known that only 17% of patients indicate that the pre-operatively expected pain improvement is actually what they experience within 2 years after lumbar surgery.[15] In this study a fairly high percentage of patients was found who had a post-operative nerve root block (6.7%) and / or used opioids (15.6%). Eight out of 10 post-operative opioid users also used opioids before surgery when we checked this. Due to the lack of literature on this topic we cannot relate these findings to international results or studies.

Remarkable findings in this study were the wide variations in the number of primary LDH surgeries per hospital per year and the variation in outcomes between the different hospitals. The variation in outcomes was particularly large in hospitals with a low number of primary LDH per year (Figures 1–4), but this may be due to the low numbers. An analysis of results over several years may clarify whether there is a relationship between the number of primary LDH surgeries per year and (undesirable) outcomes. In this study we did not find such a relation. However, we saw that with nerve root blocks or opioid use and for the combined outcome measure, some hospitals with relatively low numbers of primary LDH showed higher percentages of undesirable outcomes (Figures 2–4). An analysis over several years might be needed to address the question whether a relationship exists, and to establish a minimum yearly volume of primary lumbar disk hernia surgeries. Such a reference volume value does not exist (yet) in the Dutch health care.

Clinical outcomes are important in the context of value-based health care and patient- and outcome-oriented care.[16] Internationally, standard sets of outcome measures for patients with LDH are known. In 2012, the International Consortium for Healthcare Outcomes (ICHOM) developed a standard set of outcome indicators for "Low Back Pain," including LDH as an indication area. This standard set contains the patient-reported outcome domains: pain, functioning, quality of life, work status and use of pain medication. In addition, this set contains the outcome domains reported by the physician: mortality, complications and re-operations.[8] In this study, some of these outcome measures were evaluated. However, in order to gain full insight into the quality of surgical care, all patient-related (clinical and patient-reported) outcome domains are important, i.e. "what matters to patients."[8,17] A national spine registry currently exists in which these measures are implemented. In the future, it would be interesting to combine the claims data with these outcome registration data, as to gain full

insight into the quality and value of the surgical care provided to patients with HNP.

In this study the outcome measures of surgically treated patients were investigated. It is still unknown how the conservatively treated group performs. Previous studies showed that pain was relieved more quickly in patients who received surgical treatment, but that difference between surgery and conservative treatment groups was no longer present after 3 months. The risk for complication is lower for conservative treatment of LDH than for surgery and conservative treatment is preferred for the vast majority of patients.[18] To compare the outcomes of the surgically treated group of patients with those in the conservatively treated group a follow-up study is necessary.

Strengths and Limitations

This study is based on national claims data. Only patient outcomes available in the claims data could be included in the analyses. Therefore, any beneficial surgery outcome, like fast recovery and return to work, could not be evaluated. Also, outcome domains relevant to the patient, such as the degree of pain experienced, quality of life and functioning, could not be investigated for the same reason. This means that studies based on claims data only, are not sufficient to evaluate the total quality of care. The strength of studies based on claims data is that very large numbers of patients can be analyzed and that patients can easily be followed over many years. Because nationwide data from all Dutch inhabitants is available, no inclusion or selection bias is present. Analyzing data from such a database is relatively cheap and an attractive alternative to evaluate treatments in daily practice.[19]

Several limitations should be mentioned. First, particular information about insured patients cannot be deduced from claims data. For example, it was not possible to determine whether or not opioid use was related to pain due to surgery and whether the patient actually took the medication. Combining the health insurers' claims data with patient-related outcome measures from the national spine registry could provide a more detailed insight. Secondly, comparing hospitals was not the aim of this study. This study's goal was to gain insight and to describe patient-relevant outcomes after primary LDH. Therefore, a case mix correction per hospital was not applied. In the third place, due to the use of claims data an anatomical location of the re-intervention level is unknown. In our study, in accordance with literature, all reoperations were combined. Fourth, laminectomy was excluded because it is not used for LDH surgery only. By excluding laminectomy, a more homogeneous population was defined, but this may have resulted in underestimating the number of patients with primary lumbar disk hernia surgery and the number of re-operations.

Conclusion

In conclusion, we found that about 1 out of 4 patients after primary lumbar disk herniation surgery had a serious complication in the first follow up year that prompted further medical treatment. There is a wide variation in registered complication rates between hospitals with a trend that supports concentration of lumbar disk herniation care. Studies on factors that predict postoperative complications and on factors that prevent these complications are needed.

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Declaration of Conflicting Interests

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ORCID iDs

Maike H. J. Schepens, PharmD, MBA https://orcid.org/0000-0003-4934-398X
Miranda L. van Hooff, PhD https://orcid.org/0000-0001-5313-6436

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