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ORIGINAL ARTICLE

Microdiscectomy for sciatica: reality check study of long-term surgical treatment effects of a Lumbosacral radicular syndrome (LSRS)

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Abstract

Purpose It remains unclear whether the long-term results of RCTs regarding the outcome of microdiscectomy for lumbosacral radicular syndrome (LSRS) are generalizable. The purpose of this study was to determine the external validity of the outcome preseneted in RCTs after microdicectomy for LSRS in a patient cohort from a high-volume spine center.

Methods Between 2007 and 2010, 539 patients had a single level microdiscectomy for MRI disk-related LSRS of whom 246 agreed to participate. Questionnaires included visual analogue scores (VAS) for leg pain, RDQ, OLBD, RAND-36 and Likert scores for recovery, leg and back pain. Lumbar re-operation(s) were registered.

Results Mean age was 51.3, and median time of follow-up was 8.0 years. Re-operation occurred in 64 (26%) patients. Unfavorable perceived recovery was noted in 85 (35%) patients, and they had worse leg and back pain than the 161 (65%) patients with a favorable recovery: median VAS for leg pain 28/100 mm versus 2/100 mm and median VAS for back pain 9/100 mm versus 3/100 mm, respectively. In addition, the median RDQ and OLBD scores differed significantly: 9 vs 3 for RDQ and 26 vs 4 for OLBD, respectively ($p < 0.001$).

Conclusion In this cohort study, the long-term results after microdiscectomy for LSRS were less favorable than those obtained in RCTs, possibly caused by less strict patient selection than in RCTs. Our findings emphasize that patients, who do not meet the same inclusion criteria for surgery as in RCTs, should be informed about the chances of a less favorable result.

Keywords Spine · Neurosurgery operative procedure · Discectomy · Treatment outcome

Introduction

In recent years, some well-conducted, randomized controlled trials (RCTs) concerning the (long-term) outcome of microdiscectomy for lumbosacral radicular syndrome (LSRS) have been published [1–4]. The Sciatica trial showed that 79% of patients had a favorable outcome five years after conventional microdiscectomy, as perceived by themselves [1]. Subsequently, an RCT comparing tubular to conventional microdiscectomy for the treatment of sciatica in a more general population showed serious persistent symptoms in 25% of the patients five years after surgery [2]. The reoperation rates in these studies were 6% and 13%, respectively, and a large variation in reoperation rates does exist after lumbar discectomy [5].

As randomized controlled studies only enroll patients using strict criteria, the reported results might not mirror the reality of day-to-day treatment of LSRS patients in spine centers throughout the world. To study this so-called external validity, we studied the long-term outcome in a consecutive cohort of patients who had undergone a lumbar microdiscectomy in a major spine center in the largest city and capital of the Netherlands.

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Materials and methods

Study population

All 539 patients, between January 2007 and January 2010 in the OLVG, the largest community hospital and spine center in Amsterdam (the Netherlands) who consecutively received microdiscectomy treatment because of, at least, six weeks of leg pain, which was monoradicular, single level and where the dermatome of LSRS matched the level and was disk related confirmed on the MRI, were eligible for inclusion. Patients who received a prior lumbar operation and patients with difficulty understanding the Dutch language were excluded.

In 2016, 510 patients were asked by telephone interview to participate in this study, and when they agreed, a questionnaire with informed consent letter was sent. A second and a third reminder were sent and a second telephone call was performed, if there was no reply after three months. The 246 (46%) patients who provided informed consent were used for analysis (Fig. 1). The study protocol was approved by the Institutional Medical Ethics Committee.

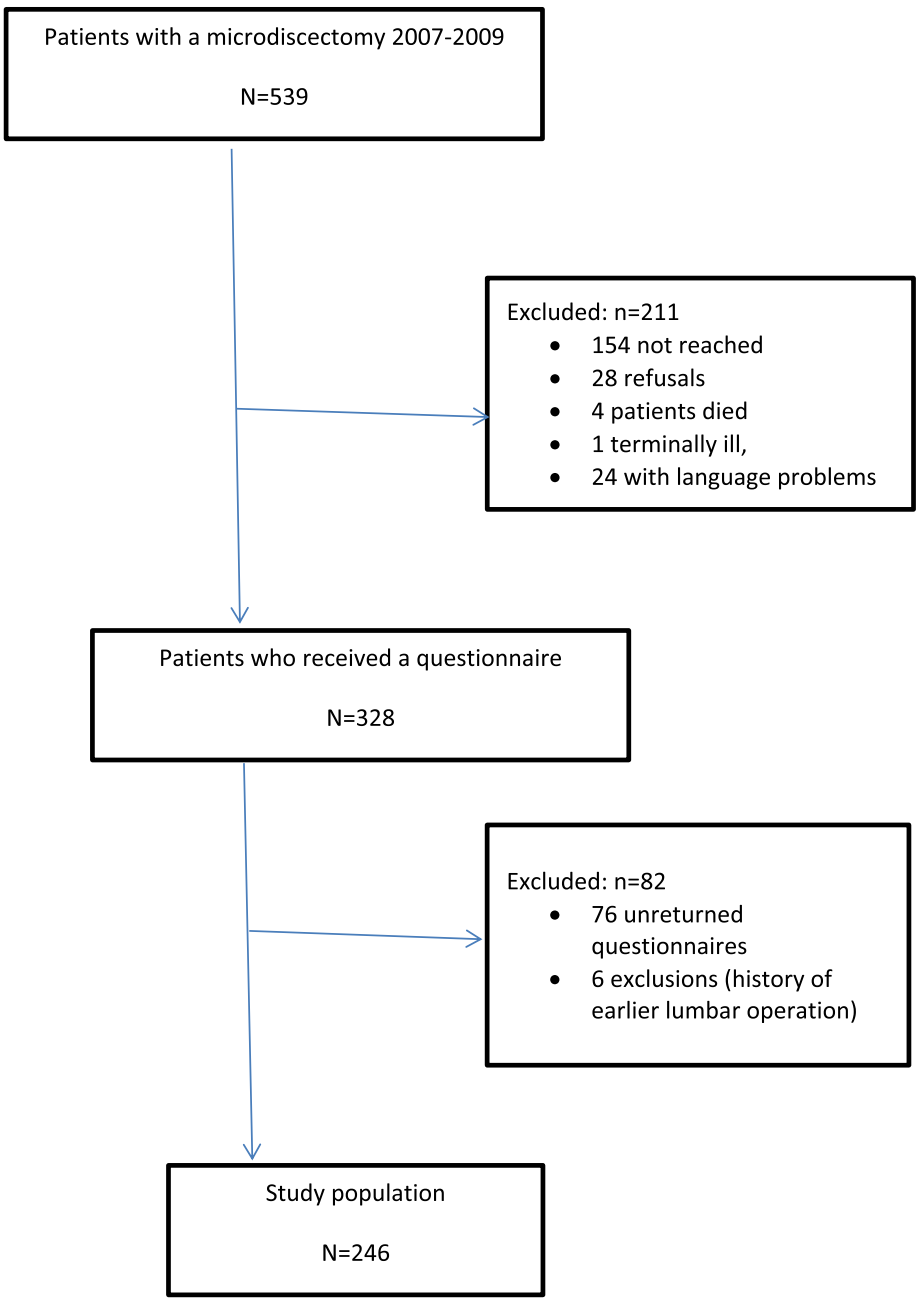

Fig. 1 Flowchart

Data collection

Baseline characteristics (age, gender, Body Mass Index (BMI), smoking, Diabetes Mellitus and level of herniation) were recorded from the original medical records and referral letters. Follow-up periods and whether there had been a re-operation were retrieved from the original medical records and checked with the answers in the questionnaires.

The questionnaires included the visual analogue scores (VAS) for leg and back pain (0-100 mm)[6]; the Roland-Morris Disability Questionnaire modified for Sciatica (RDQS): a sciatica-specific disability scale that measures functional status in patients with pain in the leg and/or back (scores range from 0 to 23, with higher scores indicating less function by higher lumbar spine-related disability) [7]; the Oswestry low back disability questionnaire (OLDB) of which the Oswestry Disability Index (ODI) can be derived (0% –20% indicates minimal disability, 21%–40% moderate disability, 41%–60%: severe disability, 61%–80%: crippling back pain and 81%–100% means these patients are either bed-bound or have an exaggeration of their symptoms)[8]; the RAND-36 measure of health-related quality of life [9]; and the seven-point Likert scale for general perceived recovery, leg pain and back pain, ranging from complete recovery or no pain (1) to worse than ever (7). The questionnaires also included a question about any lumbar re-operation(s), in the same hospital or elsewhere.

The collected data were coupled to a unique identification code and recorded in OpenClinica, a web-based software tool [10] designed to capture clinical study data, in agreement with applicable regulations regarding privacy of study subjects.

Surgical technique of the primary surgery

Patients were operated through a 2.5–5 cm midline incision via a unilateral or bilateral approach under general or epidural anesthesia in a jackknife position, by either of four experienced (5–20 years) neurosurgeons. Surgical procedures were carried out using a headlight-loupe magnification (2.5-3x). A small laminotomy or medial facetectomy was performed when needed. The compressed nerve root was identified and carefully mobilized, and the herniated disk or sequester was removed with rongeurs to free the nerve. Any loose fragments were removed from the disk space to prevent re-herniation, but no aggressive discectomy was attempted. Incidental perioperative durotomy was closed with 6/0 polypropylene sutures and/or with Tachosil®, or a subcutaneous-derived fat patch. The wound was closed in two layers, the skin with intra- or subcutaneous sutures.

Statistical analysis

Continuous variables were tested with the Shapiro–Wilk test for normal distribution (values > 0.9 are considered as normally distributed). Normally distributed continuous variables are represented as a mean with standard deviation. Continuous variables that are not normally distributed are represented as median with an interquartile range (IQR; 25%–75%). Normally distributed variables were tested with the Student's T test, and data that were not normally distributed were tested with the Mann–Whitney U test. Categorical variables were tested with the Fisher's exact test. Likert scores were dichotomized into favorable (score 1 = complete and 2 = nearly complete recovery) and unfavorable outcome (score 3 = some recovery to score 7 = worse than ever). Values of $P < 0.05$ were considered statistically significant. Data were exported from OpenClinica into Statistical Package for the Social Sciences Software (IBM SPSS 25; IBM Corp., Armonk, New York, USA) for statistical analysis.

Results

Study population

The baseline characteristics of all 246 patients (mean age 51.3 years (SD 9.8); 56% female) are presented in Table 1. Median time of follow-up was 8.0 years [IQR 7.0–8.0].

Table 1 Baseline characteristics of 246 patients who had had a microdiscectomy for a lumbar root nerve compression 2007–2010

Characteristic	
Mean age in years (SD)	51.3 (9.8)
Female (%)	136 (55)
Mean BMI[#] (SD)	26.1 (3.9)
Active smoker[$], n (%)	59 (24)
Median follow-up in years [IQR}	8 [7, 8]
DM[$], n (%)	8 (3)
Level of herniation[&], n (%)	
L2-L3	2 (0.8)
L3-L4	11 (4.5)
L4-L5	86 (35.0)
L5-S1	109 (44.3)

BMI Body Mass Index

[#]data from 63 patients missing; [$]data from 61 patients missing; [&]data from 38 patients missing

Early re-operations because of perioperative complications

Five (2%) patients had a re-operation for of an immediate postoperative complication (three for persistent cerebrospinal fluid leakage and two for postoperative epidural hematoma with cauda equina syndrome).

Re-operations because of recurrent sciatica

Of 246 patients, 64 (26%) had at least one lumbar re-operation because of recurrent sciatica during long-term follow-up and 24 (10%) patients two or more reoperations. Forty-seven (19%) patients had a re-operation at the same level and 37 (15%) a same side, same level, re-discectomy ("true" recurrence). Seven patients had a re-operation at a different level, and in 10 patients, the level of reoperation could not be retrieved. The median time window between first and reoperation was 20.5 months (IQR 5.8–51.3).

Outcome scores at follow-up

All patients

After a median follow-up of eight years, 84 patients (34%) reported an unsatisfactory outcome (Likert score 3–7) concerning the general perceived recovery and 161 patients (66%) reported a satisfactory outcome (Likert score 1 or 2 (Table 2)).

An unfavorable outcome with respect to perceived leg pain was present in 68 patients (28%) and a favorable outcome in 173 (72% (Table 3)). Ninety-one patients (38%) reported an unfavorable outcome with respect to perceived back pain and 151 a favorable outcome (62% (Table 4)).

For the total group, the median VAS score for leg and back pain was 3.5 mm [IQR 1–20] and 7.5 mm [IQR 2–30], respectively, at the median follow-up of eight years. The median total score of the RDQ was 2 [IQR 0–8] and for the Oswestry 8 [IQR 2–22] (Table 2). For the median RAND 36 scores of the total group, see Table 2.

The differences in the median VAS for leg and back pain in patients with an unfavorable general perceived perception of recovery versus a favorable perceived perception of general recovery were both significant, showing more perceived pain in the unfavorable group than in the favorable group (both $p < 0.001$, 28/100 mm (IQR 7–53) vs 2/100 mm (IQR 0–5) for leg pain and 9/100 mm (IQR 5–13.8) vs 3/100 mm (IQR 1–11) for back pain). In addition, the median RDQ and OLBD scores were significantly higher, indicating more disability in the group of patients with an unfavorable perceived perception of recovery (9 (IQR 5–13.8) vs 3 (IQR 1–11) for RDQ and 26 (IQR 16–39.5) vs 4 (IQR 0–10 for OLBD). All the scores of the RAND 36 were significantly lower in the unfavorable group (Table 2).

Patients with unfavorable outcome concerning leg pain and back pain had also significantly higher pain scores for leg and back pain, higher disability scores (RDQ and Oswestry) and lower RAND 36 scores compared to patients with favorable outcome (Tables 3 and 4).

Table 2 Dichotomized long-term outcome scores for general perceived recovery in 246 patients who had had a microdiscectomy for a lumbar root nerve compression

	Total [IQR] ($n=246$)	Favorable outcome[$,&] ($n=161$; 66%)	Unfavorable outcome[$,&,$] ($n=84$; 34%)	p value
median VAS leg pain	3.5 [1–20]	2 [0–5]	28 [7–53]	< 0.001
median VAS for back pain	7.5 [2–30]	3 [1–11]	9 [5–13.8]	< 0.001
median RDQ score	2 [0–8]	1 [0–3]	9 [5–13.8]	< 0.001
median RAND 36	–	–	–	
-Bodily pain	77.6 [57.1–100]	89.8 [77.6–100]	44.9 [33.2–66.8]	< 0.001
-Physical functioning	80 [61.3–95]	90 [75–100]	60 [36.3–75]	< 0.001
-Social functioning	87.5 [62.5–100]	100 [87.5–100]	62.5 [50–87.5]	< 0.001
-Physical role	100 [25–100]	100 [100–100]	25 [0–75]	< 0.001
-Emotional role	100 [66.7–100]	100 [100–100]	100 [16.7–100]	< 0.001
-Mental health index	80 [64–88]	80 [72–88]	72 [48–84]	< 0.001
-Vitality	65 [45–75]	70 [56.3–75]	50 [35–65]	< 0.001
-General health perception	70 [50–81.3]	75 [62.5–85]	45 [30–65]	< 0.001
median OLBD	8 [2–22]	4 [0–10]	26 [16–39.5]	< 0.001

[$]good and poor outcome are based on a seven point Likert score for global perception of recovery (scores 1–2: good outcome, scores 3–7: poor outcome); &:Likert score for global perception of recovery is missing in $n=1$

OLBD Oswestry low back disability questionnaire; *RDQ*: Roland Disability Questionnaire; *IQR*: interquartile range

Table 3 Dichotomized long-term outcome scores for leg pain in 246 patients who had had a microdiscectomy for a lumbar root nerve compression

	Total ($n=246$)	Favorable outcome[$,&] ($n=173$; 72%)	Unfavorable outcome[$,&$] ($n=68$; 28%)	p value
median [IQR] VAS leg pain	3.5 [1–20]	2 [0–5]	37 [20–61.5]	< 0.001
median [IQR] VAS for back pain	7.5 [2–30]	3 [1–15]	39.5 [20–65.8]	< 0.001
median [IQR] RDQ score	2 [0–8]	1 [0–3]	9.5 [6–15.8]	< 0.001
median [IQR] RAND 36	–	–	–	
-Bodily pain	77.6 [57.1–100]	89.8 [77.6–100]	44.9 [25–57.1]	< 0.001
-Physical functioning	80 [61.3–95]	90 [75–95]	55 [35–73.8]	< 0.001
-Social functioning	87.5 [62.5–100]	100 [75–100]	62.5 [40.6–87.5]	< 0.001
-Physical role	100 [25–100]	100 [75–100]	25 [25–75]	< 0.001
-Emotional role	100 [66.7–100]	100 [100–100]	100 [0–100]	< 0.001
-Mental health index	80 [64–88]	80 [68–88]	72 [48–84]	< 0.001
-Vitality	65 [45–75]	65 [55–75]	45 [35–65]	< 0.001
-General health perception	70 [50–81.3]	75 [60–85]	50 [30–65]	< 0.001
median [IQR] OLBD	8 [2–22]	4 [0–10]	29 [18.5–43.5]	< 0.001

[$]good and poor outcome are based on a seven point Likert score for leg pain (scores 1–2: good outcome, scores 3–7: poor outcome); &:Likert score for leg pain is missing in n = 5

OLBD Oswestry low back disability questionnaire; *RDQ*: Roland Disability Questionnaire; *IQR*: interquartile range

Table 4 Dichotomized long-term outcome scores for back pain in 246 patients who had had a microdiscectomy for a lumbar root nerve compression

	Total ($n=246$)	Favorable outcome[$,&] ($n=151$; 62%)	Unfavorable outcome[$,&$] ($n=91$; 38%)	p value
median [IQR] VAS leg pain	3.5 [1–20]	2 [0–5]	23 [4–49]	< 0.001
median [IQR] VAS for back pain	7.5 [2–30]	3 [1–6]	37 [20.5–63]	< 0.001
median [IQR] RDQ score	2 [0–8]	0 [0–2]	9 [4–13]	< 0.001
median [IQR] RAND 36	–	–	–	
-Bodily pain	77.6 [57.1–100]	89.8 [77.6–100]	57.1 [40–77.6]	< 0.001
-Physical functioning	80 [61.3–95]	90 [75–100]	65 [40–80]	< 0.001
-Social functioning	87.5 [62.5–100]	100 [87.5–100]	62.5 [50–87.5]	< 0.001
-Physical role	100 [25–100]	100 [100–100]	25 [0–75]	< 0.001
-Emotional role	100 [66.7–100]	100 [100–100]	100 [33.3–100]	< 0.001
-Mental health index	80 [64–88]	84 [72–92]	72 [52–81]	< 0.001
-Vitality	65 [45–75]	70 [58.8–75]	52.5 [38.8–65]	< 0.001
-General health perception	70 [50–81.3]	75 [60–85]	50 [35–70]	< 0.001
median [IQR] OLBD	8 [2–22]	2 [0–10]	24 [16–36]	< 0.001

[$]good and poor outcome are based on a seven point Likert score for back pain (scores 1–2: good outcome, scores 3–7: poor outcome); &:Likert score for back pain is missing in $n=4$

OLBD Oswestry low back disability questionnaire; *RDQ*: Roland Disability Questionnaire; *IQR*: interquartile range

Patients with early re-operations because of perioperative complications

Outcome scores were available for four of the five patients. Two had an unsatisfactory outcome with respect to general perceived recovery, three had an unsatisfactory outcome with respect to leg pain, and all patients had an unfavorable outcome with respect to back pain (Tables 5, 6 and 7).

Patients with re-operation because of recurrent sciatica

In patients who had been re-operated because of recurrent sciatica, the rate of unfavorable outcome with regard to perceived recovery was higher than in those without a re-operation (57% and 25%, respectively; $p<0.001$, Table 5). In addition, the degree of satisfaction concerning leg pain was much lower in the re-operated group than

Table 5 Dichotomized long-term outcome scores for general perceived recovery in patients with or without re-operation

	Total	Outcome		*p* value
		Favorable[$,&]	Unfavorable[$,&]	
All re-operations, n (%)	69	29 (43)	39 (57)	<0.001[1]
Early re-operation for CSF leakage or cauda syndrome, n (%)	5	2 (50)	2 (50)	0.277[1]
Re-operations for recurrent sciatica, n (%)	64	27 (42)	37 (58)	<0.001[1]
No re-operation, n (%)	177	132 (75)	45 (25)	–

[$]good and poor outcome are based on a seven point Likert score for general perceived recovery (scores 1–2: good outcome, scores 3–7: poor outcome); &:Likert score for back pain is missing in $n=1$; [1] compared to group without re-operation ($n=177$)

Table 6 Dichotomized long-term outcome scores for leg pain in patients with or without re-operation

	Total	Outcome		*p* value
		Favorable[$,&]	Unfavorable[$,&]	
All re-operations, n (%)	69	32 (48)	35 (52)	<0.001[1]
Early re-operation for CSF leakage or cauda syndrome, n (%)	5	1 (25)	3 (75)	0.027[1]
Re-operations for recurrent sciatica, n (%)	64	31 (49)	32 (51)	<0.001[1]
No re-operation, n (%)	177	141 (81)	33 (19)	–

[$]good and poor outcome are based on a seven point Likert score for leg pain (scores 1–2: good outcome, scores 3–7: poor outcome); &:Likert score for back pain is missing in n = 5; [1] compared to group without re-operation ($n=177$)

Table 7 Dichotomized long-term outcome scores for perceived back pain in patients with or without re-operation

	Total	Outcome		*p* value
		Favorable[$,&]	Unfavorable[$,&]	
All re-operations, n (%)	69	25 (37)	42 (63)	<0.001[1]
Early re-operation for CSF leakage or cauda syndrome, n (%)	5	0 (0)	4 (100)	0.007[1]
Re-operations for recurrent sciatica, n (%)	64	25 (40)	38 (60)	<0.001[1]
No re-operation, n (%)	177	126 (72)	49 (28)	–

[$]good and poor outcomes are based on a seven point Likert score for back pain (scores 1–2: good outcome, scores 3–7: poor outcome); &:Likert score for back pain is missing in $n=4$; [1] compared to group without re-operation ($n=177$)

in the non-re-operated group (48% and 81%, respectively, $p<0.001$, Table 6). Concerning perceived low back pain, the number of patients with an unfavorable result (some recovery to worse than ever, concerning back pain) was higher in the re-operated group compared to the patients without a re-operation (63% and 28%, respectively, $p<0.001$, Table 7).

Discussion

Our study, of a large, single center, patient population treated with a microdiscectomy for LSRS caused by a lumbar disk herniation, shows an unfavorable outcome in 35% and a re-operation rate for recurrent sciatica in 26% of patients after eight years follow-up. The number of patients with a favorable outcome was significantly lower in the re-operated group than in the non-re-operated group.

Limited external validity of RCT's is a well-known phenomenon ascribed not only to differences between trial protocol and routine practice, differences between health care systems in different countries, but also to selection of participating centers, participating clinicians and selection of patients [11–13]. This could well explain the considerably less favorable results in our patient cohort. Very strict patient selection, or selective inclusion bias, often seen in randomized clinical trials in all areas of medicine and surgery, may also be deduced from the number of eligible patients reported: In our study, 539 consecutive patients in one spine

center over a period of three years (180/year/center) were compared to 599 eligible patients in nine participating hospitals over a period of 26 months (on average 31/year/center) in the Sciatica trial and to 1991 eligible patients in 13 centers over a period of 56 months (on average 33/year/center) in the SPORT trial [14, 15].

A possible inferred conclusion might be that inclusion criteria within these RCT's strictly follow the guidelines, namely to only perform surgery in a specific clinical syndrome, i.e., radiating pain in a dermatome correlating with MR-scan proven nerve root compression.

One therefore may surmise that the lower overall results could, in part, be caused by a more liberal indication for surgery. Although it is inevitable that some treatment variation will exist between surgeons and between centers, there is, however, no reason to expect that treatment variation between experienced spine surgeons would vary so much as to explain the lower overall results. Moreover, our results are comparable with other cohort studies such as the main lumbar spine study, which also reported a satisfactory recovery rate of only 69% (56% if the same strict criteria which we used for favorable outcome were applied (complete or nearly complete recovery)) [16], as well as the experience of perceived lower outcome results outside RCT's by the senior authors. In addition, the reoperation rate because of true recurrences (same side, same level), which was 16% in our population, was much more comparable with cohort trials, such as the cohort study of the SPORT trial after eight years (15% [17]) and other cohort trials (13.8% with a range between hospitals from 8.1 to 24.5% after four years of follow-up [5]).

The low number of patients in our patient cohort with a favorable outcome in the re-operated group may also indicate that there is a declining benefit of repeated low back surgeries, but further prospective studies are necessary [18–21].

The results of our study emphasize the need to design more pragmatic RCTs, such as Bailey et al. [22], and supplement these clinical trial data with population-based research with more comparative effectiveness research designs, so our patients can be better informed about the true risks and benefits of a microdiscectomy for lumbar sciatica, as was already suggested by Martin et al.[5]. Ideally, an individual surgeon's outcome measurement might be used as a basis for counseling patients in the future, as the data would be without dispute and fully comparable. Limitations are the lack of prospective data collection with respect to predictive factors and the lack of a control group, necessitating comparison with historical data from other published studies. The response rate of our questionnaires was less than 50%, but this does not necessarily equate to a lower study validity, as we had no indication that patients with a favorable or an unfavorable outcome were less inclined to participate [23].

The strengths of our study are that it consists of a large cohort of patients from a real-world population in a large spinal referral center with a long follow-up period without any other selection bias.

Conclusion

This single-center, long-term cohort study for the treatment of lumbosacral radicular syndrome from a spine center in a large general city patient population shows considerably less favorable results than those reported in large randomized controlled trials concerning the operative treatment of sciatica. This understanding is very useful in counseling these patients prior to surgery.

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Declarations

Conflict of interest None.

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