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CLINICAL ARTICLE

Association of time to surgery with leg pain after lumbar discectomy: is delayed surgery detrimental?

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OBJECTIVE While it has been established that lumbar discectomy should only be performed after a certain waiting period unless neurological deficits are present, little is known about the association of late surgery with outcome. Using data from a prospective registry, the authors aimed to quantify the association of time to surgery (TTS) with leg pain outcome after lumbar discectomy and to identify a maximum TTS cutoff anchored to the minimum clinically important difference (MCID).

METHODS TTS was defined as the time from the onset of leg pain caused by radiculopathy to the time of surgery in weeks. MCID was defined as a minimum 30% reduction in the numeric rating scale score for leg pain from baseline to 12 months. A Cox proportional hazards model was utilized to quantify the association of TTS with MCID. Maximum TTS cutoffs were derived both quantitatively, anchored to the area under the curve (AUC), and qualitatively, based on cutoff-specific MCID rates.

RESULTS From a prospective registry, 372 patients who had undergone first-time tubular microdiscectomy were identified; 308 of these patients (83%) obtained an MCID. Attaining an MCID was associated with a shorter TTS (HR 0.718, 95% CI 0.546–0.945, p = 0.018). Effect size was preserved after adjustment for potential confounders. The optimal maximum TTS was estimated at 23.5 weeks based on the AUC, while the cutoff-specific method suggested 24 weeks. Discectomy after this cutoff starts to yield MCID rates under 80%. The 24-week cutoff also coincided with the time point after which the specificity for MCID first drops below 50% and after which the negative predictive value for nonattainment of MCID first surpasses ≥ 20%.

CONCLUSIONS The study findings suggest that late lumbar discectomy is linked with poorer patient-reported outcomes and that—in accordance with the literature—a maximum TTS of 6 months should be aimed for.

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KEYWORDS lumbar disc herniation; discectomy; time to surgery; early surgery; late surgery; surgical timing

Lumbar disc herniation (LDH) is one of the most common indications for surgery.[6] Although the standard management of LDH includes mainly conservative methods, some patients suffering from intractable pain or neurological deficits or those with prolonged symptoms profit from lumbar discectomy.[21–23,39] Several studies have been conducted to determine the ideal timing for discectomy, but not without controversy.[2,20–22,26,30] Symptomatic LDH is often not primarily of early surgical relevance if the surgery is not emergently indicated. It has been well-established that LDH patients with motor deficits or bladder disturbance should undergo early surgery to prevent permanent deficits.[20] However, the majority of LDH cases spontaneously improve through the course of time while applying conservative methods along with analgesia.[4,7,8]

As conservative treatments do not always lead to pain relief even in the long term, discectomy may be indicated.[26] For patients without indications for emergent surgery, however, evidence-based surgical timing remains diffi-

ABBREVIATIONS ASA = American Society of Anesthesiologists; BMI = body mass index; LDH = lumbar disc herniation; MCID = minimum clinically important difference; NPV = negative predictive value; NRS = numeric rating scale; ODI = Oswestry Disability Index; PPV = positive predictive value; PROM = patient-reported outcome measure; tMD = tubular microdiscectomy; TTS = time to surgery.

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cult. While it has been generally established that elective lumbar discectomy should not be performed within 6–8 weeks from symptom onset given the inherent likelihood of spontaneous LDH resorption, it is much less clear if there is an optimal maximum waiting time to surgery (TTS) that still allows for discectomy with a favorable patient-reported outcome.[1,2,24] Several studies have indicated that a longer symptom duration is generally associated with a worse surgical outcome, although the reports have often been based on retrospective data, have evaluated pre hoc–defined TTS cutoffs, or have not taken into account long-term patient-reported outcomes.[7,20,24,26,30]

The aim of this study was to determine the impact of TTS on patient-reported leg pain improvement 12 months after surgery based on data from a prospective registry of LDH patients and to derive a suggested optimal maximum TTS cutoff that still allows for surgery without inferior results.

Methods

Patient Population

From a prospective registry of a single Dutch short-stay spine center, we identified all patients who had undergone first-time tubular microdiscectomy (tMD) for LDH between December 2010 and February 2018. All tMD procedures were performed by a senior neurosurgeon (M.L.S.), as described previously.[35,36]

At the earliest, patients were considered for surgery 6 weeks after the onset of radiculopathy, unless intractable pain under analgesia, neurological deficits, or signs of cauda equina syndrome were present. No work restrictions were set preoperatively.[36] Because of local restrictive regulations by insurance companies, patients with an age > 80 years or with an American Society of Anesthesiologists (ASA) physical status > II or body mass index (BMI) > 33 kg/m^2 cannot be considered for elective short-stay spine surgery.[36] We also included only adult patients with a complete baseline and 12-month patient-reported outcome measure (PROM) record, without prior discectomy at the index level, and with complete TTS data.

Ethical Considerations

The prospective registry has been authorized by the local institutional review board (Medical Research Ethics Committees United), and this study was performed in accordance with the 2013 Declaration of Helsinki. Written informed consent was provided by all patients included in the registry. This paper was compiled according to the STROBE statement.

Outcome Measures

TTS was defined as the time range from the first occurrence of leg pain due to radiculopathy up to the time of surgery. It was composed of the patients' anamnestic history of pain in weeks at the initial visit plus the time from the initial visit to surgery. Months were converted to 4 weeks. All patients completed standardized questionnaires including a numeric rating scale (NRS) for leg and back pain severity, whose scores ranged from 0 to 10, and a validated Dutch version of the Oswestry Disability Index (ODI) for measuring functional disability. The NRS measuring leg pain severity at 12 months was defined as the primary endpoint.

Follow-up questionnaires including the same PROMs were automatically dispatched to the patients via email at 6 weeks and 12 months after surgery. In addition, reoperations and complications were tracked and noted in a separate database.

Statistical Analysis

Continuous data are given as the mean ± standard deviation or median (interquartile range), and categorical data are expressed as numbers and percentages. The minimum clinically important difference (MCID) was defined as ≥ 30% improvement in NRS leg pain from baseline to 12 months, as defined by Ostelo et al.[18]

Crude and adjusted Cox proportional hazard models were used to detect differences in TTS between patients attaining and those not attaining MCID. Variables for adjustment—namely age, sex, BMI, as well as baseline PROMs—were selected on plausibility based on previously published data and represent potential confounders.[12,16,28,32] TTS cutoffs at every 2 weeks, from week 2 to week 52, were set. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) in reaching MCID were calculated for each cutoff. Optimal maximum TTS cutoffs were identified by a qualitative and a quantitative analysis. Qualitatively, a maximum TTS cutoff was established by evaluation of the curve representing MCID percentages after each cutoff, with the goal of identifying the cutoff after which the targeted minimum 80% likelihood of MCID can still be yielded. On the other hand, a quantitative analysis of the area under the receiver operating characteristic curve (AUC)-derived optimal cutoff was conducted ("closest-to-(0,1) criterion").[19]

A $p \leq 0.05$ on two-tailed tests was considered statistically significant. All analyses were performed in R version 3.4.3 (R Foundation for Statistical Computing).

Results

Patient Cohort

A flowchart for patient selection is represented in Fig. 1. We identified 2986 patients who had undergone tMD during the study period. There were no patients who explicitly refused participation in the registry. Of these tMD patients, 372 (12.5%) had complete data on TTS as well as on baseline and 12-month PROMs for ODI and NRS for leg pain and back pain. MCID was achieved in 308 patients (83%), with a mean improvement of −5.4 ± 3.2 in NRS for leg pain severity. Mean improvement in NRS for back pain severity and ODI was −2.20 ± 3.5 and −33.3 ± 23.0, respectively. Other baseline characteristics of the patient population are shown in Table 1.

Time to Surgery

The mean TTS was 49.1 ± 97.1 weeks, with a broad range of 1 week–14.5 years. The median TTS was 21 weeks (IQR 12–37 weeks). The median time from the initial visit to the surgery itself was measured as 10 days (IQR 6–19 days). Figure 2 demonstrates the TTS distribution.

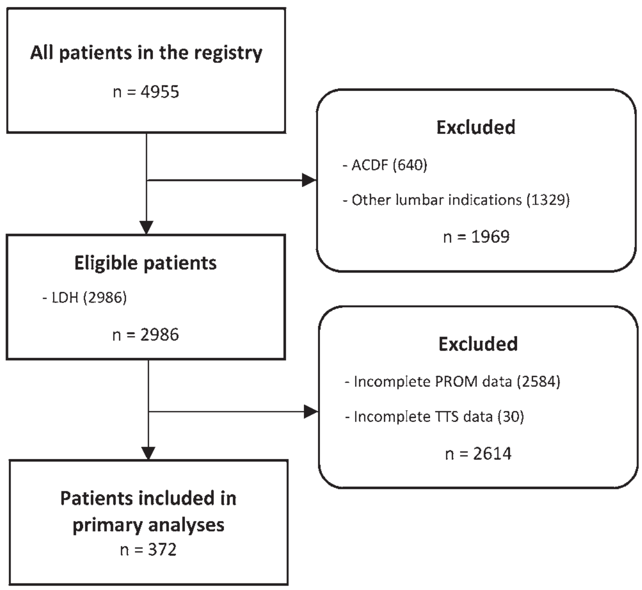

FIG. 1. Flowchart demonstrating the flow of patients throughout this analysis. ACDF = anterior cervical discectomy and fusion.

TABLE 1. Characteristics of 372 patients who underwent tMD

Characteristic	Value
Age in yrs, n = 372	48.3 ± 11.8
Active smoker, n = 179	94 (52.5%)
Male sex, n = 372	184 (49.5%)
BMI in kg/m^2, n = 372	25.3 ± 3.3
Height in cm, n = 372	177.2 ± 10.1
Weight in kg, n = 372	79.6 ± 13.5
Operation time in mins, n = 372	39.4 ± 107.3
Length of hospital stay in hrs, n = 372	23.2 ± 7.3
ASA status, n = 361	
Class I	217 (60%)
Class II	143 (39.6%)
Class III	1 (0.3%)
Index level, n = 372	
L1–2	1 (0.2%)
L2–3	4 (1.1%)
L3–4	25 (6.7%)
L4–5	169 (45.4%)
L5–S1	173 (46.5%)
Side, n = 372	
Rt	146 (39.2%)
Lt	193 (51.9%)
Medial	19 (5.1%)
Bilat	14 (3.8%)
Baseline PROM values, n = 372	
ODI	48.4 ± 18.1
NRS leg pain	7.4 ± 1.9
NRS back pain	5.2 ± 2.8
12-mo PROM change score, n = 372	
ODI	−33.3 ± 23.0
NRS leg pain	−5.4 ± 3.2
NRS back pain	−2.2 ± 3.5
Achieved MCID*, n = 372	308 (82.8%)
Median TTS in wks (IQR), n = 372	21 (12–37)

n = number of patients with available data.
Values expressed as mean ± standard deviation or as number (percent), unless indicated otherwise.
* Minimum 30% improvement in NRS leg pain from baseline to 12 months.

Association With Functional Outcome

In the crude model, attainment of MCID was associated with a shorter TTS (p = 0.018, HR 0.718, 95% CI 0.546–0.945). The corresponding Kaplan-Meier curve is shown in Fig. 3.

Similarly, after adjustment for age, sex, and BMI, the effect size was preserved (p = 0.008, HR 0.682, 95% CI 0.514–0.906). In the final adjusted model—corrected for age, sex, BMI, as well as baseline NRS for leg pain, baseline NRS for back pain, and baseline ODI—a similar result was obtained (p = 0.017, HR 0.704, 95% CI 0.528–0.0.939).

Maximum TTS

Table 2 summarizes surgical results according to TTS. The quantitatively identified, ACU-anchored optimal maximum TTS was 23.5 weeks. Percentages of patients attaining MCID after different TTS cutoffs are shown in Fig. 4. Qualitatively, the MCID percentage curve shows a continuous drop in the percentage with a progressive cutoff. The MCID percentages after the different cutoffs start off at > 82.5% until week 12, then remain > 80% until week 24. After this threshold, the percentage drops significantly down to < 75% at > 34 weeks.

Based on these two qualitative and quantitative analyses, a maximum TTS cutoff of 24 weeks was formalized. Surgery after this cutoff starts to yield MCID rates under 80%. The 24-week cutoff also coincides with the time point after which the specificity for MCID first drops below 0.500 and after which the NPV for nonattainment of MCID first surpasses ≥ 0.200.

Discussion

In an analysis using a prospective registry including 372 patients who had undergone first-time lumbar discectomy, a longer TTS was associated with a reduced likelihood for a positive surgical outcome in terms of leg pain. Based on both a qualitative and a quantitative method, an optimal maximum TTS of 24 weeks can be suggested. Lumbar discectomy within this “honeymoon phase” of up to 24 weeks after the onset of symptoms yields rates of patient-reported surgical success of 80% or higher, whereas surgery after 24 weeks is associated with inferior success rates.

Considering the TTS has relevance in surgical planning. However, the first therapies remain conservative, as time usually solves the vast majority of symptomatic herniations.[4,7,8] In fact, over a third of LDHs tend to re-

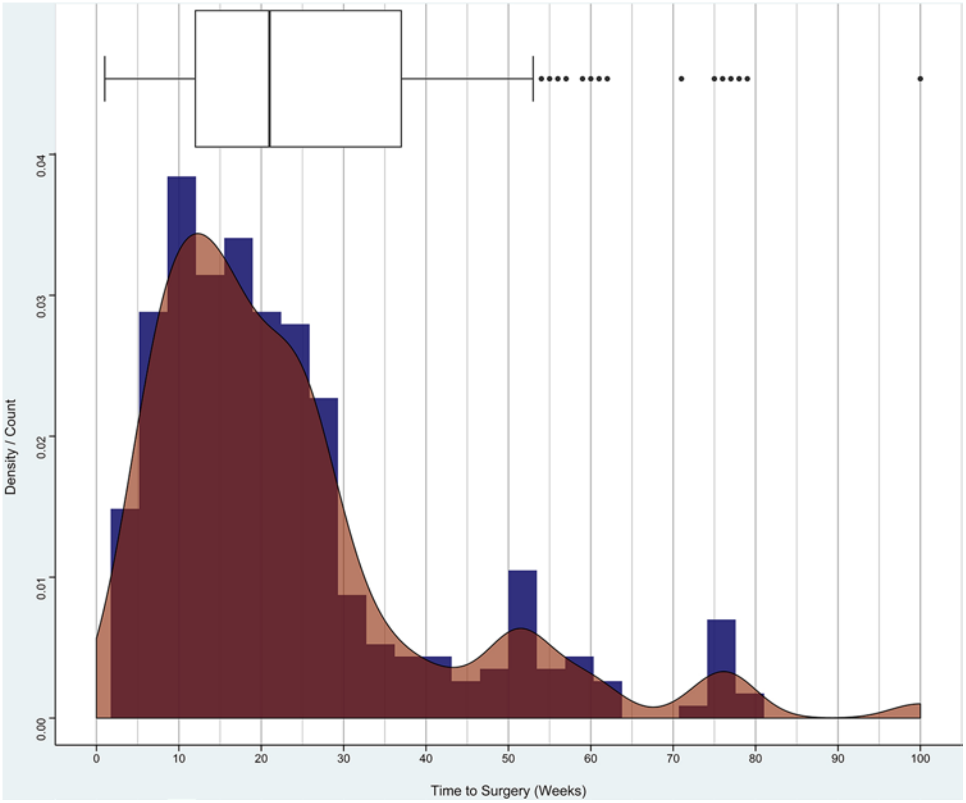

FIG. 2. Distribution of TTS. The x-axis was cut off at 2 years. The histogram demonstrates the distribution of patients among the time points. The density plot (*curve*) demonstrates a nonparametric probability density function smoothed over the patient counts (*bins*), with the y-axis demonstrating the proportion of patients within these bins. Figure is available in color online only.

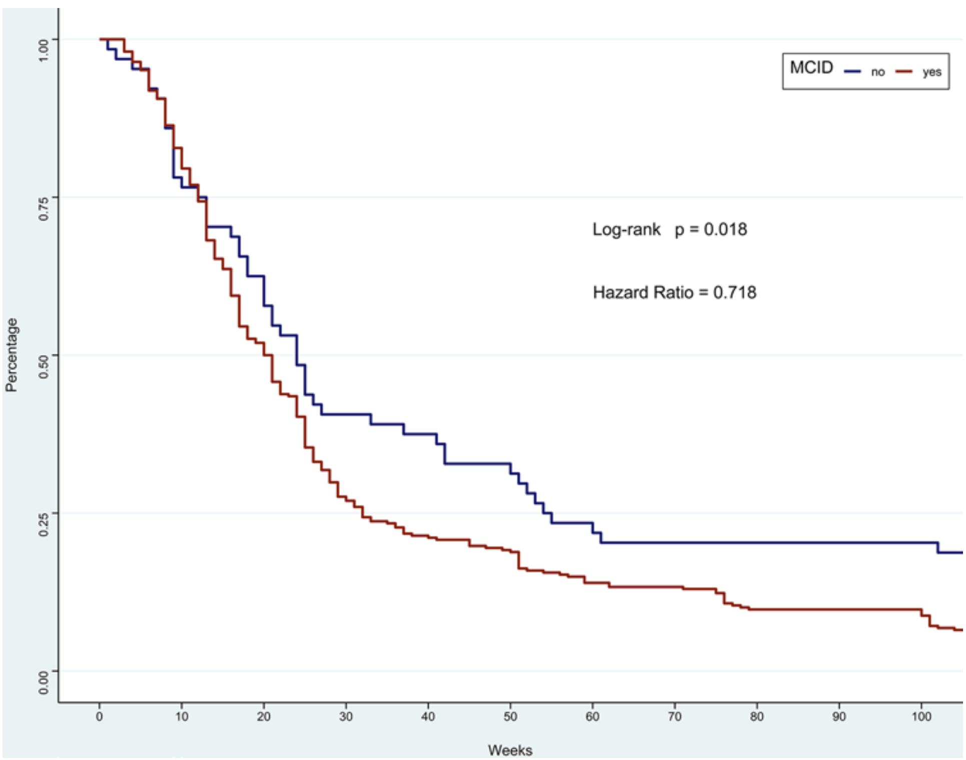

FIG. 3. Kaplan-Meier curve for TTS between patients attaining and those not attaining MCID at 12 months. Figure is available in color online only.

gress spontaneously without any therapy at all.[34] Cauda equina syndrome and progressive motor weakness remain absolute indications for urgent surgery. These absolute indications should lead to immediate surgery, as permanent functional deficits can be avoided.[13,29,34] A relative indication is set by persistent intractable pain, where surgery has been shown to massively improve health-related quality of life.[3,39]

In patients lacking these indications, conservative methods are to be considered first-line therapy. It has been suggested that prolonged symptom duration before discectomy can lead to a worse surgical outcome.[17,20,24,26,30] Our data corroborate this finding by suggesting that patients not attaining an MCID for leg pain generally underwent delayed surgery. While starting off with conservative therapy is recommended, the surgical option should be discussed early on in case of prolonged symptom duration without spontaneous regression of the herniated disc, so that discectomy can be performed swiftly before encountering a potentially detrimental exceeding of the maximum TTS cutoff leading to worse surgical outcomes.

In the current literature, however, the extent of the aforementioned optimal maximum TTS remains unclear. Several different studies of surgical timing have led to different results, as some studies have not at all identified long-term differences in functional outcome between early and delayed surgery,[21,38] while reports on the other side of the spectrum suggest a maximum 2-month duration of conservative treatment before considering surgery.[11,27] For some subgroups, even a maximum TTS of 1 month has been suggested.[17]

A systematic review by Sabnis and Diwan in 2014[30] revealed that surgery within 6 months was associated with a good outcome, although these authors noted the quality of the reviewed studies and their broadly varying range of findings as major caveats. Our results reinforce these findings, as both the MCID percentage curve– and AUC-based cutoffs independently suggested an optimal maximum TTS of 6 months associated with a high likelihood of patient-reported surgical success. Surgery before this maximum TTS cutoff of 24 weeks yields an MCID in more than 80% of patients.

Our data also showed that surgery earlier than 24 weeks, for example, at 12 weeks or less, led to even slightly higher MCID rates. This finding may be explained by earlier operations mainly occurring in patients with intractable pain. Among these patients with maximum pain scores, attaining an MCID may have been easier because of a "ceiling effect."[3,37,39] The general effect size of our results, however, remained resilient to the potential bias of ceiling effects after adjustment for baseline pain severity and functional status. Another partial explanation may lie in the fact that patients who are more skeptical of surgical treatment tend to wait longer before deciding to get surgery in the end. Especially when considering the strong link between biopsychosocial factors,[5] as well as preoperative expectations,[14,40] and surgical outcome after spine surgery, the explanation that more skeptical patients may have waited longer and potentially achieved different outcome patterns becomes plausible.

The findings of our study are not to be interpreted as a call for earlier discectomy in the general symptomatic LDH population. Rather, conservative treatment should be preferred in the early phases, and surgery should be reserved as and communicated to the patient as a "last resort." However, our data indicate that the timing of potential surgery should be discussed early on in the treatment process, so that—after a lack of spontaneous symptom resolution—surgery can be performed without delay and within 6 months from symptom onset.

TABLE 2. Leg pain outcome according to TTS

TTS Cutoff (wks)	MCID After Cutoff	Sensitivity	Specificity	PPV	NPV
2	83.0%	0.000	1.000	—	0.170
4	83.0%	0.019	0.984	0.857	0.170
6	82.8%	0.048	0.968	0.882	0.172
8	82.8%	0.094	0.921	0.853	0.172
10	83.5%	0.179	0.794	0.809	0.165
12	82.8%	0.234	0.778	0.837	0.172
14	82.4%	0.318	0.714	0.845	0.176
16	81.3%	0.367	0.714	0.853	0.188
18	80.0%	0.455	0.667	0.870	0.200
20	80.0%	0.481	0.635	0.865	0.200
22	80.1%	0.542	0.556	0.856	0.199
24*	80.1%	0.568	0.524	0.854	0.199
26	79.4%	0.649	0.444	0.851	0.206
28	79.0%	0.582	0.413	0.850	0.210
30	76.6%	0.724	0.412	0.858	0.234
32	75.2%	0.744	0.413	0.861	0.248
34	74.5%	0.763	0.397	0.861	0.255
36	74.2%	0.766	0.397	0.861	0.258
38	73.6%	0.782	0.381	0.861	0.264
40	73.3%	0.786	0.381	0.861	0.267
42	73.6%	0.792	0.365	0.859	0.264
44	75.3%	0.792	0.333	0.853	0.247
46	74.4%	0.802	0.333	0.855	0.256
48	74.1%	0.805	0.333	0.855	0.259
50	73.8%	0.808	0.333	0.856	0.263
52	72.5%	0.838	0.302	0.854	0.275

Values pertain to MCID as the primary endpoint. Cutoffs were set every 2 weeks up to 52 weeks.
* The maximum TTS cutoff identified by the qualitative and quantitative analysis.

Study Limitations

The main limitation of this study is the retrospective design of the analysis. Although all data were collected in a prospective registry, all events were noted systematically, and all patients meeting the inclusion criteria were included, selection bias cannot be excluded. Furthermore, the analysis was not predefined. The rate of loss to follow-up was high, although similar rates have been observed in other prospective registries before.[15] Loss to follow-up in prospective registries appears to be especially frequent after procedures with fast recovery, such as microdiscec-

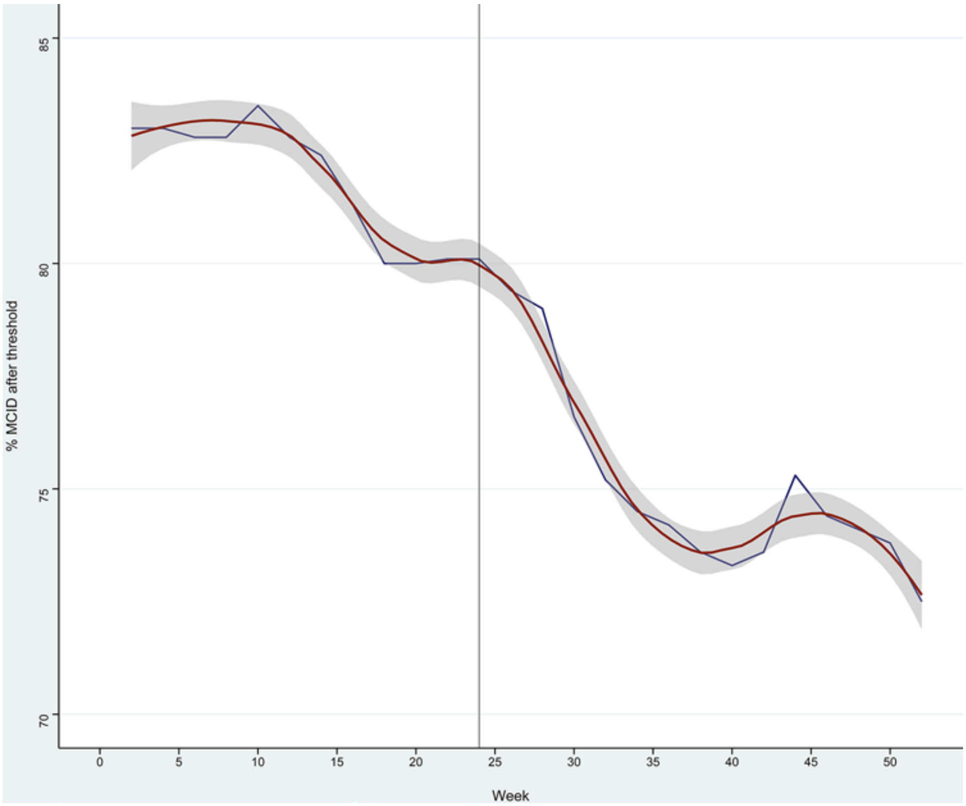

FIG. 4. MCID percentages for patients operated on after different cutoffs. The *vertical line* indicates the cutoff at 24 weeks. Figure is available in color online only.

tomy.[31] Moreover, there has been some debate on whether loss to follow-up biases outcomes after lumbar spine surgery, with mixed results.[10,31,33] It is therefore possible that loss to follow-up could influence not only PROMs per se, but also the findings toward TTS. Furthermore, we cannot make any claims as to the generalizability of our data because no external validation of our findings was performed. For these reasons, external validation of our findings in other cohorts is encouraged.

As the data stem from a single surgeon, center bias cannot be ruled out. Our data should not be extrapolated to high-risk patients, that is, those with an age > 80 years, an ASA status greater than III, and a BMI over 33 kg/m^2 because these patients were not considered for surgery given local insurance restrictions. In addition, TTS values were mainly based on the patients' self-reported anamnestic information and may therefore differ in their accuracy and reliability. To better counteract such interpatient differences, we conducted all of our TTS analyses using the integral number of weeks as the primary unit. Our data should also not be extrapolated to the association of TTS with motor deficits and their improvement after surgery, since these were not regularly and consistently captured.

Furthermore, we did not have systematic data on pain medication and specifically opioid use, as well as other pretreatments except for prior surgery, which was an exclusion criterion. Especially the chronic use of opioids may bias our findings toward the influence of TTS, as their use has been demonstrated to influence outcomes after discectomy.[9,25] Lastly, we are unable to present systematically collected data on return to work, education level, type of labor, and reasons for delayed surgery.

Conclusions

Our findings suggest that delayed lumbar discectomy is linked with a poorer patient-reported outcome in terms of leg pain severity at 12 months postoperatively and that a maximum TTS of 6 months should be aimed for. This maximum TTS was independently arrived at by two methods and further corroborated by literature reports. Additional studies and external validation are necessary to better understand surgical timing in LDH.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Staartjes, Siccoli, Schröder. Acquisition of data: all authors. Analysis and interpretation of data: Staartjes, Siccoli, Schröder. Drafting the article: Siccoli. Critically revising the article: Staartjes, Schröder. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Staartjes. Statistical analysis: Staartjes, Siccoli. Administrative/technical/material support: Staartjes, de Wispelaere, Schröder. Study supervision: Schröder.

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