Cost-effectiveness of postoperative rehabilitation after surgery for lumbar disc herniation: an analysis based on a randomized controlled trial

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OBJECTIVE The aim of this study was to examine whether routine referral to municipal postoperative rehabilitation is cost-effective in comparison to no referral after surgery for lumbar disc herniation (LDH).

METHODS One hundred forty-six patients scheduled for primary discectomy due to LDH were included. This secondary analysis, based on data from a previous randomized controlled trial, compared costs and quality-adjusted life years (QALYs) between two groups of patients recovering from LDH surgery: one group of patients received a referral for municipal physical rehabilitation (REHAB) and the other group was sent home without a referral to any postoperative rehabilitation (HOME). Primary outcomes were QALYs calculated from the EQ-5D utility score, societal costs, and incremental cost-effectiveness ratios (ICERs). The main cost-effectiveness analysis used intention-to-treat data, whereas sensitivity analyses included as-treated data. Questionnaires were collected after 1, 3, 6, 12, and 24 months postoperatively.

RESULTS The main cost-effectiveness analysis showed a small, insignificant incremental QALY of 0.021 and an incremental cost of €211.8 for the REHAB group compared to the HOME group, resulting in an ICER of €10,085. In the as-treated sensitivity analysis, the REHAB group had poorer outcomes and higher costs compared to the HOME group.

CONCLUSIONS Routine referral to municipal physical rehabilitation in patients recovering from LDH surgery was not cost-effective compared to no referral.

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KEYWORDS lumbar disc herniation; spine surgery; discectomy; rehabilitation; physical training; recovery; supervised physical exercise; cost-effectiveness; economic evaluation

LUMBAR disc herniation (LDH) is a common spinal disease with symptoms that include low-back pain and radicular pain in the lower extremities.^{13,18} The natural course of LDH is favorable, with spontaneous improvement during the initial 6–12 weeks postinjury with nonsurgical care.⁸ However, a small percentage of LDH patients require surgical discectomy, a widely accepted procedure in the treatment of LDH.⁴ In Denmark, the number of lumbar discectomies has remained stable dur-

ing the last 5 years, with approximately 2000 procedures per year, making it the second most commonly performed spinal surgical procedure in the country.¹

In Denmark, LDH patients are typically referred for rehabilitation starting 4–6 weeks postoperatively, although the evidence for beneficial effects is sparse and conflicting.¹² The latest Cochrane review¹² called for new studies evaluating the cost-effectiveness of postoperative rehabilitation since only a few previous studies investigated this

ABBREVIATIONS ICER = incremental cost-effectiveness ratio; LDH = lumbar disc herniation; MCID = minimum clinically important difference; ODI = Oswestry Disability Index; QALY = quality-adjusted life year; RTW = return to work.

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for LDH patients.^{11,13} Previous studies found no evidence to indicate that postoperative rehabilitation is cost-effective, and given that most Danish LDH patients are routinely referred for postoperative rehabilitation, it is relevant to explore the cost-effectiveness of rehabilitation strategies from a Danish societal perspective.

The aim of this study was to investigate whether routine referral for municipal physical rehabilitation is cost-effective in comparison with no referral after surgery for LDH.

Methods

This is a secondary analysis based on data from a single-center randomized controlled trial with 1:1 parallel group allocation. The data collection was designed and conducted as a single-blind trial comparing postoperative outcomes for patients referred to municipal physical rehabilitation (REHAB) to those of patients who were sent home without a referral to any postoperative rehabilitation (HOME) after surgery for LDH. The study is reported in accordance with the CONSORT guidelines¹⁰ and study details have been published (clinical trial registration no.: NCT03505918; clinicaltrials.gov). Relevant approvals for conducting the study were obtained from the regional ethics committee. Elements from the *Methods* section have been published previously.¹⁵

Briefly, eligible patients were scheduled for primary discectomy at the Spine Centre at Middelfart Hospital between September 2015 and January 2017. Inclusion criteria were age between 18 and 65 years and MRI-confirmed single-level symptomatic LDH with indications for discectomy. Exclusion criteria were previous spine surgery, psychiatric disorder, malignant disease, major surgical procedure(s) within 12 months prior to inclusion, and chronic nonspecific pain disorders (fibromyalgia, whiplash, etc.).

All patients received our standard operative treatment of either open discectomy or microdiscectomy and were hospitalized for 1–2 days. At discharge, all patients attended an informational meeting with the department's physiotherapists and were instructed to perform standard home exercises for the first 4 weeks after discharge as part of their standard care. Additionally, all patients received a standard informational booklet about disc herniation and the common recommendations after surgery. All patients were scheduled for an outpatient clinic visit with the department's physiotherapist 1 month after surgery as part of standard care.

Standard policy is to make individual rehabilitation plans for all patients, along with referral to municipal rehabilitation starting 4–6 weeks postoperatively. The REHAB group followed this standard procedure with rehabilitation at the municipal facility. REHAB patients were hereafter invited to an individual startup meeting with the municipal physiotherapists, and the rehabilitation course was planned by joint decision with the patients and the physiotherapists. However, a typical municipal rehabilitation course consists of either individual 1:1 sessions or group sessions with physiotherapists 1–2 times weekly for approximately 8–10 weeks. Further information on the

provided rehabilitation is presented in the *Results* section. The HOME group patients were seen on a 1-month outpatient basis and then released without any additional scheduled clinic visits or referrals for postoperative treatments.

Randomization

This study used 1:1 parallel block randomization with blocks of 6. Randomization occurred on the day of surgery before the surgical procedure and was performed by a physiotherapist. Patients had to select among 6 sealed envelopes for randomization. Only the physiotherapist and patients had knowledge of the assigned group. The primary investigator and surgeon remained blinded to patients' allocation during the course of this study.

Sample Size

Sample size calculation was done for the primary analysis of this study using the Oswestry Disability Index (ODI) as the primary outcome measure.³ We used an estimated mean value for the control group of 24, a standard deviation of 16, and a delta value between groups of 8. With a power of 80% and an alpha of 5%, we needed at least 64 patients in each group. The sample size was further increased by 15% to account for dropouts and death during the study. Thus, we needed to enroll 74 subjects in each arm and 148 in total.

Data Collection

Baseline characteristics were collected preoperatively, and outcome data were collected through postal questionnaires after 1, 3, 6, 12, and 24 months. Additionally, patients were contacted by phone between 1 and 2 years after surgery to confirm dates of return to work (RTW) and obtain data about the rehabilitation phase.

The 1-month health status measures were used as a baseline for the outcome assessment (quality-adjusted life year [QALY] calculations) as rehabilitation started at this point and to exclude the effects of the surgical procedure as much as possible.

Utility Scores

To evaluate the health-related quality of life, we used the Danish EQ-5D questionnaire, which evaluates 5 health dimensions on a 3-point scale. The Danish algorithm¹⁷ was used to create a utility score ranging from 0 to 1, where 1 indicates utility of perfect health and 0 indicates death. Negative scores may appear and indicate health states worse than death. The EQ-5D utility scores weighted with time intervals were used to estimate the QALYs 12 months after baseline. The minimum clinically important difference (MCID) for this utility is considered to be approximately 0.17⁶ in patients with degenerative disc disease.

The ODI, used as a supplementary functional measure, has scores ranging from 0 to 100, with 100 indicating maximum disability and 0 no disability. The MCID for this instrument is 12 points.²

To investigate the duration of postoperative sick leave for the cost evaluation, all patients were asked for the date of RTW on the 1-year follow-up questionnaire. All patients were additionally contacted by phone to confirm the

sick leave period registered in the 1-year questionnaire. Patients with missing RTW data were asked for the date during the phone interview. The sick leave period in days was counted between the date of surgery and the date of RTW. However, some patients did not report the exact date of RTW but instead estimated the weeks of absenteeism. In these cases, the weeks were converted to days. Twelve patients were unemployed or retired and were not included in the sick leave calculations.

Cost Measures

Costs were estimated from a societal perspective and included costs related to the municipal rehabilitation and use of primary healthcare services 3 months after surgery. In one of the sensitivity analyses, absence from work was included as an indirect cost.

Healthcare Costs. The hourly cost of municipal rehabilitation included the cost of physiotherapists and the facilities needed to provide rehabilitation. It was assumed that an individual rehabilitation session with a physiotherapist lasted 30 minutes and group rehabilitation sessions with 7 patients lasted 1 hour with one physiotherapist. It was further assumed that the ratio of training, preparation, and documentation was approximately 50:50, meaning that for each 60 minutes of training the physiotherapist used an additional 60 minutes for preparation and documentation.

Patients registered the number of visits to the general practitioner during the first 12 weeks postoperatively. After 12 weeks, it was assumed that there were no differences in visits to the general practitioner between the two groups. The cost of contacts with general practitioners was obtained from current fee structures according to the Danish Medical Association.⁷

The annual salary of a physiotherapist was obtained from the Danish Physiotherapist Association. We assumed that spine rehabilitation was provided by physiotherapists with at least 4 years of experience. The salary was assumed at €47,000/year and the work time of a full-time physiotherapist was assumed at 1620 hours/year (i.e., 44 weeks at 37 hours/week). We further estimated that approximately 10% of the working time was used for sick leave, courses, and education.

The cost of equipment and buildings was estimated by assuming that the cost of a new-build facility is €3350/m² and that the training facility was at least 150 m². This building cost was annualized using a 4% discount rate, as recommended by the Danish Ministry of Finance, with a 20-year depreciation period. This resulted in an annual cost estimated at €37,000 per year (i.e., €0.5 M/13.59 [annuity 4% over 20 years]). Assuming these facilities were used 2080 hours/year (i.e., 52 weeks × 5 days/week × 8 hours/day) and 10 patients used the facilities at the same time, the hourly cost per patient was estimated at €1.8 per hour. This cost was added to the additional costs per patient.

Indirect Societal Costs. The cost of absenteeism was included in the sensitivity analyses and was based on the average income for both Danish men and women between 30 and 49 years of age. Data were obtained from Statistics Denmark (www.dst.dk), and the average annual income in

2017 was €54,517 within this group. These costs were divided by 220 working days (i.e., 44 weeks at 5 days/week) to quantify the societal cost per absent workday of €216.

Cost-Effectiveness Analyses

The incremental cost-effectiveness ratio (ICER) is a commonly used measure in cost-effectiveness analyses and is calculated through division of the difference in costs and the difference in effect between two groups. The ICER thereby represents the cost per QALY gained.

By evaluating ICERs, it is possible to determine if the ICER is below a set threshold value for cost-effectiveness. In Denmark, there is no officially accepted threshold value, so decisions are made individually for each treatment. However, the National Institute for Health and Care Excellence in the United Kingdom applies a threshold value between £22,000 and £33,000 per QALY.⁹

Statistical Analysis

The primary analyses were conducted using intention-to-treat data with patients in their original groups without accounting for patients crossing groups.

Preoperative baseline characteristics were compared between the groups and analyzed with the chi-square test and unpaired t-tests and presented with numbers, frequencies, means, and p values.

EQ-5D and ODI scores are presented as group means, standard deviations, and number of valid responses before imputation. Potential patterns in missing EQ-5D data were explored between groups and baseline characteristics using graphical inspection and logistic regression. No systematic pattern could be identified. Missing utility scores were imputed as the interpolated average calculated from the earlier and later values if these were available and if the patient had not been lost to follow-up at the given time. For the remaining missing values, we performed a regression analysis adjusted for sex and age to predict missing QALY values before the production of graphs. ICERs were calculated and bootstrapped with 1000 replications. The bootstrapped ICER is presented graphically with cost-effectiveness acceptability curves where a range of threshold values is used to visualize the probability that the REHAB intervention is cost-effective. Five different sensitivity analyses were conducted to test the robustness of the ICER: United Kingdom-weighted EQ-5D index values, inclusion of 24-month EQ-5D values, inclusion of costs related to absenteeism, as-treated grouping, and per-protocol grouping. All analyses were conducted in Stata version 15.1 (StataCorp LLC), with a p value threshold of 0.05 to indicate statistical significance.

Results

Between September 2015 and January 2017, 146 eligible patients were enrolled and randomized (Fig. 1): 73 to the REHAB group and 73 to the HOME group. Follow-up rates were 78% after both 1 and 2 years. Baseline characteristics are presented in Table 1.

The municipal rehabilitation program consisted of individual 1:1 physiotherapy in 45.3% of the cases, group sessions in 50.9%, and home training with follow-ups in

FIG. 1. Flowchart explaining the grouping of patients during the study period.

3.8%. Patients typically had 1–2 weekly visits at the municipal center (93.6%) for 6–12 weeks (62.3%). One patient in both groups had visits to the general practitioner during the initial 3 months for reasons related to their back diagnosis. Unit costs related to the rehabilitation course are presented in Table 2.

TABLE 1. Baseline characteristics

Characteristic	REHAB	HOME	p Value
No. of patients	73 (50.0%)	73 (50.0%)	
Mean age, yrs (SD)	42.9 (8.9)	42.8 (11.8)	0.981
Males	63.0%	63.0%	1.000
Smokers	34.2%	39.7%	0.453
Mean BMI, kg/m ² (SD)	26.2 (4.0)	26.1 (3.9)	0.925
Preop job status			0.698
Employed	90.4%	93.2%	
Unemployed	4.1%	2.7%	
Pension	5.5%	4.1%	
Duration of leg pain			0.490
No leg pain	1.4%	0%	
<3 mos	36.9%	28.8%	
3–12 mos	45.2%	46.6%	
1–2 yrs	13.7%	17.8%	
>2 yrs	2.7%	6.8%	

EQ-5D scores improved significantly in both groups during follow-up. The improvements between the groups were comparable over time and showed insignificant and clinically unimportant improvements in the REHAB group. ODI scores in both groups also showed small improvements during follow-up and insignificant and clinically unimportant improvements in the REHAB group. The greatest improvements in both EQ-5D and ODI scores were observed from preoperative to 1-month baseline: the mean EQ-5D score improvement was 0.24 in the REHAB group and 0.26 in the HOME group. Table 3 provides a

TABLE 2. Unit costs

Cost Category	Unit Cost (2018 euros)
Direct healthcare costs	
Primary care costs	
Individual physiotherapy, per treatment session	32.5
Group physiotherapy, per session	10.8
General practitioner, per visit	19.1
Hospital costs	
Physiotherapist creating rehabilitation plan	21.3
Indirect nonhealthcare costs	
Absenteeism from work, per day	216

TABLE 3. Outcome parameters

Parameter	REHAB	HOME	ΔMean	p Value
EQ-5D (SD)				
Preop, mean (n = 72; 73)	0.511 (0.26)	0.493 (0.26)	0.018	0.68
1-mo baseline (n = 71; 71)	0.757 (0.17)	0.753 (0.14)	0.004	0.88
Mean improvements				
3 mos (n = 41; 46)	0.050 (0.13)	0.027 (0.12)	0.023	0.38
6 mos (n = 47; 40)	0.043 (0.16)	0.018 (0.10)	0.025	0.40
12 mos (n = 44; 45)	0.068 (0.19)	0.054 (0.18)	0.014	0.73
24 mos (n = 47; 41)	0.057 (0.19)	0.039 (0.17)	0.018	0.65
QALY complete data (n = 44; 46)	0.757 (0.13)	0.751 (0.19)	0.006	0.87
QALY imputed data (n = 62; 64)	0.755 (0.11)	0.734 (0.16)	0.021	0.39
ODI (SD)				
Preop (n = 71; 71)	45.3 (17.9)	43.3 (14.7)	1.88	0.49
1-mo baseline (n = 67; 71)	18.9 (15.9)	19.9 (14.2)	1.02	0.69
Mean improvements				
3 mos (n = 40; 46)	-4.75 (8.6)	-3.30 (9.86)	1.44	0.47
6 mos (n = 44; 39)	-3.06 (13.7)	-2.51 (10.37)	0.55	0.84
12 mos (n = 39; 44)	-4.95 (9.0)	-5.66 (9.12)	0.71	0.72
24 mos (n = 40; 42)	-6.65 (9.4)	-3.09 (9.11)	3.55	0.09
Mean postop sick leave, days (SD)	110.6 (137.6)	98.7 (110.5)	11.9	0.60

The parenthetical numbers in the Parameter column indicate the number of patients in the REHAB and HOME groups, respectively, who replied to the questionnaires at each follow-up point.

summary of outcome improvements during the follow-up period.

The primary cost-effectiveness analysis showed an additional QALY gain of 0.021 (−0.07;0.03) at an incremental cost of €211.8 (range €107.9–€316.9) for the REHAB group compared to the HOME group. The ICER was thereby calculated to be €10,085.7 (Fig. 2). The as-treated sensitivity analysis showed that the REHAB group was dominated by the HOME group; in other words, the HOME group had greater QALY improvements and in-

curred lower costs than the REHAB group. ICERs from additional sensitivity analyses are presented in Table 4.

The cost-effectiveness acceptability curve showed a probability of 0.71 for referral to municipal rehabilitation to be cost-effective at a threshold value of €30,000. Inclusion of the as-treated and per-protocol data decreased the probability to 0.15 and 0.37, respectively (Fig. 3).

Discussion

This cost-effectiveness analysis suggests that routine

FIG. 2. Graph illustrating the ICERs after bootstrapping with 1000 replications. Figure is available in color online only.

TABLE 4. Difference in costs, QALYs, and ICERs in REHAB patients compared to HOME patients (complete data)

	Incremental Cost (€)	Incremental QALY	ICER (Δ€/ΔQALY)
Main	211.8	0.021	10,085.7
Sensitivity			
1*	211.8	0.018	11,766.7
2†	216.2	−0.015	Dominance
3‡	1855.3	0.021	88,347.6
4§	296.2	0.002	148,100
5¶	287.9	−0.015	Dominance

* United Kingdom–weighted EQ-5D.

† 24-month EQ-5D scores included.

‡ Absenteeism costs included.

§ Per-protocol data analyzed.

¶ As-treated data analyzed.

FIG. 3. Graph illustrating the cost-effectiveness acceptability curves on main and sensitivity analyses. DK = Danish-weighted EQ-5D scores; Incl. = including; sens = sensitivity analysis; UK = United Kingdom-weighted EQ-5D scores; 24m = 24-month EQ-5D scores. Figure is available in color online only.

referral for municipal rehabilitation after surgery for LDH is not cost-effective compared to no referral. Figure 3 reveals that rehabilitation has a 71% chance of being cost-effective with a societal willingness to pay of €30,000/QALY. In the sensitivity analyses, ICERs of the REHAB group increased or were dominated by the HOME group. These results are well in line with those reported in the Morris et al. study,¹¹ which found a probability of 0.52 that postoperative rehabilitation was cost-effective at a threshold value of €58,000/QALY, and with those reported in the Oosterhuis et al. study,¹³ which found a 0.75 probability of cost-effectiveness at a threshold value of €32,000/QALY.

During the follow-up period, the REHAB group had slightly better scores on the EQ-5D compared to the HOME group, but none of these differences reached the MCID and none were of statistical significance. The HOME group had a slightly poorer mean EQ-5D score at baseline than the REHAB group.

At the 1-year follow-up, we had complete EQ-5D scores for 70.6% of the sample. This response rate is lower than anticipated and required application of imputations for the cost-effectiveness analyses. This is a potential bias, but a previous study⁵ using data from our spine database (Dane-Spine) investigated differences between the responders and nonresponders. Højmark and colleagues found no differences in patient satisfaction, disability, or pain between the groups of responders.⁵ The EQ-5D scores, however, were significantly higher in the group of nonresponders, and this could potentially underestimate the change in EQ-5D scores in the current study, but because of our randomization, we expect that the potential underestimation from the nonresponders occurred equally in both groups.

A previous study that reported on the same cohort¹⁶ as the present study did not find any statistically significant differences in duration of sick leave between the rehabilitation groups. For this reason, the costs of absenteeism were not included in the main analysis of cost-effectiveness. However, we included the cost of absenteeism in the third sensitivity analysis because it was clear that the indirect costs of absenteeism were the largest contributors to the total cost in both groups. However, the probability of referral to municipal postoperative rehabilitation being cost-effective was not improved due to this, supporting the conclusion that referral to postoperative rehabilitation is not cost-effective in comparison with no referral.

One of the strengths of this study is its design with well-executed randomization and blinding of the primary researcher during the study. In contrast to the study by Oosterhuis et al.,¹³ we evaluated cost-effectiveness using a time perspective from 3 to 24 months, whereas Oosterhuis et al. evaluated costs and effect after 26 weeks. An additional strength is that our study was conducted as a single-center study, ensuring uniform inclusion and homogeneous treatments of the patients at the hospital. However, there were uncertainties, and one was the assumption related to this kind of economic analysis. Cost estimations were partly based on assumptions, with a potential risk of either over- or underestimating the costs. However, we used publicly available unit costs in the calculations and attempted to include all relevant costs for rehabilitation. This includes training facilities, equipment, and ongoing maintenance. We collected patient diaries of external treatments and visits to their general practitioners during the initial 3 months, but for various reasons, the follow-up rate of these diaries was poor, with only 40% in both

groups, even though a higher percentage of patients (>40%) completed the additional 3-month questionnaires.

Another limitation to this study was the fact that the primary study of this cohort evaluated other outcome parameters and their association with postoperative rehabilitation, which means that the data collection was powered to detect a difference in the ODI score and not the EQ-5D score.

The rehabilitation programs in this study were not standardized for the REHAB group and this could be considered a limitation. However, we published a study¹⁴ which found that rehabilitation programs are overall comparable in terms of the type, duration, and postoperative outcomes seen among the municipalities used in this study. The aim of the present study was not to compare one type of rehabilitation program to another, but instead to evaluate the effects of prescribing postoperative rehabilitation for all LDH patients as part of our daily practice.

This study is important from a societal perspective due to the increasing public health expenditures in Denmark and the fact that the evidence for a positive effect of postoperative rehabilitation is sparse. In publicly provided healthcare systems with free access to healthcare, as in Denmark, it is especially important for politicians and healthcare professionals to reflect on efficiency when using the limited public health resources and when deciding whether all patients should be offered rehabilitation or not. Our study indicates that patient outcome is not improved by routinely referring patients to municipal rehabilitation after surgery, and the cost per QALY gained is too high to be considered as cost-effective. Based on our study, we recommend that future studies use a selective approach before referring patients to municipal rehabilitation. By an improved and more targeted patient selection, it is likely that there may be positive effects of postoperative rehabilitation in patients recovering from LDH surgery.

Conclusions

Routine referral for municipal physical rehabilitation in patients recovering from LDH surgery was not cost-effective compared to no referral.

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