

# Tubular Diskectomy vs Conventional Microdiskectomy for the Treatment of Lumbar Disk-Related Sciatica: Cost Utility Analysis Alongside a Double-Blind Randomized Controlled Trial

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Received, May 21, 2010.

Accepted, March 25, 2011.

Published Online, May 26, 2011.

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#### WHAT IS THIS BOX?

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**BACKGROUND:** Conventional microdiskectomy is the most frequently performed surgery for patients with sciatica caused by lumbar disk herniation. Transmuscular tubular diskectomy has been introduced to increase the rate of recovery, although evidence of its efficacy is lacking.

**OBJECTIVE:** To determine whether a favorable cost-effectiveness for tubular diskectomy compared with conventional microdiskectomy is attained.

**METHODS:** Cost utility analysis was performed alongside a double-blind randomized controlled trial conducted among 325 patients with lumbar disk related sciatica lasting >6 to 8 weeks at 7 Dutch hospitals comparing tubular diskectomy with conventional microdiskectomy. Main outcome measures were quality-adjusted life-years at 1 year and societal costs, estimated from patient reported utilities (US and Netherlands EuroQol, Short Form Health Survey-6D, and Visual Analog Scale) and diaries on costs (health care, patient costs, and productivity).

**RESULTS:** Quality-adjusted life-years during all 4 quarters and according to all utility measures were not statistically different between tubular diskectomy and conventional microdiskectomy (difference for US EuroQol,  $-0.012$ ; 95% confidence interval,  $-0.046$  to  $0.021$ ). From the healthcare perspective, tubular diskectomy resulted in nonsignificantly higher costs (difference US \$460; 95% confidence interval,  $-243$  to  $1163$ ). From the societal perspective, a nonsignificant difference of US \$1491 (95% confidence interval,  $-1335$  to  $4318$ ) in favor of conventional microdiskectomy was found. The nonsignificant differences in costs and quality-adjusted life-years in favor of conventional microdiskectomy result in a low probability that tubular diskectomy is more cost-effective than conventional microdiskectomy.

**CONCLUSION:** Tubular diskectomy is unlikely to be cost-effective compared with conventional microdiskectomy.

**KEY WORDS:** Cost utility, (Lumbar) disk herniation, Microdiskectomy, Randomized controlled trial, Sciatica, Tubular diskectomy

Neurosurgery 69:829–836, 2011

DOI: 10.1227/NEU.0b013e31822578f6

www.neurosurgery-online.com

**ABBREVIATIONS:** QALY, quality-adjusted life-year; VAS, Visual Analog Scale

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Unilateral transflaval microdiskectomy is the most frequently performed surgical procedure for patients with lumbar disk-related sciatica.<sup>1</sup> Transmuscular tubular diskectomy has been introduced with the idea of reducing postoperative back pain and providing faster mobilization and resumption of daily activities with potentially a faster rate of

recovery. However, scientific evidence of superiority of minimally invasive techniques is lacking. In a double-blind randomized controlled trial, we compared the effectiveness of tubular discectomy with conventional microdiscectomy.<sup>2-4</sup> This trial showed similar rates of recovery and functional outcome during the first 2 years after surgery, although patients treated with tubular discectomy reported significantly more leg pain and back pain.<sup>3,4</sup>

Previous randomized trials comparing tubular discectomy and conventional microdiscectomy did not focus on an economic evaluation.<sup>5-9</sup> We therefore performed a cost utility analysis of the data from our randomized controlled trial, comparing quality-adjusted life-years (QALYs) with societal costs at 1 year, to determine whether, given this similar effectiveness, a favorable cost-effectiveness for tubular discectomy is attained.

## METHODS

Patients with sciatica caused by lumbar disk herniation participated in a multicenter double-blind randomized controlled trial comparing tubular discectomy with conventional microdiscectomy. Details of the study protocol have been published previously.<sup>2</sup> The Medical Ethics committees of 7 participating general hospitals in the Netherlands approved the study, and all participants gave written informed consent.

A total sample size of 300 patients was calculated to detect at least a 4-point difference in the Roland Disability Questionnaire for Sciatica.<sup>10</sup> Between January 2005 and October 2006, 325 patients were enrolled. The baseline characteristics of both groups were similar.<sup>3,4</sup>

### Patients and Treatment

Eligible patients between 18 and 70 years of age presented with sciatica lasting >6 to 8 weeks and radiologically confirmed disk herniation with distinct nerve root compression. Patients with small contained disk herniations with doubtful nerve root compression were excluded. Moreover, patients with cauda equina syndrome, previous spinal surgery at the same disk level, spondylolisthesis, central canal stenosis, pregnancy, severe somatic or psychiatric diseases, inadequate knowledge of the Dutch language, or emigration planned within 1 year of inclusion were also excluded.

Randomization into tubular discectomy or conventional microdiscectomy was performed in the operating room after induction of anesthesia by opening a sealed envelope. Details of the treatment can be found elsewhere.<sup>2</sup> Conventional microdiscectomy was performed after subperiosteal dissection and retraction of the ipsilateral paravertebral muscles. The herniated disk was removed by the unilateral transflavial approach with the aid of a headlight loupe or microscope magnification, depending on the surgeon's preference. In case of tubular discectomy, the skin was retracted laterally, and the guidewire and sequential dilators (METRx, Medtronic) were placed at the inferior margin of the lamina under fluoroscopic control. A 14- to 18-mm working channel was introduced over the final dilator and attached to the table. The herniated disk was removed through the tubular retractor with microscopic magnification. For blinding purposes, an equally small midline incision was made in both procedures (25-30 mm), and patients and researchers were kept blinded to the allocated treatment during the follow-up period of 1 year.

### Utilities and QALYs

Utilities represent the valuation of the quality of life of the patients on a scale from 0 (as bad as death) to 1 (perfect health). Patients described their quality of life using the EuroQol classification system (EQ-5D), from which we calculated utilities for the United States and the Netherlands.<sup>11,12</sup> Similarly, patients reported their quality of life using the SF-36, from which we calculated the SF-6D utilities.<sup>13</sup> Both EQ-5D and SF-6D provide societal valuation, which is preferred for economic evaluations from the societal perspective. We also obtained valuations by the patients themselves using the Visual Analog Scale (VAS), ranging from 0 (worst imaginable health) to 100 (perfect health). We transformed the values to a utility scale<sup>14</sup> using the power transformation  $1 - (1 - \text{VAS}/100)^{1.61}$ .

We obtained measurements for EQ-5D and VAS at intake, randomization, and 2, 4, 6, 8, 12, 26, 38, and 52 weeks after randomization. SF-36 measurements were obtained less often: at intake and 4, 8, 26, and 52 weeks after randomization. For the EQ-5D, SF-36, and VAS measurements, 6%, 6%, and 8%, respectively, of the items were missing. From the area under the utility curves, we calculated the average utility during each separate quarter of the year after randomization and during the entire year (QALYs).

### Costs

We estimated the costs from the societal perspective during a follow-up period of 1 year. Because of the 1-year time horizon, costs were not discounted. Costs were converted into 2008 price levels by use of the general Dutch consumer price index.<sup>15</sup> Costs were translated from Euros into US dollars by use of the purchasing power parity (0.873).<sup>16</sup>

Using cost diaries, patients reported admissions to hospital, visits (specialists, general practitioner, physical therapy, and alternative health care), home care, paid domestic help, informal care, drugs and aids, and out-of-pocket expenses as result of sciatica, as well as hours of absenteeism from work.

At the follow-up examinations by the research nurse at 4, 8, 26, and 52 weeks after randomization, the research nurse collected and went through the diary with the patient. All patients completed the first diary. Of the following diaries, 4%, 5%, and 10%, respectively, were missing.

A microcost approach was used to estimate the cost of the 2 surgical procedures. The costs of the operating room (staff, operating room, equipment, and overhead), specific operating equipment, and consumables were considered. Costs of anesthesia and use of awakening room use were assumed to be equal for both procedures and therefore omitted. To calculate the cost of operating room, the time of surgery was registered for each patient. Cost for 1-minute use of the operating room was obtained from each participating hospital. The mean cost per minute of US \$15 was increased by the personnel costs of 1 neurosurgeon and 1 anesthetist (US \$4.04).<sup>17</sup> Costs of specific operating equipment of US \$20 and US \$6 for tubular discectomy and conventional microdiscectomy, respectively, were calculated on the basis of initial purchasing prices of the instruments, their yearly use and depreciation, and maintenance and interest costs. Costs of disposables amount to US \$111 and US \$85 per surgery for tubular discectomy and conventional microdiscectomy, respectively.

For other healthcare resources, we used Dutch standard prices designed to represent societal costs and to standardize economic evaluations.<sup>17,18</sup> Healthcare costs are reported, including the patients' time and travel costs.

We valued the reported hours of absenteeism from work during the first year follow-up period according to the friction cost method using a friction period of 22 weeks<sup>17</sup> at standard productivity costs of US \$38 per hour for women and US \$48 per hour for men.

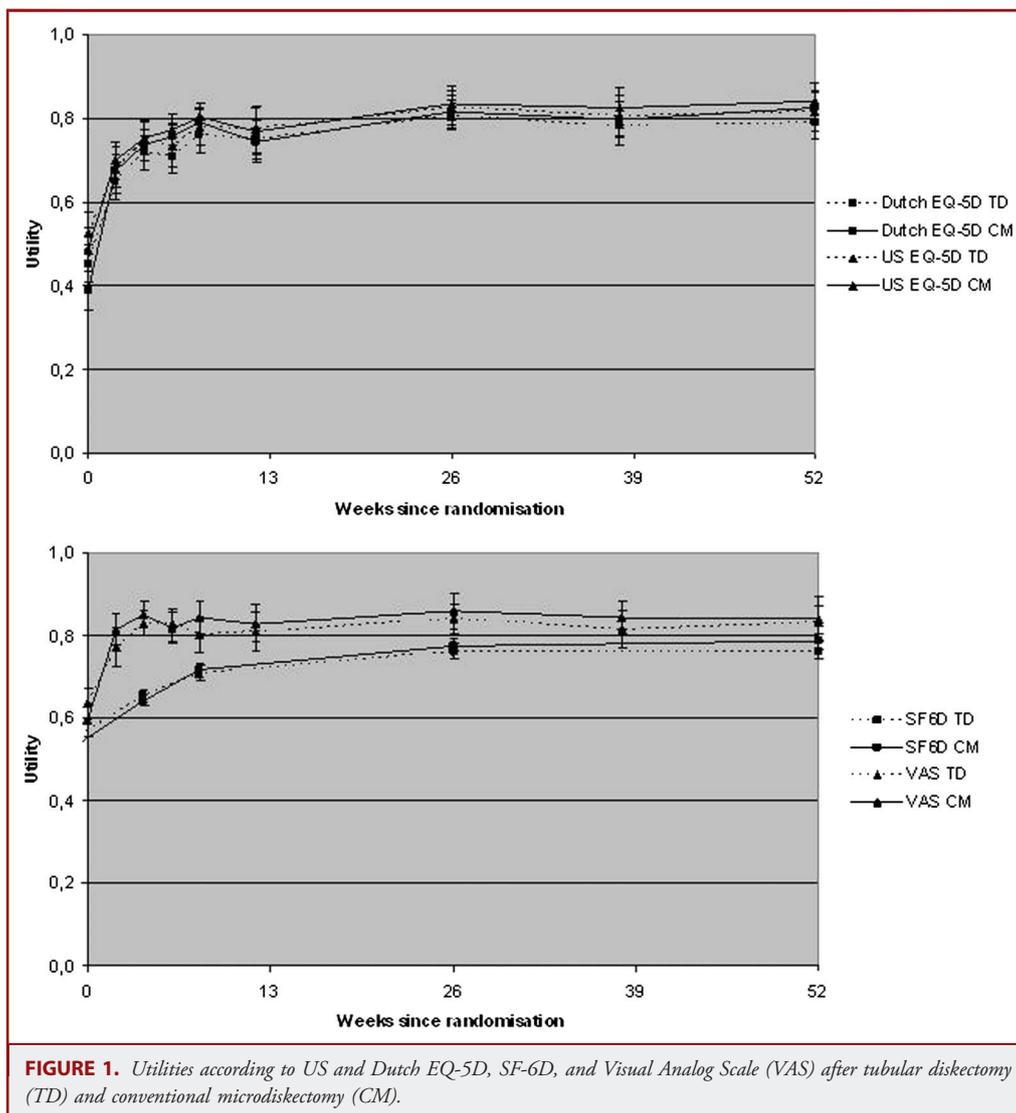
**Analysis**

All analyses followed the intention-to-treat principle. All statistical analyses were conducted with Stata 9.2 (Stata Corp, College Station, Texas). To reduce possible bias caused by missing data, we used multiple imputation by chained equations, with 5 iterations for the switching regression model.<sup>19</sup> For each missing utility measure or cost measure, an imputation regression model was used that included age, sex, body mass index, randomization group, patient’s reported functional disability measured by the modified Roland Disability Questionnaire for Sciatica,<sup>20</sup> VAS for leg pain and back pain, duration of complaints, and

all (other) utility measures and costs measures at all moments. Group differences in QALYs and costs were statistically analyzed with a standard *t* test for unequal variance.

Base-case cost utility analysis compared societal costs at 1 year and QALYs at 1 year on the basis of the US EQ-5D. Sensitivity analyses were carried out on the use of different utility measures (Dutch EQ-5D, SF-6D, or VAS) and on the perspective (societal or healthcare perspective).

Depending on the willingness to pay for obtained effectiveness, a strategy is cost-effective compared with an alternative strategy if it has a better net benefit (willingness to pay × QALYs – costs). Given the statistical uncertainty of differences between costs and QALYs, cost-effectiveness acceptability curves graph the probability that a strategy is cost-effective as a function of willingness to pay, ie,  $CEA(WTP) = \Phi(NB(WTP)/S_{NB})$ , where WTP is the willingness to pay for a QALY and NB is net benefit.<sup>21</sup>



## RESULTS

### Utilities and QALYs

The valuation of quality of life measured by the different utility measures (EQ-5D, SF-6D, and VAS) was consistently similar for patients who underwent conventional microdiscectomy and patients who underwent tubular discectomy (Figure 1).

The QALYs during all 4 quarters and according to all utility measures were also not statistically different between both groups (Table 1). The difference in QALYs according to the US EQ-5D was  $-0.012$  (95% confidence interval,  $-0.046$  to  $0.021$ ); for the Dutch EQ-5D,  $-0.014$  (95% confidence interval,  $-0.056$  to  $0.029$ ); for the SF-6D,  $-0.11$  (95% confidence interval,  $-0.037$  to  $0.014$ ); and for the VAS,  $-0.021$  (95% confidence interval,  $-0.058$  to  $0.016$ ).

### Healthcare Costs

The average costs of initial surgery, including the initial hospital admission, were US \$226 (95% confidence interval, 43 to 409) higher per patient for tubular discectomy compared with conventional microdiscectomy (see Table 1, Supplemental Content 1, <http://links.lww.com/NEU/A397>, for a detailed overview of costs of tubular discectomy and conventional

microdiscectomy per patient). Because of a lower reoperation rate after conventional microdiscectomy, the average costs of reoperation per patient were lower (US \$27), although not significantly (95% confidence interval,  $-208$  to  $263$ ). Combined with other hospital costs (other hospital admissions and specialist contacts) and healthcare costs outside the hospital (physiotherapy, general practitioner care, alternative care, home care, drugs, and aids), a nonsignificant difference of US \$460 (95% confidence interval,  $-243$  to  $1163$ ) was found for the total healthcare costs with higher costs for tubular discectomy (Table 2).

### Societal Costs

In the nonhealthcare costs, consisting mainly of productivity costs but also including domestic help, informal care, and out-of-pocket expenses, no significant differences were found. The total nonhealthcare costs after tubular discectomy were higher than after conventional microdiscectomy with a nonsignificant difference of US \$1032 (95% confidence interval,  $-1494$  to  $3557$ ). Because the societal cost is the sum of the healthcare and nonhealthcare costs, these costs also showed a nonsignificant difference (US \$1491; 95% confidence interval,  $-1335$  to  $4318$ ) in favor of conventional microdiscectomy.

**TABLE 1. Utility and Quality of Life Years After Tubular Discectomy and Conventional Microdiscectomy<sup>a</sup>**

Measure	Tubular Microdiscectomy (n = 166)	Conventional Microdiscectomy (n = 159)	Difference	p <sup>b</sup>
<b>US EQ-5D</b>				
First quarter	0.730	0.742	$-0.012$	
Second quarter	0.801	0.804	$-0.003$	
Third quarter	0.816	0.829	$-0.014$	
Fourth quarter	0.812	0.834	$-0.022$	
QALYs	0.790 (0.16)	0.802 (0.15)	$-0.012$	.47
<b>NL EQ-5D</b>				
First quarter	0.702	0.718	$-0.016$	
Second quarter	0.781	0.782	$-0.001$	
Third quarter	0.794	0.805	$-0.012$	
Fourth quarter	0.787	0.813	$-0.026$	
QALYs	0.766 (0.20)	0.779 (0.19)	$-0.014$	.53
<b>SF-6D</b>				
First quarter	0.680	0.680	$-0.000$	
Second quarter	0.754	0.766	$-0.012$	
Third quarter	0.762	0.776	$-0.015$	
Fourth quarter	0.762	0.782	$-0.020$	
QALYs	0.739 (0.10)	0.751 (0.11)	$-0.011$	.37
<b>Visual Analog Scale</b>				
First quarter	0.790	0.811	$-0.022$	
Second quarter	0.824	0.844	$-0.020$	
Third quarter	0.825	0.849	$-0.024$	
Fourth quarter	0.823	0.840	$-0.018$	
QALYs	0.815 (0.16)	0.836 (0.15)	$-0.021$	.26

<sup>a</sup>QALY, quality-adjusted life-year. Values are means (standard deviations).

<sup>b</sup>t test for unequal variance.

**TABLE 2. Mean Healthcare Costs and Societal Cost Per Patient After Tubular Diskectomy and Conventional Microdiskectomy During the First Year<sup>a</sup>**

	Tubular Diskectomy (n = 166)		Conventional Microdiskectomy (n = 159)		Difference	
	Volume	Costs, US \$	Volume	Costs, US \$	Costs, US \$	P <sup>b</sup>
<b>Surgery</b>						
Surgery, with admission to hospital		2908 (877)		2682 (805)	226	.02
Repeat surgery	10	312 (968)	7	284 (1179)	27	.82
Postsurgery hospital costs						
Other admissions to hospital	18	190	16	221	-32	.82
Neurologist <sup>c</sup>	0.4	61	0.2	24	37	.06
Neurosurgeon <sup>c</sup>	1.5	179	1.2	148	27	.24
Other specialists	66	274	60	188	86	.06
<b>Other healthcare costs</b>						
Physical therapy						
First quarter	95	560	90	562	-3	
Second quarter	61	324	55	352	-29	
Third quarter	54	228	43	177	51	
Fourth quarter	47	231	33	166	64	
Total physical therapy costs (SD)	95	1342 (1335)	91	1258 (1349)	84	.61
General practitioner <sup>c</sup>	2.5	78	2.5	72	-6	.81
Alternative care	17	64	17	43	11	.64
Home care <sup>d</sup>	0.3	6	0.1	3	4	.39
Drugs	71	70	64	77	7	.84
Aids	24	56	27	69	-13	.61
<b>Total healthcare costs (SD)</b>		<b>5529 (3020)</b>		<b>5070 (3375)</b>	<b>460</b>	<b>.20</b>
<b>Nonhealthcare costs</b>						
Paid domestic help <sup>d</sup>	9	177	3.1	83	94	.24
Informal care <sup>d</sup>	25	289	32	375	-86	.43
Out of pocket expenses	19	157	19	194	-37	.79
Productivity costs (friction costs)						
First quarter	137	6067	145	6449	-382	
Second quarter	54	2377	48	2146	231	
Third quarter	31	1381	16	700	681	
Fourth quarter	20	880	8	351	529	
Total productivity costs (SD)	243	10 705 (11068)	217	9646 (10131)	1060	.38
<b>Total nonhealthcare costs (SD)</b>		<b>11 329 (11390)</b>		<b>10 297 (10740)</b>	<b>1032</b>	<b>.42</b>
<b>Total societal costs</b>						
First quarter		10 355		10 384	-25	
Second quarter		2983		2808	153	
Third quarter		2025		1301	632	
Fourth quarter		1494		874	541	
<b>Total societal costs (SD)</b>		<b>16 858 (12 759)</b>		<b>15 367 (12 165)</b>	<b>1302</b>	<b>.30</b>

<sup>a</sup>Volumes are percentages of patients who made costs for that item unless stated otherwise.

<sup>b</sup>t test for unequal variance corrected for nonresponse with multiple imputation.

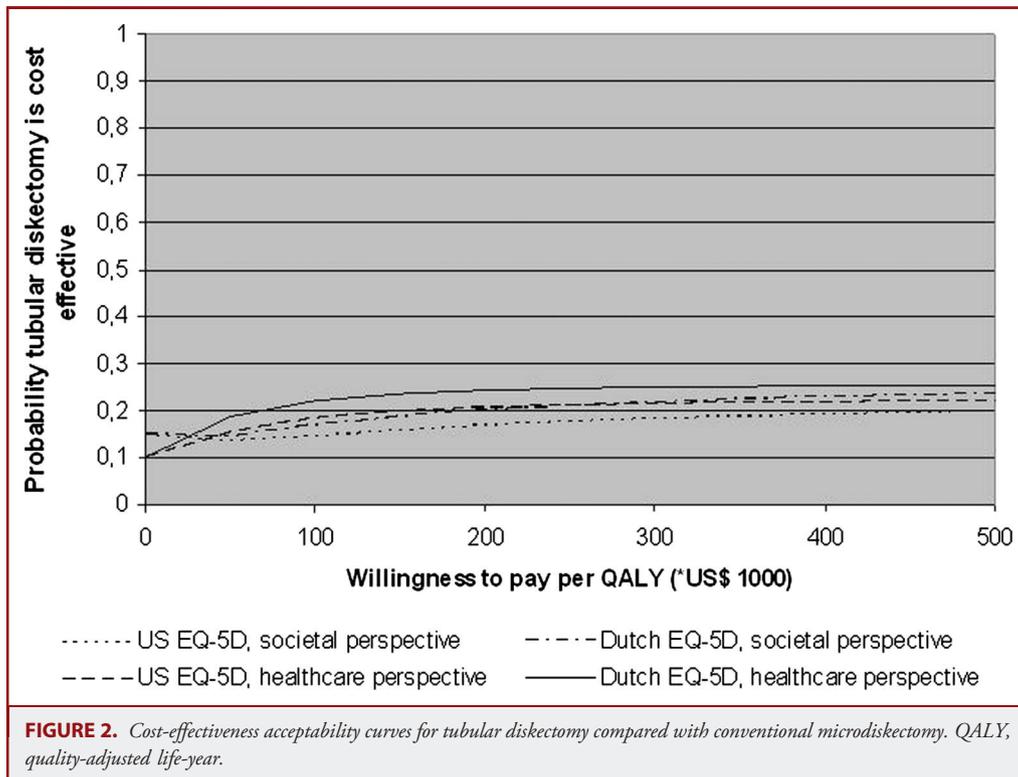
<sup>c</sup>Number of visits.

<sup>d</sup>Number of hours.

## Cost Utility Analysis

Although no statistically significant differences were found in societal costs and QALYs between tubular diskectomy and conventional microdiskectomy over the first year, the estimated nonsignificant differences in costs and QALYs were all in favor of conventional microdiskectomy. This results in a low probability that tubular diskectomy is more cost-effective than conventional

microdiskectomy. For varying levels of the willingness-to-pay threshold, the probability that tubular microdiskectomy is more cost-effective is relatively stable between 15% and 22% (Figure 2). With other utility measures, the probability of being cost-effective remains in favor of conventional microdiskectomy. In addition, from the healthcare perspective, tubular diskectomy is not preferred over conventional microdiskectomy (Figure 2).



## DISCUSSION

The present double-blind randomized controlled trial of patients with herniated disk-related sciatica compared tubular diskectomy with conventional microdiskectomy.<sup>2-4</sup> The trial showed similar rates of recovery and functional outcome, although patients treated with tubular diskectomy had less favorable results of leg pain and back pain during the first 2 years after surgery.<sup>4</sup>

In the economic evaluation, we studied whether, given this similar effectiveness, a favorable cost utility of tubular diskectomy was attained. The expected reduction in postoperative back pain, faster mobilization, and quicker resumption of daily activities with consequent faster rate of recovery after tubular diskectomy were not reflected by the utility measures; the utility measures reported are similar for both groups. The difference in mean healthcare costs was estimated at US \$460, at a disadvantage for tubular diskectomy. This nonsignificant difference consisted mostly of the difference in surgery costs, including tubular retractors, instruments, and surgery time. The assumed faster resumption of daily activities beforehand was reflected by a lower absenteeism in the first quarter in the tubular diskectomy group. However, after this initial lower absenteeism after tubular diskectomy, the difference in absenteeism during the rest of the year was in favor of conventional microdiskectomy, most likely related to the patients' perceived recovery. As a result, the nonhealthcare costs are also higher after tubular diskectomy (US \$1032). In addition, the difference in societal costs, which are the

sum of healthcare and nonhealthcare costs, of US \$1491 is also not statistically significant. However, the nonsignificant differences in QALYs and costs in favor of conventional microdiskectomy result in the conclusion that tubular microdiskectomy is unlikely to be cost-effective compared with conventional microdiskectomy, regardless of the economic threshold per QALY.

The study has several limitations. First, other settings may differ from the 7 general hospitals in the Dutch setting included in this study. Translating the results to other settings should be done with caution. Second, the duration of the economic evaluation is limited to 1 year. The differences between both treatment groups in utility, as measured by the EQ-5D and SF-6D, and in costs of physical therapy and productivity seem to increase during the year. However, additional linear regression analyses of these variables against time (in quarters) and treatment group show no systematic trend in the difference between both treatment groups. Therefore, we expect that a longer follow-up will not alter our conclusions. Furthermore, a longer time horizon would have reduced the statistical power, and the clinical evaluation showed no differences beyond the first years.<sup>3,4</sup>

In this study, we used costs of surgery instead of hospital prices. In the Dutch funding system, individual hospitals set diagnosis-treatment prices for lumbar disk surgery to facilitate competition and price containment. However, prices do not bear a consistent relation to costs. Surgery may be profitable (prices greater than costs) or subsidized by other services (prices less than costs).

Using the average hospital prices of the participating hospitals for both treatments resulted in a larger difference in mean surgery costs between the 2 treatments of US \$892, with tubular discectomy the more expensive treatment. So, regardless of the use of costs or prices, the conclusion holds that tubular discectomy is not likely to be cost-effective compared with conventional microdiscectomy.

## Disclosure

This study was funded by the Dutch Health Care Insurance Board. Trial registration information—URL: [www.isrctn.org](http://www.isrctn.org). Identifier: ISRCTN51857546. The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

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## Acknowledgments

We thank the funders of the Dutch Health Insurance Board, the patients who participated, the recruiting physicians, and the research nurses of the Sciatica research team for their work in making this trial possible. Project coordinator, principal investigators, participating institutions, and research nurses of the Leiden–The Hague Spine Intervention Prognostic Study Group: Elske van den Akker (principal investigator), Mark Arts, Ronald Brand, Wilbert van den Hout, Bart Koes, Wilco Peul (Protocol and Steering Committee); Ronald Brand (statistical analysis); Marjon Nuyten, Petra Bergman, Gerda Holtkamp, Jaenneke Donkers, Saskia Dukker, Joyce Videler, Annemarie Mast, Lidwien Smakman, Marleen van Iersel, Marina Oosterhuis, Marjolein Scholten, Annette van den Berg, Arjan Nieborg, Christi Waanders (research nurses and data collection). Enrolling physicians: Mark Arts, Fred Kloet, Wilco Peul, Rob Walchenbach, Hans Wurzer (Medical Center Haaglanden, The Hague); Rudy Kuiters, Carel Hoffmann (Haga Hospital, The Hague); Ronald Bartels, Tjemme Beems, Pieter Schutte (Canisius Wilhelmina Hospital, Nijmegen); Wee Fu Tan (Medical Center Alkmaar); Alof Dallenga (St. Fransiscus Hospital, Rotterdam); Rob Walchenbach (Vlietland Hospital, Schiedam); Fred Kloet (Reinier de Graaf Hospital, Delft).

## COMMENTS

Whereas minimal-access spine surgery as a potential less invasive alternative to standard macrosurgical and microsurgical approaches is gaining increasing importance in the treatment of lumbar disk disease,<sup>1</sup> data are lacking on whether spine surgery by a less invasive access is more cost-effective than conventional microdiscectomy. Therefore, Dr van den Akker and colleagues have conducted a multicenter trial on 325 patients with symptomatic lumbar disk herniation to analyze and compare cost utility between 2 different surgical approaches using either a so-called minimally invasive tubular system or a conventional retractor system. The authors reported on the same patient cohort and expanded the results of their previously published articles.<sup>2-4</sup> In contrast to existing studies primarily comparing clinical data and outcome of standard open microdiscectomy and minimal-access tubular or trocar microdiscectomy,<sup>1-4</sup> the novel aspects of the present work lie particularly in the determination and comparison of costs and utility using these different operative techniques by cost utility analysis alongside the randomized controlled trial. Surprisingly, compared with patients treated with conventional discectomy, patients treated with tubular discectomy showed similar rates of recovery and functional outcome in the clinical evaluation<sup>1-4</sup> and nonsignificant differences in healthcare and societal costs in the economic analysis even in favor of conventional microdiscectomy. A salient strength of the present study is its prospective double-blind randomized controlled character, the strict inclusion and exclusion criteria, the extensively analyzed data, and the

large series of patients with comparable baseline characteristics. However, corresponding to the multicenter character of the study, various surgeons at 7 hospitals, possibly with different surgical expertise and skills, have performed the interventions, which might bias the data. The fact that the tubular discectomy technique is known to be associated with a steep learning curve and to be more demanding for the surgeon than standard microdiscectomy for herniated disk<sup>1</sup> might also have influenced the study results. In addition, although a longer time horizon would have reduced the statistical power and the clinical evaluation showed no differences beyond the first year as summarized by van den Akker et al, the relatively short follow-up interval of 12 months makes definite conclusions difficult. Especially for the determination of recurrences and postoperative development of symptomatic epidural adhesions and scar tissue formation with its potentially associated economic impact, an extended follow-up interval would be desirable. Finally, as mentioned by the authors themselves, the present study is based on a Dutch patient cohort, and generalizing or translating the results of the study to other settings should be done with caution.

Despite these limitations, the present article is an important and well-done addition to the field of spine surgery and economical management of lumbar disk disease.

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Van den Akker et al present the results of an economic evaluation of tubular discectomy vs conventional microdiscectomy for sciatica that was conducted in parallel to a randomized trial. The primary analysis of the randomized trial demonstrated that tubular discectomy was not associated with any significant improvement in the Roland-Morris Disability Questionnaire score compared with conventional microdiscectomy, with secondary analyses showing that tubular discectomy was associated with poorer patient self-reported leg pain, back pain, and recovery.<sup>1</sup> The present study adds to these findings by revealing no significant difference in quality-of-life outcome or costs between these 2 procedures at 1 year. Methodologically, this is a very high-quality study, and the authors are to be congratulated for this. Given the results of the original randomized trial, the present results are not surprising, but they do add a further dimension to the interpretation of their overall findings. The main limitations of this study have been acknowledged: The follow-up is relatively short and, importantly, their study reflects the costs incurred in a specific setting (7 general hospitals in the Netherlands) and using standard Dutch cost estimates. Therefore, this study will have less applicability in settings where individual costs might be relatively different from those used in the study. Nevertheless, this is an important and high-quality addition to the literature.

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