Tubular Diskectomy vs Conventional Microdiskectomy for the Treatment of Lumbar Disk Herniation: 2-Year Results of a Double-Blind Randomized Controlled Trial

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BACKGROUND: Transmuscular tubular diskectomy has been introduced to increase the rate of recovery, although evidence is lacking.

OBJECTIVE: To evaluate the 2-year results of tubular diskectomy compared with conventional microdiskectomy.

METHODS: Three hundred twenty-eight patients with persistent leg pain caused by lumbar disk herniation were randomly assigned to undergo tubular diskectomy (167 patients) or conventional microdiskectomy (161 patients). Main outcome measures were scores from Roland-Morris Disability Questionnaire for Sciatica, Visual Analog Scale for leg pain and low-back pain, and Likert self-rating scale of global perceived recovery.

RESULTS: On the basis of intention-to-treat analysis, there was no significant difference between tubular diskectomy and conventional microdiskectomy in Roland-Morris Disability Questionnaire for Sciatica scores during 2 years after surgery (between-group mean difference [Δ] = 0.6; 95% confidence interval [CI], −0.3-1.6). Patients treated with tubular diskectomy reported more leg pain (Δ = 3.3 mm; 95% CI, 0.2-6.2) and more low-back pain (Δ = 3.0 mm; 95% CI, −0.2-6.3) than those patients treated with conventional microdiskectomy. At 2 years, 71% of patients assigned to tubular diskectomy documented a good recovery vs 77% of patients assigned to conventional microdiskectomy (odds ratio, 0.76; 95% CI, 0.45-1.28; P = .35). Repeated surgery rates within 2 years after tubular diskectomy and conventional microdiskectomy were 15% and 10%, respectively (P = .22).

CONCLUSION: Tubular diskectomy and conventional microdiskectomy resulted in similar functional and clinical outcomes. Patients treated with tubular diskectomy reported more leg pain and low-back pain, although the differences were small and not clinically relevant.

KEY WORDS: Herniation, Lumbar disk, Minimally invasive, Sciatica, Tubular diskectomy

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Worldwide, many patients are affected by the lumbosacral radicular syndrome caused by herniated disks.[1] The natural history is favorable in most cases, although patients treated surgically recover twice as fast while achieving the same pain relief as patients treated with prolonged conservative care.[2] Currently, unilateral transflaval microdiskectomy is the gold standard in the surgical treatment of lumbar disk–related sciatica. Minimally invasive lumbar disk surgery has gained popularity in recent years. Patients are expected to have reduced low-back pain, thus allowing quicker mobilization, contributing to shorter hospitalization and faster resumption of work and daily activities. Extensive data from a double-blind randomized trial comparing tubular diskectomy with conventional microdiskectomy became

ABBREVIATIONS: CI, confidence interval; **RDQ,** Roland-Morris Disability Questionnaire for Sciatica; **VAS,** Visual Analog Scale available recently.[3] Patients with herniated disk–related sciatica treated with tubular diskectomy showed rates of recovery similar to those treated with conventional microdiskectomy, although tubular diskectomy resulted in less favorable results for leg pain, low-back pain, and perceived recovery at 1 year. The 2-year results of the aforementioned trial are presented here.

MATERIALS AND METHODS

We conducted a multicenter, double-blind, randomized controlled trial among patients with sciatica caused by lumbar disk herniation in which tubular diskectomy and conventional microdiskectomy were compared in a parallel-group design. The aim of this study was to determine the effectiveness of tubular diskectomy and conventional microdiskectomy with regard to pain, functioning, and perceived recovery. Details of the study design have been published previously.[4] The study was approved by the medical ethics committee of each participating center, and written informed consent was obtained from all patients.

Patient Population and Randomization

Patients (age, 18-70 years) with sciatica resulting from lumbar disk herniation lasting $>$ 8 weeks and refractory to conservative treatment were eligible for inclusion. Magnetic resonance imaging confirmed disk herniations with distinct nerve root compression. Patients with small (less than one-third of the spinal canal diameter), 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 Dutch, or emigration planned within 1 year of inclusion were excluded. All eligible patients were examined and questioned by an independent researcher.

A computer-generated permutated-block schedule with blocks of variable length was used for randomization, with patients stratified according to each hospital and research nurse. Randomization was performed in the operating room by opening a sealed opaque envelope containing the assigned strategy. Patients and observers were blinded to the allocated treatment during the 2-year follow-up.

Treatment

Surgery was scheduled within 4 weeks of the first visit to the researcher. Participating neurosurgeons performed both types of surgical procedures and had broad experience in both techniques. Surgery was performed under general or spinal anesthesia with the patient in the prone position. The relevant disk level was verified fluoroscopically. An equally small midline incision (25-30 mm) was made with both techniques. Conventional microdiskectomy was performed by ipsilateral paravertebral muscle retraction. The herniated disk was removed by the unilateral transflaval approach with the aid of a headlight loupe or microscope magnification, depending on the surgeon's preference. In case of tubular diskectomy, the skin was retracted laterally, and the guidewire and sequential dilators (METRx, Medtronic) were placed at the inferior aspect 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. In both procedures, the herniated portion of the disk was removed. Aggressive subtotal diskectomy was never intended, and bony lamina removal, if necessary, was minimal. All removed disk material was collected and weighed. The surgeons's findings were documented.

Patients were mobilized the day of surgery and discharged as soon as possible. Patients were advised to resume their regular activities when possible.

Outcomes

The primary outcome measure was the patient's reported functional disability measured by the modified Roland-Morris Disability Questionnaire for Sciatica (RDQ).[5] Scores range from 0 to 23, with higher scores indicating worse functional status. Secondary outcomes were the 100-mm Visual Analog Scale (VAS) for leg pain and low-back pain,[6] the 7-point Likert self-rating scale for perceived recovery,[7] functional and economic status on the Prolo scale,[8] the generic health survey on the Short Form-36,[9] the Sciatica Frequency and Bothersomeness Index,[5] complications, and reoperations. Outcomes were assessed at 1, 2, 4, 6, 8, 12, 26, 38, 52, 78, and 104 weeks after randomization. Patients underwent repeated neurological examinations by the independent researchers who observed their own patients at the planned follow-ups.

Statistical Analyses

The purpose of this study was to determine the effectiveness of tubular diskectomy and conventional microdiskectomy during the first and second years after surgery. On the basis of the RDQ score, we calculated that 150 patients in each treatment group would be required to provide a power of 90% with a 2-tailed significance level of 0.05 to detect at least a 4-point difference between scores. Furthermore, 300 patients would be enough to detect a difference of 8 weeks in median time to recovery, measured by dichotomized self-assessment on the Likert scale as a function of time since randomization. Recovery was defined as complete recovery or nearly complete recovery from symptoms as measured on the Likert scale.

Differences between groups at baseline were assessed by comparing means, medians, or percentages, depending on the type of variable. When appropriate, the baseline values of variables were used as covariates in the main analyses to adjust for possible differences between the randomized groups and to increase the power of the analyses.

The outcomes for function and pain were analyzed with a repeated-measures analysis of variance using a first-order autoregressive covariance matrix. The estimated consecutive scores were expressed as means and 95% confidence intervals (CIs). Pointwise estimates and their CIs were obtained by using models with time as a categorical covariate to allow assessment of systematic patterns. Differences between randomization groups were assessed by estimating either the main effect of the treatment or the interaction between treatment and time, first as an overall effect (test within the analysis of variance framework) over the 2-year period, thus safeguarding against multiple testing. Individual CIs at various time points are at the 95% level and thus are not adjusted for multiple testing. A Cox proportional hazard model was used to compare rates of recovery by calculation of a hazard ratio. All analyses were performed according to the intention-to-treat principle.

Data collection and quality checks were performed with the secure Web-based ProMISe data management system of the Department of Medical Statistics and BioInformatics of the Leiden University Medical Center.[10] SPSS software (version 15.0) was used for all statistical analyses.[11]

RESULTS

Between January 2005 and October 2006, 328 of 402 eligible patients were enrolled. Three patients were excluded from primary analysis. Of the remaining 325 patients, 166 were randomly assigned to undergo tubular diskectomy, and 159 were assigned to conventional microdiskectomy. Baseline characteristics of the 2 groups were similar (Table 1). At the 2-year follow-up, data were available for 294 patients (90%; Figure 1).

Surgical Treatment and Complications

The mean duration of tubular diskectomy was 11 minutes longer than the duration of conventional microdiskectomy ($P < .001$). Complications occurred in 12% of the tubular diskectomy group and 8% of the conventional microdiskectomy group ($P = .27$); dural tear was the most common complication in both groups, but the difference was not statistically significant ($P = .18$). There were no differences in day of mobilization and mean hospital stay between the groups. During the 2 years of follow-up, 15% of the tubular diskectomy group underwent repeated surgery vs 10% of the conventional microdiskectomy group ($P = .22$; Table 2).

Clinical Outcome

Repeated-measures analysis resulted in similar courses over time for disability and pain. During the first 2 years after surgery,

TABLE 1. Baseline Characteristics

Baseline Characteristics	Tubular Diskectomy (n = 166)	Conventional Microdiskectomy (n = 159)
Mean age, y	41.6 ± 9.8	41.3 ± 11.7
Male sex	84 (51)	88 (55)
Mean ± SD body mass index, kg/m^2	26.0 ± 4.4	25.4 ± 4.2
Mean ± SD duration of sciatica, wk	29.2 ± 47.4	27.8 ± 23.3
Sick leave from work, n (%)	110 (66)	103 (65)
Left-side leg pain, n (%)	100 (60)	81 (51)
Miction disturbance, n (%)	29 (17)	20 (13)
Sensory disturbance, n (%)	146 (88)	139 (87)
Muscle weakness, n (%)	105 (63)	105 (66)
Asymmetrical deep-tendon reflexes in knees, n (%)	32 (20)	34 (22)
Asymmetrical deep-tendon reflexes in ankles, n (%)	60 (37)	53 (35)
Pain on straight-leg raising test, n (%)[a]	142 (90)	131 (87)
Pain on crossed straight-leg raising test, n (%)[a]	37 (24)	31 (21)
Pain on slump test, n (%)[a]	127 (83)	118 (84)
Disk herniation level, n (%)		
L3-L4	5 (3)	6 (4)
L4-L5	67 (40)	47 (30)
L5-S1	94 (57)	106 (66)
Mean ± SD Roland Disability Questionnaire score[b]	16.0 ± 4.4	16.3 ± 4.3
Mean ± SD score on Visual Analog Scale[c]		
Leg pain	62.6 ± 21.1	61.7 ± 24.0
Back pain	40.2 ± 27.0	38.3 ± 27.8
Mean ± SD Short Form-36 score[d]		
Bodily pain	27.8 ± 18.2	25.2 ± 17.7
Physical functioning	36.7 ± 20.6	34.9 ± 20.7
Mean ± SD sciatica indexes[e]		
Frequency	16.0 ± 4.4	15.5 ± 4.3
Bothersomeness	14.1 ± 4.8	14.2 ± 5.0
Patient's preference for tubular diskectomy, n (%)	59 (36)	59 (37)
Time (mean ± SD) from intake to surgery, d	12.9 ± 8.8	12.0 ± 8.0

[a] Lasègue's sign was defined as positive if the examiner observed a typically dermatomal area of pain reproduction and pelvic muscle resistance during unilateral provocative straight leg raising; crossed was defined as positive if the same experience was noted when the other leg was raised. Slump's sign was defined as positive if the examiner observed radicular pain reproduction during simultaneous straight-leg raising and lumbar flexion.
[b] The modified Roland-Morris Disability Questionnaire for Sciatica is a disease-specific disability scale that measures the functional status of patients with leg or low-back pain. Scores range from 0 to 23, with higher scores indicating worse functional status.
[c] The intensity of pain was measured by a horizontal 100-mm Visual Analog Scale, with 0 representing no pain and 100 the worst pain ever.
[d] The Short Form-36 is a generic health status questionnaire consisting of 36 questions on physical and social functioning delineating 8 domains of quality. The scale ranges from 0 to 100, with higher scores indicating less severe symptoms.
[e] The Sciatica Frequency and Bothersomeness Index assesses the frequency (from 0 [not at all] to 6 [always]) and bothersomeness (from 0 [not bothersome] to 6 [extreme bothersome]) of back and leg symptoms. The sum of the results of the questions yields indexes ranging from 0 to 24 for frequency and bothersomeness of leg pain, with lower scores indicating less severe symptoms; numbness, tingling, or both in the leg; weakness in the leg or foot; and pain in the lower back or leg while sitting.

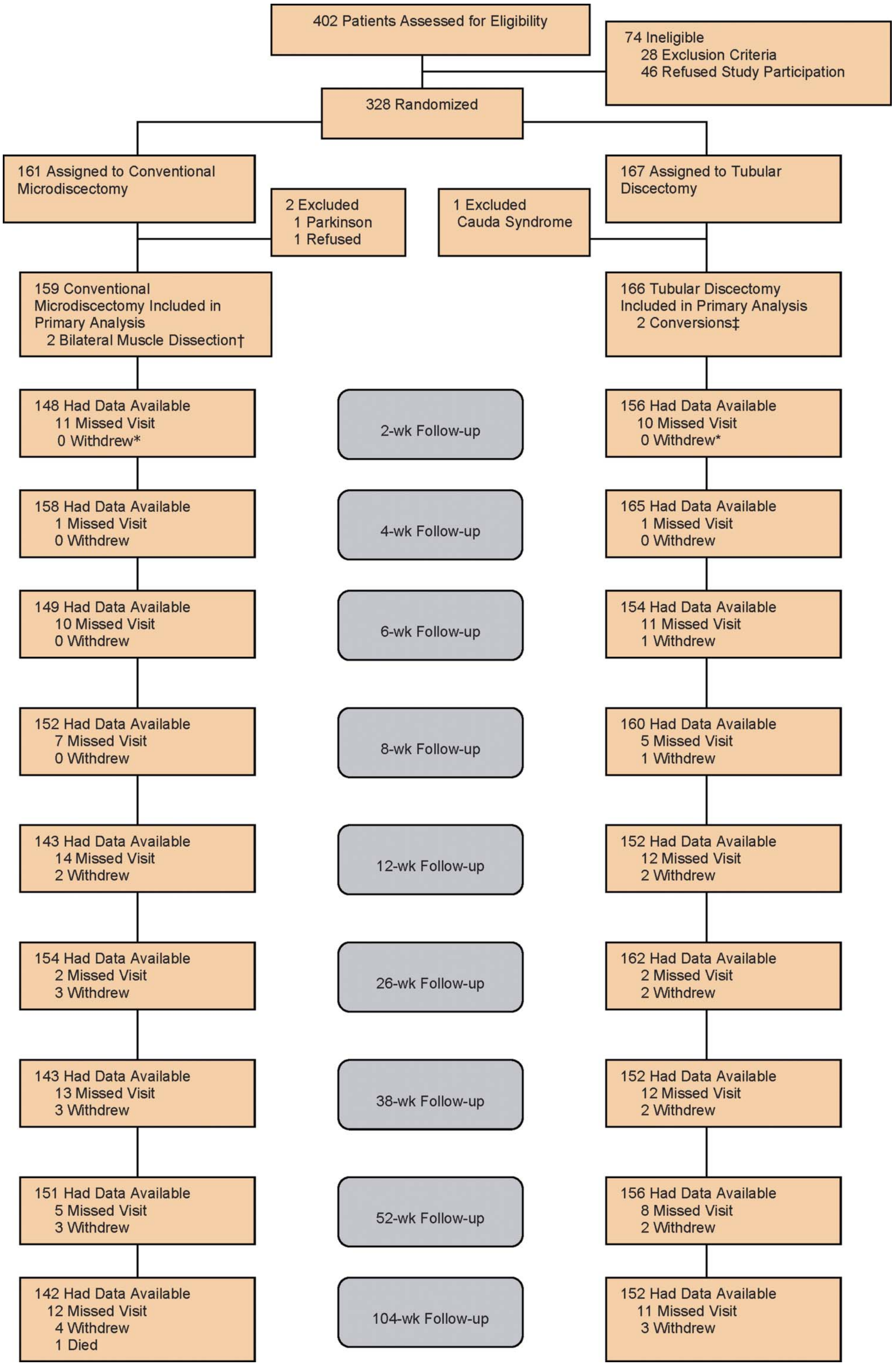

FIGURE 1. *All observed data were calculated at each time point, and no patients were excluded for repeated-measures analysis when ≥ 1 observations were missing at a certain point in time. *Cumulative over time. †Two patients underwent bilateral muscle dissection because of a large paramedian herniated disk and dural tear. ‡Two patients underwent conversion to an open procedure because of insufficient exposure and technical problems with the retractor.*

the mean ± SE RDQ score for tubular diskectomy was 5.9 ± 0.4 vs 5.3 ± 0.4 for conventional microdiskectomy. This difference in functional disability was not statistically significant (between-group mean difference [Δ] = 0.6; 95% CI, −0.3-1.6; Figure 2A).

The VAS for leg pain showed improvement in both groups. However, over the entire 2-year period, patients who underwent tubular diskectomy reported more leg pain compared with those treated with conventional surgery with a mean difference of 3.3 mm (95% CI, 0.2-6.2 mm; Figure 2B). The VAS for low-back pain showed postoperative improvement in both groups with a nonsignificant difference in favor of conventional microdiskectomy (Δ = 3.0 mm; 95% CI, −0.2-6.3 mm; Figure 2C). Treatment effects of the primary and secondary outcome measures are shown in Table 3.

Cox proportional hazards analysis showed similar rates of complete recovery. Estimated univariately by the Kaplan-Meier method, the median time until complete recovery was 2.1 weeks (95% CI,1.8-2.5) for the conventional microdiskectomy group

TABLE 2. Operative Characteristics

Operative Characteristics	Tubular Diskectomy (n = 166)	Conventional Microdiskectomy (n = 159)	*P*
Approach			
Unilateral transflaval[a]	142 (86)	126 (79)	.11
Unilateral transflaval with bony decompression[a]	24 (14)	31 (20)	
Bilateral transflaval[a]	0	2 (1)	
Mean ± SD operation time, min	47 ± 22	36 ± 16	< .001
Weight of disk removal, mean ± SD, mg	6104 ± 3555	6877 ± 3573	.08
Blood loss < 50 mL, n (%)	150 (92)	135 (85)	.08
Intraoperative complications, n (%)[b]	20 (12)	13 (8)	.27
Dural tear	14	7	
Nerve root injury	3	3	
Exploration started at wrong level	1	5	
Other[c]	2	0	
Postoperative complications, n (%)[b]	19 (11)	14 (9)	.47
Wound hematoma	2	1	
Wound infection	0	0	
Urinary tract infection	0	1	
Cerebrospinal fluid leakage	1	2	
Miction disturbances (catheter required)	3	2	
Deep venous thrombosis in the leg	0	0	
Increase in sensory deficit	5	6	
Increase in motor deficit	0	3	
Other[d]	11	1	
Day of mobilization, n (%)			
Same day as surgery	76 (46)	80 (51)	.68
Day 1	88 (53)	73 (47)	
Day 2	2 (1)	2 (1)	
After day 2	0	2 (1)	
Mean ± SD stay in hospital, d[e]	3.3 ± 1.2	3.3 ± 1.1	.82
Repeated surgery within 2 y, n (%)	23 (15)	14 (10)	.22
Recurrent disk herniation (same level)	16	9	
Disk herniation other level	1	0	
Stenosis	2	0	
Fibrosis	1	4	
Cerebrospinal fluid leakage	0	1	
Cauda equina syndrome	1	0	
Instrumented fusion	2	0	

[a]Herniated disk fragments were removed by the unilateral transflaval approach. Minimal laminotomy was performed when necessary.
[b]A patient could have > 1 complication.
[c]Other intraoperative complications included breakage of forceps and nonsterile suture material.
[d]Other postoperative complications included allergic reaction, miction disturbances not requiring a catheter, deep venous thrombosis of the arm, sensory deficit arm, sensory cerebrovascular accident, fever without focus, and psychiatric dysfunction.
[e]Total amount of days in the hospital, including the day of admission, which was usually 1 day before surgery.

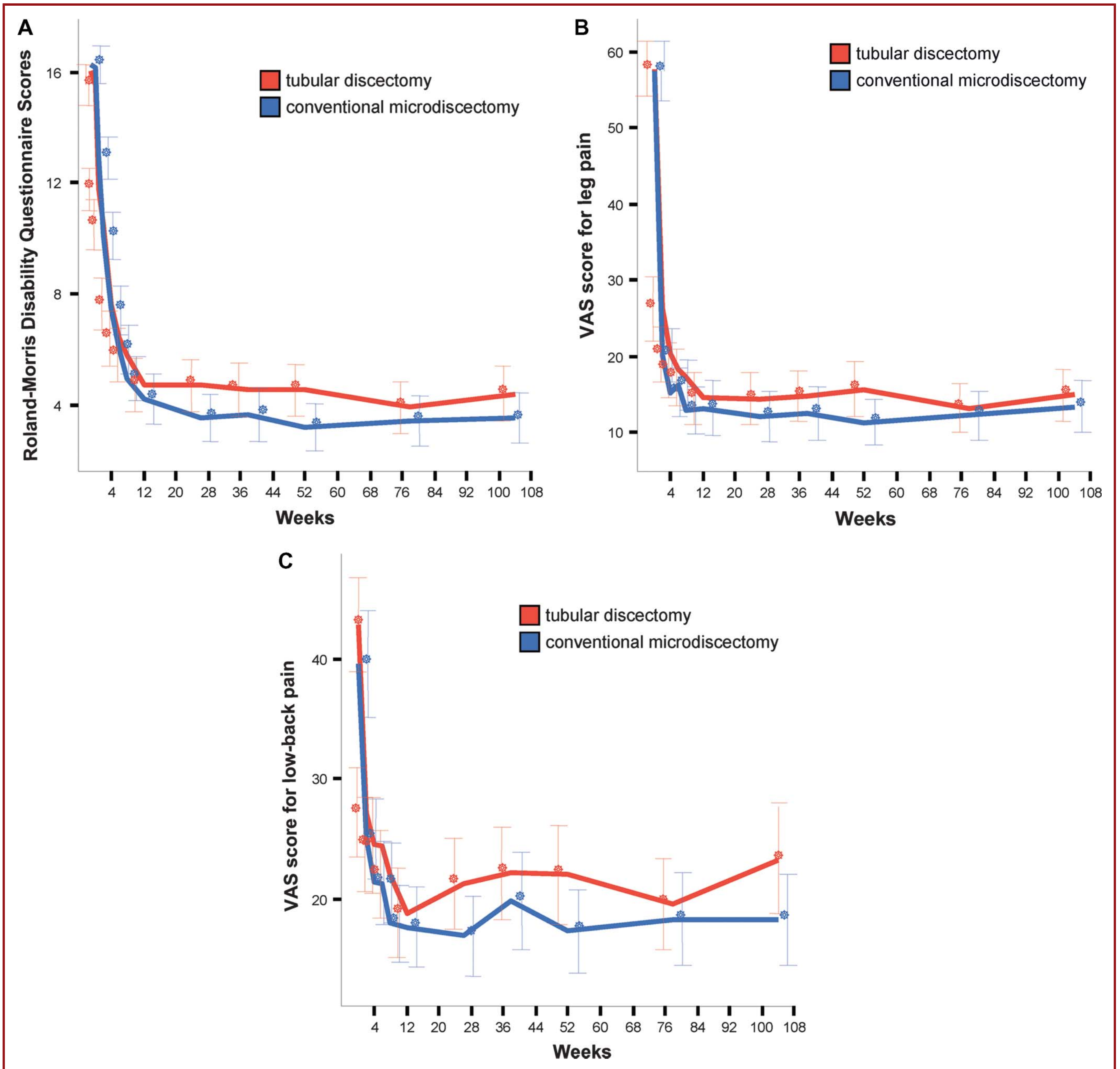

FIGURE 2. *Curves of the mean scores on the Roland Disability Questionnaire for Sciatica (**A**), Visual Analog Scale (VAS) for leg pain (**B**), and VAS for low-back pain (**C**). To enhance visualization of the curves, the data markers are offset at consecutive moments of measurement. All 3 graphs cover the 2-year period after randomization, with 95% confidence intervals (CIs) represented by vertical error bars and determined with the use of repeated-measures analysis. **A**, the curves for the mean scores on the Roland Disability Questionnaire (scores range from 0 to 23, with higher scores indicating worse functional status) did not differ significantly over the entire follow-up period of 2 years (between-group mean difference [Δ] = 0.6; 95% CI, −0.3-1.6). **B**, mean scores on the VAS for intensity of leg pain. The scales range from 0 to 100 mm, with higher scores indicating more intense pain. Patients assigned to tubular diskectomy reported more leg pain during the entire period of 2 years (Δ = 3.3 msm; 95% CI, 0.2-6.2). **C**, mean scores on the VAS for intensity of low-back pain. VAS for low-back pain showed postoperative improvement in both groups with a nonsignificant difference in favor of conventional microdiskectomy (Δ = 3.0 mm; 95% CI, −0.2-6.3).*

TABLE 3. Outcomes of the 2 Treatment Groups[a]

Outcome	Week	Tubular Diskectomy	Conventional Microdiskectomy	Difference Between Treatments (95% Confidence Interval)	P^b	P^c
Primary outcome						
Roland Disability Questionnaire score[d]	1-104	5.9 ± 0.4	5.3 ± 0.4	0.6 (−0.3-1.6)	.17	.15
	4	7.6 ± 0.4	7.4 ± 0.5	0.2 (−1.1-1.4)		
	8	5.8 ± 0.4	4.9 ± 0.5	0.8 (−0.4-2.1)		
	26	4.7 ± 0.4	3.7 ± 0.5	1.0 (−0.2-2.3)		
	52	4.7 ± 0.5	3.4 ± 0.5	1.3 (0.03-2.6)		
	104	4.5 ± 0.5	3.7 ± 0.5	0.8 (−0.5-2.1)		
Secondary outcome						
Visual Analog Scale score for leg pain[e]	1-104	17.3 ± 1.3	14.0 ± 1.3	3.3 (0.2-6.2)	.04	.08
	4	20.1 ± 1.7	15.6 ± 1.8	4.5 (−0.3-9.3)		
	8	17.2 ± 1.7	12.8 ± 1.8	4.5 (−0.4-9.3)		
	26	14.6 ± 1.7	12.7 ± 1.8	2.0 (−2.9-6.8)		
	52	16.0 ± 1.8	11.6 ± 1.8	4.4 (−0.5-9.4)		
	104	15.3 ± 1.7	14.0 ± 1.8	1.3 (−3.6-6.2)		
Visual Analog Score score for back pain[e]	1-104	22.1 ± 1.4	19.1 ± 1.4	3.0 (−0.2-6.3)	.07	.05
	4	24.6 ± 1.8	21.5 ± 1.8	3.1 (−1.9-8.1)		
	8	21.8 ± 1.8	18.0 ± 1.8	3.8 (−1.3-8.8)		
	26	21.2 ± 1.8	17.7 ± 1.8	3.5 (−1.5-8.6)		
	52	22.5 ± 1.8	17.5 ± 1.9	4.9 (−0.2-10.1)		
	104	23.5 ± 1.9	19.4 ± 1.9	4.1 (−1.2-9.4)		
Proportion of patients recovered[f]	4	0.62	0.66	0.84 (0.53-1.3)[g]		
	8	0.63	0.75	0.56 (0.35-0.92)[g]		
	26	0.67	0.77	0.62 (0.38-1.0)[g]		
	52	0.69	0.79	0.59 (0.35-0.99)[g]		
	104	0.71	0.77	0.76 (0.45-1.28)[g]		
Rate of recovery[h]	1-104	0.62 ± 0.04	0.62 ± 0.04	0.93 (0.74-1.17)		
Kaplan-Meier estimates of probability of recovery[i]	4	0.79 ± 0.03	0.83 ± 0.03	0.00 (−0.12-0.12)		
	8	0.85 ± 0.03	0.90 ± 0.02	−0.04 (−0.13-0.05)		
	26	0.89 ± 0.03	0.93 ± 0.02	−0.05 (−0.04-0.04)		
	52	0.92 ± 0.05	0.93 ± 0.04	−0.04 (−0.13-0.05)		
	104			−0.01 (−0.13-0.13)		
Short Form-36 bodily pain[j]	1-104	68.0 ± 1.7	70.9 ± 1.7	−2.8 (−6.7-1.0)	.14	.22
	4	53.2 ± 1.8	54.8 ± 1.8	−1.6 (−6.7-3.6)		
	8	63.0 ± 1.8	68.0 ± 1.9	−5.1 (−10.3-0.1)		
	26	70.5 ± 1.8	75.3 ± 1.9	−4.9 (−10.0-0.3)		
	52	72.8 ± 1.9	76.5 ± 1.9	−3.8 (−9.0-1.5)		
	104	73.2 ± 2.0	76.4 ± 2.0	−3.2 (−8.6-2.3)		
Short Form-36 physical functioning[j]	1-104	74.8 ± 1.6	77.5 ± 1.6	−2.8 (−6.5-0.9)	0.14	0.33
	4	63.9 ± 1.6	65.0 ± 1.6	−1.1 (−5.6-3.3)		
	8	71.6 ± 1.6	74.9 ± 1.6	−3.3 (−7.8-1.1)		
	26	78.7 ± 1.6	82.6 ± 1.6	−3.9 (−8.3-0.6)		
	52	79.3 ± 1.6	84.0 ± 1.6	−4.8 (−9.3-−0.2)		
	104	78.9 ± 1.7	82.4 ± 1.8	−3.4 (−8.2-1.4)		
Sciatica Frequency and Bothersomeness Index, frequency[k]	1-104	6.3 ± 0.4	5.9 ± 0.4	0.5 (−0.5-1.4)	.32	.45
	4	7.5 ± 0.4	7.2 ± 0.4	0.3 (−0.8-1.4)		
	8	6.5 ± 0.4	5.7 ± 0.4	0.8 (−0.4-1.9)		
	26	6.3 ± 0.4	5.3 ± 0.4	1.0 (−0.1-2.1)		
	52	6.1 ± 0.4	5.1 ± 0.4	1.0 (−0.1-2.2)		
	104	5.8 ± 0.4	5.6 ± 0.4	0.3 (−0.9-1.5)		
Sciatica Frequency and Bothersomeness Index, bothersomeness[k]	1-104	4.5 ± 0.4	4.0 ± 0.4	0.5 (−0.3-1.3)	0.26	0.40
	4	5.8 ± 0.4	5.5 ± 0.4	0.3 (−0.7-1.4)		
	8	5.0 ± 0.4	4.2 ± 0.4	0.8 (−0.3-1.8)		

(Continues)

TABLE 3. Continued

Outcome	Week	Tubular Diskectomy	Conventional Microdiskectomy	Difference Between Treatments (95% Confidence Interval)	P^b	P^c
	26	4.4 ± 0.4	3.3 ± 0.4	1.1 (0.0-2.1)		
	52	4.0 ± 0.4	3.1 ± 0.4	0.9 (−0.1-2.0)		
	104	3.9 ± 0.4	3.7 ± 0.4	0.2 (−0.8-1.3)		

[a]Outcomes were analyzed by repeated-measures analyses according to the intention-to-treat principle. Plus-minus values are mean ± SE.
[b]*P* value of main treatment effect assuming no interaction with time; indicates testing for average overall treatment effect over entire follow-up period of 104 weeks.
[c]*P* value of treatment-by-time interaction; indicates testing evidence for changing treatment effects over the entire period of 104 weeks.
[d]The Roland Disability Questionnaire for Sciatica is a disease-specific disability scale that measures functional status of patients with leg pain or back pain. Scores range from 0 to 23, with higher scores indicating worse functional status.
[e]The intensity of pain was measured by a horizontal 100-mm Visual Analog Scale, with 0 representing no pain and 100 the worst pain ever.
[f]Recovery was measured by a dichotomized Likert scale, defined as complete recovery or nearly complete recovery.
[g]Odds ratios (with 95% confidence interval).
[h]The hazard ratio was estimated with the unadjusted Cox model with recovery as an end point. Recovery was defined as complete or nearly complete according to the Likert 7-point scale.
[i]Probabilities on both arms and the difference between them.
[j]The Medical Outcomes Study 36-item Short-Form General Health Survey is a generic health status questionnaire consisting of 36 questions on physical and social functioning delineating 8 domains of quality. The scale ranges from 0 to 100, with higher scores indicating less severe symptoms.
[k]The Sciatica Frequency and Bothersomeness Index assesses the frequency (from 0 [not at all] to 6 [always]) and bothersomeness (from 0 [not bothersome] to 6 [extreme bothersome]) of back and leg symptoms. The sum of the results of the questions yields indexes ranging from 0 to 24 for frequency and bothersomeness of leg pain, with lower scores indicating less severe symptoms.

and 2.0 weeks (95% CI, 1.6-2.4) for the tubular diskectomy group. In the Cox proportional hazards framework, this resulted in a hazard ratio of 0.93 (95% CI, 0.74-1.17) for complete recovery of tubular diskectomy vs microdiskectomy. The odds for complete recovery at 2 years were similar in both groups (odds ratio, 0.76; 95% CI, 0.45-1.28).

The patients' global perceived recovery at 2 years was not statistically significantly different between the 2 treatment groups: 71% of the tubular diskectomy group and 77% of the conventional microdiskectomy group reported a good outcome (P = .35).

DISCUSSION

Tubular diskectomy was expected to result in faster recovery and better outcome compared with conventional microdiskectomy. However, the results of this double-blind randomized study revealed no evidence of superiority of tubular diskectomy. Regardless of the assigned surgical strategy, there was no statistically significant difference in RDQ scores during the first 2 years of follow-up. Patients assigned to tubular diskectomy reported more leg pain and more low-back pain, although the between-group mean differences were small and did not reach the minimal clinically important difference.[12]

The rationale for minimally invasive surgical procedures is that reduced tissue injury results in less back pain, faster recovery, and quick resumption of work and daily activities. Literature on general surgery, in which minimally invasive techniques were initiated, have shown clear advantages of laparoscopic appendectomy compared with open appendectomy with regard to postoperative pain, hospital stay, and recovery.[13] In lumbar disk surgery, however, we have shown that time of mobilization and rate of recovery were equivalent for minimally invasive tubular diskectomy and conventional microdiskectomy. Unexpectedly, patients treated with tubular diskectomy reported even more low-back pain during follow-up compared with patients treated with conventional surgery. Whether transmuscular muscle splitting is less invasive than subperiosteal muscle dissection can therefore be debated. Our findings may result from the fact that the lengths of skin incisions were equally small for both procedures, which might define our conventional procedure as minimally invasive surgery. The lack of benefit from tubular diskectomy over conventional surgery does not mean that tubular surgery would not have a significant advantage compared with potentially much more invasive procedures. Randomized controlled trials on more complex spine surgery are therefore needed.

The rate of repeated surgery within 2 years after the primary procedure was high and unexpected. Fifteen percent of the tubular diskectomy group and 10% of the conventional microdiskectomy group were reoperated on, mainly because of recurrent disk herniation. Although aggressive diskectomy was not intended in either patient group, the rate of recurrent disk herniation was higher than reported in the literature.[14,15] All patients participating in our trial were closely monitored by research nurses, and postoperative magnetic resonance imaging was easily accessible when patients reported persistent leg pain. This aggressive imaging strategy could possibly explain the high rate of repeated surgery. However, our study showed that neither the amount of disk removal nor the rate of recurrent disk surgery was significantly different between the 2 groups.

The complication rate between the 2 groups was similar; the most common complication was dural tear, which occurred more often in the tubular diskectomy group. It is possible that the K wire used in the tubular approach might puncture the dura or that cerebrospinal fluid leakage is observed better with microscopic magnification and might not be observed with loupe magnification. We encouraged the participating surgeons to document all complications and side effects even without any clinical consequences. This could have resulted in the remarkably high, but honest, complication rates in the present study. On the other hand, a recently published randomized trial on microendoscopic diskectomy by Teli et al[16] reported similar results.

Study Limitations

Some heterogeneity between the participating centers was shown, although the test for heterogeneity was not significant. There were center-specific treatment effects, although all participating surgeons had a large amount of experience in both treatment strategies. However, our study was not powered to detect treatment effects between individual surgeons. In our opinion, no bias occurred because the mean operation time of tubular diskectomy in our trial was 47 minutes, which is less than the 60 minutes mentioned in the assessment of the learning curve.[17] Second, only patients with larger herniated disks with distinct nerve root compression were included; those patients with smaller disk herniation were included in our parallel study of percutaneous laser disk decompression vs conventional microdiskectomy.[18] However, there is no reason to assume that the results of the present study are not valid for these patients. Finally, the hospital admission regimen during the trial period was more conservative than the current regimen, in which patients are submitted the day of surgery and frequently discharged the next day. However, this argument counts for both surgical strategies, so no bias occurred.

Comparison With Other Studies

Although this is the first double-blind trial of tubular diskectomy vs conventional microdiskectomy, the present data are comparable to previous smaller nonblinded studies. Righesso et al[19] found similar results after 2 years of follow-up. The only statistically significantly differences were the size of the skin incision and the length of hospital stay in favor of tubular diskectomy and time of surgery and immediate postoperative wound pain in favor of conventional microdiskectomy. Ryang et al[20] randomized 60 patients to open microdiskectomy and microdiskectomy using a trocar system. No significant differences in outcome, operation time, and complication rates were documented. Brock et al[21] demonstrated equivalent improvement in disability and pain, although postoperative analgetic consumption was less in patients treated with tubular diskectomy. These studies, however, were only powered to detect large effect sizes, and data were based on a selected patient cohort. A recently published randomized study documented similar results after 2 years following lumbar diskectomy with microendoscopy, microscopy, or open diskectomy, although complications were more likely with tubular diskectomy.[16]

The present data might change the daily practice of surgeons who perform tubular diskectomy as standard surgical procedure in patients with herniated disk–related sciatica. Tubular diskectomy was not found to be superior to conventional microdiskectomy, and the functional and clinical outcomes were similar during the first 2 years after surgery. Therefore, the decision on surgical strategy should be based on the preferences of patients and surgeons, bearing in mind the similar outcomes of both techniques.

CONCLUSION

Although minimally invasive lumbar disk surgery was launched to be superior to conventional diskectomy in terms of speed of recovery and outcome, the present data do not support better results of tubular diskectomy compared with open microdiskectomy. Both strategies resulted in equivalent improvement of RDQ scores during the 2 years of follow-up. Patients' scores on the VAS of leg pain and low-back pain were in favor of conventional microdiskectomy, although these small differences were not clinically relevant.

Disclosure

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COMMENT

The authors should be congratulated for conducting a well-conceived randomized controlled trial comparing the effectiveness of 2 common approaches for treating symptomatic lumbar disk herniation. The authors report 2-year results comparing tubular diskectomy and conventional microdiskectomy. This study reinforces the previously published 1-year results that showed that there are no major differences in outcome after tubular diskectomy vs conventional open surgery.

There is considerable debate regarding the advantages or not of minimally invasive approaches to the spine. This well-designed study provides Class I data that help to answer the question for lumbar disk herniation. This study does not address other types of minimally invasive surgery used for instability or for other pathologies. Further prospective studies are needed to compare the effectiveness of minimally invasive approaches with more open surgery for treating several other spinal disorders. Future studies evaluating minimally invasive strategies might also include assays for tissue injury. An economic analysis performed along with future prospective studies might also enhance our overall understanding of these types of procedures.

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