Tubular discectomy for the treatment of lumbar disc herniation : new standard or transient fashion? : Results of a double-blind randomised controlled trial

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Chapter 7

Two-year results of the trial

Tubular discectomy versus conventional microdiscectomy for the treatment of lumbar disc herniation: two-year results of a double-blind randomised controlled trial

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ABSTRACT

Background: Conventional microdiscectomy is the most frequently performed surgery for patients with lumbar disc herniation. Transmuscular tubular discectomy has been introduced to increase the rate of recovery, although evidence is lacking.

Objective: To evaluate the 2-year results of tubular discectomy compared with conventional microdiscectomy.

Methods: 328 patients with persistent leg pain (>8 weeks) due to lumbar disc herniation were randomly assigned to undergo tubular discectomy (167 patients) or conventional microdiscectomy (161 patients). Main outcome measures were scores from Roland-Morris Disability Questionnaire for Sciatica (RDQ), visual analogue scale (VAS) for leg pain and low-back pain, and Likert self-rating scale of global perceived recovery. Patients and observers were blinded during the follow-up period.

Results: Based on intention-to-treat analysis, there was no significant difference between tubular discectomy and conventional microdiscectomy in RDQ scores during 2 years after surgery (between-group mean difference, 0.6; 95% CI, -0.3 to 1.6). Patients treated with tubular discectomy reported more leg pain (between-group mean difference, 3.3 mm; 95% CI, 0.2 to 6.2 mm) and more low-back pain (between-group mean difference, 3.0 mm; 95% CI, -0.2 to 6.3 mm) as those patients treated with conventional microdiscectomy. At two years, 71% of the patients assigned to tubular discectomy documented a good recovery versus 77% of the patients assigned to conventional microdiscectomy (odds ratio 0.76; 95% CI, 0.45 to 1.28; P = 0.35). Repeated surgery rate within 2 years after tubular discectomy and conventional microdiscectomy was 15% and 10%, respectively (P = 0.22).

Conclusion: Tubular discectomy and conventional microdiscectomy resulted in similar functional and clinical outcome. Patients treated with tubular discectomy reported more leg pain and low-back pain, although the differences were small and not clinically relevant.

INTRODUCTION

Worldwide, many patients are affected by lumbosacral radicular syndrome due to herniated discs.[1] The natural history is favourable 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] Presently, unilateral transflaval microdiscectomy is the golden standard in the surgical treatment of lumbar disc-related sciatica. Minimally invasive lumbar disc surgery has gained popularity in recent years. Patients are expected to have reduced low-back pain, thus allowing quicker mobilisation, contributing to shorter hospitalisation and faster resumption of work and daily activities. Extensive data from a double-blind randomised trial comparing tubular discectomy with conventional microdiscectomy became available recently.[3] Patients with herniated disc-related sciatica treated with tubular discectomy showed similar rates of recovery to those treated with conventional microdiscectomy, although tubular discectomy resulted in less favourable results for leg pain, low-back pain and perceived recovery at one year. The two-year results of the aforementioned trial are presented here.

MATERIALS AND METHODS

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

Patient Population and Randomisation

Patients (age between 18 and 70 years) with sciatica due to lumbar disc herniation, lasting more than 8 weeks and refractory to conservative treatment, were eligible for inclusion. Magnetic resonance imaging (MRI) confirmed disc herniations with distinct nerve root compression. Patients with small (<⅓ of spinal canal diameter) contained disc herniations with doubtful nerve root compression were excluded. Moreover, patients with cauda equina syndrome, previous spinal surgery at the same disc level, spondylolisthesis, central canal stenosis,

pregnancy, severe somatic or psychiatric diseases, inadequate knowledge of Dutch language, or emigration planned within one 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 randomisation, with patients stratified according to each hospital and research nurse. Randomisation was performed in the operating room by opening a sealed opaque envelope containing the assigned strategy. Patients and observers were blind to the allocated treatment during the follow-up period of two years.

Treatment

Surgery was scheduled within four weeks of the first visit to the researcher. The 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 disc level was verified fluoroscopically. An equally small midline incision (25 to 30 mm) was made with both techniques. Conventional microdiscectomy was performed by ipsilateral paravertebral muscles retraction. The herniated disc 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 discectomy, 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 disc was removed through the tubular retractor with microscopic magnification. In both procedures, the herniated portion of the disc was removed. Aggressive subtotal discectomy was never intended and bony lamina removal was minimal, if necessary. All removed disc material was collected and weighted. 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 whenever 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-analogue 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] generic

health survey on the Short Form-36 (SF-36),[9] the Sciatica Frequency and Bothersomeness Index (SFBI)[5], complications and re-operations. Outcomes were assessed at 1, 2, 4, 6, 8, 12, 26, 38, 52, 78, and 104 weeks after randomisation. The patients underwent repeated neurological examinations by the independent researcher who observed their own patients at the planned follow-up moments.

Statistical Analyses

The purpose of this study was to determine the effectiveness of tubular discectomy and conventional microdiscectomy during the first and second year 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 two-tailed significance level of 0.05, to detect at least a 4-point difference between scores. Furthermore, 300 patients would also be enough to detect a difference of 8 weeks in median time to recovery, measured by dichotomised self-assessment on the Likert scale as a function of time since randomisation. 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. The baseline values of variables were used as covariates in the main analyses, whenever appropriate, to adjust for possible differences between the randomised groups and to increase the power of the analyses.

The outcomes for function and pain were analysed 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. Pointwise estimates and their confidence intervals were obtained by using models with time as a categorical covariate to allow assessment of systematic patterns. Differences between randomisation 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 two year period, thus safeguarding against multiple testing. Individual confidence intervals at various time points are at the 95% level and thus 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 discectomy and 159 conventional microdiscectomy. Baseline characteristics of the two groups were similar (Table 1). At two years follow-up, data were available of 294 patients (90%) (Figure 1).

Table 1: Baseline characteristics of included patients.

Baseline characteristics	Tubular discectomy (N=166)	Conventional micro-discectomy (N=159)
Mean age ± SD (years)	41.6±9.8	41.3±11.7
Male sex	84 (51)	88 (55)
Mean body mass index ± SD (kg/m²)	26.0±4.4	25.4±4.2
Mean duration of sciatica ± SD (weeks)	29.2±47.4	27.8±23.3
Sick leave from work	110 (66)	103 (65)
Left sided leg pain	100 (60)	81 (51)
Miction disturbance	29 (17)	20 (13)
Sensory disturbance	146 (88)	139 (87)
Muscle weakness	105 (63)	105 (66)
Asymmetric deep-tendon reflexes in knees	32 (20)	34 (22)
Asymmetric deep-tendon reflexes in ankles	60 (37)	53 (35)
Pain on straight-leg raising test‡	142 (90)	131 (87)
Pain on crossed straight-leg raising test‡	37 (24)	31 (21)
Pain on Slump test‡	127 (83)	118 (84)
Disc herniation level		
L3-L4	5 (3)	6 (4)
L4-L5	67 (40)	47 (30)
L5-S1	94 (57)	106 (66)
Mean Roland Disability Questionnaire score ± SD∫	16.0±4.4	16.3±4.3
Mean score on visual-analogue scale ± SD¶		
Leg pain	62.6±21.1	61.7±24.0
Back pain	40.2±27.0	38.3±27.8
Mean SF-36 score ± SD††		
Bodily pain	27.8±18.2	25.2±17.7
Physical functioning	36.7±20.6	34.9±20.7
Mean Sciatica indexes ± SD‡‡		
Frequency	16.0±4.4	15.5±4.3
Bothersomeness	14.1±4.8	14.2±5.0
Patient's preference for tubular discectomy	59 (36)	59 (37)
Time from intake to surgery ± SD (days)	12.9±8.8	12.0±8.0

Values are numbers (percentages) of patients unless stated otherwise. ‡ Lasègue's sign was defined positive if the examiner observed a typically dermatomal area of pain reproduction and pelvic muscle resistance during unilateral provocative straight leg raising, and crossed positive if the same experience was noted raising the other leg. Slump's sign was defined positive if the examiner observed radicular pain reproduction during simultaneous straight leg raising and lumbar flexion. ʃ The modified Roland-Morris Disability Questionnaire for Sciatica is a disease-specific disability scale that measures the functional status of patients with leg pain or low-back pain. Scores range from 0 to 23, with higher scores indicating worse functional status. ¶ The intensity of pain was measured by a horizontal 100-mm visual-analogue scale, with 0 representing no pain and 100 the worst pain ever. †† SF-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. ‡‡ 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.

Surgical Treatment and Complications

The mean duration of tubular discectomy was 11 minutes longer than conventional microdiscectomy (P<0.001). Complications occured in 12% of the tubular discectomy group and 8% of the conventional microdiscectomy group (P = 0.27); dural tear was the most common complication in both groups but the difference was not statistically significant (P = 0.18). There was no difference in day of mobilisation and mean hospital stay between both groups. During the two years follow-up, 15% of the tubular discectomy group underwent repeated surgery versus 10% of the conventional microdiscectomy group (P = 0.22) (Table 2).

Clinical Outcome

Repeated measurement analysis resulted in similar courses over time for disability and pain. During the first two years after surgery, the mean RDQ score (± SE) for tubular discectomy was 5.9 ± 0.4 versus 5.3 ± 0.4 for conventional microdiscectomy. This difference in functional disability was not statistically significant (between-group mean difference (Δ) =0.6; 95% CI:-0.3 to 1.6) (Figure 2 A).

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

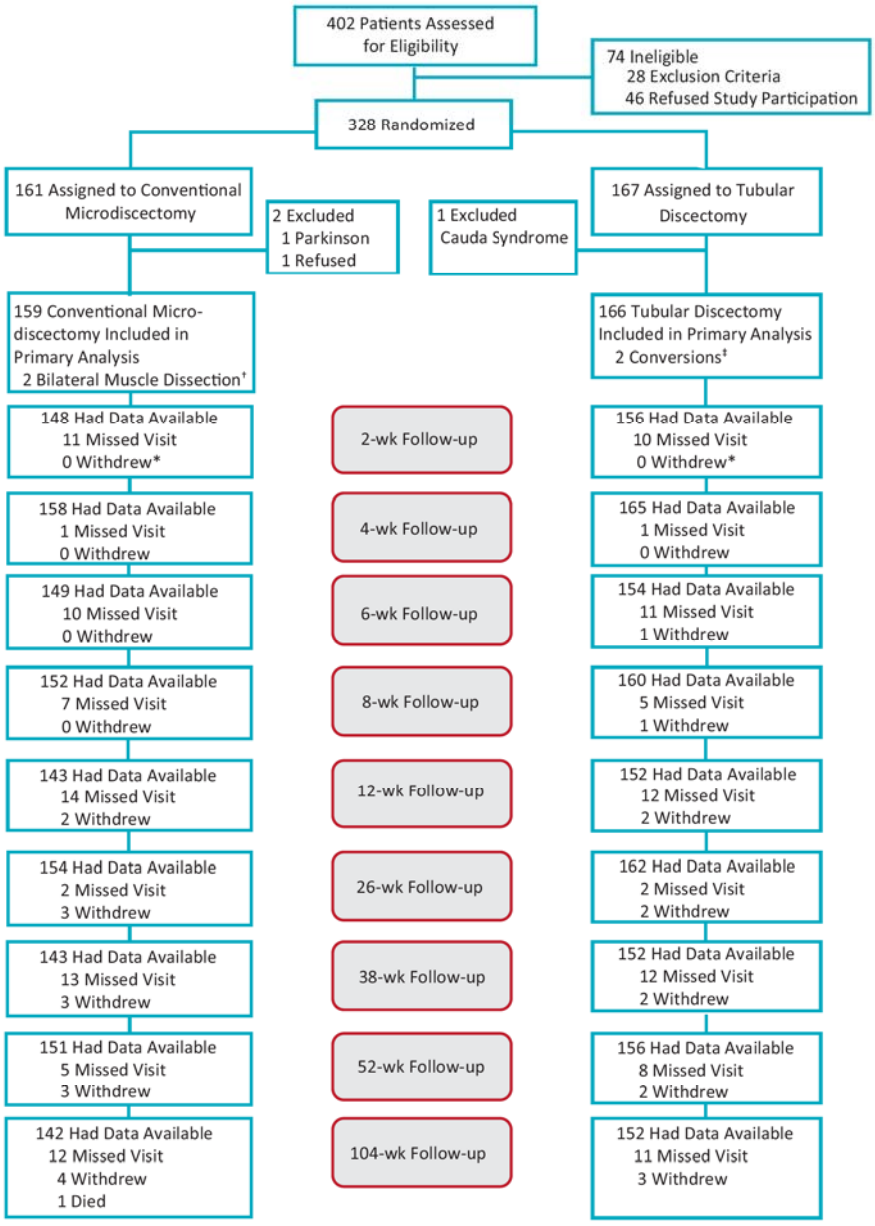

Figure 1: Flow diagram of patients through two years of study.

All observed data were calculated at each time point and no patients were excluded for repeated measurements analysis whenever one or more observations were missing at a certain point in time. * Cumulative over time. † two patients underwent bilateral muscle dissection because of large paramedian herniated disc and dural tear. ‡ two patients underwent conversion to an open procedure because of insufficient exposure and technical problem of the retractor.

Table 2: Operative characteristics of included patients.

Operative characteristics	Tubular discectomy (N=166)	Conventional microdiscectomy (N=159)	P-Value
Approach†			
Unilateral transflaval	142 (86)	126 (79)	0.11
Unilateral transflaval with bony decompression	24 (14)	31 (20)	
Bilateral transflaval	0	2 (1)	
Mean operation time ± SD (min)	47±22	36±16	<0.001
Weight of disc removal ± SD (mg)	6104±3555	6877±3573	0.08
Blood loss < 50 ml	150 (92)	135 (85)	0.08
Intraoperative complications‡	20 (12)	13 (8)	0.27
Dural tear	14	7	
Nerve root injury	3	3	
Exploration started at wrong level	1	5	
Other∫	2	0	
Postoperative complications‡	19 (11)	14 (9)	0.47
Wound haematoma	2	1	
Wound infection	0	0	
Urine tract infection	0	1	
Cerebrospinal fluid leakage	1	2	
Miction disturbances (catheter required)	3	2	
Deep venous thrombosis leg	0	0	
Increase of sensory deficit	5	6	
Increase of motor deficit	0	3	
Other ‖	11	1	
Day of mobilisation			
Same day of surgery	76 (46)	80 (51)	0.68
Day 1	88 (53)	73 (47)	
Day 2	2 (1)	2 (1)	
> Day 2	0	2 (1)	
Mean stay in hospital ± SD (days)**	3.3±1.2	3.3±1.1	0.82
Repeated surgery within 2 years	23 (15)	14 (10)	0.22
Recurrent disc herniation (same level)	16	9	
Disc 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	

Values are numbers (percentages) of patients unless stated otherwise. † Herniated disc fragments were removed by the unilateral transflaval approach.‡ Minimal laminotomy was performed when necessary. A patient could have more than 1 complication. ** Total amount of days in the hospital, including the day of admission, which was usually 1 day before surgery.

Table 3: Treatment effects of the primary and secondary outcomes.*

Outcome	Week	Tubular discectomy	Conventional micro-discectomy	Difference between treatment (95% CI)	P-value‡	P-value†
Primary outcome						
Roland Disability Questionnaire score¶	1-104	5.9±0.4	5.3±0.4	0.6 (-0.3 to 1.6)	0.17	0.15
	4	7.6±0.4	7.4±0.5	0.2 (-1.1 to 1.4)		
	8	5.8±0.4	4.9±0.5	0.8 (-0.4 to 2.1)		
	26	4.7±0.4	3.7±0.5	1.0 (-0.2 to 2.3)		
	52	4.7±0.5	3.4±0.5	1.3 (0.03 to 2.6)		
	104	4.5±0.5	3.7±0.5	0.8 (-0.5 to 2.1)		
Secondary outcome						
VAS score for leg pain‖	1-104	17.3±1.3	14.0±1.3	3.3 (0.2 to 6.2)	0.04	0.08
	4	20.1±1.7	15.6±1.8	4.5 (-0.3 to 9.3)		
	8	17.2±1.7	12.8±1.8	4.5 (-0.4 to 9.3)		
	26	14.6±1.7	12.7±1.8	2.0 (-2.9 to 6.8)		
	52	16.0±1.8	11.6±1.8	4.4 (-0.5 to 9.4)		
	104	15.3±1.7	14.0±1.8	1.3 (-3.6 to 6.2)		
VAS score for back pain‖	1-104	22.1±1.4	19.1±1.4	3.0 (-0.2 to 6.3)	0.07	0.05
	4	24.6±1.8	21.5±1.8	3.1 (-1.9 to 8.1)		
	8	21.8±1.8	18.0±1.8	3.8 (-1.3 to 8.8)		
	26	21.2±1.8	17.7±1.8	3.5 (-1.5 to 8.6)		
	52	22.5±1.8	17.5±1.9	4.9 (-0.2 to 10.1)		
	104	23.5±1.9	19.4±1.9	4.1 (-1.2 to 9.4)		
Proportion of patients recovered§	4	0.62	0.66	0.84 (0.53 to 1.3)#		
	8	0.63	0.75	0.56 (0.35 to 0.92)#		
	26	0.67	0.77	0.62 (0.38 to 1.0)#		
	52	0.69	0.79	0.59 (0.35 to 0.99)#		
	104	0.71	0.77	0.76 (0.45 to 1.28)#		
Rate of recovery‡ Kaplan-Meier estimates of probability of recovery~	1-104			0.93 (0.74 to 1.17))		
	4	0.62±0.04	0.62±0.04	0.00 (-0.12 to 0.12)		
	8	0.79±0.03	0.83±0.03	0.04 (0.13 to 0.05)		
	26	0.85±0.03	0.90±0.02	-0.05 (-0.04 to 0.04)		
	52	0.89±0.03	0.93±0.02	-0.04 (-0.13 to 0.05)		
	104	0.92±0.05	0.93±0.04	-0.01 (-0.13 to 0.13		

Outcome	Week	Tubular discectomy	Conventional micro-discectomy	Difference between treatment (95% CI)	P-value‡	P-value†
SF-36 bodily pain‡‡	1-104	68.0±1.7	70.9±1.7	-2.8 (-6.7 to 1.0)	0.14	0.22
	4	53.2±1.8	54.8±1.8	-1.6 (-6.7 to 3.6)		
	8	63.0±1.8	68.0±1.9	-5.1 (-10.3 to 0.1)		
	26	70.5±1.8	75.3±1.9	-4.9 (-10.0 to 0.3)		
	52	72.8±1.9	76.5±1.9	-3.8 (-9.0 to 1.5)		
	104	73.2±2.0	76.4±2.0	-3.2 (-8.6 to 2.3)		
SF-36 physical functioning‡‡	1-104	74.8±1.6	77.5±1.6	-2.8 (-6.5 to 0.9)	0.14	0.33
	4	63.9±1.6	65.0±1.6	-1.1 (-5.6 to 3.3)		
	8	71.6±1.6	74.9±1.6	-3.3 (-7.8 to 1.1)		
	26	78.7±1.6	82.6±1.6	-3.9 (-8.3 to 0.6)		
	52	79.3±1.6	84.0±1.6	-4.8 (-9.3 to -0.2)		
	104	78.9±1.7	82.4±1.8	-3.4 (-8.2 to 1.4)		
SFBI frequency∫∫	1-104	6.3±0.4	5.9±0.4	0.5 (-0.5 to 1.4)	0.32	0.45
	4	7.5±0.4	7.2±0.4	0.3 (-0.8 to 1.4)		
	8	6.5±0.4	5.7±0.4	0.8 (-0.4 to 1.9)		
	26	6.3±0.4	5.3±0.4	1.0 (-0.1 to 2.1)		
	52	6.1±0.4	5.1±0.4	1.0 (-0.1 to 2.2)		
	104	5.8±0.4	5.6±0.4	0.3 (-0.9 to 1.5)		
SFBI bothersomeness∫∫	1-104	4.5±0.4	4.0±0.4	0.5 (-0.3 to 1.3)	0.26	0.40
	4	5.8±0.4	5.5±0.4	0.3 (-0.7 to 1.4)		
	8	5.0±0.4	4.2±0.4	0.8 (-0.3 to 1.8)		
	26	4.4±0.4	3.3±0.4	1.1 (0.0 to 2.1)		
	52	4.0±0.4	3.1±0.4	0.9 (-0.1 to 2.0)		
	104	3.9±0.4	3.7±0.4	0.2 (-0.8 to 1.3)		

* The outcomes were analysed by repeated-measures analyses according to the intention-to-treat principle. Plus-minus values are means ± SE. CI denotes confidence interval, VAS visual-analogue scale, and SFBI the Sciatica Frequency and Bothersome Index. ‡ 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. † P-value of treatment * time interaction; indicates testing evidence for changing treatment effects over the entire period of 104 weeks. # Odds ratios (with 95% CI). ¶ 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. || The intensity of pain was measured by a horizontal 100-mm visual-analogue scale, with 0 representing no pain and 100 the worst pain ever. § Recovery was measured by a dichotomized Likert, defined as "complete recovery" or "nearly complete recovery". ∫ The hazard ratio, estimated with the unadjusted Cox model with recovery as an endpoint Recovery was defined as complete or nearly complete according to the Likert 7-point scale. ~ Probabilities on both arms and the difference between them.‡‡ The Medical Outcomes Study 36-item Short-Form General Health Survey (SF-36) is a generic health-status questionnaire consisting of 36 questions on physical and social functioning delineating eight domains of quality. The scale ranges from 0 to 100, with higher scores indicating less severe symptoms. ∫∫ 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.

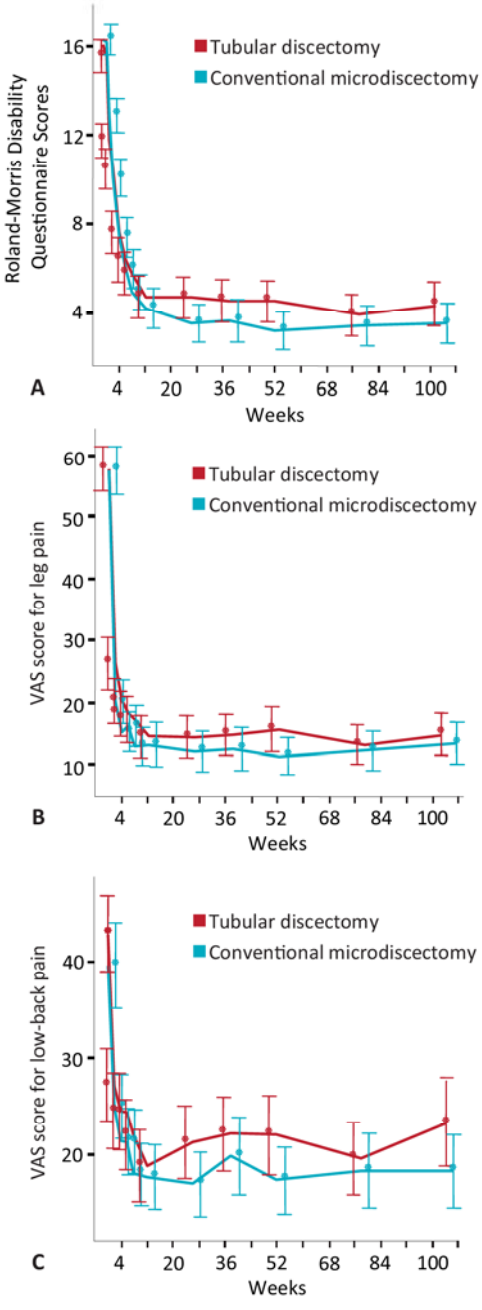

Figure 2: Outcomes over time.

Curves of the mean scores on the Roland Disability Questionnaire for Sciatica (A), Visual-Analogue Scale for leg pain (B), and Visual-Analogue Scale for low-back pain (C). To enhance visualisation of the curves, the data markers are offset at consecutive moments of measurement. All three graphs cover the 2-year period after randomisation, with 95% confidence intervals represented by vertical error bars and determined with the use of repeated-measurement analysis. In Panel 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 to 1.6). Panel B shows the 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 discectomy reported more leg pain during the entire period of 2 years (Δ = 3.3 mm; 95% CI: 0.2 to 6.2 mm). Panel C shows the 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 microdiscectomy (Δ = 3.0 mm; 95% CI: -0.2 to 6.3 mm).

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 to 2.5) for the conventional microdiscectomy group and 2.0 weeks (95% CI: 1.6 to 2.4) for the tubular discectomy group. In the Cox proportional hazards framework this resulted in a hazard ratio of 0.93 (95% CI: 0.74 to 1.17) for complete recovery of tubular discectomy versus microdiscectomy. The odds for complete recovery at two years were similar in both groups (OR 0.76; 95% CI: 0.45 to 1.28).

The patients' global perceived recovery at two years was not statistically significantly different between both treatment groups; 71% of the tubular discectomy group and 77% of the conventional microdiscectomy group reported a good outcome (P = 0.35).

DISCUSSION

Tubular discectomy was expected to result in faster recovery and better outcome compared to conventional microdiscectomy. However, the results of this double-blind randomised study revealed no evidence of superiority of tubular discectomy. Irrespective of the assigned surgical strategy, there was no statistically significantly difference in Roland-Morris disability scores during the first two years of follow-up. Patients assigned to tubular discectomy 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] Moreover, cost utility analysis resulted in a low probability that tubular discectomy is more cost effective than conventional microdiscectomy and also from the healthcare perspective, tubular discectomy is not superior to conventional microdiscectomy.[13]

The rationale of minimally invasive surgical procedures is reduced tissue injury resulting in less back pain, faster recovery and quick resumption of work and daily activities. Literature on general surgery, who initialised minimally invasive techniques, have shown clear advantages of laparoscopic appendectomy compared to open appendectomy with regard to postoperative pain, hospital stay, and recovery.[14] In lumbar disc surgery, however, we have shown that time of mobilisation and the rate of recovery were equivalent for minimally invasive tubular discectomy and conventional microdiscectomy. Unexpectedly, patients treated with tubular discectomy reported even more low-back pain during follow-up compared to those patients treated with conventional surgery. Whether transmuscular muscle splitting is less invasive than subperiosteal muscle dissection can therefore be debated. Our results may be caused by

the fact that the lenght of skin incisions were equally small for both procedures, which might define our conventional procedure as minimally invasive surgery as well.

The rate of repeated surgery within two years after the primary procedure was high and unexpected. Fifteen percent of the tubular discectomy group and 10% of the conventional microdiscectomy group were reoperated, mainly because of recurrent disc herniation. Although agressive discectomy was not intended in neither patients, the rate of recurrent disc herniation was higher than recently published in a meta-analysis.[15] All participating patients in our trial were closely monitored by research nurses and postoperative MRI was easily accessible whenever patients reported persistent leg pain. This aggressive imaging strategy could possibly explain the high rate of repeated surgery.

Limitations of the study

Some heterogeneity between the participating centers was shown although the test of heterogeneity was not significant. There were center-specific treatment effects although all participating surgeons had large experience in both treatment strategies. However, our study was not powered to detect treatment effects between individual surgeons. In our opinion, no bias occurred since the mean operation time of tubular discectomy in our trial was 47 minutes, which is less than the 60 minutes mentioned in the assessment of the learning curve.[16] Secondly, only patients with larger herniated discs with distinct nerve root compression were included, while those patients with smaller disc herniation were included in our parallel study of percutaneous laser disc decompession versus conventional microdiscectomy.[17] 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 presently, in which patients are submitted the day of surgery and frequently discharged the day after. However, this argument counts for both surgical strategies so no bias occured.

Comparison with other studies

Although this is the first double-blind trial on tubular discectomy versus conventional microdiscectomy, the present data are comparable to previous smaller non-blinded studies. Righesso et al. found similar results after two years follow-up. The only statistically significantly differences were the size of the skin incision and lenght of hospital stay in favour of tubular discectomy, and time of surgery and immediate postoperative wound pain in favour of conventional miscrodiscectomy.[18] Ryang et al. randomised 60 patients into open microdiscectomy and microdiscectomy using a trocar system. No siginificant differences

in outcome, operation time, and complication rates were documented.[19] Brock et al. demonstrated equivalent improvement of disability and pain although postoperative analgetic consumption was less in patients treated with tubular discectomy.[20] These studies, however, were only powered to detect large effect sizes and data was based on a selected patients cohort.

The present data might change the daily practice of surgeons who perform tubular discectomy as standard surgical procedure in patients with herniated disc related sciatica. Tubular discectomy was not found to be superior to conventional microdiscectomy and the functional and clinical oucome were similar during the first two years after surgery. Therefore, in our opinion, the decision making of surgical strategy should be based on the preferences of patients and surgeons, bearing in mind the similar outcomes of both techniques. For this reason, hospitals and private clinics should be warned against higher charges of minimally invasive techniques proclaiming better results.

CONCLUSIONS

Although minimally invasive surgical techniques were launched to be superior to conventional surgery with regard to speed of recovery and outcome, the present data do not support better results of tubular discectomy compared with open microdiscectomy. Both strategies resulted in equivalent improvement of Roland-Morris disability scores during the two years of follow-up. Patients' scores on the visual analogue scale of leg pain and low-back pain were in favour of conventional microdiscectomy, although these small differences were not clinically relevant.

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