Motion preservation in cervical prosthesis surgery: Implications for adjacent segment degeneration

Yang, X.

Chapter 3

The Size of Cervical Disc Herniation on MRI Does Not Correlate to Clinical Condition

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Submitted

ABSTRACT

Objective

To investigate the correlation between the size of the disc herniation and the clinical condition. Besides that, it was evaluated whether the size of disc herniation at baseline can predict clinical outcome at two-year follow-up.

Methods

A total of 108 patients who underwent anterior discectomy for a cervical radiculopathy due to a herniated disc were analysed for the size of cervical disc herniation at baseline. The size of the cervical disc herniation was qualitatively evaluated on magnetic resonance imaging (MRI), using a four-point scale which was subsequently dichotomized into mild and severe herniation. Clinical condition was evaluated by means of Neck Disability Index (NDI), 36-Item Short Form Health Survey, Visual Analogue Scoring for neck pain and for arm pain at baseline, and at two years postoperatively. Perceived recovery was assessed at two-year follow-up.

Results

At baseline, 46 patients had a mild herniation, and 62 patients had a severe herniation. At baseline, the patients in the mild herniation group had a comparable NDI (44.6 versus 43.8; P=0.799) and SF-36 (59.2 versus 59.4; P=0.895) to the patients in the severe herniation group. Likewise, disabling arm pain was comparable in the mild and severe herniation group (84% versus 73%; P=0.163), and disabling neck pain was also comparable (71% versus 63%, P=0.491). At two years after surgery, no difference was found in any of the clinical parameters between the two groups.

Conclusions

In patients who suffer from cervical radiculopathy, the size of disc herniation measured on MRI was not correlated with clinical condition at baseline, and neither to clinical outcome after surgical treatment at two-year follow-up.

INTRODUCTION

Cervical radiculopathy is a neurological disorder caused by dysfunction of nerve roots exiting the spinal cord in the cervical spine, with an incidence of 1.79 per 1,000 person-years from 2000 to 2009[1]. It typically describes as arm pain along the path of innervation of the affected roots[2], and frequently, with the setting of neck pain[3]. One of the common cause of cervical radiculopathy is a bulging or herniated disc compressing the corresponding nerve root[4].

Cervical radiculopathy is diagnosed based on anamnestic details and physical examination. Imaging of the cervical spine can reveal whether the radiculopathy is caused by compression of the spinal root, for instance by a herniated disc. Magnetic resonance imaging (MRI), which is considered the imaging procedure of choice for patients in whom cervical disc herniation is suspected, is wildly used in diagnosis and treatment planning for patients with cervical radiculopathy. MRI can provide a non-invasive morphologic evaluation of the cervical spine and intervertebral disc and reveal the evidence of degenerative changes. In addition, the size and contour of disc herniations can be measured and identified on MRI, as can the size and proportions of the spinal canal[5], possibly elucidating the aetiology of the clinically diagnosed cervical radiculopathy However, abnormal MRI findings, like bulging discs and disc degenerative changes are frequently present in the demographic of patients that present with cervical radiculopathy. This results in high rates of false-positive findings in the asymptomatic patient[6,7]. Nakashima et al.[8] reported that nearly 90% of asymptomatic subjects had disc bulging, which is defined as the intervertebral disc protruding posteriorly by more than 1 mm. Therefore, it is relevant to evaluate the relationship between the size and shape of cervical disc herniation to clinical symptoms to better understand its relevance.

The objective of the current study is to investigate the correlation between the size of the cervical disc herniation and clinical symptoms. In addition, the prognostic value of the size of disc herniation on MRI on clinical outcome in patients treated by anterior cervical discectomy for cervical radiculopathy was assessed as well.

METHODS

Study design

A prospective, randomized double-blind multicentre trial among patients with cervical radiculopathy due to single-level disc herniation was conducted (Netherlands Cervical Kinematics: NECK trial). Patients were randomly assigned into three groups: anterior cervical discectomy with arthroplasty (ACDA; activC, Aesculap AG, Tuttlingen, Germany), anterior cervical discectomy with fusion (ACDF; Cage standalone) and anterior cervical discectomy without fusion (ACD). Patients (age 18 - 65 years old) with radicular signs and symptoms in one or both arms for at least eight weeks, in who conservative therapy failed were eligible for

inclusion. All patients were diagnosed with cervical radiculopathy by a neurologist in one of the participating hospitals. If MRI demonstrated a single-level cervical disc herniation with or without osteophyte at one level (C3-C4 to C7-Th1) in accordance with clinical signs and symptoms, patients could be included as surgical candidates for the study by the consulting neurosurgeon. Patients with previous cervical surgery, absence of motion or increased anteroposterior (AP) translation or very narrow (< 3 mm) intervertebral space or severe segmental kyphosis (> 3 degrees) at the index level on static or dynamic x-rays, neck pain only or symptoms and signs of chronic myelopathy were excluded. A randomized design with variable block sizes was used, with allocations stratified according to centre. The design and study protocol were published previously[9].

Standard protocol approvals, registrations, and patient consents

The protocol was approved by the Central Medical Ethics Committee Leiden ('Commissie Medische Ethiek Leiden University Medical Centre', decision letter P08.011) and the board of directors of the Rijnland hospital Leiderdorp, Diaconessenhuis Leiden, Haaglanden Medical Centre and Antoniushove the Hague, including an approval for randomization after anaesthetic induction, in agreement with the Central Ethics Committee Leiden. The protocol was also approved by the 'Medical Ethics Committee Noord-Holland' for the Medical Centre Alkmaar (M08−038). The NECK trial was registered at Dutch Trial Register with study identifying number NTR1289. Informed consent was obtained from the participants.

Clinical outcome measurement

Neck Disability Index (NDI) is a 10-item questionnaire on three different aspects: pain intensity, daily work-related activities and nonwork-related activities. Each item is scored from 0 to 5 and the total score ranges from 0 (best score) to 50 (worst score). This 50-point score was converted to a percentage (50 points=100%). The NDI is a modification of the Oswestry Low Back Pain Index and has been shown to be reliable and valid for patients with cervical pathology[10-12].

The 36-Item Short Form Health Survey is a generic health status questionnaire that can easily be filled out at home. The questionnaire consists of 36 items on physical and social status of the patient divided into subscales. The questions are scored on a scale of 0 (worst health) to 100 (ideal health). This questionnaire has been used frequently and is validated in surgical studies on spinal column pathology[13-15]. The physical component summary (PCS) and mental component summary (MCS) are derived from the SF-36 and are summary scores for respectively the Physical Quality of Life and the Mental Quality of Life. The PCS and MCS range from 0 to 100 with higher scores representing better self-reported health.

The Visual Analogue Scale (VAS) pain measures the experienced pain intensity during the week before visiting the research nurse. Pain was assessed on a horizontal 100 mm scale varying from 0 mm (no pain) to 100 mm (worst pain imaginable). Patients do not see the

results of earlier assessments and score the pain experienced at the visit. Reliability, validity and responsiveness of VAS have been shown previously[16]. Disabling neck pain and arm pain were defined as at least 40 mm since this cut-off value is regularly used when VAS is categorized into favourable and unfavourable outcome[17,18].

Finally, patients were asked to judge their post-operative recovery ('perceived recovery') on a scale varying from 'complete recovery' to 'worse than ever' in 7 steps (7-point Likert scale). This outcome scale has been used in previous studies and is regarded valid and responsive to change[19]. 'Complete recovery' and 'almost complete recovery' are defined as a favourable result, which was used to dichotomize the data.

The improvement of clinical outcome was defined as the difference between baseline to two-year follow-up.

The clinical outcomes were comparable between three surgical treatment arms, which has been reported previously[20]. Therefore, the clinical outcomes of the patients were studied irrespective of surgical methods.

Radiological evaluation

MRI were performed at each study centre using a standardized protocol tailored to a 1.5- or 3-Tesla scanner at baseline. Standard sagittal T1 and T2 and T2 axial images were obtained, using 3-mm contiguous slices in all directions and an in-plane resolution of 1 mm^2 or less. The size of cervical disc herniation was evaluated at the operative level at both the left and right side, using a four-point scale: *normal*, completely normal; *mild*, slight bulging of herniated disc; *moderate*, pro/extrusion less than ¼ of foraminal canal; *severe*, pro/extrusion more than ¼ of foraminal canal (Figure 1). For evaluation, data were dichotomized into 'mild herniation group' for those subjects with the classification *normal* and *mild*, and 'severe herniation group' for the classification *moderate* and *severe*. The MRIs were evaluated by neurosurgeons in participating hospital and then independently confirmed by one senior neurosurgeon (CVL) dedicated to spine surgery.

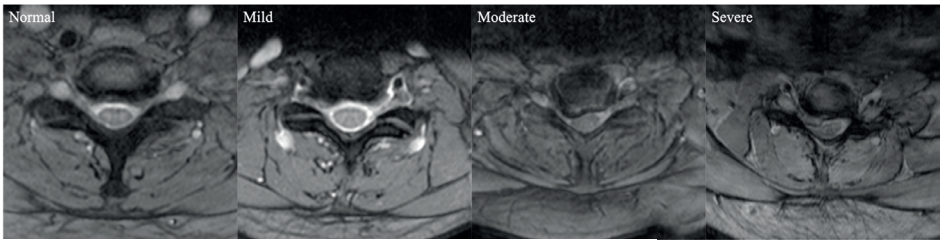

Figure 1 Classification of cervical disc herniation

Statistical analysis

All data were presented as mean ± standard deviation. Student *t*-test was used to compare continuous data and chi-square test for categorical data between groups. Differences between groups at all follow-up points were analysed with repeated measurement analysis. Tests were two tailed, and a P value of < 0.05 was considered significant. SPSS software, version 25.0 was used for all statistical analyses (SPSS, Inc., Chicago, IL, USA).

RESULTS

Demographics

In the NECK trial, 111 patients were included and randomly assigned to ACD (38 patients), ACDF (38 patients) or ACDA (35 patients). At baseline, MRI data were available for 108 patients.

Baseline characteristics are presented in Table 1. The mean age of the study population was 46.8 ± 7.9 years, ranging from 27 to 70 years. There was no difference regarding baseline characteristics between groups.

Table 1 Patient demographics

	Mild group	Severe group	P value
Population	46	62	
Age (years, mean ± SD)	47.1 ± 8.4	46.4 ± 7.8	0.685
BMI (mean ± SD)	26.9 ± 4.1	26.6 ± 4.3	0.714
Man	16 (34.8%)	35 (56.5%)	0.026*
Smoking	17 (38.6%)	27 (43.5%)	0.613
Herniated level			
C5-C6	25	31	
C6-C7	20	31	
C7-Th1	1	0	

SD: Standard deviation
BMI: Body Mass Index

Cervical disc herniation at affected side of operative level

Of 108 patients at baseline, four were classified as *normal*, 42 patients as *mild*, 59 patients as *moderate* and three patients as *severe*. Thus, 46 (43%) patients were included in the 'mild herniation' group and the other 62 (57%) patients were included in 'severe herniation' group.

Correlation of herniation size with clinical outcome

At baseline, the mild herniation group had a comparable NDI value (44.6 ± 15.2 versus 43.8 ± 16.0, P=0.799) and SF-36 (59.2 ± 6.9 versus 59.4 ± 7.7, P=0.895) in comparison to the

severe herniation group. In the mild herniation group, 84% of patients had disabling arm pain, which is similar to the 73% of patients with disabling arm pain in the severe herniation group (P=0.163). For the proportion of patients with disabling neck pain, a comparable result was shown as well (71% versus 63%, P=0.491).

At two years after surgery, the patients in the mild herniation group reported comparable NDI (Figure 2, P=0.091) and SF-36 (Figure 3, P=0.427) values compared to those in the severe herniation group. 17% of patients from the mild herniation group reported disabling arm pain, which is similar to 15% of patients of the severe herniation group (P=0.795). Disabling neck pain was demonstrated in a similar proportion of patients in both groups (22% versus 21%, 0.888). Additionally, 59% of patients in the mild herniation group had a favourable result on perceived recovery which was comparable to 70% of patients in the severe herniation group (P=0.230) (Table 2).

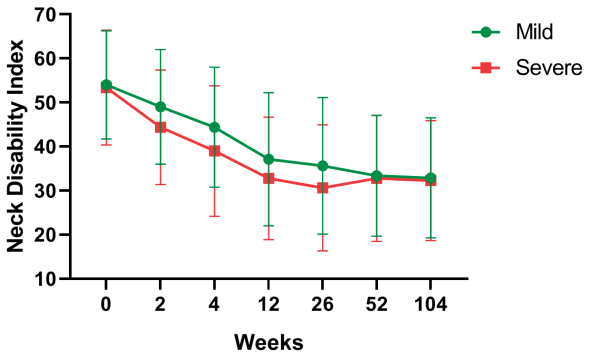

Figure 2 Neck disability index

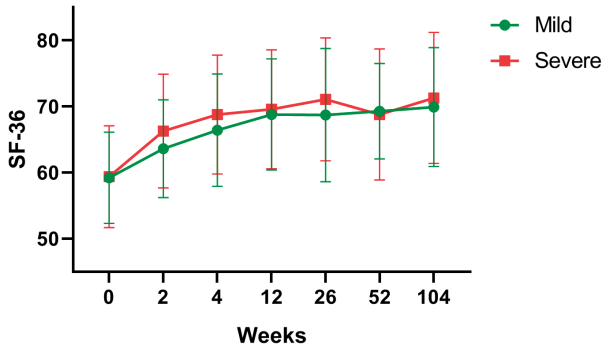

Figure 3 The 36-Item Short Form Health Survey

Table 2 Clinical outcomes

	Baseline			One-year follow-up			Two-year follow-up		
	Normal group	Severe group	P	Normal group	Severe group	P	Normal group	Severe group	P
NDI	44.6 ± 15.2	43.8 ± 16.0	0.799	20.0 ± 16.6	18.9 ± 17.4	0.840	19.1 ± 16.4	18.5 ± 19.6	0.861
SF-36	59.2 ± 6.9	59.4 ± 7.7	0.895	69.3 ± 7.2	68.8 ± 9.9	0.760	69.9 ± 9.0	71.2 ± 9.9	0.495
PCS	41.7 ± 13.5	42.8 ± 15.1	0.690	71.8 ± 22.1	70.7 ± 22.3	0.823	75.0 ± 20.8	71.1 ± 25.8	0.446
MCS	61.5 ± 21.9	55.5 ± 23.2	0.185	77.7 ± 18.3	75.2 ± 22.3	0.553	78.9 ± 17.1	73.9 ± 25.7	0.296
VAS Neck Pain (disabling pain %)	70.5% (31)	62.9% (39)	0.491	22.0% (9)	19.0% (11)	0.716	22.0% (9)	20.8% (11)	0.888
VAS Arm Pain (disabling pain %)	84.1% (37)	72.6% (45)	0.163	14.6% (6)	25.9% (15)	0.178	17.1% (7)	15.1% (8)	0.795
Liker recovery (favourable results %)	-	-	-	63.4% (26)	65.5% (38)	0.829	58.5% (24)	70.4% (38)	0.230

NDI: Neck Disability Index
PCS: Physical-component summary
MCS: Mental-component summary
VAS: Visual Analogue Scale

Improvement of clinical outcome on an individual level demonstrated that a comparable percentage of patients in both groups reported recovery (Table 3 and 4).

Table 3 The number of patients with worse or same results as baseline

	Worse	Same
NDI	6	1
SF-36	7	2
PCS	10	1
MCS	13	1
VAS Neck Pain	12	4
VAS Arm Pain	8	0

NDI: Neck Disability Index
PCS: Physical-component summary
MCS: Mental-component summary
VAS: Visual Analogue Scale

Table 4 The improvement of clinical outcomes

	Normal group	Severe group	P value
NDI	28.0 ± 15.4	27.0 ± 14.3	0.766
SF-36	11.1 ± 6.0	15.4 ± 10.1	0.144
PCS	37.1 ± 16.1	35.0 ± 17.4	0.608
MCS	16.6 ± 21.9	19.2 ± 23.9	0.613
VAS Neck Pain	39.8 ± 24.4	34.9 ± 23.1	0.368
VAS Arm Pain	54.8 ± 22.8	47.7 ± 23.9	0.169

NDI: Neck Disability Index
PCS: Physical-component summary
MCS: Mental-component summary
VAS: Visual Analogue Scale

DISCUSSION

In this study in patients with cervical radiculopathy due to disc herniation who underwent anterior cervical discectomy treatment and who were followed for two years, the size of disc herniation measured on MRI did not correlate to clinical condition at baseline. Neither was the size of the disc herniation correlating to outcome and is thus predictive for clinical outcome after surgical treatment at two-year follow-up.

MRI is indicated in patients with cervical radiculopathy that are either suffering from persistent or progressive neurological findings (including pain) that fail to respond to conservative treatment[21-24], or if malignancy is suspected. MRI is deemed to be not helpful in most cases of cervical radiculopathy because of the high rates of false-negative and false-positive MRI findings. Teresi et al.[25] reported that 57% of patients over the age of 64 years have evidence of disc herniation but do not demonstrate symptoms. Nakashima et al.[8] studied 1,211 asymptomatic volunteers and found that 88% of them had significant disc bulging, being defined as disc protrusion of more than 1 mm. On the contrary, the presence of disc extrusion has been reported to be associated with clinical symptoms, reported by Beattie et al.[26]. In the present study, we demonstrated our results on the patients of symptomatic cervical radiculopathy and studied the size of herniated disc by means of a four-point scale, compared to the previous evaluation of the presence of herniated disc only.

For the patients with cervical radiculopathy, roughly 80-88% of them will improve within four weeks of nonoperative management[22,27]. If severe symptoms persist, spinal surgery as a treatment modality is considered, and it would be interesting if the size of the herniation would correlate to the clinical burden. Our results cannot confirm this. Thus, not only is the presence of a disc herniation on MRI not distinctive for the presence of clinical signs, neither is the size of the hernia indicative for the severity of complaints.

Furthermore, it would be interesting to know whether the size of the disc herniation can predict the postoperative clinical outcome and the perceived recovery after surgical treatment. In a recent systematic review, Hill et al.[28] failed to draw a definitive conclusion on the association between MRI findings of the cervical spine with future neck pain, due to a limited number of included patients, heterogeneity of patients between studies, and the small sample size of the included studies. Moreover, none of the included articles considered outcome after surgical treatment. In agreement with these results, we could neither demonstrate a predictive aspect in the size of disc herniation on clinical outcome.

In lumbar spine the correlation between the size of disc herniation and clinical symptoms was also absent: el Barzouhi et al.[29] demonstrated that the predictive value of the size of disc herniation at baseline in decision making for lumbar disc surgery is absent, and that the size of disc herniation at baseline measured on MRI did not correlate to outcome at one-year follow-up[30]. Eventually, the MRI performed at one-year follow-up in patients with surgical treatment did not distinguish between those with a favourable outcome and those with an unfavourable

outcome[31]. Since one-year follow-up MRIs were not available in the current study on cervical spine, this correlation could not be studied.

A limitation of the current study is that the number of patients is limited. Moreover, the duration of complaints before surgery varied between patients. The time to surgery may have influenced the severity of complaints at baseline. Finally, clinical outcome was only available for the one- and two-year timepoints and it is uncertain whether we would have found similar results at other time points.

CONCLUSIONS

In patients suffering from cervical radiculopathy, the size of disc herniation does not correlate to severity of clinical symptoms at baseline, and does not allow to predict clinical outcome after surgical treatment at two-year follow-up.

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