Surgery Versus Non-Surgical Treatment for Cervical Radiculopathy: A prospective, randomized study comparing surgery plus physiotherapy with physiotherapy alone with a two year follow-up

Markus Engquist, Håkan Löfgren, Birgitta Öberg, Anders Holtz, Anneli Peolsson, Anne Söderlund, Ludek Vavruch and Bengt Lind

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Surgery Versus Non-Surgical Treatment for Cervical Radiculopathy

***A prospective, randomized study comparing surgery plus physiotherapy with physiotherapy alone with a two year follow-up*.**

Markus Engquist, MD[1]; Håkan Löfgren, MD, PhD[2]; Birgitta Öberg, PhD, RPT[3]; Anders Holtz, MD, PhD[4]; Anneli Peolsson, PhD, RPT[3]; Anne Söderlund PhD, RPT[5]; Ludek Vavruch, MD, PhD[2]; Bengt Lind, MD, PhD[6]

[1] Department of Orthopaedics, Ryhov Hospital, Sweden and Department of Orthopaedics, Institute of Clinical Sciences at Sahlgrenska Academy, University of Gothenburg, Sweden

[2] Neuro-Orthopedic Center, Ryhov Hospital, Jönköping, Sweden

[3] Department of Medical and Health Sciences, Division of Physiotherapy, Faculty of Health Sciences, Linköping University, Linköping, Sweden

[4] Department of Neuroscience, Neurosurgery, Uppsala University Hospital, Uppsala, Sweden

[5] Department of Physiotherapy, School of Health, Care and Social Welfare, Mälardalen University, Västerås, Sweden

[6] Spine Center Göteborg, Gothenburg, Sweden and Department of Orthopaedics, Institute of Clinical Sciences at Sahlgrenska Academy, University of Gothenburg, Sweden

Corresponding author:

Markus Engquist, MD

Address: Department of Orthopaedics, Ryhov Hospital, S-551 85 Jönköping, Sweden.

Phone: +46-36-321514

Fax: +46 36 321506

E-mail: markus.engquist@lj.se

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Research Ethics Committee Approval

The study was approved by the Regional Ethical Review Board at the Faculty of Health Sciences in Gothenburg, and the experiments complied with the current laws of the country of Sweden (Dnr S 222-02).

Abstract

Study Design

Prospective randomized controlled trial.

Objective

To study the outcome of anterior cervical decompression and fusion (ACDF) combined with a structured physiotherapy program compared to the same physiotherapy program alone for patients with cervical radiculopathy.

Summary of Background Data

Knowledge concerning the effects of interventions for patients with cervical radiculopathy is scarce due to a lack of randomized studies.

Methods

63 patients were randomized to surgery with postoperative physiotherapy (n=31) or physiotherapy alone (n=32). The surgical group was treated with ACDF. The physiotherapy program included general/specific exercises and pain coping strategies. The outcome measures were disability (Neck Disability Index, NDI), neck- and arm-pain intensity (VAS) and the patient's global assessment. Patients were followed for 24 months.

Results

The result from the repeated-measures ANOVA showed no significant between group difference for NDI (p=0.23).

For neck-pain intensity, the repeated-measures ANOVA showed a significant between group difference over the study period in favor of the surgical group (p=0.039).

For arm-pain intensity, no significant between group differences was found according to the repeated-measures ANOVA (p=0.580).

87% of the patients in the surgical group rated their symptoms as “better/much better” at the 12-month follow-up, compared to 62% in the non-surgical group ($p<0.05$). At 24 months the corresponding figures were 81% and 69% ($p=0.28$). The difference was significant only at the 12-month follow-up in favor of the surgical group.

Significant reduction in NDI, neck-pain and arm-pain compared to baseline was seen in both groups ($p<0.001$).

Conclusions

In this prospective, randomized study of patients with cervical radiculopathy, it was shown that surgery with physiotherapy resulted in a more rapid improvement during the first postoperative year, with significantly greater improvement in neck pain and the patient’s global assessment compared to physiotherapy alone, but the differences between the groups decreased after two years. Structured physiotherapy should be tried before surgery is chosen.

Mini Abstract/ Précis

A prospective, randomized study comparing surgery plus physiotherapy with physiotherapy alone for patients with cervical radiculopathy was conducted. Surgery resulted in a more rapid improvement during the first postoperative year, with significantly greater improvement in neck pain and the patient's global assessment compared to physiotherapy alone, but the differences between the groups decreased after two years.

Key Points

Patients with cervical radiculopathy were randomized to ACDF with physiotherapy or physiotherapy alone.

Significant improvement was found with regard to disability, neck- and arm-pain intensity, and global assessment in both groups at the 1 and 2 year follow-ups.

A significantly better result was seen after ACDF regarding neck pain and global assessment at 1 year, but only for neck pain regarding the whole follow-up-period.

Introduction

Cervical radiculopathy is a painful and relatively common condition with a reported prevalence of about 0.3 %[1]. The natural history has been reported to be favorable [2,3], and conservative treatment consisting of pain management and physiotherapy has primarily been proposed [3-5]. Surgical treatment has been suggested when there is persistent pain for more than three months, or to achieve a more rapid recovery from symptoms [5-7]. Anterior cervical decompression and fusion (ACDF) is usually considered the gold standard for surgical treatment, although clear proof of the superiority of this method is lacking. There are several studies reporting the outcome of ACDF, many reporting good results on pain relief and patient satisfaction [8-10]. However, these studies are made without a non-surgical control group, and considering the benign natural course of the disease, these data are weak with regard to evidence of the effect of surgical treatment.

In a Cochrane review (2002), it was stated that there is no reliable evidence for the effects of surgery for cervical spondylotic radiculopathy [11]. The only prospective, randomized study on this subject was published in 1997 [12], in which ACDF was compared with pragmatic physiotherapy or a cervical collar. Many authors have emphasized the need for randomized, controlled studies, evaluating the effect of surgical treatment [5,7,11,13,14].

In the current prospective, randomized, controlled study, ACDF combined with a structured physiotherapy program was compared with the same physiotherapy program alone for patients with cervical radiculopathy.

Materials and methods

From June 2003 to February 2009, patients aged 18-65 years with cervical radiculopathy, referred to and elected for surgery at three Swedish spine centers, were eligible to participate in the study. Patients fulfilling the study criteria were invited to participate, and given oral and

written information. The 68 patients who chose to participate were randomized into two groups: ACDF combined with physiotherapy (surgical group) or physiotherapy alone (non-surgical group). Five patients declined further participation soon after randomization, before the start of treatment, and were excluded. Another 37 patients who didn't want to be randomized, and therefore rejected participation before inclusion also completed the baseline questionnaires. The study was approved by the local ethics committee.

Inclusion criteria were the following:

1. Pain (with or without sensory and motor deficit) in one or both arms indicating nerve-root affection, caused by disc herniation with or without osteophytes, or a stenosis caused by osteophytes, confirmed by MRI
2. Symptom duration of eight weeks to five years.
3. One or two symptomatic disc levels.
4. In working age (18-65 years).

Exclusion criteria were the following:

1. Obvious myelopathy
2. Slight, intermittent signs of myelopathy ("mild myelopathy") but a lack of objective findings.
3. A history of neck distortion (Whiplash Associated Disorder) or "generalized" muscle-pain i.e. fibromyalgia.
4. Need for another type of surgery, i.e. vertebral body resection or foraminotomy.
5. Malignancy, inflammatory joint disease or psychiatric disorder.
6. Difficulty understanding the Swedish language.
7. Concurrent work-disabling disease
8. Other spinal disease causing pain or neurologic deficit during the last year.
9. Previous surgery in the cervical spine.

Randomization and treatment

Clinical examination was first made by the surgeon. After accepting participation in the study and signing the informed consent, the patients completed the baseline questionnaires. Randomization was then performed by a secretary at one of the centers, who for the two treatments used equal numbers of randomly distributed sealed envelopes. For administrative reasons, treatment was started approximately six weeks after randomization in both groups. A flow-chart of the study is shown in Figure 1. The treatment in the two groups is described below.

Surgical group (n=31)

The patients were operated by one of four participating senior surgeons with anterior cervical decompression and fusion. The disc and osteophytes were removed and the segment or segments fused. For a one-level fusion (n=27), a cylindrical titanium implant (BAK/C®, Zimmer, Minneapolis, MN, USA) which was filled with autologous bone collected during decompression and bone bed preparation was used. For a two-level fusion (n=4) two metal cages were used along with an anterior plate to achieve primary stability. No iliac crest grafts or other bone substitutes were used. Three months after surgery, the patients started the same physiotherapy program as those in the non-surgical group (see below). The program was then continued for a minimum of three months. The three-month time space before starting physiotherapy treatment was chosen to allow fusion healing. All segments were considered to be fused at the 3 month clinical and radiological follow up made by the surgeon.

Non-surgical group (n=32)

The physiotherapy treatment was individualized from a three-step program. The treatment received was reported for each patient. Step one consisted of neck-specific exercises and procedures for pain-relief. Step two involved general exercises, and step three involved pain coping, increasing self-efficacy and stress management strategies. The program was

performed daily by the patient at home and twice a week at the clinic, and continued for a minimum of three months.

Evaluation

Clinical examination before treatment was made by the surgeon. The baseline questionnaires were filled in before randomization. The follow-ups at 6, 12 and 24 months were performed by an observer that was not involved in the treatment of the patients. The primary outcome measure of the study was self-reported disability, and the two secondary measures were self-reported pain intensity and global assessment. Other measures collected were socio-demographic data, consumption of analgesics and post operative complications. The following methods and protocols were used:

1. Socio-demographic data were collected in the baseline questionnaire.
2. Pain intensity for “present pain” was registered using a horizontal visual analogue scale (VAS) 0-100 mm, were 0 was characterized as “no pain” and 100 as “worst pain imaginable”. Neck pain and arm pain were registered separately.
3. Disability was assessed with the Neck Disability Index (NDI) [15].
4. The patient´s global assessment consisted of the question: “After the treatment, my neck/arm problems are: ‘much better, better, unchanged, worse, much worse’”.
5. The use of analgesics was graded into four levels: “never, occasionally, every day, several times every day”.
6. Early surgical complications, such as unexpected bleeding, infection, arising neurologic deficit and thromboembolic disease, were registered at the dismissal from the hospital.

Statistics

Differences at baseline between participants and non-participants as well as between treatment groups, were analysed using Pearson´s Chi-Square test on categorical data and independent sample t-test on interval level data.

To be able to analyze treatment group differences in change over time on the whole sample, multiple imputation was used for missing values on NDI %, neck-pain intensity, arm-pain intensity, and patient´s global assessment. A fully conditional specification method was used, which means that values are imputed in the order specified in the analysis; variables were entered in reverse order (24 months follow-up values through before treatment values). NDI %, neck-pain intensity, arm-pain intensity, and patient´s global assessment was used as both predictors and outcome variables in the models and treatment group was entered as a predictor. NDI and pain intensity was predicted with multiple linear regression models and patient´s global assessment was predicted with multiple logistic regression models. The multiple imputation procedure was repeated 100 times on a total of 63 missing values (6.7%) in each dataset. A pooled dataset was used for all analysis.

Between treatment group differences, in change over time in the outcome measures; NDI %, VAS neck pain, and VAS arm pain, was analyzed with repeated-measures analysis of variance (ANOVA). Bonferroni correction was used to control the familywise error rate of multiple pairwise comparisons. Risk ratios (RR) with corresponding 95% confidence intervals (CI) were calculated for treatment group differences in the patient´s global assessment and significance tested using z-statistics. All analyses were two-sided and the significance level was set at $p<0.05$.

Results

The socio-demographic data and symptom duration at baseline are presented in Table 1. The only statistically significant difference between the treatment groups was that the patients in the surgical group were older, with a mean age difference of 4.7 years. When separately analyzed, age did not correlate to any of the main outcomes. The analysis of the 37 non-participants showed that they had significantly greater neck and arm pain, but a shorter duration of symptoms and sick-leave when compared to the study participants (Table 2).

Table 1.

Socio-demographic data of the two treatment groups before randomization. Values presented as means (SD) unless otherwise noted. P-values represent differences between groups. † Significance was calculated with t-test, ‡ Significance was calculated with chi-square test.

	Surgical group (n=31)	**Non-surgical group (n=32)**	**p-value†**
Age, years	49 (8)	44 (9)	<0.05
Duration of neck symptoms, months	15 (12)	21 (19)	N.S.
Duration of arm symptoms, months	13 (10)	17 (16)	N.S.
Duration of sick leave, months	8 (6)	10 (11)	N.S.
			p-value‡
Male, n (%)	14 (45)	19 (59)	N.S.
Smoker, n (%)	8 (32)	9 (25)	N.S.
Living alone, n (%)	7 (25)	5 (16)	N.S.
Employed, n (%)	25 (89)	26 (81)	N.S.
Sick leave (full- or part-time), n (%)	23 (82)	21 (68)	N.S.
Change of work due to neck problems, n (%)	3 (13)	3 (12)	N.S.

Drop outs

Five patients declined further participation early after randomization and were excluded before treatment. Four of these had been randomized to surgery, and one to non-surgical

treatment. Eight patients failed to fill in the 6-month questionnaire on time. Three refused the 12-month follow-up, but all patients completed the 24-month follow-up.

Table 2.

Socio-demographic data for the study participants and 37 patients that rejected participation but completed the baseline questionnaires. Values are presented as means (SD) unless otherwise noted. P-values represent differences between groups. † Significance was calculated with t-test, ‡ Significance was calculated with chi-square test.

	Participants (n=63)	**Non-participants (n=37)**	**p-value†**
Age, years	46 (9)	44 (7)	N.S.
Duration of neck symptoms, months	18 (16)	11 (9)	<0.01
Duration of arm symptoms, months	15 (13)	11 (9)	N.S.
Duration of sick leave, months	9 (8)	7 (5)	N.S.
NDI before treatment, score %	39 (14)	43 (15)	N.S.
Neck pain before treatment, VAS 0-100	49 (24)	63 (25)	<0.01
Arm pain before treatment, VAS 0-100	45 (24)	61 (19)	<0.01
			p-value‡
Male, n (%)	33 (52)	19 (51)	N.S.
Smoker, n (%)	17 (28)	10 (27)	N.S.
Living alone, n (%)	12 (20)	5 (14)	N.S.
Employed, n (%)	51 (85)	34 (92)	N.S.
Sick leave (full- or part-time), n (%)	44 (75)	18 (50)	<0.05
Change of work due to neck problems, n (%)	6 (13)	12 (32)	<0.05

Cross over

Five patients originally randomized to non-surgical treatment were operated during the study, based on their own request, and due to persistent or worsened pain. One was operated between the 6- and 12-month follow-up, and the remaining four between the 12- and 24-month follow-ups. In the analysis, data for these patients were kept in the group they were originally randomized to.

Neck Disability Index

The result from the repeated-measures ANOVA showed no significant between group difference (p=0.23) (Figure 2a). Significant NDI reduction compared to baseline was seen in both groups (p<0.001) (Table 3).

Table 3.

Neck Disability Index (NDI) and pain intensity (VAS) reduction at the different follow-ups compared to baseline. Values are presented as within group mean change (95% confidence interval). Figures and p-values display paired differences within groups. Significance was calculated using paired samples t-test with Bonferroni correction.

	Surgical group								
Compared to baseline	**6 months**			**12 months**			**24 months**		
	mean	**95% CI**	**p-value**	**mean**	**95% CI**	**p-value**	**mean**	**95% CI**	**p-value**
NDI reduction, score % 0-100	12.1	(5.9 to 18.2)	<0.001	13.9	(6.5 to 21.3)	<0.001	14.2	(5.6 to 22.7)	<0.001
Neck-pain reduction, VAS 0-100 mm	31.8	(18.5 to 45.1)	<0.001	32.5	(18.3 to 46.7)	<0.001	32.0	(16.6 to 47.5)	<0.001
Arm-pain reduction, VAS 0-100 mm	21.1	(7.0 to 35.1)	0.001	25.1	(10.1 to 40.1)	<0.001	18.1	(0.4 to 35.7)	0.042
	Non-surgical group								
Compared to baseline	**6 months**			**12 months**			**24 months**		
	mean	**95% CI**	**p-value**	**mean**	**95% CI**	**p-value**	**mean**	**95% CI**	**p-value**
NDI reduction, score % 0-100	7.7	(1.6 to 13.7)	0.006	7.1	(-0.2 to 14.4)	0.061	11.5	(3.0 to 19.9)	0.003
Neck-pain reduction, VAS 0-100 mm	16.2	(3.1 to 29.3)	0.008	14.2	(0.2 to 28.1)	0.045	17.4	(2.2 to 32.6)	0.017
Arm-pain reduction, VAS 0-100 mm	16.0	(2.1 to 29.8)	0.015	20.3	(5.5 to 35.1)	0.002	20.5	(3.2 to 37.9)	0.012

Pain intensity

The repeated-measures ANOVA showed a significant between group difference in neck-pain intensity over the study period (p=0.039) (Figure 2b). Pairwise comparisons of the reduction in neck-pain intensity, between baseline and each follow-up, indicated a significantly larger reduction for the surgical group at 12 months (mean 18.4, 95% CI 3.2 to 30.8, p=0.017).

Significant neck-pain reduction compared to baseline was also seen in both groups (p<0.001) (Table 3).

No significant between group differences in arm-pain intensity was found according to the repeated-measures ANOVA (p=0.580) (Figure 2c). Significant arm-pain reduction compared to baseline was seen in both groups (p<0.001) (Table 3).

Patient´s global assessment

In the analysis, the answers were dichotomized into better/much better ("better") and unchanged/worse/much worse ("worse"). The results are shown in Table 4. The distribution of answers between better or worse was more favorable in the surgical group, where 81 to 87% of the patients rated their symptoms as better at the different follow-up times, compared to 62 to 69% in the non-surgical group. The risk difference for recovery at 6 months was 15% (RR 1.22, 95% CI 0.92 to 1.61, p=0.16) at 12 months 25% (RR 1.39, 95% CI 1.03 to 1.88, p=0.03) and at 24 months 12% (RR 1.17, 95% CI 0.88 to 1.57, p=0.15). The difference was significant only at the 12-month follow-up in favor of the surgical group (Table 4).

Table 4.

Patient's global assessment. Figures display number of patients and risk within each treatment group at the follow-ups. Between group differences was calculated with risk ratio (95% confidence interval) and significance tested using z-statistics. † Unchanged/worse/ much worse, ‡ Better/much better

	Surgical group			Non-surgical group			Group comparison		
Follow-up	**Worse† (n)**	**Better‡ (n)**	**Risk**	**Worse† (n)**	**Better‡ (n)**	**Risk**	**Risk Ratio**	**95% CI**	**p-value**
6 months	5	26	0.84	10	22	0.69	1.22	(0.92 to 1.39)	0.180
12 months	4	27	0.87	12	20	0.63	1.39	(1.03 to 1.88)	0.031
24 months	6	25	0.81	10	22	0.69	1.17	(0.88 to 1.57)	0.281

Use of analgesics

Sixty patients answered the question about use of analgesics at baseline. 88% of these stated that they used analgesics for their neck- and/or arm-pain. 55% used a combination of two or more drugs. The drugs used were the following: paracetamol (70%), non-steroidal anti-inflammatory drugs (NSAID) (42%), tramadol (25%), gabapentin (13%), codeine (11%) salicylic acid (ASA) 9% and dextropropoxyphene (8%). Before treatment, 46% in the surgical group and 53% in the non-surgical group used analgesics every day. Six months after treatment, the figures were 19% and 30%, at 12 months 23% and 43% and at 24 months 26% and 31% respectively. There were no significant differences between the groups either at baseline or at any of the follow-ups.

Surgical complications

There were no complications related to the surgical procedures.

Discussion

The present study showed that surgery with postoperative physiotherapy was more effective than physiotherapy alone concerning neck-pain reduction and patient's global assessment. The differences between groups decreased with time. Reduced disability and arm-pain intensity was also noted in both study groups, but the differences between the groups were not significant at any of the follow-ups. The clinically important difference for NDI has been reported to be 10-38% in different studies[16]. As the between-group differences in this study are small even when significant, the results should be interpreted with care.

In the only randomized study on this topic that we have found (Persson et al) [12], the authors reported less pain in the group that underwent surgery, than in the non-surgical groups at 3-4 months but not at 15-16 months after treatment. However, they did not separate arm pain from neck pain and they studied only patients with spondylotic radiculopathy, patients with pure soft disc herniations were not included. The reoperation rate was high (37%) during the study period, which might reflect the type of surgery that was chosen as well as the composition of the study group. In the present study, all patients with radiculopathy regardless of radiological cause were included if found eligible.

The different results for arm- and neck pain intensity in the present study may be due to several reasons. Cross-over and new symptoms from adjacent level discs because of fusion in the surgical group may have influenced the results. Physiotherapy alone was also slightly more effective at reducing arm pain than neck pain, which diminishes the difference between the groups. However, the fact that surgery reduced arm pain less than neck pain is in contrast to earlier reports on the outcome of ACDF [8-10].

Hermansen et al [17] in 2011 reported greater improvement in pain intensity than in disability for patients treated with ACDF. They stated that this “may indicate that further improvement of physical function requires early more extensive postoperative rehabilitation”. In the present study, the reduction in NDI at two years among operated patients was more marked than in Hermansen’s material (average reduction 14 score % compared to between 5 and 10), which may be attributed to the comprehensive rehabilitation program that was used in the present study. Also, it is noteworthy that the reduction in NDI for the patients treated with physiotherapy alone exceeds that for the operated patients in the study by Hermansen, which could further strengthen the theory of rehabilitation being of great importance for reducing disability.

In this kind of study, intra-group changes should be interpreted with caution, as we cannot be sure of how much of these changes are due to the natural course of the condition. Considering a pain duration of up to 60 months before inclusion in the study, we nevertheless think it is interesting that 69 % of the non-surgically treated patients rated their symptoms as “better or much better” already at the 6-month follow-up, and that it is plausible that this is above the expected improvement from both placebo effects and natural course. We believe that the patients’ ability to handle the symptoms was as important a factor as the actual pain relief and that pain management may be a key factor in the non-surgical treatment of this condition.

For patients with this condition, the advantage with surgery is said to be a rather immediate pain relief. In the present study, surgery led to a more rapid improvement compared to physiotherapy alone, but the differences between the two treatments decreased with time. A similar pattern, or even no differences between groups, has been found in other studies on lumbar spine surgery in comparison with non- surgical treatment [18-20]. Considering the good effect of structured physiotherapy on many of these patients, even for those with long-standing pain, it is reasonable to suggest that patients with cervical radiculopathy should initially be treated with similar physiotherapy and that surgical treatment should be reserved for the non-responders.

The demographic analysis of the non-participants showed that they were somewhat different from the participants. They had higher pain intensity, but a shorter duration of symptoms and sick-leave. Most of them stated the desire for undergoing surgery as the reason for not wanting to be randomized. This indicates one of the problems with randomizing a group of patients referred for surgery. There is a risk that the patients having the worst symptoms will

not put themselves at risk of not having the treatment they were hoping for. Lied et al [10] found that high preoperative pain intensity was significantly associated with a greater decrease in pain intensity after surgery. Therefore, this study does not reflect the outcome for all patients fulfilling the criteria for surgery and it might be hypothesized that the better outcome in the surgical group could have been more pronounced if these patients could have been included in the study.

Recruiting patients to a randomization of this kind is not easy. Although the inclusion criteria concerning pain duration were broad, the study population in the present study was small. Considering the fact that all the outcomes at all the follow-ups were in favor of the surgical group, though sometimes not significantly, there was a risk for type 2-errors due to low power. With the use of multiple imputation for missing values, the differences between groups also tended to decrease. In this study, to achieve a power of 80%, a 10% difference in NDI was necessary Regarding pain intensity, the difference had to be 15-20 mm to reach a power of 80%.

Patients crossing over from conservative treatment to surgery is a reality for similar trials, and well known from lumbar spine studies [18,21]. In the present study the cross-over rate from non-surgical to surgical treatment was 16%. In comparison to other studies, this might be considered acceptable. However, when analyzed separately, the patients crossing over generally did better than the rest of the non-surgically treated group, and this might have reduced the differences between groups at the 24-month follow-up.

Conclusions

In this prospective, randomized study of patients with cervical radiculopathy, it was shown that surgery with physiotherapy resulted in a more rapid improvement during the first postoperative year, with significantly greater improvement in neck pain and the patient's global assessment compared to physiotherapy alone, but the differences between the groups decreased after two years. Structured physiotherapy should be tried before surgery is chosen.

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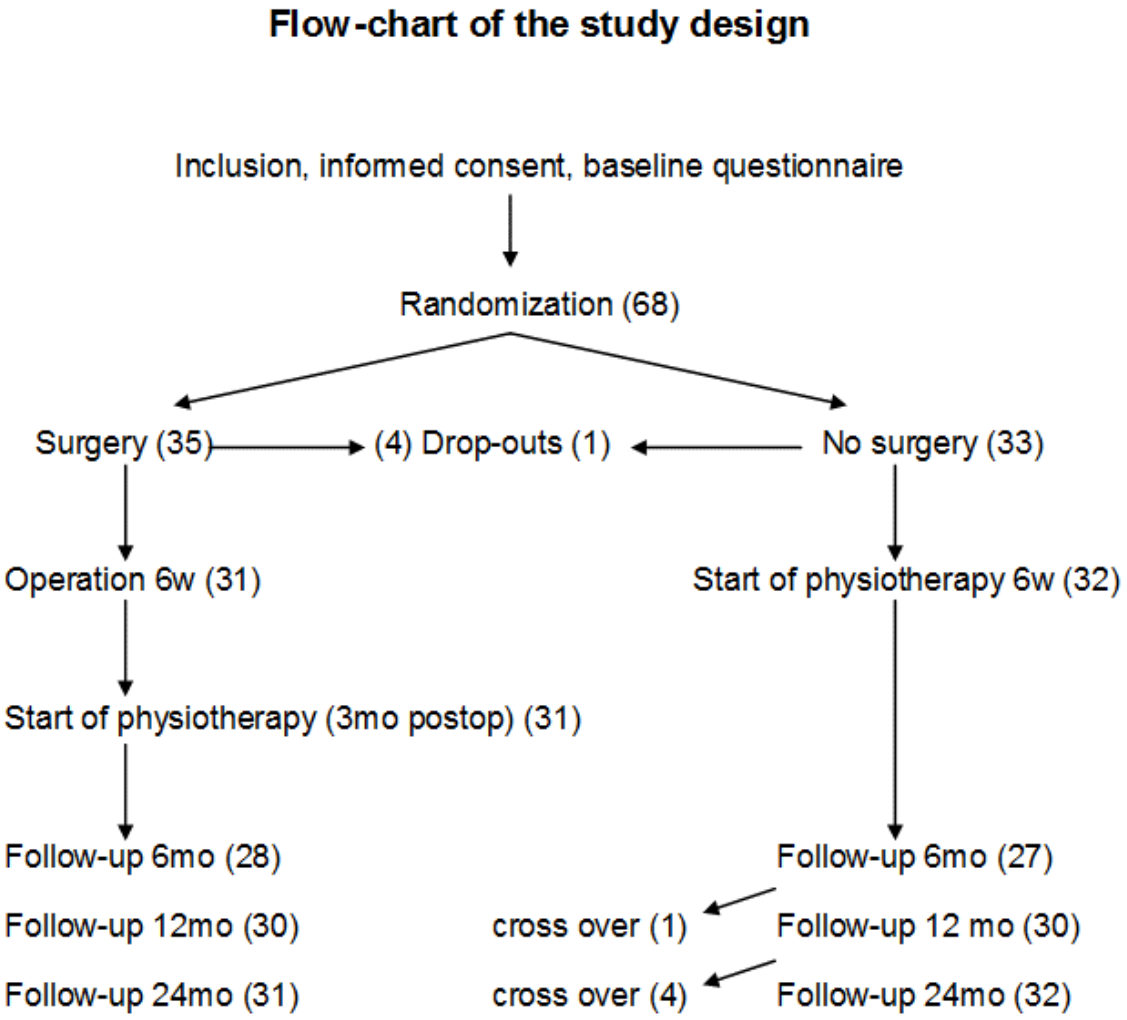

Figure 1. Flow-chart of the study design. Five patients dropped out before the start of treatment and were excluded. Four of these had been randomized to surgery. Five patients in the non-surgical group were operated during the study, one after the 6-month follow-up and four after the 12-month follow-up.

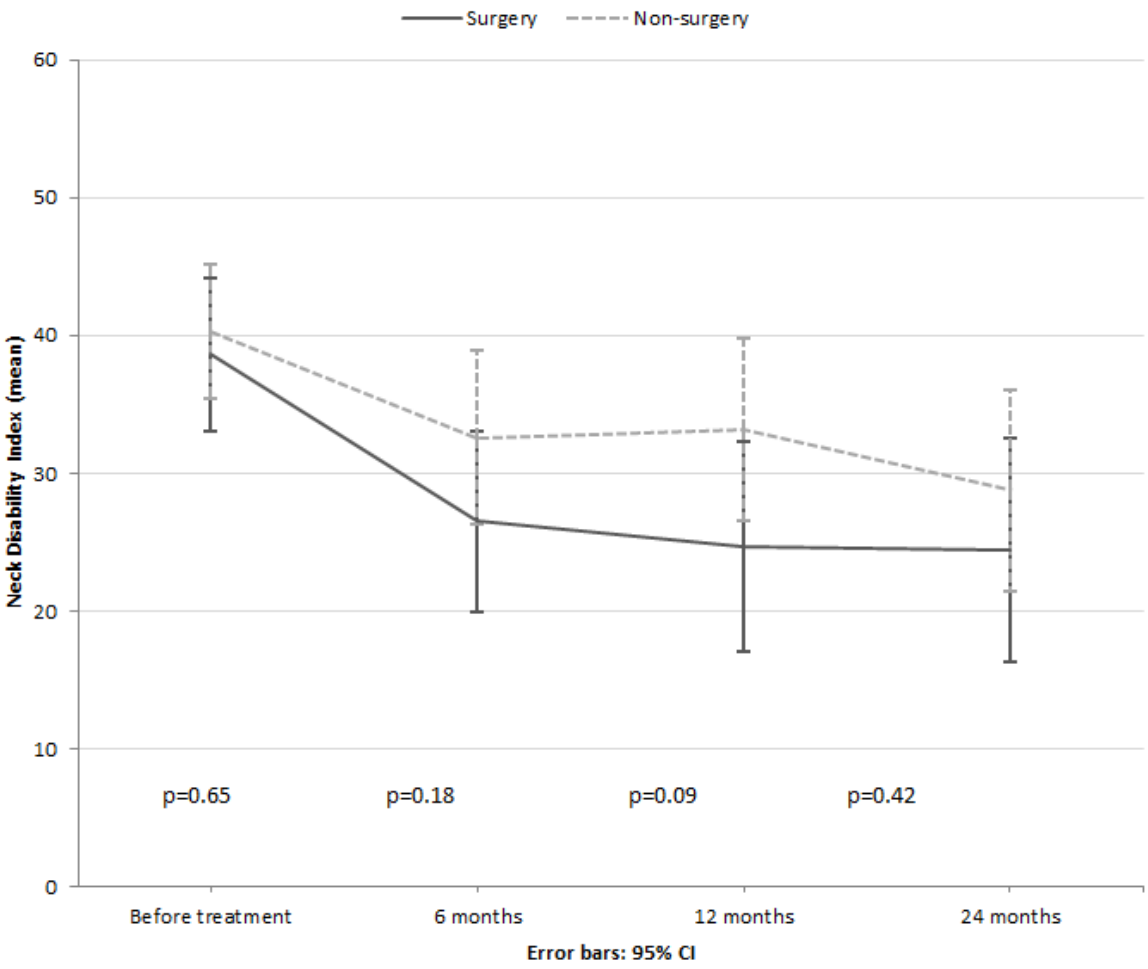

Figure 2a. Neck Disability Index (score %, 0-100) in both groups before treatment and at the follow-ups. Error bars represent the 95% confidence interval. P-values represent cross-sectional differences between groups at each follow up.

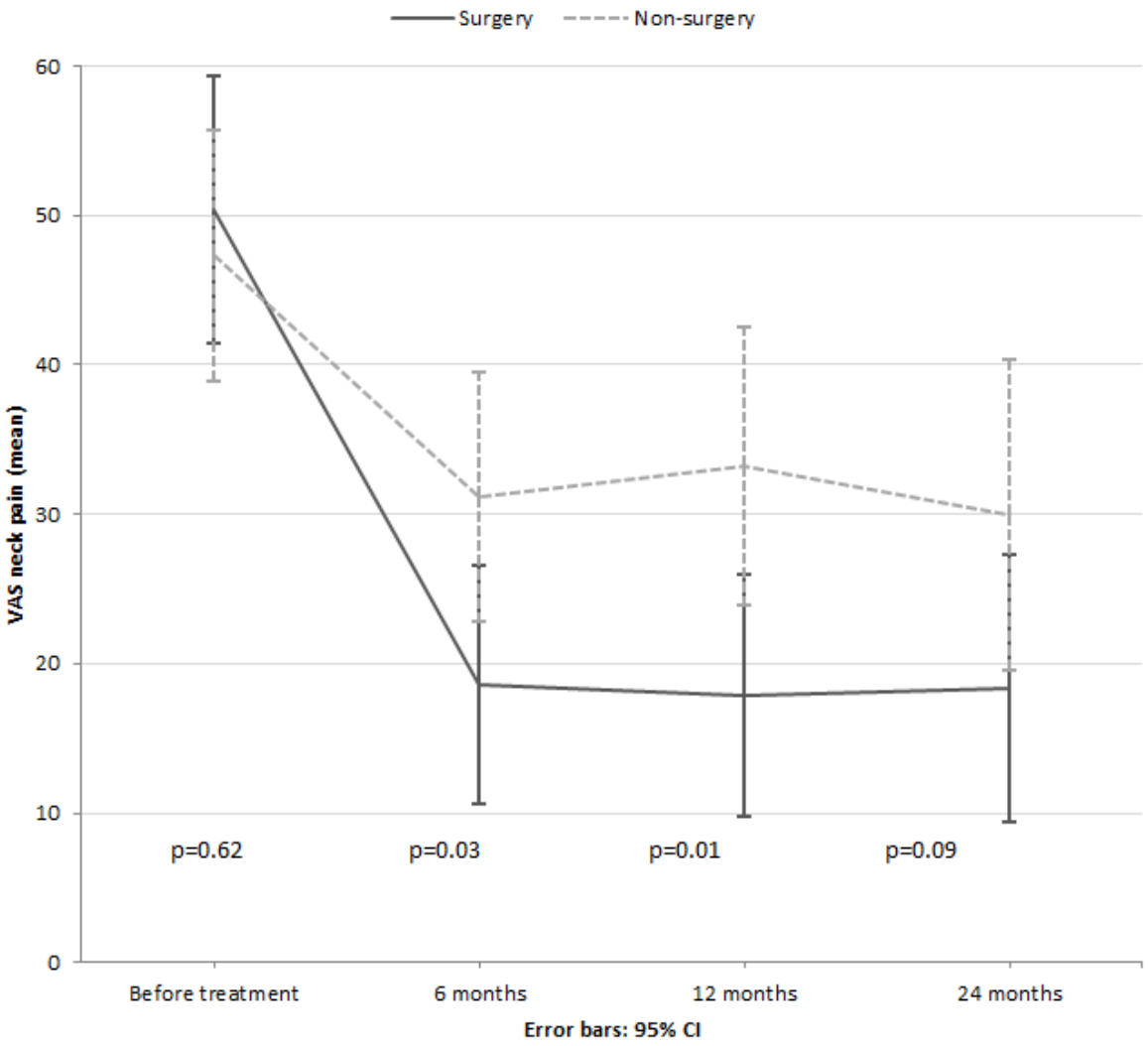

Figure 2b. Neck pain intensity (VAS, 0-100 mm) in both groups before treatment and at the follow-ups. Error bars represent the 95% confidence interval. P-values represent cross-sectional differences between groups at each follow up.

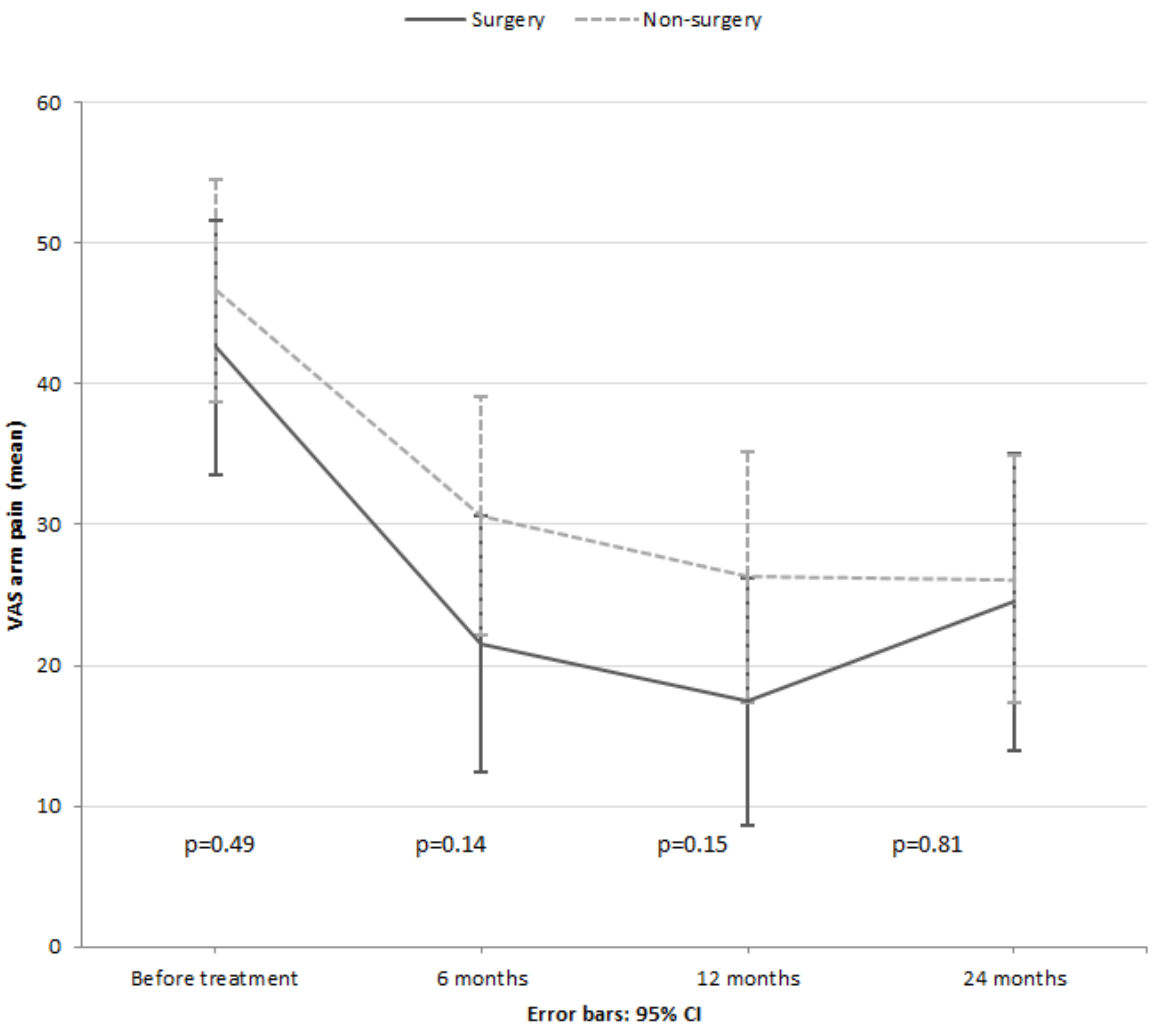

Figure 2c. Arm pain intensity (VAS, 0-100 mm) in both groups before treatment and at the follow-ups. Error bars represent the 95% confidence interval. P-values represent cross-sectional differences between groups at each follow up.