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Factors affecting the outcome of surgical versus nonsurgical treatment of cervical radiculopathy – a prospective, randomized study

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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 Sweden (Dnr S 222-02).

Abstract

Study Design

Prospective randomized controlled trial.

Objective

To analyze factors that may influence the outcome of anterior cervical decompression and fusion (ACDF) followed by physiotherapy versus physiotherapy alone for treatment of patients with cervical radiculopathy.

Summary of Background Data

An understanding of patient-related factors affecting the outcome of ACDF is important for preoperative patient selection. No previous prospective, randomized study of treatment effect modifiers relating to outcome of ACDF compared with physiotherapy has been carried out.

Methods

Sixty patients with cervical radiculopathy were randomized to ACDF followed by physiotherapy or physiotherapy alone. Data for possible modifiers of treatment outcome at one year, such as sex, age, duration of pain, pain intensity, disability (Neck Disability Index, NDI), patient expectations of treatment, anxiety due to neck/arm pain, distress (Distress And Risk Assessment Method, DRAM), self efficacy (Self Efficacy Scale, SES) health status (EQ-5D) and MRI findings were collected. A multivariate analysis was performed to find treatment effect modifiers affecting the outcome regarding arm/ neck pain intensity and NDI.

Results

Factors that significantly altered the treatment effect between treatment groups in favor of surgery were: duration of neck pain < 12 months ($p=0.007$), duration of arm pain < 12 months ($p=0.01$) and female sex ($p=0.007$) (outcome: arm pain), low EQ-5D index (outcome: neck pain, $p=0.02$), high levels of anxiety due to neck/arm pain (outcome: neck pain, $p=0.02$ and NDI, $p=0.02$), low SES score ($p=0.05$) and high DRAM score ($p=0.04$). (outcome: NDI). No factors were found to be associated with better outcome with physiotherapy alone.

Conclusions

In this prospective, randomized study of patients with cervical radiculopathy, short duration of pain, female sex, low health quality, high levels of anxiety due to neck/arm pain, low self efficacy and a high level of distress before treatment were associated with better outcome from surgery. No factors were found to be associated with better outcome from physiotherapy alone.

Key Words

Cervical radiculopathy, randomized, RCT, physiotherapy, surgery, ACDF, outcome, cervical disc degeneration, predictors, treatment effect modifier.

Key Points

- This prospective, randomized study of cervical radiculopathy examined possible treatment effect modifiers related to outcome of anterior cervical decompression and fusion followed by physiotherapy versus physiotherapy alone.
- Short duration of pain, female sex, low health status, high levels of anxiety due to neck/arm pain, low self efficacy and a high level of distress were associated with better outcome from surgery.
- Age, smoking, preoperative pain levels, type of disc herniation and level of depression did not affect the outcome between surgical and nonsurgical treatment.
- No factors were found to be associated with better outcome from physiotherapy alone.
- Gender, high distress and/ or anxiety levels or a poor health status should not disqualify patients from surgical treatment. A better treatment outcome can be expected when surgery, if needed, is performed within a year from the onset of CR symptoms

Mini Abstract/ Précis

This prospective, randomized study of surgical versus nonsurgical treatment of cervical radiculopathy examined treatment effect modifiers for surgical or nonsurgical success.

Female sex, short duration of pain, low EQ-5D, high DRAM-score, low self efficacy and high levels of anxiety due to neck/arm pain were associated with better outcome from surgery.

Introduction

Previously reported data from this prospective randomized study of surgical versus nonsurgical treatment of cervical radiculopathy showed that surgery was more effective at one year follow-up with regard to the outcome measures neck pain intensity and patients' global assessment.¹ The differences between the groups decreased over time and after two years, the only significant difference was in neck pain intensity. No significant differences were found for disability or arm pain intensity. To further improve patient selection and thereby surgical outcome, an understanding of patient-related factors that could potentially influence the results is crucial.

No prior prospective randomized studies evaluating treatment effect modifiers for the outcome of surgical versus nonsurgical treatment have been carried out. Factors that have been suggested as having a positive influence on outcome within a group of surgically treated patients include: high preoperative disability and pain levels,²⁻³ male sex,⁴⁻⁵ non-smokers,⁴⁻⁶ low preoperative disability and pain,⁴⁻⁵ high age,^{2,4} normal preoperative sensory function,² and normal score on the Distress and Risk Assessment Method (DRAM).⁶ Conversely, there are also reports of no correlation between treatment effect and sex, age, number of levels fused, disc level fused, or duration of preoperative symptoms.³ However, no randomized comparisons have been made with a nonsurgically treated group and these studies can therefore only address differences within a group of operated patients, but not cases in which surgery would have been more successful than nonsurgical treatment, or vice versa. Since the natural history of cervical radiculopathy has been reported to be favorable,⁷ the real challenge for the surgeon is to identify factors to help select patients who will benefit from surgery, since many patients may do just as well, or perhaps even better, without surgery.

In this prospective, randomized study we carry out the first sub-analysis of factors that may influence outcome for patients who undergo surgical versus nonsurgical treatment for cervical radiculopathy. We also describe the baseline characteristics of this patient group.

Material and methods

Study design and patient population

Originally, 63 patients were included in the study, as described earlier.¹ The present study consisted of the 60 patients who completed the 12 month follow-up (3 patients didn't return the questionnaires within the stipulated time span of $\pm 10\%$). Participants were randomized into either of two groups: anterior cervical decompression and fusion (ACDF) followed by physiotherapy (PT), or the same PT program alone. Overall results at 6, 12, and 24 months between the two treatment groups regarding pain intensity, disability, physical function and use of analgesics were reported in two earlier papers.^{1,8} Inclusion criteria were pain (with or without sensory and/or motor deficit) in one or both arms indicating nerve root involvement, caused by disc herniation with or without osteophytes, or stenosis caused by osteophytes, confirmed by MRI, duration of symptoms eight weeks to five years, symptoms involving one or two disc levels, and age 18-65 years.

Exclusion criteria were myelopathy, history of neck distortion (Whiplash Associated Disorder) or "generalized" muscle-pain (i.e. fibromyalgia), indication for different type of cervical spine surgery (i.e. vertebral body resection or foraminotomy), malignancy, inflammatory joint disease, psychiatric disorder, concurrent work-disabling disease, other spinal disease causing pain or neurologic deficit during the last year or prior cervical spine surgery.

After agreeing to participate in the study and signing the informed consent, patients completed baseline questionnaires. A secretary at one of the centers then randomized the patients into one of the two treatment groups, using equal numbers of randomly distributed sealed envelopes. A group of 37 patients who declined participation in the study because they did not want to be randomized, but who did complete the baseline questionnaire, was also analyzed to detect possible differences in treatment effect modifiers between these patients and the participants at baseline.

Treatment

Surgical group (n=30)

One of four participating senior surgeons performed anterior cervical decompression and fusion on the patients. The disc and osteophytes were removed and the segment or segments fused. For one-level fusion (n=26), a cylindrical titanium implant (BAK/C®, Zimmer, Minneapolis, MN, USA) filled with autologous bone collected during decompression and bone bed preparation was used. For two-level fusion (n=4), two Trabecular 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 initiated the same physiotherapy program as those in the nonsurgical group. The program was then continued for a minimum of three months. The three-month time span prior to physiotherapy was chosen to allow healing of the fusion. Following the absence of movement between fused segments on flexion-extension radiographs, all segments were considered being fused at the 3-month follow-up visit with the surgeon.

Nonsurgical group (n=30)

Physiotherapy was individualized based on a three-step program. The treatment each patient received was recorded. Step one consisted of neck exercises and procedures for pain relief. Step two involved general exercises, and step three involved pain coping strategies, increasing self-efficacy and stress management strategies. The patient carried out the exercise program daily at home and twice a week in the clinic for a minimum of three months. A more detailed description of the program has previously been published.⁹ No restrictions or changes in the use of medication were stipulated by the study protocol in any of the treatment groups.

Evaluation

The baseline questionnaires were filled in before randomization. For the present study, the 12-month follow-up carried out by an unbiased observer was chosen as the endpoint. The

reason for not choosing the 24-month follow-up was to avoid the effects of patients crossing over to surgical treatment. At the 12-month follow-up, only one patient originally randomized to nonsurgical treatment had been operated (at patient's own request, due to persistent pain), compared with five at the 24-month follow-up.¹ The data for the patient who crossed over were kept in the nonsurgical group. Moreover, the 12-month follow-up showed the greatest differences in treatment effect between groups, thereby improving the chance of finding treatment effect modifiers.

Outcome measures included self-reported disability (Neck Disability Index, NDI)⁹⁻¹⁰ (score percent 0-100) and self-reported pain intensity, which was registered on a horizontal visual analogue scale (VAS) 0-100 mm, where 0 was characterized as "no pain" and 100 as "worst pain imaginable". Neck pain and arm pain were registered separately.

Treatment effect modifiers

Twenty-four possible modifiers of treatment outcome were chosen from the baseline data: sex, age, smoking, duration of pain and intensity (visual analogue scale (VAS) 0-100) for neck and arm separately, arm/neck pain ratio, NDI, patient expectations of treatment, and potential to return to work. Patients also completed a "symptom index" questionnaire that included shoulder pain, back pain, headache, hand numbness, hand weakness, sleeping problems, and anxiety due to neck/arm pain, which could be answered with "never," "occasionally," "every day," or "always." For the purposes of analysis, the answers were dichotomized into two groups: never/occasionally or every day/always. The question regarding patient expectations of returning to work within 6 months after treatment start could be answered with "very high," "high," "neither high nor low," "low," or "very low." The answers were dichotomized into two groups where "very high/high" was scored as "high" and the other answers as "low." Patient expectations for treatment effect were scored as "full recovery", "relief", "improvement" or "no expectations", and dichotomized into "full recovery" or "relief/ improvement/no expectations."

Health and psychological parameters included: the EuroQol Five Dimensions Questionnaire (EQ-5D-3L) (index $-0.584-1$),¹¹ the EuroQol EQ-VAS (VAS 0-100),¹¹ the Zung depression scale (score 0-69),¹² the Self-Efficacy Scale (SES) (score 0-200),¹³ and the Distress and Risk Assessment Method (DRAM).¹⁴ Disc herniation/stenosis was graded by an unbiased senior radiologist as “soft” or “bony/combined.” Continuous variables were converted into categorical variables as follows: NDI, age and SES split by the median, pain intensity and EQ-5D split into two equal parts (since the different scales have different medians), duration of pain of more or less than 12 months, DRAM, and Zung in established groups.^{12,13}

Statistics

For the comparison of baseline data between participants and non-participants the independent samples t-test was used on parametric data and the Fischer's exact test or Chi-square test on non-parametric data. Results are presented in table 1.

For the main analysis, change between baseline and 12 months was calculated, and defined as treatment effect (TE), for the three outcome measures; NDI, arm pain, and neck pain.

Difference in TE was assessed with the fixed factor surgical or nonsurgical treatment.

Separate two-way, full-factorial ANOVAs on each outcome measure were analyzed, using treatment plus one additional variable as fixed factors. The two-way interaction between treatment and the additional variable was defined and interpreted as a treatment effect modifier (TEM) if the interaction effect was significant. In addition, estimated marginal means were calculated on the interaction effect to analyze the treatment effect difference within each TEM group. A positive value is in favor of surgery and a negative value is in favor of nonsurgical treatment. The results from the TEM and the estimated marginal means are presented in table 2-4. All analyses were two-sided and the significance level was set at $p < 0.05$.

Results

The only significant difference at baseline between the two treatment groups was that the patients in the surgical group were older, with a mean difference of 4.7 years ($p=0.04$).

Table 1 presents the baseline characteristics of the treated patient population and the non-participants. Participants had significantly less intense neck and arm pain, and longer duration of neck pain than non-participants. No significant differences were found for the other treatment effect modifiers compared with non-participants.

In the last 12 months before inclusion in the study, 70% of the patients had visited another physician, 50% a physiotherapist and 18% a chiropractor due to cervical radiculopathy. Of these, none experienced relief of symptoms from treatment given by the physician, 20% experienced relief from treatment given by the physiotherapist and 36% from treatment given by the chiropractor. All patients, however, had sufficient residual symptoms to be referred for surgical decision.

Tables 2-4 present the results for treatment effect modifiers in relation to each outcome measure separately. All sub-parts of each analyzed parameter consisted of at least 22% of the total patient population for trichotomized parameters and 26% for dichotomized parameters, except for type of disc herniation, where only 12% of the total population was in the “soft” group, due to a skewed distribution and a relatively high number of missing values.

Factors that significantly altered the TE between treatment groups in favor of surgery ($p<0.05$) were: duration of neck pain < 12 months (outcome measure: arm pain, $p=0.007$); duration of arm pain < 12 months (outcome measure: arm pain, $p=0.01$); female sex (outcome measure: arm pain, $p=0.007$); low EQ-5D index (outcome measure: neck pain, $p=0.02$); high levels of anxiety due to neck/arm pain (outcome measure: neck pain, $p=0.02$ and NDI, $p=0.02$); low SES score (outcome measure: NDI, $p=0.05$) and high DRAM score (outcome measure: NDI, $p=0.04$).

Other trends that favored surgery ($p < 0.1$) included: frequent headaches (outcome measure: arm pain, $p = 0.05$); frequent hand numbness (outcome measure: arm pain, $p = 0.06$); frequent shoulder pain (outcome measure: arm pain, $p = 0.09$); duration of neck pain < 12 months (outcome measure: neck pain, $p = 0.07$); female sex (outcome measure: NDI, $p = 0.09$).

Factors that did not affect outcome included age, smoking, type of disc herniation, preoperative pain levels and depression according to the Zung scale.

Discussion

The present study identified certain factors that may be of importance in the selection of patients for surgical treatment for cervical radiculopathy. The effect of surgical treatment for arm pain was better among patients with short duration of symptoms (< 12 months). This could indicate that the potential for compromised nerves to recover from compression may diminish with time, which may be a factor to consider when scheduling surgical procedures. Similar findings have been seen in lumbar disc surgery.¹⁵⁻¹⁶ Treatment effect on neck pain was not affected by duration of pain, suggesting that the effect of fusion on nociceptive pain can still be achieved after a longer periods of symptom duration. Trends ($p=0.05-0.09$) were also seen suggesting that the effect of surgery on arm pain was better among patients with frequent headaches, shoulder pain, and hand numbness - symptoms often associated with cervical radiculopathy - though no far-reaching conclusions should be drawn from this alone.

Somewhat surprisingly, a high level of anxiety due to arm/neck pain and a high DRAM score were associated with greater improvement in NDI for surgically treated patients. Although the cause is unknown, one possible explanation may be that it is more difficult for the anxious and/or distressed patient to commit to a comprehensive rehabilitation program without the extra “boost” provided by a surgical procedure. It is important to emphasize that this does not mean that patients with high DRAM scores and/or anxiety levels necessarily fared better than those with low scores within the surgical group, since the study focused on the differences between surgery followed by physiotherapy and physiotherapy alone. No significant difference in outcome related to DRAM levels could be detected among operated patients in this study, but the number of patients is small for such an analysis.

When evaluating the modifying effect of the DRAM score on treatment effect, Main et al.¹⁴ analyzed only 11 surgically treated patients, and the conclusion that patients with high DRAM scores had worse clinical outcomes was reached based on patients treated with “advice with reassurance” or “miscellaneous conservative treatments.” When combined with our results,

this finding indicates that a high score on the DRAM scale should not discourage offering surgical treatment when otherwise indicated. In a study on lumbar spine surgery,¹⁷ no correlation was found between the DRAM score and surgical outcomes measured with the Oswestry Disability Index, which supports the above conclusion. However, another report indicates that patients in the distressed group fared worse than other patients regarding improvement in disability and pain following lumbar spine surgery.¹⁸ Both these studies were conducted without a control group of nonsurgically treated patients.

Female sex was also associated with better outcomes from surgery than from nonsurgical treatment, in contrast with earlier reports of better surgical outcomes for men.⁴⁻⁵ However, these studies did not focus on the difference between surgically and nonsurgically treated patients, but only on the treatment effects within a surgically treated group.

In the present study, no differences in outcome were detected between men and women in the surgical group alone, but men fared significantly better concerning arm pain in the nonsurgically treated group ($p=0.04$). Thus our study suggests that the difference in TE regarding arm pain between groups favors nonsurgical treatment for men, rather than more favorable surgical outcomes for women. Nevertheless, as a prognostic factor for a better outcome from surgery than from physiotherapy alone, female sex was still positive in this study.

Low baseline score on the EQ-5D index was associated with greater relief of neck pain and low SES score with greater increase of the NDI score in the surgical group than in the nonsurgical group. The reason for this is unclear, but the findings indicate that a low health status and/ or self efficacy should not disqualify patients from surgical treatment for cervical radiculopathy. Since pain is an index parameter in the EQ-5D-index and has evident effect on the possibility to perform the tasks listed in the SES-score, there may also be co-variation with pain levels. High preoperative pain levels have been shown to be a factor indicating

better outcomes within a surgically treated cohort of radiculopathy patients,³ but they did not turn out to be a treatment effect modifier in the present study.

The main limit of this study is the small sample size. Therefore, the possibility of type II errors cannot be ruled out. Moreover, when performing a randomized study of this kind, there is always a risk of selection bias since patients who choose to participate in a randomization process for treatment may differ from those who do not. In the present study, participants experienced longer duration of neck pain and lower levels of neck and arm pain intensity than did non-participants, making a generalization of the results to a population with more severe pain uncertain. The fact that short duration of pain was found to be a factor leading to better surgical outcomes may help explain some of the unexpectedly poor effects on arm pain previously found in the same patient population¹, since the patients in this study had a mean symptom duration of 15-18 months. However, no differences were found between participants and non-participants regarding psychological, sociodemographic, and health parameters, suggesting that pain levels rather than personal factors influence patient willingness to participate in this kind of a randomization process.

The number of patients in the study is too small to make definitive conclusions of which patients to operate, but a reasonable clinical recommendation is that gender, high distress and/ or anxiety levels or a poor health status should not disqualify patients from surgical treatment. Optimal timing for surgery remains to be determined,¹⁹ but a better treatment outcome can be expected when surgery, if needed, is performed within a year from the onset of CR symptoms. Due to the rather limited differences in treatment effects between surgically and nonsurgically treated patients, we recommend that physiotherapy treatment should precede any surgical decision, but further studies on the effects of different treatment modalities of physiotherapy are required.

Conclusions

In this prospective, randomized study of patients with cervical radiculopathy, short duration of pain, female sex, low health quality, high levels of anxiety due to neck/arm pain, low self efficacy and a high level of distress before treatment were associated with better outcome from surgery. No factors were found to be associated with better outcome from physiotherapy alone.

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Table 1
Baseline data for the 60 study participants and 37 patients who rejected participation but completed the baseline questionnaires.

Treatment effect modifier	Level at baseline Mean (SD)	Non-participants Mean (SD)	P-value (participants – non-participants)
Age	46 (9)	44 (7)	N.S.
Duration of neck pain (months)	18 (16)	11 (9)	0.009
Duration of arm pain (months)	15 (13)	11 (9)	N.S.
Neck pain intensity (VAS 0-100)	49 (24)	63 (25)	0.009
Arm pain intensity (VAS 0-100)	45 (24)	61 (19)	<0.001
NDI	39 (14)	43 (15)	N.S.
Zung depression scale	24 (10)	24 (10)	N.S.
EQ-5D index	0.52 (0.27)	0.44 (0.36)	N.S.
EQ-VAS (VAS 0-100)	50 (18)	43 (23)	N.S.
SES	131 (32)	130 (41)	N.S.

Significance was calculated with the independent samples t-test.

Treatment effect modifier (TEM)	TEM groups	Percent at baseline (n=63)	Non participants (n=37)	p-value (participants – non-participants)
Sex	Male	52	51	NS
	Female	48	49	
Smoker	Yes	28	27	NS
	No	72	73	
Shoulder pain	Never/occasionally	52	16	NS
	Every day/ always	48	84	
	Never/occasionally	77	69	

Back pain	Every day/ always	23	31	NS
Headache	Never/occasionally	90	67	NS
	Every day/ always	10	33	
Hand numbness	Never/occasionally	43	16	NS
	Every day/ always	57	84	
Hand weakness	Never/occasionally	55	32	NS
	Every day/ always	45	68	
Sleeping problems	Never/occasionally	75	46	NS
	Every day/ always	25	54	
Anxiety due to neck/arm problems	Never/occasionally	92	71	NS
	Every day/ always	8	29	
Work expectations	High	56	66	NS
	Low	44	34	
Treatment expectations	Fully recovered	44	41	NS
	Relief/improved	56	59	
Arm/neck pain ratio (VAS)	Arm pain < neck pain	42	57	NS
	Arm pain > neck pain	58	43	
DRAM	Normal	22	24	NS
	At risk	58	52	
	Distress	20	24	

Significance was calculated with the Chi square test.

Abbreviations: NDI: Neck Disability Index; EQ-5D: EuroQol five dimensions; SES: Self Efficacy Scale; DRAM: Distress and Risk Assessment Method; NS: non significant ($p>0.05$).

Table 2

Treatment effects and group comparisons. Outcome: Neck Disability Index (0-100) at 12 months.

Treatment effect modifier (TEM)	TEM groups	Difference in treatment effect surgery – non-surgery (95%CI)	P treatment effect surgery – non-surgery	Difference in treatment effect between TEM groups	P between TEM groups
Sex	Male	2 (-9-13)	0.7	14	0.09
	Female	16 (4-27)	0.01		
Age	18-47	8 (-4-19)	0.2	4	0.6
	48-65	12 (-1-24)	0.06		
Smoker	No	10 (0-19)	0.05	6	0.6
	Yes	4 (-11-20)	0.6		
Duration of neck pain (months)	2-12	14 (2-25)	0.02	13	0.1
	>12	1 (-11-13)	0.8		
Duration of arm pain (months)	2-12	11 (1-21)	0.03	7	0.4
	>12	4 (-10-17)	0.9		
Neck pain intensity (VAS)	0-49	10 (-2-22)	0.09	1	0.9
	50-100	9 (-1-20)	0.07		
Arm pain intensity (VAS)	0-49	7 (-3-17)	0.2	3	0.7
	50-100	10 (-2-23)	0.09		
Shoulder pain	Never/occasionally	6 (-7-20)	0.4	8	0.4
	Every day/ always	14 (5-23)	0.003		
Back pain	Never/occasionally	10 (1-20)	0.04	5	0.6
	Every day/ always	5 (-9-20)	0.04		
Headache	Never/occasionally	10 (1-19)	0.03	1	1.0
	Every day/ always	11 (-4-25)	0.2		
Hand numbness	Never/occasionally	8 (-7-24)	0.3	0	1.0
	Every day/ always	8 (-2-18)	0.1		
Hand weakness	Never/occasionally	8 (-6-22)	0.3	0	1.0
	Every day/ always	8 (-2-19)	0.1		
Type of disc herniation	Soft	25 (-2-52)	0.07	12	0.4
	Bony / combined	13 (-1-26)	0.07		
	Never/occasionally	14 (3-25)	0.02		

Sleeping problems	Every day/ always	2 (9-14)	0.7	12	0.2
Anxiety due to neck/arm problems	Never/occasionally	3 (-5-12)	0.4	21	0.02*
	Every day/ always	24 (9-39)	0.002		
Work expectations	High	11 (0-21)	0.05	1	0.9
	Low	12 (1-23)	0.04		
Treatment expectations	Fully recovered	0 (-12-12)	1.0	8	0.3
	Relief/improved	8 (-2-19)	0.1		
NDI at baseline	0-40 %	4 (-6-15)	0.4	9	0.3
	41-100%	13 (0-25)	0.04		
Zung	0-16 (normal)	0 (-19-18)	1.0	10	0.3
	17-69 (at risk)	10 1-19	0.03		
EQ-5D index	>0.5	4 (-7-14)	0.5	12	0.1
	<0.5	16 (4-29)	0.01		
EQ-VAS (VAS 0-100)	50-100	7 (-4-18)	0.2	2	0.8
	0-49	9 (-4-22)	0.2		
Arm/neck pain ratio (VAS)	Arm pain< neck pain	13 (3-23)	0.01	9	0.3
	Arm pain>neck pain	4 (-7-16)	0.5		
SES	129-200	0 (-12-11)	0.9	16	0.05*
	0-128	16 (5-27)	0.006		
DRAM	Normal	0 (-18-17)	1.0		0.04*
	At risk	5 (-5-16)	0.3		
	Distress	30 (12-48)	0.002		

Treatment effect (TE) is the mean change in the outcome parameter from baseline to 12 months

Difference in TE between TEM groups was analyzed with two-way full-factorial ANOVA and difference in treatment effect compared to baseline was analyzed from the estimated marginal means of the same analysis.

** Significant difference between groups ($p < 0.05$) detected.*

Abbreviations: NDI: Neck Disability Index; EQ-5D: EuroQol five dimensions; SES: Self Efficacy Scale; DRAM: Distress and Risk Assessment Method.

Table 3

Treatment effects and group comparisons. Outcome: neck pain (VAS 0-100) at 12 months.

Treatment effect modifier (TEM)	TEM groups	Difference in treatment effect surgery – non-surgery (95%CI)	P treatment effect surgery – non-surgery	Difference in treatment effect between TEM groups	P between TEM groups
Sex	Male	13 (-9-35)	0.3	19	0.2
	Female	32 (9-54)	0.006		
Age	18-47	13 (-9-35)	0.3	20	0.2
	48-65	33 (9-56)	0.008		
Smoker	No	22 (3-41)	0.03	1	1.0
	Yes	21 (-8-50)	0.2		
Duration of neck pain (months)	2-12	38 (16-59)	0.001	29	0.07
	>12	9 (-13-31)	0.4		
Duration of arm pain (months)	2-12	31 (9-52)	0.005	18	0.3
	>12	13 (-16-42)	0.4		
Neck pain intensity (VAS)	0-49	18 (-2-37)	0.07	6	0.7
	50-100	24 (7-40)	0.006		
Arm pain intensity (VAS)	0-49	13 (-6-32)	0.2	22	0.1
	50-100	35 (13-56)	0.002		
Shoulder pain	Never/occasionally	33 (-25-33)	0.8	29	0.9
	Every day/ always	4 (15-52)	0.001		
Back pain	Never/occasionally	21 (2-40)	0.03	9	0.6
	Every day/ always	12 (-17-40)	0.4		
Headache	Never/occasionally	25 (6-44)	0.01	12	0.5
	Every day/ always	13 (-17-42)	0.4		
Hand numbness	Never/occasionally	7 (-22-36)	0.6	24	0.2
	Every day/ always	31 (12-50)	0.002		
Hand weakness	Never/occasionally	7 (-20-35)	0.6	23	0.2
	Every day/ always	30 (11-50)	0.003		
Type of disc herniation	Soft	73 (25-121)	0.005	42	0.1
	Bony/ combined	31 (6-57)	0.02		

Sleeping problems	Never/occasionally	34 (12-55)	0.003	26	0.1
	Every day/ always	8 (-14-31)	0.5		
Anxiety due to neck/arm problems	Never/occasionally	12 (-5-29)	0.2	42	0.02*
	Every day/ always	54 (23-84)	0.001		
Work expectations	High	24 (0-47)	0.05	3	0.9
	Low	21 (-3-46)	0.08		
Treatment expectations	Fully recovered	7 (-16-30)	0.6	19	0.3
	Relief/improved	26 (4-48)	0.02		
NDI at baseline	0-40 %	18 (-3-38)	0.09	6	0.7
	41-100%	24 (1-46)	0.04		
Zung	0-16 (normal)	-2 (-37-34)	0.9	28	0.2
	17-69 (at risk)	26 (8-43)	0.005		
EQ-5D index	>0.5	6 (-14-26)	0.6	36	0.02*
	<0.5	42 (19-65)	0.001		
EQ-VAS (VAS 0-100)	50-100	21 (0-41)	0.05	5	0.8
	0-49	16 (-8-40)	0.2		
Arm/neck pain ratio (VAS)	Arm pain< neck pain	16 (-5-36)	0.1	13	0.4
	Arm pain>neck pain	29 (5-53)	0.02		
SES	129-200	12 (-11-35)	0.3	17	0.3
	0-128	29 (7-51)	0.01		
DRAM	Normal	-2 (-37-34)	0.9		0.4
	At risk	24 (3-45)	0.03		
	Distress	26 (-10-61)	0.2		

Treatment effect (TE) is the mean change in the outcome parameter from baseline to 12 months

Difference in TE between TEM groups was analyzed with two-way full-factorial ANOVA and difference in treatment effect compared to baseline was analyzed from the estimated marginal means of the same analysis.

**Significant difference between groups ($p < 0.05$) detected.*

Abbreviations: NDI: Neck Disability Index; EQ-5D: EuroQol five dimensions; SES: Self Efficacy Scale; DRAM: Distress and Risk Assessment Method.

Table 4
Treatment effects and group comparisons. Outcome: arm pain (VAS 0-100) at 12 months.

Treatment effect modifier (TEM)	TEM groups	Difference in treatment effect surgery – non-surgery (95%CI)	P treatment effect surgery – non-surgery	Difference in treatment effect between TEM groups	P between TEM groups
Sex	Male	-9 (-29-10)	0.3	41	0.007*
	Female	32 (10-54)	0.005		
Age	18-47	6 (-16-28)	0.6	3	0.8
	48-65	9 (-15-33)	0.4		
Smoker	No	9 (-10-27)	0.4	3	0.8
	Yes	12 (-18-42)	0.4		
Duration of neck pain (months)	2-12	28 (9-47)	0.005	39	0.007*
	>12	-11 (-30-9)	0.3		
Duration of arm pain (months)	2-12	24 (5-43)	0.02	42	0.01*
	>12	-18 (-45-8)	0.2		
Neck pain intensity (VAS)	0-49	2 (-22-26)	0.9	13	0.4
	50-100	15 (-5-36)	0.2		
Arm pain intensity (VAS)	0-49	3 (-14-20)	0.7	17	0.2
	50-100	20 (-1-40)	0.04		
Shoulder pain	Never/occasionally	-8 (-37-20)	0.6	30	0.09
	Every day/ always	22 (3-40)	0.03		
Back pain	Never/occasionally	8 (-11-28)	0.4	1	0.9
	Every day/ always	7 (-23-37)	0.6		
Headache	Never/occasionally	1 (-18-19)	1.0	35	0.05
	Every day/ always	36 (6-66)	0.02		
Hand numbness	Never/occasionally	-15(-45-14)	0.3	34	0.05
	Every day/ always	19 (1-37)	0.04		
Hand weakness	Never/occasionally	-5 (-33-22)	0.7	21	0.2
	Every day/ always	16 (-4-36)	0.1		
	Soft	36 (-12-83)	0.1		

Type of disc herniation	Bony/ combined	16 (-8-40)	0.2	20	0.5
Sleeping problems	Never/occasionally	16 (-5-38)	0.1	14	0.4
	Every day/ always	2 (-20-24)	0.8		
Anxiety due to neck/arm problems	Never/occasionally	6 (-12-25)	0.5	15	0.4
	Every day/ always	21 (-10-52)	0.2		
Work expectations	High	7 (-16-31)	0.6	9	0.6
	Low	16 (-9-42)	0.2		
Treatment expectations	Fully recovered	-3 (-26-20)	0.8	11	0.5
	Relief/improved	8 (-13-28)	0.5		
NDI at baseline	0-40 %	4 (-16-24)	0.7	8	0.6
	41-100%	12 (-11-36)	0.3		
Zung	0-16 (normal)	-14(-49-22)	0.4	29	0.2
	17-69 (at risk)	15 (-2-33)	0.09		
EQ-5D index	>0.5	2 (-18-22)	0.8	19	0.2
	<0.5	21 (-4-47)	0.09		
EQ-VAS (VAS 0-100)	50-100	-1 (-22-20)	0.9	21	0.2
	0-49	20 (-5-44)	0.1		
Arm/neck pain ratio (VAS)	Arm pain< neck pain	12 (-8-33)	0.2	3	0.9
	Arm pain> neck pain	9 (-15-33)	0.5		
SES	129-200	-1 (-24-21)	0.9	21	0.2
	0-128	20 (-2-41)	0.08		
DRAM	Normal	-14(-49-22)	0.4		0.2
	At risk	11 (-10-31)	0.3		
	Distress	36 (-1-72)	0.06		

Treatment effect (TE) is the mean change in the outcome parameter from baseline to 12 months

Difference in TE between TEM groups was analyzed with two-way full-factorial ANOVA and difference in treatment effect compared to baseline was analyzed from the estimated marginal means of the same analysis.

** Significant difference between groups ($p < 0.05$) detected.*

Abbreviations: NDI: Neck Disability Index; EQ-5D: EuroQol five dimensions; SES: Self Efficacy Scale; DRAM: Distress and Risk Assessment Method.