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Conservative treatment versus surgery in spondylotic cervical myelopathy: a prospective randomised study

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Abstract A prospective randomised 2-year study was performed to compare the conservative and operative treatment of mild and moderate forms of spondylotic cervical myelopathy (SCM). Forty-eight patients presenting with the clinical syndrome of SCM, with a modified Japanese Orthopaedic Association (mJOA) score of 12 points or more, were randomised into two groups. Group A, treated conservatively, consisted of 27 patients, mean age 55.6 ± 8.6 years, while group B was treated surgically (21 patients, mean age 52.7 ± 8.1 years). The clinical outcome was measured by the mJOA score, recovery rate (RR), timed 10 m walk, score of daily activities (recorded by video and evaluated by two observers blinded to the therapy), and by the subjective assessment of the patients at 6, 12, and 24 months of the follow-up. There was, on average, no significant deterioration in mJOA score, recovery ratio, or timed 10 m walk within either group during the 2 years of follow-up. In the surgery group there was a slight decline in the scores for daily activities and subjective evaluation. A comparison of the two groups showed no significant differences in changes over time in mJOA score or quantified gait, but there were significant differences in the score of daily activities recorded by video at 24 months, which was a little lower in the surgical group, and also in RR and subjective evaluation, which were both worse in the surgical group at months 12 and 24. However, at month 6, this last parameter was significantly better in the surgical than in conservative group. Surgical treatment of mild and moderate forms of SCM in the present study design, comprising the patients with no or very slow, insidious progression and a relatively long duration of symptoms, did not show better results than conservative treatment over the 2-year follow-up.

Key words Spondylotic cervical myelopathy · Conservative treatment · Surgery

Introduction

Spondylotic cervical myelopathy (SCM) is the most frequent cause of myelopathy in those over the age of 50 [48]. It is believed to have a generally progressive course over a period of years, with sudden acceleration especially following a slight head and neck injury, leading to significant disability [24, 45, 49]. The treatment of SCM remains a problem, particularly in the mild and moderate forms without rapid progression. There is no strong evidence to show that decompressive surgery with an anterior or posterior approach can improve the clinical outcome of the victims of this disease. This uncertainty persists despite the fact that decompression is a logical answer to the stenotic process, and that this approach is sup-

ported experimentally [16]. Many important variables, however, play a role in a clinical situation that could be different from the experimental conditions in animals. Moreover, the surgery is associated with various risks [14, 35, 52], including the risk of operating on an irrelevant stenotic process (e.g. in patients with ALS, MS, normotensive hydrocephalus) and even a risk of perioperative mortality, with a major morbidity rate of up to 22%, e.g. with corpectomy [29]. Twenty-five percent of patients with laminoplasty suffer from severe neck and shoulder pain for more than 3 months [18], with significant morbidity from the iliac crest donor site etc.

Excellent outcomes for surgery have been presented in many studies. All of the studies, however, are retrospective, and many lack a clear design, standard criteria, control groups, and sufficient follow-up, so it is difficult to compare [13, 17, 22, 30, 32, 39, 40, 45, 50, 51]. Furthermore, several studies and critical reviews are not so optimistic. They claim that surgical treatment of myelopathy, especially of the mild and moderate forms, has not shown better results than conservative treatment in the long term, and criteria for the indication and the timing of the operation have not been established [4, 10, 24]. Prospective studies showing the advantages of operative treatment are still lacking [10, 37, 45].

In order to get some more reliable data, a prospective randomised clinical study was started in 1993 to compare the effects of conservative versus surgical treatment in a group of patients with mild and moderate forms of SCM.

Materials and methods

Experimental design

A 2-year follow-up prospective randomised clinical study was performed. A group of patients with mild or moderate clinical myelopathy was randomised (using coin toss) into two groups, to be treated surgically or conservatively. Two blinded independent investigators graded video recordings. The local Ethical Committee granted ethical approval, and each patient gave informed consent.

Population

The study sample consisted of 48 consecutive subjects, chosen from patients referred to the neurological department between 1993 and 1997 with clinical signs and symptoms of mild to moderate cervical spondylotic myelopathy (37 men and 11 women, mean age 54.2 ± 8.5 years). The following inclusion criteria were used:

1. Clinical signs and symptoms of cervical cord dysfunction
2. Magnetic resonance imaging (MRI) criteria for cervical mono- and multisegmental cord compression and/or myelopathy due to spondylosis (including soft disc herniations – see below) with or without developmentally narrow spinal canal
3. Age under 75 years
4. Modified Japanese Orthopaedic Association score > 12 points
5. Patient's consent to surgery

Patients were excluded from the study on the following criteria:

1. Decompensated depression
2. Vascular encephalopathy (dementia, hemiparesis, aphasia)
3. Contraindications to surgery: diabetes mellitus, alcoholism, cardiovascular and lung diseases, blood dyskrasias, significant osteoporosis
4. Previous surgery on the cervical spine
5. Inability to engage actively in a postoperative rehabilitation
6. Uncertainty about the presence of significant additional diseases (such as MND, MS, progressive polyarthritis)

Subjects who fulfilled the inclusion criteria and in whom other possible causes of clinical signs and symptoms were excluded [9] were enrolled into the 2-year follow-up and randomised into groups that underwent either conservative therapy (group A, 27 patients, mean age 55.6 ± 8.6 years, 22 men and 5 women) or surgical therapy (group B, 21 patients, mean age 52.7 ± 8.1 years, 16 men and 5 women). The mean duration of the symptoms was 6.4 ± 9.9 years (range 0.2–36 years) in group A and 9 ± 8.2 years (range 1–23 years) in group B. There was no significant difference between these two groups in age ($P = 0.22$), sex ($P = 0.86$), duration of illness ($P = 0.35$), the diameter of the spinal canal ($P = 0.23$), or mJOA score ($P = 0.51$), as evaluated by *t*- and χ^2 tests.

Clinical evaluation

Clinical grading

The clinical grading system proposed by the Japanese Orthopaedic Association and modified by Benzel et al. [1] (mJOA – maximum 18 points) was utilised to quantify neurological function before enrolment in the study and at 6, 12 and 24 months. The mean mJOA score at enrolment to the study was 14.2 ± 1.3 points and 13.7 ± 1.8, in groups A and B, respectively. The recovery rate was evaluated at the same time points. Each value was compared to the initial JOA score (not to the score reached at the previous end point). It was calculated according to the following formula:

$$\mathrm{RR} = \frac{\text{Postoperative (or follow-up) score} - \text{preoperative (or initial) score}}{\text{18 (normal condition)} - \text{preoperative (or initial score)}} \times 100$$

Evaluation of daily activities by video recording

A video recording was made on enrolment in the study and at 6, 12 and 24 months thereafter. The recordings consisted of patients showing how they buttoned their shirts, brushed their hair and teeth, performed a diadochokinesis, put their shoes on, walked and ran, and how they went up and down the stairs. They were evaluated by two physicians, blinded to the type of treatment. The observers assessed the patients' functional abilities using the following scale: improvement: excellent, +3 points; very good, +2; slightly better, +1; no change, 0, and deterioration: slightly worse, –1; much worse, –2; poor, –3.

Timed 10 m walk

This was measured as the time (in seconds) spent on a 10-m-long track ("walk as fast as possible, but don't run"), at 0, 6, 12 and 24 months.

Self-evaluation

The same scale as was employed in the video recording evaluation was used for the subjective estimation of the clinical status by the patients themselves at 6, 12 and 24 months.

Imaging methods

Plain anteroposterior, oblique and lateral radiographs, and dynamic scans (in flexion and extension), MRI of the cervical cord (sagittal and axial planes) in T1, T2 and gradient echo mode, and computed tomography (CT) of the cervical region were performed in all patients. The presence of congenital narrowing was identified by measurement of Pavlov's ratio (the ratio of the anteroposterior diameter of the canal to the vertebral body); it was 0.76 ± 0.13 in group A and 0.8 ± 0.13 in group B. The MRI signs of cervical cord compression at the level of C3-7 and/or myelopathy were defined as: impingement of the cervical cord, i.e. a concave defect in the spinal cord adjacent to a site of disc bulging, and/or compression of the cervical cord (compression ratio of less than 40%), and/or hyperintensity of the intramedullary T2 signal at the level of cord compression.

Therapy

Significant one-level degenerative stenosis in the surgery group (B) was found in 12 patients, two-level stenosis in 7 patients and three-level in 2 patients. Seventeen patients were operated at the level C5-6, eight at C4-5, six at C3-4, and four at C6-7. Three types of surgical procedure were performed in this series, most of them (n = 13) anterior decompression, in nine cases combined with osseous graft and in three without it. Five patients underwent a corpectomy and three a laminoplasty. Internal fixing with a Caspar plate was employed in eight patients.

In group A, one level of degenerative stenosis was found in 8 patients, two levels in 14 and three levels in 5. Conservative treatment consisted of intermittent cervical immobilisation with a soft collar, the use of anti-inflammatory medications and intermittent bed rest in patients with pain, and the active discouragement of high-risk activities and avoidance of risky environments (physical overloading, getting too cold, movement on slippery surfaces, manipulation therapies, vigorous or prolonged flexion of the head).

The patients in the surgery group underwent similar conservative treatment to the patients in the conservative group.

Table 1 Average values with standard deviations of the modified JOA score in groups A (conservative treatment) and B (surgical treatment) at months 0, 6, 12, and 24

Month	mJOA score			
	Group A		Group B	
	Mean	SD	Mean	SD
0	14.3	1.3	13.7	1.7
6	14.5	2.0	13.4	1.7
12	15.1	1.9	13.3	1.7
24	14.5	1.8	13.7	2.0

Statistical data analysis

Pairwise or multiple comparisons of the investigated groups of patients were subjected to robust non-parametric statistical tests, predominantly based on assessment of sample distributional patterns. All the ordinal scales of scores (daily activity score, subjective estimation, and recovery rate) were subsequently re-categorized with respect to the aims of study in order to obtain relatively frequent subgroups of patients. These reasonable combinations of individual score values increased the power of the applied statistical tests [41, 53].

The relative frequency profiles of more than two score records and recovery rate nearly covered the whole spectrum of possible values (0–100 %) and revealed substantial differences from normal distribution, namely in the region 0–25%. The binomial estimates (P) were then subjected to arcsine and square-root transformation,

$$(p_{tr} = \arcsin\sqrt{p})$$

which made the underlying distribution near to normal. After statistical processing, all the binomial data were transformed back by the sine function and expressed in original values (%) with correction for possible bias [53].

Pairwise comparisons of percentages were predominantly based on two sample binomial tests using standard normal approximation [53]. For limiting percentages (mainly <20%), the computations based on the relationship between F distribution and binomial distribution were applied [3, 5].

The t-test and χ^2 test were used to compare data for evaluation of other parameters.

Intention-to-treat analysis

All patients were treated as per protocol, since only those who agreed with both alternatives (conservative and surgical) prior to randomisation were included. It was not necessary to change the type of treatment during the follow-up.

Results

Modified JOA score

The individual mJOA score in all patients in groups A and B at the three follow-ups, i.e. 6, 12 and 24 months after

Table 2 Recovery rate (RR) within groups A (conservative treatment) and B (surgical treatment) at months 6, 12 and 24 of follow-up: the values presented indicate the proportion of patients from each group who reached the given values of RR at the given time points

Categorized RR values	Group A				Group B			
	6 months	12 months	24 months	Binomial tests[a]	6 months	12 months	24 months	Binomial tests[a]
RR < –40%	14.8	14.8	18.5	P = 0.158	28.6	33.3	33.3	P = 0.215
–40% < RR < 0%	11.1	3.7	3.7		14.3	19.0	14.3	
RR = 0%	44.4	48.2	37.0	P = 0.475	23.8	14.3	28.6	P = 0.275
0% < RR < 40%	18.6	22.2	14.8	P = 0.698	19.0	19.0	9.5	P = 0.363
RR > 40%	11.1	11.1	26.0		14.3	14.4	14.3	

[a] Significance level of multiple binomial tests, comparing monitored time periods within groups A and B. Statistical comparisons were performed separately for score 0 and for summarized positive and negative recovery rate values. There were no significant differences within either group during the follow-up

Table 3 Summarized assessment of daily activities recorded by video in conservatively (group A) and surgically (group B) treated patients, as evaluated by two independent and blinded observers[a], presented as detailed distribution (%) of cases reaching the category of given score (I) and summarized positive and negative scores (%) supplied with standard error of estimates (II)

Daily activities score	Group A							Group B						
	6 months		12 months		24 months		Binomial tests[b]	6 months		12 months		24 months		Binomial tests[b]
	I	II	I	II	I	II		I	II	I	II	I	II	
–3	0	7.4	0	7.4	0	18.5	$P = 0.796$	2.4	23.9	0	21.4	0	42.8	$P = 0.038$
–2	3.7	(1.8)	0	(1.8)	0	(7.2)		4.8	(9.5)	7.1	(9.1)	19.0	(11.1)	
–1	3.7		7.4		18.5			16.7		14.3		23.8		
0	85.2 (7.9)		79.6 (9.0)		70.4 (10.2)		$P = 0.256$	57.1 (11.1)		71.5 (10.1)		52.4 (11.2)		$P = 0.157$
1	7.4	7.4	12.9	12.9	11.1	11.1	$P = 0.883$	14.3	19.1	7.1	7.1	4.8	4.8	$P = 0.021$
2	0	(1.8)	0	(4.4)	0	(3.9)		2.4	(8.7)	0	(1.6)	0	(1.1)	
3	0		0		0			2.4		0		0		

[a] Because no significant difference was detected between the observers (test of homogeneity of binomial distributions), the registered values were combined prior to setting up the table. Where possible, estimates of percentages were supplied by standard errors (in parentheses)

[b] Significance level of multiple binomial tests, comparing the score at the different follow-up points within groups A and B. Statistical comparisons were performed separately for score 0 and for summarized positive and negative records

Table 4 The quantified gait (mean and SD) on a 10-m-long track in groups A and B at months 0,6, 12 and 24

Month	Group A		Group B	
	Mean time (s)	SD (s)	Mean time (s)	SD (s)
0	8.3	4.3	10.7	7.0
6	7.7	2.6	12.0	10.8
12	8.0	2.9	12.0	11.0
24	8.0	2.9	12.9	10.6

enrolment in the study or after the surgery, are tabulated against their initial status in Table 1. Three group B patients died during the follow-up period, but their deaths were physically unrelated to the surgery. No significant differences were found within and between the groups over the 24 months of follow-up.

Recovery rate

The recovery rate results are summarised in Table 2. No significant difference was found between the mean values for months 6, 12 and 24 within groups A and B. However, significant differences were revealed between groups A and B (binomial tests, $P < 0.05$) for the category of recovery rate 0%, which accounted for a significantly higher proportion of group A patients, and in the category of recovery rate < 0%, which accounted for a significantly higher proportion of group B patients at the 12 and 24 month follow-ups.

Daily activities

The scores of daily activities as recorded by video are summarised in Table 3. There was no significant difference between results at 6, 12 and 24 months within group A, while both observers found significant deterioration over time within group B. Further, there was a significant difference between groups A and B (binomial tests, $P < 0.05$) in the category "no change" (daily activities score = 0%), which accounted for a higher proportion of group A patients at all follow-ups, and in the category "deterioration" (daily activities score < 0%), which accounted for a higher proportion of group B patients.

Timed 10 m walk

The mean values for the time taken to walk 10 m, for both groups at 0, 6, 12, and 24 months are summarised in Table 4. The differences within and between the groups at 6, 12 and 24 months were not statistically significant.

Self-evaluation

The subjective evaluation of their clinical status by the patients themselves is summarised in Table 5. No difference, on average, was found within group A over the 24 months. A significant mean subjective deterioration was found in group B between months 6 and 12 ($P < 0.05$) and months 6 and 24 ($P < 0.05$), and significant differences between group A and B (binominal tests, $P < 0.05$), due to a higher proportion of group A patients in the category "no change" and a higher proportion of group B patients in the subjective estimation category score of < 0%. On the other hand, the subjective evaluation category score > 0% accounted for a significantly higher proportion of group B patients at month 6, though this was no longer the case by months 12 and 24.

Table 5 Subjective evaluation of the disease course by the patients within group A (conservative treatment) and B (surgical treatment) at the 6-, 12- and 24-months follow-ups, presented as distribution (%) of cases in each category of the scale (I), and summary of positive, non-changed and negative values supplied with standard error of estimates (II)

Score of subjective estimation	Group A							Group B						
	6 months		12 months		24 months		Binomial tests[a]	6 months		12 months		24 months		Binomial tests[a]
	I	II	I	II	I	II		I	II	I	II	I	II	
–3	0	33.3	0	44.5	0	33.3	$P = 0.303$	0	23.8	9.5	52.1	14.3	57.2	$P = 0.0.002$
–2	7.4	(10.5)	11.1	(11.1)	7.4	(10.5)		9.5	(9.5)	4.8	(11.2)	4.8	(11.1)	
–1	25.9		33.3		25.9			14.3		38.1		38.1		
0	40.7 (10.9)		40.7 (10.9)		55.6 (10.2)		$P = 0.0.175$	19.0 (11.1)		33.3 (10.1)		28.6 (11.2)		$P = 0.0.653$
1	18.5	26.0	14.8	14.8	11.1	11.1	$P = 0.0.315$	38.1	57.2	14.3	14.3	9.5	14.3	$P = 0.0.001$
2	3.7	(9.8)	0	(4.4)	0	(4.1)		14.3	(11.1)	0	(5.8)	4.8	(5.8)	
3	3.7		0		0			4.8		0		0		

[a] Significance level of multiple binomial tests comparing 6- ,12- , and 24-month follow-up scores within groups A and B. Statistical comparisons were performed separately for score 0 and for summarized positive and negative scores

Discussion

In general, the basic information required for a decision on the treatment of SCM consists of the natural history of the disease and the effects of conservative and operative treatments. The natural history of SCM has still not been thoroughly documented [23]. There is a tendency for SCM patients to progress to severe disability, but it is not known how much, how fast or how many patients in the population might suffer and what method is suitable for identifying these patients beforehand. Reports of some series refer to a steady progression in all patients [7, 11, 31, 38], while another study reported only 67% of patients as having steady, progressive deterioration [42]. On the other hand, yet another retrospective study showed that the disability is mild in the majority of cases, and that the prognosis for these mildly affected patients and even for the more severely disabled is good [32], confirming similar findings of a previous study of Lees and Turner in 1963 [26]. The only feature associated with deterioration was age. Retrospective studies, however, are prone to a significant bias. In summary, we can say that the natural history is not precisely known, and there is a tendency to deteriorate, to remain stable or to improve with approximately the same degree of probability. There is no reliable prognostic factor known that enables the determination of the outcome in an individual patient. Almost all studies are retrospective and lacking in standard and commonly accepted criteria; they merely yield some plausible hypotheses.

Many investigators have employed treatment with a cervical collar or simple observation, and have noted improvement in 29–55% of their patients [6, 33, 36, 47]. A conservative approach to the treatment of SCM is supported by a very long history of myelopathy in some patients, which can last 30 or more years without any major deterioration [49]. In the present study, the mean duration of illness was 6.4 ± 9.9 years. It reached more than 10 years in five of the patients, 4 years for more than 16, and for one patient it has lasted 36 years. Our results in the conservatively treated (group A) showed, on average, no significant change over the 2 years of follow-up regarding the evaluation of daily activities, the mJOA scale and recovery rate, the speed of gait and the subjective assessment. This does not mean that there were no changes in individual patients. Five patients improved on the mJOA scale by 2 points, one by 3 points and one by 5 points, one patient deteriorated by 5 points, one by 2 and one by 3 points. In no case in group A was an operation carried out in the course of the 2 years, not even on the patient with the 5-point decline, because he was reluctant to have surgery (despite his initial consent) and his gait was quite good. Our results showed a relatively benign history for these conservatively treated mild and moderate forms of SCM, as a group. We can speculate over whether this is due to a benign natural course or whether, and to what extent, it is influenced by the conservative treatment, especially the exclusion of patients from physical overloading (stopping the hard physical work), intermittent use of soft collar, etc. We suggest that the pain, which usually brings the patients to a physician, could be a very potent preventive factor, as it is in many other diseases. A lack of pain and killing the pain without limiting potentially harmful activities and stress, on the other hand, could accelerate the “insidious and silent” progress of the disease.

Operative treatment for SCM has been a popular form of therapy for nearly 40 years. Present surgical methods include anterior (Cloward or Smith-Robinson technique [40]) or posterior (laminectomy, hemilaminectomy) approach, both with good and probably equal results; and recently open-door laminoplasty and vertebral corpectomy have been added [21]. The indication for surgery is mostly a severe and progressive course of the disease. To the best

of our knowledge, no comparison of the effects of conservative and operative treatments has been made in a randomised controlled trial. Almost all published reports come from surgical departments and are retrospective. In many surgical and orthopaedic departments, however, almost all cases of SCM referred by neurologists are operated without considering the grade of functional deficit [20]. Very little is known about the operation in patients with a definite but mild or moderate form without progression, who represent the large majority of patients with SCM and in whom the surgery is more logical (to prevent unpredictable and severe deterioration). Because irreversible changes may occur in the spinal cord, the best results are obtained in patients who have decompression within 6 months to 1 year after the onset of symptoms and in those who have early, mild myelopathic findings [12, 15, 27].

In this study, the mean changes within the surgery group were not significant. This held true for the mJOA score, the recovery rate, the video records and the gait. The only significant difference was in the subjective assessment, which deteriorated slightly over the 2 years. There were, of course, changes in individual patients: one patient improved by 4 points on the mJOA scale, two patients by 3 points, and two by 2 points. Two patients deteriorated by 2 points, two by 3 points, and one by 4 points. Three patients expired during the follow-up in group B. All of them committed suicide in a state of depression that was not a consequence of decline in clinical status after surgery. The significant differences between groups A and B were registered in the score of daily activities recorded by video, RR, and subjective estimation (months 12 and 24) in favor of group A, but only in subjective assessment was the month 6 in favor of group B.

The most favourable papers on SCM suggest that fewer than 70% of patients with SCM subjectively improve after surgery by either an anterior or posterior approach, with or without fusion [2, 8, 45], exceptionally 87.5% [44]. But these favourable short-term results may be balanced out by the unexpectedly high incidence of late deterioration [10, 13]. Some studies report lower percentages of success [19, 28].

The results of our study are hardly comparable to those of other studies, because we were unable to find any controlled studies, and retrospective series suffer from all the usual drawbacks. Only minor neurological changes were documented in our study in both the groups compared over the 2 years. We expected improvements in the surgery group and decline among the patients treated conservatively. This did not prove to be the case. The group of conservatively treated patients did not differ in this study from those treated operatively in many parameters over the 2 years of follow-up. The only significant difference between the two groups was in score of daily activities recorded by video at 24 months, and was in favour of non-operative treatment. In both groups some individual patients improved and some deteriorated.

In conclusion, this study did not show any substantial differences in the average outcome, over a period of 2 years, of patients suffering from mild and moderate forms of SCM according to whether they were treated conservatively or surgically. Improvement and deterioration in the condition of individual patients occurred in both groups. Who is suitable for which type of therapy may hopefully be answered by an analysis within the subgroups of the patients who improved and those who deteriorated in a larger study with a longer follow-up. The 2 years of follow-up could be too short to disclose the benefit of the surgery in this group of patients.

Conclusions

1. The current study, comprising patients with no or very slow, insidious progression only, showed, on average, no significant deterioration in objective parameters (mJOA score, recovery ratio, quantified gait time,) within the two groups during the 2 years of follow-up. The subjective evaluation and score of daily activities in the surgical group decreased slightly at month 24 (and to a lesser extent 12) in comparison with month 6.

2. Comparison of the two groups showed significant differences in the score of daily activities recorded by video, in recovery rate, and in subjective evaluation by patients at 24 months, all of which were worse in the surgical group.

3. The surgical treatment of mild and moderate forms of SCM in the present study design showed no better results than conservative treatment over 2 years of follow-up.

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