Long-term follow-up results of the Cloward procedure for cervical spondylotic myelopathy

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Abstract

Purpose To assess the long-term results of anterior cervical discectomy and fusion using the Cloward procedure for the treatment of cervical spondylotic myelopathy, and to identify possible clinical outcome predictors.

Methods A total of 14 cases with a 10-year postoperative follow-up were available (82.4 % of the surviving patients). Patients underwent preoperative and postoperative neurological examination. The symptom severity was graded according to the Nurick scale. MRI measurements were obtained preoperatively. Cervical spine radiographs were obtained preoperatively and at the time of follow-up. **Results** The mean improvement of the clinical status of patients on the Nurick scale was 1.43 ± 0.51 (range 1–2) with respect to the baseline values ($p < 0.001$), with a 62.5 % recovery rate. A positive association between the improvement of the Nurick scale and the length of follow-up was detected with an age-adjusted univariate analysis ($p = 0.042$). The Nurick grade improvement was also directly related to preoperative lower limb hyperreflexia ($p = 0.039$), spasticity ($p = 0.017$), and bladder dysfunction ($p = 0.048$). At the time of follow-up, an adjacent discopathy was noted above and below the operated level(s) in eight and six patients, respectively.

Conclusions The Cloward technique is a safe and effective procedure for the treatment of cervical spondylotic

myelopathy. The patients' preoperative neurological status and the length of follow-up affect the grade of postoperative ambulatory improvement.

Keywords Cervical spondylotic myelopathy · Anterior cervical discectomy and fusion · Cloward · Long-term follow-up

Introduction

Cervical degenerative disease is often asymptomatic, but in 10–15 % of the adult population it is associated with clinical symptoms of nerve root or spinal cord compression [1]. Cervical spondylotic myelopathy (CSM) is the most common progressive spinal cord disorder in patients over 50 years old [2]. Several surgical techniques have been adopted for the treatment of CSM, with often conflicting results. Anterior cervical discectomy and fusion (ACDF) has been shown to be a highly successful procedure after long-term follow-up [3]. The gold standard for ACDF is fusion with the use of an autologous iliac crest graft [4], which is a relatively safe procedure.

The purpose of this study was to review the long-term clinical and radiological outcomes of patients with CSM who underwent ACDF using the Cloward procedure [5].

Materials and methods

Study population

The study conforms to the Helsinki Declaration. After approval from the local ethics committee, we enrolled patients who had undergone a single- or multi-level ACDF

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at our institution for primary CSM from 1994 to 2006. The inclusion criteria were: (1) the presence of spasticity and weakness in the lower limbs with or without “numb and clumsy” hands and (2) a spinal canal diameter ≤ 10 mm on magnetic resonance imaging (MRI) [6]. The exclusion criteria were radiculopathy as the only complaint, ossification of the posterior longitudinal ligament, tumours, trauma, and soft disc herniation. Further exclusion criteria were the presence of chronic systemic diseases, such as mellitus diabetes, rheumatoid arthritis, or neurodegenerative diseases.

On the basis of these criteria we selected 22 patients. Five of these patients had died before the study began. Thus, 17 patients were available for the follow-up examination. Data were available for 14 patients (1 female and 13 males), who represented 82.4 % of the survivors. Three subjects refused to participate in the study because of severe comorbidities or lack of interest. No significant differences were found between the participants and those subjects lost to follow-up with respect to age ($p = 0.608$), gender ($p = 1.000$) and number of treated levels ($p = 0.343$). The patient data are shown in Table 1.

The ACDF procedure was performed by a single surgeon as originally described by Cloward [5]. Briefly, a vertical antero-lateral approach through the soft tissues of the neck was chosen, and a drill hole was placed in the vertebral midline and through the interspace of the cervical level(s) to be fused. A Cloward instrument set was used. Complete discectomy with removal of the posterior longitudinal ligament was performed, and the posterior border of the vertebral bodies was resected to remove osteophytes and to enlarge the spinal canal. A circular bicortical graft was harvested from the anterior iliac crest and placed into the intervertebral space under cranial traction. Postoperatively, all patients wore a hard cervical collar to provide immobilisation for 6–8 weeks.

Patients' baseline and follow-up data

Preoperative patient data were obtained using a special form that has been used in our department since its foundation. Information on the patients' clinical history and operative findings have consistently been gathered on this form according to a standardized protocol. The Nurick scale, a six-grade system (0–5) of increasing ambulatory impairment, has been previously used to quantify preoperative neurological deficits [7]. In this system, grade 0 indicates the presence of signs or symptoms of nerve root involvement without evidence of spinal cord disease; grade 1 indicates the presence of signs of spinal cord disease without difficulty ambulating; grade 2 indicates a slight difficulty ambulating that does not prevent full-time employment; grade 3 indicates the presence of difficulty ambulating that prevents full-

Table 1 Baseline characteristics of the patients ($n = 14$) and post-operative results

Patients data	Mean $\pm$ SD (range), Median (range) or N
Sex	
Female	1
Male	13
Preoperative upper motor neuron signs	
Lower limb hyperreflexia	10
Lower limb spasticity	9
Bladder dysfunction	5
Preoperative Nurick grade	2.5 $\pm$ 0.85 (1–4)
1	2
2	4
3	7
4	1
Preoperative SSA ($^{\circ}$)	4.2 $\pm$ 7 (–5 to 13)
Preoperative SACS ($^{\circ}$)	25.9 $\pm$ 11.4 (6–44)
Preoperative SAD (mm)	5.6 $\pm$ 2.2 (2.6–8)
Age at the operation (years)	55.8 $\pm$ 12 (34–73)
Number of levels	2 (1–4)
1	3
2	7
3	3
4	1
Operated level	
C3–C4	4
C4–C5	11
C5–C6	10
C6–C7	5
Graft size (mm)	
12	18
14	12
Follow-up time (months)	122.8 $\pm$ 45.6 (48–199)
Postoperative Nurick grade	1.07 $\pm$ 0.83 (0–3)
0	3
1	8
2	2
3	1
Postoperative SSA ($^{\circ}$)	6.5 $\pm$ 11.4 (–3 to 37)
Postoperative SACS ($^{\circ}$)	27.6 $\pm$ 15.6 (7–54)

SSA sagittal segmental alignment, SACS sagittal alignment of the whole cervical spine, SAD spondylotic anterior-posterior diameter

time employment or the ability to do all housework, without requiring assistance ambulating; grade 4 indicates that assistance is required for ambulation; grade 5 indicates that patients are chair bound or bedridden. During the follow-up assessment, after informed consent was obtained, all the participants underwent a structured assessment. Data related to their current health status and symptoms were collected.

A physical examination, including a neurological examination for nerve root tension signs, motor strength, sensation and reflexes was conducted. The Nurick scale was used to evaluate the postoperative neurological status. As previously described [8], a Nurick grade recovery rate (RR) was computed using the following formula to evaluate the postoperative recovery of patients: $\text{NGRR} = (\text{preoperative Nurick grade} - \text{follow-up Nurick grade}) / \text{preoperative Nurick grade} \times 100$. All patients were asked to answer questions regarding their satisfaction with the original operation and reoperation (if applicable). Satisfaction with the operation was expressed through a four-step incremental scale (0 = dissatisfied, 1 = low satisfaction, 2 = moderate satisfaction, 3 = complete satisfaction) [9]. A single author who was uninvolved in the patients' primary care and who was unaware of the questionnaire results performed all the clinical assessments.

Imaging assessment

All patients underwent a roentgenographic evaluation with standard antero-posterior, lateral and oblique standing radiographs of the cervical spine. On lateral views, the preoperative and postoperative sagittal segmental alignment (SSA) and the sagittal alignment of the whole cervical spine (SACS) were measured [10]. SSA was defined as the angle between the line parallel to the upper vertebral endplate of the vertebra cephalad to the involved disc space(s) and the line parallel to the lower vertebral endplate of the caudad vertebra; SACS was defined as the angle formed by the lines parallel to the posterior border of C2 and C7, respectively (Figs. 1, 2a, b). SSA and SACS values were considered positive in lordosis and negative in kyphosis. MRI scans were obtained preoperatively from all patients, and the images were evaluated mid-sagittally at each spinal level (C3 to C7). Images were acquired by sagittal and transverse spin echo (SE, T1), sagittal turbo spin echo (TSE, T2), and transverse gradient echo (FL2D, T2) sequences. The spondylotic anterior-posterior diameter (SAD) of the spinal canal was measured at the level of the disc space as the shortest distance to the spinolaminar line. Radiological evidence of adjacent-disc disease at the time of follow-up included new anterior osteophyte formation or enlargement of existing osteophytes, new or increasing narrowing of a disc space ($\geq 30\%$) and new or increasing anterior longitudinal ligament calcification documented on plain radiographs [11]. Fusion was defined as the presence of the following features: (1) absence of radiolucent lines/area across the fusion site; (2) presence of bridging trabeculae across the fusion site. If the fusion was questionable, additional flexion-extension X-rays with the evaluation of the presence of motion between the spinous processes were performed [12].

Fig. 1 Image representing the SSA (red continuous line) and SACS (black dotted line) angles measurement

Roentgenographic measurements were performed in duplicate by two trained authors who were unaware of the patients' clinical characteristics. Cohen's kappa coefficient for intra-observer and inter-observer reliability of SSA measurement scoring was 0.85 and 0.77, respectively. A consensus decision on the scores was reached in a final common readout.

Statistical analysis

The Wilcoxon test, Mann-Whitney test and Fisher's exact test were used when appropriate, to test the significance of the differences within and between the groups. An age-adjusted univariate linear and logistic regression analysis was used to evaluate the relationship between the explanatory variables and the outcomes. Explanatory and confounding variables included in the analysis were: age (continuous), length of follow-up (continuous), preoperative bladder dysfunction (categorical), preoperative lower limb hyperreflexia (categorical), preoperative lower limb spasticity (categorical), number of levels (discrete), preoperative SAA (continuous), postoperative SAA (continuous), SAA variation (continuous), preoperative SACS (continuous), postoperative SACS (continuous), SACS variation (continuous), preoperative SAD (continuous), preoperative discopathy above the level(s) (categorical), postoperative discopathy above the level(s) (categorical), preoperative discopathy below the level(s) (categorical), postoperative discopathy below the level(s) (categorical) and preoperative

Fig. 2 A 40-year-old female who underwent one-level C6–C7 ACDF **(a)**. Postoperative lateral X-rays **(b)** shows the fusion of the operated segment and the increase of both SSA and SACS

Nurick grade (discrete). Postoperative Nurick grade (discrete), Nurick grade variation (discrete), complications (categorical), reoperation (categorical) and satisfaction (discrete) were treated as outcomes and the effect of possible predictors was checked for their value.

A p value of less than 0.05 was considered significant. The SPSS (SPSS Statistics 17.0, Inc., Chicago, IL, USA) software program for Windows was used for database construction and the statistical analysis.

Results

Clinical outcome

The mean postoperative Nurick grade was 1.07 ± 0.83 (range 0–3), with an average RR of 62.5 % at a mean 122.8-month follow-up. Three patients had no evidence of spinal cord disease, eight had a Nurick grade 1, two had a Nurick grade 2 and one had a Nurick grade 3 (Table 1). The average improvement on the Nurick scale was 1.43 ± 0.51 (range 1–2) compared with the baseline values

($p < 0.001$). Using the linear regression analysis, the Nurick grade improvement was directly related to the length of follow-up ($p = 0.042$) and the preoperative presence of lower limb hyperreflexia ($p = 0.039$), spasticity ($p = 0.017$), and bladder dysfunction ($p = 0.048$). Twelve out of 14 patients (86 %) reported moderate/complete satisfaction with the operation. The satisfaction with the operation was directly associated with Nurick grade RR ($p = 0.046$) using the logistic regression analysis. Five patients developed complications: transient vocal cord paralysis (2), transient upper limb paralysis (2), and graft collapse (1). The occurrence of complications was unrelated to the number of treated levels or the specific operated level(s). Two patients required a reoperation because of graft displacement (1) and disc herniation at another level (1). The interval between the first and the second operation were 4 months and 2 years, respectively.

Radiological parameters

Two out of 30 operated levels did not show fusion resulting in a 93.3 % fusion rate. Table 1 shows the comparison

between the baseline and follow-up radiological parameters, The mean variation of SAA and SACS angle with surgery was $2.3^\circ \pm 9.6^\circ$ (range -9° to 24°) and $1.7^\circ \pm 12.4^\circ$ (range -18° to 27°), respectively, but these differences were not significant. Two cases of postoperative segmental kyphosis were noted. Preoperative discopathy at adjacent levels was present above and below the affected level(s) in four and three patients, respectively. At the time of follow-up, an adjacent discopathy above and below the operated level(s) was present in eight and six patients, respectively. These variations were not significant. The number of adjoining discopathies at the time of follow-up with respect to preoperative roentgenograms was not related to the clinical outcomes.

Discussion

The ideal surgical treatment option for CSM remains controversial [13]. Anterior approaches to the cervical spine are recommended because they enable the surgeon to directly and safely remove the intervertebral disc and posterior osteophytes. Since its first description [5], the Cloward technique is still commonly used [14]. Notwithstanding the increasing number of techniques using artificial materials to obtain fusion of the decompressed segment through an anterior approach [3, 4, 15], the use of autologous bone graft is still valuable. When fusion of the mobile segment is required, an iliac crest autograft remains the gold standard treatment [4].

This study was carried out to evaluate the results of the Cloward procedure for the treatment of CSM using both clinical and imaging assessments at an average 10-year follow-up. Ten years after surgery we found a significant average Nurick grade improvement of 1.4, which is lower than the results of some studies [3, 16] but remains similar to [17], or higher than [18] other studies that included shorter length of follow-up. The long-term results of the Cloward procedure have been previously reported [10, 19, 20], but to the best of our knowledge no data are available on the value of Nurick improvement after an interval comparable to the length of follow-up reported in this study. The primary benefit of decompressive surgery for CSM is to slow or stop the progression of clinical symptoms. Long follow-up periods may be necessary to appreciate the stabilizing effect of vertebral fusion [21], and a subjective evaluation tool such as the Nurick score should be used as the standard to consistently measure the functional variations observed after operative treatment of CSM [14].

We found a direct correlation between Nurick grade improvement and the length of follow-up. Our data are in agreement with Wohlert et al. [19], who reported that the number of good results after the Cloward procedure for

CSM increases slightly during the observation time (1–15 years). These findings support the hypothesis that the stabilisation of the cervical spine halts the progression of the disease [22], even causing a regression of symptoms. Stabilisation may result in a delayed effect on the progression of CSM, with improvement of the symptoms over time. A further interesting finding in our study was the observation of a direct relationship between the Nurick grade improvement and the presence of preoperative upper motor neuron signs and bladder dysfunction. This finding has not been previously described in patients undergoing anterior cervical fusion and indicates that patients with more severe preoperative dysfunction benefit to a greater degree from anterior decompression and fusion. Conversely, Alafifi et al. [23] showed that subjects who failed to improve on the Nurick grading system presented with a higher prevalence of hyperreflexia and lower extremity spasticity. However, these authors reported a mean 2.5-year follow-up period that is much shorter than our follow-up. One explanation for our observation may be that anterior cervical surgery is a highly effective operation even in severe cases where signs of upper motor neuron signs exist [24]. We acknowledge that the identification of predictors of better surgical outcomes is critical, as it may influence surgical decision making, the technique of the operation and patient expectations. However, our findings should be interpreted cautiously because of the small sample size of 14 patients in the study group.

We observed a higher rate of transient dysphonia (2/14 patients) compared to the previously published data. Indeed, temporary unilateral vocal cord paralysis after anterior cervical approach has been reported with a frequency ranging from 0.98 to 8 % [25]. A possible explanation for the higher rate of temporary vocal cord paralysis may be the side chosen for the cervical approach. All the cases of our series were operated through a right sided approach and one previous study suggested that the anatomic course and relative resistance to the stretching of the right recurrent laryngeal nerve places this side at a greater risk to injury [26]. However, conflicting results have been published with respect to the relationship between side of surgical approach and the risk for nerve injury [27].

More than 85 % of our patients were satisfied with their operation. These data concur with the observation of Chagas et al. [18] on a shorter follow-up evaluation. In agreement with one study with a shorter follow-up period [8], the functional improvement on the Nurick scale was closely related to the patient's satisfaction with the operation.

One of the goals of the ACDF procedure is to maintain or restore the cervical spine lordosis [17]. Xu et al. [20] reported 36 patients evaluated 10 years after the Cloward procedure and obtained alignment angles similar to those

found in the current study. Even though the preoperative SSA was previously found to be associated with postoperative pain intensity and Neck Disability Index after a short-term follow-up [28], we failed to demonstrate a role for preoperative radiographic alignment angles as predictors of long-term postoperative outcomes. In our study, the presence of adjoining discopathies was unrelated to the clinical outcomes. These data concur with the work of Kienapfel et al. [29].

Some weakness of the current study design limit the conclusions that can be drawn from our data. Our small sample size could have clouded possible significant clinical differences. Nevertheless, some interesting relationships were appreciated despite the small sample size. Furthermore, patients were enrolled retrospectively, carrying all the limitations of this study design. Performing a prospective analysis on spine surgery for degenerative conditions with a long follow-up period is very challenging [30]. Also the use of the Nurick score in the present study is debatable because it does not evaluate the upper limb function. However, few validated evaluation tools were available for CSM when the first patients evaluated in this series were treated. Moreover, the choice to use the recovery rate to evaluate the improvement obtained with surgery rather than the simple difference between preoperative and postoperative scores, enabled us to decrease the potential discrepancy between the Nurick score recorded in this study and the assessment that can be obtained using more recent validated tools [31]. Despite the above limitations, this study provides useful information on the long-term follow-up of patients undergoing the Cloward procedure, with important methodological strengths. The length of follow-up and the homogeneous characteristics of the sample population, with one surgeon performing all the operations according to the same operative and postoperative protocol, must be considered. A further strength of our study is the use of an integrated outcome assessment, evaluating subjective and objective clinical parameters. This approach has been previously advocated to be successful in overcoming the question arising, regarding which parameters should be used to define treatment success or failure [29].

Conclusions

The current study demonstrated the safety and the efficacy of the Cloward technique after more than 10 years of follow-up. Improvement in ambulatory status directly correlates with the length of follow-up and more severe preoperative neurological deficits. These findings should be considered when discussing the expected results of CSM surgery with patients.

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Conflict of interest None.

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