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Is the efficacy of the Cloward procedure overestimated? Technique of evaluation affects the outcome

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Abstract The purpose of the present study was to investigate the influence of the evaluation technique on the outcome of the Cloward procedure in cervical radiculopathy. The retrospective study included 94 consecutive patients operated on with anterior decompression and fusion with heterologous bone (Surgibone, Unilab). There were 56 men and 38 women, with a mean age of 48 years (range 27–78 years). Sixty-six patients had a single-level fusion, 26 a two-level fusion and one patient had a three-level fusion. The follow-up rate was 91/94 (97%) and evaluation was performed by an independent observer. Pain was quantified by visual analogue scale (VAS, range 0–100), functional disability by the new functional index Cervical Spine Functional Score (CSFS, range 0–100) and by the Neck Pain Disability Index (NPDI, range 0–100). The overall clinical outcome was assessed as excellent, good, fair or poor by both the patient and by the independent observer using Odom's criteria. At a mean follow-up of 26 months (range 12–56 months) the mean pain index was 39 (range 0–98), the mean CSFS 39 (range 0–85) and the mean NPDI 32 (range 0–76). The classification of the observer was 37% excellent, 40% good, 17% fair and 6% poor, and that of the patient was 53% excellent, 23% good, 20% fair and 4% poor. In the group classified as good by the observer, all scores were above 40, suggesting considerable remaining symptoms, and only 50% had returned to work. The results suggest that previous reports on the Cloward procedure using categorizations into excellent, good, fair or poor have overestimated the efficacy of the procedure. Only an excellent, but not a good, result as classified by the patient or an independent observer reflects a successful outcome. Neither of the variables studied seems independently sufficient for a balanced reflection of the outcome. The results suggest pain (VAS) as the primary outcome measurement, which, combined with the overall evaluation by the independent observer and work status, gives a multidimensional expression of the outcome.

Keywords Outcome · Radiculopathy · Cloward · Fusion

Introduction

Anterior cervical spine decompression and fusion (ACDF) was popularized by the reports of Robinson and Smith [27] and Cloward [5], and their techniques are still considered gold standards in the surgical treatment of the degenerative cervical spine, against which new techniques such as cages should be compared.

Numerous authors have evaluated the use of the Cloward procedure in the degenerative cervical spine [2, 4, 5, 6, 7, 10, 16, 22, 23, 26, 27, 28, 30, 33, 34, 36]. Most

authors have reported excellent or good results based on Odom's criteria [2, 4, 5, 10, 16, 21, 26, 28]. In two recent prospective randomised Swedish studies, however, the outcome of ACDF was less impressive than previously reported [22, 36].

The somewhat contradictory results between prospective and previous retrospective studies suggest that the study design affects the observed outcome, and that there is a need to improve the technique of measuring outcome. Studies of the lumbar spine have shown that the results are highly influenced by the method by which they are measured. It is generally agreed that to evaluate the clinical outcome of degenerative lumbar disorders, it is necessary to use valid subjective as well as objective outcome measurements, such as work status, an independent observer and adequate follow-up [11, 12, 14, 20, 32]. Although the quantification problem in degenerative cervical disorders is similar to the situation in the lumbar spine, it is rarely considered in reports of treatment outcome.

The purpose of the present study was to investigate the possible influence of the evaluation technique on the outcome of the Cloward procedure in the degenerative cervical spine. The outcome was determined by an independent observer using subjective as well as objective measurements, including overall clinical outcome, pain, the Neck Pain Disability Index (NPDI), a new functional score, return to work and radiography.

Materials and methods

In the retrospective study, 94 consecutive patients operated on at Linköping University Hospital, 1989–1994, were identified from the surgical reports of two neurosurgeons (W.L., L.V.). There were 56 men with a mean age of 48.5 years (range 27–71 years) and 38 women with a mean age of 47.2 years (range 34–78). In all patients, the indication for surgery was neck pain with radiculopathy. Preoperatively, all patients had undergone standard clinical examinations and radiographs, including myelography or magnetic resonance imaging (MRI). Only patients with compatible clinical and radiographic findings were included.

The mean follow-up time was 26 months (range 12–56 months). Of the 94 patients, 93 underwent a clinical examination, completed questionnaires and radiographs at a minimum of 12 months postoperatively. In 12 patients, the data were not complete. Since the object of the study was to investigate the relationship between the different outcome measurements, only the 81 patients (86%) with complete data were included in the statistical analysis. This improves comparability between the different scores. Furthermore, the missing data points were randomly distributed and the overall outcome of patients with some missing data points was not significantly different from the study group, strongly suggesting no risk for selection bias.

In 24 of 81 patients, a whiplash type of injury preceded the symptoms. The radiculopathy was considered discogenic in 28 patients and spondylotic in 53 patients. An independent observer performed the clinical examination and assisted the patients in filling in the questionnaires and visual analogue scales (VAS, 100 mm).

Many sources have found the quantification of pain with VAS a valid and reliable method [26]. The pain was quantified by a standard 100 mm VAS for "pain right now" and "worst pain last week". The mean of the two pain scales was calculated and constituted a pain index (PI, range 0–100).

Cervical spine disability was quantified by the Neck Pain Disability Index (NPDI) [31], which is a combined score including functional disability as well as pain and cognitive skills. The NPDI questionnaire concerns ten areas, and for each area the patient selects one of six statements on an ordinal scale of 0–5, giving a total of 50 points as the worst outcome. The score is expressed as a percentage. The areas are: pain severity, personal care, lifting, reading, headache, concentration capacity, work, driving, sleep and leisure time. Vernon and Mior evaluated the NPDI for reliability and validity [31]. They reported a test-retest reliability, expressed as Pearson's r, of 0.89 ($P<0.05$). Validity was judged to be acceptable, and the index was found to be sensitive to changes in severity over time.

Functional disability was quantified by a new functional index based on 14 scores on the VAS (100 mm), each VAS addressing an activity related to cervical spine function. The mean of the 14 VAS scores is called the Cervical Spine Functional Score (CSFS, range 0–100). The variables are: regular work, heavy physical work, overhead work, sitting, activities of daily living (ADL), washing hair, buttoning up clothes, handwriting, sports activity, bicycling, driving, neck stiffness, weakness of arms or hands, and night pain. The reliability of the Cervical Spine Functional Score (CSFS) has been quantified at our institution, and an excellent reliability and internal consistency was found: the test-retest intraclass correlation coefficient was 0.96 and the Chronbach's alpha 0.96 [15]. The CSFS was designed to strictly address abilities reflecting primary cervical spine functions and, in contrast to the NPDI, does not include cognitive skills. For this reason, and because we found it more responsive to change than the NPDI in a previous study, we found it informative to include it in the analysis, despite the relative lack of data supporting the validity of this new score [13, 15].

The overall clinical outcome was assessed as excellent, good, fair or poor by the patients themselves as well as by the independent observer, according to Odom's criteria [21]. Work status prior to surgery and at follow-up was documented.

Heterologous bone plugs (Surgibone, Unilab Inc, NJ, USA) with a diameter of 12, 14 or 16 mm were used. Sixty-six patients had a single-level fusion, 26 a two-level fusion and one patient had a three-level fusion. All patients used a Philadelphia collar for 6 weeks postoperatively. Most patients received physiotherapy after removal of the collar. One patient refused to have radiographs taken, and one patient was not available for radiographic examination. Thus, anteroposterior and lateral radiographs were obtained in 91 out of 93 patients.

Three observers, a radiologist and two spinal surgeons not involved in the treatment of the patients assessed fusion status. The fusion was classified into solid fusion, possible pseudarthrosis or definite pseudarthrosis. In cases of a difference of opinion between the three observers, the radiologist decided the classification.

Solid fusion was defined as trabecular bone between the bone plug and the respective vertebral body. Possible pseudarthrosis was defined as a less than 1-mm wide radiolucent zone between the bone plug and the involved vertebral body. Definite pseudoarthrosis was defined as a greater than 1-mm wide radiolucent zone between the bone plug and the respective vertebra.

Full agreement between the three observers was reached in 60 out of 91 patients. In 29 of the remaining 31 patients, one observer reported a different classification from the other two, and in two patients the disagreement was total. In the statistical analysis, patients with possible pseudarthrosis and definite pseudarthrosis were pooled into one group called non-solid fusion, which was compared to the solid fusion group.

Statistical methods

Differences between groups were evaluated for statistical significance by the non-parametric Mann-Whitney test and by McNemar's

Table 1 The pain index (PI), Cervical Spine Functional Score (CSFS), Neck Pain Disability Index (NPDI) and overall outcome in all patients according to gender, fusion levels and fusion status (*Ex* excellent, *G* good, *F* fair, *P* poor)

	n	PI	NPDI	CSFS	At work (%)	Patient classification (%)				Observer classification (%)			
						Ex	G	F	P	Ex	G	F	P
Total	83	39	32	39	58	53	23	20	4	37	40	17	6
Men	49	39	32	37	57	53	23	20	4	37	41	16	6
Women	34	39	32	42	65	53	23	21	3	38	38	18	6
Single-level	59	37	31	39	66	54	25	19	2	41	41	15	3
Two-level	24	42	33	41	46	50	17	25	8	29	38	21	13
Solid	42	36	31	38	64	60	24	14	2	43	38	12	7
Non-solid	39	41	32	39	56	49	20	26	5	33	41	21	5

and the Chi-square test. To study the relationship between variables, Spearman's correlation coefficient (r) was calculated. Level of statistical significance was set at 0.05.

Results

The mean "pain right now" at follow-up was 32 (range 0–98) and the mean "worst pain last week" was 45 (range 0–96), resulting in a mean PI of 39 (range 0–98). The mean CSFS was 39 (range 0–85) and the mean NPDI 32 (range 0–76). The outcome did not differ significantly between men and women, between patients with single- and those with two-level surgeries or between patients with solid and those with non-solid fusion (Table 1). Level operated on or age did not significantly affect treatment outcome.

Among the 14 functional CSFS activities, the three highest mean disability scores were observed for overhead work (56, range 0–100), heavy physical work (61, range 0–100) and sports (45, range 0–100). Among the ten areas in the NPDI, the highest scores were reported for leisure time activities (44, range 0–100), lifting (40, range 0–100) and work (40, range 0–100).

Although the patients classified the outcome as excellent more frequently than the independent observer, the overall classification did not differ significantly between the patients and the independent observer.

Of the 81 patients with complete clinical and radiographic data, the fusion was solid in 42 patients (52%) and non-solid in 39 (48%). Of patients with a solid fusion, 84% rated the outcome as excellent or good compared to 69% of patients with a non-solid fusion (n.s.).

The patient's own classification of the outcome was most closely correlated to the PI (r=0.79, P<0.001), but also to the NPDI (r=0.70, P<0.001) and to the CSFS (r=0.69, P<0.001). Both the patient and independent observer classifications reflected particularly well the work status (Table 2, Table 3). The PI, the CSFS and the NPDI were all highly correlated to each other (r>0.81, P<0.001).

For all variables, there was a significant difference between the excellent and the good groups (Table 2, Table 3). In the group classified as excellent by the independent observer, the mean scores for all variables were below 20 and all patients were working at follow-up. This was in contrast to the good group, in which all mean scores were above 40 and only 50% had returned to work. In the group classified as good by the patient, the results were equally unimpressive. The mean PI was 50 (pain right now 42, worst pain last week 58), the CSFS 46, the NPDI 40 and only 50% had returned to work (Table 2).

The mean scores for all variables were significantly worse in the fair group than in the good group. The scores were similar in the fair and the poor group (n.s.). The small number of observations in the poor group, however, renders statistical analysis difficult.

Table 2 The mean (range) PI, CSFS, NPDI and the percentage at work according to the overall classification by the patient. The scores improved gradually from patients classified as poor to those classified as excellent, with significant differences between fair and good, and between good and excellent. The largest differences were observed between patients classified as good and excellent

	n	PI	CSFS	NPDI	At work (%)
Excellent	44	20 (0–80)	24 (0–81)	19 (0–62)	85
Good	19	50 (0–80)	46 (40–81)	40 (6–62)	50
Fair	17	70 (40–100)	66 (32–84)	54 (40–76)	23
Poor	3	80 (70–80)	66 (49–75)	44 (37–55)	0

Table 3 The mean (range) PI, CSFS, NPDI and the percentage at work according to the overall classification by the independent observer. As for the classification by the patient, the scores improved gradually, from those classified poor to those classified as excellent, with significant differences between fair and good, and between good and excellent. The largest differences were observed between patients classified as good and excellent

	n	PI	CSFS	NPDI	At work (%)
Excellent	31	10 (0–60)	14 (0–81)	13 (0–62)	100
Good	33	50 (0–80)	47 (17–81)	38 (12–62)	53
Fair	14	70 (40–100)	65 (32–84)	50 (40–76)	7
Poor	5	70 (60–90)	71 (52–84)	59 (46–75)	0

Table 4 The mean PI, NPDI, CSFS and overall classification of outcome by the patient (%) according to work status at follow-up. The group not working does not include patients on permanent disability pension or those who had retired before treatment (*Ex* excellent, *G* good, *F* fair, *P* poor)

	n	PI	CSFS	NPDI	Patient classification (%)			
					Ex	G	F	P
Working	42	25	27	22	73	20	7	0
Not working	31	62	60	50	22	28	41	9

Six patients had retired from work because of old age. Among the rest, 16% worked before surgery, compared to 58% at follow-up ($P<0.0001$). At follow-up, all variables were significantly better for patients working than for patients not working ($P<0.0001$), with the largest difference for the PI (Table 4). Before surgery, 73% used daily analgesics compared to 27% at follow up ($P<0.0001$).

Complications

There were six patients, three men and three women, with resolving postoperative dysphagia. Among these, four were operated on at C5/C6, one at C6/C7 and one at C7/T1. One woman, age 47 years, operated on at C5/C6, had a unilateral ptosis postoperatively, which was unresolved at 20 months follow-up.

Discussion

The results of this retrospective study show that the observed result of the Cloward procedure in the cervical spine varies with the outcome measurement used. The best outcome was observed for results based on the patients' overall classification. Using a VAS for pain and functional disability resulted in a clearly worse impression of the outcome.

Despite considerable residual functional disability and pain, as assessed by the pain index and disability scores, and despite one-third of the patients still being on sick leave at follow-up, three-quarters of the patients classified their overall result as excellent or good. This would indicate, in accordance with the results of a previous randomised study of lumbar spondylolisthesis conducted by one of the authors of the present paper (R.H.), that patient overall classification is not sufficient for assessment of outcome [19].

Our findings also agree with previous observations in studies on the outcome of lumbar spine surgery that show an overestimation of results when not using an independent observer. The present study supplements this observation by showing that an independent observer may also classify the result as good according to Odom's criteria, despite considerable symptoms, strongly suggesting a need for complementary outcome measurements.

In our study, only the outcome of patients classified as excellent can be considered truly satisfactory, whereas the outcome of those classified as good seems rather poor. The mean PI of the „good" group was 50, well reflecting the fact that only 50% had returned to work. The observed PI of 50 can be compared to the PI of 64 observed preoperatively in severely disabled patients with adult isthmic spondylolisthesis [19].

The observed frequency of the patients reporting an overall excellent or good outcome (76%) is similar to Cauthen et al. [3] and Kozac et al. [17], but worse than Cloward [5] in his own series of 2000 patients, with 94% excellent or good. However, if all variables in the present study are taken into consideration, our results are more in accordance with the study of Espersen et al. [7], which reported a good functional result in only 45% of 1106 patients. Similarly, the outcomes of two Swedish randomized studies using VAS for pain quantification were not impressive. Persson et al. [23] reported that ACDF with xenograft was not more efficient than conservative treatment, and the data of Zoega [36] showed no improvement of pain after single-level ACDF with autograft. Thus, a more thorough analysis of the outcome raises questions concerning the often-reported satisfactory results with the Cloward procedure [5, 17]. Since fusion status did not affect the clinical outcome in the present study, the low fusion rate does not explain our findings. On the contrary, the results may also apply to ACDF with various graft techniques, and also to anterior decompression without fusion [1, 3, 5, 8, 9, 18, 24, 29, 35]. Furthermore, studies on the lumbar spine have shown that a retrospective design tends to overestimate the outcome [20]. Thus, assuming that our study overestimated the outcome, the conclusion that the procedure may not be as efficacious as previously reported is not invalidated by the retrospective study design.

Despite a high follow-up rate (97%), some data were lost because of incomplete answers in the questionnaires and because radiographs were not obtained in all patients. Since the purpose of the study was to compare the different outcome variables, we decided to include only patients with complete clinical and radiographic data, which reduced the "follow-up rate" to 86%, but facilitated interpretation. Since the overall outcomes of patients with some data points missing were not statistically different from those of the study group, and since the missing data were randomly distributed with no indication of a systematic bias, the exclusion of patients with incomplete data seemed appropriate, particularly in view of the purpose of the study.

Our results emphasize the need for complementary outcome measurements, in addition to the commonly used overall classification of the results into excellent, good, fair or poor. Work status most closely reflected both the

patient and independent observer classifications of the outcome. Work status is the only objectively verifiable outcome variable. It does not, however, qualify as a stand alone outcome measurement, since it varies with the regional economic situation and is influenced by compensation issues. Notably, of patients not working at follow-up, 22% classified the results as excellent and 50% as excellent or good, clearly showing that the ability to work can not be used as a stand alone indicator of outcome.

The PI, the NPDI and the CSFS were all highly correlated, and discriminated equally well between patients not working and working, and between the overall classifications (excellent, good, fair and poor). Thus, the functional disability scores, the CSFS and the more global NDPI, which also includes cognitive skills such as concentration and reading, do not seem to add to the outcome analysis, they simply seem to reflect the all-important variable: pain. Furthermore, since pain is the main complaint of patients with a degenerative cervical spine disorder, and also a valid quantifiable outcome measurement, it should be a primary outcome measurement. The results of the study support the use of a combination of the overall assessment by an independent observer, the ability to work and pain quantification by VAS in outcome studies of the degenerative cervical spine.

The retrospective design is a drawback of the study. Strict inclusion criteria were not stated, and the patient material reflects a mixture of "soft and hard disc protrusions," with radiculopathy of varied duration. This, however, does not invalidate the conclusions based on the comparison of the different outcome measurements studied.

A prospective study design with longitudinal quantification of pain and functional disability would, however, more clearly show the potential usefulness of pain and functional disability quantification. Recently we reported preliminary prospective data from a randomised study, showing that pain measured on a VAS is more sensitive to change than the CSFS and the NPDI, supporting the conclusion from the present study that pain should be used as a primary outcome measurement in degenerative cervical disorders [13]. Until a final analysis of complete prospective data is available, however, it seems appropriate to report the present results. Irrespective of its retrospective nature, the study adds to our understanding of the outcome of the procedure, and clearly shows that subjective categorization of the outcome into excellent, good, fair or poor has resulted in an overestimation of the efficacy of the procedure. This information is of obvious importance in clinical practice when advising patients about the outcome of the procedure.

Conclusion

The study shows that the Cloward procedure with bovine bone in the treatment of degenerative cervical disorders results in considerable residual pain and functional disability and a high pseudarthrosis rate. The results further show that the outcome varies with the method by which it is measured. To document clinical outcome only by subjective categorization of the results by the patient or by an independent observer into excellent, good, fair or poor results in an overestimation of the outcome. Any single variable does not seem to qualify as a stand alone outcome variable. The results suggest the use of a combination of VAS for pain, work status and the overall classification of the independent observer in outcome studies of the treatment of the degenerative cervical spine.

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