

Title:

CLINICAL RESULTS OF NON SURGICAL TREATMENT FOR SPINAL
METASTASES

転移性脊椎腫瘍に対する非手術的治療の成績

Running title: Nonsurgical Therapy for Spinal Metastases

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Abstract

Purpose: In contrast with many analyses of surgical treatment for spinal metastases, there have been only a few recent, well-documented publications assessing nonsurgical treatment. This paper is a study of the outcome of nonsurgical therapy for metastatic tumors of the spine.

Methods and Materials: One hundred and one patients with spinal metastases were treated with radiation therapy and/or chemotherapy without surgical intervention between 1990 and 1995 in prospective analysis, and were followed for more than 24 months. This study included 59 men and 42 women with a mean age of 61 years (range: 14 to 81). Mean follow-up periods were 11 months for patients dying of the disease and 53 months for the survivors. Neurologic status, pain relief, functional improvement, and cumulative survival rate were assessed.

Results: Sixty-seven patients (66% of the total treated) were evaluated as being neurologically stable or improved after treatment. Pain relief was achieved in 67%, and 64% showed functional improvement. Primary lesion responsiveness to nonsurgical therapy influenced the survival, neurologic recovery, pain control, and function. Neurologic findings before therapy were useful in predicting ambulatory status after treatment.

Conclusion: Nonsurgical treatment was often successful when primary tumors had responsiveness to radiation therapy and/or chemotherapy. We found this to be evident even when neurologic deficits were found, particularly in lumbar spines. Spinal metastases of tumors with less responsiveness, unless patients were neurologically intact, responded poorly to therapy. Most of the patients who were successfully treated, enjoyed relief lasting nearly until death. Their functional ability was limited by general debility rather than by local tumor regeneration.

Key Words: spinal metastasis, neurologic status, survival, radiation therapy, chemotherapy

Introduction

Recently developed treatment modalities for malignant neoplasms have remarkably improved patient survival, even with known metastases. Spinal lesions, the most frequent bony metastases, often severely limit quality of life due to severe pain and neurologic deficits.^{1,2,3}

Many reports of surgical treatment for spinal metastases have been published. There were many reports in the 1980s describing various successful stabilization methods for posterior and anterior decompression.^{4, 5, 6, 7, 8} Tomita reported his more radical procedure, total en bloc posterior approach spondylectomy in 1993.⁹

There were patients, however, who survived for only a short period of time after surgery, while some other post-surgical patients survived, but did not realize any improvement of their activities of daily life (ADL) or betterment of their quality of life (QOL). On the other hand, we sometimes encountered patients who were successfully treated only by radiation therapy and/or chemotherapy. We attempted to determine the extent of success attainable with currently available multi-modal nonsurgical treatment in this prospective nonrandomized study of patients with spinal metastases.

Patients and methods

One hundred and eight (108) patients with spinal metastases were treated at Nagoya Memorial Hospital, in Nagoya, Japan from 1990 to 1995. Two patients moved out of Nagoya, and could not be followed for 24 months. Two patients underwent decompression surgery preceding nonsurgical treatment because bone metastasis was not positively diagnosed at that time. Three other patients had undergone surgery at other hospitals. These 7 patients were excluded from this study, while the remaining 101 patients were enrolled in this research project.

The 101 patients included 59 men and 42 women with a mean age of 61 years (ranging from 14 to 81 years). All patients were followed for a minimum of 24 months unless death supervened. The mean follow-up periods were 11 months (2 weeks to 70 months) for patients dying of disease and 53 months (24 to 81 months) for the survivors.

Lung carcinoma, including small cell lung carcinoma (2) and non-small cell lung carcinoma (17), were the most common primary lesions in this study. Other common primary lesions were breast carcinoma (15), prostate carcinoma (11), multiple myeloma (10), and hepatocellular carcinoma (9). Primary cancer in 6 cases could not be found regardless of the thoroughness of our investigation (Table 1).

Metastases were detected with bone scans and radiographs, and when possible, MRI and/or computed tomography was also performed. The cervical spine was affected in 20 patients, the thoracic spine in 58, and the lumbar spine in 60. There were multiple spinal lesions in 73 patients (72%), while the lesion was solitary in only 28 patients (28%).

Twenty patients were treated with radiation therapy, 19 with chemotherapy, and the remaining 62 patients were given combined radiation therapy and chemotherapy. Ninety-three percent (93%) of

the patients undergoing radiation therapy received a tumor dose of 40 Gy in 20 fractions, delivered over 4 weeks. All patients with neurologic deficits were given corticosteroids intravenously during the first 7 days of radiation therapy. Side effect or deterioration of their general condition resulted in discontinuing radiation therapy for 6 of the patients. Anticancer hormonal therapy was classified as chemotherapy in this series. Chemotherapy was decided upon and conducted by clinical oncologists, while radiation therapy additionally involved radiologists and orthopaedic surgeons. All patients gave informed consent for treatment.

We assessed the neurologic status, pain relief, functional ability both before and after nonsurgical treatment, and cumulative survival rate for all 101 patients. Neurologic status was evaluated according to Frankel classification of spinal cord injury (Table 2).¹⁰ Patients who maintained or regained a status equivalent to Frankel type E or D were considered good responders. Patients who were nonambulatory after treatment were considered nonresponders by this criterion. As for pain relief, improvement was defined as the disappearance or marked reduction of pain accompanied by decreases in dosage of narcotic and nonnarcotic analgesics. Functional status was simply graded as grade I, able to walk outdoors; II, able to walk only indoors (with or without walking aids); III, able to use a wheelchair but unable to walk; and IV, bedridden. Patients who maintained or regained grade I or II functional status, or improved more than one grade, were considered good responders. A patient scoring as a good responder on all three scales (neurologic outcome, pain relief, and functional ability) was defined as having been treated successfully.

Response was assessed within 1 month after completion of radiation therapy or 1 to 2 months after the start of chemotherapy. Sphincter function was difficult to evaluate and was not assessed in this series, because many patients unable to ambulate or otherwise showing poor performance status preferred the use of a Foley catheter.

Grouping and statistical analysis

The patients were divided into two groups according to their primary tumor responsiveness to radiation therapy and/or chemotherapy for data analysis. The group with responsiveness was composed of 46 patients. Lymphoma, prostate carcinoma, breast carcinoma, and small cell lung carcinoma were classified in this group, because radiation therapy plays an integral part in their treatment and are often effective.^{11, 12} Additionally, multiple myeloma and ovarian carcinoma were included in the group with responsiveness. This was done because chemotherapy has significant activity in treating these tumors.¹² Fifty-five patients with other tumors such as non-small cell lung carcinoma, hepatocellular carcinoma or colon carcinoma, where radiation therapy is not particularly effective and/or chemotherapy has only minor activity, were included in the group with less responsiveness.

A chi-square test was used to compare the results of these two groups. Cumulative survival was determined by Kaplan-Meier analysis and compared with a log-rank test.¹³ P values less than .05 were considered significant. The duration and probability of successful treatment was expressed as survivorship using Kaplan-Meier analysis. The end point was defined as the time when neurologic status or functional ability deteriorated, or pain recurred from any cause.

Results

The specific results are as follows:

I. Change of neurologic status (Frankel classification).

Sixty-seven (67) out of the 101 patients (66%) maintained or regained Frankel type D or E status and were considered good responders. Forty (40) out of the 46 patients (87%) in the group with responsiveness were good responders. On the other hand, only 27 out of 55 patients (49%) in the group with less responsiveness were considered good responders. This difference was statistically significant (chi-square test, $P < .001$; Table 3).

Forty-six (46) out of 54 patients who started treatment as a Frankel type E (85%) were considered good responders. However, only 21 out of 47 patients who had neurologic deficits were good responders. This difference was statistically significant (chi-square test, $P < .001$; Table 4, 5).

Fifteen patients in the group with responsiveness and 32 patients in the group with less responsiveness presented with neurologic deficits. Eleven (11) out of the 15 patients (73%) in the group with responsiveness were considered good responders. Only 10 out of the 32 patients (31%) in the group with less responsiveness responded favorably to therapy, with the remaining 22 (69%) suffering from neurologic deterioration and/or remaining nonambulatory. Even though 15 of these patients were Frankel type D, only 9 of them (60%) remained ambulatory. Of the 17 patients who were non-ambulatory (Frankel A through C), only 1 patient became ambulatory (Table 4, 5).

Assessment of the number of spinal metastases revealed that 68% of the patients with solitary lesions and 62% of patients with multiple

lesions were considered to be good responders (no significant difference).

II. Pain relief

Pain was found to be relieved in 68 out of 101 patients (67%). Thirty-eight (38) out of 46 patients (83%) obtained relief in the group with responsiveness. Thirty (30) out of 55 patients (55%) were considered good responders in the group with less responsiveness. These results were statistically different (chi-square test, $P = .0027$). Many of the patients who did not experience pain relief survived less than 3 months. Excluding the 21 patients whose survival was less than 3 months, 78% achieved pain relief.

III. Functional ability

Functional status improved at least one grade, or remained in favorable grades I or II in 65 out of 101 patients (64%). Thirty-nine (39) out of 46 patients (85%) in the group with responsiveness were included among these good responders. Only 26 out of 55 patients (47%) in the group with less responsiveness were functional responders. This difference was statistically significant (chi-square test, $P < .001$). Thirty-six patients failed to improve functionally. The main causes for functional disability were neurologic deficits in 19, poor general condition in 7, neurologic deficits plus poor general condition in 5, pain plus poor general condition in 3, and pain alone in 2.

IV. Cumulative survival rate

The cumulative survival rate for all 101 patients was 0.63 after 6 months, 0.45 after 12 months, and 0.3 after 24 months (Fig. 1). The cumulative survival rate in the group with responsiveness was 0.87 after 6 months and 0.76 after 12 months; that of the group with less responsiveness was 0.42 after 6 months and only 0.16 after 12 months

(Fig. 2). Survival rates of these two groups were significantly different ($P < .001$). Survival rates for patients with lung carcinoma or hepatocellular carcinoma after 6 months was no more than 0.25 and 0.1 after 1 year.

V. Comprehensive survey of successfully treated patients

Fifty-one (51) out of 101 patients (50%) were considered to have been treated successfully. Thirty-three (33) out of 46 patients (72%) in the group with responsiveness were treated successfully. Only 18 out of 55 patients (33%) of the group with less responsiveness were treated successfully (chi-square test, $P < .001$).

The mean survival and duration of the successful treatment of the successfully treated cases were 30 and 27 months, respectively. The relationships between these intervals are shown in Fig. 3, and those for each group are exhibited in Fig. 4. The effect of treatment lasted nearly until death in most of the patients in both groups. Functional ability was limited by deteriorating general condition rather than local tumor regeneration.

VI. Complications

Four patients died within 1 month after beginning treatment. All had primary or metastatic lung lesions and developed pneumonia or respiratory failure. Although these complications occurred, patients with them did not suffer from the myelosuppression resulting from either radiation therapy or chemotherapy.

The good results which were obtained by nonsurgical treatment remained stable except in one patient who experienced local tumor regrowth after 5 months and another who experienced vertebral collapse caused by radiation-related osteonecrosis. The former was

treated surgically with posterior decompression and instrumentation, and the latter was treated successfully by bracing.

Discussion

The spine is the most common site of bony metastases, which frequently give rise to neurological deficits and severe pain affecting functional capacity and QOL.

Neurologic deficits due to epidural compression are an important factor influencing the need for surgical intervention. Responsiveness to radiation therapy or chemotherapy is a reliable factor for predicting the neurologic outcome of nonsurgical treatment. Neurologically, 87% of the group with responsiveness and 49% of the group with less responsiveness were considered good responders. Patients presenting with neurologic deficits responded favorably in the group with responsiveness (73%), against only 31% in the group with less responsiveness. The frequency of neurologic recovery varied among previous reports.^{14,15,16} Maranzano reported that 69% of patients with spinal metastases arising from breast cancer became ambulatory,¹⁶ while Bach found that only 15% of patients with lung cancer regained the ability to walk.¹⁵ The difference between these two reports almost surely reflects differing primary tumor responsiveness to nonsurgical treatment modalities.

Initial neurologic status, as in previous reports, was another important factor in predicting ambulatory ability following treatment.^{15,16,17} Eighty-five percent (85%) of those patients without neurologic deficit (Frankel type E) were ambulatory after treatment and considered to be good responders in comparison to the 45% of patients with pretreatment neurologic deficits. As for nonambulatory patients (Frankel A through C), only 1 out of 17 in the group with less responsiveness became ambulatory, while 7 out of 11 in the group with responsiveness regained the ability to walk.

It is important to investigate complaints of pain before neurologic signs appear, as pain is typically the initial symptom of spinal metastasis.¹⁸ Pain was reportedly controlled by radiation therapy without surgery in 46%,¹⁹ and 72%²⁰ of patients with spinal metastases. Maranzano reported in a prospective analysis that back pain responded to radiation therapy in 80% of patients with spinal cord compression.¹⁴ The present study found pain relief in 67% of the patients treated. This rate is somewhat lower than in many recent surgical reports where about 90% of cases were reported to have experienced pain relief.^{7, 9, 21} The rate of pain relief was quite different between the group with responsiveness and the one with less responsiveness in our study. Survival of half of those patients without pain relief was less than 3 months. Surgical and nonsurgical reports cannot be compared directly because many cases in surgical series represent patients with primary lesions having responsiveness to nonsurgical treatment and good general condition.

Four characteristic findings in nonambulatory patients who were successfully treated by nonsurgical means were: a primary tumor belonging to the group with responsiveness; absence of marked instability or angulation of the spine; a gradual onset of neurological deficits; and immediate treatment after detection of spinal metastases.

Even though some patients in the group with responsiveness began treatment with neurologic deficits, nonsurgical treatment was successful when these patients had the other three features. This was especially evident when the lumbar spine was involved. Generally speaking, even in the group with responsiveness, when patients show marked spinal instability or angulation the spinal cord is usually compressed by bone and cannot be decompressed nonsurgically. Currently, laminectomy

without instrumentation is thought to have no significant difference in effectiveness in comparison to radiation therapy, and is ineffective for improving the patients' QOL.^{3, 19, 22} Therefore, decompression surgery with spinal instrumentation is preferred in some cases.

Patients with no neurologic impairment and no evidence of vertebral collapse or instability often do well with nonsurgical treatment even in the group with less responsiveness. Patients in this same group with a neurologic deficit, even when able to walk (Frankel type D), often do poorly with nonsurgical treatment. Surgery should be the treatment of choice in the following cases: when life expectancy is more than 6 months;⁵ the spinal lesion is solitary or localized on MRI and bone scans; no metastases involve critical organs such as brain, lung and liver; the patients are not of Frankel type A; and the general condition is compatible with surgery and general anesthesia. However, most cases of lung carcinoma or hepatocellular carcinoma did not satisfy these criteria, and survival periods were short.

A prospective, randomized study, incorporating a greater number of patients, is necessary for drawing any firm conclusions regarding nonsurgical or surgical indications. In the process of deciding treatment modalities, we have to take into consideration not only the degree of neurologic impairment but also the type of primary tumor. Knowing this, one can more accurately predict life expectancy and response to nonsurgical treatment.^{23, 24} Patients with very short life expectancies should probably be treated nonsurgically, and not all patients with long life expectancies require surgery.

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Figure legends

Figure 1. Cumulative survival rate for the 101 patients. Kaplan-Meier analysis.

Figure 2. Cumulative survival rate for the groups with responsiveness and less responsiveness, respectively. Cumulative survival rate for the group with responsiveness was significantly higher.

Figure 3. Survival and duration of success in 51 successfully treated cases.

Figure 4. Survival and duration of success in the group with responsiveness and the one with less responsiveness.

Table 1. Primary tumors in 101 patients

non-small cell lung carcinoma	17
breast carcinoma	15
prostate carcinoma	11
multiple myeloma	10
hepatocellular carcinoma	9
gastric carcinoma	8
malignant lymphoma	7
unknown origin	6
colon carcinoma	4
renal cell carcinoma	3
soft tissue sarcoma	2
small cell lung carcinoma	2
endometrial carcinoma	2
gall bladder carcinoma	2
osteogenic sarcoma	1
ovarian carcinoma	1
thyroid carcinoma	1
Total	101

Table 2. Frankel classification of neurologic dysfunction

Grade	Neurologic Function
A	Complete motor and sensory loss.
B	Complete motor and incomplete sensory loss.
C	Some motor function below level of involvement but no practical use, incomplete sensory loss.
D	Useful motor function below level of involvement, incomplete sensory loss.
E	Normal motor and sensory function.

Table 3. Nonsurgical treatment outcome by primary tumor type and responsiveness

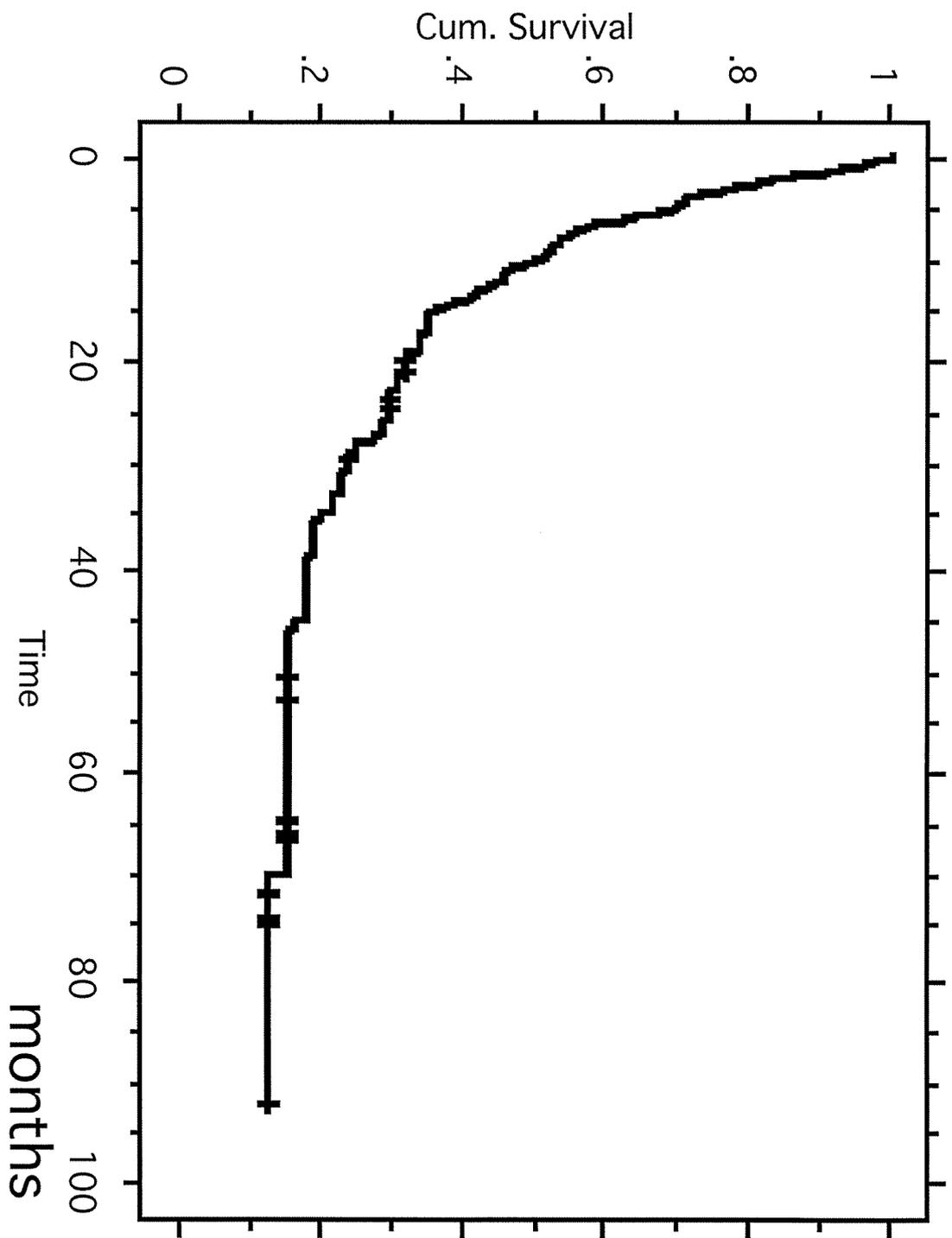
Primary tumor	Cases	Responder		
		Neurological status	Pain relief	Functional ability
breast carcinoma	15	14 (93%)	13 (87%)	14 (93%)
prostate carcinoma	11	10 (91%)	7 (64%)	9 (82%)
multiple myeloma	10	9 (90%)	10 (100%)	9 (90%)
malignant lymphoma	7	6 (86%)	6 (86%)	6 (86%)
small cell lung carcinoma	2	0 (0%)	1 (50%)	0 (0%)
ovarian carcinoma	1	1 (100%)	1 (100%)	1 (100%)
group with responsiveness	46	40 (87%)	38 (83%)	39 (85%)
non-small cell lung carcinoma	17	8 (47%)	11 (65%)	9 (53%)
hepatocellular carcinoma	9	3 (33%)	4 (44%)	3 (33%)
gastric carcinoma	8	4 (50%)	4 (50%)	2 (25%)
unknown origin	6	4 (67%)	3 (50%)	2 (33%)
colon carcinoma	4	2 (50%)	2 (50%)	3 (75%)
renal cell carcinoma	3	2 (67%)	2 (67%)	2 (67%)
soft tissue sarcoma	2	1 (50%)	2 (100%)	1 (50%)
gall bladder carcinoma	2	1 (50%)	0 (0%)	1 (50%)
endometrial carcinoma	2	1 (50%)	1 (50%)	2 (100%)
osteogenic sarcoma	1	1 (100%)	1 (100%)	1 (100%)
thyroid carcinoma	1	0 (0%)	0 (0%)	0 (0%)
group with less responsiveness	55	27 (49%)	30 (55%)	26 (47%)
Total	101	67 (66%)	68 (67%)	65 (64%)

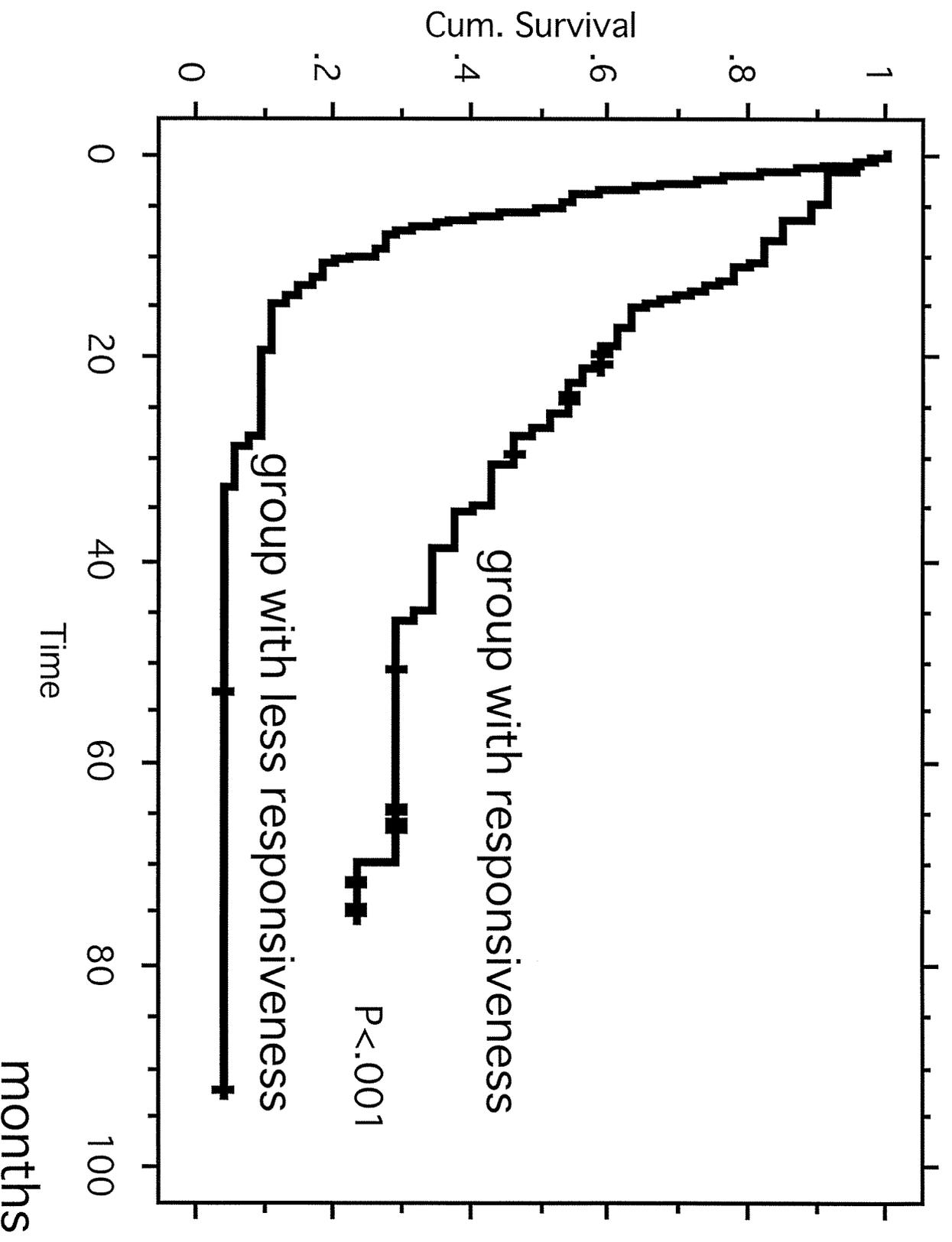
Table 4. Neurologic status before and after treatment
in the group with responsiveness (46 cases)

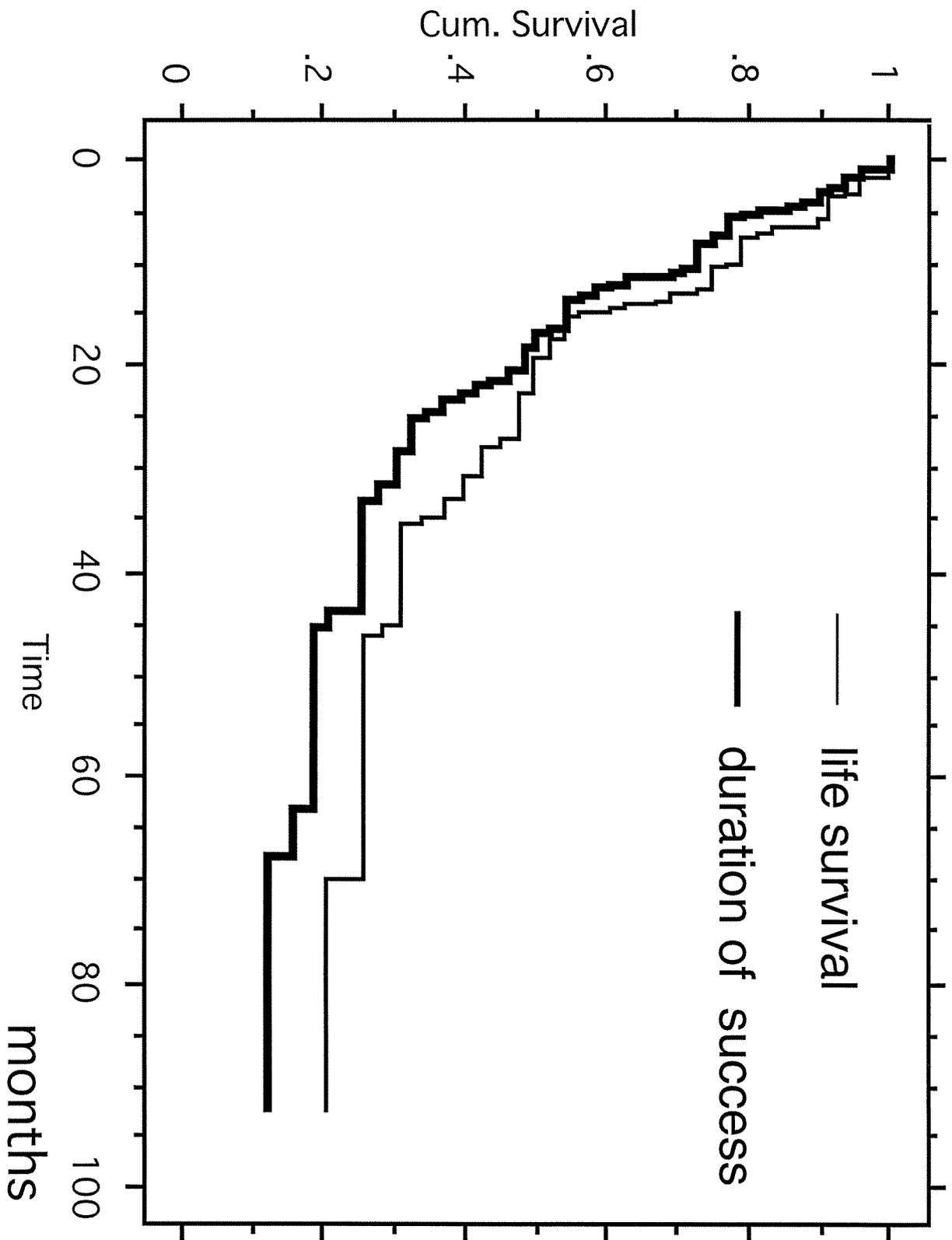
before treatment		after treatment	
Frankel type	No. of cases	Frankel type	No. of cases
A	3	A	3
B	5	A	—
		B	1
		C	—
		D	4
		E	—
C	3	A	—
		B	—
		C	—
		D	2
		E	1
D	4	A	—
		B	—
		C	—
		D	3
		E	1
E	31	A	—
		B	—
		C	—
		D	2
		E	29

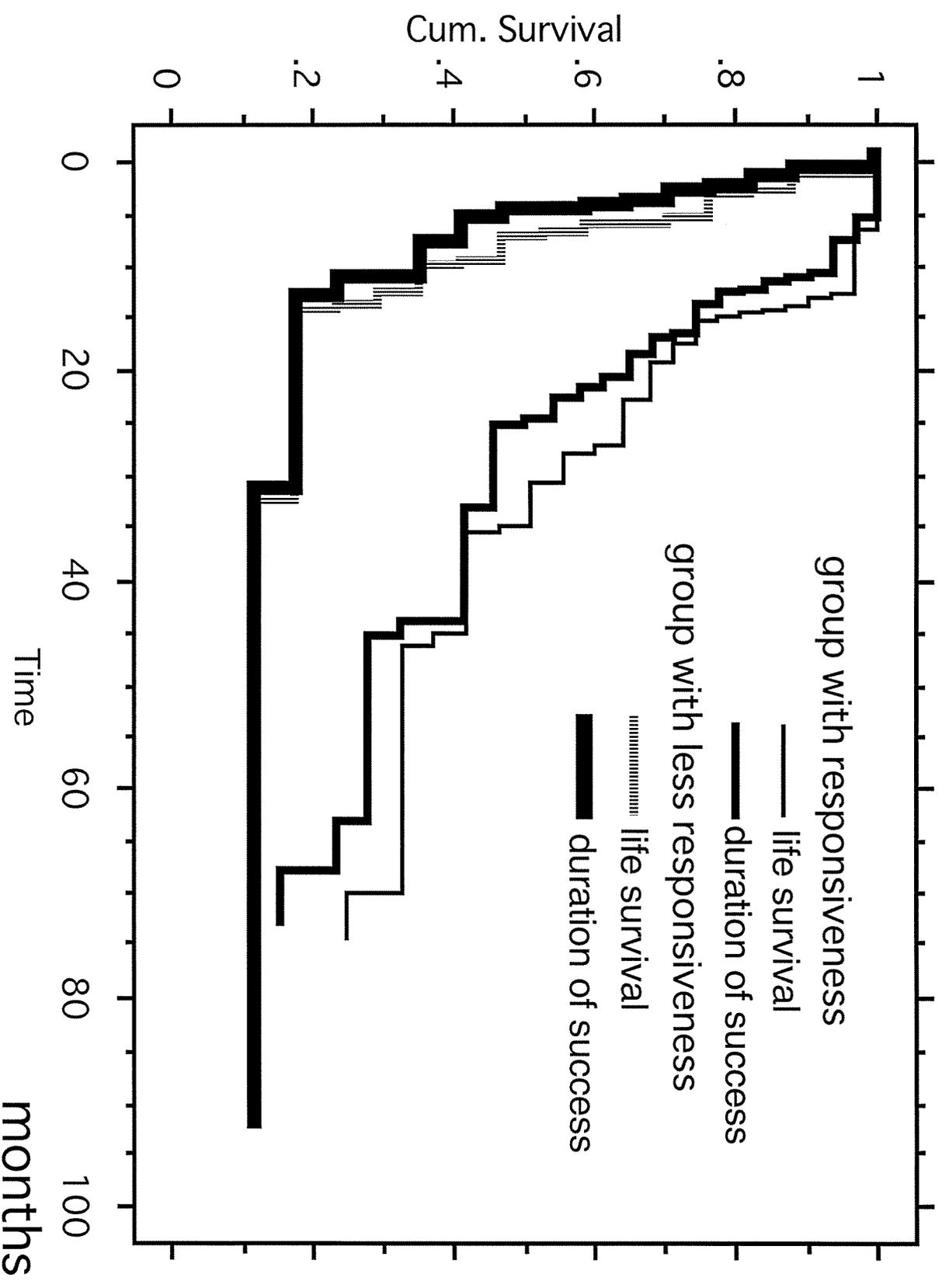
Table 5. Neurologic status before and after treatment
in the group with less responsiveness (55 cases)

before treatment		after treatment	
Frankel type	No. of cases	Frankel type	No. of cases
A	—	A	—
B	6	A	—
		B	6
		C	—
		D	—
		E	—
C	11	A	2
		B	5
		C	3
		D	1
		E	—
D	15	A	3
		B	2
		C	1
		D	7
		E	2
E	23	A	—
		B	1
		C	2
		D	3
		E	17









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