

B. Jónsson
L. Sjöström
C. Olerud
I. Andréasson
J. Bring
W. Rauschning

Outcome after limited posterior surgery for thoracic and lumbar spine metastases

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B. Jónsson (✉) · L. Sjöström · C. Olerud
W. Rauschning
Department of Orthopedic Surgery,
University Hospital,
S-75185 Uppsala, Sweden

I. Andréasson
Department of Oncology,
University Hospital, Uppsala, Sweden

J. Bring
Regional Oncology Center,
University Hospital, Uppsala, Sweden

Summary The efficacy of 'limited posterior surgery' for metastases in the thoracic and lumbar spine was studied prospectively in 51 patients (32 men and 19 women, mean age 64 years). The most common primary tumors were prostate, breast, and renal carcinoma, 37 patients had metastases in the thoracic spine and 14 in the lumbar spine. Indications for surgery were severe pain or neurologic deficit. Of the 46 patients with neurologic symptoms, 25 were unable to walk. Surgery was confined to *direct* or *indirect* decompression and stabilization with a pedicle screw fixator over few segments as possible. Pain, as well as a variety of functional performance parameters and residential status were registered preoperatively and after surgery at 3, 6, 9, and 12 months, and at 6-monthly intervals thereafter.

Pain was rated by the patient on a Visual Analog Scale, and functional performance was assessed with the Eastern Co-operative Oncology Group (ECOG) Performance Status Scale. We had no perioperative neurologic deterioration or death. Nineteen of the 25 nonambulatory patients regained their walking ability. Postoperative pain relief was significant and lasting over time. Nearly half of the patients attained improvement in functional performance. The median survival was 8 months. Older age and intact postoperative walking ability were positive factors for survival.

Key words Spinal metastases · Paraparesis · Pain · Walking ability · Pedicle fixation · Decompression · Prognostic factors · Performance status · Survival

The spine is the third most common site of metastatic involvement after the lung and the liver [4, 6, 27]. Most frequently the thoracic spine is affected [2, 8, 9, 19, 39, 52, 58]. As tumor infiltration progresses, the ensuing vertebral collapse and deformity may cause pain. Although pain can be controlled by radiotherapy early in the course of spinal metastatic involvement [12, 60], such therapy is inadequate in pathologic fractures due to vertebral weakening [60]. Up to 5% of patients with spinal metastases eventually develop neurologic deficits due to compression of the neural elements [4, 7, 13, 23]. Life expectancy is reduced as most patients with symptomatic spinal metastases also have advanced metastatic disease, and only a minority survive more than 1 year [3, 5, 37, 40].

In recent years a more active attitude towards surgical treatment of symptomatic spinal metastases has evolved [27, 38, 41, 49, 54], partly facilitated by improvements in diagnostic imaging and also by refinements in surgical techniques and instrumentation. Anterior decompression and stabilization have been reported to yield excellent results [27, 38, 54], but sometimes at the cost of rather high mortality [43, 44].

We have limited our surgical intervention to decompressing the neurovascular structures by a posterior approach and to stabilize only as few segments as necessary with a transpedicular technique. Decompression was achieved either *indirectly* by realigning the spine whenever vertebral collapse caused shortening and angular deformity, or

Table 1 Clinical data of the 51 patients who were operated on for thoracic and lumbar spine metastases

No.	Age	Sex	Primary cancer	Radiotherapy ^a	Instrumented levels	Pain		Neurologic function ^b		Performance status ^c					
						Preop	Postop	Preop	Postop	Preop	Postop				
											3 mo	6 mo	9 mo	12 mo	18 mo
1	65	M	Prostate	After	T10–12	10	0	1	0	3	2	2	–	–	–
2	80	M	Prostate	–	T2–4	4	0	2	0	4	2	2	4	4	–
3	51	M	Prostate	After	L2–5	5	0	1	0	3	2	–	–	–	–
4	59	M	Prostate	After	T2–4	5	1	2	0	4	1	1	1	1	1
5	73	M	Prostate	Before	T4–6	10	8	3	3	4	4	–	–	–	–
6	81	M	Prostate	After	T3–7	3	1	1	0	2	2	1	1	1	–
7	78	M	Prostate	After	T6–8	5	1	2	0	4	3	3	3	3	–
8	50	M	Prostate	Before	T8_10	2	2	1	0	3	2	4	–	–	–
9	73	M	Prostate	After	L1–3	8	1	1	0	4	2	2	3	3	3
10	64	M	Prostate	After	T7–9	8	4	1	0	3	4	–	–	–	–
11	67	M	Prostate	After	T4–7	7	3	1	0	3	2	2	2	2	1
12	64	M	Prostate	After	T5–7	8	4	2	0	4	2	2	2	4	–
13	76	M	Prostate	After	T4–7	3	0	2	0	4	3	4	4	4	–
14	72	M	Prostate	–	T9–11	0	0	2	0	4	4	4	2	3	3
15	52	M	Prostate	–	T4–6	4	1	2	1	4	4	–	–	–	–
16	72	M	Prostate	–	T5–7	10	0	4	1	4	3	3	1	2	2
17	65	M	Prostate	After	T8–11	5	5	2	0	4	4	2	2	2	–
18	71	M	Prostate	After	T10–12	5	5	2	0	2	4	3	3	3	3
19	71	M	Prostate	After	T5–10	6	6	1	0	2	4	4	–	–	–
20	85	M	Prostate	After	T7–9	10	0	2	0	4	3	2	2	2	2
21	81	M	Prostate	After	T9–11	10	0	1	0	3	0	1	0	1	1
22	54	F	Breast	Before	L3–5	4	2	0	0	3	2	2	1	4	–
23	57	F	Breast	After	T3–6	10	0	2	0	4	2	1	1	1	1
24	49	F	Breast	After	T8–10	6	0	1	0	1	1	1	1	4	–
25	65	F	Breast	Before	L2–4	5	3	0	0	3	3	3	–	–	–
26	66	F	Breast	After	L1–3	5	4	0	0	3	2	4	–	–	–
27	57	F	Breast	Before	T4–6	3	3	2	0	2	1	1	1	1	2
28	44	F	Breast	After	T3–5	8	4	2	1	4	–	–	–	–	–
29	64	F	Breast	Before	T1–4	8	0	1	0	2	2	1	1	1	–
30	67	M	Kidney	After	T8–12	10	1	2	1	4	3	3	3	3	3
31	60	M	Kidney	Before	T11–L1	10	1	2	0	4	3	3	–	–	–
32	49	M	Kidney	After	L2–4	8	4	1	0	3	–	–	–	–	–
33	77	F	Kidney	Before	T9–11	10	4	3	3	4	–	–	–	–	–
34	55	M	Kidney	After	L3–5	10	2	0	0	4	1	1	1	1	2
35	55	M	Kidney	–	T5–8	10	6	3	3	4	4	–	–	–	–
36	62	M	Kidney	Before	T12–14	5	5	2	0	4	–	–	–	–	–
37	79	F	Kidney	–	L2–4	5	4	1	0	4	–	–	–	–	–
38	56	M	Lungs	After	T1–3	10	0	1	0	3	3	–	–	–	–
39	73	F	Lungs	After	T7–9	8	6	1	0	4	–	–	–	–	–
40	67	F	Lungs	Before	L4–S1	6	6	2	2	2	2	–	–	–	–
41	60	M	Myeloma	After	L2–4	10	0	1	0	4	3	2	3	3	–
42	79	F	Myeloma	After	L1–3	9	1	1	0	3	1	1	1	1	1
43	50	F	Lymphoma	After	T8–12	2	1	2	0	3	3	3	3	4	–
44	54	M	Lymphoma	Before	T9–11	4	4	1	0	3	3	–	–	–	–
45	56	M	Lymphoma	After	L2–4	9	1	1	0	3	3	2	2	1	1
46	60	M	Esophagus	Before	T10–12	10	0	1	0	3	4	–	–	–	–
47	71	F	Ovary	Before	T10–12	10	4	3	3	4	–	–	–	–	–
48	42	F	Pancreas	–	T11–L1	4	4	1	0	2	–	–	–	–	–
49	84	F	Colon	–	T3–6	5	4	3	3	4	–	–	–	–	–
50	67	F	Thyroid	Before	T4–8	8	3	2	0	4	4	4	–	–	–
51	71	F	Urinary bladder	Before	L3–S1	10	0	0	0	4	2	–	–	–	–

^a Radiotherapy before or after surgery, or not at all (–)^b Neurologic function according to Brice and McKissock [10]^c Eastern Co-operative Oncologic Group Performance Status Scale (see Outcome evaluation): 0, fully active, able to perform all pre-disease activities; 1, restricted in physically strenuous activity, but

ambulatory; 2, ambulatory, capable of all self-care, up more than 50% of waking hours; 3, limited self-care, confined to bed or chair more than 50% of waking hours; 4, completely disabled, totally confined to bed or chair. – = dead

directly by resection of lamina, hypertrophied pedicles, or epidural tumor growth.

In an earlier retrospective study we reported on good and lasting pain relief and improved neurologic function [36]. In the present prospective series of thoracic and lumbar metastases, the outcome was evaluated by regular assessments of the patients' pain and functional performance during a minimum follow-up period of 18 months.

Patients and methods

From May 1991 through April 1992 surgery was performed at our department on 51 patients, 32 men and 19 women (mean age 64 years, range 42–85 years), with metastases to the thoracic ($n = 37$) or lumbar spine ($n = 14$). The most common primary malignancies were prostate, breast, and kidney carcinoma (Table 1). The patients had been referred to us from various hospitals in the Uppsala region (2 million inhabitants). Fifteen of the patients had received radiotherapy of the spine before referral.

Indications for surgery were neurologic impairment or severe pain not responding to opiates. Contraindications for surgery were complete paraplegia or poor general condition. Of 46 patients with spinal cord or cauda equina compression, 25 were unable to walk. The mean interval between the first manifestation of neurologic symptoms and surgery was 5 days (range 1 to 9 days).

Diagnostic imaging and surgical technique

Preoperative evaluation included conventional radiography and at least one neuroradiologic investigation (MRI, CT, or myelography). The surgical planning was based on the radiographic findings, such as location and size of the metastasis in the index vertebra. We also ascertained the causes of neural compression such as lytic lesions with vertebral collapse, osteoblastic thickening of pedicles or lamina, or epidural tumor growth (Table 2). Adjacent spinal segments were also examined for further metastatic lesions that might jeopardize purchase of the pedicle screws.

For reduction as well as stabilization, the Olerud pedicle fixator was used (Hospitech, Länna, Sweden) [47]. After application of the instrument, angular deformity and shortening were corrected, thereby restoring the alignment of the spine and indirectly decompressing the spinal canal (Fig. 1) [33, 46]. Laminectomy was performed in all patients with neurologic symptoms. Metastatic growth in the epidural space was resected and tumor infiltrated, hypertrophic pedicles were also removed. The instrumentation spanned one to four metastatic vertebrae (1.5 vertebrae on aver-

age). Although the rule was not to perform a posterolateral fusion, this was done in four patients (nos. 41, 42, 43, and 47). All patients received cloxacillin and dextran against infection and thromboembolism. The patients were mobilized without external supports as soon as their condition allowed, most being out of bed within a few days of surgery and could be returned to their local hospitals within 2 weeks after surgery.

Outcome evaluation

As most patients had been referred to us from remote hospitals, we evaluated pain and functional outcome using questionnaires.

The patients rated their pain on a 10-cm visual analog scale (VAS) ranging from 'no pain' to 'worst possible pain' respectively. They also marked their pain distribution on a pain drawing (Fig. 2). Neurologic function was classified according to Brice and McKissock [10] both preoperatively and before dismissal (Table 3).

Functional outcome was based on the self-assessment protocol of The Eastern Co-Operative Oncologic Group (ECOG) Performance Status Scale [62] for activities of daily living, restrictions of predisease performance, ambulatory status, self-care, work capability, and confinement to wheelchair or bed.

The questionnaires were sent to all surviving patients at 3, 6, 9, and 12 months after surgery and at 6-monthly intervals thereafter. The current residential status as well as the time spent in various nursing institutions since the last contact with us or their local physician were also recorded. If the questionnaire was not completely answered, the patient was contacted by telephone for clarification and the questionnaire was resubmitted.

Statistical analysis was performed with a commercial PC software package (Strategic Application Systems, SAS [51]). The Kaplan-Meier method was used for survival analysis [35], the survival curves being compared with the Mantel-Cox test (two-sided Log-rank test). Variables with a P value of less than 0.10 were included in multivariate analysis (Cox's proportional hazards model) to identify variables of independent significance. The selection of the prognostic factors was obtained by backward elimination procedure [14]. The results are presented as proportions (oddsratio, OR) and as 95% confidence intervals of the mean (95% CI) [15].

Results

No neurologic deterioration occurred after surgery. Six surgery-related complications were encountered. Patient no. 41 had an excessive hemorrhage due to injury of the superior gluteal artery during bone graft harvesting, but

Table 2 Type of primary tumor, location of the metastases and surgical procedure

Primary tumors	n	Lesions		Location			Fractures	Surgical procedures			
		Lytic	Blastic	Ant	Post	Ant + Post	Vertebral body collapse	Laminectomy	Pedicle resection	Reduction	Epidural tumor resection
Prostate	21	3	18	5	5	11	3	19	7	3	18
Breast	8	8	0	2	1	5	5	6	0	5	1
Kidney	8	8	0	3	0	5	5	7	0	5	7
Lung	3	3	0	2	1	0	2	2	0	2	2
Lymphoma	3	3	0	2	1	0	0	3	0	0	3
Other	8	8	0	3	0	5	5	6	0	5	5

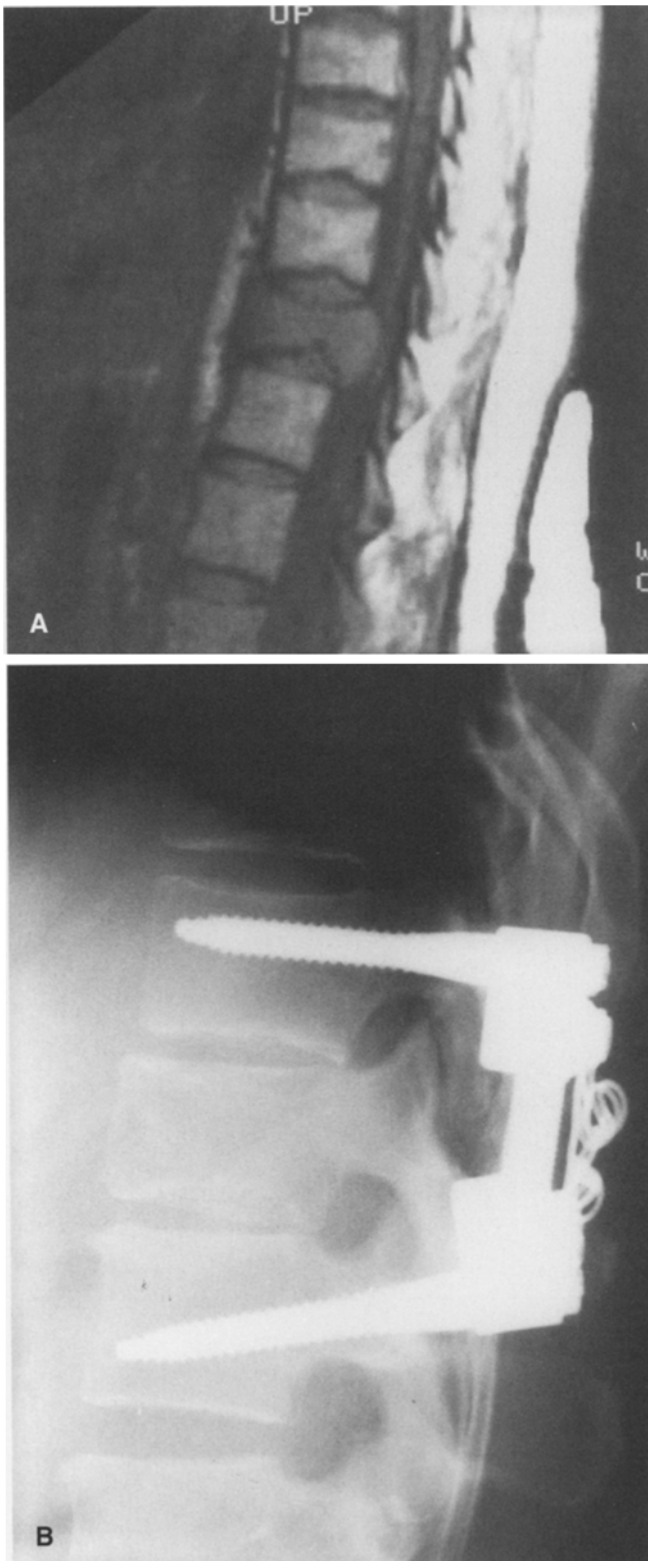


Fig. 1 A MR image showing a collapsed vertebral body in a 48-year-old woman with breast cancer metastasis in T12. The patient had intensive radiating pain to the right groin. B Plain x-ray film 1 week after surgery shows transpedicular fixation between T11 and L1

a deep venous thrombosis with uneventful course, and three patients (nos. 25, 41, and 42) developed wound infections, which resolved on antibiotic treatment.

The patients' preoperative pain ratings on the VAS (Fig. 2) yielded a median intensity of 8 (interquartile range 5–10), 18 patients rating their pain over 9 and six below 3. Postoperatively no patient reported pain aggravation (Table 1). At 3 months after surgery, the median pain rating was 1 cm (interquartile range 0–4). The pain relief was largely preserved over time (Fig. 2).

Nineteen of the 25 preoperatively nonambulatory patients regained *walking ability* after surgery (OR: 0.76; 95% CI: 0.55–0.91) (Table 2). Of the 42 surviving patients 22 manifested improved *functional outcome* (OR: 0.52; 95% CI: 0.37–0.67) 3 months after surgery. This improvement was lasting in most of the patients (Table 1).

Thirty-eight of the 51 patients (OR: 0.75; 95% CI: 0.62–0.85) could be discharged to their homes after surgery, whereas 13 patients (OR: 0.25; 95% CI: 0.14–0.40) remained hospitalized, either due to paraparesis, or due to advanced malignant disease. In the series as a whole ($n = 51$), the mean duration of cumulative hospitalization, including oncologic treatment was 2.6 months (95% CI: 1.9–3.2 months).

The 38 patients who could be discharged to their homes survived for an average of 6.6 months (95% CI: 5.0–8.2 months). Two patients (nos. 12, 13) with prostate cancer became paralyzed 3 and 4 months after surgery, respectively, and were under hospital-based home care until their death.

The overall 1-year survival rate was 0.43 (Fig. 3). Fourteen patients survived 18 months after surgery and 6 were alive at 3 years, all living at home (Table 1). The type of the primary tumor had some impact on survival, the 1-year survival rate being 0.62 among patients with prostate cancer compared to 0.38 among those with breast cancer and 0.25 among those with kidney cancer. None of the three patients with lung cancer survived 6 months. Univariate survival analysis (Table 4) and multivariate analysis (Table 5, models A, B) showed the prime predictors of long survival to be older age and intact postoperative walking ability (Table 5, model B). Life expectancy was shorter among patients under 55 years of age than in the older age groups.

Of the six patients (nos. 4, 9, 16, 18, 42, and 45) who were still alive 3 years after spinal surgery, three had functional outcome scores of 1. No further spinal surgery was done in any of the patients in this series.

fortunately recovered quickly, being discharged to his home 2 weeks later. In one patient (no. 17), a screw misplaced lateral to the pedicle was replaced. Patient 32 had

Fig. 2 Box plot displaying the 5th, 25th, 50th, 75th, and 95th percentiles of pain as rated by patients on a visual analog scale preoperatively and 3, 6, 9, 12, and 18 months postoperatively

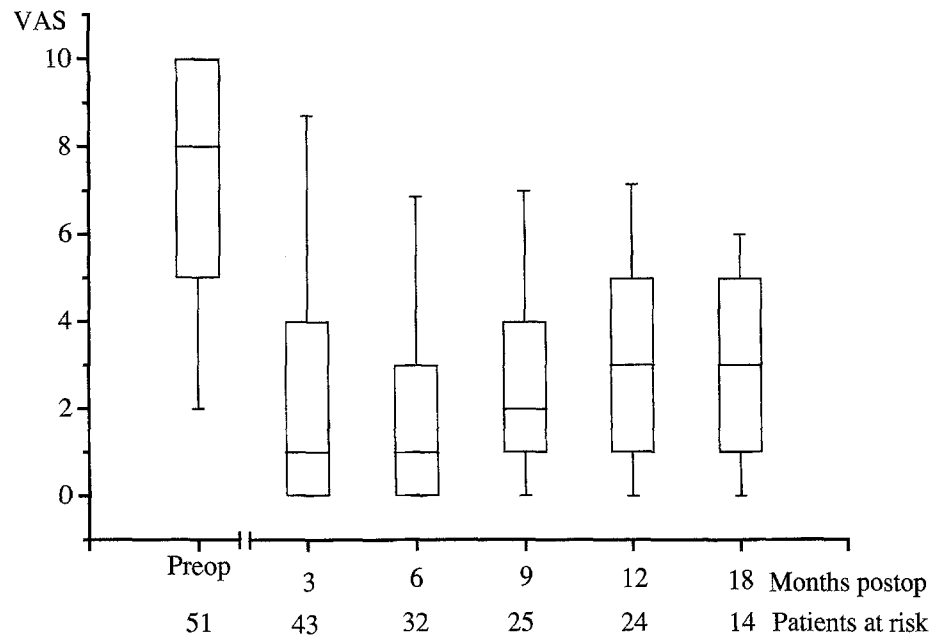


Table 3 Neurologic function according to Brice and McKissock before and after surgery

Neurologic function		Preop.	Postop.
0	No deficit or walking disability	5	41
1	Mild paraparesis, able to walk	21	4
2	Moderate paraparesis, able to move legs, cannot walk	19	1
3	Severe paraparesis, slight residual motor activity	5	5
4	Paraplegia	1	0

Discussion

Most patients with spinal metastases in advanced stages suffer severe pain [3, 5, 26, 37, 40]. Initially radiotherapy usually yields adequate pain relief [12, 60]. Fifteen of our patients had received radiotherapy prior to surgery, and 28 patients after surgery, some as early as 2 weeks postoperatively. As so many patients had received oncologic treatment, some of the lasting pain relief and improvement in function are probably attributable not only to the surgery, but also to the oncologic treatment.

Once the metastatic destruction of the vertebra(e) progresses and spinal collapse occurs, radiation therapy may no longer be effective, and surgical treatment may be indicated [25, 27, 54, 55, 60]. Laminectomy has long been the prevailing surgical technique in metastatic spines, but in presence of vertebral collapse laminectomy alone is not only ineffective in decompressing the neural elements, but may in fact increase spinal instability [1, 8, 10, 16, 25, 32]. The rather poor results of laminectomy and radiotherapy in thoracic and lumbar spine metastases with neurologic

Survival rate

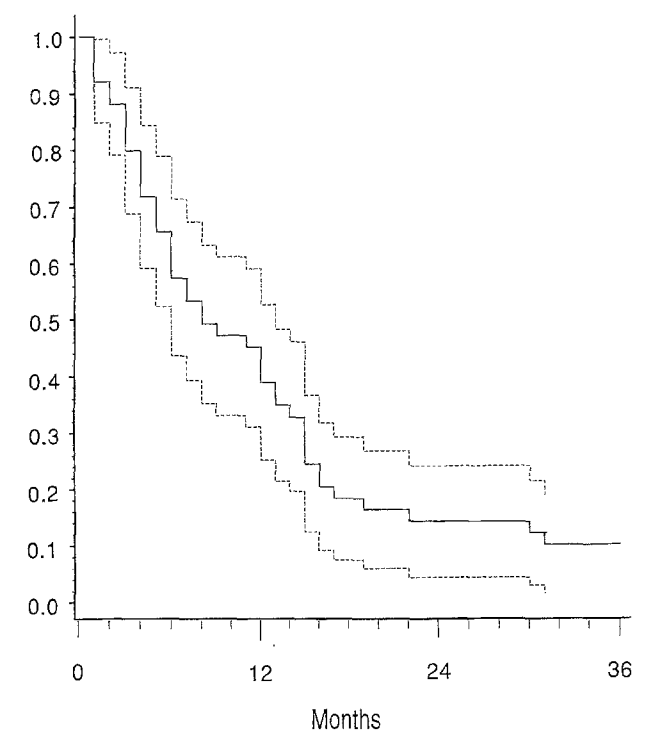


Fig. 3 The cumulative survival rate and 95% confidence interval of 51 patients after limited posterior surgery of thoracic and lumbar spine metastases

symptoms have prompted the development of new surgical concepts and techniques [27, 29, 38, 48].

Excellent results with respect to pain relief and neurologic outcome have been reported in some series [27, 38,

Table 4 Univariate survival analysis of clinical features and type of primary tumor

Variable	Category	No. of patients	Median survival months	Proportion alive after one year	<i>P</i> * value
Age (years)	< 55	10	4	0.20	0.064
	55–64	14	10	0.50	
	65–74	17	8	0.41	
	> 75	10	13	0.60	
Tumor	Prostate	21	15	0.62	0.138
	Breast	8	10	0.38	
	Kidney	8	4	0.25	
	Other	14	5	0.29	
Neurologic function**	Preop.				0.912
	0–1	27	8	0.41	
	2–4	24	9	0.46	
	Postop.				
Performance status (ECOG)	0–1	45	12	0.49	< 0.001
	2–4	6	3	0.00	
	1–2	7	11	0.43	
	3–4	44	8	0.43	

* Log-rank test

** According to Brice and McKissock

Table 5 Prognostic factors in patients operated for spinal metastases: results of the final Cox model (*n* = 51)

Variable	Model A (including all variables)				Model B (variables with <i>P</i> > 0.10 excluded)			
	Coefficient (beta)	SE	Hazard ratio	<i>P</i> value	Coefficient (beta)	SE	Hazard ratio	<i>P</i> value
Age > 55 years ^a	–1.28	0.57	0.28	0.025	–1.03	0.43	0.36	0.015
Neurologic function preop. (2–4)	–0.03	0.38	0.97	0.934	–	–	–	–
Neurologic function postop. (2–4)	1.26	0.65	3.51	0.052	1.61	0.57	4.99	0.005
Performance status (3–4)	–0.43	0.49	0.65	0.372	–	–	–	–
Pain (8–10)	0.30	0.48	1.35	0.526	–	–	–	–
Tumor: prostate cancer ^b	–0.44	0.44	0.64	0.313	–	–	–	–
Tumor: breast cancer ^b	–0.47	0.54	0.62	0.378	–	–	–	–
Tumor: kidney cancer ^b	0.09	0.51	1.10	0.860	–	–	–	–

^a The variable age has been dichotomized since there was no difference between the age groups 55–64, 65–74, and ≥ 75 in the multivariate analysis^b Compared to other tumors

54], but this approach appears to limit surgery for the relatively few patients who still are in good physical condition; most patients with advanced metastatic disease hardly tolerate major surgery [17, 43, 44, 57]. We therefore sought to minimize the operation so as not to jeopardize the well-being or even the life of the patients. This concept of ‘limited posterior surgery’ had initially been conceived as an emergency-type ‘first-line-of-defense’ operation to alleviate intractable pain and to avert an impending neurologic catastrophe, thereby gaining time for further diagnostic examinations and to plan any additional surgery that might prove necessary.

This limited type of surgery was well tolerated by our patients and also was strikingly effective in promptly and durably alleviating pain and in increasing or preserving functional performance, thereby also improving the pa-

tients’ quality of life [34]. All our patients with mild paraparesis maintained their walking ability, and of the 25 with moderate or severe paraparesis not less than 19 regained their ability to walk, most could be discharged to their homes and were capable of taking care of themselves. These results are similar to those obtained with anterior surgery [17, 24, 39, 42, 61].

As most of our patients came from distant hospitals, we used questionnaires to assess the outcome of treatment. Pain was graded with the VAS method. Visual analog scales have been used clinically for obtaining self-assessment ratings of subjective variables since the early part of this century [21, 28]. The method is sensitive [30, 45, 53], and the linear analog scale for pain yields numerical values suitable for statistical analysis [50]. The application of a pain drawing to obtain the patient’s own as-

assessment of pain localization, and the use of a questionnaire to obtain self-reports on functional ability are well-established methods and are considered more reliable in evaluating subjective conditions than assessments made by external observers [20].

Survival figures should be interpreted with caution. The excellent survival data reported after anterior surgery [27, 39, 43, 55] probably reflect a rather rigorous patient selection. Other surgeons have reported less favorable results: in a series of 26 consecutive patients operated anteriorly, Moore and Uttley had a 30% postoperative mortality, largely attributable to the patients' poor general condition [43]. Sundaresan reported a postoperative mortality of 11% [57]. Of the 17 patients in Fidler's series, 10 survived less than 6 months [17]. O'Neil et al. found a higher mortality with an anterior than with a posterior approach [44].

By limiting the surgical procedure, we could accept more patients for surgery who hardly would have tolerated extensive anterior surgery, but obviously there remain patients who no longer benefit from any surgery. Nine of our patients died within 3 months of surgery and probably should have been treated nonoperatively.

According to the final Cox model, the primary tumor type was not a significant predictor of survival. Although our small samples did not bear out statistical significance, the stage rather than the type of the tumor appeared to influence survival. Patients over the age of 55 manifested a significantly longer life expectancy than younger patients, among them were three women with highly aggressive breast cancer and one patient with pancreas cancer. Preserved postoperative walking ability was another significant positive predictor of survival [59]. Paraplegia probably increased the death risk due to lung and urinary tract infections and pressure sores, although these patients also had more advanced malignancies.

Most metastases in our study were lytic and were located predominantly in the vertebral bodies. Encroachment on the spinal canal anteriorly by vertebral body fractures [18, 22, 32] was usually successfully managed by *indirect* ligamentotaxis-type decompression, using the pedicle screw fixator for realignment of the collapsed, unstable spinal segments. Other malignancies, such as prostate cancer metastases, are typified by osteoblastic growth and hypertrophy of the pedicles causing spinal stenosis, others compress the thecal sac by infiltrating the epidural space, still others compress the dura by retropulsed tumor or bone fragments from the vertebral bodies. In such situations only *direct* surgical decompression with laminectomy and

resection of the pedicles affords effective neurovascular decompression [11, 25, 32, 56]. Irrespective of the type of decompression, *stabilization* of the spine is of paramount importance for protecting the neural elements from undue instability and minimizing painful spinal motion.

Following collapse of the anterior spinal elements, especially after reduction of kyphotic deformity, a pedicle fixator obviously acts as a load-bearing rather than a load-sharing device, therefore one would expect such a construct to be of limited longevity [47]. Surprisingly no patient in our series, including those surviving 18 months or longer, reported any symptoms indicative of implant problems, let alone any evidence of implant failure. This is surprising in view of our recent surgical specimens studies that disclosed a high incidence of implant loosening, axial migration, and pull-out of the pedicle screws as well as progression of the angulatory and translatory deformity in spite of the instrumentation [31].

Further correlative pathoanatomic-radiographic studies of metastatic spines in terminal stages may further clarify modes of implant failure and could determine indications for additional anterior column reconstruction. The timing of anterior column repair probably will depend on a variety of factors such as type, stage, and expansion of metastatic growth, the spinal region and portion of the vertebra affected, specific vertebral failure modes, the severity of neurovascular compromise, efficacy of oncologic treatment, and obviously also on individual biological factors.

Conclusion

Pedicle screw instrumentation in thoracic and lumbar metastases affords immediate and lasting pain relief. Stable realignment of the spine, with appropriate decompression, are also effective in preserving and restoring walking ability and allows most patients to return to their homes in a state of improved functional performance and quality of life. Although originally conceived as palliative, first-line-of-defense intervention, 'limited posterior surgery' constituted the definitive treatment for our patients. Preserved walking ability and older age were significant positive factors for survival.

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