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Intraoperative Radiotherapy Combined With Posterior Decompression and Stabilization for Non-Ambulant Paralytic Patients due to Spinal Metastasis

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Study Design. Retrospective examination of 96 nonambulant paralytic patients with spinal cord compression caused by metastatic cancer treated with intraoperative radiotherapy combined with conventional posterior surgery.

Objective. To improve local control of spinal metastasis by conducting posterior surgery combined with intraoperative radiotherapy (IORT) in patients with severe neurologic deficits.

Summary of Background Data. Few studies of conventional posterior surgery demonstrated satisfactory neurologic recovery for nonambulant paralytic patients with advanced spinal metastases.

Methods. Ninety-six patients underwent IORT (107 procedures) for the treatment of severe spinal cord compression because of spinal metastases. All patients were nonambulatory before surgery. Eighty-three cases (86%) were in an advanced stage of multiple spinal metastases (types 6 or 7 of the surgical classification of vertebral tumors). After posterior decompression, a single large dose of electron beam irradiation was delivered to the exposed metastatic lesion while the spinal cord was protected using a lead shield. Posterior instrumentation was also performed for most patients.

Results. Ninety-five of 107 cases (89%) obtained at least one level of neurologic improvement according to Frankel's classification and 86 cases (80%) became ambulatory after surgery. The main factors related to a nonambulatory status after surgery were preoperative neurologic status, performance status, and the presence of internal organ metastases. Of 86 postoperative ambulatory cases, only 3 became nonambulatory because of local recurrence during the follow-up period.

Conclusion. The IORT procedure is a useful technique for the treatment of spinal cord compression because of spinal metastasis, offering significant neurologic recovery and a low rate of local recurrence.

Key words: intraoperative radiotherapy, spinal metastasis, spinal cord compression, nonambulant paralysis. **Spine 2008;33:1898–1904**

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For relatively localized spinal metastasis of cancers with long pathologic courses, such as thyroid cancer, total excision of the lesion is actively applied; however, the lesion is advanced in most cases of spinal metastasis that are referred to orthopedic surgeons, and total excision is difficult. For such cases of spinal metastasis, we perform single, massive, intraoperative irradiation combined with conventional posterior decompression and stabilization (intraoperative radiotherapy,[1,2] IORT), anticipating that this treatment could provide significant neurologic recovery and also minimize local recurrence. In this study, we investigated the outcomes when this method was applied to cases of abasia (severe spinal paralysis with Frankel A, B, or C).

Materials and Methods

Patients

Of 184 patients with metastatic spinal tumors who underwent IORT at our hospital between November 1992 and June 2005, 151 who exhibited lower limb paralysis before surgery and 107 who had abasia before surgery were selected to participate in the study. Eleven patients who had mild paralysis and could not walk because of axial or radicular pain were excluded from the study. In the remaining 96 patients who continued in the study (61 males, 35 females; age range, 42–85 years; median, 64 years), the region responsible for paralysis was limited to the cervical, thoracic, and first lumbar vertebrae, and abasia was due to severe myelopathy or conus/*cauda equina* syndrome. In 9 patients, spinal metastasis developed at another site after the first IORT, and a second surgery was performed. In 2 of these patients, another spinal metastasis occurred after the second surgery, and a third surgery was performed. Thus, the total number of surgeries was 107.

The primary lesion varied among patients (Table 1). The radioresistant tumors included colorectal, renal, thyroid, and liver cancer; the radiosensitive tumors included breast and prostate cancer. In many of the cases that exhibited intermediate radiosensitivity the primary lesion was nonsmall lung cancer. In the remaining 12 cases the primary lesions were unknown, (3) urinary bladder, (2) pancreatic, (2) and 1 case each of uterine cancer, paraganglioma, malignant melanoma, carcinoma of the vulva, and pharyngeal carcinoma.

The operation site was a cervical vertebra in 10 cases, a cervicothoracic junction in 5, a thoracic vertebra in 89, and a thoracolumbar junction in 3. According to the surgical classification of vertebral tumors proposed by Tomita *et al*,[3] most cases were extracompartmental lesions, including type 5 in 9 cases (9%), type 6 in 22 cases (23%) and type 7 in 61 cases (64%). In 2 cases, the tumor was confined to the posterior elements. The predominant site of spinal cord compression was

Table 1. Primary Tumors

Primary Tumor	No. Patients (No. Surgeries)
Radioresistant tumors	
Large intestine/rectum	12 (14)
Kidney	10 (12)
Thyroid	6 (8)
Liver	7 (8)
Radiosensitive tumors	
Breast	18 (21)
Prostate	11 (11)
Malignant lymphoma	4 (4)
Myeloma	3 (3)
Lung	10 (10)
Esophagus	3 (3)
Others	12 (13)

anterior in 54 cases, lateral in 4 cases, posterior in 13 cases, and circumferential in 36 cases.

The duration of follow-up was 0.6 to 107 months in 71 fatal cases (median, 7 months), 6 to 83 months in 19 survival cases (median, 17 months), and 12 to 50 months in 6 discontinued cases (median, 26 months). Paralysis occurred in 36 of the 96 patients because of recurrence in regions previously treated with external irradiation of dosage 30 Gy or higher.

Surgical Procedure

For all patients, posterior decompression was performed and intraoperative irradiation applied for residual spinal metastatic tumor. Posterior instrumentation was performed in 77 cases: mainly 2 above and 2 below pedicle screw fixation. No anterior support or instrumentation was used.

Intraoperative Radiotherapy

Procedure in the Operating Room (Posterior Decompression and Preparation of the Irradiation Field). Preoperative embolization of the tumor blood vessels was performed for hypervascular tumors, such as metastases from renal and thyroid cancer. Laminectomy was performed at the level responsible for spinal and *cauda equina* paralysis. Epidural metastatic tumors were excised as much as possible using an ultrasonic surgical aspirator. Although anterior vertebral metastatic lesions were partially resected in cases of radioresistant tumors, they were not excised in cases of radiosensitive tumors, in anticipation that they would be treated by intraoperative irradiation. When the region to be irradiated was located in the thoracic vertebra, the transverse processes were excised to enable the cone to be set close to the vertebra. Cone size and the position of the lead plate for spinal shielding that was attached to the tip were determined based on MRI and intraoperative findings. The cone was sterilized in the radiation room. After meticulous hemostasis, the surgical field was covered with a cloth, the operating table was exchanged for a transfer table, and the patient was transferred from the operating room to the irradiation room.

Procedure in the Radiotherapy Room (Cone Setting and Electron Beam Irradiation). Figure 1 shows the cone setting for electron beam irradiation in the IORT procedure. The sterilized

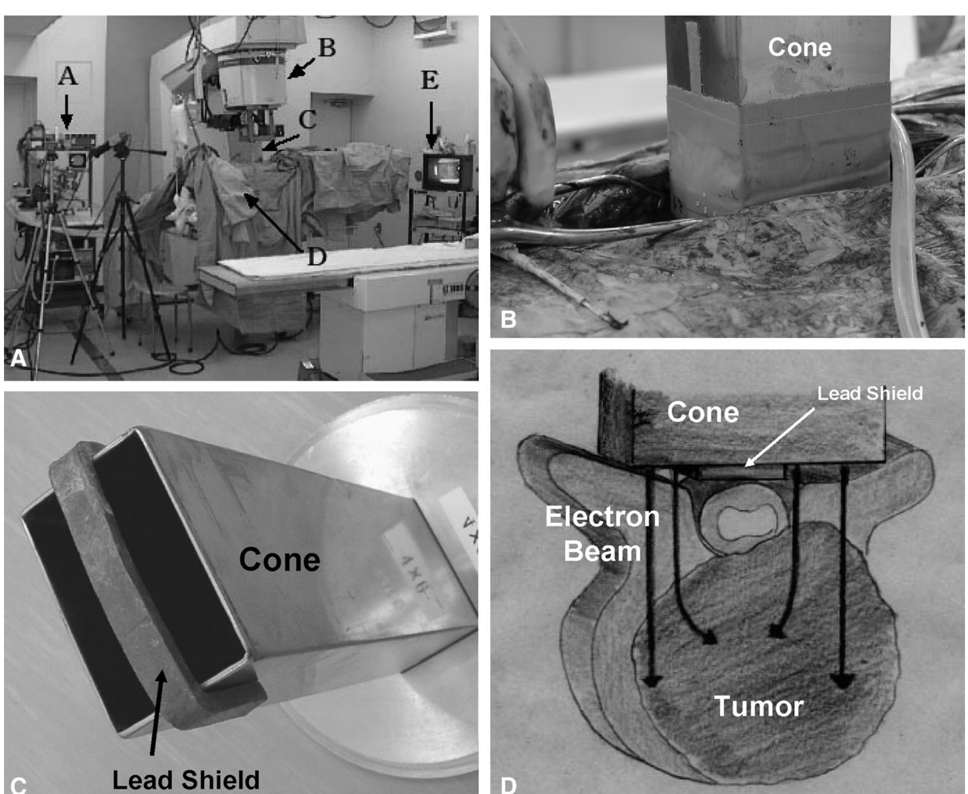

Figure 1. Photographic and schematic representations of intraoperative radiotherapy. **A**, Whole view of the irradiation room. A: Anesthesia machine; B: gantry, C: cone; D: operating table and patient; E: image from the camera located in the cone. **B**, Close-up of the cone set to the surgical field. **C**, View of the cone (4 × 6 cm) before attachment to the gantry. A lead plate (thickness, 7 mm; width, 10 mm) was set to the midline to shield the spinal cord. (**D**,) Schematic diagram of intraoperative radiotherapy.

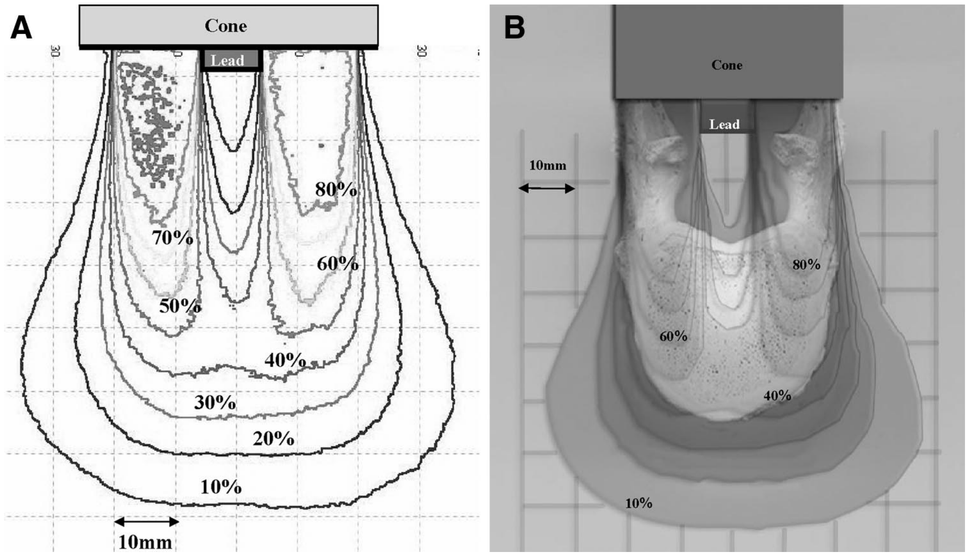

Figure 2. Dose distribution of intraoperative irradiation in a cadaver.[5] **A**, Isodose curves of dose distribution measurements. A radiation measurement film (GAF CHROMIC film, ISP Technologies Inc., Wayne, NJ) was sandwiched inside a fresh-frozen 12th thoracic vertebra from a cadaver, and immersed in water. A cone (width, 4 cm; major axis, 6 cm) attached to a lead plate (thickness, 7 mm; width, 10 mm) was used with energy of 16 MeV and dose of 2.5 Gy. The exposure was reduced to less than 10% to a depth of 17 mm in the region directly below the region shielded with the lead plate. **B**, Superimposition of isodose curves of dose distribution and the outline of the vertebra (anteroposterior diameter, 32 mm; width, 41 mm). Exposure was reduced to less than 10% in the center of the spinal canal; however, scattering of the electron beam resulted in 60% to 80% of the dose reaching the lateral sides and 40% of the dose reaching the anterior central region of the vertebra. In contrast, only 10% to 30% of the dose reached the posterior central region directly below the dural tube.

cone was attached to the gantry and precisely adjusted such that the dural tube and lead plate shield positions overlapped macroscopically; the cone was adjusted by tilting to the curve of the posterior vertebral elements using a TV monitor located within the cone. For selective cases with cervical and lumbar vertebral lesions, a 5 to 7-mm-thick lead plate was also placed on the dorsal side of the nerve root for shielding.

The electron energy was determined such that the most ventral region of the tumor would receive at least 40% of the dose; electron beam irradiation was then administered (Fig. 2). The delivered dose was 20 to 30 Gy, depending on the radiosensitivity of the metastatic tumor. Biologically, this dose corresponds to approximately 45 to 70 Gy of fractionated external irradiation, which is a very high dose. Direct exposure of the spinal cord to this dose causes myelopathy; therefore, a 5–7-mm-thick lead plate the width of the spinal cord was placed in the center of the cone to shield the spinal cord from the electron beam. Electron beams show marked scatter, spreading from behind the shielded central spinal cord region to reach the posterior region of the vertebra body located directly anterior to the spinal cord; this effect was confirmed by simulation. Electron beam irradiation was completed within approximately 5 minutes.

Procedure After Returning to the Operating Room. After intraoperative irradiation, the surgical field was covered with a cloth and the patient was transferred back to the operating room. Approximately 40 minutes was required between leaving the operation room and returning after irradiation was complete. As a rule, spinal instrumentation was also performed. Autologous bone was transplanted in selective patients, with long survival.

Assessment

The operation time, blood loss, intra- and postoperative complications, pre- and postoperative pain, pre- and postoperative performance status (PS), pre- and postoperative paralysis, presence and number of skeletal metastases other than in the spine, and the presence or absence of visceral metastasis to vital organs were investigated retrospectively from the patients' medical records. Pain was classified as follows: pain treated with narcotics, 3; pain treated with nonsteroidal anti-inflammatory drugs, 2; mild pain, 1; and no pain, 0. Evaluation of paralysis was conducted according to Frankel's classification. The severest grade of paralysis during the preoperative period was considered as the preoperative grade of paralysis. As a measure of postoperative paralysis, evaluation at the plateau between 1 and 5 months after surgery was adopted. The authors considered Frankel D1 after surgery to be ambulatory; this could be a few steps with a walker or with crutches. The association of these clinical data with the postoperative acquisition of walking ability was analyzed. The χ^2 test was used for statistical analysis.

■ Results

Operation Time, Blood Loss, and Complications

IORT was applied to 1 site in 97 surgeries, and to multiple sites in the remaining 10 surgeries (2 sites in 9 cases, and 3 sites in 1 case). The mean number of irradiated vertebrae was 2 (range, 1–6). The duration of surgery was 78 to 540 minutes (mean, 292 minutes; median, 280 minutes), and the intraoperative blood loss was 50 to 4500 mL (mean, 880 mL; median, 590 mL). The incidence of surgical complications was 15% (Table 2). One patient with thoracic vertebral metastasis from prostate cancer (83 years of age, intraoperative irradiation at 20 Gy and pre- and postoperative external irradiation to a total of 32 Gy) developed radiation myelopathy 2 years and 10 months after surgery, but remained at D1 from

Table 2. Surgical Complications

Complications	No. Patients	Treatment	Outcome
Early		Systemic complications	
Aggravation of lung cancer + pneumonia*	2	Conservative	Death
Adrenal insufficiency	1	Conservative	Cured
Paralytic ileus	1	Conservative	Cured
Aggravation of hepatic function + ascites	2	Conservative	Remission
Pulmonary embolism	1	Conservative	Cured
Neurological complications			
Epidural hematoma	1	Surgery	Cured
Cervical radicular symptoms	5	Conservative	Remission
CSF leakage	1	Conservative	Cured
Deep infection	2	Surgery Conservative	Cured (1) Remission (1)
Late			
Instrument-related problems	0		
Radiation myelopathy	1	Conservative	Unchanged
Delayed paralysis	1	Surgery	Cured
Delayed vertebral collapse	4	Surgery	Cured (3) Remission (1)

Frankel D3. Revision surgeries were needed for delayed vertebral collapse and local kyphosis in 4 patients, of whom 3 patients developed spinal paralysis requiring anterior decompression and reconstruction (2 cases) or combined anterior and posterior decompression and fusion (1 case). All three patients became ambulatory after these revision surgeries. Cranial and caudal extension of spinal instrumentation alleviated back pain in the remaining patients who suffered aggravated back pain because of delayed vertebral collapse.

Improvement of Pain and PS

Pain was reduced by 1 rank or more in 46% of cases (45/97) and the overall rate of improvement in pain, including drug dose reduction, was 60% (57/97). PS was improved by 1 rank or more in 88% of cases (97/107).

Improvement of Neurologic Status

Neurologic status improved after surgery by 1 grade or more according to Frankel's classification in 89% of cases (95/107) and was unchanged in 11% of cases (12/107); it was not aggravated in any cases (Table 3). Eighty percent (86/107) of the patients were able to walk after surgery. In patients with preoperative Frankel's C paresis, the postoperative ambulatory rate was 88% (77/88). The postoperative ambulatory rate in cases with posterior or lateral dominant spinal cord compression was 82% (14/17); for those cases with anterior dominant or circumferential spinal cord compression the rate was 80% (72/90). There was no statistical difference between the 2 groups.

Table 3. Neurological Status Before and After Surgery (Frankel's Classification)

Postoperative					
Preoperative	A	B	C	D	E
A	1				
B			9	8	1
C			11	66	11

The postoperative ambulatory rate was significantly lower in patients with renal cancer, visceral metastasis to vital organs, severe preoperative paralysis, and poor preoperative PS (Table 4). Recovery of ambulatory ability after surgery tended to be poor in patients with extraspinal bone metastasis and multiple spinal metastases, but these were not statistically significant factors. No difference was noted in the recovery from paralysis between patients with and without previous external irradiation therapy.

Eight of the 11 preoperative Frankel C patients did not regain ambulatory status because of their worsening PS in the postoperative period, resulting from cancer progression and chemotherapy, even though their muscle strength was 3 or higher on the manual muscle testing level. In patients who survived for 6 months or longer after surgery, the postoperative ambulatory rate was 98% (59/60) for Frankel C patients. In contrast, the rate for patients who survived for less than 6 months after surgery was 67% (20/30) for Frankel C patients, a significantly lower rate ($P < 0.001$) (Table 5). The duration over which ambulatory ability was maintained was also closely related to survival time (Table 5).

Of the 86 patients who were able to walk after surgery, 19 survived and 61 died, and follow-up was discontinued in 6. Of the 19 patients who survived, 9 maintained ambulatory ability whereas 10 did not. Of the 61 patients who died, 24 maintained ambulatory ability until 1 month or less before death, and the remaining 37 became unable to walk more than 1 month before death. The causes for recurrence of abasia in these 47 patients were vertebral metastasis to other than the site of surgery in 20, aggravation of liver and lung metastases in 12, metastasis to bone other than the spine in 7, delayed vertebral collapse in 3, local recurrence at the surgical site in 3, and other causes in 3 (radiation myelopathy in 1, late onset bacterial spondylitis in 1, brain infarction in 1). In the 3 cases of local recurrence, the primary lesions were thyroid, renal and liver cancers, and the onset times

Table 4. Preoperative Risk Factors in Relation to Postoperative Ambulatory Status

Factors	Items	No. IORTs	Postoperative Ambulatory Status No. (%)	χ^2	*P*
Primary cancer site	Kidney	12	7 (58)	4.16	0.0413
	Non-kidney	95	79 (83)		
Visceral metastasis to vital organs	Yes	39	26 (67)	7.31	0.0069
	No	68	60 (88)		
Preoperative neurological status	Frankel A or B	18	8 (44)	17.71	<0.0001
	Frankel C	89	78 (88)		
Preoperative performance status	4	72	52 (72)	76.20	<0.0001
	≤3	35	34 (97)		
Bone metastases other than spine	Yes	45	34 (76)	1.143	0.2850
	No	62	52 (84)		
Multiple spinal metastases (≥3)	Yes	72	55 (76)	2.216	0.1366
	No	35	31 (89)		
Previous external radiotherapy (≥30 Gy)	Yes	45	29 (81)	0.001	0.9731
	No	62	57 (80)		

were 4 years, 19 months, and 6 months after surgery, respectively.

■ Discussion

The reported postoperative ambulatory rate after posterior surgery in combination with postoperative external irradiation varies, ranging from 42% to 70%, presumably because of variations in the cancer type, degree of preoperative paralysis, and level of the responsible lesion. For example, the overall postoperative ambulatory rate in reports of numerous spinal metastases from breast cancer, prostatic cancer, myeloma, and malignant lymphoma tends to be relatively high.[4–6] In contrast, the ambulatory rate is generally low in patients with spinal metastasis from lung, uterine, or renal cancer[7,8]; therefore, the postoperative ambulatory rate tends to decrease as the proportion of these cases increases.[7,9] Regarding the level of the responsible lesion, the outcome for decompression of the cauda equina was better in the lumbar region than in the thoracic region.[10]

The overall postoperative ambulatory rate after IORT was higher in the present study than in any other large series with conventional posterior surgery and postoperative external irradiation. It should be noted that the proportion of our cases with breast cancer, prostatic cancer, myeloma, or malignant lymphoma was relatively low (38%). Furthermore, we did not include lesions caudal to the second lumbar region. Considering the impact of these negative factors on the overall results of the present study, neurologic recovery in IORT was significantly better than that for conventional posterior surgery with postoperative external irradiation.

In addition, our results were superior to the surgical results of Patchell *et al*,[11] who proved the superiority of surgical treatment to radiotherapy for the first time in a prospective randomized trial. They reported that more patients who had surgery followed by additional radiotherapy, regained the ability to walk than patients who had radiotherapy alone (10/16 [62%] *vs.* 3/16 [19%]). The surgical procedure they applied was to remove as much tumor as possible and circumferentially decompress the spinal cord. They tailored the surgical approach for each patient depending on the level of the spine involved and tumor location: for anteriorly located tumors they used an anterior approach in the cervical spine, and transversectomy or anterior approach in the thoracic and lumbar spine. In contrast, we carried out posterior decompression alone even for anterior dominant spinal cord compression. Although posterior decompression for a tumor located anteriorly is considered inadequate in terms of neurologic recovery, the results of the present study show that our technique was much more effective than that of Patchell *et al* regarding regaining the ability to walk (86/107 [80%] *vs.* 10/16 [62%]). There was no favorable factor for primary cancer site or spinal level in our patients, compared with the patients in their study. Therefore, we propose the possible superiority of intra-

Table 5. Relationship Between Postoperative Survival Time and Ambulatory Ability

Postoperative Survival Time	No. Patients Treated With IORT	Postoperative Ambulatory Rate	Postoperative Ambulatory Rate of Frankel C Patients	Time Required to Regain Ambulatory Ability	Ambulatory Duration	Ratio of Ambulatory Duration to Postoperative Survival Time or Time Before the Second Surgery†
<6 mo	33	61% (20/33)	67% (20/30)	26 days (7–8)	45 days (9–8)	48% (11–4)
≥	74*	89% (66/74)	98% (59/60)	36 days (6–32)	458 days (10–373)	70% (5–8)

*Including 5 patients in whom follow-up was discontinued.
†The ratio to the time before the final follow-up for patients in whom follow-up was discontinued.

operative irradiation to postoperative conventional radiotherapy in terms of neurologic recovery.

The advantage of IORT is that one large irradiation dose can be used with minimal damage to the surrounding normal tissue. Although the delivery of a single large dose of radiation rather than multiple, smaller fractions is a potential disadvantage, a large dose may elicit higher tumoricidal or tumor-reducing effects. In addition, shielding of the spinal cord allows delivery of a curative dose, even to radioresistant tumors. These features may explain the superiority of IORT in recovery from spinal paralysis.

In our cases, postoperative ambulatory rates were consistently good for all types of cancer, excluding patients with renal cancer. It should be noted that in the present series, patients with renal cancer exhibited multiple spinal metastases (100%), visceral metastasis to vital organs was common (58%), and Frankel B cases accounted for 25%; these statistics may explain the lower ambulatory recovery in our patients with renal cancer.

In the present series, factors related to postoperative ambulatory rate included the degree of preoperative paralysis, PS, and the presence or absence of visceral metastasis to vital organs. It is clearly established that complete preoperative motor paralysis is a significant negative factor for postoperative neurologic recovery.[4–7]

Preoperative PS and the presence or absence of visceral metastasis to vital organs were factors associated with systemic conditions. In addition to neurologic status, ambulatory ability is closely related to systemic conditions including general health, mental condition, musculoskeletal function, and the state of pain reduction. In cases with poor preoperative PS and visceral metastasis, the latter 4 conditions tended to worsen after surgery, suggesting that neither the patients' ambulatory status nor their prognosis would be good; indeed, the survival time was shorter than 6 months in 10 of 11 Frankel C patients who did not recover ambulatory ability after surgery. Regarding the indications for IORT, preoperative PS of 0 to 3, and the absence of visceral metastasis may serve as useful indicators.

The duration that ambulatory ability was maintained was also longer in patients who survived for more than 6 months after surgery. Thus, the outcome of IORT in cases with severe spinal paralysis depends on the postoperative survival, suggesting the importance of preoperative prediction of survival.

In the present study, the rate of local recurrence at the surgical site was 6%, which was markedly lower than that in posterior surgeries with follow-up of more than 1 year.[8] In all 3 patients with local recurrence, the tumor was radioresistant; patients had undergone external irradiation before IORT, and irradiation dose to the spinal cord had accumulated to a high level. Thus, IORT could not be performed at a higher (radical) dose. To increase the effect of the radiation in future treatment of radioresistant tumors, it will be necessary to achieve a much greater reduction in the target volume for intraoperative irradiation by partial intraoperative excision of the vertebral tumor *via* the posterior approach. In treating residual tumor(s), combination with intensity-modulated radiation therapy which has recently been actively employed, may be effective. Because such systems have only been installed in a limited number of facilities in Japan, greater availability of such equipment is expected in the future.

The incidence of early postoperative complications was 15%, which is comparable with that of other surgical methods.[4,6] There was no increase in the incidence of deep infection, which was a potential concern because the patients were transferred to another room for treatment. Transient radiculopathy developed in several cervical vertebral cases, but it was unclear whether this was because of acute radiation damage. Delayed radiation myelopathy occurred in only 1 patient, demonstrating that shielding of the spinal cord with a lead plate was effective.

We have applied IORT to cases with radioresistant tumors and cases with recurrent metastasis after external irradiation.[1,2] In the present study, no difference was noted in recovery from paralysis between patients with and without previous preoperative external irradiation at 30 Gy or higher, suggesting that this method is also useful in treating recurrent spinal metastases after previous irradiation.

■ Conclusion

IORT for spinal cord compression caused by metastatic spinal tumors achieved a good postoperative ambulatory rate regardless of the cancer type (excluding renal cancer) or the presence or absence of previous external irradiation treatment, thereby revealing its usefulness. Many patients lost the acquired ambulatory ability due to development of other spinal and bone metastases and aggravation of visceral metastasis to vital organs; however, only a few patients lost the ambulatory ability because of local recurrence, showing that good local control was obtained by this treatment method.

■ Key Points

- The rates of neurologic recovery and recovery of ambulatory ability after posterior surgery combined with intraoperative radiotherapy (IORT) were 89% and 80%, respectively.
- Risk factors for postoperative nonambulatory status were renal cell cancer, poor preoperative neurologic status (Frankel's A or B), poor preoperative performance status (grade 4), and presence of visceral metastasis to vital organs.
- With the available numbers, bone metastases other than spine, multiple spinal metastases, or previous treatment with external irradiation were not indicators of poor neurologic outcome.
- The rate of local recurrence of the lesion after treatment with IORT that caused deterioration of ambulatory status in the follow-up period was significantly low.

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