

## Postoperative re-irradiation using stereotactic body radiotherapy for metastatic epidural spinal cord compression

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**OBJECTIVE** This study aimed to clarify the outcomes of postoperative re-irradiation using stereotactic body radiotherapy (SBRT) for metastatic epidural spinal cord compression (MESCC) in the authors' institution and to identify factors correlated with local control.

**METHODS** Cases in which patients with previously irradiated MESCC underwent decompression surgery followed by spine SBRT as re-irradiation between April 2013 and May 2017 were retrospectively reviewed. The surgical procedures were mainly performed by the posterior approach and included decompression and fixation. The prescribed dose for spine SBRT was 24 Gy in 2 fractions. The primary outcome was local control, which was defined as elimination, shrinkage, or no change of the tumor on CT or MRI obtained approximately every 3 months after SBRT. In addition, various patient-, treatment-, and tumor-specific factors were evaluated to determine their predictive value for local control.

**RESULTS** Twenty-eight cases were identified in the authors' institutional databases as meeting the inclusion criteria. The histology of the primary disease was thyroid cancer in 7 cases, lung cancer in 6, renal cancer in 3, colorectal cancer in 3, and other cancers in 9. The most common previous radiation dose was 30 Gy in 10 fractions (15 cases). The mean interval since the most recent irradiation was 16 months (range 5–132 months). The median duration of follow-up after SBRT was 13 months (range 4–38 months). The 1-year local control rate was 70%. In the analysis of factors related to local control, Bilsky grade, number of vertebral levels in the treatment target, the interval between the latest radiotherapy and SBRT, recursive partitioning analysis (RPA), the prognostic index for spinal metastases (PRISM), and the revised Tokuhashi score were not significantly correlated with local control. The favorable group classified by the Rades prognostic score achieved a significantly higher 1-year local control rate than the unfavorable group (1-year local control rate: 100% vs 33%;  $p < 0.01$ ). Radiation-induced myelopathy and vertebral compression fracture were observed in 1 and 3 patients, respectively. No other grade 3 or greater toxicities were encountered.

**CONCLUSIONS** The results indicate that spine SBRT as postoperative re-irradiation was effective, and it was especially useful for patients classified as having a good survival prognosis according to the Rades score.

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**KEYWORDS** postoperative spine SBRT; MESCC; re-irradiation; decompressive surgery; oncology

**S**PINAL metastases are diagnosed in approximately 40% of cancer patients,<sup>10</sup> and metastatic epidural spinal cord compression (MESCC) occurs in up to 10% of adult cancer patients during their disease course.<sup>17,18</sup> MESCC is one of the most dreaded complications of met-

astatic cancer, because it usually causes progressive pain, paralysis, sensory loss, and sphincter dysfunction.

A randomized, controlled trial demonstrated that, for patients with symptomatic single-level MESCC, surgical decompression followed by conventional radiation thera-

**ABBREVIATIONS** CTV = clinical target volume; IMRT = intensity-modulated radiation therapy; IORT = intraoperative radiotherapy; MESCC = metastatic epidural spinal cord compression; OAR = organ at risk; PRISM = prognostic index for spinal metastases; PTV = planning target volume; RPA = recursive partitioning analysis; RT = radiation therapy; SBRT = stereotactic body radiotherapy.

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py (RT) of 30 Gy in 10 fractions is the first-line therapy.<sup>16</sup> However, the standard treatment has 2 limitations. First, in patients with a history of irradiation, the standard RT dose of 30 Gy in 10 fractions cannot be applied; 30 Gy in 10 fractions as second-course RT has not been proven safe in prospective clinical trials.<sup>4</sup> Second, the long-term local control rate is low. One study reported that local progression, evaluated by radiographic findings, occurred in as many as 70% of patients at 1 year after conventional postoperative RT.<sup>9</sup> With innovations in systemic therapy dramatically extending life expectancy for patients with metastatic disease, the need for safe re-irradiation and long-term local control of spinal metastases is growing.

Stereotactic body radiotherapy (SBRT) with intensity-modulated radiation therapy (IMRT) and an image guidance technique has emerged as a new treatment option for spinal metastases<sup>13</sup> and has been applied to patients following surgery.<sup>27</sup> SBRT can spare the adjacent organs at risk (OARs), while delivering high-dose radiation to the target volume. Spine SBRT, therefore, could provide safe re-irradiation and a high local control rate. The purpose of this study was to clarify the outcomes of postoperative re-irradiation using SBRT for MESCC in our institution and to identify factors correlated with local control.

## Methods

### Patients and Data Acquisition

A retrospective review of the databases of Tokyo Metropolitan Cancer and Infectious Diseases Center Komagome Hospital (Tokyo, Japan) was performed to identify patients treated with spine SBRT from April 2013 to May 2017. Patients were included if they met the following criteria: 1) MESCC diagnosed by CT or MRI; 2) the spine lesion was previously irradiated with a dose of 30 Gy in 10 fractions or a higher dose; 3) the spine lesion was treated with decompression surgery prior to SBRT; and 4) the spine lesion was treated with re-irradiation SBRT. We have conducted SBRT with an interval longer than 5 months from the latest irradiation based on the report by Sahgal et al.<sup>23</sup> Patients who had previously undergone spine SBRT to the same spinal level were excluded.

### Embolization and Surgical Procedure

Before the surgical procedure, each patient underwent preoperative angiography and embolization of segmental arteries. Selective catheterization of the corresponding and consecutive levels of segmental arteries was performed to control intraoperative bleeding.

Surgical procedures were mainly performed by the posterior approach, with decompression and fixation. Decompression of the spinal cord was accomplished by laminectomy at the level of the tumor site and curettage of the surrounding tumor. The goal of curettage was to create at least a 3-mm tumor-free space around the spinal cord. Posterior fixation was accomplished using pedicle screws, rods, and hooks. The extent of fixation was usually 2 levels above and 2 levels below the affected vertebrae (Fig. 1).

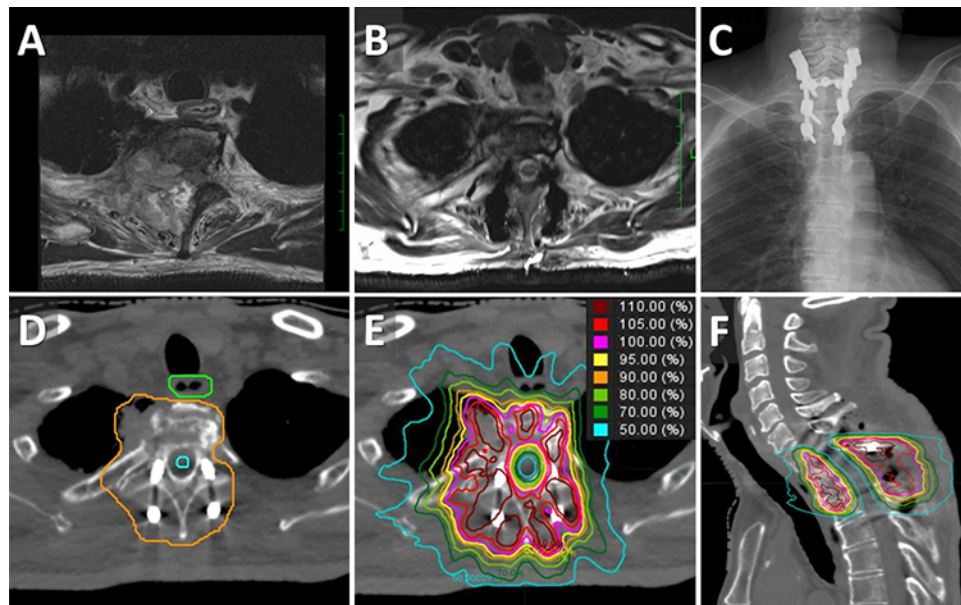
### Stereotactic Body Radiotherapy

Patients were immobilized using a full-body evacuated

cushion (CIVCO Medical Solutions) in a stable supine position. Planning CT simulation was performed with a slice thickness of 1 mm, and all patients underwent MRI for delineation of the tumor and the spinal canal. The clinical target volume (CTV) included the residual disease, the entire preoperative extent of bony epidural disease, spinal instrumentation, and the surgical incision, plus immediately adjacent bony anatomical compartments at risk of microscopic disease extension as described by contouring guidelines for postoperative spine SBRT.<sup>21</sup> (Surgical instrumentation and the incision used to be included in the CTV but no longer are.) The spinal cord and cauda equina were contoured with T2-weighted MRI. Other OARs were contoured based on simulation CT images. A 2-mm margin was added to the CTV to create the planning target volume (PTV), and a 1.5-mm margin was added to the spinal cord to create the spinal cord planning OAR volume (PRV). For the cauda equina, the thecal sac was contoured with no additional margin. The prescribed dose was 24 Gy in 2 fractions. Under the condition that the minimum dose to 95% of the PTV was greater than 70% of the prescribed dose, the delivered dose was set as high as possible to satisfy the constraints for the adjacent organs. Taking into consideration previously delivered radiation doses, dose constraints were set for the spinal cord and the cauda equina so that the maximum point dose (with point defined as 0.035 cc or less<sup>1</sup>) was less than 11.0–12.2 Gy, based on the report by Sahgal et al. (Fig. 1).<sup>23</sup> All patients received SBRT using a Vero 4-Dimensional Radiation Therapy (Vero4DRT) unit (Mitsubishi Heavy Industries, Ltd., and BrainLab AG) equipped with a 5-mm multileaf collimator, kilovoltage cone beam CT image guidance system and 6 degrees of freedom patient position corrections.

### Evaluation

The endpoints of the present study were overall survival, local control, ambulatory function, and adverse events. Local control was defined as elimination, shrinkage, or no change of the tumor according to CT or MRI obtained approximately every 3 months after the SBRT. Some factors were selected as potential predictors, and their impacts on local control were assessed with a univariate model. These factors included the degree of compression classified by the Bilsky grade,<sup>14</sup> the number of vertebral levels in the treatment target, the interval from the most recent previous irradiation to SBRT, and some prognostic scores. Recursive partitioning analysis (RPA),<sup>3</sup> the prognostic index for spinal metastases (PRISM),<sup>28</sup> the revised Tokuhashi score,<sup>28</sup> and the Rades score<sup>19</sup> were used as prognostic indices. RPA is a prognostic index for patients undergoing spine SBRT for spinal metastases. PRISM was created based on 2 prospective trials investigating SBRT for spinal metastasis. The revised Tokuhashi score is the prognostic index for determining the treatment strategy for spinal metastases reported by Tokuhashi et al. The Rades score is a prognostic index for survival after conventional RT for MESCC reported by Rades et al. Ambulatory function was evaluated on a 4-level scale: normal, walking with 1 cane, walking with a walker frame, and walking not possible. Adverse events were evaluated according to the Com-



**FIG. 1.** Images obtained in a 60-year-old man with metastatic lung cancer lesions at T1 and T2. **A:** Preoperative axial T2-weighted MR image demonstrating Bilsky grade III MESCC. **B:** Postoperative axial T2-weighted MR image demonstrating Bilsky grade Ib disease. **C:** Postoperative anteroposterior radiograph. **D:** Axial CT image with contouring for planning SBRT. **E and F:** Axial (E) and sagittal (F) CT images showing dose distribution of SBRT. Figure is available in color online only.

mon Terminology Criteria for Adverse Events (CTCAE) version 4, from the US Department of Health and Human Services (National Institutes of Health and National Cancer Institute),<sup>6</sup> and the Radiation Therapy Oncology Group (RTOG) and the European Organization for Research and Treatment of Cancer (EORTC) radiation morbidity scoring system.<sup>5</sup>

### Statistical Analysis

Overall survival was defined as the time from the start date of SBRT until death from any cause. Local control was calculated in months from the start date of SBRT to the exacerbation date for the treated vertebral segment or the last follow-up imaging study if local control was maintained; death was not included as an endpoint for local control. The overall survival and local control rates were estimated using the Kaplan-Meier method, and log-rank tests were used to evaluate correlations between local control and potential predictors of interest. Results with  $p < 0.05$  were considered statistically significant. All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University).<sup>8</sup>

## Results

### Patient Characteristics

A total of 28 patients (with 28 lesions) satisfied the eligibility criteria. Patient and tumor characteristics are summarized in Table 1. One patient had a history of radiation with a carbon-ion beam. Eight patients received intraoperative radiotherapy (IORT). At the time that these patients underwent IORT, we routinely performed it with megavolt electron beam delivery using a conventional linear accelerator for MESCC at decompression surgery. Although

a dose of 20 Gy was delivered with a posterior port, the radiation dose to the spinal cord was kept to less than 2 Gy by putting a lead plate on the spinal cord.<sup>11</sup> However, concurrent therapy with IORT and SBRT was not conducted. Twelve patients underwent decompression surgery when they were previously treated with conventional RT, and 16 patients underwent surgery at the same point in their disease process at which they had SBRT. For these 16 patients, the median time from surgery to SBRT was 4 weeks (range 2–8 weeks).

### Clinical Outcomes

The median duration of follow-up after spine SBRT was 13 months (range 4–38 months). Sixteen patients (57%) died at a median of 11.5 months (range 4–38 months) from the time of spine SBRT, and all 16 patients died of systemic disease progression. The overall survival rate at 1 year was 63% (Fig. 2). The local control rate at 1 year was 70% (Fig. 3A). The best tumor responses were tumor shrinkage in 7 cases (25%), stable disease in 16 cases (57%), and tumor progression in 4 cases (14%). Information on tumor response was not available in 1 case. Tumor elimination was not seen in any of the cases in this series. Seven patients had experienced local progression by their last follow-up, and in the 5 of these patients for whom systemic imaging follow-up was available, exacerbation or emergence of metastatic lesions in other organs was confirmed at the time of occurrence of spine local failure. Table 2 shows the results of univariate analyses of factors predicting local treatment failure. Bilsky grade, the number of vertebral levels in the treatment target, interval from the latest RT to SBRT, the timing of decompression surgery at the last RT or SBRT, RPA, PRISM, and the revised Tokuhashi score were not significantly correlated with local

**TABLE 1. Summary of clinical and demographic characteristics of the 28 patients in this study**

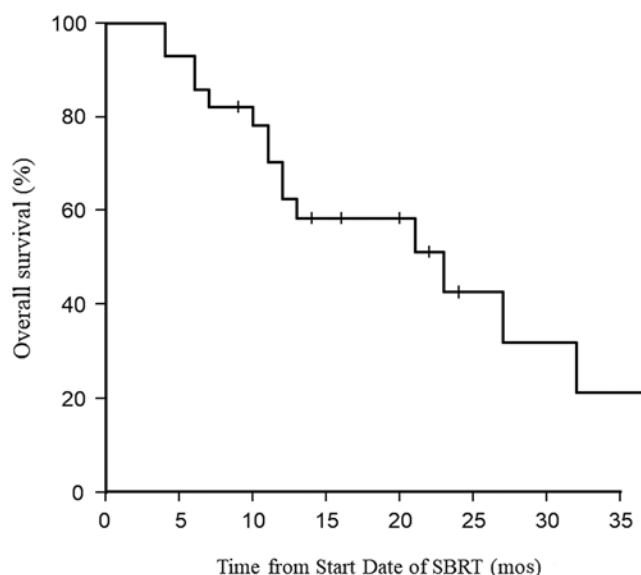
Characteristic	Value
Sex	
Male	18
Female	10
Age in yrs	
Median	62
Range	33–80
ECOG PS	
0–1	19
2	7
3	2
4	0
Lesion histopathology	
Thyroid	7
Lung	6
Renal cell	3
Colorectal	3
Other	9
Levels treated*	
Cervical	6
Thoracic	22
Lumbar	4
Systemic disease	
Controlled	8
Active	20
RT history†	
30 Gy/10 fr	15
20 Gy/1 fr (IORT)	8
40 Gy/20 fr	3
35 Gy/14 fr	3
Other	6
Interval btwn latest RT & SBRT in mos	
Median	16
Range	5–132
Surgical decompression	
At previous RT	12
At SBRT	16
Bilsky grade at SBRT	
0 or Ia (no compression)	
0	0
Ia	0
Ib or Ic (dural compression)	
Ib	12
Ic	3
II/III (cord compression)	
II	7
III	6

ECOG PS = Eastern Cooperative Oncology Group performance status; fr = fraction(s).

Values are numbers of patients unless otherwise indicated.

\* Four patients had lesions that involved more than 1 spinal region.

† Seven patients had previously undergone 2 courses of RT.

**FIG. 2.** Kaplan-Meier curve for overall survival after spine SBRT.

control. Classified by the Rades prognostic score, patients in the favorable group had significantly better local control than those in the unfavorable group (1-year local control rate: 100% vs 33%;  $p < 0.01$ ) (Fig. 3B).

Figure 4 shows the number of patients with normal to difficult walking. Comparing ambulatory function between pretreatment and 1 year after SBRT, improvement was seen in 4 cases, no change in 11, and worsening in 5.

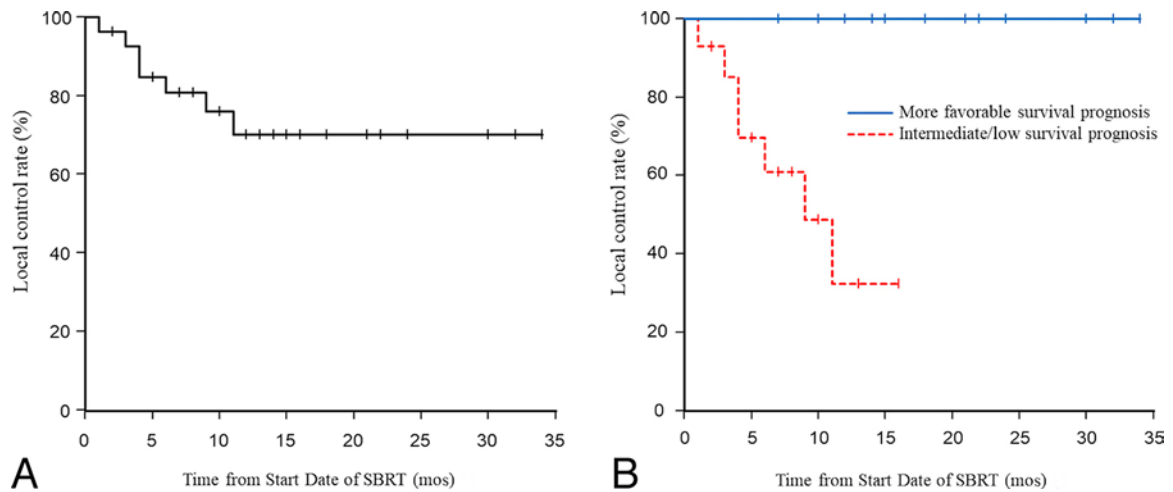
Radiation-induced myelopathy and vertebral compression fractures were observed in 1 and 3 patients, respectively. No other grade 3 or greater toxicities were encountered. The patient with radiation-induced myelopathy had treatment to T10–12 metastases with a carbon-ion beam of 70.4 GyE, with GyE defined as the physical dose multiplied by the relative biological effectiveness of carbon ions,<sup>7</sup> in 16 fractions. Seven years after carbon-ion RT, decompression surgery and SBRT were performed at the same spinal levels. Thirty months following SBRT, the patient developed complete paraplegia, with MRI showing no tumor progression.

## Discussion

The outcomes of spine SBRT as postoperative re-irradiation for MESCC were investigated. Favorable survival prognosis based on the Rades score was significantly correlated with good local control.

First-line treatment for spinal cord compression caused by metastatic cancer is surgery followed by conventional radiotherapy of 30 Gy in 10 fractions. However, this treatment has 2 limitations: the safety of conventional re-irradiation using 30 Gy in 10 fractions is unknown; and the long-term local control rate is low. Spine SBRT has the possibility to overcome these limitations of the standard treatment, since SBRT can create a steep dose gradient surrounding the spinal cord, while delivering ablative doses of radiation to the tumor. Some papers on postoperative SBRT have been published, and a systematic review





**FIG. 3.** Kaplan-Meier curve for local control after spine SBRT for the overall group (A) and stratified by Rades score (B). Figure is available in color online only.

article reported that the crude local control rate at the time of last follow-up was 88.6% in a sample of 426 patients.<sup>20</sup> This is similar what has been reported for re-irradiation SBRT without surgery. A systematic review article re-

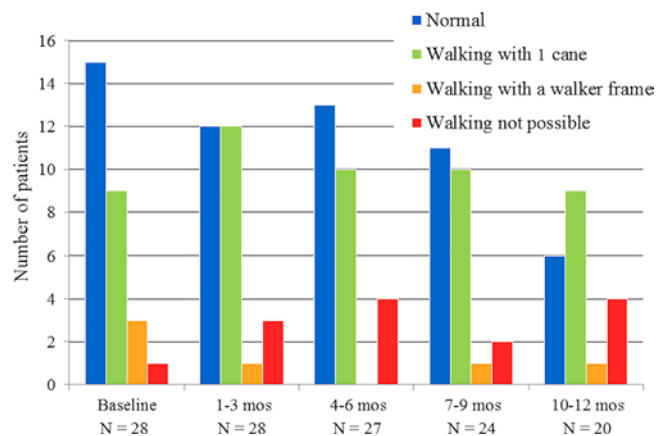
ported that spine SBRT as re-irradiation achieved a 1-year local control rate of 76%.<sup>15</sup> However, there have been no reports that were limited to patients with both elements of re-irradiation SBRT and SBRT after surgical decompression, although there are some reports that include such cases.<sup>2,12,27</sup> The results of the present study suggest that postoperative spine SBRT for MESCC as re-irradiation was effective, with local control seen on imaging and a clinically acceptable safety profile.

**TABLE 2. Univariate analysis for local control**

Variable	No. of Patients	LC Rate* at 1 Year (%)	p Value
Bilsky grade			0.09
Ib or Ic (dural compression)	15	86	
II or III (cord compression)	13	49	
No. of levels			0.32
1 or 2	13	83	
3 or more	15	61	
Interval btwn latest RT & SBRT			0.80
>12 mos	18	65	
≤12 mos	10	79	
Surgical decompression			0.66
At previous RT	12	67	
At SBRT	16	69	
RPA			0.39
Group 1	15	78	
Groups 2 & 3	13	61	
PRISM			0.52
Groups 1 & 2	15	76	
Groups 3 & 4	13	63	
Revised Tokuhashi score			0.08
Intermediate/high	18	79	
Low	10	53	
Rades score			<0.01
More favorable survival prognosis	13	100	
Intermediate/poor survival prognosis	15	33	

LC = local control.  
 \* Local control rates were calculated according to the Kaplan-Meier method, and comparisons between groups were performed using log-rank tests.

All 5 patients with local failure who had adequate imaging studies for analysis showed exacerbations or emergence of other organ lesions at the time of local failure (adequate imaging studies were not available in the other 2 cases of local failure). The 1-year survival rate in the local failure group was significantly inferior to that in the locally controlled group (43% vs 73%,  $p = 0.02$ ). In other words, the presence or absence of local failure might depend on



**FIG. 4.** Number of patients who could walk normally, with 1 cane, with a walker frame, or who had difficulty walking, before (baseline) and after SBRT (time measured from start of SBRT). Figure is available in color online only.

the progress of systemic disease, and there could be a correlation between local control and the reported prognostic indices predicting the progress of systemic disease. In the present study, the correlations of 4 prognostic indices with local control were evaluated, and the Rades score showed significant correlations with local control.

One of the most important issues in the spine SBRT setting is the correct selection of patient candidates. Compared to conventional RT, spine SBRT requires greater planning time, additional personnel involvement, and considerable technical investment. Moreover, SBRT carries additional risks compared to conventional RT, including the potential for vertebral compression fractures, myelopathy, or radiculopathy.<sup>22,24,25</sup> Therefore, it is necessary to identify which patients may benefit most from spine SBRT. The present study provides useful information for selecting eligible cases.

Among the 4 prognostic indices analyzed, the Rades score was found to be correlated with local control, and the revised Tokuhashi score also showed a strong trend toward correlation with local control. The difference between these 2 scores and the others might be due to factors that are only included in the Rades score and the revised Tokuhashi score—specifically, “type of primary tumor” and “ambulatory status before RT.” However, the bias of the above factors was not identified from the individual data, and the definitive risk factor for local control could not be identified.

The limitation of the current study is that it focused primarily on local control among many endpoints. The primary endpoint should be quality of life or ambulatory function, since this treatment is classified as palliative therapy. However, the focus was primarily on local control, and univariate analysis was performed to identify factors related to local control. Quality of life was not selected as an endpoint because it was not measured in our daily clinical practice. Regarding ambulatory function, it was difficult to evaluate the efficacy of spine SBRT because difficulty walking due to worsening of the general condition or MESCC of other level spine lesions was included. As a result, local control was adopted as a surrogate primary endpoint for ambulatory function.

The patients included in the present study had the 2 elements of re-irradiation SBRT and surgical decompression followed by SBRT. Prospective clinical trials to prove the safety and efficacy of spine SBRT in each setting are required. Spine SBRT, exhibiting strong local control, should be used especially for patients with MESCC, and high-level evidence is needed for it to be widely adopted in practice. In addition, although re-irradiation SBRT is being widely adopted in practice with the dose constraints of the spinal cord reported from a retrospective study,<sup>23</sup> it is also necessary to evaluate the outcomes by clinical trials. Based on the present results, we suggest that the Rades score should be included as an eligibility criterion in future clinical trials.

## Conclusions

The 1-year local control rate of postoperative re-irradiation using SBRT for MESCC was 70%. Postoperative

re-irradiation SBRT appeared effective for patients with a good survival prognosis, and the Rades score seemed useful for patient selection.

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### Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

### Author Contributions

Conception and design: Ito. Acquisition of data: Ito, Ogawa. Analysis and interpretation of data: all authors. Drafting the article: Ito. Critically revising the article: Nihei, Shimizuguchi. Reviewed submitted version of manuscript: all authors. Study supervision: Nihei.

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