Clinical & Experimental Metastasis (2026) 43:14
https://doi.org/10.1007/s10585-026-10398-x

RESEARCH PAPER

Clinical utility of the ESTRO–EORTC classification in oligometastatic disease treated with stereotactic body radiotherapy: a single-institution retrospective study

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Received: 2 July 2025 / Accepted: 9 February 2026

Abstract

This study aimed to classify patients who underwent stereotactic body radiotherapy (SBRT) for oligometastatic disease (OMD) at our institution using the consensus classification proposed by the European Society for Radiotherapy and Oncology and the European Organization for Research and Treatment of Cancer (ESTRO–EORTC) and to evaluate clinical outcomes based on this classification. Patients diagnosed with extracranial OMD who underwent SBRT, regardless of the primary tumour site, between April 2020 and December 2022 were retrospectively analysed. Based on the ESTRO–EORTC classification, cases were categorised into three OMD states: de novo, repeat, and induced OMD. We assessed overall survival (OS), local recurrence (LR) rates, and treatment-related adverse events (AEs). A total of 60 patients with 70 lesions were included, with a median follow-up of 24 months. All lesions were successfully classified according to the ESTRO–EORTC classification: 37 as de novo, 20 as repeat, and 13 as induced OMD. SBRT was delivered using the CyberKnife® system, with a median dose of 35 Gy in five fractions. The median OS for all patients was 71 months. The 1- and 2-year LR rates were 7.6% and 12%, respectively. Among OMD states, induced OMD had the poorest OS (median: 41 months), compared with de novo OMD (not reached) and repeat OMD (71 months). Only one Grade ≥3 AE was observed. All SBRT-treated OMD cases at our institution were successfully classified using the ESTRO–EORTC system. The classification showed potential prognostic value, suggesting its utility for stratifying patients with OMD.

Keywords Oligometastatic disease · Stereotactic body radiotherapy · Metastasis-directed radiotherapy

Introduction

The concept of oligometastasis was first proposed by Hellman and Weichselbaum, characterised by limited metastatic progression, despite the presence of distant lesions. It was initially suggested that such cases could potentially be cured through metastasis-directed treatments, such as radiotherapy and surgery [1]. Since then, numerous studies have evaluated treatment outcomes of oligometastatic disease (OMD) across various cancer types and examined how disease characteristics influence prognosis [2–6]. However, determining the true efficacy of local therapies remains challenging, as the definition of OMD encompasses a range of metastatic conditions, inevitably introducing clinical heterogeneity.

To address this issue, a working group from the European Society for Radiotherapy and Oncology (ESTRO) and European Organization for Research and Treatment of Cancer (EORTC), as part of the OligoCare project, recently developed an expert consensus classification system (ESTRO–EORTC classification) based on a systematic review of the literature on oligometastases [7]. This system highlights the necessity of appropriate imaging modalities such as positron

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Published online: 20 February 2026

emission tomography/computed tomography (PET/CT) for the clinical diagnosis of OMD. It classifies OMD into three main states—de novo, repeat, and induced—and further subdivides them into nine categories based on responses to a set of diagnostic questions and additional factors such as the presence or absence of systemic therapy. Recent studies have reported the clinical utility of this classification system and its association with patient outcomes [8, 9].

In Japan, the National Health Insurance System approved coverage of stereotactic body radiation therapy (SBRT) for up to five oligometastatic lesions in 2020. Nevertheless, systemic therapy remains the standard of care for malignant tumours with distant metastases, and the optimal indications and timing for SBRT in OMD are still not well established. Furthermore, in routine practice, various factors, such as prior treatments, number and size of lesions, and anatomical relationships between target lesions and surrounding organs at risk, affect both decision-making and outcomes of SBRT. Although not yet routinely adopted in Japan, the ESTRO–EORTC classification may help standardise criteria for identifying patients most likely to benefit from metastasis-directed SBRT.

In this study, we retrospectively analysed treatment details and clinical outcomes of patients diagnosed with OMD and treated with SBRT at our institution. We also evaluated the clinical applicability of the ESTRO–EORTC classification in routine practice.

Patients and methods

Disease definition and classification

This retrospective, single-institution study analysed patients with oligometastases from solid organ malignancies, regardless of histology, who were treated with SBRT between April 2020 and December 2022 at the Japanese Red Cross Medical Center. According to the ESTRO–ASTRO consensus [10], OMD was defined as the presence of a maximum of five metastases across less than two organs, excluding lesions spreading through pleural effusion, ascites or cerebrospinal fluid, which are not suitable for metastasis-directed radiotherapy (MDRT). Patients with brain metastasis were excluded from this analysis.

OMD was evaluated by two radiation oncologists based on pre-SBRT examinations, including brain magnetic resonance imaging (MRI); CT of the neck, chest, abdomen, and pelvis; PET/CT; or bone scintigraphy if PET/CT was not performed. Lesions were classified into three OMD states according to the ESTRO–EORTC classification: de novo OMD (first-time diagnosis), repeat OMD (following a prior history of OMD), and induced OMD (following prior polymetastatic disease) [7].

SBRT procedure

SBRT was delivered using the CyberKnife® M6 system (Accuray Japan K.K., Tokyo), with treatment planning and dose calculation performed using Accuray Precision® Ver. 3.3.1.3. The gross tumour volume (GTV) was delineated on plane CT images with 1-mm slices, supported by image fusion with other modalities (e.g. PET/CT) for accurate contouring of the tumour. The clinical target volume (CTV), where applicable, was determined based on tumour infiltration and location. In cases with tumour respiratory movement exceeding 10 mm requiring motion-tracking, the internal target volume (ITV) was determined using four-dimensional CT or CT images acquired during maximum inspiration, maximum expiration, and free-breathing. Finally, the planning target volume (PTV) was determined with a margin of 4–8 mm from the CTV or ITV. The Synchrony® Fiducial Tracking™ with Respiratory Modeling™ was used in cases that requiring tumour tracking, using fiducial markers placed in or near the tumour to synchronise beam delivery with respiratory motion. Otherwise, the Synchrony® Spine Tracking Supine™, which uses the bony anatomy of the spine for localisation, was used for guidance. Doses and organ-at-risk (OAR) constraints were primarily based on a phase II trial protocol from Canada [11]. The prescribed dose covered 95% of PTV, with the isodose line adjusted to 70–80% of the maximum dose. PTV coverage was reduced as needed to meet OAR constraints. The use of systemic therapy was decided based on consensus recommendations by the EORTC–ESTRO OligoCare consortium [12].

Outcomes and statistical analysis

The primary endpoint of the analysis was overall survival (OS), measured from the time of OMD lesion diagnosis. The patients receiving multiple SBRT courses at different time points, the first treated OMD lesion was used as the reference. Secondary endpoints included the cumulative incidence of local recurrence (LR) and adverse events (AEs) evaluated per treated lesion. LR was defined as recurrence within the PTV and was measured from the initiation of SBRT. AEs were evaluated according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. OS was calculated using the Kaplan–Meier method. Log-rank tests were used to assess the differences in OS among the three major oligometastatic states. The cumulative incidence of LR was calculated using Gray's test, with death as the competing risk. Statistical significance was defined

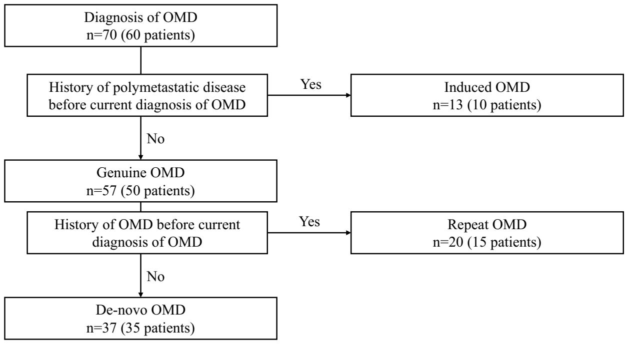

Fig. 1 Classification flowchart of the patients with oligometastatic disease (OMD) patients analysed in this study, based on the ESTRO–EORTC classification. A total of 70 lesions (60 patients) were classified based on the presence or absence of a history of polymetastatic disease and/or prior OMD before the current diagnosis. Cases were classified into 'De-novo OMD' (37 lesions, 35 patients), 'Repeat OMD' (20 lesions, 15 patients) and 'Induced OMD' (13 lesions, 10 patients) OMD states

as $p < 0.05$. All analyses were performed using EZR [13], a free software based on R Commander.

Ethics statement

This study was approved by the Ethical Committee for Clinical Studies, Japanese Red Cross Medical Center (No. 1519; 21 June 2023).

Results

A total of 60 patients who underwent 70 SBRT treatments were eligible and included in this study. The classification process for eligible cases and baseline characteristics is summarised in Fig. 1 and Table 1. The median age was 70 years. The most common primary tumour histologies were head and neck (21%), and colorectal (21%) followed by lung (14%), liver (13%), breast (6%), and prostate (4%). The most frequently treated lesion site was the lymph nodes (60%), followed by the lung (19%), and bone (10%). Forty-eight lesions (69%) were diagnosed as OMD under systemic therapy. Most patients (83%) had a single metastatic lesion treated with metastasis-directed radiotherapy (MDRT). The median prescribed dose was 35 Gy (range: 24–60 Gy) in five fractions (range: 3–10 fractions), with the most frequent prescription being 35 Gy in five fractions for 23 targets (33%). All treated OMDs were successfully classified into three major OMD states using ESTRO–EORTC classification: 37 lesions (52%) were de-novo OMD, 20 (29%) were repeat OMD, and 13 (19%) were induced OMD. Further subclassification into nine OMD states was conducted, with results summarised in Online Resource 1.

Table 1 Baseline characteristics of oligometastatic lesions treated with stereotactic body radiotherapy

		n (%)	De-novo OMD	Repeat OMD	Induced OMD
Total lesion		70	37	20	13
Age	Median (Range)	70 (43–94)			
Primary tumor histology	Lung	10 (14%)	1	3	6
	Colorectal	15 (21%)	1	11	3
	Breast	4 (6%)	4	0	0
	Prostate	3 (4%)	3	0	0
	Head and neck	15 (21%)	12	1	2
	Liver	9 (13%)	5	1	0
	Others	14 (20%)	8	4	2
Treated lesion	Lymph node	42 (60%)	22	13	7
	Bone	7 (10%)	6	1	0
	Lung	13 (19%)	8	4	1
	Adrenalgrand	5 (7%)	1	1	3
	Others	3 (4.3%)	0	1	2
number of lesions	1	58 (83%)	33	14	11
	2	6 (9%)	2	3	1
	3	0 (0%)	0	0	0
OMD diagnosis under systemic therapy	Yes	48 (69%)			
	No	22 (31%)			
Dose	Median (Range)	35 Gy (24–60 Gy)			
fraction	Median (Range)	5 fr (3–10 fr)			

OMD, Oligometastatic disease

The median follow-up period from the initial diagnosis of OMD was 24 months (range: 0–50), and the median OS was 71 months (95% confidence interval [CI]: 41–not reached [NR]). The 1- and 2-year OS rates were 94% (95% *CI* 82–98) and 86% (95% *CI* 72–94), respectively. Kaplan–Meier curves for OS of all patients and each OMD state are shown in Fig. 2. Patients with induced OMD had a shorter median OS (41 months, 95% *CI* 3–NR) compared to de-novo OMD (NR, 95% *CI* 31–NR) and repeat OMD (71 months, 95% *CI* 33–NR), but these trends were not statistically significant ($p = 0.50$).

During the follow-up period, LR was observed in six patients. Cumulative incidence curves for LR across all

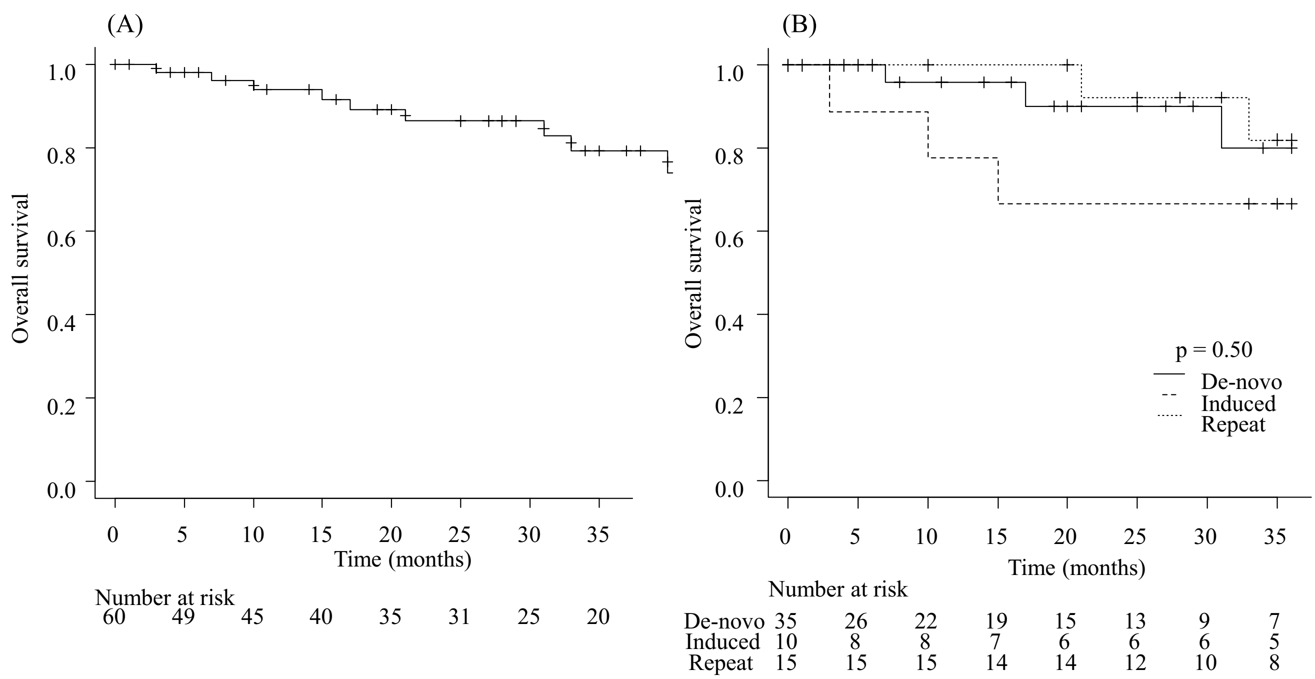

Fig. 2 Kaplan–Meier curves showing (**a**) Overall survival (OS) for all patients and (**b**) OS for each oligometastatic disease (OMD) states. In Fig. 2B, the solid line indicates de-novo OMD; the dashed line, induced OMD; and the dotted line, repeat OMD

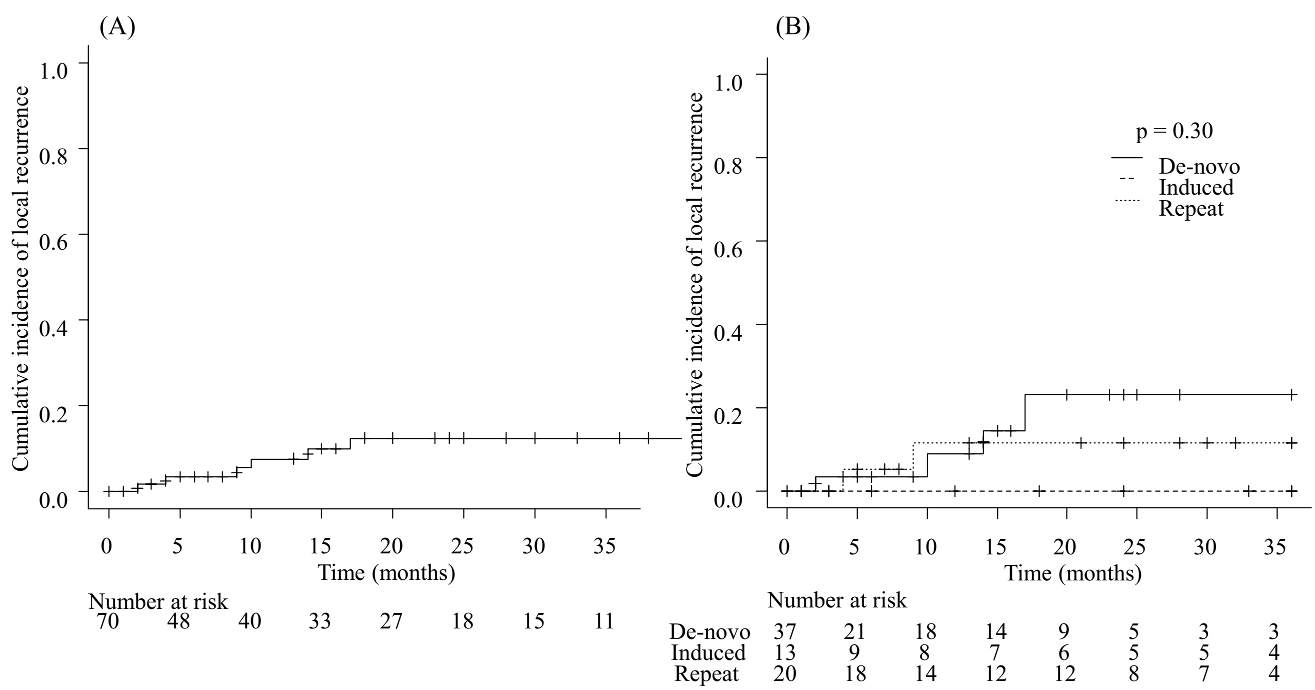

Fig. 3 Cumulative incidence curves of (**a**) local recurrence (LR) in all oligometastatic disease (OMD) lesions and (**b**) LR according to OMD state. In Fig. 3B, the solid line indicates de-novo OMD; the dashed line, induced OMD; and the dotted line, repeat OMD

targeted lesions and for each OMD state are shown in Fig. 3. The cumulative incidence of LR at 1 and 2 years for all 70 lesions was 7.6% (95% *CI* 2.4–17) and 12% (95% *CI* 4.9–24), respectively. No significant differences in LR were observed between the OMD states ($p=0.30$). Two patients (two lesions) with LR received salvage therapies. The first case involved repeat OMD of a bone lesion from duodenal papillary cancer, treated with 27 Gy in three fractions. LR was diagnosed with systemic therapy three years after SBRT and managed with re-irradiation using proton beam radiotherapy. The second case was a de novo OMD lung lesion from gastric cancer, treated with 48 Gy delivered in four fractions. LR was diagnosed 10 months later and was subsequently managed by surgical resection. Both patients were alive at the time of final follow-up. No significant association was observed between primary tumour histology and LR (data not shown).

The most common AE following SBRT was Grade 1 radiation pneumonitis (n=8, 11%), followed by Grade 1 dermatitis (n=5, 7%), and pain (n=1, 1%). Only one patient experienced a Grade ≥2 AE. This case, classified as Grade 3 adrenal insufficiency, occurred on day 3 during SBRT of the right adrenal gland and manifested as hypoglycaemia, which was treated with intravenous glucose and corticosteroids. Given the patient's history of left adrenalectomy and adrenal insufficiency, this AE was more likely attributable to relative adrenal insufficiency rather than to acute toxicity from RT.

Discussion

Since the concept of oligometastasis was introduced by Hellman and Weichselbaum [1], several studies have reported the effectiveness of MDRT for oligometastases, particularly its contribution to improving not only PFS but also OS in patients with OMD [2–6, 14–18]. More recently, ESTRO and EORTC developed a comprehensive classification system and nomenclature for OMD [7]. Willmann et al. evaluated clinical outcomes following SBRT for 542 lesions in 385 patients with 1–5 extracranial metastases, using the ESTRO–EORTC classification [8]. Lung cancer was the most common primary tumour (134 cases, 34.8%), and in the majority of patients (348 cases, 90.4%), only one or two metastatic lesions were present. Although their study was a retrospective single-institution study, they were able to classify all cases using the ESTRO–EORTC classification, demonstrating its feasibility and clinical applicability. Similarly, in our study, all patients were successfully categorised using the ESTRO–EORTC classification. Our findings are consistent with those of Willmann et al. and support the reproducibility and clinical applicability of this system for consistent and standardised categorisation of OMD.

Regarding its prognostic value, Willman et al. reported that induced OMD, characterised by a history of polymetastatic disease, had a significantly shorter OS among 385 patients with various primary tumour histologies [8]. Similarly, Chen et al. found that induced oligoprogressive disease was associated with a shorter OS in patients with non-small cell lung cancer (NSCLC) treated with definitive radiotherapy [19]. Our results similarly demonstrated shorter OS in patients with induced OMD compared to those with de novo or repeat OMD, although the difference did not reach statistical significance (Fig. 2b). While our study did not evaluate OMD subclassification into nine states, several studies have indicated the poor prognostic impact of oligoprogression, a condition in which OMD lesions progress during active systemic therapy [9, 19, 20]. Baker et al. validated the prognostic utility of the ESTRO–EORTC classification in a prospective cohort of 381 patients in the SABR-5 trial, finding that oligoprogression was associated with shorter OS (HR, 2.05; $P=0.004$) [9]. These findings suggest that oligoprogression may reflect resistance to systemic therapy and a more aggressive tumour biology, conditions in which metastasis-directed therapy may be limited. Overall, this evidence reinforces the importance of the ESTRO–EORTC classification for prognostic evaluation and guiding treatment decisions.

In terms of local control, SBRT, with its high precision and ablative-dose prescription, plays an essential role in metastasis-directed therapy alongside surgery. In our cohort, the 1- and 2-year LR rates of 7.6% and 12%, respectively, are consistent with previous studies, confirming the effectiveness of SBRT in achieving high local control, even in real-world clinical settings [20–22]. For instance, Poon et al. reported a 13.8% rate of local failure within the SBRT field at first progression, based on an international retrospective analysis of 1033 patients with oligometastasis treated with SBRT [21]. Despite these favourable outcomes, careful management of LRs is required. In the present study, six patients experienced local failure, with two undergoing salvage treatment using re-irradiation with proton beam therapy and surgery. These cases underscore the need to consider focal treatment options, including re-irradiation, in the management of post-SBRT LRs.

Safe delivery of SBRT is essential for maximising overall oncological outcomes in the management of OMD, which requires a multidisciplinary approach incorporating both systemic and metastasis-directed therapy. In this study, we observed minimal severe AEs and manageable mild toxicities such as Grade 1 pneumonitis. A key strategy in minimising SBRT-related toxicity is prioritising OAR dose constraints over planning target volume (PTV) coverage. This approach was supported by Cereno et al. in a secondary analysis of the SABR-5 trial [23], where the relationship between the planned and delivered PTV dose was evaluated using the coverage compromise index (CCI). The mean CCI across all patients was 0.88. Lesions with a CCI < 0.90, indicating under-coverage, comprised 196 lesions (36%), but comparison with those having a CCI ≥ 0.90 revealed no significant differences in LR or progression-free survival (PFS). Based on these findings, we prioritise OAR dose constraints over full PTV coverage in routine practice. Furthermore, adherence to the consensus recommendations of the EORTC–ESTRO Oligo Care Consortium is crucial, particularly when SBRT is combined with targeted therapies or immune checkpoint inhibitors. [12]. The consensus, based on systematic literature review and expert opinion, strongly recommends avoiding concurrent administration of anti-vascular endothelial growth factor antibodies and multi-kinase inhibitors (e.g. sunitinib, sorafenib) during SBRT. At our institute, we ensure an interval of ≥ 1–2 weeks between administration of these drugs and the delivery of SBRT.

This study has several limitations. First, its retrospective nature introduced a strong selection bias. The analysis was limited to patients who underwent SBRT rather than the entire OMD population, restricting the generalisability of the findings. Second, treatment decisions and optimisations were based on the discussion of radiation oncologists, potentially leading to variability in treatment approaches. Third, because of the small sample size, this study could not analyse differences across all nine OMD subclassification states. Finally, the assessment of AEs relied on medical records, which may have led to an underestimation of toxicities. To overcome these limitations, prospective studies are needed. Randomised phase 3 studies, such as SABR-COMET-3 (1–3 OMD of multiple histologies) (Clinicaltrials.gov identifier: NCT03862911) and SABR-COMET-10 (4–10 OMD of multiple histologies) (Clinicaltrials.gov identifier: NCT03721341), are currently ongoing [24, 25]. In Japan, organ-specific studies such as JCOG2108 (NSCLC postoperative metachronous oligorecurrence) and JCOG2110 (breast cancer with 1–3 oligometastases) are also in progress. These studies are expected to provide further evidence of the efficacy and safety of SBRT in the management of OMD.

In this single-institution retrospective analysis of SBRT for OMD, all treated lesions were successfully classified using to the ESTRO–EORTC system. Induced OMD showed a trend toward shorter OS, supporting the utility and reproducibility of the classification in clinical practice. The median OS for patients treated with SBRT was 71 months, with a 1-year LR rate of 7.6%, and no severe SBRT-related toxicities were observed. These findings suggest that SBRT is an effective and safe treatment option for selected patients with OMD.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10585-026-10398-x.

Acknowledgements This study was supported by the University of Tsukuba's institutional funds. We would like to thank the staff involved in cancer care at the Japanese Red Cross Medical Center for their general support of this study.

Author contributions Masaaki Goto and Tetsuo Nonaka contributed to the study conception and design. Material preparation, data collection and analysis were performed by Masaaki Goto, Tetsuo Nonaka, Daiki Maruyama, Genki Ishii, Masatoshi Nakamura and Keiichiro Baba. The first draft of the manuscript was written by Masaaki Goto and Tetsuo Nonaka and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding This study was supported by the University of Tsukuba's institutional funds.

Data availability The data are not publicly available to preserve individuals' privacy.

Declarations

Conflict of interests Hideyuki Sakurai has the following conflicts of interest: serves as an outside director of B dot Medical Inc. and is engaged in collaborative research with Hitachi High-Tech Corporation. All other authors declare no conflicts of interest.

Ethics approval This study was approved by the Ethical Committee for Clinical Studies, Japanese Red Cross Medical Center (No. 1519; 21 June 2023).

Consent to participate This retrospective study used an opt-out approach, and information regarding the study was disclosed on the institutional website. The requirement for written informed consent was waived by the institutional review board.

Consent for publication This study does not contain any individual person's data in any form (including individual details, images or videos), and therefore consent to publish was not required.

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