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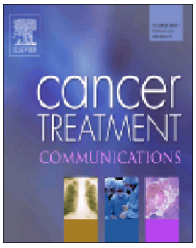

Oligometastases: Defined by prognosis and evaluated by cure

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Abstract
Recently, the state of oligometastases has been spotlighted in the treatment strategy for metastases. Aggressive local treatment for oligometastases, including pulmonary resection, stereotactic body radiotherapy (SBRT), radiofrequency ablation, and cryoablation has been the subject of research. Among studies on the local treatment, those on SBRT more often evaluated local control as the primary outcome, and those on pulmonary metastasectomy more often evaluated overall survival as the primary outcome. Oligometastases is a disease concept that is defined by a state of limited systemic metastatic tumors for which local ablative therapy could be curative. By definition, the purpose of local treatment for oligometastases is cure, and the primary outcome to be analyzed should be disease-free survival. As systemic adjuvant therapy in addition to local treatment with complete ablation has some effect on micrometastases, in clinical research on oligometastases, the only treatment modality under evaluation should be local ablation. There are multiple discrete indications for the local treatment of metastatic lesions. The purposes of these indications are (a) the intent to cure oligometastases, (b) the intent to prolong survival as a part of multidisciplinary therapy, and (c) local control for palliative care. In order to appropriately evaluate the significance of local treatment, the outcomes should depend on the indication for treatment. The corresponding outcomes to consider are (a) disease-free survival, (b) overall survival, and (c) local control. Factorial analysis of each outcome corresponding to each indication for local therapy would yield information on each clinical presentation to help decide treatment.

1. Introduction

In general, metastatic malignancies are associated with a poor prognosis, and systemic chemotherapy and molecular targeted therapy are the standards of treatment [1–4]. With the exception of histologic types that are very sensitive to chemotherapy, most solid tumors in the metastatic state are rarely curative and those patients ultimately die of their

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disease. Recently, the state of oligometastases has been spotlighted in the treatment strategy for metastases [5-7]. Aggressive local treatment for oligometastases, including pulmonary resection, stereotactic body radiotherapy (SBRT), radiofrequency ablation [8], and cryoablation [9]—either alone or combined with systemic chemotherapy—has been the subject of research [6,7].

Currently, SBRT is indicated in patients who are considered nonsurgical candidates; however, the administration of SBRT has rapidly become a widely adopted treatment modality [7,10]. SBRT results in minimal morbidity and provides high local control rates for medically inoperable stage I non-small cell lung cancer [11]. Several studies have evaluated SBRT for pulmonary metastases, for example from colorectal cancer [12]. Table 1 shows recent representative studies of local treatment for colorectal cancer. In deciding local treatment, oligometastases is more often considered an indication for SBRT than pulmonary metastasectomy. Recent SBRT research commonly refers to oligometastases in the discussion of treatment indications [7]. More recently, the state of oligometastases has been discussed in pulmonary metastasectomy [6,13].

Despite an increasing interest in oligometastases, the definition of the term "oligometastases" can be very confusing because it has been dependent on the particular research. Many researchers have defined oligometastases as metastases that are limited in both number (typically, less than 5) and location. Another confusing issue is outcome evaluation; researchers have evaluated the outcome of oligometastases by overall survival or local control. In previous reports of local treatment for colorectal cancer, regardless of whether the indication for treatment was oligometastases, reports on SBRT more often evaluated local control as the primary outcome, and reports on pulmonary metastasectomy more often evaluated overall survival as the primary outcome (Table 1). Due to the confusing definitions, treatment indications, and outcome evaluation for oligometastases, improper discussions and conclusions result when attempting to link published evidence to clinical practice. Here, we review oligometastases and other indications for local treatment, and we discuss adequate outcome measures for future trials.

2. Original concept of oligometastases

Hellman and Weichselbaum originally proposed the state of oligometastases in 1995 based on a consideration of the multistep nature of cancer progression [5]. They proposed the existence of an oligometastatic state that was an "intermediate between purely localized lesions and those widely metastatic" [5]. The state was expounded to be "amenable to a curative therapeutic strategy" and "amenable to localized therapy" [5]. This concept is very attractive and realistic; in actual clinical practice, when clinicians decide to perform local treatment such as pulmonary resection for metastatic tumors, they presume curability to some extent. Many recent studies of local ablation for metastatic malignancies actually refer to the concept of the oligometastatic state in their discussions [6,7,13]. As some

Table 1 Recently published studies of local treatment and outcomes for metastatic colorectal cancer.

Author, year	Study design	Treatment indication	Treatment (no. of cases)[a]	Outcome evaluated
Inoue, 2013 [32]	Retro	Not described	SBRT (37/87 patients)	OS, LC
Widder, 2013 [33]	Retro	Oligometastases	Metastasectomy (68) SBRT (31/42 patients)	Primary: OS Secondary: PFS, LC
Duncker-Rohr, 2013 [34]	Retro	$\leq$ 5 cm diameter	SBRT (8/39 patients)	LC, OS
Takeda, 2011 [35]	Retro	Oligometastases	SBRT (15/34 patients)	LC
Kim, 2009 [36]	Retro	Isolated metastases	SBRT (13 patients)	OS, LC, PFS
Rusthoven, 2009 [37]	Pros (phase I/II)	1-3 metastases and $<$7 cm	SBRT (9/38 patients)	LC, OS
McCammon, 2009 [38]	Retro	Not described	SBRT (?/165 lesions)	LC
Norihisa, 2008 [39]	Retro	Oligometastases	SBRT (9/34 patients)	OS, LC, PFS
Milano, 2008 [40]	Retro	Oligometastases (5 or fewer)	SBRT (?/103 lesions)	LC
Renaud, 2014 [41]	Retro	Traditional criteria	Metastasectomy (320)	OS
Embun, 2013 [42]	Retro	Not described	Metastasectomy (543)	Not shown
Iida, 2013 [43]	Retro	Not described	Metastasectomy (1030)	OS
Treasure, 2012 [44]	Pros	Traditional criteria	Metastasectomy	Not shown
Blackmon, 2012 [45]	Retro	Not described	Metastasectomy (229)	OS, RFS
Chao, 2012 [46]	Retro	Not described	Metastasectomy (143)	OS, recurrence rate
Hamaji, 2012 [47]	Retro	Not described	Metastasectomy (518)	OS
Borasio, 2011 [48]	Retro	Traditional criteria	Metastasectomy (137)	OS
Riquet, 2010 [49]	Retro	Traditional criteria	Metastasectomy (127)	OS
Hwang, 2010 [50]	Retro	Traditional criteria	Metastasectomy (125)	OS, LC
Onaitis, 2009 [30]	Retro	Not described	Metastasectomy (378)	OS, RFS
Watanabe, 2009 [51]	Retro	Traditional criteria	Metastasectomy (113)	OS, LC

Traditional criteria: representative term for criteria proposed in the era from 1960s to 1980s.Retro: retrospective; Pros: prospective; SBRT: stereotactic body radiation therapy; OS: overall survival; LC: local control; PFS: progression-free survival; and RFS: recurrence-free survival.

[a]Number of SBRT cases is shown as number of cases of colorectal cancer divided by number of cases of all other cancers.

researchers have noted, it seems plausible that oligometastases are limited metastatic tumors that could be cured with local treatment [14].

The distinguishing characteristic of oligometastases is based on the concept of curability as the outcome. With this approach, a correct diagnosis of oligometastases is only confirmed once it has been determined whether the patient is cured. Therefore, the term "oligometastases" does not simply represent a clinical appearance at the time of treatment decision-making but instead includes the outcome of curability with local ablation. By definition, the purpose of local treatment for oligometastases is cure rather than the prolongation of survival, the decrease in tumor volume, or palliative care. Therefore, in order to identify the clinical appearance suggestive of oligometastases at the time of decision-making, a retrospective factorial analysis for oligometastases focusing on the outcomes of cure would be necessary.

3. Pulmonary metastasectomy

In the pre-SBRT era, the treatment with a curative intent for metastatic tumors in the lung and liver was surgical resection. Pulmonary metastasectomy has been a commonly performed surgery. One of the most frequently reported tumors for pulmonary metastasectomy is colorectal cancer. In current practice, pulmonary resection for metastatic tumors from colorectal cancer is advocated based on numerous retrospective reports, despite the fact that the effectiveness of this procedure remains unclear due to a lack of randomized controlled trials [13]. A recent systematic review and meta-analysis showed that overall survival ranged from 27% to 68% after pulmonary resection of metastases [15]. Multifactorial analysis for overall survival revealed some risk factors for poor overall survival, including short disease-free interval, multiple lesions, and elevated prethoracotomy CEA.

From the 1960s to the 1980s, multiple expert groups proposed indications for the surgical resection of metastatic tumors [16–18]. These criteria were very similar, and most clinicians accepted and followed them in clinical practice. In 1965, the original criteria proposed by Thomford et al. [16] were: (1) the patient must have a good risk for surgical intervention, (2) the primary malignancy is controlled, (3) there is no evidence of metastatic disease elsewhere in the body, and (4) roentgenologic evidence of pulmonary metastasis is limited to one lung. The criteria (3) and (4) above are now modified as follows: (3) no extrapulmonary metastasis exists or, if present, metastasis can be controlled by surgery or other modalities, and (4) pulmonary metastases are thought to be completely resectable [19]. Likewise, Martini and McCormack et al. [17,20] and Mountain et al. [18] reported similar criteria based on their experiences. Among all criteria, two are consistent between researchers—controlled primary tumor and no extrapulmonary lesion—and are considered to represent the clinical appearance of developing tumors at the time of treatment decision-making. The tumor situation described by these criteria appears similar to that of an oligometastatic state. However, the Thomford criteria do not take into account prognosis, whereas the concept of oligometastases includes the prognosis of cure.

In research studies, pulmonary metastasectomy has been primarily evaluated by overall survival. Overall survival represents the entire duration of various treatments, including local ablation, and does not depend on cure but rather on length of time that patients are alive. In the case of colorectal cancer, development of new agents such as irinotecan, oxaliplatin, and biologic agents targeting either epidermal growth factor receptor or vascular endothelial growth factor have greatly prolonged overall survival since the late 1990s [21,22]. Adjuvant chemotherapy after metastasectomy for liver and lung metastases from colorectal cancer has been shown to have a significant survival benefit [23]. To effectively prolong overall survival, multidisciplinary therapy is superior for metastatic disease [24,25]. In this approach, the goal of local treatment might not necessarily be cure, and a decrease of tumor volume might be acceptable for the purpose of treatment. Although there is an opinion that prolonged survival due to improved systemic chemotherapy increases chance of local treatment, the significance of pulmonary metastasectomy itself on overall survival in multidisciplinary therapy becomes ambiguous. The indication for pulmonary metastasectomy to prolong overall survival remains an unresolved issue that necessarily requires a randomized prospective study, but in the era of quick-paced drug development, it is considered almost impossible to identify the significance of the local therapy in any analysis of overall survival.

4. Treatment for oligometastases

For various malignancies, systemic chemotherapy and molecular targeted therapy have been proven to be effective for metastatic disease and are considered a standard treatment strategy. In the clinical setting, when local treatment achieves complete resection or complete ablation, the addition of systemic chemotherapy has tended to yield a favorable outcome [23,26,27]. Systemic treatment has a proven effect on systemic metastatic disease, most likely even on lesions that have not appeared as clinical physiological findings. As noted above, oligometastases are limited metastatic tumors that might be cured with local treatment. From a pathophysiological perspective, the oligometastatic state denies the existence of micrometastases, which are too small to be detected. Systemic adjuvant therapy in addition to local treatment with complete ablation has some effect on micrometastases and would obscure the significance of the local treatment. In order to evaluate the correctness of the clinical decision-making in diagnosing the oligometastatic state, local treatment alone for oligometastases, not combined with systemic treatment, would reveal the significance of local treatment on the outcome of cure. With that in mind, the treatment modality for clinical research on oligometastases should only be local ablation, or variations in systemic therapy should be minimized or controlled for where possible.

5. Evaluation of oligometastases

There is controversy over the existence of an oligometastatic state [28,29]. Although it is very difficult strictly to verify the existence of an oligometastatic state using the

Table 2 Indications for local treatment: differences between the Thomford criteria and oligometastases.

	Thomford criteria	Oligometastases
Definition	(1) Tolerable risks (2) Controlled primary tumor (3) No extrapulmonary lesion (4) Limited to one lung	Limited metastatic tumors that could be cured with local treatment
Representation of the above definition	Clinical appearance of tumor and surgical tolerability	Concept with a prognostic reference
Purpose of treatment	Prolonged survival	Cure
Outcome to evaluate	Overall survival	Disease-free survival

Table 3 Multiple indications for the local treatment of metastatic disease and corresponding outcomes to evaluate.

Objective	Oligometastases	Limited clinical appearance of metastatic tumors	Symptomatic or potentially symptomatic local tumors
Purpose of treatment	To cure	To prolong survival	Palliative care
Role of local treatment	To cure	To decrease tumor volume	Palliative care
Treatment under evaluation	Local therapy	Multidisciplinary therapy	Multidisciplinary therapy
Modality of local treatment	Surgery or radiotherapy	Surgery or radiotherapy	Radiotherapy is superior
Outcome to evaluate	Disease-free survival	Overall survival	Local control

scientific method, there seems to be no doubt that a few metastases are in mid-course of development into malignant tumor. Thus, what needs to be discussed is not whether oligometastases exist but rather, what kind of clinical appearance represents the oligometastatic state.

Compared to the Thomford criteria [16], which judge the indication for surgical resection simply by clinical appearance, oligometastases is a concept that is defined by the prognosis of cure. This comparison is shown in Table 2. By its precise definition, the clinical diagnosis of metastatic tumors as oligometastases can only be made correctly at the time when the patients are determined to be cured or not cured. Given this perspective, the purpose of local treatment for oligometastases is to cure patients, rather than decrease tumor volume, prolong survival, or alleviate patients' symptom. Therefore, in clinical research, which evaluates the treatment of oligometastases, the primary outcome to be analyzed should be disease-free survival, which is defined by no recurrence, rather than overall survival, which is defined regardless of recurrence.

Most previous clinical research of local ablation for metastatic disease has evaluated overall survival and local control. A summary of recent studies of local treatment for colorectal cancer is shown in Table 1. Even in research of oligometastases, the evaluated outcomes were still overall survival and local treatment [6,7,28]. Discussion regarding the methodology in the evaluation of oligometastases is limited [28]. In past reports of local treatment for metastatic disease, disease-free survival has rarely been evaluated [14,30]; Onaitis et al. reviewed patients undergoing pulmonary resection for colorectal metastases and reported recurrence-free survival separate from overall survival [30]. Their factorial analysis of recurrence showed that age younger than 65 years, female, disease free interval less than 1 year, and number of metastases greater than three, were all risk factors for recurrence, and they also discussed the chance for cure with pulmonary resection of metastases.

Aside from disease-free survival, the proportion of patients who have long-term disease-free survival or cure may be an effective and appropriate evaluation for oligometastases. Tomlinson et al. reviewed patients who had undergone resection of colorectal liver metastases and showed that 97% of 10-year survivors were disease-free and appeared to be cured of their disease [31]. These researchers determined the cure rate to be at least 17% and potentially as high as 25%. The aims of their study were to define cure after resection of colorectal liver metastases, to determine the cure rate based on actual survivors, and to identify clinical characteristics associated with a cured patient to improve patient selection for surgical therapy. This approach would be applicable for research of oligometastases.

6. Indications for local therapy and corresponding outcomes

In the past, the indication for local therapy for metastatic malignancies has been discussed, but the relationship between the indications and the outcomes has not been given academically rigorous consideration. Although the indications for

local therapy of metastases discussed from the 1960s to the 1980s did not explicitly include oligometastases, neither did those indications exclude this disease state.

There are multiple discrete indications for the local treatment of metastatic lesions, as shown in Table 3. The purposes of these indications are (a) the intent to cure oligometastases, (b) the intent to prolong survival as a part of multidisciplinary therapy, and (c) palliative care. In order to appropriately evaluate the significance of local treatment, the outcomes should depend on the indication for treatment. The corresponding outcomes to consider are (a) disease-free survival, (b) overall survival, and (c) local control. Factorial analysis of each outcome corresponding to each indication for local therapy would yield information on each clinical presentation to help decide treatment.

7. Summary

Oligometastases is a disease concept that is defined by a state of limited systemic metastatic tumors for which local ablative therapy could be curative. By definition, the purpose of local treatment for oligometastases is cure, and the primary outcome to be analyzed should be disease-free survival. Systemic adjuvant therapy in addition to local treatment with complete ablation has some effect on micrometastases. In clinical research on oligometastases, the only treatment modality under evaluation should be local ablation. In order to appropriately evaluate the significance of local treatment, the outcomes addressed should depend on the indication for treatment: the intent to cure oligometastases, the intent to prolong survival as a part of multidisciplinary therapy, and local control for palliative care.

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Conflict of interest

No significant conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.

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