OLIGOMETASTATIC BREAST CANCER: DEFINITIONS, DIAGNOSTIC ADVANCES, AND TREATMENT STRATEGIES

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ABSTRACT

Background: Oligometastatic breast cancer (OMBC) is considered an transitional state between locally confined and widespread metastaticbreast cancer. It is characterized by a limited number of metastatic lesions (commonly ≤5 lesions across ≤2 organs) and a potentially favorable response to definitive local therapies such as surgery or stereotactic body radiation therapy (SBRT).

Objective: To review recent advances in imaging and molecular biology in OMBC, elucidate the potential for long-term disease control through multimodal treatment strategies, and discuss ongoing challenges in standardizing diagnosis and management.

Content: Although metastatic breast cancer has traditionally been regarded as incurable, accumulating evidence suggests that a selected subgroup of patients with OMBC may achieve prolonged disease-free survival following aggressive treatment. However, there remains significant heterogeneity in the definition of OMBC across studies, including variations in imaging criteria, number and location of metastatic lesions, timing of metastasis (de novo versus metachronous), and molecular characteristics. The ESTRO-EORTC classification system has proposed 17 criteria for comprehensive assessment and distinguishes among different OMBC states, including genuine, induced, and repeat oligometastatic disease.

Most currently available data on OMBC management derive from retrospective studies and small phase II trials, while evidence from randomized controlled trials remains limited. This lack of high-level evidence poses challenges in standardizing treatment strategies, particularly regarding the role of local therapies in the context of increasingly personalized systemic treatment.

Recent advances in tumor biology and diagnostic technologies have opened new perspectives. Molecular biomarkers such as PIK3CA mutations, YAP/TAZ expression, and circulating tumor

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DNA (ctDNA) dynamics show promise in risk stratification, patient selection, and early detection of recurrence. Meanwhile, modern imaging modalities, including whole-body PET/CT with specific tracers, enable more accurate identification of metastatic burden and support appropriate classification of OMBC.

Conclusion: OMBC represents a distinct subgroup of breast cancer with unique prognostic implications and potential for improved outcomes. Accurate characterization of tumor biology combined with individualized treatment strategies may optimize clinical outcomes. Large-scale randomized trials are warranted to validate the benefit of aggressive interventions and to establish standardized treatment guidelines for this patient population.

Keywords: Oligometastatic breast cancer (OMBC); Stereotactic body radiation therapy (SBRT); Multimodal therapy; ESTRO-EORTC classification; Circulating tumor DNA (ctDNA); PET/CT imaging; Molecular biology; Personalized treatment.

1. INTRODUCTION

Oligometastasis in the Era of Advances in Diagnosis and Treatment

Randomized trials such as SABR-COMET have demonstrated that comprehensive metastasis-directed therapy may improve progression-free survival (PFS) and overall survival (OS), while also suggesting the potential for durable disease control and, in selected cases, long-term remission in patients with oligometastatic disease. The rigorous study design and well-defined patient population have strengthened the clinical validity of these findings. However, the EA2108 trial in patients with stage IV breast cancer did not demonstrate a survival benefit with the addition of early locoregional therapy to systemic treatment, indicating that the role of this strategy should be carefully considered within specific disease scenario.

Notably, although SABR-COMET supports the benefit of aggressive local therapy targeting metastatic lesions, the proportion of breast cancer patients included in this trial was limited. In contrast, the NRG-BR002 trial, specifically conducted in oligometastatic breast cancer, failed to demonstrate a survival benefit from metastasis-directed local therapy. Importantly, this study did not mandate the use of positron emission tomography-computed tomography (PET/CT) and lacked standardization of systemic therapy. Subgroup analyses revealed no survival advantage even among patients with a single metastatic lesion; moreover, a higher incidence of new metastatic lesions was observed in the local therapy group, and patients with triple-negative breast cancer (TNBC) exhibited poorer outcomes. Collectively, these findings underscore the necessity of integrating and maintaining effective systemic therapy, as well as the importance of standardized imaging and treatment strategies in future clinical trials evaluating oligometastatic breast cancer.

2. DEFINITION OF OLIGOMETASTASIS

2.1 Clinical and Imaging Criteria

Oligometastasis is commonly defined as the presence of up to five metastatic lesions, confined to defined anatomical regions and amenable to local treatment modalities. Hellman et al. initially proposed this definition and further analyzed its clinical applications and limitations. For instance, the ESTRO and EORTC criteria emphasize the role of clinical disease course and lesion number in defining the oligometastatic state.

2.2. Biological Basis

The rationale for local therapy in oligometastatic disease is based on the hypothesis that early intervention to reduce tumor burden may induce a state approaching cure, thereby improving prognosis. However, data from ovarian cancer studies have raised questions regarding this assumption. Specifically, in ovarian cancer, initiating treatment based solely on an increase in CA125 levels (approximately six months earlier on average) compared with treatment initiation after radiologic detection of disease on CT did not result in differences in clinical outcomes. Furthermore, although secondary cytoreductive surgery is commonly employed in ovarian cancer, its survival benefit has not been consistently demonstrated. These findings call into question the validity of applying local treatment strategies in oligometastatic breast cancer.

Differences in tumor biology across cancer types may significantly influence the effectiveness of local or locoregional interventions. Therefore, treatment strategies for oligometastatic disease should incorporate not only tumor burden but also molecular and biological characteristics. Future studies should integrate these aspects to develop novel therapeutic approaches tailored to the unique biology of oligometastatic disease.

Emerging evidence suggests that oligometastasis may represent a distinct biological entity. Mutations such as PIK3CA H1047R and overexpression of markers such as YAP/TAZ have been associated with oligometastatic breast cancer (OMBC) and may predict a more favorable response to local therapies.

3. TREATMENT STRATEGIES IN OLIGO-METASTASIS

3.1. Role of local therapies

In the management of oligometastatic disease, local treatment modalities-including stereotactic body radiation therapy (SBRT), surgical resection, and radiofrequency ablation (RFA)-play a pivotal role in achieving high rates of local control and optimizing survival outcomes when appropriately integrated with systemic therapy. SBRT is particularly effective for small lesions in the brain, lung, and liver, with excellent local control rates in selected patient populations. Proton therapy has shown promising results in liver metastases with minimal toxicity, while surgical resection remains the standard of care for lesions amenable to complete removal. However, in de novo stage IV breast cancer, the role of primary tumor resection remains controversial.

From a biological perspective, removal of the primary tumor has been hypothesized to confer immunomodulatory benefits, analogous to strategies previously applied in renal cell carcinoma. Conversely, an opposing hypothesis suggests that surgical intervention may promote disease progression through alterations in the immune microenvironment and the release of growth factors. Retrospective studies have yielded heterogeneous results and are subject to selection bias, while also failing to fully reflect advances in modern systemic therapies. Meta-analyses have suggested an improvement in 3-year survival in patients undergoing surgery, particularly in those with oligometastatic disease; however, a major limitation is the lack of comprehensive data on targeted therapies such as anti-HER2 agents.

Randomized clinical trials have reported conflicting findings. The study by Soran et al. demonstrated a long-term survival benefit, particularly in subgroups with ER/PR-positive, HER2-positive disease, or bone-only metastases, despite baseline imbalances between study arms. In contrast, trials such as those conducted by Badwe et al., POSYTIVE, and ECOG-ACRIN E2108 did not demonstrate an overall survival benefit from locoregional therapy, although improvements in local control were occasionally

observed. Notably, the BOMET MF14-01 study, which included patients with bone-only metastases, reported a significant improvement in 5-year survival in the local therapy group; however, its generalizability is limited by the absence of contemporary systemic therapies and imbalances between study cohorts.

Overall, there is currently no consensus regarding the indication for primary tumor surgery in metastatic breast cancer. The benefit appears to be more pronounced in patients with low metastatic burden, particularly those with oligometastatic or bone-only disease, and in the context of well-controlled systemic disease. Therefore, optimal management strategies should be based on careful patient selection, comprehensive assessment of tumor biology, and close integration with modern systemic therapies, rather than routine application of surgery.

3.2. Role of local therapies for metastatic lesions

The management of metastatic breast cancer (MBC) remains fundamentally based on systemic therapy, including chemotherapy, endocrine therapy, immunotherapy, and targeted agents, with a median overall survival (OS) ranging from 18 to 60 months depending on tumor subtype and disease burden. In the oligometastatic setting, prognosis appears more favorable, and the potential benefit of curative-intent strategies has been increasingly explored; however, current evidence remains inconsistent.

Real-world data in patients with HER2-positive disease and a single metastatic site have demonstrated that first-line treatment with trastuzumab plus pertuzumab significantly improves progression-free survival (PFS) ($p < 0.0001$) and overall survival (OS) ($p = 0.004$).

The phase II/III NRG-BR002 trial enrolled patients with ≤4 metastatic lesions (≤5 cm) who did not progress following systemic therapy and compared standard treatment (with palliative radiotherapy as needed) versus a comprehensive metastasis-directed approach using SBRT and/or surgery. The results did not demonstrate an improvement in PFS (23 months in the standard arm versus 19.5 months in the metastasis-directed therapy arm).

Local treatment modalities considered in curative-intent strategies include metastasectomy, SBRT, external beam radiotherapy (EBRT), and radiofrequency ablation (RFA). However, there remains a lack of predictive biomarkers and robust prospective data to guide patient selection. In summary, systemic therapy remains the cornerstone of treatment, while curative-intent approaches in oligometastatic disease should be individualized based on tumor biology, number and location of metastases, and the degree of systemic disease control.

4. ORGAN-SPECIFIC TREATMENT STRATEGIES IN OLIGOMETASTATIC DISEASE

4.1. Liver

The liver represents one of the most common sites of oligometastatic involvement, particularly in colorectal and breast cancer. In breast cancer, hepatic metastases-along with pulmonary and osseous metastases-are among the most frequently observed sites. The overall 5-year survival rate in this population ranges from approximately 4% to 12%, while 5-15% of patients present with isolated or liver-limited metastatic disease.

Although no prospective trials have definitively established the benefit of hepatic metastasectomy, retrospective studies suggest improved survival in selected patients, with 5-year survival rates exceeding 30% and median overall survival ranging from 25 to 70 months. Favorable prognostic factors include achievement of

microscopically negative margins (R0 resection), younger age, hormone receptor–positive or HER2-positive disease, and a favorable response to initial systemic therapy. A matched case–control study conducted in Europe demonstrated that the combination of systemic therapy (including trastuzumab in HER2-positive patients) and hepatic resection significantly improved overall survival compared with systemic therapy alone (82 vs. 31 months; HR 0.28; $p < 0.001$). However, the role of repeat hepatic resection remains insufficiently characterized. In patients who are not candidates for surgery due to comorbidities or unfavorable lesion location, alternative local modalities such as radiofrequency ablation (RFA) or microwave ablation (MWA) may be considered. Retrospective data suggest that laparoscopic RFA combined with surgery is associated with longer overall survival compared with systemic therapy alone (47 vs. 9 months; $p = 0.0001$).

Regarding radiotherapy, stereotactic body radiation therapy (SBRT) and proton beam therapy (PBT) represent minimally invasive options with high local control rates (>90%). A nationwide cohort study in Japan reported a 3-year local control rate of 100% with PBT in patients with breast cancer liver metastases. However, SBRT is less frequently utilized in the liver due to the risk of radiation-induced liver disease and limitations in treating larger lesions. Additionally, the role of liver transplantation is currently under investigation in highly selected patients with favorable tumor biology.

In summary, the management of liver metastases in the oligometastatic setting requires careful patient selection and prioritizes a multidisciplinary approach integrating systemic therapy with appropriate local treatment strategies.

4.2. Bone

Bone is the most common site of metastasis in breast cancer. Local treatment is typically indicated in the presence of spinal cord compression, pathological fractures, or pain. In the oligometastatic setting, curative-intent treatment may be considered in selected patients with a limited number of osseous lesions.

Retrospective data suggest that this subgroup of patients may achieve better symptom control and potentially improved survival outcomes. However, it should be noted that patients with bone metastases often have a more favorable prognosis and respond well to systemic therapy; moreover, surgical intervention for bone lesions may be associated with significant complication rates. Therefore, radiotherapy is generally the preferred modality.

In cases of bone-only oligometastases, high-dose stereotactic radiotherapy (HSRT/SBRT) has demonstrated substantial benefit, with reported 5-year and 10-year overall survival rates of 83% and 75%, respectively, compared with 31% and 17% in patients without bone-only disease ($p = 0.002$). For isolated sternal metastases, surgery or radiotherapy is recommended. A phase II study evaluating SBRT or intensity-modulated radiotherapy (IMRT) to all metastatic lesions (predominantly bone) reported 1-year and 2-year progression-free survival rates of 75% and 53%, respectively.

Historically, bone metastases have been primarily managed with radiotherapy due to its efficacy in pain relief and local control. SBRT is particularly effective in solitary bone metastases, achieving durable local control with low toxicity. However, distinguishing true oligometastatic bone disease from more widespread skeletal involvement remains challenging, necessitating careful imaging evaluation and biopsy when appropriate. While the role of SBRT in improving quality of life has been well established, its impact on overall survival requires further investigation.

4.3. Lung

Oligometastatic lung disease can be managed with either surgical resection or stereotactic body radiation therapy (SBRT), depending on patient characteristics and lesion features. Surgery is particularly valuable when histopathological confirmation is required to differentiate primary lung cancer from metastatic disease, which may occur in approximately 12-57% of surgically resected pulmonary lesions. Video-assisted thoracoscopic surgery (VATS) has improved procedural safety while reducing invasiveness.

Several studies have demonstrated improved progression-free survival (PFS) in patients undergoing pulmonary metastasectomy. A landmark study reported a 5-year survival rate of 38% and a median overall survival (OS) of 37 months following complete resection. A meta-analysis of 16 studies demonstrated a pooled 5-year survival rate of 46% after surgery. Favorable prognostic factors include a disease-free interval (DFI) >36 months, solitary metastasis, estrogen receptor (ER) positivity, small lesion size, and achievement of microscopically negative margins (R0). In contrast, DFI ≤3 months, multiple lesions, and ER-negative status are associated with poorer outcomes. However, perioperative morbidity and mortality should be carefully considered.

SBRT represents a noninvasive alternative with high rates of local control and low toxicity, although radiation-induced pneumonitis remains a potential risk. The phase II SABR-COMET trial, which included multiple tumor types (with approximately 50% of treated lesions located in the lung), demonstrated improved overall survival with SBRT compared with standard palliative care (median OS 50 vs. 28 months; HR 0.47). A meta-analysis of 10 studies involving 467 patients with oligometastatic breast cancer treated with SBRT reported 1-year and 2-year local control rates of 97% and 90%, respectively, with overall survival rates of 93% at 1 year and 81% at 2 years.

Currently, no randomized trials have directly compared surgery with SBRT in oligometastatic lung disease from breast cancer. Therefore, treatment selection should be individualized based on the number of lesions, disease-free interval, tumor biology, and patient performance status.

4.4. Brain (Without Extracranial Metastases)

Brain metastases represent a poor prognostic factor across multiple malignancies. In a subset of selected breast cancer patients, brain metastases may occur in the absence of extracranial disease. Although the underlying mechanisms remain unclear, one potential explanation is the limited penetration of certain systemic therapies across the central nervous system.

Local treatment should be considered for patients with isolated brain metastases. In cases of a solitary lesion, surgical resection may be preferred. However, other factors, such as patient performance status, must also be taken into account. In patients with multiple brain lesions, stereotactic radiosurgery (SRS) is generally recommended [24]. Whole-brain radiotherapy (WBRT) may be considered in cases where surgery or SRS is not feasible due to extensive intracranial disease. Several studies have shown that adjuvant WBRT following surgical resection improves local control but does not confer an overall survival benefit and is associated with neurocognitive toxicity. Following local therapy, there remains insufficient evidence regarding the continuation of systemic therapy or the optimal duration of treatment, if administered.

4.5. Lymph Nodes

Distant lymph node metastases, particularly contralateral axillary metastases (CAMs), may represent a subgroup of oligometastatic disease

with one of the highest potentials for curative treatment. Emerging evidence suggests that CAMs should be considered a "quasi-oligometastatic" entity, in which aggressive local treatment strategies may achieve durable remission.

In cases of CAMs without concomitant visceral metastases, surgical resection combined with systemic therapy may provide significant clinical benefit, with improvements observed in both progression-free survival (PFS) and overall survival (OS) in selected patients.

5. ONGOING CLINICAL TRIALS

Multiple phase III trials are currently underway worldwide to evaluate the impact of local therapies on clinical outcomes in patients with oligometastatic breast cancer (Table 1). Most of these studies use progression-free survival (PFS) as the primary endpoint; however, the JCOG2110 trial is notable as the only study employing overall survival (OS) as the primary endpoint. SBRT represents the principal intervention across these trials, while surgical approaches are generally reserved for cases in which SBRT is not feasible. Notably, several studies include triple-negative breast cancer (TNBC) as a predefined subgroup; however, based on findings from the NRG-BR002 trial, the benefit of local therapy in this population remains controversial. In contrast, ongoing and future trials focusing on estrogen receptor (ER)-positive or HER2-positive subtypes are anticipated to yield more promising results. The outcomes of these ongoing prospective trials are expected to clarify the indications and optimal integration of local therapies in the oligometastatic setting. Detailed analyses of these results will provide critical evidence to refine treatment strategies for this unique metastatic state.

6. CLINICAL IMPLICATIONS OF CTDNA AND LIQUID BIOPSY IN OLIGOMETASTATIC BREAST CANCER

Liquid biopsy, including the analysis of circulating tumor DNA (ctDNA), circulating tumor cells (CTCs), and exosomes, has emerged as a minimally invasive tool for real-time monitoring of tumor dynamics. ctDNA analysis may facilitate patient stratification, enabling treatment intensification with systemic therapy or early implementation of local interventions prior to radiologic disease progression. In parallel, molecular profiling of CTCs or exosomal RNA can identify emerging mechanisms of resistance and potential therapeutic targets. Integration of liquid biopsy into clinical practice holds promise for optimizing surveillance strategies and enhancing personalized disease management. At the molecular level, the presence of ctDNA following local therapy in early-stage breast cancer has been associated with a higher risk of recurrence. The median time to overt metastatic relapse is typically less than one year, suggesting that early detection of ctDNA positivity may allow identification of metastatic disease at a subclinical stage, when disease burden may still be limited. Accordingly, intensified imaging surveillance in ctDNA-positive patients may be beneficial, although further validation from prospective clinical trials is required. Conversely, in patients with oligometastatic breast cancer who have undergone curative-intent treatment, the role of adjuvant systemic therapy remains controversial. A key unresolved question is whether ctDNA positivity should serve as an indication for additional systemic therapy, which warrants further investigation in future studies.

Table 1. Ongoing Prospective Trials Evaluating the Prognostic Impact of Local Therapies in Oligometastatic Breast Cancer

NCT Number	Study Title	Conditions	Interventions	Primary Outcome Measures	Phases	Enrollment	Start Date
NCT04698252	Local Therapy for ER/PR-positive Oligometastatic Breast Cancer (LARA)	Breast Cancer	Radiotherapy/ surgery/ radiofrequency ablation	Two-year progression-free survival (PFS): The PFS is defined as the time from randomization until the date of progression or death. The 2-year PFS rate represents the probability of a patient being free of progression 2 years after randomization and will be estimated using the Kaplan–Meier method from the baseline to 2 years later.	PHASE 2	74	1 April 2021
NCT03808337	Investigating the Effectiveness of Stereotactic Body Radiotherapy (SBRT) in Addition to Standard of Care Treatment for Cancer That Has Spread Beyond the Original Site of Disease	Triple-Negative Breast Cancer/Non-Small-Cell Lung Cancer	SBRT/systemic therapy/standard of care	Progression-free survival: To determine whether stereotactic body radiotherapy administered to all sites of metastatic disease in patients with oligometastatic non-small-cell lung cancer or triple-negative breast cancer improves progression-free survival (PFS), defined as time from randomization to disease progression or death, compared to standard-of-care therapy alone, for up to 2 years.	PHASE 2	145	16 January 2019
NCT03808662	Randomized Study of Stereotactic Body Radiation Therapy (SBRT) in Patients With Oligoprogressive Metastatic Cancers of the Breast and Lung	Triple-Negative Breast Cancer/Non-Small-Cell Lung Cancer	SBRT/standard of care	Progression-free survival: To study if the addition of early SBRT to the treatment of extra-cranial oligoprogressive metastatic disease could prolong the PFS compared to treatment with no SBRT. The PFS is defined as the time from randomization to disease progression or death and measured for up to 52 weeks after the final participant is enrolled.	PHASE 2	107	16 January 2019
NCT06135714	Metastasis-directed Therapy for Oligometastases of Breast Cancer (JCOG2110: ORIGAMI)	Breast Cancer	Systemic therapy for 12 weeks after primary registration/radiation therapy (SBRT/conventional RT) and surgery/same systemic therapy after secondary registration	Overall survival after second registration over 5 years.	PHASE 3	340	8 November 2023
NCT02089100	Trial of Superiority of Stereotactic Body Radiation Therapy in Patients With Breast Cancer (STEREO-SEIN)	Breast Cancer	SBRT/systemic treatment	Progression-free survival (PFS), events: Local recurrence, distant progression of target metastases, any new metastasis, death from any cause. Definition of progression is based on RECIST1.1 criteria. Progression is assessed locally, in any metastasis present at time of randomization or in any newly diagnosed metastasis, with minimal follow-up of 3 years for all patients.	PHASE 3	280	1 February 2014
NCT04646564	Radiotherapy for Extracranial Oligometastatic Breast Cancer	Breast Cancer	Standard of care/ radiotherapy + standard of care	Progression-free survival: Time from randomization to disease progression at any site or death. Measured over 2 years.	PHASE 3	170	6 April 2021

7. CONCLUSION

Although metastatic breast cancer is traditionally considered an incurable disease, a subset of patients with a limited metastatic burden may achieve prolonged disease control when treated with an aggressive multimodal approach combining systemic therapy and definitive local interventions.

Significant advances in systemic treatment-including anti-HER2 therapies, CDK4/6 inhibitors, immunotherapy, and antibody-drug conjugates-together with improved early detection of metastatic disease, have contributed to improved survival outcomes and have expanded the potential for curative-intent strategies in oligometastatic breast cancer. However, the optimal timing for definitive local intervention remains unclear, and the lack of well-designed clinical trials continues to limit the establishment of standardized treatment strategies. In the current context, a rational approach involves a neoadjuvant-like strategy with initial systemic therapy, followed by definitive surgery and/or radiotherapy, and subsequent adjuvant systemic treatment. Although cure cannot be guaranteed, a proportion of patients may achieve durable remission, potentially lasting for many years or even lifelong. Therefore, further strategic clinical trials and a multidisciplinary, personalized treatment approach are essential to optimize long-term disease control in this unique patient population.

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