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Metastasis-directed thermal ablation in patients with metastatic breast cancer and visceral oligoprogression or oligopersistence: a cohort study☆

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ABSTRACT

Background: Patients with visceral oligoprogressive and oligopersistent metastatic breast cancer (mBC) may benefit from metastasis-directed thermal ablation (TA) to all sites of metastasis, while maintaining the same systemic treatment, in order to delay the time to treatment failure (TTF). This study aims to assess the outcomes provided by this multimodal strategy.

Methods: We conducted a single-center, cohort study including consecutive patients with visceral oligoprogressive and oligopersistent mBC as per ESTRO/EORTC criteria, who underwent TA to all sites. Oligoprogression was defined as progressive disease in ≤5 metastatic sites with at least one other metastatic site maintaining the disease control; oligopersistence as ≤5 persistent lesions after systemic therapy. The main endpoint was post-TA progression-free survival (pTA-PFS).

Results: 43 patients with oligoprogressive (cohort A) and 43 with oligopersistent (cohort B) disease were included; 4 (5 %) reported a TA-related adverse event. Overall, 122 visceral lesions were treated. In cohort A, median PFS before oligoprogression was 14.9 months (95 % CI, 9.7–20.1). After TA, 32 patients continued the same systemic treatment and 11 switched therapy; pTA-PFS was 9.1 months (95 % CI, 4.8–13.4), unchanged after excluding patients who switched systemic therapy. In cohort B, median PFS before oligopersistence was 7.8 months (95 % CI, 7.4–8.3). After TA, 35 patients continued the same systemic treatment, while 8 de-intensified to maintenance therapy; pTA-PFS was 16.7 months (95 % CI, 11.1–22.2).

Conclusion: Selected patients with visceral oligoprogressive and oligopersistent mBC appear to benefit from TA and systemic treatment continuation or modulation. This strategy can be implemented for selected patients in the framework of a multidisciplinary tumor board's shared decision.

1. Introduction

Metastatic breast cancer (mBC) is the leading cause of cancer-related death in women and is biologically and clinically heterogeneous disease, ranging from aggressive, polymetastatic disease to low-volume, indolent disease, in which metastasis-directed local treatments can be integrated to postpone the time to treatment failure (TTF), namely the time to more toxic treatments, and improve quality of life [1–3].

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(EORTC) consensus defined the spectrum of low volume metastatic solid tumors and codified the categories of oligoprogression and oligopersistence [4].

Oligoprogression denotes disease progression during a systemic therapy in a limited number of metastatic lesions, commonly maximum five in any organ, with most other lesions controlled by or responsive to systemic therapy [4]. Because it might be driven by treatment-resistant subclones not present in other metastatic sites, local treatment to oligoprogressive sites while continuing the same systemic regimen may prolong the TTF.

Instead, oligopersistence is defined as the persistence of few metastatic lesions (therapeutically-induced oligometastatic disease) after a partially effective systemic treatment [4]. In this setting, local treatments can consolidate the response to systemic therapy, and may allow its deintensification.

Metastasis-directed thermal ablation (TA) may have a role in selected patients with visceral oligoprogressive or oligopersistent mBC. Indeed, in patients with colorectal liver metastases, thermal ablative methods, especially radiofrequency ablation and microwave ablation, have demonstrated noninferiority to surgical resection in terms of efficacy with fewer adverse events [5]. Compared to surgery, TA is less invasive and generally less costly.

Data on metastasis-directed TA for patients with visceral oligoprogressive or oligopersistent mBC defined by ESTRO/EORTC criteria are lacking. This study aims to assess the safety, activity and efficacy of thermal ablative methods in this setting.

2. Methods

2.1. Study population

We conducted a single-center, retrospective, cohort study on a prospectively maintained database at European Institute of Oncology (IEO) IRCCS, Milan, Italy. We collected data from consecutive patients aged ≥18 years old, with a histologically confirmed diagnosis of mBC, who received a diagnosis of visceral oligoprogressive or oligopersistent metastatic disease and underwent TA to all sites at IEO, from January 2007 to December 2023.

After the TA, patients could continue the same systemic treatment until subsequent progression or unacceptable toxicity, or switch to a subsequent line of systemic treatment despite the procedure (including a de-intensified maintenance therapy according to tumor biology). All cases were discussed at the weekly multidisciplinary tumor board including at least breast medical oncologists, breast surgeons, radiation oncologists, radiologists and interventional radiologists. All patients underwent whole body imaging (either computed tomography [CT] scan or magnetic resonance imaging [MRI]) during the systemic treatment every 12 ± 2 weeks, as per IEO internal guidelines. Patients with oligoprogressive or oligopersistent mBC involving the central nervous system were excluded.

Patients with visceral oligoprogressive disease were included in cohort A. Oligoprogression was defined as radiologic (at MRI or CT scan) progression per RECIST 1.1, as assessed by the tumor board, in ≤5 extracranial metastatic sites, with at least one other metastatic site maintaining the disease control [6,7].

Patients with visceral oligopersistent disease were included in cohort B. Oligopersistence was defined as the finding at MRI or CT scan of ≤5 persistent extracranial metastatic sites after systemic therapy.

All information was obtained through access to medical records. The study was approved by the IEO institutional review board (project code: UID 2742) and was conducted in accordance with the principles stated in the Declaration of Helsinki and with the principles of good clinical practice.

2.2. Endpoints

The following endpoints were assessed: post-thermal ablation progression-free survival (pTA-PFS) in all comers, defined as the time from the first scan showing oligoprogressive or oligopersistent mBC to the subsequent PD in any site or death, whichever occurred first; and post-thermal ablation time to treatment failure (pTA-TTF), defined as the time from the first scan showing oligoprogressive or oligopersistent mBC to systemic treatment discontinuation or death, whichever occurred first.

2.3. Statistical analyses

Descriptive statistics were used to analyze patients' characteristics. Clinical and biological variables were grouped in standard categories whenever reasonable. Continuous variables were expressed as the median and interquartile range (IQR). Categorical variables are expressed as numbers (N), proportions (%), and 95 % confidence intervals (95 % CI). pTA-PFS and pTA-TTF were calculated by Kaplan-Meyer method. Analyses were conducted using SPSS (version 28.0.1.0) and Stata (version 18.0).

3. Results

3.1. Oligoprogressive disease (cohort A)

Among patients with visceral oligoprogressive mBC (N = 43), 37 (86 %) had hormone receptor (HR)-positive/HER2-negative mBC, 4 (9 %) had HER2-positive mBC and 2 (5 %) had triple-negative disease (Table 1). Overall, 21 (49 %) of them had oligometastatic disease (i.e., ≤5 lesions) when the systemic treatment was initiated, the median line of therapy was 2 (IQR: 1–3).

After a median interval from systemic treatment initiation of 14.9 months (95 % CI, 9.7–20.1), all patients experienced oligoprogression and received TA to all oligoprogressive sites. The median number of oligoprogressive lesions was 1 (IQR: 1–1.5), with 39 patients having lesions in the liver, 3 in the lung and 1 patient with a lesion in the adrenal gland. Among the procedures, microwave ablation was used in 38 patients (88 %), and radiofrequency ablation was performed in 5 patients (12 %). The median cumulative ablation time was 21 min (IQR: 12–30), and the median number of probes was 1 (IQR: 1-1). Three patients experienced a hematoma as procedure-related adverse event. The best radiographic response in the treated lesions was complete response, partial response and progressive disease in 40 (93 %), 1 (2 %) and 2 (5 %) patients, respectively.

Thirty-two (75 %) patients continued the same systemic treatment after the procedure, while 11 (25 %) switched the systemic treatment (Supplementary Table 1).

After a median follow-up of 42.3 months (95 % CI, 24.8–59.8), 36 patients experience a subsequent progression of disease: 9 in a TA-treated lesions and 27 due to the appearance or progression of new lesions. The median pTA-PFS was 9.1 months (95 % CI, 4.8–13.4) (Fig. 1A). After excluding 11 patients who switched the systemic treatment, the median pTA-PFS among 32 patients continuing the same systemic treatment after the procedure was 9.1 months (95 % CI, 4.5–13.7).

Seven patients underwent a second local treatment with TA in the same (n = 5) or subsequent systemic lines of treatment. Thirty-four patients interrupted the systemic treatment, the median pTA-TTF was 11.0 months (95 % CI, 5.8–16.1) (Fig. 1B).

3.2. Oligopersistent disease (cohort B)

Among patients with visceral oligopersistent mBC (N = 43), 27 (63 %) had HR-positive/HER2-negative mBC, 13 (30 %) had HER2-positive mBC and three (7 %) had triple-negative disease (Table 1). Overall, 40

Table 1
Patient characteristics and features of oligoprogressive and oligopersistent disease.

	Cohort A Oligoprogressive disease (N = 43)	Cohort B Oligopersistent disease (N = 43)
Patient characteristics		
Age at diagnosis, median (IQR)	42 (37–53)	49 (43–55)
Age at oligoprogression or oligopersistance, median (IQR)	53 (46–58)	54 (48–64)
Breast cancer		
Histotype: ductal | lobular | other, n (%)	35 (81) | 3 (7) | 5 (12)	39 (91) | 4 (9) | 0 (0)
De novo metastatic disease, n (%)	10 (23)	10 (23)
Breast cancer phenotype		
HR+/HER2-, n (%)	37 (86)	27 (63)
HER2+, n (%)	4 (9)	13 (30)
Triple-negative, n (%)	2 (5)	3 (7)
Line of therapy for mBC, median (IQR)	2 (1–3)	1 (1–2)
1st line, n (%)	18 (42)	31 (72)
Oligometastatic disease, n (%)	21 (49)	40 (93)
Type of systemic treatment		
ET, n (%)	22 (51)	18 (42)
ET monotherapy, n (%)	5 (12)	10 (23)
ET plus CDK4/6i or mTORi, n (%)	17[a] (40)	8 (19)
Chemotherapy, n (%)	17 (40)	12 (28)
Anti-HER2 therapy, n (%)	4 (9)	13[b] (30)
Median pre-oligoprogression or oligopersistance PFS, months (95 % CI)	15 (10–20)	8 (7–8)
Oligo-p/r/p features		
Number of oligo-progressive sites, median (IQR)	1 (1–1)	1 (1–1)
Number of oligo-progressive lesions, median (IQR)	1 (1–2)	1 (1–2)
Visceral oligoprogression or oligopersistance, n (%)	43 (100)	43 (100)
Liver, n (%)	39 (91)	42 (98)
Approach: MWA | RFA, n (%)	38 (88) | 5 (12)	27 (63) | 16 (37)
Access modality: percutaneous | laparoscopic, n (%)	43 (100) | 0 (0)	40 (93) | 3 (7)
Cumulative ablation time (minutes), median (IQR)	21 (12–30)	23 (12–49)
Number of probes, median (IQR)	1 (1–1)	1 (1–1)
Adverse Events, n (%)	3 (7)	1 (2)
Total number of lesions	**N=59**	**N=63**
Diameter of the treated lesions (mm), median (IQR)	15 (9.5–22)	12 (8–18)
Lesions with diameter ≥3 cm, n (%)	7 (12)	5 (8)
Presence of critical structures, n (%)	17 (29)	14 (22)
Lesions with complete ablation, n (%)	59 (100)	58 (92)
Hydrodissection performed, n (%)	14 (24)	12 (19)

Keys: CDK4/6i, CDK4/6 inhibitor; CI, confidence interval; ET; endocrine therapy; HER2+, HER2-positive; HER2-, HER2-negative; HR+, hormone receptor-positive; IQR, interquartile range; mBC, metastatic breast cancer; mTORi, mTOR inhibitor; MWA, microwave ablation; n, number; PFS; progression-free survival; RFA, radiofrequency ablation.

[a] 1 patient was under everolimus and exemestane.

[b] 5 patients combined with chemotherapy.

(93 %) of them had oligometastatic disease (i.e., ≤5 lesions) when a systemic treatment was initiated, the median line of therapy was 1 (IQR: 1–2). Twenty-eight (65 %) experienced a partial response and 15 (35 %) a stable disease as best response, after a median interval from systemic treatment initiation of 7.8 months (95 % CI, 7.4–8.3).

Subsequently, all patients underwent TA, with 40 (93 %) receiving TA for all oligopersistent sites. The median number of oligopersistent lesions was 1 (IQR: 1–2), with 42 patients having lesions in the liver and 1 patient with a lesion in the adrenal gland.

Among the procedures, microwave TA was used in 27 patients (63 %), and radiofrequency TA was performed in 16 patients (37 %). The median cumulative ablation time was 23 min (IQR: 12–49), and the median number of probes was 1 (IQR: 1-1). A hematoma in one patient was the only TA-related adverse event. The best radiographic response in the treated lesions was complete response, partial response and progressive disease in 38 (88 %), 3 (7 %) and 2 (5 %) patients, respectively.

Thirty-five (81 %) patients continued the same systemic treatment after the procedure, while 8 (19 %) switched to a de-intensified systemic treatment from standard-dose chemotherapy (e.g., with taxanes, vinorelbine or anthracyclines) to maintenance with endocrine therapy, trastuzumab single agent and/or low-dose, metronomic chemotherapy.

After a median follow-up of 57.5 months (95 % CI, 35.8–79.2), 32 patients experienced a subsequent progression of disease: 9 in a TA-treated lesion and 23 due to the appearance of new lesions. The pTA-PFS was 16.7 months (95 % CI, 11.1–22.2) (Fig. 2A). Thirteen patients underwent a second local treatment with TA in the same or subsequent systemic lines of treatment. Thirty patients interrupted the systemic treatment, reporting a median pTA-TTF of 16.7 months (95 % CI, 11.9–21.4) (Fig. 2B).

4. Discussion

In this study, patients with visceral oligoprogressive or oligopersistent mBC appeared to benefit from metastasis-directed TA and systemic treatment continuation or deintensification. To the best of our knowledge, this is the first cohort study to evaluate this strategy at the patient-level (rather than the lesion-level) using the ESTRO/EORTC classification [4].

We reported that TA, either microwave or radiofrequency technique, is a safe, active, and feasible. In this cohort, where most patients had a single and small (≤3 cm) liver lesion, complete radiographic response after TA was approximately 90 %, consistently with prior series reporting rates above 90 % for small lesions [8–12]. Subsequent progression within a TA-treated lesion occurred in 27 % of patients (18 of 68; 18 patients had not yet progressed at the data cutoff), in line with reported local-recurrence rates of 15 %–50 %, which increase with lesion size [8,12,13].

Overall, TA-related adverse events were uncommon: only 4 patients (5 %) reported an TA-related hematoma, consistently with previous retrospective cohort studies confirming the safety of this procedure (proportion of major complications: ≤5 %) [8,9]. Feasibility was clinically relevant, highlighting its potential for successful and widespread implementation in routine practice.

In terms of efficacy, median pTA-PFSs were 9.1 months (95 % CI, 4.8–13.4) in cohort A, even after excluding patients who switched systemic therapy, and 16.7 months (95 % CI, 11.1–22.2) in cohort B. Both estimates appeared clinically meaningful, since the lower boundary of the 95 % CI exceeded 3 months, therefore was longer than typical CT-scan interval for patients with mBC receiving sequential systemic therapies. Cross-study comparisons are limited by differences in selection of patients, classification of disease progression/persistence and definition of progression-free survival; prior retrospective series largely enrolled patients with liver-only disease and often used overall survival as the primary endpoint [8,11,14].

We acknowledge that the observed clinical benefit likely reflects rigorous and strict patient selection by the multidisciplinary tumor board: most patients had hormone receptor-positive/HER2-negative disease; were receiving first- or second-line therapy after a prolonged PFS before oligoprogression or oligopersistence; had low tumor burden (oligometastatic disease at systemic treatment baseline); and presented with a single oligoprogressive or oligopersistent lesion, ≤3 cm in 90 % of cases. Furthermore, some patients underwent a second local treatment with TA in the same systemic line of treatment, highlighting the indolent evolution of the disease.

In such patients, this multimodal strategy challenges the traditional paradigm of sequential systemic therapies with local treatments used

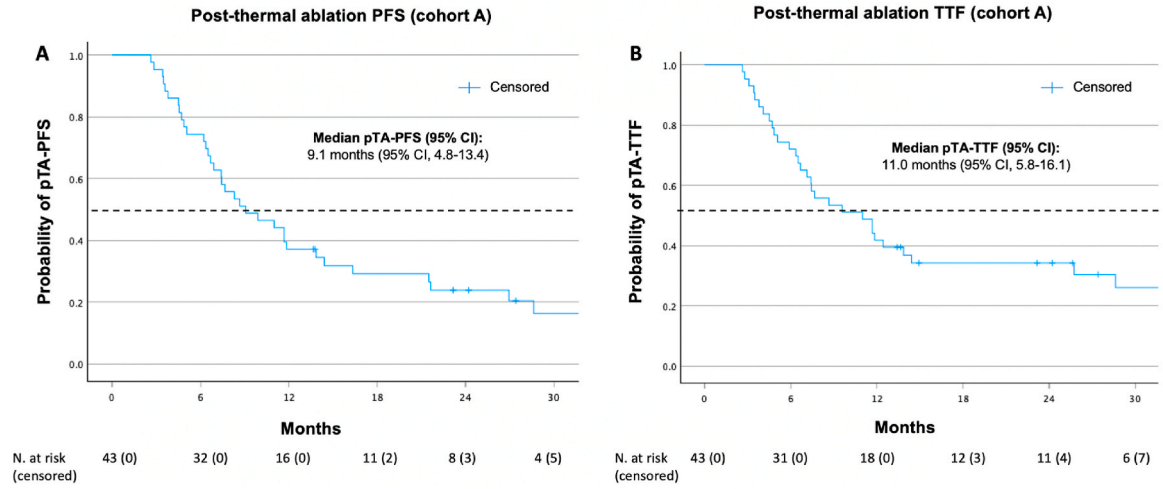

Fig. 1. Kaplan-Meier analysis of post-thermal ablation progression-free survival (A) and time to treatment failure (B) in patients with oligoprogressive disease.
Keys: CI, confidence interval; n, number; pTA-PFS, post-thermal ablation progression-free survival; pTA-TTF, post-thermal ablation time to treatment failure.

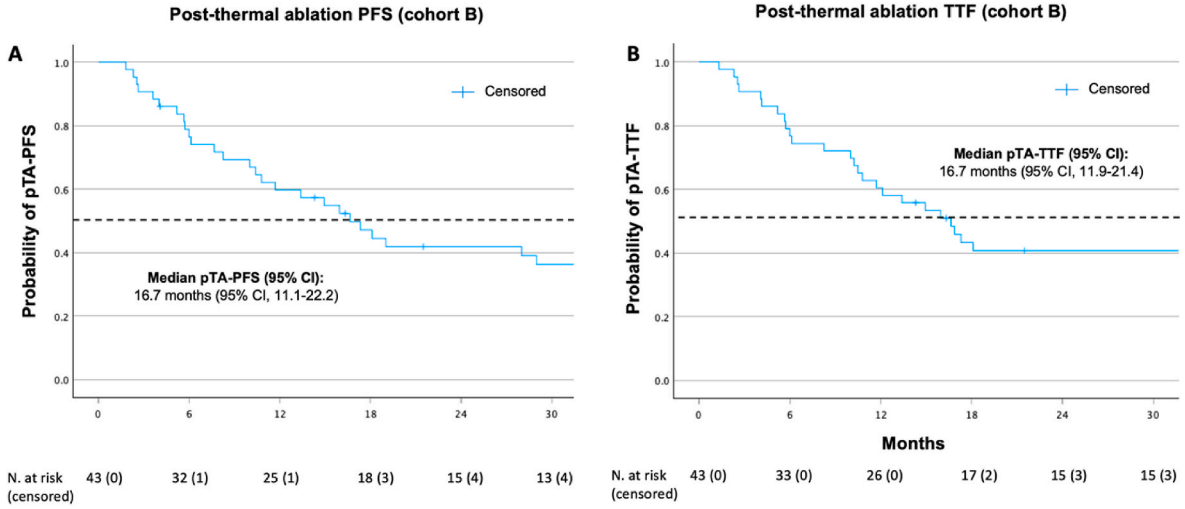

Fig. 2. Kaplan-Meier analysis of post-thermal ablation progression-free survival (A) and time to treatment failure (B) in patients with oligopersistent disease.
Keys: CI, confidence interval; n, number; pTA-PFS, post-thermal ablation progression-free survival; pTA-TTF, post-thermal ablation time to treatment failure.

primarily for palliation. However, decisions about feasibility and potential efficacy of local therapy should be made in a multidisciplinary setting involving medical and radiation oncologists, surgeons, and interventional radiologists, on the basis of disease and patient characteristics. Interestingly, according to the ESTRO-ASTRO consensus, the definition of oligometastatic disease depends more on the feasibility of local therapy (i.e., the ability to deliver safe and clinically meaningful radiotherapy with curative intent to all metastatic sites) than on the number of lesions [15].

The limitations of this analysis include: its retrospective observational design, although consecutive patients from a prospectively maintained database were included; the heterogeneity of systemic regimens received by the patients; the use of different imaging modalities, with differing sensitivity and specificity, however imaging was consistent for individual patients; the inclusion of patients from a single cancer center with extensive experience in ablative techniques, which may limit generalizability. Furthermore, the study lacks a comparison arm without TA, for example including patients who modulate systemic treatment or continued it beyond oligoprogression or oligopersistence.

5. Conclusion

In conclusion, selected patients with visceral oligoprogressive and oligopersistent mBC could benefit from metastasis-directed TA and continuation of systemic treatment, suggesting its potential implementation in clinical practice, in the framework of a multidisciplinary tumor board's shared decision.

Confirmation in prospective, randomized trials with patient-centered end points (i.e., overall survival and quality of life) is required to establish its efficacy and optimal use within the treatment trajectory of patients with mBC.

CRediT authorship contribution statement

Nadia Bianco: Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Carmine Valenza:** Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Monica Milano:** Writing – original draft, Formal analysis, Data curation, Conceptualization. **Roberta Multinu:** Writing – review & editing, Data curation, Conceptualization. **Elena Battaiotto:** Writing – review & editing, Data curation. **Matteo Cavallone:** Writing – review &

editing, Data curation. **Giulia Malvezzi:** Writing – review & editing, Data curation. **Dario Trapani:** Writing – review & editing, Data curation. **Paolo Della Vigna:** Writing – review & editing, Data curation. **Guido Bonomo:** Writing – review & editing, Data curation. **Gianluca M. Varano:** Writing – review & editing, Data curation. **Daniele Maiettini:** Writing – review & editing, Data curation. **Maria Giovanna Pitoni:** Writing – review & editing, Data curation. **Claudia Sangalli:** Project administration, Data curation. **Elisabetta Munzone:** Writing – review & editing, Supervision, Data curation. **Giuseppe Curigliano:** Validation, Supervision, Data curation. **Marco A. Colleoni:** Writing – review & editing, Validation, Supervision, Formal analysis, Data curation, Conceptualization. **Franco Orsi:** Writing – review & editing, Validation, Supervision, Data curation, Conceptualization.

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All the competing interests were outside the submitted work. All other authors have no potential conflicts of interest to disclose.

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Appendix A. Supplementary data

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