Metabolic complete response on 18FDG-PET-CT is a key predictor of Progression-Free Survival in metastatic luminal breast cancer treated with CDK4/6 inhibitors (CDK4/6i).

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Introduction

CDK4/6 inhibitors combined with endocrine therapy are the standard first-line treatment for HR+/HER2- metastatic breast cancer (MBC). However, predictive markers of treatment benefit remain limited. We hypothesized that 18F-FDG PET-CT may provide early prognostic insights in HR+/HER2- MBC. We evaluated the association between metabolic complete response (CMR) on PET-CT and progression-free survival (PFS) in patients treated with first-line CDK4/6 inhibitors and endocrine therapy.

Methods and Materials

- Retrospective cohort study
- 95 patients with HR+/HER2– metastatic breast cancer
- First-line CDK4/6 inhibitor + endocrine therapy (2018–2023)
- Serial **18F-FDG PET-CT** for treatment response assessment
- **Definition of CMR:** Complete absence of metabolic uptake on PET-CT at any time during first-line therapy
- Patients classified as **CMR** vs **non-CMR**
- **Endpoints:** PFS (primary), OS (secondary)
- **Analysis:** Kaplan–Meier and Cox regression

Results

- **Progression-Free Survival (PFS)**

CMR: 35.1 months x Non-CMR: 23.9 months
p = 0.0004

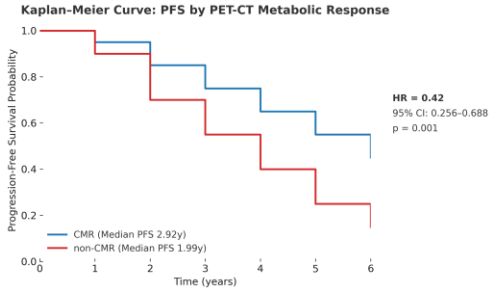
- **PFS Association:** CMR independently associated with longer PFS

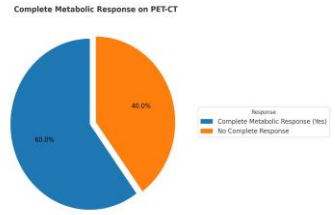
HR = 0.42 (95% CI 0.256–0.688) p = 0.001

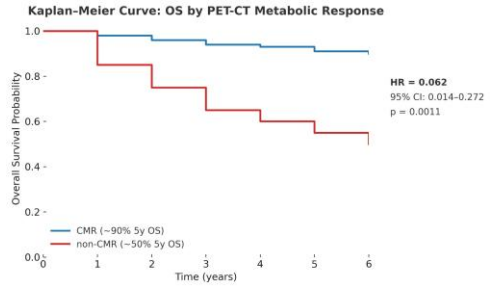
- **Overall Survival (OS):** HR = 0.062 (95% CI 0.014–0.272) p = 0.0011
- **5-Year OS**: CMR: ~95% x Non-CMR: ~30%
- **Multivariate Analysis:** CMR = only independent predictor of survival

Table 1- Clinical and Histopathological Characteristics

Characteristic	Category	N	%
Sex	Female	95	100.0
	Male	0	0.0
Age (years)	Mean ± SD	60.18 ± 13.06	–
	Median (range)	60 (33–83)	–
Histology	Ductal	71	74.7
	Lobular	12	12.6
	Mixed	3	3.2
	NA	6	6.3
Histologic Grade (SBR)	Grade I	6	6.3
	Grade II	58	61.0
	Grade III	18	18.9
	NA	13	13.7
Ki-67 (%)	< 20%	21	22.1
	20–50%	45	47.4
	> 50%	17	17.9
Estrogen Receptor (ER)	Low (<70%)	7	7.4
	Moderate (70–89%)	17	17.9
	High (90–100%)	61	64.2
	NA	10	10.5
Adjuvant Hormone Therapy	Yes	53	55.8
	No	42	44.2
Metastatic Site	Breast	12	12.6
	Bone	11	11.6
	Liver	4	4.2
	Lymph nodes	4	4.2
	Other*	8	8.4
	NA	52	54.7







Discussion

- CDK4/6 inhibitors + endocrine therapy remain the first-line standard for HR+/HER2– metastatic breast cancer according to major guidelines
- Current guidelines do not recommend modifying therapy based solely on early metabolic response, but acknowledge the growing interest in PET-CT as a prognostic tool.
- 18F-FDG PET-CT may offer early and non-invasive prognostic insight, especially where conventional imaging is limited (e.g., bone-only disease).
- In this study, CMR strongly correlated with longer PFS and OS, suggesting PET-CT may help identify patients with particularly favorable outcomes
- Despite the promising association, the evidence is retrospective, and broader adoption requires:
  Prospective validation
  Standardization of timing and criteria (e.g., PERCIST)
  Demonstration that treatment decisions guided by PET-CT improve outcomes
- Clinically, PET-CT may support risk stratification and research-based treatment individualization, but should not yet guide routine therapeutic changes in HR+/HER2– MBC.

Conclusions

Metabolic complete response on PET-CT strongly correlates with improved PFS and OS in HR+/HER2- MBC treated with first-line CDK4/6 inhibitors. PET-CT may serve as a valuable non-invasive prognostic biomarker to guide early treatment decisions in clinical practice.

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