Abemaciclib plus Endocrine Therapy in HR+/HER2− Advanced Beast Cancer: Insights from an Italian Retrospective Observational Study

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OBJECTIVE

- This retrospective study aimed to describe the demographic and clinical characteristics of patients with HR+/HER2− ABC treated with abemaciclib in combination with endocrine therapy (ET), and to evaluate the effectiveness of this treatment in routine clinical practice in Italy.

CONCLUSIONS

- These real-word results are consistent with those from the MONARCH 2 and MONARCH 3 trials, confirming the effectiveness of abemaciclib in combination with ET for patients with HR+/HER2− ABC, across endocrine-resistant (ER) and endocrine-sensitive (ES) settings.
- Two years after treatment initiation, 45.7% of patients remained progression-free and 38.2 % continued therapy, indicating that abemaciclib is an effective and manageable therapeutic option for patients with ABC.
- Efficacy was not compromised for patients who reduced their dose, reinforcing the importance of appropriate use of patient management strategies to improve abemaciclib treatment persistence and clinical outcomes.
- Only 8.0% of patients discontinued treatment due to toxicity after dose reduction, indicating that dose reduction helps to maintains patients on treatment

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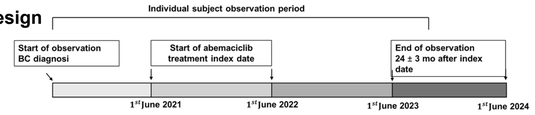
BACKGROUND

- Abemaciclib has been approved in Italy since January 2020 for the treatment of advanced breast cancer (ABC) characterized by hormone receptor-positive and human epidermal growth factor receptor 2-negative (HR+/HER2−) status.
- The drug has demonstrated improvements in both progression-free survival (PFS) and overall survival (OS) in affected women.

METHODS / STUDY DESIGN

- **Study design:** Retrospective observational study conducted in 13 Italian sites.
- **Population:** Patients with HR+/HER2− ABC starting abemaciclib between June 2021 and Jun 2022
- **Observation period:** For each patient, data were collected from initial diagnosis until death, disease progression, loss to follow-up, or up to a maximum of 24 ± 3 months after abemaciclib initiation, whichever occurred first.
- **Primary endpoint:** 24-month rwPFS in real-world setting. rwPFS rate estimated using Kaplan-Meier method.
- **Co-primary endpoints**: Real-world overall response rate (rwORR), real-world clinical benefit rate (rwCBR), real-world time to treatment discontinuation (rwTDT).

Figure 1: Study Design



RESULTS

Patient Characteristics

- N = 199 patients initiated abemaciclib in combination with fulvestrant or an aromatase inhibitor.
- ECOG PS 0–1: 97.5%
- Median age 63.0 years (range: 33.0 – 84.0)

Disease Profile

- Endocrine-sensitive (ES): 43.2% (n=86), including 60 de novo metastatic cases.
- Endocrine-resistant (ER): 44.2% (n= 88)
  - ER 1L: 80.7% (n=71)
  - ER 2L+: 19.3% (n=17)
- Endocrine resistance/sensibility unknown: 12.6% (n=25)
- Most frequent metastatic sites: bone 61.8%, visceral 45.2% (liver involvement in 51.1%), brain metastases 4.0%.

RESULTS

Treatment Patterns

Lines of Therapy with Abemaciclib + ET

- **First-line (1L):** 88.4% (n = 176)
  - **Endocrine profile in first line therapy** :
    - ES: 47.2% (67.4% de novo metastatic, 32.6% relapsed post-adjuvant).
    - ER: 40.3% (31.4% primary, 68.6% secondary)
  - **Combination agent in first line therapy:**
    - ES: 81.9% with aromatase inhibitors
    - ER: >90% with fulvestrant
- **Second-line (2L) and beyond (≥2L):** 11.6% (n = 23)*
- **In the overall population,** the most common combination agent was fulvestrant (51.3%), followed by letrozole (45.7%), among AIs.

Dose Management of Abemaciclib

- Initial dose of 150 mg BID: 92.3% (n=180)
- Dose modifications: 60.8% (n=121)
- Dose reductions: 53.2% (n=106)

Treatment Discontinuation (Table 1)

- 58.3% (n=116) permanently discontinued abemaciclib.
  - Among patients who discontinued abemaciclib, 67.2% (n= 78 out of 116) discontinued the combination agent simultaneously.
- At the end of the observation period (approximately 24 months), 38.2 (n=76) remained on treatment

Time to Treatment Discontinuation: Median rwTDT: 21.2 months (95% CI: 17.1–25.2)

Table 1:Abemaciclib Dose Adjustments and Discontinuation in the Overall Population During The Observation period of 24 ±3 months.

Abemaciclib Dose Management	Patients %
Dose reductions	53.2%
Discontinuation rate	58.3%
Discontinuations due to PD	37.7%
Discontinuations due to AEs	12.6% (8.0% after dose reduction)

*Detailed data stratified by ES and ER status, as well as combination therapy for ≥2L treatment, are not reported due to the limited sample size

Effectiveness outcomes

Median study observation period was 23.6 months (IQR: 21.2–24.1; range: 0–26.7

Table 2: Effectiveness Endpoints at 24 Months in Patients with HR+/HER2− ABC Treated with Abemaciclib + ET.

Effectiveness Endpoints in the Overall Population	
Endpoints	Results
rwPFS at 24 months (%)	45.7
rwPFS (months)	22.2 (95% CI: 19.2-25.3)
rwPFS (months) after dose reduction	26.3 (95% CI: 21.6–31.0)
rwORR (%)	46.1 (95% CI: 38.6-53.7)
rwCBR (%)	68.5 (95% CI: 61.2-75.3)

Figure 2: Progression Free Survival Curves in Patients with HR+/HER2− ABC Treated with Abemaciclib + ET, Stratified by ES and ER

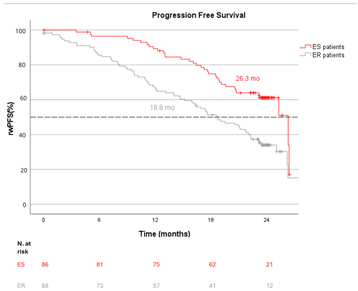


Table 3. Median rwPFS and rwPFS rate at Last Observation Timepoint (24 ±3 months) by ES and ER in Patients Treated with Abemaciclib + ET.

rwPFS by ES/ER		
rwPFS	ES	ER
Median rwPFS (months)*	26.3 (95% CI: 22.9-29.8)	18.8 (95% CI: 14.9-22.5)
rwPFS rate at 24 mo (N events)	61.2% (32)	34.0% (59)

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