Retrospective study evaluating eligibility, treatment patterns, and clinicopathologic factors associated with adjuvant abemaciclib use in patients with high-risk estrogen receptor-positive (ER+) HER2-negative (HER2-) early breast cancer (EBC)

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Introduction

- 2 years of adjuvant abemaciclib (adj abema) and endocrine therapy (ET) is standard for high-risk ER+HER2- EBC[1-6].
- With a median follow-up of 76.2 months, the latest monarchE (NCT03155997) analysis documented[7]:
  - **Improved overall survival** (OS):
    -15.8% reduction in the risk of death (**HR = 0.842**; 95% CI, 0.722–0.981; P = .027)
    -7-yr OS: 86.8% with abema-ET vs 85.0% with ET (Δ 1.8%)
  - **Sustained** invasive disease-free survival (**IDFS**) **improvement**:
    -**HR = 0.734**; 95% CI, 0.657–0.820; P<.0001
    -7-yr IDFS: 77.4% with abema-ET vs 70.9% with ET (Δ 6.5%)
  - **Sustained** distant relapse-free survival (**DRFS**) **improvement**:
    -**HR = 0.746**; 95% CI, 0.662–0.840; P<.0001
    -7-year DRFS: 80.0% vs 74.9% (absolute difference = 5.1%)
- Although eligibility rates are known[8], real-world use remains unclear.
- Therefore, we sought to evaluate the **treatment gap** between eligible and treated patients and their clinicopathologic differences.

Methods

- Patients with ER+HER2- EBC eligible for adj abema per monarchE cohort 1 criteria (≥4 positive nodes, or 1–3 nodes plus G3 or tumor ≥5 cm), who had surgery between the date of the Food and Drug Administration (FDA) approval (10/12/2021) and the data lock (04/15/2024), were retrospectively identified from a single institution database.
- Patients were classified as EAT (**eligible and treated**) if an adj abema start date was recorded, or ENT (**eligible, not treated**) if no abema initiation was documented.
- Clinicopathologic features were compared using chi-square or Wilcoxon tests (p<.05 significant).

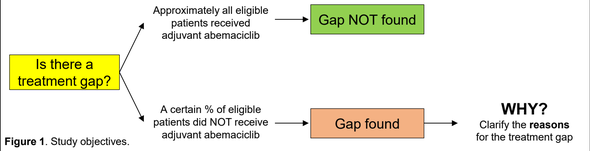


Figure 1. Study objectives.

Results: patient population and treatment gap

129 pts were identified; 78 (**60.5%**) received adj abema, 51 (**39.5%**) did not. Selected clinicopathologic characteristics are shown in **Table 1.**

Characteristic	Eligible, not treated (n = 51)	Eligible, treated (n = 78)	Total (n = 129)	P value
Age (median, range)	65.5 (30.3 - 82.7)	50.8 (31.6 - 77.2)	58.2 (30.3 - 82.7)	**< 0.001**
g*BRCA1-2* mut., n. (%)	4 (7.8)	4 (5.1)	8 (6.2)	0.712
cT category, n. (%)				0.219
cT1	19 (37.3)	24 (30.8)	43 (33.3)	
cT2	19 (37.3)	33 (42.3)	52 (40.3)	
cT3	7 (13.7)	17 (21.8)	24 (18.6)	
cT4	1 (2.0)	0 (0.0)	1 (0.8)	
cN category, n. (%)				**0.004**
cN0	40 (78.4)	40 (51.3)	80 (62.0)	
cN+	11 (21.6)	36 (46.2)	47 (36.4)	
Histology, n. (%)				**0.040**
Invasive ductal	40 (78.4)	41 (52.6)	81 (62.8)	
Invasive lobular	6 (11.8)	21 (26.9)	27 (20.9)	
Mixed	4 (7.8)	10 (12.8)	14 (10.9)	
Grade, n. (%)				**< 0.001**
G1, well differentiated	0 (0)	8 (10.3)	8 (6.2)	
G2, moderately differentiated	15 (29.4)	42 (53.8)	57 (44.2)	
G3, poorly differentiated	35 (68.6)	28 (35.9)	63 (48.8)	
Unknown	1 (2.0)	0 (0)	1 (0.8)	
ER status, n. (%)				ND
ER ≥ 10%	51 (100.0)	78 (100.0)	129 (100.0)	
Management of primary tumor, n. (%)				ND
Upfront Surgery	48 (94.1%)	78 (100.0%)	126 (97.7%)	
Unknown	3 (5.9%)	0 (0.0%)	3 (2.3%)	
pT category, n. (%)				0.129
pT1	16 (31.4)	13 (16.7)	29 (22.5)	
pT2	21 (41.2)	33 (42.3)	54 (41.9)	
pT3	13 (25.5)	30 (38.5)	43 (33.3)	
pT4	0 (0.0)	1 (1.3)	1 (0.8)	
pN category, n. (%)				**< 0.001**
pN1	40 (78.4)	35 (44.9)	75 (58.1)	
pN2	9 (17.6)	30 (38.5)	39 (30.2)	
pN3	2 (3.9)	13 (16.7)	15 (11.6)	
Adjuvant systemic treatment, n. (%)				0.149
Adjuvant chemotherapy	4 (7.8)	0 (0.0)	4 (3.1)	
Adjuvant ET	22 (43.1)	31 (39.7)	53 (41.1)	
Both	22 (43.1)	47 (60.3)	69 (53.5)	
Neither	3 (5.9)	0 (0.0)	3 (2.3)	
Adjuvant olaparib, n. (%)	1 (2.0)	3 (3.8)	4 (3.1)	0.657
Adjuvant ribociclib, n. (%)	3 (4.3)	0 (0.0)	3 (2.3)	0.120
Surgery year, n. (%)				0.426
2021	4 (7.8)	7 (9.0)	11 (8.5)	
2022	20 (39.2)	34 (43.6)	54 (41.9)	
2023	18 (35.3)	31 (39.7)	49 (38.0)	
2024	9 (17.6)	6 (7.7)	15 (11.6)	

Table 1. Patient characteristics. ER, estrogen receptor; gBRCA, germline BReast CAncer gene; ND , not done.

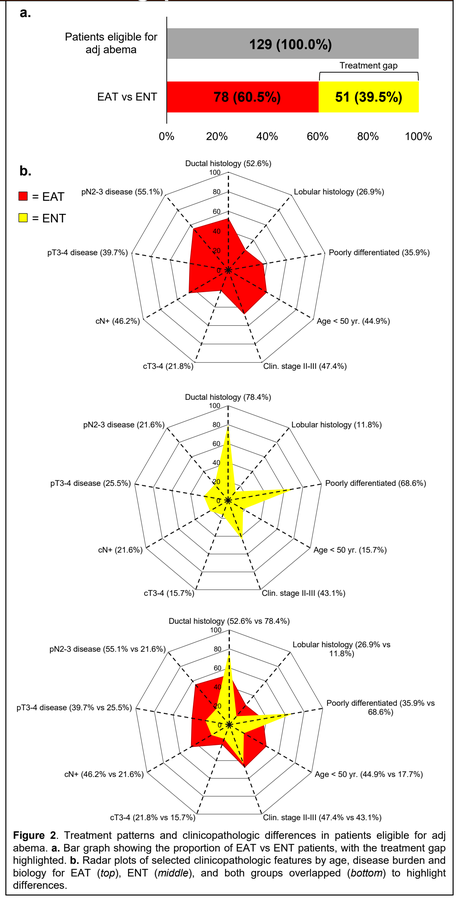


Figure 2. Treatment patterns and clinicopathologic differences in patients eligible for adj abema. **a.** Bar graph showing the proportion of EAT vs ENT patients, with the treatment gap highlighted. **b.** Radar plots of selected clinicopathologic features by age, disease burden and biology for EAT (*top*), ENT (*middle*), and both groups overlapped (*bottom*) to highlight differences.

Results: reasons for the treatment gap

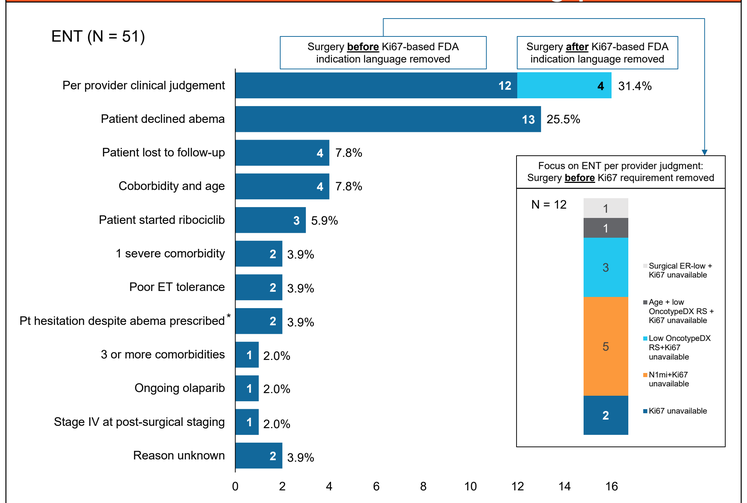


Figure 3. **Reasons for not receiving adj abema**. Bar graph showing the main reasons ENT patients did not receive adj abema. The inset bar graph (*right*) highlights ENT patients not treated per provider judgment when surgery was performed before removal of the Ki67-based FDA requirement. *Patient hesitation refers to cases where adj abema was prescribed by the time of data lock but not started, as the patient requested more time to consider treatment due to personal concerns.

Discussion and Conclusion

- A **real-world treatment gap** was observed between patients EAT and ENT.
- Factors associated with non-initiation of adj abema included:
  - Older age
  - Lower nodal burden
  - Patient preference
  - Comorbidities
  - Surgery prior to removal of Ki67-based FDA requirement
- **Clinical considerations**:
  - Updated monarchE data demonstrate OS benefit with adj abema[7].
  - Exploratory analyses from monarchE indicate no loss of efficacy with protocol-guided dose reductions[9] and the phase II TRADE trial showed dose escalation may improve tolerability without compromising efficacy[10].
- **Take-home message**: Emerging data should encourage clinicians to initiate adj abema in eligible high-risk patients and work toward reducing treatment gaps in routine practice.

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Acknowledgments

The authors would like to thank the patients and their families for generously contributing to this research. The authors also acknowledge Eli Lilly and Company for their funding support.

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