PS3-07-12 (1963) The CONCISE Study : A Pan-UK Real-World Audit of Adjuvant Abemaciclib Use in High-Risk Early Breast Cancer

The CONCISE
A Pan-UK Real-World Audit of Adjuvant Abemaciclib Use in High-Risk Early Breast Cancer

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B. Baraka[1], A. Ghose[3], H. Abdallah[5], A. Maniam[4], Y. Owoseni2, A. Konstantis14, S. Horne[6], A. Nazir[6], L. Mooney[7], F. Nazeer[8], N.Atsumi[4], L. McAvan[9], M. Abraham[10], E. Bean[11], D. Morgan[12], G. Langford[12], E. Morris[13], R. Muhammad[14], E. Daniels[15], R. Pravinkumar[16], S.Mohammed[17], S. Raza[18], C. Blair[19], R. Khan[20], M. Tsalic[6], R. Kussaibati[6], R. Douglas[7], K. Panagiotis[21], S. Waters[12], J. Smith[11], E.Papadimitraki[13], C. Michie[16], C. Wilson[20], O. Ayodele[2];

1 Nottingham University Hospitals NHS Trust, 2 University Hospitals of Leicester NHS Trust, 3 Barts Cancer Centre, 4 Portsmouth Hospitals University NHS Trust, 5 Cambridge Clinical Research Centre, Cambridge University Hospitals NHS Foundation Trust, 6 University Hospitals Birmingham NHS Foundation Trust, 7 Northern Ireland Cancer Centre, 8 Royal Surrey Cancer Centre, Royal Surrey NHS Foundation Trust, 9 University Hospitals Coventry and Warwickshire NHS Trust, 10 Dorset Cancer Centre, University Hospitals Dorset NHS Foundation Trust, 11 Northern Centre for Cancer Care, Newcastle upon Tyne Hospitals NHS Foundation Trust, 12 Velindre Cancer Centre, Velindre University NHS Trust, 13 University College London Hospitals NHS Foundation Trust, 14 Princess Alexandra Hospital NHS Trust, 15 Dyson Cancer Centre, Royal United Hospitals Bath NHS Foundation Trust, 16 Edinburgh Cancer Centre, 17 Great Western Hospitals NHS Foundation Trust, 18 Hull University Teaching Hospitals NHS Trust, 19 University Hospitals of Bristol and Weston NHS Trust, 20 The Christie NHS Foundation Trust, 21 Frimley Health NHS Foundation Trust.

Background

Breast cancer is the most common cancer in the UK, representing about 15% of all new diagnoses and around 56,400 cases annually in women[1]. Patients with hormone receptor–positive (HR+), HER2-negative (HER2–), node-positive early breast cancer (EBC) have a high recurrence risk—up to 30% at five years[2]—supporting the need for treatment intensification.

Adjuvant Abemaciclib (AA) was approved in the UK in July 2022 following the MonarchE trial results. There have been some local and regional experience audits in the UK (East Midlands and Portsmouth) to date with variable efficacy and tolerability rates.

This study aims to record the UK real-world experience focusing on tolerability and efficacy of abemaciclib in patients with HR+, HER2-, node +, high-risk EBC compared to the MonarchE trial with evaluation of treatment toxicities, discontinuation, and dose reduction rates.

Introduction

The MonarchE trial presented/introduced Abemaciclib as a new standard of care for patients with high-risk HR+/HER2– early breast cancer. However, experiences in routine clinical practice may differ from trial settings, especially when it comes to treatment tolerability and adherence.

CONCISE study aims to capture a real-world picture of how Abemaciclib is being used across the UK, focusing on how well patients tolerate the treatment and how outcomes compare with those seen in phase 3 trial.

Methods

This multicentre, retrospective study included patients ≥18 years with HR+/HER2– EBC and high-risk features (≥4 positive axillary lymph nodes, or 1–3 nodes with tumour ≥5 cm or grade 3) treated with AA between April 2019 and April 2025. Patients not treated with AA or received it in ABC setting were excluded. Data collected included demographics, disease and treatment characteristics, and outcomes. Clinical information sourced from the multidisciplinary team (MDT) records at each participating site. The primary aim was to evaluate the real-world use of AA. Secondary aims included toxicity, dose reduction, discontinuation, and correlation with age, endocrine therapy type, and prior chemotherapy.

Results

A total of 1,028 patients were included; 98.5% were female and 82.8% Caucasian, with a median age of 54 years. Majority were post-menopausal (56.5%). Most patients had stage II (57.5%) and grade 2 (52.6%) tumours. Lymph node involvement was present in 95% (median = 5 nodes). Chemotherapy was administered in 88.4% (neoadjuvant 16.3%, adjuvant 72.1%). Endocrine backbone(AI, 86.2% vs Tamoxifen 13.8%).The median duration of AA was 15.5 months. At the time of analysis, 25.3% had completed the full 2-year course with 74.7% remaining on treatment. AA was discontinued in 15.9% due to toxicity and 3.8% due to disease progression (median discontinuation time: 10.3 months). Single dose level reduction occurred in 64.6%, with further reduction in25.4%.Common toxicities included diarrhoea (76.4%, ≥Grade 2 in 40%), neutropenia (43.4%, ≥Grade 2 in 61.1%), anaemia (33.2%, ≥Grade 2 in 11.7%), thrombocytopenia (10%, ≥Grade 2 in 6.8%)and transaminitis (17.2%, ≥Grade 2 in 25%). There were 21 deaths (2.0%) of which 16 were cancer-related and one attributed to treatment-related renal failure.

Results (cont'd)

Table 1.Baseline Demographics&Disease Characteristics (n = 1,028)

Characteristic	n (%) or Median (Range)
Female sex	98.5%
Caucasian ethnicity	82.8%
Median age (years)	54
Post-menopausal	56.5%
Tumour stage	
- Stage II	57.5%
- Stage III	42.5%
Tumour grade	
- Grade 2	52.6%
- Grade 3	47.4%
Lymph node involvement	95%
Median no. of positive nodes	5

Discussion

Two years of AA in combination with endocrine therapy (ET) is an internationally approved standard of care with (NCCN) category 1[3] and (ESMO) Magnitude of Clinical Benefit Scale score A[4] recommendation for patients with HR+, HER2–, node-positive EBC at high risk of recurrence. With a median follow-up of 42 months, Abemaciclib demonstrated a persistent benefit in invasive disease-free survival (IDFS) and (DRFS) beyond the 2-year treatment period, with all patients off treatment [5-7].

The observed toxicity profile and treatment modifications in this real-world cohort suggest that patients outside of trial settings may face greater challenges in tolerating AA. Factors such as comorbidities, age, and variations in supportive care may influence adherence, highlighting a need for further exploration into predictors of treatment tolerability and outcomes.

Table 2. Treatment Exposure, Toxicities, and Outcomes

Parameter	Value / n (%)
Chemotherapy administered	88.4%
- Neoadjuvant	16.3%
- Adjuvant	72.1%
Endocrine backbone	
- Aromatase inhibitor (AI)	86.2%
- Tamoxifen	13.8%
Median duration of AA	15.5 months
Completed 2-year AA course	25.3%
Remaining on treatment	74.7%
Discontinuation	
- Due to toxicity	15.9%
- Due to disease progression	3.8%
Median time to discontinuation	10.3 months
Dose reductions	
- Single reduction	64.6%
- Further reduction	25.4%
Common toxicities	
- Diarrhoea	76.4% (≥Grade 2: 40%)
- Neutropenia	43.4% (≥Grade 2: 61.1%)
- Anaemia	33.2% (≥Grade 2: 11.7%)
- Thrombocytopenia	10.0% (≥Grade 2: 6.8%)
- Transaminitis	17.2% (≥Grade 2: 25%)
Deaths	21 (2.0%)
- Cancer-related	16
- Treatment-related (renal failure)	1

Conclusions

AA remains an effective adjuvant option in high-risk EBC, but managing side effects is key to optimizing adherence and outcomes in routine clinical settings.

Contact
Dr Olubukola Ayodele
University Hospitals of Leicester NHS Trust
Email: olubukola.ayodele@nhs.net

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