PS2-02-12 (2362): Tolerability of Adjuvant Abemaciclib in Older Adults with High-Risk Early Breast Cancer: Multicentre UK Real-World Data from the CONCISE Study

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

SAN ANTONIO BREAST CANCER SYMPOSIUM®
UT Health San Antonio Mays Cancer Center | AACR American Association for Cancer Research

H. Abdallah[1], O. Ayodele[2], A. Ghose[3], Y. Owoseni[2], A. Maniam[4], B. Baraka[5], S. Horne[6], A. Nazir[6], L. Mooney[7], F. Nazeer[8], N.Atsumi[4], L. McAvan[9], M. Abraham[10], E. Bean11, 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], A. Konstantis[14];

1 Cambridge Clinical Research Centre, Cambridge University Hospitals NHS Foundation Trust, 2 University Hospitals of Leicester NHS Trust, 3 Barts Cancer Centre, 4 Portsmouth Hospitals University NHS Trust, 5 Nottingham University Hospitals NHS 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 malignancy in the UK, accounting for around 15% of all new cancer diagnoses, with approximately 56,800 new cases annually [(1)]. Most patients present with early-stage disease, yet recurrence remains a significant risk despite optimal therapy. Endocrine therapy (ET) is the cornerstone of adjuvant treatment for hormone receptor-positive (HR+), HER2-negative breast cancer, but long-term relapse can occur.

A meta-analysis of over 62,000 patients showed recurrence rates of 19–41% within 5–20 years after ET, largely influenced by nodal status and tumour size [(2)].

Introduction

The introduction of CDK4/6 inhibitors has transformed the management of metastatic HR+ breast cancer. Abemaciclib demonstrated a significant improvement in invasive disease-free survival (IDFS) in the monarchE trial [(3,4)] for patients with high-risk, node-positive, HR+, HER2-negative early breast cancer (EBC). However, only 15.6% of patients in monarchE were aged ≥65, and no dedicated geriatric safety analysis was performed.

Managing older adults with EBC is challenging due to comorbidities reduced physiological reserve, and polypharmacy.

On this basis, NICE approved adjuvant Abemaciclib (AA) with ET in July 2022 for high-risk, node-positive, HR+, HER2-negative EBC [(5)]. Yet, randomised trials such as monarchE may not fully reflect real-world practice. There is limited evidence on the safety, tolerability, and adherence of AA in older patients, highlighting the need for real-world evaluation.

Aims and Methods

Aims

To evaluate the real-world use, safety, and tolerability of AA with ET across UK centres of a dedicated subgroup analyses in geriatric cancer patients (≥ 65 years old) within the CONCISE study.

Methods

The CONCISE study is a retrospective, multicentre audit of UK practice across 21 centres, including patients treated with AA from July 2022 to April 2025. Data were collected using the Ledidi platform and analysed using descriptive statistics in Jamovi. Key outcomes include treatment duration, dose modifications and adverse events (AEs), stratified by two subgroups: Cohort 1 (age 65-75) and Cohort 2 (>75). Group comparisons were performed using chi-squared and t-test.

Results

Of 1,026 patients, 215 (21%) were aged ≥65: 152 in Cohort 1 (median age 69) and 63 in Cohort 2 (median age 78). Most were female (96.3%) and Caucasian (88.4%). Stage II disease was most common (56.7%), with grade 2 tumours (57.8%) and nodal involvement (72.8%).

Chemotherapy use differed by age: in Cohort 1, 68% received adjuvant chemotherapy and 11% neoadjuvant chemotherapy; in Cohort 2, only 31% received adjuvant chemotherapy and one patient had neoadjuvant chemotherapy.

Median AA duration was 12.6 months in Cohort 1 vs. 8.3 months in Cohort 2 (p=0.028). Discontinuation of the treatment due to toxicity was significantly more common in Cohort 2 (79%) than in Cohort 1 (49%) [p=0.002]. Treatment completion (24 months) was achieved in 47% (Cohort 1) and 21% (Cohort 2). At data cut-of, 53% and 40% of patients remained on treatment in Cohorts 1 and 2, respectively. Disease progression occurred in 4% (Cohort 1) and 0% (Cohort 2).

Results (cont'd)

One-level dose reductions were required in 70% (Cohort 1) and 76% (Cohort 2) [p=0.29], while further reductions were needed in 34% and 38% [p=0.55], respectively. The most frequent AEs were diarrhoea (75% vs. 71.4%), anaemia (40% in both), and neutropenia (34.2% vs. 30.2%), with grade ≥2 rates comparable between groups.

Table 1. Adverse events (AE) of Abemaciclib according to the age groups

	<65, N= 811			Group 1 (65-75) N= 152			Group 2 (>75) N= 63		
	All G % ,(n)	≥G2 % ,(n)	≥G3% ,(n)	All G % ,(n)	≥G2 % ,(n)	≥G3% ,(n)	All G % ,(n)	≥G2 % ,(n)	≥G3% ,(n)
Diarrhoea	77.1%, (625)	29%, (235)	4.9%, (40)	75% (114)	36.8% (56)	9.2%, (14)	71.4% (45)	36.5% (23)	7.9%, (5)
Anaemia	31.4%, (255)	3.1%, (25)	0.2%, (2)	40% (61)	6.6% (10)	0%, (0)	40%, (25)	8%,(5)	1.6%, (1)
Neutropenia	46.1%, (374)	28.6%, (232)	9.4%, (76)	34.2% (52)	19.7%, (30)	3.9%, (6)	30.2%, (19)	16%, (10)	3.2%, (2)
Thrombocytopenia	8.5%, (69)	0.5%, (4)	0.1%, (1)	13.8% (21)	1.3%, (2)	1.3%, (2)	20.6%, (13)	1.6%, (1)	0%, (0)
Elevated ALT	16.3%, (132)	2.5%, (20)	0.1%, (1)	20.4% (31)	7.2%, (11)	3.3%, (5)	20.6%, (13)	6.4%, (4)	4.8%, (3)
AKI	20%, (162)	1.7%, (14)	0.1%, (1) (G5)	28.3%, (43)	5.3%, (8)	1.3%, (2)	27%, (17)	7.9%, (5)	1.6%, (1)

Conclusions

In this large UK real-world cohort, older adults with high-risk EBC experienced similar AE profiles to younger counterparts, but with numerically higher discontinuation rates, particularly in those aged >75. Dose reductions were common across both age groups. These findings underscore the importance of careful patient selection, supportive care, and geriatric assessment when offering AA in routine clinical practice.

SABCS Arti Hurria Travel Award in Geriatric Oncology Award

Contact
Dr Hossameldin Abdallah
Cambridge Clinical Research Centre, Cambridge University Hospitals NHS Foundation Trust
Email: Hossameldin.Abdallah@nhs.net

References

1. Cancer Research UK. Breast cancer statistics [Internet]. London: Cancer Research UK; 2022 [cited 2025 Nov 08]. Available from: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer
2. Pan H, Gray R, Braybrooke J, Davies C, Taylor C, McGale P, et al. 20-Year risks of breast-cancer recurrence after stopping endocrine therapy at 5 years. *N Engl J Med*. 2017;377(19):1836–46.
3. Johnston SRD, Harbeck N, Hegg R, Toi M, Martin M, Shao Z, et al. Abemaciclib combined with endocrine therapy for the adjuvant treatment of HR+, HER2–, node-positive, high-risk, early breast cancer (monarchE). *J Clin Oncol*. 2020;38(34):3987–98.
4. Johnston SRD, Toi M, O'Shaughnessy J, Rastogi P, Huober J, Campone M, et al. Abemaciclib with endocrine therapy in high-risk early breast cancer: results from the monarchE study 4-year update. *Ann Oncol*. 2022;33(10):1059–73.
5. National Institute for Health and Care Excellence (NICE). Abemaciclib with endocrine therapy for treating early breast cancer [TA761]. London: NICE; 2022.

This presentation is the intellectual property of the author/presenter. Contact them at Hossameldin.Abdallah@nhs.net for permission to reprint and/or distribute.

© Poster Template by Genigraphics® 1.800.790.4001 www.genigraphics.com