VANDERBILT HEALTH | Specialty Pharmacy

REAL-WORLD DOSING OF ABEMACICLIB: ONE-YEAR EVALUATION OF OFF-LABEL DOSING AND MODIFICATIONS

Stephanie G. White, PharmD[1], CSP | Jared Crumb, PharmD[1] | Christopher Rodriguez, PharmD Candidate[2] | Josh DeClercq, MS[3] | Chelsea P. Renfro, PharmD[1]

[1]Vanderbilt Specialty Pharmacy, Vanderbilt University Medical Center | [2]Vanderbilt Specialty Pharmacy Student Research Program | [3]Department of Biostatistics, Vanderbilt University Medical Center

PURPOSE

To describe initial abemaciclib dose, dose modifications, and time to modification for patients initiating a dose of abemaciclib lower than the FDA-recommended starting dose of 150mg twice daily.

STUDY DESIGN

Single-center, retrospective cohort analysis of data collected from an electronic medical record and specialty pharmacy management system. Patients were followed for 12 months from the initiation of abemaciclib.

STUDY POPULATION

Inclusion criteria:

Starting abemaciclib at an initial dose less than 150mg twice daily for HR+, HER2- early high-risk and metastatic breast cancer between 10/12/2021 and 8/31/2023 at one academic medical center

Exclusion criteria:

Evidence of any other primary malignancy; documented prior use of any cyclin-dependent kinase (CDK) 4/6 inhibitor; participation in a clinical trial

OUTCOMES

- Initial doses
- Number of dose modifications (increases or decreases)
- Time to modification
- Common adverse effects (AE)

Figure 1. Study Timeline

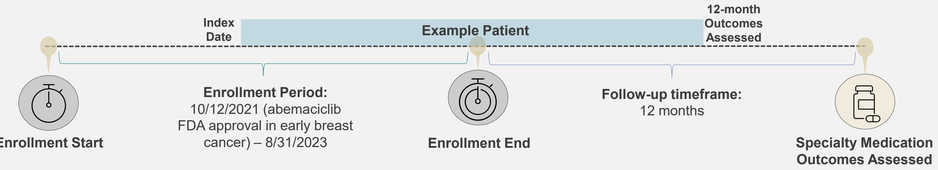
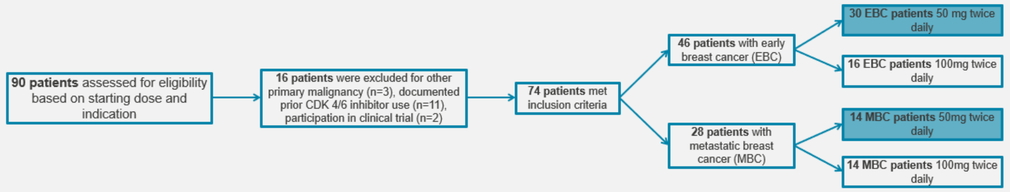


Figure 2. Study Attrition



HIGHLIGHTS

- Dose modifications were common during the first twelve months on therapy, with 96% (n=69/72) of patients with a dose modification having at least one dose increase and 47% (n=34/72) having at least one dose decrease.
- Future analysis will describe dosing patterns, treatment holds, and discontinuations up to 2 years from treatment initiation.

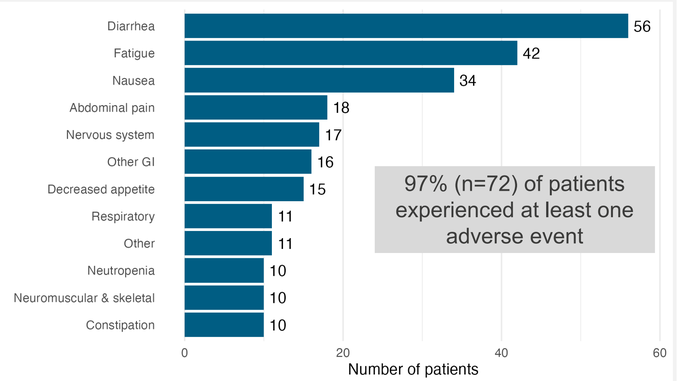
RESULTS

Table 1. Baseline Demographics

Characteristic	Breast Cancer Indication: Early, N = 46 n (%)	Metastatic, N = 28 n (%)	Overall, N = 74 n (%)
Age, years-median (IQR)	55 (43-66)	58 (50-69)	57 (46-67)
Sex, female	46 (100)	28 (100)	74 (100)
Race			
White	38 (83)	22 (77)	60 (81)
Black	3 (6)	4 (14)	7 (9)
Asian	1 (2)	1 (4)	2 (3)
Other*	4 (9)	1 (4)	5 (7)
ECOG Performance Satus prior to start			
0	13 (28)	7 (25)	20 (27)
1	33 (72)	18 (64)	51 (69)
2	0 (0)	3 (11)	3 (4)
CCI, median (IQR)	4 (2-5)	7 (6-8)	4.5 (3-7)
Pre-existing GI condition, yes	26 (57)	16 (57)	42 (57)
Menopausal status			
Pre-menopause	17 (37)	9 (32)	26 (35)
Post-menopause	26 (57)	19 (68)	45 (61)
Peri-meonopause	2 (4)	0 (0)	2 (3)
Undocumented	1 (2)	0 (0)	1 (1)
Previous treatment, yes	45 (98)	21 (75)	66 (89)

*Other: American Indian/Alaska Native, Hispanic/Latino(a), Middle Eastern or North African, Unknown

Figure 3. Most Common Adverse Events[a]



[a]Display of AE experienced in ≥10 patients, not all categories are displayed

Figure 4. Dose Modification and Time to Modification

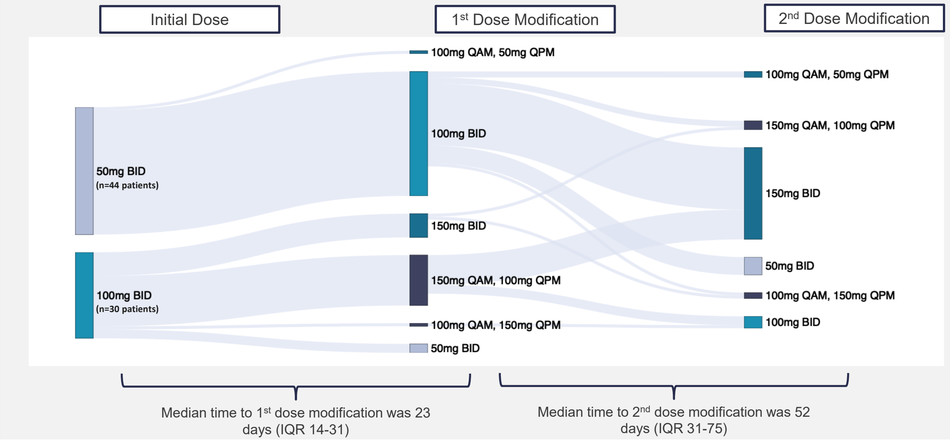
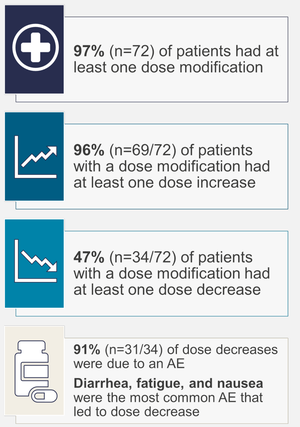


Figure 5. Summary of Modifications



Abbreviations: FDA = Food and Drug Administration; HR = hormone receptors; HER = human epidermal growth factor receptor; CCI = Charlson Comorbidity Index; GI = gastrointestinal; BID = twice daily; QAM = once daily in the morning; QPM = once daily in the evening; IQR = interquartile range

Acknowledgement: Autumn D. Zuckerman, PharmD, BCPS, CSP; Brooke D. Looney, CSP; Leena Choi, PhD