Abstract Number: 4CPS-034

L01- ANTINEOPLASTIC AGENTS

Real-world safety and tolerability in patients treated with Abemaciclib and endocrine therapy: a retrospective observational study

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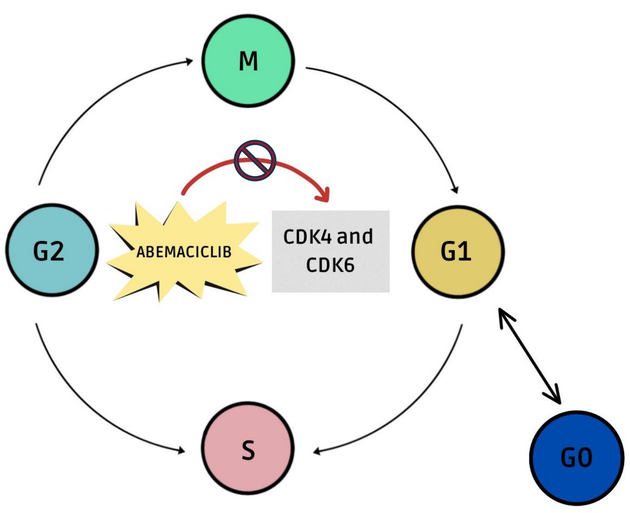
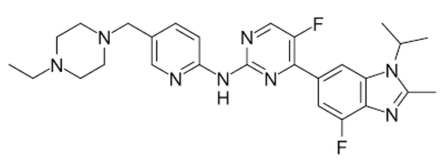
Background and importance

Abemaciclib is a selective CDK4/6 inhibitor and it is authorized in combination with endocrine therapy (ET). Its use was associated with superior outcomes compared to ET alone in women with HR+/HER2- metastatic breast cancer (mBC), providing a new standard of care for this patient population.





Aim and Objectives

The aim of the study was to evaluate the safety profile of abemaciclib, the severity and types of toxicities and the factors leading to discontinuation of treatment.

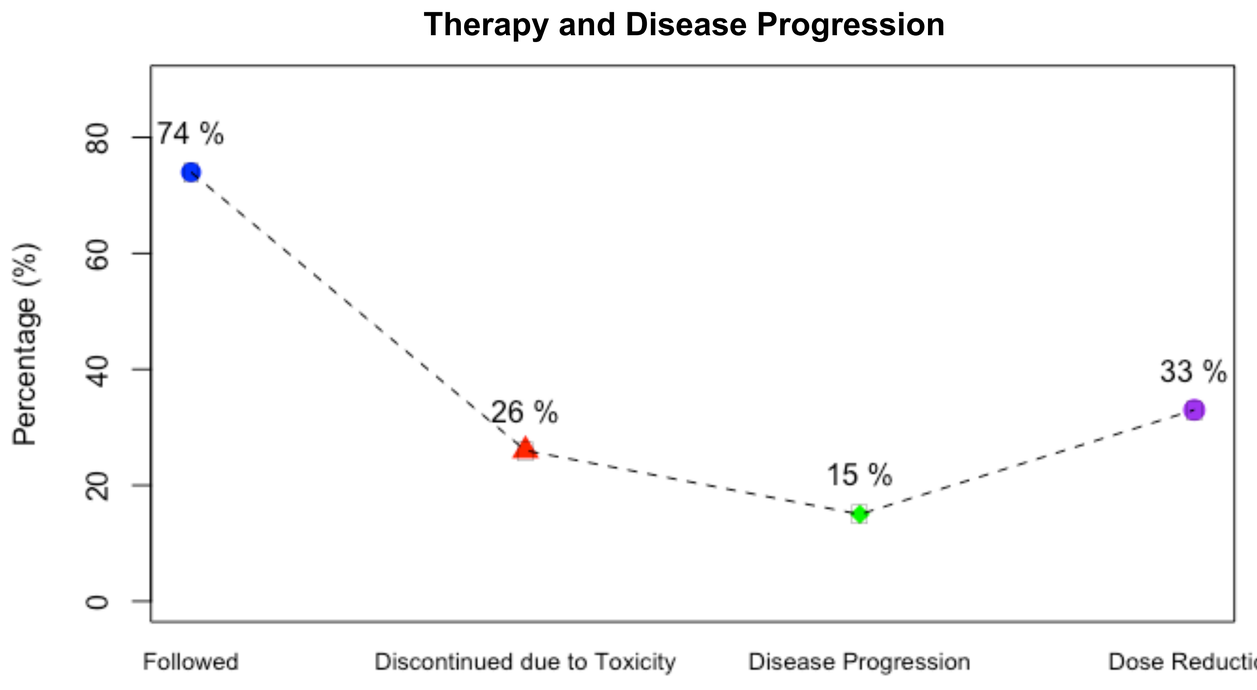
Material and methods

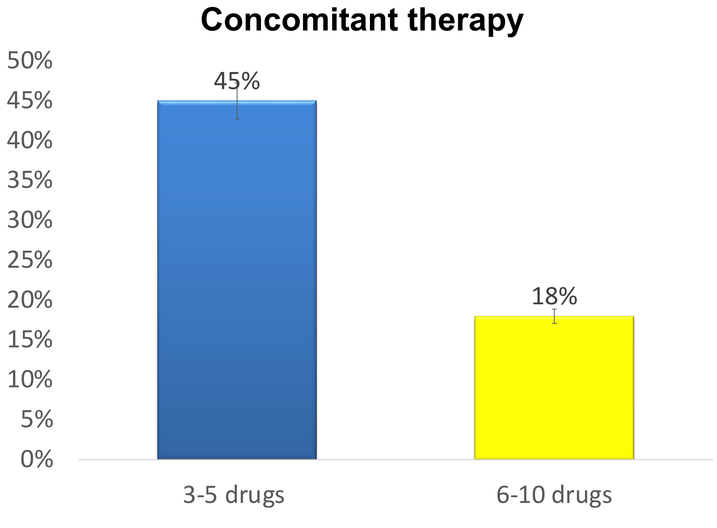
A retrospective, observational, descriptive study was carried out at a tertiary care hospital. Women aged >18 years with HR+/HER2- mBC receiving abemaciclib in combination with ET between June 2019 and July 2022 were included. Variables: age, hormonal therapy in combination, concomitant therapies, duration of treatments, adverse events (AEs), dose adjustment and treatment discontinuation. AEs were classified according to CTCAE. Clinical and analytical data were collected from electronic clinical records.

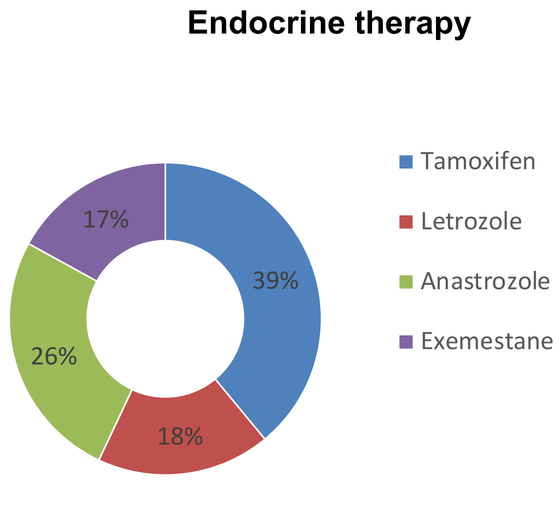
Results

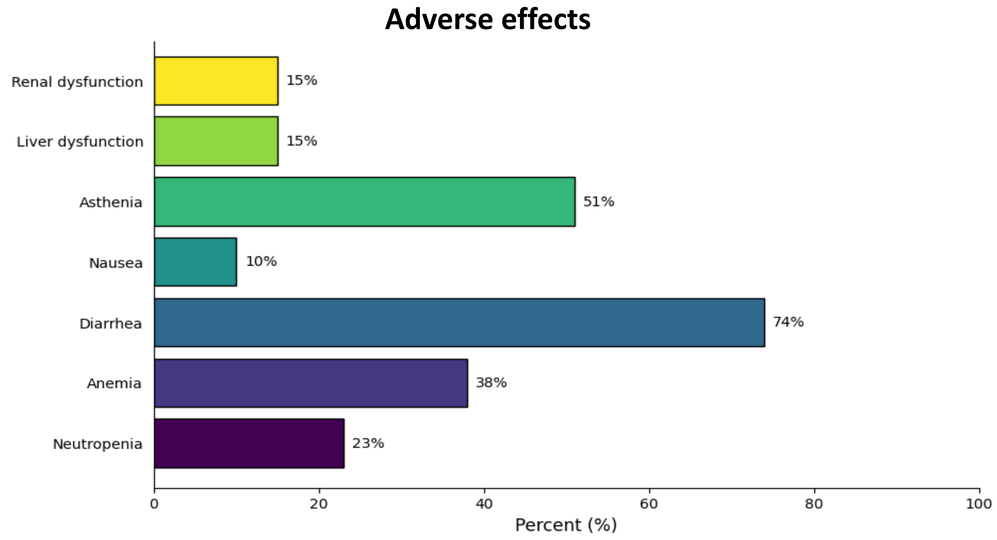
39 patients were included, median age was 68 (56-76) years. Abemaciclib was administered in combination with tamoxifen (39%), letrozole (18%), anastrozole (26%) and exemestane (17%).
67% of patients reported at least one comorbidity. 45% of patients used 3-5 drugs and 18% used 6-10 drugs as concomitant therapy. 74.4% followed for the whole duration of the study, while 25.6% discontinued therapy due to toxicity. Disease progression was experienced by 15.4% of patients and dose reduction was achieved in 33% of cases.
AEs occurred in 89.7% of patients, of these 74% were mild to moderate (G1-G2) and 26% were severe (G3-G4). The most common AEs reported were neutropenia in 23% of patients(55.5% G3-G4), anaemia 38.5%, diarrhea 74.3% (only one severe), nausea 10.2%, asthenia 51.3%(10% G4), liver dysfunction 15.4%(33.3% G3-G4), renal dysfunction 15.4%.

Multivariate regression analysis showed an increase of serious AEs associated with the use of abemaciclib in combination with 3-5 concomitant therapies ($p<0.001$) and 6-10 concomitant treatments ($p=0.018$).









Conclusion and relevance

Our data showed that the concomitant use of polytherapy is associated with higher toxicity in patients affected by mBC treated with abemaciclib+ET. However, this combination demonstrated an acceptable safe and tolerable profile. Most AEs were reversible and well controlled with concomitant medications and/or dose modifications, according to the reported toxicity data from the clinical trials.

Contacts

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