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PLAIN LANGUAGE SUMMARY

Adjuvant abemaciclib in early-stage breast cancer: hypothesis-generating safety observations from a real-world cohort study

Federico Sottotetti[1], Simone Figini[2], Giulia Gambini[3], Gianpiero Rizzo[2], Giulia Chessa[1], Erica Quaquarini[2], Raffaella Palumbo[1], Lorenzo Perrone[2], Barbara Tagliaferri[1], Alessandra Ferrari[1], Catherine Klersy[3], Paolo Pedrazzoli[2,4], Laura Deborah Locati[1,4], Angioletta Lasagna[2]

[1]Medical Oncology Unit, Istituti Clinici Scientifici Maugeri IRCCS, Pavia, Italy; [2]Medical Oncology Unit, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy; [3]Biostatistics and Clinical Trial Center, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy; [4]Department of Internal Medicine and Medical Therapy, University of Pavia, Pavia, Italy

Article available at: https://doi.org/10.7573/dic.2025-7-5

Background of the study

Breast cancer is increasingly diagnosed in older women (aged ≥70 years), a group of patients not often included in clinical trials. Treatment guidelines, based mainly on younger patients, do not fully account for the complex needs of older people, like the presence of multiple health conditions (comorbidities) and overall frailty.

Hormone receptor-positive (HR^+) metastatic breast cancer is often treated with endocrine therapy, but resistance is common. CDK4/6 inhibitors (like palbociclib, ribociclib and abemaciclib) combined with hormone therapy have become standard for advanced HR^+/HER^- breast cancer, helping to overcome resistance. Real-world data suggests these inhibitors are generally well-tolerated across all ages in the advanced setting.

Recently, CDK4/6 inhibitors have also been shown to improve outcomes in the adjuvant setting (treatment given after initial therapy) for HR^+/HER^- early-stage breast cancer, but limited data exists specifically for older patients.

Study goal and design

This retrospective, multicentre study aimed to compare the safety and effectiveness of adjuvant abemaciclib in older women (≥70 years) versus younger women (<70 years) in a real-world clinical setting in Italy.

The study retrospectively reviewed the records of 54 patients (54 total, 6 older subgroup, 48 younger subgroup) with HR^+/HER^- early-stage breast cancer who received at least 3 months of adjuvant abemaciclib due to a high risk of recurrence. The hypothesis was that older patients might experience more toxicities and require more dose reductions.

Key findings

- **Toxicity:** Adverse events of any grade were extremely common overall (98.1% of patients). All older patients (6/6) and almost all younger patients (97.9%) experienced at least one side effect.
- **Types of toxicity:** Side effects were mostly of low-to-moderate grade and manageable. The most frequent were haematological (related to blood cells, especially neutropenia) and gastrointestinal (mainly diarrhoea). These findings are consistent with previous trials.
- **Dose reductions:** Almost half of all patients (48.2%) required a dose reduction. However, dose reductions were more frequent and occurred earlier in the older subgroup (66.7%) compared to the younger subgroup (45.8%).

Conclusion

While adjuvant abemaciclib toxicities were generally common but manageable (low-to-moderate grade) across the entire group, older patients showed a numerically higher rate of dose reductions.

This suggests that older adults, potentially due to a higher burden of comorbidities and reduced phys-

iological reserve, may be more vulnerable to treatment-related toxicities. The small sample size of older patients limits definitive conclusions, but the finding suggests a potential need for personalized dosing and early, careful monitoring for older women receiving adjuvant abemaciclib. The authors recommend confirmation of these findings in larger, prospective studies.