INTRODUCTION

In 2022, several new drugs were approved by the EMA for the treatment of patients with early breast cancer (eBC) at high risk of recurrence: the CDK4/6 inhibitor abemaciclib in hormone-receptor positive, HER2-negative (HR+ HER2-) patients, pembrolizumab in HR-positiv, HER2-negativ (HR- HER2-) patients, and olaparib in patients with triple-negative eBC (TNBC). These drugs have demonstrated improved outcomes in clinical trials with patients with eBC at high risk of recurrence and thus are offered an additional target treatment option. Here, the current status in routine care is investigated. Our data show that between 6% (HER2+) and up to 62% (TNBC) of patients can be classified as high risk for recurrence in routine care, varying depending on the criteria used. Abemaciclib and pembrolizumab were quickly implemented into the treatment of these patients. BRCA1/2 is not yet routinely tested, especially not in patients with HR+, HER2- eBC and in those younger than 70 years (data not shown). Future analyses will investigate the impact of these new drugs on the outcome of patients with high-risk eBC in their respective subgroups.

RESULTS

Between April 2022 and June 2022, 297 patients with eBC were recruited at start of their first systemic treatment. At time of interim database cut on 30th June 2022, 422 patients with HR+, HER2- patients with HER2- and 679 patients with triple-negative eBC were evaluable.

CDK4/6 inhibitor abemaciclib

Of 343 patients with HR+/HER2-, 22/312 (12%) so far fulfilled the “high risk” criteria to receive abemaciclib (HER2- and 72% or HR+ and ≥ T2). Figure 2A shows patients with HR+/HER2- who started treatment with a neoadjuvant therapy. For 22/312 of these patients, abemaciclib was prescribed. For 116 patients, BRCA1/2 testing was documented and 2/116 (1.7%) were found to be BRCA1/2 wildtype/missing. 45 patients with HR+/HER2- started their chemotherapy with olaparib. Of note, some BRCA1/2 tests were performed after pembrolizumab treatment and some adolescent and young patients with triple-negative eBC qualifying for and receiving olaparib.

CONCLUSIONS

The recently approved drugs abemaciclib, pembrolizumab and olaparib have demonstrated improved outcome in clinical trials with patients with eBC at high risk of recurrence and thus offer an additional target treatment option. Here, the current status in routine care is investigated. Our data show that between 6% (HER2+) and up to 62% (TNBC) of patients can be classified as high risk for recurrence in routine care, varying depending on the criteria used. Abemaciclib and pembrolizumab were quickly implemented into the treatment of these patients. BRCA1/2 is not yet routinely tested, especially not in patients with HR+, HER2- eBC and in those younger than 70 years (data not shown). Future analyses will investigate the impact of these new drugs on the outcome of patients with high-risk eBC in their respective subgroups.