A real-world assessment of PI3KCA testing and alpelisib treatment patterns among metastatic breast cancer patients in a community oncology setting

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INTRODUCTION

Breast cancer genomic studies have identified recurrent oncogenic mutations in PIK3CA gene that encode the catalytic alpha subunit of phosphatidylinositol 3-kinase (PI3K) as the most common oncogenic mutations in hormone receptor-positive (HR+) metastatic BC (mBC), with a prevalence of over 40%1,2,3. SOLAR-1 is a study of alpelisib (alpelisib) with or without fulvestrant among patients with hormone receptor-positive (HR)+/ ER+, PIK3CA-mutated metastatic breast cancer (mBC) treated with anti-estrogen therapy.4

RESULTS

1. Cohort summary: We identified 1077 patients diagnosed with HR+, HER2- metastatic breast cancer between January 1, 2015 and June 30, 2020 for whom PIK3CA, HR, HER2 status and systemic treatment were known. Patients were classified into PIK3CA mutant and wild-type based on the identity of mutations in PIK3CA gene. About 40% of PIK3CA-mutant patients had been assessed for this study in SOLAR-1 trial, and ~30% of patients had received another PIK3CA-mutated treatment. PIK3CA-mutant patients were further stratified based on HR+ status and whether patients were treated with alpelisib or placebo. PIK3CA mutant population is in Fig. 1A. Mucular composition of cancers is shown in Fig. 1B. Comparison of patient characteristics for treated and not treated with alpelisib is provided in Table 1.

2. Treatment patterns: HR+HER2-PIK3CA+ patients treated with alpelisib was administered most frequently as a second line of therapy (Fig. 2A). Alpelisib treatment was most frequently preceded by treatment with CDK4/6 inhibitor and the last line of treatment recorded for 74 of 102 patients (Fig. 2B). Of the 74 pts, 43 were receiving alpelisib treatment at the time of data abstraction (ongoing treatment at time of data abstraction), 16 patients had died, and the remaining 15 patients either left the practice or were awaiting their next regimen. Overall, 60 of 102 patients received CDK4 inhibitor at some point in their history of alpelisib treatment.

3. Alpelisib duration and dosage: HR+HER2-PIK3CA+ patients Median duration of alpelisib treatment (Kaplan-Meier estimate) was 6.31 months. No difference in alpelisib duration among patients with and without prior treatment with CDK4 inhibitor and was the last line of treatment recorded for 74 of 102 patients (Fig. 2B). Of the 74 pts, 43 were receiving alpelisib treatment at the time of data abstraction (ongoing treatment at time of data abstraction treatment as of 12/3/2020). 16 patients had died, and the remaining 15 patients either left the practice or were awaiting their next regimen. Overall, 60 of 102 patients received CDK4 inhibitor at some point in their history of alpelisib treatment.

4. HR+HER2-PIK3CA+ patients not treated with alpelisib Of the 228 HR+HER2-PIK3CA+ patients not treated with alpelisib, 82 were alive at the time of alpelisib approval (June 30, 2016). Of these 82 patients a total of 63 (77.2%) were treated with an alpelisib analog (e.g., fulvestrant). 19% of patients had been receiving treatment for metastatic disease at the time of alpelisib approval. Of 177, 134 patients received a CDK4 inhibitor, 14 patients did not have a CDK4 inhibitor, and 10 patients were lost to follow-up. Of 80 patients, 46 were receiving CDK4 inhibitor at the time of data abstraction (ongoing treatment at time of data abstraction) as of 12/3/2020. 13 had died before the practice or were awaiting their next regimen.

METHODS

Texas Oncology electronic medical records (EMR) and Precision Medicine molecular databases were used to identify patients who met the following criteria:

- Patients diagnosed between January 1, 2015 and June 30, 2020
- Evaluated for a PIK3CA mutation and have known PIK3CA gene status
- PIK3CA-mutated BC among clinical trial participants (except nonmelanoma skin cancer or carcinomas in situ prior to diagnosis of mBC)
- At least 18 years of age at the time of first diagnosis of BC
- Patients may be alive or deceased at the date of data abstraction
- Not died ever enrolled in the intervention clinical trials evaluating PIK3 inhibitors

The date of data abstraction was December 31, 2020, allowing for a minimum 6 months follow-up. Given that alpelisib was approved in May 2019, treatment plans seen for alpelisib-treated patients only reflect 1.5 years of alpelisib use with Texas Oncology.

Footnotes

Patients with SOLAR-1 treatment.5

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References