# Results

The study analyzed data from the Flatiron Database, specifically focusing on postmenopausal women or men with HR+/HER2‒ metastatic breast cancer (MBC) who started treatment with palbociclib plus an aromatase inhibitor (AI) or AI alone as first-line therapy. The study period was from February 3, 2015, to March 31, 2020. The total number of patients included in the analysis was 2,888, with 1,324 patients in the palbociclib plus AI group and 1,564 patients in the AI alone group. Out of these, there were 10 men in the palbociclib group and 19 men in the AI alone group.  
  
After adjustment using stabilized inverse probability of treatment weighting (sIPTW), the patient characteristics were generally balanced between the two treatment groups. The median age of patients in both groups was 70 years. The majority of patients in each group were white, accounting for approximately 68% of the patients.  
  
The median duration of follow-up after sIPTW adjustment was 23.9 months in the palbociclib plus AI group and 24.5 months in the AI alone group.  
  
In terms of overall survival (OS), the unadjusted analysis of the full cohort showed that patients in the palbociclib group had a significantly longer median OS compared to the AI group. After sIPTW adjustment, the median OS was 49.1 months in the palbociclib group and 43.2 months in the AI group. The hazard ratio for OS was 0.76, indicating a lower risk of death in the palbociclib group. The OS rates at 24, 36, and 48 months were also higher in the palbociclib plus AI group compared to the AI alone group.  
  
The propensity score matching (PSM) sensitivity analysis also showed a longer median OS in the palbociclib group compared to the AI group. The hazard ratio for OS in the PSM-adjusted analysis was 0.72.  
  
The study also assessed real-world progression-free survival (rwPFS). Similar to OS, the unadjusted analysis showed a significantly longer median rwPFS in the palbociclib group compared to the AI group. After sIPTW adjustment, the median rwPFS was 19.3 months in the palbociclib group and 13.9 months in the AI group. The hazard ratio for rwPFS was 0.70, indicating a lower risk of disease progression in the palbociclib group. The PSM analysis also showed a longer median rwPFS in the palbociclib group compared to the AI group.  
  
Subgroup analyses were conducted to assess the impact of different factors on OS and rwPFS. These analyses showed a consistent benefit of palbociclib plus AI across most subgroups.  
  
Regarding subsequent second-line treatments, approximately 50% of patients in the palbociclib group and 65% of patients in the AI alone group had data available. Among these patients, around 21% in the palbociclib group and 33% in the AI group received a CDK4/6 inhibitor as second-line treatment.  
  
In summary, the study demonstrated that the addition of palbociclib to an AI as first-line therapy for HR+/HER2‒ MBC resulted in improved overall survival and real-world progression-free survival compared to AI alone. These findings were consistent across various subgroups.