# 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 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. Among these patients, there were 10 men in the palbociclib group and 19 men in the AI alone group.  
  
Patient characteristics were generally balanced after adjustment using stabilized inverse probability of treatment weighting (sIPTW). The median age of patients in both treatment groups, after sIPTW adjustment, was 70 years. The majority of patients in each treatment group were white, accounting for approximately 68% of 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 median OS was significantly longer in the palbociclib group compared to the AI group. After sIPTW adjustment, the median OS (95% confidence interval [CI]) was 49.1 months (45.2–57.7) in the palbociclib group and 43.2 months (37.6–48.0) in the AI group. The hazard ratio for OS was 0.76 (95% CI, 0.65–0.87), indicating a significant benefit in favor of 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 significant OS benefit with palbociclib plus AI. The median OS (95% CI) in the PSM-adjusted analysis was 57.8 months (47.2–not estimable) in the palbociclib group and 43.5 months (37.6–48.9) in the AI group, with a hazard ratio of 0.72 (95% CI, 0.62–0.83).  
  
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 rwPFS (95% CI) was 19.3 months (17.5–20.7) in the palbociclib group and 13.9 months (12.5–15.2) in the AI group, with a hazard ratio of 0.70 (95% CI, 0.62–0.78). The PSM analysis yielded similar results, with a median rwPFS (95% CI) of 19.8 months (17.3–21.9) in the palbociclib group and 14.9 months (12.9–16.9) in the AI group, and a hazard ratio of 0.72 (95% CI, 0.63–0.82).  
  
Subgroup analyses were conducted to assess the consistency of the OS and rwPFS benefits across different patient subgroups. The results showed a consistent benefit with palbociclib plus AI in most subgroups examined.  
  
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, a smaller proportion in the palbociclib group (21%) received a CDK4/6 inhibitor as second-line treatment compared to the AI group (33%).  
  
In summary, the study demonstrated that the addition of palbociclib to 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 benefits were observed across various patient subgroups.