中文題目：細胞週期蛋白依賴型激酶 4/6 抑制劑於賀爾蒙受器陽性之轉移性乳癌的真實世界數據分析

英文題目：Real-world treatment outcome of cyclin-dependent kinase 4/6 inhibitors in hormone receptor-positive metastatic breast cancer

作　　者：梁祐誠[1], 郭耀隆[2], 李國鼎[2], 徐慧萍[2], 羅竹君[2], 黃建璋[2], 蔡瑞鴻[3], 陳雅萍[3], 楊舜如[3], 鍾為邦[3], 陳尚鴻[3,4]

服務單位：[1]國立成功大學醫學院附設醫院內科部, [2]國立成功大學醫學院附設醫院外科部, [3]國立成功大學醫學院附設醫院腫瘤醫學部, [4]國家衛生研究院癌症研究所

Background:
Cyclin-dependent kinase (CDK) 4/6 inhibitors are the emerging treatment for patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) metastatic breast cancer (MBC). Despite the encouraging survival results from clinical trials, the studies investigating clinical benefits of these inhibitors in routine clinical practice are scarce. In this study, we retrospectively analyzed the treatment outcome of patients receiving CDK 4/6 inhibitors in Taiwan.

Methods:
We reviewed the treatment course of patients with HR+/HER2– MBC that had started CDK 4/6 inhibitor treatment at National Cheng Kung University Hospital between July 2017 and December 2018. Tumor responses and progression-free survival (PFS) were determined based on radiologic, biochemical, and clinical criteria. The correlations between clinical characteristics and tumor responses to CDK 4/6 inhibitors were analyzed using the Fisher's Exact Test. Survival outcomes were estimated and analyzed using the Kaplan-Meier method and the Log-rank test, respectively. In all analyses, a P value<.05 was recognized as being statistically significant.

Results:
During a median follow-up of 703 days, a total of 35 patients with a median age of 57 years were included (18 for ribociclib, 17 for palbociclib). The numbers of patients receiving CDK 4/6 inhibitors as first- and beyond first-line therapy were 15 and 20, respectively. Among these patients, the use of CDK 4/6 inhibitors were most frequently combined with aromatase inhibitors (74.3%), followed by fulvestrant (22.9%), and tamoxifen (2.8%). The overall clinical benefit rate of CDK 4/6 inhibitor (complete and partial response + stable disease) was 82.6%; however, de novo MBC group was significantly correlated with progressive disease (P = 0.043). The 12-month PFS rates for patients in first- and beyond first-line therapy group were 73.3% and 35%, respectively. In overall 35 patients receiving CDK 4/6 inhibitors, ages younger than 60 years old (P = 0.031), de novo MBC (P = 0.004), luminal B subtype (P = 0.005), ER+ tumor cell percentages lower than 30% (P = 0.01) and beyond first-line therapy group (P = 0.03) were associated with shorter PFS. Additionally, de novo MBC (P = 0.023), luminal B subtype (P = 0.036), and ER+ tumor cell percentages lower than 30% (P = 0.016) were unfavorable prognostic factors for PFS in the first-line therapy group, and de novo MBC (P = 0.01) for the beyond first-line therapy group.

Conclusion:
CDK 4/6 inhibitors are effective treatments for patients with HR+/HER2– MBC in Taiwan. Survival analyses of this study reveal that younger ages, de novo MBC, luminal B subtype, low ER+ tumor cell percentages and beyond first-line therapy are unfavorable prognostic factors in patients receiving CDK 4/6 inhibiters.