CONCOMITANT USE OF PROTON PUMP INHIBITORS AND PALBOCICLIB: IS THERE A REAL IMPACT ON RESPONSE?

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Abstract number: 4CPS-197

ATC code: L01- Antineoplastic agents

Background and importance

The concomitant use of palbociclib with proton pump inhibitors (PPIs) has recently been associated with a reduction in PFS (progression-free survival)[1]. However, the results of the study are questionable for methodological reasons.

Aim and objectives

To determine whether concomitant use of palbociclib with PPIs in our cohort of patients with metastatic breast cancer is associated with clinical response.

Materials and methods

Retrospective observational study including all patients who started treatment with palbociclib between December 2016- November 2021 Demographic and clinical data were obtained from the electronic clinical records. Patients were categorized whether they were taking concomitant PPIs or not.
Primary endpoints included both PFS and OS (overall survival).
PFS and OS were analysed through Kaplan-Meier survival curves using the log-rank test to check differences between curves. The Cox regression model was used to identify independent risk factors for PFS and OS.

Results

A total of 87 patients were included. Demographic and clinical characteristics are shown in Table 1.

Table 1. Patients' characteristics.

	Total patients (n=87)
Age in years, mean±SD	63.4 ± 12.8
Female, *N* (%)	85 (97.7%)
Body mass index (BMI) in kg/m^2, mean±SD	26.6 ± 5.6
Baseline ECOG PS 0-1, *N* (%)	80 (87.0%)
Line of therapy, *N* (%) 1 2 ≥3	 63 (72.4%) 17 (19.5%) 7 (8.1%)
Concomitant drug, *N* (%) Fulvestrant Aromatase inhibitor	 33 (37.9%) 54 (62.1%)
Concomitant PPI, *N* (%)	32 (36.8%)

Fifty-two patients (59.8%) discontinued treatment and 39 (44.8%) required ≥1 dose reduction. Median PFS and OS were 19.9±13.6 and 26.0±14.3 months, respectively.
In univariate analysis, concomitant treatment with fulvestrant and ≥3 treatment line, were significantly associated with PFS (HR 1.83; 95%CI (1.05-3.20) p=0.032 and HR 8.88; 95%CI (3.32-23.8) p<0.001, respectively). Treatment lines 2 and 3, were significantly associated with OS (HR 2.68; 95%CI (1.13-6.34) p=0.025 and HR 14.6; 95%CI (4.87-43.6) p<0.001, respectively).
Patients with PPIs were not associated with a significantly prolonged median PFS (log-rank p=0.560) (Figure 1) nor OS (log-rank p=0.058) (Figure 2).

Figure 1. Kaplan-Meier progression-free survival (PFS) by concomitant PPI.

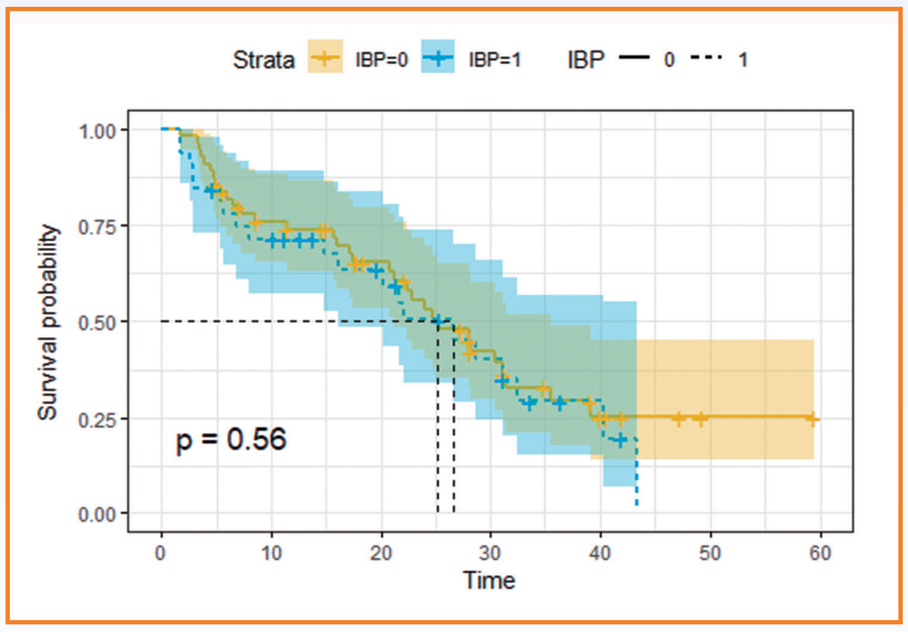
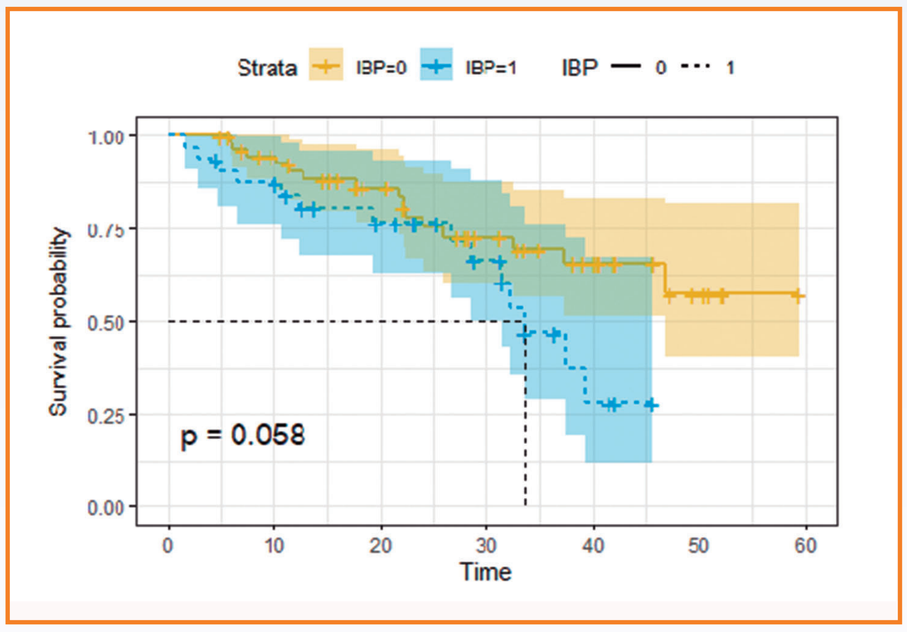


Figure 2. Kaplan-Meier overall survival (OS) by concomitant PPI.



Conclusion and relevance

Contrary as described in the literature, patients in our cohort under concomitant treatment with PPIs showed no negative impact on PFS nor OS. However, studies with larger numbers of patients, multivariate analysis and longer follow-up are needed to confirm these results.

References: 1. Del Re M et al. ESMO Open. 2021;6(5):100231.

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