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COMPARATIVE EFFICACY OF ABEMACICLIB AND PALBOCICLIB AS ADJUVANT TREATMENT IN PATIENTS WITH EARLY BREAST CANCER

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BACKGROUND AND IMPORTANCE

Abemaciclib in **combination** with **endocrine therapy (ET)** has recently been authorized for **adjuvant treatment** of patients with **human epidermal growth factor receptor 2 (HER2) negative** and **luminal early breast cancer (EBC)** at **high risk of recurrence.**

AIM AND OBJETIVES

To assess the comparative efficacy between abemaciclib and palbociclib in HER2-negative, high risk of recurrence and luminal EBC patients and **to establish** whether these drugs can be considered **equivalent therapeutic alternatives (ETA),** through an **adjusted indirect treatment comparison (ITC).**

MATERIALS AND METHODS

1. A **bibliographic search** was conducted to identify **phase III clinical trials** with abemaciclib or palbociclib as adjuvant treatment in a **similar EBC population** (luminal type, HER2-negative and high risk of recurrence), **duration and endpoints.**
2. The primary endpoint was **Invasive Disease-Free Survival (IDFS)** and ET was used as a common comparator.
3. **Similar clinical trials, consistent results and efficacy demonstration** against the common comparator (ET) were required for the adjusted ITC.

RESULTS

Two trials were included, one of each drug. Both of them were phase III trials, randomised, in patients with HER2-negative, high risk and luminal EBC. **Differences were found in the trial design** (abemaciclib open-label vs. palbociblib double-blind), **number of patients included** (abemaciclib N=5637 vs. palbociclib N=1250), **treatment duration** (abemaciclib two years vs. palbociclib one year) **and percentage of patients pretreated with taxane, anthracycline or both** (abemaciclib 37% vs. palbociclib 99%). Clinical trials were not similar due to these differences.

Abemaciclib was effective in HER2-negative, high risk and luminal EBC. However, palbociclib was not. IDFS abemaciclib group was statistically significant (HR=0.70; 95% CI: 0.59-0.82; p<0.0001) with a median follow-up of 27 months (90% patients completed treatment). In contrast, IDFS palbociclib group was not statistically significant (HR=0.93; 95% CI: 0.74-1.17; p=0.525) with a median follow-up of 43 months (92% patients completed treatment).

Regarding consist results, **2-year IDFS rate was different too**: abemaciclib 93% vs. palpociclib 88%. **In short, relevant methodological limitations were detected so adjusted ITC was not possible.**

CONCLUSION AND RELEVANCE

Abemaciclib and palbociclib cannot be considered ETA in HER2-negative, high risk and luminal EBC, although **abemaciclib** demonstrated **efficacy as adjuvant treatment in these patients.**