4CPS-292 EFFECTIVENESS AND SAFETY OF IBRUTINIB IN CHRONIC LYMPHATIC LEUKAEMIA: MULTICENTRE STUDY

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10.1136/ejhpharm-2021-eahpconf.124

Background and importance Ibrutinib is a potent B-cell tyrosine kinase inhibitor involved in the proliferation and survival of chronic lymphatic leukaemia (CLL) B cells. This study was mainly motivated by suspensions for toxicity.

Aim and objectives The objective was to analyse the effectiveness and safety of ibrutinib in CLL.

Material and methods This was a retrospective observational study including all patients with CLL treated with ibrutinib until September 2020 from two hospitals. Data were obtained from Farmatools and clinical records. SPSS Statistics V.17.0 was used for statistical analysis. The analysed variables were demographic and clinical data (D/C), treatment, effectiveness and safety.

- D/C: number of patients; sex; age; the presence of mutations in chromosome TP53 (mut-TP53) and deletion of chromosome 17 (del17p); progression to Richter (PR).
- Treatment: previous lines (PL_{IBRUTINIB}); duration of treatment (DT_{IBRUTINIB}).
- Effectiveness: progression free-survival (PFS) and overall survival (OS) using Kaplan-Meier statistical analysis.
- Safety: the most frequent number, type and degree of adverse events (AE) according to the common terminology criteria for adverse events (CTCAE) V.4.03 and necessary treatment modifications (TM) (dose reduction (DR), treatment suspension (TS), both (DR-TS)).

Results

- D/C: 60 patients (58% men); median age 80 years (55–98); mut-TP53 (8.3%), del17p (15%); PR (8.3%).
- Treatment: PL_{IBRUTINIB} (56% one-third, 3% ≥four); median DT_{IBRUTINIB} 13.5 months (1–53).
- Effectiveness: at 12–24 months, PFS was 79.3–72.8%; OS was 85.1–76.4%. Mean values obtained were xPFS=38 months±3.3 (95% CI 31.7 to 44.5) and xOS=40.5 months ±2.9 (95% CI 34.8 to 46.2).
- Safety: the most frequent AE (≥15%) were diarrhoea, pneumonia, skin rash and haematomas. The most frequent G3–4 AE (≥5%) were neutropenia, pneumonia, skin rash, anaemia and atrial fibrillation. A 53% TM by AE: 23% TS, 19% DR-TS and 11% DR.

Conclusion and relevance The effectiveness and safety results obtained were similar to those of pivotal studies (PS). PFS and OS at 12–24 months in our study (79.3–72.8% and 85.1–76.4%) were lower than the results of PS (89.8–82.3% and 90.2–89.6%). With regard to the safety data, PS showed lower dropout rates due to AE (6% vs 23%) and lower dose reductions (8% vs 19%) although the toxicity profile and the most frequent G3–4 AEs were similar to the PS.

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Conflict of interest No conflict of interest

4CPS-293 EFFICACY AND SAFETY OF CYCLIN DEPENDENT KINASE INHIBITORS IN METASTATIC BREAST CANCER

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10.1136/ejhpharm-2021-eahpconf.125

Background and importance Cyclin dependent kinase inhibitors (CDKs) have demonstrated efficacy in the treatment of hormone receptor positive (RH+) and human epidermal growth factor receptor 2 (HER2-) metastatic breast cancer.

Aim and objectives To evaluate the efficacy and safety of cyclin inhibitor drugs (CDK) in patients with metastatic breast cancer.

Material and methods An 18 month, single centre, retrospective study (January 2019 to June 2020) that included all patients with metastatic breast cancer treated with palbociclib (PB), ribociclib (RB) and abemaciclib (AB) was conducted. The following variables were collected: age, sex, time of disease follow-up, time of treatment with the drug, neoadjuvant/adjuvant and previous hormonal therapy. Efficacy was evaluated by calculating progression free survival (PFS) for each drug, applying the Kaplan-Meier statistic. Progression was analysed according to the radiological criteria response evaluation criteria in solid tumours (RECIST V.1.1). The occurrence of adverse effects (AEs) leading to early dose reduction/suspension of the drug was analysed according to the common terminology criteria for adverse events (CTCAE).

Results 98 women (mean age 62.8 (34–86) years) were included in the study. 53.1% received PB (n=52), 25.5% (n=25) RB and 21.4% (n=21) AB. Mean follow-up time of the disease was 7.5 years. Mean duration of treatment was 9.5 months (0.1–34.3). 59.2% (n=58) received previous adjuvant therapy, 20.4% (n=20) neoadjuvant and 74.5% (n=73) hormonal.

Median PFS was AB vs PB (17.4 vs 11.9 months, p=0.008); AB vs RB (17.4 months vs not reached, p=0.065), PB vs RB (p=0.034). 34.7% (n=34) suspended treatment due to progression and 15.3% (n=15) due to toxicity. 54.1% (n=53) of patients had doses reduced due to AEs during treatment: PB (45.3%, n=24), RB (24.5%, n=13) and AB (30.2%, n=16). The most common AEs were: haematological (69.8%, n=37), gastrointestinal (17%, n=9), skin (9.4%, n=5), asthenic syndrome (9.4%, n=5), renal (5.7%, n=3), hepatic (5.7, n=3) and other (3.8%, n=2).

Conclusion and relevance PFS was more favourable for AB than for PB, but not for RB. Likewise, RB treatment had a higher PFS than PB (p≤0.05). More than 50% of patients had their dose reduced due to the appearance of AEs, with PB being the least tolerated. This highlights the need for close monitoring of these AEs, which impairs long term efficacy.

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Conflict of interest No conflict of interest