PO75

RETROSPECTIVE ANALYSIS OF ADVANCED LUMINAL BREAST CANCER PATIENTS TREATED WITH ENDOCRINE THERAPY (ET) AND PALBOCICLIB WITHIN A COMPASSIONATE USE PROGRAMME

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Introduction: Palbociclib combined with fulvestrant has been granted EMA approval in November 2016 for patients with hormone receptor-positive (HR+), HER2-negative (HER2-) metastatic breast cancer (MBC) who have received prior ET. However, the benefit of palbociclib in MBC patients progressing after multiple treatment lines and especially after mTOR inhibition is unknown. In this retrospective study, we report on safety and activity of palbociclib and ET after ≥ at least 4 lines of standard treatment for HR+/HER2- MBC.
Material and Methods: This is a single center (Inst. Jules Bordet, Belgium) retrospective analysis of Pfizer's compassionate use program (active between October 2015 and February 2017) of palbociclib in combination with ET for patients with HR+, HER2- MBC progressing after ≥4 lines of standard treatment for MBC. Study outcomes were overall response rate, disease control rate (DCR) at 24 weeks, progression-free survival, overall survival, and safety. Descriptive statistics and survival analyses were performed.
Results: A total of 21 patients with HR+, HER2- MBC received palbociclib: 17 (81%) in combination with an aromatase inhibitor (AI) and 4 (19%) with fulvestrant. Median age was 58 years (range, 37–80). The majority (90.5%) of patients were enrolled after visceral progression. Median number of prior treatment lines for MBC was 6 (range, 4–13). Sixteen patients (76.2%) had been treated with mTOR inhibitors prior to palbociclib. Three patients (14.3%) achieved a partial response (with two of them having progressed on everolimus) and 4 patients (19.0%) experienced a stable disease (SD). DCR ≥ 24 weeks was 19.0%. One patient progressing on 13 prior treatment lines showed SD for 54.3 weeks with palbociclib + AI. The most common adverse events (AE) of any grade were neutropenia and fatigue: 16 patients (76.2%) experienced neutropenia of grade ≥3, and 2 (9.5%) fatigue of grade ≥3. One patient was diagnosed with febrile neutropenia. Four patients are still on treatment at the time of this analysis; an updated analysis including PFS will be presented at the conference.
Conclusion: In heavily pretreated MBC, palbociclib and ET showed activity with disease response and durable disease stabilization even in women previously exposed to mTOR inhibitors. Toxicity profile in this heavily pretreated MBC population was comparable to that seen in pivotal trials.

PO76

PRELIMINARY DATA FROM A PROSPECTIVE NON-INTERVENTIONAL STUDY TO CHARACTERIZE REAL-WORLD TREATMENT PATTERNS AND OUTCOMES OF WOMEN WITH ER+/HER2-ADVANCED/METASTATIC BREAST CANCER

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Background: ER+ HER2- breast cancer makes up majority of breast cancer cases in Europe (67%), but real world practice patterns, outcomes, and limitations of current therapies are poorly understood in this population. In light of an ongoing need for more effective treatment strategies, this study seeks to address this knowledge gap in a population of ER+ HER2- advanced or metastatic breast cancer (ABC/MBC) in Italy and Germany.
Methods: A prospective, non-interventional study collecting medical information together with periodic patient-reported outcomes is being conducted in women aged ≥18 years receiving first or second line treatment for ER+ HER2- ABC/MBC. Patients are being monitored for 2 years from enrollment. Data on baseline characteristics and treatment patterns for the first 99 (of an anticipated 500) study enrollees from 26 centers are reported.
Results: All 99 patients enrolled at the time of this interim analysis were Caucasian. The median age was 60.5 years and most patients were postmenopausal (76.8%). Nearly 95% of patients were metastatic and the remaining had locally advanced, unresectable disease. Visceral metastasis was present in 42.6% of patients. Nearly half of patients were initially diagnosed with early/limited regional disease (stage I – IIIA; 49%). For these patients, median duration of adjuvant therapy was 3 years and median time to diagnosis of advanced disease was 5.6 years. At study entry, 69 patients (69.7%) initiated first line of therapy for ABC/MBC. The majority of patients entering the study in first line received chemotherapy (53.6%). Across all patients, fulvestrant was the most commonly used regimen (22%). The most common first line regimen was paclitaxel + bevacizumab (23.2%), followed by letrozole (18.8%) and fulvestrant (17.4%). For the 30 patients initiating their second line of systemic therapy at study entry, the most commonly received treatment was fulvestrant (33.3%), followed by exemestane + everolimus (16.7%). At the most recent follow-up, 91.9% of patients were still receiving the same therapy regimen initiated at study entry.
Conclusions: Preliminary data suggest that chemotherapy is widely used for first line ABC/MBC, followed closely by endocrine therapies. These treatment patterns diverge from expectations based on current treatment guidelines, indicating potential unmet need with available therapies.

PO77

METRONOMIC CHEMOTHERAPY (mCHT) IN HER2-VE ADVANCED BREAST CANCER (ABC) PATIENTS (PTS): WHEN CARE OBJECTIVES MEET PATIENTS' NEED. PRELIMINARY RESULTS OF THE VICTOR-6 STUDY

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Background: mCHT is the minimum biologically effective dose of a chemotherapeutic agent, given at regular dosing regimen with no prolonged drug free interval, that leads to anti-tumor activity. Old regimens included Cyclophosphamide-Methotrexate (CM), whereas in the last years new regimens, such as Vinorelbine (VRL) and Capecitabine (CAPE)-based have been developed. Aim of this observational retrospective ongoing study is to describe the use of mCHT in ABC pts across 5 years and the clinical characteristics of the pts together with efficacy of old (CM-like) vs new (VRL/CAPE-based) metronomic regimens in terms of response and disease control.
Methods: We retrospectively identified from clinical records those HER2-ve ABC pts who have received any kind of mCHT in the years 2011–2015, alone, or in combination with a non-metronomic drug. Standard statistical approaches were used for describing the sample characteristics. Logistic and non proportional hazard analysis were used to identify factors associated with response, and time to treatment failure and survival, respectively. This preliminary analysis focuses on Response Rate (RR) and Disease Control Rate (DCR).
Results: From June 2011 to December 2015, 267 pts have been identified till now and 233 are fully evaluable. Median age at mCHT start was 67 years. 81% was HR+ and 33% had non-visceral metastatic disease. 22% of the pts received CM, 55% VRL-based and 23% mCAPE-based regimens. mCHT use increased over the time from 15.0% (2011) to 30% (2015). As 1st-line treatment, CM was administered in 27% of compared with more than 48% of patients receiving CAPE/VRL-based regimens.
Overall Response Rate (ORR) was 28% and Disease Control Rate (DCR) was 79%. Median duration of mCHT was 6.2 months. New generation metronomic regimens produced higher ORR in comparison to old ones (32% vs 13.5%), with similar duration of treatment (6.4 vs 5.4 months, respectively).
Conclusions: The use of mCHT in the treatment of HER2-ve ABC pts has deeply changed across the last 5 years, being new generation regimens used in earlier lines of treatment, producing interesting results in terms of objective response and disease control. Toxciity data are under evaluation.

PO78

RANDOMIZED PROSPECTIVE STUDY: PACLITAXEL EVERY-3-WEEKLY PACLITAXEL AND VERSUS WEEKLY VINORELBINE IN METASTATIC BREAST CANCER

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Background: Single-agent chemotherapy (CT) is widely used in the management of HER2-negative breast cancer patients (pts). As both Paclitaxel (P) and Vinorelbine (V) have demonstrated efficacy in the treatment of Metastatic Breast Cancer (MBC), they are recommended among the standard available CT agents for MBC patients. This study compares the efficacy and safety profile of most frequently used three treatment regimens: Paclitaxel every-3-weeks (3-w-P) versus weekly Paclitaxel(w-P) and versus weekly Vinorelbine (w-V) in MBC. Primary objective: Time to progression (TTP). Secondary objectives: Evaluation of safety profiles, clinical benefit and response rate (RR) of all arms.
Methods: In this open-label randomized prospective study, pts were randomized (2:2:1) to receive either: Intravenously 3-w-P every 21 days, w-P 80 mg/m²/week (day 1, 8, 15) every 28 days or w-V 25 mg/m²/week (day 1, 8, 15) every 28 days. Main eligibility criteria: Age ≥18 years, documented metastatic disease previously untreated by CT for metastatic setting, ER/PR positive and HER2-negative disease, or triple negative disease. ECOG ≤ 2.
Results: From April 2014 to April 2015, 95 pts were included. 39 received 3-w-P; 38 received w-P and 18 received w-V per protocol. Median age was 58 years (range 38-79), median duration of treatment 11.5 weeks (range 9-24). The clinical benefit rate (defined as complete response, partial response plus stable disease) was observed in 82.8% vs 96.3% vs 100% respectively for 3-W-P vs W-P vs W-V arms. Efficacy: With a median follow up of 24 months (m), median time to progression (primary endpoint) was 10.3m, 9.8m and 9.6m in 3-w-P arm, w-P and in w-V arm respectively ($p = 0.006$). The clinical benefit rate was observed in 82.8% vs. 96.3% vs. 100% respectively for 3-w-P vs. w-P vs. w-V arms. Safety: W-V was much better tolerated with fewer G3/4 toxicity events (n = 2) than w-P and 3-w-P (n = 23 and 16). Neuropathy G3/4 was mostly reported in 3-w-P and w-P arm than in V arm (75% vs. 69% vs. 17%). G3/4 alopecia was reported in both P arms (94%) when in V arm G3 alopecia was only in 6% of pts.
Conclusion: Weekly Paclitaxel appeared as effective as every-3-weekly regimen and weekly Vinorelbine, however neurotoxicity is a treatment-limiting toxicity for both Paclitaxel regimen. Vinorelbine had fewer significant Grade 3/4 toxicities than both Paclitaxel arms and had better RR. Larger randomised studies are needed to determine the efficacy and overall survival of Paclitaxel versus Vinorelbine

PO79

REAL WORLD PRESCRIPTION PATTERNS IN METASTATIC HR+ BREAST CANCER. ANALYSIS FROM INSTITUTO NACIONAL DE CANCEROLOGIA, MEXICO CITY

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Background: Metastatic breast cancer represented 13% of all new cases at our Institution. Besides endocrine therapy is the treatment choice for hormonosensitive (HR) tumors according international guidelines, in our center most patients are treated with chemotherapy, main reasons are high disease burden, younger age, and drugs availability. The aim of this review is to analyze the prescription patterns in metastatic setting.
Methods: Retrospective analysis from our local database; 184 consecutive cases were selected from 2007–2011. We included patients with the novo-metastatic disease, ER+ or PR+ and/or HER2+ or –. Statistical analysis was done with SPSS v.20. Local IRB approved the review.
Results: Median age was 49.49 years-old (25.9–86.9), ER/PR+, HER2 negative was presented in 76.6% and ER/PR/HER2 positive in 23.4%. Median lines of palliative treatment were 3 (0–11). 50% received 1–3 treatment lines and 50% received more than four treatment regimens. Six patients (3.3%) were not candidate to any systemic treatment, received palliative care. Chemotherapy as first