

Results: 72 patients were included: 52 received abemaciclib as first line, 20 as second line; in 49 patients abemaciclib was administered in combination with an aromatase inhibitor, in 23 with fulvestrant. 95.8% of patients experienced at least one adverse event. The most common was diarrhea (79.2%), mainly G1 (66.7% of cases). Other common toxicities were: neutropenia (56.9%), increased serum creatinine (38.9%), anemia (37.5%), nausea (34.7%), fatigue (23.6%) and hypertransaminasemia (22.2%). Toxicities were mainly low grade; 10.1% of adverse events where G3-4. 48.6% of patients required a temporary interruption of abemaciclib and 45.8% a dose reduction. All 17 patients aged ≥ 70 required a dose reduction. A concomitant palliative radiotherapy was administered in 16 patients: in all cases radiotherapy was regularly completed; a temporary interruption of abemaciclib was required in 3 patients due to hematologic toxicities. In patients with measurable disease, ORR was 55.7%, significantly higher in first line compared to second line (70.5% vs 17.7%, $p < 0.001$). ORR was not significantly different between full and reduced dose (46.9% vs 65.5%, $p = 0.143$). At the time of the present analysis, 51 patients are still on therapy. Treatment discontinuations were due to disease progression in 17 patients, and to adverse events in 4 (G3 increased ALT in 1 patient and persistent G2-3 cutaneous toxicity in 3 patients).

Conclusions: In a real-world population, abemaciclib was associated with a meaningful rate of objective response, with a favourable safety profile. Side effects were mostly low grade, manageable with temporary interruptions or dose reductions.

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123P Clinical and pathological characteristics of male breast cancer at the Institute for Oncology including first-line treatment in hormone receptor positive tumours

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Background: Male breast cancer (MBC) is a rare disease that accounts for less than 1% of all diagnosed breast cancers and less than 1% of all cancers in men. Prognosis depends upon tumour size, histological grade, nodal status, hormone receptor status and it is equivalent to that in stage-matched female patients.

Methods: In this study we retrospectively evaluated consecutive data from medical records 166 MBC cases diagnosed from 1991 to 2020 at the Institute for Oncology and Radiology of Serbia.

Results: Median age at diagnosis was 65 years (range 29-90). Most patients were diagnosed in clinical stage II and III (77%). Modified radical mastectomy was performed in about 75%, while others underwent simple mastectomy or wide excision. Invasive ductal carcinoma was the most common histological type (71.7%), predominantly grade 2 (73.5%). Most tumours were less than 5 cm in diameter (69.3%). About 35.5% of patients had negative axillary lymph nodes involvement, 19.9% up to 3 positives, 19.9% had more than 3 positive axillary lymph nodes. Most tumours were oestrogen and progesterone receptor positive (63.2%), for about 32% hormone receptor status is unknown (data from '90), and only three patient had human epidermal growth factor receptor 2, HER 2 positive breast cancer. About 38% of patients were treated with adjuvant chemotherapy, 64.5% had adjuvant hormone therapy, 56.6% had postoperative radiotherapy. During period of follow-up (range 1-11 years) 36.7% of patients had relapse of disease (61/166): locoregional in 10.8% (18/166), bones only 12% (20/166), visceral organs 13.8% (23/166). They were predominantly treated with systemic hormone therapy (44/61), mostly tamoxifen, 20 patients received chemotherapy, 31 patient underwent palliative radiotherapy. During follow-up 56 patients died due to disease progression (33.7%).

Conclusions: MBC patients had more advanced disease at the presentation. Like postmenopausal women majority of the tumours were hormone receptor positive, treated mainly on the same principles as female breast cancer. Ongoing analysis will compare survival in females with breast cancer matched with known prognostic factors.

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124P Talazoparib in locally advanced or metastatic breast cancer patients: Experience from an early access program in Turkey

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Background: Talazoparib is a potent PARP inhibitor and has shown progression-free survival (PFS) advantage in phase III EMBRACA study which randomized BRCA-mutant breast cancer patients. In this study, we aimed to determine the real-life efficacy and safety profile of Talazoparib in BRCA-mutant breast cancer patients in Turkey.

Methods: In this study, advanced breast cancer patients with BRCA1 or BRCA2 mutation who received Talazoparib treatment via early access program were retrospectively analyzed. The data of the patients collected from 24 different oncology centers in Turkey.

Results: There were 47 advanced breast cancer patients (46 female and one male). The median age was 41.5. The percentages of the disease-subtype were 63.8% for hormone-positive disease and 36.2% for triple-negative (TNBC) disease. 76.6% of the patients had visceral and 12.8% of the patients had CNS metastasis. Previous exposure to platinum compounds was 53.2%. 48.9% of the patients (n=23) received the drug as first, second, or third-line. The rest of the patients (n=24, 51.1%) received Talazoparib treatment after third-line treatment. The objective response rate (ORR) was 31.9% (n=15) and disease-control rate was 61.7% (n=29). In 10.6% of patients complete response was achieved with Talazoparib treatment. After median 13.6 months (min-max. 6.5 - 21.5) follow-up, the median PFS (29 event) for Talazoparib treatment was 6.5 months (5.0 - 8.1 months, 95% CI). The median PFS for the patient subgroup who received the treatment in the first, second, or third-line was 9.9 months (4.4 - 15.5 months, 95% CI). The median PFS was 12.6 and 5.1 months for BRCA1 (n=18) and BRCA2 (n=21) patients, respectively. There were no PFS differences between subgroups according to hormone-receptor status or TNBC. The median OS for Talazoparib treatment had not been reached but the estimated 12-month OS rate was 73.6%. At least one side effect reported in 61.7% of the patients and grade 3-4 toxicity was seen in 14 patients (29.8%). The most common side effect was hematologic cytotoxicity.

Conclusions: Our study demonstrated favorable PFS and ORR results in a heavily-pretreated real-life BRCA-mutant advanced breast cancer cohort.

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125TIP SGNTUC-019: Phase II basket study of tucatinib and trastuzumab in previously treated solid tumours with HER2 alterations: HER2-mutated breast cancer cohort

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Background: Tucatinib (TUC), a highly selective HER2-directed TKI recently approved for HER2 overexpressed/amplified (HER2+) metastatic breast cancer (BC), on the basis of a statistically significant and clinically meaningful PFS, OS, and ORR benefit for the addition of TUC to trastuzumab (Tras) and capecitabine. TUC is being developed as a novel therapy for patients (pts) with metastatic BC, CRC, and gastric cancer. In