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Capecitabine A Viewpoint by Joanne L. Blum

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Capecitabine is a tumour-selective fluoropyrimidine carbamate with high activity in preclinical xenograft models of breast, colorectal, gastric and cervical cancer. It has shown activity in metastatic breast cancer and has been approved by the FDA for the treatment of metastatic breast cancer which is resistant to treatment with paclitaxel or anthracyclines.

In the pivotal trial which led to FDA approval, 20% of 135 patients with measurable disease responded (complete plus partial response) to treatment with capecitabine (2510 mg/m²/day for 2 weeks of each 3-week cycle). Disease progression had previously occurred in all patients despite paclitaxel therapy. Furthermore, 91% of patients participating in the trial and all patients showing a response to treatment had previously received anthracycline therapy. Particularly striking was the long duration of survival noted among capecitabine recipients who responded to treatment or who had stable disease. [1]

This study has been confirmed by a subsequent phase II trial involving 75 patients with disease progression despite either paclitaxel or docetaxel who were now receiving capecitabine (2510 mg/m²/day for 2 weeks of each 3-week cycle). The response rate in this trial was 24%. [2]

Capecitabine (2510 mg/m²/day for 2 weeks of each 3-week cycle) was compared with intravenous cyclophosphamide, methotrexate and fluorouracil (CMF; administered on day 1 every 3 weeks) as first-line chemotherapy in elderly women with

metastatic breast cancer, and response rates were 25% and 16%, respectively.^[3]

A small phase II randomised trial compared the efficacy of capecitabine (2510 mg/m²/day for 2 weeks of each 3-week cycle) with paclitaxel (175 mg/m² on day 1 every 3 weeks) in patients failing previous anthracycline treatment. Response rates were 36% with capecitabine compared with 26% with paclitaxel. [4]

The most common adverse events associated with capecitabine include hand-and-foot syndrome, diarrhoea, nausea, vomiting and fatigue. The majority of treatment-related events are of mild or moderate intensity (grade 1 or 2). The incidence of severe or life-threatening (grade 3 or 4) adverse events is low and decreases with increasing duration of therapy. Alopecia does not occur and myelosuppression is uncommon. The favourable toxicity profile of this oral chemotherapeutic agent, which can be administered at home, in conjunction with its significant efficacy in heavily pretreated patients, has led to an important advance for patients with metastatic breast cancer.

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