

## INAPPROPRIATE DOSES OF CHEMOTHERAPY IN ITALIAN BREAST CANCER PATIENTS ENROLLED IN CLINICAL TRIALS

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**Aims and background:** The dose of delivered chemotherapy is important to evaluate the appropriateness of the anticancer treatment. This aspect has been scarcely studied in Italy. About 7 years ago, the Italian Group for Antiemetic Research (IGAR) published a large controlled study on the effectiveness of different antiemetic prophylaxis in patients submitted to moderately emetogenic chemotherapy, where the prescribed chemotherapy was recorded. The aim of our study was to evaluate the incidence of undertreatment and to detect clinical and nonclinical factors able to explain its variability.

**Methods:** An observational study on the IGAR databank was performed to evaluate the incidence of undertreatment in the prescription in conditions of clinical trial, where the doses belonged to the eligibility criteria, and to analyze the importance of clinical and nonclinical factors using multifactorial logistic models.

**Results:** 317 patients receiving cyclophosphamide, methotrexate, and fluorouracil (CMF) and 224 anthracycline-based chemotherapy were considered. In the CMF-treated patients,

22.4% received full doses, whereas in 53.6% all three drugs of the schedule were down-dosed. In the anthracycline-treated group, 38.6% and 3.4% of patients submitted to chemotherapy containing epirubicin and doxorubicin, respectively, were undertreated. Logistic models showed that undertreatment in CMF-treated patients depended significantly on the geographic area and setting of chemotherapy administration. Although not significant, differences between age class and Karnofsky performance status were also detected. In the epirubicin-treated group, all these factors were significant.

**Conclusions:** The undertreatment of cancer patients is a relevant problem, because it could give, in daily clinical practice, worse results than those reported in clinical studies. Considering the setting of a clinical trial where our study was carried out, the incidence of undertreatment is surprisingly high. We do not know whether today, about 8 years after the IGAR study was carried out, the inappropriate dose of chemotherapy is still as frequent as we reported, but surely the topic deserves more attention.

**Key words:** appropriateness, downdose, inappropriate doses of chemotherapy, undertreatment.

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