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A PILOT STUDY OF A DAY ONE AND EIGHT EVERY THREE WEEKS ADMINISTRATION OF DOCETAXEL IN METASTATIC CANCER PATIENTS

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Aims and background: **Docetaxel is an active agent in metastatic cancers. The standard administration every 3 weeks frequently causes gastrointestinal toxicity and severe myelosuppression. These are rare with a weekly docetaxel regimen, which instead produces severe asthenia. To develop a new docetaxel schedule associated with mild myelosuppression and less fatigue, we conducted this pilot study to determine the feasibility and the maximum tolerated dose of a day one and eight every three weeks administration of docetaxel.**

Patients and methods: **The first 3 patients were treated with a dose of 40 mg/m^2 on day one and eight, which was then escalated by increments of 5 mg/m^2 on both days up to determine the maximum tolerated dose, defined as the dose level associated with the same dose-limiting toxicity in at least 33% of patients.**

Results: **Twenty-one metastatic cancer patients entered the study, with a median age of 57 years and a median performance status of 1. The escalation of dose continued up to 55 mg/m^2, where 2 of the 6 enrolled patients presented grade 3 diarrhea, which was our dose-limiting toxicity. Myelosuppression was mild, and no febrile neutropenia was observed. None of the patients showed grade 4 non-haematological toxicity. Only 9.5% of them presented grade 3 asthenia, whereas grade 3 diarrhea and mucositis were revealed in 19% and 9.5%, respectively. All grade 3 non-hematological toxicities were observed in heavily pretreated or elderly patients.**

Conclusions: **The recommended dose of docetaxel was 50 mg/m^2, but the regimen could not be recommended in heavily pretreated patients. However, it could become an option in an outpatient setting after a phase II study that better defines its toxicity profile and evaluate its antitumor activity.**

Key words: docetaxel, metastatic cancers, new schedule.

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