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PHASE II STUDY OF A COMBINATION CHEMOTHERAPY WITH WEEKLY DOCETAXEL AND GEMCITABINE IN PREVIOUSLY TREATED METASTATIC ESOPHAGEAL SQUAMOUS CELL CANCER

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**Aim:** This multicenter, phase II study was conducted to assess the efficacy and safety of weekly docetaxel plus fixed-dose rate (FDR) gemcitabine as second-line chemotherapy in patients with metastatic esophageal squamous cell carcinoma (SCC).

**Methods:** Esophageal SCC patients with documented progression after fluoropyrimidine-based first-line chemotherapy were treated with docetaxel 35 mg/m² and gemcitabine 1,000 mg/m² iv at FDR (10 mg/m²/min) on days 1 and 8. Treatment was repeated every 21 days until disease progression, unacceptable toxicity, or consent withdrawal. Primary endpoint was response rate (RR), and secondary endpoints were safety, progression-free survival (PFS) and overall survival (OS).

**Results:** A total of 33 patients were registered onto this prospective study. Combination or weekly docetaxel and FDR gemcitabine was well tolerated: the most common treatment-related adverse events were anemia (97%), fatigue (64%) and neutropenia (55%). Grade 3 or 4 neutropenia was developed in 13 patients (39%) and three episodes of febrile neutropenia were observed. One patient with lung and extensive lymph node metastases died of respiratory failure after receiving fourth cycles of chemotherapy, and the possibility of drug-induced pneumonitis could not be completely excluded. The overall RR was 30% with one complete and 9 partial responses. Stable disease was documented in 19 patients (58%). The median PFS and OS were 6 (95% CI 5-8) and 9 (95% CI 7-11) months, respectively.

**Conclusions:** The weekly combination of docetaxel and FDR gemcitabine showed a promising antitumor activity and tolerability in previously treated, metastatic esophageal SCC.

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