Abstract:

Introduction: We report a comparative analysis of 2 sequential, prospective phase II trials on the efficacy of platinum/leucovorin/5-fluorouracil (PLF) +/- paclitaxel (T-PLF) in the neoadjuvant treatment of adenocarcinoma of the esophagus (AEG I). Patients and Methods: Inclusion criteria were histologically proven, locally advanced AEG I stage uT3/4 anyN cM0/M1a. 67 patients were treated with either PLF (n = 32) or T-PLF (n = 35). Paclitaxel (80 mg/m²) was added to PLF on days 1, 15, and 29. Primary endpoint was the response. Additionally, 5-year survival was analyzed. Results: The study population was well balanced, apart from an imbalance in clinical cM1a (33.3% PLF vs. 8.6% T-PLF; p = 0.01). Histopathological response rates (23.3% PLF vs. 25.0% T-PLF) showed no significant difference. Clinical response rates were improved for T-PLF (21.9 vs. 45.7%; p = 0.04). Median overall survival for clinical and histopathological responders was significantly improved for T-PLF (p = 0.005, p = 0.01), but not for PLF (p = 0.08, p = 0.25). Median overall survival was better with T-PLF without reaching statistical significance (18.9 months PLF vs. 43.1 months T-PLF; p = 0.27). Toxicity was slightly increased by paclitaxel. No treatment-related deaths occurred. Conclusion: Our
data failed to demonstrate statistically significant superiority of the T-PLF regimen except for clinical response. However, there was a trend towards improved survival.

Stichworte: Paclitaxel; Adenocarcinoma of the esophagus; Neoadjuvant chemotherapy

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