Paclitaxel and carboplatin vs gemcitabine and vinorelbine in patients with adeno- or undifferentiated carcinoma of unknown primary: a randomised prospective phase II trial.

Abstract:
Platinum/taxane combinations are widely used in patients with carcinoma of unknown primary (CUP), yielding response rates of 30% and median overall survival of 9-11 months in selected patients. Yet these combinations have not been subject to a randomised trial to overcome selection bias, a major problem in CUP. We randomised 92 patients to either paclitaxel/carboplatin (arm A) or the non-platinum non-taxane regimen gemcitabine/vinorelbine (arm B). The primary endpoint was rate of practicability as defined: application of $\geq$2 cycles of therapy (1) with a maximal delay of 1 week (2) and survival of $\geq$8 months (3). Practicability was shown in 52.4% (95% CI 36-68%) in arm A and in 42.2% (95% CI 28-58%) in arm B, respectively. The median overall survival, 1-year survival rate and response rate of patients treated in arm A was 11.0 months, 38, and 23.8%, arm B 7.0 months, 29, and 20%. In conclusion, the paclitaxel/carboplatin regimen showed clinically meaningful activity in this randomised trial (Clinical trial registration number 219,'Deutsches KrebsStudienRegister', German Cancer Society.)