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Title: Efficacy and safety of full oral vinorelbine (NVBO) on D1 and D8 with carboplatin (CBDCA) as first line treatment in advanced non-small lung cancer (NSCLC) patients: Results of a prospective study in nonrandomized population of 259 patients

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Body: Background The purpose was to evaluate the activity and feasibility of CBDCA together with NVBO in 1st line treatment NSCLC patients. Patients and methods 259 patients (80,7% men, 19,3% women, median age 65 years) with advanced NSCLC received NVBO 80 mg/m² on D1 and D8 with CBDCA AUC5 on D1 every three weeks. Results At inclusion was PS 0 in 18,2% PS 1 in 71,7% and PS 2 in 10,1% patients. Most patients had stage IIIB (37,5%) and stage IV NSCLC (50,2%), only 12,4% stage IIIA. Adenocarcinoma was confirmed in 20,1%, squamous-cell carcinoma in 58,7%, large-cell carcinoma in 3,1% and other in 18,4%. CR was confirmed in 0,4%, PR in 46,7%, SD in 22,4% and 30,5% progressed. Median cycles was 4, the dosage of NVBO was without changes in 61% patients, reduced was in 4,7% and escalated in 24,8%. Major toxicities (grade 3-4) were neutropenia in 26,9%, leucopenia in 19,8%, anemia in 2,7%, and thrombocytopenia in 2,3% patients. Febrile neutropenia was observed in 6,6% patients. Gastrointestinal toxicity grade 3-4 was observed in 18,4% patients. The estimated mOS was 13,8 moths. and the estimated mPFS was 9,4 months by median follow-up 8,5 months. The differences between groups of pts according to PS (0+1 vs. 2) were statistically significant ($p < 0,001$) better for patiens with PS 0+1. The differences between groups according histology wewe not statistically significant. Conclusions The treatment with NVBO and CBDCA was well tolerated with evidence of high antitumour activity. This combination was active in all groups patients according histology.