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Gemcitabine Plus Oral Vinorelbine as Salvage Therapy Treatment for Patients With Advanced Non-small-cell Lung Cancer and Squamous Histology − a Galician Lung Cancer Group Study (GGCP042/09) Grupo Galego De Cancro De Pulmón (GGCP)

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Background: Until recently, histology had not been consistently described as a prognostic or predictive variable in advanced NSCLC studies. In this new scenario, patients with squamous histology (SCC) remain with limited treatment options, particularly in the 2nd line setting, where docetaxel and erlotinib are the only approved agents. Compared to single agent chemotherapy (CT) in second line, doublet CT seems more toxic without modest improvement in overall survival (OS), but some combinations have achieved encouraging results. Combination CT with third-generation, non-platinum agents [i.e., gemcitabine (G), vinorelbine (V)] might play a role as salvage therapy. The aim of this study is to evaluate the activity and tolerance of G in combination with oral V in pretreated patients with SCC-advanced NSCLC.
Material and Methods: 24 pre-treated patients (p) with NSCLC of stage IIIB/IV and SCC histology were treated with G (1.250 mg/m^2 i.v.) plus V (60 mg/m^2 p.o.) on days 1 and 8, of each 21-day cycle, up to 6 cycles, unless disease progression or unacceptable toxicity. Baseline characteristics: median age: 61 yrs. (range: 50−82); 96% male; 79% stage IV; 92% performance status ECOG 0−1. The primary end point was progression-free survival (PFS).
Results: The most common non-hematologic toxicities were grade 1−2 asthenia (45.8%; only 1 p grade 3), anorexia (25%), and grade 1−2 nausea/vomiting (12.5%/25%). Half of the p experienced grade 1−2 anaemia. Neutropenia occurred in 38% of the p (13% grade 3−4), but only 1 patient experienced febrile neutropenia. 6 p (25%) developed serious adverse events leading to hospitalization. Median of administered cycles vas 4 (range: 1−6), with a mean dose intensity of 93.4% for both drugs. There were two deaths due to massive haemoptysis (8.3%).
Among evaluable p (63%), response rates were 13.3% and an additional 60% controlled the disease. Median PFS was 3.8 months (95% CI: 1.8−5.8); and median OS was 6.9 (95% CI 1.0–12.8).
Conclusions: Compared to historical controls, the combination of i.v. G plus oral V as salvage therapy of patients with SCC advanced NSCLC seems to be as effective as single agents, with an encouraging disease-control rate. Although the combination is relatively well tolerated, it is associated to a higher incidence of haematological adverse events, with 40% of patients developing neutropenia (13% severe). Non-hematologic toxicities were manageable. The combination of GV is an effective regimen in 2nd-line therapy, but the safety profile of the available options should be considered when deciding the optimal therapy in this setting.

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Effectiveness of Bevacizumab (BV) Maintenance in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) Treated in US Community Practices

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Background: BV has demonstrated safety and efficacy when combined with first-line (1L) chemotherapy (CT) and continued as monotherapy to progression (PD) for patients with nonsquamous (ns) advanced NSCLC. In recent analyses of US treatment (tx) patterns, BV is often discontinued after induction CT, and not continued until PD as per the US label.
Methods: A retrospective analysis of data from US community practices (Cancer Clinics of Excellence) was conducted to understand patterns of BV use with induction CT, continuation of BV maintenance to progression (BTP), and outcomes. Patients with advanced ns NSCLC receiving 1L treatment from 1/1/07 to 12/31/08 were identified. Tx and outcomes data were collected through 6/30/10 or date of death/last follow-up visit. Survival analyses (Kaplan–Meier with log-rank test) estimated OS of patients who received BTP vs. No BTP, among those who were alive and PD-free after completion of induction BV+chemo. As data collection is ongoing, preliminary results are reported.
Results: Among 600 ns NSCLC patients identified, 224 (37%) received BV with 1L CT, 83% of which was a platinum-based CT doublet. Of 224 patients who received 1L BV+CT, 22% (n = 50) continued BTP. Patients in the BTP and No BTP groups were similar in age, histology, stage at diagnosis. The 5 most common reasons for patients not receiving BTP: unresolved tx-related toxicity (12%), lack of tx response (14%), plans to use BV in future tx (9%), switched to other tx (9%), poor ECOG performance status (7%). Of those who were alive and PD-free at completion of induction chemo, median OS was longer in the BTP cohort (n = 37) vs. the No BTP cohort (n = 71) (23.3 vs 14.7 months, respectively, p = 0.012). Incidence of BV-related toxicities was consistent with reports from clinical trials. Further analysis of the final dataset will be conducted.

Table: Baseline characteristics

	BTP (n = 50)	No BTP (n = 174)
Female (%)	60	52
Median age (y)	68	69
Adenocarcinoma (%)	70	72
Stage at Dx (%)		
I−II	10	8
IIIA	6	6
IIIB	18	15
IV	62	67
Unknown	4	4
ECOG PS (%)		
0	30	14
1	30	35
⩾2	6	14
Unknown	34	37

Conclusions: In this preliminary analysis of treatment in US community practices, longer OS was observed in patients with ns advanced NSCLC receiving BTP relative to No BTP. While additional data is being collected, these results suggest that continued VEGF suppression may be important in ns NSCLC treatment.

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Clinical Responses to EGFR-tyrosine Kinase Inhibitor Retreatment in Non-small Cell Lung Cancer Patients Who Benefited Prior Gefitinib Therapy

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Background: Gefitinib was the first epidermal growth factor receptor-tyrosine kinase inhibitor (EGFR-TKI) approved for the treatment of advanced non-small cell lung cancer (NSCLC). Few treatment options are available for NSCLC patients who have responded to gefitinib treatment and demonstrated tumour progression. The present study was conducted to evaluate the efficacy and toxicity of the 2nd EGFR-TKI administration.
Materials and Methods: We retrospectively analyzed 11 patients who had obtained a partial response (PR) or stable disease (SD) with gefitinib treatment and were re-treated with EGFR-TKI after failure of the initial gefitinib treatment.
Results: Three patients (27%) were treated with gefitinib as the 2nd EGFR-TKI, and 8 patients (73%) received erlotinib. Only one patient (9%) showed PR, 7 (64%) achieved SD, and 3 (27%) had progressive disease. The disease control rate was 73% (95% CI, 43–91%) and the median progression-free survival was 3.4 months (95% CI, 2−5.2). The median overall survival from the beginning of the 2nd EGFR-TKI and from diagnosis were 7.3 months (95% CI, 2.7−13) and 36.7 months (95% CI, 23.6–43.9), respectively. No statistical differences in PFS or OS were observed between gefitinib and erlotinib as the 2nd EGFR-TKI (PFS, P = 0.23 and OS, P = 0.052).
We further compared the clinical courses of the patients with those of gefitinib responders who were not treated with a 2nd EGFR-TKI following gefitinib failure. We reviewed the medical records at our institute and found 9 patients with backgrounds that were similar to those of the 2nd EGFR-TKI patients (sex, age (<70 years old or ⩾70 years old), histology, and response to gefitinib treatment). No statistical differences in PFS to 1st gefitinib treatment were noted between both groups (9.8 months in the 2nd TKI group and 8.7 months (95% CI, 7.6−9.8) in the control group, P = 0.87). All of the identified control patients had been treated with platinum-doublet chemotherapy before gefitinib but had not received 2nd EGFR-TKI. The OS from the start of the initial gefitinib treatment tended to be longer in patients who received a 2nd EGFR-TKI (median OS, 21.5 months (95% CI, 14.6–