Materials and Methods: We retrospectively reviewed 81 advanced NSCLC patients who experienced disease progression following tumour response and durable (⩾ 6 months) disease stabilization from first-line or second-line gefitinib. Post-progression survival (PPS) and characteristics were investigated and compared in patients who resumed TKIs (n = 16) and who did not resume (n = 65).
Results: Most of patients were female never-smokers with adenocarcinoma. Median overall PPS was 10.3 months (95% CI; 7.458–13.142). Age, gender, smoking history, histology, ECOG performance status (PS) at the start of gefitinib, initial stage and platinum-based chemotherapy (PBC) after gefitinib were not significant predictors for PPS. Using pemetrexed after gefitinib showed significantly longer PPS (18.5 vs 8.6 months, HR = 0.45, p = 0.008). Resuming gefitinib had a trend to lengthen the PPS but, lost its significance by multivariate analysis (27.4 vs 8.8 months, HR = 0.53; p = 0.095).

Table: Response to resumed TKIs

Response	Gefitinib resumed (n = 11)	Erlotinib resumed (n = 5)
PR	3	1
SD	5	2
PD	3	2

Conclusions: In NSCLC patients who assumed to have clinically acquired resistance to TKIs had relatively long PPS. Resuming TKIs or using pemetrexed after PD on gefitinib could improve the PPS.

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AVAPERL1 (MO22089) − Interim Safety of Maintenance (mtc) Bevacizumab (bev) + Pemetrexed (pem) in Patients (pts) With Advanced Non-squamous Non-small Cell Lung Cancer (nsNSCLC) After First-line (1L) Bev-cisplatin (cis)-pem Treatment (Tx)

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Background: 1L bev-based Tx followed by mtc bev offers clinical benefit over chemotherapy alone, as do either 1L cis-pem or mtc pem. AVAPERL1 investigates whether continuing pem with bev offers additional benefit over bev alone after 1L bev-cis-pem. AVAPERL1 is fully enrolled; follow-up is ongoing.
Materials and Methods: Eligible pts with advanced, metastatic or recurrent nsNSCLC who achieve CR/PR/SD after 4 cycles of bev-cis-pem were randomized to receive bev or bev+pem until disease progression or unacceptable toxicity. Adverse events (AEs) were graded by NCI CTC v.3.0 (MedDRA coding).
Results: As of 11Feb11, 373 pts who received ⩾1 dose of any study drug were included in the safety analysis. Baseline characteristics were reported at ESMO 2010 (Barlesi, 430P). 244 pts (59%) initiated mtc Tx. Median follow-up, 7.6 months. *Safety population*: Overall AEs are shown in Table 1. The most common grade (G)⩾3 AEs with onset in 1L or mtc are neutropenia (8%), fatigue/asthenia (4%) and anemia, dyspnea, hypertension (HTN) and pulmonary embolism (PE) (3% each). The most common SAEs with onset in 1L or mtc are pneumonia and PE (3% each), and diarrhea, nausea, neutropenia and renal failure (2% each). *Mtc phase*: More pts treated with bev+pem (90%) reported AEs with onset in mtc than those treated with bev (79%). The most common (⩾10%) AEs in the bev+pem arm are fatigue/asthenia and HTN (22% each), nausea (20%), constipation, cough and dyspnea (12% each), anorexia (11%), and diarrhea (10%) and those in the bev arm are HTN (17%), fatigue/asthenia (12%) and cough (10%). The number of G ⩾ 3 AEs with onset in mtc was greater in the bev+pem arm (56 events, 33% pts) than in the bev arm (30 events, 18% pts), with the most common being neutropenia (4%) in the bev+pem arm, and PE (3%) in the bev arm. The number of SAEs with onset in mtc was greater in the bev+pem arm (33 events, 20% pts) than in the bev arm (15 events, 13% pts), with the most common being pneumonia and TIA (2% each) in the bev+pem arm, and PE and general deterioration (2% each) in the bev arm.
Conclusions: 1L bev-cis-pem was tolerable. More G⩾3 AEs and SAEs with onset in mtc were reported in pts treated with bev+pem than bev and this increased toxicity may be attributable to pem.

Table 1

	Safety population, N = 373	Bev mtc, n = 119	Bev+pem mtc, n = 125
Any G AE			
n	3450	1105	1500
% pts	95	96	97
G⩾3 AE			
n	349	76	106
% pts	53	40	47
SAE			
n	218	35	70
% pts	39	23	36
% pts with AE by phase			
1L	88	84	89
Mtc	55	79	90
% pts with AE by intensity			
G1/2	85/77	92/81	90/83
G3/4	45/9	36/5	43/6
G5	6	3	4

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Total Direct and Segmented Medical Cost-of-Care for Stage IV (Adv) Non-Small Cell Lung Cancer (NSCLC) in a Private Insurance Population

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Background: New treatments for stage IV (adv) NSCLC have emerged this past decade. The direct medical cost-of-care for adv NSCLC has not recently been studied. Our primary objective was to characterize the direct cost of adv NSCLC from 2000−9. We also want to determine cost segmented by time in the disease course (diagnosis, active treatment, end-of-life), cost impact of new therapies, and cost trend from 2000−9.
Methods: This PharMetrics claims database study uses a retrospective cohort study design. Diagnosed NSCLC patients ⩾20 years were included. Small cell lung cancer was excluded. Sub analyses include division into disease segments and time periods representative of changes in therapy available throughout the study period. The study period was divided into the “pre” (2000−2), “transition” (2003−5), and “current” (2006−9) periods to account for the change from standard chemotherapy to the introduction of pemetrexed, TKIs, and the biologics.
Results: The study sample contains 5,847 eligible patients. Over the study period the mean total cost of care was $162,134 per patient (patients receiving ⩾ 5 months of therapy; n = 432), while the mean per patient per month (pppm) cost was $10,284 (med [median] $7,696; SD $12,295). Diagnosis cost was $9,162 pppm (med $6,978; SD $8,328). Active mean treatment cost was $10,141 pppm (med $7,807; SD $10,435) and end-of-life mean cost was $18,033 pppm (med $12,301; SD $19,370). Pemetrexed (5%), TKIs (6%), and biologic agents (5%) accounted for 16% of the active treatment segment. In total, they accounted for 4% of overall cost. Cost of “pre” was $8,662 pppm (med $6,747; SD $8,747), “transition” was $10,578 pppm (med $7,722; SD $13,716), and “current” was $10,141 pppm (med $7,731; SD $11,186).
Conclusions: The mean total direct cost of care for advanced NSCLC was over $160,000 per patient or $10,284 pppm. The most costly segment was end-of-life at $18,033 pppm. The newer agents (pemetrexed, TKIs, and biologics) represent only a modest portion of the active treatment cost, which was a mean of $10,141 pppm, but represented only a very small portion of total cost. The “current” time period retained similar costs as the “transition” period.