of SQC relapses have been found 6 moths later than in AD. Clinical relapse has been proven 6 to 18 months after CYFRA relapse. The increase of CYFRA 21-1 level has required more extensive and frequent bronchological examination which provided the reoperation of 4,2% patients in the same stage of the disease.

Conclusions: These results show that tumor marker CYFRA 21-1 has prognostic and predictive value in surgical treatment of primary lung neoplasms.

774 POSTER

Quality of life assessment and final results of a randomised Phase II Study with single-agent Gemcitabine and Docetaxel given sequentially every 3 weeks show effective treatment in advanced NSCLC

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Gemcitabine (G) and Docetaxel (D) have been shown to be effective in chemotherapy-naïve and pretreated patients (pts) and are not cross-resistant. We have tested G/D in doses of 1250 mg/m^2 /100 mg/m^2 and a q3w schedule G: day 1,8 / D: day 1 (Proc ASCO 2001; 20: 337a [Abstract 1346]) giving G or D initially up to 6 cycles and in case of tumor progression switching to D and G, respectively, (up to 6 cycles). 330 patients with median age of 64 (range 29-85) entered the study (stage at study entry IIIB/IV 11%/89%; WHO performance status 0 or 1/>1: 81%/19%; histology adenomatous/squamous/miscellanous 48%/26%/26%), and all 321 evaluable patients have been analyzed. In median survival, no statistical significant difference can be seen between the treatment arms A/B 6.3/8.6 mos (KaplanMeier: log-rank p=0.206). The corresponding confidence intervals (CI) are A/B [5.2;7.2]/[7.1;10.3]. The 1-Year-Survival-Rate of A/B is 28%/31% with 12(7.5%)/17(10.5%) censored observations. So far the treatment arms A and B can be statistically considered as equally effective. The quality of life (QoL) evaluation was measured by using the EORTC QLQ-C30 with annexed LC13 questionnaire. 88%/96% (A/B) of pts participated in the QoL evaluation (a total of 1346 forms (QLF)). Compliance of pts was high: in the first 6 interrogations (till 5th cycle) the rate was varying between 68%/70% and 86%/86% (A/B). 57%/50% pts were evaluable per protocol for baseline data (1st QLF) and after the 2nd cycle (3rd QoL evaluation). The individual tolerance toward the treatment was measured by the weighted sum score of the individual difference of the first 13 questions: There was no statistical significant difference between A and B (p-value is 0.3913 in the Wilcoxon rank sum test with an estimate of -0.077 and a CI of [-0.154;0.077]). Missing values and different scales have been adjusted by recalculating the mean scores for every patient and sub-number. Additionally scores of question 1-7, 8-28, 29-30 of EORTC-QLQ-C30, and 31- 42, and the two parts of question 43 of LC13, symptom scale ss14, scores of EORTC-QLQ-C30 and LC13 have been analyzed by the Wilcoxon rank sum test (base-line vs 3rd QLF). For all tests only a statistical significant difference between arm A/B can be seen for the score of LC13 (p-value of 0,0001) and for the Score 31-42. Question 43 alone is not different. The result is that in part LC13 pts of arm A feel as good as at base-line and pts in arm B do not so (M(A)=0,00 and M(B)=0,22). The same test was used for the base-line vs 6th QLF (28/37 pts in arm A/B, respectively). At this time point no differences in any of the scores can be seen. The use of G and D as carried out in the two arms is effective. Only a significant difference in QoL assessment in the annexed part of LC13 (baseline vs 3rd QLF) can be seen between the two drugs; in the main measurement of QoL there is no difference.

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Standards of care for patients with small cell lung cancer (SCLC): a survey of clinical practice within the European Union (EU)

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To assess the actual chemotherapeutic regimens currently employed for the management of SCLC in Europe, a survey of cancer treatment centres across the EU was conducted by GlaxoSmithKline clinical development during 2002. The survey comprised a series of questions based on theoretical clinical cases regarding the choice of first- and second-line therapies. One hundred and seventy-two cancer treatment centres were identified and numbered questionnaires were sent to each. One hundred and one replies were received by the deadline for database entry. Of the respondents, 90% were from university hospitals or secondary referral centres.

The percentage of SCLC patients treated with each of the major first-line treatment regimens within the EU are as follows:

Treatment Regimen	% of SCLC Patients Treated	
	Limited Disease	Extensive Disease
cisplatin/etoposide	59	38
carboplatin/etoposide	28	38
platin not otherwise specified	11	10
doxorubicin-based	2	11

At relapse of the SCLC, treatment of patients who are of adequate performance status is clearly based on treatment-free interval, and recovery from treatment-specific toxicities. For a patient with a short treatment-free interval (6 weeks), 78% of clinicians would use chemotherapy and all of them would use a cross-over regimen. For a patient with a longer treatment-free interval (3 months), at least 93% of clinicians would use chemotherapy and the majority would use a cross-over regimen. When the treatment-free interval is even longer (2 years), the management is most likely to be re-treatment with the first-line regimen. If there is residual toxicity from the first-line regimen, cross-over is the common practice, even after a long treatment-free interval. The primary basis for the decision-making in relapsed SCLC is the published literature in the light of the local clinical experience. Details of the survey results will be presented.

776 POSTER

An economic analysis of the TAX 326 trial: a multicenter randomized study of docetaxel + cisplatin (DC) or docetaxel + carboplatin (DCb) vs. vinorelbine + cisplatin (VC) as first-line therapy in advanced non-small cell lung cancer (NSCLC)

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Lung cancer is a leading cause of cancer mortality in North America. The annual direct costs of lung cancer care in the United States are estimated at over $5 billion US. Systemic therapy in patients with advanced NSCLC has been shown to prolong survival and improve symptom control in the first- and second-line setting. TAX 326, a randomized trial, compared DC or DCb with a current standard, VC. Patients treated with DC had longer median survival than those treated with VC (11.3 vs. 10.1 months, p=0.044) and better quality of life scores. Patients treated with DCb had similar survival to those treated with VC (9.4 months). Consequently the DCb arm was not included in this analysis. A retrospective cost-effectiveness analysis was performed of the DC and VC arms of the TAX 326 trial, evaluating direct medical costs of therapy from the viewpoint of Canada's public healthcare system. Costs were derived from the Princess Margaret Hospital/University Health Network, a tertiary cancer center, in 2002 Canadian dollars. Resource use was determined through prospective trial data provided by Aventis Pharma. Of the 1218 patients in the intent-to-treat TAX 326 population, 1203 received protocol treatment and were included in this cost analysis. The mean incremental survival benefit in the DC arm over VC was 30 days. Docetaxel use was more costly, and the cost-effectiveness (CE) of DC over VC was $48,933 CAD (approximately $30,583 USD) per year of life gained (LYG). The largest cost in the DC arm was chemotherapy (46%), and in the VC arm was hospitalization (46%). In univariate sensitivity analyses, CE estimates were most sensitive to changes in survival and chemotherapy cost. Variation in total chemotherapy cost (±20%) yielded CE estimates of $31,616 to $66,251 CAD per LYG. Variation in survival (± 2 SD) yielded CE estimates of $24,467 to $734,000 CAD per LYG. Treatment with DC first-line in advanced NSCLC significantly improves survival, quality of life and symptom control compared with VC. While cost should not be