Lung Cancer™ UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

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Howard West, MD

SPECIAL ISSUE

Proceedings from a Clinical Investigator "Think Tank"

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STATEMENT OF NEED/TARGET AUDIENCE

Lung cancer is the leading cause of cancer mortality in the United States in both men and women, resulting in more deaths than breast, prostate, colon and pancreatic cancer combined. Progress in the screening, prevention and treatment of this disease has been modest, and about 85 percent of patients who develop lung cancer will die from it. In addition, a sense of therapeutic nihilism has pervaded the medical community in the past. Chemotherapy, surgery and radiation therapy have had a modest effect on patient outcomes; however, recent improvements have been seen in time to progression and survival in lung cancer clinical trials. Published results from ongoing clinical trials lead to the continuous emergence of new therapeutic agents and changes in the indications for existing treatments. In order to offer optimal patient care — including the option of clinical trial participation — the practicing medical oncologist must be well informed of these advances. To bridge the gap between research and patient care, *Lung Cancer Update* uses one-on-one discussions with leading oncology investigators. By providing access to the latest research developments and expert perspectives, this CME program assists these physicians in the formulation of up-to-date clinical management strategies.

GLOBAL LEARNING OBJECTIVES

- Critically evaluate the clinical implications of emerging clinical trial data in lung cancer treatment, and incorporate these data into management strategies in the adjuvant, neoadjuvant, locally advanced and metastatic settings.
- Counsel appropriately selected patients about the availability of ongoing clinical trials.
- Develop and explain a management strategy for treatment of elderly patients and those with poor performance status in the adjuvant, neoadjuvant, locally advanced and metastatic settings.
- Integrate emerging data on utilization of targeted molecular therapies and molecular and genetic assays in the development of individual management strategies for patients with lung cancer.
- Counsel patients with localized primary lung cancer about the risks and benefits of adjuvant chemotherapy.
- Identify the impact of smoking-related comorbidities on the treatment of patients with lung cancer and integrate smoking cessation into the management strategy for these patients.

PURPOSE OF THIS ISSUE OF *LUNG CANCER UPDATE*

The purpose of this special edition of *Lung Cancer Update* is to support these global objectives by offering the perspectives of Drs Choy, Edelman, Herbst, Kim, Kris, Lilenbaum, Lynch, Miller, Pass, Sandler, Socinski and West on the integration of emerging clinical research data into the management of lung cancer.

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TABLE OF CONTENTS

Topics Discussed by Faculty

Dr Sandler: ECOG-E4599 update including ASCO data sets; nonprotocol use of bevacizumab for Stage IV disease

Dr Herbst: Bevacizumab combined with erlotinib; new anti-angiogenic agents

Dr Lilenbaum: ASCO abstracts 7022 (treatment of PS2 patients) and 7034 (meta-analysis of trials of docetaxel and vinca alkaloids)

Dr Lynch: Tissue markers to predict response to tyrosine kinase inhibitors (TKIs)

Dr Kris: TKIs in nonsmokers; bronchoalveolar carcinoma

Dr Miller: Algorithms for management of metastatic disease in various patient subsets

Dr Edelman: ASCO abstracts 7007 (CALGB-9633), 7010 (IALT) and 7026 (genomic prognosis)

Dr Socinski: ASCO abstracts 7008 (LACE), 7009 (BR10-elderly) and 7011 (CISCA)

Dr Kim: Optimal options for adjuvant therapy on and off protocol, including entry on ECOG 1505, evaluating chemotherapy alone or with bevacizumab

Dr Pass: RTOG/SWOG Intergroup N2 non-small cell lung cancer (NSCLC) trial

Dr Choy: Chemoradiation for unresectable, locally advanced NSCLC

Dr West: Hoosier Oncology Group trial in locally advanced disease; SWOG trials of bevacizumab with chemoradiation

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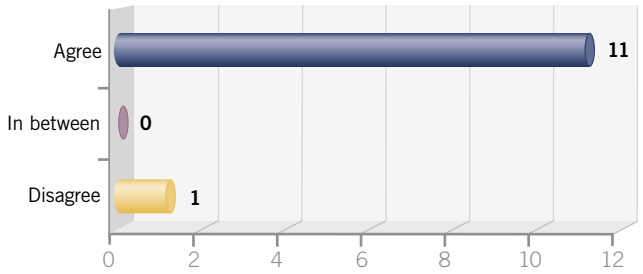
SECTION 1

BEVACIZUMAB COMBINED WITH CHEMOTHERAPY AS FIRST-LINE THERAPY OF ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)

FACULTY POLL QUESTION 1

Chemotherapy in combination with bevacizumab is the current standard of care for patients who meet the entry criteria for the ECOG-E4599 trial.



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

Select Excerpts from the Discussion

CD 1, Tracks 2, 4

DR LOVE: Tom, do you agree or disagree with the statement that for a patient who would have met the entry criteria for ECOG-E4599, the current standard of care is chemotherapy with bevacizumab?

DR LYNCH: Agree.

DR LOVE: Should bevacizumab be continued until disease progression?

DR LYNCH: Agree.

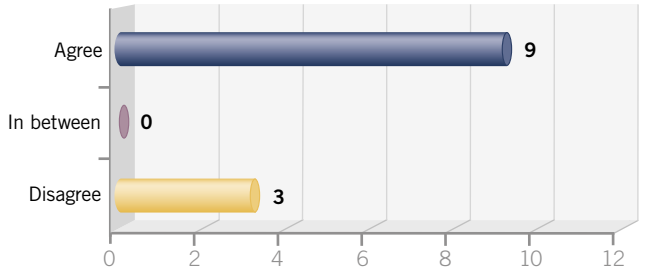
DR LOVE: Why do you feel that way?

DR LYNCH: If I'm going to practice evidence-based medicine, I'd want to treat my patients the way they were treated on ECOG-E4599 (Sandler 2005), until we have evidence that dictates otherwise. I also like the idea of continuing bevacizumab after finishing the chemotherapy because micrometastatic disease or smaller-volume disease might be present that you may be influencing.

DR LOVE: I'll ask Alan the same questions.

FACULTY POLL QUESTION 2

In patients who demonstrate stable disease after six cycles of chemotherapy with bevacizumab, I continue bevacizumab as maintenance therapy.



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

DR SANDLER: The answers are yes and yes. It's interesting that other clinical investigators don't necessarily have the same thoughts. The objections raised include the fact that this is only one randomized Phase III study, and we're waiting for a second. That is fair, and I usually reply, "Is anybody using erlotinib?"

Only one randomized Phase III study supports erlotinib (Shepherd 2005), and everybody has pretty much jumped on that one. I personally wouldn't want to put a family member on a study that included a control arm without bevacizumab. More toxicity is associated with bevacizumab and chemotherapy than with chemotherapy alone, but I believe it's clinically acceptable.

DR LOVE: What about bevacizumab and other chemotherapy agents?

DR LYNCH: I need to see data to suggest that you can safely administer bevacizumab with carboplatin/docetaxel and carboplatin/gemcitabine, but I suspect you can.

DR LOVE: Does "suspect" mean you're comfortable with using it off protocol?

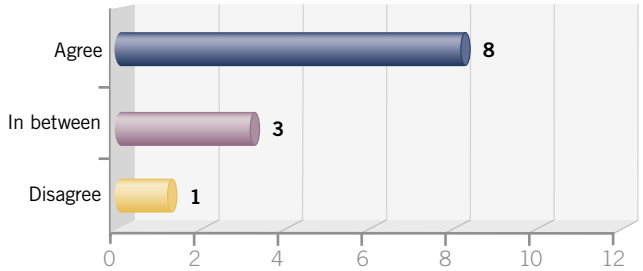
DR LYNCH: Last night, I was driving to the airport with a practicing oncologist who's going to use carboplatin/docetaxel with bevacizumab. He said he has administered it to patients and had no problems. I expect that it will probably be okay. However, I won't use it off protocol until I see some data suggesting it's safe. I expect it will be safe, but I've stayed with carboplatin/paclitaxel until we have some of the initial data, which we'll have very soon.

DR LOVE: Ed, specifically which chemotherapy regimens are you using with bevacizumab?

DR KIM: At MD Anderson, we're enrolling patients in a trial of carboplatin/docetaxel and bevacizumab. We have about 14 patients on the trial, and we

FACULTY POLL QUESTION 3

I am comfortable using bevacizumab with chemotherapy combinations other than carboplatin/paclitaxel outside of a protocol setting.



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

haven't seen many serious toxicities. We had one person with hemoptysis who had an adenocarcinoma, a noncavitary lesion.

It wasn't in the mediastinum, but it was more centrally located. It was an incidental hemoptysis that occurred, and we took him off the study.

It was interesting because the tumor response was cavitary. We also had one person who had febrile neutropenia, but you expect some of that with chemotherapy alone.

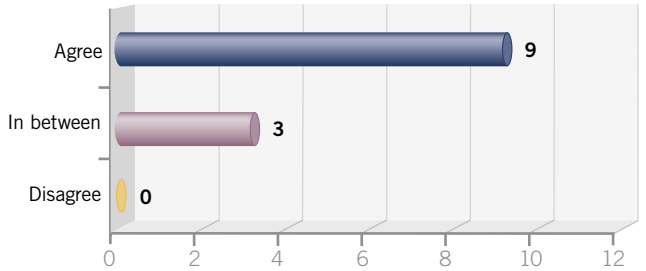
DR LILENBAUM: It's the gemcitabine-based doublets that remain somewhat worrisome. I believe most people feel comfortable using docetaxel as opposed to paclitaxel. Many people have done it safely. I'm not sure why it should be a concern.

Gemcitabine is more of a concern. We are doing a Phase II study of oxaliplatin and gemcitabine with bevacizumab. We haven't seen any significant complications, such as bleeding or thrombocytopenia, or more episodes of febrile neutropenia than expected. So I expect it to turn out okay. The best evidence for that is that in an NCI Phase III adjuvant study, a setting in which you want to be extra careful about toxicities, most people felt comfortable including a gemcitabine-based regimen.

DR HERBST: I believe one of the reasons people feel comfortable is that the registration trial in Europe, evaluating bevacizumab with chemotherapy, is being conducted with gemcitabine combinations. Although those data are talked about, we haven't seen them, but one would assume that people have considered that database as they've gone forward. My feeling is that we can probably use all the combinations, but I agree that we need to see the data.

FACULTY POLL QUESTION 4

A significant part of the mechanism of antitumor action of bevacizumab in NSCLC is improved delivery of chemotherapy to the tumor.



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

CD 1, Track 6

DR LOVE: Roy, can you comment on the mechanism of action of bevacizumab?

DR HERBST: We really don't know. Is it working by enhancing chemotherapy? That's one thought. Is it working to increase drug delivery? Probably. Is it working directly on tumor cells? Data suggest that tumor cells have VEGF receptors. Is it working in the maintenance setting to suppress angiogenesis and endothelial and tumor cells? Because we have many more compounds coming down the pike, we need to do some mechanistic studies.

CD 1, Tracks 11-12

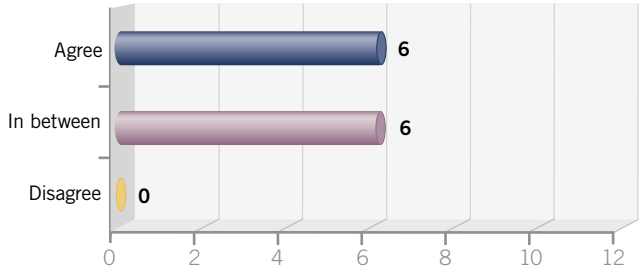
DR LOVE: Tom, when you start a patient on chemotherapy and bevacizumab in the first-line metastatic setting, what do you tell them about the risks?

DR LYNCH: I tell them that their risk of dying from chemotherapy increases from about one percent to about three to four percent, but I emphasize that the overall risk of dying from the disease will be reduced. In the end, the chance of living longer will be greater on chemotherapy combined with bevacizumab.

We talk about hemoptysis and the fact that it's rare but can still happen. We also talk about stroke and other thromboembolic phenomena. When we consider the colorectal experience with bevacizumab, we're all pretty confident that bevacizumab is associated with a real but small increase in thromboembolic phenomena, which is not trivial for patients with lung cancer.

FACULTY POLL QUESTION 5

The hemoptysis seen with bevacizumab in NSCLC is probably associated with tumor response.



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

I believe that in the end, what drives our enthusiasm for bevacizumab is the fact that in a trial of patients with Stage IV disease, it demonstrated a substantial and clinically meaningful prolongation of survival (Sandler 2005). This is why I believe all of us here would endorse using it in this setting. You have to inform your patient about the risks, and I believe most patients will decide it's worth it.

DR LOVE: It's been said that perhaps hemoptysis is a manifestation of response. Can you comment on that?

DR SANDLER: My bias, particularly for the squamous cell histology, is that it may be a manifestation of a brisk response to treatment and that cavitation ultimately results.

CD 1, Track 14

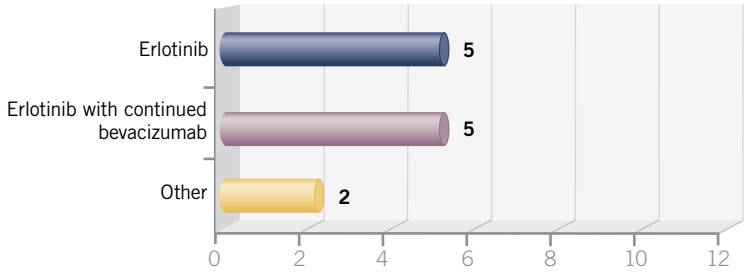
DR LOVE: Roy, can you discuss findings from the trial combining bevacizumab with erlotinib that was presented at ASCO 2006?

DR HERBST: A randomized Phase II trial of 120 patients was reported by Lou Fehrenbacher from Kaiser at ASCO. The treatment arms included chemotherapy (docetaxel or pemetrexed) with placebo or bevacizumab versus bevacizumab with erlotinib. In this second-line setting, bevacizumab enhanced both the EGFR inhibitor, erlotinib, and chemotherapy (Fehrenbacher 2006).

The results were reasonably good regarding time to progression, but the numbers were small. The hazard ratios were 0.66 for chemotherapy in combination with bevacizumab and 0.72 for erlotinib in combination with bevacizumab. The 95 percent confidence intervals crossed one. So these were not statistically significant data, but they were suggestive of a trend. Toxicity and

FACULTY POLL QUESTION 6

A 60-year-old nonsmoker has an excellent response to bevacizumab/paclitaxel as first-line therapy of metastatic disease and is continued on bevacizumab. At 16 months, the patient develops slow but definite disease progression. Outside a protocol setting, this patient should be offered:



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

drug discontinuation due to adverse events were much less frequent among the patients who received the less toxic erlotinib/bevacizumab combination (Fehrenbacher 2006).

CD 1, Track 17

DR LOVE: Outside of a clinical trial, have you used or would you consider using bevacizumab for a patient with previously treated brain metastases?

DR LYNCH: No. We're participating in the trial to answer that question. Patients have their brain metastases radiated first, and then they receive treatment. Because of the restrictions in eligibility for ECOG-E4599, I believe we have to follow an evidence-based approach, and I have not been using bevacizumab in this setting outside of a protocol.

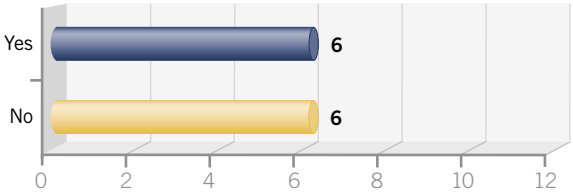
DR LOVE: What about resected brain metastases?

DR LYNCH: Resected brain metastases would not have been included in ECOG-E4599.

DR MILLER: Aren't we amending the current clinical trials to allow patients with previously radiated brain metastases? These contraindications have relative degrees. Certainly squamous histology and hemoptysis are much more powerful contraindications (Gordon 2001). This drug is very active in patients with glioblastoma multiforme — huge tumors with lots of edema — and we're undertaking approval

FACULTY POLL QUESTION 7

Have you used or will you consider using bevacizumab in a patient with known treated brain metastases outside of a clinical trial setting?



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

strategy trials for those patients. We usually obtain the blessing of a neurologist to use bevacizumab, but we certainly have done it.

DR HERBST: I would wait until the data are available, which I expect will be soon. One trial, called PASSPORT, will determine if you can use chemotherapy with bevacizumab for patients with previously treated brain metastases. ■

SELECT PUBLICATIONS

Auberger J et al. **Targeted therapies in non-small cell lung cancer: Proven concepts and unfulfilled promises.** *Curr Cancer Drug Targets* 2006;6(4):271-94. **Abstract**

Davila E et al. **Phase II trial of oxaliplatin and gemcitabine with bevacizumab in first-line advanced non-small cell lung cancer (NSCLC).** *Proc ASCO* 2006;**Abstract 17009**.

Dowlati A et al. **Prospective correlative assessment of biomarkers in E4599 randomized phase II/III trial of carboplatin and paclitaxel ± bevacizumab in advanced non-small cell lung cancer (NSCLC).** *Proc ASCO* 2006;**Abstract 7027**.

Fehrenbacher L et al. **A phase II, multicenter, randomized clinical trial to evaluate the efficacy and safety of bevacizumab in combination with either chemotherapy (docetaxel or pemetrexed) or erlotinib hydrochloride compared with chemotherapy alone for treatment of recurrent or refractory non-small cell lung cancer.** Presentation. *Proc ASCO* 2006;**Abstract 7062.**

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Sandler A. **Bevacizumab and non-small cell lung cancer.** Presentation. *Lung Cancer Update* Think Tank Meeting 2006. No abstract available

Sandler AB et al. **Randomized phase II/III trial of paclitaxel (P) plus carboplatin (C) with or without bevacizumab (NSC #704865) in patients with advanced non-squamous non-small cell lung cancer (NSCLC): An Eastern Cooperative Oncology Group (ECOG) trial — E4599.** Presentation. *Proc ASCO* 2005;**Abstract 4.**

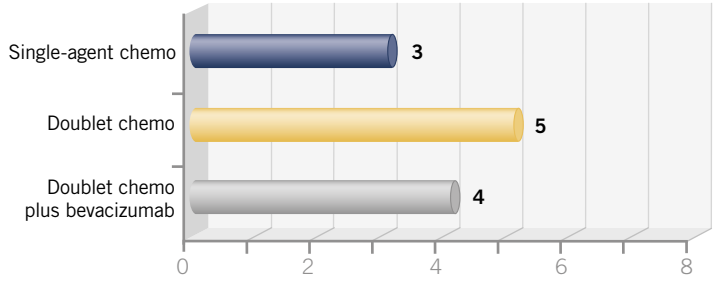
Shepherd FA et al; National Cancer Institute of Canada Clinical Trials Group. **Erlotinib in previously treated non-small-cell lung cancer.** *N Engl J Med* 2005;353(2):123-32. **Abstract**

SECTION 2

TREATMENT FOR PATIENTS WITH POOR PERFORMANCE STATUS

FACULTY POLL QUESTION 8

A 60-year-old patient presenting with extensive NSCLC was previously functioning normally and now has a performance status of 2 because of tumor-related symptoms. What is your most likely recommendation?



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

Select Excerpts from the Discussion

CD 1, Track 18

DR LOVE: Mark, can you discuss how you approach patients who have a poor performance status and metastatic disease?

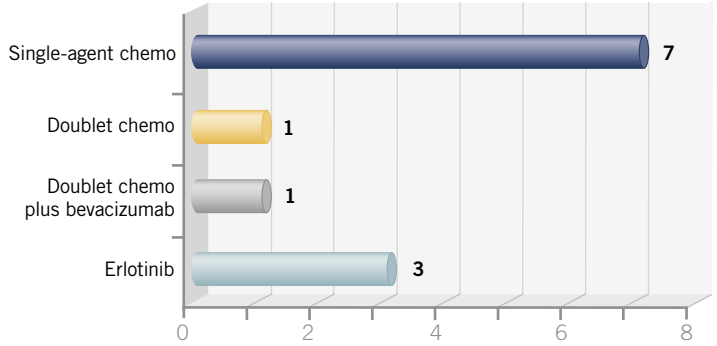
DR SOCINSKI: We all see patients with poor performance status who three months earlier were playing 18 holes of golf. They became sick because they developed cancer — they had no comorbidities.

I tend to be more aggressive with those patients than with the other group of patients, who were on oxygen two years ago and have an ejection fraction of 25 percent. Those patients aren't going to get much better with chemotherapy. So I take a different approach and tend to use single agents.

For the first group of patients, for whom I believe the performance status is pushed by the cancer, I trust the CALGB (Lilenbaum 2005) and Rogerio's

FACULTY POLL QUESTION 9

A 60-year-old patient presents with extensive NSCLC, previously functioning poorly due to COPD, with current performance status 2, apparently unrelated to the tumor. What is your most likely recommendation?



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

data (Lilenbaum 2006), and I believe that two drugs are better than one in that setting.

DR LOVE: Rogerio, how do you approach the patient with a performance status of two because of either the tumor or nononcologic morbidities?

DR LILENBAUM: This is something we've discussed for a while now, since the CALGB study was presented. Intuitively, you would like to approach these two subsets of patients a little differently. Yet we have no prospective data or validation that this is the best practice.

A patient who was relatively healthy three or four months ago and now has rampant disease-related symptoms and a rapidly declining performance status should receive combination chemotherapy. With patients who have had a borderline functional status, comorbidities, et cetera, and the impact of the cancer on their overall performance status is either relatively minor or not assessable, I tend to be more cautious and use single-agent therapy. Again, that's because it makes sense but not because we have any data.

SELECT PUBLICATIONS

Lilenbaum R et al. **Randomized phase II trial of single agent erlotinib vs standard chemotherapy in patients with advanced non-small cell lung cancer (NSCLC) and performance status (PS) of 2.** Presentation. *Proc ASCO* 2006;**Abstract 7022.**

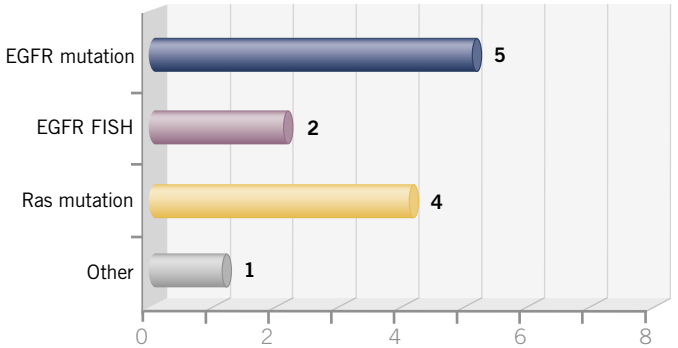
Lilenbaum RC et al. **Single-agent versus combination chemotherapy in advanced non-small-cell lung cancer: The Cancer and Leukemia Group B (study 9730).** *J Clin Oncol* 2005;23(1):190-6. **Abstract**

SECTION 3

CLINICAL USE OF EGFR TYROSINE KINASE INHIBITORS (TKI)

FACULTY POLL QUESTION 10

The most useful molecular variable for selecting patients likely to receive clinical benefit from EGFR TKI therapy is testing for:



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

Select Excerpts from the Discussion

CD 1, Tracks 20-22

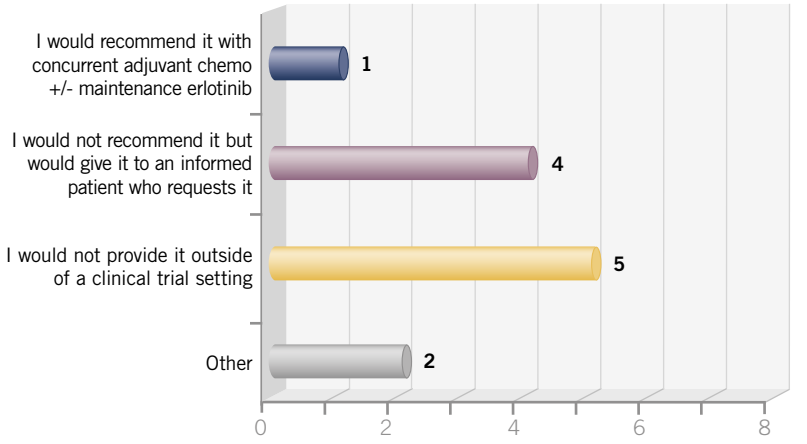
DR LOVE: Vince, can you discuss the role of EGFR mutation testing in clinical practice?

DR MILLER: Doctors can send slides to Genzyme and obtain a mutation status within seven to 10 working days with adequate tissue. We know KRAS is an adverse prognostic factor in lung cancer, and patients with KRAS mutations probably do not benefit from EGFR tyrosine kinase inhibitors, and they're better suited to chemotherapy (Tsao 2006).

We're designing a trial at Memorial in which patients will have a biopsy and we'll look for the KRAS mutation. We will exclude those patients with KRAS mutations because we don't consider it fair for them to receive erlotinib.

FACULTY POLL QUESTION 11

What is the role of erlotinib in a never-smoker following resection of a Stage II NSCLC?



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

DR LOVE: From a practical clinical perspective, in which situations — adjuvant, locally advanced or metastatic — do you think a doctor should consider using these assays?

DR MILLER: There are those who argue that with advanced disease, a one-month trial with erlotinib can be performed rather than doing the assays, but Rogerio's data suggest to me that in an unselected population you might be better off with chemotherapy (Lilenbaum 2006).

Certainly in the adjuvant setting I'd want to know the mutation status because I would want adjuvant erlotinib if I had an EGFR mutation or was a never smoker.

DR PASS: Do we have any data on adjuvant erlotinib?

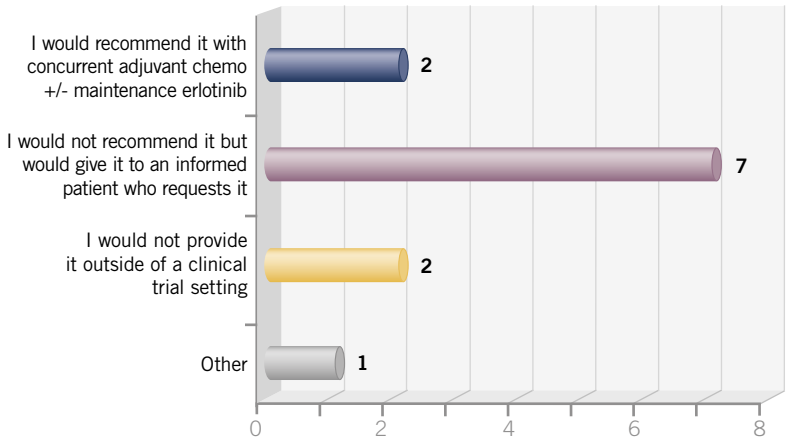
DR EDELMAN: There are no data to support the use of an expensive drug with significant toxicity.

DR PASS: In my heart of hearts, for the patient who is a never smoker or has a mutation, I have to say that I can't, off trial, dissuade him or her from erlotinib because it makes sense to me.

Obviously, the trial must be performed so we have the answer to Marty's question: If we compare erlotinib with the best adjuvant chemotherapy regimens, is that the way to go?

FACULTY POLL QUESTION 12

What is the role of erlotinib in a patient with an EGFR mutation-positive or EGFR FISH-positive tumor following resection of a Stage II NSCLC?



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

But I believe we're talking about a selected population. In that situation, I can't go against the patient who has read all the data and wants to go that route.

DR EDELMAN: I want to see data. I have equipoise, which is why I can put a patient on a Phase III trial. I don't know the answer.

DR LYNCH: I've softened on this issue. I believe for patients who have mutation-positive disease, you need to have a detailed discussion with them. They're not going to be able to wait for the Phase III trials to be conducted, and obviously, I endorse the concept of Phase III trials.

However, for that patient with mutation-positive disease, I have a long discussion with them, and I don't believe it's crazy to consider adding erlotinib after chemotherapy. ■

SELECT PUBLICATIONS

Lilenbaum R et al. **Randomized phase II trial of single agent erlotinib vs standard chemotherapy in patients with advanced non-small cell lung cancer (NSCLC) and performance status (PS) of 2.** Presentation. *Proc ASCO* 2006;**Abstract 7022**.

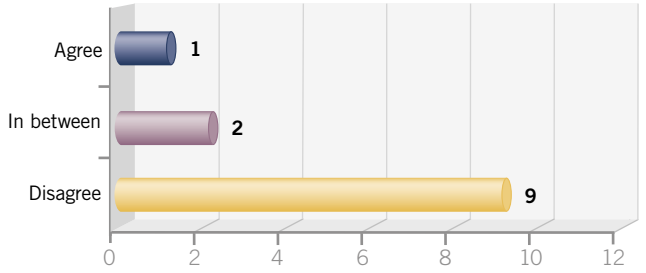
Tsao M et al. **An analysis of the prognostic and predictive importance of K-ras mutation status in the National Cancer Institute of Canada Clinical Trials Group BR.21 study of erlotinib versus placebo in the treatment of non-small cell lung cancer.** *Proc ASCO* 2006;**Abstract 7005**.

SECTION 4

ADJUVANT SYSTEMIC THERAPY FOR NSCLC

FACULTY POLL QUESTION 13

Adjuvant chemotherapy should be discussed and presented as a treatment option with most patients with PS 0 and Stage IA NSCLC.



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

Select Excerpts from the Discussion

CD 2, Track 2

DR LOVE: Tom, how did you answer the question, do you think adjuvant chemotherapy should be discussed and presented as a treatment option to most patients with Stage IA NSCLC and a performance status of zero?

DR LYNCH: I answered "in between" because I do see the occasional patient with Stage IA disease that I talk to about adjuvant chemotherapy.

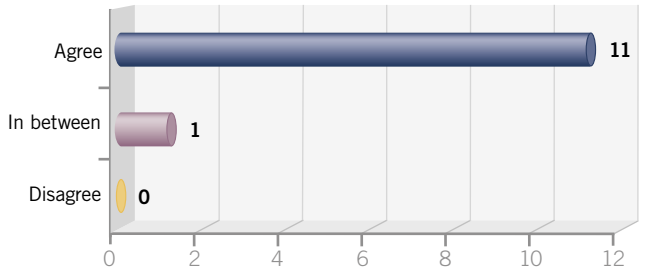
DR LOVE: What if a patient with Stage IA disease asks, "I understand there are side effects, but will adjuvant chemotherapy lower my already modest or low risk for recurrence?"

DR LYNCH: I tell them I expect it probably will, to the best of our ability to estimate.

DR EDELMAN: If you had asked me six months or one year ago, I would have probably agreed with Tom. The occasional patient appeared with Stage IA disease with whom I would discuss this.

FACULTY POLL QUESTION 14

Adjuvant chemotherapy should be discussed and presented as a treatment option with most patients with PS 0 and Stage IB NSCLC.



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

But we've learned from the CALGB-9633 update that smaller tumors generally didn't benefit (Strauss 2006). So now I'm a lot more conservative.

CD 2, Tracks 4-6

DR LOVE: Ed, what chemotherapeutic regimen do you use in the adjuvant setting?

DR KIM: I will talk to patients and tell them, "If you go by the data, it is cisplatin/vinorelbine." I also tell them that I'll use cisplatin/docetaxel based on the study by Frank Fossella.

In the metastatic setting, it was similar in efficacy but had a better side-effect and quality-of-life profile (Fossella 2003). I usually go with docetaxel. Vinorelbine requires a central line for administration because it's a vesicant.

DR LOVE: Rogerio, how do you approach patients with Stage IB disease?

DR LILENBAUM: CALGB-9633 had a great impact on my practice.

Up until ASCO 2006, I discussed with patients and colleagues the initial analysis of CALGB-9633, which I considered Level 1 evidence, and, in patients with Stage IB disease, I felt comfortable using carboplatin/paclitaxel. However, that has changed since the updated analysis of CALGB-9633 (Strauss 2006).

I still recommend that most patients with Stage IB disease receive adjuvant chemotherapy, but whenever possible I use a cisplatin-based regimen, usually docetaxel. I've used gemcitabine once in a while, despite the absence of data.

If I see a patient who is clearly not a good candidate for cisplatin, I will use carboplatin but with a much lower level of confidence than I had before ASCO. ■

SELECT PUBLICATIONS

Birim O et al. **Survival after pathological stage IA nonsmall cell lung cancer: Tumor size matters.** *Ann Thorac Surg* 2005;79(4):1137-41. **Abstract**

Douillard JY et al. **Adjuvant vinorelbine plus cisplatin versus observation in patients with completely resected stage IB-IIIA non-small-cell lung cancer (Adjuvant Navelbine International Trialist Association [ANITA]): A randomised controlled trial.** *Lancet Oncol* 2006;7(9):719-27. **Abstract**

Dunant A et al. **Adjuvant chemotherapy for non-small cell lung cancer: Contribution of the International Adjuvant Lung Trial.** *Clin Cancer Res* 2005;11(13 Pt 2):5017-21. **Abstract**

Fossella F et al. **Randomized, multinational, phase III study of docetaxel plus platinum combinations versus vinorelbine plus cisplatin for advanced non-small-cell lung cancer: The TAX 326 study group.** *J Clin Oncol* 2003;21(16):3016-24. **Abstract**

Jones DR et al. **Stage IB nonsmall cell lung cancers: Are they all the same?** *Ann Thorac Surg* 2006;81(6):1958-62. **Abstract**

Kawai H et al; The Japan National Hospital Study Group for Lung Cancer. **Smoking history before surgery and prognosis in patients with stage IA non-small-cell lung cancer — A multicenter study.** *Lung Cancer* 2005;49(1):63-70. **Abstract**

Kudoh S et al. **Phase III study of docetaxel compared with vinorelbine in elderly patients with advanced non-small-cell lung cancer: Results of the West Japan Thoracic Oncology Group Trial (WJTOG 9904).** *J Clin Oncol* 2006;24(22):3657-63. **Abstract**

Paccagnella A et al. **Adding gemcitabine to paclitaxel/carboplatin combination increases survival in advanced non-small-cell lung cancer: Results of a phase II-III study.** *J Clin Oncol* 2006;24(4):681-7. **Abstract**

Potti A, Ganti AK. **Adjuvant chemotherapy for early-stage non-small cell lung cancer: The past, the present and the future.** *Expert Opin Biol Ther* 2006;6(7):709-16. **Abstract**

Ramlau R et al. **Phase III study comparing oral topotecan to intravenous docetaxel in patients with pretreated advanced non-small-cell lung cancer.** *J Clin Oncol* 2006;24(18):2800-7. **Abstract**

Roselli M et al. **Postsurgical chemotherapy in stage IB nonsmall cell lung cancer: Long-term survival in a randomized study.** *Int J Cancer* 2006;119(4):955-60. **Abstract**

Schuette W et al. **Phase III study of second-line chemotherapy for advanced non-small-cell lung cancer with weekly compared with 3-weekly docetaxel.** *J Clin Oncol* 2005;23(33):8389-95. **Abstract**

Strauss GM et al. **Adjuvant chemotherapy in stage IB non-small cell lung cancer (NSCLC): Update of Cancer and Leukemia Group B (CALGB) protocol 9633.** Presentation. *Proc ASCO* 2006;**Abstract 7007.**

Visbal AL et al. **Adjuvant chemotherapy for early-stage non-small cell lung cancer.** *Chest* 2005;128(4):2933-43. **Abstract**

Wakelee HA et al. **Current status of adjuvant chemotherapy for stage IB non-small-cell lung cancer: Implications for the New Intergroup Trial.** *Clin Lung Cancer* 2006;8(1):18-21. **Abstract**

Winton T et al; National Cancer Institute of Canada Clinical Trials Group; National Cancer Institute of the United States Intergroup JBR.10 Trial Investigators. **Vinorelbine plus cisplatin vs observation in resected non-small-cell lung cancer.** *N Engl J Med* 2005;352(25):2589-97. **Abstract**

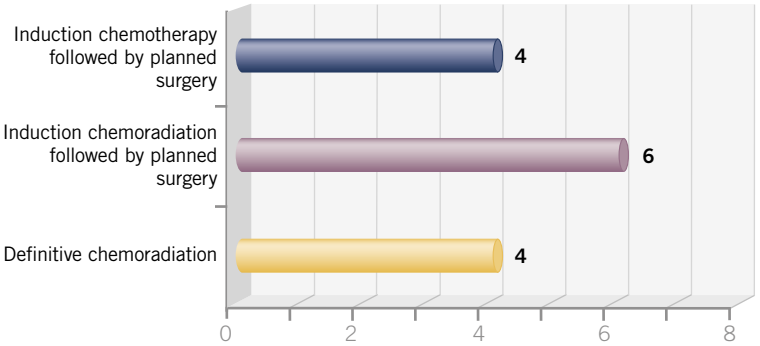
Yamamoto N et al. **Randomized phase II study of carboplatin/gemcitabine versus vinorelbine/gemcitabine in patients with advanced nonsmall cell lung cancer: West Japan Thoracic Oncology Group (WJTOG) 0104.** *Cancer* 2006;107(3):599-605. **Abstract**

SECTION 5

MANAGEMENT OF STAGE III NSCLC

FACULTY POLL QUESTION 15

For nonbulky Stage IIIA, N2-positive NSCLC in a patient with a good performance status, my most common recommendation is:



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

Select Excerpts from the Discussion

CD 2, Track 14, 17

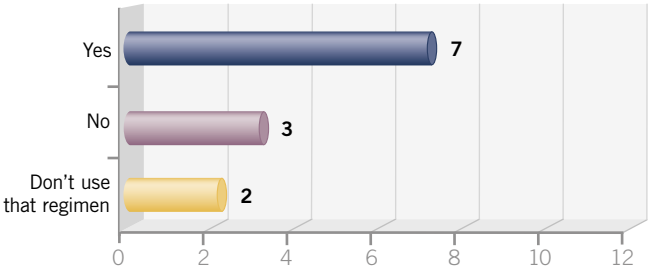
DR LOVE: Harvey, your RTOG-0412 trial will evaluate induction cisplatin/docetaxel with or without radiation therapy followed by surgery and consolidation docetaxel in patients with Stage IIIA NSCLC. Based on Kathy Albain's 2005 ASCO report of the RTOG-9309 study, will the RTOG-0412 study be amended to exclude patients receiving pneumonectomies?

DR PASS: It is difficult to predict which patient is going to require a pneumonectomy based on the preoperative studies. I am concerned about the right pneumonectomies, but the data with regard to these sort of morbidities simply do not bear out at other institutions.

DR CHOY: We hope this study will change patterns of practice. If you survey oncologists about whether they use preoperative chemotherapy or chemoradiation therapy in patients with Stage IIIA disease, you will see an even split. We

FACULTY POLL QUESTION 16

When using the SWOG-S9504 regimen for locally advanced disease (etoposide, cisplatin and radiation therapy followed by docetaxel), do you generally use myeloid growth factors with consolidation docetaxel?



SOURCE: Survey of Think Tank Participants, July 13, 2006, Miami, Florida.

need to answer the question, and this study will answer it. This is probably the last time we'll have this kind of trial.

DR KRIS: I'm not a big fan of this trial.

DR LOVE: Mark, which question would you like to see addressed in this patient population?

DR KRIS: I'd like to compare groups of patients, one of which is receiving an intervention for which we have some literature-based expectation to improve survival. That does not exist for the addition of radiation therapy to chemotherapy as induction.

DR LOVE: What would you like to see studied in this patient population?

DR KRIS: Induction erlotinib in people who don't smoke.

DR LYNCH: Mark, this is still a question that, for 15 years, we've danced around. I believe this question has prevented us from introducing novel agents for patients with Stage III disease.

I would love to avoid the burden of having to use chemoradiation before surgery. But my radiation oncologist points out that the best data still are with chemoradiation followed by surgery.

CD 2, Track 24

DR LOVE: Jack, can you comment on the new data presented at ASCO on the SWOG-S9504 regimen?

DR WEST: The Hoosier Oncology Group trial (HOG LUN 01-24/USO 02-33) asked the question of whether consolidation docetaxel added anything to definitive chemoradiation therapy. This trial has been ongoing for a few years, and the safety data were presented at ASCO 2006. Of the 241 patients accrued, two thirds were randomly assigned after definitive chemoradiation therapy to consolidation docetaxel or observation.

Of the patients assigned to docetaxel, only 29 percent were able to complete three cycles, 22 percent required dose reductions, one third required growth factor support and five percent required blood transfusions.

The Hoosier Oncology Group presentation highlighted the toxicity challenges. Of the patients assigned to consolidation docetaxel, 20 percent were hospitalized: one third for febrile neutropenia, 19 percent for infections without neutropenia, and 9.5 percent for pneumonitis.

Four treatment-related deaths occurred, accounting for 5.5 percent of the patients treated with docetaxel (Bedano 2006).

CD 2, Tracks 26-27

DR LOVE: Rogerio, do you use consolidation docetaxel off study? Do you use growth factors?

DR LILENBAUM: Yes to both those questions. The HOG trial is probably not sufficiently powered to detect a statistically significant difference in outcome for maintenance docetaxel.

DR LOVE: If it were sufficiently powered, what do you think it would show?

DR LILENBAUM: I believe it would show a positive result.

DR KIM: I like using the SWOG-S9504 regimen. Sometimes it's difficult to administer the consolidation therapy. It mostly depends on how the concurrent chemoradiation is tolerated by the patient.

Hak, when is it safe to use myeloid growth factors around the setting of radiation? We're hesitant to use them during radiation, but should we wait six or 10 weeks? Or is it okay to start after the radiation machine is turned off?

DR CHOY: I believe this hesitation is because of the old Paul Bunn study using GM-CSF for patients with small-cell lung cancer who received chemoradiation therapy. They had significant pneumonitis (Bunn 1995).

Those are the only data we have at this point, so a lot of people are reluctant to use growth factors with radiation. I believe you can use them with radiation, but we have no data. Rogerio is going to conduct an RTOG study of chemoradiation therapy with G-CSF followed by pegfilgrastim.

DR LILENBAUM: We took the SWOG-S9504 regimen and added growth factors during the chemotherapy and radiation therapy, which has not been done since the Bunn study.

Among the first 10 patients, we've had no major complications. We felt it was reasonable to bring this question into a large Phase II trial. It may change the way we use chemotherapy and radiation. ■

SELECT PUBLICATIONS

Akerley W et al. **Induction paclitaxel/carboplatin followed by concurrent chemoradiation therapy for unresectable stage III non-small-cell lung cancer: A limited-access study — CALGB 9534.** *Clin Lung Cancer* 2005;7(1):47-53. **Abstract**

Bedano PM et al. **Phase III study of cisplatin (P) plus etoposide (E) with concurrent chest radiation (XRT) followed by docetaxel (D) vs observation in patients (pts) with stage III non-small cell lung cancer (NSCLC): An interim toxicity analysis of consolidation therapy.** Presentation. *Proc ASCO* 2006;**Abstract 7043.**

Belani CP et al. **Combined chemoradiotherapy regimens of paclitaxel and carboplatin for locally advanced non-small-cell lung cancer: A randomized phase II locally advanced multi-modality protocol.** *J Clin Oncol* 2005;23(25):5883-91. **Abstract**

Belani CP et al; Eastern Cooperative Oncology Group. **Phase III study of the Eastern Cooperative Oncology Group (ECOG 2597): Induction chemotherapy followed by either standard thoracic radiotherapy or hyperfractionated accelerated radiotherapy for patients with unresectable stage IIIA and B non-small-cell lung cancer.** *J Clin Oncol* 2005;23(16):3760-7. **Abstract**

Bunn PA Jr et al. **Chemoradiotherapy with or without granulocyte-macrophage colony-stimulating factor in the treatment of limited-stage small-cell lung cancer: A prospective phase III randomized study of the Southwest Oncology Group.** *J Clin Oncol* 1995;13(7):1632-41. **Abstract**

Divers SG et al. **Phase I/IIa study of cisplatin and gemcitabine as induction chemotherapy followed by concurrent chemoradiotherapy with gemcitabine and paclitaxel for locally advanced non-small-cell lung cancer.** *J Clin Oncol* 2005;23(27):6664-73. **Abstract**

Fournel P et al. **Randomized phase III trial of sequential chemoradiotherapy compared with concurrent chemoradiotherapy in locally advanced non-small-cell lung cancer: Groupe Lyon-Saint-Etienne d'Oncologie Thoracique-Groupe Francais de Pneumo-Cancerologie NPC 95-01 Study.** *J Clin Oncol* 2005;23(25):5910-7. **Abstract**

Hirsh V et al. **Phase II trial with carboplatin/gemcitabine induction chemotherapy followed by radiotherapy concomitantly with paclitaxel/gemcitabine in stage III non-small cell lung cancer (NSCLC).** *Proc ASCO* 2006;**Abstract 7139**.

Jeremic B et al. **Concurrent hyperfractionated radiotherapy and low-dose daily carboplatin and paclitaxel in patients with stage III non-small-cell lung cancer: Long-term results of a phase II study.** *J Clin Oncol* 2005;23(6):1144-51. **Abstract**

Kelly K et al. **Low incidence of pneumonitis on SWOG 0023: A preliminary analysis of an ongoing phase III trial of concurrent chemoradiotherapy followed by consolidation docetaxel and Iressa/placebo maintenance in patients with inoperable stage III non-small cell lung cancer.** *Proc ASCO* 2005;**Abstract 7058**.

Lee DH et al. **Phase II study of induction chemotherapy with gemcitabine and vinorelbine followed by concurrent chemoradiotherapy with oral etoposide and cisplatin in patients with inoperable stage III non-small-cell lung cancer.** *Int J Radiat Oncol Biol Phys* 2005;63(4):1037-44. **Abstract**

Perry MC et al. **Updated analysis of a Phase III study of surgical resection and chemotherapy (paclitaxel/carboplatin) (CT) with or without adjuvant radiation therapy (RT) for resected stage III non-small cell lung cancer (NSCLC) CALGB 9734.** *Proc ASCO* 2005;**Abstract 7145**.

Thomas P et al. **Randomized multicentric phase II study of carboplatin/gemcitabine and cisplatin/vinorelbine in advanced non-small cell lung cancer GFPC 99-01 study (Groupe francais de pneumo-cancerologie).** *Lung Cancer* 2006;51(1):105-14. **Abstract**

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **ECOG-E4599 evaluated which chemotherapy regimen in combination with bevacizumab?**
   a. Cisplatin/docetaxel
   b. Carboplatin/docetaxel
   c. Cisplatin/paclitaxel
   d. Carboplatin/paclitaxel
   e. None of the above
2. **Although an increased risk of treatment-related deaths is associated with bevacizumab and chemotherapy among patients with metastatic NSCLC, overall survival is still improved.**
   a. True
   b. False
3. **Which of the following risks are associated with treatment of NSCLC with bevacizumab?**
   a. Hemoptysis
   b. Stroke
   c. Hypertension
   d. All of the above
   e. None of the above
4. **In a randomized Phase II trial of second-line therapy, fewer patients treated with _____ discontinued because of an adverse event.**
   a. Erlotinib and bevacizumab
   b. Chemotherapy and bevacizumab
   c. Chemotherapy alone
   d. None of the above
5. **Patients with brain metastases were allowed to enroll in ECOG-E4599.**
   a. True
   b. False
6. **The SWOG-S9504 regimen consists of etoposide, cisplatin and radiation therapy followed by _____.**
   a. Paclitaxel
   b. Docetaxel
   c. Gemcitabine
   d. Erlotinib
7. **Trials of adjuvant erlotinib in patients with Stage II NSCLC have demonstrated a significant improvement in both overall and disease-free survival.**
   a. True
   b. False
8. **CALGB-9633 evaluated adjuvant therapy with _____ in patients with Stage IB disease.**
   a. Cisplatin/vinorelbine
   b. Carboplatin/vinorelbine
   c. Cisplatin/paclitaxel
   d. Carboplatin/paclitaxel
   e. None of the above
9. **The primary objective of RTOG-0412 is to determine whether induction with chemotherapy or chemoradiation is better for patients with Stage III NSCLC.**
   a. True
   b. False
10. **Patients with NSCLC and EGFR tumor mutations have an increased rate of tumor response to EGFR tyrosine kinase inhibitors.**
    a. True
    b. False

Post-test answer key: 1d, 2a, 3d, 4a, 5b, 6b, 7b, 8d, 9a, 10a

EVALUATION FORM

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GLOBAL LEARNING OBJECTIVES

To what extent does this issue of *LCU* address the following global learning objectives?

- Critically evaluate the clinical implications of emerging clinical trial data in lung cancer treatment and incorporate these data into management strategies in the adjuvant, neoadjuvant, locally advanced and metastatic settings. . . . . 5 4 3 2 1 N/A
- Counsel appropriately selected patients about the availability of ongoing clinical trials. . . . . 5 4 3 2 1 N/A
- Develop and explain a management strategy for treatment of elderly patients and those with poor performance status in the adjuvant, neoadjuvant, locally advanced and metastatic settings. . . . . 5 4 3 2 1 N/A
- Integrate emerging data on utilization of targeted molecular therapies and molecular and genetic assays in the development of individual management strategies for patients with lung cancer. . . . . 5 4 3 2 1 N/A
- Counsel patients with localized primary lung cancer about the risks and benefits of adjuvant chemotherapy. . . . . 5 4 3 2 1 N/A
- Identify the impact of smoking-related comorbidities on the treatment of patients with lung cancer and integrate smoking cessation into the management strategy for these patients. . . . . 5 4 3 2 1 N/A

OVERALL EFFECTIVENESS OF THE FACULTY MEMBERS

To what extent do you feel the faculty members' comments were helpful or not helpful?

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. . . . . .

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OVERALL EFFECTIVENESS OF THE ACTIVITY

Objectives were related to overall purpose/goal(s) of activity.	5	4	3	2	1	N/A
Related to my practice needs.	5	4	3	2	1	N/A
Will influence how I practice.	5	4	3	2	1	N/A
Will help me improve patient care.	5	4	3	2	1	N/A
Stimulated my intellectual curiosity.	5	4	3	2	1	N/A
Overall quality of material.	5	4	3	2	1	N/A
Overall, the activity met my expectations.	5	4	3	2	1	N/A
Avoided commercial bias or influence.	5	4	3	2	1	N/A

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Which of the following modules did you find particularly relevant to your practice? Please elaborate on what about the topics and comments were helpful to you.

- ☐ Bevacizumab Combined with Chemotherapy as First-Line Therapy of Advanced Non-small Cell Lung Cancer (NSCLC)
- ☐ Clinical Use of EGFR Tyrosine Kinase Inhibitors (TKI)
- ☐ Treatment for Patients with Poor Performance Status
- ☐ Adjuvant Systemic Therapy for NSCLC
- ☐ Management of Stage III NSCLC

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Will the information presented cause you to make any changes in your practice?

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.....

What other topics would you like to see addressed in future educational programs?

.....

What other faculty would you like to hear interviewed in future educational programs?

.....

Additional comments about this activity:

.....

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