A Step Forward for Cooperative Group Cancer Nursing Research

On June 13, 2002, the Cancer and Leukemia Group B (CALGB) Oncology Nursing Committee sponsored the first “Cooperative Group Cancer Nursing Research Summit,” held in Washington, DC. This initiative, led by Ellen Lavoie Smith, MS, ARNP, AOCN, and Susan Bauer-Wu, DNSc, RN, involved nurse leaders representing the National Cancer Institute (NCI), the National Institute of Nursing Research (NINR), the Komen Foundation, the American Cancer Society (ACS), and the Oncology Nursing Society (ONS). In addition, nine cooperative research groups were represented (CALGB, SWOG, RTOG, COG, GOG, ECOG, NSABP, NCTC, ACOG). Also in attendance were several nurse researchers and clinical nurse experts.

The goal of the meeting was to exchange information and begin collaborations to facilitate the conduct of multi-site nursing research within the cooperative group setting. This meeting was the first step to building new collaborative relationships between clinical nurse experts who are knowledgeable of cooperative group systems and esteemed nurse researchers desiring an affiliation with cooperative groups as a means to conduct important nursing research. Five meeting objectives were identified:

- To understand the nursing research structure and culture of other organizations
- To investigate funding opportunities for collaborative group nursing research
- To develop strategies to integrate nursing research into the cooperative group research agenda
- To establish a collaborative, national network through which nursing studies can be conducted
- To increase national awareness of nursing research opportunities within cooperative groups

Why was the summit so important?

In order to truly understand the magnitude and relevance of this unique gathering of nurse leaders, it is important to recognize historical barriers, which have influenced how nursing research has been conducted in the past. Unlike medical research, nationwide, most nursing research has been conducted at single institutions, utilizing small and minimally diverse patient populations, thus limiting the generalizability of nursing knowledge to the broader population. Large, multi-center nursing research has taken place only rarely. Through gaining access to a wealth of scientific expertise and a larger, more diverse patient population within a national cooperative group, nurses at all levels can facilitate scientifically credible nursing research. Therefore, this research summit serves as a first step toward monumental changes in how nursing research could be accomplished in the future, resulting in paramount advances in nursing science and resultant improvements in patient care.

Donna Berry, PhD, RN, AOCN of the University of Washington stated, “...it is now time to acknowledge our differences (between medicine and nursing) and history, and create something different for the future ...this meeting is a very important first step.”

Are nurses currently conducting research within cooperative group settings?

The current state of cooperative group nursing research spans a wide range. Within the nine groups represented at the summit, nursing research studies have been conducted in all but three groups. However, only approximately eleven nursing studies have been completed over the past 50 years of cooperative group existence, compared to thousands of medical studies. Ten additional studies are either currently accruing patients or have been approved but are pending funding and eleven studies are in the development phase. In those groups that have not yet developed nursing studies, facilitation of nursing research was clearly identified as a goal for the future.
MESSAGE FROM THE GROUP CHAIR

It's that time again in the life cycle of the CALGB when we take stock of our accomplishments and chart our course for the future, i.e., grant renewal time. The CALGB competing renewal application was submitted to the National Cancer Institute on June 1, 2002. The Central Office grant, which supports most of the activities of the Group, was 1917 pages and weighed in at 20 pounds. The Statistical Center, the Leukemia Correlative Sciences Committee and 12 main member institutions also submitted separate applications. A site visit will be conducted on October 15, 2002 by a team of expert reviewers assembled by NCI and our new budget period will commence April 1, 2003. The preparation of our application requires the input of many people—all of the committee chairs, vice chairs and statisticians; many of the institutional PIs; the senior staff in the Central Office and Statistical Center; and the directors of our major repositories, reference laboratories and centralized resources. The competing renewal process affords us an opportunity to reflect on the many changes that have occurred in CALGB during the past 5 years and to focus on our plans for the future. The Group is very different from 5 years ago in many ways.

We have appointed 8 new committee chairs, recruited 70 new study chairs and appointed 100 new committee members. Four new committees have been formed (Melanoma, Imaging, CARE, SQAC) to further enhance the scope and quality of CALGB research. We created a “special member” category to allow investigators with special expertise from non-CALGB institutions to participate in CALGB research. This scientific reorganization has led to a surge in CALGB protocol activations. Prior to 1998, we activated about 20 new protocols each year. From 1998-2001 CALGB activated a total of 123 protocols, an average of more than 30 protocols annually.

A number of administrative changes were also made in the Group to simplify and facilitate the participation of institutions in CALGB activities. The Board of Directors agreed that physician practices as well as hospitals could be members of CALGB and created a new category of CALGB institutional membership, At-Large member, to permit independent participation of physician practices, hospitals and academic medical centers that have outstanding data management and accrual but do not have the full scope of activities required of main members. The Board of Directors also voted to provide representation on the Board—one representative for each CCOP At-Large member as well as two people to represent the non-CCOP At-Large members in recognition of their major contributions to CALGB.

Perhaps most importantly, we restructured our payment programs in CALGB so that all institutions now receive direct reimbursement for accrual to cooperative group studies. There are no longer unfunded institutions in CALGB!

As the Group has expanded in size and scope we have come to rely on the Internet and electronic mail to communicate. Our web site (www.calgb.org) has been expanded and redesigned and is now our primary means of distributing documents and meeting information. All protocols and forms are now distributed via the web site; on-line patient registration was introduced in July 1999 and will become web-based later this year. A web-based version of LabTrak is also in beta testing and will be available Group-wide in the coming months. The capacity for electronic communications has permitted us to extend direct patient registration privileges to all CCOPs and At-Large members and, as recently announced to the Board of Directors, we now have the capacity to allow direct registration by all affiliates as well. We have also introduced the Teleforms system for data submission, a process that permits data forms to be submitted by fax to the Statistical Center and scanned into the database immediately upon receipt. We have also continued our efforts at data reduction and, in the past 5 years, have simplified protocol eligibility criteria whenever possible, eliminated the use of flow sheets for phase 3 trials, truncated long-term follow-up and eliminated the requirement for continuing follow-up of patients for more than 268 CALGB protocols.

As the CALGB programs have grown, we have aggressively sought additional funding to keep pace with the expanding research enterprise. Since 1998, CALGB investigators have submitted 56 grant applications to NIH seeking support for various CALGB research projects. Remarkably, 22 (39%) of these applications have been funded; an extraordinary success rate that is well ahead of the national average and a testimony to the quality of our work. We have had strong support from the National Institute of Aging and various private foundations (particularly the Breast Cancer Research Foundation and the TJ Martell Foundation) and productive collaborations with the pharmaceutical industry that have brought new resources to the Group.

Our investigators have worked hard to inform the medical community of our study results by presenting abstracts at national meetings and submitting manuscripts for publication. As of this writing, CALGB has 133 manuscripts that have been published or accepted for publication since 1998, many in high impact factor journals such as the New England Journal of Medicine (3 papers); Blood (9); Journal of Clinical Oncology (34); Journal of the National Cancer Institute (7); Clinical Cancer Research (9); Cancer Research (7); Science (1) and Nature (1).
Another tangible measure of CALGB productivity is accrual to our studies and accrual by our institutions to studies offered by CALGB and other cooperative groups. Accrual by CALGB institutions to treatment studies has steadily increased during the past 4 years and now runs between 3000 and 3500 registrations annually. Overall accrual to CALGB studies is in the range of 5000-5500/year. A comparison of our accrual during the period 1998-2002 to that during the prior grant cycle (1993-1997) is compelling. Accrual to CALGB-coordinated therapeutic trials is up 22% CALGB institution accrual to therapeutic trials is up 37% and total accrual by CALGB institutions has increased by 45%. If you think you are working harder, you are!

We have accomplished a great deal in CALGB during the past 4 years and my thanks go out to all who have worked so hard to make CALGB a success. We can be proud that CALGB studies result in tangible improvements in the outcomes of patients with cancer. CALGB 9011 established fludarabine as acceptable first line therapy for patients with CLL; CALGB 9221 demonstrated significant improvement in the quality of life of patients with MDS treated with 5-azacytidine and a significant prolongation in the time to development of acute leukemia; CALGB 9344 revealed that AC followed by Taxol produces superior disease-free survival for women with stage II breast cancer compared with AC alone; CALGB 9730 confirmed the benefits in response, TTP and survival of doublet compared with single agent chemotherapy in all patients with metastatic non-small cell lung cancer and CALGB 9343 showed that elderly women with early stage breast cancer can safely be spared the inconvenience, expense and morbidity of breast irradiation. We expect the next generation of CALGB studies to be every bit as important and I look forward to continuing to work with all of you to develop our programs, nurture our young investigators and, most importantly, relieve the burden of cancer for our patients and their families.

New Commercial Adverse Event Procedure

Effective July 15, 2002, reporting of expedited adverse events for commercial agents must be done using the Adverse Event Expedited Reporting System (AdEERS) for all CALGB-coordinated studies. The AER section on the CALGB web site has been updated and additional information may also be found in the July 15, 2002 protocol posting.

Changes to Data Collection Procedures

New federal requirements have changed some CALGB data collection procedures. In response to the Health Insurance Portability and Accountability Act (HIPAA), patient initials will be collected instead of patient names at registration and on all CALGB data collection forms, effective July 15, 2002. The format for patient initials will be last, first and middle. For example, Jane B. Doe will be written as D, J B. All registration/randomization worksheets and new forms will reflect the change. Although forms currently in use will not be modified, patient initials should be substituted for patient names when these forms are completed.

The National Cancer Institute (NCI) is requiring that the MedDRA v. 5.0 codes replace the International Medical Terminology (IMT) codes in reporting adverse events. Study-specific adverse event forms for new, active and recently closed CALGB studies are being modified to collect MedDRA codes. New versions of the forms and a copy of the CTC v2.0 with the MedDRA codes will be available at the CALGB web site. Please use the new versions of the forms to submit data.

In response to a new NCI requirement, a pre-existing conditions form is being added to phase I and II studies that include an investigational agent supplied by the NCI Division of Cancer Treatment and Diagnosis. This form will be used to collect baseline abnormalities found during the patient’s initial history and physical examination. The form will resemble the study-specific adverse event form, but attribution fields will not be included.

Beginning July 15, new primaries (tumors not likely resulting from therapy for a previous cancer) and secondary malignancies (tumors resulting from treatment for a previous cancer) do not need to be reported in an expedited manner. CALGB has developed the New Primary Cancer Form (C-1001) for reporting of new primaries to the Statistical Center. A diagnosis of AML/MDS following treatment for cancer on NCI-sponsored trials of investigational agents should be reported to the Central Office using the NCI/CTEP Secondary AML/MDS Report Form; the Secondary AML/MDS Form (C-215 v 5.0) should be submitted to the Statistical Center. Report all other secondary malignancies using the routine adverse event reporting mechanisms outlined in the protocol.

As a result of new federal requirements regarding reporting of race and ethnicity, CALGB has developed the Patient Race and Ethnicity Form to be completed by the patient prior to registration. The information on this form should be used to indicate the patient’s race and ethnicity at registration. The form should not be submitted to the Statistical Center.
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Several cooperative groups currently lead the way, with the most significant progress occurring within the Children’s Oncology Group (COG). This group conducted a similar “State of the Science in Pediatric Oncology Nursing Research Summit” in February, 2000. Outcomes of this summit have lead to increased collaboration among nurse researchers, scientists from other disciplines, advanced practice nurses, and staff nurses. Research initiatives stemming from the pediatric summit will focus on fatigue, cognitive and biological consequences of central nervous system treatment, adjustment to treatment, and self care behaviors in children and adolescents.

Another initiative involves a pediatric nurse researcher, Pam Hinds, PhD, RN, CS. She is hoping to receive grant funding to support a Cooperative Group Nursing Research Education Model. If funded, this project will define and execute educational and network building strategies, with the goal of facilitating nursing research. Three cooperative groups (COG, RTOG, and SWOG) have been targeted to benefit from this effort. However, if successful, this strategy could be applied to build stronger nursing research structures within other cooperative groups.

In addition to nurse initiated studies, nurses at all levels have made significant contributions to the design and execution of medical and behavioral science focused studies, functioning as consultants, study coordinators, clinical research associates, as well as co-investigators. Nurses are beginning to identify nursing-specific outcomes from these non-nurse initiated studies. Dissemination of these findings through publication of results in peer-reviewed journals will be important.

Opportunities for Nursing Research

Several areas of scientific focus were identified by summit participants. Claudette Varricchio, DSN, RN, FAAN of the National Institute of Nursing Research (NINR) stated that funding is available for cancer nurse researchers targeting clinical trial development in several areas. These areas include:

- Health promotion in diverse populations
- Neuro-function and sensory conditions
- Immune responses and oncology
- End of life
- Disease prevention
- Symptom management
- Minority health issues

In addition, the NINR is committed to the development of nurse researchers through career development and training grants, one-on-one consultative assistance, and by making available educational programs pertaining to clinical trial development through the NINR website.

Ann O’Mara, PhD, RN of the National Cancer Institute (NCI) described how nurse initiated cancer control and symptom management research funded by the NCI, could be funneled through Community Clinical Oncology Programs (CCOPs), thus facilitating accrual at a cooperative group level. Dr. Mara also stated that studies investigating quality of life outcomes, which are often embedded within treatment protocols as secondary endpoints, would be much better if nurses were more involved.

Gail Mallory, PhD, RN, CNAA, Director of Research for the Oncology Nursing Society (ONS), stated that the Advanced Nursing Research and Clinical Trials special interest groups (SIGs) are also interested in ways to further advance nursing science through research. Towards this end, the ONS Foundation awarded over one million dollars in small research grants in 2001. These smaller grants can be stepping stones toward obtaining larger grants from NINR, NCI, and the ACS. In addition, the ONS has funded nurse researcher travel and subsequent involvement in cooperative group initiatives, with recent support having been awarded to the COG. Areas of research priority most likely to receive funding through the ONS in 2002-2005 include research in cancer symptoms and side effects such as:

- Successful relief strategies for side effects
- Identification of symptom clusters and their associated outcomes
- Pain, neutropenia, depression, anorexia, and cognitive impairment

Archie Bleyer, MD, of the MD Anderson CCOP also gave a presentation. He provided evidence supporting the lack of improvement in overall survival for cancer patients between the ages of 25-39, primarily due to poor clinical trial participation by this group. Dr. Bleyer challenged summit nurse leaders to target this young adult and older adolescent patient population when designing research agendas.

Barriers to Cooperative Group Nursing Research

Several barriers were identified which must be considered when developing strategies to advance a nursing research agenda within cooperative group settings. The following list summarizes areas for future focus by summit participants:

- Funding is needed for clinical trial execution (more funding is currently available for intervention studies), travel for nurse researchers and clinical experts to attend cooperative group meetings, and future Nursing Research Summits
- Educate academically focused nurses regarding strategies for navigating within cooperative group systems and of important, yet subtle requirements within grant applications that will lead to funding
- Educate/mentor clinical nurse experts regarding research methodology
- Link nurse researchers with clinical nurse experts
- Education within cooperative groups regarding the contributions of nurse researcher/clinical nurse dyads
- Consider concerns regarding who owns the data and authorship
- Develop a common language when articulating the vision
- Merge nursing science into cooperative group agendas
- Identify and establish connections with nurse researchers not present at this summit

Next Steps

Dissemination of summit outcomes via:
- Cooperative Group, ONS Special Interest Group, and ONS Newsletters
- DCP Newsletter (NCI Prevention Newsletter)
- Presentation at upcoming cooperative group meetings

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**What’s New on the Web Site**

**Interim Study Summary Reports**
These reports are prepared twice yearly before the CALGB Group Meetings in early Summer and late Fall. A study summary report is completed for each active and just closed study. This report includes: the roles of the participants (study chair, statistician, data coordinator, etc.), the schema, objectives, and eligibility criteria along with the current accrual and toxicities. Updated CALGB study summary reports are available on the CALGB Web Site. We offer the study summary reports grouped by committee, or by individual study. If you would like to download the latest study summary reports by committee, they are located at the Member Site in the Protocols section. Individual study summary reports can be found on the individual protocol page along with the protocol documents, protocol updates, replacement pages, forms, model consent forms, etc.

**Oncology Nursing Section**
We have recently expanded the Info for Professionals section on the web site to include information for the CALGB Oncology Nursing Committee. In this new section there are links to useful information on the web site submitted by Oncology Nurses, a contact list of the Oncology Nursing Committee Members, a listing of open positions within the Oncology Nursing Committee, meeting information, Oncology Nursing Research projects and more.

**CRA Meeting PowerPoint Presentations Available**
If you missed the June 2002 CALGB Group Meeting, or want to review information that was presented at the CRA Committee Meeting and the CRA Continuing Education Workshop, you can download slides from the following at the CALGB Web Site in the CRA section:

From the CRA Committee Meeting 6/13:
- CALGB Statistical Center Update, Robin Heinze, Data Coordinator
- Cancer Trials Support Unit, Regulatory Data Base, Martha Hering
- TrialCheck Demonstration, Carrie Froseth, National Coalition of Cooperative Groups

From the CRA Continuing Ed Workshop on 6/14:
- Research Provisions of the HIPAA Privacy Rule, Julie Kaneshiro, Division of Policy, Planning and Special Projects, DHHS Office for Human Research Protections
- Central IRB, Jackie Goldberg, Administrator for Central IRB, NCI, Clinical Trials Monitoring Branch
- Medicare Coverage of Clinical Trials, Shana Olshana, M.P.H., Center for Medicare & Medicaid Services, HCFA

If you presented at the June 2002 Group Meeting and would like your presentations posted at the CALGB Web Site, please contact Jennifer Zelazny at jzelazny@uchicago.edu.

**CALGB Whom to Ask Updated**
If you have a question for a CALGB staff member but do not know who to contact, please look at our updated “CALGB Staff: Whom to Ask” in the CALGB Directory section on the Member Site. Contact information is listed by office (Central Office, Statistical Center, and Data Operations), and then by responsibility. For example, you can find Data Coordinators, Statisticians, and Protocol Editors by disease area, listed with the person’s name, title, phone number and email address. This section is very useful for both new CALGB members as well as a great reference for anyone who needs specific questions answered.

If you have a suggestion for web site content, contact Jennifer Zelazny at calgb-web@uchicago.edu.
CALGB YOUNG INVESTIGATOR AWARDS

2002 Recipients
Cancer Research Grants for CALGB Oncology Fellows

Leonardo A. Sirulnik, M.D., University of Chicago
A Phase I-II Pilot Study to Evaluate the Biological Activity of Valproic Acid Alone & in Combination with All-Trans-Retinoic Acid (ATRA) in Relapsed or Refractory Acute Myeloid Leukemia (except M3, FAB Classification)

Charles J. Ryan, M.D., Memorial Sloan-Kettering Cancer Center
Use of Molecular Studies of Drug Targets in Residual Prostate Tumors to Generate Hormone and Novel Drug Combinations

Lucy A. Godley, M.D., University of Chicago
The Role of Interferon Consensus Sequence Binding Protein (ICSBP)-Deficiency in Patients with Myelodysplastic Syndrome/Acute Myeloid Leukemia and the -5/del(5q) Cytogenetic Abnormality

Ramamoorthy Nagasubramanian, M.D., University of Chicago
Investigating Cyclophosphamide-Induced Leukemia in Mice

Attaya Suvannasankha, M.D., Roswell Park Cancer Institute
Breast Cancer Resistance Protein (BCRP) in AML

Leonardo A. Sirulnik, M.D., University of Chicago
A Phase I-II Pilot Study to Evaluate the Biological Activity of Valproic Acid Alone & in Combination with All-Trans-Retinoic Acid (ATRA) in Relapsed or Refractory Acute Myeloid Leukemia (except M3, FAB Classification)

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Use of Molecular Studies of Drug Targets in Residual Prostate Tumors to Generate Hormone and Novel Drug Combinations

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Ramamoorthy Nagasubramanian, M.D., University of Chicago
Investigating Cyclophosphamide-Induced Leukemia in Mice
TrialCheck: A Valuable Search Engine for Busy Clinicians

TrialCheck, a web-based cancer clinical trials search engine developed by the Coalition of National Cancer Cooperative Groups, is gaining popularity among cooperative group members due to its unique search capabilities. If you have not yet registered, visit www.trialcheck.org for access to this valuable service. TrialCheck contains almost 400 NCI- and FDA-sponsored cancer clinical trials offered by seven of the ten national cooperative groups in the country. In addition, several government-approved industry trials from Pharmacia Corporation and Eli Lilly and Company are now included, and other pharmaceutical trials will be included in the next several months.

Including abstracts and eligibility criteria for many of the trials, TrialCheck also lists all the IRB-approved locations where the cooperative group trials are open and enrolling patients. TrialCheck is available to medical professionals in the field of cancer research and treatment through the cooperative group members of the Coalition, ONS and ASCO.

How TrialCheck Works

"With its brief questionnaire format, TrialCheck helps relieve the burden placed on research physicians and their staffs by saving valuable time in the search for appropriate clinical trials for their patients," says Robert L. Comis, MD, president of the Coalition.

Users perform searches by answering eight basic questions about the patient's medical history. A quick search function requires answers to only five questions. In seconds, the search yields a list of trials matching the stated criteria with links to the sponsoring organizations and to NCI professional and patient summaries.

TrialCheck's Strengths

Timely information. The participating entities download to the Coalition on a routine basis.

Screening process. The patient-based screening process eliminates trials rather than searching for agents or types and phases of trials.

Easy format and intuitive design. Answering as few as five, but no more than eight questions in a clear presentation makes TrialCheck easy to use.

Content. TrialCheck has excellent referral capability because of the inclusion of IRB-approved locations where trials are open and enrolling patients.

Coordinator function. Customization through the TrialCheck Coordinator function makes it easy for users to have all their institution's trials in one database.

Flexibility. Other organizations, such as pharmaceutical companies, will be able to add trials that will be searched with the same filter and screening process.

Customization Maximizes TrialCheck's Value

Instead of relying on hard copy, TrialCheck can be customized by users with the TrialCheck "Coordinator" function. By choosing to "add" only the trials that are available at their institution in one quick search, saving valuable time. "Physicians and nurses can then discuss all the treatment options available for patients, including those that might be through a clinical trial," says Dr. Comis.

TrialCheck was launched in October 2001. To date, TrialCheck has more than 2400 registered users including physicians, nurses, and clinical research associates. Since its debut, TrialCheck screenings returned 40,000 trials in the results.

Clinicians will soon be able to access TrialCheck via a new PDA format currently in development. In addition, a patient advocate version of TrialCheck will be available in the next few months.

The Coalition of National Cancer Cooperative Groups (www.cancertrialshelp.org) is the nation's premier network of cancer clinical trials specialists. Its mission is to improve the quality of life and survival of cancer patients by increasing participation in cancer clinical trials. Members of the Coalition include cooperative groups, patient advocate organizations, and cancer research and treatment centers.

Register today to access TrialCheck by visiting www.trialcheck.org.

Cancer Nursing Research

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-Journal Publications - Journal of Clinical Oncology and Oncology Nursing Forum
-Letter to the Editor in a Nursing Research Journal
-Lay-Publications - New York Times
-ONS Board Presentation
-Press Release to the National Coalition of Cooperative Groups

Education

Apply Cooperative Group Nursing Research Education Model, as described in a recent grant submission by Pam Hinds, PhD, RN, CS, to all cooperative group nursing committees.

Obtain Funding

Apply for NCI-R13 Conference Grant - Might be co-funded by NINR. This could be a mechanism to support future summit meetings. Susan Bauer-Wu, DNSc, RN will submit the application.

Network Building to Involve Additional Nurse Researchers

Plan the next summit to coincide with the ONS/ACS Seventh National Conference on Cancer Nursing Research in February 2003. Pam Hinds, PhD, RN, CS will be invited to present her Cooperative Group Nursing Education Model. Deborah Watkins Bruner, PhD, RN of the RTOG nursing group has volunteered to coordinate another summit meeting to coincide with a future RTOG meeting.

Ellen Lavoie Smith, MS, ARNP, AOCN
Chair - CALGB Nursing Committee
Director, Advanced Practice Nursing
Department of Hematology/Oncology
Dartmouth Hitchcock Medical Center/Norris Cotton Cancer Center
Single-agent (SA) versus combination chemotherapy (CC) in advanced non-small cell lung cancer (NSCLC): CALGB 9730. A randomized trial of efficacy, quality of life (QOL), and cost-effectiveness #2

Rogerio C Lilenbaum, James Herndon, Marcy List, Chris Desch, Dorothy Watson, Jimmie Holland, Jane C Weeks, Mark R Green, Cancer and Leukemia Group B, Chicago, IL. CC is the standard of care for good PS patients with advanced NSCLC. However, data from selected trials and meta-analyses do not conclusively demonstrate that CC produces superior survival compared to optimal SA therapy. Further, data on the impact of CC vs. SA on QOL and resource utilization are lacking. Therefore, the CALGB conducted a phase III randomized trial of carboplatin (C) and paclitaxel (P) (CP) vs. P alone in pts with stage IIIB (malignant effusion) and IV NSCLC to compare survival, QOL, and cost-effectiveness. Eligibility: measurable/evaluable disease, PS 0-2, no brain metastases, adequate organ function. Stratification: stage (IIIB/IV), PS (0-1/2), and age (>/>70). Treatment: P 225mg/m2 over 3 hours or the same P plus C at AUC of 6, both IV on d1 every 3 weeks for up to 6 cycles. 584 pts were entered from 10/97 to 1/01. Median age 63.5y; 158 pts were >70. M/F: 399/185, PS 0-1/2: 130/164. Unstratified Survival: median survival (months) and one-year survival estimates on 4/98 and 7/01; 562 PS 0-1, 25 PS 2; 267 females, 320 males. Operating Room compared to a bedside CT. Patients reported that they were more comfortable, felt safer, and had better control of their pain coupled with a decrease in fatigue. Improved pain control for TI is owed to heightened post-op vigilance over routine provision of analgesia at the bedside. This assessment provides clinicians and patients with data to balance the quality of life advantage against the risk of respiratory complications with thoracoscopic MPE drainage.

Patients receiving TI had greater drainage on day 1 (p = 0.0001). Respiratory complications were greater with the TI (p = 0.004). 30-day survival rates and success of the pleurodesis did not differ between the two study arms. QOL was measured using the EORTC QLQ-30 (European Organization of Research & Treatment of Cancer Quality of Life Evaluation, 30 items), a Pain Visual Analog Scale and a Symptom-specific Treatment Assessment examining convenience, safety, comfort, cost, and control of pain using four-point Likert scales. The EORTC QOL scores were assessed at baseline and at 30 days. No significant difference was found at baseline. The decrease in fatigue in the TI group differed significantly from the increase in fatigue in the CT group (p = 0.016). Pain measured by self-report visual analogs daily during survival was equivalent for both groups. The TI group reported greater comfort (p = 0.011) and perception of safety (p = 0.013) over the CT group. The satisfaction with and perception of pain control tended toward significance, favoring the TI group. The results show a QoL advantage with equal mortality and increased morbidity of a minimally invasive TI done in the Operating Room compared to a bedside CT. Patients reported that they were more comfortable, felt safer, and had better control of their pain coupled with a decrease in fatigue. Improved pain control for TI is owed to heightened post-op vigilance over routine provision of analgesia at the bedside. This assessment provides clinicians and patients with data to balance the quality of life advantage against the risk of respiratory complications with thoracoscopic MPE drainage.

Randomized phase III intergroup trial (CALGB 9732) of etoposide (VP-16) and cisplatin (DDP) with or without paclitaxel (TAX) and G-CSF in patients with extensive stage small cell lung cancer (ED-SCLC). #1169

Harvey B Niell, J. E Herndon, A. A Miller, D. M Watson, A. Sandler, K. Kelly, R. Marks, M. R Green, Univ of Tennessee, Memphis, TN; CALGB Statistical Center, Durham, NC; Wake Forest U School of Medicine, Winston-Salem, NC; Vanderbilt Univ, Nashville, TN; U of Colorado Cancer Center, Denver, CO; Mayo Clinic, Rochester, MN; Medical U South Carolina, Charleston, SC.

Purpose: Prospective evaluation of survival impact of TAX added to VP-16 and DDP as initial therapy for patients with ED-SCLC. Methods: Intergroup phase III trial. Eligibility: ED-SCLC, PS 0-2 (later restricted to 0-1), measurable/evaluable disease and no prior therapy. 587 patients accrued between 4/98 and 7/01; 562 PS 0-1, 25 PS 2; 267 females, 320 males. Arms balanced for gender and PS. 294 patients assigned arm A (VP-16 80 mg/m2 D 1-3, DDP 80 mg/m2 D 1 repeated Q 3 wks X 6), 293 arm B (identical to Arm A plus TAX 175 mg/m2/3 hours D 1 and G-CSF 5 µgm/kg D 4-18 of each cycle). Results: 318/470 targeted deaths occurred when data released by CALGB monitoring committee. A 1-sided logrank test showed no significant difference in survival (p = 0.327). Median survival (months) and one-year survival estimates on arms A vs B are 9.84 (8.69, 11.2) and 10.33 (9.64, 11.1) and 35.7 (29.2, 43.7) and 36.2% (30.0, 44.3%) respectively. Given the current data and assuming a hazard ratio of 1.3 for future
events, the conditional probability of concluding a benefit from adding TAX after 12 additional months of follow-up is P=0.04. Toxicity: Grade ≥ 3 toxicities on arms A,B:ANC 63%, 44%, platelets 11%, 21%, anemia 15%, 18%, vomiting 11%, 13%, total neurologic 10%, 25%, overall 84%, 77%. Grade 5 toxicities A/B 2.7%, 6.4%. Conclusion: Addition of TAX to VP-16 and DDP as initial therapy in ED-SCLC adds to the rate of grade 5 toxicity without a significant survival advantage. Supported in part by Bristol-Myers Pharmaceutical.

CALGB 39809: Randomized phase II trial of gemcitabine/irinotecan and gemcitabine/docetaxel in stage IIB (malignant pleural effusion) or stage IV NSCLC. #1344

Caoi Max S Rocha Lima, Naiyer A Rizvi, Karen Zhang, James E Herndon, Jeffrey Crawford, Gerald W King, Mark R Green, H. Lee Moffitt Cancer Center, Tampa, FL; Lombardi Cancer Center, Washington, DC; CALGB Statistical Center, Durham, NC; Duke University Medical Center, Durham, NC; Hematology & Oncology Associates, Greenville, SC; Medical University of South Carolina, Charleston, SC.

Purpose: Non-platinum combinations may improve efficacy and lower the toxicity (T) associated with the current treatment of advanced NSCLC. Two phase I trials performed at CALGB institutions defined the recommended phase II doses of the two chemotherapy arms evaluated in this randomized phase II trial: Arm 1 (gemcitabine/irinotecan 1000 mg/m2/100 mg/m2) and arm 2 (gemcitabine/docetaxel 1000 mg/m2/40 mg/m2). Both treatment arms were given on a day 1 and 8 every 21-day cycle. Methods: 80 patients (pts) with PS 0-1 were randomized (78 pts - 39 pts per arm - eligible) between September 1999 and October 2000. The primary endpoint of the study was response. Survival was also evaluated. Randomization was stratified by disease status (newly diagnosed stage IV with CNS metastases, newly diagnosed stage IV without CNS metastases, newly diagnosed stage IIB due to malignant pleural effusion, and recurrent/progressive disease after surgery or radiotherapy). A single stage design to differentiate between a 20% and 40% response rate was applied. Results: The distribution of pts was similar in both arms except for a higher median age (63.2 vs 56.5) in arm 2 and a higher proportion of males (71.8% vs 46.1%) in arm 1. The most common grade 3 or 4 toxicities were neutropenia (26% in both arms), fatigue (arm 1: 13%, arm 2: 22%), nausea (arm 1: 18%, arm 2: 3%), vomiting (arm 1: 13%, arm 2: 3%), and diarrhea (arm 1: 13%, arm 2: 10%). One early death/arm occurred. In arm 1 a pt had a cardiopulmonary arrest on Cycle 1 day 3 (C1D3), unclear if treatment related. In arm 2 a pt died of pulmonary embolism and sepsis on C1D2, considered to be not treatment related. Conclusions: Both doublets are tolerable as first-line therapy for good PS pts with advanced NSCLC. RRs are disappointing in both arms. The median and one-year survivals from arm 2 are appealing and rarely observed in cooperative group trials.

### Efficacy Data

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<th>Arm</th>
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<tr>
<td>RR (%)</td>
<td>12.8</td>
<td>23.1</td>
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<td>SD, 4 C (%)</td>
<td>48.7</td>
<td>41</td>
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<tr>
<td>FFS (M)</td>
<td>3.5</td>
<td>4.9</td>
</tr>
<tr>
<td>MS (M)</td>
<td>7.9</td>
<td>12.8</td>
</tr>
<tr>
<td>1 YS (%)</td>
<td>16</td>
<td>55</td>
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</table>

RR response rate; SD stable disease; C cycles; FFS median failure free survival; M (months); MS median survival; YS-year survival.

A model for predicting survival in men with hormone refractory prostate cancer (HRCaP): an analysis of CALGB studies #2480

Susan Halabi, Eric J Small, Philip W Kantoff, Nancy A Dawson, Ellis G Levine, Nicholas J Vogelzang, Duke University, Durham, NC; University of California, San Francisco, CA; Dana-Farber Cancer Inst, Boston, MA; University of Maryland, Baltimore, MD; Roswell Park Cancer Inst, Buffalo, NY; University of Chicago, Chicago, IL.

Objective: to develop and validate a model that can be used to predict the overall survival probability among HRCaP. Methods: Data from six clinical trials conducted by the CALGB were pooled. Patients were enrolled from 1991-1998 and had metastatic adenocarcinoma of the prostate. The proportional hazards model was used to develop a multivariate model based on pre-treatment factors and to construct a nomogram. The model was assessed for its predictive performance using bootstrapping. The area under the receiver operating characteristics curve (ROC) was calculated as a measure of predictive discrimination. Calibration of the model predictions was assessed by comparing the predicted probability to the actual survival probability. Results: Of the 1101 patients, 957 patients died. The median survival duration was 14 months (95% CI 13-15). The final model included the following factors: LDH, prostate specific antigen, alkaline phosphatase, Gleason sum, ECOG performance status, hemoglobin, and disease measurability. A nomogram is constructed based on the above mentioned pretreatment factors. Conclusion: This model can be used to predict the survival probability and to select patients based on their prognostic factors to participate in randomized clinical trials.

African-American race is associated with longer survival in patients with metastatic hormone-refractory prostate cancer (HRCaP) in four randomized phase III Cancer and Leukemia Group B trials 9181, 9182, 9583, 9480 #725

Timothy D Gilligan, Susan Halabi, Philip W Kantoff, Nancy A Dawson, Ellen B Kaplan, Eric J Small, Nicholas J Vogelzang, Dana-Farber Cancer Inst, Boston, MA; Duke University, Durham, NC; University of Maryland, Baltimore, MD; Univ of California San Francisco, San Francisco, CA; University of Chicago, Chicago, IL.

African-American men experience a higher prostate cancer (CaP) incidence and mortality than any other racial or ethnic group in the U.S. African Americans with prostate cancer tend to have shorter survival compared to whites, and they tend to be diagnosed at a younger age and with more advanced stage disease. We performed a pooled analysis of outcomes by race in CALGB trials 9181, 9182, 9583, and 9480 to determine whether there were differences in survival in HRCaP when treatment differences were minimized. Pts were recruited between the years 1992 and 2000, and they all had progressive HRCaP and an ECOG performance status (PS) 0-2. The trials evaluated (1) low dose versus high dose megestrol; (2) hydrocortisone with or without mitoxantrone; (3) antiandrogen withdrawal with or without ketoconazole; and (4) three different doses of suramin. The trials enrolled a total of 1020 patients. The final analysis was based on 988 patients, including 144 (15%) African Americans and 844 (85%) whites (the
Phase III dose-randomized study of imatinib mesylate (Gleevec,STI571) for GIST: intergroup S0033 (CALGB 80004) early results #1651

George D Demetri, Catherine Rankin, Christopher Fletcher, Robert S Benjamin, Charles Blanke, Margaret Von Mehren, Vivien Bramwell, Robert G Maki, Ronald Blum, Karen Antman, Laurence Baker, Ernest Borden, Dana Farber Cancer Institute, CALGB, and Sarcoma Intergroup, Boston, MA; SWOG, San Antonio, TX; Dana Farber Cancer Inst and Intergroup, Boston, MA; M.D. Anderson Cancer Center and Intergroup, Houston, TX; ECOG, Philadelphia, PA; NCI Canada, London, ON, Canada; CALGB, New York, NY.

Imatinib has previously been reported to induce a high rate of objective responses in patients (pts) with advanced GIST, but the optimal dose remains unclear. To answer this definitively, pts with advanced GIST were randomized between two different doses of Imatinib,400 mg vs.800 mg orally per day. The primary aim was to assess the impact of Imatinib dose on survival and secondarily to evaluate response rates and confirm the tolerability of Imatinib therapy for GIST. ELIGIBILITY: Pts with measurable or evaluable GIST with documented expression of KIT receptor tyrosine kinase (CD117 positive) and disease measurable, hemoglobin, and years since diagnosis in a multivariate analysis, the survival of African Americans was significantly longer (HR=0.80, 95% CI 0.66-0.98, p=0.033). The result was the same if Gleason sum was excluded from the multivariate analysis. Further exploration of this unexpected finding is warranted.

Increased mortality associated with higher dose cyclophosphamide plus fludarabine (CF) in advanced stage indolent lymphoma patients treated on E1496, an Eastern Cooperative Oncology Group (ECOG) and CALGB study (59902) #1125

Howard Hochster, Edie Weller, Timothy Kuzel, Stanley Frankel, Sandra Horning, New York University, New York, NY; Dana-Farber Cancer Inst, Boston, MA; Northwestern University, Chicago, IL; Greenebaum Cancer Center, Baltimore, MD; Stanford University, Stanford, CA.

E1496 was initiated 3/98 as a randomized comparison of CF (cyclophosphamide 1000 mg/m² d1 plus fludarabine 20 mg/m² d1-5) q 4 weeks, as previously piloted in ECOG (JCO 18:987, 2000), compared to CVP (cyclophosphamide 1000 mg/m² d1, vincristine 1.4 mg/m² d1, prednisone 100 mg/m² d1-5) q 3 weeks, each to best response plus 2 cycles (max = 8). This was followed by second randomization to maintenance rituximab (R) versus observation. Eligibility criteria included stage III-IV indolent lymphoma, PS 0-1, adequate organ function and measurable disease. Patients were stratified according to age, tumor burden, histology, and B symptoms. Retreatment was held for ANC <1500 and platelets <100,000. GCSF was given for ANC <500 lasting >5 days; cyclophosphamide was reduced 25%, then 50% for additional episodes of hematologic toxicity. Based on safety concerns, accrual to the CF arm was suspended 1/00, and then discontinued in 11/00, at which time the study was revised to CVP induction for all patients with randomization to maintenance R vs. observation. With a median follow-up of 2 years, 32 of 115 CF patients died compared to 8 of 119 CVP patients; although median survival has not yet been reached, progression-free survival is the same (p = 0.30), the survival curves differ (p < 0.001). Characteristics of the 32 CF patients who died were: median age 63 yrs, 53% male, 72% follicular histology, 78% high tumor burden, and 28% B symptoms. Although initial review suggests myelotoxicity and infection as major causes of death (COD), a review by 3 physicians and 2 statisticians for consensus COD and treatment relationship is underway. Full results will be presented. CONCLUSION: CF in this dose and schedule results in unacceptable early mortality in indolent lymphoma and is not recommended (though this may not apply to other CF doses or schedules). Accrual to E1496 continues with 349 of 515 planned patients entered as of 11/01.

Efficacy of peripheral androgen blockade on prostate cancer: initial results of CALGB 9782 #727

Joel Picus, Susan Halabi, Arif Hussein, George Philips, Ellen Kaplan, Eric Small, Nicholas J Vogelzang, Washington University School of Medicine, St Louis, MO; Duke University, Durham, NC; University of Maryland, Baltimore, MD; University of Vermont, Burlington, VT; University of California, San Francisco, CA; University of Chicago, Chicago, IL.

Patients with rising PSA after definitive local therapy have a number of treatment options. Without evidence of metastatic disease, many patients are reluctant to embark on testosterone suppression therapy with its associated toxicities. We undertook a multi-institutional trial, which enrolled 101 patients to study the ability of peripheral androgen blockade...
to affect rising PSA, and represents the largest study of this therapy to date. All patients had undergone previous definitive therapy defined as either a radical prostatectomy or radiation therapy. All patients were then found to have a rising PSA, above 1 ng/ml. Patients were also found to have no detectable evidence of recurrent disease, other than the rising PSA. Specifically, exams, CT scans, and bone scans showed no evidence of disease. Sixty-nine patients are available for this preliminary analysis. Their median age was 70, with 82% being Caucasian. The median PSA at the time of entry was 3.7, with 75% above 2.6, and 25% above 6 ng/ml. Patients received a combination of Finasteride, at a dose of 5 mg/day, and Flutamide, at a dose of 250 mg TID. Response was defined as a decline of PSA by >80% from the baseline, and this was achieved by 68/69 patients (98.6%). Many of the patients nadired at <0.2 (68%) which is a level that most laboratories consider an undetectable PSA. These nadirs occurred fairly rapidly with a median time to nadir of 3 months. Minimal toxicity has been reported to date. With a median follow-up of 16 months, only 1/69 patients progressed on therapy. These data indicate that this hormonal therapy is easily tolerated and very effective at lowering the PSA. Quality of life data has been obtained prospectively. Longer-term follow-up will be required to better define time to failure and response to additional hormonal maneuvers.

**Analysis of surgical salvage after failure of primary therapy in rectal cancer: results from INT 0114 (CALGB 9081) #507**

Joel E Tepper, Michael O’Connell, Hollis Donna, Donna Niedzwiecki, Elizabeth Cooke, Robert J Mayer, Univ of North Carolina School of Medicine, Chapel Hill, NC; Mayo Clinic, Rochester, MN; CALGB Statistical Center, Durham, NC; Dana-Farber Cancer Inst, Boston, MA.

INT 0114 was designed to study the effect of various chemotherapy regimens delivered after potentially curative surgical resection of T3, T4 and/or N+ rectal cancer. Adjuvant therapy consisted of 2 cycles of 5-FU based chemotherapy followed by pelvic irradiation with chemotherapy and 2 more cycles of chemotherapy post RT. A total of 1792 patients were entered on study and 1696 were evaluable. After a median of 8.9 years of follow-up, 721 patients (43%) had disease recurrence and an additional 10% died without evidence of disease. A subset analysis was undertaken to investigate the prevalence and impact of salvage therapy among patients with recurrent disease. 530 patients had a single site first recurrence (73.5% of all recurrences). A full analysis of 338 of the patients with single site recurrences has been completed. Single-site first recurrences in the liver, lung, or pelvis occurred in 291 (86%) of the single site recurrences) patients with 102 (35%) of these undergoing surgical resection for attempted cure. 5-year survival from date of recurrence is shown below. [table] Overall survival differed significantly between the resected and non-resected groups (p<0.0001) with overall 5-year probabilities of 0.25 and 0.02, respectively. Controlling for worst performance status at the time of recurrence does not alter this relationship. Patients with salvage surgery had significantly increased survival (p<0.001) for each site. Conclusion: Attempted surgical salvage of rectal cancer recurrence is performed commonly in the US. The chance of a long-term cure with such intervention is approximately 25%.

Survival after resection by site

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<th>Site of solitary recurrence</th>
<th>Number of pts (%)</th>
<th>Number (%) resected</th>
<th>No resection</th>
<th>Resection</th>
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<tr>
<td>Liver</td>
<td>123 (42%)</td>
<td>90 (30%)</td>
<td>28 (23%)</td>
<td>65 (52%)</td>
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<tr>
<td>Lung</td>
<td>103 (35%)</td>
<td>83 (30%)</td>
<td>27 (35%)</td>
<td>76 (73%)</td>
</tr>
<tr>
<td>Local</td>
<td>65 (22%)</td>
<td>50 (38%)</td>
<td>16 (25%)</td>
<td>49 (76%)</td>
</tr>
<tr>
<td>Total</td>
<td>291 (100%)</td>
<td>223 (76%)</td>
<td>74 (24%)</td>
<td>217 (74%)</td>
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A phase II study of estramustine, docetaxel, and carboplatin (EDC) with G-CSF support in men with hormone refractory prostate cancer (HRPC): CALGB 99813 #779


Estramustine plus docetaxel chemotherapy is active in hormone refractory prostate cancer (Savarese et al., JCO 9:2509-16, 2001). Platinum agents have modest but potentially additive benefits in HRPC. We studied the combination of estramustine, docetaxel and carboplatin (EDC) with G-CSF support in a multicenter phase II trial. Eligibility included patients with progressive HRPC who had not received prior chemotherapy. Other requirements included ECOG performance status (PS) 0-2, no significant cardiac or thrombotic events within the past year, no peripheral neuropathy and adequate renal, hematologic and liver function. Treatment consisted of estramustine 280 mg po TID on days 1-5, docetaxel 70 mg/m2 iv on day 2 and carboplatin AUC (5) iv on day 2, repeated every 21 days. G-CSF was started on day 6 and continued until ANC > 5000/ul. Decadron premedication (8 mg po BID) was given on days 1-3 of each cycle. Prophylactic low-dose coumadin was recommended. Forty patients were treated. Median age 68 yrs. Baseline PS 1 in 77%. Prior secondary treatments included ketoconazole in 53% and aminglutethimide in 10%. Thirty-eight patients are evaluable for response and/or toxicity. Of 17 with measurable disease, 8 had a partial response (47%95 CI, 20-75%) and 5 had stable disease. Of 35 patients with elevated pretreatment PSA levels, 25 (71%) experienced at least a 50% decline in PSA, while 19 (54%) had at least a 75% decline. Median duration of response is 4.8 months (95% CI, 5.3-10.8) and median disease-free progression is 7 months (95% CI, 1.4-9.8). Grade 3 or 4 neutropenia was seen in 24%, though febrile neutropenia occurred in only 1 patient. Grade 3 anemia and thrombocytopenia were seen in 8% and 16%, respectively. Non-hematologic toxicities were usually grade 1 or 2. Two patients developed deep venous thromboses and one patient had myocardial infarction, treated medically. 11% had grade 3 fatigue, 8% grade 3 diarrhea. In summary, EDC combination therapy is active and well-tolerated in men with HRPC. Randomized trials are necessary to determine if adding carboplatin to estramustine and docetaxel improves survival.
**CALGB PUBLICATIONS**

**Breast Committee**

<table>
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**Cancer in the Elderly Committee**

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**Cancer Control and Health Outcomes**

**Clinical Economics**

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<tr>
<td>309801</td>
<td>Accepted Abstract</td>
<td>Characterization of patient utility for chemotherapy induced nausea and vomiting (CINV)</td>
<td>SM Grunberg, JE Herndon, Zhang K, A Kessinger, Christian D, Weeks J</td>
<td>Journal of Supportive Care in Cancer, 2002</td>
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**Quality of Life**

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<tr>
<td>9033</td>
<td>Accepted Manuscript</td>
<td>Health-related quality of life in small-cell lung cancer patients: quality of life companion to CALGB 9033</td>
<td>MJ Naughton, SA Shumaker, JE Herndon, AA Miller, AB Kornblith, D Chao</td>
<td>Quality of Life Research, 2002</td>
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9221  Published Manuscript  
Impact of azacytidine on the quality of life of patients with myelodysplastic syndrome treated in a randomized phase III trial: A Cancer and Leukemia Group B Study  

9334  Published Abstract  
Quality of life (QOL) advantage of sclerosis for malignant pleural effusion (MPE) via talc thoracoscopy over chest tube infusion of talc slurry: Cancer and Leukemia Group B study 9334  
Proc ASCO 21:1418, 2002

9670  Accepted Manuscript  
Survey of oncologist's perceptions of barriers to accrual of older breast cancer patients to clinical trials  
Cancer, 2002

GI Committee

80004  Published Abstract  
Phase III dose-randomized study of imatinib mesylate (Gleevec, STI571) for GIST: intergroup S0033 (CALGB 80004) early results  
Proc ASCO 21:1651, 2002

8897  Published Manuscript  
Survelliance for Second Primary Colorectal Cancer after Adjuvant Chemotherapy: An Analysis of Intergroup 0089  
RJ Green, Metlay J, Propert K, PJ Catalano, JS MacDonald, RJ Mayer, DG Haller  
Annals of Internal Medicine 136 No. 4:261-269, 2002

89804  Published Abstract  
Oxaliplatin or CPT-11 + 5-fluorouracil/leucovorin or oxal + CPT-11 in advanced colorectal cancer: initial toxicity and response data from GI intergroup study N9741 (CALGB 89804)  
Proc ASCO 21:511, 2002

89805  Published Abstract  
Phase II chemoradiation trial using gemcitabine in patients with locoregional adenocarcinoma of the pancreas  
Blackstock A, Tempo R, M D Niedzwiecki, DR Hollis, RJ Mayer, JE Tepper  

GU Committee

9181/9182  Published Manuscript  
Importance of serum hemoglobin in hormone refractory prostate cancer  
RT Vollmer, PW Kantoff, NA Dawson, NJ Vogelzang  
Clinical Cancer Research 8:1049-1053, 2002

9480  Accepted Manuscript  
A phase III study of three different doses of suramin administered with a fixed dosing schedule in patients with advanced prostate cancer: results of CALGB 9480  
J Clin Oncol, 2002

9680  Published Manuscript  
Higher doses of mitoxantrone among men with hormone refractory prostate cancer: a Cancer and Leukemia Group B study  
Levine E, Halabi S, Kaplan EB, Roberts JD, Rago R, Atkins JN, Vogelzang NJ  
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9782  Published Abstract  
Efficacy of peripheral androgen blockade on prostate cancer: initial results of CALGB 9782  
J Picus, S Halabi, NA Dawson, EJ Small  
Proc ASCO 21:727, 2002

99813  Published Abstract  
A phase II study of estramustine, docetaxel, carboplatin (EDC) with G-CSF support in men with hormone refractory prostate cancer (HRCaP): An analysis of CALGB studies  
S Halabi, PW Kantoff, NA Dawson, Levine E, EJ Small, NJ Vogelzang  
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9081  Published Abstract  
Analysis of surgical salvage after failure of primary therapy in rectal cancer: results from Intergroup 0114/CALGB 9081  
J Tepper, M O’Connell, D Hollis, Niedzwiecki D, E Cooke, Mayer RJ  
Proc ASCO 21:507, 2002
Leukemia Committee

19802  Published Abstract
Treatment of adult acute lymphoblastic leukemia (ALL): phase II trial of dose intensification of daunorubicin and cytarabine followed by high-dose methotrexate and intrathecal methotrexate in place of cranial irradiation
W Stock,RK Dodge,JW Vardiman,CD Bloomfield,Caligiuri M,SR Frankel,RM Stone,RA Larson
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8921  Submitted Manuscript
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9011  Submitted Manuscript
Therapy-related myeloid leukemias are observed in patients with chronic lymphocytic leukemia after treatment with fludarabine and chlorambucil: results of an intergroup study CALGB 9011
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9013  Submitted Manuscript
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RT Silver,BL Peterson,TP Szatrowski,BL Powell,W Stock,AJ Carroll,CD Bloomfield,CA Schiffer,RA Larson
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BA Peterson,RK Dodge,Bhalla K,EJ Lee,JT Carpenter,GI Berk,SL George,CA Schiffer
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JC Byrd,Peterson B,Piro L,A Saven,JW Vardiman,RA Larson,Schiffer C
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9221  Published Manuscript
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9311  Submitted Manuscript
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Leukemia, 2002

9420  Submitted Manuscript
Post remission therapy with low-dose interleukin-2 with or without intermediate pulse dose interleukin-2 therapy is well tolerated in elderly patients with acute myeloid leukemia:Cancer and Leukemia Group B Study 9420
Farag S,SL George,EJ Lee,RK Dodge,Becknell B,Fehniger T,LR Silverman,J Crawford,RA Larson,CA Schiffer,MA Caligiuri
Clin Cancer Res, 2002

9620  Published Abstract
Autologous stem cell transplantation for acute myeloid leukemia in second remission
C Linker,George S,Hurd D,RA Larson
Blood 98:689a (2881), 2001

9621  Published Abstract
Consolidation therapy by cytogenetic risk in adults with AML < 60 years in first complete remission
JE Kolitz,SL George,RK Dodge,Hoke E,DD Hurd,BL Powell,E Velez-Garcia,MA Caligiuri,JO Moore,JW Vardiman,Linker C,CD Bloomfield,RA Larson
Blood 98:2879, 2001

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Dose escalation studies of Ara-C(A),daunorubicin (D),and etoposide (E) with and without multidrug resistance (MED) modulation with PSC-833 (P) in untreated adults with acute myeloid leukemia (AML) <60 years: final induction result
JE Kolitz,SL George,RK Dodge,Hoke E,DD Hurd,BL Powell,E Velez-Garcia,MA Caligiuri,JO Moore,JW Vardiman,CD Bloomfield,RA Larson
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Concurrent rituximab and fludarabine has a higher complete response rate than sequential treatment in untreated chronic lymphocytic leukemia (CLL) patients
Blood 98:3212, 2001
Phase III study of the multidrug resistance (MDR) modulator PSC-833 in previously untreated acute myeloid leukemia (AML) patients ≥ 60 years old: correlation of outcome with functional MDR
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8461  Published Abstract
Cytogenetics for treatment stratification in adult acute myeloid leukemia (AML)
Bloomfield CD, J Byrd, S Farag, K Mrozek, R Dodge, K Archer, SW Whitman, Larson RA, A Carroll, Caligiuri MA

8461  Published Abstract
Secondary chromosome aberrations in adult acute lymphoblastic leukemia (ALL) with t(9;22)
M Wetzler, RK Dodge, Mrozek K, CC Stewart, AJ Carroll, JW Vardiman, RA Larson, CD Bloomfield
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Isolated trisomy is an adverse prognostic factor in adults with acute myeloid leukemia (AML): results from Cancer and Leukemia Group B (CALGB) 8461

8763  Submitted Manuscript
Molecular monitoring of residual disease in adult patients with acute lymphoblastic leukemia: results of CALGB Study 8763
Reynolds C, Herrera M, RK Dodge, TP Szatrowski, BL Powell, CA Schiffer, RA Larson, CD Bloomfield, J Sklar

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Expression of BAALC predicts adverse prognosis in adult de novo acute myeloid leukemia with normal cytogenetics: a Cancer and Leukemia Group B study
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Lymphoma

59902  Published Abstract
Increased mortality associated with the cyclophosphamide 1000 mg/m2 & Fludarabine 20 mg/m2 qd x 5 (CF) arm in patients with low grade lymphoma treated on E1496/CALGB 59902
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Peterson BA, Petroni GR, Frizzera G, Barcos MP, Bloomfield CD, Nissen N, Hurd DD, Henderson E, Sartiano GP, Johnson JL, Holland JF, Gottlieb A
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8251  Accepted Editorial
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NEJM letter to the editor, 2002

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A Randomized comparison of ABVD vs MOPP/ABV for the treatment of advanced Hodgkin’s disease: report of an intergroup trial
DB Duggan, GR Petroni, JL Johnson, JH Glick, RI Fisher, Connors J, BA Peterson
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OW Press, LeBlanc M, Lichter A, Grogan T, Unger J, TH Wasserman, Gaynor E, BA Peterson, Miller T, RI Fisher
Pharmacology & Experimental Therapeutics
9661  Submitted Manuscript
A phase I trial of escalating doses of trastuzumab combined with daily subcutaneous interleukin-2: report of Cancer and Leukemia Group B 9661
Clinical Cancer Research, 2002

Radiation Oncology
39808  Published Abstract
70 Gy thoracic radiotherapy (TRT) concurrent with cycle 3 of chemotherapy is feasible for limited stage small cell lung cancer (L-SCLC): preliminary analysis of CALGB 39808
JA Bogart, JE Herndon, AP Lyss, Watson D, J Crawford, Miller A, Turisi A, MR Green

Respiratory Committee
39802  Published Abstract
Feasibility of video-assisted thoracic surgery (VATS) lobectomy for early stage lung cancer: Results of CALGB 39802
Swanson S, Herndon J, D’Amico A, Demmy T, McKenna R, Green M, Sugarbaker D
Proc ASCO 21:1158, 2002

39809  Published Abstract
Randomized phase II trial of gemcitabine/irinotecan and gemcitabine/docetaxel in stage IIIB (malignant pleural effusion) or stage IV NSCLC: CALGB 39809
CS Rocha Lima, Lee H, NA Rizvi, JE Herndon, Zhang K, J Crawford, GW King, MR Green
Proc ASCO 21:1344, 2002

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A phase Ib/II study of recombinant human gamma interferon in patients with advanced non-small cell lung cancer: A Cancer and Leukemia Group B study
J Crawford, JL Garst, JE Herndon, SQ Ringenberg, LA Glenn, H Jaffe, KJ Propert, MR Green
Lung Cancer, 2002

8837  Published Abstract
Long term survival data from CALGB 8837: Radiation Dose Escalation and Concurrent Chemotherapy (CT) in Limited Stage Small Cell Lung Cancer (LD-SCLC). Possible Dose-Survival Relationship for Total Radiation Dose and Dose Intensity
NC Choi, JE Herndon, Rosenman J, Carey R, Chung C, Bogart J, Seagren S, MR Green
Proc ASCO 21:1190, 2002

9238  Submitted Manuscript
Determination of operative risk with pulmonary exercise testing in patients with resectable lung cancer: results of Cancer and Leukemia Group B 9238
Lancet, 2002

9430  Accepted Manuscript
Novel doublets in extensive small cell lung cancer: a randomized phase II study of topotecan plus cisplatin or paclitaxel, CALGB 9430
AP Lyss, JE Herndon, Lynch T, Turisi A, Watson D, SJ Greethlein, MR Green
Clinical Lung Cancer, 2002

9631  Published Manuscript
High dose doxorubicin, dexrazoxane and GM-CSF in malignant mesothelioma: a phase II study CALGB 9631
Kosty MP, Herndon JE, Vogelzang NJ, Kindler HL, Green MR

9730  Published Abstract
Single agent versus combination chemotherapy in advanced NSCLC: a CALGB randomized trial of efficacy, quality of life, and cost-effectiveness: CALGB 9730
Proc ASCO 21:2, 2002

9732  Published Abstract
Randomized phase III intergroup trial of etoposide (VP-16) and cisplatin (DDP) +/- paclitaxel (Tax) and G-CSF in patients with extensive stage small cell lung cancer (ED-SCLC): CALGB 9732
HB Niell, JE Herndon, AA Miller, MR Green
Proc ASCO 21:1169, 2002

Comprehensive Published Manuscript
Outcomes among African-American and non African-American patients with advanced non small cell lung cancer receiving chemotherapy: meta analysis of CALGB studies 8931, 8932, 9132, 9532, and 9731
Blackstock A, II J, ED Paskett, MC Perry, Graziano SJ, Muscato, MP Kosty, WL Akerley, JC Holland, S Fleishman, MR Green
JNCI 94 No.4:284-290, 2002
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<td>9865</td>
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<td>APC promoter hypermethylation contributes strongly to loss of APC expression in colorectal cancers with allelic loss on 5q</td>
<td>Arnold C, Goel A, Compton C, Niedzwicki D, RJ Mayer, MM Bertagnolli, Boland C</td>
<td>Gastroenterology 122(5A):S886, 2002</td>
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## CRA & NURSING YEARS OF SERVICE RECOGNITION

### 15 years plus

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METHODS: The regimens reported on here (doses in mg/m²) were CPT-11 125 + 5FU/LV, Oxal + 5FU/LV, or Oxal + CPT-11 closed in 4/01 due to toxicity issues. Accrual per arm approximated 275 of 375 planned pts. We will have follow-up > 1 year on all patients by May 2002 permitting an initial comparison between these three arms.

METHODS: The regimens reported on here (doses in mg/m²) are CPT-11 125 + LV 20/5FU 500 day (d) 1,8,15, and 22 every q 6week (w) (original Saltz regimen); Oxal 85 d 1 + LV 200/5FU 400 bolus + 600 as a 22 hour infusion d 1,2 q 2 w (de Gramont FOLFOX 4 regimen); Oxal 85 + CPT-11 200 d1 q3w (Wasserman regimen). RESULTS: Pts/arm were 279 on CPT-11+5FU/LV, 269 on Oxal+5FU/LV, and 265 on Oxal + CPT-11. Deaths within 60 days of entry were: 13 CPT-11+5FU/LV (6 GI syndrome, 3 vascular syndrome, 2 both, 3 other toxicity, 3 disease), Oxal+5FU/LV 5 (1 vascular, 2 other toxicity, 2 disease), Oxal + CPT-11 5 (1 GI, 0 vascular, 2 other toxicity, 2 disease) (Rothenberg et al, JCO 19, p3801 2001). The imbalance in early deaths resulted in temporary study closure and subsequent initial dose reduction on the CPT-11 (125 to 100) + 5FU (500 to 400)/LV (20) arm. Common grade > 3 toxicities for 710 evaluable patients are shown in the table below. Data on response rate will be presented at the meeting. CONCLUSIONS: In our experience, at the initial dose levels the CPT-11 + 5FU/LV regimen used here was associated with an excessive number of early deaths compared to the two other regimens. The toxicity profile of the Oxal + 5FU/LV regimen is the most favorable of these regimens. Enrollment continues to the modified CPT-11 + 5FU/LV regimen and the Oxal + 5FU/LV regimen. Supported by NIH Grant CA25224, Pharmacia Corporation, and Sanofi Pharmaceuticals.

Adjuvant chemohormonal therapy for primary breast cancer should be sequential instead of concurrent: initial results from intergroup trial 0100 (SWOG 8814/CALGB 9194) #143

Kathy S Albain, Stephanie J Green, Peter M Ravdin, Charles D Cobau, Ellis G Levine, James N Ingle, Kathleen I Pritchard, Daniel J Schneider, Martin D Abeloff, Larry Norton, I. C Henderson, Danika Lew, Robert B Livingston, Silvana Martino, C. K Osborne, for SWOG, ECOG, CALGB, NCCTG, and NCIC-CTG, Loyola University Medical Center, Maywood, IL.

PURPOSE: Both adjuvant chemotherapy and tamoxifen (T) are of proven value for hormone receptor-positive (R+) breast cancer. But, there are no data regarding the proper timing of these two systemic modalities. Laboratory evidence suggests that T antagonizes the cytotoxicity of certain chemotherapy drugs. Thus, we conducted a phase III trial to determine 1) if CAFT (oral cyclophosphamide, Adriamycin, 5FU X6; T, 5 years) is superior to T alone in postmenopausal women with node (+), R (+) disease, the results of which were previously reported showing a strong survival benefit for CAFT+T; and 2) if CAFT followed by T (CAFT-T) is superior to concurrent therapy followed by T (CAFT-T), reported herein. METHODS: After stratification by nodes, PgR and interval from surgery, patients were randomized to T, CAFT, or CAFT-T in a 2:3:3 ratio. One-sided testing at p = 0.04 was planned for the hypothesis that CAFT-T is superior to CAFT-T. RESULTS: Of 1477 eligible patients, 361 received T, 566 CAFT-T, and 550 CAFT+T. Toxicities were similar between CAFT-T and CAFT-T. Median follow-up is 8.5 years. At 6 years DFS curves began to diverge. Eight-year DFS estimates are 67% for CAFT-T and 62% for CAFT-T, with one-sided p = 0.045 after adjustment for stratification factors. Both CAFT arms are superior to T alone (8-year DFS = 55%). Multivariate analysis showed that 4 (+) nodes, PgR (+), T3 tumors and African American race were predictors of adverse DFS. The CAFT-T/CAFT-T hazard ratio was 1.18 (.98-1.43) after adjustment for these factors. The survival comparison is currently not significant.
**PROTOCOL NEWS**

### BREAST COMMITTEE

**NEW**

- **40101** — Cyclophosphamide and Doxorubicin (CA) (4 vs 6 cycles) versus Paclitaxel (12 weeks vs 18 weeks) as Adjuvant Therapy for Women with Node-Negative Breast Cancer: A2x2 Factorial Randomized Study  
  **Study Chair:** L. Shulman, MD

- **49805** — A Phase III Randomized Double Blind Study of Letrozole Versus Placebo in Women with Primary Breast Cancer Completing Five or More Years of Adjuvant Tamoxifen  
  **Study Chair:** H. Muss, MD

### CANCER CONTROL & HEALTH OUTCOMES

- **9473** — Phase I/II trial of omega-3 fatty acids for cancer cachexia  
  **Study Chair:** C. Burns, MD

### GI COMMITTEE

- **9581** — Phase III Randomized Study of Adjuvant Immunotherapy with Monoclonal Antibody 17-1A Versus No Adjuvant Therapy Following Resection for Stage II (Modified Astler-Coller B2) Adenocarcinoma of the Colon  
  **Study Chair:** T. Colacchio, MD

### GU COMMITTEE

- **90102** — A Phase II study of cisplatin, gemcitabine and ZD1839 (Iressa) (IND #31187; NSC 715505) for the treatment of advanced urothelial tract carcinoma  
  **Study Chair:** G. Phillips, MD

- **90105** — Phase II Study of STI571 (Gleevec) in Patients with Refractory Seminoma  
  **Study Chair:** C. Ryan, MD

### LEUKEMIA COMMITTEE

- **10001** — A Phase II Trial of Sequential Chemotherapy, STI 571, and Transplantation for Adults with Newly Diagnosed Ph+ Acute Lymphoblastic Leukemia  
  **Study Chair:** M. Wetzler, MD

- **10002** — Phase II Study of Rituximab and Short Duration, High Intensity Chemotherapy with G-CSF Support in Previously untreated Patients with Burkitt’s Leukemia/Lymphoma (Acute Lymphoblastic Leukemia L-3 and Small Non-Cleaved Non-Hodgkin’s Lymphoma)  
  **Study Chair:** J. Byrd, MD

### LEUKEMIA CORRELATIVE SCIENCE

- **9720** — Phase III Study of MDR Modulation with PSC-833 (NSC#648265) Followed by Immunotherapy with rIL-2 (NSC#373364) Vs. No Further Therapy in Previously untreated Patients With AML * 50 Years  
  **Study Chair:** M. Baer, MD

- **9768** — Assessment of the AML1/ETO and CBFB/MYH11 Fusion Transcripts in Patients with Acute Myeloid Leukemia  
  **Study Chair:** M. Caligiuri, MD

### MELANOMA WORKING GROUP

- **509802** — A Randomized Phase III Trial of Concurrent Biochemotherapy with Cisplatin, Vinblastine, Dacarbazine, IL-2, and Interferon Alpha-2b versus Cisplatin, Vinblastine, Dacarbazine alone in Patients with Metastatic Malignant Melanoma  
  **Study Chair:** F. Haluska, MD

### PHARMACOLOGY & EXPERIMENTAL THER.

**NEW**

- **60102** — A pharmacogenetic case control study of severe diarrhea and life-threatening neutropenia in patients treated with irinotecan, 5-fluorouracil and leucovorin  
  **Study Chair:** M. Ratain, MD

### RESPIRATORY COMMITTEE

**NEW**

- **30102** — Phase III Comparison of Catheter Based Therapy of Pleural Effusions in Cancer Patients (Optimal Pleural Effusion Control, OPEC)  
  **Study Chair:** T. Demmy, MD

- **30104** — A Randomized Phase II Study of Exisulind for the Treatment of Patients with Extensive Stage Small Cell Lung Cancer  
  **Study Chair:** R. Govindan, MD

- **30106** — ZD1839 with Induction Paclitaxel and Carboplatin followed by Concomitant Radiation with Weekly Paclitaxel and Carboplatin in Stage III NSCLC: A Phase I/II Study  
  **Study Chair:** N. Ready, MD

### SOLID TUMOR CORRELATIVE SCIENCE

**NEW**

- **150007** — Contrast-Enhanced Breast MRI and Correlative Science to Characterize Tumor Response in Patients Undergoing Neoadjuvant Treatment for Locally Advanced Breast Cancer  
  **Study Chair:** L. Esserman, MD

- **150012** — Contrast-Enhanced Breast MRI for Evaluation of Patients Undergoing Neoadjuvant Treatment for Stage III Breast Cancer (ACRIN 6657)  
  **Study Chair:** N. Hylton, MD
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but the curves began to separate after 8 years with more late events on CAFT-T than CAF-T. Additional follow-up for survival is required, since due to the strong CAF benefit over T alone, there are fewer events than projected in the CAF arms. CONCLUSION: Delaying T until after CAF resulted in an estimated DFS advantage of 18% when compared to the concurrent use of these agents. These data are consistent with the hypothesis that T may antagonize drugs used in this or similar regimens and support a practice standard of starting adjuvant T when chemotherapy is completed.

Results of CALGB 39802: feasibility of video-assisted thoracic surgery (VATS) lobectomy for early stage lung cancer #1158

Scott J Swanson, James Herndon, Anthony D’Amico, Todd Demmy, Robert McKenna, Mark Green, David Sugarbaker, Brigham and Women’s Hospital, Boston, MA; Duke University, Durham, NC; Ellis Fischel Cancer Center/University of Missouri-Columbia, Columbia, MO; Cedars-Sinai Medical Center, Los Angeles, CA; Medical University of South Carolina, Charleston, SC.

OBJECTIVE: Evaluate feasibility of VATS lobectomy for small lung cancers using a prospective, multi-institutional design. METHODS: VATS lobectomy as specifically defined is an anatomic lobectomy using individual hilar dissection and node sampling or dissection and 2-4 small incisions without rib spreading. Lobes are removed in a bag through one port enlarged up to 8 cm. Eleven VATS lobectomy credentialed surgeons from 6 institutions participated. Between 1998 and 2001, 128 patients with nodules in outer half of lung suspected as non-small cell lung cancer ≤ 3 cm, CT-scan-confirmed clinical stage I disease, and without evidence of adenopathy were prospectively registered for VATS lobectomy. At lobectomy, mediastinoscopy or ipsilateral thoracoscopic mediastinal node sampling ruled out N2 disease in all patients and complete, standard resection insured by rigorous protocol guidelines. Feasibility, primary endpoint, was determined by perioperative measures and defined as successfully completing a VATS lobectomy in ≥ 85% of patients without excess morbidity (< 10%). Secondary endpoints, long-term morbidity, local recurrence and survival were also measured. RESULTS: 128 patients, 66 males, median age 66 (37-86), PS 0 (67%) or 1 (20%) underwent surgery. 106 (83%) had stage I lung cancer. 97/111 (87%) patients with evaluable data had successful VATS lobectomies. Lobes resected were (using standard abbreviations): RUL 23(24%), RML 2(2%), RLL 18(19%), LUL 35(36%), LLL 12(12%), not specified 7(7%). Median procedure length was 130 minutes (47-428), median chest tube duration 3 days (1-14). At time of lobectomy, 58/97 (60%) patients had a diagnostic biopsy. Within 30 days, 2 in 97 (2.1%) deaths occurred, neither directly related to VATS technique; 8/97 (8.2%) patients had grade 3/> complications, only one intraoperative bleeding. CONCLUSIONS: Specifically defined VATS lobectomy avoiding rib spreading is feasible in a prospective, multi-institutional setting. A follow-up Phase III study is being written to define its benefit.
# FUTURE CALGB MEETINGS

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