Cancer and Leukemia Group B Surgery Committee

Leslie J. Kohman

Abstract
Surgeons play a vital role in the Cancer and Leukemia Group B by providing patients and specimens for studies of the common solid tumors, and more recently, by serving as investigators who conduct surgically focused research protocols and contribute to the correlative science studies in the Group. Surgical activities encompass thoracic, gastrointestinal, breast, and genitourinary cancers and melanoma. Surgical quality assurance is also an important focus. This article will describe the development and importance of a robust and vigorous surgical component to a strong cooperative group and highlight the many trials conducted by the Cancer and Leukemia Group B surgeons and their contributions to advancement of the care of the patient with solid organ malignancy.

The origins of surgical activities within the Cancer and Leukemia Group B (CALGB) are unrecorded. There have been five identified chairs of the Surgery Committee:

Robert Crichlow (~ 10 years of service)
- Former Chair of Surgery at Dartmouth, now retired.

Alfred M. Cohen (? - 1988)
- Former Chief of Colorectal Surgery at Memorial Sloan Kettering Cancer Center;
- Executive Vice President of Health Affairs and Director of the Markey Cancer Center, University of Kentucky.

- Chair of Surgery and Co-director, Winship Cancer Center, Emory University;

- Richard E. Wilson Professor of Surgical Oncology, Harvard Medical School;
- Chief, Division of Thoracic Surgery, Brigham and Women’s Hospital.

Leslie J. Kohman (2004 - present)
- Director of Thoracic Oncology Program, State University of New York Upstate Medical University.

History

Under the leadership of James F. Holland, M.D., Group Chair 1963 to 1981, the CALGB expanded from a focus on childhood leukemia to include most hematologic malignancies and certain adult solid tumors (1968) and breast cancer (1969). The surgery modality committee was one of several added during this time to broaden the scope of clinical investigation. O. Ross McIntyre became Group Chair in 1990. During his tenure, the CALGB broadened its area of scientific interest in gastrointestinal tumors and initiated studies in prostate cancer, thus opening the way for additional participation by surgical oncologists.

In the early days, surgeons felt that their primary purpose was to contribute to the multidisciplinary nature of the group, especially near grant resubmission time. Medical oncologists and laboratory researchers typically viewed surgeons primarily as a source of patients and specimens. Bob Crichlow recalls Jim Holland as being good at encouraging surgeons to join and trying to give them something to do in the Group, but there were no financial resources to support this activity. The lack of funds to support the travel of surgeons to meetings, along with lack of a sense of true collaboration, were major barriers to surgical participation during the early years. With the development of groups, such as the National Surgical Adjuvant Breast and Bowel Project, there was not much interest among surgeons for a group that had “leukemia” in its name. The surgeons who remained active often did so out of loyalty and admiration for Drs. Holland, Frei, and McIntyre.

Bill Wood was exceptional as a surgical oncologist because he served 10 years (1978-1988) as Chair of the CALGB Breast Committee and as such was viewed by many as more of a breast oncologist than a surgeon. When his tenure leading the Breast Committee ended, he was briefly the Chair of the Surgery Committee (1988-1991). During this time, there were no surgery protocols per se, but he tried valiantly to recruit surgeons into the breast and gastrointestinal activities of the Group. It remained difficult to get surgeons to come to meetings; thus, he instituted instructional sessions, such as laparoscopy for staging, to try to draw them in. Surgeons continued to feel disenfranchised and the elements for a successful surgical effort remained elusive: reliable funding and a true sense of collaboration and respect. In the 1987 grant renewal, reviewers noted a low level of surgical activity. The CALGB recognized the need for improved surgical participation, and Dr. Wood was provided with small amounts of funds from the Chairman’s development fund to convene surgeons in subsequent years.
The next significant steps were taken by Dr. Mark Green, Chair of the Respiratory Committee. He invited all members to bring a thoracic surgeon to a meeting convened at the Boston Logan Airport Hilton Hotel in 1989. David Sugarbaker of Brigham and Women’s Hospital was charged with forming a thoracic surgeon cadre within the Respiratory Committee. The response of CALGB thoracic surgeons was gratifying. A multimodality approach to stage III non–small cell lung cancer (NSCLC; protocol 8935) served as the initial focal point for thoracic surgical activities. Thoracic surgeons joined and became active in CALGB and developed a portfolio of trials of interest to surgeons. The Respiratory Committee has continued to be interested in and supportive of questions of interest to surgeons.

The protocols emphasized careful and detailed pretreatment surgical staging and trimodality therapy involving high-risk surgery, chemotherapy, and radiation as well as effective quality control. These studies led to a growing sense of accomplishment on the part of all participants as true multidisciplinary strategies requiring surgical leadership were developed and implemented. The full integration of these thoracic surgeons and their activities provided the foundation for the development of expanded surgical activity in the Group. Thoracic Surgery remains the strongest surgical subgroup in CALGB and is the envy of thoracic surgeons in other multimodality cooperative groups.

With the success of the protocols in respiratory cancer, and with the CALGB renewing its activities in gastrointestinal cancer, the conditions were now right to reorganize surgical activities within the Group. In 1991, Dr. McIntyre increased the amount of support to the Surgical Committee using funds from the Chairman’s development account. As Chair of the Surgery Committee, Dr. Sugarbaker organized three subcommittees (thoracic, breast, and gastrointestinal) and appointed enthusiastic and respected chairs and vice-chairs for each. A trial was developed by the Gastrointestinal Committee surgeons that asked a surgical feasibility question (CALGB 8984, Sphincter Preservation for Rectal Cancer, chaired by Dr. Glenn Steele), and additional surgical questions were built into a number of planned clinical trials.

It became clear that for the Committee to achieve the next level of participation, additional resources would be required. In the 1992 grant renewal application, a separate U10 application, with Dr. Sugarbaker as PI, was submitted to provide the opportunity for focused peer review of plans for an expanded surgical program. This grant was funded and became the first (and to date only) separately funded Surgery Committee grant within the multidisciplinary cooperative groups. It supported three major areas of activity:

- Surgical education and quality control at main member and affiliated institutions;
- Increase of patient accrual to CALGB studies in lung, breast, and gastrointestinal cancer;
- Promotion of accrual to correlative science studies.

The CALGB leadership had the foresight to recognize that surgeons need a different style of nurturing than other specialists in the Group, and that they did not have access to the usual resources via the institutional Principal Investigator, almost without exception a medical oncologist. It also became apparent that to allow robust patient accrual to surgical studies, the Group would have to identify and develop a cadre of surgical Clinical Research Associates who knew how to work with surgeons. These Clinical Research Associates could go to the OR to collect specimens and had special expertise in interpreting operative reports and completing forms relating to surgical complications and the details of procedures that was necessary for quality control activities. These Clinical Research Associates reported to surgeons, belonged to Departments of Surgery, and were not dependent for their support on medical oncologists.

One surgeon from each CALGB main member institution was selected to serve as “surgical coordinator” for the institution and as a cadre member of the Surgery Committee. Each surgical coordinator is responsible for opening surgery-related protocols at their site, overseeing surgical data management and monitoring, and reporting on surgical accrual and activity at the main member institution and its affiliates. A large part of their responsibilities is education within their institutions and emphasizing cooperative group participation. With the success of the U10, funding was distributed to institutions that had manifested ability to accrue to surgical trials. This supported the surgical Clinical Research Associates and allowed additional accrual to surgical trials. Surgeons were funded for travel to attend meetings and became deeply involved in the science and research activities of the Group. A number of current leaders in American surgery received a major component of their professional development through association with CALGB members and activities.

At the time of grant renewal in 1997, the funds of the U10 had been parlayed into fully supported surgical Clinical Research Associates at 12 institutions. Fifteen surgery-intrinsic protocols had been activated and additional studies were in development (see Table 1).

CALGB also competed successfully for research support via the U01 mechanism for several intergroup protocols that investigated the feasibility and use of minimally invasive surgical techniques (see Table 2).

Surgeons were elected to the Executive Committee and served as chairs of several of the solid tumor correlative science working groups. At the time of the grant renewal in 2002, in response to a prior critique regarding the integration of surgical activities in the Group, the Surgery Committee aligned its funding structure with that of the Group and submitted a continuation application as a component of the Chairman’s grant. To enhance its unique function in the development and conduct of protocols addressing primarily surgical questions, the Surgery Committee now is authorized to sponsor studies directly, with appropriate representation of relevant disease and other modality committees. The protocols approved thus far under this mechanism are shown in Table 3.

Besides the original three disease-related subcommittees, a Genitourinary Surgical Subcommittee has been formed which has many protocols in development. They have recently completed accrual to a difficult protocol (protocol 9687) investigating the safety and feasibility of radical prostatectomy after failed radiotherapy and are eager to start accruing on 150406, the Renal cancer tumor bank. The Surgery Committee continues to show strong collaboration with the disease committees (Respiratory, Breast, Gastrointestinal, and Genitourinary).
The CALGB is also accomplished in surgical quality assurance and quality control, under the guidance of Judy Smith, M.D. of Roswell Park Cancer Institute. The Group now has a highly sophisticated and detailed method of analyzing and assuring quality in surgical oncology research, by discipline, protocol, and institution. The Surgical Quality Assurance Committee performs four broad functions: determination of surgery intensive protocol status, review of the surgical components of protocols for appropriate quality assurance content and issues, review of all quality assurance data for each protocol and institution, and provision of data for and implementation of continuous quality improvement.

A surgery intrinsic protocol is defined by the CALGB as a protocol that focuses on surgery and/or surgical treatment or techniques or is primarily surgical in nature (tissue acquisition). Other studies may be surgery intensive protocols if a surgeon is the primary investigator and/or surgeons accrue or treat the patients while on study. The surgery intensive protocols form the backbone of the surgical trial portfolio. All surgery intensive protocols must have a surgeon as the

### Table 1. CALGB surgical protocols activated before 1997

<table>
<thead>
<tr>
<th>Protocol no.</th>
<th>Title</th>
<th>CALGB accrual</th>
<th>Total accrual</th>
<th>Date opened</th>
<th>Date closed</th>
<th>Reason</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>8634</td>
<td>Neoadjuvant chemoradiotherapy plus surgery in stage IIIA NSCLC</td>
<td>45</td>
<td>45</td>
<td>5/86</td>
<td>2/88</td>
<td>Met goal</td>
<td>19</td>
</tr>
<tr>
<td>8935</td>
<td>Trimodality in stage IIIA (N2) NSCLC</td>
<td>80</td>
<td>80</td>
<td>8/89</td>
<td>2/92</td>
<td>Met goal</td>
<td>4–8</td>
</tr>
<tr>
<td>8984</td>
<td>Local excision + chemotherapy/radiotherapy for distal rectal cancer</td>
<td>82</td>
<td>180</td>
<td>5/90</td>
<td>10/95</td>
<td>Met goal</td>
<td>15, 16</td>
</tr>
<tr>
<td>89901</td>
<td>Preoperative chemoradiotherapy in locally advanced rectal cancer</td>
<td>18</td>
<td>18</td>
<td></td>
<td></td>
<td>Met goal</td>
<td>20</td>
</tr>
<tr>
<td>9134</td>
<td>Preoperative radiotherapy vs chemoradiotherapy in stage IIIA NSCLC</td>
<td>57</td>
<td>250</td>
<td>7/92</td>
<td>12/94</td>
<td>Slow accrual</td>
<td>21</td>
</tr>
<tr>
<td>9238</td>
<td>Exercise testing to predict surgical outcomes in NSCLC</td>
<td>422</td>
<td>382</td>
<td>8/93</td>
<td>7/98</td>
<td>Met goal</td>
<td>3</td>
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<tr>
<td>9270</td>
<td>Aspirin for colorectal adenoma prevention</td>
<td>272</td>
<td>719</td>
<td>5/93</td>
<td>1/00</td>
<td>Met goal</td>
<td>22</td>
</tr>
<tr>
<td>9334</td>
<td>Talc vs thorascopy in pleural effusions</td>
<td>317</td>
<td>501</td>
<td>12/94</td>
<td>9/99</td>
<td>Met goal</td>
<td>12</td>
</tr>
<tr>
<td>9335</td>
<td>VATS wedge and radiotherapy in high-risk T1 NSCLC</td>
<td>54</td>
<td>65</td>
<td>11/94</td>
<td>9/99</td>
<td>Met goal</td>
<td>23</td>
</tr>
<tr>
<td>9336</td>
<td>Thoracoscopic removal of pulmonary metastases</td>
<td>2</td>
<td>2</td>
<td>12/94</td>
<td>4/96</td>
<td>Slow accrual</td>
<td></td>
</tr>
<tr>
<td>9343</td>
<td>Tamoxifen ± radiotherapy for breast cancer in women over 70</td>
<td>307</td>
<td>647</td>
<td>7/94</td>
<td>2/99</td>
<td>Met goal</td>
<td>13</td>
</tr>
<tr>
<td>9380</td>
<td>Thoracoscopy for staging esophageal cancer</td>
<td>92</td>
<td>134</td>
<td>2/95</td>
<td>9/99</td>
<td>Met goal</td>
<td>24</td>
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<tr>
<td>9395</td>
<td>Perioperative chemotherapy, surgery, Post-operative chemotherapy for colon cancer</td>
<td>297</td>
<td>800</td>
<td>9/93</td>
<td>5/00</td>
<td>Met goal</td>
<td>25</td>
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<tr>
<td>9481</td>
<td>Hepatic artery chemotherapy for hepatic metastases from colon</td>
<td>130</td>
<td>135</td>
<td>1/96</td>
<td>12/00</td>
<td>Met goal</td>
<td>26, 27</td>
</tr>
<tr>
<td>9633</td>
<td>Chemotherapy after surgery for stage IB NSCLC</td>
<td>220</td>
<td>345</td>
<td>10/96</td>
<td>1/04</td>
<td>Met goal</td>
<td>1</td>
</tr>
<tr>
<td>9687</td>
<td>Salvage prostatectomy in radiotherapy failure</td>
<td>49</td>
<td>49</td>
<td>5/97</td>
<td>3/06</td>
<td>Met goal</td>
<td></td>
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### Table 2. CALGB minimally invasive surgery protocols

<table>
<thead>
<tr>
<th>Protocol no.</th>
<th>Title</th>
<th>CALGB accrual</th>
<th>Total accrual</th>
<th>Date opened</th>
<th>Date closed</th>
<th>Reason</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>9334</td>
<td>Talc vs thorascopy in pleural effusions</td>
<td>317</td>
<td>501</td>
<td>12/94</td>
<td>9/99</td>
<td>Met goal</td>
<td>12</td>
</tr>
<tr>
<td>9335</td>
<td>VATS wedge and radiotherapy in high-risk T1 NSCLC</td>
<td>54</td>
<td>65</td>
<td>11/94</td>
<td>9/99</td>
<td>Met goal</td>
<td>23</td>
</tr>
<tr>
<td>9336</td>
<td>Thoracoscopic removal of pulmonary metastases</td>
<td>2</td>
<td>2</td>
<td>12/94</td>
<td>4/96</td>
<td>Slow accrual</td>
<td></td>
</tr>
<tr>
<td>9380</td>
<td>Thoracoscopy for staging esophageal cancer</td>
<td>92</td>
<td>134</td>
<td>2/95</td>
<td>9/99</td>
<td>Met goal</td>
<td>24</td>
</tr>
<tr>
<td>39802</td>
<td>VATS lobectomy: a feasibility study</td>
<td>128</td>
<td>128</td>
<td>12/98</td>
<td>7/01</td>
<td>Met goal</td>
<td>28</td>
</tr>
<tr>
<td>39803</td>
<td>VATS restaging for stage IIIA NSCLC</td>
<td>75</td>
<td>75</td>
<td>9/98</td>
<td>9/03</td>
<td>Met goal</td>
<td>29</td>
</tr>
<tr>
<td>39804</td>
<td>VATS vs open resection pulmonary metastases</td>
<td>12</td>
<td>12</td>
<td>2/99</td>
<td>9/00</td>
<td>Slow accrual</td>
<td></td>
</tr>
<tr>
<td>30102</td>
<td>Talc vs small catheter in pleural effusions</td>
<td>55</td>
<td>67</td>
<td>5/02</td>
<td>12/04</td>
<td>Slow accrual</td>
<td>Brief report pending</td>
</tr>
<tr>
<td>140302</td>
<td>Minimally invasive surgery esophageal cancer</td>
<td>5</td>
<td>19</td>
<td>04/04</td>
<td>open</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
chair or co-chair of the protocol and have an approved Surgical Quality Assurance component. Other protocols, such as adjuvant protocols, that involve surgery, surgical diseases, or surgeons are designated surgery non-intensive protocols. The Surgical Quality Assurance Committee meets four times annually to provide objective data on quality assurance for all protocols involving surgery. Findings by institution are reported to the Institutional Performance Evaluation Committee, and this input is considered by that committee in making decisions regarding overall institutional performance. Findings by protocol are reported to the study chair. Methods have also been established to certify surgeons as competent to perform pulmonary resection after induction therapy, various minimally invasive (laparoscopic or thoracoscopic) procedures, and frozen tissue collection, among others. Handbooks have been published on the requirements for protocol-related operations and the way to report them.

### Surgery Committee Contributions to Correlative Science

Organized surgical activity within the context of cooperative group science provides a unique opportunity to procure accurately annotated surgical tumor specimens for correlative science research. A subgroup of the Thoracic Surgery Subcommittee has developed the ability to procure process and ship frozen tissue specimens in an organized fashion, and the Lung Cancer Tissue Bank protocol (CALGB 140202) is actively accruing at a greater than anticipated rate. In addition, a study of melanostatin expression as a prognostic factor in early-stage melanoma (CALGB 500195) is nearing its accrual goals. Although this protocol does not involve frozen tissue, surgeons are key to its success because many early-stage melanoma patients are not seen by other oncologists. Another initiative, the Kidney Tumor Bank (frozen tissue), will soon begin patient enrollment.

### Intergroup Participation

In addition to CALGB studies, CALGB surgeons have participated actively in surgical trials initiated by other groups, shown in Table 4.

### Other Accomplishments

Surgeons have been key in identifying patients for adjuvant trials. In particular, CALGB 9633 (1), which established the benefit of chemotherapy after resection of stage IB NSCLC could not have been done without the active, committed participation of surgeons because these patients are not traditionally referred to medical oncologists. In addition to the publication of completed trials, CALGB surgeons published a guide to cooperative group staging and treatment in multidisciplinary lung cancer trials (2), showing that a group of committed team surgeons can accomplish standardization of surgical outcomes. CALGB surgeons also established that video-assisted thoracic surgery is a safe technique for benign mediastinal tumors (3) and contributed to practice guidelines for colorectal cancer.

### Table 3. CALGB protocols sponsored by the surgery modality committee

<table>
<thead>
<tr>
<th>Protocol no.</th>
<th>Title</th>
<th>PI</th>
<th>Accrual</th>
<th>Goal</th>
<th>Date opened</th>
</tr>
</thead>
<tbody>
<tr>
<td>140202</td>
<td>Lung Cancer Tissue Bank</td>
<td>David Sugarbaker, M.D.</td>
<td>429</td>
<td>900</td>
<td>7/04</td>
</tr>
<tr>
<td>140203</td>
<td>Sentinel node mapping for lung cancer</td>
<td>Thomas D’Amico, M.D.</td>
<td>16</td>
<td>150</td>
<td>9/04</td>
</tr>
<tr>
<td>140302</td>
<td>Minimally invasive surgery for esophageal cancer</td>
<td>David Sugarbaker, M.D.</td>
<td>5</td>
<td>105</td>
<td>4/04</td>
</tr>
<tr>
<td>159902</td>
<td>Molecular markers in pleural lavage</td>
<td>Alice Boylan, M.D.</td>
<td>364</td>
<td>364</td>
<td>7/00</td>
</tr>
<tr>
<td>150406</td>
<td>Renal Cancer Tissue Bank</td>
<td>Jodi Maranchie, M.D.</td>
<td>1000</td>
<td></td>
<td>Pending</td>
</tr>
<tr>
<td>140501</td>
<td>VATS lobectomy registry</td>
<td>Scott Swanson, M.D.</td>
<td>450</td>
<td></td>
<td>Pending</td>
</tr>
<tr>
<td>140503</td>
<td>Lobe vs sublobar for &lt;2 cm NSCLC</td>
<td>Nasser Altorki, M.D.</td>
<td>1297</td>
<td></td>
<td>Pending</td>
</tr>
</tbody>
</table>

* This trial began before formal approval of the Surgery Committee to sponsor trials; it is a true surgical protocol with a correlative science endpoint.

### Table 4. CALGB participation in intergroup surgical protocols

<table>
<thead>
<tr>
<th>Protocol no.</th>
<th>Title</th>
<th>CALGB accrual</th>
<th>Total accrual</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>9091/RTOG 8911</td>
<td>Chemotherapy/surgery vs surgery alone for esophageal cancer</td>
<td>91</td>
<td>444</td>
<td>30</td>
</tr>
<tr>
<td>9293/MDACC 91-025</td>
<td>Isoretinoin to prevent second primaries in NSCLC</td>
<td>329</td>
<td>1379</td>
<td>31</td>
</tr>
<tr>
<td>9396/NCCITG 93-46-53</td>
<td>Lap-assisted vs open colectomy in colon cancer</td>
<td>108</td>
<td>900</td>
<td>32</td>
</tr>
<tr>
<td>9495/SWOG 9416</td>
<td>Chemotherapy, radiotherapy plus surgery in pancoast tumors</td>
<td>30</td>
<td>111</td>
<td>33</td>
</tr>
<tr>
<td>9592/RTOG 9309/INT 0139</td>
<td>Chemoradiotherapy ± surgery in stage IIIA (N2) NSCLC</td>
<td>43</td>
<td>612</td>
<td>34</td>
</tr>
<tr>
<td>49801/RTOG 9804</td>
<td>Local excision + radiotherapy for ductal carcinoma in situ</td>
<td>61</td>
<td>Goal 1790</td>
<td>Still accruing</td>
</tr>
<tr>
<td>79803/ECOG 5597</td>
<td>Chemoprevention with selenium for stage I NSCLC</td>
<td>122</td>
<td>Goal 1750</td>
<td>Still accruing</td>
</tr>
<tr>
<td>140302/ECOG 2202</td>
<td>Minimally invasive esophagectomy</td>
<td>5</td>
<td>Goal 105</td>
<td>Still accruing</td>
</tr>
</tbody>
</table>
Key Scientific Accomplishments

A few key protocols will be highlighted here; the remainder are described in Tables 1-3.

Thoracic

CALGB 8935: Sequential trimodality trial in pathologically staged IIIA(N2) NSCLC. Seventy-four patients with mediastinoscopically staged IIIA(N2) NSCLC from 30 CALGB-affiliated hospitals received preoperative cisplatin and vinblastine chemotherapy. Patients with responsive or stable disease underwent standardized surgical resection and radical lymphadenectomy. Patients who underwent resection received sequential adjuvant therapy with two additional cycles of cisplatin and vinblastine followed by thoracic irradiation. Sixty-three patients (86%) had exploratory thoracotomy, and 46 of those (75%) had resectable lesions. Operative mortality was only 3.2% (2 of 63). In 10 patients (22% of the 46 having resection), the disease was pathologically downstaged. There was no correlation between radiographic response to the induction chemotherapy and downstaging at surgical resection. Patients undergoing resection had significantly improved survival at 3 years compared with patients not having resection (4–8). This study established the ability of a large cohort of surgeons to do difficult surgery after induction therapy safely and accurately. In addition, two principles emerged in this group of patients: that radiographic response does not correlate with pathologic response and that persistent nodal positivity after induction therapy carries a very poor prognosis.

CALGB 9761: Occult micrometastases in stage I NSCLC. This trial established two important facets in surgically treated lung cancer. First, that surgeons are capable of collecting fresh frozen tumor and normal lung and bone marrow with good specimen quality; and second, that there is a much higher incidence of nodal positivity in clinical stage I patients than previously recognized (9–11). Five hundred two patients having surgery for clinical stage I lung cancer had a complete mediastinal node dissection, and half of each node was flash frozen and sent for immunohistochemical analysis. In addition, a bone marrow aspirate from the iliac crest was done by the surgeon and analyzed similarly. Key findings include that immunohistochemistry detects twice as many positive regional lymph nodes as H&E staining, that standard and quantitative real-time reverse transcription-PCR for carcinoembryonic antigen detect an equal number of occult nodal metastases (although quantitative reverse transcription-PCR may allow greater precision), and that preoperative diagnosis and staging of stage I NSCLC is right in only 62% of cases.

CALGB 9334: A phase III intergroup study of talc poudrage versus talc slurry sclerosis for malignant pleural effusion. This was the largest multi-institutional study ever published on the treatment of malignant pleural effusion. Five hundred one patients with malignant pleural effusion were randomized to treatment of malignant pleural effusion. Five hundred one was the largest multi-institutional study ever published on the comparison of talc poudrage and talc slurry sclerosis for malignant pleural effusion. End points were freedom from recurrence of effusion requiring retreatment, degree of lung expansion, and quality of life. Both methods of talc delivery were similar in efficacy; thoracoscopy may be better for patients with breast and lung primaries. Respiratory complications were frequent in both groups. This study established bedside chest tube drainage with talc sclerosis as the gold standard for management of this common and troubling problem, thus avoiding the extra cost and risk of thorascopic surgery. This CALGB study made an important contribution to the evaluation of new technology (12).

Breast Cancer

CALGB 9343: A randomized comparison of lumpectomy plus tamoxifen with and without irradiation in women 70 years of age or older who have clinical stage I, estrogen receptor–positive carcinoma of the breast. Six hundred thirty-six women ages ≥70 years with clinical stage I, estrogen receptor–positive breast cancer treated with lumpectomy were randomized to tamoxifen plus radiotherapy or tamoxifen alone. The patients without radiotherapy had a slightly higher incidence of local or regional recurrence, but this did not lead to increased rates of mastectomy, distant metastases, or decrease in overall survival. This landmark trial showed that lumpectomy plus adjuvant therapy with tamoxifen alone is a realistic choice for the treatment of women ages ≥70 years who have clinical stage I, estrogen receptor–positive breast cancer. This result has been a boon to many older women who do not wish to undergo radiotherapy, often at facilities far from their homes. They now know that omitting post-operative radiation will not compromise their survival (13). Although this study primarily asked a radiation question, surgeons chaired the study and were the portal for enrollment of patients with early-stage breast cancer. This study also established CALGB as a group with special interest and expertise in surgical trials relating to the elderly (14).

Gastrointestinal Cancer

CALGB 8984: Sphincter sparing treatment for distal rectal adenocarcinoma. This showed that sphincter preservation can be achieved with excellent cancer control without initial sacrifice of anal function in most patients. After local recurrence, salvage resection seemed effective (15, 16).

Analysis of 26 prospectively accrued patients with distal rectal adenocarcinomas, who underwent sphincter preservation treatment, showed that tumors that invade only the submucosa can safely be treated with surgery alone, and that tumors that invade the muscularis or further can be safely treated with surgery combined with chemoradiotherapy. None of the patients had either local or distant recurrence, with a median follow-up of 21 months. All patients were fully continent. The results imply that resection of distal rectal adenocarcinoma with sphincter preservation, and adjuvant therapy when appropriate, can achieve local and distant control equal to the conventional Miles’ abdominoperineal resection but without the need for a permanent colostomy.

CALGB 80001: Sentinel node staging of resectable colon cancer. This multi-institutional study (25 surgeons, 13 institutions, and 91 patients) found that for patients with node-positive colon cancer, sentinel node examination with multilevel sectioning failed to predict nodal status in 54% of cases. When used alone, it is unlikely to improve risk stratification for resectable colon cancer. This will save money and time and is an excellent example of how negative results can provide important information (17, 18).
Conclusion

Over the last 25 years, the Surgery Committee of CALGB has grown from a peripheral component of the Group into a vital, central component of the Group. It is the largest and most active of the surgical committees in any of the multidisciplinary cooperative groups. Its Surgical Quality Assurance Program improves surgical performance and insures protocol compliance. Surgeons continue to participate fully in CALGB and make important contributions to treatment and correlative science studies.

References


Clinical Cancer Research

Cancer and Leukemia Group B Surgery Committee
Leslie J. Kohman


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