Complete Summary

GUIDELINE TITLE

Complementary therapies and integrative oncology in lung cancer: ACCP evidence-based clinical practice guidelines. (2nd Edition)

BIBLIOGRAPHIC SOURCE(S)

Cassileth BR, Deng GE, Gomez JE, Johnstone PA, Kumar N, Vickers AJ, American College of Chest Physicians. Complementary therapies and integrative oncology in lung cancer: ACCP evidence-based clinical practice guidelines (2nd edition). Chest 2007 Sep;132(3 Suppl):340S-54S. [124 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
IMPLEMENTATION OF THE GUIDELINE
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SCOPE

DISEASE/CONDITION(S)

Lung cancer

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Family Practice
Oncology
Pulmonary Medicine

Radiation Oncology
Thoracic Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Patients
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers

GUIDELINE OBJECTIVE(S)

To differentiate between "alternative" therapies, often promoted falsely as viable options to mainstream lung cancer treatment, and complementary therapies, adjunctive, effective techniques that treat symptoms associated with cancer and its mainstream treatment, and to describe the evidence base for use of complementary therapies

TARGET POPULATION

Individuals with lung cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Complementary and Alternative Therapies

1. Mind-body modalities (e.g. meditation, yoga, hypnosis, relaxation techniques, cognitive-behavioral therapy, biofeedback, and guided imagery)
2. Massage therapies
3. Acupuncture
4. Botanical agents (only in the context of a clinical trial)

Therapies considered but not recommended:

1. Deep or intense pressure in massage
2. Therapies based on putative manipulation of bioenergy fields
3. Electrostimulation wristbands
4. Dietary supplements that may interact with other drugs
5. Alternatives to mainstream care

MAJOR OUTCOMES CONSIDERED

- Reduction of physical and emotional symptoms
- Quality of life
- Survival

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Overview

The formal systematic reviews of the five new topic areas were guided by the appropriate chapter editors and their writing committees, in concert with the Executive Committee of the panel.

The two EPC research teams conducted a variety of systematic computerized bibliographic database searches including the following: (1) a search for systematic reviews, guidelines, and meta-analyses published since the last ACCP lung cancer guideline (MEDLINE, The Cochrane Library, National Guidelines Clearinghouse); (2) targeted searches for reviews in each of five selected treatment sections (solitary pulmonary nodules, stage I and II, stage IIIA, stage IIIB, stage IV); these searches, run in OVID version of MEDLINE, were performed in July and August 2005 and were limited to publication years since 1995, English language, and human subjects; and (3) searches related to SCLC are described in the evidence chapter on SCLC.

Search terms included the medical subject heading terms lung neoplasms (exploded) and bronchial neoplasms for the lung cancer concept. Each topic search utilized key words specific to the key questions of interest (complete search strategies are available on request from the authors).

Strategy Specific for Complementary Therapies and Integrative Oncology in Lung Cancer

Sources searched included English-language clinical trials or reviews in MEDLINE and relevant chapters in recent major oncology text books and government Web sites. MEDLINE was searched for articles published from 1980 to 2006. These searches were conducted from December 2005 through April 2006. A multidisciplinary panel of experts in oncology and integrative medicine evaluated the evidence for complementary (not alternative) therapies in the care of patients with lung cancer. Because few complementary modalities are geared to patients with only a single cancer diagnosis, symptom-control research conducted with other groups of patients with cancer was also included. Data on complementary therapies such as acupuncture, massage therapy, mind-body therapies, herbs and other botanicals, and exercise were evaluated. Recommendations were based on the strength of evidence and the risk-to-benefit ratio.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

High Randomized controlled trials (RCTs) without important limitations or overwhelming evidence from observational studies*

Moderate RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies*

Low or very low Observational studies or case series

*Although the determination of magnitude of the effect based on observational studies is often a matter of judgment, the guideline developers offer the following suggested rule to assist this decision: a large effect would be a relative risk >2 (risk ratio < 0.5) [which would justify moving from weak to moderate], and a very large effect is a relative risk > 5 (risk ratio < 0.2) [which would justify moving from weak to strong]. There is some theoretical justification in the statistical literature for these thresholds (the magnitude of effect that is unlikely or very unlikely to be due to residual confounding after adjusted analysis). However, once the decision is made, authors should be explicit in justifying their decisions.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Quality of evidence is scored in three categories with high-quality evidence obtained from randomized controlled trials (RCTs) without important methodologic limitations based on the study design, the consistency of the results, and the directness of the evidence. In extraordinary circumstances, significant and consistent evidence from observational studies could also be ranked as high quality. RCTs with important methodologic limitations or flaws, inconsistent results, or indirect or imprecise results would be scored as medium quality, as well as exceptionally strong evidence from observational studies. Other observational studies or case-series data would fall into the low quality of evidence category. It is the interface of the quality of the evidence and the balance of benefits to harms or burdens that determines the strength of the recommendation, with a 1A recommendation being the strongest and 2C the weakest.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Writing committees studied the evidence and summary tables or reviewed the literature for their assigned topics, developing their arguments for the recommendations and suggested grading of those recommendations that were put forth for early drafts. The Executive Committee of the panel, composed of the Chair, Vice-Chair, methodologist, and both project managers, reviewed drafts of each chapter of the manuscript during the writing process. Sections that were determined to be potentially overlapping were shared among the appropriate chapter editors, and conference calls were organized to coordinate the placement of these sections and to confirm that there would be no conflicting information or recommendations.

A conference of the panel was convened in July 2006, prior to which time all panelists, including representatives from the invited organizations, were requested to review the complete manuscript and identify recommendations for which the proposal, wording, or grading were determined to be controversial or could be interpreted as controversial by others, incorrectly evolved from the evidence, disagreement existed with regard to the proposal or the grading, or required full panel discussion and further review for any reason. When the panelists who were present were not in unanimous agreement with the proposed recommendations or the grading of the recommendations, informal group consensus techniques were employed. After the meeting, a series of conference calls were convened to finish the discussions and finalize the recommendations. There were a few chapters for which there was insufficient time for full dialogue during the meeting; in the interest of ensuring that the recommendations followed the evidence, the conference calls were necessary. This process ensured the "buy-in" of the panelists and was deemed to be a worthwhile effort.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of Recommendations Scale

Grade	Recommendation
1A	Strong
1B	Strong
1C	Strong
2A	Weak
2B	Weak
2C	Weak

Relationship of Strength of the Supporting Evidence to the Balance of Benefits to Risks and Burdens

Balance of Benefits to Risks and Burdens				
Quality of Evidence	**Benefits Outweigh Risks/Burdens**	**Risks/Burdens Outweigh Benefits**	**Evenly Balanced**	**Uncertain**

Balance of Benefits to Risks and Burdens				
Quality of Evidence	**Benefits Outweigh Risks/Burdens**	**Risks/Burdens Outweigh Benefits**	**Evenly Balanced**	**Uncertain**
High	1A	1A	2A	
Moderate	1B	1B	2B	
Low or very low	1C	1C	2C	2C

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following final chapter revisions and incorporation of these ultimate recommendations and grading, a concluding review was conducted by the guideline panel Executive Committee. The guidelines were then submitted for review and approval to the American College of Chest Physicians Health and Science Policy Committee (ACCP HSP) Committee, as well as the Thoracic Oncology Network of the college.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of evidence and recommendation grades (1A-2C) follow the recommendations.

A distinction between "complementary" and "alternative" therapies is required. *Complementary therapies*, used as adjuncts to mainstream care, are supportive measures that help control symptoms, enhance well-being, and contribute to overall patient care. *Alternative therapies*, conversely, are often unproved or disproved, promoted for use instead of mainstream treatment, or are offered as viable therapeutic options. This is especially problematic in oncology, when delayed treatment can diminish the possibility of remission and cure. Over time, some complementary therapies are proven safe and effective. These become integrated into mainstream care, producing integrative oncology, a combination of the best of mainstream cancer care and rational, data-based, adjunctive complementary therapies. Most complementary and alternative medicine (CAM) practices can be loosely grouped into five categories according to the National Institutes of Health (NIH) National Center for Complementary and Alternative Medicine (see Table below).

Table: Categories and Examples of Complementary and Alternative Therapies

Biologically based practices	Herbal remedies, vitamins, other dietary supplements
Mind-body techniques	Meditation guided imagery
Manipulative and body-based practices	Massage, reflexology
Energy therapies	Magnetic field therapy
Ancient medical systems	Traditional Chinese medicine, ayurvedic medicine, acupuncture

1. It is recommended that all patients with lung cancer be specifically asked about the use of CAM. **Grade of recommendation, 1C**
2. It is recommended that all patients with lung cancer be given guidance about the advantages and disadvantages of complementary therapies in an open, evidence-based, and patient-centered manner by a qualified professional. **Grade of recommendation, 1C**
3. In lung cancer patients, mind-body modalities are recommended as part of a multi-modality approach to reduce anxiety, mood disturbances, or chronic pain. **Grade of recommendation, 1B**
4. In lung cancer patients experiencing anxiety or pain, massage therapy delivered by an oncology-trained massage therapist is recommended as part of a multimodality treatment approach. **Grade of recommendation, 1C**
5. The application of deep or intense pressure is not recommended near cancer lesions or anatomic distortions, such as postoperative changes, as well as in patients with a bleeding tendency. **Grade of recommendation, 2C**
6. For lung cancer patients, therapies based on putative manipulation of bioenergy fields are not recommended. **Grade of recommendation, 1C**
7. Acupuncture is recommended as a complementary therapy when pain is poorly controlled or when side effects, such as neuropathy or xerostomia from other modalities, are clinically significant. **Grade of recommendation, 1A**
8. Acupuncture is recommended as a complementary therapy when nausea and vomiting associated with chemotherapy are poorly controlled. **Grade of recommendation, 1B**
9. Electrostimulation wristbands are not recommended for managing chemotherapy-induced nausea and vomiting. **Grade of recommendation, 1B**
10. When the patient with lung cancer does not stop smoking despite use of other options, a trial of acupuncture is recommended to assist in smoking cessation. **Grade of recommendation, 2C**
11. In patients with lung cancer with symptoms such as dyspnea, fatigue, chemotherapy-induced neuropathy, or postthoracotomy pain, a trial of acupuncture is recommended. **Grade of recommendation, 2C**
12. In patients with a bleeding tendency, it is recommended that acupuncture be performed by qualified practitioners and used cautiously. **Grade of recommendation, 1C**
13. It is recommended that dietary supplements, particularly herbal products, be evaluated for side effects and potential interactions with other drugs. Those that are likely to interact with other drugs, such as chemotherapeutic agents, should not be used concurrently during chemotherapy or radiation, or before surgery. **Grade of recommendation, 1B**

14. In patients with lung cancer who either do not respond to or decline antitumor therapies, it is recommended that use of botanical agents occur only in the context of clinical trials. **Grade of recommendation, 1C**
15. It is recommended that patients be advised to avoid therapies promoted as "alternatives" to mainstream care. **Grade of recommendation, 1A**

Definitions:

Quality of Evidence Scale

High - Randomized controlled trials (RCTs) without important limitations or overwhelming evidence from observational studies*

Moderate - RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies*

Low or very low - Observational studies or case series

*Although the determination of magnitude of the effect based on observational studies is often a matter of judgment, the guideline developers offer the following suggested rule to assist this decision: a large effect would be a relative risk > 2 (risk ratio < 0.5) [which would justify moving from weak to moderate], and a very large effect is a relative risk > 5 (risk ratio < 0.2) [which would justify moving from weak to strong]. There is some theoretical justification in the statistical literature for these thresholds (the magnitude of effect that is unlikely or very unlikely to be due to residual confounding after adjusted analysis). However, once the decision is made, authors should be explicit in justifying their decisions.

Grade of Recommendations Scale

Grade	Recommendation
1A	Strong
1B	Strong
1C	Strong
2A	Weak
2B	Weak
2C	Weak

Relationship of Strength of the Supporting Evidence to the Balance of Benefits to Risks and Burdens

Balance of Benefits to Risks and Burdens				
Quality of Evidence	**Benefits Outweigh Risks/Burdens**	**Risks/Burdens Outweigh Benefits**	**Evenly Balanced**	**Uncertain**
High	1A	1A	2A	
Moderate	1B	1B	2B	
Low or very low	1C	1C	2C	2C

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of complementary therapies available for lung cancer patients

POTENTIAL HARMS

Hypnosis

A small percentage of patients may experience dizziness, nausea, or headache. These symptoms usually result from patients being brought out of trances by inexperienced hypnotherapists.

Massage Therapy

Serious adverse events are rare and associated with exotic types of massage or untrained practitioners. In work with cancer patients, the application of deep or intense pressure should be avoided, especially near lesions or anatomic distortions such as postoperative changes. Patients with bleeding tendencies should receive only gentle, light-touch massage.

Acupuncture

The most common minor adverse events included local bleeding and needling pain, both in 0.05% of patients. It is prudent to avoid acupuncture at the site of tumor or metastasis, limbs with lymphedema, areas with considerable anatomic distortion attributable to surgery, and in patients with thrombocytopenia, coagulopathy, or neutropenia. Cancer patients require certified practitioners who are experienced in treating patients with malignant diseases.

Herbs and Botanical Products

Because botanicals contain biologically active constituents, they carry health risks if not used properly. The botanical kava kava, for example, proved more effective than placebo in treating anxiety, stress, and insomnia, and it was considered a viable alternative to benzodiazepines because of its benefits and absence of dependency and addiction. However, later reports associate this herbal remedy with severe hepatotoxicity resulting in death.

Herbs may attenuate or lessen the effect of a drug either by direct action on its target or by altering its pharmacokinetics. Herbs such as feverfew, garlic, ginger, and ginkgo have anticoagulant effects and should be avoided by patients using warfarin, heparin, aspirin, and related agents. Red clover, Dong quai, and licorice, because of their phytoestrogen components, should not be used by patients using tamoxifen or aromatase inhibitors. St. John's wort was a popular product for depression, at least equivalent in efficacy to tricyclics and selective serotonin reuptake inhibitors in mild to moderate depression and with a side effect profile superior to both. It was found, however, that St. John's wort induces cytochrome P450 CYP3A4. Reduced plasma levels of SN38, an active metabolite of irinotecan, have been reported after simultaneous use. Such metabolic interactions preclude St. John's wort for patients on medications metabolized by CYP3A4.

Although not an herb, grapefruit juice was found to significantly change the plasma level of many prescription drugs. Further study found that furanocoumarin derivatives inhibit intestinal CYP3A4, which consequently increases the bioavailability of drugs that are substrate to first-pass metabolism by this enzyme.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The publication of the *Diagnosis and Management of Lung Cancer: ACCP Evidence-Based Clinical Practice Guidelines; Second Edition* in *CHEST* is the first of two dissemination vehicles. The circulation of the journal is 23,000 subscribers and libraries, including six translations and distribution to 107 countries. All subscribers received a copy of this full-text guideline. The American College of Chest Physicians (ACCP) Clinical Resource on Lung Cancer is composed of a printed publication and an accompanying CD-ROM, containing a quick reference guide for physicians and other health-care providers, patient-targeted educational materials, and a set of slides for use in educational or clinical contexts. In addition, the recommendations and grading are personal digital assistant downloadable from the clinical resource. This product is available for purchase from the ACCP. The patient education materials are accessible free of charge on www.chestnet.org.

The implementation and translation of evidence-based clinical practice guidelines facilitates knowledge uptake, critical for practice change, and should ultimately lead to better patient-focused care. The HSP Subcommittee on Implementation has proposed to collaborate with the Governors, Thoracic Oncology Network, and other groups within the ACCP to disseminate and implement the guidelines in their local communities. Residency and specialty training programs are encouraged to use the guidelines in journal clubs and grand rounds. Other organizations that were invited to send representatives to the final conference and review the proposed drafts were also requested to endorse the guidelines and market them to their membership through their own communication channels.

IMPLEMENTATION TOOLS

Patient Resources
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Cassileth BR, Deng GE, Gomez JE, Johnstone PA, Kumar N, Vickers AJ, American College of Chest Physicians. Complementary therapies and integrative oncology in lung cancer: ACCP evidence-based clinical practice guidelines (2nd edition). Chest 2007 Sep;132(3 Suppl):340S-54S. [124 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Sep

GUIDELINE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Chest Physicians

GUIDELINE COMMITTEE

American College of Chest Physicians (ACCP) Expert Panel on Lung Cancer Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Author: Douglas Arenberg, MD, FCCP

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Funding for both the evidence review and guideline development was supported by educational grants from AstraZeneca LP, Bristol-Myers Squibb Company, Eli Lilly and Company, Genentech, and Sanofi-Aventis. Representatives from these companies were neither granted the right of review, nor were they allowed participation in any portion of the guideline development process. This precluded participation in either conference calls or conferences. No panel members or ACCP reviewers were paid any honoraria for their participation in the development and review of these guidelines.

The ACCP approach to the issue of potential or perceived conflicts of interest established clear firewalls to ensure that the guideline development process was not influenced by industry sources. This policy is published on the ACCP Web site at www.chestnet.org. All conflicts of interest within the preceding 5 years were required to be disclosed by all panelists, including those who did not have writing responsibilities, at all face-to-face meetings, the final conference, and prior to submission for publication. The most recent of these conflict of interests are documented in this guideline Supplement. Furthermore, the panel was instructed in this matter, verbally and in writing, prior to the deliberations of the final conference. Any disclosed memberships on speaker's bureaus, consultant fees, grants and other research monies, and any fiduciary responsibilities to industry were provided to the full panel in writing at the beginning of the conference and at submission for publication.

ENDORSER(S)

American Association for Bronchology - Disease Specific Society
American Association for Thoracic Surgery - Medical Specialty Society
American College of Surgeons - Medical Specialty Society
American Society for Therapeutic Radiology and Oncology
Asian Pacific Society of Respirology - Disease Specific Society
Oncology Nursing Society - Professional Association
Society of Thoracic Surgeons - Medical Specialty Society
World Association of Bronchology - Disease Specific Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available to subscribers of Chest - The Cardiopulmonary and Critical Care Journal.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Executive Summary:

- Alberts MW. Diagnosis and management of lung cancer executive summary. Chest 2007 Sep;132(3 Suppl):1S-19.

Background Articles:

- Alberts WM. Introduction: diagnosis and management of lung cancer. Chest 2007 Sep;132(3 Suppl):20S-22.
- McCrory DC, Lewis SZ, Heitzer J, Colice GL, Alberts WM. Methodology for lung cancer evidence review and guideline development. Chest 2007 Sep;132(3 Suppl):23S-28.
- Alberg AJ, Ford JG, Samet JM. Epidemiology of lung cancer. Chest 2007 Sep;132(3 Suppl):29S-55.

Electronic copies: Available to subscribers of Chest - The Cardiopulmonary and Critical Care Journal.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

The following is also available:

- ACCP clinical resources: Diagnosis and management of lung cancer: ACCP evidence-based clinical practice guidelines (2nd edition).

Available from the American College of Chest Physicians Web site.

PATIENT RESOURCES

The following are available:

- Lung cancer guides: lung cancer...am I at risk? Patient education guide. Northbrook (IL): American College of Chest Physicians, 2004. 12 p.
- Lung cancer guides: What if I have a spot on my lung? Do I have cancer? Patient education guide. Northbrook (IL): American College of Chest Physicians, 2004. 16 p.
- Lung cancer guides: living with lung cancer. Patient education guide. Northbrook (IL): American College of Chest Physicians, 2004. 12 p.
- Lung cancer guides: advanced lung cancer: issues to consider. Patient education guide. Northbrook (IL): American College of Chest Physicians, 2004. 12 p.

Electronic copies: Available in Portable Document Format (PDF) from the American College of Chest Physicians (ACCP) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information

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NGC STATUS

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