Complete Summary

GUIDELINE TITLE

Diagnosis of lung cancer: the guidelines.

BIBLIOGRAPHIC SOURCE(S)

Rivera MP, Detterbeck F, Mehta AC. Diagnosis of lung cancer: the guidelines. Chest 2003 Jan;123(1 Suppl):129S-36S. [35 references] PubMed

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SCOPE

DISEASE/CONDITION(S)

Lung cancer

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Oncology
Pulmonary Medicine
Thoracic Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide clinically relevant, evidence-based guidelines for the diagnosis of suspected lung cancer

TARGET POPULATION

Patients with suspected lung cancer who have abnormal chest radiograph findings or symptoms caused by either local or systemic effects of the tumor.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnostic modalities for suspected lung cancer:

1. Sputum cytology
2. Flexible bronchoscopy and ancillary procedures (biopsy, cytobrushing, washing, transbronchial needle aspiration [TBNA], and bronchoalveolar lavage [BAL])
3. Transthoracic needle aspiration (TTNA), including use of computed tomography scan or fluoroscopy guidance
4. Use of aspiration needle, aspiration biopsy needle, or cutting biopsy needle

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Accuracy of diagnostic modalities (diagnostic error rate)

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

As a first step in identifying the evidence for each topic, the guideline developers sought existing evidence syntheses including guidelines, systematic reviews, and meta-analyses. They searched computerized bibliographic databases including MEDLINE, Cancerlit, CINAHL and HealthStar, the Cochrane Collaboration Database of Abstracts of Reviews of Effectiveness, the National Guideline Clearinghouse, and the National Cancer Institute Physician Data Query database. Computerized searches through July 2001 used the MeSH terms

Strategy specific for lung cancer diagnosis

For the topic on diagnostic workup of lung cancer, the guideline developers formulated four key questions that were to be answered by a comprehensive critical review of the published evidence:

1. What are the performance characteristics (sensitivity and specificity) for sputum cytology for the diagnosis of lung cancer with special consideration for the location of the tumor (central versus peripheral)?
2. What are the performance characteristics (sensitivity and specificity) of flexible bronchoscopy and its ancillary procedures (biopsy, cytobrushing, washing, transbronchial needle aspiration [TBNA], and bronchoalveolar lavage [BAL]) for the diagnosis of central (endobronchial), as opposed to peripheral, tumors and for peripheral lesions < 2 cm and > 2 cm in diameter?
3. What are the performance characteristics (sensitivity and specificity) for transthoracic needle aspiration (TTNA) as a diagnostic modality with particular emphasis on the size and the location of the suspected cancer?
4. What is the diagnostic error rate when differentiating between non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC) that is generated by various diagnostic techniques (bronchoscopy and sputum cytology)?

To address these questions, Duke University, supported by a contract from the American College of Chest Physicians, conducted a computerized search of the MEDLINE bibliographic database from 1966 to July 2001, HealthStar, and the Cochrane Library. They searched using the terms lung neoplasm, bronchial neoplasm, bronchoscopy, biopsy, needle, sputum, cytodiagnosis, yield, predictive value of tests, and sensitivity and specificity. In addition, they searched the reference lists of included studies, practice guidelines, systematic reviews, and meta-analyses.

They selected studies of at least 50 patients with suspected lung cancer that compared test results with a reference standard consisting of pathology/histology, definitive cytologic diagnosis, or radiographic follow-up of at least 1 year. In addition, the following diagnostic tests were considered: sputum cytologic examination (expectorated or aspirated, spontaneous or induced); flexible bronchoscopy (including any of biopsy, brushing, washing, TBNA, or BAL); and TTNA. Studies were required to report sufficient data to permit completion of a 2 x 2 table comparing test results with a reference standard diagnosis. If too few studies met this criterion, then they identified studies that described the diagnostic yield (sensitivity) among patients with lung cancer. When possible, diagnostic performance was estimated separately for patients with central (endobronchial) lesions, peripheral lesions greater than 2 cm in diameter, and peripheral lesions less than 2 cm in diameter.

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

The United States Preventive Services Task Force (USPSTF) scheme offers general guidelines to assign one of the following grades of evidence: good, fair, or poor.

In general, good evidence included prospective, controlled, randomized clinical trials, and poor evidence included case series and clinical experience. Trials with fair quality of evidence, for instance, historically controlled trials or retrospective analyses, were somewhere in between. In addition to the strength of the study design, however, study quality also was considered. The United States Preventive Services Task Force approach considers well-recognized criteria in rating the quality of individual studies for a variety of different types of study design (e.g., diagnostic accuracy studies and case-control studies). The thresholds for distinguishing good versus fair and fair versus poor evidence are not explicit but are left to the judgment of panelists, reviewers, and members of the executive committee.

Assessment of the Scope and Quality of Clinical Practice Guidelines

Clinical practice guidelines identified from the systematic search were evaluated by at least four reviewers using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each writing committee received a comprehensive list of existing systematic reviews and meta-analyses as well as guidelines published by other groups. In addition, for five the key topics (prevention, screening, diagnosis, and staging [invasive and noninvasive], new systematic reviews were undertaken (see "Description of Methods Used to Collect the Evidence" and "Description of Methods Used to Analyze the Evidence" fields). For all other topics, writing committees were responsible for identifying and interpreting studies that were not otherwise covered in existing syntheses or guidelines.

The guidelines developed by the writing committee were distributed to the entire expert panel, and comments were solicited in advance of a meeting. During the meeting, proposed recommendations were reviewed, discussed, and voted on by the entire panel. Approval required consensus, which was defined as an overwhelming majority approval. Differences of opinion were accommodated by revising the proposed recommendation, the rationale, or the grade until consensus could be reached. The evidence supporting each recommendation was

summarized, and recommendations were graded as described. The assessments of level of evidence, net benefit, and grade of recommendation were reviewed by the executive committee.

Values

The panel considered data on functional status, quality and length of life, tolerability of treatment, and relief of symptoms in formulating guideline recommendations. Cost was not explicitly considered in the guideline development process. Data on these outcomes were informally weighted, without the use of explicit decision analysis or other modeling. The values placed on types of outcomes varied with clinical scenarios. For example, in some situations they considered life expectancy, such as the effects of early detection. In other situations they weighed quality of life more heavily, such as in palliative care and in interpreting small increases in life expectancy with chemotherapy for stage IV disease.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The guideline developer's grading scheme is a modification of the United States Preventive Services Task Force (USPSTF) grades to allow recommendations for a service when (1) evidence is poor, (2) the assessment of the net benefit is moderate to high, and (3) there is consensus among the expert panel to recommend it. This change was necessary because, unlike preventive services (i.e., the routine offering of tests or treatments to well people) in which the burden of proof is high, clinical decisions about the treatment of patients with lung cancer often must be based on an interpretation of the available evidence, even if it is of poor quality. This adaptation distinguished between interventions with poor evidence for which there is consensus (grade C) and interventions with poor evidence for which there is not consensus (grade I).

Grades of Recommendations and Estimates of Net Benefit

The grade of the strength of recommendations is based on both the quality of the evidence and the net benefit of the service (i.e., test, procedure, etc).

Grade A The panel strongly recommends that clinicians routinely provide [the service] to eligible patients. An "A" recommendation indicates good evidence that [the service] improves important health outcomes and that benefits substantially outweigh harms.

Grade B The panel recommends that clinicians routinely provide [the service] to eligible patients. A "B" recommendation indicates at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

Grade C The panel recommends that clinicians routinely provide [the service] to eligible patients. A "C" recommendation indicates that there was consensus among the panel to recommend [the service] but that the evidence that [the service] is effective is lacking, of poor quality, or conflicting, or the balance of benefits and harms cannot be reliably determined from available evidence.

Grade D The panel recommends against clinicians routinely providing [the service]. A "D" recommendation indicates at least fair evidence that [the service] is ineffective or that harm outweighs benefit.

Grade I The panel concludes that the evidence is insufficient to recommend for or against [the service]. An "I" recommendation indicates that evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined, and that the panel lacked a consensus to recommend it.

Net Benefit

The levels of net benefit are based on clinical assessment. Estimated net benefit may be downgraded based on uncertainty in estimates of benefits and harms.

Substantial Benefit: Benefit greatly outweighs harm

Moderate Benefit: Benefit outweighs harm

Small/weak Benefit: Benefit outweighs harm to a minimally clinically important degree

None/negative Benefit: Harms equal or outweigh benefit, less than clinically important

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After extensive review within the expert panel and executive committee, the guidelines were reviewed and approved by the American College of Chest Physicians (ACCP) Health and Science Policy Committee and then by the American College of Chest Physicians Board of Regents.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is rated based on the levels of evidence (good, fair, poor), net benefit (substantial, moderate, small/weak, none/negative), and the grades of the recommendations (A, B, C, D, I). Definitions are presented at the end of the "Major Recommendations" field.

General Approach to Diagnosis

1. In patients suspected of having small cell lung cancer (SCLC) based on the radiographic and clinical findings, the diagnosis should be obtained by whatever method is easiest (i.e., sputum cytology, fine needle aspirate [FNA], and bronchoscopy, including transbronchial needle aspiration [TBNA]), as dictated by the patient´s presentation. Level of evidence, fair; benefit, moderate; grade of recommendation, B
2. In patients suspected of having lung cancer who have an accessible pleural effusion, a definitive diagnosis of the pleural effusion via thoracentesis should be made first. Level of evidence, fair; benefit, substantial; grade of recommendation, B
3. In a patient with an accessible pleural effusion, if the results of pleural fluid cytology are negative (after at least two thoracentesis procedures), thoracoscopy should be performed as the next step. Level of evidence, fair; benefit, moderate; grade of recommendation, B
4. In patients who are suspected of having lung cancer and who have a solitary extrathoracic site that is suspicious of metastasis, the diagnosis should be obtained by a fine-needle aspiration or biopsy of the distant site. Level of evidence, fair; benefit, substantial; grade of recommendation, B
5. In patients who are suspected of having lung cancer and who present with lesions in multiple distant sites that are typical for metastases, but in whom biopsy of a metastatic site would be technically difficult, a diagnosis of the primary lung lesion should be obtained by whatever method is easiest and safest (i.e., sputum cytology, bronchoscopy, or transthoracic needle aspiration [TTNA]). Level of evidence, poor; benefit, moderate; grade of recommendation, C
6. In patients who are suspected of having lung cancer and who have no known distant metastases or pleural effusions but have extensive infiltration of the mediastinum based on radiographic studies, a diagnosis should be obtained from the mediastinal tissue by whatever method is most efficacious (i.e., bronchoscopy with transbronchial needle aspiration, TTNA, or mediastinoscopy) as dictated by the location of the tumor. Level of evidence, fair; benefit, moderate; grade of recommendation, B
7. A patient with a solitary peripheral lesion that is even moderately suspicious for lung cancer, who appears to have early-stage disease (i.e., negative findings on a chest computed tomography [CT] of the mediastinum) and is a surgical candidate, should undergo excisional biopsy and subsequent lobectomy if a resectable lung cancer is confirmed. Level of evidence, poor; benefit, substantial; grade of recommendation, C

Diagnosis of Primary Tumor

8. In patients with a central lesion who present with or without hemoptysis, sputum cytology (at least three specimens) is a reasonable first step (in centers with a formal program directed at the acquisition, handling, and interpretation of sputum samples) in the diagnostic workup. Level of evidence, fair; benefit, substantial; grade of recommendation, B
9. In patients with a peripheral lesion that is suspicious for lung cancer, sputum cytology (in centers with a formal program directed at the acquisition, handling, and interpretation of sputum samples) may confirm the diagnosis of lung cancer. However, further testing to diagnose definitively a peripheral

lung lesion must follow a negative result on sputum cytology. Level of evidence, fair; benefit, moderate; grade of recommendation, B

10. In a patient with a central lesion, bronchoscopy is the most sensitive way to confirm a diagnosis of cancer. Level of evidence, fair; benefit, substantial; grade of recommendation, B
11. In a patient with a central lesion that is suspicious for lung cancer, further testing to definitively rule out cancer must follow a nonspecific benign result on bronchoscopy. Level of evidence, fair; benefit, substantial; grade of recommendation, B
12. In a patient with a small (i.e., < 2 cm) peripheral lesion, the sensitivity of bronchoscopy is low. Therefore, a nonspecific result on bronchoscopy of a peripheral lesion that is suspicious for lung cancer requires further testing to definitively rule out cancer. Level of evidence, good; benefit, substantial; grade of recommendation, A
13. In the case of a peripheral lung lesion, TTNA has a much higher sensitivity than bronchoscopy. It is the procedure of choice for confirming the diagnosis of lung cancer in patients in whom it is indicated (i.e., those in whom preoperative therapy is planned or surgery is not feasible). Level of evidence, good; benefit, substantial; grade of recommendation, A
14. A nonspecific result on TTNA of a lesion that is suspicious of being a lung cancer carries a high false negative (FN) rate, and therefore further testing to establish a definitive diagnosis should be pursued. Level of evidence, good; benefit, substantial; grade of recommendation, A
15. In patients with a lesion that is even moderately suspicious for lung cancer who appear to have limited disease and are surgical candidates, TTNA has no role (unless preoperative therapy is planned). These patients should undergo excisional biopsy and subsequent lobectomy if a lung cancer is confirmed. Level of evidence, good; benefit, moderate; grade of recommendation, B
16. In a patient who is suspected of having lung cancer, the diagnosis of non-small cell lung cancer (NSCLC) made on cytology (i.e., from sputum, TTNA specimens, or bronchoscopic specimens) is highly reliable and can be accepted with a high degree of certainty. Level of evidence, good; benefit, moderate; grade of recommendation, B
17. The possibility of an erroneous diagnosis of SCLC on a cytology specimen must be kept in mind if the clinical presentation or clinical course is not consistent with that of SCLC. In such a case, further testing to establish a definitive cell type should be pursued. Level of evidence, good; benefit, substantial; grade of recommendation, A

Levels of Evidence

In general, good evidence included prospective, controlled, randomized clinical trials, and poor evidence included case series and clinical experience. Trials with fair quality of evidence, for instance, historically controlled trials or retrospective analyses, were somewhere in between.

Grades of Recommendations

Grade A The panel strongly recommends that clinicians routinely provide [the service] to eligible patients. An "A" recommendation indicates good evidence that

[the service] improves important health outcomes and that benefits substantially outweigh harms.

Grade B The panel recommends that clinicians routinely provide [the service] to eligible patients. A "B" recommendation indicates at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

Grade C The panel recommends that clinicians routinely provide [the service] to eligible patients. A "C" recommendation indicates that there was consensus among the panel to recommend [the service] but that the evidence that [the service] is effective is lacking, of poor quality, or conflicting, or the balance of benefits and harms cannot be reliably determined from available evidence.

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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

The ability to choose the best modality to diagnose a suspected lung cancer will maximize the yield of the selected procedure for both diagnosis and staging and avoid performing multiple or unnecessary invasive procedures for the patient, with special attention to the projected treatment plan.

POTENTIAL HARMS

- Risk of false-positive and false-negative test results
- Risks involved in invasive test procedures

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

1. The American College of Chest Physicians (ACCP) is developing a set of PowerPoint slide presentations for physicians to download and use for physician and allied health practitioners education programs.
2. The ACCP is developing a Quick Reference Guide (QRG) in print and PDA formats for easy reference.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Rivera MP, Detterbeck F, Mehta AC. Diagnosis of lung cancer: the guidelines. Chest 2003 Jan;123(1 Suppl):129S-36S. [35 references] PubMed

DATE RELEASED

2003 Jan

GUIDELINE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

The guideline development panel was composed of members and nonmembers of the American College of Chest Physicians (ACCP) who were known to have expertise in various areas of lung cancer management and care, representing multiple specialties from the following 13 national and international medical associations:

- Alliance for Lung Cancer Advocacy, Support, and Education (a patient support group)
- American Association for Bronchology
- American Cancer Society
- American College of Physicians
- American College of Surgeons Oncology Group
- American Society of Clinical Oncology
- American Society for Therapeutic Radiology and Oncology
- American Thoracic Society
- Association of Community Cancer Centers
- Canadian Thoracic Society
- National Comprehensive Cancer Network
- Oncology Nurses Society
- Society of Thoracic Surgeons

The specialties included pulmonary/respiratory medicine, critical care, medical oncology, thoracic surgery, radiation oncology, epidemiology, law, and medical ethics.

SOURCE(S) OF FUNDING

Funding for both the evidence reviews and guideline development was provided through an unrestricted educational grant from Bristol-Myers Squibb, which had no other role in the evidence review or guideline development process or content.

GUIDELINE COMMITTEE

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

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: M. Patricia Rivera, MD, FCCP; Frank Detterbeck, MD, FCCP; and Atul C. Mehta, MD, FCCP

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Information about potential conflicts of interest were collected from each member of the expert panel or writing committee at the time of their nomination in accordance with the policy of the American College of Chest Physicians (ACCP). Information on conflicts of interest for each panelist is listed in the guideline.

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:

Evidence Summary

- Schreiber G, McCrory DC. Performance characteristics of different modalities for diagnosis of suspected lung cancer: summary of published evidence. Chest 2003 Jan;123(1 Suppl):115S-128S.

Background Articles

- Alberts WM. Lung cancer guidelines. Introduction. Chest 2003 Jan;123(1 Suppl):1S-2S.
- McCrory DC, Colice GL, Lewis SZ, Alberts WM, Parker S. Overview of methodology for lung cancer evidence review and guideline development. Chest 2003 Jan;123(1 Suppl):3S-6S.
- Harpole LH, Kelley MJ, Schreiber G, Toloza EM, Kolimaga J, McCrory DC. Assessment of the scope and quality of clinical practice guidelines in lung cancer. Chest 2003 Jan;123(1 Suppl):7S-20S.
- Alberg AJ, Samet JM. Epidemiology of lung cancer. Chest 2003 Jan;123(1 Suppl):21S-49S.

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.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 22, 2003. The information was verified by the guideline developer on August 18, 2003.

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Date Modified: 11/15/2004