CHEST

Official publication of the American College of Chest Physicians

Como International Conference Position Statement*: Lung Cancer Screening for Early Diagnosis 5 Years After The 1998 Varese Conference

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Chest 2005;127;1146-1151
DOI 10.1378/chest.127.4.1146

ISSN:0012-3692

Como International Conference Position Statement*

Lung Cancer Screening for Early Diagnosis 5 Years After The 1998 Varese Conference

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Background: **Lung cancer is the most common cause of cancer death in the world. Nonetheless, public policy organizations have consistently recommended against screening for lung cancer, with the result that screening is not widely practiced. The Como Conference was undertaken to consider the need for a change in the existing recommendations against screening.**
Purpose: **The primary objective of the Como Conference was to consider whether there is sufficient scientific evidence to advise screening for lung cancer among asymptomatic individuals outside the context of a clinical trial. Methodological issues that are relevant to the proper interpretation of early detection trials were carefully considered. Advantages and problems associated with technological advances in CT scans and digital chest radiographs (CXRs) were fully explored. Economic issues relevant to screening were also considered.**
Recommendations: **It is recommended that physicians assume responsibility for informing high-risk individuals regarding options for screening for lung cancer. Targeted high-risk individuals include middle-aged or elderly men and women who are current or former cigarette smokers of > 20 to 30 pack-years without serious medical comorbidities. It is recommended that such persons be informed that symptomatic lung cancer is usually advanced and incurable, while surgery for early lung cancer offers a far better chance of cure. They should also be informed about advances in imaging technology, as they relate to CT scans and CXRs.**
Conclusions: **Whenever possible, high-risk individuals should be encouraged to enroll in ongoing trials. For subjects who, though eligible, do not have access to such trials, a process of shared decision-making between physicians and at-risk individuals is strongly recommended. After discussion of the existing state of knowledge, high-risk individuals should be made aware that it is reasonable for them to choose to undergo testing for lung cancer.**
(CHEST 2005; 127:1146–1151)

Key words: chest roentgenogram; cigarette smoking; computed tomography; consensus statement; early detection; lung cancer; mortality; overdiagnosis bias; screening; survival

Abbreviations: ACS = American Cancer Society; CXR = chest radiograph; NCI = National Cancer Institute

The Como International Conference on lung cancer screening for early diagnosis was held in Como, Italy, on November 8, 2003. The primary objective of the Como Conference was to consider the available evidence regarding screening for lung cancer and to determine whether testing should be offered to asymptomatic individuals who are at high-risk for the disease.

Currently, lung cancer is the most common cancer in the world. This is true both with regard to incidence (1.2 million new cases annually represent-

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Manuscript received October 21, 2004; revision accepted December 14, 2004.

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ing 12.3% of all cancers) and mortality (1.1 million annual deaths or 17.8% of total cancer mortality).[1] Despite the global burden of disease, the absence of unequivocal evidence from previous randomized controlled trials[2–6] has prevented screening from being recommended by any public policy organization. Instead, strategies directed toward reducing lung cancer mortality have focused almost exclusively on tobacco control. Diagnostic procedures to detect lung cancer have traditionally been recommended only when symptoms develop. However, it has long been recognized that symptomatic lung cancer is usually advanced-stage disease. Moreover, advanced-stage lung cancer is almost always fatal.

The 1998 Varese Conference

Five years ago, the "International Conference on Prevention and Early Diagnosis of Lung Cancer" was held in Varese, Italy. The proceedings of the Varese Conference,[7] which was published in 2000 and included 34 articles, provides one of the most comprehensive sources of information on this subject that has ever appeared in the medical literature.

At the completion of the Varese Conference, a consensus statement was generated.[8,9] With regard to prevention, the statement reaffirmed the fact that "because cigarette smoking is the vastly predominant cause, lung cancer is almost entirely preventable." However, it also pointed out that "even after quitting, long term smokers remain at high-risk for prolonged periods."

The consensus statement also recognized the more favorable prognosis of lung cancer treated at an early stage. For example, it asserted that among those with lung cancer, "outcome is dramatically better when the disease is detected at an early stage and surgically treated. Unfortunately, at this time, the majority of lung cancers are diagnosed when the disease is overtly symptomatic, and in an advanced stage when prognosis is extremely poor."

While the consensus statement recognized the potential of early detection to improve outcome in lung cancer, a consensus was not reached that screening for lung cancer should be offered outside the context of an experimental trial. Because of ambiguities in the data, the consensus statement concluded that existing studies provide us "with an imperfect basis for health policy."

The Varese Conference helped to revitalize interest in screening for lung cancer.[10] Based on recommendations from the Varese Conference, the American Cancer Society (ACS) modified its narrative about testing for early lung cancer detection.[11–13] While not recommending screening, the ACS endorsed the practice that individuals who are at high-risk for lung cancer should be informed about their risk, and that those who seek testing for early lung cancer detection should be informed about options for testing for early detection, and about the current state of knowledge on its risks, benefits, and harms, so that they could make an informed decision. The ACS also stressed the importance of quality control and appropriate follow-up.

The Varese Conference was an important catalytic event that helped to reawaken interest in lung cancer screening. It helped to establish that the existing scientific evidence about screening was not a sound basis for the prevailing view that lung cancer screening was ineffective. Nonetheless, although a substantial body of evidence suggests that testing for early lung cancer has the potential to reduce lung cancer deaths,[10,14] screening for lung cancer continues to be viewed in the mainstream as experimental. Accordingly, testing for the early detection of lung cancer is not widely practiced outside the context of a clinical trial.

Five years after the Varese Conference, the Como Conference was held to consider whether there existed a sufficient scientific basis to go beyond the 1998 Varese consensus statement. The particular emphasis was on considering what might be offered to those high-risk individuals who are not participating in an existing clinical trial.

Como Conference: Position Statement

Several studies on screening for lung cancer are currently ongoing in many parts of the world. These include randomized trials in the United States and Europe,[15,16] as well as the International Early Lung Cancer Action Project.[17] Whenever possible, high-risk individuals should be strongly encouraged to participate in available trials. It is critical that these trials be completed in a timely manner, because they will provide the most definitive evidence with regard to the benefit and risks of screening for lung cancer.

Both clinicians and individuals who are at high risk for lung cancer presently do not have specific or consistent guidance about the balance of benefit and harm that is associated with testing for the early detection of lung cancer. While the results of early randomized trials were not definitive due to known methodological limitations, and observational studies also have known limitations, a better prognosis and more successful treatment have been consistently evident when lung cancer is diagnosed and treated at an early stage. Moreover, new imaging technologies have been developed over the last 10 years that can detect smaller cancers. For these reasons, it is

reasonable that individuals who are at high risk for lung cancer should be informed about their risk, and what is known and unknown about the potential benefits, limitations, and harms associated with testing for early lung cancer detection.[8,9,11–13]

Como Conference Recommendations

Individuals who are at high risk for lung cancer should undergo a discussion with their physician regarding lung cancer risk and the options for testing for the early detection of lung cancer. High-risk individuals include men and women who are > 45 to 50 years of age, who are current or former cigarette smokers with at least 20 to 30 pack-years of cumulative exposure, and who do not have life-limiting comorbidities. Although there remain uncertainties regarding the benefits and risks associated with lung cancer screening, we think that it is wrong for these discussions not to take place. It is recommended that such discussion should include the following points:

- Smoking cessation should be strongly urged for current smokers, and assistance for smoking cessation should be provided.
- Former smokers should be informed about their continuing risk of lung cancer.
- Whenever possible, high-risk individuals should be strongly encouraged to participate in available trials, or protocol-controlled observational studies.
- Individuals who are at high risk for lung cancer should be informed that symptomatic lung cancer is usually in an advanced stage and is usually incurable.
- Treatment of early stage lung cancer with surgical resection offers a better chance for a successful outcome.
- Available methods of imaging for the early detection of lung cancer in asymptomatic subjects include the chest radiograph (CXR) and CT scan.
- There have been the following major recent advances in imaging technology: multi-slice CT scanning; and energy subtraction and computer-aided detection for CXRs.
- The available data show that the CT scan is a more powerful imaging tool than CXR for detecting smaller cancers. However, the CT scan also detects a high rate of noncalcified nodules, most of which are benign. While indeterminate, they nonetheless require further evaluation. Further evaluation includes returning for additional imaging tests after 3 to 6 months or biopsy. Lung biopsy procedures, including surgery, carry a significant risk of complications.
- After discussion of the current state of knowledge, it is reasonable for an individual at risk to choose to undergo testing for lung cancer.

Medical and public health organizations should work together to develop educational materials that facilitate shared decision making between at-risk individuals and their medical providers. Such materials should inform doctors and patients about the risk of lung cancer in current and former smokers, and, particularly, should dispel the misconception that stopping smoking begins a process of reducing risk to the level of a never-smoker.

Any testing for lung cancer, if it is performed, should take place in settings with experience in the interpretation of imaging procedures for the detection of small lung cancers, and there should be ready access to multidisciplinary teams who work in a coordinated manner for further evaluation and follow-up.[12] Efforts should be made to minimize anxiety and the performance of unnecessary invasive procedures.

Appendix

A Brief Consideration of the Evidence

The objective of this position statement is to encourage clinicians and high-risk individuals to consider both the benefits and risks associated with screening for lung cancer. While it does not recommend a specific "best" screening strategy, it is intended to convey the concept that accumulating evidence over the last 5 years supports the conclusion that screening for lung cancer, either with a CXR or a CT scan, is a reasonable option. To facilitate discussions between clinicians and patients, a brief consideration of the evidence on lung cancer screening is appropriate.

The epidemiologic and clinical rationale for screening for lung cancer is strong. Lung cancer is the most common and most deadly malignancy in the world.[1] When diagnosed on the basis of signs or symptoms, lung cancer is usually incurable and lethal. Indeed, in the United States 60% of lung cancer patients die within 1 year of diagnosis.[18] Because screening for lung cancer is not widely practiced, the vast majority of patients are symptomatic at diagnosis. Accordingly, the 5-year survival rate in persons with lung cancer is 11% worldwide and 14% in the United States.[1,19] Among patients with lung cancer, 85% will actually die from their disease.[20]

In dramatic contrast, lung cancer is highly curable when complete resection is performed for stage I non-small cell lung cancer. Among patients with stage I disease, cure rates increase with decreasing tumor size. For example, cure rates are 69% when the tumor size is < 1.5 cm compared to 43% when the tumor size is > 4.5 cm.[21]

The question of whether evidence exists from randomized trials that screening for lung cancer is superior to no screening is controversial. It is true that the findings of three National Cancer Institute (NCI)-sponsored randomized trials[4,22,23] in the United States and a randomized trial from Czechoslovakia[24] that was conducted in the 1970s and 1980s have been interpreted as indicating that CXR screening was ineffective. This is because of a failure to demonstrate significant reductions in lung cancer mortality in populations that were randomized to CXR screening. On the other hand, these same trials have consistently demonstrated significant and rather dramatic improvements in long-term survival in experimental populations.

In the Mayo Lung Project,[25] the 5-year survival rate was more than twofold higher in the group randomized to CXR screening (33% vs 15%, respectively).While the Memorial Sloan-Kettering Project[26] and the Johns Hopkins Lung Project[27] failed to demonstrate an advantage for the addition of sputum cytology investigation to an annual CXR alone, long-term survival was far superior to the contemporary data.[28] In the Memorial Sloan-Kettering study,[26] the 5-year survival rate was 35% in both groups.

Screening has been interpreted as being ineffective, because the mortality/survival discrepancy has been interpreted as indicating that CXR screening led to the overdiagnosis of lung cancer.[29–33] However, this has been a point of debate. A direct analysis of the data has suggested that the overdiagnosis was minimal and does not account for the survival/mortality discrepancies in these trials.[34,35]

Indeed, long-term survival was only achieved among those persons undergoing surgical resection in these trials.[35,36] In the Mayo Lung Project,[14] there were no long-term survivors among 185 lung cancer patients who did not undergo resection. In dramatic contrast, 50% of 181 resected patients were cured. Sobue et al[37] have reported similar findings from Japan. There is, accordingly, no direct evidence that many nonlethal or "lanthanic"[38,39] lung cancers exist.

Furthermore, a recent analysis[40] has indicated that overdiagnosis secondary to comorbid disease is minimal in lung cancer. Read et al[40] examined the records of 11,558 patients with lung, breast, prostate, and colon cancers, and concluded that concurrent comorbidity had the greatest prognostic impact among groups with the most favorable survival (*ie*, those patients with localized prostate cancer and breast cancer) and the least impact among groups with the poorest survival rates, which included most patients with lung cancer.[40]

An important question is whether a CXR or a CT scan should be the preferred method of screening. There is no question that the CT scan represents a technological advance and has much greater sensitivity than the conventional CXR. The conventional CXR is known to be scarcely sensitive to the presence of tumors that are < 2 cm in diameter.[10,41]

A CT scan is clearly capable of detecting lesions than are too small to be reliably detected on a conventional CXR. In four nonrandomized studies,[42–45] which included two in the United States[43,44] and two in Japan,[42,45] 52% to 85% of cancers detected by CT scan were small stage IA lesions. In each study, many CT scan-detected cancers were not visible on a CXR. The ability to detect small early-stage cancers has the potential to translate into substantial improvements in survival.

Indeed, impressively high survival was reported from the Anti-Lung Cancer Association Project in Japan.[45] Among 36 lung cancers that were detected on initial or repeat screening, the overall 5-year survival rate was 71% (95% confidence interval, 52 to 90%).[45]

However, unresolved issues remain with regard to CT scan screening. Problems with specificity have led to a high rate of false-positive findings in these observational studies.[43–46] A higher false-positive rate with CT scans compared to CXRs was recently reported in the NCI-sponsored Lung Screening Study.[47] In this randomized trial, which included 3,318 current or former smokers, false-positive findings were observed in 18.6% and 9.4%, respectively, of patients in the CT scan and CXR arms.

While a CT scan is more sensitive than a CXR, the detection of nodules on a CT scan that are not due to cancer presents problems with regard to anxiety and the possibility of performing unnecessary invasive procedures. In the Anti-Lung Cancer Association study,[45] only 51% of patients (36 of 71 patients) undergoing biopsy because of nodules detected on CT scans were found to have lung cancer. To cope with this problem, the International Early Lung Cancer Action Project trial[48] used a protocol that was explicitly designed to minimize such operations for benign disease. This algorithm is updated periodically based on the total experience, and its objective is to determine what further diagnostic studies are recommended when a small nodule is detected on CT scan screening.[48] In the Mayo spiral CT scan screening trial,[49] 18% of all thoracic surgical procedures performed were for benign disease.

While the evidence supports the idea that overdiagnosis was not responsible for spurious survival advantages in older NCI-sponsored randomized trials focusing on CXR screening,[34] no comparable evidence yet exists with regard to CT scan screening.[50,51] In the Lung Screening Study,[47] there were 30 cancers detected by CT scan compared to 7 cancers detected by CXR on baseline screening. Higher lung cancer detection rates probably reflect the increased efficiency of CT scanning in the detection of small lung cancers, with its associated longer lead time. However, it is conceivable that some of the detected cancers might never have become life-threatening during the life of the patient.

Unresolved issues with regard to false-positive findings and overdiagnosis have implications with regard to the appropriateness and cost-effectiveness of CT scan screening.[49,52–54] Accordingly, a definitive answer to the question of whether a CT scan is superior to a conventional CXR must await the results of ongoing randomized trials, particularly the National Lung Screening Study in the United States.[55]

It should also be noted that technical advances have likely improved on the effectiveness of CXRs, as employed in the older NCI-sponsored trials. Such enhancements include digital radiography, energy subtraction, and computer-aided detection.[56] These newer CXR technologies have not been incorporated into ongoing randomized trials, including the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial[57] and the National Lung Screening Study.[55]

Based on the existing evidence, high-risk individuals can be informed that if they choose to undergo screening for lung cancer, either a CXR or a CT scan is a reasonable option. It should be considered that in many parts of the world CT scanning is not widely available, and in the United States it may not be affordable by economically disadvantaged individuals. If a high-risk individual chooses to undergo screening and CT scanning is not available or affordable, annual CXR screening should be recommended.

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Chest 2005;127; 1146-1151
DOI 10.1378/chest.127.4.1146