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Helical Computed Tomography (CT) for Lung Cancer Screening for Asymptomatic Patients

Executive Summary

The overall prognosis for lung cancer is generally poor, with a 5-year survival rate less than 15%. In Minnesota, an estimated 2,300 new cases of lung cancer are diagnosed each year and approximately 2,200 individuals die of lung cancer.¹ Despite evidence that early detection can result in substantially increased long-term survival, a number of clinical trials have not demonstrated a decrease in lung cancer-related mortality or a definitive increase in survival associated with annual screening of high risk individuals with chest x-ray and sputum cytology. Recently, there has been renewed interest in lung cancer screening utilizing helical computed tomography (CT), which can provide relatively high resolution images with a 20 second imaging time and relatively low levels of radiation exposure.

Findings

To date, there have been no published randomized studies that have adequately evaluated the use of helical CT for lung cancer screening in high risk populations. Several recently published studies from Japan and from the United States compared the cancer detection rate of helical CT with that of chest radiography in a cohort of asymptomatic individuals who were either smokers or ex-smokers. These studies documented that helical CT improved the rate of detection of non-calcified and suspicious lesions compared with chest x-ray, and that cancer nodules identified by helical CT were generally at an earlier stage than those detected on chest x-ray. However, the false-positive rates were much higher with helical CT than with chest x-ray, and none of the studies was able to demonstrate a true increase in survival or a decrease in lung cancer-related mortality as a result of helical CT examination.

At the present time, the National Cancer Institute and the United States Preventive Services Task Force recommend against routine screening of asymptomatic persons for lung cancer with chest radiography or sputum cytology, and stress that the highest priority should be given to programs for smoking cessation, which is by far the most effective way to reduce lung cancer deaths. These organizations have not yet made a recommendation regarding the use of helical CT for lung cancer screening. Several large-scale randomized controlled trials are currently in progress to determine if helical CT scanning can improve health outcomes for patients at high risk of lung cancer. Experts in the field have expressed concern that these studies must be completed and analyzed before lung cancer screening with helical CT becomes common practice, so that the true effect of screening can be determined.

Conclusions

While helical CT scans may be able to detect pulmonary nodules at an earlier stage, at the present time there is no evidence from randomized controlled trials that screening asymptomatic individuals for lung cancer with helical CT scan increases actual survival time or reduces lung cancer-related mortality.

The use of helical CT is valuable for case finding in individuals with specific concerns or for diagnosis of pulmonary lesions in symptomatic individuals. Several large-scale randomized controlled trials are currently in progress to determine if helical CT scanning can improve health outcomes for patients at high risk of lung cancer.

Due to the high false-positive rate associated with helical CT, detection of lung cancer by routine screening of asymptomatic individuals with helical CT may trigger a cascade of unnecessary care and secondary testing.

Recommendations

Physicians should utilize a helical CT scan for specific indications in individual patients.

The potential long-term efficacy and cost-effectiveness of the use of helical CT scanning for lung cancer screening needs to be established through additional published studies before becoming common practice.

Background

Helical computed tomography (CT) is a radiographic technique that can provide high resolution threedimensional images of the lungs during a single breath-hold with less radiation exposure than conventional computed tomography scanning. This imaging technique has been proposed as a way to screen for early lung cancer lesions in asymptomatic high risk individuals.

Lung cancer is the second most commonly occurring noncutaneous cancer in the United States, accounting for 28% of all cancer deaths. Approximately 170,000 new patients will be diagnosed with lung cancer in the U.S. during 2000, and current estimates are that only 15% will achieve long-term survival. In Minnesota, an estimated 2,300 new cases of lung cancer are diagnosed each year and approximately 2,200 individuals die of lung cancer.¹ The most important risk factor for lung cancer is tobacco use, and primary prevention measures to reduce smoking are considered to have the greatest potential to reduce lung cancer mortality. However, there is evidence that early detection of non-small cell tumors, which account for approximately 75% of lung cancers, can result in increased long-term survival.²⁻⁵ This has formed the rationale for screening programs aimed at early detection of lung cancer.

Over the past three decades, lung cancer screening with chest x-ray and sputum cytology has been investigated in several large clinical trials at major cancer research institutions.⁶⁻⁹ None of these studies provided strong evidence that screening can reduce lung cancer mortality. Screening with chest x-ray combined with sputum cytology appeared to detect lung cancer at an earlier stage, although the improvement in case survival seen in screened patients relative to cases diagnosed through typical care may simply reflect length or lead-time bias, and not an actual increase in survival time. Unfortunately, these lung cancer screening studies had significant design flaws, and utilized older technologies such as microscopic evaluation of sputum cells and conventional chest radiography, tests that lacked sensitivity to detect half of the lung cancer cases that arose during screening. Recently, there has been renewed interest in lung cancer screening utilizing newer, more sensitive imaging technologies, such as helical CT.⁵⁻¹⁰

Helical CT, also known as spiral CT, was introduced in the 1980s following the development of the power slip ring, a device that allows electric power to be transferred from a stationary power source onto a continuously rotating gantry. This permits the x-ray tube to rotate around the patient while the examination table advances at a constant rate. The emitted x-rays trace a spiral path through the patient and are picked up by x-ray detectors contained within the scanner gantry. Helical CT scanners can image entire anatomic regions like the lungs during a 20- to 30-second breath hold, about 10 times faster than conventional CT scanners, and with less overall radiation exposure. Unlike conventional CT scanning, which involves acquiring a stack of individual slices that may be misaligned due to patient motion or breathing in between each slice acquired, helical CT produces a set of data for the entire scanned region with no spatial or temporal gaps. This data set is then computer-reconstructed to provide detailed, high-quality, three-dimensional pictures of complex structures.¹¹

For an helical CT lung scan, the patient lies in a supine position on the examination table while the table slowly moves through the scanner gantry. The patient is asked to lie quietly during the scan and to hold his or her breath for a short period of time, usually 15 to 20 seconds. Low-dose scans are often used for screening purposes to minimize the amount of radiation exposure the patient receives. If a suspicious lesion is detected, a higher dose CT scan may be performed to provide a higher resolution image. A lung scan is non-invasive, does not require administration of contrast material or other preparation, and no sedation is necessary.¹¹

Patient Selection Criteria

The benefits of screening asymptomatic, high risk individuals for lung cancer have not been proven, and therefore, no specific patient selection criteria have been defined. There is evidence that helical CT scanning is more sensitive that conventional chest x-ray for detecting and evaluating pulmonary lesions, and therefore, this type of imaging may be considered appropriate as a case-finding tool in selected individuals who do not have specific symptoms of lung cancer, but who are at high risk, and who have particular concerns regarding this disease.¹²

In the Guide to Clinical Preventive Services, Second Edition, the United States Preventive Health

Services states that routine screening for lung cancer with chest radiography and/or sputum cytology in asymptomatic persons is not recommended (Appendix I).¹³ Although this conclusion is based on evidence from studies in which patients were screened with chest x-ray and sputum cytology rather than helical CT, the concerns raised about the effect of screening on overall mortality, and the potential for confounding by lead-time bias, length bias, and over-diagnosis bias apply to helical CT screening as well.

While many authors remain skeptical regarding the value of periodic lung cancer screening, some advocate the use of routine lung cancer screening, believing that early detection of lesions leads to real increase in long-term survival.^{2,14} This belief is based in part on a post-hoc analysis done by Flehinger et al. (1992) of data from the original studies evaluating screening by chest x-ray. This analysis demonstrated that the 5-year survival of patients who were diagnosed with stage 1 lung cancer by screening and who then received surgical treatment was significantly better than the survival of similar patients who were diagnosed during screening but who did not undergo surgery. This finding led the authors to conclude that survival time is actually prolonged in cases detected at an early stage during screening, and is not an artifact of lead-time or length bias.² However, this analysis did not provide details about the patients who did not undergo surgical resection of the nodules, and did not exclude the potential contribution of co-morbid conditions to outcome.

Other investigators suggest that there may be additional benefits accrued from a regular lung cancer screening program. Buckshee et al. (1999) presented a paper at the 85th Scientific Assembly and Annual Meeting of the Radiology Society of North America (RSNA) that described the reaction of current and former smokers enrolled in the Early Lung Cancer Action Program (ELCAP). Both men and women in the study expressed high overall satisfaction with the screening program, and wanted to continue annual CT screening. An unanticipated benefit of the screening was that many of the enrollees quit or decreased smoking after enrollment, and stated that the review of their CT images with the ELCAP radiologists had prompted the change and provided the necessary focus for maintenance of their non-smoking behavior.¹⁵

Findings

The key question regarding lung cancer screening by any method is whether screening produces a health benefit through increasing survival time, improving quality of life, or reducing lung cancer-related mortality. This question remains unanswered at the present time for chest x-ray and for helical CT, although there is evidence that helical CT scanning is more sensitive than conventional chest x-ray, and can detect cancers at an earlier stage (Appendix II). However, helical CT scanning also produces considerably more false-positive results than does chest x-ray, which may lead to unnecessary care and secondary testing.

The sensitivity and specificity of helical CT for detection of malignant pulmonary lesions have not been well documented, in part due to variations in imaging technique, skill of the radiologist, and the lack of a criterion standard for a negative CT scan result. A study by Diederich et al. (1999) using postmortem specimens and patients with histologically confirmed lung nodules indicated that low-dose helical CT had a sensitivity of 67%, 89%, and 100% for nodules = 5 mm in diameter, 6 to 10 mm in diameter, and = 10 mm in diameter, respectively.¹⁶ The optimal technique for low-dose helical CT scanning for lung cancer screening has not been definitively determined, although most studies agree that 5 mm is the lower limit of detection under most imaging protocols.¹⁷⁻¹⁹

The false-positive rate is relatively high, although a positive result is generally followed with additional imaging tests before an invasive procedure, such as biopsy, is performed. The study by Henschke et al. (1999) used high resolution chest CT scan as a secondary test if suspicious lesions were noted on low-dose helical CT scan. If the nodule had benign-appearing calcifications in extent and distribution, smooth edges, and was less than 20 mm in diameter, it was considered benign. Patients with nodules of 5 mm in diameter which did not meet these benign criteria, were followed with repeated high-resolution CT scans in 3, 6, 12 and 24 months. Patents with nodules 6-10 mm in diameter were either followed with high-resolution CT or subjected to biopsy, and if the patient exhibited a lesion > 10 mm in diameter, then a biopsy was performed.²⁰

Quality of Evidence

While there are a number of studies comparing lung cancer detection rates using helical CT versus chest x-ray (Appendix III), there are no published randomized studies that have examined the question of whether lung cancer survival is increased or mortality reduced in high risk individuals who have

undergone annual screening with helical CT compared with similar individuals who have not undergone screening. This type of study is essential to provide unbiased data that will answer the question of whether lung cancer screening is an effective intervention for reducing lung cancer-related mortality.

Following publication of the 1999 study by Henschke et al., the NIH National Cancer Advisory Board (NCAB) debated the need for a randomized clinical trial to evaluate the affect of helical CT screening on survival and lung cancer-related mortality. Several members of the NCAB expressed concern that if helical CT lung cancer screening becomes incorporated into standard practice based on current observational data, future studies to validate its efficacy would be difficult. They noted that although the results of the Henschke et al. (1999) were promising, it was essential that the results be validated and evaluated in a larger patient population. These experts strongly supported testing of lung cancer screening by helical CT in a large-scale, 5-year, randomized controlled clinical trial with mortality from lung cancer as the primary endpoint. They emphasized that data from smokers and ex-smokers should be analyzed separately, since after 10 years the lung cancer risk for ex-smokers approaches that of individuals who have never smoked. Several board members favored testing helical CT lung cancer screening in diverse settings to more closely reflect actual clinical practice conditions than might be found in academic institutions.⁵

Technical Issues

Use of helical CT scanning for mass lung cancer screening might pose significant problems related to availability of imaging facilities. According to a report by the NCAB, there is currently a 6-month waiting list for people to get a helical CT scan in certain regions of the country.⁵

Credentialing and Licensing

Licensed radiological technologists perform helical CT scanning, and images are evaluated and interpreted by physicians who specialize in the field of radiology. No additional credentialing or licensing is currently required.

Safety

Low-dose helical CT for lung cancer screening delivers approximately twice as much radiation as a conventional chest x-ray. No adverse events have been associated directly with helical CT scanning, although patients may undergo additional unnecessary diagnostic tests if the initial helical CT scan yields false-positive results.²⁰ A risk-benefit analysis from Japan, where smoking rates are very high and annual lung cancer screening with helical CT is in widespread use, concludes that the benefit of helical CT screening for lung cancer exceeds the risk of radiation exposure for men over 40 years of age and for women over 45 years of age. However, this analysis is based on the assumption that lung cancer screening with helical CT prolongs the mean life expectancy of individuals at high risk for lung cancer.²¹

Cost and Cost-effectiveness

Helical CT for lung cancer screening is generally less expensive than a full conventional CT scan.20 In Minnesota, a helical CT scan costs between \$300-\$500, significantly more than a conventional chest x-ray, which typically costs approximately \$50.²²

There are limited data on the cost-effectiveness of helical CT scanning for lung cancer screening. Most of the information comes from Japan, where annual lung cancer screening with routine chest radiographs is considered standard practice and is supported by the Ministry of Health and Welfare. A Japanese-language report by liunima et al. (1994) indicated that in a comparison with chest radiography, low-dose helical CT screening is 4 times better in terms of the net person-years saved, but about 1.4 times worse in cost-effectiveness than conventional radiography.²³ Definitive clinical evidence documenting a decrease in mortality or a true increase in survival associated with lung cancer screening is needed before accurate cost-effectiveness analyses can be performed. Some researchers have hypothesized that simultaneous screening for other diseases such as emphysema and cardiovascular disease could enhance the cost-effectiveness of helical CT screening.¹⁴ Screening of asymptomatic individuals may also result in anxiety and a "cascade of care" which could result in unnecessary medical expenses and risk to the patient.

Future of Procedure

Use of helical CT for lung cancer screening is an area of active investigation. Under an initiative proposed by the NIH/NCI Division of Cancer Prevention, the American College of Radiology Imaging Network (ACRIN) has been established. This organization is conceived as an integrated group of radiologist researchers, other physician specialists, and related basic and clinical scientists committed to improving the health and longevity of cancer patients through the advancement of diagnostic imaging and imageguided interventional procedures. One of the first studies to be undertaken by this group of clinical researchers is a multicenter, randomized controlled trial of 6000 individuals at high risk of lung cancer. This study has been designed to address whether screening using lung cancer-associated molecular markers in blood or sputum epithelial cells and low-dose helical CT can improve lung-cancer specific mortality. The experimental group will undergo annual screening with blood and sputum analyses for various biomolecular markers, sputum cytology, and low-dose helical CT. The control cohort will undergo annual chest radiographs. Both groups will also complete annual respiratory health and qualityof-life questionnaires. The primary end-point of the study will be lung cancer specific mortality; intermediate end-points of surgical stage and tumor size at time of diagnosis will also be assessed, as both are known to correlate with improved survival. The relative diagnostic accuracies of the imaging and molecular screening tests in distinguishing benign and malignant lung nodules will be compared using pathology (or accepted clinical surveillance) as the truth standard. The frequency of unnecessary thoracotomy for benign disease will be measured. Quality-of-life and cost-effectiveness data will be used to examine the benefits of screening in defined high risk individuals. This study, along with other similar randomized trials, should be able to provide definitive answers to the questions surrounding the use of helical CT as a screening method for lung cancer in high risk individuals.²⁴ It is likely that in the future, molecular and genetic testing of lung fluids may be used for early detection of lung cancer. In a recent report, Fliss et al. (2000) reported that patients with lung cancer show specific mutations in the mitochondrial DNA of cells contained within lung fluid, and that these mutations were not present in the patients' normal blood cells. This type of genetic testing can be automated, and could eventually provide a very early method of detecting lung cancer. Other authors have reported specific oncogene activation, tumor suppressor gene deletion, genomic instability, and abnormal methylation in sputum cells from patients with lung cancer, suggesting that genetic analysis of sputum cells may provide a sensitive method to detect early lung cancer. 10,25,26

Conclusions

While helical CT scans may be able to detect pulmonary nodules at an earlier stage, at the present time there is no evidence from randomized controlled trials that screening asymptomatic individuals for lung cancer with helical CT scan increases actual survival time or reduces lung cancer-related mortality.

The use of helical CT is valuable for case-finding in individuals with specific concerns or for diagnosis of pulmonary lesions in symptomatic individuals. Several large-scale randomized controlled trials are currently in progress to determine if helical CT scanning can improve medical outcomes for patients at high risk of lung cancer.

Due to the high false-positive rate associated with helical CT, detection of lung cancer by routine screening of asymptomatic individuals with helical CT may trigger a cascade unnecessary care and secondary testing.

Recommendations

Physicians should utilize a helical CT scan only for specific indications in individual patients.

The potential long-term efficacy and cost-effectiveness of the use of helical CT scanning for lung cancer screening needs to be established through additional studies.

Appendix I: Recommendations from Government Agencies and Professional Organizations Regarding Helical CT Scanners

Food and Drug Administration (FDA): Helical CT scanners are approved as Class II medical devices (FDA, 2000).

Health Care Financing Administration (HCFA): HCFA does not have a national coverage policy regarding use of helical CT for lung cancer screening (HCFA, 2000).

National Cancer Institute (NCI): NCI currently recommends against routine screening of asymptomatic

persons for lung cancer with chest radiography or sputum cytology (NCI, 2000).

U.S. Preventive Services Task Force: Currently recommends against routine screening of asymptomatic persons for lung cancer with chest radiography or sputum cytology (HSTAT, 2000).

Appendix II: Methodology

Clinical information and evidence evaluated for this report was obtained from a search of MEDLINE, EMBASE, HealthSTAR, and Current Contents databases spanning the years 1985 to October 2000. Search terms included helical CT or spiral CT as keywords, subject words and title words, combined with lung cancer and screening. In addition, information was obtained from the National Cancer Institute (NCI) and the Radiological Society of North America (RSNA).

To date, the majority of studies evaluating the effectiveness of lung cancer screening have involved conventional chest radiography in combination with sputum cytology, and there have been no randomized controlled trials that address the effect of helical CT lung cancer screening on lung cancer-related mortality. Several recently published reports, three from Japan and one from the United States, describe studies in which asymptomatic subjects at risk for lung cancer due to smoking were screened with chest radiography as well as helical CT, and the cancer detection rates of the two imaging techniques were compared. There were also a number of studies published in Japanese language journals that evaluated the effect of mass lung cancer screening on mean life expectancy of the screened cohort compared with unscreened populations. The results of these studies were available in English only in abstract form, and therefore could not be thoroughly evaluated. Moreover, it is unclear if the results of lung cancer screening in Japan, where a very large proportion of the population smokes and there is relatively little emphasis on smoking cessation, would be applicable to the United States population.

The clinical studies regarding the use of helical CT for lung cancer screening are summarized in Appendix III.

These studies confirm that helical CT improves the rate of detection of non-calcified and suspicious lesions compared with chest x-ray, and that lesions diagnosed with helical CT are generally smaller and at an earlier stage than those detected with chest x-ray. However, none of the studies provided evidence regarding an effect of screening on survival or mortality rates in the patient populations screened. Moreover, the false-positive rate for helical CT was much higher than for chest x-ray, and in these studies, a large proportion of patients with a positive helical CT scan underwent unnecessary testing to rule out lung cancer.

Appendix III: Clinical Studies Evaluating Helical Computed Tomography for Lung Cancer Screening

Key: CT, computed tomography; FN, false-negative; FP, false-positive; PPV, positive predictive value

AUTHORS/STUDY DESIGN	STUDY POPULATION	RESULTS	CONCLUSIONS/COMMENTS
Kaneko et al. (1996)* National Cancer Center Hospital, Tokyo and National Cancer Center East Hospital, Chiba, Japan Prospective study to compare low-dose helical CT with chest radiography for screening and detection of peripheral lung cancer	1369 smokers (1232 men, 137 women; mean age 60; range 38-83)	Peripheral lung cancer was detected in 15/3457 (0.3%) examinations; 11 (73%) of these cases were detected only by low-dose helical CT 14/15 (93%) tumors were stage I 629 CT scans had abnormalities not proven to be cancerous; FP rate, 18% 109 chest radiographs had abnormalities not proven to be cancerous; FP rate, 0.3%	Peripheral lung cancer detection rate was higher for low-dose helical CT than for chest radiography; FP rate also much higher Limitations: no definitive confirmation of negative test results; no data on effect of screening by CT scan on survival or mortality

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Sone et al. (1998) Shinshu University School of Medicine, Matsumoto, Japan Prospective study to compare helical CT screening for lung cancer with conventional chest x- ray and sputum cytology	5483 volunteers from the general population 10,966 age-, sex- and smoking history- matched controls from same population	low-dose helical CT alone (n=1516) or helical CT and miniature chest fluorophotography or chest x-ray (n=3967) Controls underwent miniature chest fluorophotography; heavy smokers also had cytological evaluation of sputum Positive or equivocal findings were confirmed w/ radiography, transbronchial biopsy or re-examination at 3, 6, 12, 18, and 24 mos after initial screening	detection rate 0.48% w/helical CT; 0.03-0.05%	Helical CT had higher lung cancer detection rate than miniature chest fluorophotography or conventional chest x-ray Limitations: nonrandomized study; no confirmatory test for negative test results; no data regarding effect of screening on lung cancer-related mortality
			secondary testing	
Kakinuma et al. (1999)* National Cancer Center Hospital East, Kashiwa; National Cancer Center Hospital, Tokyo; National Shikoku Cancer Center Hospital, Matsuvama; Japan Anti- Tuberculosis Association, Shizuoka Branch, Japan Prospective study to compare low-dose helical CT with chest radiography for screening and detection of peripheral lung cancer	1443 smokers (1273 men, 170 womer; mean age, 61; range, 40-85)		Lung cancer was detected in 22 pts during the study period; 7 cases were missed at the initial helical CT examination, but were visible on the images from this examination during retrospective evaluation Missed nodules ranged from 4-13 mm diameter; 3 were originally diagnosed as old tuberculosis lesion or granuloma; 4 were considered normal Frequency of missed cancers in this study was 0.26%; interval to detection ranged from 6-18 mos; 6 tumors were stage I, 1 tumor was stage II at time of detection	Small nodules (=10 mm) can be missed on low-dose helical CT scan; unknown effect of FN rate on survival, mortality rate Limitations: f/u time not long enough to determine true FN rate; no data on survival, mortality rate associated w/ early detection
Henschke et al. (1999)	1000 asymptomatic smokers (541 men, 459		Noncalcified nodules were	Low-dose helical CT detected 4 times as many cancers as chest x-ray; CT detected cancers were
Early Lung Cancer Action Program (ELCAP): Weill Medical College of Cornell University, New York Presbyterian Hospital, New York University Medical Center, New York, NY; and McGill University, Montreal, CN Prospective multicenter nonrandomized study to compare helical CT with conventional chest x-ray for lung cancer screening Outcome measures: cancer detection rate, specificity; survival	women; median age, 67) Eligibility criteria: age 60 yrs or older; history of at least 10 pack-yrs of smoking; no history of cancer; fit to undergo thoracic surgery	views) and helical low- dose CT Radiographs and CT scans were evaluated independently by 2-3 readers Follow-up testing was based on an algorithm based on size of abnormalities; positive findings were confirmed w/ high resolution CT and/or biopsy	detected in 233 (23%) subjects by first helical CT scan compared w/ 68 (7%) by chest x-ray Malignant disease was confirmed in 27 (2.7%) subjects with positive CT scan and in 7 (0.7%) with positive chest x- ray 26/27 CT detected cancers were resectable 206 lesions detected by CT were not confirmed as	Emetha a trior and the second concentrate concentrate the second much earlier stage than reported for lung cancer pts detected w/ usual care; however, false-positive rate was very high Limitations: uncontrolled study; no data on survival or lung cancer-specific mortality; unknown if detection of cancers at an earlier stage will lead to increase in survival or decrease in mortality; follow- up not completed and therefore sensitivity of helical CT cannot be determined

*Study populations overlap

Appendix IV: Public Comment

This report was made available for a thirty-day public comment period from October 2, 2000, to November 2, 2000. The public comment period was announced in the State Register on October 2, 2000. No public comment was received.

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