Summary

✓ Compared to chest radiography, multi-slice/helical computed tomography (CT) is able to detect lung cancers of smaller size and at an earlier stage, when better outcomes may be possible.

✓ However, the rate of detecting benign lung nodules is high using these technologies. False positives can result in undue anxiety and/or additional tests that may be invasive and expensive.

✓ Currently evidence does not exist to suggest that detecting early stage lung cancer reduces mortality. Randomized controlled trials are underway to investigate this issue.

✓ Presently, even for smokers, screening for lung cancer with multi-slice/helical CT would be premature.

The Technology

Computed tomography (CT) produces cross-sectional images of the body using X-rays which are differentially absorbed when passing through body tissues of different densities. Two major components of a CT scanner are a gantry and a computer processor. The gantry, which is comprised of an X-ray tube and a detector array, takes consecutive images or rotates around the patient, gathering data which are then converted to images by the computer processor.

In conventional CT scanning, the tube cannot rotate continuously so images are collected one slice at a time. The scanning is relatively slow and resulting images are prone to artifacts caused by movement. Helical CT, also known as spiral CT, was developed with the introduction of slip ring technology. This allows the X-ray tube to rotate around a patient, while the table carrying the patient advances continuously. It permits data to be acquired rapidly, reduces artifacts due to movement and increases resolution. Slices are as thin as 1 mm and the scan time is about one breath-hold (15 to 20 seconds).3

Multi-slice CTs (MSCTs), which are a new generation of helical CTs with multiple detectors, have a greater imaging speed and detection capability than single-slice helical CTs. MSCT allows multiple image slices to be simultaneously acquired during a single rotation of the X-ray tube (Figure 1). MSCTs with the capacity to simultaneously acquire 4, 8, 16 and 32 slices, have been developed.4,5

Regulatory Status

Several types of helical CTs have been granted Class III licenses by Health Canada.6 (Diagnostic and therapeutic devices are categorized as Class III, if they are potentially hazardous or represent immediate danger if they fail.)

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Patient Group

Lung cancer is the leading cause of cancer death among Canadians. For 2003, it is estimated that there will be 21,100 new cases and 18,800 deaths due to lung cancer. Smoking is associated with approximately 85% of lung cancer cases. Amongst lung cancers, non-small cell lung cancer (NSCLC) accounts for 80%. NSCLC has four stages (I, II, III and IV). The five-year survival rate progressively decreases with increasing stage, being 60 to 80% and less than 5% for stages I and IV, respectively. If detected at an early stage, surgical resection may be possible. Symptoms of lung cancer are usually not evident until the disease is at an advanced stage, when prognosis is poor.

Current Practice

Sputum cytology, chest X-rays (CXR) and bronchoscopy have been used to detect lung cancer in people suspected of having the disease. These methods all have disadvantages. Sputum cytology and CXRs lack sensitivity and bronchoscopy is an invasive procedure. None of these technologies are currently recommended for lung cancer screening; i.e. detecting lung cancer in asymptomatic people.

The Evidence

Non-randomized studies have shown that the detection capability for helical CT exceeds that of CXR and sputum cytology. The comparison of lung cancer detection rates with helical CT versus CXR in the general population and smokers, and the percentage of lung cancers detected by helical CT that were stage I, are shown in Table 1.

Detection rates for non-calcified pulmonary nodules with helical CT were 23 to 43% with single array detector and 66% with multi-array detector technology. The rate of benign nodule detection is high. In a lung cancer screening study using helical CT, 21% of surgeries performed for suspected malignant pulmonary nodules found benign nodules. CT screening studies demonstrated positive predictive values in the range of 8 to 12% (i.e. of those with a positive test, only 8 to 12% truly have the disease) and sensitivities in the range of 55 to 93% (i.e. of those with the disease, 55 to 93% have a positive test).

No evidence demonstrating a decreased mortality from lung cancer screening with MSCT/helical CT is currently available. There is also no evidence to show that an increase in detecting early stage lung cancer results in a decrease in detection of late stage disease.

Table 1: Lung cancer screening studies using helical computed tomography and chest radiography or helical CT alone

<table>
<thead>
<tr>
<th>Author</th>
<th>No. of participants (description)</th>
<th>Participants found to have lung cancer (%) using helical CT</th>
<th>Participants found to have lung cancer (%) using CXR</th>
<th>Proportion of stage I cancers in lung cancers detected by helical CT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diederich et al.</td>
<td>817 (100% smokers or ex-smokers)</td>
<td>1.35</td>
<td>N/A</td>
<td>64</td>
</tr>
<tr>
<td>Henschke et al.</td>
<td>1,000 (100% smokers or ex-smokers; 14% had asbestos exposure)</td>
<td>2.70</td>
<td>0.70</td>
<td>85</td>
</tr>
<tr>
<td>Nawa et al.</td>
<td>7,956 (62.1% smokers or ex-smokers)</td>
<td>0.45</td>
<td>N/A</td>
<td>86</td>
</tr>
<tr>
<td>Sobue et al.</td>
<td>1,611 (62% smokers and 25% ex-smokers)</td>
<td>0.81</td>
<td>0.31</td>
<td>77</td>
</tr>
<tr>
<td>Sone et al.</td>
<td>3,967 (general population)</td>
<td>0.48</td>
<td>0.03</td>
<td>84</td>
</tr>
<tr>
<td>Swensen et al.</td>
<td>1,520 (61% smokers and 39% ex-smokers)</td>
<td>1.51</td>
<td>N/A</td>
<td>61</td>
</tr>
</tbody>
</table>

CT = computed tomography
CXR = chest X-rays
N/A = not applicable
Ongoing and proposed randomized controlled trials (RCTs) will investigate whether screening for lung cancer with MSCT/helical CT decreases mortality. The final results of a US study involving 50,000 participants are expected by 2009. The actual reduction in mortality, rather than survival, must be evaluated to eliminate lead-time bias (where early diagnosis shows an apparent increase in survival time though time of death is unaltered), length-time bias (where the detection of slow growing tumours appears to improve survival time) and over-diagnosis bias (where there is an apparent increase in survival time through detection of slow-growing tumours that are not clinically significant).

A recent cost-effectiveness analysis (using a computer-simulated model) comparing helical CT screening with no screening, showed that the incremental cost per quality adjusted life-year (QALY) was US$116,300 for current smokers.21

### Adverse Effects
Lung scanning with a helical CT is a non-invasive procedure. However, false positives often result in additional diagnostic tests, which may be invasive and may cause additional adverse events. False positives may result in unnecessary surgery with associated morbidity and mortality.15 Also false positives can cause undue anxiety and stress. The radiation exposure, though more than that for CXRs, is usually less than that for conventional CT due to shorter scanning times. However, increased radiation dose is necessary to maintain high quality images with the thin slices that are possible with MSCT.4

### Administration and Cost
Helical CT scanning is usually performed as an outpatient procedure at a hospital or imaging centre. The cost to purchase helical CT scanners ranges from US$375,000 to US$1.57M, the cost for MSCTs being at the high end.4 Additional imaging software packages cost US$4,000 to US$10,000.4 Operating costs and physician fees are additional. The cost of a single CT scan is $255 to $500.22,23 The follow-up of lung nodules suspected to be malignant would entail additional costs.

### Concurrent Developments
Imaging techniques (autofluorescence bronchoscopy, virtual bronchoscopy, optical coherent tomography, confocal micro-endoscopy, and positron emission tomography) and molecular techniques (detection of nuclear riboprotein, methylation related silencing of genes and malignancy associated changes) are under investigation for the early detection of lung cancer.24,25

### Rate of Technology Diffusion
With the current state of evidence, or lack thereof, the use of helical CT for lung cancer screening is unlikely to be widely recommended. Currently the National Cancer Institute (US) does not support it.26 A recent cost-effectiveness analysis showed that lung cancer screening with helical CT will not be cost-effective without substantial reductions in mortality due to screening, high rates of adherence to screening, low rates of over-diagnosis and a lower cost per CT scan.21

### Implementation Issues
Helical CT is an expensive technology, both to purchase and to operate. Work-ups following detection of suspicious lung nodules are expensive and may be invasive. Currently, evidence does not exist to suggest that screening for lung cancer with MSCT/helical CT reduces lung cancer mortality or improves quality of life.

## References


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