International Early Lung Cancer Action Program
The I-ELCAP Investigators (www.IELCAP.org)

Since CT screening for lung cancer began in 1993 in the context of the Early Lung Cancer Action Project (ELCAP) (1, 2), it has expanded to the NY-ELCAP (3) and then into an international collaboration called I-ELCAP (4) with over 50,000 people who have had baseline and annual repeat screening. At baseline, it was been found that 15% had a positive result of the initial CT test and at annual repeat screening, 6% had a positive result (5). The updated definition of a positive result of the initial CT test at *baseline* (6) is an updated version of that originally used in original ELCAP: at least 1 solid or part-solid noncalcified nodule 5 mm or more in diameter, and/or at least 1 nonsolid noncalcified nodule 8 mm or more in diameter. When noncalcified nodules were identified but all of them were too small to imply a positive result, a repeat CT one year later was called for. For *repeat* screening, the definition of positive result of the initial CT test remained the same as the original ELCAP: any newly identified noncalcified nodule that evidently had grown since the prior screen, greater than 3 mm; the definition of growth was updated to account for nodule consistency: alternatives to any enlargement, identified visually by the radiologist, of the entire nodule included growth of the solid component of a part-solid nodule and development of a solid component in a previously nonsolid nodule.

The I-ELCAP regimen provides recommendations for the work-up, but the actual decision is left to each screenee and his/her referring physician. In the I-ELCAP approach, this does not compromise the validity of the study as long as actions, results of the subsequent tests, and interventions are documented for each screenee. Adherence to the regimen, however, does affect the performance of the regimen as it determines the frequency of unnecessary biopsy or surgery and the timeliness of the diagnosis which ultimately determines the stage and resectability of the screen-diagnosed lung cancer. Thus, for adequate performance of any screening regimen, adherence by the screenees and their referring physicians is important.

Following the I-ELCAP protocol, over 90% of the recommended biopsies resulted in a diagnosis of malignancy (3, 5). Thus, the recommendations turned out to be quite successful as to avoidance of undue invasive procedures, complications, and cost. Detailed pathologic review of the specimens showed all were genuine lung cancers and showed the differences between cancers diagnosed in the baseline round from those diagnosed in the repeat rounds (7).

These screenings have resulted in over 80% of the screen-diagnoses as being of clinical Stage I diagnosis (5). We also found a significant decrease in the frequency of Stage I with increasing tumor diameter (8). The percentages of Stage I cases were much higher than those reported from the SEER registry data, although the trend was evident in the SEER data as well (9). Long-term follow-up of early diagnoses in the SEER was also addressed (10, 11).

Long-term follow-up of these screen-diagnosed cases showed that the curability rate as estimated by the 10-year Kaplan-Meier survival rates for all cases, regardless of stage and treatment, was 80%. If the cancer was in clinical Stage I and promptly resected, the 10-year rate was 92% (4). Such high survival rates of small resected Stage I lung cancers had already been reported much (12, 13). Our estimates do not have lead time bias as addressed in our responses to the letters to the Editor (14).

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