ID #1908: Non-Invasive Bioconductance Measurement as Adjunctive Diagnostic Technique of Lung Cancer in Subjects with Abnormal Chest CT

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Introduction
- The increasing utilization of CT to assess for lung cancer presents a significant challenge to physicians and patients, as a large number of pulmonary lesions detected are indeterminate.
- Current follow-up recommendations for these lesions are complex and depend on several factors, including lesion size and patient history.
- These recommendations include multiple follow-up CT exams, resulting in considerable expense, radiation exposure, and patient anxiety.1
- A non-invasive adjunctive technology to CT, which can differentiate between malignant and benign lung lesions, would be a useful treatment-enabling tool.
- The bioelectrical properties of cancerous tissue are well characterized in the scientific and the medical literature and have shown to vary significantly from normal, benign tissue.2
- This study investigated computerized bioconductance (CB) as an adjunctive technology to CT in evaluating indeterminate lung lesions.

Methods
- In a clinical trial utilizing CB technology (See Poster #1939) at Johns Hopkins School of Medicine, 41 subjects were evaluated for lung cancer based on a suspicious chest lesion seen on CT.
- CB results were compared with patients’ diagnosis by biopsy or with follow-up CT scans.
- Measurements were analyzed using a proprietary classifier algorithm that calculated a composite score to discriminate between benign and malignant lesions.

Results
- 29 subjects had confirmed lung cancer by pathology, and 12 subjects had benign results.
- CB correctly categorized 26 of 29 malignant lesions for 89.7% sensitivity and a positive predictive value of 96.3%.
- CB correctly categorized 11 of 12 lesions as benign for 91.7% specificity and a negative predictive value of 78.5%.
- ROC area as a binary variable = 91%.
- ROC area as a continuous variable = 94.5%.

Conclusions
- Transthoracic bioconductance is a non-invasive technique that can be used to discriminate between malignant and benign lung lesions.

Results (Continued)

<table>
<thead>
<tr>
<th>Lesion Stage</th>
<th>Category</th>
<th>Malignant (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage IA</td>
<td></td>
<td>7 (24%)</td>
</tr>
<tr>
<td>Stage IB</td>
<td></td>
<td>4 (14%)</td>
</tr>
<tr>
<td>Stage II</td>
<td></td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Stage III</td>
<td></td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Stage IV</td>
<td></td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Stage V</td>
<td></td>
<td>11 (38%)</td>
</tr>
</tbody>
</table>

Patient A
CT for a patient with a small lesion that pathology showed as a moderately differentiated (G2) squamous cell carcinoma. Patient staged as T1NOMx.

Patient B
CT images from a patient with a small moderately differentiated (G2) adenocarcinoma with bronchoalveolar features. Patient staged as T1NOMD.

Examples of 2 cases with a positive CB score for cancer

References

Patient Demographics

Category | Benign (12) | Malignant (29)
---|-------------|-------------|
Average Age | 61 | 65 |
Age Range | 34-77 | 40-80 |
Sex: Female | 3 (25%) | 16 (55%) |
Sex: Male | 9 (75%) | 13 (45%) |
Race: White | 10 (83%) | 18 (62%) |
Race: Black | 2 (17%) | 10 (34%) |
Race: Asian | 0 | 1 (3%) |

Histology

<table>
<thead>
<tr>
<th>Histology</th>
<th>Benign (%)</th>
<th>Malignant (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory</td>
<td>6 (50%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Epithelial</td>
<td>1 (8%)</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Granuloma</td>
<td>1 (8%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Granulomatous Inflammation</td>
<td>1 (8%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Fibrous Scar</td>
<td>1 (8%)</td>
<td>17 (58%)</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>12 (86%)</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Small Cell Carcinoma</td>
<td>2 (17%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Analysis

CB Test Algorithm
- Each subject receives a composite test score ranging from 0-100 indicative of malignancy.
- Algorithm establishes optimal cut point for sensitivity & specificity results.

ROC Performance of the CB Test