Investigations of Breast Cancer Screening Using a Novel in vitro Diagnostics Technology.

Sub-category: General Screening

Category: Risk Assessment, Prevention, Early Detection, and Screening

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Abstract Disclosures

Abstract:

**Background:** A newly developed in-vitro diagnostic technology named Cancer Differentiation Analysis Technology (CDA) was investigated for breast cancer screening. The CDA technology is a blood-sample based, multi-level, multi-parameter diagnostic method which detects signals from both proteins and cells, in which multiple aspects and parameters of information were collected to improve diagnostic accuracy. **Methods:** Blood samples from breast cancer group (n = 222), and control subjects (n = 204) were collected in EDTA tubes. CDA values were measured using a CDA medical device. The results were shown in Table 1 and Figure 1 below. **Results:** The average CDA values of breast cancer and control groups were 50.43 and 34.03 (rel. units) respectively. The results indicated that breast cancer could be significantly distinguished from the control (p < 0.001). Area under ROC curve was 0.914. When Youden Index reached the maximum, sensitivity and specificity was 82.0% and 89.2% respectively. **Conclusions:** Initial results showed that CDA technology could be a potential candidate for breast cancer screening.

<table>
<thead>
<tr>
<th>Group</th>
<th>Sample Size</th>
<th>Age Range</th>
<th>Age Mean</th>
<th>Age Median</th>
<th>CDA Mean (rel. units)</th>
<th>CDA Median (rel. units)</th>
<th>CDA STDEV</th>
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</thead>
<tbody>
<tr>
<td>Control</td>
<td>204</td>
<td>30 - 84</td>
<td>60</td>
<td>60</td>
<td>34.03</td>
<td>34.81</td>
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<td>Breast Cancer</td>
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<td>23 - 79</td>
<td>53</td>
<td>54</td>
<td>50.84</td>
<td>50.43</td>
<td>9.69</td>
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