Computerized resting ECG analysis for the detection of coronary artery stenosis after coronary revascularization in comparison with angiographic findings

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Disclosures

• Dr. J.T. Shen is founder and managing member of Premier Heart LLC and co-inventor of the web-based 3DMP method

• The other authors have no disclosures to make
3DMP

**Digital Database Driven Multi Phase**

- A Computerized Expert ECG System
  - Sophisticated mathematical analysis
  - Validated digital patient database
- An innovative, non-invasive diagnostic device for myocardial ischemia due to coronary artery disease
Signal and Digital Data Processing

Leads II and V5 recorded for 82s → Amplify, digitize and FFT → Signal averaging 16 segments at 5.12s @ 100 Hz

Amplify, digitize, encrypt and transmit

Decryption FFT

Positive indices identified Patterns matched against a 35,000-patient database

Six mathematical transformations

Automatic Report Generation
3DMP Database

• 35,000 cases
  • Confirmed medical diagnosis
  • Benchmark references for pattern recognition

• Proprietary software for data interpretation
  • Automated comparison to database
  • Diagnosis of myocardial ischemia

• Automatic scoring system
  • Quantitative assessment of severity of myocardial ischemia
Clinical Study

- Previous study (Weiss et al, 2002) showed good sensitivity and specificity of 3DMP in the prediction of hemodynamically relevant coronary stenosis

- Evaluation of 3DMP in patients after revascularization (PCI, CABG) w/o acute chest pain
  - Follow-up for re-stenosis, de novo stenosis, graft stenosis
- Convenience sample of an unselected patient population scheduled for coronary angiography
- Comparison to angiography
Patients

• 213 patients scheduled for follow-up angiography
  • 68 female, 68.2 +/- 8.3 yoa
  • 145 male, 61.8 +/-9.8 yoa

• Coronary revascularization at least 6 weeks before study
  • 147 PCI, 63.2 +/-10.3 yoa
    • 55 female (37%), 68.6 +/- 7.8 yoa
    • 92 male (63%), 60.0 +/- 10.2 yoa
  • 66 CABG, 65.3 +/- 8.6 yoa
    • 13 female (20%), 66.3 +/- 10.0 yoa
    • 53 male (80%), 65.0 +/- 8.3 yoa
Coronary Angiography

- Standard procedures
- Immediate classification of results by angiographer
- Independent classification by second cardiologist
- Dichotomous classification of hemodynamically relevant coronary stenosis
  - Stenosis “NO”: < 70% stenosis (< 50% LCA)
  - Stenosis “YES”: > 70% stenosis (> 50% LCA)
- Both investigators blinded against 3DMP results
3DMP ECG

• Prior to angiography after 20 min rest
• Limb leads and V5
• 82 second simultaneous recording of leads II and V5
• Amplification, digitization, transmission to central server (after ECG quality check)
• Calculation of severity score (0 to 20)
  • Higher values associated with higher likelihood of coronary stenosis
  • Cut-off > 4 indicative of hemodynamically relevant stenosis
• ECG technician and Premier Heart staff blinded against angiograms
Coronary Stenosis

- 71 of 213 patients (33%)
- No gender or age differences
- More frequent in CABG group
Severity Score

Age groups
- 65
- 65+

Severity Score
Coronary Stenosis

Coronary Stenosis

Severity Score

Coronary Stenosis

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Severity Score
Severity Score

Coronary Stenosis

Gender
- female
- male

Revascularization in Patient History
- PCI
- CABG

Severity Score

malefemaleGender

Severity Score

Coronary Stenosis

malefemaleGender

Severity Score

Coronary Stenosis
ROC Curves

Source of the Curve
- All pts (AUC 0.909)
- Reference Line

Sensitivity vs. 1 - Specificity
# Prediction of Coronary Stenosis

<table>
<thead>
<tr>
<th>3DMP Severity Score</th>
<th>Angiography</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Stenosis</td>
</tr>
<tr>
<td>&lt; 4</td>
<td>126</td>
</tr>
<tr>
<td>&gt;= 4</td>
<td>16</td>
</tr>
</tbody>
</table>
# Prediction of Coronary Stenosis

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>a priori</th>
<th>Correct</th>
<th>Sens</th>
<th>Spec</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>213</td>
<td>0.333</td>
<td>0.901</td>
<td>0.930</td>
<td>0.887</td>
<td>0.673</td>
<td>0.981</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>68</td>
<td>0.309</td>
<td>0.868</td>
<td>0.905</td>
<td>0.851</td>
<td>0.548</td>
<td>0.978</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>145</td>
<td>0.345</td>
<td>0.917</td>
<td>0.940</td>
<td>0.905</td>
<td>0.733</td>
<td>0.982</td>
</tr>
<tr>
<td><strong>&lt;65 yoa</strong></td>
<td>117</td>
<td>0.325</td>
<td>0.915</td>
<td>0.921</td>
<td>0.911</td>
<td>0.706</td>
<td>0.980</td>
</tr>
<tr>
<td><strong>65+ yoa</strong></td>
<td>96</td>
<td>0.344</td>
<td>0.885</td>
<td>0.939</td>
<td>0.857</td>
<td>0.643</td>
<td>0.981</td>
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<tr>
<td><strong>PCI</strong></td>
<td>147</td>
<td>0.279</td>
<td>0.898</td>
<td>0.878</td>
<td>0.906</td>
<td>0.582</td>
<td>0.980</td>
</tr>
<tr>
<td><strong>CABG</strong></td>
<td>66</td>
<td>0.455</td>
<td>0.909</td>
<td>1.000</td>
<td>0.833</td>
<td>0.806</td>
<td>1.000</td>
</tr>
</tbody>
</table>
Summary

• Computerized resting ECG analysis
• Prediction of coronary stenosis after revascularization
  • 90% correct predictions, sensitivity 93%, specificity 89%
  • PPV 67%
  • NPV 98%

• No significant effects on performance from Gender, Age, Type of Revascularization

• Further validation warranted (and planned)
Clinical Implications

• Non-invasive prediction of coronary stenosis
• Screening for stenosis
• Feasible in patients with contraindications to stress testing
• Similar rule-out performance like stress testing (awaits further study)
• Simple application by technicians
• Presence of a physician not required