Predicting Coronary Stenosis by Computer-Enhanced, Resting Electrocardiogram

Effect of Gender, Age, and Revascularization on Sensitivity and Specificity

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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, encrypt and transmit

Amplify, digitize and FFT

Signal averaging 16 segments at 5.12s @ 100 Hz

Decryption FFT

Automatic Report Generation

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

Six mathematical transformations
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

• Large single-center convenience sample of an unselected patient population scheduled for coronary angiography

• Comparison to angiography

• Focus on effect of gender, age, and previous revascularization on performance of the method
Patients

• 758 patients scheduled for angiography
  • 277 female, 65.3 +/- 10.6 yoa
  • 481 male, 60.5 +/-10.7 yoa
  • 433 under 65 yoa,
  • 325 65 yoa and over
• 545 patients without previous coronary intervention
  • 61.6 +/- 11.2 yoa, 38% female
• 213 patients after coronary revascularization at least 6 weeks before study
  • 63.8 +/- 9.8 yoa, 32% female
  • 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

- 319 of 758 patients (42%)
  - 46% primary
  - 28% post PCI
  - 46% post CABG
- Overall, stenosis more frequent in men and older patients
- No gender or age differences after revascularization
Severity Score

![Severity Score Graph]

- Coronary Stenosis
  - no
  - yes

Severity Score

0  2  4  6  8  10  12  14

*
Severity Score

Coronary Stenosis

Gender
- female
- male

Age group
- < 65
- 65+

Severity Score

Coronary Stenosis

no

yes

0

2

4

6

8

10

12

14

*
Severity Score
ROC Curves

Source of the Curve
- All pts (AUC 0.873)
- Reference Line

Source of the Curve
- female (AUC 0.880)
- male (AUC 0.869)
- <65 yoa (AUC 0.892)
- 65+ yoa (AUC 0.838)
- Reference Line
ROC Curves

Source of the Curve
- female, <65 yoa (AUC 0.886)
- female, 65+ yoa (AUC 0.859)
- male, <65 yoa (AUC 0.887)
- male, 65+ yoa (AUC 0.827)
- Reference Line

Source of the Curve
- no revasc (AUC 0.857)
- PCI (AUC 0.907)
- CABG (AUC 0.891)
- any revasc (AUC 0.909)
- Reference Line
# Prediction of Coronary Stenosis

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<thead>
<tr>
<th>3DMP Severity Score</th>
<th>No Stenosis</th>
<th>Stenosis</th>
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<tbody>
<tr>
<td>&lt; 4</td>
<td>376</td>
<td>63</td>
</tr>
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<td>&gt;= 4</td>
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<table>
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<th>Angiography</th>
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<td>35</td>
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<td><strong>Total</strong></td>
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<td><strong>Male</strong></td>
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<td>65+ years</td>
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<tr>
<td>No Revasc</td>
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<tr>
<td>PCI</td>
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<tr>
<td>CABG</td>
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Summary

• Computerized resting ECG analysis
• Prediction of coronary stenosis
  • 87% correct predictions, sensitivity 89%, specificity 86%
  • adjusted PPV 77%
  • adjusted NPV 94%
• No significant effects on performance from Gender, Age, Type of Revascularization
• Further studies warranted (and planned)
Conclusions

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