COST MODEL FOR A NEW ACOUSTIC DIAGNOSTIC AID TO RULE OUT CORONARY ARTERY DISEASE

Winther S¹, Böttcher M², Wahler S³, Bolin K⁴

¹Aarhus University Hospital, Aarhus N, Denmark,
²Hjertemedicin Hjerteforskningsklinikken, Herning, Denmark,
³St. Bernward GmbH, Hamburg, Germany,
⁴University of Gothenburg, Gothenburg, Sweden
AGENDA

• The technical and methodical principles of acoustic diagnosing coronary heart disease (CAD)
• Cardiologic care system in Denmark
• Clinical evidence of the method
• Application of the cost model and results
The technical and methodical principles of acoustic diagnosing coronary heart disease

- The development of acoustics in CAD:
Diagnosis of CAD using an electronic stethoscope

- As in other arteries a stenosis causes flow turbulence, which makes noise
- The sounds are weak, but detectable using advanced signal processing

Master thesis in 2005
(Claus Graff & Samuel Schmidt)

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Case Reports 1967

A Diastolic Murmur Arising in a Stenosed Coronary Artery

William Dock, M.D. and Sml Zonerach, M.D.
Brooklyn, New York

In a man with heart failure due to hypertension and ventricular aneurysm, a diastolic murmur was recorded in a sharply localized area, and only when he was erect. This high pitched murmur seemed to have arisen in a stenosis (occlusional thrombus) of the descending branch of the left coronary artery.
Heart sounds and CAD murmurs

What you listens for today:
Murmurs from defective heart valves

Noise from stenotic coronary arteries
• Not audible in most cases
• Up to 1000 times weaker than other heart sounds

Frequency spectrum (M. Akey et. al.)
The CADScore® Algorithm

- Filter
- Identify acoustic features
- Combine features

Diastole

CADScore Algorithm

- 0: Low risk
- 99: High risk
Main clinical studies

Registration study
AC003SH (2013)

N=228
Symptomatic, no CAD diagnosed
One center (DK)

VALIDATE (2016)

Dan-NICAD (2014-2016)

N=1,675
Symptomatic, no CAD diagnosed
Two centers (DK)

N=231
Symptomatic, scheduled for CAG
Two centers (GER)

Planned
Stress-ECG

N=1,000
Symptomatic, undiagnosed
Multiple centers (GER/UK)

Planned Dan-NICAD II

N=2,000
New Algorithm
Multiple centers (DK/SWE)

CE Mark August 2015

Screening Studies

Diagonal performance of an acoustic-based system for coronary artery disease risk stratification

Simon Winther,1 Louise Nissen,2 Samuel Emil Schmidt,1 Jelmer Sybren Westra,1 Laust Dupont Rasmussen,1 Lars Lyhne Knudsen,2 Lene Helleskov Madsen,2 Jane Kirk Johansen,1 Bjørne Skogstad Larsen,1 Johannes Jan Struijk,1 Lars Frost,6 Niels Ramsing Holm,1 Eui-Sal Hej Christensen,1 Hans Erik Bolker,7 Morten Böttcher2
Suspected CAD flow through the system

- **Identification of Chest Pain**
  - Intermediate or High Risk
  - Low pretest likelihood of CAD

- **Stress Test (Treadmill)**
  - Intermediate or High Risk
  - Low Risk
  - Medical Management

- **Stress-Echo/MPI/Nuclear Imaging**
  - Indeterminate CAD
  - Low Risk
  - Medical Management

- **cCTA**
  - High Risk
  - Likely severe CAD

- **Invasive Coronary Angiography**
  - Stenosis Appropriate for Intervention
  - No Interventional Target

- **Percutaneous Coronary Intervention**
  - Medical Management

**Physician Key**
- Primary Care Practitioner
- General Card.
- Radiologist
- Interventional Card.
The CADScor® system for diagnosing CAD risk using acoustic properties

- The CADScor® System consists of a disposable patch and reusable sensor/touch-screen interface
- The product is based on the concept that atherosclerosis in coronary vessels will produce unique murmurs detectable by advanced acoustic equipment during diastole

- Minimal training requirements
- Measurement takes around 5-8 min.
- Noninvasive
- No patient exposure to radiation or contrast dye
- High negative predictive value
- Relatively low capital and consumable costs
**ESC SCAD guidelines 2013**

**Characteristics of tests commonly used to diagnose the presence of coronary artery disease**

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress ECG</td>
<td>45-50</td>
<td>85-90</td>
<td>93%</td>
</tr>
<tr>
<td>Stress Echo</td>
<td>80-85</td>
<td>80-88</td>
<td>97%</td>
</tr>
<tr>
<td>Stress SPECT</td>
<td>73-92</td>
<td>63-87</td>
<td>95%</td>
</tr>
<tr>
<td>Dobutamin Stress Echo</td>
<td>79-83</td>
<td>82-86</td>
<td>97%</td>
</tr>
<tr>
<td>Dobutamin Stress MRI</td>
<td>79-88</td>
<td>81-91</td>
<td>97%</td>
</tr>
<tr>
<td>Vasodilator Stress Echo</td>
<td>72-79</td>
<td>92-95</td>
<td>96%</td>
</tr>
<tr>
<td>Vasodilator Stress SPECT</td>
<td>90-91</td>
<td>75-84</td>
<td>98%</td>
</tr>
<tr>
<td>Coronary CT</td>
<td>95-99</td>
<td>64-83</td>
<td>99%</td>
</tr>
<tr>
<td>CADScore*</td>
<td>81-90</td>
<td>45-53</td>
<td>97%</td>
</tr>
</tbody>
</table>

*not in guideline
99 % Socialized medicine so few private clinics
General practitioners refer to outpatient clinics for workup
Workup means: Cardiologist – Echo - ECG bloodtest and history.
Activity:
• Invasive angiography 7,000 per year - 1.4 per 1,000 (Germany: 8.6)
• Cardiac CT 5,000 per year.
• Perfusion test ( Rb-PET) 3,000 per year
Excercise test not used
Stress Echo not used
Flow of study AC003SH

Patients referred to CCTA or ICA For CAD diagnostics

Excl.: Pregnancy, diastolic murmur, heart surgery, arrhythmias, etc.
Results of AC008SH

Result of diagnostics

- Non CAD: 54%
- Non obstructive CAD: 28%
- Obstructive CAD: 18%

No CAD

- ≤20: 60
- >20-30: 30
- ≥30: 10

CAD

- ≤20: 10
- >20-30: 30
- ≥30: 60
Pre-test probability of CAD
Diamond-Forrester updated

<table>
<thead>
<tr>
<th>Age</th>
<th>Typical angina</th>
<th>Atypical angina</th>
<th>Non-anginal pain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Men</td>
<td>Women</td>
<td>Men</td>
</tr>
<tr>
<td>30–39</td>
<td>-</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>40–49</td>
<td>71.4</td>
<td>-</td>
<td>22.2</td>
</tr>
<tr>
<td>50–59</td>
<td>73.3</td>
<td>60</td>
<td>10.6</td>
</tr>
<tr>
<td>60–69</td>
<td>78.0</td>
<td>57.1</td>
<td>32.9</td>
</tr>
<tr>
<td>70–79</td>
<td>72.7</td>
<td>43.8</td>
<td>36.4</td>
</tr>
<tr>
<td>&gt;80.93</td>
<td>83.3</td>
<td>75</td>
<td>23.6</td>
</tr>
</tbody>
</table>

- **<15%** No further testing
- **15%>** Intermediate risk
- **<85%** CTA
- **>85%** >50% SPECT, C-MRT, D-MRT, X-Echo

2014 KBV Guidelines
Patient flow by DF assessment

- High risk: 41
- Interm. risk: 68
- Low. risk: 90
- Very low risk: 29
- 255 persons enrolled

Flow Chart:
- N-Contr. CT: 5
- Cor. CT: 11
- MPI: 9
- CAD: 71
- CAG: 35
- No-CAD: 184
- Relapse: 3
- Cor. CT: 1
- MPI: 2
- CAG: 2

06.11.2017
Price tag and change of probabilities

- **Danish hospital tariff 2016 - Cardiology**
  - Non contrast CT
    - DKK 906
  - Contrast CT
    - DKK 2,621
  - MPI DKK 3,015
  - CAG DKK 5,997
  - (CADSCORE DKK 350)

- **Risk changes after combination of scores**

<table>
<thead>
<tr>
<th></th>
<th>DF-Score</th>
<th>DF-Score + CADScore</th>
</tr>
</thead>
<tbody>
<tr>
<td>very low</td>
<td>6,1%</td>
<td>23,2%</td>
</tr>
<tr>
<td>low</td>
<td>64,5%</td>
<td>39,0%</td>
</tr>
<tr>
<td>inter</td>
<td>20,6%</td>
<td>18,0%</td>
</tr>
<tr>
<td>high</td>
<td>8,8%</td>
<td>19,7%</td>
</tr>
</tbody>
</table>

06.11.2017
Patient flow by new assessment

- **High risk**: 61 persons
- **Interm. risk**: 48 persons
- **255 persons enrolled**: 61 + 48 = 109
- **Low. risk**: 49 persons
- **Very low risk**: 70 persons

**Flow through assessments**

- **N-Contr. CT**
  - 2
c
- **Cor. CT**
  - 6
  - 5
- **MPI**
  - 2
  - 25
- **CAG**
  - 71
- **CAD**
  - 71

**Patient outcomes**

- **Relapse**: 7
- **Cor. CT**: 2
- **MPI**: 6
- **CAG**: 184
- **No-CAD**: 184

**Total patients identified**: 109
Changes in examination

Frequencies in the model

- Non-contrast CT: -37.9%
- Contrast CT: -43.1%
- MPI: -29.0%
- CAG: +4.9%

06.11.2017
Results

- Overall costs for diagnostics was DKK 6,096 applying acoustic testing and DKK 6,379 without; saving DKK 274 per patient.
Drawbacks of the model

- 28% CAD is not the typically expected population
- Free combination of DF and Score is not anymore in the focus of development
- Newly published study has 8-times more patients

- But the main consideration remains: How to improve the pre-test probabilities to avoid futile diagnostic