Cost-cost analysis for ultra-sensitive phonocardiography used as primary test for coronary artery disease in Germany

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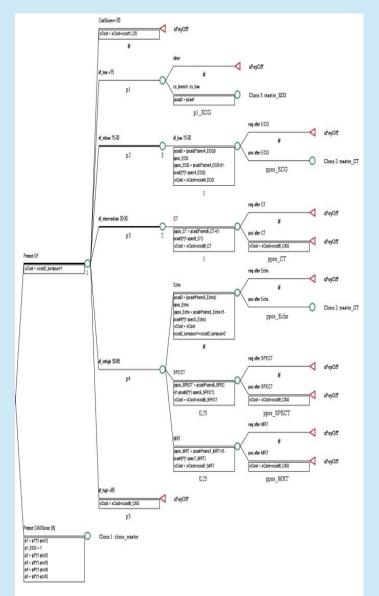
Objectives:

- Coronary artery disease (CAD) is still the most common cause of death globally.
- Chest pain that occurs regularly with activity, after eating, or at other predictable times is the most common sign of CAD.
- Nevertheless around 90% patients showing up in German GP offices with chest pain suffer from other diseases.
- The pathway for diagnosing CAD in the German ambulatory sector is partly driven by reimbursement structures. The statutory sick-funds do not cover for e.g. coronary-CT. There is an imbalance between guidance and reimbursement.
- Ultra-sensitive phonocardiography is a new technology to aid the early rule-out of CAD, which proofed to be cost-saving applying ESC-guidance.
- This cost comparison modeled the consequences of applying this new test to German reimbursement reality.
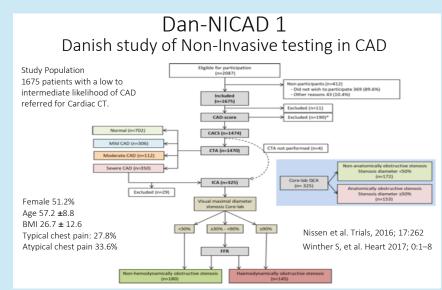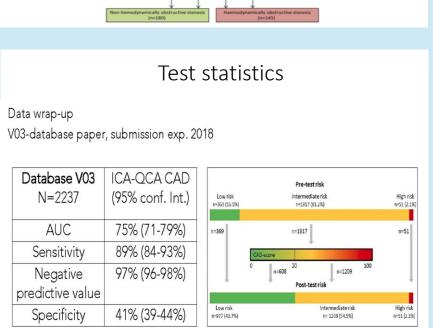
Methods:

- Development of a decision tree model based on the 2016 German CAD-diagnostic algorithm
- Only methods were accepted which are reimbursed by statutory sick-funds in the ambulatory setting.
- Implementation of the results of a database of 1,664 symptomatic patients of the rule out device and modeled a population of typical patients showing up in a physicians´ office with chest pain.
- Charges were derived from the 2018 German EBM-tariff.
- Probabilistic sensitivity analysis (PSA) was performed.
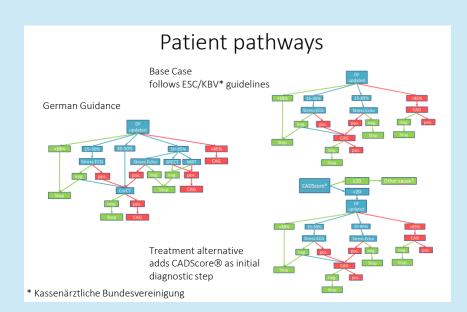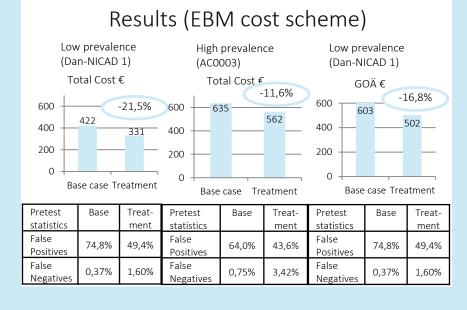- Analytic tools were MS-Excel 2016 and TreeAge®.

Results:

- The population had a mean age of 57.5 years, 51.5% female of which 10.5% suffered from obstructive CAD.
- Use of phonocardiography (CADScore®, Acarix A/S) in addition to the recommended pretest probability calculator (Diamond-Forrester) caused a reduction in diagnostic costs of 21.5% (422 € vs. 331 €), excluding the additional cost of the CADScore® System.
- The main reason for the cost reduction is the sharp increase in the proportion of patients with either very low pretest probability (<15%) or CAD being ruled out by the phonocardiography system.
- The percentage of patients being ruled out from further diagnostics increased from 14.4% to 41%.

- The use of coronary angiography in the diagnostic process dropped from 22.0% to 16.9%.
- Sensitivity analyses applied to the sensitivity and specificity of the phonocardiography system confirmed the cost advantage of the phonocardiography system over a wide range parameter range.
- However, an increase in the overall false negative rate of the diagnostic process has to be noted (26% without, 33% with phonocardiography), whereas the false positive rate dropped from 13.5% (without) to 9.7% (with ultra-sensitive phonocardiography).

Dan-NICAD 1
Danish study of Non-Invasive testing in CAD

Study Population
1675 patients with a low to intermediate likelihood of CAD referred for Cardiac CT.

Female 51.2%
Age 57.2 ±8.8
BMI 26.7 ± 12.6
Typical chest pain: 27.8%
Atypical chest pain 33.6%

Nissen et al. Trials, 2016; 17:262
Winther S, et al. Heart 2017; 0:1–8

Patient pathways

Base Case
follows ESC/KBV* guidelines

German Guidance

Treatment alternative
adds CADScore® as initial diagnostic step

* Kassenärztliche Bundesvereinigung

Test statistics

Data wrap-up
V03-database paper, submission exp. 2018

Database V03 N=2237	ICA-QCA CAD (95% conf. Int.)
AUC	75% (71-79%)
Sensitivity	89% (84-93%)
Negative predictive value	97% (96-98%)
Specificity	41% (39-44%)

Results (EBM cost scheme)

Low prevalence (Dan-NICAD 1) — Total Cost €: Base case 422, Treatment 331, -21,5%

High prevalence (AC0003) — Total Cost €: Base case 635, Treatment 562, -11,6%

Low prevalence (Dan-NICAD 1) — GOÄ €: Base case 603, Treatment 502, -16,8%

Pretest statistics	Base	Treatment	Pretest statistics	Base	Treatment	Pretest statistics	Base	Treatment
False Positives	74,8%	49,4%	False Positives	64,0%	43,6%	False Positives	74,8%	49,4%
False Negatives	0,37%	1,60%	False Negatives	0,75%	3,42%	False Negatives	0,37%	1,60%

Conclusions:

- Ultra-sensitive phonocardiography has proven to be a clinically relevant diagnostic measurement in several clinical trials. The economic effect was mainly driven by a reduction of coronary CTs.
- Given the German scheme with coronary-CT in the guidelines, but not reimbursed the ultra-sensitive phonocardiography proved also to reduce costs for the same diagnostic success.
- Saved radiation and overall cohort risk-reduction was not studied. The use of this new technology may save overall financial resources in CAD diagnostic in Germany.

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