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®, Acardix 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).

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.