

Noninvasive Detection of Coronary Artery Disease Using Resting Phase Signals and Advanced Machine Learning

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- None

Company

- None

Background

- ***Artificial intelligence (AI)*** techniques are increasingly being applied to cardiovascular (CV) medicine, yielding diagnostic tools that may significantly enhance the care of cardiac patients
- ***cardiac Phase Space Tomography Analysis (cPSTA)*** is a novel technology that employs machine learning to assess the presence of significant coronary artery disease (CAD)

Utilization of the *cardiac* Phase Space Tomography Analysis (cPSTA) System



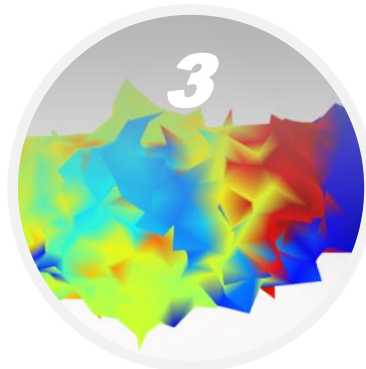
cPSTA System Scan

The phase signals emitted by the heart are scanned while the patient is lying down



Data Transfer

The patient's data is automatically transferred to the cloud using Wi-Fi or cellular data connection



Cloud Computing

Advanced mathematics and machine-learned algorithms transform and analyze the data

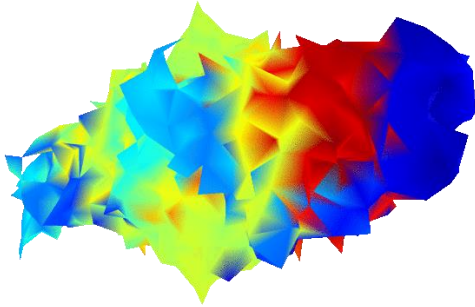


Physician Portal

Imaging results from the scan are available in a secured web portal for interpretation

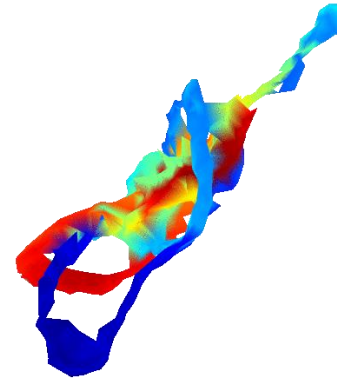
Phase Space Tomography

*Solid Appearing
Uniform in Nature*



CAD-

*Contains Arcs
Angulation in
Space*



CAD+

Stage I of the Coronary Artery Disease Learning and Algorithm Development (CADLAD) Trial

CADLAD is an ongoing prospective, multicenter, non-significant risk study sponsored by Analytics 4 Life designed to:

1

Develop machine-learned algorithms to assess the presence of CAD (defined as one or more $\geq 70\%$ stenosis, or fractional flow reserve < 0.80)

2

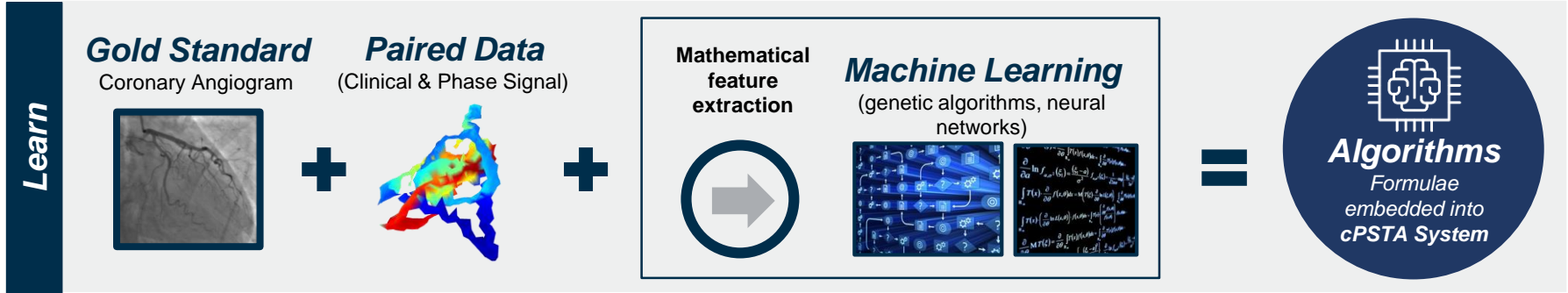
Test the accuracy of these algorithms prospectively in a verification cohort

CADLAD Study Locations



Methods

Stage I of the CADLAD Trial



The Stage I Cohort

606 phase signals were obtained from subjects at rest, just prior to angiography

Angiographic results were paired with phase signal data

A training set of 512 subjects were used for machine learning

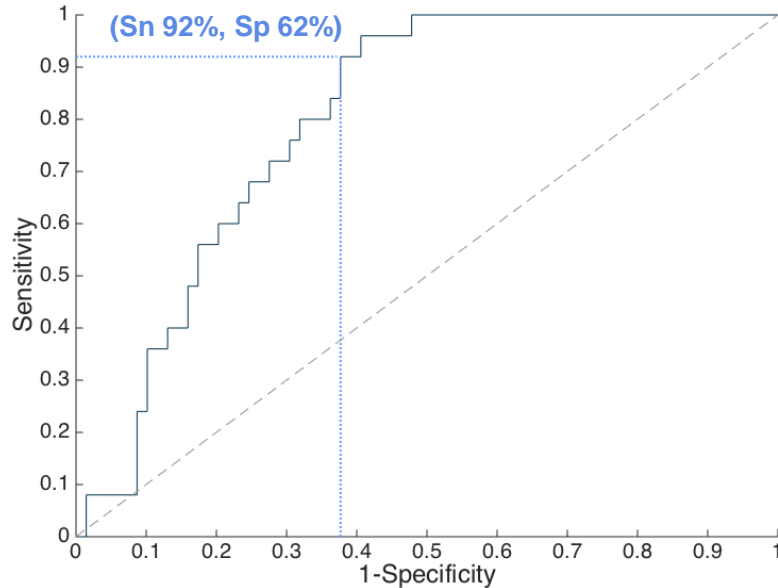
A verification set of 94 subjects was reserved for blind testing

Demographics of Population

Characteristics	Development (n=512)	Test (n=94)	p-value
Mean Age - Years (Range)	61.5 ± 10.7	59.0 ± 9.8	0.04
Male (%)	60.2%	69.1%	NS
Female (%)	39.8%	30.9%	NS
Mean BMI (Range)	31.3 ± 7.0	32.5 ± 7.6	NS
Diabetes Mellitus (%)	31.4%	35.1%	NS
Hypertension (%)	72.9%	75.5%	NS
Hypercholesterolemia/Hyperlipidemia (%)	71.3%	70.2%	NS
CAD Negative (%)	69.1%	73.4%	NS
CAD Positive (%)	30.9%	26.6%	NS

**All comparisons of p-values were greater than 0.05 except AGE which was p=0.04*

AUC-ROC Curve for cPSTA Assessment of CAD



CADLAD Stage I	
Number of subjects (total signals)	606
Number of subjects for ML Training Cohort	512
Number of subjects in Validation Cohort	94
AUC-ROC Curve	0.80

Results

CADLAD Stage I

Test	Sensitivity Range	Specificity Range
CADLAD (n=94)	92% (CI=74% to 100%)	62% (CI=51% to 74%)
Exercise SPECT ¹	73 to 92%	63 to 87%
Exercise ECG ¹	45 to 50%	85 to 90%

*** Negative Predictive Value for CADLAD was 96% (CI=85% to 100%)**

Conclusions

The findings of Stage I of the CADLAD trial demonstrate:

- Features extracted from phase signals can be employed in machine learning to develop final mathematical predictors that assess the presence of significant CAD
- Performance of the cPSTA is comparable to the most commonly employed functional test of MPI
- Acquisition of phase signals:
 - Requires no ionizing radiation or contrast
 - Requires no physiologic or pharmacologic stress
 - Requires minimal patient time
 - No safety issues were observed (no AEs in 606 procedures)
- The cPSTA System holds promise for value-based healthcare

Thank You

