

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



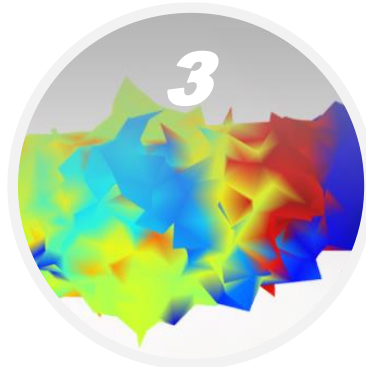
1

**cPSTA
System Scan**
The phase signals emitted by the heart are scanned while the patient is lying down



2

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



3

**Cloud
Computing**
Advanced mathematics and machine-learned algorithms transform and analyze the data

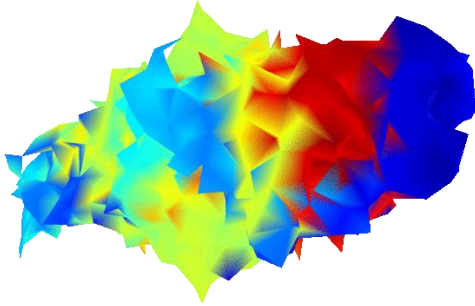


4

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

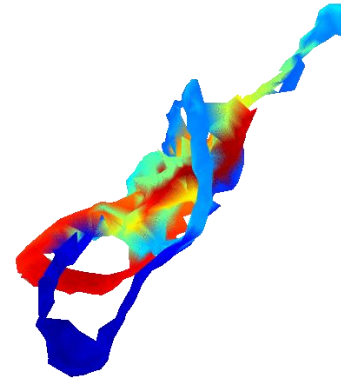
Phase Space Tomography

*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

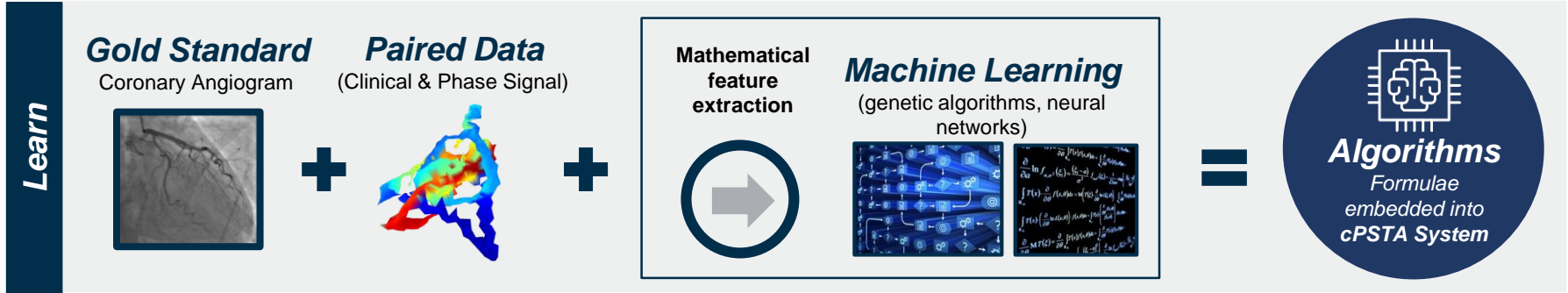
Test the accuracy of these algorithms prospectively in a verification cohort

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

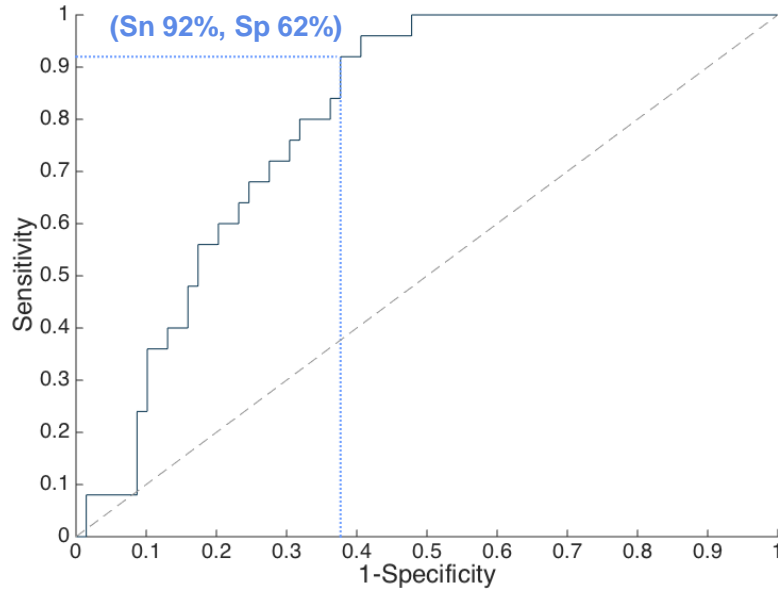
A verification set of 94 subjects was reserved for blind testing

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

