NewCardio 3D ECG Platform

for Detection of ACS

Visual3Dx™

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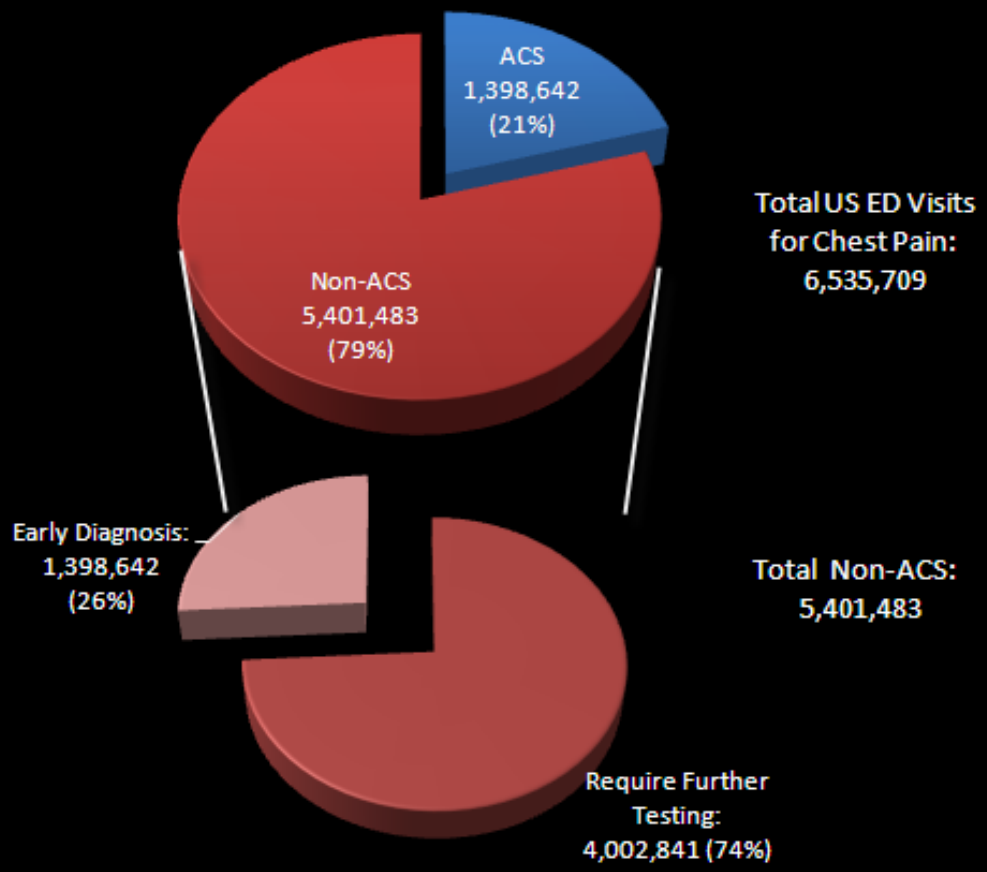
On behalf of NewCardio, Inc.

ED Evaluations of Chest Pain in the US: Results of Diagnostic Evaluation



Opportunities

- Opportunity (Non-ACS):
  - Save health care costs by decreasing the number of pts that now receive additional testing to be ruled out:
    - estimated cost savings could reach $1B/yr
- Opportunity (ACS):
  - Improve patient outcomes by decreasing the door-to-balloon time:
    - The ACC/AHA PCI guideline is for a door-to-balloon time <90 minutes in patients with STEMI
    - Per ACC/AHA estimates, this is an infrequently accomplished goal

Visual3Dx Goals in ACS

- Best 12-lead ECG human readers have an average:
  - ~50% sensitivity and
  - ~85+% specificity

- To achieve opportunities, ED physician's confidence in assessing ACS at first triage must increase

- Visual3Dx goals in ACS detection:
  - Substantial superiority in sensitivity AND
  - Non-inferior specificity

Visual3Dx Technical Approach

- Transform 12-Lead ECG input to X, Y, Z heart vector components using available algorithm, eg, Inverse Dower (ID):

  $\vec{H}$ = ID * $\vec{V}$, *where*

  $\vec{V}$ = (*I, II,* V_1-V_6), *and*

  ID = $\begin{vmatrix} .156 & -.00893 & -.173 & -.0747 & .122 & .231 & .239 & .194 \\ -.223 & .875 & .056 & -.018 & -.104 & -.0209 & .0408 & .047 \\ .0225 & .101 & -.229 & -.310 & -.246 & -.0626 & .0550 & .109 \end{vmatrix}$

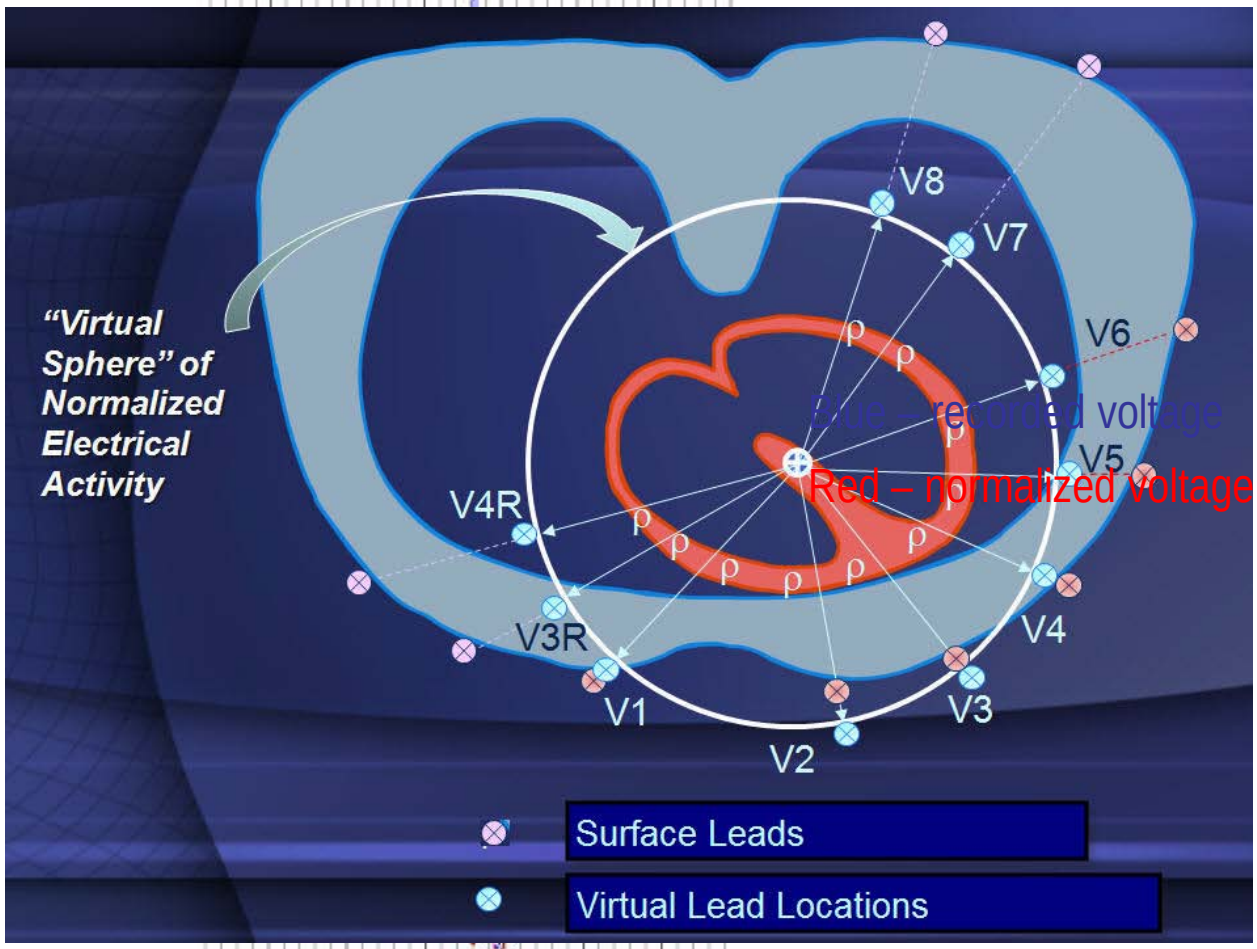
- Normalize lead vectors to equalize electrical representation from all regions of the heart
  - Calculate electrical attenuation factors ρ_i for each precordial lead (V_1-V_6)
  - Generate common attenuation factor ρ from individual ρ_i
  - Use ρ to determine time-dependent normalized voltage in any measured or virtual ECG Lead

Visual3Dx: The "Virtual Sphere"

- Use ρ to derive time-dependent voltage at any virtual lead site:

$$Vd(t) = \overrightarrow{H(t)} * \overrightarrow{Li} * \rho$$

- Can be used to generate "virtual sphere" of normalized electrical activity
- Normalized voltage can be determined for any point on the virtual sphere at any time



Visual3Dx: Results of Clinical Studies

- Visual3Dx sensitivity compared to the standard ECG in 51 patients undergoing coronary intervention
- ECGs recorded during 117 balloon occlusions (46 LAD, 34 RCA, 37 LCx).
- Results:

Site	Number	Visual3Dx			12 lead ECG			
		pos	neg	sens	pos	neg	sens	*p*
LAD	46	38	8	83%	32	14	70%	NS
RCA	34	33	1	97%	21	13	62%	<0.001
LCx	37	34	3	92%	25	12	68%	<0.001
Total	117	105	12	90%	78	39	67%	<0.001

LAD = Left Anterior Descending; RCA = Right Coronary Artery; LCx = Left Circumflex

Visual3Dx: Results of Clinical Studies

- Beth Israel Deaconess Study with N = 122 consecutive pts who:
  - presented to BIDMC ED with chest discomfort
  - were admitted to BIDMC for suspected MI
  - developed elevated cardiac troponin I levels within 48 hrs of admission
  - underwent coronary angiography within 6 hrs of admission

Visual3Dx: Results of Clinical Studies

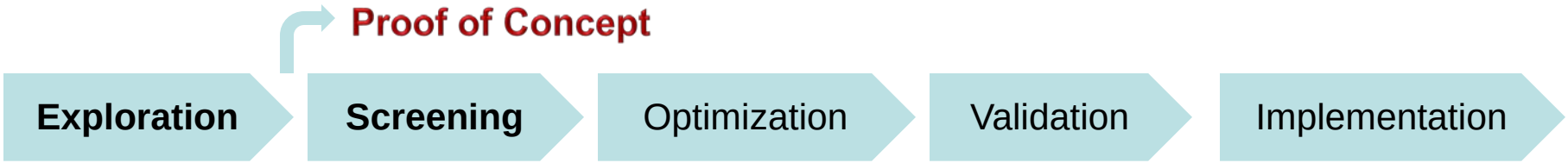
Sensitivity of Visual3Dx vs. 12-lead ECG on an artery-by-artery basis
(**Beth Israel Deaconess Study**)

Number of Positive Tests / Total Pts (%)				
	All	**LAD**	**RCA**	**LCx**
Standard 12-Lead	80/122 (66%)	30/43 (70%)	35/51 (69%)	15/28 (54%)
Visual3Dx	103/122 (84%)	35/43 (81%)	44/51 (86%)	24/28 (86%)
Relative gain in sensitivity	**+ 29%**	+ 16%	**+26%**	**+60%**
p value (V3Dx vs. 12-L ECG)	< 0.01	ns	< 0.01	< 0.001

LAD = Left Anterior Descending; RCA = Right Coronary Artery; LCx = Left Circumflex

Visual3DX: Development of New ACS Markers

- ACS: STEMI, Non-STEMI, and UA
  - Additional confounding abnormalities - LBBB, Pacing, LVH
- Markers:
  - Single 2D parameters from VM lead, 12L ECG, vector loops
  - 3D parameters
  - Repolarization Markers and Depolarization Markers
- Statistical Models



Visual3Dx Preliminary Results

- **DB1**: Emergency Department All-comers (460 pts)
  - Non-ACS = 320 pts
  - STEMI = 70 pts
  - NSTEMI = 70 pts

- **DB2**: ACS and Pseudo-ischemia dataset (238 pts)
  - 120 ACS pts
  - 118 PSDI pts – LVH, RBBB, ERS

Visual3Dx Preliminary Results

Dataset	Sens	Spec	Sens+Spec	STEMI	NSTEMI
DB1	78	84	162	85	70
DB2	87	95	182	93	68
Human reader	57	89	146	81	33