The Non-Invasive Cardiac System – Cardiac Surveyor (NICaS CS)—An Ambulatory Tool for the Diagnosis of Asymptomatic Coronary Artery Disease

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Abstract
Over half of those who succumb annually to coronary artery disease (CAD) in the US die a sudden cardiac death (SCD) before they are ever diagnosed or treated. The two main causes of these deaths are fatal arrhythmias borne by left ventricular systolic dysfunction (LVSD) associated with viable (hibernating) myocardium, and acute infarctions of silent ischemia. The common denominators of these diagnostic entities are that they are asymptomatic in their pre-clinical phase, and that they have the same therapeutic solution, which is revascularization in a timely manner. In this article we describe: a new ambulatory impedance apparatus, the Non-Invasive Cardiac System – Cardiac Surveyor (NICaS CS), to be used by the family doctor in the community to diagnose these cardiac conditions while still asymptomatic, at a very low cost; the first two case reports that led to the new discovery; and the diagnostic results of a series of tests performed with the NICaS CS on 518 people in a private clinic (at the cost of $50 each).

Keywords
Coronary artery disease, sudden cardiac death, left ventricular systolic dysfunction, ambulatory impedance apparatus, Non-Invasive Cardiac System – Cardiac Surveyor (NICaS CS)

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According to Myerburg and Costellanos, the introduction of cardiac revascularization to medicine (coronary artery bypass grafting [CABG]) almost 50 years ago led to a decline in the age-adjusted mortality from coronary artery disease (CAD), but brought no change to the fraction of coronary deaths that are sudden and unexpected. Of the 650,000 who die annually in the US of CAD, 300,000–350,000 succumb to sudden cardiac death (SCD), and another 57,000 to end-stage systolic congestive heart failure (CHF). This prognostic picture has not changed since the era before the introduction of revascularization by CABG operations in the late 1960s. With the new technology described here, the responsibility for timely diagnosis of asymptomatic CAD can be transferred from costly medical institutions to primary care physicians (PCPs) in the community. This alternative strategy of cost-effective early diagnosis will facilitate at last the completion of the revolution of revascularization that began half a century ago.

Methods
The Technology
Three consecutive models of the current technology were developed, the first being the Non-Invasive Cardiac System (NICaS). This was an impedance cardiographic (ICG) monitor for non-invasive measurement of the cardiac output (CO) and its derivatives. The electrode configuration includes one electrode at the patient’s wrist and the other at an ankle. Unlike the thoracic ICG (TIC), where the algorithm is based on the first derivatives of the impedance change (dR/dt), in the NICaS the algorithm is based on the ΔR as is. In addition, this algorithm is distinguished by the inclusion of a number of correcting coefficients:

\[
SV = \frac{\Delta R_{\text{L}} \cdot \left(\alpha + \beta K_{\omega} H F\right)}{R R_{1} \beta}
\]

where SV is the cardiac stroke volume (ml), ΔR is the resistance change during the cardiac cycle (Ω), R is the basal resistance (Ω), R1 is a corrected basal R (Ω), ρ is the blood electrical resistivity (Ω cm), L is the patient’s height (cm), Kω is a correcting factor for bodyweight, HF is the hydration factor related to the body water composition, α is the time interval (seconds) between opening of the aortic valve (the beginning of the systolic impedance change) and peak systolic value of the ΔR waveform, and \((\alpha+\beta)/\beta\) is the ratio of the systolic time plus the diastolic time divided by the diastolic time of the ΔR waveform.

A crucial character in this formula is the \(\alpha\), which is determined by the strength of the cardiac contractility (left ventricular [LV] function) and the elasticity of the arterial tree. In normal conditions, some of the energy of the LV contraction produces forward blood flow during systole, and the majority is briefly stored as potential energy in the distended arteries for the diastolic phase.
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Figure 1: The First Two Cases on Which the Granov–Goor Index Algorithm Was Designed

<table>
<thead>
<tr>
<th>Case 1 (EG)</th>
<th>Jan 16 05</th>
<th>Apr 17 05</th>
<th>May 10 06</th>
<th>May 15 06</th>
<th>May 25 06</th>
<th>May 28 06</th>
<th>Jul 11 06</th>
<th>Apr 22 07</th>
<th>Apr 14 08</th>
<th>Sept 24 09</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac index (CI)</td>
<td>1.76</td>
<td>2.13</td>
<td>1.74</td>
<td>1.71</td>
<td>CABG x 4</td>
<td>2.94</td>
<td>3.02</td>
<td>2.29</td>
<td>2.5</td>
<td>2.59</td>
</tr>
<tr>
<td>GGI (retro calculation)</td>
<td>8.41</td>
<td>8.39</td>
<td>5.63</td>
<td>6.65</td>
<td>8.21</td>
<td>8.90</td>
<td>10.23</td>
<td>9.60</td>
<td>9.46</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Case 2 (DAG)</th>
<th>Nov 17 05</th>
<th>Dec 19 05</th>
<th>Apr 25 06</th>
<th>May 28 06</th>
<th>Jun 23 06</th>
<th>Jun 25 06</th>
<th>Jul 6 06</th>
<th>Aug 6 06</th>
<th>Oct 5 06</th>
<th>Feb 11 07</th>
<th>Apr 14 08</th>
<th>Aug 31 08</th>
<th>Sep 2 09</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac index (CI)</td>
<td>3.84</td>
<td>2.71</td>
<td>2.19</td>
<td>2.13</td>
<td>Stent</td>
<td>2.75</td>
<td>2.8</td>
<td>2.25</td>
<td>2.81</td>
<td>3.04</td>
<td>3.13</td>
<td>4.00</td>
<td>3.52</td>
</tr>
<tr>
<td>GGI (retro calculation)</td>
<td>12.76</td>
<td>10.42</td>
<td>9.47</td>
<td>7.08</td>
<td>10.44</td>
<td>10.16</td>
<td>7.91</td>
<td>9.06</td>
<td>11.31</td>
<td>11.86</td>
<td>12.27</td>
<td>13.21</td>
<td></td>
</tr>
</tbody>
</table>

CI = cardiac index; GGI = Granov–Goor Index. Any GGI >11.0 is recorded as 11.0.

This original NICaS monitor was upgraded to the NICaS 2004 Slim model for two reasons: to introduce to medicine a cost-effective, ambulatory tool that can be used by any doctor, anywhere, in the diagnosis, prevention, and management of systolic CHF; and to upgrade the accuracy and reliability of the cardiac output (CO)/cardiac index (CI) results and their derivatives. Comparison of the results of the NICaS Slim 2004 (approved by the US Food and Drug Administration [FDA] in July 2007) versus the other ICG technologies reveals a limit of agreement (two standard deviations [2SD]) between the NICaS 2004 and gold standard thermodilution (TD) of ±1.0l/minute⁻¹ (a 20% disparity), whereas the limit of agreement (2SD) of the BioZ versus TD is ±2.2l/minute⁻¹ (a 44% disparity), and the 2SD limit of agreement of whole body electrical bioimpedance (WBEB) versus TD is ±1.5l/minute⁻¹ (a 34% disparity).

Cardiac Index as a Presenting Sign of Asymptomatic Left Ventricular Systolic Dysfunction

The evolution of the final model, the NICaS CS (Cardiac Surveyor), was circumstantial. The NICaS CS has been approved by the US Food and Drug Administration (FDA) 510(K) No. K080941 (July 2009). During the developmental progress of the NICaS 2004 Slim in 2005–2006, the interim variants of the technology were tested on three company employees, two of whom then underwent revascularization.

Case 1

This was a 54-year-old male with insulin-dependent diabetes and old Q-wave in leads III and AVF, who was otherwise asymptomatic. In his first test, a subnormal CI was noted (see Figure 1). After the fourth study, elective coronary angiography was performed, and Case 1 underwent urgent CABG x 4 operation. Post-operatively, Case 1 noticed a significant improvement in his physical condition, and his CI stabilized at around 2.5l/minute⁻¹/m².

Case 2

This was a 73-year-old asymptomatic male, eight years post-CABG (x 2). During the first six months of investigative testing, Case 2 underwent four NICaS tests, which revealed a gradual decline in his CI from 3.8 to 2.13l/minute⁻¹/m² (see Figure 1). As he was asymptomatic, the decline in the CI was attributed to a technical incompetence of the NICaS. Frustrated, and preparing to abandon the entire project, Case 2 suddenly and unexpectedly developed a stormy clinical picture of acute myocardial infarction (MI). A profound ST-segment elevation in leads II, III, AVF, and RV (V3R, V4R), and reciprocal ST depression in leads I and AVL, were observed on electrocardiogram (ECG) performed in the ambulance. During the emergent percutaneous coronary intervention (PCI), a nearly
occlusive thrombus of the orifice of the dominant right coronary artery, which perfused 80% of the entire heart, was aspirated, followed by stenting.

After returning to work, it was incidentally noticed that both cases revealed a gradual improvement in their CI results (see Figure 1), indicating that both had had asymptomatic left ventricular systolic dysfunction (ALVSD) that was associated with the regenerative reserve of a viable (hibernating) myocardium.10–14

The Impedance Algorithm for Assessment of Asymptomatic Left Ventricular Systolic Dysfunction

At that time, five ICG algorithms were recognized for non-invasive assessment of LVSD. All were based on systolic time intervals (STI), including the Heather index,11 velocity index,12 acceleration index, and the two systolic time interval (STI) indices.13,14 As the correlation coefficient between these algorithms and echocardiographic left ventricular ejection fraction (LVEF) ranged between 0.463 and 0.55 (p<0.001),18–20 the need was felt for a more specific algorithm for the assessment of ALVSD conditions in the general population 24 and 42% of those in CAD25 are associated with a viable (hibernating) myocardium, a positive GGI result obliges further diagnostic work-up to determine viability.

Diagnosis of ALVSD: a GGI <10.0 raises suspicion of ALVSD. Since 30% of ALVSD conditions in the general population and 42% of those in CAD are associated with a viable (hibernating) myocardium, a positive GGI result obliges further diagnostic work-up to determine viability.

Conclusions

An ambulatory cardiac diagnostic apparatus, the NICaS CS, is available for incorporation in the family doctor’s personal kit. This apparatus is ideal for the management of CHF.

Events of rising TPR and reduction in CI during monitoring of the CO/CI and their derivatives during night sleep (at home),19 as well as during mental stress tests,27 are indicative of silent ischemia and risk of SCD.
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