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Secretoneurin ELISA

the next big thing?

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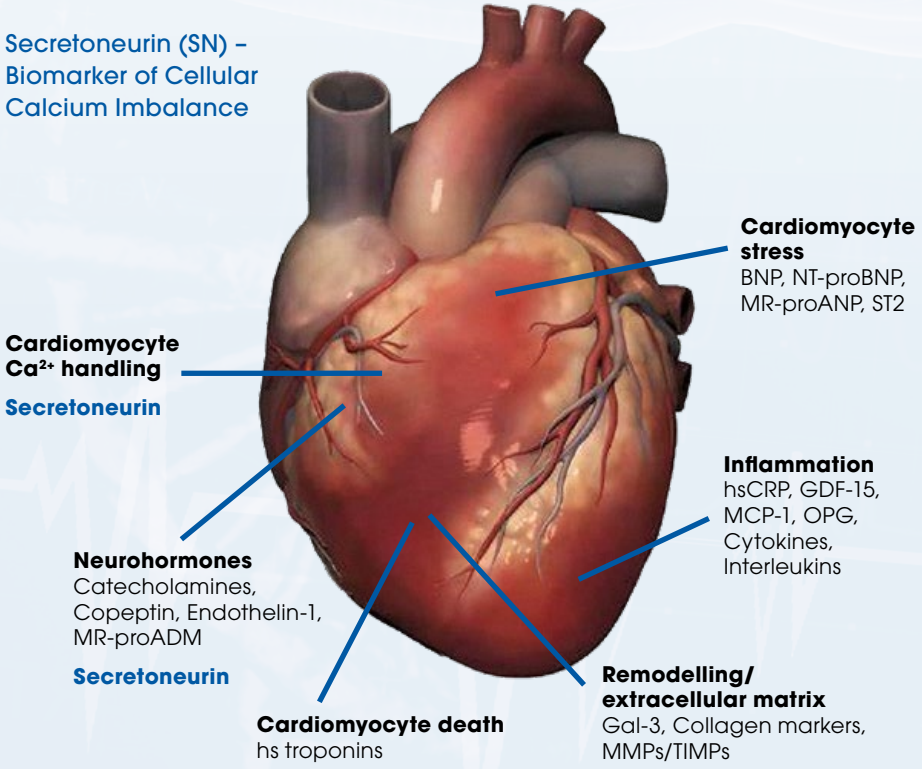
Secretoneurin the next big thing?

Novel cardiovascular biomarker modulating hearts calcium regulation

Secretoneurin (SN) is a 33-amino acid peptide and the biological active fragment of secretogranin II[1], a protein in the granin family[2]. SN is produced by neuroendocrine- and heart muscle cells and is detectable in the blood stream[3].

SN is associated with biological processes linked to heart cell calcium handling, a key mechanism in the regulation of heart rhythm[1,2]. This in contrast to other commonly used biomarkers such as cardiac troponins and N-terminal proB-type natriuretic peptide (NT-proBNP). This unique biological function may explain why SN has been shown to be an independent and strong predictor of mortality in all major patient cohorts tested, including patients with chronic heart failure, ventricular arrhythmia, acute heart failure, and acute respiratory failure patients with CVD and severe sepsis[3,4,5,6].



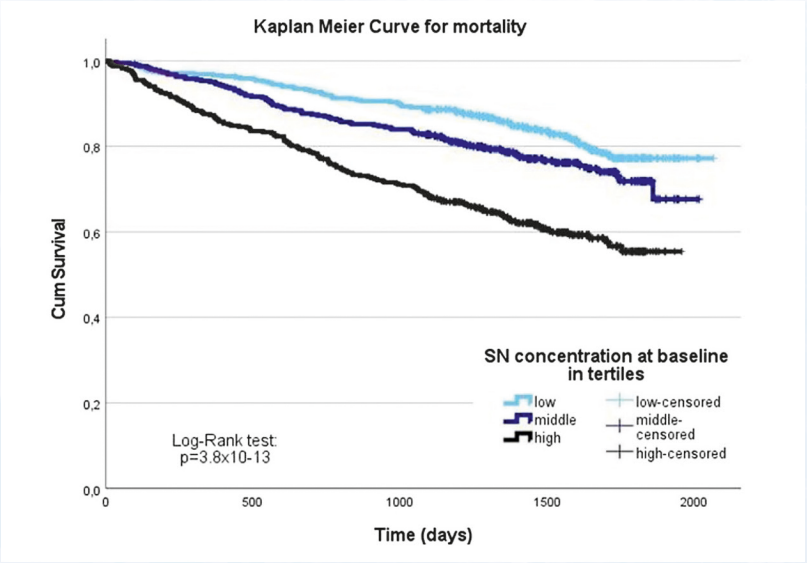
Diagnostic/prognostic evidence for the value of SN[6,7]

The Italien GISSI (Gruppo Italiano per lo Studio della Sopravvivenza nell'Insufficienza Cardiaca)-Heart Failure (HF) study demonstrated that SN provided strong prognostic information concerning the end-point death from all causes. This association remained statistically significant after adjustment for other known risk factors and risk markers, including age, sex, indices of the heart's pumping function (LVEF) and indices of renal function.

The GISSI-HF study included patients with chronic heart failure with both reduced and preserved ejection fraction, suggesting that SN may predict death in both patient groups.

In other studies of patients with acute heart failure, including after cardiac arrest, circulating SN concentrations are also increased in proportion with mortality risk.

GISSI-Heart Failure trail[6]
SN at randomization and mortality, n=1224



The prognostic information obtained from SN was independent of that obtained from BNP, suggesting that these two biomarkers provide complementary information

Existing technologies to achieve HF risk stratification and their limits

Technology		HF risk stratification potential	
ECG (Electrical impulses)		Low	Arrhythmia is only detected if happing during the live scan
Echocardiogram (Heart function, blood flow)		Low	LVEF is the standard used in guidelines, but has limitations
IVD tests / Biomarkers	**BNP**	Medium	Signals Myocyte stretch, not arrhythmia
	NT-proBNP	Medium	Signals Myocyte stretch, not arrhythmia
	Troponin	Medium	Signals Myocyte damage, not arrhythmia
	Gal-3	Medium	Signals inflammation and fibrosis, not arrhythmia
	ST2	Medium	Signals cardiac tissue fibrosis. Predicts higher HF mortality, but not arrhythmia
	Secretoneurin (SN)	High	Ca^{2+} imbalance → Arrhythmia

"Prognostication in chronic HF patients has become increasingly important. (…) With the progressive improvement in HF therapeutic management and resulting decrease in mortality new, more precise, and thereby more clinically useful, prognostic tools are needed."

Aldo P. Maggioni MD and colleagues, EURObservational Research Program-me, ESC, as a conclusion to the research of large-scale study on performance of prognostic risk scores for HF[8]

SN's role in heart function[7]

Cardiomyocyte Ca^{2+} imbalance is at the core of most triggered arrhythmias in CVD. The effects of SN on myocardial Ca^{2+}-handling seem to suggest that the gene upregulation and increased protein production observed during myocardial dysfunction are beneficial and likely reflect a compensatory mechanism.

Accordingly, SN is not only a very promising cardiovascular biomarker but also a direct cardiomyocyte Ca^{2+} regulator with therapeutic potential.

Circulating SN-concentrations, and change in circulating SN concentrations, are being evaluated as tool for prediction of serious ventricular arrhythmias

Ongoing clinical trials of patients with ICDs include the SMASH-1 (Scandinavian Multicenter Study to AdvanceRisk Stratification in Heart Disease – Ventricular Arrhythmias) and the MADIT-CRT (Multicenter Automatic Defibrillator Implantation with Cardiac Resynchronization Therapy) studies.

Several clinical trials now support the use of SN as a complementary biomarker to troponins, BNP and NT-proBNP which currently are the most frequently used biomarkers of heart failure development

Secretoneurin ELISA
Cat. No. 100-01

The CardiNor Secretoneurin ELISA Assay is an in vitro diagnostic test designed to detect and quantify the level of human secretoneurin (SN) in serum and plasma. It is indicated to be used in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with heart failure.
The test is intended to be used by professionals.

Principle of the assay

The CardiNor Secretoneurin ELISA Assay is a homogenous Immunoassay.

Technology	: ELISA
Kit size	: 96
Sample Type	: serum, plasma
Sample pretreatment	: 1:10 diluted
Samply volume	: 100 µl
Standard range	: 10–250 pmol/L
Incubation time	: 2 h 10 min
Substrate	: TMB 450 nm
Internal Controls	: 2
Regulatory Status	: CE

Two secretoneurin-specific sheep monoclonal antibodies (MABs) are used in the assay. One MAB is biotinylated and the second is HRP-conjugated. The biotinylated antibody is added to the wells of a streptavidin coated microtiter plate. After washing, diluted calibrators, controls and samples are added, and secretoneurin present is bound to the immobilized antibody. After incubation of samples the wells are washed to remove unbound sample material, and the HRP-conjugated antibody is added. After incubation and wash the TMB substrate is added. The blue colour developed is directly proportional to the amount of secretoneurin present in the calibrators, controls, and samples. The stop solution changes the colour from blue to yellow, and the intensity of the colour is measured in a microtiter plate reader.

The analytical performance studies for human Secretoneurin ELISA were performed according to the appropriate CLSI guidelines:

- LoQ: 7.6 pmol/L
- LoD: 5.1 pmol/L
- Linearity: 11.8–299.2 pmol/L
- No false low secretoneurin results were obsereved for serum samples up to 5000 pmol/L
- Intra-assay precision: 2.7–4.6% CV
- Inter-assay precision: 5.3–8.7% CV

References

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Statement from the General Manager

"The CardiNor's Secretoneurin ELISA is an excellent visionary contribution to the field of cardiovascular diagnostics. We are convinced that our customers in the different supplied territories will be offered an excellent and innovative unique diagnostic tool in research and routine",
believes Dr. Arndt Stüber, General Manager of Demeditec.

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