

## BSP: HyperQ™ Newsletter

Winter 2016

### HyperQ in the clinic: new findings, broader clinical application

#### [HyperQ Stress Test: a breakthrough in diagnostic ergometry](#)

Recent publications substantiate HyperQ's unprecedented accuracy in diagnosing ischemic heart disease using stress testing protocols. A study titled "*High-frequency QRS analysis compared to conventional ST-segment analysis in patients with chest pain and normal ECG referred for exercise tolerance test*", by Conti et al., was recently published in *Cardiology Journal* ([Cardiol J. 2015;22\(2\):141-9](#)).

The study compared the diagnostic value of conventional exercise ECG with high-frequency HyperQ exercise test, in 337 patients who presented to the ED with chest pain but with normal ECG, troponin, and echocardiography. In this challenging population, the results demonstrated higher sensitivity of HyperQ when compared to exercise test (63% vs. 26%;  $p < 0.05$ ), and incremental diagnostic value of HyperQ (area under ROC curve: 0.655, 95% CI 0.60-0.71). The researchers concluded that in patients with chest pain submitted to exercise ECG, the novel exercise HyperQ analysis shows a valuable incremental diagnostic value over ST-segment analysis.



A pilot study by Popovic et al., presented at the 2015 ESC congress in London (*European H J. (2015), 36, 88*), compared the stress-HyperQ analysis to conventional ST-segment analysis, in patients with chest pain that have undergone percutaneous coronary intervention (PCI).

The study prospectively tested the diagnostic performance of exercise ECG and exercise HyperQ analysis in patients already treated with PCI, referred to angiography again because of chest pain.

The results validated both HyperQ's increased specificity compared with conventional stress test (74% vs. 50%) and its increased accuracy (72% vs. 58%). A notable finding was that the number of ECG leads with ischemic HyperQ response correlated with the severity of CAD.

#### [HyperQ-based Ischemia monitoring](#)

Accumulating clinical evidence validates HyperQ's efficiency in monitoring cardiac ischemia and alerting on ischemic events.

A study performed in collaboration with the Tel Aviv University, and presented at the International Dead Sea Symposium (2014), assessed the potential usefulness of HyperQ monitoring in patients with chest pain and suspected acute coronary syndrome (ACS). Continuous HyperQ monitoring was found to be feasible in patients with chest pain and suspected ACS. It may provide sensitive indication of myocardial ischemia in these patients, and may aid in their risk stratification and management.



Another study, done at the Soroka University Medical Center in Israel, demonstrated the potential usefulness of HyperQ analysis in diagnosing myocardial ischemia in patients with acute myocardial ischemia (AMI) before and following reperfusion.

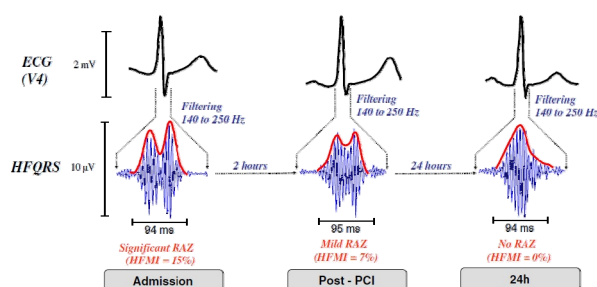
The researchers analyzed five-minute-long HyperQ recordings from patients with AMI upon

their admission to the intensive coronary care unit (ICCU), following coronary revascularization and after additional 24 hours.

They concluded that HyperQ analysis in patients with AMI provides information about the existence and severity of myocardial ischemia, and that HyperQ analysis may aid in risk stratification of patients with suspected myocardial ischemia, complementarily to conventional ECG.



A publication in the Journal of Electrocardiology, titled “Quantifying QRS changes during myocardial ischemia: Insights from high frequency electrocardiography” (JEC 2014;47(4):505-511), reviewed the value of HyperQ analysis in cases of demand ischemia and supply ischemia, as reported in several recent studies.



When reviewed in the context of supply ischemia, HyperQ ischemia index, based on high-frequency QRS morphology index, was found to be higher in patients with acute coronary syndrome (ACS), compared to non-ischemic, with good sensitivity in patients without ST elevation. Consequently, it may provide a novel solution for the improved diagnosis and monitoring of myocardial ischemia.



### HyperQ integrated in an expanding line of ECG workstations by Schiller AG

HyperQ solution suite has been natively integrated within the recently announced high-end electrocardiograph **AT-170** by Schiller AG.

The AT-170, a multi-use workstation of compact size, joins Schiller's existing leading products of the Cardiovit line, in offering HyperQ recording and analysis capabilities at both resting and stress-test conditions.

### New technologies, new patents

#### Implantable HyperQ devices

In 2015, BSP's patent relating to implantable HyperQ solutions was granted. The patent is named “*Detection and Monitoring Using High Frequency Electrogram Analysis*” (US Pat. No. 9167980). It covers an implantable unit for measuring and analyzing HF recordings from internal cardiac electrodes in various scenarios, with reference to different optimization schemes and diagnostic algorithms.

Among the clinical implementations covered by the patent are monitoring for cardiac ischemia, alert in cases of ischemic episodes and in cases of angina. This patent is an important component in building BSP's IP assets and technological validations towards its implantable products line.

#### HyperQ monitoring solutions

Another patent granted in the US, named “*Apparatus and method for detecting myocardial ischemia using analysis of high frequency components of an electrocardiogram*” (US Pat. No. 8626275), covers HyperQ based ischemia detection solution at resting condition.

The patent protects BSP's technology for detecting and analyzing morphological changes

in the HyperQ signal, and the device and algorithms for specific evaluation and monitoring of ischemic burden. Clinical applications referred to are alerts in cases of acute coronary syndromes and transient ischemic episodes, detection of ischemic events and diagnostic indications for myocardial infarction.

The patent supports and substantiates BSP's evolving line of non-stress HyperQ products and monitoring solutions.

**Wider horizons for HyperQ with HORIZON 2020: EU's research and innovation program**

**HyperQTotal project: 1<sup>st</sup> phase approved**

Horizon 2020 is the biggest EU Research and Innovation program ever, with nearly €80 billion of funding available over 7 years (2014 to 2020). In 2015, BSP submitted a proposal and grant request for a project titled "HyperQTotal", under the section "development of diagnostic medical devices" of the program, with a planned budget of €3.5 million.

The aim of the project is to develop the second generation of HyperQ solutions line, providing higher rates of sensitivity and clinical accuracy, and further reducing unnecessary invasive and radioactive procedures.

The first phase of the project, which includes feasibility studies and detailed work plans, was approved in December 2015, and an initial funding of €50,000 was granted in order to complete this first stage.

**ECGuard™: BSP's mHealth solution**

**HyperQ's home application**

A conceptual design of a HyperQ-based solution intended for personalized mobile

platforms has been prepared and presented to potential collaborators.

The ECGuard™ will use a combination of traditional ECG analysis, together with BSP's unique HyperQ evaluation technology, to provide a highly effective tool letting users and their caregivers assess heart performance, perform on-demand ECG tests with high accuracy and evaluate cardiac wellbeing, at rest or during exercise, anytime, anywhere.

ECGuard's recording and evaluation may be performed during routine exercise training, creating a unique stress-test environment without the need for visiting a heart clinic. Routine use of the system may provide an on-going reference for effective evaluation of heart condition, while offering critical indication in acute conditions, for immediate alert.

ECGuard's recordings may be uploaded to the cloud, stored, analyzed and viewed remotely by clinicians, for professional real-time or off-line evaluation and advice.

**Implantable HyperQ solution: preclinical evaluation**

An effort to integrate BSP's HyperQ technology into existing implantable cardiac solutions is currently underway. A notable scientific advisory committee was recruited in order to support this effort, including Dr. Douglas weaver, Dr. Hani Sabbah, and Dr. Michael Gibson.

In 2015 BSP embarked on two sets of animal studies: an acute ischemia study, where the implantable HyperQ technology is tested in anesthetized animals, and a chronic ischemia study, in which long-term testing of the technology is performed on conscious animals.

Results and conclusions gained in these studies are expected to boost BSP's endeavors in the implantable solutions R&D front.