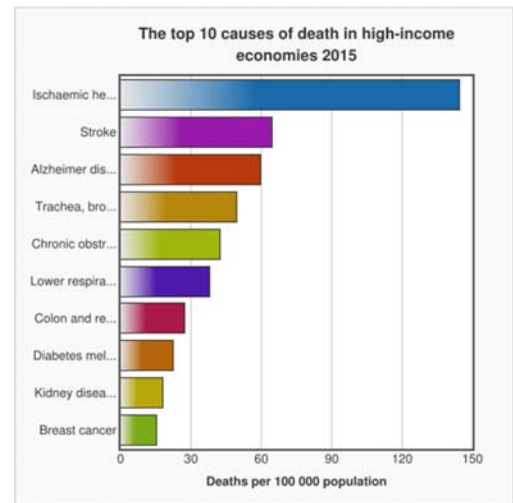
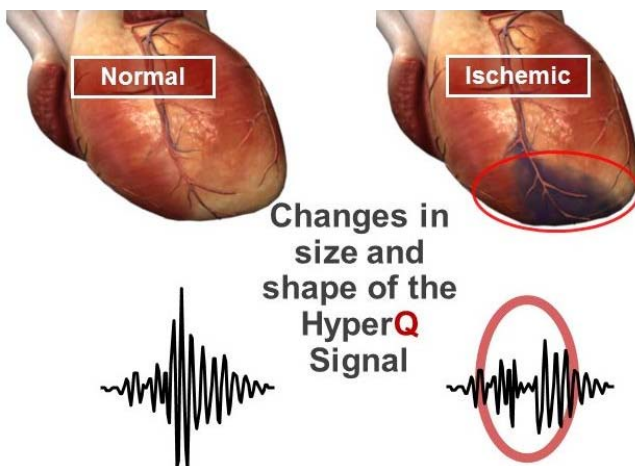


The Problem

Ischemic heart disease (IHD) is at the top of the list of causes of death by the World Health Organization. In developed countries the problem is even more pronounced. It is not only lethal, it is also one of the largest expenses in healthcare with an estimated cost of \$182 B in the US in 2015. Unfortunately, symptoms of IHD such as shortness of breath, chest pain, fatigue, etc. are not uncommon. Thus, millions of patients are seeking medical help, but the vast majority do not have IHD. The challenge is to find those patients that are at risk and to prescribe further tests and treatment. It is important to note that once diagnosed, treatment and monitoring of IHD patients significantly reduce morbidity and mortality. Stress ECG tests have been the “gatekeeper” for decades and are still the most common tests today. But in recent years it has become clear that these tests are missing most of the patients with sensitivity reported by the European Society of Cardiology to be 45%-50%!



For lack of better options, patients are sent for expensive tests that often carry some risks associated with radiation - nuclear imaging and CT angiography are common examples. Recent studies have shown that 90% or more of these patients have a negative result, i.e., almost all of these patients do not have IHD. This is raising questions in the cardiology community about the “appropriate use” criteria. On the other hand, patients considered to be “low risk” are often sent home without any tests since the risks and costs of imaging tests are not deemed suitable. While this may be a sound decision by the healthcare organizations, patients who do not feel well and know that their chest pain may be related to an impending heart attack, are not relieved when they are told to wait for their condition to deteriorate before they are prescribed any specific diagnostic tests.



The Solution

BSP (TASE: BSP) has developed HyperQ – a breakthrough in signal processing of ECG signals based on decades of scientific research. HyperQ is using high frequency signals from the QRS complex of the ECG (HFQRS) in order to accurately detect ischemia. The first commercial product of the HyperQ technology, which is FDA approved and CE marked, is HyperQ Stress. By

analyzing the HFQRS of an ordinary exercise ECG test, the clinician can now obtain much more accurate results – typically the sensitivity increases from around 40% to around 70% almost doubling the number of patients with IHD who are correctly diagnosed! In fact, the actual impact of HyperQ is much greater

since the exercise ECG test is unchanged. Thus, all of the data from the original test is still available and these are essentially two tests for the price of one.

Several clinical studies of HyperQ Stress covering thousands of patients have proven the superior accuracy in diagnosing ischemia as well as its practical implementation in the setting of an ordinary stress test. In 2013 the American Heart Association included HFQRS in its statement on exercise standards for testing pointing out that it has been “found to have useful test performance for detection of coronary artery disease”. The HyperQ software is designed to work with almost any modern stress ECG device and requires only little or no modifications to the device. The HyperQ is protected by 13 patents and 4 patent applications and already built into the advanced line of ECG devices by the leading Swiss manufacturer Schiller AG and is sold to Schiller’s customers worldwide.

The Market

There are currently about 40 million stress ECG tests performed annually around the world. In the US there are about 6 million such tests every year, but there are many other diagnostic tests for IHD. A study in 2014 showed that patients referred for stress tests all across the US were mostly referred for nuclear imaging (almost 70%) and the rest for stress echo (about 20%) or stress ECG (about 10%). An accurate stress ECG test such as HyperQ not only has the potential to win the stress ECG market but also to take some of the patients that are currently referred to the much more expensive imaging tests. A study by BSP has shown annual potential savings of \$1.2 B in the US alone due to reduction in unnecessary imaging tests, which today are mostly prescribed to healthy patients.

Competitors

There are two main categories of competitors to the HyperQ Stress technology: ECG based and imaging tests. Conventional stress ECG suffers from inherent lack of accuracy. There are several software products for interpreting ECG, mostly for inexperienced users. These do not improve the accuracy but rather help users who are not cardiologists to obtain results that are on par with cardiologists. Some research labs and startup companies are promoting advanced interpretations of ECG signals, but there is not a single one with a significant body of evidence based on blinded clinical trials and thousands of patients such as HyperQ. Imaging tests are considerably more expensive than exercise ECG and often have associated risks. Their proliferation can be attributed in part to the lack of a “gatekeeper” and their use is already raising doubts regarding the appropriate use of such modalities in modern healthcare systems.

Business model

In the preliminary phase, BSP relies on sales of HyperQ Stress licenses for ECG devices. The principal short term goals are gaining clinical recognition by cardiologists and ECG manufacturers and ramping up sales. After securing reimbursement codes, the company intends to shift to a “pay-per-test” model where HyperQ will be offered as a Software-as-a-Service. This will open a potential market of \$1 B in worldwide sales.