Spotting AF

– STOPPING STROKE

Zenicor

Stroke claims lives

In Europe, someone has a stroke every 20 seconds. It's the disease that gives rise to the most days of care at European hospitals and is estimated to cost society around EUR 90 billion a year.

Around 1.5 million people in Europe are affected each year, with around 20 percent of these expected to die and around 30 percent being left with serious disabilities.

Many are forced to live with emotional, cognitive and motor impairments and are unable to live an independent life without a great deal of help from society. The need for long-term rehabilitation and care is extensive and may continue for the rest of the person's life.

Stroke is one of our most widespread diseases, affecting many more people than the stroke victims themselves – including family, friends and colleagues.

Those particularly at risk are patients with atrial fibrillation, around 11 million people in Europe. A further 5 million are thought to suffer from atrial fibrillation without being aware of it.

There are effective methods to prevent stroke

Atrial fibrillation is costly for society. The costs for e.g. care, sickness absence (for both companies and society at large), disabled transport services and medication amounts to around EUR 35 billion.

People with atrial fibrillation are substantially undertreated, with around half not receiving the treatment they need.

" Each stroke that can be prevented avoids suffering and care costs. Through screening, we could halve the number of strokes caused by atrial fibrillation. We're talking savings of billions of euro. "

Mårten Rosenqvist, Professor of Medicine at Karolinska Institutet, Stockholm

It doesn't have to be like that. Today, there are effective methods and treatment options for preventing stroke. Through a few simple measures, thousands of lives could be saved and human suffering prevented.

In close collaboration with researchers, the Swedish company Zenicor Medical Systems has developed a thumb-ECG, an effective method of diagnosing people with atrial fibrillation. These individuals are in the risk zone and need treatment to avoid being afflicted by stroke.

A solution benefiting the many

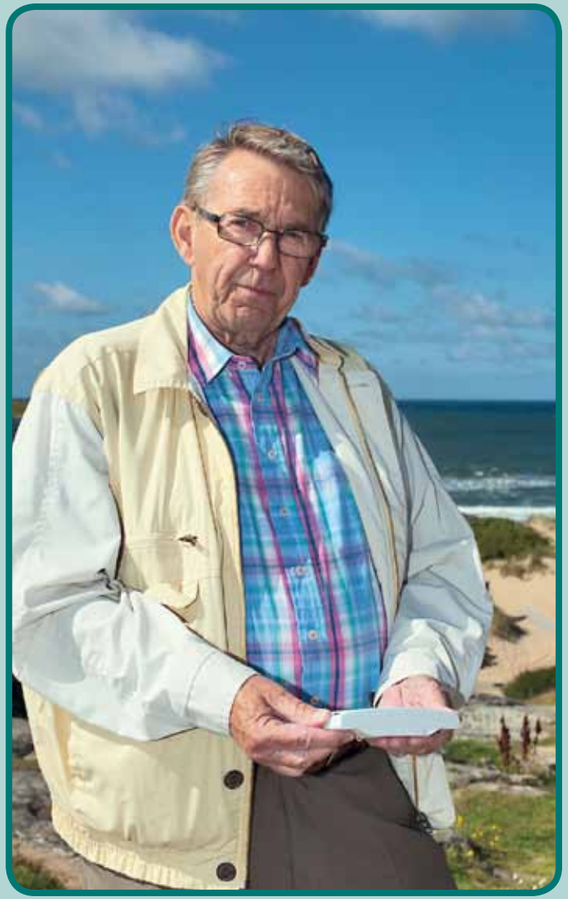
The thumb-ECG is a Swedish medical technology innovation that enables remote ECG readings. Patients can themselves record their ECG, wherever they are. The reading is sent automatically to the care provider for analysis via a built-in wireless mobile connection.

The method meets all the criteria set by the World Health Organization (WHO) to justify screening. It is cost-effective and has been evaluated in a number of scientific studies.

Long-term recording using thumb-ECG paid off

For several years, Rolf Johnsson had struggled with heart palpitations. He could suddenly wake up in the middle of the night and feel his heart racing, an experience that was both frightening and anxiety-ridden. Despite repeated hospital examinations, nothing abnormal was found.

It wasn't until Rolf tried recording his heart activity over a longer period using a thumb-ECG that his doctor discovered he was suffering from atrial fibrillation, one of the most common causes of stroke.



Terrifying experience

The heart normally beats 50 to 100 times a minute in adults. If the person is worried, under stress or has exerted themselves physically, the heart beats faster. But Rolf's heart could suddenly start to beat violently for no particular reason.

"It all started a few years ago. Having an experience like that is really tough, and also terrifying. Sometimes it helps if I lie down and rest for a while – my heart rate returns to normal again after about 20 minutes. But sometimes, it hasn't helped – at worst, the palpitations have lasted up to two hours."

On some occasions, Rolf has been forced to seek acute help and been taken to hospital by ambulance. There, while waiting for the doctor, his pulse has suddenly gone down and his heart rate returned to normal. The last time it happened, Rolf was sent home and told that he didn't need to contact his healthcare provider if it happened again.

"I thought that was a very strange thing to say – I felt scared and unsafe, and thought that there must be something wrong with me."

Despite being examined using a 24-hour ECG, the doctor could not find anything wrong with Rolf. Nor did recording

his heart activity over a longer period provide any signs of a deviation.

Thanks to a tip, he found out about a research study at the hospital in Halmstad, Sweden. All residents aged between 75 and 76 in Halmstad municipality were given the chance to take part in a screening programme, with the aim of detecting atrial fibrillation.

"I'm glad I was included in the study. Using a handy little device that takes an ECG using the thumbs, I could record my heart activity myself over a two-week period and have the results analysed remotely by a cardiologist. It turned out that there was a slight deviation, so I was asked to carry on with the measurements for another two weeks."

During these two weeks, it happened again. Rolf's heart was racing, and the palpitations woke him up. He quickly got out his thumb-ECG to measure his heart function. This time, the doctor was finally able to confirm that Rolf suffered from atrial fibrillation, one of the most common disruptions to the heart's rhythm and the underlying cause of Rolf's palpitations.

"I'd been going around with atrial fibrillation without even knowing it, and I wasn't aware either that I had a greater risk of having a stroke. I'm now being treated with medication to reduce this risk, and of course, this feels great. I wish more people had the chance to take ECG measurements over a longer period. If I hadn't been accepted onto the study, maybe my atrial fibrillation would never have been discovered," says Rolf.

" I'd been going around with atrial fibrillation without even knowing it, and I wasn't aware either that I had a greater risk of having a stroke. I'm now being treated with medication to reduce this risk, and of course, this feels great. "

ATRIAL FIBRILLATION: THE FACTS

- Atrial fibrillation is a disorder in the heart's rhythm that involves the atrium contracting very rapidly and out of sync with the ventricular chambers. The heart is forced to work much harder and less efficiently than normal.
- Atrial fibrillation involves a deterioration in heart function and a greater risk of forming blood clots that are circulated in the body via the blood vessels, which may lead to stroke.
- The risk of premature death is significantly increased due to an increased occurrence of cardiac arrest, heart failure and stroke.
- If atrial fibrillation is detected and treated in time, stroke can be prevented in 50 to 70 percent of cases.
- It is the most common form of arrhythmia and occurs in around two to three percent of the population.
- To prevent strokes, many patients with atrial fibrillation are treated with medication that reduces the coagulation ability of the blood, known as anticoagulants.

Source: Swedish National Board of Health and Welfare

Had atrial fibrillation without knowing it

Stina Ringman is one of many hundreds of thousands of Swedes suffering from atrial fibrillation. She doesn't know how long she's had an abnormal heart rhythm. It wasn't until she was 75 and was called in for an examination that the abnormality was detected. Today, she takes anticoagulants and goes for regular check-ups.

Able to take daily measurements at home

Stina Ringman was surprised when she found out she suffered from atrial fibrillation. She had never experienced any of the symptoms that are otherwise common: palpitations, irregular heart rhythm, shortness of breath, swollen legs or dizziness.

"I was given the chance to use a thumb-ECG for two weeks. I was loaned equipment by my healthcare provider and was able to take daily measurements at home. It was quick and extremely easy compared to having to go to the hospital at regular intervals to take an ECG."

Why she should suffer from atrial fibrillation is something of a mystery. According to her, she lives a healthy life, doesn't smoke, isn't overweight, eats a balanced, healthy diet and takes long walks every day.

The causes of atrial fibrillation have not been entirely determined. However, research shows that there is a strong link between atrial fibrillation and other cardiovascular diseases such as stroke, angina, high blood pressure and heart failure. Obesity, sleep apnoea and genetic factors may also lie behind abnormalities in heart rhythm. Today, Stina is being treated with warfarin, an anticoagulant that lessens the risk of blood clots and stroke.

"I'm glad that I was called to the hospital and got the chance to use a thumb-ECG; I'm afraid that the fibrillation would not have been detected otherwise," she says.

What is a thumb-ECG?

There are several different methods for diagnosing abnormal heart rhythm, such as atrial fibrillation. Usually, an appointment is made by the healthcare provider to take an ECG. However, a longer process of recording is sometimes preferred, and a digital ECG recorder is then used instead. But this method is long-winded and requires the patient to be equipped with ECG cables and electrodes. There is also a great risk that any deviation will be overlooked, as ECGs are only taken over a few days.

Today, this process can be performed much more simply, reliably and cost-effectively using a thumb-ECG. The method was developed by Zenicor Medical Systems in collaboration with Swedish researchers.

Wireless transfer of ECG data

Using Zenicor's thumb-ECG, patients can themselves record their ECG data using a small, hand-held device that fits in a handbag or pocket – regardless of where they are at the time. By pressing a button and then placing both thumbs on the device for around 30 seconds, an ECG reading can be sent wirelessly via the mobile network to the healthcare provider. The ease of use of the device means that several different patient groups can use the thumb-ECG, including children and the elderly.

The advantage of the thumb-ECG compared to other methods is that it allows for longer periods of investigation. It has also been proven that the thumb-ECG offers a greater ability to diagnose heart rhythm abnormalities than other methods and it is more reliable.

Zenicor Medical Systems was founded in 2003 and is now one of Sweden's leading medtech companies in the field of remote cardiological diagnostics. Thumb-ECGs are used for diagnosing and monitoring heart patients at around 150 hospital clinics in the Nordic region.
In 2011 the company was designated 'Medtech Company of the Year' by industry journal Medtech Magazine, along with the organisations Leading Healthcare and Invest Sweden.

Screening reduces suffering and costs

Having atrial fibrillation means that you also have a five times greater risk of having a stroke. Stroke is the third most common cause of death after heart attack and cancer, and the most common cause of physical, emotional and cognitive disability in adults.

Life changes radically after a stroke. For those stroke victims who survive, the way back is long and arduous. Many of them never regain their former state of health and are forced to live with severe disabilities and a poorer quality of life for the rest of their lives.

By preventing stroke and identifying individuals who are in the risk zone at an early stage, society can be saved millions and millions of euro, mortality is reduced, and people are spared the suffering that stroke entail.

First pilot study in Halmstad

"We can become much better than we are today at saving lives, reducing suffering and saving society enormous costs. Many people with atrial fibrillation are not aware that they are suffering from heart rhythm abnormalities that can be detected using a thumb-ECG."

"We also need to identify people who have been diagnosed but who are not currently receiving adequate treatment – or are not receiving treatment at all," says Johan Engdahl, cardiologist and consultant at the medical clinic at the hospital in Halmstad, Sweden.

He was one of those behind the initiative to conduct an initial pilot study, in which all 75 and 76 year-olds in Halmstad were invited to take part in screening for atrial fibrillation using a thumb-ECG. Just over 400 people participated and recorded their ECG data twice a day for two weeks.

The results of the study show that around 14 percent of participants had atrial fibrillation and were offered treatment with anticoagulants. The proportion of patients with newly detected fibrillation was seven percent. This means that twice the number of patients received treatment with anticoagulants.

Many applications

The thumb-ECG is also suitable for other important applications, according to Engdahl.

"There's a great need within healthcare to investigate palpitations. In some cases, they're caused by heart rhythm abnormalities, but not always. There's also a major need to investigate individuals who have already had a stroke. Using a thumb-ECG, stroke departments could easily find out if atrial fibrillation is the underlying cause of the individual being afflicted by stroke. If it is, then it needs to be treated with medication.

Another application is monitoring patients with abnormal heart rhythms that have undergone ablation.

Reduce the number of stroke cases and save thousands of lives

In light of the results of the pilot study, a new, more extensive screening study has been initiated by Stockholm County Council and Region Halland in Sweden. The purpose is to scientifically substantiate the benefits of screening for atrial fibrillation.

Mårten Rosenqvist, Professor of Medicine at Karolinska Institutet, is leading the study, which covers 13,000 people between the ages of 75 and 76 resident in Stockholm County and in Halland. The study also covers a control group of equal size that does not undergo any screening.

The study, which will continue until 2014, aims to identify at an early stage individuals in the risk zone for stroke and offer them the correct treatment.

All participants record their own ECG data twice a day for 14 days using a thumb-ECG.

Johan Engdahl, cardiologist and consultant at the medical clinic at the hospital in Halmstad, Sweden, was one of those behind the initiative to conduct an initial pilot study, in which all 75 and 76 year olds in Halmstad were invited to be screened for atrial fibrillation using a thumb-ECG.

" The study shows clearly that stroke can be prevented. By identifying the right individuals and offering treatment with medication, the risk of being affected can be reduced by up to 70 percent. "

With a few simple methods, the number of stroke cases could be reduced and thus save thousands of lives.

Apart from laying the foundations for screening and diagnosing a larger number of atrial fibrillations, greater compliance with the national guidelines for heart and stroke care would mean significantly more patients would receive medication to prevent stroke.

A third measure is to increase the use of national quality registers for patients with atrial fibrillation. Using the registers, you can follow how patients are treated and followed up on in the healthcare system, as well as how as a prescriber you can receive support in prescribing medication.

Research to improve public health

The screening project, which is about identifying patients with atrial fibrillation using a thumb-ECG, was given an honourable mention by Athenapriset, which presents awards for Swedish clinical research. Behind Athenapriset are Vinnova (Swedish Governmental Agency for Innovation Systems), medical sector newspaper Dagens Medicin, LIF (trade association for the research-based pharmaceutical industry in Sweden), Swedish Association of Local Authorities and Regions (SALAR), Sweden Bio and Swedish Medtech.

"This kind of encouragement means a great deal. The attention also gives us greater scope for continuing to finance the project so that, in the long term, we can prevent invalidity and disability for many people," says Professor Rosenqvist.

Are there financial benefits to screening for atrial fibrillation?

Stroke is one of the most expensive diseases in our society. The costs of stroke that can be attributed to atrial fibrillation amount to over EUR 30 billion a year.

"It's patently obvious that the costs of screening for atrial fibrillation are lower than those for not screening for it. Today, thousands of people are living with atrial fibrillation without knowing it, and without treatment. As they run a higher risk of having a stroke, each detection is important. The factors that determine whether a screening programme will be cost-

effective are that many people are affected and that the cost of what you want to prevent is high," says Professor Lars-Åke Levin at the Center for Medical Technology Assessment (CMT) at Linköping University, Sweden.

He is leading the health economics analysis of the screening study in Stockholm and Halland.

Screening cost-effective

Screening for atrial fibrillation provides major benefits for society and for patients through reduced care costs, less suffering and improved quality of life, according to Professor Rosenqvist.

"Each stroke that can be prevented avoids suffering and care costs. Through screening, we could halve the number of strokes caused by atrial fibrillation.We're talking savings of billions of euro," says Professor Rosenqvist.

In his opinion, ensuring that research and development of new methods and treatment options are applied and do not simply remain within the research community is matter of urgency.

" An expected effect is cost savings, which in turn open the door to greater opportunities for initiatives for the most seriously ill. Research and development must focus on saving lives and ensuring quality of life if it is to be considered successful. "

Stig Nyman (Christian Democrats), county council commissioner at Stockholm County Council, Sweden.

" The scientific council at Region Halland has allocated research funding to and supports the screening study. The aim of the study, to investigate whether it is worth carrying out a screening programme in order to detect untreated atrial fibrillation that can lead to stroke, is a matter of urgency. It is a key issue for study. Major benefits for individuals and healthcare are in sight. "

Per Herrström, associate Professor, general practitioner and chair of the scientific council at Region Halland, Sweden.

Vital to prevent stroke in cases of atrial fibrillation

Extensive research has shown how important it is to detect and treat atrial fibrillation, as it impairs blood circulation in the heart's atrium and increases the risk of blood clots in the brain, or stroke.

The dominant medication in atrial fibrillation has long been warfarin, an anticoagulant that reduces the blood's coagulation ability and thus the risk of forming blood clots. Treatment with warfarin probably also lessens the risk of dementia and premature death.

In recent years, anticoagulant treatment has undergone development, and there are now several medicines to choose from. This provides greater choice and a wider range of treatment options for people with atrial fibrillation.

Half of patients do not get the treatment they are entitled to

For a patient with atrial fibrillation, it is important to receive the correct treatment continuously. Unfortunately, surveys show that around half of all those with atrial fibrillation do not receive the treatment they are entitled to. This means that thousands and thousands of people are affected by stroke unnecessarily each year.

Once a patient has had a stroke, it's important to know that it may be due to previously undetected atrial fibrillation. The risk of developing atrial fibrillation is even greater after a stroke. If it is not treated, there is a major risk that the patient will have another stroke.

The treatment that suits the individual is best determined in consultation with a doctor.

What is most important, however, is that people with atrial fibrillation are actually identified and given the correct treatment.

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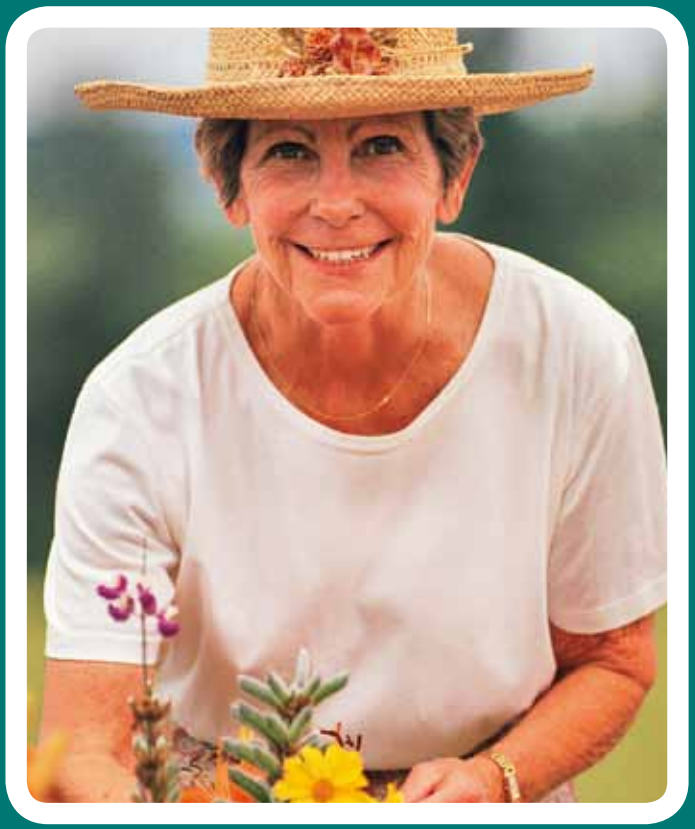

” Each day, several hundred people are given a correct diagnosis with the help of equipment from Zenicor. Thanks to this, these individuals can receive the correct treatment, thus allowing us to prevent a large number of people from being afflicted by stroke.
Research and development is crucial to meeting the challenges that society and future healthcare services are faced with. The thumb-ECG from Zenicor is an example of a Swedish medtech innovation that contributes to improving quality of life and public health for people all over the world. ”

Mats Palerius
CEO, Zenicor Medical Systems AB

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