Sleep Apnoea Patients Get Rid of the Mask

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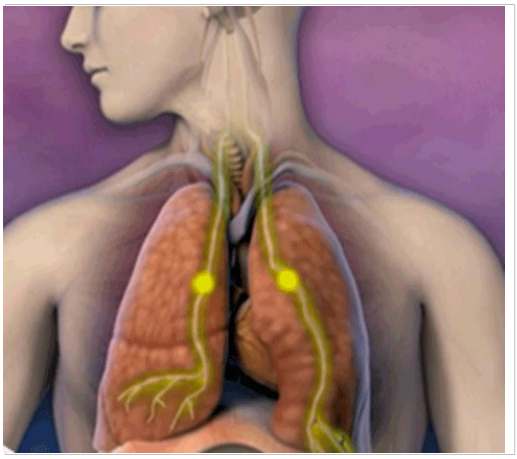

Source: Respicardia

A new implantable device treats central sleep apnoea (CSA) in heart failure patients.

Central sleep apnoea (CSA) is a dangerous comorbidity in approximately 35% of heart failure patients and doubles the risk of death. Patients have to wear a mask during sleep – and compliance is at an estimated 50% ,since the mask is considered uncomfortable, and disturbing a healthy sleep. Even worse, the masks have been shown to work only in some patients under certain conditions in CSA.

According to preliminary results of a **still ongoing clinical trial** presented at the Heart Failure Congress 2014, held 17-20 May in Athens, Greece, help might be under way. The Remede system is an implantable device that basically works like a pacemaker, sending small electric pulses. The system, developed by Minnesota-based start-up **Respicardia**, uses unilateral transvenous phrenic nerve stimulation to prevent CSA before it occurs. The pulse generator, hermetically sealed in a titanium case, is implanted under the skin just below the collar bone. It contains a sensor lead to monitor breathing and a stimulation lead that is threaded into one of the veins near the phrenic nerve.

A controller/programmer unit serves to receive, monitor, and/or adjust the pulse generator. The pulses stimulate the patient's diaphragm via the phrenic nerve, causing it to contract. Thus the system is actively regulating breathing patterns during the night, rather than only reacting when the patient stops breathing. After implantation the device can be programmed to guard the patient's sleeping times and not interfere with the patients breathing while he's awake.

The one-year results of the Remede system pilot study were revealed for the first time by lead author Professor William T. Abraham from the Ohio State University. "The Remede system", says Abraham, "is the first fully implantable device to treat central sleep apnoea in heart failure patients. Unlike traditional mask based therapies, the Remede system is acceptable to patients and improves their sleep and heart function."

In the trial, 46 patients with moderate to severe CSA were implanted with the device in 2013. After one year, the device led to significant improvements in sleep and showed a reduced apnoea-hypoponea index. Patients also spent less time with low blood oxygen levels at night. REM sleep and sleep efficiency were improved, and so was the patient's heart rate variability. As a result they were less sleepy and, according to the **Minnesota Living with Heart Failure Quality of Life** questionnaire, showed a significant improved life quality.

The team also observed what they called "reverse remodeling": In patients with Remede, the heart shrank and the left ventricular diastolic volume decreased significantly. The heart became stronger showing significant improvements in left ventricular ejection fraction, improvements on which Abraham commented: "These are changes that generally correlate with improvement in long term clinical outcomes."

He added: “Patients using the device tell us they haven’t slept so well in years. They have more energy and can do their normal daily activities without falling asleep. They also don’t have to fight with a mask.”

The trial is ongoing for US regulatory approval by the FDA, and final results are expected by the end of 2015.

By Ute Eppinger