AngelMed Guardian® System for detection of myocardial infarction

TECHNOLOGY

The AngelMed Guardian® System is an implantable device intended for use in the early detection of some types of heart attacks, called ST segment elevation myocardial infarctions (STEMIs).

The implantable component, which is similar in size and shape to a pacemaker, is surgically placed in a left pectoral pocket. It aims to detect coronary artery occlusions by analysing ST segment shifts (abnormalities on an electrocardiogram, or ECG) in combination with heart rates. This is done via a single lead running from the device to the apex of the right ventricle to monitor and record the electrical impulses of the heart. Signals are transmitted wirelessly from the implanted device to an external display unit. When the device algorithm determines that a coronary occlusion has occurred, alerts are produced via a vibrotactile stimulus from the implanted device and audio and visual alerts from an external display. Depending on the severity of the alert, the patient is then instructed to seek emergency medical attention or a consultation with their clinician. A wide range of information about the heart including heart rate, ECG traces and long-term changes in ST segments are also recorded by the device.

The device is intended for use in patients with a high risk of recurrent ST segment elevation myocardial infarctions who have coronary artery disease and do not require an implantable cardioverter defibrillator. The National Institute for Health and Care Excellence estimate that the average number of STEMIs occurring in the UK is 75 cases per 100,000 people per year.

Angel Medical Systems Inc. developed the device, which was CE marked in June 2010. The company anticipate the earliest that the device is likely to become commercially available in the UK is early 2014. No cost information was available for this alert.

The device was included in a report by the Agency for Healthcare Research and Quality in the USA in January 2012.
www.effectivehealthcare.ahrq.gov/tasks/sites/ehc/assets/File/Cardiovascular_Hi_Impact.pdf
POTENTIAL FOR IMPACT

Intracardiac detection of ST segment elevations is currently possible using some implantable cardioverter defibrillators, but this appears to be the first device to alert the patient in real time. The company state that a key innovative feature of the AngelMed Guardian® System is the algorithm used to identify coronary occlusions (blockages). They expect that use of the device will help to detect STEMI s earlier than is currently possible and before symptoms are noticed by the patient.

If shown to be effective and accurate in detecting coronary occlusions, use of this device may lead to earlier treatment for STEMI s in selected high risk patients and a likely improvement in patient outcomes and mortality. The company expect that the cost of purchasing and using the device will be balanced by improved health outcomes for those with coronary artery disease, including a reduction in patients progressing to heart failure. Costs associated with using the device will include the surgery required to implant the device. Staff training and service reorganisation is likely to be required to implement remote monitoring in this way.

The overall impact of this device will be dependent on its accuracy, as false alarms may lead to patient distress and increased resource use without any clinical benefit. The balance of costs and disadvantages to benefits will also depend on the method of risk stratification used to determine whether a patient is eligible for implantation with this device.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS

Day MC, and Young C. This is Your Heart Speaking. Call 911. Ergonomics in Design 2012;20(2):4-12. http://erg.sagepub.com/content/20/2/4.abstract


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INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.