Cost effectiveness of blood pressure device evaluated

October 15 2009

A study conducted by the University of Rochester Medical Center demonstrates that, for certain patient populations, an experimental device that lowers blood pressure may be a cost effective treatment. The implantable device, called Rheos, is in advanced stages of testing for individuals with drug resistant hypertension.

The study - which appears this month in the *Journal of Clinical Hypertension* - used data from two large population-based studies and compared the incidence of adverse health events such as stroke and heart attack for groups of individuals with and without the blood pressure lowering benefit of the device. Researchers then projected the health care costs associated with those events over a patient's lifetime. The results show that if Rheos continues to perform at a level consistent the initial findings in ongoing clinical trials, then the device is a cost effective way to control hypertension.

"Our goal was to determine whether or not the benefit of Rheos would offset the higher upfront costs," said Kate C. Young, Ph.D., MPH, an instructor in the departments of Surgery and Neurology at the University of Rochester and lead author of the study. "What we found is that the device's cost effectiveness is dependent upon the degree to which it can reduce blood pressure and the starting point of the patient."

The Rheos High Blood Pressure or Hypertension Therapy System - which is being developed by CVRx, Inc. of Minneapolis - consists of a battery-powered implantable generator, which is inserted under the skin

near the collarbone, and two carotid sinus leads, which run from the generator to the left and right carotid sinus in the neck.

The device activates the carotid baroreceptors - a key regulator of the body's cardiovascular system - which prompts signals that are interpreted by the brain as a rise in blood pressure. The brain then works to counteract this perceived rise in blood pressure by sending signals to other parts of the body that relax the blood vessels and inhibit the production of stress-related hormones. These changes enable the heart to increase blood output, while maintaining or reducing its workload, thereby reducing blood pressure when it is elevated and alleviating the symptoms of heart failure.

Rheos is currently undergoing Phase III clinical trials at sites throughout the U.S., including Rochester where physicians were the first in the nation to implant the device back in 2005. The device is also being used in a newer study which is evaluating its utility in treating patients with congestive heart failure.

While the majority of individuals can effectively control their blood pressure through nutrition, exercise, and medication, there are individuals who do not adequately respond to treatment, which often consists of a regimen of multiple medications. This condition is called drug resistant hypertension and the Rheos device is currently being testing in individuals with this condition.

Individuals with uncontrolled or resistant hypertension are at a far greater risk for a number of adverse cardiovascular events such as stroke, myocardial infarction (heart attack), heart failure, kidney disease, and death. For example, with every 20mm Hg increase in systolic blood pressure the risk of stroke doubles. By reducing blood pressure, the Rheos device lowers an individual's risk for these adverse health events.

Using data from two large population-based studies - the Framingham Study and the Anglo-Scandinavian Cardiac Outcomes Trial - researchers were able create hypothetical cohorts of individuals with and without the lower blood pressure benefits of the device. Using this data, researchers were then able to project out over time the health care costs for each group.

Individuals without the device would be at greater risk and therefore have a greater incidence of adverse health events resulting in higher health care costs (hospitalization, rehabilitation, nursing home care, etc.) over their lifetime. However, individuals with Rheos would have higher upfront costs; researchers estimated that the cost associated with implanting the device - both the surgery and the cost of the device itself - to be $20,000, an amount comparable to other medical devices such as a deep brain stimulator.

The study then set out to determine what the difference between lifetime medical costs would be, how many years of good health Rheos would help achieve, and at what cost. To measure good health, the researchers employed an analytical tool called quality adjusted life years (QALY), which is defined as a year of perfect health.

While the precise definition is a source of debate in medical circles, it is generally accepted that if a treatment is less than $50,000 per QALY, then it is considered to be cost effective. The study found that the Rheos needed to lower blood pressure by 24mm Hg in order to be cost effective. In current trials the device has been shown to lower blood pressure by 30 to 35mm Hg. The study also found that for individuals with extremely high blood pressure (greater or equal to 206mm Hg) or diabetes, the device was cost effective even if it lowered blood pressure by only 20mm Hg.

"In the past, the question asked of new treatments was 'did it work?' and

if it did we offered it to everyone," said University of Rochester cardiologist J. Chad Teeters, M.D., a co-author of the study. "Now the question that is being asked is 'what are we gaining for the extra money?' and there is a higher bar for acceptance of new technologies. This study provides us with an important framework to help evaluate the final results of the clinical trials."

Source: University of Rochester Medical Center (news : web)