Device to revolutionize preventive blood clot care after joint replacement surgery

April 6 2010

A mobile compression device is as effective as medication at preventing the formation of blood clots after hip replacement surgery but provides greater patient safety, according to a study in the March issue of the *Journal of Bone & Joint Surgery*.

"This device is as useful as blood thinners for the reduction of blood clots after hip replacement and it's superior in safety," said Douglas E. Padgett, M.D., chief of Adult Reconstruction and Joint Replacement at Hospital for Special Surgery, one of the investigators and final author. "This has the potential to change the paradigm as to how we prevent blood clots after hip replacement. The efficacy is the same, the safety is markedly better and the cost is comparable. This essentially raises the specter of 'can we use mechanical agents in lieu of the pharmacologic agents to prevent blood clots.'"

Roughly 30 percent to 50 percent of patients undergoing joint replacement surgery, either hip or knee replacement, will develop thromboembolic disease unless they receive preventive care. In people with this condition, blood clots form in veins; if a clot breaks away, it can travel to the lungs causing pulmonary embolism and death. For preventive care, doctors have the choice of using blood thinners or a compression device that wraps around the leg and pumps the leg to maintain normal blood flow.

"The College of Chest Physicians believes the best way to prevent blood clots is to use pharmacologic agents to thin the blood and make it

difficult to clot," Dr. Padgett said. "Orthopedic surgeons on the other hand have to balance the desire to reduce the risk of blood clots with the reality that many of these chemical modalities that thin the blood are in fact associated with bleeding and hemorrhagic complications."

Until now, the compression devices available were large, could only be used in hospitals and prevented walking. Recently, a company has manufactured a small, battery-operated compression device that people can wear that allows for its use outside of the hospital. The sleeve fits over a patient's calves in a form fitting manner and is secured with Velcro. The mobile device is smart in that it applies intermittent, sequential pressure to the leg in correlation with the patient's respiratory cycle, maximizing blood flow to reduce the risk of clot formation. The device is approved by the Food and Drug Administration.

"The other devices that are available are stationary. These are mobile," said Dr. Padgett. "Back in the day, people used to stay in the hospital for upwards of 10 days, but we are in a whole new day and age now. Patients are leaving the hospital after 48 hours after hip replacement, but it is still the same operation."

To test the effectiveness and safety of the mobile compression devices, investigators recruited 410 patients who were undergoing hip replacement from a number of hospitals, including Hospital for Special Surgery, Mayo Clinic, Scripps Clinic and the Cleveland Clinic. Patients were randomized to either the compression device, use of which started during surgery and then for 10 days after surgery, or low-molecular-weight heparin, a commonly used blood thinner, for ten days. At ten days, most patients are ambulatory and do not need the device. Of the patients who consented, 392 patients were evaluable in terms of safety and 386 patients were evaluable in terms of efficacy. Doctors could tell whether patients were actually wearing the device by checking the internal timer in the pump unit. The timer detects the amount of time

that the device is properly functioning and is actually being worn by the patient.

To look for deep vein blood clots, doctors conducted ultrasounds on patients' calves and thighs 10 to 12 days after surgery. The investigators found that in patients taking heparin, major bleeding occurred in 6 percent whereas no patients using the mobile device developed major bleeding. Major bleeding events are those that require transfusions or additional surgeries. Blood clots in deep veins below the knee formed in 3 percent of patients in both groups, but blood clots in deep veins above the knee formed in 2 percent of patients receiving heparin compared with 1 percent of patients using the mobile device. Clots that occur above the knee are more dangerous, in that these clots are more likely to break off and travel to the lung where they can result in death.

"This study allows us to take the next step which is to test the device in a larger study with an even larger recruitment of number of centers and number of patients to see if in fact we can quite frankly start to use this device for all elective hip replacements, and eventually knee replacements, and get rid of using chemical prophylaxis," Dr. Padgett said. Hospital for Special Surgery will be using the device in the Rapid Recovery total hip replacement protocol for patients who are being discharged within 48 hours.

The mobile device, called the Continuous Enhanced Circulation Therapy plus Synchronized Flow Technology compression device, is manufactured by Medical Compression Systems, located in Or Akiva, Israel. Medical Compression Systems provided some funding for the study.

Provided by Hospital for Special Surgery