New custom-designed treatment option for high-risk aortic aneurysms

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Vascular surgeons at NewYork-Presbyterian/Weill Cornell Medical Center are investigating the use of custom-designed stent grafts for the treatment of thoracoabdominal aortic aneurysms—a potentially deadly enlargement of the main artery carrying blood from the heart to the body and vital organs—for patients deemed high risk for open surgery. The FDA-approved clinical trial aims to address the unmet need for minimally invasive stent graft devices that can provide a safe and effective treatment for patients with aneurysms located in the aorta in both the chest and abdomen. No stent graft treatment is currently commercially available for these patients.

Treatment of thoracoabdominal aortic aneurysms, complex aneurysms that span both the thoracic aorta in the chest and the abdominal aorta, usually consists of open surgery, which carries up to a 20 percent risk of death because of the complexity of the operation. In addition, many patients undergoing this surgery are elderly and may have other medical conditions, precluding the option of surgery or making it highly risky.

The study is led by Dr. Darren Schneider, chief of vascular and endovascular surgery at NewYork-Presbyterian/Weill Cornell Medical Center and associate professor of surgery at Weill Cornell Medical College. The stent grafts are custom designed for each patient's anatomy by the NewYork-Presbyterian/Weill Cornell study team and are manufactured by Cook Medical. The stent grafts are assembled during the operation with up to five custom- placed branches for the various critical vessels that supply blood to the kidneys, liver, intestines and other organs, allowing for a precise fit.

"What's unique about this trial is that it's with a special minimally invasive stent graft device that will now allow us to fix thoracoabdominal aortic aneurysms without the large incisions used in the traditional open surgery," said Dr. Schneider. "It's our hope that with this new technology, we can fix these complex aneurysms and spare patients from the risk of major complications and death associated with open surgery."

An aneurysm is a common condition in which a portion of the aorta becomes enlarged and weakens. It can then rupture, bleed and lead to death. For several years, surgeons have been using minimally invasive techniques to implant a stent graft—a fabric tube enmeshed in a metal framework—for repair of less complex aneurysms of the lower abdominal aorta or the descending thoracic aorta, two regions of the aorta without branch vessels that supply blood to critical abdominal organs. The stent graft is inserted through the femoral artery in the groin and advanced into the aorta using X-ray guidance. The stent graft then creates a new liner in the aorta and stops the dangerous flow of blood into the aneurysm sac, protecting the patient from a rupture.

This option, however, has not been available for thoracoabdominal aortic aneurysms, complex aneurysms that span both the thoracic aorta in the chest and the abdominal aorta and involve the part of the aorta with the critical branches that supply blood to the major abdominal organs. Based on earlier studies conducted at other medical centers, use of these branched stent grafts may make treatment of thoracoabdominal aortic aneurysms much safer for patients.

NewYork-Presbyterian/Weill Cornell is the only center in the Northeast known to have this technology. The prospective, nonrandomized study will enroll up to 30 patients over two and a half years. The first procedure in the study was performed in January 2014. Investigators will analyze the results in comparison to patients treated with open surgical repair of thoracoabdominal aortic aneurysms and to existing data on stent graft repair of thoracoabdominal

aortic aneurysms.

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