

PRESS RELEASE

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Randomized Controlled Multi-Center Trial Demonstrates Reduced Treatment Time and Drug Dose with EKOS vs. Catheter-Directed Thrombolysis in Peripheral Arterial Occlusions



EKOS[®]

BOTHELL, Wash., Apr 15, 2013 (BUSINESS WIRE) -- EKOS Corporation, a privately held medical device company located in Bothell, Washington, announced the results of DUET, the world's first and only multi-center randomized trial that compares ultrasound-accelerated, catheter-directed thrombolysis (USAT) to standard side-hole, catheter-directed thrombolysis (CDT) for the treatment of acute peripheral arterial thrombotic occlusions.

Results of the DUET trial were presented at the 35th Annual Charing Cross International Symposium by Jean-Paul de Vries, M.D., Ph.D., Head, Department of Vascular Surgery, St. Antonius Hospital (Nieuwegein, The Netherlands), on behalf of his study collaborators at four Dutch medical centers.

The DUET study enrolled 60 patients, of which 28 were randomly selected for treatment with the EKOS system, a unique device that generates ultrasound energy while simultaneously delivering a physician prescribed low dose clot-dissolving drug. The advantage of this combination is that the ultrasound conditions the clot, resulting in more effective delivery of the drug; thus ensuring faster and more complete clot dissolution. Dr. de Vries commented, "If this new technology could reduce treatment by 12 hours compared to standard CDT, then the additional device cost would be more than offset by savings in hospital and personnel time. An additional bonus would be if the incidence of bleeding associated with clot-dissolving drugs could be reduced."

All 60 patients were selected to represent the most challenging examples of arterial thromboembolic infrainguinal disease with symptom duration between 1 and 7 weeks. Average duration of symptoms was 19 days in both groups. All other factors including average clot length and coexisting disease also appeared similarly in both groups.

Despite challenges in placing catheters in these patients, technical success was achieved in 80% of all cases. The hourly thrombolytic drug dose rate (Urokinase) was identical for both groups and angiogram images were obtained every six hours (except overnight). The images were reviewed by an independent Data Safety Monitoring Board to determine when uninterrupted flow had been established and all thrombus (>95%) removed. On average, patients treated with USAT were completed 12 hours sooner than those treated with standard CDT.

Dr. de Vries concluded, "Our study objectives were met. EKOS significantly reduces treatment time with no increase of serious adverse events. Plans are underway to commence the DUET II which will be a non-randomized trial using the EKOS system with an even lower hourly drug dose with an expectation of further reducing bleeding complications."

Acute arterial occlusions occur in over 100,000 patients each year in the United States. It can occur in patients in all age groups. Those with chronic occlusive disease, who may present with delayed onset of symptoms, further add to the population of patients affected. Failure or delay in seeking treatment can lead to permanent disability including eventual amputation of the affected limb. CDT has been a primary tool in treating these occlusions but long treatment times are expensive and more important, are associated with a high risk of bleeding complications.

Dr. Barry Katzen, Medical Director, Baptist Cardiac and Vascular Institute (Miami, FL), explained, "The DUET results confirm our years of experience using the EKOS system; that ultrasound assisted thrombolysis reduces treatment times and associated thrombolytic drug dose."

President and CEO of EKOS Corporation, Robert W. Hubert, concluded, "The DUET study represents one of two multi-center randomized trials recently completed which confirm the significant benefits of EKOS in treating thromboembolic disease. We commend Dr. de Vries and his colleagues on their results."

About EKOS Corporation: EKOS Corporation pioneered the development and clinical application of ultrasound infusion technologies in medicine, introducing its first system for the treatment of vascular thrombosis in 2005. Today, interventional radiologists, cardiologists, cardiothoracic and vascular surgeons at leading institutions around the world use the EKOS EkoSonic(R) Endovascular System to provide faster, safer and more complete dissolution of thrombus.

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