ESCVS NEWS

December 2013

Roy K. Greenberg, MD, 1964-2013

It is with great sadness that the announcement of the passing of Dr. Roy Greenberg reached ESCVS.

His innovations and research have helped to create our current treatment of complex aortic disease, and his contributions were fundamental in the era of endovascular therapy.

ESCVS wants to express his sorrow to the family of Dr. Greemberg and will remember him always as one of the leading exponents of the global scientific community.

A memorial service to honor Dr Roy Greenberg will be held on January 11, 2014, at 1:00 PM at the InterContinental Hotel (9801 Carnegie Avenue, Cleveland, OH).

ESCVS NEWS

ESCVS patronages a "cell terapy" multicentric study in CLI

Terumo Harvest SmartPReP2 to be used in preparation of concentrated bone marrow cells as alternative therapy in "no indication" CLI.

Critical limb ischemia incidence is high, and despite the achievements in revascularizations techniques, the evolution to major amputation is still possible in a great number of patients.

Avoiding major amputation is the first goal, but not many therapeutic possibilities after failure of surgical/endovascular treatment. The use of autologous staminal cells from bone marrow aspirate seems to be potentially useful to reduce amputation rates.

The Harvest SmartPReP2 Bone Marrow Aspiration Concentrate System (BMAC2), Terumo, is intended to be used at point-of-care for the safe and rapid preparation of autologous nucleated cell concentrate from Bone Marrow Aspiration (BMA) for administration into ischemic tissues of the affected limb due to No Option Critical Limb Ischemia. The major advantages in using the Terumo Harvest SmartPReP2 compared to the standard procedure are that the preparation is quite quick (15 mins), the concentrated cells are very rich in both platelets and granulocites and in vascular endothelial growth factor.

The study has been proposed recently by Prof Tulga Ulus (uluss@yahoo.com), Vascular Advisor and member of the Editorial Board of ESCVS. More details here:

http://www.escvs.com/pdf/paod-study-protocol-escvs.pdf

In this study 150 patients with PAOD will be randomly allocated in a 2:1 ratio to either receive autologous BMCs-Tx, or a control group no stem cell therapy

The cells derived from bone marrow and concentrated by the Terumo Harvest machine will be injected close to the ischemic areas, lesions or gangrene.

Main endopoints are:

•Change in subject's perception of pain (analog pain scale).

•Amputation-free survival

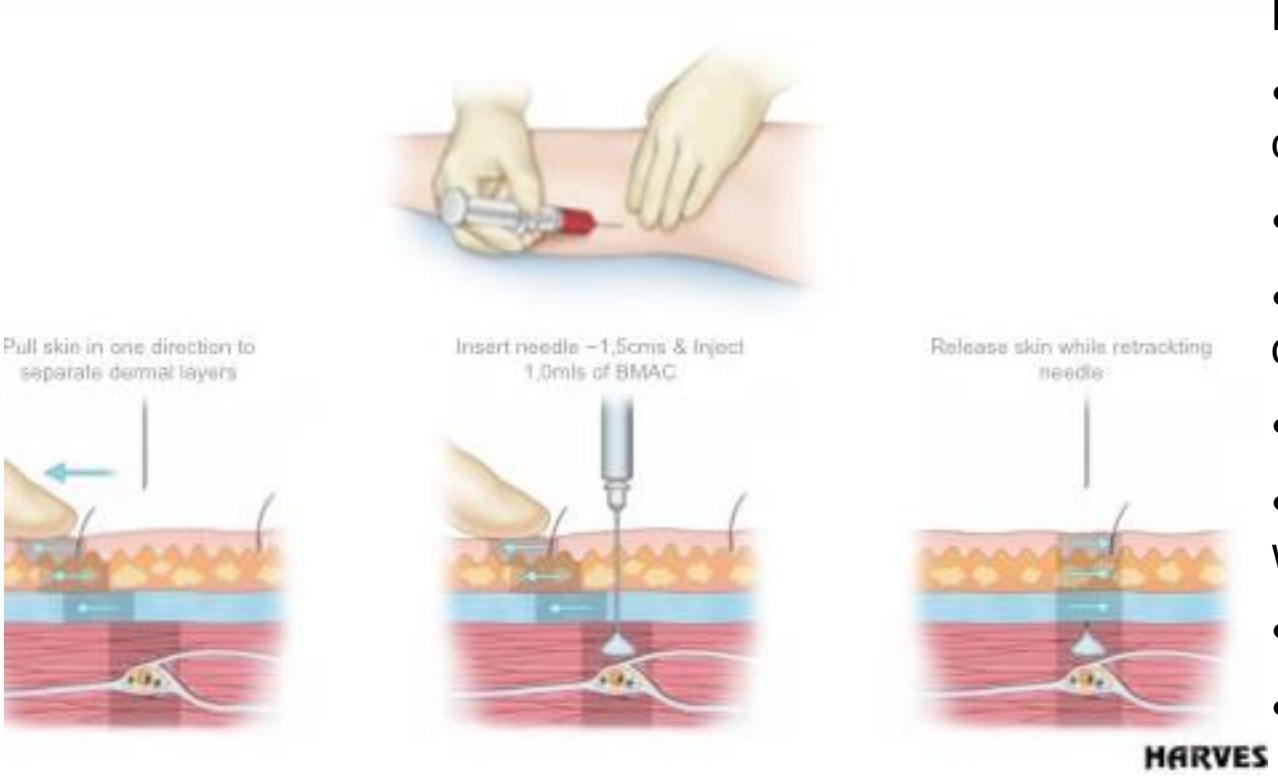
•Change in pain free walking distance (claudication)

•Change in TcPO2

•Change in ABI, TBI, maximal walking distance

•Change in quality of life.

•Reduction in pain medication.



NEWS from PRESS

Medtronic has received CE-mark approval for a new Symplicity renal denervation system.

The system consists of a 4 French multielectrode catheter (Symplicity Spyral) and a radio frequency generator (Symplicity G3).

The new system reduces ablation time and provide easy deliverability during renal denervation procedures for patients with uncontrolled hypertension.

Spyral catheter features four electrodes that are able to deliver simultaneous or selective radiofrequency energy into the renal artery wall to disrupt the output of overactive sympathetic nerves. It is compatible with a 6 French guide catheter and is delivered over a 0.014 inch guidewire via a rapid exchange system.

The press release adds that the catheter is powered by the new G3 radiofrequency generator, which it says leverages the benefits of Medtronic's proprietary Symplicity treatment algorithm with its built-in safety features. The system uniquely offers physicians control and flexibility with the ability to turn specific electrodes on and off to accommodate different anatomies. The G3 generator includes a new touch screen user interface compatible with the single-electrode Symplicity catheter.

Interim first-in-human data for Humacyte bioengineered blood vessel

For the first time surgical data from patients have been reported for the Humacyte investigational bioengineered vessel; the prelimiray data come from 28 study participants out of a total of 30 in Poland. The first patients were implanted with the vessels in December 2012, and the vessels were used for haemodialysis in February 2013. The primary endpoints of the study are safety, tolerability, and patency to be examined at each visit within the first six months after graft implantation.

The first patient data suggest that the Humacyte investigational bioengineered vessel may potentially be associated with low rates of vessel clotting, low infection rates, and low rates of surgical interventions. Low rates of clotting and intervention are consistent with preclinical data from animal testing that indicated little intimal hyperplasia. Preclinical data also indicated that, in animals, investigational vessels were remodeled to become living and more similar to native tissue.

In the Polish study, the investigational vessel has remained patent, with no indication of an immune response in recipients, no aneurysms, and flow rates and durability suitable for dialysis.

Longer follow-up and additional clinical studies will be required to confirm these preliminary observations.

ESCVS NEWS

VIP vascular international Padova congress meets North America, 26th-28th June 2014, Padova IT

Two years after the first VIP Congress, in which the preferred guests were Latin American surgeons, North American surgeons will be at the center of the scientific scene in the 2014 edition. Asia will then play a special role during the 2016 congress.

The program focuses on the treatment of arterial diseases: technical aspects and future perspectives in vascular and endovascular surgery will be discussed by an outstanding international faculty.

Several sessions dedicated to free papers selected by the Scientific Committee will permit the choice of the best presentations (age < 38 y). The winners will also receive the refund of their registration fee and a free ticket for the gala dinner.

The congress will be held in the historical center of Padova,Italy, a city with a prominent role in the history of science (Galileo, Copernico) and of medicine (Vesalius, Morgagni, Harvey, Falloppio, etc..), also well-known for its beauty, homeland of Giotto's masterpiece (the Scrovegni Chapel frescoes), St. Anthony's basilica and Prato della Valle. Padova is very close to Venice (25 km), to Verona (45 km), to Treviso countryside and to the Dolomites (100 km). We recommend you to participate to this unique event together with your families and hope you will have the opportunity to extend your stay to enjoy one of the most amazing cities in the world!

Franco Grego and Giovanni Deriu

http://vipcongress2014.org/

In.Pact Amphirion DEB Recalled for Below-the-Knee Disease Based on Trial Results

Based on data from the IN.PACT DEEP clinical study, Medtronic (Minneapolis, MN) has recalled and stopped selling its In.Pact Amphirion drug-eluting balloon (DEB) for below-the-knee (BTK) revascularization in patients with critical limb ischemia. After 12 months of follow-up in the IN.PACT DEEP study, there was no difference found between the In.Pact Amphirion treatment group and the standard balloon angioplasty control group in any of the study's three primary outcomes.

The study also identified a a trend toward an increased rate of major amputations in the DEB study arm.

The IN.PACT DEEP study was a multicenter randomized controlled trial to determine the safety and efficacy of treatment with the In.Pact Amphirion DEB for BTK revascularization in patients with critical limb ischemia. Prespecified primary efficacy endpoints included clinically driven target lesion revascularization (TLR) and late lumen loss. The primary safety endpoint was a composite of all-cause death, major amputation, or TLR. The study randomized 358 patients (2:1) to treatment with either the In.Pact Amphirion DEB or standard balloon angioplasty.

ESCVS NEWS

2014 Main Congresses and Meetings

- ISET—26th Annual International Symposium on Endovascular Therapy (Miami, USA 18–22 Jan 2014)

- Controversies & Updates in Vascular Surgery (Paris, France 23-25 Jan 2014)

- LINC—Leipzig Interventional Course (Leipzig, Germania 28–31 Jan 2014)

- iCON 2014 – International Congress on Endovascular Interventions (Phoenix, USA 9-13 Feb 2014)

- DFCon 2014 – Diabetic Foot Global Conference (Los Angeles, USA, 20-22 Mar 2014)

- **63th ESCVS International Congress (Nice, France 24-28 Apr 2014)**

- 2nd VIPcongress (Europe meets North America) (Padova, Italy, 26-28 Jun 2014)

- 18th Critcal Issue, (Malmo, Sweeden, 27 e 28 June 2014)