scheduled control in 41/45 patients. At all scheduled controls shrinkage was statistically significant. The mean size of 41 lesions evaluated at presentation, one, six and twelve months follow up was 34.12 mm (9-80, SD ±15.52), 29.93 mm (6-70, SD±14.86), 29.10 mm (6-70, SD±14.96) and 26.88 (6-63, SD±15.39) respectively. Diameter reduction rate was 15.5%, 3.8% and 11% at 1, 6 and 12 months (statistically significant: $p<0.05$). Presence of mural thrombus did not influence shrinkage timing ($p>0.05$), while complex lesion anatomy (presence of side branches) delay shrinkage ($p<0.05$).
Conclusions: data at one year FU show that CMPS is an effective device for repair of PAA and VAA with/without collateral branches, with significant shrinkage of the sac, allowing a broader group of patients to be treated with endovascular repair with results comparable to other traditional endovascular technique.

TCT-6

Biodegradable polymer-based Biolimus A9-eluting stent for the treatment of infrapopliteal arteries in critical limb ischemia: long-term clinical and angiographic follow-up.

Eugenio Stabile[1], Luigi Salemme[1], Giovanni Sorropago[1], Angelo Cioppa[1], Vittorio Ambrosini[1], Grigore Popusoi[1], Armando Pucciarelli[1], Linda Cota[1], Tullio Tesorio[1], Paolo Rubino[1]
[1]Clinica Montevergine, Mercogliano, Italy

Background: To present angiographic and clinical results of a retrospective registry assessing the performance of a biodegradable polymer-based Biolimus A9-eluting stent (BES) in the treatment of focal below the knee atherosclerotic disease.
Methods: From 05/2009 to 05/2011, 25 patients (17 men; mean age 71.8 ± 6.7 years) with chronic lower limb ischemia (Rutherford categories 3-6) underwent primary BES placement in focal infrapopliteal lesions. Dual antiplatelet theraphy (DAPT) was prescribed for six month. The primary endpoint was freedom from angiographic in-stent stenosis (ISRS) >50%. Clinical endpoints were death, amputation, and bypass surgery. Results were correlated with patient and lesion characteristics and cumulative outcomes were assessed with Kaplan-Meier analysis.
Results: Technical success was achieved in all cases. Freedom from ISRS were 100 % after 6 months, 96.0% after 12 months, and 92.0% at 12 months. No stent occlusions occurred. During clinical follow-up of 25 patients over a mean 14 ± 6 months, there were no deaths, no mayor amputations, and no need for bypass surgery. Clinical status improved in all the patients.
Conclusions: Treatment of focal infrapopliteal lesions with BES showed encouraging angiographic results in this registry. Clinical improvement was robust and particualry evident in CLI patients. Six months of DAPT were sufficient to prevent stent thrombosis. Further studies are needed to evaluate the potential clinical benefit of BES as compared to balloon angioplasty or bare metal stents in the treatment of infrapopliteal lesions.

TCT-7

Plaque Excision as a Treatment Option for Critical Limb Ischemia: 1-Year Results of the DEFINITIVE LE Study

James McKinsey[1], Thomas Zeller[2], Lawrence Garcia[3]
[1]Columbia/Cornell New York Presbyterian Hospital System, New York, NY, [2]Universitaets-Herzzentrum Freiburg-Bad Krozingen, Bad Kronzingen, Germany, [3]St. Elizabeth's Medical Center, Boston, MA

Background: The endovascular treatment of patients with critical limb ischemia (CLI) is complex and poorly studied. Plaque excision allows the debulking of the atherosclerotic plaque without the need of leaving a foreign body behind. The DEFINITIVE LE study was a global study that assessed the effectiveness of plaque excision using the SilverHawk® and TurboHawkTM Systems (Covidien/ev3, Plymouth, MN) for PAD in femoropopliteal and tibial-peroneal arteries with specific evaluation of patients with claudication and CLI.
Methods: The DEFINITIVE LE study enrolled 200 patients (278 lesions) with CLI who underwent revascularization with plaque excision. . Endpoints were assessed by independent core laboratories. The primary endpoint for CLI patients was freedom from major unplanned amputation of the target limb at 1 year.
Results: In 200 patients in the DEFINITIVE LE study with CLI, mean age was 72.1 years, 50% were male, and 69.0% had diabetes. Other frequent comorbidities included hypertension (92.5%), hyperlipidemia (76.5%) and renal insufficiency (24.0%). The mean lesion length was 7.1 cm and 24.5% of lesions were ≥ 10 cm. The mean baseline stenosis was 75.8% and 36.8% of lesions were calcified. At 6 months and at 1 year, freedom from amputation was 97.3% and 95.8%,. Primary patency was 86.9% at 6 months and 69.2% at 1 year. Other secondary endpoints demonstrated significant, sustained improvements as shown below.

Outcome	Baseline	3-Month Follow-Up	6-Month Follow-Up	12-Month Follow-Up
Rutherford Clinical Category				
RCC 4	37.00%	n/a	2.10%	5.30%
RCC 5	53.00%	n/a	21.00%	14.30%
RCC 6	10.00%	n/a	5.60%	4.50%
Ankle-Brachial Index	0.59 ± 0.18	n/a	0.70 ± 0.26	0.78 ± 0.26
EQ-5D Score	0.64 ± 0.22	n/a	0.74 ± 0.21	0.74 ± 0.21
EQ-5D Visual Analog	60.2 ± 20.8	n/a	68.3 ± 19.2	70.2 ± 18.1
Wound Healing (Wagner scale)				
0	1.80%	51.70%	62.40%	72.20%
1	54.60%	25.00%	28.60%	17.40%
2	19.60%	10.00%	3.00%	4.30%
3	6.10%	5.00%	1.50%	0.90%
4	16.00%	6.70%	4.50%	1.70%
5	1.80%	1.70%	0.00%	3.50%

Conclusions: Plaque excision for CLI results in high rates of limb salvage and good primary patency at 1 year, as well as improvements in wound healing, clinical status as measured by RCC and ABI, and improved quality of life for this challenging patient population. This was accomplished with a very low rate of stent use which would allow for future intervention with new technology that may be excluded if a stent were in place.

Renal Denervation

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TCT-9

Morphological assessment of renal arteries after radiofrequency catheter-based sympathetic denervation in a porcine model

Michael Joner[1], Kristin Steigerwald[2], Karl-Ludwig Laugwitz[3]
[1]Deutsches Herzzentrum München, Munich, Germany, [2]Deutsches Herzzentrum München, Munich, Bavaria, [3]Deutsches Herzzentrum München und 1. med. Klinik TUM, Munich, Bavaria

Background: Catheter-based renal artery denervation has been successfully introduced as alternative treatment for patients suffering from drug-resistant essential hypertension. However, the local morphological changes within the vessel wall accompanying this technique remain elusive and we sought to characterize these by utilizing the Simplicity® (Medtronic Ardian, Mountain View, CA, USA) radiofrequency catheter approach.
Methods: Following treatment of seven pigs, renal arteries were assigned to either the acute (n=6), sub-acute (10-day follow-up, n=6) or control (untreated, n=2) group. At follow-up blood analysis, final angiography and optical coherence tomography (OCT)-imaging of the treated arteries were performed and renal arteries and kidneys were processed for histopathology and immunohistochemistry.
Results: Radiofrequency derived energy application to the vessel wall induced transmural tissue coagulation and loss of endothelium resulting in local thrombus formation also detectable by OCT. At 10 days, the luminal surface was almost completely re-endothelialized. Mural wall damage was replaced by fibrotic tissue and the adventitial layer showed strong inflammatory infiltration including vasculogenesis. Remnant autonomic nerve fascicles within the lesion segments of the sub-acute group displayed enhanced vacuolic degeneration and an impaired neurofilament protein immunostaining pattern. Examination of the kidneys revealed no abnormalities and blood parameters remained within the physiological range.
Conclusions: Catheter-based application of radiofrequency energy resulted in circumscribed transmural injury within the arterial wall affecting autonomic nerve fascicles in a delayed manner. Acute loss of endothelialization resulted in thrombus formation leaving kidney perfusion unimpaired.