clinical applications including acute ischemia, removal of emboli that occurred during other endovascular procedures, and after failed thrombolysis is encouraging. Optimal technique will be discussed.

Drug-Coated Balloons vs Standard Percutaneous Transluminal Angiopathy for the Treatment of Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery Disease: New Insights from the IN.PACT SFA Randomized Trial

J.R. Laird

Purpose: Drug-coated balloons (DCB) have shown promise in improving outcomes for patients with peripheral artery disease (PAD). Twelve-month outcomes following treatment of symptomatic femoro-popliteal disease with a paclitaxel-coated balloon versus treatment with percutaneous transluminal angioplasty (PTA) were compared.
Material and Methods: The IN.PACT Superficial Femoral Artery (SFA) Trial is a prospective, multicenter, single-blinded, randomized trial in which 331 patients with intermittent claudication or ischemic rest pain due to femoropopliteal PAD were randomly assigned in a 2:1 ratio to treatment with DCB or PTA. The primary efficacy endpoint was primary patency, defined as freedom from restenosis or clinically driven target-lesion revascularization at 12 months.
Results: Baseline characteristics were similar between the 2 groups. The mean lesion length and percent of total occlusions for the DCB and PTA arms were 8.94 ± 4.89 and 8.81 ± 5.12 cm ($p = 0.82$) and 25.8% and 19.5% ($p = 0.22$), respectively. DCB resulted in higher primary patency vs. PTA (82.2% vs. 52.4%; $p < 0.001$). The rate of clinically driven target-lesion revascularization was 2.4% in the DCB arm compared with 20.6% in the PTA arm ($p < 0.001$). There was a low rate of vessel thrombosis in both arms (1.4% after DCB and 3.7% after PTA ($p = 0.10$). There were no device- or procedure-related deaths and no major amputations. A prespecified gender subgroup analysis was performed and showed consistent results in male and female gender, with no significant treatment-by-gender interactions on the primary endpoints ($p > 0.15$). Primary patency (75.7% vs. 43.8%; $p = 0.004$) and clinically driven TLR (4.1% vs. 25.7%; $p < 0.001$) results were statistically superior in female subjects treated with the DCB.
Conclusions: In this prospective, multicenter, randomized trial, DCB was superior to PTA and had a favorable safety profile for the treatment of patients with symptomatic femoro-popliteal PAD. The DCB response was consistent between genders and showed favorable results in females

New Insights from Real-World Femoral-Popliteal Drug-Coated Balloon Treatment: 1-Year Results from IN.PACT Global Study, Including Long Lesions

G. Tepe

Purpose: Randomized trial data have demonstrated superior safety and efficacy of IN.PACT Admiral Drug-coated Balloon (DCB; Medtronic, Santa Rosa, California) vs. PTA for the revascularization of mostly TransAtlantic Inter-Society Consensus (TASC) A-B femoro-popliteal lesions in patients with claudication and rest pain. A prospective, single-arm study, the IN.PACT global study, was conceived to expand the appraisal of DCB towards the real-world treatment of patients with the same peripheral artery disease symptoms, including those patients with lesions > 15 cm in length.
Material and Methods: The IN.PACT global study is a rigorous, independently adjudicated and monitored multicenter, international, 1500 patient, single-arm study of DCB revascularization of femoro-popliteal stenosis and occlusions with a minimum length of 2 cm. One-year results from the first 655 patients enrolled are presented. The majority had severe (58.2%) or moderate (27.3%) claudication or ischemic rest pain (10.9%) at baseline, and 41.2% were diabetic. The mean lesion length was 12.23 cm, 35.8% of lesions were total occlusions, and 21.4% of lesions represented in-stent restenosis. The primary endpoint was clinically driven target lesion revascularization at 12 months.
Results: At 12 months, the rate of clinically driven target lesion revascularization was 8.7%. An analysis by lesion length on the subset of subjects (N=514) with unilateral limb treatment of single lesions was also performed. The clinically driven target lesion revascularization rate in lesion lengths greater than 15 cm was 11.5% (22/191), confirming the performance of the IN.PACT Admiral DCB in long lesions.
Conclusions: Preliminary results from the IN.PACT Global Study indicate that the IN.PACT Admiral DCB is safe and efficacious in the treatment of real-world femoro-popliteal lesions, and continues to perform well in long lesions.

Transarterial Chemoembolization Outcomes in Downstaging Hepatocellular Carcinoma Patients beyond the Milan Criteria

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Purpose: In this study, we evaluated outcomes of transarterial chemoembolization (TACE) for tumor downstaging in patients with hepatocellular carcinoma (HCC) beyond Milan criteria.
Material and Methods: From 1 January 2008 to 1 January 2013, a total of 564 patients with a diagnosis of HCC were listed for liver transplantation. Patients included in the study were determined to be outside of the Milan criteria but within the University of California-San Fransisco (UCSF) downstaging criteria at the time of diagnosis and subsequently underwent either conventional transarterial chemoembolization (c-TACE) or drug-eluting bead TACE (DEB-TACE). Patients who underwent previous therapies at the time of intervention were excluded. The primary outcome variable was overall survival. Secondary outcome variables included effectiveness of TACE at tumor downstaging, progression-free survival prior to transplant, and disease recurrence after transplant.
Results: Seventeen patients (median age 58 years; 5 female, 12 male) met the criteria for inclusion in this study. Patients underwent a median (range) of 3 (1-6) TACE procedures (c-TACE 17; DEB-TACE 20). Downstaging to within the Milan criteria was successful in 13 patients (76%). Of the 13 patients who were successfully downstaged, 9 underwent liver transplantation (orthotopic 7; living donor 2), 1 remained on the transplant list within Milan criteria, 2 re-progressed beyond Milan criteria (79, 624 days), and 1 died without disease progression of septicemia after a complicated post-operative course following colectomy for pancolitis. Univarate analysis of survival (log-rank test) showed a survival benefit in downstaged vs. non-downstaged patients when censored for transplant ($p = 0.004$) and when uncensored ($p = 0.001$). There was disease-free survival in the 9 patients who underwent transplantation. There was one HCC recurrence observed 3.8 years post-transplant.
Conclusions: In our experience, transarterial chemoembolization is effective at downstaging patients with T3 disease to within the Milan criteria with favorable post-transplant disease free survival.

Percutaneous Thrombectomy with the AngioVac Aspiration Device: a Single-Center Experience

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Purpose: To describe a single-center experience with the AngioVac device (Angiodynamics, Latham, New York), a 22 Fr percutaneous aspiration thrombectomy device designed for venous aspiration, extra-corporeal filtration, and venous re-infusion.
Material and Methods: Institutional Review Board exemption was obtained for retrospective analysis of the medical records from 13 consecutive cases using the AngioVac device 1 January 2012 through 1 September 2014.
Results: Mean patient age was 49 years (range 24 to 71 years). Nine patients had thrombus located in the inferior vena cava (IVC), 3 in the right heart, and 1 in the pulmonary artery. Cardiothoracic or peripheral vascular surgical services evaluated the patients and deemed them ineligible for surgery. Nine cases were clinically and angiographically successful. No adjunctive therapy, such as venous stent placement, was required. One patient experienced hyperkalemic cardiac arrest after successful thrombectomy and survived after 5 minutes of advanced cardiovascular life support. Four cases were unsuccessful. One patient with enlarging high volume pulmonary embolism (PE) and right atrial mass, later found to be a tumor thrombus, died due to iatrogenic PE, and 1 patient with pulmonary artery thrombus experienced acute cardiogenic shock after her tricuspid valve was damaged by the advancing cannula. The patient survived open tricuspid valve repair and pulmonary artery thrombectomy. One case was abandoned prior to thrombectomy because sufficient bypass flow could not be established, and 1 case was abandoned after the cleared IVC immediately re-occluded with thrombus.
Conclusions: In our experience, aspiration thrombectomy using the AngioVac device is safe and effective in removing central caval thromboses. The use of the AngioVac device to remove thrombus in the right heart is effective but may carry a higher risk of severe complication. Pulmonary artery thrombectomy is the most challenging because of the complexity of advancing the cannula through the heart and the high likelihood of an unstable patient.