OR2.2

Preliminary Results of the Indigo/Penumbra System in the Treatment of Acute Arterial Lower Limb Occlusions

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Objectives: Surgical thromboembolectomy was the mainstay of treatment for acute limb ischemia (ALI), but in recent years, different endovascular thrombectomy devices have been introduced as alternative treatment options. The aim of this study is to evaluate, in a controlled setting, the preliminary results in terms of early safety and effectiveness of the Penumbra/Indigo Systems in patients with acute lower limb malperfusion due to peripheral acute occlusions (INDIAN Study). Methods: Patients with diagnosis of ALI were collected and treated with Penumbra/Indigo devices. The primary outcome was the technical success of thromboaspiration (evaluated with the thrombolysis in myocardial infarction [TIMI] score classifications before and after use of the device) and the clinical success at follow-up (defined as an improvement of Rutherford classification at 1-month follow-up). The secondary endpoints include the absence of any serious adverse events at discharge, primary patency at 1 month, and limb salvage at 1 month. Results: A total of 136 patients were recruited. The mean Ankle brachial index (ABI) before the procedure 0.46, Rutherford class for ALI IIB was present in 39% of the patients, the mean lesion length was 110 mm, and TIMI score 0 was recorded in 79%. After the thromboaspiration alone, TIMI score 2-3 was restored in 89.6% of patients and after additional procedure in the 95.4%. At 1-month follow-up, Rutherford class for ALI I was present in 90.2% of patients and serious adverse events were reported in nine patients (6.6%, of whom 1 amputation 0.8%). Conclusion: Preliminary results of the INDIAN Study showed that aspirationbased extraction technique with Indigo/Penumbra is safe and effective for revascularization of acute peripheral arterial occlusion as a primary therapy, and it can represent a viable tool as a secondary therapy after other surgical or endovascular techniques.

OR2.3

Percutaneous Mechanical Athero-Thrombectomy Using the Rotarex®S Device in Peripheral Artery In-Stent Restenosis or Occlusion: A French Retrospective Multicenter Study on 128 Patients

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Objectives: To ascertain the safety and mid-term outcomes of Rotarex®S rotational atherectomy plus thrombectomy device (Straub Medical AG, Wangs, Switzerland) with or without adjunctive treatment (e.g., percutaneous transluminal angioplasty

[PTA]/drug-coated balloon [DCB]/stenting) in patients with instent restenosis (ISR) or occlusion in the iliac and/or infrainguinal arteries. Methods: This was a French multicenter retrospective study of all patients treated by in-stent percutaneous mechanical debulking (PMD) of the lower limbs with Rotarex®S device between January 2013 and November 2018. Results: The cohort consisted of 128 patients (88 men and 40 women), aged 39-94 years (median, 66.7 years). All patients presented with cardiovascular risk factors. Overall, 51.5% of the patients had critical limb ischemia. The study demonstrated a technical success of 96.9% in the population with PMD and adjunctive PTA (95/128, 74.2%) or adjunctive DCB (16/128, 12.5%) or both (13/128, 10.2%). At 12-month follow-up, the primary patency rate was 92.3% and the secondary patency rate was 91.4%. The rate of limb salvage was 93.7%. We accounted for 32 (25%) reinterventions with mean time from Rotarex®S treatment to reintervention of 7.1 ± 8.2 months. Target lesion revascularization (TLR) was 19.5% (25/128). Seven (5.5%) patients developed distal embolism that responded to endovascular treatment. At mean follow-up, major adverse events observed were death (18/128, 14.1%), myocardial infarction (9/128, 7.0%), stroke (2/128, 1.6%), and renal failure (3/128, 2.3%). Conclusion: Recanalization with Rotarex®S rotational atherectomy plus thrombectomy device is a treatment of choice for arterial ISR/ occlusions of the iliac and/or infrainguinal arteries, regardless of the age of the thrombus, with satisfying TLR. Only adjunctive PTA is often necessary to further improve the recanalization.

OR2.4

Angiosome-Targeted Angioplasty in the Management of Ischemic Foot Ulcers

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Objectives: Based on the angiosome concept in critical limb ischemia patients who presented with isolated tibial lesions and foot ulcers, we evaluated and compared the clinical outcomes, ulcer healing, and amputation-free survival between patients with successful angiosome-targeted tibial angioplasty alone (direct revascularization [DR]), patients with indirect revascularization (IR) in whom the dilated vessels successfully were the nonangiosome target, and those who underwent combined revascularization (CR) (both DR and IR were achieved). Methods: We retrospectively analyzed a total of 66 critical limb ischemia patients who presented with ischemic foot ulcer with isolated tibial vessel lesions at Mansura University Hospital from January 2014 to January 2016. DR of the ischemic angiosome was performed in 37.8% (n = 25), IR in 33.3% (n = 22), and CR in 28.7% (n = 19) of patients. All patients were evaluated for the status of wound healing and limb salvage at 1, 3, 6, and 12 months. The study endpoints were major amputation or death, limb salvage, and ulcer epithelialization at 12 months. **Results:** The mean follow-up was 11.08 ± 3.2 , ranging from 3 to 13 months. On Kaplan-Meier analysis, 65% of the patients were diabetic. Ulcer healing rate at 12-month follow-up based on the angiosome hypothesis among groups CR, DR, and IR was 94.7, 66.7, and 57.17%, respectively, with a significant P =0.013 between CR and DR and a significant P < 0.001 between CR and IR. However, on comparing the DR and the IR groups, the mean time to complete ulcer healing was not statistically