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Procedural Outcomes of Orbital Atherectomy Treatment of Peripheral Arterial Disease in an Outpatient Office-Based vs. Hospital Setting

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Background: Despite the increasing use of atherectomy, few studies have compared outcomes of endovascular procedures performed in an outpatient office-based laboratory (OBL) to those performed in the traditional hospital setting. As the trend for increased outpatient treatment continues, it is critical to begin to assess the procedural outcomes of atherectomy in the OBL setting.

Methods: We analyzed the CONFIRM registry series, a data collection of patients with peripheral arterial disease (PAD) who were treated with orbital atherectomy in both the OBL and hospital settings.

Results: We found that 36% of patients in both the hospital and OBL groups were classified as Rutherford class 3 (p=0.96) and the lesions treated were moderately to severely calcified (angiographic evaluation) in 83% and 90% of hospital and OBL setting, respectively (p=0.07). Final residual stenosis, after adjunctive therapy, was 10 ± 11% in the hospital group and 11 ± 17% in the OBL group (p=0.32). Dissections, including flow limiting and non-flow limiting, occurred in 11.4% of lesions in the hospital group vs. 6.5% in the OBL group (p=0.12). Adjusted logistic regressions showed no difference in any individual complication rate or the overall complication rate.

Conclusions: Orbital atherectomy treatment of PAD in an office-based laboratory was found to be comparable to treatment in a hospital setting. Due to the emergence of more office-based laboratories utilizing orbital atherectomy, a follow-up prospective study is warranted to further investigate the comparative outcomes within a larger patient population.

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Intravascular Ultrasound in the Treatment of Infragenital Vessels: Indications of Usage and Efficacy Analysis

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Introduction: Intravascular ultrasound (IVUS) is used in infragenital vessels in a variety of fashions, the results of which are not well understood in terms of improving procedure efficiency and reducing complications.

Methods: We retrospectively selected 38 endovascular procedures between 2007 and 2013 from the Excellence in Peripheral Arterial Disease (XLPAD) registry that utilized IVUS in the superficial femoral artery and/or popliteal artery. We matched this cohort with a random sample of 38 procedures from the XLPAD registry to achieve non-significant differences in lesion complexity and presenting symptoms. The indications for IVUS use were categorized, and comparisons were made to assess for significant differences in procedure duration, contrast volume, fluoroscopy time, dose area product radiation exposure, and procedure complications.

Results: Use of IVUS was mainly to diagnose lesion complexity prior to crossing (n=10, 26.3%) and to confirm intraluminal position after crossing (n=11, 28.9%). IVUS was associated with longer procedure times (180.2 ± 53.1 min vs. 144.1 ± 54.1 min; p=0.008), but without significant differences in procedure complications (2.6% vs. 7.9%; p=0.615), fluoroscopy time (44.6 ± 21.4 min vs. 39.0 ± 22.4 min; p=0.277), radiation exposure (251.3 ± 139.9 Gy·cm² vs. 247.1 ± 137.2 Gy·cm²; p=0.903), and contrast volume (215.4 ± 88.5 mL vs. 197.0 ± 87.5 mL; p=0.367).

Conclusion: IVUS is mostly used to aid in crossing the long, complex infragenital lesions, and is associated with longer procedure times without losing efficiency or increasing complications.

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Pooled Analysis of the CONFIRM Registries: Impact of Gender on Outcomes in Patients Treated for Peripheral Arterial Disease with Orbital Atherectomy

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Background: At presentation, females with peripheral arterial disease (PAD) are older, have smaller vessels, and additional comorbidities, all contributing to more severe disease. Compared with males, females have marginally worse outcomes including limb salvage, morbidity, and mortality after lower extremity revascularization procedures. Female gender may be associated with an increased risk of adverse events after endovascular treatment of PAD.

Methods: CONFIRM I, II, and III are large, multi-center, non-randomized, all-comers registries of over 3,000 patients with PAD who were treated in the U.S. with the Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc., St. Paul, MN). In the CONFIRM series, 60% of patients were male compared to 40% female. This analysis compared the final residual stenosis achieved after treatment with OAS as well as the rate of acute procedural complications in female and male patients in the CONFIRM series.

Results: Females were older (73.2 ± 10.7 vs. 70.4 ± 10.2, p<0.001) and had a trend towards higher prevalence of critical limb ischemia (Rutherford Categories 4-6: 46% vs. 42%, p=0.075). The final percent stenosis in females and males was 9% ± 11% and 11% ± 11%, respectively (p<0.001). Females had a higher rate of total dissection, including flow limiting, non-flow limiting, and unknown type (13.3% vs. 9.9%, p<0.001). However, females and males had similar rates of flow-limiting dissection (1.6% vs. 1.4%, p=0.62). Females and males had similar rates of perforation (0.8% vs. 0.7%, p=0.57), slow flow (4.4% vs. 4.5%, p=0.96), vessel closure (1.8% vs. 1.2%, p=0.11), spasm (6.8% vs. 6.0%, p=0.24) and thrombus formation (1.3% vs. 1.2%, p=0.74). Females had a trend towards increased embolism (2.8% vs. 1.9%, p=0.07).

Conclusion: The gender analysis of the CONFIRM registries revealed that there was successful lesion modification with orbital atherectomy in both female and male patients; however, females had a higher rate of dissection (all types). This difference is likely due to the older age and higher percentage of critical limb ischemia in females versus males in this study. These results, however, suggest that additional studies should be completed to further understand the increased risks for females versus males during endovascular procedures.