Impact of moderate and severe chronic kidney disease in patients undergoing percutaneous and surgical carotid artery revascularization: Insights of the Healthcare Cost and Utilization Project's National Inpatient Sample

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BACKGROUND Carotid artery stenting (CAS) has evolved into an alternative modality for the treatment of symptomatic and asymptomatic high-grade carotid artery stenosis, particularly in patients considered to be at a high surgical risk for carotid endarterectomy (CEA). There is limited data on the outcomes of patients with moderate and severe chronic kidney disease (CKD) (stage 3 and 4) undergoing CAS or CEA.

METHODS The Healthcare Cost and Utilization Project's National Inpatient Sample was screened for hospital admissions of patients undergoing CAS and CEA from 2003-2012. Clinical characteristics and outcomes were identified in patients with stage 3 and 4 CKD. The primary outcome of interest was major adverse cardiac and cerebrovascular events (MACCE) (in-hospital death, acute myocardial infarction (AMI) and acute cerebrovascular accident (CVA)).

RESULTS Our study population consisted of 3,608 patients that underwent CEA and 746 patients that underwent CAS. Patients undergoing CAS had significantly higher rates of coronary artery disease and peripheral vascular disease (Table). CAS patients experienced significantly higher rates of MACCE compared with patients that underwent CEA, mainly driven by a higher rate of in-hospital strokes (Table). In a multivariable analysis, CAS (OR 1.52, 95% CI 1.25-1.84) was independently predictive of MACCE.

CONCLUSIONS In patients with moderate and severe CKD, CAS was associated with similar rates of in-hospital mortality and AMI rates but higher rates of stroke when compared with CEA.

ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Carotid artery stenting, Carotid endarterectomy, Chronic kidney disease

Table 1. Demographics, clinical characteristics and in-hospital outcomes

<table>
<thead>
<tr>
<th>Category</th>
<th>CEA</th>
<th>CAS</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years ± SD)</td>
<td>74.3 (±8.6)</td>
<td>74.0 (±8.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Race - White (%)</td>
<td>2,496 (81.8%)</td>
<td>547 (81.9%)</td>
<td>0.025</td>
</tr>
<tr>
<td>Coronary artery disease (%)</td>
<td>2,134 (59.2%)</td>
<td>476 (63.8%)</td>
<td>0.017</td>
</tr>
<tr>
<td>Peripheral vascular disease (%)</td>
<td>1,020 (28.3%)</td>
<td>252 (33.3%)</td>
<td>0.002</td>
</tr>
<tr>
<td>COPD (%)</td>
<td>802 (22.2%)</td>
<td>164 (22.0%)</td>
<td>0.906</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>1,808 (50.1%)</td>
<td>366 (49.1%)</td>
<td>0.597</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>1,381 (39.7%)</td>
<td>695 (82.2%)</td>
<td>0.599</td>
</tr>
<tr>
<td>Hyperlipidemia (%)</td>
<td>2,270 (62.9%)</td>
<td>420 (54.3%)</td>
<td>0.475</td>
</tr>
<tr>
<td>MACCE (%)</td>
<td>593 (16.4%)</td>
<td>168 (22.5%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>In-hospital AMI (%)</td>
<td>185 (5.1%)</td>
<td>44 (5.9%)</td>
<td>0.387</td>
</tr>
<tr>
<td>In-hospital stroke (%)</td>
<td>406 (11.3%)</td>
<td>134 (18.0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>In-hospital death (%)</td>
<td>50 (1.4%)</td>
<td>50 (1.3%)</td>
<td>0.911</td>
</tr>
</tbody>
</table>

CONCLUSIONS Comparable perioperative and late outcomes were observed for hybrid endovascular repair of proximal aortic disease compared with open surgical repair, despite a higher reintervention rate during follow-up. Therefore, hybrid repair may be considered as an acceptable treatment alternative to surgery, particularly in patients at high surgical risk.

ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Aortic disease, Endovascular therapy, Hybrid cardiac procedure

TCT-785 Comparison of hybrid endovascular and open surgical repair for proximal aortic arch diseases

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BACKGROUND To compare the outcomes of hybrid endovascular and open surgical repair for proximal aortic arch diseases.

METHODS A total of 55 consecutive patients with an aortic arch aneurysm or aortic dissection involving any of zone 0 to 1 (39 male, age 63.4±14.3 years) who underwent a hybrid endovascular repair (n=35) or open surgical repair (n=20) from 2006 to 2014 were included in a retrospective analysis. Perioperative and late outcomes were compared.

RESULTS The two groups had similar baseline characteristics, except age and EuroSCORE II, which were higher in the hybrid group. Perioperative mortality or stroke did not differ significantly between the two groups, but tended to be lower in the hybrid repair group than in the open repair group (31.4% vs. 30.0%, p=0.144). Incidences of other morbidities did not differ. During follow-up, similar overall survival was observed between the hybrid group and the open repair group (87.3% vs. 79.7% at 1 year and 83.8% vs. 72.4% at 3 years; p=0.319). However, significantly lower reintervention-free survival was observed for hybrid repair compared with open repair (83.8% vs. 100% at 1 year and 65.7% vs. 100% at 3 years; p=0.022).

CONCLUSIONS A Single Center Experience Of Zilver PTX For Femoro-Popliteal Lesions

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BACKGROUND To compare the outcomes of hybrid endovascular and open surgical repair for proximal aortic arch diseases.
BACKGROUND Clinical trial data show overall favorable outcomes of paclitaxel-eluting stents for the treatment of femoro-popliteal (FP) occlusive disease. However, the external validity of trial results may be restricted to less complex FP lesions, and limited data on outcomes of paclitaxel-eluting stents in real world practice have been published.

METHODS This study is a retrospective analysis of data of all the patients who received Zilver® PTX® for FP lesion from February 2013 to October 2014 at MedStar Washington Hospital Center in Washington, DC. The primary endpoint of this study was primary patency, defined as a peak systolic velocity ratio < 2.0 by Doppler ultrasound, or angiographic diameter stenosis < 50%, or freedom from clinically driven target lesion revascularization.

RESULTS A total of 78 patients received Zilver® PTX® for FP lesions in the pre-specified time period. Of them, 63 had follow-up data and were included in this study. The mean age was 66.3±9.4 years, and 57.1% of the patients were men. Participants had a high prevalence of diabetes (49.2%), hypertension (93.7%), hyperlipidemia (92.7%), previous coronary revascularization (52.4%), or previous peripheral arterial disease (77.8%). Critical limb ischemia was present in 25.4% of the patients, Trans-Atlantic Inter-Society Consensus (TASC) class C or D in 76.2%, in-stent restenosis (ISR) in 36.5%, and total occlusion in 69.8%. The mean lesion length was 218±128 mm, the mean number of stents was 2.0±1.0, and total stent length was 189.0±128.5 mm. Mean follow-up was 270.4±190.3 days. Primary patency rate at 1 year was 66.7% by Kaplan-Meier survival curve. When compared with patients with primary patency at follow-up, those with an adverse outcome had higher prevalence of TASC II class C or D lesions (100% vs. 68.8%, p=0.013), and were more likely to have ISR (66.7% vs. 27.1%, p=0.012), longer lesion (291.3±138.7 vs. 195.7±117.1, p=0.011), and incomplete coverage of the lesion (full coverage of lesions: 40% vs. 77.9%, p=0.001).

CONCLUSIONS Post marketing use of Zilver® PTX® for the treatment of FP lesions is associated with lower patency rates compared with clinical trial data. This may be related to the high prevalence of TASC II class C or D lesions and ISR in real world practice. Future studies should be more representative of contemporary clinical practice.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Femoropopliteal artery, Paclitaxel-eluting stent, Restenosis, in-stent

TCT-787

Evaluation of Cell Proliferation in Adaptive Neointimal Remodeling Following Arteriovenous Fistula in a Large Animal Model

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BACKGROUND Arteriovenous fistula (AVF) dysfunction caused by venous intimal hyperplasia persists as a significant threat to AVF long-term patency. Beyond conventional vascular planimetry we aim to evaluate the use of cell proliferation markers in neointima in a swine model of AVF.

METHODS Femoral AVF were surgically performed in nine swine by anastomosis. AVFs were followed for 30–90 days. At termination, AVFs were harvested and histological and planimetric analysis was performed. Immunohistochemistry for cellular proliferation was performed at the anastomosis levels as well as the arterial (A) and venous (V) anastomosis side.

RESULTS At 3 days, AVF displayed matching dimensions between V and A, with a vascular area of 13.2±4.3±2mm2 in A and 15.1±9.4 mm2 in V. By 90 days, the vascular area on V increased by approximately 4-fold (58.6±23.5 mm2) while A increased by less than 3-fold (37.3±15.4 mm2). These planimetric ratios remained consistent in the proximal A and distal V at 3 (A:14.3±3.1 mm2; V:36.8±14.8 mm2) and 90 days (A:40.2±12.8 mm2;V:68.6±28.2 mm2). At 3 days, percent area of stenosis (%AS) at the anastomosis was minimal (A:1.8±1.5%; V:5.6±1.1%). However, at 90 days, V demonstrated markedly increased %AS (21.9±16.5%) compared to A (6.9±2.9%), reflecting V being arterialized. Ki67 cell proliferation indices were high at 3 days evidenced by high Ki67 index in V (159.2±134.7 cells/mm2), and highest values were recorded in the V distal outflow side. Ki67 counts significantly decreased at 90 days (35.2±22.4 cells/mm2).

CONCLUSIONS Proliferation markers (Ki67) provide valuable assessment of vascular response. The AVF swine model provides an ideal scenario where conventional planimetry data describes the structural outcome while proliferative markers provide a dynamic picture of the biological vascular response.

CATEGORIES OTHER: Pre-Clinical/First In-Human Studies

KEYWORDS Animal model, AV fistula, Neointimal hyperplasia

TCT-788

The PRIIM Study: Interim results for the novel Penumbra/Indigo Thrombectomy system for acute ischemia in the peripheral and visceral vasculature

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BACKGROUND There are serious risks associated with untreated peripheral and visceral arterial thromboembolism. The Penumbra/Indigo System is a novel, highly trackable and efficient aspiration system in the peripheral vasculature. Reported herein are the initial results from a prospective trial. In cases of failed thrombolysis, acute ischemia, or patients with distal emboli due to a prior intervention, thrombectomy using the Penumbra/Indigo System was implemented. The primary sites of occlusion were the popliteal (38.9%), renal (9.3%), superficial femoral (18.5%), posterior tibial (7.4%), profunda femoris (3.7%), superior mesenteric (3.7%), anterior tibial (9.3%), renal (3.7%), common femoral (1.9%), and brachial (1.9%) arteries.

METHODS A total of 55 patients have been enrolled in this retrospective trial. In cases of failed thrombolysis, acute ischemia, or patients with distal emboli due to a prior intervention, thrombectomy using the Penumbra/Indigo System was implemented. The primary sites of occlusion were the popliteal (38.9%), renal (9.3%), superficial femoral (18.5%), posterior tibial (7.4%), profunda femoris (3.7%), superior mesenteric (3.7%), anterior tibial (9.3%), renal (3.7%), common femoral (1.9%), and brachial (1.9%) arteries.

RESULTS The mean patient age was 70.4±12.9 years. At baseline, 60.9% (34/55) patients reported an angiographic TIMI score of 0-1, and 4 patients were unable to be assessed. Before any intervention was performed, 37.7% (20/53) of patients received only thrombolytic therapy, 9.4% (5/53) received only mechanical intervention, 7.5% (4/53) received both therapies, and 45.3% (24/53) had no prior treatment and were treated with the Penumbra/Indigo Systems as frontline. Median time from symptom onset to procedure was 5.0 days (IQR 2.0-24.0). Post-procedure, 96.1% (49/51) of patients were successfully revascularized to TIMI 2 (39.2%) or TIMI 3 (56.9%). Six patients had SAEs, none related to the device.

CONCLUSIONS Experience with the Penumbra/Indigo System demonstrates that using thrombo-aspiration for peripheral and visceral thromboembolism can lead to promising results in safety and effectiveness. This validates possible use across a wide range of applications in the peripheral vasculature.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Peripheral, Peripheral arterial disease, Thrombectomy

TCT-789

Comparison of stent-based revascularization strategies for femoropopliteal peripheral artery disease in diabetics and non-diabetics

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BACKGROUND There are limited data on outcomes of stent-based treatment of femoropopliteal peripheral artery disease (PAD) in patients with diabetes mellitus (DM).

METHODS Consecutive patients between January 2006 and March 2015 enrolled in the observational Excellence in Peripheral Artery Disease (XPAD) registry (NCT01904851) were analyzed. Index limb procedures of patients with stent implants were included in the analysis. Outcomes tracked were major adverse limb events (MALE; target limb revascularization, surgical revascularization, and unplanned above-ankle amputation in target limb) and major adverse