Minimal Invasive Endovascular Therapy of the Supraaortic Vessels

PhD Thesis outline

Tamás Mirkó Paukovits MD

Semmelweis University
School of clinical Ph.D. studies

Tutors:

Viktor Bérczi MD, PhD, DMSc

Kálmán Hüttl, professor

Reviewers:

Endre Nagy, MD, PhD,

Ildikó Vastagh, MD, PhD,

Head of PhD final examination board: Dr. Zoltán Szabó professor emeritus

Final PhD examination board members:

Gyula Jámbor, MD, PhD,

Gábor Rudas, MD, PhD,

Budapest

2013

Introduction

Proximal common carotid artery (pCCA) is defined as a supraaortic vessel tract between the ostium and bifurcation of the CCA. The innominate artery (IA) is a supraaortic vessel originating from arcus aortae and dividing into the right subclavian artery and right common carotid. Stenotic lesions of the pCCA and AA are scarce. While stenotic and occlusive lesions of the internal carotid artery provide 40% of all large vessel related ischaemic cerebrovascular lesions, pCCA lesions cause 1%-2% of them. Only 0.5% of all ischaemic lesions originate from a IA stenotic lesion. Considering the scarcity of these lesions, no evidence is available regarding the therapeutic alternatives of these stenoses and occlusions. For proximal common carotid artery and innominate artery lesions, no multicenter, randomised trials are available. Therefore, no evidence based decision can be made on the treatment of these stenoses and occlusions. There are only a few reports involving small series of patients - describing mostly mixed populations,

including subclavian and vertebral artery lesions - concerning the success rates and safety of angioplasty and or stenting of these proximal supraaortic vessels. opulations. Natural history and effect of the best medical therapy alone is not known for these lesions. Thus, the effectiveness of this treatment in preventing stroke and guidelines for pCCA and IA endovascular treatment are yet to determined.

Objectives

Endovascular therapy and follow-up of the proximal common carotid

The purpose of our study was to assess the primary success and safety of pCCA intervention with or without stent implantation in a single-center, retrospective study on 153 lesions in 147 patients over the past 13 years.

Endovascular therapy and follow-up of the innominate artery

The aim of the study performed at a tertial referral center was to retrospectively evaluate the primary technical and clinical success rate, safety and efficacy of the angioplasty (PTA) of IA with or without stent placement in the treatment of innominate artery lesions.

Patients and methods

Retrospective analysis of proximal common carotid artery interventions

Between January 1, 1994 and December 31, 2006, 153 percutaneous transluminal angioplasties (PTA) (including six repeat PTA [rePTA]/stenting procedures done in the follow-up period) were performed on 147 consecutive patients with significant proximal common carotid artery (pCCA) stenosis. Eighty-four percent of the lesions were ostial stenoses, 14% proximal stenoses, and 2% combined. Inclusion criteria for endovascular treatment were 70% luminal diameter stenosis in patients with ipsilateral ischemic neurologic symptoms or 85% stenosis in asymptomatic patients. Contraindications included suspected vessel thrombus, severe calcification, or extreme tortuosity. The decision for treatment was made by consensus between the interventional radiologist, the vascular surgeon, and/or the neurologist. Informed consent of patients was obtained before the procedure in all patients. The average diameter stenosis was 81.5%. Patient age

ranged from 21 to 83 years (mean = 60.6 years). The group included 76 men and 71 women. The majority of patients had atherosclerotic lesions, 10 patients had stenoses due to irradiation, and one had Takayasu arteritis. There were 104 patients who were hypertensive, 30 with diabetes, 59 with hyperlipidemia, and 34 smokers. Lower limb arterial stenoses were found in 40 patients, while 35 patients had coronary atherosclerosis. There were 32 common carotid artery interventions performed on the right and 121 on the left. Forty-six patients were symptomatic and 101 patients were asymptomatic, including 57 patients with contralateral carotid or vertebrobasilar symptoms and 44 patients with no neurological symptoms. Presenting symptoms in the symptomatic group were amaurosis fugax on the ipsilateral side (n = 9), hemispheric symptoms (n = 27), and aphasia in (n =10) patients. In the asymptomatic group, contralateral amaurosis fugax (n = 6), dysarthria (n = 2), contralateral lateralizing symptoms (n = 25), subclavian steal (n = 9), drop attack (n = 2), and aphasia from the contralateral side (n = 13) occurred. Greater than 50% stenoses and/or occlusions in other supra-aortic arteries were diagnosed in 124/153 (81.0%) of the cases. A stent was implanted in 108

cases. Patients were continued on acetylsalicylic acid indefinitely after the PTA, provided that there was no contraindication. Thirty-six patients were on dual antiplatelet therapy. One hundred fifteen out of 147 patients (78.2%) (undergoing 120/153 [78.4%] successful procedures) had follow-up visits that included carotid duplex scanning and a neurological examination. Clinical follow-up was performed up to 7 years, and mean follow-up time was 24.7 months. Follow-up was carried out by an independent neurologist and results obtained through reviewing the medical records and clinical notes of the patients. New relevant neurological symptoms, such as occurrence of stroke or death were assessed as complications of the procedure. The Kaplan-Meier method was employed to calculate cumulative primary and secondary patency rates and the log rank test was used to compare cumulative patency rates between PTA and PTA/stent groups. The occurrence of TIA, any stroke, or death was monitored during in-hospital stay (24 to 48 hours) (periprocedural), at 30 days (perioperative), and through the time to the most recent follow-up.

Retrospective analysis of innominate artery interventions

Our study describes 72 consecutive patients who underwent 77 angioplasty of the innominate artery. The current retrospective cohort study has been carried out at our Institute between the 1st of January 2000 and 31st of February 2009. There were 39 women (54.2%) and 33 men (45.8%). Patients had a mean age of 56.6 (range 28–82) years. Intervention was performed when the patient had clinical symptoms and/or clinically significant stenosis or occlusion of the brachiocephalic vessel. Preprocedural symptoms consisted of 16 (20.8%) hemisensory or motor deficit, eight (10.4%) amaurosis fugax. 40 (52%) patients suffered of right-upper limb claudication and 28 (36.4%) patients complained of dizziness. There were 19 asymptomatic patients (24.7%) whose angiographies were carried out under the suspicion of stenoses on other supra-aortic arteries, revealing the lesions in the innominate artery. Concerning the patients' co-morbidity, 25 patients (34.7%) had previous myocardial infarction, 47 patients (65.3%) had hypertension, 13 (18.6%) person suffered from type II diabetes mellitus, 30 (41.7%) had hyperlipidaemia

(cholesterol >5.2 mmol/1), 36 patients (50%) had symptomatic arterial occlusion in their lower extremities and 33 (45.8%) smoked. The initial diagnosis of innominate artery stenosis or occlusion was based on the clinical data, pulse palpation of the radial arteries and blood pressure measurement on both arms. Preprocedural examination consisted of colour duplex scan (CDS) of the extracranial arteries in all patients. Post-stenotic flow pattern in the common carotis artery (CCA) was considered indicative of a likely proximal stenosis of the subclavian artery. Retrograde flow in the right vertebral artery on duplex scan (14 patients; 18.2%) defined subclavian steal syndrome. Stenoses and occlusions were verified by preprocedural diagnostic angiography in all cases, done in the same session with the treatment. The lesions were measured according to NASCET study. There were seven innominate vessel occlusions (9.1%), nine subocclusive lesions (11.7%) and 61 greater than 60% stenoses (79.2%). Angiography revealed 13 (16.9%) simultaneous supra-aortic stenoses, which have been treated in one stage with the innominate artery lesions. These consisted of seven (9.1%) subclavian stenoses (five left, one right, one bilateral), one (1.3%) left

subclavian occlusion, three (3.9%) ICA (two left, one right) stenoses and two (2.6%) left CCA stenoses. Aspirin (125 mg daily) was continued (provided there was no contraindication) for at least 6 months after PTA. Sixteen (20.8%) patients were treated with dual antiplatelet therapy, depending the individual decision of the radiologist. Patients were usually discharged 1 day after the procedure. Postoperative clinical evaluation and follow-up examination was carried out 6 weeks, 3 months and 6 months after PTA, and annually thereafter. Besides regular controls, patients were advised to come immediately to our clinic if they had any acute symptoms. Clinical examination included pulse palpation; blood pressure measurements on both arms; subclavian, common carotid and vertebral artery CDS on both sides and completion of a check list containing routine questions regarding residual or new symptoms and co-morbidities. During the follow-up examinations, the innominate artery was considered to be patent without significant stenosis if the right radial pulse was palpable, the blood pressure difference between the two arms was 30 mmHg or less and the flow in the vertebral artery was antegrade. Restenosis was defined as higher than 30 mm Hg

difference in blood pressure between the two arms, recurrent symptoms, retrograde flow in the right vertebral artery and/or more than 50% lumen reduction of the treated vessel at follow-up.

For statistical analysis, the Kaplan-Meier method was employed to calculate cumulative primary and secondary patency rates.

Results

Results of retrospective analysis of proximal common carotid artery interventions

The initial technical success rate was 98.7% (151 of 153 lesions in 147 patients). In two cases, the angioplasty was not successful. There were no procedure related deaths. Eight neurological complications (5.2%) occurred during the in-hospital stay: 3/153 (2%) ipsilateral major strokes during the procedure, 3/153 (2.0%) ipsilateral, 1/153 (0.7%) contralateral TIAs within 4 hours of the procedure, and 1/153 (0.7%) dizziness. Eight of 153 (5.2%) access site bleedings (four of them required surgical treatment), 1/153(0.7%) acute left ventricular failure with respiratory distress, and 1/153 (0.7%) bradycardia were also noted. The periprocedural death/all-stroke rate was 2.0% (3/153). The 30-day death/all-stroke rate was 2.5% (3/120). One hundred fifteen out of 147 (78.2%) patients, representing 120/153 (78.4%) successful procedures were available for follow-up evaluation. Eleven unrelated deaths (gastrointestinal and hepatic malignancy) occurred 35 days to 52 months

following the procedure. More than 50% diameter restenosis was detected in 11/115(9.6%) patients: 51% to 69% diameter restenoses n = 2; 70% to 99% stenoses n = 6; occlusion n = 3. Eight patients (7.0%) had angiography due to different indications. Angiography revealed one 50% to 69% stenosis, and there was no indication for rePTA in this patient. Seventy percent to 99% restenosis was detected in seven patients. Successful rePTA was done in six cases; one patient refused the offered intervention. Follow-up of rePTA patients revealed restenosis in 3 cases at 14, 16, and 18 months following rePTA. Two asymptomatic patients showed new neurological symptoms: one contralateral TIA (19 months postprocedure) and one minor stroke (52 months postprocedure). The cumulative primary patency rate was 97.9% ± 2.1% at 1 year, 82.0%±7.1% at 4 years, and 73.5% ± 12.7% at 84 months. The cumulative secondary patency rate was 100% at 1 year, 88.0% ± 7.0% at 4 years, and 88.0% ± 7.0% at 84 months (Fig 3, A). The mean primary and secondary patency times were 23.9 and 24.9 months, respectively. In the PTA-only group, the primary patency rate was 97.2% ± 3.6% at 1 year, 86.5% ± 11% at 4 years, and 79.1% ± 11% at 84 months. In the PTA

+ stent group, the primary patency rate was 96.0% ± 2.5% at 1 year and 88.2% ± 5.3% at 4 years and 58.1% ± 12% at 74 months In the PTA ± stent group, longest follow-up was 74 months. Log-rank test showed no statistical difference in primary (P=.825) and in secondary (P = .680) cumulative freedom from restenosis between PTA alone (n = 34) or PTA/stent (n = 84).

Results of retrospective analysis of innominate artery interventions

All the lesions but 5 (6.5%) were crossed with balloon catheter and treated successfully with PTA. Twenty-eight (36.4%) successful balloon angioplasties, and 49 (63.6%) PTAs with stent deployment were carried out. The initial technical success rate was 93.5% for procedures. In six (7.8%) cases, after stent deployment, control DSA showed unsatisfactory morphology and/or higher than 50% residual stenosis. This was eliminated with repeated PTA. Other supra-aortic PTAs in the same session with the innominate artery intervention were carried out in 13 (16.9%) cases. Clinical primary success was achieved in all but one of the 58 symptomatic cases, resulting a 98.3% clinical success

rate: 32 patients have become symptomless and 25 patients showed moderate reductions of the preprocedural symptoms. None of the nineteen asymptomatic patients became symptomatic during or after the procedure within 48 h. There was neither lethal nor major neurologic complication nor myocardial infarction during the procedures or within 30 days of the intervention. Dissection of aortic arch, or supra-aortic arteries was not observed. There were two (2.6%) minor neurologic complications: one left-sided transient hemiparesis occurred during the procedure and one patient lost consciousness for a short period of time 2 h following the procedure. Access site complications included four (5.2%) access site bleedings, resulting in a groin hematoma, one (1.3%) of them required surgical evaluation an suture. In one (1.3%) case, palmar and finger pain was experienced, suggesting transient microemboli. The mean follow-up time was 42.3 months (range 2−103 months). Clinical follow-up including both measured data (blood pressure on both upper extremities, color duplex scan of CCA) and patient history data (progression of the symptoms, new symptoms and data on actual medication) is available for 65/72 (90.3%) of all

patients and 68/77 (88.3%) of all procedures. All but five (6.5%) patients, who were available for follow-up, had bilateral satisfactory radial pulse, and anterograde flow was visualised in the right vertebral artery. The difference between the arms decreased to less than 10 mmHg in all but 10 (13.9%) patients. In these patients the blood pressure difference was >30 mmHg, and nine (11.7%) of them showed relevant symptoms, fulfilling the inclusion criteria for control angiography. Significant restenosis were identified in four (5.2%) cases and re-occlusion in one case (1.3%). Successful re-PTA was done in all five cases, in one patient with stent deployment. Further follow-up showed open innominate vessels. Cumulative primary patency was 100% at 12 months, 98 ± 1.6% at 24 months, and 69.9 ± 8.5% at 96 months. The cumulative secondary patency was 100% at 12 and 24 months, and 81.5 ± 7.7% at 96 months. Log-rank test showed no significant difference (p=0.79) in primary cumulative patencies between PTA alone and PTA/stent. Six patients died during follow-up in non-procedure-related diseases.

Conclusion

Proximal common carotid artery interventions

Our series is one of the two studies published on transfemoral angioplasty of solely ostial and proximal common carotid artery stenosis. The primary technical success rate is high (98.7%) with a 2.5% 30-day all stroke/death rate. These results should help vascular surgeons and interventional radiologists to consider risk versus benefit when deciding treatment options for ostial and proximal common carotid artery significant stenoses. Our study should also draw attention to the lack of data on natural history or effect of best medical treatment alone for these lesions, making evidence-based decision making currently impossible for treatment of symptomatic or asymptomatic ostial and proximal common carotid artery significant stenoses.

Innominate artery interventions

Data on endovascular treatment of solely innominate artery lesions are scarce; most of these studies focussed on the

treatment of the combination of several supra-aortic arteries simultaneously, and only limited number of innominate artery lesions are evaluated, mostly with short-time follow-up. Therefore, any conclusions from these studies are limited. Our study is one of the three papers published on angioplasty/stenting of solely the innominate artery. It is a part of CIRSE 2013 guideline. The primary technical success rate is high (93.5%) with a 0% 30-day all stroke/death rate.

In conclusion, percutaneous, transluminal interventions, performed on proximal supraaortic arteries as pACC and IA are safe, associated with excellent primary technical succes rate, and accompanied by low neurological complication rate and mortality. In the recent years they have become real therapeutical alternative for open surgical approaches. In most cases, percutaneous interventions are the primary treatment of choice, and surgical treatment has during the recent years been limited to tackle unsuccessful endovascular therapy.

Publications

1. **Paukovits TM,** Nemes B, Hüttl K, Bérczi V: [Percutaneous, endovascular treatment of innominate artery lesions is a safe procedure]. Orv Hetil. 2011 Oct 23;152(43):1745-50
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