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Analysis of periinterventional complications of intracranial angioplasty and stenting: A single center experience

Toni Silber[a], Ulf Ziemann[a], Ulrike Ernemann[b,1], Felix Bischof[a,*,1]

[a] Center of Neurology, Hertie-Institute for Clinical Brain Research, University of Tübingen, Germany
[b] Department of Diagnostic and Interventional Neuroradiology, University of Tübingen, Germany

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ABSTRACT

Background and purpose: Treatment of symptomatic intracranial atherosclerotic disease by angioplasty and stenting (PTAS) is limited by a high rate of periinterventional strokes. We performed a detailed analysis of these strokes at our center in order to identify strategies to reduce the risk of periinterventional complications.
Methods: Case records and imaging data of 80 patients with a symptomatic 70–99% stenosis of a major intracranial artery treated with PTAS between July 2007 and December 2013 were reviewed. All patients had a sufficient response to aspirin and clopidogrel. Periinterventional strokes were categorized as either ischemic (perforator territory, distal embolic or delayed stent thrombosis) or hemorrhagic (intraparenchymal, subarachnoid).
Results: Periinterventional complications occurred in 6/80 (7.5%) patients, consisting of 2 ischemic strokes (2.5%, both perforator territory), 3 hemorrhagic strokes (3.8%, 2 intraparenchymal due to reperfusion injury, 1 subarachnoid due to vessel rupture) and one death (1.3%) unrelated to stroke. All strokes occurred within 24 h after PTAS.
Conclusion: Our retrospective data analysis suggests that the risk of periinterventional stroke after PTAS of symptomatic intracranial atherosclerotic disease might be reduced by sufficient antiplatelet therapy and optimized management of patients with high risk for reperfusion injury or perforator strokes, including selection of a stenting device adapted to individual vessel morphology.

1. Introduction

Cerebral stroke is the second leading cause of death and accounts for almost 10% of all deaths worldwide [1]. Intracranial atherosclerotic disease (ICAD) is responsible for 8–10% of all ischemic strokes and the risk of developing a second stroke in these patients is 15 percent per year [2]. Treatment of patients with intracranial artery stenosis with warfarin provides no benefit over treatment with aspirin but is associated with higher rates of adverse events [3]. A large prospective multicenter trial comparing maximal medical management alone and maximal medical management with percutaneous transluminal angioplasty and stenting (PTAS) using the Wingspan stent system in patients with symptomatic 70–99% stenosis of a major intracranial artery was stopped because patients in the PTAS group showed a higher rate of stroke and death within 30 days following randomization than patients treated with medical management alone [4]. Medical management in this trial included 325 mg aspirin per day, 75 mg clopidogrel per day for 90 days, and rigorous management of risk factors.

Here, we present a series of 80 patients with a symptomatic 70–99% intracranial artery stenosis in which PTAS was performed. The decision to perform PTAS was taken after careful analysis of the morphology of the stenosis and the associated interventional risk profile. In all patients, clopidogrel and aspirin response was confirmed by laboratory testing prior to intervention. Periinterventional complication rate in this cohort was 7.5%. Complications mainly consisted of perforator stroke and reperfusion injury.

Abbreviations: PTAS, percutaneous angioplasty and stenting; ASA, acetylsalicylic acid; SAMMPRIS, stenting and aggressive medical management for preventing recurrent stroke in intracranial stenosis; SES, self-expanding stent; BES, balloon expanding stent; IPH, intraparenchymal hemorrhage; ICP, intracranial pressure; VA, vertebral artery; BA, basilar artery; MCA, middle cerebral artery; ICA, internal cerebral artery; TRAP, thrombin receptor activating peptide.

* Corresponding author at: Center of Neurology, Hertie-Institute for Clinical Brain Research, University of Tuebingen, Hoppe-Seyler-Str 3, 72076 Tübingen, Germany. Tel.: +49 7071 29 83269; fax: +49 7071 29 5260.
E-mail address: felix.bischof@uni-tuebingen.de (F. Bischof).
[1] These authors contributed equally to this work.

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2. Methods

2.1. Study design

We performed a retrospective analysis of electronic case records and imaging data of patients with a transient ischemic attack (TIA) or non-disabling stroke due to a 70–99% stenosis of a major intracranial artery who underwent PTAS at our institution between July 2007 and December 2013.

2.2. Patient population and eligibility criteria

The eligibility criteria were based on the conditions of the SAMMPRIS-trial [5]. Specifically, patients with a TIA or non-disabling stroke (modified Rankin score ≤ 3) within 30 days of intervention attributed to a stenosis of 70–99% of the diameter of a major intracranial artery were included in the analysis. Affected vessels include the intracranial carotid artery, the middle cerebral artery, the intracranial vertebral artery and the basilar artery. The degree of stenosis was assessed by computerized tomographic angiography (CTA) or magnetic resonance angiography (MRA) and confirmed by cerebral angiography according to the WASID criteria [3,6]. A TIA is defined as neurologic symptoms, which completely resolve within 24 h. A non-disabling stroke is a stroke with a National Institutes of Health Stroke Scale (NIHSS) of less than 7 on a scale of 0–42. Patients with a dissection or an aneurysm of a cerebral artery, patients with cerebral angiitis and patients who were treated for more than one intracranial artery stenosis within 30 days were excluded from the study. Ultimately, 80 PTAS-treated patients were included.

2.3. Study objectives

The primary objective of the study was to evaluate the incidence of ischemic stroke, hemorrhagic stroke or death within 30 days of intervention.

2.4. Intervention

Patients were treated with 100 mg aspirin and 75 mg clopidogrel per day for at least 3 days prior to intervention. Patients who required more urgent intervention received a loading dose of 600 mg clopidogrel. Aspirin and clopidogrel response were determined by impedance aggregometry (TRAP-testing). A TRAP-test of >60 U and asprin < 30 U was considered a sufficient aspirin response. A TRAP-test > 60 U and clopidogrel < 45 U was considered a sufficient response to clopidogrel. Patients with an insufficient clopidogrel response received 2×75 mg clopidogrel per day and were only included if this led to a sufficient response. All PTAS were performed under general anesthesia by interventional neuroradiologists at the Department for Diagnostic and Interventional Neuroradiology, University of Tübingen. All patients planned for PTAS underwent a diagnostic cerebral angiography to determine the degree and morphology of the stenosis as well as atherosclerotic changes and tortuosity of the extra- and intracranial vasculature. PTAS was not performed in cases in which a high periinterventional risk was anticipated due to perforating arteries originating from the stenosis or due to extreme proximal vessel tortuosity. In patients considered suitable for PTAS, the intervention was performed in the same session as the diagnostic angiography.

During intervention, patients were heparinized to a doubled activated clotting time. After insertion of a guiding catheter (Envoy, Cordis) into the supplying extracranial artery via a transfemoral or transbrachial approach, the stenosis was treated with either a self-expanding or a balloon-expanding stent. Self-expanding stents (Wingspan, Boston Scientific) were employed for very tortuous stenotic segments with variable proximal and distal vessel diameters. In these cases a predilatation with a balloon (Gateway, Boston Scientific) was performed. Balloon-expandable stents were increasingly used after very flexible balloon-mounted coronary stents (Coroflex Blue Ultra, Braun) became available and were employed after obtaining informed consent. Following intervention, platelet inhibition was continued with clopidogrel for 6–12 months, and with aspirin infinitely.

2.5. Follow up

Patients were observed for 30 days following intervention. 78 patients (97.5%) had follow-up assessments at our institution, in 2 cases (2.5%) information was obtained from hospitals to which these patients had been transferred. All patients received clopidogrel and aspirin, appropriate treatment for hypertension, blood glucose levels and lipid lowering agents. Ultrasound examination of the treated artery was performed 24 h after the intervention in cases in which the artery was accessible by ultrasound. Patients were repeatedly examined by trained neurologist during their stay. Cranial MRI or CT were performed in all patients who developed a new neurological deficit in the follow up period.

2.6. Classification of events

Patient records and electronic imaging data were reviewed and all primary objectives, ischemic stroke, hemorrhagic stroke or death within 30 days after intervention as well as subclassification as perforator stroke (perforating artery covered by the stent), reperfusion hemorrhage (intracerebral bleeding within the territory of the stented vessel) and detection of dissections were performed in consensus by three primary investigators (TS, UE, FB). Delayed stent occlusion was diagnosed if there was any evidence for stent occlusion upon clinical, radiological or ultrasound examination. A stroke was considered disabling, if the modified Rankin scale score was >2 at day 30.

2.7. Statistics

Statistical analysis was performed using R software release 2.9.2.

3. Results

The baseline characteristics of the 80 patients are shown in Table 1 and the measures of risk factors at baseline are shown in Table 2. The mean age of the 58 men (72.5%) was 68.4 years and of the 22 women (27.5%) was 72.1 years. 93% of men and 91% of women had arterial hypertension, 39.6% of men and 45% of women had diabetes mellitus and 64% of women but only 55% of men had hyperlipidemia (Table 2). In 23.8% (19 of 80 patients) there had been a stroke in the past history more than 30 days prior to the qualifying event. PTAS was applied to middle cerebral artery ($n = 30$, 37.5%), vertebral artery ($n = 21$, 26.3%), basilar artery ($n = 18$, 22.5%) and the intracranial internal carotid artery ($n = 11$, 13.8%). 37 patients were treated with 38 self-expanding stents and 43 patients were treated with balloon dilating stents (Table 3). In four cases, a dissection of a cerebral artery developed during the procedure (Table 4). All four dissections were in the vertebral artery and were caused by the catheter while stenting the distal vertebral or basilar artery. None of the dissections caused clinical symptoms and there were no dissections in any other vessel. Three of the four dissections were stented. None of the patients with iatrogenic dissections reached any of the primary endpoints.

The combined probability of the primary endpoints was 7.5% (6 of 80 patients, 95% CI: 2.8–15.6, Table 5). The time between qualifying event and intervention in these patients ranged from one to 15