Angioplasty Using Drug-coated Balloons in High-grade Ostial Vertebral Artery Stenosis: First Experiences in a Small Case Series

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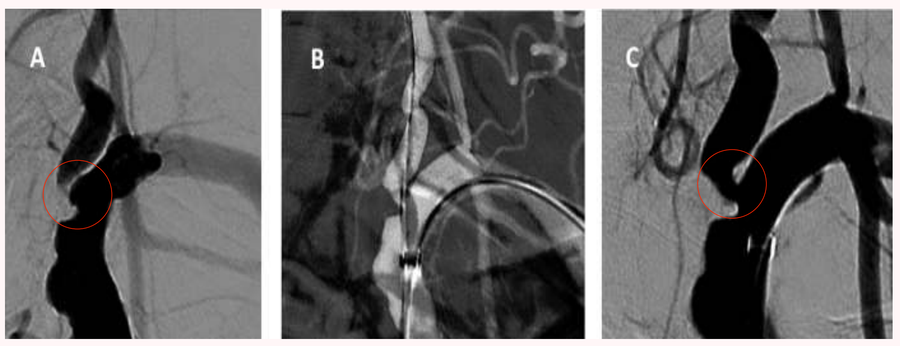
Background

Approximately 20-25% of ischemic strokes occur in the posterior circulation; and 10-20% of the patients with ostial vertebral artery stenosis (OVAS) will suffer from a stroke[1]. There is an ongoing debate on the treatment modalities for OVAS patients whether patients benefit from endovascular or from best-medical treatment alone since the VIST, VAST and CAVATS trial. Today, best medical treatment using antiplatelet agents is considered first-line treatment of OVAS. However, endovascular OVAS treatment might be considered especially in patients with hemodynamic vertebrobasilar insufficency, bilateral >70% vertebral artery stenosis (VAS) and in patients with unilateral VAS with contralateral hypoplastic or occluded vessels. Initial good clinical results and high success rates have been reported for percutaneous angioplasty with or without stenting. However, the re-stenosis rate was reported as high as 10-67%.

During the last decade, drug-eluting stents (DES) and drug-coated balloons (DCB) have been established in the field of interventional cardiology with convincing short- and long-term results . DES in patients with high grade OVAS appear to have lower re-stenosis rates compared to the previously used bare-metal stents (BMS). Data on treatment of high-grade OVAS with DCB is scarce.

Purpose

In this case series we assessed feasibility and safety of DCB-PTA in patients with high-grade OVAS using Neuro Elutax SV (Aachen Resonance, Aachen, Germany) and SeQuent Please NEO (B.Braun, Melsungen, Germany) .



Patient with known extensive atherosclerotic arteriopathy of supra-aortic arteries:
A) Pre-procedural angiogram of a high-grade, excentric OVAS of the left vertebral artery.
B) Intra-procedural inflated angioplasty balloon (SeQuent Please NEO). 4-times angioplasty with 2 times 10mmx2mm SeQuent-Please NE0 and 2 times with a 10mmx3mm SeQuent Please NEO.
C) Post-procedural angiogram with residual stenosis (50%) with good restoration of ante-grade flow and partial regress of ipsi-lateral occipito-vertebral anastomoses.

Material and Methods

Retrospective, mono-center case series of six patients with high-grade ostial vertebral artery stenosis treated with PTA using a drug-coated balloon.

Outcome measurement were post-procedural angiographic stenosis degree according to the VOTE method criteria, as well as the post-procedural short-term (within 24hours) and long-term ultra-sonographic stenosis degree. Additionally, all peri-procedural complications as well as clinical follow-up (mRS) were assessed.

References

1) Savitz SI, Caplan LR: Vertebrobasilar disease. *N Engl J Med* 2005, 352(25):2618-2626.

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3) Gruber P, Garcia-Esperon C, Berberat J, Kahles T, Hlavica M, Anon J, Diepers M, Nedeltchev K, Remonda L: Neuro Elutax SV drug-eluting balloon versus Wingspan stent system in symptomatic intracranial high-grade stenosis: a single-center experience. *J Neurointerv Surg* 2018, 10(12):e32.

4) Gruber P, Braun C, Kahles T, Hlavica M, Anon J, Diepers M, Nedeltchev K, Berberat J, Remonda L: Percutaneous transluminal angioplasty using the novel drug-coated balloon catheter SeQuent Please NEO for the treatment of symptomatic intracranial severe stenosis: feasibility and safety study. *J Neurointerv Surg* 2018.

Results

Clinical Characteristics	N=6
Sex (male) – no. (%)	3 (50%)
Age in years – median (IQR)	72 (66-76)
Hypertension – no. (%)	6 (100%)
Atrial Fibrillation – no. (%)	3 (50%)
Dyslipidemia – no. (%)	4 (64%)
Nicotine abuse – no. (%)	5 (83%)
Diabetes mellitus – no. (%)	0 (0%)
Kidney failure – no. (%)	7 (32)
NIHSS on admission – median (IQR)	0 (0-0)
Most common clinical symptom: vertigo/ dizziness	4 (67%)

IQR, interquartile range; no., number; NIHHS, National Institute of Health Stroke Scale;

Lesion Characteristics	N=6
Lesion side (left) – no. (%)	6 (100%)
Pre-interventional stenosis degree VOTE in perecentage – median (IQR)	73% (60-80)
Lesion length in mm – median (IQR)	6mm (4-13)
Contralateral vertebral artery (VA)	
Hypoplastic V4-Segment of the VA – no. (%)	2 (34%)
Occlusion/ Pseudoocclusion of the VA– no. (%)	2 (34%)
High-grade Stenosis– no. (%)	1 (17%)
Moderate Stenosis– no. (≤50%)	1 (17)

IQR, interquartile range; no., number; VA, vertebral artery; VOTE, vertebral origin treatment with endovascular method

Procedure Characteristics	N=6
General Anesthesia – no. (%)	4 (67%)
Neuro Elutax SV as first DCB – no. (%)	5 (83%)
SeQuent Please NEO as first DCB – no. (%)	1 (17%)
Change to another DCB – no. (%)	1 (17%)
Second larger-size DCB use – no. (%)	4 (67%)

DCB, drug-coated balloon; no., number

Outcome Measures	N=6
Post-interventional stenosis degree VOTE in perecentage – median (IQR)	45% (25-50)
Mean Follow-up period in months	5.3
Recurrent clinical ischemic event – no.	0
Re-stenosis rate at follow-up – no.	0
Major peri-procedural complicaions – no.	0
Dissection – no.	0
Vessel perforation – no.	0
Hemorrhage – no.	0
Distal Ischemic Event – no.	0
Mortality – no.	0

IQR, interquartile range; no., number; VOTE, vertebral origin treatment with endovascular method

Discussion and Conclusion

Our preliminary results demonstrated that OVAS treatment with DCB in appropriately selected patients is feasible, safe and revealed sustained short-outcome results. These findings are in line with a previous case report of DCB in OVAS[2]. Promising results have been shown for DCB treatment in symptomatic intracranial atherosclerotic disease (ICAD). These results might even encourage the use of DCB also in the extra-cranial vasculature[3,4].

Thus, DCB-PTA might be considered as a novel treatment option in patients with ostial vertebral artery stenosis.