Background and Importance: The endovascular treatment of recurrent wide-necked bifurcation aneurysms at the basilar tip remains very challenging. Many different techniques and devices have emerged in the recent years as potential options but results remain less than controversial. The pCANvas is a relatively new device wielding neck-bridging properties with a hemodynamically active membrane acting as blood flow disrupter.

Clinical presentation: We present the clinical case of a patient in whom multiple endovascular and microsurgical attempts failed to achieve the definitive treatment of a large and wide-necked basilar tip aneurysm. The patient underwent successful endovascular implantation of the novel pCANvas device across the recurrent aneurysm neck. The divice limited the blood flow to the anerysmal lumen and thus promoted faster thrombosis. Third month follow-up confirmed complete obliteration of the aneurysm.

Conclusion: The application of the pCANvas device offers a potential treatment option in difficult and recurrent aneurysms. The endovascular flow disruption is a relatively new feature aiming to create conditions for intraluminal thrombosis and is certainly promising for treatment of complex bifurcation aneurysm.

Introduction

The tip of the basilar artery is one of the most common location for posterior circulation aneurysms. (1) Nowadays, endovascular coiling is commonly the first option in treatment for such aneurysms, but because of the high recurrence rates advanced endovascular techniques are necessary. (2, 3) Over the past two decades, a variety of technological advances have increased the treatment options as well as the safety and efficacy of the endovascular approach, which now includes balloon-assisted coiling, stent-assisted coiling, flow diversion, intrasaccular flow disruption and aneurysm neck reconstruction. The emergence of the "waffle cone technique", consisting of the deployment of a self-expanding stent with its distal end in the aneurysmal lumen and subsequent coil embolization. This approach gives new treatment option for wide necked bifurcation aneurysms. The pCANvas is a new optimized third-generation device designed as an alternative to the waffle cone technique. The major upgrade from its ancestors - pCONus1 and pCONus2, is the biocompatible membrane on the distal end of the device. The membrane promotes faster thrombosis by redirecting and limiting the blood flow into treated aneurysm. (2)

This case illustrates the use of a new hybrid device for treating challenging and recurrent aneurysm at the level of basilar artery bifurcation and highlights the features of an intra- and extrasaccular flow-disruption mechanism behind the pCANvas.

Technique

A 62-year-old female was admitted to the outpatient department of our hospital with a history of slurred speech, urine incontinence, dysphagia, unstable gait, as well as a paretic right arm and muscle spasticity. The patient has been diagnosed with a giant BA wide-necked aneurysm 18 years before the admition to our hospital. Twelve years ago, surgical approach for direct microsurgical clipping has been attempted and has failed due to difficulties in visualization of the posteriorly directed perforators from the basilar apex and ipsilateral branch arteries. According to patient's medical record although the aneurysm has undergone several sessions of repeated simple endovascular coiling at another department, multiple episodes of recanalization have occurred through the years since the initial diagnosis. Increase of the size of the aneurysmal lumen has also been observed.

MRI examination perfermed right after admission, demonstrated aneurysm recurrence, secondary aneurysmal growth due to coil compaction and coil migration into an intrasaccular thrombus. It revealed severe compression of the midbrain, the optic chiasm, as well as the third ventricle and causing occlusive hydrocephalus (Fig. 1).

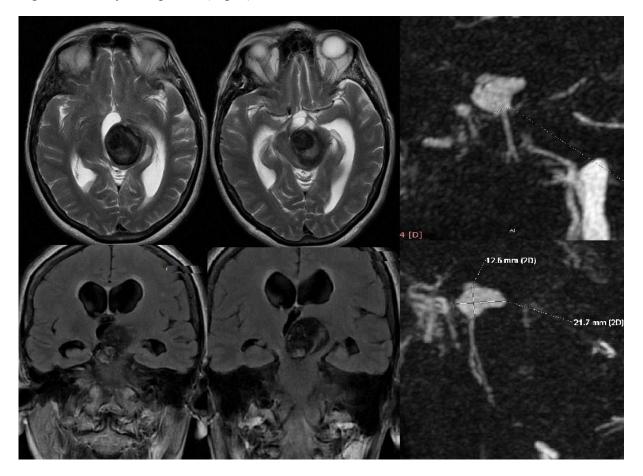


Fig. 1 Axial (a, b) and coronal (c, d) T2-weighted and Fluid-attenuated inversion recovery (FLAIR) images demonstrating giant previously treated and partially recanalized aneurysm at the level of the basilar bifurcation. Time-of-flight (TOF) MR images (e, f) showing the width of the aneurysmal neck and the incorporation of the origins of both posterior cerebral arties

The aneurysm was harboring wide neck, complex geometrical characteristics, making the correct measurement impossible. The aneurysmal fundus was dislocating and causing stenosis to the right posterior cerebellar artery (Fig. 2).

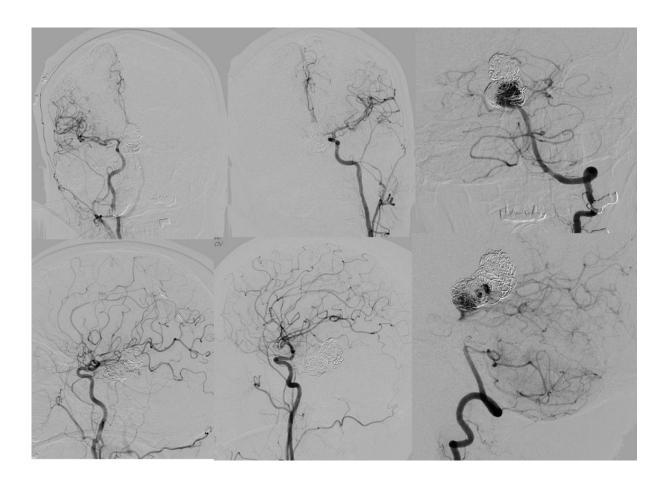


Fig. 2 Posterior-anterior view (a, b, c) and lateral view (d, e, f) Digital substraction angiography (DSA) images demonstrating central inflow and dislocation of the previously implanted coils. No pattern of both posterior communicating arteries was observed.

After implantation of a ventricular-peritoneal shunt system the patient improved moderately. After interdisciplinary clinical discussion the patient was referred to the interventional neuroradiology department and pCANvas – assisted occlusion was chosen as a course of action. Written informed consent was obtained from the patient regarding any possible complications. The aim of the treatment was to achieve definite elimination of the aneurysm from the cerebral circulation and to avoid any further regrowth and recanalization of the aneurysm.

The patient underwent full double antiplatelet therapy prior to the endovascular treatment -75 mg Acetylsalicylic acid and 75 mg Clopidogrel per day were administered for 5 days before the procedure. Under general anesthesia, the right common femoral artery was catheterized using the Seldinger technique. DSA confirmed recurrent inflow into the neck of the aneurysm of the basilar artery bifurcation. A 6 Fr Chaperon guiding catheter (Microvention, USA) was navigated into the left vertebral artery over exchange length wire. Under roadmap guidance, a Headway 27 microcatheter (Microvention, USA) was navigated over a Synchro 2 guidewire (Stryker Neurovascular, USA) into the basilar artery, and selectively placed into the aneurysmal sac. The device was fully flushed and then loaded inside the microcatheter. The pCANvas was carefully positioned and deployed at the level of the aneurysm neck. Successful device detachment was confirmed under fluoroscopy. (Fig. 3,4). The procedure was performed by the head of our Interventional Radiology Department, S. S., who has more than 10 years of experience in the field of neuroradiology.

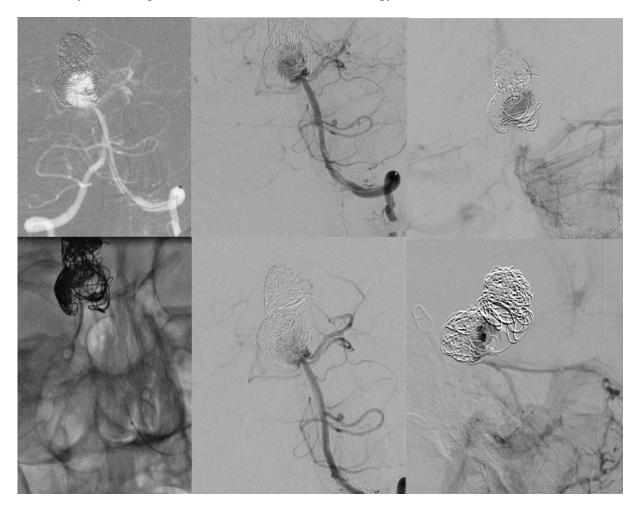


Fig.3 Posterior-anterior roadmap image (a) and working projections (b, c, d) Digital substraction angiography (DSA) demonstrating successful implantation of pCANvas at the desired target location. The markers of the device are covered from previously deployed coils. Posterior-anterior (e) and lateral view (f) of the final angiogram confirmed a sufficient stagnation of contrast media due to flow disruption by the stent's membrane.

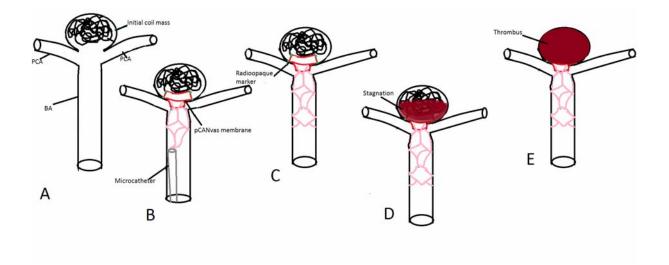


Fig 4. A schematic drawing of the embolization procedure. A. Schematic presentation of the anatomical configuration of the aneurysm before the procedure. B. The process of deploying the pCANvas via Headway 27 microcatheter. C. Fully expanded and detached pCANvas D. Stagnation during control DSA at the end of the procedure. E. Fully thrombosed aneurysm seen at the follow-up DSA

During the intraoperative DSA control contrast injections, notable reduction of the blood flow and intraluminal stagnation of contrast media were observed. Since avoiding further aneurysmal regrowth as well as reduction of the mass effect were essential in this case, subsequent coiling was not performed. We suggest that the biocompatible membrane on the distal end of the device and intrasaccular flow disruption features of the device were sufficient enought to achieve maximum post-operative volume reduction.

The postoperative period was uneventful and the patient was discharged 10 days later in stable condition without any new neurological deficits. A dual antiplatelet therapy with 75mg of Clopidogrel for 6 months and 100 mg Acetylsalicylic acid for 12 months was prescribed.

On the third-month follow-up angiogram, there was no evidence of aneurysmal recurrence or visible contrast penetration into the aneurysm sac, compatible with complete obliteration of the aneurysm. Further, MRI studies demonstrated signs of an ongoing thrombosis at the level of the neck (Fig. 5)

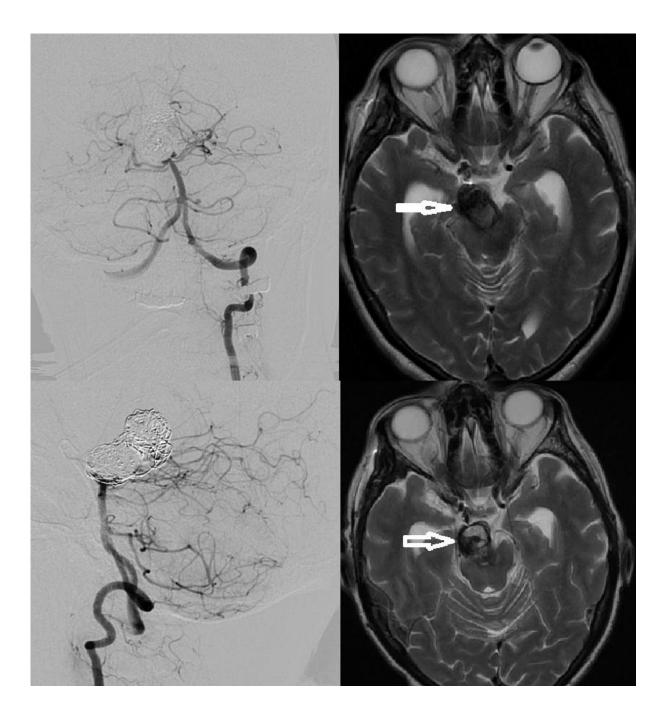


Fig.5 Posterior-anterior view (a) and lateral view (c) Digital substraction angiography (DSA) on 3-month-control with no evidence of recanalization across the aneurysmal neck and both posterior cerebral arteries are patent. Axial (b, c) T2-weighted magnetic resonance images demonstrate thrombus formation above the implanted pCANvas stent

Unfortunately, the patient passed away 8 months later due to the bulbar paresis in another hospital and no long-term angiographic follow-ups were obtained.

Discussion

The endovascular treatment of the wide-necked intracranial aneurysms has been a challenging task. Endovascular coiling alone may not achieve the best results if the aneurysmal neck is ≥ 4 mm and the aneurysmal fundus/neck ratio is ≥ 1 . (3, 4) A multicenter retrospective study BRANCH (WNBA of the middle cerebral artery and the basilar apex treated by endovascular techniques) compared and analyzed the angiographic outcomes of endovascular treatment of WNBAs with different FDA approved devices. The study demonstrates 30.6% Raymond Roy class one occlusion rate of endovascular treatment of wide-neck MCA and BA apex aneurysms at mean follow up of 48.8 weeks. (5) The authors highlighted the need of novel devices specially designed to treat such complex intracranial aneurysms.

Currently for treating WNBAs many devices and techniques are available. One of the earliest and easiest to use solutions was the 3D coils. These coils create large and small loops alternating at 90° angles, creating a complex 3D shape as they are used usually as the first framing coil. (6) This approach grants favorable results for aneurysms with relatively high width when compared to shorter or wide-necked aneurysms. (6)

The use of one or more balloon microcatethers in balloon-assisted coiling technique has led to good results but its major limitation is the relatively increased risk of ischemic and thromboembolic events because of the temporary interruption of the parent vessel blood flow. (7, 8) Moreover, the non-detachable balloon protection is not permanent and the risk of postoperative coil migration is substantial. The Y- stenting technique is a technically difficult alternative to remodel vascular bifurcations. Two stents, braided or laser cut, are deployed parallel to one another ("kissing") or inside one another ("crossing") forming a Y shape. (9) This provides a scaffold for further coiling and avoids herniation of the parent vessel.

Devices designed especially for the WNBA have been developing at increasing pace. In a recently published study, Adjunctive Neurovascular Support of Wide-necked aneurysm Embolization and Reconstruction (ANSWER), Spilotta et al. reported the results of using the Pulse Rider device. The authors declared 3 intraoperative complications of 34 cases and satisfactory occlusion in 79.4% of cases on day zero. (10) The percentage increased to 87.9% after the 6 months' follow-up.

Another option is the WEB device - a nitinol braided-wire intravascular device that causes rapid flow disruption of the aneurysmal blood flow followed by subsequent thrombosis. The technical success ranges between 92.9% to 98.7%, but the satisfactory occlusion rate of the late follow ups ranges from 80% to 82%.(11)

Recently, another available option for broad based aneurysms is the eCLIPs device. It provides flow diversion effect along the aneurysm neck as well as bridging properties for further embolization. A recent study reported 76% technical success rate and 73.9% adequate occlusion rate after the 6 months follow up. (12)

Medina embolization system (MED; Medtronic) is a 3D coil combined with woven cage designed as a hybrid device combining features of a detachable coil and an intrasaccular disruption device. The technical success rate of MED was measured at 93.3% but the mid-term adequate occlusion rates vary greatly between 80-90% depending on the study. (9, 11)

The pCONus is a nitinol laser-cut neck bridging device, existing in two variations – the pCONus1 with 4 intraluminal petals and the pCONus2 with 6 intraluminal petals. Several studies reported satisfactory results of both pCONus1 and pCONus2. Aguiae-Perez et al. reported 28 cases with 28 WNBAs treated by pCONus1-assisted coiling. In 89% of the cases one pCONus1 stent was able to provide stability for the coils and protect the parent vessels. On angiographic follow-up in 59% full occlusion was achieved, in 27.3% neck remnant was visible and in 13.6% aneurysm remnant was for results of 2017 the full occlusion rate of pCONus1 treated aneurysms was 67.7% on one-year follow-up. (13) In 29% of cases neck remnants were observed and in 3.3% there was an aneurysm remnant.

The evolution of pCONus1 – the pCONus2 – added two additional petals to the device crown for greater neck coverage, as well as for optimization of the positioning in difficult anatomy. In a series of 12 cases treated with the pCONus2 device, in 10 cases full occlusion was achieved as immediate angiographic result, with neck remnants visible in the other two. (14) The follow-up at mean 4.6 months after the procedure the adequate occlusion rate was 83%.

The pCANvas device is a third generation device suitable for the waffle cone technique. Unlike the previous pCONus1 and pCONus2 devices, the pCANvas possesses a square membrane on its distal end that gives the advantage of some flow-modifying potential in combination with its neck bridging qualities. The membrane is easily punctured with a standard guidewire, allowing for additional coiling after deployment. Since hemodynamics plays key role in recanalization of previously coiled aneurysms, the flow modifying potential of the pCANvas was of great interest. An in vitro study compared the flow modulation properties of the pCONus1, the Solitaire AB (Medtronic, USA) and the pCANvas. (15) The results proved that none of the devices were causing an increase of the intraluminal blood flow. The preimplantation/postimplantation flow ratio showed slight decrease of the intra-aneurysmal flow for the Solitaire AB and pCONus1 devices, 0.96 and 0.91 respectively. On the other hand, the pCANvas showed significant decrease of the intraluminal blood flow with preimplantation to postimplantation flow ration of 0.4. The consequences of these promising results were questioned by Lylyk et al. in a case series of 17 patients with 17 WNBAs treated with the pCANvas alone. Of all the patients 13 were assessed as Raymond Roy Class 3 occlusion, 2 showed only neck remnants (RRC 2) and 2 showed no filling (RRC3). Since many WNBA are lobulated or have difficult geometry, sizing of the pCANvas may prove to be challenging and the risk of malposition of the device may be high. In regards with these conditions the authors suggest that continuous coaxial flow around the pCANvas membrane is probable, leading to ineffective lumen thrombosis. (2)

According to our limited experience with this technique we believe that the pCANvas offers the advantage of a bifurcation device with hemodynamically active membrane which directs the blood

flow away. The flow reduction qualities of the device may lead to faster thrombosis and thus reduce the chances of recanalization.

Conclusion

We present a case of a previously treated and recanalized complex basilar tip aneurysm. In our opinion the hemodynamic effect of the pCANvas related to a thin polymer membrane covering the four distal petals of the implant resulted in complete occlusion of the aneurysm at third month follow-up. This case illustrates the challenges of treating WNBAs and highlights the potential usage of intrasaccular flow-disruption devices along with extrasaccular remodelling devices in patients harboring such kind of lesions.

References

1. Brown R, Broderick J. Unruptured intracranial aneurysms: epidemiology, natural history, management options, and familial screening. The Lancet Neurology. 2014;13(4):393-404.

2. Lylyk P, Chudyk J, Bleise C, Henkes H, Bhogal P. Treatment of Wide-Necked Bifurcation Aneurysms. Clinical neuroradiology. 2018:1-1.

3. Aguilar-Perez M, Kurre W, Fischer S, Bazner H, Henkes H. Coil Occlusion of Wide-Neck Bifurcation Aneurysms Assisted by a Novel Intra- to Extra-Aneurysmatic Neck-Bridging Device (pCONus): Initial Experience. American Journal of Neuroradiology. 2013;35(5):965-971.

4. Brinjikji W, Cloft H, Kallmes D. Difficult Aneurysms for Endovascular Treatment: Overwide or Undertall? American Journal of Neuroradiology. 2009;30(8):1513-1517.

5. De Leacy R, Fargen K, Mascitelli J, Fifi J, Turkheimer L, Zhang X et al Wide-neck bifurcation aneurysms of the middle cerebral artery and basilar apex treated by endovascular techniques: a multicentre, core lab adjudicated study evaluating safety and durability of occlusion (BRANCH). Journal of NeuroInterventional Surgery. 2018;11(1):31-36.

6. Cloft HJ, Joseph GJ, Tong FC, Goldstein JH, Dion JE. Use of three-dimensional Guglielmi detachable coils in the treatment of wide-necked cerebral aneurysms. American Journal of Neuroradiology. 2000 Jun 1;21(7):1312-4.

7. Moret J, Cognard C, Weill A, Castaings L, Rey A. The "remodelling technique" in the treatment of wide neck intracranial aneurysms: angiographic results and clinical follow-up in 56 cases. Interventional Neuroradiology. 1997 Mar;3(1):21-35.

8. Spiotta A, Bhalla T, Hussain M, Sivapatham T, Batra A, Hui F et al. An Analysis of Inflation Times During Balloon-Assisted Aneurysm Coil Embolization and Ischemic Complications. Stroke. 2011;42(4):1051-1055.

9. Henkes H, Weber W. The Past, Present and Future of Endovascular Aneurysm Treatment. Clinical Neuroradiology. 2015;25(S2):317-324.

10. Spiotta A, Derdeyn C, Tateshima S, Mocco J, Crowley R, Liu K et al. Results of the ANSWER Trial Using the PulseRider for the Treatment of Broad-Necked, Bifurcation Aneurysms. Neurosurgery. 2017;81(1):56-65.

11. Jia Z, Shi H, Miyachi S, Hwang S, Sheen J, Song Y et al. Development of New Endovascular Devices for Aneurysm Treatment. Journal of Stroke. 2018;20(1):46-56.

12. Chiu A, De Vries J, O'Kelly C, Riina H, McDougall I, Tippett J et al. The second-generation eCLIPs Endovascular Clip System: initial experience. Journal of Neurosurgery. 2018;:482-489.

13. Gory B, Aguilar-Pérez M, Pomero E, Turjman F, Weber W, Fischer S et al. One-year Angiographic Results After pCONus Stent-Assisted Coiling of 40 Wide-Neck Middle Cerebral Artery Aneurysms. Neurosurgery. 2017;80(6):925-933.

14. Lylyk P, Chudyk J, Bleise C, Sahl H, Pérez M, Henkes H et al. The pCONus2 Neck-Bridging Device: Early Clinical Experience and Immediate Angiographic Results. World Neurosurgery. 2018;110:e766-e775.

15. Pérez M, Henkes H, Bouillot P, Brina O, Slater L, Pereira V. Intra-aneurysmal hemodynamics: evaluation of pCONus and pCANvas bifurcation aneurysm devices using DSA optical flow imaging. Journal of NeuroInterventional Surgery. 2015;8(11):1197-1201.