Pipeline embolization device case series

Yan et al., retrospectively reviewed 126 consecutive patients with 128 large intracranial aneurysm or giant intracranial aneurysms which were treated with different endovascular techniques between January 2014 and February 2017 in the Beijing Tiantan Hospital and Beijing Tsinghua Changgeng Hospital. They then compared clinical and angiographic outcomes, as well as the technical events rate among different treatment modalities.

In this study, complete occlusion at last follow-up was achieved in 65.6%, 90.5% and 72.0% of aneurysms in Stent assisted coiling (SAC), Parent artery occlusion (PAO) and Pipeline embolization device (PED) group (P=0.119). Both at 6 months (OR=1.81, P=0.396) and last angiographic follow-up (OR=3.64, P=0.123), PAO was not superior to PED regarding complete occlusion rate. Retreatment rate was statistically different among 3 groups (P<0.001) and the rate was highest in the SAC group (21.9%). The rates of hemorrhagic events and ischemic events were not significantly different among 3 groups (P=0.581). However, mass effect exacerbation was more frequently seen in SAC group (24.4% vs 7.7% and 3.3%, P=0.004). Major complication rate was higher in PAO group compared with PED group, however, the difference did not reach statistical difference (19.2% vs 16.4%, OR=1.21, P=0.763). The rate of technical events was statistically different in three groups (p=0.0437) and these problems occurred more often during the employment of PED (18.0%).

For large and giant internal carotid artery aneurysm, the outcome for endovascular treatment remains poor, even after the introduction of Pipeline embolization device [1].

2018

From January 2016 to September 2017, 58 patients with 58 aneurysms were treated with pipeline embolization device in the Department of Interventional Neuroradiology, Beijing Neurosurgical Institute and Beijing Tiantan Hospital, Capital Medical University, Department of Neurosurgery, Beijing Tsinghua Changgung Hospital, School of Clinical Medicine, Tsinghua University, Department of Interventional Neuroradiology, Beijing Neurosurgical Institute and Beijing Tiantan Hospital, Capital Medical University, in China.

Aneurysms were manually segmented from the DICOM file and we calculated 16 shape features voxel by voxel on the segmented aneurysm image. Along with other 13 clinical and radiographic variables, Zhang et al., performed univariate and multivariate analysis to explore predictors of incomplete occlusion.

At last angiographic follow up (median: 6.2 months), complete occlusion was achieved in 41 aneurysms (70.7%). In multivariate analysis, mal apposition of stent (OR=0.03; 95%CI, 0.00-0.32; P=0.004) and higher Elongation value (OR=0.03; 95%CI, 0.01-0.17; P<0.001) were independently associated with incomplete occlusion of aneurysms. Compared with aneurysms with complete occlusion, incompletely occluded aneurysms had larger values of Elongation (median: 0.890 vs 0.766; P<0.001), the optimal cutoff value of Elongation for occlusion status classification was 0.862. Predicting accuracy, sensitivity, specificity, positive prediction value, negative predictive value and AUC of the logistic regression model were 0.879, 0.902, 0.824, 0.925, 0.778 and 0.872, respectively.

The results suggested that mal apposition of stent and higher Elongation value were independent negative predictors of aneurysms occlusion following flow diversion [2].

The study cohort was comprised of 109 patients. The mean aneurysm size was, 20.2% were located in the posterior circulation, and 11.9% were ruptured. The most common reasons for off-label use were aneurysm size (50.5%), location (25.7%) or both (10.1%). The mean follow-up was 9 months. Complete occlusion was achieved in 82.5% of cases at last angiographic follow-up and mRS decline was found in 18.8% of the cases. On univariate analysis, age, aneurysm size aneurysm morphology, aneurysm location, and the reason for off label use as well as the rupture status were not associated with clinical decline or aneurysm occlusion on angiography. On multivariate analysis PED treatment of a ruptured aneurysm was found to be an independent predictor of a postoperative decline in mRS, and size as the only reason for off-label PED use was found to be an independent predictor of complete occlusion on final angiography.

The off-label use of the PED has a reasonable risk to benefit profile for appropriately selected aneurysms. Posterior circulation location and fusiform morphology do not appear to be associated with worse clinical or angiographic outcomes [3].

2017

Records of patients with distal internal carotid artery (ICA) aneurysms treated with PED at our institution between 2012 and 2017 were retrospectively reviewed. Regions of interest were selected proximally to PED over the cavernous ICA and distally over the middle cerebral artery (MCA), and then transit times were determined using syngo iFlow software (Siemens). Ratio of MCA to ICA transit time was compared before, after treatment, and at follow-up. Ratios were also compared between DIPH+ and DIPH- subgroups. Correlations between aneurysm size, age, and ratios were investigated. Results Fifty-three patients were included. The ratio of MCA to ICA transit time decreased significantly after PED deployment (1.13 vs. 1.22, $p < 0.01$). The ratio in the DIPH + subgroup ($n = 4$) was significantly lower (1.00 vs. 1.14, $p = 0.01$) and decreased significantly more (21% vs. 4.4%, $p = 0.02$) compared to the DIPH- subgroup ($n = 49$). The ratio tended to be higher in larger aneurysms at baseline ($r = 0.25$, $p = 0.07$) but not after PED treatment ($r = 0.11$, $p = 0.15$). Age did not correlate with ratio. Conclusion The ratio of MCA to ICA transit time decreases following PED treatment and decreases more in patients with DIPH. These contrast transit time changes can be detected in real-time immediately after PED deployment [4].

2016

Kan et al., report on a cohort of 15 patients with 16 cerebral aneurysms that incorporated an end vessel with no significant distal collaterals, which were treated with the PED. The cohort includes 7 posterior communicating artery aneurysms, 5 ophthalmic artery aneurysms, 1 superior cerebellar artery aneurysm, 1 anterior inferior cerebellar artery aneurysm, and 2 middle cerebral artery aneurysms. None of the aneurysms achieved significant occlusion at the last follow-up evaluation (mean 24 months). Based on these observations, the authors do not recommend the use of flow diverters for the treatment of this subset of cerebral aneurysms [5].

2015

Thirty-three patients who underwent treatment with the PED of a recurrent previously coiled aneurysm were retrospectively identified. Efficacy was assessed in terms of angiographic occlusion at the latest cerebral angiogram, recurrence and retreatment rates after PED placement, and clinical outcome at the latest follow-up. Safety was assessed by looking at the complications, morbidity, and mortality after PED treatment.

The mean patient age was 53 years. The mean percent recurrence from coiling to PED placement was 34%. The mean time from coiling to PED placement was 40 months. PED treatment resulted in complete aneurysm occlusion in 76.7% of patients and near-complete aneurysm occlusion (≥90%) in 10%, for a total rate of complete and near-complete aneurysm occlusion of 86.7%. All patients, including those with incomplete aneurysm occlusion, had a significant reduction in aneurysm size. Two aneurysms required another retreatment after PED placement (6.2%). Ninety-seven percent of patients had a good clinical outcome. Complications were observed in 1 patient (3%), who suffered an intracerebral hemorrhage. There were no mortalities.

The use of the PED in the management of recurrent, previously coiled aneurysms is safe and effective in achieving aneurysm occlusion [6)].

Xiang et al. performed computational modeling of 3 PED-treated complex aneurysm cases. The patient in Case 1 had a fusiform vertebral aneurysm treated with a single PED. In Case 2 the patient had a giant internal carotid artery (ICA) aneurysm treated with 2 PEDs. Case 3 consisted of tandem ICA aneurysms (III-a and III-b) treated by a single PED. The authors' recently developed high-fidelity virtual stenting (HiFiVS) technique was used to recapitulate the clinical deployment process of PEDs in silico for these 3 cases. Pretreatment and posttreatment aneurysmal hemodynamics studies performed using CFD simulation were analyzed. Changes in aneurysmal flow velocity, inflow rate, wall shear stress (WSS), and turnover time were calculated and compared with the clinical outcome.

In Case 1 (occluded within the first 3 months), the aneurysm had the most drastic flow reduction after PED placement; the aneurysmal average velocity, inflow rate, and average WSS were decreased by 76.3%, 82.5%, and 74.0%, respectively, whereas the turnover time was increased to 572.1% of its pretreatment value. In Case 2 (occluded at 6 months), aneurysmal average velocity, inflow rate, and average WSS were decreased by 39.4%, 38.6%, and 59.1%, respectively, and turnover time increased to 163.0%. In Case 3, Aneurysm III-a (occluded at 6 months) had a decrease by 38.0%, 28.4%, and 50.9% in average velocity, inflow rate, and average WSS, respectively, and turnover time increased to 139.6%, which was quite similar to Aneurysm II. Surprisingly, the adjacent Aneurysm III-b had more substantial flow reduction (a decrease by 77.7%, 53.0%, and 84.4% in average velocity, inflow rate, and average WSS, respectively, and an increase to 213.0% in turnover time) than Aneurysm III-a, which qualitatively agreed with angiographic observation at 3-month follow-up. However, Aneurysm III-b remained patent at both 6 months and 9 months. A closer examination of the vascular anatomy in Case 3 revealed blood draining to the ophthalmic artery off Aneurysm III-b, which may have prevented its complete thrombosis.

This proof-of-concept study demonstrates that HiFiVS modeling of flow diverter deployment enables detailed characterization of hemodynamic alteration by PED placement. Posttreatment aneurysmal flow reduction may be correlated with aneurysm occlusion outcome. However, predicting aneurysm treatment outcome by flow diverters also requires consideration of other factors, including vascular anatomy [7)].

Between March 2012 and September 2014, 130 patients with 139 intracranial aneurysms (8 ruptured) were treated with the PED under CS at the Departments of Neurosurgery, Radiology, and Neurology, School of Medicine and Biomedical Sciences Gates Vascular Institute at Kaleida Health, and Toshiba Stroke and Vascular Research Center, University at Buffalo, State University of New York; Jacobs Institute, Buffalo, New York.

Procedure details and time (including duration, radiation exposure, and fluoroscopy) and procedure-related complications were retrospectively reviewed.

A total of 155 PED deployment procedures were performed under CS. Treatment was successfully completed in all cases. Anesthesia was converted from CS to general anesthesia during 5 procedures. Mean interval from patient entry at the endovascular suite to procedure initiation was 18 minutes (range, 5 minutes-1 hour 10 minutes). Mean procedure length was 1 hour 25 minutes (range, 30 minutes-3 hours 51 minutes). Mean ± SD values for fluoroscopy time and radiation exposure were 36.17 ± 18.4 minutes and 1367 ± 897 mGy, respectively. The mean amount of contrast material administered was 211.37 ± 83.5 mL. Permanent neurological complications were seen in 4 patients (3%).

CS for PED placement for intracranial aneurysm treatment is feasible and safe. Procedure and fluoroscopy times and amount of radiation exposure are similar to or less than described in reports of PED placement under general anesthesia. CS allows direct neurological evaluation and earlier detection of and response to intraprocedural complications [8)].

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30 patients harboring 30 aneurysms were analyzed. 39 devices were placed properly. Multiple Pipeline embolization devices (PEDs) were used in 7 cases. In 28 devices the distal end opened fully from the beginning with a complete wall apposition. In the remaining 11 devices, distal-end opening of the devices was instant but partial, but fully opened easily after recapture. Among the 30 procedures, recapture and reposition of the Pipeline Flex was performed four times owing to proximal migration/malposition of the device during delivery. Four intraprocedural/periprocedural complications occurred, of which 2 resulted in major complications, with neurologic deficits persisting for longer than 7 days. The 30-day morbidity rate was 6.6%, with no deaths. No aneurysm rupture or parenchymal hemorrhage was seen [9)].

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29 anterior circulation unruptured saccular aneurysms with a mean size of 6.99 mm treated with the PED in a single center were retrospectively studied. The overall occlusion rate was 79.3% after a mean follow-up of 9.2 months. Four aneurysms were related to the fetal-type posterior communicating artery (PComA), and all were refractory to flow diverter treatment. Female gender was significantly associated with a higher occlusion rate. We present the anatomical features and propose possible pathophysiological mechanisms of these PComA aneurysms that failed flow diverter treatment.

A PComA aneurysm with persistent fetal-type circulation appears to be particularly refractory to flow diverter treatment, especially when the aneurysm incorporates a significant portion of the PComA. Our experience suggested that flow diverting stents alone may not be the ideal treatment for this

subgroup of aneurysms, and alternative modalities should be considered. Female patients were found to have a significantly higher rate of treatment success [10].

Navarro et al. describe their early experience in treating 3 unruptured pediatric brain aneurysms using the Pipeline embolization device (PED). The first patient, a girl with Majewski osteodysplastic primordial dwarfism Type II who was harboring multiple intracranial aneurysms, underwent two flow diversion procedures for a vertebrobasilar aneurysm and a supraclinoid internal carotid artery aneurysm. The second patient underwent PED placement on a previously coiled but enlarging posterior communicating artery aneurysm. All procedures were uneventful, with no postsurgical complications, and led to complete angiographic obliteration of the aneurysms. To the authors' knowledge, this is the first series of flow diversion procedures in children reported in the medical literature. While flow diversion is a new and relatively untested technology in children, outcomes in adults have been promising. For challenging lesions in the pediatric population, flow diversion may have a valuable role as a well-tolerated, safe treatment with durable results. Many issues remain to be addressed, such as the durability of flow diverters over a very long follow-up and vessel response to growth in the presence of an endoluminal device [11].

2014

Eleven patients with 13 aneurysms were included in this study. All patients had an ipsilateral posterior cerebral artery arising from the basilar artery (P1). In the immediate post-procedural setting, four patients (36%) had diminished Pcomm flow rates. After a mean follow-up of 12.6±6.7 months, three Pcomm arteries (27%) were occluded and two Pcomm arteries (18%) had diminished flow. Of patients with diminished flow/occluded Pcomm at follow-up, 80% (4/5) had diminished flow at initial post-procedure angiography compared to none of the six patients without diminished/occluded flow immediately post treatment. No patients suffered new neurologic symptoms at follow-up.

Approximately one half of Pcomm arteries demonstrated occlusion or decreased flow at follow-up if the ostia are covered with a flow diversion device. Covering the Pcomm ostium in patients with a P1 did not result in any neurologic deficits [12]

2013

108 patients with recently unruptured large and giant wide-necked aneurysms were enrolled in the study. The primary effectiveness endpoint was angiographic evaluation that demonstrated complete aneurysm occlusion and absence of major stenosis at 180 days. The primary safety endpoint was occurrence of major ipsilateral stroke or neurologic death at 180 days.

PED placement was technically successful in 107 of 108 patients (99.1%). Mean aneurysm size was 18.2 mm; 22 aneurysms (20.4%) were giant (>25 mm). Of the 106 aneurysms, 78 met the study's primary effectiveness endpoint (73.6%; 95% posterior probability interval: 64.4%-81.0%). Six of the 107 patients in the safety cohort experienced a major ipsilateral stroke or neurologic death (5.6%; 95% posterior probability interval: 2.6%-11.7%).

PED offers a reasonably safe and effective treatment of large or giant intracranial internal carotid artery aneurysms, demonstrated by high rates of complete aneurysm occlusion and low rates of adverse neurologic events; even in aneurysms failing previous alternative treatments [13].

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