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Use of pipeline flow diverting stents for wide neck intracranial aneurysms: A retrospective institutional review

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ABSTRACT

Background: Intracranial aneurysms (ICA) if inadequately treated may result in serious morbidity and mortality. Wide-neck; large/giant, fusiform, and dissecting aneurysms are not well treated using the conventional coil embolization technique. Recent advance in endovascular treatment and technology has introduced flow diverter devices including pipeline embolization devices (PED) and Silk stents that have been shown to be more effective in treating these more complicated aneurysms. Flow Diverter devices offer a more physiologic approach to ICA treatment.

Methods: We conducted a retrospective chart review of 23 adult patients who underwent aneurysm treatment utilizing the pipeline stent at Duke University Medical Center from July 2011 to March 2013.

Results: Majority of patients (19, 82.7%) showed angiographic evidence of complete obliteration of aneurysm at 6 months follow-up, with sustained clinical improvement on modified Rankin scale score. All of the patients tolerated the procedure well with no intra-operative hemorrhage or intra-operative thromboembolic complications.

Conclusions: Our experience shows that use of PED offers a safe and effective strategy for treatment of complex ICA. Larger prospective studies are needed to confirm these observations.

Key words: Flow diverter, intracranial aneurysm, pipeline device

Both Authors AA and SG contributed equally as first author for the manuscript.

Introduction

Intracranial aneurysms (ICA) result in serious morbidity and mortality.[1] In the past, selective coil embolization has been used and widely accepted as an effective method to treat most simple cerebral aneurysms.[2] The traditional coil embolization strategy is accepted as safe and technically feasible saccular aneurysms with a narrow neck or easily accessible dome.[3,4] However, it has been shown that wide-neck, large/giant, fusiform, and dissecting aneurysms are not well-treated using the conventional coil embolization technique.[5,6] Emerging data suggests that coil embolization may result in recanalization rates of 50-60% in large aneurysms or fusiform aneurysms.[2] Recurrence rates of aneurysms treated with coil embolization range from 9% to 32%, respectively. Incomplete occlusion and larger neck size are risk factors for aneurysm recurrence.[7] As a result, other technology and materials are being incorporated in aneurysm treatment. Recent advance in endovascular treatment and technology has introduced flow diverter devices including pipeline embolization devices (PED) and Silk stents shown to be more effective in treating these more complicated aneurysms not well-addressed by the conventional coil embolization technique.[5,6,8]

Flow diverter devices offer a more physiologic approach to ICA treatment.[9] The flow diverter devices are placed across the aneurysm neck, disrupt, and divert the flow to the point of stagnation, and eventually lead to aneurysm thrombosis.

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Flow diverter devices facilitate neointimal regrowth and remodeling of the arterial wall.[10,11] With the flow diverter one can exclude the aneurysm sac from the circulation without catheterizing it reducing the rate of rupture and lowering the recanalization rate.[5,6]

The PED is a microcatheter-delivered, self-expanding, cylindrical stent composed of a mesh of 48 individual cobalt chromium and platinum strands, which was initially approved for treating ICA between the petrous and superior hypophyseal segments of the internal carotid artery, which has now been extended to treat lesions of different sizes and configurations throughout the anterior and posterior intracranial circulation.[11]

Materials and Methods

This was a retrospective study of patients undergoing ICA repair using PED at Duke University Hospital. Duke Institutional Review Board approved the research protocol for this study.

Study population

All adult patients (age more than 18 years at the time of presentation) who were diagnosed with ICA and who underwent evaluation and treatment between July 1, 2012 and March 31, 2013 were identified using the appropriate current procedural terminology codes and inclusion characteristics. Patients were excluded from the study if patients were treated with other types of stents and if successful deployment of stent was not possible.

Clinical details prior to intervention and following intervention at discharge and follow-up were obtained. Demographic details, intervention details, follow-up, and complication details were obtained from electronic medical records (eBrowser™) and from the Duke Decision Support Repository (DSR). DSR is a quality assured custom-built data warehouse containing integrated clinical and financial data of all patients admitted to the Duke Health Care System.

Results

A total of 23 patients met the inclusion criteria [Table 1]. There was a significant preponderance of women (19, 82.7%) as compared to men (4, 17.3%) in our cohort. The mean age of the patient population was 52.5 years. Of the total 23 aneurysms treated, 18 (78.2%) were in anterior circulation as compared to 5 (21.8%) in the posterior circulation. All of the cases were treated on a selective basis and none of the patients had presented acutely with subarachnoid hemorrhage. Majority of treated aneurysms (12, 52.2%) were of moderate size with maximum aneurysm dimension between 11 mm and 24 mm. Our cohort mainly consisted of aneurysms with wide-neck, with mean aneurysm neck size of 7.7 mm. Nearly half of the patients (47.8%) underwent 1 stent placement and the remaining half (47.8%) underwent 2 stents placement for flow diversion. There was evidence of immediate post procedure angiographic occlusion of aneurysm in about two-third of cases. Remaining one-third of patients showed evidence of near occlusion or subtotal occlusion of aneurysm immediately after the procedure. Majority of patients (19, 82.7%) showed angiographic evidence of complete obliteration of aneurysm at 6 months follow-up. The mean modified Rankin scale score (mRS) of patients at presentation was two. Patients showed sustained recovery at discharge and also at 3 months follow-up with mean mRS of 1.7 and 1.8, respectively. All of the patients tolerated the procedure well with no intra-operative hemorrhage or intra-operative thromboembolic complications. One patient developed post procedure small brainstem infarct resulting in minimal hemiparesis, whereas one patient

Table 1: Patient demographic data, aneurysm characteristics, and procedure details

Demographic variable	Number (%)
Total patients (*n*)	23 (100)
Age (years, mean)	52.5±15.7
Gender (*n*)	
Men	4 (17.3)
Women	19 (82.7)
HTN	7 (30.4)
DM	1 (4.3)
CAD	3 (13.0)
History of smoking	6 (26.8)
Number of aneurysms (*n*)	
Anterior circulation	18 (78.2)
Posterior circulation	5 (21.8)
Aneurysm size (mm)	
<10	7 (30.4)
11-24	12 (52.2)
>24	4 (17.4)
Aneurysm neck (mean, mm)	7.7±3.5
SAH on presentation (*n*)	0 (0)
Number of stents used	
1	11 (47.8)
2	11 (47.8)
>2	1 (4.3)
Intra-operative hemorrhage	0 (0)
Intra-operative thromboembolic complications	0 (0)
Post procedure vascular complications	1 (4.3)
Other postoperative morbidities (cranial nerve palsy)	1 (4.3)
Immediate angiographic aneurysm occlusion	
Total	16 (69.6)
Sub-total	7 (30.4)
Partial	0 (0)
Complete obliteration of aneurysm at 6 months follow-up	20 (86.9)
mRS score (mean)	
At presentation	2±1
At discharge	1.7±1
At 90 days postdischarge	1.8±1.3

HTN – Hypertension; DM – Diabetes mellitus; CAD – Coronary artery disease; mRS – Modified rankin scale; SAH – Subarachnoid hemorrhage developed extraocular cranial nerve palsies (3, 4, and 6th) which showed good recovery at 3 months follow-up.

Discussion

The development of flow diversion devices, both PED and Silk stents, has been shown to be a safe and effective option in treating challenging intracerebral aneurysms not adequately or safely addressed through standard coil embolization or surgical options.[5,12] The technology of reconstructing the parent vessel wall through a stent that results in aneurysm thrombosis and neointimal proliferation of the new vessel wall has been shown to be effective in treating wide-neck, large or giant, and fusiform or dissecting aneurysms.[5]

Our results support previous observations about the safety and efficacy of using PED for treatment of complex and wide-neck aneurysms. Our cohort consisted of 23 patients with mean aneurysm neck size of 7.7 mm. Our experience showed a complete angiographic occlusion rate of 69.6% immediately after the procedure, with angiographic evidence of complete occlusion in 86.9% of patients at 6 months follow-up. These results are similar to those reported in the literature. In the pipeline for the Intracranial Treatment of Aneurysms trial that included 31 patients, follow-up angiography demonstrated a complete occlusion rate of 93.3% at 6 months.[13] Szikora *et al*. reports a complete occlusion rate of 94.4% in a series of 18 patients utilizing PED for treating wide-necked large or giant aneurysms.[14] In a study from Buenos Aires that included a series of 63 aneurysms, Lylyk *et al*. have reported a complete occlusion rate of 95% at 12 months with no complications.[15]

The Pipeline for Uncoilable or Failed Aneurysms Study or PUFS is an ongoing study following 108 patients with 110 aneurysms due to complete in June 2014 following wide-necked (≥4 mm) and either large (10-25 mm) or giant (≥25 mm) aneurysms that has demonstrated an approximately 81% occlusion rate. Device placement in this study was 99% successful as reviewed by Withers *et al*.[16] As reiterated by Kan *et al*., on the basis of the PUFS data, the PED gained Food and Drug Administration approval for the treatment of large or giant wide-necked ICA in the ICA from the petrous to the superior hypophyseal segments in April 2011.[13]

Piano *et al*. demonstrated an 86% aneurysmal sac occlusion rate at 6 months and 1 year follow-up without recanalization of the occluded aneurysms. In addition, Piano *et al*. demonstrated a 93% occlusion rate of the subgroup of paraclinoid and supraclinoid aneurysms which was thus felt as one of the best targets for flow diverter devices because of the artery caliber, greater proximity of the artery, and presence of limited perforators.[5]

Majority of patients in our cohort tolerated the procedure very well. There were no intra-operative hemorrhagic or thromboembolic complications in any of the subjects. However, one patient developed brainstem infarction after the procedure and another patient developed multiple extra ocular cranial nerve palsies after the procedure. Barring these two patients, none of the patients developed any other procedure related morbidities. The mean modified Rankin score showed modest improvement at discharge which was sustained at 3 months follow-up. Kan *et al*. speculates that any hemorrhage distal to a PED treated aneurysm reflects hemorrhagic transformation of a perioperative ischemic stroke as all patients are on dual antiplatelet therapy.[13] Yu *et al*. stated that a major concern with flow diverters is their inability to always immediately occlude the aneurysm with risk of rupture during the latency period.[6] Only post flow diverter placement aneurysm rupture cases reported by Yu *et al*. were minimal and only involved the Silk flow diverter, as opposed to the PED.[6] Current hypothesis offered by Yu *et al*. for vessel rupture with PED includes proximal migration of the PED and aneurysmal wall weakening secondary to the high content of proteolytic enzymes formed within non organized red thrombus from stagnation.[6] There have been reports of acute ischemic strokes secondary to vessel branch occlusion after use of pipeline flow diverter devices.[17]

Conclusions

Our experience shows that use of PED offers a safe and effective strategy for treatment of complex ICA. Our results are in agreement with currently available studies. Our study does have a few limitations as the study is a retrospective series based on a small number of patients. Larger prospective trials may shed more light on this issue.

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