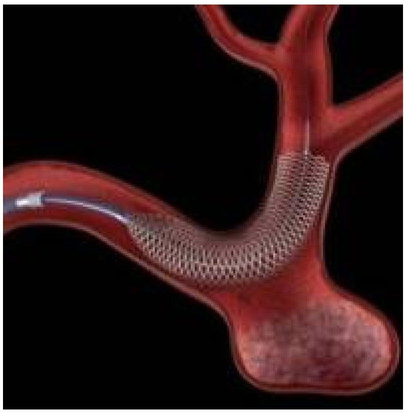
Flow diverter stent



A flow diverter stent, also known as a flow diverter device, is a type of medical device used in neurointerventional surgery for flow disruption

Types

There are several types of flow diverter stents, including:

Braided stents: These are composed of multiple strands of metal or polymer fibers woven together to create a mesh structure. They offer good flexibility and conformability, but may be prone to kinking and fracture.

Laser-cut stents: These are made from a single piece of metal or polymer that is cut using a laser to create a mesh structure. They offer precise control over the size and shape of the stent, but may be less flexible than braided stents.

Hybrid stents: These combine the braided and laser-cut techniques to create a stent with the best features of both. They are composed of a braided outer layer and a laser-cut inner layer, providing good flexibility and control.

Tubular stents: These are simple cylindrical tubes made from metal or polymer that are inserted into the blood vessel to provide support. They are less effective at diverting flow than other types of stents and may be prone to migration.

Bioresorbable stents: These are made from materials that dissolve over time, such as poly-l-lactic acid or magnesium alloys. They are intended to provide temporary support while the blood vessel heals, and do not need to be removed after the healing process is complete.

Indications

Flow diverter stent indications

Antiplatelet Therapy in Flow Diversion

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Mechanism of action

These stents are placed in the parent artery at the level of the aneurysm neck to disrupt the intra-aneurysmal flow thus favoring intra-aneurysmal thrombosis.

While endoluminal flow diverters function from within the parent artery by providing a scaffold for endothelial cell growth at the neck of the aneurysm and induction of intra-aneurysmal thrombosis [1] endosaccular devices mimic the endoluminal devices but within the aneurysmal sac itself. [2].

The mechanism of action that results in aneurysm exclusion from the circulation initially involves flow redirection with the subsequent development of a neointimal covering on the surface of the FDS that reconstructs the parent vessel and excludes the aneurysm from the circulation [3].

They take advantage of altering hemodynamics at the aneurysm/parent vessel interface, resulting in gradual thrombosis of the aneurysm occurring over time. Subsequent inflammatory response, healing, and endothelial growth shrink the aneurysm and reconstruct the parent artery lumen while preserving perforators and side branches in most cases. Flow diverters have already allowed treatment of previously untreatable wide necked aneurysm and giant aneurysms.

The emerging strategy of maximum FD compaction can double aneurysmal flow reduction, thereby accelerating aneurysm occlusion. Moreover, ultrahigh blood shear stress was observed through FD pores, which could potentially activate platelets as an additional aneurysmal thrombosis mechanism [4].

Flow-diversion technique is well-suited for the treatment of large, giant, wide-necked, and fusiform intracranial aneurysms because it does not rely on endosaccular packing with coils but rather on the strategy of placing a stent across the aneurysm “neck” or across the diseased segment of a vessel in case of a fusiform aneurysm. Over time, neointimal endothelium covers the flow diverter such that it becomes incorporated into the parent vessel wall and occludes the aneurysm from the circulation, effectively repairing the diseased parent vessel segment [5].

The use of FD has recently expanded to cover many types of IAs in various locations. Some institutions even attempt FD as first line treatment for unruptured IAs.

Devices

Double layered flow diverter

p64

The woven endobridge aneurysm embolization device (WEB) is the first intrasaccular flow-diverter device dedicated to IA treatment.

This treatment was feasible and mostly used in bifurcation aneurysms (MCA, BA, ICA) with unfavorable anatomy. Further studies are needed to precisely evaluate the indications, safety, and efficacy of this new technique [6].

Pipeline embolization device

Silk flow diverter

Surpass flow diverter

The most widely used devices are the pipeline embolization device (PED), the SILK flow diverter (SFD), the flow redirection endoluminal device (FRED), and Surpass. Many questions were raised regarding the long-term complications (i.e., delayed bleeding and device migration), the optimal regimen of dual antiplatelet therapy (APT), and the durability of treatment effect [7].

Method

The FD technique relies on a concept of endoluminal reconstruction of the parent artery and the aneurysm neck by excluding the aneurysm from the circulation. The stasis of blood flow in the aneurysm leads to an inflammatory response followed by thrombosis and “healing” of the aneurysm while the stent acts as a scaffold for neointimal proliferation and remodeling of the parent vessel. Therefore, the FD approach is considered physiologic as it restores the normal homeostasis. A recent study showed that flow-diverter device (FDD) reduces the velocity in the aneurysm sac significantly more than multiple “non-flow diverter” stents, even though both dramatically reduce the aneurysmal fluid movement [8].

To break the communication between the parent artery and the aneurysm while maintaining a patency of sidewall branches, the device must fulfill two requirements: a low porosity (metal-free to metal-covered area) and a high pore density (number of pores per square millimeters for a given porosity) [9] [10]. However, sidewall branch occlusions do not always lead to ischemia since collaterals may maintain flow to the dependent area. Even more, when collaterals are not present, the increased demand for tissue perfusion may, in some cases, generate a pressure gradient sufficient to maintain an anterograde flow through the device [11]. The technique involves navigating an FDD through the arterial system and deploying it across the aneurysm neck. Proper deployment is essential as inadequate wall apposition may decrease the flow with consequent thrombus formation at the interface followed by thromboembolic events [12]. Proper deployment and adequate wall apposition can be achieved by balloon (Boston angioplasty) [13] , though not always needed. More so, the increased turbulence along with the lytic enzymes released from platelet aggregation predisposes to a possible lysis of the aneurysmal wall that can usually occur in the following days post-op [14].

see http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3938101/#B10

Complications

Flow diverter stents (FDS) are well established in the treatment of intracranial aneurysms which are difficult to treat with conventional endovascular techniques. However, they carry a relatively high risk of specific complications compared to conventional stents. A minor but frequent finding is the occurrence of reversible in-stent-stenosis (ISS) that tend to resolve spontaneously over time. Here, we report the case of a patient in their 30s who were treated with FDS for bilateral paraophthalmic internal carotid artery (ICA) aneurysms. ISS was found at the respective early follow-up examinations on both sides and had resolved at the 1-year follow-up examinations. Surprisingly ISS reoccurred on both sides in later follow-up examinations and again resolved spontaneously. The recurrence of ISS after the resolution is a finding that has not been described previously. Its incidence and further development should be investigated systematically. This might contribute to our understanding of the mechanisms underlying the effect of FDS [15)]

The use of FDS can affect vessels covered by the device and other arteries of the circle of Willis adjacent to the FDS. The phenomena illustrated in the hypoplastic branches appear to be a compensatory response to the hemodynamic changes induced by the diverter and to the altered flow in the circle of Willis [16)].

Case series

Flow diverter stents (FDSs) are widely used to treat aneurysms in the clinic. However, even the same flow diverter (FD) use on different patients' aneurysm sites can cause unexpected hemodynamics at the aneurysm region yielding low success rates for the overall treatment. Therefore, the present study aims to unfold why FDs do not work as they are supposed to for some patients and propose empirical correlation along with a contingency table analysis to estimate the flow stasis zones in the aneurysm sacs.

The present work numerically evaluated the use of FRED4518 FDS on six patients' intracranial aneurysms based on patient-specific aneurysm geometries. Computational fluid dynamics (CFD) simulation results were further processed to identify the time evolution of weightless blood particles for six patients' aneurysms.

Stagnation zone formation, incoming and outgoing blood flow at the aneurysm neck, and statistical analysis of six patients indicated that FRED4518 showed a large flow stasis zone for an aspect ratio larger than 0.75. However, FRED4518, used for aneurysms with an aspect ratio of less than 0.65, caused small stagnant flow zones based on the number of blood particles that stayed in the aneurysm sac.

A patient-specific empirical equation is derived considering aneurysms' morphological characteristics to determine the amount of stagnated fluid flow zones and magnitude of the mean aneurysm velocity in the aneurysm sac for FRED4518 based on weightless fluid particle results for the first time in the literature. As a result, numerical simulation results and the patient data-driven equation can help perceive stagnated fluid zone amount before FRED4518 placement by shedding light on neuro-interventional surgeons and radiologists [17)].

Kiselev et al., from the Centre of Angioneurology and Neurosurgery of E.N. Meshalkin National Medical Research Center in Novosibirsk, Russia, performed a prospective randomized comparison of clinical and surgical outcomes of flow diversion versus PVO and bypass in patients with complex anterior circulation aneurysms.

39 out of 40 patients (97.5%) from matched flow diverter (FD) group reached good clinical outcome. In the matched bypass group acceptable outcome was achieved in 32 (80%) out of 40 patients (difference between groups $p = 0.029$). The morbidity and mortality rates were 15% and 5%, respectively. Difference in the rates of favorable outcomes, compared by $\chi 2$ met statistical significance ($p = 0.014$). The rate of complete aneurysm occlusion at 6 months was 42.5% in the FD group and 95% in surgical group ($p < 0.0001$). The rate of complete occlusion at 12 months was 65% in the FD group and 97.5% in surgical group. The difference between groups was still significant ($p = 0.001$). There were no significant differences between groups by occurrence of ischemic ($p = 0.108$) and hemorrhagic ($p = 0.615$) complications.

The study demonstrated superior clinical outcomes for endovascular flow diversion in comparison with bypass surgery in treatment of complex aneurysms. Though, both techniques grant similar percentage of major neurologic complications and comparable cure rate for cranial neuropathy. Nevertheless, flow diversion is associated with significantly lower early obliteration rate, thus possesses patient for risks of prolonged dual antiplatelet regimen and delayed rupture. Hence, it's important to stratify patient by the natural risk of aneurysm rupture prior to treatment selection [18].

Eleven patients with 12 aneurysms were treated with flow diverters. Two patients had ruptured dissecting aneurysms. One patient with a basilar trunk aneurysm died of acute in stent thrombosis and another patient died of brain stem ischaemia at 32 months follow-up. One patient had ischaemia with permanent neurological deficit. Two aneurysms are still open at up to 30 months follow-up. Flow diversion was used in 2% of all endovascular treatments. Both our own poor results and the high complication rates reported in the literature have converted our initial enthusiasm to apprehension and hesitancy. The safety and efficacy profile of flow diversion should discourage the use of these devices in aneurysms that can be treated with other techniques [19].

Flow Diversion complications

Flow Diversion complications

Systematic review and metaanalysis

A systematic electronic database search was conducted using MEDLINE, PubMed, Springer, and EBSCO for all accessible articles on FDDs published until December 2014. Abstracts, full-text manuscripts, and the reference lists of retrieved articles were analyzed. Random effects meta-analysis was used to pool the occlusion rate outcomes across studies.

Fifty-nine studies containing efficacy data on 2263 patients with more than 2493 treated aneurysms were included in the analysis. The overall complete occlusion rate was 82.5% (95% CI, 78.8%-86%)

across studies. The success rate of FDD implantation was 97.4% (95% CI, 95.4%-99.4%). The occlusion rate for anterior circulation aneurysms was 83.3% (95% CI, 71.2%-95.4%); with regard to complete occlusion, the odds ratio for anterior circulation aneurysms was significantly higher than that of posterior circulation IAs (odds ratio, 1.93; 95% CI, 1.00-3.73).

FDDs have high technical success rates in the management of IAs. Additional studies on well-designed multicenter randomized controlled trials will be required to validate the findings of the present study and to identify the best therapeutic strategy for IAs depending on their size, location, and characteristics [20].

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