

WEB FLOW DISRUPTION: A NEW MODALITY FOR THE ENDOVASCULAR TREATMENT OF SOME COMPLEX ANEURYSMS

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Intrasaccular flow disruption is a new and innovative treatment for intracranial aneurysms. In the first clinical experience with WEB dual layer (WEB-DL), the indications for treatment were ruptured or unruptured, wide-neck bifurcation aneurysms often challenging for the endovascular treatment. Initial series of the literature have shown a high feasibility of the treatment with low morbidity and no mortality. Anatomical results show a high rate of adequate occlusion (complete occlusion and neck remnant), some neck remnants being in fact just opacification of the proximal recess of the device. New WEB devices were recently developed (WEB-SL and WEB-SLS) and their introduction in clinical practice wills potentially enlarged indications for this treatment.

Key words: aneurysms, endovascular treatment, flow disruption, WEB.

The superiority of aneurysm coiling versus clipping has been demonstrated in randomized trials and endovascular treatment is now the first line treatment for both ruptured and unruptured aneurysms [1, 4–6]. However coiling is not applicable to all intracranial aneurysms. Aneurysms with a complex anatomy (fusiform aneurysms, wide-neck aneurysms, large and giant aneurysms) are in some cases untreatable or difficult to treat with standard coiling. It is the reason why more complex endovascular techniques have been developed like balloon-assisted coiling (balloon remodeling technique), stent-assisted coiling, and flow diversion [7].

Wide-neck aneurysms have been, since the beginning of coiling, challenging for the endovascular approach. The balloon remodeling technique, stent-assisted coiling, and the use of flow diverters have all increased the numbers of aneurysms,

which may be treated using an endovascular technique, especially in aneurysms having a sidewall (lateral) geometry [8, 9, 12]. However the treatment of wide-neck aneurysms located at vascular bifurcations remains challenging despite the use of complex techniques like double balloon remodeling technique or Y-stenting. These methods are frequently technically difficult and their use remains relatively limited. The use of intra-luminal flow diverters does not, with few exceptions, address aneurysms of this type. Moreover, while balloon-assisted coiling may be used in both ruptured and unruptured aneurysms, the use of stent-assisted coiling and intravascular flow diversion is more or less limited to unruptured aneurysms due to the need of dual antiplatelet treatment.

The concept of intrasaccular flow disruption

Flow disruption is a new technique using an intra-aneurysmal device placed at the level of the neck to disrupt the intra-aneurysmal flow and subsequently create intra-aneurysmal (and intra-device) thrombosis. As the surface exposed at the level of the neck is smooth, it is also a good support for the development of neointima.

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Preliminary animal studies concluded that treatment with the WEB device was associated with promising rates of immediate and long-term aneurysm occlusion in the rabbit elastase aneurysm model [2]. Angiographic aneurysm occlusion was evaluated at 1, 3, 6, and 12 months, and the study also included histopathologic analysis.

The WEB device

The device is composed of an inner and outer nitinol braid held together by proximal, middle, and distal radio-opaque markers and creating two compartments: one distal and one proximal. The WEB implant is deployed similarly to endovascular coil systems through microcatheters with an internal diameter ≥ 0.027 ". The detachment system is electrothermal and instantaneous. The WEB received CE Mark for unruptured and ruptured aneurysms.

The WEB device is available in diameters between 5–11 mm and heights from 4–9 mm, which shows that this treatment is applicable to medium-sized aneurysms (Fig. 1).

Procedural modalities with WEB

The treatment of aneurysms with WEB is done using similar techniques as are used in the treatment of aneurysms with coils (e.g., general anesthesia, intraoperative treatment with intravenous heparin, single or double femoral approach). Single or Dual antiplatelet treatment is not necessary for WEB treatment and pre-, intra-, and post-operative antiplatelet therapy is managed as

indicated for typical endovascular treatment with coils (or stent and coils if this approach is a potential alternative treatment).

Accurate evaluation of aneurysm anatomy (aneurysm morphology, aneurysm transverse diameter and height, and neck size) using magnetic resonance imaging (MRA), 2D, and 3D-digital subtraction angiography (DSA) is necessary to determine if the treatment with WEB is indicated and the appropriate device sizing. Sizing is a critical part of the procedure as if the device is undersized, it will not sufficiently block the neck and the aneurysm treatment will be incomplete. On the other hand, if the device is oversized, the risk is not to increase the pressure against the aneurysm wall (as the radial force is very low), but to have a protrusion of the device in the parent vessel. The sizing recommendation is to average the available aneurysm widths and heights and select a WEB that is 1 mm greater than the ave-

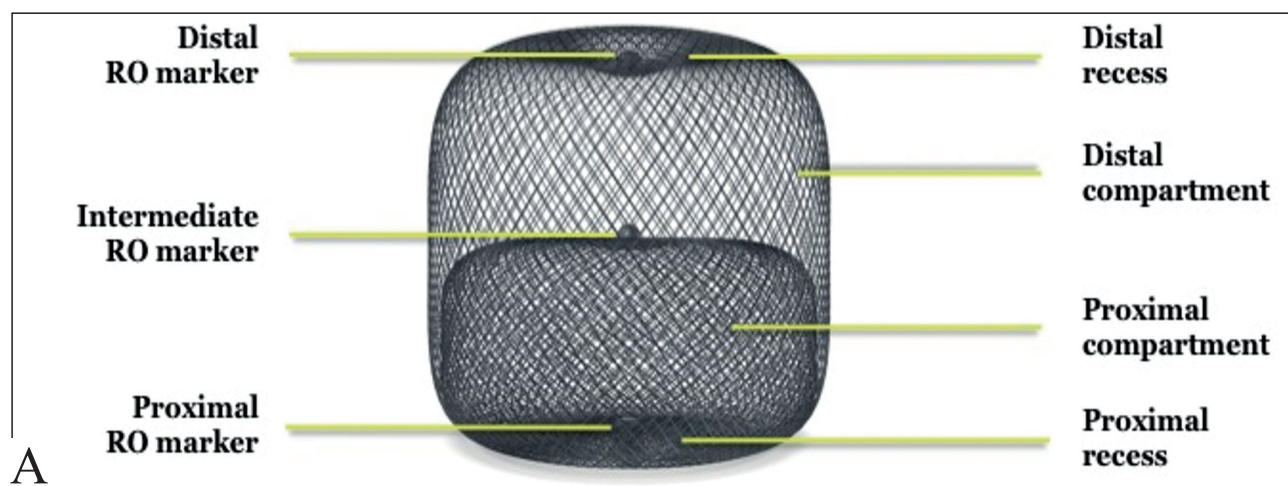
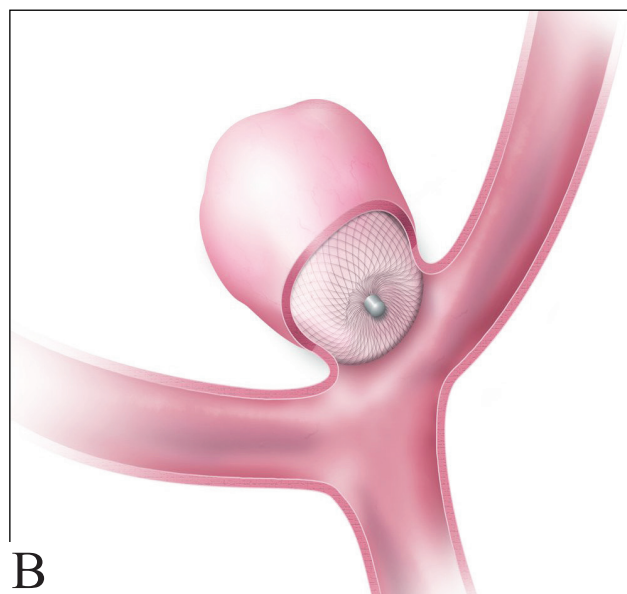


Fig. 1. A — WEB device; B — WEB device inserted in an aneurysm

rage width and 1 mm smaller than the average/minimum height. The WEB can be placed at the neck of the aneurysm and, if it does not fill the entire aneurysm volume (i.e. blebs or additional height), the implant still provides effective contrast stasis and eventual thrombosis in those distal areas and the aneurysm overall.

After the positioning of a guiding catheter into the internal carotid artery (ICA) or vertebral artery (VA), the aneurysm is catheterized with dedicated Via and Via + microcatheters (Sequent) according to the size of the device to be deployed in the aneurysm. The WEB device chosen according to aneurysm measurements is then positioned in the aneurysmal sac. A control angiogram is performed to check the position of the device in the aneurysm and to evaluate flow stagnation inside the aneurysm. If the position is not satisfactory, the device is resheathed and repositioned. If the size is not appropriate, the device is resheathed and another device is deployed into the aneurysm. When the right-sized device is correctly positioned, a final DSA run is performed. Treatment with ancillary devices (balloon, coils and stent) can be performed if deemed necessary by the treating physician. In the already published series (Table), additional treatment was performed in 10.5 % to 23.8 % of cases.

Clinical Results

Three series were to date published in the literature regarding Flow Disruption (1 monocenter and 2 multicenter) [3, 10, 11].

These 3 series clearly show that the most frequent indications for WEB treatment are wide-neck (66.7 % to 100.0 %) bifurcation aneurysms. In order of frequency, the most common aneurysmal locations treated with WEB are middle cerebral artery, basilar artery, anterior communicating artery and internal carotid artery.

The feasibility of the treatment is high (95.0 % to 100.0 %) showing that, despite the fact that a bigger microcatheter is necessary for this type of treatment, it still is as successful as standard coiling. Failures were mostly encountered at the beginning of the experience with the device and were related to difficulties for microcatheterization or inappropriate sizing.

Despite the very specific population (wide-neck bifurcation aneurysms) and the fact that the series includes the first cases treated with this new technique (i.e. learning curve), the rate of adverse events was low. Intraoperative rupture was observed in one case at the beginning of the experience of one center, the device being inadvertently deployed in a daughter sac. So according to the fact that this rupture is reported in 2 series with a different number of patents, the rate of intraoperative is between 3.0 and 5.3 %. In the ATENA series dealing with unruptured aneurysms, intraoperative ruptures were observed in 2.6 % of the procedures [6].

WEB thromboembolic events were globally observed with a rate comprised between 5.3 and 15.6 % in the series with favorable outcome in most of them. The rate of thromboembolic events is quite similar to what was reported in ATENA (unruptured aneurysms) and CLARITY

Table. Clinical and anatomical results in the series of the literature

	Pierot et al [7]	Pierot et al [8]	Pierot et al [9]
Centers	3	1	5
Period	Oct 2010/Jan 2012	Jan 2011/Jun 2012	Oct 2010/Jul 2012
Patients/Aneurysms	20/21	19/20	33/34
Ruptured	1/21	4/20	2/34
MCA/BA/Acom/ICA	8/5/4/4	14/2/2/1	34/0/0/0
Neck \geq 4 mm	14/21 (66.7 %)	20/20 (100.0 %)	30/34 (88.2 %)
Feasibility	21/21 (100.0 %)	19/20 (95.0 %)	33/34 (97.1 %)
Add. Treatment	5/21 (23.8 %)	2/19 (10.5 %)	4/33 (12.1 %)
Morbidity (mRS > 2)	0/20 (0.0 %)	1/19 (5.3 %)	1/32 (3.1%)
Mortality	0/20 (0.0 %)	0/19 (0.0 %)	0/33 (0.0 %)
Adequate Occl. (TO + NR)	12/15 (80.0 %)	13/14 (92.9 %)	25/30 (83.3 %)

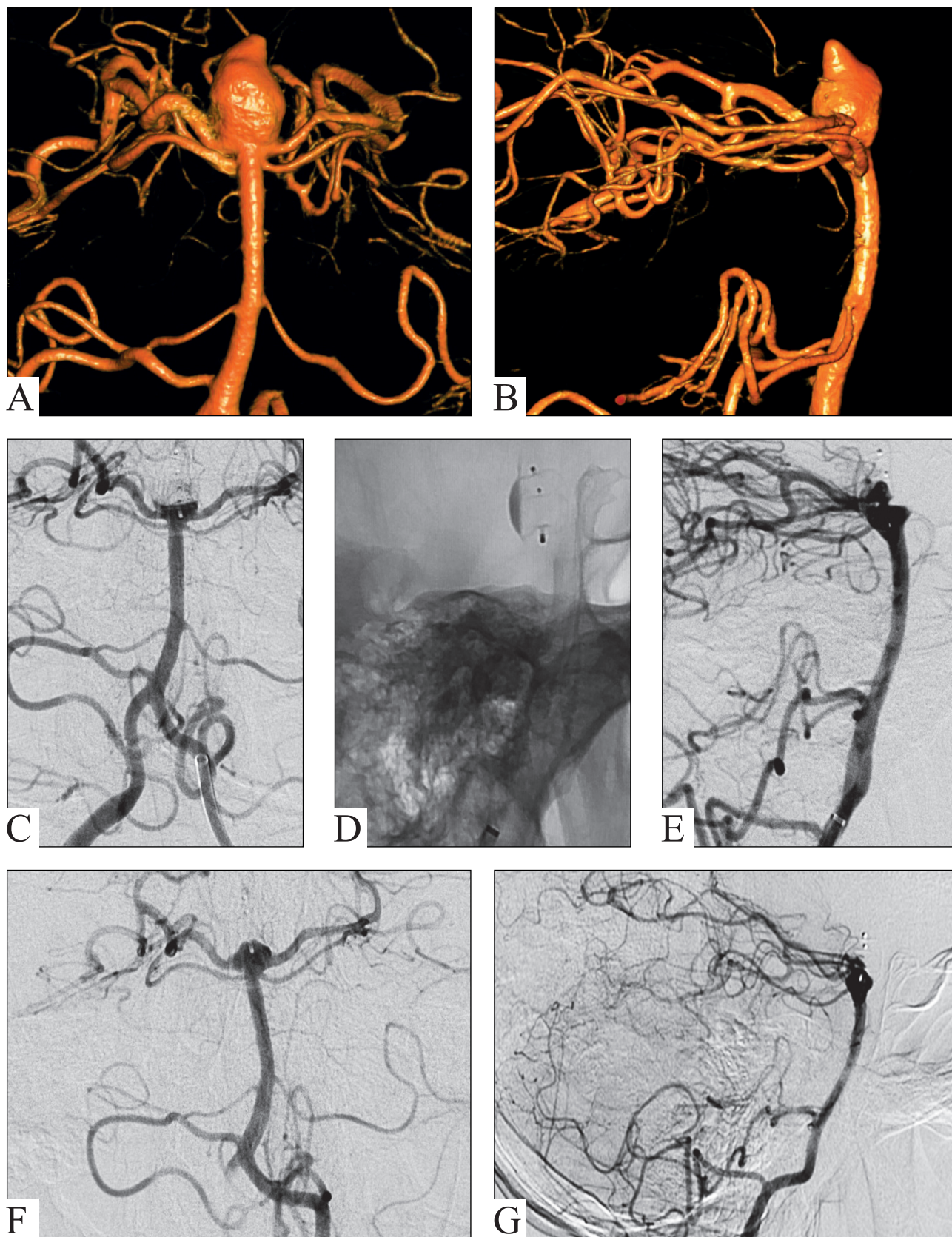


Fig. 2. 35-year old male, presenting with severe SAH (WFNS 3, Fischer 4): A and B — 3D-DSA (frontal and lateral views) showing a wide-neck basilar aneurysm with both P1 segments arising from the neck; C — post-operative DSA (frontal view) showing no more flow in the distal compartment of the WEB and residual flow in the proximal; D and E — DSA (lateral view, unsubtracted and subtracted) showing the device (2 compartments and 3 markers) and a residual flow in the posterior part of the proximal compartment; F and G — 6 months DSA showing a good occlusion of the aneurysm with an opacification of the proximal recess (which has not to be interpreted as a neck remnant)

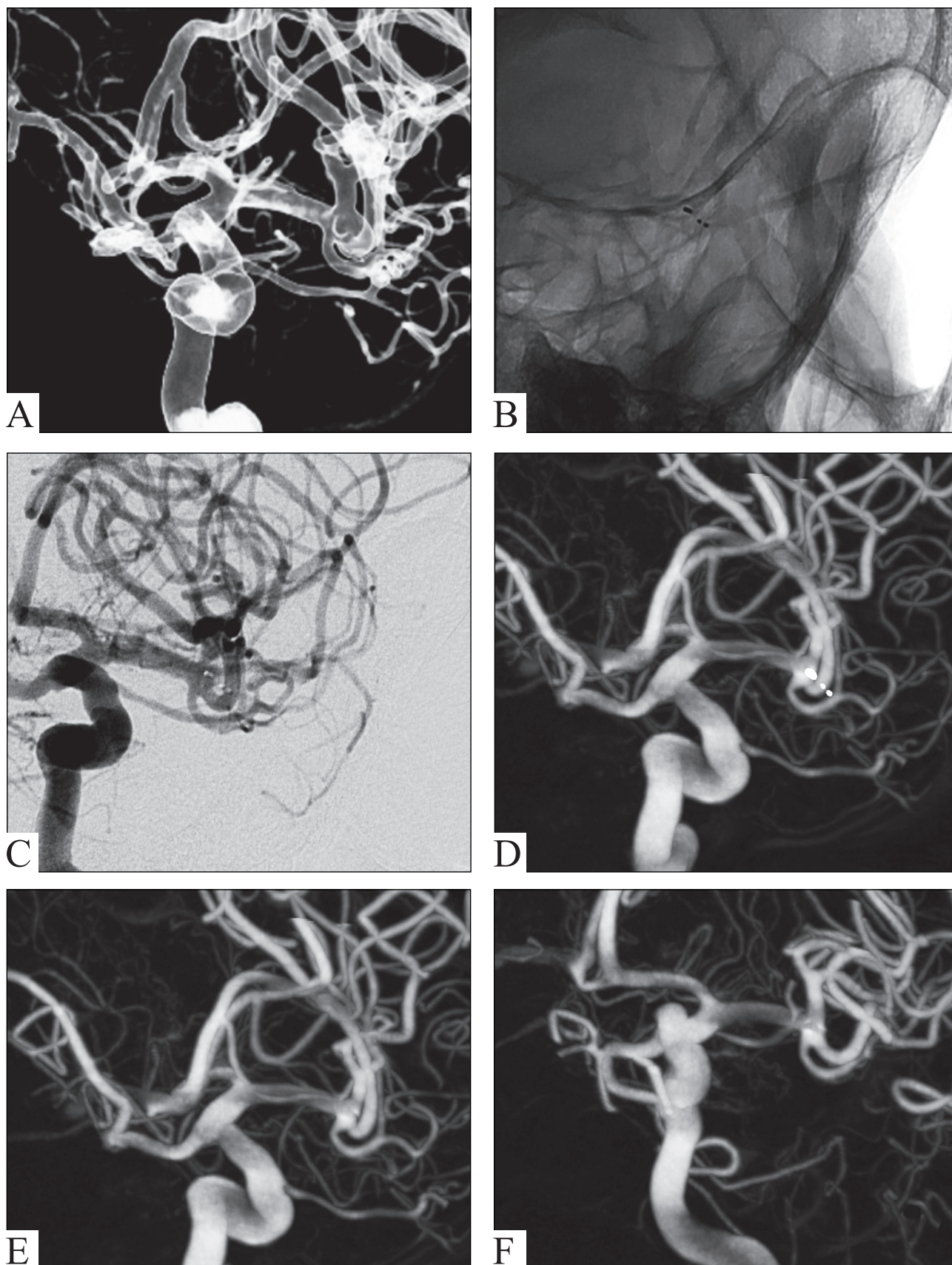


Fig. 3. 51-year old female harboring a wide-neck middle cerebral artery aneurysm with one branch arising from the neck: A — 3D-DSA (oblique view) showing the aneurysm; B — unsubtracted DSA (oblique view) showing the device in place in the aneurysm (3 markers); C — immediate postoperative DSA (oblique view) showing no residual flow in the fundus and residual flow at the level of the neck; D, E and F — one-year control DSA (oblique view, unsubtracted and subtracted) showing a complete occlusion of the aneurysm. The 3 markers are well depicted on the unsubtracted view

(ruptured aneurysms) (respectively, 7.1 % and 13.3 %) [1, 6].

Finally the mortality was 0.0 % in all series and morbidity between 3.0 and 5.3 % similar to what was reported in large series dealing with standard endovascular treatment (Table).

Anatomical results

In the 3 series, only mid-term anatomical results were evaluated and not in all patients. The rate of adequate occlusion (total occlusion or neck remnant) was high, between 80 and 92.9 %. In the largest series dealing with middle cerebral aneurysms, mid-term aneurysm occlusion was evaluated by DSA in 30/33 aneurysms (90.9 %), 2 to 12 months after treatment (median: 6.0 months). Total occlusion was observed in 8/30 aneurysms (26.7 %) (Fig. 2 and 3), neck remnant in 17/30 aneurysms (56.7 %), and aneurysm remnant in 5/30 aneurysms (16.7 %). The rate of neck remnant was unexpectedly high, but it is probably related to the fact that the proximal concave recess creates an image that is erroneously interpreted as neck remnant.

Long-term follow-up is currently under analysis in the group of patients treated at the beginning of the experience with WEB to determine the stability of the WEB treatment (Table).

The future

New WEB devices have been developed and received recently CE Mark: WEB SL (single lay-

er) and WEB SLS (single layer spherical). In contrast to the WEB DL (dual layer) described above, these new devices have just a single layer of nitinol braid. Advanced braiding techniques have created a single layer device that is designed to create a sufficient disruption of intraaneurysmal flow to obtain a rapid intraaneurysmal thrombosis. Single-layer devices have a lower profile compared to the WEB DL, which will permit the use of smaller microcatheters and may improve navigation.

Two shapes have been developed for these single-layer devices: the WEB SL has a similar barrel-shape as the WEB DL and the WEB SLS has a spherical shape. This will potentially enlarge the indications for WEB treatment to sidewall aneurysms.

Conclusion

WEB Flow Disruption is a new, innovative endovascular technique dedicated to the treatment of ruptured and unruptured wide-neck bifurcation aneurysms. Initial clinical experience has shown high feasibility of the treatment with good safety profile (no mortality and low morbidity). The efficacy has still to be precisely analyzed with evaluation of long-term stability of the treatment, but initial results are promising.

WEB Flow Disruption offers a new option for the treatment of complex wide-neck bifurcation aneurysms and, potentially with the new single layer WEBs, additional aneurysms.

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СИСТЕМИ WEB ДЛЯ ВІДХИЛЕННЯ ПОТОКУ КРОВІ: НОВИЙ СПОСІБ ЛІКУВАННЯ ОКРЕМИХ СКЛАДНИХ ЦЕРЕБРАЛЬНИХ АНЕВРИЗМ

Л. П'ЄРО

Шпиталь Мейсон Бланш, Реймс, Франція

Внутріаневризмальне відхилення потоку — це новий та інноваційний спосіб лікування внутрішньочерепних аневризм. У першому клінічному досвіді з використанням двошарових WEB або «WEB dual layer» (WEB – DL) описано лікування досить спірних відносно застосування ендovasкулярної методики аневризм, що розірвалися і не розірвалися, з широкими шийками, які розташовані на біфуркаціях. Первинні літературні дані показали великі можливості такого лікування з низькими показниками інвалідизації та летальності. Анатомічний результат продемонстрував високий рівень адекватної оклюзії аневризм (тотальна оклюзія та оклюзія із залишковою шийкою), причому частину залишкових шийок можна було розглядати тільки як контрастування вигинів самої системи, що імплантується. Нові WEB-системи, такі як WEB – SL і WEB – SLS розроблені зовсім нещодавно, їх введення в клінічну практику обіцяє потенційно розширити покази для ендovasкулярного лікування.

Ключові слова: аневризми, ендovasкулярне лікування, відхилення потоку, WEB.

ПОТОВОКООТКЛОНЯЕМЫЕ СИСТЕМЫ WEB: НОВЫЙ СПОСОБ ЛЕЧЕНИЯ НЕКОТОРЫХ СЛОЖНЫХ ЦЕРЕБРАЛЬНЫХ АНЕВРИЗМ

Л. ПЬЕРО

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Внутріаневризмальное потокоотклонение — это новый и инновационный способ лечения внутричерепных аневризм. В первом клиническом опыте с использованием двухслойных WEB или «WEB dual layer» (WEB – DL) описано лечение достаточно спорных в отношении применения эндovasкулярной методики аневризм: разорвавшихся и неразорвавшихся, с широкими шейками, расположенных на бифуркациях. Первичные литературные данные показали большие возможности такого лечения с низкими показателями инвалидизации и летальности. Анатомический результат продемонстрировал высокий уровень адекватной окклюзии аневризм (тотальная окклюзия и окклюзия с остаточной шейкой), причем часть остаточных шеек можно было рассматривать только как контрастирование изгибов самой имплантируемой системы. Новые WEB-системы, такие как WEB – SL и WEB – SLS разработаны совсем недавно, и их введение в клиническую практику обещает потенциально расширить показания для эндovasкулярного лечения.

Ключевые слова: аневризмы, эндovasкулярное лечение, потокоотклонение, WEB.