

MULTILAYER FLOW MODULATOR FOR THE TREATMENT OF TAAAs

74

C. VAISLIC, A. BENJELLOUN, J.-N. FABIANI, J.-F. BONNEVILLE, S. CHOCRON

Abstract

Current treatment of thoracoabdominal aneurysms is associated with significant morbidity and mortality. The most feared and devastating complication is paraplegia accompanied by sphincter and posture problems. To try and reduce these complications we have treated patients with multilayer flow modulators which preserve collateral circulation and branch patency. The multilayer flow modulation concept offers a completely novel approach to thoracoabdominal aneurysm treatment. Aneurysms are excluded physiologically rather than mechanically while preserving vital collateral circulation and enhancing branch patency. Here we present the key principles of the hemodynamic flow modulation concept and its application in peripheral aneurysms as well as FIM cases for the treatment of thoracoabdominal aneurysms. The enrollment of a non randomized multi-center trial with the Cardiatis multilayer flow modulator, for thoracoabdominal aortic aneurysm patients, with no alternative treatment, is currently being completed in France.

Mortality following surgical treatment of TAAA averages between 6% and 15% for elective procedures and between 50% to 60% for emergency operations 1-3. With 15% morbidity for elective procedures, complications are often major with significant risk of renal failure and respiratory insufficiency. This prolongs IC time. Paraplegia is the most feared and devastating complication and frequently leads to sphincter and posture problems. In all cases it is a severe invalidity and in France, since the law of 4th March 2002, leads to systematic claims for compensation before the CRCIs (regional medical accident compensation boards). To reduce these complications adjuvant therapies have been proposed: distal aortic perfusion by circulation bypass or passive shunt 4-6 profound general or local hypothermia with circulatory shutdown, drainage of the cephalarachidian fluid, re-attachment of the Adamkiewicz artery or intercostal arteries as well as postoperative surveillance 7, 8. In every interventional cardiovascular reference work, complete chapters are dedicated to this issue, and whole sessions are dedicated to this at international congresses.

The results of endovascular treatment for infrarenal and descending thoracic aortic aneurysms are now comparable with standard open surgical procedure. However, endovascular repair in the thoracoabdominal aorta has been limited due to the complexity of keeping visceral and renal arteries perfused. Attempts are being made to adapt endoluminal stent-grafts by using custom fenestrations and branched grafts. While preliminary data shows concept feasibility, these techniques are still investigational and require highly-skilled endovascular specialists and custom-made devices 7.

Flow modulators – The future?

The innovative multilayer flow modulating device offers a paradigm shift approach to the treatment of these complicated aneurysms by physiologically (rather than mechanically) excluding aneurysms from circulation, while keeping branches patent and preserving critical collateral circulation. The Multilayer Aneurysm Repair System (MARS) is a flow modulator and part of the FluidSmart® technology platform developed by Cardiatis, Isne – Belgium.

Its 3D geometrical structure gives rise to several important hemodynamic and biological effects:

- in a saccular aneurysm, it reduces the vortex velocity within the aneurysm sac creating a remodelled, organized thrombus;
- it transforms turbulent flow into laminar flow, preserving collateral circulation when overstenting collaterals or in a fusiform aneurysm;
- it accelerates and channels flow into a branching aneurysm (open branch enhancement), and accelerates shear flow along the parent vessel, resulting in the inhibition of intimal hyperplasia.

Preclinical animal studies have shown that endothelialisation of the MARS starts from the struts of the stent and not from the wall. This phenomenon has now been validated in over 300 clinical cases using the MARS for peripheral and visceral aneurysms.

The MARS is self-expanding and is composed of multiple cobalt alloy interconnected braided layers²⁻⁵. The 3D geometrical configuration guarantees an optimal porosity range for stents from 2 to 50 mm in diameter, thereby providing unique flow modulating features.

We present FIM humanitarian cases using the MARS for patients with a TAAA at risk of imminent rupture and not fit for open surgery or other therapeutic alternatives.

In the prospective non-randomized multicentre trial for thoracoabdominal aneurysms with the Cardiatis multilayer flow modulator, the last patient for an AFSSAPS (ethical committee approved) was enrolled in November 2010. Results will be published in 2011 when the one year follow up will be completed. The inclusion criteria included patients not fit for open surgery, endovascular or hybrid procedures.

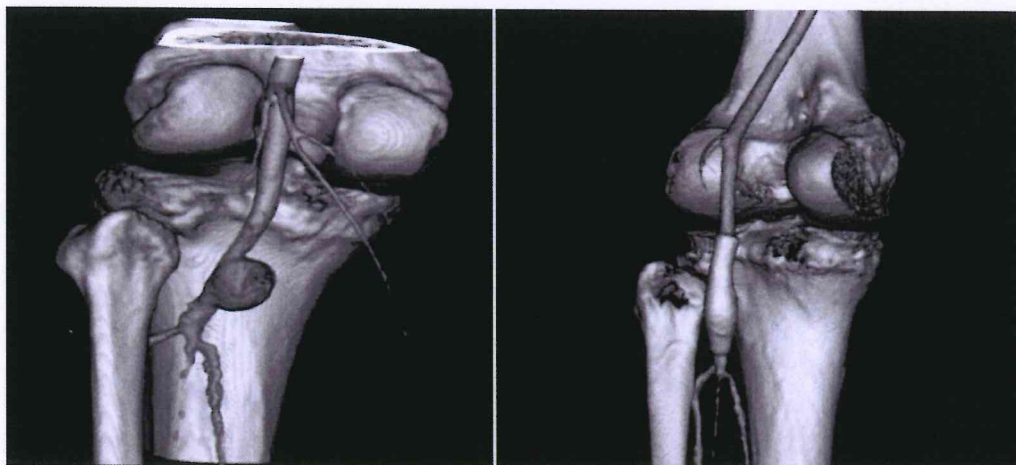


Fig. 74.1. – Popliteal aneurysm treated with MARS and FU at 1 month. Prof. Angelo Argentero, Chirurgie vasculaire, Ospedale Maggiore, Lodi, Italy.

Should this device prove to be efficacious, this type of intervention could readily become more available to patients, due to the device's ease of use and its ability to be used by more medical professionals (including vascular surgeons and interventional radiologists) than the treatment alternatives.



Fig. 74.2. – Branching renal aneurysms treated with Cardiatis Multilayer Flow Modulator.

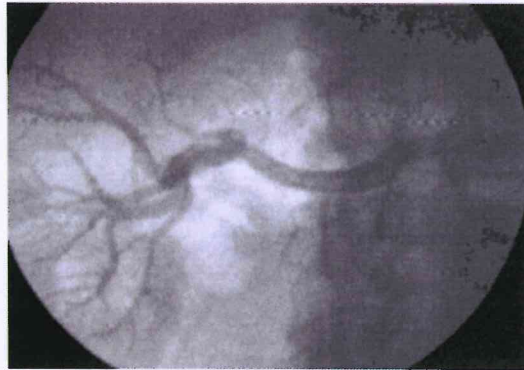


Fig. 74.3. – FU 6 months – exclusion of aneurysm and perfused collaterals and patent branches.

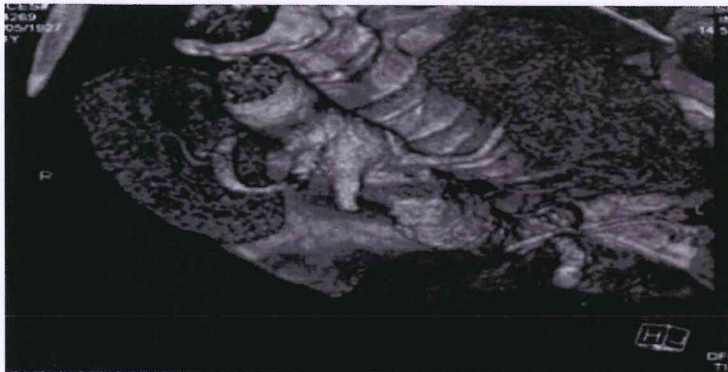


Fig. 74.4. – 30 month FU showing the 2 patent branches. Dr. Antonios Polydorou, Cardiologist, Evangelismos Hospital Athens, Greece.

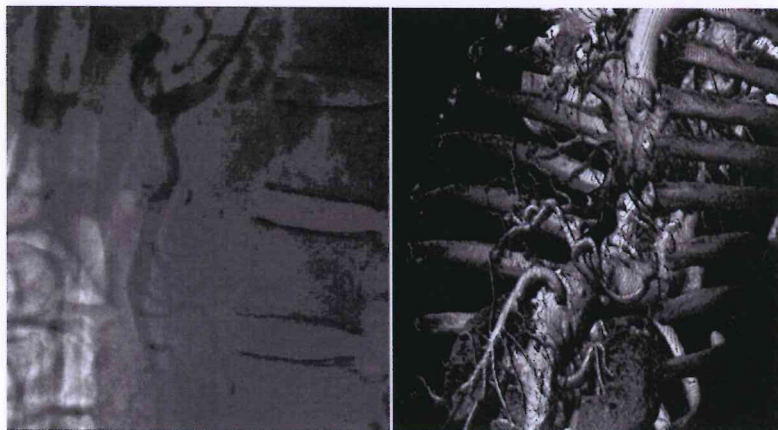


Fig. 74.5. – SM aneurysm treated with Cardiatis multilayer flow modulator, post implant and FU at 1Y. Dr. Sameer Dani, Cardiologist, Life care Institute of Medical Science & Research, Ahmedabad, India.

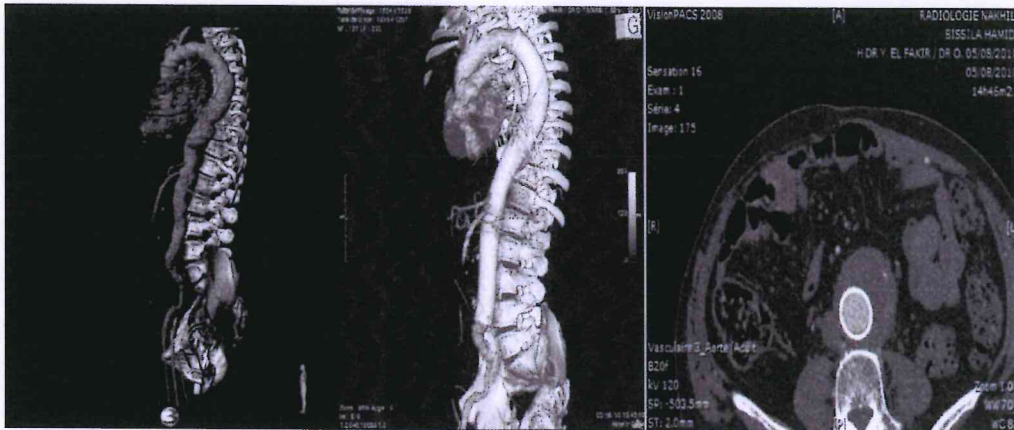


Fig. 74.6. – *Left*. Male age 67, underwent right hepato-renal graft in 1991. Presented with respiratory insufficiency and pain. Detected TAAA (right renal artery left iliac bifurcation). The image in the *Middle* shows FU at 1 year with exclusion of aneurysm and preservation of collaterals. Prof. Amira Benjelloun, Vascular Surgeon, Clinique C'ur et Vaisseaux, Rabat, Morocco.

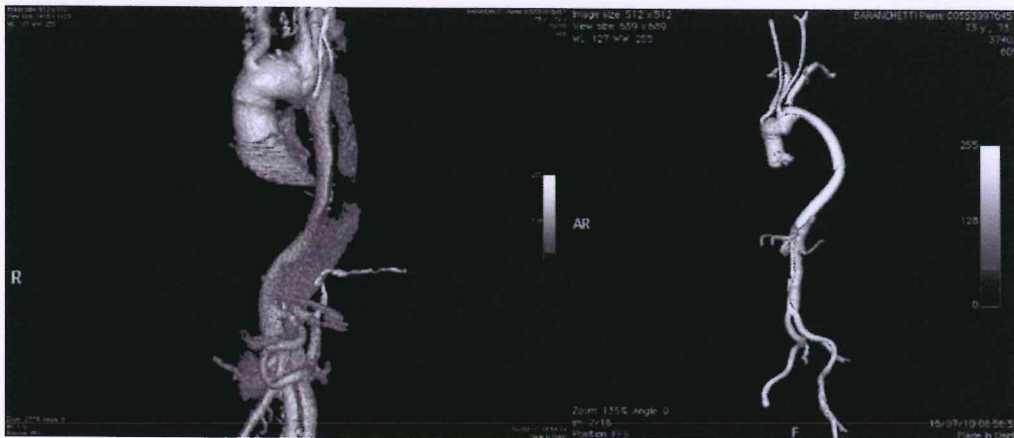


Fig. 74.7. – 2006 stent graft placement for ascending aortic dissection with reattachment of the TABC, renal artery stented for left back pain, due to compression. Aneurismal progression. *March 2010* Placement of Cardiatis multilayer flow modulator at the descending thoracic aorta. At 1 Month FU complete obliteration of the (FI) from the descending TAA distal of the left subclavian artery and excellent patency of visceral arteries⁸. Pr. Sidney Chocron, chirurgien cardiaque, CHU Jean Minjot de Besançon, France.

References

1. 2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM Guidelines for the Diagnosis and Management of Patients With Thoracic Aortic Disease. *Circulation* 2010;121:e266-e369.
2. D'Elia P, Tyrrell M, Sobocinski J, Azzaoui R, Koussa M, Haulon S. Endovascular thoracoabdominal aortic aneurysm repair: a literature review of early and mid-term results. *J Cardiovasc Surg (Torino)* 2009;50(4):439-45.
3. Bakoyiannis CN, Economopoulos KP, Georgopoulos S, Klonaris C, Shialarou M, Kafeza M, Papalambros E. Fenestrated and branched endografts for the treatment of thoracoabdominal aortic aneurysms: a systematic review. *J Endovasc Ther* 2010;17(2):201-9.

4. Patel HJ, Upchurch GR Jr, Eliason JL, Criado E, Rectenwald J, Williams DM, Deeb GM. Hybrid debranching with endovascular repair for thoracoabdominal aneurysms: a comparison with open repair. *Ann Thorac Surg* 2010;89(5):1475-81.
5. Ferrero E, Ferri M, Viazzo A, Gaggiano A, Maggio D, Berardi G, Piazza S, Cumbo P, Pecchio A, Lamorgese V. Hybrid open and endovascular repair of recurrent visceral aortic patch aneurysmal expansion after previous thoracoabdominal aortic aneurysm repair: case report and description of technique. *Minerva Chir* 2010;65(3):393-400.
6. Biasi L, Ali T, Loosemore T, Morgan R, Loftus I, Thompson M. Hybrid repair of complex thoracoabdominal aortic aneurysms using applied endovascular strategies combined with visceral and renal revascularization. *J Thorac Cardiovasc Surg* 2009;138(6):1331-8.
7. Kieffer E, Chiche L, Godet G, Koskas F, Bahnini A, Bertrand M, Fléron MH, Goarin JP, Warnier de Wailly G, Benhamou AC. Type IV thoracoabdominal aneurysm repair: predictors of post-operative mortality, spinal cord injury, and acute intestinal ischemia. *Ann Vasc Surg* 2008;22(6):822-8.
8. Chocron S, Vaislic C, Bonneville JF. Multilayer stents in the treatment of chronic type B dissection. *Annals of thoracic surgery*, in press.