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Efficacy and Durability of Multilayer Flow Modulators in Aortic Aneurysms

ABSTRACT

KEY WORDS: multilayer flow modulators, aortic aneurysm, endovascular management

BACKGROUNDS. In favourable anatomical conditions, endovascular abdominal aneurysm repair (EVAR) or thoracic endovascular aortic repair (TEVAR) are the established treatments of aortic aneurysms. The treatment of other areas is more complex and demands more complex endovascular procedures or open surgery. Multilayer flow modulators (MFM) were developed to treat aortic aneurysms in areas where standard EVAR or TEVAR are not feasible. MFM implantation is simple and arterial coverage by the device should not compromise arterial flow. The aim of our study was to determine long-term efficacy and durability of MFM in the treatment of aortic aneurysms. METHODS. Our study included 16 male and one female patient, treated in a 91-month period (starting in March 2011); the follow-up period extended to March 2023. The patient mean age was 68 years and none of the patients were suitable for EVAR, TEVAR, or open surgical management. The data collection was concluded in May 2023; the median follow-up was 25 months (range 7–76 months). RESULTS. MFMs were successfully implanted in all patients, with no 30-day mortality observed. By the end of the follow-up period, five patients were alive. Three patients died due to an aortic rupture at 9th, 40th, and 51st month post-implantation, respectively. Most additional procedures were performed due to Type 1a endoleak, with one occurring within the first month, and four occurring later. During the follow-up, we observed occlusions of two superior mesenteric arteries, one renal artery, one subclavian artery, and one celiac trunk. Only the renal artery occlusion was symptomatic. No cases of paraplegia were detected. The mean aneurysmal flow volume was reduced in most patients (64.5%); however, this did not correspond to a reduction in mean volume or mean diameter, which increased in 59% and 88.2% of patients, respectively. CONCLUSIONS. MFMs are simple and safe to implant in patients with aortic aneurysm, however, the long-term results did not confirm the efficacy and durability of the procedure in the majority of patients. Further studies will be needed to highlight reasons for our results.

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BACKGROUNDS

Endovascular exclusion of aortic aneurysms, including procedures like endovascular abdominal aneurysm repair (EVAR) or endovascular thoracic aortic repair (TEVAR), became available more than 30 years ago and have proved effective and durable in short- and long-term follow-ups *(1, 2)*. However, anatomical limitations still present a major drawback in the treatment of aortic regions where the branching of aortic vessels prevents stent graft implantation. Open surgical treatment, available for almost 70 years, represents a more invasive approach in often fragile and elderly patients, requiring aortic clamping and a complex aortic approach, especially in areas where simple endovascular treatment is not feasible *(3)*. The aortic arch, thoracoabdominal and perirenal aorta are still areas where complex open or endovascular solutions are required in order to avoid vital organ ischaemia, including the spinal cord.

Alternatively, multilayer flow modulators (MFMs) (Cardiatis, Isnes, Belgium) were proposed for the treatment of aortic aneurysms more than a decade ago, introducing flow-laminating technology, which successfully treated intracerebral aneurysms *(4)*. MFMs are woven 3-layered stents, aimed to laminate flow through an aneurysm, producing gradual aneurysmal thrombosis without compromising flow in the aortic branches. The MFMs is self-expandable and easy to position, since there is no need to avoid branching arteries, and no significant reduction in blood pressure is required during deployment.

In Slovenia, aortic MFMs became available in 2011, however, due to unclear results of the aortic MFMs and alternative endovascular options, like fenestrated and branched endovascular aortic repair options (FEVAR, BEVAR), they have not been implanted since 2019. The aim of our study was to evaluate the efficacy and durability of MFMs implanted in our patients with aortic aneurysms in order to determine long--term results, which are currently lacking in literature, as is the case with many devices with questionable or poor efficacy.

METHODS

Between March 2011 and October 2019, 16 male and one female patient (median age 68 years; range 48–81) were treated with MFM implantation for an aortic aneurysm. All the procedures were elective, the decision for MFM implantation was made by a multidisciplinary board because no open or endovascular alternative treatment was feasible. A computed tomography angiography (CTA) was used for both diagnostic and control imaging, with all procedures performed by two experienced interventional radiologists completely percutaneous with surgical back-up in case of a failed percutaneous haemostasis. Six patients were treated for an aneurysm of the thoracic aorta, in four of which, the aortic arch was affected, in other four, the abdominal aorta was dilated. Three patients were treated for an aneurysm of the thoracoabdominal aorta. The follow-up extended until May 2023; over-all and aorta-related survival were determined, along with complications and changes in diameter, flow-volume and aneurysmal volume. Causes of death were obtained from the National Registry.

All procedures were performed under general anaesthesia. Patients received antibiotic prophylaxis and 5000 IU of heparin during the procedure. Clopidogrel was prescribed for three months, and acetylsalicylic acid was prescribed for lifelong use. Haemostasis was achieved by percutaneous suture systems by Abbott Laboratories IL, USA (ProStar/ProGlide), 22 and 24 Fr introducers were used.

The statistical analysis was performed by GraphPad Prism 10 (GraphPad Software Inc, San Diego, CA, USA). Diameters were measured on CTA images by two experienced radiologists, who also performed sizing

that was confirmed by the manufacturer. Flow-volume and aortic volume were measured by the manufacturer, using Osirix (Pixmeo, Geneve, Switzerland).

RESULTS

The median follow-up period of patients exceeded two years (median 25 months; range 7–76). The 30-day post-procedural mortality rate was 0%. One patient (5.9%) died due to an aortic rupture during the first year of follow-up. As of May 2023, five patients (29.4%) have still been alive. There were three aortic ruptures during the follow-up period, occurring at 9th, 40th and 51st month after MFM implantation.

Periprocedural complications during the first 30 days following MFM implantation occurred in three cases, none of which required conversion to open surgery. A stent graft was implanted proximally to seal a Type 1a endoleak in one patient. Another patient experienced a retrograde dissection, which was managed conservatively as no extension was detected on CTA controls. A dissection of the celiac trunk was observed in one patient without clinical symptoms. No cases of paraplegia, vital organ ischemia, or aortic rupture were observed during the first month of the follow-ups.

Aortic branch occlusions following MFM implantations were observed in another five patients. This included a renal artery occlusion leading to renal failure, two occlusions of superior mesenteric artery, an occlusion of the celiac trunk, and an occlusion of the subclavian artery, all of which were asymptomatic. Additionally, an ischemic stroke occurred months after MFM implantation in the aortic arch of a female patient caused by thrombosis of a carotid artery in a previously stenosed brachiocephalic trunk and carotid artery; the event occurred during stent implantation. This patient did not comply with the prescribed medical treatment, which likely contributed to the thrombosis.

Additional procedures were performed in seven patients (41.2%) overall. One procedure occurred within the first 30 days, and six were carried out between one and 74 months after MFM implantation. During this period, the most common reason was a Type 1a endoleak in four patients, where three MFMs and one stent graft were added due to poor sealing. The remaining two patients had two additional MFMs implanted, one due to MFM migration and another due to MFM displacement.

The median aneurysmal volume during the follow-up period increased from 309 to 355 ml, and the median aneurysmal diameter increased from 58 to 76 mm. However, the aneurysmal volume decreased in five patients, remained stable in another two, and increased in 10 patients (59%). The aneurysmal diameter increased in almost 90% of patients (15 patients, 88.2%), decreased in one patient, and remained stable in another patient.

During the follow-up period, a flow in the aneurysm was present in 14 patients, in two of these, there were no presence of thrombi. A complete aneurysmal thrombosis was present in only three patients (17.6%). Aneurysmal flow volume was reduced in 11 patients (64.7%) and increased in all the remaining ones.

DISCUSSION

The endovascular management of aortic aneurysms in designated anatomic areas proved its long-time durability and effectiveness throughout the decades *(2)*. Other anatomical regions remain challenging for EVAR/TEVAR and for open surgical management due to high morbidity and mortality rates *(5)*.

Flow-lamination technology proved effective in the management of intracranial aneurysms, and aortic MFMs were proposed as a simple alternative with acceptable morbidity and mortality rates on a short and mid-term basis *(4, 6)*. However,

long-term results still remain questionable, and the aim of our study was to determine the efficacy and durability of such treatment in our patients.

The first patient was treated in 2011. In the following 91 months, we treated 17 consecutive patients with aortic aneurysms, unsuitable for other endovascular or open surgical repair. MFM implantation proved technically simple, and all the procedures were performed completely percutaneous. The relatively high number of reinterventions in the first patients was reduced after changes in the device's design. Clinically symptomatic occlusions of covered aortic branches were rare, and no paraplegia was present during the follow-up period.

In almost two thirds of the patients, the aneurysmal flow was reduced, however, this did not translate into a stabilization of the aneurysmal diameter or volume in the majority of the patients. A possible explanation is proposed in the study by Antkiewicz and colleagues, which reports that MFM does not reduce pressure in the aneurysmal sac, in contrast to branched endovascular repair (BEVAR), which significantly reduces aneurysmal pressure *(7)*.

Limitations

The main limitations of our study are the small sample size and the variety of aneurysm anatomical locations treated over nearly eight years. None the less, our study represents an insight into the long-term efficacy and durability of treating aortic aneurysms with MFM, which the literature currently lacks. Despite that, additional studies and larger follow-up series should determine why in some patients MFM positively influences aneurysmal course – in 40.1% of our patients, the aneurysmal volume decreased or remained stable, and the aneurysmal diameter was reduced in one and remained stable in another patient.

CONCLUSIONS

The reduction of aneurysmal flow volume in the majority of our patients did not equate to mean diameter and mean aneurysmal volume reduction. Consequently, despite the simplicity of the MFM implantation procedure, it did not demonstrate long-term benefits in the majority of patients. However, in a minority of patients, MFM implantation benefits were detected, and further data will provide clearer insight into the reasons behind these results.

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