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Is endovascular treatment with multilayer flow modulator stent insertion a safe alternative to open surgery for high-risk patients with thoracoabdominal aortic aneurysm?

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HIGHLIGHTS

- There is a paucity of evidence on the subject with complete absence of RCTs.
- The studies support MFMS as a safe alternative in the management of high-risk TAAA.
- MFMS maintains branch vessel patency when used in accordance to the IFU.
- MFMS should not be used outside the IFU as undesirable outcomes have been reported.
- A personalised approach is advised considering patient comorbidities and wishes.

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ABSTRACT

A best evidence topic in cardiothoracic and vascular surgery was written according to a structured protocol. The question addressed was whether endovascular treatment with multilayer flow modulator stents (MFMS) can be considered a safe alternative to open surgery for high-risk patients with thoracoabdominal aortic aneurysm (TAAA). Altogether 27 papers were identified using the reported search, of which 11 represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes, results, and study limitations are tabulated. The outcomes of interest were all-cause survival, aneurysm-related survival, branch vessel patency and major adverse events. Aneurysm-related survival exceeded 78% in almost all studies, with the exception of one where the MFMS was inserted outside the instructions for use. In that study the aneurysm-related survival was 28.9%. The branch vessel patency was higher than 95% in 10 studies and not reported in one. At 12-month follow-up, several studies showed a low incidence of major adverse events, including stroke, paraplegia and aneurysm rupture. We conclude that MFMS represent a suitable and safe treatment for high-risk patients with TAAA maintaining branch vessel patency when used within their instructions for use. However, a number of limitations must be considered when interpreting this evidence, particularly the complete lack of randomised controlled trials (RCTs), short follow-up in all studies, and heterogeneity of the pathologies among the different populations studied. Further innovative developments are needed to improve MFMS safety, expand their instructions for use, and enhance their efficacy.

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1. Introduction

A best evidence topic was constructed according to a structured protocol. This is fully described in a previous publication [1].

2. Clinical scenario

You have been referred an 85-year-old man with an asymptomatic thoracoabdominal aortic aneurysm (TAAA) type II (Crawford's classification) diagnosed on computed tomography angiogram with a maximum diameter of 68 mm in the descending aorta. Comorbidities include chronic obstructive pulmonary disease (COPD), obesity, diabetes mellitus type II, hypertension, and

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chronic renal failure. The patient tells you that in view of his age and comorbidities he is keen for a minimally invasive approach and asks you whether endovascular treatment with insertion of multilayer flow modulator stents (MFMS), a new treatment which his family read about on Google, would be a suitable option for him. To confirm the therapeutic option and achieve the best possible outcome in this high-risk patient, you perform a literature review yourself.

3. Three-part question

In [high-risk patients with thoracoabdominal aortic aneurysm] are [multilayer flow modulator stents] a safe alternative to open surgery for achieving [better survival and lower morbidity]?

4. Search strategy

A literature search was performed using PubMed, Ovid, Embase, and Cochrane databases using the terms ("aortic aneurysm, thoracic"[MeSH Terms] OR ("aortic"[All Fields] AND "aneurysm"[All Fields] AND "thoracic"[All Fields]) OR "thoracic aortic aneurysm"[All Fields] OR ("thoracoabdominal"[All Fields] AND "aortic"[All Fields] AND "aneurysm"[All Fields]) OR "thoracoabdominal aortic aneurysm"[All Fields]) AND multilayer[All Fields] AND flow [All Fields] AND ("stents"[MeSH Terms] OR "stents"[All Fields] OR "stent"[All Fields]).

In addition, the reference lists of the relevant papers were searched. The search was current as of 23rd January 2017.

5. Search outcome

Twenty seven papers were identified using the reported search. Two authors (C.P. and G.G.) independently assessed the titles and abstracts of the identified articles to determine potential relevance. Any disagreement was resolved by discussion or with the opinion of the senior author (T.A.) After reviewing the abstracts, 21 papers were selected to be fully appraised in view of relevance and methods used. From these, 2 were short communications, 2 involved overlap of patient groups (the most recent was included), 6 were irrelevant, one was a narrative review, and one article was in French (all excluded except for the latter). Inclusion criteria included studies of any size, prospective or retrospective in design that assessed outcomes for patients with thoracoabdominal aneurysm. All patients included had to have received appropriate treatment. Exclusion criteria included studies reporting on patients with peripheral or visceral aneurysms. Narrative review articles and studies where the patients had not been sub-grouped according to the anatomical site of the aneurysm to allow distilling of the evidence specifically for thoracoabdominal aneurysms were also excluded. Based on design, number of patients and origin (high volume/specialised centres and national registries) 11 papers were chosen as representative to answer the clinical question.

6. Results

The results of the 11 papers (one meta-analysis, 4 prospective studies, and 6 retrospective studies) are summarised in Table 1.

7. Discussion

In 2016, Hynes et al. [2] published a meta-analysis of MFMS reviewing data on 171 patients with complex aortic pathology (59.1% had TAAA). They found that the aneurysm-related survival rate was 78.7% at 1 year and 66.6% at 18 months. At 18 months, this rate was 93.3% within the instructions for use (IFU) subgroup in contrast to a rate of 25.6% for patients treated outside the IFU. Technical success was 76.6%, with 95.5% of technical failures occurring in cases performed outside the IFU. All-cause survival rate was 53.7% at 1 year and 37.4% at 18 months. There were no cases of spinal cord ischemia, renal insult or stroke.

Lowe et al. [3] analysed the outcomes of MFMS in 14 patients. Among these, 50% had TAAA. All-cause, aneurysm-related and growth-free survivals were 79%, 86% and 28.5% respectively at 1 year. The 30-day mortality was 7% whilst at a mean follow-up of 22.8 months it reached 50% with one rupture. There were MFMS dislocations in 28.6% of patients with 35% of cases requiring reintervention.

In their prospective study, Bouayed et al. [4] assessed the effects of use of MFMS in 41 aortic lesions. Among these, 20 were TAAA. 30-day mortality was 5.26% due to aneurysmal rupture and myocardial infarction whilst 12-month mortality was 23.68%. The aneurysmal sac was not supplied in 30% of TAAA cases and poorly supplied in 70%. Visceral patency was 100%.

Vaislic et al. [5] evaluated one-year outcomes following the use of MFMS in 23 patients with type II and III TAAA. At 12 months, all-cause mortality was 4%, complete sac thrombosis was achieved in 75% of patients and branch patency rate was 96.5%. Moreover, at 12 months there were reinterventions in 22% of patients and the aneurysm diameter increased in 10% whilst remained stable in 90%.

Sultan et al. [6] presented the results of 103 patients treated with MFMS under IFU. Among the cases, 72.8% had TAAA. At 1 year, aneurysm-related survival was 91.7% (no rupture occurred), all-cause survival was 86.8% and the covered branch patency was 95.3%. The incidence of stroke and paraplegia were 1.9% and 0.99% respectively at 12 months.

In another study, Sultan et al. [7] appraised the consequences of treatment with MFMS outside the IFU in 38 patients, among which 39.5% had TAAA. During the follow up (10.0 ± 6.9 months), all-cause mortality was 89.5%, of which 71.1% were aneurysm-related. At 18 months, overall survival, freedom from aneurysm-related death and rupture-free survival were 17.5%, 25.0% and 31.5% respectively. Visceral branch occlusions were observed in 21% of patients. There were no reported cases of stroke or paraplegia.

Sultan and Hynes [8] retrospectively reviewed 1-year results of 55 patients, of which 56.4% had TAAA, treated with MFMS. At 1 year, aneurysm-related survival was 93.7% (no rupture occurred), all-cause survival was 84.8%, intervention-free survival was 92.4%, and all side branches were patent. Complications included bleeding (7.3%), stroke (3.6%) and reintervention (7.3%).

Henry et al. [9] analysed the use of MFMS in 18 patients (55.5% of which had TAAA). Technical success was 100% and 30-day mortality was 0%. At 8 months, aneurysm-related and all-cause survivals were 100% and 83.3% respectively, with branch patency rate being 100%. In the TAAA group, the mean aneurysm diameter decreased at 6 months.

Pane et al. [10], Debing et al. [11], and Polydorou et al. [12] all reported similar outcomes following treatment of TAAA with MFMS. They concluded that use of the medical device is feasible and seems to be a solution for the management of TAAA. The authors also inferred that MFMS can stabilize aneurysm diameter and ensure the patency of collateral vessels.

When looking collectively at the existing evidence, there are certain important points for consideration. First and foremost, there is a complete absence of randomised controlled trials (RCTs) on the subject. Secondly, there are no long-term follow-up studies. Thirdly, a significant amount of heterogeneity exists in terms of the variety concerning both the anatomy (location) and pathology (type) of aneurysms treated with MFMS. As a result, certain studies contradict others, especially when it comes to reporting mid-term results with some authors concluding that "the treatment of

Table 1
Best evidence papers.

Author, date and country	Patient Group	Study type (level of evidence)	Outcomes	Key results	Comments
Hynes et al. [2], Ireland	171 patients (mean age 68.8 years) TAAA - 59.1% (type I 7.6%; type II 14%; type III 16.4%; type IV 9.9%; unclassified 11.1%) Descending thoracic aortic aneurysm - 0.6% AAAs - 22.2% Type B dissections - 11.7% Saccular aneurysms - 8.2% Arch aneurysms - 4.7%	Meta-analysis of observational non-comparative studies and case series (level 2b)	Primary endpoint Aneurysm-related survival Secondary endpoints Technical success All-cause survival Neurologic complications Renal impairment Visceral ischemia Branch vessel patency Aneurysm expansion	Mean follow-up was 9 months Aneurysm-related survival was 78.7% at 1 year and 66.6% at 18 months (mean follow-up 9 months, mean aneurysm diameter 6.7 ± 1.6 cm) Aneurysm-related survival rates at 18 months: 93.3% (MFMS used within the IFU) and 25.6% (MFMS used outside the IFU) Technical success - 76.6% (95% of technical failures occurred in cases that were performed outside of the IFU) All-cause survival were 97.1% at 30 days, 53.7% at 1 year, and 37.4% at 18 months No cases of spinal cord ischemia, renal insult, or stroke Branch patency rate of 97.8%	Conclusions MFMS technology is able to treat thoracoabdominal pathology safely Poor outcomes were explained by a lack of appreciation of the device's limitations and its application outside the IFU Randomised clinical trials, registries and continued assessment are essential before the MFMS can be widely disseminated Limitations The numbers in this review are not enough to enable meaningful subgroup analysis Poor quality of the data (case reports)
Lowe et al. [3], United Kingdom	Fourteen patients with mean age of 74.6 years Crawford TAAA - 50% of the presented pathologies: Type II - 7.1% Type III - 14.3% Type IV - 28.6% Aortic arch aneurysm - 14.3% Perirenal aortic aneurysm - 35.7%	Prospective cohort study (level 2a)	Growth-free survival Maximal aneurysm diameter 30 day mortality Aortic side branch patency All complications Reintervention	Mean follow-up of 22.8 months At 1 year: All-cause survival - 79% Aneurysm - related survival - 86% (one rupture, one perioperative death) Growth-free survival - 28.5% Visceral branch patency rate of 98% at 1 year (no embolic episodes or symptoms of ischemia) Median increase in aneurysm size of 9 mm at 12 months, and of 11 mm at mean follow up 30-day mortality - 7% At mean follow-up 50% of patients died: Rupture - 7.1% Myocardial infarction - 14.3% (7.1% procedure-related and 7.1% unrelated at 17 months) COPD/pneumonia (not device or procedure-related) - 7.1% Multiorgan failure post implantation - 7.1% Unknown - 14.3% MFMS dislocation in 28.6% of patients Reinterventions in 35% of patients, with 7% of post-re-intervention death	Conclusions MFMS had little influence on the natural history of complex aortic aneurysms The device was unstable and dislocated frequently None of the aneurysms treated shrank and the majority of aneurysms in patients who survived over 12 months continued to grow The role of MFMS remains unclear Limitations Small number of patients Variety of pathologies
Bouayed et al. [4], Algeria	Thirty eight patients on which 41 procedures were performed on 41 lesion locations	Prospective cohort study (level 2a)	Aneurysm location Aneurysm diameter 30-day and 12-	Mean follow-up was 12 months (1–20 months) “Initial technical success” was 100% with no cases of paraplegia, stroke, or mesenteric ischemia	Conclusions Multilayer stents may represent a treatment option for dissection and complex aortic aneurysms in frail patients which would

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Table 1 (*continued*)

Author, date and country	Patient Group	Study type (level of evidence)	Outcomes	Key results	Comments
	25 male and 13 female Mean age 63 years (40–84 years) Series divided into 4 groups: - First group: 21 cases (20 thoracoabdominal aneurysms comprising of 2 Crawford type I, 4 type II, 4 type III, 10 type IV, and one aneurysm of the entire thoracic aorta). Average diameter: 71 mm (54–98 mm) - Second group: 7 cases with aneurysms in juxta and infrerenal aorta. Average diameter: 73 mm (62–97 mm) - Third group: 5 cases of false aneurysms - Fourth group: 8 cases of aortic dissection hematoma		month all-cause mortality Complications Need for open conversion Length of hospital stay	Mean length of hospital stay was 7 days (4–14 days) Complications Three complications relating to the surgical approach occurred, all treated surgically "with success" Two patients developed post-operative renal failure, one of them requiring haemodialysis (2.63%) There was no need for open conversion Mortality 30-day mortality was 5.26% One patient died due to aneurysmal rupture in the first postoperative day and one died following a massive myocardial infarction after the procedure 12-month mortality was 23.68% (9 deaths, none related to the aneurysm)	otherwise be at high morbidity and mortality risk (i.e. if they were to undergo open surgery) The results are of interest with regards to false aneurysms and true aneurysms without significant collateral supply Limitations Small number of patients Heterogeneous groups (in terms of aneurysm type and location) No controls Single centre study
Vaislic et al. [5], France	Twenty-three high surgical risk patients with mean age of 75.8 years Crawford TAAA Type II - 43.5% Type III - 56.5% Mean aneurysm diameter 6.5 ± 0.9 cm	Prospective multicentre non-randomised trial (level 2a)	Primary endpoints All-cause mortality Complete sac thrombosis Branch vessel patency Secondary endpoints Major adverse events Reintervention Technical endpoints Technical success Change in aneurysm sac size Volume Analysis	Follow-up of 12 months At 12 months: All-cause mortality - 4% Complete sac thrombosis in 75% of patients Covered branch patency rate of 96.5% Major adverse events at 12 months - Complications: neurological (4%), gastrointestinal (4%) and Access (4%) - Procedure/device: misplacement (9%), endoluminal obstruction (4%), thrombosis (4%) and hematoma (4%) - Endoleaks (22%): type I (13%) and type III (9%) Reinterventions 4% of patients at 30 days (conversion to surgery) 22% of patients in 12 months (MFMS implant in 13%/stent-graft implant in 4%/conversion to surgery in 4%) Technical success of 100% Aneurysm diameter at 12 months - Increased in 10% of patients - remained stable in 90% of patients	Conclusions Successful endovascular treatment with MFMS Radiographic evidence of progressive sac thrombus formation No cases of spinal cord ischemia, aneurysm rupture, device migration and reported systemic complications Limitations Non-randomised trial 12 months of follow up (longer time expected for sac shrinkage in large TAAA involving visceral branches)

Sultan S et al. [6], Ireland	One hundred and three patients with mean age of 69.2 years Crawford TAAA - 72.8% of the presented pathologies: Type I - 10.7% Type II - 13.6% Type III - 25.2% Type IV - 23.3% Arch aneurysms - 6.8% AAA - 14.6% Stanford type-B dissection - 5.8% Mean aneurysm diameter 6.4 ± 1.66 cm	Retrospective multicentre cohort study (level 2b)	Primary endpoints at 1 year Rupture and aneurysm-related survival All cause survival Patency of visceral branches Incidence of stroke and paraplegia Technical endpoints Aneurysm sac volume modulation at 1 year Technical success One-year freedom from reintervention	Mean follow-up was 11.6 ± 3.31 months (median = 6 months) At 1 year: Aneurysm related survival - 91.7% (no rupture) All-cause survival- 86.8% Covered branch patency - 95.3% Incidence of stroke - 1.9% Incidence of paraplegia - 0.99% Total volume increased - 6.79% Thrombus volume increased - 21.3% Maximum sac volume increased - 12.6% Residual flow volume decreased - 11.78% Total average increase in sac volume - 5.07% 30-day mortality 0% and morbidity 5.8% (paraplegia 0.99%; SMA occlusion 0.99%; renal artery thrombosis 0.99%; access problem 2.9%) Technical success of 97.1% One-year intervention free survival - 89.3%	Conclusions Increasing sac volume, thrombus or diameter size was not associated with rupture MFMS implantation instigates a process of aortic remodelling involving initial thrombus deposition, which slows between 6 and 12 months MFMS is associated with less operative trauma, shorter procedure time and reduced hospital stay The study has demonstrated the proof of concept of this disruptive technology Limitations Brevity of follow-up study Variation in the pathologies and anatomies of patients
Sultan et al. [7], Ireland	Thirty-eight patients with mean age of 71 years treated with MFMS outside the IFU Crawford TAAA - 39.5% of the presented pathologies: Type I - 2.6% Type II - 18.4% Type III - 13.2% Type IV - 5.3% 66.7% of TAAA were ruptured at presentation Mean aneurysm diameter 7.1 ± 1.1 cm	Retrospective multicentre cohort study (level 2b)	Primary endpoints Rupture Aneurysm-related death All-cause mortality Occlusion of visceral branches Stroke Paraplegia Technical endpoints Change in mean aneurysm diameter Freedom from leaks Technical success Freedom from reintervention	Mean follow-up of 10.0 ± 6.9 months: Aneurysm-related deaths - 71.1% All-cause mortality - 89.5% Freedom from aneurysm-related death was 37.5% at 12 months and 25% at 18 months Rupture-free survival estimates were 39% at 12 months and 31.5% at 18 months Overall survival was 29% at 12 months and 17.5% at 18 months Visceral branch occlusions were observed in 21.0% of patients (pre-existing side branch stenosis >50% with calcification in all of the side branches that experienced postoperative complications) No stroke and paraplegia The average growth rate of aneurysm diameter was 0.12 ± 0.16 cm/month Sac expansion occurred in all cases No sac stabilization or shrinkage Technical success was zero (in 81.6% of the cases there was a failure to land the device) Reinterventions were required in 28.9% of patients for endoleak (failure modes I and II) or stent foreshortening Factors with significance influence on the risk of aneurysm-related death: maximum aneurysm diameter ($p = 0.025$), previous TEVAR ($p = 0.03$) and inadequate overlap between MFMS devices ($p < 0.002$)	Conclusions MFMS is a safe technique, at least in the short term (no perioperative complications), which reflects its simplicity of use The MFMS is not a solution for patients living on borrowed time and should not be used indiscriminately in patients in whom other modalities of aortic repair are not feasible The use of MFMS must adhere to the IFU This technology commands further innovative developments and robust scientific and clinical data

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Table 1 (*continued*)

Author, date and country	Patient Group	Study type (level of evidence)	Outcomes	Key results	Comments
Sultan et al. [8], Ireland	Fifty-five patients with mean age of 64.5 years Crawford TAAA - 56.4% of the presented pathologies: Type I - 14.5% Type II - 5.5% Type III - 16.4% Type IV - 20% Mean aneurysm diameter 6.04 ± 1.66 cm	Retrospective multicentre cohort study (level 2b)	Primary endpoint Aneurysm related survival and rupture at 1 year Secondary endpoints All-cause survival Visceral branch patency Adverse events Reintervention Technical endpoints Technical success Rates of change in total sac, thrombus and flow volumes	Mean follow-up was 8.2 ± 5.3 months (median 6, range 3–18) Aneurysm related survival at 1 year - 93.7% (no rupture occurred) All cause survival at 1 year - 84.8% Intervention free survival at 1 year - 92.4% Covered branch patency rate of 100% at 1 year Adverse Events at 1 year Bleeding - 7.3% Stroke - 3.6% Reintervention at 1 year - 7.3% Technical success of 98.2% Total average increase in sac volume at 1 year - 3.26% The ratio of thrombus to total volume stayed almost constant over the 12 months at 0.48 ($p = 0.743$) The ratio of flow to total volume fell from 0.21 to 0.12 at 12 months ($p = 0.069$)	Conclusions MFMS implantation instigates a process of aortic remodelling involving initial thrombus deposition Increasing sac size did not lead to rupture The MFMS offers promise for resolution of complex thoracoabdominal pathology with off-the-shelf availability Further development and technical refinement is required Long-term follow-up of the registry patients is mandatory before establishing a randomised controlled study Limitations Brevity of follow-up study Variation in the pathologies and anatomies of the patients treated Issues of registry: data collection, patient compliance and the variety of follow-up protocols and pharmacotherapies
Henry et al. [9], France	Eighteen high surgical risk patients (mean age 67 years) Crawford TAAA - 55.5% (mean age 56 year-old) Type I - 22.2% Type II - 11.1% Type IV - 22.2% Aneurysm diameter - 60 −130 mm	Retrospective case series (level 3)	Technical success 30-day mortality Aneurysm-related survival All-cause survival Side branch patency Aneurysm diameter	Mean follow-up of 8 months Technical success of 100% 30-day mortality - 0% (with no complications) At mean follow-up: Aneurysm- related survival of 100% All-cause survival of 83.3% Intervention-free survival of 100% Branch patency rate of 100% TAAA group Mean diameter reduction at 6 months (17.25 mm reduction for transverse diameter ($p = 0.009$) and 13.83 mm for the anteroposterior diameter ($p = 0.011$))	Conclusions MFMS can help prevent aneurysm-related mortalities while maintaining branch vessel patency Treatment with MFMS leads to progressive aneurysm sac thrombosis and shrinkage Additional study and follow up needed Limitations Small number of patients
Pane et al. [10], Italy	Eight patients with mean age of 75.5 years Aortic Aneurysms - 50% TAAA type II - 25% TAAA type IV - 12.5% JAAA- 12.5%	Retrospective case series (level 3)	Technical success Mortality Rupture Secondary intervention Major	Mean follow-up was 22.1 months Technical success of 87.5% 30-day mortality - 0% (with no major complications) Survival rate of 87.5% (12.5% - death unrelated to MFMS treatment)	Conclusions MFMS may represent a viable alternative to the endovascular approach in treating aortic conditions MFMS can stabilize aneurysm diameter and ensure the patency of collateral vessels Limitations

	Mean max aneurysm diameter - 6.9 cm		complications Patency of collateral vessels Volume analysis	MFMS and branch patency rate of 100% during follow up No secondary endovascular or open surgical procedures In aortic aneurysms, the total aneurysm volume increased 7.6% at 12 months Overall trend to increase in thrombosis was observed in all cases	Small series - results must be confirmed by larger series and longer follow-up studies
Debing et al. [11], Belgium	Six patients with mean age of 74 years 67-mm type III TAAA 65-mm aortic arch aneurysm 60-mm juxtarenal AAA 59-mm juxtarenal saccular AAA 58-mm juxtarenal aneurysm 72-mm juxtarenal AAA	Prospective case series (level 3)	Technical success 30-day mortality Aneurysm-related survival All-cause survival Side branch patency Volume analysis Reintervention	Median follow-up was 10 months Technical success of 100% 30-day mortality - 16.7% Aneurysm-related survival - 83.3% (16.7% of patients died due to aneurysm rupture) Branch patency rate of 100% 66.7% of aneurysms were completely thrombosed between 1 and 6 months after the procedure At 6 months, the sac volume was decreased in 33.3% of patients, increased in 33.3% patients and remains stable in 16.7% No stent migrations, retractions, thrombosis, fractures, or reinterventions	Conclusions The device preserves flow into the covered aortic branches and completed aneurysm thrombosis occurs gradually The stent did not prevent rupture immediately after the implantation Limitations Small series - larger series and longer follow- up is mandatory to prove the efficacy of this technology
Polydorou et al. [12], Greece	Twenty-two high risk patients with mean age of 67 years Crawford TAAA - 81.8% (mean aneurysm 58 mm) TAA- 4.5% AAA- 13.6%	Retrospective case series (level 3)	Technical success 30-day mortality Aneurysm-related survival All-cause survival Side branch patency Adverse Events	Mean follow-up for the thoracic aneurysm was 28 months, for the aortic aneurysms was 12 months and for thoracoabdominal aneurysm 12 months Technical success of 100% 30-day mortality - 9.1% Aneurysm-related survival and all-cause survival - 90.9% The 6 and 12 month follow up CT angiograms showed patent arterial side branches, thrombus inside the sac or shrinkage of the sac Adverse events Stroke - 4.5% Myocardial Infarction - 4.5% No vascular or systematic complications	Conclusions The use of the MFMS is feasible and seems to be safe for the management of aortic aneurysm with side branches MFMS seems to be efficacious as the side branches remain patent and the aneurysm is excluded Limitations Brevity of study Variety of pathologies

Abbreviations: MFMS = multilayer flow modulator stent; TAAA = thoracoabdominal aortic aneurysm; TAA = thoracic aortic aneurysm; AAA = abdominal aortic aneurysm; JAAA = juxtarenal abdominal aortic aneurysm; IFU = indications for use; TEVAR = thoracic endovascular aortic repair; COPD = chronic obstructive pulmonary disease; SMA = superior mesenteric artery.

aneurysms with MFMS seems to have encouraging midterm results" [10] whilst others reporting that "the role of MFMS remains unclear" [3]. Despite the many limitations in the literature, there seems to be a consensus that MFMS, when used within their IFU, may represent a valuable option in those patients where open surgery is deemed high-risk. Finally, existing studies also concur that in addition to robust scientific and clinical data, further innovative developments are needed to improve MFMS safety, expand their instructions for use, and enhance their efficacy.

8. Clinical bottom line

In addition to the mortality associated with open TAAA repair, fundamental risks include compromising the blood flow to the spinal cord and/or viscera. In this context, MFMS appear to represent a safe alternative in the management of complex aneurysms. In this paper, the outcomes in patients with TAAA undergoing endovascular repair with MFMS were evaluated. Several studies showed that the use of MFMS in the treatment of TAAA is associated with a low incidence of complications, including stroke, paraplegia and aneurysm rupture. In addition, these studies demonstrated acceptable rates of aneurysm-related survival and visceral branch patency. On the other hand, undesirable outcomes have been reported when the MFMS is used outside the IFU.

Thus, we conclude that endovascular treatment with MFMS insertion is a safe treatment for TAAA in high-risk patients, associated with maintenance of branch vessel patency, provided they are used in accordance to the IFU. However, a number of limitations must be considered when interpreting this evidence. Firstly, the complete lack of RCTs, secondly, the absence of long-term follow-up studies, and thirdly, the heterogeneity of the pathologies among the different populations studied. Despite these limitations, MFMS appear to offer a suitable and safe alternative to open surgery for TAAA cases where open surgery is deemed high-risk.

Ethical approval

Not required.

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Author contribution

C Pinto – conducted literature search and co-wrote article with G Garas.

G Garas – conducted literature search and co-wrote article with C Pinto.

L Harling – assisted in writing of article.

A Darzi – assisted in writing of article.

R Casula – conceived paper with T Athanasiou and assisted in writing of article.

T Athanasiou – conceived paper with R Casula and assisted in writing of article.

Conflicts of interest

None.

Trial registry number – ISRCTN

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