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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?

Caroline Pinto, George Garas*, Leanne Harling, Ara Darzi, Roberto Casula, Thanos Athanasiou

Department of Surgery and Cancer, Imperial College London, St. Mary's Hospital, London, United Kingdom

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.

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

* Corresponding author. Department of Surgery and Cancer, Imperial College London, St Mary's Hospital, 10th Floor QEQM Wing, London W2 1NY, United Kingdom.
E-mail address: g.garas@imperial.ac.uk (G. Garas).

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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