A technical note and report of two patients with acute aortic syndrome who were treated with the new generation Ankura thoracic stent graft

Theodoros Kratimenos1 | Constantine N. Antonopoulos2 | Dimitrios Tomais1 | Panagiotis Dedeilias2 | Michail Argiriou2

1Department of Interventional Radiology, Evangelismos General Hospital, Athens, Greece
2Department of Cardiothoracic and Vascular Surgery, Evangelismos General Hospital, Athens, Greece

Correspondence
Constantine N. Antonopoulos, Department of Cardiothoracic and Vascular Surgery, Evangelismos General Hospital, Ipsilantou 45-47, 10676 Athens, Greece.
Email: kostasantonopoulos@gmail.com

1 INTRODUCTION

Acute aortic syndrome, including aortic dissection, penetrating aortic ulcer (PAU), and intramural hematoma (IMH) is a life-threatening clinical emergency. We report our initial experience, along with technical considerations, with two cases of acute aortic syndrome, who were treated with the new generation thoracic endograft (Ankura, Lifetech).

Recent evidence implicates the use of thoracic endovascular aortic repair (TEVAR) in the event of complications.1 An increased number of patients has been successfully treated with endovascular approach, which indicates improvements with the use of older and novel devices and experience gained so far.2 Our aim was to present our initial experience with the use of a new generation thoracic device in two patients who presented with acute aortic syndrome. For both patients, we obtained informed consent for using anonymous data and images for research purposes.

2 CASE PRESENTATION

2.1 Case 1

A 78-year-old woman presented to the Emergency Department of our hospital with acute chest pain, radiating to the back and lasting for 5 hours. Medical history revealed poorly controlled hypertension, smoking, and hyperlipidemia. Upon admission, the blood pressure was 185/95 mm Hg, with a heart rate of 95 beats per minute (BPM). Initial screen with chest X-ray, electrocardiogram (ECG), transthoracic ultrasound (TTU), and blood samples, including troponin levels did not reveal any abnormality. A Computed Tomography Angiography (CTA) revealed a penetrating aortic ulcer (PAU) in the descending thoracic aorta (DTA) with ipsilateral pleural effusion (Figure 1). The patient was hospitalized and initially treated with analgesia, blood pressure, and rate control with beta-blocker and nitroglycerin. However,
Despite the medical management the patient continued to report uncontrolled pain and an endovascular intervention was thereafter decided. Based on the anatomic measurements, obtained by the CTA, the new generation thoracic stent graft Ankura (TAA3834B160; Lifetech Scientific Co., Ltd.) was chosen and thereafter implanted through a femoral approach. Coverage of the left subclavian was necessary for appropriate sealing, while the final angiography did not reveal opacification of the PAU. The patient was transferred to the ICU for further monitoring. During the first postoperative, the patient reported complete resolution of the chest and back pain, while the blood pressure returned to normal. The patient was discharged 5 days later.

2.2 | Case 2

A 64-year-old patient male, with prior history of heavy smoking and arterial hypertension presented to our Emergencies with back pain. He reported having this pain for 2 days, worsening during the last 3 hours, which was not controlled with paracetamol. Blood pressure measured 180/70 mm Hg, with 85 BPM. All screening diagnostic and laboratory exams were normal. However, a CTA scan revealed an intramural hematoma (IMH) in the DTA, with a maximum diameter of 48 mm (Figure 2). The patient was offered proper analgetic and anti-hypertensive treatment and he was transferred to the ICU for monitoring. Due to the continuous symptomatic status and the sizing of the IMH, we decided to proceed with thoracic endovascular aortic repair (TEVAR). A standard transfemoral approach was followed, and the new generation thoracic stent graft Ankura (TAA4036B160; Lifetech Scientific Co., Ltd.) was implanted without coverage of the left subclavian artery. Final angiography revealed complete sealing. The patient was discharged 3 days later, while he reported complete resolution of pain.

3 | DISCUSSION

The European Society for Vascular Surgery (ESVS) recently presented clinical practice guidelines document for surgeons and other physicians who are involved in the overall care of patients with DTA disorders. Among the recommendations, IMH and PAU should be initially treated with medical therapy and intensive care monitoring. However, in symptomatic and complicated patients, TEVAR should be considered, with an IIa Class of evidence. In our case series, both patients presented with symptoms of chest and back pain, which continued despite the initial analgetic and “dp/dt” lowering therapy, and both patients were treated in terms of complicated acute aortic syndrome. Apart from the presence of recurrent pain, other criteria implying complicated IMH include expansion of the IMH, periaortic hematoma, and intimal disruption, while initial measure of >20 mm in diameter or >10 mm in depth or progression of total aortic diameter indicate complicated PAU.3
Thoracic endovascular aortic repair has shown promising results for the treatment of complicated acute aortic syndrome. Long-term goals include promoting positive aortic remodeling\(^4\) and diminishing the incidence of progression to aortic dissection and aneurysm formation.\(^1\) A recent study\(^1\) has shown that patients with acute IMH who offered optimal medical treatment had a significantly increased rate of aortic-related mortality and aortic-related adverse events compared to patients treated with TEVAR. Commercially available endografts for TEVAR include self-expanding, with the skeleton consisting of metallic Nitinol (Gore; Medtronic; Bolton, Cook) with an external membrane made of polytetrafluoroethylene (Gore) or polyester (Medtronic, Cook, Bolton)\(^5\) with bare or covered proximal and distal ends. In a recent study,\(^6\) the authors presented results with the use of the previous generation of Ankura Thoracic Stent Graft (Lifetech). The study showed promising results and early evidence of a safe, effective, and durable endoprosthesis for the treatment of DTA aneurysms. The endograft has been also tested in more complex cases, with TEVAR and physician-modified technique to reconstruct the supra-aortic branches and showed satisfactory short- to middle-term results.\(^7\)

We expanded the use of Ankura Thoracic Stent Graft (Lifetech) for the treatment of acute aortic cases. In this case series, we presented our experience with the use of the new generation Ankura Thoracic Stent Graft (Lifetech). To the best of our knowledge, this is the first report in the literature. We chose to present two acute aortic cases, in order to test the new endograft in the emergency setting. The new generation Ankura Thoracic Stent Graft (Lifetech) is the evolution of the previous version of thoracic endograft (Figures 3 and 4). According to the manufacturer’s instructions for use (IFU), the new endograft has an e-PTFE dual membrane that is thinner compared to the previous version, with no suture on the main body, aiming to avoid pinhole leakage and type IV endoleak. The tip capture mechanism in the proximal end has remained unchanged, aiming to provide precise placement and controlled deployment and a connecting bar on the outer curvature, with the purpose to provide axial support and avoid stent shortening. The asymmetric waves design conforms to the natural curvature and aims to reduce possibility of kinking. The endograft has both slow, controlled, and quick deployment options and comes in straight and tapered configuration, with different diameters, namely 20-38 mm with 20 Fr outer diameter (OD) to 38-46 mm (22 Fr OD) and various lengths: 40-200 mm. The tapered endografts are available with 4, 6, and 8 mm difference in the diameter of the proximal and distal end.

Our initial experience with the endograft, although limited so far, was satisfactory. Compared to the previous version, the new Ankura thoracic stent graft has a lower profile (20-22 Fr vs 21-24 Fr in the previous device). This characteristic was very helpful while treating the first patient (case 1), in whom femoral and iliac arteries were narrow (<7 mm). The new Ankura endograft comes with a nose cone that permits enhanced trackability and flexibility in the aortic arch. There are two clearly evident radiopaque markers in the...
proximal covered part (an “8” shape marker which is placed in the outer aortic curve and a “0” shape marker in the inner curve), which enhance precision during deployment and help in orientation. Interestingly, we noticed an upgraded quality in the plastic parts of the delivery system and we witnessed a new ergonomic design, which permitted a better control of the device during the deployment and especially during the fast deployment.

4 | CONCLUSION

Our first initial experience with two acute aortic thoracic cases treated with the new generation of the Ankura Thoracic Stent Graft (Lifetech) was encouraging and showed promising results. The implanting physician may find the use of this novel endograft both practical and safe. However, more studies with large and diverse cohort of patients are needed before sound conclusions can be drawn.

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CONFLICT OF INTEREST
None declared.

AUTHOR CONTRIBUTION
All authors qualified for authorship according to the following criteria: contributed substantially to conception and design, acquired, analyzed and interpreted the data; drafted the manuscript and revised it critically for important intellectual content; approved the final version to be published. Each author: participated sufficiently in the work to take public responsibility for appropriate portions of the content; agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors read and approved the final manuscript.

ETHICAL APPROVAL
Hospital’s ethics committee approved the study. The study conforms to recognized standards of “Declaration of Helsinki.”

DATA AVAILABILITY STATEMENT
We state that the findings of this study can be taken up from the corresponding author upon reasonable request.

ORCID
Constantine N. Antonopoulos https://orcid.org/0000-0003-0696-695X

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