Ascyrus Medical Dissection Stent In the treatment of acute type A Aortic dissection. A First-Hand Experience

Mouhammad Kanj[1], Benoit Cosset[2], Alexandre Oliny[2], and Fadi Farhat[2]

[1]Department of Cardiothoracic Surgery Faculty of Medical Science Lebanese University Beirut Lebanon
[2]Hopital Cardio-vasculaire et Pneumologique Louis Pradel

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Abstract

Background: Acute type A aortic dissection is associated with a significant perioperative morbidity and mortality. Ascyrus Medical Dissection Stent (AMDS) is a novel bare stent graft developed to be used as an adjunct to standard surgical approach to promote true lumen expansion and therefor enhance aortic remodeling. **Patients and Methods:** From March 2021 to March 2022, four consecutive patients who presented with acute Debakey type I aortic dissection underwent emergent surgical repair with an inclusion (David) procedure and implantation of an AMDS. We analysed patient's files prospectively and described the perioperative outcomes. **Results:** All four device implantations were successful. Overall 30-day mortality was 0 %. Malperfusion that was present in two patients pre-operatively improved after AMDS implantation. At follow up, no aortic reinterventions were needed. No aortic injury related to the device was noted. Favourable changes in aortic true lumen and false lumen dimensions were found in most of our patients but the AMDS was compressed at the isthmus in one patient. **Conclusion:** AMDS is a reliable and secure device. However, its benefits remain unclear when it comes to a positive remodeling and seems less likelihood comparable to a frozen elephant trunk. The main reason seems to be an insufficient radial force of the AMDS.

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Mouhammad Kanj, MD[1,2], Benoit Cosset, MD[2], Alexandre Oliny, MD[2], Fadi Farhat, MD,PhD[2]. 1) Department of Cardiothoracic Surgery, Faculty of Medical Science, Lebanese University, Beirut, Lebanon. 2) Department of Cardiovascular Surgery, Louis Pradel Hospital, Lyon, France.**Conflict of interest:** none declared.**Funding:** none.**Word Count:** 1920.**Data availability Statement**: The data that support the findings of this study are available from the corresponding author upon reasonable request.**Consent statement:** Not applicable.**Corresponding Author: Pr** Fadi Farhat**Infirmerie Protestante**1-3 Chemin de Penthod 69300 Caluire-et-Cuire, France Tel +33 4 26 10 17 61 Fax + 33 4 72 00 74 92 E-mail :*fadi.farhat@infirmerie-protestante.com*

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Conclusion: AMDS is a reliable and secure device. However, its benefits remain unclear when it comes to a positive remodeling and seems less likelihood comparable to a frozen elephant trunk. The main reason seems to be an insufficient radial force of the AMDS.

Key Words: Acute Aortic Dissection, AMDS, Remodeling

Introduction:

Acute Debakey type I aortic dissection is a debilitating disease that may be complicated by organ malperfusion in 30% to 40% and carries a high mortality rate[1-3]. The standard surgical repair by hemiarch or arch reconstruction using an open distal anastomosis successfully manages the primary entry tear by resection; however, the distal false lumen may remain perfused and subsequently pressurized and the true lumen yet incompletely expanded. This may result in ineffective treatment of malperfusion and over time by a growth of the aortic diameter leading to repeated interventions, mainly on the descending aorta.

The Ascyrus Medical Dissection Stent (AMDS, Artivion, Kennesaw, USA) is a new device developed to be used in adjunct to current surgical aortic dissection repair and is designed to improve short-term malperfusion syndrome and supposed to lessen long-term aneurysmal evolution.

This hybrid prosthesis is composed of proximal PTFE felt sutureg line attached to an uncovered Nitinol wire braided stent (figure1). Bozso et al. have shown on the DARTS trial the security and feasibility of the AMDS implantation, and the capacity of this device to improve aortic remodeling[4,5]. Mehdiani et al. also showed that AMDS can be safely performed in patients who need partial replacement of the aortic arch beyond zone 0[6]. We report the first French implantation of the AMDS.

Patients and Methods:

1.Patients Characteristics and Data Collection:

During a 1-year period (March 2021 through March 2022), four consecutive patients received the AMDS hybrid prosthesis at the decision of the same attending surgeon for treatment of type I Debakey aortic dissections. Demographic data, comorbidities, operative procedures and post-operative variables were analyzed prospectively. Baseline characteristics of the study population are summarized in table 1.

2.Operative Technique:

A re-implantation technique (David V) was performed in all patients. All patients underwent emergency surgery with CPB initiated with arterial cannulation via the right axillary artery and venous cannulation of the right atrium, then general cooling was started. The ascending aorta was cross clamped and myocardial protection was ensured through antegrade cold crystalloid cardioplegia followed by intermittent administration of selective coronary cardioplegia throughout the clamping time. Resection of the aortic root leaving 3 to 4 mm of aortic remnants above the aortic valve annulus was done systematically. Six sub-annular U stiches were placed and anchored to a Valsalva Dacron tube (28-30mm diameter). The aortic valve commissures were attached within the Valsalva Dacron tube.

At a rectal temperature of 28 °C, and with cerebral monitoring by NIRS, hypothermic peripheral circulatory arrest was started. Cerebral perfusion was ensured by blood injection (7.5 to 10 ml/kg/min) into the right subclavian artery and by clamping the origin of the Brachiocephalic artery and the Left Common Carotid artery. Exploration of the aortic arch demonstrated no supplementary entry tears in any patient. Transection

of the aorta was performed 1 cm proximal to the origin of the Innominate trunk. A 55-55 mm uncovered AMDS was systematically used and deployed over a guidewire in the true lumen of the descending aorta. Anastomosis between the aorta and the AMDS collar was performed with a addition of a Dacron tube and reinforced by an external Teflon felt. General cardiopulmonary bypass was then re-initiated for rewarming after the aortic arch was purged and the Dacron tube clamped .

During rewarming time, re-implantation of the aortic remanents into the valsalva Dacron tube with running 4.0 Polypropylene sutures then re-implantation of the coronary ostia were performed. In one patient, the dissection reached the coronary right ostium needing repair. End to end anastomosis between the two Dacron tubes was done using before declamping and CPB was weaned in a standard manner withour inotropic support in any patient.

3.Statistical analysis:

Statistical analysis and graphics were done using statistical software (IBM® SPSS® Statistics version 26.0; GraphPad Prism® version 8.0).

Results:

1.Baseline Characteristics:

The baseline clinical characteristics are presented in table 1. Mean age was 61(+/-8) years old

and 3 patients were male (75%). One patient had Marfanoid habitus. All patients had a previous medical history of hypertension. Mean Euroscore-II was 22(+/-18) %. CT-Angiography was done pre-operatively then on post-operative day 1 and 30 for all patients (figure 2). Primary tear was identified in the ascending aorta in all patients. Two patients (50%) had evidence of dynamic intestinal malperfusion by compression of the true lumen. One of those patients had also evidence of coronary malperfusion and severe aortic insufficiency. Another patient had preoperative acute neurological deficit marked with aphasia and decreased consciousness.

2.Operative Data:

A re-implantation technique (David V) was performed in all patients along with implantation of the AMDS. Surgical and perioperative data are presented in table 2. The mean cross clamping time, cerebral perfusion time and cardiopulmonary bypass time were respectively 85(+/-6), 15(+/-2) and 113(+/-8) min. Circulatory arrest was attempted at a body core temperature of 28°C.

3.Postoperative outcomes:

Mortality and serious adverse events are summarized in table 3. One patient had smooth postoperative course without complications. The patient who had severe aortic insufficiency with coronary and intestinal malperfusion developed right ventricular dysfunction and required hemodyalisis post-operatively. He also developed right brachial plexus palsy with full recovery and totally relieved from intestinal malperfusion. The other patient with intestinal malperfusion developed hemorrhagic shock post-operatively with severe abdominal pain. An exploratory laparotomy revealed a huge hemoperitoneum that was drained. The patient who had neurological deficit developed multiple small cerebral emboli due to atrial fibrillation. He also developed ventilator-associated pneumonia and acute renal insufficiency requiring hemodialysis. His consciousness improved with time. No aortic reinterventions were needed. No aortic injury related to the device was noted. Mortality rate was zero at the post-operative day 30. Patients were discharged from the hospital after an average of 21 days.

4.Comparison of CT measurements:

Figure 3 shows comparison of CT measurements of the different aortic diameters.

The mean total aortic diameter remained stable at the aortic arch and descending thoracic aorta in all patients. It increased at the isthmus in one patient (by 31%). The false lumen was obliterated at the aortic arch in three patients and decreased in size (by 60%) in the fourth one. At the level of the isthmus it increased

in only one patient because of reperfusion. However, at the level of the descending thoracic aorta, the mean false lumen size decreased in all patients (by 43%). Regarding the mean true lumen size, it increased in all patients (by 91%) compared with baseline. However, the stent was compressed in one patient at the level of the isthmus (figure 4). No distal anastomosis re-entry tear was observed. A new entry tear was identified in one patient at the level of abdominal aorta far below the distal AMDS tip.

Discussion

Even if the surgery of an acute Debakey type I aortic dissection is performed with an open distal anastomosis and is mostlikely managed by a hemiarch aortic reconstruction, this approach has a main disadvantage, that is to leave entry tears in the proximal descending thoracic aorta leading to false lumen patency in some patients, increasing the need for re-operation[7-10]. Total arch replacement with Frozen Elephant Trunk allows for distal extension of a stent graft implant into the true lumen of the descending aorta excluding re-entry tears in the arch and proximal descending thoracic aorta. In the setting of acute aortic dissection and deeply ill patients, this approach can increase the CPB and circulatory arrest times, and exposes patients to additional risks of paralysis, stroke and haemorrhage[11,12]. It may be more useful in particular situations in the setting of aortic dissection like when there is arch aneurysm, or there is an entry tear within the arch or in the proximal descending thoracic aorta associated with the dissection[13].

Between these two approaches, the AMDS represents a novel hybrid solution providing long thoracic coverage alleviating malperfusion and excluding entry tears without significantly increasing the complexity of surgery[4-6].

DARTS trial has shown a good rate of aortic remodeling. However, this was a composite criterion; positive remodeling was defined on evidence of false lumen obliteration, complete false lumen thrombosis and favourable changes in aortic dimensions[14,15]. Our real-life experience shows that these results are more the consequence of lumen's diameters correction than a complete false lumen thrombosis, being possibly due to the primary entry tear exclusion. There was no need for a redo surgery in our four patients, but we think that the presence of Nitinol in the arch could jeopardize a second procedure at this level.

In the two patients having intestinal malperfusion we noticed clinical improvement. One of them remains having intestinal angina due to dissection of the superior mesenteric artery. Favourable changes in aortic true lumen and false lumen dimensions were found in most of our patients but the AMDS was compressed at the isthmus in one of them. We did not have any mortality in our patients. This shows that AMDS is a reliable and secure device. However, its benefits remain unclear when it comes to a positive remodeling and seems less likelihood comparable to a frozen elephant trunk. The main reason seems to be an insufficient radial force of the AMDS, which tend to lengthen rather to expand.

Many studies addressing the radial force of endovascular stents emphasized on the importance of understanding radial force when selecting a stent for every patient. Radial force of endovascular stents provides effective support for blood vessels, maintains adequate lumen patency, and secures fixation to artery wall[16]. It varies among stent designs, and differences depend on the type of stents, the site of deployment or layer characteristics of each stent[17,18]. In vivo, endovascular stents would be affected by the vessel curvature, blood pressure, vascular smooth muscles characteristics and much more dynamic factors[17]. Surgeons should evaluate the possibility of stent deformities during and after surgery[19]. It is believed that treatment of dissection with endovascular stent requires fewer radial force compared with the treatment of aneurysm because too much radial force at distal ends may lead to new entry tears. However, the arch geometry for thoracic aorta requires larger radial forces to seal[20]. In its initial experience on AMDS stent, Montagner et al. concluded that the low radial force of AMDS stent is intended just to readapt the intima against the media and adventitia and it is the subsequent expansion of the true lumen that will drive the resolution of malperfusion[21]. Furthermore, they emphasized on the importance of low radial force of the AMDS stent which can unlikely damage the intima. They also reported three failures of device deployment, one of them being due to high turtosity of the aorta causing kinking and incomplete AMDS expansion[22].

Eventhough we observed improvement of malperfusion, this may be attributed only to primary entry tear

resection. Actually, the radial force of the AMDS is not adequate to guarantee distal expansion of the true lumen, especially in case of visceral malperfusion and this was seen in one of our patients. AMDS implantation should be avoided in patients with aortic calcifications or kinking to prevent incomplete stent expansion.

Another feature should be mentioned is that the AMDS is an uncovered stent. In this condition, any entry tear not excluded by this bare stent will remain active. This is why, we should absolutely avoid AMDS implantation in patients with any primary entry tear in the

aortic arch.

The main limitations of this study remain in its small sample size, its retrospective design and the absence of long-term follow-up.

Conclusion

This initial study suggests that the AMDS is safe, feasible and reproducible adjunct to the standard surgical repair for acute Debakey type I aortic dissection without extending the procedure time. However, its benefits remain unclear when it comes to a positive remodeling.

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Baseline Characteristics	**Value**
Age (y)	61 (51-69)
Male Gender (%)	75 (3/4)
Malperfusion (%)	50 (2/4)
Preoperative Stroke (%)	25 (1/4)
Hypertension (%)	100 (4/4)
COPD (%)	0
Reoperation	0

Table 1: Baseline Characteristics of the study population.

Characteristic	**Value**
Successful device deployment	100%
David V procedure	100%
Mean cardiopulmonary bypass time (min)	113(+/-8)
Mean cross clamping time (min)	85(+/-6)
Mean cerebral perfusion time (min)	15(+/-2)

Table 2: Procedural data.

Mortality and serious adverse events	**Value**
30-day mortality	0%
Neurological deficit	25% (1 patient)
Acute renal failure requiring hemodialysis	50% (2 patients)
Hemorrhagic shock	25% (1 patient)
Aortic injury associated with device implantation	0%
Device related reintervention	0%
Stent compression	25% (1 patient)

Table 3: Mortality and Serious Adverse Events.

Figure 1: Expanded Ascyrus Medical Dissection Stent.

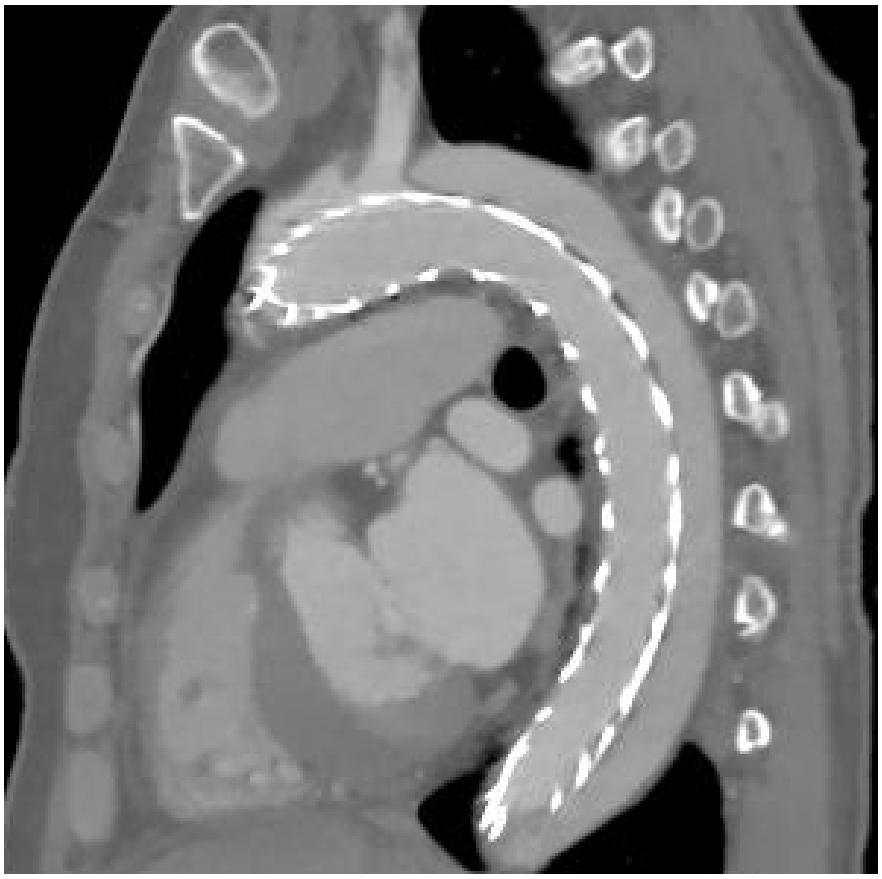

Figure 2: Computed tomography angioscanner showing the deployed AMDS in the true lumen.

Hosted file

`image3.emf` available at https://authorea.com/users/402067/articles/589094-ascyrus-medical-dissection-stent-in-the-treatment-of-acute-type-a-aortic-dissection-a-first-hand-experience

Figure 3: Comparison of the CT measurements of the different aortic diameters.

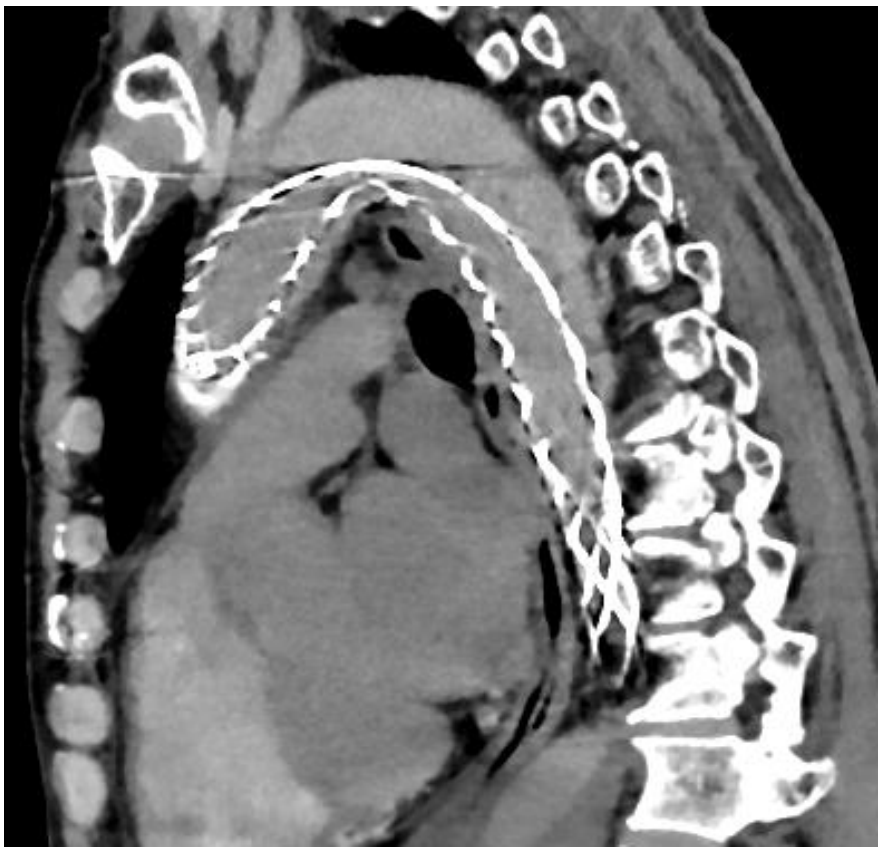

Figure 4: Compression of the AMDS at the isthmus in one patient.