ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

DOTTORATO DI RICERCA IN

SCIENZE CHIRURGICHE

Ciclo 36

**Settore Concorsuale:** 06/E1 – CHIRURGIA CARDIO-TORACO-VASCOLARE

**Settore Scientifico Disciplinare:** MED/22 - CHIRURGIA VASCOLARE

# OUTCOMES OF HYBRID ENDOVASCULAR REPAIR OF AORTIC ARCH PATHOLOGIES SAFETY, DURABILITY AND PATENCY OF HYBRID APPROACH FOR ENDOVASCULAR AORTIC REPAIR INVOLVING THE AORTIC ARCH

**Presentata da:** Paolo Spath

| **Coordinatore Dottorato** | **Supervisore** |
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Esame finale anno 2024

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## SUMMARY

*Introduction:*

Endovascular aortic repair (EVAR) has recently gained prominence as the preferred treatment for patients considered high-risk for open surgery. This is particularly true for pathologies of the thoracic, thoraco-abdominal aorta, and the aortic arch. Complexities may increase with the need to engage the supra-aortic vessels (SAV) to ensure a stable repair. Several contemporary methods are available, such as the use of fenestrated/branched thoracic endovascular aortic repair (TEVAR). In situations where these devices are unavailable, a hybrid strategy combining surgical debranching of one or more SAV with extra-anatomical bypass presents a viable and current alternative. While consistent literature on this topic is limited, these procedures have been extensively performed in the field of vascular surgery. The aim of this study was to assess the safety, durability, and patency of the hybrid approach for endovascular aortic repairs involving the aortic arch

*Methods:*

A retrospective and prospective analysis was conducted, spanning from January 2011 to September 2023. Patient selection criteria encompassed all ranges of aortic pathologies, including aneurysms, dissections, ulcers, and failures of previous treatments, elective or urgent procedures. At least one of the SAV must have been revascularized by surgical bypass/reimplant. Anatomical subgroups were performed if the treated aortic pathology was in the aortic arch or if the aortic arch represented the proximal healthy landing zone for a more extensive aortic repair. All kind of endovascular repair associated to SAV-debrancing were included, involving thoracic endovascular aortic repair (TEVAR) (simple TEVAR) or custom-made TEVAR and/or TEVAR associated with fenestrated/branched EVAR (advanced procedures). Primary endpoints were the incidence of hybrid repair and configurations; technical success of the hybrid procedures; SAV-debranching related complications at 30-day; any 30-day reintervention and follow-up patency of SAV-debranching. Secondary endpoints were mortality, major adverse events and clinical success at 30-days and subgroup analysis of early primary and secondary endpoints. Secondary follow-up endpoints were overall survival and freedom from reinterventions.

*Results:*

The study cohort comprised 67 patients, 43 (63%) male, with a mean age of 71 years. Anatomical subgroups comprised aortic arch diseases and thoracic/thoracoabdominal pathologies requiring proximal landing zones in the arch in 17 (25%) and 50 (75%) of cases, respectively. Procedural subgroups included simple tube TEVAR in 45 (67%) cases and advanced endovascular techniques in 22 (33%), respectively. Overall debranching were 71 and the most common SAV-debranching procedure was left-common-carotid to left-subclavian bypass performed in 72% of cases. Technical success of the hybrid procedure was achieved in 94% of cases. Debranching-related complications occurred in 16% of patients, with the most common issue being bleeding requiring reintervention in 6 (9%) of cases. Overall reintervention were 15 (27%). Secondary endpoints at 30 days demonstrated a 10% mortality rate (2% in elective cases), with 35% of major adverse events and an overall clinical success achieved in 54 (80%) patients. Subgroup analysis did not show any differences for anatomical subgroups;

advanced procedures when compared to standard TEVAR showed higher reinterventions rates (36% vs 15%, p:.050) and lower clinical success rates (63% vs 89&; p: .019). Follow-up time was median 12 months (range 2-37) and overall survival rate was of 75% and 85% at 12 and 36 months, respectively, with no aortic-related mortalities. The assisted patency of SAV debranching remained at 100% without occlusion events and two reinterventions after 8 days and six months were managed by endovascular means.

Conclusions:

Endovascular hybrid repair of the aortic arch represents a valid solution in case of pathologies of the aortic arch or requiring an healthy sealing in zone 0-2. Supra-aortic-vessel revascularization and endovascular procedures show a high technical success, however reinterventions are still non negligeable and mainly related to access complications. The overall clinical success is satisfactory over 80% influenced mainly by advanced thoracoabdominal procedure complexities and urgent scenarios. Mid-term debranching patency is high, without occlusion and with rare complications manageable by non-invasive endovascular procedures, however strict follow-up adherence is vital to guarantee adequate results.

**KEY WORDS:** Aortic Arch, Arch Fenestrated Endograft, Arch Branched Endograft, Custom-Made Arch Endograft, Cervical Debranching, Review.

# 1. INTRODUCTION

## 1.1 Aortic Arch Definition

Aortic Arch is defined as the tract of the aorta emerging directly above the level of the aortic valve which starts from the plane of the coronary arteries known as sino-tubular-junction (STJ)[1]. The aortic arch is derived from the left branch of the fourth pharyngeal arch during the embryonic development. It represents the prolongation of the ascending thoracic aorta, which begins at the level of the upper border of the second sternocostal joint of the right side.

The distal portion of the aortic arch lies to the left of the trachea, transverses downwards, and ends adjacent to the inferior border of T4. Here the aortic arch continues as the descending aorta.

The first portion of the aortic arch is defined as ascending thoracic aorta, with the proximal side at the level of the coronary arteries and the distal part at the level of the innominate artery (IA).
From this point the aortic arch properly gives origin from the upper convexity to the supra-aortic-trunks (SAT) (Fig.1) that supply blood flow to upper limbs and cerebral circulation. The IA gives origin to the right common carotid artery (RCCA) for the cerebral blood supply of the right hemispheric brain, and the right subclavian artery (RSA) for the blood supply of the upper right limb. After the first tract of the RSA generally the right vertebral artery (RVA) gives origin for the blood supply of the right posterior cerebral vascularization.

The second aortic vessel is the left common carotid artery (LCCA) directly having origin from the aortic arch with a long intrathoracic territory about 7 cm long and giving the blood supply for the left cerebral vascularization. The third vessel is the Left Subclavian Artery (LSA) giving blood supply to the left upper limb. Likewise the right side, the Left Vertebral Artery (LVA) origins from the LSA, suppling the posterior vascularization of cerebellum.[2]

Soon after the origin of the LSA, the aortic isthmus represents the border between the aortic arch and the descending thoracic aorta (DTA).

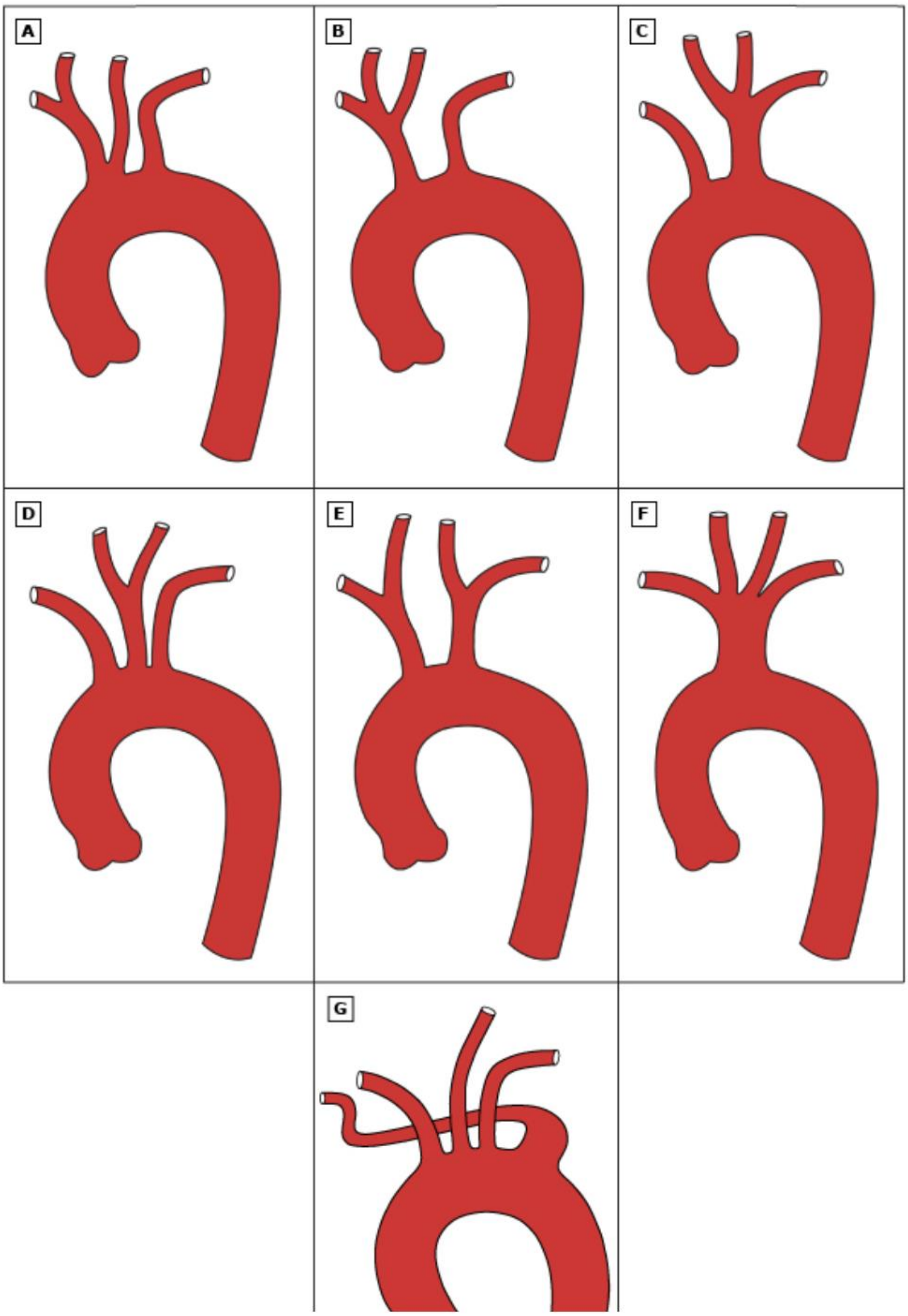


**Figure 1: Variations in the origin of the aortic arch branches.**
(A) and (B) represent the majority of anomalies found in the general population. (A) Common origin of the left common carotid artery and brachiocephalic artery (bovine arch). Represents 73 percent of all branch variations. (B) Origin of the left common carotid from the mid- to upper brachiocephalic artery. Represents 22 percent of all branch variations. (C) Common carotid trunk giving origin to the left subclavian artery. (D) Common carotid trunk, independent from both subclavian arteries. (E) Left and right brachiocephalic arteries. (F) Single arch vessel (brachiocephalic artery) originates the left common carotid and left subclavian arteries. (G) Aberrant takeoff of the right subclavian artery from the left and passing behind the aortic arch vessels.
With this anomaly, dilation of the proximal subclavian can occur and is termed a Kommerell diverticulum.

**Source: UpToDate**.

## 1.2 Aortic Arch Pathologies

The pathologies associated to the aortic arch are different and can be summed up as follows:

- Aortic Arch Aneurysm (Arch-AA)
- Aortic Dissection involving the aortic arch (Arch-AD)
- Aortic Arch Penetrating Aortic Ulcer (Arch-PAU)
- Thoraco-Abdominal Aortic Aneurysm (TAAA) involving the aortic arch
- Post-dissection thoraco-abdominal aortic aneurysm (PD-TAAA) involving the aortic arch

### 1.2.1 Aortic Arch Aneurysm

The degenerative disease at this level is represented by the **Aortic Arch Aneurysm**. According to the definition the aortic aneurysm is defined as a full-thickness dilatation when the diameter of the vessel reaches more the 50% of its native diameter.[3] True aneurysms involve all three layers of the arterial wall (intima, media, adventitia).

At the level of the aortic arch the normal diameter is approximately around 30 mm. Aortic arch aneurysms include any thoracic aneurysm which involves the brachiocephalic vessels.[2]

Atherosclerosis is without any doubt the main etiology of aneurysm of the aortic arch. The aneurysms found in connection to ascending thoracic aorta are most of times the consequence of cystic medial degeneration. Among the causes we find Marfan syndrome, Ehlers– Danlos syndrome, Turner syndrome, Loeys–Dietz syndrome, familial TAA syndrome, and Behcet disease[4] Deceleration injuries have been considered to provoke dilation of the segment just after the aortic arch.[5]

Together with the risk factors at the basis of atherosclerosis like for example smoking, hypertension, and hypercholesterolemia, that all together increase aortic wall stress, we should consider pheochromocytoma, cocaine use, coarctation, weight lifting that increase the development of aortic arch aneurysm, as well.[6]

It is not easy to determine the incidence and prevalence of aortic arch aneurysms with a large number of cases being diagnosed incidentally.[7] Thoracic aortic aneurysms (TAAs) are estimated to have an incidence of around 10 cases per 100

000 person-years. On the other hand, aneurysms involving the aortic arch constitute a minor proportion of TAAs, accounting for about 10% of the total cases of thoracic aorta aneurysms. Moreover they are far more frequent among male patients, accounting for almost four times more than females.(3,8)

### 1.2.2 Aortic Arch Dissection involving the Aortic Arch

**Aortic dissection** (AD) is defined as a separation of the layers of the aortic wall provoked by an intimal tear (Fig.2).

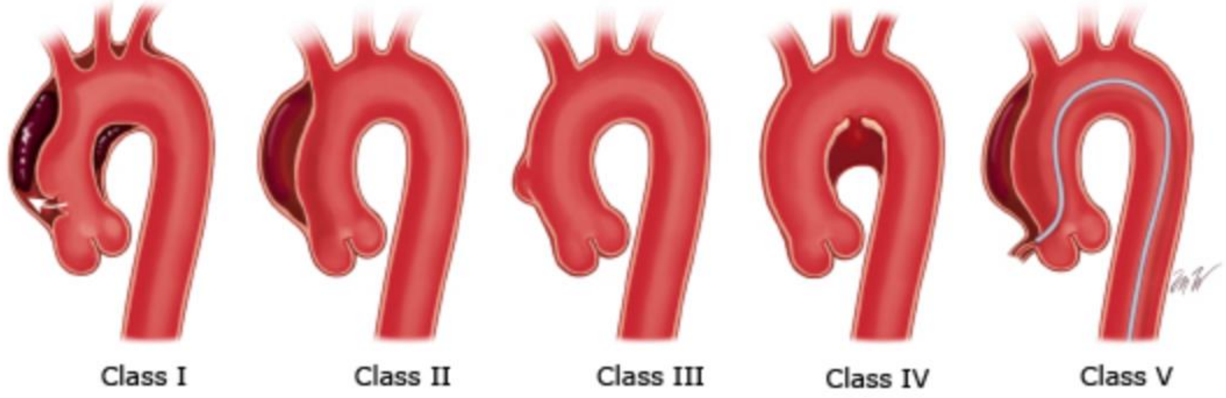


**Figure 2.**
Class I – Classic dissection with separation of intima/media and dual lumens; there is a flap between true and false aneurysm and clot in false lumen.
Class II – Intramural hematoma with separation of intima/media but no intraluminal tear or flap on imaging.
Class III – Limited intimal tear without hematoma and eccentric bulge at tear site (limited dissection).
Class IV – Atherosclerotic ulcer penetrating to adventitia with surrounding hematoma that is usually subadventitial.
Class V – Iatrogenic or traumatic dissection (eg, due to a cardiac catheterization). **Source: UpToDate**

The initial intimal tear can take place in the ascending aorta or descending aorta and sometimes can originate in the abdominal aorta, therefore the aortic arch is generally involved either as the direct origin of the dissection or for the repair.[9]

The dissection can propagate proximally or distally from the initial tear but can also involve the aortic valve, coronary arteries, or branches of the aortic arch or thoracic or abdominal aorta[10]. This propagation provokes lots of the associated clinical features of aortic dissection (acute chest or back pain, neurologic, coronary, cerebral, spinal, extremity, visceral).[10]

Two systems of classification of aortic dissection (Fig. 3) are commonly used,[11,12] the DeBakey and the Stanford. Between these two the Stanford system is mainly used and divides aortic dissections which involve the ascending aorta as type A, no matter what the site where the primary intimal tear occurs, and all the other dissections as type B.

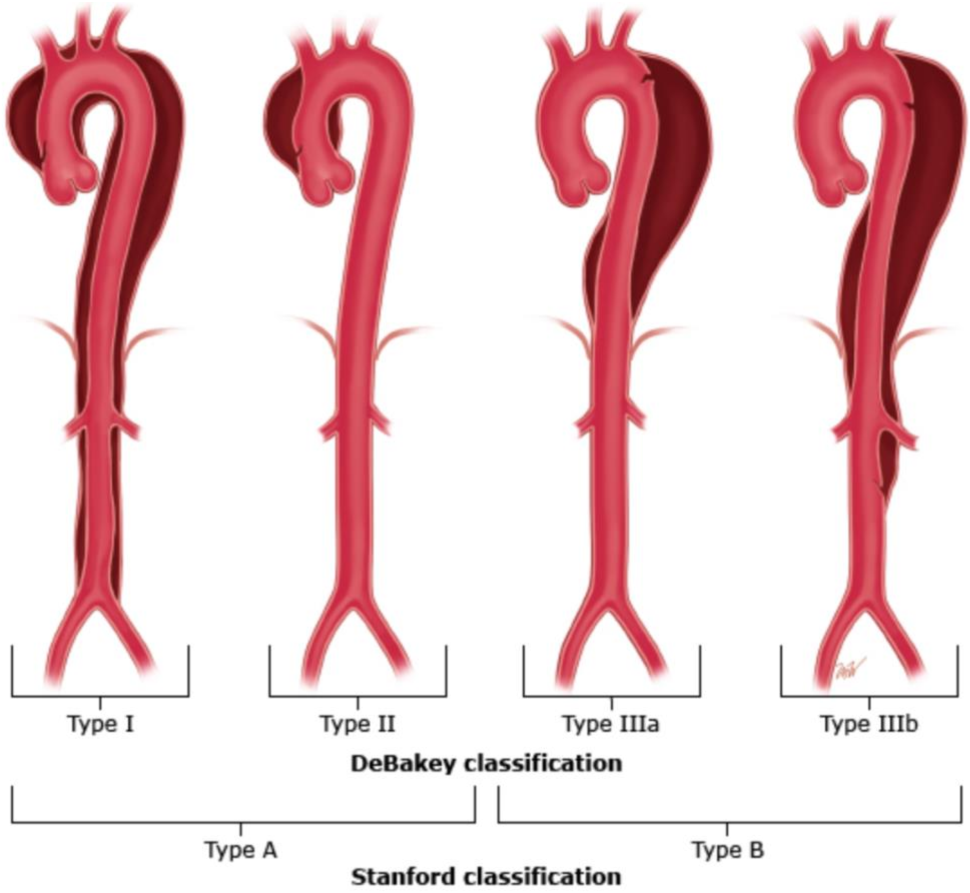


**Figure 3:** Aortic dissection classifications. **Source: UpToDate**

Furthermore it is important to highlight that ascending aortic dissections can occur almost twice as descending dissections and aortic arch is involved in up to 30 percent.[13]

The DeBakey system, on the other hand, considers the site where the tear originates, with type 1 originating in the ascending aorta and propagating as far as the aortic arch, type 2 originating in and confined to the ascending aorta, and type 3 originating in the descending aorta and extending distally or proximally, but not proximal to the left subclavian artery.

In the past years, type B aortic dissection was classified simply as acute (<14 days) or chronic (>14 days) from the time of symptom presentation, which was based on the timing of death in the era of open surgery[14]. The Society of Vascular Surgery (SVS)/Society of Thoracic Surgery (STS) reporting guidelines have furnished further classifications based on the timing from the onset of symptoms as follows[15]:
Hyperacute – <24 hours
Acute – 1 to 14 days
Subacute – 15 to 90 days
Chronic – >90 days

Acute aortic dissection comprehend the most part of acute aortic syndromes[14,15]. Risk factors associated with acute aortic dissection include hypertension, atherosclerosis, prior cardiac surgery, known aneurysm, known connective tissue disorder, bicuspid aortic valve, and prior aortic surgery[16]. Once more the acute aortic dissection is more diffused among men (65 percent in an International Registry of Acute Aortic Dissections [IRAD] review), while women tend to be older at presentation (67 versus 60 years).[16]

Distal type B dissection refers to descending aortic dissection and entry distal to the LSA. The evolution of the term non-A-non-B aortic dissection is an evolution of the description, with an entry tear that is in between the IA and LSA.[17] In a recent study which involved 43 patients with descending aortic dissection and dissection components in the aortic arch, the authors found 21 patients with entry in the DTA and 22 patients with entry within the aortic arch. The incidence of non-A-non-B dissection was 11% among all patients with acute aortic dissection.[18] Patients with non-A- non-B dissection presented with a common origin of the IA and LCCA in 28% and an arch origin of the left vertebral artery in 16% that is associated therefore to an increase rate of non-A-non B dissection.[18]

Clinical presentation, open or endovascular treatment and results in non-A- non-B dissection patients differ from the ones reported for patients with type B dissection. As it seems that the involvement of the arch in the dissection process of the DTA has a deep impact on clinical course and outcome; therefore it is reasonable that these patients are not classified as type B, but as non-A-non-B aortic dissection. [19]

### 1.2.3 Aortic Arch Penetrating Aortic Ulcer

**Penetrating aortic ulcer** refers to a region of the aorta with an ulcer-like projection shape, where the aortic intima progresses through the aortic wall. Penetrating aortic ulcers can be found in association with atherosclerotic lesions of the aortic wall.[20]
Penetrating aortic ulcer may be associated with hematoma within the media and may evolve to perforation or aortic dissection. Penetrating ulcer is the primarily lesion in <5 percent of all aortic dissections.[21,22]
The large part of penetrating aortic ulcers are located in the descending thoracic aorta (85 to 95 percent), but they can also occur in the ascending aorta or arch.[20–22]

Penetrating aortic ulcers account for 2 to 7 percent of acute aortic syndromes[23]. The patients with this kind disease are elderly people and show the usual risk factors for atherosclerosis, including hypertension, hyperlipidemia, coronary artery disease, tobacco use, and infrarenal abdominal aortic aneurysm.[21,23]

### 1.2.4 Thoraco-abdominal Aortic Aneurysms involving the Aortic Arch

Thoraco-abdominal aortic aneurysm can be defined as an aneurysm continuing from the descending thoracic aorta extending into the abdominal aorta. Starting from the origin of the left subclavian artery to the aortoiliac bifurcation many different configurations may occur.
The etiologies of aortic aneurysms can be caused by several genetic disorders. It has been observed that patients with Marfan syndrome, an autosomal dominant condition resulting in abnormal fibrillin, frequently develop aortic aneurysms. Ehlers-Danlos syndrome, a collagen disorder, also provokes similar clinical findings in some patients. Among the disorders associated with aortic aneurysms we can find Turner's syndrome, polycystic kidney disease, Loeys-Dietz syndrome, syphilis, arteritis, and traumatic injury[24].

The first TAAA classification scheme based on the anatomic extent of the aneurysm was described by Crawford in 1986[25]. According to this, Type I involves most of the descending thoracic aorta from the origin of the left subclavian to the suprarenal abdominal aorta. Type II is the most extensive, extending from the subclavian to the aortoiliac bifurcation. Type III involves the distal thoracic aorta to the aortoiliac bifurcation. Type IV TAAAs are limited to the abdominal aorta below the diaphragm. Successively Safi's group modified this classification adding Type V, which extends from the distal thoracic aorta including the celiac and superior mesenteric origins but not the renal arteries[26]. (Fig. 4)

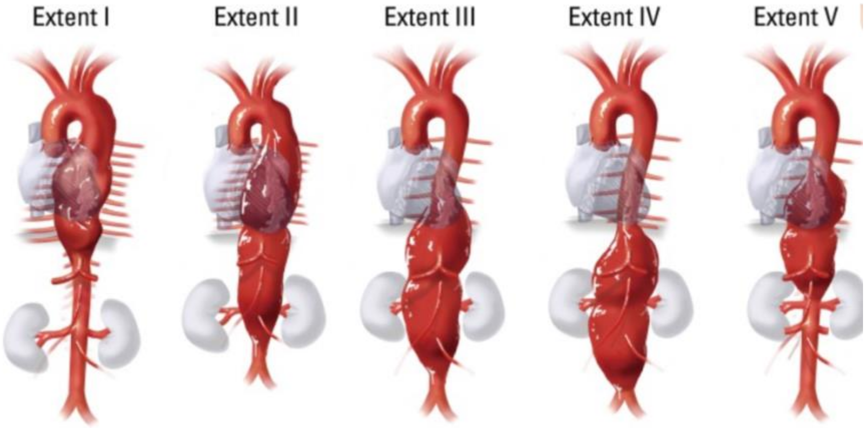


**Figure 4:** Schematic representation of the modified Crawford classification scheme for thoracoabdominal aortic aneurysm extents
Aortic dissection classifications. **Source: Annals of Cardiothoracic Surgery**

As seen, type II TAAAs may involve the aortic arch: in fact in order to reach a healthy sealing zone the need to cover LSA or more SAT may extend the need for endovascular repair into the aortic arch. [27,28]

Post-dissection thoraco abdominal aortic aneurysm (PDTAAA) represent an important subtype of TAAA and are approximately found in 30% of patients with chronic aortic dissections will ultimately experience progressive aneurysmal dilation. [29]These include arch aneurysm and thoracoabdominal aortic aneurysm (TAAA) repairs.[30]Overall, it is estimated that approximately 20-40% of patients with C-TBAD develop enlargement of the FL require treatment and approximately

25% of DTAA or TAAA are associated with dissections.[31] A false lumen thoracic aneurysm can be treated with thoracic endovascular aortic repair (TEVAR) covering the entry tear of dissection flap and extending the endograft distally down to celiac trunk. However, from 6.6% to 84.0% exhibit continuous thoracic aortic growth despite TEVAR. In the subset of patients post-TEVAR, aortic dilatation is observed in patients with persistent and patent FL. This entity can be handled with different techniques in order to occlude false lumen backflow including embolization, Candy plug, and the Knickerbocker technique. [32]

## 2. PATIENT EVALUATION AND MEDICAL TREATMENT

Sometimes chest radiographic imagining, done for unrelated indication, may give hints for aortic arch pathologies and are represented by widening of the mediastinal silhouette, abnormalities of aortic contour, or tracheal deviation.[33]

But chest X-rays are not precise to exclude the presence of aortic aneurysms and are inadequate to differentiate between an aneurysm and conditions like mediastinal mass, torturous aorta and require definitive aortic imaging.

The best imagining modalities of choice for accurate detection of aortic Arch pathologies are computed tomography angiography (CTA) or magnetic resonance angiography (MRA) . They are useful to delineate aortic anatomy, size, branch artery involvement. [34]

Echocardiography can be used as well to visualize the aorta and its major branches. The suprasternal view is best for viewing the aortic arch, whereas orthogonal and longitudinal scanning plans are useful when the involvement of the innominate artery, left subclavian artery or left common carotid artery is also suspected. Coronary angiography and echocardiography are also performed as part of regular preoperative investigations done in order to determine the need for a concomitant cardiac procedure. Also, as maintaining brain perfusion is critical while carrying out open surgeries involving the aortic arch, carotid duplex scanning is also routinely instituted in order to access for carotid stenosis.[34]

Medical therapy is administered as a first step in the management of aortic arch lesion in order to decrease risk factors for atherosclerosis, to slow the rate of expansion, and to lower contrast the development of the complications, including dissection or rupture.[35]

American Heart Association guidelines on medical treatment of patients with thoracic aortic disease have recommend since 2012 that strict control of hypertension, the optimization of lipid profile, stop smoking , and other atherosclerosis risk-reduction measures should be instituted for patients with small aneurysms as well as for patients who are not considered to be surgical candidates (Class 1 recommendation, level of evidence: C).[3]

Guidelines on surveillance imaging suggest that for isolated aortic arch aneurysms less than 4.0 cm in diameter, it is reasonable to re-image using CT or MRI, at 12-month intervals, in order to check  enlargement of the aneurysm, while for wider aneurysm the interval should be reduced to 6-months.[3]

## 3. INDICATION FOR AORTIC ARCH REPAIR

As a matter of fact, there are few recommendations for accurate detection of Aortic Arch pathologies because of the few data on the natural history of the aortic arch pathologies requiring interventions, as well as on the different results of arch open surgery.

The current guidelines recommend surgery in isolated arch aneurysms at a diameter of 55 mm and in the majority of patients, this will determine the threshold for intervention. (Class IIa Level B)[19]

Another criteria for aortic arch repair is the presence of symptoms, such as refractory pain, cerebral or visceral malperfusion, enrlaged diameter, in case of a dissection. Penetrating Aortic Ulcers do not have a clear threshold for repair and it is thought that in asymptomatic patients with PAU, a diameter >20 mm and a neck >10 mm have a higher risk of progression and early intervention should be evaluated[36].

On the same analysis wider PAU or signs of progression such as saccular aneurysm degeneration or the evidence of outer hematoma or progression to dissection or intramural hematoma show evidence of progression of the PAU and therefore favour treatment.[21]

Beside this indication, evidence of aortic rupture at the level of the arch or rapid growth of an aneurysm (>10 mm over 12 months) are considered as criteria for treatment.

### 3.1 Consideration on the indication of Aortic Arch Repair in the modern era

Nowadays and from an interventional point of view the major pathologies involving the aortic arch can be classified as pathologies that directly origin and involve the aortic arch and pathologies that involve the aortic arch in order to reach an healthy sealing zone according to Hishimaru’s zones. (Fig. 5).

The aortic arch is therefore divided in the following Zone:

- Zone 0 (ZO): from sino-tubular junction to the IA
- Zone 1 (Z1): from the distal aspect of IA to the left CCA
- Zone 2 (Z2): from the distal aspect of LCCA to Left subclavian artery

**Figure 5.** Definition of attachment zones, also known as Ishimaru zones (printedwith permission from_Campbell Medical Illustration). **Source: Editor's Choice – Current Options and Recommendations for the Treatment of Thoracic Aortic Pathologies Involving the Aortic Arch: An Expert Consensus Document of the European Association for Cardio-Thoracic Surgery (EACTS) &amp; the European Society for Vascular Surgery (ESVS).**(19)

Lesion involving Z0 or requiring a landing zone in this area are considered proximal arch lesion. Theoretically, a standard endovascular repair would cover all SAT and IA.

Lesion involving Z1 or requiring a landing zone in this area are considered mid-arch lesion and a standard endovascular repair could permit a direct vascularization of IA.

Finally lesions involving Z2 or requiring a landing zone in this area are considered distal-arch lesion and standard endovascular repair may cover only LSA.

## 4. SURGICAL REPAIR OF THE AORTIC ARCH

Open repair of the aortic arch is still considered as the standard treatment for the management of ascending thoracic aortic pathologies, including ascending aortic arch aneurysm and acute ascending thoracic aortic dissection.

For descending thoracic aortic pathologies including the aortic arch (aneurysm dissection, aortic injury), endovascular repair is emerging as an elected initial approach, given the lower rates of perioperative morbidity and mortality.

Aortic arch pathologies repaired using an open surgical approach include[3]:

Type A (ascending) acute aortic dissection or intramural hematoma in the ascending/aortic arch.

Bicuspid aortic valve with progressive aortic stenosis and regurgitation that ultimately requires valve replacement. In addition, bicuspid aortic valves are often associated with ascending aortic aneurysms even in the absence of significant valve disease

Aneurysm of the ascending aorta meeting diameter or expansion criteria for repair.

Patients with genetically mediated syndromes and indications for repair should undergo open surgical repair rather than endovascular repair. For patients with non-syndromic pathologies, there is no evidences in favor of an open or endovascular approach and both could be used.

The open surgical repair of the aortic arch implies the need for access to the arch vessels and therefore requires interruption of cerebral blood flow and the need for cerebral protection[37].

Consequently it is needed to perform a deep hypothermic circulatory arrest and to prepare the patient to aortic cross-clamping with complete interruption of blood flow to the brain vessels.

Cerebral protection can be accomplished using retrograde cerebral perfusion or selective antegrade cerebral perfusion.

Retrograde cerebral perfusion involves perfusing the superior vena cava with cold oxygenated blood in a retrograde manner in conjunction with cardiopulmonary bypass. Deoxygenated blood containing cellular metabolic byproducts returns via the carotid orifices. Retrograde cerebral perfusion compared with hypothermic circulatory arrest alone reduce significantly the risk of stroke. [38]

With selective antegrade cerebral perfusion, blood flow is established antegrade via grafts that are anastomosed to the right axillary or innominate artery, or selective cannulation of the cerebral vessels with balloon-tip catheters. Advantages of selective antegrade cerebral perfusion include the ability to control flow, and perfusate temperature to the brain. [39]

Both retrograde cerebral perfusion or selective antegrade cerebral perfusion show that very good results can be achieved. Although there are no good direct comparisons to establish superiority of one technique, there are numerous publications favoring one strategy over another[40].

Total arch repair – Replacement of the entire aortic arch is favored for aneurysms of the entire arch (Fig. 6); acute dissections where the arch is aneurysmal or if there is extensive destruction and leakage; chronic dissection when the arch is enlarged; and for distal arch aneurysms that also involve the proximal descending thoracic aorta.

The entire arch is excised, and the arch vessels are individually re-anastomosed to the replaced arch. After the anastomoses are completed, each of these grafts is cannulated and selective antegrade perfusion is given. Total arch repair typically mandates adjunctive antegrade cerebral perfusion techniques because circulatory arrest times can be extensive.

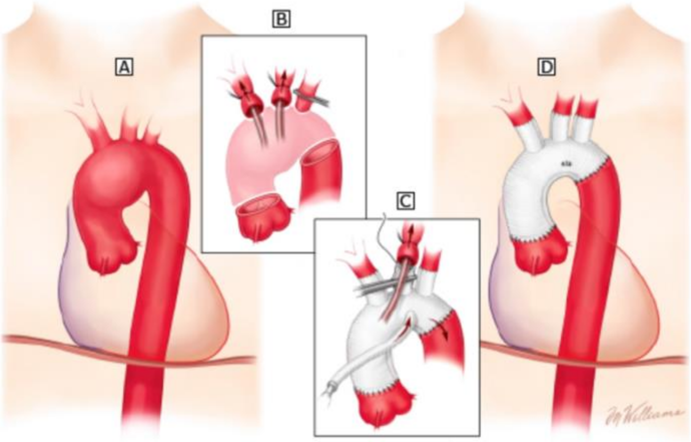


**Figure 6:** Aneurysm of the aortic arch (A) requires excision of all the involved arch tissue. Balloon occlusion catheters are used to deliver antegrade cerebral perfusion to the innominate and left carotid arteries (B). Once the proximal and distal graft anastomoses are completed, antegrade flow can be re-established to the rest of the body while the grafts are anastomosed to the head vessels to complete the repair (D).**Source: UpToDate**

The elephant trunk technique is often used in total arch replacement. The elephant trunk technique leaves a graft inside the distal aorta (trunk) (Fig.7), which can then be used for a proximal anastomosis in future operations. At the beginning it has been described as a two-stage operation but can be performed in one stage. With a frozen elephant trunk procedure, the arch is replaced in the manner of a traditional elephant trunk, but instead of performing a second open operation to replace the descending aorta, a thoracic aortic stent-graft is placed into the graft either at the initial operation or at a later date. This allows for a one-stage repair[41].

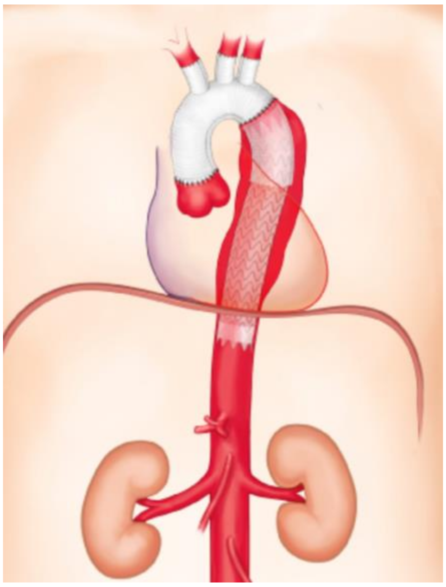


**Figure 7:** open elephant trunk repair is used, in which the ascending aorta and branch vessels are replaced, followed by endovascular stent-graft repair of the descending aorta. **Source: UpToDate**

Hemiarch repair – With a hemiarch repair, the arch vessels (brachiocephalic, left carotid, left subclavian artery) that are not involved in the disease process can be preserved and excised as a patch. The patch is anastomosed to a polyethylene tube graft that spans the entire arch. In a single distal aortic anastomosis, circulatory arrest times are significantly shorter if compared to extensive arch reconstructions. Therefore, this technique lends itself well to adjunctive retrograde cerebral perfusion techniques.

Once the distal aortic anastomosis is completed, antegrade (anatomical) circulation to both the body and brain are restored, the patient is rewarmed, and attention is turned back to the proximal aortic reconstruction.
Once this anastomosis is complete, the cross clamp is removed and the heart is re-perfused.

Because of the operative complexity, it does not sound strange that perioperative morbidity and mortality following thoracic aortic repair is high if compared to most elective surgical procedures. Factors associated with an adverse 30-day outcome (death, paraplegia, paraparesis, stroke, or acute renal failure) after open surgery for thoracoabdominal aneurysm include preoperative renal insufficiency, advanced age, symptomatic aneurysm, and Crawford type II aneurysm (proximal descending to infrarenal aorta).
The subsets of aortic arch and Crawford type II aneurysms (proximal descending to infrarenal aorta) have the highest morbidity and mortality rates[42]. Even higher rates are associated with emergency surgery for thoracoabdominal aneurysm that has ruptured or dissected. In one series, perioperative mortality among 19 patients undergoing emergency thoracoabdominal repair was 42 percent. [43]

Mortality rates have decreased significantly in later series with rates of peri-operative mortality from 26 to a recent 3% , perhaps attributable to improving technology and increased use of protection procedures. [44]

In studies documenting outcomes through the mid-1990s, overall 30-day stroke rates were 20 % with ascending and arch aneurysm repair, and spinal and renal injury rates were 15 percent with repair of a descending aneurysm. [45]

The risk of spinal cord ischemia and consequential paraparesis/paraplegia is between 8 and 30%. An increased long-term morbidity as well as mortality are associated with spinal cord injury. In a series of 1509 patients who underwent descending aneurysm repair, paraparesis or paraplegia developed in 16%.[45] In another report based on the same group, the incidence of postoperative acute renal failure was severe enough to require dialysis was 7%[46].

# 5. CURRENT ENDOVASCULAR REPAIR OF THE AORTIC ARCH

The endovascular treatment of the aortic arch represents an alternative to the actual gold standard that is still represented by open aortic repair.

The main problem with surgical repair is represented by the need for cerebral protection in order to guarantee perfusion.

Nowadays recent development of techniques, as previously showed, permit to obtain a mortality rates of 5-20% and neurological events in a range from 5% to 18%. [47,48]

Endovascular strategies are flexible and depend on the type of the repair, the lesion localization and the expertise and availability of endovascular devices of the surgical team.

The main advantage of endovascular arch repair is to avoid aortic cross-clamping and hypothermic circulatory arrest, and it is the treatment that can be chosen in case of patients that are deemed as unfit for open surgery by a multidisciplinary team.

**Hybrid arch repair** is an endovascular procedure associated to a compulsory open surgical step of vascular debranching, not permitting a total endovascular repair of the aortic arch and not being available for Zone 0 lesion treatment.

The actual available and currently used devices for total endovascular repair of the aortic arch are the following:

- **In situ modified aortic arch fenestration**
- **Parallel Stent-Graft Techiniques (Chimney)**
- **Custom-Made Fenestrated/Scallopped devices**
- **Custom-Made Inner branched devices.**

## 5.1 Challenges associated to Endovascular Repair of the Aortic Arch

Many challenges are associated to endovascular treatment in the aortic arch.

As described by Haulon et al. [49] the main criteria both from an anatomical and clinical point of view may be summarized as following:

**Anatomic Criteria:**

Arch aneurysms and chronic dissections, no previous mechanical aortic valve replacement

Ascending aortic length ≥ 50 mm (measured from sinotubular junction to origin of innominate artery)

Sealing zone in the ascending aorta ≥ 40 mm in length and ≤ 38 mm diameter

Sealing zone in the innominate artery ≥ 20 mm in length and ≤ 20 mm in diameter

Access able to accommodate 22- or 24-F sheaths

**Physiologic Criteria:**

Minimum of 2-year life expectancy

Negative stress test (cardiology clearance required in the setting of positive stress test)

No class III or IV congestive heart failure

No stroke or myocardial infarction in the last year

No significant carotid bifurcation disease (≥ 75% stenosis by North American Symptomatic Carotid Endarterectomy Trial criteria)

Estimated glomerular filtration rate by modification of diet in renal disease method $\geq 45$ mL/min/1.73 $m^2$

First of all the choice of an **adequate sealing zone** should be carefully selected.

An adequate sealing zone should consider at least more than 25 mm of an healthy aorta, without calcification or thrombus.

The aortic neck in the arch should be with a minimal tapering and with a diameter < 38 mm. The aortic arch angulation should not exceed 60°.

The choice of an adequate sealing zone is mandatory in order to make a prevention of catastrophic events such as loss of the device during maneuvers, migration or major endoleaks. At the same time an adequate length of the sealing zone may be in favor for aortic remodeling and may warrant against disease progression.

Another main topic in the choice of the correct endograft for endovascular repair is the **durability of the device** in the aortic arch. All commercially available endografts have been tested on duration in thoracic and abdominal aorta. But the fatigue load requested in the aortic arch is sensibly higher due to constant movement of the vessels and a higher pulsatility in this region that is twice to three times higher than in other segments of the aorta. At the same time, respiration and cardiac pulsation may affect the relative movements of arch branches and may determine kinking of the main aortic graft and stress and fracture for bridging stents.

One of the main issues facing endovascular repair of the aortic arch is aroused for the high **anatomical variability** of this region. First of all, there are 3 types of aortic arches (Fig.8), based on the relationship of the innominate artery (IA) to the aortic arch. [50]

In a type I aortic arch, all vessels originate in the same horizontal plane as the outer curvature of the aortic arch. In a type II aortic arch, the IA originates between the horizontal planes of the outer and inner curvatures of the aortic arch. In a type III aortic arch, the IA originates below the horizontal plane of the inner curvature of the aortic arch

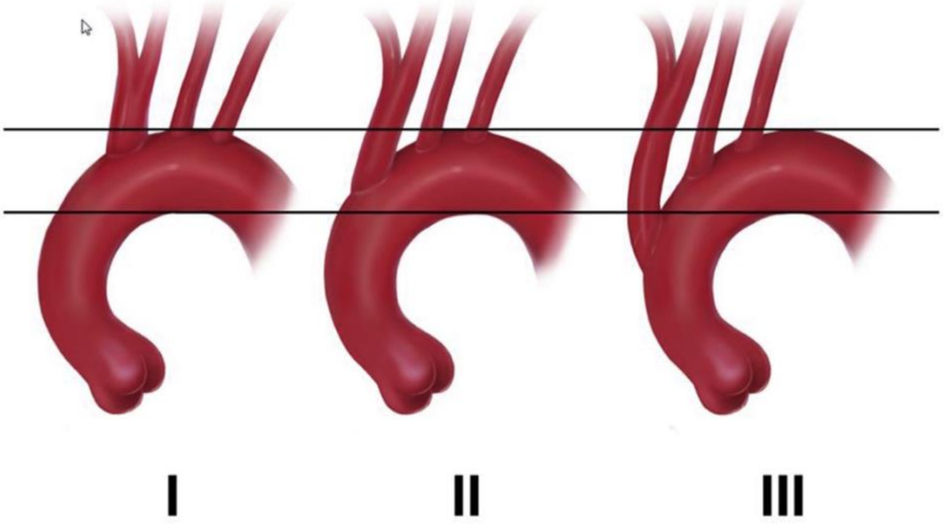


**Figure 8.** Aortic arch configurations **Source: Editor's Choice – Current Options and Recommendations for the Treatment of Thoracic Aortic Pathologies Involving the Aortic Arch: An Expert Consensus Document of the European Association for Cardio-Thoracic Surgery (EACTS) &amp; the European Society for Vascular Surgery (ESVS)** [19]

At the same time anatomic anomalies (eg, aberrant right subclavian artery (Fig.1), vertebral artery directly from descending thoracic aorta, lusory right subclavian artery) may be handled during endovascular repair and may force the surgical group to perform adjunctive surgical bypasses (Fig.9)

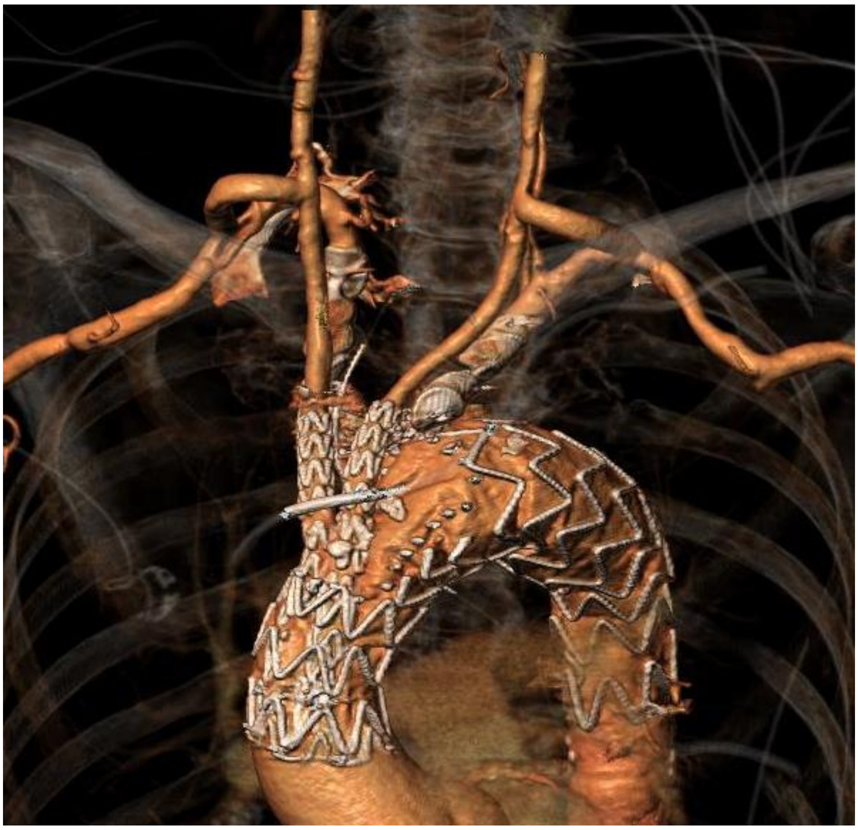


**Figure 9.** Patient with right lusory artery and Kommerel's diverticulum treated with aortic arch endografting and double carotid-subclavian bypass with embolization of the origin of both subclavian arteries. **Source: Vascular Surgery, University of Bologna, Italy**

These considerations may lead to some issues concerning difficulties in alignment of the endograft, the need for extra manipulation determining a higher risk of cerebral embolization and post-operative stroke and unintended coverage of one of the branches or coronary arteries determining the need for bailout rescue procedures.

These problems come along with the long distance between the insertion point of the endograft (femoral arteries) and the place of deployment, carrying the difficulties of precise control release due to long delivery system. That is the reason auto-aligning features are now available in these devices leaving to the surgeon the need of longitudinal adjustments without the need of rotational maneuvers.

Finally **aortic valve** may represent a major issue: devices in order to be precisely placed are meant to cross the aortic valve plane with guide wires and delivery systems. As a consequence of that aortic valve damages and risk of embolization from fragments need to be taken into account. In order to contrast these issues, endovascular devices have been shaped with short and atraumatic tips in order to limit valve interaction and reducing damage. Mechanical aortic valve replacement represented an exclusion criteria for endovascular repair. Recently new endovascular devices with very short custom-made delivery system tips with bullet nose and without the need to cross the aortic valve have made this procedures no longer contraindicated for patient with mechanical valve replacement. [51]

## 5.1 Hybrid Endovascular Repair of the Aortic Arch.

The procedures for revascularization of the aortic arch in case of the choice of an Hybrid procedure are directly related to the aortic zone in which the lesion is collocated and the healthy sealing zone available to permit a safe release of a thoracic endograft which requires at least 2 cm of healthy sealing zone.

The incidence of cervical debranching has increased in the era of thoracic stent grafting because of reduced morbidity rates as compared to traditional arch debranching procedures that require a median sternotomy and aortic cross clamping.

### 5.2.1 Hybrid Endovascular Repair Landing in Zone 2

For TEVAR landing in zone 2 the coverage of LSA should be avoided. In fact, even in urgent setting this can be achieved in order to guarantee a reduction of operation time, the patency of LSA is mandatory importance in some particular cases such as in case of coronary bypass with mammary artery or in case of a left axillo-femoral bypass[52]. Another mandatory case is when the patient has the occlusion of right subclavian artery, or when the LSA is dominant or is the donor artery for an arterial-venous fistula. A recent review[53] has shown that stroke in patient without LSA revascularization may reach 8.4% compared to 0% in patient with revascularization of LSA, with 26.2% of these strokes originating from the posterior circulation.

The most common mean for revascularization of LSA in case of Zone 2 coverage is LCCA to LSA bypass. In brief this bypass is performed by a supraclavicular incision, identifying vagus nerve and brachial plexus, with or without ligation of the lymphatic duct. The bypass is performed using generally a prosthetic graft, showing a better patency rate and lower stoke rate than a vein graft bypass, 94% vs 58% and 6% vs 39% at 5-years, respectively (Fig. 10).[54]

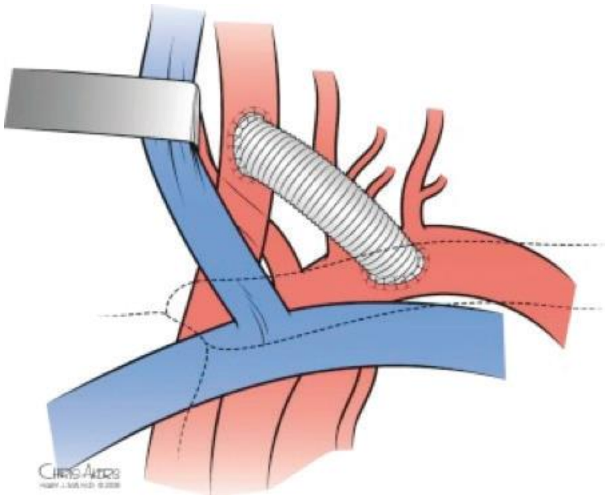


**Figure 10.** A carotid -subclavian bypass. **Source: Rutherford Vascular Surgery, 8th Edition, Elsevier 2014.**

Another viable option is to perform a transposition of LSA on the LCCA. This route may be preferable in order to avoid the usage of a prosthetic endograft even if the procedure is disadvantaged by a more difficult surgical exposure and an higher rate of post-operative complications related to access problems. The results after 70 months follow-up [55] show a 100% patency with a rate of complication of 15%, with 3% of permanent neurologic disability. This technique presents absolute contraindications in case of left mammary coronary bypass or in case of a very proximal origin of left vertebral artery.

### 5.2.2 Hybrid Endovascular Repair Landing in Zone 1

Contrary to the LSA that can be not revascularized in some particular cases such as urgent treatments, in case of healthy sealing zone in Zone 1 with coverage of LCCA the revascularization is mandatory in order to prevent catastrophic consequences. This revascularization can be achieved by means of a carotid-to-carotid crossover bypass.

The procedure is carried out by means of two small longitudinal incisions at the level of common carotid artery (CCA) and the anastomoses in the intrathoracic segment of common CCA. The bypass is always performed with a prosthethic PFTE or Dacron bypass and the diameter generally used varies from 6 to 8 mm (Fig.11). The route of this bypass is generally retropharyngeal and the 5-year patency rate and stroke rate is reported of 94% and 6%, respectively. [56]

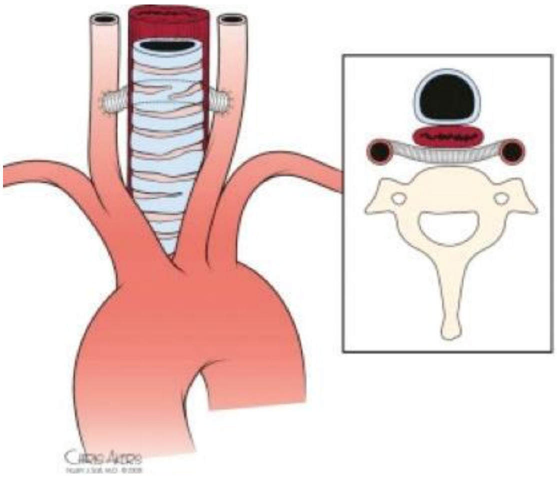


**Figure 11.** A carotid -carotid crossover bypass. **Source: Rutherford Vascular Surgery, 8th Edition, Elsevier 2014.**

After having performed the carotid-to-carotid crossover bypass a LCCA-LSA bypass may be performed as previously mentioned. An alternative option to this approach is represented by a direct bypass from the RCCA to the LSA with direct reimplant of the LCCA on the bypass and stump suture of the proximal segment of LCCA. (Fig. 12).

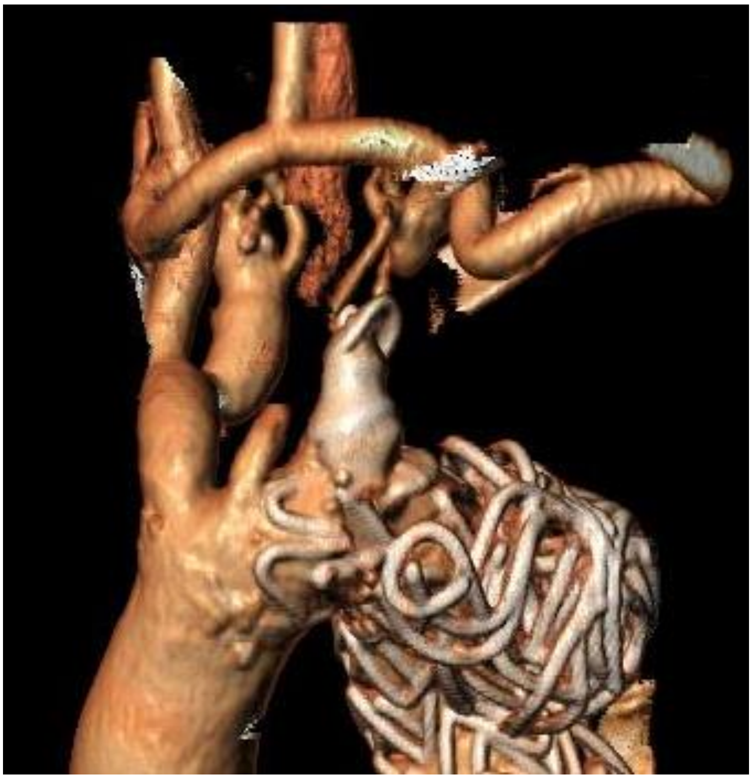


**Figure 12.** Patient treated with right carotid – left subclavian artery graft 8mm PTFE bypass and direct reimplant of left carotid artery and stump ligation of proximal intra-thoracic left carotid artery. **Source: Vascular Surgery, University of Bologna, Italy**

A secondary option to perform revascularization in case of coverage of Z1 is to perform an axillo-axillary crossover bypass together with a prosthetic jump from the bypass to the LCCA[57].

### 5.2.3 Hybrid Endovascular Repair Landing in Zone 2

In case of an endovascular repair where healthy landing zone for TEVAR is reached in Zone 0, theoretically all SAT would be covered.

Therefore the first option available is to perform a sternotomy, and by means of a longitudinal clamping of the ascending thoracic aorta performing a graft from the ascending aortic to IA and from the RCCA to the remaining SAT as previously showed in Zone 1 section. (Fig.13)

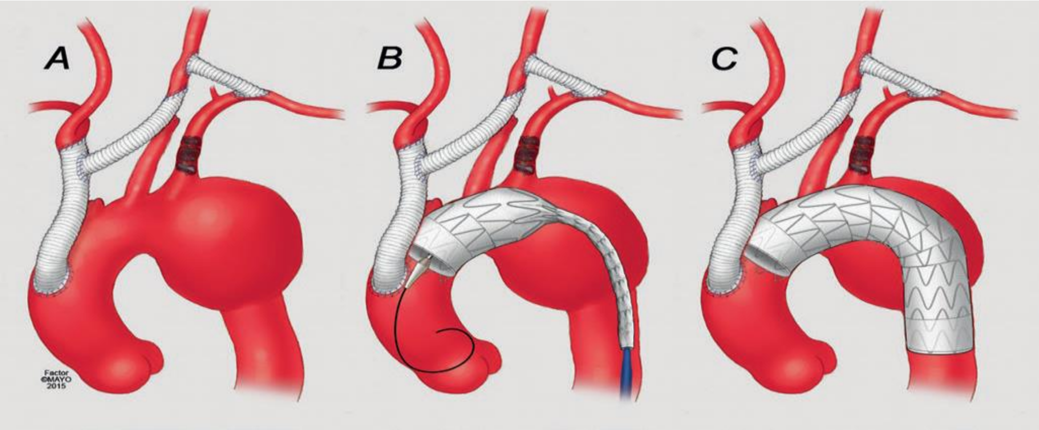


**Figure 13:** Arch debranching done with ascending aortic to innominate and left common carotid graft (a). Retrograde deployment of a Gore stent graft introduced via trans-femoral approach (b and c). **Source: Endovascular Aortic Repair, Oderich Gustavo S, Springer, for Mayo Foundation for Medical Education and Research, 2017.**

This technique is technical demanding, losing the opportunity for avoiding sternotomy in very high risk patient[58].

Another option can be represented by the usage of a chimney parallel graft for the IA and a RCCA-LSA bypass with reimplant of LCCA as previously showed, in order to guarantee branches blood flow (Fig. 14). [59]

This technique is feasible but all cerebral vascularization is sustained by one parallel stent graft with high risks of catastrophic neurological event in case of graft thrombosis.

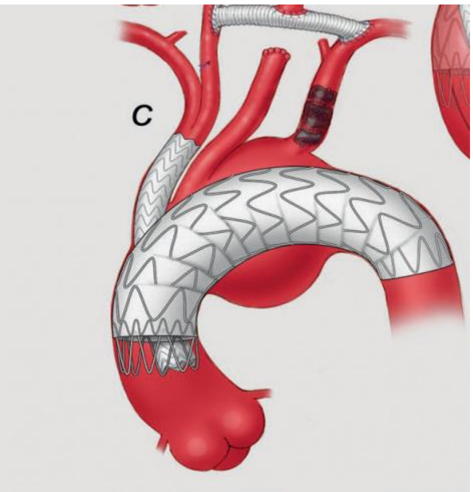


**Figure 14:** Thoracic repair with chimney revascularization of IA surgical debranching by means of carotid to left subclavian bypass and left common carotid artery reimplant. **Source: Endovascular Aortic Repair, Oderich Gustavo S, Springer, for Mayo Foundation for Medical Education and Research, 2017.**

Another option described by Criado in 2009 is to perform a right femoral artery to right common carotid artery retrograde bypass and from that performing a RCCA to LSA bypass with reimplant of LCCA [60].
This technique is feasible but all cerebral vascularization is sustained by one retrograde bypass with risks of major complete stroke in case of bypass thrombosis even for low pressure event.

### 5.2.4 Outcomes of Hybrid Endovascular Arch Repair

Overall, hybrid repair consisting of TEVAR and debranching shows a high rate of patency, up to 100% for LSA bypass.[61]

One of the largest review was conducted by Moulakakis over 26 studies and 820 patients. In this review the 41% of procedures were performed in Zone 0, 28% in Zone 1 and 29% in Zone 2. The overall mortality was 12%, with a 7.6% of stroke and 3.6% of spinal cord ischemia (SCI).[62]
In this series therefore results are still affected by a high rate of complications similar to open surgical repair (Mortality 9.5%, SCI 5%, Stroke 6.2%), but on the other hand these interventions were conducted on patients deemed as high risk for open surgery and therefore that would not have received any treatment for their pathology. On the same hand the results are comparable between two different groups of patients with different comorbidities and risk factors.
In a recent monocentric paper published in 2019 by Konstantinou et al [63] over 211 debranching performed from 2010 to 2017 for aneurysmal pathologies of the aortic arch, 78% LCCA-LSA bypass was performed and 8.1% was the rate of transposition of subclavian artery, with an overall 86% of cases landing in Z2.
The thirty day mortality was 7.6% and seemed to be more affected by one step debranching procedure. The major stroke rate was 4.3% and were all correlated to combined debrancing procedure with 0% after carotid-sublcavian bypass.
Local complications were noticeable with 11% of local bleeding and 10% of re-intervention. 9.5% of cases presented peripheral neurological damages after intervention.

Finally patency rate was satisfactory, with 98% of primary patency and 100% of secondary patency after 7 years follow-up.

## 5.3 In situ Arch Fenestration in the Aortic Arch

The ideal candidate for in situ arch fenestration during TEVAR is a patient that requires arch vessel revascularization in an urgent or emergent setting and does not have complicated aortic arch or target vessel anatomy. Patients with a type III aortic arch, severe anatomies should not be treated with in situ aortic arch fenestration and are at higher risk for failure. Revascularization should be done by other means in these patients. There is no real comparison between needle puncture fenestration or laser fenestration. It seems that laser mean creates less tearing of the endograft material and is superior to needle puncture, therefore limiting the potential for type III endoleaks in comparison to needle puncture. However, laser use to create fenestrations is not without limitations. [59]

In summary, while laser fenestration appears to be a more attractive modality than needle puncture, a durable result is affected by numerous variables including graft material, arch vessel angulation, type of balloon, and size of balloon.

In brief in order to revascularize LSA, when the TEVAR is advanced an introducer sheath is delivered via the LSA and the Laser device is advanced against TEVAR and fabric is perforated by laser heat in order to obtain a passage for 0.018 guidewire. After that guide is exchanged with 0.035 floppy and a subsequent 0.035 stiff guidewire. On this guide a 6mm cutting balloon is used to create the required space for fenestration. After that a balloon expandable 8 to 10 mm stent-graft is advanced and is released one-quarter inside the aorta and three-quarters inside the target vessel with flaring of the proximal side using a 14x20 mm balloon. [59]

Similar technique is suggested to perform an in situ laser fenestration for LCCA and a revascularization of LSA by means of surgical technique is needed. (Fig. 15 and Fig. 16)

Results are limited to some studies and generally LSA was the most performed in situ fenestration with high rate of technical success and a mortality rate ranging from 2 to 14%. Stroke rate is variable from 0 to 28% with no cases of SCI of reported endoleaks [64,65].

These results show therefore a noticeable rates of complications in a feasible technique with nearly 100% of technical conferring a role during treatment of acute and emergency situation enabling a quick procedure and avoiding risks for open surgical repair in unfit patients.[66]

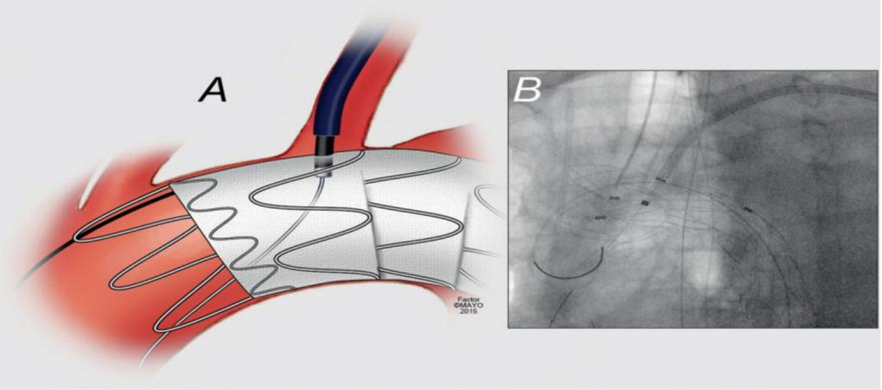


**Figure 15:** Laser fenestration created with gentle forward pressure and application of laser energy. A 0.018 inch wire passed through the fenestration.(b) Fluoroscopic view post laser fenestration and wire passage**Source: Endovascular Aortic Repair, Oderich Gustavo S, Springer, for Mayo Foundation for Medical Education and Research, 2017.**

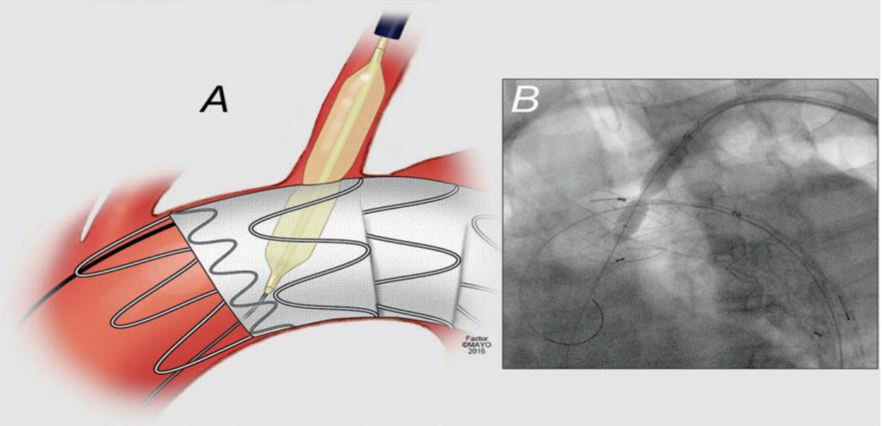


**Figure 16:** Laser fenestration created with gentle forward pressure and application of laser energy. A 0.018 inch wire passed through the fenestration.(b) Fluoroscopic view post laser fenestration and wire passage**Source: Endovascular Aortic Repair, Oderich Gustavo S, Springer, for Mayo Foundation for Medical Education and Research, 2017.**

## 5.4 Parallel stent graft technique in the Aortic Arch

In order to reduce the incidence of mortality related to open surgical repair even with new technologies that still ranged from 2 to 20%[67] and in order to supply the unavailability of fenestrated/branched endograft for urgent and unplanned repair or in centers without high skill in performing advanced endovascular procedures, parallel graft is proposed as an alternative.

As widely described even in other segments of the aorta, even in the aortic arch chimney procedures are performed with the insertion of a stentgraft in the target vessel (cannulated retrogradely from peripheral to central vascularization) and a simultaneous release of TEVAR. [68 ,69]

In particular cases, a vessel cannulation from the bottom is possible and a retrograde perfusion of the arch branch is obtained in a snorkel technique (Fig.17).

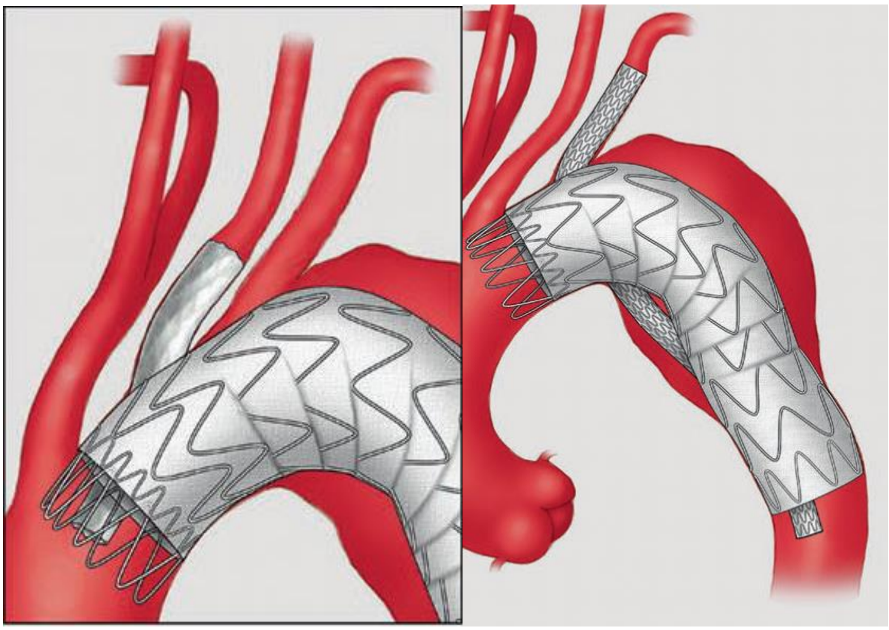


**Figure 17:** On the left, Chimney repair of left common carotid artery parallel with thoracic endogaft. On the right, periscope technique for retrograde perfusion of left subclavian artery. **Source: Endovascular Aortic Repair, Oderich Gustavo S, Springer, for Mayo Foundation for Medical Education and Research, 2017.**

Results presented by Moulakakis et al. [69] in 2013 showed acceptable results for treatment of LSA with a reduction of mortality to 5% in very high risk patients. The stroke rate associated to chimney procedures was up to 4%.

One of the main issues is the presences of type Ia endoleak up to 11%, strongly associated to the presence of blood flow into gutter channels.

PERICLES study published in 2016[70] gathered a population of 95 patients with PAU, degenerative aneurysms, type B dissections and endoleak Ia after previous TEVAR repair forcing to reach a healthy sealing zone in the aortic arch.

The authors[70] showed perioperative results over 102 chimney, with the presence of 10% of type Ia endoleaks at completion angiography. Among them, 5 were spontaneously solved whereas 5 were persistent needing for a re-intervention. Perioperative patency rate was achieved in all cases, and 60 patients were treated with self-expandable stent-graft and 30% with balloon-expandable stent-grafts.

30-day results showed a 4% stroke rate and 2 deaths. As stated, 5% was the rate of re-intervention for gutter endoleak.

Freedom from re-intervention was 96% and 88% and one-year and five-years respectively, with 2 patients with occlusion of stent-graft, 2 patients with severe kinking and 1 patient showing gutter endoleak with need of re-intervention.

In conclusion, parallel graft for the aortic arch represents a good option in case of urgent repair when an off-the-shelf endograft is not available yet, but concerns on the durability of the repair and the effectiveness on the presence of high rate of endoleaks may be in favor in elective cases in case of bailout maneuver for accidental coverage of one of the arch branches.

## 5.5. Fenestrated/Scallop endograft of the Aortic Arch.

Fenestrated and scalloped endograft of the aortic arch are custom-made devices designed on the specific anatomy of the patient to treat mid-distal arch pathologies.[71]

Their typical configuration is with a pre-cannulated fenestration for LSA and a big wide scallop for LCCA or in case of a bovine arch for common IA (Fig. 18).

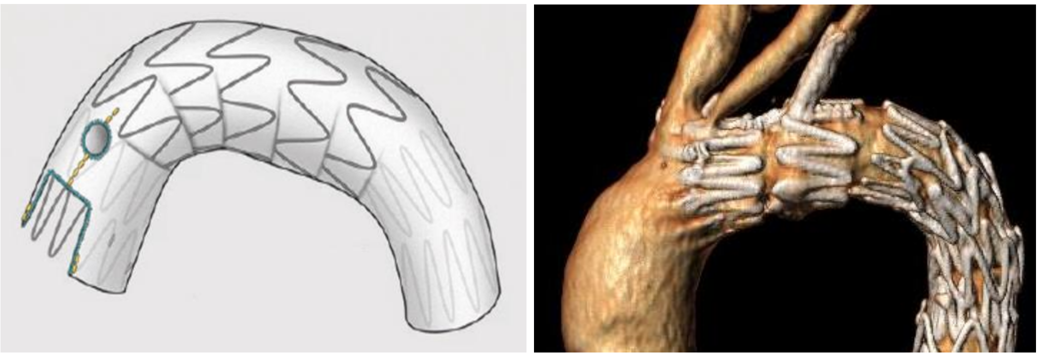


**Figure 18:** Left: Configuration of fenestrated and scalloped endograft by Cook Medical. . **Source: Endovascular Aortic Repair, Oderich Gustavo S, Springer, for Mayo Foundation for Medical Education and Research, 2017.** Right: Patient treated for PAU of the distal aortic arch with Cook Medical endograft with fenestration for LSA and wide proximal scallop for IA/LCCA. **Source: Vascular Surgery, University of Bologna, Italy**

In case of a fenestration for LCCA the scallop is allocated for IA and LSA is revascularized by means of a carotid-LSA bypass in standard fashion (Fig.19).

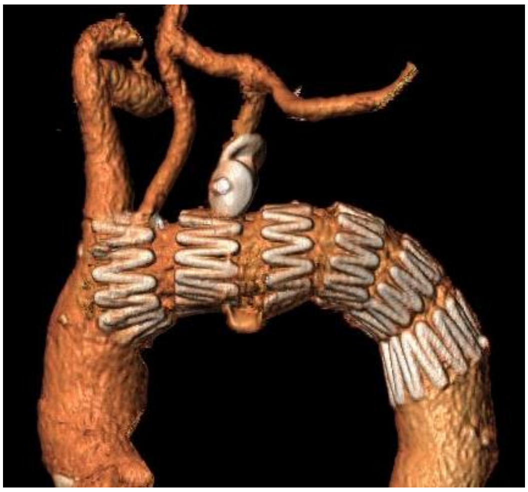


**Figure 19:** Patient treated for PAU of the distal aortic arch with Cook Medical endograft wide proximal scallop for IA and LCCA and coverage of LSA. LSA was proximal embolized with endovascular plug and revascularized by means of carotid subclavian bypass. . **Source: Vascular Surgery, University of Bologna, Italy**

Fenestrated and scallop endograft are used to treat distal arch pathologies or in case of proximal extension of healthy sealing zone in order to preserve LSA vascularization without mandatory surgical debranching step. The technology is directly originated from the use of FEVAR in the abdominal aorta for juxtarenal and pararenal aneurysms or type IV TAAAs, with wide experience with Cook Medical devices.[72]

Problems may arouse in case of anatomical difficulties: in fact the long sheathed delivery system does not permit precise adjustments. Therefore Fenestrated arch endografts typically come in longer delivery systems compared to standard thoracic endografts and are precurved to facilitate self-alignment of the endograft in the aortic arch during introduction and deployment. The principle of self-alignment is essential, with the possibility of only rotational manipulation to reduce the manipulation acts in the aortic arch.

Fenestrated endografts in the arch come generally with a precannulated fenestration that needs to be connected with a through-and-through wire technique.

This route aids the cannulation of the vessel and the advancing of the delivery system, increasing though manipulation maneuvers in the aortic arch.

At the same time deployment of the graft should be extremely precise in order to open fenestration in front of the dedicated vessel and to prevent unintended coverage of the target vessel.

Bridging stent-graft deployment is carried out in the similar fashion as FEVAR in the abdominal aorta and the usage of balloon expandable stent-graft with appropriate size and flaring is recommended.

Analyzing the result fenestrated TEVAR for aortic arch did not require always a debranching of the aortic arch and in a large experience reported by Tsilimparis et al[73] the need for SAT debranching was around 40%. In 33% of cases endograft was deployed with sealing zone in zone 0, due to scallop for in a context of distal arch disease. Technical success rate is pretty high (94%) due to misalignment of the endograft and loss of target vessel resulting in stroke and death. In the same cohort of patients, 30-day mortality rate was 20% for FEVAR patients compared to patients treated by branched endograft (0%) even without statistical significance.

Two main drawbacks of the fenestration technique are represented by the presence of large aneurysm when the distance between the fenestration and the target vessel is too long, and the aortic lesion where the healthy sealing zone is in zone 0.

In the first situation, bridging stents would be exposed to extreme mechanical stress therefore with amplification of the risk of stent-graft fracture or migration.

The latter situation, such as type A dissection or large aneurysm of the aortic arch, cannot effectively being treated with fenestrated endograft, because no space to reach healthy sealing zone in ascending aorta, exposing therefore to high risk of bird-beaking and type Ia endoleak, and the incapability to guarantee effective vascularization of SAT.[73, 74]

### 5.6 Branched Endograft of the Aortic Arch

In order to face the main drawback of fenestrated endograft as reported by Tsilimparis et al. [73] inner branched endograft technologies have been designed, with the largest experience made by Cook Medical since 2009.

The specific design of Cook Medical Arch Branched endograft was designed to cover the need for aneurysmal dissection [75] and the endograft is made with one or two proximal sealing stents together with barbs for active fixation in order to prevent distal migration. (Fig. 20)

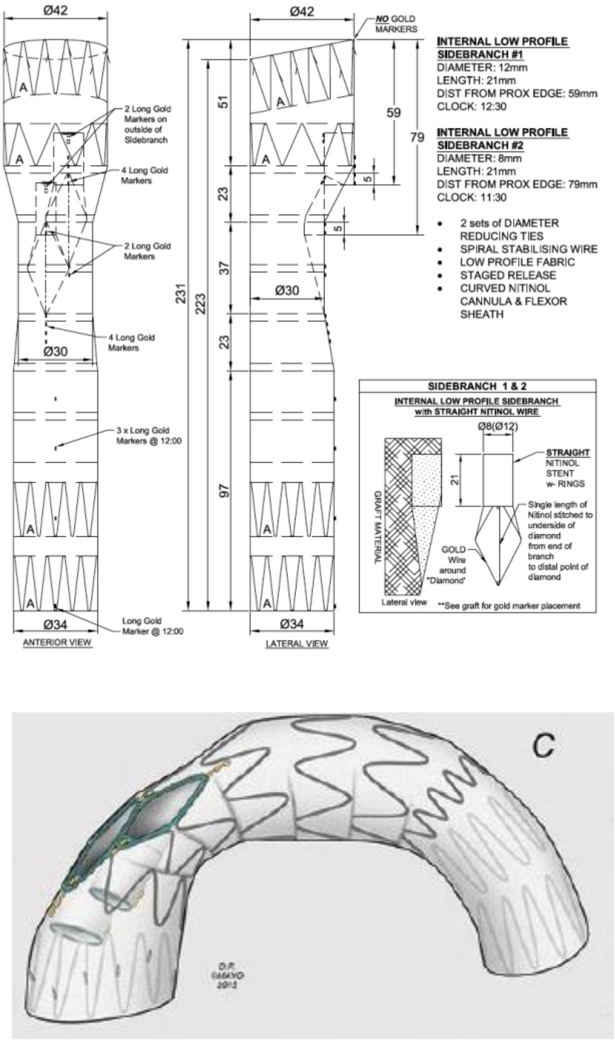


**Figure 20:** Upper: Schematic representation of pre-operative planned endograft with two-inner branched endograft. **Source: Cook Medical for Vascular Surgery, University of Bologna, Italy** Lowert: Drawing representation of deployed mainbody with one proximal stent and two diamond-shape side branches. **Source: Endovascular Aortic Repair, Oderich Gustavo S, Springer, for Mayo Foundation for Medical Education and Research, 2017.**

The diameter of the aorta should be lower than 38 mm with a healthy sealing zone of 40 mm from the sino-tubular junction to the origin of the IA.

The delivery system is a long delivery sheath ranging from 22 to 24 Fr, in order to avoid bird breaking and Ia endoleaks. At the same, time, in order to face the three dimensional angulation challenge of the aortic arch vessels and anatomy, the device comes along with a antialignment system where the diamond-shape tunnels for the SAT are automatically placed on the greater and outer curvature of the device. This tool permits to reduce to minimum the rotational movement and manipulation and only longitudinal adjustments  are required.

The procedure, [76–78] in brief is carried with a femoral artery cutdown access where the main body is placed. The delivery system may require a temporary or permanent conduit prosthetic bypass in order to smoothly deliver the endograft.

After that the main body is released over rapid ventricular pacing with drop of the systemic pressure and precise deployment in order not to cover coronary ostia.

From a surgical cutdown of RCCA (in order to place a dedicated limb component) and of LCCA in order to place a standard stent graft bridging stent, the endovascular procedure is accomplished.

The surgical cutdown of both common carotid arteries and their cross-clamping during the procedure is a valuable option in order to decrease embolization due to debris to the cerebral arteries or air embolization. Preventive measures should be take such as systemic heparinization higher than 300 Activated Clotting Time (ACT) and heparinized saline flushing of the graft with more than 120 cc (or flushed with CO2[79]).

In case of a double branch device the revascularization of LSA should be done in a previous step (in the same operation or in a different prior step) by means of a LCCA-LSA prosthetic bypass as described.

New technologies are arising with the usage of three-inner branch device in order to treat all SAT by means of endovascular repair in the aim to minimize risk of[80–82] access related complication during subclavian bypasses or transpositions.

In this case, after the deployment of two inner branched as described, the LSA is cannulated by a dedicated pre-cannulated route and a dedicated bridging stent is placed, conferring a retrograde vascularization. This retrograde-fashion revascularization route permits to have more space in the aortic arch and to reduce conflict with other stent-grafts directed to carotid arteries, to preserve the LSA for future aortic endovascular procedures and to have a direct route downwards DTA (Fig.21).

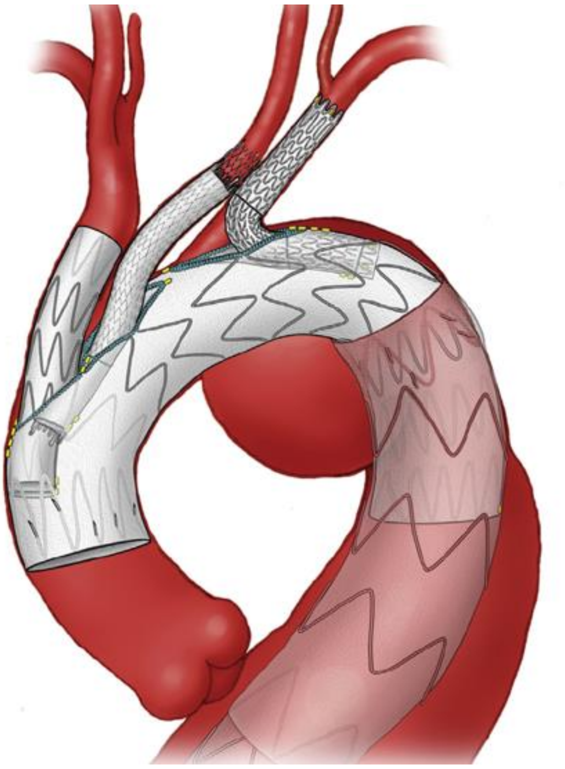


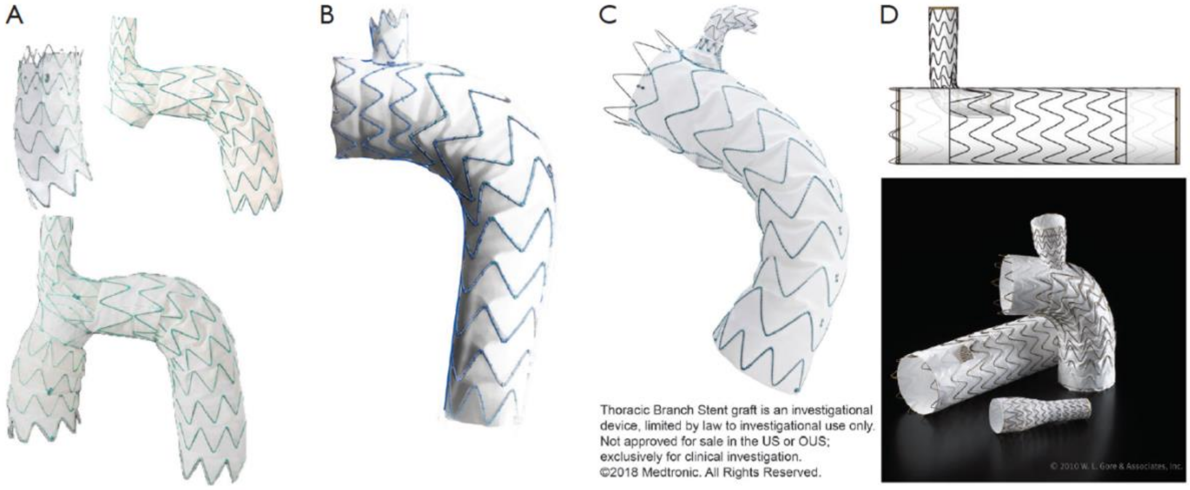
**Figure 21:** Drawing representation of three-inner branched endograft by Cook Medical. **Source: Mayo Foundation for Medical Education and Research.**

Large clinical experiences with Cook Arch Branched device were described in 2016 on 27 patients and in 2018 on 30 patients, respectively[76,77]. In both experiences the technical success was reached in 100% with no peri-operative mortality events.

The rate of 30-day mortality was ranging from 3.7% to 10%, while the cumulated stroke rate (transient and permanent) was between 3.3% and 11% and SCI between 0% and 7%. These results represent a still high percentage of major complications, but should be taken into great account the high risk nature of patients that would never been considered fit for open surgical repair.

At the same time, the usage of branched endograft after previous open aortic surgical repair of the ascending aorta showed satisfactory results with 0% of mortality, stroke and SCI rates at 30-days, suggesting that ascending aortic surgery may represent an ideal landing zone for branched devices in the aortic arch.[83]

Other branched devices are available on the market and some of them present a configuration one-branched(Fig.22)[84]. They can be mainly used for DTA aneurysms with landing zone extending into zone 2, in order to revascularize LSA: Mona LSA by Medtronic (Santa Rosa, CA) and Gore TBE (Flagstaff, AZ. In case of Zone 0 deployment these devices may be used in order to revascularize IA and then revascularization of the other branches is acquired via cervical debranching such as with Nexus stent graft for zone 0 from Endospan (Herzlia, Israel).



Thoracic Branch Stent graft is an investigational device, limited by law to investigational use only. Not approved for sale in the US or OUS; exclusively for clinical investigation.
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**Figure 22:** Single-branched endografts. (A) NexusTM Stent Graft System for zone 0 from Endospan (Herzlia, Israel), this endograft is customizable with an additional fenestration for the left common carotid artery. Image provided courtesy of Endospan; (B) CastorTM branched endograft from MicroPort Medical Co., Ltd. (Shanghai, China), customizable with two additional fenestrations. Image provided courtesy of MicroPort Medical; (C) thoracic branch stent graft from Medtronic Vascular (Santa Rosa, CA, USA). Image provided courtesy of Medtronic Vascular; (D) GORE® TAG® thoracic endoprosthesis with retrograde internal branch from W.L. Gore (Flagstaff, AZ, USA). Image provided courtesy of W.L. Gore & Associates, Inc. **Source: Status of Branched endovascular aortic arch repair (van Bake T et al.)**(84)

The other device available for landing in Zone 0 e directly revasculazing the IA and LCCA is Relay Branch thoracic stent graft system (Fig.23) (Terumo Aortic coming with two anterograde tunnels that give way to a large cannulation window.[85]

Supra-aortic branch grafts are deployed within the tunnels. The tunnels feature Lock Stents provide secure engagement with the stent apices of the branch grafts to prevent modular disconnection.

Generally LSA is revascularized during the same procedure by means of a carotid-subclavian bypass.

The main body of the device is inserted via surgical cutdown or percutaneous of the common femoral arteries. After having deployed the main body using rapid pacing, the aforementioned tunnels are cannulated via surgical cutdowns and the supra-aortic extensions are inserted. The first results show on 15 patients with outcomes including an in-hospital mortality rate of 6.7%, disabling stroke rate of 6.7%, and nondisabling stroke rate of in 13.3%.  Type I and III endoleaks occurred in 6.7%.

**Figure 23:** Right: The RelayBranch thoracic stent graft system (Terumo Aortic) **Source: Terumo Aortic.** Left: CTA final control after treatment with two-inner branched endograft by Terumo Aortic. **Source: Vascular Surgery, University of Bologna, Italy**

# 6. SCIENTIFIC BACKGROUND AND AIM OF THE STUDY

Endovascular aortic repair (EVAR) has emerged as the treatment of choice for patients deemed unsuitable for open surgery, particularly for pathologies affecting the thoracic, thoraco-abdominal aorta, and the aortic arch[86-89]. The efficacy of both fenestrated and branched endografts has demonstrated a preference for endovascular repair over open approaches for both reno-visceral target vessels[90-92] and supra-aortic vessels (SAV)[93].

During EVAR, the aortic arch and SAV may be implicated when stent graft coverage extends to zones 0, 1, and 2, which might encompass the brachio-cephalic trunk (BCT), left common carotid artery (LCCA), or left subclavian artery (LSA). In this domain, distinct aortic arch pathologies, such as aneurysms, penetrating aortic ulcers (PAU)[86,94], and Kommerell's diverticulum or lusoria right subclavian artery[95-97], along with acute aortic syndromes in non-A/non-B configurations[86.87,89,98,99] and thoraco-abdominal aortic aneurysms—both chronic[90] and post-dissection[100]—might necessitate engagement of at least one SAV for a secure repair.

International guidelines emphasize the significance of preserving the SAV, particularly underlining the revascularization of the LSA to mitigate the risk of stroke[86,89] and to maintain the spinal cord network[101-104], especially when extensive healthy aortic coverage could sacrifice multiple segmental arteries[105-107].

Presently, a variety of arch devices, both in fenestrated (f-TEVAR) and inner branched (b-TEVAR) configurations, are available. These necessitate bridging stents for connection from the graft to the supra-aortic vessel (TSV), boasting a technical success rate exceeding 90% and a reasonable mortality rate, as recently reported[93]. However, these devices might require a customization period, potentially limiting their use in urgent scenarios, in addition to having anatomical constraints[108].

For such cases, revascularization utilizing proximal chimney[109,110] or physician-modified, or in-situ laser fenestration grafts may be an option, but these carry inherent risks like proximal "gutter" endoleak, misalignment, and type I-III endoleak[98, 111-114]. Alternatively, surgical debranching of one or more SAVs can offer a more extended proximal landing zone for standard TEVAR device placement while ensuring vessel revascularization[93,115,116]. This procedure requires exposing a donor artery (typically LCCA or right common carotid artery) and a receiving artery (usually LSA or occasionally right subclavian artery)[116,117,118]. In select revascularization designs, reimplantation of the LCCA, left vertebral artery, or LSA may be executed. Following arterial exposure, an extra-anatomical bypass is performed, and the revascularized artery's proximal segment is either plugged or ligated. These operations can be conducted concurrently with the endovascular repair or in a separate session[117].

Konstantinou's dedicated study involving 201 patients[117] unveiled a high success rate for the hybrid approach but identified local complications like bleeding and reinterventions in 11% and 10% of instances, respectively. Concurrently, peripheral neurological complications were noted in up to 9.5% of cases, suggesting that staggered procedures might yield safer outcomes.

Another study juxtaposed with endovascular f-TEVAR[118] and highlighted a 29.4% local complication rate attributable to the surgical revascularization procedure, along with a 35.5% unplanned reintervention rate during follow-up associated with the thoracic stent-graft.

A recent meta-analysis[93] revealed that, even within the endovascular approach using aortic arch f/b-TEVAR devices, surgical debranching retains a significant role, primarily due to specific graft configurations. Of the 571 patients examined, 295 underwent surgical hybrid procedures, with the LCCA-LSA graft bypass being predominant[8] , thus highlighting the primarily importance of these procedures even in the newest available endovascular solutions.

This study's objective is to appraise the safety, durability, and patency of the hybrid approach for endovascular aortic repairs concerning the aortic arch, after 10 years of experience in a single center retrospective cohort. We aimed to determine the technical success rate, understand any complications (graft-related, access-related, neurological) stemming from debranching, and evaluate the surgical revascularization's relative patency as well as the outcomes of the hybrid aortic procedures in both short and mid-term intervals.

# 7. MATERIALS AND METHODS

The study has been designed as a single-center study. The involved center provided data collected on treatment of aortic patients required hybrid procedures with SAV debranching revascularization + endovascular repair. since January 2011 until September 2023.

This study provides a retrospective analysis, conducted from 2011 to October 2020 and a prospective analysis conducted form November 2020 up to September 2023, main focus of this PhD thesis research.

## 7.1 Patient's selection and inclusion criteria

In this study all consecutive patients who underwent hybrid procedure consisting in surgical debranching of at least one SAV + endovascular repair with endograft for acute/non acute aortic syndrome, chronic aortic aneurysm/post-dissection aortic aneurysm of the aortic arch and thoracic/thoracoabdominal aorta, failure of previous aortic treatments (both open or endovascular), were included.

A minimum number of 70 patients was considered to include to perform the study. With this cohort size, a significance level of 0,05 and a power of 90 % can be achieved, estimating a 15 % difference in the primary outcome.

### Inclusion criteria

- Age >18 years

- Patients submitted to surgical debranching of at least one of the SAV (right CCA, LCCA, right SA, LSA, reimplants of the above cited or vertebral arteries) associated with stent-graft placement Figure

- Aneurysm, penetrating aortic ulcer of the aortic arch
- Acute and chronic type B and nonA-nonB aortic dissections involving or requiring a proximal landing zone between 0-2 zones
- Acute and chronic type B and nonA-nonB penetrating aortic ulcers involving or requiring a proximal landing zone between 0-2 zones
- Acute and chronic type B and nonA-nonB intra-mural hematoma involving or requiring a proximal landing zone between 0-2 zones
- Degenerative aneurysm, penetrating aortic ulcer, post-dissection aneurysm of the thoracic aorta involving or requiring a proximal landing zone between 0-2 zones
- Post-dissection aneurysm, penetrating aortic ulcer, post-dissection aneurysm of the thoracic aorta involving or requiring a proximal landing zone between 0-2 zones
- Failure of previous aortic procedures (both endovascular or surgical) requiring a repair comparable to the previous listed above and involving or requiring a proximal landing zone between 0-2 zones
- Elective and urgent/emergent procedures

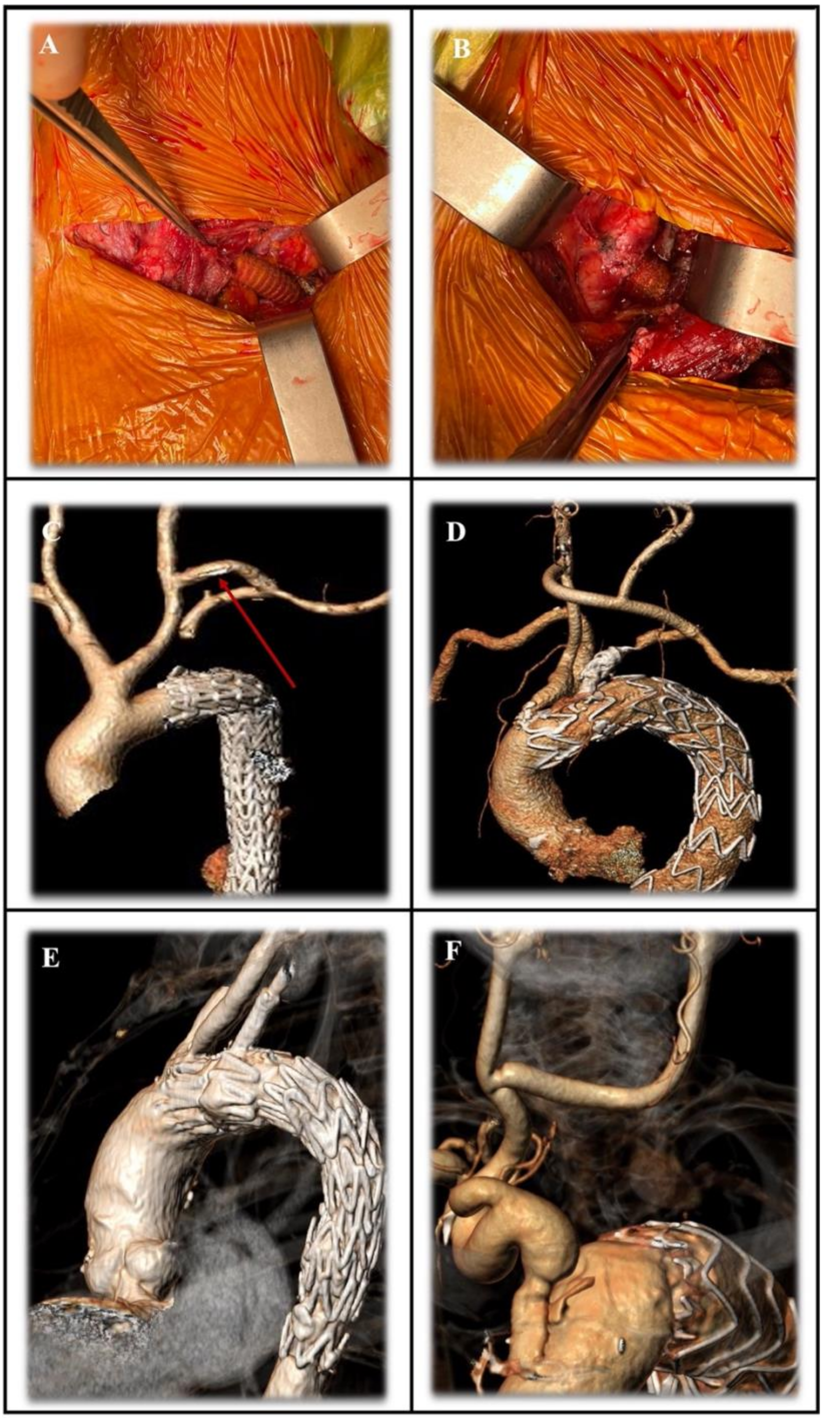
### Exclusion criteria

- Age < 18
- Patients treated with chimney/physician modified/in-situ/laser fenestrations for SAV revascularization
- Patients treated with open surgical repair of the aortic arch

## 7.2 Interventions:

### Surgical debranching of supra-aortic vessels (Figure 24):

- All patients receiving a surgical extra-anatomical bypass requiring exposing a donor artery (typically LCCA or right common carotid artery) and a receiving artery (usually LSA or occasionally right subclavian artery). In select revascularization designs, reimplantation of the LCCA, left vertebral artery, or LSA may be executed.

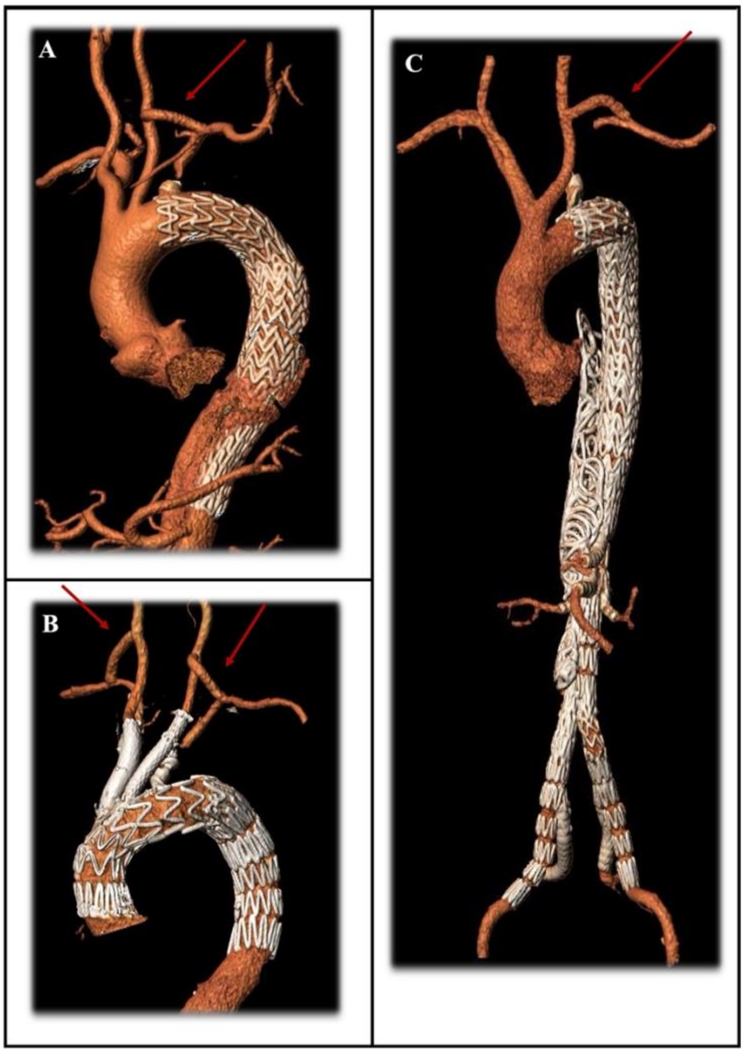


- **Figure 24:** Panel reporting type of supra-aortic-vessels revascularization: A) Dacron Silver 8 mm T-L anastomosis on left subclavian artery after antero-jugular tunnelization B) Dacron Silver 8 mm T-L anastomosis on left common carotid artery C) Complete left-common-carotid to left-subclavian bypass; D) Carotid-carotid-subclavian bypass (right-carotid to left subclavia artery with reimplant of left common carotid artery); E) Reimplant of left vertebral artery on the left common carotid artery; F) Reimplant of left common carotid artery on right common carotid artery. **Source: Vascular Surgery, University of Bologna, Italy.**
-

**Endovascular Procedures (Figure 25):**

- All patients receiving an fenestrated/branched thoracic endovascular aortic repair (TEVAR), a simple TEVAR, a TEVAR with distally a fenestrated branched EVAR.

- Thoracic endovascular aortic repair TEVAR (with simple tube graft)
- Fenestrated/branched TEVAR (f/b-TEVAR) with dedicated fenestrated either branched devices;
- f/b-EVAR procedures for the throaco-abdominal aorta
- All company devices and bridging stents will be included.



- **Figure 25:** Panel reporting type of endovascular procedure associated to supra-aortic-vessel revascularization (red arrows): A) left-common-carotid to left-subclavian artery bypass associated with simple tube TEVAR; B) Bilateral common carotid artery – subclavian artery bypasses associated to double inner branch arch custom-made-device endograft; C) left common-carotid-artery to left subclavian artery bypass associated to TEVAR and Fenestrated EVAR and double iliac branch device for post-dissection thoracoabdominal aortic aneurysm Crawford's type II- Figure B and C represent cases of advanced technologies repair. **Source: Vascular Surgery, University of Bologna, Italy.**

## Subgroups analysis:

All patients receiving an hybrid procedure combining a surgical debranching of SAV and an endovascular procedure.

- *Subgroup analysis 1: Hybrid procedure based on the presenting disease*

  - Hybrid repair of aortic arch disease

  - hybrid repair for thoracic/thoraco-abdominal disease with proximal landing zone in the aortic arch
- *Subgroup analysis 2: type of endovascular repair associated with debranching*
  - Debranching + Standard TEVAR procedure
  - Debranching + Advanced endovascular procedures

### 7.3 Endpoints of the study

**Primary endpoint:**

1) **Incidence of hybrid endovascular procedures:** Type of SAV revascularization, type of endovascular repair associated and aortic pathology, single/multiple stage procedures
2) **Technical success of the hybrid endovascular procedure:** technical success of the SAV debranching and the endovascular repair requiring SAV revascularization
3) **Debranching/hybrid procedures related complications:** MAEs related to SAV revascularization/hydrid endovascular procedure; neurological/access complications
4) **Overall reintervention:** overall number of reinterventions stratified for access, stent graft and debranching related reinterventions in the first 30-days.
5) **Freedom from SAV related events/patency:** over follow-up analysis.

**Secondary endpoint:**

1) **Sub-group analysis of primary endpoints:** comparing procedures for pathologies involving the aortic arch or with landing zone into the aortic arch; comparing procedures performed with simple TEVAR either with advanced endovascular procedures
2) **30 day mortality:** Aorta / Non-aorta related, procedure-related mortality.
3) **Major adverse events (MAE) at 30-days of the entire procedure – including:** Myocardial infarction; Respiratory failure requiring prolonged (>24 hours from anticipated) mechanical ventilation or reintubation; renal function decline resulting in >50% reduction in baseline eGFR or new-onset dialysis, Bowel ischemia requiring surgical resection or not resolving with medical therapy / Major stroke and Paraplegia (grade 3).
4) **Clinical success – hybrid procedure**:
    - Absence of death from the initial procedure, secondary intervention, or aorta-related cause;
    - Absence of persistent type I or type III endoleak;
    - Absence of failure due to device integrity issues;
    - Absence of graft infection or thrombosis
    - Absence of conversion to open surgical repair
    - Absence of permanent paraplegia, disabling stroke, or dialysis that resulted from the initial operation or a secondary intervention to treat the original aortic disease
5) **Follow-up Overall survival** (aortic related, procedure related and overall)
6) **Follow-up freedom from Re-interventions** (aortic related, procedure related and overall)

### 7.4 Data Collection

This study is a retrospective analysis of clinical outcomes of patients submitted both in elective and urgent/emergent setting to hybrid procedure, consisting in surgical debranching of at least one SAV + endovascular repair with endograft for acute/non acute aortic syndrome, chronic aortic aneurysm/post-dissection aortic aneurysm of the aortic arch and thoracic/thoracoabdominal aorta, failure of previous aortic treatments (both open or endovascular). Only retrospective data were be collected, including all patients operated between January 2013 and September 2023.

Data were collected from hospital medical records alone and uploaded in anonymized fashion to a data collection sheet. The data collection sheet has been developed and agreed between the research team. There were not performed additional interventions or actions related to the patients, meaning no additional burden to the hospital infrastructure except for data collection from hospital records.

The data collected included cardiovascular risk factors, diagnosis details (aneurysm location, status, extent and diameter), treatment details (graft used, surgery details, technical success), outcome details (treatment success, mortality, hospital complications, follow-up time, follow-up mortality, re-interventions and aneurysm diameter changes).

### 7.5 Ethics and IRB approval

All patients signed Patient Information and Informed Consent Form for the procedures.

EC approval of the clinical study has been received by the center IRB CE AVEC 108/2022/Oss /AOUBo.

This study was conducted in compliance with the latest version of the Declaration of Helsinki, laws and regulations of the country in which the study is conducted, including data protection laws, the Clinical Investigation Agreement and the Clinical Investigation Plan and accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[34]

The principles of the Declaration of Helsinki have all been implemented in this study by means of the patient informed consent process, EC approval, clinical trial registration, risk benefit assessment, publication policy, etc.

### 7.6 Statistics

The data were analyzed and processed using SPSS version 26.0 (IBM Corp, Armonk, NY) for Mac Os. We will perform descriptive statistics as well as comparative analysis using univariate tests, such as Chi2 (Fisher's exact test when appropriate) and student-t test (Mann-Whitney test when appropriate), and multivariate analysis using linear and logistic regressions, when appropriate adjusting for confounders. Time-to-event outcomes were analyzed using Kaplan-Meyer curves and Log-Rank test, and cox-regression analysis will be used for multivariate analysis.

# 8. RESULTS

## 8.1 Population included in the study

In the study inclusion period 68 patients received a treatment in the aortic arch.

The mean age was 71 years (IQR 7) and 43 (63%) were male patients.

Among the treated patients, 67 (98.5%) had at least 1 surgical debranching of the supra-aortic vessel.

The unique patient without debranching was treated with an inner triple custom-made device for all the SAV for a penetrating aortic ulcer of zone 2 (**Figure 26**).

**Figure 26:** Patient treated for PAU of the aortic arch with Cook Medical Three-Inner-Branch for IA, LCCA and LSA in latero-lateral (left) and antero-posterior (right) view. **Source: Vascular Surgery, University of Bologna, Italy.**

Therefore overall 67 patients were included in the study and met the inclusion criteria.

More specifically, 17 (25%) were treated in urgent /emergent setting and 50 (75%) were instead treated under elective conditions.

Demographics of patients are summarized in Table I.

**Table I: Preoperative risk factors of the included patients**

| **Risk Factors** | N | % |
|---|---|---|
| Male | 43 | 63 |
| Octogenarians | 20 | 30 |
| Hypertension | 68 | 100 |
| Tobacco use | 54 | 80 |
| Dyslipidemia | 44 | 65 |
| Diabetes | 18 | 26 |
| BMI > 31 | 5 | 7 |
| Chronic renal impairment | 28 | 41 |
| Hemodialysis | 1 | 2 |
| Coronary artery disease | 20 | 30 |
| Chronic obstructive pulmonary disease | 28 | 41 |
| Peripheral artery occlusive disease | 8 | 13 |
| Cerebrovascular disease | 15 | 22 |
| Atrial fibrillation | 6 | 9 |
| Anticoagulant medication | 7 | 11 |
| Previous Aortic Surgery | 27 | 39 |
| ASA score IV | 41 | 61 |
|  | Median | IQR |
| Age (years) | 71 | 7 |

BMI: Body mass index; ASA: American Society of Anesthesiology score; IQR: interquartile range

Going to analyze the temporal distribution of this cohort, an early and late experience were divided in 8 (12%) and 59 (88%) patients, respectively.

Early experience was from 2011 to 2015 with the use of mobile C-arm; late experience was from 2016 to 2023 with the use of Hybrid Room facilities.

In details, late experience was subdivided into a retrospective collection from January 2026 to October 2020 was composed by 24 patients (36%) and 25 (52%) from November 2020 to September 2023, representing a prospective collection during the PhD study period

### 8.2 Anatomical subgroups

From an anatomical point of view landing zone in the aortic arch was reached in zones 0, zone 1 and zone 2 in 4 (6%), 24 (36%) and 39 (58%) of cases, respectively.

In details,  17 (25%) patients were treated for pathologies of the aortic arch and 50 (75%) were treated for pathologies of the thoracic and thoracoabdominal aorta requiring a proximal landing zone in the aortic arch. (Table II).

In the first anatomical subgroup of patients, penetrating aortic ulcer was the leading disease up to 10 (15%) of cases; in the second subgroup, type-B aortic dissection or intramural hematoma was the highest reason for repair in 15 (22%) of cases.

**Table II: Type of aortic diseases included in the study.**

| **Type of Aortic Disease** | N | % |
|---|---|---|
| Arch Degenerative Aneurysm | 3 | 4 |
| Arch Penetrating Aortic Ulcer | 10 | 15 |
| Type non-A/non-B dissection | 3 | 4 |
| Supra-Aortic-Vessel Aneurysm | 1 | 2 |
| Descending Thoracic Aortic Aneurysm | 8 | 12 |
| Thoraco-Abdominal Aortic Aneurysm | 11 | 16 |
| Descending Thoracic Aorta PAU | 7 | 10 |
| Type-B Aortic Dissection/IMH | 15 | 22 |
| Post-Dissection TAAA | 2 | 3 |
| Proximal TEVAR failure | 7 | 12 |
| Overall | 67 | 100 |

In red cases representing the anatomical subgroup of pathologies of the aortic arch; in black cases representing the anatomical subgroup of pathologies requiring a proximal landing zone into the aortic arch.

PAU: Penetrating aortic Ulcer; IMH: Intramural Hematoma; TAAA: Thoracoabdominal aortic aneurysm; TEVAR: Thoracic endovascular aortic repair.

Among the patients that were treated under urgent setting, 2 (12%) were type non-A/non-B dissection in the aortic arch group and 15 (88%) were in the proximal sealing in the arch group, respectively.

### 8.3 Procedural subgroups

Analyzing the procedures, out of the 67 patients, 45 (67%) received a supra-aortic debranching followed by a simple tube TEVAR device.

Among the remaining advanced procedures (Table III), 7 cases were custom made devices for the aortic arch lesions.

Overall, 71 SAV bypasses were performed, with 4 bilateral carotid-carotid subclavian bypasses.

As reported in Table III the most common reconstruction was left-common-carotid to left subclavian artery bypass, performed in 48 cases (67%).

Wo cases of direct reimplant ( 1 left common carotid artery and one left vertebral artery directly emergent from the aortic arch) were performed.

**Table III: Type of endovascular repair and type of supra-aortic-vessels revascularization in the study**

| **Procedural subgroups** | **Zone 0 N** | **Zone 1 N** | **Zone 2 N** | **Overall N (%)** |
|---|---|---|---|---|
| **Debranching + Advanced procedures** | **4** | **9** | **9** | **22 (33%)** |
| Debranching + Arch CMD devices | 4 | 3 | 0 | 7 |
| Debranching + TEVAR + F/B-EVAR | 0 | 6 | 9 | 15 |
| **Debranching + simple TEVAR** | **0** | **15** | **30** | **45 (67%)** |
| **Overall patients** | | | | **67 (100)** |
| **Type of arterial reconstructions** | Zone 0 N | Zone 1 N | Zone 2 N | Overall bypass N(%) |
| CS bypass | 2 | 6 (bovine arch) | 36 | 48 (67) |
| CCS bypass | 0 | 16 | 1 | 18 (23) |
| Right CS bypass | 2(2 bilat CS) | 0 | 2 (2 bilat CS) | 6 (7) |
| Direct arterial reimplant | 0 | 2 | 0 | 3 (3) |
| **Overall reconstructions** | **6** | **24** | **41** | **71 (100)** |

All procedures were performed under general anesthesia. During the procedures spinal cord ischemia prevention protocols were applied[104]. In details, in 24 (36%) of cases a spinal fluid drainage was positioned: one case for a CMD device in the aortic arch, the remaining for procedure involving the thoracic (55%) and thoraco-abdominal (4%) aorta.

Rapid ventricular pacing was used overall in 40 (60%) of cases: 4 (10%) cases for deployment of CMD devices in proximal landing zone; 17 (43%) for deployment in zone 1 and 19 (48%) for deployment in zone 2.

In details, arch devices required rapid pacing in 7 out of 7 CMD procedures; debranching + simple TEVAR was the procedure with the highest number of need for reduced cardiac output in 25 (62%) of events.

### 8.4 Primary Endpoints at 30 days.

Technical success of the hybrid procedure was reached in 63 (94%) of patients, and data for success, debranching related complications and overall reinterventions are reported in Table IV.

**Table IV: Early Primary endpoints of the study.**

| **Early Primary Results** | N | % |
|---|---|---|
| **Technical Success Hybrid Procedure** | **63** | **94** |
| SAV debranching Technical Success | 66 | 98 |
| Stent-graft Technical Auccess | 64 | 96 |
| **Debranching related complications** | **11** | **16** |
| Requiring reinterventions | 7 | 10 |
| Neurological | 4 | 6 |
| Bleeding | 6 | 9 |
| **Overall re-interventions** | 15 | 27 |
| Overall | 67 | 100 |

One reported case of technical failure was related to the debranching procedure, with the presence of dissection of the right common carotid artery at the level of the first anastomosis for a carotid-carotid-subclavian bypass, treated with stenting after the 8 days (**Figure 27**). The other remaining reintervention was for an intraoperative mortality during the F/B-EVAR procedure and two cases of proximal 1A endoleaks.

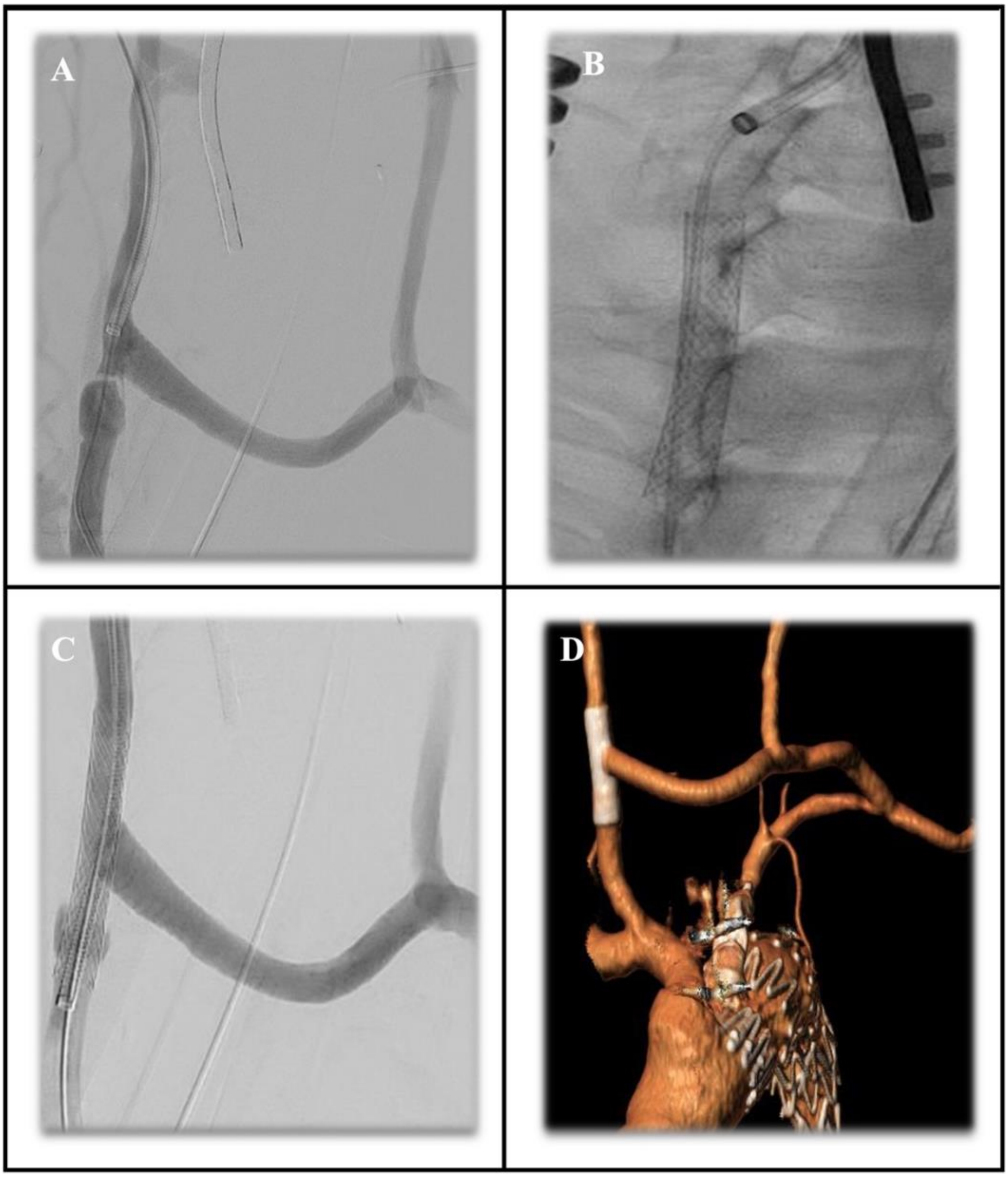


**Figure 27:** Patient with early supra-aortic-vessel debranching complication: A) dissection at the level of the proximal anastomosis on the right common carotid artery over a carotid-carotid-subclavian bypass; B) placement of Wallstent 9x40mm; C) Control angiography and D) Post-operative computed tomography angiography showing patency of the bypass e complete resolution of the symptomatic dissection.

Overall, debranching related complications were 11 (16%) and beside the already reported dissection of right common carotid artery other 6 required reinterventions due to bleeding at the level of the surgical access.

## 8.5 Secondary Endpoints at 30 days.

Secondary endpoints are reported in Table V. In details 7 (10%) patients died within the first 30-day period. Among them 6 were patients reated during urgent procedure, and 1 out of 50 elective patients (2%) died within first 30-days.

Clinical success was determined by the 7 cases of 30-day death and two cases of cerebral hemorrhage with clinical impairment, one case of paraparesis, one case with renal artery loss resulting in permanent dialysis and two cases of persistent endoleak, 1 with type III and type I, respectively.

Among the 15 (22%) overall reported reinterventions, as stated 7 were for SAV revascularization issues.

The remaining 8 cases were femoral access complications in 6, one case of endoleak from target visceral vessels of a thoraco-abdominal repair and a proximal 1A endoleak of a TEVAR (already reported as cause for technical failure).

**Table V: Secondary Endpoints at 30 days**

| Early Secondary Results | N | % |
|---|---|---|
| **Mortality** | **7** | **10** |
| **Major Adverse Events** | 24 | 35 |
| Major stroke | 0 | 0 |
| Pulmonary | 8 | 12 |
| Cardiac | 7 | 10 |
| Renal | 3 | 4 |
| Dyalisis | 2 | 3 |
| Spinal Cord ischemia | 8 | 12 |
| Permanent Paraplegia | 4 | 6 |
| Bowel ischemia | 1 | 1 |
| **Clinical Success** | 54 | 80 |
| Overall | 67 | 100 |

Subgroups analysis (Table VI) was performed comparing primary and secondary early endpoints comparing patients treated for pathologies of the aortic arch (Arch diseases) VS patients with sealing n the aortic arch (Arch sealing) and comparing patient undergoing a SAV debranching + simple tube TEVAR procedure (Simple

TEVAR) VS patients undergoing SAV debranching + advanced endovascular procedure (Advanced procedure).

No statistical significance was found comparing the anatomical subgroups of patients; comparing the procedural subgroups, patients with advanced endovascular procedure reported to have a tendency for higher rate of reinterventions (p:.050) and a lower overall clinical success (p:0.019).

**Table VI: Subgroup analysis of primary and secondary outcomes.**

| **Early Results** | **Overall** (%) | **Arch Diseases** (%) | **Arch Sealing** (%) | **P value Arch disease VS Arch Sealing** | **Simple TEVAR** (%) | **Advanced procedure** (%) | **P value Simple TEVAR VS AdvancedProcedure** |
|---|---|---|---|---|---|---|---|
| Technical Success | 94 | 94 | 94 | . 753 | 96 | 91 | .389 |
| Debranching Complications | 16 | 6 | 20 | .165 | 17 | 13 | .480 |
| Debranching Reinterventions | 10 | 14 | 0 | .111 | 9 | 13 | .417 |
| Mortality | 10 | 6 | 12 | .425 | 7 | 18 | .153 |
| MAEs | 35 | 36 | 35 | .600 | 31 | 46 | .189 |
| Reinterventions | 22 | 26 | 12 | .192 | 15 | 36 | .050 |
| Clinical Success | 80 | 78 | 88 | .296 | 89 | 63 | .019 |
| Overall N (%) | 67 (100) | 17 (25) | 50 (75) | | 45 (67) | 22 (33) | |

MAE: Major adverse events, N: Numbers. P value significance is lower or equal 0.050 and statistical value is performed using Pearson's Chi-square test.

### 8.6 Follow-up primary and secondary endpoints

The median follow-up was 12 months (interquartile range 2-37). In this period the cumulative follow-up mortality was 13 (22%) cases and no aortic related mortalities were observed.

The SAV debranching assisted patency was 100% without occlusion events.
During the follow-up 3 events were reported: after the reported reintervention after 8 days, one case of symptomatic with amaurosis fugax thrombotic apposition at the level of LCCA ostium was found 6 months after CMD device with proximal scallop for LCCA and BCT and left carotid-subclavian bypass. The case was solved by stent-graft deployment at the ostium of the vessel (**Figure 28**).

Finally, an asymptomatic stenosis of carotid-carotid-subclavian bypass was found after 24 months and is currently under double antiplatelet therapy in close follow-up. Freedom from SAV related events at 12 and 36 months was 97% and 94%, respectively. No occlusion were registered and thank to those two SAV related reinterventions the follow-up assisted patency is 100%.

Secondary endpoints were overall survival and overall freedom from reinterventions, that were calculated at 12 and 36 months, being 75% and 85% and 66% and 73%, respectively.

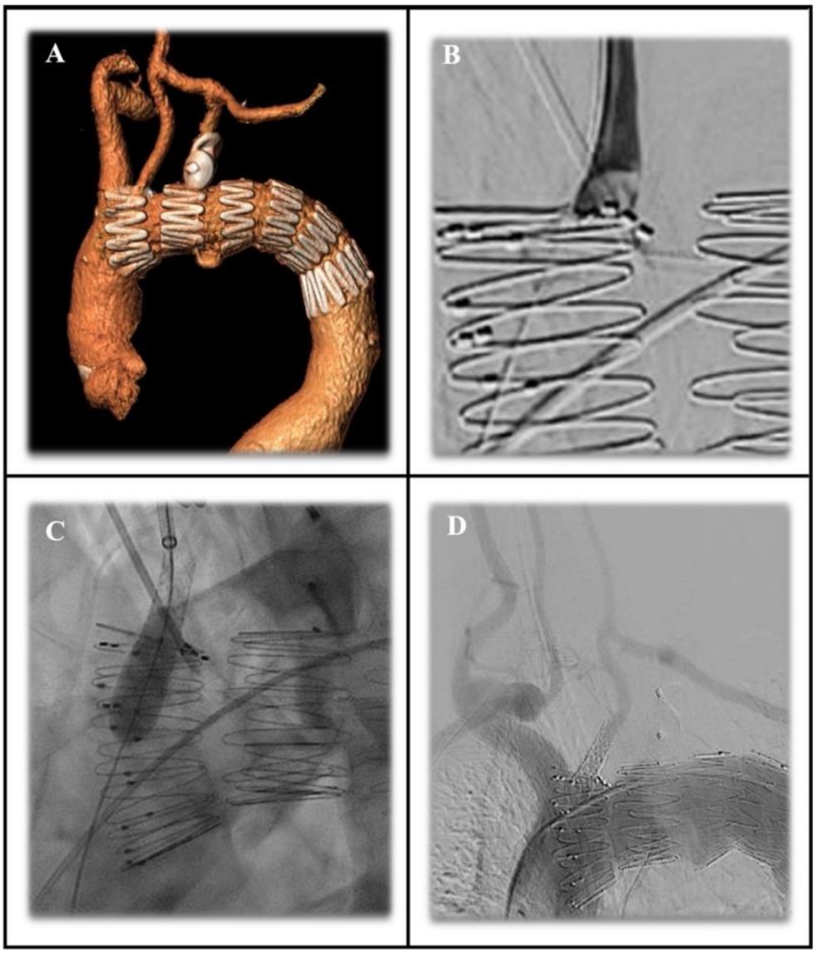


**Figure 28:** Patient with 6-months supra-aortic-vessel debranching complication: A) custom-made device with proximal scallop for left common carotid artery and brachio cephalic trunk with performed carotid-subclavian bypass and proximal plug of left subclavian artery; B) six months angiographic control showing thrombotis apposition at the ostium of the left common carotid artery; C) placement of balloon-expandable Advanta 7x22 and Advanta 7x32; D) Final angiography showing resolution of the defect and patency of the bypass.

## 9. DISCUSSION

Endovascular aortic repair (EVAR) has revolutionized the treatment landscape for aortic pathologies, particularly in cases where open surgery is considered high-risk or not feasible[86].

This study focuses on a hybrid approach, combining surgical debranching of supra-aortic vessels (SAV) with endovascular graft placement, and assesses its feasibility, technical success, clinical outcomes, and long-term patency. In this discussion, we delve into the key aspects of the results, highlighting both the strengths and areas for further improvement.

The treatment of aortic arch aneurysms still represents an important challenge in the surgical field with important drawbacks concerning open surgical repair with the need of aortic cross-clamping, mild to moderate hypothermia and the need for extra-corporal circulation and cardio-pulmonary bypass, with technical demanding skills. At the present time, open surgical repair for aortic arch pathologies still remains the gold standard of care in patient considered fit for open surgery whereas the risk of mortality is still remarkable from 2 to 20% as well as the risk of stroke up to 10-15% of cases.[120,121]

That is the reason why even in the latest guidelines of Vascular Surgery and Cardio-Thoracic Surgery  the endovascular treatment has been proposed has been proposed as a viable option for patient unfit for open surgical repair with reasonable life expectancy and favorable anatomy.[86] The advantages of endovascular repair in this subset of patient is to minimize surgical trauma, avoid cardiac arrest and cardiopulmonary bypass and therefore reducing the risk of major adverse event in an already sicker population.

At the same time, the extension of thoraco-abdominal aortic aneurysm into the aortic arch is fairly common and that may require to use some adjunctive procedures besides fenestrated and branched procedures for visceral vessels, such as the placement of one or more thoracic endograft and cervical debranching of at least one supra-aortic vessel or the usage of a fenestrated/branched endograft in order to treat the proximal landing zone.[100, 122]

*Procedural findings and perioperative significant factors*

In this study the most commonly performed supra-aortic trunk revascularization is the left-common-carotid to left-subclavian artery bypass, performed up to 72%, similar to 78% reported by Konstantinou et al.[117] or Tsilimparis et al.[123]

The study underscores the feasibility of the endovascular hybrid repair approach for aortic arch pathologies. This is particularly significant given the complexities associated with the aortic arch and its proximity to SAV. The high technical success rate of 94% is a testament to the proficiency of the surgical and interventional teams involved in this approach. It demonstrates that, despite challenges, the procedure can be executed effectively and safely.

At the same time, as reported by the study of 201 patients by Konstantinou[117] with 11.4% of bleeding and 9.5% of neurological associated complications and by Voigt[124] over 112 patients, with 29% of carotid-subclavian bypass associated complications, these procedures are still demanding both for the surgeons and for the patient.

In our report, slightly in favor when compared to literature, we report an overall 16% of debranching related complication, with a smaller amount of nerve-palsy but still the presence of 9% of bleeding requiring reintervention.

In our study we have reported all procedures and following a similar distribution to the review performed by Andrasi et al.[116] we have divided the procedures on the basis of anatomical perspective, with a smaller cohort of patients with specific arch pathologies, whereas the widest cohort was determined by patients with thoracic and thoracoabdominal aortic diseases with proximal landing zone in the aortic arch. In the last cited review, the mortality was significantly increased when a more proximal landing zone is reached.

This is not supported by a more recent systematic review and metanalysis by this group[93] with no substantial difference in terms of clinical results comparing zone 0 and overall arch results.

In our cohort of patients presented in this study with SAV debranching, , no differences in terms of primary and secondary endpoints were reported in the anatomical subgroup analysis.

Similar to what was performed by Konstantinou[117] and Bellamkonda[125] we stratified our results even in subgroups of patients according with procedures.

In the first cited study they subdivided cases if they were treated in one single procedure (SAV debranching + TEVAR) or in staged procedures, finding this latter procedure associated with significant higher mortality up to 9.5%.

In our cohort was impossible to make such a comparison since we have performed all SAV debranching procedure with at least the positioning of one endovascular stent-graft in the same access to the operating room.

In the study performed by Bellmkonda [125] over 300 patients with SAV debranching, the authors report cases with simple TEVAR, and then associated mortality with one bypass (6.8%) or two bypass (22.6%).

In our results we performed a subgroup analysis based on the complexity of the endovascular procedure associated with SAV-debranching if a simple TEVAR either a fenestrated or branched TEVAR or EVAR was performed.

In our findings, no differences are present in terms of mortality (overall 10%, considering 2% in elective conditions) while more advanced procedures were associated to trend in more frequent reinterventions and a lower level clinical success, speculatively associated to more complex and extensive aortic procedures.

The relatively low incidence of disabling stroke (0%) is also a positive outcome, demonstrating that the procedure can be performed with minimal neurological complications.

A noteworthy finding is that the primary endpoints of the study do not appear to be significantly affected by the type of repair or the localization of the aortic disease. This suggests that the endovascular hybrid repair approach is adaptable and can yield consistent outcomes across a diverse range of clinical scenarios. It reinforces the versatility of the technique as a viable option for high-risk patients with various aortic pathologies.

### *Follow-up significant factors*

The long-term patency of SAV debranching is a critical consideration in assessing the durability of the hybrid approach[86,93]. The study reports excellent SAV patency rates with no occlusion events. This is a positive indication that the debranching procedures effectively maintain blood flow to the supra-aortic vessels over time. This finding is reported by vast majority of literature with preference of prosthetic materials over the vein graft over nearly two times fold[126].

In similar studies on SAV patency, Voigt[124] reports 95% long-term patency and Konstantinou[117] 98% at one year, confirmed by Spath et al even in the field of CMD devices in the aortic arch[93].

This relevant aspect is sustained by assisted patency thanks for accurate follow-up and prompt reintervention that was performed in two cases and with one case under pharmacology therapy.

### *Reinterventions and Access-Related Complications*

One area that warrants attention is the rate of early reinterventions. The study notes a 10% reintervention rate, primarily attributed to access-related complications.

A similar rate is found in related studies[93,116, 117, 124,125] and still represent an important issue regarding vessel handling and surgical exposure. Access-related issues during debranching can pose challenges and drive up to 30% of nerve injuries[124], and strategies to minimize such complications should be explored further. At the same time, access related complications are associated with the use of large bore sheath from femoral and iliac access, and these aspects are more related to the type of the aortic complex procedure, as extensively reported especially for hostile accesses.[127]

*Limitations*

The study presents several noteworthy limitations that deserve consideration. Firstly, the combined retrospective and prospective analysis, while advantageous in capturing data over an extended period, introduces inherent limitations related to data quality, completeness, and potential selection biases. Moreover, the relatively small patient cohort, especially when subgroup analyses are contemplated, raises concerns about the potential for statistical type-B errors.

This limitation underscores the need for larger-scale studies to validate the findings robustly.

Furthermore, the study encompasses a heterogeneous patient population, encompassing a variety of aortic diseases and clinical presentations, which can introduce variability in outcomes. The inclusion of both elective and urgent cases further adds complexity to the cohort, as the urgency of intervention may impact procedural outcomes. At the same time, extensive subgroup analysis would have underlined granularity of results, without precise findings.

Another notable limitation is the absence of an evaluation of the surgeon's "learning curve" and the potential influence of evolving devices and materials over the study period, since the study reported the entire experience of the center that has evolved over more than one decades, with a significant increase in numbers and complexity within the last two-quartiles of the study period.

Addressing these limitations in future research endeavors will contribute to a more comprehensive understanding of this complex surgical approach.

## 10. CONCLUSIONS

This comprehensive retrospective and prospective study, encompassing a decade of experience in aortic repair at a single center, underscores the safety and effectiveness of the hybrid approach involving surgical debranching of supra-aortic vessels and endovascular graft placement.

This experiences high technical success rate, acceptable mortality rate especially for elective cases, and excellent SAV patency rates, underscoring the potential of this technique especially when approaching complex aortic arch pathologies in high-risk patients. However, the study also highlights the need for continued efforts to minimize early reinterventions, particularly associated to access-related complications. Long-term follow-up will be essential to validate the durability of this procedures and ensure its sustained success in managing complex aortic diseases.

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