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Review

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Optimization of the proximal sealing in thoracic endovascular aortic repair (TEVAR)

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Abstract

Thoracic endovascular aortic repair (TEVAR) today represents the first option for the treatment of most pathologies involving the descending thoracic aorta. Proximal endograft failure, which includes endograft migration or type IA endoleak, represents the most frequent complication during the mid-term and long-term period. Proximal sealing length is the single most important factor affecting the technical success and durability of TEVAR. Other factors related to aortic arch anatomy, fluid dynamics, type of endograft, or type of pathology, may influence the risk of proximal endograft failure, and should be considered during the endovascular planning of the proximal sealing length. This review summarizes the evidence on the factors affecting the risk of proximal endograft failure, and provides the rationale for the choice of the proximal sealing length during TEVAR, based on specific patients' characteristics.

Keywords: Thoracic aortic aneurism, thoracic endovascular aortic repair, aortic dissection, endoleak, sealing zone, aortic arch, thoracic aorta

INTRODUCTION

Thoracic endovascular aortic repair (TEVAR) today represents the first option for the treatment of most pathologies involving the descending thoracic aorta. Compared to open thoracic aortic repair, TEVAR

provides low invasiveness, a low rate of perioperative complications, and satisfactory early and mid-term results, and is accepted as a first-line option for the treatment of descending thoracic aneurysms, acute aortic syndromes, and aortic traumatic injuries, in the presence of a suitable anatomy[1,2]. One of the main drawbacks of the endovascular treatment is that approximately 10%-20% of patients receiving TEVAR may still require a reintervention during the long-term follow-up, mainly related to proximal endograft failure leading to a type Ia endoleak[3,4].

Both the technical success and the long-term durability of TEVAR may depend on a proper selection of an adequate proximal sealing zone. The instructions for the use of currently available thoracic endografts recommend a proximal sealing length (PSL) of at least 2 cm. However, this may be controversial, as there are many clinical, anatomical, hemodynamic, pathological, and procedural factors that may interact and should be considered during the choice of the proximal sealing zone. This narrative review aims to summarize the current knowledge on the factors that may influence the decision-making of the proximal sealing length during the endovascular planning of TEVAR, in order to optimize the clinical outcomes after thoracic endografting. In literature, aorta-related mortality after TEVAR varies upon the treated pathology, specifically, 9.7% in blunt aortic trauma, 5.57% in elective aneurysm repair, 19% in ruptured aneurysm repair, 2.6%-9.8% in acute type B aortic dissection, and 4.2% in chronic type B aortic dissection[2].

ANATOMICAL AND HEMODYNAMIC FEATURES

Classification of proximal landing zones

The aortic landing zones used during endovascular repair are classically described by Ishimaru's anatomical classification. This divides the aorta into consecutive segments primarily in relation to the emergence of aortic side branches. Zone 0 includes the ascending aorta to the innominate artery (IA), zone 1 from the IA to the left common carotid artery (LCC), zone 2 from LCC to the left subclavian artery (LSA), zone 3 goes from the origin of LSA to the proximal thoracic descending aorta (2 cm), zone 4 from 2 cm below the LSA to the mid portion of the descending thoracic aorta (usually identified by the level of the 6th thoracic vertebrae), and zone 5 from the mid-thoracic aorta to the origin of the celiac artery [Figure 1]. The need to reach a 2 cm-long proximal sealing may often require landing in the aortic arch (zones 0-3)[5]. In recent years, the endovascular approach has become more aggressive, and extension in the arch (after a surgical supra-aortic vessels debranching) enables the expansion of the indication for thoracic endovascular repair to patients with an unsuitable proximal landing zone below the LSA[6].

Classification of the aortic arch anatomy

The aortic arch is characterized by a complex curved anatomy and tortuosity along the three spatial planes. The direct geometrical consequence is that the length of endograft-to-wall apposition, which reflects the actual ability of sealing, is usually shorter along the inner curvature of the arch compared to the outer curvature[7] but it can also be anterior, posterior or cranial, depending on the tilt of the endograft[8]. An excessive aortic curvature may be responsible for the so-called bird beak configuration, which occurs when the endograft does not adapt to the inner curve of the aorta and leads towards the outer curve, leaving a triangular-shaped gap between the stent-graft and the aortic wall [Figure 2], that is associated with type Ia endoleaks[9]. Also, aortic curvature is associated with inaccurate deployment at the intended landing zone, incomplete endograft apposition to the aortic wall, and wedge apposition[10-12].

Aortic arch anatomy can be classified into three types based on its angulation and the take-off distribution of the supra-aortic trunks (SAT) [Figure 3]. Type I aortic arch is characterized by the three SATs originating in the same horizontal plane as the outer curvature of the arch. In type II aortic arch, the IA originates between the horizontal planes of the outer and inner. In type III aortic arch, the IA originates below the

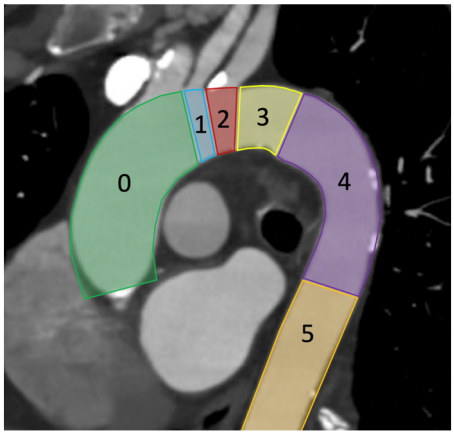

Figure 1. Multiplanar reconstruction (MPR) of a computed tomography angiography (CTA) scan of the aortic arch showing the landing zones according to Ishimaru's classification.

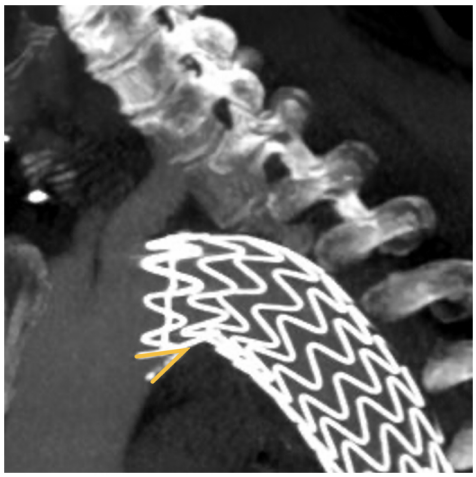

Figure 2. Post-procedural CTA scan after TEVAR highlighting the endograft malapposition at the level of the inner curve of the arch determining the presence of "bird beak".

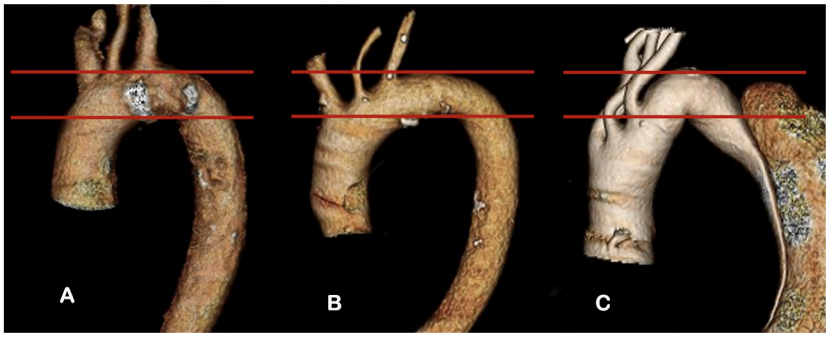

Figure 3. Aortic arch type I (A), type II (B), and Type III (C) based on the aortic arch curvature and the take-off distribution of the supra-aortic trunks.

horizontal plane of the inner curvature of the aortic arch[13]. The arch types have different distributions among patients with different aortic pathologies. Type II and type III aortic arches are associated with

greater angulation and may be associated with a higher incidence of endograft malapposition.

Recently, it has been proposed an integrated classification combining Ishimaru's zone with the aortic arch type, and defining the Modified Arch Landing Areas Nomenclature (MALAN)[14]. The rationale is that aortic arch landing zones 0, 1, 2 and 3 are located in a curved portion of the aorta, with different grades of curvature. Each proximal landing zone (PLZ) has a different grade of curvature; for example, zone 0 is generally the straightest segment of the arch if compared to zones 2 and 3, and therefore, zone 0 TEVAR has a lower probability of presenting malapposition. According to MALAN classification, landing zones 2/III and 3/III identify hostile PLZ for TEVAR because of their angulated anatomy, and are associated with a poor outcome, resulting in a higher incidence of type Ia endoleak, endograft migration and retrograde dissection[15].

The arch curvature and angle seem to be predictors of stent graft migration, requiring reintervention[16]. The severity of aortic curvature is also directly related to the tortuosity index of the aorta, which has been addressed as an independent risk factor for endograft malapposition[17] and the presence of post-operative bird-beak[18,19] [Figure 4]. These factors may give us an estimated risk of failure of the endograft, but they do not represent strict exclusion criteria. To the best of our knowledge, the only strict exclusion criteria is the aortic diameter since the largest endograft available on the market is 46 mm.

Hemodynamic features

The aortic arch is the most mobile and flexible segment of the aorta, with continuous movements depending on the cardiac cycle and blood pressure. Stress zones are evident, and this can be a determining factor for its endovascular treatment, both during endograft deployment (being responsible for inaccurate positioning, or the windsock effect) and during the long-term follow-up (contributing to endograft migration, misplacement, and consequent endoleaks).

Aortic arch anatomical configuration plays a direct role in the determination of the displacement forces that act on thoracic endografts, particularly when the treatment involves a proximal landing zone in zones 0, 1 or 2. In such cases, morphological issues and subsequent considerations about hemodynamic drag forces become crucial.

The stent graft is constantly exposed to drag forces determined by the cardiac output and this is an essential key to figure out in the understanding of TEVAR pitfalls. The correct sealing in the PLZ with complete apposition of the stent graft to the aortic wall is inescapable to gain the long-term efficacy of TEVAR. Stent graft changes over time together with the aorta and therefore the PLZ.

The displacement forces act in a vectorial way and are orthogonal to the outer curvature of the aortic arch and therefore to the greater curvature of the endograft, leading to continuous cranial oriented stress force in the arch and in a sideway direction in the first portion of the descending aorta[20].

Drag forces act in a three-dimensional configuration and have variable magnitudes in different zones of the thoracic aorta, influenced by angulation and tortuosity, with higher values in zone 3[21].

The combination of the anatomical aspects and fluid dynamics appears to be the key to a better understanding of the mechanism that leads to the long-term failure of TEVAR.

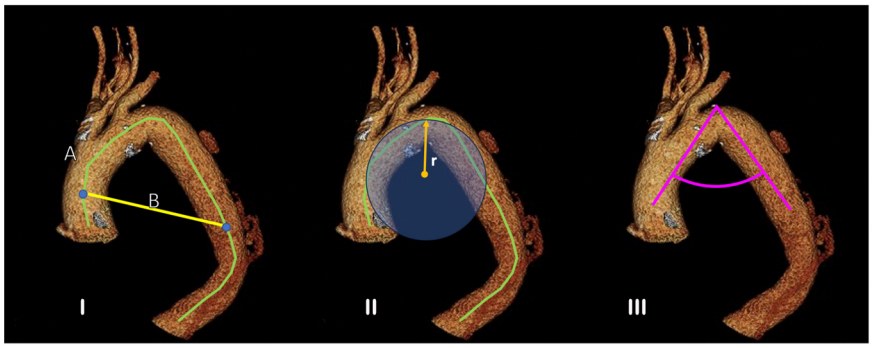

Figure 4. Aortic tortuosity index (TI) value is obtained by dividing the interested aortic length measured at center line by the geometric length (A/B= TI) (I). Radius of curvature is an approximative measure of aortic arch curvature. The higher the "*r*" value, the less curved the arch can be considered (II). Aortic arch angle is calculated at the highest point of the aortic arch between a line toward a mid-arterial point in the ascending aorta and one in the descending at the level of pulmonary artery bifurcation (III).

Displacement forces have been found to be higher in zone 0 than in other arch zones. However, TEVAR performed at this level has lower endoleaks and migration rate compared to other PLZ and this could be explained by a lower tortuosity and angulation and the chance to obtain a longer PLZ securing a more stable proximal fixation and sealing of the endograft[22]. The unfavorable hemodynamic asset of the ascending aorta seems to be compensated by a more reliable and regular anatomic configuration, suggesting the decisive role of PLZ.

According to the MALAN classification, zone 3/II and 3/III have also shown the presence of relevant displacement forces with an orthogonal vector to the aortic longitudinal axis comparable to the one found in the ascending aorta. Instead of zone 0, proximal landing areas in zones 3/II and 3/III are characterized by significant angulation and tortuosity that should need an adequately long PLZ to ensure effective and long-lasting sealing[23]. Zone 3 in angulated aortic arch type II and III seems unfavorable for a standard TEVAR procedure with a commonly accepted 20 mm sealing zone length. The presence of the left subclavian artery limits the applicability of a standard TEVAR and requires the use of scalloped/branched devices or a carotid-subclavian bypass. In elective cases, it is advisable to preserve the left subclavian artery to prevent spinal cord ischemia; additionally it is raccomended suspending dual antiplatelet therapy to allow spinal drainage if signs of ischemia occur. Intra-operative heparinization is mandatory with active clotting time to be monitored (target > 250 s). Post-operative single antiplatelet is recommended.

ENDOGRAFT CHARACTERISTICS

The progressive improvements in the results of endovascular procedures are directly related to the growing experience of the physicians and continued improvement in the materials. Research and development of new endograft and ancillary components are central. In TEVAR, the continuous research of the ideal endograft is an ongoing process, with the aim to achieve excellent conformability to aortic arch curvatures, navigability through tortuous and narrow anatomies, precision of deployment, and durability over time. In adjunct, TEVAR should also avoid any excessive stress on the aortic wall at the landing sites to prevent retrograde dissection (RTAD) or stent graft-induced new entry tear (SINE).

The precision of deployment is mainly dependent on the mechanism of endograft deployment.

Currently, endografts have two possible mechanisms. The majority of devices present a pin-pull method of delivering the graft by unsheathing it in a proximal to distal fashion. Thus, deployment is partially

dependent on the operator pin-pull force, which could ultimately lead to a forward misplacement of the graft if not properly and dynamically applied[24].

The second available mechanism (Gore CTAG, Gore & Associates, Flagstaff-USA) implies a two-stage delivery system that enhances stability during deployment[12]. It is also incorporated with an angulation system that allows angulating the proximal tip of the delivery system to better adapt to the aortic anatomy, thereby leading to enhanced wall apposition[25].

There are no available direct comparisons between the two mechanisms of deployment, but preliminary data seem to highlight a high precision with the use of the active control system[12,25].

For devices with a pin-pull deployment, the presence of a proximal bare metal stent (BMS) confers a higher stability during the deployment, maintaining the proximal end of the device captured to the delivery system until it is finally released, and helps to promote endograft-to-wall apposition once the device is deployed. However, the use of endografts with a proximal BMS should be avoided in the treatment of dissections or more proximal landing zones (zones 0 and 1) since it is associated with the occurrence of RTAD[26].

Other endografts without proximal BMS present different adjunctive mechanisms aimed to improve stability and accuracy of deployment; the Relay® NBS Plus (Terumo Aortic, Sunrise, Florida, USA) has two nitinol supporting wires[27] that promote the apposition of the endograft to the lesser curvature during the deployment. Further data are still necessary to establish the advantages and disadvantages of each different deployment system.

PROXIMAL SEALING LENGTH

Proximal sealing length

Proximal sealing length is the single most important factor affecting the technical success and durability of TEVAR in terms of proximal endograft failure. Although a proximal sealing length of 20 mm is usually recommended for TEVAR, the benefit of adequate sealing also has to be weighed against the possible technical challenges and complications related to a more proximal coverage, with the associated need for SAT rerouting, and increased risk for neurological complications in cases with more proximal landing[2,28]. This concept is corroborated by current series that report the use of a > 2 cm proximal sealing length in just 25%-60% of cases[29-33] [Table 1].

Conversely, the use of a shorter landing zone has been described to be an independent predictor of type I endoleak and a long PLZ seems to guarantee a higher probability of long-term efficacy of TEVAR[29].

In a single-center experience, we aimed to identify the optimal sealing length based on different anatomical characteristics[33]. We found that overall, the risk of proximal endograft failure is strictly dependent on the proximal sealing length, and that for all landing zones in the arch (0, 1, 2 and 3), a 20 mm sealing length can be considered acceptable only for type I aortic arches. Differently, in type II and III arches, it may be advisable to obtain a proximal sealing length of 25-30 mm, in order to prevent endograft migration or type Ia endoleaks during time [Figure 5]. Based on these results, we developed an internal protocol for the optimization of the proximal landing zone according to the anatomical arch characteristics [Table 2].

The significant role played by the proximal sealing zone emphasizes two crucial aspects of TEVAR procedures. (1) In order to achieve favorable long-term outcomes, it is essential to preserve the extension in the aortic arch. However, it is important to carefully consider the benefits of this approach against the

Table 1. Literature review of selected articles reporting the impact of sealing zone length in TEVAR

Study	Year	N. of patients	Aortic pathology	Cases < 2 cm sealing length
Boufi *et al.*[29]	2015	84	AD,TAA,BTAI, PAU, IMH	40%
Kuo *et al.*[30]	2019	71	AD	68%
Yoon and Mell[31]	2020	63	AD, TAA, BTAI, PAU	71%
Lombardi *et al.*[32]	2021	110	AD	83%
Piazza *et al.*[33]	2021	140	AD, TAA, BTAI, PAU	11%

AD: Aortic dissection; TAA: thoracic aortic aneurysm; BTAI: blunt traumatic aortic injury; PAU: penetrating aortic ulcer; IMH: intramural heamatoma.

Table 2. Proximal sealing zone optimal and safest length calculation for thoracic endovascular aortic repair stratified by aortic arch type and sealing zone[32]

Proximal sealing	Minimum recommended sealing length (mm)	Safest sealing length (mm)
Type I arch		
Overall	20	25
Zones 2 and 3 only	20	25
Type II arch		
Overall	25	30
Zones 2 and 3 only	25	30
Type III arch		
Overall	25	30
Zones 2 and 3 only	25	30

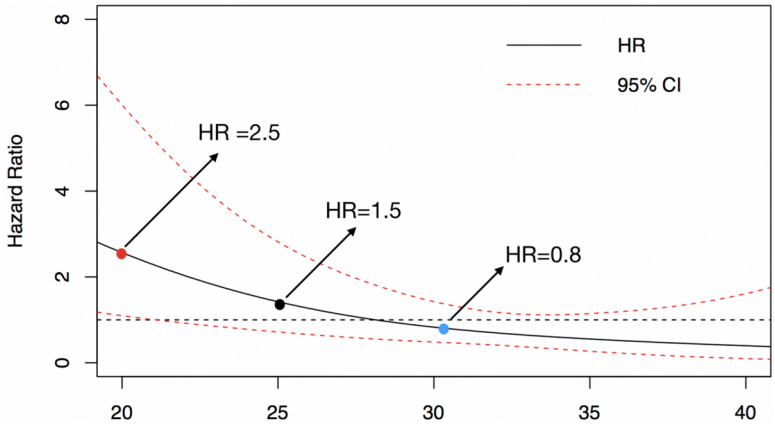

Figure 5. Penalized smooth splines function of the hazard ratios for proximal endograft failure *vs.* proximal sealing length after TEVAR. The 95% confidence interval is represented by the dashed red line.

potential complexities associated with more intricate debranching procedures. Therefore, the planning of each case should be tailored to the specific anatomical and clinical conditions of the patient.

It is important to acknowledge that there may be challenging anatomical situations, such as type III arches with steep angulations, where achieving complete graft-to-aortic wall apposition in the proximal landing zone is only partially attainable. In such cases, the debranching of supra-aortic vessels and the planning of the proximal landing zone must be meticulously executed, taking into account the unique anatomical characteristics of the patient. This approach aims to maximize the length of endograft apposition and its

associated benefits. Alternative options, such as the use of dedicated branched/fenestrated endografts, physician-modified grafts, or chimney grafts, can also be considered to enable the utilization of more proximal landing zones. However, it is important to note that physician-modified endografts are considered off-label and should only be contemplated in highly specific and carefully selected cases where standard off-the-shelf or custom-made devices are not available.

Custom-made devices are gaining importance in treating challenging anatomies. Nonetheless, it is essential to recognize that the sealing zone of these devices differs from that of standard TEVAR due to the presence of fenestrations and branches, thus necessitating a distinct analysis and consideration.

In cases where achieving an optimal sealing length is not feasible, a more rigorous follow-up after TEVAR may be recommended, particularly for patients with challenging anatomies. (2) During the procedure, the sealing length within the planned landing zone should be maximized. Therefore, stent graft deployment accuracy has great value. To increase the precision of deployment, some ancillary techniques may be used. Different methods to reduce aortic blood wave impulse have been described and the most widely accepted seems to be rapid pacing, venous inflow occlusion or pharmacological induced hypotension. Rapid pacing seems to meet the criteria of safety and efficacy together with the shortest duration of induced hypotension and quick recovery after cessation[34].

SPECIFIC PATHOLOGY CONSIDERATIONS

Acute or subacute aortic dissection

Thoracic endovascular aortic repair (TEVAR) has become the standard treatment for complicated type B aortic dissections (TBADs), and is also gaining importance in the treatment of uncomplicated dissections during the subacute or early chronic phase. In these cases, the aim of TEVAR is to cover the entry tear, direct the flow into the true lumen, and promote false lumen thrombosis. As usual, at least 2 cm of proximal healthy aorta is recommended as proximal sealing length, but the definition of a "healthy" aorta may not be straightforward in these cases. The false lumen often extends proximally over the intimal tear; therefore, coverage of one or more SATs may be required [Figure 6].

A clear inverse relationship has been described between the proximal sealing length and associated adverse outcomes[30,32]; particularly, it has been demonstrated that landing in non-healthy aorta, where there is evidence of intramural hematoma, substantially increases the risk of retrograde dissection.

Therefore, in order to avoid dreadful complications such as retrograde dissection, and promote long-term durability, at least 2 cm of non-dissected aorta should be covered.

Another important point is that a 1:1 oversize is usually sufficient, and an excessive oversize is associated with the risk of RTAD. For the same reason, the use of proximal free-flow or barbs should be avoided[35].

Anatomical factors may contribute to the complexity of TEVAR for acute type B dissections. The arch anatomy correlates with the risk of aortic dissection, through the creation of fluidodynamic effects that favor the formation of the intimal tear. In particular, type III arch is associated with a specific, consistent and abnormal secondary flow pattern, which may account for its high prevalence in patients with type B aortic dissection[36].

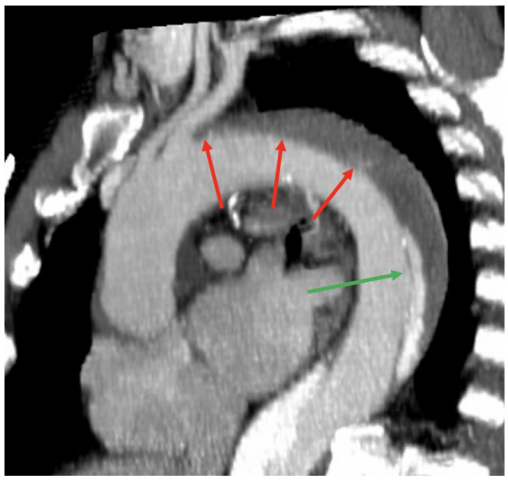

Figure 6. CTA showing a case of acute type B aortic dissection with the entry tear located in the descending aorta (zone 4) and presenting intramural hematoma extended proximally to the left subclavian artery. In this case, adequate sealing zone should be obtained in zone < 3.

This justifies the relatively high prevalence of type III aortic arches in patients with type B aortic dissection[37]; furthermore, the angulation and tortuosity of the true and false lumens may carry significant clinical implications for the treatment and prognosis of aTBAD. In our opinion, these anatomical unfavorable characteristics should be carefully evaluated, especially in the case of acute uncomplicated type B dissections, where the benefit of an early TEVAR is still debated[1,2].

Intramural hematoma and penetrating aortic ulcer

Intramural hematoma (IMH) is a rare disease, and the experience with the endovascular treatment of IMH is limited. The technical and procedural details of TEVAR for IMH are not standardized yet, but the same basic concepts of aortic dissection do apply. However, there is not a clear intimal tear to be covered, and the role of TEVAR for IMH is unclear. In our experience, we reserve TEVAR just for IMH complicated by evolution to aortic dissection or rupture. The proximal sealing length should be at least 2 cm, starting from the aorta unaffected by IMH [Figure 7]. Similarly to TBAD, the avoidance of proximal BMS and excessive oversizing (maximum 10%) in the proximal and distal sealing zones should be followed.

Penetrating aortic ulcer is a different disease that usually occurs in the descending thoracic aorta in the context of a non-aneurysmal atherosclerotic aorta[38]. PAUs may be associated with a peri-aortic hematoma, where the aortic wall is still fragile. Thus, at least 2 cm of healthy aorta free from signs of hematoma should be used as the proximal landing zone [Figure 8].

Degenerative aneurysm

The most frequent pathology treated by TEVAR is degenerative aneurysm. When dealing with atherosclerotic aneurysms, the length of the proximal neck plays a crucial role in ensuring secure fixation and long-term sealing. In our experience, the proximal sealing length is defined not only by its diameter, which allows for proper placement and anchoring of the endograft with the right oversize, but also by the presence of a completely healthy aorta in that region. Long-term complications following TEVAR for thoracic aneurysms are often associated with disease progression and neck dilatation, similar to what has been observed in the abdominal aorta. This could explain why a larger aorta is at a higher risk (HR 1.06, $P = 0.003$) of experiencing complications related to the proximal endograft. Another possible reason is that the thoracic endograft faces greater displacement forces when there is a significant amount of "free space"

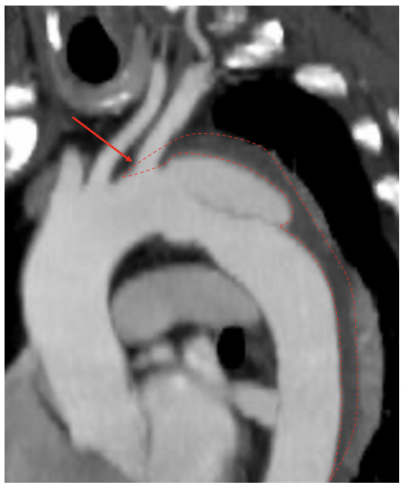

Figure 7. CTA with multiplanar reconstruction of an intramural hematoma, complicated by a focal type B dissection, with hematoma extension in the aortic arch.

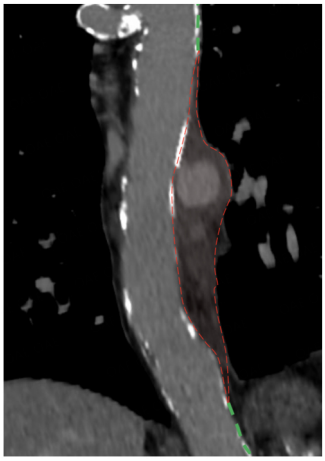

Figure 8. CTA with multiplanar reconstruction of a penetrating aortic ulcer (zone 5) with associated intramural hematoma. Dashed red line highlights its proximal and distal extension; recommended landing zone should be at the level of the green dashed line.

between the endograft and the dilated aortic wall, leading to an increased risk of gradual loss of sealing over time[33].

In type I aortic arches we usually plan 20 mm sealing length proximally, 25 mm sealing length in type II and III arches whenever possible. Regardless of the sealing zone and arch type, a minimum 25 mm sealing length is also recommended in cases of evident angulation, thrombus or calcifications[33].

Chronic dissection

Chronic dissections are characterized by a progressive dilatation primarily of the proximal descending thoracic aorta (zones 2 and 3)[38]. Thus, TEVAR may not always be anatomically feasible due to the overall enlargement of the aortic arch, making zones 1, 2 and 3 unsuitable for a standard thoracic endograft. Moreover, a prior ascending aorta substitution may be present in those cases with residual dissection after type A repair. In our experience, the use of aortic arch endografts is particularly helpful for the treatment of chronic dissection, since they allow safe landing in zone 0, guaranteeing a minimally invasive treatment.

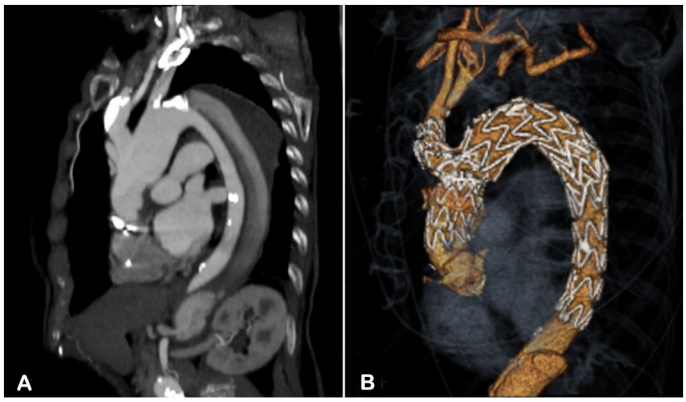

Figure 9. CTA showing an acute TBAD in a highly angulated type III aortic arch with no adequate sealing zone in zone 1 or 2, and requiring an extensive coverage of the aortic arch with a proximal landing zone in zone 0 (A). Final result 3D reconstruction of the hybrid treatment with a single branched arch endograft and supra-aortic trunks debranching (right common carotid artery-left subclavian artery bypass and left common carotid artery reimplantation on the graft) (B).

Figure 10. Left subclavian artery coverage can be a valid option to gain a more appropriate proximal sealing zone both in terms of length and aortic healthy wall. Urgent LSA coverage appears to be safe in the treatment of aortic blunt traumatic injuries.

The main anatomical limitations to the use of arch endografts are represented by the presence of a mechanical aortic valve, a short ascending aorta < 30-40 mm (depending on the endograft type), or a large ascending aorta > 40 mm in diameter [Figure 9].

Blunt traumatic aortic injuries

A short landing zone may be sufficient for traumatic aortic injuries since the adjacent aorta is essentially undiseased. However, it has also to be considered that traumatic injuries often occur in young patients, with angulated ("gothic") aortic arches and associated unfavorable displacement forces, and at the same time, it may be advocated to guarantee long-term durability. Intentional LSA coverage, followed by eventual LSA revascularization in a second-stage procedure, has been proven to be safe in the urgent setting without the risk of major neurological complications or spinal cord ischemia[39] [Figure 10]. However, the long-term results after TEVAR for traumatic injuries are still not completely clear.

Gaps in knowledge

Despite significant advancements in endovascular techniques, there are still gaps in our knowledge regarding the optimal management of the sealing zone. One major knowledge gap lies in the understanding of the impact of the endograft rigidity on the aortic arch. How the endograft impacts anatomical variations, such as tortuosity and angulation of the aorta, on the long-term adequacy of the sealing zone remains an area of ongoing research. Further investigations are required to determine the optimal device selection and deployment strategies in challenging anatomical cases. Closing these knowledge gaps will contribute to improving patient outcomes and refining the techniques used in TEVAR procedures.

CONCLUSION

Length of proximal sealing represents the most important factor associated with early and long-term results after TEVAR. A shorter proximal sealing length is associated with an increased risk of endograft migration or type Ia endoleak, especially if < 2 cm. A longer sealing protects from proximal endograft failure, but may require a more aggressive SAT debranching or the use of a more complex endovascular approach, with associated technical challenges and increased perioperative risk. During the preoperative planning of the proximal sealing length, specific anatomical, hemodynamic, pathological, and clinical factors should be evaluated in order to optimize the clinical outcomes, tailoring an optimal sealing length to each patient.

DECLARATIONS

Authors' contributions

Made substantial contributions to the conception and design of the study and performed data analysis and interpretation: Squizzato F, Spertino A, Grego F, Antonello M, Piazza M

Performed data acquisition, as well as provided administrative, technical, and material support: Squizzato F, Spertino A, Grego F, Antonello M, Piazza M

Availability of data and materials

Not applicable.

Financial support and sponsorship

None.

Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

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