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INTEGRATED STUDY MASTER'S FINAL THESIS

Literature Review of Thoracoabdominal Aortic Aneurysm Endovascular Treatment Clinical Trials

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ABBREVIATIONS

TAAA – Thoracoabdominal Aortic Aneurysm

FEVAR – Fenestrated Endovascular Aneurysm Repair

BEVAR – Branched Endovascular Aneurysm Repair

F/B-EVAR – Fenestrated/Branched Endovascular Aneurysm Repair

SCI – Spinal Cord Ischemia

PMEG – Physician-Modified Endograft

CTA – Computed Tomography Angiography

CSF – Cerebrospinal Fluid

MAP – Mean Arterial Pressure

IDE – Investigational Device Exemption

TVV – Target Visceral Vessel?

TALE – Thoracoabdominal Aortic Life-Altering Event

OR – Open Repair / Odds Ratio (context dependent)

HR – Hazard Ratio

CI – Confidence Interval

ACC/AHA – American College of Cardiology / American Heart Association

PMEGs – Physician-Modified Endografts

AKI – Acute Kidney Injury

SANTRAUKA

Torakobdominalinė aortos aneurizma yra reta liga, tačiau klinikiškai svarbi, nes negydant mirtingumas yra labai didelis. Atviras chirurginis gydymas yra auksinis standartas torakobdominalinės aortos aneurizmos gydymui. Tai sudėtinga operacija, ir daugelis pacientų nėra tinkami kandidatai jai atlikti. Ši priežastis paskatino mažiau invazinio endovaskulinio gydymo vystymąsi. Fenestruotas endovaskulinis aneurizmos gydymas ir šakotas endovaskulinis aneurizmos gydymas dabar naudojami kaip svarbūs gydymo variantai, ypač pacientams, kuriems operacijos rizika yra didelė.

Šioje aprašomojoje literatūros apžvalgoje išanalizuoti dabartiniai duomenys apie torakoabdominalinės aortos aneurizmos endovaskulinį gydymą. Buvo atlikta paieška PubMed, Cochrane Library ir ClinicalTrials.gov duomenų bazėse. Įtraukti tyrimai, paskelbti 2010–2025 m. Buvo nagrinėjami klinikiniai tyrimai, registrų tyrimai ir pagrindiniai lyginamieji tyrimai.

Daugumoje analizuotų publikacijų fenestruoto endovaskulinio aneurizmos gydymo ir šakoto endovaskulinio aneurizmos gydymo techninis sėkmės rodiklis buvo aukštas ir siekė daugiau nei 90 %. Lyginant su atviru gydymu, endovaskulinis gydymas dažnai buvo susijęs su mažesniu perioperaciniu sergamumu, trumpesne hospitalizacijos trukme. Nugaros smegenų išemija, inkstų komplikacijos ir pakartotinių intervencijų dažnis išlieka aktualūs. Ilgalaikiai tyrimai parodė, kad aneurizmos izoliacija buvo veiksminga, o su aneurizma susijęs mirtingumas buvo mažas. Tačiau bendras mirtingumas vis dar išlieka aukštas.

Turimi duomenys patvirtina, kad endovaskulinis gydymas yra veiksmingas pasirinkimas tam tikriems pacientams, turintiems torakoabdominalinę aortos aneurizmą. Tačiau dauguma duomenų vis dar yra stebimieji ir nerandomizuoti. Reikia daugiau ilgalaikių prospektyvinių ir randomizuotų tyrimų, apimančių palyginimą su kitomis gydymo strategijomis, ilgalaikius rezultatus ir komplikacijų prevencijos priemones.

SUMMARY

Thoracoabdominal aortic aneurysm (TAAA) is a rare disease, however it is still clinically important since mortality is very high if untreated. Open repair is the gold standard of TAAA repair. It is a major operation and many patients are not ideal candidates for it. It led to the development of less invasive endovascular repair. FEVAR and BEVAR are now used as important treatment options, especially in patients with high operative risk.

This narrative literature review analyzed the current evidence on endovascular repair of TAAA. PubMed, Cochrane Library, and ClinicalTrials.gov were searched. Studies published between 2010 and 2025 were included. Clinical trials, registry studies, and major comparative studies were considered.

In most analyzed publications, technical success of FEVAR and BEVAR was high, usually above 90%. Compared with open repair, endovascular repair often had lower perioperative morbidity. Patients in

endovascular group usually had a shorter hospital stay. SCI, renal complications, and reinterventions rates remain relevant. Long-term studies showed that aneurysm exclusion was effective and aneurysm-related mortality was low. Although, overall mortality was still high.

The available evidence supports endovascular repair as an effective option in selected patients with TAAA. However, most evidence is still observational and non-randomized. More long-term prospective studies and randomized studies are needed. These studies should address comparison with other treatment strategies, long-term outcomes, measures for complications prevention.

KEYWORDS

Thoracoabdominal aortic aneurysm; endovascular repair; fenestrated endovascular aneurysm repair; branched endovascular aneurysm repair; clinical outcomes

1. INTRODUCTION

Thoracoabdominal aortic aneurysm is a dilatation of the aorta involving both the descending thoracic and abdominal segments. It is a rare condition, with an estimated incidence of approximately 5.9 per 100,000 persons per year and accounting for about 10% of all aortic aneurysms (1). Despite its low prevalence, TAAA is clinically significant. Reported overall mortality of ruptured aortic aneurysms is around 80–90%, with almost 60% of the patients not reaching the hospital.(2,3).

TAAAs are often asymptomatic in the early stages and are frequently detected incidentally. Without treatment, they may enlarge progressively, with rupture risk increasing mainly according to aneurysm diameter, growth rate, and symptoms. Rupture is associated with very high mortality, which makes timely selection of patients for repair clinically important (4).

TAAA is characterized by considerable anatomical complexity. The extent varies between patients, ranging from limited segments to involvement of a large portion of the aorta. The most commonly used system to describe TAAA is the Crawford classification. The classification describes five types of TAAA. More extensive aneurysms, types I-III, involve a larger portion of the aorta and are associated with more difficult treatment and worse outcomes (1)

Treatment of thoracoabdominal aortic aneurysms has changed over time. The first successful repair was done by Etheredge and colleagues in 1955 with an open approach. After that open surgery stayed the main method of treating TAAA. However, the complexity and physiological burden of open TAAA repair lead to the development of less invasive strategies.

The development of endovascular aneurysm repair was an important step in aortic surgery. In 1994, Dake and colleagues demonstrated the first successful endovascular thoracic aorta repair. This showed that stent grafts could be used in the descending thoracic aorta.(5)

TAAA treatment is more difficult because the aneurysm involves the part of the aorta where the renal and visceral arteries arise. Simple stent-graft coverage would block blood flow to these organs. Because of this, new methods were needed. In 1999, Quiñones-Baldrich and colleagues presented a hybrid approach. It combined open surgical debranching of the visceral arteries with endovascular aneurysm exclusion (6). The aim was to reduce the need for full open thoracoabdominal operation. This approach allowed TAAA repair in patients unsuitable for total open repair.

A further important step was total endovascular TAAA repair. In 2001, Chuter and colleagues reported the use of a multi-branched stent graft for TAAA (7). This technique excludes aneurysm and preserves

the blood flow to the renal and visceral arteries endovascularly. Since then, research and development of fenestrated and branched endovascular grafts has expanded significantly. These devices can now be custom-made for individual patients or produced as off-the-shelf devices for common anatomical patterns and emergency TAAA repairs.

These developments have expanded treatment options, especially for high-risk patients. The nature of the endovascular procedure may be associated with reduced perioperative physiologic stress. Therefore, it can be hypothesized that an endovascular approach may have better outcomes than open repair.

The aim of this literature review is to evaluate current evidence on endovascular treatment of thoracoabdominal aortic aneurysms, with attention to clinical trials and major clinical studies.

2. METHODOLOGY

A narrative literature review was performed using the PubMed and Cochrane Library databases. Data on ongoing and completed clinical trials were reviewed using ClinicalTrials.gov.

The search included the following keywords and their combinations in English: “thoracoabdominal aortic aneurysm”, “TAAA”, “open repair”, “endovascular repair”, “hybrid repair”, “visceral debranching”, “FEVAR”, “BEVAR”, “stent-graft”, “mortality”, “spinal cord ischemia”, “reintervention rates”, “graft patency”, and “complications”. Related terms, spelling variants, and synonyms were used when appropriate.

Articles were selected based on titles and abstracts. Full-text articles were then reviewed to assess their relevance. Studies published in English between 2010 and 2025 were included.

Studies were included if they were directly related to TAAA treatment and reported clinical outcome data. The main focus of this review was endovascular treatment, studies evaluating fenestrated, branched, or other endovascular approaches were prioritized. Most included studies had more than 100 patients. Smaller studies were included only when they were considered critical for the review. Open and hybrid repair studies were not the main focus of this review. They were included only when they added relevant background information, allowed comparison with endovascular treatment, or helped to describe treatment indications and outcomes. Studies were excluded if they were not related to TAAA treatment, did not report clinical outcome data, or were limited to editorials or opinion articles.

3. CLINICAL BACKGROUND AND TREATMENT PRINCIPLES OF TAAA

3.1 CRAWFORD CLASSIFICATION

The Crawford classification is used to describe extent of TAAA. This classification aids in surgical planning, estimating risk of the procedure. It is also used to compare outcomes of TAAA repairs.

• Type I: The aneurysm starts above the sixth intercostal space, right after the left subclavian artery. It involves the descending thoracic aorta and the celiac trunk, but does not reach the renal arteries.

• Type II: The aneurysm starts above the sixth intercostal space, just after the left subclavian artery. It involves both the descending thoracic and abdominal aorta. It includes the renal artery region and may extend to the aortic bifurcation.

• Type III: The aneurysm starts below the sixth intercostal space in the lower descending thoracic aorta. It extends into the abdominal aorta. It involves the renal arteries and may reach the aortic bifurcation.

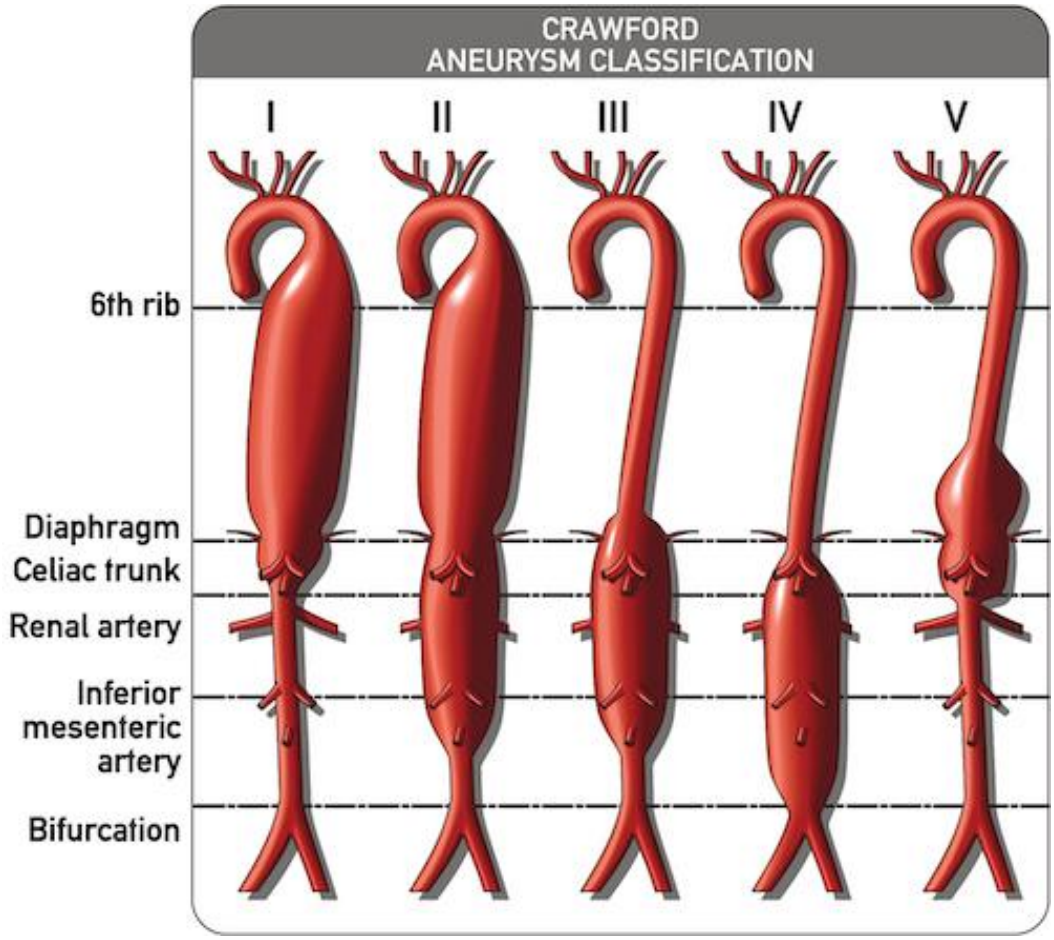


Figure 1. Crawford classification of TAAA (8).

• Type IV: The aneurysm starts at the level of the twelfth intercostal space or at the diaphragm. It involves the entire abdominal aorta to the aortic bifurcation.

• Type V: The aneurysm starts below the sixth intercostal space and involves the distal descending thoracic aorta. It extends to just above the renal arteries and does not involve them.

Types of TAAA with anatomical landmarks according to Crawford classification can be found in Figure 1.

Numerical outcome data stratified by Crawford type are available mainly from open surgical repair series. In a meta-analysis of 9,963 patients undergoing open TAAA repair, pooled mortality was 6.97% for type I, 10.32% for type II, 8.02% for type III, and 7.20% for type IV aneurysms (9). This supports the clinical observation that Crawford type II aneurysms carry the highest operative risk. Similarly, in a large single-center series of 3,309 open TAAA repairs, the composite adverse outcome was highest after type II repair and lowest after type IV repair (10).

3.2 NATURAL HISTORY AND RISK OF RUPTURE

Untreated TAAA has poor prognosis. This is partly because many patients do not have symptoms before a serious complication develops. In most patients, the first presentation is already a major event. This can be rupture, acute dissection, embolization, or compression of nearby organs (11). In untreated disease, mortality can be very high. Reported 5-year mortality can reach 80% (12). Aortic rupture is related to massive blood loss and hemodynamic instability, leading to high mortality outside of a medical facility. Contemporary data on completely untreated TAAA are limited, because large aneurysms are usually repaired once they reach guideline thresholds (1).

Around 70% of TAAAs are related to progressive structural weakening of the aortic wall. Genetic or connective tissue disorders are responsible for another 15–20% (11). The aortic wall degeneration involves several mechanisms, including extracellular matrix breakdown, elastin and collagen degradation, inflammatory-cell infiltration, smooth-muscle-cell loss or dysfunction, oxidative stress, and medial degeneration (13).

Aneurysm diameter is one of the main measurable factor used in clinical practice. It predicts risk of rupture, dissection, and potentially death (1). Reported TAAA growth is about 0.10–0.42 cm/year. However, this is only a general range and does not apply equally to all patients. growth may be faster in larger aneurysms, women, smokers, and patients with chronic dissection or connective-tissue disease (11). As aneurysm size increases, arterial pressure generates progressively higher wall stress. This

promotes further aneurysm expansion and increases the risk of rupture or dissection. In descending thoracic and thoracoabdominal aneurysms, a diameter of 6.0 cm has been associated with an annual risk of rupture, dissection, or death of approximately 19% (11). Chronic aortic dissection is another important pathway, because persistent false-lumen pressurization may cause progressive thoracoabdominal aortic dilatation (11).

Important risk factors include older age, male sex, hypertension, smoking history, COPD, atherosclerosis, and family history of aortic aneurysm or dissection (11). Heritable causes include Marfan syndrome, Loeys-Dietz syndrome, vascular Ehlers-Danlos syndrome, and familial thoracic aortic disease (11). Women with TAAA usually present with a smaller baseline aortic diameter, but they have a higher rupture risk and a worse presentation profile, although the evidence remains observational (11). Summary of the risk factors and complications associated with TAAA can be found in Table 1.

Table 1. Risk factors and complications associated with TAAA

Group	**Factors / complications**
General cardiovascular risk factors	Older age; hypertension; smoking history; COPD; atherosclerosis
Genetic and patient-related risk factors	Family history of aortic aneurysm or dissection; heritable connective tissue disease, (Marfan syndrome, Loeys-Dietz syndrome, vascular Ehlers-Danlos syndrome, and familial thoracic aortic disease);
Disease progression factors	Aneurysm diameter; rapid aneurysm growth; chronic aortic dissection
Acute complications	Rupture; acute dissection (true-lumen collapse or branch-vessel obstruction)
Chronic or local complications	Distal embolization (ex. mural thrombus); compression of adjacent structures; fistulization (ex. aorto-esophageal, rare)
Table note: : Data summarized from published literature (1,11,14)	

3.3 INDICATIONS FOR TREATMENT

Treatment indication for TAAA is based on the balance between rupture risk and the risk of repair. All modes of TAAA repair are associated with perioperative risks. So the intervention should be considered only in patients who have a higher natural risk than the procedural one. The main factors that influence the decision about the intervention are aneurysm diameter, symptoms, growth rate, aneurysm morphology, presence of a connective tissue disease, type of operation (planned or emergent), anatomical suitability for repair, and the patient's overall operative risk.(1)

The 2022 ACC/AHA guideline recommends repair when the maximal aneurysm diameter is ≥6.0 cm. Repair of ≥5.5 cm aneurysm is also considered reasonable, when performed by experienced surgeons within a multidisciplinary aortic team. Repair may also be reasonable at <5.5 cm when features associated with higher rupture risk are present. including rapid growth, aneurysm-related symptoms, significant change in aneurysm appearance, saccular morphology, or presence of penetrating atherosclerotic ulcers. Rapid growth is defined as a confirmed increase in diameter of ≥0.5 cm/year.(1)

Table 2. 2022 ACC/AHA guideline recommendations

Class of Recommendation	**Level of evidence**	**Recommendations**	**Group of patients**
1	B-NR	TAAA repair is recommended.	Patients with intact degenerative TAAA with the diameter of ≥6.0 cm
2a	B-NR	TAAA repair is reasonable.	Patients with intact degenerative TAAA with the diameter of ≥5.5 cm. If the repair is performed by experienced surgeons in a Multidisciplinary Aortic Team.
2a	B-NR	TAAA repair is reasonable	Patients with intact degenerative TAAA with the diameter of <5.5 cm. If there are features associated with an increased risk of rupture.

Symptoms related to the aneurysm are an important indication for treatment, regardless of the measured diameter. Commonly reported symptoms related to the aneurysm include persistent back, chest, abdominal, or flank pain. They may indicate instability and increased rupture risk. Therefore, symptomatic TAAA should not be managed according to diameter alone.

Ruptured TAAA requires urgent intervention. According to the ACC/AHA guideline, open repair is recommended in ruptured TAAA requiring urgent intervention, with class 1 recommendation. Endovascular repair may be reasonable in selected hemodynamically stable patients, but only in centers with appropriate endovascular expertise and access to suitable fenestrated or branched stent-grafts. Guidelines give class 2b recommendations for this approach.

Ruptured TAAA repair is a life-saving treatment. While open repair is preferred in this setting, endovascular repair is still possible. Hemodynamic stability, anatomy, device availability, and institutional experience might influence the decision of the preferred mode of repair.

3.4 MAIN TREATMENT APPROACHES

Treatment approaches for TAAA include open surgical repair, hybrid repair, and total endovascular repair. The choice of mode of repair depends on aneurysm extent, patient age and comorbidities, anatomical suitability, urgency of treatment, and institutional expertise (1,15). Open repair is an important treatment option when long term durable reconstruction is required or when endovascular repair is not anatomically suitable. Hybrid repair is appropriate in selected cases when total open repair carries too high perioperative risk and total endovascular repair is not feasible. Total endovascular repair has become more prevalent in the last 15 years, performed in patients considered high risk for open surgery(16). However, it requires detailed procedural planning and access to specialized devices.

3.4.1 OPEN SURGICAL REPAIR

Open TAAA repair surgically replaces the aneurysmal segment of the aorta with a prosthetic graft and includes revascularization of the renal and visceral arteries. It requires thoracoabdominal exposure and aortic cross-clamping. It is a major operation associated with substantial physiological stress and a risk of serious complications. These include perioperative mortality, bleedings requiring blood transfusion, respiratory complications (due to prolonged ventilation and thoracotomy), spinal cord ischemia, renal injury etc. Therefore, selection of a patient who is fit for the operation is crucial. It is mostly recommended in younger patients and in patients with connective tissue disorders.(1,10,17)

3.4.2 HYBRID REPAIR

Hybrid repair combines open surgical and endovascular approaches. During the open stage, a laparotomy is performed to complete visceral debranching and revascularization of the visceral arteries with bypass grafts. The endovascular stage excludes the aneurysm with a stent-graft, with landing zones above and below the diseased segment of the aorta. This approach avoids thoracotomy, aortic cross-clamping, and replacement of the aorta with an artificial graft, although it still requires major abdominal surgery. Due to similar outcomes to other modes of repair and the cumulative risk of complications from both open and endovascular operations, its use has declined (17). Currently, hybrid repair is reserved for high-risk patients and those unsuitable for open repair or total endovascular repair.

3.4.3 TOTAL ENDOVASCULAR REPAIR

Total endovascular repair excludes TAAA using endovascular stents deployed via peripheral arterial access. This approach may reduce physiological stress by avoiding thoracotomy, laparotomy, aortic cross clumping, and avoiding open surgical manipulation of aorta or visceral arteries. However, it requires suitable vascular anatomy, precise preoperative planning, and specialized devices. Total endovascular repair is the focus of this review, and its technical principles are discussed in detail in the following chapter.

4. ENDOVASCULAR REPAIR PRINCIPLES

The main goal of endovascular TAAA repair is to isolate the aneurysm sac from systemic arterial pressure. A stent-graft is placed within the aorta redirecting blood flow through a new artificial lumen. Landing zones of the graft should be in healthy segments of the aorta above and below the aneurysm. The aneurysm sac remains intact but is excluded from direct systemic arterial flow, as a result lowering the risk of expansion and rupture. In TAAA, this approach presents additional anatomical challenges because blood supply to the visceral and renal vessels must be preserved. To address them, two main approaches have developed: FEVAR and BEVAR (1).

4.1 FENESTRATED AND BRANCHED ENDOVASCULAR REPAIR

The main goal of endovascular TAAA repair is to isolate the aneurysm from systemic arterial pressure. A stent-graft is placed within the aorta, with landing zones in healthy segments below and above the diseased portion, redirecting blood flow through a new artificial lumen. The aorta remains intact but is excluded from direct systemic arterial flow. In ideal conditions it significantly reduces the risk of expansion and rupture. Endovascular TAAA repair has unique challenges. Due to the inability to alter

aortic anatomy, isolation of the aneurysm and preservation of blood supply to the visceral arteries must be achieved at the same time in a confined space. Two main approaches have developed for this purpose: FEVAR and BEVAR.

4.2 PRINCIPLES OF FENESTRATED AND BRANCHED ENDOVASCULAR TAAA REPAIR

A FEVAR aortic endograft features reinforced openings, or fenestrations, which are positioned opposite the ostia of the target vessels. After the main graft is deployed, the visceral arteries are stented through these openings with bridging stents.(18)

A BEVAR endograft features side branches instead of openings. These branches are oriented toward the target vessels and are fixed with bridging stents. This allows a longer and often more forgiving connection with the bridging stent. This may be useful in an angulated part of the aorta or when target vessels arise from an aortic segment with an aneurysm.

The technical difference between FEVAR and BEVAR is mainly related to stent alignment and necessary intra-aortic space. FEVAR requires minimal intra-aortic space, but precise longitudinal and rotational positioning, because each opening must match the ostium of the target artery. BEVAR is less dependent on exact ostial matching but still requires appropriate orientation in relation to the target vessel. However, more intra-aortic space is required for branch positioning, fixation and normal function.(19)

Bridging stents connect the main aortic endograft to the visceral arteries and maintain organ perfusion after the repair (20). Their stability mainly depends on appropriate diameter selection, adequate overlap, correct orientation, and minimization of tension(21,22). Target vessel anatomy, with sharp angles, small diameter, or calcification, may render bridging stent placement challenging (22).

CTA is the gold standard for TAAA diagnosis and preoperative planning. It is used to evaluate the extent of the aneurysm, vessel anatomy, and the presence of dissection. Operative planning is based on measurements of aortic diameters and assessment of proximal and distal landing zones. Important characteristics of visceral arteries are obtained as well, including diameters, angulation, and spatial arrangement. Assessment of the access vessels for sufficient size and absence of calcification, thrombus, or occlusion is also routinely performed preoperatively.

The next step after the technical feasibility of the operation has been assessed is device selection. This depends on whether the patient’s anatomy requires a patient-specific graft, an off-the-shelf configuration, or a physician-modified endograft.

4.3 DEVICE PLANNING AND DEVICE TYPES

Custom-made devices are designed according to the individual patient's anatomy, so their main advantage is anatomical precision. The position of fenestrations or branches can be adapted to the exact location of the celiac trunk, superior mesenteric artery, and renal arteries. Additional modifications may also be used in complex anatomy, such as unusual spacing between target vessels, accessory renal arteries, difficult vessel orientation, or large changes in aortic diameter along the planned repair segment. (23)

The main limitation of custom-made devices is manufacturing time. Production may take several weeks, making them unsuitable for rapidly expanding, ruptured, or otherwise urgent TAAA cases (24). Therefore, custom-made devices are most appropriate in elective cases. Better anatomical fit outweighs the risk of waiting for a clinically stable patient.

Off-the-shelf branched devices are manufactured in advance and are not patient-specific. Their main advantage is rapid availability, which makes them useful in urgent or semi-urgent cases when treatment delay would increase patient risk. These devices usually have a standardized configuration designed to incorporate the main visceral and renal arteries (25).

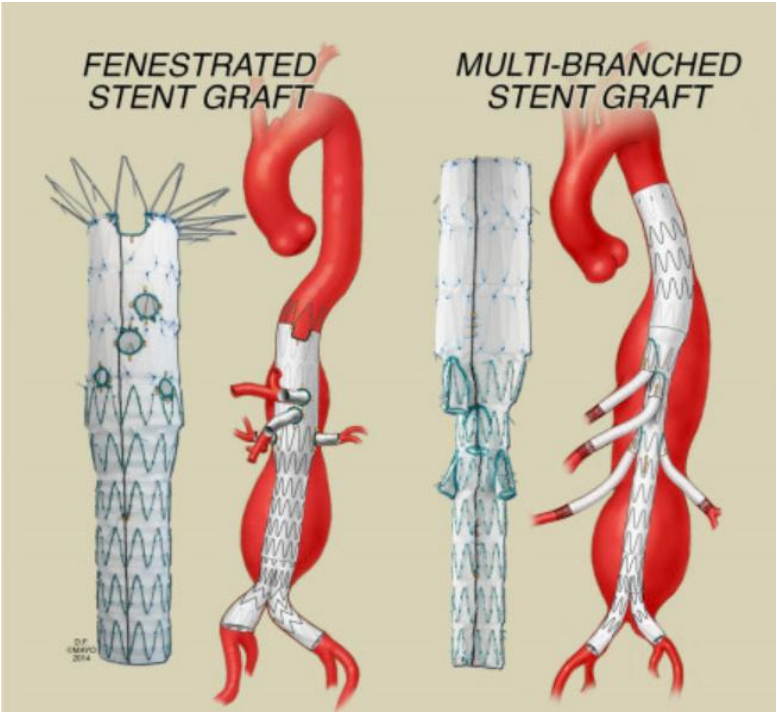
The main limitation is that the branch positions are fixed. Therefore, the patient's anatomy must fit the available device. Off-the-shelf devices may be unsuitable when visceral vessels are very close together, arise at unusual angles, or do not match the standard branch orientation.

Physician-modified endografts are another option when no suitable manufactured device is available. In this approach, a commercially available endograft is modified by the operating team before implantation. Fenestrations or branches can be created or changed according to the patient's anatomy. This gives more flexibility than a standard off-the-shelf device, while still avoiding industrial production time.

However, PMEGs also have important limitations. Their preparation depends strongly on operator experience and institutional protocols. Unlike commercially manufactured grafts, they are not produced through the same standardized industrial process. Therefore, there are remaining concerns about reproducibility, quality control, regulatory status, and long-term reliability. For this reason, PMEGs should not be considered equivalent to approved manufactured devices (26).

In practice, off-the-shelf devices and PMEGs address different clinical needs. Off-the-shelf devices are useful when rapid treatment is required and the available design is suitable. PMEGs are more adaptable,

but depend more on local expertise and technical control. Their use is therefore usually limited to selected patients in experienced centers when manufactured options are not suitable.



. **Figure 2. Schematic depictions of FEVAR and BEVAR**

Technical limitations in endovascular TAAA repair are not only related to graft design (23). They may also occur during accesss and device delivery. Narrow, calcified, or tortuous iliac arteries can make introduction of large sheaths difficult (27). In some patients, access vessel problems may limit safe device delivery or require additional preparatory procedures (28).

The condition of the aorta itself can also create procedural difficulties (23). Extensive thrombus or calcification may increase the risk of embolization and interfere with safe device manipulation (29,30). A narrow aortic lumen may reduce the working space inside the vessel and make catheter movement more difficult during the procedure (31,32) .

Implantation can also become difficult during the operation, especially the anatomy does not provide stable support for wires and catheters. These problems may increase procedure time and technical difficulty. They can also increase radiation exposure for the patient and operating team. Contrast load is another limitation, especially in patients with impaired renal function (33,34). Also endovascular TAAA repair often requires repeated angiography to guide device positioning (35).

4.4 SPINAL CORD ISCHEMIA

The spinal cord is supplied by the anterior and posterior spinal arteries, as well from intercostal and lumbar branches. The artery of Adamkiewicz is usually located between T8 and L2 vertebrae and it is the main contributor to lower spinal cord perfusion. Endovascular TAAA repair may interrupt part of this segmental and collateral circulation. Therefore, measures for maintaining perfusion and preserving collateral flow should be taken.(36)

Staged repair is one of the strategies used to reduce the risk of SCI in extensive FEVAR/BEVAR. The repair is divided into separate steps, so that spinal cord collateral circulation has time to adapt (37). One approach to staging involves stenting part of the aorta in one procedure and completing fenestrated or branched stent implantation in another operation. Another approach includes formation of controlled endoleak in the first stage, for example by delaying completion of one branch, bridging stent, or iliac limb (38). It keeps temporary blood flow to intercostal or lumbar arteries before final exclusion. This controlled endoleak is closed during a second stage(23). However, this strategy is used only in selected high-risk cases, as it requires another intervention and it is related to risks of non-excluded aneurysm.

Another approach for SCI prevention is CSF drainage. Lowering CSF pressure can improve spinal cord perfusion pressure, because perfusion is influenced by both arterial pressure and pressure within the spinal canal. In high-risk patients, CSF pressure is often maintained below approximately 10–15 mmHg. Adequate blood pressure control is also important. Systemic hypotension can lead to spinal cord hypoperfusion after repair. Therefore, MAP is usually maintained at least around 90 mmHg in the early postoperative period, with higher targets such as 90–100 mmHg used when neurological deficit is suspected (39,40)

5. LITERATURE REVIEW RESULTS

5.1 FIRST PROOF-OF-CONCEPT AND EARLY CLINICAL FEASIBILITY STUDIES

First, Chuter et al. and Anderson et al. showed that total endovascular TAAA repair was technically possible. However, the evidence was still based on very small and selected patient groups (7,41).

Later series showed that endovascular repair could be performed in high-risk patients, often not suitable for open surgery, with acceptable outcomes in terms of technical success and early mortality. However, the authors highlighted that the operation was technically demanding, with a learning curve and a need for thorough operative planning and postoperative patient surveillance (42–45).

The studies by Haulon, Clough, and Guillou included larger institutional populations with longer follow-up. These papers supported the idea that FEVAR/BEVAR could be a less invasive alternative to open TAAA repair in selected high-risk patients, with results comparable to open surgical approach. These studies showed the need for long-term data on durability, reintervention, branch patency, and spinal cord or renal complications (46–48)

5.2 EARLY TECHNICAL F/BEVAR STUDIES

Early repairs were mainly based on custom-made grafts. This ensured best anatomical fit, but it also made treatment dependent on manufacturing time. Sweet et al. evaluated whether a standardized off-the-shelf multibranched stent-graft could be used instead of fully customized grafts. Analysis of the anatomy of 66 patients referred for endovascular, showed that 58 patients (88%) were suitable for repair with the standardized graft. This study showed that many patients who would previously need custom-made devices could potentially be treated with a pre-made design, which could reduce treatment delay (49).

Chuter et al. then compared outcomes of custom-made and standardized multibranched thoracoabdominal stent-grafts. The study included 28 patients treated between 2008 and 2010, with 14 custom-made grafts and 14 standardized grafts. All stent-grafts were implanted successfully, and there were no perioperative deaths. There were no significant differences between the two groups in operative time, fluoroscopy time, contrast use, blood loss, branch angle, or branch length. These results showed that custom and standardized grafts implantation were of similar procedural complexity and similar early outcomes (50).

Further development of standardized grafts is reflected in publications reporting early and intermediate results of physician-modified grafts and off-the-shelf grafts.

Reily et al. study evaluated PMED and manufactured grafts with the caudally directed cuff. This study included 81 patients with TAAA or pararenal aneurysms and included 306 implanted branches. All devices and branches were successfully inserted and deployed. Overall mortality was 6.2%, including 3.7% perioperative mortality and 2.5% late treatment-related mortality. Permanent paraplegia occurred in 3.7%, transient paraplegia or paraparesis in 19.8%, and postoperative dialysis in 4.9%. During a mean follow-up of 21.2 months, no aneurysm ruptures occurred. Primary branch patency was 94.8%, and primary-assisted patency was 95.1%. However, 32 patients, or 39.5%, required reintervention, most often because of access complication, endoleaks, branch stenosis or occlusion (51).

Sweet et al. reported initial experience with physician-modified fenestrated-branched endografts for TAAA repair. This study included 24 consecutive patients with TAAA and 88 intended target vessels. Target-vessel stenting was successful in 84 vessels, or 95.5%. Treatment success was reported in 21 patients (88%), at a mean follow-up of 11 months. Thirty-day mortality was 4%, with one SCI complication-related death. One additional patient, died 4 months after the operation after prolonged postoperative recovery. One patient recovered after the operation, however with permanent SCI. One renal reintervention was required during follow-up. No device failures were reported (52).

Overall, these studies showed the transition from patient-specific custom-made grafts toward more standardized multibranched repair.

5.3 CLINICAL OUTCOMES FROM PROSPECTIVE AND STRUCTURED FEVAR/BEVAR STUDIES

5.3.1 EARLY STRUCTURED FEVAR/BEVAR EVIDENCE

The studies by Eagleton, and Schanzer reported more structured outcomes for manufactured FEVAR/BEVAR.

Schanzer et al. reported 100 endovascular aneurysm repairs from one center. However, the cohort included mixed aneurysm types: 4 common iliac artery aneurysms, 42 juxtarenal aneurysms, 18 pararenal aneurysms, and 36 TAAA cases. Among the TAAA cases, there were type I (n = 1), type II (n = 4), type III (n = 12), type IV (n = 18), and arch aneurysm (n = 1) cases. Technical success was achieved in 89% of patients. The 30-day mortality was 3%. Other 30-day events included target artery occlusion in 6%, renal failure requiring dialysis in 5%, access complications in 8%, paraparesis in 1%, and bowel ischemia in 1%. There were no cases of myocardial infarction, paralysis, or stroke. At 1 year, survival was 87%, freedom from type I or III endoleak was 97%, target-vessel patency was 92%, and freedom from aortic rupture was 100%. (53).

Eagleton et al. reported 354 high-risk patients with type II and III TAAA. This cohort included 1305 fenestrations/branches and 96% of target vessels were successfully stented. Perioperative mortality was higher after type II repair than after type III repair, 7.0% vs 3.5% correspondingly. Permanent SCI occurred in 4% of patients, renal failure requiring hemodialysis in 2.8%, and 27 branches (7.6%) required reintervention for stenosis or occlusion. At 36 months, freedom from aneurysm-related death was 91%, while freedom from all-cause mortality was 57% (54).

5.3.2 US PHYSICIAN-SPONSORED IDE EXPERIENCE

Several publications from the Oderich et al report fenestrated-branched EVAR experience.

2017 publication reports 185 consecutive patients treated from 2007 to 2013. It included PMEG and off the shelf devices. Technical success was 94%. The 30-day mortality was 4.3%, with lower mortality for extent IV TAAA than for extent I–III TAAA, 1.8% vs 8.2%. Early major adverse events occurred in 32% of extent IV cases and 36% of extent I–III cases. At 5 years, survival was 56% for extent IV and 59% for extent I–III TAAA, while freedom from any reintervention was only about 50% in both groups. Primary target-vessel patency was 93% at 5 years (55).

In another prospective nonrandomized study, Oderich et al. included 127 patients with pararenal aneurysms or TAAA treated with manufactured F-BEVAR devices, with supraceliac sealing zones. The study included 47 pararenal aneurysms, 42 extent IV TAAA, and 38 extent I–III TAAA. A total of 496 renal-mesenteric arteries were incorporated, and technical success of target-vessel incorporation was 99.6% (493/496). There were no 30-day or in-hospital deaths, no dialysis, no rupture, and no conversion to open repair. Major adverse events occurred in 27 patients (21%). At 1 year, primary and secondary target-vessel patency were 96% and 98%, and patient survival was 96% (18).

Another study by Oderich et al. included 430 patients, with 133 pararenal aneurysms and 297 TAAAs. In this study custom-made F/B grafts and off-the-shelf t-Branch grafts were used. In total, 1673 visceral arteries were incorporated. The 30-day mortality was 0.9% (4 deaths). New dialysis was required in 2%, permanent paraplegia occured in 2%, and stroke in 2%. After a mean follow-up of 26 months, there were 3 aortic-related deaths. At 5 years, freedom from all-cause mortality was 57%, freedom from aortic-related mortality was 98%. Primary target-vessel patency was 94%, however freedom from secondary intervention was 64% (56).

5.4 MULTICENTER EXPERIENCE

Randomized evidence in TAAA repair is very difficult to obtain. Therefore, registries are important for evaluating outcomes and real-world results of FEVAR and BEVAR. Although this is not the highest level of evidence, it still supports the hypothesis that endovascular repair can be effective in selected patients.

5.4.1 F-BEVAR EUROPEAN REGISTRIES

This section focuses on included publications that reported exclusively F/BEVAR outcomes. Publications reporting mixed cohorts of open, hybrid, and endovascular TAAA repair will be discussed in a separate section.

The Italian Multicenter Fenestrated and Branched registry reported by Gallitto included 596 patients treated in four Italian university centers from 2008 to 2019. TAAA group included 351 patients, juxtarenal aneurysm group included 124 patients, and pararenal aneurysm group included 121 patients.. Most procedures were elective, with 520 elective cases and 76 urgent cases. The main outcomes were perioperative mortality, major complications, target visceral vessel patency, reintervention, and survival. Perioperative mortality was 5%. SCI occurred in 47 patients (8%), and permanent paraplegia occurred in 17 patients (3%). Postoperative cardiac, pulmonary, and renal complications occurred in 7%, 8%, and 13% of patients, respectively. During follow-up, freedom from target visceral vessel occlusion was 96% at 1 year and 93% at 3 years. Freedom from reintervention was 92% at 1 year and 85% at 3 years. Overall survival was 88% at 1 year and 78% at 3 years. TAAA anatomy, post-dissection TAAA, and bowel ischemia were associated with a higher risk of reintervention (57).

The Swedvasc registry study reported by Yu et al included 339 patients treated with endovascular TAAA repair in Sweden from 2018 to 2023. The study used data from the Swedish Vascular Registry and included all national endovascular TAAA repairs during this period. There were 235 elective and 104 emergency patients. Most procedures were concentrated in a small number of centers, with 94.4% performed in five centers. The main outcomes were early mortality, major complications, thoracoabdominal aortic life-altering events (TALEs), SCI, renal failure, and midterm survival (58).

In the elective group, 30-day, 90-day, and 1-year mortality were 2.6%, 3.5%, and 12.4%, respectively. Major complications occurred in 16.2%, vascular complications in 9.8%, and TALEs in 14%. SCI occurred in 8.1% and renal failure in 4.7%. Estimated survival after elective repair was 89.3% at 1 year and 73.5% at 4 years.

In the emergency group, 30-day, 90-day, and 1-year mortality were 12.5%, 17.6%, and 26.9%, respectively. Major complications occurred in 20.2%, vascular complications in 12.5%, and TALEs in 24%. SCI occurred in 8.7% and renal failure in 9.6%. Estimated survival after emergency repair was 75.2% at 1 year and 56.5% at 4 years. During the study period, SCI decreased from 20% to 2.3%, while prophylactic spinal drainage also decreased from 68% to 14%.(58)

Findings of these studies are summarized in the Table 3.

Table 3. European registries F/BEVAR outcomes.

Study / country / source	Pts	30-d / early mortality	Long-term mortality / survival	SCI / paraplegia	Comments
IMF&B Gallitto 2021, Italy,	596 F/B, incl. 351 TAAA	Periop: 5%	Survival: 88% at 1 y, 78% at 3 y	SCI 8%; permanent paraplegia 3%	good TVV patency, high reinterventions rates
Yu 2026, Sweden, Swedvasc	339 pts / 476 repairs: 235 elective, 104 emergency	- 2.6% elective, - 12.5% eergency	1-y mort.: 12.4% elective, 26.9% emergency. 4-y surv.: 73.5% elective, 56.5% emergency	SCI: 8.1% elective, 8.7% emergency	

5.4.2 US AORTIC CONSORTIUM

One of the largest long-term evidence on elective F/B-EVAR comes from the analysis of the US Aortic Research Consortium dataset. Oderich et al analyzed data from a prospective multicenter cohort study, based on eight nonrandomized physician-sponsored IDE studies (NCT02089607, NCT02050113, NCT02266719, NCT02323581, NCT00583817, NCT01654133, NCT00483249, NCT02043691, and NCT01874197) (59).

Analysis included 1,109 patients after elective F/B-EVAR for asymptomatic intact TAAA. The study period was from January 1, 2005, to June 30, 2020. This study was mainly focused on aortic-related mortality and aortic rupture after F/B-EVAR. Patients were excluded from the analysis if they had symptomatic or ruptured TAAA, or genetic aortic disease. In total, 589 patients had extent I–III TAAA and 520 had extent IV TAAA according to Crawford classification. Patient-specific devices were used in 962 patients, while off-the-shelf multibranched stent grafts were used in 147 patients. Reported technical success was 96.2%.

Early mortality was 2.7%, and early aortic rupture occurred in 0.4% of patients. Early major adverse events occurred in 20.4%. Any SCI was reported in 8.7%, paraplegia in 5.1%, permanent paraplegia in 2.7%, and permanent SCI in 3.1%. Other early complications included acute kidney injury in 10.0%, stroke in 2.7%, new-onset dialysis in 2.0%, and bowel ischemia in 1.2%. Early TAAA life-altering

events, which were defined as death, permanent SCI, permanent dialysis, or stroke, occurred in 7.8% of patients.

At 5 years, cumulative aortic-related mortality was 3.8%, and cumulative aortic rupture was 2.7%. Patients with extent I–III TAAA had higher risk for late aortic-related mortality and late rupture. However, the all-cause mortality was much higher, reaching 45.7% at 5 years, and secondary interventions were needed in 40.3% of patients. Target-vessel patency was not stated in the outcomes in this paper.

This publication is unique, as it includes a substantial cohort of patients that underwent elective endovascular TAAA repair. It focuses mainly on aortic-related mortality and rupture related outcomes. It also reports a long follow-up period on F/B-EVAR outcomes. This study supports successful long-term endovascular aneurysm exclusion, with low aortic-related death and rupture. However, it highlights the fact that these patients remain medically fragile, reflected by high general mortality, and necessity of long-term surveillance and frequent reintervention. It is important to mention that as this study is prospective and non-randomized, interpretation is limited by patient selection, elective-only treatment in experienced centers (59).

5.4.3 OUTCOMES DIFFERENCES IN HOSPITALS

These real-world studies show that F/BEVAR outcomes are influenced by center experience, case complexity, device use, and follow-up systems. Overall, this evidence suggests that centralized care in experienced centers may be beneficial for improving outcomes after complex F/BEVAR.

Hawkins et al. analyzed the Vascular Quality Initiative Thoracic Endovascular Aortic Repair / Complex EVAR database (60). The main goal of the study was to compare center-level outcomes after elective F/BEVAR. The study included 4,302 procedures performed in 163 centers between 2014 and 2021. Centers were divided into four quartiles according to their mean annual procedure volume. Q1 represented the lowest-volume centers, Q2 and Q3 represented intermediate-volume centers, and Q4 represented the highest-volume centers. The number of patients was similar between groups.

In-hospital mortality was not significantly different between quartiles and was ~3.3% overall. One-year survival was also not significantly different between center-volume groups and was 89.4% overall.

However, the study showed that major complication rates varied between quartiles. Major complications were statistically significantly more frequent in the highest-volume quartile. Reported rates were 14.9% in Q1, 12.8% in Q2, 13.3% in Q3, and 20.1% in Q4 with adjusted $p < 0.001$.

Importantly, PMEGs were used statistically significantly more often in higher-volume centers, especially in Q2 and Q4. At the same time, endoleaks at the end of the procedure was less common in higher-volume centers: 34.9% in Q1, 32.8% in Q2, 30.0% in Q3, and 29.0% in Q4, p = 0.003.

This study showed that outcomes are dependent on center experience, case complexity, use of physician-modified devices, and local follow-up systems. The study did not show a clear mortality advantage for higher-volume centers. However, it might be related to the fact that higher-volume centers accept more complex cases, reflected by more frequent use of PMEGs. Results of the study are summarized in the Table 4.

Table 4. Outcomes differences in hospitals stratified by volume of procedures.

Outcome / variable	Overall	Q1: very-low volume	Q2: low volume	Q3: medium volume	Q4: high volume	P value
Mean annual center volume	163 centers	<4 cases/year	>4 to <9 cases/year	>9 to <15 cases/year	>14 cases/year	NA
Patients / procedures	4,302	1,059	1,063	1,120	1,060	NA
In-hospital mortality	142/4,302; 3.3%	35/1,059; 3.3%	30/1,063; 2.8%	33/1,120; 2.9%	44/1,060; 4.2%	p = 0.308
Major complications	15.2%	14.90%	12.80%	13.30%	20.10%	adjusted p < 0.001
Any complication	19.0%	18.00%	15.90%	16.60%	25.10%	p < 0.001
Physician-modified graft use	13.4%	4.50%	18.70%	11.30%	19.20%	p < 0.001
Endoleaks at end of procedure	31.7%	34.90%	32.80%	30.00%	29.00%	p = 0.003
1-year survival / mortality	89.4%	89%	90.3%	90.1%	88.3%	P = 0.298

Zettervall et al. assessed whether outcomes after F/BEVAR differed between IDE and non-IDE hospitals(61). The study included 8,017 Medicare patients treated with F/BEVAR in 549 hospitals between 2016 and 2023. In total, 2,226 procedures (27.8%) were performed in hospitals with an IDE program, while 5,791 procedures were performed in hospitals without an IDE program. IDE hospitals had much higher annual case volume (22.3 vs 1.2 cases per year, $p < 0.001$). IDE hospitals also treated more complex cases. TAAA rates were 54.0% of IDE cases and 20.1% of non-IDE cases. Four-vessel F/BEVAR was performed in 62.9% vs 22.3%, $p < 0.001$.

Thirty-day mortality was lower in IDE hospitals, 3.0% vs 4.9%. After adjustment, treatment in an IDE hospital remained associated with lower 30-day mortality, with adjusted odds ratio 0.47 (95% CI 0.32–0.69). Crude 3-year mortality was similar between groups, 26.0% vs 27.1%. However, adjusted midterm mortality was lower in IDE hospitals, with adjusted hazard ratio 0.81 (95% CI 0.69–0.95). In the four-vessel F/BEVAR subgroup, 30-day mortality was 2.4% vs 5.0%.

Results of the study are reported in the Table 5.

Table 5 . Outcomes differences in IDE and non-IDE hospitals

Outcome	IDE hospitals	Non-IDE hospitals
Annual case volume	22.3/year	1.2/year
TAAA cases	54.00%	20.10%
Four-vessel F/BEVAR	62.90%	22.30%
30-day mortality	3.00%	4.90%
Adjusted 30-day mortality	OR 0.47	Reference
Crude 3-year mortality	26.00%	27.10%
Adjusted midterm mortality	HR 0.81	Reference
30-day mortality four-vessel subgroup	2.40%	5.00%

This study showed that F/BEVAR outcomes were better in IDE hospitals despite case complexity. It supports the importance of experience, case volume, device access, and outcome monitoring in complex endovascular aortic repair (61).

5.4.4 DEVICE SPECIFIC F/BEVAR EVIDENCE

The Cook Zenith platform is the most widely reported device family in TAAA F/BEVAR studies. This includes custom-made fenestrated-branched grafts and the off-the-shelf Zenith t-Branch. However, newer devices, such as E-nside, are also increasingly reported.

The study reported by Kölbel et al included 542 patients treated with the Zenith t-Branch off-the-shelf multibranched stent graft between 2014 and 2019. Majority (90%) of the patients had TAAA. Urgent

cases composed 37% of the reported patients. Thirty-day mortality was 12.3% overall, including 8.5% in elective patients, 15% in symptomatic patients, and 30% in contained rupture. SCI occurred in 10.5%, including permanent SCI in 4%. Technical success was 97% and early target vessel patency was above 99%. The endoleak I and III rates were both 2.7%. Long term mortality is not reported in this study (62).

The INBREED registry reported by Piazza et al included 206 patients treated with the E-nside off-the-shelf inner-branched graft. The cohort included 111 TAAA patients and 95 patients with complex abdominal aortic aneurysms. Urgent repair was performed in 28.6% of cases. In the early-outcomes analysis, 90-day mortality was 5.2% overall, including 2.1% after elective repair and 16% after urgent repair. At 2 years, overall survival was 90.3%, freedom from aortic-related death was 96%, freedom from target vessel instability was 95.9%, and freedom from reintervention was 98%. Renal artery primary patency was 96.1% (63,64).

The B.R.I.O. study reported by Piazza et al included 163 TAAA patients from 2020 to 2023. This multicenter retrospective study compared the inner-branched E-nside device with the outer-branched Zenith t-Branch device. 79 patients were treated with E-nside and 84 with t-Branch. 30-day mortality was 1% and 2%, respectively. Major adverse events occurred in 18% and 21%, and elective SCI in 5% and 8%. At 1 year, freedom from target vessel instability was 96% after E-nside and 95% after t-Branch. The study showed similar outcomes between the devices, with low early mortality and comparable rates of adverse events (65).

The EXTENT study by Abisi et al included 260 patients treated with EDE-iBEVARs. The cohort included 116 TAAA, 95 suprarenal or juxtarenal aneurysms, and 49 previous open repair or EVAR failures. Endograft and target vessel branches deployment was successful in 98% for both. At 3 years, freedom from aneurysm-related mortality was 97%, freedom from all-cause mortality was 89%, and freedom from reintervention was 76%. SCI occurred in 12 patients (5%), with complete paraplegia in 4 patients. Late branch occlusion occurred in 1.5% of branches (66).
Summary of the device-specific studies can be found in Table 6.

Table 6. Outcomes of device-specific studies.

Study	Device	Patients	Mortality / survival	SCI	Durability
Kölbel 2021	Zenith t-Branch	542; 90% TAAA	30-d mortality 12.3%	SCI 10.5%; permanent 4%	Early TV patency >99%
INBREED / Piazza 2025	E-nside	206; 111 TAAA	2-y survival 90.3%; ARM-free 96%	NR	Reintervention-free 98%; renal patency 96.1%
B.R.I.O. / Piazza 2024	E-nside vs t-Branch	163 TAAA	30-d mortality 1% vs 2%	SCI 5% vs 8%	1-y TV instability-free 96% vs 95%
EXTENT / Abisi 2024	EDE-iBEVAR	260; 116 TAAA	3-y ARM-free 97%; survival 89%	5%	Reintervention-free 76%; branch occlusion 1.5%

5.5 OPEN VS ENDOVASCULAR REPAIR

Comparative evidence between open and endovascular TAAA repair based mainly on observational data. No randomized or controlled clinical trials comparing endovascular repair with open surgical repair for TAAA were found during the review. Therefore, the evidence comes from registries, administrative datasets, propensity-matched cohort studies, and meta-analyses of non-randomized studies.

5.5.1 OUTCOMES AND COST EFFECTIVENESS

The WINDOWS registry reported by Michel et al. was one of the first comparative registry studies in France. It compared F/B-EVAR with open surgical repair for complex aortic aneurysms from 2010 to 2012. The study included 1,946 patients, 268 in F/B-EVAR cohort and 1,678 in open repair cohort. The following comparisons refer to F/B-EVAR vs open repair, respectively. Overall, 30-day mortality was not significantly different (6.7% vs 5.4%). F/B-EVAR was more expensive, with costs of €38,212 vs €16,497. After stratification by aneurysm type, outcomes differed between anatomical groups. Mortality was similar for para/juxtarenal aneurysms (4.3% vs 5.8%, p = 0.26) and for supradiaphragmatic (11.9% vs 19.7%, p = 0.70). However, mortality was higher after F/B-EVAR in

infradiaphragmatic TAAA (11.9% vs 4.0%, p = 0.010). Costs were also different between aneurysm groups, although F/B-EVAR was more expensive overall (67).

Another early comparative study did not include a cost analysis, but it provides additional outcome data from a propensity-matched comparison of endovascular and open repair.

Ferrer et al. analyzed 341 patients in three Italian centers from 2007 to 2014. Endovascular repair was performed in 84 patients and open repair in 257 patients. After propensity score matching, 65 pairs were analyzed. The following results refer to endovascular repair vs open repair, respectively. Early mortality did not differ significantly between groups (7.7% vs 6.2%, p = 1). Paraplegia (9.2% vs 10.8%, p = 1), any SCI (12.3% vs 20.0%, p = 0.34), and renal insufficiency (9.2% vs 12.3%, p = 0.78) were also not significantly different. However, respiratory insufficiency was lower after endovascular repair (0% vs 12.3%, p = 0.006), as was the composite early endpoint (18.5% vs 36.0%, p = 0.03). Survival and freedom from reintervention at 24 months were similar between groups(68)

Locham et al. analyzed 879 patients with intact TAAA from a U.S. hospital database. The study included patients from 2009 to 2015. Endovascular repair was performed in 481 patients, and open repair in 398 patients. The following results refer to endovascular repair vs open repair, respectively. In-hospital mortality was also lower after endovascular repair (5% vs 15%, p < 0.001). Hospital stay was shorter after endovascular repair (5 vs 11 days, p < 0.001). Any major complications were significantly less frequent after endovascular repair (29.1% vs 64.1%, p < 0.001). Specific complications were also lower after endovascular repair, including renal failure (13.5% vs 34.7%, p < 0.001), stroke (2.3% vs 6.5%, p = 0.002), paraplegia/SCI (2.9% vs 7.8%, p = 0.001), cardiac complications (13.1% vs 40.0%, p < 0.001), and pulmonary complications (10.2% vs 21.6%, p < 0.001). Interestingly, median total hospital cost was lower after endovascular repair ($36,612 vs $44,355, p = 0.004). However, central supply cost, including endografts and stents, was higher after endovascular repair ($17,472 vs $5,501, p < 0.001) (69).

Canadian population-based date was reported by Rocha et al. The study included 664 patients between 2006 and 2017. Of them 303 were after endovascular repairs and 361 after open repairs. After propensity score matching, 241 pairs were included. The following results refer to endovascular repair vs open repair, respectively. In-hospital mortality was lower after endovascular repair (10.8% vs 17.4%, p = 0.04). Complications (17.4% vs 26.1%, p = 0.02), discharge to rehabilitation facilities (10.0% vs 18.7%, p = 0.02), and hospital stay (6 vs 12 days, p < 0.01) were lower after endovascular repair. Long-term mortality was not significantly different (HR 1.09, 95% CI 0.78–1.50), and 8-year overall survival

was similar (41.3% vs 44.6%, p = 0.62). However, reinterventions were much more common after endovascular repair (HR 2.64, 95% CI 1.54–4.55). A separate cost analysis from the same cohort showed that median total cost at 1 month was higher after endovascular repair in the unmatched cohort (C$64,892 vs C$36,647, p < 0.01) and after propensity matching (C$64,892 vs C$33,605, p < 0.01). Costs from 1 month to 1 year were not significantly different, but among patients alive at 1 year, median total cost remained higher after endovascular repair (C$83,242 vs C$52,003, p < 0.01) (70,71).

The Italian PRO-ENDO TAAA study by Bertoglio et al. compared staged F/B-EVAR with elective open repair in a high-volume center. It included patients from 2013 to 2021. From 789 treated TAAA patients, propensity matching identified 102 pairs. The following results refer to F/B-EVAR vs open repair, respectively. F/B-EVAR was associated with lower early mortality (5% vs 13%, p = 0.048), major adverse events (17% vs 60%, p < 0.001), permanent SCI (3% vs 10%, p = 0.045), respiratory complications (18% vs 91%, p < 0.001), cardiac complications (6% vs 16%, p = 0.024), and renal injury (6% vs 27%, p < 0.001). However, access complications were higher after F/B-EVAR (27% vs 6%, p < 0.001). No differences in survival or reinterventions were observed at 2 years. Interestingly, even though device-related expenses increased the overall cost of F/B-EVAR, endovascular repair was still more cost-effective than open repair when major adverse events were considered (€56,365 vs €64,903 per patient) (72).
Table 7 summarizes the cost of the repair in the discussed analyses.

Table 7. Summary of cost comparison of F/B-EVAR.

Study	Cost, endovascular/F/B-EVAR vs OR
Michel et al., 2015, WINDOWS, France	€38,212 vs €16,497
Locham et al., 2018, Premier Database, USA	$36,612 vs $44,355
Rocha et al., 2021, Ontario cohort, Canada	C$64,892 vs C$33,605
Bertoglio et al., 2023, PRO-ENDO TAAA, Italy	€56,365 vs €64,903

A recent single-center study suggested that F/B-EVAR may have better early outcomes than open repair, but long-term outcomes did not show a clear advantage and may be worse after endovascular repair.

Huang et al. reported a more modern single-center comparison of elective TAAA repair from 2008 to 2020. The study included 504 patients, with 357 in F/B-EVAR group and 147 in open surgical group.

The use of F/B-EVAR increased from 16.7% in 2008 to more than 80% after 2017. The following results refer to F/B-EVAR vs open repair, respectively. Early major adverse events were lower after F/B-EVAR (25.8% vs 49.0%). Early mortality was also lower after F/B-EVAR (2.5% vs 6.8%). In overlap-weighted analysis, F/B-EVAR was associated with lower early major adverse events (aOR 0.28, 95% CI 0.18–0.41, $p < 0.001$) and lower early mortality (aOR 0.35, 95% CI 0.17–0.73, $p = 0.005$). Importantly, 5-year survival estimates were lower after F/B-EVAR than after open repair (52.2% vs 78.0%), but late survival was not significantly different after weighting (HR 1.33, 95% CI 0.74–2.39, $p = 0.34$) (73).

5.5.2 META-ANALYSES

Individual studies report different and sometimes conflicting outcomes. So meta-analyses provide a useful way to summarize comparative evidence. However, their conclusions remain limited, since most data are observational, non-randomized, and heterogeneous. The following section reviews the major meta-analyses comparing open and endovascular TAAA repair.

Rocha et al. 2020 meta-analysis included early outcomes from 71 studies, with 24 endovascular and 47 open repair studies. Endovascular patients were older and had more coronary artery disease, chronic obstructive pulmonary disease, and diabetes. Overall SCI was higher after endovascular repair (13.5% vs 7.4%, $p < 0.01$), but permanent paralysis was similar (5.2% vs 4.4%, $p = 0.39$). Postoperative dialysis was lower after endovascular repair (6.4% vs 12.0%, $p = 0.03$), while permanent dialysis at discharge was similar (3.7% vs 3.8%, $p = 0.93$). Perioperative mortality was not significantly different between endovascular and open repair (7.4% vs 8.9%, $p = 0.21$) (74).

The updated meta-analysis by Vigezzi et al. included 64 studies and compared F/B-EVAR with open repair. Endovascular-treated patients were older and had higher comorbidity. In-hospital mortality was similar after endovascular and open repair (7% vs 9%, $p = 0.22$). Reintervention was higher after endovascular repair (19% vs 13%, $p < 0.01$). Transient SCI was similar (7% vs 6%, $p = 0.28$). Interestingly permanent SCI was lower after endovascular repair (4% vs 6%, $p < 0.01$). Renal injury was also lower after endovascular repair (8% vs 13%, $p = 0.02$). The authors concluded that endovascular repair may be a safer alternative to open repair, but the results were affected by heterogeneity, publication bias, and absence of randomized trials (75).

Table 8. Summary of outcomes in open vs endovascular studies

Study / country / type of study	Pts	30-d / early mortality	SCI / paraplegia
Michel 2015, France, WINDOWS, registry/cost study	268 F/B + 1,678 OR	30-d: 6.7% F/B vs 5.4% OR, p = 0.40	NR
Ferrer 2016, Italy, 3 centres, propensity-matched cohort	341 total; 84 EVAR, 257 OR; 65 matched pairs	Early: 7.7% EVAR vs 6.2% OR, p = 1.00	Paraplegia: 9.2% vs 10.8%, p = 1.00; any SCI: 12.3% vs 20.0%, p = 0.34
Locham 2018, USA, Premier database, administrative cohort/cost study	879 intact TAAA; 481 EVAR, 398 OR	In-hosp: 5% EVAR vs 15% OR, p < 0.001	Paraplegia/SCI: 2.9% vs 7.8%, p = 0.001
Rocha 2021, Canada, Ontario cohort, population-based/cost study	664 total; 303 EVAR, 361 OR; 241 matched pairs	In-hosp: 10.8% EVAR vs 17.4% OR, p = 0.04	NR
Bertoglio 2023, Italy, PRO-ENDO TAAA, propensity-matched cohort/cost-effectiveness study	789 total; 102 matched pairs	Early: 5% F/B vs 13% OR, p = 0.048	Permanent SCI: 3% vs 10%, p = 0.045
Huang 2025, single-centre cohort	504 total; 357 F/B-EVAR, 147 OR	Early: 2.5% F/B-EVAR vs 6.8% OR; weighted aOR 0.35, p = 0.005	NR
Rocha 2020, systematic review/meta-analysis	71 studies; 24 EVAR, 47 OR	Periop: 7.4% EVAR vs 8.9% OR, p = 0.21	SCI: 13.5% vs 7.4%, p < 0.01; permanent paralysis: 5.2% vs 4.4%, p = 0.39
Vigezzi 2024, systematic review/meta-analysis	64 studies	In-hosp: 7% F/B vs 9% OR, p = 0.22	Transient SCI: 7% vs 6%, p = 0.28; permanent SCI: 4% vs 6%, p < 0.01

Overall, the literature suggests that endovascular repair is often associated with better early perioperative outcomes, shorter hospital stay, and fewer respiratory or renal complications. However, these advantages are partly influenced by patient selection, center expertise, anatomical extent, and study design. Long-term survival is not consistently superior after endovascular repair, and several studies report higher rates of reinterventions after endovascular operations. Therefore, the available evidence supports F/B-EVAR as an important alternative to open repair in selected patients, but it does not establish universal superiority of one approach for all TAAA patients.

5.6 OPEN VS ENDOVASCULAR VS HYBRID TAAA REPAIR

Some comparative studies also include hybrid repair. The following section reviews the largest publications.

The German DRG microdata study by Geisbüsch et al. used nationwide hospital data from 2005 to 2014. It included 2,607 TAAA patients, with 856 F/B-EVAR, 1,422 open repairs, and 354 hybrid repairs. The use of endovascular repair increased during the study period, from 6% in 2005 to 76% in 2014. In-hospital mortality was 10.6% after F/B-EVAR, 23.9% after open repair, and 30.9% after hybrid repair. F/B-EVAR was associated with lower mortality than open repair. Rupture, older age, comorbidity, and lower hospital volume were associated with higher mortality(76).

The Swiss DRG study by Stoklasa et al. included 885 TAAA cases from 2009 to 2018. F/B-EVAR was used in 44.2% of cases, open repair in 39.5%, and hybrid repair in 9.8%. In non-ruptured TAAA, hospital mortality was similar between the three groups: 6.6% after F/B-EVAR, 7.4% after open repair, and 7.6% after hybrid repair. Acute paraplegia was 2.6%, 5.2%, and 5.1%, respectively. However, dialysis was highest after hybrid repair, 20.3%, compared with 6.0% after F/B-EVAR and 8.7% after open repair (77).

Arnaoutakis et al. reported a smaller single-centre comparison of extent II and III TAAA. The study included 198 patients: 92 treated with FEVAR, 40 with hybrid repair, and 66 with open repair. Thirty-day mortality was 4% after FEVAR, 13% after hybrid repair, and 12% after open repair. Permanent SCI was similar between groups, with 3% after FEVAR, 3% after hybrid repair, and 6% after open repair. In adjusted analysis, open repair had a higher early mortality risk than FEVAR. However, survival at 1 and 5 years was not significantly different. Five-year survival was 55% after FEVAR, 60% after hybrid repair, and 59% after open repair (78)

The network meta-analysis by Liu et al. compared open, endovascular, and hybrid repair. It included 11 comparative studies, with 2,222 open repairs, 1,574 endovascular repairs, and 537 hybrid repairs. Endovascular repair had lower one-month mortality than open repair and hybrid repair. It also had lower renal complication rates than both other approaches. Long-term survival was not significantly different between the three strategies(79).

Muston et al. reviewed staged TAAA repair, including open, endovascular, and hybrid approaches. However, this evidence should be separated from the main comparison, because it focused on staged repairs. In this review, SCI was highest after staged endovascular repair, while 30-day mortality was highest after staged open repair. Therefore, it can be mentioned only if staged repair is discussed separately(80).

Overall, these studies support the findings from the open vs endovascular section. F/B-EVAR often shows better early outcomes than open repair and hybrid repair, especially for early mortality and renal complications. Hybrid repair may still be useful in selected patients, but the available evidence does not show advantage over F/B-EVAR. The results are limited by patient selection, center experience, aneurysm extent, and the mix of elective and ruptured cases.

Table 9. Summary of publications comparing open, endovascular and hybrid TAAA repairs.

Study / country / source	Pts	30-d / early mortality	SCI / paraplegia	Comments
Geisbüsch 2019, Germany, national DRG study	2,607 TAAA: 856 F/B, 1,422 OR, 354 hybrid	In-hosp: 10.6% F/B, 23.9% OR, 30.9% hybrid	NR	Hybrid had highest early mortality.
Stoklasa 2023, Switzerland, national DRG study	885 TAAA: 44.2% F/B, 39.5% OR, 9.8% hybrid	Non-ruptured: 6.6% F/B, 7.4% OR, 7.6% hybrid	Paraplegia: 2.6% F/B, 5.2% OR, 5.1% hybrid	Similar mortality; dialysis highest after hybrid.
Arnaoutakis 2020, USA, single-centre retrospective cohort	198 extent II/III TAAA: 92 FEVAR, 40 hybrid, 66 OR	30-d: 4% FEVAR, 13% hybrid, 12% OR	Permanent SCI: 3% FEVAR, 3% hybrid, 6% OR	Lower early mortality after FEVAR.
Liu 2023, systematic review and network meta-analysis	4,333 total: 1,574 EVAR, 2,222 OR, 537 hybrid	1-mo mortality lower with EVAR vs OR and hybrid	NR / pooled complications	EVAR had better early results.
Muston 2023, systematic review/meta-analysis of staged repair	924 staged TAAA repairs	30-d: 3.6% endovascular, 3.8% hybrid, 6.0% open	SCI: 9.8% endovascular, 3.2% hybrid, 1.4% open	Only for staged repair context.

6. DISCUSSION

Endovascular TAAA repair emerged as a less invasive alternative for patients unsuitable for open repair. The first important step in development was done by Chuter et al. and Anderson et al. They showed that branched endovascular grafts are technically feasible for TAAA repair (7,41). These studies proved that TAAA repair could be performed without open operation.

Later publications showed that FEVAR and BEVAR could be used in high-risk patients. However, technical limitations of the method became clearer. These included extensive perioperative planning, precise device positioning, and long-term follow-up. Therefore, the early evidence showed feasibility but also showed a strong dependence on center experience(42–44).

Another important step was the development of standardized/off-the-shelf devices. Manufacturing time of custom-made grafts limits their use to elective cases. Sweet et al. and Chuter et al. showed that standardized multibranched designs could be suitable for many patients and could be used in time sensitive cases (49,50).

Experience and development of the endovascular TAAA grafts made TAAA repair accessible for broader population. PMEGs devices improved availability of endovascular approaches even more. However, their use is heavily related to center and operator expertise. Therefore, PMEGs may be useful when manufactured devices are not available, but they may raise questions about reproducibility, quality control, and durability.

Generally available evidence supports F/BEVAR for TAAA repair. In the US Aortic Research Consortium cohort of 1,109 elective F/B-EVAR patients, technical success was 96.2%, early mortality was 2.7%, and early aortic rupture occurred in 0.4%. At 5 years, aortic-related mortality was 3.8% and cumulative rupture was 2.7 (59). Comparative observational studies suggest a possible early mortality advantage of endovascular repair over open repair, with reported mortality differences such as 5% vs 15%, 10.8% vs 17.4%, 5% vs 13%, and 2.5% vs 6.8% in different cohorts (69,70,73).

However, endovascular TAAA repair is still associated with serious complications. In large studies, reported complications include SCI, renal injury, endoleaks, target-vessel patency, and reintervention. In the US Aortic Research Consortium cohort, any SCI occurred in 8.7%, permanent SCI in 3.1%, acute kidney injury in 10.0%, and new dialysis in 2.0% (59). Other studies reported type I/III endoleak rates around 2.7 (62). Target-vessel patency was usually high, reaching 92–99% in selected reports (53,62). Reintervention remains a major limitation, ranging from high freedom from reintervention in

some device-specific studies to secondary interventions in 40.3% of patients at 5 years in the US Aortic Research Consortium cohort(59,64).

SCI is one of the most serious complications after endovascular repair. While several preventive strategies exist (staged repair, CSF drainage, and maintenance of spinal cord perfusion), SCI rates are still high. In the Swedvasc registry, SCI occurred in 8.1% of elective and 8.7% of emergency endovascular TAAA repairs(58). However, the same registry showed a decline in SCI from 20% to 2.3% during the study period, suggesting that modern practice may reduce occurrence of this complication. There is an evident difference in outcomes between single and multiple staged repairs outcomes. However the comparative evidence is very limited and reported SCI rates vary greatly (80).

Endovascular repair is often better suited for older and high-risk patients. It avoids thoracoabdominal exposure, aortic cross-clamping, and major physiological stress. The choice should not depend only on technical feasibility of F/BEVAR. Age, comorbidities, life expectancy, anatomy, genetic diseases and possible reinterventions should be considered (17,23). This is proved by current review evidence that the open and endovascular approaches should be viewed as complementary rather than as direct replacements for each other.

Urgency is another important factor. Elective endovascular repair allows more time for planning, device selection and production, and staged treatment. It is not possible in urgent cases. Studies with off-the-shelf branched devices show that urgent TAAA repair can be technically successful, though mortality is worse in comparison with elective cases. Comparative evidence with urgent open repairs is also limited (62,81).

Post-dissection TAAA is also a special anatomical subgroup. These patients may have a narrow true lumen, a dissection septum, different origins of visceral arteries, and more complex landing zones. Because of this, F/BEVAR in post-dissection aneurysms is technically more demanding than in degenerative aneurysms. Recent evidence suggests that endovascular repair is feasible in this group. Though more evidence is needed (82–84).

In comparison with open repair endovascular is more expensive. While there were a hypothetis that due to shorter stay and operative time it might be less expensive. Cost of the graft, more frequent reinterventions make this procedure more expensive than the open repair.
Cost is another limitation of endovascular TAAA repair. F/B-EVAR may reduce hospital stay and some early complications. Therefore, it may theoretically reduce some hospital-related costs. However, the

procedure requires expensive grafts, bridging stents, repeated imaging, long-term follow-up, and often reinterventions. These factors can increase the overall cost. Several studies reported higher costs after endovascular repair, especially when device cost and reinterventions were included (67,70,71).

The evidence is not completely consistent. Some studies suggest that shorter hospitalization and fewer early major complications may compensate the high device cost. In these analyses, F/B-EVAR was not more expensive when early morbidity and major adverse events were included (69,72). However, interpretation is limited because the available studies were performed in different countries and healthcare systems. Some cohorts include patients from much earlier treatment periods. Therefore, results may not differ significantly in comparison with current prices, and follow-up strategies. The economic advantage of endovascular TAAA repair is still unestablished.

TAAA repair outcomes may differ between graft platforms. Devices vary in branch design, anatomical fit, availability, and operator experience. The strongest evidence is available for Cook Zenith custom-made grafts and Zenith t-Branch. Newer devices include E-nside/E-xtra, EDE-iBEVAR and Gore TAMBE(85,86). TAMBE is especially relevant in the US as an off-the-shelf device for TAAA and pararenal aneurysms.

Other systems, such as G-Branch, and fenestrated Anaconda have also been reported, but their evidence is still smaller or less TAAA-specific compared with the most established platforms(87,88). However, their evidence is smaller or less specific to TAAA. Therefore, device-specific outcomes should be interpreted carefully. There is still not enough evidence that one platform might be superior to another (62,65,66).

7. CONCLUSIONS

1. TAAA is a rare but deadly disease. The main clinical problem is the high mortality after rupture. Therefore, treatment decisions must balance rupture risk against operative risk.

2. Open repair remains an important treatment option. It is still relevant in younger patients, patients with connective tissue disease, and patients with anatomy unsuitable for endovascular repair.

3. The strongest evidence supports F/B-EVAR in selected patients and experienced centers. Large cohorts show high technical success, acceptable early mortality, comparable aortic-related mortality after elective repair.

4. Endovascular repair often may have better early outcomes than open repair. Several comparative studies report lower early mortality, fewer major complications, shorter hospital stay, and fewer respiratory or renal complications after F/B-EVAR. However, evidence is not complete.

5. Long-term superiority of endovascular repair is not proven. Late survival is often similar between endovascular and open repair, and overall mortality remains high

6. SCI remains one of the most serious complications. Modern prevention strategies may reduce its incidence, but SCI rates are still prevalent.

7. Reintervention is a major limitation of F/B-EVAR. Target-vessel problems, endoleaks, and device-related issues require long-term imaging surveillance and reinterventions.

8. Hybrid repair has a limited role. It may be useful in selected patients, but current evidence does not show a clear advantage over total endovascular repair or open repair.

9. Current evidence is limited by study design. Most data come from observational cohorts, registries, and meta-analyses. There are no randomized trials proving superiority of one treatment strategy for all TAAA patients.

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