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Original Article

Midterm outcomes of zone 0/1 landing hybrid thoracic endovascular aortic repair procedures

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Abstract

Aim: The combination of endovascular and open surgical techniques in hybrid procedures represents an innovative therapeutic strategy for the management of aortic arch diseases. Despite reported short-term results, the procedural success in years remains unclear and requires more research. We investigated the mid-term results of our hybrid thoracic endovascular aortic repairs (TEVAR) in zone 0/1.

Material and Methods: From May 2016 to December 2024, thirteen patients with aortic arch diseases who were unsuitable for open surgery and who underwent zone 0/1 landing hybrid TEVAR procedures were enrolled. The patients treated with in situ fenestrations, physician-modified techniques and periscope graft techniques were excluded. Demographics, aortic pathologies, operative features, survival outcomes, and complications in years were analyzed.

Results: We performed hybrid TEVAR procedures for eight patients presenting with residual type A aortic dissection – aneurysm, four with an arch aneurysm and one with Kommerell's diverticulum. The mean follow-up was 32 months (range: min 1 year-max 5 years). The early mortality rate was 15% (2 patients), and the overall mortality rate was 46% (6 patients). Two cerebrovascular events and one retrograde aortic dissection were observed. Renal impairment, endoleak, and graft migration were absent.

Conclusion: Hybrid TEVAR in Zones 0 and 1 could be applicable and acceptable for complex aortic arch pathologies in high-risk and frail patients who are inappropriate for open surgery. Aiming to achieve a secure proximal landing zone with a Hybrid approach can improve the results.

Keywords: Aneurysm, aortic arch, endovascular techniques

INTRODUCTION

Aortic arch pathologies require various approaches, including open surgery, advanced endovascular repairs, and hybrid procedures. Thoracic endovascular aortic repair (TEVAR), a trending treatment for thoracic and thoracoabdominal aortic aneurysms (TAAAs), offers a solution in the aortic arch. Ensuring a secure sealing zone in zones 0, 1, and 2 of the Ishimaru classification needs complex endovascular techniques like periscope grafts, chimneys, physician-modified fenestrated endograft or debranching surgery [1-4]. The gold standard for treating aortic arch aneurysms is open surgical repair (OSR). However, TEVAR may serve as a viable and less invasive alternative, particularly for patients who are ineligible for OSR due to high surgical risk. In contrast, OSR is generally preferred in younger patients with lower surgical risk. [5-7].

According to the guidelines of the European Societies for Vascular Surgery and Cardiothoracic Surgery, endovascular treatment of the aortic arch may be a viable option for high-risk patients who are unsuitable for open surgery, provided their life expectancy and anatomical conditions are taken into careful consideration. [8,9]. Endovascular treatments provide advantages by minimizing surgical trauma and removing the requirement for cardiopulmonary bypass, which together lead to lower perioperative mortality and morbidity [10]. Despite its

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complexity, the endovascular approach combined with hybrid procedures and debranching of the supra-aortic trunks can render a solution with low operative mortality [11]. Fenestrated and branched TEVAR (F/B TEVAR), parallel grafts (PG), and techniques involving physician-modified or in situ fenestration are innovative advanced procedures and deemed appropriate for urgent situations or as bailout procedures for the frail high-risk patient cohort [4,6].

In clinical practice, aortic aneurysms often involve extensive segments of the aorta particularly in zones 0 and 1. As a result, more sophisticated and advanced endovascular techniques are required to achieve a sufficient and secure proximal landing site for the graft, especially when the proximal landing zone (PLZ) extends into zone 0 of the ascending aorta. Recent advancements in surgical devices and techniques, including vascular revascularization of the aortic arch, have prompted research into the outcomes of TEVAR procedures with zone 0 landing. While there are reliable results for TEVAR performed in other aortic regions, there is a lack of convincing mid-term findings for TEVAR in zones 0 and 1. Current studies on zone 0 TEVAR are largely limited to retrospective analyses and case reports. Moreover, the absence of standardized, commercially available stent grafts specifically designed for zone 0 TEVAR has hindered comprehensive investigation into the efficacy of TEVAR in zones 0 and 1 [12].

With growing innovations and expanding expertise in the endovascular treatment of the aortic arch, we explored our results. We reviewed the early and midterm outcomes of zone 0/1 hybrid TEVAR procedures to evaluate their effectiveness and acceptability.

MATERIAL AND METHODS

We carried out this retrospective, single-centre observational cohort study by the Declaration of Helsinki, and the protocol was approved by the Ankara Bilkent City Hospital Scientific and Ethical Evaluation Committee for Medical Research (TABED 1-24-570) (25.09.2024). Before the operations, informed consent was obtained from the participants.

From May 2016 to December 2024, we performed Hybrid TEVAR procedures in thirteen patients with different aortic arch pathologies requiring zone 0 or zone 1 proximal landing and at high risk for open surgery. Patients requiring endovascular aortic repair with a landing area in Ishimaru zones 0 or 1 first underwent debranching surgery of the aortic arch branches, followed by TEVAR. Patients treated with other advanced endovascular techniques were excluded from the study. The treated aortic pathologies, associated comorbidities, operative techniques, and outcomes were thoroughly analyzed.

Operative Techniques

All patients received a detailed preoperative evaluation using high-resolution multislice computed tomographic angiography (CTA). The plan of the operation and the size of the devices were conducted with the assistance of advanced three-dimensional vascular imaging software (RadiAnt DICOM Viewer v2021.2, 64-bit) and three-dimensional reconstructions of the computed tomography (CT) scans. Following preoperative assessment, simultaneous extra-anatomical bypass and TEVAR were performed in a single session by the same endovascular surgical team. For Zone 0 TEVAR, supra-aortic vessel (central) debranching was achieved via sternotomy (or hemi-sternotomy), with a partial clamp applied to the ascending aorta. A pre-prepared Y-shaped graft (8 mm main body, 6 mm and 8 mm distal ends) was anastomosed end-to-side to the ascending aorta, and its distal ends were sequentially anastomosed end-to-end to the right innominate and left carotid arteries. For the left subclavian artery (LSA), a Dacron graft was used via a left supraclavicular incision where the LSA was difficult to access behind the aortic arch, alternatively, a left carotid-to-left subclavian bypass was performed. The LSA was tied off at its origin to prevent type 2 endoleak. For Zone 1 TEVAR, peripheral debranching was performed, with inflow for the bypass originating from the right carotid or right subclavian artery, depending on patient-specific factors and surgeon preference. All operations were carried out under general anesthesia in a hybrid operating room. Spinal fluid drainage was performed preoperatively for all patients. The right femoral artery was surgically exposed, and percutaneous access to the left femoral artery was obtained for pigtail catheterization. After heparin administration, a pigtail catheter was positioned in the aortic arch for direct visualization of the supra-aortic branches. The optimal viewing angle (40°-45° left anterior oblique) was determined preoperatively using 3D reconstructions of the aneurysm. Radiopaque markers were sutured around the distal bypass in sternotomy cases for accurate stent graft deployment. Stent graft oversizing was 10-20% for Stanford type B dissections and ~20% for thoracic aneurysms. During deployment, mean arterial pressure (MAP) was reduced to 50-70 mmHg, by management of anesthesiologists, or rapid pacing (~150 beats per minute) was used to reduce MAP. Completion angiography was routinely conducted to verify bypass patency and absence of endoleaks. Postoperative follow-up was conducted at 1, 6, and 12 months, with additional evaluations scheduled according to the patients' clinical status.

Definitions

Technical success was defined as the proper deployment of the aortic stent graft, the patency of bypasses performed on the aortic arch branches, with no evidence of type I and/or type III endoleaks on completion of angiography. Spinal cord ischemia (SCI) was defined as the presence of paraplegia or paraparesis following an

endovascular approach and classified as temporary or permanent. SCI was defined as temporary if there was complete resolution and expected return to baseline function and permanent if there was partial or no improvement compared to the baseline examination. Renal impairment was defined as postoperative acute kidney injury (based on RIFLE or KDIGO criteria) or a decrease of more than 30% in the estimated glomerular filtration rate (eGFR) during early follow-up. Heart failure, myocardial infarction, and myocardial ischemia necessitating intervention were enrolled as cardiac events.

Primary and Secondary Endpoints

The primary endpoint was to assess and explore all causes of mortality in 5 years. The secondary endpoints comprised early mortality, endoleaks, SCI, renal impairment, and cardiac events in the postoperative 1-month follow-up.

Statistics

Continuous variables with a normal distribution were expressed as 'mean±standard deviation (SD)', whereas categorical variables were presented as frequencies and percentages. Survival outcomes were evaluated using Kaplan-Meier analysis. All statistical analyses were conducted using SPSS software (version 20.0 for Windows, SPSS Inc., Chicago, IL, USA).

RESULTS

A total of thirteen patients underwent endovascular treatment with Zone 0-1 TEVAR landing. Of these, eight patients (61%) were treated for post-dissection aneurysms, four (31%) for aortic arch aneurysms, and one (8%) for an aberrant subclavian artery aneurysm (Kommerell's Diverticulum). Nine endografts were deployed in Zone 0, while four endografts were deployed in Zone 1 (Table 1).

Table 1. Aortic pathologies and landing zones in cohort

	Patient (n)	%
Thoracic aortic pathology		
Post-dissection aneurysm (Operated type A aortic dissection)	8	62
Aortic arch aneurysm	4	30
Aberrant right subclavian artery aneurysm (Kommerell's Diverticulum)	1	8
TEVAR landing zone		
Zone 0	9	70
Zone 1	4	30

All patients were male, and ineligible for open surgery. All patients had American Society of Anesthesiologists (ASA) status 4. The median age of the patients was 76 years old (IQR: 72-81). The median follow-up time was 914 days (IQR: 382-1481). Hypertension was the most observed comorbid disease (n=11, 85%) (Table 2).

Table 2. Patient demographics

Demographic data	n (13) or median	% or IQR
Age (min 69 max 82 years old)	Median: 76	IQR: 71 to 79
Follow up time: (min 4-day, max 2308)	Median: 914	IQR: 382 to 1481
Male	13	100
Hypertension	11	85
Hyperlipidemia	9	70
Chronic obstructive pulmonary disease	9	70
Coronary artery disease	7	53
Coronary artery bypass grafting	3	23
Chronic renal insufficiency (Creatinine>2 mg/dl)	1	8
Peripheral artery disease	4	30
Preprocedural cerebrovascular event	2	15
Cancer	4	30

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Prior to endovascular approach, a carotid-carotid crossover bypass was performed for four patients and a supra aortic revascularization was performed for nine patients (Figures 1,2).

Figure 1. Central debranching and Zone 0 TEVAR procedures

Figure 2. Periferal debranching Zone 1 Tevar procedure: a saccular aneurysm is presenting in the aortic arch, distal to the left subclavian artery, giving rise to an aberrant right subclavian artery; the right common carotid artery is occluded, while both common carotid arteries originate from a common origin

Early (30 day) mortality rate was 15% (2/13). One patient had a cerebrovascular event (hemorrhage) and died on the fourth day and the other died as planned discharge on the seventh day and no reason was proven. A total of six patients died in the follow-up period and all-cause mortality rate was 46%. After a month of postoperative surgery, four patients died. The most common cause of mortality was cancer (n=2). Retrograde aortic dissection was observed in one patient with an ascending aorta diameter of 37 mm, and the patient died in the third postoperative month. SCI, renal impairment, endoleak, graft migration were not observed (Table 3).

Table 3. Operational outcomes

	n	%
Early mortality	2	15
All-cause mortality	6	46
Renal impairment	0	0
Spinal cord ischemia	0	0
Cardiac event	2	15
Retrograde aortic dissection	1	8
Endoleak	0	0
Open conversion	1	8

Overall survival rate was 85% in 1st month, 77% in 1st year, 77% in 2nd year, 61% in 3rd year, 61% in 4th year, 56 % in 5th year, 56 % in 6th year (Figure 3). There was one aorta related death observed in zone 1 group. In the Zone 0 group, there were five deaths during follow-up, which were unrelated to the aorta.

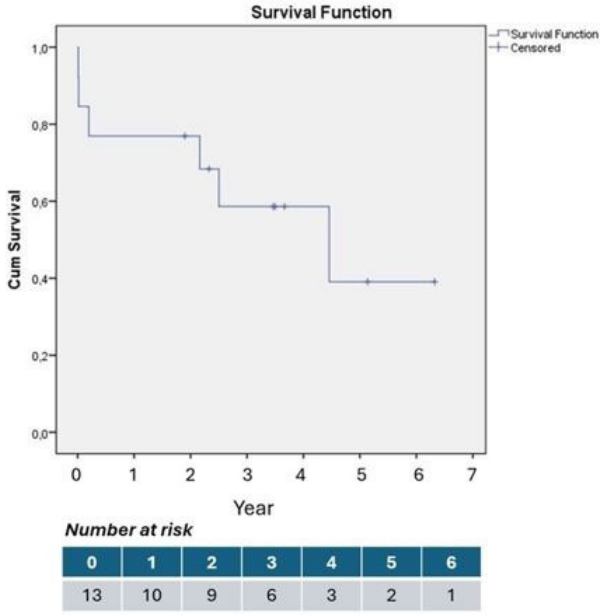

Figure 3. Midterm survival curve in hybrid Zone 0-1 TEVAR procedures

DISCUSSION

Our study contributes to the increasing amount of evidence regarding the use of hybrid TEVAR for aortic arch pathologies, particularly in frail patients who are ineligible for OSR. Our results demonstrate that zone 0 landing hybrid TEVAR is a feasible and relatively safe alternative for patients with high comorbidities achieving satisfactory midterm results. However, the study also highlights the limitations and challenges of this approach, particularly in terms of survival and the necessity for additional progress in device technology.

Timely surgical intervention is essential for the management of aortic arch aneurysms and dissections; however, there is a lack of extensive and detailed data to establish the most effective surgical strategies in relation to postoperative outcomes. To address the challenges associated with the absence of dedicated stent grafts for aortic arches, a variety of procedures and innovative devices or techniques have been developed. These techniques include hybrid surgery, as well as fenestrated, chimney, and branched TEVAR approaches, while newer devices aim to offer safer and simpler alternatives. However, the reviewed studies reveal that there is no established protocol regarding the selection of techniques or devices for zone 0 TEVAR [13,14].

OSR is the preferred treatment for a fit and young patient. However, if the patient is frail and at an older age with high open surgical risk, alternative pathways like advanced skilled endovascular procedures or hybrid procedures may be more

suitable. The decision to perform hybrid endovascular or open surgical repair should be determined by patient-specific factors, anatomic considerations, and institutional expertise, as outlined in current guidelines [8]. This study evaluated the early and midterm outcomes of Zone 0-1 hybrid TEVAR procedures, focusing on survival, technical success, and complications. The findings provide valuable insights into the feasibility, safety, and durability of this approach.

Oishi reported that zone 0/1 TEVAR is associated with a higher rate of neurological complications compared with OSR and is also associated with a heightened risk of postoperative endoleaks. In contrast, our findings do not align with these results [5]. In our cohort, no cases of ischemic stroke or paraplegia were observed, and there was only one case of intracranial hemorrhage, which accounted for early mortality. Additionally, our patient population consisted exclusively of frail individuals with high surgical risk, which may have influenced the outcomes. The systematic review by Sharaf et al. comparing hybrid repair and total arch replacement also supports the notion that hybrid approaches are associated with similar rates of short-term complications, such as neurologic dysfunction and acute kidney injury, but higher rates of reintervention [15]. Out of the 12 studies analyzed, 7 directly evaluated the postoperative incidence of acute kidney injury (AKI) and permanent neurological dysfunction (PND) between patients who underwent conventional open surgery and those who underwent hybrid procedures. The findings indicated no significant variation in the occurrence of AKI or PND between the two groups. No cases of PND, AKI, or reinterventions were detected throughout the follow-up phase of our study. The limited sample size, the omission of advanced endovascular techniques and relatively short follow-up duration may have resulted in an underestimation of the true incidence of these results. Furthermore, the review emphasized the need for prospective studies to better evaluate midterm and long- term survival, a gap that our study partially addresses by providing midterm survival data.

Survival outcomes are the main discussion on Hybrid TEVAR in Zones 0 and 1. The 5-year survival rate for patients with TAA who did not undergo any intervention was merely 54% [8]. The Kaplan-Meier survival analysis demonstrated an overall survival rate of 85% in 1st month, 77% in 1st year and 56 % in 5th year. These results represent a reasonable outcome compared to previously reported survival rates at 5 year (48%,75%,78%,82%) for hybrid TEVAR in high-risk patient populations, where comorbidities and advanced age significantly impact long-term outcomes [16-19]. Moreover, most common causes of death during the follow-up period were not related to the aorta. The 15% early mortality rate observed in this study highlights the high-risk nature of the patient cohort, all of whom were classified as having ASA status. Reported early mortality rates in the literature vary between 2% and 30% [19,20]. The most observed mortality reason was cancer, which was not related to the procedure like cardiac reason in mid-term follow-up.The impact of frailty on outcomes, as highlighted by Kishimoto et al., is particularly relevant to our findings [21]. In their study, frail patients undergoing hybrid aortic arch repair had significantly worse midterm survival compared to non-frail patients (43.0% versus 67.7%), primarily due to non- aorta-related causes. Similarly, in our cohort, the majority of late mortalities were attributed to non-procedural causes, such as cancer and other comorbidities. This underscores the importance of patient selection and the need for a multidisciplinary approach to optimize outcomes in this high-risk population.

The study reported a 100% technical success rate, with no evidence of endoleak, and the patency of all bypasses was confirmed through completion angiography. Technical success rates in the literature range from 88% to 100% [22,23]. These findings underscore the feasibility of hybrid TEVAR in zones 0 and 1, even in frail patients with significant comorbidities who are not candidates for OSR.

Zone 0 TEVAR still faces major challenges due to the limited availability of long-term follow-up data and the lack of standardized devices. As noted by Dhanekula et al., advancements in device technology, such as fenestrated and branched stent grafts, hold promise for improving outcomes in aortic arch repair [14]. However, these devices are not yet widely available in many regions, including ours, necessitating the use of alternative techniques such as hybrid approaches. The management of short proximal necks and restricted landing zones with TEVAR continues to pose significant challenges. In such complex cases, the utilization of physician-designed or custom-made endovascular grafts (CMEGs) may be necessary to ensure the patency of the aortic arch branches. Experience with these approaches continues to develop without long-term follow-up. When the anatomy is suitable, endovascular treatment with scalloped or fenestrated CMEGs in Zones 0 and 1 is a viable option for managing aortic arch disease affecting the supra aortic trunks (SAT)s [24]. Future research should aim to assess the long-term durability of these methods and the development of off-the-shelf devices specifically designed for zone 0/1 TEVAR.

The primary rationale behind hybrid aortic arch endovascular procedures is to reduce surgical risk by avoiding median sternotomy and cardiopulmonary bypass. Hybrid procedures can be performed without either for Zone 1 landing. However, while debranching surgery enables Zone 0 landing, median sternotomy remains necessary in such cases. In our series, only one patient died due to retrograde type A aortic dissection (RTAD) who underwent zone 1 interventions. RTAD has been reported as 2.5-23% of incidence with up to 37.1% rate of mortality in the meta analysis [13,25].

The absence of SCI cases in our study suggests that the use of a cerebrospinal fluid catheter was effective. This observation

is promising, as SCI remains a major concern in thoracic aortic interventions, particularly in cases requiring extensive thoracic aortic coverage [26]. Additionally, no deterioration in renal function was observed. Addressing these complication rates is essential for the broader adoption of Zone 0/1 TEVAR. Nevertheless, OSR remains the gold standard for patients suitable for surgical intervention; however, it is associated with significant adverse outcomes, including mortality rates of approximately 2.2-10% and stroke rates of 5.8% [5,15]. In our limited experience, we have employed hybrid TEVAR in cases involving high-risk or frail patients deemed unsuitable for open surgery, while refraining from its use in younger patients at present.

The follow-up period, while adequate for evaluating midterm outcomes, does not provide sufficient data to assess the long-term durability of the procedure. The findings of this study indicate that hybrid TEVAR in Zones 0 and 1 is a viable and effective approach for the management of complex aortic arch pathologies in high-risk patients. However, the observed high early mortality rate and declining survival over time underscore the importance of meticulous patient selection and optimization of perioperative care. Future research should prioritize larger, multicenter cohorts to validate these results and investigate strategies to minimize complications and enhance long-term outcomes. Moreover, the creation of stent grafts specifically tailored for Zone 0-1 TEVAR has the potential to enhance the safety and effectiveness of the procedure.

There are several limitations to this study. First, being a retrospective study, the data were collected retrospectively, which may have introduced potential biases. Second, it includes cases from a single center and a single team. Additionally, patients who underwent advanced endovascular techniques were excluded from the study. As a result, the relatively small sample size in our study limits the generalizability of the findings. A small sample size reduces the statistical power of the analysis and makes it challenging to evaluate the impact of rare conditions. Therefore, the applicability of our results to larger populations should be interpreted with caution. Lastly, our study was conducted in a single center, and no comparisons were made with data from other centers. This limits the applicability of the results to different patient groups or geographic regions. Future studies with larger, multi-center, and prospective designs are needed to overcome these limitations and validate our findings.

CONCLUSION

Hybrid TEVAR in Zones 0 and 1 is a feasible and effective treatment option for managing complex aortic arch pathologies in high-risk patients who are unsuitable for OSR. Further research is necessary to assess the feasibility and safety of extending hybrid TEVAR to low-risk patients, thereby broadening its clinical applicability.

Ethics Committee Approval: The study design and protocol was approved by the Ankara Bilkent City Hospital Scientific and Ethical Evaluation Committee for Medical Research (TABED 1-24-570) (25.09.2024).

Patient Consent for Publication: Before the operations, informed consent was obtained from the participants.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

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