Total endovascular arch repair: Initial experience in Bologna

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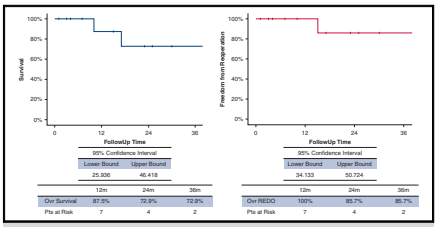
ABSTRACT

Objectives: In the last few years, fenestrated, branched, or scalloped custom grafts have become available for aortic arch repair. Open surgery is the gold standard, but arch thoracic endovascular aortic repair (TEVAR) is indicated for high-risk patients. We focused on total endovascular aortic arch replacement with a zone 0 or zone 1 landing zone to describe its short- and long-term outcomes.

Methods: We retrospectively analyzed patients who underwent arch TEVAR with a zone 0 or zone 1 landing zone at our center. We then performed a Kaplan-Meier analysis for survival and freedom from reintervention at follow-up.

Results: From May 2017 to November 2023, 15 patients underwent elective arch TEVAR, having been deemed unfit for open surgery. Mean age was 74.7 ± 7.8 years. The most frequent procedure was fenestrated endovascular aortic repair with a left carotid-subclavian bypass (LCSB) (6; 40%), followed by double-branched graft with LCSB (5; 33.3%) and triple-branched graft (2; 13.3%) and scalloped graft with LCSB (2; 13.3%). There was 1 in-hospital death (6.7%). Perioperative stroke occurred in 2 cases (13.3%). Mean follow-up (FU) time was 16.4 ± 15.1 months. There were 3 deaths at FU, all for noncardiovascular causes, and 1 stroke at FU. One patient required further stenting of the brachiocephalic trunk for a type III endoleak. Survival at 12 months was 87.5% and freedom from reintervention was 85.7%.

Conclusions: Total endovascular aortic arch repair with custom-made prosthesis is a safe and effective procedure in patients with prohibitive surgical risk. Stroke remains the main complication with significant rates. (JTCVS Techniques 2024;28:1-7)



Long-term results of total EV arch repair. Survival and freedom from redo at FU.

CENTRAL MESSAGE

Total endovascular arch repair with custom-made prosthesis shows promising results in patients with prohibitive risk for open surgery. Stroke rates, however, are significant.

PERSPECTIVE

The literature on total endovascular arch repair mostly consists of single-center retrospective studies with a small population and a few systematic reviews. Most of these, however, include cases of hybrid repair and partial stenting of the aortic arch. Our goal was to describe data on patients who underwent an arch TEVAR with a zone 0 or zone 1 landing zone in terms of short- and long-term results.

See Commentary on page 8.

In the last few decades, outcomes of open aortic arch surgery dramatically have improved thanks to the progress in techniques and perioperative management, especially regarding cerebral protection. Aortic arch surgery, however, is still to be considered a complex field, with a reported incidence of perioperative mortality varying from 4.6% to 23.1%,[1-3] depending largely on whether the indication was acute type A aortic dissection. Open surgery is still the "gold standard" treatment for aortic arch disease, even in the most recent guidelines,[4] which recommend considering hybrid or endovascular options in patients who are deemed unsuitable for surgery (class of recommendation IIb, Level of Evidence C). This group is only destined to grow because of the aging population of patients affected

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Abbreviations and Acronyms

BCT = brachiocephalic trunk
BEVAR = branched endovascular aortic repair
CT = computed tomography
EL = endoleak
FEVAR = fenestrated endovascular aortic repair
LCCA = Left common carotid artery
LCSB = left carotid-subclavian bypass
LSA = left subclavian artery
SAT = supra-aortic trunk
TEVAR = thoracic endovascular aortic repair

by aortic arch pathologies, many of whom would be reintervention.

This cohort of patients who require alternative treatment, combined with the advancements of endovascular techniques, has caused a rapid growth in the field of endovascular treatment of aortic arch pathologies. Several options, including fenestrated, branched, or scalloped custom grafts, have become available to adapt to the complex anatomy of the aortic arch.[5] Thoracic endovascular aortic repair (TEVAR) with a proximal landing zone in zone 0 or 1 has been performed more and more in recent years. However, literature is still lacking. Furthermore, much data on the matter include procedures with a zone 2 landing zone or hybrid arch replacement with debranching of the supra-aortic trunks (SATs) followed by TEVAR. Both these options don't require endovascular management of cerebral vascularization; therefore, they differ from zone 0 or zone 1 procedures. Our aim is to focus on total endovascular aortic arch replacement with a zone 0 or zone 1 landing zone to describe its short- and long-term outcomes.

METHODS

Study Design

This is a single-center, retrospective study. All patients who underwent total endovascular aortic arch repair with a zone 0 or zone 1 landing zone from May 2017 to November 2023 were included. Preoperative characteristics, surgical strategy, long- and short-term results were retrospectively analyzed.

Ethical Statement

The Declaration of Helsinki and its later amendments were respected. Informed consent for primary intervention was obtained from all participants included in this study. However, the study was approved by our internal institutional review board (D.P., G.D.G., L.L. Codex; August 10, 2023), and consent for publication was not required according to the Italian National Policy in the matter of Privacy Act on retrospective analysis of anonymized data. The data underlying this article are available in the article.

Statistical Analysis

All continuous variables were expressed as mean ± standard deviation, whereas categorical data are summarized as absolute numbers and percentages. A Kaplan-Meier analysis was performed to evaluate survival and freedom from reintervention at follow-up. Statistical analysis was performed with SPSS, version 26.0 (IBM Corp).

Surgical Technique

The endovascular treatment of aortic arch disease comprises many options. Hybrid procedures mainly consist in SATs debranching and subsequent TEVAR. The present work is focused on completely endovascular procedures, among which fenestrated and branched stent grafts are the main options. Both techniques originated in the field of thoracoabdominal aortic aneurysms[6] and were later adapted for the complex anatomy of the aortic arch.

Fenestrated aortic grafts allow blood flow to the SAT through special "windows" in the stent graft, whereas branched grafts present specific "branches" that can be placed in 1 or more SATs. In a "double-branch" procedure, the branches are placed in the brachiocephalic trunk (BCT) and left common carotid artery (LCCA), generally accompanied by a left carotid-subclavian bypass (LCSB), whereas in "triple branch" procedure, the left subclavian artery (LSA) is also stented (Figures 1 and 2). A third option is represented by scalloped stent grafts, in which the patency of SATs is assured through a wider "scallop" on the graft.

Fenestrated grafts allow extensive coverage of the aortic arch, granting a long landing zone in the proximal arch or ascending aorta. The release of the prosthesis is crucial, requiring good proximal and distal sealing and perfect alignment to match the SATs ostiums. Long-term sealing preservation might be a problem, as the large fenestrations in the outer curvature of the stent-graft could cause endoleaks. When perfect sealing at the level of SATs is made tricky by aneurysmal dilation of the arch or particular aortic morphologies, a branched stent graft is considered to be a more suitable solution, as the presence of branches might improve sealing. Scalloped stent grafts are mainly used to preserve blood flow in the LSA, even in urgent or emergent settings as wider scallops might not require a custom-made prosthesis. However, the scallop can also be placed on the LCCA in place of a smaller fenestration, though the bigger window might make sealing more difficult.

At our center, all endovascular procedures are performed in a state-of-the-art hybrid operating room by a multidisciplinary team composed of cardiac surgeons and interventional radiologists, both specialized in aortic pathology. All the prosthesis were custom-made on the basis of the patients' preoperative computed tomography (CT) scan.

When indicated, LCSB is performed immediately before the endovascular procedure. In these cases, the LSA is then embolized to prevent endoleaks. The most used main access is the femoral artery. In case of branched endovascular aortic repair (BEVAR), surgical exposition of the right axillary or common carotid artery and LCCA is also necessary. Careful deairing of the prosthesis is mandatory in order to reduce the risk of air embolism. The stent graft is carefully released during ventricular pacing. In BEVAR, the stent grafts for the SATs are released after the main body. Double antiplatelet therapy is recommended to all patients who undergo arch stenting for 3 to 6 months, followed by single antiplatelet therapy with aspirin, which is continued indefinitely.

Our postoperative protocol includes a predischarge CT scan, taken approximately 5 days after surgery, whereas the follow-up CT scans are performed and evaluated at our outpatient clinic specific for aortic pathologies by a cardiac surgeon and a radiologist.

RESULTS

Between May 2017 and November 2023, 15 patients underwent TEVAR with a zone 0 or zone 1 landing zone at our institution. The patients' preoperative characteristics are illustrated in Table 1. Mean age was 74.7 ± 7.8 years, and most patients (80%) were male. When it came to indications, the most frequent was aortic aneurysm (6, 40%),

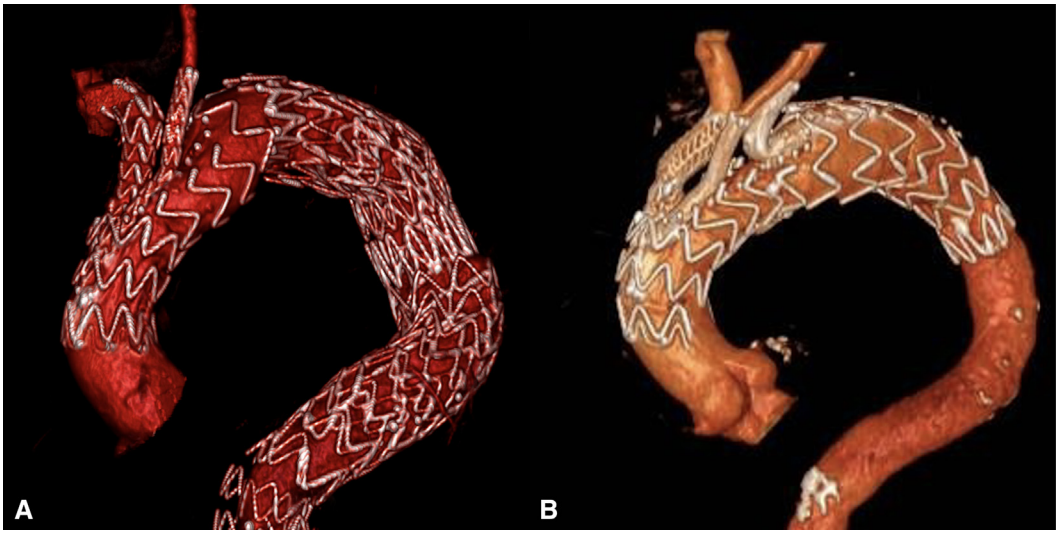

FIGURE 1. Results of arch branched endovascular aortic repair at the postoperative computed tomography scan. Double-branch with a left carotid-subclavian bypass (A) and triple-branched prosthesis (B).

followed by penetrating ulcer (5, 33.3%), aortic dissection (2, 13.3%), and pseudoaneurysm (2, 13.3%).

The most performed procedure was fenestrated endovascular aortic repair (FEVAR) with a LCSB (6, 40%), followed by repair through a double-branched graft with LCSB (5, 33.3%), triple-branched graft (2, 13.3%), and scalloped graft with LCSB (2, 13.3%). The landing zone was zone 0 in 11 cases (73.3%) and zone 1 in the remaining 4 cases (26.7%).

The procedure was technically successful in all cases. There was only 1 in-hospital death (6.7%), which was attributable to ischemic diffuse bilateral stroke with hemorrhagic transformation in a patient who underwent a BEVAR with a double-branched graft. There was no report of spinal cord injury or retrograde dissection, whereas in-hospital stroke occurred twice (13.3%). The other stroke patient had also undergone double-branched TEVAR and presented a lesion in the right middle cerebral artery territory. In both cases, the CT scan showed patency of the SAT stents with no sign of dissection.

The patients' mean follow-up time was 16.4 $\pm$ 15.1 months, 12-month survival was 87.5%, and freedom from reintervention was 85.7% (Figure 3). Long-term results are reported in Table 2 and Figure 4. During follow-up, 3 patients (21.4%) died, no case of aortic-related death was reported. One stroke (7.1%) happened at follow-up in a patient who underwent double-branched TEVAR: he presented a left cerebellar ischemic stroke and the CT scan showed partial thrombosis of the LCCA stent.

Endoleak (EL) at follow-up was present in 2 (14.3%) cases, both were type III EL. Among these, 1 patient had a small EL originating from the common BCT/LCCA fenestration which did not require intervention. Another one presented a type III EL originating from the BCT stent, which required further stenting of the BCT 11 months after the original procedure.

DISCUSSION

The introduction of total endovascular options for the treatment of aortic arch pathology allowed us to offer alternative solutions for otherwise inoperable patients. Since their introduction, the progress of technologies and surgical techniques allowed this field to grow rapidly and treat increasingly complex aortic pathologies. However, zone 0 and zone 1 TEVAR, compared with TEVAR for other aortic zones, lacks high-quality evidence to support its use because studies on the matter include case reports, case series, and retrospective studies. Even the 2024 aortic guidelines present a low class of recommendation because of the relative youth of the field and the lack of definitive consensus in literature.

Two recent meta-analysis comprising a relatively large cohort for the field reported a 7.5% to 16% incidence of in-hospital mortality and 8.9% to 14% incidence of stroke, which is in accordance with our data.[7,8] This goes to show how TEVAR of the arch is not free from risk. However, these studies also included hybrid arch replacement procedures, which once again shows how literature on "real" total endovascular arch repair is scarce.

Stroke is the most common and feared complication of endovascular arch repair, with a reported incidence even greater than open arch surgery.[9] It also proved to be linked to TEVAR with a zone 0 landing zone compared with more distal landing zones.[10] Severe atherosclerosis of the aortic

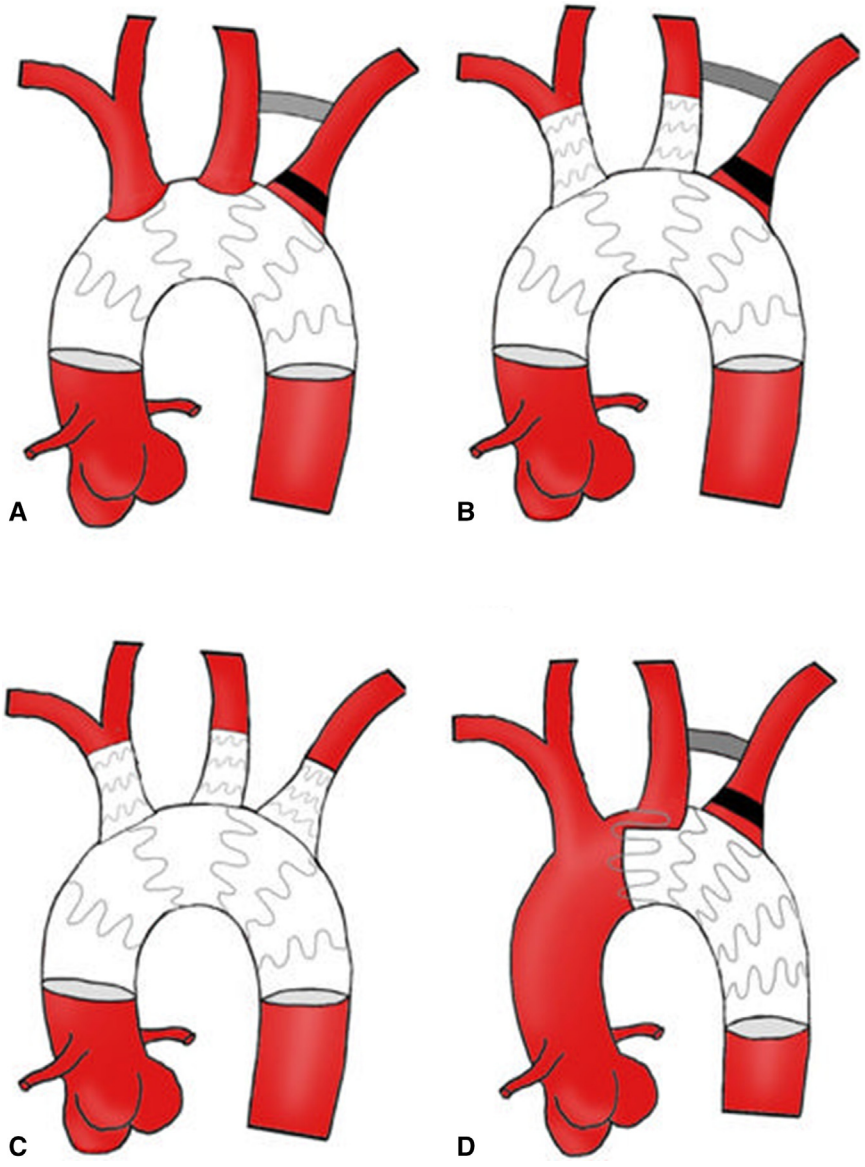

FIGURE 2. Schematic representation of the 4 techniques used in this cohort of patients. A, FEVAR with LCSB and LSA embolization; (B) double-branch stenting with LCSB and LSA embolization; (C) triple-branched stenting; (D) scalloped graft on the LCCA with a zone 1 proximal landing zone, LCSB and LSA embolization. *FEVAR*, Fenestrated endovascular aortic repair; *LCSB*, left carotid-subclavian bypass; *LSA*, left subclavian artery; *LCCA*, left common carotid artery.

wall and aneurysms as indication have both been linked to stroke, whereas LSA revascularization doesn't seem to have an impact.[11-13]

Stroke can occur both as the result of embolization (solid or air) and to SAT hypoperfusion during or after the procedure. The main steps to minimize its risk include careful consideration of the underlying pathology, as atherosclerotic lesions present high risk of embolism, evaluation of the cerebral arterial anatomy and of possible variations of the Circle of Willis. However, the main precaution a surgeon can take consists in the careful de-airing of the delivery system with abundant saline solution in order to minimize the risk of air embolism. Air embolism during arch TEVAR has been thoroughly investigated, even in some in vitro models,[14,15] and seems to be one of the main determinants of stroke. Avoiding intraoperative hypotension also seems to play a role in stroke prevention.[16] Careful patients selection and intraoperative management seem to be the only options to prevent stroke.[17]

Interestingly, a greater incidence of stroke in FEVAR and BEVAR compared with standard endovascular aortic repair has been reported in literature, even in the field of

TABLE 1. Preoperative characteristics of the population

Preoperative variable	N = 15
Age, y	74.7 ± 7.8
Male sex, n (%)	12 (80%)
Baseline pathology, n (%)	
Aneurysm	6 (40%)
Penetrating ulcer	5 (33.3%)
Dissection	2 (13.3%)
Pseudoaneurysm	2 (13.3%)
Hypertension, n (%)	11 (73.3%)
Coronary artery disease, n (%)	1 (6.7%)
Chronic obstructive pulmonary disease, n (%)	5 (33.3%)
Renal failure, n (%)	2 (13.3%)
Mean ascending aorta diameter. mm	37.64 ± 4

abdominal aortic repair.[18] This might be attributable to more manipulation of wires and catheters, which may disrupt plaque or thrombus.

In our experience, all the postoperative strokes happened in patients who underwent BEVAR. Literature is lacking on direct comparisons between arch BEVAR and FEVAR, especially when it comes to zone 0 or zone 1 landing zones. Tsilimparis andc colleagues[19] reported greater mortality and stroke rate in the FEVAR group compared with BEVAR, which differs from our experience. However, both studies have a limited population due to the relative rarity of the procedures, so differences may easily be fortuitous.

In our experience, all patients who showed potential neurologic symptoms or doubts about the patency of SATs at the CT scan were promptly clinically and radiologically evaluated. Because stroke is still common, centers in which this kind of procedures are performed should have a readily available neurology and neuroradiology service.

Another factor to consider is that such complex procedures require a learning curve, which cannot prescind from experienced operators, a dedicated team and a large volume of patients. These requirements make it so that this kind of procedures should always be performed in high-volume aortic centers.

Total endovascular repair of the aortic arch represents a revolutionary option for a cohort of patients who, because of the ageing of the population and advancement of technologies, is only going to expand in the future. It also provides a potentially resolutive one-step treatment for lesions limited to the aortic arch, such as penetrating ulcers. Despite its reduced invasiveness and psychological impact on the patients, it is not free from complications. However, it showed feasible results in the short and long term, which justify its use the high surgical risk cohort. Patient selection is fundamental to obtain good results and it cannot happen without a skilled aortic team, including cardiovascular surgeons and interventional radiologists.

Study Limitations

Because of the relative rarity of this procedure, only a retrospective study with a small population could be

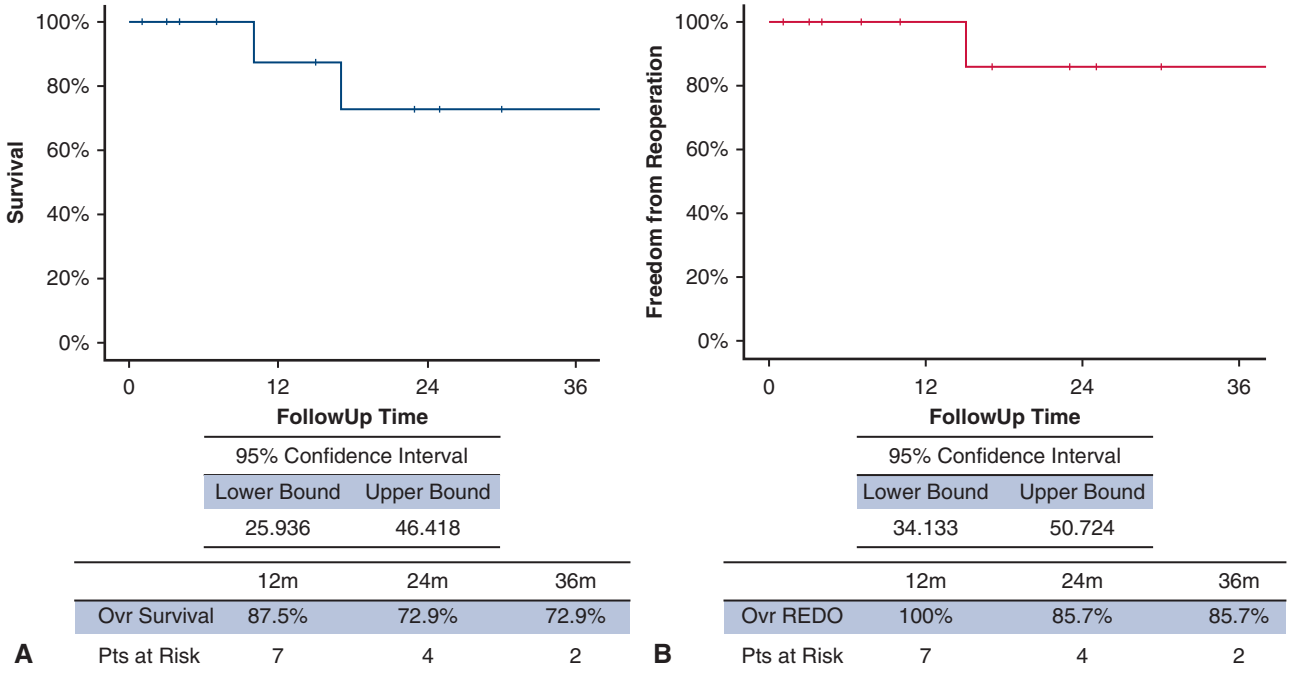

FIGURE 3. Survival (A) and freedom from reintervention (B) at follow-up.

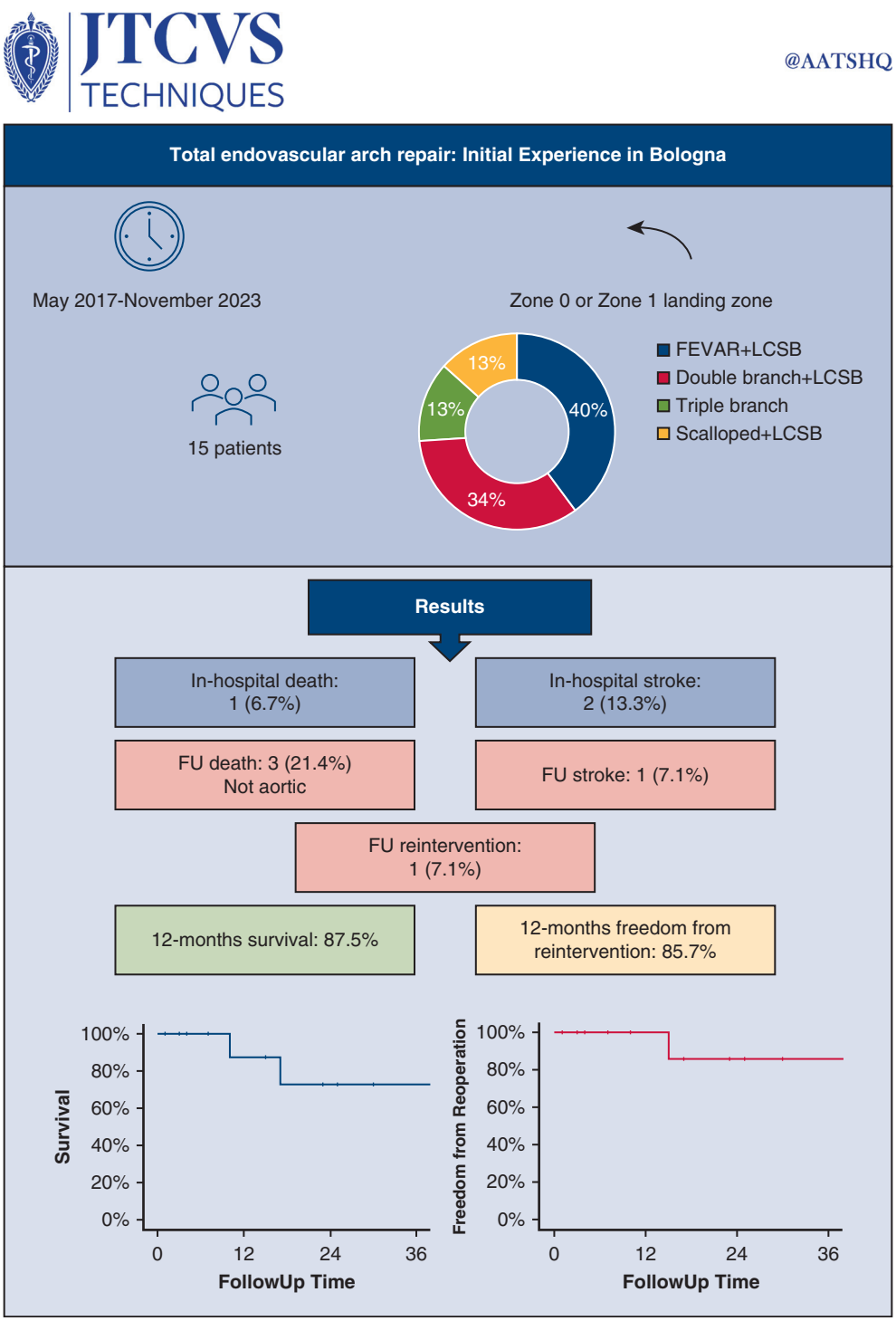

FIGURE 4. Main results of total endovascular aortic arch repair in the period May 2017-November 2023. *FEVAR*, Fenestrated endovascular aortic repair; *LCSB*, left carotid-subclavian bypass; *FU*, follow-up.

performed on the matter. This is especially true when only zone 0 or zone 1 landing zone procedures are considered, as most studies available in literature and systematic reviews also include more distal landing zones or hybrid procedures. Because of the small number of patients, we were unable to perform a comparison between FEVAR and BEVAR. In the future, a multi-centric comparative study should be performed.

TABLE 2. Long-term results

Variable	N = 14
Death at follow-up	3 (21.4%)
Aortic death	0
Other causes	3 (100%)
Stroke at follow-up	1 (7.1%)
Epiaortic trunks stents patency	13 (92.9%)
Prosthesis migration	0
Endoleak	2 (14.3%)
Reintervention	1 (7.1%)

CONCLUSIONS

Total endovascular repair of the aortic arch is a complex procedure, but it presents acceptable short- and long-term results. It should be reserved for high-risk patients who are deemed unfit for surgery by an experienced, multidisciplinary team.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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