



Review

Early experience at our center with the Gore thoracic branch endoprosthesis (TBE)

Experiencia inicial en nuestro centro con la prótesis torácica con rama de Gore (TBE)

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Abstract

Introduction: thoracic endovascular aortic repair (TEVAR) may require intentional coverage of the left subclavian artery (LSA) in up to 40% of cases, which may increase the risk of neurological complications. The GORE® TAG® Thoracic Branch Endoprosthesis (TBE) is the first off-the-shelf device approved for aortic repair with zone 2 landing, allowing preservation of LSA perfusion.

Objective: to evaluate the clinical and radiological outcomes of the initial experience with the TBE prosthesis at Miguel Servet Hospital.

Materials and methods: we retrospectively analyzed 7 consecutive patients treated with the TBE device between April 2024 and May 2025. Perioperative clinical data, technical outcomes, and clinical and radiological follow-up were collected. Median follow-up was 6 months.

Results: technical success was achieved in 100% of cases, with no mortality. One minor neurological event and 2 vascular access-related complications were observed. The LSA branch remained patent in all patients. One type III endoleak required secondary intervention. Median length of hospital stay was 5 days. No additional complications were observed during follow-up.

Conclusions: in our initial experience, the TBE device demonstrated favorable technical success, low complication rates, and no mortality. Outcomes were comparable to those reported with other aortic arch devices.

Keywords:

Thoracic aorta.
Ishimaru zone 2. Left
subclavian artery
(LSA). TEVAR (Thoracic
Endovascular Aortic
Repair). GORE® TAG®.
TBE (Thoracic Branch
Endoprosthesis).

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Resumen

Introducción: la reparación endovascular de aorta torácica (TEVAR) puede requerir cubrir en un 40 % de los casos la arteria subclavia izquierda (ASI), lo que aumenta el riesgo de complicaciones neurológicas. En este contexto, la prótesis GORE® TAG® con rama, TBE (*Thoracic Branch Endoprosthesis*), es el primer dispositivo no customizado aprobado para la reparación de aorta con anclaje en zona 2 sin comprometer el flujo hacia ASI.

Objetivo: evaluar los resultados clínicos y los radiológicos de la experiencia inicial en el Hospital Miguel Servet con la prótesis TBE.

Material y métodos: siete pacientes tratados entre abril de 2024 y mayo de 2025 con la prótesis TBE. Se han recogido de manera retrospectiva los datos clínicos perioperatorios, los resultados técnicos y el seguimiento clínico y el radiológico de cada uno de ellos durante una mediana de seguimiento de 6 meses.

Resultados: éxito técnico del 100 %, sin mortalidad. Un evento neurológico leve y 2 complicaciones de accesos vasculares. Permeabilidad de la rama a ASI del 100 %. Una endofuga de tipo III tratada en segundo tiempo. Mediana de estancia hospitalaria de 5 días y seguimiento de 6 meses sin que se objetiven complicaciones.

Conclusiones: en nuestra experiencia, presentamos buenos resultados en cuanto a éxito técnico, mortalidad y tasa de reintervenciones con el uso de esta prótesis. Las complicaciones fueron mínimas y comparables al uso de otros dispositivos de arco.

Palabras clave:

Aorta torácica.
Zona 2 de Ishimaru.
Arteria subclavia
izquierda. Tratamiento
endovascular. GORE®
TAG®. TBE (*Thoracic
Branch Endoprosthesis*).

INTRODUCTION

Over the past 20 years, rapid advances along with increased experience in thoracic endovascular aortic repair (TEVAR) have established this technique as the treatment of choice for aneurysmal disease, type B dissections, and traumatic injuries.

Anatomy is not always favorable, and in up to 40% of cases, coverage of the left subclavian artery (LSA) is required to achieve an adequate proximal seal (1).

Currently, prophylactic revascularization of the LSA to prevent associated neurologic injury remains controversial. According to the current recommendations of the European Society for Vascular Surgery (ESVS), revascularization should be considered when intentional coverage of the LSA is planned during elective TEVAR in patients at risk of neurologic complications (class IIa recommendation, level of evidence B). Similarly, revascularization should be performed in cases with prior coronary bypass using the left internal mammary artery, a dominant left vertebral artery, or a functioning arteriovenous access for hemodialysis in the left upper limb.

The GORE® TAG® Thoracic Branch Endoprosthesis (TBE) is the first noncustomized, CE-marked device approved and marketed for the repair of descending aortic disease requiring zone 2 anchoring while maintaining flow to the LSA.

This article presents the initial experience at our center, a pioneer in Spain, with this device.

MATERIAL AND METHODS

Objectives

To evaluate the clinical and radiologic outcomes of the initial experience at *Hospital Miguel Servet* (Zaragoza, Spain) using the GORE® TAG® Thoracic Branch Endoprosthesis (TBE).

Patient inclusion criteria and anatomic requirements

Clinical inclusion criteria included patients with thoracic aortic disease requiring proximal landing in Ishimaru zone 2 and with suitable anatomy for TBE implantation.

Regarding anatomic requirements for TBE implantation, according to the manufacturer's instructions for use, a minimum of 20 mm of proximal aortic landing zone distal to the left common carotid artery origin and a diameter greater than 16 mm are required, as well as an LSA diameter greater than 6 mm. Minimum femoral or iliac access must be 6.7 mm (20 Fr), and left brachial access 1.65 mm (5 Fr), allowing for radial access.

Patients

From April 2024 through May 2025, 7 patients were treated with the TBE device at our center.

Perioperative clinical data and technical outcomes were collected, as well as retrospective clinical and radiologic follow-up for each patient. Patient clinical characteristics are shown in table I.

Device characteristics and design

The GORE®TAG® Thoracic Branch Endoprosthesis is a self-expanding modular device made of expanded polytetrafluoroethylene (ePTFE), reinforced in its entire length with a nitinol wire and incorporating radiopaque gold markers for fluoroscopic visualization. It consists of an aortic component with an uncovered proximal portion capable of anchoring in zone 2; a precannulated internal branch located on the greater curvature, available in 2 sizes, into which a self-expanding stent is deployed for the LSA, left

carotid artery, or brachiocephalic trunk depending on the landing zone; and an optional proximal aortic extender (2) (Fig. 1).

Surgical technique

In all cases, under general anesthesia administered by the cardiothoracic group at our hospital, the procedure was performed percutaneously after placement of a temporary pacemaker via the right jugular vein. Interventions were performed in our standard operating room equipped with a C-arm fluoroscopy system, as described below.

Systemic heparinization was performed with 1 mg/kg of unfractionated heparin to achieve an activated clotting time (ACT) of approximately 250-300 seconds, monitored and adjusted per protocol by

Table I. Clinical characteristics of patients and anatomy of aortic disease

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Sex	Male	Female	Male	Female	Male	Female	Male
Age (years)	51	64	51	59	74	74	72
Medical history	Smoker; asthma on inhalers; dyslipidemia	Hypertension; subclinical hyperthyroidism; dyslipidemia	Dyslipidemia	Smoker; hypertension	Hypertension; cured prostate cancer	Hypertension; dyslipidemia; hypothyroidism; Sjögren syndrome	Hypertension; diabetes; dilated cardiomyopathy; non-Hodgkin lymphoma in complete remission; dyslipidemia
NYHA functional class	I	II	I	I	I	II	I
Indication for TBE	Saccular arch aneurysm	Type B aortic dissection; distal hemiarth fusiform aneurysm	Posttraumatic pseudoaneurysm (7 mm × 12 mm), aortic isthmus	Intramural hematoma with penetrating ulcer	Intramural hematoma with 9-mm penetrating ulcer	Intramural hematoma and arch dilatation	Type IA endoleak after thoracoabdominal aortic aneurysm (TAAA) repair (cTAG + E-nside)
Maximum aortic diameter	50 mm	60 mm	25 mm	29 mm	28 mm	55 mm	58.8 mm (sac growth of 6 mm in 7 mo)
Distance from proximal neck to left carotid artery	27 mm	30 mm	24 mm	28 mm	27 mm	24 mm	25 mm



Figure 1. Gore thoracic branch endoprosthesis. It consists of a main body with a retrograde branch for implantation of the self-expanding stent into the LSA and an optional proximal aortic extension.

anesthesia. Intraoperative cerebral perfusion was monitored using near-infrared spectroscopy; at our center, the INVOSTM system is used.

Procedure specifications are shown in table II.

Ultrasound-guided percutaneous puncture of the left radial artery was performed for advancement of a 5-Fr introducer sheath and a 0.035-mm Jagwire Boston® guidewire (450 cm) into the left descending coronary aorta. Ultrasound-guided femoral access was obtained: one for pigtail catheter placement and another for insertion of a snare catheter into the left descending coronary aorta to perform a through-and-through maneuver. In cases of dissection, intravascular ultrasound (IVUS) was used to ensure that the guidewire remained in the true lumen. Subsequently, via the through-and-through access, a 0.035-mm hydrophilic Terumo guidewire

Table II. Summary of technical characteristics of each intervention

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Temporary pacemaker	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cerebrospinal fluid drainage	No	Yes	No	Yes	Yes	Yes	Yes
LSA access (ultrasound-guided puncture)	Yes, 5-Fr	Yes, 5-Fr	Yes, 5-Fr	Humeral dissection, 5-Fr	Humeral dissection, 5-Fr	Humeral dissection, 5-Fr	Humeral dissection, 5-Fr
Right CFA access (ultrasound-guided puncture)	Yes, 20-Fr	Yes, 22-Fr	Yes, 22-Fr	Yes, 24-Fr	Yes, 24-Fr	Yes, 26-Fr	Femoral dissection, 24-Fr
Left CFA access (ultrasound-guided puncture)	Yes, 5-Fr	Yes, 5-Fr	Yes, 5-Fr	Yes, 5-Fr	Yes, 5-Fr	Yes, 5-Fr	No (occluded axis); right radial puncture, 5-Fr
Technical success	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TBE size (mm)	34 × 150	37 × 150	31 × 150	34 × 150	34 × 150	40 × 150	37 × 150
LSA branch size (mm)	8 × 12	8 × 10	8 × 10	8 × 10	8 × 10	8 × 12	8 × 12
Distal extension	No	cTAG 37 × 150; 31 × 100	No	cTAG 34 × 200	cTAG 34 × 100; 31 × 150	cTAG 40 × 200; 40 × 150	cTAG 40 × 200
Proximal extension	No	No	No	No	No	No	No

was advanced in parallel for exchange to a Lunderquist wire, followed by placement of a DrySeal introducer sheath appropriate to the device size. Afterwards, the TBE was advanced over both guidewires (the system includes a precannulated port through which the Jagwire must be introduced), maintaining tension on the through-and-through and ensuring no crossing occurred. This step is critical to prevent endograft rotation and achieve proper branch orientation. After confirming correct positioning by angiography, the stent-graft was deployed in zone 2 without the need for rapid ventricular pacing.

Subsequently, a stent was implanted in the LSA branch and molded.

In cases requiring coverage of a longer thoracic aortic segment, distal extension with cTAG® was performed after TBE implantation.

Finally, control angiography was performed to confirm proper positioning of all components, exclusion of the disease, and patency of the LSA branch. Endovascular material was removed under fluoroscopy. Femoral access for the TBE was closed using Perclose ProGlides™, the contralateral femoral access with Mynxgrip™, and radial access with manual compression.

Definitions

Technical success was defined as correct deployment and implantation of the stent-graft in zone 2, with preserved LSA patency and absence of type I or III endoleaks on final angiography (3).

Clinical success was defined as the absence of neurologic events, component thrombosis, conversion to open surgery, and treatment-related death (3).

Perioperative mortality was defined as death occurring within the first 30 days after the procedure; stroke was defined as a neurologic deficit lasting more than 24 hours diagnosed by a neurologist or confirmed by imaging (3).

Follow-up

Patients underwent control CCTA prior to hospital discharge and subsequently at 6 months. At 1 year, a new CCTA and associated clinical evaluation will be performed.

RESULTS

The patients' mean age was 63 years (51–74), with 4 men and 3 women. The most frequent comorbidities included hypertension ($n = 5$), dyslipidemia ($n = 4$), and a past medical history of smoking ($n = 2$). Three patients had endocrine disorders (subclinical hyperthyroidism or hypothyroidism), and 2 had a past medical history of oncologic disease (cured prostate cancer and non-Hodgkin lymphoma in remission). One patient had dilated cardiomyopathy and another bronchial asthma. Regarding functional status, most patients were in New York Heart Association (NYHA) class I, except for 2 patients classified as class II.

Aortic disease

Indications for treatment with TBE included saccular arch aneurysm ($n = 1$), chronic type B dissection with fusiform aneurysm ($n = 1$), posttraumatic pseudoaneurysm ($n = 1$), intramural hematoma with penetrating ulcer ($n = 2$) and without ulcer but with a dilated arch ($n = 1$), and a type IA endoleak after previous thoracoabdominal aneurysm repair with branched stent-graft ($n = 1$).

Clinical characteristics of the patients and the anatomic features of the aortic disease are shown in table I.

TBE stent-graft implantation

In all cases, device deployment was performed under rapid ventricular pacing at 180 bpm to achieve a systolic blood pressure of approximately 50–60 mmHg.

Prophylactic cerebrospinal fluid drainage was performed in patients in whom more than 150 mm of descending thoracic aorta was covered to prevent spinal cord ischemia ($n = 3$).

In 2 cases, a small left humeral artery approach was used to perform the through-and-through maneuver; in the remaining cases, this was achieved via ultrasound-guided radial puncture.

The sizes of the implanted stent-grafts are shown in table II.

During the procedures, no intraoperative cerebral perfusion abnormalities were detected in any patient. The mean procedural time ranged from approximately 120 to 240 minutes.

Figure 2 illustrates sequences of control angiography before and after aneurysm exclusion in our first patient.

Postoperative results

Two vascular access complications were reported: one left femoral pseudoaneurysm treated with percutaneous thrombin injection and one acute ischemia of the right lower limb requiring femoropopliteal thrombectomy and femoral patch angioplasty with a biologic patch.

One patient presented a left insular infarction within the first 24 hours, with minimal facial hemiparesis at discharge. The same patient experienced a second transient episode of hypersomnolence without radiologic findings or persistent deficit.

During hospitalization, one case of postimplantation syndrome and one headache due to cerebrospinal fluid drainage puncture were observed, both resolving with conservative treatment.

No intraoperative endoleaks were detected. In one patient, CCTA performed prior to discharge revealed a type III endoleak at the junction between the main component branch and the self-expand-

ing stent for the LSA; therefore, a 2nd surgical act was scheduled, during which remodeling was performed using a molding and occlusion balloon (MOD).

Patients remained in the recovery unit for 24 to 48 hours and, after transfer to the ward, ambulated without complications.

The median length of stay was 6 days (3-9).

Follow-up

From April 2024, when the first case was performed, through May 2025, the median follow-up was 6 months (1-13).

There were no mortality or complications during follow-up.

On CCTA prior to discharge, all patients showed correct exclusion of their aortic pathology, with patency of the LSA branch.

Table III summarizes postoperative results and follow-up for each patient.

DISCUSSION

This article describes the initial experience with the GORE® TAG® Thoracic Branch Endoprosthesis (TBE) system at our center. All patients who underwent implantation met the manufacturer's instructions for use.

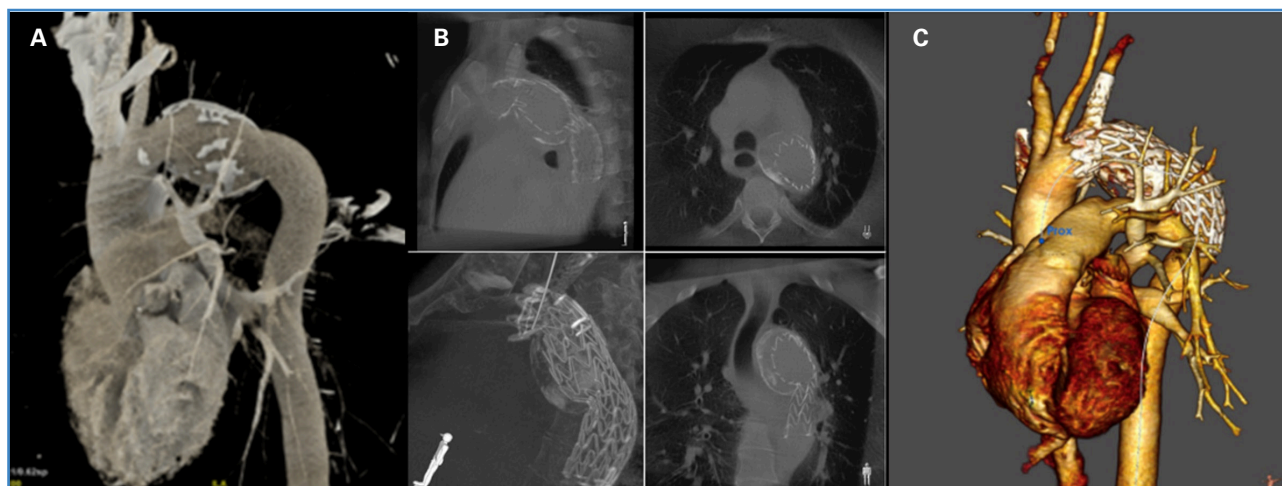


Figure 2. A. Preoperative CT reconstruction of our first treated patient. B. Final intraoperative control after stent-graft implantation. C. Postoperative CT reconstruction 1 week after the procedure.

Table III. Postoperative and follow-up outcomes of each patient

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Postoperative bleeding	No	No	No	No	No	No	No
Vascular access complications	Left femoral pseudoaneurysm	No	No	No	No	No	Yes; acute right lower limb ischemia
Neurologic deficit (transient or permanent)	No	Yes; left insular infarction	No	No	No	No	No
Type I or III endoleak at discharge	No	No	No	No	No	Type III	No
Other events	No	Postimplantation syndrome	No	No	Postpuncture headache; CSF drainage	No	No
Reinterventions	No	No	No	No	No	Yes; Trilobe/ MOD remodeling for type III endoleak	Yes; right femoropopliteal thrombectomy
Mortality	No	No	No	No	No	No	No
Postoperative length of stay (days)	3	3	5	6	6	9	6
Follow-up time (until May 2025)	13 months	10 months	7 months	6 months	6 months	5 months	1 month

Although this device has been designed to avoid the need for rapid ventricular pacing, due to our extensive experience in TEVAR and the availability of a dedicated cardiothoracic anesthesia team, we preferred to implant a temporary pacemaker to improve visualization and control during deployment.

As a technical consideration to avoid guidewire crossing, we recommend that once the introducer sheath has been positioned, the main guidewire should be removed and the through-and-through maneuver performed. Subsequently, while maintaining tension on the through-and-through, a hydrophilic guidewire is advanced; over this, a catheter is introduced and exchanged for a rigid Lunderquist guidewire.

In the first patient, this sequence was not followed, and difficulties were encountered in advancing the stent-graft due to repeated guidewire crossing. Ultimately, the recommended sequence was ap-

plied, achieving proper positioning of the device. In the remaining cases, this sequence was followed, resulting in smooth stent-graft navigation without guidewire entanglement.

Perioperative technical success after TBE implantation in our series was 100%. Regarding complications, one permanent but non-disabling neurologic event was reported: a small left insular infarction within the first 24 hours after the procedure, evaluated and managed conservatively by Neurology. As a sequela, the patient developed right lower facial hemiparesis, which has improved over time. Stroke, which may occur during aortic arch manipulation due to embolization of solid material or air from the delivery system, is a serious complication described in endovascular repair, with reported rates between 0% and 14% (4). To minimize this risk, several techniques have been described, such as the use of filters or carbon dioxide flushing of the delivery sys-

tem. In our case, as we limited our intervention to zone 2, no protection techniques were used. In the literature, the incidence rate of these complications with TBE, even in acute aortic pathology (5), is similar to initial experiences with other branched arch devices and standard TEVAR without arch involvement. These results are also comparable to those of LSA revascularization using extra-anatomic bypass (6).

During follow-up, no mortality or radiologic complications were observed. Branch patency was 100%, with complete exclusion of the disease. One type III endoleak was identified. In the reviewed literature, a higher frequency of this type of endoleak has been observed with TBE vs standard TEVAR procedures. This is due to the junction between the aortic component branch portal and the self-expanding stent in the LSA, highlighting the importance of balloon molding at this site, as performed in our patient 6 during a 2nd surgical act. This type of endoleak requires follow-up to determine which cases are self-limited and which may require future reintervention (6,7).

Currently, other endovascular strategies exist for LSA preservation, such as noncustomized branched devices (Castor/Crator type), in situ fenestration, or physician-modified stent-grafts. These alternatives have shown acceptable results in selected series, particularly in complex anatomies or urgent cases; however, they present greater technical variability, depend heavily on surgeon experience, and in some cases involve off-label use or manual modifications, which may have regulatory implications (8-12). In this context, TBE is currently the only noncustomized device approved in Europe for targeted preservation of the LSA in aortic repair requiring zone 2 anchoring.

Limitations of the study

Our study has the inherent limitations of an initial, single-center series with a small number of patients. Nevertheless, it represents one of the first analyses of early experience with TBE use in Spain.

As a result, the learning curve is still ongoing and, so far, limited to elective procedures. No conclusions can be drawn regarding durability and long-term

outcomes due to the relatively short follow-up period; however, the initial results are comparable to those reported in international centers with larger series (8).

CONCLUSIONS

The results of endovascular repair using the Gore® TAG® Thoracic Branch Endoprosthesis system in a selected population of patients with favorable anatomy are promising. In our experience, excellent outcomes were observed in terms of technical success, mortality, and reintervention rates.

Considering the reported neurologic events, our results are comparable to those described in the current literature for other arch devices and even for extra-anatomic bypass revascularization. Clinical experience and follow-up in Spain remain limited; however, international studies support its efficacy and safety pending long-term results.

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