

The Gore Global Registry for Endovascular Aortic Treatment (GREAT)

Real-world experience in Brazil and worldwide with the GORE® EXCLUDER® AAA Endoprosthesis, GORE® C3® Delivery System, GORE® TAG® Thoracic Endoprosthesis, and Conformable GORE® TAG® Thoracic Endoprosthesis.

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At 8,514,877 km² and with 203,429,773 people, Brazil is the largest country in South America. Eighty-seven percent of its population lives in urban areas, with a life expectancy of 68.97 and 76.27 years for men and women, respectively. According to the Brazilian Ministry of Health (DATASUS), cardiovascular diseases account for 31.5% of all deaths, the highest mortality rate for cardiovascular diseases in the Americas, representing 286 deaths per 100,000 inhabitants per year; the United States has 179 deaths per 100,000 per year. These rates are at epidemic proportions, becoming an emerging concern and a priority for the Brazilian Ministry of Health.¹

The prevalence of aortic aneurysm disease in Brazil is similar to that in the occidental world, affecting 5% of men over age 65. In 2012, approximately 10,000 patients were treated for aortic aneurysms, and less than 50% underwent endovascular techniques.¹

Recent studies have shown that approximately 65% of all abdominal aortic aneurysm repairs in the United States were performed through endovascular techniques, while in Europe, the average is 40%.² Due to new advances and technologies, the trend has been a rise in endovascular aneurysm repair (EVAR) coming closer to being the first choice for aneurysm repair.

The GORE EXCLUDER Device and GORE TAG Device (Gore & Associates, Flagstaff, AZ) have been commercially available for more than 15 years and 13 years in Brazil with more than 750 GORE EXCLUDER Devices featuring C3 Delivery System and 3,500 GORE TAG Devices and Conformable GORE TAG Devices implanted through 2012.^{3,4}

The Gore Global Registry for Endovascular Aortic Treatment (GREAT) was designed to evaluate real-world

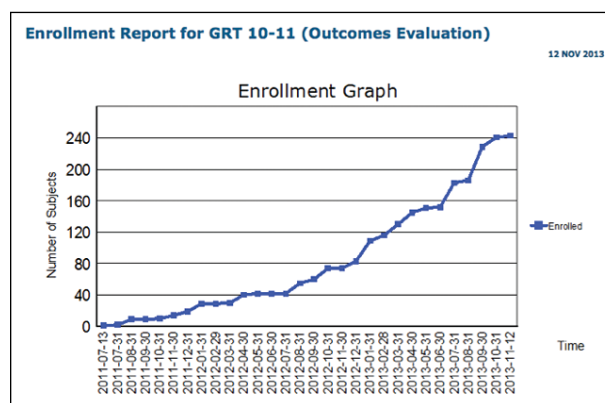


Figure 1. Gore GREAT registry–Brazil enrollment, as of November 2013.

outcomes after treatment with aortic endovascular products (GORE EXCLUDER Device, GORE C3 Delivery System, GORE TAG Device, and Conformable GORE TAG Device) used in global markets (United States, Europe, Australia, and Brazil) and to identify the trends of on-label and off-label use of the devices. In order to reach this goal, the Internet-based registry will collect data from 10 years of follow-up on 5,000 patients from up to 300 sites worldwide.⁵

This is the first time that Brazil has participated in a global, multicenter registry for aortic stent-grafts.

THE GREAT REGISTRY IN BRAZIL

Ten institutions located in seven states were selected for the Gore GREAT registry–Brazil. Recruitment of consecutive patients began in July 2011. The Gore

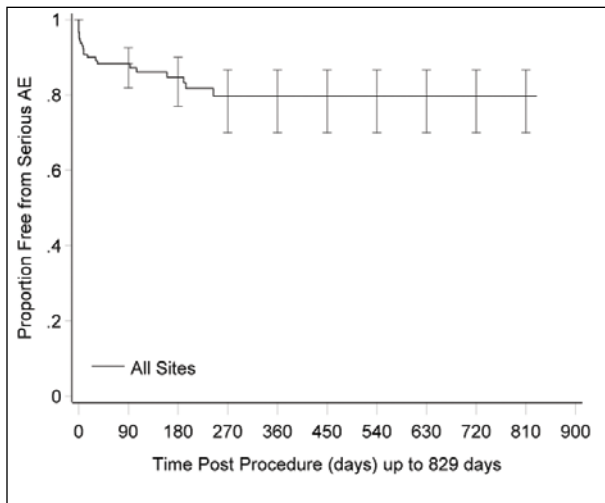


Figure 2. The Kaplan-Meier curve for freedom from serious adverse events.

GREAT-Brazil enrollment target was 300 patients by the end of 2013. In November 2013, we stood at 243 patients (Figure 1).

Within the 243 patients enrolled so far, 80.4% were men, 75% were white, and the mean age was 68.9 years old (median 70; range, 42–87). Primary pathology indicating treatment was abdominal aortic aneurysm (61.8%), followed by descending thoracic aortic aneurysm (16.9%), common iliac aneurysm (11.2%), thoracoabdominal aneurysm (5.1%), type B uncompli-

cated dissection (4.5%), and others. Eighty-three percent of the GORE TAG Thoracic Endoprostheses were used outside the instructions for use (IFU), as were 55% of the placed Conformable GORE TAG Thoracic Endoprostheses, and 47.3% of the deployed GORE EXCLUDER AAA Endoprostheses. Cases treated with GORE EXCLUDER AAA Endoprostheses were challenging in 17.1% (proximal neck length < 1.5 cm and/or those with infrarenal neck angle > 60°).

Among the procedures, 91% were primary endovascular repair, 5.1% were reintervention after open repair, and 3.9% were reintervention after endovascular repair. Cutdown was performed in 95.6% of the cases, and percutaneous access was performed in 15% of the cases. Procedural survival rate was 100%, and mean hospital stay was 7.8 days (median 4; range, 1–82).

The 30-day mortality rate was 3.9%. Stroke/transient ischemic attack (considered serious adverse events), paraplegia/paraparesis, reinterventions, conversion to open repair, and device-related reinterventions are outlined in Table 1. The Kaplan-Meier curve for freedom from serious adverse events is shown in Figure 2.

THE GORE GREAT REGISTRY WORLDWIDE

Among enrolled patients worldwide (N = 909 at data export in November 2013), 83.2% were men, and the mean age was 72.3 years. The majority of treatment indication was abdominal aortic aneurysm (79.4%), followed by descending thoracic aortic aneurysm (6.4%),

TABLE 1. GORE GREAT REGISTRY—BRAZIL

Key Outcomes Since Initial Procedure Across Analysis Windows						
	Procedure	1 Month	6 Months	1 Year	2 Years	Total (Procedure–2 Years)
All Reinterventions ¹	0 (0%)	4 (3.1%)	2 (2.0%)	0 (0%)	0 (0%)	6 (3.3%)
Device-Related Reinterventions ¹	0 (0%)	2 (1.6%)	2 (2.0%)	0 (0%)	0 (0%)	4 (2.2%)
Number of Subjects With Any Follow-Up and/or Event ²	180	127	101	44	4	180
Subjects With Any Event Below	2 (1.1%)	8 (6.3%)	6 (5.9%)	0 (0%)	0 (0%)	16 (8.9%)
Mortality	0 (0%)	5 (3.9%)	4 (4.0%)	0 (0%)	0 (0%)	9 (5.0%)
Stroke/TIA ³	1 (0.6%)	1 (0.8%)	0 (0%)	0 (0%)	0 (0%)	2 (1.1%)
Paraplegia/Paraparesis/Spinal Cord Ischemia ³	1 (0.6%)	1 (0.8%)	0 (0%)	0 (0%)	0 (0%)	2 (1.1%)
Analysis time window definitions: Procedure (0 day), 1 Month (1–59 days), 6 Months (60–240 days), 1 Year (241–545 days), 2 Years (546–910 days), 3 Years (911–1,276 days), 4 Years (1,277–1,641 days), 5 Years (1,642–2,006 days), 6 Years (2,007–2,371 days), 7 Years (2,372–2,736 days), 8 Years (2,737–3,101 days), 9 Years (3,102–3,466 days), 10 Years (3,467–3,831 days)						
¹ All reinterventions include any invasive or minimally invasive measure related to the initial aortic procedure performed at any time following the initial procedure; device related reinterventions include any invasive or minimally invasive measure related to a deficiency of the device(s) implanted into the aorta performed at any time following the initial procedure.						
² Subjects are counted in the denominator if either had any reported date of contact ≥ start of window and/or reported event in the window; all subjects with initial procedure date are counted in Procedure and Total windows.						
³ Only those considered serious adverse events.						

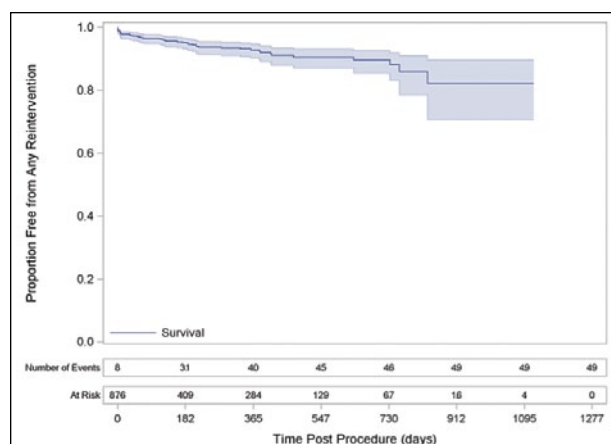


Figure 3. Kaplan-Meier curves for patients free from any reinterventions. The shading represents the confidence intervals.

and common iliac aneurysm (6.2%). Other treatment indications were found in 2% of the cases and included abdominal aneurysm rupture, aortic dissection, internal iliac aneurysm, and others. For abdominal aneurysm, only a GORE EXCLUDER Device was placed in 99% of the cases; in the remaining cases, a GORE EXCLUDER Device and GORE TAG Device were used. For descending thoracic aortic aneurysm, only a GORE EXCLUDER Device was placed in 1% of the cases, a GORE TAG Device was placed in 94.7%, and a GORE EXCLUDER Device and GORE TAG Device were placed in 3% of the cases. Finally, for common iliac aneurysms, only a GORE EXCLUDER Device was placed in 96% of the procedures. The GORE TAG Thoracic Endoprosthesis was used outside the IFU in 76.5% of the cases that it was placed; the Conformable GORE TAG Thoracic Endoprosthesis, in 54.5%; and the GORE EXCLUDER AAA Endoprosthesis, in 49.4%.

The procedures were performed as primary treatment in 95.1% of the cases, whereas the remaining were reinterventions after previous endovascular or open surgical repair. Percutaneous access was performed in 33.4%; cutdown was used in 75.6% of the cases. There was no perioperative death. Endoleak rates after the procedure were 0.2% for type IA, 0.1% for type IB, and 0% for type III. At 1 year, rates were 0% for type IA, 0% for type IB, and 0% for type III. At 2 years, rates were 0% for type IA, 0.8% for IB, and 0% for type III. No migration or fracture of the device was identified through 2 years of follow-up.

Kaplan-Meier curves for patients free from any reinterventions and patients free from device-related reintervention are as shown in Figure 3 and Figure 4, respectively. Any reinterventions were defined as any invasive or minimally invasive measure related to the initial aortic procedure performed at any time following the initial procedure. Device-related reinterventions were defined

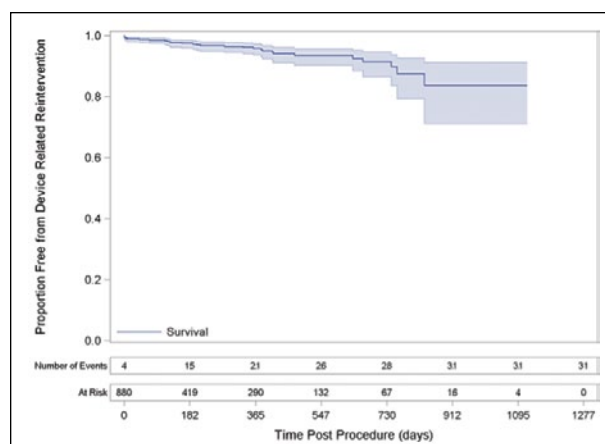


Figure 4. Kaplan-Meier curves for patients free from device-related reintervention. The shading represents the confidence intervals.

as any invasive or minimally invasive measure related to a deficiency of the device(s) implanted into the aorta performed at any time following the initial procedure.

CONCERNS

Endovascular approaches for aortic disease repair have been used extensively in recent years. Even though published patient outcomes and device performance confirmed good results, these procedures were mainly performed in high-volume centers and do not disclose the real-world reality. Furthermore, despite the fact that procedural success could match these data, it is crucial to compare long-term outcomes. Bearing in mind this possible disparity, the Gore GREAT registry may have a distinctive role because it is able to evaluate worldwide outcomes and is also capable of comparing real-world experience with high-volume center results, including 10-year follow-up.

Regarding the Gore GREAT registry–Brazil, concerns about the reliability of patient information were raised because it is the first time Brazil is participating in a global, multicenter registry with aortic stent-grafts. However, we cannot lose sight of the fact that Brazil is the largest country in South America, representing a significant portion of the global stent-graft market and with great growth potential, and it is therefore an important section of the real-world results. Moreover, being part of a worldwide trial is the most efficient method of learning and training research centers to achieve levels of excellence. This feature becomes even more important when we realize that the real-world results will only be truly reliable when the enrollment of patients is equal to the proportion of procedures performed worldwide; even if this is unlikely to happen, we need to keep moving in this direction.

Concerning the Gore aortic endovascular devices, we must remember that an essential aspect of endovascular

procedures is the accuracy of the device deployment. The redesigned GORE EXCLUDER Endoprosthesis featuring C3 Delivery System allows repositioning of the stent-graft, ensuring higher precision on the endograft placement.^{6,7} The newer design of the Conformable GORE TAG Device allows a better accommodation in the aortic arch, especially with tight aortic arches and smaller aortic diameter, decreasing endoleak rates.⁸ Such improvements in endovascular devices are leading us to their widespread application and oftentimes with off-label use. This is a great feature for many patients, but it can also induce problems and complications. To date in Brazil and worldwide, outcomes show that the GORE EXCLUDER Device and Conformable GORE TAG Device are safe and effective, presenting low rates of serious adverse events and reintervention when we analyze the Kaplan-Meier free-from-device-related-reintervention curve (Figure 4). Nevertheless, even with documented favorable outcomes, surgeons should be aware that troubles could arise, especially when the devices are used outside the IFU.

CONCLUSION

Initial Gore GREAT registry results demonstrate that Gore aortic endovascular devices are secure and offer advantages, particularly with the GORE C3 Delivery System, which allows device repositioning, and the Conformable GORE TAG Device, which permits better accommodation to the aortic arch. Such improvements in device technology have clearly increased off-label use as surgeons become more confident with endovascular procedures. Although this is lifesaving for many patients, it may cause problems and complications, therefore endovascular devices should not be misused.

Despite the criticism against registry studies regarding possible bias and lack of methodological rigor, the snapshot gained gives us a true landscape of EVAR and TEVAR results in the real world. A 10-year follow-up

registry, such as the Gore GREAT registry, will provide important real-world data from across the globe. ■

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