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Thoracic Endovascular Aortic Repair of Aortic Arch Pathologies with the Conformable Thoracic Aortic Graft: Early and 2 year Results from a European Multicentre Registry

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WHAT THIS PAPER ADDS

The conformable TAG is a next generation device specifically designed for aortic arch pathologies showing high conformability with a low rate of major device related events. Endovascular therapy of aortic arch pathologies is technically demanding and associated with significant stroke risk.

Objective: To assess safety, effectiveness and clinical outcome of the conformable thoracic aortic endograft (CTAG) in the treatment of aortic arch pathologies.

Methods: Between October 2009 and December 2010, 100 consecutive patients (65 men; mean age 65 years) with aortic arch pathologies were treated with the CTAG device in five European centres. Indications were thoracic aortic aneurysm ($n = 57$), Type B dissection ($n = 24$), intramural haematoma ($n = 4$), penetrating aortic ulcer ($n = 9$), and traumatic transection ($n = 6$). Emergency procedures were performed in 33%. The proximal landing zone (LZ) was LZ 0 in 7%, LZ 1 in14%, LZ 2 in 43%, and LZ 3 in 36%. Data were collected prospectively and analysed for technical and clinical success. Conformability and deployment accuracy were analysed on intra-operative angiography and post-operative computed tomography. Mean follow up was 24 ± 19 months (range, 0.3–36 months).

Results: The 30 day, 1 and 2 year survival rates were 90%, 81%, and 74% respectively. The 2 year survival was 80% in the elective and 62% in the emergency groups ($p = .20$). The major 30 day complication rate was 34%: primary Type Ia endoleak affected 1%, retrograde dissection in 1%, and the paraplegia and stroke rates at 30 days were 4% and 11%. Age > 70 years was an independent predictor for mortality and complications. The primary technical success rate was 92%; device deployment was successful in 100% and accurate in 99%. Conformability to the aortic arch was achieved in 95%.

Conclusion: The CTAG stent graft shows high deployment accuracy, good conformability, and clinical effectiveness in the treatment of aortic arch pathologies. However, thoracic endovascular aortic repair in the arch is associated with a relatively high stroke rate. Further studies with more patients and longer follow up are needed to evaluate the long-term results.

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INTRODUCTION

Thoracic endovascular aortic repair (TEVAR) of a variety of thoracic pathologies[1–7] has been shown to be an attractive alternative to open surgery with low procedural morbidity and mortality, and acceptable mid-term results. This has established TEVAR as the first line treatment for a broad range of thoracic aortic disease affecting the descending thoracic aorta. These pathologies involve the aortic arch in up to 60% of cases.[8,9]

Thoracic devices were initially developed from prototypes used in the infrarenal aorta.[10,11] It has long been recognized that thoracic devices perform well in the descending thoracic aorta, but do not conform to the anatomy of the aortic arch.[12] This is especially true when the radius of curvature of the arch is very tight. Rigid

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devices have caused perforation in the arch and have been implicated in the conversion of Type B to Type A aortic dissection with disastrous consequences.[12–14] Stent grafts which do not conform to the contours of the aortic arch can sit proud of the inner curvature of the arch forming a "bird beak" on imaging. The length of the graft, which is not in contact with the aorta, is related to the risk of device collapse, which can result in sudden aortic occlusion and death. Failure to comply with the arch anatomy may increase the risk of device associated complications, resulting in aortic rupture and death. The conformable thoracic aortic graft (CTAG, WL Gore & Assoc., Flagstaff, AZ, USA) is one of the first compliant devices to be specifically designed for use in the arch and to conform with its geometry. It overcomes problems of misalignment, bird beaking resulting in endoleak, compression or collapse of the device. To date there is no evidence of the superiority of any single device over its competitors.[15]

The aim of this study was to report the procedural, 30 day and 2 year results for the CTAG in a variety of acute and chronic aortic arch pathologies in a multicentre European registry.

METHODS

Study design and primary study endpoints

The European CTAG Registry is a prospective multicentre, post-market, single arm study, initiated by physicians and designed to analyse the procedural performance and 2 year clinical results of the CTAG for endovascular repair of different aortic arch pathologies in zones 0–3.[16] A total of 100 consecutive patients who underwent either elective or urgent TEVAR at five European centres were included in the study.

The primary endpoints of the study were early and mid-term mortality of TEVAR in the arch (Zones 0–3), overall rate of serious adverse events (SAEs), and assessment of conformability of the CTAG device.

Patient population

A cohort of 100 patients (65 men; median age, 65 ± 1.41; range, 29–86 years) received TEVAR between October 2009 and December 2010 for a variety of underlying thoracic aortic pathologies. Indications for treatment included 57 thoracic aortic aneurysms (TAA) ($n = 47$ elective, $n = 10$ urgent), 24 with Type B dissections (16 acute and 8 chronic), four intramural haematomas (IMHs), nine penetrating aortic ulcers (PAUs), and six traumatic transections. The majority of patients were considered to be at high risk for open surgery because of comorbidities, according to the American Society of Anesthesiologists Score, previous aortic surgery (14%) and emergency conditions (33%), and were therefore selected for endovascular treatment as first choice. Exclusion criteria included patients with aortic pathologies needing device deployment in proximal landing zone (LZ) 4 according to Ishimaru et al.[16]

Device and procedure description

The CTAG device is an evolution of the thoracic aortic graft (TAG, WL Gore & Assoc.). Modifications compared to the TAG device have been reported before.[17] When placed in a curved position the device shows no tendency to straighten, which enables the device to adopt a stable position in the aortic arch after deployment. The reduction in length of the inner curvature is achieved by telescoping consecutive segments of the inner radius of the device throughout its length (Fig. 1).

Standard pre-procedural imaging by computed tomography angiography (CTA) was used to determine the length and diameter of the device based on the CTAG sizing chart (Fig. 1). Proximal LZs were defined as where the proximal aortic neck length represented a sufficient attachment segment for proper CTAG apposition and was based on the classification of Ishimaru et al.[16] A stiff guidewire was positioned on the outer curvature of the arch and the CTAG was inserted proximal to, and then withdrawn distally from, the optimum deployment site in order to ensure that no tension would cause any forward motion during deployment. Post-ballooning (Trilobe balloon, WL Gore & Ass.) was used selectively but not in acute aortic dissections, intramural haematoma, and traumatic transections in order to avoid retrograde dissection.[14] Completion angiography was routinely performed to verify the implant position and to detect endoleaks.

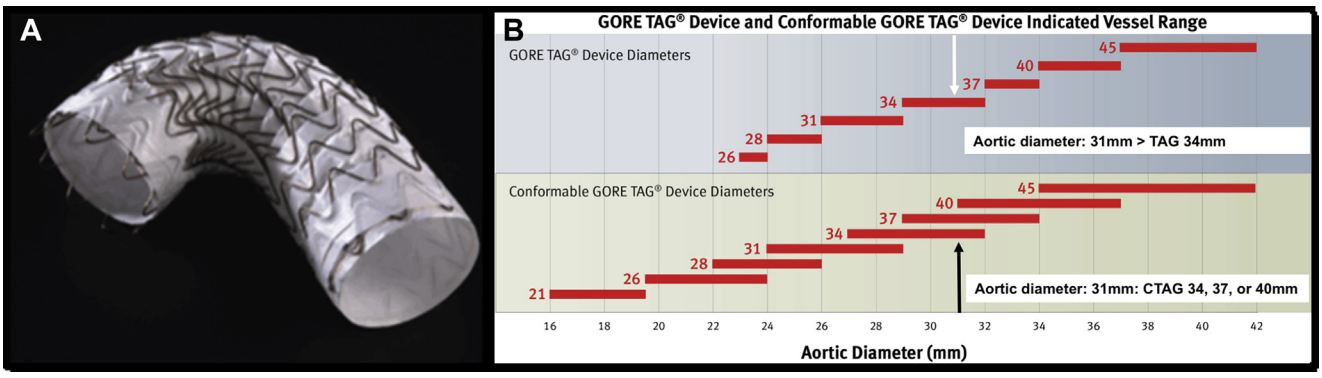

Figure 1. (A) The Gore conformable thoracic aortic graft (CTAG) endoprosthesis demonstrates high conformability due to design changes. (B) Oversizing windows indicate the option of selecting three different device diameters: oversizing with CTAG (lower green chart) for the same aortic diameter according to the underlying pathology compared to one available size with the former TAG (upper grey chart).