

Thoracic endovascular aortic repair with branched Inoue Stent Graft for arch aortic aneurysms



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ABSTRACT

Background: Thoracic endovascular aortic repair (TEVAR) for thoracic aortic aneurysms (TAAs) is in rapid expansion due to its minimal invasiveness. However, TEVAR for an arch aneurysm with a straight stent graft needs surgical reconstruction for supra-aortic vessels. A branched stent graft pioneered by Inoue (branched Inoue Stent Graft [ISG]) has been expected to resolve this problem, but its utility remains to be established in the real clinical setting. This study evaluated the long-term clinical outcome of branched ISGs for TAAs.

Methods: Among 217 consecutive patients who underwent TEVAR with ISGs between March 2003 and September 2013, 89 patients with TAAs were treated with implantation of the branched ISG (single branch: $n = 64$; double branch: $n = 18$; triple branch: $n = 7$). The primary end point was freedom from aneurysm-related death. Secondary end points included peri-procedural adverse events, freedom from all-cause death and major adverse events (composite of aneurysm-related death, surgical conversion, aneurysm rupture, persistent type I or III endoleak, graft infection, graft occlusion, graft migration, and aneurysm expansion), changes of aneurysm diameter, stroke, and any endovascular reintervention during follow-up.

Results: All deployments of branched ISGs were successful. The 30-day mortality was 4.5% (single branch, 3.1%; double branch, 0%; triple branch, 29%), and periprocedural stroke was 16% (single branch, 7.8%; double branch, 33%; triple branch, 42%). At 1 and 5 years, freedom from aneurysm-related death was 93% and 93%, respectively, and freedom from all-cause death was 85% and 59%, respectively. Survival free of major adverse events was 76% at 5 years. The cumulative incidence of stroke was 11% at 5 years. Three patients underwent surgical conversion because of persistent type I endoleak. One branch graft occlusion was observed at the left subclavian artery in a patient who received a double-branched graft.

Conclusions: Periprocedural outcome of the single-branched ISG was acceptable, and long-term safety and efficacy were demonstrated. However, the procedural complications of the multibranched ISG leave room for improvement. (*J Vasc Surg* 2017;66:1340-8.)

Thoracic endovascular aortic repair (TEVAR) for thoracic aortic aneurysms (TAAs) is in rapid expansion because it is less invasive. Recent reports indicate the feasibility of TEVAR for TAA in various clinical conditions.¹⁻⁷ TAA of the descending aorta is a good indication for TEVAR with the straight stent grafts that are now commercially available. However, patients with an arch aneurysm that

involves the supra-aortic vessels need conventional open repair. Extra-anatomical surgical bypass for those vessels, which is called debranched-TEVAR (dTEVAR),⁸⁻¹¹ or complex endovascular procedures, such as chimney technique^{12,13} or in situ fenestration,¹⁴ are needed to preserve neck vessels for TEVAR with a straight stent graft. Although dTEVAR is less invasive than conventional open arch replacement, mortality and morbidity are higher,^{8,9,11} and sometimes it is difficult to perform for complicated patients because of old age or severe comorbidities.

To resolve these problems straightforwardly, Inoue devised a branched stent graft of unibody construction, the branched Inoue Stent Graft (ISG), that allows repair of arch aneurysm without extra-anatomical surgical reconstruction or a complex endovascular procedure.¹⁵⁻¹⁸ Saito et al¹⁷ have reported short- to midterm feasibility of TEVAR with the single-branched ISG.¹⁷ However, long-term clinical follow-up with larger numbers of patients is still unclear. This study evaluated the long-term clinical outcomes of TEVAR with the branched ISG for arch aneurysms.

METHODS

Study population

This study was a physician-initiated, noncompany sponsored, prospective registry of the ISG in Kyoto University

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Hospital. The study protocol was approved by the Kyoto University Graduate School of Medicine Ethics Committee, and all participants gave written informed consent. The study was registered in the University Hospital Medical Information Network Clinical Trial Registry (UMIN000005430).

From March 2003 to December 2013, 217 consecutive patients with TAA or aortic dissection underwent TEVAR with the ISG. Straight ISGs were used in 74 patients, abdominal branched ISGs in 13, and thoracic branched ISGs in 130. Among the 130 patients with the branched ISG, 32 were excluded from the present analysis because they constituted an etiologically distinctive cohort that had aortic dissection ($n = 31$) or a patent ductus arteriosus ($n = 1$). Nine patients were excluded because of a secondary TEVAR after the primary procedure ($n = 7$) or an additional TEVAR after surgical replacement of the proximal aortic arch ($n = 2$) (Fig 1). This study included 89 patients (single branch, $n = 64$; double branch, $n = 18$; triple branch, $n = 7$) who underwent TEVAR with a branched ISG for TAA.

Study device and implant procedure: branched ISG

Study device. The ISGs were produced by PTMC Institute, Kyoto, Japan. They were made according to three-dimensional structural models generated on the computer from computed tomography (CT) images of TAAs. To this end, we have developed specialized software to design an optimized stent graft for each patient. The branched ISG is a custom-made all-in-one stent graft consisting of an aortic trunk section and branch sections which were sewn together (Figs 2 and 3; Supplementary Fig 1, online only). The main body and branch section of the ISG are constructed with a woven Dacron (DuPont, Wilmington, Del) polyester graft on which extra flexible nickel titanium rings are put for reinforcement and self-expandability. Further, small Dacron cuffs are attached to the proximal and distal edges of the graft to make the sealing between the graft and aortic inner wall tighter and less invasive. The main body and branch section were prepared separately from two series of Dacron grafts with varying diameters in 2-mm increments from 18 to 46 mm and from 8 to 20 mm, respectively. Then, they were sewn together in the appropriate combination and geometry. The branches in double- and triple-branched devices were attached specially based on the distance apart and axial location of the target vessels as predetermined by the computer-aided design system.

Selection criteria and contraindications. The single-branched graft requires a proximal landing zone that retains two margins of at least 5 mm in their total length being located on both sides of the left subclavian artery (LSCA) so that at least one cuffed sealing ring can be securely placed therein. Similarly, the double-branched graft requires a bipartite proximal landing zone sized at

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected registry data
- **Take Home Message:** Thoracic endovascular aortic repair was performed in 89 consecutive patients for aortic arch aneurysm with branched Inoue Stent Graft with 100% technical success, a mortality of 4.5%, and a periprocedural stroke rate of 7.8% with single-branched device and higher with multiple branches. Freedom from aneurysm-related death at 5 years was 93%.
- **Recommendation:** The single-branched Inoue Stent Graft is safe and durable, with acceptable periprocedural complications. Caution using multiple branches is warranted.

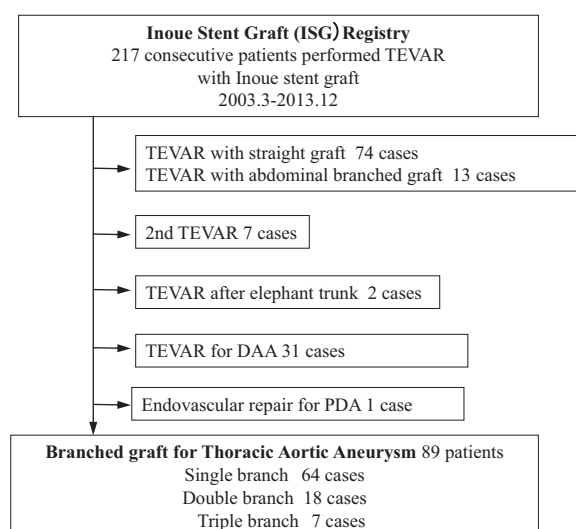


Fig 1. Study flow chart. DAA, Dissecting aneurysm of aorta; PDA, patent ductus arteriosus; TEVAR, thoracic endovascular aortic repair.

least 5 mm in total and located on both sides of the left common carotid artery (LCCA) (Fig 2, A and B). The triple-branched graft requires at least 20 mm proximal to the brachiocephalic artery. The acceptable range of diameters in the aorta and the branch vessels is 16 to 42 mm for the main graft and 7 to 18 mm for the branched grafts. In either type of branched graft, therefore, an enlarged aorta >42 mm in diameter at the proximal landing zone is contraindicated.

Implant procedure. Structural details of the implant procedures of the variously branched ISGs have been reported by Inoue and Saito.^{15,16,19} The ISG structure includes several function wires. A carrying wire is attached to the proximal end of the ISG main body, and traction wires are attached to each distal end of the main body and branch sections. These wires are detachable by pulling back the thin wire that pass through the function

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