Endovascular treatment of infrarenal aortic aneurysm using the ANKURA stent graft – one-center case series

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Introduction

The prevalence of abdominal aortic aneurysm (AAA) in the general population is 4–8%; it is nine times more common in men than women and rises to 9% starting from the sixth decade of life. A real breakthrough in AAA management was the advent of minimally invasive endovascular repair. Compared to open repair, endovascular aneurysm repair (EVAR) is undoubtedly less invasive and less traumatic for the patient. It is associated with lower blood loss and transfusion rates, shorter hospital stay and faster recovery [1–3].

EVAR patients show lower 30-day mortality (1.6%) than those who undergo open surgery (4.8%); the advantage is even more pronounced in high-risk cardiac or pulmonary disease. Long-term survival is comparable, mostly because EVAR is performed in patients who are not eligible for open repair, i.e., those with compromised cardiac or pulmonary function. Also, some patients may need follow-up CT angiography, which increases the risk of development or exacerbation of chronic renal disease [4].

Material and methods

This retrospective non-randomized one-center report presents short- and mid-term outcomes of elective EVAR performed in 52 patients with infrarenal abdominal aortic aneurysms. All received the ANKURA AAA stent graft (Lifetech) – one of the new grafts on the medical market. Eligibility for endovascular treatment was verified by CT angiograms subsequently analyzed using the Endosize software (Therenva, France). Prior to stent placement the patients underwent laboratory tests and cardiovascular examination including EaCG and echocardiography with EF. Cardiac risk was estimated with the VQI-CRI (Vascular Quality Initiative Cardiac Risk Index for Prediction of Myocardial Infarction after Vascular Surgery) [5].

Postoperative in-hospital assessment included the length of ICU admission, hematocrit, creatinine and post-EVAR complications. Demographic data and clinical characteristics of the patients are presented in Table I. Statistical analysis of data was performed in Statistica software v. 13.3 (StatSoft).

The ANKURA is a suprarenal nitinol stent graft. Its modules are self-expanding and coated with multilayer ePTFE. The main body delivery system is 21–23F in diameter while the iliac extensions are 18F. There are anchor pins at the proximal end (bare segment over ePTFE coating) that fix the stent inside the aorta at the level of the renal arteries. The stent graft system is delivered through the common iliac arteries using surgical or percutaneous access. Following expansion of the stent body, iliac extensions are implanted in the iliac arteries. After implantation is completed, ballooning is performed with a low-pressure balloon.

Patients found eligible for stent graft implantation according to ANKURA IFU (proximal neck length > 15 mm, proximal neck diameter 18–32 mm, proximal neck angulation ≤ 60°, distal iliac artery anchorage zone ≥ 15 mm, iliac arteries diameter 8–20 mm) received single antiplatelet therapy with aspirin (ASA 75 mg/day) prior to EVAR. Aspirin was continued postoperatively in combination with infusion of unfractionated heparin in a dose of 10–15,000 IU over 24 h. Perioperative antibiotic therapy was performed. Starting on postoperative day 1, the patients received a prophylactic dose of low-molecular-weight heparin (LMWH) and double antiplatelet therapy (DAPT: aspirin 75 mg/day + clopidogrel 75 mg/day).

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LMWH was administered for 10 days and DAPT for 30 days according to the center's experience.

Follow-up consisted of color duplex Doppler ultrasound within 30 days and then 3–42 months of stent graft implantation. Duplex examination was performed by two experienced operators. To reduce the risk of contrast-induced nephropathy and irradiation, CT angiography was only performed in patients with suspected/confirmed endoleaks. Thirty patients have been followed up for over 24 months now.

Results

Fifty-two patients after elective ANKURA AAA stent graft implantation were included in the analysis. Follow-up was 4–42 months (mean: 23). In all patients the VQI-CRI was 4.5% or higher. In 51 (98%) patients percutaneous access was used with vascular closure devices (ProGlide, Abbot). Procedural data are presented in Table I. There were no deaths, acute limb ischemia or acute kidney failure during hospital stay. Also, there was no need for a repeat procedure. Five patients died within 3 to 42 months after stent graft implantation of sudden cardiac death (n = 1), neoplastic disease (n = 2), stroke (n = 1) and COVID (n = 1). There have been no deaths related to the device or the EVAR procedure.

No acute kidney failure was diagnosed during the inpatient stay; this also concerned the 2 patients admitted with chronic kidney disease. The mean pre- and post-EVAR creatinine levels were 86 mmol/l and 78 mmol/l, respectively; the difference was statistically significant (Wilcoxon test). The decrease in creatinine concentration probably resulted from patient preparation for endovascular treatment and balanced fluid replacement after the procedure.

Post-EVAR decreases in hemoglobin (14.3 g/dl to 12.2 g/dl) and hematocrit (42.6% to 36%) reached the level of statistical significance (Wilcoxon test). No patient needed blood transfusion during hospital stay. Technical success, i.e., system placement, stent graft implantation, no intraoperative access site complications, was achieved in 98.1% of cases.

Despite the pre-procedural CT angiography, the ANKURA stent graft could not be placed in 1 (1.9%) patient due to narrow and highly tortuous iliac arteries. A repeat procedure with a lower-profile stent graft performed 3 weeks later proved successful.

During 30 days of stent graft implantation, type I and III endoleaks were revealed in 1 (1.9%) patient; an additional proximal extender and left iliac extension were placed, resulting in adequate sealing. Within 3 months of the procedure another patient was diagnosed with inferior mesenteric arterial type II endoleak and sac enlargement; Onyx embolization via the superior mesenteric artery and Riolan arch effectively closed the leak. Within 24 months still another patient had inferior mesenteric arterial type II endoleak with sac enlargement, successfully closed with Onyx. Three (5.7%) patients had type II endoleak with no aneurysm sac enlargement; the patients continue to be followed up. Type II endoleak was seen in a total of 5 (9.5%) patients; considering type I and III endoleaks, the overall endoleak rate was 11.4%.

Aneurysm diameter has been monitored in all patients. Sac enlargement > 5 mm was found in 2 (3.8%) patients who had undergone a repeat intervention due to type II endoleak. A > 5 mm decrease in aneurysm diameter was revealed in 39 (74%) patients. No sac shrinkage

Table I. Demographic, clinical data and procedural data (n = 52)

Parameter	Median/range or *N* (%)
Age	70/60–87
Men	44 (83)
Diabetes	10 (19)
Coronary artery disease (CAD)	23 (43)
Hypertension	45 (83)
Peripheral artery disease	18 (34)
CAD after PCI	7 (13)
CAD after CABG	3 (5)
Smoking	23 (43)
Aneurysm diameter	56/47–83
Neck length	25/16–56
Neck angle	20/0–55
Ejection fraction (%)	55/35–65
Chronic renal failure	2 (3.8)
VQI-CRI (%)	5.8/4.5–9.7
Local anesthesia	52 (100)
Percutaneous access	51 (98)
Stent graft ballooning	52 (100)
Access site complication	0 (0)
Fluoroscopy [s]	650/335–1100
Contrast [ml]	150/100–350
Discharge [days]	2/2–4

Table II. Follow-up and SAE

In hospital and 30 days	*N* (%)
Failed implantation	1 (1.9)
Acute renal failure	0
Endoleak type I	1 (1.9)
Endoleak type II	0
Endoleak type III	1 (1.9)
Stent graft migration	0
Stent graft thrombosis	0
Acute limb ischemia	0
Myocardial infarction	1 (1.9)
Death	1 (1.9)
Device- and procedure-related death	0
Reintervention	1 (1.9)

was seen in 11 (21%) participants, and these patients require more frequent color duplex Doppler examination (every 4 months according to the center's protocol of post-EVAR patient evaluation).

Within 12 months of endovascular repair, 1 (1.9%) patient developed thrombotic occlusion of stent graft extension with resultant intermittent claudication (walking distance 100 m). He underwent surgery; extension patency was restored, angioplasty was performed and a self-expanding stent placed. Procedure- and SAE-related data are shown in Tables I and II.

Conclusions

The results of this case series seem to confirm the safety and efficacy of elective ANKURA stent graft placement for AAA. Early and mid-term complication rates are comparable to those of other stent grafts with suprarenal fixation; the proportions of endoleaks and repeat interventions were 11.4% and 7.6%, respectively, which is consistent with literature data on elective EVARs [5–10]. No deaths related to the device or the EVAR procedure were noted. The relatively small sample size is the main limitation to this study. Further follow-up of the presented patients is necessary, especially in those with no sac shrinkage. Reducing the diameter of the delivery system may facilitate placement of the Ankura stent graft.

Conflict of interest

The authors declare no conflict of interest.

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