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Review Article

Recent Development and Long-Term Results of Open vs EVAR for Pararenal Abdominal Aortic Aneurysms

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In this article, I would like to discuss on the two different treatment options (Open vs EVAR) for pararenal abdominal aortic aneurysm (the term "PRAAA" is not clearly defined and classified). Recently, complex endovascular treatment [Fenestrated EVAR (F-EVAR), Chimney (Snorkel) EVAR (C-EVAR, S-EVAR), Branched EVAR (B-EVAR)] have been developed and applied in selected patients, with encouraging early results; however, the high rate for secondary reinterventions and long-term results remain uncertain. This article introduce new devices and a new concept with endovascular aneurysm sealing (EVAS) are currently available on the market for the treatment of PRAAA. Open repair of PRAAA can be performed with low mortality and long-term survival is favorable from single-center experience in the real world and others. We conclude that open repair remains the golden standard treatment in most centers for PRAAA. However, EVAR of PRAAA may represent an alternative option in high-risk patients. Because the indications and circumstances for PRAAA vary based on patient-specific comorbidities and anatomy, it is recommended that vascular surgeons should be familiar with both treatment strategies and tailor-made strategy for improved long-term results for PRAAA. (This is a translation of Jpn J Vasc Surg 2018; 27: 303–308.)

Keywords: pararenal abdominal aortic aneurysm, EVAR, open repair

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Introduction

Among the types of endovascular aortic repair (EVAR) for the treatment of pararenal abdominal aortic aneurysm (PRAAA), techniques such as fenestrated EVAR (F-EVAR), chimney (snorkel) EVAR (C-EVAR/S-EVAR), and branched EVAR (B-EVAR) are performed primarily in Europe and the United States, where favorable initial results have been reported. However, covered stents for the chimney or branched procedures have not yet been introduced in Japan, and thus these EVAR techniques are performed only in a limited number of facilities using privately-imported covered stents. For those using typical medical insurance, the standard technique is generally F-EVAR using currently available devices, physician-modified endografts, and bare stent C-EVAR. Meanwhile, many facilities opt for open graft replacement (GR) because long-term outcomes of EVAR treatment of pararenal abdominal aortic aneurysm are uncertain. At our center, we treat 100–150 cases of abdominal aortic aneurysm (AAA) surgery annually, and EVAR is selected for 70%–80% of patients with infrarenal AAA. However, GR is the first-line treatment for pararenal abdominal aortic aneurysm, and F-EVAR and EVAR are performed only on limited types of patients. We consider GR to be the first-line treatment and discuss here the EVAR technique for pararenal abdominal aortic aneurysm in practical terms.

Definition and Classification of Pararenal Abdominal Aortic Aneurysm

AAA is classified into the following three types: suprarenal, juxtarenal/pararenal, and infrarenal.[1)] The definition of the Japanese term for pararenal abdominal aortic aneurysm collectively means juxtarenal (pararenal) and suprarenal AAA. These classifications were established for the procedure of GR in 1991, i.e., before the development of EVAR; therefore, these suggestions cannot be considered as the ultimate standard of care. The SVS Ad Hoc Committee published its first report regarding EVAR standards in 1997; however, they did not specifically discuss this

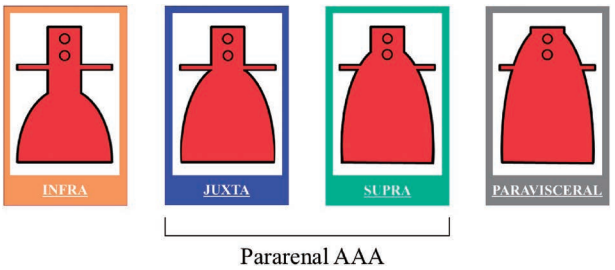

Fig. 1 Definition of AAA.

concern of classification regarding abdominal aortic aneurysm.[2] A subsequent report in 2002[3] was consistent with the classification introduced in 1991. Meanwhile, throughout most literature, the Japanese term for pararenal AAA (PRAAA) is shown to include both juxtarenal as well as suprarenal AAA. The current article is also based on the same assumption, although it is not intended to establish a consensus guideline (**Fig. 1**). In the era of stent grafts (SG), new classifications of infrarenal aneurysm (distant from the renal artery), juxtarenal aneurysm (below the kidneys without involving the renal artery), pararenal aneurysm [involving the renal artery but not involving the superior mesenteric artery (SMA)], suprarenal aneurysm (involving the SMA), and paravisceral aneurysm [involving the celiac artery (CA)], are accepted for the purpose of determining the anatomical site of the aneurysm.[4,5] According to this classification system, the Japanese term for pararenal abdominal aortic aneurysm is a collective term that includes juxtarenal AAA as well. Although there seems to be no dispute about this definition, caution should be exercised in interpreting the term "pararenal." Since the revised version (2011) of Japan's Guidelines for Diagnosis and Treatment of Aortic Aneurysm and Aortic Dissection do not include the definition and classification of pararenal AAA, up-to-date redefinition and reclassification are necessary for future discussion of the results of surgical treatment of this disease.

Recent Advances in EVAR for Pararenal Abdominal Aortic Aneurysm

This section introduces the pipeline products from stent graft manufacturers that have not been approved in Japan but are currently used overseas in clinical settings. Treatment methods based on novel concepts, such as endovascular aneurysm sealing (EVAS), are also put to clinical use. Due to space limitations, this article shows only the images of the devices and does not include the details of these devices. These images are published after obtaining permission from the manufacturer.

1. COOK Medical, Bloomington, Ind

a. Zenith Fenestrated AAA Endovascular Graft (**Fig. 2**): CE Mark obtained in 2005, FDA approval obtained in 2012

b. Zenith t-branch Thoracoabdominal Endovascular Graft, p-branch Endovascular Graft (**Fig. 3a**): CE Mark obtained in 2012

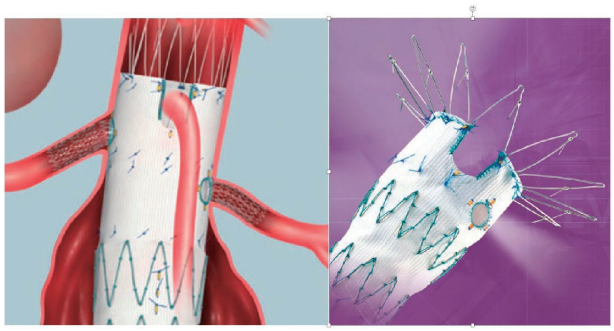

Fig. 2 Zenith fenestrated EVAR.

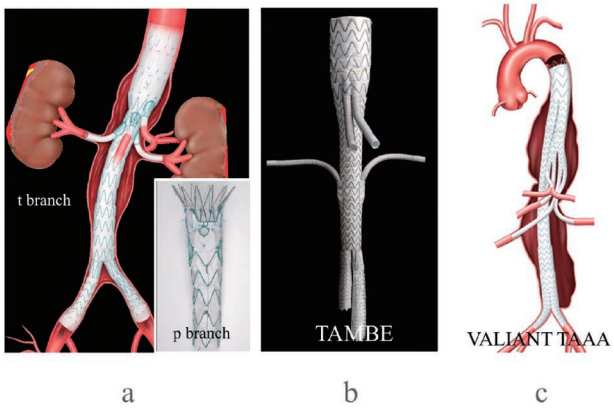

Fig. 3 Custom-made/off-the shelf branched device.

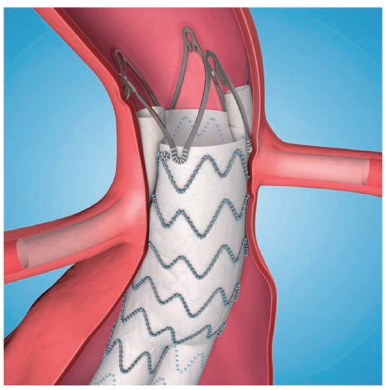

Fig. 4 Chimney (snorkel) EVAR with endurant.

2. W.L. Gore & Associates, Flagstaff, AZ, USA

a. C-EVAR with Excluder & VIABAHN Endoprosthesis

b. GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE) (**Fig. 3b**)

3. Medtronic, Inc., Santa Rosa, CA, USA

a. C-EVAR with Endurant Stent Graft System (**Fig. 4**):

Fig. 5 Aptus Heli-FX EndoAnchor System.

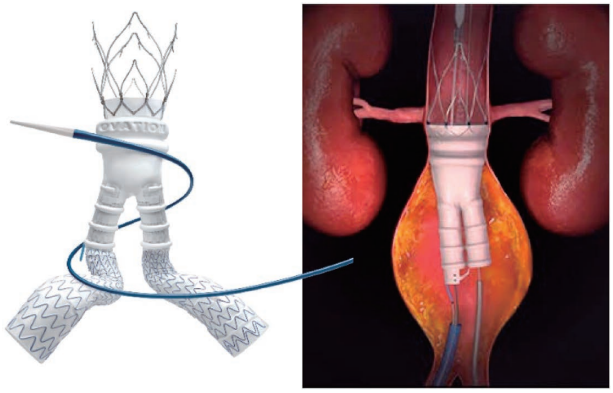

Fig. 6 Ovation with new concept for PRAAA.

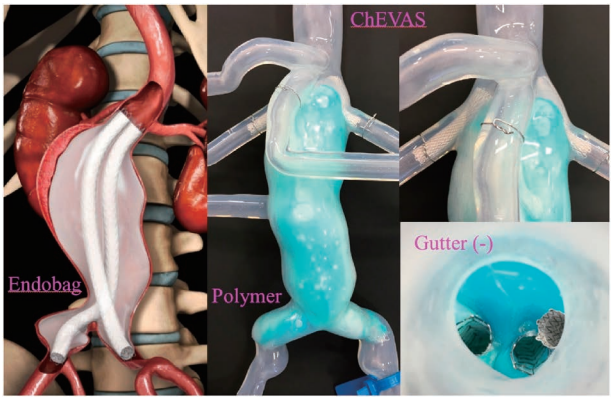

Fig. 7 Nellix with new concept for PRAAA.

CE Mark obtained in 2016

b. Aptus Heli-FX EndoAnchor System (**Fig. 5**): CE Mark and FDA approval obtained in 2011, CE Mark and FDA approval obtained in 2017 for short necks (4–10 mm) + Endurant

c. Valiant TAAA Stent Graft System (**Fig. 3c**)

4. Endologix, Inc., Irvine, CA, USA

a. Ovation Abdominal Stent Graft System (**Fig. 6**): CE Mark obtained in 2010, FDA approval obtained in 2012

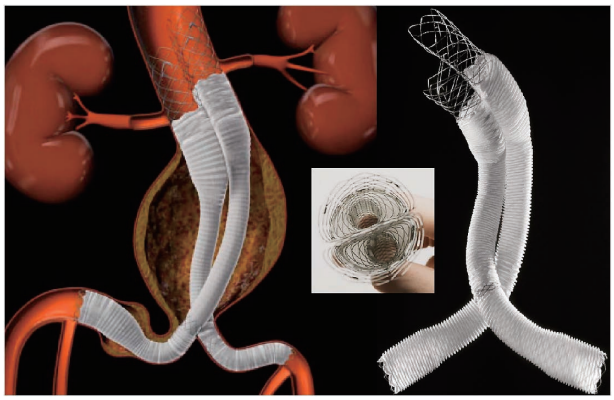

Fig. 8 Altura with new concept for PRAAA.

b. Nellix EndoVascular Aneurysm Sealing System (**Fig. 7**): CE Mark obtained in 2013

5. Lombard Medical Ltd., Didcot, United Kingdom

Altura Endograft System (**Fig. 8**): CE Mark obtained in 2015

Strategies and Long-Term Results of Pararenal Abdominal Aortic Aneurysm Treatment

Similar to that with infrarenal AAA, the treatment strategies available for pararenal abdominal aortic aneurysm are GR and EVAR. Because both are cumbersome surgical procedures, surgical facilities may prefer just one out of convenience, and thus tend to avoid selecting the other. However, vascular surgeons should have sufficient knowledge of the proper techniques of GR involving suprarenal aortic cross-clamping for each individual patient background and the latest EVAR technique for improving the surgical treatment of patients with pararenal abdominal aortic aneurysm.

Open GR

Precautions for GR

A successful surgical result of GR can be expected for pararenal abdominal aortic aneurysm as well as infrarenal AAA, so long as the patient can tolerate the surgery and the surgeon is highly skilled in performing the procedure. However, GR is more invasive in pararenal abdominal aortic aneurysm than in infrarenal AAA, and there will certainly be patients who are unable to tolerate it. A surgeon performing GR must be careful for pararenal abdominal aortic aneurysm while managing the operative field of the proximal aortic cross-clamping site, locating the cross-clamping site, and preventing ischemia in internal organs and kidneys than for infrarenal AAA. For managing the operative field of the proximal aortic cross-clamping site, a retractor such as Omni-tract (Integra,

Plainsboro, NJ, USA) should be effectively used. If it is impossible to manage, it is considered helpful to promptly separate the left renal vein and reconstruct it following the GR procedure. Results of previous studies suggest that, if reconstruction is difficult, the left renal vein can be ligated, thereby avoiding prolonged surgery duration and blood loss, as lack of reconstruction does not affect acute- or chronic-phase renal function.[6,7] The general rule is to use computed tomography (CT) to select a site free of calcification or atheroma for proximal aortic cross-clamping prior to surgery. In the case of pararenal abdominal aortic aneurysm, special caution must be taken against atheroemboli because important aortic branches will be in the area around the cross-clamping site. Additionally, vascular lesions are highly likely to be associated with ostial branch stenoses, and therefore, the surgeon must consider the possibility that cross-clamping can easily cause branch occlusion and organ ischemia. Fatal results were obtained with some cases of pararenal abdominal aortic aneurysm at our center due to surgery performed without considering this possibility. Sugimoto et al. reported that chronic-phase renal function during suprarenal aortic cross-clamping depends on preoperative renal function.[7] There is a report that simple suprarenal aortic cross-clamping does not affect renal function[8]; it has also been reported that administering glucocorticoid, mannitol, or cold Ringer's solution to patients with preoperative renal insufficiency or patients undergoing prolonged cross-clamping does not affect renal function[9]; however, the opinions vary. In reality, the general approach would be to select simple cross-clamping for patients with good renal function (eGFR $\geqq$ 60 mL/min/1.73 m^2) with a short cross-clamping time ($\leq$ 30 min), patients who require more time for inserting balloon catheters for infusion, and patients with a risk of atheroemboli. Renal protective treatment should be selected for all other types of patients.

Single-center study of GR treatment results

This section reports the surgical and long-term results of GR as the first-line treatment for pararenal abdominal aortic aneurysm at our center.[10]

Patients and methods: In total, we report on 60 cases of PRAAA (6.6%, age 72 $\pm$ 8 years, 51 male and 9 female patients with a preoperative AAA diameter of 64 $\pm$ 15 mm) among 906 consecutive cases of AAA surgery performed at our center between April 2007 and December 2016 (333 cases of GR and 573 cases of EVAR). The PRAAA cases were defined as GR cases that required suprarenal aortic cross-clamping and EVAR cases with the proximal neck length of $<$ 10 mm. Among these, there were 54 cases of juxtarenal AAA (JRAAA) and 6 cases of suprarenal AAA (SRAAA). The breakdown on the basis of surgical procedure was 53 cases of GR (88%) and seven cases of EVAR (12%). Among the GR cases, there were 42 cases of GR with simple suprarenal aortic cross-clamping (23 cases of lateral cross-clamping and 19 cases of bilateral cross-clamping), five cases of lateral aortic reconstruction GR with simple suprarenal aortic cross-clamping, six cases of GR with cardiopulmonary bypass (CPB, five cases of renal artery reconstruction, and one case of reconstruction of a major abdominal branch). Simple cross-clamping was performed and/or infusion of cold Ringer's solution was given during suprarenal aortic cross-clamping. Among patients for whom EVAR was indicated, three were elderly and frail, two had undergone Y-grafting, one had a large abdominal incisional hernia, and one patient had undergone laparotomy six times. All EVAR cases were outside instructions for use (IFU), and the stretched infrarenal aneurysm wall or a mural thrombus was left in place as the landing zone. The devices used were Endurant (Medtronic, Inc., Santa Rosa, CA, USA) in five cases, Excluder (W.L. Gore & Associates, Flagstaff, AZ, USA) in two cases, atypical use of proximal extension in six cases, and Endurant IIs (Medtronic, Inc., Santa Rosa, CA, USA) in one case.

Results: Surgery duration was 352 $\pm$ 105 min (mean $\pm$ SD) and the duration of renal artery clamping was 47 $\pm$ 12 min. The hospital mortality of PRAAA was 1.7% (1/60 cases, elective GR in the same time period: 1.4%, EVAR: 0.7%). The deaths were caused by intestinal necrosis secondary to the obstruction of blood flow to the superior mesenteric artery impaired by clamping forceps. Postoperative dialysis was performed in only one of the fatal cases. The length of postoperative hospital stay was 19 $\pm$ 14 days. No postoperative endoleak was found in the EVAR cases. The follow-up period was 41 $\pm$ 30 months, and survival rate was 87.8% at 3 years and 65.5% at 5 years after surgery. None of the cases required secondary intervention.

Conclusions: 1) For the PRAAA surgery cases at our center, the hospital mortality was 1.7% and 5-year survival rate was 65.5%. These favorable results suggest that the surgical strategy of GR as the first-line treatment is appropriate. 2) There was a group of only seven high-risk patients (12%) with PRAAA for whom fenestrated/branched EVAR was indicated instead of GR. These patients were treated with domestically-available devices outside the IFU. The long-term outcomes remain to be determined.

GR treatment results in literature

The 30-day mortality for elective GR is 1%–5% and 2.5%–5.8% for infrarenal AAA.[11] Ferrante et al. reported single-center early results of GR that are consistent with our findings: 30-day mortality of 2.5%, acute renal failure rate in 11% patients, transient hemodialysis in 3% patients, and chronic dialysis in 0.5% patients.[12] In our

clinic, late survival was approximately 70% (80% for the general population without AAA, adjusted for age and sex) at 5 years and approximately 40% at 10 years for infrarenal AAA.[13,14] Furthermore, in the study by Ferrante et al., late survival is comparably favorable with 78% at 5 years and 60.5% at 10 years for PRAAA.[12] Meanwhile in Japan, Maeda et al. reported a comparison between GR and EVAR for JRAAA, including 30-day mortality (GR: 2.5 and JRAAA: 1.4%), 1-year (GR: 97.5 and JRAAA: 92.6%), 3-year (GR: 95.5 and JRAAA: 92.6%), 5-year (GR: 90.5 and JRAAA: 87.7%), and 7-year survival rate (GR: 89.8 and JRAAA: 74.3%). The rate of freedom from aorta-related death at 7 years after surgery was 97.5% for GR and 98.6% for JRAAA. There was no significant difference in survival rate between procedures at any follow-up interval. However, the rate of additional treatment was significantly higher in EVAR than in GR.[15]

EVAR

In our single-center study, patients with pararenal abdominal aortic aneurysm who required EVAR due to their high risks accounted for only 0.8% of all the patients that underwent AAA surgery. In a review article by Tanious et al., F-EVAR and C-EVAR were comparable in terms of clinical outcomes, and were equally appropriate in comparison with GR.[16]

Treatment results of F-EVAR

The first report of F-EVAR using a custom-made SG and a covered stent was published in 1996 by Park et al.[17] According to a review article by Cross et al., the 30-day mortality is 2.0%.[18] Di et al. reported a surgery success rate of 92.8%, an early branch graft patency rate of 98.3%, 30-day mortality of 2.5%, type I endoleak incidence of 2.1% at 12 months after surgery, and a primary patency rate of 94.5%.[19] The Zenith fenestrated device (**Fig. 2**) yielded favorable results according to the pivotal U.S. fenestrated trial (USFT),[20] and was approved by FDA for the first time in April 2012. Oderich et al. conducted a multicenter prospective study of the Zenith fenestrated device and found that the 30-day mortality was 1.5%, 5-year survival was 91%, rate of freedom from MAE was 79%, and renal artery patency rate was 81%. Additionally, 91% patients did not suffer from renal function deterioration and 63% did not require secondary treatment.[21]

Treatment results of C-EVAR (S-EVAR)

The earliest report of S-EVAR was published in 2003 by Greenberg, and the first case series was reported in 2008. The most frequently used chimney grafts are VIABAHN (W.L. Gore & Associates, Flagstaff, AZ, USA), Advanta V12, and iCAST stents (Maquet Getinge Group, Rastatt, Germany). In Japan, C-EVAR is mainly performed using bare stents but has potential issues such as gutter leak. However, VIABAHN was granted pharmaceutical approval on February 15, 2016 (indications include traumatic or iatrogenic vascular injury and superficial femoral arterial stenosis or occlusive lesions), and is now available for treatments not covered under health insurance. Wilson et al. have reported a surgery success rate of 92.6%, an early branch graft patency rate of 98.7%, 30-day mortality rate of 3.4%, type 1a endoleak incidence of 10.2%, and a primary patency rate of 97.7% at 6 months after surgery.[22]

Moreover, data of 898 chimney grafts among 517 patients in the PERICLES registry demonstrated a surgery success rate of 97.1%, early mortality of 4.9%, type 1a endoleak incidence of 0.4%, and a 17.1-month primary patency rate of 94%.[23] A prospective study of Endurant by Donas et al. involving 128 patients reported good results, including a surgery success rate of 100%, type 1a endoleak incidence of 1.6%, 30-day mortality of 0.8%, an early branch graft patency rate of 95.7%, and 93.1% of the patients did not require retreatment.[24] Meanwhile in Japan, Igari et al. reported results of C-EVAR using bare stents, in which the surgery success rate was 91.6%, the hospital mortality rate was 8.3%, and the renal artery stent patency rate was 93.3% immediately after surgery (85.6% at 1 year and 85.6% at 3 years). The survival rate was 90.9% at 1 year and 90.9% at 3 years, and the proportion of patients who did not require retreatment was 90.9% at 1 year and 75.8% at 3 years after surgery.[25]

Treatment results of B-EVAR

Since the preparation of a custom-made SG requires 3–6 weeks, off-the-shelf branch SGs are increasingly used in recent years.[26,27] Farber et al. performed B-EVAR using a Zenith p-branch device in 76 patients and found two cases of intestinal ischemia and eight cases (11%) of renal artery occlusion within the follow-up period (mean length: 25 ± 13 months). However, the 30-day mortality rate was 0%.[28]

Overall Conclusion

The long-term results of EVAR for pararenal abdominal aortic aneurysm and the rate of additional treatment suggest that GR is an appropriate first-line treatment for pararenal abdominal aortic aneurysm. However, there are a small number of patients who are unable to tolerate the GR procedure, but long-term results of EVAR are expected to be as favorable as those of GR in the case of high-risk patients. It is recommended that vascular surgeons should be well-trained for GR and EVAR procedures so that they can provide surgical treatment tailored to individual patients, to improve long-term surgical results of

pararenal abdominal aortic aneurysm treatment.

Disclosure Statement

The author has no conflict of interest to declare.

Additional Note

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