Recent Update of Endovascular Type 2 Endoleak Management

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─── **Abstract** ───

EVAR has been used clinically for almost three decades, and it has been widely applied in clinical practice and has been applied to difficult cases as devices and techniques have evolved. Although the major advantage of EVAR is its lower perioperative mortality, compared with open surgery, late-onset complications such as endoleaks have become major issues, requiring lifelong follow-up after EVAR. The clinical guidelines have been updated, and many systematic reviews/meta-analyses and multi-center registries have been published; surgeons must keep up-to-date regarding these changes. In this review, the author reviews evidence on the recent update of the type 2 endoleak management.

Key words: endoleak, type 2 endoleak, endovascular aneurysm repair, EVAR, management

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Introduction

The use of endovascular aneurysm repair (EVAR) as a treatment for abdominal aortic aneurysms (AAAs) has rapidly spread since the 1990s. EVAR has now been used to treat numerous cases of AAA in developed countries. Although the major advantage of EVAR is its lower perioperative mortality than open surgery, late-onset complications such as endoleaks (ELs) have become major issues, requiring lifelong follow-up after the procedure [1-5].

ELs are important stent-graft-specific complications that have been extensively discussed. An EL is defined as residual blood flow into an aneurysm after stent-graft placement [6-7]. Type 1 ELs (T1ELs) and type 3 ELs (T3ELs) have both been shown to be related to aneurysm rupture after stent-graft placement. Class I recommendations in the European Society for Vascular Surgery (ESVS) guidelines [8] and level 1 recommendations in the Society for Vascular Surgery (SVS) guidelines [9] have been made, and there is no opinion on their management. Meanwhile, no agreement exists about the prevalence, natural course, or recommended treatment for type 2 ELs (T2ELs), and the ESVS guidelines currently state that the timing of treatment for T2ELs is a class IIb recommendation and that intervention for T2ELs is a class IIa recommendation. Despite more than two decades of discussion, these conclusions remain controversial.

This review focuses on systematic reviews/meta-analyses of T2ELs over the past 10 years, multicenter studies over approximately the past 3 years, and single-center studies with a large cohort. The indications for the treatment of T2 ELs and the specific management strategies will be discussed for each clinical question.

Diagnosis of T2ELs

The chapters on follow-up imaging after EVAR in the ESVS guidelines [8] and the literature search and evidence summary in the SVS guidelines [9] report that computed tomography angiography (CTA) is the gold-standard imaging technique for T2ELs and other types of EL [10]. Even at present, CTA is selected as the primary imaging modality for surveillance after EVAR [8, 9]. Because the imaging protocol plays an important role in CTA especially in the diagnosis of T2ELs, which requires three phases of imaging (unenhanced, arterial, and delayed phases), radiation exposure and contrast nephropathy are post-EVAR issues that require lifelong surveillance. Several systematic reviews of the

diagnostic performance of contrast-enhanced (CE) ultrasound (US) have been reported to resolve these problems [11], and the usefulness of CE-US for the detection of T2 ELs has also been reported, with a high sensitivity of 0.94 and a specificity of 0.93 for the detection of T1ELs and a sensitivity of 0.97 and a specificity of 1.00 for the detection of T3ELs. Other articles have also reported a similar usefulness for the detection of each type of EL [12, 13]. However, as the utility of US is dependent on the operator and patient-related factors, screening with CE-US alone is not recommended and evaluations in conjunction with computed tomography (CT) are required [8].

A systematic review has shown that magnetic resonance imaging is more sensitive, especially for the detection of T2 ELs, than CE-CT [14], and its usefulness has been described in the ESVS and SVS guidelines [8, 9].

Prevalence of T2ELs

Numerous systematic reviews and multicenter registry studies have reported prevalence rates ranging from 8% to 44% [15]. Although no fixed prevalence rate has been reported in a decade, the prevalence of T2ELs has been reported to be around 10%-20% [16-20] and Sidloff et al. reported a prevalence of 10.24% (1515/14,794) in a large cohort [21]. With respect to the prevalence of these reported T2ELs, advances in diagnostic modalities and methods have played increasing roles in detection [19]. Guo et al. reported that the prevalence of T2ELs was 13% before 2010 and 27% after 2010, and these results may be attributed to the improved accuracy of imaging tools for surveillance after EVAR. Thus, the detection of ELs might be increasing as a result of the improved imaging tools and techniques that are now available. In a Japanese single-center study reported by Morisaki et al. in 2017 [22], the prevalence of T2ELs was 32.7%, which was consistent with the results reported by Guo et al. [19]. However, the prevalence of T2ELs in Morisaki et al.'s report [22] was clearly higher than those in previous reports, and differences in coagulability arising from racial differences may be associated with the differences in the reported prevalences of T2ELs [23, 24]. Fujimura et al. [23] reported a T2EL prevalence of 28.1% in an East-Asian population, which was clearly higher than the previously reported data for a Caucasian population. Fujimura et al. also reported that a T2EL was clearly a significant risk factor for sac expansion after EVAR [23]. In a report on a national survey of EVAR in Japan [25], a high T2EL prevalence of 16.6% at discharge was reported, which was consistent with the data for T2ELs at discharge reported by Fujimura et al. (21.7%) [23].

Differences in the prevalence of T2ELs according to the type of stent graft have also been widely discussed, with some papers reporting no significant differences among stent grafts [11, 19, 21, 26] and another reporting significant differences [27]. Systematic reviews generally indicated no differences among stent grafts. However, Fujimura et al. [23]

reported an apparently high prevalence of T2ELs of 40.1% among patients treated with the Excluder stent graft (W. L. Gore & Associates, Flagstaff, AZ, USA), and racial differences in coagulability [24] may also contribute to differences in the prevalence of T2ELs according to the stent graft.

Natural course and long-term treatment outcomes of T2ELs

A number of systematic reviews and multicenter registry studies have been reported [16, 17, 20-23, 26-32]. Although there have been many discussions in the past about the timing of treatment strategies and interventions, they mostly remain controversial. T2ELs after EVAR are thus an important clinical question requiring clarification in the future.

Early or perioperative T2ELs and late or delayed T2ELs are often defined as T2ELs occurring within 30 days of EVAR and T2ELs occurring 30 days after EVAR, respectively [17, 27, 29]. Pineda et al. [30] defined late T2ELs as those detected 1 year after EVAR. Therefore, the differences in the definitions of early/perioperative T2ELs and late T2 ELs in the medical literature should be investigated. T2ELs often disappear during the follow-up period [8, 9, 33]. Indeed, among 186 patients with early T2ELs for whom detailed clinical courses were available, 71.5% were reported to show improvement with conservative management in a multicenter registry study reported by Kumar et al. [27].

The effect of T2ELs on aneurysmal sac enlargement after EVAR has been extensively investigated and was also described in the ESVS and SVS guidelines [8, 9]. At present, T2ELs reportedly have no effect on the rupture and survival rates after EVAR, although they affect the postoperative enlargement of the aneurysm diameter.

According to a multicenter study by Sakaki et al. [16], T2 ELs were observed in 16.6% of patients at 12 months after EVAR and aneurysm enlargement was observed in 14.2% of patients at 5 years after EVAR. Furthermore, a subgroup analysis according to the presence or absence of T2ELs revealed that aneurysm diameter enlargement was seen in 30.7% of the patients with T2ELs and in 8.7% of those without T2ELs. The authors concluded that early intervention for T2ELs might be an appropriate strategy when the aneurysm is relatively large and continuing to dilate at 12 months after EVAR. These findings are consistent with those reported by Pineda et al. [30], who evaluated aneurysm diameter enlargement in patients with and without T2ELs at 1 year after EVAR.

Little data are available about the rupture of aneurysms after EVAR. According to the results of EVAR trials 1 and 2 reported by Wyss et al. [26], 27 aneurysms (3.2%) ruptured during the follow-up period (average, 4.8 years) in 848 patients who had undergone EVAR. The data summary showed some strongly significant associations between rupture and previous detection of serious complications. However, caution should be taken in interpreting these data because they

represent mixed information of T1ELs and T3ELs. Aneurysm rupture after EVAR associated with isolated T2ELs is even rarer, with a prevalence ranging from 0% to 1.0% [20-22, 27, 29, 31, 32, 34] in many reports. In a large cohort of 14,794 patients reported by Sidloff et al. [21], 14 cases (0.9%) of ruptured aneurysms (sac increment, 8 cases; sac decrement, 1 case; stable, 2 cases; no change, 3 cases) and isolated T2ELs were reported among 1515 patients with T2EL, and one-third of these rupture cases did not have sac expansion. Ajalat et al. [29] reported one case of ruptured aneurysm death in which all types of EL were absent. The rate of late aneurysm rupture was < 1% in other reports [16, 20, 27, 30, 32], and there have been several reports of no aneurysmal rupture during the follow-up period [31, 35]. However, these low rupture rates are based on retrospective studies in which intervention was often performed for persistent T2ELs with sac expansion; thus, the true natural history of T2ELs remains unknown [8].

Preoperative risks of T2ELs

Many systematic reviews and multicenter studies have been reported [18, 19, 27, 35-40]. Preoperative anatomical risks are usually reported in terms of the combination of the presence or absence of inferior mesenteric artery (IMA) patency and the number of patent side branches, mainly in the lumbar artery (LA). In a report by Piazza et al. [35], four anatomic features (patency of a > 3-mm IMA; patency of at least three pairs of LAs; patency of two pairs of LAs and the median sacral artery, accessory renal artery, and IMA [< 3 mm]; and intrasac thrombus volume < 35%) were listed, and the authors concluded that these features were strong predictors of both persistent T2ELs and T2EL-related interventions. Conversely, no preoperative anatomical risk factors were reported in two other studies [27, 37], and together with the preemptive branch embolization described later, the presence and identification of preoperative anatomical risk factors are still controversial clinical questions even to date.

With respect to the risks related to patient characteristics, several reports have concluded that older age is associated with an increasing risk of T2ELs, whereas smoking is associated with a decreasing risk [19, 27, 40]. Guo et al. [19] reported that the presence of AAAs with a large diameter over a long period of time may play a role in the higher risk in older patients. A study of 8638 cases from the EUROSTER registry reported by Koole et al. [40] showed a decrease in intraoperative perfusion from the IMA and LAs in smokers, and demonstrated that smoking increased the risk of stent-graft migration.

Criteria/threshold for intervention

The ESVS guidelines [8] state that a $\geq$ 10 mm threshold for sac diameter expansion associated with T2ELs represents level C evidence and is a class IIb recommendation, whereas reintervention for T2ELs meeting this threshold represents level C evidence and is a class IIa recommendation. However, many reports have described reintervention in cases with an increase in aneurysm diameter of $\geq$ 5 mm as the threshold. Conversely, several references recommend conservative treatment, and even at this stage, a consensus has not been reached. The SVS guidelines [9] specify that reintervention for T2ELs with sac expansion represents a level 2 (weak) recommendation with a quality of evidence of C (low), whereas conservative treatment for T2ELs without an increased sac diameter represents a level 1 (strong) recommendation with a quality of evidence of B (moderate).

The ESVS guidelines [8] also take issue with the lack of a definition for a successful intervention (technical success, clinical success), which affects the interpretation of the results of each report.

Treatment outcomes for T2ELs (conservative/intervention/surgical)

In the systematic review reported by Ultee et al. [15], little evidence supported the efficacy of secondary interventions for T2ELs, and the clinical course after intervention may not differ from that after conservative treatment. Although a high technical success (defined as no evidence of residual flow entering the aneurysmal sac at the end of the procedure) rate of 87.9% was reported in the intervention arm, the recurrence rate of T2ELs after reintervention was 31.6% and the rate of a stable or decreased sac diameter was 78.4% [15]. They also mentioned that a T2EL in combination with sac growth may actually be the result of an expected underlying T1EL or T3EL [41, 42], and they questioned the accuracy of the diagnosis of isolated T2ELs. When interpreting this report in conjunction with that by Guo et al. [19], it may be necessary to consider the influence of the ability to diagnose T2ELs during the reporting period. In a large cohort study, Sidloff et al. [21] reported a clinical success (defined as no recurrence of T2EL) rate of 68.4% and a rate of a stable or decreased sac diameter of 49.2%.

Two reports in East-Asian populations from Japan [23, 43] also mentioned a high probability of sac diameter enlargement after treatment for T2ELs. Horinouchi et al. [43] suggested that transcatheter arterial embolization for T2ELs should be performed before the sac enlarges to > 10 mm, although this protocol differs from the ESVS guideline recommendations, because the progress of sac diameter enlargement after treatment for T2ELs was significantly associated with a sac diameter of $\geq$ 55 mm at the time of the initial intervention for T2ELs. Fujimura et al. [23] reported that transarterial embolization of isolated T2ELs with sac expansion using a triaxial system resulted in only a 12.5% resolution of T2ELs at 16 months. Neither of the two reports [23, 43] was satisfactory in terms of the outcome of reintervention for T2ELs.

Surgical intervention

No systematic reviews have directly compared endovascular interventions with open/laparoscopic treatments, although several systematic reviews of surgical approaches have been reported [44, 45]. In these reviews, high technical success rates of 90% and 30-day mortality rates of 1.5% or 0% were reported. At present, laparoscopic ligation is considered a feasible and safe technique and may be less harmful in terms of radiation exposure compared with endovascular surgery. However, the ESVS guidelines state that surgical treatment is obviously more invasive and should be reserved for cases in which endovascular intervention has failed [8]; thus, surgical treatment for T2ELs is positioned as a second-line treatment. Robotic surgery using the da Vinci surgical system has also been reported [46], and further minimization of surgical invasiveness is anticipated in this field.

Which interventional approach is recommended?

Although several systematic reviews and multicenter studies have been reported, the definitions of technical and clinical success are often not stated, and the ESVS guidelines have noted this matter as a concern [8]. In many reports, technical success is defined as the absence of any evidence of residual flow entering the aneurysm sac at the end of the procedure. Clinical success is often defined as T2EL resolution upon follow-up imaging, and clinical success is usually separately discussed from the change in sac diameter after reintervention. Of note, clinical success is not always linked to the change in sac diameter after an intervention for T2ELs [15].

Guo et al. [47] reported that a translumbar approach had higher rates of both technical and clinical success, although statistically not significant. In addition, the rates of procedure-related complications were the same, and the translumbar approach was also reported to be superior in terms of both the total procedure time and the fluoroscopic time. Systematic reviews by Ultee et al. [15] and Sidloff et al. [21] reported better results for the translumbar approach, and the ESVS guidelines also mention the advantages of this approach [8]. In addition, a translumbar approach using fusion guidance [48, 49] had a high success rate and a short procedure time, indicating the usefulness of fusion guidance.

With respect to the transarterial approach, transarterial embolization for T2ELs using a triaxial system in an East-Asian population was reported from Japan [23, 43]; however, the technical and clinical success rates were not satisfactory.

Preemptive branch embolization

The ESVS guidelines [8] do not recommend preemptive branch embolization at this time. Although the ESVS guidelines state that preemptive branch embolization may reduce the T2EL risk during the follow-up period, the benefit of a reduced number of late reintervention or a decreased incidence of rupture remains to be proven [8]. The results of future studies, including ongoing clinical trials, are eagerly awaited.

Multiple multicenter and single-center studies have reported preemptive branch embolization, and differences in the target site of embolization and the vessel diameter have been observed. Most studies examined embolization of the IMA alone. Preoperative risk has been discussed above, and a threshold for intervention for the IMA of ≥ 2.5 to ≥ 3 mm has been reported. In data for a Caucasian cohort, the threshold vessel diameter was considered to be ≥ 3 mm. In East-Asian data, thresholds of ≥ 2.5 and ≥ 3 mm have been reported, partly because of a smaller average body size in this population.

In many reports, preemptive IMA embolization has been associated with a decrease in T2ELs and a decrease in T2 EL-related aneurysm size [50-54]. However, Chew et al. [55] reported that the significant difference disappeared after 6 months and LA patency was a significant risk factor for persistent T2ELs. Embolization of all IMAs and LAs > 2 mm has been reported in Japan [56], resulting in a significant reduction in T2ELs at 1 week after EVAR, compared with non-embolized groups. However, long-term results have not yet been reported, and a follow-up report is expected.

Outside of Japan, sac embolization using coils and fibrin glue instead of branch embolization has been reported [36, 57]. However, both reports were from single-center studies of small cohorts, and careful evaluations are necessary. Dosluoglu et al. [36] defined the presence of four or more patent LAs, a patent IMA ≥ 3 mm, and a flow lumen diameter ≥ 30 mm as high-risk factors when determining candidates for sac embolization. Although these factors are not significantly different from the preoperative risk factors described above, postoperative CT scans showed severe metallic artifacts as a result of the metallic coils, and a significant decrease in the diagnostic accuracy of postoperative T2EL is expected. Therefore, these results should be carefully evaluated.

A multicenter, core-laboratory-adjudicated, and randomized study, named "Clarify IMA," is currently in progress [58]. The inclusion criteria were determined for the East-Asian population as IMA diameter ≥ 2.5 mm, fusiform AAA with diameter ≥ 50 mm, or rapid enlargement of a sac ≥ 5 mm in diameter within 6 mm, suggesting that this study could be an important milestone for preemptive branch embolization.

Conclusion

EVAR has been clinically used for almost three decades, and devices and techniques are constantly evolving. Accordingly, the clinical guidelines have been updated, and many systematic reviews/meta-analyses and multicenter registry

studies have been published. Surgeons must be up-to-date with these changes. However, many controversial clinical questions remain about T2ELs after EVAR, and even in the ESVS and SVS guidelines, the recommendation level remains low.

Conflict of interest: nothing to declare

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