# Outcomes of percutaneous endovascular intervention for type II endoleak with aneurysm expansion

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*Objective:* Type II endoleak (T2EL) with aneurysm expansion is believed to place patients at risk for aneurysm-related mortality (ARM). Treatment with glue and/or coil embolization of the aneurysm sac, inferior mesenteric artery (IMA), and lumbar branches via translumbar or transarterial approaches has been utilized to ablate such endoleaks, and thus decrease ARM. We evaluated the midterm results of percutaneous endovascular treatment of T2EL with aneurysm expansion.

*Methods*: Single-institution, 5-year (January 2003 to August 2008) retrospective study of all endovascular interventions for T2EL with sac expansion. Blinded, independent review of all available pre- and post-T2EL intervention computed tomography (CT) scans was performed. Aneurysm sac maximal transverse diameters and aneurysm sac growth rates prior to and following T2EL intervention were analyzed.

*Results*: Forty-two patients (34 male, eight female; mean age, 75) underwent T2EL intervention at  $26 \pm 20$  months after endovascular aneurysm repair (EVAR) and were subsequently followed for  $23 \pm 20$  months. Seven out of 42 patients (17%) underwent repeat T2EL intervention. Interventions included 44 translumbar sac embolizations, and transcatheter embolizations of nine IMAs and seven lumbar/hypogastric arteries. Aneurysm diameter was  $6.1 \pm 1.6$  cm at EVAR,  $6.6 \pm 1.5$  cm at initial T2EL treatment, and  $6.9 \pm 1.7$  cm at last follow-up. There were no significant differences in the rates of aneurysm sac growth pre- and post-T2EL treatment. At last follow-up imaging, recurrent or persistent T2EL was noted in 72% of patients. Of 42 patients, nine (21%) received operative endoluminal correction of occult type I or type III endoleaks that were diagnosed during the T2EL angiographic intervention. There were no aneurysm ruptures or ARMs during follow-up; overall mortality for the 5-year study period was 24%.

*Conclusions:* In this series, percutaneous endovascular intervention for type II endoleak with aneurysm sac growth does not appear to alter the rate of aneurysm sac growth, and the majority of patients display persistent/recurrent endoleak. However, diagnostic angiographic evaluation may reveal unexpected type I and III endoleaks and is therefore recommended for all patients with T2EL and sac growth. While coil and glue embolization of aneurysm sac and selected branch vessels does not appear to yield benefit in our series, the diagnosis and subsequent definitive treatment of previously occult type I and III endoleaks may explain the absence of delayed rupture and ARM in our series. (J Vasc Surg 2012;55:1263-7.)

Endovascular aneurysm repair (EVAR) has become established as an alternative to open abdominal aortic aneurysm repair over the past 2 decades.<sup>1,2</sup> The early advantages in morbidity and mortality conferred by EVAR are

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Copyright © 2012 by the Society for Vascular Surgery. doi:10.1016/j.jvs.2011.10.131 substantially offset by the need for serial endograft surveillance and frequent reinterventions.<sup>2-5</sup> There is little debate regarding the merit of prompt treatment of type I and III endoleaks. The necessity, optimal timing, and most efficacious type of secondary intervention for type II endoleak (T2EL) have generated greater controversy, although it is widely accepted that intervention is unnecessary if the aneurysm sac size remains stable or diminishes.<sup>6-8</sup>

As the natural history of T2EL is not fully understood, proposed treatment algorithms are in part based upon anecdotal experience<sup>9</sup> or outcomes of retrospective studies evaluating all patients diagnosed with T2EL, rather than those patients with accompanying sac enlargement.<sup>6-8,10</sup> Specifically, these reports promote the selective use of angiographic modalities to treat T2EL but do not detail mid- and long-term outcomes of these interventions. Such information is necessary to define whether these treatments offer complete or partial success in halting aneurysm sac growth and preventing rupture. As our institution followed a routine policy of percutaneous endovascular intervention for all T2ELs associated with aneurysm sac growth of >5 mm, the purpose of this study was to specifically evaluate results of our 5-year experience with this technique.

# **METHODS**

A 5-year (January 2003 to August 2008) retrospective study of all patients treated for aneurysm enlargement associated with T2EL was performed within the Barnes-Jewish Care Network. This study was conducted in accordance with the approval of the Institutional Review Board of Washington University Medical School. Patient demographics, including concurrent illnesses, medications, radiologic follow-up, and treatment modalities, were catalogued in a database created via Microsoft Access (Microsoft Inc, Redmond, Wash).

All obtainable follow-up imaging reports after initial EVAR were recorded, and all available radiographic images were compiled. Fifty-nine percent of pre-T2EL intervention images from referring institutions were not available for review due to Institutional Review Board-related constraints. In those instances, the written imaging reports were used to document the presence of endoleak and the size of the abdominal aortic aneurysm (AAA) sac. Ninetyone percent of post-T2EL intervention images were available for review, including 137 computed tomography (CT) scans and two abdominal ultrasounds, as almost all patients were followed at our institution after these interventions. To standardize our image review, all available images (both pre- and post-T2EL intervention) were independently reviewed by an abdominal imaging radiologist who was blinded to the initial reported findings of the studies. The independent radiologist reviewer documented the AAA sac size, presence of endoleak, and type of endoleak.

Deaths were recorded by reviewing hospital records and by interrogating the Social Security Death Index (SSDI). The follow-up period was defined as the time from initial EVAR to the most recent imaging study. Closeout of the study was February 2009, allotting at least 6 months of follow-up from the last T2EL treatment recorded in this study.

In addition to calculating the absolute changes in AAA sac size, we also analyzed whether percutaneous endovascular intervention favorably altered the rate of growth of the sac. "Slope" values represent the regression line calculated by plotting aneurysm sac size against time. Two time periods were compared: the interval between EVAR and initial intervention for T2EL, and the interval between initial intervention for T2EL and last documented follow-up imaging. A minimum of two imaging studies within each time interval were required to generate a slope value. The equation for the slope of the regression line is:

$$b = \frac{\sum (x - \overline{x})(y - \overline{y})}{\sum (x - \overline{x})^2}$$

Slope values prior to and following T2EL intervention were compared using the Mann-Whitney *t*-test.

Statistical analysis was performed using the statistical software package InStat (GraphPad Software Inc, La Jolla, Calif) and Microsoft Excel (2003) (Microsoft Inc).

Table I. Demographics and comorbidities

Demographic/comorbidity	Percentage of patients
Female	19
Hypertension	86
Coronary artery disease	60
Diabetes mellitus	17
COPD/home O <sub>2</sub> use	12
CRI (creatinine $\geq 2$ )	5
ESRD	0
Active smoking	14
EF <40%	0
PAD/cerebrovascular disease	24
Symptomatic AAA at EVAR	7
Ruptured AAA at EVAR	5

AAA, Abdominal aortic aneurysm; COPD, chronic obstructive pulmonary disease; CRI, chronic renal insufficiency; EF, ejection fraction; ESRD, end-stage renal disease; EVAR, endovascular aneurysm repair; PAD, peripheral arterial disease.

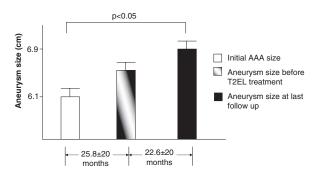
 Table II. Initial angiographic approach to type II endoleak

Angiographic approach	Number of patients (%)
Transabdominal Transaxillary Transfemoral Transfemoral, then translumbar Translumbar Translumbar, then transfemoral	$\begin{array}{c}1\ (2)\\1\ (2)\\10\ (24)\\13\ (31)\\16\ (38)\\1\ (2)\end{array}$
Total	42 (100)

## RESULTS

Forty-two consecutive patients were identified as having undergone angiographic intervention for T2EL with aneurysm sac expansion. The average age of the patient was 75 (range, 52-89). Patient demographics and medical comorbidities are classified in Table I. At the time of T2EL intervention, mean aneurysm sac diameter was 6.5 cm (range, 4.0-10.6 cm). The approaches used for diagnostic angiography are detailed in Table II. Percutaneous endovascular interventions, inclusive of repeat treatments, comprised 44 translumbar embolizations, seven transcatheter embolizations of lumbar or hypogastric vessels, and nine inferior mesenteric artery embolizations. Seven out of 42 patients (17%) required a repeat percutaneous T2EL intervention after initial treatment, while nine out of 42 patients (21%) required subsequent redo femoral cut-down and placement of additional endografts to repair type I or III endoleaks. There were no instances of aneurysm rupture or aneurysm-related mortality. Overall mortality rate in the 5 years of follow-up from study initiation was 24% (10 of 42 patients).

Incidence of type 2 endoleak accompanied by sac growth. We could not obtain the total number of EVARs performed at the referring institutions during the study period and therefore cannot provide a global denominator to assess the incidence of T2EL accompanied by sac growth. However, 16 of the 42 patients underwent initial



**Fig 1.** Abdominal aortic aneurysm (*AAA*) diameter changes over time. \*P < .05 for AAA size at last follow-up vs initial AAA size. *Error bars* = one standard deviation. *T2EL*, Type II endoleak.

EVAR at our institution, and we performed 712 total EVARs over the study period. Thus, our institutional incidence of T2EL with sac growth was 2.2%.

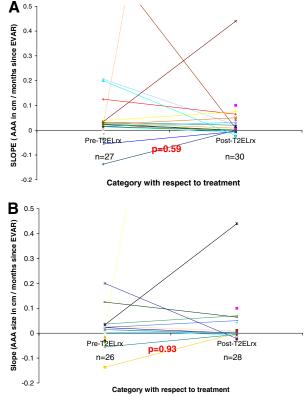
**Maximal aneurysm diameter.** Changes in maximal aneurysm diameter are noted in Fig 1. Aneurysm diameter was  $6.1 \pm 1.6$  cm at EVAR, with growth to  $6.6 \pm 1.5$  cm at time of initial T2EL treatment. After percutaneous endovascular intervention for T2EL, there was continued growth to  $6.9 \pm 1.7$  cm at last follow-up. At a mean follow-up of 48 months (from initial EVAR to last follow-up), the increase in aneurysm size was statistically significant  $(6.1 \pm 1.6 \text{ cm to } 6.9 \pm 1.2 \text{ cm}, P < .05)$ .

Aneurysm growth rates. There was no significant difference in pre- and post-T2EL treatment growth rates (Fig 2, A). When we excluded those patients who underwent operative endovascular correction of occult type I and III endoleaks, there was also no change in growth rate (Fig 2, B).

Endoleak persistence and recurrence. The incidence of persistent or recurrent endoleak at last follow-up is shown in Fig 3. Interpretation of CT findings after sac embolization with radio-opaque materials can be challenging; therefore, all available postembolization scans were reviewed by an independent, blinded abdominal imaging radiologist, with documentation of endoleaks and aneurysm sac diameter. Arterialand delayed-phase imaging are utilized in our post-EVAR CT angiography protocol; the delayed images were noted to be more efficacious for detection of endoleaks. At last follow-up, 72% of patients (per independent image review) had documentation of persistent or recurrent T2EL.

Diagnosis and treatment of type I and III endoleaks. Nine of 42 patients (21% of the cohort) ultimately received operative intervention after initial diagnosis of a T2EL. In each of these patients, operative endovascular intervention was undertaken after angiography demonstrated previously occult type I or III endoleaks. Collectively, there were five repairs for type I endoleak and four repairs for type III endoleak performed. Despite successful treatment of the type I and III endoleaks, seven of these nine patients (78%) continued to display continued sac growth in follow-up.

**Embolization modality.** The most frequent method of embolization was translumbar introduction of coils and/or glue to the aneurysm sac. A minority of patients received



**Fig 2. A**, Aneurysm growth rate stratified before and after initial type II endoleak (*T2EL*) percutaneous endovascular intervention for all patients. **B**, Aneurysm growth rate stratified before and after initial T2EL percutaneous endovascular intervention, excluding those patients who received operative endoluminal correction of type I and III endoleaks. *AAA*, Abdominal aortic aneurysm; *EVAR*, endovascular aneurysm repair.

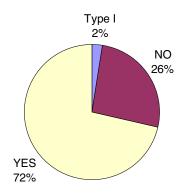


Fig 3. Patients with type II endoleak (T2EL) at latest follow-up.

transarterial coil embolization of branch vessels, either with or without translumbar sac embolization. The mode of embolization did not appear to affect outcomes with regards to aneurysm growth, as pre- and post-T2EL treatment slope values were also unchanged (P = .284) in the subset of patients that received transarterial coil embolization.

**Procedural complications.** There were no deaths related to percutaneous endovascular intervention for T2EL. A solitary instance of contrast nephropathy (2.4%) was noted, with spontaneous recovery and no need for hemodialysis.

## DISCUSSION

Despite reports promulgating the importance of treating type II endoleak,<sup>7,11,12</sup> the natural history of these phenomena is not fully defined. The literature is replete with multiple suggested routes of T2EL ablation, including laparoscopic ligation of the inferior mesenteric artery,<sup>13</sup> concurrent operative lumbar embolization,<sup>14,15</sup> post-EVAR embolizations,<sup>16,17</sup> and post-EVAR operative approaches.<sup>18</sup> Previously, our institutional experience has shown that continued observation of persistent T2EL with stable aneurysm sac size is both safe and cost-effective.<sup>6</sup> In light of this prior work, we believe continued aneurysm sac growth to be of greater concern than the continuous or intermittent documentation of sac perfusion and view aneurysm diameter stabilization or shrinkage as the sine qua non of successful endoleak intervention.

In this report, we catalogue the outcomes of percutaneous endovascular intervention in 42 patients who presented with T2EL accompanied by aneurysm enlargement. Translumbar sac embolization and transarterial branch vessel embolization were the most frequently used modalities for T2EL treatment. We found that the rate of aneurysm growth in these patients is slow (<10% total aneurysm diameter increase per year), but does not appreciably diminish after one or more interventions for T2EL. Despite single or repeated percutaneous endovascular intervention, sac size continued to gradually increase. Finally, blinded assessment by an expert abdominal radiologist confirmed that over two-thirds of patients had persistent or recurrent T2EL at completion of the study period.

By most measures, the outcomes of percutaneous endovascular treatments for T2EL with aneurysm growth in this study were disappointing. Indeed, the one finding that may have positively impacted patient outcomes, and salvaged the role of angiographic interventions for this condition, was the unexpected diagnosis of type I and III endoleaks in a substantial minority (21%) of patients. A strong argument can be made that the subsequent definitive treatment of these occult type I and III endoleaks may have contributed to the absence of aneurysm rupture and aneurysm-related mortality in our patient cohort.

Even if we recognize value in the diagnosis of previously occult seal zone failures, the optimal management of the remaining patients with T2EL and aneurysm sac expansion remains unclear. Unfortunately, recent reports do not show any substantial mid- or long-term follow-up for patients who are treated using similar angiographic embolization techniques.<sup>6-8,10</sup> Even when used during initial EVAR<sup>14</sup> or with follow-up via innovative ultrasound techniques,<sup>17,19</sup> results are not available beyond 2 years. Hypertension is prevalent in our patient cohort and has been identified as a preoperative T2EL risk factor in the population treated with the Zenith graft (Cook Medical Inc, Bloomington, Ind).<sup>20</sup> Aggressive medical control of hypertension is strongly recommended for this patient cohort. Prospective data collection from multiple institutions with substantial EVAR cohorts will be necessary to provide a stronger evidence base for the management of these challenging patients. As concern has grown regarding the cumulative doses of radiation incurred by CT angiography follow-up to 5 years and beyond, alternative means of surveillance have been sought, including magnetic resonance angiography and contrast-enhanced ultrasound.<sup>21</sup> In our practice, stable and shrinking aneurysms are often monitored by transabdominal ultrasound, with CT angiography reserved for the evaluation of new sac growth or other concerning findings.

We recognize several significant limitations to this study. It is limited by its retrospective nature with according selection bias and without control for timing or type of T2EL treatment. As noted in the Methods section, the majority of pre-T2EL intervention images were not available for direct review, although the great majority of critical postintervention follow-up images were able to be directly reviewed. Percutaneous endovascular interventions were conducted by a solitary expert interventional radiologist at a single institution; multicenter data would strengthen the generalizability of our findings. The translumbar route was the predominant approach utilized, with a minority of transfemoral approaches. In each instance, our interventional radiologist pursued all promising routes until angiographic success had been achieved. The possibility remains that other approaches to endoleak ablation, including aggressive laparoscopic clipping of all sac branches or multivessel transarterial embolization, might better mitigate perigraft flow, but convincing long-term outcomes data for such approaches are lacking. Several types of grafts were used, and the study was insufficiently powered to adequately assess aneurysm growth trends between these different graft types. Gaps in initial medical history and changing medications made it impossible to track the potential effect of hypertension and anticoagulant/antiplatelet medications in these patients. Despite review of available medical records and the SSDI, some patients expired without known cause, and occult aneurysm-related mortality remains a potential etiology

In summary, our data question the efficacy of percutaneous endovascular interventions for T2EL accompanied by aneurysm sac growth. We recommend dedicated angiographic evaluation of these patients, with prompt treatment of occult type I and III endoleaks. Further study is required to define if any subset of patients with T2EL and aneurysm growth would benefit from targeted percutaneous endovascular intervention, or other modes of endoleak ablation.

## AUTHOR CONTRIBUTIONS

Conception and design: AA, LS, CM, DP, NS, PG

- Analysis and interpretation: AA, LS, CM, DP, JC, NS, BR, PG
- Data collection: AA, CM, DP, PG
- Writing the article: AA, CM, DP
- Critical revision of the article: AA, LS, DP, JC, NS, PG
- Final approval of the article: AA, LS, CM, DP, JC, NS, BR, PG
- Statistical analysis: AA, PG

Obtained funding: Not applicable Overall responsibility: AA, PG

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#### INVITED COMMENTARY

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This article questions our current assumptions concerning the treatment outcomes of type II endoleaks. While it is generally acknowledged that these leaks occur frequently and are usually merely annoying, the results of treating more pernicious type II endoleaks that are accompanied by sac enlargement are largely unknown. These latter leaks, while rare, are often complicated, involving several sets of lumbar arteries, the inferior mesenteric artery, and extensive collateral networks. It is not surprising that simple embolization of the lumber, mesenteric, or internal iliac branches would not control these leaks. In fact, several groups have pointed this out, recommending translumbar approaches with coils and glue, and insisting on complete obliteration of the leak "nidus" within the sac.

Until now, many of us probably thought that this direct sac approach would be definitive and long-lasting. This article questions that assumption by indicating that 72% of patients who underwent treatment had not only persistent leaks, but more important, continuing sac growth. But probably the authors' most important point is that the aneurysms of some patients with persistent type II leaks and sac enlargement harbor unsuspected type I or type III leaks. Thus, they recommend angiography on all patients with any type of leak and an enlarging aneurysm. This advice is reasonable and widely accepted.

The authors recognize several weaknesses in their evaluation of their data. The most glaring is the inability of the authors to evaluate almost 60% of the preoperative computed tomography scans, relying on the initial radiologic report, a practice fraught with inaccuracies. While this damages the calculations of the preoperative slope value, it does not change the fact that the leaks persisted or recurred despite treatment. In addition, the reader has to accept the complete abolition of the endoleak since no images were provided. Furthermore, the interventional radiologist who performed the procedures favored translumbar sac embolization over other modalities.

As any good article should, the report raises questions: Should there be a size threshold reached before treatment of type II leaks? Does sac enlargement of 5 mm in a 5-cm aneurysm have the same prognosis as 5 mm growth in an 8-cm aneurysm? Should we perform angiography on patients with a long infrarenal neck, small aneurysm, and 5-mm sac increase? What is the best method for imaging and treating these leaks? Hopefully, this article will stimulate other groups to look at their data and help answer these questions.