

# Static sac size with a type II endoleak post-endovascular abdominal aortic aneurysm repair: surveillance or embolization?

Kyriacos Patatas<sup>a</sup>, Lynn Ling<sup>a</sup>, Joel Dunning<sup>b</sup> and Vivek Shrivastava<sup>a,\*</sup>

<sup>a</sup> Department of Vascular Radiology, Hull Royal Infirmary, Hull, UK

<sup>b</sup> Department of Cardiothoracic Surgery, James Cook University Hospital, Middlesbrough, UK

\* Corresponding author. Consultant Vascular Radiologist and Honorary Senior Lecturer (HYMS), Department of Vascular Radiology, Hull Royal Infirmary, Anlaby Road, Hull HU3 2JZ. Tel: +44-1482-875875; Ext 4136/secretary 4608; fax: +44-1482-675162; e-mail: vivek.shrivastava@hey.nhs.uk (V. Shrivastava).

Received 8 March 2012; accepted 19 April 2012

## Abstract

A best evidence topic was written according to a structured protocol. The question addressed was whether embolization is superior to surveillance for a type II endoleak associated with a static sac size post-endovascular abdominal aortic aneurysm repair (EVAR). Four hundred and sixty-one papers were identified, of which 10 papers presented the best evidence to answer the clinical question. The author, journal, date and country of publication, patient group studied, study type, and relevant outcomes and results are tabulated. A review of the available literature suggests that most type II endoleaks are innocuous and will seal spontaneously during the long-term follow-up, even when they persist for more than 6 months. An analysis of the large European Collaborators on Stent-Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) registry that includes prospective data on 2463 patients from 87 European hospitals showed that type II endoleaks were not associated with an increased risk of rupture; this correlates well with the large single-centre studies included in this review. Based on the available evidence, we conclude that the management of most isolated type II endoleaks should be conservative—with close radiological follow-up—even when persistent, with intervention restricted to those associated with sac enlargement >5 mm over a 6-month period or >10 mm when compared with pre-EVAR diameter.

**Keywords:** Abdominal aortic aneurysm • Endovascular repair • Endoleak • Conservative management

## INTRODUCTION

A best evidence topic was constructed according to a structured protocol as previously described [1].

## CLINICAL SCENARIO

A 75-year-old male patient has an elective endovascular repair (EVAR) for a 7.2-cm abdominal aortic aneurysm. A small type II endoleak identified at the end of the procedure was not treated. On the post-procedural and 6-month follow-up CT angiography, there is still evidence of the type II endoleak, but the aneurysm sac size is unchanged. The case is discussed at the vascular multi-disciplinary meeting and you are asked whether percutaneous embolization should be attempted. You are unsure whether there is any evidence to suggest that embolization is superior to conservative management for such a case. You decide to carry out a literature search to find the best available clinical evidence to manage the patient.

## THREE-PART QUESTION

Is [percutaneous embolization] superior to [conservative management] for a [type II endoleak]?

## SEARCH STRATEGY

A Medline search from 1948 to November 2011 using the OVID interface [exp type II endoleak(s)/OR type 2 endoleak(s)] AND [exp embolization/OR embolization] AND [exp management]. The reference lists of selected articles were also manually searched to identify relevant articles.

## SEARCH OUTCOME

Four hundred and sixty-one papers were found using the reported search. From these, 10 papers were identified that provided the best evidence to answer the question. These are presented in Table 1. The relevant papers included one meta-analysis, one multicentre study and eight retrospective single-centre studies.

## RESULTS

The boundaries of the anatomical and clinical suitability for EVAR are being pushed and as a result, patients with increasingly tortuous vascular anatomy and younger patients with less surgical co-morbidity are being offered EVAR. The recent publication of the long-term outcomes of the EVAR trials has shown a

**Table 1:** Best evidence papers

Author, date and country	Patient group	Outcomes	Key results	Comments
Gelfand <i>et al.</i> (2006), Ann Vasc Surg, Australia [5]  Meta-analysis Level 2a	Ten EVAR trials were reviewed with a total of 2617 cases	Mean follow-up of 20 months (range 0–47) Incidence of type II endoleak Incidence of rupture Frequency and success of secondary interventions	Incidence on discharge/30 day was 6–17% and decreased to 1–5% at 1 year No incidence of rupture related to type II endoleak Secondary interventions carried a success rate of 11–100%	This study suggests that type II endoleak should be followed up to 1 year, and intervention undertaken for sac enlargement occurring after 6 months or persistence for >12 months without sac enlargement
Van Marrewijk <i>et al.</i> (2004), Eur J Vasc Endovasc Surg, Netherlands [6]  Multicentre Level 2a	Three thousand five hundred ninety-five patients from 114 institutions that collaborated in the EUROSTAR registry	Three-year follow-up Incidence of type II endoleak Incidence of sac enlargement and aneurysm rupture Outcome events	Incidence of isolated type II endoleak was 9% Freedom from enlargement was 93% at 3 years in patients without, but 81% with type II endoleak Conversion to open repair or rupture were not significantly associated with type II endoleak	This study examined a selected patient cohort, excluding the influence of type I and III endoleaks. The authors suggests that more frequent surveillance examinations are indicated than in patients without collateral endoleak, and that the indication for re-intervention is primarily dictated by aneurysm expansion
Steinmetz <i>et al.</i> (2004), J Vasc Surg, USA [10]  Retrospective study Level 2b	Four hundred eighty-six consecutive patients who underwent EVAR at a single institution over a 7-year period	Mean follow-up 22 months (1–84) Incidence of type II endoleak Incidence of persistent type II endoleak Incidence of sac enlargement Incidence of rupture Success of embolization	Incidence of type II endoleak was 18.5% Incidence of persistent endoleak 7% Aneurysm sac enlargement was identified in 5 (1%) All 5 had successful embolization No aneurysm rupture occurred in patients with type II endoleak	The authors suggest that selective intervention to treat type II endoleaks which persist for 6 months and are associated with aneurysm enlargement (>5 mm) is safe
Silverberg <i>et al.</i> (2006), J Vasc Surg, USA [7]  Retrospective study Level 2b	Nine hundred fifty-six patients who underwent EVAR at a single institution over an 8-year period	Mean follow-up 22 months (1–72) Incidence of type II endoleak Rate of spontaneous seal Incidence of sac enlargement Rate of type II endoleaks free of sac enlargement	Incidence of type II endoleak was 16% 75% of type II endoleaks sealed spontaneously within a 5-year period, and 80% of patients with type II endoleaks remained free of sac enlargement >5 mm over a 4-year period No patients with type II endoleak experienced rupture or required conversion to open repair 12% of patients with endoleak (2% of total) required embolization for sac expansion	The authors recommend that close follow-up of patients with type II endoleak who show no signs of aneurysm expansion is a safe approach, thus sparing the patients from unnecessary secondary procedures and the inherent risk of complications from these interventions
Tolia <i>et al.</i> (2005), Radiology, USA [11]  Retrospective study Level 2b	Eighty-three patients who underwent EVAR at a single institution over 1-year period	Follow-up period of 1.5–4.5 years (mean 2.5) Incidence of type II endoleaks Incidence of sac enlargement Incidence of sac rupture Rate of embolization	Incidence of type II endoleak was 19% 80% of the endoleaks were managed with continued observation 62.5% sealed spontaneously during follow-up and 37.5% persisted with stable or decreased sac size No ruptures occurred 20% of endoleaks (5% of total) were embolized due to increasing sac size	The authors recommend that most type II endoleaks can be managed conservatively if the aneurysmal sac diameter is stable or has decreased, due to the high rate of spontaneous resolution and low risk of rupture

Continued

Table 1: Continued

Author, date and country	Patient group	Outcomes	Key results	Comments
Rayt <i>et al.</i> (2009), Eur J Vasc Endovasc Surg, UK [8]  Retrospective-prospective study Level 2b	Three hundred sixty-nine consecutive patients who underwent EVAR at a single institution over a 12-year period	Mean follow-up 4 years Incidence of type II endoleak Data regarding sac growth, intervention and outcome	Out of 25 isolated type II endoleaks, 72% demonstrated no increase in sac size and 24% showed an enlargement of the sac After a mean follow-up of 4 years, half of patients remain under observation (with an enlarging or stable sac), whilst the other half have spontaneously sealed 20% of those patients ( $n = 5$ ) have an enlarging sac There were no ruptures or aneurysm-related deaths and no patients required conversion to open	The authors have employed a policy of conservative management for type II endoleaks at their institution. Treatment for type II endoleaks has only been performed if there was a documented increase in sac size of >5 mm over a 6-month period, or an overall increase of more than 10 mm from the preoperative measurement Only one patient underwent intervention for a type II endoleak, however, the aneurysm sac continues to grow (last scan 13 cm). The patient has remained asymptomatic throughout a 10 year period and is unfit for any other form of intervention
Arko <i>et al.</i> (2001), J Endovasc Ther, USA [9]  Retrospective study Level 2b	Forty-six patients over a 2 year period at a single institution	Compared 3 groups: 16 patients with persistent type II endoleaks, 14 patients with transient type II endoleak (<6 months), and 16 patients with no endoleak	There was no significant change in aneurysm diameter from the preoperative value in the persistent endoleak group, whereas the aneurysm shrank in the other two groups. No secondary interventions were performed in the transient endoleak and no endoleak groups Embolization was performed in 5 (31%) of 16 persistent endoleak cases; however, although technically successful did not obliterate the endoleak No aneurysm rupture and no surgical conversions occurred in any group	The mean diameter enlargement in the persistent endoleak group was 1.8 mm. The authors suggest that— since the presence of a type II endoleak made no difference in overall outcome—it is not a reliable predictor of patient who may be at risk of rupture
Jones <i>et al.</i> (2007), J Vasc Surg, USA [12]  Retrospective study Level 2b	873 patients who underwent EVAR at a single institution over a 12-year period	Median follow-up of 32.6 months This study examined the incidence and outcomes of type II endoleaks	Incidence of type II endoleak was 18.8% Of these, 80% resolved spontaneously within 6 months, and 20% (3.8% of total) had persistent (>6 months) endoleak Persistent type II endoleak was associated with increased risk of aneurysm sac growth and re-intervention rate but not aneurysm-related mortality. It was also shown to be a predictor of aneurysm rupture 56% of patients treated for persistent endoleak had successful treatment	The authors conclude that the natural history of untreated persistent type II endoleaks is not benign. They state that this is the first study to demonstrate a significant relationship between type II endoleak and aneurysm rupture. They suggest that patients with persistent type II endoleak (>6 months) should be considered for more frequent follow-up or more aggressive approach to re-intervention

Continued

Table 1: Continued

Author, date and country	Patient group	Outcomes	Key results	Comments
Sarac <i>et al.</i> (2012), J Vasc Surg, USA [13]  Retrospective study Level 2b	One hundred forty embolization procedures over an 8-year period at a single institution	Five year follow-up Outcome post type II endoleak embolization In general, treatment was initiated if there was a persistent endoleak and the aneurysm grew >5 mm	No aneurysm rupture occurred The in-hospital/30 day complication rate was 8.6% At 1 year, freedom from second embolization procedure was 85% and freedom from sac growth was 81.5%. These decreased to 75.8 and 43.7%, respectively, at 5 years	The authors conclude that secondary intervention is successful early in reducing risk of further sac growth in persistent endoleak; however, a significant number of patients continue to have late sac expansion and require repeat procedures. They advocate close long-term surveillance for treated patients
Sheehan <i>et al.</i> (2006), J Vasc Surg, USA [14]  Retrospective study Level 2b	One thousand nine hundred nine patients who underwent EVAR during an 8-year period at 5 institutions	Three year follow-up Overall incidence of type II endoleak and comparison among different graft types	At 6 months, the overall rate of type II endoleak was 16.3% Resolution of endoleak occurred in 54 (33%) of 164 between 1 and 6 months, in 37 (33%) of 112 between 6 and 12 months, in 20 (35%) of 57 between 12 and 24 months and in 5 (20%) of 25 between 24 and 36 months	No endograft had a long-term statistically significant difference in the rate of type II endoleak. The long-term prevalence and clinical significance were masked by different treatment patterns and spontaneous resolution

significantly higher incidence of delayed rupture in the EVAR group which, in the longer term, removes the survival advantage of EVAR over open surgical repair [2–4]. Although the vast majority of late ruptures are due to type 1 endoleaks, the publication of an increased incidence of delayed rupture in EVAR patients (compared with open surgical repair) has brought the issue of management of type 2 endoleak to the fore [3].

Gelfand *et al.* [5] performed a meta-analysis of 10 EVAR trials in 2006, involving a total of 2617 cases. The incidence of type II endoleak at 30 days was 6–17%, which steadily decreased to 1.5% at 1 year. They found no association between ruptures and type II endoleak. They recommend that type II endoleaks be followed for up to 12 months, expecting that most will disappear spontaneously. If sac enlargement occurs after 6 months, percutaneous intervention should be considered. Persistent type II endoleaks without sac enlargement may be followed closely with CT or ultrasound surveillance. Definitive elective treatment is indicated if the endoleak persists for >12 months. Indications for early intervention include a symptomatic or pulsatile sac or sac enlargement of >5 mm over a 6-month period.

Van Marrewijk *et al.* [6] analysed the data of 2463 patients from 87 European institutions that collaborated in the EUROSTAR registry. At 3-year post-EVAR, they showed that a type II endoleak was not associated with conversion to open repair or sac rupture. The authors conclude that secondary intervention is not indicated for type II endoleak unless the aneurysm clearly shows expansion. However, they define significant sac expansion as  $\geq 8$  mm maximum transverse diameter increase over pre-procedure measurements compared with the majority of other studies which used  $\geq 5$  mm [5, 7–9]. Similarly, Steinmetz *et al.* [10] also showed that the conservative approach of embolizing a type II endoleak only when persistent (i.e. more than 6 months) and associated with an aneurysm sac growth of  $\geq 5$  mm was safe. However, their median follow-up was only 22 months

and there is increasing evidence to show that late complications and rupture can occur up to 8 years after EVAR [3]. Silverberg *et al.* [7], Rayt *et al.* [8] and Tolia *et al.* [11] also showed that type II endoleaks have a relatively benign course if the sac size remains static and that the rate of spontaneous seal continues to increase with time and the close follow-up of patients. Jones *et al.* [12] found a clear distinction between persistent type II endoleak (>6 months) and those that sealed spontaneously within 6 months with no evidence of sac expansion. The latter were found to be innocuous and not associated with any increased was associated with an increased morbidity or mortality, while the former was associated with an increased incidence of aneurysm sac growth and re-intervention rate.

Sarac *et al.* [13] analysed the outcome and long-term success of treating type II endoleaks. They advocate early treatment for type II endoleaks that are associated with an increase in sac size. However, even in this sub-group of patients who have their initial type II endoleak successfully treated, continued surveillance is important as up to 20% had recurrence that required further treatment at 5-year post-EVAR.

## CLINICAL BOTTOM LINE

The available evidence suggests that the majority of isolated type II endoleaks are innocuous and will seal spontaneously during the long-term follow-up, even when they persist for more than 6 months, and the vast majority of studies have not demonstrated an association with the increased risk of rupture or aneurysm-related mortality. However, if a type II endoleak is associated with a significant sac enlargement (i.e. >5 mm over a 6-month period), intervention is indicated, usually in the form of a percutaneous embolization of the feeding vessels. The caveat is that there is no randomized data and that most studies had a

mean follow-up period of approximately 3 years longer follow-up in patients with type II endoleak is lacking.

**Conflict of interest:** none declared.

## REFERENCES

- [1] Dunning J, Prendergast B, Mackway-Jones K. Towards evidence-based medicine in cardiothoracic surgery: best BETS. *Interact CardioVasc Thorac Surg* 2003;2:405-9.
- [2] Wyss TR, Brown LC, Powell JT, Greenhalgh RM. Rate and predictability of graft rupture after endovascular and open abdominal aortic aneurysm repair: data from the EVAR Trials. *Ann Surg* 2010;252:805-12.
- [3] Greenhalgh RM, Brown LC, Powell JT, Thompson SG, Epstein D, Sculpher MJ. Endovascular versus open repair of abdominal aortic aneurysm. *N Engl J Med* 2010;362:1863-71.
- [4] Greenhalgh RM, Brown LC, Powell JT, Thompson SG, Epstein D. Endovascular repair of aortic aneurysm in patients physically ineligible for open repair. *N Engl J Med* 2010;362:1872-80.
- [5] Gelfand DV, White GH, Wilson SE. Clinical significance of type II endoleak after endovascular repair of abdominal aortic aneurysm. *Ann Vasc Surg* 2006;20:69-74.
- [6] van Marrewijk CJ, Fransen G, Laheij RJ, Harris PL, Buth J. Is a type II endoleak after EVAR a harbinger of risk? Causes and outcome of open conversion and aneurysm rupture during follow-up. *Eur J Vasc Endovasc Surg* 2004;27:128-37.
- [7] Silverberg D, Baril DT, Ellozy SH, Carroccio A, Greyrose SE, Lookstein RA *et al.* An 8-year experience with type II endoleaks: natural history suggests selective intervention is a safe approach. *J Vasc Surg* 2006;44:453-9.
- [8] Rayt HS, Sandford RM, Salem M, Bown MJ, London NJ, Sayers RD. Conservative management of type 2 endoleaks is not associated with increased risk of aneurysm rupture. *Eur J Vasc Endovasc Surg* 2009;38:718-23.
- [9] Arko FR, Rubin GD, Johnson BL, Hill BB, Fogarty TJ, Zarins CK. Type-II endoleaks following endovascular AAA repair: preoperative predictors and long-term effects. *J Endovasc Ther* 2001;8:503-10.
- [10] Steinmetz E, Rubin BG, Sanchez LA, Choi ET, Geraghty PJ, Baty J *et al.* Type II endoleak after endovascular abdominal aortic aneurysm repair: a conservative approach with selective intervention is safe and cost-effective. *J Vasc Surg* 2004;39:306-13.
- [11] Tolia AJ, Landis R, Lamparello P, Rosen R, Macari M. Type II endoleaks after endovascular repair of abdominal aortic aneurysms: natural history. *Radiology* 2005;235:683-6.
- [12] Jones JE, Atkins MD, Brewster DC, Chung TK, Kwolek CJ, LaMuraglia GM *et al.* Persistent type 2 endoleak after endovascular repair of abdominal aortic aneurysm is associated with adverse late outcomes. *J Vasc Surg* 2007;46:1-8.
- [13] Sarac TP, Gibbons C, Vargas L, Liu J, Srivastava S, Bena J. Long term follow-up of type II endoleak embolisation reveals the need for close surveillance. *J Vasc Surg* 2012;55:33-40.
- [14] Sheehan MK, Ouriel K, Greenberg R, McCann R, Murphy M, Fillinger M *et al.* Are type II endoleaks after endovascular aneurysm repair endograft dependent? *J Vasc Surg* 2006;43:657-61.