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Patients' compliance with post- EVAR follow-up and its impact on the outcome

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Disclosures

Speaker's name: Prof. Athanasios D. Giannoukas

I do not have any potential conflict of interest related to my
presentation



Endovascular aortic aneurysm repair (EVAR) has emerged as the treatment-of-choice for the management of elective and ruptured abdominal aortic aneurysms (AAAs)

1. Dangas G et al. Open versus endovascular stent graft repair of abdominal aortic aneurysms: A meta-analysis of randomized trials. *JACC Cardiovasc Interv* 2012; 5: 1071–80.
2. Stather PW et al. Systematic review and meta-analysis of the early and late outcomes of open and endovascular repair of abdominal aortic aneurysm. *Br J Surg* 2013; 100: 863–72.
3. [Braithwaite B](#) et al.; IMPROVE Trial Investigators. [Endovascular strategy or open repair for ruptured abdominal aortic aneurysm: one-year outcomes from the IMPROVE randomized trial.](#) *Eur Heart J.* 2015 Aug 14; 36 : 2061-69.



Achille's heel of EVAR: post-operative complications during follow up period such as Endoleak, sac expansion and risk of rupture and re-interventions

Paravastu SC et al. Thomas SM. Endovascular repair of abdominal aortic aneurysm. Cochrane Database Syst Rev 2014; 1: CD004178. doi: 10.1002/14651858.CD004178.pub2.

Pintoux D et al. Long-term influence of suprarenal or infrarenal fixation on proximal neck dilatation and stent-graft migration after EVAR. Ann Vasc Surg 2011; 25: 1012–9.

Jouhannet C et al. Reinterventions for type 2 endoleaks with enlargement of the aneurismal sac after endovascular treatment of abdominal aortic aneurysms. Ann Vasc Surg 2014; 28: 192–200.

Nordon IM et al. Secondary interventions following endovascular aneurysm repair (EVAR) and the enduring value of graft surveillance. Eur J Vasc Endovasc Surg. 2010; 39: 547-54.



EVAR is associated with a high rate of secondary interventions ranging from 3.7% - up to 8.7% at 12 months with a cumulative incidence of 14% at 4 years

Nordon IM et al. Secondary interventions following endovascular aneurysm repair (EVAR) and the enduring value of graft surveillance. *Eur J Vasc Endovasc Surg.* 2010; 39: 547-54.

Hobo R et al. Secondary interventions following endovascular abdominal aortic aneurysm repair using current endografts. *J Vasc Surg* 2006; 43: 896-902.



Lifelong imaging surveillance is recommended to detect and treat complications during follow-up which are often asymptomatic

The rationale is the prevention of AAA rupture or AAA/stent-graft related morbidity and mortality

Paravastu SC et al. Thomas SM. Endovascular repair of abdominal aortic aneurysm. *Cochrane Database Syst Rev* 2014; 1: CD004178. doi: 10.1002/14651858.CD004178.pub2.

Pintoux D et al. Long-term influence of suprarenal or infrarenal fixation on proximal neck dilatation and stent-graft migration after EVAR. *Ann Vasc Surg* 2011; 25: 1012–9.

Jouhannet C et al. Reinterventions for type 2 endoleaks with enlargement of the aneurismal sac after endovascular treatment of abdominal aortic aneurysms. *Ann Vasc Surg* 2014; 28: 192–200.

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SVS PRACTICE GUIDELINES

From the Society for Vascular Surgery

SVS practice guidelines for the care of patients with an abdominal aortic aneurysm: Executive summary

Elliot L. Chaikof, MD, PhD,^a David C. Brewster, MD,^b Ronald L. Dalman, MD,^c Michel S. Makaroun, MD,^d Karl A. Illig, MD,^e Gregorio A. Sicard, MD,^f Carlos H. Timaran, MD,^g Gilbert R. Upchurch Jr, MD,^h and Frank J. Veith, MD,ⁱ *Atlanta, Ga; Boston, Mass; Palo Alto, Calif; Pittsburgh, Pa; Rochester, NY; St. Louis, Mo; Dallas, Tex; Ann Arbor, Mich; and Cleveland, Ohio* J Vasc Surg 2009;50:880

- Imaging surveillance strategy with CTA at 1 and 12 months.
- Additional CTA at 6 months in the presence of endoleak in the first month's CTA.
- After the first year, CTA is recommended every 12 months, with the alternative option of an ultrasound imaging if normal post-operative results were detected during the first year's CTA.



Different imaging protocols have been also developed and implemented in various treatment centers:

- Magnetic Resonance Angiography (MRA)
- Contrast-enhanced Ultrasonography (CEUS).

Habets J et al. Magnetic resonance imaging is more sensitive than computed tomography angiography for the detection of endoleaks after endovascular abdominal aortic aneurysm repair: a systematic review. *Eur J Vasc Endovasc Surg* 2013 ; 45: 340-50.

Karthikesalingam A et al. Systematic review and meta analysis of duplex ultrasonography, contrast-enhanced ultrasonography or computed tomography for surveillance after endovascular aneurysm repair. *Br J Surg* 2012; 99: 1514-23.



AIM

To assess the existing evidence on:

- the patients' compliance with the current imaging-protocols
- factors associated with compliance
- the potential influence of patient adherence to imaging-protocol on the outcomes

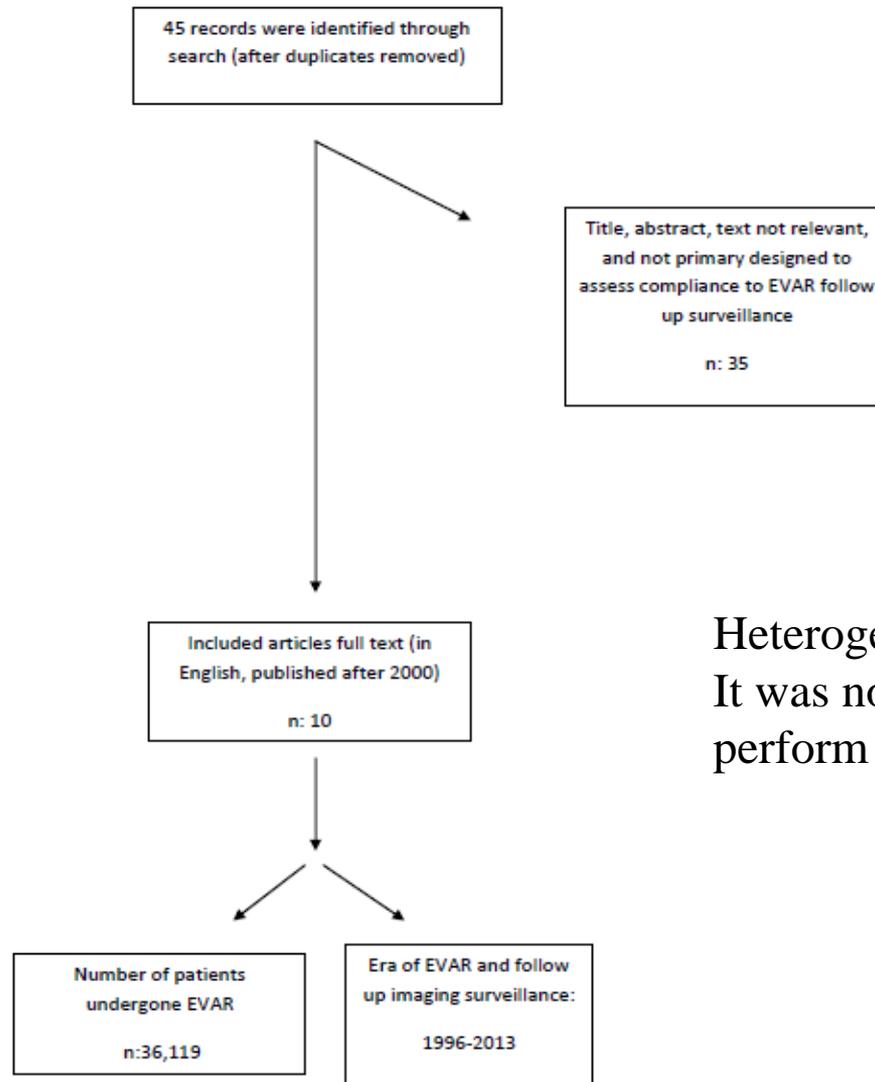


Evidence acquisition

MEDLINE (database provider PubMed), EMBASE (database provider Ovid) and Cochrane Central Register of Controlled Trials.

Major eligibility criterion: to report on the evaluation of post-EVAR follow up compliance.

The systematic review protocol, the selection process, and reporting were based on the 2009 **PRISMA** (Preferred Reporting Items for Systematic reviews and Meta-Analyses) statement



Heterogeneity in the data and outcomes:
It was not deemed appropriate to perform a meta-analysis.

Characteristics of the studies

Author	Journal	Date	Country	Study group	Treatment and follow-up period study group
AbuRahma et al.	JVS	2016	USA	West Virginia University Charleston Area Medical Center institutional.	2001-2013
Garg et al.	JVS	2015	USA	Medicare.	2002-2011
Wu et al.	JVS	2015	USA	University of Michigan performed by the Section of Vascular Surgery.	2001-2011
Schanzer et al.	JVS	2015	USA	Medicare.	2001-2008
Waduud et al.	Cardiovasc Intervent Radiol	2015	UK	NHS Greater Glasgow and Clyde, NHS Lothian, NHS Grampian, and NHS Tayside.	2001-2012
Godfrey et al.	Cardiovasc Intervent Radiol	2015	UK	University hospital of Southampton-Regions of Winchester, Southampton, Lymington and on the Isle of Wight	2008-2013
Kret et al.	JVS	2013	USA	Division of Vascular Surgery and the Dotter Interventional Institute at Oregon Health and Science University.	2004-2011
Sarangarm et al.	Annals of Vasc Surg	2010	USA	Albuquerque Veterans Affairs Medical Center (VAMC)	1999-2006
Jones et al.	JVS	2007	USA	The Greenville Hospital System University Medical Center.	1999-2005
Leurs et al.	Annals of Vasc Surg	2005	Europe	EUROSTAR Project	1996-2004

The overall quality of the included studies was weak
Summary of the bias assessment in each of these

Author	Selection bias	Performance bias	Detection bias	Attrition bias	Selective reporting bias
AbuRahma et al.	Low risk	High risk	High risk	High risk	High risk
Garg et al.	Low risk	High risk	Low risk	High risk	Low risk
Wu et al.	Low risk	High risk	High risk	High risk	Low risk
Schanzer et al.	Low risk	High risk	Low risk	High risk	Low risk
Waduud et al.	Low risk	High risk	Low risk	High risk	High risk
Godfrey et al.	Low risk	High risk	Low risk	High risk	High risk
Kret et al.	Low risk	High risk	High risk	High risk	High risk
Sarangarm et al.	Low risk	High risk	High risk	High risk	High risk
Jones et al.	Low risk	High risk	High risk	High risk	High risk
Leurs et al.	Low risk	High risk	Low risk	High risk	Low risk

Demographics, medical history of patients and distance from the treatment center

Total number of patients: 36,119

Mean follow up ranging from 25 to 73 months

Studies	AbuRahma et al.	Garg et al.	Wu et al.	Schanzer et al.	Waduud et al.	Godfrey et al.	Kret et al.	Sarangarm et al.	Jones et al.	Leurs et al.
Sex (male)	82%	51%	81.9%	82%	89%	93.3%	79.4%	NA	NA	NA
Race (white)	97.7%	51%	96.8%	94%	NA	NA	NA	NA	NA	NA
Age	NA	76	74	76.3	76	77.1	71.9	71	NA	NA
HT	86%	NA	NA	71%	NA	77%	73%	NA	NA	NA
HL	65%	NA	NA	54%	NA	65.3%	49.5%	NA	NA	NA
DM	21%	NA	NA	20%	NA	34%	11.8%	NA	NA	NA
CAD	58%	NA	NA	46%	NA	45.2%	32.8%	NA	NA	NA
COPD	33%	NA	NA	NA	NA	NA	15.2%	NA	NA	NA
CRF	20%	NA	NA	NA	NA	12.8%	11.8%	NA	NA	NA
Distance (miles)	NA	NA	43	NA	NA	20.4	<60; 52%, 60-120; 23%, >120; 25%	>100; 44%	>50; >90%	NA



Definition and percentages of incomplete or loss of follow up for each study

Author	Definition of incomplete or loss of follow up	Incomplete follow up	Loss of Follow up
AbuRahma et al.	Patients did not have any follow-up imaging (CT and/or duplex ultrasound) for 2 years at any time during their follow-up and/or missed their first post-EVAR imaging over 6 months.	57%	35%
Garg et al.	Gaps for intervals >15 months between consecutive images or if >15 months elapsed after the last imaging.	57%	30%
Wu et al.	No further vascular surgical follow-up, surveillance imaging, or further documentation beyond their last missed appointment.	52.7%	41.4%
Schanzer et al.	No abdominal imaging study within their last two years of follow-up.	NA	22% in 1 year, 38% in 3 years, 50% in 5 years
Waduud et al.	No imaging in the first 12 months or missed any subsequent annual imaging appointments thereafter.	43%	NA
Godfrey et al.	Non-compliance was defined as not having imaging within the preceding 12 months (± 2 months) unless otherwise documented within radiology reports or patient notes.	NA	27.9%
Kret et al.	No imaging for more than 1 year since their last documented surveillance imaging and follow-up clinic visit.	NA	56%
Sarangarm et al.	Patient who missed more than two consecutive follow-up office visits.	15%	NA
Jones et al.	Patients who missed two or more consecutive follow-up office visits.	NA	33%
Leurs et al.	Patients who came infrequently and did not attend all scheduled visits.	65%	NA

Factors associated with complete or incomplete and loss of follow up surveillance; comments of each studies (continued)

Author	Factors associated with complete surveillance	Factors associated with incomplete or loss of follow up	Comment
AbuRahma et al.	NA	Peripheral arterial disease, carotid artery disease and hostile neck AAA.	Additional studies are needed to verify if strict post-EVAR surveillance is necessary and to determine its effect on long-term clinical outcome.
Garg et al.	Congestive heart failure, renal failure, lymphoma and metastatic cancer solid tumors.	Increasing age, Medicaid eligibility, low-volume hospitals and rupture of AAA.	Additional studies are necessary to determine if variability in postoperative surveillance affects long-term outcomes.
Wu et al.	Absence of social work consultation, family history of AAA, shorter driving distances, shorter hospital stay.	NA	Further research individualizing surveillance protocols based on risk level of late complications and noncompliance and prospective studies examining resulting survival benefits of compliance are warranted.
Schanzer et al.	NA	Advanced age and presentation with an urgent/emergent intact aneurysm or ruptured aneurysm, Previously diagnosed chronic diseases and South and West regions of the US.	Quality improvement efforts to encourage improved compliance with imaging follow-up, especially in older patients with multiple co-morbidities and in those who underwent EVAR urgently or for rupture, are necessary.
Waduud et al.	NA	NA	Further studies are required to establish the most clinically appropriate and cost-effective surveillance strategy.



Factors associated with complete or incomplete and loss of follow up surveillance; comments of each studies

Godfrey et al.	A trend was seen towards compliance in the upper Socioeconomic status.	Radiation concerns, logistics (transport problems), correspondence failure.	Identifying reasons for non-compliance is essential in ensuring the success of surveillance programmes. and to be able to offer more individualized follow-up. There is a need for a trial to explore patients' attitudes and factors that would enhance current and future compliance.
Kret et al.	NA	NA	Further study is needed with regard to ideal duration of long-term follow-up.
Sarangarm et al.	NA	NA	Additional studies evaluating the potential barriers against patient adherence to follow-up regimens are needed in order to help in the selection of good candidates for EVAR.
Jones et al.	NA	NA	These data expose a potential under-appreciated limitation of EVAR, questioning whether the findings in clinical trials defining the efficacy of EVAR can be routinely extrapolated to ordinary practice.
Leurs et al.	Smoking, hyperlipidemia, and unfit for open surgery or general anesthesia patients.	NA	Further assessment is indicated to evaluate the effectiveness of different frequencies of surveillance visits.



In contrast to clinical practice guidelines, our study demonstrates that almost half of the patients had incomplete or complete loss of follow up

This may reflect:

- Patients' failure to understand the natural history of the intervention they have subjected to
- Physicians' failure to convince their patients on the need and the benefits of surveillance
- Systems' failure to establish a simple and patients' friendly surveillance protocol



Even in studies which showed that complete follow up had no survival benefit for patients



Authors questioned their results because of a great number of patients in their series who were lost or had incomplete follow-up.

A recent report showed that follow up surveillance after EVAR may be less intensive in real world practice outside clinical trials.

Jones WB, et al. Lost to follow-up: a potential under-appreciated limitation of endovascular aneurysm repair. J Vasc Surg. 2007; 46: 434-40.

A Simple Booklet for Patient Follow-Up After Endovascular Abdominal Aortic Aneurysm Repair Procedures

Angiology
63(8) 634-637
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sagepub.com/journalsPermissions.nav
DOI: 10.1177/0003319711435937
<http://ang.sagepub.com>



Pavlos N. Antoniadis, MD¹, Konstantinos D. Kyriakidis, MD¹, and Kosmas I. Paraskevas, MD²

From the Southern Association for Vascular Surgery

J Vasc Surg 2007;46:190

Optimizing compliance, efficiency, and safety during surveillance of small abdominal aortic aneurysms

Paul A. Armstrong, DO, Martin R. Back, MD, Dennis F. Bandyk, MD, Ann S. Lopez, ARNP, Shelly K. Cannon, ARNP, Brad L. Johnson, MD, and Murray L. Shames, MD, *Tampa, Fla*

the use of a prospectively-maintained surveillance database managed by a non-physician provider with limited additional resources and with a reliance on telephone contact, resulted in a high degree of patient compliance, reduced unnecessary patient travel, and provided practical clinic use



ELSEVIER



Is There a Benefit of Frequent CT Follow-up After EVAR?

N.V. Dias*, L. Riva, K. Ivancev, T. Resch, B. Sonesson, M. Malina

Vascular Center Malmö-Lund, Malmö University Hospital, Entrance 59 – 7th floor, 205 02 Malmö, Sweden

J ENDOVASC THER
2012;19:151–156

151

◆ CLINICAL INVESTIGATION ◆

Early Follow-Up After Endovascular Aneurysm Repair: Is the First Postoperative Computed Tomographic Angiography Scan Necessary?

Kyriakos Oikonomou, MD¹; Felipe C. Ventin, MD¹; Kosmas I. Paraskevas, MD¹;
Peter Geisselsöder, MD²; Wolfgang Ritter, MD²; and Eric L. Verhoeven, MD, PhD¹

¹Department of Vascular and Endovascular Surgery and ²Department of Radiology,
Klinikum Nürnberg, Germany.

◆ ◆

Less-frequent follow up is sufficient in the majority of patients, which may simplify the surveillance protocol, reduce radiation exposure and the total costs of EVAR, but this strategy may arguably lead to further loss of follow up.



Limitations in the existing literature

- ✓ Heterogeneity of the data and outcomes
- ✓ Difference among follow up imaging protocols
- ✓ Lack of global data on the patients' compliance with post-EVAR protocols, because the observations were derived from the USA and Europe



Our study highlights

- ❑ The presence of a gap between the ‘state of art’ of EVAR procedures and their recommended surveillance protocols and the clinical practice in real word practice.

- ❑ Further prospective multicenter studies or registries with certain follow-up protocols or registries are needed to assess the factors associated with patients’ post-EVAR follow up compliance and its influence on the outcomes.



Conclusions

- Patients' compliance with follow-up protocol after EVAR is poor (about 50%)
- In the existing literature there is heterogeneity and several biases which do not allow a proper meta-analysis to be carried out
- Several factors such as **advanced age, symptomatic or ruptured aneurysm, history of coexisting chronic diseases,** and **socio-economic factors** such as treatment in low-volume hospitals, health insurance eligibility and certain regions of the USA were associated with incomplete or loss of follow-up.




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