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European Society for Vascular Surgery (ESVS) AAA Guidelines Focused Update on patients treated with the Nellix EndoVascular Aneurysm Sealing (EVAS) system

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European Society for Vascular Surgery (ESVS) AAA Guidelines Focused Update on patients treated with the Nellix EndoVascular Aneurysm Sealing (EVAS) system

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What this paper adds

European Society for Vascular Surgery (ESVS) Guidelines are renewed with some regularity, usually every 5 years. ESVS Guidelines Focused Updates are issued to convey important new data that has emerged in between the publication of the full Guidelines, that affects patient safety or in a decisive way impact decision-making or management of the patients. This Focused Updates provides guidance on

surveillance and management of patients who had undergone AAA repair with an Endovascular Aneurysm Seal (EVAS) device.

Abstract

Objective: To provide guidance on the surveillance and management of patients treated with Endovascular Aneurysm Seal (EVAS).

Method: Based on a scoping review of risk for late serious aortic-related adverse events in patients treated with EVAS for AAA, the European Society for Vascular Surgery (ESVS) AAA Clinical Practice Guidelines Writing Committee agreed on recommendations graded according to the European Society of Cardiology (ESC) grading system.

Results: EVAS has a very high incidence of late endograft migration resulting in proximal type 1 endoleak with risk of rupture, requiring open conversion with device explant. The reported mortality for elective explantation varies between 0% and 14%, while acute conversion for rupture has a very dismal prognosis with 67-75% mortality.

Conclusion It is recommended that all patients in whom a Nellix device has been implanted should be identified, properly informed and enrolled in enhanced surveillance. If device failure is detected, early elective device explant should be considered in surgically fit patients.

Keywords: *Abdominal aortic aneurysm, Endovascular Aneurysm Sealing, EVAS, Nellix, Surveillance, Endoleak, Rupture, Conversion, Guidelines*

Introduction

The European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms recommended that conceptual new technologies, such as Endovascular Aneurysm Sealing (EVAS), should only be used within studies approved by research ethics committees and with informed consent, until properly evaluated. The reportedly higher rates of leaks around the Nellix® implant (Endologix®, Inc, Irvine, Calif, USA), endograft migration and aneurysm sac enlargement, further strengthened the position that EVAS was not suitable for use in clinical practice (1), and subsequently, the manufacturer ended its production (Endologix, Nellix End of Life Communication. May 10, 2022). However, there was no clear guidance on surveillance and management of patients who had already undergone AAA repair with an EVAS device.

The ESVS AAA Guidelines Writing Committee therefore initiated a literature review, and the current accumulated knowledge suggests that patients treated with EVAS for AAA may be at high risk for serious aortic-related adverse events, which justifies an updated guidance on the surveillance and management of patients already treated with EVAS. It is also appropriate to reiterate the ESVS 2019 AAA Clinical Practice Guidelines Recommendation #58 (1).

ESVS 2019 AAA Guidelines Recommendation #58	Class	Level	References
New techniques/concepts (such as endovascular aneurysm sealing with endobags) are not recommended in clinical practice and should only be used with caution, preferably within the framework of studies approved by research ethics committees, until adequately evaluated	III	C	Wanhainen et al. 2019

Method

A Scoping Review of risk for late serious aortic-related adverse events and follow-up routines in patients treated with EVAS for AAA was performed based on literature search in PubMed up to 07 December 2022, using the title search terms; “Endovascular Aneurysm sealing”, “EVAS” and ”Nellix”. Reference checking and manual searching by the members of the writing committee added other relevant literature. Full text original articles as well as published abstracts were included.

Based on a synthesis of the available evidence, the ESVS AAA Guidelines Writing Committee agreed on recommendations. The recommendations are graded according to the European Society of Cardiology (ESC) grading system, where the strength (class) of each recommendation is graded from I to III and the letter A to C marks the level of evidence. As per standard ESVS Guidelines procedure, this document has been reviewed and approved by the members of the ESVS Guidelines Steering Committee.

Results

EVAS Failure Mechanism

The main mechanisms of EVAS failure result from caudal migration of the stent-grafts and separation of the endobags leading to type 1a endoleak, sac pressurization and aneurysm expansion (2-4). Failure of these endografts often occurs beyond two-years from implant (2-5). In a recent systematic review and meta-analysis including 703 patients from seven studies with mean follow-up of more than 2 years (range 24-72 months), the pooled est mated incidence of type 1 endoleak, migration, and reintervention was 25%, 22%, and 27% respectively (5), and by 4-years up to 100% of patients may demonstrate AAA sac expansion (6). Furthermore, it has become apparent that the failure mechanisms persisted despite the refinement of the instructions for use of EVAS (7). Device migration and proximal type 1 endoleak may lead to secondary AAA rupture with an incidence of 9.3% with two thirds of patients not surviving the event (3).

EVAS Surveillance

Experience from centres where large numbers of EVAS procedures were performed, initially prioritized the identification of all patients in whom these devices had been implanted and then enrolled them in enhanced surveillance programs including initial CTA, clinical assessment, and subsequent duplex imaging every six months and plain abdominal radiographs to identify sac expansion, device migration and

endoleaks. If problems were identified, an additional CTA was performed to provide a more detailed assessment.

It is important that clinicians actively inform their patients in a clear and transparent manner, regarding the high mid- and long-term failure rates of EVAS, and a frank face-to-face consultation should be undertaken to explain the need for enhanced surveillance and potential problems that may occur. A formal “duty of candour“ process with written communication to all patients is advocated (2)

Management of device migration and endoleak

The management of a failing Nellix device presents a number of challenges in comparison to a standard EVAR. The small stent calibre and the two flow lumens through separate devices preve t the use of proximal extension cuffs. Proximal extension with further Nel ix devices often described as Nellix-in Nellix application (NINA), with or without the addition of chimney parallel grafts (ChNINA) to the visceral arteries, did show some initial promise with reasonable 1–year results (8). However, much like the early attempts to embolize proximal Type 1a endoleaks (3,9), the NINA approach has not been demonstrated to be durable at preventing device migration during extended follow-up (2,4). Finally, Endologix recently announced in a targeted communication that the production of the Nellix devices and its accessories has been ended, which prevents any further secondary intervention or bailout treatment with these systems going forward (Endologix, Nellix End of Life Communication. May 10, 2022). Proximal extension with a

fenestrated/branched EVAR device may be an alternative option, but due to limited data, this method needs further evaluation (10,11).

Open conversion with device explant is the treatment of choice for patients with failing EVAS if they are deemed fit enough to undergo the intervention (3,4). The Nellix devices are relatively easy to remove from the proximal neck as there is no active fixation, however the balloon-expandable stent-grafts in the iliac arteries may be more challenging to remove and care must be taken to avoid intimal dissection. Alternatively, they can be partially resected with the distal end left in situ and incorporated into the distal anastomoses. The mortality associated with device explantation can, however, be significant. A series of 21 explants including four for ruptured AAA reported no in-hospital mortality and similar results were reported in another series of eight elective explants, although mortality for explant in ruptured AAA patients in the same centre was 67% (3,12). In a recent single-centre report from Norway, 29% (40/137) of patients treated with EVAS had open conversion due to type 1 endoleak with sac expansion after mean 39 months follow-up. The overall perioperative (30-day) mortality was 20% (8/40), 75% (3/4) among emergency conversions and 14% (5/36) among elective conversions (13). A further contemporary series of 44 explants for various indications also identified significantly poorer outcomes in urgent or emergency cases (14). Therefore, these data would support early explantation of failing devices in fit patients in an elective setting.

Conclusion

The ESVS AAA Guidelines Writing Committee decided that it was important to publish this *Focused Update* before the fully updated guidelines will be available in 2024 to highlight the issues with EVAS failure, to promote patient safety and to encourage clinicians to identify all patients in whom a Nellix device has been implanted. These patients should be enrolled in enhanced surveillance programmes and if device failure is detected, be offered early elective device explant. We do recognize that in the elderly, frail and co-morbid patients not suitable for explant, a conservative management strategy or alternative complex endovascular techniques may be more appropriate.

Recommendation 1	**Class**	**Level**	**References**
Patients who have undergone Endovascular Aneurysm Sealing (EVAS) with the Nellix ® (Endologix ®) prosthesis should be identified, properly informed and enrolled in enhanced surveillance.	I	C	Consensus

Recommendation 2	**Class**	**Level**	**References**
Explantation of failing Endovascular Aneurysm Sealing (EVAS) Nellix ® prostheses	I	C	Consensus

(Endologix ®) is recommended as the preferred treatment in surgically fit patients.			

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