Eur J Vasc Endovasc Surg (2018) 56, 342–348

Editor's Choice – Mid-term Migration and Device Failure Following Endovascular Aneurysm Sealing with the Nellix Stent Graft System – a Single Centre Experience

Seamus C. Harrison *, **Andrew J. Winterbottom, Patrick A. Coughlin, Paul D. Hayes, Jonathan R. Boyle**

Division of Vascular and Endovascular Surgery, Addenbrooke's Hospital, Cambridge University Hospital Trust, Cambridge, UK

WHAT THIS PAPER ADDS

Endovascular aneurysm sealing in the treatment of abdominal aortic aneurysms is a novel concept. Longer-term experience with the Nellix stent graft is reported. A high rate of graft failure was found, usually more than 2 years post implant. Stent failure is specifically related to caudal migration and stent separation. Further understanding of the role of such technology in the management of patients with an AAA is needed before it can be used in mainstream practice.

Objective: Endovascular aneurysm sealing (EVAS) with the Nellix stent graft system is a novel concept in the management of abdominal aortic aneurysm (AAA) that aims to reduce the prevalence of all endoleaks following endovascular repair. There are few data describing the longer-term durability of this approach. The aim was to report the longer-term outcomes following EVAS in a single centre.

Methods: This is a retrospective review of all patients that underwent Nellix at Cambridge University Hospitals Foundation Trust. Factors that are described as device failure include secondary sac rupture, graft explantation, further surgical procedures for Type 1 endoleak, or major migration of the stent grafts with pressurisation of the aortic sac.

Results: A total of 161 patients have been treated with Nellix. The indications included primary AAA ($n = 115$), ruptured AAA ($n = 4$), salvage of other aortic grafts ($n = 18$), primary iliac aneurysm ($n = 6$), and chimney EVAS (ChEVAS) for pararenal AAA ($n = 18$). In total there have been 42 graft failures in patients treated with EVAS for primary AAA. The 4 year freedom from graft failure was 42% in patients treated for primary AAA. Failures mostly occurred more than 2 years post-Nellix implant. There were eight secondary sac ruptures (incidence 2.4 per 100 person years) and there have been 14 graft explants.

Conclusions: Failure of aneurysm sealing following treatment with Nellix has been more common than anticipated and can cause aortic rupture. Post-operative surveillance of Nellix stent grafts is crucial to identify features of failure.

Article history: Received 7 February 2018, Accepted 7 June 2018,

Keywords: Abdominal aortic aneurysm, Endovascular sealing, EVAS, Nellix, Endoleak, Graft failure

INTRODUCTION

Endovascular aneurysm repair (EVAR) of intact abdominal aortic aneurysms has early survival benefits compared with open surgery, and EVAR[1] now accounts for 70% of elective repairs in the UK.[2] There are, however, concerns regarding the long-term durability of EVAR and recently reported long-term outcomes from the EVAR 1 study demonstrate significant late aneurysm related mortality following EVAR, mostly attributable to secondary sac rupture.[3]

Endovascular aneurysm sealing (EVAS) with the Nellix stent graft system (Endologix Inc., Irvive, CA, USA) is a novel concept in AAA repair.[4] The system is based upon two balloon expandable stents attached to "endobags" that are filled in situ with a soluble polymer that "seals" the aneurysm. The system was designed to improve long-term durability of minimally invasive AAA repair primarily by reducing the incidence of endoleaks of any kind. Other perceived benefits of the system included reduced procedure times and radiation dose.[5] Finally, when the system was first introduced the anatomical instructions for use (IFU) were more liberal than other stent graft manufacturers, thereby increasing the applicability of minimally invasive repair.[6] The graft, was until recently described as a "sac anchoring endoprosthesis", suggesting that conventional neck anatomy played a smaller role in the mechanism of aneurysm exclusion.

* Corresponding author. Addenbrooke's Hospital, Hills Road, Cambridge CB2 0QQ, UK.

E-mail address: seamus.harrison@addenbrookes.nhs.uk (Seamus C. Harrison).

1078-5884/

https://doi.org/10.1016/j.ejvs.2018.06.031

Early reported outcomes for the Nellix device were extremely favourable in terms of procedural success, survival, and freedom from endoleak.[7–9] Subsequent publications have reported successful use outside the original IFU, in combination with parallel stents (chimney EVAS or ChEVAS),[10] for the salvage for failed conventional EVAR[11] and for ruptured AAA.[8] All papers have relatively short follow up (<2 years). Despite seemingly favourable results, there has been progressive and substantial refinement with regard to the device IFU such that the morphological suitability for on-label EVAS has been considerably narrowed. Though the data prompting a more conservative IFU have not been published, it may be that this came in response to observations of device failure made in early registries. Furthermore, Endologix has issued a field safety notice about the management of failing Nellix stent systems and recent scientific meetings have had sessions dedicated to both open and endovascular salvage of failing Nellix.[12] Despite this, published data regarding the mechanism and clinical features of Nellix failure, remain sparse limited to a single publication reporting a novel classification of Type 1a Endoleak following Nellix.[13]

Cambridge University Hospitals Foundation Trust (CUHFT) is a major teaching hospital and tertiary referral centre in the east of England, carrying out 150—200 aortic procedures per annum. The Nellix stent graft was introduced to CUHFT in 2013 for the treatment of AAA. Throughout 2017 it became apparent that there was a higher than expected rate of Nellix failures, prompting an internal review of all patients that had been treated with the Nellix system. The purpose of this article is to report the findings to the wider vascular surgery community.

METHODS

This was a retrospective review of all patients treated with the Nellix device at CUHFT between February 2013 and August 2017. All patients who had a Nellix stent graft implanted during this period were included. All patients underwent cross sectional imaging prior to intervention. Elective cases were discussed in a weekly vascular surgery multidisciplinary meeting. The rationale for use of Nellix was varied. To develop competence with a new graft, initial cases were selected on the basis of having anatomy suitable for EVAR but with features that may predispose to Type 2 endoleaks such as large lumbar arteries. As experience grew, patients with more challenging anatomies were treated. Many of the patients treated had been deemed unsuitable for open repair or more complex endovascular procedures such as fenestrated EVAR. Each Nellix implantation was performed by a team that included both a consultant vascular surgeon and a consultant vascular radiologist, each with previous experience in EVAR. The vast majority of cases were supported by a product specialist.

Post-operative surveillance followed the institution's standard EVAR surveillance protocol: a computed tomography (CT) angiogram within the first three months post-stent implantation with subsequent ultrasound surveillance and abdominal X-ray every 6 months within the first 2 years and then yearly thereafter. The protocol was altered for EVAS specifically from early 2017 with the introduction of bi-annual duplex and plain abdominal films.

In late 2017, all surviving patients that had Nellix implanted were contacted by the vascular surgery team at CUH and invited for enhanced surveillance and a "duty of candour" clinic with a vascular surgeon. The purpose of this clinic was to inform the patients of a higher than anticipated failure rate following Nellix implantation.

Definitions and descriptions

All patients treated with the Nellix device in CUHFT were included in the analyses. The results are presented in subgroups according the primary indication for Nellix treatment (primary AAA, juxtarenal AAA requiring ChEVAS, primary iliac aneurysms, and salvage of other aortic repairs). Nellix failure is defined as (a) a combined triad of caudal migration of the Nellix stents greater than 5 mm, separation of the endobags (>5 mm), and sac enlargement (>5 mm), with or without visible endoleak, (b) secondary rupture of the AAA, (c) surgical explant of the graft, (d) or any attempted intervention for a Type 1 Endoleak. Concerning imaging features (CIF) are defined as isolated graft migraftion >5 mm, any stent separation or a sac size increase more than 5 mm.

For the purpose of this study two authors (A.J.W./S.C.H.) have reviewed all pre- and post-operative imaging (CT angiogram/duplex/plain abdominal X-ray) for all patients. All findings have been documented in the patient's electronic record and patients have been updated. Each preoperative CT angiogram was re-analysed and the suitability for EVAS was based on the initial Nellix IFU, the suitability for standard EVAR or complex endovascular AAA repair (fenestrated or branched EVAR — FEVAR/BEVAR), or whether there was no other endovascular solution to treat the AAA. This classification was made on purely anatomical grounds and physiological parameters were not considered.

Statistical analysis

All analyses were carried out using Stata V10. Survival was estimated using Kaplan—Meier estimates. Outcomes following EVAS were compared in patients that were within and outside the original Nellix IFU using the log-rank test. Incident rates of graft failure, secondary sac rupture, and explant were calculated. Data were censored on April 1, 2018.

RESULTS

Overall survival and follow up following Nellix at CUH

In total, Nellix stent grafts were implanted in 161 patients in CUH. This includes both elective and emergency cases (emergency $n = 20$). The median follow up was 4.4 years (IQR 3.30—4.85 years). During follow up, 52 patients have died. All surviving patients were successfully contacted as part of the ongoing review. Seven surviving patients have not had recent imaging because they have been deemed unfit for ongoing surveillance.