

# Initial experience with the Nellix EndoVascular Aneurysm Sealing system for treating patients with abdominal aortic aneurysms: a case controlled comparative study

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## Abstract:

**Background-Aim:** The Nellix EndoVascular Aneurysm Sealing (EVAS) system is a novel approach to abdominal aortic aneurysm (AAA) endovascular repair whereby two PTFE stents deployed infrarenally, are used to exclude the aneurysm and biocompatible polymer is employed to fill and seal the AAA sac. The aim of this study was to assess the preliminary results of the Nellix stent-graft system and compare them with those obtained in patients treated with a well-established endograft of the same material and infrarenal fixation as the Excluder stent-graft.

**Methods:** A retrospective analysis of prospectively collected data from September 2014 to December 2018 identified 41 elective AAA patients treated with the Nellix endograft, in comparison to a matched group of 82 patients treated with the Excluder stent-graft. Endpoints included technical and clinical success, freedom from any secondary intervention, any type of endoleak and aneurysm related death.

**Results:** Primary technical success was achieved in all patients with null 30-day mortality. There was one limb thrombosis during the second postoperative day in the EVAS group. The Nellix group had lower levels of radiation burden, contrast media and duration of the procedure when compared to the Excluder group. During a median follow-up period of 23 months (range 1-53 months) there were no differences in clinical success, freedom from reintervention and aneurysm related death. One type Ib endoleak (2.4%) and three migrations (7.3%) were observed in the Nellix group requiring two reinterventions (4.9%). There were also six type II endoleaks, all in the Excluder group (7.4%), during the follow-up period (log rank=0.01). Five type II endoleaks resolved spontaneously, while in one patient the endoleak remained without any change in aneurysm sac diameter.

**Conclusion:** The initial experience with the Nellix stent graft system in the present cohort is quite promising, with successful aneurysm sealing and acceptable mid-term results, despite the current controversies. Further and larger studies are needed to fully evaluate the long-term results of this particular endograft.

## INTRODUCTION

Endovascular aneurysm repair (EVAR) has gained wide acceptance as the primary treatment choice in patients with favorable anatomy.<sup>1</sup> Even though a marked benefit in perioperative mortality has been demonstrated in randomized controlled trials, such benefit decreases or even lost over time.<sup>2</sup> Aneurysm related adverse events such as endoleak and migration

still occur consisting a challenge not only for the interventionists but also for the stent-grafts. Especially, type II endoleak (ETII) after EVAR seem a common finding and despite its usual benign course may sometimes lead to a worse outcome<sup>3</sup>. Endografts' manufacturers are constantly designing new devices to eliminate or even prevent complications related to EVAR.

In 2011, a novel concept of endovascular abdominal aortic aneurysm (AAA) treatment was introduced in clinical practice<sup>4</sup>. Endovascular Aneurysm Sealing (EVAS) technique, is characterized by obliteration of the aneurysmal sac by polymer-filled endobags, while maintaining the normal flow to lower extremities with two balloon expandable stent frames covered with expanded polytetrafluoroethylene. Its design aims mostly to reduce the rate of type II endoleaks, by using the filling of the aneurysm sac with the endobags to provide positional stability of the endograft and sealing of side branch flow. The single-piece conformation of the stents eliminates the threat of component separation and type III endoleaks.

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Other benefits of the system include reduced procedure times and radiation dose, respect to well established aortic stent grafts.<sup>5-7</sup> The early results of Nellix device were encouraging showing a high aneurysm exclusion rate and low frequency of endoleak and migration rates, even when used outside the original 2013 IFUs.<sup>5-8</sup> Despite this, in response to observations of device failure made in some early registries, the endograft's IFUs were progressively refined. In 2016, the new device's IFUs, narrowed considerably the range of morphological characteristics that render an aneurysm suitable for on-label EVAS.<sup>9</sup> Nevertheless, published data regarding safety and durability of the Nellix stent graft deployment in the long-term, still missing.

The aim of this study is to assess the early and mid term results of the Nellix stent graft system in terms of safety and durability and compare them with those of a well-established endograft as the Excluder (Gore & Associates, Flagstaff, AZ, USA).

## MATERIALS AND METHODS

### Study design

We conducted a case control study in order to evaluate the efficacy and safety of EVAS using the Endologix Nellix device. Between September 2014 and December 2018 472 patients with infrarenal AAA were operated. 41 (8.68%) of them were electively treated with EVAS using the Endologix Nellix device. The operations were conducted at the University General Hospital of Ioannina and the University General Hospital of Larissa. The patients' data were prospectively collected and inserted in a dedicated database including demographics, preoperative risk factors, operative time, contrast media use, patient outcomes, length of stay and complications.

All of the patients had AAAs with morphological characteristics suitable for endovascular repair. An informed consent was signed before the procedure. Sizing and planning before the endovascular procedure were performed using a 3Mensio (Medical Imaging BV, Bilthoven, The Netherlands) dedicated reconstruction software.

The procedures were performed with bilateral femoral artery exposure under general anesthesia, or with ultrasound guided percutaneous catheterization. All interventions took place in an adequately equipped operating room using a BV Pulsera 12" mobile fluoroscopic C-arm unit (Philips Healthcare, Best, The Netherlands) and a radiographic carbon table equipped with side-table shielding (Varay Laborix, Bourges, France). The post-operative follow up protocol of the patients included physical examination and imaging control with a computed tomography angiography and/or a color duplex scanning at 1, 6, 12, and yearly after the procedure.

### Technical aspects of the Nellix device

Nellix stent graft (Endologix, Irvine, Calif), is a sac-anchoring endoprosthesis which can be used to treat patients with adverse aortic neck and iliac anatomy as well as patients with standard neck and iliac anatomy. It consists of two balloon ex-

pandable stent frames covered with expanded polytetrafluoroethylene that maintain blood flow to lower extremities. The endoframes are surrounded by polymer-filled endobags which ensure the complete seal of the aneurysm, without the need of proximal and distal fixation of the endograft.<sup>10,11</sup> This way it anchors the endograft in the aneurysmal sac on one hand, while eliminates the space for endoleak on the other. In 2016 IFUs were refined to include a considerably limited range of anatomical eligible features for EVAS using the Nellix system. More specifically, the proximal maximum neck diameter reduced from 32 to 28mm while the distal maximum iliac diameter from 35 to 25mm. A new anatomical feature was introduced represented by the amount of thrombus in the aneurysmal sac. The thrombus ratio, resulting from the maximum aortic aneurysm diameter to the maximum aortic blood lumen diameter, according to the revised IFU, should be less or equal to 1.4. Such an indication wasn't taken in consideration at all at the original 2013 IFU.

### Comparison group

The comparison group was selected from the sample of elective infrarenal EVARs using the Excluder stent graft during the same period. The Gore Excluder stent graft is a third-generation modern device featuring an original ePTFE design with a flexible catheter-mounted introduction and active infrarenal attachment with barbs. This endograft has the same fabric material as the Nellix endoframes while both have infrarenal fixation. In order to identify a control group with less selection bias, after the original cohort was formed, one of the investigators (G.K.), blinded to patient data apart from age, sex, and AAA diameter, matched the patients from the Nellix group 1:2 with individuals from the cohort treated with the Excluder endograft (112 patients, 23.7%). The two groups matched for age (<2 years), sex, and AAA diameter (<1 cm). The final population of this analysis included 123 patients, 41 patients in the Nellix and 82 patients in the Excluder group.

### Outcome measurements

The definitions of the outcomes were established according to the reporting standards included in the guidelines of Society for Vascular Surgery/American Association for Vascular Surgery.<sup>12</sup> Technical success for both groups was defined as successful deployment of the endograft and completion of the procedure with no type I or III endoleaks and without the need for a secondary intervention within the first 24 hours. Clinical success was defined as freedom from aneurysm expansion >5 mm, type I or III endoleaks, aneurysm rupture, conversion to open surgery, graft infection, migration, or thrombosis, and aneurysm-related death during follow-up periods. PIS was defined as the presence of fever (persisting body temperature >38\_C lasting for >1 day during hospitalization) and leukocytosis (white blood cell [WBC] count >12,000/mL), with negative blood culture results.<sup>13</sup>

### Statistical analysis

Data are expressed as mean  $\pm$  standard deviation except for non-Gaussian parameters that are presented as median and

interquartile range. Categorical data are presented by absolute values and percentages (%). Statistical significance between the groups for continuous variables used the independent t-test for normally distributed data or the Mann-Whitney U-test for nonparametric data. The Pearson  $\chi^2$  test or the Fisher exact test was used for categorical variables, as appropriate. Midterm follow-up data were analyzed by Kaplan-Meier life-table analysis, and results were compared by the log-rank test. Statistical analyses used IBM SPSS Statistics ver. 20.0 software (IBM Co., Armonk, NY, USA). A P-value of <0.05 was considered statistically significant.

## RESULTS

Among 41 patients treated with EVAS, in 9 (21.9%) with suitable femoral artery anatomy, the endograft delivery occurred through percutaneous vascular access. Patient demographic data and preoperative risk factors are presented in Table 1. No significant differences in comorbidities were noted between the two groups.

The median aortic neck length was 26.5 mm in the Nellix group and 29.4 mm in the Excluder group ( $p=0.95$ ). The median maximum diameter of the aneurysm in the respective groups was 56.8 mm vs. 57.6 mm ( $p=0.15$ ). Angulations of the proximal neck were not significantly different between groups. Neck circumferential characteristics of >30% thrombus or >30% calcification were also statistically similar. There

were 2 patients (5%) in the Nellix group with mild aneurysmal disease of the common iliac arteries (diameter <20mm) which were inside the original IFU. In the Nellix group, 40 patients were treated inside the Nellix IFU and only one outside. In the Excluder group all patients were treated inside the IFU of the specific endograft. In the Nellix group, 33 patients (80%) were treated according to the 2016 IFU and 7 patients (20%) according to the original IFU.

Perioperative data are summarized in Table 2. General anesthesia was used in all patients of both groups. The median operation time ( $p=0.04$ ) as well as radiation burden ( $p=0.014$ ) and contrast media used ( $p<0.001$ ), were significantly lower in the Nellix compared to the Excluder group.

Technical success was achieved in all patients. No intraoperative conversion, migration, type I or III endoleak at the completion angiogram, or death were recorded at the end of the procedure. All renal arteries were patent at the completion angiography. No complications occurred in patients treated percutaneously. One patient with a significant common iliac artery tortuosity that has been underestimated suffered from limb thrombosis during the second postoperative day and was treated successfully with a fem-fem crossover bypass. Post implantation syndrome was encountered in 8.0% of the patients of the whole cohort with no differences between the groups ( $P=1$ ). Median hospital stay was 3 days for both groups ( $P=0.49$ ).

Baseline characteristics	Nellix group N=41	Excluder group N=82	p
<b>Demographics</b>			
Age (years), median (range)	72 (54-89)	73 (55-84)	0.8
Male gender (N,%)	40 (97)	80 (97)	1
<b>Preoperative risk factors (N,%)</b>			
Hypertension	25 (60)	58 (70)	0.69
Coronary artery disease	16 (40)	29 (35)	1
COPD	12 (30)	21 (25)	1
Hyperlipidemia	29 (70)	50 (60)	0.71
Diabetes	4 (10)	16 (20)	1
Cardiac failure	4 (10)	16 (20)	1
Smoking	12 (30)	25 (30)	0.69
<b>AAA anatomy</b>			
Neck length, mm	26.5 (16-60)	29.4 (15-60)	0.95
Suprarenal angle, degrees	7.5 (5-10)	9 (5-13)	0.28
Infrarenal angle, degrees	15 (10-40)	15 (5-40)	0.71
Maximum aneurysm diameter, mm	56.8 (51-96)	57.6 (50-93)	0.15
Thrombus >30%, N (%)	4 (10)	7 (8)	1
Calcification >30%, N (%)	8 (20)	13 (16)	1

**Table 1.** Baseline characteristics of the two groups

Perioperative characteristics	Nellix group N=41	Excluder group N=82	p
Procedure duration, min	80 (60-110)	98 (80-130)	0.04
Contrast media, ml	42 (30-80)	55.5 (30-110)	0.014
Radiation burden, mGy	80 (45-110)	102 (52.6-167)	<0.001
Post implantation syndrome, N (%)	3 (7)	7 (8.5)	1
Hospital length of stay, days	3 (3-6)	3 (3-5)	0.59

**Table 2.** Perioperative data

During a median follow-up of 23 months (range, 1- 53 months), there were two reinterventions (4.9%) in two patients in the Nellix group and none in the Excluder group (log rank=0.09). None of the patients was lost to follow-up. One patient had bilateral large common iliac artery aneurysms, was treated outside the IFU with the Nellix device and showed a significant type Ib endoleak in both sides during the 6<sup>th</sup> month follow-up. He was successfully treated in two stages with two extensions to both external iliac arteries. No internal iliac artery embolization was performed, as there was a short distance between the external and internal iliac arteries' orifices and an adequate seal to both EIAs was accomplished.<sup>14</sup> He remains well at 2 year of follow-up with no symptoms of pelvic ischemia. One patient suffered a gradually significant (18mm) proximal graft migration without a type I endoleak at 24 months follow-up. Despite the absence of an endoleak we decided to treat the significant migration by endovascular means, extending the proximal sealing zone with an Altura (Lombard Medical, Oxfordshire,UK) stent graft. No graft-related deaths were recorded, while no conversion to open repair occurred. There were another two caudal migrations (7mm and 8mm) at 1 year and 2 years respectively without however a type I endoleak that remain under close surveillance. Six type II endoleaks (all in the Excluder group) were discovered during the follow-up period. Five endoleaks spontaneously resolved, while in only one patient the endoleak remained without any change in aneurysm sac diameter (log rank=0.01).

## DISCUSSION

Type II endoleak (ETII) is a common finding up to 20% after EVAR and despite its usual benign course may sometimes lead to a worse outcome.<sup>3, 15</sup> There is a lack of level-1 evidence in this group of patients, and most studies are underpowered to fully understand the natural history of ETII due to the low event rate of complications and the inadequate long-term follow-up.<sup>16</sup> Even though an EII has a reasonable chance of thrombosing spontaneously, in some patients they might progress and result in sac enlargement and rupture.<sup>3</sup> To avoid such a worse outcome, these patients will need a reintervention. The Nellix concept aims to prevent type II endoleaks by completely excluding aortic collateral branches from the aneurysm sac. Sillingardi et al<sup>17</sup> presented a dual-center report of 64 patients treated with Nellix (2013-2014). During a median follow-up of 17 months, there was only 1 (1.6%) ETII noted. These results are in accordance with the findings of the present study showing a null type II endoleak incidence after EVAS.

In EVAR successful proximal infrarenal endograft fixation and sealing is critical to avoid both migration and endoleak complications. Several endografts have used different modalities to acquire AAA exclusion. The Nellix device fix the endograft in the aneurysmal sac on one hand, while eliminate the space for endoleak on the other. The Gore Excluder endograft, disposes an active proximal fixation mechanism. Adequate oversizing and the presence of barbs incorporated on the proximal neck of the main body ensures the stent-graft's infrarenal fixation and prevents type Ia endoleak due to distal migration. Different clinical studies have documented the

clinical outcomes and occurrence of type Ia endoleaks and/or migration after EVAS. In a multicenter retrospective cohort study conducted in Italy by Gossetti et al (IRENE study), at 1 year follow up period, the incidence of endoleaks reported, was 1.4% for type Ia, 0.7% for type Ib, and 1.1% for type II, with freedom from aneurysm-related reintervention rate at 94.7%.<sup>18</sup> Another multicenter retrospective observational study performed at six clinical centers in Europe and one in New Zealand, showed similarly, encouraging short term results. Böckler et al who carried out this study, involved 171 patients with AAA treated with EVAS. After a median follow up period of 5 months (range, 0-14 months), type Ia endoleak was observed in five patients (3%), type Ib endoleak in four patients (2%), and type II endoleak in four patients (2%) with aneurysm-related reintervention rate of 9% (15 patients).<sup>19</sup> No aneurysm ruptures or open surgical conversions occurred. These studies suggest that endovascular aneurysm sealing with the Nellix device, appears feasible with high aneurysm exclusion rate and low overall complication and reintervention rates.

However, Harrison et al, in a retrospective review of 115 patients treated with Nellix endograft reported a 36.5% graft failure rate (caudal migration of the stents, separation of the endobags, and pressurisation of the sac). Only 19 patients treated in this cohort met the revised IFU for Nellix. Device failure was higher when used outside the original IFU (16.6 per 100-person years vs. 10.6 per 100-person years).<sup>20</sup> Additionally, in a Dutch retrospective study conducted by Zoethout et al involving 264 patients who underwent elective EVAS, 168 (63.3%) patients were treated within the IFU 2013 criteria; of these 48 (18.2%) were in compliance with the revised IFU 2016 version.<sup>21</sup> The rate of endoleaks within the IFU 2013 group was 5.4% (8 type Ia and 1 type Ib), whereas in the IFU 2016 subgroup was 2.1% (3 type Ia, p=0.583). In the present report we compared the behavior of the Nellix device with the behavior of an endograft with infrarenal fixation of the same material. During a median follow-up period of nearly 2 years, we found no significant differences in type I endoleak or migration occurrence between the two endografts. In the present study, patients were carefully selected according to the device IFU not having a complex unsuitable anatomy. This strategy may explain the acceptable short and mid-term results in comparison with the previously mentioned studies.<sup>20, 21</sup> For example, in the Harrison et al study nearly one third of the patients were treated outside the IFUs, while a significant proportion of patients had complex anatomy for standard EVAR and had been turned down by other vascular centers.

The refined version of recommended IFU for the Nellix device was introduced in late 2016.<sup>22</sup> Zoethout et al by comparing 2-year clinical outcomes of patients treated within IFU 2013 and IFU 2016 found less complications, though not significant, in the IFU 2016 group when compared to the IFU 2013 group.<sup>21</sup> However, the applicability of Nellix has significantly reduced with the 2016 IFU, showing that this device seems not suitable for many AAA anatomies. In the present study 33 patients (80%) were treated according to the 2016 IFU; there were two reinterventions in one patient treated in-

side and one outside the 2016 IFU.

Radiation exposure during EVAR carries a potential risk toward patient safety.<sup>23</sup> In the present study EVAS showed a benefit by exposing patients to less radiation compared to EVAR. Ockert et al<sup>24</sup> and Antoniou et al<sup>25</sup> reported similar outcomes with reduced radiation exposure in EVAS compared to EVAR. This is useful to the patient as well as the operating team, in view of the cancer-causing risk associated to the radiation exposure.

The Nellix device is deployed through two 17 Fr (external diameter) tapered nose delivery catheters inserted via the femoral arteries. Hence, the delivery catheter diameter is adequate for percutaneous vascular access when femoral anatomy is suitable. In our study, 9 patients were treated with percutaneous EVAS while for postoperative artery sealing, a perclose vascular closure device was used (Perclose ProGlide, Abbott, Santa Clara, USA).

An important issue is represented by post implantation syndrome (PIS), the clinical and biochemical expression of an inflammatory response following EVAR. Both, the Nellix as well as the Excluder stent grafts are constructed of PTFE fabric supported by metal endoframes. Even if with lower rates than the polyester made stent grafts, it is possible for PTFE endografts to develop PIS.<sup>26</sup> Consistently to the literature, an overall rate of PIS was encountered in 8.0% of the patients, with no differences between the groups.

Computational fluid dynamics analysis aimed to study the flow conditions in the Nellix endograft, showed no significant alteration of the hemodynamic properties after the stent graft's implantation, resulting in optimal hemodynamic efficiency.<sup>27</sup>

In 2019 the CE mark for the Nellix device has been suspended following a voluntary recall and field safety notification issued by the company. This action reflects the 2019 ESVS guidelines recommending against the use of EVAS technique in clinical practice except when being used only within the framework of approved clinical studies.<sup>1</sup> The controversy found in the literature regarding the Nellix outcome in several studies maybe explained by the patient selection and doctor's experience. We may assume that due to the EVAS simpler applicability (lack of contralateral cannulation, less radiation and time), more doctors with less endovascular experience have used the platform with doubtful results. We believe that the proper selection according to specific anatomic criteria always within the IFUs is of paramount importance for achieving the best outcome when treating an AAA patient with EVAS.

The major limitations to the present study include its retrospective nature and the relatively small number of patients included in both groups. Despite this, all patients selected were treated consecutively with the Nellix stent graft system under stable conditions, and the case-controlled Excluder group was matched 2:1 to the Nellix group. In any case, these results must be interpreted with caution until validated by larger studies.

## CONCLUSION

The initial experience with the Nellix stent graft system in the present cohort is quite promising, with successful aneurysm sealing and acceptable mid-term results despite the current controversies. Further and larger studies are needed to fully evaluate the long-term results of this particular endograft.

## REFERENCES

- 1 Wanhainen A, Verzini F, Van Herzele I, Allaire E, Bown M, Cohnert T, et al. Editor's Choice - European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms. *Eur J Vasc Endovasc Surg.* 2019;57:8-93
- 2 United Kingdom EVAR Trial Investigators, 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.
- 3 Kouvelos G, Koutsoumpelis A, Lazaris A, Matsagkas M. Late open conversion after endovascular abdominal aortic aneurysm repair. *J Vasc Surg.* 2015;61:1350-6.
- 4 Donayre CE, Zarins CK, Krievins DK, Holden A, Hill A, Calderas C, Velez J, White RA. Initial clinical experience with a sac-anchoring endoprosthesis for aortic aneurysm repair. *J Vasc Surg.* 2011;53:574-82.
- 5 Ockert S, Heinrich M, Kaufmann T, Syburra T, Lopez R, Seelos R. Endovascular aortic sealing with Nellix reduces intraoperative radiation dose when compared to endovascular aortic repair. *J Vasc Surg* 2018;67:1068-73.
- 6 Reijnen MM, de Bruin JL, Mathijssen EG, Zimmermann E, Holden A, Hayes P, et al. Global experience with the Nellix endosystem for ruptured and symptomatic abdominal aortic aneurysms. *J Endovasc Ther* 2016;23:21-8.
- 7 Bockler D, Holden A, Thompson M, Hayes P, Krievins D, de Vries JP, et al. Multicenter Nellix endovascular aneurysm sealing system experience in aneurysm sac sealing. *J Vasc Surg* 2015;62:290-8.
- 8 Carpenter JP, Cuff R, Buckley C, Healey C, Hussain S, Reijnen MM, et al. One-year pivotal trial outcomes of the Nellix system for endovascular aneurysm sealing. *J Vasc Surg* 2017;65:330-6.
- 9 Zerwes S. Seduction and its impact on instructions for use. *J Endovasc Ther.* 2016;23:693-4.
- 10 Batagini NC, Hardy D, Clair DG, et al. Nellix EndoVascular Aneurysm Sealing System: Device description, technique of implantation, and literature review. *Semin Vasc Surg.* 2016;29:55-60.
- 11 Van den Ham LH, Zeebregts CJ, de Vries JP, et al. Abdominal aortic aneurysm repair using Nellix EndoVascular Aneurysm Sealing. *Surg Technol Int.* 2015;26:226-31.
- 12 Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al; Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of The Society for Vascular Surgery/American Association For Vascular Surgery. Reporting standards for endovascular aortic an-

- eurysm repair. *J Vasc Surg* 2002; 35:1048-60.
- 13 Arnaoutoglou E, Kouvelos G, Papa N, Kallinteri A, Milionis H, Koulouras V, Matsagkas M. Prospective evaluation of post-implantation inflammatory response after EVAR for AAA: influence on patients' 30 day outcome. *Eur J Vasc Endovasc Surg*. 2015;49:175-83.
  - 14 Kouvelos GN, Koutsoumpelis A, Peroulis M, Matsagkas M. In endovascular aneurysm repair cases, when should you consider internal iliac artery embolization when extending a stent into the external iliac artery? *Interact Cardiovasc Thorac Surg*. 2014;18:821-4.
  - 15 Spanos K, Nana P, Kouvelos G, Koutsias S, Arnaoutoglou E, Giannoukas AD, Matsagkas M. Factors associated with elimination of type II endoleak during the first year after endovascular aneurysm repair. *J Vasc Surg*. 2019 May 18. pii: S0741-5214(19)30331-3.
  - 16 Brown A, Saggu GK, Bown MJ, et al. Type II endoleaks: challenges and solutions. *Vasc Health Risk Manag*. 2016; 12:53-63.
  - 17 Silingardi R, Coppi G, Ferrero E, et al. Midterm outcomes of the Nellix Endovascular Aneurysm Sealing System: a dualcenter experience. *J Endovasc Ther*. 2016;23:695-700.
  - 18 Gossetti B, Martinelli O, Ferri M, Silingardi R, Verzini F; IRENE Group Investigators. Preliminary results of endovascular aneurysm sealing from the multicenter Italian Research on Nellix Endoprosthesis (IRENE) study. *J Vasc Surg*. 2018;67:1397-403.
  - 19 Böckler D, Holden A, Thompson M, Hayes P, Krievins D, de Vries JP, Reijnen MM. Multicenter Nellix Endovascular Aneurysm Sealing system experience in aneurysm sac sealing. *J Vasc Surg*. 2015;62:290-8.
  - 20 Harrison SC, Winterbottom AJ, Coughlin PA, Hayes PD, Boyle JR. Editor's Choice- Mid-term Migration and Device Failure Following Endovascular Aneurysm Sealing with the Nellix Stent Graft System - a Single Centre Experience. *Eur J Vasc Endovasc Surg*. 2018;56:342-8.
  - 21 Zoethout AC, Boersen JT, Heyligers JMM, et al. Two-year outcomes of the Nellix endovascular aneurysm sealing system for treatment of abdominal aortic aneurysms. *J Endovasc Ther*. 2018;25: 270-81.
  - 22 Important Update to Field Safety Notice Nellix® Endovascular Aneurysm Sealing System Updated Instructions for Use (IFU) [Internet]. Hpra.ie. 2016 [cited September 1, 2018]. Available from: [https://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical\\_Devices/Updates\\_and\\_Safety\\_reporting/Field\\_Safety\\_Corrective\\_Action/FSN/2016/November/HSA%206004101-148-16-02\\_54%20FSN.pdf](https://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Field_Safety_Corrective_Action/FSN/2016/November/HSA%206004101-148-16-02_54%20FSN.pdf). Accessed July 28, 2018.
  - 23 Machado R, Ferreira VM, Loureiro L, Gonçalves J, Oliveira P, Almeida R. Radiation exposure in endovascular infra-renal aortic aneurysm repair and factors that influence it. *Braz J Cardiovasc Surg*. 2016;31:415-21.
  - 24 Ockert S, Heinrich M, Kaufmann T, Syburra T, Lopez R, Seelos R. Endovascular aortic sealing with Nellix reduces intraoperative radiation dose when compared to endovascular aortic repair. *J Vasc Surg*. 2018;67:1068-73.
  - 25 Antoniou GA, Senior Y, Iazzolino L, et al. Endovascular aneurysm sealing is associated with reduced radiation exposure and procedure time compared with standard endovascular aneurysm repair. *J Endovasc Ther*. 2016;23:285-9.
  - 26 Arnaoutoglou E, Kouvelos G, Papa N, Gartzonika K, Milionis H, Koulouras V, Matsagkas M. Prospective evaluation of postimplantation syndrome evolution on patient outcomes after endovascular aneurysm repair for abdominal aortic aneurysm. *J Vasc Surg*. 2016;63:1248-55.
  - 27 Raptis A, Xenos M, Kouvelos G, Giannoukas A, Matsagkas M. Haemodynamic performance of AFX and Nellix endografts: a computational fluid dynamics study. *Interact Cardiovasc Thorac Surg*. 2018;26:826-33.