UNEXPECTED MID-TERM RESULTS AFTER ENDOVASCULAR ANEURYSM SEALING

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Disclosure

Speaker name:

Rosa Villardefrancos, MD.

I have the following potential conflicts of interest to report:

Consulting
Employment in industry
Stockholder of a healthcare company
Owner of a healthcare company
Other(s)

✓ I do not have any potential conflict of interest
Endovascular Aneurysm Sealing: A new promising concept

Endovascular Aneurysm Sealing: Early and Midterm Results From the EVAS FORWARD Global Registry

Matt M. Thompson, MD, FRCS¹, Jan M. Heyligers, MD, PhD², Paul D. Hayes, MD, FRCS³, Michel M. P. J. Reijnen, MD, PhD⁴, Dittmar Böckler, MD, PhD⁵, Hubert Schelzig, MD⁶, Jean-Paul P. M. de Vries, MD, PhD⁷, Dainis Krievins, MD, PhD⁸, and Andrew Holden, MBChB, FRANZCR, EBIR⁹ for the EVAS FORWARD Global Registry Investigators

FREEDOM FROM TYPE I → 96%
FREEDOM FROM TYPE II → 98%
FREEDOM FROM OPEN CONVERSION → 98%
FREEDOM FROM REINTERVENTION → 92%
UNEXPECTED RESULTS: MIGRATION

2016

Migration of the Nellix endoprosthesis

Andrew England, PhD, Francesco Torella, MD, FRCS, Robert K. Fisher, MD, FRCS, and Richard G. McWilliams, FRCR, EBIR, Manchester and Liverpool, United Kingdom

IFU Re-definition
Re-defined IFU: What about applicability?

<table>
<thead>
<tr>
<th>Influence of the Revised Nellix Instructions</th>
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<tbody>
<tr>
<td><strong>APPLICABILITY:</strong> 75% → 34%</td>
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<tr>
<td><strong>SIGNIFICANT DIFFERENCES:</strong> ENDOLEAK MIGRATION</td>
</tr>
<tr>
<td><strong>NO SIGNIFICANT DIFFERENCES:</strong> SURVIVAL FREEDOM FROM REINTERVENTION</td>
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</tbody>
</table>

Katherine M. Stenson, MD, MRCS\(^1\) and Peter J. E. Holt, PhD, FRCS\(^1\)
At that time,

We needed to evaluate our experience....
OBJECTIVE

To evaluate the incidence, consequences and failure model of migration after endovascular aneurysm sealing (EVAS) with the Nellix Endoprosthesis (Endologix Inc, Irvine, CA, USA)
METHODS

- Retrospective single-centre study
- June 2013 - October 2016
- n=17 patients
- CT images:
  - First postoperative CT
  - Latest CT
  - Distance: proximal part of the stent-graft ↔ reference visceral vessel
METHODS

 DEFINITIONS:

✓ Migration: >10mm downwards movement

✓ Displacement: ≥4mm downwards movement

RESULTS

- First postoperative CT-scan:
  - 0% Endoleaks
  - 0% Thrombosis
  - 0% Migration
  - 0% Mortality
RESULTS

- Follow-up: **50.44 months** (28-70)

- Migration (>10 mm): **6 (35.3%)**
- Displacement (≥4mm): **10 (58.9%)**
- Endoleaks:
  - 1a: 2 (11.76%)
  - 1b: 1 (5.88%)

36 months
RESULTS

PROCEDURE

Re-defined IFU

APPLICABILITY??

IFU: 88.2% (n=15)
Outside IFU: 11.76% (n=1)
<50mm AAA diameter
Trombus index >1.4

IFU: 94.12% (n=16)
Outside IFU: <50mm AAA diameter
Trombus index >1.4
RESULTS

☐ TREATMENT:
  ✓ Patients with endoleaks or migrations >10mm
  ✓ Fit for surgery
RESULTS

- **LATE REINTERVENTION RATE:**
  - 29.41% (n=5)
  - 4 Conversions to OR (MIGRATIONS)
    - 2 symptomatic
    - 2 asymptomatic
  - 1 Endovascular treatment (DISPLACEMENT / TYPE Ib)
RESULTS

- **LATE REINTERVENTION RATE:**
  
  29.41% (n=5)

  - 4 Conversions to OR
    - (MIGRATIONS)
      - 2 symptomatic
      - 2 asymptomatic

  - 1 Endovascular treatment
    - (DISPLACEMENT / TYPE Ib)
RESULTS

- **MORTALITY**: 35.3% (n=6)
  - 4 Non-related AAA
  - 1 PO graft explant (symptomatic)
  - 1 AAA rupture
RESULTS

- **MORTALITY:** 35.3% (n=6)
  - 4 Non-related AAA
  - 1 PO graft explant (symptomatic)
  - 1 AAA rupture

DISPLACEMENT
NO MIGRATION
INSIDE NEW IFU
4 months
08/2015

48 months
04/2019
Dmax. ↑ 5mm

56 months
12/2019
NO MIGRATION
Dmáx ↑ 15 mm
AAA RUPTURE
CONCLUSIONS

- Migration of the Nellix endoprosthesis is more common than anticipated and can cause aortic rupture.

- The Sealing concept as it was initially defined does not work.

- All patients treated with Nellix System complying initial IFU are in risk of rupture and complications related to the aneurysm sealing failure.
CONCLUSIONS

➢ Proper and intensive image follow-up should be performed to identify failures and fix them before rupture occurs.

➢ In our experience, new IFU don’t prevent rupture.

➢ Which is the best option (follow-up/treatment) for patients treated with the Nellix System?
➢ How can we anticipate future problems in these patients?
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