Update On The Nellix Graft And EVAS: Will Nellix Be A Failure Or A Phoenix Surmounting Its Problems

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Disclosure
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I have the following potential conflicts of interest to report:

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

I do not have any potential conflict of interest

PROMISING RESULTS, DESPITE PUSHING IFU (GLOBAL REGISTRY)

FF TYPE II ENDOLEAK, RUPTURE, ARM, ACM

2015

2018-2019

2017

M A T R I T Y

EVAS FORWARD

Global Registry, ALL-COMERS (37% OFF-IFU)

IDE: N=333, CONTROLLED

2013-2014

ROOT CAUSE ANALYSES

Clinical
Imaging
Engineering
Statistical

1Y FREEDOM FROM ENDOLEAK, REINTERVENTION, RUPTURE

2Y EVENTS

TYPE IA ENDOLEAK
MIGRATION
SAC GROWTH

2016

CONFIRMATORY TRIAL
GEN2 NELLIX DEVICE
RIGOROUS TRAINING
BEST PRACTICES
EXTERNAL CORE LAB
CASE REVIEW BOARD
PROCTORING
DEDICATED CASE SUPPORT
EU PEER-TO-PEER
SECONDARY INT APPROVED

IFU/PROCEDURE Refined

PREDICTABLE OUTCOMES

Endologix products and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability.

Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only.

CAUTION: The Nellix® EndoVascular Aneurysm Sealing System is an investigational device. Limited by federal (or United States) law to investigational use only.

- Publication of results from early clinical series
- Suspension and restoration of CE mark
- Strict adherence to anatomical indications
- Publication ACM and mid-term results

EVAS DEVELOPMENT CYCLE

EVAS-RISING FROM THE ASHES?

Unmet needs of EVAR
Understand new therapy
Replicate traditional EVAR results
Proven design intent
Hierarchy of outcomes
UNMET NEEDS EVAR

- EVAR confers no benefit in ACM / ARM (c.f open)
- EVAR associated with higher rate of AAA rupture (c.f open)
- Patients live longer than expected – durability paramount
- AAA sac expansion after EVAR controversial, common, predictive of rupture and lower patient survival


Lessons Learned

Recognition that Nellix was the first generation of a new therapy as opposed to an iteration of EVAR

Increased rigor in case selection and control of therapy

Generation of clinical evidence to support decision making

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WHAT PROBLEM(S) IS EVAS TRYING TO SOLVE

Type 2 Endoleaks

Sac expansion and biologic effects

Durability of proximal seal - polymer

REPLICATE TRADITIONAL OUTCOMES

ADHERENCE TO ANATOMICAL INDICATIONS AND ADEQUATE PROCEDURE

Design Intent and EL2

EVAS ASSOCIATED WITH INCREASED PATIENT SURVIVAL

VQI Propensity weighting study

HR 2.0 (AAA>5.5cm)

SUMMARY AND CONCLUSIONS

- EVAS is a different therapy to EVAR
- EVAS now being understood through careful accumulation of evidence and rigorous case selection (EVAS2)
- Expanded application in ChEVAS will be investigated in COMPLEX study
- Design intent with regard to sac management and Type 2 endoleak met
- Accumulating evidence regarding impact of sac behavior on survival after aneurysm treatment
- Effects need to be mechanistically understood
- Potential impact on AAA management may be of profound significance