Flow Diversion, Training and Reporting Standards

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Disclosures

• I have no financial conflicts of interest
• My experience with flow diversion is limited to the on-label use of the first generation Pipeline Embolization Device (PED)
• I have no experience with
  – Pipeline Flex
  – SILK
  – Surpass
  – FRED
  – Intra-saccular flow diverters
Society of Neurointerventional Surgery (SNIS)

• SNIS supports and represents neurointerventional surgeons with heritage in radiology, neurosurgery, and neurology
• Dedicated to excellence in the minimally-invasive care of patients with stroke, brain aneurysms, and other diseases of the head, neck and spine
• The society maintains sets of standards and guidelines for neurointerventional procedures prepared by a committee of senior members with various training backgrounds
Why Flow Diversion (FD)?

- Wide-necked, large, and fusiform cerebral aneurysms are a difficult subset
- Flow modification seen in early stent-coiling led to idea of flow diversion
- SILK Device obtained CE Mark approval 2008
- Based on the Pipeline for Uncoilable or Failed Aneurysms (PUFS) trial, PED approved in U.S. 2011
- SNIS believes this is an important, safe tool for the approved vessel segments
Flow Diversion for Giant Aneurysm

Multiple overlapping flow diverting stents placed in cavernous ICA
FD Training Standards

- SNIS expects any FD operator to have completed a dedicated neurointerventional training program
  - ACGME-accredited endovascular surgical neuroradiology fellowship
  - CAST-accredited endovascular neurosurgery fellowship
  - Reputable non-accredited fellowship program
- SNIS supports any and all FDA mandated requirements/conditions for use
- SNIS supports all manufacturer mandated requirements/conditions for use
FD Training Standards

- SNIS recommends attendance of advanced user courses offered by a manufacturer
- SNIS facilitates the exchange of ideas and physician mentoring at our annual meeting and at other cerebrovascular meetings we sponsor
- Off-label option should exist for patients only in whom clipping, coiling or parent vessel occlusion is not an option
- SNIS leads the NeuroVascular Quality Initiative (NVQI) which includes a FD module
FD Training Standards

• Judgment
  – This skill exceeds all others for FD operators
  – Difficult for any governing body to teach and/or control
SNIS FD Reporting Standards

• We must approach any new technology with a thoughtful and judicious approach
• We must also deliver healthcare value
• Disparate reporting make FD literature a challenge
• Single-center series have tremendous selection bias
• Temporary and permanent complications (neurological or otherwise) are of equal import
  – Temporary or silent in one patient may be disastrous in another
SNIS FD Reporting Standards

• Complications can be analyzed in many ways
  – Those at time of procedure vs. delayed
  – Those associated with any neurointervention vs. FD
  – Temporary vs. permanent
  – Neurological vs. Non-neurological
  – Classification schemes
    • e.g. IntrePED  (Kallmes, D.F. et al. AJNR 2015)
      – Spontaneous rupture
      – Intracerebral hemorrhage
      – Parent artery stenosis
      – Stroke
      – Cranial neuropathy
SNIS FD Reporting Standards

• SNIS is generating a document to establish homogeneous endpoints and facilitate communication of experience with FD across platforms

• Not intended to advocate for FD but rather promote maturation and rigor

• Goals - SNIS standards document (expected publication July 2015)
  – Standardize definitions
    • Stenosis vs. thrombosis, endoleak, vessel wall apposition, etc.
  – Standardize the pre-procedure evaluation
    • Aneurysm and parent vessel characteristics, dual-antiplatelet induction strategies, etc.
  – Standardize procedure detail and event reporting
    • Equipment used, procedural complications, etc.
  – Standardize post-procedure outcome reporting and follow-up
    • Complications, angiographic follow-up, occlusion scale, etc.
Conclusions

• Flow diversion is a young science requiring the highest standards in judgment and technique.
• SNIS members complete rigorous training programs that prepare them for the cognitive and technical skills required for FD.
• SNIS is committed to the publication and adoption of reporting standards for FD.
• SNIS believes on-label use of FD is safe and appropriate.
• SNIS believes data reporting (such as the NVQI) should occur for all neurointerventional procedures.