Tilo Kölbl, Fiona Rohlffs, Stephan Haulon, Roger Greenhalgh
Disclosure

Speaker name: Tilo Kölbl

has the following potential conflicts of interest to report:

- Research-grants, travelling, proctoring speaking-fees, IP, royalties with Cook Medical.
- Consulting with Philips
- Consulting, Speaking fees from Getinge
- IP, Consulting with Terumo Aortic
- Shareholder Mokita-Medical GmbH

Speaker name: Fiona Rohlffs

- none
Background of STEP

Stroke is a major concern in TEVAR

- Incidence 3-11%
- Anterior/posterior circulation
- Silent undetected strokes up to 87%
- Mortality 20%

Perera et al. 2015; Br J Surg 102: s2: 5
Feezor et al. 2007; J Endovasc Ther 14:568-73
Böckler et al. 2016; Eur J Vasc Endovasc Surg: in press
Aim of STEP

To provide best practice for endovascular procedures for the ascending aorta, aortic arch, great vessel branches and high TEVAR to lower the risk of cerebral embolism

- Ascending aorta: tube grafts, scalloped stent-grafts
- Arch procedures: fenestrated and branched aortic arch stent-grafts (Great vessel involvement)
- Descending aorta: high standard TEVAR procedures landing in zone 2 (Ishimaru)
Pathologies

- Air
- Thrombus
- Particles / Plaque

Stroke from Thoracic Endovascular Procedures
The STEP Collaboration

Bolton Medical

COOK® MEDICAL

GORE

JOTEC®

Medtronic
The STEP Collaboration

Frank Arko
Carlos Bechara
Adam Beck
Dittmar Böckler
Martin Czerny
Michael Dake
Matthew Eagleton
Dennis Gable
William Jordan
Marwan Youssef
Ahmed Koshty
Gustavo Oderich
Jean Panneton
Geert Schurink
Santi Trimarchi
Rod White
Characteristics of the STEP Collaboration

Independent

All-encompassing

Open

Interdisciplinary

Built to learn from each other

Safe treatment for patients
STEP Phase 1: Questionnaire to KOL

General Questions on experience to evaluate current practice

Key Findings
Experience of KOL (n = 18)

- Zone 0 = 143 years (range 3 – 15)
- Zone 1 = 193 years (range 4 – 15)
- Zone 2 = 232 years (range 6 – 20)
Company Representatives

- Bolton Medical: 7
- COOK Medical: 14
- GORE: 8
- Jotec: 1
- Medtronic: 8
Interdisciplinary team central to the final decision for treatment strategy

- **100%**
  - Zone 0
  - Zone 1
  - Zone 2
How soon before the procedure should the imaging be done (maximum tolerated)?

- >3 months
- >1 – ≤3 months
- ≤1 months

1: ,,depends on urgency“
1: ,,as soon as possible“
Anticoagulation:

- Procedure should be done under anti platelet therapy
- Activated clotting time (ACT) should be 250 – 350s
Revascularisation of LSA

- Preoperatively
- Procedurally

Intra-procedural MOD Consensus

Revascularisation of LSA

- Selectively = 10
- Routinely = 8
- Simultaneously = 7
- In advance = 9
- Case dependent = 2

- Prevention of spinal cord ischemia (all)
- AV-Fistula (all)
- LIMA Bypass (all)
- Access for TEVAR procedure (n=3)
- Other:
  - Elective vs emergent status
  - Prevention of stroke and arm ischaemia
  - Dominant left arm
  - Young patient
Pre-Procedural

Intra-Procedural

Consensus

Use of Cardiac Output Reduction

Zone 0
Use of Cardiac Output Reduction

Zone 0

100%
Cardiac Output Reduction Technique

- Rapid Ventricular Pacing (RVP), n = 14
- Inferior Vena Cava Occlusion (IVCO), n = 1
- RVP or IVCO, n = 1
- Adenosine or RVP, n = 2
Embolisation Prevention Techniques

- Carotid Artery Clamping, $n = 9$
- CO2 flushing Technique, $n = 6$
- Other:
  - Minimize Arch wire and device manipulation, $n = 1$
  - Place filters in supraaortic vessels, $n = 0$
Adjunctive Techniques

- CT Fusion Technique, \( n = 12 \)
- Cone Beam CT in addition to final angiogramm, \( n = 9 \)
- Intraoperative Monitoring of Brain Function routinely:
  - yes = 12, no = 6:
    - TCD, \( n = 4 \)
    - NIRS, \( n = 11 \)
    - Cerebral oxymetry, \( n = 2 \)
    - EEG, \( n = 3 \)
Which imaging technique do you prefer to visualise the stent-graft for follow-up?

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**When?**:

- Pre discharge (few days after procedure), \( n = 13 \)
- After 1 month, \( n = 3 \)
- If urgent procedure pre-discharge, if elective procedure after few weeks, \( n = 2 \)
- Anti platelet therapy

- Postprocedural ICU: Zone 0 $n = 18$
  Zone 1 $n = 15$
  Zone 1 $n = 14$
Neurologic Evaluation

Pre-op MRI Zone 0 + 1
- Mandatory = 4
- If needed = 11
- Never = 3

Post-op MRI Zone 0 + 1
- Mandatory = 1
- If needed = 17
- Never = 0

Almost no expert neurologic testing, just 2 centers
Neurocognitive testing is not established, just 1 center
Intraoperative monitoring of brain function is not standardized
Best method of brain function monitoring is not clear
STEP Phase 2

Post-TEVAR evaluation of cerebral damage by DWMRI:

- Number, size and distribution of SBI
- Association with
  - Patient and procedural factors
  - Landing zone
  - Type of device (tubular, fenestrated, branched)
  - Protective techniques
Summary

- TEVAR is plagued by continuous high frequency of stroke and SBI
- STEP-Initiative has collected current practice from 18 KOL in TEVAR from around the world.
- STEP phase 2 will study cerebral damage in real world. First results to be presented at Charing Cross Symposium 2019
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