Background of the STEP Study

Stroke is a major concern in TEVAR

- Incidence 3-11%
- Complex TEVAR up to 20%
- Silent undetected strokes up to 87%
- Mortality 20%

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

Aims of the STEP Study

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)

Features of the STEP Study

- Independent
- All-encompassing
- Open
- Interdisciplinary

Built to learn from each other

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

Safe treatment for patients
The 18 STEP Collaborators

Manufacturer Nominees

- Frank Arko
- Carlos Bechara
- Adam Beck
- Dittmar Böckler
- Martin Czerny
- Michael Dake
- Matthew Eagleton
- Dennis Gable
- Stéphan Haulon
- William Jordan
- Tilo Köbel
- Ahmed Koshty
- Gustavo Oderich
- Jean Panneton
- Geert Schurink
- Santi Trimarchi
- Rod White
- Marwan Joussef

Questionnaire on experience, current practice and options of centres

STEP Collaboration

Experience of KOL (n = 18)

<table>
<thead>
<tr>
<th>Zone</th>
<th>Cumulative years of experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>143 years</td>
</tr>
<tr>
<td>1</td>
<td>193 years</td>
</tr>
<tr>
<td>2</td>
<td>232 years</td>
</tr>
</tbody>
</table>

Numbers of procedures per Zone and per year

- Zone 1, n = 135 (77%)
- Zone 0, n = 171 (21%)
- Zone 2, n = 510 (62%)

STEP Phase 1

Consensus Areas Current Practice

- A multidisciplinary team essential for the treatment strategy in Ishimaru zone 0
- Pre-procedural CT-A as preferred diagnostic study to visualize the pathology
- General anaesthesia for Procedures of the ascending aorta, fenestrated and branched arch procedures
- Heparin should be used for intraoperative anticoagulation, ACT should be in the range of 250 – 350s
- Cardiac output reduction techniques should be used while operating in zone 0
- CT-Angiography is the preferred imaging technique for follow-up
- Intensive Care Unit surveillance should be chosen for patients after endovascular therapy of zone 0

STEP Phase 2

- Need for evaluation of stroke, cerebral infarction, SBI, cognitive function
- Need for quantification of stroke and markers of loss of cerebral function
- Imaging is crucial → DWMRI → Performed on day 2 – 7 post procedure
  
  Post procedure DW MRI show:
  - Old and new cerebral infarction
  - Haemodynamic or embolic infarction
  - Extent of lesion
  - Relationship to reduction of cardiac output

Step Phase 2 Limitations

- Common agreement to establish DWMRI among collaborators
- BUT...
  - Feedback on survey and Questionnaire for phase 2 demonstrates limitation of funding for the DWMRI (not accepted as standard of care)
- DESPITE:
  - DW MRI ability to recognise if stroke or loss of cerebral function was procedure associated (or happened before)
  - Need for monitoring of technical improvement for better results in the long-term

Results STEP Phase 2

3 centres already able to perform DWMRI:

- Total number of cases: 37
- DW-MRI in all patients, mean POD for study 4.5 days (range 2 – 8), 8 days just in 1 patient
- CO2 flushing in all 3 centres
- Clamping of carotid artery, cardiac output reduction (Arch Branch Procedures)

- Paris
  - 10 patients
  - 12/2018 – 03/2019

- Mayo Clinic
  - 1 patient
  - 04/2019

- Hamburg
  - 26 patients
  - 09/2018 - 04/2019
**Results STEP Phase 2**

Procedures performed:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>TEVAR</td>
<td>21</td>
<td>57%</td>
</tr>
<tr>
<td>FTEVAR</td>
<td>2</td>
<td>5%</td>
</tr>
<tr>
<td>TEVAR + In situ</td>
<td>4</td>
<td>11%</td>
</tr>
<tr>
<td>BTEVAR</td>
<td>8</td>
<td>22%</td>
</tr>
<tr>
<td>Ascending aortic tube graft</td>
<td>2</td>
<td>5%</td>
</tr>
</tbody>
</table>

Additional Chimney, CS-Bypass or in-situ fenestration during procedure: 10 procedures (27%)

<table>
<thead>
<tr>
<th>Landing Zones</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>10</td>
<td>27%</td>
</tr>
<tr>
<td>1</td>
<td>12</td>
<td>32%</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
<td>19%</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>22%</td>
</tr>
</tbody>
</table>

**Combined Results**

New Lesions on DW MRI total Cohort

- 27 patients (73%)
- 10 patients (27%)

**Combined Results**

New Lesions on DW MRI total Cohort PER LANDING ZONE

**Symptomatic Stroke**

1/37 patients (2.7%) with neurological symptoms:
- ataxia, hemianopia
- multiple infarctions and haemorrhages in posterior circulation
- Procedure: TEVAR with t-branch

**Conclusions**

- STEP-Study built to pool experience
- Clinical stroke rate is substantial
- Platform to exchange/share experience and learn from each other
- DWMRI useful to detect SBI → evaluation of current practice, but limited funding
- Long-Term aim: investigate preventive strategies to provide best practice in TEVAR