Helifix Anchors in the thoracoabdominal aorta

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

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

☐ I do not have any potential conflict of interest
Graft migration and rotation still represents a major concern for complex EVAR

CX 2006: European Survey of fenestrated grafts

- 273 patients with 1st gen fenestrated COOK graft
- Partially unstented/ stented target vessels
- 4% renal artery occlusion
- 4% new onset of hemodialysis (contrast / complication related)
- 4% mortality during FU
More complex grafts were the answer, but migration also in multi fenestrated or branched grafts (downward and sideways migration).
Oderich G. et al., Results of the US Multicenter Prospective Study evaluating Zenith fenestrated endovascular graft for treatment of juxtarenal AAA
22% Re-Interventions in this study, ¾ of them required for renal artery stenosis or occlusion
6 mo FU: no visible changes compared to the index procedure.
11 mo FU with visible compression of the left RA stent and almost stable axis of the right RA stent.
Basic considerations

Migration prevention is one of the most important issues for the overall outcome of complex T/EVAR
- Target vessels and organs involved: bowel ischemia, deterioration/loss of renal function
- Secondary EL at any level
- Open repair is suprarenal, supravisceral or thoracoabdominal

Helifix Endoanchors are effective in standard EVAR for primary and secondary use (de Vries, JP et al.; JVS, JEVT, LINC, ...) to prevent migration over the long term

Should they not be beneficial for any EVAR
Challenges in complex aneurysm repair

Results for any repair (secondary procedure) with Helifix

- FU for 9-38 mo without detectable changes in nativ X-ray or DUS/ CT
- Even after uplifting of migrated graft and crushed stent
- No target vessel/ organ loss/ no EL/
- No need for any reintervention
Challenges in complex aneurysm repair

• Can we use the beneficial effect of anchors to improve the overall outcome of primary EVAR
• Can we reduce the risk of the index procedure for patient (contrast media, operation time, distal ischemia time, manipulation)
• and staff (radiation time)
• By using anchors and reduction of device complexity
Prospective evaluation of „downsized“ fEVAR

- Short necks <4mm
  - Typical CE marked graft (scallops/ fenestrations)
  - Stent/ no stent
  - Anchor below and above target vessels
- No neck/ juxtarenal/ suprarenal
  - 2 Fenestrations and 1 scallop instead of multifenestrated device
  - 2 covered stents
  - Anchor above and between target vessels
Next step: Downsizing fEVAR

Selection criteria

• Sealing option with a fenestrated / scalloped device (exclusion criteria for EVA with at least 4mm long circumferential graft to wall contact to place minimum 4 anchors in the recommended position)
Minimum requirements for primary fixation for juxtarenal AAA/ 2 fenestrations and no/ 1 scallop sealing zone above renal level
Minimum requirements for primary fixation scallop and two fenestrations sealing zone between/below renals

Appropriate placement is part of the planning
Current technique for fEVAR / fTEVAR

Fixation of the graft with balloon inflated to avoid stentrecoil during repair / Helifix interaction

Avoid stent damage on the aortic side

Stenting for scallops redundant (?)
Any adverse events in 12 cases up to 34 mo

72% of target vessels were stented
6.8% (n=2) of stented target vessel showed complications
all vessels could be recanalized
Helifix Anchor in complex T/EVAR

- 12 patients with fEVAR for juxta/suprarenal/short neck AAA
  6-34 mo FU (downsizing group)
- Any repair and primary use for various fEVAR/fTEVAR
- No migration, no component separation
- No postop mechanical complications (incl. material fatigue)
- No infection
- No aneurysm related mortality
- Recurrent bilateral renal stent thrombosis from unknown reason
- Solved with rotational thrombectomy, 1 kidney lost, stable creatinin at 3.8mg%
- Anticoagulation after second occlusion, no further event
Standard FU procedures focussing on migration indicators

Baseline CT < 30 days
Native X-ray
DUS

Now 6/12/24...FU
Native x-ray
DUS
As standard FU
CT to the examiners discretion
In conclusion: in the midterm anchors are beneficial in complex aortic repair independent from the involved segments

- reliable performance of graft and anchor for up to 38 mo
- Procedure complexity can be reduced and related complications are less probable (CIN, radiation dose, time, LA)
- FU becomes less invasive: DUS incl. target organs, native X-ray/CT
- Target vessel implants might become redundant (?)
- If migration related target vessel complications are nil, then component related complications will be more distal/ or infrarenal only
- No target vessel involvement: much easier/ infrarenal repair in case of complications is a widespread offered option
- Only remaining problem: no reimbursement for primary use
Thank you for your attention

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