The outcome of the AFX Endologix endograft in the prevention of type II endoleaks

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I have the following potential conflicts of interest to report:

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

☒ I do not have any potential conflict of interest
OUR EXPERIENCE: October 2012 - October 2017

Sixty-two patients (52 male and 10 female)
Age from 62 to 86 years old
BMI 27.9 ± 5.5

Comorbidities

Hypertension 83%
Smoking 72%
Dislipidemia 66%
Coronary disease 26%
Diabetes 19%
Renal failure 13%

Aneurysm’s morphology

43 pts with AAA (5.9cm media)
8 pts with aortic bleb (4.5cm media)
4 pts with isolated iliac aneurysm (3.0cm media)
3 pts with bilateral iliac aneurysm (3.0cm media)
2 pts with distal aortic anastomotic false-aneurysm
The proximal neck morphology was out from IFU indications in 18% of patients
- Neck length < 15 mm in 13%
- Neck diameter > 32 mm in 5%
OUR EXPERIENCE 62 pts: procedural data

In 25 cases (40.3%) a proximal cuff was deployed in 14 with infrarenal proximal fixation in 11 with suprarenal proximal fixation (8/11 with Medtronic Endurant cuff)

In 11 cases (17.7%) iliac extension were deployed with an associated hypogastric coils embolization in 7

Fluoroscopy time exposure: 35 min (range: 11 to 90 min)
Contrast media volume: 60 ml (range: 25 to 160 ml)
Procedure time*: 120 ± 55 min
Blood loss: 200 ± 120 ml

No need for blood transfusion in any case

* From skin incision to wound closure
Medium follow-up time: 36 months (3 to 57 months)

All patients were submitted to echocolor Doppler at 3, 6 and 12 months and yearly after.

Echo Contrast media was used not routinely but only in selected cases.

AngioCT were carried out at one year in all patients or when clinical or instrumental data suggested a possible complication occurred.
OUR EXPERIENCE 62 pts: results

a) No intra and post-operative mortality
b) No intra-operative surgical conversion
c) No graft related mortality during follow-up
d) No complications on the arterial access sites
e) No graft explant

In one case (1.6%) limb occlusion occurred one month post-op and a fem-fem bypass was carried out.
OUR EXPERIENCE 62 pts: results

- No evidence of any endoleaks type at completion
- Angiography
- No type I (a or b) endoleak during follow-up
- No type II endoleak during follow-up
- No type III endoleak during follow-up

In 4 cases the ECD showed some images suspected for type II endoleaks, but the post 3 months angioTC did not confirmed the non invasive data that remain negative for remaining follow-up
AngioTC at 6 months

AngioTC at 12 months

AngioTC at 3 years
The AFX device consists of a main bifurcated body and a proximal aortic extension which affix firmly to the aorta bifurcation and provides sealing and reducing the possibility of stent’s migration.

The possibility of deployment in tight aortic bifurcation with low incidence rate of limbs thrombosis or flow competition (if ballooning occur) is a main concern to underline.

The use of an AFX main body combined with an Endurant cuff in patients with adverse anatomy seems feasible, showing favourable results without adverse effects at the mid-term follow-up.
The multilayer ePTFE material (STRATA) is attached only to the proximal and distal ends of the graft and allows ePTFE to move independently and conform to abnormal surfaces facilitating sealing of the sac (type I endoleak prevention) and blocking reverse flow from lumbar and inferior mesenteric artery (type II endoleak prevention)

The very low dose of contrast media employed during main body deployment is a major concern in patients with renal failure and AFX endograft should be considered the first choice in these pts

In our experience the incidence rate of type II endoleaks is lower in comparison to our experience with other endografts

Obviously, one of the major limitations of this study is the lack of long-term results and the relatively small number of patients
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