The ICVR Prospective AAA Project - IPAP

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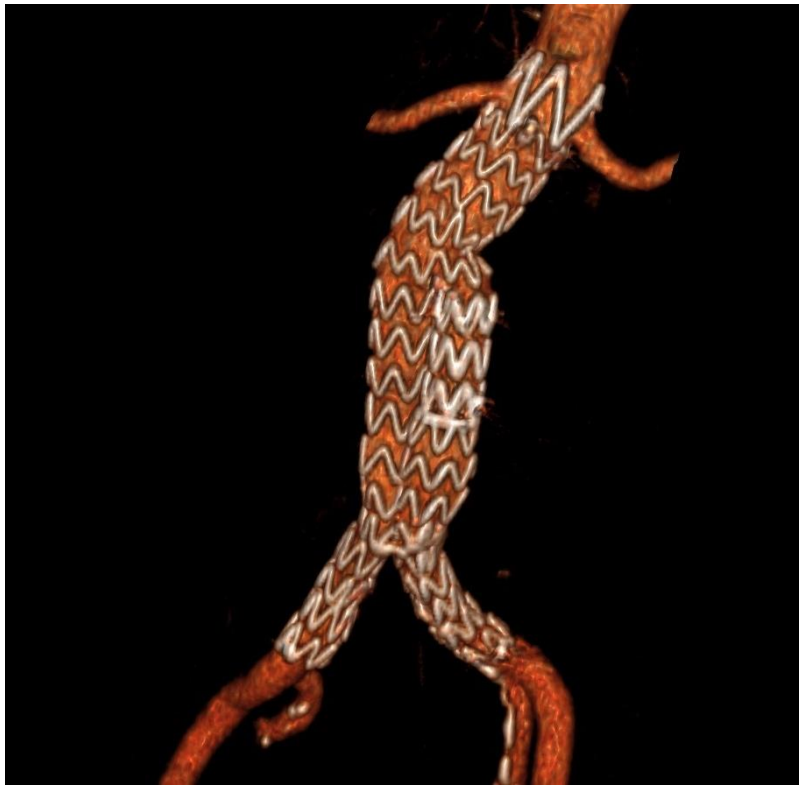
ICVR EVAR device performance study



Aim:

- To compile large-scale registry-based data on device performance in AAA repair in contemporary practice

Rationale:

- International registry-based collaboration offers a unique opportunity for large datasets capturing rare events

Study design

- Registry-based data collection on EVAR procedures
- Minimum data-set including
  - Patient characteristics
  - Basic anatomical variables
  - Device description
- Two-years follow-up, with identification of key EVAR-related failures

Data collection – minimum dataset

Demographics
Age
Gender
Intact
Cardiac ds
Pulmonary ds
Cerebrovascular disease
Preoperative creatinine

Aorta-specific data
Neck diameter (outer to outer)
Neck length
Neck angulation
AAA diameter
Indication (AAA, IAA, Both)

Procedure specific
Proximal device manufacturer and model
R iliac device (s) manufacturer and model
L iliac device(s) manufacturer and model
Unintentional branch vessel loss
Adjunct procedures (access-related, renal artery stenting, other)

Follow-up data collection

30-days
Date of Death
Reintervention, if yes define indication, type and time in days from primary surgery
Perioperative complication, if yes select what complication from a predefined list
1-year
Date of Death
Reintervention, if yes define indication, type and time in days from primary surgery
2-years
Date of Death
Reintervention, if yes define indication, type and time in days from primary surgery

Next steps

- Most registries have indicated interest to participate in IPAP
- Finalisation of data collection sheats and initiation of study by mid 2017
- Center-based or national-based data collection possible

Aim to initiate study 2017, with first round of ”early adapter” registries