With Short-Necked AAAs Or Those With Undesirable Necks Outside IFUs, Poor EVAR Outcomes Can Be Expected With All Endograft Devices

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Disclosures
- Case Proctoring, Cook Medical

Baseline aortic anatomy is a key determinant of EVAR appropriateness and long term clinical success.

Reality?
Aneurysm rupture occurred in 5.4% of patients after EVAR.

84 patients classified according to neck IFU. Outside IFU (30%): “Significantly higher migration, device-related complication, and secondary intervention rates.”

238 patients classified according to neck length (>15, 10-15, <10). “...short necks associated with significantly higher early (12%, 42%, 54%) and late (8%, 54%, 53%) type I endoleaks.”

258 patients classified according to neck IFU. Outside IFU (63%): “Significantly higher rates of early type I endoleak and intervention (9% vs. 22%).”

565 patients classified according to IFU. Outside IFU (39%): “…lower freedom from graft-related adverse event” “…EVAR treatment outside IFU should be performed cautiously, and perhaps not at all in...candidates for open.”

Clinical outcomes for hostile versus favorable aortic neck anatomy in endovascular aortic aneurysm repair using modular devices

39,996 EVAR patients. “Aneurysm rupture occurred in 5.4% of patients after EVAR....”
Conical neck is strongly associated with proximal failure in standard endovascular aneurysm repair.

A single center’s first 100 late endovascular aneurysm repair explants

156 consecutive patients classified according to neck IFU. “A conical neck is...single strongest factor associated with proximal failure.”

100 open conversions: “morbidity 48%, mortality 17%”

…The incidence of endograft failure continues to rise... and can occur even after a decade of successful EVAR repair.”

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

5-year post-EVAR rate of sac enlargement was 41%.”

Anatomy deemed acceptable for EVAR has continued to liberalize and several of these factors are independently associated with aortic aneurysm sac enlargement.

Delayed open conversions after endovascular abdominal aortic repair

44 open conversions: “morbidity 55%, mortality 18%”

…and the number of OCs have increased. This trend is likely to continue because of the rising number of EVARs...performed outside of instructions for use.”
Selection bias
• Lack of outcome data correlating enlargement with clinical events
• Dated experience with many first generation devices
• No device-specific data

BJS, October, 2012
478 patients classified according to IFU.
Outside IFU (59%).
Mean follow up 44 months.

Always two sides to a story.

1736 patients from 17 Kaiser Hospitals
“…In our cohort of EVAR patients…overall mortality, aneurysm-related mortality, and reintervention were unaffected by IFU adherence.”

1736 patients ➔ 489 Analyzed ➔ 440 had follow-up
≈25% patients treated with EVAR were included in the study
Power (type II error)?

“A post hoc analysis...showed that 7573, 2535, 1212 in each group...needed to show a statistical difference.”

No major difference in outcomes for endovascular aneurysm repair stent grafts placed outside of instructions for use

566 patients classified according to IFU. Outside IFU (69%): “Despite most EVAR patients...treated outside IFU...no difference in outcomes.”

Mean follow-up of 3.5 years...

“566 patients classified according to IFU. Outside IFU (69%): “Despite most EVAR patients...treated outside IFU...no difference in outcomes.”