What Has Changed Since Our Circulation Article: I Now Believe Some Off-Label Use Of EVAR Devices Is Justified And Safe

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Disclosures
• Case Proctor, Cook Medical

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

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

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.”
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 1 endoleaks

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

44 open conversions: "morbidity 55%, mortality 18%"

…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.

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

"31% of patients treated outside the most liberal Instructions For Use (IFU) parameters."

"5-year post-EVAR rate of sac enlargement was 41%."
478 patients classified according to IFU. Outside IFU (59%). Mean follow up 44 months.

1736 patients from 17 Kaiser Hospitals

…In our cohort of EVAR patients…overall mortality, aneurysm-related mortality, and reintervention were unaffected by IFU adherence.

Power (type II error)?

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

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Total AAA Code Rupture Mortality 2009-2015 (YTD)

"Code Rupture" In House Mortality Ruptured AAA 2009-2015 (Ruptures=63)