Anatomical Considerations for choosing Different EVAR Devices

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Disclosures

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No Conflict of Interest to report

Factors Device Choice

Initially 2001: 20-54% suitable for EVAR in Trials
Men about two times women
Higher risk patients less than 50%
With single device rate as low as 20%.

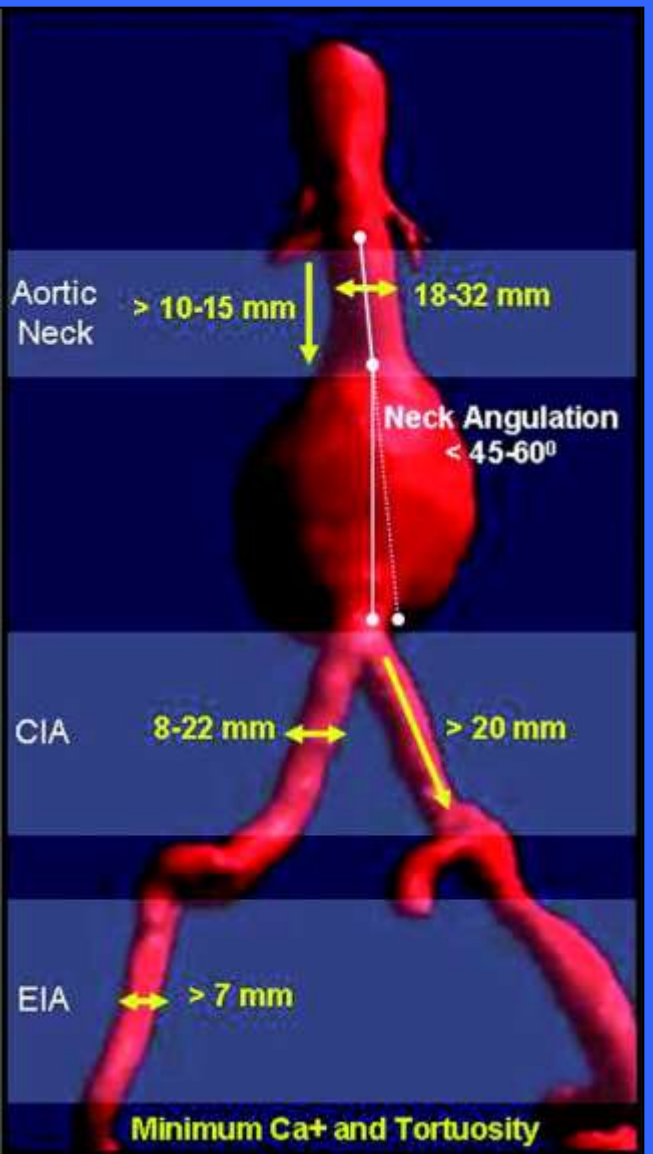
Now 2017; 45-80% suitable for EVAR

Complications
Endoleak Type 1-5
Limb occlusion
Device Migration
Aneurysm Rupture
Buttock Claudication

Patient	Reduced Mortality and Morbidity
Aneurysm	Long Term Seal, Migrate, Patency
Cost Availability	Device,LOS,Reintervention,Followup

Aneurysm Anatomy most critical factor for success of EVAR

Anatomy conditions defined by IFU that are packaged with FDA approved commercial EVAR device.

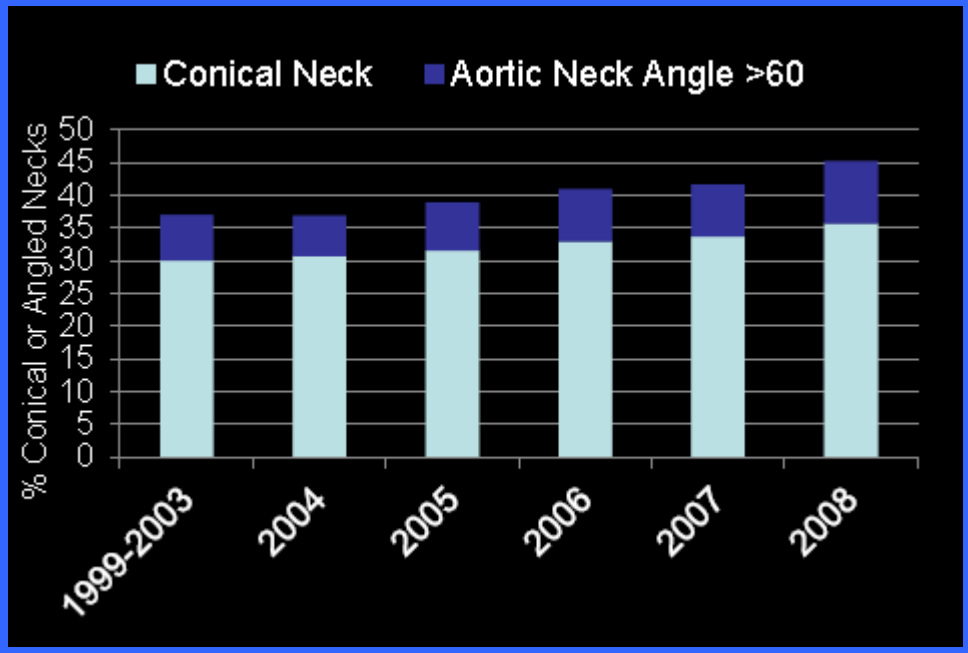


FDA data base analysis of 10,288 patients treated with approved EVAR devices between 1999 and 2008

31-58% of patients Outside IFU compliance

Use outside of IFU is increasing

Main Reason : Hostile Neck Anatomy



Schanzer Circulation 2011:123(2): 2848-55

Clinical Impact of Hostile Neck Anatomy

Endoleak late Type 1 Significant increase
Hostile neck Anatomy (9.5%) vs favourable neck anatomy (4.5%) ($p<0.01$)

Total interventions Significant increase
HNA (22.8%) vs FNA (11.4%) ($p=0.02$)
Schanzer 2012 EJVES

Meta-analysis (7 studies) 1559 pts Antoniou et al JVS 2013
Hostile neck versus Favourable Neck.
Endoleak late type 1
HNA four times (OR 4.563) compared to FNA

HNA 9 times risk of aneurysm related mortality in one year compared to FNA.

Devices

Over last 27 yrs global aortic endograft use increased rapidly

Many Companies

Wide Range of designs

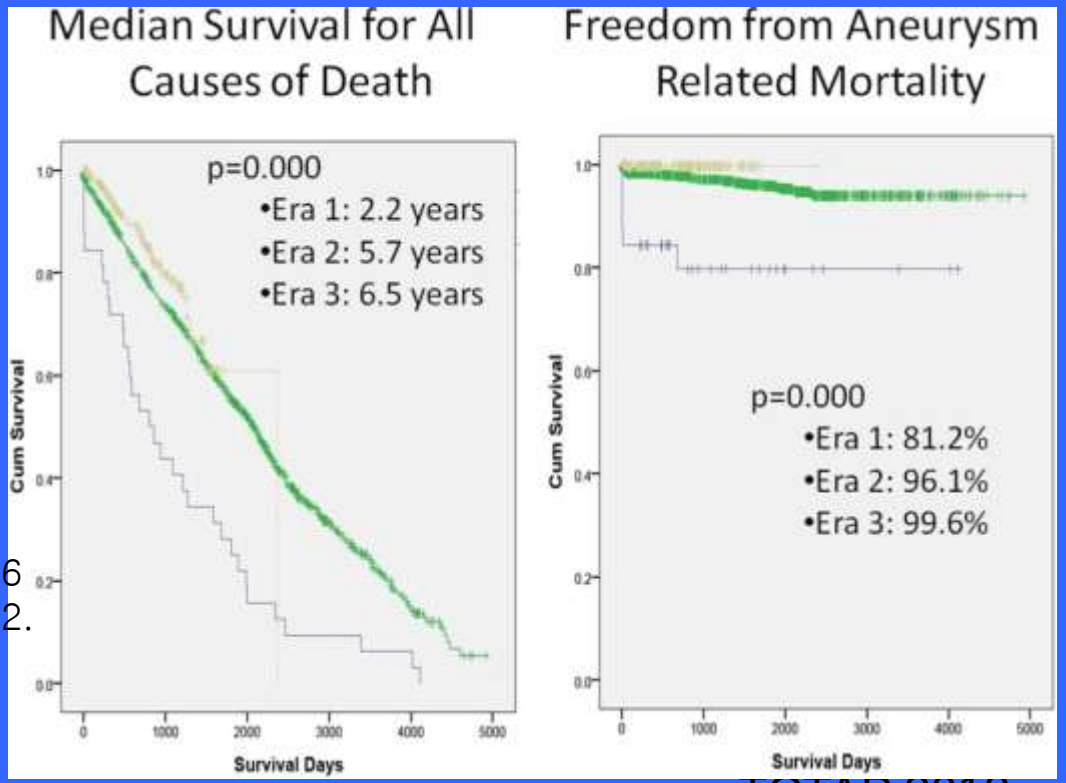
Advantages
- Intention is to increase inclusion criteria
- Decrease technical Radiation, Procedure time
- Clinical complications
- Decrease secondary interventions

Devices are improving outcomes
- Engage registry
- Pythagoras registry
- GREAT Gore C3
- Innovation

No single device for All EVAR.

Era1: 1992-96
Era2: 1997-2006
Era3: 2007-2012.

Tadros 2018 JVS



Device Features

Low Profile

Low Permeability Material

Conformable kink resistant limbs ring or helical stent

Limbs Modular or unibody

Varying sizes and lengths for aorta and iliac

Fixation Suprarenal vs infrarenal

Seal Polymer Inflatable and conformable

Stent Nitinol, CoCh, Stainless steel

Delivery system

Deployment Delivery, Method, Accurate, Markers, Steady

Repositioning Body and iliac

Contralateral limb cannulation Size of limb, Preloaded wire

Extra Equipment needed eg snare, magnetic wire

EVAR Devices

Infrarenal

Gore C3

Repositionable, Unsheathed (Can bend in proximal neck), Low profile, Flexible , Endoanchors , IBD available

Anaconda

Repositionable, Sheathed, Magnetic access wire, Very Flexible

AORFIX Articulated Pythagoras trial Very Angulated Neck

NELLIX

Suprarenal

Zenith normal and LP

Sheathed, Low profile, IBD available

Endurant

Sheathed, Flexible, Medium profile

Ovation IX and Alto

Low Profiile Polymer Seal , Staged Deployment, Sheath, Preloaded wire

Incraft

Low profile

Anatomy Assessment and Planning

Patient	Clinical	Yourself
Aneurysm	Imaging assessment	Yourself and/or company
Planning Sheet	Company, Your own	
Imaging	Good Quality and detailed planning	
	Essential for challenging aneurysm anatomy	
	eg aneurysm neck, iliac etc	
Spiral MD CTA	Gold standard	Have Standardized protocol
3D centerline CT Reconstruction		
	Tend to overestimate length in angulated neck	
Software	3mensio, TeraRecon, etc	
	Workstation or Online sites	

3D Printed Models Difficult cases

Aneurysm Anatomy

Arch of the aorta to the upper thigh
Disease of lumen arch, descending, origin neck vessels
Access vessels left and right subclavian,
Thoracic aorta Diameter, Surface, Lumen, Ulcers, Previous graft
Visceral Branches Coeliac, SMA, Renal
No, Size, Lumen
Anatomy of the Aneurysm
Site and size and length, lumen, Thrombus
Aortic neck Length,Angulation,Diameter,Calcification,Thrombus,Configuration
This is the Biggest problem facing EVAR
All parameters of proximal neck need to be integrated
Crucial to choose Device and for most effective interventional technique
IMA and Lumbar
Aortic Bifurcation Calcification, Diameter, Orientation of iliac origins
Iliac artery Common, External and Internal
Size, Patency, Tortuosity, Calcification, Length
Femoral Size, Calcification, Bifurcation, Previous surgery

Anatomy, Device and Procedure

ON COMPLETION

Procedure EVAR or Open

Device Configuration Tube, Bifurcation, Fenestrated, Branched, Hybrid
Size and Lengths

Angulation of neck for renal and or iliac artery for positioning of imaging
Aortic bifurcation for cannulation, Can choose device

Adjunct equipment eg Dilators, Stents, Coils, Plugs, Outback Device, Snare
Refresh memory of Device, IFU or deployment sequence before
Suboptimal deployment can occur from relative inexperience with the device

Company Rep needed or not

Experience with a variety of devices is advisable (properties and construction)

Hostile Neck Anatomy

Neck length <15mm

Neck diameter>32mm

Neck Angulation >60 Degrees

Neck calcium or thrombus

Conical Necks

Device Options for Hostile Aortic Neck

Standard graft
Standard graft with Aptus Anchor
Standard Graft with Initial tube graft
Ovation
Nellix
Anaconda
Endurant
Aorfix

OR

CHIMPS
Fenestrated

No ideal device exists for Hostile Neck

device familiarity, availability, neck angulation, adjunctive devices (endoanchors) , access vessels

Choice : number of abnormal neck features and severity of abnormality.

Conclusions

AAA treatment with EVAR is increasing both in and out of IFU

Treatment of complex aneurysm anatomy is challenging

Severely Angulated Infrarenal necks and tortuous iliac arteries are outside the IFU of most Current EVAR Devices

Device Advances : implantation, overcome anatomy and improve outcomes

3D model for planning and choosing device

Knowledge and Experience with more than one device Necessary

For IFU Cases	All third generation devices suitable
	My personal choice Infrarenal, Low profile, Flexible device
Non IFU cases	Factors : number, site and severity of anatomical problems
	Can combine some devices
Choice of Device	Primary and Secondary Factors to consider
	Technical success and ease of procedure
	Clinical Success short and long term
	Cost and Availability

Never Forget OPEN repair as an option

Followup is essential especially with abnormal anatomy.