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CHAPTER

OCTOBER 11, 2025 • CENTRAL BANK CENTER • LEXINGTON, KY

Track 2B
Cardiothoracic and EP

Trainee Presentation: Mohammad Malik

Complex Aortic Arch Disease

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PGY-2 Integrated Cardiothoracic Surgery

University of Kentucky Medical Center

Disclosures

- None

"There is no disease more conducive to clinical humility than aneurysms of the aorta"

- Sir William Osler

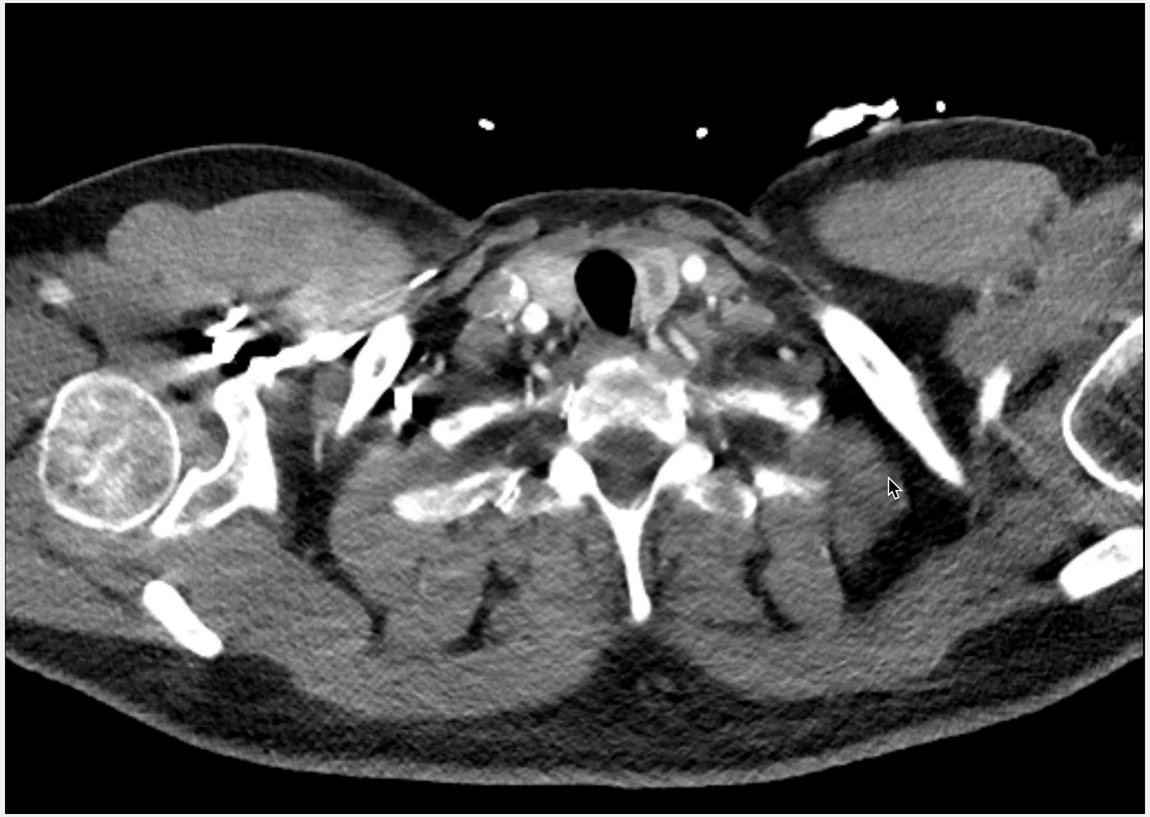
Introduction

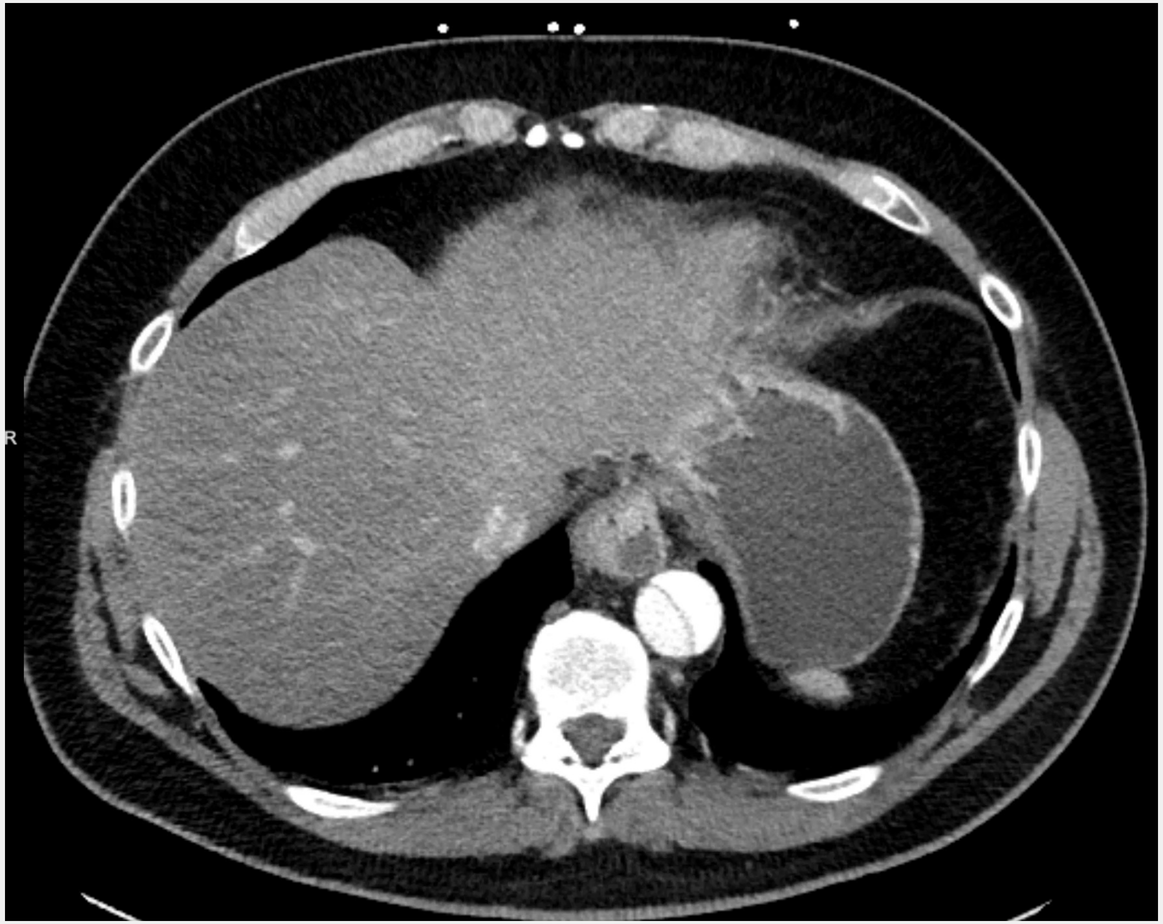
- Aortic arch pathology remains one of the most technically demanding challenges in cardiovascular surgery
- Anatomic complexity: managing variable arch branching patterns and pathology extending to descending thoracic aorta
- Cerebral protection strategies: maintaining adequate brain perfusion during circulatory arrest
- Neurologic complications: stroke, spinal cord ischemia, neurocognitive decline postoperatively

Case 1

- 60-year-old with PMHx of hypertension and obesity who presented to ED due to sudden onset chest and back pain while jogging.
- Denied any family history of aneurysms or connective tissue disorders

Imaging





Interventions

- The patient was taken emergently to the operating room for repair of his Stanford Type A dissection
- Celiac axis, left renal artery, and IMA all originated from the false lumen
- Vascular surgery consulted intra-operatively

Surgical Procedure

- Cardiac Surgery: Repair of ascending aorta (valve-sparing) with DHCA using a 28mm 1 branch Dacron graft (using the hemiarch technique) – 52 minutes of circulatory arrest time

- Vascular Surgery: Zone 3 TEVAR deployed antegrade from the arch during DHCA

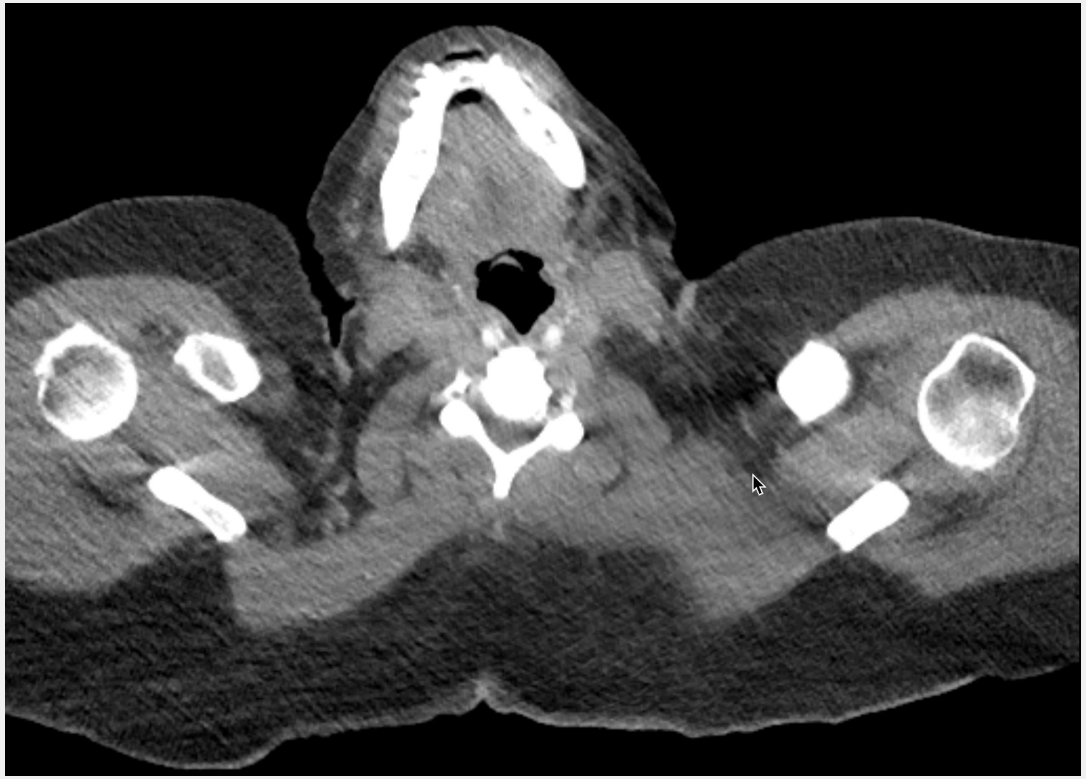
Post-Operative Course

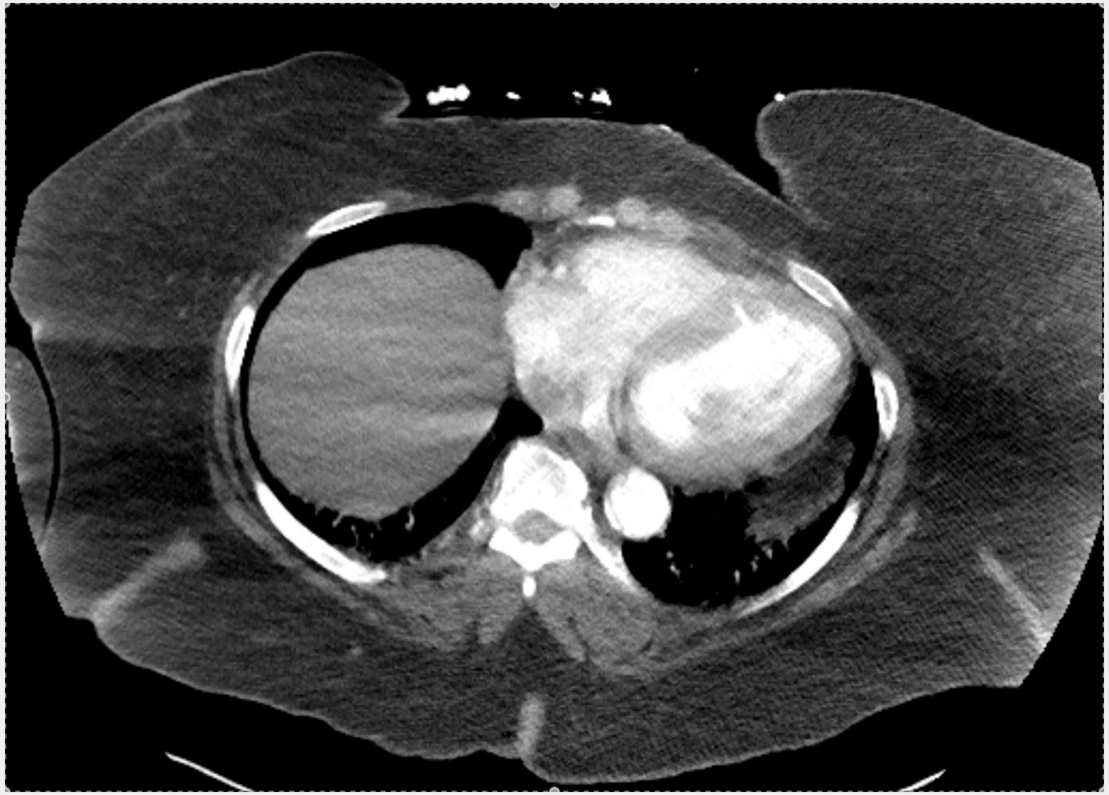
- Post operative admission to CVICU
- Uncomplicated ICU course
- Discharged home POD 13 with follow up with Cardiac and Vascular Surgery

Case 2

- 53-year-old female with PMHx of hypertension, obesity, and hypothyroid presented as a transfer from OSH with chest and severe abdominal pain
- CTA at OSH revealed Stanford Type A aortic dissection

Imaging





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Interventions

- False lumen perfusing SMA, celiac trunk, and both renal arteries
- The patient was taken emergently to the operating room for repair of her Stanford Type A dissection
- General surgery consulted as well to evaluate for ischemic bowel

Surgical Procedure

- General Surgery – diagnostic laparoscopy – healthy, well-perfused appearing stomach, small bowel, colon, and liver.

- Vascular Surgery – hot wire dissection fenestration and Zone 4 TEVAR

- Cardiac Surgery – Ascending aorta resection and replacement with 30mm Dacron graft (hemiarch technique) with DHCA and resuspension of aortic valve – 22-minute circulatory arrest time

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Post-Operative Course

- Post operative admission to CVICU
- ICU course complicated by iatrogenic anterior spinal cord stroke with resulting impairment of mobility and neurogenic bladder.
- Discharged to an acute rehab facility on POD 15

Considerations in Complex Aortic Arch Disease

- Complex Aortic Arch disease – Key Takeaways and Future Directions
  - Hybrid and endovascular approaches expand possibilities but introduce new challenges
  - Balancing cerebral protection, technical feasibility and long-term durability
  - Success depends on multidisciplinary collaboration

Talk 1: Melissa Perrotta

Coarctation of the Aorta: A Systemic Vasculopathy that Requires Life-long Care

KY ACC 20th Annual Meeting

Melissa L. Perrotta, MD, FAAP, FACC
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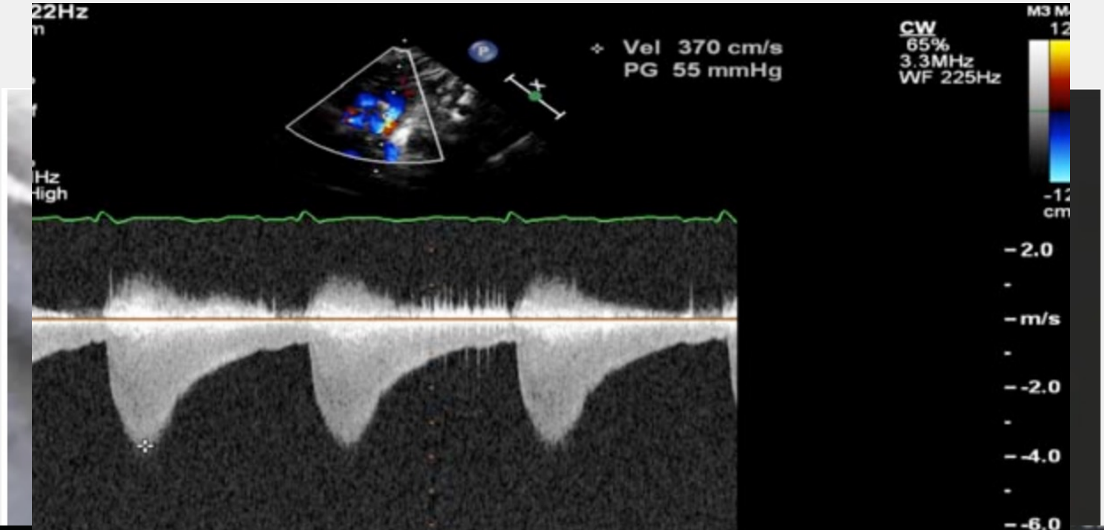
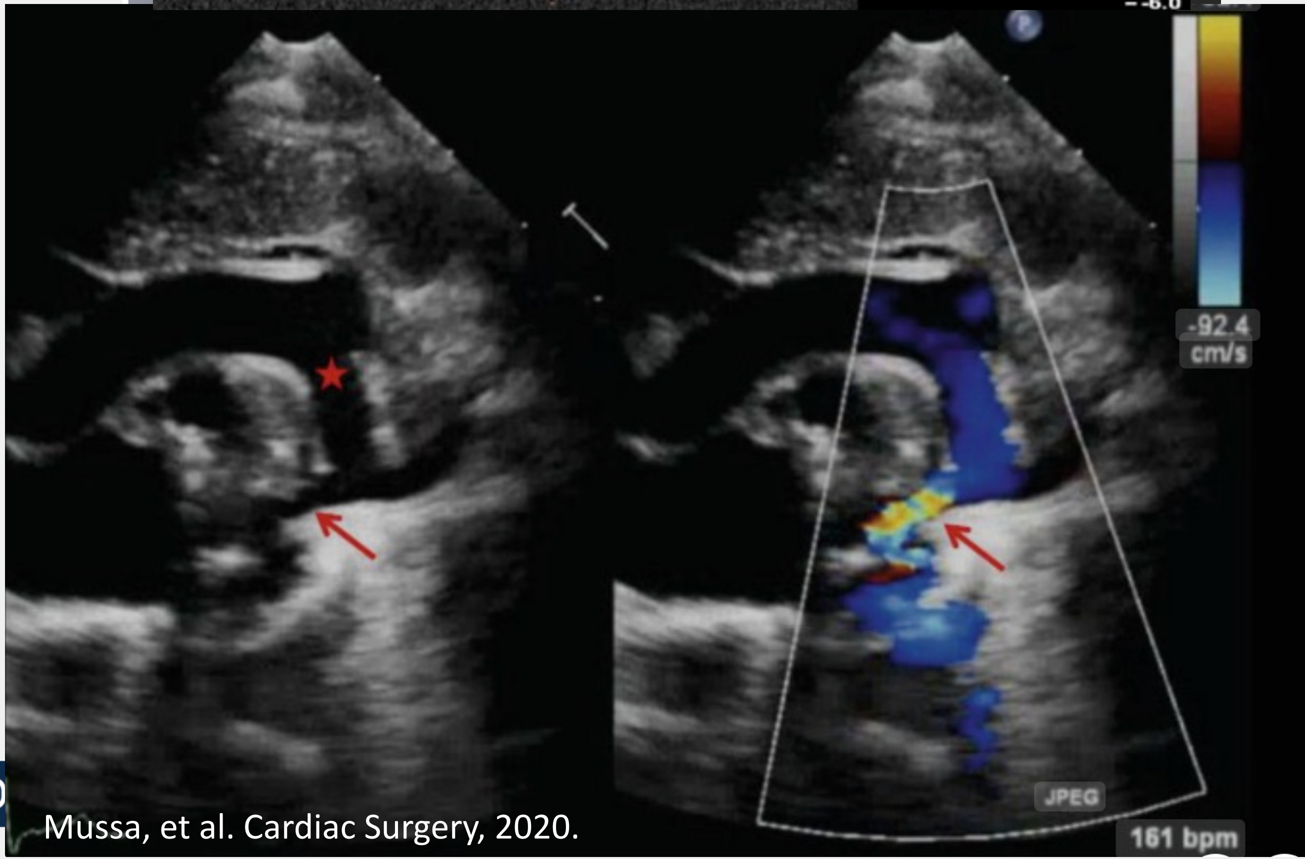
University of Louisville School of Medicine, Norton Children’s Hospital
Louisville, KY

I have no relevant disclosures

Coarctation of the Aorta

- Definition: Discrete stenosis in the upper thoracic aorta, at or near point of insertion of ductus arteriosus, restricting blood flow to DAo
    - +/- isthmus & transverse arch hypoplasia
    - +/- long segment and/or tortuous
- Histology:
    - thick intimal and medial ridges that protrude posteriorly and laterally into the aortic lumen (posterior ‘shelf’)
    - Distal to CoA →intimal proliferation and disruption of elastic tissue due to high-velocity jet→risk of infective endocarditis, intimal dissections or aneurysms
- Echo is diagnostic





Mussa, et al. Cardiac Surgery, 2020.

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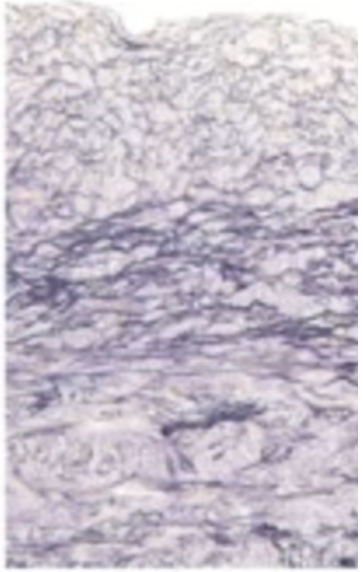
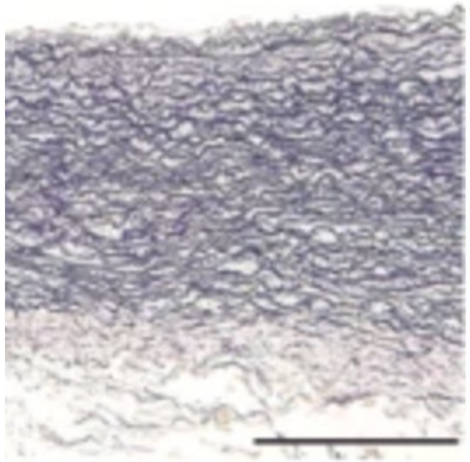
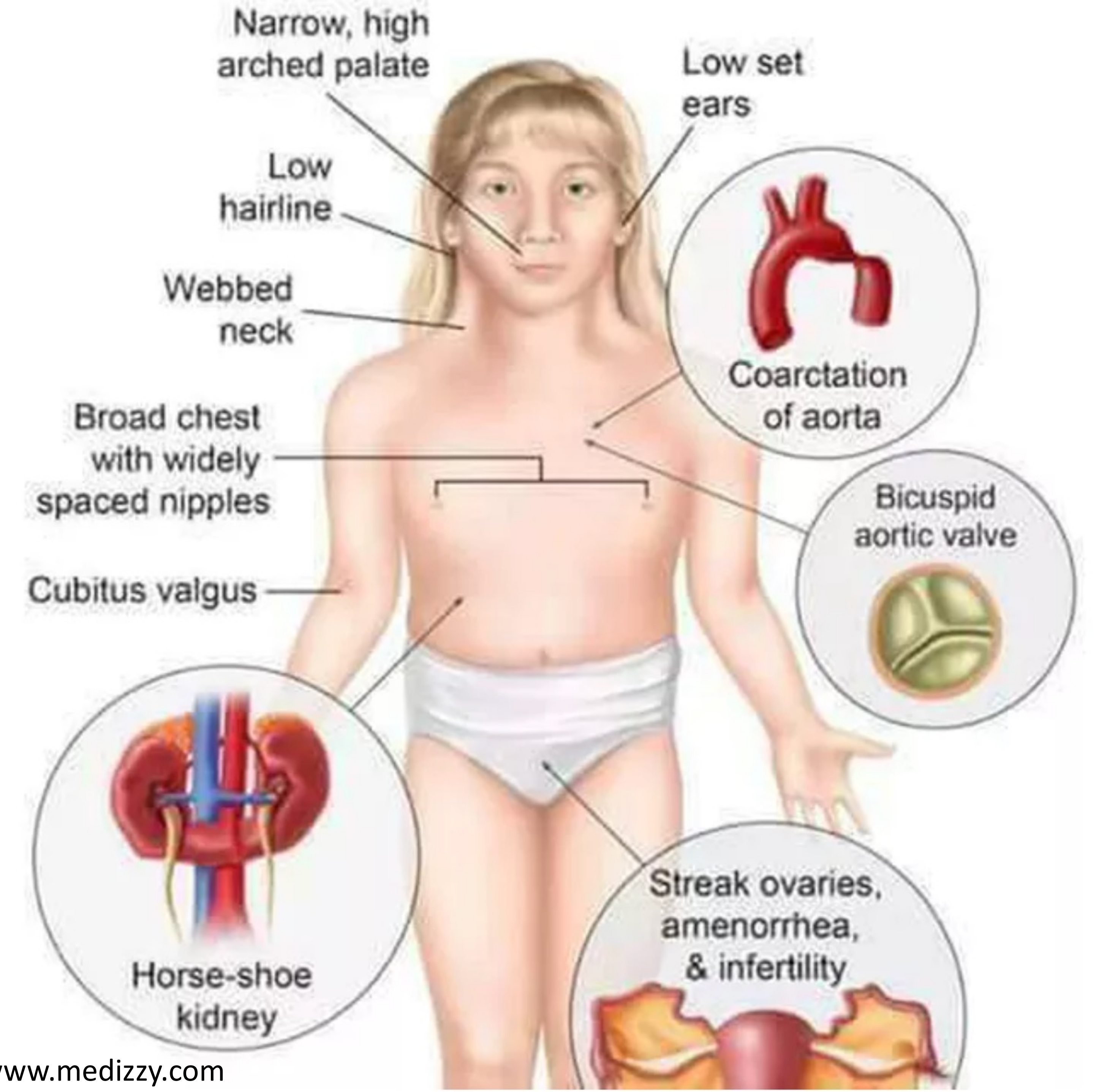
Elastica van Gieson stain







www.medizzy.com

Yokoyama, et al. *The Journal of Phys*

Epidemiology

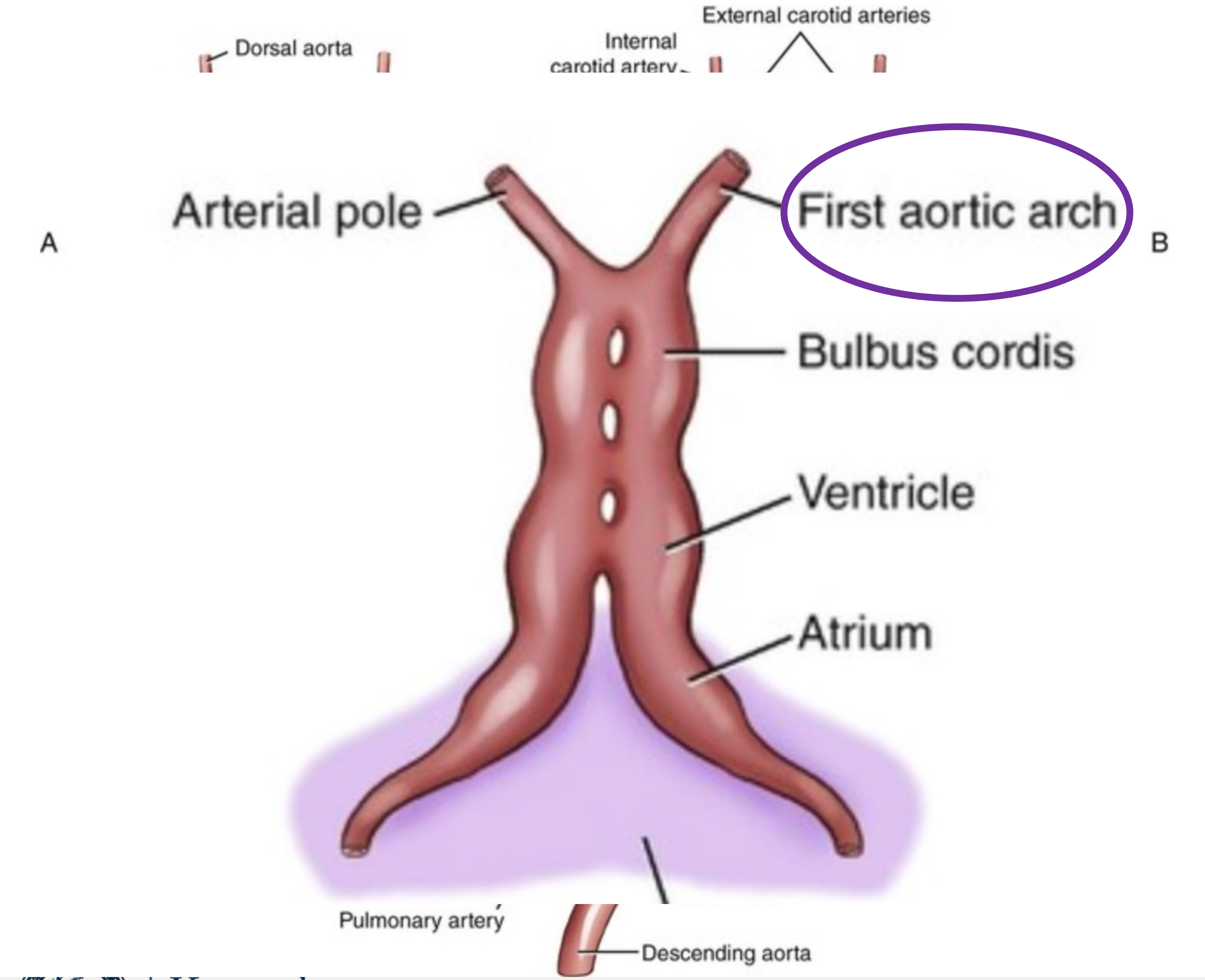
- CHD incidence is 1% (1 in 100 births)
- CoA = 5-8% of all CHD

  Isolated CHD 1 in 2,500 births (more rare)
- Reduced long-term survival – mean age of death 38 years

  Causes of death

  - CAD
  - CHF
  - SCD – 25x risk
  - Cerebral vascular accidents
  - Ruptured aortic aneurysm

Coarctation of the Aorta - Embryology



Primitive Heart Tube

Aortic arch develops in first 6-8 weeks of fetal life

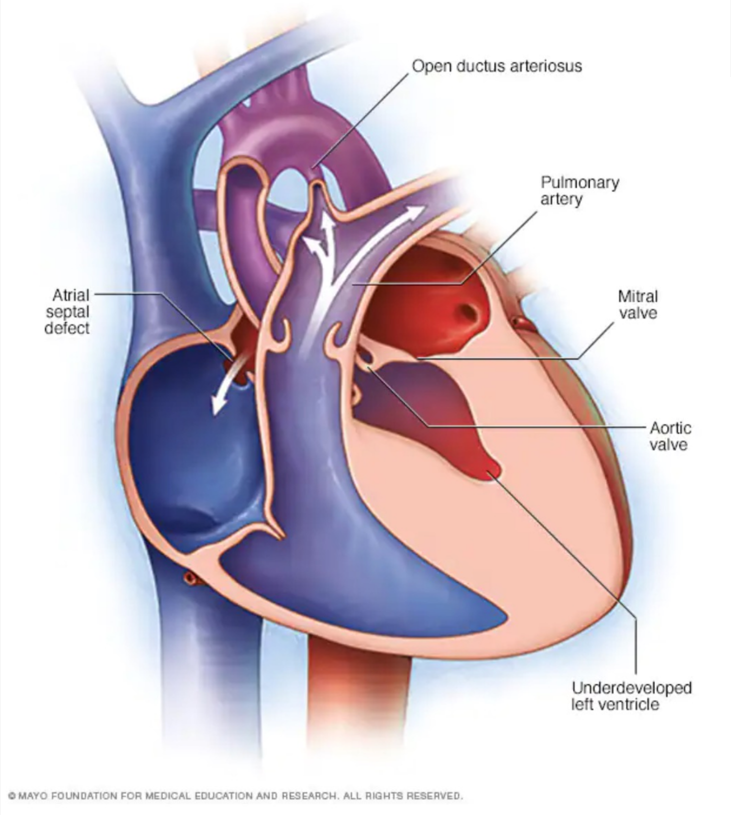
- L 4th arch develops thoracic aortic arch and isthmus
- R 4th arch involutes
- 6th arches develop proximal pulmonary arteries, L 6th arch develops distally into ductus arteriosus
  - Abnormal development of the 4th and 6th arches results in coarctation

https://radiologykey.com/embryology-and-physiology-of-the-fetal-heart/

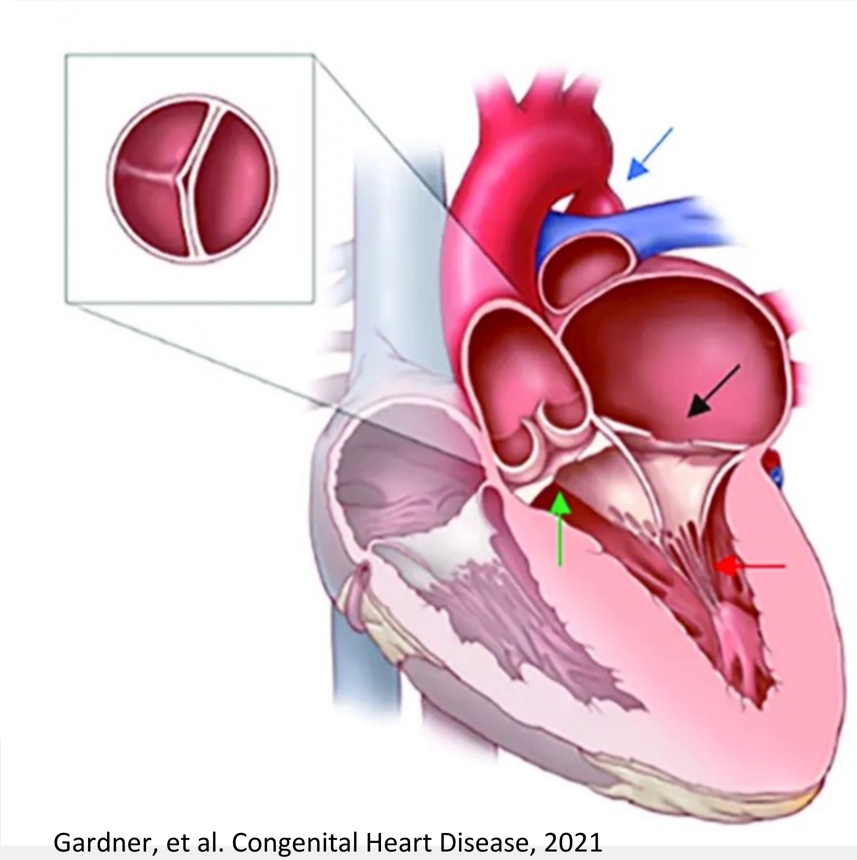
Commonly Associated CHD Lesions

- Bicuspid aortic valve – up to 85%
- Ventricular septal defect (VSD) – perimembranous and outlet types
- Other more severe left-sided heart obstructive lesions: hypoplastic left heart syndrome (HLHS), Shone's Complex

HLHS



Shone's



Gardner, et al. Congenital Heart Disease, 2021

Common Vascular Associations

- Berry aneurysms of the brain – 3-5%
  - Many different views on frequency of screening with CTA or MRA
    - At least once in adulthood vs Every 3-5 years
    - Family history
    - New neurologic symptoms –increased headaches, vision changes, TIA-type symptoms
- Early development of coronary artery disease
  - HTN and endothelial dysfunction
    - Disturbed laminar flow or turbulent flow reduces wall shear stress and promotes endothelial dysfunction, a precursor to atherosclerosis
    - Development of early MI or need for PCI heavily influenced by modifiable risk factors
    - Responsible for up to 20% of late deaths in coarctation of the aorta

→CoA should be regarded as a condition of generalized vasculopathy rather than a simple isolated narrowing of the aorta

Known Genetic Mutations

- May have familial associations with CoA or other left-heart lesions such as BAV, Shone's complex, HLHS
- Monogenic syndromic conditions including Kabuki (*KMT2D*) and Noonan (Ras-MAP kinase signaling pathway genes) syndromes associated with isolated CoA
- Turner's syndrome (complete or partial loss of an X-chromosome in females), often with BAV
  - 7-12% with CoA
  - 35% of CoA are Turner's
- NOTCH1 variants

Case #1

A 9-day old, former full-term baby boy presents to the pediatric ED with 2 days of fussiness, poor feeding, lethargy and pallor. On exam, the baby is listless, with cool, mottled extremities and an overall gray hue to the skin. Capillary refill is 5-6 seconds in the feet. Brachial pulses are 1+, while femoral and posterior tibial pulses are poorly palpable. Cardiac auscultation reveals no murmurs. Pulse oximetry in the baby's right hand is 98% while in the right foot is 88%. His mother says the pregnancy was uncomplicated, though she did have an echocardiogram during her pregnancy due to her history of bicuspid aortic valve. After establishing IV access, administering a 20 cc/kg crystalloid bolus, and sending initial labs, what is the next step in management?

a) Measure 4-extremity blood pressures

b) Order a STAT transthoracic echocardiogram

c) Activate the cardiac catheterization lab

d) Start an infusion of prostaglandin E1 at 0.1 mcg/kg/min

Case Review

What's Going On??

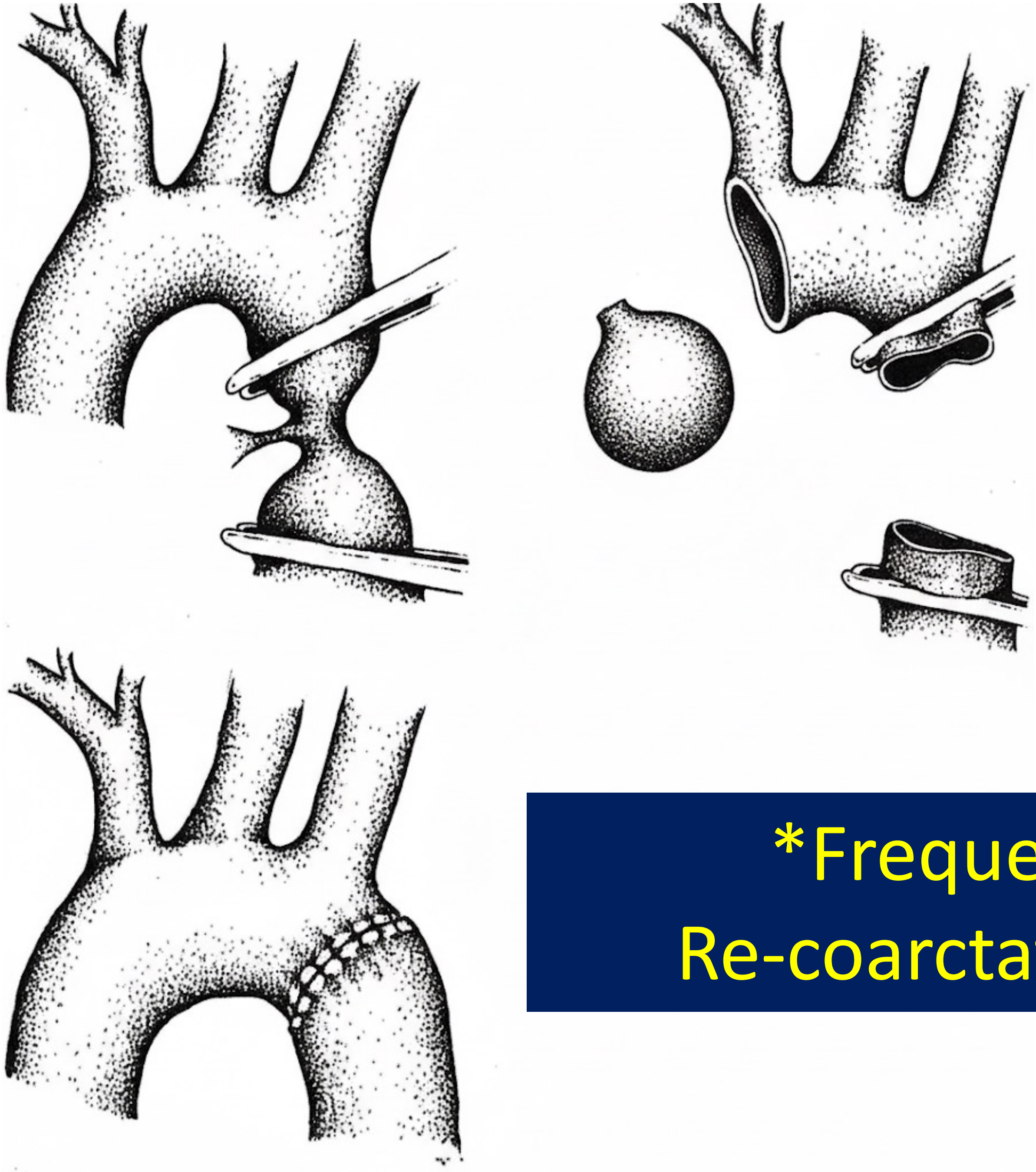
Ductal closure resulting in critical coarctation of the aorta → Poor perfusion to organs distal to the descending aorta → Increased LV afterload → LV systolic failure → Cardiogenic shock

Next Steps:

- PGE1
- TTE
- CTA
- Surgical coarctation repair
    - Why not send the baby to the cath lab?
        - Aneurysm risk 5-10%; High risk of re-coarctation with angioplasty only; stents don't grow

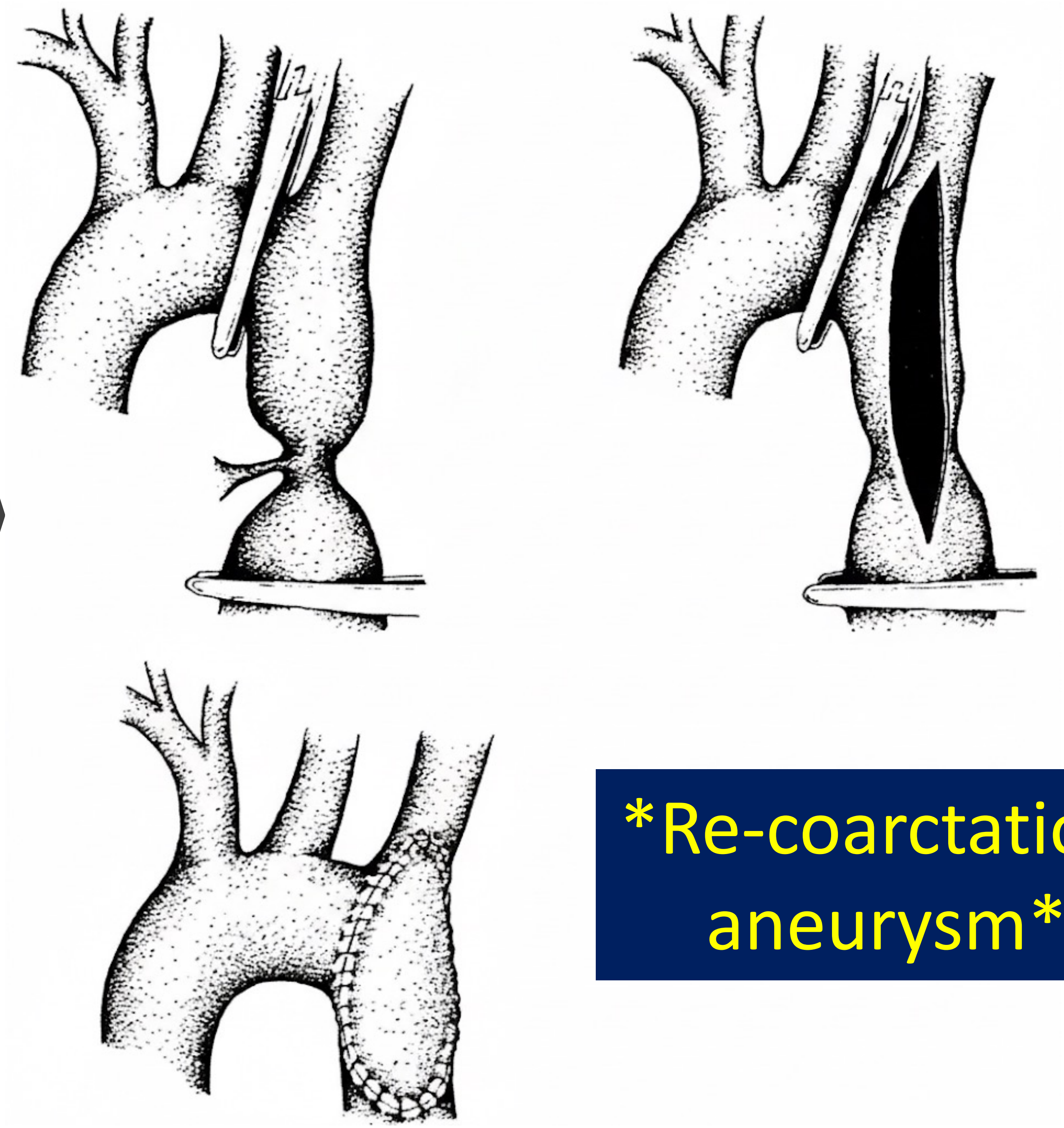
Surgical Coarctation Repairs

End-to-End Anastomosis



Frequent Re-coarctation

Patch Aortoplasty



Re-coarctation, aneurysm

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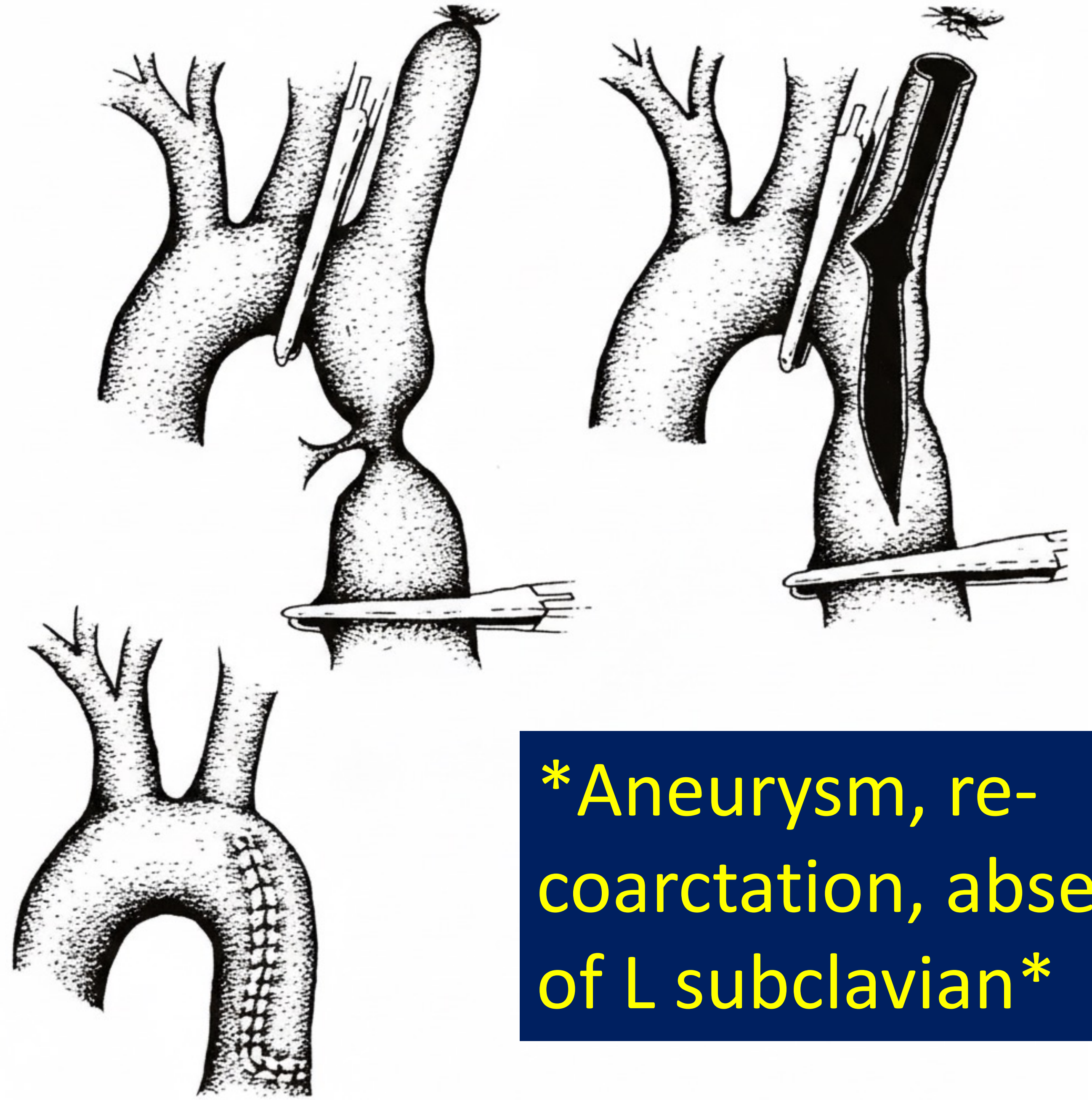
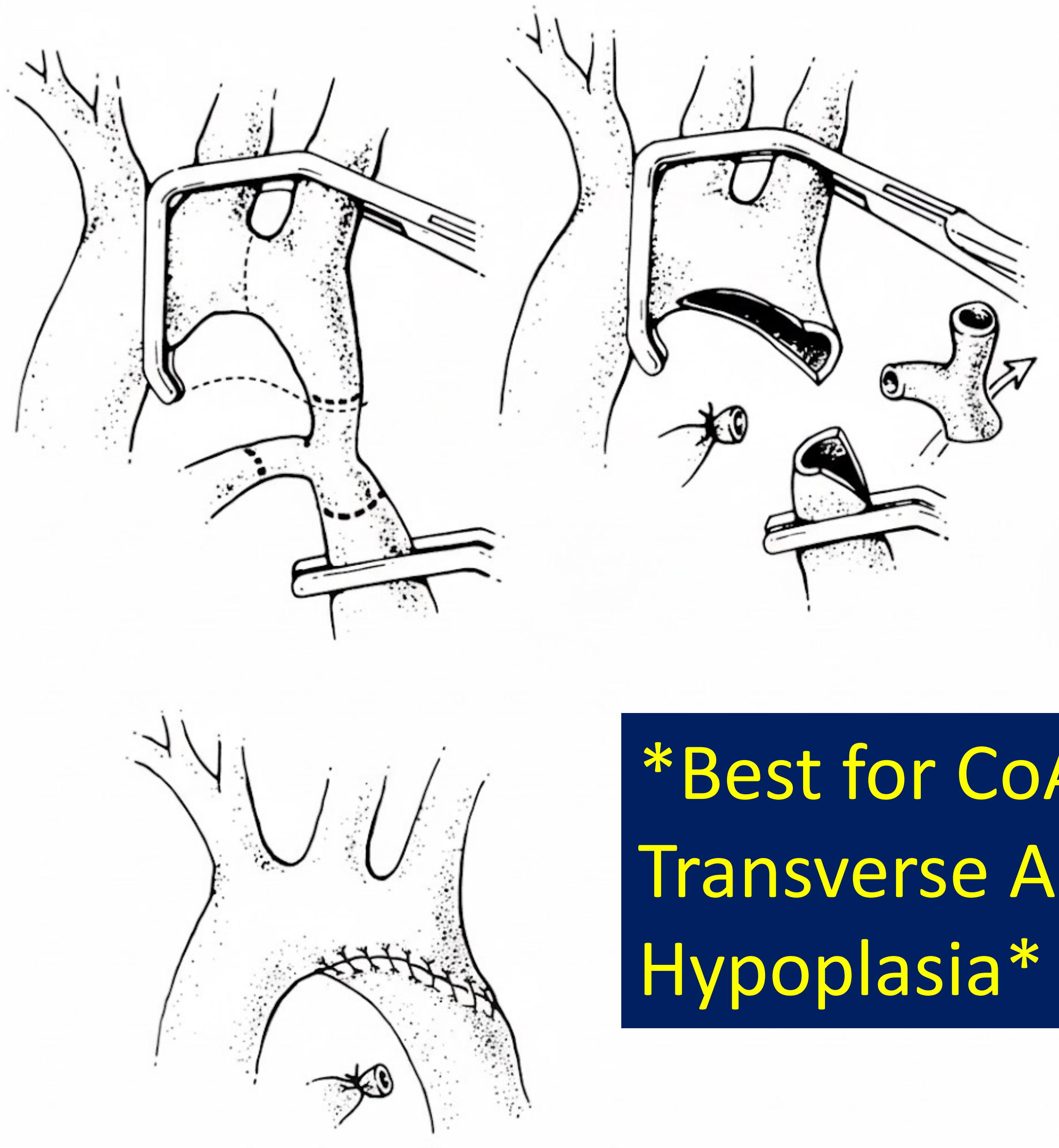
Left Subclavian Flap Repair



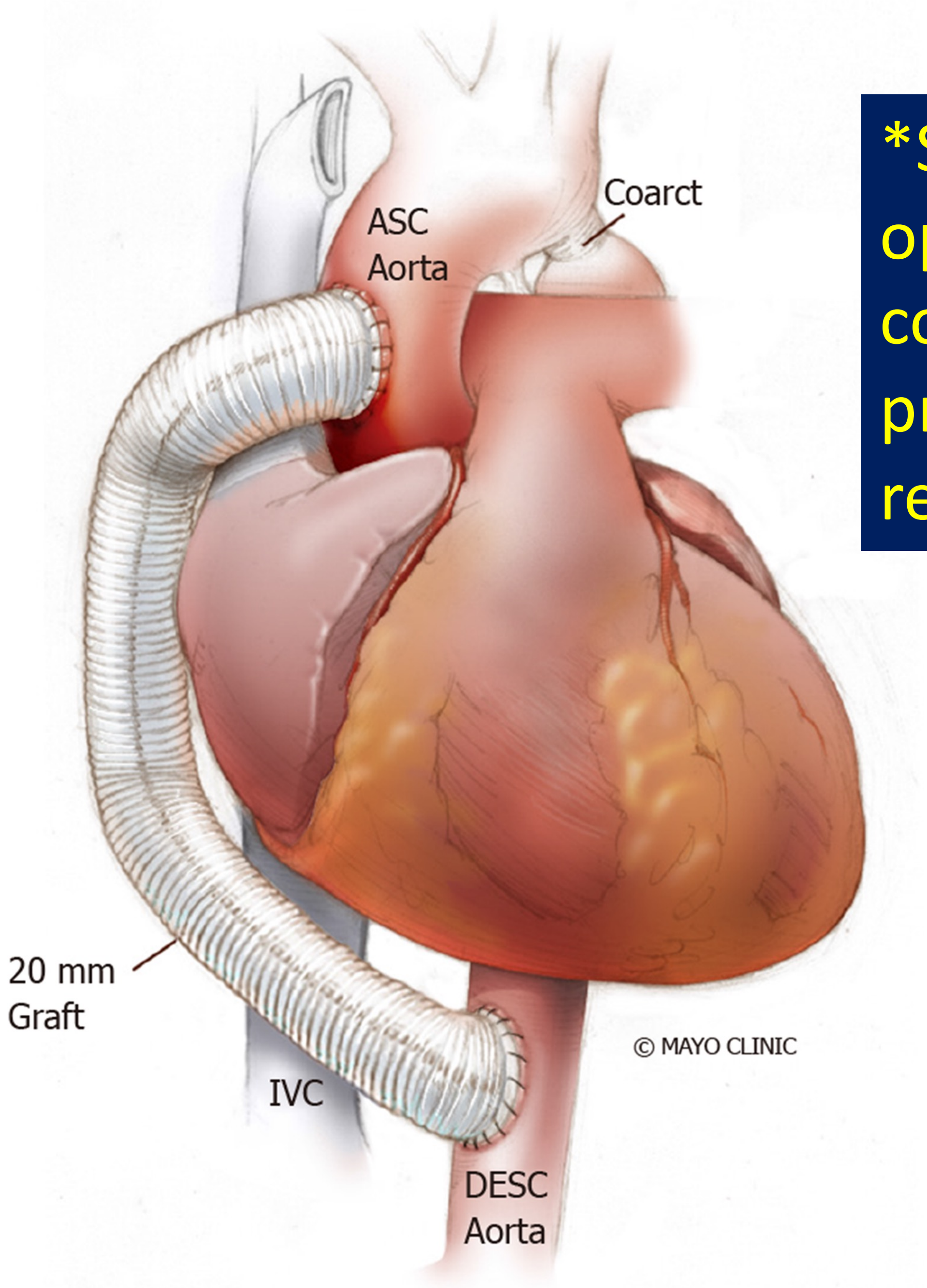
Aneurysm, re-coarctation, absence of L subclavian

Extended end-to-end repair



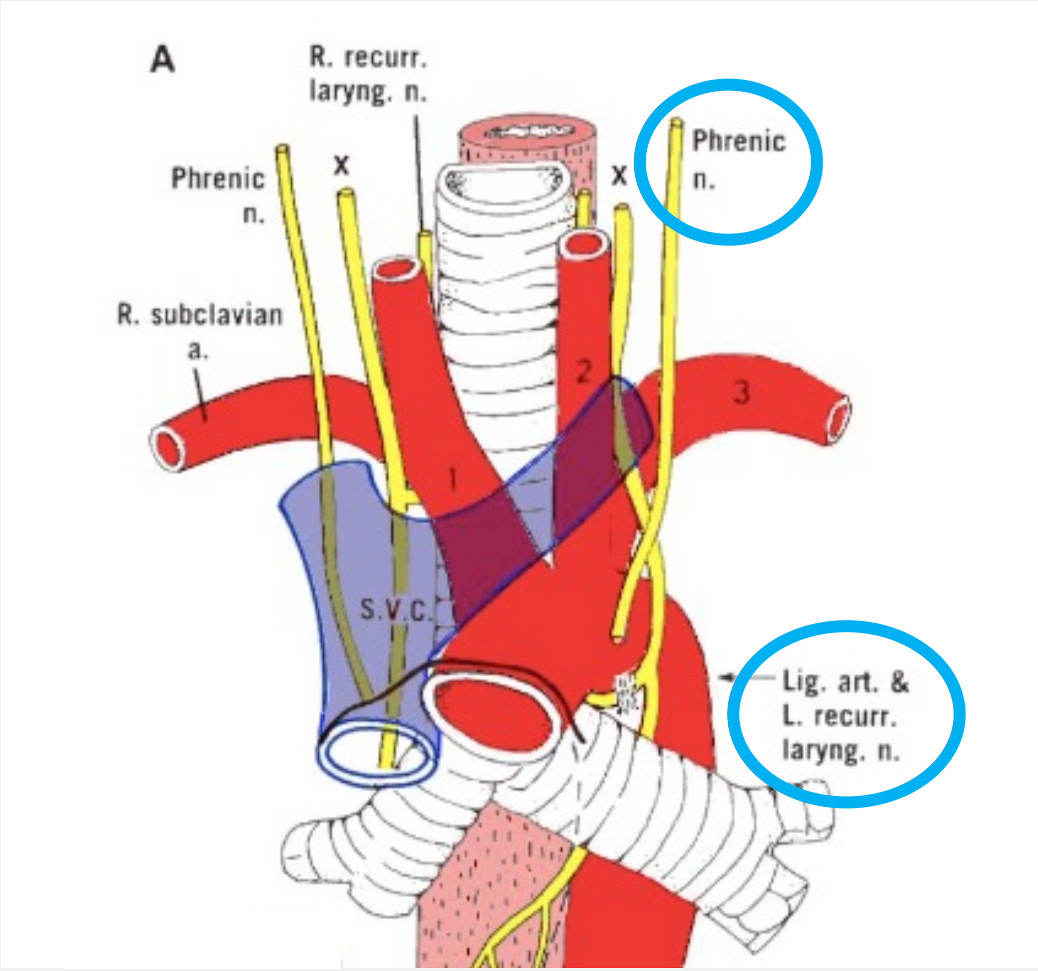
Best for CoA + Transverse Arch Hypoplasia

Extra-anatomic Grafts



*Safer surgical option for re-coarctation after prior operative repair in adults

Early Complications of Coarctation Repair



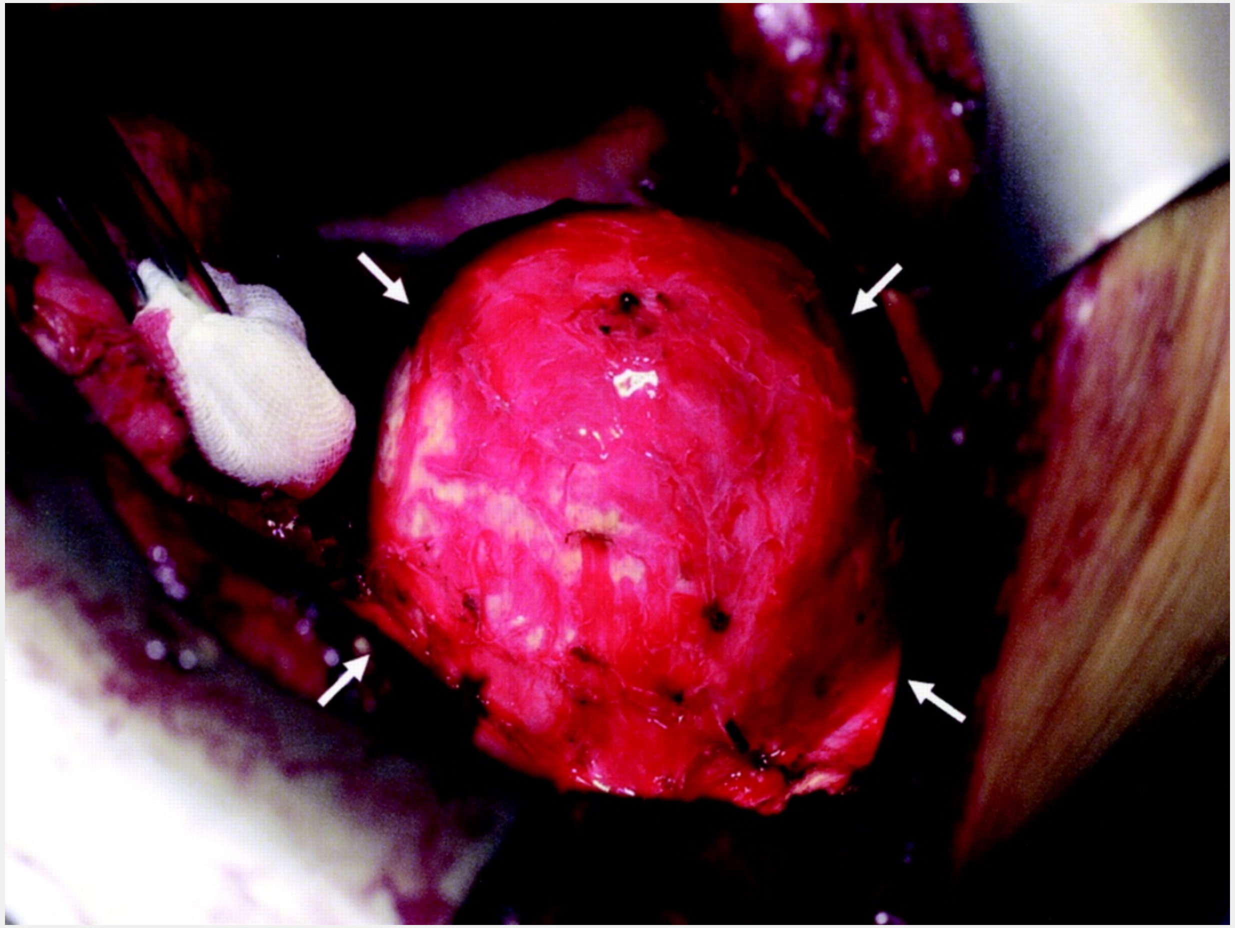
http://www.dartmouth.edu/~humananatomy

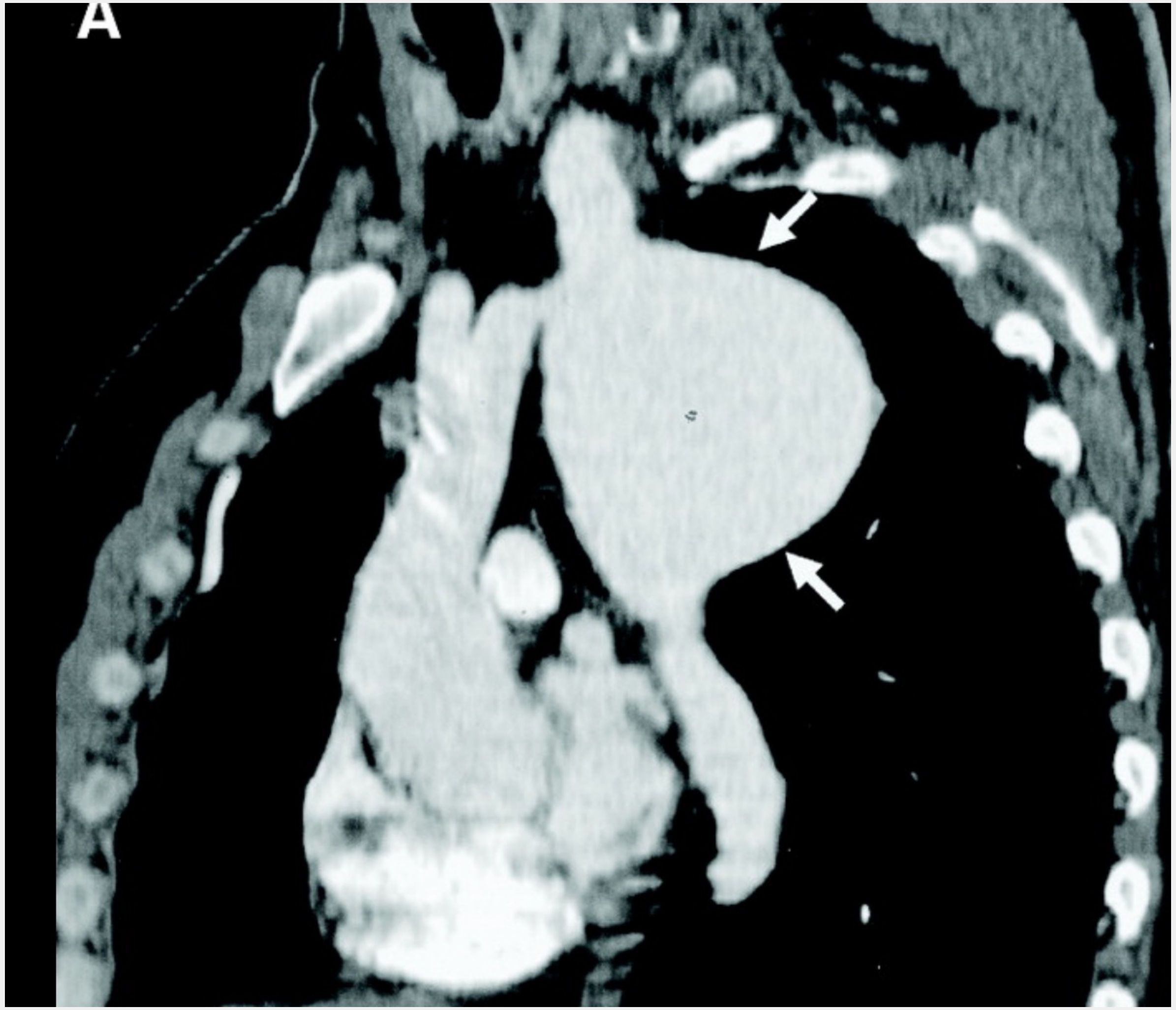
- Post-coarctation syndrome: paradoxical hypertension
- Spinal cord ischemia and paralysis
- Recurrent laryngeal nerve or phrenic nerve injury
- Chylothorax
- Bleeding
- Infection

Late Complications of Coarctation Repair

- Systemic HTN
- Recoarctation
  - Reoperation usually in older patients and w/ complex arch anatomy, such as long-segment coarctation, or hypoplasia, and requires techniques like prosthetic or subclavian patch aortoplasty, bypass grafts from AAO to DAo and less commonly simple resection
- Aortic aneurysm & dissection
  - @ site of repair; often years after repair, +/- HTN -
  - Risk factors: later age; patch aortoplasty (24%)
  - Treatment is surgical – resection and graft
    - No specific guidelines
  - Pseudoaneurysm – weakening with outpouching of the adventitial thin layer of the aorta usually @ suture line; higher risk of rupture → repair immediately
  - AAo aneurysm - usually associated with aortopathy (BAV, Marfan's, etc)
- Sudden cardiac death

Aortic aneurysm at site of Dacron Patch

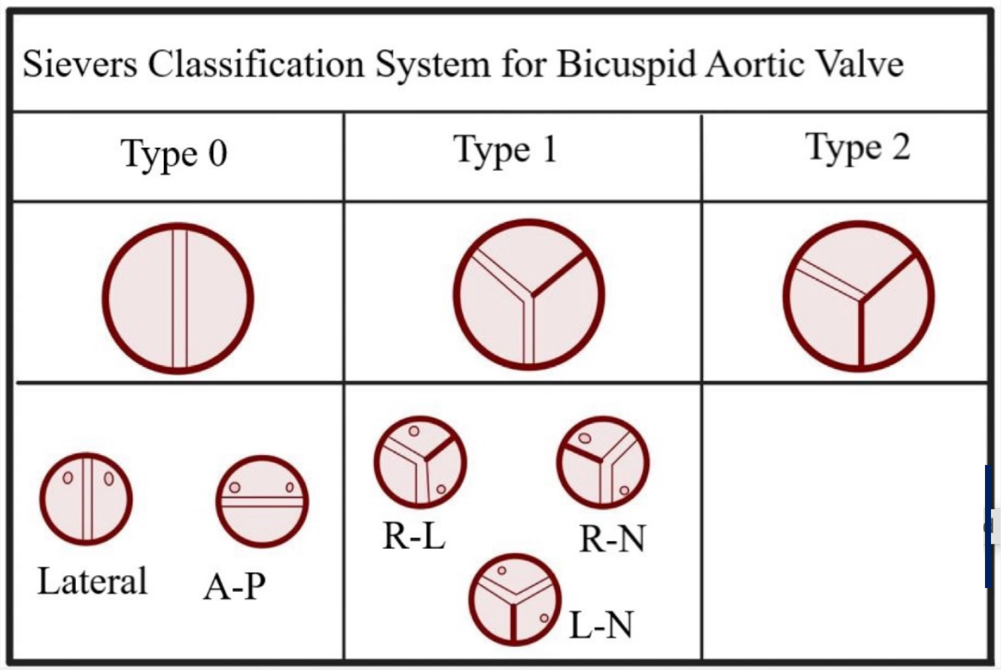




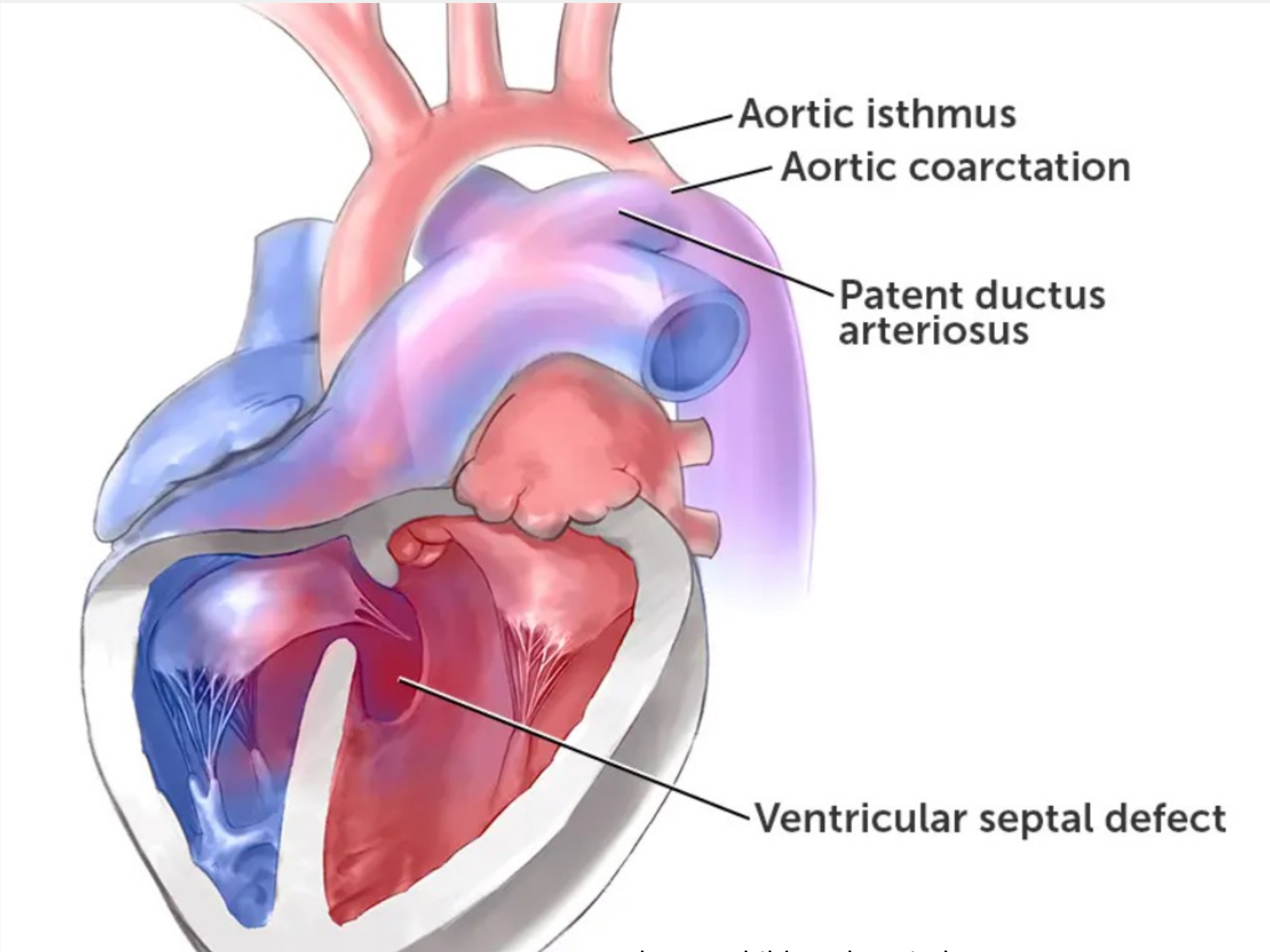
Augustin, et al. Circulation, 2006

Case: Re-coarctation with transverse arch hypoplasia

- 27yo F dx during pregnancy with RUE HTN
- Native anatomy: BAV, CoA, VSD, PDA



Bulut, et al. *J. Cardiovasc. Dev. Dis.* **2023**

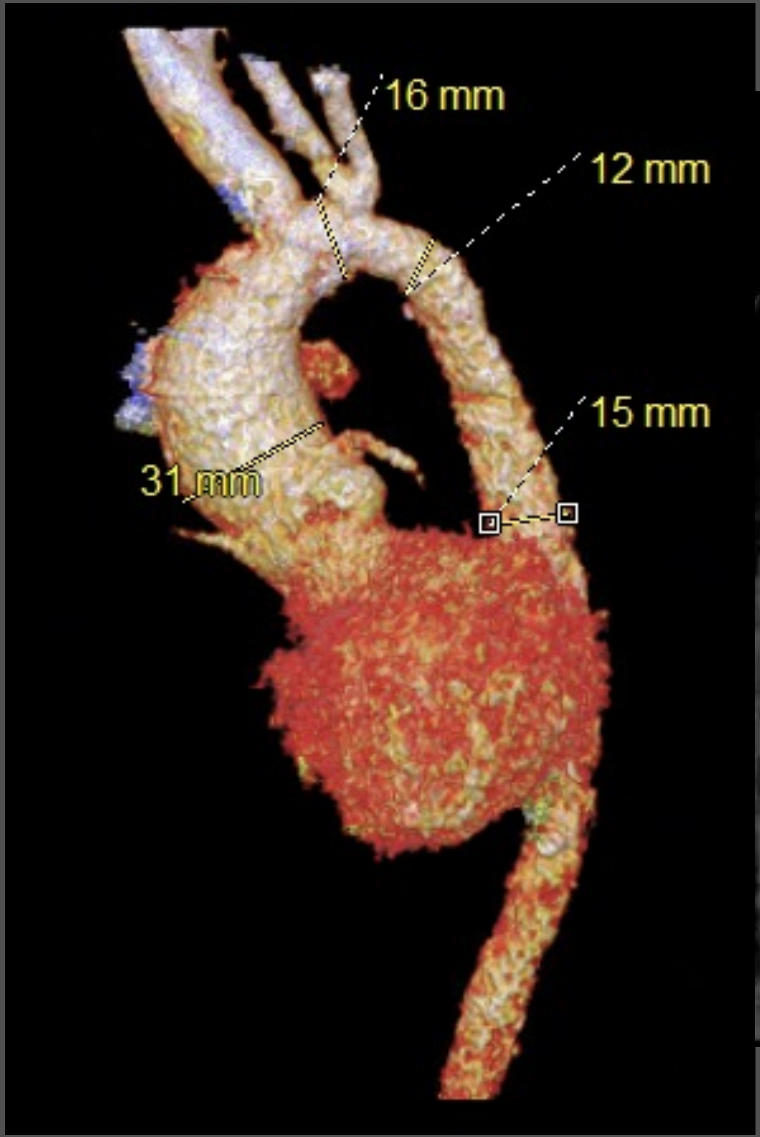


www.bostonchildrenshospital.org

Case, cont'd: Extra-anatomic Graft

- Surg #1: **end-to-end anastomosis**, PAB, PDA ligation
- Surg #2: PA-debanding, VSD patch closure, **patch angioplasty of residual coarctation**, L subclavian reimplanted on L carotid
- 20 mmHg BP gradient between RUE + LUE, RUE + LE
- Labetalol during pregnancy
- Urgent C/S @ 33w for diastolic HF symptoms, NSVT
- Surg #3: **20 mm Hemashield graft from AAo** to Dao
  - No change in gradient
  - Able to come off anti-HTN meds

Pre-op: Diffuse hypoplasia of transverse and descending aorta with re-coarctation at isthmus



Post-op: 20 mm Dacron graft from AAO to DAo

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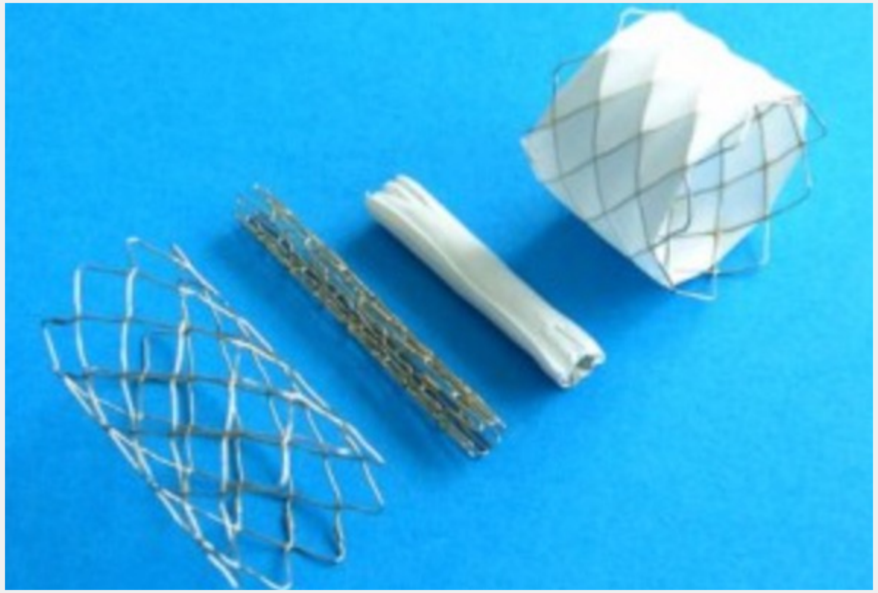
Percutaneous Coarctation Intervention

Balloon Angioplasty and Stenting

- Indication: Native or recurrent coarctation after surgical repair
- Procedure:
  - **Angioplasty** produces linear intimal and medial tears to increase lumen size; heals ~ 8 wks
  - **Bare metal or Balloon-expandable covered stents**
    - Support dilated segment; prevent restenosis (decrease recoil)
    - Covered stents protect fragile aortic tissue (Turner's, advanced age); may decrease risk of late aneurysm formation
      - More durable than angioplasty alone



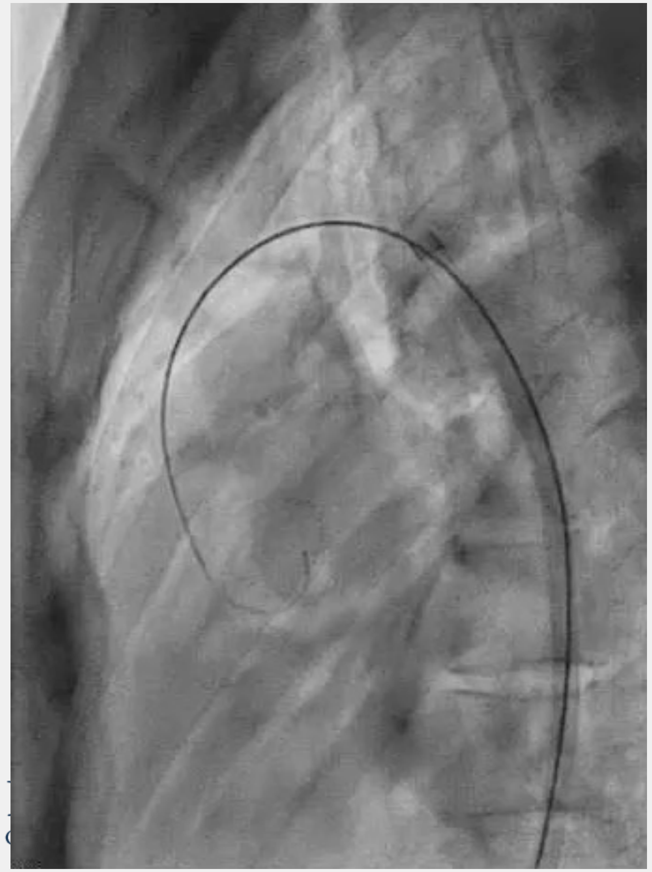
https://www.bvmmedical.com/Products/cp-stent/

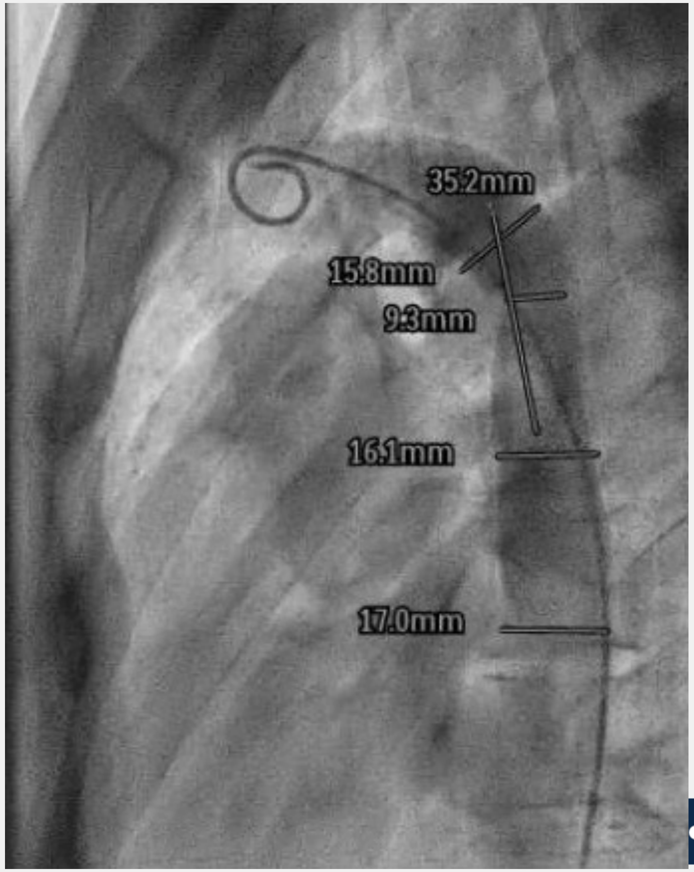
Case: Re-coarctation with angioplasty + stent

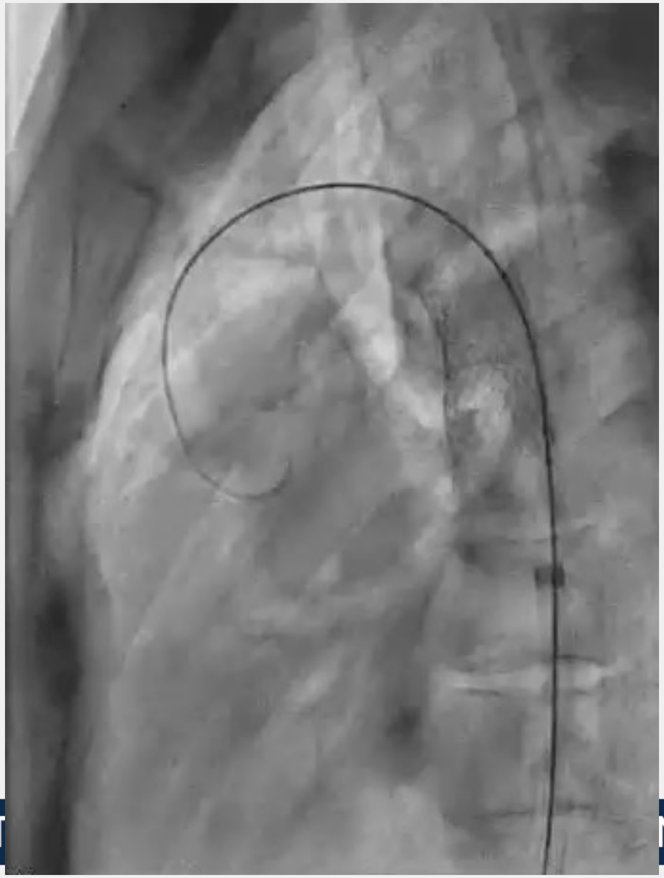
- 42 yo F with fatigue, exercise-induced HTN (SBP 241 mmHg), 30 mmHg resting gradient (echo)
- Native anatomy: BAV, VSD, coarctation of aorta

- Surg #1: L subclavian flap repair of coarctation, VSD closure (4 weeks)
- Surg #2: Patch angioplasty of residual coarctation, residual VSD closure

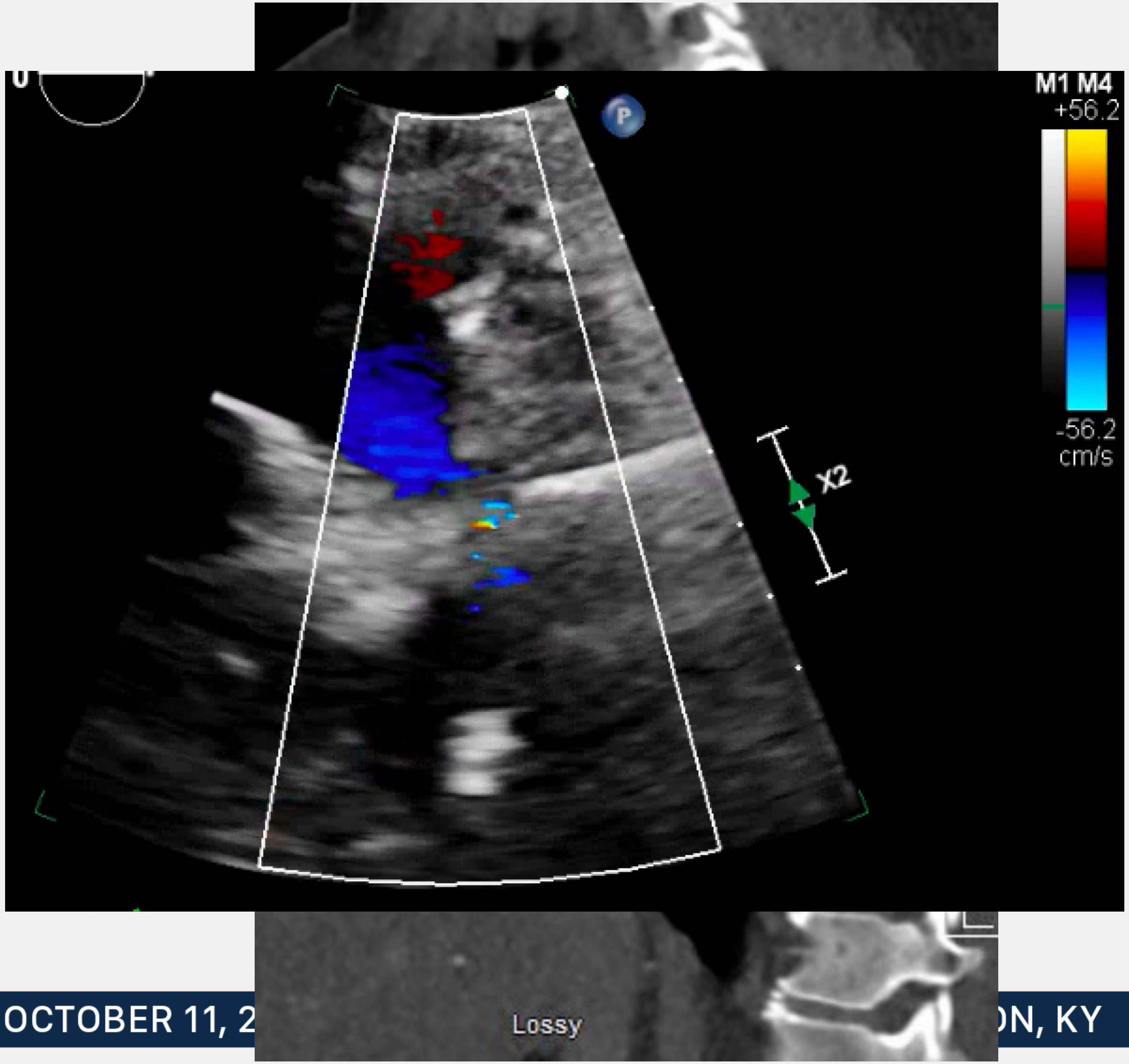
- Cath: Medtronic 36 mm EV 3 stent
- Post cath: AAO 118/54, DAo 117/52; Reported increased energy







Case of Congenital versus Acquired CoA



Congenital vs Acquired CoA

- CT + MRA w/calcified stricture in postductal region of aorta
- Cath under GA with 15 mmHg arch gradient, narrowing close to L subclavian → no procedure
- Referred to vascular surgery → Gore-TAG 28 x 15 mm aortic graft, 10 x 60 subclavian branch graft
- BP at follow up: <120/80 mmHg

Guidelines & Follow-Up

Circulation

Frequency of Routine Follow-Up and Testing	Physiological Stage C* (mo)	Physiological Stage D* (mo)
Outpatient ACHD cardiologist	6–12	3–6
ECG	12	12
TTE†	12	12
CMR‡/CCT§	12–24	12–24
Exercise test‖	24	12

COR	LOE	Recommendations
Diagnostic		
I	B-NR	1. Initial and follow-up aortic imaging using CMR or CTA is recommended in adults with coarctation of the aorta, including those who have had surgical or catheter intervention.[S4.2.6-1–S4.2.6-3]
I	C-EO	2. Resting blood pressure should be measured in upper and lower extremities in all adults with coarctation of the aorta.
Diagnostic		
IIa	C-LD	3. Ambulatory blood pressure monitoring in adults with coarctation of the aorta can be useful for diagnosis and management of hypertension.[S4.2.6-4]
IIb	B-NR	4. Screening for intracranial aneurysms by magnetic resonance angiography or CTA may be reasonable in adults with coarctation of the aorta.[S4.2.6-5,S4.2.6-6]
IIb	C-LD	5. Exercise testing to evaluate for exercise-induced hypertension may be reasonable in adults with coarctation of the aorta who exercise.[S4.2.6-4,S4.2.6-7]
Therapeutic		
I	B-NR	6. Surgical repair or catheter-based stenting is recommended for adults with hypertension and significant native or recurrent coarctation of the aorta.[S4.2.6-1,S4.2.6-2,S4.2.6-8–S4.2.6-12]
I	C-EO	7. GDMT is recommended for treatment of hypertension in patients with coarctation of the aorta.[S4.2.6-13]
IIb	B-NR	8. Balloon angioplasty for adults with native and recurrent coarctation of the aorta may be considered if stent placement is not feasible and surgical intervention is not an option.[S4.2.6-14]

Long-term Follow up of Pediatric Coarctation Repairs in Adulthood

- HPI
  - HTN
  - Claudication symptoms with exertion
  - Back pain, headaches
- Exam
  - 4 extremity BPs *every visit*
    - Manual LE BP with cuff around the calf, and using DP/PT pulse (manual or Doppler)
    - Upper-to-lower gradient > 20 mmHg considered suspicious for re-coarctation
  - Palpation of radial, femoral and/or DP/PT pulses and assessing for delay
    - If you start with radial and DP/PT pulses and feel a delay, you must check femoral pulses
    - Keep in mind prior L subclavian artery flap repair will result in absence of L radial pulse
    - Significant collateral formation may result in normal peripheral pulses, masking a radio-femoral delay
      - Collaterals may be audible as an interscapular murmur

Long-term follow up

- Imaging
  - Echo for LV systolic and diastolic function, reassessment of associated lesions (BAV, VSD repair, etc), aortic arch anatomy and gradient
    - Echo peak systolic gradient > 20 mmHg considered significant
  - CTA or MRA
    - Every 3-5 years or sooner for concerning clinical or echo findings suggestive of anatomic complications
- Exercise testing
  - Helpful in borderline cases of arch obstruction or pre-pregnancy assessment to unmask exercise-induced HTN – tx with GDMT, BB
  - Otherwise every 3-5 years on average
- Cardiac catheterization
  - Percutaneous intervention if peak-to-peak > 20 mmHg

Summary

- Coarctation of the aorta is not simply an isolated narrowing of the aorta
  - Systemic vasculopathy
- Surgical intervention in childhood requires life-long follow-up for:
  - Complications common to repair type →reoperation vs cath intervention
  - Associated vascular anomalies which may not develop until adulthood (Berry aneurysms, CAD)
  - Systemic HTN, even in absence of recurrent CoA
- 2018 ACC/AHA ACHD Guidelines provide recommended timing of follow-up and screening tests based on Anatomic and Physiologic Class

Talk 2: Gery Tomassoni

Pulsed Field Ablation (PFA) In Atrial Fibrillation (AF)

Gery Tomassoni, MD, FACC, FHRS

Chairman of CVSL, Vice President of Research,

Director of Electrophysiology

Financial Disclosures

Atricure, Inc., Relationship: Honoraria/Speaking/Consulting Fee, Membership on Advisory Committees or Review Panels

Zoll Medical Corporation, Relationship: Honoraria/Speaking/Consulting Fee, Membership on Advisory Committees or Review Panels

Abbott, Relationship: Honoraria/Speaking/Consulting Fee.

Vektor Medical, Inc., Relationship: Honoraria/Speaking/Consulting Fee, Membership on Advisory Committees or Review Panels.

Impulse Dynamics USA, Relationship: Honoraria/Speaking/Consulting Fee, Membership on Advisory Committees or Review Panels

Boston Scientific, Relationship: Honoraria/Speaking/Consulting Fee.

Orchestra Biomed, Relationship: Stock Options – Privately Held (including start-up companies)

Haemonetics, Relationship: Honoraria/Speaking/Consulting Fee, Role: Membership on Advisory Committees or Review Panels

S4 Medical, Relationship: Stock Options – Privately Held, Role: Consulting

PFA Discussion

Present day issues with AF management

Definition of Pulsed Field Electroporation

- Waveform & Catheter Variables
- Potential benefits over RFA

Available PFA systems

Efficacy & Safety (PAF & Persistent AF)

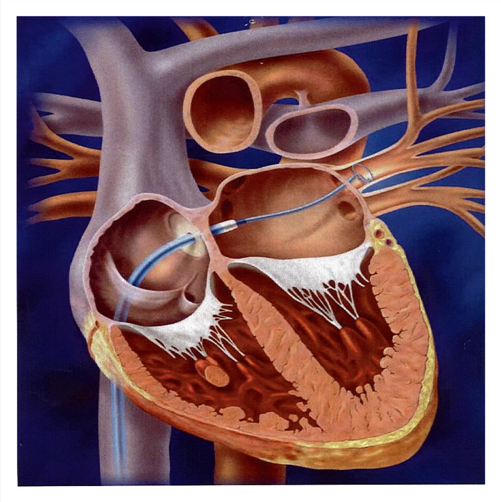
Unexpected specific adverse events

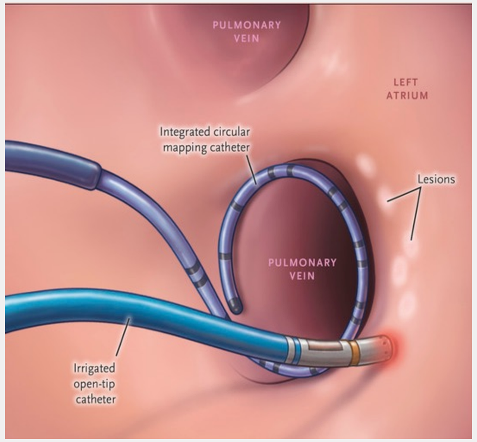
Future/next steps

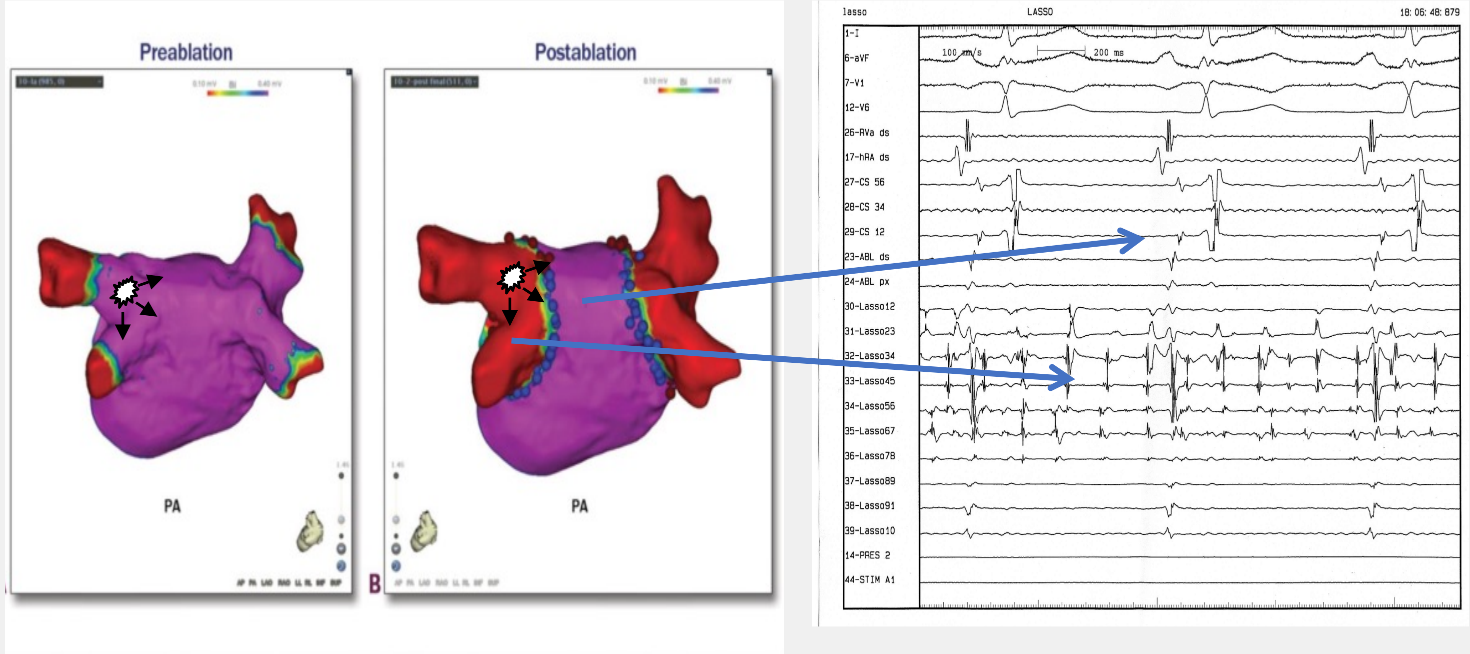
Treatment Strategies for AF

Medications vs Radiofrequency Catheter Ablation (RFCA)

Medications only successful ~ 33% of patients, high rate of side effects, & can be proarrhythmic



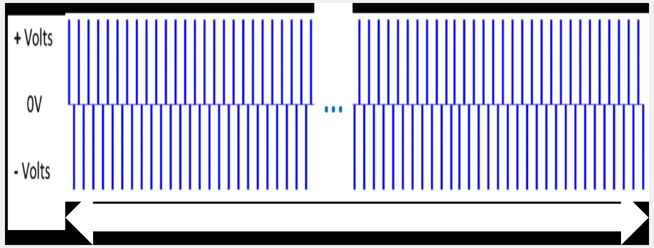




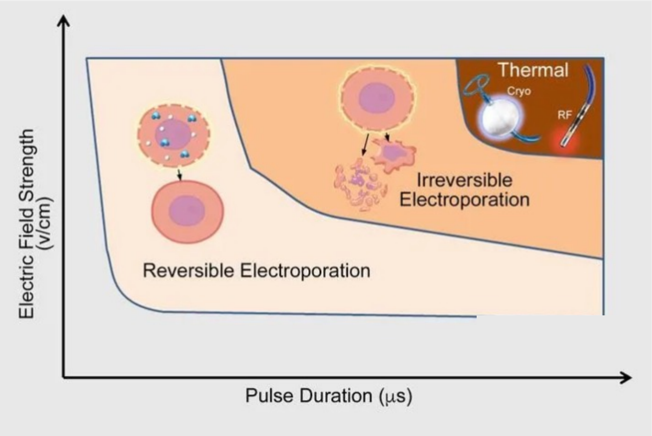
Current Issues with RFCA of AF

- Long procedural time (2-4 hrs)
- Energy not limited to cardiac tissue (complications: esophagus ulcers/fistula, lung/pleurisy, phrenic nerve palsy, pulmonary vein stenosis)
- Frequent post-operative symptoms (GI, CP, SOB)
- Two transeptal punctures needed
- Point-by-point ablation
  - AF recurrence rates after single procedure can be high (10-30%)
  - Success/complication rates ***highly-dependent*** on skill level of the operator
- Patient access to EP limited by small number of cases done daily
  - Earlier ablation in AF course better long-term (5 & 10 year) success with less recurrence

PFA



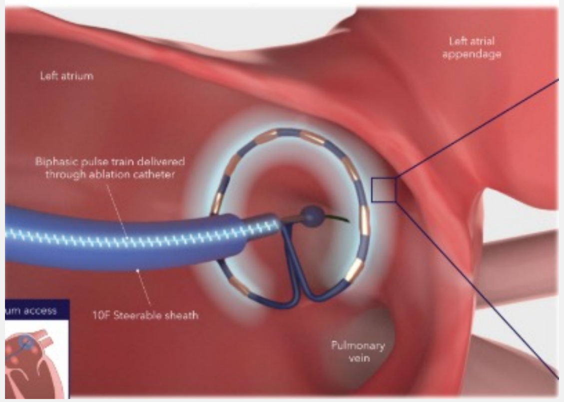
Non-thermal energy delivered as rapid **high voltage (2 kV)** electric pulses to ablate cardiac tissue through the mechanism of irreversible electroporation.



Electroporation: The mechanism of killing tissue through exposure to high electric field gradients that induce a permanent, hyper-permeabilization of the cell membranes, leading to cell death.

- Creates tiny pores in the cell membrane of **targeted cardiac cells**
- Pores are fatal to the cardiac cells while sparing surrounding tissues from heat or cold damage

Energy delivered via different catheter electrode designs (pentaspline, sphere, globe, circular/lasso)



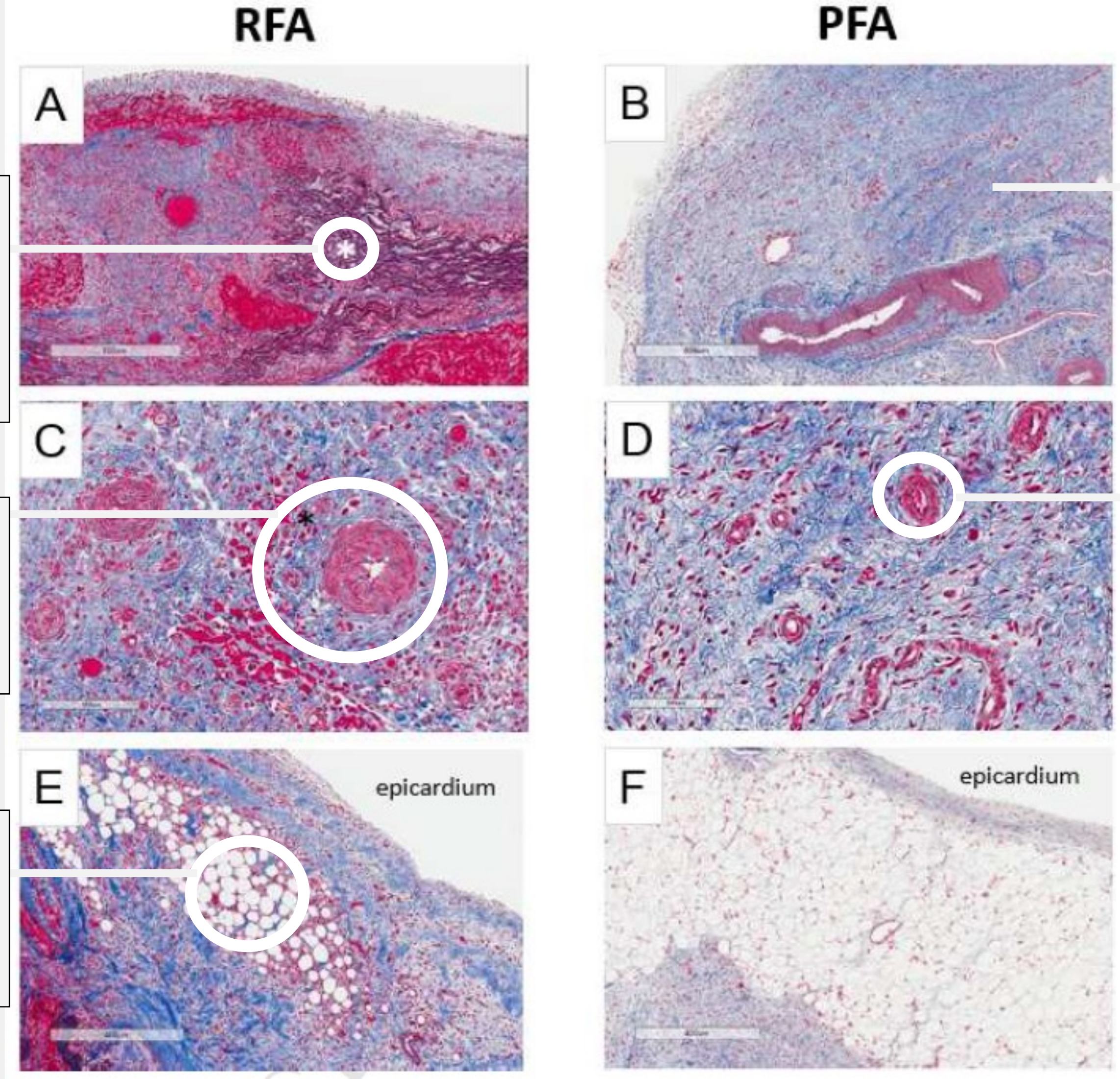
Sugrue, A, et al. Cardiac ablation with pulsed electric fields: principles and biophysics. EP Europace 2022.

Reduced collateral damage of PFA compared to RFA

RF: myocardial sequesters, hemorrhage and thrombosis present in cardiac tissue.

RF: remodeled arterioles, interstitial hemorrhage

RF: Fibrosis and lipogranulomatous inflammation



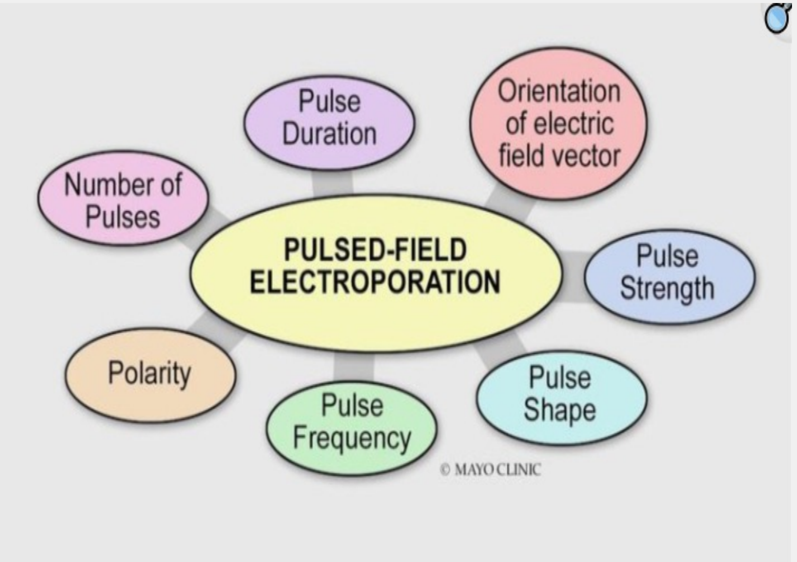
PFA:
homogenous fibrosis
normal patent vessels

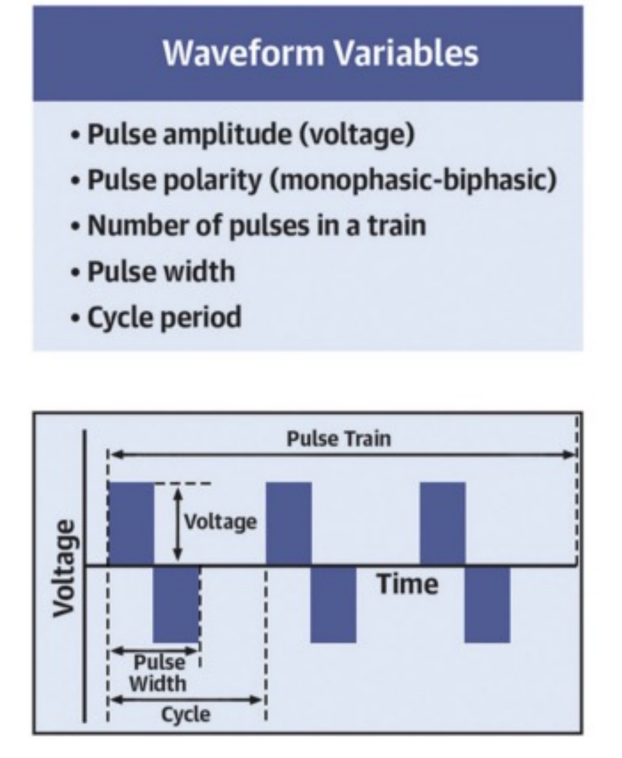
PFA:
normal arterioles
no hemorrhage

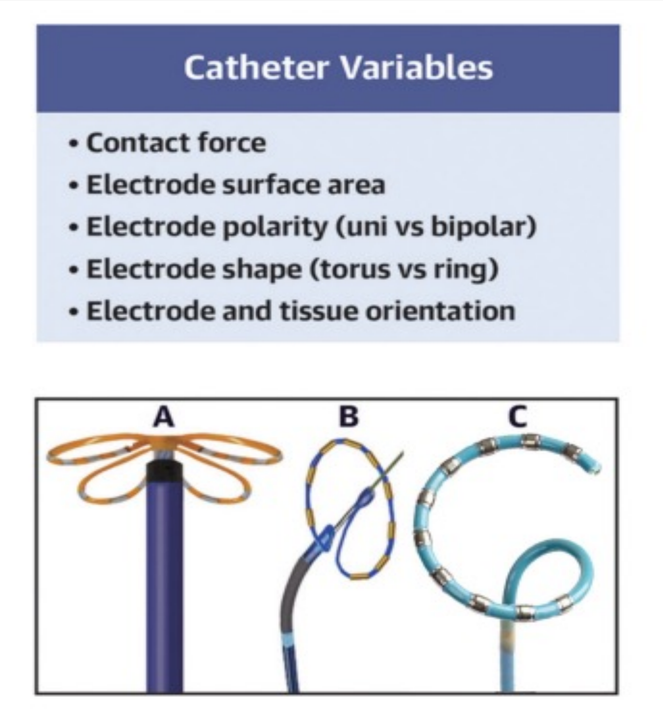
PFA:
normal epicardial fat

[1]Stewart MT, et al. Intracardiac Pulsed Field Ablation: Proof of Feasibility in a Chronic Porcine Model. Heart Rhythm 2019;16:754–764

PF Electroporation Effect







Ezzeddine FM, at al. Pulsed Field Ablation: A comprehensive Update. J Clin Med. 2024 Sep 1;13(17): 5191. doi.

Potential benefits of PFA over RFA

Ablation lesions more predictable, contiguous, transmural, & does not require perfect electrode-tissue contact

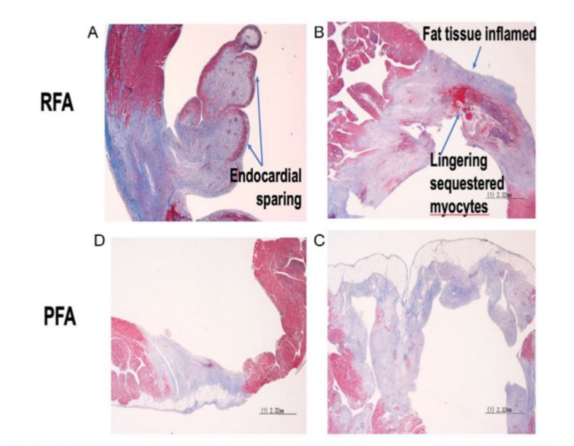
- Procedure less dependent on skill level of operator
- Lower AF recurrence, higher success

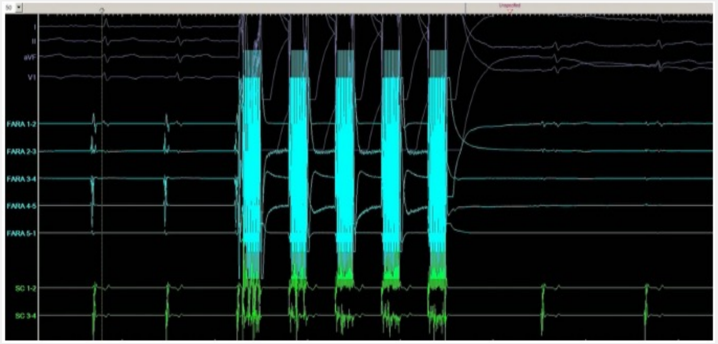
Delivers energy (high voltage 2 kV) as a single pulse over a large area

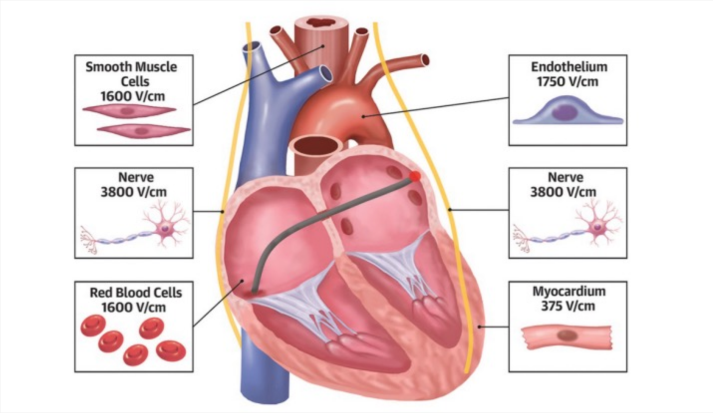
- Shorter procedural & anesthesia times, quicker pt recovery

Cardioselective: Minimal to no effect to surrounding structures: esophagus, lung, nerve, arteries, pulmonary veins

- Less post-operative symptoms (CP, SOB, GI disturbances)

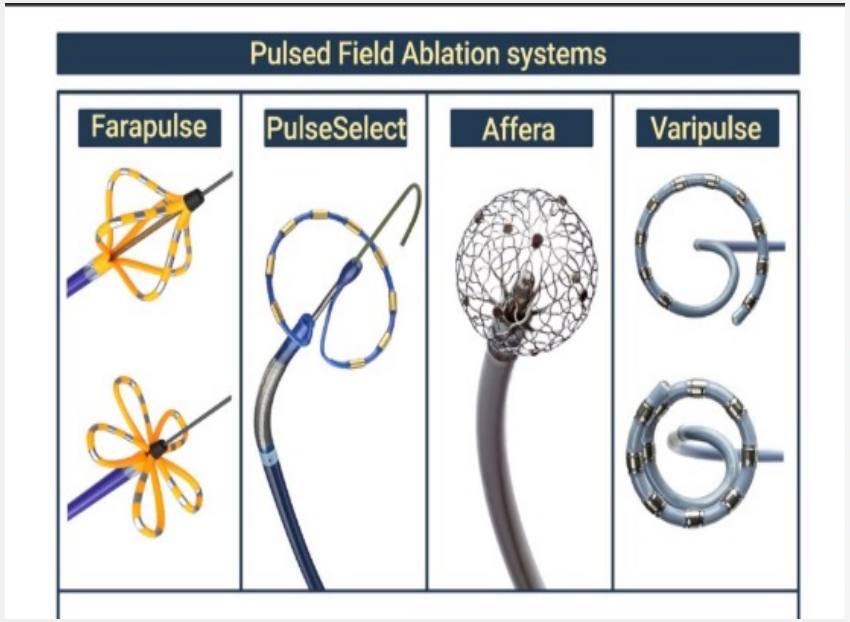


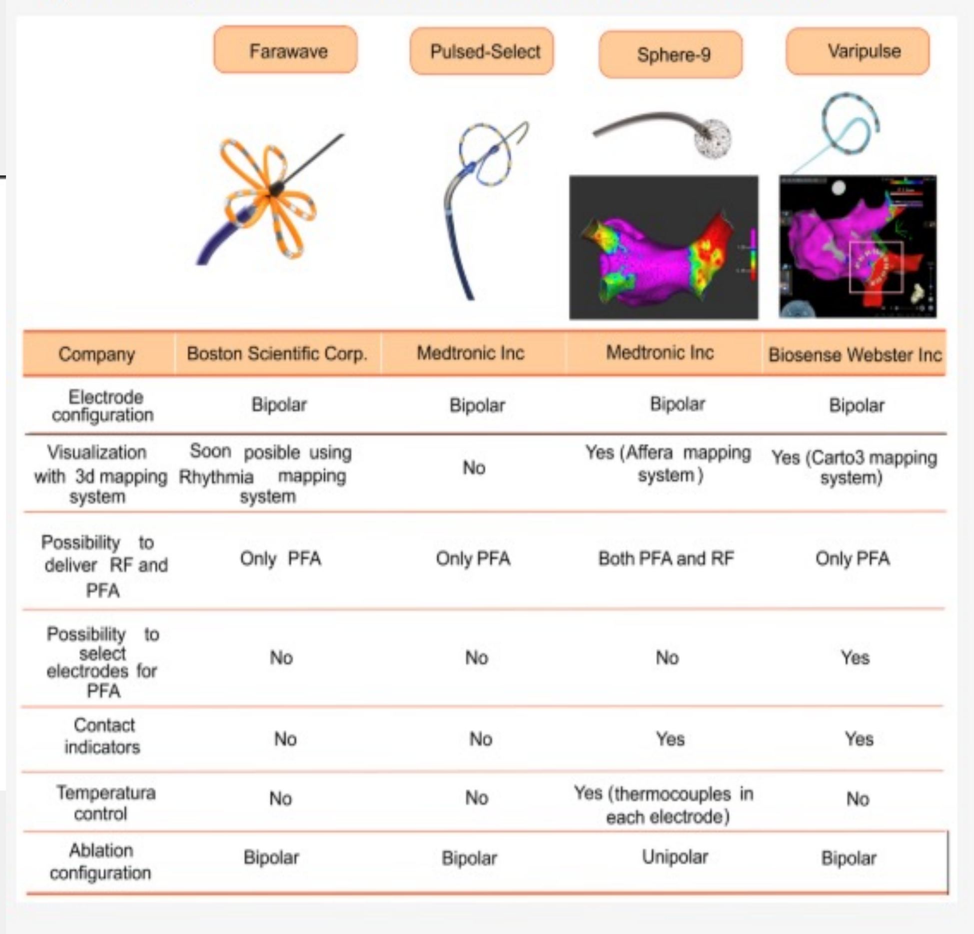




Ezzeddine FM, at al. Pulsed Field Ablation: A comprehensive Update. J Clin Med. 2024 Sep 1;13(17): 5191. doi.

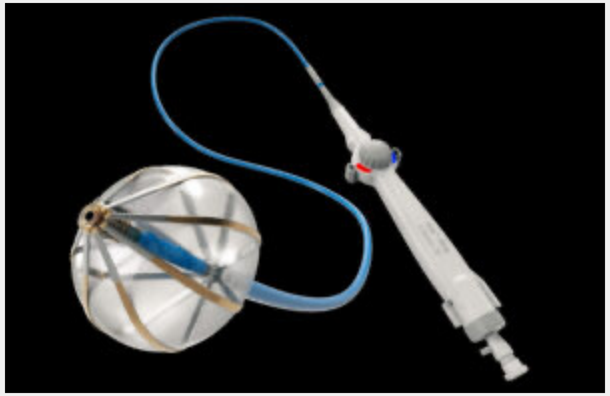
PFA Systems





	Farawave	Pulsed-Select	Sphere-9	Varipulse
Company	Boston Scientific Corp.	Medtronic Inc	Medtronic Inc	Biosense Webster Inc
Electrode configuration	Bipolar	Bipolar	Bipolar	Bipolar
Visualization with 3d mapping system	Soon posible using Rhythmia mapping system	No	Yes (Affera mapping system)	Yes (Carto3 mapping system)
Possibility to deliver RF and PFA	Only PFA	Only PFA	Both PFA and RF	Only PFA
Possibility to select electrodes for PFA	No	No	No	Yes
Contact indicators	No	No	Yes	Yes
Temperatura control	No	No	Yes (thermocouples in each electrode)	No
Ablation configuration	Bipolar	Bipolar	Unipolar	Bipolar

Kardium Globe System: FDA approval 9/2025



Volt PFA Catheter (awaiting FDA approval)

Carta-Bergaa A, et al. Pulsed Field Ablation of Atrial Fibrillation: A novel technology for safer and faster ablation. Biomedicines September 2024. 12(10) 2232.
Lyengar SK, at al. The promise of pulsed field ablation and the challenges ahead. Frontiers in Cardiovascular Medicine. October 2023.

Advent Trial

Drug-refractory paroxysmal atrial fibrillation in a 1:1 ratio to undergo PFA or conventional RF or cryoballoon ablation

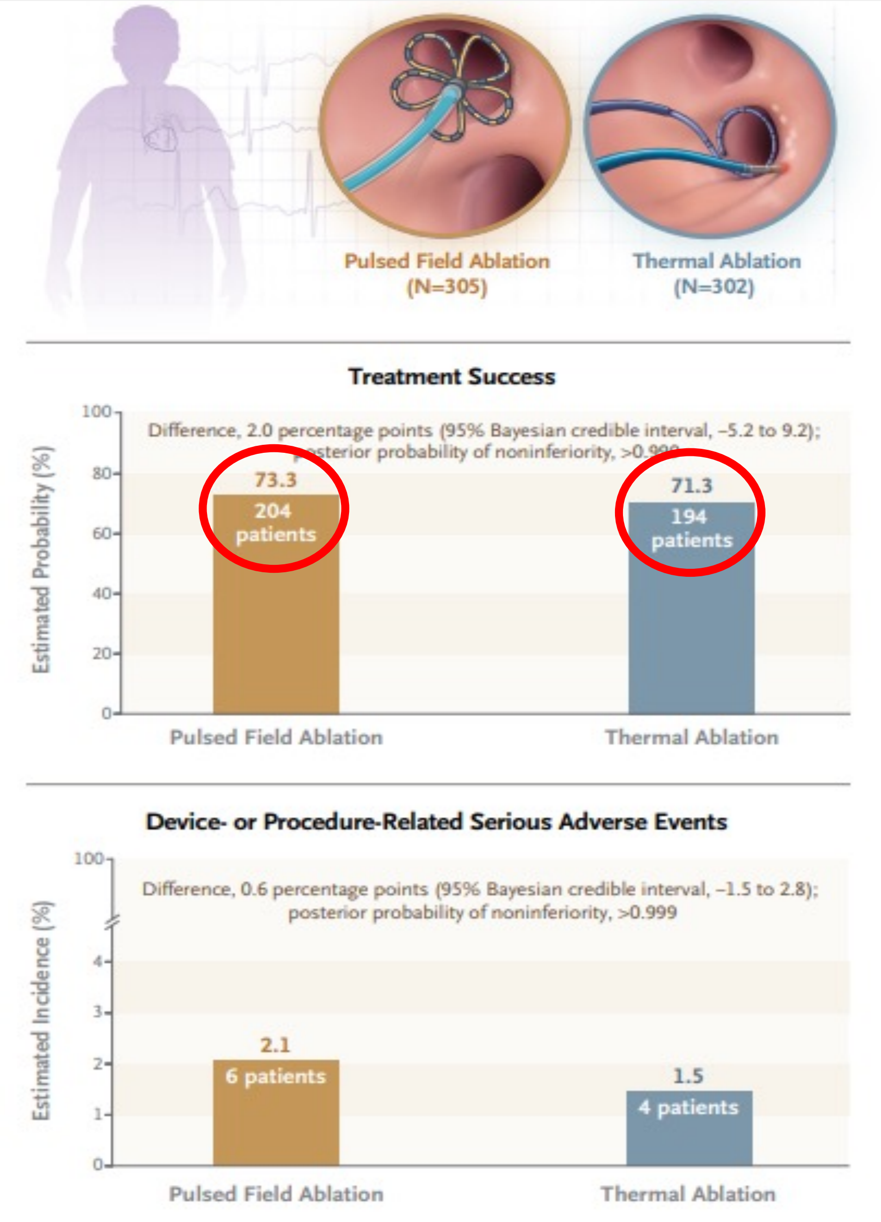
PVI: Farapulse pentasline catheter (Farawave) vs. a commercially available saline-irrigated, contact force–sensing catheter or cryoballoon catheter

Holter monitoring at 6 & 12M with TTM

No difference in treatment success or complications

1 TIA with PFA

Zero PV stenosis, PN palsy, or AE fistula



Reddy V, et al. Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation. NEJM August 2023;389:1660-1671

PulseSelect™ pulsed field ablation system for the treatment of patients with paroxysmal or persistent atrial fibrillation

Trial design & study population

Paired single arm. Prospective, non-randomized clinical study

Global multicenter study

- **9 countries**
- **41 sites**
- **67 operators**

300 patients treated

150 Paroxysmal
150 Persistent

Symptomatic AF patients refractory to class I or III AADs

96% (287) of patients completed 12-month follow up

Over-the-wire, 9 electrode, 9Fr, Bidirectional, loop-shaped design

Safety outcomes

0 Esophageal
events 0 PV
stenosis

0 Phrenic nerve injury

0/300 Vagal nerve injury
0/300 Vascular access complications
0/300 Cardiovascular Hospitalization
0/300 Death
0/300 pulmonary edema
0/300 systemic pulmonary embolism

Safet
0.7%
Primary adverse events

Procedural data

	PAF	PsAF
Time between first and last application (min)	58±28	64±28
Total pulsed field ablation energy delivery (sec)	25±8	29±10

Rigorous arrhythmia monitoring

1 2 3 4 5 6 7 8 9 10 11 12

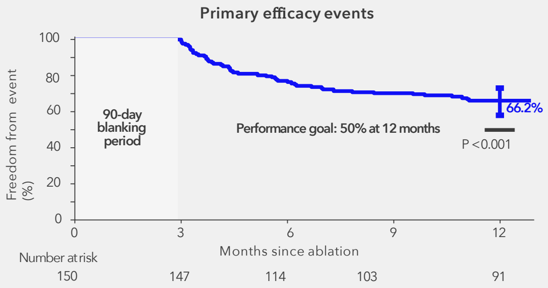
3-month ECG
6-month ECG
24-hour Holter monitoring
12-month ECG
24-hour Holter monitoring

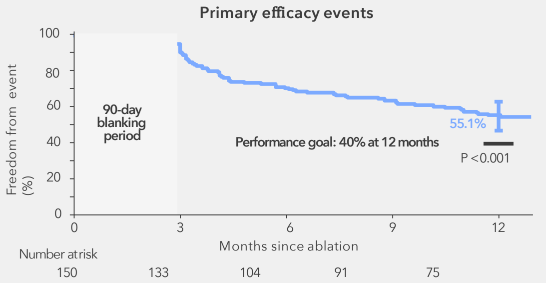
Weekly and symptomatic trans-telephonic monitoring

Efficacy outcomes

80% PAF
81% PsAF
Freedom from symptomatic AF/AT/AFL

70% PAF
62% PsAF
Freedom from AF/AT/AFL





Acute procedure failure, AF/AFL/AT recurrence, cardioversion, repeat ablation, new/re-initiated/increased AADs, any subsequent AF surgery

Verma, A, et al. Pulsed field ablation for the treatment of atrial fibrillation: PULSED AF pivotal trial. Circulation 147.19 (2023): 1422-1432.

Advantage Trial

Prospective, single-arm, multicenter pivotal investigational device exemption study of Persistent AF patients undergoing PVI+PWA with the pentaspline PFA catheter.

12M follow-up: 24-hour Holter monitoring at 6 and 12 months and twice monthly and symptomatic TTM

Primary composite effectiveness endpoint: acute ablation success and freedom from the following: documented recurrence of AF/AFL/atrial tachycardia (AT) of ≥30 seconds, re-ablation for AF/AFL/AT, any electrical cardioversion for AF/AFL/AT, and use of new or escalated doses of class I/III AADs or amiodarone.

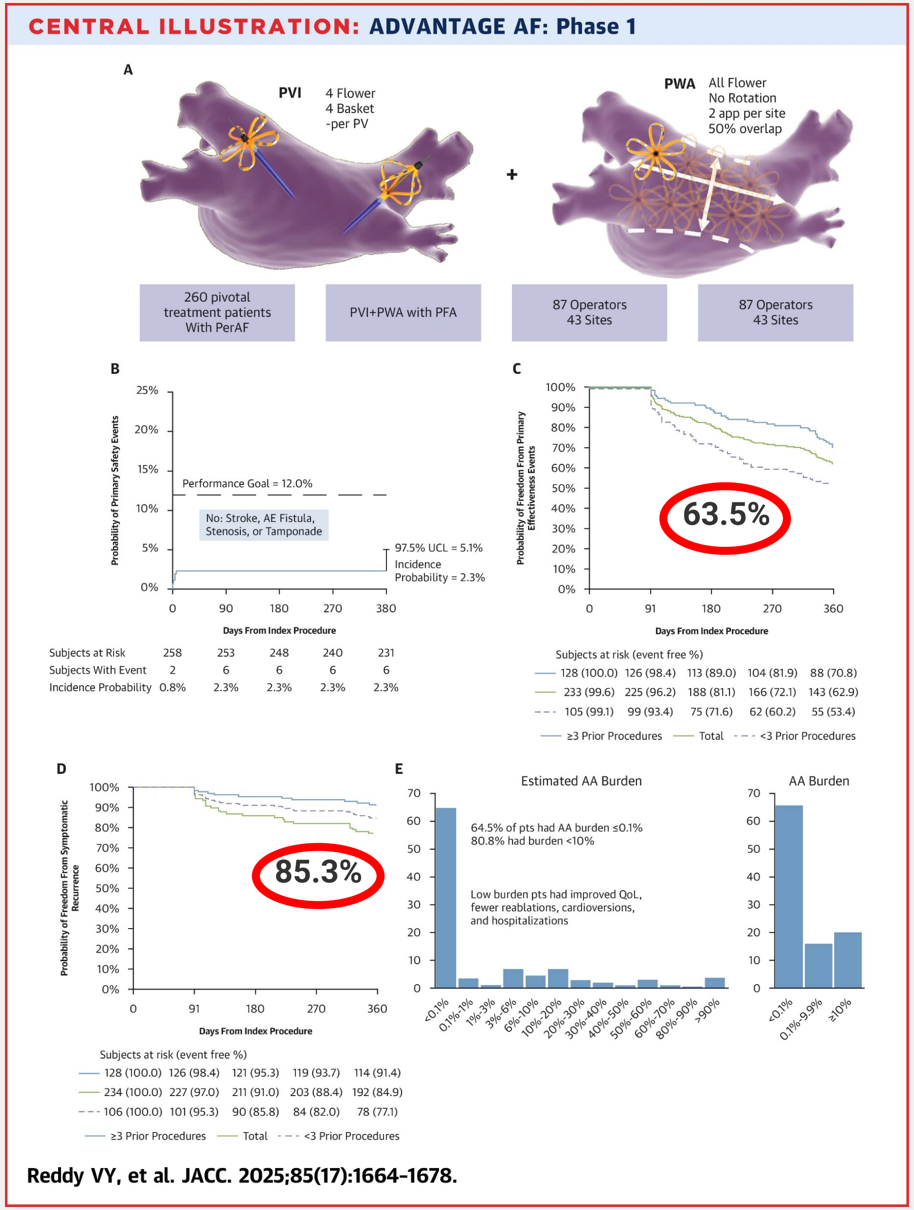
Acute PVI success: 99.6%   Acute PW isolation: 100%

Primary safety endpoint: 2.3% including

1 pericarditis, 1 MI, 4 pulmonary edema;

no tamponade, stroke, PV stenosis, or esophageal fistula occurred

AA Burden: low burden (<10%) had better QoL, less procedures



Vivek Y. Reddy et al. Pulsed Field Ablation for Persistent Atrial Fibrillation: 1-Year Results of ADVANTAGE AF. *JACC* April 2025; 85:1664-1678.

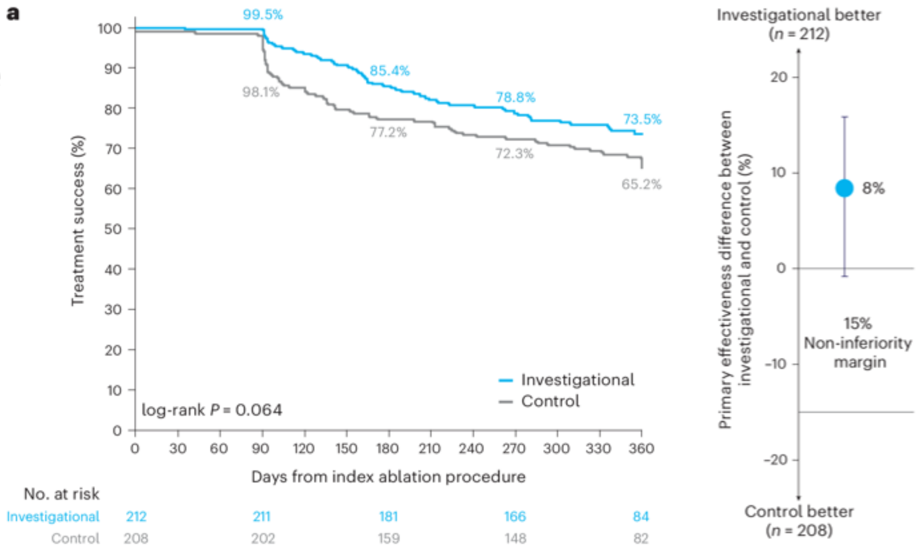
SPHERE Per-AF Pivotal IDE Results

Purpose: To evaluate the safety and effectiveness of the Sphere-9 Catheter with Affera Mapping and Ablation system for the treatment of persistent AF

Design: Prospective, global, multicenter, randomized (1:1) study (212 Sphere-9, 208 THERMOCOOL SMARTTOUCH SF)

Effectiveness

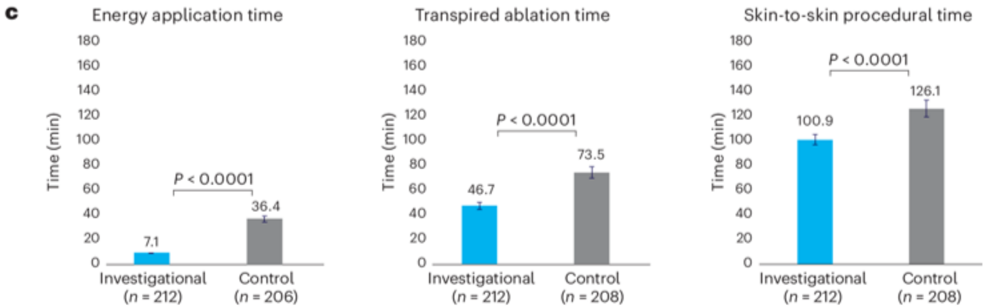
Freedom from **primary effectiveness endpoint** failure was **73.8%** in the investigational arm and **65.8%** in the control arm (difference: **8.0%** [95% CI, -0.9 to 16.8]). Treatment with Sphere-9 was **non-inferior** compared to the control (*p*<0.0001) with respect to effectiveness.



Safety

Primary safety events were observed in **1.4%** vs **1.0%** of the investigational and control groups, respectively. Treatment with Sphere-9 was **noninferior** compared to the control (p<0.0001) with respect to safety.

- No coronary artery spasm reported
- No atrio-esophageal fistula
- No phrenic nerve paralysis



29 mins less **27 mins less** **25 mins less**

Efficiency

Treatment with the investigational device resulted in a **statistically significant decrease** in **procedural times** compared to the control.

Additional Procedural Characteristics

Effectiveness Endpoints	Sphere-9	Control
Fluoroscopy time (min)	4.9 ± 6.6	6.3 ± 9.1
PVI time (min)	25.9 ± 10.7	53.6 ± 28.8
Total fluid delivered (ml)	482.0 ±142.6	727.1 ± 378.7
>1 transseptal access	4.7%	38.0%
>1 mapping and/or ablation catheter used in LA	2.8%	98.1%

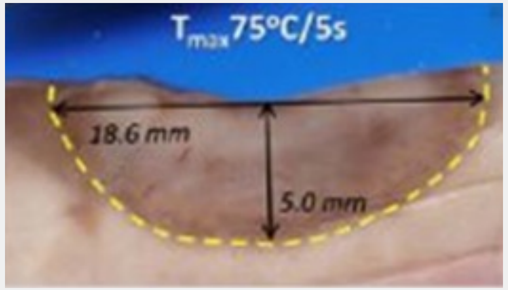
Anter E, et al. Dual-energy lattice-tip ablation system for persistent AF: a randomized trial. Nature Medicine May 2024;30:2303-2310.

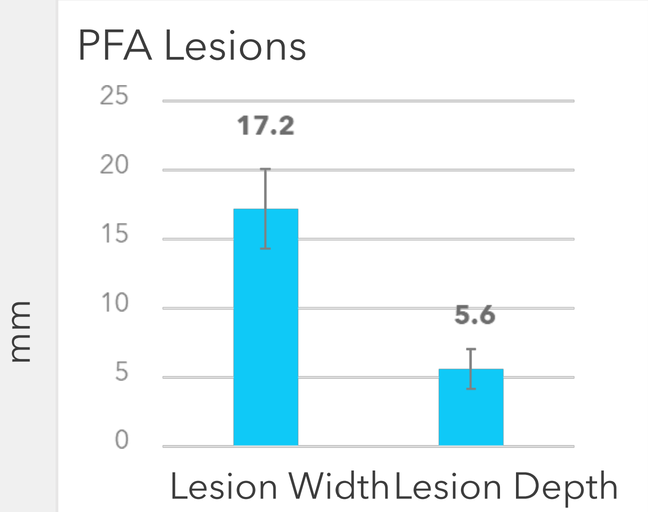
Affera Sphere-9 Catheter

Key Principles of Wide Area Focal Ablation

RFA Lesions

Sphere-9 RF: Thigh Prep



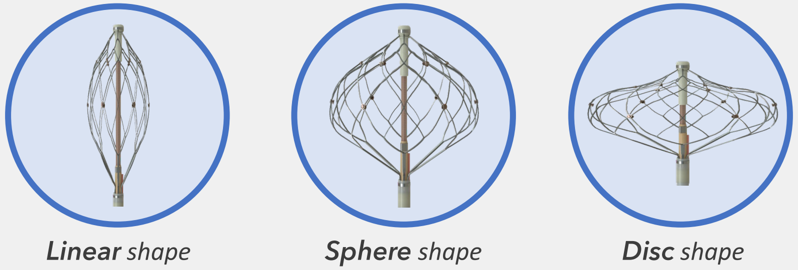


Radiofrequency Mode

- Temperature controlled RF delivery
- Ablation electrode has effective surface area 10x larger than standard irrigated ablation catheters[1]
- Lattice behaves as continuous conductive electrode and delivers wider lesions than 3.5mm catheter (18.7±3.3 vs 12.2±1.7 mm)

Pulsed Field Mode

- Delivers proprietary unipolar, biphasic waveform to cause cell death by irreversible electroporation
- As with RF, entire ablation electrode delivers PFA energy
- Consists of a train of microsecond-scale pulses

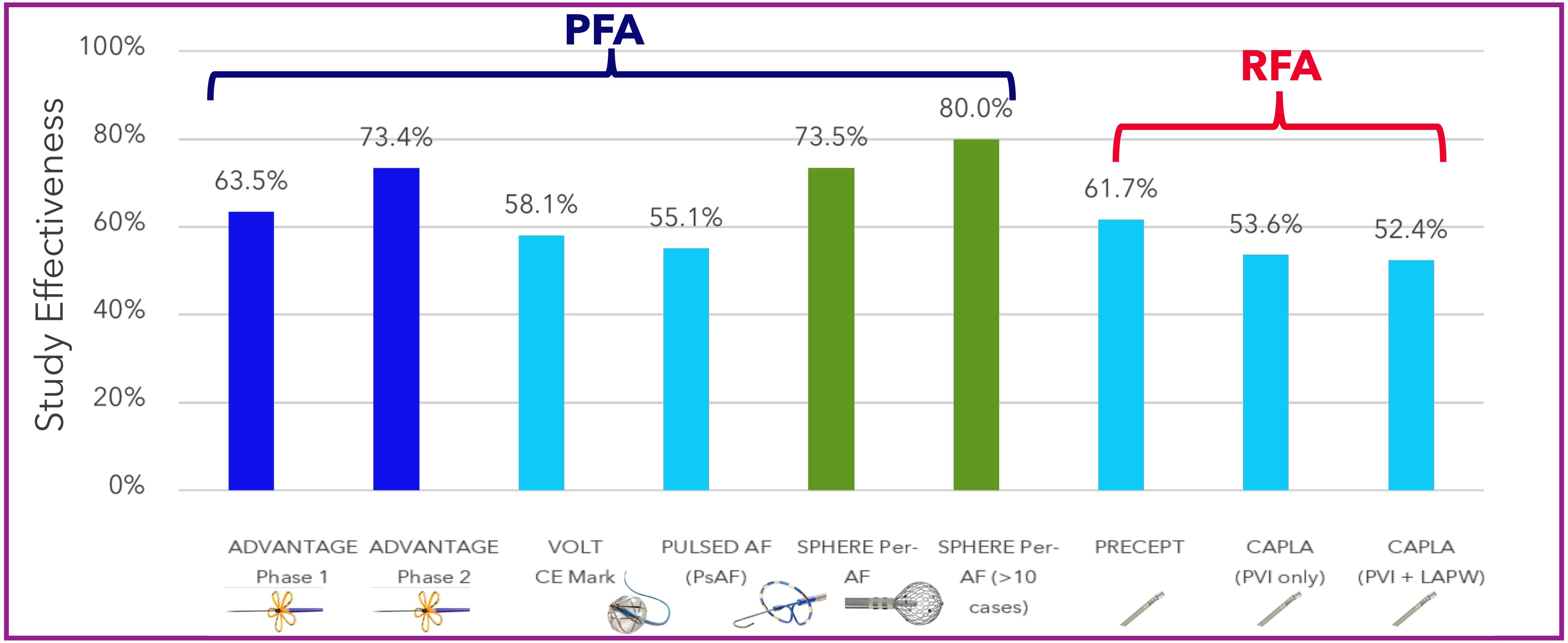


Expand/collapse to various shapes

1. M Barkagan et al. Expandable lattice electrode ablation catheter: a novel RF platform allowing high current at low density for rapid, titratable, and durable lesions. Circ A&E 2019. DOI 10.1161/ CIRCEP.118.007090.
2. HD Yavin et al. PFA in ventricular myocardium using a focal catheter: the impact of application repetition on lesion dimensions. Circ A&E 2021. DOI 10.1161/CIRCEP.121.010375.

Persistent AF Ablation Studies

Primary effectiveness rates*



Reddy VY, et al. One-Year Results of ADVANTAGE AF. J Am Coll Cardiol. 2025;85(17):1664-1678. doi: 10.1016/j.jacc.2025.03.515.

Reddy VY, et al. ADVANTAGE AF-Phase 2. Circulation. 2025 24. doi: 10.1161/CIRCULATIONAHA.125.074485.

Verma Aet al. PULSED AF Pivotal Trial. Circulation. 2023;147(19):1422-1432. doi: 10.1161/CIRCULATIONAHA.123.063988.

Anter E, et al. SPHERE PER-AF pivotal trial. Nat Med. 2024;30(8):2303-2310. doi: 10.1038/s41591-024-03022-6.

Mansour M, et al. The Prospective Multicenter PRECEPT Trial. JACC Clin Electrophysiol. 2020;6(8):958-969. doi: 10.1016/j.jacep.2020.04.024.

Kistler PM, et al. The CAPLA Randomized Clinical Trial. JAMA. 2023;329(2):127-135. doi: 10.1001/jama.2022.23722

* Results not adjusted for differences in patient population and trial design

FARAPULSE CLINICAL STUDIES

REAL-WORLD EXPERIENCE

MANIFEST PF
MANIFEST 17K

EUROPEAN REGISTRIES

FARADISE
FARAVERSE

GLOBAL REGISTRIES

DISRUPT AF
MANIFEST US

US REGISTRIES

>200k commercial patients treated with FARAWAVE

CLINICAL TRIALS

ADVENT

PAROXYSMAL PATIENTS
FIRST RCT PFA v THERMAL
FARAWAVE TO MARKET

ADVANTAGE

DRUG-REFRACTORY PERS AF
INDICATION EXPANSION
FARAPOINT TO MARKET

AVANT GUARD

1st LINE PERSISTENT AF
FIRST RCT PFA v AADs
INDICATION EXPANSION

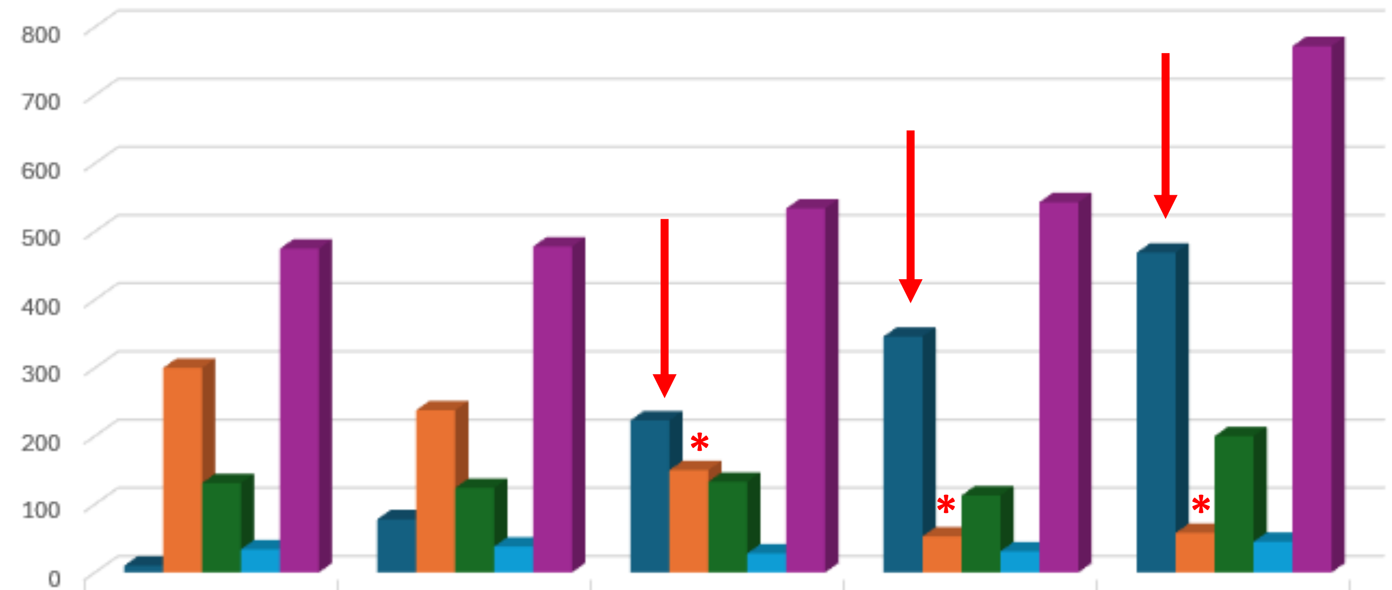
2020 2021 2022 2023 2024 2025

PFA Effect on Clinical Volumes

Cardiac Ablation Volumes
63% increase in total ablations FY25 Qtr2 vs FY24 Qtr2

4 Baptist EP centers in KY

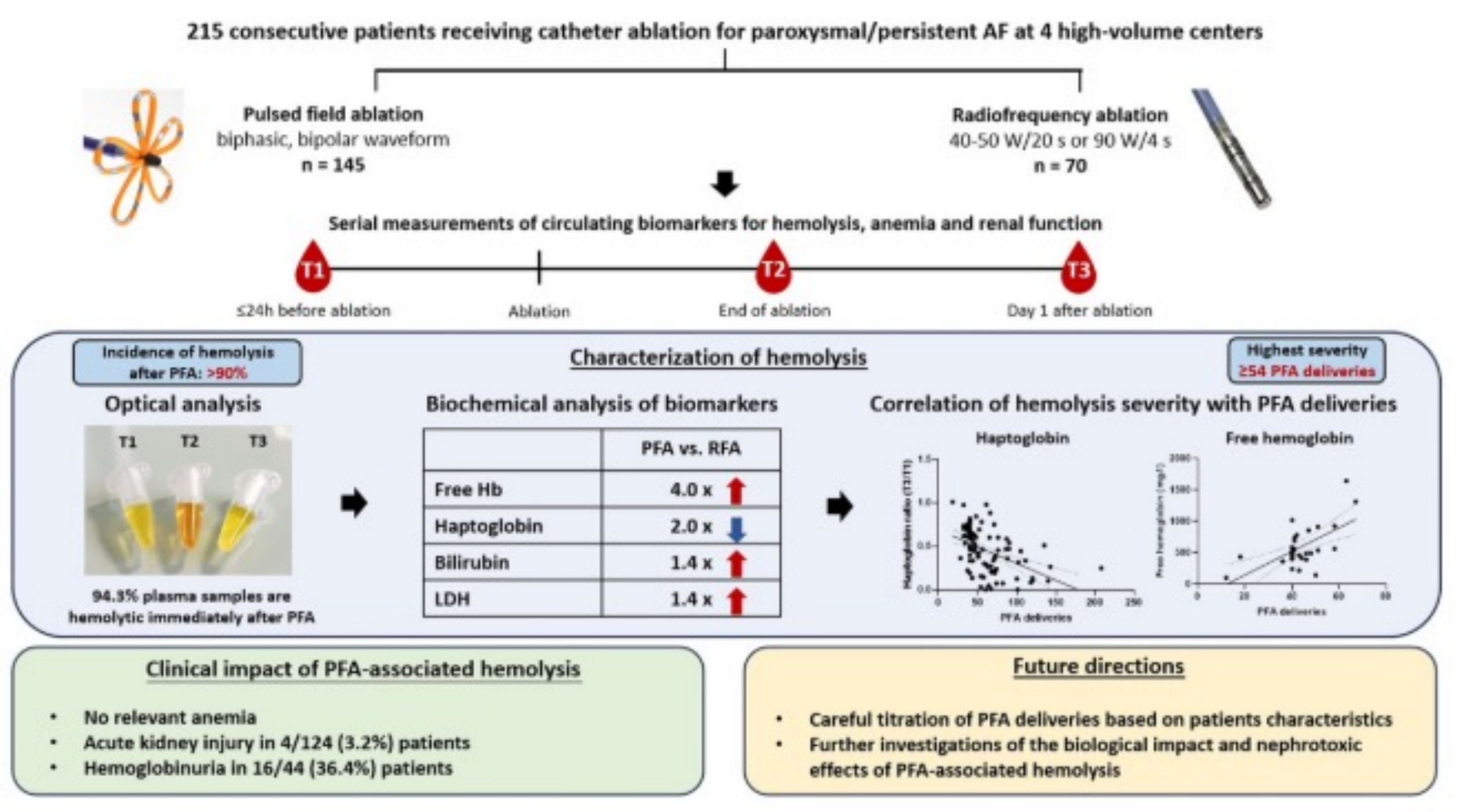
BAPTIST HEALTH -Cardiac Ablations



	FY24QTR2	FY24QTR3	FY24QTR4	FY25QTR1	FY25QTR2
PFA	10	78	223	346	469
* PVA	300	238	150	53	58
SVT	131	124	133	113	200
VT	34	38	28	31	45
Total	475	478	534	543	772

PFA PVA SVT VT Total

PFA Effect on Hemolysis/Renal function



Minimize # of PFA deliveries esp. in pts with GFR < 50 ml/min

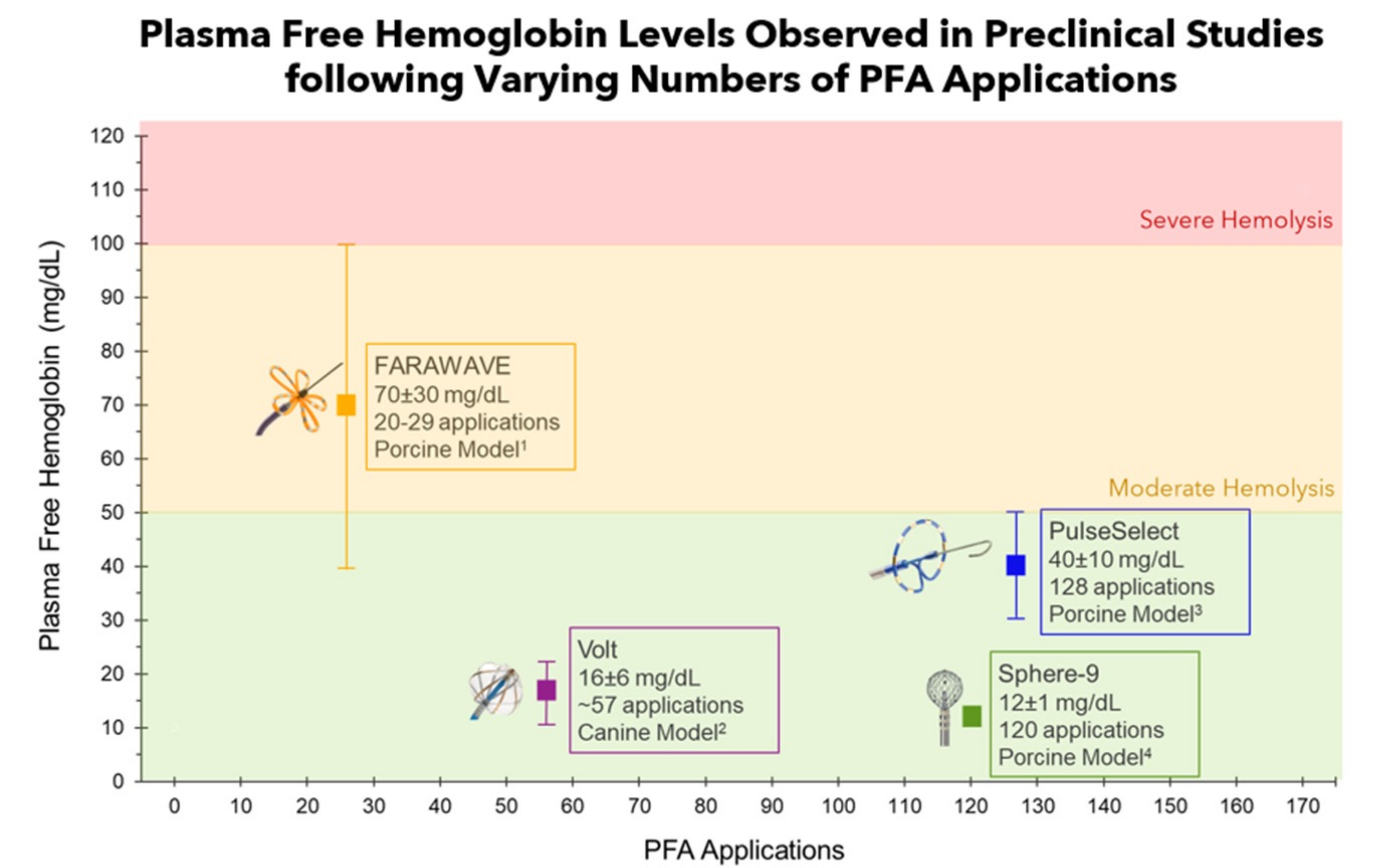
Tissue contact with catheter critical to avoid intravascular hemolysis

IV hydration for pts with preexisting renal disease or # of PFA deliveries > 70

Popa ME. et al. Characterization and clinical significance of hemolysis after PFA for atrial fibrillation: Results of a multicenter analysis. Circulation October 2024. 17(10).

Severity of Hemolysis with PFA in Preclinical Models

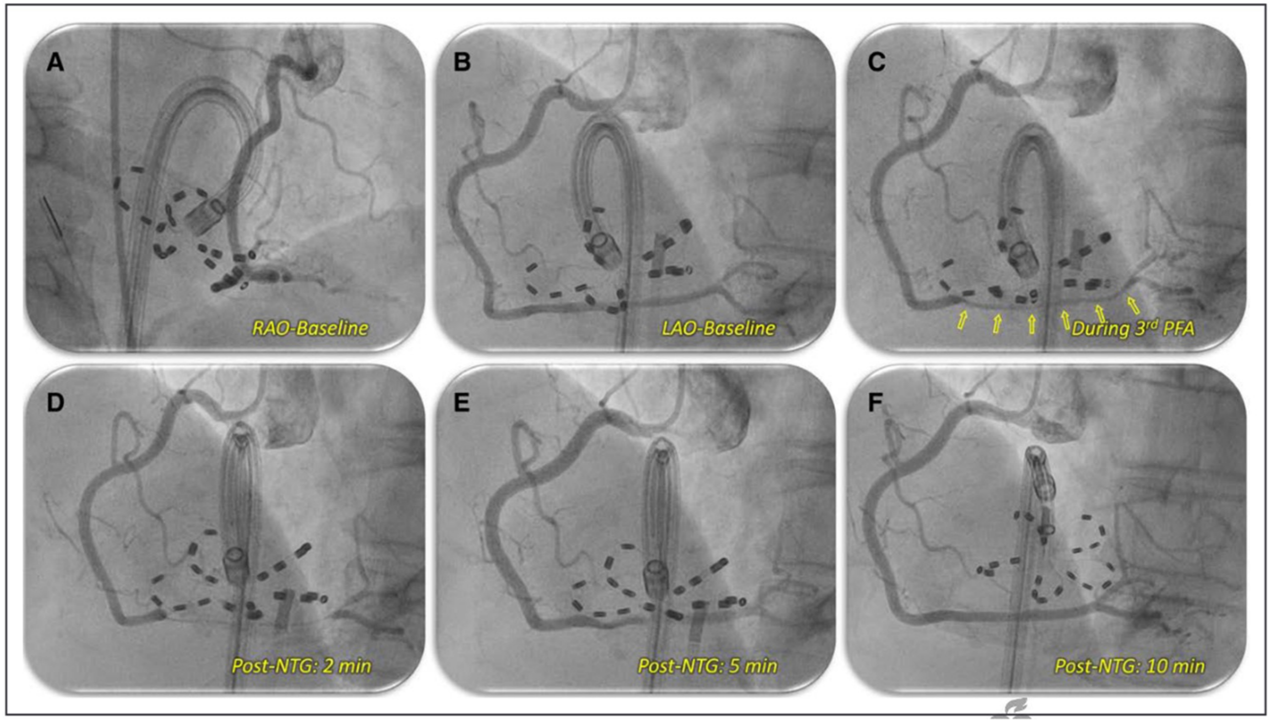
PFA System Comparisons

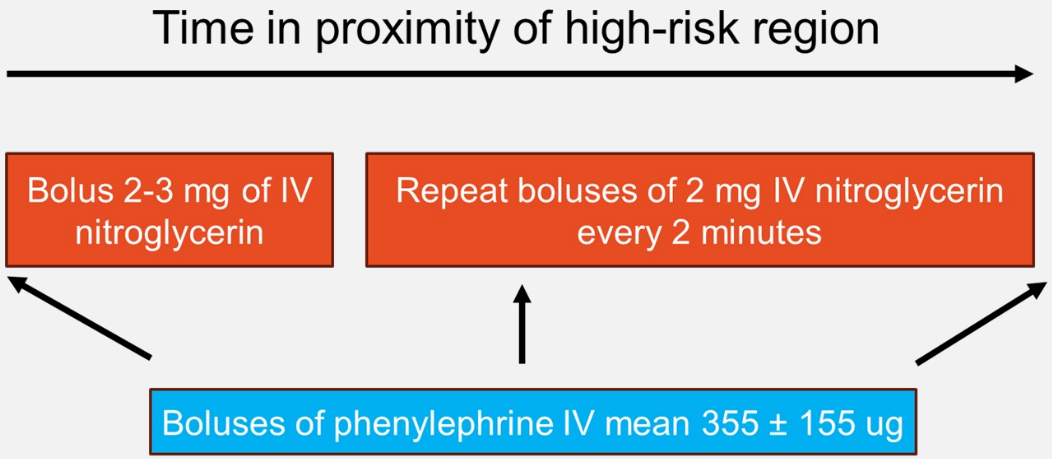


1. Nies M, Koruth JS, Mlcek M, et al. Hemolysis After Pulsed Field Ablation: Impact of Lesion Number and Catheter-Tissue Contact. *Circ Arrhythm Electrophysiol*. 2024;17(6):e012765.
2. Overmann JA et al. Hemolysis Profile of a Novel Balloon-Filled Basket Pulsed Field Ablation Catheter. Presented at AF Symposium 2025.
3. Mattison L, Verma A, Tarakji KG, Sigg DC. Hemolysis After Pulsed Field Ablation: The Role of Dose and Contact in an Acute Porcine Model. *Circ Arrhythm Electrophysiol*. 2024:e013317.
4. Watanabe K et al. In-vivo Preclinical Analysis of Hemolysis after Pulsed Field Ablation using a Lattice-Tip Catheter: Impact of Contact and Irrigation. Presented at AF Symposium 2025.

PFA-Induced Coronary Vasospasm

- Tends to occur more on the CTI, mitral isthmus
- Most areas in LA are free from this problem





Malyshev, Reddy, et al, JACC EP 2024

Balancing pharmaceutical cocktail during time spent at risk

Reddy V, et al. Coronary artery spasm during pulsed field ablation to treat atrial fibrillation. Circulation September 2022.146; 24. 1808-1819.

Malyshev Y, et al. Nitroglycerin to Ameliorate Coronary Artery Spasm During Focal Pulsed-Field Ablation for Atrial Fibrillation. JACC EP May 2024.10;5. 885-896.

Effect of PFA on human coronary arteries: A longitudinal study with intracoronary imaging

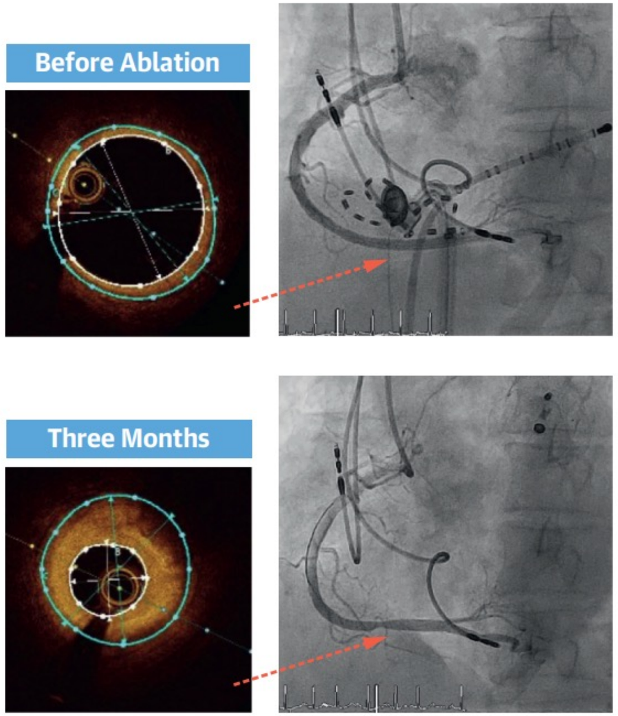
Patients and Study Design:

- 21 patients:
  - After PVI, patients underwent MI or CTI ablation.
  - PFA completed with Farawave.
- Angiography and OCT reviewed changes in coronary artery in 19 patients.

Data:

- Imaging:
  - 3 months post-ablation, median change detected CA narrowing:
    - Increase in vascular wall area = 0.40 mm² (17.1%)
    - Reduction in luminal area (LA) = 0.70 mm² (10.1%).
- Safety:
  - Prevalence of coronary spasm:
    - 3 (15%) vessels had moderate spasm.
    - 9 (45%) vessels had server spasm.
- Long term outcomes (median of 16 months):
  - **No patients developed angina, acute coronary syndrome or required revascularization.**

OCT Showed Changes in Coronary Arteries after PFA

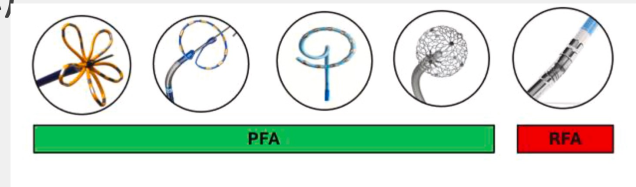


PFA of CTI and MI associated with acute spasm and mild narrowing of coronary arteries at 3 months. Intracoronary vasodilator therapy may prevent acute spasm; however, risk of arterial stenosis remains.

MT Tam, JY Chan, CP Chan, EB Wu, A Lai, AC Au, WK Chi, G Tan, BP Yan. JACC: Clinical Electrophysiology. 2025. DOI: 10.1016/j.ijcha.2025.101674

NEMESIS-PFA: Investigating Collateral Tissue Injury Associated With Pulsed Field Ablation

Multicenter, observational registry of patients who underwent AF ablation from March 2024 onwards with any approved PFA systems—either a circular multielectrode array, spherical, pentaspline, or variable loop catheter—or radiofrequency ablation (RFA)



Procedural characteristics, biomarkers for myocardial injury, hemolytic anemia, and renal function, and left atrial function in select patients were assessed

	RFA Δ Change	PFA Δ Change	P Value[a]
Troponin,[b] ng/dL	127.5 (54.5-177.0)	13,551.0 (7,307.5-22,401.5)	<0.001
NTproBNP,[c] pg/dL	–	593.0 (159.0-1,928.0)	–
Hemoglobin, g/dL	−1.2 (−2.0 to 0.0)	−2.3 (−3.0 to −1.4)	<0.001
Creatinine, mg/dL	0.9 (0.8-1.1)	1.0 (−0.1 to 0.1)	0.007
Lactate dehydrogenase, IU/L	26.5 (−31.5 to 88.8)	107.5 (41.0-195.8)	<0.001
Haptoglobin, mg/dL	−33.5 (−84.5 to 25.3)	−102 (−138.0 to −56.0)	<0.001
Reticulocyte count,[c] %	–	0.4 (−0.3 to 1.0)	–
Plasma-free Hgb,[d] mg/dL	13.1 ± 3.5	61.2 ± 12.5	<0.001

Values are median (Q1-Q3).

Postprocedurally, all biomarkers worsened, suggestive of worse myocardial injury, hemolytic anemia, and kidney injury. Only N-terminal pro–B-type natriuretic peptide (NTproBNP), a marker of atrial stretch, was statistically unchanged.

Table 4 Delta Changes in Post-Procedural Biomarkers by Number of Applications

	<79 Applications	79-110 Applications	>110 Applications	P Value[a]
Troponin,[b] ng/dL	3,072.0 (124.5 to 123[illegible]21.0)	16,730.0 (10,261.5 to 24[illegible]989.5)	16,963.0 (9,801.0 to 34,221.0)	<0.001
NTproBNP, pg/dL	273.0 (−244.0 to 573.0)	236.0 (−611.5 to 1,330.5)	593.0 (−984.0 to 593.0)	0.487
Hemoglobin, g/dL	−2.4 (−2.4 to [−0.2])	−2.2 (−3.0 to −1.3)	−2.4 (−3.5 to −1.5)	0.001
Creatinine, mg/dL	0.0 (−0.1 to 0.1)	0.0 (−0.1 to 0.1)	0.0 (−0.1 to 0.2)	0.496
Lactate dehydrogenase, IU/L	76.0 (15.0 to 147.0)	104.0 (26.3 to 191.5)	157.0 (63.0 to 274.0)	<0.001
Haptoglobin, mg/dL	−90.5 (−131.5 to −34.0)	−96.5 (−137.3 to −36.0)	−99.0 (−135.0 to −27.3)	0.740
Reticulocyte count, %	0.1 (−0.5 to 0.9)	0.6 (−0.3 to 1.0)	0.4 (−0.4 to 1.0)	0.665

Table 5 Delta Changes in Post-Procedural Biomarker by Pulsed-Field System

	Circular Multielectrode (n = 111)	Pentaspline (n = 548)	Spherical (n = 96)	Variable Loop (n = 18)	P Value[a]
Troponin,[b] ng/dL	13,407.0 (8,690.0 to 22,952.0)	14,672.5 (7,923.3 to 24,216.5)	12,753.0 (7,094.5 to 20,450.0)	6,758.0 (3,424.0 to 11,170.0)	<0.001
NTproBNP,[c] pg/dL	–	675.0 (−871.5 to 6350.0)	414.5 (−289.0 to 698.0)	–	0.333
Hemoglobin, g/dL	−1.5 (−2.6 to −0.8)	−2.5 (−3.2 to −1.7)	−1.6 (−2.4 to −0.5)	−1.7 (−2.1 to −0.4)	<0.001
Creatinine, mg/dL	0.0 (−0.1 to 0.1)	0.0 (−0.1 to 0.1)	0.0 (−0.1 to 0.1)	−0.1 (−0.1 to 0.0)	0.004
Lactate dehydrogenase, IU/L	85.0 (30.0 to 217.0)	117.0 (49.0 to 209.3)	61.0 (1.8 to 122.8)	76.0 (6.0 to 137.0)	<0.001
Haptoglobin, mg/dL	−102.5 (−139.3 to −74.0)	−110.5 (−143.0 to −73.8)	−62.0 (−109.0 to −17.0)	−81.5 (−129.5 to −27.5)	<0.001
Reticulocyte count, %	1.5 (1.3 to 1.8)	1.9 (1.6 to 2.4)	1.6 (1.3 to 2.0)	1.7 (1.5 to 2.4)	0.244

Values are median (Q1-Q3).

There were slight changes in postprocedural biomarkers when assessed by PFA system. Most clinical injury was associated with the Pentaspline system.

Abbreviations as in Tables 1 and 3.

Current PFA technologies are associated with higher troponin leak, hemolysis, & renal dysfunction than RFA.

Lakkireddy D, et al. JACC: Clinical Electrophysiology April 2025; 11(8).

Phrenic Nerve Injury (PNI)

In 64 consecutive patients, right phrenic nerve function monitored using CMAP (compound motor action potentials) before, during, and after PFA

41% (26 pts) developed PNI

19% (12 pts) incomplete recovery at end of procedure (NL CXR)

Last 25 pts

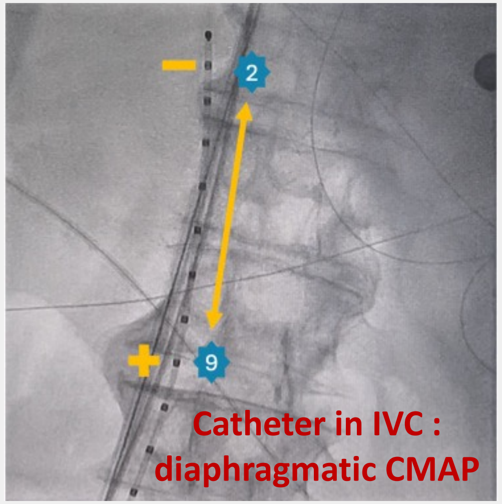
12 pts w intra-procedural PNI

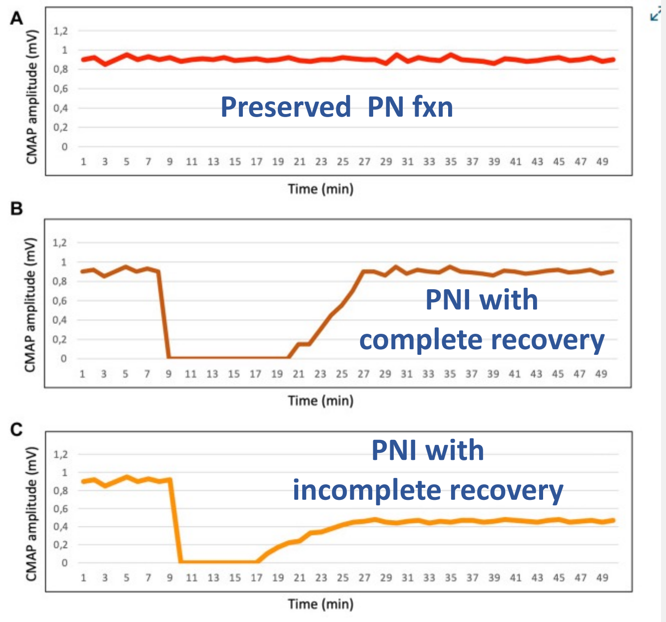
6 pts had persistent incomplete PNI

24 % Incidence of PNI at discharge

At 3M, 1 pt had persistent dysfunction by fluoroscopy

PNI: frequent complication of PFA. Incomplete paralysis is commonly observed at the end of the procedure.





Chehirlian L, et al. High incidence of phrenic nerve injury in patients undergoing pulsed field ablation for atrial fibrillation. Heart Rhythm August 2025 doi.org/10.1016/j.hrthm.2025.08.010

CIED & Pulsed Field Ablation

Pulsed-field ablation (PFA) in patients with cardiac implantable electronic devices (CIED): Is it safe?

Conclusion

Bipolar PFA does not damage CIED or leads, but clinically relevant electromagnetic interference (EMI) does occur

Impact on clinical practice

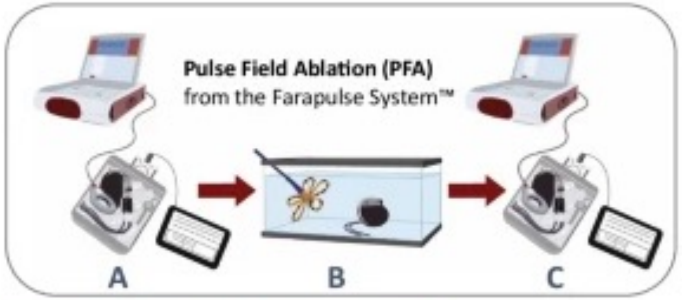
Bipolar PFA do not harm CIEDs, however due to occurring electromagnetic interference (EMI)appropriate peri-procedural programming is vital

Study Objective

PFA is an innovative catheter ablation technology with potential risk to directly damage CIEDs or cause electromagnetic interference (EMI). Aim of our study was to assess the impact of PFA on CIEDs

Methods

- A representative sample of CIED (N=44) was analyzed for damage after ex-vivo exposition to PFA pulses (N=1980), applied from the Farapulse System™ (Farapulse Inc., Menlo Park, USA). (B)
- All devices were checked before (A) and after(C) PFA application for proper sensing- and pacing-functionality as well as for integrity of shock circuits in ICDs using a heart simulator.



Results

- No malfunction or damage to CIEDs or leads detected after PFA
- However detection of clinically relevant oversensing

Carsten L et al. Pulsed Field Ablation in patients with cardiac implantable electronic devices: an ex vivo assessment of safety. Journal of ICE January 2024

Characterization of Additional Atrial Arrhythmias (AAA) during Pulsed Field Ablation of Paroxysmal and Persistent Atrial Fibrillation

Of the 221 pts ablated, 117 (53%) had PAF & 104 (47%) had Pers AF.

AAA were present in 99/221 (45%) pts (62 males/37 females, age 66±10 yrs).

30/117 (26%) PAF pts and 69/104 (66%) Pers AF pts had AAA.

A total of 152 AAA were inducible.

- 83 (55%) Typical RA flutter
- 57 (37%) AT
  - 41 (72%) LA in origin
  - 16 (28%) RA in origin
- 7 (5%) LA flutter
- 5 (3%) AVnRT

145/152 (95%) AAA were ablated using the Farapulse Farawave™ catheter.

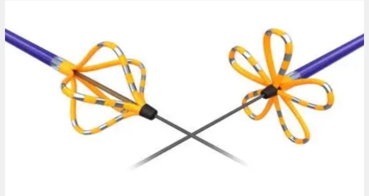
	PAF	Pers AF
AAA	35 (23%)	117 (77%)
RA FL	24 (69%)	59 (50%)
AT	7 (20%)	50 (43%)
AVnRT	4 (11%)	1 (0.8%)
LA FL	0	7 (6%)

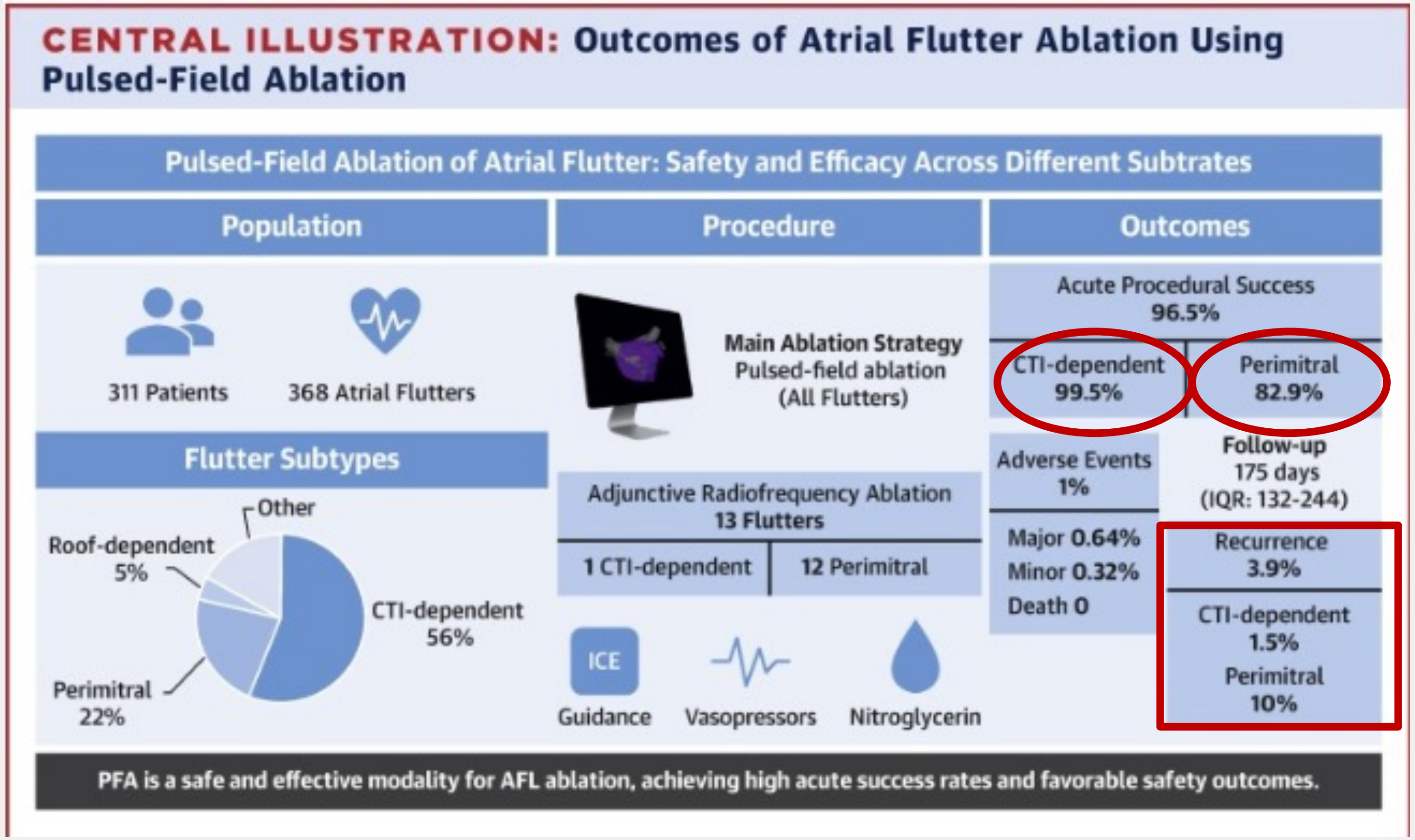
	AAA (99 pts)	Non-AAA (122 pts)
# of PFA pulses	67 ± 14	53 ± 13
Procedure time	76 ± 32 min	77 ± 27 min
Fluoro dose	62 ± 54 mGy	63 ± 83 mGy

Tomassoni G, et al. Characterization of Additional Atrial Arrhythmias (AAA) during Pulsed Field Ablation of Paroxysmal and Persistent Atrial Fibrillation. HRS Abstract 2025

Pulsed-Field Ablation of Atrial Flutter: Insights From a Large Volume U.S. Center

CTI dependent & Mitral Isthmus Flutter





Demian J, et al. JACC Clin Electrophysiol. 2025;10.1016/j.jacep.2025.06.036

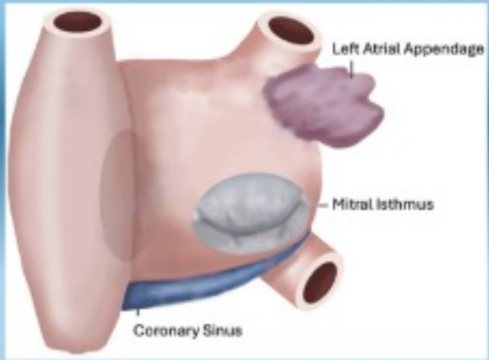
Pulsed-Field Ablation of Coronary Sinus, LAA, and Mitral Isthmus

Farapulse pentaspline catheter (Farawave)

Study Population

- 236 consecutive patients with long-standing persistent AF
- Previous failed AF ablation with PV and PW isolated
- CS and LAA isolation and MI ablation using the Pentaspline PFA catheter

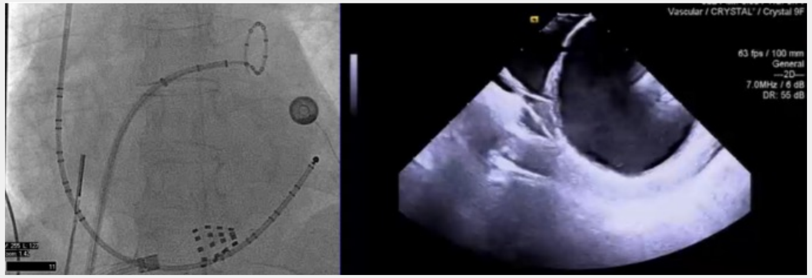
Procedural Outcomes

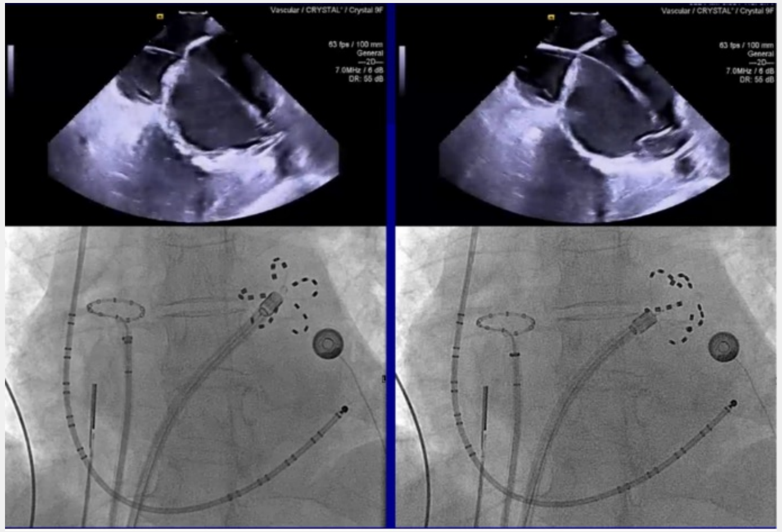


Isolation/Block	Acute	Post-Adenosine	3 Months
LAA	100%	98.3%	4.6%
CS	62.2%	40.2%	1.3%
MI	100%	85.2%	5.5%

Conclusion

PFA achieves acute isolation of extra-PV targets, but long-term durability remains limited





La Fazia VM, et al. Feasibility and Safety of Pulsed Field Ablation for Coronary Sinus and Left Atrial Appendage Isolation and Mitral Isthmus Ablation: Acute and Chronic Findings. Circulation: arrhythmia and Electrophysiology August 2025; 18(9).

PFA Conclusions

Rapidly adapted and growing procedure for AF with new data being reported on a daily basis

Efficacy at least non-inferior compared to RFA for PAF/persistent AF
- Significant reduction in AA burden
- Excellent first pass PV and LA posterior wall isolation (100%)

Shorter procedural & anesthesia times, quicker pt recovery with less post-operative symptoms

Cardioselectivity: Minimal to no effect on esophagus, lung, or pulmonary veins

Low risk for <u>significant clinical</u> PN injury, coronary artery vasospasm
- May not be as selective as originally thought especially on arteries, RBC's, and nerves

Long term data presently limited on PFA effectiveness for atrial flutters especially LA in origin (MI, CS)

Future/Next Steps

Long-term data (>2 years) on Efficacy and Safety

Optimizing energy delivery/Waveforms

- Fine tune preexisting waveforms or newer waveforms for more precise ablation
- Less muscle stimulation/need for GA/improve lesion durability

Advancing catheter technology

- Verification of lesion delivery
- More integrated RFA/PFA catheters (reduce potential complications, less need to utilize multiple catheters, lower cost)

Understanding/continued assessment of unanticipated complications

Expanding Indications beyond PVI/LA posterior wall ablation

- Targeting non-pulmonary vein triggers
- Longstanding Persistent or Permanent AF
- Atypical atrial flutters
- Ventricular tachycardia

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Kentucky
CHAPTER

Diffuse right coronary artery spasm occurring 45 minutes post PFA for AF

Reason to Read: Case report of remote right coronary artery spasm 45 mins after procedure.

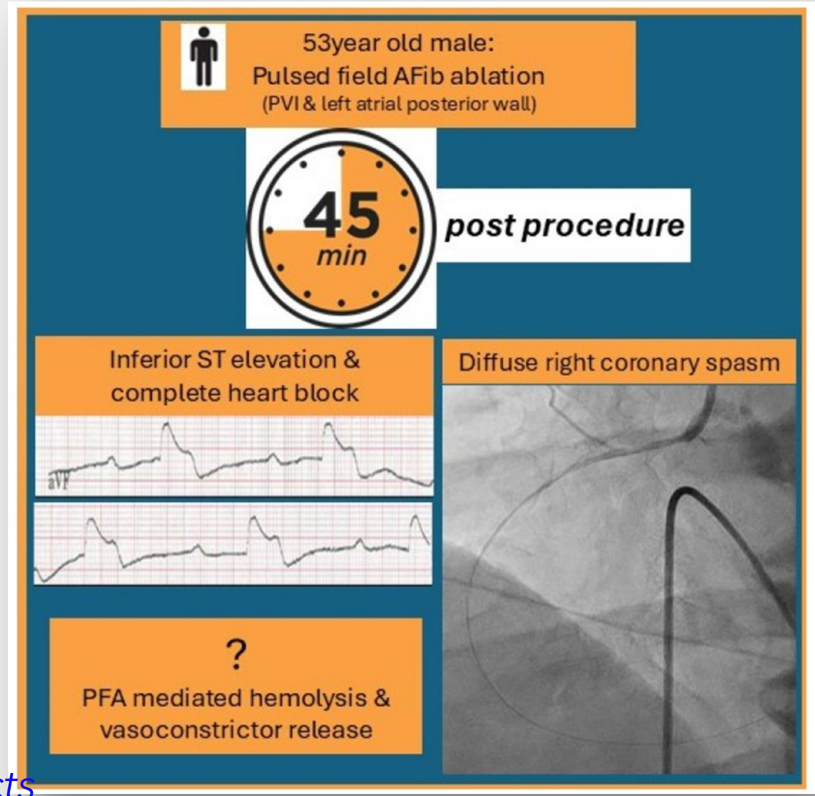
Patients and Procedure:

- 53-year-old AF ablation with Farapulse
- 56 total PFA applications:
  - 32 for PVI and 4 for anterior lesions on superior PVs
  - 20 for LA posterior wall

Event and Discussion:

Delayed coronary spasm

- 45 mins post-procedure.
  - Hypoxic, hypotensive, and bradycardia with ST elevation & heart block.
- Patient reintubated for critical CPR.
  - Pacing, coronary balloon dilatation, and nitrate administration
- Blood test revealed progressive fall in hemoglobin and rise in bilirubin.



Acute PFA induced hemolysis and secondary release of RBC breakdown products into circulation may participate in delayed coronary spasm.

V Luther, et al. Heart Rhythm. 2025. DOI 10.1016/j.hrthm.2025.03.1978

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