

Transcatheter Bypass of Left Atrium to Right Atrium via Coronary Sinus

William Gray, M.D.

Professor of Medicine, Sidney Kimmel School of Medicine, Thomas Jefferson University
System Chief of Cardiovascular Division, Main Line Health
Phillip D. Robinson Endowed Chair of Cardiovascular Medicine

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Background



- Heart failure (HF) impacts **64 million people** worldwide.¹



- **Shortness of breath** is the most prevalent symptom when hospitalized for acute HF.⁴



- HF is a **leading cause of hospitalization** in North America and Europe.^{2,3}



- HF **affects quality of life (QoL)** more profoundly than many other chronic diseases.⁵

Heart failure is a growing global pandemic

Treatment options & medical management

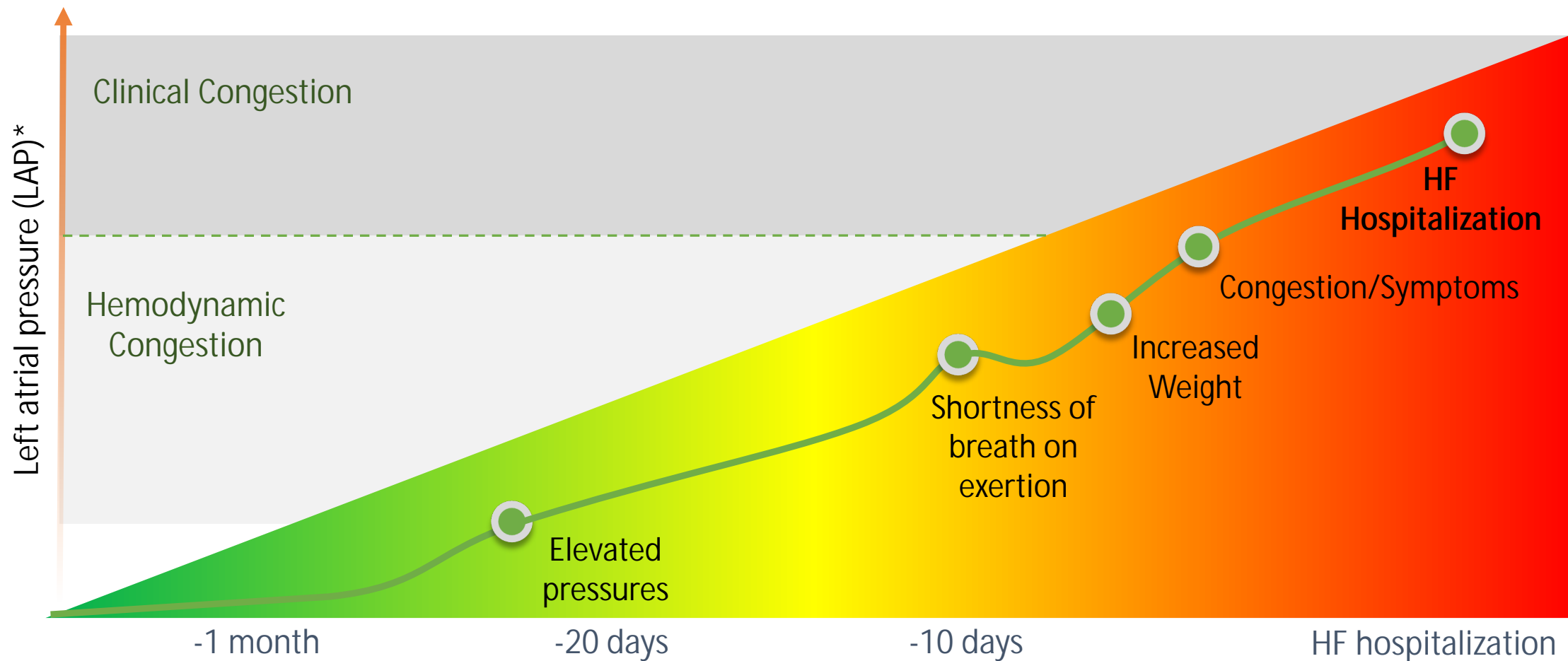
Patients with HF may experience multiple debilitating symptoms, including:

- Shortness of breath
- Peripheral edema
- Ascites
- Exertional intolerance
- Pulmonary edema

Although most patients with symptomatic HF are treated with established Guideline Directed Medical Therapy (GDMT) to manage their condition,¹ there are several important limitations associated with the use of these treatments:

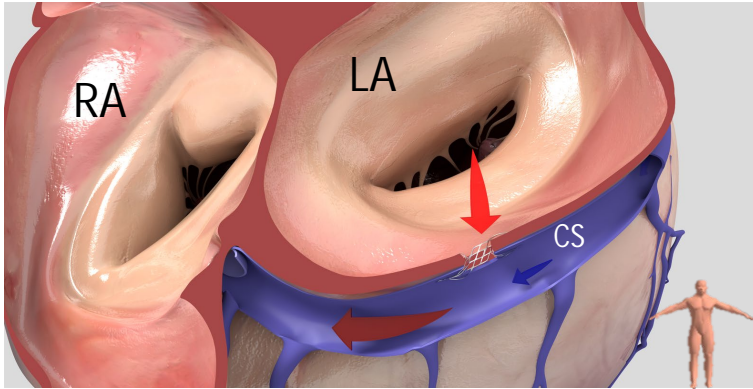
- Contribute to polypharmacy (multiple medication use) and medication nonadherence¹
- Not consistent benefit across the spectrum of LVEF, i.e., preserved HF (heart failure with preserved ejection fraction or HFpEF) EF > 50%^{1,2}
- Fail to improve hospitalization rates or clinical outcomes³

Elevated LAP precedes HF hospitalization

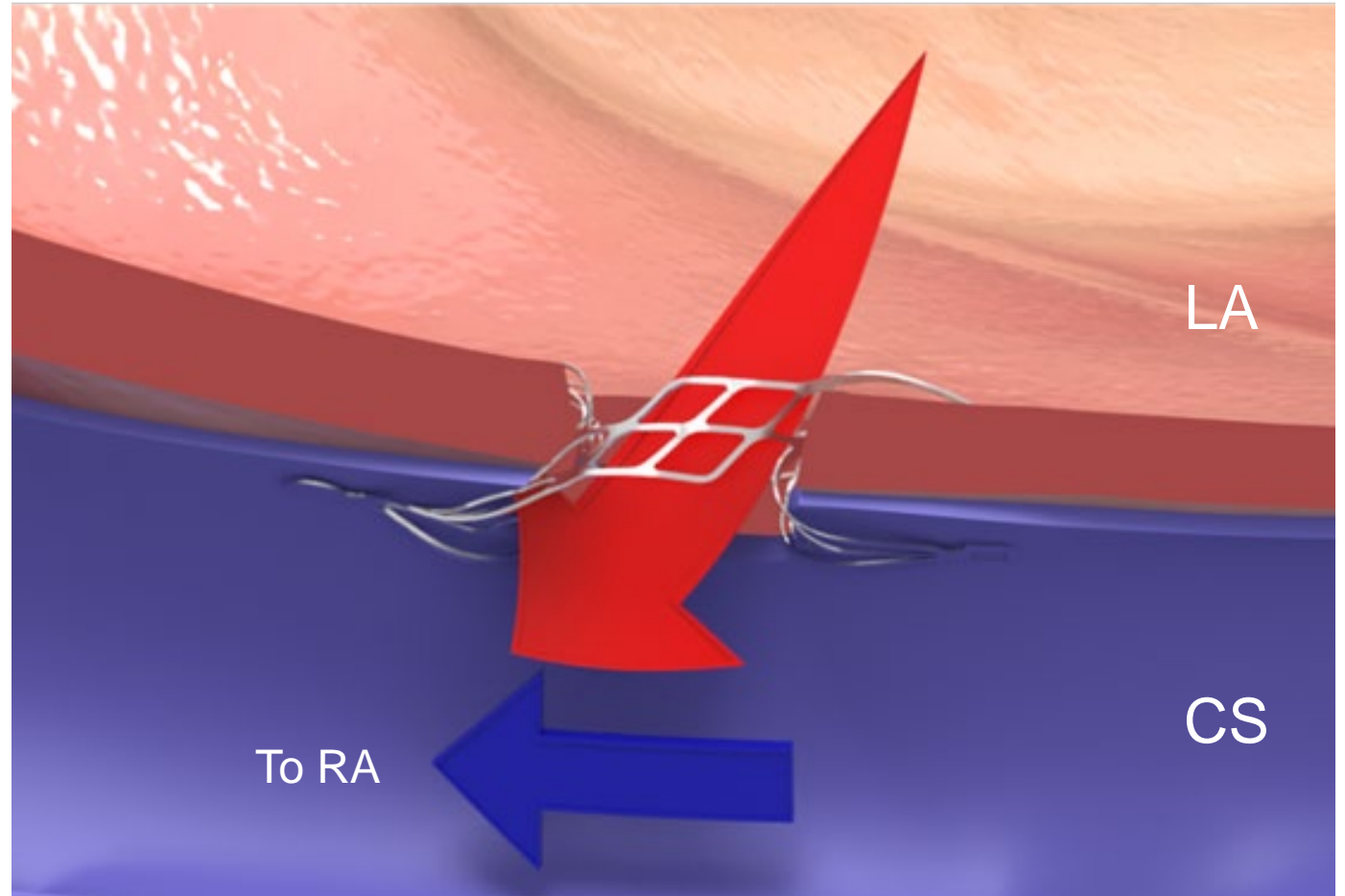


- Patient data on left atrial pressures from CHAMPION HF Trial
- Adapted from Adamson PB, et. al. Pathophysiology of the transition from chronic compensated and acute decompensated heart failure: new insights from continuous monitoring devices. Curr Heart Fail Rep. 2009 Dec;6(4):287-92.
- Adapted from Zile MR., et. al. Transition From Chronic Compensated to Acute Decompensated Heart Failure. Circulation 118, 1433–1441.

Anatomic positioning of the Edwards APTURE transcatheter shunt system



The Edwards APTURE transcatheter shunt uses the natural blood flow path of the coronary sinus (CS) to the right atrium (RA) to relieve elevated pressure in the left atrium (LA).



Edwards APTURE transcatheter shunt system

The Edwards APTURE transcatheter shunt system is an innovative solution for heart failure patients with elevated left atrial pressure

Key features of the system:

- Nitinol shunt implant with 7mm opening that sits between the left atrium and coronary sinus with four arms for positioning and radiopaque markers for added visibility
- 20 Fr (ID) steerable guide sheath provides guidewire and catheter support from the right jugular access through the right atrium and into the coronary sinus.
- The guide sheath handle is held in position with a stabilizer throughout the procedure.
- 16 Fr access catheter enables guidewire access from the coronary sinus into the left atrium.
- 16 Fr implant system enables positioning and implantation of the transcatheter shunt

APTURE transcatheter shunt



APTURE guide sheath, APTURE stabilizer, APTURE access catheter, and APTURE implant system



Left atrium to right atrium via coronary sinus shunt procedural steps (slide 1 of 2)

Procedure Step	Description
1	After general anesthesia is induced, the patient is intubated. A transesophageal echocardiography (TEE) probe is inserted and positioned to obtain appropriate views of the coronary sinus and left atrium.
2	Right jugular vein access is obtained using conventional methods, and a guidewire is inserted prior to dilation of the access site.
3	The guide sheath is inserted over the guidewire into the right atrium and deflected towards the coronary sinus ostium. Fluoroscopic and echocardiographic guidance are used to cannulate the coronary sinus with a guidewire. The stabilizer is used maintain positioning of the guide sheath.
4	An angiographic marker catheter is advanced over the guidewire into the coronary sinus. Contrast is injected to acquire appropriate imaging to identify the target pierce location for access into the left atrium and for placement of the shunt implant. The marker catheter is then exchanged for a stiff coronary sinus guidewire.

Left atrium to right atrium via coronary sinus shunt procedural steps (slide 2 of 2)

Procedure Step	Description
5	The access catheter is advanced over the guidewire into the coronary sinus. The needle is advanced into the left atrium to create access, which is confirmed using TEE. The needle is exchanged for a guidewire into the left atrium.
6	A dilation balloon is inserted over the guidewire into the left atrium. The balloon is positioned across the shared wall between the coronary sinus and left atrium. The balloon is inflated to dilate the access hole created by the needle. The balloon is deflated and removed.
7	The implant system is inserted over the guidewire and advanced into the left atrium. After advancing the distal coronary sinus arm of the implant, a contrast shot is performed using fluoroscopy to confirm capture of the wall between the coronary sinus and left atrium. After confirmation, the shunt implant is released, and the implant system is retracted and removed.
8	Proper positioning and functioning shunt is confirmed by TEE. The guide sheath is removed from the access site and the right jugular vein access is closed.

Identifying the APTURE transcatheter system in the medical record

The Edwards APTURE transcatheter shunt system received FDA Breakthrough Device Designation on October 18, 2021.

Documentation of the APTURE transcatheter shunt system will be included in the operative report and may be referred to as:

- APTURE
- APTURE shunt
- APTURE transcatheter shunt
- Coronary sinus shunt
- Left atrium to coronary sinus shunt
- Left atrium to coronary sinus shunting
- Transcatheter Atrial Shunt System
- Atrium/coronary sinus bypass
- Left atrium/coronary sinus bypass
- Transcatheter bypass of left atrium into coronary sinus

Questions