

Selecting Optimal Patients for Atrial Shunts: Implications of Left Atrial Hypertension at Rest and Exercise

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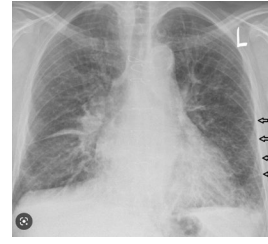
Axon, Eli Lilly, Occlutech, Rivus

Faculty disclosure information can be found on the app

HFpEF phenotypes

- Overt volume overload → diuretics
- Many patients do not have volume overload:
 - No symptoms at rest
 - Exertional dyspnea
 - No edema, nl JVP, clear lungs
 - ↓ natriuretic peptides, nl CXR, nl echo
 - Diagnosis of HFpEF challenging
- The problem with diuretics
 - They work all the time
 - Polyuria (lifestyle, sleep disturbance, etc.)
 - Electrolyte problems
 - Acute kidney injury (AKI)/dehydration
 - Orthostasis
 - Cramps

Overt volume overload



No volume overload




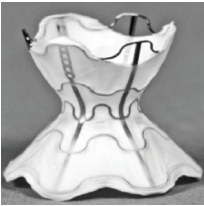



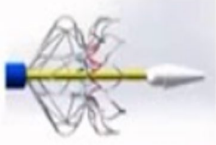
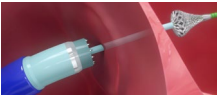
Interatrial Shunts

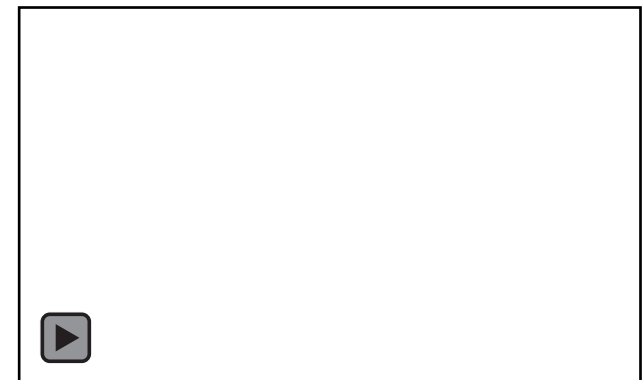
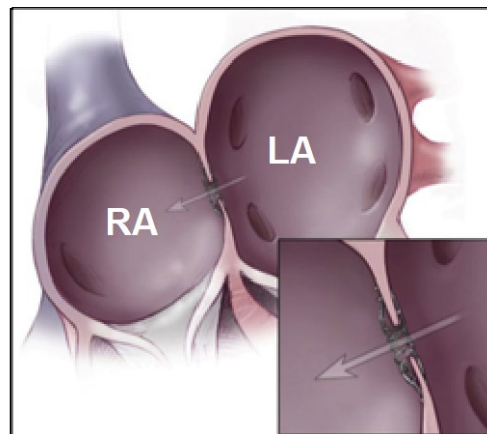
- May produce little shunting at rest if LA pressure is not elevated & closer to RA pressure)
- When LA pressure rises during exercise, the shunt allows decompression of the LA
- *Sensor AND therapy* for high LA pressure with exercise

Pressure valve



Interatrial shunt devices/procedures

Device	Corvia	V-Wave	Occlutech	Edwards	Alleviant	NoYA	InterShunt
							
Type	Implant	Implant	Implant	Implant	Procedure	Procedure	Procedure
Description	Nitinol stent	Nitinol/PTFE hourglass	Nitinol braid with central orifice	Tubular nitinol device with retention arms	Coring catheter	RF catheter	Cutting catheter
Shunt size	8 mm	5.1 mm	4, 6, 8, 10 mm	7 mm	6 mm	4-12 mm	4 mm



Courtesy of Sanjiv Shah

Atrial shunt device for heart failure with preserved and mildly reduced ejection fraction (REDUCE LAP-HF II): a randomised, multicentre, blinded, sham-controlled trial

*Sanjiv J Shah, Barry A Borlaug, Eugene S Chung, Donald E Cutlip, Philippe Debonnaire, Peter S Fail, Qi Gao, Gerd Hasenfuß, Rami Kahwash, David M Kaye, Sheldon E Litwin, Philipp Lurz, Joseph M Massaro, Rajeev C Mohan, Mark J Ricciardi, Scott D Solomon, Aaron L Sverdlow, Vijendra Swarup, Dirk J van Veldhuisen, Sebastian Winkler, Martin B Leon, on behalf of the REDUCE LAP-HF II investigators**

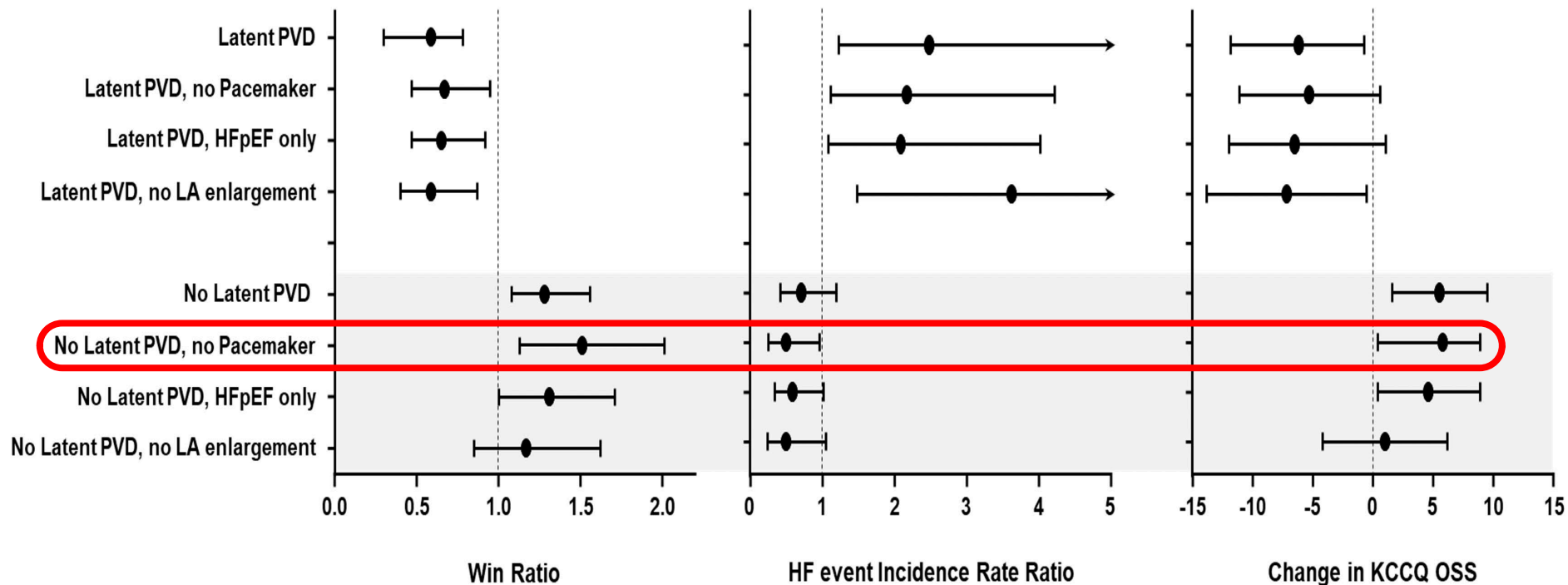
- N=608, multicenter (multinational), RCT
- Pivotal study of Corvia atrial shunt
- Primary endpoint (hierarchical composite of)
 - 1) incidence of and time to CV mortality or first nonfatal ischemic stroke through 12 months,
 - 2) total rate of HF events up to 24 months,
 - 3) change in KCCQ OSS score at 12 months

Neutral result: No difference in primary outcome or individual components

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Responder analysis

Latent PVD = peak exercise PVR ≥ 1.74 WU



~ 50% of patients fall into responder group

Borlaug BA...Shah SJ.
Circulation 2022

Left Atrial Hypertension in HFpEF

- Two phenotypes (both have exercise PCWP \geq 25 mmHg)
- Resting LAH (*RELAH*): resting PCWP \geq 15 mmHg
- Exercise Induced LAH (*EILAH*): resting PCWP $<$ 15 mmHg

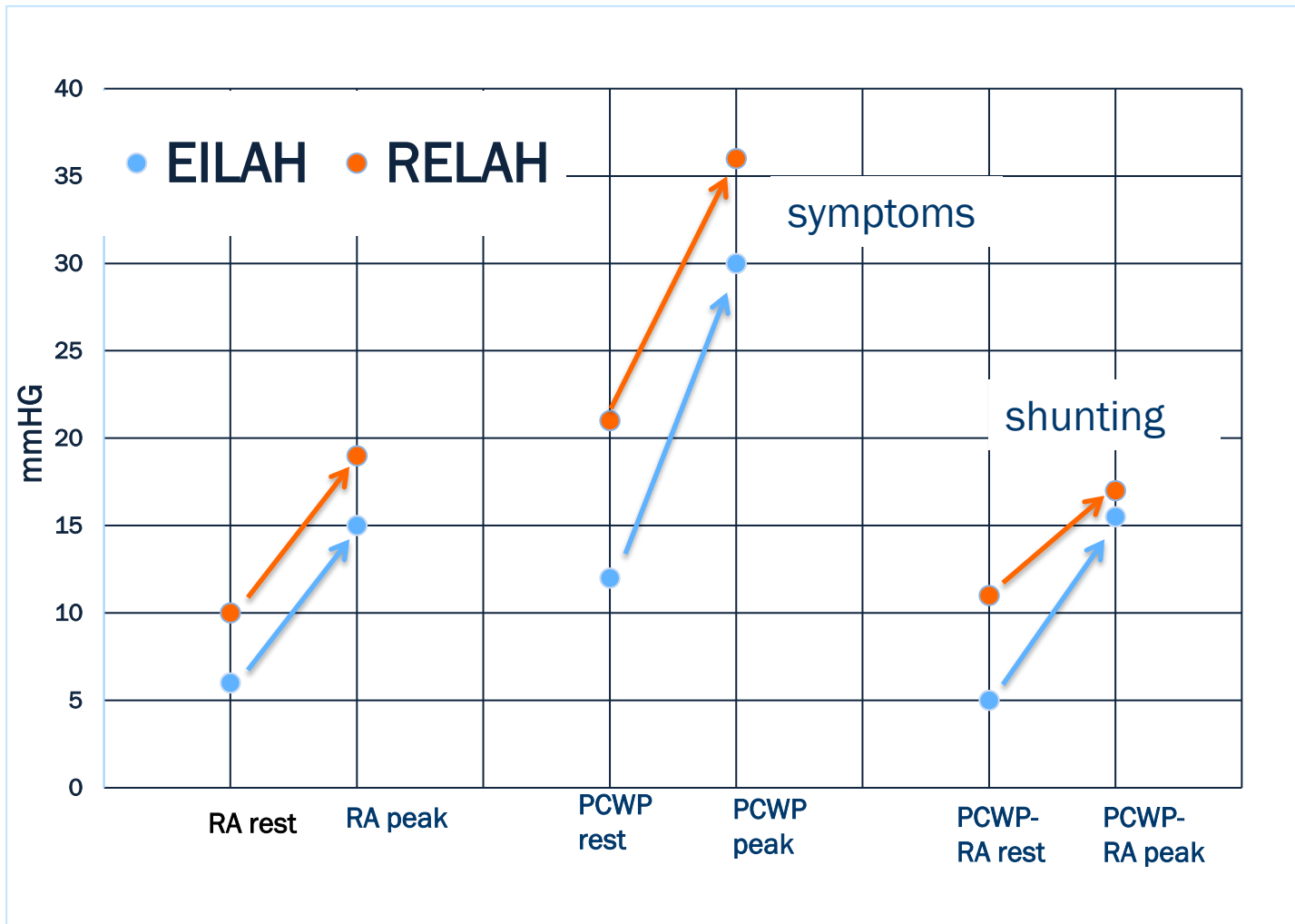
Exercise-Induced Left Atrial Hypertension (EILAH)

- Resting PCWP < 15 with exercise PCWP \geq 25 mmHg
- 29% of total population
- Similar symptom severity (KCCQ 52.1 vs. 49.5)
- Lower NP levels (\downarrow 30-50%)
- Longer 6MWD (326 vs. 295 m)
- Less Atrial Fibrillation (34.6% vs. 58.8%)
- Lower LV mass, LA volumes, E/e' & better LV & LA strain (all $p < 0.001$)

Resting vs. Exercise-Induced Left Atrial Hypertension and the Corvia atrial shunt

- EILAH more likely to have “responder characteristics”
- Peak exercise PVR < 1.74 WU (60% vs. 46%, $p=0.001$)
- No rhythm device (46% vs. 63%, $p < 0.001$)
- Win ratio 1.56 for EILAH ($p=0.08$) vs. 1.51 for RELAH ($p=0.02$) in patients with the responder profile

LA to RA pressure gradient drives flow through the shunt



Lower resting LA-RA gradient, but equivalent peak gradient
Less shunting at rest, equivalent shunting at peak exercise

Conclusions

- At least 30% of HFpEF patients have normal resting PCWP
- EILAH group has equally severe symptoms but may have earlier or less severe stage of HFpEF
- Enriched with responder characteristics
- EILAH appears to have similar response rate to atrial shunt (underpowered)
- Hemodynamics suggest EILAH have less shunting at rest, but increased with exercise
- RESPONDER-HF confirmatory trial recently started