

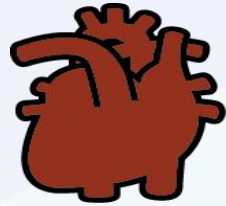
Otras opciones intervencionistas en IC

Omar Abdul-Jawad Altisent, MD, PhD

IC en Europa– Un verdadera epidemia



EUROPEANS SUFFER



> 3.

NEW H
DIAGNO
YEAR²

Paciente típico:

- Edad avanzada
- IC con FEp o FEr
- Co-morbilidades (IRC, EPOC, etc)
- CF III NYHA a pesar TMO
- Re-hospitalización / BNP altos

IN 5

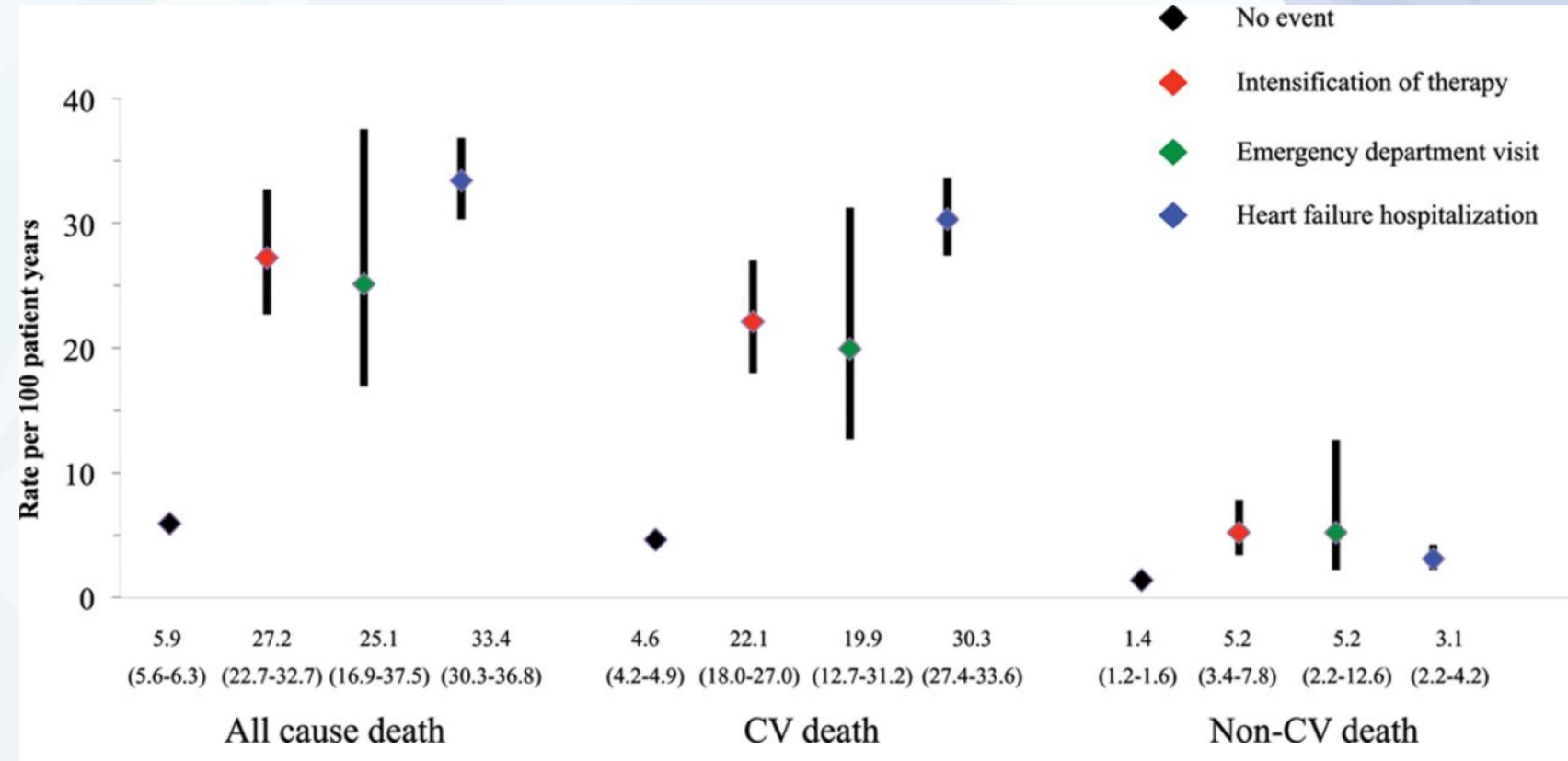
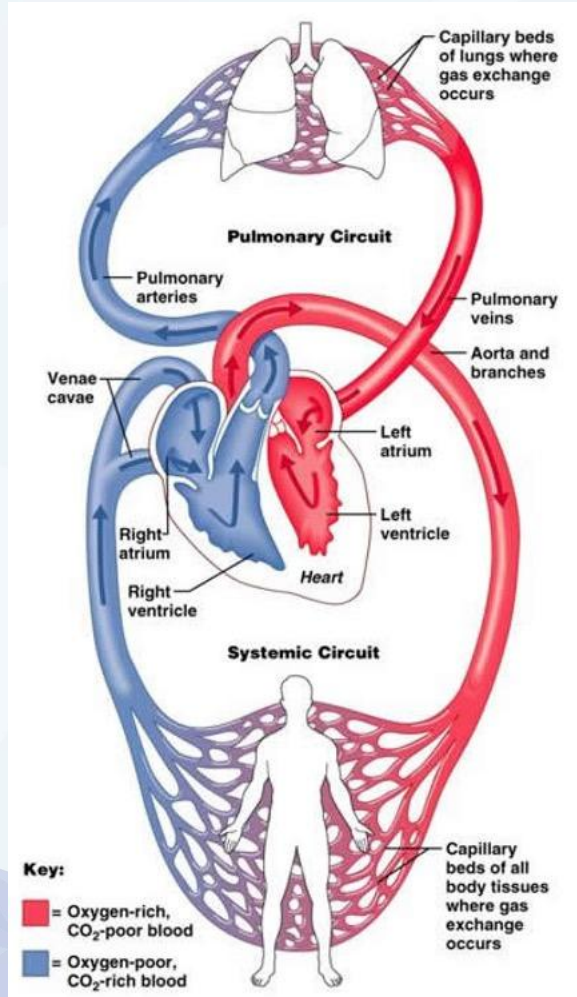
ULTS ARE AT RISK
DEVELOPING HF
ER THEIR
ETIME³

HEART FAILURE
HOSPITALIZATIONS EACH YEAR⁴

References:

- (1) Braunschweig, F. What are the costs of heart failure? *Europace*, 13, ii13-ii17. DOI:10.1093/europace/eur081
- (2) López-Sendón, J. (2011) The heart failure epidemic. *Medicographia*, 33(4), 363-369
- (3) Lloyd-Jones, D. M., Larson, M. G., Leip, E. P., et al. (2002) Lifetime risk for developing congestive heart failure: the Framingham Heart Study. *Circulation* 106(24), 3068-72.
- (4) Madaleine Pharmaceuticals (2014) Retrieved September 24, 2015, from <http://madeleinepharma.com/wp-content/uploads/2014/11/Madeleine-Pharmaceuticals-Fact-SheetNovember-2014.pdf>

Paciente Congestivo = Peor Outcome



La monitorización no hemodinámica no reduce el riesgo de re-hospitalización

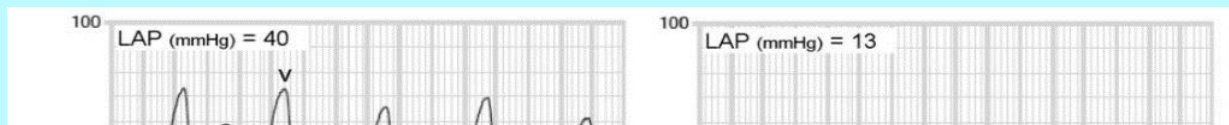
TRIAL	N	PARAMETER MONITORED	IMPACT ON HF HOSPITALIZATION	JOURNAL
TELE-HF ¹	1,653	Signs/symptoms, daily weights	None	<i>The New England Journal of Medicine, 2010</i>
TIM-HF ²	710	Signs/symptoms, daily weights	None	<i>Circulation, 2011</i>
TEN-HMS ³	426	Signs/symptoms, daily weights, BP, nurse telephone support	None	<i>Journal of the American College of Cardiology, 2005</i>
BEAT-HF ⁴	1,437	Signs/symptoms, daily weights, nurse communications	None	<i>American Heart Association, 2016</i>
INH ⁵	715	Signs/symptoms, telemonitoring, nurse coordinated DM	None	<i>Circulation Heart Failure, 2012</i>
DOT-HF ⁶	335	Intrathoracic impedance with patient alert	Increased	<i>Circulation, 2011</i>
Optilink ⁷	1,002	Intrathoracic impedance	None	<i>European Journal of Heart Failure, 2011</i>
REM-HF ⁸	1,650	Remote monitoring via ICD, CRT-D or CRT-P	None	<i>European Society of Cardiology, 2017</i>
MORE CARE ⁹	865	Remote monitoring of advanced diagnostics via CRT-D	None	<i>European Journal of Heart Failure, 2016</i>
Total	8,793	MULTIPLE TRIALS, > 8,500 PATIENTS: No reduction in HF hospitalization		

- 1. Chaudhry SI, et al. *N Engl J Med*, 2010.
- 2. Koehler F, et al. *Circulation*, 2011.
- 3. Cleland JG, et al. *J Am Coll Cardiol*, 2005.
- 4. Ong MK, et al. *JAMA Intern Med*, 2016.
- 5. Angermann DE, et al. *Circ Heart Fail*, 2012.
- 6. van Veldhuisen DJ, et al. *Circulation*, 2011.

La elevación de la PAI es causa de síntomas, morbilidad y mortalidad

ADHF occurs when LAP is elevated for days to weeks

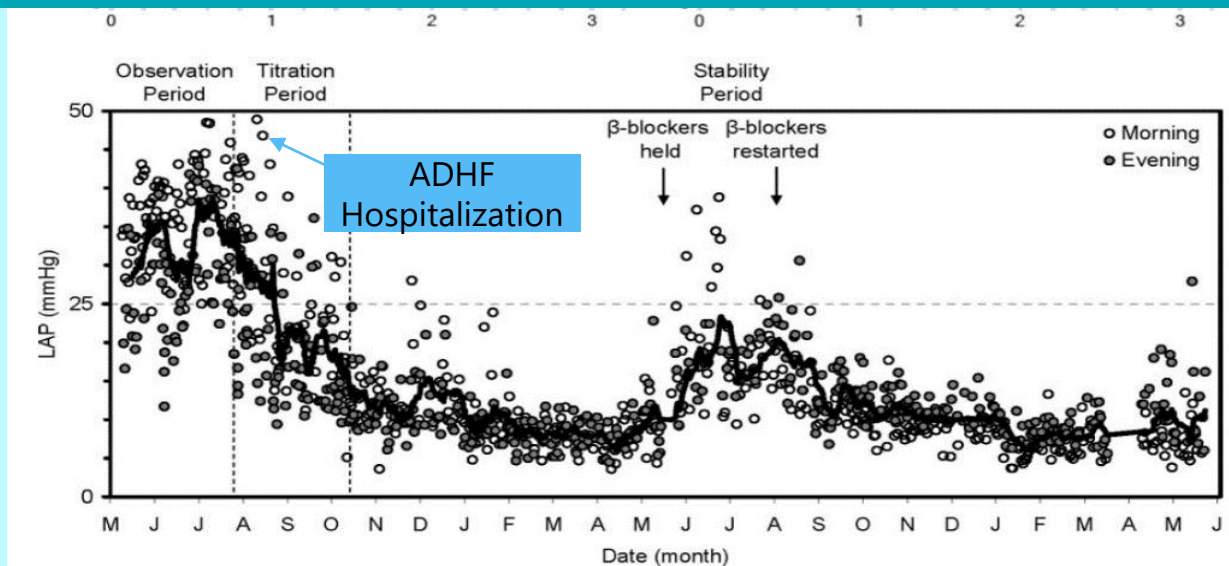
LAP tracings from single day typically show marked variations



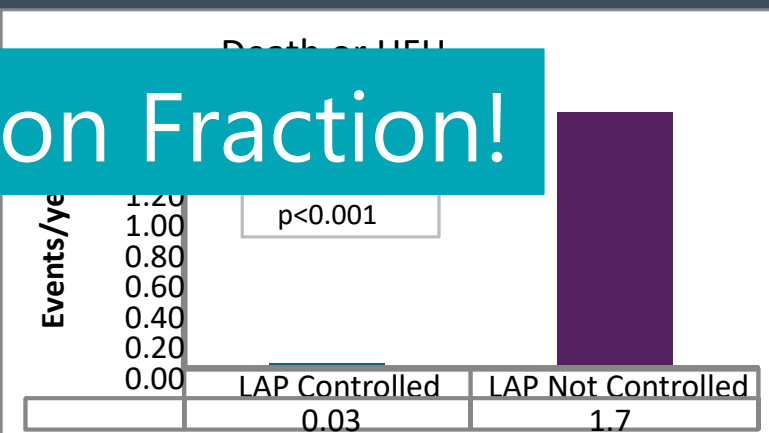
LAP = 40
LAP = 13

Regardless of Left Ventricular Ejection Fraction!

LAP readings over 2 years showing sustained LAP > 25 mmHg preceding ADHF event

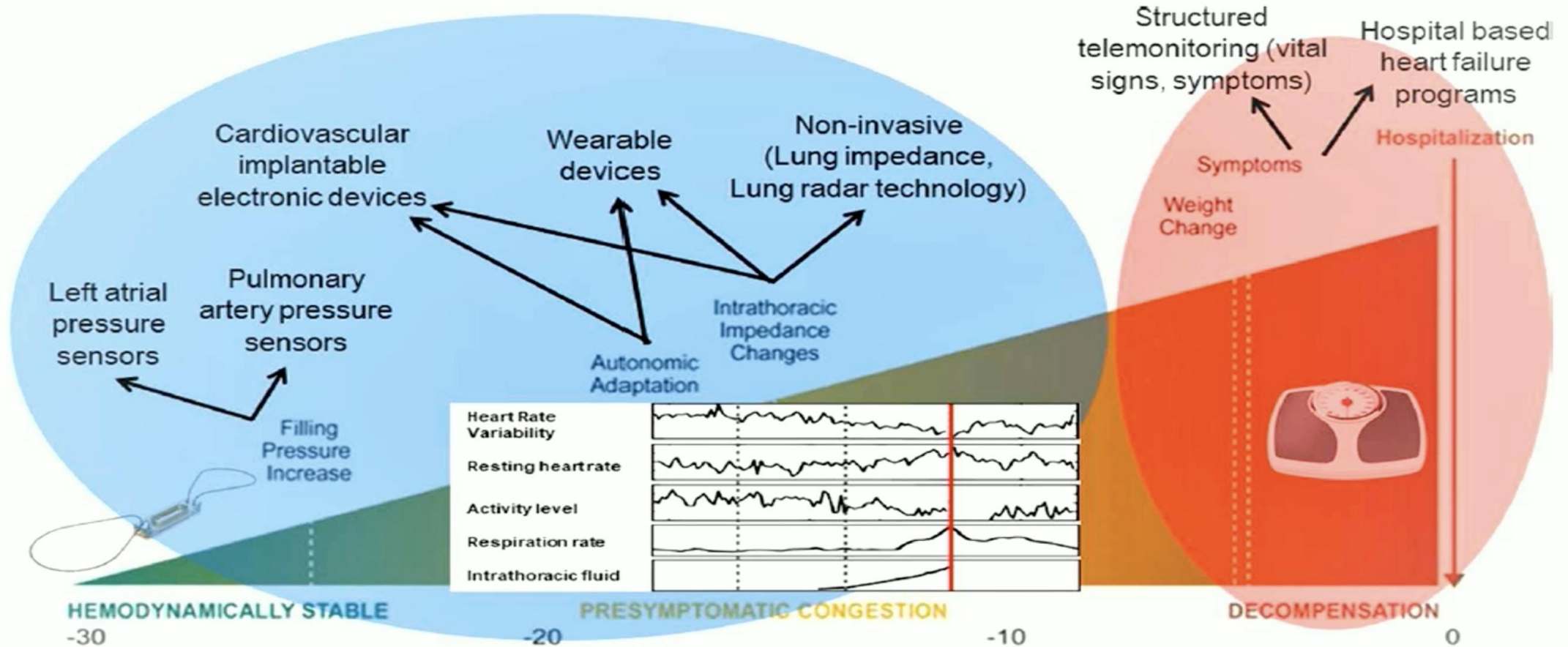


Controlling LAP reduces HF events



When LAP controlled (trend ≤ 18 mmHg) by pressure-guided medication adjustment, there were significantly fewer HF events

Identify Hemodynamic Congestion Early



Klein L. *Circ Heart Fail.* 2021;14:e8770-e8772.

Dispositivos percútanos para el tratamiento de la IC

- **1- Detección precoz de alteraciones hemodinámicas**
 - a. Sensores de presión: pulmonar, auricular izquierda, bi-auricular, VCI, etc**
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Detectores de presión

CardioMEMS

Sensor Concept

Rigid Deflecting "Membrane"

- 1 μm Capacitor Gap
- 1 nm Deflection / mmHg

$$f = \frac{1}{2\pi\sqrt{L C(P)}}$$

Frequency vs Pressure graph showing $f(P-max)$ and $f(P-0)$. Pressure waveform is also shown.

Sensor Cross section

Nanometer deflections

$C(P)$

L

SJM-MEM-0915-0192(2)a | Information contained herein for DISTRIBUTION outside of the U.S. ONLY. 6

Arteria Pulmonar Izquierda

A

myCordella™ Hub & Peripherals

Daily vital signs, symptoms & patient engagement

+

Cordella™ Pulmonary Artery Pressure Sensor

Adds 20s PAP reading to daily routine

Secure Cloud Server

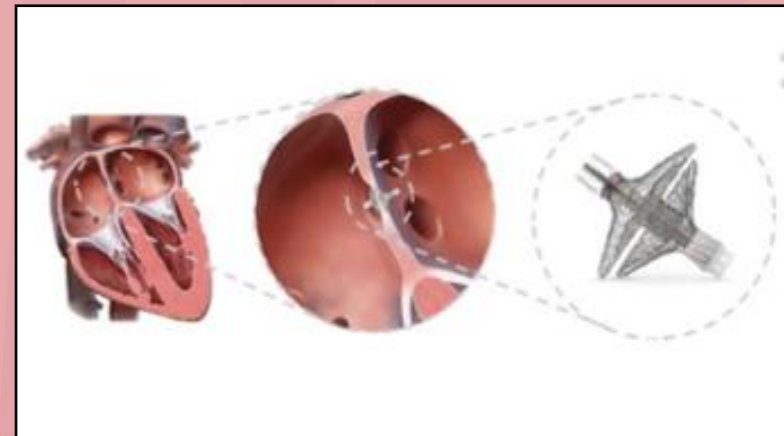
myCordella™ Patient Management Portal (PMP)

B

Proximal Anchor, Distal Anchor, Sensor Body

Arteria Pulmonar Derecha

V-LAP



Aurícula Izquierda

1- Sensores de presión: CardioMEMS

Delivers insight into the early onset of worsening HF to more proactively manage HF patients and improve outcomes

PULMONARY ARTERY PRESSURE SENSOR



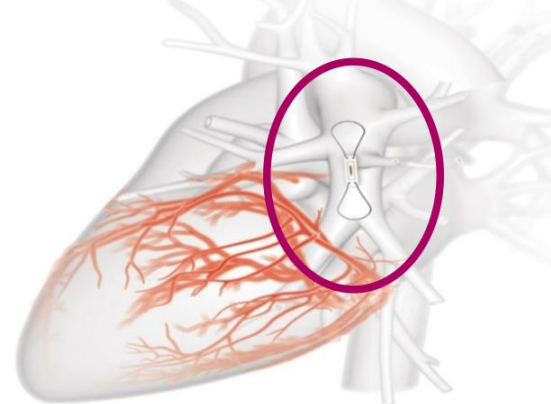
PATIENT ELECTRONICS SYSTEM



MERLIN.NET™ PCN



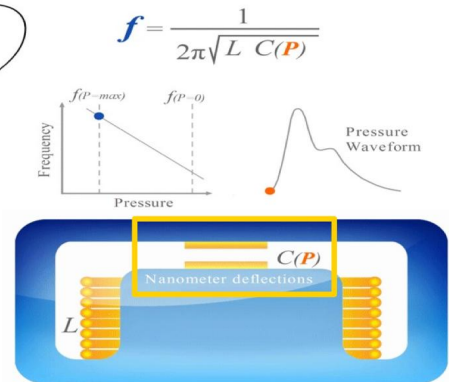
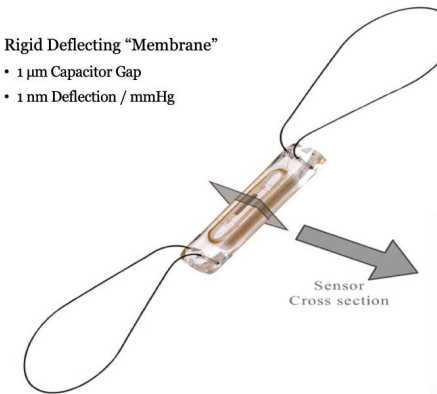
TARGET LOCATION FOR PA PRESSURE SENSOR



Sensor Concept

Rigid Deflecting "Membrane"

- 1 μm Capacitor Gap
- 1 nm Deflection / mmHg



Detectores de presión: funcionamiento

Step 1

Review trended PA pressure data, a leading indicator of worsening HF¹



Step 2

Regularly review vital signs (class 1 recommendation)¹

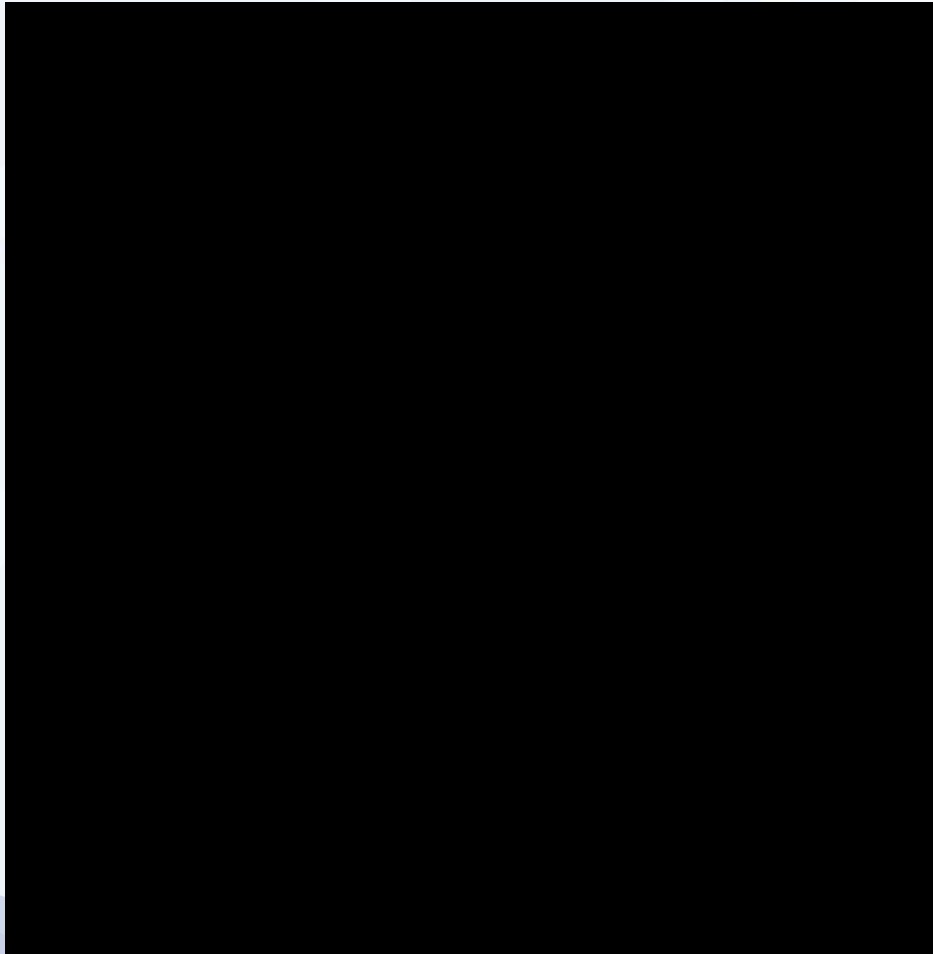


Step 3

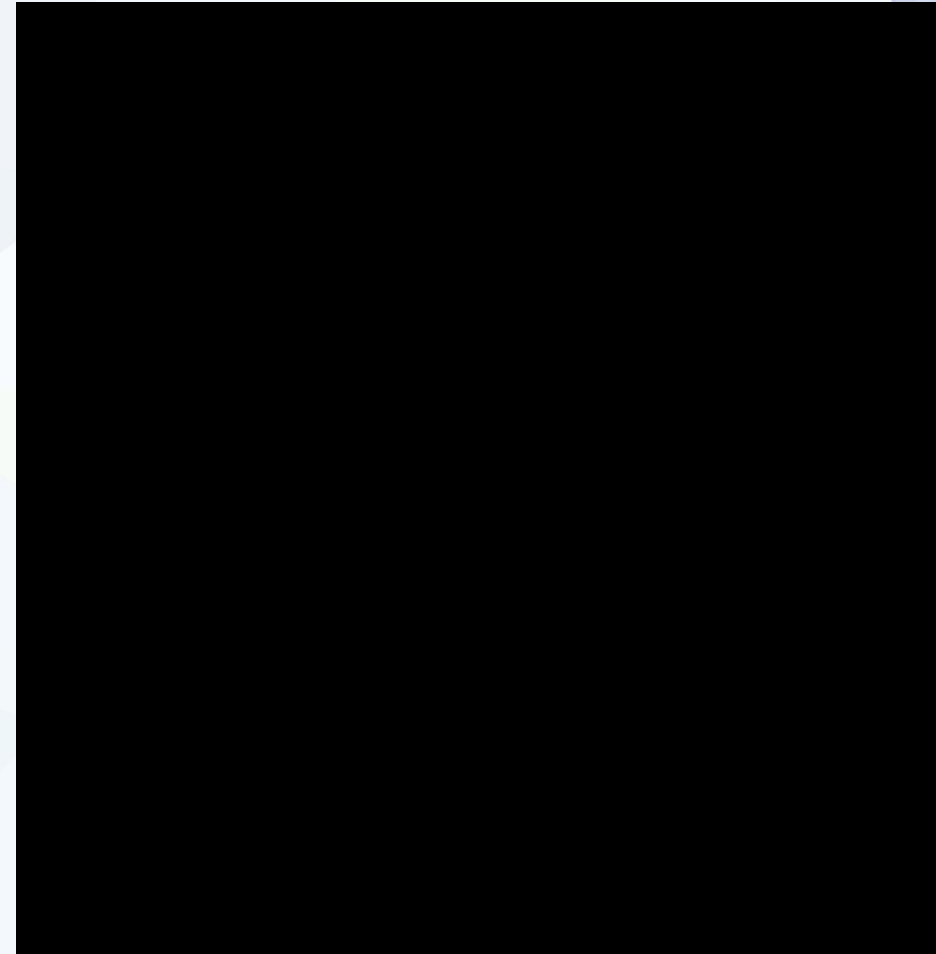
Optimize medical therapy to normalize PA pressure or address rising PA pressure



CardioMEMS Implante



Rama Arteria Pulmonar Izquierda >7mm



Liberación y calibración del dispositivo

Acceso venoso femoral 12F

Calibración del CardioMEMS acorde con el cateterismo derecho



This screen prompts the user to 'Enter mean pressure measured with Swan' with the value '25' entered in a text field. Below the text field is a numeric keypad with buttons for digits 0-9, a decimal point, and a double left arrow. At the bottom right, there are 'Cancel' and 'Apply' buttons.

Importancia del Cateterismo derecho

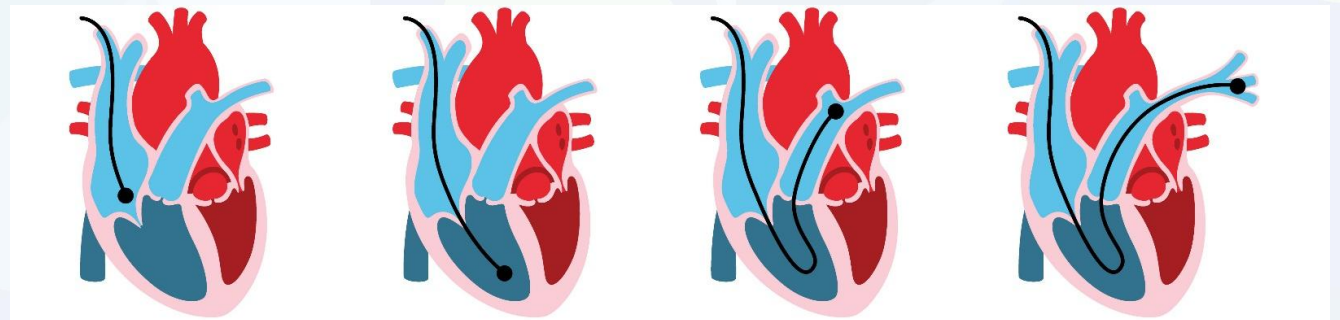


En ausencia de valvulopatía hay concordancia de presiones entre las cámaras cardiacas

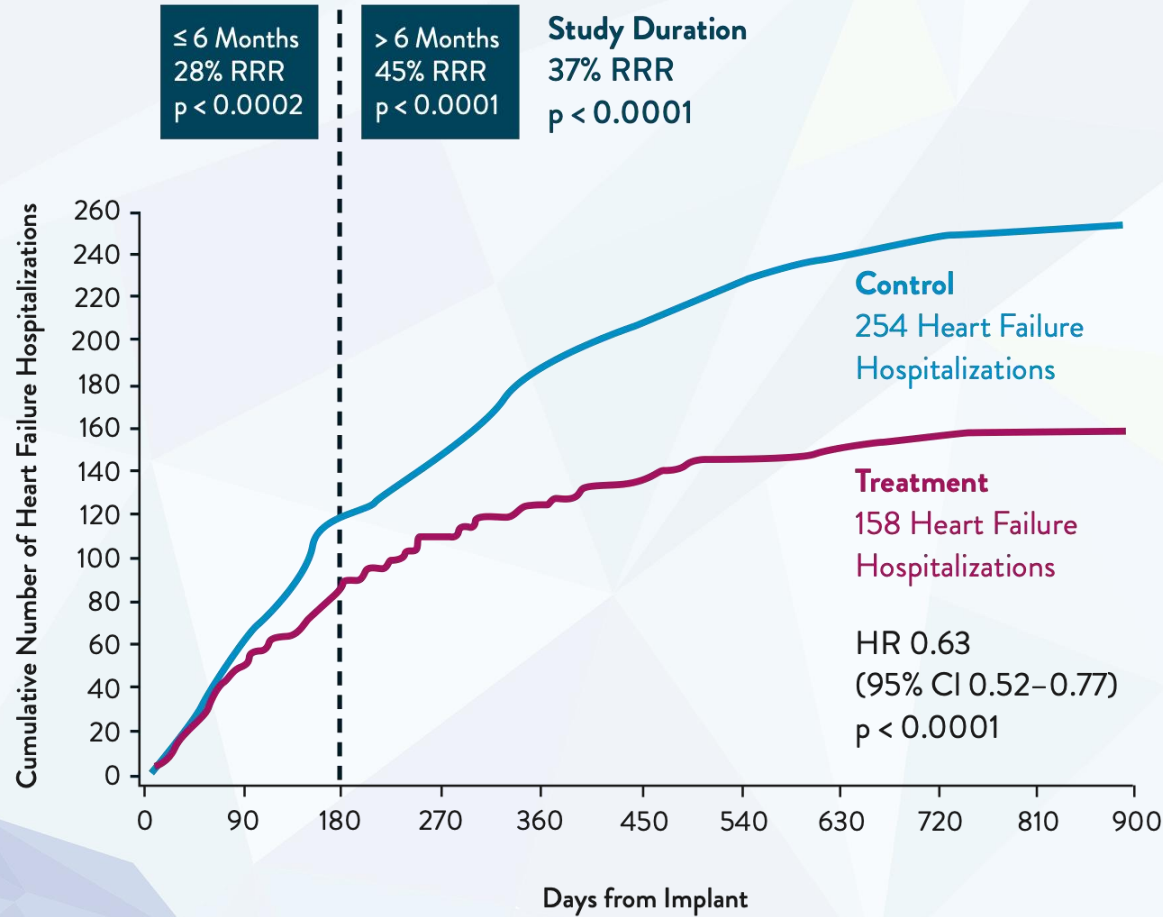
$PTDVI \approx PAI \approx \text{Wedge}$

$PSVD \approx PSAP$

$PDVD \approx PAD$




CardioMEMS: Estudio CHAMPION



No. at Risk	0	90	180	270	360	450	540	630	720	810	900
Control	280	267	252	215	179	137	105	67	25	10	0
Treatment	270	262	244	210	169	131	108	82	29	5	1

- The treatment group required < 1 medication change per patient per month compared to the control group (9.1 ± 7.4 vs. 3.8 ± 4.5 changes per patient during the first six months of follow-up; $p < 0.0001$).
- During the entire follow-up (mean 15 months), PA pressure-guided therapy (treatment group) significantly reduced heart failure hospitalizations by 37% compared to the control group ($p < 0.0001$; **Figure 1**).
- The treatment group had a lower risk of death or freedom from first heart failure hospitalization during the entire follow-up period compared to the control group ($p = 0.0086$).

Hemodynamic Management data with CardioMems

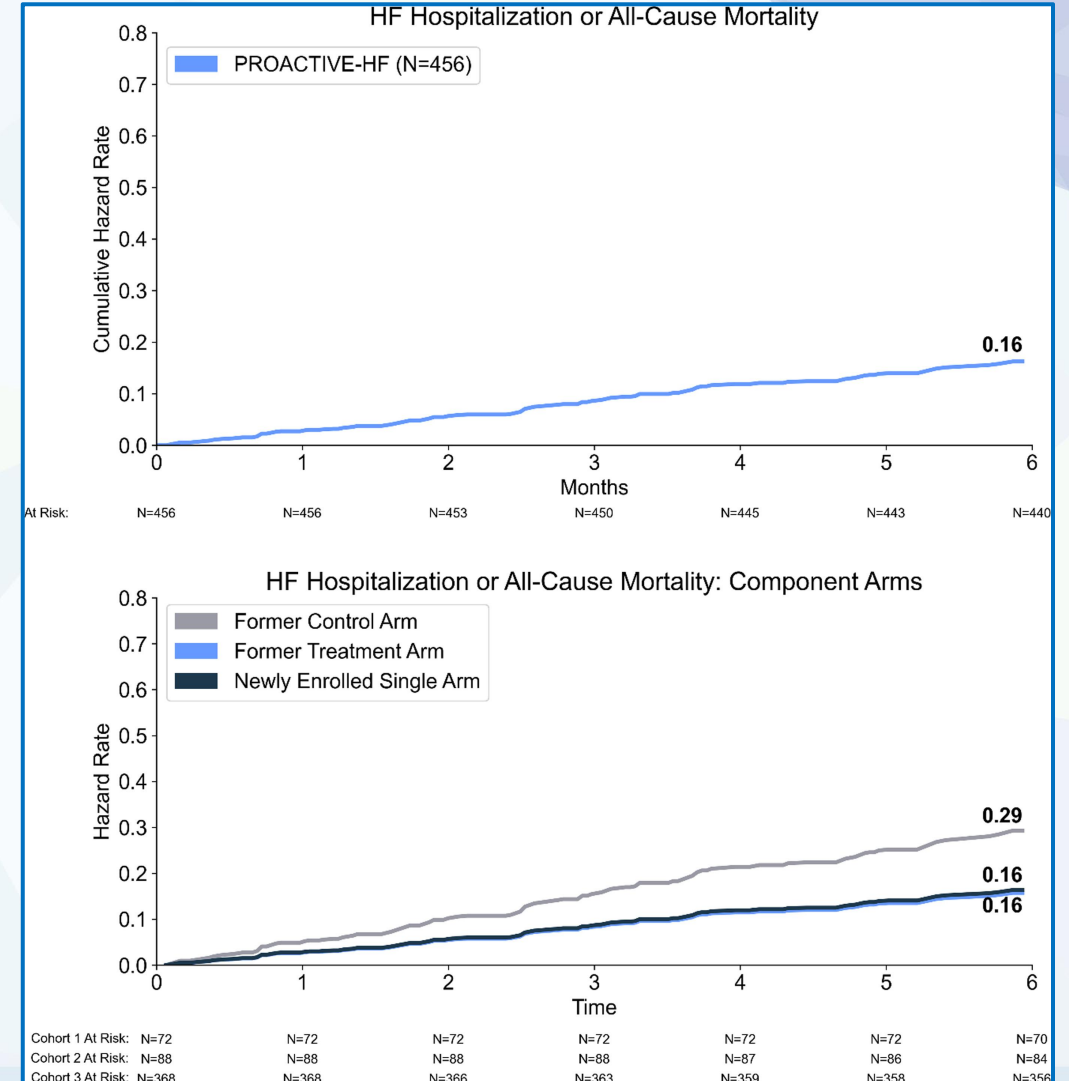
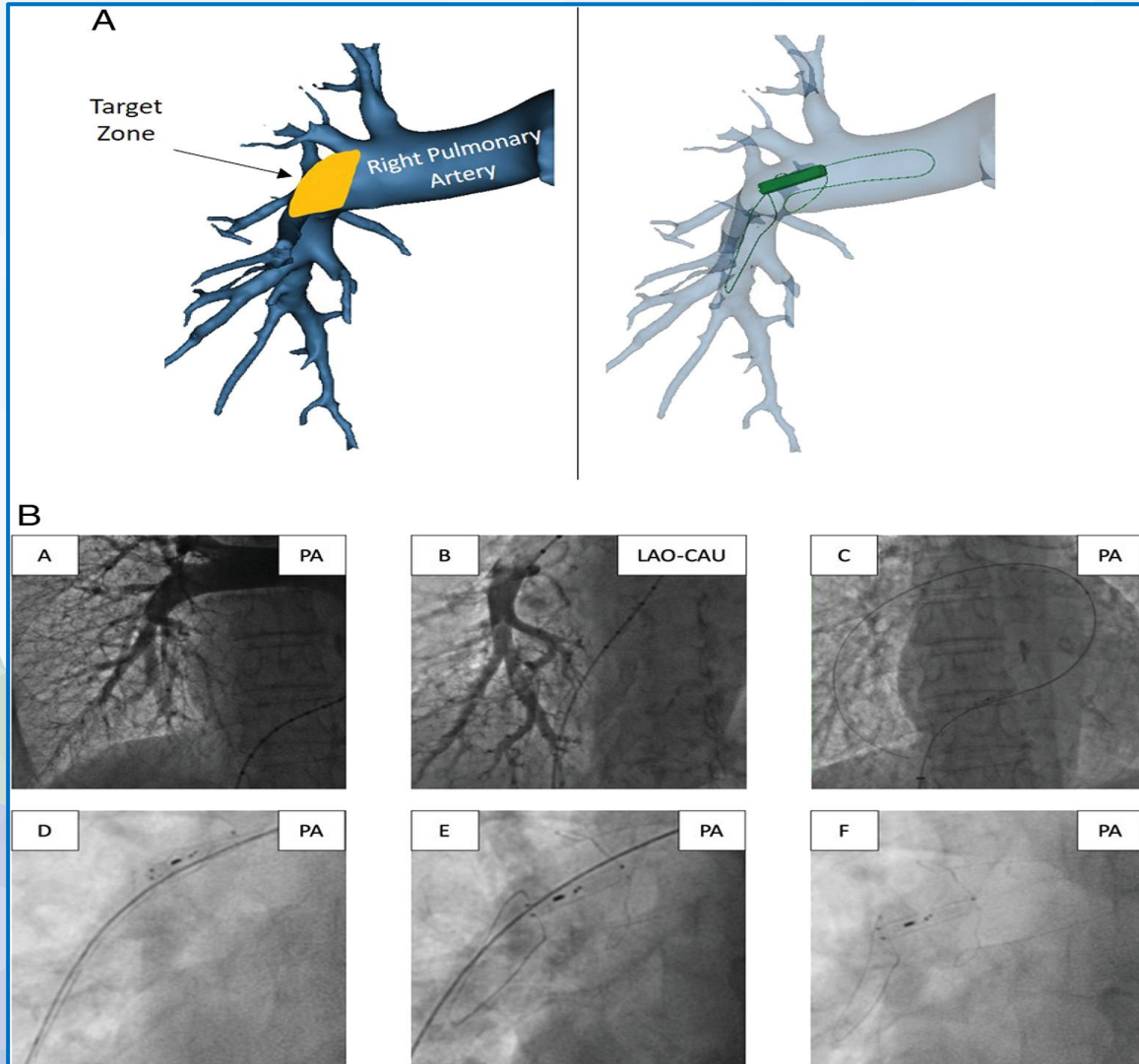
Study	N	Follow up	 Reduction in HFH	p-value
RCT: GUIDE-HF ^{1, 2}	1,000	8.4 mo.	28%	p < 0.01
RCT: CHAMPION IDE ³	550	18 mo.	33%	p < 0.0001
Contemporary Control: Propensity Matched ⁴ Outcomes	2174	12 mo.	24%	p < 0.001
MEMS-HF European Study ⁵	234	12 mo.	62%	p < 0.0001
Post-approval Study: US ^{6,7}	1200	24 mo.	57%	p < 0.0001

1. GUIDE-HF RCT manuscript accepted by Lancet and as LBCT at 2021 European Society of Cardiology Congress
2. NYHA Class II/III pre-COVID 19 follow-up

3. Abraham, W. , 2011 and 2016, *Lancet* (18mo. median follow-up)
4. Abraham, J., 2019, *JAMA*

5. Angermann, C., 2020, *ESC*
6. Shavelle, D., 2020, *Circulation: HF*
7. PAS 2 year follow up completed. Manuscript pending

Hemodynamic Management data with Cordella: PROACTIVE-HF trial

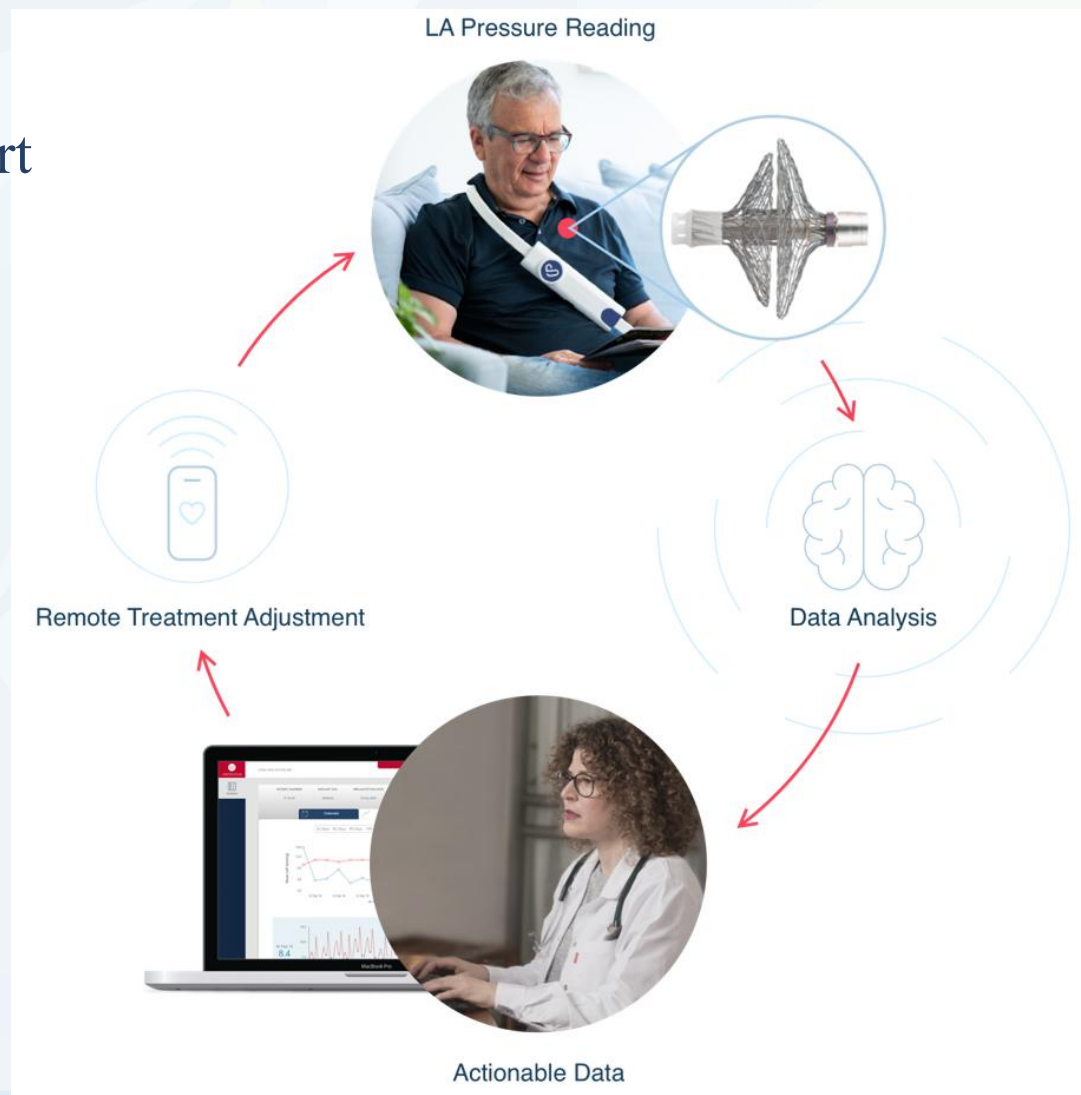


The V-LAP care cycle

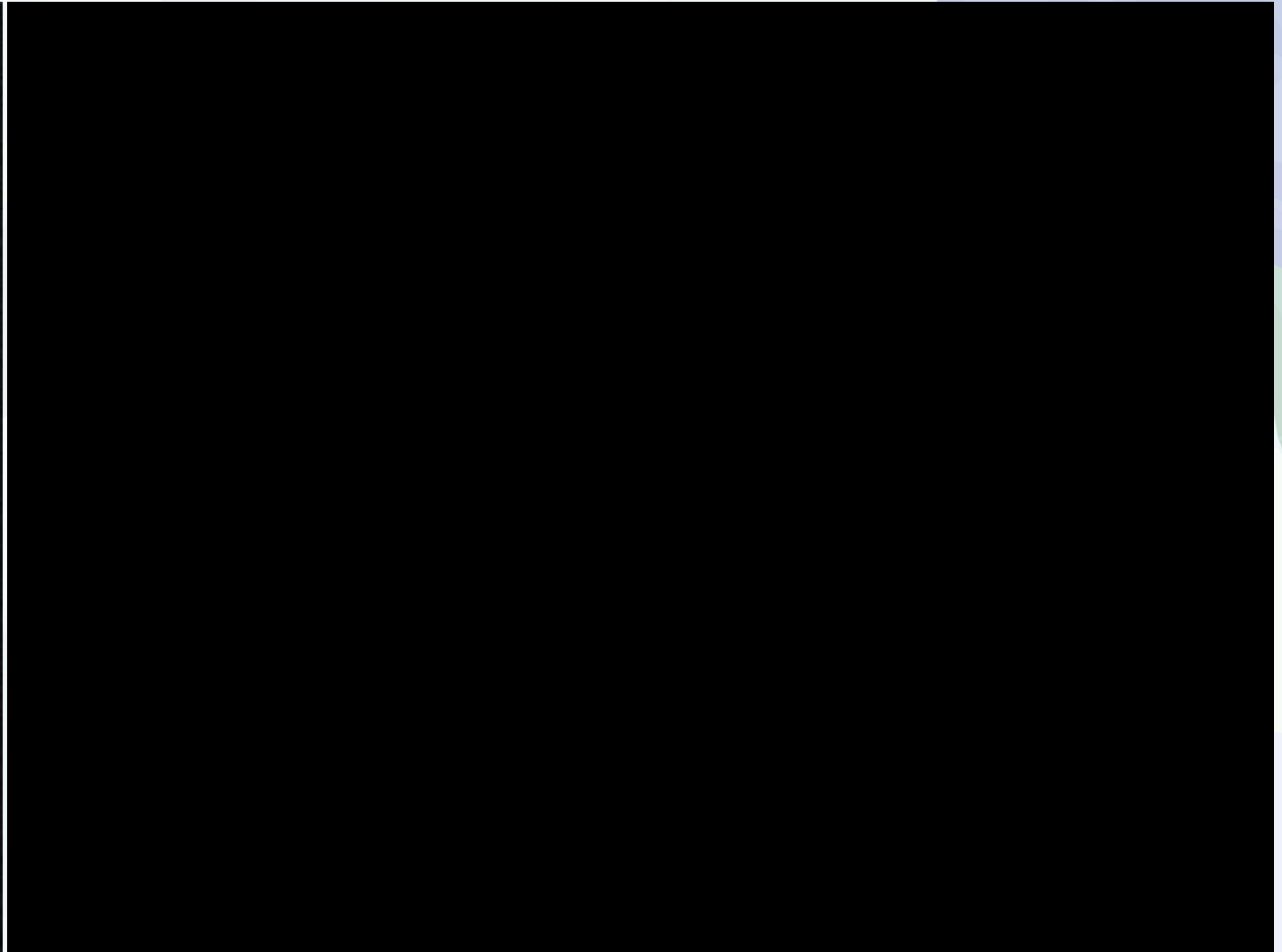
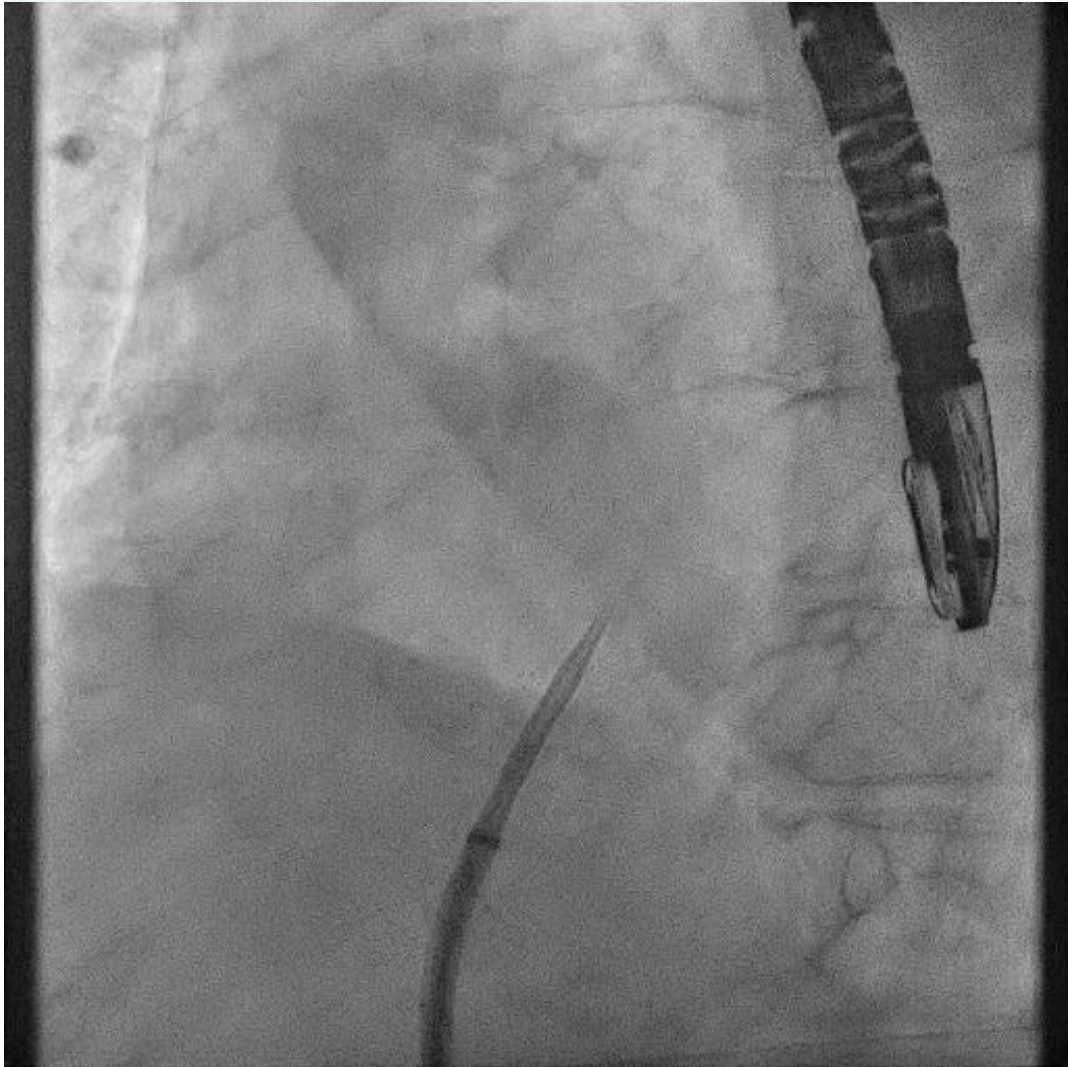
Introducing V-LAP:

The World's First In-Heart Microcomputer

- ✓ Wireless
- ✓ Digital
- ✓ Battery free
- ✓ Miniature



The V-LAP: Procedure

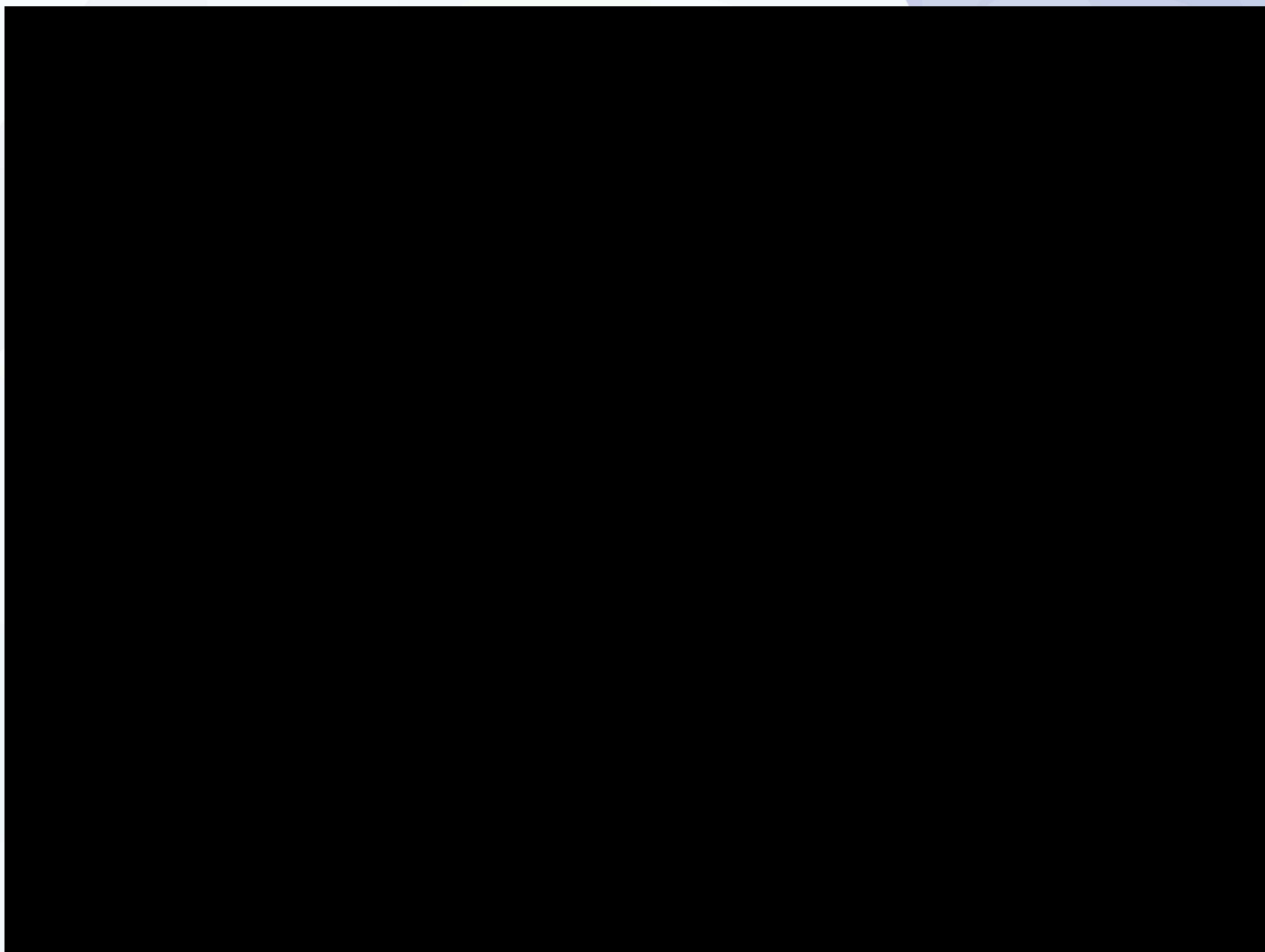


Acceso venoso femoral 12F

The V-LAP: Procedure



Fluoroscopia OAI 45^a



ETE 50°

VECTOR-HF I

Aims

To evaluate safety, usability and technical performance of V-LAP™ left atrial pressure remote monitoring system in advanced chronic heart failure patients.

Conclusion

The V-LAP™ system appears to be safe and accurate. Initial evidence also suggest possible improvement in clinical symptoms of HF.

Population

NYHA Class III chronic HF patients with at least one HF-related hospitalization or recurrently elevated (NTpro-)BNP levels over previous 12 months

Mean age: 69 years

Mean LVEF: 34 %



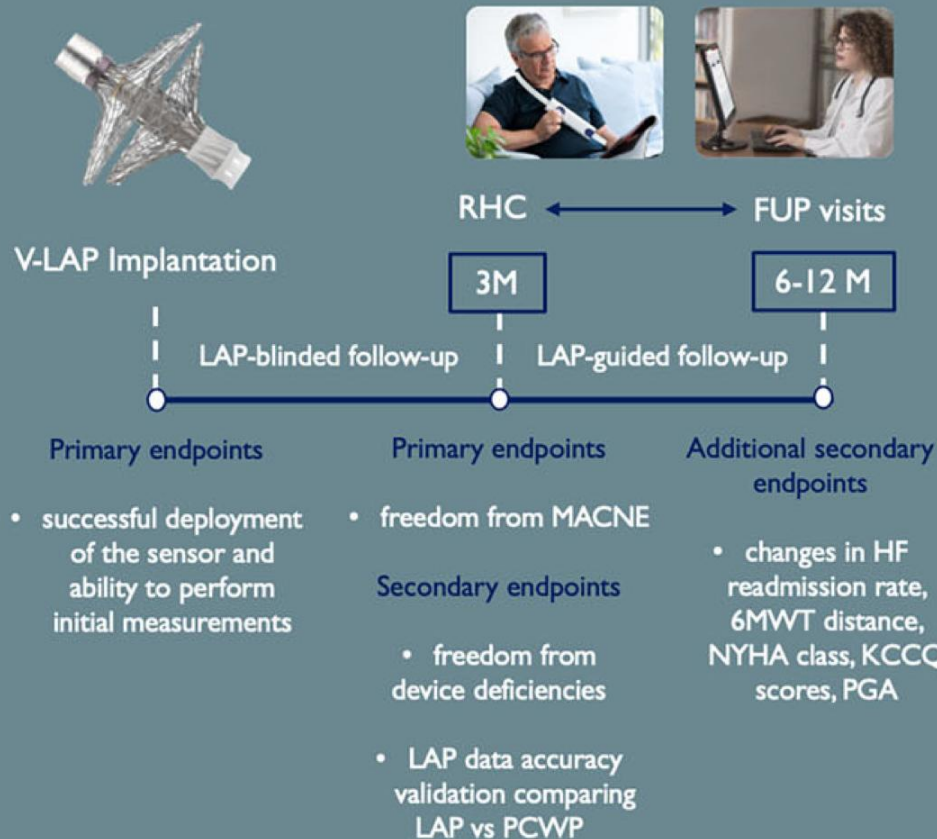
Enrollment & Locations

30/30 enrolled patients

14 sites across Europe and Israel



Study Design



Results

Primary endpoints

100 %
successful
V-LAP implantation

97 %
freedom from
MACNE at 3 months

Secondary endpoints

100 %
freedom from device
deficiencies at 3 months

-0.22±4.92 mmHg
LAP vs PCWP
mean difference

Additional endpoints*

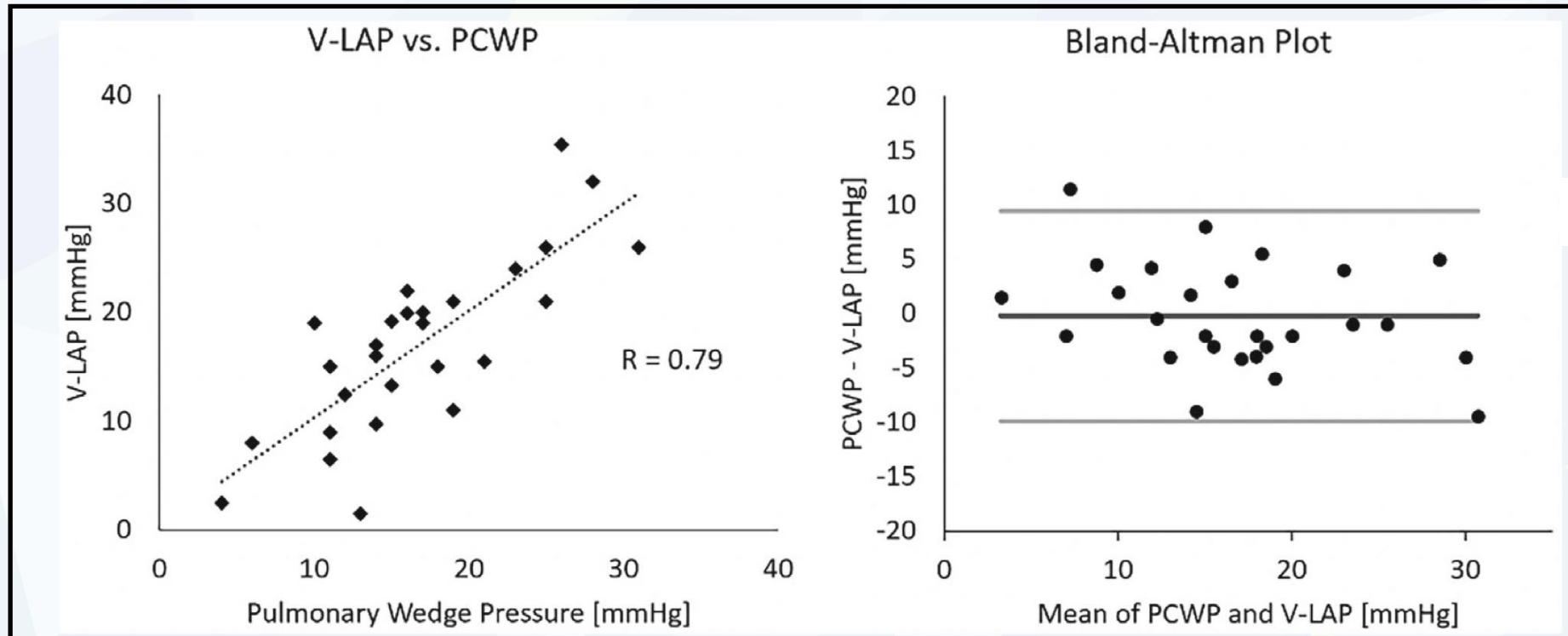
6M significant improvement in 6MWT distance (P=0.047) and NYHA class (P=0.004)

12M significant improvement in 6MWT distance (P=0.035) and NYHA class (P=0.003)

*follow-up is still ongoing

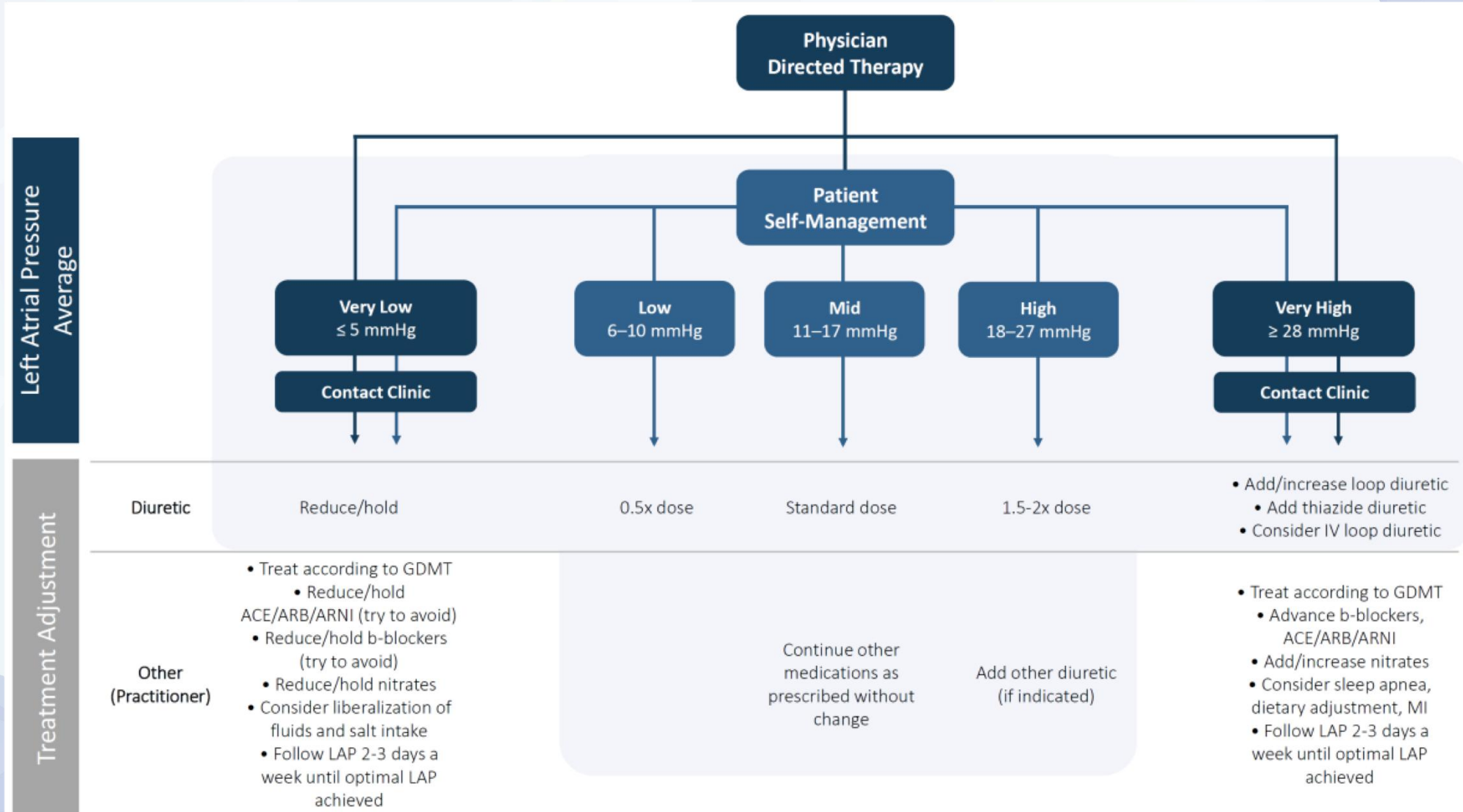
Vector I: Performance Accuracy Endpoint Status at 3M

- *Lin's concordance and Bland Altma plot from mean left atrial pressure and (LAP) and PCWP*



- *V-LAP vs. PCWP mean difference: -0.22 ± 4.92 mmHg*
- *Pearson Correlation $R=0.79$ ($P < .0001$); Lin's CCC*

Vector II Trial: Patient self-management



Dispositivos percútanos para el tratamiento de la IC

- **1-** Detección precoz de alteraciones hemodinámicas
 - a. Sensores de presión: pulmonar, auricular izquierda, bi-auricular, VCI, etc

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Dispositivos de Shunt para la IC

V-Wave Interatrial Shunt Device



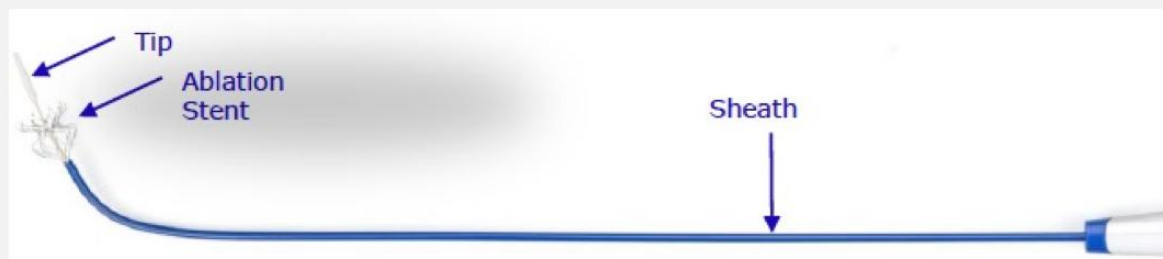
Corvia Interatrial Shunt Device



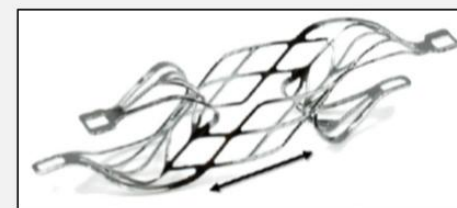
Occlutech Atrial Flow Regulator



Noya RF-based Interatrial Shunt System



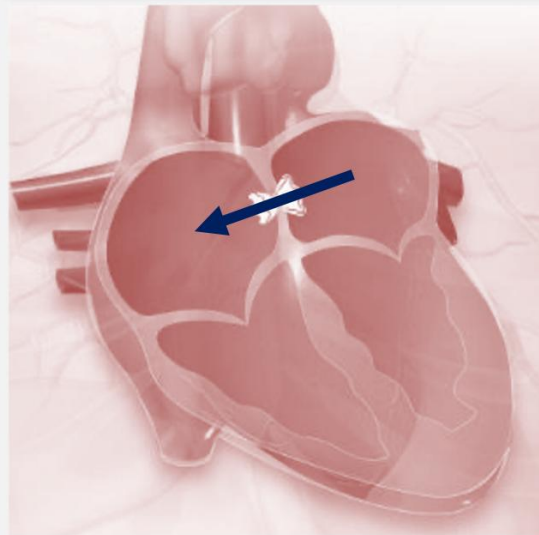
Edwards LA-Coronary Sinus Shunt



And, more to come!

Interatrial Shunting in Heart Failure

IMPACT OF V-WAVE SHUNT



Excess LA volume
shunted to RA

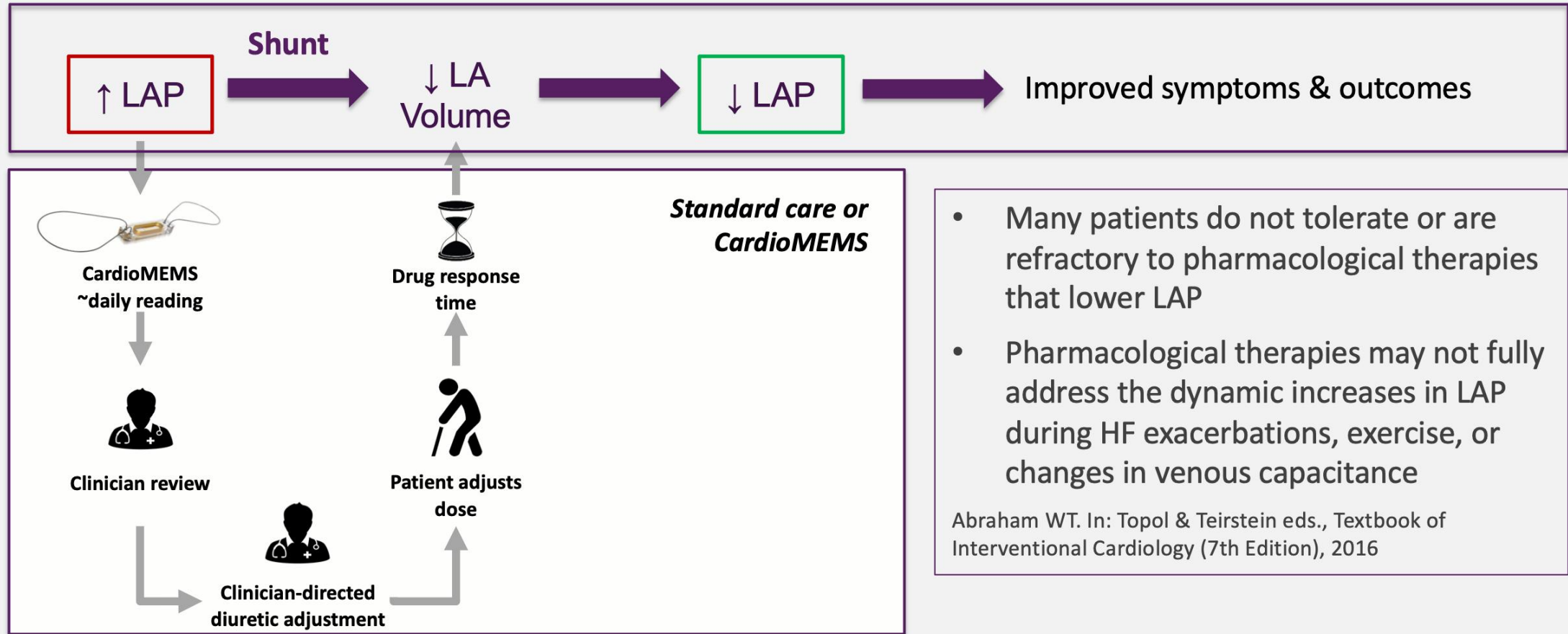
↓ LAP, LVEDP

↓ LV PA pressure

- Reduced pulmonary congestion and events
- Improved functional status, symptom relief
- Signs of LV remodeling
- Maintenance of RV function

Interatrial Shunting Self-Regulates LAP 24/7

Standard Care & Pressure-guided Management Have Delays & Failure Points

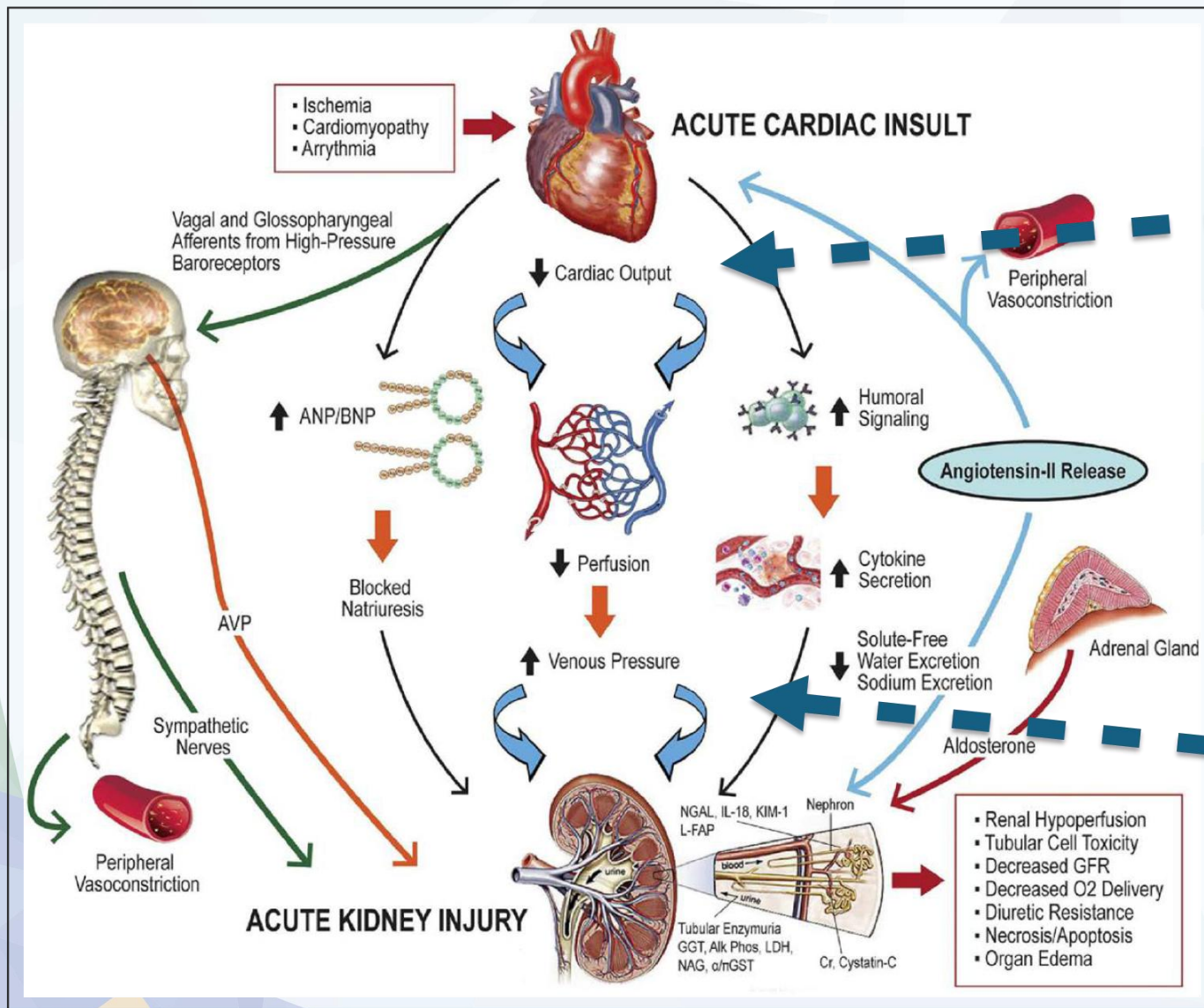


- Many patients do not tolerate or are refractory to pharmacological therapies that lower LAP
 - Pharmacological therapies may not fully address the dynamic increases in LAP during HF exacerbations, exercise, or changes in venous capacitance
- Abraham WT. In: Topol & Teirstein eds., Textbook of Interventional Cardiology (7th Edition), 2016

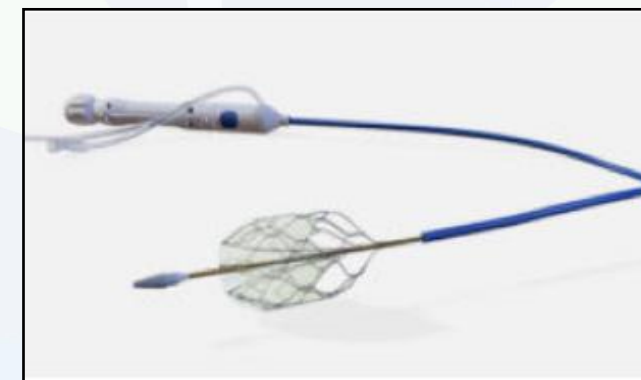
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4. Sd. Cardiorenal: Actuación sobre componente hemodinámica



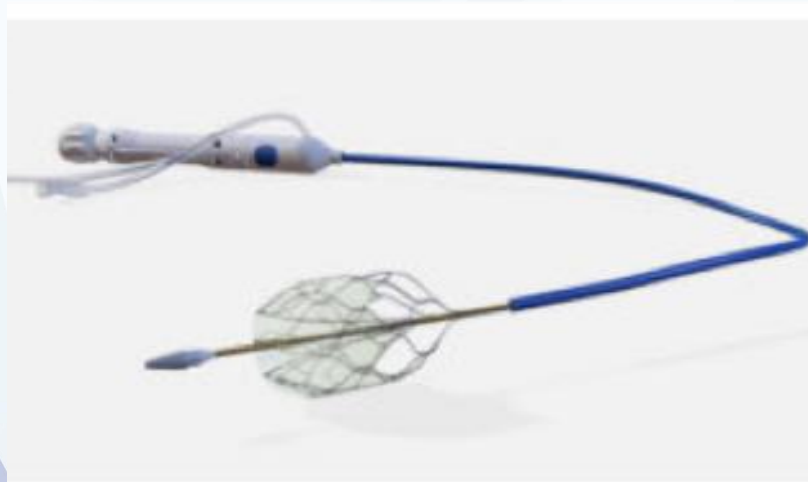
Aortix



Doraya

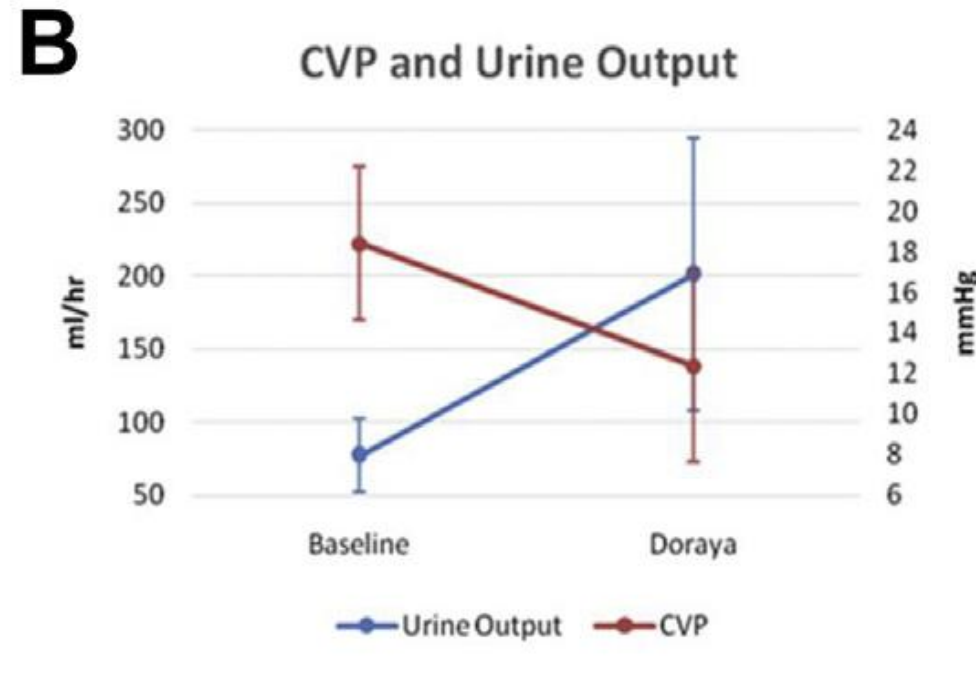
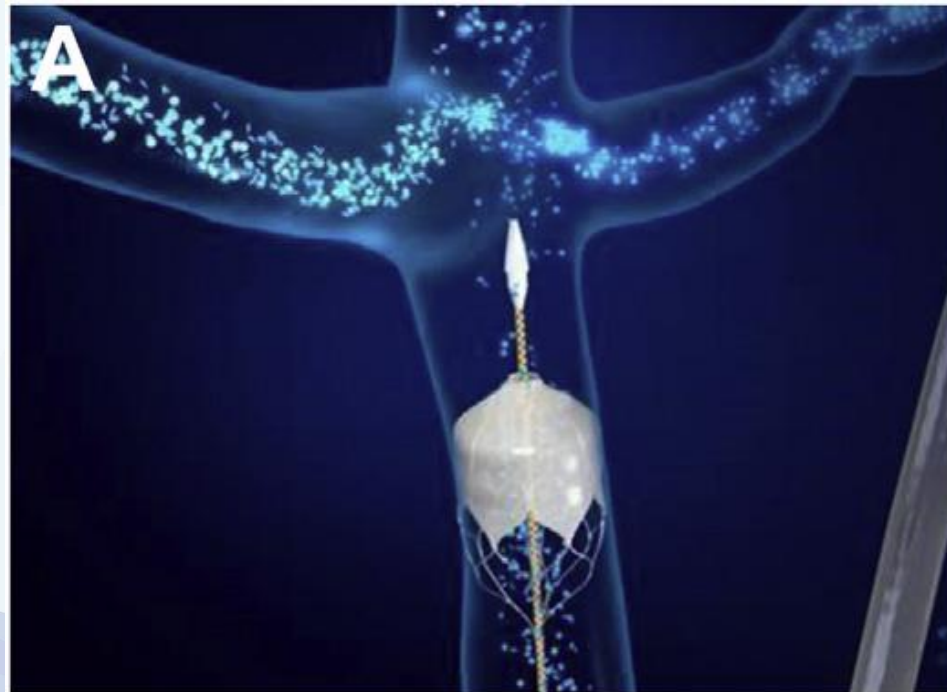
4. Sd. Cardiorenal: estudios en marcha

Doraya Catheter	- Venous renal flow modulator via femoral vein (12F) - Decrease renal hypertension and RV pre-load	NCT03234647	Multicenter, First-in-Man, single group (feasibility and safety)	-ADHF with poor diuretic response	9	Enrolling ended May 2021 - Device or procedure serious adverse event at 60 days.
Aortix	-Arterial renal flow modulator via femoral artery (18F) - Pump that increase aortic flow (up to 5L/min), increase renal perfusion pressure and reduce LV after-load	NCT04145635	Multi-center, prospective non RCT, feasibility and safety	-ADHF with HFrEF or HFpEF -Worsening renal function after 48 h of iv diuretic (increase 0.3 mg/dL) -Persistent congestion (PCWP \geq 20 or central venous pressure \geq 12mmHg)	60 (ongoing)	Enrolling (estimated completion 2022) -Endpoints: 30 day serious adverse event, serious procedural adverse event, device performance; 7-d decrease central venous pressure or PCWP $>$ 20%; change in urine output; decrease BNP by 20%



Doraya Catheter

FIGURE 1 The Location of the Catheter in the Inferior Vena Cava and its Clinical Effects





Forty-nine years old man was admitted to the hospital in context of **acute heart failure**. Physical examination revealed the presence of **anasarca** (weight 150 kg)

Septal mid-wall late gadolinium enhancement on cardiac magnetic resonance imaging was identified, suggesting nonischemic dilated cardiomyopathy—previous coronary angiography without stenoses.

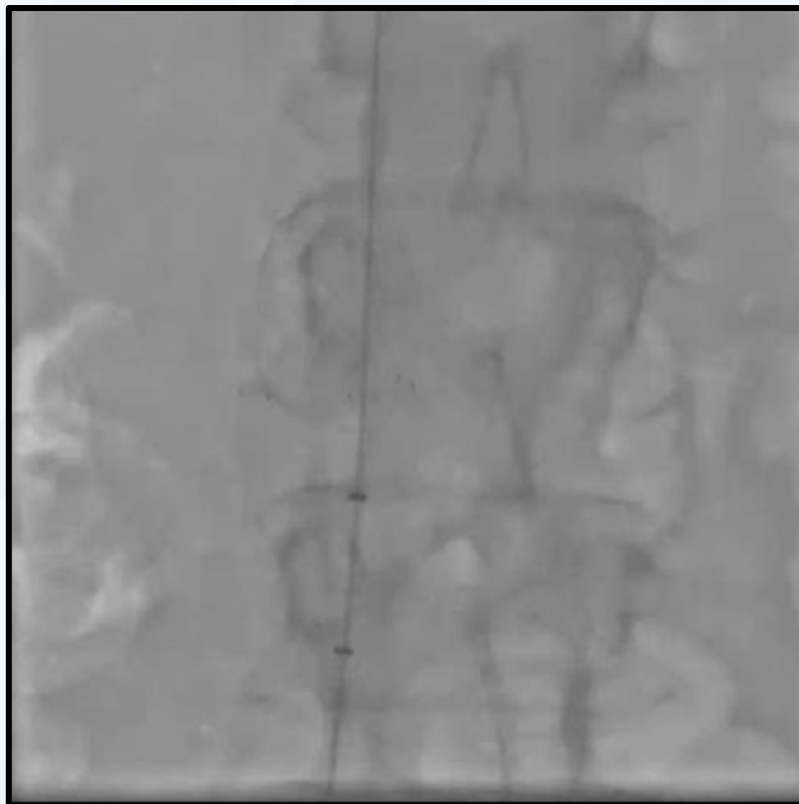
Diuretic therapy was started (sequential nephron blockade with 250 mg of furosemide, 50mg of hydrochlorothiazide, 25 mg spironolactone, and bumetamide) **without clinical improvement.**

Doraya Catheter was implanted.

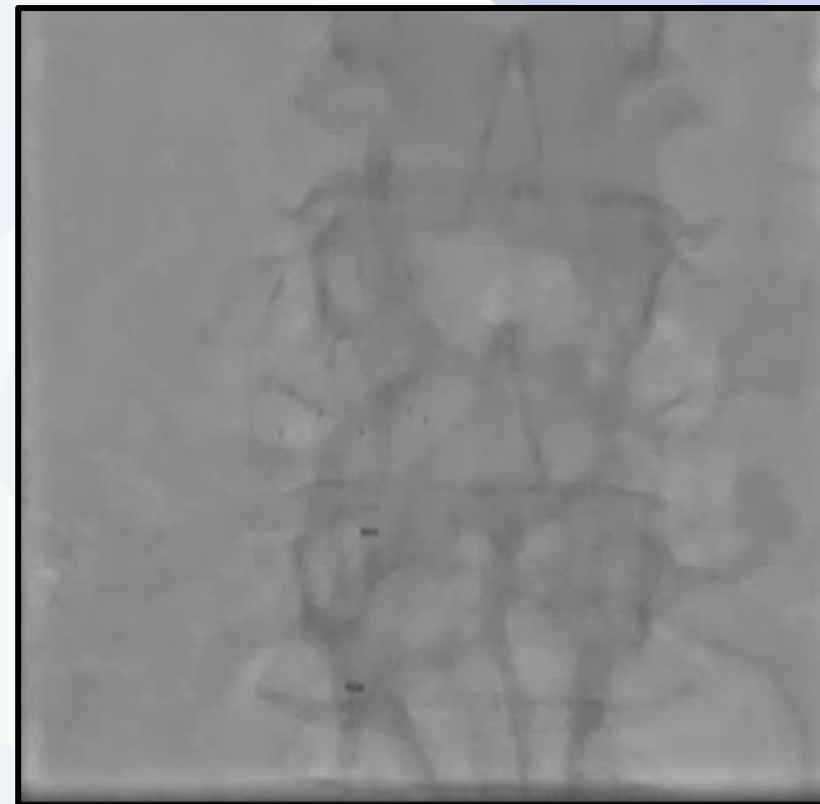
Doraya Catheter Procedure



Localización de vena renal

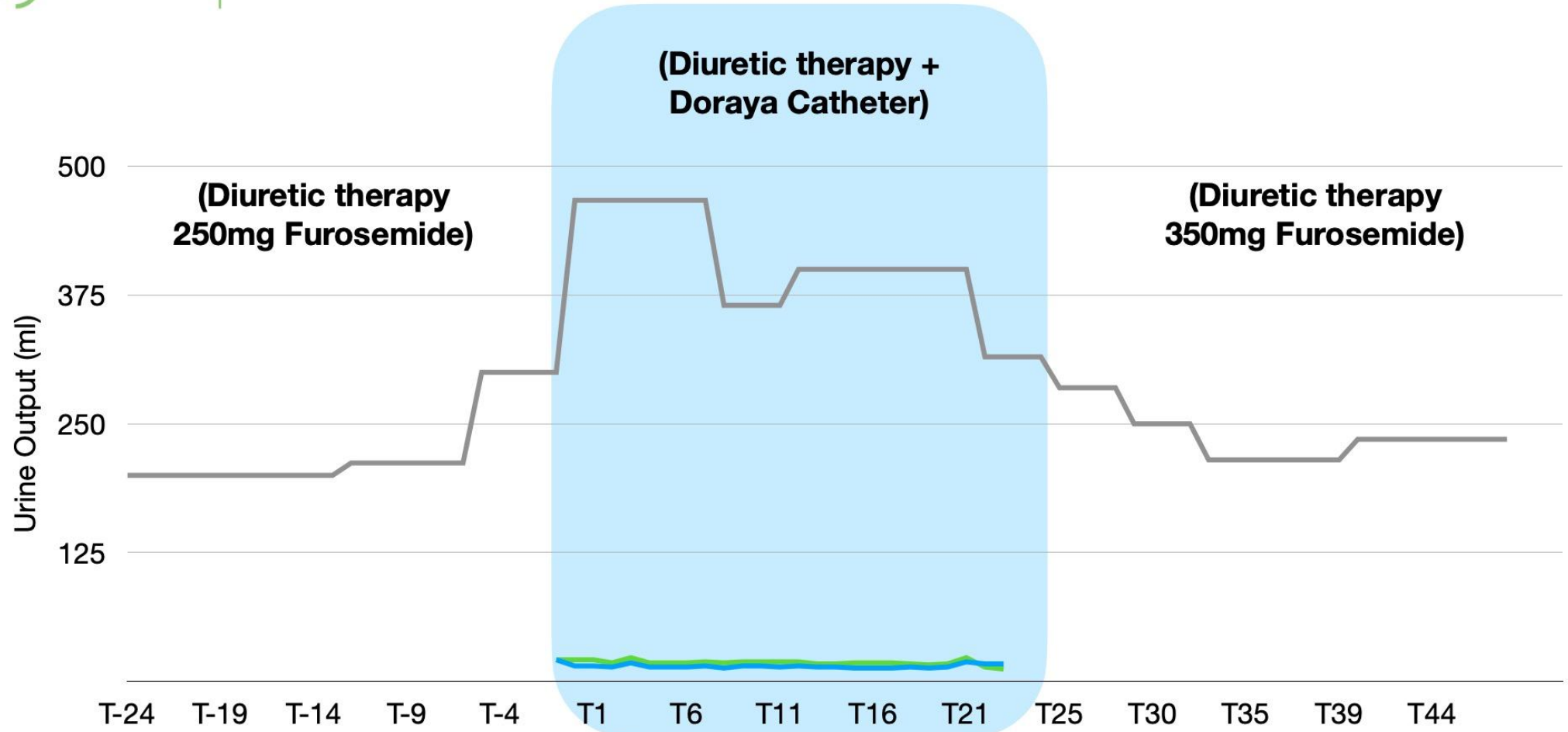


Despliegue Catheter Doraya



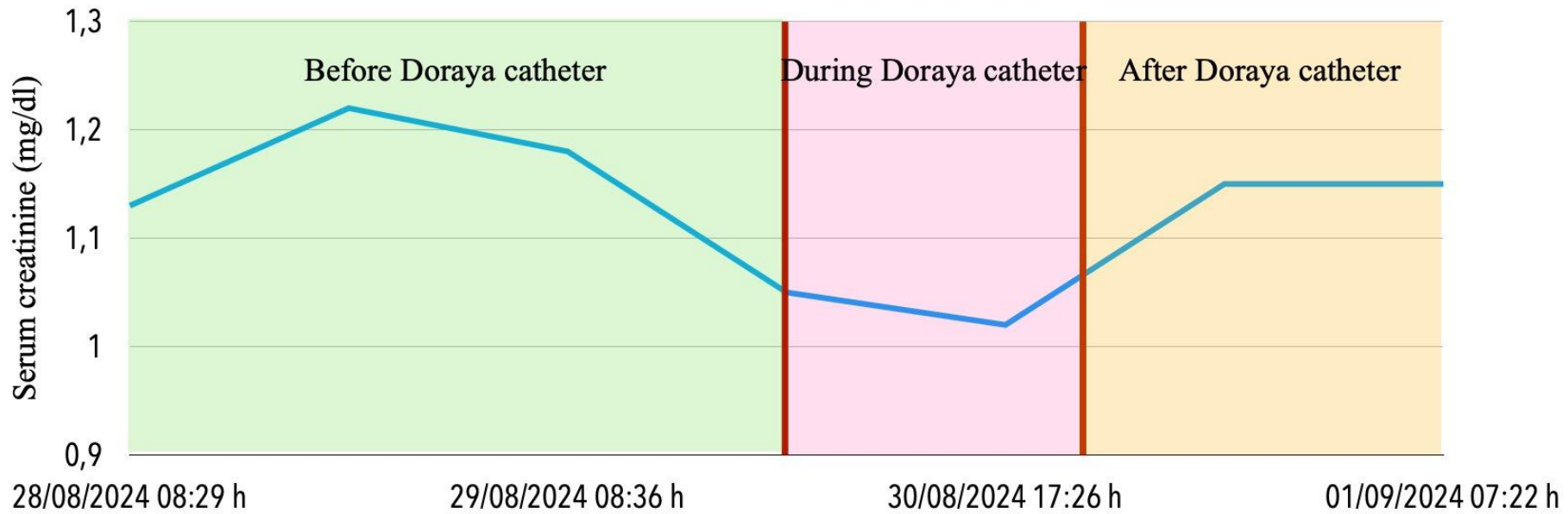
Resultado tras el Despliegue

Tiempo de dispositivo: 5 min



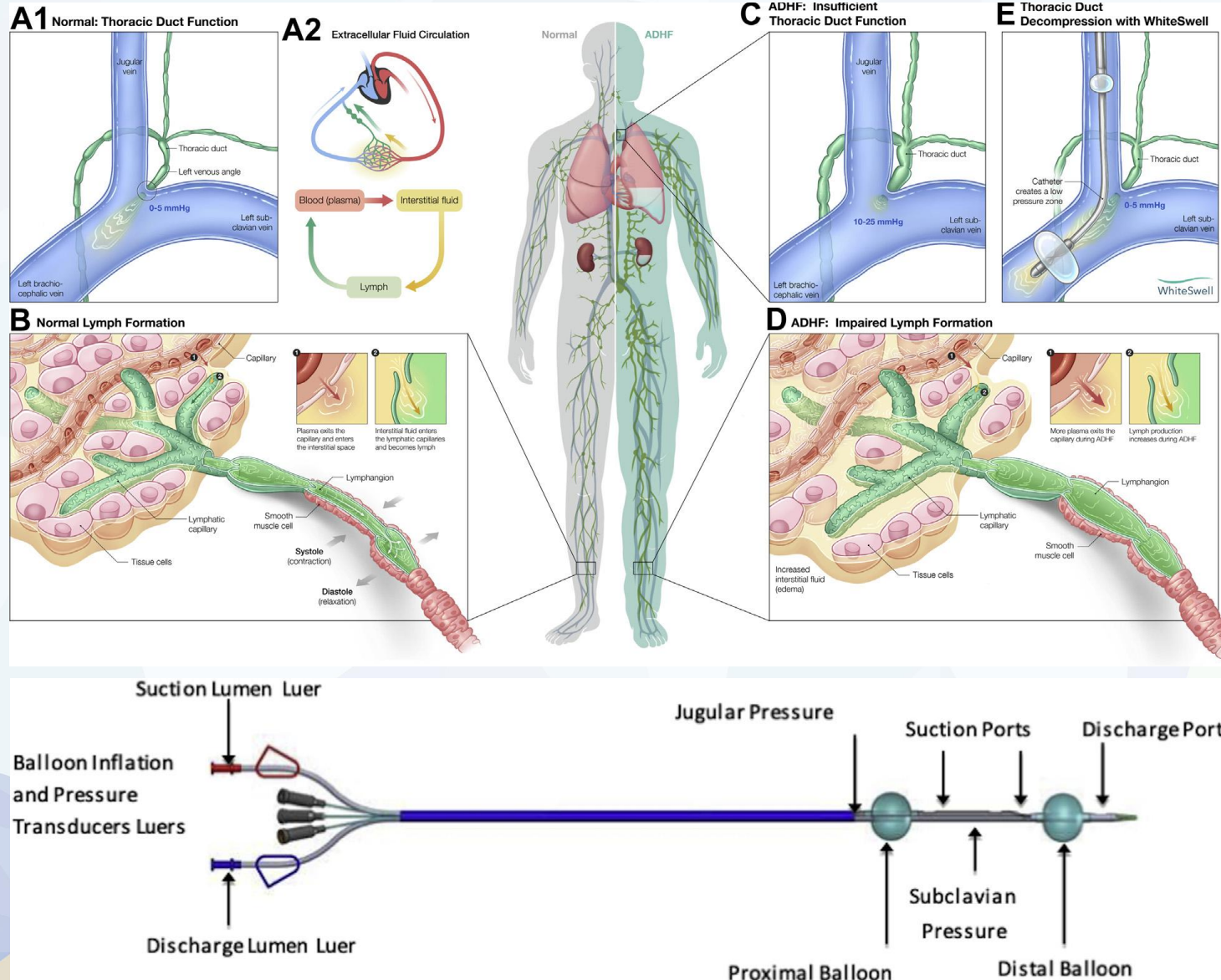


Recording serum creatinine level

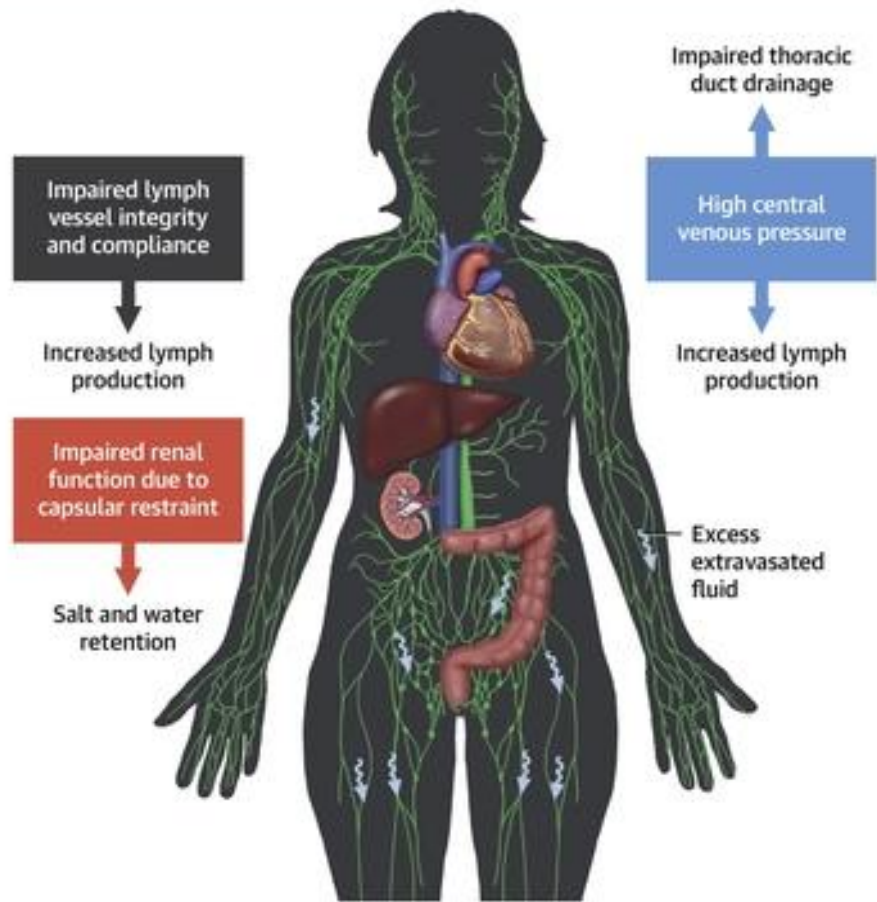


Dispositivos percútanos para el tratamiento de la IC

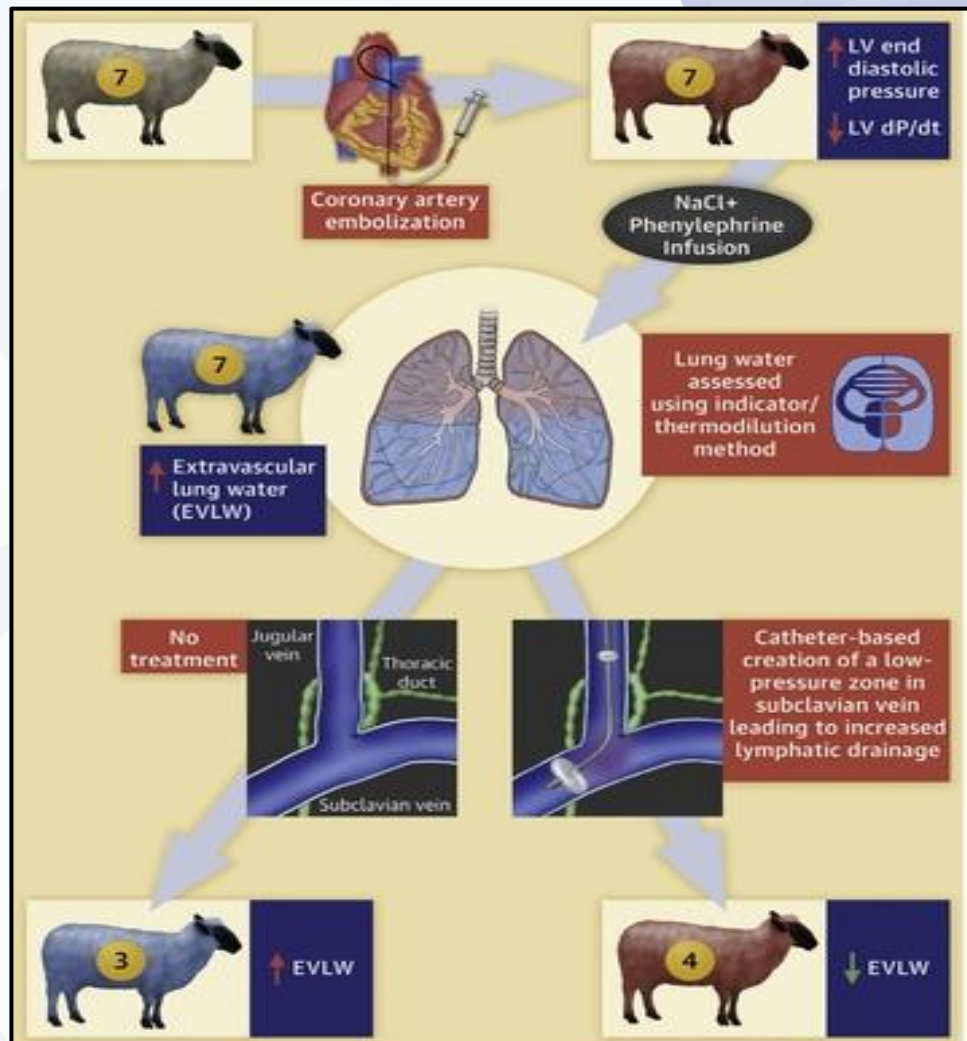
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- 4- Dispositivos para la reabsorción del líquido linfático



CENTRAL ILLUSTRATION: Dysregulation of the Lymphatic System in Heart Failure



Fudim, M. et al. J Am Coll Cardiol. 2021;78(1):66-76.



Abraham, W.T. et al. J Am Coll Cardiol Basic Trans Science. 2021;6(11):872-81

Muchas gracias

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