corvia®

RESPONDER-HF

Information for Healthcare Professionals

A clinical trial confirming the efficacy of atrial shunt therapy for heart failure patients with an EF≥40%

Over **26 million people** suffer from **heart failure (HF)** worldwide.[1]

More than half have an ejection fraction (EF) over 40%[2], termed heart failure with preserved (HFpEF) or mid-range (HFmrEF) ejection fraction, which is characterized by left atrial and ventricular stiffness and elevated filling pressures.

These high filling pressures are the primary contributor to HF symptoms and often result in hospitalization and death.[3,4]

Now, a novel therapy called atrial shunting is available via the RESPONDER-HF study. It is the only direct treatment for high left atrial pressure (LAP), and an opportunity to provide symptom relief to your HF patients.

RESPONDER-HF CLINICAL TRIAL

Corvia Medical is conducting the RESPONDER-HF clinical trial to confirm the clinical efficacy of the Corvia® Atrial Shunt System in HF patients with elevated LAP, an ejection fraction over 40%, and who remain symptomatic despite standard Guideline Directed Medical Therapy (GDMT).

The Corvia Atrial Shunt is the most clinically and scientifically studied atrial shunt for the reduction of LAP in symptomatic HF patients.

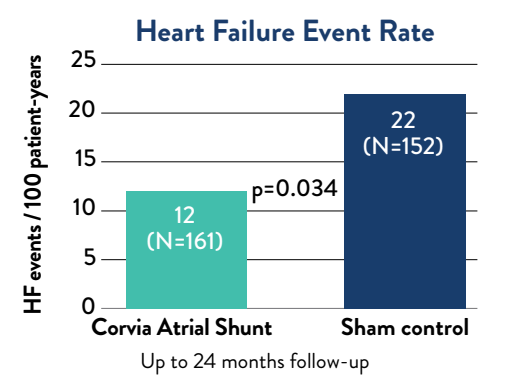
Evidence from multiple clinical studies demonstrates consistent, durable results in over 550 patients with >1200 patient-years of follow-up:[5]

>99%
patency+

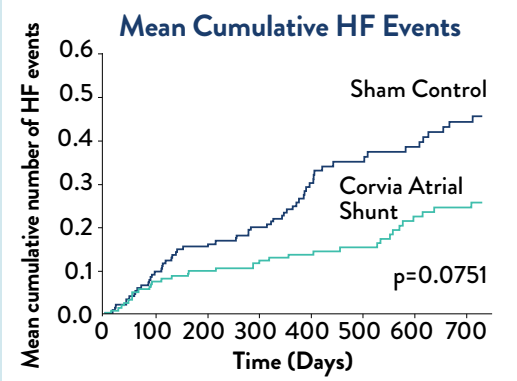
>97%
freedom from ischemic stroke†

Responder group data (n=313) from **REDUCE LAP-HF II**, the largest device therapy trial in HFpEF, reinforces the safety and efficacy of the Corvia Atrial Shunt and has newly defined the treatable patient population for atrial shunt therapy.

Heart Failure Events[6]



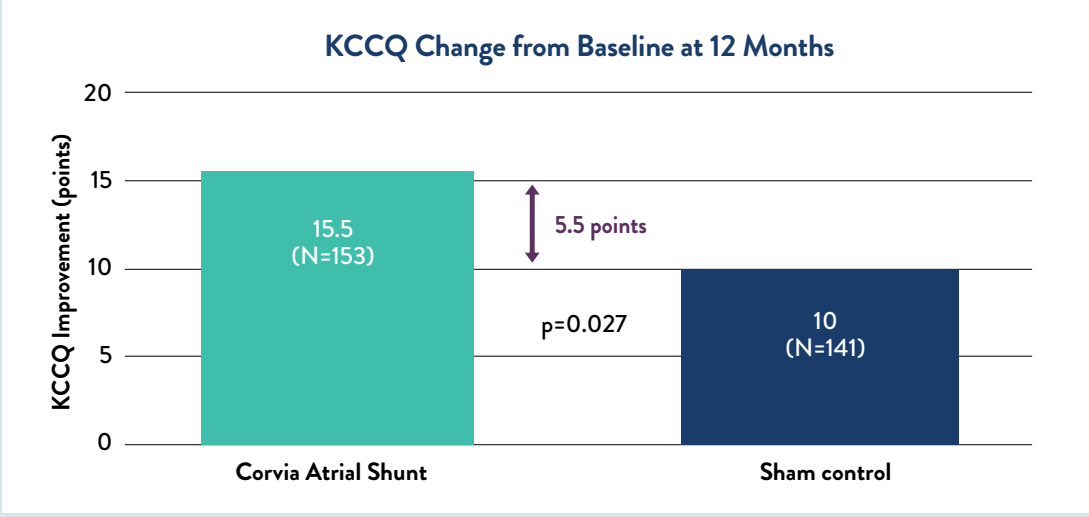
Shunt therapy led to a 45% reduction in the rate of HF events



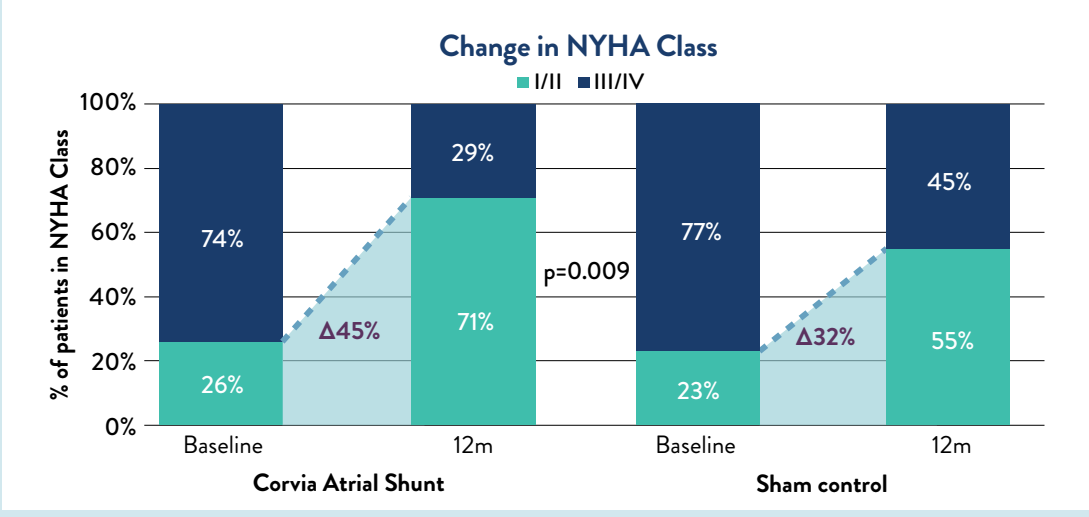
HF event curves separate early and continue to diverge

+Flow detected with no echocardiographic evidence of thrombus at one year or beyond
†Analysis through 3 years

Quality of Life/Health Status[6]



Shunt patients had a 55% greater improvement in KCCQ



Over 40% more shunt patients improved to NYHA Class I/II

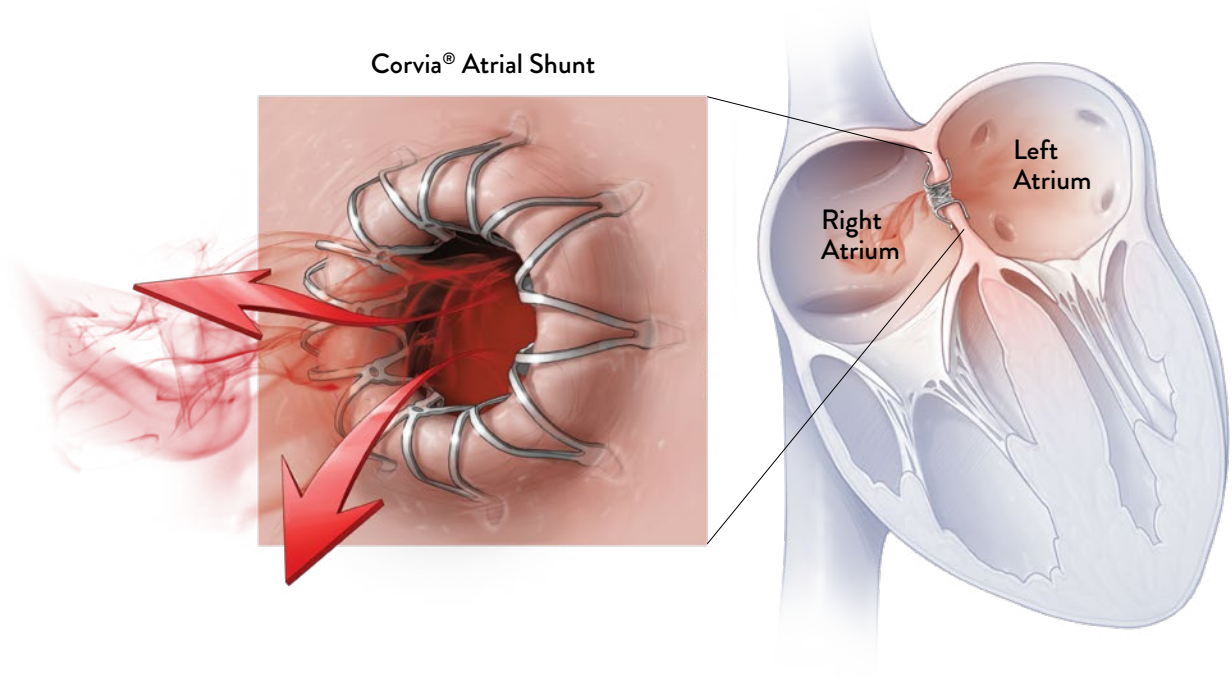
CORVIA ATRIAL SHUNT

- First therapeutic device designed to directly address elevated LAP, the primary cause of HF symptoms
- Provides continuous and dynamic LAP reduction at any activity level
- Only requires short term dual antiplatelet therapy
- Therapy is not dependent upon daily pressure monitoring

HOW IT WORKS

Placed by an interventional cardiologist or electrophysiologist during a catheter-based procedure, the Corvia Atrial Shunt creates a passage between the left and right atria. This passage allows blood to flow from the high pressure left atrium to the lower pressure right atrium, thereby reducing pressure in the left side of the heart and the lungs.

By facilitating continuous and dynamic decompression of the left atrium, the Corvia Atrial Shunt has been shown to significantly reduce HF hospitalizations, and improve heart failure symptoms and quality of life.[6,7]



WHO SHOULD BE CONSIDERED?

If you have patients over the age of 40 who have symptomatic HF or unexplained exertional dyspnea, they may be candidates for the RESPONDER-HF study.

Key Inclusion Criteria

- Left ventricular ejection fraction ≥40%
- New York Heart Association class II–IV
- Relatively normal right ventricular function
- Elevated left-sided filling pressures
- Absence of significant valve disease
- Absence of a cardiac rhythm management device

H_2FPEF SCORING MODEL[8]

Created to simplify the identification of HFpEF patients among those with exertional dyspnea. The total score correlates with the probability of a HFpEF diagnosis.

	Clinical Variable	Values	Points	
H_2	**H**eavy	Body mass index > 30 kg/m^2	+2	☐
	Hypertensive	On > 2 anti-hypertensives	+1	☐
F	Atrial **F**ibrillation	Paroxysmal or Persistent AF	+3	☐
P	**P**ulmonary Hypertension	RVSP > 35 mmHg	+1	☐
E	**E**lder	Age > 60 years	+1	☐
F	**F**illing Pressure	E/e′ > 9	+1	☐
			Score (Sum of above numbers)	☐

A score of	3	4	5	6+
Indicates a HFpEF probability of	>50%	>70%	>80%	>90%

Consider sending high probability HFpEF patients for further evaluation

A score of **4** means a greater than **70%** chance of HFpEF

POTENTIAL RISKS

As with any procedure and permanent implant, there are potential risks, and individual results may vary. Potential risks include adverse dye reaction, allergic reaction to implant, apnea, arrhythmia, bleeding, blood clot, cardiac arrest, cardiac perforation, death, decreased cardiac output, device malposition, device embolization, device fracture, endocarditis, fever, hematoma, hemolysis, hypotension, hypertension, mal-deployment of the device, infection, sepsis, nerve damage, pericardial tamponade, myocardial perforation, pleural or pericardial effusion, pseudoaneurysm, renal failure, embolization of air/tissue/thrombus, thrombosis and worsening heart failure.

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6. Borlaug, BA, Blair, J, Bergmann, MW et al. Latent Pulmonary Vascular Disease May Alter the Response to Therapeutic Atrial Shunt Device in Heart Failure. *Circulation*. 2022;10.1161.
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8. Reddy YNV, Carter RE, Obokata M, Redfield MM, Borlaug BA. A Simple, Evidence-Based Approach to Help Guide Diagnosis of Heart Failure With Preserved Ejection Fraction. *Circulation*. 2018;138(9):861-870.

For more information, please contact:

Place Study Site Principal Investigator Contact Information Here
(Avery 5160 — Label Size 2.625″ x 1″)

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