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REDUCE LAP-HF II

Corvia® Atrial Shunt in heart failure with preserved or mildly reduced ejection fraction

2-YEAR RESPONDER GROUP HIGHLIGHTS[1]

50%
Reduction in HF event rate compared to sham control

46%
Greater improvement in KCCQ-OSS* compared to sham control

98%
Patency

CONCLUSION

The Corvia Atrial Shunt improved quality of life and reduced heart failure (HF) symptoms and events through 2 years without a safety signal in appropriately selected HF patients with an ejection fraction (EF) ≥40%.

BACKGROUND

REDUCE LAP-HF II is the world's first phase III randomized trial for atrial shunting in HF. It defined the optimal patient population for atrial shunt therapy (the "responder" population) and demonstrated the Corvia Atrial Shunt was safe, significantly reduced HF events, and improved quality of life in the responder population compared to sham control at one year.[2]

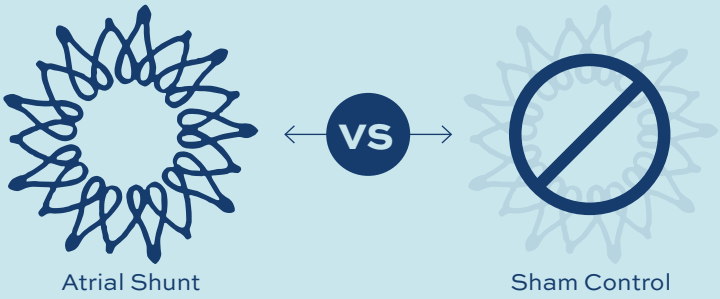
RELEVANCE

This two-year data, the longest follow-up from a randomized controlled trial on atrial shunt therapy, provides valuable insight into the Corvia Atrial Shunt's long-term potential to meet the significant unmet need in heart failure patients with EF≥40%.

STUDY POPULATION

Randomized, double-blind, placebo-controlled

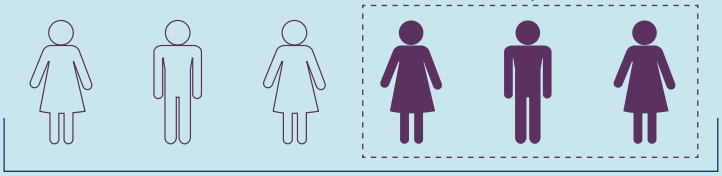
621 patients



PATIENTS INCLUDED: ≥40 years with symptomatic HF and EF ≥40% with elevated exercise PCWP (≥25 mm Hg) and left-to-right gradient (≥5 mm Hg)

RESPONDER COHORT Identified (n=313)

Patients without significant pulmonary vascular disease (PVR<1.74 WU) and no pacemaker



Overall Population

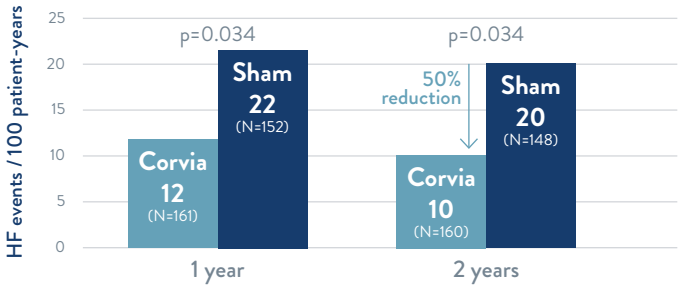
Follow-Up Blinding Maintained Through 2 Years

*Kansas City Cardiomyopathy Questionnaire Overall Summary Score

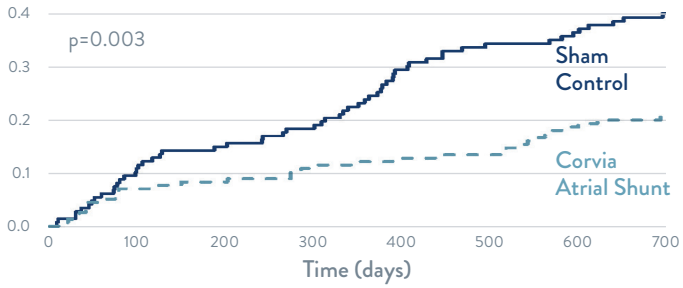
Responder Population Outcomes Through 2 Years[1,2] (n=313)

HEART FAILURE EVENTS

Heart Failure Event Rate[3]



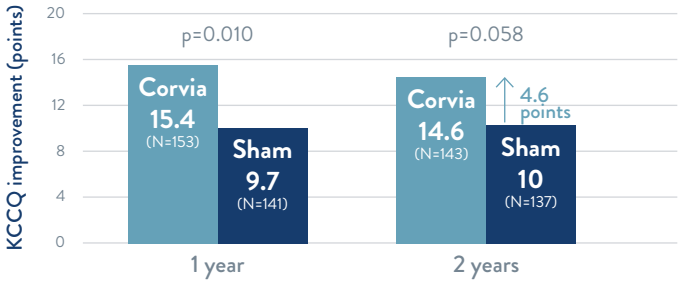
Mean Cumulative Heart Failure Events[4]



Shunt therapy led to a 50% reduction in the rate of HF events

QUALITY OF LIFE

KCCQ-OSS Change from Baseline



Shunt patients sustained improved health status with 46% greater improvement (+4.6 points) in KCCQ

Learn More

Prof. Finn Gustafsson and Prof. Maja Cikes share their thoughts on the 2-year data from REDUCE LAP-HF II

KEY SAFETY OUTCOMES

Events in Responders through 2 years	Corvia Atrial Shunt (N=161)	Sham control (N=152)	p-value
Cardiovascular mortality	3/160 (1.9%)	2/148 (1.4%)	0.72
Non-fatal ischemic stroke	3/160 (1.9%)	0/148 (0.0%)	--
New or worsening kidney dysfunction	14/160 (8.8%)	22/148 (14.9%)	0.10
Major adverse cardiac events	6/160 (3.8%)	4/148 (2.7%)	0.61
Thrombo-embolic complications	1/160 (0.6%)	1/148 (0.7%)	0.96
≥30% Decrease in TAPSE	5/160 (3.1%)	4/148 (2.7%)	0.83

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PS00698, MKT1020 (US/CA/AU) Rev01 2024-08

1. Gustafsson, F, Petrie, M, Komtebedde, J. et al. 2-Year Outcomes of an Atrial Shunt Device in HFpEF/HFmrEF: Results From REDUCE LAP-HF II. *J Am Coll Cardiol HF*. 1 Jun 2024. https://doi.org/10.1016/j.jchf.2024.04.011
2. 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/CIRCULATIONAHA.122.059486.
3. Incidence rate ratio (IRR) at 1- and 2-years = 0.49 [95% CI: 0.25-0.95], p=0.034
4. Statistical analyses conducted by Baim Institute for Clinical Research. Data on file.