corvia®

REDUCE LAP-HF II

3-Year Responder Group Highlights

Context and key findings

REDUCE LAP-HF II is the largest device therapy trial for heart failure patients with EF≥40%. The study discovered a specific phenotype of heart failure (HF) patients who respond positively to atrial shunt therapy, termed “Responders”.

Now with follow-up data spanning three years, Responders with the Corvia® Atrial Shunt continue to experience significantly fewer HF events and an improved quality of life compared to sham control.

Compared to sham

50%
Fewer patients **hospitalized**

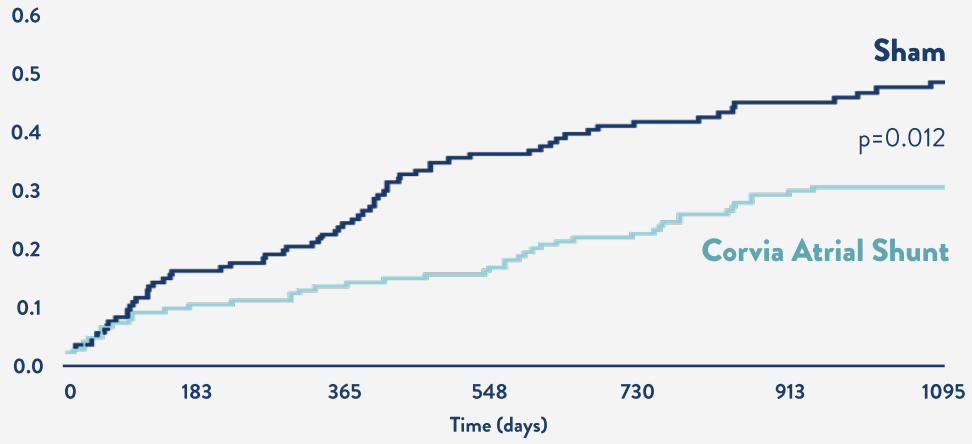
>10 points
Greater Improvement in **KCCQ-OSS**

72%
More patients **improved ≥1 NYHA Class**

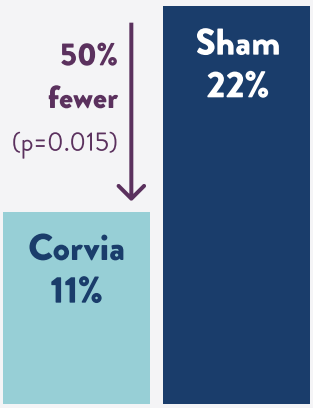
Safe
No statistically significant differences in key safety endpoints

Consistent HF event reduction through 3 years[1]

Mean cumulative heart failure events
HF hospitalizations or visits for worsening HF



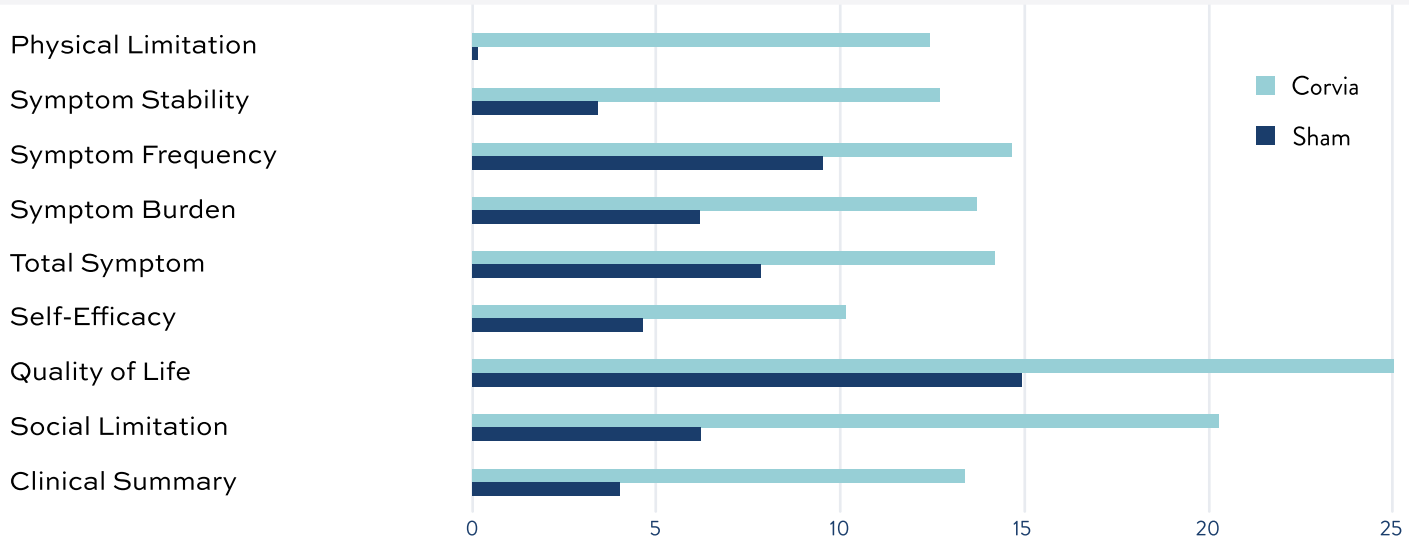
% of patients with a HF hospitalization



3-year KCCQ improvement consistent across all domains[2,3]

Study data suggest the Corvia Atrial Shunt is an effective therapy for improving quality of life.

Improvement over baseline: Overall Summary Score



90% More Corvia Atrial Shunt patients experienced a **>20 point KCCQ-OSS** improvement by year 3 vs sham patients

NNT = 5 Treating **just 5 patients** with the Corvia Atrial Shunt yields an additional patient with a large (>20 point) 3-year KCCQ improvement

Key Safety Outcomes[1,2]

No statistically significant differences in CV mortality, stroke, or other SAEs vs sham.

Events in Responders through 3 years	Corvia Atrial Shunt (N=161)	Sham (N=152)	p-value
Cardiovascular mortality	4.4%	2.2%	0.35
Non-fatal ischemic stroke	1.9%	0.0%	0.25
Thrombo-embolic complications (TIA)	0.0%	1.5%	0.21
New or worsening kidney dysfunction	10.7%	19.3%	0.04
Newly acquired persistent or permanent atrial fibrillation or flutter	5.7%	6.7%	0.72
Myocardial infarction	2.2%	2.5%	1.00

Consider giving your HFpEF patients a new opportunity to find relief.

Learn more about our ongoing confirmatory study, RESPONDER-HF

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PS00749, MKT1024 (US/CA/AU) Rev01 2025-04

1) Litwin, Sheldon E., et al. "Long term safety and outcomes after atrial shunting for heart failure with preserved or mildly reduced ejection fraction: 5-year and 3-year follow-up in the REDUCE LAP-HF I and II trials." American Heart Journal 278 (2024): 106-116.

2) Statistical analyses conducted by Baim Institute for Clinical Research. Data on file.

3) All subjects blinded to treatment arm for two years.

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