corvia®

# REDUCE LAP-HF II CLINICAL TRIAL SUMMARY

## RESPONDER GROUP HIGHLIGHTS

- 50% of study patients demonstrated significant clinical benefit (responder group)
- 45% reduction in heart failure event rate vs. sham control
- 55% greater improvement in KCCQ vs. sham control at 12 months
- Exercise phenotyping identified as critical for patient selection

# CORVIA® ATRIAL SHUNT

Implanted in over 550 patients worldwide and reviewed in more than 20 publications, the Corvia Atrial Shunt is the world's most clinically and scientifically studied atrial shunt for the reduction of Left Atrial Pressure (LAP) in HFpEF/HFmrEF patients. Results from multiple REDUCE LAP-HF studies have demonstrated the safety and efficacy of the device.

Recently published in *Circulation*, results from REDUCE LAP-HF II, the world's first phase III randomized trial for atrial shunting in heart failure, reinforce the safety and efficacy of the device, and have newly defined the treatable patient population for atrial shunt therapy.

## REDUCE LAP-HF II TRIAL DESIGN[1]

**PURPOSE: Evaluate the clinical efficacy and safety of the Corvia Atrial Shunt to improve quality of life and reduce HF related symptoms and events in patients with HFpEF or HFmrEF.**

**STUDY POPULATION**
**(N=626 randomized)**

- Symptomatic HF
- Ongoing GDMT
- Age ≥40
- LVEF ≥40%
- Preserved RV function
- Elevated exercise PCWP (≥25 mm Hg) with left-to-right gradient (≥5 mm Hg)
- Pulmonary vascular resistance (PVR) <3.5 Wood units at rest or peak exercise

**ATRIAL SHUNT TREATMENT**
**(N=314)**

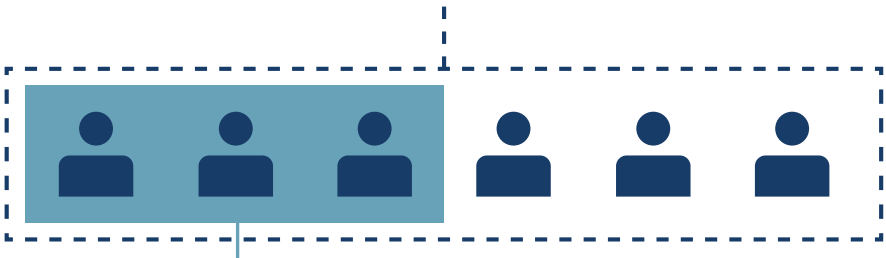
**SHAM CONTROL**
**(N=312)**

## TRIAL OUTCOME

**50% of the study population benefited significantly from atrial shunt therapy despite an overall neutral trial[2,3]**

**OVERALL POPULATION**

Neutral primary outcome when including all patients (win ratio=1)[4]

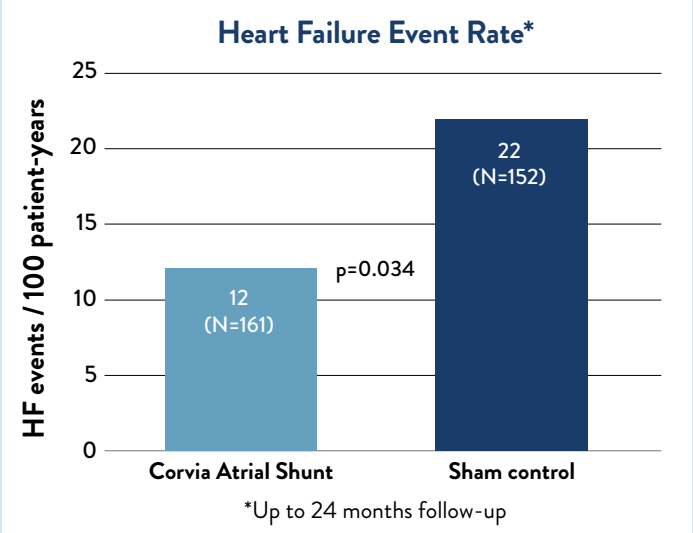


**RESPONDER GROUP**
**(n=313)**

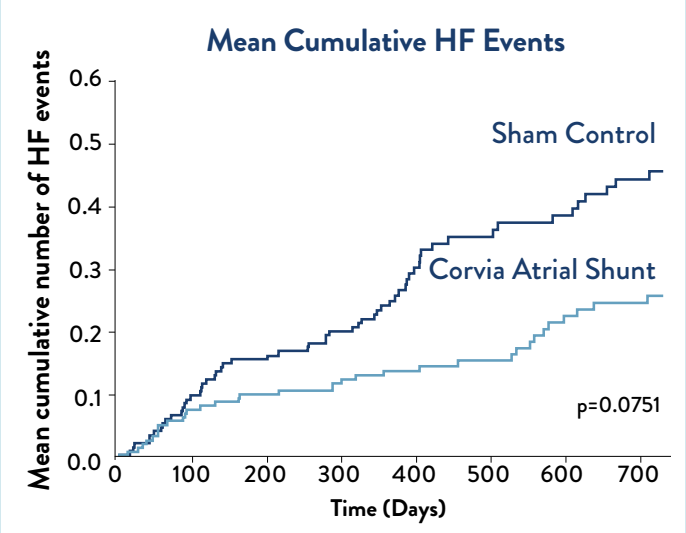
Positive outcome in patients with normal exercise PVR (<1.74 WU)[5] and no cardiac rhythm device (win ratio=1.5, p=0.004)

# RESPONDER GROUP OUTCOMES (N=313)

## HEART FAILURE EVENTS

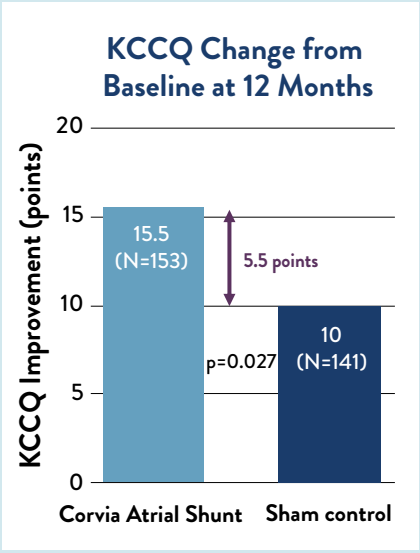



Shunt therapy led to a 45% reduction in the rate of HF events

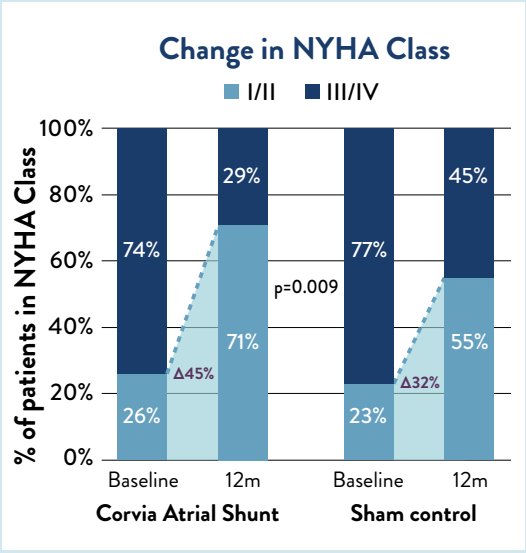



HF event curves separate early and continue to diverge

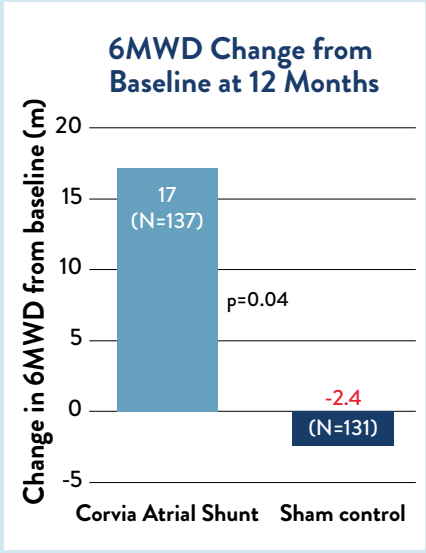
## QUALITY OF LIFE




Shunt patients had a 55% greater improvement in KCCQ




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




Shunt patients significantly improved 6MWD

## KEY SAFETY OUTCOMES

| Responder population at 1 year | Atrial Shunt therapy (N=161) | Sham control (N=152) | P-value |
|---|---|---|---|
| Cardiovascular mortality | 1/161 (0.6%) | 0/152 (0.0%) | 0.96 |
| Non-fatal ischemic stroke | 1/161 (0.6%) | 0/152 (0.0%) | 0.96 |
| New or worsening kidney dysfunction | 12/161 (7.5%) | 16/152 (10.5%) | 0.34 |
| Major adverse cardiac events | 3/161 (1.9%) | 0/152 (0.0%) | 0.95 |
| Other thrombo-embolic complications | 0/161 (0.0%) | 0/152 (0.0%) | — |
| ≥30% Decrease in TAPSE | 3/161 (1.9%) | 3/152 (2.0%) | 0.94 |

## LEARN MORE

Global experts Prof. Andrew Coats, Dr. Barry Borlaug, Dr. Sanjiv Shah and Prof. Gerd Hasenfuß provide insight into the REDUCE LAP-HF II responder group findings and contextualize the study results within the broader HFpEF landscape.

## CORVIA CLINICAL PROGRAM

**Pilot Study**
Observational study, 2013
(n=11)

**REDUCE LAP-HF**
Observational study, 2015
(n=64)

**REDUCE LAP-HF I**
Randomized, blinded, sham-controlled trial, 2016
(n=44)

**REDUCE LAP-HF II**
Randomized, blinded, sham-controlled trial, 2020
(n=626)

**RESPONDER-HF**
Randomized, blinded, sham-controlled trial to validate REDUCE LAP-HF II Responder Group outcomes
ENROLLING
(n=260)

Date indicates year enrollment completed.


REFERENCES

1. Berry N, Mauri L, Feldman T,. et al. Transcatheter InterAtrial Shunt Device for the treatment of heart failure: Rationale and design of the pivotal randomized trial to REDUCE Elevated Left Atrial Pressure in Patients with Heart Failure II (REDUCE LAP-HF II). *Am Heart J*, 2020; 226:222-31.
2. Shah SJ, Borlaug BA, Chung ES, et al. Atrial shunt device for heart failure with preserved and mildly reduced ejection fraction (REDUCE LAP-HF II): a randomised, multicentre, blinded, sham-controlled trial. *Lancet*. 2022;399(10330):1130-1140.
3. 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.
4. In win ratio calculation, all patients are compared with each other in pairwise manner on values of the components in a hierarchical manner (1 = neutral, >1 treatment better, <1 sham better).
5. Upper tertile, which roughly corresponds to peak exercise in a healthy adult >55 years (≤1.8WU).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**The Corvia Atrial Shunt System**

is indicated for the improvement in quality of life and reduction of heart failure related symptoms and events in patients with heart failure with preserved (HFpEF) or mid-range ejection fraction (HFmrEF) with elevated left atrial pressures, who remain symptomatic despite standard Guideline Directed Medical Therapy (GDMT). See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events.