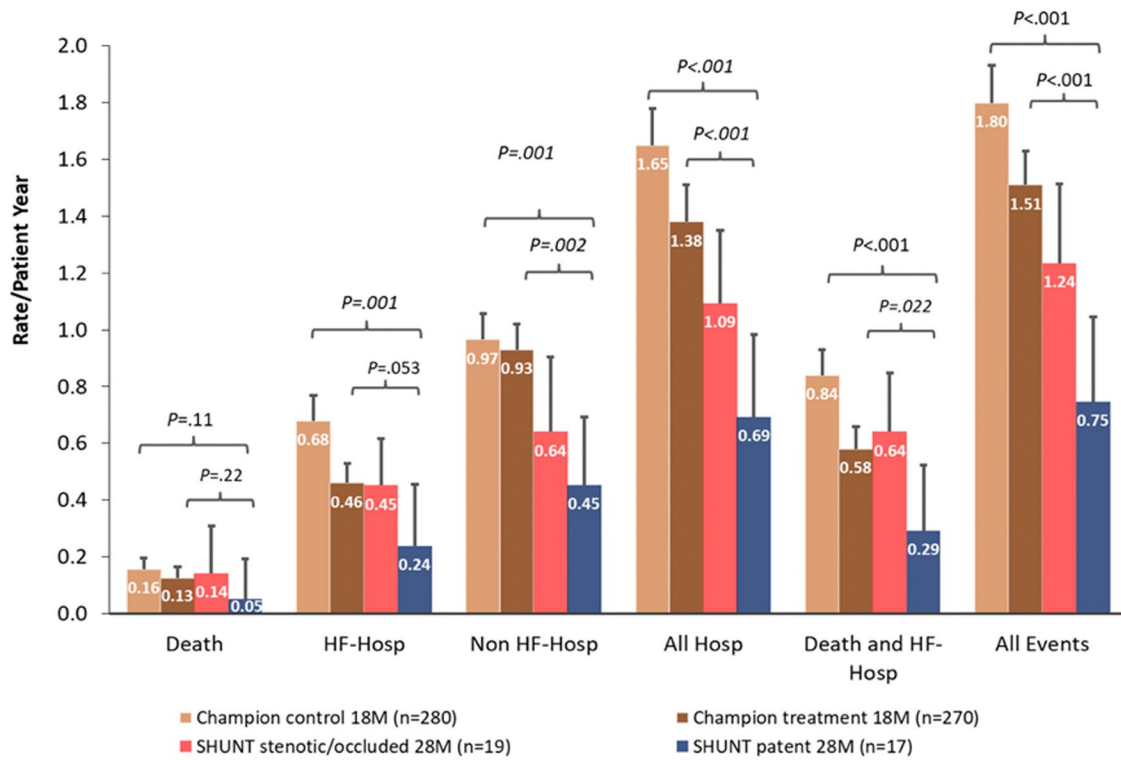


Supplementary Material

Supplementary Material Figure 1. Clinical events in the CHAMPION trial compared to the initial experience with the V-Wave device.



Supplementary Material Table 1. Ongoing and future studies on interatrial shunting.

	Condition	Device	Study design	Number of participants	Primary endpoints
REDUCE LAP-HFrEF (NCT03093961)	HFrEF	IASD System II (Corvia Medical)	Prospective, non-randomized	10	Peri-procedural, and 6 months Major Adverse Cardiac and Cerebrovascular Events (MACCE) and systemic embolic events in patients implanted with the IASD. The percent of subjects who have successful device implantation and the percent of subjects left to right flow through the device assessed by an echo-cardiographic core laboratory.
REDUCE LAP HF II (NCT03088033)	HFpEF	IASD System II (Corvia Medical)	Multicenter, Prospective, Randomized Controlled, Blinded Trial	608	Composite of (a) incidence of and time-to-cardiovascular mortality or first non-fatal, ischemic stroke through 12 months; (b) total rate (first plus recurrent) per patient year of heart failure (HF) admissions or healthcare facility visits for IV diuresis for HF through 12 months and time-to-first HF event; and (c) change in baseline KCCQ total summary score at 12 months.
REDUCE LAP HF III (NCT03191656)	HFpEF or HFmrEF	IASD System II (Corvia Medical)	Observational registry	100	Device and or procedure related serious adverse cardiac events. Improvement in quality of life using KCCQ score and EQ5D score; improvement in functional NYHA class.
RELIEVE-HF (NCT03499236)	HFpEF or HFrEF	V-Wave Interatrial Shunt System	Multicenter, Prospective, Randomized Controlled, Blinded Trial	500	Safety: percentage of Treatment patients experiencing major device-related Major Adverse Cardiovascular or Neurological Events (MACNE) during the first 30-days after randomization, compared to a pre-specified Performance Goal. Effectiveness: hierarchical composite of death, heart transplant or left ventricular assist device (LVAD) implantation, HF hospitalisations, and change in 6-minute walk test (6MWT).
PRELIEVE (NCT03030274)	HFrEF or HFpEF	Occlutech AFR device	Prospective, Non-randomized,	30	Incidence of Serious Adverse Device Effects (SADE) following implantation such as: device dislocation / embolization, damage to the tricuspid or mitral valve caused by the device, intractable arrhythmias caused by the device and any circumstances that require device removal.