Original research

Prospective multicentre single-arm study of an interatrial shunt in heart failure with reduced ejection fraction (SUSTAIN-HF): 1-year clinical and haemodynamic outcomes

Changdong Zhang,[1] Yucheng Zhong,[1] Qiaozhen Li,[2] Guangyuan Song,[3] Jian Yang,[4] Xiaoping Peng,[5] Yan Li,[6] Qingwei Ji,[7] Geng Li,[1] Jun Tian,[1] Mei Liu,[1] Qing Wang,[8] Ming Sun,[1] Changyu Qin,[1] Xueli Wang,[1] Song Chen,[1] Xiaoke Shang,[1] Nianguo Dong [9]

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For numbered affiliations see end of article.

Correspondence to
Dr Nianguo Dong; sxs_dng@163.com and Dr Xiaoke Shang; sxs_sxk@163.com

CZ, YZ and QL contributed equally.

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ABSTRACT

Background Evidence for atrial shunt devices in heart failure with reduced ejection fraction (HFrEF) is limited. This study aimed to evaluate the 1-year clinical and haemodynamic outcomes associated with an atrial shunt device in this population.

Methods In this prospective, multicentre, single-arm cohort study of an interatrial shunt in heart failure with reduced ejection fraction (SUSTAIN-HF), 120 symptomatic HFrEF patients (left ventricular ejection fraction; LVEF ≤40%) on guideline-directed medical therapy were enrolled across 16 centres in China. The intervention was implantation of the D-Shant atrial shunt device. Prespecified primary outcomes were the changes from baseline to 1 year in 6 min walk distance (6MWD) and New York Heart Association (NYHA) functional class. Secondary outcomes included quality of life (Kansas City Cardiomyopathy Questionnaire; KCCQ), echocardiographic parameters and adjudicated adverse events.

Results Between October 2017 and December 2021, 120 patients were enrolled. At 1-year follow-up, implantation of the shunt device was associated with significant improvements in clinical outcomes. The mean 6MWD increased by 54.1 m (95% CI 45.9 to 62.3; p<0.0001), and the KCCQ overall score was improved by 16.5 points (95% CI 13.9 to 19.1; p<0.0001). The proportion of patients in NYHA class III/IV decreased from 95.0% to 22.9% (p<0.0001). The annualised rate of heart failure hospitalisation was reduced from 3.3 to 0.3 events per patient-year (p<0.0001). LVEF increased by 9.0% (95% CI 6.9% to 11.1%; p<0.0001). The primary safety endpoint, a composite of major adverse cardiac and device-related events at 1 year, occurred in 15.0% of patients, driven primarily by cardiovascular death.

Conclusions In this prospective cohort study of symptomatic HFrEF patients, treatment with the D-Shant atrial shunt device was associated with significant improvements in functional capacity, quality of life and rates of heart failure hospitalisation at 1 year. The single-arm design precludes definitive conclusions on treatment efficacy, underscoring the need for randomised, sham-controlled trials.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Evidence supporting atrial shunt device implantation in patients with heart failure with reduced ejection fraction (HFrEF) remains limited, especially regarding long-term functional and haemodynamic benefits.

WHAT THIS STUDY ADDS

⇒ This multicentre study demonstrates that in a cohort of HFrEF patients, atrial shunt device implantation was associated with significant 1-year improvements in New York Heart Association class, 6 min walk distance and quality of life, alongside a marked reduction in rehospitalisation rates.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These hypothesis-generating findings support the rationale for further investigation of atrial shunt therapy in HFrEF through rigorously designed randomised, sham-controlled trials to establish efficacy and refine patient selection.

INTRODUCTION

Atrial shunt devices have emerged as a promising therapeutic option for heart failure (HF), attracting significant attention since their introduction.[1–3] The core principle involves creating a left-to-right interatrial shunt to decompress the left atrium, thereby alleviating the pulmonary congestion that drives symptoms in left HF.[4 5] HF is a complex clinical syndrome broadly categorised into HF with reduced ejection fraction (HFrEF) and HF with preserved ejection fraction (HFpEF).[6] HFrEF, defined as a left ventricular ejection fraction (LVEF) ≤40%, is primarily associated with impaired myocardial contractility from conditions like ischaemic heart

disease or dilated cardiomyopathy.[7 8] Despite the 'four pillars' of guideline-directed medical therapy, many HFrEF patients remain highly symptomatic, with poor quality of life and frequent hospitalisations, underscoring a significant unmet clinical need for novel therapeutic strategies.[9 10]

Initial enthusiasm for atrial shunting was largely focused on HFpEF. The REDUCE LAP-HF (Reduce Elevated Left Atrial Pressure in Patients With Heart Failure) I trial showed that the Corvia IASD effectively reduced left ventricular filling pressure and improved functional status.[11] However, the pivotal REDUCE LAP-HF II randomised trial yielded overall neutral results, highlighting the heterogeneity of the HFpEF population and suggesting that patient selection is critical.[3 12] More recently, the RELIEVE-HF trial, which included both HFpEF and HFrEF patients, found that while the HFpEF subgroup experienced adverse outcomes, the HFrEF subgroup showed a signal towards improved prognosis.[4] These findings, though preliminary, suggest that HFrEF may be a more suitable target for atrial shunt therapy. Nevertheless, robust clinical evidence for atrial shunting specifically in HFrEF patients remains notably limited.[13]

The D-Shant atrial shunt device is the first of its kind developed in China, with preliminary results from its first-in-human study already reported in our two previous trials.[14 15] This study was designed to address the evidence gap by evaluating the safety and clinical outcomes associated with the D-Shant device in a large, multicentre HFrEF cohort. Our primary objectives were to assess the 1-year changes in functional capacity, clinical status and haemodynamics. We also aimed to explore baseline predictors of clinical outcomes to help generate hypotheses for refining patient selection for this emerging therapy.

MATERIALS AND METHODS

Study population and design

This was a national, multicentre, prospective, single-arm cohort study evaluating an interatrial shunt in heart failure with reduced ejection fraction (SUSTAIN-HF) conducted across 16 cardiac centres in China. The study was registered at the Chinese Clinical Trial Registry (ChiCTR-ONC-17011730). The protocol was approved by the institutional review board of Union Hospital, Tongji Medical College, Huazhong University of Science and Technology (No. 2021–0546), and all patients provided written informed consent before any study-related procedures. A total of 188 patients were assessed for eligibility, of whom 120 met the criteria and were enrolled. The flow of participants is detailed in the Consolidated Standards of Reporting Trials diagram (figure 1).

The sample size was not based on a formal power calculation but was a convenience-based sample determined by the recruitment capacity across the participating centres over a predefined period. The target enrolment of 120 patients was considered sufficient to provide initial estimates of safety, feasibility and clinical outcomes to generate hypotheses for future randomised controlled trials.

Key inclusion criteria were: age ≥18 years; a diagnosis of chronic HFrEF (LVEF ≤40%); persistent symptoms (New York Heart Association (NYHA) functional class II–IV) despite at least

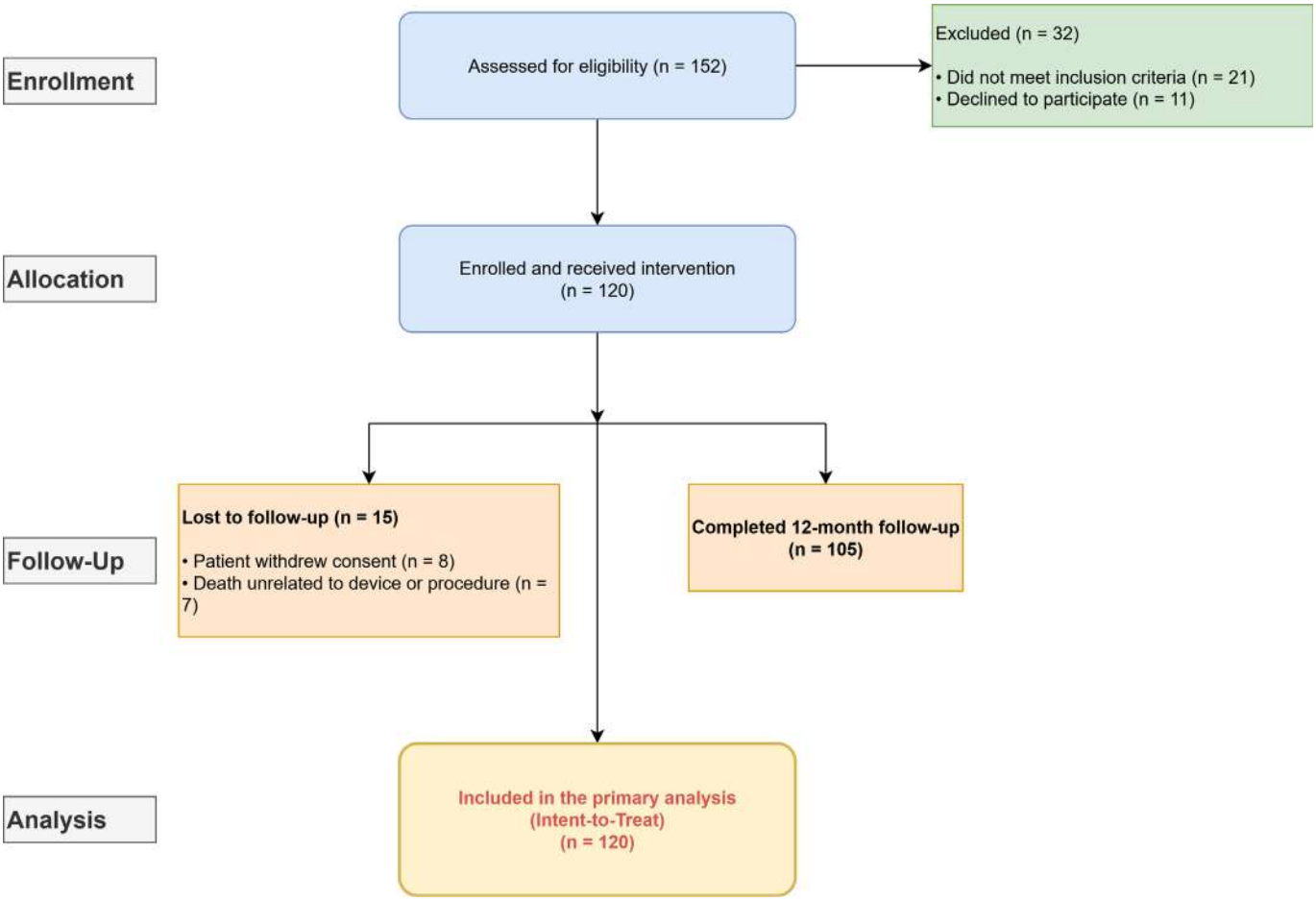

Figure 1 CONSORT 2010 flow diagram. CONSORT, Consolidated Standards of Reporting Trials.

Table 1 Baseline clinical, echocardiographic and haemodynamic characteristics (N=120)

Characteristic	Value
Demographics and clinical profile	
Age (years), mean±SD	61.7±11.5
Male, n (%)	85 (70.8)
Atrial fibrillation at baseline, n (%)	45 (37.5)
Heart failure aetiology, n (%)	
Ischaemic cardiomyopathy	40 (33.3)
Dilated cardiomyopathy	70 (58.3)
Other	10 (8.3)
NYHA functional class, n (%)	
II	6 (5.0)
III	98 (81.7)
IV	16 (13.3)
Prior HF hospitalisations (per year), mean±SD	3.3±1.8
Key functional and quality of life measures	
6 min walk distance (m), mean±SD	291.7±89.4
KCCQ overall summary score, mean±SD	64.7±15.4
Key echocardiographic and haemodynamic measures	
LV ejection fraction (%), mean±SD	30.8±5.8
LV end-diastolic diameter (cm), mean±SD	6.71±0.95
Moderate or severe mitral regurgitation, n (%)	68 (56.7)
Mean left atrial pressure (mm Hg), mean±SD	16.5±6.3
Mean pulmonary artery pressure (mm Hg), mean±SD	24.8±9.4

Data are presented as mean±SD for continuous variables and n (%) for categorical variables.
KCCQ, Kansas City Cardiomyopathy Questionnaire; LV, left ventricular; NYHA, New York Heart Association.

4 weeks of stable, guideline-directed medical therapy; at least one hospitalisation for HF in the past year; and elevated natriuretic peptides (NT-proBNP ≥1000 pg/mL for sinus rhythm, ≥1600 pg/mL for atrial fibrillation or equivalent B-type natriuretic peptide (BNP) levels). All patients were required to have invasive haemodynamic confirmation of elevated left-sided filling pressures, defined as a resting mean left atrial pressure (LAP) or pulmonary artery wedge pressure (PAWP) ≥15 mm Hg, or a peak exercise PAWP ≥25 mm Hg with a resting left-to-right atrial pressure gradient ≥5 mmHg.

Key exclusion criteria were clinically significant primary valvular disease or coronary artery disease requiring intervention; high-risk factors for sudden cardiac death without an implanted defibrillator; significant right ventricular dysfunction (eg, RV fractional area change (RVFAC) < 25%) or severe pulmonary hypertension (mean right atrial pressure >12 mm Hg, pulmonary artery systolic pressure >70 mm Hg or pulmonary vascular resistance >5 Wood units); anatomical abnormalities precluding transseptal access; presence of intracardiac thrombus; recent myocardial infarction or cardiac surgery (<1 month); and severe non-cardiac comorbidities. A complete list of eligibility criteria is provided in online supplemental methods S1.

Intervention: D-shant device and procedure

The D-shant atrial shunt device is a self-expanding, retrievable implant made from a nickel-titanium alloy braid. Its design features reinforced structural support at the shunt orifice to maintain patency and prevent compression after implantation. The device is available in orifice diameters of 4, 6, 8 and 10 mm, allowing for personalised shunt sizing. Device selection was guided by a clinical algorithm based on the patient's exercise tolerance and LAP. For patients in NYHA class III with LAPs of 20–40 mm Hg, a 6 mm device was typically chosen. For more severe patients (NYHA III-IV, LAPs >40 mm Hg), a smaller 4 mm shunt was selected to mitigate excessive shunting. Conversely, for less severe, stable patients (NYHA II-III, LAPs <20 mm Hg), an 8 mm device was considered. The chosen size was systematically reduced by one level (2 mm) if there was evidence of right heart dilation or dysfunction or significant pulmonary hypertension, to minimise the risk of right heart volume overload. A detailed step-by-step description of the implantation protocol is found in online supplemental methods S1.

All implantation procedures were performed under local anaesthesia with conscious sedation, guided by both fluoroscopy and transoesophageal echocardiography (TEE). Access was obtained via the right femoral vein for baseline right heart catheterisation. Following successful transseptal puncture under TEE guidance, the atrial septum was dilated with a high-pressure balloon. The D-shant delivery sheath was then advanced into the left atrium, and the device was deployed across the septum. Postdeployment haemodynamics (left atrial pressure, LAP; right atrial pressure, RAP; pulmonary artery pressure, PAP) and shunt flow were immediately assessed. If the haemodynamic effect was deemed suboptimal or excessive, the device could be fully retrieved into the sheath and exchanged for a different size before final release.

Endpoints and assessments

The primary endpoints were the changes from baseline to 1 year in 6 min walk test distance and NYHA functional class. Secondary endpoints included changes in quality of life (Kansas City Cardiomyopathy Questionnaire (KCCQ) score),[16] echocardiographic parameters (LVEF, LV dimensions, diastolic function), invasive haemodynamics (immediately postprocedure) and the annualised rate of HF-related rehospitalisations. Safety endpoints included a composite of major adverse cardiac and device-related events (MACDE), defined as all-cause mortality, stroke, device embolisation or cardiac tamponade, adjudicated by an independent clinical events committee. Assessments were

Table 2 Key efficacy outcomes at baseline and 1-year follow-up

Outcome measure	Baseline (N=120)	1-year follow-up	Mean change (95% CI)	P value
NYHA functional class ≥III, n (%)	114 (95.0%)	24/105 (22.9%)	−72.1%	**<0.0001**
6MWD (m), mean±SD	291.7±89.4	345.8±91.2	+54.1 (45.9 to 62.3)	**<0.0001**
KCCQ overall summary score, mean±SD	64.7±15.4	81.2±15.0	+16.5 (13.9 to 19.1)	**<0.0001**
Left ventricular ejection fraction (%), mean±SD	30.8±5.8	39.8±12.2	+9.0 (6.9 to 11.1)	**<0.0001**
Annualised rate of HF hospitalisation (events/person-year)	3.3	0.3	−3.0	**<0.0001**

Data are presented as n (%) or mean±SD The 1-year follow-up cohort consists of patients who completed the 1-year visit. Mean change and 95% CI for 6MWD and KCCQ were derived from linear mixed-effects models. P value for NYHA Class change was derived from McNemar's test. P value for LVEF change was from a paired t-test.
HF, heart failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVEF, left ventricular ejection fraction; 6MWD, 6 min walk distance; NYHA, New York Heart Association.

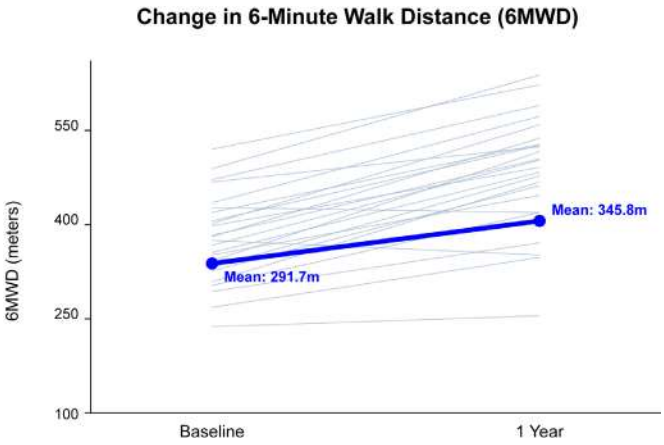

Figure 2 Individual patient changes in 6 min walk distance (6MWD) from baseline to 1 year. Spaghetti plot showing individual trajectories for all patients with available data. The thick blue line represents the mean change estimated by the mixed-effects model.

performed at baseline, discharge and at 1, 3, 6 and 12-month postprocedure.

Statistical analysis

Continuous variables are presented as mean±SD or median with IQR, and normality was assessed using the Shapiro-Wilk test. Comparisons between groups were made using independent samples t-tests or Mann-Whitney U tests. Categorical variables were described as counts and percentages and compared using the χ^2 or Fisher's exact test. For within-group longitudinal changes, paired t-tests or Wilcoxon signed-rank tests were used. For longitudinal analysis of continuous endpoints (6 min walk distance (6MWD) and KCCQ), linear mixed-effects models were used to account for missing data and intrasubject correlation over time. These models included all available data from all 120 enrolled patients under a missing-at-random assumption. All analyses were conducted using GraphPad Prism (V.9) and SPSS (V.26). A two-sided p value of <0.05 was considered statistically significant.

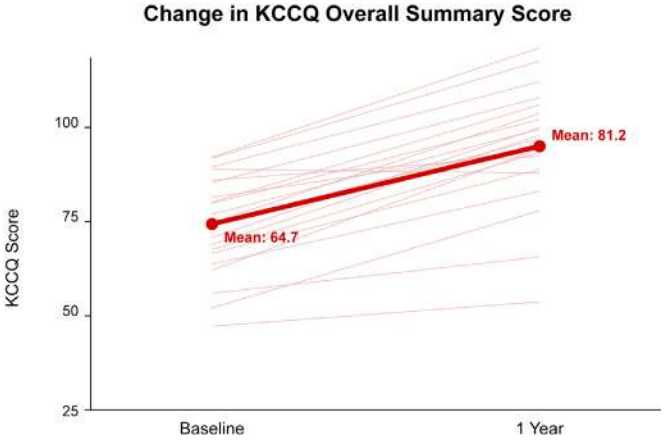

Figure 3 Individual patient changes in KCCQ overall summary score from baseline to 1 year. Spaghetti plot showing individual trajectories for all patients with available data. The thick blue line represents the mean change estimated by the mixed-effects model. KCCQ, Kansas City Cardiomyopathy Questionnaire.

Table 3 Adjudicated adverse events through 1-year follow-up (N=120)

Adverse event category	Periprocedural (<7 days), n (%)	Postdischarge to 1 year, n (%)	Total at 1 year, n (%)
Composite safety endpoint (MACDE)			
All-cause mortality, stroke, device embolisation, cardiac tamponade	1 (0.8)	17 (14.3)	**18 (15.0)**
Individual events			
All-cause mortality	0 (0.0)	12 (10.0)	**12 (10.0)**
Cardiovascular death	0 (0.0)	6 (5.0)	6 (5.0)
Non-cardiovascular death	0 (0.0)	6 (5.0)	6 (5.0)
Stroke (ischaemic or haemorrhagic)	0 (0.0)	2 (1.7)	**2 (1.7)**
Device-related thrombus or embolisation	0 (0.0)	0 (0.0)	**0 (0.0)**
Major bleeding (BARC 3 or 5)	1 (0.8)	3 (2.5)	**4 (3.3)**
Worsening right heart failure (requiring hospitalisation)	0 (0.0)	5 (4.2)	**5 (4.2)**
New-onset sustained atrial fibrillation/flutter (>30 s)	2 (1.7)	7 (5.9)	**9 (7.5)**
Device malposition/migration requiring intervention	0 (0.0)	0 (0.0)	**0 (0.0)**

Events were adjudicated by an independent clinical events committee.
BARC, Bleeding Academic Research Consortium; MACDE, major adverse cardiac and device-related events.

RESULTS

Baseline characteristics and procedural outcomes

The 120 enrolled patients represented a typical advanced HFrEF population, with a mean age of 61.7±11.5 years and a mean LVEF of 30.8±5.8%. The cohort was highly symptomatic, with 114 patients (95.0%) in NYHA class III or IV at baseline. The aetiology of HF was predominantly non-ischaemic, with dilated cardiomyopathy in 70 patients (58.3%) and ischaemic cardiomyopathy in 40 (33.3%). Patients had a significant comorbidity burden and a history of frequent hospitalisations (mean 3.3 in the prior year). Baseline invasive haemodynamics confirmed elevated filling pressures, with a mean LAP of 16.5±6.3 mm Hg. The implantation procedure was successful in all 120 patients, with a mean shunt diameter of 6.0±1.3 mm. Baseline characteristics are summarised in table 1.

Clinical and functional outcomes at 1 year

At 1-year follow-up, there were significant associations with improvements in primary and secondary clinical endpoints (table 2). The proportion of patients in advanced NYHA class (III/IV) decreased from 95.0% to 22.9% (p<0.0001). Based on the mixed-effects model, the mean 6MWD significantly increased by 54.1 m (95% CI 45.9 to 62.3; p<0.0001) from a baseline of 291.7±89.4 m. Quality of life, measured by the KCCQ overall summary score, also showed a substantial and clinically meaningful improvement of 16.5 points (95% CI13.9 to 19.1; from 64.7±15.4; p<0.0001). The annualised rate of HF-related rehospitalisation decreased more than tenfold, from 3.3 events per person-year preimplantation to 0.3 events post-implantation (p<0.0001). Individual patient trajectories for 6MWD and KCCQ are displayed in figures 2 and 3, respectively. Detailed longitudinal data for these outcomes are shown in online supplemental figure S1.

Haemodynamic and echocardiographic changes

The atrial shunt induced immediate and significant haemodynamic changes. Mean LAP was reduced from 16.5±6.3 mm Hg to 11.6±5.4 mm Hg (p<0.001), and the mean pulmonary

artery pressure fell from 24.8±9.4 mm Hg to 21.5±8.1 mm Hg (p=0.004). Right atrial pressure and cardiac index remained unchanged. Over the 1-year follow-up, serial echocardiography demonstrated associations with significant favourable structural remodelling of the left ventricle. The mean LV internal diameter in diastole decreased from 6.71±0.95 cm at baseline to 6.19±1.13 cm at 1 year (p<0.001), while LVEF significantly improved from 30.8%±5.8% to 39.8%±12.2% (p<0.0001), indicating improved systolic function. Exploratory correlation analysis showed a modest but significant association between the reduction in LV end-diastolic diameter and the improvement in 6MWD (r=−0.28, p=0.011), but not with the change in KCCQ score (r=−0.15, p=0.14) (online supplemental table S3). Detailed haemodynamic and echocardiographic data are provided in online supplemental tables S1 and S2.

Safety outcomes

The implantation procedure was well tolerated with no periprocedural deaths, strokes or device embolisations. Over the 1-year follow-up, the primary composite safety endpoint (MACDE) occurred in 18 patients (15.0%). There were 12 deaths (10.0%), of which 6 were adjudicated as cardiovascular. Two non-fatal ischaemic strokes (1.7%) occurred. There were no instances of device migration, embolisation or need for surgical intervention. A comprehensive summary of adjudicated adverse events is provided in table 3.

DISCUSSION

This study, the largest to date evaluating a specific atrial shunt device in an exclusively HFrEF population, provides compelling hypothesis-generating evidence regarding its safety and association with favourable clinical outcomes. Implantation of the D-Shant device was associated with significant, durable improvements in functional capacity, quality of life and a dramatic reduction in HF rehospitalisations at 1-year follow-up. These clinical benefits were substantiated by objective evidence of acute haemodynamic improvement and chronic favourable left ventricular reverse remodelling.

The magnitude of the observed improvements is clinically impressive. The 54 m increase in 6MWD and the 16.5-point increase in KCCQ score both surpass established thresholds for minimal clinically important differences, reflecting a substantial positive impact on patients' daily lives.[17] The greater than tenfold reduction in a hard clinical endpoint like HF hospitalisation strongly supports the potential therapeutic value of this intervention. Our findings of a 9.0% absolute improvement in LVEF and a significant reduction in hospitalisations are consistent with, and perhaps more pronounced than, the positive signals observed in the HFrEF subgroup of the RELIEVE-HF trial,[18] which reported a trend towards fewer HF events in its open-label phase. This consistency across different devices and patient populations strengthens the rationale for targeting left atrial decompression in HFrEF.

Limitations

The foremost limitation of our study is its single-arm, non-randomised design, which prevents us from drawing definitive causal inferences and separating the device's effects from potential placebo effects or the impact of intensive follow-up within a trial setting.[19] The observed improvements in subjective endpoints like KCCQ and NYHA class may be particularly susceptible to these biases. While the magnitude of change in objective endpoints like hospitalisations and LVEF is compelling, confirmation in a sham-controlled randomised trial is the necessary next step. Second, the modest sample size limits the precision of our safety estimates and our ability to perform robust subgroup analyses. Third, missing data due to patient attrition, including death, could introduce bias, although we attempted to mitigate this by using mixed-effects models for our primary analyses.

CONCLUSION

In this large, prospective, multicentre cohort study of HFrEF patients, implantation of the D-Shant atrial shunt device was safe and associated with significant and clinically meaningful improvements in functional capacity, quality of life and rehospitalisation rates at 1 year. These findings support atrial shunting as a promising therapeutic strategy for a selected HFrEF population, generating a strong hypothesis for further evaluation. Randomised controlled trials are now warranted to definitively establish the efficacy of this therapy.

Author affiliations
[1]Department of Cardiovascular Surgery, Huazhong University of Science and Technology, Wuhan, Hubei, China
[2]Echocardiography Room of Heart Center, Wuhan Children's Hospital (Wuhan Maternal and Child Healthcare Hospital),Tongji Medical College, Huazhong University of Science & Technology, Wuhan, China
[3]Beijing Anzhen Hospital Affiliated to Capital Medical University, Beijing, Beijing, China
[4]Department of Cardiovascular Surgery, The First Affiliated Hospital of Air Force Medical University, Xi'an, Shananxi, China
[5]Department of Cardiovascular Medicine, The First Affiliated Hospital of Nanchang University, Nanchang, Jiangxi, China
[6]Department of Cardiovascular Medicine, The Second Affiliated Hospital of Air Force Medical University, Xi'an, Shananxi, China
[7]Department of Cardiovascular Medicine, Guangxi Zhuang Autonomous Region People's Hospital, Nanning, Guangxi, China
[8]Hubei University of Technology, Wuhan, Hubei, China
[9]Union Hospital, Tongji Medical College, Wuhan, Hubei, China

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Contributors CZ, YZ and QL contributed equally to this work and share first authorship. They were responsible for conceptualisation, investigation, data curation, and writing—original draft. GS, JY, XP, YL and QJ participated in formal analysis and data interpretation. GL, JT, ML, CQ, QW, XW, SC and MS contributed to methodology and validation. XS and ND served as supervisors, contributed to project administration and provided final approval. ND is the guarantor of this work. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study was registered at Chinese Clinical Trial Registry with the registration number: ChiCTR-ONC-17011730. The study received ethical approval from the ethics committees of the leading research units. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer-reviewed.

Data availability statement Data are available upon reasonable request. The data and materials used and/or analysed during the current study are available from the corresponding author on reasonable request.

ORCID iD
Nianguo Dong https://orcid.org/0000-0001-5080-4523

REFERENCES

1 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;145:1592–604.
2 Kar S, Doshi SK, Alkhouli M, *et al*. Rationale and design of a randomized study comparing the Watchman FLX device to DOACs in patients with atrial fibrillation. *Am Heart J* 2023;264:123–32.
3 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. *The Lancet* 2022;399:1130–40.
4 Stone GW, Lindenfeld J, Rodés-Cabau J, *et al*. Interatrial Shunt Treatment for Heart Failure: The Randomized RELIEVE-HF Trial. *Circulation* 2024;150:1931–43.
5 Reed GW, Harmon EK, Harb S, *et al*. Design and Rationale of the V-Wave Shunt MitraClip Study. *Am J Cardiol* 2024;227:29–36.
6 McDonagh TA, Metra M, Adamo M, *et al*. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J* 2021;42:3599–726.
7 Redfield MM. Heart Failure with Preserved Ejection Fraction. *N Engl J Med* 2016;375:1868–77.
8 Bloom MW, Greenberg B, Jaarsma T, *et al*. Heart failure with reduced ejection fraction. *Nat Rev Dis Primers* 2017;3:17058.
9 Heidenreich PA, Bozkurt B, Aguilar D, *et al*. 2022 ACC/AHA/HFSA Guideline for the Management of Heart Failure. *J Card Fail* 2022;28:e1–167.
10 Cotter G, Davison BA, Mebazaa A, *et al*. Medical Therapy of Heart Failure with Reduced Ejection Fraction-A Call for Comparative Research. *J Clin Med* 2021;10:1803.
11 Kaye DM, Hasenfuß G, Neuzil P, *et al*. One-Year Outcomes After Transcatheter Insertion of an Interatrial Shunt Device for the Management of Heart Failure With Preserved Ejection Fraction. *Circ Heart Fail* 2016;9:e003662.
12 Yan C, Li H, Wan L, *et al*. Left atrial pressure normalisation by graded radiofrequency atrial septostomy in heart failure with preserved ejection fraction: a single-arm pilot study. *Heart* 2025;111:1020–7.
13 Gustafsson F. Interatrial shunt devices for heart failure. *Nat Rev Cardiol* 2023;20:717–8.
14 Shang X, Liu M, Zhong Y, *et al*. Clinical study on the treatment of chronic heart failure with a novel D-shant atrium shunt device. *ESC Heart Fail* 2022;9:1713–20.
15 Zhou Y, Li H, Fang L, *et al*. Biventricular longitudinal strain as a predictor of functional improvement after D-shant device implantation in patients with heart failure. *Front Cardiovasc Med* 2023;10:1121689.
16 Green CP, Porter CB, Bresnahan DR, *et al*. Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. *J Am Coll Cardiol* 2000;35:1245–55.
17 Spertus J, Peterson E, Conard MW, *et al*. Monitoring clinical changes in patients with heart failure: a comparison of methods. *Am Heart J* 2005;150:707–15.
18 Rodés-Cabau J, Lindenfeld J, Abraham WT, *et al*. Interatrial shunt therapy in advanced heart failure: Outcomes from the open-label cohort of the RELIEVE-HF trial. *Eur J Heart Fail* 2024;26:1078–89.
19 Harjola V-P, Mebazaa A, Čelutkienė J, *et al*. Contemporary management of acute right ventricular failure: a statement from the Heart Failure Association and the Working Group on Pulmonary Circulation and Right Ventricular Function of the European Society of Cardiology. *Eur J Heart Fail* 2016;18:226–41.
20 Zhang CD, Zhong Y, Li Q, *et al*. AS-1325 Impact of Atrial Shunt Device on Prognosis and Risk Factors in Heart Failure With Reduced Ejection Fraction (SUSTAIN-HF): A National, Multicenter, Phase III, Single Group Clinical Study. *J Am Coll Cardiol* 2025;85:D7.