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ORIGINAL ARTICLE

Real-world evidence in a national health service: results of the UK CardioMEMS HF System Post-Market Study

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Abstract

Aims The CardioMEMS HF System Post-Market Study (COAST) was designed to evaluate the safety, effectiveness, and feasibility of haemodynamic-guided heart failure (HF) management using a small sensor implanted in the pulmonary artery of New York Heart Association (NYHA) Class III HF patients in the UK, Europe, and Australia.

Methods and results COAST is a prospective, international, multicentre, open-label clinical study (NCT02954341). The primary clinical endpoint compares annualized HF hospitalization rates after 1 year of haemodynamic-guided management vs. the year prior to sensor implantation in patients with NYHA Class III symptoms and a previous HF hospitalization. The primary safety endpoints assess freedom from device/system-related complications and pressure sensor failure after 2 years. Results from the first 100 patients implanted at 14 out of the 15 participating centres in the UK are reported here. At baseline, all patients were in NYHA Class III, 70% were male, mean age was 69 ± 12 years, and 39% had an aetiology of ischaemic cardiomyopathy. The annualized HF hospitalization rate after 12 months was 82% lower [95% confidence interval 72–88%] than the previous 12 months (0.27 vs. 1.52 events/patient-year, respectively, $P < 0.0001$). Freedom from device/system-related complications and pressure sensor failure at 2 years was 100% and 99%, respectively.

Conclusions Remote haemodynamic-guided HF management, using frequent assessment of pulmonary artery pressures, was successfully implemented at 14 specialist centres in the UK. Haemodynamic-guided HF management was safe and significantly reduced hospitalization in a group of high-risk patients. These results support implementation of this innovative remote management strategy to improve outcome for patients with symptomatic HF.

Clinical registration number: ClinicalTrials.gov identifier: NCT02954341.

Keywords CardioMEMS™ HF System; Clinical trial results; UK; Haemodynamic monitoring; Heart failure; Pulmonary artery pressure

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Introduction

Heart failure (HF) prevalence is increasing worldwide at an alarming rate, and despite breakthroughs in medical therapies, it accounts for more than 1 million hospitalizations in the USA and Europe annually, with high social and economic costs.[1,2] Multiple clinical trials[3–6] have demonstrated the benefits of haemodynamic-guided HF management in

both patients with HF with preserved and reduced ejection fraction by monitoring and reducing ambulatory pulmonary artery (PA) pressures. Rising PA pressures are associated with increased mortality,[4] decompensation requiring hospitalization,[5] and reduced functional capacity and quality of life (QoL).[6] Remote patient management with the CardioMEMS HF System is superior to traditional clinical management strategies facilitating personalized therapy and meaningful reductions in HF hospitalizations (HFHs) and improved QoL in large clinical trials.[7–10]

In Europe, Australia, and particularly in the UK, the open-label prospective CardioMEMS HF System Post-Market Study (COAST) was implemented to examine feasibility, safety, and clinical benefit of haemodynamic-guided management strategy for patients with HF in these diverse geographies. Important innovations are needed to improve the value and effectiveness of remote, virtual patient management in the new era of the SARS-CoV-2 pandemic.

Methods

The COAST is a prospective, open-label registry examining the safety and feasibility of managing symptomatic patients with HF using frequently assessed PA pressures. Details concerning the rationale and the design of this study have been reported previously.[11] The study protocol was approved by all responsible ethics committees and was conducted in accordance with the Declaration of Helsinki principles. All participants provided written informed consent prior to any study-related procedure. COAST enrolled patients with persistent New York Heart Association (NYHA) Class III symptoms and at least one HFH within 12 months prior to enrolment, regardless of ejection fraction. Patients with HF with reduced ejection fraction were required to be treated with a beta-blocker for 3 months and an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker for 1 month, unless the investigator deemed the patient to be intolerant to such therapy. The study inclusion and exclusion criteria are listed in *Table 1*.

In total, 138 patients were enrolled and implanted in the COAST-UK portion of the study. One hundred and three patients were consented, and 100 successfully implanted completed follow-up before the COVID-19 pandemic emergency was declared in the UK (March 2020). A precipitous decline in cardiovascular hospitalizations, including acute myocardial infarction and HF, during the pandemic altered the a priori assumptions associated with the COAST. The clinical results of haemodynamic-guided HF care prior to the pandemic are therefore reported here (n = 100). This methodology to remove the unanticipated impact of the COVID-19 pandemic is similar to the analyses of other prospective trials.[12,13]

Following sensor implant, patients were taught how to obtain daily PA sensor interrogation for pressure measurements. Investigators were provided specific guidelines regarding euvolaemic ranges and general strategies to achieve haemodynamic stability (systolic 14–35 mmHg, diastolic 8–20 mmHg, and mean 10–25 mmHg; see the Supporting Information). Elevation or decrease PA pressure

Table 1 COAST inclusion and exclusion criteria

Inclusion criteria
1 Written informed consent obtained from subject
2. ≥18 years of age
3. Diagnosis of NYHA Class III HF
4. At least one HF hospitalization within 12 months of baseline visit
5. Subjects with reduced LVEF HF should be receiving a beta-blocker for 3 months and an ACE-I or ARB for 1 month unless, in the investigator's opinion, the subject is intolerant to beta-blockers, ACE-I, or ARB
6. Subjects with a BMI ≤ 35. Subjects with BMI > 35 will require their chest circumference to be measured at the axillary level; if >65 in., the patient will not be eligible for the study
7. Subjects with pulmonary artery branch diameter ≥7 mm (implant target artery—assessed during the RHC)
8. Subjects willing and able to comply with the follow-up requirements of the study
Exclusion criteria
1 Subjects with an active infection
2. Subjects with history of recurrent (>1) pulmonary embolism or deep vein thrombosis
3. Subjects who, in the investigator's opinion, are unable to tolerate an RHC
4. Subjects who have had a major cardiovascular event (e.g. myocardial infarction, open heart surgery, and stroke) within 2 months of baseline visit
5. Subjects with cardiac resynchronization device (CRT) implanted <3 months prior to enrolment
6. Subjects with a glomerular filtration rate (GFR) <25 mL/min (obtained within 2 weeks of the baseline visit) who are non-responsive to diuretic therapy or who are on chronic renal dialysis
7. Subjects with congenital heart disease or mechanical right heart valve(s)
8. Subjects likely to undergo heart transplantation or VAD within 6 months of baseline visit
9. Subjects with known coagulation disorders
10. Subjects with a hypersensitivity or allergy to aspirin and/or clopidogrel (not applicable for subjects taking anticoagulation therapy or other approved anti-platelet therapy)

ACE-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; HF, heart failure; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; RHC, right heart catheterization; VAD, ventricular assist device.

outside the patient's baseline was considered to arise from volume shifts, either overload (above thresholds) or depletion (below thresholds). The study protocol did not require using a specific pressure to guide remote decision-making or to determine a hypervolaemic or hypovolaemic status of the patients (see the Supporting Information).

Endpoints

All 103 patients consented for the study were included in the primary safety evaluation. Subjects with unsuccessful implantations were followed for 30 days to evaluate safety. The remaining 100 patients were followed for 2 years to evaluate the primary safety endpoints. The two primary safety endpoints were freedom from device/system-related complications (DSRCs) and freedom from pressure failure at 2 years after implant (details on DSRCs and pressure sensor failure definitions are provided in the Supporting Information) compared with a pre-specified performance goal of 80% and 90%, respectively.

The primary clinical impact of haemodynamic monitoring was evaluated by comparing the rate of HFH during the 12 month period before sensor implant with the 12 months after implantation.

The NYHA functional class assessment and the EQ-5D-5L questionnaire, administered to assess the patient's QoL, were performed at baseline and 6 and 12 month follow-up visits.

The PA pressure change over time was evaluated using absolute change and with the area under the curve methodology, which quantifies the duration of time that a patient spends at a pressure lower (or higher) than their baseline PA pressure.

Statistical analyses

Data were summarized using univariate statistics (e.g. *N*, mean, standard deviation, median, minimum, and maximum) or frequency (e.g. *N* and %) as appropriate for continuous or categorical variables, respectively. Enrolment is defined as having a successful sensor implant. The primary time point for efficacy analysis was 12 months after enrolment, while safety was analysed for 24 months after enrolment.

The population for the primary clinical impact and analyses consisted of all subjects who received a sensor implant. The primary efficacy analysis compared the annualized HFH rate at 1 year with the HFH rate in the year prior to enrolment using a one-sample, one-sided Poisson rate test. The primary clinical impact endpoint was considered met if the one-sided, upper 97.5% confidence interval for the PMS rate parameter was less than the rate in the year prior to enrolment.

The population for safety analysis consists of all subjects who underwent the sensor implant procedure, regardless of its successful completion. The primary safety analysis was based on the following objective performance criteria: (i) the lower limit of the one-sided 97.5% confidence interval on the freedom from DSRC rate at 24 months is $>$80%, and (ii) the lower limit of the one-sided 97.5% confidence interval on the freedom from pressure sensor failure rate at 24 months is $>$90%. The study was judged to have provided positive safety results if both tests of the primary safety analysis endpoints are statistically significant (i.e. $P < 0.025$).

Additional analyses included daily PA pressure home reading compliance (defined as the number of days with a reading divided by the total number of days of patient follow-up spent outside the hospital) and the weekly compliance (defined as the number of weeks with at least one reading taken on 1 day out of the total weeks of the follow-up period spent outside the hospital).

Events were adjudicated by investigators responsible for patients' clinical care.

Results

The first 100 out of 103 consented patients were successfully implanted between July 2017 and October 2018 at 14 centres across the UK; their baseline characteristics are reported in *Table 2*. Sensor implant was unsuccessful in three patients due to haemoptysis, anatomical constraints, or inability to gain venous access, and these patients were followed for 30 days for safety purposes; 6 and 12 month visits were completed by 88 and 80 patients, respectively (*Figure 1*, CONSORT diagram).

Safety assessments

The primary safety endpoints of freedom from DSRCs and freedom from pressure sensor failure at 2 years were 100% and 99% with a lower limit of their confidence interval (96.5%, $P < 0.0001$ and 94.6%, $P = 0.0006$, respectively) exceeding the pre-specified performance goals of 80% and 90%, respectively. There were no DSRC events, and a single-sensor failure (1 of 100 implanted patients) was reported. Ten deaths were recorded after 12 months of follow-up. Eight patients out of the 100 implanted (8%) died because of cardiac causes including HF in six subjects (6%), one patient with acute myocardial infarction, and one subject with cardiogenic shock. One death was due to carcinoma, and one was unwitnessed and reported as unknown cause.

Heart failure hospitalization rates

The rate of HFH after 1 year after implant was lower in the cohort compared with the year prior to implant. There were 165

Table 2 Demographics and baseline characteristics

Characteristic	COAST-UK (n = 100)	
Age (years)	69.0 ± 11.9 (100)	
Male	70.0% (70/100)	
Ischaemic cardiomyopathy	39.0% (39/100)	
ICD/CRT-D	39.0% (39/100)	
Preserved ejection fraction	45.2% (42/93)	
BMI (kg/m^2)	30.0 ± 6.8 (100)	
Hypertension	58.0% (58/100)	
Coronary artery disease	51.0% (51/100)	
Diabetes mellitus	43.0% (43/100)	
Chronic obstructive pulmonary disease	19.0% (19/100)	
Chronic kidney disease		
Stage 2 (eGFR between 62 and 89 mL/min/1.73 m^2)	29.0% (29/100)	
Stage 3 (eGFR between 30 and 59 mL/min/1.73 m^2)	64.0% (64/100)	
Stage 4 (eGFR between 15 and 29 mL/min/1.73 m^2)	6.0% (6/100)	
Glomerular filtration rate (mL/min/1.73 m^2)	51.3 ± 17.4 (100)	
Heart failure medications	HFpEF (n = 42)	HFrEF (n = 51)
Beta-blockers	73.8% (31/42)	96.1% (49/51)
ACE inhibitor/ARB/ARNi	66.7% (28/42)	84.3% (43/51)
Beta-blocker + ACE inhibitor/ARB/ARNi	47.6% (20/42)	82.4% (42/51)
Aldosterone antagonist	47.6% (20/42)	86.3% (44/51)
Loop diuretic	100.0% (42/42)	96.1% (49/51)
PA systolic pressure	49.5 ± 17.0 (98)	
PA mean pressure	33.7 ± 11.1 (98)	
PA diastolic pressure	23.3 ± 8.2 (98)	
Wedge pressure	18.9 ± 10.0 (99)	

ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; ARNi, angiotensin receptor neprilysin inhibitor; BMI, body mass index; CRT-D, cardiac resynchronization therapy defibrillator; eGFR, estimated glomerular filtration rate; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; ICD, implantable cardioverter defibrillator; PA, pulmonary artery.
Data are presented as mean ± standard deviation (n) or % (n).

HFH (1.52 events/patient-year) before implant compared with 27 HFH (0.27 events/patient-year) after implant resulting in a significant risk reduction of 82% (IRR 0.18 [95% confidence interval—CI 0.12–0.28]; $P < 0.0001$; *Figure 2*).

Pulmonary pressures

During the first year of follow-up, PA pressures decreased significantly from baseline. Pulmonary pressures were lowered during the 12 months of haemodynamic-guided care with significant differences observed in PA systolic (−4.2 ± 6.6 mmHg), PA diastolic (−2.7 ± 3.7 mmHg), and PA mean pressures (−3.3 ± 4.5 mmHg) ($P < 0.0001$ for all, *Table 3*). The area under the curve (mmHg-day) reduction at 1 year was significant for all three PA pressure parameters (−1437.3 ± 2300.6 systolic; −936.1 ± 1269.6 diastolic; and −1132.7 ± 1576.0 mmHg-days, mean; $P < 0.0001$, *Table 3* and *Figure 3A*).

Patient experience

Daily home upload compliance rates were high (85.9 ± 19.3% [95% CI 82.1–89.7%]), as were weekly upload compliance rates (94.5 ± 14.2% [95% CI 91.7–97.3%]) (*Figure 3B*). The five different components of the patient's QoL questionnaire and the QoL index were stable throughout the study duration; a paired analysis performed for the mean visual analogue scale score component of the QoL assessment showed an improvement at 12 months with a 2.0 ± 18.6 positive change compared with baseline, although not statistically significant (P = 0.1933, *Table 4*). Functional class improved during study follow-up with 43% of subjects improving from NYHA Class III to NYHA Classes I and II after 12 months (*Table 5*).

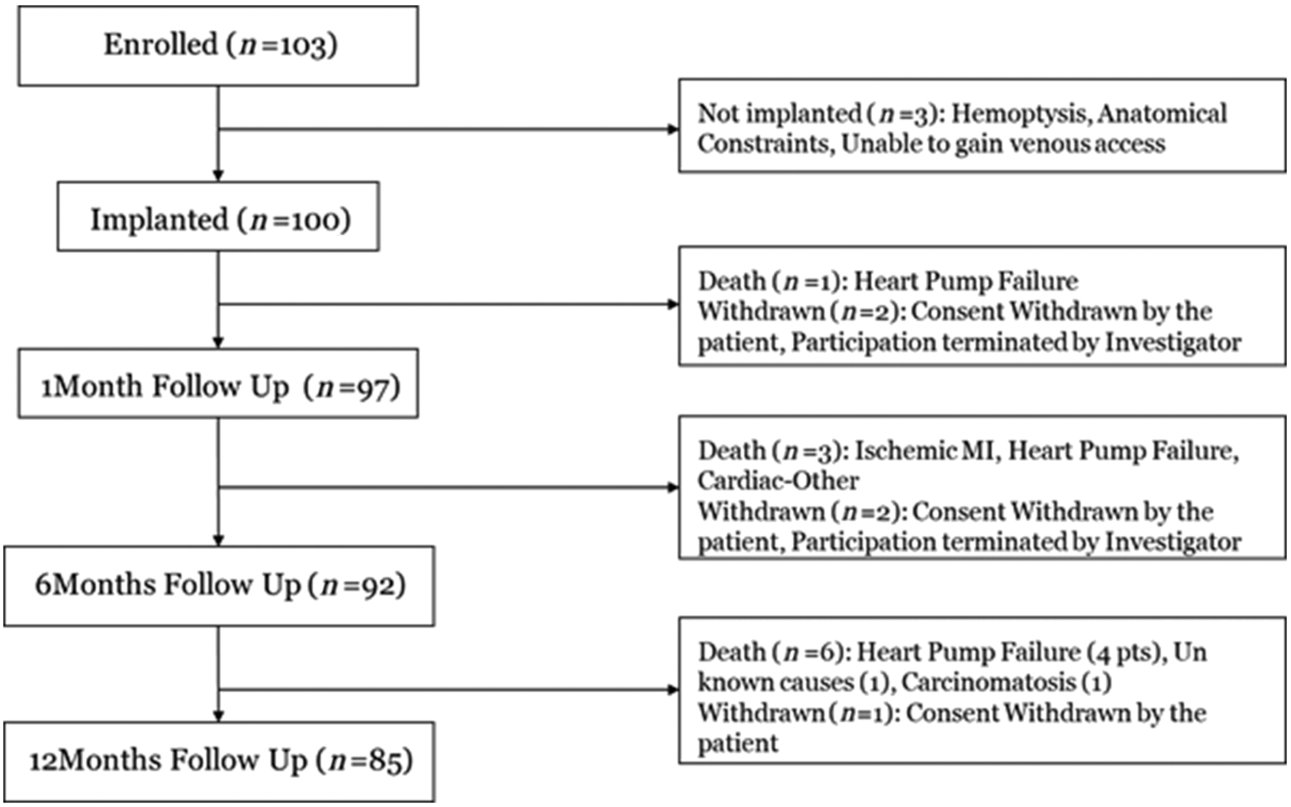
Medication changes

A total of 664 medication changes were performed during the first 12 months of follow-up. Diuretics were the most often changed medication class with 339 changes in loop diuretics in 83 subjects (184 dosage increases and 155 dosage decreases). Thiazide diuretics were modified 83 times in 26 patients. Adjustments in neurohormonal antagonists were also observed in the study period. There were 47 changes in beta-blockers, 37 changes in aldosterone antagonists, and 49 changes in angiotensin antagonists.

Discussion

The COAST-UK demonstrates that haemodynamic-guided HF management, utilizing a permanently implanted PA sensor

Figure 1 CONSORT diagram.



to remotely acquire pressures, is safe and feasible in the UK National Health Service. The clinical impact of adjusting medications based on frequently acquired PA pressures was meaningful and consistent with the results reported in other geographies. Patient compliance with the upload process was very high, and investigators effectively lowered PA pressures with appropriate medication adjustments, mostly using diuretics, but PA pressure monitoring also led to changes in neurohormonal antagonism. These findings were observed regardless of the baseline ejection fraction. The rate of complications associated with implantation of the PA sensor used in this study was low and consistent with previous studies, providing an acceptable risk:benefit ratio for the management strategy.

Studies examining remote management of patients with HF using daily weight assessments coupled with frequent symptoms reporting have had disappointing clinical results. Incorporating non-haemodynamic diagnostic information from cardiac resynchronization pacemakers or implantable cardioverter defibrillators has also failed to reduce the rate of hospitalization. In a recent prospective trial involving central patient monitoring (in which patients were afforded remote access to healthcare providers 24 h/day 7 days/week), days alive and out of hospital (as a primary endpoint) was significantly improved. The predominant impact of this approach, however, was reduced mortality with little impact on HFH rates. Results from COAST-UK underscore the need for remotely obtained physiological signals to closely reflect HF pathophysiology to provide an actionable disease management system. Haemodynamic monitoring provides an understanding of changes in volume shifts that precede decompensation and the opportunity to monitor the effectiveness of remote changes in medications.

More effective methods to provide remote and virtual health care are required to continue to meet the needs of high-risk patients with HF in the midst of the COVID-19 global pandemic. The goals of face-to-face visits in HF management are to carefully assess volume and perfusion with the hopes of pre-empting volume overload, which accounts for over 90% of decompensation events requiring hospitalization. Additionally, in-person visits allow patients to express concerns and to encourage adherence to lifestyle and medical therapies. Prospective randomized clinical trial data demonstrate that the strategy of using remote PA pressure monitoring is superior to concomitant control patients who are managed with traditional tools, such as daily weights and early symptom detection. The COAST-UK corroborates this concept, using historical control analysis, with a marked improvement in longitudinal clinical stability and reduced decompensation events. Reduced event rates were directly associated with

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Figure 2 Heart failure hospitalization (HFH) reduction.

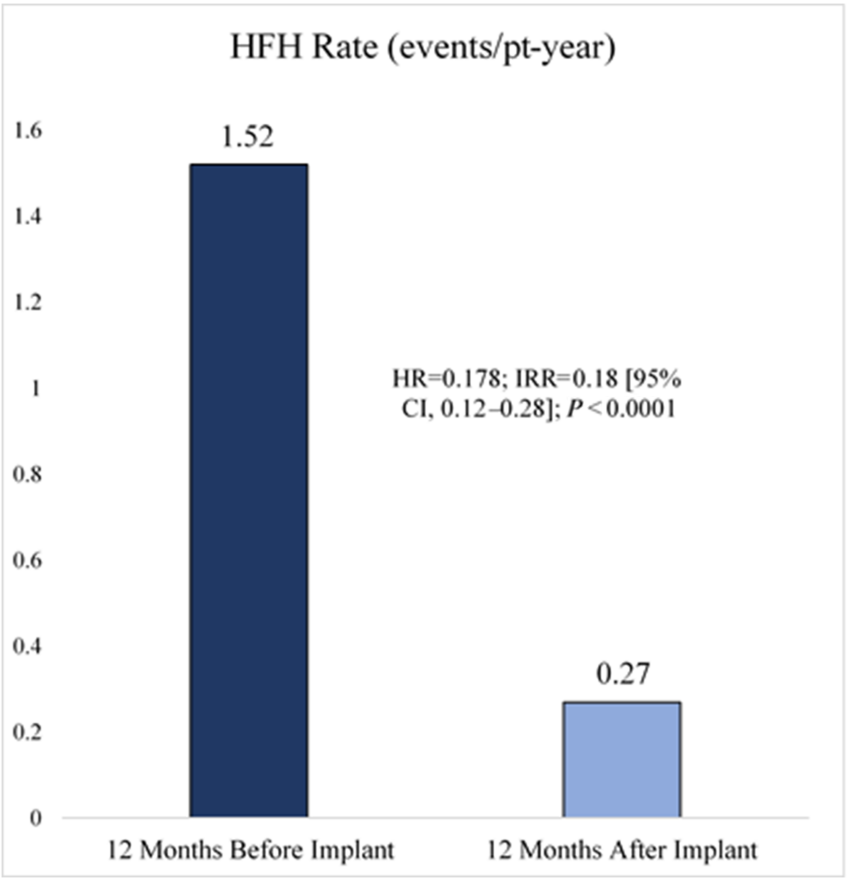


Table 3 PA pressure change and AUC at 12 months

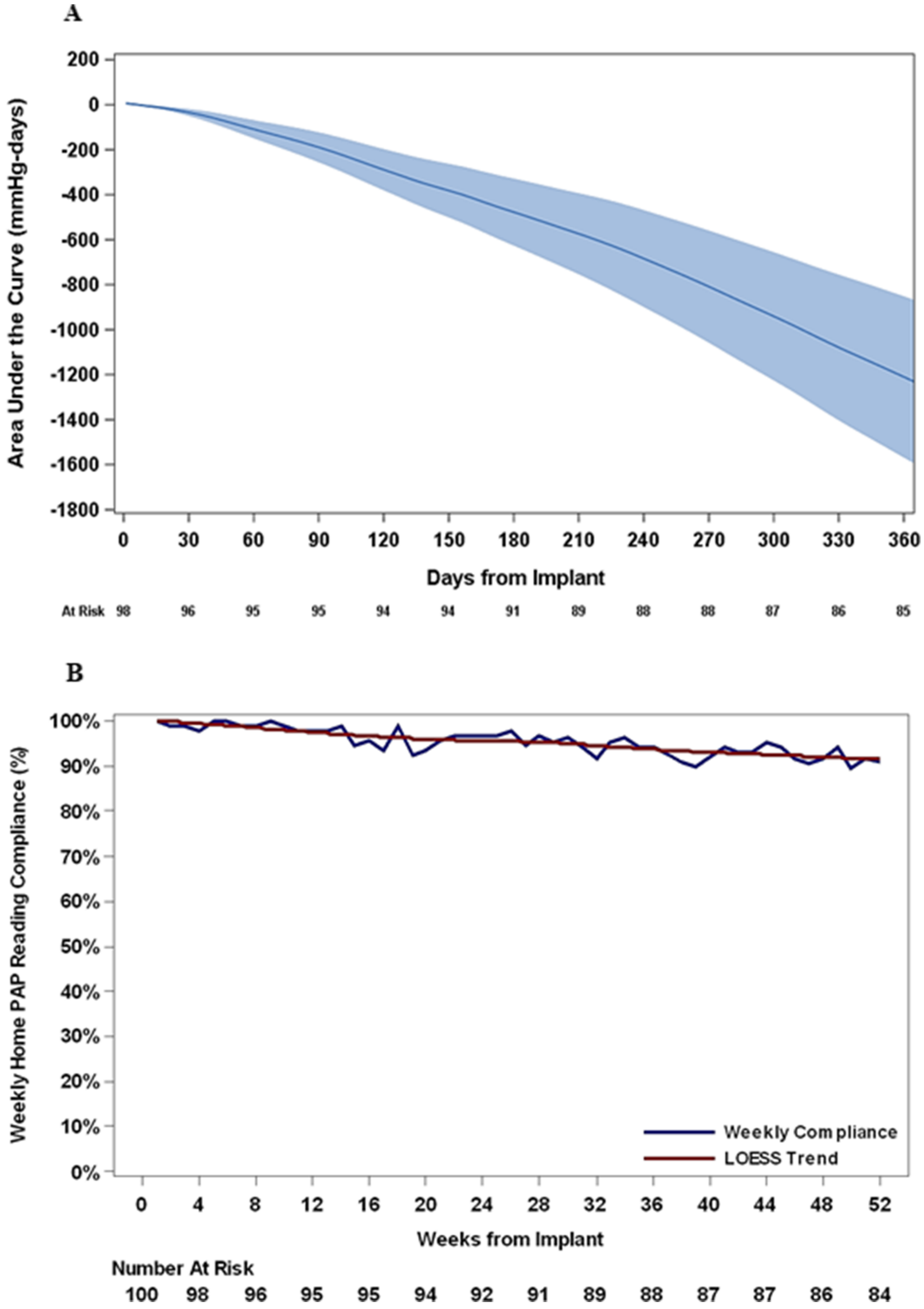
	Baseline	12 months	*P*-value
PA systolic pressure	49.52 ± 16.99 (98)	42.00 ± 16.67 (79)	—
Baseline to 12 month average pressure change	n/a	−4.24 ± 6.58 (98)	$P < 0.0001$
Baseline to 12 month AUC	n/a	−1437.31 ± 2300.60 (98)	$P < 0.0001$
PA mean pressure	33.72 ± 11.09 (98)	28.11 ± 11.01 (79)	—
Baseline to 12 month average pressure change	n/a	−3.33 ± 4.55 (98)	$P < 0.0001$
Baseline to 12 month AUC	n/a	−1132.73 ± 1576.04 (98)	$P < 0.0001$
PA diastolic pressure	23.33 ± 8.21 (98)	18.89 ± 8.13 (79)	—
Baseline to 12 month average pressure change	n/a	−2.72 ± 3.74 (98)	$P < 0.0001$
Baseline to 12 month AUC	n/a	−936.09 ± 1269.57 (98)	$P < 0.0001$

AUC, area under the curve; PA, pulmonary artery; SD, standard deviation.
Data are presented as mean ± SD, (*n*).

reduction in PA pressures and improved HF-related functional status reflected in improved NYHA symptom classification. The COAST-UK cohort began the investigation with less imposing symptoms compared with previously published studies[9] making detecting QoL improvement difficult using the EQ-5D instrument. Improvement in NYHA class for most patients, coupled with a significant reduction in need for hospitalization, portrays improved clinical status after 12 months of follow-up.

Prospective, open-label, unblinded, historical control studies are always limited by the lack of a contemporary control group as a comparator. It is possible that patients enrolled in COAST did not have structured HF management in the 12 months prior to sensor implantation (although the high background use of guideline-directed medical therapy suggests that the patients were well treated at baseline) and any placebo effect of remote monitoring was uncontrolled. The magnitude of hospitalization reduction seen in

Figure 3 (A) Area under the curve. (B) Weekly home pulmonary artery pressure (PAP) reading compliance.



COAST-UK (82%) cannot be used as a point estimate of effectiveness without control of these confounding factors. However, the results reported here are entirely consistent with those in other large studies with similar design and support the usefulness of PA pressure monitoring as a management strategy superior to usual clinical care.

Table 4 EQ-5D-5L visual analogue scale score paired analysis

	Baseline	6 months	6 month change from baseline	12 months	12 month change from baseline	*P*-value[a]
All data collected	64.1 ± 19.7 [60.1–68.1]	65.6 ± 18.4 [61.4–69.8]	NA	65.3 ± 19.9 [60.7–69.9]	NA	NA
6 month paired analysis	63.3 ± 18.3 [59.0–67.6]	66.2 ± 18.6 [61.8–70.5]	2.9 ± 17.5 [−1.2 to 7.0]	NA	NA	0.1693[b]
12 month paired analysis	63.5 ± 19.9 [58.8–68.2]	NA	NA	65.4 ± 20.2 [60.6–70.2]	1.9 ± 20.8 [−3.0 to 6.9]	0.4344[c]
6 and 12 month paired analysis	61.9 ± 18.2 [57.3–66.5]	64.9 ± 18.3 [60.3–69.5]	3.0 ± 18.0 [−1.6 to 7.5]	63.9 ± 19.8 [58.9–68.9]	2.0 ± 18.6 [−2.7 to 6.7]	0.1933[b]
						0.3957[c]

Data are presented as mean ± standard deviation, (*n*) [95% confidence interval]. Confidence interval calculated by normal approximation.
[a]*P*-value from paired *t*-test.
[b]Comparing 6 month change from baseline.
[c]Comparing 12 month change from baseline.

Table 5 New York Heart Association class summary

	Baseline	6 months	12 months
Class I	0 (0.0%)	4 (4.0%)	3 (3.0%)
Class II	0 (0.0%)	32 (32.0%)	41 (41.0%)
Class III	100 (100.0%)	46 (46.0%)	36 (36.0%)
Class IV	0 (0.0%)	3 (3.0%)	0 (0.0%)
Death	0 (0.0%)	4 (4.0%)	10 (10.0%)
Withdrawn	0 (0.0%)	4 (4.0%)	5 (5.0%)
Evaluation not done	0 (0.0%)	7 (7.0%)	5 (5.0%)

Data are presented as *n* of patients (%).

In summary, the COAST-UK demonstrates that PA pressure-guided therapy is safe and feasible, with a high likelihood of achieving meaningful clinical benefits, in the UK National Health Service system. The clinical benefit of this management strategy extends to patients with HF regardless of ejection fraction. Remote PA pressure monitoring is an opportunity to intensify and improve HF management and outcome in an era that heavily relies on virtual and remote encounters.

Conflict of interest

M.R.C. reports grants and personal and study conduction fees from Abbott. A.F. reports research grants and speaker honoraria from Abbott. P.C. reports speaker honoraria from Abbott. P.F. reports study conduction fees from Biotronik, British Heart Foundation, Bristol Myers Squibb, Novo Nordisk, Johnson & Johnson, Sanofi, Amgen, and Bayer; personal fees from Novartis and Pharmacosmos; and grants and personal fees from Medtronic. B.C. reports personal fees from Abbot, Medtronic, Biotronik, Novartis, and AstraZeneca and non-financial support from Merit Medical. I.L. and T.R.B. report personal fees from Abbott. C.C. reports consulting fees from Abbott; speaker honoraria from AstraZeneca, Novartis, and Bayer; and travel/meeting attendance support from Novartis. R.S.G. reports grants, personal fees, and non-financial support from Abbott; grants, personal fees, and other from Boston Scientific (BSCI); and personal fees from Novartis, AstraZeneca, Vifor, Boehringer Ingelheim, Servier, and Pharmacosmos. K.G. reports honoraria from Novartis and AstraZeneca. G.C.-W., A.Z., C.H., and D.R. have nothing to disclose. H.S.L. reports honoraria from Abbott. A. P. reports grants from Medtronic and personal fees from Medtronic and Abbot. S.P. reports support for educational activities from Abbott. C.G. and J.H. are Abbott employees. P.B.A. is an Abbott employee and stockholder.

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Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Data S1. Supporting Information.

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