NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure

In chronic heart failure your heart muscle is weak and not able to pump blood around your body strongly enough. This causes pressure to increase in the pulmonary artery (the blood vessel that takes blood from the heart to the lungs). In this procedure, a small electronic pressure sensor is inserted through the skin (percutaneous) into a vein in the thigh or the neck and then into the pulmonary artery. The sensor sends daily blood pressure measurements to a monitor in your home. The monitor sends the measurements to your care team, who can assess whether your treatment needs adjusting. The aim is to manage treatment and reduce hospital admissions.

Contents

Abbreviations

Word or phrase	Abbreviation
Area under the curve	AUC
Body mass index	BMI
Chronic heart failure	CHF
Confidence interval	CI
Clinical summary score	CSS
Ejection fraction	EF
Hazard ratio	HR
Heart failure	HF
Heart failure with reduced ejection fraction	HFrEF
Heart failure with preserved ejection fraction	HFpEF
Minnesota living with heart failure questionnaire	MLHFQ
New York Heart Association Class	NYHA class
Number needed to treat	NNT
Overall summary score	OSS
Pulmonary artery pressure	PAP
Relative risk reduction	RRR
Standard deviation	SD
Visual analogue scale	VAS

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in February 2021.

Procedure name

- Percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure

Professional societies

- British Cardiovascular Society
- British Society for Heart Failure
- Royal College of Physicians
- Royal College of Physicians and Surgeons of Glasgow
- Royal College of Physicians of Edinburgh

Description of the procedure

Indications and current treatment

Heart failure (HF) happens when the pumping action of the heart is impaired by structural or functional abnormalities. It can lead to reduced blood flow to the body tissues and increased filling pressure in the heart. This causes congestion and oedema in the lungs (causing breathlessness) and the body (causing swelling in the legs). Symptoms include breathlessness, reduced exercise tolerance, oedema, fatigue and malaise.

Diagnosis and management of CHF is described in NICE's guideline on chronic heart failure in adults. Treatments include lifestyle changes, medicines, device implantation (to help control heart rhythm) and heart surgery (such as a bypass operation or a heart transplant).

CHF needs regular monitoring to identify signs of deterioration and modify treatment, with the aim of improving the patient's quality of life and avoiding hospital admissions. Monitoring includes assessment of functional capacity, fluid status, blood pressure, cardiac rhythm, renal function, and cognitive and nutritional status. Medication is reviewed and adjusted if necessary. Implantable devices to monitor haemodynamic changes may assist HF monitoring.

What the procedure involves

A delivery catheter is introduced into a large vein (usually the femoral vein) under local anaesthesia. Under radiological guidance, the catheter is used to pass a small pressure sensor through the heart and into a suitable branch of the pulmonary artery. The pressure sensor is deployed and the delivery catheter removed. Data on pulmonary artery pressure (PAP), such as pressure trend information and PAP waveforms, are transmitted from the sensor to an external monitor in the patient's home. The monitor securely transmits the data to a remote database from where the information can be accessed by the HF team. Collection and transmission of data are usually done by the patient daily or more frequently if required by the HF team.

This procedure allows the provision of data to guide the management of CHF, with the aim of reducing hospitalisations caused by HF.

Outcome measures

The **Minnesota Living with Heart Failure Questionnaire** (MLHFQ) is a commonly used health-related quality of life questionnaire for patients with HF. It includes 21 items, and each item is scored in a 6-point Likert scale (0 to 5), thus the total score ranges from 0 to 105. Lower scores indicate a better quality of life, a 5-point difference is stated as the minimally important difference by the scale developers.

The **Kansas City Cardiomyopathy Questionnaire** (KCCQ) is a 23-item questionnaire to describe health-related quality of life in patients with HF. It quantifies physical limitation, symptoms (frequency, severity and recent change over time), quality of life, social interference and self-efficacy. All KCCQ scores are scaled from 0 to 100 and higher scores reflect better health status. Scores are frequently summarised in 25-point ranges to represent health status: 0 to 24 being very poor to poor, 25 to 49 being poor to fair, 50 to 74 being fair to good, and 75 to 100 being good to excellent.

The **EQ-5D-5L** consists of the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The **EQ VAS** records the patient's self-rated health on a vertical VAS that takes values between 100 (best imaginable health) and 0 (worst imaginable health).

The **New York Heart Association (NYHA)** functional classification system is used to define the progression of HF according to severity of symptoms and limitation to physical activity. Classes 1 and 2 describe mild HF with no or slight limitation of physical activity; class 3 describes moderate HF with marked limitation of physical activity; and class 4 describes severe HF, when patients are unable to carry out any physical activity without discomfort.

Efficacy summary

HF hospitalisations

In a randomised controlled trial of 550 patients with NYHA class 3 HF, the rate of admissions to hospital for HF statistically significantly reduced in patients who had PAP-guided management (treatment group) by 33% (hazard ratio [HR] 0.67 [95% CI 0.55 to 0.80], p<0.0001) compared with patients who had guideline-directed standard of care management (control group) during the 18-month randomised access period (Abraham 2016). During the 13-month open access period, the rate of HF hospital admissions in the former control group statistically significantly reduced by 48% (HR 0.52 [95% CI 0.40 to 0.69], p<0·0001) compared with the control group during randomised access. During the same open access period, the rate of HF hospital admissions did not statistically significantly reduce in the former treatment group compared with the treatment group during randomised access (HR 0.93 [95% CI 0.70 to 1.22], p=0.58).

In a case series of 1,200 patients with NYHA class 3 HF, the rate of HF hospitalisations was statistically significantly lower at 1 year after PAP sensor implantation compared with the year before implantation (0.54 events/patient-year compared with 1.25 events/patient-year, HR 0.43 [95% CI 0.39 to 0.47], p<0.0001) (Shavelle 2020).

In a case series of 1,114 patients with PAP sensor implants for NYHA class 3 HF, the cumulative incidence of HF hospitalisations was significantly lower at 6 months after implantation compared with 6 months before implantation (HR 0.55 [95% CI 0.49 to 0.61], p<0.001) (Desai 2017). At 12 months after implantation (n=480), the cumulative incidence of HF hospitalisations was also statistically significantly lower compared with 12 months before implantation (HR 0.66 [95% CI 0.57 to 0.76], p<0.001).

In a non-randomised comparative study of 2,174 patients with NYHA class 3 HF, the cumulative incidence of HF hospitalisations at 12-month follow up was statistically significantly lower in patients with a PAP sensor implantation compared with patients without a PAP sensor implantation (0.65 events/patient-year compared with 0.88 events/patient-year; HR 0.76 [95%CI 0.65 to 0.89], p<0.001) (Abraham 2019).

In a case series of 234 patients with NYHA class 3 or 4 HF, the rate of HF hospitalisations statistically significantly decreased by 62% at 12 months after PAP sensor implantation compared with the year before implantation (0.60 compared with 1.55 events/patient-year; HR 0.38, 95% CI 0.31 to 0.48; p<0.0001) (Angermann 2020).

In a case series of 15 patients with NYHA class 3 HF, HF hospitalisation was reported in 1 patient within the first 90 days post implantation (Mullens 2020).

All-cause hospitalisations

In the randomised controlled trial of 550 patients, the rate of all-cause admissions to hospital statistically significantly reduced in patients who had PAP-guided management (treatment group) by 16% (HR 0.84 [95% CI 0.75 to 0.95], p=0.0032) compared with patients who had guideline-directed standard of care management (control group) during the 18-month randomised access period (Abraham 2016). During the 13-month open access period, the rate of all-cause hospital admissions in the former control group statistically significantly reduced by 21% (HR 0.79 [95% CI 0.67 to 0.92], p=0.0034) compared with the control group during randomised access. During the same open access period, the rate of all-cause hospital admissions did not statistically significantly reduce in the former treatment group compared with the treatment group during randomised access (HR 0.87 [95% CI 0.74 to 1.03], p=0.10).

In the case series of 1,200 patients, the rate of all-cause hospitalisations was also statistically significantly lower at 1-year post-implantation compared with the year pre-implantation (1.67 events/patient-years compared with 2.28 events/patient-years, HR 0.73 [95% CI 0.68 to 0.78], p<0.0001) (Shavelle 2020).

In the case series of 1,114 patients, the rate of all-cause hospitalisations statistically significantly reduced at 6 months after implantation compared with 6 months before implantation (HR 0.69 [95% CI 0.64 to 0.75], p<0.001) (Desai 2017). Statistically significant reduction in all-cause hospitalisations was also reported in 480 patients who were followed up for 12 months post implantation compared with the pre-implantation interval (HR 0.77 [95% CI 0.70 to 0.86], p<0.001).

In the non-randomised comparative study of 2,174 patients, over the 12-month follow-up period, 1,846 all-cause hospitalisations were reported in patients with a PAP sensor implantation compared with 1,818 all-cause hospitalisations in patients without a PAP sensor implantation (Abraham 2019).

Change in pulmonary artery pressure

In the case series of 1,200 patients, PAP statistically significantly declined from baseline during 1 year after PAP sensor implantation (AUC, −790.9±2097.0 mmHg-days) (Shavelle 2020). The pattern of PAP changes differed according to baseline mean PAP at the time of sensor implantation. The AUC was 499.3±2005.0 mmHg-days for patients with a baseline mean PAP less than 25 mmHg (n=211; mean PAP increased by 1.5±5.8 mmHg, p<0.0002), - 444.1±1643.7 mmHg-days for patients with a baseline mean PAP between

25 and 35 mmHg (n=435; mean PA pressure decreased by 1.3±5.0 mmHg, p<0.0001), and -1560.2±2137.7 mmHg-days for patients with a baseline mean PAP of 35 mmHg or more (n=550; mean PAP decreased by 4.8±6.2 mmHg, p<0.0001).

In a case series of 2,000 patients with PAP sensor implants for NYHA class 3 HF, the mean PAP statistically significantly reduced from 34.9±10.2 to 31.6±10.4 mmHg after 6-month hemodynamic-guided care (p<0.001), and the AUC was -32.8 mmHg-days at 1 month, -156.2 mmHg-days at 3 months, and - 434.0 mmHg-days at 6 months (Heywood 2017).

In the case series of 234 patients, comparing with baseline, mean changes in diastolic PAP, systolic PAP and mean PAP were -3.1±5.1 mmHg, -3.4±7.7 mmHg and -3.3±6.1 mmHg respectively at 6 months after implantation and were 4.6±6.2 mmHg, -5.5±9.3 mmHg and -5.0±7.3 mmHg respectively at 12 months (all p<0.0001) (Angermann 2020). Similar statistically significant reductions were described in AUC at 6 and 12 months after implantation compared with baseline (6 months compared with baseline: diastolic PAP, - 556±917 mmHg-days; systolic PAP, -605±1,390 mmHg-days; mean PAP, - 585±1,095 mmHg-days; 12 months compared with baseline: diastolic PAP, - 1,674±2,248 mmHg-days; systolic PAP, -1,998±3,396 mmHg-days; mean PAP, - 1,828±2,680 mmHg-days; all p<0.0001).

Improvement in quality of life

In the randomised controlled trial of 550 patients, mean MLHFQ scores were 47 for the treatment group and 57 for the control group at 12-month follow up (p=0.0267) (Abraham 2016).

In the case series of 234 patients, overall KCCQ summary score statistically significantly improved from 47.0±24.0 at baseline to 60.5±24.3 at 12 months post implantation (p<0.0001), clinical summary score also statistically significantly improved from 51.2±24.8 to 62.4±24.1 (p<0.0001) (Angermann 2020). During the same period, sum score from the 9-item patient health questionnaire statistically significantly improved from 8.7±5.9 to 6.3±5.1 (p<0.0001) and EQ-5D-5L VAS score changed from 54.4±20.7 to 61.1±21.1. In the same study, NYHA classification improved in 89 patients (38%) at 6 months and 83 patients (35.5%) at 12 months; at both times, 4 patients (1.7%) had worsened to NYHA class 4.

In the case series of 15 patients, improvements in KCCQ score and NYHA classification were reported at 90 days following PAP sensor implantation compared with baseline (exact data were not reported) (Mullens 2020).

Length of hospital stay

In the non-randomised comparative study of 2,174 patients, mean (standard deviation [SD]) length of hospital stay was 6.6 (SD 6.5) days in patients with a PAP sensor implantation compared with 6.5 (SD 5.8) days in patients without a PAP sensor implantation (p=0.70) (Abraham 2019). Mean (SD) total time in hospital for HF was 3.7 (SD 9.5) days per patient and 4.4 (SD 10.3) days per patient, respectively.

Safety summary

Overall device-related or system-related complications

The overall combined device-related or system-related complication rate was 0.02 events per patient-year during a follow up of 31 months in the randomised controlled trial of 550 patients (Abraham 2016).

The rate of device-related or system-related complications was 0.4% (n=5) at 1-year follow up in the case series of 1,200 patients (Shavelle 2020).

Mortality

Death was reported in 50 patients (40 cardiac deaths and 10 non-cardiac deaths) who had PAP-guided management and in 64 patients (48 cardiac deaths, 15 non-cardiac deaths and 1 unknown) who had guideline-directed standard of care management during the 18-month randomised access period in the randomised controlled trial of 550 patients (Abraham 2016). The difference in mortality rates between the 2 groups was not statistically significant (HR 0.80 [95% CI 0.55 to 1.15], p=0.23). No deaths were considered to be related to the device, system or procedure in the entire follow-up period.

Death was reported in 139 patients during the 6-month period after implantation in the case series of 1,114 patients (Desai 2017). For patients who were followed up for 12 months (n=480), death was described in 106 patients.

The mortality rate at 12 months was statistically significantly lower in patients with a PAP sensor implantation than patients without a PAP sensor implantation (0.23 deaths per year compared with 0.30 deaths per year; HR 0.70 [95% CI 0.59 to 0.83], p<0.001) in the non-randomised comparative study of 2,174 patients (Abraham 2019).

Death was reported in 16 (7%) patients after 6 months post-implantation and in 31(14%) patients after 12 months in the case series of 234 patients (Angermann 2020). Of the 31 deaths (19 cardiac-related, 6 non-cardiac related and

6 unknown), 3 possibly related to the implant procedure and 28 did not relate to the device, delivery system or a protocol-required procedure.

Death was reported in 22 patients (about 0.4%) after PAP sensor implantation in a review of 5,500 patients in the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database (Vaduganathan 2017). Causes of death were antecedent pulmonary artery injury or haemoptysis (n=6), HF-related (n=4) and unknown or likely unrelated (n=12).

Cardiac complications

Abnormal heart rate or rhythm was reported in 2 patients and cardiac decompensation in 1 patient in the case series of 234 patients (Angermann 2020). These serious adverse events were relevant to the implant procedure or protocol-related procedure.

Endocarditis was reported in 1 patient in the case series of 234 patients (Angermann 2020). This serious adverse event related to the delivery system and implant procedure.

Transient complete heart block was described in 1 patient because the sensor passed through the right heart in the case series of 15 patients (Mullens 2020). This event resolved without treatment and clinical sequalae.

Thromboembolism

Pulmonary embolisation or device-related thrombosis was described in 5 patients in the review of 5,500 patients in the US FDA MAUDE database (Vaduganathan 2017).

Thrombus at femoral artery was reported in 1 patient in the case series of 234 patients and this event related to the implant procedure (Angermann 2020).

(Pulmonary) artery complications

Pulmonary artery injury or haemoptysis was reported in 28 patients (0.5%) in the review of 5,500 patients in the US FDA MAUDE database (Vaduganathan 2017). These events resulted in intensive care unit stays (n=14), intubations (n=7) and deaths (n=6).

Haemoptysis was reported in 2 patients and arteriovenous fistula in 1 patient in the case series of 234 patients (Angermann 2020). These events related to the delivery system or implant procedure.

Pulmonary artery perforation was reported in 1 patient and pseudoaneurysm formation in 1 patient in the case series of 234 patients (Angermann 2020). These serious adverse events related to the implant procedure.

Post-procedure minor haemoptysis was reported in 2 patients in the case series of 15 patients (Mullens 2020). One patient did not need any treatment and the other had single dose of protamine.

Renal failure

Renal failure was reported in 3 patients in the case series of 234 patients (Angermann 2020). This event related to the implant procedure.

Bleeding or infection

Access site-related bleeding or infection was reported in 15 patients in the review of 5,500 patients in the US FDA MAUDE database (Vaduganathan 2017).

Bleeding was reported in 2 patients and bruising in 1 patient in the case series of 234 patients (Angermann 2020). These events related to the implant procedure.

Serious infection was reported in 4 patients in the case series of 234 patients (Angermann 2020). These events related to the device, delivery system or implant procedure.

Device failure, malfunction or migration

Sensor failure, malfunction or migration was reported in 46 patients, and of these, 35 needed recalibrations, 13 reimplantations and 11 hospitalisations (for reintervention, HF or over-diuresis) in the review of 5,500 patients in the US FDA MAUDE database (Vaduganathan 2017). Five sensors could not be used despite recalibration.

Lead dislodgement or migration (serious adverse event) was reported in 3 patients in the case series of 234 patients (Angermann 2020).

Pressure sensor failure was reported in 1 patient at 1-year follow up in the case series of 1,200 patients (Shavelle 2020).

Pressure sensor failure was reported in 1 patient in the case series of 234 patients (Angermann 2020).

Sensor not detaching from the delivery system was reported in 1 patient, sensor migration in 3 patients, reading not possible in 1 patient in the case series of 234 patients (Angermann 2020). These events were not associated with an

adverse event experienced by the patients but resulted in malfunction of the device.

Dislodgement of sensor was reported in 1 patient in the case series of 15 patients (Mullens 2020). The sensor was dislodged from the target location of deployment into the main pulmonary artery during withdrawal of the delivery system; this event resolved without treatment and there was no compromise to sensor performance.

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, professional experts described the following anecdotal or theoretical adverse event: patient fatigue with remote monitoring daily.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure. The following databases were searched, covering the period from their start to 15 February 2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The inclusion criteria were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with chronic heart failure.
Intervention/test	Insertion and use of implantable pulmonary artery pressure monitor.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 12,787 patients from 1 randomised controlled trial (Abraham 2016), 1 case control study (Abraham 2019), 5 case series (Angermann 2020; Desai 2017; Heywood 2017; Mullens 2020; Shavelle 2020) and 1 review of US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database (Vaduganathan 2017).

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

Summary of key evidence on percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure

Study 1 Abraham WT (2016)

Study details

Study type	Randomised controlled trial (CHAMPION)
Country	US (64 centres)
Recruitment period	2007 to 2009
Study population and number	n=550 (270 management with PAP sensor [treatment group] compared with 280 guideline-directed standard of care management [control group]) Patients with NYHA class 3 HF
Age and sex	Treatment group: mean 61.3 years; 72% (194/270) male Control group: mean 61.8 years: 73% (205/280) male
Patient selection criteria	Inclusion criteria: patients with NYHA class 3 HF, regardless of left ventricular ejection fraction or cause, who had been admitted to hospital for HF in the previous year while receiving guideline-directed drug and device treatments at optimum or best-tolerated doses were eligible for inclusion.
Technique	PAP sensor (Champion, CardioMEMS, USA) was used (consisting of passive, radiofrequency sensor without batteries or leads, and external electronic reader).
Follow-up	31 months (18 months of randomised access and 13 months of open access)
Conflict of interest/source of funding	This study was funded by St Jude Medical Inc. WTA and RCB: received consulting fees and honoraria from CardioMEMS, St Jude Medical. PBA and JGB: employees of St Jude Medical. LWS and JAL: no competing interests

Analysis

Follow-up issues: Of the 550 patients, 347 patients (177 in the former treatment group and 170 in the former control group) completed the randomised access period and transitioned to the open access period. During the randomised access period, 93 patients in the treatment group and 110 patients in the control group exited for reasons that were balanced between the 2 groups with death being the most common reason for withdrawal.

Study design issues: This prospective, parallel, single-blinded, multicentre study (CHAMPION trial; NCT00531661) examined the extended efficacy of PAP-guided management in reducing hospital admissions for HF over 18 months of randomised follow-up and the clinical effect of open access to pressure information for an additional 13 months in patients formerly in the control group. The primary efficacy outcome was the rate

of hospital admissions between the treatment group and control group in both the randomised access and open access periods. Analyses were done using intention to treat.

Patients were randomly assigned (1:1) by centre in block sizes of 4 by a secure validated computerised randomisation system to the treatment group, in which daily uploaded PAP were used to guide medical therapy, or to the control group, in which daily uploaded pressures were not made available to investigators. Patients in the control group received all standard medical, device, and disease management strategies available. Patients then remained masked in their randomised study group until the last patient enrolled completed at least 6 months of study follow up (randomised access period) for an average of 18 months.

Study population issues: There was no statistically significant difference in baseline demographic and clinical characteristics between groups.

Key efficacy findings

- Number of patients analysed: 550

Long-term clinical outcomes from randomised access and open access periods

	Randomised access treatment group (n=270)	**Randomised access control group (n=280)**	**Statistical analysis**
Admissions to hospital HF	182 (0.46)	279 (0.68)	Diff 97 (0.23); NNT 4; HR 0.67 (33% RRR; 95% CI 0.55 to 0.80); p<0.0001
Death and admissions to hospital for HF	232 (0.58)	343 (0.84)	Diff 111 (0.26); NNT 4; HR 0.69 (31% RRR; 95% CI 0.59 to 0.82); p<0.0001)
Death	50 (19%)	64 (23%)	Non-significant; HR 0.80 (95% CI 0.55 to 1.15); p=0.23
Death or first admission to hospital for HF	121 (45%)	145 (52%)	Diff 24 (7.0%); HR 0.77 (23% RRR; 95% CI 0.60 to 0.98); p=0.0330
All-cause admissions to hospital	554 (1.38)	672 (1.65)	Diff 118 (0.26); NNT 4; HR 0.84 (16% RRR; 95% CI 0.75 to 0.95); p=0.0032
Deaths and all-cause admissions to hospital	604 (1.51)	736 (1.80)	Diff 132 (0.29); NNT 3; HR 0.84 (16% RRR; 95% CI 0.76 to 0.94); p=0.0017
	Randomised access control group (n=280)	**Open access former control group (n=170)**	**Statistical analysis**
Admissions to hospital for HF	279 (0.68)	64 (0.36)	Diff 215 (0.32); NNT 3; HR 0.52 (48% RRR; 95% CI 0.40 to 0.69); p<0.0001

Death and admissions to hospital for HF	343 (0.84)	85 (0.51)	Diff 258 (0.33); NNT 3; HR 0.61 (39% RRR; 95% CI 0.48 to 0.78); p<0.0001
Death	64 (23%)	21 (12%)	Non-significant; HR 0.71 (95% CI 0.43 to 1.17); p=0.17
Death or first admission to hospital for HF	145 (52%)	49 (29%)	Diff 96 (23%); HR 0.53 (47% RRR; 95% CI 0.38 to 0.73); p<0.0001
All-cause admissions to hospital	672 (1.65)	230 (1.30)	Diff 442 (0.35); NNT 3; HR 0.79 (21% RRR; 95% CI 0.67 to 0.92); p=0.0034
Deaths and all-cause admissions to hospital	736 (1.80)	251 (1.52)	Diff 485 (0.28); NNT 4; HR 0.85 (15% RRR; 95% CI 0.72 to 0.99); p=0.0351
	Randomised access treatment group (n=270)	**Open access former treatment group (n=177)**	**Statistical analysis**
Admissions to hospital for HF	182 (0.48)	78 (0.45)	Non-significant; HR 0.93 (95% CI 0.70 to 1.22); p=0.58
Death and admissions to hospital for HF	232 (0.61)	109 (0.67)	Non-significant; HR 1.09 (95% CI 0.86 to 1.39); p=0.46
Death	50 (19%)	31 (18%)	HR 1.40 (95% CI 0.89 to 2.23); p=0.15
Death or first admission to hospital for HF	121 (45%)	55 (31%)	Non-significant; HR 0.85 (95% CI 0.61 to 1.17); p=0.32
All-cause admissions to hospital	554 (1.51)	218 (1.32)	Non-significant; HR 0.87 (95% CI 0.74 to 1.03); p=0.10
Deaths and all-cause admissions to hospital	604 (1.65)	249 (1.61)	Non-significant; HR 0.97 (95% CI 0.83 to 1.14); p=0.75

Data are n (events per patients-year), or n (%), unless otherwise indicated. Diff=difference

Cardiac deaths in the treatment group accounted for 80% (n=40) of the mortality with 20% (n=10) non-cardiac. Cardiac deaths in the control group accounted for 75% (n=48) of the mortality with 23% (n=15) noncardiac and 2% (n=1) unknown. During open access, there were 43 exits in the former control group and 58 in the former treatment group. The cause of death in the former treatment group was cardiac in 81% (n=25), non-cardiac in 13% (n=4), and unknown in 6% (n=2). In the control group, 62% of deaths were cardiac (n=13), 24% (n=5) were non-cardiac, and 14% (n=3) were unknown.

Patient interactions with investigators during the 6-month primary endpoint period:

- Treatment group: mean 6.5 contacts (1,024 office visits, 723 telephone calls)
- Control group: mean 6.4 contacts (1,042 office visits, 686 telephone calls)

Emergency department being the primary route of entry to the hospital during the 18-month randomised access period:

- Treatment group: 119 admissions
- Control group: 209 admissions
- p=0.009

Elective admissions from a clinic visit or study visit did not statistically significantly differ between the treatment group (n=63) and the control group (n=70; p=0.73).

Quality of life measured with the MLHFQ at 12 months: 47.0 in the treatment group compared with 56.5 in the control group, p=0.0267

Supplemental analysis of MLHFQ for 12-month follow up used a last observation carried forward technique to account for patients not having a 12-month follow-up visit.

Key safety findings

First 6 months of the trial:

- Device-related or system-related complications: n=8 (1%)
- Procedure-related adverse events: n=7 (1%)

These events included: groin haematomas (n=2); epistaxis (n=1); haemoptysis (n=1); hospitalisation related to anticoagulation treatment (n=3); prolonged hospitalisation secondary to resumption of therapeutic anticoagulation (n=1); exacerbation of pre-existing atrial arrhythmias during right-heart catheterisation (n=2); febrile illnesses (n=2); pulmonary in situ thrombus during right-heart catheterisation (treated with anticoagulation) (n=1); cardiogenic shock (n=1); atypical chest pain (n=1); and delivery-system failure that needed a snare to remove the delivery system (n=1) (Abraham 2011)

No further device-related or system-related or procedure-related deaths were reported in the entire follow-up period. The overall combined device-related or system-related complication rate was 0.02 events per patient-year in the entire follow-up period. No sensor failures occurred after 31 months of average follow-up.

Study 2 Shavelle DM (2020)

Study details

Study type	Case series
Country	US (104 centres)
Recruitment period	2014 to 2017
Study population and number	n=1,200 patients with NYHA class 3 HF
Age and sex	Mean 69 years; 62% (748/1200) male
Patient selection criteria	Inclusion criteria: Patients with CHF, NYHA class 3 symptoms and a prior HF hospitalisation within 12 months, regardless of ejection fraction; patients with HFrEF needing a beta blocker for 3 months and an ACE (angiotensin-converting enzyme) inhibitor or ARB (angiotensin receptor blocker) for 1 month unless the investigator deemed the patient to be intolerant to β-blockers, ACE inhibitors, or ARB; patients with BMI >35 kg/m^2 needing to have a chest circumference <65 inches measured at the axillary level. The target pulmonary artery branch for pressure sensor implantation was needed to have a diameter ≥7 mm. Exclusion criteria: active infection, history of recurrent (>1) pulmonary embolism or deep vein thrombosis, inability to tolerate right heart catheterisation, major cardiovascular event (such as myocardial infarction, open heart surgery, stroke, etc) within the previous 2 months, cardiac resynchronisation therapy implanted within the previous 3 months, glomerular filtration rate <25 mL/min per 1.73 m^2 (obtained within 2 weeks of pressure sensor implant), non-responsiveness to diuretic therapy or need for chronic dialysis, congenital heart disease or mechanical right heart valve, anticipated need to undergo heart transplantation or surgical ventricular assist device within the next 6 months, known coagulation disorders and hypersensitivity or allergy to aspirin, and clopidogrel.
Technique	PAP sensor (CardioMEMS) was used.
Follow-up	1 year
Conflict of interest/source of funding	Funding: The study was funded by Abbott. 12 authors: research support Abbott; 3 authors: Abbott employees.

Analysis

Follow-up issues: Patients were assessed at 1, 6 and 12 months after implantation. Implants were attempted in 1,214 patients. Unsuccessful pressure sensor implantation happened in 14 patients, who were followed for 30 days for safety events. The 6-month visit was completed in 1013 patients and the 12-month visit was completed in 875 patients.

Study design issues: This multi-centre, prospective, open-label, observational, single-arm trial (CardioMEMS post-approval study; NCT02279888) assessed the efficacy and safety of PAP-guided therapy in routine clinical practice. The primary efficacy outcome was the difference between rates of adjudicated HF hospitalisations at

1 year after implantation compared with the year before implantation. Safety end points were freedom from device-related or system-related complications at 2 years and freedom from pressure sensor failure at 1 year. For the primary effectiveness end point of HFH rate during 1 year, 300 patients were estimated to provide >90% power to meet the efficacy goal (upper confidence limit less than the HF hospitalisation rate in the year before enrollment), using a 1-sample, 2-sided Poisson CI with α of 0.05. At the time of reporting, the 2-year follow up was not yet concluded, so authors reported the efficacy and safety findings at 1 year.

A device-related or system-related complication was defined as an adverse event that was related or was possibly related to the system and resulted in at least one of the following: treatment with invasive means other than intramuscular medication or right heart catheterisation, death or explant of device. Pressure sensor failure was defined if no readings could be obtained from the device after troubleshooting the system to rule out problems with the external electronics.

Study population issues: Of the 1,200 patients, 53% had HFrEF (EF <40%), 30% had HFpEF (EF >50%), and 17% had HF with mid-range EF (40%≤ EF ≤50%). Among those with HFrEF, 94.8% were receiving a β-blocker, 68.0% were receiving ACE inhibitor/ARB/ARNI (angiotensin receptor–neprilysin inhibitor), and 66.4% were receiving both a β-blocker and ACE inhibitor/ARB/ARNI. Use of an aldosterone agonist in those with HFrEF was 54.6%.

Key efficacy findings

Number of patients analysed: 1,200 (286,666 pressure transmissions)

Change in PAP during 1 year: AUC, −790.9±2097.0 mmHg-days

- Patients with a baseline mean PAP <25 mmHg (n=211): AUC, 499.3±2005.0 mmHg-days
    - Mean PAP increased by 1.5±5.8 mmHg from 20.2±4.9 mmHg at baseline, p<0.0002
- Patients with a baseline mean PAP between 25 and 35 mmHg (n=435): AUC, -444.1±1643.7 mmHg-days
    - Mean PAP decreased by 1.3±5.0 mmHg from 30.2±2.8 mmHg at baseline, p<0.0001
- Patients with a baseline mean PAP ≥35 mmHg (n=550): AUC, -1560.2±2137.7 mmHg-days
    - Mean PAP decreased by 4.8±6.2 mmHg from 43.0±6.8 mmHg at baseline, p<0.0001

Proportion of patients who had a change in medication during 1 year: 94.1%, with an average of 1.6 medication changes per patient per month.

- Change in medication related to increased PAP: 81.8%
- Change in medication related to decreased PAP: 55.8%
- Change in medication unrelated to PAP: 82.8%

Subgroup analysis of patients with HFrEF (n=637) taking an ARNI

- Baseline: 16.6%
- 12 months: 27.5%
- p<0.001

HF hospitalisations and all-cause hospitalisations pre-implant and 1 year post-implant stratified by baseline mean PA pressures

	Baseline mean PAP <25 mmHg (n=211)	25≤ baseline mean PAP <35 mmHg (n=435)	Baseline mean PAP ≥35 mmHg (n=550)	All patients (n=1,200)
HF hospitalisations, events/patient-years	0.978 compared with 0.295, HR 0.30 (95% CI 0.22 to 0.41)	1.221 compared with 0.519, HR 0.43 (95% CI 0.36 to 0.51)	1.374 compared with 0.649, HR 0.47 (95% CI 0.41 to 0.54)	1.249 compared with 0.535, HR 0.43 (95% CI 0.39 to 0.47)
All-cause hospitalisations, events/patient-years	2.158 compared with 1.287, HR 0.60 (95% CI 0.48 to 0.74)	2.263 compared with 1.586, HR 0.70 (95% CI 0.63 to 0.79)	2.321 compared with 1.891, HR 0.81 (95% CI 0.74 to 0.89)	2.277 compared with 1.667, HR 0.73 (95% CI 0.68 to 0.78)

All p values <0.0001

HF hospitalisations for those who survived to 1 year: HR 0.35 (95% CI 0.31 to 0.39), p<0.0001

Survival at 1-year postimplant: 83.9% (95% CI 81.7% to 85.9%)

There were significant baseline differences in disease severity of patients who survived to 1 year compared with those who died.

HF hospitalisation rate 1 year preimplant and 1-year postimplant stratified by EF ranges:

- HFrEF <40% (n=637): 1.33 compared with 0.61 events/patient-years, HR 0.46 (95% CI 0.40 to 0.52), p<0.0001
- 40%≤ HFrEF ≤50% (n=198): 1.26 compared with 0.48 events/patient-years, HR 0.38 (95% CI 0.30 to 0.49), p<0.0001
- HFrEF >50% (n=363): 1.13 compared with 0.40 events/patient-years, HR 0.40 (95% CI 0.32 to 0.50), p<0.0001

HF hospitalisations for patients with HFrEF having both an ACE inhibitor/ARB/ARNI and β-blocker (n=423): 1.21 compared with 0.53 events/patient-years, HR 0.44 (95% CI 0.37 to 0.52), p<0.0001

Key safety findings

Device-related or system-related complications: n=5 (0.4%)

Freedom from device-related or system-related complications at 1 year: 99.6%

Pressure sensor failure: n=1 (0.1%)

Freedom from pressure sensor failure at 1 year: 99.9%

Study 3 Heywood JT (2017)

Study details

Study type	Case series (retrospective)
Country	US (47 cites)
Recruitment period	2014 to 2016
Study population and number	n=2,000 Patients with PAP sensor implants for NYHA class 3 HF
Age	Mean 70 years; 60% (1,169/2,000) male
Patient selection criteria	Inclusion criteria: implantation of the CardioMEMS HF system between June 6, 2014, through June 9, 2016; the first 2000 sequentially implanted patients. Exclusion criteria: patients without pressure information in the week after implantation.
Technique	CardioMEMS HF system (St. Jude Medical) was used.
Follow-up	Mean 333 days (SD 125)
Conflict of interest/source of funding	This study was sponsored by St. Jude Medical, Sylmar, CA. 8 authors having a consulting relationship with St. Jude Medical. 1 author receiving research support from and having a consulting relationship with St. Jude Medical. 3 authors: salaried employees of St. Jude Medical.

Analysis

Study design issues: This retrospective analysis examined patient pressure transmission adherence and PAP changes comparing baseline with 6 months in the first 2000 patients implanted with the sensor after commercial release in the US. Deidentified data from the remote monitoring Merlin.net (St. Jude Medical) database were used to examine PAP trends from the first consecutive 2000 patients with at least 6 months of follow up.

Changes in PAP were evaluated with an AUC methodology to estimate the total sum increase or decrease in pressures during the follow-up period relative to the baseline pressure. PAP trends were compared with the historic CHAMPION clinical trial. No information about healthcare use, medication changes, quality of life or other important outcomes was available in the database used for this analysis.

Study population issues: Of the 2,000 patients, 34% had preserved EF. The mean EF for the population was 33.5%. The LVEF in all the patients ranged from 5% to 75%.

Compared with the CHAMPION clinical trial, the 2000 general-use patient group was older, had more women implanted with the sensor, and was more likely to have HFpEF ($p<0.01$). Baseline measures of systolic, diastolic, and mean PAPs were statistically significantly higher in the general-use cohort ($p<0.05$). A total of 10 patients did not have baseline pressure information and were excluded from the study.

Key efficacy findings

- Number of patients analysed: 2,000

Mean PAP trends (ACU, mmHg-days)

	1 month	3 months	6 months
CHAMPION control (n=275)	3.1±6.7 (n=270)	-5.5±24.7 (n=251)	42.0±65.0 (n=228)
CHAMPION treatment (n=270)	-7.0±7.7 (n=266)	-59.3±27.6 (n=257)	-150.0±71.0 (n=236)
General-use cohort (n=2,000)	-32.8±2.9 (n=1,920)	-156.2±10.6 (n=1,816)	-434.0±27.5 (n=1,655)

The general-use patients had an AUC of -32.8 mmHg-days at the 1-month time mark, -156.2 mmHg-days at the 3-month time mark, and -434.0 mmHg-days after 6 months of hemodynamic guided care, which was significantly lower than the treatment group in the CHAMPION trial.

PAP reductions in the general-use patients were significantly higher compared with the CHAMPION trial treatment patients who had an AUC of −150.1 mmHg-days after 6 months of pressure-guided care (p<0.0001).

Mean PAP in the general-use group: 34.9±10.2 mmHg at baseline compared with 31.6±10.4 mmHg after 6 months, p<0.001

Mean PAP trends (ACU, mmHg-days)

	1 month	3 months	6 months
Baseline mean PAP ≥35 mmHg			
CHAMPION control (n=107)	-31.7±11.9 (n=105)	-167.2±41.7 (n=100)	-412.1±111.0 (n=88)
CHAMPION treatment (n=94)	-53.8±13.7 (n=93)	-307.3±47.7 (n=90)	-858.3±126.3 (n=77)
General-use cohort (n=958)	-65.6±4.7 (n=911)	-316.9±17.0 (n=851)	-875.8±44.2 (n=765)
35 mmHg > Baseline mean PAP ≥25 mmHg			
CHAMPION control (n=95)	15.5±9.0 (n=93)	49.9±33.9 (n=85)	217.3±96.9 (n=79)
CHAMPION treatment (n=97)	6.8±12.3 (n=95)	27.4±42.9 (n=92)	34.4±103.9 (n=86)
General-use cohort (n=692)	-12.1±4.1 (n=666)	-61.8±14.5 (n=635)	-169.1±36.4 (n=582)
Baseline mean PAP <25 mmHg			
CHAMPION control (n=73)	37.6±12.2 (n=72)	168.3±42.7 (n=66)	470.2±95.9 (n=61)
CHAMPION treatment (n=79)	32.0±12.0 (n=78)	131.9±36.0 (n=75)	379.6±91.3 (n=73)
General-use cohort (n=350)	14.12±5.2 (n=343)	76.6±17.0 (n=330)	163.0±43.6 (n=308)

Mean PAP in the general-use group:

- <25 mmHg: 20.8±3.4 mmHg at baseline compared with 21.8±6.9 mmHg at 6 months, p=0.008
- 25 to 35 mmHg: 30.2±2.8 mmHg at baseline compared with 29.1±7.3 mmHg at 6 months, p=0.0002
- ≥35 mmHg: 43.5±6.7 mmHg at baseline compared with 37.4±9.9 mmHg at 6 months, p<0.0001

Subgroup analysis of the general-use group

	1 month	3 months	6 months
Ejection fraction ≥40 (n=346)	-30.2±6.7 (n=341)	-133.1±23.7 (n=330)	-418.8±58.1 (n=310)
Ejection fraction <40 (n=678)	-31.4±5.0 (n=658)	-160.3±18.1 (n=630)	-437.9±47.5 (n=576)
Female (n=786)	-29.0±4.5 (n=761)	-140.3±16.5 (n=712)	-396.6±42.0 (n=653)
Male (n=1,169)	-35.4±3.8 (n=1,116)	-167.4±14.1 (n=1,064)	-456.0±37.1 (n=967)

HFpEF compared with HFrEF at 6 months: -418.84 mmHg-day compared with -437.89 mmHg-day, p=0.81
Female compared with male at 6 months: -396.6 mmHg-day compared with -458.0 mmHg-day, p=0.28

Total transmissions during 333±125 days: n=446,450

Days between transmissions ranged from 1.07 days in the first 30 days after implantation to 1.27 days after 6 months.

Median use for patients <65 years of age was 96.9% (IQR 72.7% to 100.0%) and for those ≥65 years of age was 100% (IQR 87.5% to 100.0%; p<0.001). Median use for men was 98.4% (IQR 82.9% to 100.0%) and for women was 100% (IQR 82.9% to 100.00%; p=0.099).

Key safety findings

No safety data were reported.

Study 4 Desai AS (2017)

Study details

Study type	Case series (retrospective)
Country	US
Recruitment period	2014 to 2015
Study population and number	n=1,114 Patients with PAP sensor implants for NYHA class 3 HF
Age and sex	Mean 71 years; 64% male
Patient selection criteria	PAP sensor implants were identified by inpatient claims associated with the procedure codes 38.26, 02HQ30Z, or 02HR30Z and outpatient claims associated with Current Procedural Terminology codes C9741 and C2624. Patients with continuous, fee-for-service (non–health maintenance organisation) Medicare insurance enrollment (Parts A and B) for at least 6 months before and after implantation, retaining those who died at any time post-implant (6-month cohort).
Technique	PAP sensor was used and implanted.
Follow-up	6 to 12 months
Conflict of interest/source of funding	Not reported

Analysis

Study design issues: This retrospective cohort study used Centres for Medicare and Medicaid Services administrative claims data from the Standard Analytic File to examine the effectiveness of ambulatory hemodynamic monitoring in reducing HFH outside of the clinical trial setting. An independent review of the results was done by external health care economic consultants before publication.

Study population issues: At baseline, common comorbidities included diabetes (n=727), hypertension (n=1,089) and chronic obstructive pulmonary disease (n=861) for the 6-month follow-up cohort (n=1,114); and diabetes (n=311), hypertension (n=471) and chronic obstructive pulmonary disease (n=384) for the 12-month follow-up cohort (n=480).

Study limitations: These analyses were derived from Medicare claims data; so, there were no details regarding medical history, ejection fraction, the indication for PAP sensor implantation, quality of life, device safety and so on.

Key efficacy findings

- Number of patients analysed: 1,114

Mean time from the most recent HF hospitalisation to device implantation: 63.2±47.5 days for 832 patients in the 6-month cohort (implantation happened in the ambulatory setting)

Clinical outcomes before and after PAP sensor implantation for the 6- and 12-month cohorts

	6-month cohort (n=1,114)		12-month cohort (n=480)	
	Pre-implant	Post-implant	Pre-implant	Post-implant
Follow-up, patient-years	557	513	480	413
All-cause hospitalisations	1,899	1,119	1,387	859
Proportion of patients with at least 1 hospitalisation for all-cause, %	81%	50%		
HF-related	1,020	381	696	300
Proportion of patients with at least 1 hospitalisation for HF-related, %	59%	22%		
Median number of HF hospitalisations per patient	0.92	0.37		
Non-HF-related	879	738	691	559
Days alive and out of hospital, %	93.9%	95.6%	94.8%	95.7%
Ventricular assist device or transplant	0	17	0	15
Deaths	0	139	0	106

Cumulative HF hospitalisations before and after device implantation:

- 6-month cohort: HR 0.55 (95% CI 0.49 to 0.61), p<0.001
  For the Poisson model, the incidence rate ratio was 0.60 (95% CI 0.53 to 0.68), and for the negative binomial regression models it was 0.64 (95% CI 0.57 to 0.73).
- 12-month cohort: HR 0.66 (95% CI 0.57 to 0.76), p<0.001

All-cause hospitalisations before and after device implantation:

- 6-month cohort: HR 0.69 (95% CI 0.64 to 0.75), p<0.001
- 12-month cohort: HR 0.77 (95% CI 0.70 to 0.86), p<0.001

Subgroups analysis: HF hospitalisations during period before and after PAP sensor implant (6-month cohort)

		No. of patients	HR (95% CI)
Age	<75 years	654	0.57 (0.49 to 0.66)
	≥75 years	460	0.50 (0.42 to 0.60)
Sex	Male	711	0.53 (0.45 to 0.61)
	Female	403	0.58 (0.48 to 0.69)
Type of implant	Outpatient	832	0.50 (0.44 to 0.58)
	Any	114	0.55 (0.49 to 0.61)

Excluding deaths		975	0.36 (0.31 to 0.42)
Excluding death/VAD/Transplant		958	0.36 (0.31 to 0.42)

Key safety findings

No safety data were reported.

Study 5 Abraham J (2019)

Study details

Study type	case control study
Country	US
Recruitment period	Treatment group: 2014 to 2016 Control group: 2013 to 2016
Study population and number	n=2,174 (1,087 with a PAP sensor implantation [treatment group] compared with 1,087 without a PAP sensor implantation [control group]) Patients with NHYA class 3 HF
Age and sex	Treatment group: mean 73 years; 65% (706/1,087) male Control group: mean 74 years; 65% (706/1,087) male
Patient selection criteria	Inclusion criteria: PAP sensor implants were identified by inpatient claims associated with the procedure codes 38.26, 02HQ30Z, or 02HR30Z and outpatient claims associated with Current Procedural Terminology codes C9741 and C2624. Patients with continuous, fee-for-service Medicare insurance enrollment (Medicare parts A and B) for at least 12 months before and after sensor implant. Exclusion criteria: Health maintenance organisation paid claims are excluded from the CMS data set; accordingly, health maintenance organisation-insured patients were excluded to avoid incomplete data.
Technique	Implantation of the PAP monitoring system (CardioMEMS hemodynamic sensor, Abbott.
Follow-up	12 months
Conflict of interest/source of funding	All funding for this study was provided by Abbott. All authors reported conflicts of interest.

Analysis

Study design issues: This concurrent matched cohort study used Centres for Medicare and Medicaid Services administrative claims data from the Standard Analytic File to examine the association between ambulatory hemodynamic monitoring and rates of HF hospitalisation at 12 months in clinical practice. The primary outcomes were HF hospitalisations and cumulative days lost because of HF hospitalisation or death at the 12 months after the anchor date.

Claims data include part A inpatient claims, part B outpatient claims and the associated denominator files. A stepwise, iterative algorithm was used to identify the closest match between a patient who received an implant and a patient who did not receive an implant.

Study population issues: At baseline, the treatment and control groups were matched for age, demographic characteristic, history of implantable cardioverter defibrillator or cardiac resynchronisation therapy device (45.4% for each group), comorbidities (arrhythmia, 74.5% in the treatment group compared with 75.8% in the control group, p=0.52; hypertension, 86.9% compared with 88.6%, p=0.27; diabetes, 53.1% compared with

51.9%, p=0.61; pulmonary disease, 55.9% compared with 58.7%, p=0.21; renal disease, 49.7% compared with 53.4%, p=0.09), and without end-stage renal disease (98.3% for each group).

There were no statistical differences between the 2 groups among the remaining 25 comorbid conditions at baseline. Chronic ischemic heart disease was not a matching criterion yet was similarly prevalent between the treatment and control groups (72.2% [785/1,087] compared with 70.0% [761/1,087], p=0.26). HF hospitalisations were matched temporally for the 2 groups (HR 0.99 [95% CI 0.95 to 1.05], p=0.97). The mean (SD) difference between hospitalisation timing was 39.5 (38.5) days, and the mean (SD) cumulative days in hospital for the year prior to implant were 12.7 (12.7) days per patient for the treatment group and 11.4 (11.4) days per patient for the control group.

This retrospective analysis substantially extended the findings of a prior analysis of ambulatory haemodynamic monitoring in a smaller population of Medicare recipients that did not have a separate control group (Desai et al. 2017).

Study limitations: Important clinical information, such as ejection fraction, natriuretic peptide levels and renal function, are not known. Medical therapy, indications for PAP sensor implant, and complications of sensor implant are not available. Residual confounding by unmeasured covariates remains possible.

Key efficacy findings

- Number of patients analysed: 2,174

Clinical outcomes during follow-up period

	Treatment group (n=1,087)	**Control group (n=1,087)**
Clinical events		
HF hospitalisation, no. of inpatient events	616	784
Death	241 (22.2%)	325 (29.9%)
Ventricular assist device or transplant	20 (1.8%)	13 (1.2%)
Hospitalisation for any cause, no. of inpatient events	1,846	1,818
Patients with ≥1 clinical event		
HF hospitalisation, inpatient events	345 (31.7%)	422 (38.8%)
HF hospitalisation or death, inpatient events	469 (43.1%)	597 (54.9%)
Hospitalisation for any cause	695 (63.9%)	695 (63.9%)
Hospitalisation for any cause or death	735 (67.6%)	783 (72.0%)

Comparative effectiveness of PAP sensor-based management on clinical event rates and days lost

	Treatment group (n=1,087)	Control group (n=1,087)	HR or risk ratio (95% CI)	Absolute difference, d	P value
Clinical event rates per patient per year					
HF hospitalisation, inpatient events	0.65	0.88	0.76 (0.65 to 0.89)	NA	<0.001
Mortality, death per year	0.23	0.30	0.70 (0.59 to 0.83)	NA	<0.001
HF or death	0.90	1.23	0.73 (0.64 to 0.84)	NA	<0.001
Days lost per patient					
To death	46.2	64.2	0.72 (0.62 to 0.84)	-17.9	<0.001
To HF hospitalisation or death	50.0	68.4	0.73 (0.63 to 0.85)	-18.5	<0.001
To any-cause hospitalisation or death	56.9	74.5	0.77 (0.68 to 0.85)	-17.5	<0.001

HRs, 95% CIs, and p values for events were derived using the Andersen-Gill extension of the Cox proportional hazards model. Mortality rates are the Kaplan-Meier estimates of mortality.
Risk ratio: mean, 95% CI, HR and p values for comparing days lost were derived from nonparametric bootstrap model.

The percentage of days lost because of HF hospitalisation or death was reduced in the treatment cohort (13.7% [95%CI 12.1% to 15.3%]) compared with the control cohort (18.8% [95% CI 16.9% to 20.7%]; risk ratio, 0.73 [95% CI 0.63 to 0.85]; p<0.001). The treatment cohort lost a mean (SD) of 50.0 (98.3) days per year compared with 68.4 (116.0) days per year lost in the control cohort.

Sensor implant was associated with a difference of 17more days alive and out of the hospital.

Mean (SD) length of hospital stay:

- Treatment group: 6.6 (6.5) days
- Control group: 6.5 (5.8) days
- p=0.70

Mean (SD) total time in hospital for HF:

- Treatment group: 3.7 (9.5) days per patient
- Control group: 4.4 (10.3) days per patient

Sensitivity analysis of comparative effectiveness of PAP sensor-based management:

Bootstrap model

	Treatment group (n=1,087)	**Control group [IQR] (n=41,347 patients matched to the treatment group)**	**Relative risk [IQR]**	**p value**
HF hospitalisation, HFH per year	0.65	0.93 [0.90 to 0.95]	0.70 [0.68 to 0.72]	p<0.01
Mortality, death per year	0.22	0.31 [0.30 to .032]	0.71 [0.69 to 0.73]	p<0.01
Received care at the same centres	**Treatment group (n=774)**	**Control group [IQR] (n=8,973)**	**Relative risk [IQR]**	**p value**
HF hospitalisation, HFH per year	0.52	0.81 [0.80 to 0.84]	0.64 [0.63 to 0.66]	p<0.01
Mortality, death per year	0.22	0.28 [0.27 to 0.29]	0.76 [0.74 to 0.79]	p<0.01

Key safety findings

No safety data were reported.

Study 6 Angermann (2020)

Study details

Study type	Case series (MEMS-HF)
Country	Germany (26 centres), the Netherlands (4 centres) and Ireland (1 centre)
Recruitment period	2016 to 2019
Study population and number	n=234 Patients with NYHA class 3 or 4 HF
Age and sex	Mean 68 years; 78% (183/234) male
Patient selection criteria	Inclusion criteria: patients aged ≥18 years with predominant NYHA class 3 symptoms over the last month and ≥1 HF hospitalisation in the previous year. Patients with reduced LVEF needed to be on guideline-directed medical therapy, as tolerated. Exclusion criteria: known coagulation disorders or inability to take 2 types of blood thinning medications for 1 month after sensor implantation; patients for heart transplant, ventricular assist device implantation or hospice care in the next 12 months; not expected to be able to complete study follow-up requirements.
Technique	CardioMEMS™ HF system (Abbott, Sylmar, CA, USA) was used.
Follow-up	12 months
Conflict of interest/source of funding	This work was supported by Abbott, Sylmar, CA, USA. All authors but 2 reported conflicts of interest.

Analysis

Follow-up issues: A total of 239 patients were enrolled; 236 entered the safety analysis and 234 the efficacy analysis; no patient was lost to follow up. Patients were contacted weekly by their caregiver for the first month postimplant and every 2 to 4 weeks thereafter. Patient-reported outcomes were assessed at baseline, 6 and 12 months.

Study design issues: This prospective non-randomised multicentre study (NCT02693691) designed to characterise the utility of the CardioMEMS™ HF system (Abbott, Sylmar, CA, USA) over 12-month follow-up.

Study physicians had formal implant training. Non-physician caregivers were offered education in HF disease management strategies and received written instructions about how to apply PAP-guided care. Local study teams trained patients in device usage, ensured that they understood their responsibility for daily PAP measurement, and provided information and materials enabling self-monitoring of vital parameters and HF signs or symptoms. Treatment adjustments were communicated directly to patients.

KCCQ was used to capture health status. Depressive symptoms were assessed using the 9-item patient health questionnaire depression module (PHQ-9) 21 (score 0 to 3 per item [sum-score 0 to 27]; higher values indicate more severe depression). Additionally, patients completed the EQ-5D-5L questionnaire including a visual analogue scale (EQ-VAS), where respondents rate their current overall generic health on a 0 to 100 hash-marked VAS.

Co-primary safety endpoints were device-related or system-related complications, defined as a (serious) adverse event definitely or possibly related to the PAP sensor or external electronics that was treated invasively or resulted in patient death or explant of the device. Pressure sensor failure was defined as an inability to obtain readings after troubleshooting the system to exclude problems with external electronics.

Key efficacy findings

- Number of patients analysed: 234

HF hospitalisation: 12-month follow up: 38.9% (n=91) of patients had experienced ≥1 HF hospitalisations; in most patients (27.8%) events happened during the first 6 months post-implant.

- 12 months post-implant compared with the pre-implant year, the HF hospitalisation rate decreased by 62% (0.60 compared with 1.55 events/patient-year; HR 0.38 [95% CI 0.31 to 0.48]; p<0.0001)
- the corresponding reduction in patients completing ≥12-month follow up was 66% (HR 0.34 [95% CI 0.26 to 0.44]; p<0.0001).

Cumulative crude changes in PAP:

- 6 months compared with baseline: dPAP, -3.1±5.1 mmHg; sPAP, -3.4±7.7 mmHg; mPAP, -3.3±6.1 mmHg; all p<0.0001
- 12 months compared with baseline: dPAP, -4.6±6.2 mmHg; sPAP, -5.5±9.3 mmHg; mPAP, -5.0±7.3 mmHg; all p<0.0001

Change in AUC:

- 6 months compared with baseline: dPAP, -556±917 mmHg-days; sPAP, -605±1,390 mmHg-days; mPAP, -585±1,095 mmHg-days; all p<0.0001
- 12 months compared with baseline: dPAP, -1,674±2,248 mmHg-days; sPAP, -1,998±3,396 mmHg-days; mPAP, -1,828±2,680 mmHg-days; all p<0.0001

Change in NYHA class

Events	Baseline (n=234)	6 months	12 months
NYHA class 1		3.0%	3.4%
NYHA class 2		35.0%	32.1%
NYHA class 3	99.6%	44.9%	39.7%
NYHA class 4	0.4%	1.7%	1.7%
Deaths		7.7%	13.8%
Withdrawn		5.6%	8.5%

Patient-reported outcomes

Questionnaire	Baseline[a]	6 months[a]	Score change and p-value (6 months	12 months[a]	Score change and p-value (12

			compared with baseline)[b]		**months compared with baseline)[b]**
Kansas city cardiomyopathy questionnaire					
OSS	47.0±24.0 (227) [43.8 to 50.1]	59.8±23.9 (195) [56.4 to 63.2]	11.9±1.5 [9.0 to 14.9] p<0.0001	60.5±24.3 (175) [56.9 to 64.1]	12.7±1.6 [9.6 to 15.7] p<0.0001
OSS mPAP<35 mmHg	51.3±25.3 (103) [46.4 to 56.3]	63.0±22.7 (90) [58.2 to 67.7]	10.1±1.9 [6.4 to 13.8] p<0.0001	65.0±22.1 (83) [60.2 to 69.8]	12.32±1.9 [8.5 to 16.1] p<0.0001
OSS mPAP≥35 mmHg	43.8±22.5 (117) [39.7 to 48.0]	57.9±24.8 (100) [53.0 to 62.8]	13.9±2.4 [9.2 to 1.6] p<0.0001	57.0±25.4 (89) [51.6 to 62.3]	13.0±2.5 [8.1 to 17.8] p<0.0001
CSS	51.2±24.8 (227) [48.0 to 54.5]	62.0±25.0 (195) [58.4 to 65.5]	9.8±1.6 [6.7 to 12.9] p<0.0001	62.4±24.1 (175) [58.8 to 66.0]	10.1±1.6 [6.9 to 13.4] p<0.0001
CSS mPAP<35 mmHg	57.1±26.4 (103) [51.9 to 62.3]	65.3±23.0 (90) [60.5 to 70.2]	6.8±2.0 [2.9 to 10.6] p=0.0007	66.1±22.2 (83) [61.3 to 71.0]	7.7±2.0 [3.8 to 11.7] p=0.0002
CSS mPAP≥35 mmHg	46.9±22.4 (117) [42.8 to 51.0]	60.0±26.5 (100) [54.7 to 65.3]	12.8±2.5 [7.9 to 17.6] p<0.0001	59.6±25.4 (89) [54.2 to 64.9]	12.3±2.6 [7.2 to 17.4] p<0.0001
9-item patient health questionnaire					
Sum score	8.7±5.9 (225) [7.9 to 9.5]	6.7±5.4 (195) [5.9 to 7.5]	-1.8±0.3 [-2.4 to -1.1] p<0.0001	6.3±5.1 (175) [5.6 to 7.1]	-2.1±0.4 [-2.8 to -1.4] p<0.0001
Sum score mPAP<35 mmHg	8.3±6.0 (101) [7.1 to 9.5]	6.4±5.6 (90) [5.3 to 7.6]	-1.7±0.5 [-2.7 to -0.7] p=0.0006	6.0±4.9 (83) [4.9 to 7.1]	-2.0±0.5 [-3.0 to -1.1] p<0.0001
Sum score mPAP≥35 mmHg	8.8±5.8 (117) [7.8 to 9.9]	6.8±5.1 (100) [5.8 to 7.8]	-1.8±0.5 [-2.8 to -0.9] p=0.0002	6.4±4.9 (89) [5.3 to 7.4]	-2.2±0.5 [-3.2 to -1.2] p<0.0001
EQ-5D-5L VAS					
VAS	54.4±20.7 (227) [51.7 to 57.1]	59.8±21.3 (195) [56.8 to 62.8]	4.9±1.5 [1.9 to 7.9] p=0.0015	61.1±21.1 (174) [58.0 to 64.3]	6.1±1.6 [3.0 to 9.3] p=0.0002
VAS mPAP<35 mmHg	57.5±21.3 (103) [53.3 to 61.6]	64.1±20.3 (90) [59.8 to 68.3]	6.0±2.2 [1.7 to 10.3] p=0.0066	63.1±19.2 (83) [58.9 to 67.3]	5.1±2.2 [0.7 to 9.5] p=0.0227
VAS mPAP≥35 mmHg	51.8±20.4 (117) [48.0 to 55.5]	56.4±21.8 (100) [52.0 to 60.7]	4.3±2.3 [-0.2 to 8.8] p=0.0584	59.7±22.8 (88) [54.9 to 64.6]	7.4±2.4 [2.7 to 12.0] p=0.0021

[a]Mean±SD (n) [95% CI]
[b]Least-squares mean difference±standard error [95% CI]

Cumulative number of medication changes 12 months post-sensor implant

	Months 0 to 3	Months 4 to 6	Months 7 to 9	Months 10 to 12	Overall months 0 to 12
ACEi/ARB/ARNi	120 (0.18)	69 (0.10)	61 (0.10)	62 (0.11)	312 (0.12)
Betablockers	81 (0.12)	50 (0.08)	36 (0.06)	42 (0.07)	209 (0.08)
MR-Antagonists	70 (0.10)	37 (0.06)	35 (0.06)	28 (0.05)	170 (0.07)
Diuretics	453 (0.67)	244 (0.37)	191 (0.32)	180 (0.31)	1,068 (0.42)

Patient and caregiver adherence:

- Mean patient adherence to daily PAP transmissions: 78.1±23.5%
- Mean patient adherence to weekly PAP transmissions: 89.7±17.8%
- Caregiver adherence to weekly review of PAP data: 89.8±18.7%

Key safety findings

- Number of patients analysed: 236

Free from device-related or system-related complications: 98.3% (235/236, 95% CI 95.8 to 100%)

Free from pressure sensor failure: 99.6% (233/234, 95% CI 97.6 to 100%)

No device-related or system-related complications needed sensor removal.

Serious adverse device effects over 12 months of observation

Events	No. of patients (n=236)	No. of events	Device related	Delivery system related	Implant procedure related	Protocol-required procedure related	Not related to device/ implant/ procedure
Abnormal heart rate or rhythm	2 (0.8%)	2	0	0	2	1	0
Bleeding	2 (0.8%)	2	0	0	2	0	0
Cardiac decompensation	1 (0.4%)	1	0	0	1	0	0
Haemoptysis	2 (0.8%)	2	0	1	2	0	0
Infection	4 (1.7%)	4	1	1	4	0	0
Lead dislodgement or migration	3 (1.3%)	3	0	1	3	1	0
Pulmonary artery perforation	1 (0.4%)	1	0	0	1	0	0
Renal failure	3 (1.3%)	3	0	1	3	1	0

Other	3 (1.3%)	3	0	1	3	0	0
Endocarditis	1 (0.4%)	1	0	1	1	0	0
Pseudoaneurysm formation	1 (0.4%)	1	0	0	1	0	0
Sudden death	1 (0.4%)	1	0	0	1	0	0
Total	18 (7.6%)	21	1	4	21	2	0

A total of 21 events in 18 patients.

Non-serious adverse device effects during 12 months of observation

Events	No. of patients (n=236)	No. of events	Device related	Delivery system related	Implant procedure related	Protocol-required procedure related
AV fistula	1 (0.4%)	1	0	0	1	0
Bleeding	2 (0.8%)	2	0	0	2	0
Bruising	1 (0.4%)	1	0	0	1	0
Technical issue with using the patient unit	1 (0.4%)	1	1	0	0	0
Pressure sensor failure	1 (0.4%)	1	1	0	0	0
Readings not possible	1 (0.4%)	1	1	0	1	0
Sensor did not detach from delivery system	1 (0.4%)	1	0	1	1	0
Sensor migration	3 (1.3%)	3	3	0	1	0
Thrombus (femoral artery)	1 (0.4%)	1	0	0	1	0
TOTAL	**11 (5.0%)**	**12**	**6**	**1**	**8**	**0**

A total of 12 adverse events in 11 patients. Of the 12 events, 4 were not associated with an adverse event experienced by the patients. The remaining 8 events were related to non-serious events that did not meet the criteria for a device-related or system-related complication.

Deaths during 12 months of observation

Events	No. of deaths (n=236)	Device related	Delivery system related	Implant procedure related	Protocol-required procedure related	Not related to device/ implant/ procedure
Cardiac	19 (8.0%)	0	0	3	0	16

Non-cardiac	6 (2.5%)	0	0	0	0	6
Unknown	6 (2.5%)	0	0	0	0	6
Total	**31 (13.1%)**	**0**	**0**	**3**	**0**	**28**

After 6 and 12 months, 16 (7.0%) and 31 patients (13.8%) had died.
Of the 19 cardiac deaths, 12 were because of pump failure, 4 were because of arrhythmias, 2 were identified as 'cardiac' without additional information, and 1 was because of ischaemic heart disease. No cardiac deaths were categorised as related to the device, delivery system or protocol-required procedure, but 3 were considered as possibly related to the implant procedure.
For non-cardiac events, 3 were attributed to sepsis, 1 was reported as non-cardiac without additional information on the cause of death, 1 was due to renal failure, and 1 was due to herpes simplex encephalitis.
All 'unknown' deaths occurred outside the 30-day safety window for the device implant procedure.

Study 7 Mullens WR (2020)

Study details

Study type	Case series (SIRONA)
Country	Belgium (1 centre) and Ireland (1 centre)
Recruitment period	2017 to 2019
Study population and number	n=15 Patients with NYHA class 3 HF
Age and sex	Mena 71.4 years; 67% (10/15) male
Patient selection criteria	Inclusion criteria: patients over 18 years with NYHA class 3 HF with reduced or preserved ejection fraction treated for a minimum of 3 months and stable for 1 month prior to enrolment with at least 1 HF-related hospitalisation or equivalent within the last year. An estimated glomerular filtration rate of ≥30 mL/min/1.73m^2 and appropriate pulmonary artery anatomy, as demonstrated by computed tomography pulmonary angiogram, were also needed.
Technique	Cordella™ PAP sensor was used and implanted. Right heart catheterisation was done at baseline and at 3- and 12-month follow up in the supine position.
Follow-up	24 months
Conflict of interest/source of funding	The study was funded by Endotronix Inc. AMKR: research support from Abbott, Medtronic, Actelion, Novartis, SonIVIE, Endotronix. All other authors: nothing to disclose.

Analysis

Follow-up issues: Patients were followed up at 1, 3, 6, 9, 12, 18 and 24 months after implantation but the efficacy and safety outcomes were reported for the first 90 days following implantation.

Study design issues: This multicentre, open-label, first-in-human, feasibility study (NCT03375710) evaluated the safety and accuracy of the Cordella™ PAP sensor in 15 patients with NYHA class 3 HF. The primary safety endpoint was freedom from device-related adverse events through 30 days post-procedure and pressure sensor failure. The efficacy outcomes included accuracy of the Cordella sensor PAP measurements, compared to fluid-filled catheter 90 days post-implant, change in PAP pre- and post-implant, frequency of HF hospitalisation or equivalent, change in quality of life (KCCQ and EQ-5D-5L) and adherence to myCordella™ HF system measurements.

The clinicians were blinded to PAP the first 90 days until the accuracy check at 90-day right heart catheterisation.

Study population issues: Of the 15 patients, 4 (53%) had an ejection fraction >40% and common comorbidities included diabetes mellitus (n=4), hypertension (n=10), COPD (n=3), atrial flutter/fibrillation (n=9) and coronary artery disease (n=7).

Key efficacy findings

- Number of patients analysed: 15

Successful implantation: n=15

PAP during 90-day right heart catheterisation (PAP sensor compared with reference catheter)

	sPAP		**mPAP**		**dPAP**	
	Cordella™ sensor	Swan-Ganz catheter	Cordella™ sensor	Swan-Ganz catheter	Cordella™ sensor	Swan-Ganz catheter
No.	14	14	14	14	14	14
Mean (SD)	38.0 (14.4)	43.9 (13.5)	22.5 (11.8)	25.2 (8.5)	14.7 (10.8)	15.9 (7.1)
Median	33.9	42	18.2	22	10.3	15
Min, Max	25.2 to 77.5	26.0 to 72.0	11.9 to 56.6	15.3 to 48	4.4 to 46.2	7.0 to 36.0
Mean difference			2.7			
95% CI			-11.1 to 16.5			

One patient did not go through the 90-day right heart catheterisation because the patient had a device dislodgement during the implant procedure.

Over the first 90 days following implantation, patient adherence to daily measurement and transmission of vital signs was 99% and PAP sensor readings was 99% corroborated with improvements in KCCQ score and NYHA classification (exact data were not reported).

Key safety findings

Adverse events related to the use of the Cordella™ HF system: n=4 (all events resolved without clinical sequelae or impairment of device function)

- Dislodgement of sensor: n=1 (not needing any treatment and no compromise to sensor performance)
- Transient complete heart block: n=1 (not needing any treatment)
- Post-procedure minor haemoptysis: n=2 (1 patient had single dose of protamine)

No device system-relation complications were reported, and no sensor failure happened within 90 days.
Serious adverse event within 90 days: HF hospitalisation=1

Study 8 Vaduganathan M (2017)

Study details

Study type	Review of US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database
Country	US
Recruitment period	Database search: 2014 to 2017
Study population and number	n=5,500 (177 events) Patients with PAP sensor implants for NYHA class 3 HF
Age and sex	Not reported
Patient selection criteria	The FDA MAUDE database was searched by product class (“system, hemodynamic, implant”),model number (“CM1000,” “CM1010,” “CM2000,” and “CM3000”), brand name(“CardioMEMS” and “HF Sensor Delivery System”), and product code (“MOM,” a unique FDA designation linked to the CardioMEMS HF System device).
Technique	CardioMEMS HF system was used
Follow-up	Not reported. Time between the date of event and the date the FDA received a report: median 42 days (IQR 13 to 196 days), with 36 reports completed within 1 week of the event.
Conflict of interest/source of funding	All authors but 1 reported conflicts of interest.

Analysis

Study design issues: This study retrospectively reviewed and analysed the data from the Manufacturer and User Facility Device Experience (MAUDE) database to identify CardioMEMS HF system-related adverse events within the first 3 years of FDA approval. Although this database could not be used to establish definitive event rates, this study reported estimates of device-, system- or procedure-related adverse event rates. An estimate of total device implants in the US was obtained by sequential review of investor reports and press releases, corroborated by a direct source from Abbott.

Study population issues: Of these approximately 5500 implants, there were 155 reports (2.8%) describing 177 unique adverse events. Of 155 reports, 147 were mandatorily reported by the manufacturer/user facility (94.8%). Some patients were clinical study participants.

Key efficacy findings

- Number of patients analysed: 5,500 (177 events)

No efficacy data were reported.

Key safety findings

Adverse events: n=177 (155 reports, 2.8%). No autopsies were reported.

Pulmonary artery injury/haemoptysis: n=28 (0.5%), including 14 intensive care unit stays, 7 intubations and 6 deaths.

Technical challenges with implantation: n=18. Of these, 14 were aborted.

Sensor failure, malfunction or migration: n=46. Of these, 35 needed recalibrations, 13 implantations, and 11 hospitalisations (for reintervention, HF or over-diuresis). Five sensors could not be used despite recalibration.

Access site-related bleeding/infection: n=15

Pulmonary embolism/device thrombosis: n=5

Death: n=22 (about 0.4%)

Causes and details related to 22 deaths after CardioMEMS HF system implantation

Cause of death/contributing mechanism	Event details	Patient history
Antecedent PA injury/haemoptysis (n=6)	Distal wire migration during procedure with haemoptysis required bronchoscopy and intubation; left lower PA actively bled, requiring thrombin injection; clinical deterioration and eventual death occurred	Transposition of the great arteries with prior arterial switch
	Distal wire access lost needing reintroduction of catheter prior to delivery of sensor; small branch of left PA actively bled once balloon deflated and pulled back; subsequent massive haemoptysis required intubation and multiple coil embolisations; complicated course with multisystem organ failure, renal replacement therapy, and atrial fibrillation	
	During procedure, distal wire access was lost and needed to be repositioned/ manipulated; subsequent haemoptysis needed intubation, complicated by cardiopulmonary arrest	Patient was readmitted after 21-day hospitalisation and had device implantation
	Left lower PA microperforation occurred prior to delivery of sensor, leading to clinical deterioration and death	NA
	Required intubation; repeated angiogram revealed device implanted in nontarget vessel but with no clear source of bleeding; initially extubated but then reintubated and clinically deteriorated	NA
	Minor haemoptysis followed device implantation, which subsequently resolved; the patient died a couple days	Patient having dual antiplatelet therapy

	after device implantation, and the definitive cause was unknown	
Worsening HF (n=4)	Fall resulting in spinal fractures 1 day after device implantation; subsequent worsening HF and respiratory failure before the patient transitioned to hospice care and died	Clinical study participant
	Worsening HF and related complications	NA
	Hypoxia during procedure required supplemental oxygen; the patient subsequently died the night of the device implantation; the treating physician believed cause of death was cardiogenic shock	NA
	The patient was readmitted for worsening HF 1 day after device implantation with subsequent pulseless electrical activity arrest	NA
Cardiac arrest/unknown (n=9)	The treating physicians indicated that death was unlikely to be related to device or procedure (n=5)	One patient was a clinical study participant
	Unknown cause of death with limited event details or physician corroborating information (n=4)	NA
Unrelated (n=3)	Postimplantation renal failure and aspiration pneumonia occurred; the patient transitioned to comfort-oriented care and died	Severe peripheral artery disease needing requiring procedure around time of implant
	The patient was readmitted after device implantation to another hospital with fevers and died of sepsis/infection	NA
	The patient felt unwell with productive cough but refused to seek medical attention; the patient subsequently experienced cardiac arrest	NA

Validity and generalisability of the studies

- Studies were done in the US, Belgium, Germany, Ireland and the Netherlands; no UK data were included.
- Seven studies reported that mean age ranged from 61 to 73 years, 60% or more were male, and the follow-up period ranged from 6 to 31 months.
- Two devices (CardioMEMS™ and Cordella™) were used. CardioMEMS™ had a valid CE mark for measuring and monitoring PAP in patients with NYHA class 3 HF but Cordella™ did not (it was tested in a feasibility study [Mullens 2020]).
- There was 1 randomised controlled trial (Abraham 2016), and intention-to-treat analysis was done.
- Two studies included the same population so there was likely to be some patient overlap between them (Abraham 2019; Desai 2017).
- When reported, the majority of the population had NYHA class 3 HF and only 1 patient had NYHA class 4 HF at baseline (this patient was included in Angermann [2020]).

Existing assessments of this procedure

The European Society of Cardiology (ESC) guideline for the diagnosis and treatment of acute and chronic heart failure was published in 2016. ESC recommended that 'monitoring of pulmonary artery pressures using a wireless implantable haemodynamic monitoring system (CardioMEMS) may be considered in symptomatic patients with HF with previous HF hospitalisation in order to reduce the risk of recurrent HF hospitalisation'. This was a class 2b recommendation, with a level of evidence class B. This recommendation was based on 2 studies (Abraham et al. 2011; 2016).

A white paper from the Heart Failure Society of America Scientific Statements Committee issued a consensus statement on the remote monitoring of patient with heart failure in 2018. The committee concluded that 'clinical care with the use of the CardioMEMS device resulted in fewer HF hospitalisations than standard care in NYHA functional class III patients with recent HF-related events', and that 'additional data to confirm earlier findings, determine best practices, and define cost-effectiveness are needed'. These conclusions were

made based on 10 studies (Abraham et al. 2011, 2016; Adamson et al. 2014; Costanzo et al. 2016; Desai et al. 2017; Givertz et al. 2017; Krumholz et al. 2017; Loh et al. 2011; Sood 2018; Verdejo et al. 2007).

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedure

- Cardiac contractility modulation device implantation for heart failure. NICE interventional procedures guidance 655 (2019). Available from https://www.nice.org.uk/guidance/ipg655

Technology appraisals

- Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction. NICE technology appraisal guidance 388 (2016). Available from https://www.nice.org.uk/guidance/ta388

- Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure. NICE technology appraisal guidance 314 (2014). Available from https://www.nice.org.uk/guidance/ta314

- Ivabradine for treating chronic heart failure. NICE technology appraisal guidance 267 (2012). Available from https://www.nice.org.uk/guidance/ta267

NICE guideline

- Chronic heart failure in adults: diagnosis and management. NICE guideline 106 (2018). Available from https://www.nice.org.uk/guidance/ng106

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Two professional expert questionnaires for percutaneous implantation of pulmonary

artery pressure sensors for monitoring treatment of chronic heart failure were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

A structured information request was sent to 1 company who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

There are other implantable devices for monitoring intracardiac pressure in heart failure, but these monitor pressure at other sites, such as the left atrium and right ventricular outflow tract, and use various procedures for their insertion. Therefore, these devices are out of scope for this procedure.

Ongoing trials

- CardioMEMS HF system OUS post market study (NCT02954341); observational, cohort study; Australia, Belgium, Denmark, France and UK; estimated enrollment, n=800; estimated study completion date: December 2023.

- Hemodynamic-guided management of heart failure (GUIDE-HF; NCT03387813); single-blinded, multicentre, randomised controlled trial; US and Canada; estimated enrollment, n=3,600; estimated study completion date: February 2024

- Investigation to optimize hemodynamic management of left ventricular assist devices using the CardioMEMS™ (Intellect2; NCT03247829); observational, single group, multicentre study; US, actual enrollment, n=101; actual study completion date: June 2020

- MONITOR HF multicentre randomised clinical trial (NCT7672); Netherlands, estimated enrollment, n=340

- PROACTIVE-HF IDE trial heart failure NYHA class 3 (NCT04089059); multi-centre, randomised controlled trial; US, estimated enrollment, n=970; estimated completion date: May 2024

- Pulmonary artery sensor system pressure monitoring to improve heart failure outcomes (PASSPORT-HF; NCT04398654); multicentre, randomised controlled trial; Germany, estimated enrollment, n=554; estimated completion date: May 2024

- SIRONA 2 trial heart failure NYHA class 3 (NCT04012944); open-label, multicentre, single group study; Gelgium, Germany and Ireland, estimated enrollment, n=60; estimated completion date: December 2023

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Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. European Heart Journal 37 (27): 2129-200, https://doi.org/10.1093/eurheartj/ehw128

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	15/02/2021	Issue 2 of 12, February 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	15/02/2021	Issue 2 of 12, February 2021
International HTA database (INAHTA)	15/02/2021	n/a
MEDLINE (Ovid)	15/02/2021	1946 to February 12, 2021
MEDLINE In-Process (Ovid)	15/02/2021	1946 to February 12, 2021
MEDLINE Epubs ahead of print (Ovid)	15/02/2021	February 12, 2021
EMBASE (Ovid)	15/02/2021	1974 to 2021 February 12

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Number	Search term
1	heart failure/
2	cardiomyopathy, dilated/
3	shock, cardiogenic/
4	ventricular dysfunction/
5	cardiac output, low/
6	((heart* or cardiac* or myocardial or cardio* or ventric*) adj4 (failure or decompensation or insufficient* or dysfunct* or "stand still")).tw.
7	((congestive or chronic) adj4 "heart failure").tw.
8	((dilated or congestive) adj4 cardiomyopath$).tw.
9	"cardiogenic shock".tw.
10	(("left ventricular" or "left ventricle") adj4 (failure or insufficien* or dysfunction*)).tw.
11	(lvsd or hf or chf).tw.
12	or/1-11
13	exp telemetry/
14	Wireless Technology/
15	wireless*.tw.
16	(telemetr* or biotelemetr* or radiotelemet* or teleradiometr* or telemonitor*).tw.
17	telemedicine/
18	(telemed* or telehealth or ehealth).tw.
19	electrodes, implanted/
20	(implant* adj4 (electrode* or sensor* or pressur*)).tw.
21	"Prostheses and Implants"/
22	((implant* or prosthe*) adj4 (pulmonary arter* or pulmonary valve* or pulmonary trunk*)).tw.
23	blood vessel prosthesis/
24	blood vessel prosthesis implantation/

25	or/13-24
26	blood pressure monitoring, ambulatory/
27	((pulmonary or heart or blood) adj4 pressur* adj4 (monitor* or measure* or determination* or record*)).tw.
28	(continuous adj4 ambulatory adj4 (monitor* or pressur*)).tw.
29	monitoring, physiological/
30	(physiologic* adj4 (monitor* or measure*)).tw.
31	hemodynamics/
32	(hemodynamic* or haemodynamic*).tw.
33	pulmonary wedge pressure/
34	(wedge adj4 pressur*).tw.
35	blood pressure determination/
36	or/26-35
37	((champion or chronicle) adj4 (heart or cardia* or sensor* or implant*)).tw.
38	(remon or cardiomems).tw.
39	37 or 38
40	12 and 25 and 36
41	39 or 40
42	Animals/ not Humans/
43	41 not 42

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the summary of the key evidence. It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Abraham WT (2013) Disease management: remote monitoring in heart failure patients with implantable defibrillators, resynchronization devices, and haemodynamic monitors. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology: i40-6	Review	The use of a pulmonary artery pressure measurement system has been shown to significantly reduce the risk of heart failure hospitalization in a large randomized controlled study, the CardioMEMS heart sensor allows monitoring of pressure to improve outcomes in NYHA class III heart failure patients (CHAMPION) trial.	Review article
Abraham WT (2015) The role of implantable hemodynamic monitors to manage heart failure. Heart failure clinics 11(2): 183-9	Review	Heart failure care guided by implantable hemodynamic monitors reduces the risk of heart failure hospitalisation and improves quality of life.	Review article
Abraham WT (2017) The role of implantable hemodynamic monitors to manage heart failure. Cardiology clinics 35(2): 273-9	Review	Heart failure care guided by implantable hemodynamic monitors reduces the risk of heart failure hospitalisation and improves quality of life.	Review article
Abraham J, McCann PJ, Guglin ME et al. (2020) Management of the	Review	Implantable, wireless hemodynamic sensor technology is a	Review article

patient with heart failure and an implantable pulmonary artery hemodynamic sensor. Current Cardiovascular Risk Reports 14(9): 12		promising remote monitoring platform for CHF. A phased approach using a treatment algorithm may improve the efficiency and effectiveness of pressure-guided therapy.	
Abraham J, McCann P, Wang L et al. (2019) Internal jugular vein as alternative access for implantation of a wireless pulmonary artery pressure sensor. Circulation: Heart Failure 12:e006060	Non-randomised comparative study n=262 (femoral access 73 compared with internal jugular assess 189)	Internal jugular vein access for CardioMEMS implant is a safe alternative associated with superior procedural and discharge outcomes.	This study compared the outcomes of internal jugular versus femoral implantation of CardioMEMS, with limited efficacy and safety outcomes reported.
Abraham WT and Perl L (2017) Implantable hemodynamic monitoring for heart failure patients. Journal of the American College of Cardiology 70(3): 389-98	Review	Early studies using implantable hemodynamic monitors demonstrated the potential of pressure-based heart failure management, whereas subsequent studies confirmed the clinical utility of this approach. One large pivotal trial proved the safety and efficacy of pulmonary artery pressure–guided heart failure management, showing a marked reduction in heart failure hospitalisations in patients randomised to active pressure-guided management. “Next-generation” implantable hemodynamic monitors are in development, and novel approaches for the	Review article

		use of this data promise to expand the use of pressure-guided heart failure management.	
Adamson PB, Abraham WT, Stevenson LW et al. (2016) Pulmonary artery pressure-guided heart failure management reduces 30-day readmissions. Circ Heart Fail 9: e002600	Subgroup (Medicare-eligible) analysis from the CHAMPION trial n=245	Pulmonary artery pressure-guided HF management in Medicare-eligible patients led to a 49% reduction in total HF hospitalizations and a 58% reduction in all-cause 30-day readmissions.	Sample is included in Abraham et al. (2016)
Adamson PB, Abraham WT, Bourge RC et al. (2014) Wireless pulmonary artery pressure monitoring guides management to reduce decompensation in heart failure with preserved ejection fraction. Circ Heart Fail 7: 935–44	Subgroup (HFpEF) analysis from the CHAMPION trial n=119	Hemodynamically guided management of patients with HF with preserved EF reduced decompensation leading to hospitalization compared with standard HF management strategies.	Sample is included in Abraham et al. (2016)
Adamson PB, Ginn G, Anker SD et al. (2017) Remote haemodynamic-guided care for patients with chronic heart failure: a meta-analysis of completed trials. European journal of heart failure 19(3): 426-33	Meta-analysis n=5 trials (1 relevant trial)	Haemodynamic-guided HF management using permanently implanted sensors and frequent filling pressure evaluation is superior to traditional clinical management strategies in reducing long-term HF hospitalisation risk in symptomatic patients.	CHAMPION is included in the main extraction table
Afari ME, Syed W and Tsao L (2018) Implantable devices for heart failure monitoring and therapy. Heart failure reviews 23(6): 935-44	Review	CardioMEMS has been shown to be effective in reducing heart failure hospitalisations as well as HF-related costs.	Review article
Ali O, Hajduczok AG and Boehmer JP (2020) Remote physiologic monitoring for heart	Review	When using parameters such as daily weights, remote monitoring for heart failure has not	Review article

failure. Current Cardiology Reports 22(8): 68		been demonstrated to be broadly beneficial, while remote monitoring of hemodynamic parameters to guide heart failure therapy has met with initial success.	
Almufleh A, Desai AS, Fay R et al. (2020) Correlation of laboratory haemoconcentration measures with filling pressures obtained via pulmonary arterial pressure sensors in ambulatory heart failure patients. European Journal of Heart Failure 22(10): 1907-11	Case series n=23	Change in haemoglobin was correlated with change in diastolic pulmonary arterial pressure (PAP) in ambulatory HF patients, especially at the time of HF hospitalisation.	Small sample and limited efficacy outcomes reported.
Assaad M, Sarsam S, Naqvi A et al. (2019) CardioMems device implantation reduces repeat hospitalisations in heart failure patients: A single centre experience. JRSM Cardiovascular Disease 8: 1-7	Case series n=27	In a real-world setting, the implantation of a wireless heart failure monitoring system in patients with heart failure and class 3 symptoms has resulted in 80.4% reduction in heart failure admissions and 69% reduction in all cause admissions.	Studies with a larger sample or better design are included in the main extraction table.
Assaad M, Singh R, Sarsam S et al. (2018) Impact of CardioMEMS device placement on lifestyle modifications: a "pseudo-placebo" effect beyond the expected? The Journal of international medical research 46(8): 3195-9	Case series n=40	Dyspnoea improved in 57% of patients, 70% of patients improved their diet, and 43% increased their physical activity. Only 7% of patients found it difficult to transmit the data.	Small sample and limited clinical outcomes reported.
Ayyadurai P, Alkhawam H, Saad M et al. (2019) An update on the CardioMEMS pulmonary artery pressure sensor. Therapeutic advances in	Review	The generalisability of the CardioMEMS HF system results to most patients with NYHA class 3 HF is adequate, because of a significant reduction in HF	Review article

cardiovascular disease 13: 1753944719826826		hospitalisation and very few contraindications.	
Baginski BN, Byrne KA, Vaz DG et al. (2021) Development and implementation of a remote patient monitoring program for heart failure: a single-centre experience. ESC Heart Failure	Case series n=141 (89 patients with CardioMEMS and 52 with HeartLogic)	A dual platform remote patient monitoring (RPM) program for HF using structured education, RPM-capable devices, and alert-specific medication titration reduces the likelihood of experiencing a cardiac hospitalization and cardiac-related emergency department visit in this study.	Outcomes were not reported separately for PA pressure sensor.
Bayes-Genis A, Codina P, Abdul-Jawad Altisent O et al. (2020) Advanced remote care for heart failure in times of COVID-19 using an implantable pulmonary artery pressure sensor: the new normal. European heart journal supplements : journal of the European Society of Cardiology 22: 29-32	Review	CardioMEMS is the remote haemodynamic monitoring system with the most evidence-driven efficacy, and COVID-19 has put it in the spot as a centre-stage technology for HF monitoring. In a few months of the COVID-19 epidemic, CardioMEMS has grown to maturity, making it the new normal for high-quality, high-value remote HF care.	Review article
Benza RL, Doyle M, Lasorda D et al. (2019) Monitoring pulmonary arterial hypertension using an implantable hemodynamic sensor. Chest	Case series n=26	The CardioMEMS HF System provided useful information to monitor PAH therapy and showed short- and long-term safety. Larger clinical trials are needed before its widespread use to guide therapy in patients with severe PAH with right-sided HF.	Studies with a larger sample or better design are included in the main extraction table.
Benza RL, Raina A, Abraham WT et al. (2015) Pulmonary hypertension related to	Subgroup (pulmonary hypertension) analysis	WHO Group II PH is prevalent and identifies HF patients at risk for adverse outcomes.	Sample is included in Abraham et al. (2016).

left heart disease: insight from a wireless implantable hemodynamic monitor. J Heart Lung Transplant 34: 329–37	from the CHAMPION trial n=314	Ongoing knowledge of hemodynamic variables may allow for more effective treatment strategies to reduce the morbidity of this disease.	
Biederman RWW, Doyle M, Correa-Jaque P et al. (2019) Integrated use of cardiac MRI and the CardioMEMSTM HF system in PAH: The utility of coincident pressure and volume in RV failure : The NHLBI-VITA trial. Cardiovascular Diagnosis and Therapy 9(5): 492-501	Case series n=17	It is safe and feasible to perform cardiovascular magnetic resonance (cMR) imaging with simultaneous pulmonary artery pressure readings from the CardioMEMS device.	Small sample, with the aim of investigating the feasibility and safety of measuring volumetric and pressure parameters using simultaneous cMR volumetric data and time-resolved pressure waveforms from previously implanted CardioMEMS devices.
Chaudhry SP and Stewart GC (2017) New pharmacological and technological management strategies in heart failure. Vascular health and risk management 13: 111-21	Review	Given the requirement of review of the transmitted data by a health care provider, CardioMEMS must be embedded within a robust heart failure disease management program to have a real impact.	Review article
Brugts JJ, Manintveld OC and van Mieghem N (2018) Remote monitoring of pulmonary artery pressures with CardioMEMS in patients with chronic heart failure and NYHA class III: First experiences in the Netherlands. Netherlands Heart Journal 26(2): 55-7	Case report n=1	CardioMEMS has been shown to be safe and reliable, and effective in reducing the number of hospitalisations for heart failure by guided therapy based on pulmonary artery pressures.	Single case report

Carmona-Rubio A, Gonzalez-Bonilla HM and Jacob MS (2020) Implementing CardioMEMS monitoring and interventions into clinical practice. Current Treatment Options in Cardiovascular Medicine 22(9): 25	Review	Pulmonary artery pressure monitoring with the CardioMEMS monitoring system can help physicians tailor medical therapy in patients with heart failure remotely. Monitoring patients in the outpatient setting could reduce the need for hospitalisations for acute decompensated heart failure; and hence, reduce the mortality and morbidity rates in this population.	Review article
Clark DE, Fowler R, Zalawadiya S et al. (2019) CardioMEMS implantation in patient with a systemic right ventricle. JACC: Case Reports 1(3): 394-5	Case report n=1	The patient successfully had CardioMEMS implantation and has since remained out of the hospital with improved functional class.	Single case report
Costanzo MR, Stevenson LW, Adamson PB et al. (2016) Interventions linked to decreased heart failure hospitalisations during ambulatory pulmonary artery pressure monitoring. JACC Heart Fail 4: 333-44	Subgroup analysis (medical therapy) from the CHAMPION trial n=550	Incorporation of a PA pressure-guided treatment algorithm to decrease filling pressures led to targeted changes, particularly in diuretics and vasodilators, and was more effective in reducing HF hospitalisations than management of patient clinical signs or symptoms alone.	Sample is included in Abraham et al. (2016).
Dahal K, Austin B, Azrin M et al. (2020) A successful CardioMEMSTM implantation via brachial vein access: A case report. Cardiovascular Revascularization	Case report n=1	This report showed the first case of successful CardioMEMS™ implantation via brachial vein access.	Single case report

Medicine 21 (11supplement): 168-70			
Danaf JA, Butler J and Yehya A (2018) Updates on device-based therapies for patients with heart failure. Current heart failure reports 15: 53-60	Review	Pulmonary artery pressure-guided HF management reduces HF hospitalisation with improvement in quality of life in patients with HFrEF on GDMT.	Review article
Davey R and Raina A (2016) Hemodynamic monitoring in heart failure and pulmonary hypertension: From analog tracings to the digital age. World journal of transplantation 6(3): 542-7	Review	Some devices, such as the CardioMEMS and thoracic impedance monitors present as part of implantable cardiac defibrillators, are supported by a body of evidence which show the potential to reduce HF related morbidity and have received regulatory approval.	Review article
Diedrich L, Dockweiler C, Kupitz A et al. (2018) Telemonitoring in heart failure : Update on health-related and economic implications. Herz 43(4): 298-309	Review	telemonitoring is a promising approach that could empower patients with heart failure and allow them to take a much more active part in their own management.	Review article
Doshi RN, Carlson S, Agarwal R et al. (2019) Association between arrhythmia and pulmonary artery pressure in heart failure patients implanted with a cardiac defibrillator and ambulatory pulmonary artery pressure sensor. Journal of Innovations in Cardiac Rhythm Management 10(9): 3815-21	Non-randomised comparative study n=162	In this real-world cohort of implantable cardioverter-defibrillators recipients who received a pulmonary artery pressure sensor (PAP), a high baseline pressure was associated with a high burden of ventricular arrhythmias. PAP sensor-guided reduction in mean PAP in patients with symptomatic HF was associated with a reduction in arrhythmia burden.	Studies with a larger sample or better design were included in the main extraction table.

Dzhioeva O and Belyavskiy E (2020) Diagnosis and management of patients with heart failure with preserved ejection fraction (HFpEF): Current perspectives and recommendations. Therapeutics and Clinical Risk Management 16: 769-85	Review	An important pre-specified subgroup analysis of the CHAMPION trial showed significant efficacy in patients with HFpEF.	Review article
Emani S (2017) Remote monitoring to reduce heart failure readmissions. Current heart failure reports 14(1): 40-7	Review	Remote hemodynamic monitoring is currently the most efficacious based on data, but is not without its own imperfections.	Review article
Feldman DS, Moazami N, Adamson PB et al. (2018) The utility of a wireless implantable hemodynamic monitoring system in patients requiring mechanical circulatory support. ASAIO journal 64(3): 301-8	Subgroup (LVAD implantation) analysis from the CHAMPION trial n=27	PA pressures declined significantly post LVAD implant in all patients, but the magnitude of decline was higher in patients with PA pressure monitoring. Implantable hemodynamic monitoring appeared to improve the timing of LVAD implantation as well as optimise LVAD performance when compared with current methods.	Sample is included in Abraham et al. (2016).
Givertz MM, Stevenson LW, Costanzo MR et al. (2017) Pulmonary artery pressure-guided management of patients with heart failure and reduced ejection fraction. Journal of the American College of Cardiology 70(15): 1875-86	Subgroup (HFrEF) analysis from the CHAMPION trial n=456	PA pressure-guided HF management reduces morbidity and mortality in patients with HFrEF on guideline-directed medical therapy, underscoring the important synergy of addressing hemodynamic and neurohormonal targets of HF therapy	Sample is included in Abraham et al. (2016).

Gorthi J, Hunter CB, Mooss AN et al. (2014) Reducing heart failure hospital readmissions: A systematic review of disease management programs. Cardiology Research 5(5): 126-38	Systematic review Pulmonary artery pressure monitoring for HF n=1 study	Invasive telemonitoring is a potentially effective means of reducing HF hospitalisations, but only 1 study using pulmonary artery pressure monitoring was able to demonstrate a reduction in HF hospitalisations.	The key cited paper (CHAMPION study) is included in the main extraction table.
Gronda E, Vanoli E, Zorzi A et al (2020) CardioMEMS, the real progress in heart failure home monitoring. Heart failure reviews 25(1): 93-8	Review	Early management in response to increased pulmonary pressure is able to provide the most effective therapeutic intervention to prevent heart failure exacerbations.	Review article
Hussein AA and Wilkoff BL (2019) Cardiac implantable electronic device therapy in heart failure. Circulation Research 124(11): 1584-97	Review	There is a growing interest in devices for hemodynamic monitoring purposes, which have been primarily shown to reduce heart failure hospitalisations.	Review article
Imamura T and Narang N (2021) Advances in hemodynamic monitoring in heart failure patients. Internal Medicine 60(2): 167-71	Review	The use of a CardioMEMS™ led to a 30% reduction in HF readmissions, equating to massive reductions in healthcare expenditures and reduced disease-specific morbidity	Review article
Jermyn R, Alam A, Kvasic J et al. (2017) Hemodynamic-guided heart-failure management using a wireless implantable sensor: Infrastructure, methods, and results in a community heart failure disease-management program. Clin Cardiol 40: 170-6	Non-randomised comparative study n=77	Hemodynamic-guided HF management leads to significant improvements in NYHA class and HF hospitalisation rate in a real-world setting compared with usual care delivered in a comprehensive disease-management program.	Studies with a larger sample or better design are included in the main extraction table.

Juhl AR, Larsen JJ, Rossing K et al. (2020) Pulmonary artery pressure as a method for assessing hydration status in an anuric haemodialysis patient - A case report. BMC Nephrology 21(1): 266	Case report n=1	This case report observes a close correlation between pulmonary artery pressure and fluid overload in a limited amount of observations. Monitoring pulmonary artery pressure via CardioMEMS could hold great potential as a real-time guidance for fluid balance during haemodialysis, though adjusted cut-off values for pulmonary pressure for anuric patients may be needed.	Single case report
Karamichalakis N, Parissis J, Bakosis G et al. (2018) Implantable devices to monitor patients with heart failure. Heart failure reviews 23(6): 849-57	Review	Identifying HF aggravation early, before it leads to hospitalisation is critical and remote hemodynamic monitoring can be a valuable tool, improving outcomes in CHF patients. Wireless pulmonary artery pressure monitoring seems to reduce re-admission risk and is currently approved for this purpose in patients with HF.	Review article
Kilic A, Katz JN, Joseph SM et al. (2019) Changes in pulmonary artery pressure before and after left ventricular assist device implantation in patients utilizing remote haemodynamic monitoring. ESC heart failure 6(1): 138-45	Non-randomised comparative study n=436	PA pressure monitoring may provide insight into optimal timing for LVAD implantation and assist in the clinical management of patients with mechanical circulatory support.	Limited clinical data which were relevant to this procedure were reported.

Kittipibul V, Singh H, Flowers R et al. (2020) The utility of CardioMEMS in left ventricular assist device patients with gastrointestinal bleeding. Journal of Cardiology Cases 22(6): 276-9	Case series n=2	Early recognition of hemodynamic changes by CardioMEMS device might help clinicians to detect the preclinical phase of GI bleeding and intervene before patients develop severe symptoms and associated morbidity.	Studies with a larger sample or better design are included in the main extraction table.
Kobrossi S, Myers M and Orasanu G (2020) Correlation between CardioMEMS and HeartLogic in predicting heart failure events. JACC: Case Reports 2(14): 2270-4	Case report n=1	A 59-year-old male was admitted with acute on chronic decompensated heart failure. Review of his CardioMEMS device and HeartLogic index were helpful in guiding management of his volume status. This paper highlights the correlation between 2 monitoring systems which could be used to predict heart failure events.	Single case report
Krahnke JS, Abraham WT, Adamson PB, et al (2015) Heart failure and respiratory hospitalisations are reduced in patients with heart failure and chronic obstructive pulmonary disease with the use of an implantable pulmonary artery pressure monitoring device. J Card Fail 21: 240–9	Subgroup (COPD) analysis from the CHAMPION trial n=187	HF management incorporating hemodynamic information from an implantable PA pressure monitor significantly reduces HF and respiratory hospitalisations in HF subjects with comorbid COPD compared with standard care.	Sample is included in Abraham et al. (2016).
Lander MM, Aldweib N and Abraham WT (2021) Wireless hemodynamic monitoring in patients with heart failure. Current heart failure reports 18(1): 12-22	Review	Wireless hemodynamic monitoring with a pulmonary artery pressure sensor is a highly effective and safe method to assess for worsening intracardiac pressures that may	Review article

		predict heart failure events, giving lead time that is valuable to keep patients optimised. Implantation of this device has been found to improve outcomes in heart failure patients regardless of preserved or reduced ejection fraction.	
Letourneau MM, Brancheau D, Estes J et al. (2020) Take me higher: A case of heart failure at high altitude detected using the cardioMEMS^{TM} HF system. American Journal of Case Reports 21: 1-5	Case report n=1	Increased elevation can lead to falsely elevated PA pressure readings by the CardioMEMS device. However, this report presents the case of a patient with a disproportionate elevation of his hemodynamic pressure measurements, indicating an exacerbation of heart failure. This case shows the value of the CardioMEMS device in detecting PA pressure changes in these unique circumstances.	Single case report
Leung CC (2019) Current role of the CardioMEMS device for management of patients with heart failure. Current Cardiology Reports 21(9): 98	Review	Management of HF using the CardioMEMS device has been shown to reduce HF hospitalisations and improve quality of life regardless of ejection fraction. Patients best suited for this device are those with recurrent congestive symptoms despite optimal medical therapy.	Review article
Linde C and Braunschweig F (2017) Cardiac resynchronization	Review	Pressure sensors for daily monitoring and transmission of pulmonary artery	Review article

therapy follow-up: role of remote monitoring. Heart Failure Clinics 13(1): 241-51		pressures compared with controls are linked to reduced need for heart failure hospitalisations in patients with heart failure with and without CRT-D therapy.	
Manavi T, Vazquez P, Tubassam M et al. (2020) Determination of optimal implantation site in central venous system for wireless hemodynamic monitoring. IJC Heart and Vasculature 27: 100510	Case series n=20	The area between the iliac join and the lower renal vein (and the 2nd and 3rd lumbar veins) is an optimal site for the accommodation of a hemodynamic sensor.	Small sample, with the aim of identifying an optimal site for implantation in the central venous system of a hemodynamic wireless sensor for HF monitoring.
Mangi MA, Nesheiwat Z, Kahloon R et al. (2020) CardioMEMSTM system in the daily management of heart failure: review of current data and technique of implantation. Expert review of medical devices 17(7): 637-48	Review	CardioMEMS™ is relatively safe and cost-effective, reduces heart failure hospitalisation rates, and fits into intermediate to high-value medical care.	Review article
Mangi MA, Rehman H, Rafique M et al. (2017) Ambulatory heart failure monitoring: a systemic review. Cureus 9(4): e1174	Review	CardioMEMS™ showed a higher reduction of HF hospitalisation compared to any other devices.	Review article
Michard F (2017) A sneak peek into digital innovations and wearable sensors for cardiac monitoring. Journal of clinical monitoring and computing 31(2): 253-9	Review	Daily home monitoring of pulmonary artery pressures with wireless implantable sensors has been shown to be associated with a significant decrease in hospital readmissions for heart failure.	Review article
Moayedi Y and Ross HJ (2017) Advances in heart	Review	Haemodynamic congestion may be more	Review article

failure: a review of biomarkers, emerging pharmacological therapies, durable mechanical support and telemonitoring. Clinical science 131(7): 553-66		reliable than current methods of assessing patients including symptoms, clinical examination, daily weights and biomarker measurements alone.	
Nachman D, Asleh R and Amir O (2020) Novel technologies in the management of heart failure with preserved ejection fraction: a promise during the time of disappointment from pharmacological approaches? Current opinion in cardiology 36: 211-8	Review	Device-based therapies for heart failure with preserved ejection fraction (HFpEF) showed encouraging safety and efficacy results in various stages of the disease. Further efforts are needed to ensure that these devices will reach clinical use and contribute to the management of HFpEF patients.	Review article
Ollendorf DA, Sandhu AT and Pearson SD (2016) CardioMEMS HF for the management of heart failure-effectiveness and value. JAMA internal medicine 176(10): 1551-1552	Review	Evidence from the CHAMPION trial suggests that CardioMEMS may provide an incremental net health benefit over the current standard of care for HF, given reductions in HF-related hospitalisation.	Review article
Oseran AS, Afari ME, Barrett CD et al. (2021) Beyond the stethoscope: managing ambulatory heart failure during the COVID-19 pandemic. ESC Heart Failure	Review	use of existing remote heart failure monitoring sensors when applicable (e.g. CardioMEMS) are emerging as an important tool for the effective management of heart failure patients during the COVID-19 pandemic.	Review article
Palaniswamy C, Mishkin A, Aronow WS et al. (2013) Remote patient monitoring in chronic	Review	Remote monitoring has a substantial potential to improve the management and outcome of patients with	Review article

heart failure. Cardiology in review 21(3): 141-50		HF. Current data examining the efficacy of remote monitoring technologies in improving outcomes have shown inconsistent results.	
Papavasileiou LP, Santini L, Forleo GB et al. (2016) Novel devices to monitor heart failure and minimize hospitalisations. Expert Review of Cardiovascular Therapy 14(8): 905-13	Review	Hemodynamic parameters can guide medical management of patients and reduce hospitalisation. Remote monitoring of these patients can reduce in clinic visits and/or hospitalisations.	Review article
Perego, Giovanni Battista, Oldani, Matteo, Pellegrini, Dario et al. (2017) Correlation between pulmonary artery pressure and thoracic impedance: Insights from daily monitoring through an implanted device in chronic heart failure. International journal of cardiology 245: 196-200	Case series n=10	During hemodynamic guided therapy, diastolic PAP (dPAP) decreased from 27.8±10.2 mmHg to 24.0±8.0 mmHg ($p<0.001$); nonsignificant variations of TI were observed. A significant negative correlation was found between the variations of TI and PAP vs. baseline ($p<0.001$). Episodes of sustained increase of PAP preceded subsequent periods of TI decrease by 5.6±3.9 days, but the former were poor predictors of the latter (sensitivity 0.37).	Studies with a larger sample or better design are included in the main summary.
Piotrowicz E (2017) The management of patients with chronic heart failure: the growing role of e-Health. Expert review of medical devices 14(4): 271-7	Review	The evidence suggests that remote monitoring could identify life-threatening deterioration and helps heart failure patients avoid seeking medical assistance in hospitals and that home-based telerehabilitation is well accepted, safe, effective and has high	Review article

		adherence among HF patients.	
Pour-Ghaz I, Hana D, Raja J et al. (2019) CardioMEMS: where we are and where can we go? Annals of translational medicine 7(17): 418	Review	CardioMEMS has shown to be effective in prevention and reduction of HF hospitalisations in patients with HFrEF and HFpEF.	Review article
Rali AS, Shah Z, Sauer A et al. (2017) Late migration of a CardioMEMS™ wireless pulmonary artery hemodynamic monitoring sensor. Circulation. Heart failure 10(4)	Case report n=1	This study reported a case in which the sensor was deployed in an appropriate-sized artery but had a late migration after 4 months.	Single case report
Raina A, Abraham WT, Adamson PB et al. (2015) Limitations of right heart catheterisation in the diagnosis and risk stratification of patients with pulmonary hypertension related to left heart disease: insights from a wireless pulmonary artery pressure monitoring system. The Journal of heart and lung transplantation : the official publication of the International Society for Heart Transplantation 34(3): 438-47	Subgroup analysis from the CHAMPION trial n=537 patients with at least 1 PA pressure reading taken from home during the first week after sensor implantation	Using only RHC, WHO II PH may be significantly under-diagnosed. In patients with left-sided HF and resting mean PA pressure ≤25 mmHg during RHC, more frequent PA pressure monitoring using an IHM device can provide additional data for improved diagnosis and patient risk stratification compared with a single RHC alone.	Sample is included in Abraham et al. (2016).
Rali AS, Shah Z, Sauer AJ et al. (2018) Haemoptysis after CardioMEMS implantation: Case report and review. The American journal of case reports 19: 382-5	Case report n=1	This case report discusses haemoptysis as a potential life-threatening complication of CardioMEMS sensor implantation while suggesting possible aetiologies and avoidance strategies. As the utilization of this	Single case report

		technology expands in the years to come, a more comprehensive national registry for surveillance of device related complications will be crucial.	
Reghunathan A, Chick JFB, Gemmete JJ et al. (2018) Endovascular retrieval of a CardioMEMS heart failure system. Radiology Case Reports 13(2): 386-8	Case report n=1	The patient suffered no immediate postprocedural complications but died 5 days after the procedure from multiorgan failure secondary to sepsis.	Single case report
Salavitabar A, Bradley EA, Chisolm JL et al. (2020) Implantable pulmonary artery pressure monitoring device in patients with palliated congenital heart disease: Technical considerations and procedural outcomes. Catheterisation and cardiovascular interventions: official journal of the Society for Cardiac Angiography & Interventions 95(2): 270-9	Case series n=14	Transcatheter implantation of an implantable hemodynamic monitor is feasible in select complex adult CHD patients with advanced HF. Further studies evaluating integration of ambulatory hemodynamics and the impact on clinical care are needed.	Studies with a larger sample or better design are included in the main extraction table.
Sarsam S, Kaspar G, David S et al. (2017) Early detection of subclinical aortic valve endocarditis with the CardioMEMS heart failure system. The American journal of case reports 18: 665-8	Case report n=1	While the CardioMEMS heart failure system is effective in reducing readmission rates for patients with class 3 heart failure, it can detect early hemodynamic changes from conditions other than congestive HF. This case illustrated the CardioMEMS-assisted early diagnosis of infective endocarditis	Single case report

		prior to clinical deterioration.	
Shah M, Zimmer R, Kollefrath M et al. (2020) Digital technologies in heart failure management. Current Cardiovascular Risk Reports 14(8): 9	Review	Digital management of HF has emerged as a promising avenue for prevention of HF hospitalisation. Although some technologies have shown to improve clinical outcomes, further studies are needed on currently existing technologies to assess their viability as tools in preventing rehospitalisation.	Review article
Singh R, Scarfone S and Zughaib M (2020) Wedged sensor in distress? lessons learned from troubleshooting dampened transmitted pa waveforms of CardioMEMS device. Case Reports in Cardiology 2020: 3856940	Case report n=1	CardioMEMS is a cost-effective tool to help reduce heart failure hospitalisations. Device migration is a rare complication and can lead to inaccurate data. However, as seen in this case, the device can be successfully recalibrated and can continue to be utilized to help reduce heart failure admissions.	Single case report
Sousa C, Leite S, Lagido R et al. (2014) Telemonitoring in heart failure: a state-of-the-art review. Rev Port Cardiol 33(4): 229-39	Review	This review underscores the need for careful assessment of telemonitoring as a disease management system before its widespread adoption.	Review article
Tschope C, Alogna A, Spillmann F et al. (2018) The CardioMEMS system in the clinical management of end-stage heart failure patients: three case reports. BMC cardiovascular disorders 18(1): 155	Case series n=3	This case series underlines the potential impact of CardioMEMS™ derived data in the daily clinical management of end-stage HF patients. The new concept to combine CardioMEMS™ in the setting of an outpatient levosimendan program	Studies with a larger sample or better design are included in the main extraction table.

		as well as a bridge to LVAD-implantation/heart transplantation looks promising but needs further investigations.	
Tse G, Chan C, Gong M et al. (2018) Telemonitoring and hemodynamic monitoring to reduce hospitalisation rates in heart failure: A systematic review and meta-analysis of randomised controlled trials and real-world studies. Journal of Geriatric Cardiology 15(4): 298-309	Systematic review and meta-analysis n=8 studies relating to pulmonary artery pressure sensor	Hospitalisation rates were significantly reduced using pulmonary pressure monitoring (HR: 0.58, 95% CI: 0.50 to 0.66; $p<0.001$; $I^2=67\%$) or left atrial pressure monitoring (HR: 0.16, 95% CI: 0.04 to 0.68; $p<0.05$).	Limited efficacy data which were relevant to this procedure, were reported. Of the relevant studies, some patient overlap presented.
Tolia S, Khan Z, Gholkar G et al. (2018) Validating left ventricular filling pressure measurements in patients with congestive heart failure: CardioMEMSTM pulmonary arterial diastolic pressure versus left atrial pressure measurement by transthoracic echocardiography. Cardiology Research and Practice 2018: 8568356	Case series n=17	This study illustrates a direct linear correlation between PAdP measured by CardioMEMS and simultaneous measurement of LV filling pressures derived by echocardiography.	Small sample, with the aim of examining the correlation between CardioMEMS and echocardiography-derived estimates of central hemodynamics.
Tran JS, Wolfson AM, O'Brien D et al. (2019) A systems-based analysis of the CardioMEMS HF sensor for chronic heart failure management. Cardiology Research and Practice 2019: 7979830	Case series n=78	This study suggests that more frequent patient transmissions and health care provider reviews of the CardioMEMS system are associated with a decreased number of HFH days, but larger multicentred studies are required.	Limited efficacy data were reported.
Veenis JF and Brugts J J (2020) Remote	Review	The use of the pulmonary artery	Review article

monitoring for better management of LVAD patients: the potential benefits of CardioMEMS. General thoracic and cardiovascular surgery 68(3): 209-18		pressure device provided by the CardioMEMS leads to a better and more optimal LVAD management, leading to a better pump function.	
Vanoli E, D'Elia E, La Rovere MT et al. (2016) Remote heart function monitoring: role of the CardioMEMS HF System. Journal of cardiovascular medicine (Hagerstown, Md.) 17(7): 518-23	Review	The reports from the CHAMPION study encourage the use of CardioMEMS but larger populations are needed to definitively prove its value.	Review article
Veenis JF, Birim O and Brugts JJ (2019) Pulmonary artery pressure telemonitoring by CardioMEMS in a patient pre- and post-left ventricular assist device implantation. European journal of cardio-thoracic surgery : official journal of the European Association for Cardio-thoracic Surgery	Case report n=1	The case shows the feasibility of pulmonary artery monitoring with the CardioMEMS sensor for the preoperative optimisation of patients with end-stage heart failure undergoing LVAD surgery. CardioMEMS aids in the remote monitoring of LVAD patients with the potential of identifying complications, pump dysfunction or filling status alterations.	Single case report
Veenis JF and Brugts JJ (2020) Remote monitoring of chronic heart failure patients: invasive versus non-invasive tools for optimising patient management. Netherlands Heart Journal 28(1): 3-13	Review	The CardioMEMS is the most promising (invasive) remote monitoring tool currently available. The haemodynamic information allows for a window of timely and adequate intervention based on raised PAP, preventing an upcoming HF decompensation. Additionally, its safety and durability have been	Review article

		tested and confirmed in post-marketing studies.	
Veenis JF, Radhoe SP, van Mieghem NM et al (2021) Remote hemodynamic guidance before and after left ventricular assist device implantation: short-term results from the HEMO-VAD pilot study. Future cardiology	Non-randomised comparative study n=10	This pilot study demonstrates that combining CardioMEMS monitoring with LVAD therapy is safe and generates the hypothesis that patients with an mPAP >25 mmHg before LVAD surgery identify a very high-risk group for adverse clinical outcomes.	Studies with a larger sample or better design are included.
Visco V, Esposito C, Vitillo P et al. (2020) It is easy to see, but it is better to foresee: A case report on the favourable alliance between CardioMEMS and levosimendan. European Heart Journal - Case Reports 4(4)	Case report n=1	The case supports the combination of CardioMEMS and levosimendan for the optimal management of patients with advanced HF. The results further strengthen the development of a randomised clinical trial to demonstrate the clinical usefulness of this device in combination with the levosimendan infusion programme in advanced HF patients.	Single case report
Volterrani M, Spoletini I, Angermann C et al. (2019) Implantable devices for heart failure monitoring: the CardioMEMS TM system. European heart journal supplements : journal of the European Society of Cardiology 21: m50-3	Review	Reductions in HF-related hospitalisations are achievable by novel device-based telemonitoring strategies. Such a novel diagnostic adjunct should be incorporated into existing HF disease management strategies.	Review article
Wang JT and Frishman WH (2017) Pulmonary pressure monitoring for patients with heart	Review	HF patients of certain subgroups, including those with left heart dysfunction and those with preserved left	Review article

failure. Cardiology in review 25(2): 53-8		ventricular ejection fraction, could benefit from pulmonary pressure monitoring in controlling their HF. Larger studies are needed to determine whether mortality can be reduced with pulmonary pressure monitoring.	
Wolfson AM, Fong M, Grazette L et al. (2018) Chronic heart failure management and remote haemodynamic monitoring. Heart (British Cardiac Society) 104(23): 1910-9	Review	Remote pulmonary artery pressure-guided HF management reduced future HF hospitalisations. Tight haemodynamic management of patients with HF may be an additional pillar of therapy alongside established guideline-directed medical and device therapy.	Review article
Wolfson AM, Grazette L, Saxon L, et al. (2017) Baseline diastolic pressure gradient and pressure reduction in chronic heart failure patients implanted with the CardioMEMS™ HF sensor. ESC heart failure 5(3): 316-21	Non-randomised comparative study n=32	Decreased pulmonary artery diastolic pressures (PADP) reduction was not seen in combined pre-capillary and post-capillary PH compared with isolated post-capillary PH patients. Higher PADP baseline was associated with greater ΔPADP. Larger studies are needed to elaborate the findings	Small sample, with the aim of evaluating whether a higher baseline diastolic pressure gradient measured at the time of CardioMEMS™ HF sensor implantation is associated with lower reductions in PADP.
Yacoub MH and McLeod C (2018) The expanding role of implantable devices to monitor heart failure and pulmonary hypertension. Nature reviews. Cardiology 15(12): 770-9	Review	Considerable progress in the development and application of implantable devices for monitoring HF has been achieved during the past 20 years. The current second-generation	Review article

		devices, with wearable recording and communicating readers and automated signal analysis, have the potential to allow continuous monitoring of intravascular pressure, analogous to Holter monitoring of the ECG.	
Yandrapalli S, Raza A, Tariq S et al. (2017) Ambulatory pulmonary artery pressure monitoring in advanced heart failure patients. World Journal of Cardiology 9(1): 21-6	Review	Wireless left atrial pressure-guided and PA pressure-guided management of HF can have a substantial positive effect on reducing the financial burden of HF and improving the overall morbidity and mortality in this population.	Review article